EDITORIAL COMMENTARY

Suction First vs Drying First

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Kumar, et al. [1] have published an open-label, randomized controlled trial in this issue of *Indian Pediatrics*. Among newborn infants depressed at birth, who required the initial steps of resuscitation, they compared the effect of performing suction first or drying first on the composite outcome of hypothermia at admission or respiratory distress at 6 hours of age.

Their rationale for conducting this clinical trial was that the neonatal resuscitation program (NRP) of the American Academy of Pediatrics recommends suction followed by drying, whereas the Indian version of neonatal resuscitation program (1st edition) recommends the sequence of drying followed by suctioning [2,3]. To add to the confusion, the newborn resuscitation module of Facility Based Newborn Care follows the AAP recommendation [4]. Neither of the two sequences is evidence-based. The modification in the Indian NRP results from a concern about the increased risk for hypo-thermia in low- and middle-income countries.

For the better part of the history of neonatology, the steps of neonatal resuscitation were based on expert opinion rather than evidence. It is only for the last few decades that various steps of neonatal resuscitation have been subjected to well conducted randomized cont-rolled trials and systematic reviews [5-9]. The initial steps of resuscitation are applicable to a huge number of newborn infants. Therefore, it is even more important that the initial steps be tested in clinical trials, as a small improvement may result in massive gains at the population level. The steps must be tested both for their necessity as well as the sequence in which they are done.

Given this background, Kumar, et al. [1] must be complimented for conducting a clinical trial on a question that- although apparently minor- could potentially have far-reaching consequences. The current version of the NRP recommends the initial steps of resuscitation for 3 situations- (*a*) preterm, (*b*) apneic or gasping, (*c*) poor muscle tone [2]. The authors have included infants who fulfilled criteria (*b*) and (*c*). There were preterm infants included in the study, who happened to fulfil the other criteria. Thus, the results of their study may not be generalizable to preterm infants who are neither apneic nor limp but who undergo the initial steps of resuscitation as per the current NRP protocol.

The authors conducted the randomization and concealment of allocation well. However, they should have given a justification why they opted to choose a composite outcome that included respiratory distress within 6 hours of birth. I have concerns about the sample size calculation in this trial. The sample size has been calculated for a single-group descriptive study designed to detect a 10% incidence of delivery room resuscitation. This has no relevance to the current study, where the sample size should have been calculated for an expected difference in the composite outcome between two groups. The baseline incidence could have been derived from the unit data of the authors. One can reasonably assume that the effect size in the study would be small, and I expect the true sample size would be much larger than that recruited by the authors.

The authors analyzed several clinically relevant short-term outcomes. There was no statistically signi-ficant difference in the composite outcome between the two groups, based upon which the authors concluded that it makes little difference to the outcome whether newborns are suctioned first or dried first, and either approach is acceptable. The conclusion is worded as if the trial had been conducted as a noninferiority trial or an equivalence study. Since the trial was not designed as a noninferiority trial, the absence of statistically significant difference does not necessarily imply equivalence of the two approaches, and it would have been more appropriate to conclude that the trial failed to detect a statistically significant difference between the two approaches.

The authors have correctly analyzed the issues related to hypothermia in their study and observed that body temperature in the labor room may have been a more relevant outcome, rather than at the time of admission into the NICU. They had a remarkably high

incidence of need for bag and mask ventilation, with almost every subject who underwent the initial steps of resuscitation, requiring bag and mask ventilation.

Not withstanding some of the limitations of this clinical trial and some of the atypical findings, the fact remains that this trial is probably one of the first of its kind. It focuses one's attention on the need to have uniform recommendations and clinical practices. It also demonstrates the urgent need for large, multicentric well-conducted randomized controlled trials on simple questions that affect day-to-day neonatology practice. Hypothermia at birth is a bigger issue in low- and middle-income countries than high-income countries, and countries like India must take the lead in conducting simple, large trials of this kind. The findings of the current clinical trial could form the basis of planning larger trials with adequate sample size.

Funding: None; *Competing interests:* None stated.

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