

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.

The concerns raised by the authors regarding lack of safety of cooling methods used in the Neonatal units in India and lack of data on safety and efficacy of cooling when initiated after 6 hours of age have been addressed in our manuscript [3]. The NICHD Neonatal Research Network data from high-income countries on cooling for neonatal encephalopathy between 6 and 24 hours of age was recently published [4].

A large phase III randomized controlled trial of whole body cooling is currently ongoing in several public sector tertiary neonatal units in India, Bangladesh and Sri Lanka [5]. All recruited babies are having detailed neuro-developmental follow up at 18 months using Bayley III Infant and Toddler Assessment. Once completed, this would be the largest ever cooling trial and should provide the definitive answer for safety and efficacy of cooling therapy in these settings. We agree, until these data are available, cooling therapy in Indian neonatal units should be considered as experimental, and it may be prudent to obtain informed parental consent after discussing the risk benefits.

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Medical Council of India Revised Criteria for Research Publications: A Dilemma

With reference to the special editorial published recently in *Indian Pediatrics* [1], we have a few more suggestions to offer. As per recent MCI notification regarding credit for only first and corresponding author [1], in our opinion all authors should get their due credit. A way forward can be to give weighted scores to all authors in the serial order of their authorship. This may prevent pressure of gift authorship, as even the last author will get some credit points for his/her contribution with regards to publication [2]. Moreover, scores can be assigned to publications in indexed, non-indexed, national or international journals. Similarly, the indexing agencies can also be scored rank-wise and weighted scores can be assigned accordingly. This systematic transparent method of weighted scoring in every aspect of publication will lay a foundation for common, uniform and objective system of evaluation for researchers all over India.

The editorial [1] further comments that two/five/seven/ten of best papers should be considered for promotion in the academic ladder – but how to evaluate or rank the best papers? This question still remains unanswered. The suggested systematic scoring mechanism can also help here.

One more point to ponder is that why only 'original research' papers are to be considered for promotion of faculty [3]. As 'research' is just a part of Medical teacher's job, the other publications like editorials, commentaries, short articles, case series should also be considered; though, maximum marks/credits can be allotted for research articles. All of these contribute to new ideas, innovations and dissemination of scientific reasoning and thoughts. Every manuscript – whether it is a case report, systematic review or meta-analysis – contributes in one way or other for generating new evidence.

In today's paperless era, it is all the more essential that some quality e-journals should be recognized and included for credits of publication. It will pave the way for medical teachers to fulfill the eligibility for appointment and promotion. As a result, the new medical colleges being started by the government as a policy measure at district level will not face the shortage of