

HL, Juszczak E, *et al.* TOBY Study Group. Moderate hypothermia to treat perinatal asphyxial encephalopathy. *N Engl J Med.* 2009;361:1349-58.

4. Kendall GS, Kapetanakis A, Ratnavel N, *et al.* Passive cooling for initiation of therapeutic hypothermia in neonatal encephalopathy. *Arch Dis Child Fetal Neonatal.* Ed 2010; 95:F408-12.

REPLY

We appreciate the interest shown in our study [1] and the opportunity to clarify the important points raised by the author of this letter.

We had a total of 1514 rectal temperature recordings in the 20 babies during the 72 hours maintenance phase of hypothermia. During this time, 90.4% of the temperature recordings were within the target temperature range. Five percent of the temperatures were below and 4.6% above the target range. Of the lower temperature readings, only 1% was below 32°C. The lowest recorded temperature was 30.8°C. In addition to this, we have temperature data on the babies we have cooled since the study. Of 1200 temperature recordings in a further 18 babies, 92% of the temperature recordings were in the target range. We agree that this degree of temperature maintenance is exceptionally good compared to other studies including the ICE trial which used a similar cooling method [2]. We believe that good nursing and careful monitoring can achieve these results even with low technology methods. It is our experience that with adequate training and careful monitoring, the desired temperature range can be easily maintained.

The study design did not have blood gas criteria as inclusion criteria for outborn babies. This being so, we had mentioned that “there was significant acidosis among inborn babies at admission”. This was not supposed to preclude the presence of acidosis in outborn babies. All the outborn babies recruited had a blood gas at admission (mean time, 3.7 hours of life). All but one of the outborn babies were acidotic at admission (mean base excess -11; mean bicarbonate 14.8).

Further, if we look at the western trials, the criteria for recruitment were neonatal encephalopathy with the presence of 1 of 4 criteria (low pH or elevated base excess on cord gas, low APGAR score or need for ventilation at 10 minutes) and not the presence of all 4 [2-5]. We fail to see why the criteria for a trial cannot be designed to suit a local population but must always follow a Western precedent! We had strict criteria for study entry which was followed to the letter. The ground reality in India is that most of the asphyxiated babies admitted into a neonatal unit are outborn where a cord pH or early blood gas will

not be available. For example, during the 6 months of our trial, there were 53 outborn babies as compared to only 15 inborn babies with HIE. We recruited outborn babies with encephalopathy who had needed prolonged resuscitation at birth and this is representative of babies who would benefit from cooling as per the Western data. It is worth noting that out of the 53 outborn babies with HIE, only 8 reached before 6 hours and could be cooled. This is a major issue that needs to be addressed if cooling is to reach those babies who need it most.

We would like to point out to the authors that Kendall, *et al* looked at correlation of rectal and skin temperature among transported babies who were passively cooled [6]. They also had only 152 paired rectal and skin temperature readings. This is unlike our cohort, who were actively cooled in a neonatal unit and about 1745 paired temperature readings were analysed. Similar to our findings, good correlation between rectal and skin temperature was seen in the study published by Horn, *et al.* [7]. However, at this point of time, the standard of care is to monitor rectal temperature continuously and we do not advocate or follow only skin temperature when we cool babies.

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