

Aspiración endotraqueal para la prevención del síndrome de aspiración de meconio: un ensayo controlado aleatorio.

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Resumen:

La versión actual del Programa de reanimación neonatal ya no favorece la succión endotraqueal de rutina (SET) en recién nacidos no vigorosos con líquido amniótico teñido de meconio (MSAF) debido a la posibilidad de daños relacionados con el procedimiento y beneficios cuestionables. Sin embargo, requiere una investigación adicional sobre este procedimiento para proporcionar una respuesta definitiva. El presente estudio se realizó para evaluar el papel del SET en neonatos no vigorosos de = 34 semanas de gestación nacidos a través de MSAF sobre la incidencia del síndrome de aspiración de meconio (SAM). En este ensayo controlado aleatorio abierto, 132 recién nacidos no vigorosos con MSAF fueron aleatorizados para recibir SET (n = 66) o no SET (n = 66) durante la reanimación en la sala de partos (DRR). La variable de resultado primaria fue la incidencia de SAM. Las variables de resultado secundarias fueron requerimiento de RRD, necesidad de asistencia respiratoria, desarrollo de complicaciones, duración de la hospitalización y mortalidad. Ambos grupos fueron comparables con respecto a las características maternas y neonatales. La incidencia de MAS fue de 21 (31.8%) y 15 (22.7%) casos en los grupos SET y no SET, respectivamente (riesgo relativo (RR), 1.400, intervalo de confianza (IC) del 95%, 0.793-2.470). Los dos grupos no difirieron con respecto a la RRD, la necesidad de asistencia respiratoria y el desarrollo de complicaciones. Nueve (13,6%) neonatos en el grupo SET y 5 (7,5%) en el grupo sin SET murieron ($p > 0,05$). La mediana (rango intercuartil) de la duración de la estancia hospitalaria fue de 54 (31-141) y 44 (26-102) h en los grupos SET y no SET, respectivamente ($p > 0.05$). Conclusiones: El SET de rutina al nacer no es útil en prevención de SAM en neonatos no vigorosos de = 34 semanas de gestación nacidos a través de MSAF. Registro de ensayos: Registro de ensayos clínicos de la India (CTRI / 2015/04/008819). Lo que se sabe: la aspiración endotraqueal de rutina es de beneficio cuestionable en pacientes no Recién nacidos vigorosos con líquido amniótico teñido de meconio y pueden tener la posibilidad de daños relacionados con el procedimiento. Lo nuevo: la succión endotraqueal de rutina al nacer no es útil para prevenir el síndrome de aspiración de meconio en recién nacidos no vigorosos de = 34 semanas de gestación nacidas a través de meconio manchado de líquido amniótico.



Endotracheal suctioning for prevention of meconium aspiration syndrome: a randomized controlled trial

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Abstract

The current version of Neonatal Resuscitation Program no longer favors routine endotracheal suctioning (ETS) in non-vigorous newborns with meconium-stained amniotic fluid (MSAF) due to possibility of procedure-related harms and questionable benefits. However, it calls for additional research on this procedure to provide a definitive answer. The present study was conducted to evaluate the role of ETS in non-vigorous neonates of ≥ 34 weeks' gestation born through MSAF on the incidence of meconium aspiration syndrome (MAS). In this open-label randomized controlled trial, 132 non-vigorous neonates with MSAF were randomized to receive ETS ($n = 66$) or no-ETS ($n = 66$) during delivery room resuscitation (DRR). Primary outcome variable was incidence of MAS. Secondary outcome variables were requirement of DRR, need of respiratory support, development of complications, duration of hospitalization, and mortality. Both the groups were comparable with respect to maternal and neonatal characteristics. Incidence of MAS was 21 (31.8%) and 15 (22.7%) cases in ETS and no-ETS groups, respectively (relative risk (RR), 1.400, 95% confidence interval (CI), 0.793–2.470). The two groups did not differ with regard to DRR, need for respiratory support, and development of complications. Nine (13.6%) neonates in ETS group, and 5 (7.5%) in no-ETS group died ($p > 0.05$). Median (interquartile range) duration of hospital stay was 54 (31–141) h and 44 (26–102) h in ETS and no-ETS groups, respectively ($p > 0.05$).

Conclusions: Routine ETS at birth is not useful in preventing MAS in non-vigorous neonates of ≥ 34 weeks' gestation born through MSAF.

Trial registration: Clinical Trials Registry of India (CTRI/2015/04/008819).

What is Known:

• Routine endotracheal suctioning is of questionable benefit in non-vigorous newborns with meconium stained amniotic fluid and may have a possibility of procedure-related harms.

What is New:

• Routine endotracheal suctioning at birth is not useful in preventing meconium aspiration syndrome in non-vigorous newborns of ≥ 34 weeks' gestation born through meconium stained amniotic fluid.

Keywords Delivery room resuscitation · Endotracheal suctioning · Meconium aspiration syndrome · Meconium-stained amniotic fluid

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Abbreviations

CI	Confidence interval
DRR	Delivery room resuscitation
ETS	Endotracheal suctioning
MAS	Meconium aspiration syndrome
MSAF	Meconium-stained amniotic fluid
NRP	Neonatal resuscitation program
PPHN	Persistent pulmonary hypertension of newborn
RR	Relative risk
SD	Standard deviation
TTN	Transient tachypnea of newborn

Introduction

Meconium aspiration syndrome (MAS) is an important cause of morbidity and mortality in newborns. Since there is no specific therapy for MAS, the focus of care has centered on delivery room practices aimed at prevention of meconium aspiration and consequently MAS. The delivery room management of such infants has evolved over last 30 years towards less aggressive approach. Intrapartum oropharyngeal suctioning of meconium-stained fetuses [12, 13] and postnatal endotracheal suctioning (ETS) of vigorous newborns delivered through meconium-stained amniotic fluid (MSAF) [15] have been abandoned altogether because of lack of any benefit. Even the practice of endotracheal suctioning of meconium stained non-vigorous newborns has been questioned due to procedure-related harms and uncertain benefits. Because of these concerns, the current version of Neonatal Resuscitation Program (NRP) no longer favors routine endotracheal suctioning in non-vigorous meconium-stained newborns [16].

Two recently conducted randomized controlled trials in India have failed to show any difference in clinical outcome with or without ETS in non-vigorous neonates born through MSAF [3, 9]. However, both these studies did not include late preterm newborns (34–36 weeks) where the passage of meconium in utero is not an uncommon event.

A recent multi-center cohort study has reported that though the change of practice in NRP guidelines has not led to higher rates of MAS but non-suctioned neonates experienced increased NICU admissions with respiratory distress, and higher rates of mechanical ventilation, oxygen use and surfactant administration, raising some concerns on the safety and efficacy of this approach [4].

The objective of the present trial was to investigate the role of endotracheal suctioning on the prevention of MAS in non-vigorous newborns of ≥ 34 weeks' gestation delivered through MSAF.

Methods

This open-label randomized controlled trial was conducted in SS Hospital, Banaras Hindu University, Varanasi, India, from January 1, 2014, to September 30, 2015. The study protocol was approved by the Institute Ethics Committee. Written informed consent was obtained from pregnant woman and/or her husband when she presented to hospital in labor with meconium-stained amniotic fluid. If there was insufficient time to obtain consent before delivery, the baby was not included in the study. Randomization occurred soon after delivery when a baby with meconium-stained amniotic fluid was found to be non-vigorous at birth. The trial was registered with Clinical Trials Registry of India (CTRI/2015/04/008819).

Inclusion criteria

Non-vigorous singleton neonates of gestational age ≥ 34 weeks delivered through MSAF comprised the study population. Non-vigorous was defined as presence of one or more of the following features at birth:

1. Apnea/gasping breathing
2. Heart rate < 100 /min
3. Poor muscle tone

Exclusion criteria

1. Major congenital anomaly
2. Maternal chorioamnionitis

Randomization

The newborns fulfilling the eligibility criteria were randomized to receive ETS or no-ETS using computer-generated random permuted blocks of 4, 6, and 8. The randomization sequence was prepared by an independent person not involved in study. Allocation of newborns to ETS or no-ETS group was done using serially numbered opaque and sealed envelopes.

Intervention

Newborns were resuscitated in delivery room as per American Academy of Pediatrics (2010) NRP guidelines [8]. All deliveries were attended by two Pediatric residents trained in NRP. After delivery, if newborn appeared to be non-vigorous, baby was placed under radiant heat warmer and positioned by placing a shoulder roll. Oro-pharyngeal suctioning of meconium was done by 12-Fr suction catheter using a negative pressure not exceeding 100 mm of Hg. By this time one member of the team opened the sealed envelope and baby was assigned to ETS or no-ETS group. In ETS group, endotracheal suctioning of meconium was done under direct laryngoscopy until no more meconium was retrieved from trachea (generally twice or thrice). After ETS, the remaining initial steps of resuscitation were completed including drying, repositioning, tactile stimulation, and evaluation to decide further course of action as per NRP guidelines. In no-ETS group, after oro-pharyngeal suctioning of meconium, the remaining initial steps of resuscitation were completed without performing endotracheal suctioning. Pulse oximetry was not used during delivery room resuscitation due to non-availability of pulse oximeter in delivery room during the time period when the study was conducted.

Antenatal and perinatal details

Antenatal details of the mothers including age, receipt of antenatal care, complications of pregnancy, evidence of fetal distress, mode of delivery, nature of meconium (thick or thin), and relevant investigations were noted.

Postresuscitation care

After resuscitation, neonates were brought to NICU for close observation and management. Hourly monitoring of respiratory rate, heart rate, capillary filling time, chest wall retractions, grunting, reduced breath sounds, episodes of desaturation ($\text{SpO}_2 < 90\%$), or cyanosis was done using a predesigned proforma. Neonates were observed for the development of MAS and other complications, such as hypoxic-ischemic encephalopathy (HIE), air leak syndromes and primary pulmonary hypertension (PPHN), infection, metabolic disturbances, hematologic abnormalities, and cardiac, renal, and hepatic dysfunction.

Investigations included blood glucose, serum electrolytes, chest X-ray, sepsis screen (complete blood count, absolute neutrophil count, band cell count, C-reactive protein, micro-ESR), blood culture, arterial blood gas analysis, and renal function tests. Other hematological, biochemical, and radiological investigations were done as and when necessary. 2-D echocardiography with color Doppler was done to diagnose PPHN. Supportive management in the form of respiratory support (oxygen inhalation, CPAP, or mechanical ventilation), parenteral nutrition, and feeding were provided as per our NICU protocol. No antibiotics were given routinely unless sepsis screen (≥ 2 criteria) and/or blood culture was positive. Progress during the hospital stay, development of complications, and outcome were noted.

Outcome variables

The primary outcome variable was the incidence of MAS. MAS was defined as persistence of respiratory distress (respiratory rate $> 60/\text{min}$, chest wall retractions, grunting, or cyanosis) beyond 2 h of age and characteristic radiological abnormalities of asymmetric patchy opacities, with or without hyperinflation in chest X-ray. If chest X-ray was normal or showed perihilar streaky markings, the case was labeled as transient tachypnea of newborn (TTN). Secondary outcome variables were requirement of delivery room resuscitation, need of respiratory support in NICU, development of complications, duration of hospitalization, and mortality.

Sample size calculation

For sample size calculation, we used the previously published study by Ting and Brady, reporting MAS in 28% of suctioned infants compared with 57% in the no-suction group [10]. Expecting a similar difference of the occurrence of MAS in ETS vs. no ETS groups, with a confidence level of 95%, power of 90%, and attrition rate of 10%, the estimated sample size was 132, with 66 subjects in each group (www.openepi.com/Menu/OE_Menu.htm).

Statistics

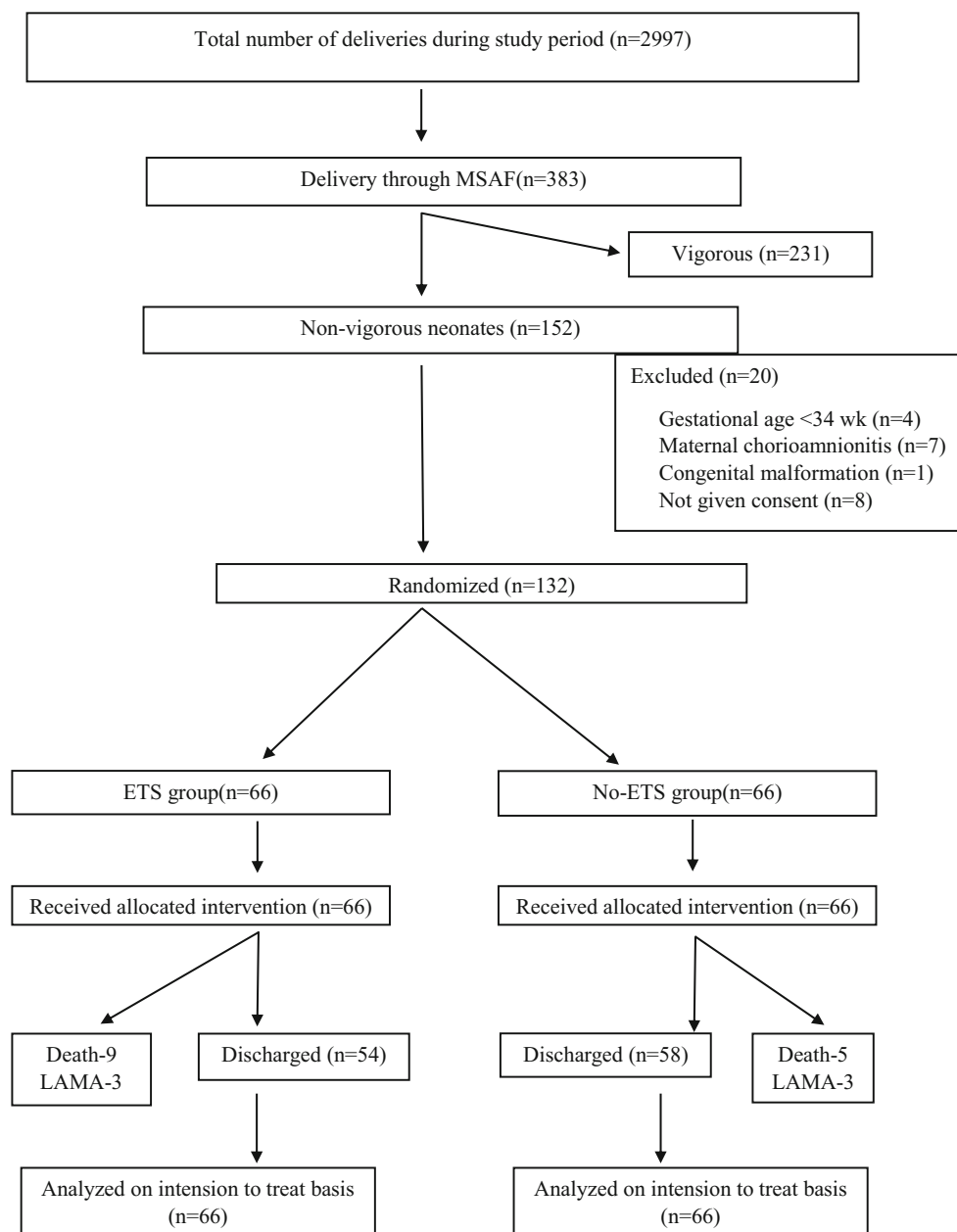
The statistical program SPSS version 16.0 was used for data entry and analysis. Independent samples *t* test/Mann-Whitney *U* test, Chi square test, and Fisher exact test were used as applicable to compare parametric and non-parametric variables. Relative risk and 95% confidence interval were calculated for outcome variables. A *p* value of < 0.05 was considered statistically significant.

Results

The flow of participants in the study is summarized in Fig. 1. Of the 2997 newborns delivered during the study period, 383 newborns had MSAF, 152 were found to be non-vigorous after birth, and 132 were randomized after excluding 20 newborns for various reasons. All newborns received their allocated intervention and data were analyzed on intention to treat basis. Both the groups were comparable with respect to the maternal and neonatal characteristics (Table 1). Only one third of mothers in each group received adequate antenatal care. Two-third cases in each group had fetal distress. Thick meconium consistency was noted in 42.4% and 45.4% cases in ETS and no-ETS groups, respectively. Transient tachypnea of newborn occurred in 29 (43.9%) and 27 (40.9%) newborns in ETS and no-ETS groups, respectively (data not shown).

Outcome variables are summarized in Table 2. Incidence of MAS was 21 (31.8%) and 15 (22.7%) cases in ETS and no-ETS groups, respectively (RR 1.032, 95% CI, 0.721–1.476). There was no difference in the incidence of MAS based on low APGAR score (< 3 versus 4–6) at 5 min. No differences were noted in the requirement of delivery room resuscitation in two groups. Forty-one (62%) newborns in ETS group and 37 (56%) in no-ETS group required positive pressure ventilation in delivery room. Regarding respiratory support, CPAP was required in 15 (22.7%) newborns in ETS group and 11 (16.6%) newborns in no-ETS group (RR 1.363, 95% CI, 0.677–2.743). There was no difference in the duration of CPAP

Fig. 1 Flow of participants in the study. *ETS* endotracheal suctioning, *No-ETS* no endotracheal suctioning, *LAMA* left against medical advice, *MSAF* meconium-stained amniotic fluid



(mean \pm SD was 38.9 ± 12.5 and 42.8 ± 11.4 h in ETS and no-ETS groups, respectively; $p = 0.063$). Nine (13.6%) and 8 (12.1%) infants were ventilated in ETS and no-ETS group, respectively (RR 1.363, 95% CI, 0.677–2.743). The median duration and inter quartile range (IQR) of mechanical ventilation was 34 (28–74) h and 24 (16–71) h in ETS and no-ETS groups, respectively ($p = 0.468$). Nine (13.6%) neonates in the ETS group and 5 (7.5%) in the no-ETS group died (RR 1.773, 90% CI, 0.627–5.011). Median (IQR) duration of hospital stay was 54 (31–141) h and 44 (26–102) h in ETS and no-ETS groups, respectively ($p = 0.941$).

Complications in two study groups are tabulated in Table 3. No difference was found in complication rates between two

groups. The most common complications observed in study population were perinatal asphyxia, shock, seizures, PPHN, acute kidney injury, thrombocytopenia, and metabolic derangements such as hyponatremia, hypocalcemia, and hypo-/hyperkalemia.

Discussion

The present study shows that endotracheal suctioning of non-vigorous newborns delivered through meconium-stained amniotic fluid failed to prevent MAS in these neonates. Incidence of MAS was 31.8% in suctioned group

Table 1 Baseline maternal and neonatal characteristics

Characteristic	ETS group (<i>n</i> = 66)	No-ETS group (<i>n</i> = 66)	<i>P</i> value
Maternal characteristics			
Age (years), mean ± SD	26.4 ± 4.5	25.2 ± 4.0	0.278 (NS) ^a
Antenatal care (≥ 3 antenatal visits), <i>n</i> (%)	24 (36.3)	23 (34.8)	1.000 (NS) ^b
Pregnancy induced hypertension, <i>n</i> (%)	7 (10.6)	5 (7.5)	0.763 (NS) ^b
Pre-eclampsia/eclampsia, <i>n</i> (%)	6 (9)	10 (15.1)	0.424 (NS) ^b
Fetal distress, <i>n</i> (%)	47 (71.2)	47 (71.2)	1.000 (NS) ^b
Oligohydramnios, <i>n</i> (%)	7 (10.6)	6 (9)	1.000 (NS) ^b
Mode of delivery			
SVD, <i>n</i> (%)	8 (12.1)	17 (25.7)	
LSCS, <i>n</i> (%)	57 (86.3)	49 (74.2)	0.074 (NS) ^b
Forceps, <i>n</i> (%)	1 (1.5)	0	
Meconium consistency			
Thick, <i>n</i> (%)	28 (42.4)	30 (45.4)	0.860 (NS) ^b
Thin, <i>n</i> (%)	38 (57.5)	36 (54.5)	
Neonatal characteristics			
Birth weight (g) (mean ± SD)	2620 ± 696	2528 ± 598	0.422 (NS) ^a
< 2500 g, <i>n</i> (%)	28 (42.2)	30 (45.4)	0.726 (NS) ^b
≥ 2500 g, <i>n</i> (%)	38 (57.8)	36 (54.6)	–
Gestational age (weeks), median (IQR)	38 (36–40)	38 (36–40)	0.400 (NS) ^b
34–36 weeks, <i>n</i> (%)	9 (13.6)	12 (18.2)	0.152 (NS) ^b
37–41 weeks, <i>n</i> (%)	57 (86.3)	51 (77.2)	–
≥ 42 weeks, <i>n</i> (%)	0 (0)	3 (4.5)	–
Male, <i>n</i> (%)	35 (53.0)	29 (43.9)	0.384 (NS) ^b
1-min Apgar score			
≤ 3, <i>n</i> (%)	33(50)	27(40.9)	
4–6, <i>n</i> (%)	33(50)	34(51.5)	0.060(NS) ^b
7–10, <i>n</i> (%)	0	5(7.6)	
5-min Apgar score			
≤ 3, <i>n</i> (%)	3 (4.5)	4 (6.1)	
4–6, <i>n</i> (%)	10 (15.2)	11 (16.7)	0.892 (NS) ^b
7–10, <i>n</i> (%)	53 (80.3)	51 (77.3)	
Respiratory distress at admission			
Yes, <i>n</i> (%)	53 (80.3)	54 (81.8)	1.000 (NS) ^b
No, <i>n</i> (%)	13 (19.6)	12 (18.1)	
Downe score at admission, median (IQR)	4 (2–6)	4 (2–5)	0.860 (NS) ^b
Oxygen saturation at admission (%), median (IQR)	94 (92–95)	94 (92–95)	0.747 (NS) ^b

ETS endotracheal suctioning, No-ETS no endotracheal suctioning, SD standard deviation, NS not significant, HIV human immunodeficiency virus, SVD spontaneous vaginal delivery, LSCS lower segment cesarean section

^a Independent samples *t* test

^b Chi square test

^c Fisher exact test

and 22.7% in non-suctioned group (*p* value 0.328). This is consistent with recently published data [3, 9]. The earlier evidence of beneficial role of tracheal suctioning of meconium was based on comparison of suctioned newborns with historic controls with apparent selection bias in the group of intubated babies included in those studies [2, 7,

14]. We observed a high rate of transient tachypnea of newborn in our study cohort. Twenty-nine (43.9%) newborns in ETS group and 27 (40.9%) in no-ETS group developed TTN. Diagnosis was primarily made by chest X-ray appearance which was either normal or showed perihilar streaky markings. All these newborns made

Table 2 Outcome variables

	ETS group (n = 66)	No-ETS group (n = 66)	P value	Relative risk (95% CI)
Primary outcome variable				
Incidence of MAS, n (%)	21 (31.8)	15 (22.7)	0.328 (NS) ^a	1.400 (0.793–2.470)
Secondary outcome variables				
Details of delivery room resuscitation				
Only initial steps, n (%)	23 (34.8)	26 (39.3)	0.201 (NS) ^a	0.884 (0.566–1.381)
Positive pressure ventilation with bag and mask, n (%)	10 (15.1)	12 (18.1)	0.815 (NS) ^a	0.833 (0.387–1.793)
Positive pressure ventilation with bag and tube, n (%)	31 (46.9)	25 (37.9)	0.378 (NS) ^a	1.240 (0.830–1.852)
Chest compression, n (%)	3 (4.5)	5 (7.5)	0.717 (NS) ^b	0.600 (0.149–2.409)
Injection adrenaline, n (%)	1 (1.5)	2 (3.0)	1.000 (NS) ^b	0.500 (0.046–5.381)
Normal saline bolus, n (%)	0 (0.0)	2 (3.0)	1.000 (NS) ^b	0.333 (0.014–8.037)
Respiratory support				
Oxygen hood, n (%)	24 (36.3)	28 (42.4)	0.478 (NS) ^a	0.857 (0.560–1.311)
CPAP, n (%)	15 (22.7)	11 (16.6)	0.512 (NS) ^a	1.363 (0.677–2.743)
Mechanical ventilation, n (%)	9 (13.6)	8 (12.1)	1.000 (NS) ^a	0.888 (0.365–2.162)
Duration of mechanical ventilation (h), median (IQR)	34 (28–74)	24 (16–71)	0.468 (NS) ^a	–
Outcome				
Improved and discharged, n (%)	54 (81.8)	58 (87.9)	0.815 (NS) ^a	1.500 (0.656–3.429)
Death, n (%)	9 (13.6)	5 (7.5)	0.815 (NS) ^a	1.773 (0.627–5.011)
LAMA, n (%)	3 (4.5)	3 (4.5)	1.000 (NS) ^b	1.000 (0.209–4.775)
Duration of hospital stay (h), median (IQR)	54 (31–141)	44 (26–102)	0.941 (NS) ^a	

CI confidence interval, CPAP continuous positive expiratory pressure, ETS endotracheal suctioning, No-ETS no endotracheal suctioning, LAMA left against medical advice, MAS meconium aspiration syndrome, NS not significant

^a Chi square test

uneventful recovery on oxygen supplementation via head box only. Some investigators consider TTN as part of the spectrum of MAS [15]. We do not agree with this viewpoint as the diagnosis of MAS is difficult to justify in the absence of characteristic chest X-ray appearance of asymmetric patchy opacities, with or without hyperinflation.

Failure of endotracheal suctioning to prevent MAS could be attributed to occurrence of aspiration of meconium in utero [14] and inability to retrieve meconium from trachea due to migration of meconium to distal airways. Even if meconium is retrieved on tracheal suctioning, distal airways, beyond the reach of tracheal suctioning, may still be plugged with meconium. This could explain failure of endotracheal suctioning to prevent MAS in such newborns. In addition to mechanical obstruction of airways and chemical pneumonitis, other factors which may contribute to the pathophysiology of MAS include inactivation of surfactant [5], persistent pulmonary hypertension [11], and activation of Toll-like receptors [1]. Studies reporting a lack of correlation between the presence of meconium in the trachea at delivery and clinical severity of MAS further raise doubts of the utility of performing tracheal suctioning at birth [6].

Tracheal suctioning has a potential to cause complications in newborn. Tracheal suctioning, particularly repeated attempts, can cause vagal stimulation, injury to vocal cords,

and breakdown of mucosal barrier [15]. Tracheal suctioning is also a difficult procedure to perform. If not accomplished in a time-sensitive manner, this may delay the initiation of effective resuscitation, leading to worsening of hypoxia, acidosis, and hypercapnia, potentially intensifying pulmonary hypertension and adverse long-term neurological outcome [13]. Thus, there are potential harms of the procedure without providing any tangible benefit to the baby. However, it should be appreciated that maintaining a patent airway is a prerequisite for successful resuscitation. Tracheal suctioning may occasionally be required in a meconium-stained nonvigorous newborn where positive pressure ventilation fails to achieve adequate chest expansion or increase in heart rate despite ventilation corrective measures. Therefore, a person skilled in neonatal intubation should always be available in case the need arises.

Respiratory failure secondary to MAS remains a major cause of neonatal morbidity and mortality. In our study, the two groups did not differ with regard to the use of CPAP or mechanical ventilation. The duration of mechanical ventilation was also comparable in two groups. Our study shows that the severity of respiratory morbidity is unaltered whether trachea is suctioned or not. Our observations are contrary to a recent study which reported higher rates of mechanical ventilation in non-suctioned newborns, indicating increased

Table 3 Complications developed during hospital stay

Complication	ETS group (<i>n</i> = 66)	No-ETS group (<i>n</i> = 66)	<i>P</i> value	Relative risk (95% CI)
Perinatal asphyxia, <i>n</i> (%)	8 (12.1)	10 (15.1)	0.800 (NS) ^a	0.800 (0.336–1.899)
PPHN, <i>n</i> (%)	4 (6.2)	2 (3.1)	0.680 (NS) ^b	2.000 (0.379–10.547)
Seizures, <i>n</i> (%)	6 (9)	5 (7.5)	1.000 (NS) ^a	1.200 (0.385–3.739)
Shock, <i>n</i> (%)	9 (13.6)	4 (6.0)	0.242 (NS) ^b	2.352 (0.761–7.270)
Acute kidney injury, <i>n</i> (%)	4 (6.0)	4 (6.0)	1.000 (NS) ^b	1.000 (0.261–3.831)
Blood culture positive sepsis, <i>n</i> (%)	2 (3.0)	0	0.496 (NS) ^b	5.000 (0.244–102.198)
Pulmonary hemorrhage, <i>n</i> (%)	1 (1.5)	3 (4.5)	0.619 (NS) ^b	0.333 (0.035–3.122)
Gastrointestinal bleeding, <i>n</i> (%)	2 (3.0)	2 (3.0)	1.000 (NS) ^b	1.000 (0.145–6.890)
Intracranial bleeding, <i>n</i> (%)	1 (1.5)	1 (1.5)	1.000 (NS) ^b	1.000 (0.063–15.654)
Hypoglycemia, <i>n</i> (%) (blood glucose < 45 mg/dL)	3 (4.5)	3 (4.5)	1.000 (NS) ^b	1.000 (0.209–4.775)
Hyperglycemia, <i>n</i> (%) (blood glucose > 125 mg/dL)	2 (3.0)	0 (0)	0.496 (NS) ^b	5.000 (0.244–102.198)
Hyponatremia, <i>n</i> (%) (serum sodium < 130 meq/L)	12 (18)	11 (16.6)	1.000 (NS) ^a	1.107 (0.526–2.328)
Hypertatremia, <i>n</i> (%) (serum sodium > 150 meq/L)	2 (3)	0 (0)	0.496 (NS) ^b	5.000 (0.244–102.198)
Hypocalcemia, <i>n</i> (%) (ionized calcium < 1 meq/L)	12 (18)	15 (22.7)	0.666 (NS) ^a	0.812 (0.412–1.599)
Hyperkalemia, <i>n</i> (%) (serum potassium > 5.5 meq/L)	4 (6.0)	4 (6.0)	1.000 (NS) ^b	1.000 (0.261–3.831)
Hypokalemia, <i>n</i> (%) (serum potassium < 3.5 meq/L)	5 (7.5)	4 (6.0)	1.000 (NS) ^b	1.250 (1.351–4.450)
Platelet count (μL)				
100,000 to < 150,000, <i>n</i> (%)	11 (16.6)	16 (24.2)	0.388 (NS) ^a	0.687 (0.345–1.367)
< 100,000, <i>n</i> (%)	2 (3.0)	7 (10.5)	0.440 (NS) ^b	0.400 (0.080–1.989)

CI confidence interval, ETS endotracheal suctioning, No-ETS no endotracheal suctioning, NS not significant, PPHN primary pulmonary hypertension

^a Chi square test

^b Fisher exact test

severity of MAS in these neonates [4]. However, this was a pre- and postintervention cohort study with many limitations including difference in rates of fetal distress, late preterm, and postterm births which might have influenced study findings.

We observed numerous complications in our study population, ranging from perinatal asphyxia, seizures, PPHN, shock, acute kidney injury, thrombocytopenia, and metabolic derangements such as hyponatremia, hypocalcemia, and hyper-/hypokalemia. Tracheal suctioning made no difference to rates of complications in two groups. Mortality rate and duration of hospitalization were also comparable in two groups. Thus, tracheal suctioning at birth does not lessen the risk of complications or mortality risk in these babies. In view of our findings, it is difficult to justify the practice of endotracheal suctioning in non-vigorous meconium-stained newborns.

Our study has several limitations. First, this was an unblinded trial so the possibility of bias exists in conclusions drawn from this study. Second, we did not use pulse oximetry monitoring during delivery room resuscitation which would have provided information regarding oxygenation status during tracheal suctioning. Third, no developmental follow-up of study population is available. To conclude, endotracheal suctioning at birth does not reduce the incidence of MAS, complication rates, and mortality risk in non-vigorous neonates born through MSAF.

Authors' contributions Prof Ashok Kumar and Prof Sripama Basu conceptualized and designed the study, coordinated and supervised data collection, drafted the initial manuscript, and reviewed and revised the manuscript. Dr. Preetam Kumar designed the data collection instruments, collected data, carried out the initial analyses, 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.

Compliance with ethical statements

Conflict of interest The authors declare that they have no conflict of interest.

Ethical approval The trial was ethically approved by the Institute Ethics Committee of Institute of Medical Sciences, Banaras Hindu University, Varanasi, India.

Clinical trial registration The trial was registered under Clinical Trials Registry of India (CTRI/2015/04/008819).

Informed consent Informed consent was obtained from all individual participants included in the study.

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