Endotracheal Suction for Nonvigorous Neonates Born through Meconium Stained Amniotic Fluid: A Randomized Controlled Trial

Subhash Chettri, MBBS, Bethou Adhisivam, DNB (Ped), and B. Vishnu Bhat, MD, MD

Objective To assess whether endotracheal suctioning of nonvigorous infants born through meconium stained amniotic fluid (MSAF) reduces the risk and complications of meconium aspiration syndrome (MAS).
Study design Term, nonvigorous babies born through MSAF were randomized to endotracheal suction and no-suction groups (n = 61 in each). Risk of MAS, complications of MAS and endotracheal suction, mortality, duration of neonatal intensive care unit stay, and neurodevelopmental outcome at 9 months were assessed.
Results Maternal age, consistency of meconium, mode of delivery, birth weight, sex, and Apgar scores were similar in the groups. In total, 39 (32%) neonates developed MAS and 18 (14.8%) of them died. There were no significant differences in MAS, its severity and complications, mortality, and neurodevelopmental outcome for the 2 groups. One infant had a complication of endotracheal suctioning, which was mild and transient.
Conclusions The current practice of routine endotracheal suctioning for nonvigorous neonates born through MSAF should be further evaluated. *(J Pediatr 2015;166:1208-13).*
Trial registration Clinical Trial Registry of India: CTRI/2013/03/003469.

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Meconium stained amniotic fluid (MSAF) complicates 3% to 14% of pregnancies[1] with an incidence directly proportional to the gestational age.[2] Although 5% to 10% of neonates born through MSAF develop meconium aspiration syndrome (MAS),[1,3,4] it accounts for 10% of all causes of respiratory failure in neonates with a mortality of 20% in developing countries.[1] Moreover, neonates exposed to meconium are more likely to have other complications such as sepsis, seizures, neurologic impairment, and prolonged neonatal intensive care unit (NICU) stay.[5]

Although chemical pneumonitis, inflammation, infection, and surfactant inhibition by meconium have a role in MAS, airway obstruction and filling of alveoli by meconium are the most important mechanisms contributing to the pathophysiology.[6] As such, clearing of the airway by routine intrapartum oropharyngeal suction and immediate postnatal endotracheal suction became standard interventions to prevent MAS.[7] Meconium is aspirated in utero when a fetus gasps in response to asphyxia, which is more likely to have occurred in nonvigorous infants who are at a higher risk for MAS than vigorous infants.[8] Many authors have suggested a selective approach in choosing neonates for endotracheal suctioning.[9] In 2000, a study by Wiswell et al,[10] concluded that endotracheal suction had no benefit for the reduction of morbidity and mortality in vigorous babies, and the recommendation for routine suctioning was deleted from Neonatal Resuscitation Program (NRP).[11] A meta-analysis of 4 studies by Halliday and Sweet in 2001 supported this change in the guidelines.[12] The new recommendations did not increase the incidence of meconium aspiration.[13]

The efficacy of endotracheal suctioning for nonvigorous meconium stained neonates has not been evaluated.[3,6,8,9,14-16] Complications of intubation include apnea, bradycardia, upper airway injury, vocal cord dislocation, bleeding, hoarseness, and stridor.[10] Intubation may also delay the initiation of positive pressure ventilation, which may be critical to reverse asphyxia and stabilize the neonate. We conducted this randomized controlled trial, to assess whether endotracheal suctioning reduces the incidence of MAS in nonvigorous infants born through MSAF.

Methods

This randomized controlled trial was conducted from February 2013 to July 2014 in the Neonatology Division of Jawaharlal Institute of Postgraduate Medical Education and Research, Pondicherry, India. The study was approved by the Institute Scientific Advisory and Ethics Committee (IEC/SC/2012/5/175).

MAS	Meconium aspiration syndrome
MSAF	Meconium stained amniotic fluid
NICU	Neonatal intensive care unit
NRP	Neonatal Resuscitation Program
RR	Relative risk

From the Neonatology Division, Department of Pediatrics, Jawaharlal Institute of Postgraduate Medical Education and Research (JIPMER), Pondicherry, India

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As there are no previous studies comparing endotracheal suction vs no-suction in nonvigorous neonates, the study by Ting and Brady[17] with vigorous infants was used to estimate a sample size (28% of suctioned infants developed MAS compared with 57% in the no-suction group). For a CI of 95% and power of 80%, a minimum sample size of 51 in each group was calculated using OpenEpi v 2 (http://www.openepi.com/Menu/OE_Menu.htm). Expecting 20% loss of subjects in follow-up, the final sample size estimated was 61 in each group.

All term live neonates, born through MSAF and nonvigorous at birth were included. Term babies were defined as those delivered at 37 or more weeks of gestation calculated using last menstrual period or antenatal ultrasound. Nonvigorous was defined as the presence of at least one of the following: heart rate <100/min, decreased muscle tone, and/or not breathing or crying (NRP 2010). Neonates with major congenital anomalies detected prenatally were excluded. The term "fetal distress" was used for nonreassuring fetal heart tracings defined as category III fetal heart rate tracings, which included either (1) absent baseline fetal heart rate variability and any one of the following recurrent late decelerations, recurrent variable decelerations, or bradycardia and (2) sinusoidal pattern.[18] Consistency of meconium was classified as: (1) thin: watery consistency fluid; (2) moderate: opaque fluid without particles; or (3) thick: fluid of pea soup consistency or opaque fluid containing particulate material.[10] MAS was defined as respiratory distress in an infant born through MSAF with characteristic radiological changes and whose symptoms cannot be otherwise explained.[15] The classic chest radiograph findings in MAS were described as diffuse, asymmetric patchy infiltrates with hyperinflation, or segmental or lobular atelectasis.[10] Respiratory distress was defined as persistence of grunting, retractions, tachypnea (respiratory rate >60/min), cyanosis, or apnea for more than 2 hours after birth.[15] The Cleary and Wiswell score was used to define severity of MAS as: (1) mild MAS: requires less than 40% oxygen for less than 48 hours; (2) moderate MAS: requires more than 40% oxygen for more than 48 hours with no air leak syndromes; and (3) severe MAS: requires assisted ventilation for more than 48 hours.[3] For this study, perinatal asphyxia was defined as Apgar ≤6 at 5 minutes of birth with cord blood pH <7 and base deficit of >12. The Wernovsky score [= dopamine dose (mcg/kg/min) + dobutamine dose (mcg/kg/min) + 100 × epinephrine dose (mcg/kg/min)] was used for severity of shock.[19]

The study procedure was a slight modification of a similar study of meconium suctioning for vigorous infants by Wiswell et al.[10] As per our department policy, one pediatrics resident, trained in neonatal resuscitation is present 24 hours a day in the labor rooms to attend all deliveries. Obstetrician would inform the pediatrician at the first detection of MSAF in any mother in labor. The pediatrician would ask for consent from the mother. In case the MSAF is detected unexpectedly (just before delivery or after anesthesia for cesarean) or any time where the obstetrician or pediatrician feels the labor has progressed to a stage that it is inappropriate to take the consent, the baby was excluded from the trial. If the mother consented for the trial, the infant was randomized to either the suction or no-suction group using a computer-generated sequence and sealed opaque envelopes opened immediately prior to birth. The degree of vigor was assessed within 5-10 seconds of birth. Vigorous infants were excluded, and the randomization assignment was discarded. Nonvigorous infants in the suction group were intubated and endotracheal suction was done, using suction pressure of 80-100 mm Hg (medflo wall suction device; Sree Krishnaa Industries, Coimbatore, India). Suction pressure was applied continuously while withdrawing the endotracheal tube. If meconium was present and there was no bradycardia (heart rate <60/min), the procedure was repeated again for a maximum of 2 suctions. After 2 endotracheal suctions, the baby was repositioned and oropharyngeal suction was given through first mouth, then nose, using suction catheter attached to medflo wall suction device with same pressure as for endotracheal suction, following which the baby was dried and the other steps of resuscitation were carried out. A second resuscitator would simultaneously auscultate for heart rate and if it was less than 100/min, positive pressure ventilation was given using a self-inflating bag (250 mL) with an appropriate size mask. If allocated to no-suction group, only oronasopharyngeal suction was done through first mouth, then nose, using a suction catheter attached to medflo wall suction device. In both the groups, any further resuscitation was given as per the NRP 2010 guidelines including intubation. As the randomization was done prior to the birth of the infants, many randomization assignments were not used, and the balance between the groups could be compromised. We continued the trial until 61 infants were enrolled in each group. All the neonates in the study were admitted to the NICU for observation and managed according to standard NICU protocol. The infants were followed up until 9 months of age in the outpatient department. Motor and neurodevelopment were assessed using Developmental Assessment Scales for Indian Infants[20] (**Figure**; available at www.jpeds.com).

Statistical Analyses

Continuous variables are reported as mean and SDs and compared using Student *t* test. If continuous variables did not follow a normal distribution, they were given as median with the IQR and compared using Mann-Whitney test. The categorical outcomes are expressed as percentages and compared across groups using χ^2/Fisher exact tests as appropriate. A *P* value of <.05 was considered statistically significant.

Results

During the study period, 16 116 babies were born in our institute, out of which 1271 (7.8%) were born through MSAF. Among these 48 had unexpected MSAF (43 vigorous, 5 non-vigorous), and were not randomized. Of the 1223 infants with MSAF, 1115 were eligible and 993 were vigorous and hence their randomization was discarded (**Figure**). In