

THE VALIDITY OF USING HAND TOUCH METHOD COMPARED TO DIGITAL THERMOMETRY IN DETECTION OF HYPOTHERMIA AMONG FULL TERM NEONATES DELIVERED AT THE OBSTETRIC ADMITTING SECTION OF A TERTIARY HOSPITAL

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CLINICAL ABSTRACT

RATIONALE: Hypothermia is a risk factor for neonatal morbidity and mortality hence it is important to identify a diagnostic test for hypothermia which can be readily available to health care workers.

OBJECTIVE: To determine the validity of using hand touch method in detection of neonatal hypothermia as compared to digital thermometer.

STUDY DESIGN: Cross-sectional study

SETTING: Obstetric Admitting Section of a tertiary hospital

STUDY POPULATION: Full-term neonates who fulfilled the following: delivered within 24 hours, birth weight of at least 2.5 kilograms, without congenital anomalies, not clinically ill, and with consent from the mother/father/guardian were included.

METHODOLOGY: Hand touch method was done on 300 full term neonates by two health care workers who were blinded to each other's assessment followed by rectal temperature determination using digital thermometer. The sensitivity, specificity, positive and negative predictive values, and likelihood ratios of hand touch method against digital thermometer were determined. Age of gestation, birth weight, sex, clinical signs of illness, and maternal risk factors were described.

RESULTS: Of the 300 full term neonates included, 47% were males, with a mean birth weight of 2,969 grams. Prevalence of hypothermia was 37% and presence of maternal risk factor was associated in 38% of cases. The sensitivity and specificity of hand touch method against the digital thermometer were 69% and 97%, while the positive and negative predictive values were 93% and 84%, respectively. The likelihood ratio for hypothermia was 22, and 0.3 for non-hypothermia.

CONCLUSION: Hand touch method can be recommended as an easy, inexpensive, and feasible tool to rule in hypothermia among neonates, especially in areas of the community where thermometer is scarce, after giving adequate training to health care workers.

KEYWORDS: neonatal hypothermia, hand-touch method, sensitivity, specificity, likelihood ratios

I. TITLE

The Validity of Using Hand Touch Method Compared to Digital Thermometry in Detection of Hypothermia Among Full Term Neonates Delivered at the Obstetric Admitting Section of a Tertiary Hospital.

II. INTRODUCTION

Neonatal hypothermia is a widely known risk factor for neonatal morbidity and mortality. In the Philippines, 3.4% of the 2.4 million live births die before 5 years of age annually. In 2006 demographics, there were 32 deaths per 1000 live births among under-five age group, and 37% of these were due to neonatal causes.(1) This makes the Philippines one of the 42 countries accounting for 90% of all global under-five deaths. Around 50% of these deaths occur in the neonatal period and 25% in the first 2 days of life. (2)

The morbidities associated with hypothermia in newborn infants are many and includes hypo/hyperglycemia, respiratory distress, hypoxia, metabolic acidosis and coagulation defects. (3) If adequate thermal protection is not begun immediately after birth, there will be rapid heat loss, with the skin temperature losing up to 4°C in the first minutes of life. (4) Immediate actions are therefore warranted to avoid these consequences, which brings us to the development of essential newborn care. The goal of Essential Newborn Care is to rapidly reduce the number of newborn deaths by following a simple, concise and

straightforward guideline which includes: immediate and thorough drying of the newborn, early skin-to-skin contact between mother and newborn, properly-timed cord clamping and cutting, and non-separation of newborn and mother for early breastfeeding. According to the WHO, implementation of this protocol has the potential to avert approximately 70 percent of newborn deaths that are due to preventable causes, without additional cost to both families and hospitals. (5) Among the pillars of essential newborn care, which is prevention of hypothermia, is given emphasis. Therefore, maintaining temperature at the time of birth is one of the primary goals of neonatal resuscitation and is one of the key determinants of neonatal outcome.

Review of Related Literature

All newborn babies are prone to heat loss, particularly in the first few hours after birth because of large surface area per unit of body weight. (4) Newborn loses heat by evaporation, conduction, convection, and radiation. (6) According to studies, heat loss among pre-term and underweight babies is more common compared to normal weight or full term babies. This is seen in a study done by Mullany et al in rural Southern Nepal involving 23,240 babies, where almost 30% of infants had low birth weight (< 2500 g) and those between 2000-2499 grams and 1500-1999 grams were at 1.49 and 4.32 times greater risk of hypothermia, respectively. Very low birth weight (VLBW) babies were 11.63 times more likely than normal weight infants to have axillary temperatures of <35.0°C. This is due to larger surface

to mass ratios and rapid transepidermal loss of water through the compromised skin barrier. (4) It therefore shows that the weight of an infant is one of the most important independent factors related to neonatal hypothermia.

World Health Organization (WHO) defines normothermia as a core temperature of 36.5°C to 37.5°C. Hypothermia is defined as a core temperature of <36.5°C and categorized as mild when the temperature is 36.0 to 36.4°C, moderate when the temperature is 32 to 35.9°C, and severe when the temperature is <32°C. (7) Hyperthermia on the other hand, is temperature above 37.5°C. This is usually associated with infection and a search for a possible focus of infection should be done. However, hyperthermia can also be due to increased ambient temperature, hence loosening or removing of clothes can also be done to decrease the neonate's temperature. (6)

Digital thermometer can be used in the newborn for thermal detection. Some studies however, have tried using hand touch method in assessing the newborn's temperature. In a study done by Tuitui et al at Nepal, where the incidence of neonatal hypothermia is as high as 87%, the use of hand touch method among 100 full-term neonates delivered within 24 hours at a local university hospital has a sensitivity and specificity of 95.6% and 70.1% respectively, in detection of neonatal hypothermia against low-reading mercury thermometer. (8) Another study done at Nepal by Ellis et al, shows that the use of touch by health workers to detect hypothermia in 250 newborns

examined, has a high sensitivity (80%) but low specificity (36%–74%) compared with axillary thermometry. (9) Agarwal et al also had the same validity testing, involving 152 newborns in Indian slum dwellings, and found that human touch had moderate diagnostic accuracy when compared with axillary digital thermometry (kappa: 0.38, sensitivity: 74.5%, specificity: 68.5%). (10) Despite these, they still recommend peripheral palpation for the detection of hypothermia, at least in the first instance, and if assessed to be cold, further assessment and enhanced thermal care will be done. (9) Also, human touch appeared to be simpler and feasible and just requires adequate training for proper thermal detection. (10)

In developing countries, like the Philippines, where less than half (43%) of all Philippine deliveries occur in hospitals and where most of the deliveries are carried out at home or in local health centers by midwives or traditional birth attendants, hand touch method is a practical way of assessing the baby's temperature, although the most common way of temperature determination is by using a thermometer. (2) As defined by World Health Organization, human touch can detect if the baby is in thermal comfort if with warm and pink feet, is in cold stress if the feet were cold and the trunk warm, and with hypothermia if both feet and trunk were cold to touch. (6)

All hypothermic infants are at increased risk of morbidity and mortality in both home and facility settings. Prevention of cold stress starting immediately at birth is critical and when identified, appropriate steps for warming

must be initiated. Key to this goal is a practical and efficient way of monitoring temperature of neonates so that timely interventions can be made to prevent hypothermia. Presently among our health care workers, there is no standard practice with regards to bringing thermometers in their community. It is then important to identify such a diagnostic which can be available to health care workers especially in areas in the country where resources are scarce. Hence, we would like to determine the diagnostic validity of using hand touch method in detection of neonatal hypothermia as compared to the conventional digital thermometer.

III. RESEARCH OBJECTIVES

a. General Objective

- i. To determine the validity of using hand touch method in detection of neonatal hypothermia as compared to digital thermometer.

b. Specific Objectives

- i. To describe the characteristics of neonates born at the obstetric admitting section of a tertiary hospital.
- ii. To determine the sensitivity, specificity, positive predictive value, negative predictive value, and likelihood ratios of using hand touch method compared to digital thermometer in detection of hypothermia among full term neonates.

IV. STUDY DESIGN

This is a cross-sectional study that was done on three hundred full-term neonates delivered at the Obstetric Admitting Section of a tertiary hospital comparing the diagnostic validity of hand touch method versus digital thermometry in detection of hypothermia.

V. METHODOLOGY

Sample size

The sample size for the population of this study is determined using prevalence rates of 74% and 80% in Nepal where the study on hand touch method was already done. The desired level of confidence is at 95% with a standard value of 1.96. The margin of error is at 10% with a standard value of 0.1. The sample size is then multiplied by the design effect (2), hence the sample size is 300 patients. The formula for computing the sample size:

$$n = \frac{t^2 \times p(1-p)}{m^2}$$

n = required sample size

t = confidence level at 95%

p = estimate of prevalence of hypothermia

m = margin of error at 10%

The study was carried out in the catcher's area of the Obstetric Admitting Section of a tertiary hospital. Three hundred full-term neonates were selected who fulfilled the

inclusion criteria: delivery within 24 hours, birth weight of at least 2.5 kilograms and with consent from the mother/father/guardian. Prematurity, those with birth weight less than 2.5 kilograms, congenital anomalies, and clinically ill were excluded from the study. Informed consent was obtained from the neonate's mother/father/guardian before examination.

A. Preparation Prior to the Actual Study

The health care workers (two nurses) who participated in this study underwent one hour lecture on temperature determination. They were taught how to determine hypothermic versus non-hypothermic by comparing glass bottles filled with water with temperatures ranging from $< 36.5^{\circ}\text{C}$ to $\geq 36.5^{\circ}\text{C}$. They touched the glass bottles using the dorsum of their hand and identified which was hypothermic and not hypothermic. Both of them correctly determined which of the glass bottles were hypothermic or not-hypothermic (10 out of 10 determinations), hence they were included in the study.

Rectal temperature was taken using the digital thermometer (SANITAS Fieber-thermometer 01/1, Germany; accuracy $\pm 0.1^{\circ}\text{C}$). The health care workers (pediatric resident/nurse/intern/clerk) who did the rectal temperature determination were taught how to use the digital thermometer. The temperature probe was placed in the rectal area until there was temperature recorded on the digital thermometer (this was determined when an acoustic sound was heard few minutes after placing the digital thermometer

inside the rectum of the patient). Using digital thermometry, neonates were classified as hypothermic ($< 36.5^{\circ}\text{C}$) or not hypothermic ($\geq 36.5^{\circ}\text{C}$).

There are factors that may affect the health care worker's determination of the baby's temperature, such as ovulation, hyperthyroidism, ambient temperature, etc. The health care worker who will be doing the hand touch method of temperature determination should therefore, have hands which are not of extreme temperatures. The temperature of their hands was measured by placing the thermometer probe on the palm of the health care worker's hand until the temperature was recorded, once normothermic ($36.5\text{--}37.5^{\circ}\text{C}$), they started the hand touch method.

B. Study Proper

The study was done at the Obstetric Admitting Section of a tertiary hospital. The procedure was explained to the mother/father/guardian of the baby. The consent was secured prior to the examination, from the mother if obtained before the delivery or from the father or guardian after the delivery of the baby. The health care workers did hand washing first, followed by temperature determination of their hands, to make sure that the hands were normothermic. This was followed by placing the dorsum of the hand on the trunk of the neonate for a few seconds, until it was determined if the baby was hypothermic or not. By this hand touch method, neonates were classified as hypothermic ($< 36.5^{\circ}\text{C}$) or not hypothermic ($\geq 36.5^{\circ}\text{C}$). The health care workers washed their hands after the

procedure. Another health care worker (pediatric resident/nurse/intern/clerk), then measured the rectal temperature of the baby, by first wiping the probe of the digital thermometer with alcoholised cotton, then inserting it to the rectum of the baby. The probe was wiped again with alcoholised cotton after the temperature was determined. The health care workers were blinded to each other's assessment. If the baby were determined to be hypothermic or hyperthermic, appropriate measures were then done to keep the patient within normal temperature.

DATA ANALYSIS.

Using the digital thermometer reading as the reference test, the sensitivity, specificity, positive and negative predictive values, and likelihood ratios of hand touch method with 95% confidence interval were determined and compared. Age of gestation, birth weight, sex, clinical signs of illness, maternal risk factors were described for each participant. Data compilation and analysis were done using the Microsoft Office Excel program.

VI. ETHICAL CONSIDERATIONS

This research is about comparison of the diagnostic validity of hand touch method to digital thermometry in detection of neonatal hypothermia among full term neonates delivered at the Obstetric Admitting Section of a tertiary hospital. This involved human touch and placement of digital thermometer in the rectal area of the neonate. As a participant in this study, the child was not exposed to any

serious risk. Determination of temperature did not disturb the routine care being provided to the neonates at the neonatal resuscitation area.

The use of a digital thermometer for temperature determination has no record of any risk. The benefit to the child was that he/she was provided close monitoring for hypothermia by the health care worker during their stay at the neonatal resuscitation area. The results of this study might not benefit the child directly but will benefit future patients by providing information that may justify the use of hand touch method in assessing for hypothermia among neonates. No payment was given to the child as a result of participation in the study.

The health care workers (two nurses) who participated in this study got the consent from the neonate's mother prior to the delivery. Otherwise, consent was taken from the father or guardian if the mother has already delivered prior to examination. The risks, benefits, and the methodology were explained to the mother or father. All their questions were answered accordingly.

The protocol of this study was submitted to the Ethics Review Board of a tertiary hospital for ethical review and approval. The study was conducted only upon approval from the Ethics Review Board. All patient information collected in this study will be kept strictly confidential, except as may be required by the law. The child or family will not be identified by name when the results of the study are published. They are given the right to know the results of the study at the end of the trial. Any

additional information about the study results are provided to them at its conclusion, upon their request. Expenses of the study were funded by the investigator.

VII. RESULTS

The results of this study showed that out of the 300 full term neonates who were included in this study, 47% were males, with a mean birth weight of 2,969 grams (range: 2,500 – 4,150 grams). The presence of maternal illness or risk factor was associated with hypothermia in 38% of cases as shown in Table 1. In Table 2, the prevalence of hypothermia ($<36.5^{\circ}\text{C}$) was 37% (mean: 36.5°C , range: $34.5\text{--}37.8^{\circ}\text{C}$). The sensitivity and specificity of the hand touch method against the digital thermometer were 69% and 97%, respectively, while the positive predictive value and negative predictive value were 93% and 84%, respectively. The likelihood ratio for hypothermia was 22, while the likelihood ratio for non-hypothermia was 0.3 only as shown in Table 3.

VIII. DISCUSSION

A clinically useful diagnostic tool for detection of neonatal hypothermia should be simple, rapid, inexpensive, and, most importantly, accurate. The use of hand touch method in determining neonatal hypothermia easily fulfills the criteria of simplicity, rapidity and its being inexpensive. This study focused on the validity and accuracy of hand touch method in detection of hypothermia among full term neonates delivered at the Obstetric

Admitting Section of a tertiary hospital.

According to this study, detection of neonatal hypothermia has a high specificity (97%), but low sensitivity (69%). This shows that with hand touch method, if a baby were determined to be non-hypothermic, there is a 97% chance that the baby is really non-hypothermic, however due to its low sensitivity it is likely that hand touch method may miss one-third of those neonates who are truly hypothermic if used as a screening tool. On the other hand, once a baby is detected to be hypothermic, there is 93% probability that the baby is truly hypothermic, and because of its high likelihood ratio for hypothermia, there is a 22-fold increase in the odds of detecting hypothermia among those who are truly hypothermic, while only 0.3 or 3 out of 10 neonates will be detected to be non-hypothermic by hand touch method among those who are truly not hypothermic.

The possibility to easily, rapidly, and reliably detect hypothermia is very important for the clinician. Therefore, if a neonate were deemed to be not hypothermic, this would assure the clinician that they have not missed detection of hypothermia. Also, if the neonate were deemed to be hypothermic, further assessment and enhanced thermal care will be done to prevent neonatal morbidity and mortality.

The sensitivity, specificity, positive predictive value, negative predictive value, and likelihood ratios were comparable with the previous studies done on hand touch method in

detection of neonatal hypothermia. Although variability among studies exists, this study confirms that hand touch method is very specific in detection of neonatal hypothermia, but not very sensitive. Of the studies mentioned earlier done at Nepal and Indian slum dwellings, all of them have a higher sensitivity and lower specificity which are opposite to the data of this study, which has a low sensitivity and higher specificity in detection of neonatal hypothermia. These differences may be due to the subjective findings of the health care workers who did the hand touch method. These may also be due to the differences of the location and equipment used in temperature determination. One study used low-reading thermometer as compared to the use of digital thermometer in this study, and one study placed the thermometer in the axillary area in contrast to the rectal area as the location for placement of the thermometer in this study (8, 9). Ambient temperature can also affect the results of this study and another variable which has caused the difference in the result is the number of participants in this study. Hence it is emphasized that the data of this study were based on a relatively small sample and larger series are needed for verification of the results.

IX. CONCLUSION

Hand touch method is a rapid, simple, and inexpensive diagnostic tool for detection of neonatal hypothermia. Although hand touch method can reliably determine those who are truly hypothermic, its use for the detection of

neonatal hypothermia is limited due to its low sensitivity. Despite this, its clinical use for the determination of neonatal hypothermia is very important so that appropriate measures for thermoregulation can be instituted to prevent neonatal morbidity and mortality. In this regard, hand touch method can be recommended as an easy, inexpensive, and feasible tool to detect hypothermia among newborn babies especially in areas of the community where thermometer is scarce after giving adequate training to health care workers.

X. BIBLIOGRAPHY

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XI. APPENDIX

Appendix I

Table 1. Characteristics of Neonates Born at the Obstetric Admitting Section of a tertiary hospital

Characteristics:	N=300
Mean Age of Gestation	39 weeks (range: 37-41 weeks)
Number (%) of males/females	Males 47% Females 53%
Developed Clinical Signs of Illness	None
Mean Birth Weight	2,969 grams (range: 2,500 – 4,150 grams)
Maternal Illness/Risk Factors	
Urinary Tract Infection	14 (18.2%)
Premature rupture of membranes	10 (13%)
Pre-eclampsia	9 (11.7%)
Bronchial Asthma	6 (7.8%)
Hypertension	5 (6.4%)
Young Primigravid	4 (5.2%)
Gestational Diabetes Mellitus	4 (5.2%)
Placenta Previa	4 (5.2%)
Gestational Hypertension	3 (3.9%)
Chronic Hepatitis B Infection	3 (3.9%)
Upper Respiratory Tract Infection	3 (3.9%)
Elderly Primigravid	2 (2.6%)
Diffuse non-toxic goiter	2 (2.6%)
Gravidocardiac	1 (1.3%)
Hypothyroidism	1 (1.3%)
Condyloma Acuminata	1 (1.3%)
Neurofibromatosis Type I	1 (1.3%)
Rheumatic Heart Disease	1 (1.3%)
Parkinson's Disease	1 (1.3%)
Beta-Thalassemia	1 (1.3%)
Epilepsy	1 (1.3%)

Table 2. Distribution of Neonates with Hypothermia and Non-Hypothermia Detected by Hand Touch Method and Digital Thermometry

Hand Touch Method	Digital Thermometer < 36.5°C	Digital Thermometer ≥ 36.5°C	Total
Hypothermic	76	6	82
Non-hypothermic	34	184	218
Total	110	190	300

Table 3. Diagnostic Validity of Hand Touch Method Versus Digital Thermometry in Temperature Determination

Diagnostic Validity of Hand Touch Method in Detecting Neonatal Hypothermia Compared to Digital Thermometry (N=300; 95% CI)	
Sensitivity	69% (54-77%)
Specificity	97% (93-99%)
Positive Predictive Value	93% (84-97%)
Negative Predictive Value	84% (78-89%)
Likelihood Ratio (Hypothermia)	22
Likelihood Ratio (Non-hypothermia)	0.3

Appendix II

INFORMED CONSENT

I, _____, mother/father/guardian of _____, do fully understand that my child will be included in the study of 'The Validity of using Hand Touch Method Compared to Digital Thermometry in Detection of Hypothermia among Full Term Neonates Delivered at the Obstetric Admitting Section of a tertiary hospital.' The study is being done to determine the diagnostic validity of using hand touch method in detection of neonatal hypothermia as compared to digital thermometer among full term neonates delivered at the Obstetric Admitting Section of a tertiary hospital.

Procedure of the study

The study will be carried out in the delivery area of the Obstetric Admitting Section of a tertiary hospital. 300 full-term neonates will be selected who fulfil the inclusion criteria; such as, delivered within 24 hours, birth weight of at least 2.5 kilograms and with consent from the mother. Those who are preterm, less than 2.5 kilograms, with congenital anomalies, and who are clinically ill will be excluded in the study. Informed consent will be obtained from the neonate's mother/father/guardian prior to examination either before the delivery or after the delivery of the baby. The neonate's body temperature will be assessed first by hand touch followed by rectal digital thermometer. The health care worker will palpate the baby's trunk using the dorsal surface of the right hand to feel the coldness or warmth of the newborn. Neonates will be classified as hypothermic ($< 36.5^{\circ}\text{C}$) and not hypothermic ($\geq 36.5^{\circ}\text{C}$).

Rectal temperature will be taken using the digital thermometer (SANITAS Fieber-thermometer 01/1, Germany; accuracy $\pm 0.1^{\circ}\text{C}$). The temperature probe will then be placed in the rectal area until there is temperature recorded on the digital thermometer (this is determined when an acoustic sound is heard few minutes after placing the digital thermometer inside the rectum of the patient). Neonates will be classified as hypothermic ($< 36.5^{\circ}\text{C}$) or not hypothermic ($\geq 36.5^{\circ}\text{C}$).

The sensitivity, specificity, positive predictive value, negative predictive value, and likelihood ratios of the hand touch method for temperature assessment will be calculated against digital thermometer readings.

Possible complications and risks from the study

As a participant in this study, your child will not be exposed to any serious risk. Determination of temperature will not disturb the routine care being provided to the neonates at the neonatal resuscitation area.

The use of a digital thermometer for temperature determination has no record of any risk.

Benefits from the study

The benefits to your child will be that he/she will be provided close monitoring for hypothermia by the investigator during their stay at the neonatal resuscitation area. Once patient is determined to be hypothermic, warmth will be provided for the neonate by giving warm linen or placing a droplight near the baby's bed. The results of this study might not benefit your child directly but will benefit future patients by providing information that may justify the use of hand touch method in assessing for hypothermia among neonates.

Refusal to participate

Your participation in the study is voluntary. You may withdraw your child anytime without penalty and this will not affect the present and future treatment of your child.

Payment as a result of the complications of the study

There are no medications in this study. No payment will be given to the child as a result of participation in the study.

Rights of the participants

Participation in the study is voluntary. Refusal to participate will not influence the care of your child in the hospital in any way. Though we would like all participants to complete the study, you are free to withdraw any time. If at any time you have any questions or concerns related to the study, you may contact the ethics review board of the tertiary hospital.

Confidentiality

All information collected in this study will be kept strictly confidential, except as may be required by law. Your child or family will not be identified by name when the results of the study are published. You have a right to know the results of the study at the end of the trial. Any additional information about the study results will be provided to you at its conclusion, upon your request. The results of this study will be presented in local and international conferences and will be written for possible publication in a scientific journal.

Alternatives to participation in the study

If you do not want your child to participate in this study, your child will still be seen every day by the doctors and health care workers in the hospital and provided treatment according to the regular treatment protocol of the hospital.

Should you agree to participate, please sign your name below, indicating that you have read and understood the nature of the study, and that all your inquiries concerning the activities have been answered to your satisfaction.

Consent

I have had the study explained to me and have read the contents of this form/had the contents of this form read to me. I have been given the opportunity to ask questions and have them answered to my satisfaction. I understand that my child's temperature will be determined using hand touch method and digital thermometer. I am willing for my child to be enrolled in this study.

Signature of parents/guardian

Hospital personnel who explained consent

Date/time

Date/time

Signature of witness

Signature of witness

Date/time

Date/time