RESEARCH PAPER

Effect of Gastric Lavage on Meconium Aspiration Syndrome and Feed Intolerance in Vigorous Infants Born with Meconium Stained Amniotic Fluid – A Randomized Control Trial

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Objective: To compare the incidence of meconium aspiration syndrome and feed intolerance in infants born through meconium stained amniotic fluid with or without gastric lavage performed at birth.

Setting: Neonatal unit of a teaching hospital in New Delhi, India.

Design: Parallel group unmasked randomized controlled trial.

Participants: 700 vigorous infants of gestational age ≥34 weeks from through meconium stained amniotic fluid.

Intervention: Gastric lavage in the labor room with normal saline at 10 mL per kg body weight (*n*=350) or no gastric lavage (*n*=350). Meconiumcrit was measured and expressed as ≤30% and >30%.

Outcome Measures: Meconium aspiration syndrome, feed intolerance and procedure-related complications during 72 h of observation.

Results: 5 (1.4%) infants in lavage group and 8 (2.2%) in no lavage group developed meconium aspiration syndrome (RR 0.63, 95% CI 0.21, 1.89). Feed intolerance was observed in 37 (10.5%) and 53 infants (15.1%) in lavage and no lavage groups, respectively (RR 0.70, 95% CI 0.47, 1.03). None of the infants in either group developed apnea, bradycardia or cyanosis during the procedure.

Conclusion: Gastric lavage performed in the labor room does not seem to reduce either meconium aspiration syndrome or feed intolerance in vigorous infants born through meconium stained amniotic fluid.

Keywords: *Neonate, Prevention, Respiratory distress, Risk factors, Vomiting*.

Trial Registration: CTRI/2014/03/004495

Meconium stained amniotic fluid (MSAF) complicates 7% to 22% deliveries, with meconium aspiration syndrome (MAS) developing in approximately 10% of babies with MSAF [1,2]. Amount of meconium in the amniotic fluid, fetal acidemia and fetal heart rate are some of the factors determining the risk of MAS [3,4]. The infant born through MSAF may ingest or aspirate meconium *in utero*, during delivery or after birth. Due to the chemical nature and vasoconstriction action of the meconium, the MSAF might cause meconium induced gastritis leading to feed intolerance. After birth, infant may also vomit and aspirate MSAF resulting in 'secondary meconium aspiration syndrome' [5]. Gastric lavage soon after birth is advocated to prevent these complications. Some clinicians advise gastric lavage with normal saline but others advocate use of soda bicarbonate for stomach wash [6-8]. Interestingly, none of the practices of gastric lavage is based on scientific evidence and is followed at most centers by convention.

The insertion of infant feeding tube in the stomach is an invasive procedure and might cause immediate complications like apnea, bradycardia, cyanosis and traumatic injury and late adverse effects like impaired sensitivity to pain [6-9]. We, therefore, planned this study to compare the frequency of MAS and feed intolerance between the infants born through MSAF with and without gastric lavage performed in the labor room, and also to evaluate safety of the procedure.

METHODS

This parallel group unmasked randomized controlled trial was conducted in the Division of Neonatology of University College of Medical Sciences and GTB Hospital, Delhi, India. The study was approved by the institutional Ethics Committee for Human Research. Written informed consent was obtained from the mother before delivery.

Assuming proportion of MAS as 15% among those

born with MSAF [10], level of significance 5%, power 80%, and 50% relative difference of MAS in infants with or without gastric lavage, a sample size of 700 infants (350 in each group) was calculated to be sufficient. Study participants included neonates of both genders with gestational age ≥34 weeks, who were born through MSAF and were vigorous at birth. Babies with gross congenital anomalies, those born to mothers with suspected chorioamnionitis, and those receiving methyldopa during pregnancy were excluded from the study. The gestational age was calculated by Naegle's rule and Modified Ballard's scoring [11]; latter was taken into account if difference in the gestational age estimated by two methods was greater than two completed weeks.

Eligible newborns were randomized through computer generated random numbers to assign them into intervention (lavage) or control group. Coding scheme was concealed in serially numbered, opaque, and sealed envelopes by a person not directly involved in the study. Parents were informed of the group, their infant was included in, after randomization.

About 15 mL MSAF was obtained in a clean kidney tray with the help of a sterilized plain rubber catheter No.10 passed through vagina or directly in the kidney tray during delivery. In cases of caesarean section, liquor was collected in a 20 mL disposable syringe by an obstetrician after giving uterine incision. Meconiumcrit was assessed by centrifuging 10 mL MSAF at 1000 rpm for 10 min in a 20 mL glass test tube.

The infant was placed under radiant warmer. Oxygen sensor of the Pulse Oximeter (Welch Allyn, USA) was attached to the ulnar aspect of the right wrist. After initial stabilization in the labor room, gastric lavage was carried out in the intervention group. An orogastric tube (#10 Fr) was passed into the stomach, after measuring the length as per the standard procedure, and lavage was done with normal saline (10 mL/kg body weight). In control group, gastric lavage was not performed. The heart rate, oxygen saturation, apnea and color of the infant were monitored during gastric lavage and till 20 min after removal of orogastric tube. In control group also, above parameters were recorded for same the duration. Heart rate <120 bpm and >160 bpm were taken as bradycardia and tachycardia respectively. Apnea was defined as cessation of breathing for >20 sec or for any duration associated with cyanosis or bradycardia. SpO_2 < 85% after 15 min of birth was taken as significantly low. Local trauma to the oropharynx was assessed by naked eye examination twice in first 12 h of life. Breastfeeding was started within 60 min after normal delivery and within two hours after caesarean section. *X*-ray chest was obtained within 4 h in all infants, and was repeated if infant developed respiratory distress.

The respiratory distress was monitored by Downe's score at birth [13] and repeated every 6 h for first 24 h, and every 12 h for next 48 h. When Downe's score was ≥3 a repeat *X*-ray chest was obtained and MAS was treated as per standard treatment protocol. MAS was defined as the presence of respiratory distress in an infant born through MSAF, whose symptoms could not be otherwise explained and with radiological evidence of meconium aspiration [14]. Intolerance to enteral feeding was evaluated one hour after initiation of breastfeeding and every six hour thereafter for 72 h. Feed intolerance was considered if there was history of vomiting at least two times in 24 h, or there was pre-feed aspirate of >50% of previous feed even once in 24 h in case baby was fed expressed breast milk by orogastric tube, or increase in abdominal girth by 2 cm on two occasions in 24 h. Vomiting was differentiated from regurgitation by the associated features like retching/ tachycardia/ salivation/ sweating [15]. When a baby developed feed intolerance, gastric lavage was carried out with normal saline if it was not done earlier; weight and urine output were monitored and breastfeeding was continued as per the unit protocol. In case infant continued with feed intolerance after 24 h, a repeat gastric lavage was done with the normal saline and breastfeeding was continued.

Primary outcome measure was proportion of infants developing meconium aspiration syndrome within 72 h of age in both groups. Secondary outcome measures were proportion of infants developing feed intolerance after initiation of breastfeeding till 72 h in two groups and number of babies showing adverse effects of gastric lavage (apnea, bradycardia, cyanosis, local trauma).

Statistical analysis: Data were analyzed by SPSS 16.0 statistical software. Meconiumcrit was compared in two groups by Student's 't' test. The comparison of the qualitative variables such as MAS and feed intolerance in the study and control groups were done using Chi square test. *P* value of <0.05 was considered as statistically significant.

RESULTS

A total of 700 infants (350 each in intervention and control group) were enrolled and successfully completed the study (***Fig.* 1**). The baseline demographic and clinical characteristics of enrolled infants are presented in ***Table* I**.

A significant difference was noted in number of vomiting episodes in first 24 hours (*P*=0.001), while no statistical difference was noted in incidence of MAS and

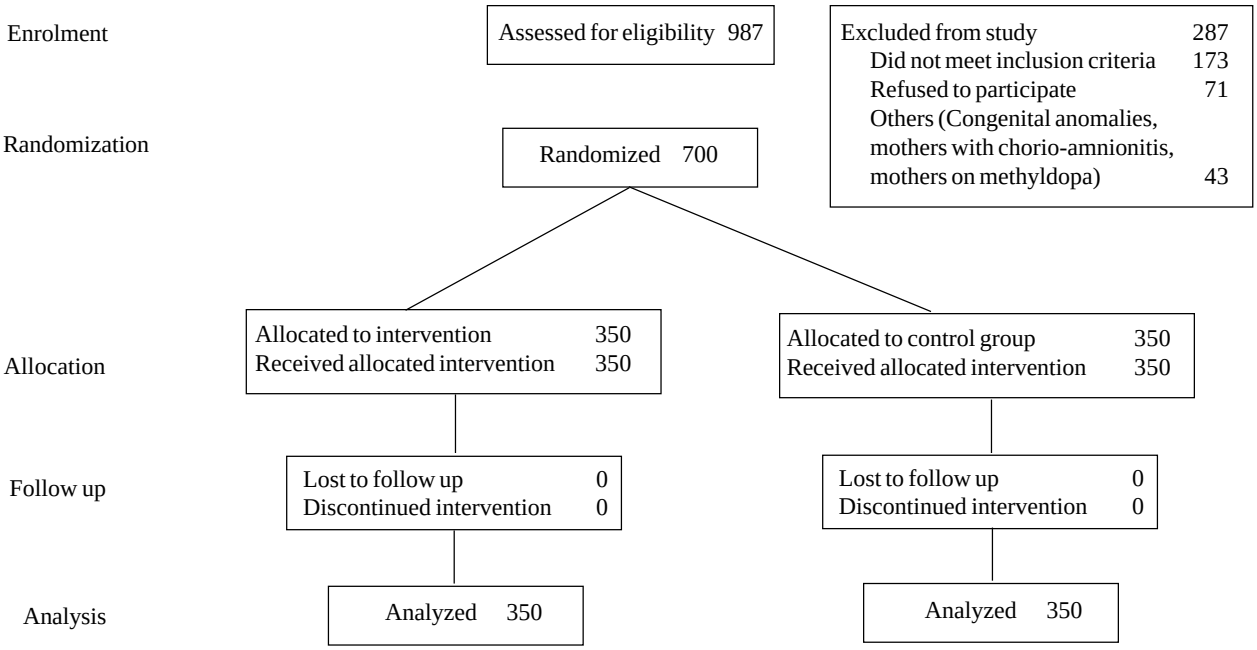

FIG. 1 *Consort flow diagram for the study.*

TABLE I COMPARISON OF PERINATAL AND NEONATAL PARAMETERS IN STUDY AND CONTROL GROUPS

Variables	*Intervention group (n=350)*	*Control group (n=350)*
Perinatal Characteristics		
Primipara	190 (54.3)	185 (52.9)
Meconiumcrit		
≤30%	249 (71.1)	260 (74.3)
>30%	101 (28.9)	90 (25.7)
Fetal bradycardia	46 (13.1)	41 (11.7)
Fetal tachycardia	16 (4.6)	14 (4.0)
Caesarian delivery	129 (36.9)	109 (31.1)
Forceps/ Vacuum	5 (1.4)	6 (1.7)
Breech	8 (2.3)	3 (0.9)
APGAR Score*		
1 min	8.9 (0.3)	8.9 (0.3)
5 min	9.0 (0.3)	9 (0.3)
Neonatal Characteristics		
Male gender	182 (52.0)	193 (55.1)
Preterm birth	94 (26.9)	97 (27.4)
Birth weight (g)*	2684 (398)	2706 (398)
Length (cm)*	48.1 (1.4)	48.2 (1.4)
Head circumference (cm)*	33.5 (0.8)	33.6 (0.8)

*Values in No. (%) or *mean (SD).*

feed intolerance in the two groups (***Table* II**). Gastric lavage prevented occurrence of first episode of vomiting within 6 hour of initiation of breastfeeding but did not affect eventual development of feed intolerance. Overall, feed intolerance developed in 90 (12.8%) infants after initiation of breastfeeding. However, all infants improved after 48 h of age (***Table* III**). Out of 90 infants who suffered from feed intolerance, 63 (70%) were born with meconiumcrit ≤30%, and in 27 (30%) babies, the meconiumcrit was >30% (P>0.05).

No baby developed apnea, bradycardia or local trauma in the study group; SpO_2 < 85% at 15 min was observed in one baby in the control group and two babies in the intervention group (P>0.05).

DISCUSSION

In this randomized controlled trial on vigorous infants born through meconium stained amniotic fluid, we documented that gastric lavage performed immediately after birth in labor room did not reduce the incidence of MAS and feed intolerance. No procedure related complication was observed following gastric lavage.

Investigators could not be blinded for intervention due to the nature of intervention, and results cannot be generalized on non-vigorous infants, constitute few study limitations. Also, the study was not adequately powered to detect smaller changes in the incidence of MAS and feeding intolerance.

TABLE II EFFECT OF GASTRIC LAVAGE ON DEVELOPMENT OF MECONIUM ASPIRATION SYNDROME AND FEED INTOLERANCE

Outcome	*Intervention group (n=350), No.(%)*	*Control group (n=350), No.(%)*	*RR (95% CI)*
Meconium aspiration syndrome	5 (1.4)	8 (2.2)	0.63 (0.21, 1.89)
Feed Intolerance	37 (10.5)	53 (15.1)	0.70 (0.47, 1.03)
Vomiting episodes in 24 h	76	115	0.66 (0.52, 0.85)
0-6 h	30 (8.5)	47 (13.4)	0.64 (0.41, 0.96)
6-12 h	32 (9.1)	38 (10.8)	0.84 (0.54, 1.32)
12-24 h	14 (4)	30 (8.5)	0.47 (0.25, 0.86)
Vomiting episodes in 24-48 h	6 (1.7)	10 (2.8)	0.38 (0.15, 0.95)

In a similar study from India, Sharma, *et al*. [6] randomized 267 babies in gastric lavage and 269 babies to no gastric lavage group. They followed up infants for development of retching, vomiting and secondary meconium aspiration syndrome till the time they were discharged from the hospital. None of the babies developed secondary meconium aspiration syndrome in any group [6]. Evidence from several other studies also does not support gastric lavage preventing feed intolerance in infants born with MSAF [5,7,15-17]. A recent systematic review by Deshmukh, *et al*. [18] concluded that gastric lavage may improve feed tolerance in neonates born to MSAF; however small sample size in included studies, and probable bias were the limitations. Our study is in conformity with above observations that routine gastric lavage in MSAF babies does not seem to prevent development of MAS, irrespective of the concentration of meconium in the amniotic fluid, mode of delivery or birthweight. Gastric lavage also does not seem to reduce incidence of feed intolerance either, though the first episode of vomiting after initiation of breastfeeding may be prevented. However, the procedure of gastric lavage appears safe, without immediate complications like apnea, bradycardia, cyanosis or local trauma. We recommend further studies addressing the issue of MAS and feed intolerance on non-vigorous infants to generate stronger evidence in favor or against gastric lavage performed in the labor room.

Contributors: SG: data collection and prepared initial draft of manuscript; MMAF: conceptualized study, analyzed and scrutinized data, and finalized the manuscript; MN: supervised data collection and contributed to manuscript writing; PB: reviewed literature, manuscript editing and analysis. All authors approved final version of the manuscript.

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WHAT IS ALREADY KNOWN?

- Gastric lavage in infants born through meconium stained amniotic fluid is performed to prevent secondary meconium aspiration syndrome and feed intolerance.

WHAT THIS STUDY ADDS?

- Gastric lavage in vigorous infants born through meconium stained amniotic fluid does not seem to reduce the incidence of meconium aspiration syndrome or feed intolerance.

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