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Editorial Office:

2nd Floor PMA Building, North Avenue, Quezon City 1105 Philippines
Contact Numbers: +(632) 929-7361; +(632)929-6366; Fax: +(632) 929-6951
Website: www.philippinemedicalassociation.org;
E-mails: info@philippinemedicalassociation
philmedas@yahoo.com; philmedas@gmail.com

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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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Middle Fingertip to Rascette Line Measurement Novel Approach to Endotracheal Tube Depth for Filipinos: A Pilot Study*

Joel P. Cabañas, MD¹

ABSTRACT

A predetermined endotracheal tube depth prior to intubation ensures correct tube placement relative to the carina. The objective of this study was to determine if the topographic measurement from the middle fingertip (MFT) to Rascette line (RL) or "wrist line" correlates with acceptable endotracheal tube (ET) depth during orotracheal intubation. This was a prospective, analytical cross-sectional pilot study of 54 adult Filipino patients who underwent general anesthesia with orotracheal intubation. The middle fingertip to Rascette line measurement was utilized as the basis for endotracheal tube depth with ET secured on the right corner of the mouth. After intubation, a chest x-ray was performed to measure the distance from the endotracheal tube tip to the carina. The study showed that the average middle fingertip to Rascette line measurement among Filipinos was 18.79cm (± 1.08) which resulted in 85.19% of patients with ET tip to carina within the acceptable distance of 2-5cm, with a mean value of 3.17cm. The mean MFT to RL measurement in females was 18.28cm and 19.81cm in males. The mean distance of ET tip to carina in females was 2.91cm and 3.66cm in males. There was a significant positive correlation between the middle fingertip to Rascette line measurement and height. This study also documented the total length from the right corner of the mouth to carina, by adding middle fingertip to Rascette line measurement and the distance from ET tip to carina, resulting in a mean value of 23.46cm (± 2.06) in males and 21.19 cm (± 1.73) in females. In conclusion, middle fingertip to Rascette line measurement is an acceptable

technique to determine individualized endotracheal tube depth during orotracheal intubation. This topographic measurement resulted in 96.29% of ET tip ≥ 1 cm above the carina.

Keywords: *middle fingertip, Rascette line, middle fingertip to Rascette line measurement, orotracheal intubation*

INTRODUCTION

Endotracheal intubation is the gold standard for airway management and most commonly performed procedures in the field of anesthesiology, emergency medicine and, critical care.¹ One of the fundamental responsibilities of an anesthesiologist is to establish airway patency during general anesthesia to ensure adequate ventilation and oxygenation.² One of the major concerns during intubation is incorrect placement and inappropriate depth of endotracheal tube (ET) within the airway associated with serious complications which can lead to morbidity and mortality. Over-insertion may result in endobronchial intubation, one-lung ventilation, and collapse of the other lung which may finally result in hypoxia.³ Unintended bronchial intubation accounts for 4% of the adverse respiratory events in pediatric patients and 2% among the adult population. On the other hand, under-insertion of the tube may inappropriately place the inflated cuff over the vocal cords leading to vocal cord trauma, laryngeal nerve compression, and inadvertent extubation.⁴ Therefore, determining the correct depth of endotracheal tube is crucial and should be individualized.

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¹From West Visayas State University Medical Center, Iloilo City

There are several methods of estimating optimal endotracheal tube length in orotracheally intubated adult patients. This includes auscultation for bilateral breath sounds along with symmetrical chest expansion⁵, and palpation of the cuff at the suprasternal notch.⁶ However, auscultation alone is still inadequate for assessing the actual depth of endotracheal tube insertion⁷ and it cannot rule out endobronchial tube placement. Chest radiography has been commonly used to confirm proper positioning of the endotracheal tube tip post-intubation. Although fiberoptic bronchoscopy (FOB) is the definitive way of confirming the position of the endotracheal tube tip, it requires expertise to handle, not routinely available in the operating theater, and is costly.⁴

The standard insertion tube depth for orotracheal intubation is 21cm for women and 23cm for men (21/23 rule) among Caucasians.⁸ Such rough estimations however can lead to inadvertent endobronchial intubation especially among Filipinos with expected shorter tracheal length. Individualized measurement of endotracheal tube length provides optimal tube depth, avoids malpositioning and significantly limits tube adjustment after successful intubation. At present, there has been no data on the optimal endotracheal tube depth among Filipinos. The general objective of the study is to determine if the middle fingertip to Rascette line measurement correlates with acceptable endotracheal tube depth during orotracheal intubation. Specifically, the study aims; 1) To determine the average tube length of patients undergoing orotracheal intubation. 2) To determine if there is a significant difference in the tube length between males and females. 3) To determine if the topographic measurement from the middle fingertip to Rascette line will result in equal breath sound on auscultation, symmetrical chest rise, oxygen saturation of 98-100%, and normal end-tidal carbon dioxide (ETCO₂) levels. 4) To determine if topographic measurement from middle fingertip to Rascette line will result in endotracheal tube tip positioned above the carina. 5) To determine if topographic measurement from the middle

fingertip to Rascette line could provide an acceptable measurement of endotracheal tube length after orotracheal intubation without repositioning.

MATERIALS AND METHODS

Study Design

This was a prospective, analytical cross-sectional pilot study design.

Study Setting

This study was conducted at the Operating Room Complex of the said institution.

Population and Sampling Technique

A total of 54 adult Filipino patients, 19 years old and above, admitted as service accommodation, either for emergency or elective surgery, under general anesthesia via orotracheal intubation through direct laryngoscopy or video laryngoscopy. The respondents were selected purposively for the conduct of research regardless of gender. Due to the recent pandemic there has been a large decline in the number of operations. The latest census was an average of 20 cases of intubation per month, a total of 240 estimated cases for 2020. With the increasing cases of COVID-19 in the community, the operation of elective cases in the institution where the study was conducted was temporarily suspended from August to September 2021. This dramatically decreased the number of possible participants of the study because almost 90% of study participants were from elective surgery cases. Thus, this research was amended into a pilot study with 54 sample size study participants and was approved by the Unified Research Ethics Review Committee.

Inclusion Criteria: American Society of Anesthesiologists (ASA) 1 to 3 adult Filipino patients under service accommodation, 19 years and above of either sex, scheduled either for emergency or

elective surgery under general anesthesia via orotracheal intubation through direct laryngoscopy or video laryngoscopy. All patients who were included in the study had negative RT-PCR results for Covid-19.

Exclusion Criteria: Patients who refused to be part of the study and those who did not sign the informed consent were excluded. Patients categorized as American Society of Anesthesiologists (ASA) 4 to 6, with severe anatomical defects of the face, neck and upper airway were part of exclusion criteria. Patients who will undergo nasotracheal intubation, and with findings of pneumothorax or atelectatic lungs prior to intubation were also excluded. Pregnant patients and those with hand deformities from trauma, burns or amputations were excluded. Patients scheduled for operation at the Covid Operating Room were not included in the study. Patients for bronchoscopy or fluoroscopy-guided brush biopsies performed in the operating room were excluded. Patients who are mentally ill due to psychological or developmental disorders who could not give his/her consent were also excluded from the study.

DATA COLLECTION PROCEDURE

The researcher was the one who performed the procedural steps in measuring middle fingertip to Rascette line of all study participants using the same calibrated measuring T-square (see Appendix 1 and 2).

Preoperative Procedure: A standard preoperative evaluation form, approved and registered with the Quality Assurance Office, was administered to the patient by the anesthesiologist in-charge. The assessment was done by the researcher based on the inclusion and exclusion criteria. Once qualified, the patient was invited by the researcher to participate in the study. As the patient agreed, the consent form either in English or Hiligaynon was explained to the patient and once amenable was made to affix his/her signature.

At the time of surgery, the patient was positioned on the operating table with the head in a neutral position provided with appropriate head support or pillow. ASA standard monitors such as non-invasive blood pressure (NIBP), electrocardiogram (ECG), pulse oximeter, and capnography (if available) were provided to the patient. Oxygen at 2 liters per minute via nasal cannula was delivered to the patient while preparing for induction.

The anesthesiologist in-charge chose the estimated endotracheal tube size for females from 6.0mm, 6.5mm and 7.0mm internal diameter (ID). As for male patients, the ET size ranged from 7.0mm, 7.5mm, 8.0mm and 8.5mm ID. The size of the endotracheal tube used corresponds to the estimated size of the little finger of each patient.

Induction of Anesthesia: Preoxygenation with 100% oxygen via fitted face mask for 3- 5 minutes was performed prior to induction of general anesthesia for elective cases. For emergency operations where, rapid sequence induction (RSI) was warranted, the anesthesiologist in-charge preoxygenated the patient by instructing him/her to have 8 breaths with full inhalation and exhalation (maximum capacity breath) for 60 seconds or 4 full breaths in 30 seconds. Adequate preoxygenation was essential to provide an increased length of time before oxygen desaturation occurs in an apneic patient while the anesthesiologist was securing the airway.

The anesthesiologist in-charge decided on his/her preferred anesthetic medication for induction, appropriate for the clinical status of the patient. Once the patient was paralyzed and the condition was appropriate for intubation, laryngoscopy was performed using video laryngoscope C-MAC D-blade (Karl Storz) or Macintosh blade size 3 or 4.

The anesthesiologist in-charge of performing the intubation made sure that the pre-

determined tube measurement is at the level of the patient's right corner of the mouth. Once the identified level of the tube was on the right corner of the mouth, the anesthesiologist halted further tube insertion. The anesthesiologist also ensured that the ET cuff has passed through the vocal cords. The assistant anesthesiologist performed 5 point auscultation to assess for bilateral and equal breath sounds at the same time observing bilateral chest rise. Monitoring with capnography if available to confirm endotracheal tube placement was observed with the presence of 6 consecutive waveforms. Pulse oximetry reading was also documented within 1 minute after tube placement. Endotracheal tube cuff inflation was done using an appropriate volume of air. The endotracheal tube was secured using a surgical plaster on the right corner of the mouth while maintaining the head and neck in a neutral position.

Post-Intubation: Post intubation chest radiograph using a portable x-ray machine was done to measure the distance of the endotracheal tube tip relative to the carina. Fiberoptic bronchoscopy was not utilized to confirm ET tip location in this study because it is an aerosol generating procedure. The acceptable distance of ET tip to carina in this study was between 2-5cm. If the post-intubation x-ray reading of the tube to carina distance was not within the acceptable value, the anesthesiologist in-charge will deflate the cuff and adjust the tube until the acceptable ET tip to carina distance (2-5cm) was reached. The measured ET to carina distance after tube adjustment was also recorded in the data collection form. Collected data underwent review for completeness of information needed and was secured in a brown envelop at the office of the Department of Anesthesiology.

DATA PROCESSING AND ANALYSIS

Data were analyzed using SPSS version 22 and presented as mean $\pm$ SD, number of patient and

percent. Continuous variables (such as age, height, weight, ET tip to carina distance, middle fingertip to Rascette line measurement) were presented as mean $\pm$ SD. Categorical variables (Mallampati Class, patients needing ET repositioning, patients with clear breath sounds after intubation) were presented as absolute number (n) and percentage (%). Mann-Whitney U and Wilcoxon W test was used to analyze the statistical difference between males and females with an alpha value set at 0.01. Pearson correlation plot was also utilized to analyze the correlation between middle fingertip to Rascette line and height.

ETHICAL CONSIDERATIONS

Confidentiality was strictly observed with regards to personal information gathered from study participants. Data gathering and data handling were done in accordance with the Data Privacy Act of 2012. The data collection started after approval from the Unified Research Ethics Review Committee (URERC). Only the researchers directly involved in this study and the statistician have access to the actual data collected for statistical analysis. The data was stored in a password-protected laptop of the researcher and the statistician. After 5 years the data and forms will be discarded.

RESULTS

A total of 54 underwent operation from March 2021 to September 2021 consented to take part in the study. Out of 54 patients, 10 underwent an emergency operation and 44 were under elective surgery. Overall, 6 (11.11%) patients were categorized as ASA 1, 32 (77.78%) ASA 2 and 6 (11.11%) were ASA 3. There were

36 (66.67%) female and 18 (33.33%) male patients who participated in the study with ages 19 to 69 years old. The standing height of patients ranged from 147 to 175cm.

Overall, the average middle fingertip (MFT) to Rascette line (RL) measurement was 18.79cm

(± 1.08). In males it ranged from 17cm to 21cm with a mean value of 19.81cm (± 0.99) while in female patients it ranged from 17cm to 20cm with a mean value of 18.28cm (± 0.70).

The Mann-Whitney U and Wilcoxon W test output shows that there was a significant difference in the mean rank of middle fingertip to Rascette line between male and female with $p=0.000$ (alpha value = 0.01)

All patients who underwent intubation had symmetrical chest expansion, equal breath sounds, with oxygen saturation of 99 to 100%. Capnography monitoring was only used to 24 (44.44%) patients because there was only one monitor available in the operating theater. This was used by another patient when 30 (55.56%) of study participants without capnography monitoring underwent an operation. Single attempt intubation was successfully performed using a Macintosh blade or video laryngoscope D-blade.

Utilizing the MFT to RL measurement resulted to the distance of endotracheal tube (ET) tip to the carina with a mean value of 3.17cm (± 1.25). This was within the acceptable range of 2-5cm to ensure safe ET placement in the trachea. Using the predetermined MFT to RL measurement as ET depth for intubation, resulted in a mean distance of the ET tip to carina of 2.91cm (± 1.22) in females and 3.66cm (± 1.36) in males.

Out of 54 patients, 46 (85.19%) had ET tip 2-5cm from the carina which is the acceptable distance without tube repositioning. However, 6 (11.11%) and 2 (3.7%) patients had endotracheal tubes <2cm and >5cm away from the carina respectively. Using the MFT to RL measurement, 52 out of 54 patients (96.29%) had ET tip positioned ≥ 1 cm above the carina, while 1 patient with ET tip directly at the carina and 1 patient with right mainstem endobronchial intubation. The farthest distance of the ET tip from the carina in the study measures 6.1cm.

Using the Pearson correlation plot, there was a significant relationship between middle fingertip to Rascette line measurement and height of patients as seen in Figure 1 below. It can be observed that middle fingertip to Rascette line measurement and height were significantly related with covariance (5.034) and correlation (0.756) values were both positive. Thus, taller patient tends to have longer MFT to RL measurements.

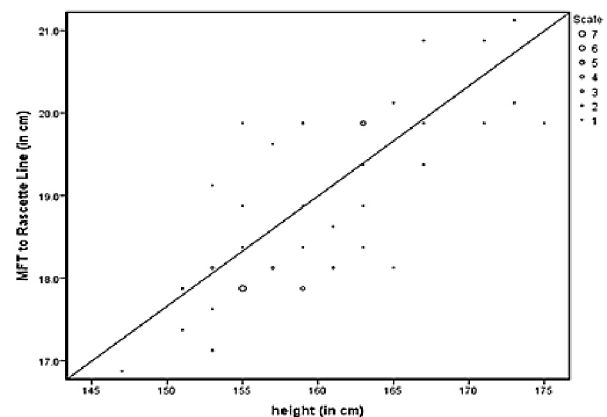


Figure 1. Correlation of middle finger tip to Rascette line and height using Pearson correlation plot.

In addition, this study also documented the entire length from the right corner of the mouth to the carina. This was derived by adding the middle fingertip (MFT) to Rascette line (RL) measurement and the distance from the ET tip to the carina (see Appendix 3). The distance from the right corner of the mouth to carina in male patients ranged from 21.1 to 26.1cm with a mean value of 23.46cm (± 2.06) as shown in Figure 2. While in females it ranged from 17.5 to 24.4cm with a mean value of 21.19 cm (± 1.73) in Figure 3. Mann-Whitney U and Wilcoxon W test output shows that there was a significant difference in the mean rank of the distance from the right corner of the mouth to carina between male and female with $p=0.000$ (alpha value = 0.01).

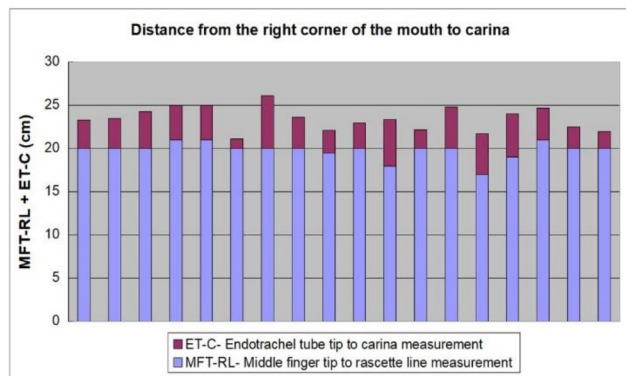


Figure 2. Total distance from the right corner of the mouth to carina among Filipino male patients.

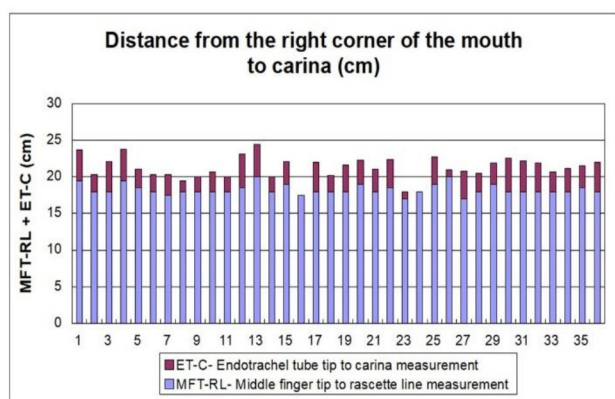


Figure 3. Total distance from the right corner of the mouth to carina among Filipino female patients.

Furthermore, Figure 4 shows that there was a significantly high degree of correlation between the distance from the right corner of the mouth to carina and the height of patients with $p=0.000$ (alpha value = 0.01). The covariance (6.903) and correlation (0.612) values were both positive which shows that taller patients tend to have a longer distance of measurement from the right corner of the mouth to carina. Thus endotracheal tube depth should be individualized because the risk of endobronchial intubation is higher among female and shorter patients.

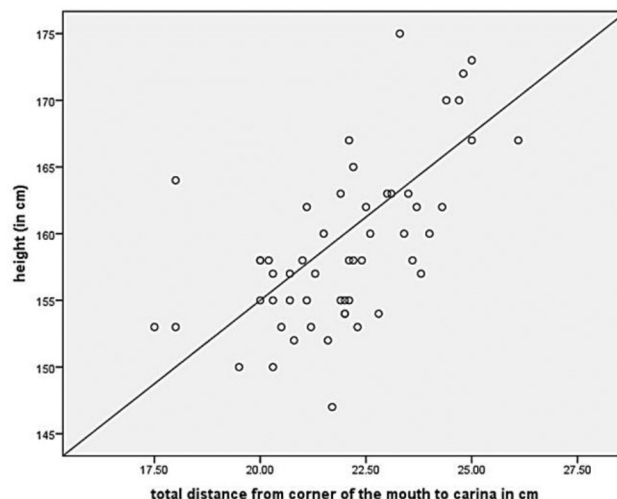


Figure 4. Correlation of distance from the right corner of the mouth to carina and height using Pearson correlation plot.

Endotracheal intubation is a primary technique in securing the airway and ensuring adequate ventilation of patients for surgery under general anesthesia. Proper positioning of endotracheal tube (ET) tip in relation to carina remains a concern. This pilot study was the first to provide data on acceptable endotracheal tube depth during intubation among adult Filipinos using middle fingertip to Rascette line as a topographic measurement.

In this prospective, analytical cross-sectional pilot study, out of 54 adult intubated patients, the mean middle fingertip (MFT) to Rascette line (RL) measurement was 18.79cm (± 1.08). Utilizing the MFT to RL measurement as a basis for predetermined endotracheal tube depth, 85.19% of patients had an acceptable distance of ET tip to carina within 2-5cm. The mean distance of the endotracheal tube tip to carina in this study was 3.17cm (± 1.25) with the patient in a neutral supine position.

The average endotracheal tube (ET) depth in females was shorter at 18.28cm (± 0.70) compared to 19.81cm (± 0.99) in males. After intubation, chest x-ray was performed to measure the distance of ET tip

relative to the carina. The mean distance from ET tip to carina was shorter in females which is 2.91cm and 3.66cm in males. In this study, 85.19% (46) of patients had an acceptable ET tip of 2-5cm away from the carina which is considered safe. The remaining 11.11% (6) patients had ET tip <2cm and 3.7% (2) >5cm away from the carina. Out of 6 patients with ET tip <2cm, 1 female patient with ET tip at the right mainstem bronchus, 1 female patient with ET tip directly at the carina, 4 patients with ET tip 1-1.5cm from the carina (1 male, 3 females). For two patients with ET to carina distance of >5cm, it was 1 male with 6.1cm and 1 female with 5.4cm distance. These findings suggest that the middle fingertip to Rascette line measurement is about 96.29% accurate in estimating the position of the ET tip ≥ 1 cm above the carina.

The result of our study is comparable to the study done by Techanivate et. al⁶, on 100 adult Thai patients utilizing the Chula formula which is $4\text{cm} + (\text{patient height in cm}/10\text{cm})$ to calculate ET depth. In their study, the mean ET depth was 19.6cm in females and 20.8cm in males. The mean distance from the ET tip to carina was 3.0cm in females and 4.1cm in males measured through fiberoptic bronchoscopy. The mean distance from the vocal cords to the upper border of the ET cuff was 4.6 cm in females and 4.5 in males. This study has 99% accuracy in estimating the proper position of orotracheal tube provided there is a known height of the patient for the formula. However, in our study, the distance of vocal cords from the upper border of ET cuff was not possible to measure through chest x-ray.

The use of standard 21/23cm rule for endotracheal depth was studied in 83 Caucasian patients by Roberts et. Al.⁹ This resulted in 97% acceptable ET placement, with a mean distance of ET tip from carina of 3.45cm for females and 4.1cm for males. For Filipinos with shorter stature, the use of the 21/23 cm rule could possibly result in endobronchial intubation to several patients. Ong et al,¹⁰ reported in their study that using the 21/23 rule

in Asian populations increases the risk of endobronchial intubation. According to Sitzwohl et al,¹¹ the use of 21/23 conventional methods for ET depth will result in deep intubation and recommended that the depth of ET from the central incisor should be 20cm in females and 22cm in males. Park et al,¹² reported that ET depth is safe at 20cm for Korean males and 18cm for females, whereas Varshney et al,¹ reported that the ET depth in the Indian population was 20.26cm for males and 18.23 for females secured from the right corner of the mouth. Hence, endotracheal tube depth should be individualized considering the ethnicity and height of patients accompanied by a thorough physical examination, clinical assessment and appropriate monitoring.

Amos et al,¹³ analyzed 708 intubated ICU patients admitted in Ng Teng Fong General Hospital Singapore and found out that in all ethnic groups (Chinese, Malay, Indian, etc) the average ET depth was 22cm, while 21cm in females and 22cm in males. In this study, ET tip to carina distance was 2-5cm in 58.7%, >5cm in 26.6%, 2cm in 12.4% and 2.3% had endobronchial intubation. Their mean ET depth was longer compared to our study which was 18.79cm among Filipinos, 18.28cm in females and 19.81 in males. The large difference is probably due to different ethnic groups that were included in their study population.

Topographic measurement of the middle fingertip to rascette line as an estimate of endotracheal tube depth resulted in all patients with symmetrical chest expansion, bilateral clear breath sounds and oxygen saturation of 99-100%. Repositioning was done to 8 patients (2 males, 6 females) with of ET tip to carina distance of <2cm and >5cm away. This was to ensure that the patients ET tip was within the acceptable range of 2-5cm away from the carina. However, there were still 2 female patients with ET tips both estimated less than 2cm because 1 had an initial ET tip directly close to the carina and 1 had right mainstem endobronchial intubation. In these 2 patients, ET was pulled out 1cm

only because of the fear that ET cuff would accidentally pass beyond the VC and the risk of dislodge may occur. Repeat chest x-ray was not done to 8 patients who underwent tube repositioning. There was no occurrence of perioperative airway events to all study participants and all patients were immediately extubated post-operatively. Brunel et al,¹⁴ reported that in 5% with mainstem bronchial intubations, half of these patients still present with equal bilateral breath sounds on auscultation. This is possible especially if the Murphy's eye of the ET tube faces towards the contralateral mainstem bronchus. Endobronchial intubation was more common in females than in males and frequently occur during emergency intubations.

Based on Pearson correlation coefficient analysis, there was a positive relationship between middle fingertip to Rascette line measurement and height. Taller patients tend to have longer middle finger tip to Rascette line measurement. Endotracheal tube depth directly correlates to the height of the patient. Varshney et al,¹ found that the upper airway length has significant correlation with height, arm span and vertebral column length ($p < 0.01$). Therefore, shorter patients require more vigilant and careful evaluation during endotracheal intubation.

Our study also documented the entire length from the right corner of the mouth to carina. With the patient in a neutral supine position, this can be derived by adding the middle fingertip to Rascette line measurement and the measured distance from the endotracheal tube tip to carina. The distance from the right corner of the mouth to carina in male patients ranged from 21.1 to 26.1cm with a mean value of 23.46cm (± 2.06) and in females, it ranged from 17.5 to 24.4cm with a mean value of 21.19 cm (± 1.73). This is comparable to the study done by Kumari et al,¹⁵ where they used a fiberoptic bronchoscope to measure the distance from the lip to carina which was 21.3cm in females and 22.9cm in males. Varshney et al,¹ reported that the distance

from lip to carina was 21.62 cm (± 1.34) in females and 24.32cm (± 1.81) in males.

Our study had some limitations. The study was not able to document the distance from the vocal cord to the proximal border of the ET cuff because the cuff was not visible under the chest x-ray. The distance from the vocal cord to the proximal border of the cuff should be adequate to avoid critical incidents of inadvertent extubation and compression of recurrent laryngeal nerve. The study was not able to reach its original sample size of 80 patients due to a lack of study participants. Admission of elective cases for surgery was put on hold temporarily for almost 2 months due to the surge of Covid-19 cases. The investigators decided to amend the research into a pilot study and extend its duration for data collection. The amendments were approved by the Unified Research Ethics Review Committee.

The present study confirms the applicability and reliability of the middle fingertip to Rascette line measurement as an estimate of endotracheal tube depth. A simple method such as this to determine appropriate tube depth for intubation could help avoid endotracheal tube malpositioning. The recommended lengths of the ET for orotracheal intubation have been proposed based on patient height and suggested formulas for which vary with different ethnic populations.

In conclusion, middle fingertip (MFT) to Rascette line (RL) measurement is an acceptable technique to determine endotracheal tube (ET) depth during orotracheal intubation. The mean airway distance is shorter among Filipino population with an average endotracheal depth of 18.28cm (± 0.70) for females and 19.81cm (± 0.99) for males. The success rate of properly positioned ET tip ≥ 1 cm above the carina is 96.29% in the present study, with 85.19% within the acceptable ET tip to carina distance of 2-5cm. Height positively correlates with the MFT to RL measurement at the same time with the total length from the right corner of the mouth to carina. Using

the MFT to RL measurement provides individualized ET depth and prevents malpositioning during intubation. This technique may be useful during emergency intubations particularly in settings where a chest x-ray is not readily available to assess the level of the endotracheal tube tip in the trachea.

Further study is suggested using a larger sample size or in a multi-center, with an equal number of male and female study participants, would be helpful in establishing the effectiveness of this technique. It is also recommended to expand study participants including the pediatric population 18 years old and below for they are at higher risk of endotracheal tube malpositioning. The use of fiberoptic bronchoscopy would be essential if further studies would include determining the distance of the vocal cords to the proximal border of the endotracheal tube cuff. Middle fingertip to Rascette line measurement is also recommended to study its applicability for endotracheal tube depth with other races.

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APPENCIDES

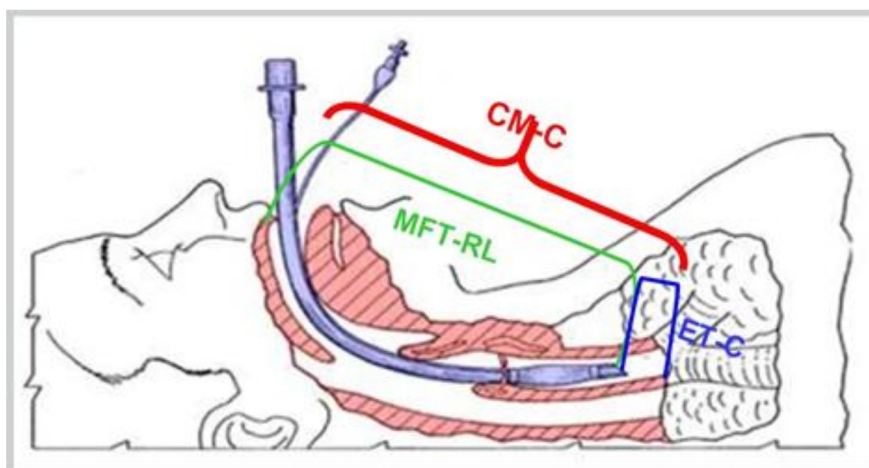
Appendix 1. Rascette line or Wrist line



Appendix 2. Middle finger tip to Rascette line measurement



Appendix 3. Total distance from the right corner of the mouth to carina



Performance Evaluation of Standard™ Q Covid-19 Ag Saliva Test in Detection of Covid-19 Among Patients in Tertiary Hospital*

Rosita Mae Q. Santos, MD¹

ABSTRACT

Newer diagnostic tests for COVID-19 such as antigen tests are being used for rapid identification of cases. Compared to reverse transcriptase polymerase chain reaction (RT-PCR), these tests offer simpler collection and processing. This study aims to determine the accuracy of a SARS-CoV-2 antigen-detecting rapid diagnostic test (Ag-RDT) using saliva compared to nasopharyngeal and oropharyngeal swab (NPS/OPS) RT-PCR among patients tested in the Emergency Room at Makati Medical Center. Patients who underwent NPS/OPS RT-PCR and who consented to participate in the study were asked to submit salivary sample to be analyzed using the Standard™ Q Covid-19 Ag Saliva Test kit. A total of 366 samples were collected. The overall accuracy was 81.69% with a sensitivity of 63.58% and a specificity of 97.93%. Subgroup analyses as to processing time, number of days from symptom onset, and presence or absence of symptoms had no effect the overall accuracy. The Standard™ Q Covid-19 Ag Saliva Test kit was able to satisfy the $\geq 97\%$ specificity recommended by the WHO for SARS-CoV-2 Ag-RDTs but did not meet the minimum performance requirements of $\geq 80\%$ sensitivity. A positive test results can help in the initiation of early treatment and isolation of cases, but a negative test should still be confirmed by NPS/OPS RT-PCR test.

Keywords: Saliva Test for COVID-19, SARS-CoV-2 Ag-RDTs, COVID-19 Antigen Test

BACKGROUND

Coronavirus disease 2019 (COVID-19), is a respiratory disease that has overwhelmed the world since the first quarter of 2020. Among the most important strategies to slow down and decrease the spread of the disease is early detection and isolation. There are several diagnostic tests that identifies SARS-CoV-2 virus. Some are specimens from the nasopharyngeal, oropharyngeal cavity, nasal mid-turbinate, anterior nares, nasopharyngeal or nasal wash or aspirate, and recently, on saliva.¹

The gold standard for detecting and diagnosing SARS-CoV-2 is the reverse transcriptase polymerase chain reaction (RT-PCR).² Respiratory samples collected through nasopharyngeal swab (NPS) and oropharyngeal swab (OPS) are recommended specimens for SARS-CoV-2 RT-PCR testing.³ Newer diagnostic tests offer alternative methods to collect respiratory samples such as saliva antigen tests. These tests offer simpler collection procedures for both patient and laboratory staff. Initial reports show that the accuracy of saliva RT-PCR tests in detecting SARS-CoV-2 is comparable to NPS/OPS RT-PCR.

OBJECTIVE

The aim of this study to determine the sensitivity and specificity of COVID-19 antigen saliva test compared to NPS/OPS RT-PCR. Furthermore, it aims to determine the accuracy of these tests among patients tested for SARS-CoV-2

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¹From Makati Medical Center

in the Emergency Department and the outpatient laboratory.

RESEARCH QUESTION

Is the COVID-19 antigen saliva test an accurate test to detect SARS-CoV-2 as compared with the gold standard NPS/OPS RT-PCR test?

SIGNIFICANCE

Evaluating the performance of a certain diagnostic test is needed prior to the use of any new diagnostic tests. The COVID-19 saliva antigen test offer advantages compared to the NPS/OPS RT-PCR including faster turn-around-time, ease of procedure, and cost-effectiveness. This test can also be deployed in outbreak settings during contact investigation without the need for trained staff to do NPS/OPS.

Published studies on the saliva antigen tests for COVID-19 have shown that saliva specimen is comparable to nasopharyngeal specimens and sometimes even yield more positive results.^{4,5} Performing a validation study in the local setting is important to determine the performance of the tests in our own population. The results of this study will guide the hospital and doctors in crafting guidelines on the use of these tests in the diagnosis of COVID-19.

LITERATURE REVIEW

DIAGNOSTIC TESTS FOR COVID-19

Reverse Transcriptase Polymerase Chain Reaction

Reverse Transcriptase Polymerase Chain Reaction (RT-PCR) is a simple approach that uses a DNA template to amplify unique in vitro DNA fragments. The estimated sensitivity is approximately 70% while the specificity is about 95%.

Results from RT-PCR test can be affected by the method of collection and viral load sample.^{6,7} There is a relatively high false negative result for RT-PCR when used during the early course of illness. Viral evolution and timing of collection may affect the results.⁸

RT-PCR is the gold standard for diagnosing SARS-CoV-2 infection by recognizing viral genomes in different samples and detecting the viral RNA.^{7,9} It is highly sensitive and specific and may be used to detect COVID-19 early.¹⁰ It may yield to a false negative result depending on the environment, handling, technique and expertise of handler. Furthermore, viral load and stage of illness may also affect the results.⁹ A combination of clinical, molecular and serological tests may be adjunct in identifying sensitivity and specificity for SARS CoV-2.⁹

The most widely used method for detecting SARS CoV-2 infections is the RT-PCR but this may be costly due to the laboratory equipment, the need for highly skilled personnel and the test can take days to generate results.¹¹

Antigen Test

Antigen tests are immunoassays that detect specific viral proteins or antigens. Once detected, it may signify current viral infection. These antigen tests are relatively inexpensive, can be done at point-of-care setting, and have faster turnaround-time.²

Antigen tests detect the viral protein present in the specimen and can provide rapid results.¹³ These tests have lower sensitivity than most nucleic acid-based assays and recognize the existence of virus at the time of testing thus, it can be used as a screening test.^{3,13}

Standard™ Q COVID-19 Ag Saliva Test

Intended Use¹⁵

The Standard™ Q COVID-19 Ag Saliva Test qualitatively detects the specific antigens of SARS-CoV-2 that exist in the human saliva specimen by using a rapid chromatographic immunoassay. The test is facilitated by healthcare professionals as an aid to early detection of SARS-CoV-2 among patients with signs and symptoms of COVID-19. The product is designed for medical professional use only.

Trained healthcare professionals are exclusively allowed to facilitate the test and interpret results. Confirmatory testing by RT-PCR is still required and the results of the saliva antigen test should not be the only basis for the diagnosis.

Test Principle¹⁵

STANDARD Q COVID-19 Ag Saliva Test consist of two pre-coated lines, "C" (Control) line, "T" (Test) line on the nitrocellulose membrane surface. The lines are invisible on the window before the specimen application. Coated with mouse monoclonal anti-SARS-CoV-2 antibody is the test line region while coated with anti-Chicken IgY antibody is the control region. The detection of SARS-CoV-2 antigen depends on the mouse monoclonal anti-SARS-CoV-2 antibody bound with color particles.

SARS-CoV-2 antigen interacts with the monoclonal antibody SARS-CoV-2 antibody bound with the color particles producing a colored antigen-antibody particle complex which transfers on the membrane and attached to the mouse monoclonal anti-SARS-CoV-2 antibody. If SARS-CoV-2 antigen is existent, a colored test line will appear on the result window and if none is detected, no color appears in the test line. The control line is for procedural purposes and is present if the test is

properly performed and the reagents for testing are working accordingly.

A study conducted in Bangkok Thailand compared real time RT-PCR assay test (Allplex 2019-nCoV Assay) using respiratory samples versus SARS-CoV-2 antigen detection test (Standard Q COVID-19 Ag test) using saliva specimen. Comparable results were noted with SARS-CoV-2 antigen test having sensitivity of 98.33% (95% CI, 91.06-99.96%) and specificity of 98.73% (95% CI, 97.06-99.59%) for real-time RT-PCR.¹⁴

RESEARCH DESIGN AND DATA ANALYSIS

The research was a prospective study. The researchers enrolled patients continuously from February 2021 until the projected sample size was reached by May 2021. The results of the saliva test were not divulged to the attending physicians or the patients because it was a validation study. Results were analyzed and the following parameters were reported: sensitivity, specificity, positive predictive and negative predictive values, and likelihood ratio, and accuracy. Data were statistically treated using McNemar's Test.

INCLUSION AND EXCLUSION CRITERIA

All patients who underwent SARS-CoV-2 oropharyngeal and nasopharyngeal swab RT-PCR were recruited to participate in the study. Participants below 18 years provided assent and also informed consent from parents or legal guardian. Those who did not sign consent or assent for the Saliva Antigen test were not included in the study. Subjects who were not able to submit saliva (i.e., intubated, unconscious, children who cannot be instructed to collect saliva) were also excluded.

WITHDRAWAL FROM THE STUDY

The participants were given the option to withdraw anytime during the study. If he/she wishes

to withdraw from the study, notification to the principal investigator or any members of the research team must be given either verbally or in writing. Withdrawing from the study requires a form to be filled out to document the process.

If the specimen was already processed (with results) prior to withdrawal, it cannot be undone, furthermore, the data collected prior to withdrawal were included in the study. Further collection of additional personal health information was discontinued. Since this is a validation study, results were unofficial and were not included in the patient's medical record nor relayed to the participant and attending physician until the end of the study (when requested).

The data gathered from a patient who withdrew from the study were included in the data analysis. This was explained to the participant. Data management (security of forms and patient data) were the same for all participants.

METHODOLOGY

SAMPLE SIZE

The OpenEpi, Version 3 was used to compute for the sample size. Based on the current report of WHO (as of January 5, 2021), the positivity rate in the Philippines is 8.4%. The margin of error used is 3%. At 95% confidence interval, result showed that the sample size is 329.

To account for the missing data, there should be additional 10%. The computation is as follows:

$$N_{final} = 329 + .10N_{final}$$

$$0.90N_{final} = 329$$

$$N_{final} = 365.56$$

The final sample size is 366.

Sample Size for Frequency in a Population	
Population size (for finite population correction factor or fpc)(N):	1000000
Hypothesized % frequency of outcome factor in the population (p):	8.4% +/- 3
Confidence limits as % of 100 (absolute +/- %)(d):	3%
Design effect (for cluster surveys-DEFF):	1
Sample Size(n) for Various Confidence Levels	
ConfidenceLevel(%)	Sample Size
95%	329
80%	141
90%	232
97%	403
99%	567
99.9%	925
99.99%	1293
Equation	
Sample size $n = [DEFF * Np(1-p)] / [(d^2 / Z^2_{1-\alpha/2} * (N-1) + p * (1-p)]$	
Results from OpenEpi, Version 3, open source calculator--SSPropor	
Print from the browser with ctrl-P	
or select text to copy and paste to other programs.	

Procedure for Enrollment

Patients who underwent NPS/OPS RT-PCR testing at the Emergency Department were recruited to the study. Those who were willing to participate were oriented on the study and asked to sign the consent form. Participants were informed during consenting that the demographic, clinical and laboratory information that they indicated on the Department of Health Case Report Form (DOH CRF) will also be used for the study. This minimized the use of paper for questionnaires and also the time spent by the patient answering forms. The investigators validated the content of the DOH CRF to ensure completeness of information. Picture Archiving and Communication System (PACS) database of the hospital was used to obtain radiologic data. Results of RT-PCR were retrieved from the Electronic Medical Record. The patient's medical record number (MRN) were recorded on the data collection tool to cross-reference RT-PCR results and Saliva test result.

Procedure for collection of specimens

1. After collection of nasopharyngeal and oropharyngeal swab for RT-PCR, the patient was asked to submit a saliva specimen for the Covid-19 Ag Saliva test.

2. The patient was instructed not to eat, smoke, or chew gum 30 minutes before submitting saliva specimen.
3. The patient was provided with a labeled saliva container containing the initials of the patients and unique study number.
4. The patient was instructed to clear out mucus from the back of the nose and throat at least three times.
5. The patient was asked to lift the specimen collection cup close to his/her mouth and avoid touching the lid of the container with lips or hands.
6. The patient was asked to breath in and cough hard directly into the specimen cup.
7. The patient was asked to spit out the saliva with snorted nasal mucus into the specimen collection cup.
8. The specimen collector will stir the saliva and mucus specimen more than 10 times using a sterile swab.
9. The specimen was handled and processed according to the manufacturer's recommendation.
 - Test device and collected specimen were in room temperature prior to testing.
 - Instructions for using the kit were carefully read.
 - The back of the foil pouch was checked for expiration date. Expired kits were discarded.
 - Examined the test device and the foil pouch containing the desiccant.
 - Inserted the swab into the extraction buffer tube and stirred the swab more than 5 times.
 - Swab was removed to extract the liquid by squeezing the sides of the tube.
 - Nozzle cap was secured tightly onto the tube.
 - Three (3) drops of extracted specimen were instilled on the test device.
 - Read the test result in 15-30 minutes.

10. Results were photographed, recorded and interpreted by a licensed trained health care professional.
11. Results from the RT-PCR test for SARS-CoV-2 were recorded by the researcher.

ETHICAL CONSIDERATIONS

Ethical considerations and ethical principles set out in relevant guidelines (Declaration of Helsinki, WHO Guidelines, ICH-GCP, National Ethics Guidelines for Health Research) were strictly followed.

The participants were asked if he/she preferred the Filipino or English consent form. Consent forms were carefully read and reviewed by participants. The investigators discussed the study thoroughly with the patient and/or legal guardians. It was well emphasized that the participants have the right to withdraw from the study at any given time. Enough time was given for the participant to ask questions.

Vulnerability of subjects was considered. Coercion in any level was not tolerated. The primary investigator, together with a person of no interest in the study, who acted as witness, obtained from the participants their informed consents. They were provided with the contact numbers of the investigators for any questions regarding the study. The number of the IRB chair was included on the consent forms and the participant was informed that he/she can report any irregularities, such as but not limited to coercion, in the obtaining of consent to the IRB.

The participant affixed his/her signature to the informed consent form including the date of signing of the consent form.

For participants below 18 years old, an assent form was accomplished. Informed consent was obtained first from the parent/s or legal

guardian, then an assent form was presented to the participant. It was emphasized to the participant that he/she may decline to join the study and may withdraw anytime during the study. A minor without assent was not included in the study.

Privacy and confidentiality of participants were maintained. In order to ensure confidentiality, participants were assigned a unique study ID number. The numbers were only known to the investigators. The laboratory staff who processed the specimen were blinded and was given access only to the unique patient ID. Only the investigators had the list containing the patient's name and the corresponding ID number. Once all patients were enrolled, the results of RT-PCR tests were retrieved using the list with the patient's name and corresponding ID number.

The name of the patient did not appear on any other form to be used in the study. The name of the patients on the copy of the DOH CRF and all lab results were covered with either a sticker or a black marker. Forms were kept in a drawer with a lock. The database for data entry only included the patient ID.

The risk for harm was minimal. Only patients who consented to participate were included in the study. Since this was a validation study, the results of the tests were not used in the management of the patient. The results of the saliva test can be provided to the patient after completion of the study. The participants did not instantaneously directly benefit from the study because the official RT-PCR results were needed and the one relayed to the patient, since the diagnostic test is still undergoing a validation study. Participants will not be given tokens for participating in the study. The risk for injury is minimal because patients will just need to spit out saliva. No sputum induction or invasive procedure was performed. Should there be study-related injuries (injuries related to spitting of saliva), medical management were properly accorded.

No conflict of interest from the authors was declared in this research. The diagnostic test kits were provided for by the manufacturer/distributor for free but for the sole purpose of the research. Results were not altered in any way based on these circumstances.

All research data were managed only by the research trial team. All files were kept in secure areas and only accessible by the research trial team.

RESULTS AND DISCUSSIONS

DEMOGRAPHICS

The study has enrolled a total of 366 patients. Informed consents were signed by patients who willingly volunteered to be part of the study. Two (2) patients were included in the pediatric age group. The age group and gender of patients are presented in the Table 1. Most patients sought consult within 7 days of the illness (86%). The most common symptoms are respiratory in presentation - i.e. cough, fever and colds. Sixty-five (17.81%) were asymptomatic.

Table 1. Patient Characteristics

	N = 366 (%)	
Age Group (years)	No	Percentage
14-17	2	(0.55)
18-29	84	(22.95)
30-39	94	(25.68)
40-49	58	(15.85)
50-59	54	(14.75)
60-69	38	(10.38)
70-79	23	(6.28)
80-89	13	(3.56)
Gender	No	Percentage
Male	186	(50.81)
Female	180	(49.19)
Days of Illness	No.	Percentage
0-7	315	(86.06)
8-14	34	(9.29)
More than 14	17	(4.64)

Presenting Symptoms	No.	Percentage
Cough		153
Fever		152
Colds		72
Throat Discomfort		62
Body Malaise		45
Disturbance in Breathing		44
Diarrhea		39
Headache		30
Loss of taste or smell		14
Other symptoms		79
Asymptomatic		65

There were four patients who were positive for Saliva Antigen test but were negative for RT-PCR. Two of them had normal chest radiographs, one had a pleural effusion with pulmonary mass, and another one had pneumonia on chest xray.

Among the 63 patients who tested positive for Saliva Antigen but were negative for RT-PCR, 11 did not have radiographs, 18 had normal chest xray results, and 34 had infiltrates on chest radiographs.

SENSITIVITY AND SPECIFICITY

Evaluation of the sensitivity and specificity of the antigen saliva test was done. Table 2 shows the sensitivity and specificity analysis of the data.

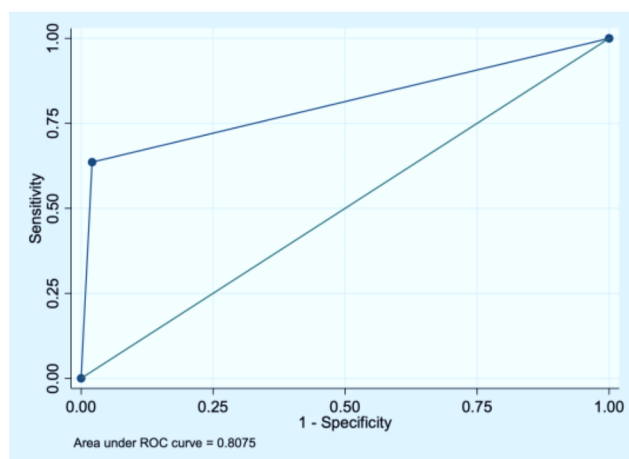
Table 2. Two-by-two table comparing the RT-PCR and Saliva Antigen Test

Saliva Antigen Test	RT-PCR		Total	P-value
	Positive	Negative		
Positive	110	4	114	<0.0001
Negative	63	189	252	
Total	173	193	366	

Using McNemar's Test, results showed that there is significant difference between the proportion of patients diagnosed with COVID-19 using Saliva Test and PCR Test.

Table 3 shows the different measures of validity of the saliva antigen test. The probability of Saliva antigen test in correctly identifying patients with COVID-19 was 63.58% (Sensitivity). The probability of Saliva Test in correctly identifying patient without COVID-19 was 97.93% (Specificity). Among those who have COVID-19 based on Saliva Test findings, the probability of having COVID-19 was 96.49% (PPV). On the other hand, among those without infection based on Saliva Test findings, the probability of not having the disease is 75% (NPV). The positive likelihood ratio of 30.68 indicates that there is a high increase in probability of having COVID-19, given a positive Saliva test. The negative likelihood ratio of 0.37 indicates that there is around 25% decrease in probability of having COVID-19, given a negative Saliva Test. The overall accuracy indicates that out of 366 patients tested for COVID-19, 81.69% of them have the same result for Saliva Test and PCR Test.

	Saliva Antigen Test
Sensitivity	63.58%
Specificity	97.93%
Positive predictive value	96.49%
Negative predictive value	75.00%
Likelihood ratio (+)	30.68
Likelihood ratio (-)	0.37
Overall accuracy	81.69%



Further analyses of the saliva antigen test as to processing time, day of illness on presentation, and presence or absence of symptoms were done.

The time from saliva collection to actual start of the processing of the samples were taken into account. There was a total of 251 (68.57%) samples which were processed within an hour from collection and 115 (31.43%) were processed beyond one hour. Table 4 shows the analysis of data based on the processing time. Result showed that there is no sufficient evidence to conclude that the diagnostic accuracy of Saliva Test is different according to processing time.

Table 4. Validity of Saliva Antigen Test Based on Processing Time

Saliva Test	PCR		Total
	Positive	Negative	
≤60 mins			
Positive	74	3	77
Negative	42	132	174
Total	116	135	251
>60 mins			
Positive	36	1	37
Negative	21	57	78
Total	57	58	115

Processing Time	≤60 mins	>60mins
Sensitivity	63.79%	63.16%
Specificity	97.78%	98.28%
Positive predictive value	96.10%	97.30%
Negative predictive value	75.86%	73.08%
Likelihood ratio (+)	28.71%	36.63%
Likelihood ratio (-)	0.37	0.37
Overall accuracy	82.07%	80.87%
P-value	0.99	

It is recommended that patients be tested for SARS CoV-2 antigen between 5-7 days of symptom onset. However, some patients seek consultation and treatment beyond 7 days of symptom onset. Majority of the patients (n = 315; 86.06%) had their saliva antigen tests done within 7 days of symptom onset. The researchers analyzed these group of patients and is presented on Table 5. Result showed that there is no sufficient evidence to conclude that the diagnostic accuracy of Saliva Test is different according to days of illness.

Table 5. Validity of Saliva Antigen Test Based on Number of Days from Symptom Onset

Saliva Test	PCR		Total
	Positive	Negative	
≤7 mins			
Positive	93	4	97
Negative	48	170	218
Total	141	174	315
>7 mins			
Positive	17	0	17
Negative	15	19	34
Total	32	19	51

Day of Onset	≤7 mins	>7mins
Sensitivity	65.96%	53.13%
Specificity	97.70%	100.00%
Positive predictive value	95.88%	100.00%
Negative predictive value	77.98%	55.88%
Likelihood ratio (+)	28.69	-
Likelihood ratio (-)	0.35	0.47
Overall accuracy	83.49%	70.59%
P-value	0.29	

Lastly, the researchers further grouped the data for the patients with symptoms and those who were asymptomatic at the time of testing. At the time of testing, those who were asymptomatic were 65 patients (17.81%). Table 6 shows the distribution of symptomatic and asymptomatic patients at the time of saliva collection. Result showed that there is no sufficient evidence to conclude that the diagnostic accuracy of Saliva Test is different according to presence of symptoms.

Table 6. Validity of Saliva Antigen Test Based on Presence of Symptoms

Saliva Test	PCR		Total
	Positive	Negative	
Without symptoms			
Positive	4	1	5
Negative	6	54	60
Total	10	55	65
With symptoms			
Positive	106	3	109
Negative	57	135	192
Total	163	138	301

Presence of Symptoms	Without	With
Sensitivity	40.00%	65.03%
Specificity	98.18%	97.83%
Positive predictive value	80.0%	97.25%
Negative predictive value	90.0%	70.31%
Likelihood ratio (+)	22.0	29.91
Likelihood ratio (-)	0.611	0.36
Overall accuracy	89.23%	80.07%
P-value	0.14	

ANALYSIS

The Saliva Antigen test exhibits a high specificity (96.10% - 100%) in detecting SARS CoV-2 among patients suspected to have Covid-19. The diagnostic test shows modest sensitivity (40% - 65.96%) in detecting SARS CoV-2 among Covid-19 suspects. Several subgroup analyses that were done (i.e. processing time, day of onset of symptoms, and presence of symptoms at the time of collection), did not have sufficient evidence that the diagnostic accuracy of the Saliva antigen differ among several factors considered.

The diagnostic test may be used as an alternative method in detecting SARS CoV-2 among patients, however, a negative result needs to be correlated with clinical condition of the patient and confirmed using RT-PCR.

In a study by Mijljb Ristić, et al, the same diagnostic test kit (Standard Q Covid-19 Antigen Test) was used in 120 symptomatic patients. The overall sensitivity was 58.1% (95% CI, 42.1-73.0) but was higher in the first five days of the symptom onset, with its sensitivity ranging from 66.7% to 100%.¹⁷ This was consistent in our study, wherein the sensitivity is higher in those patients whose

symptoms are within 7 days, but statistical analysis did not show sufficient evidence to conclude that the diagnostic accuracy of Saliva Test is different according to days of illness.

There were a number of similar studies regarding Standard Q Covid-19 Ag Test. All studies showed high specificity and modest sensitivity in detecting SARS-CoV-2 infection among patients.

A prospective study was done in Brazil and Germany and published in the product brochure of Standard Q Covid-19 Ag Test for Nasopharyngeal Swab. A total of 1659 patients were enrolled, the pooled sensitivity in Germany was 76.6% (95% CI, 61.97-87.70) and pooled specificity was 99.3% (95% CI, 98.6 - 99.6%). The pooled sensitivity and specificity in Brazil were 88.68% (95% CI, 81.06-94.01%), and 97.6% (95% CI, 95.2-98.8%), respectively.¹⁸

In the study of Nalumansi, nasopharyngeal swab of 262 patients were analyzed and showed a sensitivity of 70.0% (95% CI, 60-79) and a specificity of 92% (95% CI, 87-96).

There is an emphasis on importance of early diagnostic testing when suspecting an infection most especially when molecular testing is not accessible. RT-PCR is still required to confirm the diagnosis.¹⁹

CONCLUSION AND RECOMMENDATIONS

The overall accuracy of the Standard Q Covid-19 Ag Test using saliva samples was 81.69%, with a sensitivity of 63.58% and a specificity of 97.93%. Among those who have COVID-19 based on Saliva Test findings, the probability of having COVID-19 was 96.49% (PPV). On the other hand, among those without COVID-19 based on Saliva Test findings, the probability of not having COVID-19 is 75% (NPV). The positive likelihood ratio of 30.68

indicates that there is a high increase in probability of having COVID-19, given a positive Saliva test. The negative likelihood ratio of 0.37 indicates that there is around 25% decrease in probability of having COVID-19, given a negative Saliva Test. The overall accuracy indicates that out of 366 patients tested for COVID-19, 81.69% of them have the same result for Saliva Test and PCR Test.

Several factors were considered and analyzed using McNemar's test. All subgroup analyses, as to processing time, presentation from day of onset of symptoms, and presence or absence of symptoms, did not show sufficient evidence to conclude that the results of the saliva antigen test is different according to the parameters mentioned.

Saliva antigen test may be used as an alternative method in detecting SARS CoV-2 among patients, especially in situations where a more sensitive test is unavailable. The high specificity of the diagnostic test may be used to detect disease and start early treatment and isolation. A negative result needs to be correlated with the clinical condition of the patient and confirmed further using a more sensitive test, like RT-PCR.

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Perceptions and Attitudes of 4th Year Medical Students in Clinical Clerkship in the Era of the Coronavirus Disease 2019*

April Esther O. Caguimbay, MD¹

ABSTRACT

Background: In the advent of coronavirus disease 2019 global crisis, hands-on patient care and in-hospital training of fourth year medical students were suspended across the globe and shifted to remote online education. The aim of this study is to assess the perception and attitude of the 4th year medical students about clinical clerkship training during the COVID-19 pandemic.

Methods: An online survey was sent to fourth-year medical students in three medical schools in Iloilo City, from July 2021 to October 2021. The survey questionnaire is a combined dichotomous, multiple-choice, and Likert response scale questions.

Results: Of the hundred sixty-eight students who completed the online survey, sixty-six percent did not experience hospital rotation. On average, students were very interested in COVID-19 (8.83) and willing to join in patient care if requested by a hospital or university to help during COVID-19 pandemic (8.65), but felt they were not ready (70%) due to a lack of the ability for clinical practice (90%). Most (82%) of the students expressed they wanted to maintain hands-on clinical practice education despite the pandemic. Overall, students who have experienced hospital rotation have a higher level of understanding of how much their life, behavior (9.30), and role as a medical student (9.74) were affected by the pandemic as compared to the rest of the students.

Conclusion: This present pandemic has affected the medical students as a whole in areas of their role as students, behavior, and life. Their lack of confidence despite willingness to help correlated to their inadequate clinical experience. Specific policy adjustments concerning the curriculum of clinical clerkship during this time of pandemic should be revisited to tailor fit the students' needs for safe education to help them prepare to become a competent medical practitioner.

Keywords: COVID-19, Medical student, Medical clerkship, Perception, Attitude

INTRODUCTION

The ongoing coronavirus disease -2019 (COVID-19) pandemic caused by the novel severe acute respiratory syndrome-coronavirus-2 (SARS-CoV-2) continues to be a global crisis with devastating effects across all sectors of society. In less than a year, the highly infectious SARS-CoV-2 virus has rapidly spread in all continents of the world infecting over 179 million persons resulting in approximately 3.8 million deaths Worldwide⁽¹⁾. The Philippine situation was not different from other countries. As of June 2021, cases are still rising with 1.36 million confirmed cases, 23, 621 deaths nationwide, and approximately 5800 new cases every day⁽²⁾. Because of its high infectivity, new variants⁽³⁾ and with this rate of increase of new cases, have left no one in doubt that the COVID-19

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¹From Department of Internal Medicine, St. Paul's Hospital of Iloilo

pandemic is exerting enormous pressure on healthcare systems around the world ⁽⁴⁾.

In adherence to the disease spread control protocols, great impact on the social, political, economic, health and education were felt. Every aspect was slowed down and brought a threat of collapse. The health care system is severely challenged, not only the remaining front liners but also its future workforce quality was placed in jeopardy.

Clinical clerkship is an integral period in a medical student's life where they are allowed the opportunity to gain exposure to a variety of specialties and subspecialties while developing the clinical skills necessary to become a competent physician ⁽⁵⁾. Because of the pandemic, this was disrupted. Last May 31, 2020, the Association of Philippine Medical Colleges (APMC), together with the Commission on Higher Education (CHED), suspended the face-to-face or in-person clinical rotations in hospitals of both clinical clerkship and internship programs and home-based flexible learning strategies shall continue to be implemented instead (APMC, May 2020). Due to this, medical students are experiencing this unique training environment for the first time during their clinical training. The impact of this situation on their acquisition of clinical knowledge and skills and how this may affect their future career choices remains unknown.

OBJECTIVES OF THE STUDY

To assess the perception and attitude of the 4th year medical students about clinical clerkship training during the COVID-19 pandemic.

Specific Objectives

Specifically, the study will aim to:

1. Determine the demographic characteristics of respondents in terms of age, medical school

presently enrolled in, areas of rotation, and duration of hospital exposure.

2. Determine the students' perception of their roles as clinical clerks-on-training during the COVID-19 pandemic.
3. Determine the students' attitude toward clinical clerkship training during the COVID 19-pandemic.
4. Determine the impact of COVID-19 pandemic to 4th year medical students.

SIGNIFICANCE OF THE STUDY

Clinical clerkship is an important year, marking the final year of medical education. It is when students put to use the 3 years of medical knowledge they have garnered in medical school into clinical practice. It is also when they are exposed to the hospital setting and are allowed to handle patients with close supervision from their residents and consultants. Students are allowed to elicit patient histories, do a complete physical examination, interpret laboratory results, write progress notes, assist in surgeries and medical procedures, and where the correlation of theoretical knowledge and patient's clinical presentation is honed.

In circumstances such as COVID-19 pandemic, the safety of our 4th year medical students is a priority. But due to the present setup, students' clinical exposure and learning are greatly compromised, as they are restricted to mingle face-to-face and to be exposed in the hospital setting. In this scenario, and with the need to train our future doctors, it is important to understand their concerns and attitudes toward the clerkship training in a hospital setting. Moreover, the development of alternative clerkship programs that will provide high-quality medical education and new modes of student- patient interaction that will teach the core competencies for patient care is an important issue to address. This study aimed to assess the

perception of their role and attitudes of medical students about these changes to clinical clerkship training programs in Iloilo City, Philippines during the COVID-19 pandemic.

In line with this, the results of this study may be disseminated to the Medical Schools involved and to the Association of Philippine Medical Colleges (APMC) with the necessary permission.

DEFINITION OF TERMS

- **Clinical Clerk** – A fourth-year medical student undergoing rotation in a clinical department of a hospital such as internal medicine, family medicine, pediatrics, surgery, obstetrics and gynecology, ENT, etc.
- **Clinical Clerkship** – In medical education, refers to the practice of medicine by medical students during their final year of study, under the supervision of a health practitioner.
- **Perception** - in this study, it is defined as a medical student's mental impression or a way of regarding, understanding, or interpreting his or her role during COVID-19 pandemic.
- **Attitude** – in this study, it refers to a set of emotions, beliefs, and behavior of a medical student in her/his 4th year of medical education toward clinical clerkship during this time of the pandemic.
- **Covid-19** – or coronavirus disease 2019 is a disease caused by a coronavirus that was first reported in 2019 at Wuhan, China, and eventually became a pandemic.
- **Pandemic** - a disease that spreads over a whole country or the whole world.
- **Impact** – in this study, it is defined as the effect of COVID-19 pandemic on the medical students' lifestyle, psychological aspects, and medical education.

REVIEW OF THE RELATED LITERATURE

The coronavirus disease 2019 (COVID-19) pandemic has led to widespread uncertainty and affected every corner of the globe ⁽⁶⁾. In the Philippines, it has had profound medical, political, and financial impacts ^(7,8,9). While much study and talks surround the present and potentially persisting political, financial, and public health aftermath of the COVID-19 pandemic, the dialogue regarding how COVID-19 will affect undergraduate medical education (UME) and its long-term effect is somewhat unexplored ⁽¹⁰⁾.

Ideally, clinical clerk is part of the team as a learner who needs guidance in the field of clinical practice. Development of students' professional identity depends on teaching and role modeling in these settings as students learn to prioritize patients and their welfare. However, with the emergence of a highly contagious pandemic, students may transmit the virus unintentionally or even contract the disease. Other contributing factors that limit the role of students in this clinical environment include the high cost of COVID-19 testing available locally, lack of adequate personal protective equipment (PPE), diminished value of education with the cancelation of surgical procedures and routine appointments, and the transition of medical consultation to telehealth formats. During the initial emergence of COVID-19, and with the PPE shortage, students were excluded in the care of suspected or confirmed COVID-19 patients. Medical schools began to remove students from the clerkship environment as infection rates increased. On March 17, 2020, the Association of American Medical Colleges provided guidelines suggesting that medical schools support pausing clinical rotations for medical students ⁽¹¹⁾. In the Philippine setting, this was soon followed by the Association of Philippine Medical Colleges issuing a complete suspension of the internship program in the National Capital Region and eventually in the whole country from March 15 to April 12, 2020 ⁽¹²⁾ in compliance with the advisory of the Department of Health ⁽¹³⁾ and the World Health Organization ⁽¹⁴⁾.

Reasons for medical schools' cancellation of clinical clerkship at the start of the pandemic are (1) to flatten the curve, minimize face-to-face patient interaction to curtail the spread of COVID-19, (2) to decrease the risk of exposure of the medical students, and lastly, (3) to ensure adequate supply of personal protective equipment to the healthcare workers to protect themselves during this pandemic. The cancellation of clerkship has little changes on the didactics, as it may be replaced by recorded or live - stream lectures, but the loss of collaborative experience can be greatly impacted with subsequent effects on their preparedness and confidence as a clinician. Also, preparedness in the areas of teamwork, communication skills, clinical and practical skills, working in the hospital on the ward, paper works, working on-call, triaging of patients, management of acutely sick patients, prescribing, and good bedside manners are affected ⁽¹⁵⁾. Because of the above reasons, it will be important to record and study the full extent of changes being made during this time, including in the aspect of medical education, to help ensure our medical students progress forward despite these challenges and uncover better ways to support them to transition into the healthcare workforce in the long-term ^(16,17).

METHODOLOGY

Study Design

This study utilized a cross-sectional survey research design with a web-based 3- fields/23-item questionnaire and was conducted from July 01, 2020 – October 31, 2021, and this evaluated the 4th year medical students' perception and attitudes on clinical clerkship under the COVID-19 outbreak and the pandemic's psychological impact to the students and their medical education. This study was spread among a total of 295 fourth-year medical students enrolled in the 3 medical schools in Iloilo City, Philippines, namely, Central Philippine University - College of Medicine (COM), West Visayas State University – COM, and Iloilo Doctors College – COM.

STUDY SETTING

This research was conducted in the 3 medical institutions in Iloilo City, namely, Central Philippine University - College of Medicine (COM), West Visayas State University – COM, and Iloilo Doctors College – COM.

Study Period

This study was conducted from July 01, 2021, to October 31, 2021

STUDY POPULATION

Inclusion Criteria:

The study included all clinical clerks currently enrolled at Central Philippine University - COM, West Visayas State University – COM, and Iloilo Doctors Hospital – COM, who were willing to participate in the study and have given their consent.

Exclusion Criteria:

The study excluded clinical clerks currently enrolled at Central Philippine University - COM, West Visayas State University – COM, and Iloilo Doctors Hospital – COM, who were not willing to participate in the study.

Population Size:

Since the total population size was 295 participants for three groups, the computation of sample size used the population proportion. Wherein, the population size was known, the confidence level was 95% and the margin of error was 5%. The computation is shown below:

$$n = N \cdot X / (X + N - 1),$$

where

$$X = Z_{\alpha/2}^2 \cdot p \cdot (1-p) / MOE^2,$$

and $Z_{\alpha/2}$ is the critical value of the Normal distribution at $\alpha/2$

(e.g. for a confidence level of 95%, α is 0.05 and the critical value is 1.96), MOE is the margin of error, p is the sample proportion (0.5), and N is the population size.

$$X = ((1.96)^2) * (0.5) * (0.5) / (0.05^2) = 0.9604 / 0.0025 = 384.16$$

$$n = (295 * 384.16) / (384.16 + 295 - 1) = 113,327.2 / 678.16 = 167.1098265895954$$

The computed sample is 168 participants.

Group	Population Size	Proportional Allocation (Pop'n size/Total Pop'n size)	Monthly Sample Size (proportion X Total sample size (168))	Final Monthly Sample Size
WVSU	120	0.406779661	68.33898305	68
Iloilo Doctors	92	0.311864407	52.39322034	53
CPU	83	0.281355932	47.26779661	47
Total Pop'n Size	295		Total Sample Size	168

Random samples from each stratum were taken in a number proportional to the stratum size when compared to the total population.

DATA COLLECTION PROCEDURE

After the approval of the Department of Internal Medicine Research Committee, St. Paul's Hospital Institutional Review Board, and West Visayas State University Unified Research Ethics Review Committee, letters were sent to different Deans of all Medical Schools here in Iloilo City for permission to conduct. Permission was granted. We have contacted the 4th year medical students' leaders/president of each medical school to obtain the email address of each student. Once the emails were obtained, a link to a self-administered questionnaire in google form was sent to all 4th year medical students of different medical schools in Iloilo, City, Philippines. Only one Google account under the name of one of the two researchers containing the questionnaire in google form was the sole destination of all the responses. Only the researcher who owns the google account had the authority to disseminate the questionnaire and only the researchers have the access to the electronic response and the data of the respondents. It only took approximately 20-30 minutes to completely answer the questionnaire. The questionnaire asked

to answer regarding the student's demographic data and also, they were asked to complete the questionnaire adapted from the study of Hong J, et al. ⁽¹⁸⁾ in English, which was translated into the local dialect (Hiligaynon). Permission was given by the authors of the study for the questionnaire's use and its translation. The questionnaire was translated by 2 individuals, a writer in Hiligaynon with a Ph.D. in Filipino and a professor with a Ph.D. in Linguistics. Only one response to the questionnaire per person/ email address was permitted as programmed to the online platform (google forms). Participants were not paid for their participation, as stated on the informed consent.

SURVEY QUESTIONS

Survey questions were developed by a team consisting of three medical students, three psychiatry residents, and three psychiatry professors from Korea⁽¹⁸⁾. The questions were modified and will focus on three domains of interest, namely, [1] the perception of 4th year medical students regarding their role during the pandemic era; [2] students' attitude toward clinical clerkship training during the COVID 19- pandemic; and lastly, [3] the impact of COVID-19 on medical students.

The first part has seven items that elicited information on the perception medical students have toward their duties during the pandemic. The following questions were asked: A1. How interested are you in COVID-19? (0: never-10: very interested); A2. How important is a social responsibility to medical students? (0: not important-10: very important); A3. In some countries, medical students work as frontline healthcare workers. Do you feel positive or negative about this? (0: very negative-10: very positive); A4. Do you think students are ready to be in the medical field in a pandemic situation? (0: never-10: definitely); A5. If you are requested by a hospital or university to help during the COVID-19 pandemic, are you willing to participate in patient care or assistance? (0: never-10: definitely); A6. Do you agree with having early graduation or being

awarded a temporary license in the event a new infectious disease situation occurs in the future and students are required to enter the medical field quickly? (0: disagree–10: agree); A7. Do you think you can practice medicine even though you are a trainee? (Yes or No)

Face-to-face education was interrupted and modes of teaching and learning were modified since the start of the pandemic. However, since clinical exposure and experience in the hospital is an integral part of the medical curriculum, the second part of the questionnaire assessed the attitude of medical students regarding the change in the mode of their clerkship training. Therefore, on the second part of the questionnaire, the following questions were asked: B1. Do you think that medical school education is working properly during the COVID-19 pandemic? (0: disagree–10: agree); B2. Do you think you should graduate on schedule and practice medicine, even if your medical school training is not complete due to the ongoing pandemic situation? (0: never–10: definitely); B3. To what extent do you feel medical school education must change to fit into the new normal era? (0: not needed to be changed–10: definitely to be changed); B4. How should hands-on clinical practice education be reduced or replaced during the pandemic? (Needs to be reduced vs. maintained); B5. During COVID-19, how do you think patients will accept students who are trainees? (same as usual/positively/negatively)

The third part assessed the psychological impact of COVID-19 on medical students, their education, and their daily lives. Therefore, we asked the following questions: C1. How has your amount of study time changed compared to before the COVID-19 situation? (0: definitely reduced–10: definitely increased); C2. How has your level of academic-related stress changed compared to before the COVID-19 situation? (0: definitely reduced–10: definitely increased); C3. How much has the current COVID-19 situation affected your studies? (0: never affected–10: definitely affected); C4. Are you afraid of interacting with a typical patient (during clinical

practice) as a medical student? (0: never afraid–10: very afraid); C5. Are you afraid of interacting with a suspected coronavirus patient as a medical student (during clinical practice)? (0: never afraid–10: very afraid); C6. Are you afraid of interacting with a confirmed coronavirus patient as a medical student (during clinical practice)? (0: never afraid–10: very afraid); C7. How much do you think the current COVID-19 pandemic affects your life and behavior? (0: never affected–10: definitely affected); C8. How much do you think the current COVID-19 pandemic affects your role as a medical student? (0: never affected–10: definitely affected).

Most of the questions were closed-ended to facilitate the categorization of the participants' answers. We used a unipolar 10-point Likert-type scale (example 0: never affected–10: definitely affected) to measure the perception, attitude, and impact. Open-ended questions were also used to invite a variety of opinions from participants. Dichotomous questions were scored using a two-point scale. Questionnaires were sent via email or cellular phone number in the google form. The present study was approved by the Institutional Review Board of St. Paul's Hospital Iloilo and West Visayas State University Unified Research Ethics Review Committee.

ETHICAL CONSIDERATIONS

During this time of great change in modalities of training of our future doctors, it is important to understand their concerns and attitudes toward the clerkship training, so that problems identified will be addressed and modifications will be done appropriately, and that future medical practice tragedy will somehow be prevented.

Before conduction, this study was reviewed and approved by the Department of Internal Medicine Research Committee, St Paul's Hospital Institutional Review Board, and by the Unified Research Ethics Review, West Visayas State

University. To determine the student's willingness to participate, consent for the conduction of this study was placed on the 1st page of the google form sent to each student via email. It was programmed as "required" thus the study only proceeded when they were willing to join, indicated by ticking the "Yes" button at the bottom of the consent form. Students who chose not to participate indicated by ticking the "No" button, did not proceed with the study, and were directed straight to the end of the form. Researchers' signature was not included in the informed consent due to the nature of the online survey. Student's confidentiality was treated with utmost importance. Once electronic responses were obtained, before the data processing, each response was printed and a unique number code was individually assigned to keep their identities anonymous and thus prevented accidental revelation of their names. Only the researchers have access to the electronic response and the data of the respondents. There shall only be minimal risk brought about by this study to the participants. Medical or psychosocial support shall be provided in case the need arises. Once researchers were notified by the affected participant, an arrangement for evaluation, counseling, or possible medical or psychosocial management will be done at the expense of the researchers. It was stated in the informed consent that she/he may withdraw or discontinue participating at any time without penalty or liability if he/she may feel uncomfortable joining the survey. Data gathered was fully encrypted and password-protected known only to the researchers. Access was granted only to the research team only for confirmation or validation purposes. Subsequent uses of records and data will be subject to standard data use policies which protect the anonymity of individuals and institutions. After the study, all collected records will be deleted after 2 years and we will ensure that no trace of information related to the subjects included in the study remains accessible. A copy of the finished study will be given to each participating medical school and Association of Philippine Medical Colleges (APMC) with the

necessary permission. It may be published or presented appropriately for educational purposes, but utmost confidentiality of the respondents' data will be ensured at all times such that no respondent will be singled out. No vulnerable participants will be included in the study.

STATISTICAL ANALYSIS

Data gathered were subjected to appropriate statistical analysis. For questions with answers of 0-10, T-test or ANOVA was used. The Chi-square was used to determine the relationship of demographic profile with attitude and perception. Mean, frequency and percentage were used to describe the demographics profile and level of attitude/perception and impact itself.

RESULTS

A total of 168 medical clerks randomly selected out of 295 fourth-year medical students from the 3 medical schools in Iloilo City completed the online survey. The proportion of students coming from different schools was calculated by proportional allocation. Seven out of ten participants were male (74%). The average age of participants was 25 years old, 23 years old as youngest and 32 years old as oldest. See *Table 1*

Table 1. Demographic Profile

Profile	Category	N	%
Sex	Male	124	74%
	Female	44	26%
School	CPU	47	28%
	IDC	53	32%
	WVSU	68	40%
Age	Mean = 25yo Youngest = 23yo		
	Oldest = 32yo		

Sixty-six percent (66%) of the participants did not experience hospital rotation. The top four areas of rotation were Pediatrics (20%), Internal Medicine (19%), Surgery (17%), and Obstetrics & Gynecology (17%). The average length of stay of participants during rotation was 15 days, 14 days as shortest, and 100 days as longest. See Table 2.

Table 2. Area of Rotation and Length of Stay

Variable	Category	N	%
Experience Hospital Rotation	No	111	66%
	Yes	57	34%
Pedia	No	135	80%
	Yes	33	20%
Internal Medicine	No	136	81%
	Yes	32	19%
Surgery	No	140	83%
	Yes	28	17%
Obstetrics and Gynecology	No	140	83%
	Yes	28	17%
Psychiatry	No	165	98%
	Yes	3	2%
Family Medicine	No	162	96%
	Yes	6	4%
ENT	No	165	98%
	Yes	3	2%
Anesthesia	No	165	98%
	Yes	3	2%
Ophthalmology	No	167	99%
	Yes	1	1%
Community	No	166	99%
	Yes	2	1%
Radiology	No	167	99%
	Yes	1	1%
Duration of Stay	Mean = 25 days, Min = 14		
	Max = 100 days		

Table 3. The Perception of 4th year Medical Students regarding their role during Pandemic Era

Question	Answer	n%	Mean	Interpretation
A1			8.83	Very Interested
A2			9.64	Very Important
A3			7.83	Very Positive
A4			6.06	Neutral
A5			8.65	Definitely
A6			5.77	Neutral
A7	No	118(70)		
	Yes	50(30)		
A7.a	Lack of ability for clinical practice	106(90)		
	Medical license issue	12(10)		
A8	Acting as an assistant for healthcare professionals	23(14)		
	Acting as an informer to neighbors about the COVID-19	17(10)		
	Actively learning about the COVID-19	8(5)		
	All of the above	6(4)		
	Be actively involved in clinical practice, if possible	26(15)		
	Focusing on medical education and learning as trainees	88(52)		

Table 4 shows the overall students' attitude toward clinical clerkship training during the COVID 19- pandemic. Students did not agree nor disagree that medical school education was working properly during COVID-19 pandemic (5.22). Also, students had a neutral thought that they should graduate on schedule and practice medicine even if their medical school training is not complete due to the ongoing pandemic situation (6.65). However, students thought that medical school education definitely should change to fit into the new normal era (8.60).

Almost all of the students wanted to maintain hands-on clinical practice education (82%) and half of them thought that medical students can gain clinical experience in the pandemic era through meeting the patients (56%). Education, patient care, and social accountability were the top three most important outcomes of medical education during the pandemic era. Lastly, almost half of students thought that patients will accept them as usual trainees (44%).

Table 4. Students' attitude toward clinical clerkship training during the COVID-19 pandemic

Question	Answer	n%	Mean	Interpretation
B1			5.22	Neutral
B2			6.65	Neutral
B3			8.60	Definitely to be change
B4	Needs to be maintained	138(82)		
	Needs to be reduced	30(18)		
B5	Via meeting the patients	94(56)		
	Via meeting standardized patients or medical models	60(36)		
	Online education	4(2)		
	Virtual reality	3(2)		
	others	7(4)		
B6	Communication and collaboration	25(15)		
	Education and research	41(24)		
	Patient care	38(23)		
	Professionalism	4(2)		
	Self-development	25(15)		
	Social accountability	35(21)		
B7	Negatively	61(36)		
	Positively	33(20)		
	Same as usual	74(44)		

Table 5 shows the overall impact of COVID-19 on medical students. On average, there was no amount of study time changed compared to before the COVID-19 situation (5.51). However, there was an increase in the level of academic-related stress (8.30) and it affected the studies of students (8.65). Students were neither never nor afraid of interacting with typical (4.58) or suspected coronavirus patients as medical students (5.96). Nevertheless, students were very afraid of interacting with confirmed coronavirus patients (6.74). Lastly, the life, behavior (9.00), and role as medical (9.10) students were definitely affected by the current COVID-19 pandemic.

Table 5. The Impact of COVID-19 on Medical Students

Question	Mean	Interpretation
1. How has your amount of study time changed compared to before the COVID-19 situation?	5.51	No change
2. How has your level of academic-related stress changed compared to before the COVID-19 situation?	8.30	Definitely increased
3. How much has the current COVID-19 situation affected your studies	8.65	Definitely affected
4. Are you afraid of interacting with a typical patient (during clinical practice) as a medical student?	4.58	Neutral
5. Are you afraid of interacting with a suspected coronavirus patient as a medical student (during clinical practice)?	5.96	Neutral
6. Are you afraid of interacting with a confirmed coronavirus patient as a medical student (during clinical practice)?	6.74	Very afraid
7. How much do you think the current COVID-19 pandemic affects your life and behaviour?	9.00	Definitely affected
8. How much do you think the current COVID-19 pandemic affects your role as a medical student?	9.10	Definitely affected

RELATIONSHIP OF PROFILE WITH PERCEPTION, ATTITUDE, AND IMPACT

I. Sex

Tables 6,7 and 8 show the result of the test of difference and relationship of Sex in terms of *Perception, Attitude, and Impact*. The test was only significant in terms of item #2 in "*The Impact of COVID-19 on Medical Students'* set questions

($p=0.012$). Hence, there was a significant difference in the level of stress change before and during the COVID-19 between male and female students. Male (8.49) students experienced a higher than average increase in stress compared to female (7.75) students, see *Table 8*. Furthermore, the rest of the tests were not significant. Therefore, the Sex variable had no significant relationship with the rest of the *Perception, Attitude, and Impact* questions.

Table 6. The perception of 4th year medical students regarding their role during pandemic era

Question	Answer	n%	Male		Female		P-value
			Mean	n(%)	Mean	n(%)	
A1			8.87		8.73		0.546
A2			9.72		9.43		0.097
A3			7.85		7.80		0.879
A4			6.02		6.18		0.663
A5			8.77		8.34		0.121
A6			5.82		5.61		0.681
A7	No	118(70)		88(75)		30(25)	0.727
	Yes	50(30)		36(72)		14(28)	
A7.a	Lack of ability for clinical practice	106(90)		79(75)		28(26)	0.702
	Medical license Issue	12(10)		10(83)		2(17)	
A8	Acting as an assistant for healthcare professionals	23(14)		18(78)		5(22)	0.641
	Acting as an informer to neighbours about the COVID-19	17(10)		11(100)		6(55)	
	Actively learning about the COVID-19	8(5)		6(75)		2(25)	
	All of the above	6(4)		3(50)		3(50)	
	Be actively involved in clinical practice, if possible	26(15)		21(81)		5(19)	
	Focusing on medical education and learning as trainees	88(52)		65(74)		23(26)	

Table 7. Students' attitude toward clinical clerkship training during the COVID-19 pandemic

Question	Answer	n%	Male		Female		P-value
			Mean	n(%)	Mean	n(%)	
B1			5.36		4.82		0.188
B2			6.76		6.36		0.340
B3			8.54		8.75		0.451
B4	Needs to be maintained	138(82)		101(73)		37(27)	0.695
	Needs to be reduced	30(18)		23(77)		7(23)	
B5	via meeting the patients	94(56)		72(77)		22(23)	0.504
	Via meeting standardized patients or medical models	60(36)		42(70)		18(30)	
	Online education	4(2)		4(100)		0(0)	
	Virtual reality	3(2)		2(67)		1(33)	
	others	7(4)		4(57)		3(43)	
B6	Communication and collaboration	25(15)		20(80)		5(20)	0.499
	Education and research	41(24)		32(78)		9(22)	
	Patient care	38(23)		30(79)		8(21)	
	Professionalism	4(2)		3(75)		1(25)	
	Self-development	25(15)		15(60)		10(40)	
	Social accountability	35(21)		24(69)		11(31)	
B7	Negatively	61(36)		44(72)		17(28)	0.921
	Positively	33(20)		25(76)		8(24)	
	Same as usual	74(44)		55(74)		19(26)	

Table 8. The impact of COVID-19 to Medical Students

Question	Male	Female	P-value
1. How has your amount of study time changed compared to before the COVID-19 situation?	5.57	5.32	0.564
2. How has your level of academic-related stress changed compared to before the COVID-19 situation?	8.49	7.75	0.012
3. How much has the current COVID-19 situation affected your studies?	8.70	8.50	0.496
4. Are you afraid of interacting with a typical patient (during clinical practice) as a medical student?	4.70	4.23	0.308
5. Are you afraid of interacting with a suspected coronavirus patient as a medical student (during clinical practice)?	6.14	5.45	0.117
6. Are you afraid of interacting with a confirmed coronavirus patient as a medical student (during clinical practice)?	6.90	6.30	0.201
7. How much do you think the current COVID-19 pandemic affects your life and behaviour?	9.04	8.89	0.431
8. How much do you think the current COVID-19 pandemic affects your role as a medical student?	9.11	9.05	0.754

II. Age

Tables 9, 10, and 11 show the result of a test of the relationship of Age with *Perception, Attitude, and Impact*. All of the tests were not significant. Therefore, Age variable had no significant relationship with the rest of the *Perception, Attitude, and Impact* questions.

Table 9. The perception of 4th year medical students regarding their role during pandemic era

Question	r-value	p-value
A1	-0.020	0.800
A2	-0.025	0.750
A3	-0.096	0.217
A4	-0.074	0.342
A5	-0.014	0.860
A6	-0.095	0.222
A7	0.044	0.570
A7.a	0.130	0.157

Table 10. The perception of 4th year medical students regarding their role during pandemic era

Question	r-value	p-value
B1	-0.055	0.482
B2	-0.102	0.187
B3	0.085	0.273
B4	0.122	0.115

Table 11. The impact of COVID-19 on Medical Students

Question	r-value	p-value
1. How has your amount of study time changed compared to before the COVID-19 situation?	0.061	0.432
2. How has your level of academic-related stress changed compared to before the COVID-19 situation?	-0.041	0.595
3. How much has the current COVID-19 situation affected your studies?	0.082	0.288
4. Are you afraid of interacting with a typical patient (during clinical practice) as a medical student?	-0.051	0.509
5. Are you afraid of interacting with a suspected coronavirus patient as a medical student (during clinical practice)?	0.076	0.324
6. Are you afraid of interacting with a confirmed coronavirus patient as a medical student (during clinical practice)?	0.097	0.210
7. How much do you think the current COVID-19 pandemic affects your life and behaviour?	0.066	0.398
8. How much do you think the current COVID-19 pandemic affects your role as a medical student?	0.102	0.190

III. School

Tables 12, 13, and 14 show the result of the test of difference and relationship of *School* in terms of *Perception, Attitude, and Impact*. The test was only significant in terms of item #6 in "Students' attitude toward clinical clerkship training during the COVID 19-pandemic" ($p=0.003$), item #3 ($p=0.041$) in "The Impact of COVID-19 on Medical Students" and item #8 in "The Impact of COVID-19 on Medical Students" set of questions ($p=0.000$). Hence, there was a significant relationship between the chosen important outcome of medical training

and the school of students. Also, there was a significant difference in the level of how much the studies and role as medical students were affected between schools. The important outcomes with the highest number chosen were education & research (both CPU and IDC) and social accountability (WVSU), (see Table 13). On average,

CPU students had the highest level of how much their studies (9.13) and role as medical students (9.74) were affected by the pandemic (see Table 14). Furthermore, the rest of the tests were not significant. Therefore, the *School* variable had no significant relationship with the rest of the *Perception, Attitude, and Impact* questions.

Table 12. The perception of 4th year medical students regarding their role during pandemic era

Question	Answer	n%	CPU		IDC		WVSU		P-value
			Mean	n(%)	Mean	n(%)	Mean	n(%)	
A1			8.81		8.74		8.93		0.738
A2			9.66		9.64		9.63		0.989
A3			7.94		7.58		7.96		0.522
A4			6.11		5.60		6.38		0.142
A5			8.74		8.55		8.68		0.812
A6			5.64		5.47		6.09		0.477
A7	No	118(70)		30(25)		38(32)		50(42)	
	Yes	50(30)		17(34)		15(30)		18(36)	
A7.a	Lack of ability for clinical practice	106(90)		24(23)		36(34)		47(44)	0.092
	Medical license issue	12(10)		7(58)		3(25)		2(17)	
A8	Acting as an assistant for healthcare professionals	23(14)		11(48)		6(26)		6(26)	0.408
	Acting as an informer to neighbors about the COVID-19	17(10)		3(27)		8(73)		6(55)	
	Actively learning about the COVID-19	8(5)		3(38)		1(13)		4(50)	
	All of the above	6(4)		1(17)		1(17)		4(67)	
	Be actively involved in clinical practice, if possible	26(15)		7(27)		7(27)		12(46)	
	Focusing on the medical education and learning as trainees	88(52)		22(25)		30(34)		36(41)	

Table 13. Students' attitude toward clinical clerkship training during the COVID 19- pandemic

Question	Answer	n%	CPU		IDC		WVSU		P-value
			Mean	n(%)	Mean	n(%)	Mean	n(%)	
B1			4.32		5.26		5.81		0.003
B2			6.55		6.51		6.84		0.0705
B3			8.94		8.68		8.29		0.090
B4	Needs to be maintained	138(82)		38(28)		40(29)		60(43)	0.727
	Needs to be reduced	30(18)		9(30)		13(43)		8(27)	
B5	Via meeting the patients	94(56)		3(30)		22(23)		44(47)	0.130
	Via meeting standardized patients or medical models	60(36)		16(27)		24(40)		20(33)	
	Online Education	4(2)		0(0)		3(75)		1(25)	
	Virtual reality	3(2)		2(67)		1(33)		0(0)	
	Others	7(4)		1(14)		3(43)		3(43)	
B6	Communication and collaboration	25(15)		6(24)		7(28)		12(48)	0.003
	Education and research	41(24)		14(34)		18(44)		9(22)	
	Patient care	38(23)		11(29)		9(24)		18(47)	
	Professionalism	4(2)		2(50)		0(0)		2(50)	
	Self development	25(15)		8(32)		13(52)		4(16)	
	Social accountability	35(21)		6(17)		6(17)		23(66)	
B7	Negatively	61(36)		21(34)		17(28)		23(38)	0.682
	Positively	33(20)		7(21)		12(36)		14(42)	
	Same as usual	74(44)		19(26)		24(32)		31(42)	

Table 14. The Impact of COVID-19 on Medical Students

Question	CPU	IDC	WVSU	P-value
1. How has your amount of study time changed compared to before the COVID-19 situation	6.02	5.53	5.13	0.173
2. How has your level of academic-related stress changed compared to before the covid	8.32	8.19	8.37	0.844
3. How much has the current COVID-19 situation affected your studies?	9.13	8.64	8.32	0.041
4. Are you afraid of interacting with a typical patient (during clinical practice) as a medical student?	4.55	4.26	4.84	0.497
5. Are you afraid of interacting with a suspected coronavirus patient as a medical student (during clinical practice)?	5.62	5.85	6.28	0.345
6. Are you afraid of interacting with a confirmed coronavirus patient as a medical student (during clinical practice)?	6.68	6.64	6.85	0.898
7. How much do you think the current COVID-19 pandemic affects your life and behaviour?	9.23	8.81	8.99	0.163
8. How much do you think the current COVID-19 pandemic affects your role as a medical student	9.74	8.83	8.85	0.000

IV. Experience Hospital Rotation

Tables 15, 16, and 17 show the result of the test of difference and relationship of *Experience Hospital Rotation* in terms of *Perception, Attitude, and Impact*. The test was only significant in terms of item #7 ($p=0.012$) in "*The Impact of COVID-19 on Medical Students*" and item #8 in "*The Impact of COVID-19 on Medical Students*" set of questions ($p=0.000$). Hence, there was a significant difference in the level of how much the life, behavior, and role

of medical students were affected between students who experienced hospital rotation and didn't. On average, students who had experienced hospital rotation had a higher level of how much their life, behavior (9.30), and role as medical students (9.74) were affected by the pandemic compared to students who did not experience hospital rotation (see Table 17). Furthermore, the rest of the tests were not significant. Therefore, the *School* variable had no significant relationship with the rest of the *Perception, Attitude, and Impact* questions.

Table 15. The perception of 4th year medical students regarding their role during pandemic era

Question	Answer	n%	No		Yes		P-value
			Mean	n(%)	Mean	n(%)	
A1			8.77		8.96		0.368
A2			9.60		9.72		0.471
A3			7.76		7.98		0.470
A4			6.03		6.12		0.786

A5			8.59		8.77		0.488
A6			5.70		5.89		0.684
A7	No	118(70)		79(67)		39(33)	0.712
	Yes	50(30)		32(64)		18(36)	
A7.a	Lack of ability for clinical practice	106(90)		74(70)		33(31)	0.161
	Medical license issue	12(10)		5(42)		7(58)	
A8	Acting as an assistant for healthcare professionals	23(14)		12(52)		11(48)	0.780
	Acting as an informer to neighbors about the COVID-19	17(10)		2(109)		5(45)	
	Actively learning about the COVID-19	8(5)		5(63)		3(38)	
	All of the above	6(4)		4(67)		2(33)	
	Be actively involved in clinical practice, if possible	26(15)		18(69)		8(31)	
	Focusing on the medical education and learnings as trainees	88(52)		60(68)		28(32)	

Table 16. Students' attitude toward clinical clerkship training during the COVID 19-pandemic

Question	Answer	n%	No		Yes		P-value
			Mean	n(%)	Mean	n(%)	
B1			5.36		4.47		0.056
B2			6.76		6.74		0.746
B3			8.54		8.86		0.120
B4	Needs to be maintained	138(82)		92(67)		46(33)	0.727
	Needs to be reduced	30(18)		19(63)		11(37)	
B5	Via meeting the patients	94(56)		59(63)		35(37)	0.109
	Via meeting standardized patients or medical models	60(36)		40(67)		20(33)	
	Online education	4(2)		4(100)		0(0)	
	Virtual reality	3(2)		1(33)		2(67)	
	Others	7(4)		7(100)		0(0)	

B6	Communication and collaboration	25(15)		18(72)		7(28)	0.433
	Education and research	41(24)		22(54)		19(46)	
	Patient care	38(23)		26(68)		12(32)	
	Professionalism	4(2)		2(50)		2(50)	
	Self-development	25(15)		17(68)		8(32)	
	Social accountability	35(21)		26(74)		9(26)	
B7	Negatively	61(36)		35(57)		26(43)	0.193
	Positively	33(20)		24(73)		9(27)	
	Same as usual	74(44)		52(70)		22(30)	

Table 17. The impact of COVID-19 on Medical Students

Question	No	Yes	p-value
1. How has your amount of study time changed compared to before the COVID-19 situation	5.35	5.81	0.265
2. How has your level of academic-related stress changed compared to before the COVID-19 situation?	8.29	8.32	0.921
3. How much has the current COVID-19 situation affected your studies?	8.47	9.00	0.052
4. Are you afraid of interacting with a typical patient (during clinical practice) as a medical student?	4.60	4.53	0.858
5. Are you afraid of interacting with a suspected coronavirus patient as a medical student (during clinical practice)?	6.11	5.67	0.275
6. Are you afraid of interacting with a confirmed coronavirus patient as a medical student (during clinical practice)?	6.77	6.68	0.852
7. How much do you think the current COVID-19 pandemic affects your life and behaviour?	8.85	9.30	0.012
8. How much do you think the current COVID-19 pandemic affects your role as a medical student?	8.77	9.74	0.000

V. Length of Stay during Rotation

Tables 18, 19, and 20 show the result of a test of the relationship of *Length of Stay during Rotation* with *Perception, Attitude, and Impact*. All of the tests were not significant except item #7 ($p=0.012$) in "*The Impact of COVID-19 on Medical Students*" and item #8 in "*The Impact of COVID-19 on Medical Students*" set of questions ($p=0.000$). Hence, there was a significant relationship between the level of how much life, behavior, and role of

medical students were affected by pandemic and length of stay during rotation. Furthermore, the relationship was directly proportional. Longer/shorter length of hospital stay during the rotation corresponds to a higher/lower level of how much the life, behavior ($r=0.193$), and role ($r=0.272$) of medical students were affected by pandemic (see Table 20). In addition, the rest of the tests were not significant. Therefore, the *Length of Stay* variable had no significant relationship with the rest of the *Perception, Attitude, and Impact* questions.

Table 18. The perception of 4th year medical students regarding their role during pandemic era

r-value	p-value
0.111	0.153
0.045	0.562
-0.005	0.944
0.003	0.971
-0.016	0.836
0.029	0.705
0.024	0.754
0.050	0.592

Table 19. Students' attitude toward clinical clerkship training during the COVID 19-pandemic

Question	r-value	p-value
B1	-0.008	0.918
B2	0.093	0.229
B3	-0.012	0.878
B4	-0.036	0.641

Table 19. Students' attitude toward clinical clerkship training during the COVID-19 pandemic

Question	r-value	p-value
1. How has your amount of study time changed compared to before the COVID-19 situation	0.012	0.887
2. How has your level of academic-related stress changed compared to before the COVID-19 situation?	-0.070	0.366
3. How much has the current COVID-19 situation affected your studies?	0.085	0.275
4. Are you afraid of interacting with a typical patient (during clinical practice) as a medical student?	0.005	0.949
5. Are you afraid of interacting with a suspected coronavirus patient as a medical student (during clinical practice)?	0.029	0.706
6. Are you afraid of interacting with a confirmed coronavirus patient as a medical student (during clinical practice)?	0.041	0.601
7. How much do you think the current COVID-19 pandemic affects your life and behaviour?	0.193	0.012
8. How much do you think the current COVID-19 pandemic affects your role as a medical student?	0.272	0.000

DISCUSSION

Clinical exposure of 4th year medical students is a crucial part of their medical education but due to COVID-19 pandemic, this was abruptly disrupted like the other medical schools around the world ⁽¹⁹⁾. This study aimed to assess what the medical students think their roles were during the time of the pandemic, their views of the new medical

education delivery system, their lifestyle as a student, and the impact this pandemic had on them. The study focused on the clinical clerks of the 3 medical schools in the city of Iloilo. The results revealed that disruption of the clinical training of the students had brought impact on their confidence for clinical practice. They agreed that changes should be made in the clerkship training at this time of pandemic but are not sure if the

present educational methods of learning are effective. Lastly, in this study, it was perceived that there was an increase in students' academic-related stress.

The Role of Medical Students in the Pandemic Era

In this study, it revealed that despite the danger that this pandemic has brought to each life of the frontliners, especially on a medical doctor, the level of interest of clinical clerks in COVID-19 was high (8.83) which was a little bit higher (7.06) than the level of interest in COVID-19 of the students in Korea⁽¹⁸⁾. It was also noted that social responsibility was high among the medical students (9.64). Although, they are not equipped with the clinical experience, were not sure if they are ready to participate in patient care, and think that they should focus on medical education and learning for now, but if the need arises in the future, respondents were willing to participate or assist in patient care. In contrast to the previous statement, students were neutral regarding having their graduation early or receiving a temporary license to augment the medical workforce in the future infectious disease situation, due to their lack of clinical skill. In countries like the USA, UK, Italy, South Africa, and Brazil, due to a national emergency or anticipation of one, expedite graduation was awarded to medical students in the condition that they will serve as frontline physicians^(5,20,21). In line with this, confusion on what was the role of clinical clerks in times of pandemics was placed under mitigation. The threat to life this pandemic has and the uncertainty it has brought, the students' role differs from country to country. Medical clerks were indeed students, but at the same time were clinicians-in-training. The American Association of Medical Colleges (AAMC) suspended student clerkship and instructed medical schools that medical student involvement should be reserved for critical health care professional shortage only. Possible reasons for the suspension of clerkship were concerns about the risk of infection to patients and students, PPE shortage, and associated liability issues⁽²²⁾. In the Philippines,

APMC advised pulling out of clerks from their respective hospital rotations. In this study most of the clinical clerks had no hospital exposure at all and only a few of them have a very short clinical experience, as compared to what was required hours of hospital rotation pre pandemically. This affected their confidence in handling patients as reflected in this study. In an article, the authors stated that allowing medical students to serve in the current circumstance may improve the medical student's patient care skills long before the healthcare system reaches a personnel crisis and, in some cases may even help prevent such crisis from occurring⁽²²⁾. This was one of the important things that the governing body that looks after the well-being of the medical students should consider in making policies.

Students' attitude toward clinical clerkship training during the COVID-19 Pandemic

Medical students around the world experienced a sudden shift from bedside rounds education to e-learning. In one study in Libya, students were concerned about how e-learning could be applied to provide clinical experience, especially since the final year of medical education depends heavily on bedside teaching⁽¹⁹⁾. Different educational platforms for non-contact lectures have been made available for this purpose to somehow fill the loss of access to physical hospital exposure. This rapid transition had left us with so many concerns, the result of which would be evaluated in the near future; as the products of this kind of educational modality proceed to further residency training and or clinical practice after their national board examination. In this study, respondents have a neutral response regarding the question that if that medical school education was working properly during COVID-19 pandemic^(5,22). In Korea, students favorably viewed the current online education system, but their professors and graduates who valued clinical practice expressed doubts about its effectiveness⁽¹⁸⁾. Moreover, participants in this study thought that medical school education should be

changed to fit into the new normal era (8.60). However, almost all of the students wanted to maintain the hands-on clinical practice education (82%) and thought that medical students can gain clinical experience in the pandemic era through patient encounters (56%) compared to other modalities; in contrast with the study done by Hong et al at University of Ulsan College of Medicine. Students in this university preferred simulated patients and models, online learning, and virtual reality over that of meeting an actual patient. Almost half the medical students here in Iloilo city thought that patients would accept them as usual trainees (44%) despite the ongoing pandemic in contrast to the Korean and Japanese studies that the students worried that they would be perceived as COVID-19 transmitters^(18,22,23). Lastly, education, patient care, and social accountability were the top three most important outcomes of medical education during the pandemic era. Of note, there was a significant relationship between chosen and important outcomes among students coming from a private and government school. The important outcome with the highest number chosen was education & research from students in private schools and social accountability from a public school.

Impact of COVID-19 on Medical Students

On average, there was no significant change in the study time among 4th year medical students as compared before the COVID-19 situation (5.51) the same result was obtained among other medical students in Asia⁽¹⁸⁾. Although the current situation provides more free time to students because there was a cancellation of extracurricular activities, only a few of the students were spending more time studying. Free time was invested in other activities like developing new hobbies and new habits such as reading, cooking, playing instruments, painting, etc.⁽²⁴⁾. However, in this study, there was a perceived increase in the level of academic-related stress (8.30) and this definitely affected the studies of students (8.65). Academic stress has been long

recognized as a predictor of poor mental health in medical students⁽²⁵⁾. The drastic change in the methods of learning may be a trigger for students who are already susceptible to high levels of academic stress⁽²⁶⁾, especially for those transitioning from a student to a doctor⁽²⁷⁾. Between male and female students, male (8.49) students experienced a higher increase in stress level compared to female (7.75) students. There are inconsistencies reported in different studies done in the past regarding gender -related stress. This was attributed to the differences in the social and educational environment^(28,29,30,31,32). Medical students in the city were neither not afraid nor afraid of interacting with typical (4.58) or suspected coronavirus patients (5.96) but were very afraid of interacting with confirmed coronavirus patients (6.74). The same reaction was observed with the other medical students in the previous study⁽⁵⁾. Lastly, the life, behavior (9.00), and their role as medical (9.10) students were definitely affected by the current COVID-19 pandemic. The students who were able to participate in in-hospital patient care and had a longer duration of stay had a greater understanding of the effect of COVID-19 pandemic had on their training, role as a student, behavior, and life as a whole.

Limitations

Our study has limitations. Firstly, our study was conducted in only one city here in the Philippines, therefore the results might not be reflective of the national medical education condition as results may vary from different schools and regions. Secondly, there is not enough published literature in this area for comparison and contrast with our findings. To our knowledge, no study has been made yet in our locality. However, despite the above limitations. We are hopeful that our findings will be able to provide valuable information about the perceptions and attitudes of clinical clerks during the time of the pandemic.

CONCLUSIONS

In conclusion, the respondents were predominantly male, with a mean age of 25 years old. Less than half of them were able to experience in-hospital clinical exposure. The areas that they were to rotate were Pediatrics, Internal Medicine, Surgery and Obstetrics and Gynecology respectively with the mean duration of 15 days total hospital exposure. Most of the students perceived that during this pandemic they cannot participate in patient care due to lack of clinical experience despite their willingness to help. They still see their goal at this time is education and to learn more as trainees. They agreed that medical education at this time should change to tailor fit their needs for safe education but on the other hand expressed their desire to maintain and be able to experience hands-on in-hospital patient care. This study also revealed that the present pandemic has affected the students as a whole in areas of their role, behavior, and life.

RECOMMENDATIONS

The researchers would like to recommend the following:

1. A similar study on a national scale should be conducted for the gathering of information regarding the challenges our clinical clerks are experiencing so that a program or policy should be made to improve the medical education during the pandemic crisis in the present time and the future.
2. Alternative teaching approaches (virtual medical interviews, electronic health records, electronic problem-based learning, etc.) for a clinical clerkship with regular evaluation of its effectiveness should be explored so that the best method tailored fit to the needs of the students will be formulated.

3. Despite the present pandemic, medical clerks who are willing to experience clinical rotation should be allowed with strict compliance to health safety precaution guidelines with consent from the student's family.
4. In line with the above recommendation, if clinical clerks would be allowed to experience clinical exposure, rigorous training of putting on a personal protective suit should be done with a regular repeat performance in front of their clinical instructor for checking and evaluation to ensure their safety.
5. Regular psychological assessment should be done on the medical students so that appropriate support will be given on time.
6. Coping strategies should be explored and taught to these students to help them cope with their personal daily stresses.

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Multisystem Inflammatory Syndrome in Children*

Angela Mae B. Montero, MD¹

ABSTRACT

Multisystem inflammatory syndrome in children (MIS-C) is a condition which is associated with Coronavirus that mimics Kawasaki Disease (KD) where organ dysfunction is evident which includes the heart, lungs, kidneys, brain, skin, eyes, or gastrointestinal organs.

This report describes the first case of Multisystem Inflammatory Syndrome in children in Region 1. Our patient is a 3 year old female who presented with sudden onset of high grade fever, abdominal pain and diarrhea, a month after recovering from COVID-19 infection. On admission, the patient was irritable, febrile with conjunctival erythema, reddish dry lips, slightly distended and non-tender abdomen, erythematous rash over umbilicus, feet and hands, minimal edema of hands and feet. Laboratories requested showed elevated inflammatory markers, elevated BNP, Troponin I, elevated D-dimer, fibrinogen and prolonged activated partial thromboplastin time (APTT) and prothrombin time (PT) (Appendix A,B,C,H). 2D-echocardiography showed left ventricular dysfunction, moderate mitral regurgitation, minimal pericardial effusion and right coronary artery ectasia (Appendix F). On second hospital day, she had hypotension hence was transferred to Intensive Care Unit which required initiation of inotropes and close care monitoring. Intravenous Immunoglobulin (IVIg) and corticosteroids were also started. She was discharged stable and improved on seventh hospital day with a repeat 2D-echocardiogram showing

improved left ventricular function and decrease in right coronary artery dilation.

Prompt recognition of this syndrome allows clinicians to acquire appropriate laboratory testing, initiate treatment and provide families with accurate prognostic information.

Keywords: Multisystem Inflammatory Syndrome, COVID-19, Intravenous immunoglobulin

OBJECTIVES

1. To present a case of Multisystem Inflammatory Syndrome in children.
2. To present the incidence of Multisystem Inflammatory Syndrome
3. To discuss the clinical features, causes, criteria, treatment and outcome of MIS-C.

INTRODUCTION

On December 31, 2019 the World Health Organization reported cases of pneumonia of unknown cause in Wuhan City, China. A novel coronavirus was identified as the cause by Chinese authorities on 7 January 2020 and was named "2019-nCoV".

The World Health Organization has designated the disease COVID-19, which stands for coronavirus disease 2019. The virus that causes COVID-19 is designated severe acute respiratory syndrome coronavirus 2 (SARS-Cov 2).

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¹From Region 1 Medical Center, Dagupan Pangasinan

In children, COVID-9 is generally mild. However, in rare cases, children maybe critically affected, and medical manifestations may also vary from adults (1). Multisystem Inflammatory Syndrome in children is a rare complication associated to COVID-19 infection presented as high grade fever, elevated inflammatory markers and organ dysfunction occurring 4-6 weeks after infection (5). The incidence of MIS-C is uncertain, occurring <1% of children with previously infected confirmed SARS-CoV-2 infection

CASE

This is a case of a 3 year old female who was admitted due to fever. History started five weeks prior to admission, when the patient was exposed to a COVID-19 confirmed patient, she was subjected to COVID RT-PCR which turned out positive. She was admitted at a local isolation facility in which she exhibited loose stools for 1 -2 days without other accompanying symptoms. A repeat RT-PCR was done on tenth day of illness which turned out negative.

On interim, the patient remained asymptomatic until six days prior to admission where she had sudden onset of highgrade fever (highest temperature of 38.7C) with no other reported symptoms. Paracetamol was given with partial relief of symptoms.

Four days prior to admission, persistence of fever associated with abdominal pain and 3-4 episodes of loose stools hence consult was done. Urinalysis result showed urinary tract infection. Patient was sent home and started on cefixime.

Two days prior to admission, persistence of fever and loose stools with erythematous rash appearing over the periumbilical area, hands and feet. (Figure 1 and 2)



Figure 1. Erythematous rash noted at periumbilical area



Figure 2. Erythematous rash hands appeared two days before admission

One day prior to admission, persistence of fever accompanied by reddish eyes with non-purulent discharge and severe abdominal pain prompted consult and was subsequently admitted.

On admission, the patient was irritable, febrile with conjunctival erythema, reddish dry lips, no strawberry tongue, no palpable cervical lymphadenopathy, slightly distended abdomen with normoactive bowel sounds, nontender, erythematous rash over umbilicus, feet and hands, minimal edema of hands and feet (Figure 3 and 4). The patient was referred to pediatric rheumatology with an assessment of probable COVID-19 multisystem inflammatory syndrome in children. Laboratory results showed elevated inflammatory markers (ESR and CRP) as well as leukocytosis with neutrophilia and lymphopenia on complete blood count (Appendix A,B). The patient's SARS COV 2 antibody test showed a positive IgG result (Appendix J).



Figure 3. Erythematous rash now prominently seen over feet with noted minimal edema



Figure4. Progression of erythematous rash on hands accompanied by minimal edema

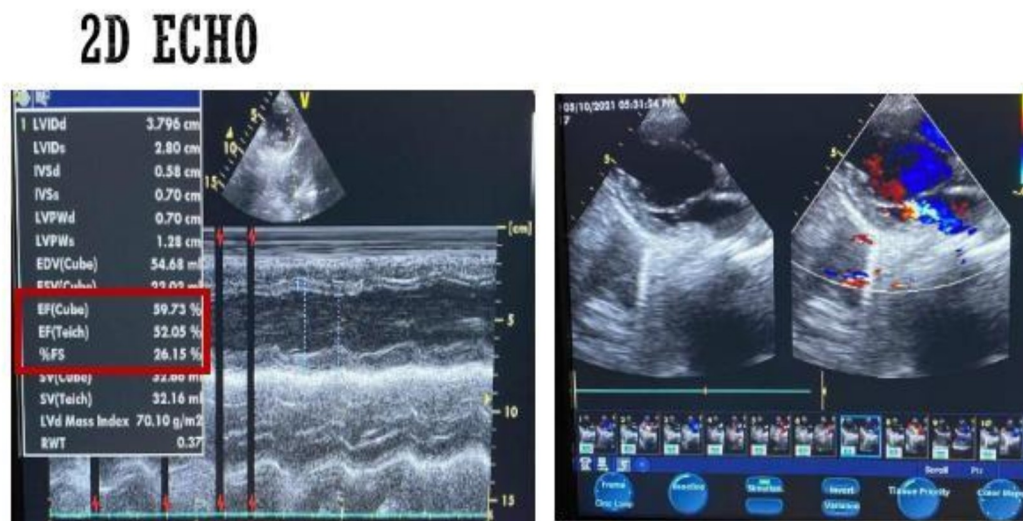


Figure 5. 2D-Echocardiography

On the second hospital day, the patient was hypotensive (BP of 80/60mmHg). She was transferred to Pediatric intensive care unit (PICU). Dopamine was shifted to norepinephrine and dobutamine. Intravenous immunoglobulin was given at 2g/kg, prednisone and aspirin were continued.

On third hospital day, after IVIg infusion, the patient was stable with no recurrence of fever and abdominal pain. Inotropes were gradually tapered and norepinephrine was eventually discontinued. Blood and urine culture and sensitivity were unremarkable (Appendix G). The patient was transferred to a regular ward.

On fifth hospital day, repeat 2D Echo showed improved left ventricular function and decrease in right coronary artery dilation. Dobutamine drip was discontinued. She was discharged stable and improved on 7th hospital day. Take home medications were digoxin, aspirin and prednisone (tapering).

Differential Diagnosis

	Rule In	Rule Out
1. Kawasaki Disease	Fever Conjunctival erythema Erythematous rash on hands and feet	Gastrointestinal Symptoms Shock More Elevated Inflammatory markers
2. Toxic Shock Syndrome	Fever Erytematous Multisystem involvement Hypotension	Positive Blood cultures Positive for Serologic tests
3. Bacterial Sepsis	Fever Shock Elevated Inflammatory markers	Blood culture and Sensitivity: No growth Urine Culture and Sensitivity: no growth

DISCUSSION

Multisystem inflammatory syndrome in children (MIS-C) is a condition where body parts can become inflamed, including the heart, lungs,

kidneys, brain, skin, eyes, or gastrointestinal organs (1). It is diagnosed clinically based on signs and symptoms presented by the patient persistent fever and dysfunction of one or more organs, such as the heart or gastrointestinal system, together with laboratory examinations to look for signs of inflammation in the body. Testing is also done to rule out other possible causes of the symptoms, such as other infections (2).

MIS-C patients had a male to female ratio of 1.37 to 1. Majority of patients had symptoms appearing around 4-6 weeks after COVID 19 infection. Hispanic and African MIS- C were commonly affected than non-Hispanic and Asians. Hispanic patients had more severe disease outcomes.

Table 1 shows the preliminary case definition of CDC and WHO.

Table 1

CDC case definition (ALL 4 CRITERIA MUST BE MET)	WHO case definition (ALL 6 CRITERIA MUST BE MET)
1. Age <21 years	1. Age 0 to 19 years
2. Clinical presentation consistent with MIS-C, including ALL of the following: a. Fever	2. Fever for >3 days
b. Laboratory evidence of inflammation Including but not limited to any of the following: • ↑CRP • ↑ESR • ↑Fibrinogen • ↑procalcitonin • ↑D-dimer • ↑ferritin • ↑LDH • ↑IL-6 level • Neutrophilia • Lymphocytopenia • Hypoalbuminemia	3. Clinical signs of multisystem involvement (at least 2 of the following) • Rash, bilateral nonpurulent conjunctivitis or mucocutaneous inflammation signs(oral hands or feet) • Cardiac dysfunction, pericarditis, valvulitis or coronary abnormalities • Hypotension or shock • Evidence of coagulopathy • Acute gastrointestinal symptoms (diarrhea, vomiting or abdominal pain)
c. Multisystem involvement 2 or more organ systems involved	4. Elevated markers of inflammation (eg, ESR, CRP or procalcitonin
d. Severe illness requiring hospitalization	
3. No alternative plausible diagnoses	5. No other obvious microbial cause of inflammation
4. Recent or current SARS-CoV 2 infection or exposure	6. Evidence of SARS-CoV 2 infection

Our patient is a 3 year old female who had intermittent high grade fever, with more than 2 multisystem involvement, all inflammatory markers were elevated. CDC included D-dimer, ferritin, lactate dehydrogenase. Both required that infections and other causes must have been ruled out and both required evidence of a recent or current sars cov 2 infection or exposure. Our patient's case satisfied both CDC and WHO case definition for MIS-C.

Our patient was noted to have overlapping signs and symptoms of (KD). However, clinical features of our patient that differed from KD are the following: 1. Abdominal pain; 2. Diarrhea; 3. Abnormal cardiac enzymes; 4. Immediate improvement of cardiac function after single IVIg treatment; 5. Higher inflammatory markers than patients with KD; 5. Previously diagnosed with COVID-19 or has exposure to patients positive to COVID-19.

Table 2 shows the difference between MIS-C and KD.

Table 2

MIS-C	KAWASAKI DISEASE
Affects older children and adolescents	Typically affects infants and young children
Black and Hispanic children	Higher incidence in East Asia and children of Asian descent
Gastrointestinal symptoms are very common	Less prominent in classic KD
Myocardial dysfunction and shock occur more commonly	Less common with classic KD
More ELEVATED inflammatory markers	Elevated inflammatory markers
Absolute lymphocyte and platelet counts tend to be lower	Thrombocytosis

Whittaker, E, Clinical characteristics of 88 children with a pediatric inflammatory multisystem syndrome temporally associated with SARS-CoV2. JAMA, 2020;324(3):259-269



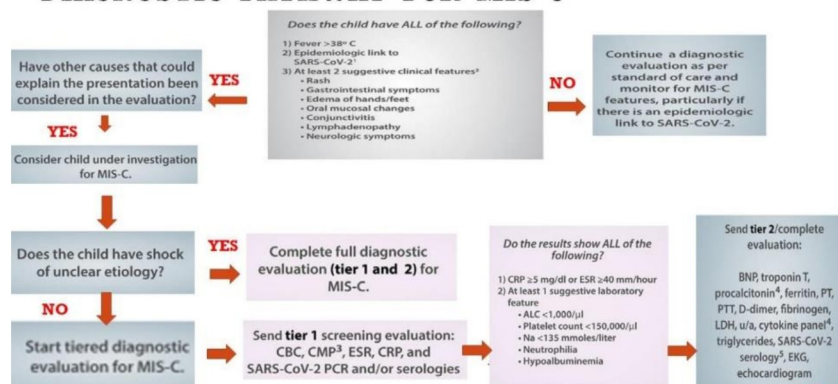
Different signs and symptoms related to MIS-C are not specific, however, diagnosis should be based on high index of suspicion and clinical judgment, taking into account the patient's history,

severity of organ dysfunction and strongly elevated inflammatory markers.

Table 3 shows Diagnostic Pathway for MIS-C according to American College of Rheumatology

Table 3

DIAGNOSTIC PATHWAY FOR MIS-C



Treatment goals of MIS-C are to stabilize patient with life threatening manifestations such as shock and to prevent long-term sequelae which may include coronary artery aneurysm, myocardial fibrosis/scarring, and fixed cardiac conduction abnormalities (4). Children diagnosed with MIS-C need close observation. Patients need to be admitted to the hospital, and some may need intensive care. Pediatric specialists in rheumatology, critical care, and cardiology can anticipate and address different aspects of the illness. Treatments include IV immunoglobulin (used to treat Kawasaki disease), and anti-inflammatory drugs (corticosteroids, and drugs blocking IL-1 or IL-6). Anakinra, an Interleukin 6 antagonist receptor may be considered for treatment of refractory to IVIg and glucocorticoids or in patients with contraindications to these treatments. Our patient was started on prednisone and aspirin when inflammatory marker results were elevated. Low-dose aspirin was used to decrease the risk of blood clots. Captopril, furosemide and digoxin was started when 2D Echo result showed left ventricular dysfunction, right coronary dilation, mitral regurgitation and pericardial effusion. Other treatments may be used depending on the results of laboratory tests.

SUMMARY

I have reported a case of Multisystem Inflammatory Syndrome in a 3-year-old female who presented with a 6 days history of fever. The incidence is uncertain, cases usually peak several weeks after being positive to COVID-19 or exposed to a confirmed patient. Prompt recognition of this syndrome enables clinicians to obtain proper diagnosis, treatment, and provide families with accurate prognostic information.

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Appendix A

CBC	05/09	05/13
WBC	25.0	16.3
N	0.91	0.82
L	0.06	0.15
M	0.03	0.03
RBC	3.89	3.45
Hgb	108	97
Hct	0.31	0.28
MCV	78.4	80.9
MCH	27.8	28.1
MCHC	35.4	43.8
Platelet	356	618

Appendix B

	05/09	05/13
ESR	75mm	
CRP	20.71	99.67
Procalcitonin	9.58ng/mL	
Serum LDH	335	289
AST	48	
ALT	36	
Creatinine	0.6 mg//dL	
Serum Albumin	3.3g/dL	

Appendix C

	05/10	05/13
BNP	>4130 (H)	
Fibrinogen	8.34g/L H	
Serum Ferritin	275.89 H	
D dimer	2345.02ng/mL H	2003.28
Troponin I	0.47 ng/mL H	0.09
Triglyceride		158

Appendix D

SERUM ELECTROLYTES (05/09)		
Na	130	136 - 149
K	3.4	3.8 – 5.0
Ca	7.8	8.4 – 10.2

Appendix E

05/09/2021	05/09/2021
CHEST XRAY: Reticular opacities seen in the right inner to mid lung zones, Pneumonia	Whole abdominal ultrasound: Enlarged liver with fatty changes, splenomegaly, enlarged but morphologically unremarkable kidneys

Appendix F

05/09/2021	05/09/2021
- Fair left ventricular systolic function at 52% to 54% - RCA dilation - o Proximal 0.24cm to 0.36cm - o Middle 0.22 to 0.35 - o Distal 0.19 to 0.33cm - Pericardial effusion 0.47 to 0.75cm, RV side - No vegetation	- Good LV function 66% - MR trivial - + pericardial effusion 0.44 to 0.64cm, RV side - RCA dimensions: - o Proximal 0.19 to 0.31 - o Middle 0.21 to 0.34 - o Distal 0.18 – 0.32

Appendix G

05/10 Blood Culture and sensitivity – No Growth	Urine Culture and Sensitivity – no Growth
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Appendix H

	05/09	05/13
APTT	64.8 H	28.9
PT	13.4	14.0
Control	12.9	12.9
% activity	91.5%	82.1%
INR	1.04	1.08

Appendix I

5/11/ Urinalysis
Yellow, slightly turbid
Glucose: Negative Protein: Negative
pH 6.0 Specific Gravity: 1.010
RBC: 1-3 Pus cells: 6-8
Bacteria: Few

Appendix J

05/10/2021
RT PCR – Negative
COVID Antibody TEST:
IgM: negative
IgG : positive

Treatment goals of MIS-C are to stabilize patient with life threatening manifestations such as shock and to prevent long-term sequelae which may include coronary artery aneurysm, myocardial fibrosis/scarring, and fixed cardiac conduction abnormalities (4). Children diagnosed with MIS-C need close observation. Patients need to be admitted to the hospital, and some may need intensive care. Pediatric specialists in rheumatology, critical care, and cardiology can anticipate and address different aspects of the illness. Treatments include IV immunoglobulin (used to treat Kawasaki disease), and anti-inflammatory drugs (corticosteroids, and drugs blocking IL-1 or IL-6). Anakinra, an Interleukin 6 antagonist receptor may be considered for treatment of refractory to IVIg and glucocorticoids or in patients with contraindications to these treatments. Our patient was started on prednisone and aspirin when inflammatory marker results were elevated. Low-dose aspirin was used to decrease the risk of blood clots. Captopril, furosemide and digoxin was started when 2D Echo result showed left ventricular dysfunction, right coronary dilation, mitral regurgitation and pericardial effusion. Other treatments may be used depending on the results of laboratory tests.

SUMMARY

I have reported a case of Multisystem Inflammatory Syndrome in a 3-year-old female who presented with a 6 days history of fever. The incidence is uncertain, cases usually peak several weeks after being positive to COVID-19 or exposed to a confirmed patient. Prompt recognition of this syndrome enables clinicians to obtain proper diagnosis, treatment, and provide families with accurate prognostic information.

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Appendix A

CBC	05/09	05/13
WBC	25.0	16.3
N	0.91	0.82
L	0.06	0.15
M	0.03	0.03
RBC	3.89	3.45
Hgb	108	97
Hct	0.31	0.28
MCV	78.4	80.9
MCH	27.8	28.1
MCHC	35.4	43.8
Platelet	356	618

Appendix B

	05/09	05/13
ESR	75mm	
CRP	20.71	99.67
Procalcitonin	9.58ng/mL	
Serum LDH	335	289
AST	48	
ALT	36	
Creatinine	0.6 mg//dL	
Serum Albumin	3.3g/dL	

Human Otoacariasis in a 40-Year Old Filipino Male: A Case Report*

Jaeziel S. Lopez, MD¹

ABSTRACT

A 40-year old male, Filipino, farmer, from Bakun, Benguet, presented with a 9 months history of itchiness of right ear. He reported that he was able to collect 4-5 insects every time he cleans his ear. Consult was done with an Ears, Nose and Throat specialist and video-otoscopic examination revealed multiple animate foreign body (mites) at different stages of development. The patient underwent 5 sessions of ear flushing with warm water at intervals of 2 weeks for 3 months. Collected insects were referred to an entomologist and were identified as *Suadasia pontifica* Oudemans, belonging to family: *Acaridae*. Follow up consult after 5 sessions of ear flushing revealed complete removal of mite infestation of his right ear. Patient was instructed to do ear flushing twice daily using warm water mixed with 70% isopropyl alcohol to eradicate any eggs left behind. No other medications were given. Based on Philippine Journal of Otolaryngology – Head and Neck Surgery, Health Research and Development Information Network, and Cochrane Database of Systematic Reviews, this is the first reported case of human otoacariasis in the Philippines.

Keywords: Mites, Mite infestation, Acari, Otoacariasis, *Suadasia pontifica* Oudemans

INTRODUCTION

Foreign bodies are commonly encountered in ears, nose, throat outpatient clinic and emergency department. Animate foreign bodies constitute up to 14% of cases, majority being the cockroaches¹.

Otoacariasis is a very peculiar and rare condition wherein the foreign body in question is an arthropod of the Acari subclass, be it a mite or a tick². A study conducted in the State of Karnataka, India revealed that more than 80 % of the human otoacariasis cases are due to ticks³. Mite infestation in the human ear is an extremely rare phenomenon, with a handful reported cases since 1977². There are reports of human otoacariasis from Saudi Arabia (*Loxanoetus*), South Africa and United States (*Otobius*), Nepal (*Dermacentor*), Malaysia (*Dermacentor* and *Haemaphysalis*), Sri Lanka (*Amblyomma*, *Boophilus*, *Hyalomma*, *Dermacentor*, *Rhipicephalus* and *Haemaphysalis*)⁵, South Korea (*Haemaphysalis longicornis*)⁴, Iran (*Rhyzoglyphus*)⁵, Taiwan (*Suidasia pontifica*)⁶, and Thailand (*Suidasia pontifica*)⁷. Most recent report of said case was in Korea on the year 2018. This report represents the first documented case of human otoacariasis in the country.

This report aims to document a case of human otoacariasis and to present a brief discussion of human otoacariasis infestation.

*2nd Place, 2022 Philippine Medical Association Case Report Presentation, May 20, 2022

¹From Baguio General Hospital and Medical Center, Baguio City

CASE REPORT

This is a case of a 40-year old male, Filipino, farmer, residing in Bakun, Benguet. Nine months prior to consult, he started to complain of itchiness of his right ear prompting him to clean his ear with cotton buds daily. The patient reported that he noticed insect-like objects on the cotton buds he used. There was no associated ear trauma, ear discharge, ear bleeding, tinnitus, and ear pain. No consult or any intervention was done.

Interval history revealed persistence of itchiness of the right ear with increasing severity. He was able to collect 2-4 insects every time he cleans his ear with cotton buds. He also complained of animate foreign body sensation in his right ear. However, he denied ear discharge, ear pain, tinnitus, headache, dizziness, fever and other subjective complaints. No other household member presented with the same condition.

In attempt to eradicate insect infestation, he filled his right ear with gin liquor and then manually cleaned his ear using cotton buds which provided temporary relief. However, a week after said self-intervention, ear pruritus with associated animate foreign body sensation recurred. Due to the pandemic, no consult was done.

The patient continued to present with the above stated condition until a month prior to consult. The severity of itchiness of his right ear became intolerable prompting him to seek consult at a local health unit wherein he complained of severe itchiness of the right ear with associated animate foreign body sensation and insects collected from ear cleaning. He was then advised to seek consult with an ENT.

On video-otoscopic examination, the skin lining the right ear canal was erythematous. There were noted multiple animate foreign bodies (mites) at different stages of development (eggs, larva and adult stage) crawling in the right mastoid cavity, no

noted discharge and/or bleeding. Noted with presence of Type V Tympanoplasty and granulation tissue overlying the eustachian tube (Figures 3). Further history revealed that the patient underwent Mastoidectomy, Right when he was 24 years old. Gradual loss of hearing was noted since the said procedure and total loss of hearing of his right ear was noted at 30 years of age. Patient also claimed that he often carries manure as part of his daily activity in his fieldwork.

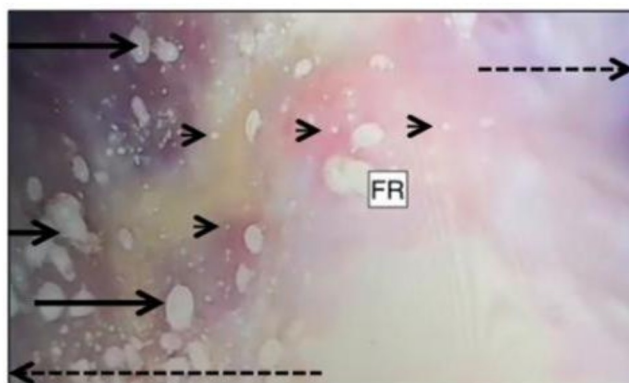


Figure 1: Video-otoscopic image of right mastoid cavity.
FR: Facial Ridge; Arrow: Adult mite; Arrow Head: Eggs;
Dashed arrow to the left: Towards the mastoid cavity area; Dashed arrow to the right: Toward the external auditory canal



Figure 2: Video-otoscopic image of superior portion of right mastoid cavity.
TM: Tegmen Mastoideum; Arrow: Adult mite;
Arrow Head: Eggs



Figure 3: Video-Otoscopic image of right external auditory canal
GT: granulation tissue overlying the area of tympanic membrane, Arrow: Adult mite

One week after the initial ear flushing, the patient's symptoms persisted and mites were still present. Collected insects (Figure 4) were submitted to an entomologist for review and were identified as *Suidasia pontifica* Oudemans. Due to the limited view provided by the video-otoscopy submitted, specific stages of development were not confirmed.

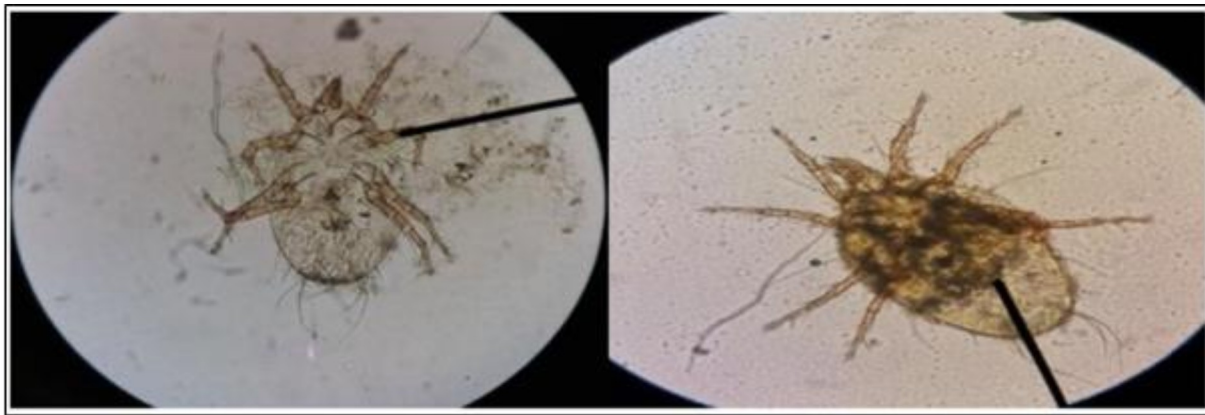


Figure 4: Specimens (adult stage) obtained from the patient on a wet mount viewed under a light microscope MPO

The patient underwent 5 sessions of ear flushing with warm water at intervals of 2 weeks for 3 months which revealed complete removal of mite infestation of his right ear (Figures 5-7). Patient and watcher were instructed to do ear flushing twice daily for 4 weeks using warm water mixed with 70% isopropyl alcohol to eradicate any eggs left behind. Patient was advised to observe proper hygiene such as hand washing before and after handling products in the field. No other medications were given.

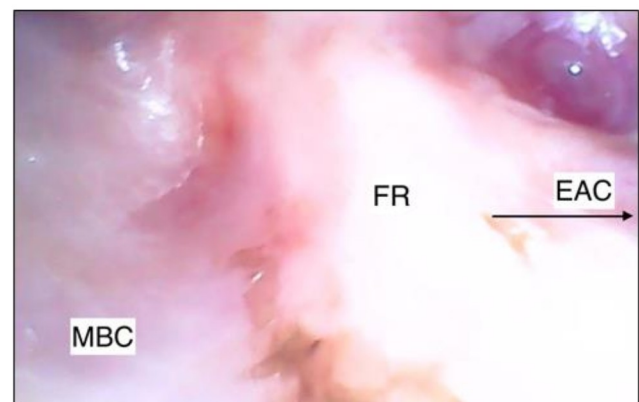


Figure 5: Video-otoscopic image of right mastoid cavity
FR: Facial Ridge; EAC: External auditory canal; MBC: Mastoid bowl cavity



Figure 6: Video-otoscopic image of superior portion of right mastoid cavity.
TM: Tegmen mastoideum

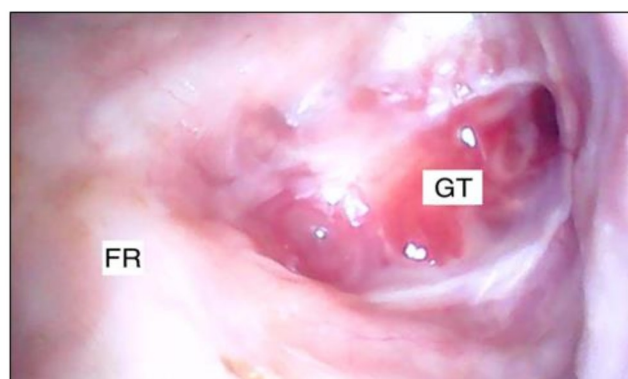


Figure 7: Video-otoscopic image of the right external auditory canal
FR: Facial Ridge; GT: Granulation tissue overlying the area of tympanic membrane

DISCUSSION

Acarid, (subclass *Acari* or *Acarida* or *Acarina*), is any member of the subgroup of the arthropod class *Arachnida* that includes the mites and ticks. *Suidasia pontifica* (*Acaridida: Suidasiidae*) is commonly found in most tropical countries where temperature and humidity are high throughout the year; mostly associated with stored agricultural products such as rice grain, rice flour, cereals, animal feed and even inside our houses⁸. Mites belonging to family *Acaridae* infest stored foods (preferably in damp places), prefer high relative humidity, and usually are fungivores. Mites are common inhabitants of stored products of all kinds including grain and grain based commodities

at all stages of processing. They commonly infest grain during harvesting, transporting, processing for consumption and storage. Mites are described to have a fungivorous character of mites as they fed on hyphae of various fungi available⁹.

Occasionally mites can gain access to the human ears and can cause otoacariasis as occupational problem. The local lesions observed in ear infection such as skin congestion, increased vascular permeability and raised temperature creates favorable conditions for their development. Mites are facultative commensals surviving on secretions, exudates and microflora in ears of certain mammals. Also, it is more plausible to believe that environmental factors (hot, humid, damp climate), occupation (agricultural workers, veterinarians, poultry workers), and an underlying ear infection (otitis externa, otitis media, mastoiditis, etc.) can predispose to mite infestation⁹.

Suidasia pontifica Oudemans is a mite that is cosmopolitan in distribution and is particularly widespread in the Oriental Region^{9,12}. In Malaysia, the species was found as a common inhabitant of house dust¹¹. The Philippines is not an exception to the list of the species' distribution range. Within this country, *Suidasia pontifica* is widely distributed and occurs on different plants, organic debris, litter, moss, decaying vegetation, upper layer of soil, poultry houses, house dust, stored foods, other arthropods and even on vertebrates. Pacia et al., studied the biology of *Suidasia pontifica* at University of the Philippines Los Baños. The said species passes through egg, larval, protonymphal, deutonymphal and adult stages ranging from 10-25 days. The total number of eggs laid by mated females ranged from 289-0907 eggs while those unmated ones, as they present parthenogenesis, ranged from 1 to 116 eggs¹².

Cases of human otoacariasis (also called as parasitic otitis) by ticks have been reported from various countries but ear infestation caused by mites is less common and under reported⁹. Paleri V. and Ruckley RW. reported a case of recurrent infestation of mastoid cavities with the storage mite *Sancassania berlesie*¹⁰. Samung Y et al., ang Ho, SH., reported similar cases of mite infestation due to *Suidasia pontifica*^{6,7}.

The patient works as a farmer generally tending crops and started to present with ear itching on the month of March, during the harvest season of cabbages in Bakun, Benguet where humidity was high. The patient may have acquired infection while handling contaminated harvest. Possibly the mites entered the ear from dust or by direct transfer from hands. Several species of mites have been reported to infest stored products⁹. It is suggested that good personal hygiene such as hand washing after handling products in the fields or in stores is an important preventive measure.

CONCLUSION

Human otoacariasis is rarely documented and underreported in literature. One must suspect tick and/or mite infestation for patients coming in with otalgia and/or ear pruritus, and animate foreign body sensation from rural areas with agricultural occupation. They should be carefully examined for possibility of infestation. Several species of mites have been associated with human otoacariasis hence; appropriate method for collection of mites to permit correct identification is needed. Preventive measure includes observance of good personal hygiene such as hand washing after handling products in the field.

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A Rare Case of Food Bolus Impaction on top of Stricture Formation secondary to a 12- year Retained Foreign Body (Denture) in the Esophagus of a 34-year old Male: A Case Report*

Kris Anne T. Estoesta, MD; Donnie Jan L. Segocio, MD, FPSO-HNS

ABSTRACT

Objectives: This paper aims to present a rare case of a 34-year old male who had esophageal food bolus impaction on top of stricture formation secondary to a retained 12-year esophageal foreign body (denture). It also aims to state the significance of proper and comprehensive history taking, physical examination and corresponding ancillary procedures to arrive at its diagnosis and to highlight the importance of a multidisciplinary team in the prevention and management of complicated foreign body (FB) impaction.

Methods:

Design: Case Report

Setting: Government Tertiary Hospital

Patient: One

Results: A 34-year old male presented with one day history of dysphagia after ingesting a chunk of pork. He had no other symptoms and was not in any respiratory distress. Physical examination was unremarkable except for missing dentition (teeth #8, #9 by universal notation system). Radiographic imaging, esophagogram and contrast-enhanced chest CT scan revealed partial proximal esophageal obstruction probably secondary to retained foreign body at the level of T5 vertebra. Rigid esophagoscopy with removal of foreign body (food bolus) was done. However, there was difficulty insinuating the scope

beyond this level. Further investigation and the use of multispecialty collaboration eventually led to the retrieval of a 12-year denture covered by a bi-mucosal flap with surrounding stricture formation.

Conclusion: Foreign body impaction, while more commonly found in the pediatric population, may also occur in adults especially those with edentulism, psychiatric disorders, alcoholism and preexistent esophageal pathologies. In rare cases, patients may be asymptomatic resulting to a delay in its diagnosis. In addition to a well-taken history and physical examination, direct visualization and computed tomography are vital for evaluation. A multidisciplinary approach is critical in its management especially when anticipating difficult extraction and considering FB impaction complications.

Keywords: *chronic esophageal foreign body, stricture formation, rigid esophagoscopy, laparotomy, case report*

CASE REPORT

A 34-year old male who was previously well consulted at the emergency room with a chief complaint of dysphagia. A day prior, he had experienced sudden dysphagia after ingesting a portion of pork approximately 2x2cm in size at a drinking bout. He drank water in an attempt to relieve himself but vomited shortly after. He had no other symptoms such as choking, drooling, odynophagia,

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From Department of ENT-HNS, Southern Philippines Medical Center, Davao City

chest pain, fever, and abdominal pain. Past medical history, family medical history and personal social history were all unremarkable.

The patient was seen awake, oriented, ambulatory and not in respiratory distress. It was noted that the patient had dentures and missing maxillary central incisors. There were no unusualities seen upon examination of the oral cavity, as well as in the oropharynx. Upon indirect laryngoscopy using a 70-degree rigid endoscope, there were no masses, Jackson's sign, vocal cord immobility and foreign body visualized. The rest of the head and neck examination were unremarkable.

The primary consideration at this time was food bolus impaction; hence, the patient underwent cervical and chest radiographic imaging which then revealed a straightened cervical spine probably due to myospasm, at least two linear metallic densities, with maximum length of 1.0cm and 0.7cm seen posterior to the carina at the level of T6-T7 and widening of the upper mediastinum which suggests acute mediastinitis (Fig. 1 and 2). A review of the patient's history revealed that he had lost his malfitting, frequently dislodged, maxillary partial denture after a drinking bout 12 years prior to his admission. He had attempted to search for it, but was unsuccessful. Since the said event, he did not experience symptoms such as drooling, choking, dysphagia, odynophagia, fever and chest pain. He had also sought consult with a dentist for new dentures. It was then that the possibility of a chronic esophageal foreign body, specifically a wired denture, was considered on top of the food bolus.

Further workup using esophagogram and a 254-slice contrast-enhanced chest CT scan with sagittal and coronal cuts were done to further assess for mediastinitis and foreign body impaction. These revealed partial proximal esophageal obstruction probably secondary to retained foreign body at the level of T5 vertebra with marked proximal esophageal dilatation and minimal milking of contrast to the distal esophagus and stomach (Fig.

3). There was also a curved metallic density approximately measuring 1.4cm at the level of the carina, with thickening of the esophageal wall and dilatation of the proximal esophagus above the foreign body with no evidence of pneumomediastinum or pleural effusion, bilateral pneumonia with emphysematous changes, and cavity formation in the left (Fig. 4). Due to these findings suggestive for obstruction, the patient was scheduled for stat diagnostic rigid esophagoscopy with removal of foreign body. He was also started on ceftriaxone 2g IV OD, clindamycin 600mg IV Q8, omeprazole 40mg IV OD while on NPO, dexamethasone 8mg IV Q8.

Intraoperatively, a meat bolus which was 2cm in diameter was visualized and removed from the second esophageal constriction, 22cm from the central incisors with note of an abrasion occupying the same area. However, no metallic foreign body was seen. There was also granulation tissue seen obstructing the esophageal lumen making the insinuation of the rigid esophagoscope difficult. The procedure was then terminated and a referral was made to gastroenterology service for esophagogastroduodenoscopy (EGD) under sedation as well as general surgery for evaluation and possible exploratory laparotomy (double set-up) in the event that the foreign body could not be removed via EGD. In addition to this, the patient was started on blenderized feeding via nasogastric tube (NGT) while waiting for the second procedure.

The EGD showed a foreign body, most likely a denture, covered by a bi-mucosal flap and embedded in the mucosa of the lateral wall of the mid-esophagus, 32cm from the maxillary incisors (Figure 5). Mucosectomy as well as release of the bi-flap were performed. Multiple maneuvers were then done to move the denture upward. However, there was difficulty extracting the foreign body due to stricture formation superior to it. The denture (Figure 6), which indeed had wires, was then pushed towards the stomach. Mini laparotomy, gastrotomy, removal of foreign body (denture) and primary repair of

gastrotomy under general anesthesia were subsequently done by general surgery. The final diagnosis in our case was Foreign Body (Food Bolus) Impaction, 2nd esophageal constriction on top of Chronic Foreign Body (Denture) Impaction with stricture formation, 3rd esophageal constriction.

Removal of the nasogastric tube was done on post-operative day 2 and the patient was then started on general liquids. He was then discharged on post-operative day 3 with no subjective complaints. Follow up consult was done a week after surgery for removal of sutures. At this time, the patient still did not complain of symptoms such as dysphagia, odynophagia, drooling, vomiting, chest pain and fever. He was advised for repeat EGD but was not able to comply.

DISCUSSION

Foreign body ingestion resulting to esophageal foreign body impaction (EFBI) is a common cause for emergency room consultation [3]. This may occur in adults with advanced age, complete or incomplete edentulism, psychiatric disorders, intellectual disability, alcohol intoxication and preexistent pathologies such as strictures (~37%), malignancy (~10%), esophageal rings (~6%), achalasia (~2%) and eosinophilic esophagitis (~33%) [1,2]. This is especially common in the pediatric population between ages 6 months to 6 years [3].

Chronic esophageal foreign bodies (CEFB), defined as foreign body impaction of more than or equal to one week, can have serious sequelae such as bronchoesophageal fistula, aortoesophageal fistula, esophageal stricture with obstruction, pulmonary edema, esophageal diverticulum, and esophageal perforation with overlying mediastinitis or abscess which may possibly lead to death [4,5].

Based on a comprehensive search of existing databases such as PubMed, and

MedLinePlus, there have been multiple accounts of chronic esophageal foreign bodies. Most of which were in the pediatric population. However, there was one published case report on May 2020 of a 45-year-old female who had a 13-year history of denture impaction in the mid- esophagus which was managed using right thoracotomy and esophagotomy. Though these two case reports appear similar due to the long, symptom-free period of the foreign body impaction, our case is unique, because it is the only one which presented with dysphagia due to a superimposed acute food bolus impaction.

The diagnosis of EFBI can be established in most cases at the time of the incident [6]. It is imperative that the duration, symptoms and type of foreign body ingested are promptly noted. The clinical presentation of a patient may vary depending on which clinical phase of foreign body he/she is in. The first phase, also known as the initial stage, implicates airway obstruction, choking, gagging immediately after the incident. The second phase or the asymptomatic stage starts when the reflex weakens and lasts from hours to weeks, resulting to a delayed diagnosis. The last phase is when complications such as obstruction, pneumonia mediastinitis, perforation, etc. arise [7]. In our case, the patient was in the third phase wherein he already had stricture formation.

Diagnostic evaluation and the urgency of intervention should be based on the type of foreign body, subjective and objective findings. Foreign bodies are classified according to size, surface consistency (sharp versus blunt), material (food, drugs, battery, magnet) and characteristics such as radiodense, metallic and/or chemically inert. Radiographic imaging with two views is recommended as initial evaluation to gather data such as location, configuration, quantity and dimension of the foreign body. Computed tomography (CT) scan may be used for non-radiodense and small radiodense foreign bodies. It is also more sensitive (100%) compared to x-ray (32%).

The use of contrast medium is discouraged in some literature as a radiological diagnostic due to the risk of aspiration, difficulty in evaluating the mucosa and the possibility of concealing the foreign body [2].

Rigid endoscopy, as compared to flexible esophagoscopy, has the advantage of a dilated lumen and permits removal of foreign bodies under direct visualization. Since it uses endotracheal intubation, it also lowers the risk of aspiration during the procedure [8]. It is also used to assess the whole length of the esophagus after the removal of foreign bodies to assess for abrasions, tears or bleeding. Hence, it remains the gold standard of treatment especially for sharp, penetrating, complicated foreign bodies.

Our patient underwent rigid esophagoscopy with removal of foreign body (food bolus) within 24 hours of admission. Subsequently, EGD and gastrostomy were used to dislodge and remove the remaining mediastinal mass which was actually a denture with surrounding stricture and granulation tissue formation.

Consequently, according to Aiolfi et al., surgical intervention using an open approach should be considered in cases with esophageal perforation and in instances where there is inability to remove a foreign body after multiple endoscopic attempts [1]. After endoscopic removal was deemed unattainable in our patient, he was referred to general surgery for mini laparotomy, gastrotomy and removal of foreign body.

Our patient did not complain of dysphagia but had endoscopic evidence of esophageal stricture. Further management for benign esophageal strictures is based on its classification (simple or complex). Simple strictures pertain to those that are generally short (<2cm) with a decreasing proximal margin and lumen located its center. Insinuation of endoscopes beyond the level of simple strictures is not difficult [9, 10]. Complex strictures, on the other hand, have irregular margins

and are longer (≥ 2 cm). An esophagus with a significantly reduced lumen is always classified as having a complex stricture. Schatzki found that strictures which led to a reduced esophageal lumen diameter of ≤ 20 mm (radiographically measured) presented with recurrent dysphagia. [9] This was not present in our patient. Further workup, however, is required to evaluate his need for esophageal dilatation for his benign inflammatory esophageal stricture and to mitigate the risk of developing other future complications such as recurrent foreign body impaction, dysphagia, and pulmonary aspiration resulting to reflux of food components.

Though it is important to discuss the management of foreign body impaction, it is likewise important to point out that foreign body impaction is preventable. According to Felton et al., patients who use dentures should have annual follow up with their dentist for evaluation of oral health status, cleaning and adjustment to ensure the proper fit and function of their dentures. [11] Loosening of dentures could inevitably lead to ingestion which is what happened to our patient.

CONCLUSION

This report highlights the importance of prompt evaluation, diagnosis and treatment of foreign body impaction which is a common cause for emergency room consultation in all ages. In assessing the patient, it is important to note the duration, symptomatology, type of foreign body and subjective findings.

Chronic esophageal foreign body impaction can lead to serious complications such as fistula, esophageal strictures, obstruction, perforation and mediastinitis; thus, prompt evaluation and treatment are warranted.

Radiographic imaging is a good screening tool for radiodense foreign bodies and is used to determine different information such as orientation,

number, location, and characteristic. CT scan may also be used for nonradiodense and small radiodense foreign bodies.

Rigid esophagoscopy is the preferred treatment because it is both diagnostic and therapeutic. It should be done before invasive surgical intervention is ensued. In our case, the patient underwent gastrostomy due to multiple failed attempts in endoscopic removal of the foreign body.

A significant factor that led to the success of the foreign body removal was also the multidisciplinary approach taken wherein different services exhibited good communication and collaboration to achieving one common goal.

Last but not the least, foreign body impaction is preventable. Regular check up with a dentist is recommended to ensure proper fit of dentures and to mitigate the risk of foreign body impaction.

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Figures

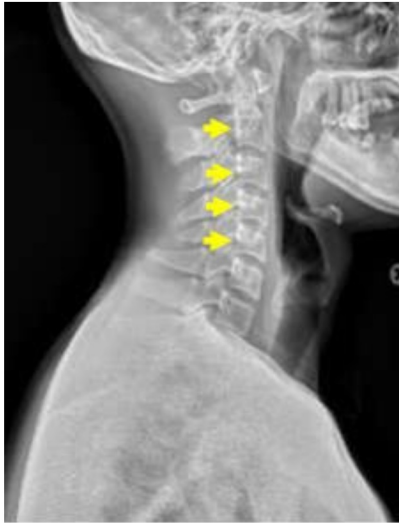


Figure 1. Cervical x-ray of patients showing straightened cervical spine most probably due to myospasm



Figure 2. Chest x-ray of patient with metallic linear densities (yellow arrows, encircled) measuring 1.0cm and 0.7cm at level T6-7 vertebra

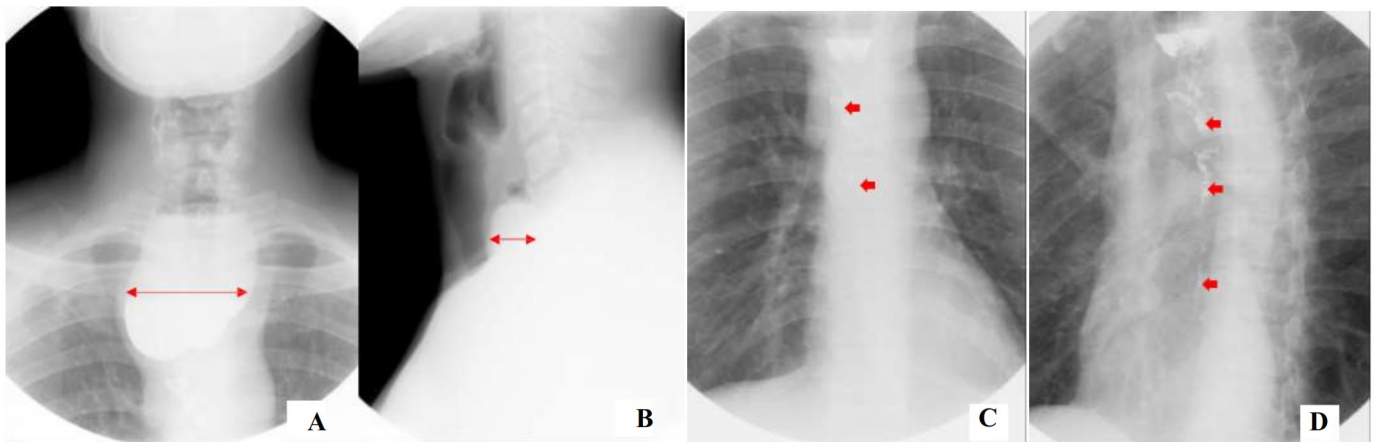


Figure 3. Esophagogram of patient showing marked proximal esophageal dilatation (A, B) and minimal milking of contrast to the distal esophagus and stomach (C, D)

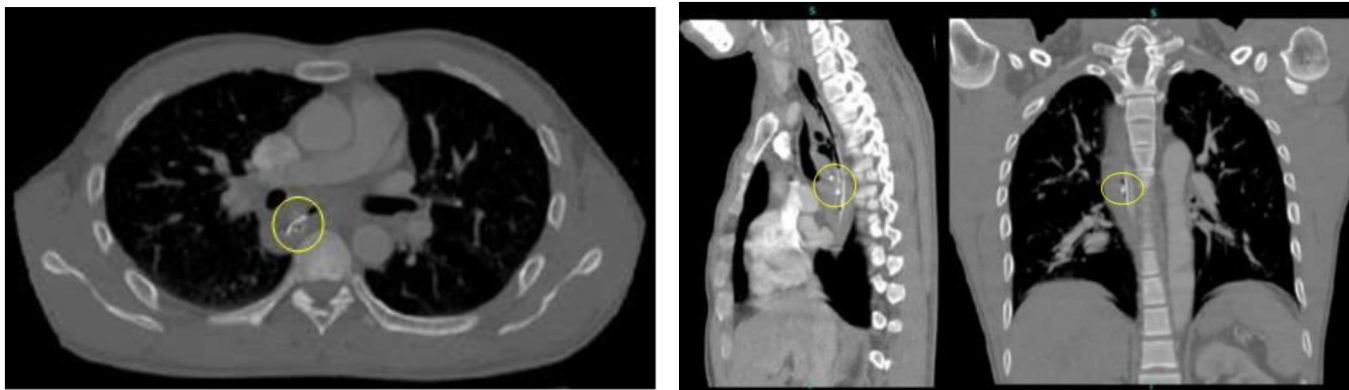


Figure 4. Axial, coronal and sagittal CT cuts showing linear hyperdensities (encircled) at levels T5-7



Figure 5. Esophageal foreign body (red arrows) and stricture (yellow arrows) forming two lumina



Figure 6. Removed foreign body (denture) with embedded wires (red arrows)

Appendix

Table of Literature Discussing Chronic Esophageal Foreign Bodies Retrieved through a Comprehensive Search of PubMed, and MedlinePlus using the keywords: "chronic", "denture", "esophagus", and "foreign body"

	Author(s)	Year of Publication	Title of Study	Type of Study	Remarks
1	S Shahi, T Bhandari, P Thapa, D Shrestha, and K Shrestha	2020	Foreign body esophagus: Six years of silence	Case Report	DOI:10.1177/2050313X20944322 6-month history of progressive dysphagia in a 55-year-old female with retained denture in the esophagus for 6 years
2	R Karthikeyan, I Chandramohan S M, S Harikrishnan, Vigneshwaran VB, and B Singh	2020	Lost Denture Found in Esophagus After a Decade: A Rare Case Report	Case Report	DOI: 10.7759/cureus.8042 Population: 45-year-old female 6 month-history of progressive dysphagia in a 55-year-old female with retained denture in the esophagus for 13 years
3	NA Tashtush, ZA Bataineh, DH Yusef, TM Al Quran, LA Rousan, R Khasawneh, AJ Aleshawi, EM Altamimi	2019	Ingested sharp foreign body presented as chronic esophageal stricture and inflammatory mediastinal mass for 113 weeks: Case report	Case Report	DOI:10.1016/j.amsu.2019.07.028 Foreign body impaction for 113 weeks wherein patient underwent partial gastrectomy and with note of re- stricture formation treated with Mitomycin-C and esophageal dilatation Population: 36-month old female
4	L Cao, N Chen, Y Chen, M Zhang, Q Guo, Q Chen, B Cheng	2018	Foreign body embedded in the lower esophageal wall located by endoscopic sultrasonography: A Case Report	Case Report	DOI:10.1097/MD.00000000000011275 Population: 55-year old male Presented with gastrointestinal complaints for 10 days
5	S Yahyaoui, I Jahaouat, I Brini, A Sammoud	2017	Delayed diagnosis of esophageal foreign body: A case report	Case Report	DOI:10.1016/j.ijscr.2017.05.028 Population: 6-month old male
6	G Mohajeri, S Fakhari, Z Ghaffarzadeh, M Piri-Ardakani	2016	A case of the long time presence of a large foreign body in esophagus without complication	Case Report	DOI: 10.4103/2277-9175.191001 Population: 57-year old male Retained denture for a period of 9 months which was removed via gastrostomy
7	G Dar, F Ganie, M Ishaq, K Jan, Z Ali, G Lone, M Beigh, T Abdullah, M Dar, M Sidiq	2015	Prolonged Impacted Denture in the Esophagus: A Case Report and Review of the Literature	Case Report	PMCID: PMC4771285 Population: 57-year-old male Diagnosed case of esophageal adenocarcinoma who has foreign body (denture) impaction for 3 years
8	RR Naidoo, MBChb, and AA Reddi, FCS Cardio	2014	Chronic Retained Foreign Bodies in the Esophagus	Case Series	DOI:10.1177/0003489414521145 Population: 3 and 6-year old With retained foreign body for 2 months and 2 weeks respectively

9	JC Schramm, RK Sewell, KS Azarow, SC Raynor, SF Abdessalam	2014	Chronic cervical esophageal foreign bodies in children: surgical approach after unsuccessful endoscopic management	Case Report	DOI:10.1177/0003489414521145 Population: Age at diagnosis were 14 months to 4.5 years Foreign bodies were retained for 1 to 10 months
10	P Glover, T Westmoreland, R Roy, D Sawaya, H Giles, M Nowicki	2013	Esophageal diverticulum arising from a prolonged retained esophageal foreign body	Case Report	DOI:10.1016/j.jpedsurg.2012.11.032 Population: 5-year old female Presented with 2-year history of respiratory symptoms
11	JAH Kropf MD, R Jeanmonod MD, DM Yen MD	2013	An Unusual Presentation of a Chronic Ingested Foreign Body in an Adult	Case Report	DOI:10.1016/j.jemermed.2011.06.061 Population: 82-year old female Complaints were odynophagia and worsening pharyngitis for 4 months
12	S Cole, D Kearns, A Magit	2011	Chronic esophageal foreign bodies and secondary mediastinitis in children	Retrospective	DOI:10.1177/000348941112000809
13	G M Narasimhappa, Arun K Baranwal, Sunit C Singhi	2009	Impacted esophageal foreign body mistaken for chronic pharyngitis	Retrospective Case Report	DOI: 10.1007/s12098-009--0152-8]
14	M Khemiri, A Labbessi, Y Tlili, F Ben Mansour, S Boukthir, S Barsaoui	2008	[Digestive hemorrhage revealing a chronic esophageal foreign body. Report of a pediatric case]	Case Report	DOI:10.1016/j.arcped.2008.08.004 Article in French, No English translation available
15	RS Miller, JP Willging, MJ Rutter, K Rookkapan	2004	Chronic esophageal foreign bodies in pediatric patients: a retrospective review	Retrospective cohort	DOI:10.1016/j.ijporl.2003.09.021 Population: pediatric 41 (8%) patients from May 1990-January 2002 6 presented with chronic esophageal foreign body (≥ 7 days); 2 of which had >14 weeks duration
16	PJ Knight	2004	Hooking a chronically embedded esophageal coin	Case Report	DOI:10.1016/j.jpedsurg.2003.09.022 Population: 11-month old Patient had 1-month history of cough with no witnessed foreign body ingestion
17	TW Haegen, HA Wojtczak, SS Tomita	2003	Chronic inspiratory stridor secondary to a retained penetrating radiolucent esophageal foreign body	Case Report	DOI:10.1053/jpsu.2003.50066 Population: 17-month-old female 6-month history of inspiratory stridor
18	BF Gilchrist, EP Valerie, M Nguyen, C Coren, D Klotz, ML Ramenofsky	1997	Pearls and perils in the management of prolonged, peculiar, penetrating esophageal foreign bodies in children	Retrospective cohort	DOI: 10.1016/s0022-3468(97)90554-6 Population: Average of 3 years old Had retained foreign body for 2 months to 2 years
