



# JOURNAL OF THE PHILIPPINE MEDICAL ASSOCIATION

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The first page should contain the title, subtitle (if any), all authors' full names and highest earned academic degrees, and hospital or institutional affiliations. It must also include disclaimer, if any.

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## **Research is Exploring Uncharted Areas**

**Research is like exploring uncharted areas, and then correcting if there are any errors on the map. Doctors who do research are challenged to heal better, heal more and maybe consider searching for what was once thought to be incurable.** As such, we enter into a new era of even greater depth and acknowledgment of the research that our Filipino research community needs. We are looking also towards the younger generation of physicians who have undergone their medical education in an era where research is heightened. Medical schools include research and encourage students to pursue publication and presentation.

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**Maria Christina H. Ventura, MD, FPPS**  
Editor-in -Chief



# Comparison of Platelet Concentration Levels Obtained from Ethylenediaminetetraacetic Acid Tube (EDTA) versus Commercially Available Platelet Rich Plasma (PRP) Kit in Filipino Adult Males with Androgenetic Alopecia: A Cross-Sectional Quantitative Study\*

Maria Monica L. Manalo, MD<sup>1,a</sup>; Maria Franchesca S. Quino-Calayag, MD, FPDS, FDSP-PDS<sup>2,a</sup>

## ABSTRACT

**Background:** Platelet rich plasma (PRP) is increasingly used as an adjunct treatment for androgenetic alopecia (AGA). PRP preparation involves anticoagulant tubes, such as PRP kits or regular tubes such as EDTA. Studies have shown that platelet concentration in PRP correlates with the growth factors present. However, there is limited data regarding the platelet yield across different anticoagulant tubes. This study will aid in the use of EDTA tube as an alternative to the commercially available PRP kits.

**Objective:** This study aims to determine the platelet concentration level obtained in EDTA tubes versus the commercially available PRP kit in patients with AGA.

**Methodology:** This was a cross-sectional, quantitative study in 27 adult males with AGA. The venous blood extracted were placed in EDTA and PRP kit tubes and were centrifuged. A hemoanalyzer was used to obtain the platelet concentration levels. Statistical analyses using paired t-test was performed using the STATA MP Software.

**Results:** Comparative analyses indicated that the mean difference in platelet concentration between the PRP kit and EDTA was -472.67 (95% CI = -575.40 to -369.93). Thus, the mean platelet concentration ( $t=-9.46$ ,  $p=0.001$ ) was statistically different between the two groups with a significantly higher mean platelet concentration with EDTA as compared to the PRP kit.

**Conclusion:** The platelet concentration levels obtained from the EDTA tubes were higher than the PRP kit. Thus, the EDTA tube may be a good alternative to the costly commercially available PRP kit.

**Keywords:** Platelet Rich plasma, EDTA, PRP Kit, Androgenetic alopecia

**Commercial funding:** N/A

**Conflict of interest:** N/A

## INTRODUCTION

The prevalence of androgenetic alopecia (AGA) has substantially increased worldwide affecting 80% of men and 50% of women in the course of their life. Platelet rich plasma (PRP) preparations are increasingly being used in regenerative medicine, as well as for hair growth.<sup>[1]</sup> Platelet levels at 1,000,000 platelets/ $\mu$ L or 2-7 times its native concentration in whole blood is considered as the therapeutically effective in inducing tissue regeneration. Activated PRP was proved to contain the therapeutic platelet levels capable of promoting hair growth due to its antiapoptotic effects by activating antiapoptotic regulators like Bcl-2 and Akt; thus, extending dermal papilla cell lifespan.<sup>[2]</sup> The rationale for the use of high platelet concentration is based on their capacity to release large amounts of growth factors and cytokines from alpha granules, which augment healing and repair in tissues with low regenerative potential.<sup>[3]</sup>

All systems of PRP preparation follow a similar method which involves collecting blood in anticoagulant tubes such as sodium citrate or ethylenediaminetetraacetic acid (EDTA), centrifuging to separate RBCs and platelets, and activating the platelets to release growth factors (GF). However, PRP composition may vary due to differences in platelet and GF concentrations, collection volume, anticoagulant, centrifuge parameters, and activators. Clinical outcomes may differ based on injection methods, frequency, and intervals.<sup>[4]</sup>

There are a variety PRP kits and anticoagulant tubes for which PRP preparation may be performed; varying in price, size, anticoagulant used and PRP yield. These contain different anticoagulants and separator gels, which may influence platelet yield and its therapeutic effect.

Commercially available PRP kits are designed to produce autologous PRP by centrifuging peripheral blood

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*Disclosures:* The author has formally acknowledged and signed a disclosure affirming the absence of any financial or other relationships (including personal connections), intellectual biases, political or religious affiliations, and institutional ties that could potentially result in a conflict of interest.

\*1<sup>st</sup> Place, 31<sup>st</sup> Philippine Medical Association Residents' Research Presentation Original Paper, May 17, 2025

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in a vacuum tube. Some of these kits use a thixotropic gel for cell separation and sodium citrate as an anticoagulant. They are simpler systems with a single centrifugation step in a closed system with a high platelet recovery.

Currently, there is only a single Food and Drug Administration (FDA) approved PRP kit available in the country. These kits offer the simplicity and ease of preparation of PRP at the expense of high costs. On the other hand, an economical variety of anticoagulant tubes are available, such as the blood collection tubes with EDTA, sodium citrate and acid citrate dextrose solution A (ACD-A). However, data regarding the platelet concentrate yield of EDTA tubes, in comparison with commercially available PRP kits and their effectiveness for PRP injection in patients with AGA remains to be limited, especially in the Philippines.

The outcome of the study included the platelet concentration level and mean platelet concentration level obtained from the EDTA and PRP tubes, in order to determine their significant difference, and evaluated the demographics and clinical profile of male patients with androgenetic alopecia.

## REVIEW OF RELATED LITERATURE

### Platelet Rich Plasma

Platelet-rich plasma (PRP) is defined as the processed liquid fraction of autologous peripheral blood that exhibits a platelet concentration exceeding baseline levels. PRP is prepared by centrifugation of autologous, anticoagulated whole blood in either 1 or 2 steps to separate it into 3 components composed of a top plasma layer, middle leukocyte layer, and bottom red blood cell (RBC) layer in order to collect a concentrate of platelets in plasma.<sup>[3]</sup> Within the platelets are the alpha granules which contain various growth factors, including platelet-derived growth factor (PDGF), vascular endothelial growth factor (VEGF), epithelial growth factor (EGF), transforming growth factor-beta (TGF- $\beta$ ), and insulin-like growth factor (IGF) which facilitate the mitogenesis and differentiation of monocytes, fibroblasts, stem cells, keratinocytes, and endothelial cells.<sup>[5]</sup>

### Platelet Rich Plasma for Androgenetic Alopecia

PRP has been used for AGA treatment, although its precise mechanism in promoting hair growth remains inadequately defined. Activated PRP is thought to enhance hair cycling by prolonging the anagen phase, inhibiting apoptosis and the catagen phase, and facilitating a more rapid transition from telogen to anagen phase. The growth factors in PRP stimulate the stem cells located in the bulge area of hair follicles, promoting neovascularization and folliculogenesis.<sup>[6]</sup>

### Anticoagulant Tubes

A number of anticoagulant tubes are available for the collection of blood and in the preparation of PRP. Commonly used tubes are EDTA, ACD-A and sodium citrate tubes.

In a study by do Amaral, et al., (2016)<sup>[7]</sup>, blood samples collected using EDTA demonstrated a higher platelet count compared to those collected with sodium citrate and ACD. On average, the platelet count in SC was 16.28% lower than that in EDTA, while the count in ACD was 23.01% lower than in EDTA and 7.94% lower than in SC.

### Comparison Between Commercially Available PRP Kits and Anticoagulant Tubes

In a study conducted by Trevisson-Redondo et al., (2021)<sup>[8]</sup>, the efficacy of three PRP concentration systems, namely the Easy PRP Kit, GloPRP, and Wego, was compared, alongside two types of anticoagulant tubes, EDTA and sodium citrate. The results indicated no significant differences in the average concentrations of PRP platelets and white blood cells between GloPRP when using either EDTA or sodium citrate; however, the Easy PRP Kit demonstrated significantly superior results compared to the other methods highest PRP: whole blood ratio (2.41 times versus 0.00- 1.13 times baseline for Easy PRP Kit).

Remarkably, both tube-based methods achieved efficiencies of 56% (EDTA) and 60% (sodium citrate) of the total platelets concentrated by the Easy PRP Kit, surpassing the commercial GloPRP systems, which recovered only 46%.

In a narrative study conducted by Collin, Alexander, and Barkatali (2021)<sup>[9]</sup>, results have shown that numerous commercial PRP preparation kits are available, each exhibiting varying concentrations of components. Currently, there is no consensus regarding the optimal concentrations of these components. Several classifications of platelet PRP have been proposed; however, none have been rigorously validated. The exact implications of the varying components of these systems are still unknown. It is evident that there is significant heterogeneity among the various commercial PRP systems. Therefore, this limits conclusions drawn from pooled PRP studies.

A small number of studies have been done comparing commercially available tubes with EDTA, sodium citrate and ACD-A as anticoagulant tube for PRP but results have been inconsistent and varied. A relatively few number of commercially available PRP tubes have been used in the country with only a single FDA approved

PRP tube. Currently, there are only limited studies comparing the efficacy of these tubes in achieving a high mean platelet concentration in comparison to the anticoagulants tubes (e.g. EDTA, sodium citrate, ACD-A).

### Significance of the Study

This study will aid in the use of EDTA tubes as an alternative to the commercially available PRP kits. Thus, increasing the availability of PRP injection as a therapeutic option for AGA and other disease for which PRP may be of use, e.g. wound healing in trauma, joint injury and, aesthetics. This will aid in providing a greater number of patients with PRP as treatment option for AGA, not only in the Philippines but also in the greater parts of the world.

### Research Question

Among patients with AGA, is the platelet concentration obtained from EDTA tubes comparable to the commercially available PRP kit?

## OBJECTIVES OF THE STUDY

### General Objective

- To determine the platelet concentration level obtained in EDTA tubes versus the commercially available PRP kit in patients with AGA

### Specific Objectives

- To determine the demographic profile (age and civil status) and clinical characteristics (age at diagnosis, stage of AGA, smoking history, alcohol use, treatment history, family history of AGA) of the participants
- To determine the platelet concentration levels of PRP obtained with the use of EDTA tubes
- To determine the platelet concentration levels of PRP obtained with the use of the commercially available PRP kit
- To determine if there is a significant difference in the platelet concentration levels among the two

## METHODS

### Study Design

This is a cross-sectional, quantitative study that determined and compared the platelet concentration levels obtained from the EDTA tubes and commercially available PRP kit via a platelet determination test among adult male patients with AGA. The protocol was reviewed and approved by the Technical Review Board and the Institutional Ethics Review Board of the institution.

### Study Setting

This was conducted in the outpatient department of a tertiary government hospital fully equipped study center for this study from November 2023 to July 2024.

### Study Population

This study included all adult male androgenetic alopecia patients, aged 18-60 seen at the outpatient department of a tertiary government hospital.

### Inclusion Criteria

All clinically diagnosed adult male patients, aged 18-60 years old with AGA seen at the outpatient department of a tertiary government hospital were included in this study.

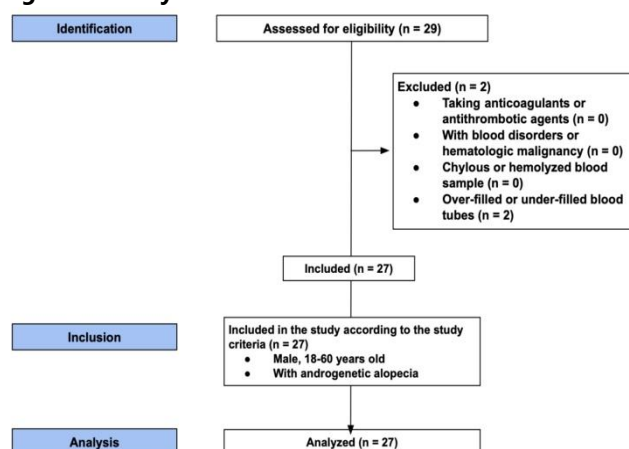
### Exclusion Criteria

Participants taking anticoagulants or antithrombotic agents, with blood disorders or hematologic malignancy and those who declined to give their consent to undergo the procedure were excluded in this study. Blood samples from participants which are chylous, hemolyzed, with over-filled, and under-filled tubes were excluded from the study.

### Withdrawal Criteria

The patients may withdraw from the study anytime that they decide not to participate in the study without any implications.

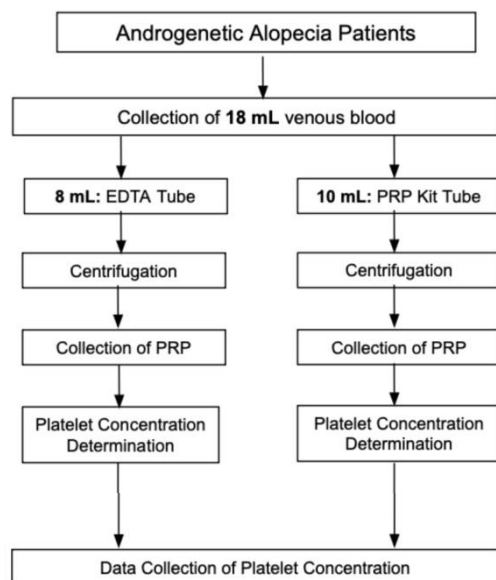
**Figure 1. Study Framework**



As seen in *figure 1*, during the period from November 2023 to July 2024, 29 male patients were assessed for eligibility. Of these 29, 27 patients were included according to the exclusion criteria wherein two participants had under-filled blood sample tubes.

### Data Gathering Procedures

- Participants were recruited via a convenient non-probability sampling.
- An informed consent was given to each participant prior to the procedure.
- A total of 18 ml of venous blood were collected from the vein in the antecubital fossa of each participant using 10 ml syringes. These were distributed in two separate tube types, 8 ml for the EDTA tube and the other 10 ml were used for the commercially available PRP kit tube
- Centrifugation protocol used for the EDTA tubes <sup>[10]</sup>:
  - First spin: 100 g for 10 min
  - Recovery of the upper layer
  - Second spin: 400 g for 10 min
  - Upper ½ of the volume (platelet poor plasma) was discarded
  - Collection of PRP in a Red Top Tube
- Centrifugation protocol used for the commercially available PRP kit:
  - 1,500 RCF
  - Collection of PRP in a Red Top Tube
- \*Extraction and Centrifugation process were done in the outpatient department of a tertiary government hospital
- PRP samples were ran under the hemoanalyzer (Mindray CAL 6000) at the clinical laboratory of a tertiary government hospital for platelet count determination. Prior to processing, the PRP were mixed by inversion, manually for 30 seconds for minimization of the gradient.



**Figure 2. Study Methodology**

t tests - Means: Difference between two dependent means (matched pairs)

Analysis: A priori: Compute required sample size

|                |                                  |             |
|----------------|----------------------------------|-------------|
| <b>Input:</b>  | Tail(s)                          | = One       |
|                | Effect size dz                   | = 0.5       |
|                | $\alpha$ err prob                | = 0.05      |
|                | Power (1 - $\beta$ err prob)     | = 0.8       |
| <b>Output:</b> | Noncentrality parameter $\delta$ | = 2.5980762 |
|                | Critical t                       | = 1.7056179 |
|                | Df                               | = 26        |
|                | Total sample size                | = 27        |
|                | Actual power                     | = 0.8118316 |

**Figure 3. Sample size calculation using G\*Power software**

### Sample Size

Figure 3 shows that the minimum sample size for this study was computed using G\*Power software based on platelet mean difference between two tubes with effect size = 0.5 (medium), level of significance = 0.05 and power = 0.80 as shown below. Thus, the researcher included at least 27 patients for this study whose blood samples were used for both the EDTA tube and commercially available PRP tube. <sup>[11]</sup>

### Sampling Method

Convenient, non-probability sampling was done to recruit 27 adult male patients aged 18-60 years old, diagnosed with AGA at the outpatient department of a tertiary government hospital.

### Statistical Analysis

Statistical analyses were performed using STATA MP – Parallel Edition Statistical Software, Version 18, College Station, TX: StataCorp LP. A  $p$ -value <0.05 was considered statistically significant. Descriptive statistics included mean and standard deviation for normally-distributed, continuous data; median and interquartile range for ordinal data and non-normal, continuous data; and, frequency and proportion for nominal data. Data normality was analyzed using skewness, kurtosis, and Shapiro- Wilks test. Comparative analyses of the platelet concentration was conducted using paired  $t$ -test. In addition, the mean difference and their respective 95% confidence intervals (CI) were reported. <sup>[12]</sup>

## RESULTS

### Demographic Characteristics

Table 1. Demographic Characteristics of the Participants (N = 27)

| Characteristics                            | Frequency (f) | Percentage (%) | Mean (SD) or Median (IQR) |
|--------------------------------------------|---------------|----------------|---------------------------|
| Age (Years; x, SD)                         |               |                | 37.67                     |
| Age of Onset of Androgenic Alopecia (f, %) |               |                |                           |
| 18 to 30 Years Old                         | 12            | 44.44%         |                           |
| 31 to 40 Years Old                         | 5             | 18.52%         |                           |
| 41 to 60 Years Old                         | 10            | 37.04%         |                           |
| Marital Status (f, %)                      |               |                |                           |
| Single                                     | 9             | 33.33%         |                           |
| Married                                    | 18            | 66.67%         |                           |
| Smoking Status (f, %)                      |               |                |                           |
| Non-Smoker                                 | 21            | 77.78%         |                           |
| Smoker                                     | 6             | 22.22%         |                           |
| Alcohol Consumption (f, %)                 |               |                |                           |
| Non-Drinker                                | 9             | 33.33%         |                           |
| Drinker                                    | 18            | 66.67%         |                           |
| Psychoactive Substances (f, %)             | 0             | 0.00%          |                           |
| Metabolic Diseases (f, %)                  |               |                |                           |
| Thyroid Disease                            | 0             | 0.00%          |                           |
| Diabetes Mellitus                          | 3             | 11.11%         |                           |
| Hypertension                               | 10            | 37.04%         |                           |
| Dyslipidemia                               | 2             | 7.41%          |                           |
| Treatment History (f, %)                   |               |                |                           |
| Minoxidil                                  | 4             | 66.67%         |                           |
| Hair Growth Shampoo                        | 2             | 33.33%         |                           |

Table 1 presents the demographic characteristics of the participants. It can be noted that the mean age of the participants was 37.67 years old (SD = 12.12), and the majority had the onset of androgenic alopecia at the age of 18 to 30 years old (44.44%). Results also indicated that most participants were married (66.67%), were non-smokers (77.78%), were alcoholic beverage drinkers (66.67%), and had not used psychoactive substances (0.00%). The most prevalent metabolic disease among the participants were hypertension (37.04%) and diabetes mellitus (11.11%). Results also showed that 22.22% of the participants previously received treatment for hair loss, and among them, the most common was the use of minoxidil (66.67%).

### Descriptive Statistics of Male Pattern Baldness or Hair Loss

Table 2. Descriptive Statistics of the Male Pattern Baldness or Hair Loss using the Norwood Hamilton Scale among the Participants (N = 27)

| Norwood Hamilton Scale | Frequency (f) | Percentage (%) | 95% Confidence Intervals (CI) |
|------------------------|---------------|----------------|-------------------------------|
| Stage II               | 1             | 3.70%          | 0.09% to 18.97%               |
| Stage IIA              | 6             | 22.22%         | 8.62% to 42.26%               |
| Stage III              | 8             | 29.63%         | 13.75% to 50.18%              |
| Stage IV               | 5             | 18.52%         | 6.30% to 38.08%               |
| Stage IVA              | 2             | 7.41%          | 0.91% to 24.29%               |
| Stage V                | 4             | 14.81%         | 4.19% to 33.73%               |
| Stage VI               | 1             | 3.70%          | 0.09% to 18.97%               |

The descriptive statistics of the male pattern baldness or hair loss using the Norwood Hamilton Scale are shown in Table 2. It can be noted that the most prevalent male pattern baldness was Stage III (29.63%), followed by Stage II-A (22.22%) and Stage IV (18.52%). Only 3.70% had Stage II and Stage VI hair loss among the recruited participants.

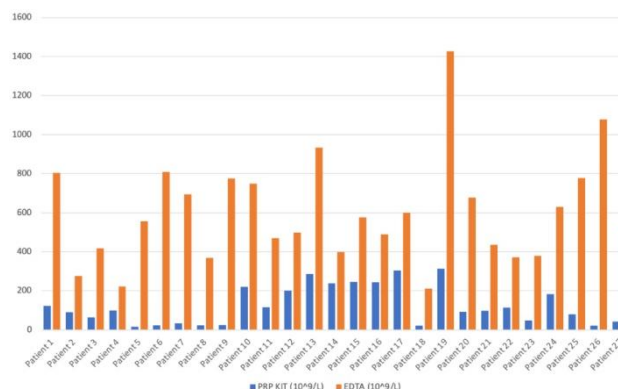


Figure 4. Comparative Graphs of the Platelet Concentration Obtained in PRP Kit and EDTA Tube

### Comparative Analyses of Platelet Outcomes

Table 3. Comparative Analyses of the Outcomes (Platelet Concentration) among the Participants according to the Type of Platelet Rich Plasma (PRP) Tube Used (N = 27)

| Outcomes                                    | Type of Platelet Rich Plasma Tube (PRP) (N = 27) |                 |                                      |                  | Mean Difference (95% CI)     | Test Statistic | p-value (Two-Tailed) |
|---------------------------------------------|--------------------------------------------------|-----------------|--------------------------------------|------------------|------------------------------|----------------|----------------------|
|                                             | PRP Kit                                          |                 | EDTA                                 |                  |                              |                |                      |
|                                             | Mean (SD) [Range]                                | 95% CI          | Mean (SD) [Range]                    | 95% CI           |                              |                |                      |
| Platelet Concentration (10 <sup>9</sup> /L) | 124.52 (97.75) [15.00 To 313.00]                 | 85.85 To 163.19 | 597.19 (271.53) [212.00 To 1,427.00] | 489.77 To 704.60 | -472.67 (-575.40 to -369.93) | -9.46*         | 0.001                |

\*Significant at 0.05

Table 3 and Figure 4 illustrates the comparative analyses of the platelet concentration according to the type of PRP tube used. Analyses indicated that the skewness and kurtosis of the data were 0.61 ( $p=0.145$ ) and 1.91 ( $p=0.141$ ), respectively, and Shapiro-Wilk's Test yielded a  $p$ -value of 0.056. These statistical tests indicate that the outcome was normally-distributed. It can be noted that the mean platelet concentration using the PRP kit tube was 124.52 (SD=97.75; Range=15.00 to 313.00), while the EDTA tube had a mean platelet concentration of 597.19 (SD=271.53; Range=212.00 to 1,427.00). Comparative analyses indicated that the mean difference in platelet concentration between the PRP kit tube and EDTA tube was -472.67 (95% CI = -575.40 to -369.93). This result indicated that the mean platelet concentration ( $t=-9.46$ ,  $p=0.001$ ) was statistically different between the

PRP kit tube and EDTA tube. In particular, it can be noted that the mean platelet concentration was significantly higher in the EDTA tube compared with the PRP kit tube.

## DISCUSSION

Androgenic alopecia continues to be the most prevalent hair disorder for which no satisfactory treatment exists. Currently, there have been a variety of treatment options for AGA, with only two FDA approved medications, the topical minoxidil and oral finasteride. Given the limited effectiveness of current therapies for AGA, PRP has emerged as a promising alternative treatment. With the advent of PRP, currently, there is only a single FDA approved PRP kit in the country and it utilizes sodium citrate as an anticoagulant. In an effort to enhance the economic accessibility of PRP for all patients with androgenetic alopecia, blood collection anticoagulant tubes, such as those containing EDTA, may serve as alternative to proprietary PRP kit tubes.

Platelet rich plasma is defined as a volume of plasma derived from a patient's own blood with a platelet concentration higher than the baseline level. For clinical effectiveness, the platelet concentration should be at least  $1,000 \times 10^3$  cells/ $\mu$ L in the plasma.<sup>[13]</sup> The regenerative potential of PRP relies on the concentration of released growth factors. Growth factors in platelet granules of PRP attach to the bulge area of hair follicles, thus, stimulating hair growth with a crucial role in starting and sustaining the healing process.<sup>[14]</sup> In a study by Eppley, et al., (2004)<sup>[15]</sup>, the quantification of platelet concentration combined with growth factor analysis and its implications in wound healing was determined which revealed that the concentration of growth factors also increased with increasing platelet number. Therefore, a higher platelet concentration would indicate an elevated level of growth factors, thereby enhancing the regenerative potential of the obtained PRP.

Platelets are rich in growth factors that facilitate tissue repair mechanisms, including epidermal growth factor (EGF), platelet-derived growth factor (PDGF-AA and -AB), and transforming growth factor (TGF)- $\beta$ . These growth factors function in accelerating angiogenesis and promoting collagen synthesis, ultimately facilitating wound healing and tissue regeneration. In a study conducted by Lee, et al., (2024)<sup>[16]</sup>, they determined the correlation of growth factors with the platelet levels in PRP, Pearson correlation analysis indicated a strong positive correlation between PDGF, TGF, and EGF levels and the platelet concentration in the final PRP product, with correlation coefficients of  $r = 0.697$  ( $p < 0.0001$ ),  $r = 0.488$  ( $p < 0.0001$ ), and  $r = 0.572$  ( $p < 0.0001$ ), respectively.

Dermal papilla cells regulate hair morphogenesis and growth by producing growth factors which are essential for maintaining the hair follicle in the anagen phase. Thus, upregulating these growth factors within dermal papilla cells represents a potential strategy for prolonging the anagen phase and subsequently increasing hair density, most especially in patients with androgenetic alopecia.<sup>[17]</sup>

Table 3 shows that the mean platelet in the EDTA group was significantly higher than the PRP Kit group. Consequently, the maximum platelet concentration value obtained from the EDTA group was at 1,470,000 cells/ $\mu$ L as compared to the maximum platelet concentration of the PRP kit group at 313,000 cells/ $\mu$ L. Thus, the EDTA group achieved the level at which platelet concentration was deemed to be effective for PRP use in 2 of the participants.

In a systematic review by Fadadu et al., (2018)<sup>[18]</sup> the platelet concentration factor varied significantly across 33 systems studied, ranging from 0.52 to 9.7 times the baseline platelet concentration from the whole blood. Only 11 of the 33 systems and protocols met the ideal concentration of PRP at 1,000,000 cells/ $\mu$ L. These systems varied in their PRP tubes, spin settings, anticoagulants, activators and separator gels. Although  $1,000 \times 10^3$  cells/ $\mu$ L was the platelet concentration level for which the regenerative capacity of PRP is therapeutically effective, an optimal platelet concentration for PRP has not yet been established.

A potential key difference in methodology between the two groups appears to be the use of tubes containing thixotropic polyester separator gel, the anticoagulant and the centrifugation methods used. The centrifuged blood in the PRP kit tube resulted into three distinct layers: a clear, yellowish plasma layer on top, which included a platelet poor plasma (PPP) layer above and a PRP layer below, a middle layer of cell separator gel containing leukocytes, and a red blood cell layer at the bottom. The tube was then resuspended to mix the plasma, thrombocyte, and leucocyte, forming the final PRP. Conversely, the EDTA tubes utilized lacked a separator gel. Thus, manual separation of the plasma from the centrifuged whole blood was done and PRP was obtained after two centrifugation steps as compared to the single centrifugation step done in the PRP kit group. The initial centrifugation (or soft spin), which applies a low centrifugal force, separates whole blood into three distinct layers: red blood cells, the buffy coat, and plasma. The subsequent centrifugation (or hard spin), which involves a higher centrifugal force, concentrates the platelets at the bottom of the plasma phase in order to obtain the PRP.<sup>[19]</sup>

In a study conducted by Reksodiputro, M. H. (2021)<sup>[20]</sup>, wherein the same PRP kit was used in the determination of platelet count in PRP, they have concluded that the low platelet count obtained using the PRP kit may probably be caused by the trapping of platelets in the separator gel tube. This may explain the results described in table 3 and figure 4 wherein the PRP Kit group had a significantly lower platelet concentration levels as compared to the EDTA group ( $t = -9.46$ ,  $p = 0.001$ ).

The PRP kit employed in this study used sodium citrate as an anticoagulant, in contrast to the ethylenediaminetetraacetic acid used in EDTA tubes. According to Carvalho, et al. (2024)<sup>[21]</sup>, the platelet concentration levels obtained from EDTA tubes were significantly higher than the sodium citrate tubes with a mean platelet concentration in PRP for SC-collected samples at 1,858,410 cells/mm<sup>3</sup> (range, 102,000 to 4,260,000), and 3,458,222 cells/mm<sup>3</sup> (range, 1,476,000 to 5,322,000) for EDTA-collected samples. The platelet recovery rate was higher with EDTA in comparison to SC (51.04% vs. 29.85%,  $p = 0.005$ ). Similarly, the results described in table 3 show that the EDTA tube group was superior to the PRP kit which uses sodium citrate as an anticoagulant.

PRP kits offer the advantage of ease and simplicity of use within a closed system. On the other hand, the use of EDTA tubes entail a double spin and separation process in order to obtain the PRP. Despite the ease of use of PRP kits, certain factors such as the presence of separator gels, which may decrease the platelet levels, and the anticoagulant utilized may affect the platelet concentration levels in the PRP produced, potentially decreasing its therapeutic efficacy.

## CONCLUSION

The platelet concentration levels obtained from the EDTA tubes were significantly higher than the commercially available PRP kit levels. Indirectly, an increase in platelet concentrate results in an increased level of growth factors. Therefore, we can conclude that the EDTA tube may be a good alternative to the costly commercially available PRP kit.

## RECOMMENDATIONS

With the results of the study, it is recommended to have further clinical studies with the use of EDTA tubes in hair restoration therapies. Additional studies may be done with a larger sample size to encompass a larger representative of the population wherein EDTA may be compared to other variants of PRP kits in combination with the anticoagulant tubes available in the country.

Further research on a randomized controlled trial comparing the therapeutic effect of PRP using EDTA tubes versus PRP kits in relation to the platelet concentration levels in patients with androgenetic alopecia (AGA) may be conducted.

## LIMITATION

This study is limited to the collection of data from the laboratory results of the platelet concentration levels of the participants and did not include the administration of PRP injection in the participants. Furthermore, it was limited to the use of a single type of commercially available PRP kit and did not completely represent all variants. This study only included adult male patients with AGA and did not include females and other age groups.

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## A Study of Functional Outcomes Generated in a Brief Animal-Assisted Therapy Among Chronic Patients of a Health Care Facility\*

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### ABSTRACT

**Background:** Schizophrenia, a common mental disorder, is associated with cognitive impairment in middle-aged and older adults. Research highlights challenges such as white matter loss, dementia risk, psychosocial issues, nursing home admissions, and limited cognitive benefits from antipsychotics. Animal-Assisted Therapy (AAT) is an emerging intervention for mental and physical illnesses, including schizophrenia.

**Methods:** This quasi-experiment included 20 patients from a health care facility, selected through purposive sampling based on inclusion/exclusion criteria.

**Results:** AAT significantly improved lower body strength (CST) and cognitive abilities (MOCA- P) but had no effect on agility (TUG). Male participants showed greater improvements than females in all domains: CST (+7.8), TUG (-2.365), and MOCA-P (+12). The dropout rate was 50% for females and 20% for males, primarily due to eligibility for discharge.

**Conclusion:** AAT significantly enhances lower body strength and cognitive function but does not improve agility. It is a safe, feasible adjunct therapy for chronic mental health conditions, though targeted interventions for mobility challenges are needed.

**Keywords:** Schizophrenia, functional outcomes, Animal-Assisted Therapy, AAT, Ghair Stand Test, Montreal Cognitive Assessment-Primary, Timed Up and Go, GST, MOGA

### INTRODUCTION

In Kaplan & Sadock's Comprehensive Textbook of Psychiatry, schizophrenia was described as one of the most common serious mental disorders in the Synopsis of Psychiatry<sup>1</sup>. Schizophrenia affects 1% of the population, with a quarter being middle- aged and older<sup>2</sup>. It leads to increased oXidative stress, accelerated aging, and a shorter life eXpectancy compared to the general population. The study also stated that cognitive impairment is a core deficit in schizophrenia, impacting functional recovery. Middle-aged patients with schizophrenia eXperience accelerated white matter loss, increased dementia risk, physical and psychosocial challenges, and a higher risk of admission to nursing homes. Antipsychotic medication is generally less effective in improving cognition.

Research on human-animal interactions is still relatively new. Nonetheless, animal-assisted therapy (AAT) is increasingly being researched as a potential treatment for physical and mental illnesses, including schizophrenia<sup>3</sup>. Some studies have shown positive health effects, but the results have been miXed. Human-animal interactions (HAI) describe a wide spectrum of interactions and relationships between animals and humans and are of growing interest to researchers, the public, and the media<sup>4</sup>.

The purpose of this research was to study the Functional Outcomes Generated in Brief Animal-Assisted Therapy (AAT) Among Chronic Patients of a health care facility. It also aimed to eXplore the effect of AAT on cognitive, physical, and socialfunctions among adult patients with schizophrenia.

### METHODOLOGY

#### Study Design

Quasi-eXperimental study design is often described as non-randomized pre-post intervention studies. This design is often used to evaluate the benefits of a specific intervention<sup>5</sup>.

#### Sampling Technique

Twenty participants were recruited for this study, and they were selected from the chronic male and female wards. Among the patients admitted in each ward, purposive sampling was selected according to the inclusion and eXclusion criteria.

In this quasi-experimental study on the functional outcomes of brief Animal-Assisted Therapy (AAT) among chronic patients of a health care facility, a sample size of 20 participants was strategically selected. This decision was

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*Disclosures:* The author has formally acknowledged and signed a disclosure affirming the absence of any financial or other relationships (including personal connections), intellectual biases, political or religious affiliations, and institutional ties that could potentially result in a conflict of interest.

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influenced by the novelty of conducting such a study in a mental hospital setting in the Philippines, as well as by findings from systematic reviews, which show that previous AAT studies often utilized sample sizes ranging from 20 to 24 participants<sup>6</sup>. Here are the key points to explain this choice:

1. **Establishing Guidelines:** Since this is the first study of its kind in a mental hospital in the Philippines, it is crucial to establish and refine guidelines. A smaller sample size allows the researchers to develop and test these guidelines effectively without the complexity of managing a larger group.
2. **Ensuring Safety:** The safety of participants is a top priority, especially in a mental health setting. By starting with a smaller group, the researchers can closely monitor the participants, identify any potential risks, and ensure that appropriate safety measures are in place.
3. **Managing Concerns:** With 20 participants, the research team can better manage any concerns or issues that arise during the study. This manageable number allows for more individualized attention and a more thorough understanding of the challenges that may be encountered.
4. **Preliminary Insights:** This pilot study aims to generate preliminary data that can provide valuable insights into the effectiveness of animal-assisted therapy. The findings from this small sample can help identify trends, highlight potential challenges, and uncover variables that may impact the therapy's outcomes. These insights are crucial for refining the study design before proceeding with larger-scale research.
5. **Feasibility and Manageability:** Conducting a pilot study with a smaller number of participants helps the researchers assess the feasibility of the study design and the logistics involved. It allows them to fine-tune procedures and protocols before scaling up to a larger study. A sample size of 20 allows the research team to conduct the study within a controlled and safe environment. This limited number facilitates easier coordination and monitoring of participants, ensuring that the therapy sessions can be administered consistently and effectively.
6. **Data Collection and Analysis:** A smaller sample size enables the research team to collect and analyze data more efficiently. This preliminary data can provide valuable insights and help in making necessary adjustments to improve the study design. By starting with 20 participants, the study aims to ensure a controlled, safe, and manageable environment that will help establish a solid foundation for future

research. This approach helps to address any unforeseen issues, refine the study protocols, and ultimately contribute to the success and reliability of larger-scale studies in the future.

In summary, a sample size of 20 is justified as it facilitates manageable, efficient, and insightful research that lays the groundwork for future studies investigating the therapeutic benefits of animal-assisted therapy among patients with Schizophrenia.

#### 1. Unit of Study

Patients admitted in the male and female chronic wards of a health care facility.

### Materials and Procedures

#### Locale of Study

The research was conducted in wards of a health care facility.

#### Method of Study Selection

##### a. Inclusion Criteria:

- i. Diagnosis of schizophrenia according to the fifth edition of the Diagnostic and Statistical Manual of Mental Disorders.
- ii. Ages nineteen to fifty-nine years old.
- iii. Those with stable physical health conditions are based on clinician evaluation.
- iv. Participants with no reportable incidents or accidents for at least a month.
- v. Provision of written informed consent.

##### b. Exclusion Criteria:

- i. Participants with severe cognitive impairment: aphasia or inability to follow three-step instructions.
- ii. Participants with an allergy to or fear of dogs
- iii. Participants with a history of aggression toward animals
- iv. Participants with a history of restraint
- v. Participants with a history of Bronchial Asthma, confirmed diagnosis of coagulation disorders, Seizure Disorder, Diabetes Mellitus, Hypertension, Intellectual Disability, Obsessive-Compulsive Disorders
- vi. Non-ambulatory participants
- vii. Re-admissions who had already participated in the study
- viii. No informed consent was given.

#### Research Instrument

##### i. Montreal Cognitive Assessment (MoCA)

The MoCA-P is a 30-point scale that evaluates visuospatial ability, executive functions, naming, attention, language repeat, language fluency, delayed recall memory, abstraction, calculation, and orientation. The total score indicates global cognitive function. Evidence has shown that the MoCA-P is sensitive to detect cognitive impairment in patients with schizophrenia.

##### ii. Chair Stand Test (CST)

The CST is a performance-based test, which requires participants to rise from a straight sitting position to a full standing position with their arms folded across their chest as many times as possible within 30 seconds. The test was completed on a seat placed near a wall. The number of repetitions was recorded. Higher scores represented better lower body strength

##### iii. Timed Up-and-Go (TUG)

The TUG is a widely used performance-based test that requires participants to stand up, walk, turn, and sit down. The time to perform the test is recorded in seconds. A lower score indicates better agility. The TUG has previously been used as an outcome measure to examine the effect of an exercise program in patients with schizophrenia and has good reliability.

#### Selection Process

Participation was offered to the selected patients admitted to the chronic wards who met all the inclusion criteria and none of the exclusion criteria. The list of admitted patients was acquired during the time of recruitment and the individuals were invited to participate. The research was explained to them and the first twenty (10 women and 10 men) who responded to the invitation and provided written consent were recruited. Participants who were successfully discharged and transferred to another ward were not replaced anymore. Since this is a pilot study and the first of its kind, there is no intention to ensure the representativeness of the population. Rather, the feasibility and appropriateness of conducting such an intervention is of priority and may also be reflected in the notes section of the Human-Animal Interaction-observer tool used in this study. Further studies may be recommended after the completion of this research.

#### Socio-Demographic Data

The socio-demographic data that will be collected are age, gender, civil status, medical ailments, presence of pets in the household, kinds of pets, duration

of living with the pets. The information was collected through a form and guided by nursing attendants and the principal investigator to ensure that the data are filled in with utmost accuracy and correctness. The form may be viewed in Appendix 2

#### Intervention

Requesting permission to conduct the study was performed first. Communitails, Inc. was coordinated and requested their participation in the study. Coordination with the proper authorities, specifically the chief of PETRO, Medical Training Office (MTO), and head of wards were also accomplished. The research proposal and other important documents were forwarded to these authorities for their review. All recommendations and comments were taken into consideration.

Early coordination was done with Communitails to explore partnership in providing HATs to participate in this study. Two weeks prior to the start of the group sessions, Human-Animal teams (HATs) were oriented regarding the study's objectives, protocols, and other ethical and safety considerations. Topics such as but not limited to confidentiality, patients' profiles, and their diagnoses, how to communicate with patients, proper interaction with patients and safety protocols shall be discussed. Informed consents were also collected from the handlers to affirm their participation in the research.

Participants received their usual treatment programs, consisting of nursing interventions, pharmacotherapy, occupational therapy, psychotherapy, and recreational activities. A total of eight group sessions were conducted for two different groups (one male and one female). Sessions were done at least once a week for each of the two groups in a wide and quiet room, appropriate for AAT. Sessions were planned, drafted, and agreed upon in advance by the Communitails professionals and the principal investigator. In each session, specific objectives were worked on utilizing different group dynamics.

Each session was facilitated by the principal investigator, who is a Resident in-training in partnership with a trained and certified Communitails Human-Animal Teams (HAT) and other staff as deemed relevant.

At the start of the first activity, the participants did pre-measures (MoCA-P, CST and TUG) tests guided by the principal investigator followed by the fifteen-minute warm-up session to build rapport and included participant greetings, introduction of the therapy dogs by their handlers, and the session orientation, the forty minutes main therapeutic activities. These therapeutic activities were categorized into the following four types:

physical activities, cognitive activities, social activities, and activities for positive emotion. Brief descriptions of the activities are listed in Appendix 1. Another set of tests mentioned above were done prior to the conclusion and feedback.

The succeeding sessions started with the fifteen-minute warm-up session, the forty minutes main therapeutic activities and the 5-minute feedback session were carried out each therapeutic activity and was facilitated by the researcher. Participants were encouraged to express their feelings and experiences during the animal-assisted therapy. Lastly, the activity ended with participants answering the Human-Animal Interaction Scale (HAIS) in Appendix 3. The activity concluded with the patients answering the post-measures (MoCA-P, CST, and TUG), still being guided by the principal investigator.

#### a. Animal Resources

For this study, only dogs were involved as therapy animals. The specific breeds were Corgi, Dachshund, French Bulldog, and Mini Schnauzer. The Communitails team was paid 10,000.00 per session to cover the time of the human-animal team, steward, and administrative costs, as agreed.

The intervention included Human-Animal teams (HATs), which were composed of the therapy dog and the handler. Before being HATs, they were selected for having a suitable character and appropriate aptitude, with a calm, docile, and obedient temperament, and training that enriched the sessions. The handlers and their partner animals must complete a specific training process with positive training techniques and habituation to the hospital environment to be able to easily adapt to different situations. They are trained in animal welfare, human-animal bonds, infection control, and risk management, standards of practice in health facilities, and canine body language. All the animals need to be cleared by their veterinarians to be in good health. Dogs need to comply with basic standards of vaccination, anti-parasitic treatment, and hygiene. These are all part of the certification process provided by Communitails. As a team, they have undergone screening, evaluation, and learning visits. Certifications are renewed after 2 years.

Communitails provided updated vaccination records and training the HATs attended. Example of criteria for screening HATs:

#### Environment:

- Observation of the dog with its handler in various situations based on the planned or spontaneous intervention, and natural environments.

- The dog must remain under control and easily redirect.
- The dog must not regularly vocalize inappropriately according to the context, population, or environment, and may be easily redirected, and presented safely.
- The dog must not overreact to distractions or unusual situations in the environment (e.g. sudden noises/movement, etcetera).

#### Social:

- The dog must present itself in a safe and approachable manner.
- The dog must display genuine interest in socializing with people and receiving attention from a variety of people, demonstrating appropriate responses.
- Observation of the dog with its handler with different groups/individuals, representative of the participant groups with which the dog will work.
- The dog must be assessed walking through a crowded area.
- The dog must not get over-excited or show continual signs of stress.
- The dog must demonstrate control around food, toys, and other resources and show no signs of resource guarding.
- If the dog is required to play as part of the AAI work, this must be assessed to ensure it will play appropriately.
- If the dog is required to work in the presence of other dogs, it must be well-mannered around other dogs with consideration given to normal canine communication and development.
- Dogs must show a good level of adaptability and enjoy interacting with the population with which it is expected to work.

#### Handling:

- The dog should remain relaxed with different people petting, checking over, and handling/grooming the dog if that is what is expected in the dog's normal line of work.

The dog's evaluation must include reaction to strangers, children, people on floor, level of obedience, grooming acceptance, walking on loose leash, ability to respond off-leash if appropriate, behavior in a crowd, responding to its name, ability to work with other animals in the environment and show resilience without any adverse reactions, appropriate reaction to distractions, ability to be redirected, acclimation to healthcare

equipment and environment, ability to be alone, and separation from the handler.

Dogs should demonstrate appropriate contextual responses in these situations. Where possible, the dog must be evaluated in the environment, under similar conditions, and with a similar population to which it will be working. The team will be evaluated before a session, and then during a mock or actual session. The dog must wear appropriate collars or harnesses, leashes, etc. that it would wear in a typical session. If a dog is expected to walk together with a participant and handler, or on a double leash, or off leash that must be evaluated as well.

**b. Risk Assessment from the Animal Assisted Intervention International website as stated in the animal assisted intervention international website**

The welfare of the dog during AAI:

- The dog must have access to an appropriate area and be given opportunities, as required, for rest, access to water, and access to toileting facilities before and after each session.
- Dogs must be given breaks based on activity level, development level, stress levels, weather, etc.
- Dogs need to have their own space and places to get away if desired
- Animals can choose to be with participants or move away and handlers can adjust intervention accordingly
- Sessions must be terminated immediately if the dog's welfare is in danger of being compromised.
- The dog must not mix with unfamiliar dogs on-site without careful consideration and supervision.
- If more than one dog is used in a working session, ideally, the dogs would have time to familiarize themselves with each other in advance.
- The hospital's access protocol and hygiene measures for hand washing, change of clothes, surface disinfection/cleaning, first aid, and acute crisis management protocols were followed.

The welfare of participants during AAI as mentioned in the Animal-Assisted Intervention International Standards of Practice:

- All AAI personnel (healthcare/human service providers, dog handlers, etc.) supporting the participant must demonstrate positive human interaction with the participant and have appropriate social skills, and verbal, and nonverbal communication.
- As mentioned in the Animal-Assisted Intervention International Standards of Practice (2013), providers respect the autonomy of participants and implement

an informed consent process before all interactions.

- AAI providers are expected to have specific training and supervision or mentoring in their area of AAI. Training includes clinical work, risk management, and informed consent:
  1. An Introduction to AAI (separate course focused on AAA/AAT/AAE) course or training (human-only)
  2. An AAI skills training for the human-animal team,
  3. An AAI human-animal team evaluation,
  4. An AAI practicum (either AAA/AAT/AAE) in which the human-animal team demonstrates AAI skills with volunteer (nonclinical) clients,
  5. Clinical supervision with an AAI-trained supervisor (this is more relevant for AAT/E)
- Participants are always supervised
- The AAI delivery team was trained in or had access to individuals trained in human first aid and animal first aid. Contact details of local veterinary and medical services and any other identified support were available in case of an emergency
- Orientation prior to the start of the intervention date was made for both the hospital staff and Communitails team
  - A brief discussion about Schizophrenia, confidentiality issues, expectations, and do's and don'ts for the Communitails team
  - A brief discussion about Communitails, animal welfare, expectations and do's and don'ts for the hospital staff

Termination of Services

- AAT services must be discontinued if the intervention is no longer supporting goals, if there are any health concerns of humans or dogs, or if there are any changes to the environment, dog handler, or population that are not conducive to the dog's skills or well-being.
- Participants who will be symptomatic will be removed from the activity and will be escorted back to the ward of origin. They shall be labeled as "dropouts."
- Dropout participants shall be immediately reassessed by the principal investigator and shall document it in their charts with corresponding recommendations.
- Participants who will have a bite accident shall be removed from the activity and will be assisted to the Emergency Room for appropriate treatment. They shall also be labeled as dropouts and shall be assessed by the principal investigator.

### c. Principal Investigator's Training:

The following are the training programs completed by the Principal Investigator to ensure adequate skills and knowledge about the implementation of animal-assisted therapeutic activities.

- Animal-Assisted Interventions (AAI) in Counseling: An Introductory Course for Mental Health Professionals (August 19, 2021)
- Philippine Human-Animal Bond Conference (July 1-2, 2022)
- Communitail's Animal Assisted Intervention (AAI) Training Course
  - Module 1: Fundamentals of Animal-Assisted Interventions
  - Module 2: Animal-Assisted Interventions in Practice

### Statistical Treatment of Data

To determine the difference between male and female performance in the tests used. Student t-test and Mann-Whitney test is employed depending on the normality of the distribution of the male and female scores. Shapiro-Wilk test is used for the identification of the normality of distribution. To determine the difference between pre-test and post-test scores on functional outcomes, the researcher employed a paired sample t-test and to see its effect size, the researcher used Cohen's d. On the missing values due to dropping out or choosing not to participate of the participant due to health issues and comfortability, the researcher has used an approach called Last observation carried forward (LOCF), this is the best approach of imputation since the nature of data gathering is that the participants are tested at each end of session. This is also helpful as the reason for dropping out is due to missing at random. Specifically, the participants were being transferred to another ward or were successfully assisted back home by the time of the study. As such, the research respects the circumstances of the client and was removed from the study which is at random. It is therefore assumed that their last score will remain stable across the next session.

## RESULTS AND DISCUSSION

In this section, the results and discussion of the study were discussed, it will talk about the findings of the statistical analysis of the quasi-experimental. It used a paired sample t-test of the 1st point of measurement with the 8th (last) point of measurement. Then the comparison of gender used and the independent sample t-test.

## Results

Out of 20 participants, 13 (65%) participants were retained at the end of the study. Out of the 7 (35%) participants who dropped out, 6 were returned to their families successfully after positive assessment and were deemed possible to be returned to the society and 1 was transferred to another ward. There had been one (1) event where the therapy dog had to be withdrawn earlier due to safety reasons. Because of the incident, one (1) of the ten (10) male participants declined to attend the next session. Debriefing was done to both participants and the Human-Animal team. The participant rejoined the next sessions and finished. Due to the drop out of almost half of the participants, the researcher decided to use an imputation known as the last observation carried forward (LOCF). This was done due to the availability of initial data which all of them have. Excluding the 9 participants from the analysis would make the analysis faulty. As such, the researcher decided to use LOCF instead of other imputation methods.

Among the twenty (20) participants, 8 (40%) were ages 5-9 years old. (85%) were single and none had a presence of medical illnesses. All (100%) of them have pets at home and 18 (90%) have dogs.

The hypothesis for the effect of brief animal-assisted therapy in functional outcomes among chronic patients of a health care facility is that Brief Animal-Assisted Therapy (AAT) cannot improve functional outcomes among the chronic patients of a health care facility. This is explored in this part of the chapter.

The principal investigator used mean and standard deviation for the measurement of central tendency and variation for the data used for the CST, TUG, and MOCA-P. The three data were all continuous variables. The data was analyzed first using the Shapiro-Wilk test to understand if the data are normally distributed, the result of the Shapiro-Wilk test found that the data are normally distributed. The result is in Table 4: Descriptives of the scores of functional outcomes. Due to that, the researcher decided to proceed with a normal t-test or student t-test for the comparison of the pre-test and post-test.

The mean for the CST, TUG, and MOCA-P for its pre-tests are 12.3s, [GR1] 8.5s, and 13.9s with standard deviations of 3.27, 2.63, and 7.5s, respectively. On the other hand, the mean for the CST, TUG, and MOCA-P for its post-test are 17.60, 9.44, and 18.20 with standard deviations of 5.9, 2.72, and 9.60, respectively. The descriptives are reported in Table 1. The values presented show that the data has a measure of dispersion that is good.

Table 1: Descriptive scores of functional outcomes

| Functional Outcomes Scores | N  | Mean   | SD    |
|----------------------------|----|--------|-------|
| 8th CST                    | 20 | 17.600 | s.s86 |
| 1st CST                    | 20 | 12.3s0 | 3.26s |
| 8th TUG                    | 20 | 9.441  | 2.719 |
| 1st TUG                    | 20 | 8.s79  | 2.633 |
| 8th MOCA-P                 | 20 | 18.200 | 9.600 |
| 1st MOCA-P                 | 20 | 13.9s0 | 7.ss7 |

The researcher tested for the normality of distribution to determine if the data were normally distributed to determine the analysis to be done on the data. In the test of normality, the researcher found that for CST, TUG, and MOCA-P the W is 0.9s3, 0.936, and 0.9s4 with p-values of 0.410, 0.199, and 0.426, respectively. This W-value indicates that the data are normally distributed as it is close to one while the p-value indicates whether it is significant or not if it is less than 0.0s. All the value shows that the data are normally distributed and are significant. This information is all presented in Table 2: Test of normality.

Table 2: Test of Normality (Shapiro-Wilk)

| Post-test  | Pre-test   | W     | p     |
|------------|------------|-------|-------|
| 8th CST    | 1st CST    | 0.9s3 | 0.410 |
| 8th TUG    | 1st TUG    | 0.936 | 0.199 |
| 8th MOCA-P | 1st MOCA-P | 0.9s4 | 0.426 |

Note. Significant results suggest a deviation from normality.

\*Significant

The data are normally distributed, normally dispersed, the researcher has proceeded to use paired sample t-tests to compare the post-test and pretest functional outcome scores and identify the difference in the scores after undergoing animal- assisted therapy. The result found that the t-statistics of CST and MOCA-P are 4.104 and 4.443, respectively. This t-statistic is found significant as its p-values are 0.0006037 and 0.0002793. On the other hand, the difference in all participants' TUG is found to be non-significant with a value of 1.673. The difference in the mean per functional outcomes is s.2s, 0.862, and 4.2s, respectively.

This leads us back to the hypothesis that Brief Animal-Assisted Therapy (AAT) cannot improve functional outcomes among the chronic patients of a health care facility. As presented, the functional outcomes of CST, and MOCA-P namely, lower body strength and cognitive ability are found to be improved as evidenced by the pre-

test and post-test difference scores. However, the agility functional outcomes that are represented by TUG are found to be not significant. There we can say that the functional outcomes (CST and MOCA-P) improved due to the presence of animal-assisted therapy. This means that we fail to accept the null hypothesis as evidenced by the significant difference between the two functional outcomes.

In addition to that, the researcher tried to find the effect size of the animal- assisted therapy through Cohen's d. Cohen's d that the researcher found out that the CST and MOCA-P have 0.918 and 0.993, respectively. While the TUG's Cohen's d is 0.374. This shows that the presence of animal-assisted therapy is effective in improving the client's functional outcome in terms of gross motor skills and cognitive ability. On the other hand, there is a small effect size of the animal-assisted therapy on the mobility of the client since the value of Cohen's d is only 0.374 making it only small in effect size.

Table 3: Paired Samples T-Test of pre-test and post-test

| Post Test   | Pretest     | t     | df | p         | Cohen's d | SE Cohen's d |
|-------------|-------------|-------|----|-----------|-----------|--------------|
| 8th CST     | 1st CST     | 4.104 | 19 | 6.037e-4* | 0.918     | 0.326        |
| 8th TUG     | 1st TUG     | 1.673 | 19 | 0.111     | 0.374     | 0.199        |
| 8th MOCA- P | 1st MOCA- P | 4.443 | 19 | 2.793e-4* | 0.993     | 0.121        |

Note. Student's t-test.

\*Significant

The hypothesis on the difference in functional outcomes generated in a brief animal-assisted therapy between male and female patients in the chronic wards is that there is no difference in the functional outcomes Generated in a Brief Animal-Assisted Therapy (AAT) between male and female patients of a health care facility. This hypothesis is explored in this section.

Only s (s0%) women and 8 (80%) men were retained by the end of the study. There was a 3s% dropout of participants due to them being discharged and returned to their homes, and one being transferred to another ward. They have been found eligible for return after careful assessment according to the center's standards.

In the analysis of the comparison of two gender groups, the researcher used the Student's t-test and Mann Whitney test on table 2. This is for the reason that after the Shapiro-Wilk test that was done, the researcher found out that the normality of distribution of the data in CST and TUG are normally distributed while for MOCA-P it was not normally distributed. This was after getting a

0.0006364 for the p-value of the W statistic that is 0.688, this indicates that the data are not normally distributed. This information is all presented in table 3: descriptive statistics.

In addition to this information, the researcher used both mean and median with standard deviation and interquartile range (IQR) as a measure for central tendencies and dispersion. This is the reason for previous finding of normality of distribution wherein the MOCA-P males are not normally distributed. As such, it is decided that both t-test and Mann Whitney U test will be used as a measure for difference which uses mean and median, respectively.

As presented in Table 3, the mean of males and females in CST is 21.400 and 13.800 with standard deviations of s.337 and 2.300, respectively. With TUG, the mean is 8.2s8 seconds and 10.623 seconds with standard deviations of 2.s48 and 2.4s1, respectively. On the other hand, the Median of MOCA-P of males and females is 24.s00 and 12.s00 with IQR of 4.s00 and 11.2s0, respectively.

Table 4: Descriptive Statistics of final measurement of functional outcomes grouped by sex

| Statistical measurement | 8th CST |        | 8th TUG |        | 8th MOCA-P |        |
|-------------------------|---------|--------|---------|--------|------------|--------|
|                         | Male    | Female | Male    | Female | Male       | Female |
| Median                  | 21.s00  | 14.000 | 7.630   | 9.87s  | 24.s00     | 12.s00 |
| Mean                    | 21.400  | 13.800 | 8.2s8   | 10.623 | 24.000     | 12.400 |
| Std. Deviation          | s.337   | 2.300  | 2.s48   | 2.4s1  | 7.s13      | 7.961  |
| IQR                     | 8.s00   | 1.7s0  | 3.0s0   | 3.7ss  | 4.s00      | 11.2s0 |
| Shapiro-Wilk            | 0.923   | 0.899  | 0.890   | 0.928  | 0.688      | 0.967  |
| P-value of Shapiro-Wilk | 0.381   | 0.213  | 0.168   | 0.431  | 6.3*e-4*   | 0.864  |

\*Significant

The t-statistics in CST and TUG are 4.13s and -2.11s with p-values of 0.0006216 and 0.049 which are both statistically significant. On the other hand, the Mann Whitney u score of MOCA-P is 87.s00 with a p-value of 0.00s which is also statistically significant. These are all presented in Table 4: Independent Samples T- test. Which leads us back to the hypothesis, "There is no difference in the functional outcomes Generated in a Brief Animal-Assisted Therapy (AAT) between male and female patients in the chronic wards of a health care facility". With the findings all statistically significant, we can reject the null hypothesis and accept the alternative hypothesis that is, "There is a difference in the Functional Outcomes Generated in a Brief Animal-Assisted therapy between male and female patients in the chronic wards of a health care facility"

Table 5: T-Test of functional outcomes

| Functional Outcome | Test         | Statistic | df | p         |
|--------------------|--------------|-----------|----|-----------|
| 8th CST            | Student      | 4.13s     | 18 | 6.216e-4* |
|                    | Mann-Whitney | 93.s00    |    | 0.001*    |
| 8th TUG            | Student      | -2.11s    | 18 | 0.049*    |
|                    | Mann-Whitney | 22.000    |    | 0.03s*    |
| 8th MOCA-P         | Student      | .3s1      | 18 | 0.004*    |
|                    | Mann-Whitney | 87.s00    |    | 0.00s*    |

\*Significant

The difference in the male and female performance are as follows: for CST, 7.8, for TUG -2.36s, for MOCA-P 12. This means that the lower body strength, agility and cognitive ability for male patients with chronic schizophrenia are better after the animal-assisted therapy.

## DISCUSSION

This study investigated the functional outcomes of a brief Animal-Assisted Therapy (AAT) intervention among chronic patients of a health care facility. The results indicated a significant improvement in lower body strength, as measured by the CST, and cognitive abilities, as assessed by the MOCA-P. However, no significant changes were observed in agility, measured by the Timed Up and Go (TUG) test. When compared to the study by Chen et al<sup>2</sup> the AAT group in their study showed a greater increase in lower extremity strength and, like our study, no improvement in agility. However, a key difference was that cognitive function improved in our study, whereas it did not show a significant change in their sample.

Furthermore, the study aimed to test the hypothesis that there would be no difference in the functional outcomes of brief Animal-Assisted Therapy (AAT) between Male and female patients in the chronic wards of a health care facility. However, the results led to the rejection of the null hypothesis and the acceptance of the alternative hypothesis, indicating that gender differences do exist in the outcomes of AAT. Of the 20 participants, there was a significant dropout rate, with s0% of women (s out of 10) and 80% of men (8 out of 10) completing the study. The dropout was mainly due to participants being deemed eligible to return home after assessments. Statistical analyses revealed that while the data for lower body strength (CST) and agility (TUG) were normally distributed, cognitive ability (MOCA-P) was not, leading to the use of both t-tests and the Mann-Whitney U test. The results showed significant differences between

males and females in CST, TUG, and MOCA-P. Specifically, male participants showed greater improvements in lower body strength (CST), agility (TUG), and cognitive ability (MOCA-P) compared to females, with differences in performance scores of 7.8 for CST, -2.36s for TUG, and 12 for MOCA-P. These findings suggest that male patients with chronic schizophrenia had better functional outcomes from AAT than female patients, highlighting the importance of considering gender differences when assessing the efficacy of such interventions.

## **CONCLUSION and RECOMMENDATION**

### **Strengths and Limitations**

In terms of strengths, the study employed robust analytical methods, such as paired t-tests and Cohen's d, to assess the intervention's impact across multiple functional domains, including motor skills, mobility, and cognition. The use of the Last Observation Carried Forward (LOCF) technique for imputing missing data helped to maintain the validity of the study despite participant dropouts.

However, the study had some limitations, including a small sample size, which restricts the generalizability of the findings, and the potential for dropout-related bias, which could have affected the statistical power. Additionally, as the study was conducted in a single setting, the results may not be applicable to other mental health facilities or populations.

### **RECOMMENDATION**

Further research is needed to expand on these findings, with larger studies involving more diverse populations and longer follow-up periods to assess the sustained effects of Animal-Assisted Therapy (AAT) over time. Additionally, exploring complementary therapies that specifically target agility could help address the mobility challenges observed in this study, offering a more comprehensive approach to functional improvements. To maximize the potential benefits of AAT, it is also important to consider its integration into holistic care models within mental health facilities. By incorporating AAT alongside other therapeutic interventions, mental health programs can provide a more well-rounded approach to supporting patients' physical and cognitive health.

## **CONCLUSION**

In conclusion, the study rejects the null hypothesis for both lower body strength (CST) and cognitive abilities (MOCA-P), confirming that Animal-Assisted Therapy (AAT) leads to significant improvements in these areas. However, the null hypothesis is not rejected for agility (TUG), indicating that AAT had no significant effect on this functional domain. The findings suggest that AAT may serve as a valuable adjunctive therapy for chronic mental health patients, particularly in enhancing lower body strength and cognitive function. The lack of improvement in agility underscores the need for more targeted interventions that address mobility and agility challenges. Furthermore, the study supports the feasibility and safety of AAT in clinical settings, as no adverse reactions were reported, highlighting its potential as a safe and beneficial intervention for individuals with chronic mental health conditions.

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# Every Contact Leaves a Trace: A Cross-Sectional Study of Medico-Legal Cases in a Tertiary Hospital\*

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## ABSTRACT

**Background:** Cutaneous findings are the most common manifestations of abuse. Hence, a thorough dermatologic evaluation is crucial to rule out the possibility of injuries - accidental or intentional. Underreporting and incomplete documentation were also identified research gaps. The objectives of this study are to establish a baseline database, describe trends in the WCPU and ER medicolegal cases, and identify relationships among demographics, cutaneous findings, and injuries.

**Methodology:** This is a case-control study conducted in a Tertiary Hospital in the Philippines. Medico-legal records from the emergency room and WCPU during 2019-2023 were retrieved and analyzed.

**Results:** There were 2,611 WCPU Cases and 9511 ER Cases. Only 2,663 ER Cases (28%) have complete findings. The majority of the physically abused patients in the ER and WCPU perpetrators were adult males. Most WCPU patients were minor females. Only 25% of the WCPU cases were reported within three days. The majority of sexual perpetrators are not strangers to their victims. A significant fraction of sexual abuse is also incestuous. Several significant cutaneous findings suggestive of physical abuse were observed in this study. Intuitively, Gunshot wounds and stab wounds were associated with intentional injuries. Contusion and hematoma were more likely seen in cases of assaults involving accessible areas during altercations – the cheek, eye, eyelid, and nose. Injuries over protected body sites such as the chest and neck also warrant suspicion of intentional injuries. The abdomen, back, and chest were sites of predilection for both GSW and stab wounds.

**Conclusion:** It should be second nature for all physicians to identify dermatologic and demographic cues to rule out possible cases of abuse.

**Keywords:** Medico-legal cases, Physical Abuse, Rape, Forensic Dermatology, Dermatology

## INTRODUCTION

Dermatologic Examination highlights a careful visual inspection, thorough history-taking, and diagnostic tests (e.g. biopsy) to come up with plausible diagnoses of skin lesions<sup>[1]</sup>. Not obvious to most, dermatologic evaluation takes into consideration different etiologies including ruling the possibilities of injuries - may it be accidental or intentional. This is crucial since cutaneous lesions are the most common manifestations of abuse<sup>[2]</sup>. Diseases like atopic dermatitis may mimic asphyxiation. Cigarette burns may present as ulcers with rolled-out borders seen in tumors. This proves an undeniable relationship between dermatology and forensic science<sup>[3,4,5]</sup>.

Forensic dermatology is a highly specialized field that deals with the examination of the skin, hair, and nails to identify the cause and mechanism of injury<sup>[3]</sup>. It is not fully practiced in most countries including the Philippines. Currently, its utility is almost exclusive to medico-legal cases. However, screening for possible abuse should be second nature for all physicians<sup>[3,4,5]</sup>.

seen in the Emergency Room (ER) and Women and Children Protection Unit (WCPU) in a Tertiary hospital. Underreporting and incomplete reporting of findings were identified research gaps. Hence, the importance of delving into the completeness of dermatologic evaluation and the creation of a baseline census of medico-legal cases. The study identified the demographic profiles, cutaneous findings, and their associations to recognize dermatologic cues of physical abuse. The researcher also described the trends of medico-legal cases during the SARS- CoVid pandemic.

## METHODOLOGY

### Study Design

The study used a cross-sectional design. This was utilized to identify associations between and among age (minor or pediatric vs. adult patients), sex (male vs. female), nature of abuse (sexual vs physical; incest vs non-incest), type of injury, site of injury, and nature of injury (physical abuse vs accidental injuries; vehicular, Emergency Room (ER) and the Women and

*Disclosures: The author has formally acknowledged and signed a disclosure affirming the absence of any financial or other relationships (including personal connections), intellectual biases, political or religious affiliations, and institutional ties that could potentially result in a conflict of interest.*

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Children Protection Unit (WCPU) in a tertiary hospital.

### Study Setting

The study was conducted at a Tertiary Hospital in the Philippines that offers medico-legal and Women and Children Protection Unit services. Data gathering and analysis were conducted for twelve months.

### Study Population

The study included medico-legal cases with records in the ER and WCPU seen from 2019-2023. 2,611 cases from the Women Children Protection Unit and 2,663 cases in the Emergency Room were deemed complete.

### Inclusion Criteria

Inclusion criteria are as follows: 1. Male or Female, 2. Adult and Pediatric patient, 3. Those who availed medico-legal services in the ER or WCPU from years 2019-2023, 4. With accessible and complete Medical Records.

The confidential and legal nature of WCPU cases limited the investigator's access to the entirety of the case files. Hence, for this study the researcher defined a complete WCPU record to include the date of consult, victim's age and sex, type of abuse, duration of reporting, and perpetrator's age, sex, and relation to the victim.

A complete ER record includes the date of consult, patient's age and sex, and type, site, and nature of injury. Records without specific site and nature of injury were still included in the demographics to further elucidate the completeness of forensic dermatology documentation in the ER setting.

### Exclusion Criteria

Medico-legal cases seen before Year 2019 and after 2023 will be excluded. Those records deemed as incomplete by the research standards were also excluded.

### Study Procedure

Data gathering commenced after the permission was granted and the accomplishment of necessary documents. The primary researcher gathered data supervised by Medical Records and WCPU Representative. Codes and identifiers had been used to uphold confidentiality. Unnecessary personal data were not accessed and obtained. Data were initially recorded in an Excel file and were stored in a secured and password-protected computer. Statistical Package for Social Sciences (SPSS) was used to process the data.

### Tools and Instruments

The primary tool utilized in this study is a secured, encrypted, and password-secured laptop. Microsoft Excel will be used for storage. SPSS was used for data analysis.

### Data Analysis

The collected data will be presented through tables and figures which will be further analyzed through Statistical Package of Social Sciences as the main Statistical Software. Pearson chi-square was used to analyze the level of association. Odds ratio is utilized to further elucidate risks. Only completed records will be subjected to Pearson chi-square and odds ratio computation. Confidence interval of  $p < 0.05$  was set to determine the level of significance in this study.

### Results

**Table 1A. Demographics of Medico-Legal Patients in the ER**

|                         | Number of Cases (%) |
|-------------------------|---------------------|
| <b>ER Patients</b>      |                     |
| Total:                  | 9511                |
| <b>Complete:</b>        | <b>2663 (28%)</b>   |
| With missing data:      | 6848 (72%)          |
| <b>Sex</b>              |                     |
| Male:                   | 2010 (76%)          |
| Female:                 | 653 (24%)           |
| <b>Age</b>              |                     |
| Mean:                   | 31 years old        |
| Median:                 | 29                  |
| Mode:                   | 23                  |
| Range:                  | 1-90                |
| <b>Age Group</b>        |                     |
| Adult ( $\geq 19$ y/o): | 2246 (84%)          |
| Pediatric (0-18 y/o):   | 417 (16%)           |
| <b>Nature</b>           |                     |
| Accident                | 1725 (65%)          |
| Physical Abuse          | 938 (35%)           |
| <b>Sex</b>              |                     |
| Male                    | 642 (68%)           |
| Female                  | 296 (32%)           |
| <b>Age</b>              |                     |
| Mean:                   | 32 years old        |
| Median:                 | 29                  |
| Mode:                   | 21                  |
| Range:                  | 1-84                |
| <b>Age Group</b>        |                     |
| Adult ( $\geq 19$ y/o): | 806 (86%)           |
| Pediatric (0-18 y/o):   | 132 (14%)           |

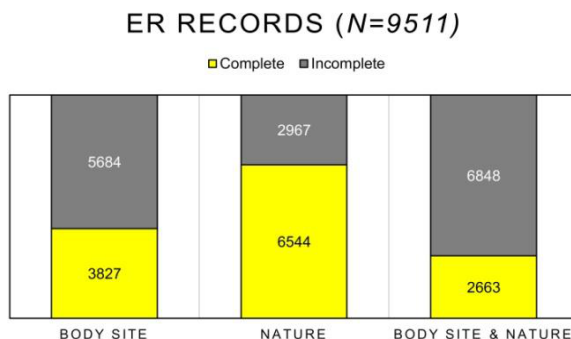
**Table 1B. Demographics of WCPU Patients**

|                         | Number of Cases (%) |
|-------------------------|---------------------|
| <b>WCPU Patients</b>    |                     |
| Total:                  | 2611                |
| Sex                     |                     |
| Female:                 | 2525 (97%)          |
| Male:                   | 86 (3%)             |
| Age                     |                     |
| Mean:                   | 15.5 years old      |
| Median:                 | 14                  |
| Mode:                   | 14                  |
| Range:                  | 9 mo. – 91 y/o      |
| Age Group               |                     |
| Minor (0-18 y/o):       | 2036 (78%)          |
| Adult ( $\geq 19$ y/o): | 575 (22%)           |

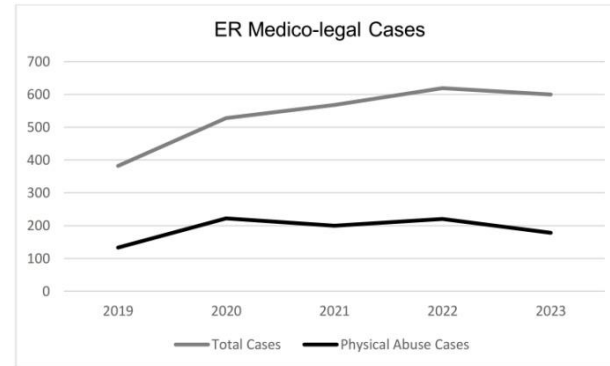
**Table 1C. Demographics of WCPU Perpetrators**

|                          | Number of Cases (%) |
|--------------------------|---------------------|
| <b>WCPU Perpetrators</b> |                     |
| Total:                   | 2611                |
| Sex                      |                     |
| Male:                    | 2581 (99%)          |
| Female:                  | 30 (1%)             |
| Age                      |                     |
| Mean:                    | 32 years old        |
| Median:                  | 30                  |
| Mode:                    | 18                  |
| Range:                   | 6 – 89              |
| Age Group                |                     |
| Minor (0-18 y/o):        | 345 (13%)           |
| Adult ( $\geq 19$ y/o):  | 2266 (87%)          |

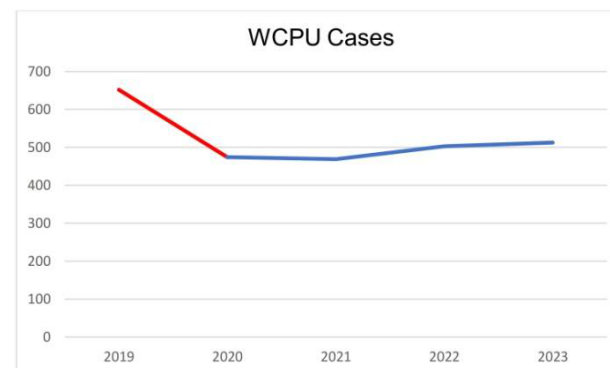
There were 2,663 ER cases and 2,611 WCPU cases with complete records. Most ER patients were adult male patients. While the majority of the WCPU cases were minor female patients. Most perpetrators were adult male patients. However, there are still few minor perpetrators (13%), the youngest being 6 years old.



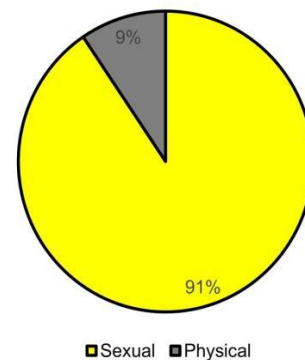
**Figure 1. Distribution of complete and incomplete records of Medico-legal ER cases.** Out of all the 9511 ER cases, 60% has no specified body site, 31% did not specify the nature of injury, and majority (72%) of the ER records lacks site or nature of injuries.



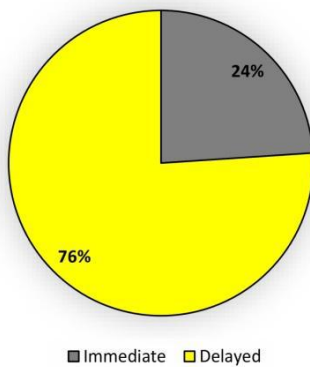
**Figure 2. Trends of ER Medico-legal cases during 2019-2023.** There is a 66% increase in the number of medico-legal cases and physical abuse from 2019 to 2020. The number of cases during the pandemic (2020-2022) remains almost constant.



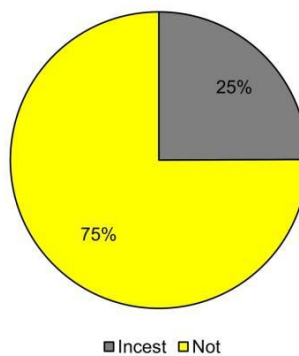
**Figure 3. Trends of WCPU cases during 2019-2023.** The number of reported WCPU cases fell during the pandemic. In 2019, there were 652 cases while the following years had 474, 469, 503, and 513 cases, respectively.

**Types of Abuse (n = 2611)**

**Figure 4. Nature of abuse in WCPU cases.** Majority (91%) of abuse cases in WCPU are sexual in nature.

**Reporting (n = 2611)**

**Figure 5. Proportion of Immediate (acute or  $\leq 3$  days) vs Delayed (chronic or  $> 3$  days) reported cases.** Only 24% of the WCPU patients consulted within three days from the incidence of abuse.

**Nature of Sexual Abuse (n = 2611)**

**Figure 6. Nature of Sexual abuse.** 25% of the sexually abused WCPU cases are incestuous in nature.

**Table 2. Most Common Perpetrators in WCPU Case**

| Relation        | Cases | % of cases |
|-----------------|-------|------------|
| Boyfriend       | 305   | 12%        |
| Neighbor        | 305   | 12%        |
| Uncle           | 258   | 10%        |
| Father          | 218   | 9%         |
| Acquaintance    | 167   | 6.40%      |
| Cousin          | 147   | 5.60%      |
| Stepfather      | 136   | 5.20%      |
| Friend          | 109   | 4.10%      |
| Husband         | 98    | 3.80%      |
| Live-in Partner | 91    | 3.50%      |
| Grandfather     | 82    | 3.10%      |
| Brother-in-law  | 47    | 1.80%      |
| Relative        | 41    | 1.60%      |
| Chatmate        | 33    | 1.30%      |
| Stranger        | 29    | 1.10%      |
| Suitor          | 23    | 0.90%      |

This table shows that most abused patients are familiar and related to their perpetrators. Most common perpetrators were boyfriend (12%), neighbor (12%), uncle (10%), and father (9%).

**Table 3. Significant findings in the demographics of both victims and perpetrators, type of abuse and incestuous relationship of WCPU Cases**

|        | <i>p</i> (<0.05) | Patient Odds Ratio |       | <i>p</i> (<0.05) | Perpetrator Odds Ratio |        |
|--------|------------------|--------------------|-------|------------------|------------------------|--------|
|        |                  | Age                |       |                  | Age                    |        |
|        |                  | Minor              | Adult |                  | Adult                  | Minor  |
| SA*    | 0.000            | 5.8                | -     | -                | -                      | -      |
| Incest | 0.000            | 1.8                | -     | 0.000            | 1.8                    | -      |
|        |                  | Sex                |       |                  | Sex                    |        |
|        |                  | Female             | Male  |                  | Male                   | Female |
| SA*    | 0.000            | 11.4               | -     | 0.000            | 8.8                    | -      |
| Incest | 0.001            | 3.3                | -     | -                | -                      | -      |

SA - Sexual Abuse

Minor patients are five to six times more likely to be sexually abused (SA) and are also twice more likely to be abused by a relative. Female patients are eleven times more likely to be sexually abused than males. They are also three times more likely abused by a relative. Adult perpetrators are almost twice more likely to commit incestuous sexual abuse. While male perpetrators are eight to nine times more likely to commit sexual abuse.

**Table 4. Nature of Injury Summary Table**

|                          | Cases      |
|--------------------------|------------|
| <b>Accidents</b>         | 1725 (65%) |
| Vehicular Accident       | 1,339      |
| Motor vehicular Accident | 212        |
| Work-related injury      | 110        |
| Foreign body injury      | 64         |
| <b>Physical Abuse</b>    | 938 (35%)  |
| Assault                  | 822        |
| Stabbing                 | 87         |
| Gunshot wound            | 29         |

Accidents comprised 65% of the medico-legal cases in the ER. Out of the accidents, majority are caused by vehicular (78%) and motor vehicular accidents (12%). While, physical abuse cases are commonly associated with assault (88%).

**Table 5. Most common type of injuries in Physical Abuse Cases**

| Injuries      | Cases | Percentage |
|---------------|-------|------------|
| Abrasion      | 482   | 51%        |
| Contusion     | 159   | 17%        |
| Laceration    | 123   | 13%        |
| Stab wounds   | 46    | 5%         |
| Gunshot wound | 25    | 2.6%       |
| Fracture      | 24    | 2.5%       |
| Hematoma      | 24    | 2.5%       |
| Stab wounds   | 46    | 1.3%       |
| Hematoma      | 45    | 1.3%       |
| Avulsion      | 31    | 0.9%       |
| Gunshot wound | 26    | 0.8%       |

The majority of the Physical abuse cases in the ER reported abrasion (44%), followed by multiple physical injury (23.7%), laceration (10.3%), contusion (6.4%), and fracture (4.6%).

**Table 6. Significant findings between demographics and types of injury in physical abuse cases**

|               | <u>Adult</u>     |            | <u>Male</u>      |            |
|---------------|------------------|------------|------------------|------------|
|               | <i>p</i> (<0.05) | OR*        | <i>p</i> (<0.05) | OR         |
| Gunshot wound | <b>0.035</b>     | <b>4.4</b> | <b>0.034</b>     | <b>3.4</b> |
| Laceration    | <b>0.003</b>     | <b>3.2</b> | <b>0.000</b>     | <b>3.4</b> |
| Stab wounds   | <b>0.042</b>     | <b>3.9</b> | <b>0.002</b>     | <b>3.9</b> |

\*OR – Odds Ratio

Adult physical abuse patients are more likely to present with gunshot wound (OR: 4.4), stab wounds (3.9), or laceration (OR: 2.9) in the ER than pediatric patients. Male patients are three to four times more likely to present with gunshot wound, laceration, or stab wounds compared to female patients.

**Table 7. Significant findings between types of injury vs site of injury of physical abuse cases**

| <u>Site</u> | <u>Laceration</u> |            | <u>Stab wounds</u> |             | <u>GSW</u>       |            |
|-------------|-------------------|------------|--------------------|-------------|------------------|------------|
|             | <i>p</i> (<0.05)  | OR         | <i>p</i> (<0.05)   | OR          | <i>p</i> (<0.05) | OR         |
| Abdomen     | -                 | -          | <b>0.000</b>       | <b>11.4</b> | <b>0.042</b>     | <b>2.7</b> |
| Back        | -                 | -          | <b>0.001</b>       | <b>5.3</b>  | -                | -          |
| Chest       | -                 | -          | <b>0.000</b>       | <b>4.5</b>  | -                | -          |
| Eyebrow     | <b>0.000</b>      | <b>13</b>  | -                  | -           | -                | -          |
| Eyelid      | <b>0.000</b>      | <b>5.2</b> | -                  | -           | -                | -          |
| Hand        | <b>0.020</b>      | <b>2.4</b> | -                  | -           | -                | -          |
| Head        | <b>0.000</b>      | <b>3.1</b> | -                  | -           | -                | -          |
| Lip         | <b>0.016</b>      | <b>2.1</b> | -                  | -           | -                | -          |

Lacerations caused by physical abuse are most commonly seen in the eyes (OR: 13), eyelid (5.2), hand (2.4), head (3.1), or lips (2.1). Stab wounds are typically seen on the abdomen (11.4), back (5.3), or chest (4.5). Gunshot wounds (GSW) are mostly seen at the abdomen (2.7).

**Table 8. Significant findings between nature of injury (Physical Abuse vs. Accidental) and types of injury in emergency room cases**

| <u>Types of Injuries</u> | <i>p</i> (<0.05) | <u>Nature of Injury</u> |            |
|--------------------------|------------------|-------------------------|------------|
|                          |                  | Physical Abuse          | Accidental |
|                          |                  | Odds Ratio (OR)         |            |
| Abrasion                 | <b>0.000</b>     | -                       | <b>1.4</b> |
| Avulsion                 | <b>0.011</b>     | -                       | <b>3.7</b> |
| Contusion                | <b>0.000</b>     | <b>5.7</b>              | -          |
| Fracture                 | <b>0.000</b>     | -                       | <b>3.1</b> |
| GSW*                     | <b>0.000</b>     | <b>47</b>               | -          |
| Hematoma                 | <b>0.010</b>     | <b>2.1</b>              | -          |
| MPI**                    | <b>0.000</b>     | -                       | <b>3.5</b> |
| Stab wounds              | <b>0.000</b>     | <b>89</b>               | -          |

\*GSW – Gunshot wound, \*\*MPI – Multiple physical injuries

Contusion (5.7), gunshot wounds (OR: 47), hematoma (2.1), and stab wounds (89) are more characteristic of Physical abuse seen in the ER. Abrasion (1.4), avulsion (3.7), fractures (3.1), and multiple physical injuries (3.5) are more likely seen in accidental injuries.

**Table 9. Significant findings between assault, stabbing, gunshot wound, vehicular accidents, work-related injuries vs type and site of injury of emergency room cases**

| <u>Physical Abuse</u>  |       |                  |    | <u>Accident</u>                 |       |                  |    |
|------------------------|-------|------------------|----|---------------------------------|-------|------------------|----|
|                        |       | <i>p</i> (<0.05) | OR |                                 |       | <i>p</i> (<0.05) | OR |
| <u>Assault</u>         |       |                  |    | <u>Vehicular Accident</u>       |       |                  |    |
| <u>Types of Injury</u> |       |                  |    | <u>Types of Injury</u>          |       |                  |    |
| Contusion              | 0.000 | <b>7.1</b>       |    | Abrasions                       | 0.000 | <b>2.4</b>       |    |
| Hematoma               | 0.001 | <b>2.6</b>       |    | Contusion                       | 0.000 | <b>3.5</b>       |    |
| <u>Sites of Injury</u> |       |                  |    | MPI*                            | 0.000 | <b>3</b>         |    |
| Cheek                  | 0.000 | <b>4.1</b>       |    | Swelling                        | 0.004 | <b>4.3</b>       |    |
| Chest                  | 0.022 | <b>1.6</b>       |    | <u>Sites of Injury</u>          |       |                  |    |
| Eye                    | 0.000 | <b>3.8</b>       |    | Ankle                           | 0.000 | <b>2.4</b>       |    |
| Eyelid                 | 0.000 | <b>3.3</b>       |    | Elbow                           | 0.000 | <b>1.6</b>       |    |
| Lip injuries           | 0.000 | <b>4.8</b>       |    | Face                            | 0.041 | <b>1.8</b>       |    |
| Neck                   | 0.000 | <b>3.5</b>       |    | Knee                            | 0.000 | <b>3.2</b>       |    |
| Nose                   | 0.000 | <b>3.4</b>       |    | Leg                             | 0.000 | <b>3</b>         |    |
| <u>Stabbing Injury</u> |       |                  |    | <u>Motor Vehicular Accident</u> |       |                  |    |
| <u>Sites of Injury</u> |       |                  |    | <u>Types of Injury</u>          |       |                  |    |
| Abdomen                | 0.000 | <b>6.2</b>       |    | Contusion                       | 0.003 | <b>1.8</b>       |    |
| Back                   | 0.000 | <b>4.5</b>       |    | Dislocation                     | 0.044 | <b>3.5</b>       |    |
| Chest                  | 0.000 | <b>6.1</b>       |    | Fracture                        | 0.000 | <b>3</b>         |    |
| <u>Gunshot Wound</u>   |       |                  |    | <u>Types of Injury</u>          |       |                  |    |
| <u>Sites of Injury</u> |       |                  |    | Ankle                           | 0.030 | <b>2</b>         |    |
| Abdomen                | 0.000 | <b>8</b>         |    | Feet                            | 0.014 | <b>1.9</b>       |    |
| Back                   | 0.000 | <b>5.6</b>       |    | <u>Work-Related Accident</u>    |       |                  |    |
| Chest                  | 0.000 | <b>7.6</b>       |    | <u>Types of Injury</u>          |       |                  |    |
|                        |       |                  |    | Laceration                      | 0.000 | <b>13</b>        |    |
|                        |       |                  |    | <u>Sites of Injury</u>          |       |                  |    |
|                        |       |                  |    | Foot                            | 0.000 | <b>4.6</b>       |    |
|                        |       |                  |    | Finger                          | 0.000 | <b>15.7</b>      |    |
|                        |       |                  |    | Hand                            | 0.000 | <b>10.1</b>      |    |

\*MPI: Multiple physical injuries

Assault victims more commonly present with contusion (OR: 7.1) or hematoma (2.6) on the cheek (4.1), chest (1.6), eye (3.8), eyelid (3.3), lip (4.8), neck (3.5), or nose (3.4). Stab wounds and Gunshot wounds are typically observed on the abdomen (6.2, 8), back (4.5, 5.6), or chest (6.1, 7.6). Characteristic findings of vehicular accidents are abrasions (2.4) contusion (3.5), multiple physical injuries (MPI) (3), and swelling (4.3) on the ankle (2.4), elbow (1.6), face (1.8), knee (3.2), or leg (3). Motorcycle vehicular accidents are commonly associated with contusion (1.8), dislocation (3.5), fractures (3) on the ankle (2), or foot (1.9). Work-related injuries will more likely present with laceration (13) on the foot (4.6), finger (15.7), or hand (10.1).

## DISCUSSION

Several significant cutaneous findings suggestive of physical abuse were observed in this study. Intuitively, Gunshot wounds (GSW) and stab wounds were associated

with intentional injuries. Contusion and hematoma were more likely seen in cases of assaults involving accessible areas during altercations - the cheek, eye, eyelid, and nose. Injuries over protected body sites such as the chest and neck also warrant suspicion of intentional injuries [7,8,9]. In a study by Naidoo, lips are the most common site of oral injuries [10]. A study by Dougherty noted that gunshot wounds (GSW) most commonly involved the extremities [11]. For this study, the abdomen, back, and chest were sites of predilection for both GSW and stab wounds. These identified sites are more than merely indications to rule in or out possible abuse. They are also useful guides for a more thorough dermatologic examination.

Adult males comprised the majority of physical abuse cases in the ER. They typically present with lacerations, GSW, and stab wounds. Lacerations typically involved the hands, consistent with defensive wounds during altercations.

Children still accounted for 15% of physical abuse cases in the ER. In 2021, seven million children died because of child abuse worldwide. In a study conducted by UNICEF Philippines last 2016, 80% of the 3,866 respondents experienced some forms of violence. 60% of them experienced any form of physical violence during childhood [12]. Hence, it is important to implement programs geared towards child safety and protection.

Majority of the patients seen in WCPU were sexually abused female children aged 14-15 years old. Unfortunately, the youngest patient was nine months old. Overall, 17.1% of children experienced any forms of sexual violence. While, 15% of them also experienced physical, psychological, and sexual abuse [12].

The Inter-Agency Council on Violence Against Women and their Children (IACVAWC) noted a 30% decline in physical abuse cases from 2019-2020 [13]. Interestingly, the recorded physical abuse cases in the ER increased by 66% during the start of the pandemic, when most victims were also confined within their homes. A study by Philippine Statistics Authority last 2017, noted that 26% of females in the country has ever experienced physical, emotional, or sexual violence by their partners. 14% of female experienced physical violence, while 5% experienced sexual violence by their partners [14]. In the study by UNICEF Philippines last 2021, majority (60%) of physical abuse and 13% of sexual abuse happen at home [12]. This further supports the study findings that the majority of sexual perpetrators are not strangers to their victims. A significant fraction of sexual abuse is also incestuous in nature.

There was a 27.2% decrease in recorded cases of Violence against Women and Children. IACVAWC Secretariat emphasized that the pandemic restrictions prevent individuals from reporting [13]. Consistent with the national average, there was a 27% decreased of WCPU cases from 2019-2020. However, the unit remained operational during the pandemic. In retrospect, it is vital to have a functional unit even during a pandemic.

Another significant finding in this study noted the delay in the consultation following abuse. To preserve pertinent evidences, a rape kit must be conducted as soon as possible. Although an immediate consultation is advantageous, sexual assaults must be reported within three days for legal and medical purposes. Presence of sperm cells may still be detected during this period which could help to further build their legal cases [15]. Emergency contraception may be administered to prevent pregnancy [16]. To avoid developing Sexually Transmitted Diseases, post-exposure HIV prophylaxis and doxycycline prophylaxis may also be administered [17,18]. However, the utility of the aforementioned were limited due to the delays in reporting. This can be a significant opportunity for health or legal programs to improve victims' health-seeking behavior and reporting.

Cases of abuse in the Philippines were underreported. This study found the lack of fully a standardized, updated, centralized and digitized database a serious issue. 72% of the records were excluded due to incomplete documentation. This further emphasized the need for a standardize and uniform forensic dermatology reporting.

## **CONCLUSION**

Abuse can happen to anyone at any time. However, this study underscores the susceptibility of female and children to such maltreatments. It is also unfortunate to learn that most perpetrators of sexual abuse are related to their victims. This was further aggravated by the pandemic. Victims were forced to be confined in their home together with their abusers. They are also restricted from reporting their perpetrators. This highlighted the need for functional and responsive centers that can consistently cater to abuse patients.

Cutaneous findings are important indicators of intentional injuries. Hence, it should be second nature for all physicians to identify dermatologic and demographic cues of abuse. There should be mandated integration and reinforcement on the screening of possible signs of abuse into medical education, residency training, nursing program, law enforcement, and social services, including their respective board examinations. Medico-legal

evaluation should also be carefully conducted and reported completely. This will help build better baseline databases and in turn improve our understanding on the current landscape of these issues at hand. As a result, better laws and protocols focusing on child safety and providing safe spaces <sup>[19]</sup> will be established and reinforced.

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## Folliculotropic Mycosis Fungoides Presenting with Secondary Cutis Verticis Gyrata in a Filipino Male\*

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### ABSTRACT

Mycosis fungoides (MF) is the predominant type of primary cutaneous lymphoma, accounting for at least 40%. It usually occurs in middle to late adulthood with the average age of diagnosis between 55 and 60 years. Folliculotropic MF is a variant that clinically presents with patches, plaques, and unusual hair loss within lesions. It predominantly involves the head and neck region. This usually presents with intense pruritus and commonly with secondary bacterial infection. Cutis verticis gyrata is a rare skin condition characterized by thickening and folding of the scalp, resulting in a furrowed or ridged appearance, and rarely associated with mycosis fungoides. A 46-year-old male, Filipino, presented with a 1-year history of generalized follicular papules, erythematous plaques, and subsequently presented with cutis verticis gyrata. Histopathological examination revealed findings consistent with folliculotropic MF. This was further confirmed by CD3, CD4, CD5 which revealed strongly positive immunohistochemical staining. To the best of our knowledge, there is currently only one published case of folliculotropic MF that presented with cutis verticis gyrata and only four cases of cutis verticis gyrata published locally.

Keywords: Mycosis fungoides, cutaneous lymphoma, cutis verticis gyrata, folliculotropic mycosis fungoides

### INTRODUCTION

Mycosis fungoides, also known as classic MF, is the most prevalent primary cutaneous lymphoma.<sup>1</sup> It tends to occur more frequently in males typically between the ages of 55 and 60. It is believed that genetic factors, as well as prolonged exposure to allergens or carcinogens found in industries such as glass, pottery, paper, and wood, can predispose individuals to develop mycosis fungoides. The disease can be classified based on the appearance of skin manifestations, which include patches, plaques, or tumors. These skin lesions typically appear on non-sun exposed areas and can range from being asymptomatic to being associated with intense pruritus. In some cases, patients may also experience erythroderma, often with sparing of skin folds, described as the "deck chair" sign.<sup>1</sup> Additionally, patients may report symptoms such as fever, chills, weight loss, general discomfort, difficulty sleeping due to severe pruritus, and problems regulating body temperature.<sup>1</sup>

Folliculotropic MF is a variation that shares similarities with the classic form but primarily affects the head and neck area. It is identified by the infiltration of T-cells targeting hair follicles, potentially resulting in the degradation of hair follicles with or without mucinous involvement. In contrast to the classic form, folliculotropic MF displays follicular papules, acneiform lesions, indurated plaques, and tumors.<sup>1</sup>

Cutis verticis gyrata is a rare skin condition characterized by scalp thickening and folding, leading to a furrowed appearance commonly seen in diseases including neuropsychiatric pathologies, inflammatory, genetic, and endocrine pathologies.<sup>2</sup> It can be further divided into three distinct forms: primary essential, primary non-essential, and secondary.

We report a case of a Filipino male who presented with severe pruritus and widespread follicular papules, erythematous plaques, and nodules, along with localized hair loss, and convoluted folds and furrows on the scalp. The patient was diagnosed with folliculotropic MF based on examination of histopathological and immunohistochemical analysis. This case report will discuss the clinical features and relate the histopathological findings in a patient with folliculotropic MF and cutis verticis gyrata.

### CASE REPORT

A 46-year-old male, Filipino, teacher from Batangas, with Fitzpatrick skin type IV presented with generalized papules and plaques. Lesions started one year prior to consultation when patient noted appearance of erythematous papules and plaques on the abdominal area. The lesions were associated with daily, intermittent pruritus graded 7/10. He had no known exposure to

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carcinogens from glass factories, potteries, mineral dust, wood burning, paper, and wood industry. He had no fever, weight loss, malaise. The lesions were noted to spread on the trunk and lower extremities with associated increased in pruritus despite application of potent steroids.

One month prior to consultation, along with persistence of previous lesions on the trunk and upper and lower extremities, the patient noted intensely pruritic tumors on the face and scalp. There was subsequent focal loss of hair on the scalp, face, and body. Impaired sweating was noted on the lesions.

The review of systems, past medical and family histories were unremarkable. He has been a non-smoker, non-alcoholic beverage drinker and denied illicit drug use. The patient worked as a teacher, living with his wife, niece, and nephew. He has no history of recent travels to other cities or provinces.

Cutaneous examination showed multiple, well-defined, discrete erythematous papules, plaques, and nodules on the head with hair loss noted on the eyebrows. There were well-circumscribed convoluted folds and deep furrows observed on the scalp with focal hair loss noted on the folds. The patient also presented with grouped follicular erythematous papules and indurated plaques on the chest, abdomen, and bilateral upper and lower extremities. Generalized erythema of the trunk and extremities was noted, with well to ill-defined areas of sparing on the folds of the abdomen, axillary areas, antecubital areas, and legs. Focal desquamation was observed on the palms and soles, while no nail changes or lesions on the oral mucous membranes were present (Figure 1). Furthermore, no palpable cervical and axillary lymphadenopathy was detected.

Blood chemistries revealed elevated triglycerides and HDL (high-density lipoprotein). A complete blood count showed leukocytosis, while the red blood cells appeared normal in size, shape, and color on the peripheral blood smear. No nucleated red blood cells or evidence of inclusions were observed. The WBC distribution was appropriate, with no reactive or immature forms detected. The platelets appeared normal in number and morphology. Furthermore, urinalysis findings and chest radiography were normal.

Punch biopsies were taken on different sites. The biopsy from a nodule on the scalp (Figure 2) showed that the epidermis is flat with grenz zone underneath it. Throughout the dermis are infiltrates of atypical

lymphocytes with hyperchromatic nuclei and irregular nuclear contours. There were plenty of atypical mitotic figures noted. Similar cells in a lichenoid pattern was appreciated in the biopsy taken from the erythematous plaque on the abdomen. The follicles showed deposits of mucin on alcian blue staining (Figure 3). The atypical cells stained positive with CD3, CD4, CD5, and CD45 and were negative for CD20, CD8, CD7, CD30, confirming that this is a T-cell lymphoma (Figure 4).

Correlation of the patient's clinical features and the histopathological results established the diagnosis of folliculotropic MF. The patient was prescribed a combination of clobetasol propionate 0.05% ointment and petroleum jelly, to be applied twice daily for one month which offered slight reduction in size of lesions with a significant decrease in pruritus, and better sleeping patterns. The patient was referred to the Medical Oncology department for further evaluation and treatment. However, he opted not to comply due to his personal preference.



Figure 1. Clinical presentation of the patient showed A) pale erythematous papules and nodules on head, B) well-circumscribed convoluted folds and deep furrows on the scalp with focal hair loss noted on the folds, C) generalized erythema with well to ill-defined areas of sparing on the folds of the abdomen, axillary areas, antecubital areas and, D) grouped follicular erythematous papules with indurated plaques on the chest, abdomen.

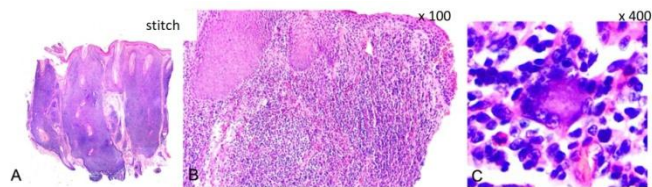


Figure 2. Photomicrograph of the nodule from the scalp showed A) a flattened side with grenz zone beneath it. Throughout the dermis are dense infiltrates of lymphocytes in a nodular pattern. B) Focal areas showed epidermotropism of lymphocytes. C) Close up showed atypical lymphocytes with numerous eosinophils. H&E stain; original magnification: A) stitch view B) x 100 C) x400

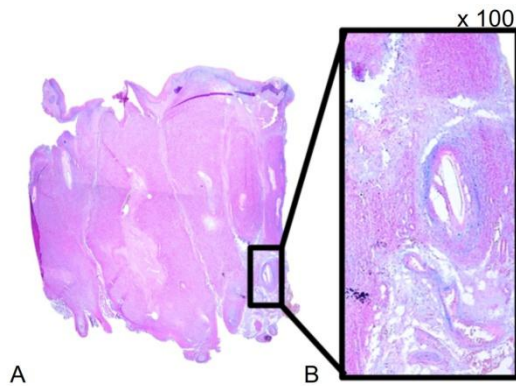


Figure 3. Alcian blue stain showed the presence of follicular mucinosis. (Original magnification A) stitch view B) x 100)

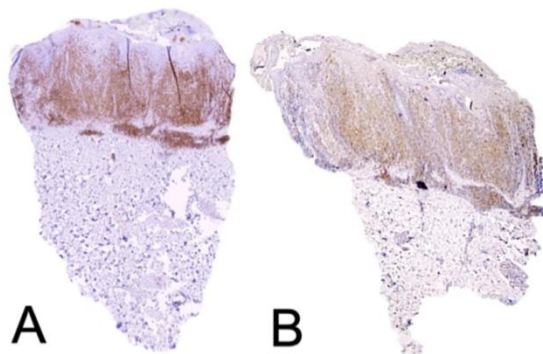


Figure 4. Immunohistochemical staining. A) CD3 and B) CD4 stain showed strong cytoplasmic staining and membrane accentuation. (original magnification A) and B) stitch view)

## DISCUSSION

According to the 2016 revision of the World Health Organization<sup>3</sup>, folliculotropic MF, the most frequent variant, is characterized by invasion of hair follicles by atypical T-cells. It comprises only 5% of all lymphomas. Other variants include pagetoid reticulosis, granulomatous slack skin, and hypopigmented MF. Currently, there are only a few published studies on folliculotropic MF.

Early diagnosis is challenging due to unspecific signs and symptoms. Folliculotropic MF affects men more than women, lesions commonly seen on the head and neck region.<sup>1</sup> However, a study by Gerami et al.<sup>4</sup>, showed that it is not uncommon for it to manifest on the trunk. Studies conducted by Van Doorn et al.<sup>5</sup> and Gerami et al.<sup>4</sup> characterizing folliculotropic MF cases showed that patients presented with erythroderma, patches, plaques, papules, nodules and tumors, acneiform lesions, madarosis, scalp scarring alopecia, cutis verticis gyrata. These lesions are associated with pruritus and commonly develop secondary bacterial infection<sup>1</sup>. Our patient

exhibited erythroderma with intensely pruritic erythematous follicular papules and plaques on the head, trunk, extremities and hair loss but had no episode of secondary bacterial infection which is consistent with the characteristic skin lesions of folliculotropic MF. As the disease advances, bulky tumor masses form, and the face may take on a leonine appearance.<sup>4</sup> Our patient exhibited with well-defined cutis verticis gyrata with localized hair loss specifically on these folds.

Findings from available literature, including reports by Gerami et al.<sup>4</sup>, Van Doorn et al.<sup>5</sup>, Muniesa et al.<sup>6</sup>, and Demirkesen et al.<sup>7</sup>, identify alopecia, papules, plaques, tumors, and nodules as the most common clinical features of folliculotropic MF. Our patient's presentation aligns with these descriptions, except for the presence of acneiform lesions and leonine facies. Interestingly, among these studies, only one case has been reported with cutis verticis gyrata, underscoring its rarity even within the folliculotropic MF variant. To the best of our knowledge, the present case represents only the second documented case worldwide and the first reported in the Philippines.

Cutis verticis gyrata is an uncommon skin disorder characterized by excessive growth of the skin on the scalp or face, resulting in folds resembling the convolutions of the cerebral cortex. It has been suggested that elevated levels of growth hormone (GH) and insulin-like growth factor 1 (IGF-1) play a role in its pathogenesis. Our patient subsequently developed cutis verticis gyrata. Chamli et.al described the three distinct forms of cutis verticis gyrata: primary form either essential or non-essential, and secondary form.<sup>2</sup>

Primary essential cutis verticis gyrata affects the skin without any associated underlying conditions. On the other hand, primary non-essential cutis verticis gyrata is often associated with neuropsychiatric abnormalities and ophthalmological abnormalities. It is also the most common form. Our patient did not have any associated conditions previously mentioned.

Secondary cutis verticis gyrata occurs when there are modifications in the skin trophicity due to associated abnormalities or underlying conditions such as liver diseases, paraneoplastic syndromes (associated with certain types of cancers), inflammatory dermatoses (psoriasis and eczema), genetic conditions (neurofibromatosis, Noonan syndrome, Turner syndrome etc.), endocrine disorders (diabetes mellitus, myxedema etc.) and iatrogenic causes such as using minoxidil (a medication for hair loss). Our patient presented with the secondary form of cutis verticis gyrata from the folliculotropic MF.

In total, 36 published cases of cutis verticis gyrata were identified in the literature. Of these, 10 were primary essential, 3 primary non-essential, and 23 secondary. Notably, only three cases have been reported in the Philippines, underscoring the rarity of this condition in the local setting. A detailed summary of these published cases is provided in Supplementary Table 1.

Histologically, folliculotropic MF is characterized by the presence of infiltrates surrounding the hair follicles, ranging from perifollicular to diffuse patterns. These infiltrates consist of T cells with cerebriform and hyperchromatic nuclei. In most cases, there is follicular mucinosis, which can be visualized through Alcian blue, or colloidal iron staining as seen in our patient. While infiltration of the follicular epithelium (folliculotropism) may occur, concurrent infiltration of the epidermis (epidermotropism) is uncommon in folliculotropic MF.<sup>8</sup> Our patient exhibited a dense, diffuse, nodular dermal infiltrate of small to medium-sized atypical lymphocytes and eosinophils. This infiltration was associated with folliculotropism, leading to focal flattening of some areas of the epidermis. Additionally, there were observed epidermotropism and superficial perivascular infiltrates, all consistent with the histological characteristics of folliculotropic MF.

Histopathologic patterns namely early follicular MF and advanced follicular MF were recently recognized. Early follicular MF is characterized by follicular papules, patches, plaques, acneiform lesions associated with a good prognosis. On the other hand, advanced follicular MF is characterized by infiltrated, follicular plaques or tumors associated with a poor prognosis<sup>10</sup> which is similar with our patient. Moreover, studies have shown that patients with denser and deeper infiltrates, syringotropism, as well as the presence of eosinophils and plasma cells typically exhibit an aggressive form of the disease.<sup>10</sup>

Immunohistochemical stainings CD3 and CD20 were utilized to determine whether it is of T or B cell lineage. Since it was positive for CD3, it indicated a T-cell origin. In folliculotropic MF, increased CD4:CD8 ratio is typically observed, which is consistent with our patient. Insignificant staining of CD8 helps rule out CD8-positive lymphoproliferative disorders. The loss of CD7, as seen in our patient, is often the first pan T cell marker to be lost in MF, and it is associated with a poorer prognosis. CD30 staining which showed insignificantly positive in our patient, was conducted to exclude the possibility of large cell transformation and indicates a worse prognosis. The CD45 stain, which is positive in our patient, is expected to be significant in hematolymphoid cells and pronounced

staining in tumor cells is associated with a poorer prognosis.

Staging plays a crucial role in determining the appropriate treatment and prognosis of patients with mycosis fungoides. The International Society for Cutaneous Lymphomas (ISCL) and the European Organization of Research and Treatment of Cancer (EORTC) proposed a revised clinical staging system in 2007, based on the TNMB classification. Early-stage disease (IA-IIA) is characterized by patches and/or plaques, while advanced-stage disease (IIB-IV) involves tumors, erythroderma, or nodal, blood, and/or visceral involvement.<sup>11</sup> Based on the limited information in our patient, it can be inferred that the patient's minimum stage classification is stage III, as he presented with erythroderma at the time of diagnosis.

There are various treatment options available for folliculotropic MF, depending on the extent of the disease. These options range from skin-directed therapies such as topical corticosteroids, imiquimod, and reiquimod, as well as local and total electron beam therapy and phototherapy. Systemic therapies can also be utilized like retinoids, interferons, targeted monoclonal antibodies (e.g., alemtuzumab, brentuximab vedotin, mogamulizumab), and single-agent chemotherapy (methotrexate, pegylated liposomal doxorubicin, gemcitabine, and pentostatin).

Considering that the patient is classified as at least stage III, the National Comprehensive Cancer Network clinical practice guidelines (NCCN-CPG)<sup>12</sup> in Oncology for primary cutaneous lymphoma recommend systemic therapy in combination with skin-directed therapy. Combination therapy such as extracorporeal plasmapheresis plus interferon alpha and/or a retinoid may also be considered. Ten-year survival prognosis for patients with FMF differ according to the stage and presentation: 72% in skin-limited early stages, 28% in skin-limited advanced stages, and 2% in FMF with extracutaneous localizations at first presentation.<sup>13</sup>

## CONCLUSION

We reported an exceptionally rare case of folliculotropic MF presenting with secondary cutis verticis gyrata in a Filipino male. To the best of our knowledge, this is only the second documented case worldwide with this presentation. Our case also represents the 4th documented case of cutis verticis gyrata in the Philippines, highlighting its rarity. Accurate diagnosis requires close clinical, histopathologic, and immunohistochemical correlation.

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**SUPPLEMENTARY TABLE 1**

| Case | Age/Sex | CVG Type              | Associated Condition(s)                | Country                         |
|------|---------|-----------------------|----------------------------------------|---------------------------------|
| 1    | 19 / M  | Primary Essential     | None                                   | France – Alzaid et al. 2021     |
| 2    | 22 / F  | Primary Essential     | None                                   | France – Alzaid et al. 2021     |
| 3    | 25 / M  | Primary Essential     | None                                   | France – Alzaid et al. 2021     |
| 4    | 31 / M  | Primary Essential     | None                                   | France – Alzaid et al. 2021     |
| 5    | 42 / M  | Primary Essential     | None                                   | France – Alzaid et al. 2021     |
| 6    | 14 / F  | Primary Essential     | None                                   | France – Alzaid et al. 2021     |
| 7    | 28/M    | Primary Essential     | None                                   | Brazil – Yang et al 2014        |
| 8    | 25 / M  | Primary Essential     | None                                   | Morocco – Mai et al 2019        |
| 9    | 53/ M   | Primary Essential     | None                                   | Bosnia – Zeljko 2016            |
| 10   | 28 / M  | Primary Essential     | None                                   | Tunisia – Chamli et al 2022     |
| 11   | 35/M    | Primary Non Essential | Schizophrenia                          | India – Nachinolcar et al 2021  |
| 12   | 32 / M  | Primary Non Essential | Epilepsy                               | Tunisia – Chamli et al 2022     |
| 13   | 15/M    | Primary Non Essential | Epilepsy                               | Saudi – Aldawsari et al 2025    |
| 14   | 60 / F  | Secondary             | Infiltrating ductal carcinoma (breast) | Pakistan –Rahman et al. 2012    |
| 15   | 25 / M  | Secondary             | Cerebriform intradermal nevus (CIN)    | China – Zeng & Guo 2021         |
| 16   | 46 / F  | Secondary             | CIN                                    | USA – Fronek et al. 2021        |
| 17   | 28 / M  | Secondary             | Blue nevus, pigmented nodules          | India – Sarkar et al. 2014      |
| 18   | 45 / M  | Secondary             | CIN                                    | Mexico – Huerta et al. 2014     |
| 19   | 22 / M  | Secondary             | CIN                                    | India – Ghosh et al. 2012       |
| 20   | 14 / M  | Secondary             | CIN                                    | India – Tagore et al. 2011      |
| 21   | 17 / F  | Secondary             | CIN                                    | China – Zhang et al. 2011       |
| 22   | 38 / F  | Secondary             | Combined blue and congenital nevus     | Germany–Muhlhoff et al. 2010    |
| 23   | 43 / F  | Secondary             | Intradermal nevus                      | Brazil – Bonalumi et al. 2010   |
| 24   | 48 / M  | Secondary             | Intradermal nevus                      | Spain – Alcántara et al. 2010   |
| 25   | 16 / M  | Secondary             | Neurofibroma                           | France – Alzaid et al. 2021     |
| 26   | 34 / M  | Secondary             | Dissecting cellulitis                  | France – Alzaid et al. 2021     |
| 27   | 67 / F  | Secondary             | CIN                                    | France – Alzaid et al. 2021     |
| 28   | 38 / M  | Secondary             | Lipoedema                              | France – Alzaid et al. 2021     |
| 29   | 29 / M  | Secondary             | Folliculitis fibrosis                  | France – Alzaid et al. 2021     |
| 30   | 44 / M  | Secondary             | Chronic folliculitis                   | France – Alzaid et al. 2021     |
| 31   | 51 / M  | Secondary             | Acromegaly                             | France – Alzaid et al. 2021     |
| 32   | 54 / F  | Secondary             | Endocrine pathology                    | Tunisia – Chamli et al 2022     |
| 33   | 18/M    | Secondary             | Congenital melanocytic nevi            | Philippines – Sison et al 2017  |
| 34   | 0/M     | Secondary             | Probably Noonan Syndrome               | Philippines – Cain 2018         |
| 35   | 28/M    | Secondary             | Primary pachydermoperiostosis          | Philippines – Zamora et al 2022 |
| 36   | 28/M    | Secondary             | Psoriasis                              | USA – Le Nguyen et al 2016      |

# Primary Care Approach to Pornography-Induced Psychogenic Erectile Dysfunction: A Case Report\*

Mark Louie C. Mann, MD, FPSP, DPSA, CPC-FP<sup>1,a</sup>, Manuel Jr. S. Vidal, MD<sup>2,a</sup>

## ABSTRACT

This case report presents a 22-year-old male with Pornography-Induced Psychogenic Erectile Dysfunction (ED), highlighting the growing prevalence of this condition in young men and emphasizing the importance of recognizing and addressing it in primary care settings. The patient presented with the primary complaint of an inability to sustain an erection, with erections lasting only for approximately one minute. He had an unremarkable past medical and family history, was a previous smoker, and engaged in occasional alcoholic beverage consumption. Psychological assessment revealed moderate erectile dysfunction, problematic use of pornography, and minimal anxiety.

A comprehensive treatment plan was implemented, incorporating lifestyle modifications, pharmacotherapy and psychological interventions (Motivational Interviewing, Brief Strategic Therapy, and Educational Counseling). The patient demonstrated a positive response to treatment, with significant improvements in both erectile function and control over pornography consumption, as evidenced by follow-up assessments.

This case underscores the need for healthcare professionals to routinely inquire about pornography consumption habits when assessing patients with ED, particularly young men. It emphasizes the importance of a thorough assessment, including medical, psychological, and sexual history, for accurate diagnosis and effective treatment.

Furthermore, it demonstrates the value of an integrated treatment approach, addressing both physical and psychological factors, for optimal outcomes. Finally, it highlights the importance of patient education to enhance treatment adherence and motivation for change.

**Keywords:** Primary Care Approach, Pornography, Psychogenic Erectile Dysfunction, Motivational Interview, Case Report

## INTRODUCTION

Erectile dysfunction (ED) is a common condition affecting approximately 150 million men worldwide, with significant impacts on quality of life and psychological well-being [1]. While traditionally associated with older age and organic causes like vascular disease, ED is increasingly prevalent in younger men, with psychogenic factors playing a significant role. Recent research suggests a possible link between excessive pornography consumption and psychogenic ED, particularly in young men [2]. This association warrants further investigation within primary care settings, where most men initially present with sexual health concerns.

The complex interplay of psychological factors in ED, including anxiety, depression, and relationship issues, is well-documented, and the emphasis of the role of specific psychogenic predictors in non-organic ED, such as low self-esteem and fear of failure [3]. A comprehensive intersystemic assessment is crucial for understanding the etiology of psychogenic ED. This case report focuses specifically on the potential impact of pornography consumption on sexual function.

This case report presents the case of a young adult male who presented to a primary care clinic with complaints of ED. The patient's history revealed significant pornography use, with features suggestive of compulsive behavior. This case highlights the importance of recognizing and addressing pornography-related psychogenic ED in primary care. Early identification and intervention can prevent progression to more severe forms of ED and improve overall well-being.

## Patient information

This is a case of a 22-year-old Filipino male who works as an office worker. He presented to the clinic with the chief complaint of an inability to sustain an erection, with erections lasting only for approximately one minute. He has an unremarkable past medical history and family history.

The patient is a previous smoker (1-2 pack years) and an occasional alcoholic beverage drinker. He denies any current use of illicit drugs and is not taking any maintenance medications. He reports eating a balanced

*Disclosures: The author has formally acknowledged and signed a disclosure affirming the absence of any financial or other relationships (including personal connections), intellectual biases, political or religious affiliations, and institutional ties that could potentially result in a conflict of interest.*

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Filipino diet, having an active lifestyle. He is currently in a relationship.

Sexual function and history reveals the patient having difficulty achieving and maintaining erections sufficient for satisfactory sexual intercourse, describing his erections as partial and lasting only about one minute. These difficulties began approximately 1 month ago and have persisted since, with a sudden onset potentially indicative of a psychological etiology. The patient denies other sexual concerns like loss of libido or ejaculation problems. He is currently in a heterosexual relationship for a year and describes a healthy working relationship. He reports feeling significant pressure to perform sexually, believing his partner has high expectations. He demonstrates a good understanding of sexual function and the potential causes of erectile dysfunction.

The patient reported viewing pornography several times a day, ranging from 3 to 5 times, and spending an average of 1 hour per week engaged in this activity. He reported inability to control pornography use, despite wanting to cut back, and he experienced irritability when unable to access pornography. He also noted that he needed to view increasingly explicit material to achieve the same level of arousal.

Clinical findings

The patient's physical examination was unremarkable. Vital signs and BMI were within normal limits. Examination of the cardiovascular, respiratory, gastrointestinal, and genitourinary systems revealed no abnormalities. Neurological examination was also normal.

Timeline

Table 1. Timeline of Patient Consultations, Diagnostic Tests, and Interventions for Erectile Dysfunction

| DATE       | CONSULTATION SUMMARY                       | DIAGNOSTIC AND SCREENING TEST        | INTERVENTION                                                                                                                                                                                                                                                        |
|------------|--------------------------------------------|--------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 9/22/2024  | History and PE                             | IIEF-5*, GAD 7* and PHQ-9*           | <ul style="list-style-type: none"><li>For Laboratory evaluation: FBS, HbA1c, thyroid function tests, lipid profile, serum morning testosterone, BUN and creatinine, CBC, and urinalysis</li><li>Catharsis-Education-Action</li><li>Lifestyle Modification</li></ul> |
| 9/25/2024  | Follow up Laboratory result Interpretation | SHIM*                                | <ul style="list-style-type: none"><li>Motivational Interview</li><li>Phosphodiesterase-5 inhibitors (PDE5i) Sildenafil 50mg/tab</li></ul>                                                                                                                           |
| 10/12/2024 | Follow up Medication Review                | CYPAT*                               | <ul style="list-style-type: none"><li>Educational Counseling</li></ul>                                                                                                                                                                                              |
| 10/21/2024 | Follow up                                  | _____                                | <ul style="list-style-type: none"><li>Motivational Interview</li><li>Brief Strategic Therapy</li></ul>                                                                                                                                                              |
| 11/14/2024 | Follow up                                  | IIEF-5, GAD 7, PHQ-9, SHIM and CYPAT | <ul style="list-style-type: none"><li>Brief Strategic Therapy</li></ul>                                                                                                                                                                                             |

\*International Index of Erectile Function (IIEF-5), General Anxiety Disorder - 7 (GAD-7) , Patient Health Questionnaire - 9 (PHQ-9), Sexual Health Inventory for Men (SHIM) Questionnaire and Cyber Pornography Addiction Test (CYPAT)

Diagnostic Assessment

Results of laboratory investigations, including FBS, HbA1c, thyroid function tests, lipid profile, serum morning testosterone, BUN and creatinine, CBC, and urinalysis, were all within normal limits. While nocturnal penile tumescence testing and Duplex Doppler imaging were considered for further evaluation, these were not conducted due to financial constraints.

Several screening tools were employed to assess the patient's psychological state and sexual function. The International Index of Erectile Function (IIEF-5) [4] yielded a score of 11, indicating moderate erectile dysfunction. The Sexual Health Inventory for Men (SHIM) Questionnaire [5] score was 17, suggesting mild ED. A Cyber Pornography Addiction Test (CYPAT) [6] resulted in a score of 42, interpreted as problematic use of pornography. The Patient Health Questionnaire-9 (PHQ-9) [7] showed a score of 4, indicating no depression, and

the General Anxiety Disorder 7 (GAD-7) [8] had a score of 1, suggesting minimal anxiety.

Based on the patient's history, physical examination, normal laboratory results, and psychological assessment findings, a diagnosis of Pornography-Induced Psychogenic Erectile Dysfunction was made.

**Table 2.** Patient's Baseline IIEF-5 Scores for Erectile Dysfunction

Please choose the appropriate column for each question about your sexual abilities over the past four weeks.

|               | Question                                                                                                                      | 1                                         | 2              | 3         | 4                  | 5                       | Score | Interpretation                        |
|---------------|-------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------|----------------|-----------|--------------------|-------------------------|-------|---------------------------------------|
| 1             | How do you rate your confidence that you could get and keep an erection?                                                      | Very low                                  | Low            | Moderate  | High               | Very high               | 22-25 | No erectile dysfunction               |
| 2             | When you had erections with sexual stimulation, how often were your erections hard enough for penetration?                    | Never or almost never                     | A few times    | Sometimes | Most times         | Almost always or always | 17-21 | Mild erectile dysfunction             |
| 3             | During sexual intercourse, how often were you able to maintain your erection after you had penetrated (entered) your partner? | Never or almost never                     | A few times    | Sometimes | Most times         | Almost always or always | 12-16 | Mild to moderate erectile dysfunction |
| 4             | During sexual intercourse, how difficult was it to maintain your erection to completion of intercourse?                       | Extremely difficult                       | Very difficult | difficult | Slightly difficult | Not difficult           | 8-11  | Moderate erectile dysfunction         |
| 5             | When you attempted sexual intercourse, how often was it satisfactory for you?                                                 | Never or almost never                     | A few times    | Sometimes | Most times         | Almost always or always | 5-7   | Severe erectile dysfunction           |
| <b>Result</b> |                                                                                                                               | <b>11 (Moderate erectile dysfunction)</b> |                |           |                    |                         |       |                                       |

**Table 3.** Patient's Baseline PHQ-9 for Depression

|               |                                                                                                                                                                          | Not at all              | Several days | More than half the days | Nearly every day |
|---------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|--------------|-------------------------|------------------|
| 1             | Little interest or pleasure in doing things                                                                                                                              | 0                       | 1            | 2                       | 3                |
| 2             | Feeling down, depressed, or hopeless                                                                                                                                     | 0                       | 1            | 2                       | 3                |
| 3             | Trouble falling or staying asleep, or sleeping too much                                                                                                                  | 0                       | 1            | 2                       | 3                |
| 4             | Feeling tired or having little energy                                                                                                                                    | 0                       | 1            | 2                       | 3                |
| 5             | Poor appetite or overeating                                                                                                                                              | 0                       | 1            | 2                       | 3                |
| 6             | Feeling bad about yourself — or that you are a failure or have let yourself or your family down                                                                          | 0                       | 1            | 2                       | 3                |
| 7             | Trouble concentrating on things, such as reading the newspaper or watching television                                                                                    | 0                       | 1            | 2                       | 3                |
| 8             | Moving or speaking so slowly that other people could have noticed? Or the opposite — being so fidgety or restless that you have been moving around a lot more than usual | 0                       | 1            | 2                       | 3                |
| 9             | Thoughts that you would be better off dead or of hurting yourself in some way                                                                                            | 0                       | 1            | 2                       | 3                |
| <b>Result</b> |                                                                                                                                                                          | <b>4 (None-minimal)</b> |              |                         |                  |

If you checked off any problems, how difficult have these problems made it for you to do your work, take care of things at home, or get along with other people?

|                      |                    |                |                     |
|----------------------|--------------------|----------------|---------------------|
| Not difficult at all | Somewhat difficult | Very difficult | Extremely difficult |
|----------------------|--------------------|----------------|---------------------|

Provisional Diagnosis and Proposed Treatment Actions

| PHQ-9 Score | Depression Severity | Proposed Treatment Actions                                                                                                                                                                        |
|-------------|---------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 0 – 4       | None-minimal        | None                                                                                                                                                                                              |
| 5 – 9       | Mild                | Watchful waiting; repeat PHQ-9 at follow-up                                                                                                                                                       |
| 10 – 14     | Moderate            | Treatment plan, considering counseling, follow-up and/or pharmacotherapy                                                                                                                          |
| 15 – 19     | Moderately Severe   | Active treatment with pharmacotherapy and/or psychotherapy                                                                                                                                        |
| 20 – 27     | Severe              | Immediate initiation of pharmacotherapy and, if severe impairment or poor response to therapy, expedited referral to a mental health specialist for psychotherapy and/or collaborative management |

**Table 4.** Patient's Baseline General Anxiety Disorder - 7 (GAD-7) for Anxiety

| Over the last two weeks, how often have you been bothered by the following problems? | Not at all                 | Several days | More than half the days | Nearly every day |
|--------------------------------------------------------------------------------------|----------------------------|--------------|-------------------------|------------------|
| 1. Feeling nervous, anxious, or on edge                                              | 0                          | 1            | 2                       | 3                |
| 2. Not being able to stop or control worrying                                        | 0                          | 1            | 2                       | 3                |
| 3. Worrying too much about different things                                          | 0                          | 1            | 2                       | 3                |
| 4. Trouble relaxing                                                                  | 0                          | 1            | 2                       | 3                |
| 5. Being so restless that it is hard to sit still                                    | 0                          | 1            | 2                       | 3                |
| 6. Becoming easily annoyed or irritable                                              | 0                          | 1            | 2                       | 3                |
| 7. Feeling afraid, as if something awful might happen                                | 0                          | 1            | 2                       | 3                |
| <b>Result</b>                                                                        | <b>1 (minimal anxiety)</b> |              |                         |                  |

If you checked any problems, how difficult have they made it for you to do your work, take care of things at home, or get along with other people?

|                      |                    |                |                     |
|----------------------|--------------------|----------------|---------------------|
| Not difficult at all | Somewhat difficult | Very difficult | Extremely difficult |
|----------------------|--------------------|----------------|---------------------|

| Scoring GAD-7 Anxiety Severity |                  |
|--------------------------------|------------------|
| 0-4                            | minimal anxiety  |
| 5-9                            | mild anxiety     |
| 10-14                          | moderate anxiety |
| 15-21                          | severe anxiety   |

**Table 5.** Baseline Patient's Cyber Pornography Addiction Test (CYPAT) result

|                                                                                                            | Never                                                   | Rarely | Sometimes | Often | Always |
|------------------------------------------------------------------------------------------------------------|---------------------------------------------------------|--------|-----------|-------|--------|
| Sometimes, I feel unable to control the watching of porn sites.                                            | 1                                                       | 2      | 3         | 4     | 5      |
| I neglected my partner or my family because I had to watch porn sites.                                     | 1                                                       | 2      | 3         | 4     | 5      |
| I ignored my commitments to look at porn sites.                                                            | 1                                                       | 2      | 3         | 4     | 5      |
| I told myself to stop using online pornography but I didn't succeed                                        | 1                                                       | 2      | 3         | 4     | 5      |
| I feel that online pornography is like a drug for me                                                       | 1                                                       | 2      | 3         | 4     | 5      |
| I have continued watching porn sites despite some negative consequences.                                   | 1                                                       | 2      | 3         | 4     | 5      |
| Sometimes, I watch porn sites to forget circumstances or painful situations.                               | 1                                                       | 2      | 3         | 4     | 5      |
| Porn sites make me feel less alone                                                                         | 1                                                       | 2      | 3         | 4     | 5      |
| I have lost some important relationships because of watching porn sites                                    | 1                                                       | 2      | 3         | 4     | 5      |
| I watch porn sites in contexts where I should not (e.g. in other people's home, at school or at work ...). | 1                                                       | 2      | 3         | 4     | 5      |
| I get sexually aroused only when I watch online pornography.                                               | 1                                                       | 2      | 3         | 4     | 5      |
| <b>Result</b>                                                                                              | <b>42 (Higher risk of problematic use or addiction)</b> |        |           |       |        |

| Interpretation |                                                        |
|----------------|--------------------------------------------------------|
| 11-22          | Suggest a lower risk of problematic use.               |
| 23-33          | May indicate a moderate risk of problematic use.       |
| 34-55          | Suggest a higher risk of problematic use or addiction. |

**Table 6.** Baseline Patient's Sexual Health Inventory for Men (SHIM) Questionnaire result

| Question                                                                                                                           |                                  |                            |                                                 |                                      |                                                |                              | SHIM Scores | You may have        |
|------------------------------------------------------------------------------------------------------------------------------------|----------------------------------|----------------------------|-------------------------------------------------|--------------------------------------|------------------------------------------------|------------------------------|-------------|---------------------|
| How do you rate your confidence that you could get and keep an erection?                                                           |                                  | Very low<br>1              | Low<br>2                                        | Moderate<br>3                        | High<br>4                                      | Very High<br>5               | 1-7         | Severe ED           |
| When you had erections with sexual stimulation, how often were your erections hard enough for penetration (entering your partner)? | No sexual activity<br>0          | Almost never or never<br>1 | A few times (much less than half the time)<br>2 | Sometimes (about half the time)<br>3 | Most times (much more than half the time)<br>4 | Almost always or always<br>5 | 8-11        | Moderate ED         |
| During sexual intercourse, how often were you able to maintain your erection after you had penetrated (entered) your partner?      | Did not attempt intercourse<br>0 | Almost never or never<br>1 | A few times (much less than half the time)<br>2 | Sometimes (about half the time)<br>3 | Most times (much more than half the time)<br>4 | Almost always or always<br>5 | 12-16       | Mild to Moderate ED |
| During sexual intercourse, how difficult was it to maintain your erection to completion of intercourse?                            | Did not attempt intercourse<br>0 | Extremely difficult<br>1   | Very difficult<br>2                             | Difficult<br>3                       | Slightly difficult<br>4                        | Not difficult<br>5           | 17-21       | Mild ED             |
| When you attempted sexual intercourse, how often was it satisfactory for you?                                                      | Did not attempt intercourse<br>0 | Almost never or never<br>1 | A few times (much less than half the time)<br>2 | Sometimes (about half the time)<br>3 | Most times (much more than half the time)<br>4 | Almost always or always<br>5 | 22-25       | No signs of ED      |
| <b>Result</b>                                                                                                                      | <b>17 (Mild ED)</b>              |                            |                                                 |                                      |                                                |                              |             |                     |

### Therapeutic intervention

The treatment plan for this case of Pornography-Induced Psychogenic Erectile Dysfunction addressed both the psychological and physical aspects of the condition, starting with lifestyle modifications to improve sleep, moderate alcohol intake, and encourage continued smoking cessation. To address the erectile difficulties, the patient was prescribed a phosphodiesterase-5 inhibitor (sildenafil 50mg/tablet), one tablet to take an hour before sexual intercourse, and psychological interventions were incorporated, including Motivational Interviewing to encourage behavior change, Brief Strategic Therapy to develop coping mechanisms for managing pornography consumption, and Educational Counseling to enhance the patient's understanding of his condition. The patient was cooperative and positively responded to the prescribed management plan.

### Follow-up and outcomes

The patient's progress was closely monitored through a series of follow-up appointments. He initially responded well to sildenafil, reporting improved erectile function within 10 days of starting treatment, and expressed a commitment to addressing his pornography use. Within 35 days of his initial consultation, significant improvements were noted in both erectile function and control over pornography consumption, evidenced by an IIEF-5 score showing no erectile dysfunction, a SHIM score indicating no signs of ED, and a CYPAT score suggesting a lower risk of problematic pornography use. Repeat GAD-7 and PHQ-9 assessments at the 35-day mark showed continued minimal anxiety and no depression. Throughout the entire 35-day follow-up period, the patient demonstrated good adherence to the treatment plan, which included medication, lifestyle modifications, and psychological interventions such as motivational interviewing and brief strategic therapy. No adverse events were reported.

**Table 7. Patient's IIEF-5 Scores and Erectile Function Severity Following Treatment**

Please choose the appropriate column for each question about your sexual abilities over the past four weeks.

| Question                                                                                                                        | 1                                   | 2              | 3         | 4                  | 5                       | Score | Interpretation                        |
|---------------------------------------------------------------------------------------------------------------------------------|-------------------------------------|----------------|-----------|--------------------|-------------------------|-------|---------------------------------------|
| 1 How do you rate your confidence that you could get and keep an erection?                                                      | Very low                            | Low            | Moderate  | High               | Very high               | 22-25 | No erectile dysfunction               |
| 2 When you had erections with sexual stimulation, how often were your erections hard enough for penetration?                    | Never or almost never               | A few times    | Sometimes | Most times         | Almost always or always | 17-21 | Mild erectile dysfunction             |
| 3 During sexual intercourse, how often were you able to maintain your erection after you had penetrated (entered) your partner? | Never or almost never               | A few times    | Sometimes | Most times         | Almost always or always | 12-16 | Mild to moderate erectile dysfunction |
| 4 During sexual intercourse, how difficult was it to maintain your erection to completion of intercourse?                       | Extremely difficult                 | Very difficult | difficult | Slightly difficult | Not difficult           | 8-11  | Moderate erectile dysfunction         |
| 5 When you attempted sexual intercourse, how often was it satisfactory for you?                                                 | Never or almost never               | A few times    | Sometimes | Most times         | Almost always or always | 5-7   | Severe erectile dysfunction           |
| <b>Result</b>                                                                                                                   | <b>22 (No erectile dysfunction)</b> |                |           |                    |                         |       |                                       |

**Table 8. Patient's PHQ-9 Depression Screening Results Following Treatment**

Over the last 2 weeks, how often have you been bothered by any of the following problems?

|                                                                                                                                                                            | Not at all              | Several days | More than half the days | Nearly every day |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|--------------|-------------------------|------------------|
| 1 Little interest or pleasure in doing things                                                                                                                              | 0                       | 1            | 2                       | 3                |
| 2 Feeling down, depressed, or hopeless                                                                                                                                     | 0                       | 1            | 2                       | 3                |
| 3 Trouble falling or staying asleep, or sleeping too much                                                                                                                  | 0                       | 1            | 2                       | 3                |
| 4 Feeling tired or having little energy                                                                                                                                    | 0                       | 1            | 2                       | 3                |
| 5 Poor appetite or overeating                                                                                                                                              | 0                       | 1            | 2                       | 3                |
| 6 Feeling bad about yourself — or that you are a failure or have let yourself or your family down                                                                          | 0                       | 1            | 2                       | 3                |
| 7 Trouble concentrating on things, such as reading the newspaper or watching television                                                                                    | 0                       | 1            | 2                       | 3                |
| 8 Moving or speaking so slowly that other people could have noticed? Or the opposite — being so fidgety or restless that you have been moving around a lot more than usual | 0                       | 1            | 2                       | 3                |
| 9 Thoughts that you would be better off dead or of hurting yourself in some way                                                                                            | 0                       | 1            | 2                       | 3                |
| <b>Result</b>                                                                                                                                                              | <b>1 (None-minimal)</b> |              |                         |                  |

If you checked off any problems, how difficult have these problems made it for you to do your work, take care of things at home, or get along with other people?

|                             |                           |                       |                            |
|-----------------------------|---------------------------|-----------------------|----------------------------|
| <b>Not difficult at all</b> | <b>Somewhat difficult</b> | <b>Very difficult</b> | <b>Extremely difficult</b> |
|-----------------------------|---------------------------|-----------------------|----------------------------|

Provisional Diagnosis and Proposed Treatment Actions

| PHQ-9 Score | Depression Severity | Proposed Treatment Actions                                               |
|-------------|---------------------|--------------------------------------------------------------------------|
| 0 – 4       | None-minimal        | None                                                                     |
| 5 – 9       | Mild                | Watchful waiting; repeat PHQ-9 at follow-up                              |
| 10 – 14     | Moderate            | Treatment plan, considering counseling, follow-up and/or pharmacotherapy |
| 15 – 19     | Moderately Severe   | Active treatment with pharmacotherapy and/or psychotherapy               |

**Table 9. Patient's GAD-7 Anxiety Screening Results Following Treatment**

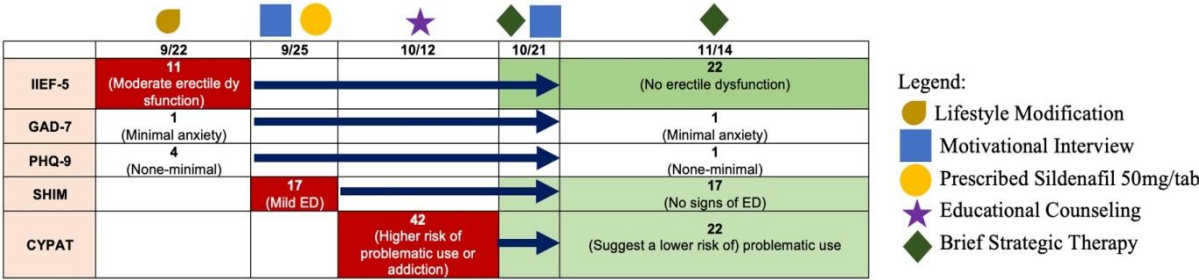
| Over the last two weeks, how often have you been bothered by the following problems?                                                               | Not at all         | Several days        | More than half the days | Nearly every day    | Scoring GAD-7 Anxiety Severity |                  |
|----------------------------------------------------------------------------------------------------------------------------------------------------|--------------------|---------------------|-------------------------|---------------------|--------------------------------|------------------|
|                                                                                                                                                    |                    |                     |                         |                     | 0-4                            | minimal anxiety  |
| 1. Feeling nervous, anxious, or on edge                                                                                                            | 0                  | 1                   | 2                       | 3                   | 5-9                            | mild anxiety     |
| 2. Not being able to stop or control worrying                                                                                                      | 0                  | 1                   | 2                       | 3                   | 10-14                          | moderate anxiety |
| 3. Worrying too much about different things                                                                                                        | 0                  | 1                   | 2                       | 3                   | 15-21                          | severe anxiety   |
| 4. Trouble relaxing                                                                                                                                | 0                  | 1                   | 2                       | 3                   |                                |                  |
| 5. Being so restless that it is hard to sit still                                                                                                  | 0                  | 1                   | 2                       | 3                   |                                |                  |
| 6. Becoming easily annoyed or irritable                                                                                                            | 0                  | 1                   | 2                       | 3                   |                                |                  |
| 7. Feeling afraid, as if something awful might happen                                                                                              | 0                  | 1                   | 2                       | 3                   |                                |                  |
| Result                                                                                                                                             |                    | 1 (minimal anxiety) |                         |                     |                                |                  |
| If you checked any problems, how difficult have they made it for you to do your work, take care of things at home, or get along with other people? |                    |                     |                         |                     |                                |                  |
| Not difficult at all                                                                                                                               | Somewhat difficult |                     | Very difficult          | Extremely difficult |                                |                  |

**Table 10. Patient's CYPAT Results Following Treatment for Problematic Pornography Use**

|                                                                                                            | Never                                               | Rarely | Sometimes | Often | Always | Interpretation |                                                        |
|------------------------------------------------------------------------------------------------------------|-----------------------------------------------------|--------|-----------|-------|--------|----------------|--------------------------------------------------------|
| Sometimes, I feel unable to control the watching of porn sites.                                            | 1                                                   | 2      | 3         | 4     | 5      | 11-22          | Suggest a lower risk of problematic use.               |
| I neglected my partner or my family because I had to watch porn sites.                                     | 1                                                   | 2      | 3         | 4     | 5      | 23-33          | May indicate a moderate risk of problematic use.       |
| I ignored my commitments to look at porn sites.                                                            | 1                                                   | 2      | 3         | 4     | 5      | 34-55          | Suggest a higher risk of problematic use or addiction. |
| I told myself to stop using online pornography but I didn't succeed                                        | 1                                                   | 2      | 3         | 4     | 5      |                |                                                        |
| I feel that online pornography is like a drug for me                                                       | 1                                                   | 2      | 3         | 4     | 5      |                |                                                        |
| I have continued watching porn sites despite some negative consequences.                                   | 1                                                   | 2      | 3         | 4     | 5      |                |                                                        |
| Sometimes, I watch porn sites to forget circumstances or painful situations.                               | 1                                                   | 2      | 3         | 4     | 5      |                |                                                        |
| Porn sites make me feel less alone                                                                         | 1                                                   | 2      | 3         | 4     | 5      |                |                                                        |
| I have lost some important relationships because of watching porn sites                                    | 1                                                   | 2      | 3         | 4     | 5      |                |                                                        |
| I watch porn sites in contexts where I should not (e.g. in other people's home, at school or at work ...). | 1                                                   | 2      | 3         | 4     | 5      |                |                                                        |
| I get sexually aroused only when I watch online pornography.                                               | 1                                                   | 2      | 3         | 4     | 5      |                |                                                        |
| <b>Result</b>                                                                                              | <b>17 (Suggest a lower risk of problematic use)</b> |        |           |       |        |                |                                                        |

**Table 11.** Patient's SHIM Scores for Erectile Function Following Treatment

|                                                                                                                                    |                             |                       |                                            |                                 |                                           |                         |             |                     |
|------------------------------------------------------------------------------------------------------------------------------------|-----------------------------|-----------------------|--------------------------------------------|---------------------------------|-------------------------------------------|-------------------------|-------------|---------------------|
| Over the past six months                                                                                                           |                             |                       |                                            |                                 |                                           |                         | SHIM Scores | You may have        |
| Question                                                                                                                           |                             | Very low              | Low                                        | Moderate                        | High                                      | Very High               |             |                     |
| How do you rate your confidence that you could get and keep an erection?                                                           |                             | 1                     | 2                                          | 3                               | 4                                         | 5                       | 1-7         | Severe ED           |
|                                                                                                                                    |                             |                       |                                            |                                 |                                           |                         | 8-11        | Moderate ED         |
|                                                                                                                                    |                             |                       |                                            |                                 |                                           |                         | 12-16       | Mild to Moderate ED |
|                                                                                                                                    |                             |                       |                                            |                                 |                                           |                         | 17-21       | Mild ED             |
|                                                                                                                                    |                             |                       |                                            |                                 |                                           |                         | 22-25       | No signs of ED      |
| When you had erections with sexual stimulation, how often were your erections hard enough for penetration (entering your partner)? | No sexual activity          | Almost never or never | A few times (much less than half the time) | Sometimes (about half the time) | Most times (much more than half the time) | Almost always or always |             |                     |
|                                                                                                                                    | 0                           | 1                     | 2                                          | 3                               | 4                                         | 5                       |             |                     |
| During sexual intercourse, how often were you able to maintain your erection after you had penetrated (entered) your partner?      | Did not attempt intercourse | Almost never or never | A few times (much less than half the time) | Sometimes (about half the time) | Most times (much more than half the time) | Almost always or always |             |                     |
|                                                                                                                                    | 0                           | 1                     | 2                                          | 3                               | 4                                         | 5                       |             |                     |
| During sexual intercourse, how difficult was it to maintain your erection to completion of intercourse?                            | Did not attempt intercourse | Extremely difficult   | Very difficult                             | Difficult                       | Slightly difficult                        | Not difficult           |             |                     |
|                                                                                                                                    | 0                           | 1                     | 2                                          | 3                               | 4                                         | 5                       |             |                     |
| When you attempted sexual intercourse, how often was it satisfactory for you?                                                      | Did not attempt intercourse | Almost never or never | A few times (much less than half the time) | Sometimes (about half the time) | Most times (much more than half the time) | Almost always or always |             |                     |
|                                                                                                                                    | 0                           | 1                     | 2                                          | 3                               | 4                                         | 5                       |             |                     |
| Result                                                                                                                             | 22 (No signs of ED)         |                       |                                            |                                 |                                           |                         |             |                     |



**Figure 1.** Changes in IIEF-5, GAD-7, PHQ-9, SHIM, and CYPAT Scores Over Time Undergoing Treatment for Erectile Dysfunction

DISCUSSION

This case report presents a 22-year-old male with Pornography-Induced Psychogenic Erectile Dysfunction who was successfully treated with a combination of lifestyle modifications, pharmacotherapy (sildenafil), and psychological interventions. Erectile Dysfunction (ED), defined as the consistent inability to achieve or maintain an erection firm enough for satisfactory sexual intercourse, can significantly impact quality of life [1]. Diagnosing psychogenic ED often involves excluding organic causes through medical history, physical examination, and laboratory tests, while considering factors like sudden onset, situational nature, and the presence of morning erections [9] . In this case, the patient's young age, normal physical examination and laboratory results, and the self-reported link between pornography use and ED pointed towards a psychogenic etiology.

The patient's positive response to sildenafil, a PDE5 inhibitor, highlights the importance of a comprehensive approach to treating erectile dysfunction (ED). Sildenafil likely aided recovery by increasing blood flow to the penis,

which facilitates erection hardness and duration. This is achieved as PDE5 inhibitors prevent the breakdown of cyclic guanosine monophosphate (cGMP), a molecule that promotes smooth muscle relaxation in the corpus cavernosum [1]. A key strength of this report is its detailed documentation of the patient's history, assessment findings, and treatment interventions, providing valuable insights into the management of this type of ED. The use of standardized screening tools allowed for objective measurement of the patient's progress. However, as a single case report, it cannot be generalized to the broader population, and further research is needed. This case aligns with growing evidence suggesting a link between excessive pornography consumption and erectile dysfunction, particularly in younger men. The successful integration of psychological interventions underscores the importance of addressing the underlying psychological factors contributing to ED. Research has demonstrated the efficacy of various psychological interventions for ED, including cognitive-behavioral therapy (CBT), mindfulness-based approaches, and sex therapy [2,10,11]. These interventions can help individuals identify and

modify maladaptive thoughts and behaviors that contribute to sexual difficulties, reduce performance anxiety, and improve communication and intimacy with partners. Similarly, in this case, we observed significant improvement in the patient's erectile function and a reduction in problematic pornography use following the integration of motivational interviewing and brief strategic therapy. The patient's significant improvement following the combined treatment approach suggests a causal relationship between the interventions and the observed outcomes.

This case report offers several important "take-away" lessons for healthcare professionals. It highlights the need to routinely inquire about pornography consumption habits when assessing patients with ED, especially young men. It emphasizes the importance of a thorough assessment, including medical, psychological, and sexual history, for accurate diagnosis and effective treatment. Furthermore, it demonstrates the value of an integrated treatment approach, addressing both physical and psychological factors, for optimal outcomes. Finally, it underscores the importance of patient education to enhance treatment adherence and motivation for change. This case report contributes to the understanding of Pornography-Induced Psychogenic Erectile Dysfunction and provides valuable guidance for healthcare professionals in managing this increasingly prevalent condition.

### Patient Perspective

At the end of the management, the patient reported, "At first, I was really embarrassed to talk about my problem, but I'm glad I finally did. I didn't realize how much my pornography use was affecting my life, especially my relationship with my girlfriend. The medication helped me with the physical part of the problem, but the counseling sessions were what really made a difference. They helped me understand why I was using pornography so much and gave me the tools to change my habits. I feel much more confident now, and my relationship with my girlfriend is better than ever."

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# Multiple Bone Metastases in an Elderly Filipino with Basal Cell Nevus Syndrome\*

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## ABSTRACT

Basal Cell Nevus Syndrome (BCNS) is a rare autosomal dominant disorder characterized by a range of abnormalities, most notably multiple basal cell carcinomas (BCCs), odontogenic keratocysts, and palmar and/or plantar pits. BCC is the most common form of skin cancer globally. It is typically locally invasive and very rarely metastasizes, with distal metastases occurring in only 0.00028% to 0.55% of cases.

We present a case of a 68-year-old Filipino woman who was diagnosed with BCNS. She presented with multiple black nodules and plaques on her face and neck, histopathologically confirmed as BCCs. In addition, the presence of palmoplantar pits and calcification of the falx cerebri met three of the six major criteria for BCNS. Computed tomography (CT) and bone scans, revealed multiple bone metastases in the cranium, spine, sternum, and ribs. No previous cases of metastasis in a BCNS patient have been reported in the Philippines, making this the first documented case.

Keywords: *Basal Cell Nevus Syndrome, Basal Cell Carcinoma, Bone Metastases*

## INTRODUCTION

Basal Cell Nevus Syndrome (BCNS), also known as Gorlin syndrome, is a rare autosomal dominant (AD) disorder characterized by a wide range of phenotypic abnormalities. The hallmark features of BCNS include multiple basal cell carcinomas (BCCs), palmoplantar pits, and odontogenic cysts. The diagnosis is made by fulfilling certain major and minor criteria, with confirmation possible through genetic analysis, particularly identifying mutations in the PTCH1 gene, which plays a critical role in the Hedgehog signaling pathway.<sup>1</sup>

BCC is the most common skin cancer and usually occurs on sun-exposed skin, predominantly in lighter-skinned individuals. It is generally locally invasive, with very rare distant metastasis, at 0.028% to 0.55%. The most common metastatic sites are the lymph nodes, lungs, and bones.<sup>2</sup> Although the BCCs associated with BCNS also rarely metastasize, the potential for metastasis underscores the need for vigilant monitoring.<sup>3</sup>

This report describes a Filipino woman with multiple black nodules and plaques on the face, neck, and trunk, diagnosed as multiple BCCs histopathologically. In addition findings of palmoplantar pits and calcification of the falx cerebri on imaging, met three of the six major criteria for basal cell nevus syndrome (BCNS). Further imaging revealed the rare occurrence of multiple bone metastases. We document a rare occurrence of bone metastases from BCCs in a person with BCNS.

## Case Report

We present a 68-year-old Filipino woman, who worked as a seamstress from Bulacan. She had a 40-year history of multiple dark brown papules initially on the neck, which later involved the face and trunk. The lesions steadily increased in number over the years. At this time, the patient also noted the presence of asymptomatic multiple small pinkish pitting lesions on the bilateral palms and soles. Twenty years prior to consultation, she noted the onset of black nodules and plaques on the face and left arm, which gradually increased in size. There was no associated pain, tenderness, pruritus, bleeding nor discharge. There was no history of trauma prior to the appearance of lesions.

Eight years prior to consult, she noted new onset growth of a thick black plaque on the left preauricular area. Initially, no consult was done. She later noted new black nodules on the forehead and on the left angle of the lip that rapidly grew. These lesions were now associated with occasional pruritus (3/10) but no pain, bleeding or discharge. In the interim, she noted progressive enlargement of these new lesions still with no associated pain or bleeding.

Six years prior, she sought consult with a private surgeon in Bulacan, wherein the lesion on the forehead was completely excised but no biopsy was done. The patient only came back for removal of sutures and no further follow-up consult was done.

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*Disclosures: The author has formally acknowledged and signed a disclosure affirming the absence of any financial or other relationships (including personal connections), intellectual biases, political or religious affiliations, and institutional ties that could potentially result in a conflict of interest.*

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Four years prior, she noted a new rapidly growing black nodule on the same area as the previously excised lesion on the forehead. The nodule grew in size to approximately 2x2cm, associated with minimal pruritus (3/10), bleeding upon minimal trauma, but no pain. In the interim, there was new growth of multiple rapidly growing asymptomatic black nodules and plaques on the face. There was no associated weight loss, malaise, loss of appetite, or bone pains. No consultation was done. One week prior to consultation, still with the above lesions, the patient sought consultation at a private hospital and was given mupirocin ointment which she applied twice daily for one week, with no noted change in the lesions. She was then advised to consult a dermatologist for biopsy.

The patient previously had Stevens-Johnson syndrome secondary to allopurinol intake for her hyperuricemia in 2012. She was diagnosed to have bilateral cataracts in 2024. The patient had no history of radiation therapy. The patient had no history of seizures, mental retardation, cleft lip/palate or syndactyly. One of her sisters was diagnosed with ovarian cancer, while the other sister with thyroid cancer. There is no history of any family members with the same lesions or increased number of nevi. There is no known family history of skin cancer.

The patient is a non-smoker, non-alcoholic beverage drinker. She previously worked as a caretaker of a fishery, with approximately four hours daily sun exposure from 8AM-12NN and with no use of sunscreen or any sun protection. She had no history of sunburns and tans easily to a moderate brown.

Cutaneous examination showed multiple, well-defined, round to irregularly shaped, dark brown to black nodules and plaques, some topped with ulcerations, hemorrhagic crusts and white scales on the forehead, left preauricular area, left upper lip area. There were multiple, discrete, round, dark brown papules on the face, neck, central chest, abdomen and central back (Figure 1). There were also multiple, discrete, round to irregularly shaped, small, 1-2mm, pinkish, depressed papules on the bilateral palms and soles (Figure 2). The patient had a head circumference of 77cm.

There were no nail and mucosal changes noted. Her hair was white streaked with black and gray hair, with no thinning and no alopecia. There were no palpable cervical nor axillary lymphadenopathies detected.

A four-millimeter skin punch biopsy was done on five representative sites on the face (Figure 3). All five sites (central forehead, left forehead, left temporal, preauricular, and perioral) showed absent epidermis, dermis presenting with islands of basaloid cells with peripheral palisading and artifactual clefting. There was mucin deposition within tumor islands. There were melanophages within tumor islands and surrounding stroma, as well as mild infiltrates of lymphocytes and histiocytes (Figure 4).

Laboratory tests showed decreased hemoglobin and hematocrit, elevated uric acid at 12.6mg/dl and elevated creatinine at 9.8mg/dl. Multiple radiographs were done to screen for other specific skeletal malformations and radiologic changes however radiographs of the chest, thoracic cage, bilateral hands and feet were found to be unremarkable.

However, cranial and facial CT scans without contrast showed mixed sclerotic and lytic changes which involved the bones of the cranium, face, 1st and 2nd posterior ribs representing osseous metastasis. There were multiple, calcific densities seen in the falx cerebri as well as bilateral cerebellar tentorium. Plain chest CT revealed mixed sclerotic and lytic changes involving the thoracic spine, sternum and ribs, representing osseous metastases. The bone scan of the skull revealed a photopenic defect in the maxilla and mandible which suggests an osteolytic lesion from osseous metastasis.

Due to the detection of distal metastasis, the patient was referred to medical oncology and subsequently to radiation oncology. However, the patient's acute kidney injury needed to be addressed first before any management of metastasis. She was advised for genetic testing and a positron emission tomography (PET) scan. However, due to logistical challenges, the patient was unable to maintain consistent follow-up and succumbed to the disease six months after the initial diagnosis.



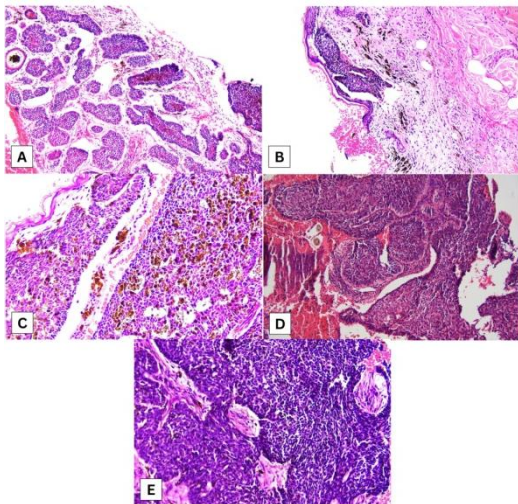
Figure 1. Multiple, well-defined, round to irregularly shaped, dark brown to black nodules and plaques, some topped with hemorrhagic crusts and white scales on the forehead, left preauricular area, left upper lip area. Also noted were multiple, discrete, round, dark brown papules on the face, neck, central chest, abdomen and central



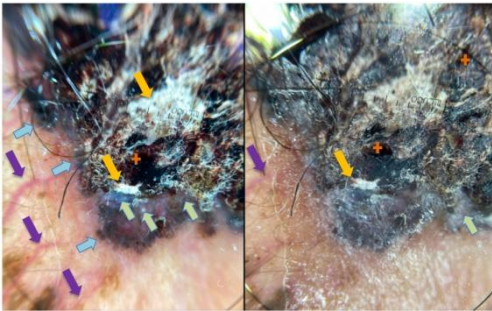
**Figure 2.** Multiple, discrete, round to irregularly shaped, small, 1-2mm, pinkish, depressed papules on the bilateral palms and soles.



**Figure 3.** Five sites and lesions where 4mm skin punch biopsies were done (red asterisks).



**Figure 4.** Histopathologic imaging of lesions of the A) center forehead, B) left forehead, C) left temporal, D) periauricular, and E) perioral areas. All findings consistent with basal cell carcinoma.



**Figure 5.** Dermoscopy showed ulcerations (orange cross), blue gray globules (blue arrows), white blotches (green arrows), arborizing vessels (violet arrows) and white scales (yellow arrows).

| Year | Authors              | Age/Sex |                                                                                            |
|------|----------------------|---------|--------------------------------------------------------------------------------------------|
| 2009 | Ledesma-Pacia et al. | 67/F    | Multiple BCCs, palmoplantar pits odontogenic cysts, Basal cell carcinoma from a palmar pit |
| 2013 | Sabido et al.        | 11/F    | Multiple BCCs, palmoplantar pits                                                           |
| 2017 | Magbuhat et al.      | 46/F    | Multiple BCCs, palmoplantar pits, odontogenic cysts, calcification of the falx cerebri     |
| 2020 | Habaluyas et al.     | 48/M    | Multiple BCCs, palmoplantar pits, odontogenic cysts, calcification of the falx cerebri     |
| 2020 | Balatibat et al.     | 50/F    | Multiple BCCs, palmoplantar pits, Bifid                                                    |

**Table 1.** A summary of the reported cases of Basal Cell Nevus Syndrome in the Philippines and the phenotypic abnormalities they presented with.

BCCs are the most prevalent cancers in humans. It would most often develop on the sun-exposed skin of lighter-skinned individuals and is relatively rare in dark skin due to inherent photoprotection of melanin and melanosomal dispersion. Cumulative exposure to ultraviolet (UV) is the main causal factor in the development of BCC.<sup>1</sup> The number of BCCs present in BCNS would vary from 50 to hundreds more often affecting the thorax, cervicofacial area, neck and, abdomen. There is also a high risk of recurrence for BCCs in this syndrome.<sup>11</sup>

Metastasis for BCCs is a very rare occurrence with rates varying from 0.00028% to 0.55%. The most common sites of metastasis are the regional lymph nodes (53%), lungs (33%), and bone (20%).<sup>2</sup> Similar to sporadic BCCs, the BCCs involved in BCNS rarely metastasize.<sup>3</sup> The rarity of metastasis in BCNS-related BCCs makes this case particularly notable, especially given the extensive bone involvement.

In the literature there are only five published reports describing BCNS with distal or distant metastasis and only one case report of BCNS with multiple bone metastasis.<sup>11-15</sup>

| Year | Authors         | Age/Sex | Metastatic sites                                                |
|------|-----------------|---------|-----------------------------------------------------------------|
| 1968 | Taylor et. al.  | 65/F    | Lung                                                            |
| 1987 | Winkler et. al. | 48/M    | Lung, pleura, diaphragm, pericardium, epicardium and myocardium |
| 2010 | Lamon et al.    | 54/M    | Bone                                                            |
| 2011 | Bajon et. al.   | 34/M    | Submandibular lymph node                                        |
| 2014 | Biliret et. al. | 50s/M   | Lung                                                            |

**Table 2.** A summary of the reported cases of distal or distant metastasis accompanying Basal Cell Nevus Syndrome globally.

One case report by Lamon et al. revealed a similar scenario of bone metastasis from BCCs in a 54-year-old male patient with BCNS. A total of 21 interventions were done for this patient including surgical excisions, external radiotherapy and photodynamic therapy. However, the disease continued to progress and lesions recurred. Further workup with MRI, bone scan and vertebral bone biopsy revealed metastasis at the 12<sup>th</sup> thoracic vertebra. Six months later, bone scintigraphy revealed new metastases at the parietal bone, chest wall, right shoulder, left scapula, and thoracic rachis.<sup>11</sup>

Although surgical excision remains the gold standard for BCC, the extensive number of lesions that occur with BCNS necessitates consideration of alternative therapies. Radiotherapy is relatively contraindicated in patients with BCNS as it is associated with an increased risk of BCCs in the irradiated area.<sup>15</sup> A study by Sekulic et al. demonstrated that vismodegib, a hedgehog pathway inhibitor, is effective in treating advanced BCC and BCNS, with response rates of 30% for metastatic and 43% for locally advanced BCC. It offers a promising option for managing advanced diseases such as in this case.<sup>16</sup>

### Conclusion and Recommendations

We report a rare occurrence of bone metastases from BCCs in a patient with BCNS, a rare AD disorder. A high level of suspicion and early recognition are crucial for effective disease management. Early detection allows a holistic approach to diagnostics and the prompt initiation of targeted interventions, which can significantly improve patient outcomes. By identifying a condition at its onset, healthcare providers can implement preventive measures to halt disease progression, monitor the patient's status, and swiftly initiate multidisciplinary medical care.

Future studies should focus on the genetic and molecular mechanisms underlying BCNS-associated metastases to improve risk stratification. Additionally,

establishing standardized protocols for long-term monitoring of patients with BCNS, including regular imaging and multidisciplinary collaboration, may aid in earlier detection of rare complications such as bone metastases.

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# Cutaneous Polyarteritis Nodosa as a Sequela of Rheumatic Fever in a 7-Year-Old Filipino Male: A Case Report\*

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## ABSTRACT

**Introduction.** Childhood Polyarteritis Nodosa (PAN) is a rare, systemic necrotizing vasculitis of the small to medium-sized vessels with an uncertain global distribution. The primary etiology is unknown. However, PAN is commonly associated with preceding Group A streptococcus infection in children. The most common cutaneous manifestations of PAN include tender subcutaneous nodules, livedo reticularis, digital ischemia and ulceration. To date, no reports have documented cutaneous PAN as a sequela of rheumatic fever.

**Case Report.** This is a report of a 7-year-old Filipino male who presented with multiple, well-defined erythematous to hyperpigmented, firm, tender nodules, with some areas of lace or net-like macules and patches, some resolved leaving hyperpigmentation measuring 1x1 cm to 2x2 cm on the lower back, bilateral upper and lower extremities accompanied by fever, malaise, arthralgia and myalgia with a previous history of rheumatic fever. A 6mm skin punch biopsy revealed findings consistent with PAN. The patient was managed with prednisone. Due to the limited response to treatment, he was eventually given mycophenolate mofetil.

**Conclusion.** Childhood polyarteritis nodosa (PAN) is a rare form of necrotizing inflammation of the medium-sized blood vessels primarily linked to Group A streptococcal infection in children, with no known reported cases associated with rheumatic fever. However, in this case, we were able to observe that PAN could present as a probable rare sequela of rheumatic fever. This warrants close follow-up among such patients.

**Keywords:** *polyarteritis nodosa, rheumatic fever, vasculitis*

## INTRODUCTION

The exact etiology of PAN is unknown.<sup>9,21</sup> However, immune complex-mediated pathogenesis has been suggested based on the presence of IgM and C3 on affected arterial walls.<sup>3</sup> Preceding streptococcal pharyngitis, viral infection, exposure to vaccines and medications are known to trigger PAN.<sup>21</sup> The most frequently reported infectious cause in adult and pediatric populations is Group A streptococcus, confirmed by elevated levels of anti-streptolysin (ASO) and positive culture in 86% of cases.<sup>2</sup> Hepatitis B, commonly known to cause PAN in adults, is now rarely associated with childhood PAN with the advent of good vaccination practices.<sup>21</sup> Patients with PAN often present with tender, erythematous subcutaneous nodules, livedo reticularis or racemose, and ulceration.<sup>4,5</sup> The clinical features of PAN can vary depending on the blood vessels and organs affected. PAN has two subtypes (1) Classic or Systemic

PAN, and (2) Cutaneous PAN. Commonly associated symptoms include fever, malaise, abdominal pain, myalgia, and arthropathies. Involvement of the heart, kidneys, and testes may manifest as hypertension, hematuria, proteinuria, and, in some cases, testicular pain.<sup>3</sup> As of this writing, the authors have not encountered any literature identifying cutaneous PAN in the pediatric population as a sequela of rheumatic fever.

## CASE REPORT

This is a report of a 7-year-old Filipino male from Metro Manila who was admitted due to patches and nodules. History started eight weeks prior to consult, patient presented with pain and swelling of the left knee and leg. At that time, the patient had no fever, sore throat, difficulty in ambulation or cutaneous lesions. Six weeks prior to consult, there was reported progression of the swelling, now involving the left ankle and foot and

*Disclosures: The author has formally acknowledged and signed a disclosure affirming the absence of any financial or other relationships (including personal connections), intellectual biases, political or religious affiliations, and institutional ties that could potentially result in a conflict of interest.*

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accompanied by a febrile episode. Consult was done with a private physician where the patient was given an unrecalled diagnosis and pain medication but with no noted improvement hence he was advised admission under the Pediatric service. Admitting impression at that time was rheumatic fever with arthritis. Diagnostic tests done revealed leukocytosis with predominance of neutrophils on CBC, elevated ASO titer at 400 IU/mL, and elevated ESR at 84 mm/Hr. An echocardiography done revealed mild tricuspid and pulmonic regurgitation with a normal ejection fraction at 60%. The patient was then started on Penicillin G 475,000 TIV every 6 hours and Paracetamol 190 mg TIV every 4 hours as needed for fever, with noted improvement and was subsequently discharged with Aspirin 80mg/tab 3 tablets every 6 hours for 5 days (50 mg/kg/dose) and Paracetamol 250mg/5mL 10mL every 8 hours to complete 7 days as his take home medications and was advised to follow up at the outpatient department. The patient was apparently well until eight days prior to consult, when undocumented fever developed without other associated symptoms. No lesions were noted at this time. Paracetamol syrup as needed for fever was given which provided temporary lysis of fever. No other medications were taken nor applied. No consultation was done. Four days prior to consult, still with persistence of fever, patient's mother noted appearance of multiple erythematous macules, patches and nodules on the medial aspect of the left foot associated with arthralgia of the bilateral knees, with no noted pruritus, stinging sensation nor tenderness. No medications were taken nor applied and still no consultation done. In the interim, there was an increase in the number of lesions, now also seen on the bilateral upper extremities, knees, shins, medial aspect of the right foot and lower back, still with arthralgia, febrile episodes and swelling of the feet now also accompanied by malaise and myalgia. Persistence of symptoms prompted consult at the emergency room and subsequent admission by the pediatric service as a case of Arthritis secondary to cutaneous vasculitis. He was then referred to Pediatric Rheumatology service for the arthritis and Dermatology service for skin biopsy. Past medical history was unremarkable with no prior history of blood transfusion, needle stick injury nor any history of Hepatitis B nor C infection. Pertinent physical examination revealed multiple, well-defined erythematous to hyperpigmented, firm, tender nodules with some areas of lace or net-like macules and patches, some resolved leaving hyperpigmentation measuring 1x1 cm to 2x2 cm on the bilateral upper and lower extremities and lower back (Figures 1A-O) accompanied by swelling of the 2nd,

3rd, 4th digits of the right hand and non-pitting edema of bilateral hands and feet. There were no noted oral lesions nor blanching on diascopy. The rest of the organ systems were unremarkable.

Diagnostic tests done to rule out systemic involvement and other potential causes revealed leukocytosis on CBC and elevated levels of ESR and CRP while blood culture, kidney and liver function tests, urinalysis, Chest X-ray and electrocardiogram were all normal. However, due to the patient's limited financial resources, work-up for Hepatitis B and C were not done. A 6 mm punch biopsy was taken from a slightly erythematous to hyperpigmented nodule over the left leg (Figures 2A-B).

Patient was then started on Prednisone 5mg/tab, 1 tablet twice daily, Mupirocin 2% ointment to biopsy site twice a day for 7 days, Naproxen 275 mg tab, 1/2 tab twice daily for the pain, Paracetamol as needed for fever and Piperacillin-Tazobactam 1750 mg/IV every 8 hours. Daily wound care, use of mild soap and application of emollients were advised. On the subsequent hospital days, there was noted improvement as evidenced by resolution of erythema on most lesions, decrease in size of nodules leaving behind hyperpigmented macules and patches with no new lesions noted (Figures 3A-D), no recurrence of febrile episodes nor pain. Wound on biopsy site was well-coaptated with no noted discharge. Removal of suture from the biopsy site was also done during this admission.

Skin punch biopsy revealed findings consistent with Polyarteritis Nodosa. Microscopic finding showed on scanning view, a septal panniculitis with large vessel vasculitis and small vessel vasculitis at the dermal-fat junction (Figure 4). On closer view, the blood vessel is medium sized artery with fibrin deposition and neutrophils in its thick walls and surrounded by a marked inflammatory infiltrate, dense mixed cell infiltrates composed of neutrophils, eosinophils and histiocytes with no thrombus. The lobules of fat are partially involved and thinly infiltrated by neutrophils (Figure 5). Other sections showed small blood vessels occluded by thrombus and surrounded by neutrophils, located in the deep reticular dermis; nuclear dust not prominent. The overlying epidermis is unremarkable. There was a sparse to moderate, superficial and deep, perivascular infiltrate of lymphocytes and eosinophils in the dermis.

The patient was subsequently discharged as a case of Cutaneous Polyarteritis Nodosa with the following take home medications: Paracetamol syrup 250 mg/5mL syrup 4 mL every 4 hours as needed for fever; Naproxen 275 mg/tab 1/2 tablet twice daily as needed for pain; Prednisone 5mg/tab, 1 tablet twice daily; mild soap and

emollients. Upon follow up with the Pediatric service, there was noted resolution of previous skin lesions. However, still with appearances of new livedo reticularis lesions in the interim over the lower extremities. No new subjective complaints were noted. Prednisone 5mg/tab, 1 tablet twice daily was continued and patient was started on Mycophenolate mofetil 500 mg/tab, 1 tablet twice daily due to the limited response to prednisone and was advised monthly follow up.

## CASE DISCUSSION

Childhood Polyarteritis Nodosa, a rare, systemic disease similar to rheumatic fever, is caused by Group A streptococcus.<sup>19,21</sup> It presents as vasculitis of the small to medium-sized blood vessels affecting multiple organ systems.<sup>19,21</sup> It has two subtypes: (1) Classic or Systemic PAN and (2) Cutaneous PAN, which accounts for >30% of childhood PAN.<sup>7</sup> Both subtypes present with cutaneous lesions and constitutional symptoms. However, the classic subtype has multi-organ involvement with more severe presentations in contrast to the cutaneous subtype, which has minimal organ involvement, mostly limited to the skin, musculoskeletal, or peripheral nerves.<sup>8</sup> Clinical presentation largely depends on the involved blood vessels and organs affected.<sup>3</sup> In this case, cutaneous PAN was considered because aside from cutaneous lesions and constitutional symptoms presented by the patient, there was only limited organ involvement, mainly the musculoskeletal system, in contrast to classic PAN, where there is multi-organ involvement.

## ETIOPATHOGENESIS

The exact etiopathogenesis of PAN is not fully known.<sup>9</sup> However, the presence of IgM and C3 deposits on affected vessels suggests an immune complex-mediated mechanism.<sup>21</sup> Various triggers such as streptococcal infection, viral illnesses, and exposure to vaccines and medications are known to predispose to developing PAN.<sup>21</sup> Group A streptococcus, as evidenced by elevated anti-streptolysin O (ASO) and positive throat culture, is the most commonly reported infectious cause associated in the pathogenesis of PAN in both adults and children.<sup>3,8,21</sup> Pathologically, these predisposing factors act as antigenic triggers which contribute to the immune-complex formation and deposition on the vessel wall, leading to development of segmental and transmural inflammation and subsequent fibrinoid necrosis which are prone to aneurysm.<sup>10,21</sup> PAN has also been linked to Parvovirus B19 infection, autoimmune diseases such as rheumatoid arthritis, hairy cell leukemia and loss-of-function mutations in the CECR1 gene or deficiency of

adenosine deaminase 2 (ADA2) linked to the adenosine inflammatory-response pathway responsible in regulating inflammation.<sup>5,8,11</sup>

Since there has been no previous report of PAN induced by rheumatic fever, and this is the first case encountered as of this writing, the probable cause, in this case, was an initial infection with Group A streptococcus as evidenced by the elevated ASO titer resulted in a complex immune response leading to rheumatic fever and subsequently to PAN. This begins with molecular mimicry where Group A streptococcus antigen, such as M protein, resembles the host's protein. This resemblance leads to immunological cross-reactivity between host and bacterial antigens during infection.<sup>22</sup> The cross-reactive antigens on Group A streptococcus mimic the host molecules and induce an autoimmune response against the host tissue during the infection.<sup>22</sup> This eventually leads to the development of Group A streptococcus sequelae, such as rheumatic fever.<sup>22</sup> Over time, this autoimmune dysregulation will activate the complement cascade, forming immune complexes and deposits on blood vessel walls.<sup>21</sup> These immune complexes cause inflammation and damage, as observed in PAN.<sup>21</sup>

## EPIDEMIOLOGY

The mean age at diagnosis of childhood PAN is 9 years old with no gender predilection.<sup>3</sup> Although there is insufficient data available worldwide for both childhood PAN and rheumatic fever induced PAN, individuals of Asian descents are found to be more likely affected by vasculitis.<sup>1,2</sup>

## HISTOPATHOLOGY

The histopathologic finding of PAN usually shows necrotizing medium vessel vasculitis with mixed cellular infiltrates.<sup>1</sup> The fibrinoid necrosis of the vessel wall frequently observed in PAN, is likewise microscopically observed in rheumatic fever.<sup>3,12</sup>

## HISTORY AND PHYSICAL EXAMINATION

Rheumatic Fever commonly presents with fever (>90% of patients) and arthritis (>75% of patients) which involves the large joints particularly the elbows, knees and ankles.<sup>18</sup> Other clinical manifestations of rheumatic fever include carditis (>50% of patients) presenting as tachycardia and cardiac murmurs, sydenham chorea (30% of patients).<sup>18</sup> Rarely, rheumatic fever can have cutaneous manifestations (<1% of patients) such as erythema marginatum and subcutaneous nodules characterized by firm, mobile and painless nodules typically located on the

extensors and is often associated with presence of carditis.<sup>3,4</sup>

The most common cutaneous findings of PAN are dusky red to purple firm, painful subcutaneous nodules that may vary from 0.5 to 1 cm, livedo reticularis or racemosa on the trunk, upper extremities and lower extremities particularly on the knees, anterior legs and dorsum of the feet as well as digital ischemia and ulceration.<sup>4,13</sup> Reports in the literature indicate that cutaneous lesions accompanied by arthralgia or myalgia are more common in children with PAN.<sup>14,15</sup> Constitutional symptoms are often present in children such as fever, malaise, weight loss and arthralgia.<sup>13</sup> In contrast, gastrointestinal, renal and neurologic involvement are more often encountered in adults with PAN.<sup>16</sup> Additional clinical presentations are largely dependent on the blood vessels and organs involved such as abdominal pain in patients where mesenteric artery inflammation is present; hypertension, myocardial infarction, hematuria and proteinuria in renovascular arteries involvement.<sup>3,8</sup>

In this case, the patient initially presented with fever, arthritis and arthralgia, consistent with the clinical diagnosis of rheumatic fever. Seven weeks later, multiple erythematous, firm, painful subcutaneous nodules developed, accompanied by constitutional symptoms of fever, malaise, arthralgia and myalgia. These clinical manifestations were consistent with cutaneous PAN.

## EVALUATION

The diagnosis of cutaneous polyarteritis nodosa in the pediatric age group is mainly clinical and is confirmed by biopsy of fresh, well-developed cutaneous lesion preferably taken within 24 to 48 hours to determine the size of blood vessel involved.<sup>3,5,7,8</sup> Based on the established diagnostic criteria for childhood PAN brought about by the collaborative efforts by European League Against Rheumatism (EULAR), Pediatric Rheumatology International Trials Organization (PRINTO) and Pediatric Rheumatology European Society (PRES), it is required to fulfill 1 of the 2 major criteria, either evidence of necrotizing vasculitis of small or medium sized vessels on biopsy or aneurysms, stenosis or occlusion on angiography plus 2 out of 5 of the following minor criteria, namely:<sup>5</sup>

1. Presence of skin involvement (livedo reticularis, tender subcutaneous nodules, superficial or deep infarctions)
2. Myalgia, muscle tenderness
3. Hypertension
4. Peripheral neuropathy (sensory neuropathy or motor mononeuritis multiplex) and

5. Kidney involvement (proteinuria, hematuria or RBC cast or GFR <50% of normal value for age).<sup>5</sup>

Currently, there is no specific laboratory test to diagnose cutaneous PAN in the pediatric group. However, these routine laboratory, serologic and imaging studies such as CBC, liver and kidney function tests, hepatitis profile, ASO titer, chest X-ray, and angiography are requested to aid in determining the extent of disease and organ involvement and to exclude other possible causes.<sup>9</sup> Anemia, leukocytosis with elevation of acute phase reactants such as ESR and CRP are frequently encountered.<sup>13</sup>

## TREATMENT AND MANAGEMENT

Glucocorticoids remain the gold standard of therapy for polyarteritis nodosa using oral prednisone (1 to 2mg/kg/day) and intravenous pulse therapy at 30 mg/kg/day.<sup>3</sup> Mild PAN may be managed with steroid monotherapy.<sup>3</sup> Alkylating agents such as cyclophosphamide aid as adjunctive therapy. For systemic or refractory cases, azathioprine, mycophenolate mofetil, plasma exchange and tumor necrosis factor alpha inhibitor have been found to be successful.<sup>3</sup> Patients with infection-associated PAN should receive treatment based on the etiologic agent.<sup>13</sup>

## CLINICAL COURSE AND PROGNOSIS

Most cases of PAN with limited cutaneous involvement have a relatively benign course.<sup>20</sup> Previous studies have reported better prognosis for children than adults presenting with cutaneous PAN with mortality rate of 1 to 4% in children versus 14.5 to 24.6% in adults.<sup>14,15</sup> The extent of extracutaneous organ involvement is a major factor in determining the prognosis of polyarteritis nodosa.<sup>17</sup> Individuals who have limited organ involvement have a better prognosis than those with widespread organ involvement.<sup>17</sup> It is important to highlight early diagnosis as untreated classic PAN can be fatal secondary to cardiovascular or renal failure.<sup>17</sup>

In patients with a history of rheumatic fever and are diagnosed with PAN, it is crucial not only to monitor the disease progression and relapse of PAN, but also to remain vigilant for potential recurrence of rheumatic fever which is observed in over 65% of patients.<sup>19</sup> This substantially increases the risk of developing rheumatic heart disease, particularly in those who initially presented with symptoms of carditis.<sup>19</sup> Close monitoring and good compliance to medications are essential to prevent disease progression.

## SUMMARY/CONCLUSION

This is a case of a 7-year-old Filipino male with a known history of rheumatic fever as revealed by elevated ASO titer which presented subsequently with subcutaneous nodules on the lower back, bilateral upper and lower extremities accompanied by fever, arthralgia, myalgia and malaise. These clinical manifestations were consistent with the diagnosis of cutaneous PAN which was later confirmed by 6mm punch biopsy. The patient was then managed with prednisone. He was subsequently started on mycophenolate mofetil due to his limited response to initial treatment.

The likelihood and diagnosis of Polyarteritis Nodosa should be considered in children presenting with fever, tender subcutaneous nodules, arthralgia, and livedo reticularis, along with a history of rheumatic fever, although uncommon. Most cutaneous PAN have a benign course and is manageable with corticosteroids and steroid-sparing agents to maintain remission of the disease.

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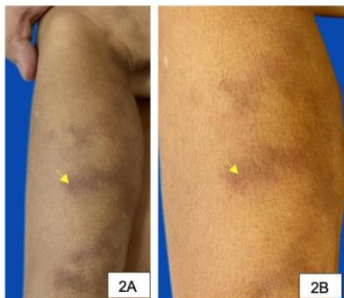
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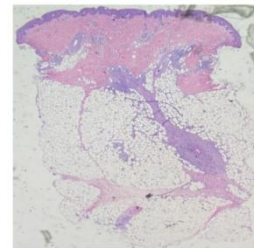
**Figures 1A-O.** Images upon referral. Multiple, well-defined slightly erythematous to hyperpigmented, firm, tender nodules with some areas of lace or net-like macules and patches, some resolved leaving hyperpigmentation.



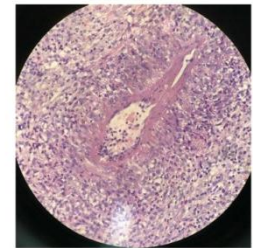
**Figures 2A-B.** A 6 mm punch biopsy taken from a nodule on the left leg.



**Figures 3A-D.** Images on subsequent hospital days. There was noted improvement as evidenced by resolution of erythema on most lesions, decrease in size of nodules leaving behind hyperpigmented macules and patches.



**Figure 4.** On scanning view, a septal panniculitis with large and small vessel vasculitis at the dermal-fat junction.



**Figure 5.** A medium-sized artery with fibrin deposition and neutrophils in its thick walls surrounded by a dense mixed cell inflammatory infiltrates composed of neutrophils, eosinophils and histiocytes. No thrombus formation noted. The lobules of fat are slightly involved and thinly infiltrated by neutrophils.

# Efficacy and Safety of Laser-Assisted Drug Delivery compared with Intralesional Triamcinolone Acetonide Monotherapy in the Treatment of Keloids and Hypertrophic Scars: A Single Blind Randomized Controlled Trial\*

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## ABSTRACT

**Background:** Keloids and hypertrophic scars are overgrowth of fibrous tissue after damage to the skin. There have been various published treatment modalities for these lesions. Currently, there are still no published studies on the use of laser-assisted drug delivery for hypertrophic scars and keloids in the Philippine setting.

**Objective:** To determine the efficacy and safety of laser-assisted drug delivery versus intralesional steroid injection alone for the treatment of keloid and hypertrophic scar.

**Methods:** This was a single center, randomized single-blind controlled study. Participants were randomly assigned into a control group (intralesional steroid injection) or a treatment group (laser-assisted drug delivery). The procedure was done monthly for four sessions. Assessment of lesions using the Vancouver Scar Scale was done at baseline and monthly post-sessions.

**Results:** A total of 42 participants completed the study, which was divided into two groups of 21 samples each. Results showed that the mean difference in overall skin score from baseline to fourth treatment session was significantly lower in the laser-assisted drug delivery group than the intralesional group ( $-0.48 \pm 0.75$  vs.  $-0.24 \pm 0.54$ ,  $t=2.31$ ,  $p=0.026$ ). No adverse events were noted throughout the study period.

**Conclusion:** It is a promising option to use non-ablative fractional CO<sub>2</sub> laser-assisted drug delivery as the treatment outcome was comparable to using intralesional steroid injection as monotherapy for keloids and hypertrophic scars.

**Keywords:** Keloid, Hypertrophic Scar, Laser-Assisted Drug Delivery, Intralesional Steroid Injection

**Commercial funding:** N/A

**Conflict of interest:** N/A

## INTRODUCTION

Wound healing is an intricate and complex series of processes. Phases of wound healing are inflammation, granulation tissue formation, and tissue remodeling, which results in tissue structure integrity.<sup>[1]</sup> A cutaneous scar results from overgrowth of fibrous tissue after damage to the skin, representing an exuberant healing response.<sup>[2]</sup> Keloid epidemiology is limited and scattered, with the average keloid incidence estimated only to be 5–10% in African, 0–0.1% in Asian, and <0.1% in other countries. Keloids and hypertrophic scars have equal sex distribution and have the highest incidence in the second to third decade of life.<sup>[3]</sup> Hypertrophic scars are a common complication of burn injury, with incidence even greater in developing countries. Previous studies have reported diverging incidences of hypertrophic scarring, with incidence rates varying from 40% to 94% following surgery and from 30% to 91% following burns.<sup>[4]</sup>

The disfiguring appearance of keloids or hypertrophic scars lead to aesthetic, physical concerns, and psychological distress. In a study done by Kassi et al.

(2020), Dermatology Life Quality Index (DLQI) was used to assess the Quality of Life (QoL) of black Africans with keloid scars. This study noted a score of 61.66% DLQI among patients with hypertrophic and keloid scars, associated with pain ( $p=0.046$ ), pruritus ( $p=0.81$ ) and functional disorders ( $p=0.29$ ).<sup>[5]</sup> On the other hand, in the study done by Lu et al. (2021), the Symptom Checklist-90 (SCL-90) results showed that scores on sensitivity to interpersonal relationships, depression and anxiety were higher in the visible scar group than in the invisible scar group or the normal scar group. Depression and anxiety scores were higher in the group with invisible scars than in the normal group, and mental health of female patients was affected more than male patients. Therefore, they recommended further psychological and clinical interventions for patients with keloid and hypertrophic scars.<sup>[6]</sup>

Intralesional corticosteroid injections, silicone bandages, and local pressure are a few of the commonly utilized treatment regimens for keloid and hypertrophic scars. Ekstein, S. et al (2021), showed the regression rate of

*Disclosures: The author has formally acknowledged and signed a disclosure affirming the absence of any financial or other relationships (including personal connections), intellectual biases, political or religious affiliations, and institutional ties that could potentially result in a conflict of interest.*

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keloid using triamcinolone acetonide injection to be 50-100%, while recurrence rate was at 33% to 50% at 1 year and 5-years post-treatment respectively.<sup>[7]</sup> Other second-line therapy for refractory cases, in turn, includes ablative or non-ablative laser therapy and surgical excision associated with the use of silicone gel (Schuch et al., 2019).<sup>[8]</sup>

Ablative and non-ablative laser treatments available for keloid treatment were used by Nghi and colleagues in 2019. Fractional CO2 laser at 10,600nm and erbium: YAG with 2,940 nm laser are examples of ablative lasers that cause local tissue destruction by emitting energy that is absorbed by skin water. While non-ablative lasers such as 980-nm diode laser, 1064-nm Nd:YAG laser, and 585 or 595-nm pulsed-dye lasers, target skin chromophores like hemoglobin or melanin and cause selective damage to blood arteries that supply the scar.<sup>[9]</sup>

With the advancement in laser technology, several studies proved the effectiveness of fractional photothermolysis in scar treatment as monotherapy. Although several researches provide promising data on the use of laser in the treatment of keloids and hypertrophic scars, randomized control trials on the use of non-ablative fractional CO2 laser are still lacking and are warranted to determine its effectivity and efficiency. The fractional CO2 laser was chosen on the basis of a study done by Srivastava et al. (2019), wherein fractional laser showed greater scar improvement than pulsed-dye laser or Q-switched laser.<sup>[10]</sup> Khansa et al. (2016) reported mixed results of laser-based treatments in different Fitzpatrick skin types, with a higher risk of side effects observed in keloids in skin of color.<sup>[11]</sup>

### **Significance of the Study**

Hypertrophic scars and keloids are difficult to treat and require various approaches to therapy. New discoveries and improvements in laser technology provide alternatives in the treatment of hypertrophic scars and keloids in terms of function, symptoms and cosmetic appearance. As of this writing, there are still no published studies on the use of non-ablative fractional CO2 lasers for hypertrophic scars and keloids in the Philippine setting. Hence, this study aims to determine if non-ablative fractional CO2 laser with topical application and intralesional injection of triamcinolone acetonide is superior to intralesional injection of triamcinolone acetonide alone in the treatment of keloid and hypertrophic scar.

### **RESEARCH QUESTION**

Among patients with keloids and hypertrophic scars of less than 2 years duration, is non-ablative fractional CO2 laser with topical application and intralesional injection of triamcinolone acetonide superior in efficacy and safety to intralesional injection of triamcinolone acetonide monotherapy?

### **OBJECTIVES OF THE STUDY**

#### **General Objective:**

To determine the efficacy and safety of non-ablative fractional CO2 laser with topical application and intralesional injection of triamcinolone acetonide versus intralesional injection of triamcinolone acetonide alone for the treatment of keloid and hypertrophic scar among patients at the Out-Patient Department of a tertiary government hospital.

#### **Specific Objective**

1. To determine and compare the mean Vancouver Scar Scale between patients who received non-ablative fractional CO2 laser followed by topical and intralesional steroid injection and patients who received intralesional steroid injection monotherapy.
2. To determine and compare the difference of mean Vancouver Scar Scale from baseline to fourth treatment session between patients who received non-ablative fractional CO2 laser followed by topical and intralesional steroid injection and patients who received intralesional steroid injection monotherapy.
3. To determine and compare the presence of adverse effects between patients who received non-ablative fractional CO2 laser followed by topical and intralesional steroid injection and patients who received intralesional steroid injection monotherapy.

### **B. METHODS**

This study employed a prospective, single center, single-blind randomized controlled trial design. The protocol was submitted, reviewed and approved by the Technical Review Board and Institutional Ethics Review Board of the institution. Convenience sampling methodology using lesional count was used to recruit participants with keloid and hypertrophic scars at the Out-Patient Department of a tertiary government hospital.

#### **B.1. Selection and Description of Participants**

**Target Population:** The participants were recruited from the patients seen at the Out-Patient Department of a tertiary government hospital.

**Inclusion Criteria:**

1. Male or female with age > 18 years old.
2. Clinical diagnosis of keloid or hypertrophic scar of less than 2-year duration, diagnosed through clinical presentation, diagnosed for the first time at the Out-Patient Department.

**Exclusion Criteria:**

1. Pregnant or lactating at the time of diagnosis and/or initiation of and during treatment.
2. History of intake of oral retinoids in the past 6 months.
3. Signs of active infection or lesions suspicious of malignancy.
4. History of prior treatment to the keloid or hypertrophic scar, either in a form of topical and/or intralesional modalities of treatment in the past 12 months.

**Drop-out Criteria:** Participants were considered dropped out if they missed more than 30 days after the previous session and/or used any topical medication other than the ones used during the study period.

**Withdrawal Criteria:** Participants withdrew from the trial anytime without any implications, especially if participants developed any severe reactions or contraindication to the interventions given.

**B.2. Technical Information****Study Outcomes**

The primary outcomes of this study were the changes in the Vancouver Scar Scale mean scores from baseline to post-treatment between the control and treatment group. The secondary outcomes were the changes in mean differences from baseline to post-treatment between the control and treatment group and the proportion of participants who experienced adverse events from either group.

**Tools and Methods**

1. Approval from the Institutional Ethics Review Board was obtained prior to conducting the study.
2. Patients diagnosed with keloids and hypertrophic scars seen by the residents at the Out-Patient Department were recruited and endorsed to the investigators.
3. The investigators assessed the eligibility of the participants. Study objectives, procedures, risks, and benefits were explained to the participants.

4. The participants were asked to sign an informed consent form to ensure voluntary participation.
5. Baseline data was obtained from the participants on the first study visit. This data included demographic data (age and sex), type and nature of lesion and location.
6. The participants were endorsed to the assessor other than the primary investigators for baseline assessment of the Vancouver Scar Scale. Baseline photographs were taken. For Vancouver Scar Scale, height was measured with calipers; pliability was by palpation; vascularity was assessed by visual inspection; and pigmentation was scored after blanching using a glass slide and comparing it with the surrounding skin.
7. The participants were given a unique identification number and were assigned to either group A (control group) or group B (treatment group).
8. For the control group, triamcinolone acetonide 40mg/mL solution was injected with a dose of 0.25 mL/cm<sup>3</sup> on lesions < 3cm and 0.5 mL/cm<sup>3</sup> on lesions > 3cm. Participants were assessed for adverse events following intralesional injection.
9. For the treatment group, participants underwent fractional CO<sub>2</sub> laser with the following energy doses depending on the Vancouver Scar Scale score: VSS 0-3 = 15 mJ, 4-6 = 20 mJ, 7-9 = 25 mJ and 10-13 = 30 mJ. Depth was fixed at level 3 and density of 10.
10. Immediately following the fractional CO<sub>2</sub> laser, triamcinolone acetonide 40mg/mL was applied on the lesion at a dose of 0.1mL/cm. After which, triamcinolone acetonide 40mg/mL solution was injected with a dose of 0.25 mL/cm<sup>3</sup> on lesions < 3cm and 0.5 mL/cm<sup>3</sup> on lesions > 3cm. Participants were assessed for adverse events following laser-assisted drug delivery.
11. The participants were asked to follow-up monthly for 4 months. During each study visit, participants were assessed with any adverse events. Lesions were also measured by the assessors using the Vancouver Scar Scale and photographs were taken for documentation. Doses and settings for both control group and treatment group were adjusted based on the Vancouver Scar Scale.

**B.3. Statistics****Sample Size Computation**

Sample size (*priori*) computation for Analysis of Covariance (ANCOVA) was conducted using G\*Power version 3.1.9.4. From the study of Srivastava et al. (2018),

the mean Vancouver Scar Scale (VSS) of the laser-assisted drug delivery group ( $n_1$ ) was 0.80 (SD=0.50) at 15<sup>th</sup>-week follow-up. In contrast, the intralesional triamcinolone acetonide group ( $n_2$ ) had a mean VSS score of 0.25 (SD=0.42) on the 15<sup>th</sup> week follow-up.[10] These values can be used to estimate an effect size  $f$  of 0.596 (moderate). With these parameters and with a power of 90%, an effect size  $f$  of 0.596, and a significance level of 5.00% (two-tailed), a minimum sample size of 32 lesions is necessary. However, the sample size was adjusted to account for a 20% attrition or drop-out rate. Hence, the final sample size for the study was a total of 40 lesions (20 lesions in each treatment arm).

### Randomization and Blinding

Lesions were randomly assigned into two groups through block randomization using a Microsoft Excel number generator: Group A (control group: Intralesional injection of triamcinolone acetonide 40mg/mL alone) and Group B (treatment group: Fractional CO<sub>2</sub> laser with topical application and intralesional injection of triamcinolone acetonide 40mg/mL).

Randomization was carried out by an assessor not part of the clinical trial. Codes generated were stored in an opaque envelope and accessed at the termination of the study. For all participants who agreed to participate, photography of the affected site (with standardized angle, lighting, and position) and measurements of the vascularity, pigmentation, pliability, and height were done for documentation from baseline to follow-up. In order to protect subjects' anonymity, each subject was assigned with a unique identification code upon enrollment. Their identification codes were used in the summary of results instead of their names or other possible identifiers.

### Statistical Analysis

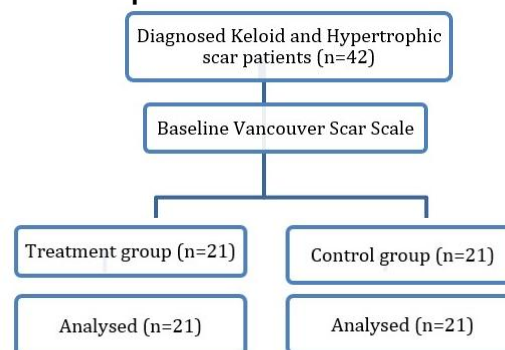
Statistical analyses were conducted using STATA MP – Parallel Edition Statistical Software, Version 18, College Station, TX: StataCorp LP. A significance level ( $\alpha$ ) of 0.05 was considered statistically significant. Descriptive statistics included mean and standard deviation for normally-distributed, continuous-level data; and, frequency and proportion for nominal data. [19] Between-group comparisons of the demographic and clinical characteristics and baseline efficacy outcomes according to treatment group allocation were conducted using Chi-Square Test of Homogeneity, if the expected frequency per cell is less than 5, for nominal data; Mann-Whitney  $U$  Test, for ordinal or non-normally-distributed, continuous data; and, independent  $t$ -test for normally-distributed, continuous data. [19] On the other hand, between-group comparisons (intralesional injection vs. laser-assisted

delivery groups) of the skin assessment scores, both overall and indicators (vascularity, pigmentation, pliability, and height), at the different follow-up periods were performed using Analysis of Covariance (ANCOVA). [20] The mean scores were adjusted (adjusted mean) to significant confounders which included the pre-test scores and the respective preceding follow-up scores. [19] The within-group comparisons of the overall skin assessment score and the different indicators from baseline to the different follow-up periods in each treatment group were conducted using Repeated-Measures Analysis of Variance (RM-ANOVA). [19] Afterwards, post-hoc ANOVA using Bonferroni adjustment was performed to identify pairwise comparisons between the baseline and follow-up periods in each treatment group. [19]

### C. RESULTS

A total of 42 lesions were included in the study, which were randomly assigned into a control group (intralesional triamcinolone acetonide 40mg/mL alone) or a treatment group (laser-assisted drug delivery) with 21 scar assigned per treatment arm.

**Figure 1: Participant flow**



**Table 1. Demographic and clinical characteristics of the participants according to their group allocation**

| Characteristics              | Group Allocation (N = 42) |                          |                | Test Statistic | p-value (Two-Tailed) |
|------------------------------|---------------------------|--------------------------|----------------|----------------|----------------------|
|                              | Control Group (n = 21)    | Treatment Group (n = 21) | Total (N = 42) |                |                      |
| Age (Years; $\bar{x}$ , SD)  | 33.34 (13.33)             | 26.76 (5.10)             | 30.00 (10.50)  | 2.08*          | 0.044                |
| Sex (f, %)                   |                           |                          |                | 9.72*          | 0.004                |
| Male                         | 4 (19.05%)                | 14 (66.67%)              | 18 (42.86%)    |                |                      |
| Female                       | 17 (80.95%)               | 7 (33.33%)               | 24 (57.14%)    |                |                      |
| Nature of Skin Lesion (f, %) |                           |                          |                | 8.86           | 0.167                |
| Acne                         | 10 (47.62%)               | 13 (61.90%)              | 23 (54.76%)    |                |                      |
| Post-Surgical                | 2 (9.52%)                 | 0 (0.00%)                | 2 (4.76%)      |                |                      |
| Trauma                       | 2 (9.52%)                 | 2 (9.52%)                | 4 (9.52%)      |                |                      |
| Varicella                    | 4 (19.05%)                | 1 (4.76%)                | 5 (11.90%)     |                |                      |
| Tattoo                       | 1 (4.76%)                 | 5 (23.81%)               | 6 (14.29%)     |                |                      |
| Vaccine                      | 1 (4.76%)                 | 0 (0.00%)                | 1 (2.38%)      |                |                      |
| Burns                        | 1 (4.76%)                 | 0 (0.00%)                | 1 (2.38%)      |                |                      |
| Site of Skin Lesion (f, %)   |                           |                          |                | 9.89           | 0.248                |

|                            |             |              |             |      |       |
|----------------------------|-------------|--------------|-------------|------|-------|
| Chest                      | 7 (33.33%)  | 5 (23.81%)   | 12 (28.57%) |      |       |
| Neck                       | 1 (4.76%)   | 0 (0.00%)    | 1 (2.38%)   |      |       |
| Shoulder                   | 3 (14.29%)  | 8 (38.10%)   | 11 (26.19%) |      |       |
| Arm                        | 2 (9.52%)   | 5 (23.81%)   | 7 (16.67%)  |      |       |
| Back                       | 3 (14.29%)  | 3 (14.29%)   | 6 (14.29%)  |      |       |
| Breast                     | 2 (9.52%)   | 0 (0.00%)    | 2 (4.76%)   |      |       |
| Hand                       | 1 (4.76%)   | 0 (0.00%)    | 1 (2.38%)   |      |       |
| Knee                       | 1 (4.76%)   | 0 (0.00%)    | 1 (2.38%)   |      |       |
| Foot                       | 1 (4.76%)   | 0 (0.00%)    | 1 (2.38%)   |      |       |
| Type of Skin Lesion (f, %) |             |              |             | 1.02 | 1.000 |
| Hypertrophic Scar          | 1 (4.76%)   | 0 (0.00%)    | 1 (2.38%)   |      |       |
| Keloid                     | 20 (95.24%) | 21 (100.00%) | 41 (97.62%) |      |       |

Note:  $\bar{x}$  = Mean, SD = Standard Deviation, f = Frequency, % = Percentage

\*Significant at 0.05  
\*Significant at 0.01

Clinico-demographic profiles of patients showed a mean age of the subjects was 30.00 years old (SD=10.50), with most being females (57.14%), and had acne scars secondary to acne vulgaris as skin lesions (54.76%). Results also showed that the majority of the subjects had skin lesions in their chest (28.57%) and shoulders (26.19%), and the majority of the participants had keloids (97.62%).

**Table 2. Comparison of baseline scar assessment scores using the Vancouver Scar Scale in the control and treatment group**

| Baseline Scar Assessment | Group Allocation (N = 42) |                          |                | t-Value | p-value (Two-Tailed) |
|--------------------------|---------------------------|--------------------------|----------------|---------|----------------------|
|                          | Control Group (n = 21)    | Treatment Group (n = 21) | Total (N = 42) |         |                      |
| Overall Baseline Score   | 6.81 (1.91)               | 7.57 (1.36)              | 7.19 (1.69)    | -1.49   | 0.145                |
| Vascularity              | 1.38 (0.80)               | 2.00 (0.63)              | 1.69 (0.78)    | -2.77*  | 0.008                |
| Pigmentation             | 1.14 (0.48)               | 1.14 (0.57)              | 1.14 (0.52)    | 0.00    | 1.000                |
| Pliability               | 2.24 (0.83)               | 2.90 (0.30)              | 2.57 (0.70)    | -3.46†  | 0.001                |
| Height                   | 2.05 (0.59)               | 1.52 (0.51)              | 1.79 (0.61)    | 3.07†   | 0.004                |

Values are presented as Mean (Standard Deviation)

\*Significant at 0.05  
†Significant at 0.01

The between-group comparisons of the baseline scar assessment scores using the Vancouver Scar Scale between the two groups are illustrated in Table 2. It can be noted that the overall baseline score of the control group and treatment group were 6.81 (SD=1.91) and 7.57 (SD=1.36), respectively, and these values were not significantly different ( $t=-1.49$ ,  $p=0.145$ ).

Results also showed that the mean scores of the treatment group in terms of vascularity ( $2.00 \pm 0.63$  vs.  $1.38 \pm 0.80$ ,  $t=-2.77$ ,  $p=0.008$ ) and pliability ( $2.90 \pm 0.30$  vs.  $2.24 \pm 0.83$ ,  $t=-3.46$ ,  $p=0.001$ ) were significantly higher. In contrast, the mean height ( $1.52 \pm 0.51$  vs.  $2.05 \pm 0.59$ ,  $t=3.07$ ,  $p=0.004$ ) in the treatment group was significantly lower compared to the control group.

**Table 3. Comparison of follow-up scar assessment mean scores using the Vancouver Scar Scale in the treatment and control groups**

| Follow-up Scar Assessment         | Group Allocation (N = 42) |                          |                | F-Value | p-value (Two-Tailed) |
|-----------------------------------|---------------------------|--------------------------|----------------|---------|----------------------|
|                                   | Control Group (n = 21)    | Treatment Group (n = 21) | Total (N = 42) |         |                      |
| Overall 1-Month Follow-up Score   | 6.76 (0.28)               | 7.19 (0.28)              | 6.76 (0.28)    | 1.19    | 0.283                |
| Vascularity                       | 1.62 (0.07)               | 1.67 (0.07)              | 1.62 (0.07)    | 0.21    | 0.651                |
| Pigmentation                      | 1.00 (0.08)               | 1.14 (0.08)              | 1.00 (0.08)    | 1.54    | 0.222                |
| Pliability                        | 2.33 (0.14)               | 2.53 (0.14)              | 2.33 (0.14)    | 0.90    | 0.350                |
| Height                            | 1.77 (0.09)               | 1.90 (0.09)              | 1.77 (0.09)    | 0.97    | 0.331                |
| Overall 2-Month Follow-up Score   | 6.17 (0.23)               | 5.40 (0.23)              | 6.17 (0.23)    | 5.22    | 0.028                |
| Vascularity                       | 1.38 (0.09)               | 1.33 (0.09)              | 1.38 (0.09)    | 0.11    | 0.747                |
| Pigmentation                      | 1.00 (0.09)               | 0.77 (0.09)              | 1.00 (0.09)    | 3.53    | 0.068                |
| Pliability                        | 2.02 (0.14)               | 1.84 (0.14)              | 2.02 (0.14)    | 0.82    | 0.371                |
| Height                            | 1.71 (0.09)               | 1.53 (0.09)              | 1.71 (0.09)    | 1.72    | 0.197                |
| Overall 3-Month Follow-up Score   | 5.16 (0.18)               | 4.65 (0.18)              | 5.16 (0.18)    | 3.82    | 0.058                |
| Vascularity                       | 1.27 (0.08)               | 1.11 (0.08)              | 1.27 (0.08)    | 2.07    | 0.158                |
| Pigmentation                      | 0.86 (0.07)               | 0.71 (0.07)              | 0.86 (0.07)    | 2.02    | 0.164                |
| Pliability                        | 1.76 (0.09)               | 1.48 (0.09)              | 1.76 (0.09)    | 4.76*   | 0.035                |
| Height                            | 1.27 (0.09)               | 1.35 (0.09)              | 1.27 (0.09)    | 0.41    | 0.527                |
| Overall Post-Test Follow-up Score | 4.55 (0.13)               | 4.78 (0.13)              | 4.55 (0.13)    | 1.55    | 0.220                |
| Vascularity                       | 1.10 (0.05)               | 1.19 (0.05)              | 1.10 (0.05)    | 2.11    | 0.155                |
| Pigmentation                      | 0.79 (0.00)               | 0.79 (0.00)              | 0.79 (0.00)    | 0.00    | 1.000                |
| Pliability                        | 1.52 (0.07)               | 1.53 (0.07)              | 1.53 (0.07)    | 0.00    | 0.983                |
| Height                            | 1.16 (0.07)               | 1.26 (0.07)              | 1.16 (0.07)    | 1.15    | 0.290                |

Values are presented at Adjusted Mean (Standard Error) after adjustment for the confounding effect of pre-test scores and the respective preceding follow-up scores.

Table 3 depicts the between-group comparisons of the follow-up skin assessment scores between the two treatment groups. It can be noted that the mean pliability scores using laser-assisted drug delivery was most improved at the third month of follow-up (Adjusted  $\bar{x} = 1.48$ ,  $SE=0.09$ ) compared to the control group (Adjusted  $\bar{x} = 1.76$ ,  $SE=0.09$ ). The mean overall mean overall skin assessment, vascularity, pigmentation, and height ( $p>0.05$ ) were not significantly improved at month 1 and 2 of treatment.

**Table 4. Comparison of the mean difference scores in Vancouver Scar Scale of patients in the treatment and control group**

| Vancouver Scar Scale          | Treatment Group Allocation (N = 42) |                                       | t-statistic | p-value (Two-Tailed) |
|-------------------------------|-------------------------------------|---------------------------------------|-------------|----------------------|
|                               | Intralesional Injection (n = 21)    | Laser-Assisted Drug Delivery (n = 21) |             |                      |
| Baseline to 1-Month Follow-up | -0.14 (0.36)                        | -0.43 (0.60)                          | 1.88        | 0.068                |
| Vascularity                   | -0.14 (0.48)                        | 0.00 (0.32)                           | -1.14       | 0.260                |
| Pigmentation                  | -0.10 (0.70)                        | -0.19 (0.60)                          | 0.47        | 0.639                |
| Pliability                    | -0.05 (0.22)                        | 0.14 (0.48)                           | -1.66       | 0.105                |
| Height                        | -0.33 (1.43)                        | -0.10 (1.18)                          | -0.59       | 0.559                |

| Baseline to 2-Month Follow-up   | -0.14 (0.36) | -0.76 (0.76) | 3.35 <sup>†</sup>  | 0.002 |
|---------------------------------|--------------|--------------|--------------------|-------|
| Vascularity                     | -0.19 (0.51) | -0.33 (0.66) | 0.79               | 0.437 |
| Pigmentation                    | -0.43 (0.81) | -0.86 (0.73) | 1.80               | 0.079 |
| Pliability                      | -0.24 (0.44) | -0.10 (0.44) | -1.06              | 0.295 |
| Height                          | -1.05 (1.43) | -1.76 (1.79) | 1.43               | 0.160 |
| Baseline to 3-Month Follow-up   | -0.24 (0.54) | -0.76 (0.77) | 2.56 <sup>†</sup>  | 0.014 |
| Vascularity                     | -0.24 (0.54) | -0.48 (0.75) | 1.18               | 0.244 |
| Pigmentation                    | -0.57 (0.81) | -1.33 (0.66) | 3.34 <sup>†</sup>  | 0.002 |
| Pliability                      | -0.67 (0.48) | -0.29 (0.46) | -2.61 <sup>*</sup> | 0.013 |
| Height                          | -1.67 (1.32) | -2.90 (2.00) | 2.37 <sup>*</sup>  | 0.023 |
| Baseline to Post-Test Follow-up | -0.24 (0.54) | -0.48 (0.75) | 2.31 <sup>†</sup>  | 0.026 |
| Vascularity                     | -0.24 (0.54) | -0.48 (0.75) | 1.18               | 0.244 |
| Pigmentation                    | -0.67 (0.80) | -1.43 (0.75) | 3.20 <sup>†</sup>  | 0.003 |
| Pliability                      | -0.81 (0.51) | -0.33 (0.58) | -2.82 <sup>*</sup> | 0.007 |
| Height                          | -2.00 (1.55) | -3.05 (2.09) | 1.85               | 0.072 |

Values are presented as Mean (Standard Deviation) \*

Significant at 0.05 †

Significant at 0.01

Table 4 depicts the between-group comparisons of the mean differences of the follow-up and baseline skin assessment scores between the treatment groups. Results showed that the mean difference in overall skin score from baseline to post-test was significantly lower in the laser-assisted drug delivery group than the intralesional group ( $-0.48 \pm 0.75$  vs.  $-0.24 \pm 0.54$ ,  $t=2.31$ ,  $p=0.026$ ). Similarly, it can be noted that the laser-assisted drug delivery group ( $-1.43 \pm 0.75$ ) had a significantly lower ( $t=3.20$ ,  $p=0.003$ ) mean difference in pigmentation score compared to the intralesional injection group ( $-0.67 \pm 0.80$ ). It is also interesting to note that the effect size for the between-comparisons yielded partial eta-squared ( $\eta^2$ ) values of 0.219 for baseline-to-2-month follow-up, 0.141 for baseline-to-3-month follow-up, and 0.118 for baseline-to-post-test comparisons. These values denote that 21.90%, 14.10%, and 11.80% of the differences in mean difference scores at these timeframes were attributed to the administration of the intervention (laser-assisted drug delivery).

**Figure 4a. Trend in mean overall scar assessment scores of the control group and experimental group**

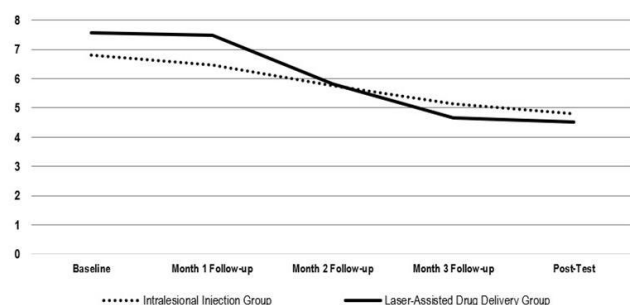
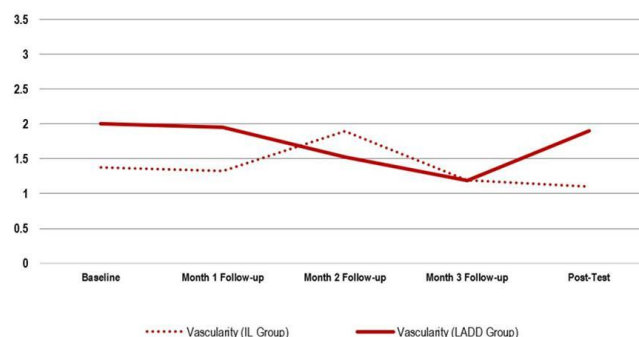
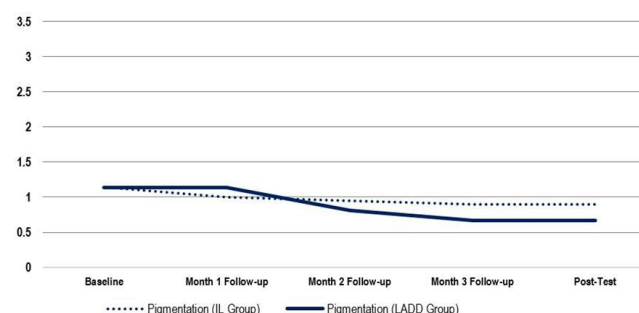


Figure 1. Trend in Mean Overall Scar Assessment Scores of the Intraleisional Injection Group (Control) and Laser-Assisted Drug Delivery Group (Experimental)

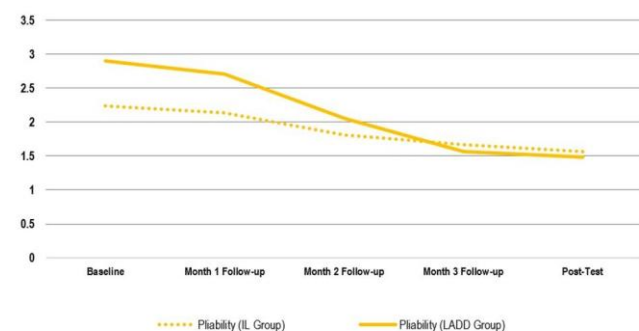
**Figure 4b. Trend in mean scores in vascularity of the control and experimental group**



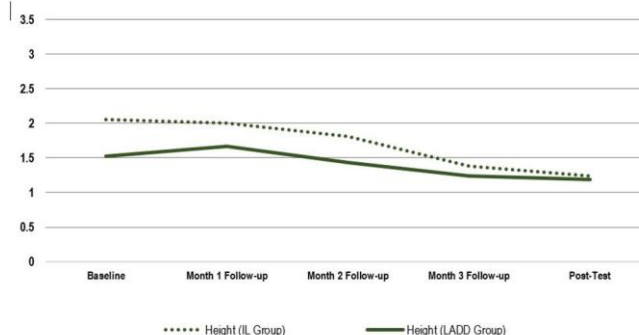
**Figure 4c. Trend in mean scores in pigmentation of the control and experimental group**



**Figure 4d. Trend in mean scores in pliability of the control and experimental group**



**Figure 4e. Trend in mean scores in height of the control and experimental group**



The within-group comparisons of the overall skin assessment scores at the different timeframes for each treatment group are presented in Figures 4a, 4b, 4c, 4d, and 4e. For the intralesional injection group, results showed that the mean vascularity, mean pliability, mean height, and mean overall skin assessment scores were significantly different across the five different timeframes ( $p < 0.05$ ). Post-hoc analyses, using Bonferroni adjustment, that the overall mean score was not significantly different between baseline and 1-month follow-up ( $p = 1.000$ ), but it significantly decreased starting 2-month ( $p = 0.032$ ) until 3-month ( $p = 0.001$ ) and post-test ( $p = 0.001$ ) follow-up periods. For the mean pliability scores, results showed that the comparisons of baseline scores were not significantly different with the 1-month ( $p = 1.000$ ) and 2-month ( $p = 0.250$ ) follow-up periods. However, the mean scores at 3-month ( $p = 0.042$ ) and post-test ( $p = 0.010$ ) follow-ups were significantly lower compared to the baseline mean score. Focusing on the height of skin lesions, it can be noted that the mean scores significantly decreased, compared to baseline score, starting 3-month follow-up ( $p = 0.001$ ) until post-test follow-up period ( $p = 0.001$ ). Post-hoc ANOVA analyses of the pairwise comparisons for vascularity and pliability did not show significant differences between the baseline scores and the follow-up scores ( $p > 0.05$ ).

In a different light, results for the laser-assisted drug delivery group showed that the overall skin score and the four indicators or parameters were significantly different across the various timeframes ( $p < 0.05$ ). It is interesting to note that the mean overall skin assessment scores had a downward trend from baseline, which was significantly lower starting 2-month follow-up ( $p = 0.002$ ) until post-test follow-up ( $p = 0.001$ ). Vascularity and pliability scores ( $p < 0.05$ ) were most improved at 2-month follow-up compared to baseline, while scar pigmentation and height ( $p > 0.05$ ) had no statistically significant improvement at two months.

**Figure 5a and 5b. Comparison Photos in the Control Group**

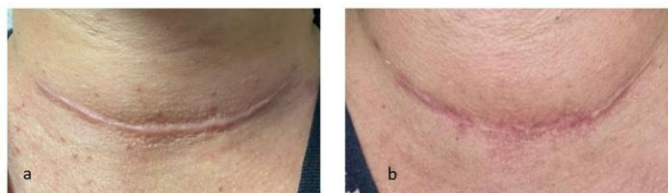


Figure 5a. Hypertrophic scar on the neck post-thyroidectomy, with marked improvement after treatment completion



Figure 5b. Keloid on the chest secondary to acne, with noted improvement after 3 treatment sessions

**Figure 6a and 6b. Comparison Photos in the Treatment Group**

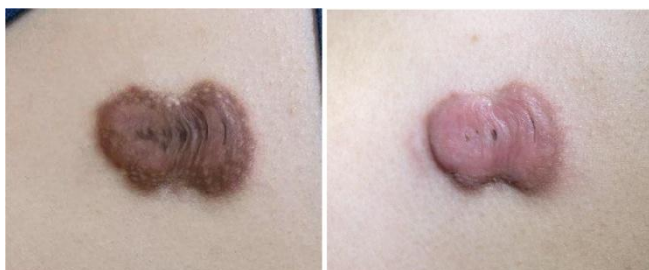


Figure 6a. Keloid on the upper back secondary to varicella, with noted improvement in pigmentation and pliability after treatment completion



Figure 6b. Keloid on the chest secondary to acne, with noted thinning of lesion after treatment completion

## DISCUSSION

Focusing on the treatment group utilizing fractional CO<sub>2</sub> laser with topical application and intralesional injection of triamcinolone acetonide 40mg/mL, results of this study showed that the overall skin score was significantly decreased from baseline to post-treatment, with notable differences at 2-month follow-up until the end of all treatment sessions. Results depicted in table 3 showed that there was no statistical difference in the mean overall skin assessment scores between the two groups at post-test follow-up; however upon further analysis, the mean difference in overall skin score from baseline to post-test was significantly lower in the laser-assisted drug delivery group than the intralesional group.

Figure 4 showed the trend in the decrease of the mean overall scar assessment scores for both groups. Both groups showed a downward trend from baseline; however on further analysis, there was a more rapid decrease in the treatment group compared to the control group. There was notable difference in scar appearance after 2 sessions of fractional CO<sub>2</sub> laser with topical application and intralesional injection of triamcinolone acetonide, as compared to the later improvement seen in control group after 3 sessions of intralesional injection of triamcinolone acetonide 40mg/mL alone. Adverse events were investigated immediately after every treatment session and on subsequent follow-ups. During the course of the study, no adverse events were noted from both groups. This underscored the efficacy of fractional CO<sub>2</sub> laser with topical application and intralesional injection of triamcinolone acetonide 40mg/mL in terms of faster improvement in scar appearance and characteristic.

Similar findings were seen in international publications using ablative fractional CO<sub>2</sub> laser. A study by Waibel et al. (2013) provided good evidence on the effectiveness and safety of combination therapy of fractional CO<sub>2</sub> laser with topical application of triamcinolone acetonide suspension in the improvement of keloids and hypertrophic scars in terms of texture, hypertrophy and dyschromia, with no complications noted.<sup>[22]</sup> Another study done by Alexander et al. (2019), showed statistical improvement in height and length of keloids and hypertrophic scars after combination of ablative fractional CO<sub>2</sub> laser with intralesional steroid.<sup>[14]</sup> Srivastava et al. (2018) revealed that among the scar parameters, pigmentation is not completely resolved by any modalities (TAC, verapamil or fractional CO<sub>2</sub> laser), as was also seen in this study.<sup>[10]</sup>

### **Adverse Event**

Results in table 4 also showed there was a decrease in the efficacy of laser-assisted drug delivery overtime as evidenced by the partial eta-squared values of 0.219 for baseline-to-month 2 follow-up, 0.141 for baseline-to-month 3 follow-up, and 0.118 for baseline-to-post-test comparisons. These findings were attributed to the adjustment in the setting of fractional CO<sub>2</sub> laser during each visit depending on the Vancouver Scar Scale. As the VSS score decreased, the energy dose of the laser also decreased accordingly. These adjustments were necessary to ensure safety and to prevent any adverse event following treatment.

This study provides novel knowledge on the use of non-ablative fractional CO<sub>2</sub> laser with topical application of triamcinolone acetonide suspension in the improvement of keloids and hypertrophic scars. Non-

ablative fractional CO<sub>2</sub> laser was noted to maintain an intact epidermis while reaching the deeper reticular dermis by increasing the irradiance and using a higher or lower pulse energies depending on the depth of the lesion.

### **Limitations of the Study**

The sample size of this study was limited by the number of sessions, treatment duration, concentration and dose of steroid applied or injected. The treatment sessions were limited to 4 sessions that were 1 month apart. This study was also limited to lesions of less than 2-year duration. Intralesional steroid injection was also limited to 40mg/mL of triamcinolone acetonide, requiring further studies on the effectiveness of lower doses of corticosteroid injections.

### **CONCLUSION AND RECOMMENDATION**

It is a promising option to use non-ablative fractional CO<sub>2</sub> laser-assisted drug delivery as the treatment outcome was comparable to using intralesional steroid injection as monotherapy for keloids and hypertrophic scars. No significant difference was seen in the mean overall skin assessment scores from baseline to post-treatment follow-up, however, the mean difference in overall skin score from baseline to fourth treatment session was significantly lower in the laser-assisted drug delivery group than the intralesional group. No adverse events were noted throughout the study period. These findings gave emphasis on the superiority in efficacy and safety of non-ablative fractional CO<sub>2</sub> laser as an adjunct to topical application and intralesional steroid injection for the treatment of keloid and hypertrophic scar. Future research and studies are recommended to investigate the effects of other laser machines and lesions with longer duration (>2 years). Long-term follow-up is also suggested to monitor the improvement or possible recurrence of lesions after the end of the study.

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## A 4-Year Retrospective Epidemiological Study of Common Dermatoses Among Pediatric from a Tertiary Referral Center in Pangasinan\*

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### ABSTRACT

**Background:** Pediatric dermatoses are multifactorial and diverse. Environmental factors play a significant role in skin disease. This study described the prevalence of common dermatoses among pediatric population seen at a tertiary referral center in Pangasinan.

**Methods:** This was a 4-year retrospective, single center, chart review study in a tertiary referral hospital in Pangasinan. The researchers reviewed both electronic and medical charts of all pediatric outpatient and inpatient referrals with dermatoses from January 1, 2019 to December 31, 2022 by utilizing Proportion sampling technique.

**Results:** This study reviewed a total of 501 (Males, 49.5% and Females, 50.5%) outpatient and inpatient pediatric patients who consulted due to skin related concerns. The majority of the patients were school-age children and adolescents followed by newborns, infants and toddlers respectively. Scabies infestation (n=76, 15.2%), Acne vulgaris (n=53, 10.6%) and Atopic dermatitis (n=48, 9.6%) were the top 3 common dermatoses among pediatric age groups. Scabies was the top diagnosis for both male (n=37, 14.9%) and female (n=39, 15.4%). Acne vulgaris (n=50, 31.6%) was the most common diagnosis in the adolescent age group.

**Conclusions:** There was wide variation in the most common dermatosis according to age, sex, and year. Poor sanitation, overcrowding and low socioeconomic status are important factors for the increased prevalence of parasitic infestations. Acne vulgaris was seen almost exclusively in adolescents. This study served as a preliminary epidemiological report on pediatric dermatoses in Region 1 Medical Center that may pave the way for well-controlled and better designed researches in the future.

**Keywords:** *pediatric dermatology, common pediatric dermatoses, epidemiological study*

**Commercial funding:** N/A

**Conflict of Interest:** N/A

### INTRODUCTION

Skin diseases account for a significant proportion of pediatric consultations. Ethnic, socioeconomic, and environmental factors influence their incidence. The increasing frequency of pediatric skin diseases represents a significant part of morbidity in children.

Epidemiology of skin diseases in the pediatric population differ from that of adults mainly because some diseases may only be seen exclusively amongst children. The presentation and manifestation of several of these diseases are also different. Hence, the approach to treatment and management are not the same. Children are more vulnerable that needs special attention and care when it comes to treatment.

According to Castelo-Soccio, et. al, cutaneous problems are frequently seen in pediatric patients, there are up to 30 percent of pediatric primary care visits that involves a skin-related problem. Common dermatoses that are seen are atopic dermatitis, seborrheic dermatitis, contact dermatitis, and acne. (Castelo-Soccio L, 2017)

The common practice in dermatology is in the outpatient setting. However, there are some skin conditions where a child has to be admitted for cutaneous disease or a secondary systemic illness. The pediatricians are usually the first line with the pediatric patients. Thereafter, intra-hospitalization referrals are given to the respective departments. There are only a few studies describing the inpatient consultations in dermatology regarding the pediatric population and their effects on the management as inpatient. There are also few studies available about the epidemiology of pediatric skin diseases. There are not enough studies focusing on pediatric dermatology and in patient dermatology referrals here in the Philippines. This study will be of a great help for future studies alike. (Fatma S. Afsar, 2017)

Common dermatoses are often not recognized and misdiagnosed by non-dermatologists. Cutaneous problems may be present at the time of hospitalization or may develop during the stay in hospital, requiring consultation with a dermatologist. (Daye et al., 2019)

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Dermatoses are common in the pediatric population. They have certain disorder seen in this age group such as the prevalence of the diaper dermatitis and genetic disorders. Pediatric dermatological problems are common, but may require a consultation with dermatology. In other countries, appropriate diagnosis and therapy are sometime delayed and have few studies that have focused on pediatric dermatoses. This study will contribute to a better knowledge of pediatric skin conditions in our work environment.(Ahogo et al., 2018)

The pediatric skin diseases are common, multifactorial and diverse. Environmental factors play a significant role in skin disease. This study aimed to describe the prevalence of common dermatoses among pediatric population with ages 0-18 seen at a tertiary referral center in Pangasinan.

### SIGNIFICANCE OF THE STUDY

The aim of this study was to know the incidence rates and prevalence of pediatric skin diseases in our institution that was seen by the Dermatology Department that can subsequently serve as reference material for future comparative studies as the department is part of a tertiary care teaching hospital. The aim for this study was to know how important early diagnosis and on updated management of common diseases for both dermatologist and non-dermatologist physician. The aim of this Epidemiological study was to determine the pattern of skin diseases among children which are important for proper health care planning and management. This study will also be of great help to educate health care workers about the common dermatoses seen in the pediatric population.

### OBJECTIVES

The main objective of this study was to determine the epidemiological profile of common dermatoses of patients aged 0-18 years old, who were seen at the outpatient dermatology clinic, outpatient pediatric clinic with dermatoses, inpatient dermatology referrals at Region 1 Medical Center(R1MC) during the period January 2019 – December 2022.

The specific objectives declared below was attained at the end of this research study. The following was presented:

1. To determine the clinico-demographic profile of cases of pediatric dermatoses noted in the outpatient dermatology clinic, outpatient pediatric clinic with dermatoses, inpatient dermatology referrals at Region 1 Medical Center from January 2019 – December 2022 according to:

1.1 Age;

1.2. Sex; and

1.3. Location

2. To determine the top 10 most common dermatoses per year and overall for the year 2019-2022
3. To determine the top 10 most common dermatoses by sex
4. To determine the top 10 most common dermatoses by age groups: neonates (0-28 days); infants (1mo-12 months); toddler (13 months-3 years old); school age children (3 years- 12 years old); and adolescent (13-18 years).

### METHODOLOGY

This was a 4-year retrospective study, single center, chart review study. We reviewed all the electronic records and medical charts of all patients aged 0–18 years, who were seen at the outpatient dermatology clinic, outpatient pediatric clinic with dermatoses and inpatient dermatology referrals at Region 1 Medical Center during the period January 1, 2019 – December 31, 2022

#### Inclusion Criteria:

1. All patients aged 0-18 year old who consulted at R1MC who consulted due to skin related concerns (inpatient and outpatient).
2. All patient with 1<sup>st</sup> time consults
3. Patients that are for follow up with new complaints and diagnosis compared to the previous consults will be included in the study
4. If the patient has more than 1 diagnoses, all diagnoses will be accounted for.

#### Exclusion Criteria:

1. Patients with incomplete data in the electronic medical records and medical charts.
2. Patients with vague diagnoses.
3. Follow ups with the same diagnosis as the 1<sup>st</sup> consult will be excluded in the study.
4. Patients with diagnosis not related to dermatology.

#### Sampling Technique

In the investigation that was carried out, the researcher conducted Proportion sampling technique in the study. The formula below will be used.

$$n = \frac{[(DEFF) (NP) (1-p)]}{[d^2/Z^2(1-\alpha/2(N-1)+p(1-p))]}$$

Utilizing this formula, the investigator set the design effect for cluster survey to 1.0 with 50% anticipated frequency and confidence level of 95%. Based on the previous census, at least n=10,000 patients presenting dermatoses was encountered within the inclusive years. Employing Proportion sampling technique, the investigator obtained n=370 patients for analysis.

### Sample Size for Frequency in a Population

Population size(for finite population correction factor or fpc)(N): 10000

Hypothesized % frequency of outcome factor in the population (p): 50%+/-5

Confidence limits as % of 100(absolute +/- %)(d): 5%

Design effect (for cluster surveys-DEFF): 1

### Sample Size(n) for Various Confidence Levels

| Confidence | Level(%) | Sample Size |
|------------|----------|-------------|
| 95%        |          | 370         |
| 80%        |          | 162         |
| 90%        |          | 264         |
| 97%        |          | 450         |
| 99%        |          | 623         |
| 99.9%      |          | 978         |
| 99.99%     |          | 1316        |

Equation

$$\text{Sample size } n = \frac{[DEFF \cdot Np(1-p)]}{[(d^2/Z^2)_{\alpha/2} \cdot (N-1) + p \cdot (1-p)]}$$

### Statistical Treatment of Data

The researcher encoded the data on Microsoft Excel version 2017. The researcher utilized Statistical Package for Social Sciences (SPSS) version 23 for Macintosh. The following statistical analyses was proposed.

Frequency Distribution and Percentage. These used to determine the clinico-demographic profile and specific dermatoses noted in the Department Dermatology at Region 1 Medical Center from January 2019 – December 2022 according to age, sex, and location.

Chi Square. This was used to determine the significant difference between specific dermatoses encountered in the Department Dermatology at Region 1 Medical Center from January 2019 – December 2022 when grouped according to age, sex, and location.

### Data Gathering

A written request was given to the head of the medical records section prior to data gathering. A list of patients aged 0-18 year old who consulted at R1MC due to skin related concerns (inpatient and outpatient) was requested and prepared by the medical records section. The electronic medical records and charts was retrieved and reviewed.

Epidemiologic data (age, sex, location), family and personal history, ancillary diagnostics, and final diagnosis will be extracted from the patient's medical records. The patients was classified into five different age groups: neonates (0-28 days); infants (1mo-12 months); toddler (13 months-3 years old); school age children (4 years- 12 years old); and adolescent (13-18 years).

The primary investigator was responsible for collection, data gathering and to warrant that the data to be collected was complete and accurate. All records was kept at a secured cabinet and the computer used was password protected and was stored safely at all times, only the researchers involved in this study had access to the results. All resources of data which was indicative to the identity of the participants in the action research will be destroyed after completion of the study. Only necessary information and ICD codes was gathered and no other revealing personal information was recorded upon throughout the study. All information was encoded in a password-protected computer and will be deleted after 3 months from the completion the study. There was no monetary benefits and incentives of any kind that was used in this research study. All information was kept confidential.

### Outcome measures

The primary outcome of this study was to describe the clinico-demographic profiles of patients aged 0–18 years, who were seen at the outpatient dermatology clinic, outpatient pediatric clinic with dermatoses and inpatient dermatology referrals at Region 1 Medical Center from January 2019 to December 2022. Secondary outcomes included the magnitude of consults involving pediatric patients who were seen at the outpatient dermatology clinic, outpatient pediatric clinic with dermatoses and inpatient dermatology referrals at R1MC, as well as the extent of dermatological concerns by identification and enumeration of the most common dermatoses affecting the patients aged 0–18 years, who were seen at the outpatient dermatology clinic, outpatient pediatric clinic with dermatoses and inpatient dermatology referrals at R1MC from January 2019 to December 2022.

## Ethical Considerations

This study was in compliance with declaration of Helsinki. The researcher confirmed adherence to the principle of Helsinki 2008. This protocol was reviewed by Region 1 Medical Center Research Committee. There were no physical risks associated with this study. All information gathered from the chart review remained confidential among the investigators. Each participant was coded. The names of the patients did not appear in any report or publications. During and after the research procedure, all records was kept at a secured cabinet and the computer used was password protected and will be stored safely at all times, only the researchers involved in this study had access to the results. All resources of data which was indicative the identity of the participants in the action research will be destroyed after completion of the study. Only necessary information and ICD codes was gathered and no other revealing personal information was recorded upon throughout the study. All information was encoded in a password-protected computer and will be deleted after 3 months from the completion the study. This research adhered to the principles of transparency, legitimate purpose, and proportionality in the collection, retention, and processing of personal information (Data Privacy Act of 2012). There were no direct benefits to the participants in the study. There was no monetary benefits and incentives of any kind that was used in this research study. Informed consent was not used. All information was kept confidential. The rights to publication belong to the primary author and there are plans for publication in the future.

## RESULTS

Between January 2019 and December 2022, we reviewed charts of 501 pediatric patients (inpatient and outpatient) who consulted due to skin related concerns, with first time consults and new complaints. 248 Male (49.5%) and 253 Female (50.5%), were included in the study (*Figure 1*).

According to the age group, we reviewed 18 neonates (3.6%), 60 infants (12%), 105 toddlers (21%), 160 school-aged children (31.9%), 158 adolescents (31.5%). (*Figure 2*)

454 patients (92%) who consulted resides within Pangasinan area, majority of whom lives in Dagupan City (188 patients, 37.5%) and 41 patients (8%) consulted resides outside Pangasinan (*Figure 3*).

The 10 most common pediatric dermatoses in the year 2019 (*Table 1*.) were as follows: Scabies infestation (17.1%), Atopic dermatitis (8.1%), Bullous impetigo (6.5%), Impetigo contagiosa (5.7%), Infantile seborrheic dermatitis

(4.9%), Urticaria (4.9%), Seborrheic dermatitis (4.1%), Tinea corporis (4.1%), Allergic contact dermatitis (3.3%), Acne vulgaris (3.3%), Molluscum contagiosum (3.3%), Tinea versicolor (3.3%).

The 10 most common pediatric dermatoses in the year 2020 (*Table 2*.) were as follows: Scabies infestation (15.6%), Atopic dermatitis (14.8%), Pediculosis Capitis (7.4%), Bullous impetigo (6.6%), Seborrheic dermatitis (5.7%), Tinea versicolor (5.7%), Irritant contact dermatitis (4.1%), Acne vulgaris (4.1%), Impetigo contagiosa (4.1%), Ecthyma (3.3%).

The 10 most common pediatric dermatoses in the year 2021 (*Table 3*.) were as follows: Scabies infestation (16.8%), Acne vulgaris (16%), Atopic dermatitis (9.6%), Seborrheic dermatitis (7.2%), Ecthyma (5.6%), Tinea corporis (4%), Tinea cruris (4%), Irritant contact dermatitis (3.2%), Hansen's disease (3.2%), Allergic contact dermatitis (2.4%), Molluscum contagiosum (2.4%), Tinea versicolor (2.4%), Post-inflammatory hyperpigmentation (2.4%).

The 10 most common pediatric dermatoses in the year 2022 (*Table 4*.) were as follows: Acne vulgaris (18.3%), Scabies infestation (11.5%), Atopic dermatitis (6.1%), Bullous impetigo (5.3%), Irritant contact dermatitis (4.6%), Arthropod bite reaction (4.6%), Dyshidrotic eczema (3.1%), Ecthyma (3.1%), Hand foot and mouth disease (3.1%), Tinea versicolor (3.1%).

The overall most common type of dermatoses according to year and category between January 2019 and December 2022 was Dermatitis/ Eczema group, constituting a total of 27.5% of the study population, followed by Parasitic Infestations (21.6%) and Bacterial infections (18.0%). Other groups were Acneiform (11.4%), Fungal infections (11.2%), Viral infections (7.2%), Papulosquamous disorders (2.8%), Neutrophilic, eosinophilic disorders, mast cell disorders (2.6%), Eccrine and Apocrine disorders (2.6%), Reactive erythemas (2.2%), Tumors (2.2%), Melanocytic disorders (2%), Hair and nail disorders (1.8%), Autoimmune disorders (1.6%), Vascular disorders (1.2%), Disorders of cornification (0.4%), and others (3.4%). *The most common dermatoses according to year (2019-2022) were presented in Figure 4.*

Scabies infestation was the most common diagnosis among all common dermatoses between January 2019 and December 2022, with a total of 15.2% of the study population. Acne vulgaris (53, 10.6%) was the second most common diagnosis. Atopic dermatitis was the most common diagnosis in the dermatitis group affecting 9.6% of the study population. Seborrheic dermatitis and Bullous impetigo both accounting to 4.8% each of the study population. Irritant contact dermatitis and Tinea versicolor came in 5th both accounting to 3.6%

each of the study population followed by Pediculosis capitis and Impetigo contagiosa both accounting to 3.4% each of the study population. Other most common dermatosis were as follows: Ecthyma (16, 3.2%), Tinea Corporis (15, 3%), Arthropod bite reaction (14, 2.8%) and Molluscum contagiosum (12, 2.4%). *The top ten most common dermatoses according to year (2019-2022) were presented in Table 5.*

The overall most common type of dermatoses according to sex between January 2019 and December 2022 was the Dermatitis/ Eczema group on both sexes, constituting a total of 28.2% for Males and 26.9% for Females.

For the Male group, the second most common type of dermatoses was Bacterial infections with 19.8% of the study population, with Ecthyma (4.8%) being the most common diagnosis in the bacterial infections group. Other common diagnoses for the Male group were in order: Parasitic Infestation (18.1%), Acneiform (11.3%), Fungal infections (13.3%), Viral infections (7.7%), Papulosquamous disorders (2.8%), Neutrophilic, eosinophilic disorders, mast cell disorders (3.6%), Eccrine and Apocrine disorders (3.6%), Reactive erythemas (3.2%), Tumors (2%), Melanocytic disorders (1.2%), Hair and nail disorders (1.2%), Vascular disorders (1.2%), Autoimmune disorders (0.4%), and others (4%).

For the Female group, the second most common type of dermatoses was Parasitic Infestations with 24.9% of the study population, with Scabies infestation (15.4%) being the most common diagnosis in the Parasitic infestations group. Other common diagnoses for the Female group were in order: Bacterial infections (16.2%), Acneiform (11.5%), Fungal infections (9%), Viral infections (6.7%), Autoimmune disorders (5.5%), Hair and nail disorders (3.6%), Melanocytic disorders (3.2%), Papulosquamous disorders (2.8%), Tumors (2.4%), Neutrophilic, eosinophilic disorders, mast cell disorders (1.6%), Eccrine and Apocrine disorders (1.6%), Reactive erythemas (1.2%), Vascular disorders (1.2%), Disorders of cornification (0.8%) and others (3.2%). *The most common dermatoses according to sex were presented in Figure 5.*

The 10 most common pediatric diagnosis in Males seen between the 4 year time period were as follows: Scabies infestation (14.9%), Atopic dermatitis (10.1%), Acne vulgaris (10.1%), Seborrheic dermatitis (5.2%), Ecthyma (4.8%), Tinea versicolor (4.8%), Impetigo contagiosa (4%), Tinea corporis (3.6%), Irritant Contact Dermatitis (3.2%), Bullous impetigo (3.2%), Tinea cruris (3.2%), Arthropod bite reaction (2.8%), Urticaria (2.8%), Allergic contact dermatitis (2.4%), Miliaria rubra (2.4%), and Dyshidrotic eczema (1.2%). *The top ten most common*

*diagnosis in males were presented in Table 5.1 and Figure 5.1.*

The 10 most common pediatric diagnosis in Females seen between the 4 year time period were as follows: Scabies infestation (15.4%), Acne vulgaris (11.1%), Atopic dermatitis (9.1%), Pediculosis Capitis (6.3%), Bullous impetigo (6.3%), Seborrheic dermatitis (4.3%), Irritant Contact Dermatitis (4%), Dyshidrotic eczema (2.8%), Impetigo contagiosa (2.8%), Arthropod bite reaction (2.8%), Systemic Lupus Erythematosus (2.8%), Molluscum contagiosum (2.4%), Tinea corporis (2.4%), Post-inflammatory hyperpigmentation (2.4%), Ecthyma (2.8%), Allergic contact dermatitis (2%), Nummular eczema (2%), Furunculosis (1.6%), Pityriasis rosea (1.6%). *The top ten most common diagnosis in females were presented in Table 5.2 and Figure 5.2.*

The most common dermatoses seen between the 4-year time period in Neonates were the Dermatitis/ Eczema group, constituting a total of 33.3 of the study population, with Infantile seborrheic dermatitis (16.7%) being the most common diagnosis in Neonates. The second most common dermatoses in Neonates were Eccrine and apocrine disorders (16.7%), with Miliaria rubra (11.1%) being the most common diagnosis in the eccrine and apocrine disorders group. Other common dermatoses in the Neonatal group were as follows: Acneiform (11.1%), Bacterial infections (11.1%), Tumors (11.1%), and Disorders of cornification (5.6%). *The most common dermatoses in Neonates were presented in Figure 6 and Table 6.*

The most common pediatric dermatoses seen between the 4-year time period in Infants were as follows: Scabies infestation (25%) followed by both Atopic dermatitis and Seborrheic dermatitis being the 2<sup>nd</sup> most common diagnosis affecting 11.7%, Staphylococcal scalded skin syndrome (10%), Infantile seborrheic dermatitis (10%), Bullous impetigo (8.3%). *The most common dermatoses in Infants were presented in Table 7.*

The most common pediatric dermatoses seen between the 4-year time period in Toddlers were as follows: Scabies infestation (15.2%), Atopic dermatitis (13.3%), Bullous impetigo (8.6%), Impetigo contagiosa (7.6%), Ecthyma (6.7%), Arthropod bite reaction (6.7%), Miliaria rubra (4.8%). *The most common dermatoses in Toddlers were presented in Table 8.*

The most common pediatric dermatoses seen between the 4-year time period in School-aged children were as follows: Scabies infestation (16.3%), Atopic dermatitis (13.1%), Pediculosis capitis (7.5%), Bullous impetigo (5.6%), Impetigo contagiosa (5.6%), Dyshidrotic eczema (5%), Ecthyma (6.7%), Irritant contact dermatitis (5%), Molluscum contagiosum (5%), Tinea versicolor (5%),

Tinea corporis (3.8%), Nummular eczema (2.5%), Arthropod bite reaction (2.5%), Ecthyma (2.5%), Hansen's disease (2.5%). *The most common dermatoses in school-aged children were presented in Table 9.*

The most common dermatoses seen between the 4-year time period in Adolescent were the Acneiform group, constituting a total of 32.3% of the study population, in which Acne Vulgaris being the most common diagnosis in this category affecting 31.6% of the acneiform diagnoses group. Other most common dermatoses in adolescents were as follows: Scabies infestation (12%), Seborrheic dermatitis (6.3%), Tinea cruris (4.4%), Tinea versicolor (4.4%) Systemic lupus erythematosus (4.4%), Atopic dermatitis (3.8%), Tinea corporis (3.8%), Prurigo nodularis (3.2%), Verruca vulgaris (3.2%). *The most common dermatoses in Adolescents were presented in Table 10 and Figure 7.*

Data were entered in Excel and further analyzed in SPSS v. 26. Descriptive statistics was used to summarize the gathered data. Clinico-demographic profile and dermatoses were presented as frequencies and percentages.

## DISCUSSION

This retrospective study was done to show the prevalence of different pediatric dermatoses and pattern of its occurrence in different pediatric age groups. The results of this study are in accordance with some previous studies. The variation in the incidence of certain skin diseases among studies may depend on the method of classification or may be due to differences between populations regarding genetic, socioeconomic, or environmental factors.

A female-to-male sex ratio of 1.1:1 was found in our study. This corresponds with the findings of some similar studies. The majority of the pediatric patients with common dermatoses consulted are school-age children and adolescents (31.9% and 31.5% respectively), while newborns, infants and toddler account for 3.6%, 12%, 21% respectively. The reason behind this is may be the environmental exposure that they get in compared with the younger age groups.

There was a variation in the prevalence of dermatosis among the age groups in our study. The Dermatitis/Eczemas group was the most common dermatoses in all age groups, found in 27.5% of the study population. Atopic Dermatitis (9.6%) was the most common diagnosis among the dermatitis group but came in as the 3<sup>rd</sup> most common reason for consult overall. This was more frequent in infants, toddlers, school-aged children and adolescents. It is a major public health

problem worldwide. Other common eczemas in the pediatric age group. Seborrheic Dermatitis (4.8%) and Infantile seborrheic dermatitis (1.6%) which were seen predominantly in the neonatal/ infantile stage and adolescent age. The difference in the incidence of various dermatitis suggest that it may be due to atopy, different environmental allergens, genetic factors and climate. Irritant contact dermatitis (3.6%) was also represented in the study, this may be due to the rampant use of herbal concoctions and self-medications by the parents and/ or guardians. This was also represented in our study.

The Parasitic infestation group were the second leading dermatoses seen between the 4-year timeline, with a total of 21.6% of the study population with Scabies Infestation (15.2%) as the most common diagnosis overall. It was the most common skin disease in children and one of the leading reasons for consults for both Male and Females. This was also more frequent in infants, toddlers and school-aged children, increasing gradually with increasing age. Other common parasitic infestations were Pediculosis capitis (3.4%) which came in 6<sup>th</sup> of the most common pediatric dermatosis with a total of 3.4% of the study population and Arthropod bite reaction constituting a total of 2.8%. Poor sanitation, sharing of clothes, towel, overcrowding in households and low socioeconomic status may be an important factor for the increased prevalence of parasitic infestations in pediatric dermatoses.

In our study, Infectious group were the third most commonly encountered pediatric skin condition. Out of total Infectious (bacterial, viral and fungal) (182, 36.4%), 18% patient had bacterial infections. This was more frequent in toddlers (30.5%) and school-aged children (16.9%). The most common presentations were Bullous Impetigo (4.8%), Impetigo contagiosa (3.4%), and Ecthyma (3.2%) of the bacterial infections group. Impetigo is commonly a pediatric dermatosis who reside in hot humid climates. It is caused almost exclusively by *Staphylococcus aureus*. Poor hygiene along with poor sanitation may be the cause of increased prevalence of bacterial infections in developing countries. After bacterial infections, Fungal infections (11.2%) followed, and the most common presentation was Tinea Versicolor (3.6%) followed by Tinea Corporis (3%). The reason behind may be the hot and humid temperature in the Philippines. The finding is similar to many studies where Infectious and Parasitic infestations are common in tropical regions of many Asian and African countries. Viral infections constituted about 7.2% of the total infections. This was more frequently seen in school-aged children, and not surprisingly, the most common viral dermatoses presented were Mollusum

contagiosum (2.4%) followed by Verruca Vulgaris (1.6%) and Hand, foot, and mouth disease (HFMD) (1%). Molluscum contagiosum was more prevalent in school-aged children, whereas the peak age for warts is in the adolescent age. An outbreak of HFMD was observed during the year 2022, with infants and toddlers were frequently affected.

Acne was the most common dermatosis among the adolescent age group and the 2<sup>nd</sup> most common reason for consult. It was seen more in females (11.1%) vs males (10.1%). Acne is a noticeable dermatosis when appearance is important and embarrassment in appearance is distressing to the adolescents affected and may be the reason for consult. It may contribute to lower self-esteem, feelings of unattractiveness and worthlessness in this age group. This shows variation of the common dermatoses within the pediatric population.

Pigmentary/ Melanocytic disorders account for 2% of the cases. The incidence rate of this diagnostic group, which included post-inflammatory hyper- or hypopigmentation, Mongolian spots and pityriasis alba, may be ascribed to significant stress to the parents and shame to the affected based on the appearance of the lesions as a reason for consult at the outpatient department.

Miliaria, "heat rash," "prickly heat," or a "sweat rash," is a frequently seen skin disease triggered by blocked eccrine sweat glands and ducts. The most common dermatoses presented in the eccrine group were Miliaria Rubra (2% of the study population), followed by miliaria crystallina (0.4%) and miliaria pustulosa (0.4%), with neonates and toddlers frequently affected. It is most common in warm, humid climates during the summer months.

In this study, the incidence of the hair and nail disorders (1.8%) to be considerably lower with Alopecia areata (0.8%) being the most common dermatosis in the hair and nails group. It was more prevalent in school-aged children.

There is a high incidence of Urticaria (2.2%) in our study was surprising with 11 cases noted. Papulosquamous disorders were seen in fewer patients (2.8%) with Pityriasis rosea (1.2%) being the most commonly seen in this category, followed by Psoriasis (0.4%) and Lichen striatus (0.4%). Genodermatoses or disorders of cornification were very rare in the study population (0.4%) and a case of Harlequin ichthyosis (0.2%) was seen in this institution. In Autoimmune disorders, Systemic Lupus Erythematosus were seen in 1.6% of the study population. It was more prevalent in adolescent age group.

## CONCLUSION

In conclusion, there was wide variation in the most common dermatosis according to age, gender, and the year of consults. The majority of the pediatric patients with common dermatoses consulted are school-age children and adolescents followed by newborns, infants and toddler respectively. Scabies infestation was the most common dermatosis in children, for both Males and Females, and the leading reason for consults. Poor sanitation, sharing of clothes, towel, overcrowding in households and low socioeconomic status may be an important factor for the increased prevalence of parasitic infestations in pediatric dermatoses. Acne was the most common dermatosis among the adolescent age group and the 2<sup>nd</sup> most common reason for consult. Atopic Dermatitis was the most common diagnosis among the dermatitis group but came in as the 3<sup>rd</sup> most common reason for consult overall. The findings are similar to studies in the common dermatoses seen in the pediatric population in tropical regions of many Asian and African countries. This study serves as preliminary epidemiologic report on pediatric dermatoses in Region 1 Medical Center and may pave the way for well-controlled and better designed researches in the future.

## DISCLOSURE

There are no conflicts of interest with respect to the research, authorship, and/or publication of this research.

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## Figures and Tables

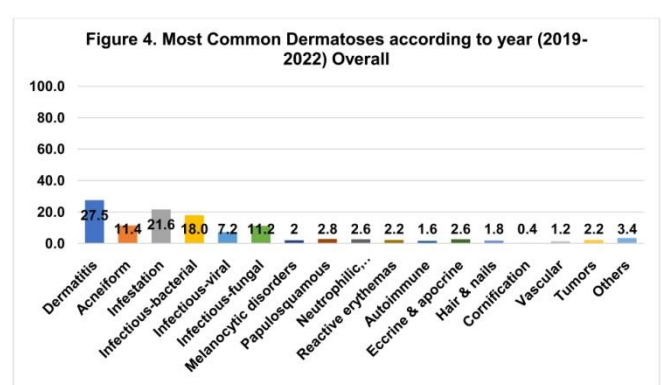
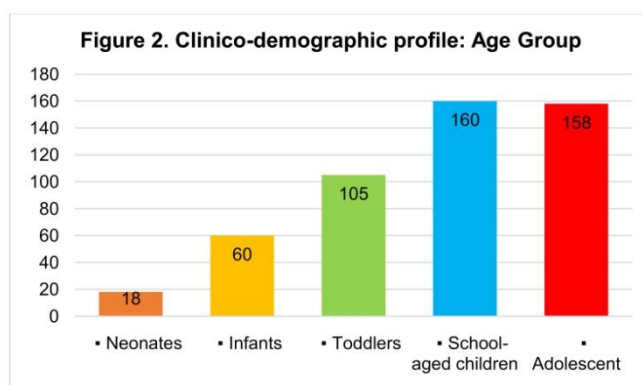
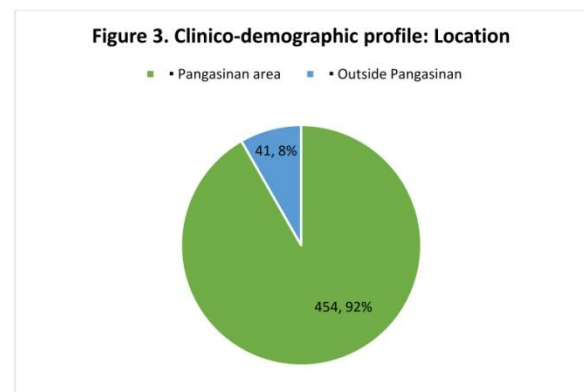
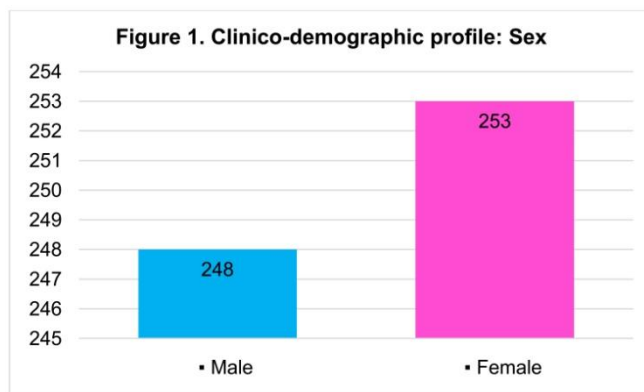


Figure 5. Most common dermatoses according to sex

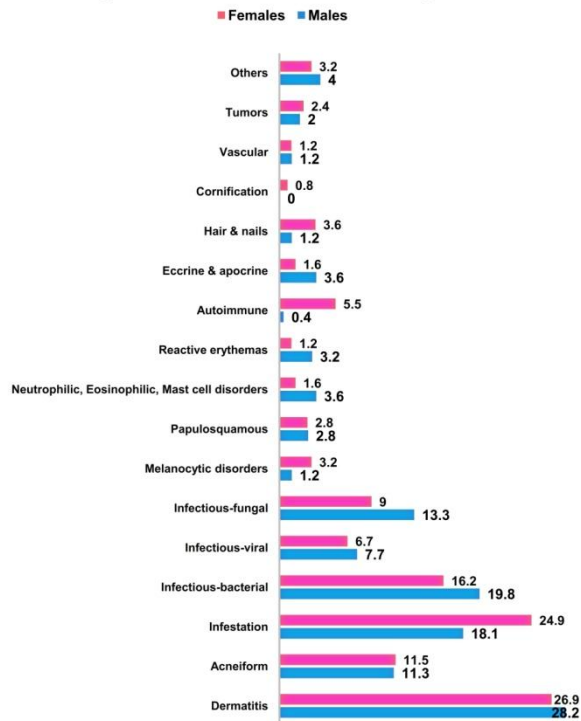


Figure 5.1. Top 10 Most Common Diagnosis in Males (%)

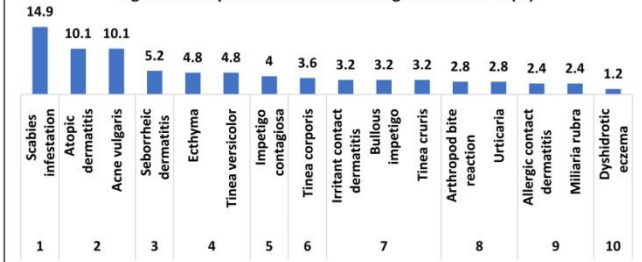


Figure 5.2. Top 10 Most Common Diagnosis in Females (%)

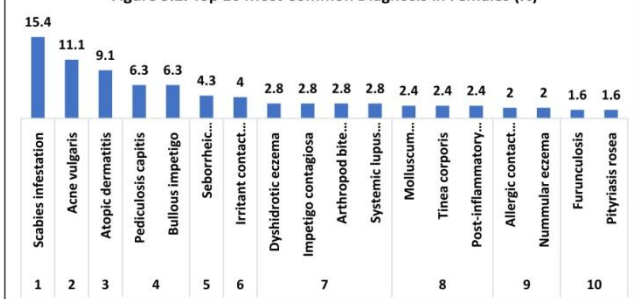


Figure 6. Most common dermatoses according to age group (Neonates)

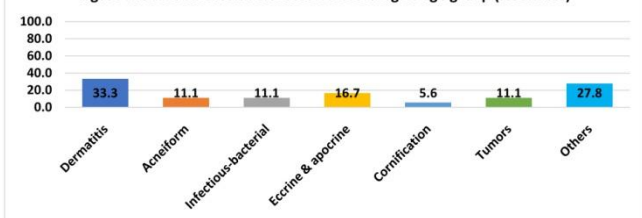


Figure 7. Most common dermatoses according to age group (Adolescent)

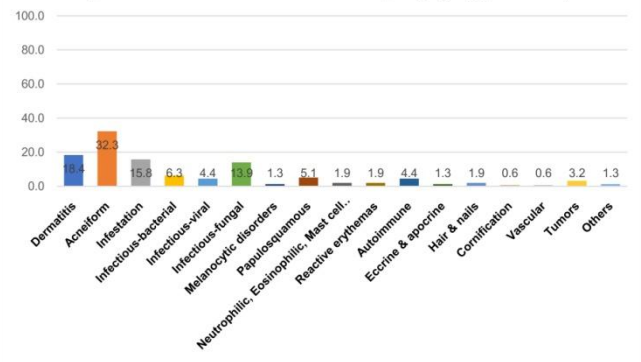


Table 1. Ten Most Common Dermatoses in 2019

|   | Diagnosis                       | n  | %    |
|---|---------------------------------|----|------|
| 1 | Scabies infestation             | 21 | 17.1 |
| 2 | Atopic dermatitis               | 10 | 8.1  |
| 3 | Bullous impetigo                | 8  | 6.5  |
| 4 | Impetigo contagiosa             | 7  | 5.7  |
| 5 | Infantile seborrheic dermatitis | 6  | 4.9  |
|   | Urticaria                       | 6  | 4.9  |
| 6 | Seborrheic dermatitis           | 5  | 4.1  |
|   | Tinea corporis                  | 5  | 4.1  |
| 7 | Allergic contact dermatitis     | 4  | 3.3  |
|   | Acne vulgaris                   | 4  | 3.3  |
|   | Molluscum contagiosum           | 4  | 3.3  |
|   | Tinea versicolor                | 4  | 3.3  |

Table 2. Ten Most Common Dermatoses in 2020

|   | Diagnosis                   | n  | %    |
|---|-----------------------------|----|------|
| 1 | Scabies infestation         | 19 | 15.6 |
| 2 | Atopic dermatitis           | 18 | 14.8 |
| 3 | Pediculosis capitis         | 9  | 7.4  |
| 4 | Bullous impetigo            | 8  | 6.6  |
| 5 | Seborrheic dermatitis       | 7  | 5.7  |
|   | Tinea versicolor            | 7  | 5.7  |
| 6 | Irritant contact dermatitis | 5  | 4.1  |
|   | Acne vulgaris               | 5  | 4.1  |
|   | Impetigo contagiosa         | 5  | 4.1  |
| 7 | Ecthyma                     | 4  | 3.3  |

Table 3. Ten Most Common Dermatoses in 2021

|   | Diagnosis                           | n  | %    |
|---|-------------------------------------|----|------|
| 1 | Scabies infestation                 | 21 | 16.8 |
| 2 | Acne vulgaris                       | 20 | 16   |
| 3 | Atopic dermatitis                   | 12 | 9.6  |
| 4 | Seborrheic dermatitis               | 9  | 7.2  |
| 5 | Ecthyma                             | 7  | 5.6  |
| 6 | Tinea corporis                      | 5  | 4    |
|   | Tinea cruris                        | 5  | 4    |
| 7 | Irritant contact dermatitis         | 4  | 3.2  |
|   | Hansen's disease                    | 4  | 3.2  |
| 8 | Allergic contact dermatitis         | 3  | 2.4  |
|   | Molluscum contagiosum               | 3  | 2.4  |
|   | Tinea versicolor                    | 3  | 2.4  |
|   | Post-inflammatory hyperpigmentation | 3  | 2.4  |

**Table 4. Ten Most Common Dermatoses in 2022**

|   | Diagnosis                   | n  | %    |
|---|-----------------------------|----|------|
| 1 | Acne vulgaris               | 24 | 18.3 |
| 2 | Scabies infestation         | 15 | 11.5 |
| 3 | Atopic dermatitis           | 8  | 6.1  |
| 4 | Bullous impetigo            | 7  | 5.3  |
| 5 | Irritant contact dermatitis | 6  | 4.6  |
|   | Arthropod bite reaction     | 6  | 4.6  |
|   | Dyshidrotic eczema          | 4  | 3.1  |
| 6 | Ecthyma                     | 4  | 3.1  |
|   | Hand foot mouth disease     | 4  | 3.1  |
|   | Tinea versicolor            | 4  | 3.1  |

**Table 5. Top 10 Most Common Dermatoses according to year (2019- 2022) Overall**

|    | Diagnosis                   | n  | %    |
|----|-----------------------------|----|------|
| 1  | Scabies infestation         | 76 | 15.2 |
| 2  | Acne vulgaris               | 53 | 10.6 |
| 3  | Atopic dermatitis           | 48 | 9.6  |
| 4  | Seborrheic dermatitis       | 24 | 4.8  |
|    | Bullous impetigo            | 24 | 4.8  |
| 5  | Irritant contact dermatitis | 18 | 3.6  |
|    | Tinea versicolor            | 18 | 3.6  |
| 6  | Pediculosis capitis         | 17 | 3.4  |
|    | Impetigo contagiosa         | 17 | 3.4  |
| 7  | Ecthyma                     | 16 | 3.2  |
| 8  | Tinea corporis              | 15 | 3    |
| 9  | Arthropod bite reaction     | 14 | 2.8  |
| 10 | Molluscum contagiosum       | 12 | 2.4  |

**Table 5.1. Top 10 Most Common Diagnosis in Males**

|    | Diagnosis                   | n  | %    |
|----|-----------------------------|----|------|
| 1  | Scabies infestation         | 37 | 14.9 |
|    | Atopic dermatitis           | 25 | 10.1 |
| 2  | Acne vulgaris               | 25 | 10.1 |
| 3  | Seborrheic dermatitis       | 13 | 5.2  |
|    | Ecthyma                     | 12 | 4.8  |
| 4  | Tinea versicolor            | 12 | 4.8  |
| 5  | Impetigo contagiosa         | 10 | 4    |
| 6  | Tinea corporis              | 9  | 3.6  |
|    | Irritant contact dermatitis | 8  | 3.2  |
|    | Bullous impetigo            | 8  | 3.2  |
| 7  | Tinea cruris                | 8  | 3.2  |
|    | Arthropod bite reaction     | 7  | 2.8  |
| 8  | Urticaria                   | 7  | 2.8  |
|    | Allergic contact dermatitis | 6  | 2.4  |
| 9  | Miliaria rubra              | 6  | 2.4  |
| 10 | Dyshidrotic eczema          | 3  | 1.2  |

**Table 5.2. Top 10 Most Common Diagnosis in Females**

|    | Diagnosis                           | n  | %    |
|----|-------------------------------------|----|------|
| 1  | Scabies infestation                 | 39 | 15.4 |
| 2  | Acne vulgaris                       | 28 | 11.1 |
| 3  | Atopic dermatitis                   | 23 | 9.1  |
|    | Pediculosis capitis                 | 16 | 6.3  |
| 4  | Bullous impetigo                    | 16 | 6.3  |
| 5  | Seborrheic dermatitis               | 11 | 4.3  |
| 6  | Irritant contact dermatitis         | 10 | 4    |
|    | Dyshidrotic eczema                  | 7  | 2.8  |
|    | Impetigo contagiosa                 | 7  | 2.8  |
|    | Arthropod bite reaction             | 7  | 2.8  |
| 7  | Systemic lupus erythematosus        | 7  | 2.8  |
|    | Molluscum contagiosum               | 6  | 2.4  |
|    | Tinea corporis                      | 6  | 2.4  |
| 8  | Post-inflammatory hyperpigmentation | 6  | 2.4  |
|    | Allergic contact dermatitis         | 5  | 2    |
| 9  | Nummular eczema                     | 5  | 2    |
|    | Furunculosis                        | 4  | 1.6  |
| 10 | Pityriasis rosea                    | 4  | 1.6  |

**Table 6. Most common dermatoses in Neonates**

|   | Diagnosis                       | n | %    |
|---|---------------------------------|---|------|
| 1 | Infantile seborrheic dermatitis | 3 | 16.7 |
| 2 | Miliaria rubra                  | 2 | 11.1 |

**Table 7. Most common dermatoses in Infants**

|   | Diagnosis                            | n  | %    |
|---|--------------------------------------|----|------|
| 1 | Scabies infestation                  | 15 | 25   |
| 2 | Atopic dermatitis                    | 7  | 11.7 |
|   | Seborrheic dermatitis                | 7  | 11.7 |
| 3 | Staphylococcal scalded skin syndrome | 6  | 10   |
|   | Infantile seborrheic dermatitis      | 6  | 10   |
| 4 | Bullous impetigo                     | 5  | 8.3  |

**Table 8. Most common dermatoses in Toddlers**

|   | Diagnosis               | n  | %    |
|---|-------------------------|----|------|
| 1 | Scabies infestation     | 16 | 15.2 |
| 2 | Atopic dermatitis       | 14 | 13.3 |
| 3 | Bullous impetigo        | 9  | 8.6  |
| 4 | Impetigo contagiosa     | 8  | 7.6  |
| 5 | Ecthyma                 | 7  | 6.7  |
|   | Arthropod bite reaction | 7  | 6.7  |
| 6 | Miliaria rubra          | 5  | 4.8  |

**Table 9. Most common dermatoses in School-aged children**

|   | Diagnosis                   | n  | %    |
|---|-----------------------------|----|------|
| 1 | Scabies infestation         | 26 | 16.3 |
| 2 | Atopic dermatitis           | 21 | 13.1 |
| 3 | Pediculosis capitis         | 12 | 7.5  |
| 4 | Bullous impetigo            | 9  | 5.6  |
|   | Impetigo contagiosa         | 9  | 5.6  |
|   | Dyshidrotic eczema          | 8  | 5    |
| 5 | Irritant contact dermatitis | 8  | 5    |
|   | Molluscum contagiosum       | 8  | 5    |
|   | Tinea versicolor            | 8  | 5    |
| 6 | Tinea corporis              | 6  | 3.8  |
|   | Nummular eczema             | 4  | 2.5  |
| 7 | Arthropod bite reaction     | 4  | 2.5  |
|   | Ecthyma                     | 4  | 2.5  |
|   | Hansen's disease            | 4  | 2.5  |

**Table 10. Most common dermatoses in Adolescents**

|   | Diagnosis                    | n  | %    |
|---|------------------------------|----|------|
| 1 | Acne vulgaris                | 50 | 31.6 |
| 2 | Scabies infestation          | 19 | 12   |
| 3 | Seborrheic dermatitis        | 10 | 6.3  |
|   | Tinea cruris                 | 7  | 4.4  |
| 4 | Tinea versicolor             | 7  | 4.4  |
|   | Systemic lupus erythematosus | 7  | 4.4  |
| 5 | Atopic dermatitis            | 6  | 3.8  |
|   | Tinea corporis               | 6  | 3.8  |
| 6 | Prurigo nodularis            | 5  | 3.2  |
|   | Verruca vulgaris             | 5  | 3.2  |

# **A Quasi-Experimental Study on the Effectiveness of Health Education on the Knowledge, Attitude and Practices about Scabies among Barangay Health Workers in Dagupan City\***

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## **ABSTRACT**

**Background:** Scabies, recognized as one of the neglected tropical diseases (NTDs) by the WHO continues to persist in our locality today. Health education emerges as an indispensable tool, aimed at enhancing the knowledge, attitudes, and practices (KAP) of Barangay Health Workers (BHWs). As the primary frontliners in our community, they encounter a wide array of skin conditions, but often lack the resources to manage them effectively.

**Objectives:** The primary objective of this study is to assess the impact of health education on the KAP of BHWs concerning Scabies infestation.

**Methods:** A quasi-experimental, one-group pre-test-post-test design assessed the effectiveness of a 30-minute face-to-face lecture on BHWs' KAP regarding Scabies infestation in the community. The study was conducted on April 25, 2023 at the Dagupan City Health office utilizing random population sampling.

**Results:** The study included 45 BHW participants, 71.11% of whom had prior Scabies knowledge mainly from seminars/training (42.22%). Initially, most had poor baseline knowledge. Less than half (46.67%) identified skin manifestations and treatment accurately. Most displayed positive attitudes toward environmental management (91.11%) and fomite infection control (77.78%). After the lecture, the participants' total scores increased.

**Conclusion:** BHWs bridge the gap between healthcare and underserved populations. Equipping them with knowledge of diseases such as Scabies is imperative. This underscores the effectiveness of health education in enhancing their KAP towards Scabies. By empowering them, we can reduce the impact of NTDs in vulnerable communities. These findings have potential implications for future training programs, awareness campaigns, and further studies involving healthcare workers.

**Keywords:** Scabies, Barangay Health Workers, Health Education

## **INTRODUCTION**

Scabies, one of the most important neglected tropical disease (NTDs)<sup>1</sup>, is a skin infestation in humans caused by the mite *Sarcoptes scabiei* var. *hominis*. It is transmitted through close physical contact or indirectly via items such as clothing, bedding, or fomites.<sup>2</sup> Scabies leads to a diffuse skin eruption characterized by papules, nodules, and vesicles, commonly affecting interdigital webs, fingers' sides, wrists' volar aspects, and lateral palms. It is accompanied by intense pruritus, often worsening at night. Vulnerable populations, such as immunocompromised individuals, children, and the elderly, are at higher risk. Scabies imposes a substantial health burden, especially in disadvantaged communities with low socioeconomic status, characterized by overcrowded living conditions, inadequate environmental management, and suboptimal personal hygiene.<sup>3</sup> Recent estimates suggest that there are 100-200 million cases of

scabies worldwide with 455 million annual incident cases.<sup>4</sup> Scabies is endemic in numerous developing countries, primarily found in hot and humid regions, including Southeast Asia. Among children, the estimated average prevalence ranges from 5% to 10%. However, recent literature on Scabies reports a wide range of prevalence estimates, spanning from 0.2% to 71%.<sup>5</sup> In the Philippines, Scabies infestation ranked as the second leading cause of disability among skin diseases in 2019. Surprisingly, despite its significance, there has been no comprehensive nationwide study documenting the epidemiological characteristics of Scabies in the country.<sup>6</sup> To bridge this gap, a study conducted at the University of the Philippines Manila sought to delineate the demographic, seasonal, and geographic profiles of Scabies in the Philippines. This was achieved by comparing secondary data from two local patient registries: the Philippine Dermatological Society (PDS) registry spanning from 2010 to 2021, and

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*Disclosures:* The author has formally acknowledged and signed a disclosure affirming the absence of any financial or other relationships (including personal connections), intellectual biases, political or religious affiliations, and institutional ties that could potentially result in a conflict of interest.

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the Philippine Pediatric Society (PPD) registry from 2009 to 2021, both of which reported cases of Scabies across the country. In the local setting particularly in our institution, among the various dermatological cases encountered in the Out-Patient Department (OPD), Scabies infestation consistently ranks among the top 10. In both 2018 and 2019, new Scabies cases were identified at a 0.04% incident rate, highlighting the persistence of this condition in our patient population.

Definitive strategies for the control of scabies, including management in endemic settings and outbreak response plans, are under development. Health education is a valuable fundamental tool to strengthen the primary level for efficient health promotion and health provision catering to those who are poor, disadvantaged, and living in far-flung areas. Some considerations included in this framework is to engage communities to promote inclusivity, sustainability, and ownership; as well as to develop and to implement packages to train and upskill the health system staff and program managers regarding Scabies control issues.<sup>4</sup> Thus, this particular study was conducted as a training ground for Barangay Health Workers in a locality in Pangasinan in an effort to control Scabies in the primary level as to prevent complications usually seen in the tertiary level.

Barangay Health Workers (BHWs) are the primary level health care workers present in the community who “serve the underserved”, those in mostly rural areas of our country. It is a stated fact that on a daily basis they are faced with a variety of skin conditions however, are unable to manage on their own. A study by Alsaidan et al. stated that the knowledge about scabies among primary care physicians was generally inadequate tapping the need for educational and training programs by health care authorities.<sup>8</sup> Hence, a primary goal exists for the primary level health care workers (HCWs) in this study in particular, Barangay Health Workers starting in our locality to be health educated through regular workshops and training courses. BHWs provide healthcare services that meet the health needs of their constituents in their barangay. Core skills, applied knowledge and a good attitude are vital for these BHWs to complete their jobs effectively and efficiently.<sup>9</sup> A study by Taburnal et al. done in Camarines Sur revealed that BHWs are moderately competent, with a satisfactory rating on attitude with personal and environmental factors having an impact on their competence.<sup>9</sup> To be well- equipped with knowledge and

skills, BHWs are encouraged to continuously attend training and seminars. Aligned with this, identifying the Knowledge, Attitudes and Practices of primary HCWs such as BHWs will further evaluate and address misconceptions, knowledge gaps, and determinants of stigma common in the community. Health education in the form of capacity building for Barangay Health Workers has been proven to be an essential element in health promotion and disease prevention therefore, providing an important role in the reduction of Scabies cases in the community.

### Conceptual Framework

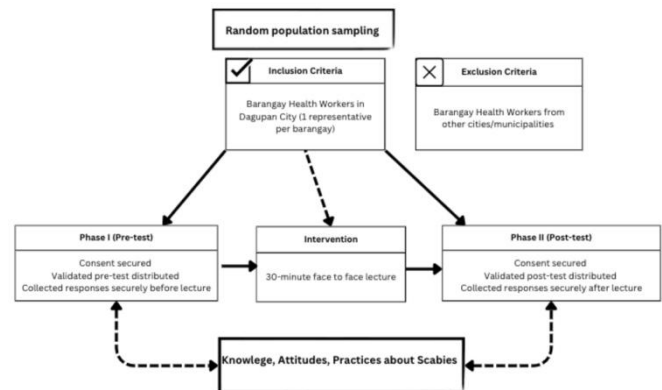


Figure 1. Conceptual Framework on Knowledge, Attitudes, Practices about Scabies

### OBJECTIVES

#### General Objectives

The main objective of this study is to determine the effectiveness of health education on knowledge, attitudes, and practices (KAP) of Barangay Health Workers (BHWs) about Scabies infestation in the community to provide a basis for the foundation for future training initiatives and awareness campaigns.

#### Specific Objectives

- To assess the professional profile of Barangay Health Workers (BHWs) in the community:
  - No. of years in practice or service
  - Basic knowledge of Scabies and resources
  - Educational attainment
- To assess the level of knowledge of BHWs on Scabies with a modified validated questionnaire regarding:
  - Causative Organism
  - Mode of transmission

- c. Incubation period
  - d. Clinical manifestations and sites of predilection
  - e. Susceptible persons
  - f. Common complications
  - g. Diagnostics and Management
3. To assess the attitudes of BHWs on Scabies with a modified validated questionnaire including:
  - a. Personal hygiene
  - b. Environmental management
  - c. Fomite treatment
  - d. Prompt treatment of patient and family members
  - e. Avoidance of skin-to-skin contact
4. To assess the practices of BHWs on Scabies with a modified validated questionnaire including:
  - a. Personal hygiene
  - b. Environmental management
  - c. Fomite treatment
  - d. Prompt treatment of patient and family members
  - e. Avoidance of skin-to-skin contact
5. To compare the level of knowledge, attitude, and practices of BHWs before and after health education conducted by a 30-minute face-to-face lecture on Scabies infestation.

The purpose of this study aimed to improve awareness and level of knowledge of BHWs related to Scabies infestation in the community by utilizing pre-test and post-test designs, implementing a health education/face-to-face lecture intervention as a future basis for training programs/workshops, awareness campaigns, and further studies.

### **Research Hypothesis**

The Knowledge, Attitudes and Practices (KAP) of Barangay Health Workers (BHWs) in Dagupan City regarding scabies are determined to identify knowledge gaps, awareness, preferences, fears, and behavioral patterns.

### **Significance of the Study**

The significance and primary endpoint of this study is to improve the Knowledge, Attitudes, and Practices (KAP) of Barangay Health Workers (BHWs)

regarding Scabies infestation through targeted health education. This endeavor serves as a crucial cornerstone, offering a basis for future training initiatives, awareness campaigns, and further research endeavors. This is for the purpose of minimizing non-detection, misdiagnosis, and inappropriate management of Scabies cases seen at the primary health care level as well as complicated cases seen at the tertiary level. Health education is pivotal in maintaining good health and should be employed in the community primarily as a key for absolute behavioral change communication strategy in especially resource-scarce areas of the community where it is primarily endemic.

### **Scope and Delimitation**

This study assessed the Knowledge, Attitudes, and Practices (KAP) of Barangay Health Workers regarding scabies. This was conducted at the Dagupan City Health Office, located in A.B. Fernandez Avenue, Dagupan City, Pangasinan. Barangay Health Workers from other cities/municipalities were excluded in this study.

## **METHODOLOGY**

### **Research Design**

A quasi experimental one group pre-test post-test design was done which determined the effectiveness of health education through a 30-minute face-to-face lecture on the knowledge, attitudes, and practices of BHWs towards Scabies infestation in the community.<sup>10</sup>

### **Research Setting**

A Dermatology trainee of a PDS-accredited institution conducted a 30-minute face-to-face lecture on Scabies infestation in coordination with Dagupan City Health Office (CHO) under the Philippines Department of Health (DOH) after approval of the hospital's research institutional review board (IRB). A modified validated questionnaire was administered both before and after the lecture addressing the participant's knowledge, attitudes, and practices related to Scabies.<sup>11</sup> The acquired test scores were systematically compiled into tables, facilitating subsequent comparison and analysis. The lecture was designed with a target duration of 2 hours to ensure comprehensive coverage of the subject matter.

### **Research Population and Sample size**

Barangay Health Workers of Dagupan City, Pangasinan (1-2 representatives of each barangay; total of 31 barangays) were invited to participate in the study in coordination with the Dagupan City Health Office. The

following formula was utilized to determine the required sample size:

$$n = \frac{m}{1 + \frac{m-1}{N}}$$

n= sample size

N= population size

E= acceptable sampling error

\*95% confidence level and p=0.5 are assumed

A minimum of 45 participants were required and included in this study to achieve a power of 95% and a level of significance of 5%, to detect an effect size of 0.5%.

### Eligibility Criteria

Barangay Health Workers of Dagupan City regardless of years of service, gender, and age are eligible to join the study.

### Sampling Methods

Participants are selected based on random population sampling. A subset population of only 1-2 representatives of each Barangay in Dagupan City (31 barangays) are randomly selected. Barangay Health Workers who were invited and consented to join the study will be enrolled. Participants who refused to sign the informed consent and sought to withdraw at any moment were both regarded to have withdrawn from the study participation.

### Data Collection

After informed consent was obtained, participants were asked to provide their demographic and professional information. Subsequently, a 14-item pre-test was administered, encompassing questions pertaining to knowledge, attitudes, and practices related to Scabies. Each question was scored as 1 for a correct answer and 0 for an incorrect answer. To assess knowledge, the correct responses were summed up to obtain a total knowledge score for each participant. Score stratification are as follows: ≤50%, 65- 50%, and ≥65% correct answers were considered indicators of poor, fair, and good knowledge of Scabies, respectively.<sup>10</sup> For attitude assessment, a 5-point Likert scale was utilized, ranging from 'Strongly agree' (5) to 'Strongly Disagree' (1). Participants' attitude scores were calculated, with a total possible score of 35. Attitudes were categorized as good (≥65%), fair (65-50%), or poor (≤50%).<sup>10</sup> Similarly, for practice assessment, a 5-point Likert scale with the same range was employed. The

total possible practice score was 25. Practice levels were categorized as good (≥65%), fair (65-50%), or poor (≤50%).<sup>10</sup> In cases where questions had multiple correct answers, respondents received a point only if they identified all the correct answers. This allowed for a comprehensive evaluation of their understanding.

After the pre-test, a 30-minute face-to-face lecture encompassing key aspects of scabies including a brief background, causative agent, mode of transmission, clinical features, sites of predilection, risk factors, complications, diagnosis, prevention, and management. The instructional approach employed an interactive lecture format complemented by clinical slide presentations. Following the lecture, a post-test was administered, mirroring the pre-test, and the resulting scores were methodically compiled and presented in tabular format for analysis.

All data files and questionnaires obtained will be securely stored within locked file cabinets at our institution. These records will be retained for a minimum of three years following the conclusion of this study. Subsequently, the collected data will be appropriately disposed of through shredding or tearing of paper documents to ensure the continued privacy and confidentiality of the information.

### Statistical Analysis Plan

Descriptive statistics will be used to summarize the demographic and professional profile as well as assessment of knowledge, attitudes and practices of participants towards Scabies infestation. Categorical variables will be presented as frequencies and percentages, while continuous variables will be expressed as means and standard deviations (or medians and interquartile ranges). The Shapiro-Wilk test for normality was conducted revealing significant results which suggests that the data deviated from normality (aka it does not follow the typical bell-curve shape). Deviation suggests that parametric tests (such as t-tests) are not ideal for data analysis. Due to deviation from normality, Wilcoxon signed-rank test (non-parametric) was conducted. A p-value less than 0.05 will be considered significant. Data was analyzed using JASP 0.17.2.1 statistical program.

### RESEARCH ETHICS

The study underwent review and approval by the hospital's Institutional Review Board with Protocol No. 2022-055. Each participant completed a written informed consent form, ensuring their anonymity and privacy were carefully safeguarded. A unique code was assigned to

every participant, facilitating the tracking of pre- and post-test results while maintaining confidentiality.

Participants did not receive gifts or financial assistance for their involvement in the study. Their participation was entirely voluntary, and they were free to decide whether to take part or not. Moreover, participants had the option to withdraw from the research at any time and for any reason, without any obligation to continue.

There are no conflicts of interest to disclose, and the author did not receive any financial grants or research funding for this study.

## RESULTS/ DATA ANALYSIS

### Demographic and Professional Profile

A total of 45 participants, all of whom were Barangay Health Workers (BHWs) randomly selected from each Barangay in Dagupan City, willingly provided informed consent. They completed both the pre-test and post-test studies following the face-to-face Scabies lecture. Among these participants, 44 were female. Twenty of the participants were High School graduates (44.44%), 17 were college graduates (37.78%), 21 of which (46.67%) had >10 years of health care service. A significant portion of the BHWs (71.11%) had prior knowledge of Scabies, primarily acquired through seminars and training sessions (42.22%), with online courses also contributing to knowledge acquisition (20%). Table 1 shows the demographic and professional profile of the participants.

Table 1. Demographic and Professional Profile of Barangay Health Workers in Dagupan City

| Respondent characteristics                  | Number (n)    | Percentage (%) |
|---------------------------------------------|---------------|----------------|
| <b>Age (Mean <math>\pm</math> SD)</b>       | 51.96 (10.23) |                |
| <b>Sex</b>                                  |               |                |
| Male                                        | 1             | 97.78          |
| Female                                      | 44            | 2.22           |
| <b>Length of Practice</b>                   |               |                |
| 0-2 years                                   | 1             | 2.22           |
| 2-5 years                                   | 8             | 17.78          |
| 5-10 years                                  | 15            | 33.33          |
| > 10 years                                  | 21            | 46.67          |
| <b>Prior Knowledge on Scabies</b>           |               |                |
| Yes                                         | 32            | 71.11          |
| No                                          | 13            | 28.89          |
| <b>Source of basic knowledge on Scabies</b> |               |                |
| Books                                       | 3             | 6.67           |
| Journals                                    | 1             | 2.22           |
| Seminars/ Training                          | 19            | 42.22          |
| Online course                               | 9             | 20.00          |

| Level of Education |    |       |
|--------------------|----|-------|
| Elementary         | 1  | 2.22  |
| High School        | 20 | 44.44 |
| College            | 17 | 37.78 |
| Vocational         | 7  | 15.56 |

### Knowledge on Scabies

In the pre-test (Table 2.A), most participants exhibited a poor level of knowledge regarding Scabies. Only a small fraction (4.44%) correctly identified the causative agent, Mite, also known as "Tungaw," while a majority (60.00%) recognized the correct culprit as *Sarcoptes scabiei* var. *hominis*. When it came to identifying the vulnerable groups affected by Scabies, a substantial number (86.67%) provided accurate responses. However, none of the participants correctly answered the incubation period at 4-6 weeks.

Approximately 55.56% were knowledgeable about Scabies transmission through physical (skin-to-skin) contact. Less than half (46.67%) were aware of the various skin manifestations of Scabies, which include erythematous patches, papules, plaques, crusted nodules in interdigital areas, axilla, genital and inguinal areas, umbilicus, and buttocks, along with nocturnal pruritus. Regarding transmission through infected fomites, the majority (93.33%) gave the correct response. However, none of the participants accurately identified the pathognomonic lesion, Burrow. A modest number (17.78%) were informed about known complications of Scabies, such as skin infections, sepsis, rheumatic heart disease, and acute glomerulonephritis. More than half (57.78%) correctly answered questions related to diagnostic tests, while 80.00% were accurate in specifying the treatment regimen for the disease. Only a few participants (8.89%) correctly identified the first-line treatment, while a smaller percentage (6.67%) correctly recognized the safe treatment regimen for pregnant women and children. Likewise, only a fraction (4.44%) accurately specified the duration and frequency of treatment.

After the face-to-face lecture, there was an increase in the total scores of the participants, most notable on these variables: cause of Scabies (91.11%), causative organism (73.33%), incubation period (64.44%), mode of transmission (97.78%), fomite infection (97.78%), diagnostic tests (93.33%), treatment regimen (97.78%), first line medications (88.89%), treatment for pregnant women and children (75.56%), and duration and frequency of treatment (51.11%).

Table II. A Comparison of Pre-Test and Post-Test Knowledge of Barangay Health Workers on Scabies

| Knowledge                                                 | Percentage of Correct Responses |           |
|-----------------------------------------------------------|---------------------------------|-----------|
|                                                           | Pre-Test                        | Post-Test |
| 1. Cause of Scabies                                       | 4.44                            | 91.11     |
| 2. Causative Organism                                     | 60.00                           | 73.33     |
| 3. Groups affected                                        | 86.67                           | 82.22     |
| 4. Incubation period                                      | 0.00                            | 64.44     |
| 5. Mode of Transmission                                   | 55.56                           | 97.78     |
| 6. Clinical Symptoms                                      | 46.67                           | 33.33     |
| 7. May be infected through clothes, towels, and bedsheets | 93.33                           | 97.78     |
| 8. Pathognomonic Lesion                                   | 0.00                            | 11.11     |
| 9. Complications                                          | 17.78                           | 22.22     |
| 10. Diagnostic tests for Scabies                          | 57.78                           | 93.33     |
| 11. Treatment Regimen for Scabies                         | 80.00                           | 97.78     |
| 12. First line medications for Scabies                    | 8.89                            | 88.89     |
| 13. Treatment for pregnant women and children             | 6.67                            | 75.56     |
| 14. Duration and frequency of treatment                   | 4.44                            | 51.11     |

### Attitude on Scabies

In the pre-test (Table 3), participants displayed predominantly positive attitudes toward various aspects, including environmental management (91.11%), fomite infection control through weekly washing and drying of mattress and pillow (77.78%), and avoiding sharing towels, clothing, and bedding (66.67%). Furthermore, positive attitudes were observed regarding prompt Scabies treatment (86.67%) and personal hygiene (73.33%). However, there was a relatively lower positive attitude score regarding the avoidance of physical contact (17.78%).

Following the face-to-face lecture, participants exhibited an overall improvement in attitudes. The post-test results (Table 4) revealed that more participants held positive attitudes toward personal hygiene and environmental management, including thorough textile cleaning (95.56%).

Table III. Pre-test responses to questions regarding Barangay Health Workers' attitude towards Scabies

| ATTITUDE                                                                                             | 1  |       | 2 |       | 3 |       | 4 |       | 5  |       | Obs. | Total Score | Mean $\pm$ SD   | Result         | Inter-pretation |
|------------------------------------------------------------------------------------------------------|----|-------|---|-------|---|-------|---|-------|----|-------|------|-------------|-----------------|----------------|-----------------|
|                                                                                                      | F  | %     | F | %     | F | %     | F | %     | F  | %     |      |             |                 |                |                 |
| I will advise patients to thoroughly wash and dry mattresses and pillows every week.                 | 1  | 2.22  | 2 | 4.44  | 1 | 2.22  | 6 | 13.33 | 35 | 77.78 | 45   | 207         | 4.60 $\pm$ 0.92 | Strongly Agree | (+)             |
| Patients who have Scabies have to be quarantined.                                                    | 18 | 40.00 | 7 | 15.56 | 3 | 6.67  | 7 | 15.56 | 10 | 22.22 | 45   | 119         | 2.64 $\pm$ 1.65 | Neutral        | (+/-)           |
| Patients should not exchange towels, clothes and beddings with others.                               | 6  | 13.33 | 0 | -     | 2 | 4.44  | 7 | 15.56 | 30 | 66.67 | 45   | 190         | 4.22 $\pm$ 1.38 | Strongly Agree | (+)             |
| Scabies patients should be avoided.                                                                  | 17 | 37.78 | 8 | 17.78 | 7 | 15.56 | 5 | 11.11 | 8  | 17.78 | 45   | 114         | 2.53 $\pm$ 1.53 | Disagree       | (-)             |
| Personal hygiene is very necessary to keep the body from Scabies.                                    | 3  | 6.67  | 2 | 4.44  | 2 | 4.44  | 5 | 11.11 | 33 | 73.33 | 45   | 198         | 4.40 $\pm$ 1.20 | Strongly Agree | (+)             |
| If found cases of Scabies, treatment should be done promptly to prevent the transmission of disease. | 3  | 6.67  | 0 | -     | 0 | -     | 3 | 6.67  | 39 | 86.67 | 45   | 210         | 4.67 $\pm$ 1.02 | Strongly Agree | (+)             |

|                                                                                            |   |      |   |   |   |   |   |      |    |       |    |     |             |                |     |
|--------------------------------------------------------------------------------------------|---|------|---|---|---|---|---|------|----|-------|----|-----|-------------|----------------|-----|
| Besides personal hygiene, there must be a good environment to prevent Scabies infestation. | 3 | 6.67 | 0 | - | 0 | - | 1 | 2.22 | 41 | 91.11 | 45 | 212 | 4.71 + 1.01 | Strongly Agree | (+) |
|--------------------------------------------------------------------------------------------|---|------|---|---|---|---|---|------|----|-------|----|-----|-------------|----------------|-----|

*F – Frequency, % - percentage of corresponding responses*

*1.00-1.80 (Strongly Disagree), 1.81-2.60(Disagree), 2.61-3.40 (Neutral), 3.41-4.20 (Agree), 4.21-5.00 (Strongly Agree)*

*(+) Positive, (-) Negative, (+/-) Neutral*

Table IV. Post-test responses to questions regarding Barangay Health Workers' attitude towards Scabies

| ATTITUDE                                                                                             | 1  |       | 2 |       | 3 |      | 4  |       | 5  |       | Obs | Total Score | Mean $\pm$ SD | Result         | Inter-pretation |
|------------------------------------------------------------------------------------------------------|----|-------|---|-------|---|------|----|-------|----|-------|-----|-------------|---------------|----------------|-----------------|
|                                                                                                      | F  | %     | F | %     | F | %    | F  | %     | F  | %     |     |             |               |                |                 |
| I will advise patients to thoroughly wash and dry mattresses and pillows every week.                 | 1  | 2.22  | 0 | -     | 0 | -    | 1  | 2.22  | 43 | 95.56 | 45  | 220         | 4.89 + 0.61   | Strongly Agree | (+)             |
| Patients who have Scabies have to be quarantined.                                                    | 15 | 33.33 | 5 | 11.11 | 0 | -    | 12 | 26.67 | 13 | 28.89 | 45  | 138         | 3.07 + 1.71   | Neutral        | (+/-)           |
| Patients should not exchange towels, clothes and beddings with others.                               | 2  | 4.44  | 1 | 2.22  | 0 | -    | 1  | 2.22  | 41 | 91.11 | 45  | 213         | 4.73 + 0.94   | Strongly Agree | (+)             |
| Scabies patients should be avoided.                                                                  | 11 | 24.44 | 4 | 8.89  | 3 | 6.67 | 12 | 26.67 | 15 | 33.33 | 45  | 151         | 3.36 + 1.61   | Neutral        | (+/-)           |
| Personal hygiene is very necessary to keep the body from Scabies.                                    | 1  | 2.22  | 0 | -     | 0 | -    | 4  | 8.89  | 40 | 88.89 | 45  | 217         | 4.82 + 0.65   | Strongly Agree | (+)             |
| If found cases of Scabies, treatment should be done promptly to prevent the transmission of disease. | 1  | 2.22  | 0 | -     | 0 | -    | 2  | 4.44  | 42 | 93.33 | 45  | 219         | 4.87 + 0.63   | Strongly Agree | (+)             |
| Besides personal hygiene, there must be a good environment to prevent Scabies infestation.           | 1  | 2.22  | 0 | -     | 0 | -    | 1  | 2.22  | 43 | 95.56 | 45  | 220         | 4.89 + 0.61   | Strongly Agree | (+)             |

*F – Frequency, % - percentage of corresponding responses*

*1.00-1.80 (Strongly Disagree), 1.81-2.60(Disagree), 2.61-3.40 (Neutral), 3.41-4.20 (Agree), 4.21-5.00 (Strongly Agree)*

### Practices on Scabies

In the pre-test (Table 5), participants exhibited positive practices in fomite infection control, including advising patients not to share clothes (68.89%), avoid sleeping on other beds (55.56%), and ensuring thorough drying of towels after use (75.56%). Additionally, an overall positive practice towards personal hygiene was observed (91.11%).

In the post-test (Table 6), there was a notable increase in positive practices, particularly with regards to good personal hygiene (97.78%), indicating a positive shift in participant behavior following the intervention.

**Table V. Pre-test responses to questions regarding Barangay Health Workers' practice towards Scabies**

| PRACTICES                                                                | 1  |       | 2 |       | 3 |      | 4  |       | 5  |       | Obs. | Total Score | Mean $\pm$ SD | Result         | Inter-pretation |
|--------------------------------------------------------------------------|----|-------|---|-------|---|------|----|-------|----|-------|------|-------------|---------------|----------------|-----------------|
|                                                                          | F  | %     | F | %     | F | %    | F  | %     | F  | %     |      |             |               |                |                 |
| I would advise patients to never share clothes with friends.             | 2  | 4.44  | 0 | -     | 2 | 4.44 | 10 | 2.22  | 31 | 68.89 | 45   | 203         | 4.51 + 0.94   | Strongly Agree | (+)             |
| I would advise patients to never sleep on other's bed.                   | 9  | 20.00 | 2 | 4.44  | 4 | 8.89 | 5  | 11.11 | 25 | 55.56 | 45   | 170         | 3.78 + 1.62   | Agree          | (+)             |
| I would advise patients to dry towel after use.                          | 2  | 4.44  | 1 | 2.22  | 0 | -    | 8  | 17.78 | 34 | 75.56 | 45   | 206         | 4.58 + 0.97   | Strongly Agree | (+)             |
| I would advise patients to take a bath every day.                        | 3  | 6.67  | 0 | -     | 0 | -    | 1  | 2.22  | 41 | 91.11 | 45   | 212         | 4.71 + 1.01   | Strongly Agree | (+)             |
| I would advise to restrict visitors until treatment regimen is complete. | 12 | 26.67 | 5 | 11.11 | 0 | -    | 9  | 20.00 | 19 | 42.22 | 45   | 153         | 3.40 + 1.72   | Neutral        | (+/-)           |

F – Frequency, % - percentage of corresponding responses

1.00-1.80 (Strongly Disagree), 1.81-2.60(Disagree), 2.61-3.40 (Neutral), 3.41-4.20 (Agree), 4.21-5.00 (Strongly Agree)

(+) Positive, (-) Negative, (+/-) Neutral

**Table VI. Post-test responses to questions regarding Barangay Health Workers' practice towards Scabies**

| PRACTICES                                                    | 1 |       | 2 |      | 3 |      | 4 |      | 5  |       | Obs. | Total Score | Mean $\pm$ SD | Result         | Inter-pretation |
|--------------------------------------------------------------|---|-------|---|------|---|------|---|------|----|-------|------|-------------|---------------|----------------|-----------------|
|                                                              | F | %     | F | %    | F | %    | F | %    | F  | %     |      |             |               |                |                 |
| I would advise patients to never share clothes with friends. | 1 | 2.22  | 0 | -    | 0 | -    | 4 | 8.89 | 40 | 88.89 | 45   | 217         | 4.82 + 0.64   | Strongly Agree | (+)             |
| I would advise patients to never sleep on other's bed.       | 5 | 11.11 | 1 | 2.22 | 1 | 2.22 | 1 | 2.22 | 37 | 82.22 | 45   | 199         | 4.42 + 1.34   | Strongly Agree | (+)             |

|                                                                          |   |       |   |   |   |      |    |       |    |       |    |     |        |                |       |
|--------------------------------------------------------------------------|---|-------|---|---|---|------|----|-------|----|-------|----|-----|--------|----------------|-------|
| I would advise patients to dry towel after use.                          | 4 | 8.89  | 0 | - | 1 | 2.22 | 1  | 2.22  | 39 | 86.67 | 45 | 206 | 4.58 + | Strongly Agree | (+)   |
| I would advise patients to take a bath every day.                        | 1 | 2.22  | 0 | - | 0 | -    | 0  | -     | 44 | 97.78 | 45 | 221 | 4.91 + | Strongly Agree | (+)   |
| I would advise to restrict visitors until treatment regimen is complete. | 9 | 20.00 | 0 | - | 1 | 2.22 | 10 | 22.22 | 25 | 55.56 | 45 | 177 | 3.93 + | Neutral        | (+/-) |

F – Frequency, % - percentage of corresponding responses  
1.00-1.80 (Strongly Disagree), 1.81-2.60(Disagree), 2.61-3.40 (Neutral), 3.41-4.20 (Agree), 4.21-5.00 (Strongly Agree)  
(+) Positive, (-) Negative, (+/-) Neutral

Comparison between Pre-test and Post-test

In the pre-test, participants demonstrated a relatively low level of knowledge, with a mean score of 5.78. However, following the intervention, there was a noteworthy increase in knowledge, resulting in a mean post-test score of 10.27. This increase was statistically significant, as indicated by a p-value of <0.001 (Table 7).  
When comparing attitudes in the pre-test and post-test, positive shifts were observed in attitudes related to fomite infection control, specifically the avoidance of sharing towels, beddings, and clothing (p-value <0.001),

as well as the practice of thoroughly washing and drying textiles (p-value 0.006). Additionally, positive attitudes toward avoiding contact with Scabies-infected individuals were evident (p-value 0.002) (Table 8).  
Similarly, in the comparison of practices between the pre-test and post-test, there was a significant improvement in positive practices related to fomite infection control, encompassing the avoidance of sharing towels, bedding, and clothing (p-value 0.006), along with the avoidance of sleeping on other people's beds (p-value 0.002) (Table 9).

Table VII. Comparison of Pre-Test and Post-Test Knowledge of Barangay Health Workers on Scabies (n=45)

| Knowledge | Mean Score | Std Dev | SE | CV   | W   | Z     | p-Value | 95% CI for Rank-Biserial Correlation |        |
|-----------|------------|---------|----|------|-----|-------|---------|--------------------------------------|--------|
|           |            |         |    |      |     |       |         | Lower                                | Upper  |
|           |            |         |    |      |     |       |         |                                      |        |
| Pre-Test  | 5.78       | 1.36    | 5  | 0.24 |     |       |         |                                      |        |
| Post-Test | 10.27      | 1.56    | 9  | 0.15 | 4.2 | -5.77 | <0.001  | -∞                                   | -0.996 |

**Table VII. Comparison of Pre-Test and Post-Test Knowledge of Barangay Health Workers on Scabies (n=45)**

| ATTITUDE                                                                                             | Pre-Test |      |          | Post-Test |      |          | Mean Difference | P-value          |
|------------------------------------------------------------------------------------------------------|----------|------|----------|-----------|------|----------|-----------------|------------------|
|                                                                                                      | Obs      | Mean | Std. Dev | Obs       | Mean | Std. Dev |                 |                  |
| I will advise patients to thoroughly wash and dry mattresses and pillows every week.                 | 45       | 4.60 | 0.92     | 45        | 4.89 | 0.61     | 0.29            | <b>0.006</b>     |
| Patients who have Scabies have to be quarantined.                                                    | 45       | 2.64 | 1.65     | 45        | 3.07 | 1.71     | 0.42            | <b>0.028</b>     |
| Patients should not exchange towels, clothes and beddings with others.                               | 45       | 4.22 | 1.38     | 45        | 4.73 | 0.94     | 0.51            | <b>&lt;0.001</b> |
| Scabies patients should be avoided.                                                                  | 45       | 2.53 | 1.53     | 45        | 3.36 | 1.61     | 0.82            | <b>0.002</b>     |
| Personal hygiene is very necessary to keep the body from Scabies.                                    | 45       | 4.40 | 1.20     | 45        | 4.82 | 0.65     | 0.42            | <b>0.01</b>      |
| If found cases of Scabies, treatment should be done promptly to prevent the transmission of disease. | 45       | 4.67 | 1.02     | 45        | 4.87 | 0.63     | 0.2.            | 0.09             |
| Besides personal hygiene, there must be a good environment to prevent Scabies infestation.           | 45       | 4.71 | 1.01     | 45        | 4.89 | 0.61     | 0.18            | 0.13             |

**Table IX. Comparison of Barangay Health Workers' practices before and after lecture**

| PRACTICES                                                                | Pre-Test |       |         | Post-Test |      |         | Mean Difference | p-Value      |
|--------------------------------------------------------------------------|----------|-------|---------|-----------|------|---------|-----------------|--------------|
|                                                                          | Obs      | Means | Std Dev | Obs       | Mean | Std Dev |                 |              |
| I would advise patients to never share clothes with friends.             | 45       | 4.51  | 0.94    | 45        | 4.82 | 0.65    | 0.33            | <b>0.006</b> |
| I would advise patients to never sleep on other's bed.                   | 45       | 3.78  | 1.62    | 45        | 4.42 | 1.34    | 0.64            | <b>0.002</b> |
| I would advise patients to dry towel after use.                          | 45       | 4.58  | 0.97    | 45        | 4.58 | 1.18    | 0.00            | 0.385        |
| I would advise patients to take a bath every day.                        | 45       | 4.71  | 1.01    | 45        | 4.91 | 0.60    | 0.20            | 0.087        |
| I would advise to restrict visitors until treatment regimen is complete. | 45       | 3.40  | 1.72    | 45        | 3.93 | 1.56    | 0.53            | 0.052        |

## DISCUSSION

Scabies infestation continues to be a prominent global health concern, impacting millions of individuals, with a notable prevalence in rural communities characterized by low socioeconomic status and high population density. This neglected tropical disease thrives in environments where overcrowding is rampant, making it essential to address its prevention and management comprehensively.

A pertinent study conducted among nursing students at Sabia University College of Jazan in 2018 revealed encouraging findings regarding their knowledge, attitudes, and practice related to Scabies prevention and

transmission. Despite their good understanding of the disease, it is noteworthy that they still recommended the inclusion of this infectious disease as part of their curriculum. This highlights the recognition of Scabies as an infectious disease of significance and emphasizes the need for continuous education and training within the healthcare sector.<sup>12</sup> Additionally, a study conducted among general practitioners (GPs) and dermatologists in Ghent, Belgium, provided insights into healthcare professionals' knowledge levels regarding Scabies. The study found that these professionals generally possessed acceptable knowledge, and their scores were influenced significantly by factors such as their profession, years of

experience, and the number of patients they encountered. This underscores the importance of tailored training and ongoing medical education to enhance healthcare practitioners' competence in dealing with Scabies cases.<sup>13</sup>

However, in contrast to these previous studies, the results of the present study among Barangay Health Workers (BHWs) reveal a different scenario. While BHWs exhibited good attitudes and practices related to Scabies prevention and control, their initial knowledge levels were relatively low. Nonetheless, the face-to-face lecture intervention led to a significant increase in their overall knowledge scores, with a p-value of  $<0.001$ , demonstrating the effectiveness of targeted health education.

Furthermore, positive shifts were observed in BHWs' attitudes, particularly regarding personal hygiene and environmental management, as well as the practice of thoroughly washing and drying textiles (95.56%). Positive practices also showed significant improvement, exemplified by the avoidance of sharing towels, bedding, and clothing (p-value of 0.006) and the avoidance of sleeping on other people's beds (p-value of 0.002). These findings emphasize the potential for knowledge-based interventions, such as the 30-minute face-to-face lecture, to bring about meaningful changes in attitudes and practices related to Scabies among frontline healthcare workers.

In summary, while Scabies remains a global health challenge, studies like this shed light on the varying levels of knowledge and preparedness among different groups of healthcare professionals. By recognizing the gaps in understanding and implementing targeted interventions, we can work toward more effective Scabies prevention and control strategies and ultimately reduce its impact on vulnerable communities.

## **CONCLUSION**

Barangay Health Workers (BHWs) hold pivotal roles within the primary healthcare system, serving as accessible and trusted units within communities for the delivery of crucial health education and services. They function as community organizers and educators, playing a vital role in reducing the burden of various diseases.<sup>7</sup> Their unique position allows them to bridge the gap between healthcare services and underserved communities, which can be especially critical in preventing complicated and potentially fatal cases that might otherwise be seen in tertiary hospitals.

Furthermore, the impact of this study extends beyond the immediate context. In the future, the

interventions and education provided to BHWs may have a substantial influence on the prevalence and incidence of Scabies within the community. Scabies is often underreported and unseen by doctors and dermatologists, making it imperative to equip frontline healthcare workers like BHWs with the knowledge and tools needed for early detection and prevention.

This study highlights the effectiveness of health education, particularly in the form of a concise 30-minute face-to-face lecture, as a means to significantly enhance the knowledge base of BHWs. The subsequent improvements observed in attitudes and practices among participants underscore the potential of such interventions to bring about positive change.

Looking ahead, this study can serve as a valuable foundation for future training initiatives and awareness campaigns focused on Scabies for Barangay Health Workers. By continually empowering these community healthcare champions, we can work towards a healthier and better-informed population, ultimately reducing the impact of neglected tropical diseases like Scabies on vulnerable communities.

## **LIMITATIONS AND RECOMMENDATIONS**

We recognize several limitations within the scope of this study. Firstly, it became evident that some questions, particularly those within the attitudes and practices section, may not have been adequately clarified for all participants during the survey administration. Addressing this issue during the survey process itself would have been beneficial in ensuring uniform comprehension among participants.

Secondly, the post-test was administered immediately after the lecture. While this allowed us to measure the immediate impact of the intervention, it presents limitations concerning the long-term retention of knowledge, comprehension, and the sustained influence on future attitudes and practices. In practice, knowledge retention and behavioral changes may require ongoing reinforcement. Therefore, regular and routine training sessions and awareness campaigns may be necessary to maintain and build upon the level of improvement observed in this study.

To enhance our assessment, we recommend that future studies consider conducting a follow-up evaluation of Knowledge, Attitudes, and Practices (KAP) surveys at a second time point, ideally at intervals of around 3 to 6 months post-intervention. This would provide valuable insights into the durability of the intervention's impact and whether any additional reinforcement or adjustments are needed over time.

Furthermore, for future comparative studies, it would be valuable to explore the effect of interventions like this one on the prevalence or incidence of Scabies cases within the community. By tracking changes in disease occurrence, we can gain a more comprehensive understanding of the intervention's overall impact on public health outcomes.

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## Effect of 100% Cocoa Powder on Ultraviolet-B Minimal Erythema Dose versus Chocolate Flavored Drink Powder among Filipinos: A Double Blind Study\*

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### ABSTRACT

**Background:** Ultraviolet radiation (UV) imposes significant negative consequences upon excessive exposure. It is a common misconception in darker skin types that there is no need for photoprotection, hence studies have been done on other adjuncts of photoprotection. Cocoa is naturally-occurring antioxidant rich in flavanols that absorbs UV radiation and scavenge reactive oxygen species.

**Objective:** The study aimed to determine the UVB photoprotective activity through minimal erythema dose determination of 100% cocoa powder versus chocolate flavored powder drink.

**Methods:** This study was a randomized, double-blind controlled trial, wherein sixty (60) Filipino subjects aged 18 years old to 59 years old with Fitzpatrick skin type IV-IV were equally divided into two groups using computer generated randomization. Group I received 100% cocoa powder, one (1) tablespoon dissolved in hot water daily for 12 weeks, while Group II received chocolate flavored drink powder, one (1) tablespoon dissolved in hot water daily for 12 weeks. Minimal erythema dose (MED) were assessed for both groups at baseline, week 6 and week 12. Laboratory testing for fasting blood sugar (FBS), blood urea nitrogen (BUN), creatinine, SGPT and SGOT was done baseline and at week 12.

**Results:** In the 100% cocoa powder group, the mean MED increased from baseline to week 6 at an average of 5.5% (p-value 0.64) which were not statistically significant, while from baseline to week 12 an statistically significant increase in mean MED was noted at 21% (p-value < 0.01). These results showed that there is significant photoprotective activity of 100% cocoa powder for intake of 12 weeks as compared to 6 weeks. In the chocolate flavored powder drink, MED remained unchanged. No significant adverse clinical symptoms and laboratory test changes were seen in this study.

**Conclusion:** Intake of 100% cocoa powder for 12 weeks have significant photoprotective activity compared to baseline among Filipinos with Fitzpatrick skin type IV-V. While chocolate flavored drink powder has no such effect.

**Keywords:** Cocoa powder, flavanols, photoprotection, Fitzpatrick skin type IV-V

### INTRODUCTION

Ultraviolet radiation plays a beneficial role in the production of vitamin D, however excessive exposure has negative consequences. These significant negative effects include sunburn, phototoxic and photoallergic reactions, and development of skin cancers<sup>1</sup>.

Skin cancer is a preventable disease and a major public health concern<sup>1</sup>. There were 2102 basal cell carcinomas and 614 squamous cell carcinomas from 2011 to 2021 based on the Philippine Dermatological Society Health Information System<sup>2</sup>. Ultraviolet (UV) radiation or sun damage is an established modifiable risk factor for carcinomas of the skin. UV avoidance and photoprotective practices is not commonly done among Filipinos since brown skin has more melanin and many believe it offers greater protection. While the incidence of skin cancer incidence is not as common among Filipinos as it is among Caucasians, it does occur locally, so it is crucial to determine other means of photoprotection.

Cocoa is a naturally-occurring antioxidant with anti-inflammatory molecules that play a role in preventing cutaneous UV damage. It is widely available, inexpensive, and serves as an efficient food supplement that may help with photoprotection. It has a high amount of flavonoids, contributing to the bitterness representing the fundamental aspects of its organoleptic and palatability characteristics<sup>3</sup>. Aside from the photoprotective properties of cocoa, it contains methylxanthines such as theobromine and caffeine, which have beneficial effects on the vascular and central nervous system.<sup>4</sup>

Few studies on photoprotection have been conducted in non-tropical countries with participants of Fitzpatrick Skin Types I to II. However, to our knowledge, no studies have been done on low- and middle-income countries, such as the Philippines, wherein frequent sun exposure is often common in daily life, and most occupations.<sup>5</sup> This further emphasizes the significance of this study since the Philippines is a tropical country and Filipinos are more predisposed to sun exposure.

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*Disclosures:* The author has formally acknowledged and signed a disclosure affirming the absence of any financial or other relationships (including personal connections), intellectual biases, political or religious affiliations, and institutional ties that could potentially result in a conflict of interest.

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This study highlights the importance of providing other means of photoprotection for Filipino patients. Dermatologists have been educating patients regarding sun protection through the use of topical/oral sunscreens, physical barriers and avoidance of prolonged sun exposure. However, due to the Philippines being a low-income country, photoprotection has not been a priority among Filipinos. This study will help our patients prevent skin cancers brought by UV radiation and promote our own economy with the use of cocoa freshly made in our country.

The goal of this randomized clinical trial is to determine and compare the photoprotective properties of cocoa powder and chocolate flavored powder drink. No measurements were done on quantifying the flavanol content of the powder drinks. Measurement of ultraviolet B (UVB) protection was done through Minimal Erythema Dose.

### Sun Damage

Ultraviolet (UV) radiation is one of the most critical risk factors for skin cancer. The most frequently exposed are outside workers, those who work outdoors for at least three hours between 9 am to 3 pm most days of the week.<sup>6</sup> Limited studies have been done in the Philippines, particularly since skin cancers are not as common among Filipinos. In a local study among Filipino traffic enforcers, researchers concluded that they have adequate knowledge and a good attitude towards sun exposure but are not applied to practice.<sup>6</sup> Thus, proper education among occupational workers and other possible sources of photoprotection may be of aid to Filipinos.

The sun's UV rays between 10 am in the morning and 4 pm in the afternoon release the highest UVA and UVB radiation. In studies, direct exposure to the sun during these hours amounting to 30 to 50 minutes may induce sunburn for skin types Fitzpatrick III and IV. One of the major factors for non-melanoma skin cancer is exposure to UVB, which promotes inflammation, oxidative stress, DNA mutation, and damage. This in turn leads to the evolution of non-melanoma skin cancers.<sup>14</sup>

### Cocoa and Photoprotection

Cocoa, from the tree *Theobroma cacao*, has many potential benefits. It contains methylxanthines such as theobromine and caffeine.<sup>4</sup> Theobromine was found to have strong inhibitory effects on the activity of nuclear enzyme poly (ADP-ribose) polymerase-1 (PARP-1), involved in inflammatory diseases such as stroke, diabetes, and chronic obstructive pulmonary disease.<sup>7</sup>

While caffeine is a compound that is associated with enhanced cognition<sup>8</sup> and enhances the vascular and central nervous system.<sup>4</sup>

Cocoa beans fresh from trees are exceptionally rich in flavanols, but their high antioxidant capacity may be greatly reduced during the manufacturing process. Regular consumption of chocolate rich in flavanol confers significant photoprotection and can thus be effective at protecting human skin from harmful UV effects but low-flavanol conventional chocolate has no such effect. It was mentioned that in human subjects, flavanol-rich chocolate improved cardiovascular risk factors including total and LDL cholesterol, blood pressure, and insulin sensitivity after 12 weeks of ingestion of high flavanol chocolate droplet snack. A study was done on the impacts on endothelial function with sugar free and sugar-sweetened cocoa consumption and found no significant difference.<sup>19</sup>

Carotenoids have gained momentum in photoprotective properties prior to cocoa. A comparative experimental study was done between low-flavanol cocoa and high-flavanol cocoa, with the determination of minimal erythema dose (MED) using a blue solar simulator. MED is a measurement tool used to examine skin tolerance to ultraviolet radiation and defined as the lowest dose that produces erythema in which the values vary per individual. It measures an individual's tendency to burn, with low MED values associated with increased photosensitivity.<sup>21</sup> Carotenoids and products containing high-flavanol cocoa have comparable photoprotective effects<sup>10</sup>. However, in another study, no statistical difference was noted between low-flavanol cocoa and high-flavanol cocoa particularly due to changes in weather season, wherein participants started the study during winter and ended in spring, and lack of compliance. Researchers found out that there was an increase in MED at week 6 than at weeks 9 and 12 compared to baseline, indicating patients' maximum compliance with the protocol at 6 weeks<sup>11</sup>.

A longer trial period of 24 weeks to also assess improvement in skin wrinkles as high flavanol is also believed to have anti-photoaging effects. It was emphasized that the consumption of dietary antioxidants is considered to be a good strategy against photo-aging and in moderately photo-aged women, regular cocoa flavanol consumption had positive effects on facial wrinkles and elasticity. Aside from photoprotection, cocoa flavanol supplementation may contribute to the prevention and progression of photoaging<sup>12</sup>.

### **Safety Profile of Cocoa**

Cocoa extract has photoprotective effects from prolonged oral administration of high flavanols which was proven by in vitro and in vivo studies. A short period of one week of administration of cocoa powder demonstrated photoprotective activity, measured by an increase in MED. Volunteers did not report any adverse effects. Researchers have concluded an increase in subjects' adherence to the protocol with the short duration of the study and that cocoa could supplement topical sunscreens for photoprotection<sup>13</sup>.

### **Effects of Cocoa Powder on Glucose, Liver and Kidney**

Long-term ingestion of cocoa was well tolerated in one study, wherein adverse effects were evaluated at the 12<sup>th</sup> and 24<sup>th</sup> week of treatment. Laboratory tests such as aspartate aminotransferase, alanine transaminase, glucose, blood urea nitrogen, creatinine, and hemoglobin and hematocrit concentrations were measured. Participants reported no subjective adverse effects and no laboratory abnormalities were noted after the 24<sup>th</sup> week of treatment, indicating a wide margin of the safety profile of cocoa<sup>12</sup>. In another study, cocoa consumption showed a reduction in total cholesterol, fasting blood glucose and in systolic and diastolic blood pressure<sup>20</sup>.

### **Safety Profile of Narrowband UVB Phototherapy**

UVB phototherapy is used to treat a variety of skin disorders. A review of literature was done on several studies using UVB phototherapy which resulted in no increased risk for non-melanoma skin cancers within a long follow-up period. These studies were done on Caucasian skin, and would even indicate safer for darker skinned individuals.<sup>15</sup> Narrowband UVB (NB UVB) phototherapy is reported to be safe, but short term erythema, pruritus and xerosis may last for up to two days. UVB Phototherapy may be discontinued in the case of prolonged erythema, pruritus and xerosis existing for more than two days.<sup>17</sup>

## **METHODOLOGY**

### **STUDY DESIGN AND SETTING**

This study was a randomized double-blind study. Patients were randomly allocated using a computer-generated software into two groups: group I (100% Cocoa powder) and group II (Chocolate flavor powder). Patients in group I received a supply of Cocoa powder on day 1 of study and on the 6th week of treatment, while group II received a supply of Chocolate flavored powder drink on day 1 of study and on the 6th week of treatment. The allocation was kept unknown to the participants and the assessor.

All participants were subjected to screening by the primary investigator at Valenzuela Medical Center Dermatology Out-Patient Department. The study was presented to the Hospital Institutional Review Board (IRB) before conducting the process.

### **SAMPLING DESIGN AND RANDOMIZATION**

The study made use of purposive sampling where only those who have satisfied the inclusion and exclusion criteria joined part of the research. Participants were randomized through block sampling (in 1:1 ratio using blocks of four) into group I (100% Cocoa powder) and group II (Chocolate flavor powder).

The primary investigator was blinded on the group assignments of the participants. Research assistant or staff assigned participants to either control group or experimental group while the researcher determined the minimal erythema dose of the patients. List of patients assigned to either group was kept by the research assistant only.

### **PARTICIPANTS**

The study included adult participants seen in the Valenzuela Medical Center Department of Dermatology.

### **INCLUSION CRITERIA**

- Ages 18 years to 59 years old
- Fitzpatrick Skin Types IV to V

### **EXCLUSION CRITERIA**

- History of severe liver, kidney diseases or uncontrolled diabetes
- Immunocompromised patients
- History of allergies against any component of trial food
- Pregnancy or lactation
- Chemical dependency or alcoholism
- Therapy with drugs with known phototoxic activities
- Any dermatological disease in the treatment area, and prolonged UV exposure

### **WITHDRAWAL CRITERIA**

- Unable to undergo blood laboratory tests for safety monitoring
- Unable to have scheduled follow-up during the course of study
- Failure to consume powder drink in at least 80% of the expected number of days within the 12-week study

- Induction of polymorphous light eruption, appearance of blisters, photoconjunctivitis and photokeratitis. Erythema, xerosis, and pruritus are minor expected side effects of phototherapy occurring within 24 hours, which may last up to 48 hours.
- Patients with any signs of allergies or serious adverse reactions to any of the experimental exposures
- Participants who request to withdraw at any point in time in the course of study

### SAMPLE SIZE CALCULATION

Sample size for this study was computed using the online sample size calculator from [powerandsamplesize.com/Calculators](http://powerandsamplesize.com/Calculators) with the assumption that the mean value of the outcome of cocoa is 0.223 MED.<sup>9</sup> Estimation was done for the study to detect a 0.114 difference in outcome values between cocoa and chocolate. In comparison of two means carried out at <5% level of significance, a sample size of 28 per group (total of 56 participants) is needed for the study to have 80% power of rejecting the null hypothesis if the alternative holds.

### MATERIALS

The cocoa powder used is made up of 100% cocoa (Family's choice Pure Cocoa Powder), FDA registered, made from the Philippines while the chocolate flavor drink (Milo Powdered Choco Malt Milk Drink) is made up of cocoa, sugar, milk, and malt extract. The appearance and color were similar in both groups. Both 100% cocoa and chocolate flavor drink were repackaged by a research assistant or staff into identical small opaque plastic canisters (Figure 1).

Subjects in the control group were given a chocolate flavored powder drink while the treatment group was given a 100% cocoa drink.

### FLOW OF THE STUDY AND RESEARCH INSTRUMENT

The participants eligible for the study after the screening were divided into two groups, group I (Cocoa) and group II (Chocolate). Prior initiation of the study, informed consent was given and signed by the participant. They were instructed to consume 15 g/day (one tablespoon) dissolved in 100-200mL of hot water for ingestion in the morning after breakfast. They may add up to one teaspoon of sweeteners such as sugar to their drink. Both groups were given small plastic canisters filled with either 100% cocoa powder or chocolate flavored powder, and refilled on the 6<sup>th</sup> week of treatment.

All participants had blood sampling for liver function tests, kidney function tests and fasting blood sugar and was evaluated at baseline and on the 12<sup>th</sup> week of treatment for safety and possible side effects such as generalized urticaria, generalized erythema and generalized morbilliform eruption. In the event that the participant will experience any of the mentioned side effects, prolonged short term adverse effects of erythema, xerosis and pruritus, and laboratory test abnormalities, participants will be assessed, managed and referred to the appropriate specialists accordingly based on current clinical practice.

Participants underwent baseline photo testing to determine Minimal Erythema Dose (MED) with the use of NB-UVB (Medisun Psori-Kamm UVB311) by exposing six (6) 1 x 1 cm untanned skin on the back to solar simulation with an initial dose of 200 mJ/cm<sup>2</sup> and increasing intervals of 200 mJ/cm<sup>2</sup>. Upon completion of the UV exposure, adequate skin markings using a permanent marker was made prior to the removal of the MED test patch, in order to more easily identify the exposed areas after 24 hours. Participants were reminded to not wash off the markings until after the skin had been examined for the MED reading. The participants followed up after 24 hours to determine MED. This was done on baseline, on the 6<sup>th</sup> and 12<sup>th</sup> week of treatment. Topical sunscreen was allowed for application except on the back. Stopping guidelines were induction of polymorphous light eruption, appearance of blisters, photo-conjunctivitis and photokeratitis. Erythema, xerosis, and pruritus are minor expected side effects of phototherapy occurring within 24 hours, which may last up to 48 hours.<sup>17</sup> If symptoms persist beyond 48 hours, patients will be reassessed for other possible causes and if there are none, phototherapy will be discontinued.

### DATA MANAGEMENT, STORAGE, PROCESSING AND ANALYSIS

In data management, it is paramount to protect the patients' privacy and confidentiality. Therefore, to ensure that the results of the study will not be linked directly with their personal information and any identifiable features, each of the patients were assigned with a unique patient code for the study. A database of patient records and their equivalent patient code were kept. During the recording of the study results, patient code was shown instead.

Two types of data that were generated, one is the hard data from the data collection form and one soft copy. The hard copies were stored safely in a secured cabinet and kept for five years until; they are disposed of via shredding. The data were encoded in Google Sheet database accessible only to the researcher and the

statistician of the study. The Google Sheet contains safety features that help in preventing unauthorized access and downloading of the data. The database will be securely deleted after the analyses based on approved objectives and until an ethics protocol closure certificate is issued.

For the study, several statistical tests were performed. For the patients' demographic profile, descriptive statistics were used such as mean and standard deviation for continuous data and frequency and Chi-square test for the categorical data.

To determine and compare the overall minimal erythema dose at baseline, 8th week and 12th week for 100% cocoa powder group and chocolate flavored powder drink group, Repeated Measures Analysis of Variance were used. Pairwise comparisons for baseline to week 6 and to week 12 will be analyzed with Tukey's Multiple Comparison test.

To identify and compare the rate of adverse effects in terms of clinical symptoms, generalized urticaria, generalized pruritus, and generalized morbilliform eruption at 8<sup>th</sup> week and 12<sup>th</sup> week, use of t-test for two proportions were done. For the laboratory tests in terms of fasting blood sugar, AST, ALT, BUN, and Creatinine were expressed in terms of mean and standard deviation and compared using Repeated Measures ANOVA.

## RESULTS AND DISCUSSION

### RESULTS

Table 1. Demographic and Clinical Profiles of participants

| Demographic Profile               | Cocoa Powder     | Chocolate Powder | P-value     |
|-----------------------------------|------------------|------------------|-------------|
|                                   | n=28             | n=28             |             |
| Age (years), mean $\pm$ SD        | 33.36 $\pm$ 0.32 | 33.08 $\pm$ 0.45 | 0.006 (NS)  |
| Sex                               |                  |                  |             |
| Male                              | 4(14.3%)         | 6(21.4%)         | 0.4852 (NS) |
| Female                            | 24(85.7%)        | 22(78.6%)        |             |
| Fitzpatrick Skin Type             |                  |                  |             |
| IV                                | 21(75%)          | 16(57.1%)        | 0.1582 (NS) |
| V                                 | 7(25%)           | 12(42.9%)        |             |
| Comorbidities                     |                  |                  |             |
| WITH                              | 6(21.4%)         | 5(17.9%)         | 0.7366 (NS) |
| Endometriosis                     | 2(7.1%)          | 0(0%)            |             |
| Bronchial asthma                  | 2(7.1%)          | 4(16.7%)         |             |
| Hyperthyroidism                   | 2(7.1%)          | 0(0%)            |             |
| Polycystic Ovarian Syndrome       | 0(0%)            | 1(4.2%)          |             |
| WITHOUT                           | 22(78.7%)        | 23(82.1%)        |             |
| Medications                       |                  |                  |             |
| WITH                              | 7(25%)           | 8(28.6%)         | 0.7628 (NS) |
| Methimazole                       | 2(7.2%)          | 0(0%)            |             |
| Terbutaline sulfate               | 1                | 0                |             |
| Budesonide/<br>Formoterol inhaler | 0                | 1                |             |
| Multivitamins                     | 5                | 7                |             |
| WITHOUT                           | 21(75%)          | 20(71.4%)        |             |

NS: Not significant, SD: Standard deviation

Table 1 revealed notable characteristics in the demographic profile, skin type, comorbidities, and medications of participants consuming cocoa powder and chocolate powder. Overall, no significant statistical difference between both groups were noted meaning both groups were the same at baseline.

Table 2. Comparative Analysis on the Level of Mean Minimal Erythema Dose Between 100% Cocoa Powder and Chocolate Flavored Powder Drink

| Treatment Group             | Mean $\pm$ SD       |                     |                     | P-value     |
|-----------------------------|---------------------|---------------------|---------------------|-------------|
|                             | Baseline            | Week 6              | Week 12             |             |
| Group I (Cocoa Powder)      | 778.57 $\pm$ 152.58 | 821.43 $\pm$ 175.03 | 942.86 $\pm$ 198.80 | < 0.001 (S) |
| Group II (Chocolate Powder) | 800 $\pm$ 133.33    | 800 $\pm$ 133.33    | 800 $\pm$ 133.33    | 1.0 (NS)    |

S: Significant, NS: Not significant, SD: Standard deviation

Greenhouse-Geisser 29.037

Linear <0.01

Quadratic = 0.193

The results of the Repeated Measures ANOVA analysis revealed significant variations in erythema dose across different time points for cocoa powder group. Among cocoa powder users, the minimal erythema dose showed a gradual increase from a baseline mean of 778.57 ( $\pm$  152.58) to 821.43 ( $\pm$  175.03) at week 6, and further to 942.86 ( $\pm$  198.80) at week 12. This progressive rise was statistically significant, as indicated by a Greenhouse-Geisser correction value of 29.037 with  $p < 0.001$ . The increase followed a linear trend, with the per protocol analysis yielding a significant linear effect ( $p < 0.01$ ). However, the quadratic trend did not reach statistical significance ( $p = 0.193$ ), suggesting that the changes over time did not follow a curvilinear pattern.

In contrast, the chocolate powder group displayed no changes in mean and standard deviation at any point.

Table 3. Percentage Change of Minimal Erythema Dose for group I (100% Cocoa Powder) between baseline to week 6 and to week 12

| Group I<br>Cocoa Powder | Difference in percentage<br>change (95% CI) | P-value   |
|-------------------------|---------------------------------------------|-----------|
| Baseline to Week 6      | 42.86 (-69.76, 155)                         | 0.64 (NS) |
| Baseline to Week 12     | 164.29 (51.67, 276.90)                      | <0.01 (S) |

NS: Not significant, S: Significant, CI: Confidence interval

Table 3 shows notable changes in the impact of cocoa powder on minimal erythema doses over time. Minimal erythema dose increase was noted from baseline to week 6 which was not statistically significant.

Meanwhile, significant statistical differences were demonstrated between mean differences from baseline to week 12. No mean differences were noted on chocolate powder group, hence pairwise comparison testing was no longer done.

Table 4. Adverse Effects of Clinical symptoms at baseline, week 6 and week 12 Between 100% Cocoa Powder and Chocolate Flavored Powder Drink

| Treatment Group                   | Baseline |          |            | Week 6  |          |   | Week 12 |          |   |
|-----------------------------------|----------|----------|------------|---------|----------|---|---------|----------|---|
|                                   | Group I  | Group II | P          | Group I | Group II | P | Group I | Group II | P |
| Localized Pruritus (<2 days)      | 1(3.6%)  | 2(8.3%)  | 0.462 (NS) | 0(0%)   | 0(0%)    | - | 0(0%)   | 0(0%)    | - |
| Stinging sensation (<2 days)      | 0(0%)    | 1(4.2%)  | 0.275 (NS) | 0(0%)   | 0(0%)    | - | 0(0%)   | 0(0%)    | - |
| Generalized Urticaria             | 0(0%)    | 0(0%)    | -          | 0(0%)   | 0(0%)    | - | 0(0%)   | 0(0%)    | - |
| Generalized Pruritus              | 0(0%)    | 0(0%)    | -          | 0(0%)   | 0(0%)    | - | 0(0%)   | 0(0%)    | - |
| Generalized Morbilliform Eruption | 0(0%)    | 0(0%)    | -          | 0(0%)   | 0(0%)    | - | 0(0%)   | 0(0%)    | - |

NS: Not significant, Group I: Cocoa powder, Group II: Chocolate powder, P: p-value

Table 4 highlights observations regarding localized pruritus and stinging sensation in the cocoa powder and chocolate powder groups. At baseline, localized pruritus lasting less than two days was reported in 1 subject (3.6%) of cocoa powder users and 2 subjects (8.3%) of chocolate powder users, with a p-value of 0.462, indicating no statistically significant difference. By week 6 and week 12, no occurrences of localized pruritus were recorded in either group, and thus, no p-values were calculated for those time points. For stinging sensation lasting less than two days, no cases were reported in the cocoa powder group at baseline, while 1 subject (4.2%) in the chocolate powder group experienced this symptom (p=0.275). Similar to localized pruritus, no instances of stinging sensation were reported in either group during the 6th and 12th weeks, eliminating the need for further p-value comparisons at those time points.

Table 5. Comparative Analysis on the Laboratory Tests Between 100% Cocoa Powder and Chocolate Flavored Powder Drink

| Treatment Group | Baseline      |                  |            | Week 12       |                  |            |
|-----------------|---------------|------------------|------------|---------------|------------------|------------|
|                 | Cocoa Powder  | Chocolate Powder | P-value    | Cocoa Powder  | Chocolate Powder | P-value    |
| FBS             | 5.03 ± 0.32   | 5.1 ± 0.45       | 0.447 (NS) | 4.92 ± 0.48   | 5.11 ± 0.38      | 0.126 (NS) |
| BUN             | 3.92 ± 1.31   | 4.4 ± 1.07       | 0.086 (NS) | 3.9 ± 1.08    | 4.48 ± 0.94      | 0.07 (NS)  |
| Creatinine      | 68.38 ± 11.95 | 71.9 ± 12.61     | 0.288 (NS) | 64.31 ± 11.99 | 62.05 ± 12.17    | 0.487 (NS) |
| SGPT            | 37.79 ± 29.02 | 36.63 ± 28.19    | 0.88 (NS)  | 43.43 ± 24.93 | 35.58 ± 20.27    | 0.202 (NS) |
| SGOT            | 26.93 ± 10.66 | 29.24 ± 15.86    | 0.525 (NS) | 31.74 ± 22.1  | 30.71 ± 22.91    | 0.865 (NS) |

NS: Not significant

The results of the t-test for two means reveal variations in laboratory parameters between the cocoa powder and chocolate powder groups at baseline and week 12. However, these changes were noted to be not statistically significant. At baseline, the fasting blood sugar (FBS) levels were  $5.03 \pm 0.32$  mmol/L in the cocoa powder group and  $5.11 \pm 0.45$  mmol/L in the chocolate powder group, with a p-value of 0.447, indicating no significant difference. However, by the 12th week, the FBS levels showed a slight decrease with the cocoa powder group reporting at  $4.92 \pm 0.48$  mmol/L and a minimal increase in the chocolate powder group at  $4.89 \pm 0.38$  mmol/L. Kidney function tests and liver function tests also showed not statistically significant results.

## DISCUSSION

Ultraviolet radiation is a component present in sunlight and may also come from artificial sources such as halogen, fluorescent and incandescent lamps. Ultraviolet B is high in energy that induces erythema and accounts for approximately 5% to 10% of the UV light that reaches the surface of the earth while Ultraviolet A is low in energy and more likely to cause pigmentation and accounts for 95% of the UV that reaches the earth's surface<sup>28</sup>. Both UVA and UVB contribute to oncogenesis, however, UVB has the higher propensity as they cause direct DNA damage causing mutations<sup>22</sup>. Several means of photoprotection has been the mainstay of prevention to excessive UV exposure such as wearing sun protective clothing, application of a broad-spectrum sunscreen with at least sun protection factor 30, usage of umbrellas, wide brimmed hats or sunglasses, as well as behavioral practices such as seeking shade when outdoors and minimized sun exposure especially during the peak of UV radiation between 10:00 am to 4:00 pm<sup>9</sup>. A higher amount of melanin is found in the upper layers of the epidermis in those with darker skin colors, therefore giving protection to the basal keratinocytes and the dermis<sup>24</sup>. This concept often misleads the general public to think that photoprotection is not a concern in those with darker skin color.

## Study Participant and Demographic Profile

Most of the population of the Philippines have Fitzpatrick skin types III to V<sup>23</sup>. Studies on the photoprotective properties of cocoa have been done on lighter skin groups and non-Asian countries<sup>9 10 11 12 13</sup>. In this study, 35 subjects with Fitzpatrick skin type IV and 19 subjects were Fitzpatrick skin type V were not statistically significant. No statistical significant differences were noted on the age, sex, presence and absence of

comorbidities and medications between the two groups making both groups comparable. Demonstrated in Figure 1, 30 subjects who received Cocoa powder and another 30 subjects who received Chocolate powder were included. Seven subjects were excluded due to diabetes mellitus and refusal to participate. A total of 2 participants (7.1%) dropped out of the Cocoa powder group and 2 participants (7.1%) out of the Chocolate powder group. Reasons for dropout included being unable to undergo MED testing (n=2), non-tolerability of taste (n=1) and withdrawal of consent (n=1). This however, did not affect the overall outcome of this study as intention to treat analysis results still showed statistically significant results on the 12<sup>th</sup> week mean MED compared to baseline for the cocoa powder group.

### **Minimal Erythema Dose**

Overall, the data highlighted distinct trajectories in minimal erythema dose changes between the groups, with the cocoa powder group demonstrating a consistent and substantial increase over the 12-week period (Figure 2-3). Both linear and time-dependent trends were evident, emphasizing a statistically significant progression in erythema dose. This implies that with the continuous intake of cocoa powder, photoprotective properties were observed through the increase of mean minimal erythema dose with an average of 5.5% increase from baseline to week 6 and an even greater increase of 21% from baseline to week 12. Upon further comparison analysis, MED results from baseline to week 6 showed no statistical significant results as compared from baseline to week 12. This demonstrates a minimum duration of intake of 12 weeks of cocoa powder for photoprotective effects. In contrast to other studies, increased photoprotective activity of cocoa was demonstrated at an even shorter duration of just one week administration due to a high flavanol and high amount of polyphenols<sup>13</sup>. The chocolate powder group demonstrated no changes in minimal erythema dose therefore giving no photoprotective activity (Figure 4). Similar results were observed in a study by William, et al. (2009), wherein intake of high flavanol chocolate or those fresh from cocoa beans for 12 weeks conferred significant photoprotection through assessment of minimal erythema dose with subjects with Fitzpatrick skin types II and III<sup>25</sup>.

### **Adverse Effects**

In this study, adverse events documented were localized pruritus and stinging sensation not lasting more than 2 days on the irradiated site. These were noted at baseline before the introduction of the cocoa powder and

chocolate powder, and were from the minimal erythema dose testing. These findings were not statistically significant and did not affect the overall outcome of the study. Similar adverse effects are also noted in other studies with minimal erythema dose testing and are transient<sup>26</sup>. Changes on the mean values of laboratory parameters from baseline were identified at week 12. A decline in laboratory values were noted on fasting blood sugar, blood urea nitrogen and creatinine tests among the cocoa powder group, however, these were deemed to be not statistically significant. Most studies on cocoa showed a beneficial decrease in fasting blood sugar due to its positive effects on insulin sensitivity<sup>27-28</sup>. This study showed no statistically significant changes on the laboratory parameters for both groups therefore not signifying any harmful or beneficial effects. These were consistent with a similar study with an even longer course of intake of cocoa for 24 weeks proving its safety<sup>12</sup>.

## **CONCLUSION AND RECOMMENDATION**

### **CONCLUSION**

This randomized controlled trial demonstrated the significant benefits of cocoa powder on photoprotection among patients with Fitzpatrick skin type IV to V. Results showed that intake of cocoa powder increases the minimal erythema dose over 12 weeks signifying photoprotection. This study can contribute to local data on photoprotective properties of cocoa powder on darker skin types as an adjunct to the basic principles of photoprotection.

### **RECOMMENDATION**

The authors of this study recommend the use of total flavonoid content assay for the powder groups for better quantification of its contents. This test was however unavailable locally at the time of the study. A longer follow-up to assess its long term effects is also recommended. Minimal erythema dose testing for UVA is advocated as well.

### **DISCLOSURE AND CONFLICT OF INTEREST**

All authors declared that there are no conflicts of interest.

### **ACHIEVEMENTS**

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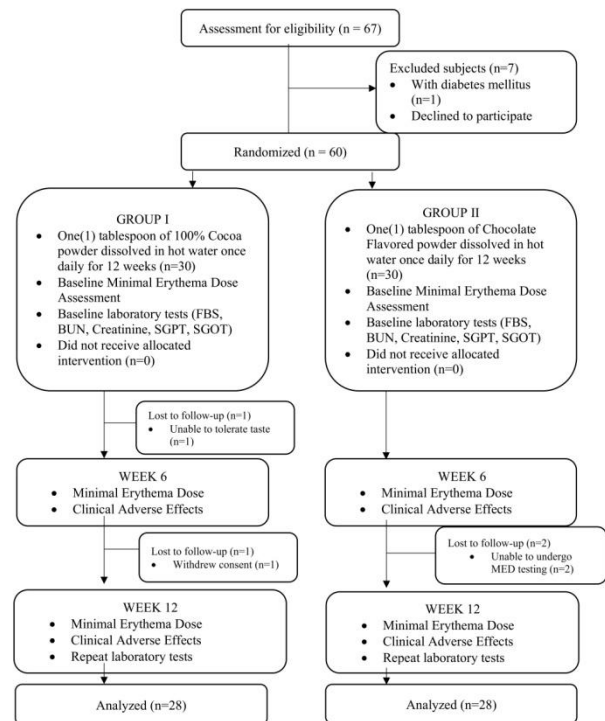
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## APPENDIX

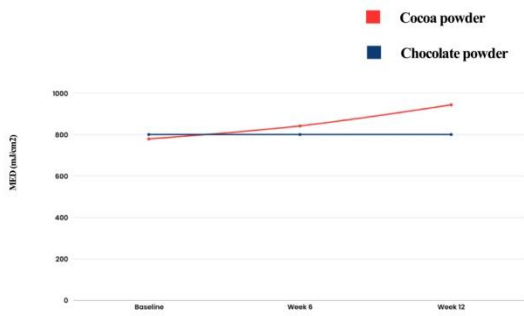
### Appendix 1. Flow diagram of methodology



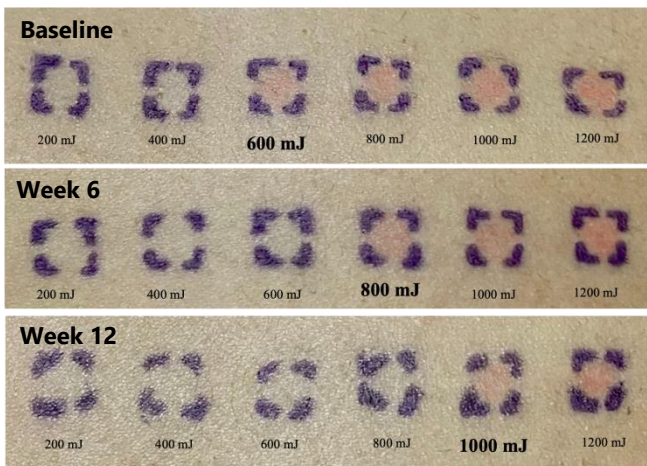
### Appendix 2. Figures



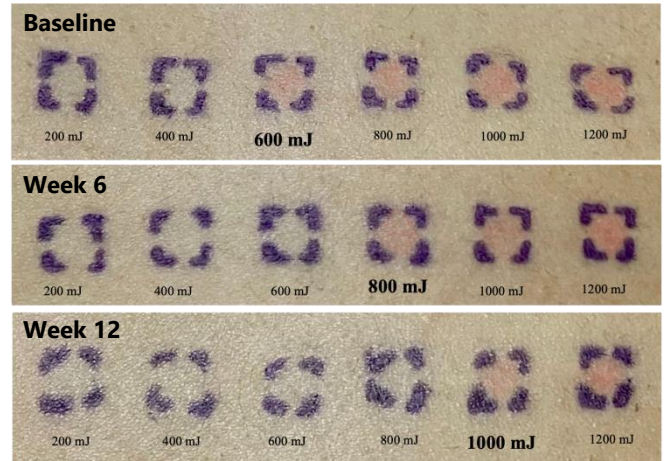
**Figure 1.** Canister containers used for group I (100% cocoa powder) and group II (chocolate flavored powder drink)



**Figure 2.** Mean MED increase between cocoa powder and chocolate flavored powder drink



**Figure 3.** Increase in minimal erythema dose from baseline to week 12 as seen in participant in cocoa powder group



**Figure 4.** No increase in minimal erythema dose from baseline to week 12 seen in chocolate powder group

## Clinicodemographic Profiles and Outcomes of Mycetoma: A Retrospective Case Series at Jose R. Reyes Memorial Medical Center

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### ABSTRACT

**Background:** Mycetoma is a chronic, progressively destructive granulomatous infection caused by fungi (eumycetoma) or bacteria (actinomycetoma). It is recognized by the WHO as a neglected tropical disease. Despite its presence globally, the incidence and burden in the Philippines remain poorly documented.

**Objectives:** To determine the prevalence, clinicodemographic profile, and outcomes of mycetoma diagnosed at the Jose R. Reyes Memorial Medical Center - Department of Dermatology from January 2014 to December 2024.

**Methods:** A retrospective chart review was conducted among patients diagnosed clinically and confirmed either microbiologically and/or histopathologically with mycetoma. Data collected included age, sex, occupation, risk factors, lesion characteristics, causative agent, diagnostic method, treatment, and outcomes.

**Results:** Four cases of actinomycetoma were identified, all with pedal involvement. The majority were male (75%) and over 40 years old. One patient had an agricultural occupation. Most were from outside Metro Manila. Histopathologic confirmation was present in all cases. Three patients were lost to follow-up. Only the patient treated for over 12 months achieved clinical improvement.

**Conclusion:** Mycetoma remains a rare but significant disease in the Philippines. Findings support existing literature on male predominance, pedal localization, and the importance of prolonged antimicrobial treatment. Greater surveillance, early diagnosis, and follow-up strategies are essential.

Keywords: *mycetoma, actinomycetoma, granulomatous infections, plantar lesion, chronic lesion*

### INTRODUCTION

Mycetoma, Maduromycosis, or Madura foot is a chronic, localized infection caused by either fungi (eumycetomas) or aerobic actinomycetes or filamentous bacteria (actinomycetomas). While most commonly seen in the feet, it can also occur in other parts of the body. It is characterized by a symptomatic triad: swelling of the affected area, multiple sinus formation, and a purulent discharge containing grains. The grains represent microcolonies of the causative agent. The progression of the disease is slow and painless, but may affect deep structures such as muscles, tendons, joints, fascia and bones. Patients are otherwise in good health with no satellite adenopathies. Diagnosis is usually based on the clinical presentation and identification of the etiological agents in the tissue by culture and histopathological exam. Eumycetomas predominantly occur in Africa and Southern Asia with *Madurella mycetomatis* being the most frequent eumycete accounting for 70% of all cases in Sudan. On the other hand, Actinomycetomas are predominately seen in the Americas with *Nocardia brasiliensis* being the most prevalent organism responsible for 86% of all cases in Mexico. Treatment usually poses a challenge and in many cases, combination of surgery and antimicrobials are preferred. An approach

that involves early diagnosis, the use of systemic antimicrobials, as well as surgical interventions, are the main issues that need to be-addressed.

According to WHO, the global burden of mycetoma is unknown, but the causative organisms of mycetoma are distributed worldwide and are endemic in tropical and subtropical areas in the so called 'Mycetoma belt', which includes the Bolivarian Republic of Venezuela, Chad, Ethiopia, India, Mauritania, Mexico, Senegal, Somalia, Sudan, and Yemen. Cases have been reported infrequently from Southeast Asian countries, including the Philippines, the majority of which has a prolonged rainy season unlike the arid regions usually associated with mycetoma. Currently, accurate data on its incidence and prevalence are not available. However, most cases have been reported from Mexico and Sudan.

To build national capacities on mycetoma, the Government of Sudan and WHO convened the First International Training Workshop on Mycetoma in Khartoum on 10-14 February 2019. It provided a unique opportunity to share experiences and standardize practices relating to diagnosis, treatment and surveillance. The workshop was followed by the Sixth International Conference on Mycetoma in Khartoum on 15-17 February

*Disclosures: The author has formally acknowledged and signed a disclosure affirming the absence of any financial or other relationships (including personal connections), intellectual biases, political or religious affiliations, and institutional ties that could potentially result in a conflict of interest.*

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2019. The Conference adopted the 'Khartoum Call for Action on mycetoma' which calls on a wide range of actors to take specific public-health and policy measures to address the burden of mycetoma.

At present, active case-finding with early diagnosis and treatment with currently available tools is the most appropriate approach for lessening Mycetoma's disease morbidity and disability.

## METHODOLOGY

Data were collected through manual review of charts of Mycetoma patients at the Dermatology Outpatient Department (OPD) of Jose R. Reyes Memorial Medical Center over an 11-year-period from January 2014 to December 2024. Specifically, the following data were collected and analyzed: patient's age, sex, occupation, area of residence, risk factors, affected site, lesion morphology, disease duration, causative agent, mode of diagnosis, treatment given, treatment duration, and outcome. The risk factors investigated included history of trauma, immunosuppression, and malnutrition. The site of affectation was also identified. Each case was assessed for its diagnostic modality, which may have included clinical evaluation alone or in combination with microbiologic and/or histopathologic confirmation.

To address potential data quality concerns, a standardized data collection tool was used to ensure consistency, completeness, and accuracy in data abstraction. The collection tool included predefined fields covering key variables mentioned in the previous paragraph. The variables aligned with the study objectives and the WHO case definitions for mycetoma ("suspected," "probable," and "confirmed"), which were retrospectively applied based on the available clinical, histopathological, and microbiological data to ensure standardization and consistent application of diagnostic criteria across the study period.

All data entries were cross-verified by two independent reviewers. In cases of missing data, the nature of the missing information (e.g., missing microbiologic or histopathologic confirmation) was documented, and such limitations were clearly acknowledged in the analysis.

## RESULTS

### Case Reports

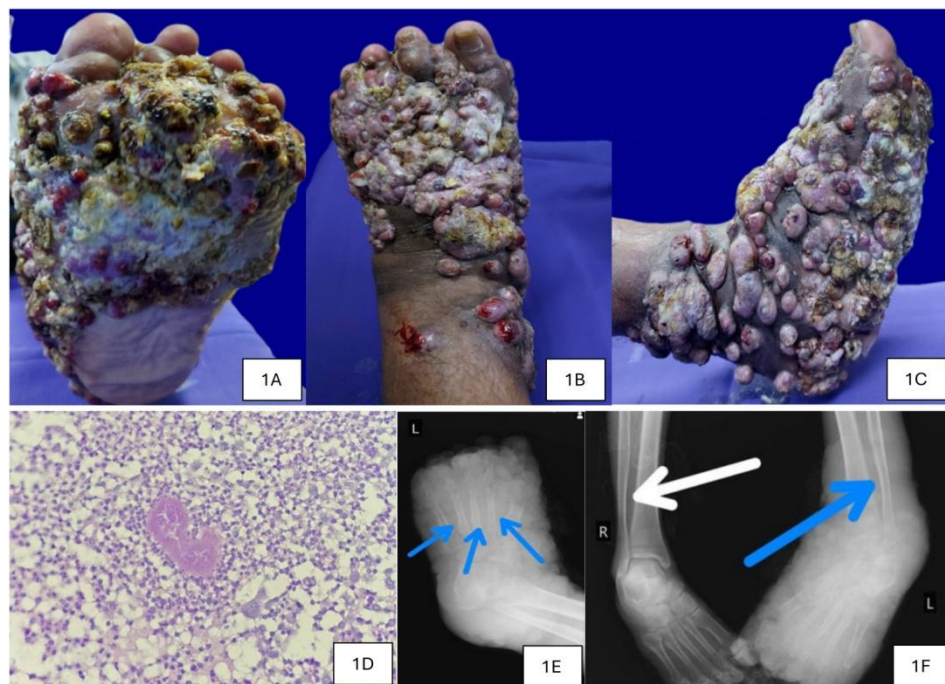
#### Case 1

A 61-year-old male construction worker from Quezon City, with no known comorbidities, a history of smoking (unknown pack-years), and occasional alcohol

intake, presented with a 25-year history of progressively enlarging nodules on the left foot (**Figures 1A-1C**). The initial lesion, a solitary asymptomatic nodule measuring approximately 0.5 cm, developed on the plantar surface of the left foot shortly after the patient had waded through floodwaters. At that time, there was no associated discharge, pain, or systemic symptoms, and the patient denied any history of trauma, radiation exposure, or prior medications. Over the years, he noted a gradual increase in both the size and number of nodules, accompanied by swelling. Ten years prior to presentation, the lesions became tender and painful on ambulation, although he remained functional in daily activities and denied fever or lymphadenopathy. Two months before consultation at our institution, the lesions progressed significantly, with marked swelling and pain that rendered the patient unable to bear weight. He also noted the development of ulcers with serosanguinous discharge, which later crusted over. This prompted medical repatriation from Saipan.

On examination, multiple well-defined erythematous nodules and tumors were observed on the dorsal, lateral, and plantar aspects of the left foot, with some showing serosanguinous discharge and crusted erosions. Lesions extended to the interdigital areas, obliterating the toe webs, while the toenails were dystrophic with distal onycholysis and subungual hyperkeratosis. There were no varicosities, and peripheral pulses were intact and symmetrical. Histopathologic analysis of a nodule showed a hyperplastic epidermis and dermal infiltrates composed of lymphocytes and neutrophils surrounding PAS-positive sulfur granules (**Figure 1D**), consistent with Actinomycetoma. No fungal hyphae were identified. Radiographic findings (**Figures 1E-1F**) demonstrated sclerotic changes in the shafts of the second to fourth metatarsals and periosteal thickening of the distal fibula, suggestive of chronic infection. Fungal culture yielded multiple contaminants, while gram staining and CBC revealed leukocytosis with neutrophilic predominance.

Based on the clinical, histologic, and radiographic findings, a diagnosis of Actinomycetoma was made. The patient was started on oral trimethoprim-sulfamethoxazole (TMP-SMX) 800/160 mg three times daily for six months and mupirocin 2% ointment applied twice daily to eroded areas for one week. Dapsone 100 mg once daily was later added following normal ancillary tests. He reported decreased pain and reduction in lesion size without adverse drug reactions and eventually lost to follow up.



**Figure 1.** Multiple well-demarcated erythematous nodules and tumors with erosions and serosanguinous discharge, some topped with yellow crusts, involving the dorsal, lateral, and plantar aspects of the left foot (1A-1C); Lesions in the interdigital spaces caused obliteration of the toes and toe webs. Dystrophic nails exhibited onycholysis and subungual hyperkeratosis; Periodic acid–Schiff (PAS) stain at 10× magnification demonstrated hyperplastic epidermis with a mixed inflammatory infiltrate composed of lymphocytes and neutrophils (1D); Radiographic imaging revealed sclerotic changes involving the shafts of the 2nd to 4th metatarsals (1E); Thickened periosteum with a uniform periosteal reaction was noted in the distal fibula (1F)  
 Images credit: Dr. MD Wong

## Case 2

A 33-year-old unemployed female from Pangasinan, with no known comorbidities and no history of smoking or alcohol intake, presented with an eight-year history of firm, asymptomatic, skin-colored papules on the left sole. The lesions persisted without intervention until three years prior to consultation, when she noted enlargement of the lesions along with white discharge and swelling. She sought consultation at a local health center and was diagnosed with a fungal infection, receiving unrecalled medications for 3 weeks which did not improve her symptoms. Persistence of the lesions prompted further medical evaluation.

An initial incision biopsy revealed granulomatous dermatitis. However, the patient was lost to follow-up. Four months later, she returned with new nodules and white discharge over the dorsum of the left foot. A repeat biopsy revealed nodular dermatitis, raising the possibility of actinomycetoma. Gram stain and PAS stain were requested. The final histopathologic diagnosis was

Actinomycetoma, although PAS stain was negative for sulfur granules. She was started on TMP-SMX 800/160 mg twice daily for four months, resulting in slight clinical improvement. She was lost to follow-up again but later returned, and the TMP-SMX dose was increased to three times daily for eight months. This led to a reduction in lesion size, drying of discharge, and lessening of pain and pruritus. The patient was subsequently lost to follow-up once more. Clinical photographs for this case were unavailable.

## Case 3

A 56-year-old male farmer from Pangasinan, with no known comorbidities, presented with a four-year history of a solitary, ill-defined hyperpigmented nodule on the left foot that progressively involved most of the dorsal aspect. He initially consulted a private dermatologist and was prescribed unrecalled topical cream and oral tetracycline 500 mg three times daily for one week,

without a specific diagnosis. He later sought a second opinion at our institution. An incision biopsy revealed findings consistent with Actinomycetoma, and a radiograph of the left foot showed diminished bone density, periosteal reaction of the fourth metatarsal, and spurring of the calcaneus.

The patient was treated with TMP-SMX 800/160 mg three times daily for nine months, resulting in improved pain, reduced swelling, and resolution of discharge. A repeat biopsy revealed scar tissue, and a follow-up X-ray showed cortical irregularity of the dorsal fourth metatarsal with associated soft tissue swelling, suggesting osteomyelitis. He was lost to follow-up for three years but returned with a two-month history of swelling and a two-week history of a fluctuant, tender nodule on the left foot. He resumed TMP-SMX therapy and was also prescribed diclofenac 50 mg as needed for pain. Two months later, he noted decreased lesion size, with intermittent eruptions resolving with medication. He reported poor response to generic TMP-SMX brands. Eight months after restarting therapy, new labs were requested, including wound gram stain, culture and sensitivity, and a repeat X-ray which again showed signs of osteomyelitis. G6PD assay was also done and yielded a value of 9.65 (low).

Dapsone 100 mg daily was added to the regimen, later tapered to every other day. The patient continued TMP-SMX for a total of 24 months and dapsone for 12 months, with significant clinical improvement including resolution of tenderness and absence of new lesions. Residual ill-defined hyperpigmented patches remained on the dorsal foot. After a two-month extension of treatment, surgical debulking and skin grafting were recommended, and he was referred to Plastic Surgery, with further plans to continue TMP-SMX and dapsone for an additional three months. Clinical photographs for this case were unavailable.

#### Case 4

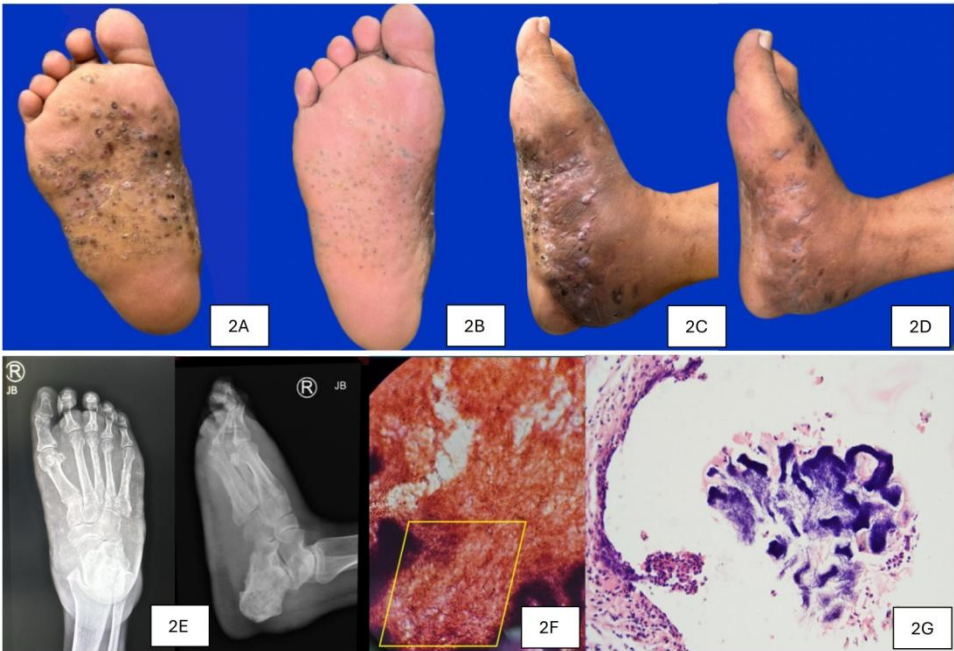
A 47-year-old male delivery man from Bulacan, a former rice field farmer for three years, with no history of smoking, alcohol intake, or known comorbidities, presented with a chronic history of right foot lesions. Fifteen years before consultation, he accidentally stepped on a barbed wire while working in a muddy field, leading to a puncture wound followed by the development of a

solitary erythematous papule with yellowish purulent discharge. This lesion resolved after one week of oral antibiotics. The patient remained asymptomatic until four years prior to consultation when he noticed a few skin-colored to pinkish papules on the dorsum of the right foot, which progressively increased in number and developed draining sinuses with purulent discharge. He denied pain, warmth, swelling, or systemic symptoms and did not seek further consultation.

Two years prior to consultation, the patient developed more lesions and nodules. An incision biopsy performed by a dermatologist in Bulacan revealed a fungal infection, for which he was prescribed unrecalled oral antifungals and a topical cream, without improvement. One year later, he sought a second opinion with a dermatologist in Pampanga who performed a punch biopsy, allegedly showing a soil-borne bacterial infection. He was treated with Doxycycline 100 mg twice daily for three months, again without improvement.

The patient later developed worsening symptoms including pain on ambulation (pain scale 8/10) and occasional pruritus, prompting referral to our institution. Examination revealed multiple skin-colored to pinkish papules and erythematous nodules on the right foot, with numerous draining sinuses and hemorrhagic to purulent discharge. There was also evident swelling of the right foot (**Figure 2A and 2C**).

X-ray of the right foot (**Figure 2E**) showed multiple lytic lesions and cortical erosions involving the tarsals, metatarsals, and phalanges, with preserved joint spaces and soft tissue swelling. Biopsy confirmed Actinomycetoma, with a positive PAS stain for sulfur granules, gram-positive filamentous bacilli (**Figure 2F**) on Gram stain and Splendore–Hoeppli phenomenon on H&E stain (**Figure 2G**). KOH mount was negative for fungal elements. The patient was treated with TMP-SMX 800/160 mg twice daily and dapsone 100 mg once daily. He showed significant improvement over the first seven months (**Figure 2B and 2D**), with resolution of swelling and decrease in the size and number of lesions, without pain, discharge, or pruritus. The patient was eventually lost to follow-up.



**Figure 2.** Multiple erythematous to hyperpigmented nodules, papules with hemorrhagic crusts, and draining sinuses on the right foot (2A, 2C); Radiograph (2E) shows multiple lytic lesions and cortical erosions; Follow-up images after 4 months (2B, 2D) of treatment showing reduced swelling, fewer papules and nodules, and resolution of crusts; Gram stain (2F) reveals gram-positive filamentous bacilli; H&E stain at 40x magnification demonstrates the Splendore–Hoeppli phenomenon (2G) *Images credit: Dr. JA Ilaya*

As shown in **Table 1**, three out of four patients (75%) were male, all of whom were over 40 years old. The single female patient (25%) belonged to the 31–40-year age group. No cases were recorded among individuals younger than 30 years. This distribution may reflect the chronic and slowly progressive nature of mycetoma, which often leads patients to seek consultation only once the disease has significantly advanced.

| Sex             | Age group |       |         |         |         |         | Total   |
|-----------------|-----------|-------|---------|---------|---------|---------|---------|
|                 | <21       | 21-30 | 31-40   | 41-50   | 51-60   | >61     |         |
| Male<br>n (%)   | -         | -     | -       | 1 (25%) | 1 (25%) | 1 (25%) | 3 (75%) |
| Female<br>n (%) | -         | -     | 1 (25%) | -       | -       | -       | 1 (25%) |

**Table 1.** Age and sex distribution of mycetoma cases (n = 4)

All cases involved pedal mycetoma, with no extra pedal lesions reported. The majority of patients were male (75%), diagnosed with actinomycetoma (100%), and residing outside Metro Manila (75%). Only one patient reported an agricultural occupation, while the remainder were classified under other occupations. No cases of eumycetoma or extra pedal involvement were identified during the study period, as shown in **Table 2**.

| Part of body | Sex        |            | Type of Mycetoma |            | Occupation   |            | Residence    |                      | Total |
|--------------|------------|------------|------------------|------------|--------------|------------|--------------|----------------------|-------|
|              | Male       | Female     | Actinomycetoma   | Eumycetoma | Agricultural | Others     | Metro Manila | Outside Metro Manila |       |
|              |            |            |                  |            |              |            |              |                      |       |
| Pedal        | 3          | 1          | 4                | -          | 1            | 3          | 1            | 3                    | 4     |
| Extra pedal  | -          | -          | -                | -          | -            | -          | -            | -                    | 0     |
| Total        | 3<br>(75%) | 1<br>(25%) | 4<br>(100%)      | -          | 1<br>(25%)   | 3<br>(75%) | 1<br>(25%)   | 3<br>(75%)           |       |

**Table 2.** Clinical and epidemiologic characteristics of mycetoma cases (n = 4), showing distribution by sex, type of mycetoma, occupation, residence, and anatomic site of involvement

As shown in **Table 3**, all patients had pedal involvement and long-standing disease ( $\geq 1$  year). Actinomycetoma was the only type identified. The most common lesion morphology was nodular. Diagnosis was made clinically and confirmed by histopathology in all cases, with microbiologic confirmation obtained in two. One patient developed deformity as a complication. No cases of eumycetoma, extra pedal disease, or severe complications such as amputation or secondary infection were observed.

|                          | Sex     |         |
|--------------------------|---------|---------|
|                          | Male    | Female  |
| <b>Co-morbidities</b>    |         |         |
| Present                  | 1 (25%) | -       |
| Absent                   | 2 (50%) | 1 (25%) |
| <b>Affected site</b>     |         |         |
| Pedal                    | 3 (75%) | 1 (25%) |
| Extra pedal              | -       | -       |
| <b>Lesion morphology</b> |         |         |
| Papule                   | 1 (25%) | -       |
| Plaque                   | -       | -       |
| Nodule                   | 2 (50%) | 1 (25%) |
| Patch                    | -       | -       |
| Ulcer                    | -       | -       |
| Pustule                  | -       | -       |
| Vesicle                  | -       | -       |
| <b>Disease duration</b>  |         |         |
| Months                   | -       | -       |
| Years                    | 3 (75%) | 1 (25%) |
| <b>Type</b>              |         |         |
| Eumycetoma               | -       | -       |
| Actinomycetoma           | 3 (75%) | 1 (25%) |
| Unknown                  | -       | -       |
| <b>Mode of diagnosis</b> |         |         |
| Clinical                 | 3 (75%) | 1 (25%) |
| Histopathological        | 3 (75%) | 1 (25%) |
| Microbiological          | 2 (50%) | -       |
| <b>Complications</b>     |         |         |
| Secondary infection      | -       | -       |
| Amputation               | -       | -       |
| Deformity                | 1 (25%) | -       |
| Atrophy                  | -       | -       |
| Pain                     | -       | -       |

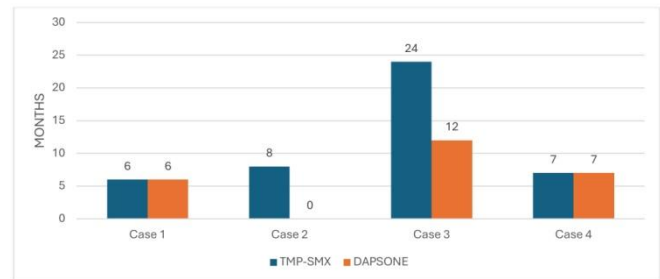
**Table 3.** Clinical profile of Mycetoma patients, stratified by sex.

As summarized in **Table 4** and **Graph 1**, three patients underwent treatment for less than 12 months and were subsequently lost to follow-up, while one patient received treatment for over 12 months and demonstrated clinical improvement. The accompanying bar graph illustrates the duration (in months) of each specific antimicrobial regimen per case, highlighting the use of trimethoprim-sulfamethoxazole (TMP-SMX) and dapsone. Combination therapy was employed in three out of four cases, with Case 3 showing the longest treatment course and the only documented improvement. These data emphasize the importance of sustained therapy and follow-up in achieving favorable outcomes.

| Type of Mycetoma | Treatment Duration | Number of Patients | Treatment Outcome |         |          |                   |
|------------------|--------------------|--------------------|-------------------|---------|----------|-------------------|
|                  |                    |                    | Improved          | Expired | Worsened | Lost to follow-up |
| Actinomycetoma   | <12 months         | 3                  | -                 | -       | -        | 3                 |
|                  | >12 months         | 1                  | 1                 | -       | -        | -                 |

Note: All cases were Actinomycetoma involving the foot

**Table 4.** Treatment duration and outcomes among patients with actinomycetoma (n = 4)



**Graph 1.** Treatment duration and regimen per mycetoma case

## DISCUSSION

Mycetoma is a chronic, progressively destructive granulomatous infection of the skin and subcutaneous tissues caused by either filamentous bacteria (actinomycetoma) or fungi (eumycetoma). It classically presents with a triad of swelling, multiple sinus tracts, and discharge containing grains<sup>9,12</sup>. The disease primarily affects the feet and lower limbs of individuals in rural, tropical regions, particularly those with frequent exposure to contaminated soil<sup>3,15,17</sup>. In 2016, the World Health Organization (WHO) classified mycetoma as a Neglected Tropical Disease (NTD) due to its chronic, debilitating course, limited diagnostic and treatment options, and disproportionate impact on impoverished populations<sup>21,22,23</sup>. This designation aims to draw global attention to the disease and promote research, surveillance, early diagnosis, and access to effective, affordable therapies.

The findings of our study are consistent with WHO's characterization. All four cases involved actinomycetoma with pedal localization, highlighting the strong association between lower extremity involvement and environmental exposure, such as barefoot walking or agricultural labor<sup>5,8,10</sup>. The absence of eumycetoma aligns with prior reports showing its predominance in arid regions like Sudan, whereas actinomycetoma is more common in Southeast Asia, including the Philippines<sup>1,14,16</sup>. This geographic variation reinforces the need for region-specific epidemiologic data and tailored public health strategies<sup>18</sup>.

A male predominance (75%) and mean patient age over 40 years reflect known global patterns, where adult males engaged in manual labor are most affected<sup>2,5,17</sup>. However, in our series, only one patient reported agricultural work, suggesting that other environmental or occupational exposures may also contribute locally. Due to the small sample size, no significant associations were found between sex, occupation, or residence and disease incidence. Nevertheless, these findings underscore the importance of

documenting risk factors in future prospective studies to support targeted case finding<sup>15,23</sup>.

A key challenge emphasized by WHO and mirrored in our findings is the difficulty in achieving long-term treatment adherence and follow-up. Three of the four patients were lost to follow-up, with only one completing over 12 months of therapy and achieving clinical improvement. This high attrition rate highlights the need for community-based education, robust referral systems, and patient support mechanisms to ensure continuity of care<sup>7,18</sup>. Without sustained treatment, patients face increased risks of recurrence, disability, and worsening quality of life which are hallmarks of the cycle of neglect WHO aims to break<sup>21,22</sup>.

Diagnostic limitations also persist. Although all patients had histopathologic confirmation, only two had microbiologic confirmation. Fungal cultures were often unavailable or contaminated, and imaging was limited to plain radiography. These challenges reflect WHO's concerns regarding diagnostic delays due to a lack of specialized laboratories and trained personnel<sup>7,22</sup>. There is a pressing need to develop point-of-care diagnostics and expand access to advanced imaging, such as MRI, which aids in disease staging and surgical planning<sup>6,11</sup>.

According to the Philippine Dermatological Society-Health Information System (PDS-HIS), a total of 101 mycetoma cases were reported from 2014 to 2024 across member institutions<sup>13</sup>. Of these, 51 were male and 50 female, suggesting a near-equal sex distribution (1.02:1), which slightly differs from the male predominance observed in our case series. Most cases occurred in young to middle-aged adults (21-50 years), particularly in the 31-40 and 41-50 age groups, supporting the role of occupational exposure during peak working years. Pediatric cases were rare, and none were documented in infants under one year old. These trends are consistent with WHO epidemiologic data and underscore the occupational risk profile of the disease<sup>3,17,23</sup>.

The geographic location of reporting institutions likely influenced case distribution. The University of the Philippines–Philippine General Hospital (UP-PGH), a major tertiary referral center in Metro Manila, reported the highest number of cases over the 11-year period. Its central location and established referral networks may have skewed case reporting toward areas with greater access to specialized care<sup>1,13</sup>. Additionally, the PDS-HIS dataset did not distinguish between actinomycetoma and eumycetoma, limiting further characterization. In contrast,

our single-center series involved exclusively adult cases of chronic pedal actinomycetoma, highlighting the importance of detailed case classification to guide treatment and inform public health policy<sup>2,8,15</sup>.

From January 2014 to December 2024, four new cases of mycetoma were diagnosed at our institution, which served a population of approximately 333,147 individuals during that period. This corresponds to an estimated incidence rate of 0.11 cases per 100,000 population per year, consistent with the global classification of mycetoma as a rare disease with low incidence but high morbidity if left untreated<sup>17,20,23</sup>. Despite its rarity, the burden of chronic disability, occupational loss, and disfigurement justifies its inclusion in national surveillance and public health programs, even in countries where it is uncommon<sup>18,21</sup>.

All statistical analyses were conducted using Fisher's Exact Test, appropriate for small sample sizes and sparse data. However, the limited number of cases ( $n = 4$ ) rendered the analyses underpowered. While trends such as male predominance, older age, and pedal localization were observed, these findings are descriptive rather than inferential. The absence of a control group and the inability to assess causation further limit generalizability<sup>15</sup>.

Despite these limitations, this study contributes valuable local data to the sparse literature on mycetoma in the Philippines and Southeast Asia<sup>1,14</sup>. It highlights the need for larger, prospective studies that incorporate microbiologic confirmation, advanced imaging for staging, and long-term follow-up to evaluate treatment outcomes<sup>6,7,10</sup>. Ultimately, our findings reinforce WHO's call to action in the Ending the Neglect roadmap, urging national and regional collaboration in research, education, and policy to reduce diagnostic delays, improve treatment adherence, and lessen the burden of this preventable and manageable condition<sup>18,21,23</sup>.

## CONCLUSIONS

Mycetoma, although rare in the Philippine setting, poses a diagnostic and therapeutic challenge due to its chronicity and potential for significant morbidity. This case series highlights the predominance of actinomycetoma, its association with pedal involvement, and a higher prevalence among older males. The importance of long-term treatment and continuity of care was also underscored by treatment outcomes. Given the WHO's recognition of mycetoma as a neglected tropical disease, greater emphasis should be placed on early detection, diagnostic access, and patient retention to ensure effective disease management.

## LIMITATIONS OF THE STUDY

This study only included mycetoma data from the outpatient department of Jose R. Reyes Memorial Medical Center, Department of Dermatology, within the period of January 2014 to December 2024. A potential selection bias may have existed, as only more clinically apparent or severe mycetoma cases may have undergone microbiologic or histopathologic confirmation which may have resulted in an overestimation of certain diagnostic categories or underrepresentation of early or mild cases. Mycetoma data from the other departments of the hospital were not included. Also, since this was a retrospective review of charts, there was an inherent physician-level variation in terms of history taking and physical examination data reporting. Furthermore, there was a high rate of loss to follow-up, which limited the assessment of long-term treatment outcomes and response to therapy which may reflect barriers to healthcare access, treatment costs, or lack of disease awareness, and highlights the need for improved patient tracking and retention strategies in chronic infectious diseases. Finally, the COVID-19 pandemic may have impacted clinic attendance, diagnostic work-up, and overall case detection during the study period.

## RECOMMENDATIONS

The results of this study highlight the need to enhance disease awareness among healthcare providers, particularly in endemic and resource-limited settings, through sustained medical education and community engagement. Expanding access to confirmatory diagnostics such as microbiologic testing, histopathology, and imaging should be prioritized in regional centers to enable timely and accurate diagnosis. The establishment of a standardized patient monitoring system, including teleconsultation, may serve as a practical and cost-efficient strategy to reduce loss to follow-up and ensure treatment continuity in underserved areas. Developing evidence-based, affordable treatment guidelines using widely available agents like trimethoprim-sulfamethoxazole and dapsone is also warranted. Furthermore, implementing a national mycetoma registry and surveillance system would provide essential data to better understand disease burden and inform public health planning. Lastly, future studies should focus on larger, prospective cohorts using standardized diagnostic and therapeutic protocols to improve outcomes for this neglected tropical disease.

## CONFLICTS OF INTEREST

None.

## FUNDING

The primary investigator personally funded this study. Neither the primary nor the co-investigators received any sponsorship.

## ACKNOWLEDGEMENT

The clinical images included in this paper were originally taken as part of routine patient documentation by Drs. Wong and Ilaya, who were the primary physicians at the time the patients were seen. As this study was a retrospective chart review, their contributions were limited to patient care and clinical photography. They were not involved in the study design, data analysis, or manuscript writing, and therefore are not listed as authors. All photographs were stored securely in the department's external archive, and written informed consent for medical photography was obtained from the patients prior to image capture.

## AVAILABILITY OF DATA AND MATERIAL

Data supporting this study are available from the corresponding author upon reasonable request.

## ETHICAL CONSIDERATIONS

This study adhered to the ethical principles outlined in the Declaration of Helsinki and the National Guidelines for Biomedical Research of the National Ethics Committee (NEC) of the Philippines. Ethics approval was obtained from the Institutional Review Board (IRB) of Jose R. Reyes Memorial Medical Center (Protocol No. 2025-052, approved on May 9, 2025). Each subject was assigned a unique study code, and all patient information was treated with strict confidentiality.

## INFORMED CONSENT

This study involved a retrospective review of medical records and did not require direct patient contact. The Institutional Review Board (IRB) of Jose R. Reyes Memorial Medical Center waived the need for individual informed consent for inclusion in this chart review. However, written informed consent for clinical photography was obtained from all patients at the time of their clinical care.

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