

Current Status of Therapeutic Hypothermia in India: Few Concerns

We read the article by Chandrasekaran, *et al.* [1], and would like to appreciate the authors for highlighting the current trends of the use of this new and fascinating modality, which have not undergone rigorous testing in low- and middle-income countries (LMIC). While following the protocols used in Western countries, it needs to be highlighted that our population differs in certain traits and results may not be same as shown in high-income countries [2,3]. Authors clearly described the results of the survey; however, we would like to highlight certain points, which might bring more clarity on this issue:

1. One of the objectives of the study was to examine the adherence of various units to the standard established cooling protocol. This is not answered in results. The author described it under broad heading of criteria for cooling. There is no clarity on definition or description of clinical criteria used by various units.
2. Majority of the units are using clinical criteria alone as deciding factor for cooling without giving due consideration to cord blood gas. Clinical criteria like Apgar scores and need of resuscitation are prone to subjective bias. It is better to use cord blood gas as criteria to define intrapartum asphyxia.
3. It is important to emphasize here that therapeutic hypothermia is not a standard of care as of now in our country, and in view of lack of long-term data on efficacy in LMIC, it is necessary to take written informed consent from the parents before offering it [2,3].
4. It will be important to know that out of the 47 units practicing therapeutic hypothermia, how many have the facility for long-term follow up for timely recognition of neurodevelopmental disabilities and institution of early stimulation program.
5. It is alarming that in private sector 65% of the cooling is done by using indigenous devices, which might be less efficacious and even harmful [4]. Also, one-fourth of the surveyed private centers are using therapeutic hypothermia beyond initial 6 hours, which may not be justified.
6. Authors rightly stated that there is need to develop national guidelines for therapeutic hypothermia. However, we still do not have sufficient evidence on

safety as well as efficacy in LMIC to formulate the guidelines. There is an urgent need for randomized trials along with long-term follow up to have more clarity on this issue. In the absence of the national guidelines, it must be practiced under strict trial protocols.

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AUTHORS' REPLY

We agree with the authors that there is insufficient evidence to support the use of therapeutic hypothermia in low- and middle-income countries [1], and randomized controlled trials are urgently required. We also agree that the profile of mothers and infants with encephalopathy due to hypoxia-ischemia may be different in high resource countries from those in LMIC [2]. The aim of our survey was merely to highlight the therapeutic creep of cooling therapy in Indian neonatal units, despite lack of such evidence [3]. Given the recall bias and subjectivity of web-based surveys, collection of specific details is unlikely to be accurate, and hence we did not attempt to collect data on eligibility criteria for cooling, morbidity and mortality and outcome of infants.

While blood gas based criteria may be useful, it may not be available round the clock in most Indian neonatal units. However, it is essential that a structured neurological examination is performed to ensure babies have moderate or severe encephalopathy, and not mild encephalopathy, before offering cooling therapy. The NICHD neurological examination has been validated in Indian settings, and if performed accurately, will identify these infants. Long term follow-up rates are extremely poor in routine clinical settings in India to provide meaningful outcome data.