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Phase Changing Material: An Alternative Method for Cooling Babies with Hypoxic Ischaemic Encephalopathy

Niranjan Thomas[a] Yogeshwar Chakrapani[b] Grace Rebekah[c] Kalyani Kareti[a]
Suresh Devasahayam[b]

Departments of [a]Neonatology, [b]Bioengineering and [c]Biostatistics, Christian Medical College, Vellore, India

Key Words
Therapeutic hypothermia · Hypoxic ischaemic encephalopathy · Phase changing material

Abstract
Background: Therapeutic hypothermia for hypoxic ischaemic encephalopathy (HIE) has been proved effective. Standard equipment is expensive, while ice packs used in low resource settings are labour intensive and associated with wider temperature fluctuations. ***Objectives:*** To assess the feasibility of using phase changing material (PCM) as an alternative method for providing therapeutic hypothermia. ***Methods:*** We retrospectively analysed 41 babies with HIE who had been cooled with PCM (OM 32™ or HS 29™) to a target rectal temperature of 33–34°C. Rectal temperature was continuously monitored and recorded every hour. If the rectal temperature was >33.8°C, cool gel packs were applied, and if the temperature was <33.2°C, the baby was covered with sheets and the warmer output turned on till the temperature stabilized at 33.5°C. The unit's standard protocol for cooling was followed for monitoring and treatment. The outcome measures were stability and fluctuation of the rectal temperature and the need for interventions to maintain the target temperature. ***Results:*** The mean (±SD) temperature during the cooling phase was 33.45 ± 0.26°C. Throughout the cooling phase, the target temperature range was maintained in 96.2% of the time. There was no temperature reading <32°C. With HS 29, ice packs were not used in any baby, and the warmer was used for a median of 7 h (interquartile range 1.5–14). ***Conclusions:*** PCM provides a low cost and effective method to maintain therapeutic hypothermia. However, careful monitoring is required during induction and the rewarming phase to avoid hypothermia outside the therapeutic range.

Introduction

Therapeutic hypothermia for hypoxic ischemic encephalopathy (HIE) reduces the combined outcome of mortality or major neurodevelopmental disability at 18 months of age (RR 0.75; 95% CI 0.68–0.83) [1]. Standard

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E-Mail karger@karger.com
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Dr. Niranjan Thomas
Department of Neonatology
Christian Medical College Hospital
Vellore 632004, Tamilnadu (India)
E-Mail niranjan@cmcvellore.ac.in

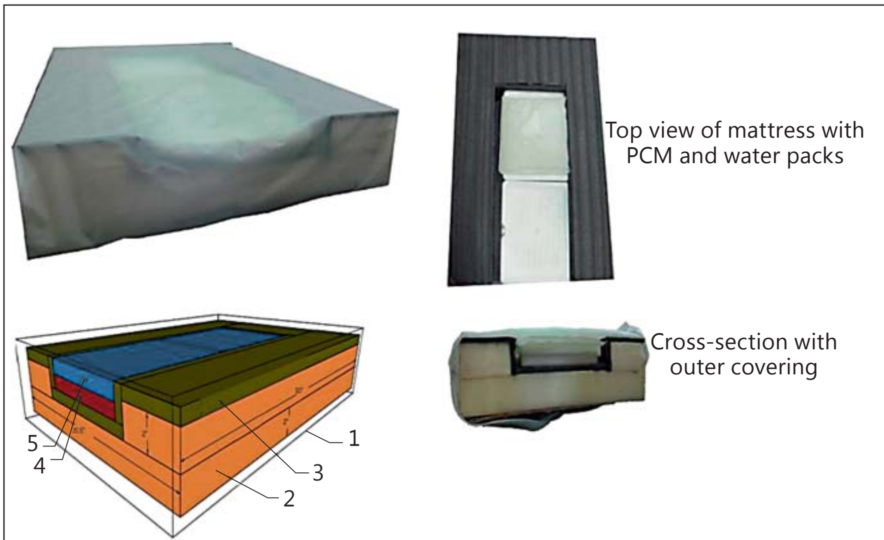

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Fig. 1. Construction of the PCM bed. The bed consists of an outer covering made of nylon (1), a hollowed-out foam layer (2) lined with an insulating material like extruded polystyrene (3), PCM blocks kept in the hollowed-out area (4) and a water mattress above the PCM blocks and below the outer covering (5).

equipment is expensive and there is a need for cheaper alternative methods. Although several trials have looked at cool gel/ice packs demonstrating feasibility, ice packs with a freezing surface temperature can be associated with wide fluctuations in temperature, episodes of severe hypothermia, increased shivering and subcutaneous fat necrosis and the need for frequent changes which requires more nursing input [2, 3]. Phase changing materials (PCMs) are made of salt hydride, fatty acid and esters or paraffin, melting at a set point. PCMs absorb and release heat at a nearly constant temperature and can store 5–14 times more heat per unit volume compared to material like water or masonry. When a baby is placed on a bed made of PCM, heat from the baby is transferred to the PCM which absorbs the heat till it melts. Hence, PCM has the potential to provide a mechanism of heat removal which will be easier and safer to use than ice packs. Keeping the melting point of the PCM at the target temperature will ensure that the baby's temperature will not fall below this temperature.

There has been one animal study and a small human trial that have looked at PCM as a mode of cooling neonates [4, 5]. We have cooled 41 babies with HIE using PCM and describe our experience in this paper.

Methods

This study is a retrospective analysis of babies cooled in the neonatal unit of the Christian Medical College, Vellore. The institutional review board approval was obtained to look at data collected as part of the Christian Medical College cooling registry. We have previously published our experience on cooling babies with cool gel packs as a feasibility trial [6]. We have been using PCM instead of cool gel since 2011.

We offered therapeutic hypothermia to babies >35 weeks gestation detected with moderate or severe encephalopathy within 6 h of life along with one of the following: cord/1 h postnatal blood gas pH <7.0 or base deficit >12 or 5-min APGAR <5 or need for ventilation >10 min. In outborn babies where blood gas and APGAR scores were not available, the need for resuscitation at birth was taken along with the presence of encephalopathy.

Verbal informed consent from the parents was obtained before cooling. Neurological examination was performed using a standardized neurological examination that was based on the modified Sarnat criteria used in the NICHD study [7]. Babies were nursed under an infant warmer which was turned off, and cooling was achieved by placing the baby on the PCM bed. The PCM bed was built using locally available material by the bioengineering department and consisted of a hollowed-out foam mattress lined with an insulating layer (extruded polystyrene) and covered with a good conducting layer (nylon) as shown in figure 1. About 2,400 g of PCM, savE OM 32™ (melting point 32°C) or savE HS 29™ (melting point 29°C; pluss polymers, New Delhi, India) was placed in each bed below the nylon cover in the hollowed-out space in the foam mattress. A water bed was placed between the PCM layer and nylon cover to provide comfort and to improve heat transfer from

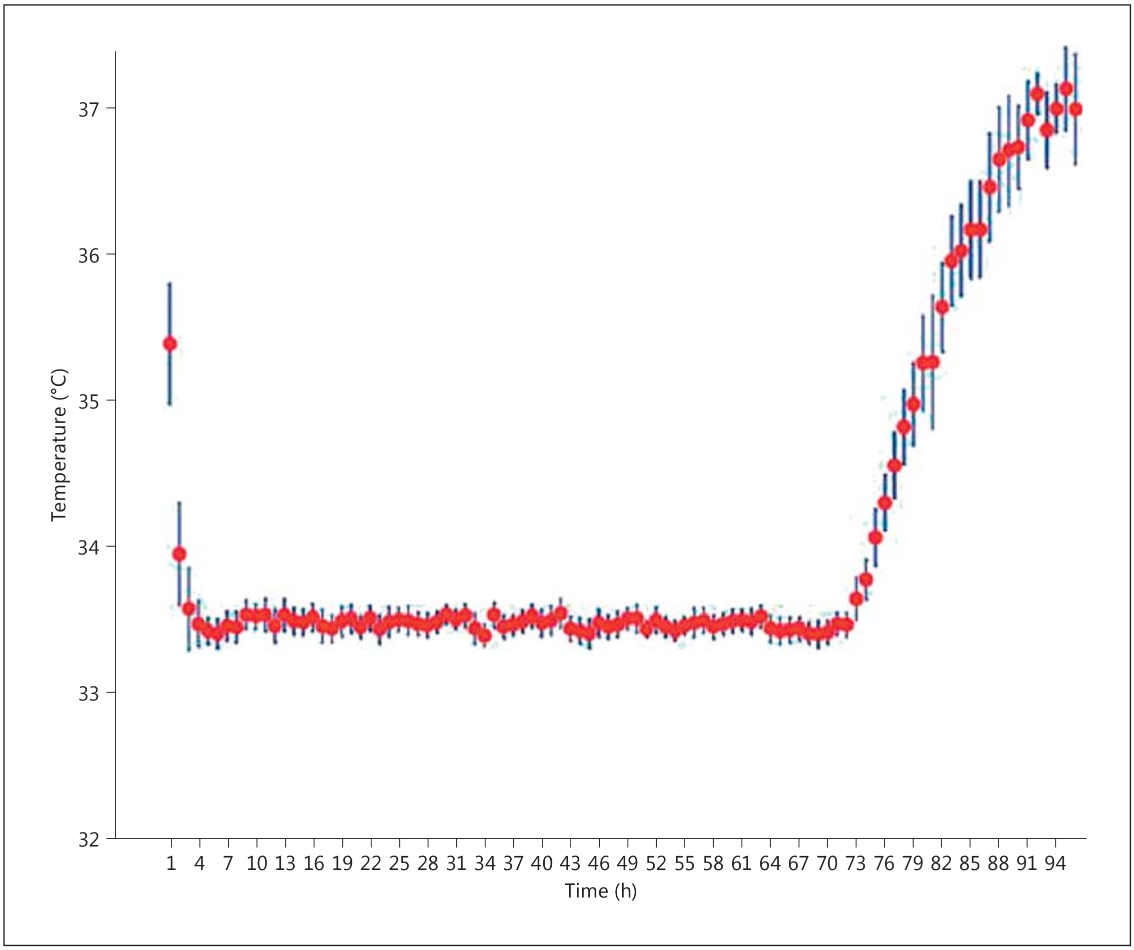

Fig. 2. Means and 95% confidence intervals of hourly temperatures during induction, maintenance and rewarming phases of cooling.

the baby to the PCM block (fig. 1). The cost of making the bed including the PCM was about EUR 40 (INR 3,000). The mattress and PCM were reusable and on an average lasted for at least 20 babies. A rectal probe (Philips ref. No. 21090 A or Draeger ref. No. 4329848-08) to monitor core temperature was inserted 5 cm within the rectum and connected to a multiparameter monitor (Philips Intellivue MP20, Phillips Healthcare, The Netherlands, or Draeger Vista XL, Draeger Medical Systems Inc., Telford, Pa., USA). The targeted rectal temperature was 33.5°C. The temperature was continuously monitored and recorded every 15 min for 4 h and then subsequently every hour for 80 h. During the cooling process, if the temperature decreased to 33.2°C, a folded cloth sheet was kept between the baby and the PCM mattress and the baby was covered with a sheet. If the temperature continued to drop, the warmer was turned on at 10–20% output (manual mode) till the temperature reached 33.5°C. Then in sequence, the warmer was turned off, the baby uncovered and the sheet removed from under the baby as the temperature rose. If the temperature rose above 33.8°C, one cool gel pack would be used till the temperature reached 33.5°C. Rewarming was achieved by turning on the warmer and raising the temperature of the baby by 0.2°C/h. All other aspects of management were as per unit protocol [6].

Results

A total of 41 babies were cooled using PCM between January 2011 and August 2014, 11 with savE OM 32 and 30 with savE HS 29. The mean birth weight was 2,867.1 ± 411.6 g and the mean gestational age 38.4 ± 1.4 weeks. There were 37 (90%) babies with stage 2 HIE and 4 (10%) with stage 3.

The mean temperature at initiation of cooling was 35.2 ± 1.1°C (fig. 2). The median time to reach the target temperature was 60 min (interquartile range, IQR, 60–

180). The mean ± SD temperature during the cooling phase was 33.45 ± 0.26°C (fig. 2). The rate of rewarming was 0.25 ± 0.09°C/h. Throughout the cooling phase, the target temperature range (33–34°C) was maintained in 96.2% of the time. During the cooling phase, episodes of temperature below 33°C were seen in 2.4% and above 34°C in 1.4% of the time. There were no temperature readings <32°C in any of the babies. Only 1 (2.4%) baby developed subcutaneous fat necrosis.

With savE OM 32, ice packs were used for a median of 12.3 h (IQR 6.9–17.5 h) and a warmer for a median of 2.3 h (IQR 0–6.5). With the savE HS 29, ice packs were not used in any baby and a warmer was used for a median of 7 h (IQR 1.5–14).

Discussion

We have shown that babies with HIE can be cooled effectively using PCM. Though not a servo-controlled system, it was easy to induce hypothermia (median 60 min), maintain target temperature (33.45 ± 0.26°C) and rewarm babies in a slow and controlled manner (0.25°C/h) using PCM.

Standard equipment like Tecotherm™, Criticool™ and the Blanketrol^{R} III system are available but expensive and beyond the reach of many centres in low-to-mid income countries. Also, high cost equipment may not be practical during transport and when several babies have to be cooled at the same time. Low cost systems that are used include cool gel/ice packs, cooling fans and water bottles [8]. Cooling fans and water bottles have not been studied well and have been associated with increased shivering and mortality [8]. Cool gel packs are also associated with increased fluctuations in temperature, need for frequent changes and potential for increased skin changes [3].

PCMs are widely used in the industry for human comfort management. They are used in textiles, buildings (for human comfort and air conditioning regulations), air conditioning, greenhouse applications, telecom shelters, wine storage and transportation and temperature control jackets for labware. PCM has also been tried in therapeutic hypothermia. Iwata et al. [4] cooled 11 piglets, 6 with PCM and 5 with water bottles. Therapeutic hypothermia was achieved with both, but PCM cooling led to a longer period within the target temperature range and provided stabler cooling. Unlike PCM, water bottle cooling required frequent changes [4].

There is only one other study that has cooled HIE babies with PCM. Thayyil et al. [5] cooled 17 babies using PCM. The rectal temperature during cooling was 33.5 ± 0.3°C. The median cooling induction time was 30 min (IQR 10–90), and the rewarming rate was 0.24°C/h [5]. This was very similar to our study and demonstrates that PCM can be used effectively to cool babies in low resource settings. It is interesting to note that the rectal temperature variations in the NICHD, TOBY and ICE trials were also similar (33.4 ± 0.4, 33.5 ± 0.5 and 33.8 ± 0.4°C, respectively) [7, 9, 10]. While the NICHD and TOBY trials used semi-automated machines, the ICE trial used ice packs. The advantage of PCM over cool gel packs is that there is no need for frequent changes, there are fewer fluctuations in temperature and the risk of skin injury is minimized. There is also a potential for PCM to be used for transport even in high income countries where the use of cool gel has been associated with a high incidence of severe hypothermia [8].

The limitations of this study are that this is a single centre's experience, and information on the influence of environmental temperature is not available.

In conclusion, PCM is an alternative, effective and low cost method of cooling babies in low-to-mid income countries and during transport. However, as this is not a servo-controlled system, careful monitoring and good nursing care are needed especially in the induction and rewarming phases. Further studies are needed to look at the influence of the environmental temperature on the PCM performance and to see if it can be replicated in other centres as well.

References

1 Jacobs SE, Berg M, Hunt R, Tarnow-Mordi WO, Inder TE, Davis PG: Cooling for newborns with hypoxic ischemic encephalopathy. Cochrane Database Syst Rev 2013; 1:CD003311.

2 Bharadwaj SK, Bhat BB: Therapeutic hypothermia using gel packs for term neonates with hypoxic ischaemic encephalopathy in resource-limited settings: a randomized controlled trial. J Trop Pediatr 2012:58:382–388.

DOI: 10.1159/000375286

3 Higgins RD, Raju T, Edwards AD, Azzopardi DV, Bose CL, Clark RH, Ferriero DM, Guillet R, Gunn AJ, Hagberg H, Hirtz D, Inder TE, Jacobs SE, Jenkins D, Juul S, Laptook AR, Lucey JF, Maze M, Palmer C, Papile L, Pfister RH, Robertson NJ, Rutherford M, Shankaran S, Silverstein FS, Soll RF, Thoresen M, Walsh WF; Eunice Kennedy Shriver National Institute of Child Health and Human Development Hypothermia Workshop Speakers and Moderators: Hypothermia and other treatment options for neonatal encephalopathy: an executive summary of the Eunice Kennedy Shriver NICHD workshop. J Pediatr 2011; 159:851–858.
4 Iwata S, Iwata O, Olson L, Kapetanakis A, Kato T, Evans S, Araki Y, Kakuma T, Matsuishi T, Setterwall F, Lagercrantz H, Robertson NJ: Therapeutic hypothermia can be induced and maintained using either commercial water bottles or a 'phase changing material' mattress in a newborn piglet model. Arch Dis Child 2009;94:387–391.
5 Thayyil S, Shankaran S, Wade A, Cowan FM, Ayer M, Satheesan K, Sreejith C, Eyles H, Taylor AM, Bainbridge A, Cady EB, Robertson NJ, Price D, Balraj G: Whole-body cooling in neonatal encephalopathy using phase changing material. Arch Dis Child Fetal Neonatal Ed 2013;98:F280–F281.
6 Thomas N, George KC, Sridhar S, Kumar M, Kuruvilla KA, Jana AK: Whole body cooling in newborn infants with perinatal asphyxial encephalopathy in a low resource setting: a feasibility trial. Indian Pediatr 2011;48:445–451.
7 Shankaran S, Laptook AR, Ehrenkranz RA, Tyson JE, McDonald SA, Donovan EF, Fanaroff AA, Poole WK, Wright LL, Higgins RD, Finer NN, Carlo WA, Duara S, Oh W, Cotten CM, Stevenson DK, Stoll BJ, Lemons JA, Guillet R, Jobe AH; National Institute of Child Health and Human Development Neonatal Research Network: Whole-body hypothermia for neonates with hypoxic-ischemic encephalopathy. N Engl J Med 2005;353:1574–1584.
8 Robertson NJ, Kendall GS, Thayyil S: Techniques for therapeutic hypothermia during transport and in hospital for perinatal asphyxial encephalopathy. Semin Fetal Neonatal Med 2010;15:276–286.
9 Azzopardi DV, Strohm B, Edwards AD, Dyet L, Halliday HL, Juszczak E, Kapellou O, Levene M, Marlow N, Porter E, Thoresen M, Whitelaw A, Brocklehurst P; TOBY Study Group: Moderate hypothermia to treat perinatal asphyxial encephalopathy. N Engl J Med 2009;361:1349–1358.
10 Jacobs SE, Morley CJ, Inder TE, Stewart MJ, Smith KR, McNamara PJ, Wright IM, Kirpalani HM, Darlow BA, Doyle LW; Infant Cooling Evaluation Collaboration: Whole-body hypothermia for term and near-term newborns with hypoxic-ischemic encephalopathy: a randomized controlled trial. Arch Pediatr Adolesc Med 2011;165:692–700.