

Endotracheal intubation at birth for preventing morbidity and mortality in vigorous, meconium-stained infants born at term (Review)

Halliday HL, Sweet D



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ABSTRACT

Background

On the basis of evidence from non-randomised studies, it has been recommended that all babies born through thick meconium should have their tracheas intubated so that suctioning of their airways can be performed. The aim is to reduce the incidence and severity of meconium aspiration syndrome. However, for term babies who are vigorous at birth endotracheal intubation may be both difficult and unnecessary.

Objectives

To determine if endotracheal intubation and suction of the airways at birth in vigorous term meconium-stained babies is more beneficial than routine resuscitation including aspiration of the oro-pharynx.

Search strategy

The search was made from Oxford Database of Perinatal Trials, Cochrane Controlled Trials Register (The Cochrane Library, Issue 3, 2002), MEDLINE from 1966 to September 2002, and information obtained from knowledgeable practising neonatologists.

Selection criteria

Randomised trials which compared a policy of routine vs no (or selective) use of endotracheal intubation and aspiration in the immediate management of vigorous term meconium-stained babies at birth.

Data collection and analysis

Data regarding clinical outcomes including mortality, meconium aspiration syndrome, other respiratory conditions, pneumothorax, need for oxygen supplementation, stridor, convulsions and hypoxic-ischaemic encephalopathy were abstracted and analysed using Revman 4.1.

Main results

Four randomised controlled trials of endotracheal intubation at birth in vigorous term meconium-stained babies were identified. Meta-analysis of these trials does not support routine use of endotracheal intubation at birth in vigorous meconium-stained babies to reduce mortality, meconium aspiration syndrome, other respiratory symptoms or disorders, pneumothorax, oxygen need, stridor, HIE and convulsions. However, the event rates of many of these outcomes is low in the reported trials making reliable estimates of treatment effect impossible.

Authors' conclusions

Routine endotracheal intubation at birth in vigorous term meconium-stained babies has not been shown to be superior to routine resuscitation including oro-pharyngeal suction. This procedure cannot be recommended for vigorous infants until more research is available.

PLAIN LANGUAGE SUMMARY

Synopsis pending.

BACKGROUND

Three non-randomised studies have suggested that careful aspiration of the airway at birth reduces both the incidence and severity of meconium aspiration syndrome (Gregory 1974; Ting 1975; Carson 1976). These authors have suggested that when thick meconium staining has occurred the obstetrician should suck out the mouth as the head crowns, using either a suction catheter or a bulb suction. Gregory et al found that 56% of meconium stained infants had meconium in the trachea, and in 10% there was meconium below the cords despite it being absent from the mouth or pharynx. Intubation of the tracheas of meconium stained babies at birth has been advocated by these authors as a means of preventing or ameliorating severe meconium aspiration syndrome.

Intubation of the trachea in an active term or post-term baby with meconium staining may be difficult and in many cases unnecessary. Four randomised studies have examined the role of routine intubation and airway aspiration of meconium stained babies.

OBJECTIVES

The objective of this overview is to examine the relative benefits and adverse effects associated with routine intubation of the trachea in vigorous meconium stained term infants.

CRITERIA FOR CONSIDERING STUDIES FOR THIS REVIEW

Types of studies

Randomised controlled clinical trials comparing a policy of endotracheal intubation and airway suction at birth with routine resuscitation including oro-pharyngeal aspiration in vigorous term meconium-stained babies were considered for this review.

Types of participants

Full-term babies with meconium staining but who were not obviously asphyxiated at birth.

Types of intervention

Infants were randomly allocated to receive endotracheal intubation and airway aspiration at birth or to have routine resuscitation as determined by the paediatrician in attendance.

Types of outcome measures

Clinical outcome measures included: mortality, meconium aspiration syndrome, respiratory symptoms (including other respira-

tory disorders), pneumothorax, need for oxygen, stridor, hypoxic-ischaemic encephalopathy and convulsions.

SEARCH METHODS FOR IDENTIFICATION OF STUDIES

See: methods used in reviews.

Randomised studies of endotracheal intubation and suction in meconium stained neonates were sought from the Oxford Database of Perinatal Trials, the Cochrane Controlled Trials Register (The Cochrane Library, Issue 3, 2002, MEDLINE (searched from 1966 to September 2002) using meconium aspiration and endotracheal intubation or airway suctioning with limits: randomised controlled trial, human and age 0-1 month, and from information obtained from practising neonatologists.

METHODS OF THE REVIEW

For each included trial information was sought regarding the method of randomisation, blinding, stratification and whether the trial was single or multicentered. Information on the trial participants included birthweight, gestational age, gender, presentation and antenatal complications. Information on clinical outcomes was analysed for mortality, meconium aspiration syndrome, respiratory symptoms (including other respiratory disorders), pneumothorax, need for oxygen, stridor, hypoxic-ischaemic encephalopathy and convulsions. Meta-analysis of the included trials was performed using Revman 4.1

DESCRIPTION OF STUDIES

Linder 1988 included 572 meconium stained babies who met the following criteria: gestational age > 37 weeks, birthweight > 2500 g, normal vaginal delivery, one minute Apgar > 8 and breathing spontaneously before being handed over to the paediatrician. Suction of the baby's mouth and nose with a catheter was performed while the head was on the perineum. Half of the team of paediatricians who participated in the study were to intubate and suction all meconium stained babies during their attendance at birth whilst the other half was instructed to refrain from doing so. Randomisation of the paediatricians was based upon the alphabetic order of their names. All the paediatricians were skilled in neonatal resuscitation, having at least 3 years of paediatric experience. On the days when paediatricians not participating in the study were

on duty, the babies born with meconium staining were routinely intubated and had airway aspiration. These babies were included in the intervention group. Aspiration of the upper and lower airways was performed by a paediatrician using a 2.5 or 3.0 mm oro-tracheal tube. Suction was continued during tube removal, and if the tracheal aspirate continued to contain meconium the procedure was repeated until clear airways were established. Meconium aspiration was diagnosed if meconium staining of the amniotic fluid was accompanied by neonatal oxygen dependency and a consistent radiographic picture.

Daga 1994 examined the outcome of 49 babies born with thick meconium staining of the amniotic fluid. These were consecutively born infants who had passed meconium in utero and were not asphyxiated at birth. They were randomly allocated to either oro-pharyngeal suction or combined oro-pharyngeal and tracheal suction. All of the babies were admitted to a neonatal intensive care unit for observation.

Liu 1998 was designed to determine if intubation of the low risk term newborn born through thin meconium affects the incidence of respiratory symptoms. Exclusion criteria included moderate (particulate) or thick ("pea-soup") meconium, fetal distress, clinical neonatal depression, prematurity (< 37 weeks), suspected intrauterine growth retardation, maternal drug abuse or maternal hypertensive disorders. Neonatal depression was defined as a hypotonic newborn who was not initiating adequate respiratory effort after 15 seconds of routine delivery room management. Non-medical exclusion criteria included: the attending obstetrician requested that the newborn not be intubated, maternal refusal of consent or late arrival of the team. Eligible infants were randomised to either an intubation group or to a non-intubation group. Infants in the intubation group were intubated with a 3.0 or 3.5 mm endotracheal tube and suctioned with a 6.0 or a 8.0 Fr suction catheter. Suction was set at 100 mmHg and was continued until clear, as tolerated. Saline lavage with sterile normal saline was initiated at the team's discretion. In these cases a minimum amount of 0.25-0.50 mL was used as needed. Finally a meconium aspirator was placed on the endotracheal tube and suction applied as the tube was removed. Management of the non-intubation group included: oronasopharyngeal suction with a bulb syringe and supplemental oxygen as clinically indicated. The outcome measurements were respiratory symptoms and the need for supplemental oxygen. 169 infants were enrolled in the study.

Wiswell 2000 included infants fulfilling the following criteria: 1) Gestation of 37 weeks or greater 2) Meconium presence in the amniotic fluid and 3) Apparent vigour immediately after birth (heart rate > 100, spontaneous respirations, reasonable tone). The degree of vigour was assessed within the first 10-15 seconds after delivery. Meconium staining of the amniotic fluid could be of any consistency. Meconium aspiration syndrome was defined as respiratory distress with consistent radiographic findings and clinical signs that could not be otherwise explained. The obstetric

policy was to suction the oro-pharynx of each meconium stained neonate prior to delivery of the infant's shoulders or trunk. Prior to delivery subjects were randomised either to intubation and intratracheal suctioning or to expectant management. Computer generated random numbers were used for assignment to these groups and group selection was determined by opening a sealed opaque envelope. When a neonate did not meet the criteria for apparent vigour the infant was excluded from the study and the randomisation assignment was discarded. A Neotech aspirator was used to suction the endotracheal tube using wall suction set at 80 to 120 mmHg negative pressure. Suction was applied continuously for 1-5 seconds as the endotracheal tube was withdrawn. If meconium was suctioned from the trachea, the procedure was repeated until no further meconium stained fluid could be retrieved. Infants randomised to the expectant group had routine delivery room care. If following initial stabilisation and assessment these babies showed signs of respiratory distress the birth attendants could intubate and suction the airways if they felt it was clinically indicated. 2094 apparently vigorous infants were enrolled from the 12 participating centres.

METHODOLOGICAL QUALITY

Linder 1988 - Imperfect randomisation based upon the alphabetic order of the attending paediatrician's name. Note inclusion of babies who were born on days when participating paediatricians were not on duty in the intubation group.

Daga 1994 - The method of randomisation is not stated. Description of the interventions is scanty.

Liu 1998 - There was random allocation of the intervention but the method is not described in either the abstract (Liu, *Pediatr Res* 1998) or the full paper. 163 infants fulfilled the criteria for entry but were not randomised due to lack of consent, late arrival of the team or obstetrician request. The obstetricians and other staff were aware of the study but were unaware of the patient randomisation in the delivery room. The NICU team was aware of the randomisation. Informed consent was obtained prior to delivery. There may have been some blinding of outcome assessment, but this is difficult to determine.

Wiswell 2000 - The intervention was randomly allocated prior to birth by opening opaque sealed envelopes. Outcome data were collected on a standardised form which was sent to a central unit for entry into a database. All investigators remained blinded until completion of the trial.

RESULTS

Linder 1988 - six babies in the airway aspiration group had respiratory complications, meconium aspiration in four, and stridor in

two. There were no respiratory complications in the conservatively managed group and no deaths in either group.

Daga 1994 - one neonate who had received oro-pharyngeal and tracheal suction died. Three babies developed pneumothorax requiring intercostal drainage; one in the tracheal suction group and two in the oro-pharyngeal suction group. Four babies developed convulsions, three of them in the tracheal suction group, one of whom developed hypoxic-ischaemic encephalopathy.

Liu 1998 - 2 of the 77 infants in the intubation group developed respiratory symptoms and one of these needed oxygen, compared to 1 of 92 infants in the non-intubation group who developed symptoms but did not need oxygen. The intubation group had significantly lower 1 minute Apgar scores but 5 minute Apgar scores were similar. There was no reported airway morbidity associated with intubation.

Wiswell 2000 - 34 of 1051 infants in the intubation group developed meconium aspiration syndrome compared to 28 of 1043 in the expectant management group. 40 of 1051 babies in the intubated group compared to 47 of 1043 of the expectant group developed "other" respiratory disorders. Five deaths occurred: 2 in the intubated and 3 in the expectant group. 17 of 1051 infants in the intubated group were not intubated for several reasons, most commonly excessively difficult intubation. 64 of 1043 babies in the expectant group were intubated after the initial assessment period because they developed clinical signs which included respiratory distress, poor respiratory effort and evidence of meconium blocking the airway. Of the 1098 successfully intubated infants (1034 from the intubated group and 64 from the expectant group), 42 (3.8%) had a total of 51 complications of the procedure which included bradycardia, laryngospasm and hoarseness but most were transient lasting 15-60 seconds.

Meta-analysis of these four studies showed the following:

- Mortality - there was no evidence that endotracheal intubation at birth had an effect on mortality (typical relative risk, 1.73, 95% CI 0.37, 8.1; number of studies 4, number of infants 2884), but the number of deaths reported was very low (4 and 2 respectively).
- Meconium aspiration syndrome - there was no evidence that endotracheal intubation reduced this outcome (typical relative risk, 1.29, 95% CI 0.80, 2.08; n=4 and 2884 respectively), but the total number of observed cases was relatively low (37 and 28 respectively).
- Other respiratory symptoms or disorders - there was no evidence that intubation affected the incidence of this outcome (typical relative risk 0.87, 95% CI 0.58, 1.31; n= 2 and 2763).
- Pneumothorax - no evidence of an effect of intubation on this outcome (typical relative risk 0.87, 95% CI 0.16, 4.92; n=2 and 621), but only four cases of pneumothorax occurred (2 and 2 respectively).

- Oxygen need - no evidence of an effect of intubation on this outcome (typical relative risk 1.49, 95% CI 0.86, 2.60; n=3 and 790).
- Stridor - there was no evidence of effect on stridor, but there were too few cases of stridor (2 and 0 respectively) in these trials to provide a reliable estimate of treatment effect (relative risk 4.29, 95% CI 0.21, 88.9; n=1 and 572).
- Convulsions - there was no evidence of effect on convulsions but there were too few cases of convulsions in these trials to provide a reliable estimate of treatment effect (relative risk 2.65, 95% CI 0.30, 23.8; n=1 and 49).
- Hypoxic-ischaemic encephalopathy - there was no evidence of effect on hypoxic-ischaemic encephalopathy but there were too few cases of hypoxic-ischaemic encephalopathy in these trials to provide a reliable estimate of treatment effect (relative risk 2.67, 95% CI 0.11, 62.4; n=1 and 49).

DISCUSSION

A number of previous non-randomised studies have suggested that aspiration of the upper and lower airways of babies with significant meconium staining is associated with an improved outcome. Babies in these studies included those who were very depressed at birth and those who were relatively vigorous. Most neonatology text books continue to recommend aspiration of the airways, both upper and lower in cases of thick or particulate meconium staining of the amniotic fluid.

Four randomised studies have addressed the problem of endotracheal intubation of vigorous meconium stained infants born at term. Although there are methodological problems with randomisation in some of these studies there is no evidence that endotracheal intubation and aspiration of the airways in non-asphyxiated meconium-stained babies is beneficial. However it is likely that routine aspiration of the upper airways is beneficial and should not be discarded. For depressed or non-vigorous newborns endotracheal intubation and suctioning should probably still be performed in infants born through meconium stained amniotic fluid, until further research is available.

AUTHORS' CONCLUSIONS

Implications for practice

Until further evidence is available routine intubation of vigorous term meconium stained babies to aspirate the lungs should be abandoned. Suctioning of the oro-pharynx may be beneficial but endotracheal intubation should be reserved for depressed or non-vigorous infants or those who develop signs of respiratory distress following initial assessment.

Implications for research

Further research is needed to define a group of term babies with meconium staining who might benefit from intubation and airway aspiration. Future studies should include unequivocal endpoints such as mortality and independently assessed radiograph reporting. It is clear that a study examining mortality as an outcome would need to be extremely large and with present knowledge might not be justifiable.

POTENTIAL CONFLICT OF INTEREST

None

ACKNOWLEDGEMENTS

None

SOURCES OF SUPPORT

External sources of support

- No sources of support supplied

Internal sources of support

- No sources of support supplied

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References to other published versions of this review

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Halliday 2001

Halliday HL. Endotracheal intubation at birth for prevention of mortality and morbidity in vigorous, meconium-stained infants born at

term (Cochrane Review). *The Cochrane Library* 2001, Issue 1.

*Indicates the major publication for the study

T A B L E S

Characteristics of included studies

Study	Daga 1994
Methods	Random allocation, method not described. Blinding of randomisation : can't tell. Blinding of intervention : no. Complete follow-up : yes. Blinding of outcome measurement : probably no.
Participants	49 consecutively born infants who passed thick meconium in utero and were not asphyxiated at birth were included. The study was conducted between February 1991 and September 1991 when the total number of births during this period was 1322.
Interventions	The treatment group had oropharyngeal suction combined with tracheal suction whereas the control group had only oropharyngeal suction. All babies were admitted to the neonatal intensive care unit for observation.
Outcomes	Mortality, pneumothorax, convulsions, HIE and duration of oxygen administration.
Notes	The figures in the summary do not tally with those in the text or table. Results in the summary have been ignored.
Allocation concealment	B – Unclear

Study	Linder 1988
Methods	Randomised controlled trial but some non-randomised babies were included in intervention group. Blinding of randomisation : no. Blinding of intervention : no. Complete follow-up : yes. Blinding of outcome measurement : probably no.
Participants	572 meconium-stained infants born between June 1984 and December 1986 who met the following criteria: gestational age > 37 weeks, birthweight > 2500 g, normal vaginal delivery, 1 minute Apgar score > 8, and breathing spontaneously before being handed over to the paediatrician were included.
Interventions	Both groups had suction of the infant's mouth and nose with de Lee catheter while the head was on the perineum. The treatment group also had endotracheal intubation using a 2.5 - 3.0 mm orotracheal tube for aspiration of the upper and lower airways. Suction was continued during tube removal. If tracheal aspirate continued to contain meconium the procedure was repeated until clear airways were established. The control group did not have endotracheal intubation.
Outcomes	Mortality, meconium aspiration syndrome, pneumothorax, need for oxygen supplementation, stridor
Notes	On days when paediatricians not participating in the study were on duty, babies born with meconium staining were managed with endotracheal intubation and aspiration and were thus included in the treatment group.
Allocation concealment	C – Inadequate

Study	Liu 1998
Methods	Random allocation, method not described. Blinding of randomisation: can't tell. Blinding of intervention: no. Complete follow-up: yes. Blinding of outcome measurements: probably no.
Participants	169 infants of low-risk born through thin meconium. Exclusion criteria included moderate or thick meconium staining, fetal distress, neonatal depression or prematurity. There were 8967 births during the study period and 7.9% were born through meconium. Thin meconium was noted in 50% of these. 163 infants were

	medically eligible but could not be randomised due to lack of consent, late arrival of the team or obstetrician request.
Interventions	Endotracheal intubation and suctioning of the airways with a suction catheter. Some infants had saline lavage. A meconium aspirator was used to apply suction as the endotracheal tube was removed. The control group did not have endotracheal intubation, but received oronasopharyngeal with a bulb syringe.
Outcomes	Outcome measures were the presence of respiratory symptoms after birth and the need for supplemental oxygen. One and 5 minute Apgar scores were also recorded.
Notes	
Allocation concealment	B – Unclear

Study	Wiswell 2000
Methods	Random allocation of the intervention just prior to birth by opening opaque sealed envelopes. Blinding of randomisation: yes. Blinding of intervention: no. Complete follow-up: yes. Blinding of outcome measurements: probably no.
Participants	2094 apparently vigorous infants were enrolled from 12 participating centres. Inclusion criteria included: gestational age 37 weeks or greater, birth through meconium stained amniotic fluid of any consistency and “vigour” immediately after birth (heart rate > 100, spontaneous respirations, reasonable tone).
Interventions	The intervention group had endotracheal intubation and suction of the airways whereas the control group had expectant management. 64/1043 (6.1%) of infants in the expectant management group needed endotracheal intubation between 1 and 7 minutes of age because of respiratory distress, poor respiratory effort or meconium blocking the airway.
Outcomes	Meconium aspiration syndrome, “other” respiratory disorders (transient tachypnoea, delayed transition, pneumonia etc.). Complications of intubation were also reported.
Notes	
Allocation concealment	A – Adequate

ANALYSES

Comparison 01. Routine tracheal intubation/suction vs control

Outcome title	No. of studies	No. of participants	Statistical method	Effect size
01 Mortality	4	2884	Relative Risk (Fixed) 95% CI	1.73 [0.37, 8.12]
02 Pneumothorax	2	621	Relative Risk (Fixed) 95% CI	0.87 [0.16, 4.92]
03 Oxygen need	3	790	Relative Risk (Fixed) 95% CI	1.49 [0.86, 2.60]
04 Meconium aspiration syndrome	4	2884	Relative Risk (Fixed) 95% CI	1.29 [0.80, 2.08]
05 Stridor	1	572	Relative Risk (Fixed) 95% CI	4.29 [0.21, 88.92]
06 Convulsions	1	49	Relative Risk (Fixed) 95% CI	2.65 [0.30, 23.77]
07 Hypoxic ischemic encephalopathy	1	49	Relative Risk (Fixed) 95% CI	2.67 [0.11, 62.42]
08 Respiratory symptoms	2	2263	Relative Risk (Fixed) 95% CI	0.87 [0.58, 1.31]

INDEX TERMS

Medical Subject Headings (MeSH)

Infant, Newborn; *Intubation, Intratracheal; Meconium Aspiration Syndrome [*prevention & control]; Randomized Controlled Trials; Suction

MeSH check words

Humans

COVER SHEET

Title	Endotracheal intubation at birth for preventing morbidity and mortality in vigorous, meconium-stained infants born at term
Authors	Halliday HL, Sweet D
Contribution of author(s)	Information not supplied by author
Issue protocol first published	/
Review first published	2000/1
Date of most recent amendment	29 September 2005
Date of most recent SUBSTANTIVE amendment	26 October 2000
What's New	The review updates the existing review of "Endotracheal intubation at birth for preventing morbidity and mortality in vigorous, meconium-stained infants born at term" published in The Cochrane Library, Issue 1, 2001. The search for eligible trials was updated to October 2002 and no new trials were found. The conclusions from the previous review remain unchanged.
Date new studies sought but none found	31 October 2002
Date new studies found but not yet included/excluded	Information not supplied by author
Date new studies found and included/excluded	Information not supplied by author
Date authors' conclusions section amended	Information not supplied by author
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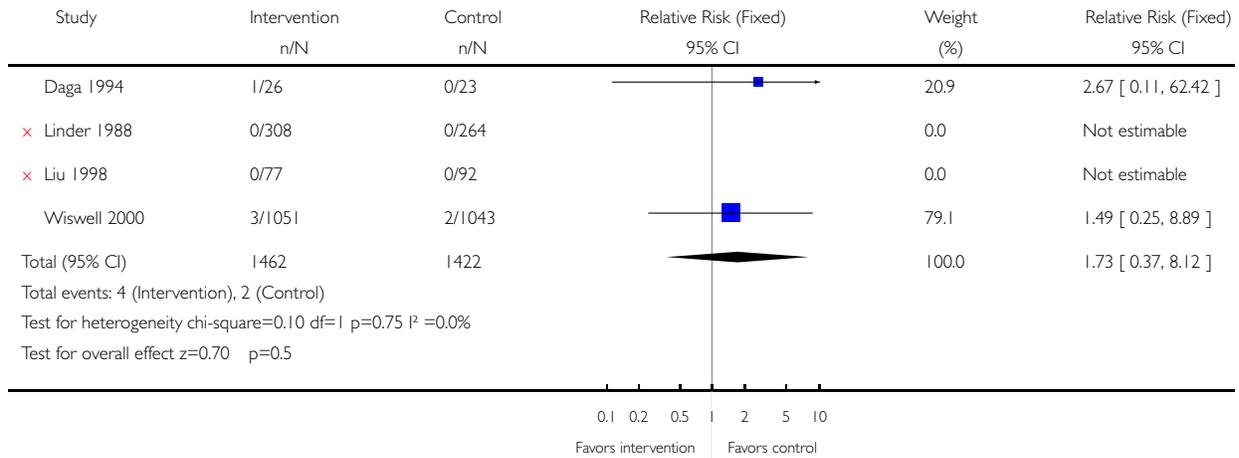
GRAPHS AND OTHER TABLES

Analysis 01.01. Comparison 01 Routine tracheal intubation/suction vs control, Outcome 01 Mortality

Review: Endotracheal intubation at birth for preventing morbidity and mortality in vigorous, meconium-stained infants born at term

Comparison: 01 Routine tracheal intubation/suction vs control

Outcome: 01 Mortality

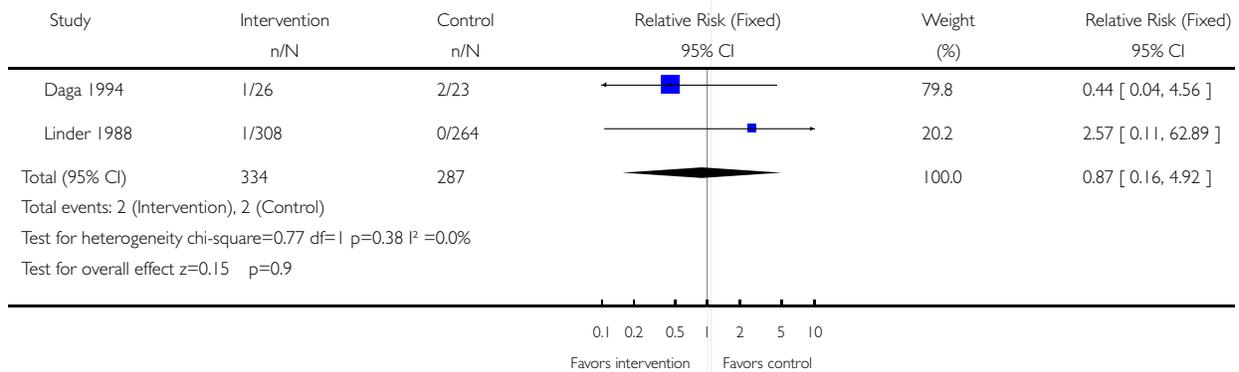


Analysis 01.02. Comparison 01 Routine tracheal intubation/suction vs control, Outcome 02 Pneumothorax

Review: Endotracheal intubation at birth for preventing morbidity and mortality in vigorous, meconium-stained infants born at term

Comparison: 01 Routine tracheal intubation/suction vs control

Outcome: 02 Pneumothorax

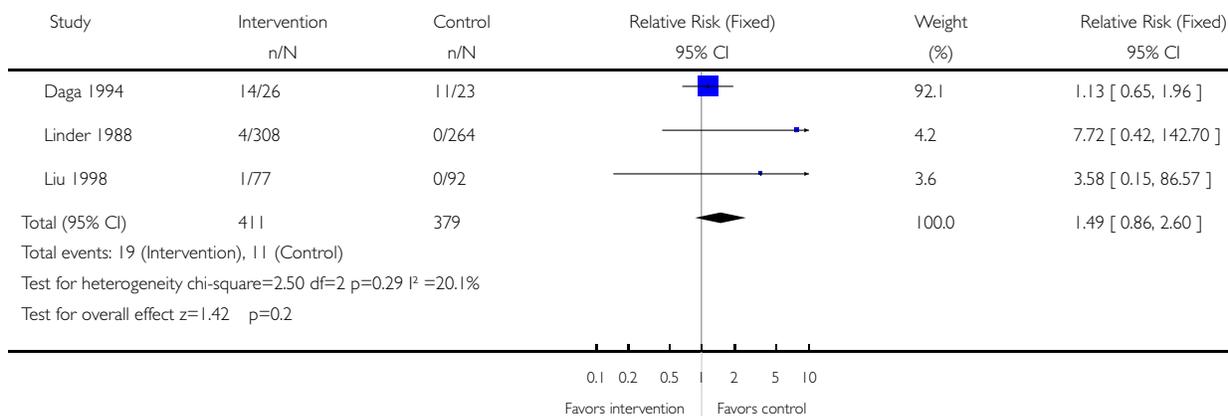


Analysis 01.03. Comparison 01 Routine tracheal intubation/suction vs control, Outcome 03 Oxygen need

Review: Endotracheal intubation at birth for preventing morbidity and mortality in vigorous, meconium-stained infants born at term

Comparison: 01 Routine tracheal intubation/suction vs control

Outcome: 03 Oxygen need

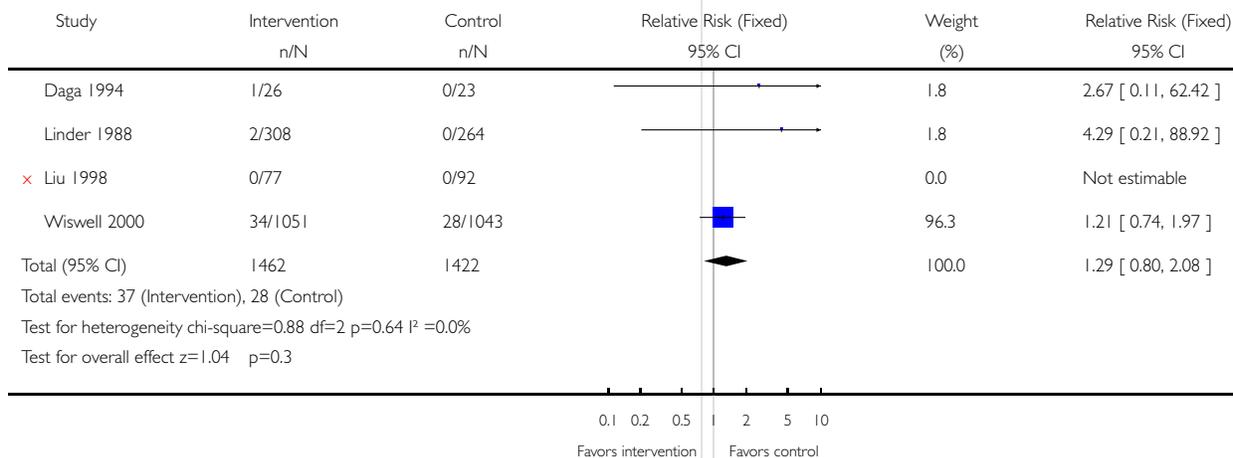


Analysis 01.04. Comparison 01 Routine tracheal intubation/suction vs control, Outcome 04 Meconium aspiration syndrome

Review: Endotracheal intubation at birth for preventing morbidity and mortality in vigorous, meconium-stained infants born at term

Comparison: 01 Routine tracheal intubation/suction vs control

Outcome: 04 Meconium aspiration syndrome

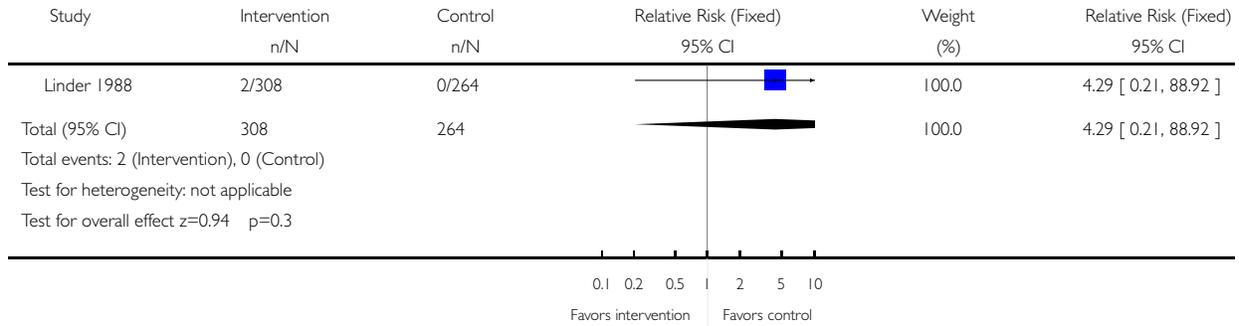


Analysis 01.05. Comparison 01 Routine tracheal intubation/suction vs control, Outcome 05 Stridor

Review: Endotracheal intubation at birth for preventing morbidity and mortality in vigorous, meconium-stained infants born at term

Comparison: 01 Routine tracheal intubation/suction vs control

Outcome: 05 Stridor

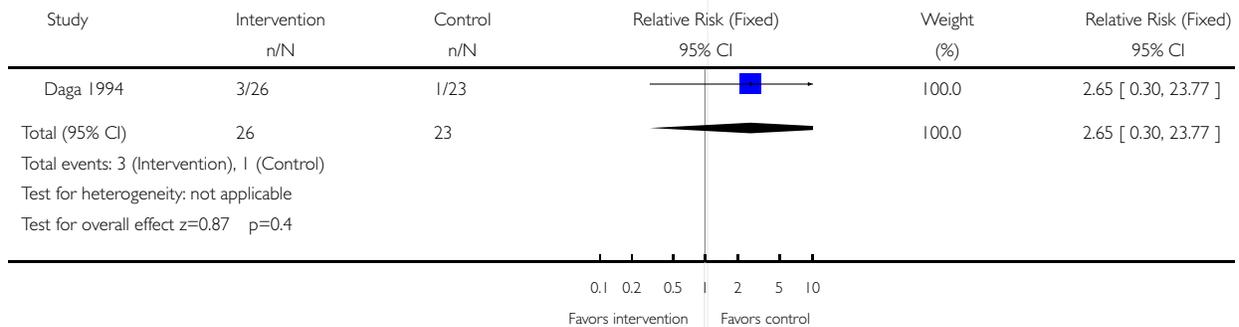


Analysis 01.06. Comparison 01 Routine tracheal intubation/suction vs control, Outcome 06 Convulsions

Review: Endotracheal intubation at birth for preventing morbidity and mortality in vigorous, meconium-stained infants born at term

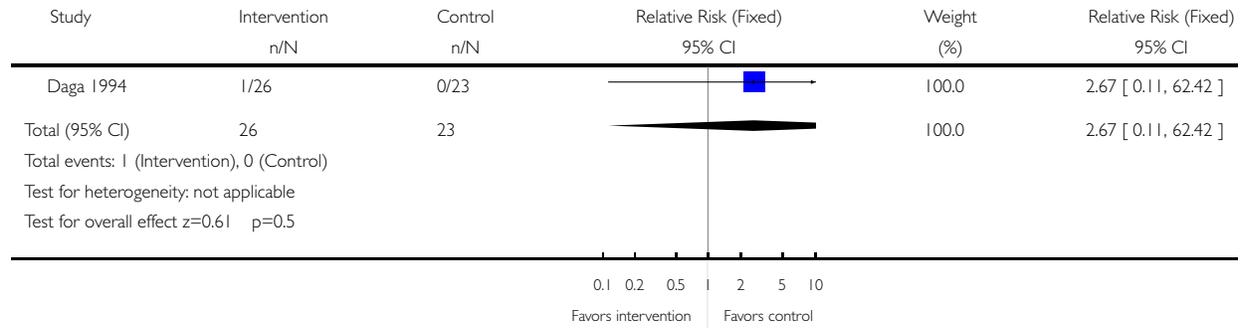
Comparison: 01 Routine tracheal intubation/suction vs control

Outcome: 06 Convulsions



Analysis 01.07. Comparison 01 Routine tracheal intubation/suction vs control, Outcome 07 Hypoxic ischemic encephalopathy

Review: Endotracheal intubation at birth for preventing morbidity and mortality in vigorous, meconium-stained infants born at term
 Comparison: 01 Routine tracheal intubation/suction vs control
 Outcome: 07 Hypoxic ischemic encephalopathy



Analysis 01.08. Comparison 01 Routine tracheal intubation/suction vs control, Outcome 08 Respiratory symptoms

Review: Endotracheal intubation at birth for preventing morbidity and mortality in vigorous, meconium-stained infants born at term
 Comparison: 01 Routine tracheal intubation/suction vs control
 Outcome: 08 Respiratory symptoms

