

Impact of Delivery Room Gastric Lavage on Exclusive Breastfeeding Rates Among Neonates Born Through Meconium-Stained Amniotic Fluid: A Randomized Controlled Trial

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Background: Delivery-room gastric lavage reduces feeding intolerance and respiratory distress in neonates born through meconium-stained amniotic fluid (MSAF).

Objectives: To evaluate the effects of gastric lavage on exclusive breastfeeding and skin-to-skin contact in neonates delivered through MSAF.

Design: Randomized controlled trial.

Participants: 110 late preterm and term neonates delivered through MSAF not requiring resuscitation beyond initial steps.

Methods: Participants randomized into gastric lavage (GL) ($n=55$) and no-GL ($n=55$) groups. The primary outcome was the rate of exclusive breastfeeding at 72 ± 12 hours of life. Secondary outcomes were time to initiate breastfeeding and establish exclusive breastfeeding, rate of exclusive breastfeeding at discharge, time to initiate skin-to-skin contact and its duration, rates of respiratory distress, feeding intolerance, and the procedure-

related complications of gastric lavage monitored by pulse oximetry and videography.

Results: Both the groups were similar in baseline characteristics. 49 (89.1%) neonates in GL group could achieve exclusive breastfeeding at 72 hours compared to 48 (87.3%) in no-GL group [RR (95% CI) 1.02 (0.89-1.17); $P=0.768$]. Initiation of skin-to-skin contact was significantly delayed and the total duration was significantly less in GL group compared to no-GL group. No difference in respiratory distress and feeding intolerance was observed. Procedure-related complications included retching, vomiting, and mild desaturation.

Conclusions: Gastric lavage did not help to establish exclusive breastfeeding, delayed the initiation of skin-to-skin contact in delivery room and reduced its total duration. Moreover, the procedure of gastric lavage was associated with neonatal discomfort.

Keywords: Feeding intolerance, Outcome, Respiratory distress, Skin-to-skincontact.

Trial registration: Clinical Trial Registry of India: CTRI/2021/03/031727.

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In utero passage of meconium complicates 9-12% of deliveries [1], exposing these neonates to the risk of developing various respiratory as well as non-respiratory complications. Over two decades back, Narchi, et al. [2], for the first time, reported the beneficial role of gastric lavage in neonates delivered through meconium-stained amniotic fluid (MSAF). Subsequently, multiple randomized controlled trials [3-6] and meta-analyses [7,8] documented similar benefits of prophylactic gastric lavage in the delivery room, particularly for the reduction in the incidence of feeding intolerance. The rationale cited by the authors for performing gastric lavage included prevention of meconium-induced gastritis, reported to be almost three times more common in this group [9], and a reduction in the risk of meconium aspiration syndrome (MAS) caused by the secondary aspiration of meconium-stained stomach contents during

vomiting [6]. Based on this evidence, many neonatal units continue to perform prophylactic gastric lavage on the basis of treating unit's protocols.

However, the trials advocating gastric lavage did not assess its effect on clinically more relevant outcomes such as the rate of early establishment of exclusive breastfeeding and initiation of skin-to-skin contact [8], which may be delayed by the intervention. Initiation of breastfeeding within one hour of birth is associated with decreased neonatal mortality and improved childhood survival [10-12]. Similarly, immediate skin-to-skin contact has

Invited Commentary: With the print issue.

enormous benefits to the mother and the infant in the form of better temperature maintenance, promotion of early breast-feeding initiation and exclusive breastfeeding rate, and improvement of mother-infant bonding [13]. The

resuscitation guidelines endorse the practice of skin-to-skin contact and early breastfeeding at birth [14].

Although, gastric lavage is apparently an innocuous procedure, but it may be associated with several short- and long-term adverse effects such as feeding tube malposition [15], oxygen desaturation, bradycardia [16], gastrointestinal perforations [17], retching, disruption of pre-feeding behavior [18], and development of functional gastrointestinal disorders later in life [19]. These adverse effects have not been rigorously assessed in previous trials.

Standard guidelines do not discuss about the role of gastric lavage in neonates born through MSAF and there is a paucity of studies that have been conducted with meticulous monitoring of the procedure. The present study was planned to evaluate the effects of gastric lavage on the establishment of exclusive breastfeeding and skin-to-skin contact, incidence of in-hospital morbidities including respiratory distress, feeding intolerance, and procedure-related complications among late preterm and term neonates delivered through MSAF.

METHODS

This parallel-group randomized controlled trial was conducted over 17 months (March, 2021 to August, 2022) after obtaining approval from the institutional ethics committee. The trial was prospectively registered with Clinical Trial Registry of India. Written informed consent in the local language was taken from the parents before enrollment.

Settings and study population: The study was conducted in a level III tertiary care hospital with a 24-bedded neonatal intensive care unit (NICU) serving as a referral center in the state. Our unit policy adheres to baby friendly hospital initiatives (BFHI), and we have a policy of initiating and aggressively promoting exclusive breastfeeding unless justified.

The study population comprised of inborn neonates of gestational age (GA) ≥ 34 weeks delivered through MSAF not requiring resuscitation beyond 'initial steps' [14]. Exclusion criteria included presence of major congenital anomalies, known contraindications to breastfeeding, and failure to obtain parental consent.

The primary outcome was the rate of exclusive breastfeeding at 72 ± 12 hours of life, defined as the proportion of neonates on breastfeeding as exclusive mode of feeding in previous 24 hours. Secondary outcomes included time to initiate breastfeeding, proportion of neonates in whom breastfeeding could be started within one hour after delivery, time to establish exclusive breastfeeding, rates of exclusive breastfeeding at discharge, time to initiate skin-

to-skin contact in vaginal deliveries and its duration, rates of feeding intolerance (defined as >2 vomiting in any 4 hour period or >3 in 24 hour; or abdominal distension i.e., increase in abdominal girth of >2 cm from baseline) [3], incidence of respiratory distress, need and duration of respiratory support, other morbidities, final outcome, duration of hospital stay, and the incidence of procedure-related complications of gastric lavage monitored by pulse oximetry and videography.

Randomization, group allocation and blinding: Randomization was done by computer-based variable-block random sequence (<http://www.sealedenvelope.com>) stratified to two gestational age-based subgroups, late preterm (34-36 weeks) and term (≥ 37 weeks), generated by an independent statistician, not involved in the study. Eligible neonates were randomly allocated soon after delivery to either gastric lavage (GL) or no-GL group. Gastric lavage was performed by designated nursing officers attending delivery, particularly trained for this purpose prior to the commencement of the trial. Allocation concealment was ensured using sequentially numbered sealed and opaque envelopes. Though the procedure was open-label due to the nature of the intervention, outcome assessors and the statistician were blinded regarding the group allocation.

Intervention: Neonates allocated to GL group were shifted to pre-warmed radiant warmer after delivery. All necessary equipment for gastric lavage were kept ready before delivery. After thoroughly drying and covering the neonate with dry warm linen, a Masimo Rad-97 pulse oximeter probe was attached to the right wrist. An 8-Fr feeding tube was inserted orally with length equal to the distance from the bridge of the nose to the earlobe and from the earlobe to a point halfway between the xiphoid process and the umbilicus. After confirming the position of the orogastric tube by aspiration of stomach contents and pushing of air, lavage was done with 20 mL of normal saline. The whole procedure was done under strict asepsis and the entire procedure was videotaped. Neonates in no-GL group were managed as per the standard resuscitation guidelines [14].

Delayed cord clamping was done in both groups except in non-vigorous newborns, where early cord clamping was done, and the neonate was shifted to pre-warmed radiant warmer for initial steps. All neonates delivered vaginally were subjected to skin-to-skin contact according to Early Essential Newborn Care package policy of World Health Organization (WHO) [20], immediately after delivery in no-GL group, and after the procedure in those who underwent gastric lavage. The time to start as well as the duration for skin-to-skin contact were recorded by a digital stopwatch.

All infants were monitored for the development of

complications, if any. Stable neonates were roomed in and nursed with their mothers in postnatal ward. Those who developed respiratory distress or any other complication were admitted to the NICU and were managed as per our unit policy. The mothers of both the groups were counseled and helped to establish exclusive breastfeeding by lacta-tional counselors. Enrolled neonates were monitored and followed up till discharge. Video-clips were scrutinized to note the clinical as well as pulse oximetry details, heart rate and peripheral oxygen saturation (SpO₂).

Previous studies have not assessed the outcome of exclusive breastfeeding at 72±12 hours of life. Thus, we based our sample size on the surrogate of exclusive breastfeeding at 0-6 months from the national data published in the National Family Health Survey (NFHS)-4. It showed exclusive breastfeeding rates of around 55% amongst children aged 0-6 months [21]. Assuming a similar exclusive breastfeeding rate in our population, to detect a difference of 25% at an alpha level of 0.05 and a power of 80%, a sample size of 52 neonates per arm was calculated (<https://sealedenvelope.com/>). Considering an attrition rate of 5%, the total sample size was calculated to be 110 (55 in each group).

Statistical analysis: Data were recorded in Microsoft Excel 2019 and analyzed in SPSS version 25.0 (IBM Corp) on

intention-to-treat basis. Categorical measurements are presented as number (%) while continuous variables are presented as mean (SD) or median (IQR). Fisher exact test or the Chi-square test was used to compare categorical variables while Student *t* test or Mann-Whitney *U* test were used to compare continuous variables. Relative risk (95% CI) was calculated, where relevant. Analysis of the primary outcome was planned a priori for the sub-groups viz., late preterm vs term, vaginally born vs cesarean section delivered, and thick vs thin MSAF. Time to achieve exclusive breastfeeding was evaluated by Kaplan Meier survival plot analysis. A *P*-value of <0.05 was considered statistically significant.

RESULTS

During the study period, 163 mothers with MSAF were assessed for eligibility, out of which 53 were excluded for various reasons. Moreover, the study had to be stopped for three months (April to June, 2021), coinciding with the second wave of COVID pandemic wherein the institute policies mandatorily separated all neonates from their mothers, compromising breastfeeding initiation and maintenance. Finally, 110 neonates were randomized into GL (*n*=55) and no-GL (*n*=55) groups. All neonates received allocated intervention and were analyzed. The flow of participants is depicted in **Fig. 1**.

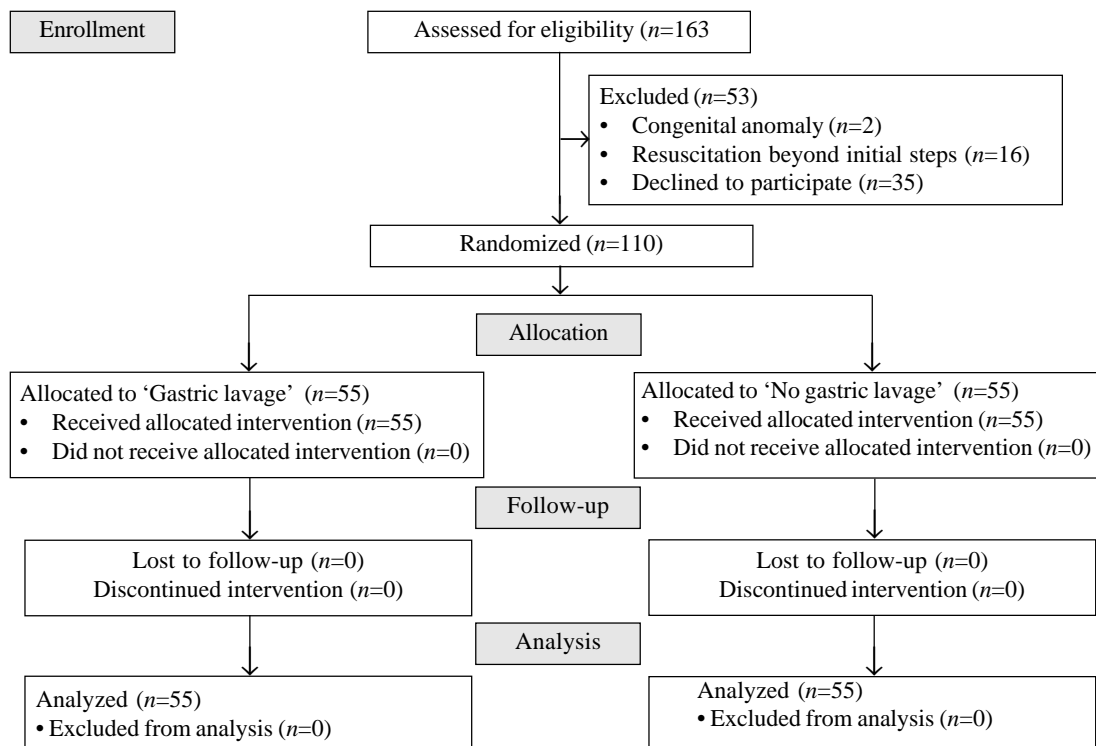


Fig. 1 Study flow diagram.

Table I Baseline Maternal and Neonatal Characteristics of Neonates Born Through Meconium Stained Amniotic Fluid Enrolled in the Study

Characteristics	Gastric lavage (n = 55)	No gastric lavage (n = 55)
<i>Maternal characteristics</i>		
Age (y) ^a	27.1 (4.8)	26.6 (4.0)
Gravida ^b	2 (1-3)	2 (1-3)
Complete antenatal care	29 (52.7)	23 (41.8)
Oligohydraminos	6 (10.9)	9 (16.4)
PV leak >18 h	7 (12.7)	7 (12.7)
Pregnancy induced hypertension	8 (14.5)	7 (12.7)
Anemia	15 (27.3)	16 (29.1)
Hypothyroidism	3 (5.5)	7 (12.7)
Fetal distress	20 (36.4)	15 (27.3)
Vaginal delivery	10 (18)	17 (31)
Thick meconium	31 (56.4)	30 (54.5)
<i>Neonatal characteristics</i>		
Birth weight (g) ^a	2695 (494)	2813 (476)
Gestational age (wk) ^a	38.5 (1.7)	38.7 (2.1)
Small for gestational age	21 (38)	16 (29)
Male	30 (54.5)	34 (61.8)
Vigorous baby	53 (96)	52 (95)
Apgar score ^b		
1 min	8 (8,9)	8 (8,9)
5 min	9 (9,9)	9 (9,9)
Received initial steps	2 (3.6)	3 (5.4)

Values in no. (%), ^amean (SD) or ^bmedian (IQR); P>0.05 for all comparisons.

Both the groups were comparable with respect to maternal variables, intrauterine growth status, consistency of meconium, mode of delivery, birth weight (BW), GA, gender, vigorous cry at birth, and Apgar score. The mean (SD) GA of GL and no-GL groups were 38.5 (1.7) and 38.7 (2.1) weeks, respectively (P=0.586) (Table I).

The rate of exclusive breastfeeding at 72±12 hours of life and other feeding outcomes are shown in Table II. A total of 49 (89.1%) neonates achieved exclusive breastfeeding at 72 hours compared to 48 (87.3%) in no-GL group [RR (95% CI) 1.02 (0.89-1.17); P=0.768]. There was no

significant difference in the time to achieve exclusive breastfeeding between the two groups [Hazard Ratio (HR) (95% CI), 0.94 (0.63-1.40); P=0.771] (Fig. 2). The median age of first breastfeeding was 2 hours in both the groups (P=0.160). There were no differences in time to initiate breastfeeding, initiation of breastfeeding within first hour of birth, time to establish exclusive breastfeeding, and the rates of exclusive breastfeeding at discharge. Analyses in the pre-planned subgroups for the primary outcome did not reveal any significant difference (Web Table I). Overall, initiation of breastfeeding within first hour was possible in 25/27 (93%) of neonates delivered vaginally compared to 15/83 (18%) among LSCS (P<0.001).

In vaginally-delivered neonates, skin-to-skin contact could be initiated in 9/10 in GL and 16/17 in no-GL group (Table III). One neonate in each group developed respiratory distress soon after birth and were shifted to the NICU. Initiation was significantly delayed in GL group [median (IQR) 0.3 (0.2,0.3) min in no-GL vs 16 (14,18) min in GL group; P<0.001]. Similarly, the total duration or dose of skin-to-skin contact was significantly longer in no-GL compared to GL group [62 (60,64) vs 50 (50,55) min; P<0.001].

No differences were observed in other morbidities including the incidence of respiratory distress, duration of respiratory support, neonatal hyperbilirubinemia, hypoglycemia, polycythemia, and the duration of hospital stay. Feeding intolerance was observed in 1 (1.8%) neonate in GL group compared to 3 (5.4%) in no-GL group (P=0.308). There was no mortality in either group. Procedure related complications in GL group included retching (n=32; 58.2%), vomiting (n=5; 9%), and mild desaturation (SpO₂ <85%) (n=10; 18.2%). None of the neonates developed apnea, significant desaturation (SpO₂<80%) or bradycardia (heart rate <100/min).

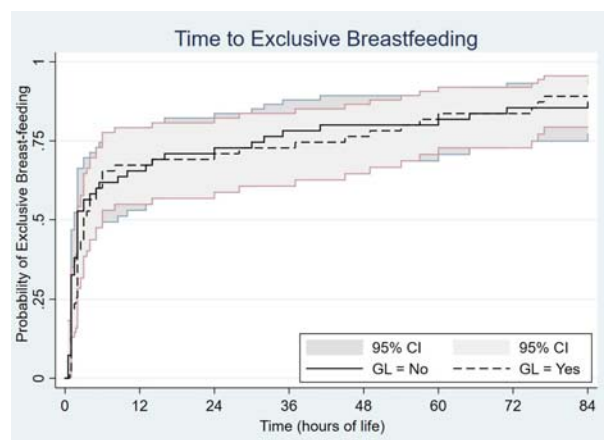
DISCUSSION

The present study sought to clarify the role of gastric lavage in late preterm and term neonates delivered through MSAF, especially with regards to breastfeeding. There was no significant difference in the rate of exclusive breast-

Table II Breastfeeding Rates and Feeding Pattern Among Neonates With Meconium Stained Amniotic Fluid

Variables	Gastric lavage (n=55)	No gastric lavage (n=55)	RR (95% CI)
Exclusive breastfeeding rate at 72 (±12) h	49 (89.1)	48 (87.3)	1.02 (0.89-1.17)
Age at first breastfeeding (h) ^a	2 (1, 5)	2 (0.5, 10)	-
Initiation of breastfeeding within first hour of birth	16 (29.1)	17 (30.9)	-
Age of establishment of exclusive breastfeeding (h) ^a	3 (1.5, 27)	2 (1, 16)	-
Exclusive breastfeeding rate at discharge	52 (94.5)	53 (96.4)	0.98 (0.90-1.06)

Values in no. (%) or ^amedian (IQR).



GL:gastric lavage in delivery room.

Fig. 2 Kaplan-Meier survival plot analysis for the outcome of 'time to achieve exclusive breastfeeding' in gastric lavage and no-gastric lavage groups.

feeding at 72 hours and at discharge, as well as the time of initiation and establishment of exclusive breastfeeding. The time of initiation of skin-to-skin contact in delivery room was significantly delayed in GL group, and the duration of skin-to-skin contact was also significantly less. Almost half of the neonates undergoing gastric lavage had retching and 14.5% had desaturation ($SpO_2 < 85\%$) as observed during the procedure.

Exclusive breastfeeding rate at 72 hours was chosen as the primary outcome variable because we postulated that a brief single intervention as gastric lavage may impact the initiation and maintenance of exclusive breastfeeding in the initial few days of hospital stay, rather than at discharge. Nearly 90% of neonates in both the groups achieved exclusive breastfeeding at around 72 hours and almost 95% at the time of discharge. The procedure of

gastric lavage did not make a significant difference in establishment of exclusive breastfeeding. A possible reason could be strict adherence to BFHI guidelines in our unit and active support for exclusive breastfeeding in both the groups. There is a paucity of studies directly comparing the effect of gastric lavage on the rate of exclusive breastfeeding in MSAF-delivered neonates.

Initiation of breastfeeding within first hour of birth was possible in only 30% neonates in either group. The rates are less than that reported by NFHS-5 (41.8%) [22] and a recent hospital-based study (43.5%) from southern India [23]. The reason for low rates in our set up could be high rates of cesarean delivery, due to it being a tertiary care referral center. Late shifting of the mother from the operation theater to ward, delayed wearing-off of anesthetic effect, and uncomfortable breastfeeding position after cesarean section probably led to this delay. Several systematic reviews corroborate this finding, with Yisma, et al. [24] reporting a 46% lower prevalence of early initiation of breastfeeding among cesarean section delivered mother-infant dyads [25].

The process of gastric lavage caused a significant delay in the initiation and the total duration of skin-to-skin contact. Delay in skin-to-skin contact deprives the neonates from its benefits including the opportunity of early feeding at breast. However, this delay of approximately 15 minutes might not be of much clinical relevance and this delay did not translate into a significant impact towards overall exclusive breastfeeding rates at 72 hours or discharge.

The present study did not find any difference in the incidence of respiratory distress and the duration of respiratory support between the two groups, which is similar to the findings reported by several previous authors [2-4,6]. Performing gastric lavage after delivery may not help to

Table III Secondary Outcomes Among Neonates with Meconium Stained Amniotic Fluid in the Two Groups

Variables	Gastric lavage (n=55)	No gastric lavage (n=55)
Underwent skin-to-skin contact ^a	9 (16.4)	16 (29.1)
Time of initiation of skin-to-skin contact after delivery (min) ^{a,b,d}	16 (14, 18)	0.3 (0.2, 0.3)
Duration of skin-to-skin contact (min) ^{a,b}	50 (50, 55)	62 (60, 64)
Respiratory distress requiring respiratory support	5 (9.1)	8 (14.5)
Duration of respiratory support (h) ^b	6 (4, 49)	4 (2-26)
Neonatal hyperbilirubinemia requiring phototherapy	10 (18.2)	7 (12.7)
Feeding intolerance	1 (1.8)	3 (5.4)
Hypoglycemia ^c	2 (3.6)	1 (1.8)
Polycythemia (Hct >65%) ^c	2 (3.6)	1 (1.8)
Duration of hospital stay (h) ^b	85 (57, 120)	80 (48, 97)

Values in no. (%) or ^bmedian (IQR). ^aOne neonate in each group developed respiratory distress soon after birth and were shifted to neonatal intensive care unit; ^casymptomatic. ^d $P < 0.001$. No child had sepsis screen and/or culture-positive sepsis. Hct: hematocrit.

WHAT IS ALREADY KNOWN?

- Delivery room gastric lavage reduces feeding intolerance, and is often claimed to decrease respiratory distress in neonates born through meconium-stained amniotic fluid (MSAF).

WHAT THIS STUDY ADDS?

- Gastric lavage in late preterm and term neonates delivered through MSAF did not affect achieving exclusive breastfeeding, though it delayed the initiation of skin-to-skin contact in delivery room and reduced its total duration.

remove meconium that has been already aspirated in the lungs. Moreover, it may be the duration of in utero hypoxia that determines the development of meconium aspiration syndrome and respiratory distress, not the amount of meconium aspirated [26]. The incidence of feeding intolerance in previous trials varied from 4.6-35% and a significant reduction in the incidence of feeding intolerance was observed after gastric lavage [2-7]. The overall incidence of feeding intolerance was low in our study, and no difference was observed between the groups. Meconium-induced gastritis leading to vomiting and feeding intolerance was not a common finding in either group of our study, and needs to be evaluated in a wider group. Though, we did not come across any serious complications of gastric lavage in our study, majority of the neonates were not comfortable during the procedure as indicated by high rate of retching and occasional vomiting and desaturation. Stringent monitoring was lacking in prior trials, except one [6], and most of them did not report any adverse events [2-6].

The major strength of our study was the meticulous observation by pulse oximetry during the procedure of gastric lavage, and strict monitoring during hospital stay. However, there is a possibility that the study was not powered enough to detect a difference of less than 25% in exclusive breastfeeding rate. This effect size for sample size calculation was chosen based on the assumption that gastric lavage would hinder the initiation of skin-to-skin contact, which in turn would lead to lower exclusive breastfeeding rates during hospital stay [27]. However, skin-to-skin contact was not practiced during cesarean deliveries in our unit, which could have attenuated the effect of gastric lavage in the overall population. Additionally, we could not study the effect of gastric lavage in non-vigorous neonates due to the small numbers ($n=5$). Though MSAF may be associated with delivery of more preterm neonates (around 5% deliveries below 33 weeks in high income countries [28]), our study did not include them and so the results may be considered only for neonates born at ≥ 34 weeks.

Gastric lavage in late preterm and term neonates

delivered through MSAF did not affect the attainment of exclusive breastfeeding. Moreover, it delayed the initiation of skin-to-skin contact in delivery room and reduced its total duration. Further, it did not reduce the incidence of respiratory distress, feeding intolerance, and other in-hospital morbidities. Thus, based on this trial, the procedure of routine gastric lavage appears unwarranted in neonates born through MSAF.

Ethics clearance: Institute Ethics Committee, All India Institute of Medical Sciences, Rishikesh; No: AIIMS/IEC/21/53/12/02/2021 dated Feb 12, 2021.

Contributors: SB, RKC, SC, PS, MP, NKB, JC: conceptualized and designed the study, coordinated, and supervised data collection, drafted the initial manuscript, and reviewed and revised the manuscript; RKC: collected all the data and reviewed and revised the manuscript. All authors approved the final manuscript as submitted and agree to be accountable for all aspects of the work.

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Note: Additional material related to this study is available with the online version at www.indianpediatrics.net

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