

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.

However, most of the recent studies have reported the incidence of MAS as 5-8% [3,4]. Moreover, in the present study itself, the incidence of MAS is quite less (1.4% in intervention arm and 2.2% in control arm). The authors should have used information from these studies to calculate the sample size for adequate power of their study.

2. We clearly miss the definition of 'vigorous infant' in the entire manuscript. Also, whether the authors also included babies with respiratory distress soon after birth is not clear.
3. One of the exclusion criteria mentioned in the methodology is; mothers receiving methyl dopa. It is not clear why these babies were specifically excluded.
4. In this study, chest X-ray was done in all participants within 4 hours of birth, irrespective of symptoms. We feel that doing X-ray in an asymptomatic baby is not ethically justified. Also, MAS is defined based on presence of clinical symptoms and abnormal chest X-ray. Chest X-ray could have been done only in babies with respiratory distress.
5. For lavage, normal saline (10mL/kg) was used. As lavage was done before the baby was weighed, the clinician must have used approximations to estimate birth weight. It would have been better if volume used for lavage was weight independent.
6. Apart from the adverse effects studied, another potential harm of this intervention is being an hindrance to routine care. If, not for this intervention, a vigorous baby born through MSAF would have received immediate skin to skin contact and early initiation of breastfeeding. However, the need to perform gastric lavage before feeding hinders this practice. This adverse effect of performing this procedure should appear in the manuscript.

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REFERENCES

1. Gidaganti S, Faridi MMA, Narang M, Batra P. Effect of gastric lavage on meconium aspiration syndrome and feed intolerance in vigorous infants born with meconium stained amniotic fluid – A randomized control trial. *Indian Pediatr.* 2018;55:206-10.
2. Deshmukh M, Balasubramanian H, Rao S, Patole S. Effect of gastric lavage on feeding in neonates born through meconium-stained liquor: A systematic review. *Arch Dis Child Fetal Neonatal Ed.* 2015;100:F394-9.
3. Fischer C, Rybakowski C, Ferdynus C, Sagot P, Gouyon J-

B. A population-based study of meconium aspiration syndrome in neonates born between 37 and 43 weeks of gestation. *Int J Pediatr.* 2011;2012.

4. van Ierland Y, de Boer M, de Beaufort AJ. Meconium-stained amniotic fluid: discharge vigorous newborns. *Arch Dis Childhood-Fetal Neonatal Ed.* 2010;95:F69-71.

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We appreciate the interest of the readers in our research article. We have the following clarifications:

1. A very wide range in the incidence of meconium aspiration syndrome (MAS) from 1.62% to 34.4% has been reported in the literature [1-3]. We could not find the incidence of MAS in the vigorous infants only, and thus, we decided to go by the incidence (15%) observed in our institution. Another reason of considering our own institutional incidence of MAS was similar demographic profile of the mothers and infants.
2. A vigorous infant was defined at birth as: spontaneous breathing/crying; HR >10 in 6 seconds; and good muscle tone. All infants were monitored by Downe's scoring for the development of respiratory distress after birth until 72 hrs of age; the first assessment was done at 30-45 min of age. Infants who developed dyspnea during this period and had radiological evidence of meconium aspiration were diagnosed as MAS.
3. Intestinal peristalsis might be affected in the infants born to mothers receiving methyl dopa as anti-hypertensive medication. Therefore, these infants were excluded from this study where feed intolerance was being studied.
4. Meconium-stained amniotic fluid (MSAF) may be aspirated *in utero* in the majority of cases. However, it can also be aspirated after birth when an infant vomits out meconium stained liquor causing secondary MAS. The definition of MAS includes respiratory distress, radiological evidence of meconium aspiration and birth through MSAF. All infants who aspirate meconium do not develop MAS and we agree that in an asymptomatic infant there is no need to do X-ray chest. But our premise is that gastric lavage will prevent development of secondary MAS where meconium is aspirated after birth. The X-ray chest was, therefore, done in this study within 4 hrs in all infants to document any radiological evidence of the intrauterine aspiration of MSAF.

We agree with readers' suggestions regarding point 5 and 6.