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[Intervention Review]

Routine oro/nasopharyngeal suction versus no suction at birth

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ABSTRACT

Background

Oro/nasopharyngeal suction is a method used to clear secretions from the oropharynx and nasopharynx through the application of negative pressure via a suction catheter or bulb syringe. Traditionally, airway oro/nasopharyngeal suction at birth has been used routinely to remove fluid rapidly from the oropharynx and nasopharynx in vigorous and non-vigorous infants at birth. Concerns relating to the reported adverse effects of oro/nasopharyngeal suctioning led to a practice review and routine oro/nasopharyngeal suctioning is no longer recommended for vigorous infants. However, it is important to know whether there is any clear benefit or harm for infants whose oro/nasopharyngeal airway is suctioned compared to infants who are not suctioned.

Objectives

To evaluate the effect of routine oropharyngeal/nasopharyngeal suction compared to no suction on mortality and morbidity in newly born infants.

Search methods

We used the standard search strategy of the Cochrane Neonatal Review group to search the Cochrane Central Register of Controlled Trials (CENTRAL 2016, Issue 3), MEDLINE via PubMed (1966 to April 18, 2016), Embase (1980 to April 18, 2016), and CINAHL (1982 to April 18, 2016). We also searched clinical trials databases, conference proceedings, and the reference lists of retrieved articles for randomised controlled trials and quasi-randomised trials.

Selection criteria

Randomised, quasi-randomised controlled trials and cluster randomised trials that evaluated the effect of routine oropharyngeal/nasopharyngeal suction compared to no suction on mortality and morbidity in newly born infants with and without meconium-stained amniotic fluid.

Data collection and analysis

The review authors extracted from the reports of the clinical trials, data regarding clinical outcomes including mortality, need for resuscitation, admission to neonatal intensive care, five minute Apgar score, episodes of apnoea and length of hospital stay.

Main results

Eight randomised controlled trials met the inclusion criteria and only included term infants (n = 4011). Five studies included infants with no fetal distress and clear amniotic fluid, one large study included vigorous infants with clear or meconium-stained amniotic fluid, and two large studies included infants with thin or thick meconium-stained amniotic fluid. Overall, there was no statistical difference between oro/nasopharyngeal suction and no oro/nasopharyngeal suction for all reported outcomes: mortality (typical RR 2.29, 95% CI 0.94 to 5.53; typical RD 0.01, 95% CI -0.00 to 0.01; I^2 = 0%, studies = 2, participants = 3023), need for resuscitation (typical RR 0.85, 95% CI 0.69 to 1.06; typical RD -0.01, 95% CI -0.03 to 0.00; I^2 = 0%, studies = 5, participants = 3791), admission to NICU (typical RR 0.82, 95% CI 0.62 to 1.08; typical RD -0.03, 95% CI -0.08 to 0.01; I^2 = 27%, studies = 2, participants = 997) and Apgar scores at five minutes (MD -0.03, 95% CI -0.08 to 0.02; I^2 not estimated, studies = 3, participants = 330).

Authors' conclusions

The currently available evidence does not support or refute the benefits or harms of routine oro/nasopharyngeal suction over no suction. Further high-quality studies are required in preterm infants or term newborn infants with thick meconium amniotic fluid. Studies should investigate long-term effects such as neurodevelopmental outcomes.

PLAIN LANGUAGE SUMMARY

Airway suctioning for newborn infants at birth

Review question: Does routine oropharyngeal/nasopharyngeal suctioning of newborn infants' airways compared to no suction have an effect on mortality and morbidity with and without meconium-stained amniotic fluid?

Background: The transition from fetus to newborn involves the clearing of lung fluid and expansion of the lungs with air. Traditionally, oro/nasopharyngeal suctioning at birth has been used routinely to remove fluids in vigorous infants at birth. While airway oro/nasopharyngeal suctioning can be successful in clearing the airway immediately after birth, the procedure can have serious consequences that may outweigh the potential benefits of oro/nasopharyngeal suctioning. This review examined the effect of oro/nasopharyngeal suctioning versus no suctioning.

Study characteristics: Eight randomised controlled trials enrolling 4011 newborn infants met our inclusion criteria.

Results: The currently available evidence neither supports nor refutes suctioning as a beneficial therapy for healthy term infants and further quality studies are needed in term and preterm newborns.

Summary of findings for the main comparison. Summary of findings table for oro/nasopharyngeal suction versus no suction

Oro/nasopharyngeal suction versus no suction at birth

Patient or population: newborn infants at birth
Setting: Delivery room
Intervention: Oro/nasopharyngeal suction
Comparison: no suction

Outcomes	Anticipated absolute effects* (95% CI)		Relative effect (95% CI)	№ of participants (studies)	Quality of the evidence (GRADE)	Comments
	Risk with no suction	Risk with Oro/nasopharyngeal suction				
Mortality (before discharge)	Study population		RR 2.29 (0.94 to 5.53)	3023 (2 RCTs)	⊕⊕⊖⊖ LOW[1,5]	Downgraded two levels due to: 1. Imprecision: Broad confidence intervals 2. Potential risk of bias (high risk of performance and detection bias)
	5 per 1000	11 per 1000 (4 to 26)				
Need for resuscitation	Study population		RR 0.85 (0.69 to 1.06)	3791 (5 RCTs)	⊕⊕⊖⊖ LOW [2,5]	Downgraded two levels due to: 1. Indirectness (studies included infants with meconium-stained amniotic fluid or clear amniotic fluid 2. Potential risk of bias (high risk of performance bias)
	87 per 1000	74 per 1000 (60 to 92)				
Hypoxic Ischaemic Encephalopathy	Study population		RR 0.76 (0.33 to 1.77)	509 (1 RCT)	⊕⊕⊖⊖ LOW [3,5]	Downgraded two levels due to: 1. Single study 2. Potential risk of bias (high risk of performance bias)
	47 per 1000	36 per 1000 (15 to 83)				

Infection	Study population		RR 0.76 (0.42 to 1.36)	509 (1 RCT)	⊕⊕⊖⊖ LOW [3,5]	Downgraded two levels due to: 1. Single study 2. Potential risk of bias (high risk of performance bias)
	94 per 1000	71 per 1000 (39 to 128)				
Admission to NICU	Study population		RR 0.82 (0.62 to 1.08)	997 (2 RCTs)	⊕⊕⊖⊖ LOW [4,5]	Downgraded two levels due to: 1. High number of non- per-protocol exclusions in one study 2. Potential risk of bias (high risk of performance bias)
	185 per 1000	152 per 1000 (115 to 200)				

*__The risk in the intervention group__ (and its 95% confidence interval) is based on the assumed risk in the comparison group and the __relative effect__ of the intervention (and its 95% CI).

CI: Confidence interval; **RR:** Risk ratio; **OR:** Odds ratio;

GRADE Working Group grades of evidence
High-quality: We are very confident that the true effect lies close to that of the estimate of the effect
Moderate-quality: We are moderately confident in the effect estimate: The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different
Low-quality: Our confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of the effect
Very low-quality: We have very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of effect

[1] Imprecision: Broad confidence intervals
[2] Indirectness: Nangia 2015, Vain 2004 enrolled infants with meconium-stained amniotic fluid, Gungor 2005, Gungor 2006 enrolled infants with clear amniotic fluid and Kelleher 2013 enrolled infants with either clear or meconium-stained amniotic fluid
[3] Single study
[4] Extensive non-per-protocol exclusions (Kelleher 2013)
[5] High risk of performance bias

BACKGROUND

Description of the condition

The transition from fetus to newborn involves the clearing of lung fluid and expansion of the lungs with air. Fluid contained in the respiratory system at birth has been deemed responsible for the increased ventilatory work observed during the initial adaptation to extrauterine life (Estol 1992).

Amniotic fluid is a clear, slightly yellowish liquid that surrounds the fetus during pregnancy and is contained in the amniotic sac. The amniotic fluid constantly circulates as the baby swallows and "inhales" the fluid, and then releases it. The amniotic fluid, provides space for the fetus to grow and move, assists lung development, keeps a constant temperature and protects the fetus from outside injury (Underwood 2005). Amniotic fluid may also contain substances that are potentially harmful such as meconium (Underwood 2005). Meconium is the earliest stool in neonates and is normally retained in the infant's bowel until after birth, but sometimes it is expelled into the amniotic fluid prior to birth or during labor and delivery. Meconium is viscous and sticky like tar, its colour usually being a very dark olive green and is composed of intestinal epithelial cells, mucus, amniotic fluid, bile and water (Vaghela 2014).The stained amniotic fluid is recognised as a sign of fetal compromise, and its thick consistency can put the neonate at risk of meconium aspiration, a potentially life-threatening pulmonary disease (Underwood 2005).

Description of the intervention

Oro/nasopharyngeal suction is a method used to clear secretions from the oropharynx or nasopharynx, or both, through the application of negative pressure via a suction cathete or bulb syringe (Waltman 2004). Negative pressure is used to clear secretions from the mouth, nose or pharynx while attempting to avoid trauma to the mucosa. If oro/nasopharyngeal suction of term infants is required, the Australian Resuscitation Council recommends using a large bore suction catheter (10 to 12 F), passed no more than 5 cm from the lips, with suction applied for only a few seconds (ARC 2010). The negative pressure used to remove secretions should not exceed 100 mmHg (13 kPa, 133 cmH_2O, 1.9 pounds per square inch (psi)) (ARC 2010). Oro/nasopharyngeal suction can be performed before the delivery of the infant's shoulders (intrapartum) (Vain 2004) or following vaginal birth (Gungor 2005) or caesarean section (postpartum) of the infant (Gungor 2006).

Recommendations in relation to oro/nasopharyngeal suctioning differ for infants with and without meconium-stained amniotic fluid, and for vigorous and non-vigorous infants at birth. Traditionally, airway oro/nasopharyngeal suction at birth has been used routinely to rapidly remove non-meconium fluid rapidly in vigorous and non-vigorous infants at birth (AHA, AAP 2006; Estol 1992). However, concerns relating to the reported adverse effects of oro/nasopharyngeal suctioning (Kattwinkel 2010) led to a practice review and routine oro/nasopharyngeal suctioning is no longer recommended for vigorous infants (Kattwinkel 2008). A 'vigorous' infant has been defined by Wiswell 2000 as a heart rate >100 beats per minute, as well as presence of spontaneous respirations and 'reasonable tone'. Reasonable tone was believed to be present if the child was exhibiting either spontaneous movements or had some degree of extremity flexion" (p. 2). Because of the lack of evidence to support or refute suctioning of the mouth and nose of non-vigorous infants at birth when an infant is born through clear amniotic fluid, oro/nasopharyngeal suctioning is only recommended by the American Heart Association and American Academy of Pediatrics (Kattwinkel 2010), these organisations' neonatal resuscitation program (NRP) (AAP, AHA 2011), and the International Consensus on Cardiopulmonary Resuscitation (ILCOR) (Perlman 2010) when the infant's airway is known to be obstructed, or when an infant requires positive pressure ventilation.

Vigorous and non-vigorous infants born through 'thick' meconium-stained amniotic fluid have been managed using endotracheal intubation and suction immediately following birth, with suction applied to the endotracheal tube as it was withdrawn (Gregory 1974). A Cochrane review compared endotracheal intubation and aspiration of the airways against oropharyngeal suctioning in non-asphyxiated meconium-stained term infants. The authors concluded that routine endotracheal intubation and tracheal suctioning at birth in vigorous term infants born through meconium-stained amniotic fluid was not superior to oropharyngeal suctioning alone. Thus, they recommended that while suctioning of the oropharynx may be beneficial, endotracheal intubation and tracheal suctioning should be reserved for non-vigorous infants (Halliday 2001). These recommendations are reflected in the 2010 International Consensus on Cardiopulmonary Resuscitation and Emergency Care Science with Treatment Recommendations (Kattwinkel 2010) and ILCOR (Perlman 2010).

How the intervention might work

Oro/nasopharynx suctioning in newborn infants is thought to help lung fluid expulsion and establish a functional residual capacity. It has been proposed that oro/nasopharyngeal suctioning improves oxygen saturation, prevents aspiration of mucous and blood from the trachea, and provides tactile stimulation to assist the initiation of respiration, and promote a successful transition from intrauterine to extrauterine life. However, other researchers have hypothesised that fluid in the airways at the time of birth is most likely to be alveolar fluid (Bland 1988) and is generally absorbed through normal physiological processes (Estol 1992). While oropharyngeal or nasopharyngeal suction, or both, can be successful in clearing the airway immediately after birth, the procedure can have serious consequences. Oropharyngeal and nasopharyngeal suctioning has been associated with irritation to mucous membranes and increased risk for iatrogenic infection (Gungor 2005; Gungor 2006), bradycardia (Cordero 1971; Gungor 2006), apnoea (Cordero 1971), hypoxaemia and arterial oxygen desaturation (Carrasco 1997; Gungor 2005; Kohlhauser 2000), hypercapnia (Skov 1992), impaired cerebral blood flow regulation (Van Bel 1988), increased intracranial pressure (Fisher 1982), and development of subsequent neonatal brain injury (Kaiser 2008). Fluctuations in cerebral blood flow have been shown to cause intraventricular haemorrhage in premature infants and neonatal animals.

Why it is important to do this review

The potential benefits of oro/nasopharyngeal suctioning may not outweigh the deleterious effect of the procedure. While routine oro/nasopharyngeal suctioning is now not recommended for vigorous healthy infants (Kattwinkel 2008; Kattwinkel 2010; Perlman 2010), it has been postulated that because a practice such as oro/nasopharyngeal suctioning has become so firmly entrenched in

some healthcare settings, it would take a 'large body of research' to change practice (Mercer 2007). In some countries, such as Australia, government funding is attached to the undertaking of procedures such as or/nasopharyngeal suctioning at birth. Thus, incentives exist to keep oro/nasopharyngeal suctioning, and strong evidence is required to change practice. The cost of catheters and suction bulbs are an added cost to the health care of newborn infants, but these costs can be eliminated if the intervention is found to be not required. Thus, it is important to know whether there is any clear benefit or harm for infants whose oro/nasopharyngeal airway is suctioned compared to infants who are not suctioned. Additionally, studies comparing outcomes in oro/nasopharyngeal suctioned infants versus those without suctioning have mainly been in term infants. The potential benefits or harms of the procedure to preterm infants who have a narrower airway than term infants have not been explored.

OBJECTIVES

To evaluate the effect of routine oropharyngeal/nasopharyngeal suction compared to no suction on mortality and morbidity in newly born infants with and without meconium-stained amniotic fluid.

Planned subgroup analyses:

- gestational age: term infants (≥ 37 weeks' gestation), preterm infants (28 to 36 weeks' gestation), very preterm infants (< 28 weeks' gestation);
- mode of delivery (vaginal birth; caesarean section);
- vigorous; non-vigorous infants;
- meconium-stained amniotic fluid; non-meconium-stained amniotic fluid;
- timing of oro/nasopharyngeal suction (perineum-intrapartum; postdelivery);
- method of oro/nasopharyngeal suction (bulb syringe; suction catheter).

METHODS

Criteria for considering studies for this review

Types of studies

We included all randomised and quasi-randomised controlled trials.

Types of participants

We included term and preterm infants at birth.

Types of interventions

Routine oropharyngeal or nasopharyngeal suction or both versus no oropharyngeal or nasopharyngeal suction at birth.

Types of outcome measures

Primary outcomes

- Mortality - before discharge; before 28 days' postnatal age.
- Need for resuscitation (endotracheal intubation OR supplemental oxygen OR chest compressions OR adrenaline) in the delivery room.
- Admission to neonatal intensive care unit or special-care nursery.

Secondary outcomes

- Five-minute Apgar score.
- Episodes of apnoea (defined as a cessation of breathing for more than 20 seconds or a shorter pause associated with bradycardia or cyanosis (AAP 2003)) during oro/nasopharyngeal suctioning or immediately following oro/nasopharyngeal suctioning, or both.
- Episodes of bradycardia (defined as a fall in heart rate of more than 30% below the baseline or less than 100 beats per minute for 10 seconds or longer) during oro/nasopharyngeal suctioning or immediately following oro/nasopharyngeal suctioning.
- Episodes of oxygen desaturation (defined as a spontaneous fall in SpO_2 of 85% for 10 seconds or longer in duration) during oro/nasopharyngeal suctioning or immediately following oro/nasopharyngeal suctioning.
- Cardiac arrhythmias during or immediately following oro/nasopharyngeal suctioning.
- Laryngospasm during or immediately following oro/nasopharyngeal suctioning.
- Length of hospital stay (days).
- Cranial ultrasound abnormalities: any ventricular haemorrhage, grade 3 or 4 according to Papile classification (Papile 1978) and cystic periventricular leukomalacia.
- Hypoxic ischaemic encephalopathy (Sarnat 1976; Thompson 1997).
- Long-term neurodevelopmental outcome (rates of cerebral palsy on physician assessment; developmental delay, i.e. developmental quotient (DQ) > two standard deviations less than the mean on validated assessment tools, e.g. Bayley's Mental Developmental Index).
- Infection (diagnosed < 7 days post delivery).

Search methods for identification of studies

Electronic searches

We used the criteria and standard methods of Cochrane and the Cochrane Neonatal Review Group (see the Cochrane Neonatal Group search strategy for specialized register).

We conducted a comprehensive search including: Cochrane Central Register of Controlled Trials (CENTRAL 2016, Issue 3) in the Cochrane Library; MEDLINE via PubMed (1966 to April 18, 2016); Embase (1980 to April 18, 2016); and CINAHL (1982 to April 18, 2016) using the following search terms: (nasopharynx OR nasopharyngeal OR oropharynx OR oropharyngeal OR oro/nasopharynx OR oro/nasopharyngeal) AND (suction*), plus database-specific limiters for RCTs and neonates (see Appendix 1 for the full search strategies for each database). We did not apply language restrictions.

We searched clinical trials registries for ongoing or recently completed trials (clinicaltrials.gov, the World Health Organization's International Trials Registry and Platform www.whoint/ictrp/search/en/, and the ISRCTN Registry).

Searching other resources

The search strategy included communication with expert informants, bibliographies of reviews and trials for references to other trials, and previous reviews including cross-references, abstracts, and conferences and symposia proceedings of the Perinatal Society of Australia and New Zealand and Pediatric Academic Societies (American Pediatric Society, Society for Pediatric Research and European Society for Pediatric Research) from 1990 to October 2014. We contacted the corresponding authors of identified randomised controlled trials for additional information about their studies when further data were required. There was no language restriction.

Data collection and analysis

We used the standard systematic review methods of Cochrane documented in the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011).

Selection of studies

Review authors (JF and JD) independently assessed for inclusion all the potential studies identified as a result of the search strategy. We resolved any disagreement through discussion.

Specifically, we:

1. merged search results using reference management software and removed duplicate records of the same report;
2. examined titles and abstracts to remove irrelevant reports;
3. retrieved full text of the potentially relevant reports;
4. linked together multiple reports of the same study;
5. examined full-text reports for compliance of studies with eligibility criteria;
6. corresponded with investigators, when appropriate, to clarify study eligibility;
7. at all stages, noted reasons for inclusion and exclusion of articles, with disagreements were resolved through consensus;
8. made final decisions on study inclusion and proceeded to data collection;
9. resolved all discrepancies through a consensus process.

Data extraction and management

We used the standardised review methods of the CNRG (neonatal.cochrane.org/en/index.html) to assess the methodological quality of included studies. Review authors independently assessed study quality and risk of bias using the following criteria documented in the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011).

Assessment of risk of bias in included studies

Review authors (JF and JD) independently assessed risk of bias for each study using the criteria outlined in the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011). We resolved any disagreement by discussion or by involving a third reviewer.

(1) Sequence generation (checking for possible selection bias)

We described for each included study the method used to generate the allocation sequence in sufficient detail to allow an assessment of whether it should produce comparable groups. We assessed the method as:

- low risk (any truly random process, e.g. random number table; computer random number generator);
- high risk (any non-random process, e.g. odd or even date of birth; hospital or clinic record number);
- unclear risk.

(2) Allocation concealment (checking for possible selection bias)

We described for each included study the method used to conceal the allocation sequence in sufficient detail and determined whether intervention allocation could have been foreseen in advance of, or during recruitment, or changed after assignment.

We assessed the methods as:

- low risk (e.g. telephone or central randomisation; consecutively numbered sealed opaque envelopes);
- high risk (open random allocation; unsealed or non-opaque envelopes, alternation; date of birth);
- unclear risk.

(3) Blinding (checking for possible performance bias)

We described for each included study the methods used, if any, to blind study participants and personnel from knowledge of which intervention a participant received. We judged studies to be at low risk of bias if they were blinded, or if we judged that the lack of blinding could not have affected the results. We assessed blinding separately for different outcomes or classes of outcomes.

We assessed the methods as:

- low risk, high risk, or unclear risk for participants;
- low risk, high risk, or unclear for personnel;
- low risk, high risk, or unclear for outcome assessors.

(4) Detection bias (checking for possible outcome assessment bias)

For each included study, we categorized the methods used to blind outcome assessors from knowledge of which intervention a participant received. As our study population consisted of neonates they would all be blinded to the study intervention. Blinding was assessed separately for different outcomes or classes of outcomes. We categorized the methods used with regards to detection bias.

Low risk: adequate, follow-up was performed with assessors blinded to group.
High risk: inadequate, assessors at follow-up were aware of group assignment.
Unclear risk: no or unclear information provided.

(5) Incomplete outcome data (checking for possible attrition bias through withdrawals, drop-outs, protocol deviations)

We described for each included study, and for each outcome or class of outcomes, the completeness of data including attrition and exclusions from the analysis. We stated whether attrition and exclusions were reported, the numbers included in the analysis at each stage (compared with the total randomised participants), reasons for attrition or exclusion where reported, and whether

missing data were balanced across groups or were related to outcomes.

Where sufficient information was reported or supplied by the trial authors, we planned to re-include missing data in the analyses. We assessed the methods as:

- low risk (< 20% missing data);
- high risk (≥ 20% missing data);
- unclear risk.

(6) Selective reporting bias (checking for possible reporting bias)

We described for each included study how we investigated the possibility of selective outcome reporting bias and what we found.

We assessed the methods as:

- low risk (where it was clear that all of the study's prespecified outcomes and all expected outcomes of interest to the review were reported);
- high risk (where not all the study's prespecified outcomes were reported; one or more reported primary outcomes were not prespecified; outcomes of interest were reported incompletely and so could not be used; study failed to include results of a key outcome that would have been expected to have been reported);
- unclear risk.

(7) Other sources of bias

We described for each included study any important concerns we had about other possible sources of bias (e.g. early termination of trial due to data-dependant process, extreme baseline imbalance, etc.). We assessed whether each study was free of other problems that could put it at risk of bias. We assessed other sources of bias as:

- low risk;
- high risk;
- unclear risk.

(8) Overall risk of bias

We made explicit judgements about whether studies were at high risk of bias, according to the criteria given in the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011). With reference to (1) to (7) above, we assessed the likely magnitude and direction of the bias and whether we considered it likely to impact on the findings. If needed, we planned to explore the impact of the level of bias through undertaking sensitivity analyses (see Sensitivity analysis).

Each criterion was judged as being at 'low risk' of bias, 'high risk' of bias, or 'unclear' risk of bias (for either lack of information or uncertainty over the potential for bias).

Quality of evidence

We assessed the quality of evidence for the main comparison at the outcome level using the Grading of Recommendations Assessment, Development and Evaluation (GRADE) approach (Guyatt 2011a). This methodological approach considers evidence from randomised controlled trials as high quality that may be downgraded based on consideration of any of five areas: design (risk of bias), consistency across studies, directness of the evidence, precision of estimates and presence of publication bias. (Guyatt 2011a). The GRADE approach results in an assessment of the quality of a body of evidence in one of four grades: 1) High: We are very confident that the true effect lies close to that of the estimate of the effect; 2) Moderate: We are moderately confident in the effect estimate: The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different; 3) Low: Our confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of the effect; 4) Very Low: We have very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of effect (Schunemann 2013).

The review authors independently assessed the quality of the evidence found for outcomes identified as critical or important for clinical decision making. These outcomes included: mortality, need for resuscitation, hypoxic ischaemic encephalopathy, infection, admission to NICU.

In cases where we considered the risk of bias arising from inadequate concealment of allocation, randomised assignment, complete follow-up or blinded outcome assessment to reduce our confidence in the effect estimates, we downgraded the quality of evidence accordingly (Guyatt 2011b). We evaluated consistency by similarity of point estimates, extent of overlap of confidence intervals and statistical criteria including measurement of heterogeneity (I^2 statistic). We downgraded the quality of evidence when large and unexplained inconsistency across studies results was present (i.e. some studies suggested important benefit and others no effect or harm, without a clinical explanation) (Guyatt 2011d). Precision was assessed based on the width of the 95% confidence interval (CI) and by calculating the optimal information size (OIS). If the total number of participants included in the pooled effect estimation was less than the number of participants generated by a conventional sample size calculation for a single adequately powered trial, we considered rating down for imprecision (Guyatt 2011c). When trials were conducted in populations other than the target population, we downgraded the quality of evidence because of indirectness (Guyatt 2011e).

We entered data (i.e. pooled estimates of the effects and corresponding 95% confidence Intervals) and explicit judgments for each of the above aspects assessed into the Guideline Development Tool, the software used to create 'Summary of findings' tables (GRADEpro 2008). We explained all judgements involving the assessment of the study characteristics described above in footnotes or comments in the Summary of findings for the main comparison.

Measures of treatment effect

We performed statistical analyses using Review Manager software (RevMan 2014). We analysed dichotomous data using relative risk (RR) and risk difference (RD). We analysed continuous data using the mean difference (MD). The 95% confidence intervals (CIs) were reported on all estimates.

Dealing with missing data

For included studies, levels of attrition were noted. We were unable to perform sensitivity analyses, due to the small number of included studies. All outcome analyses were performed on an

intention-to-treat basis (i.e. we included all participants randomly assigned to each group in the analyses). The denominator for each outcome in each trial was the number randomly assigned minus any participants whose outcomes were known to be missing.

Assessment of heterogeneity

We used Review Manager 5 (RevMan 2014) to assess the heterogeneity of treatment effects between trials. We used the two formal statistics described below:

1. The Chi^2 test for homogeneity. We calculated whether statistical heterogeneity was present using the Chi^2 test for homogeneity. Since this test has low power when the number of studies included in the meta-analysis is small, we set the probability at the 10% level of significance ($P < 0.1$) (Higgins 2011).
2. The I^2 statistic, to ensure that pooling of data was valid. The impact of statistical heterogeneity was quantified using I^2 statistics available in RevMan 2014, which describe the percentage of total variation across studies due to heterogeneity rather than sampling error. We graded the degree of heterogeneity as:
   a. < 25%, unimportant;
   b. 25% to 49%, low;
   c. 50% to 74%, moderate
   d. > 75%, high.

Where there was evidence of apparent or statistical heterogeneity, we intended to assess the source of the heterogeneity using sensitivity and subgroup analysis looking for evidence of bias or methodological differences between trials.

Assessment of reporting biases

We planned to investigate reporting and publication bias by examining the degree of asymmetry of a funnel plot, but this was not applicable because an insufficient number of studies was included in the meta-analysis for such an exploration. We tried to obtain the study protocols of all included studies and compared outcomes reported in the protocol to those reported in the findings for each of the included studies. For included trials that were recently performed, we explored possible selective reporting of study outcomes by comparing primary and secondary outcomes given in the reports versus primary and secondary outcomes proposed at trial registration, using the websites www.clinicaltrials.gov, www.controlled-trials.com and who.int/ictrp. If such discrepancies were found, we contacted the primary investigators to obtain missing outcome data on outcomes prespecified at trial registration.

Data synthesis

We analysed the data using RevMan 5 (RevMan 2014). For each intervention group, we extracted categorical data (e.g. number of episodes of bradycardia) and calculated the 95% confidence interval (CI), risk ratio (RR) and risk difference (RD). Number needed to treat for an additional beneficial outcome (NNTB) or additional harmful outcome (NNTH) was to be calculated for significant results. There were insufficient data to calculate these measures. We obtained the mean and standard deviation for continuous data and performed analysis using the mean difference (MD). The fixed-effect model was applied.

Subgroup analysis and investigation of heterogeneity

We planned to compare the effects of routine oro/nasopharyngeal suctioning in the delivery room in the following subgroup analyses, however, there were insufficient data to calculate these measures.

- gestational age: term infants (37 weeks' gestation and above), preterm infants (between 29 and 36 weeks' gestation), very preterm infants (< 29 weeks' gestation);
- mode of delivery (vaginal birth or caesarean section);
- vigorous; non-vigorous infants;
- meconium-stained amniotic fluid; non-meconium-stained amniotic fluid;
- timing of oro/nasopharyngeal suction (perineum-intrapartum; post-delivery);
- method of oro/nasopharyngeal suction (bulb syringe; suction catheter).

Sensitivity analysis

We planned sensitivity analyses for use in situations where this might affect the interpretation of significant results (e.g. where risk of bias was associated with the quality of some of the included trials or missing outcome data). None were thought necessary in this review.

RESULTS

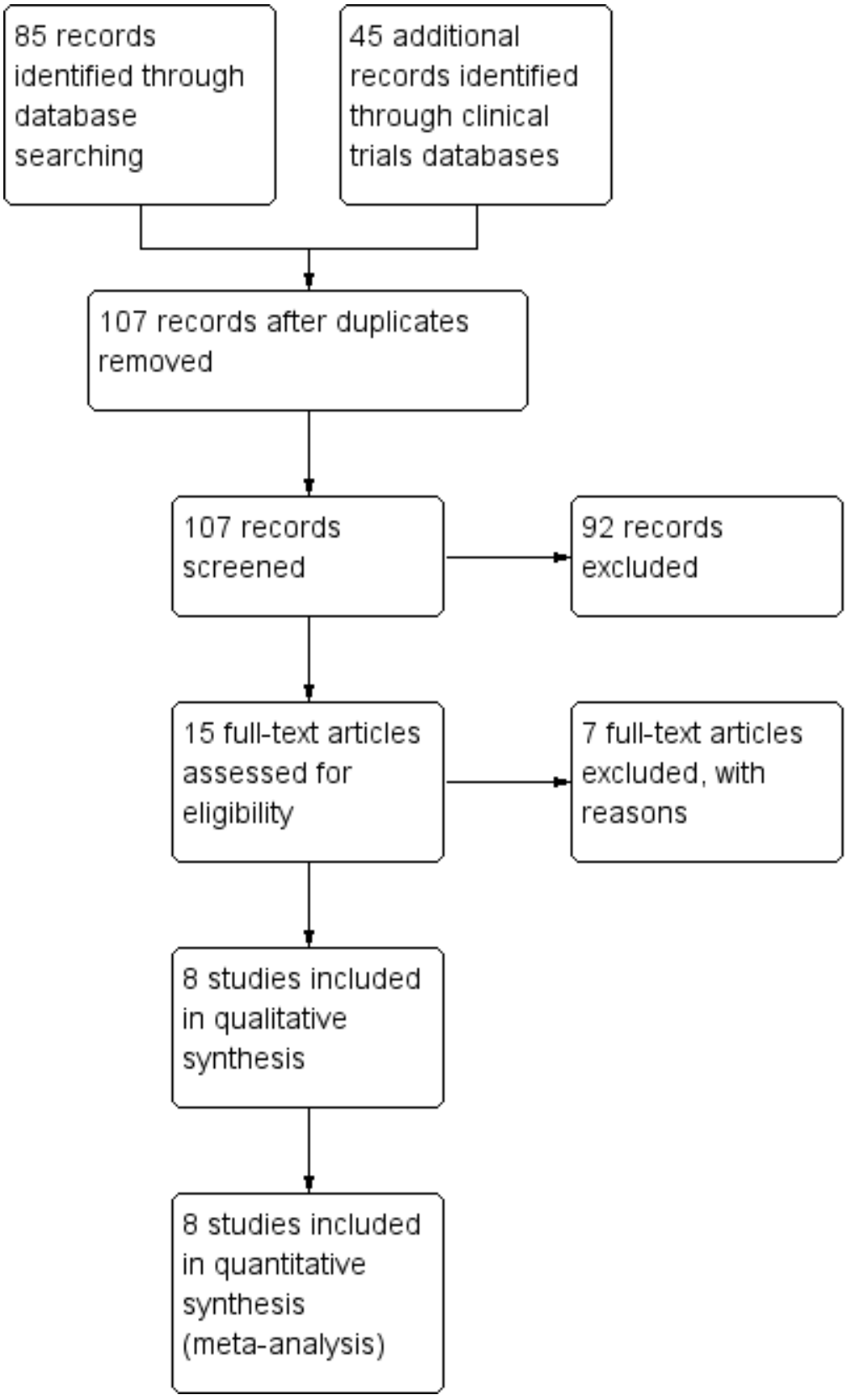
Description of studies

See: Characteristics of included studies and Characteristics of excluded studies.

Results of the search

Fifteen potential studies were identified, of which eight were included in the review. See Figure 1

Figure 1. Study flow diagram.



Included studies

Eight studies (n = 4011) were included in this review: Carrasco 1997 (n = 30); Gungor 2005 (n = 140); Gungor 2006 (n = 140); Kelleher 2013 (n = 488); Nangia 2015 (n = 509); Nejad 2014 (n = 170); Vain 2004 (n = 2514); Waltman 2004 (n = 20). Two studies compared oro/nasopharyngeal suction using bulb syringe versus no suction (Kelleher 2013; Waltman 2004) and 6 studies compared use of a suction catheter versus no suction (Carrasco 1997; Gungor 2005; Gungor 2006; Nangia 2015; Nejad 2014; Vain 2004). Studies included newborn term infants born vaginally (Carrasco 1997; Gungor 2005, Kelleher 2013; Nangia 2015; Nejad 2014; Waltman 2004), by caesarean section (Gungor 2006) or either vaginally or by caesarean section (Vain 2004). Studies included infants born with clear amniotic fluid (Carrasco 1997; Gungor 2005; Gungor 2006; Nejad 2014; Waltman 2004), meconium-stained amniotic fluid (Nangia 2015) and meconium-stained or clear amniotic fluid (Kelleher 2013).

Carrasco 1997 was a single centre study performed in Uruguay:

- Objective: To evaluate the effectiveness of oro/nasopharyngeal suction versus no suction.
- Population: Healthy term newborn infants born vaginally with clear amniotic fluid.
- Intervention: Suctioning performed with a sterile polyethylene catheter (Rusch No.3; 1.8 mm internal diameter; two lateral holes) postpartum. First the nasopharynx and then both nares were suctioned by introducing the tube not more than 6 cm. The whole procedure lasted between 8 and 10 seconds, and negative pressure did not exceed 30 cmH_2O. The no suction group received no suctioning.
- Outcomes: Apgar score, oxygen saturation.

Gungor 2005 was a single centre study performed in Turkey:

- Objective: To evaluate the effectiveness of postpartum oro/nasopharyngeal suction versus no suction.
- Population: Healthy term newborn infants born vaginally with clear amniotic fluid.
- Intervention: In the suction group, oro/nasopharyngeal suction was performed immediately postpartum by using a sterile polyethylene tube (8 ch -2, 67 mm, closed end, double hole, Bicakcilar A.S. Istanbul/Turkey) and negative pressure did not exceed 30 cmH_2O. The only intervention in the no suction group was to wipe away any visible matter.
- Outcomes: Oxygen saturation, Apgar score, heart rate, need for oxygen, need for neonatal intensive care unit admission.

Gungor 2006 was a single centre study performed in Turkey:

- Objective: To evaluate the effectiveness of postpartum oro/nasopharyngeal suction versus no suction.
- Population: Healthy term newborn infants born by caesarean section with clear amniotic fluid.
- Intervention: Oro/nasopharyngeal suctioning was performed by sterile polyethylene tube (8 Ch 2.67 mm, closed end, double hole, Bicakcilar, Istanbul) immediately after birth, whenever possible before the first breath to prevent aspiration of oronasal secretions in the suction group. The whole procedure lasted less than 15 seconds, and negative pressure did not exceed 30 cmH_2O. The only intervention in the no suction group was to wipe away any visible matter.
- Outcomes: Oxygen saturation, heart rate, Apgar score.

Kelleher 2013 was a single centre study performed in the USA:

- Objective: To evaluate the effectiveness of postpartum oro/nasopharyngeal suction versus no suction and wiping of the mouth.
- Population: Vigorous term newborn infants born vaginally with clear or meconium-stained amniotic fluid.
- Intervention: Suction in the mouth and nostrils with a bulb syringe gentle wiping externally over the face, mouth (at the discretion of the obstetric or paediatric resident), and nose with a towel (wipe group). Suction or wiping were applied immediately after the cord (postpartum) was cut. In the wipe group, if copious secretions were seen coming from the mouth, the baby's head was turned to the side to facilitate clearance.
- Outcomes: Respiratory rate, Apgar score, oxygen saturation at discharge, advanced resuscitation, tachypnoea, neonatal intensive care unit admission.

Nangia 2015 was a single centre study performed in India:

- Objective: To evaluate the effectiveness of intrapartum oropharyngeal suction versus no suction.
- Population: Newborn term infants born vaginally with meconium-stained amniotic fluid.
- Intervention: intrapartum oropharyngeal suctioning was performed after delivery of the head and the infant's mouth and nose were suctioned. Nose was suctioned after the mouth and throat oropharyngeal suctioning was performed using a 10 french suction catheter with suction pressure of 100 mmHg or De Lee's suction trap in event of electricity failure or nonavailability of suction machine. Neonates in the no intrapartum oropharyngeal suctioning group (n = 256) received no suction at the perineum after the delivery of the head before the delivery of the anterior shoulder. Neonates who were subsequently found to be non-vigorous in either group were intubated and airways were cleared with a meconium aspirator, but they were not excluded from the trial.
- Outcomes: Five-minute Apgar score, mortality, NICU admission, IPPV at birth, duration of stay in cases admitted to NICU, hypoxic ischaemic encephalopathy, antibiotics used for suspect and culture proven sepsis.

Nejad 2014 was a single centre study performed in Iran:

- Objective: To evaluate the effectiveness of intrapartum oro/nasopharyngeal suction versus no suction.
- Population: Healthy term newborn infants born vaginally with clear amniotic fluid.
- Intervention: Oro/nasopharyngeal suctioning was performed postpartum using a sterile polyethylene catheter, and negative pressure did not surpass 30 cmH_20. In the no suction group, the intervention was only to remove any visible material.
- Outcomes: Apgar score, oxygen saturation.

Vain 2004 was a multi-centre study performed in Argentina and USA:

- Objective: To assess the effectiveness of intrapartum oro/nasopharyngeal suctioning for the prevention of meconium aspiration syndrome.
- Population: Term infants born vaginally or by caesarean section through meconium-stained amniotic fluid of any consistency.
- Intervention: Intrapartum oro/nasopharyngeal suctioning was undertaken before delivery of the shoulders with an appropriately sized suction catheter (10 Fr to 13 Fr) connected to a negative pressure of 150 mmHg. The no suction group received no suctioning.
- Outcomes: Meconium aspiration syndrome, need for supplemental oxygen, mortality, mechanical ventilation, pneumothorax, duration of oxygen treatment, endotracheal intubation, suction and positive pressure ventilation in the delivery room, Apgar score, duration of mechanical ventilation in infants with meconium aspiration syndrome, duration of hospital care in infants with meconium aspiration syndrome.

Waltman 2004 was a single centre pilot study performed in the USA:

- Objective: Examine the effectiveness of intrapartum oro/nasopharyngeal bulb suctioning compared to no suctioning.
- Population: Healthy term newborn infants born vaginally with clear amniotic fluid.
- Intervention: Infants in the suction group received intrapartum oro/nasopharyngeal bulb suctioning by the attending obstetric resident when the head was delivered. First the mouth and then the nares were suctioned with a bulb syringe, one time each. The bulb was compressed to squeeze out the air, and then the tip was gently placed in the mouth, approximately 1.5 inches deep, and finger pressure was slowly released, allowing the mucus and fluid to be drawn into the bulb syringe. Following this, the compressed bulb syringe was placed in each naris at approximately 0.5 inches. Infants in the no suction group did not receive bulb syringing. All infants had their mouth and nose wiped with a towel if any visible matter was present. In the suction group, this was done prior to bulb suctioning. After drying the infant, the nursery nurse positioned the infant in the warmer, and a single-pass bulb postpartum suctioning of the mouth and nose was again performed on infants in the suction group.
- Outcomes: Apgar score, heart rate, oxygen saturation, supplemental oxygen.

Excluded studies

Seven studies were excluded from the analysis (Choi 2010; Cordero 1971; Estol 1992; Chettri 2015; Czarnecki 1999; Wiswell 2000; Pichler 2010). These are detailed in the table Characteristics of excluded studies, with reasons for their exclusion.

Risk of bias in included studies

Reviews that evaluated the effect of routine oropharyngeal/nasopharyngeal suction compared to no suction on mortality and morbidity in newly born infants with and without meconium-stained amniotic fluid were included in the analysis. Details of the methodological quality assessments are given in the Characteristics of included studies table. We completed a 'Risk of bias' table for each eligible study and presented our overall assessment of risk of bias using a 'Risk of bias' graph (Figure 2) and 'Risk of bias' summary (Figure 3).

Figure 2. Risk of bias graph: review authors' judgements about each risk of bias item presented as percentages across all included studies.

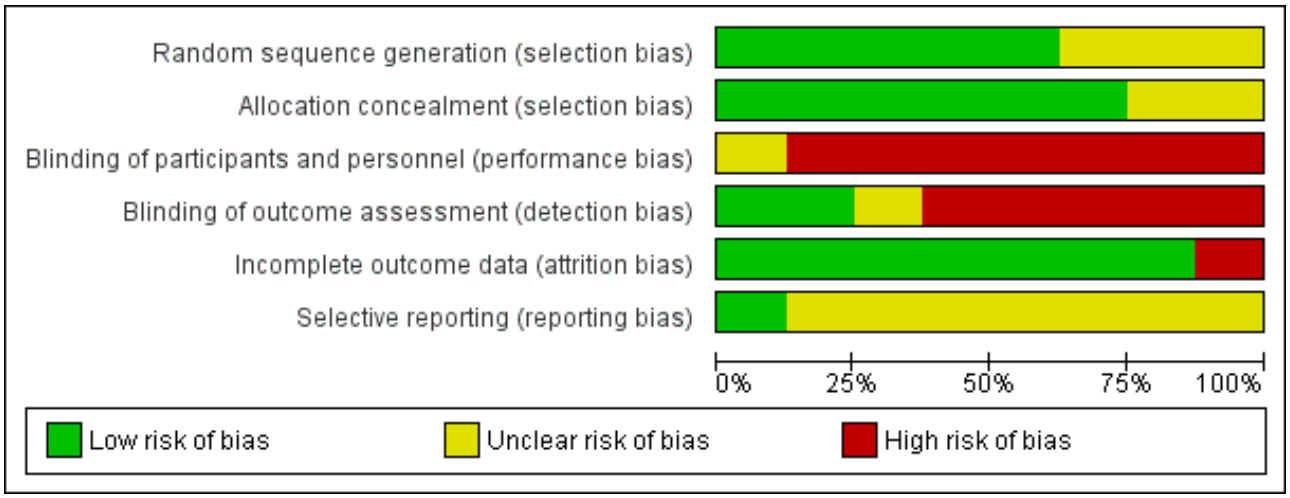
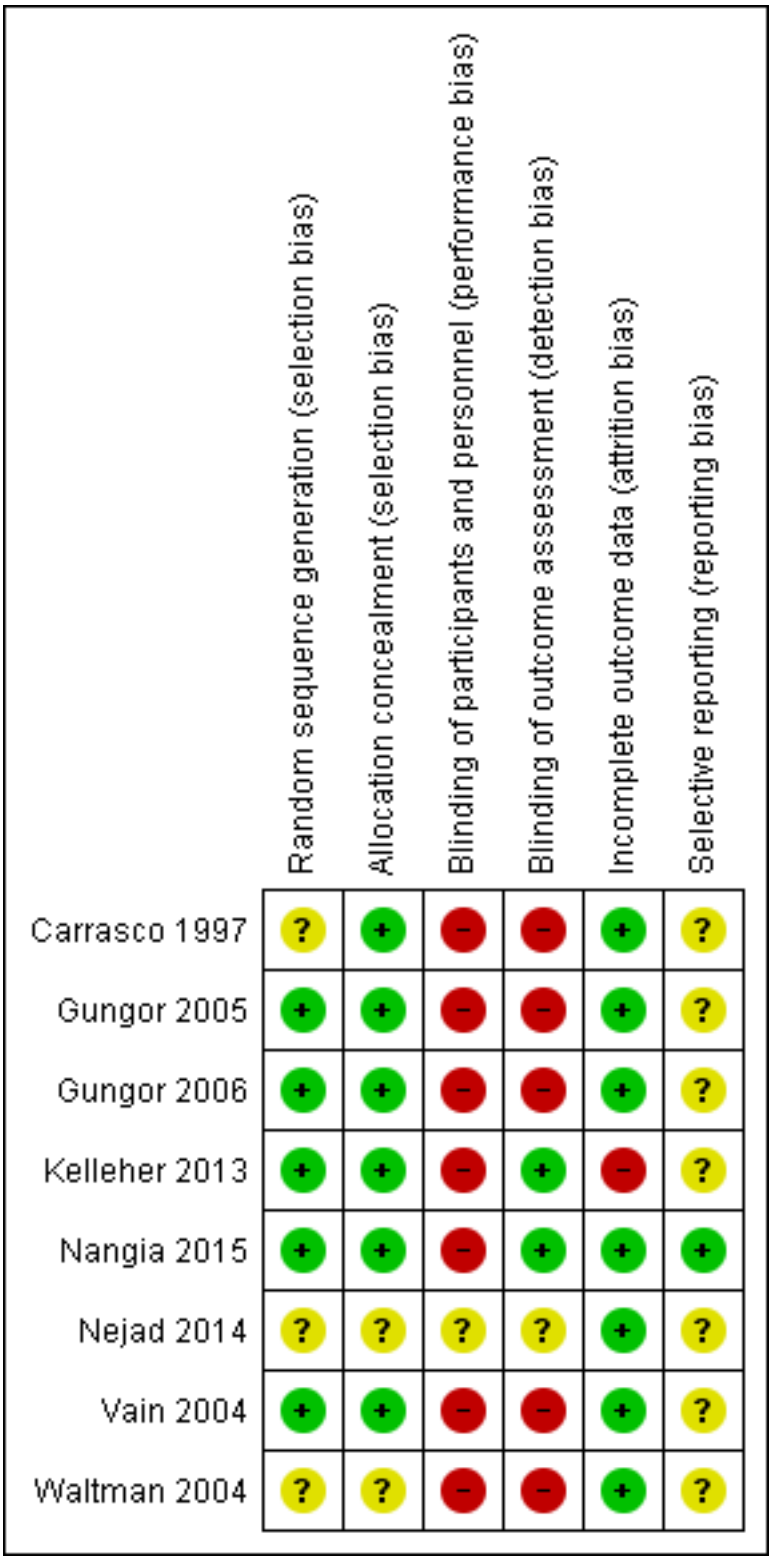


Figure 3. Risk of bias summary: review authors' judgements about each risk of bias item for each included study.



Randomisation: Gungor 2005, Gungor 2006, Kelleher 2013; Nangia 2015 and Vain 2004 used computer-generated randomisation. Carrasco 1997 reported 'fetuses were randomly assigned' and no further information was provided; Nejad 2014 reported that newborns were randomised to either oro/nasopharyngeal suction or the no suction group and no other information was provided; Waltman 2004 reported that the study was a randomised controlled trial with a two-group design and no further information was provided.

Allocation concealment: Carrasco 1997 reported that 'cards [were] taken from an envelope'; Gungor 2005; Gungor 2006 and Nangia 2015 used sealed envelopes; Kelleher 2013 reported that group allocations were stored centrally in sequentially numbered sealed envelopes that remained sealed until delivery of the infant. Vain 2004 reported that group assignments were drawn from consecutively numbered, sealed, opaque envelopes, which were opened immediately before attendance at deliveries Nejad 2014 and Waltman 2004 provided no information.

Blinding of participants and personnel: Carrasco 1997, Kelleher 2013; Nangia 2015 and Waltman 2004: no blinding; Gungor 2005 and Gungor 2006: no blinding in labour ward. 'All investigators, as well as residents and nurses who subsequently cared for the infant outside the delivery room, were unaware of the individual treatment group assignment. Vain 2004: no blinding in delivery room. All investigators, as well as clinicians who subsequently cared for the infant outside of the delivery room, were unaware of individual treatment group assignments and any trial results during the study. Nejad 2014: no information was provided

Blinding of outcome assessment: Carrasco 1997, Gungor 2005, Gungor 2006 and Waltman 2004: no blinding; Nejad 2014: not reported; Kelleher 2013: the nurses who recorded data for the outcomes after intervention were masked to the randomisation and pretreatment statuses of neonates; Nangia 2015 and Vain 2004: blinding of outcome assessment

Exclusions after randomisation: For Carrasco 1997, Gungor 2005, Gungor 2006, Nangia 2015; Nejad 2014 and Waltman 2004, outcomes were reported on all infants; Kelleher 2013: In the oro/nasopharyngeal suction group, 18 infants were excluded - 3 parents withdrew consent and 15 neonates were non-vigorous with meconium-stained fluid, 34 underwent 'wiping' (cross-over) and there were 15 other protocol deviations (loss of randomisation cards). In the 'wipe' group, 64 infants underwent oro/nasopharyngeal suction (cross-over) and there were four other protocol deviations (bulb syringes being accidentally dropped on the floor). The authors proposed that the high rate of contamination (98, 20% of 488 neonates treated), particularly from the wipe group to the oro/nasopharyngeal suction group, could reflect a bias of staff in the resuscitation area towards the use of suction rather than wiping. Trial outcomes were analysed by intention-to-treat. Vain 2004: 18 infants in the oro/nasopharyngeal suction group and 15 in the no suction group (n = 33) did not meet the entry criteria after random assignment (< 10% attrition). In the oro/nasopharyngeal suction group, 87 infants were not suctioned "because the caregiver arrived late or an unexpected failure in the suction system occurred". In the no suction group, 26 infants were suctioned "mostly because the obstetrician demanded oro/nasopharyngeal suctioning as the child's head was being delivered". Trial outcomes were analysed by intention-to-treat.

Selective reporting: Gungor 2005: The outcome 'need for neonatal intensive care' was not reported as stated in the method section of the study report. We obtained the protocol for the Kelleher 2013 study and all outcomes in the protocol and study report were identical except for 'advanced resuscitation'. This outcome in the protocol was described as "need for delivery room resuscitation including 'suctioning', intubation, positive pressure ventilation, chest compressions, and/or medication". However, the study report stated "Advanced resuscitation required at birth by intubation, positive-pressure ventilation, emergent medications, or a combination of these methods". Thus, suction and chest compressions were not included in the criteria as stated in the study protocol. We were unable to obtain other study protocols.

Effects of interventions

See: **Summary of findings for the main comparison** Summary of findings table for oro/nasopharyngeal suction versus no suction

Oro/nasopharyngeal suction versus no suction

Mortality - before discharge (Outcomes 1.1, 1.2)

Two studies (Nangia 2015; Vain 2004) reported mortality rates. Meta-analysis found no statistical difference between the suction and no suction groups but there was a trend towards higher mortality in the oro/nasopharyngeal suction group (typical RR 2.29, 95% CI 0.94 to 5.53; typical RD 0.01, 95% CI -0.00 to 0.01; studies = 2, participants = 3023).There was no heterogeneity in the studies (I^2 = 0%) (Analysis 1.1).

Vain 2004 reported that the cause of death of nine infants assigned to the oro/nasopharyngeal suction group was due to respiratory failure (four), congenital malformations (two), and sepsis (three). The causes of death for four infants in the no suction group were reportedly due to respiratory failure (two), sepsis (one) and congenital malformations (one). Vain 2004 reported mortality rates in a subgroup of infants with thick consistency meconium-stained amniotic fluid. No statistical difference was found between the oro/nasopharyngeal suction and no suction groups (RR 1.85, 95% CI 0.45 to 7.63; RD 0.02, 95% CI -0.02 to 0.05; studies = 1, participants = 319) (Analysis 1.2). However, Vain 2004 noted that the study was not powered for subgroup analysis. See Figure 4 and Figure 5.

Figure 4. Forest plot of comparison: 1 Oro/nasopharyngeal suction versus no suction, outcome: 1.1 Mortality (before discharge).

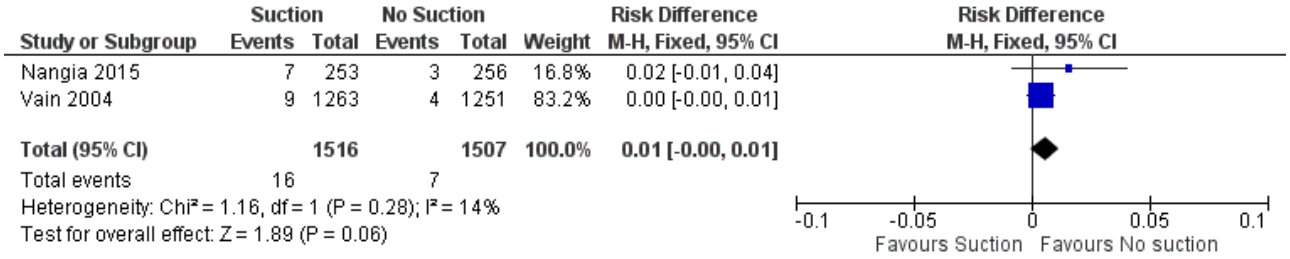
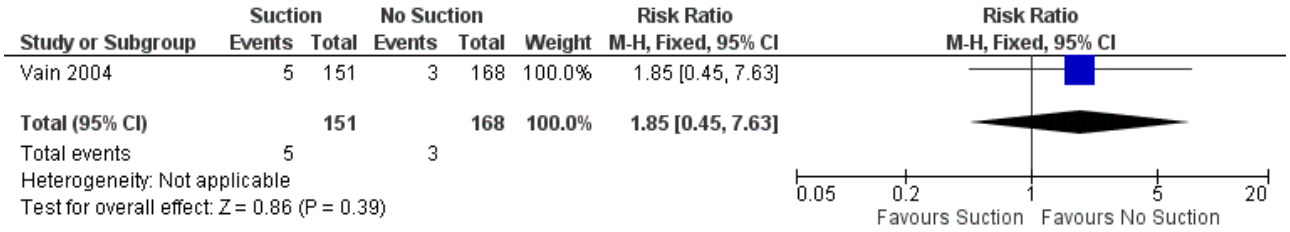


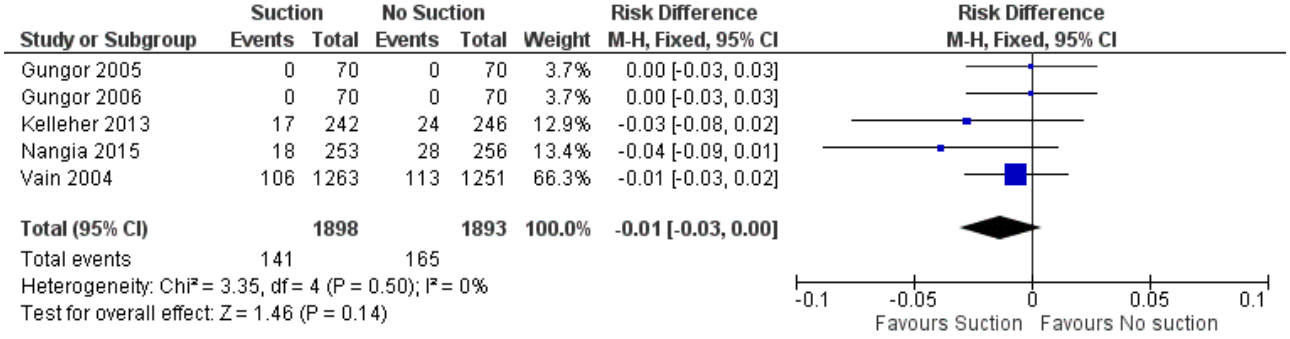
Figure 5. Forest plot of comparison: 1 Oro/nasopharyngeal suction versus no suction, outcome: 1.2 Mortality - thick consistency MSAF (before discharge).



Need for resuscitation (Outcome 1.3, 1.4)

Five studies (Gungor 2005; Gungor 2006; Kelleher 2013; Nangia 2015; Vain 2004) reported need for resuscitation. Meta-analysis found no difference between the oro/nasopharyngeal suction and no suction groups (typical RR 0.85, 95% CI 0.69 to 1.06; typical RD -0.01, 95% CI -0.03 to 0.00; 5 studies, participants = 3791). There was no heterogeneity in the studies (I^2 = 0%) (Analysis 1.3, Figure 6). Vain 2004 reported morality rates in a subgroup of infants with thick consistency meconium-stained amniotic fluid. No statistical difference was found between the suction and no suction groups in the need for mechanical ventilation (RR 1.39, 95% CI 0.56 to 3.43; RD 0.02, 95% CI -0.03 to 0.07; studies = 1, participants = 319) (Analysis 1.4). However, Vain 2004 noted that the study was not powered for subgroup analysis.

Figure 6. Forest plot of comparison: 1 Oro/nasopharyngeal suction versus no suction, outcome: 1.3 Need for resuscitation.



Admission to a neonatal intensive care unit (Outcome 1.5)

Two studies (Kelleher 2013; Nangia 2015) reported admission to a neonatal intensive care unit. Meta-analysis revealed that more neonates in the no oro/nasopharyngeal suction group were admitted to the neonatal intensive care unit than were those in the suction group. This finding was not statistically significant (typical RR 0.82, 95% CI 0.62 to 1.08; typical RD -0.03, 95% CI -0.08 to 0.01; studies = 2, participants = 997) with low degree of heterogeneity in the studies (I^2 = 27%). (Analysis 1.5). Kelleher 2013 noted that their results should be interpreted with caution as the study was not powered to assess this outcome.

Apgar score at five minutes (Outcome 1.6)

Eight studies (Carrasco 1997; Gungor 2005; Gungor 2006; Kelleher 2013; Nangia 2015; Nejad 2014; Vain 2004; Waltman 2004) reported Apgar score at five minutes. Three of the studies were able to be included in the meta-analysis (Gungor 2006; Nejad 2014; Waltman 2004). The meta-analysis revealed no statistical difference between the oro/nasopharyngeal suction and no suction groups (MD -0.03, 95% CI -0.08 to 0.02; studies = 3, participants = 330). Tests for heterogeneity were not estimated (Analysis 1.6). All studies reported no statistical difference between the oro/nasopharyngeal suction and no suction groups.

Carrasco 1997 reported no difference between the catheter oro/nasopharyngeal suction and no suction groups. All infants had an Apgar score of seven or greater at five minutes. No statistical analysis was provided by the authors. Gungor 2005 reported at the fifth minute that all the neonates in the no oro/nasopharyngeal suction group had a score of 10, while only 32 of 70 infants in the catheter oro/nasopharyngeal suction group had the same score (P = 0.001).Nangia 2015 found no difference between the catheter oro/nasopharyngeal suction groups (median 8, IQR 7 to 8) and no suction (median 8, IQR 7 to 8), P = 0.84). Kelleher 2013 found a statistically nonsignificant difference for Apgar score at five minutes between the bulb oro/nasopharyngeal suction (median 9, IQR 9 to 9) and no suction groups (median 9, IQR 9 to 9), (P = 0.27). Vain 2004 reported no statistical difference in five minute Apgar scores between the oro/nasopharyngeal catheter suction and no suction groups (P = 0.29).

Episodes of bradycardia

No studies reported on episodes of bradycardia. Gungor 2005 reported heart rate in the no suction group to be consistently

and significantly higher than in the catheter oro/nasopharyngeal suction group through the third and sixth minutes but all values remained within the normal range. Gungor 2006 reported that mean heart rates of all infants in the no suction and catheter oro/nasopharyngeal suction groups remained within the normal range during the observation period (no suction: 100 to 151 bpm versus suction 118 to 145 bpm). Kelleher 2013 reported on any respiratory rate value > 60 breaths per minute in the first 24 hours and found no difference between the no suction and bulb oro/nasopharyngeal suction groups (46% vs 46%, P = 0.94). Waltman 2004 reported that heart rates for both groups remained within a normal range (bulb oro/nasopharyngeal suction group 150 to 166 versus no suction group 166 to 173).

Episodes of oxygen desaturation

No studies reported on episodes of oxygen desaturation. Carrasco 1997 reported a significant decrease in minutes to 86% oxygen saturation in the no suction group compared to the catheter oro/nasopharyngeal suction group (mean 5.0 ± SEM 1.2 and mean 8.2 ± SEM 3.3, P < 0.05) and 92% oxygen saturation in the no suction group compared to the catheter suction group (mean 6.8 ± SEM 1.8 and mean 10.2 ± SEM 3.3, P < 0.05); Gungor 2005 reported during the first six minutes of life, that infants in the catheter oro/nasopharyngeal suction group had a lower mean oxygen saturation compared to the no suction group (P < 0.05). None of the neonates in the suction group achieved 92% oxygen saturation before the eighth minute of life. The maximum time to reach 86% was significantly shorter in the no suction group than the suction group (five vs. eight minutes, respectively, P < 0.001). None of the infants in the oro/nasopharyngeal suction group achieved 86% before the sixth minute of life. Gungor 2006 found that the maximum time to achieve oxygen saturation of 92% was six and 11 minutes, and for 86% was five and eight minutes for the catheter oro/nasopharyngeal suction and no suction groups, respectively (P < 0.001). None of the infants in the no suction group achieved oxygen saturation of 86% before the fifth minute of life. Kelleher 2013 reported no difference between the oro/nasopharyngeal bulb suction and no suction groups at discharge (P < 0.54). Nejad 2014 reported that the time to reach 92% oxygen saturation for the 'slowest' newborn in the no suction group was at nine minutes of life versus 11 minutes for the 'slowest' newborn in the catheter oro/nasopharyngeal suction group (P = 0.002). None of the infants in the suction group achieved 92% before eight minutes of life. Waltman 2004 found oro/nasopharyngeal bulb suctioning to have a slightly lower, although nonsignificant oxygen saturation level at five minutes (-3 ± 2.3%). However, at 10 minutes after birth, this trend reversed, and the suction group had a slightly higher oxygen saturation level by approximately 2.2% (± 2.1%). At 15 minutes of life, oxygen saturation levels for the suction group were significantly higher by 4.8% ± 1.7% (P = 0.005). At the end of the first 20 minutes of life, oxygen saturation levels were approximately 97% for the suction group and 92% for those in the no suction group.

Length of hospital stay (days) (Outcome 1.7)

One study (Vain 2004) reported length of hospital stay for infants who developed meconium aspiration syndrome and Nangia 2015 reported on length of hospital stay for infants that were admitted to the NICU. No statistical difference was noted between the oro/nasopharyngeal suction and no suction groups (MD -0.40, 95% CI -1.14 to 0.33; participants = 602). Tests for heterogeneity were not applicable (Analysis 1.7).

Hypoxic ischaemic encephalopathy (Outcome 1.8)

One study (Nangia 2015) reported hypoxic ischaemic encephalopathy and found no statistical difference between the oro/nasopharyngeal suction and no suction groups (RR 0.76, 95% CI 0.33 to 1.77; RD -0.01, 95% CI -0.05 to 0.02; studies = 1, participants = 509). Tests for heterogeneity were not applicable (Analysis 1.8).

Infection (Outcome 1.9)

Nangia 2015 reported on antibiotic use for suspect and culture proven sepsis and found no statistical difference between the oro/nasopharyngeal suction and no suction groups (RR 0.76, 95% CI 0.42 to 1.36; RD -0.02, 95% CI -0.07 to 0.03; studies = 1, participants = 509).Tests for heterogeneity were not applicable (Analysis 1.9).

Other outcomes

No studies reported on the following outcomes: episodes of apnoea, cardiac arrhythmias, laryngospasm, cranial ultrasound abnormalities or long-term neurodevelopmental outcomes.

Subgroup analyses

There was insufficient numbers of studies to perform subgroup analyses, however, none of the studies found a statistical difference between the oro/nasopharyngeal suction and no suction groups and thus, subgroup analyses would not have altered the results.

DISCUSSION

Summary of main results

All of the eight included RCTs enrolled term infants. Five of the studies included vigorous infants born vaginally (Carrasco 1997; Gungor 2005; Nejad 2014; Waltman 2004) or by caesarean section (Gungor 2006) with clear amniotic fluid. A large study included vigorous infants with clear or meconium-stained amniotic fluid (Kelleher 2013), one study included vigorous infants with meconium-stained amniotic fluid (Nangia 2015) and another study (Vain 2004) included vigorous or non-vigorous infants with meconium-stained amniotic fluid. Carrasco 1997, Gungor 2005, Kelleher 2013, Nejad 2014 used postpartum oro/nasopharyngeal suctioning, and Nangia 2015 and Waltman 2004 investigated intrapartum oro/nasopharyngeal suctioning.

Overall, there was no difference between the oro/nasopharyngeal suction and no suction groups for the outcomes mortality, need for resuscitation, admission to NICU, Apgar score at five minutes, length of hospital stay, hypoxic ischaemic encephalopathy and infection. None of the included RCTs reported on long-term neurodevelopmental outcomes, cranial ultrasound abnormalities, laryngospasm, episodes of bradycardia and episodes of oxygen desaturation, cardiac arrhythmias and episodes of apnoea.

The majority of the studies used a suction catheter (Carrasco 1997; Gungor 2005; Gungor 2006; Nangia 2015; Nejad 2014; Vain 2004) compared to bulb syringe (Kelleher 2013; Waltman 2004) for oro/nasopharyngeal suction. There was no difference in study outcomes whether a suction catheter or bulb syringe was used with all studies reporting no statistical difference with oro/nasopharyngeal suction compared to no suction. The studies that used a oro/nasopharyngeal suction catheter reported a wide range of negative pressure suction between 30 cmH_20 and 150 cmH_20. Carrasco 1997, Gungor 2005, Gungor 2006 and Nejad 2014 used

negative pressure suction of 30 cmH_2O. Nangia 2015 used negative pressure suction of 100 cmH_2O and Vain 2004 used negative pressure suction of 150 cmH_2O. There was no difference in the results of studies that used wiping of mouth secretions in the no suction group (Gungor 2005; Gungor 2006; Kelleher 2013; Nejad 2014; Waltman 2004) compared to studies that used no wiping of secretions in the no suction group (Carrasco 1997; Nangia 2015; Vain 2004).

Overall completeness and applicability of evidence

This Cochrane review found low-quality evidence that there is no benefit or harm to routine oro/nasopharyngeal suctioning. Despite the lack of clear evidence, the American Academy of Pediatrics (Kattwinkel 2010) recommends that oro/nasopharyngeal "suctioning immediately following birth (including suctioning with a bulb syringe) should be reserved for non-vigorous infants who have obvious obstruction to spontaneous breathing or who require positive-pressure ventilation," (p.e1402).

Only three of the included studies included infants with meconium-stained amniotic fluid. Kelleher 2013 included vigorous term infants with and without meconium-stained amniotic fluid but did not report results separately for the two groups; the authors concluded that overall wiping of the mouth and nose of neonates immediately after birth was as effective as postpartum bulb oro/nasopharyngeal suctioning. Nangia 2015 included vigorous (85%) and non-vigorous (15%) term infants with meconium-stained amniotic fluid and found no benefit of intra-partum oropharyngeal suctioning in vigorous infants. All of the non-vigorous infants received endotracheal suctioning. Vain 2004 studied vigorous and non-vigorous term infants and concluded that even infants at highest risk for meconium-aspiration syndrome such as non-vigorous infants born through the thickest-consistency meconium did not benefit from intrapartum catheter suctioning. The authors stated that the study was not powered for the assessment of outcomes for this subgroup of infants. A Cochrane review (Halliday 2001) recommended that, until further evidence was available, routine intubation of vigorous term meconium-stained babies to aspirate the lungs should be abandoned. The authors concluded that suctioning of the oropharynx may be beneficial but endotracheal intubation should be reserved for depressed or non-vigorous infants, or those who developed signs of respiratory distress following initial assessment. However, this review has found insufficient evidence to warrant oro/nasopharyngeal suctioning of vigorous term infants with meconium-stained amniotic fluid.

Kelleher 2013 suggested that the high rates of contamination, i.e. infants randomised to wiping receiving suctioning showed that staff in the resuscitation area had a preference towards the use of oro/nasopharyngeal suction compared to wiping. Vain 2004 reported that some infants assigned to wiping received oro/nasopharyngeal suction suggesting the primary reason was the obstetrician demanding oro/nasopharyngeal suctioning. Both these studies demonstrated ongoing bias of health professionals towards oro/nasopharyngeal suctioning in the delivery room.

Quality of the evidence

There was low-quality evidence for all the major outcomes. The major factors that affected the quality of evidence was the high risk of performance bias, imprecision, single study, indirectness and high number of non-per-protocol exclusions (Summary of findings for the main comparison).

AUTHORS' CONCLUSIONS

Implications for practice

The currently available evidence does not support or refute the benefits or harms of routine oro/nasopharyngeal suction over no suction in vigorous term infants.

Implications for research

Further high-quality studies are required in preterm newborns, and vigorous and non-vigorous term newborn infants born through thick meconium-stained amniotic fluid. Studies should investigate long-term effects such as neurodevelopmental outcomes.

ACKNOWLEDGEMENTS

None.

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Carrasco 1997 *{published data only}*

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* Indicates the major publication for the study

CHARACTERISTICS OF STUDIES

Characteristics of included studies *[ordered by study ID]*

Carrasco 1997

Methods	A single centre, randomised, prospective controlled trial. Dates when study conducted: Authors did not report on study dates.
Participants	30 infants. Inclusion criteria: Term labour with a single fetus, no maternal or fetal pathologic changes, no medication before or during labour, no evidence of fetal distress, clear amniotic fluid, and vaginal delivery in the cephalic presentation. Exclusion criteria: Infants who did not fit the above criteria.
Interventions	Nasopharynx suctioning immediately after birth (n = 15) versus no nasopharynx suctioning (n = 15). Umbilical cord clamped on delivery, before the first breath of the newborn infant. Suctioning performed with a sterile polyethylene tube (Rusch No.3; 1.8 mm internal diameter; two lateral holes). First the nasopharynx and then both nares were suctioned by introducing the tube not more than 6 cm. The whole procedure lasted between 8 and 10 seconds, and negative pressure did not surpass 30 cmH_2O. After suctioning, the babies in the two groups were cared for in the same way.
Outcomes	Apgar score at 1 and 5 minutes (reported as no of infants who had Apgar score of 7 or > at 1 and 5 minutes). Comparison of minute-to-minute oxygen saturation up to 20 minutes. Time (minutes) to reach 86% and 92% oxygen saturation (mean and SEM). Average SaO_2 value at 1 and 5 minutes.

Carrasco 1997 *(Continued)*

Notes	Power calculation not reported.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	'Fetuses were randomly assigned'. No further information provided
Allocation concealment (selection bias)	Low risk	'Cards taken from an envelope'
Blinding of participants and personnel (performance bias) All outcomes	High risk	No blinding
Blinding of outcome assessment (detection bias) All outcomes	High risk	No blinding
Incomplete outcome data (attrition bias) All outcomes	Low risk	Outcomes reported on all infants
Selective reporting (reporting bias)	Unclear risk	Protocol not available

Gungor 2005

Methods	A single centre, randomised, prospective controlled trial. Dates when study conducted: June 2003 to January 2004.
Participants	140 infants. Inclusion criteria: Nulliparity, term labour with a single fetus, no maternal or fetal pathologic changes during gestation and delivery, no intrapartum medication except epidural analgesia, no evidence of fetal distress, clear amniotic fluid, and spontaneous vaginal delivery in the cephalic presentation. Exclusion criteria: Women who did not fit the above criteria.
Interventions	Oro/nasopharyngeal suctioning immediately after birth (n = 70) versus no oro/nasopharyngeal suctioning (n = 70). In the suction group, oro/nasopharyngeal suction was performed immediately after birth by using a sterile polyethylene tube (8 ch -2, 67 mm, closed end, double hole, Bicakcilar A.S. Istanbul/Turkey) and negative pressure did not exceed 30 cmH_2O. The only intervention in the no suction group was to wipe away any visible matter.
Outcomes	Time to reach 92% and 86% oxygen saturation. Apgar score at 1 minute and 5 minutes (reported as no with Apgar score of 8 or 9 at 1 minute and Apgar of 10 at 5 minutes) Heart rate at 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11 minutes (mean and SD) Time to reach > 92% and > 86% at 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11 minutes (percentage)

Gungor 2005 *(Continued)*

	Need for oxygen (no.) Need for neonatal intensive care unit admission (no.)
Notes	Power calculation: "Calculations revealed that a minimum of 67 infants were needed in each group to demonstrate such a difference, at Alpha 0.05, Beta 0.10, and power 80%".

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Computer-generated random numbers
Allocation concealment (selection bias)	Low risk	Sealed envelopes
Blinding of participants and personnel (performance bias) All outcomes	High risk	No blinding in labour ward. "All investigators, as well as residents and nurses who subsequently cared for the infant outside the delivery room, were unaware of the individual treatment group assignment".
Blinding of outcome assessment (detection bias) All outcomes	High risk	No blinding
Incomplete outcome data (attrition bias) All outcomes	Low risk	Outcomes reported for all enrolled infants
Selective reporting (reporting bias)	Unclear risk	Protocol not available. The result for the outcome 'need for neonatal intensive care' not reported as stated in the method section of the article.

Gungor 2006

Methods	A single centre, randomised, prospective controlled trial. Dates when study conducted: February 2004 to October 2004.
Participants	140 infants. Inclusion criteria: Pregnant women who underwent elective repeat caesarean section in term gestation, with a single fetus, and no maternal or fetal pathologic changes during gestation. Exclusion criteria: Infants who did not fit the above criteria.
Interventions	Oro/nasopharyngeal suctioning immediately after birth (n = 70) versus no oro/nasopharyngeal suctioning (n = 70) Oro/nasopharyngeal suctioning was performed by a sterile polyethylene tube (8 Ch 2.67 mm, closed end, double hold, Bicakcilar, Istanbul) immediately after birth, whenever possible before the first breath to prevent aspiration of oronasal secretions in the suction group. The whole procedure lasted less than 15 seconds, and negative pressure did not exceed 30 cmH_2O. The only intervention in the no suction group was to wipe away any visible matter.

Gungor 2006 *(Continued)*

Outcomes	Time to reach 92% oxygen saturation at 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11 minutes (mean and SD) Proportion of groups to reach 92% and 86% oxygen saturation at 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11 minutes (%) Heart rate at 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11 minutes (mean and SD) Apgar scores 1 minute and 5 minutes (mean and SD)
Notes	Power calculation: "Calculations revealed that a minimum of 67 infants were needed in each group to demonstrate such a difference, at Alpha 0.05, Beta 0.10, and power 80%".

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Computer-generated random numbers
Allocation concealment (selection bias)	Low risk	Sealed envelopes
Blinding of participants and personnel (performance bias) All outcomes	High risk	No blinding in operating room. All investigators, as well as residents and nurses who subsequently cared for the infant outside the operating room, were unaware of the individual treatment group assignment.
Blinding of outcome assessment (detection bias) All outcomes	High risk	No blinding
Incomplete outcome data (attrition bias) All outcomes	Low risk	Outcomes reported for all enrolled infants.
Selective reporting (reporting bias)	Unclear risk	Protocol not available.

Kelleher 2013

Methods	A single centre, randomised, prospective controlled trial. Dates when study conducted: October 2010 to November 2011.
Participants	506 infants. Inclusion criteria: Neonates born at or after 35 completed weeks gestation. Exclusion criteria: Known major congenital anomalies, decision to institute comfort care, anticipated advanced resuscitation, non-vigorous neonates with meconium-stained amniotic fluid, previous enrolment in other delivery-room intervention studies. Neonates were deemed non-vigorous at birth if they had depressed muscle tone or respiration, heart rate < 100 beats per minute, or both.
Interventions	Suctioning of mouth and nostrils with bulb syringe immediately after umbilical cord (n = 242) versus no suctioning and wiping over face, mouth and nose with a towel (n = 246). Neonates underwent gentle wiping externally over the face, mouth (at the discretion of the obstetric or paediatric resident), and nose with a towel (wipe group) or suction in the mouth and nostrils with

Kelleher 2013 *(Continued)*

	a bulb syringe. Wiping or suction were applied immediately after the cord was cut and for as long as a neonate remained in the resuscitation area. In the wipe group, if copious secretions were seen coming from the mouth, the baby's head was turned to the side to facilitate clearance. Neonates who were non-vigorous with meconium-stained amniotic fluid were intubated, airways were cleared with a meconium aspirator, and they were excluded from the trial.
Outcomes	Respiratory rate in the first 24 hours after birth (mean and SD). Respiratory rates in the first 24 hours after birth at 1 hour, 8 hours, 16 hours and 24 hours (mean and SD). Apgar score at 1 and 5 minutes (median and IQR). Oxygen saturation at discharge (median and IQR). Advanced resuscitation required at birth by intubation, positive-pressure ventilation, emergent medications, or a combination of these methods (n, %). Tachypnoea: Any respiratory rate value > 60 breaths per minute in first 24 hours (n, %). Neonatal intensive care unit admission (n, %).
Notes	Power calculation: To achieve significance at alpha = 0.05 and power of 80%, a sample size of 211 neonates in each group. Sample size increased 20% to 253 neonates in each study arm.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Computer-generated random-block sequence and 1:1 parallel allocation.
Allocation concealment (selection bias)	Low risk	Group allocations were stored centrally in sequentially numbered sealed envelopes that remained sealed until delivery of the infant.
Blinding of participants and personnel (performance bias) All outcomes	High risk	No blinding.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	The nurses who recorded data for the outcomes after the intervention were masked to the randomisation and pretreatment statuses of neonates.
Incomplete outcome data (attrition bias) All outcomes	High risk	In the oro/nasopharyngeal suction group, 18 infants were excluded: 3 parents withdrew consent and 15 neonates were non-vigorous with meconium-stained fluid, 34 underwent 'wiping' (cross-over) and there were 15 other protocol deviations (loss of randomisation cards). In the 'wipe' group, 64 infants underwent suction (cross-over) and there were 4 other protocol deviations (bulb syringes being accidentally dropped on the floor). The authors stated: "This high proportion of cross-overs (98, 20% of 488 neonates treated), particularly from the wipe group to the suction group, could reflect a bias of staff in the resuscitation area to prefer the use of suction to wiping." Trial outcomes were analysed by intention-to-treat.

Kelleher 2013 *(Continued)*

Selective reporting (reporting bias)	Unclear risk	Protocol available. All outcomes in the protocol and study report were identical except for 'advanced resuscitation'. This outcome in the protocol was described as "need for delivery room resuscitation including suctioning, intubation, positive pressure ventilation, chest compressions, and/or medication". However, the study report stated "Advanced resuscitation required at birth by intubation, positive-pressure ventilation, emergent medications, or a combination of these methods". Thus, suction and chest compressions were not included in the criteria as stated in the study protocol.

Nangia 2015

Methods	A single centre, randomised, prospective controlled trial. Dates when study conducted: June 2008 to January 2009.
Participants	509 infants. Inclusion criteria: Gestation ≥ 37 weeks gestation, meconium-stained amniotic fluid, cephalic presentation, singleton pregnancy. Exclusion criteria: Babies with major congenital malformations (if known antenatally), hydrops fetalis, refusal of consent, chromosomal anomalies.
Interventions	Neonates randomised to the intrapartum oropharyngeal suctioning group (n = 253) were provided oropharyngeal suctioning at the delivery of the head before the delivery of shoulder, using a 10 french suction catheter with suction pressure of 100 mgHg or De Lee's suction trap in event of electricity failure or nonavailability of suction machine. Neonates in the no intrapartum oropharyngeal suctioning group (n = 256) received no suction at the perineum after the delivery of the head before the delivery of anterior shoulder. All infants born through meconium-stained amniotic fluid were assessed by a paediatrician as vigorous or non-vigorous. Neonates who were subsequently found to be non-vigorous in either group were intubated and airways were cleared with a meconium aspirator, but they were not excluded from the trial.
Outcomes	Five minute Apgar score (median, iQR). Mortality (n). NICU admission (n). IPPR at birth (n). Duration of stay in cases admitted to NICU (mean and SD). Hypoxic ischaemic encephalopathy (n). Antibiotics used for suspect and culture proven (n).
Notes	Unpublished study. Protocol No. NCT01328483 (ClinicalTrials.gov). Additional information and data provided by author. Power calculation performed.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Computer-generated sequence variable - block size and 1:1 parallel allocation.

Nangia 2015 *(Continued)*

Allocation concealment (selection bias)	Low risk	Group allocations were stored centrally in sequentially numbered sealed envelopes that remained sealed until delivery of the infant.
Blinding of participants and personnel (performance bias) All outcomes	High risk	No blinding due to the nature of the intervention.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	For the nurses who recorded data only for NICU admissions, the outcomes after intervention were masked to the randomisation and pretreatment statuses of neonates.
Incomplete outcome data (attrition bias) All outcomes	Low risk	All outcome data reported. Trial outcomes were analysed by intention-to-treat.
Selective reporting (reporting bias)	Low risk	Protocol available. All outcomes in the protocol and data provided by the author were identical.

Nejad 2014

Methods	Single centre randomised controlled trial. Dates when study conducted: authors did not report on study dates.
Participants	170 infants. Inclusion criteria: Healthy term infants of first and single uncomplicated pregnancies, with clear amniotic fluid, vaginal delivery and cephalic presentation. Exclusion criteria: Maternal or fetal pathological changes, medication before or during labour and evidence of fetal distress.
Interventions	Oro/nasopharyngeal suction (n = 85) versus no suction (n = 85). In the suctioned group, this was performed immediately (< 15 seconds) after birth by using a sterile polyethylene tube, and negative pressure that did not surpass 30 cmH_20. In the no suction group, the intervention was only to remove any visible material. pH, partial pressure carbon dioxide pressure (PCO_2) and partial oxygen pressure (PO_2) were determined in umbilical arterial samples. After aspiration, the newborns were separated into the two groups, were left under radiant heat and received standard care.
Outcomes	Time to reach 92% SaO_2 (mean and SD). Apgar scores at 1 minute and 5 minutes (mean and SD). SaO_2 values at 1, 2, 3, 4, 5, 9, 10 and 11 minutes (mean and SD).
Notes	Study size was calculated based on the calculation of Gungor et al (2006) and 15% was added to that value for dropout cases.

Risk of bias

Bias	Authors' judgement	Support for judgement

Nejad 2014 *(Continued)*

Random sequence generation (selection bias)	Unclear risk	"Newborns were randomised to either ONPS group or the no suction group". No other information was reported.
Allocation concealment (selection bias)	Unclear risk	Not reported.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not reported.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not reported.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Outcomes reported for all enrolled infants.
Selective reporting (reporting bias)	Unclear risk	Protocol not available.

Vain 2004

Methods	A multicentre, randomised, prospective controlled trial. Dates when study conducted: March 13, 2000 to October 1, 2001.
Participants	2514 infants. Inclusion criteria: Birth through meconium-stained amniotic fluid, gestational age of 37 weeks or longer, cephalic presentation (vaginal and caesarean section). Exclusion criteria: major congenital malformations, inability to randomise before delivery, refusal by the obstetrician to allow his or her patients to participate.
Interventions	Oro/nasopharyngeal suctioning immediately after birth (n = 1263) versus no oro/nasopharyngeal suctioning (n = 1251). In infants in the suction group, intrapartum suctioning was undertaken before delivery of the shoulders with an appropriately sized suction catheter (10 Fr to 13 Fr) connected to a negative pressure of 150 mmHg. Oropharyngeal suctioning was done first, followed by bilateral nasopharyngeal suctioning, when possible. This technique was used in infants born both vaginally and by caesarean section. No pharyngeal suctioning was undertaken after delivery unless airway obstruction was clinically apparent.
Outcomes	Meconium aspiration syndrome (MAS) defined by respiratory distress (tachypnoea, retractions, or grunting) in a neonate born through meconium-stained amniotic fluid (n, %). Need for supplemental oxygen to maintain oxygen saturation levels at 92% or greater (n, %). Oxygen requirements starting during the first 2 hours of life and lasting for 12 hours or longer (n, %). Mortality (n, %). Severe meconium aspiration syndrome (need for mechanical ventilation) (n, %). Pneumothorax (n, %). Duration of oxygen treatment - days (mean and SD).

Vain 2004 *(Continued)*

	Need for endotracheal intubation, suction and positive pressure ventilation in the delivery room (n, %). Apgar scores at 1 and 5 minutes (range). Duration of mechanical ventilation (days) in infants with meconium aspiration syndrome (mean and SD). Duration of hospital care (days) in infants with meconium aspiration syndrome (mean and SD).
Notes	Power calculation: Sample size analysis revealed that at least 2286 participants (1143 per group) needed to be enrolled in the trial to fulfil statistical equivalence between suction and no suction groups. Data provided for high-risk groups but not powered for assessment of subgroups.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Computer-generated random numbers. Infants were randomly allocated to the groups before delivery of the shoulders.
Allocation concealment (selection bias)	Low risk	Group assignments were drawn from consecutively numbered, sealed, opaque envelopes, which were opened immediately before attendance at deliveries complicated by meconium-staining by the neonatologist in charge of the resuscitation.
Blinding of participants and personnel (performance bias) All outcomes	High risk	No blinding in delivery room. All investigators, as well as clinicians who subsequently cared for the infant outside of the delivery room, were unaware of individual treatment group assignments and any trial results during the study.
Blinding of outcome assessment (detection bias) All outcomes	High risk	No blinding of outcome assessment for Apgars and need for resuscitation; Blinding of outcome assessment thereafter.
Incomplete outcome data (attrition bias) All outcomes	Low risk	18 infants in the suction group and 15 in the no suction group (n = 33) did not meet the entry criteria after random assignment (< 10% attrition). In the suction group, 87 infants were not suctioned "because the caregiver arrived late or an unexpected failure in the suction system occurred". In the no suction group, 26 infants were suctioned "mostly because the obstetrician demanded suctioning as the child's head was being delivered" (<10% attrition). Trial outcomes were analysed by intention-to-treat.
Selective reporting (reporting bias)	Unclear risk	Protocol not available.

Waltman 2004

Methods	A single centre, randomised, prospective controlled pilot trial. Dates when study conducted: authors did not report on study dates.
Participants	20 infants. Inclusion criteria: Singleton gestation, term pregnancy (37 to 42 weeks gestation), cephalic presentation, vaginal delivery, ruptured membranes < 18 hours, clear amniotic fluid, no known fetal or maternal morbidity, uncomplicated labour course.

Waltman 2004 *(Continued)*

	Exclusion criteria: Any contradictions to vaginal delivery, significant nonremedial variable or late decelerations, prolonged rupture of membranes, meconium-stained amniotic fluid, suspected maternal chorioamnionitis, any delivery emergency (i.e. shoulder dystocia).
Interventions	Oro/nasopharyngeal bulb syringe suctioning (n = 10) versus no oro/nasopharyngeal bulb syringe suctioning (n = 10). Infants in the suction group received oro/nasopharyngeal bulb suctioning by the attending obstetric resident when the head was delivered. First the mouth and then the nares were suctioned with a bulb syringe, one time each. The bulb was compressed to squeeze out the air, and then the tip was gently placed in the mouth, approximately 1.5 inches deep, and finger pressure was slowly released, allowing the mucus and fluid to be drawn into the bulb syringe. Following this, the compressed bulb syringe was placed in each naris approximately at 0.5 inches. Infants in the no suction group did not receive bulb syringing. All infants had their mouth and nose wiped with a towel if any visible matter was present. In the suction group, this was done prior to bulb suctioning. After drying the infant, the nursery nurse positioned the infant in the warmer, and a single-pass bulb suctioning of the mouth and nose was again performed on infants in the suction group.
Outcomes	Apgar scores at 1, 5 minutes, 10 minutes (mean, SD combined for both groups). Apgar scores < 9 at 1, 5, 10 minutes (n). Heart rate (mean, SD combined for both groups). Average change in heart rate over time (5 to 20 minutes after birth). Average changes in oxygen saturation over time (5 to 20 minutes after birth). Need for supplemental oxygen (n).
Notes	Power calculation: Not undertaken and reported as a pilot study. Authors stated: "The power to detect statistically significant differences is low due to the small sample size".

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	"Randomised controlled trial with a two-group design". No further information provided.
Allocation concealment (selection bias)	Unclear risk	No information provided.
Blinding of participants and personnel (performance bias) All outcomes	High risk	No blinding.
Blinding of outcome assessment (detection bias) All outcomes	High risk	No blinding.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Outcomes reported for all enrolled infants.
Selective reporting (reporting bias)	Unclear risk	Protocol not available.

Characteristics of excluded studies *[ordered by study ID]*

Study	Reason for exclusion
Chettri 2015	Endotracheal suction.
Choi 2010	Setting not specific to the delivery room.
Cordero 1971	Nonrandomised controlled trial.
Czarnecki 1999	Nonrandomised controlled trial. Setting not specific to the delivery room.
Estol 1992	Randomised controlled trial but outcome measures related to respiratory mechanics.
Pichler 2010	Randomised controlled trial but outcome measures related to regional tissue oxygenation of the brain and preductal and postductal peripheral tissue. Heart rate and pre and postductal arterial oxygen saturation.
Wiswell 2000	Intervention: Intubation and suctioning for meconium-stained amniotic fluid.

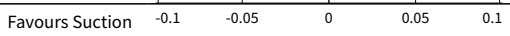
DATA AND ANALYSES

Comparison 1. Oro/nasopharyngeal suction versus no suction

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Mortality (before discharge)	2	3023	Risk Difference (M-H, Fixed, 95% CI)	0.01 [-0.00, 0.01]
2 Mortality - thick consistency MSAF (before discharge)	1	319	Risk Ratio (M-H, Fixed, 95% CI)	1.85 [0.45, 7.63]
3 Need for resuscitation	5	3791	Risk Difference (M-H, Fixed, 95% CI)	-0.01 [-0.03, 0.00]
4 Need for resuscitation - thick consistency MSAF	1	319	Risk Ratio (M-H, Fixed, 95% CI)	1.39 [0.56, 3.43]
5 Admission to NICU	2	997	Risk Ratio (M-H, Fixed, 95% CI)	0.82 [0.62, 1.08]
6 Apgar score 5 minutes	3	330	Mean Difference (IV, Fixed, 95% CI)	-0.03 [-0.08, 0.02]
7 Length of hospital stay (days)	2	602	Mean Difference (IV, Fixed, 95% CI)	-0.40 [-1.14, 0.33]
8 Hypoxic Ischaemic encephalopathy	1	509	Risk Ratio (M-H, Fixed, 95% CI)	0.76 [0.33, 1.77]
9 Infection	1	509	Risk Ratio (M-H, Fixed, 95% CI)	0.76 [0.42, 1.36]

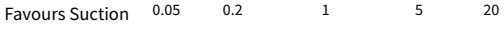
Analysis 1.1. Comparison 1 Oro/nasopharyngeal suction versus no suction, Outcome 1 Mortality (before discharge).

Study or subgroup	Suction n/N	No Suction n/N	Risk Difference M-H, Fixed, 95% CI	Weight	Risk Difference M-H, Fixed, 95% CI
Nangia 2015	7/253	3/256		16.84%	0.02[-0.01,0.04]
Vain 2004	9/1263	4/1251		83.16%	0[-0,0.01]
Total (95% CI)	**1516**	**1507**		**100%**	**0.01[-0,0.01]**
Total events: 16 (Suction), 7 (No Suction)					
Heterogeneity: Tau^2=0; Chi^2=1.16, df=1(P=0.28); I^2=13.94%					
Test for overall effect: Z=1.89(P=0.06)					



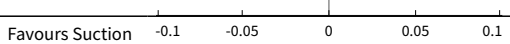
Analysis 1.2. Comparison 1 Oro/nasopharyngeal suction versus no suction, Outcome 2 Mortality - thick consistency MSAF (before discharge).

Study or subgroup	Suction n/N	No Suction n/N	Risk Ratio M-H, Fixed, 95% CI	Weight	Risk Ratio M-H, Fixed, 95% CI
Vain 2004	5/151	3/168		100%	1.85[0.45,7.63]
Total (95% CI)	**151**	**168**		**100%**	**1.85[0.45,7.63]**
Total events: 5 (Suction), 3 (No Suction)					
Heterogeneity: Not applicable					
Test for overall effect: Z=0.86(P=0.39)					

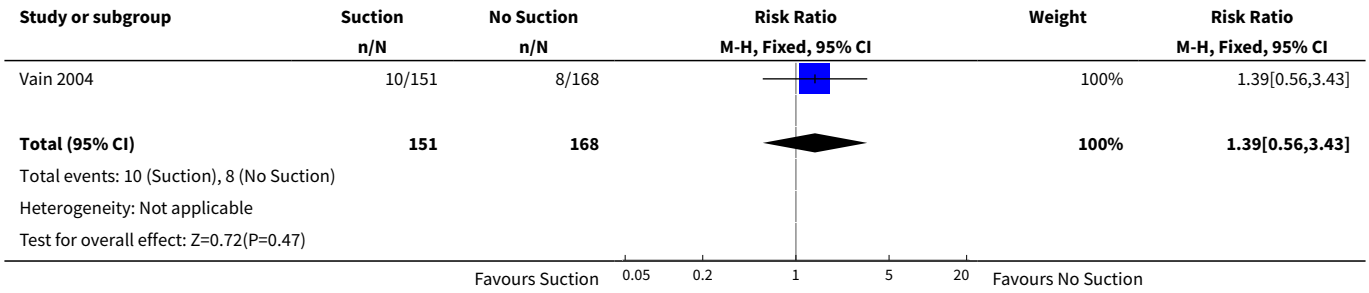


Analysis 1.3. Comparison 1 Oro/nasopharyngeal suction versus no suction, Outcome 3 Need for resuscitation.

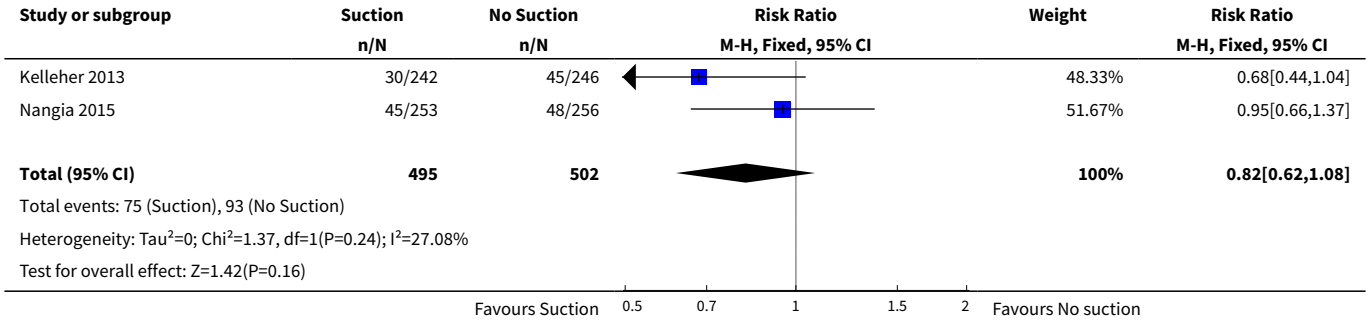
Study or subgroup	Suction n/N	No Suction n/N	Risk Difference M-H, Fixed, 95% CI	Weight	Risk Difference M-H, Fixed, 95% CI
Gungor 2005	0/70	0/70		3.69%	0[-0.03,0.03]
Gungor 2006	0/70	0/70		3.69%	0[-0.03,0.03]
Kelleher 2013	17/242	24/246		12.87%	-0.03[-0.08,0.02]
Nangia 2015	18/253	28/256		13.43%	-0.04[-0.09,0.01]
Vain 2004	106/1263	113/1251		66.32%	-0.01[-0.03,0.02]
Total (95% CI)	**1898**	**1893**		**100%**	**-0.01[-0.03,0]**
Total events: 141 (Suction), 165 (No Suction)					
Heterogeneity: Tau^2=0; Chi^2=3.35, df=4(P=0.5); I^2=0%					
Test for overall effect: Z=1.46(P=0.14)					



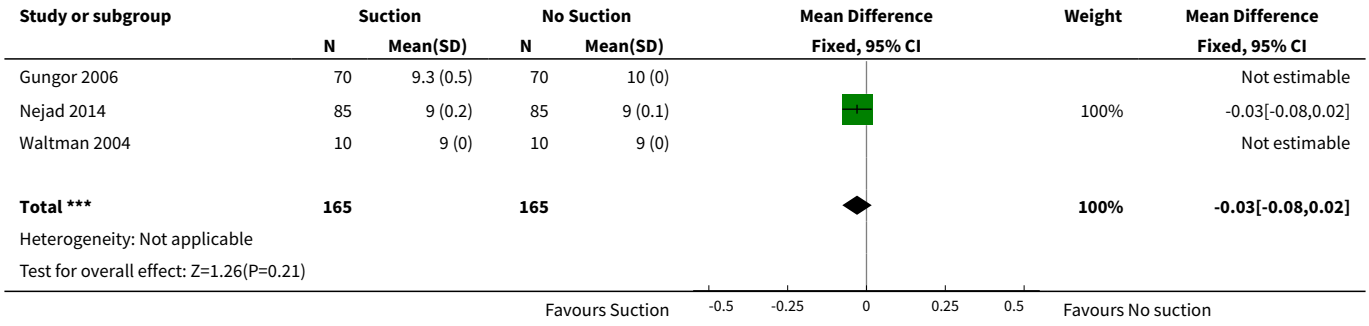
Analysis 1.4. Comparison 1 Oro/nasopharyngeal suction versus no suction, Outcome 4 Need for resuscitation - thick consistency MSAF.



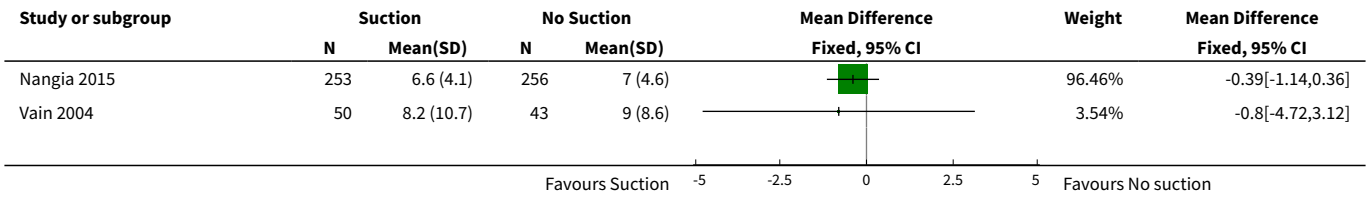
Analysis 1.5. Comparison 1 Oro/nasopharyngeal suction versus no suction, Outcome 5 Admission to NICU.

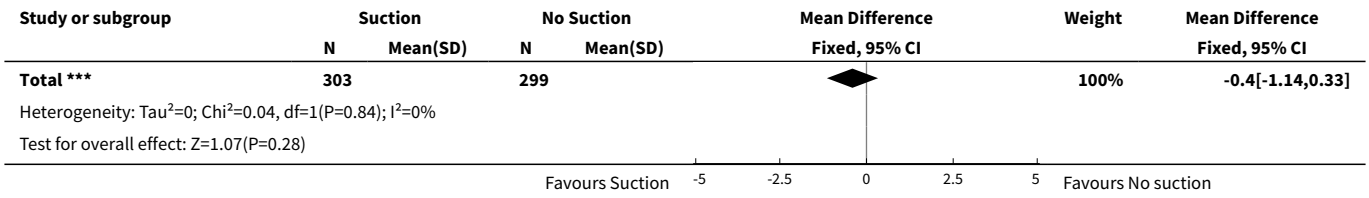


Analysis 1.6. Comparison 1 Oro/nasopharyngeal suction versus no suction, Outcome 6 Apgar score 5 minutes.

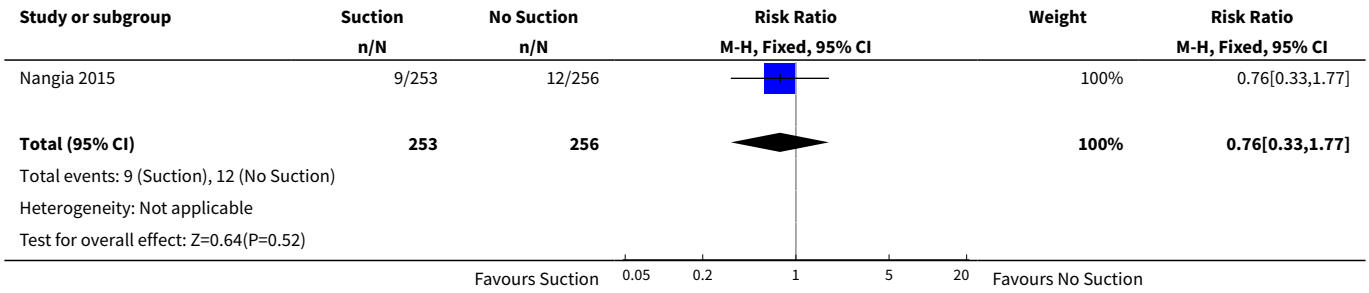


Analysis 1.7. Comparison 1 Oro/nasopharyngeal suction versus no suction, Outcome 7 Length of hospital stay (days).

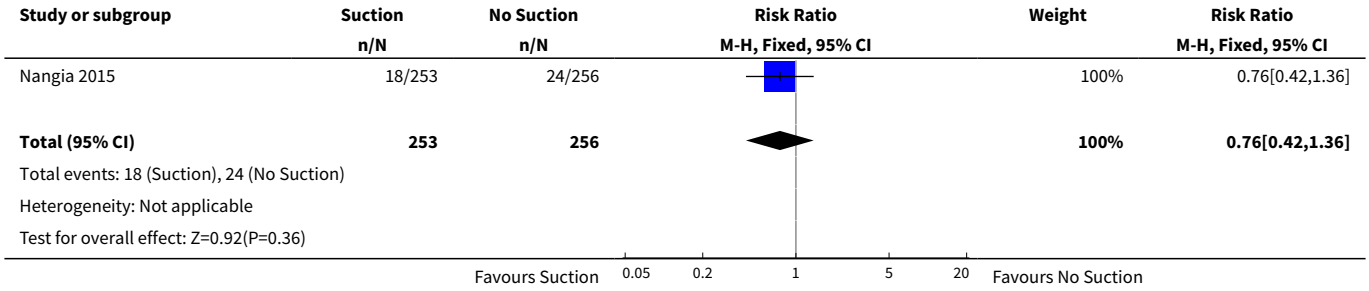




Analysis 1.8. Comparison 1 Oro/nasopharyngeal suction versus no suction, Outcome 8 Hypoxic Ischaemic encephalopathy.



Analysis 1.9. Comparison 1 Oro/nasopharyngeal suction versus no suction, Outcome 9 Infection.



APPENDICES

Appendix 1. Standard search methodology

PubMed: ((infant, newborn[MeSH] OR newborn OR neonate OR neonatal OR premature OR low birth weight OR VLBW OR LBW or infan* or neonat*) AND (randomized controlled trial [pt] OR controlled clinical trial [pt] OR Clinical Trial[ptyp] OR randomized [tiab] OR placebo [tiab] OR clinical trials as topic [mesh: noexp] OR randomly [tiab] OR trial [ti]) NOT (animals [mh] NOT humans [mh]))

Embase: (infant, newborn or newborn or neonate or neonatal or premature or very low birth weight or low birth weight or VLBW or LBW or Newborn or infan* or neonat*) AND (human not animal) AND (randomized controlled trial or controlled clinical trial or randomized or placebo or clinical trials as topic or randomly or trial or clinical trial)

CINAHL: (infant, newborn OR newborn OR neonate OR neonatal OR premature OR low birth weight OR VLBW OR LBW or Newborn or infan* or neonat*) AND (randomized controlled trial OR controlled clinical trial OR randomized OR placebo OR clinical trials as topic OR randomly OR trial OR PT clinical trial)

Cochrane Library: (infant or newborn or neonate or neonatal or premature or very low birth weight or low birth weight or VLBW or LBW)

CONTRIBUTIONS OF AUTHORS

Jennifer Dawson, Jann Foster and Peter Davis wrote the protocol. Jann Foster and Jennifer Dawson conducted the literature search, extracted the data and conducted the analyses and wrote the review.

Peter Davis and Hannah Dahlen provided comments on the review.

DECLARATIONS OF INTEREST

None.

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DIFFERENCES BETWEEN PROTOCOL AND REVIEW

None.

INDEX TERMS

Medical Subject Headings (MeSH)

*Amniotic Fluid; *Meconium; *Nasopharynx; *Oropharynx; Brain Ischemia [epidemiology]; Infant Mortality; Infections [epidemiology]; Intensive Care Units, Neonatal [statistics & numerical data]; Intention to Treat Analysis; Randomized Controlled Trials as Topic; Resuscitation [statistics & numerical data]; Suction [adverse effects] [instrumentation] [*methods]

MeSH check words

Humans; Infant; Infant, Newborn