ROLE OF ROUTINE GASTRIC LAVAGE IN TERM AND LATE PRE-TERM NEONATES BORN THROUGH MECONIUM STAINED AMNIOTIC: A RANDOMISED CONTROL TRIAL

Kumud Babu Singh1, Rashee Jain2, Rajiv Babu3, Jai Jyoti4, Manish Kumar Singh5, Ishan Parasher6

HOW TO CITE THIS ARTICLE:

ABSTRACT: Meconium staining of amniotic fluid (MSAF) has for long been considered to be a poor predictor of fetal outcome1. The incidence of meconium stained amniotic fluid ranges from 5.6% to 24.6% (median 14%). MSAF is common in pregnancies associated with antenatal complications like pregnancy induced hypertension, ante partum toxemia, obstructed or prolonged labor and fetal distress etc. AIMS AND OBJECTIVES: To evaluate the efficacy of routine gastric lavage after birth in reducing the need for subsequent stomach wash in the first two days of life in term and near term infants born through meconium stained amniotic fluid. RESULTS: Need for subsequent stomach wash in the first 48 hours of life was not different between the two groups: 9 (12.5%) infants in the routine gastric lavage group and 10 in the no lavage group (13.5%) required it (relative risk [RR]: 0.92; 95% confidence interval [CI]: 0.4, 2.1; P=0.86;) The median age at which the infants required stomach wash was also not different between the gastric lavage and no lavage groups: median 9 [range: 4-24] and 12 [range: 6-18] hours respectively. A total of 14 (19.4%) infants in the intervention group and 9 (12.2%) in the no lavage group had at least one episode of vomiting in the first 48 hours of life (RR: 1.6; 95% CI: 0.7, 3.4). The median age at first episode of vomiting was also not different between the groups. CONCLUSION: Performing routine stomach wash immediately after birth in vigorous term and late preterm infants does not reduce the requirement for subsequent stomach wash necessitated for feeding problems in the first 48 hours of life, and therefore not recommended as a routine practice.

INTRODUCTION: Meconium staining of amniotic fluid (MSAF) has for long been considered to be a poor predictor of fetal outcome1. The incidence of meconium stained amniotic fluid ranges from 5.6% to 24.6% (median 14%).2,3,4,5,6 MSAF is common in pregnancies associated with antenatal complications like pregnancy induced hypertension, ante partum toxemia, obstructed or prolonged labor and fetal distress etc. 1.A proportion of infants born through meconium stained amniotic fluid may swallow meconium and develop nausea, vomiting, retching, other feeding problems like poor sucking, and secondary aspiration (following vomiting) in early neonatal period. Presence of meconium in the stomach has been found to act as a chemical irritant, interfering with gastric function and causing undigested milk curds and feeding problems.7 Performing gastric lavage after birth could potentially reduce the risk of these complications. Keeping this in mind, many neonatal units employ the policy of performing routine gastric lavage immediately after birth in these neonates. In a recent electronic survey, we found that one-third of 12 major level iii neonatal units in the country to be following this policy by personnel communication. Unfortunately, there is not much evidence to either support or refute this practice. The only study till date – a quasi randomized
trial – did not find any significant benefit with routine gastric lavage. On the other hand, performing gastric suction at birth for any indication has been found to be associated with functional intestinal disorders in later life\(^a\). Moreover, the procedure could result in complications like bradycardia, apnea, and damage to larynx/trachea and esophagus, and even perforation of stomach\(^7,9,10\). We therefore designed this randomized controlled trial to evaluate whether stomach wash in neonates born through MSAF soon after birth reduces the need for subsequent stomach wash indicated by feed intolerance.

AIMS AND OBJECTIVES

(A) PRIMARY OBJECTIVE

1. To evaluate the efficacy of routine gastric level after birth in reducing the need for subsequent stomach wash in the first two days of life in term and near term infants born through meconium stained amniotic fluid.

(B) SECONDARY OBJECTIVE

To evaluate the effect of:

1. Incidence of vomiting and/or regurgitation in the first 48 hours of life.
2. Need for parentral fluids in the first 2 days of life.
3. Incidence of meconium aspiration syndrome (MAS).

<table>
<thead>
<tr>
<th>OBJECTIVE</th>
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<tbody>
<tr>
<td>To evaluate the efficacy of routine gastric lavage after birth in reducing the need for subsequent stomach wash in the first 2 days of life in term and near term infants born through meconium stained amniotic fluid.</td>
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<td>Need for subsequent stomach wash</td>
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<tr>
<td>Need for subsequent stomach wash in the first two days of life because of 2 or more episodes of vomiting and regurgitation with or without nausea and retching in infants born through MSAF (decided by duty staff/resident and confirmed by senior resident)</td>
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<thead>
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<tr>
<td>To evaluate the effect of such intervention on the:</td>
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<tr>
<td>1. Incidence of feed intolerance.</td>
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<td>2. Incidence of MAS and other aspiration syndromes.</td>
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<td>3. Duration of hospital stay.</td>
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<td>2. Need for parentral fluids in the first 2 days of life.</td>
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<tr>
<td>3. Meconium aspiration syndrome (MAS).</td>
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<tbody>
<tr>
<td>1. Proportion of infants who developed vomiting and/or regurgitation in the first 2 days of life.</td>
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<tr>
<td>2. Proportion of neonates who receive for parentral fluids for any reason in the first 48 hours of age.</td>
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<tr>
<td>3. Presence of 2 of the following:</td>
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<tr>
<td>1. Meconium staining of liquor or staining of nails or umbilical cord or skin.</td>
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<tr>
<td>2. Respiratory distress within 1 hour of birth.</td>
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<td>3. Radiological evidence of aspiration pneumonitis.</td>
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Table – 1: Objective and outcome variables
MATERIALS AND METHODS

Inclusion criteria
- Term and late preterm infants (≥ 36 weeks) of gestation born through meconium stained amniotic fluid (MSAF)
- Vigorous at birth

Exclusion criteria
- 5-minutes Apgar score of <5
- Major congenital anomalies
- Hemodynamic instability and/or respiratory distress requiring immediate admission in intensive care unit.

Statistical analysis: Patient information was collected in a proforma. Data entry was done using Epi-info v3.3.2. analysis was done using state 9.1 (college station, Texas, US). Data were presented as mean (SD) or number (%) as appropriate. Baseline categorical variables were compared between the groups using Chi-square/Fisher’s exact test. Baseline categorical variables were compared between the groups using Chi-square/Fisher’s exact test. Baseline continuous variables were compared between the groups using independent student’s t-test/Wilcoxon rank-sum test. P value of <0.05 was taken as significant.

Following definitions are used:
- Thin meconium – Very light green staining of the amniotic fluid.
- Thick meconium – Thick viscous greenish meconium with particulate matter.
- Meconium aspiration syndrome – Development of respiratory distress soon after birth with radiological evidence of aspiration pneumonitis (atelectasis and hyperinflation) in the presence of meconium staining of amniotic fluid or staining of umbilical cord, nail and skin.
- Vomiting – Refers to the forceful oral expulsion of gastric, or stomach, contents.
- Retching – Denotes the labored rhythmic contraction of the chest and abdominal muscles that usually comes before or accompanies vomiting.
- Apgar score – Apgar score are assigning immediately after birth, at 1 minute and 5 minutes of birth. By this score rapidly assess the cardiopulmonary status.

<table>
<thead>
<tr>
<th>Apgar sign</th>
<th>2</th>
<th>1</th>
<th>0</th>
</tr>
</thead>
<tbody>
<tr>
<td>Heart rate</td>
<td>Normal (above 100 beats per minute)</td>
<td>Below 100 beats per minute.</td>
<td>Absent (no pulse)</td>
</tr>
<tr>
<td>Breathing Effort</td>
<td>Good strong cry</td>
<td>Weak cry</td>
<td>Absent (no breathing)</td>
</tr>
<tr>
<td>Grimace (responsiveness or ‘reflex irritability’)</td>
<td>Pulls away, sneezes, or coughs with stimulation</td>
<td>Facial movement only (grimace) with stimulation</td>
<td>Absent (no response to stimulation)</td>
</tr>
<tr>
<td>Muscle tone</td>
<td>Active, spontaneous movement</td>
<td>Arms and legs flexed with little movement</td>
<td>Limp</td>
</tr>
<tr>
<td>Appearance</td>
<td>Normal color all over (hands and feet are pink)</td>
<td>Normal color (but hands and feet are bluish)</td>
<td>Bluish-gray or pale all over</td>
</tr>
</tbody>
</table>
AFD (Appropriate for gestational age) – Babies with a birth weight between 10th – 90th percentile for the period of their gestation.

SFD (Small for gestational age) – Babies with a birth weight more than 10th percentile for the period of their gestation.

LFD (Large for gestational age) – Babies with a birth weight more than 90th percentile for the period of their gestation.

Term baby – Babies with a gestational age between 37-41 week.

RESULTS: Out of 170 infants who were assessed for eligibility, 23 were excluded. Of the remaining 147 neonates, 72 and 75 were born through thin and thick meconium stain amniotic fluid respectively. Outcomes were available for 146 infants (72 in gastric lavage and 74 in no lavage group).

<table>
<thead>
<tr>
<th>Variable</th>
<th>Gastric lavage group (n=72)</th>
<th>No lavage group (n=74)</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gestational age in weeks (mean±SD)</td>
<td>38.3 ± 1.5</td>
<td>38.7 ± 1.3</td>
<td>0.08</td>
</tr>
<tr>
<td>Birth weight in grams (mean±SD)</td>
<td>2746 ± 450</td>
<td>2837 ± 423</td>
<td>0.21</td>
</tr>
<tr>
<td>Female gender</td>
<td>33 (45.8%)</td>
<td>28 (37.8%)</td>
<td>0.33</td>
</tr>
<tr>
<td>Vaginal delivery</td>
<td>34 (47.2%)</td>
<td>29 (39.2%)</td>
<td>0.61</td>
</tr>
<tr>
<td>Small-for-gestational age (SGA)</td>
<td>6 (8.3%)</td>
<td>4 (5.4%)</td>
<td>0.76</td>
</tr>
<tr>
<td>Apgar at 1 min (mean±SD)</td>
<td>8.9 ± 0.3</td>
<td>8.9 ± 0.4</td>
<td>0.97</td>
</tr>
<tr>
<td>Exclusive breast fed</td>
<td>71 (98.6%)</td>
<td>74 (100%)</td>
<td>0.49</td>
</tr>
<tr>
<td>Literate mother</td>
<td>69 (95.8%)</td>
<td>68 (91.9%)</td>
<td>0.49</td>
</tr>
<tr>
<td>Thick meconium stained liquor</td>
<td>34 (47.2%)</td>
<td>37 (50%)</td>
<td>0.74</td>
</tr>
</tbody>
</table>

TABLE 2: BASELINE VARIABLES

Baseline characteristics including gestational age, birth weight, gender, mode of delivery, Apgar score at 1 minute, and consistency of meconium were comparable between the two groups (Table.2)

Primary outcome: Need for subsequent stomach wash

Need for subsequent stomach wash in the first 48 hours of life was not different between the two groups: 9 (12.5%) infants in the routine gastric lavage group and 10 in the no lavage group (13.5%) required it (relative risk [RR]: 0.92; 95% confidence interval [CI]: 0.4, 2.1; P=0.86;)

Secondary outcomes

1. Need for subsequent stomach wash in thin and thick MSAF

There was no difference in the need for stomach wash in the first 2 days of life in either of the two pre-defined subgroups – thin and thick meconium stained amniotic fluid (RR: 1.27[95% CI: 0.5, 3.4] and 0.49 [95% CI: 0.1, 2.5] respectively; Table 3). The median age at which the infants required stomach wash was also not different between the gastric lavage and no lavage groups: median 9 [range: 4-24] and 12[range: 6-18] hours respectively.
Variable | Gastric lavage group | No lavage group | Relative risk (95% Cl) | P
--- | --- | --- | --- | ---
Need for subsequent stomach wash in infants born through: | | | | |
Thick MSL | 2/38 (5.3%) | 4/37 (10.8%) | 0.49 (0.1, 2.5) | 0.38
Thin MSL | 7/34 (20.6%) | 6/37 (16.2%) | 1.27 (0.5, 3.4) | 0.63
Age at stomach wash (hr) (median, range) | 9 (4, 24) | 12 (6, 18) | - | 0.39
Vomiting (at least one episode) | 14 (19.4%) | 9 (12.2%) | 1.6 (0.7, 3.4) | 0.23
Age at initial vomiting episode (hr) (median, range) | 12 (4, 24) | 12 (6, 18) | - | 0.39
Regurgitation (2 or more episodes) | 3 (4.2%) | 5 (6.7%) | 0.62 (0.2, 2.5) | 0.24
Nausea and/or retching | 5 (6.9%) | 6 (8.1%) | 0.86 (0.3, 2.7) | 0.79

Table 3: Other outcome variables

2. **Vomiting**: A total of 14 (19.4%) infants in the intervention group and 9 (12.2%) in the no lavage group had at least one episode of vomiting in the first 48 hours of life (RR: 1.6; 95% CI: 0.7, 3.4).

The median age at first episode of vomiting was also not different between the groups (Table 3).

3. **Regurgitation and nausea/retching**: Incidence of regurgitation (more than one episode) was comparable between the two groups (3/72 vs. 5/74; RR: 0.62, 95% CI: 0.2, 2.5).

Similarly, incidence of nausea/retching was also not different between the two groups (Table 3).

4. **Need for parental fluids in the first 48 hours**: None of the infants from either of the groups required parental fluids for any reason in the first two days of life.

5. **Meconium aspiration syndrome (MAS)**: None of the infants enrolled in the study developed MAS.

**DISCUSSION**: The present study is an attempt to answer a simple clinical question of whether routine stomach wash in the delivery room is indicated for all infants born through meconium stained liquor. Unfortunately, there is neither enough evidence nor any consensus regarding the need for such practice: only one randomized trial is available till date in this regard. Even the textbook of neonatal resuscitation by the American heart association and the American academy of pediatrics that recommended routine gastric lavage after birth in its earlier editions (1994) remain silent in the current (2005) issue. The practice is, however, still followed in many centers across the globe.

We did not find any significant difference in primary outcome as defined as need for subsequent stomach wash in the first 48 hours of life – between the group of infants who underwent routine gastric lavage after birth and the group which did not undergo the same. The consistency of
meconium thin or thick did not affect the findings of our study: there was no difference between the two groups in either of these pre-defined subgroups (Table 4). The findings are in accord with that of the previous study by Narchi et al in which none of the infants in the stomach wash group (n=227) and 13 (4.7%; n=275) in the no lavage group developed feeding problem in the first few days of life7. The authors of this non-blinded quasi-randomized trial conceded that bias could not be excluded with certainty in their study but still concluded that ‘gastric lavage is not necessary in most neonates born with meconium-stained amniotic fluid’. In our current randomized trial, we tried to eliminate the element of bias by masking the treating team and the primary investigator who recorded the outcome to the process of randomization and intervention.

We chose a slightly unconventional primary outcome variable (need for subsequent stomach wash) in our study for two reasons: (1) lack of uniform definition of ‘feed intolerance’, particularly in term and near-term neonates and (2) difficulty in documenting the outcome like regurgitation and nausea/retching. Since infants who are borne through meconium stained liquor and develop vomiting or recurrent episodes of regurgitation in the first two days of life are routinely managed with stomach wash in our unit, we decided to use this as the primary outcome of our study. To eliminate subjectivity in deciding the need for stomach wash, we standardized the existing protocol and ensured that it was strictly adhered to throughout the study period.

Secondary outcomes like incidence of vomiting, regurgitation, and nausea/retching in the first two days of life were not different between the two groups. None of the infants from either of the groups required administration of parenteral fluid for any reason. Similarly, no infant enrolled in the study developed meconium aspiration syndrome, understandably so because they were vigorous at birth and did not require any steps of resuscitation. We did not measure the duration of hospital stay in these infants. No significant adverse effect like apnea or bradycardia was observed in those infants who underwent gastric lavage.

The strengths of our study include (a) robust study design in which infants were stratified and block randomized to either of the two groups, and the treating team was blinded (b) answering a common clinical query for which the available evidence is limited and (c) an adequate sample size. The major limitation of our study was that information about outcomes like vomiting and regurgitation were obtained predominantly from the mothers and hence were prone to subjectivity. Moreover, the sample size was calculated with the assumption that 30% of infants would require subsequent stomach wash. Given that only 13.5% of these infants required it, the power of the study is likely to be low. On the hand, one can argue that such low incidence does not warrant a ‘routine’ invasive procedure like gastric lavage.

To conclude, performing routine stomach wash immediately after birth in vigorous term and late preterm infants does not reduce the requirement for subsequent stomach wash necessitated for feeding problems in the first 48 hours of life, and therefore not recommended as a routine practice.

CONCLUSION: Performing routine stomach wash immediately after birth in vigorous term and late preterm infants does not reduce the requirement for subsequent stomach wash necessitated for feeding problems in the first 48 hours of life, and therefore not recommended as a routine practice.

SUMMARY
A randomized controlled trial was done to evaluate the efficacy of routine gastric lavage after birth in reducing the need for subsequent stomach wash in the first two days of life in term and late preterm infants born through meconium stained amniotic fluid.

Primary objective of the study was to evaluate the efficacy of routine gastric lavage after birth in reducing the need for subsequent stomach wash in the first two days in term and late preterm infants born to meconium stained amniotic fluid.

Secondary objective was to evaluate the effect of such intervention on the
- Incidence of vomiting and regurgitation in the first 48 hours of life
- Need for parenteral fluids in the first two days of life.
- Incidence of meconium aspiration syndrome (MAS)

Study done at postnatal ward of a tertiary level neonatal unit, Neonatology Division from July 2008 to December 2009.

Inclusion criteria – term and late preterm infants (≥36 weeks) of gestation born through meconium stained amniotic fluid (MSAF) and vigorous at birth.

Exclusion criteria – 5-minute Apgar score of <5, major congenital anomalies, Hemodynamic instability and/or respiratory distress requiring immediate admission in intensive care unit.

Sample size estimated by a pilot study conducted in our unit in March 2008, we found that about 30% of infants born through MSAF require stomach wash in first two days of their life. To detect a reduction in the need for subsequent stomach wash from 30% to 10% (relative reduction of 66%) with power of 80% and 95% confidence level, we had to enroll 72 infants per group.

The baseline and demographic characteristics between two groups were similar.

Enrolled infants were randomly allocated to either routine gastric lavage or no gastric lavage (control) groups within 15 minutes of birth using computer generated random sequence numbers.

We stratifying infants in to two strata based on the consistency of meconium: ‘thin’ and ‘thick’ meconium stained amniotic fluid.

The treating team (resident and nursing staff incharge of the post natal wards in which the infants were cared for) and principal investigator who was responsible for monitoring, documenting, and follow – up until discharge from the hospital were blinded to the process of randomization.

Infants randomized to the invention group underwent elective gastric lavage within 15 minutes of delivery in the labor room while those allocated to the control group did not undergo gastric lavage.

Primary outcome – need for subsequent stomach wash in the first 48 hours of life was not different between the two groups: 9(12.5%) infants in the routine gastric lavage group and 10 in the no lavage group (13.5%) required it (relative risk [RR]: 0.92; 95% confidence interval [CI]: 0.4, 2.1; P=0.86).

There was no significant difference in both groups regarding age at stomach wash, age at initial vomiting, at least one or two episode of vomiting, nausea, retching, and regurgitation.

Conclusion – performing routine stomach wash immediately after birth in the vigorous term and late preterm infants does not reduce the requirement for subsequent stomach wash.
necessitated for feeding problems in the first 48 hours of life, and therefore not recommended as a routine practice.

**BIBLIOGRAPHY:**


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