Title: Effectiveness of Hypothermia Prevention Devices for Preterm Infants - Laboratory Study

Authors: Prakash Kannan Loganathan[1,2,3] Charles Dorkins[1], George Marlow[1], James Zahra[1], Mudit A Tulsianey[1], Toby J Rowles[1], Paula Chadwick[1].

Affiliations:

1.Department of Physics, University of Durham.

2. Neonatal unit, James Cook University Hospital, Middlesbrough, United Kingdom.

3. Clinical Academic office, Faculty of Medical Sciences, Newcastle University

Short Title: Efficacy of Hypothermia Prevention Devices

Corresponding Author:

Prakash Kannan Loganathan (ORCID: 0000-0003-3717-8569)

James Cook University Hospital

Marton Road, Middlesbrough TS4 3BW

Email : pkannanloganathan@nhs.net

Phone: 01642 854874

Fax: 01642854488

Number of Tables: 0

Number of Figures: 2

Word count: Abstract 153; Manuscript 1607.

Abbreviations: Trans-Warmer Infant Mattress (TWM)

Abstract

OBJECTIVE:

To compare the heat conservation efficacy of “Neohelp” and “Neowrap” and evaluate the heat production efficacy of Trans-Warmer Infant Mattress (TWM) in laboratory setting.

METHODS:

A beaker of water was heated at 60℃ was covered by “Neohelp” or two layers of “Neowrap” and left to cool in an open room for 90 minutes and calculated the decay constant. Using infra-red camera, we measured the maximum temperature and time taken to reach the temperature in the TWM.

RESULTS:

“Neowrap” took 863 seconds for the temperature to drop from 37 ^{o}C to 35 ^{o}C, compared with 941 seconds with “Neohelp”. When activated TWM reached a maximum temperature of 39.3± 0.1°C. It took 30 seconds when the activator was placed in the centre, compared with 88 seconds when it was at the corner.

CONCLUSIONS:

Compared to Neowrap, Neohelp had better heat conservation properties. Activating the metal disk from the TWM center would deliver quicker heat.

Keywords: Hypothermia, neohelp, neowrap, trans-warmer mattress

Background: Newborn hypothermia at birth remains as global challenge across all settings. The prevention of delivery room hypothermia at birth could potentially reduce neonatal morbidity and mortality(1, 2). In preterm newborns for each one degree drop in admission temperature below 36.5 deg C mortality increases by 28%(3). Similarly, the odds of mortality decreases for each 1 deg C increase in admission temperature withs odds ratio of 0.81 (95% CI 0,71-0.91)(4). Many interventions to prevent delivery room hypothermia have been studied with consistent result showing that use of plastic wraps or bags was associated with less hypothermia and higher admission temperature(5). Use of plastic wrap/bag is recommended by many international resuscitation agencies(6, 7). “Neohelp™ (Vygon)”, “Neowrap ™ (Fisher & Paykel)”, are two commonly used polyethylene/plastic covers for prevention of neonatal hypothermia. “Neohelp” is a sterile 2 layered polyethylene suit with an adjustable hood and foam back (Cost: £10/Neohelp). “Neowrap” is a medical grade polyethylene occlusive warp without any head covering (Cost: £1/Neowrap).Neohelp and NeoWrap are similar in their theoretical workings. They both reduce heat loss through evaporation, radiation, and convection. Neohelp also uses a foam pad to reduce heat losses through conduction. Both are transparent, allowing the baby to be monitored visually for any discolouration or breathing irregularities.

“Trans-Warmer Infant Mattress” which contains sodium acetate-water and on activation produces heat by crystallisation reaction (Cost: £40/trans-warmer). The efficacy of these products has not been studied. Our study objectives were to compare the heat conservation efficacy of “Neohelp” and “Neowrap” and evaluate the heat production efficacy of “Trans-Warmer Infant Mattress (TWM)” in a laboratory setting.

Methods:

"Neohelp" and "Neowrap": An experimental setup was used whereby a beaker with 250grams of water at 60℃ was covered by "Neohelp" or two layers of "Neowrap" and left to cool in an open room with environmnetal temperature of 20ºC for 90 minutes. We used two layers of "Neowrap" to mimic the physical property of two layered "Neohelp"This mass of water was chosen to ensure the temperature probe was fully submerged, ensuring accurate temperature readings. At the same time, we minimised the volume of water used in order to ensure that for a given change in heat, we would measure a large temperature change. We used mass balance with high precision for measuring the water. We avoided heating the water to temperatures higher than 60°C to minimise evaporation and heating above this temperature could cause damage to the wraps. We chose to cover the beakers with the wraps as soon as possible after the water had been heated. We expected 90-minute period of cooling would be sufficient enough to show change in temperature to calculate an accurate cooling curve.A DS18B20 temperature sensor (accuracy ±0.5°C) placed in the centre of the beaker connected to an Arduino (micro-controller kit) which measured the temperature at 0.5 second intervals. The Arduino outputted temperature readings along with a timestamp of the reading via USB to a computer, where the data was stored and analysed in Python. By measuring the temperature of water over time (heat loss by radiation), it was possible to determine the value of the decay constant for each of the devices.These enabled the determination of insulative properties using Newton's law of cooling(8). We repeated the experiment on four occasions and measurements were taken in ~0.5s intervals as this was the maximum rate at which the temperature probe could output readings The data for each material was then fitted to Newton's law of cooling by a method

of least squares regression, to obtain values for the decay constant of each curve. Using Newton's law of cooling, K value as a measure of heat loss is calculated. A large value of K corresponds to a large rate of heat loss and vice- versa for a lower value of K. Complete report including the derivation of physics equation and all the analysis were provided in the Appendix-1.

We also measured the thickness of the "Neowrap" and "Neohelp" using a micrometer. The surrounding environmental temperature was also measured intermittently to determine fluctuations and thus quantify the error due to the change in surrounding temperature.

Evaluation of TWM: We conducted two experiments: 1) Using Infra-red camera we measured maximum temperature of the mattress, the time taken to reach this maximum temperature and inhomogeneities with heat distribution within the mattress. 2) We assessed how the position (corner vs center of the mattress) of the starting metal "clicker" affects the time taken for the mattress reach its peak temperature.

Results:

"Neohelp" Vs "Neowrap": Each experiment was run four times and the average heat loss constant, K, was calculated. Using 2 layers of "Neowrap", totalling 100 µm thickness, it took 863 seconds for the temperature to drop from 37 ^{o}C to 35 ^{o}C, compared with 941 seconds for the beaker covered with "Neohelp" only, which was 80μm thick (inner layer 30 + outer layer 50μm). Thus, the beaker covered by "Neohelp" was more effective at preventing heat loss than two layers of "Neowrap" (mean K value 1.33 ± 0.02 compared with 1.46 ± 0.01 (Figure1). Over the 90-minute measurements the average fluctuation of the ambient temperature was found to be less than or equal to 1°C.

TWM: When cracked in the centre, it took 30 seconds to reach 39.0 ± 0.1°C in the centre and the maximum temperature reached was 39.3± 0.1°C. The hottest part of the mattress first dropped under 37.0 ± 0.1°C after 15 minutes and dropped under 36.0 ± 0.1°C after 36 minutes.Reaching the maximum temperature in the centre of 39.0 ± 0.1°C took 30 seconds when the activator was placed in the centre, compared with 88 seconds when it was at the corner. A thermal imaging camera showed two hot spots either side of the centre of the TWM, due to unequal distribution of gel caused by folding during packaging (Figure2).

Discussion:

We report the efficacy of three of the commonly used neonatal hypothermia prevention devices in a laboratory setting. We hypothesize that layer of air trapped between the two layers of “Neohelp” was contributing to its superior heat conservation effect rather than thickness of the material. This can be explained by the fact that the air inside the two layers of the bag is sealed, so whilst not a vacuum, the lack of any new air replacing the air inside the gap may be causing the improved performance over two layers of NeoWrap. The air between the layers will act as an insulator, preventing heat transfer from the water to the surroundings.

A baby’s head makes up as much as 20% of the total skin surface(9); which explains why a hood could have additionally contributed to Neohelp’s efficacy. The other difference is Neohelp contains a strip of Velcro on the front while NeoWrap is simply wrapped around the baby. This means when it is required to access the neonate, for example to take a temperature measurement, Neohelp can be opened to a lesser amount whereas NeoWrap must be fully unwrapped.

While the Mattress is single use only, heating sodium acetate trihydrate crystals to approximately 80°C causes the crystals to lose their water of hydration and then dissolve into this water, cooling slowly prevents any crystals from reforming meaning the reaction can occur again and TWM could be reused. In any clinical settings, the mattress must be sterilised but an easy way to heat the mattress is to submerge it in boiling water. There is however no scientific reason why the TWM could not be manufactured to be easily reusable (like commercially available reusable hand warmers), which could be cost savings. Please see the YouTube link (https://youtu.be/Lmv1_RrXiA4) on how the mattress could be reused from one of the commerically available product (https://www.lifesystems.co.uk/products/outdoor-survival/reusable-handwarmers).

This was a laboratory study and not a clinical study. Condition at the time of birth and underlying pathology (e.g., Sepsis) could influence the temperature at birth. Hence, we felt studying their physical properties in a laboratory setup would provide some information on the heat conservation efficacy of these devices. Another limitation is that we did not study the properties of these devices under resuscitaire. We also did not study the combined effect on TWM and the plastic bags/wrap. In clinical settings combined use of these devices improved admission temperature, but associated with increased rates of hyperthermia(5).The TWM are folded in half with packaging, so upon initially opening them the gel is not uniformly distributed. Also, with packaging, the metal activation disks were located in different positions. Prior to high-risk deliveries where there are high chances of using TWM, team could manoeuvre the metal disk to the center and ensure uniform distribution of gel without activation.

Performance of medical devices need to be consistent and without any major deviations, especially in neonatal population. This could be ensured by Post-market surveillance with focus on safety and efficacy of these devices(10, 11). This should be performed by regulatory bodies with standarised assessment methods(10, 11). Knowledge regarding these standarised surveillance system for these medical devices (Neohelp/Neowrap) is lacking.

Thorough this laboratory study, we have demonstrated that heat conservation by preventing radiation loss was better with “Neohelp” than “Neowrap”. Also, we have provided few practical clinical tips for the effective usage of TWM. There are cost implications in the use of these devices whether these findings translate to clinical benefits needs further study.

Conclusions:

In this laboratory study, heat conservation was better with “Neohelp” as compared to “Neowrap”. Activating the trans-warmer mattress from the centre as compared to one of the corners was found to reduce the time for the mattress to reach maximum temperature. Ensuring the gel distribution of the mattress is approximately uniform before use would help ensure uniform heat distribution.

Conference presentation: This project was orally presented in REASON international conference, United Kingdom 2022.

Statements

Acknowledgement

We would like to thank all the staff from the department of physics at University of Durham.

Statement of Ethics

Ethics approval was not obtained, as this was not applicable for this laboratory study. No written informed consent was obtained from the participants, as this was not applicable for this study.

Conflict of Interest Statement

The authors have no conflicts of interest to declare.

Funding Sources

Internal funding from Department of physics, University of Durham.

Author Contributions

C. Dorkins: was responsible for conducting the experiment, data collection, drafting initial manuscript, and approved the final manuscript.

G. Marlow: was responsible for conducting the experiment, data collection, drafting initial manuscript, and approved the final manuscript.

J. Zahra: was responsible for conducting the experiment, data collection, drafting initial manuscript, and approved the final manuscript.

M. Tulsianey: was responsible for conducting the experiment, data collection, drafting initial manuscript, and approved the final manuscript.

T. Rowles: was responsible for conducting the experiment, data collection, drafting initial manuscript, and approved the final manuscript.

Prof P Chadwick: was responsible for concept, design, interpretation of data, drafting initial manuscript, and approved the final manuscript.

Dr. Loganathan P was responsible for concept, design, interpretation of data, drafting initial manuscript, and approved the final manuscript.

All authors approved the final manuscript as submitted and agree to be accountable for all aspects of the work.

Data Availability Statement

The data will be made available upon publication to researchers who provide a methodologically sound proposal and research ethics board approval. Proposals should be submitted to pkannanloganathan@nhs.net

References

1. Abiramalatha T, Ramaswamy VV, Bandyopadhyay T, Pullattayil AK, Thanigainathan S, Trevisanuto D, et al. Delivery Room Interventions for Hypothermia in Preterm Neonates: A Systematic Review and Network Meta-analysis. JAMA Pediatr. 2021;175(9):e210775.
2. Wyckoff MH, Weiner CGM. 2020 International Consensus on Cardiopulmonary Resuscitation and Emergency Cardiovascular Care Science With Treatment Recommendations. Pediatrics. 2021;147(Suppl 1).
3. Laptook AR, Salhab W, Bhaskar B. Admission temperature of low birth weight infants: predictors and associated morbidities. Pediatrics. 2007;119(3):e643-9.
4. Laptook AR, Bell EF, Shankaran S, Boghossian NS, Wyckoff MH, Kandefer S, et al. Admission Temperature and Associated Mortality and Morbidity among Moderately and Extremely Preterm Infants. J Pediatr. 2018;192:53-9.e2.
5. McCall EM, Alderdice F, Halliday HL, Vohra S, Johnston L. Interventions to prevent hypothermia at birth in preterm and/or low birth weight infants. Cochrane Database Syst Rev. 2018;2(2):Cd004210.
6. Aziz K, Lee C, C. H, Escobedo MB, Hoover AV, Kamath-Rayne BD, et al. Part 5: Neonatal Resuscitation 2020 American Heart Association Guidelines for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care. Pediatrics. 2021;147(Supplement 1).
7. Newborn Life Support, Resuscitation Council (UK). 2021.
8. https://en.wikipedia.org/wiki/Newton%27s_law_of_cooling [Available from: https://en.wikipedia.org/wiki/Newton%27s_law_of_cooling.
9. Stothers JK. Head insulation and heat loss in the newborn. Arch Dis Child. 1981;56(7):530-4.
10. Badnjevic A. Evidence-based maintenance of medical devices: Current shortage and pathway towards solution. Technology and Health Care. 2022;31:1-13.
11. Badnjevic A, Spahic L, Jordamovic NB, Pokvic LG. A novel method for conformity assessment testing of infant incubators for post-market surveillance purposes. Technol Health Care. 2023;31(1):389-99.

Figure Legends

Figure 1: The fitted Newton's law of cooling curve for two layers of NeoWrap alongside a Neohelp showing longer time of heat conservation with Neohelp. Y-axis representing Temperature in kelvin and X-axis representing time in minutes.

Figure 2: A snapshot of the image from the Infra-Red camera showing lower temperature on the lower right-hand side of the mattress (marked by circle). Note that there is temperature scale on the right-hand side (marked by arrow) with yellow colour indicating higher temperature (close to 38.6 ^{o}C) and purple colour indicating lowest of the temperature scale.