

AUTHORS' REPLY

1. We agree completely with the finer nuances of randomization, intention-to-treat (ITT) and per-protocol analysis. However, the real question beyond these semantics is whether the study findings are valid and generalizable. We could have omitted the record and carried the analysis with 49 participants in one group and 50 in all other groups. We believe that shifting one participant from Music therapy group to control group will not hamper the validity of the results; albeit technically, it is a breach of randomization. At the same time, it is incumbent to mention this deviation from the plan following principles of honesty and integrity in research.
2. The correct gestational age for the study participants is 26-36 weeks. Although we planned to include participants starting from 26 weeks, they were not stable and hence not eligible to undergo study interventions. Thus, we ended up including neonates with gestational age 28 weeks and more.
3. In principle, we agree with the effect of mother's voice on the effect of pain. However, any randomized control study requires that the intervention be standardized and not changing. Using mother's voice as an intervention is a pragmatic approach and often not approved by reviewers. To ensure standardization and generalizability of the study, music therapy was selected. Using mother's voice would have invited comments such as duration, pitch, ethics of placing the burden of pain reduction on voice modulation on mothers who themselves may be in pain.
4. Sarnat score [2] was used in the current study, as it is one of the commonly used scores for hypoxic-ischemic

encephalopathy grading. It has been studied for applications other than original description [3] and has been also proposed to be useful in classifying hypoxic-ischemic encephalopathy in preterms [4,5]. Currently, there is lack of well-researched scoring system in preterm neonates and hence, we used Sarnat scoring despite its original description being focused on neonates more than 36 weeks. Additionally, we used Sarnat staging as an adjunct criteria in conjunction with other signs of perinatal hypoxia (fetal bradycardia and late decelerations) with intention to strengthen the exclusion of those neonates who might have suffered severe intrapartum hypoxia.

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REFERENCES

1. Shukla VV, Bansal S, Nimbalkar A, Chapla A, Phatak A, Patel D, *et al.* Pain control interventions in preterm neonates: A randomized controlled trial. *Indian Pediatr.* 2018;55:292-60.
2. Sarnat HB, Sarnat MS. Neonatal encephalopathy following fetal distress: A clinical and electroencephalographic study. *Archives Neurol.* 1976;33:696-705.
3. Shankaran S, Laptook AR, Ehrenkranz RA, Tyson JE, McDonald SA, Donovan EF, *et al.* Whole-body hypothermia for neonates with hypoxic-ischemic encephalopathy. *New Eng J Med.* 2005;353:1574-84.
4. Gopogandanahalli KR, Li J, Fahey MC, Hunt RW, Jenkin G, Miller SL, *et al.* Preterm Hypoxic-ischemic encephalopathy. *Front Pediatr.* 2016;4:114.
5. Chalak LF, Rollins N, Morriss MC, Brion LP, Heyne R, Sánchez PJ. Perinatal acidosis and hypoxic-ischemic encephalopathy in preterm infants of 33 to 35 weeks' gestation. *J Pediatr.* 2012;160:388-94.

Gastric Lavage in Infants Born with Meconium Stained Amniotic Fluid: Few Concerns

We read with interest the article by Gidaganti, *et al.* [1] published recently in *Indian Pediatrics*, which concluded that gastric lavage does not reduce either meconium aspiration syndrome (MAS) or feed intolerance in vigorous infants born through meconium stained amniotic fluid (MSAF).

The practice of gastric lavage in babies born through MSAF is being followed at many centers. A recent systematic review by Deshmukh, *et al.* [2] concluded that routine gastric lavage may improve feed tolerance in neonates born through MSAF. However, well designed studies are still needed to confirm these findings. This trial, therefore, was need-based and addressed this clinically relevant issue. We would like to highlight a few important issues:

1. For sample size calculation, the authors have assumed the incidence of MAS in babies born with MSAF as 15%, based on an old unpublished study.