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Needle aspiration versus intercostal tube drainage for pneumothorax in the newborn (Review)

Bruschettini M, Romantsik O, Zappettini S, O'Donnell CPF, Calevo MG

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[Intervention Review]

Needle aspiration versus intercostal tube drainage for pneumothorax in the newborn

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ABSTRACT

Background

Pneumothorax occurs more frequently in the neonatal period than at any other time of life and is associated with increased mortality and morbidity. It can be treated with either aspiration with a syringe (using a needle or an angiocatheter) or a chest tube inserted in the anterior pleural space and then connected to a Heimlich valve or an underwater seal with continuous suction.

Objectives

To compare the efficacy and safety of needle aspiration (either with immediate removal of the needle or with the needle left in situ) to intercostal tube drainage in the management of neonatal pneumothorax (PTX).

Search methods

We used the standard search strategy of Cochrane Neonatal to search the Cochrane Central Register of Controlled Trials (CENTRAL 2018, Issue 5), MEDLINE via PubMed (1966 to 4 June 2018), Embase (1980 to 4 June 2018), and CINAHL (1982 to 4 June 2018). 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 controlled trials, quasi-randomised controlled trials and cluster trials comparing needle aspiration (either with the needle or angiocatheter left in situ or removed immediately after aspiration) to intercostal tube drainage in newborn infants with pneumothorax.

Data collection and analysis

For each of the included trials, two authors independently extracted data (e.g. number of participants, birth weight, gestational age, kind of needle and chest tube, choice of intercostal space, pressure and device for drainage) and assessed the risk of bias (e.g. adequacy of randomisation, blinding, completeness of follow-up). The primary outcomes considered in this review are mortality during the neonatal period and during hospitalisation.

We used the GRADE approach to assess the quality of evidence.

Main results

Two randomised controlled trials (142 infants) met the inclusion criteria of this review. We found no differences in the rates of mortality when the needle was removed immediately after aspiration (risk ratio (RR) 3.92, 95% confidence interval (CI) 0.88 to 17.58; participants = 70; studies = 1) or left in situ (RR 1.50, 95% CI 0.27 to 8.45; participants = 72; studies = 1) or complications related to the procedure. With immediate removal of the needle following aspiration, 30% of the newborns did not require the placement of an intercostal tube drainage. None of the 36 newborns treated with needle aspiration with the angiocatheter left in situ required the placement of an intercostal tube drainage. Overall, the quality of the evidence supporting this finding is very low.

Authors' conclusions

There is insufficient evidence to establish the efficacy and safety of needle aspiration and intercostal tube drainage in the management of neonatal pneumothorax. The two included trials showed no differences in mortality; however the information size is low. Needle aspiration reduces the need for intercostal tube drainage placement. Limited or no evidence is available on other clinically relevant outcomes.

PLAIN LANGUAGE SUMMARY

The aspiration of pneumothorax in the newborn with a small needle compared to a larger tube placed through the intercostal space

Review question: Does the use of a needle to aspirate pneumothorax compared to an intercostal tube (a tube inserted between ribs) reduce mortality in newborns?

Background: Pneumothorax is the presence of air in the pleural space (the space between the lung and the chest wall). It is a serious condition in the newborn and may be treated by needle aspiration or chest tube placement. The former is less invasive and might avoid the need for the insertion of a chest tube, thus reducing the duration of hospital stay. However the failure of needle aspiration might subsequently lead to the need for chest tube insertion, an additional invasive procedure. This systematic review evaluates the available evidence on the effectiveness of these two techniques in treating pneumothorax in neonates.

Study characteristics: We included one study (enrolling 70 newborn infants) that compared needle aspiration followed by immediate removal to chest tube placement for the treatment of pneumothorax and one study (72 newborn infants) that compared needle aspiration with the angiocatheter left in situ to chest tube placement for the treatment of pneumothorax. Evidence is up to date as of June 2018.

Key results: The use of needle aspiration compared to chest tube placement did not reduce mortality or any complications related to the procedure. About 30% of the infants with pneumothorax who were treated with needle aspiration followed by immediate removal never required the placement of an intercostal tube; none of the infants with pneumothorax who were treated with needle aspiration left in situ required the placement of an intercostal tube. However multiple factors might explain this finding.

Quality of evidence: The two small trials identified do not provide sufficient information to determine which of the two techniques is better to treat pneumothorax in neonates. However it seems that needle aspiration might reduce the need for an intercostal tube in a relevant proportion of newborn infants.

SUMMARY OF FINDINGS

Summary of findings for the main comparison. Needle aspiration (needle removed immediately after aspiration) versus intercostal tube drainage for pneumothorax in the newborn

Needle aspiration (needle removed immediately after aspiration) versus intercostal tube drainage for pneumothorax in the newborn

Patient or population: patients with pneumothorax in the newborn

Intervention: Needle aspiration (needle removed immediately after aspiration)

Comparison: intercostal tube drainage

Outcomes	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	No. of participants (studies)	Quality of the evidence (GRADE)	Comments
	Assumed risk	Corresponding risk				
	Control	Needle aspiration (needle removed immediately after aspiration) versus intercostal tube drainage				
Mortality neonatal (first 28 days of life) - not reported			Not estimable	-		no data available
Mortality during hospitalisation	Study population		RR 3.92 (0.88 to 17.58)	70 (1 study)	⊕⊕⊕⊕ very low ^{1,2}	
	54 per 1000	212 per 1000 (48 to 949)				
Need for intercostal tube drainage	Study population		RR 0.7 (0.56 to 0.88)	70 (1 study)	⊕⊕⊕⊕ very low ^{1,2}	
	1000 per 1000	700 per 1000 (560 to 880)				
Successful evacuation of extra-pleural air - not reported			Not estimable	-		no data available
Bleeding from incision for the insertion of the needle or the tube - not reported			Not estimable	-		no data available
Haemothorax - not reported			Not estimable	-		no data available

*The basis for the **assumed risk** (e.g. the median control group risk across studies) is provided in footnotes. The **corresponding risk** (and its 95% CI) 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;

GRADE Working Group grades of evidence

High quality: Further research is very unlikely to change our confidence in the estimate of effect.

Moderate quality: Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.

Low quality: Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate.

Very low quality: We are very uncertain about the estimate.

The assumed risk is the risk of the control arm.

¹ limitations in study design: high risk for detection and performance bias (unblinded intervention)

² downgraded by two levels for imprecision: one study, few events

Summary of findings 2. Needle aspiration (needle or angiocatheter left in situ) compared to intercostal tube drainage for pneumothorax in the newborn

Needle aspiration (needle or angiocatheter left in situ) compared to intercostal tube drainage for pneumothorax in the newborn

Patient or population: patients with pneumothorax in the newborn

Intervention: needle aspiration (needle or angiocatheter left in situ)

Comparison: intercostal tube drainage

Outcomes	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	No. of participants (studies)	Quality of the evidence (GRADE)	Comments
	Assumed risk	Corresponding risk				
	intercostal tube drainage	Needle aspiration (needle or angiocatheter left in situ)				
Mortality neonatal (first 28 days of life) - not reported			Not estimable	-		no data available
Mortality during hospitalisation	Study population		RR 1.5 (0.27 to 8.45)	72 (1 study)	⊕⊕⊕⊕ very low ^{1,2}	
	56 per 1000	84 per 1000 (15 to 473)				
Need for intercostal tube drainage	Study population		RR 0.01 (0 to 0.21)	72 (1 study)	⊕⊕⊕⊕ very low ^{1,2}	
	1000 per 1000	10 per 1000				

	(0 to 210)				
Successful evacuation of extra-pleural air	Study population		RR 1	72	⊕⊕⊕⊕
	944 per 1000	944 per 1000 (840 to 1000)	(0.89 to 1.12)	(1 study)	very low ^{1,2}
Bleeding from incision for the insertion of the needle or the tube	Study population		RR 0.33	72	⊕⊕⊕⊕
	28 per 1000	9 per 1000 (0 to 222)	(0.01 to 7.92)	(1 study)	very low ^{1,2}
Haemothorax - not reported			Not estimable	-	no data available

*The basis for the **assumed risk** (e.g. the median control group risk across studies) is provided in footnotes. The **corresponding risk** (and its 95% CI) 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;

GRADE Working Group grades of evidence

High quality: Further research is very unlikely to change our confidence in the estimate of effect.

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The assumed risk is the risk of the control arm.

¹ limitations in study design: high risk for detection and performance bias (unblinded intervention)

² downgraded by two levels for imprecision: one study, few events

BACKGROUND

Description of the condition

Pulmonary air leak is caused by overdistension and rupture of the alveolar wall with air subsequently leaking from the intra-alveolar space to different anatomic locations. The most frequent neonatal forms of air leak include pulmonary interstitial emphysema, pneumomediastinum, pneumopericardium and pneumothorax (PTX). Pneumothorax is the most common air leak and occurs when air accumulates between the parietal and visceral pleura (in the pleural space). PTX occurs more frequently in the neonatal period than at any other time of life and is most often seen in the first three days of life (Irving 1990; Kottmeier 1986). It occurs in 3% to 9% of very low birth weight (VLBW) infants and is associated with increased mortality and morbidity (Bhatia 2011; Walker 2002). A large-tension PTX may increase intrathoracic pressure, which may cause increased central venous pressure and decreased venous return leading to decreased cardiac output (Fernandes 2014), hypotension, bradycardia, and an increased risk for germinal matrix-intraventricular haemorrhage (GM-IVH; Pishva 2012).

Description of the intervention

Neonatal PTX may be managed with a variety of approaches, including observation ('watchful waiting'), simple needle aspiration (thoracentesis), or insertion of a chest tube (thoracostomy and chest tube placement). Giving 100% oxygen has been used in order to induce 'nitrogen washout', though studies in term infants have reported that this treatment is not associated with faster resolution of PTX and may result in exposure to unnecessary oxygen treatment (Clark 2014; Shaheen 2014).

Thoracentesis may be the only intervention needed in an infant who is not mechanically ventilated and may be a temporising measure in an infant who requires ventilation (Katar 2006; Litmanovitz 2008). Thoracentesis consists of aspiration of air with a 10 ml to 20 ml syringe through a needle (usually 23 or 25 gauge) or an angiocatheter (18 to 24 gauge). The needle is inserted into the second or third intercostal space in the midclavicular line, passing just above the top of the rib in order to reduce the risk of lacerating the intercostal artery. Flow of air into the syringe confirms that the PTX has been reached by the needle, which should not be inserted further to avoid lung damage. If using an angiocatheter, the plastic catheter can be left in situ (Pammi 2012).

Thoracostomy is performed by placement of a chest tube (10 or 12 French size), usually in the anterior pleural space. The overlying skin is prepared with an antiseptic solution, the subcutaneous tissues are infiltrated with a local anaesthetic (such as lidocaine solution) and analgesia is administered. A small incision is made through the skin in the midaxillary line in the sixth intercostal space, the subcutaneous tissue is dissected, and a subcutaneous track to the intercostal space is made. A trochar might be used to facilitate the penetration of the tube, though this technique may be associated with an increased risk of lung perforation (Fraser 1988). The chest tube is passed into the pleural opening, turned anteriorly and directed to the location of the PTX, and then connected to a Heimlich valve or an underwater seal with continuous suction at a pressure of 10 cmH₂O to 20 cmH₂O. A less traumatic approach consists of the use of pigtail catheters, which are usually smaller (8 or 10 French) and possibly more suitable for preterm infants. Pigtail catheters are placed with a Seldinger technique, whereby the guide

wire is inserted through the catheter, which is then removed and replaced by the pigtail catheter (Pammi 2012).

The literature does not clearly define which option is best for the treatment of PTX, especially in haemodynamically stable infants with obvious signs of PTX on chest radiograph (such as mediastinal shift). In these cases, the most common treatment is thoracostomy and chest tube placement, a procedure associated with substantial complications (Kitsommart 2012; Troug 2005).

How the intervention might work

As noted above, symptomatic PTX may be treated by needle aspiration or thoracostomy and chest tube placement. The former might avoid or reduce the need for the insertion of a chest tube, a more invasive approach, and thus reduce the duration of respiratory support and hospital stay. On the other hand, the failure of needle aspiration might subsequently imply the need for chest tube insertion, an additional invasive procedure. We planned to evaluate both single and repeated aspiration procedures.

Why it is important to do this review

Newborns with PTX are at high risk of mortality, which may exceed 40% in extremely preterm infants (Bhatia 2011). It is therefore crucial to determine the best strategy for treatment. Interestingly, a Cochrane Review has been published on PTX management, but it focuses on the adult population only (Wakai 2007).

This review updates the existing review which was published in the *Cochrane Database of Systematic Reviews* in 2016 (Bruschettini 2016).

OBJECTIVES

To compare the efficacy and safety of needle aspiration (either with immediate removal of the needle or with the needle left in situ) to intercostal tube drainage in the management of neonatal pneumothorax (PTX).

METHODS

Criteria for considering studies for this review

Types of studies

We included prospective randomised clinical controlled trials and quasi-randomised trials. We planned to include cluster randomised controlled trials if the definition of participants and clusters was sufficiently clear.

Cross-over trials were not included because the intervention might have a lasting effect that compromises entry to subsequent periods of the trial.

Types of participants

Newborn infants with PTX, any gestational age and birth weight, ventilated and non-ventilated.

Types of interventions

We compared needle aspiration to intercostal tube drainage in newborns with PTX.

Two separate comparisons were planned.

1. Aspiration with needle removal immediately after aspiration vs. intercostal tube drainage in newborns with PTX.
2. Aspiration to needle (or angiocatheter) left in situ vs. intercostal tube drainage in newborns with PTX.

Aspirations could be repeated and could be performed on one or both sides of the chest. However, the condition had to be untreated prior to randomisation. Treatment with supplemental oxygen was not an exclusion criterion.

We excluded trials in which 'invasive management' (i.e. needle aspiration or intercostal tube drainage) and 'expectant management' (i.e. watchful waiting) were compared.

Types of outcome measures

Primary outcomes

Mortality: neonatal (first 28 days of life) or during hospitalisation.

Secondary outcomes

1. Need for intercostal tube drainage (yes/no). It should be noted that failure of needle aspiration may require intercostal tube drainage; however 100% of infants in the 'intercostal tube drainage' comparison group would have a drain placed.
2. Successful evacuation of extra-pleural air (as defined by the studies' authors).
3. Bleeding from incision for the insertion of the needle or the tube (any bleeding; yes/no).
4. Subcutaneous emphysema diagnosed by imaging (yes/no).
5. Haemothorax diagnosed by imaging (yes/no).
6. Duration of chest drain (days).
7. Number of chest drain insertions.
8. Duration of mechanical ventilation (MV; days).
9. Duration of MV post intervention (days).
10. Duration of respiratory support (MV or CPAP; days).
11. Duration of oxygen therapy (days).
12. Duration of hospital stay (days).
13. Sedation/agitation/pain scale during the insertion of needle or tube. This would be assessed by neonatal scales such as the Premature Infant Pain Profile (PIPP; [Stevens 1996](#)); PIPP-revised ([Gibbins 2014](#)); Neonatal Infant Pain Scale (NIPS; [Lawrence 1993](#)); CRIES score ([Krechel 1995](#)); and Neonatal Pain, Agitation and Sedation Scale (N-PASS; [Hummel 2008](#)).
14. Sedation/agitation/pain scale average daily score. This would be assessed by neonatal scales such as those mentioned for the previous outcome.
15. Germinal matrix-intraventricular haemorrhage (GM-IVH): any grade, severe IVH (grade 3 and 4) according to Papile classification (yes/no; [Papile 1978](#)).
16. Bronchopulmonary dysplasia (BPD)/chronic lung disease (CLD) defined as:
 - respiratory support or oxygen, or both, at 28 days of life ([NIH 1979](#));
 - respiratory support or oxygen, or both, at 36 weeks of postmenstrual age (PMA; [Jobe 2001](#));
 - physiological definition ([Walsh 2004](#)).

Search methods for identification of studies

We used the criteria and standard methods of Cochrane and Cochrane Neonatal (see the Cochrane Neonatal [search strategy](#) for specialized register). We searched for errata or retractions from included studies published in full-text on PubMed (www.ncbi.nlm.nih.gov/pubmed) on 17 July 2018. We did not limit the search to any particular geographical region, language or timing of publication.

Electronic searches

We conducted a comprehensive search including: Cochrane Central Register of Controlled Trials (CENTRAL 2018, Issue 5) in the Cochrane Library; MEDLINE via PubMed (1966 to 4 June 2018); Embase (1980 to 4 June 2018); and CINAHL (1982 to 4 June 2018) using the following search terms: ("Pneumothorax"[Mesh] OR Pneumothorax), 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; and the ISRCTN [Registry](#)).

Searching other resources

We also searched the reference lists of any articles selected for inclusion in this review in order to identify additional relevant articles.

Data collection and analysis

We used the standard methods of the Cochrane Neonatal Review Group. We assessed methodology regarding blinding of randomisation, intervention and outcome measurements, as well as completeness of follow-up (i.e. > 80%). Where necessary, we asked the investigators of each trial to provide unpublished outcome data. We used Cochrane's standardised statistical methods. For categorical data we calculated the risk ratio (RR), absolute risk difference (RD), number needed to treat for an additional beneficial outcome (NNTB), and the number needed to treat for an additional harmful outcome (NNTH). For continuous data we calculated the mean difference (MD). We used 95% confidence intervals (CI).

Selection of studies

Two review authors (OR, MB) independently searched and identified eligible trials that met the inclusion criteria. The review authors screened the titles and abstracts to identify potentially relevant citations. The review authors retrieved the full texts of all potentially relevant articles and independently assessed the eligibility of the studies by filling out eligibility forms designed in accordance with the specified inclusion criteria. We reviewed studies for relevance based on study design, types of participants, interventions and outcome measures. We resolved any disagreements by discussion and, if necessary, by consulting a third review author (MGC). We had planned to cite studies excluded from the review in the 'Characteristics of excluded studies' table along with the reasons for exclusion. We planned to contact the trial authors if the details of the primary trials were not clear.

Data extraction and management

Two reviewers (MB, OR) undertook data abstraction independently using a data extraction form developed ad hoc and integrated with a modified version of the Cochrane Effective Practice and Organisation of Care (EPOC) Group data collection checklist.

We extracted the following characteristics from each included trial.

1. Administrative details: author(s); published or unpublished; year of publication; year in which trial was conducted; details of other relevant papers cited.
2. Details of the trial: study design; type, duration and completeness of follow-up (i.e. > 80%); country and location of study informed consent and ethics approval.
3. Details of participants: birth weight, gestational age, and number of participants.
4. Details of intervention: kind of needle and chest tube, choice of intercostal space, pressure and device for drainage.
5. Details of outcomes, as listed above.

We resolved any disagreement by discussion between the reviewers. We described the details of ongoing studies where available, including the primary author, research question(s), methods, outcome measures, and an estimate of the reporting date. Where any queries might arise or where additional data might be required, we planned to contact the authors.

MGC entered all data into Review Manager 5 software ([Review Manager 2014](#)).

Assessment of risk of bias in included studies

Two review authors (SZ, MGC) independently assessed the risk of bias (low, high, or unclear) of all included trials using the Cochrane 'Risk of bias' tool ([Higgins 2017](#)) for the following domains.

1. Sequence generation (selection bias).
2. Allocation concealment (selection bias).
3. Blinding of participants and personnel (performance bias).
4. Blinding of outcome assessment (detection bias).
5. Incomplete outcome data (attrition bias).
6. Selective reporting (reporting bias).
7. Any other bias.

We resolved any disagreements by discussion or by inviting a third assessor to arbitrate. See [Appendix 2](#) for a more detailed description of risk of bias for each domain.

Measures of treatment effect

We extracted categorical data for each intervention group, and calculated risk ratio (RR) or absolute risk difference (RD). We obtained mean and standard deviation for continuous data and performed analysis using the mean difference (MD). We provided the 95% CI for each measure of effect. We presented NNTB and NNTD when the RD was statistically significant.

Unit of analysis issues

In cluster trials, groups of individuals are randomly allocated to study arms; outcomes are then measured based on the individual cluster members. Under such circumstances, it is necessary to adjust the results to account for the fact that the randomisation

was performed on the clusters rather than the individuals. As many cluster-randomised trials fail to report appropriate analysis, corrections for clustering are needed before they are included in a meta-analysis.

To calculate adjusted (inflated) CIs that account for the clustering, we planned to conduct an approximate analysis as suggested by the *Cochrane Handbook for Systematic Reviews of Interventions* ([Higgins 2011](#)). We would multiply the standard error of the effect estimate (from an analysis ignoring clustering) by the square root of the design effect. The design effect would be calculated from the average cluster size and the intra-cluster correlation coefficient. Intra-cluster correlation coefficient(s) would be borrowed from similar studies. If this correction was not possible, we planned to include the cluster trials in the review but would not include them in the meta-analyses.

Dealing with missing data

We planned to determine the dropout rate for each trial (and each trial outcome). We would have considered a dropout rate equal to or greater than the event rate of the control group to be significant. We planned to perform a sensitivity analysis to evaluate the overall results with and without the inclusion of studies with significant dropout rates. If a trial reported outcomes only for participants completing the trial or only for participants who followed the protocol, we planned to contact author(s) and ask them to provide additional information to facilitate an intention-to-treat analysis. We planned no assumptions regarding the outcome of infants lost to follow-up. We planned to calculate and report the percentage lost to follow-up if there was a discrepancy in the number randomised and the numbers analysed in each treatment group. Moreover we planned to request additional data from the author(s) of each trial if data on outcomes was missing or unclear.

Assessment of heterogeneity

We planned to assess clinical heterogeneity by comparing the distribution of important participant factors between trials (for example, age) and trial factors (randomisation concealment, blinding of outcome assessment, losses to follow-up, treatment type, co-interventions). We would assess statistical heterogeneity by examining the I^2 statistic ([Higgins 2011](#)), a quantity that describes the proportion of variation in point estimates that is due to variability across studies rather than sampling error. We would interpret the I^2 statistic as described by [Higgins 2003](#).

1. < 25% no heterogeneity;
2. 25% to 49% low heterogeneity;
3. 50% to 74% moderate heterogeneity; and
4. ≥ 75% high heterogeneity.

In addition, we planned to employ a χ^2 test of homogeneity to determine the strength of evidence that heterogeneity is genuine.

Assessment of reporting biases

We planned to assess publication bias using funnel plots if at least 10 clinical trials met our inclusion criteria ([Egger 1997](#); [Higgins 2011](#)).

Data synthesis

Data were summarised using Review Manager 5 ([Review Manager 2014](#)). We used the standard methods of the Cochrane Neonatal

Review Group to synthesize data using RR, RD, NNTB, NNTH, weighted mean differences (WMDs) and 95% CIs. Our preference was for a fixed-effect model to perform meta-analyses. However, in case of moderate or high heterogeneity among the studies, we planned to conduct and report meta-analyses using a random-effects model.

Quality of evidence

We used the GRADE approach, as outlined in the GRADE Handbook (Schünemann 2013), to assess the quality of evidence for the following (clinically relevant) outcomes: neonatal mortality and mortality during hospitalisation; important outcomes: need for intercostal tube drainage, successful evacuation of extra-pleural air, bleeding from incision for the insertion of the needle or the tube, haemothorax.

Two authors independently assessed the quality of the evidence for each of the outcomes above. We considered evidence from randomised controlled trials as high quality but downgraded the evidence one level for serious (or two levels for very serious) limitations based upon the following: design (risk of bias), consistency across studies, directness of the evidence, precision of estimates and presence of publication bias. We used the GRADEpro GDT Guideline Development Tool to create a 'Summary of findings' table to report the quality of the evidence.

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.

Subgroup analysis and investigation of heterogeneity

1. Gestational age (with three subgroups: < 32 weeks; 32 to 36 weeks; ≥ 37 weeks).
2. Birth weight (with three subgroups: < 1500 grams; 1500 to 2500 grams; ≥ 2500 grams).
3. Intubated versus not intubated.
4. Unilateral versus bilateral PTX.
5. Single versus repeated aspirations.

Sensitivity analysis

We planned to conduct sensitivity analyses to explore the effect of the methodological quality of the trials, checking to ascertain if studies with a high risk of bias overestimate the effect of treatment.

RESULTS

Description of studies

See [Characteristics of included studies](#) table, [Summary of findings for the main comparison](#) and [Summary of findings 2](#).

Results of the search

The literature search run in November 2015 and updated in June 2018 identified 654 and 194 references, respectively (Figure 1). After screening, we included only two randomised controlled trials (Arda 2002; Murphy 2018). We identified no ongoing trials.

Figure 1. Study flow diagram: review update

Included studies

Two trials recruiting 142 infants met the inclusion criteria ([Arda 2002](#); [Murphy 2018](#)) (see [Characteristics of included studies](#)). Both were unblinded randomised controlled trials.

The two trials were not pooled in the same comparison because in [Murphy 2018](#) the needle was removed immediately after aspiration (corresponding to comparison 1 of this review) whereas in [Arda 2002](#) it was left in situ (corresponding to comparison 2; see [Types of interventions](#)).

[Murphy 2018](#), the Needle or Drain (NORD) trial, was conducted in five European neonatal intensive care units: National Maternity

Hospital, Dublin, Ireland (26 infants); Rigshospitalet, Copenhagen, Denmark (16 infants); Azienda Ospedaliera di Padova, Padova, Italy (14 infants); Karolinska Institutet, Stockholm, Sweden (8 infants); and Ospedale dei Bambini "Vittore Buzzi", Milan, Italy (6 infants) ([Summary of findings for the main comparison](#)). The median birth weight (IQR) was 1385 (1110 to 3365) grams in the needle group and 1690 (1060 to 2025) grams in the intercostal tube group; median gestational age (IQR) was 31 (27 to 38) weeks in the needle group and 31 (27 to 35) weeks in the intercostal tube group. Inclusion criteria were PTX diagnosed on chest radiography and need for respiratory support. In the needle aspiration group, a butterfly needle or Angiocath was inserted into the second intercostal space in the midclavicular line and air was aspirated until it was no

longer aspirated freely, and the needle was then removed. The procedure was performed once: if the clinical response was poor, an intercostal tube was inserted. In the intercostal tube drainage group, a chest drain with a trocar or a pigtail drain was inserted in the fifth intercostal space in the midaxillary line. The intercostal tube was secured and connected to drainage, and the position was confirmed with a chest radiography. The primary outcome was the need for an intercostal tube insertion within 6 hours of diagnosis.

[Arda 2002](#) was conducted in term and preterm newborns with PTX in two hospitals in Turkey and compared two different techniques to treat PTX, i.e. venous catheter versus intercostal tube ([Summary of findings 2](#)). The mean birth weight (SD) was 2547 ($\pm$ 448) grams in the needle group and 2690 ($\pm$ 419) grams in the intercostal tube group; mean gestational age (SD) was 36.4 ($\pm$ 2.6) weeks in the needle group and 35.8 ($\pm$ 2.8) weeks in the intercostal tube group. Criteria to drain PTX included persistent or increased air detected in serial lung X-rays, mediastinal shifting, respiratory difficulty with cyanosis and patients with PTX on ventilator. In the needle group, an 18-gauge 45 mm long venous catheter was introduced by the surgeon without local anaesthesia through the fourth or fifth intercostal space on the anterior axillary line and, after guide needle withdrawal, the catheter was directed toward the superior part of the thoracic cavity. Of note: the needle was taped to the skin

with a dressing and left in situ (mean 27.1 hours), and not removed immediately after the aspiration. In the intercostal tube drainage group, the surgeon made an incision at the fifth or sixth intercostal space with local anaesthesia (Prilocaine hydrochloride), separated the intercostal muscle fibres, blunt-dissected a subcutaneous tunnel, pierced the pleura and inserted a 12-F standard chest tube catheter through the tunnel into the pleural space. In both groups, the chest tube or venous catheter were connected to an underwater drainage system and a chest X-ray was taken immediately after each procedure to check for the presence of residual air in the thoracic cavity. When the bubbling in the water-seal chamber stopped, the drainage system was clamped. The system was then kept closed for at least six hours. Once a final chest X-ray showed no residual air, the chest tube or venous catheter was removed. Main outcomes were duration of the procedure, duration of the tubes and catheters in place, and the rates of complications.

Excluded studies

We considered none of the other 848 identified studies eligible.

Risk of bias in included studies

See 'Risk of bias' graph ([Figure 2](#)) and 'Risk of bias' summary ([Figure 3](#)).

Figure 2. Risk of bias summary: review authors' judgements about each risk of bias item for each included study.

	Random sequence generation (selection bias)	Allocation concealment (selection bias)	Blinding of participants and personnel (performance bias)	Blinding of outcome assessment (detection bias)	Incomplete outcome data (attrition bias)	Selective reporting (reporting bias)	Other bias
Arda 2002	?	?	-	?	+	?	+
Murphy 2018	+	+	-	-	+	+	+

Figure 3. Risk of bias graph: review authors' judgements about each risk of bias item presented as percentages across all included studies.

Allocation

We judged one study as having low risk of selection bias (Murphy 2018); and one study as having unclear risk due to insufficient methodological details (Arda 2002).

Blinding

Due to the nature of the intervention, both Arda 2002 and Murphy 2018 were unblinded leading to a high risk for performance bias. We assessed the Murphy 2018 study as high risk in terms of reporting of blinding of outcome assessment. No information was available regarding Arda 2002 study.

Incomplete outcome data

We could not identify any missing outcome data.

Selective reporting

Pre-specified outcomes were available for the Murphy 2018 study in the form of a protocol and we judged it to be at a low risk of bias. The Arda 2002 study was assessed as unclear risk of bias because no protocol was identified.

Other potential sources of bias

The trials appeared free of other biases.

Effects of interventions

See: [Summary of findings for the main comparison Needle aspiration \(needle removed immediately after aspiration\) versus](#)

[intercostal tube drainage for pneumothorax in the newborn; Summary of findings 2 Needle aspiration \(needle or angiocatheter left in situ\) compared to intercostal tube drainage for pneumothorax in the newborn](#)

Comparison 1: Needle aspiration (needle removed immediately after aspiration) versus intercostal tube drainage

We identified only one trial (Murphy 2018), which included a total of 70 infants (see [Characteristics of included studies](#) and [Summary of findings for the main comparison](#)). Tests for heterogeneity were not applicable for any of the analyses as only one study was included in the comparison.

Primary outcomes

Death during hospitalisation

Nine infants died before hospital discharge, seven (21.2%) in the needle group and two (5.4%) in the chest drain group (RR 3.92, 95% CI 0.88 to 17.58; participants = 70; studies = 1) ([Analysis 1.1, Figure 4](#)). Five infants died of respiratory failure within 48 hours of study entry, three assigned to needle aspiration group (all of whom had chest drains inserted) and two assigned to chest drain group. The other four deaths in the needle group were caused by systemic thrombosis, disseminated intravascular coagulation, cardiac failure, and congenital surfactant protein B deficiency.

Figure 4. Forest plot of comparison: 1 Needle aspiration (needle removed immediately after aspiration) versus intercostal tube drainage, outcome: 1.1 Mortality during hospitalisation. **Secondary outcomes**

Need for intercostal tube drainage (it should be noted that failure of needle aspiration may require intercostal tube drainage, however 100% of infants in the 'intercostal tube drainage' comparison group would have a drain placed)

Twenty-three of the 33 newborns treated with needle aspiration needed the placement of intercostal tube drainage (RR 0.70, 95%

CI 0.56 to 0.88; participants = 70; studies = 1) ([Analysis 1.2, Figure 5](#)). Among infants less than 32 weeks' GA, 12 (71%) and 14 (82%) of the 17 infants assigned to needle aspiration had a tube drain inserted within 6 hours and during hospitalisation, respectively. Among infants at 32 weeks' GA or older, six (38%) and nine (56%) of the 16 infants assigned to needle aspiration had a tube drain inserted within 6 hours and during hospitalisation, respectively.

Figure 5. Forest plot of comparison: 1 Needle aspiration (needle removed immediately after aspiration) versus intercostal tube drainage, outcome: 1.2 Need for intercostal tube drainage. **Duration of chest drain**

Duration of chest drain in situ was 66 hours (93) and 86 hours (83) in the needle aspiration and in the intercostal tube, respectively

(MD -20.00, 95% CI -61.50 to 21.50; participants = 70; studies = 1; [Analysis 1.3, Figure 6](#)). We obtained data for this outcome directly from trial authors.

Figure 6. Forest plot of comparison: 1 Needle aspiration (needle removed immediately after aspiration) versus intercostal tube drainage, outcome: 1.3 Duration of chest drain [hours]. **Number of chest drain insertions**

Mean number of chest drain insertions was one in both the needle aspiration and chest drain group (MD 0.0, 95% CI -0.47 to 0.47; participants = 70; studies = 1; [Analysis 1.4](#)). We obtained data for this outcome directly from trial authors.

Duration of mechanical ventilation

Duration of endotracheal ventilation was 9 hours (23) and 4 (4) hours in the needle aspiration and in the intercostal tube, respectively (MD 5.0, 95% CI -2.95 to 12.95; participants = 70; studies = 1; [Analysis 1.5](#)). We obtained data for this outcome directly from trial authors.

Duration of respiratory support

[Murphy 2018](#) reported data as median/interquartile range (IQR). Duration of respiratory support was 5 days (3 to 12 days) in the

needle aspiration group versus 6 days (3 to 40 days) in the chest drain group.

Duration of oxygen therapy

Duration of oxygen therapy was 23 days (49) and 27 (38) in the needle aspiration and in the intercostal tube, respectively (MD -4.0, 95% CI -24.72 to 16.72; participants = 70; studies = 1; [Analysis 1.6](#)). We obtained data for this outcome directly from trial authors.

Duration of hospital stay

Duration of hospital stay was 24 (28) days and 46 (37) in the needle aspiration and in the intercostal tube, respectively (MD -22.0, 95% CI -37.28 to -6.72; participants = 70; studies = 1; [Analysis 1.7](#)). We obtained data for this outcome directly from trial authors.

Bronchopulmonary dysplasia (BPD)/chronic lung disease (CLD)

This outcome was reported only for the subgroup of 39 infants with GA less than 32 weeks.

1. BPD any grade was reported for 14 of the 17 infants in the needle aspiration group and in 13 of the 22 infants with intercostal tube (RR 1.39, 95% CI 0.92 to 2.10; participants = 39; studies = 1; [Analysis 1.8](#) – first subgroup analysis).
2. BPD moderate to severe was reported for 13 of the 17 infants in the needle aspiration group and in 11 of the 22 infants with intercostal tube (RR 1.53, 95% CI 0.93 to 2.51; participants = 39; studies = 1; [Analysis 1.8](#) – second subgroup analysis).

No data were reported on the following outcomes.

1. Successful evacuation of extra-pleural air.
2. Bleeding from incision for the insertion of the needle or the tube.
3. Subcutaneous emphysema diagnosed by imaging.
4. Haemothorax diagnosed by imaging.
5. Duration of MV post intervention.
6. Sedation/agitation/pain scale during the insertion of needle or tube.

7. Sedation/agitation/pain scale average daily score.
8. Germinal matrix-intraventricular haemorrhage (GM-IVH).

Comparison 2: Needle aspiration (needle or angiocatheter left in situ) versus intercostal tube drainage

We identified only one trial ([Arda 2002](#)), which included a total of 72 infants (see [Characteristics of included studies](#) and [Summary of findings 2](#)).

Tests for heterogeneity were not applicable for any of the analyses as only one study was included in the comparison.

Primary outcomes

Death during hospitalisation

Five of the patients died, three in the needle group and two in the intercostal tube group (RR 1.50, 95% CI 0.27 to 8.45) ([Analysis 2.1](#); [Figure 7](#)). It was not specified by the trials' authors whether data referred to neonatal mortality or during hospitalisation. Four patients died of sepsis and one due to congenital heart disease. None of the five deaths were linked to PTX or to its treatment.

Figure 7. Forest plot of comparison: 1 Needle aspiration vs intercostal tube drainage, outcome: 1.1 Mortality during hospitalisation.

Secondary outcomes

Need for intercostal tube drainage (it should be noted that failure of needle aspiration may require intercostal tube drainage, however 100% of infants in the 'intercostal tube drainage' comparison group would have a drain placed)

None of the newborns treated with needle aspiration needed the placement of intercostal tube drainage (RR 0.01, 95% CI 0.00 to 0.21) ([Analysis 2.2](#)).

Successful evacuation of extra-pleural air

The authors of the included study did not define any successful PTX evacuation. However two newborns in each group required re-

insertion of tube/catheter (RR 1.00, 95% CI 0.89 to 1.12) ([Analysis 2.3](#)).

Bleeding from incision for the insertion of the needle or the tube

One event occurred in the intercostal tube group, none in the needle aspiration group (RR 0.33, 95% CI 0.01 to 7.92) ([Analysis 2.4](#)).

Duration of chest drain

Duration of needle in place was shorter than duration of intercostal tube (MD -11.20 hours, 95% CI -15.51 to -6.89) ([Analysis 2.5](#); [Figure 8](#)).

Figure 8. Forest plot of comparison: 1 Needle aspiration vs intercostal tube drainage, outcome: 1.5 Duration of catheter/tube in place [hours].

Number of chest drain insertions

Infants in the needle aspiration group never required chest drain insertion, though the catheter had to be re-inserted in two cases.

Infants in the intercostal tube group required re-insertion of the tube in two cases (RR 1.00, 95% CI 0.15 to 6.72) ([Analysis 2.6](#)).

No data were reported on the following outcomes:

1. Subcutaneous emphysema diagnosed by imaging.
2. Haemothorax diagnosed by imaging.
3. Duration of mechanical ventilation.
4. Duration of MV post intervention.
5. Duration of respiratory support.
6. Duration of oxygen therapy.
7. Duration of hospital stay.
8. Sedation/agitation/pain scale during the insertion of needle or tube.
9. Sedation/agitation/pain scale average daily score.
10. Germinal matrix-intraventricular haemorrhage (GM-IVH).
11. Bronchopulmonary dysplasia (BPD)/chronic lung disease (CLD).

Subgroup analysis

We were unable to conduct any subgroup analysis as we included only one trial for each comparison.

DISCUSSION

Summary of main results

We evaluated the efficacy of needle aspiration compared to intercostal tube drainage in the treatment of pneumothorax in newborns. Only two trials enrolling 142 infants with a broad range of weight and gestational age met the inclusion criteria of this review ([Arda 2002](#); [Murphy 2018](#)). However they were not pooled in the same analysis because in [Murphy 2018](#) the needle was removed immediately after aspiration whereas in [Arda 2002](#) it was left in situ. There was insufficient evidence to determine the efficacy and safety of the two techniques due to the paucity of studies and small sample sizes. Optimal information size was not achieved for the primary outcome of this review, i.e. mortality rate. With immediate removal of the needle following aspiration ([Murphy 2018](#)), 30% of the newborns did not require the placement of an intercostal tube drainage. Of note: this rate differed between infants less than 32 weeks' GA versus infants at 32 weeks' GA or older (82% and 56%, respectively). By contrast, none of the 36 newborns treated with needle aspiration left in situ required the placement of an intercostal tube drainage ([Arda 2002](#)). The higher success rate in avoiding intercostal tube placement might be due to the procedure itself, to different population characteristics and other factors which can not be assessed in this review. Overall it seems that needle aspiration might reduce the need for intercostal tube placement in a relevant proportion of newborns. In [Arda 2002](#), duration of needle in place was shorter than duration of intercostal tube.

We identified no ongoing trials.

Overall completeness and applicability of evidence

The available evidence is insufficient to understand which is the more effective and safe intervention for treating neonatal pneumothorax. Only two randomised trial (142 newborns) assessed the study question. There were insufficient data available to assess the primary outcome of this review and other important outcomes which were identified a priori. Outcomes such as haemothorax, intraventricular haemorrhage and bronchopulmonary dysplasia were not reported. With immediate removal of the needle following aspiration as in [Murphy 2018](#), 30% of the newborns did not require the placement of an intercostal

tube drainage. Importantly, in [Arda 2002](#) the investigators inserted the needle with the intention of leaving the angiocatheter in situ; whereas in clinical practice, most practitioners aspirate air until it stops coming and then remove the needle. This discrepancy might affect the generalisability of the study results and therefore of the present review. We could not perform a priori subgroup analysis (gestational age, birth weight, intubated versus not intubated, unilateral versus bilateral PTX, single versus repeated aspirations) to detect differential effects as there was only one included RCT. Other larger trials are required to draw any conclusion.

Quality of the evidence

The overall quality of the evidence was judged to be 'very low' due to imprecision (two, small trials) and the presence of multiple biases (see [Summary of findings for the main comparison](#); [Summary of findings 2](#)).

Potential biases in the review process

It is unlikely that the literature search applied to this review may have missed relevant trials, thus we are confident that this systematic review summarises all the presently available randomised trial evidence on treatment of neonatal pneumothorax. We did not exclude any potentially relevant trial. We did not succeed in obtaining additional information on the population and the outcomes included in the trial by [Arda 2002](#). Relevant outcomes data outcomes were provided by the authors of [Murphy 2018](#). The included trials were unblinded due to the nature of the intervention (high risk for performance bias). In addition, [Arda 2002](#) was affected by unclear risk for selection and reporting bias whereas [Murphy 2018](#) was high risk for detection bias.

Agreements and disagreements with other studies or reviews

We are not aware of other reviews that address the same clinical question. We described the characteristics of the only clinical trials that have been published.

AUTHORS' CONCLUSIONS

Implications for practice

There is insufficient evidence to establish the efficacy and safety of needle aspiration and intercostal tube drainage in the management of neonatal pneumothorax. The two included trials showed no differences in mortality; however the information size is low. Needle aspiration reduces the need for intercostal tube drainage placement. Limited or no evidence is available on other clinically relevant outcomes.

Implications for research

Randomised controlled trials of neonatal pneumothorax treatment are warranted. These trials should be stratified by gestational age, describe population characteristics (e.g. presence of ventilation, unilateral or bilateral pneumothorax) and details of the procedures (e.g. single versus repeated aspirations; needle removed immediately after aspiration versus left in situ), and report on clinically relevant outcomes such as intraventricular haemorrhage and bronchopulmonary dysplasia when very preterm infants are enrolled.

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The Methods section of this review is based on a standard template used by Cochrane Neonatal.

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CHARACTERISTICS OF STUDIES

Characteristics of included studies [ordered by study ID]

Arda 2002

Methods	2-centre unblinded randomised controlled trial. Criteria to drain PTX included persistent or increased air detected in serial lung X-rays, mediastinal shifting, respiratory difficulty with cyanosis and patients with PTX on ventilator.
Participants	72 newborns with PTX. The mean birth weight (SD) was 2547.2 (± 448.1) grams in the needle group and 2690.2 (± 419.4) grams in the intercostal tube group; mean gestational age (SD) was 36.4 (± 2.6) weeks in the needle group and 35.8 (± 2.8) weeks in the intercostal tube group. Settings: 2 Turkish neonatal intensive care units, i.e. Social Security Children's Hospital and Baskent University Hospital.

Arda 2002 (Continued)

Interventions	<p>In the needle group, an 18-gauge 45 mm long venous catheter was introduced by the surgeon without local anaesthesia through the fourth or fifth intercostal space on the anterior axillary line and after guide needle withdrawal the catheter was directed toward the superior part of the thoracic cavity.</p> <p>In the intercostal tube drainage, the surgeon made an incision at the fifth or sixth intercostal space with local anaesthesia (Prilocaine hydrochloride), separated the intercostal muscle fibres, blunt-dissected a subcutaneous tunnel, pierced the pleura and inserted a 12-F standard chest tube catheter through the tunnel into the pleural space.</p> <p>In both groups, the chest tube or venous catheter were connected to an underwater drainage system and a chest X-ray was taken immediately after each procedure to check for the presence of residual air in the thoracic cavity. When the bubbling in the water-seal chamber stopped, the drainage system was clamped. The system was then kept closed for at least 6 hours. Once a final chest X-ray showed no residual air, the chest tube or venous catheter was removed.</p> <p>The same surgeon performed all procedures in both groups.</p>	
Outcomes	<p>Main outcomes were duration of the procedure, duration of the tubes and catheters in place and the rates of major complications (tube accidentally dislodged, air leakage through the incision, iatrogenic pneumothorax) and minor complications (kinking of the chest tube, bleeding from the incision, evident pain causing respiratory difficulty, catheter breakage).</p> <p>Other outcomes included mortality (unspecified) and need for re-insertion of tube/catheter.</p>	
Notes		
Risk of bias		
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Randomisation sequence generation is not specified.
Allocation concealment (selection bias)	Unclear risk	Allocation concealment is not specified.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Unblinded intervention.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not mentioned.
Incomplete outcome data (attrition bias) All outcomes	Low risk	All infants accounted for.
Selective reporting (reporting bias)	Unclear risk	We could not ascertain if there were deviations from the original protocol in the final publication (trial not registered, protocol not available).
Other bias	Low risk	Appeared free of other biases.

Murphy 2018

Methods	Randomised controlled trial comparing 2 different techniques to treat neonatal PTX.
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Needle aspiration versus intercostal tube drainage for pneumothorax in the newborn (Review)

Murphy 2018 (Continued)

Setting: NICUs in Ireland, Denmark, Italy and Sweden.

Study hypothesis: "In newborn infants with symptomatic pneumothoraces, aspirating air with a needle reduces the need for chest drain insertion".

Follow-up until hospital discharge.

Participants	<p>Sample size: 70 newborns (both term and preterm).</p> <p>Inclusion criteria: 1. PTX diagnosed on chest x-ray; 2. Need for respiratory support; 3. PTX judged as requiring treatment.</p> <p>Exclusion criteria: 1. Absence of respiratory distress; 2. Significant pulmonary hypoplasia, e.g. Potter's sequence.</p>
Interventions	Aspiration with a 23 or 25 gauge 'butterfly' needle or angiocatheter and 20 mL syringe versus chest drain insertion.
Outcomes	<p>Primary outcome measures: Chest drain insertion for management of PTX on chest x-ray within 6 hours of diagnosis.</p> <p>Secondary outcome measures: 1. Chest drain insertion before hospital discharge; 2. Duration of chest drain; 3. Number of chest drain insertions; 4. Duration of ventilation post intervention; 5. Duration of ventilation; 6. Duration of nasal continuous positive airway pressure; 7. Duration of supplemental oxygen; 8. Bronchopulmonary dysplasia – oxygen treatment at 28 days; 9. Chronic lung disease – oxygen treatment at 36 weeks' postmenstrual age; 10. Nosocomial infections; 11. Pleural effusions; 12. Duration of hospital stay; 13. Death before discharge from hospital.</p>

Notes

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Infants were randomly assigned (1:1) to needle aspiration or chest drain insertion. Randomisation was stratified by centre and gestational age at birth (< 32 vs ≥32 weeks). It has been generated the group assignment schedule at National Maternity Hospital in blocks of 4 using a random number table.
Allocation concealment (selection bias)	Low risk	Group assignment was written on cards and placed in sequentially numbered, sealed, opaque envelopes.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Unblinded intervention.
Blinding of outcome assessment (detection bias) All outcomes	High risk	Unblinded intervention.
Incomplete outcome data (attrition bias) All outcomes	Low risk	All infants accounted for.
Selective reporting (reporting bias)	Low risk	All outcomes reported.
Other bias	Low risk	Appeared free of other biases.

DATA AND ANALYSES

Comparison 1. Needle aspiration (needle or angiocatheter removed immediately after aspiration) versus intercostal tube drainage

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Mortality during hospitalisation	1	70	Risk Ratio (M-H, Fixed, 95% CI)	3.92 [0.88, 17.58]
2 Need for intercostal tube drainage	1	70	Risk Ratio (M-H, Fixed, 95% CI)	0.70 [0.56, 0.88]
3 Duration of chest drain	1	70	Mean Difference (IV, Fixed, 95% CI)	-20.0 [-61.50, 21.50]
4 Number of chest drains	1	70	Mean Difference (IV, Fixed, 95% CI)	0.0 [-0.47, 0.47]
5 Duration of mechanical ventilation	1	70	Mean Difference (IV, Fixed, 95% CI)	5.0 [-2.95, 12.95]
6 Duration of supplemental oxygen	1	70	Mean Difference (IV, Fixed, 95% CI)	-4.0 [-24.72, 16.72]
7 Duration of hospital stay	1	70	Mean Difference (IV, Fixed, 95% CI)	-22.0 [-37.28, -6.72]
8 Bronchopulmonary dysplasia	1		Risk Ratio (M-H, Fixed, 95% CI)	Subtotals only
8.1 oxygen treatment at day 28 of life	1	39	Risk Ratio (M-H, Fixed, 95% CI)	1.39 [0.92, 2.10]
8.2 oxygen treatment at 36 weeks' corrected GA	1	39	Risk Ratio (M-H, Fixed, 95% CI)	1.53 [0.93, 2.51]

Analysis 1.1. Comparison 1 Needle aspiration (needle or angiocatheter removed immediately after aspiration) versus intercostal tube drainage, Outcome 1 Mortality during hospitalisation.

Analysis 1.2. Comparison 1 Needle aspiration (needle or angiocatheter removed immediately after aspiration) versus intercostal tube drainage, Outcome 2 Need for intercostal tube drainage.

Analysis 1.3. Comparison 1 Needle aspiration (needle or angiocatheter removed immediately after aspiration) versus intercostal tube drainage, Outcome 3 Duration of chest drain.

Analysis 1.4. Comparison 1 Needle aspiration (needle or angiocatheter removed immediately after aspiration) versus intercostal tube drainage, Outcome 4 Number of chest drains.

Analysis 1.5. Comparison 1 Needle aspiration (needle or angiocatheter removed immediately after aspiration) versus intercostal tube drainage, Outcome 5 Duration of mechanical ventilation.

Analysis 1.6. Comparison 1 Needle aspiration (needle or angiocatheter removed immediately after aspiration) versus intercostal tube drainage, Outcome 6 Duration of supplemental oxygen.

Analysis 1.7. Comparison 1 Needle aspiration (needle or angiocatheter removed immediately after aspiration) versus intercostal tube drainage, Outcome 7 Duration of hospital stay.

Analysis 1.8. Comparison 1 Needle aspiration (needle or angiocatheter removed immediately after aspiration) versus intercostal tube drainage, Outcome 8 Bronchopulmonary dysplasia.

Comparison 2. Needle aspiration (needle or angiocatheter left in situ) vs. intercostal tube drainage

Outcome or subgroup title	No. of studies	No. of partici- pants	Statistical method	Effect size
1 Mortality during hospitalisation	1	72	Risk Ratio (M-H, Fixed, 95% CI)	1.5 [0.27, 8.45]
2 Need for intercostal tube drainage	1	72	Risk Ratio (M-H, Fixed, 95% CI)	0.01 [0.00, 0.21]
3 Successful evacuation of ex- tra-pleural air	1	72	Risk Ratio (M-H, Fixed, 95% CI)	1.0 [0.89, 1.12]
4 Bleeding from incision	1	72	Risk Ratio (M-H, Fixed, 95% CI)	0.33 [0.01, 7.92]
5 Duration of catheter/tube in place	1	72	Mean Difference (IV, Fixed, 95% CI)	-11.20 [-15.51, -6.89]
6 Number of chest drain insertions	1	72	Risk Ratio (M-H, Fixed, 95% CI)	1.0 [0.15, 6.72]

Analysis 2.1. Comparison 2 Needle aspiration (needle or angiocatheter left in situ) vs. intercostal tube drainage, Outcome 1 Mortality during hospitalisation.

Analysis 2.2. Comparison 2 Needle aspiration (needle or angiocatheter left in situ) vs. intercostal tube drainage, Outcome 2 Need for intercostal tube drainage.

Analysis 2.3. Comparison 2 Needle aspiration (needle or angiocatheter left in situ) vs. intercostal tube drainage, Outcome 3 Successful evacuation of extra-pleural air.

Analysis 2.4. Comparison 2 Needle aspiration (needle or angiocatheter left in situ) vs. intercostal tube drainage, Outcome 4 Bleeding from incision.

Analysis 2.5. Comparison 2 Needle aspiration (needle or angiocatheter left in situ) vs. intercostal tube drainage, Outcome 5 Duration of catheter/tube in place.

Analysis 2.6. Comparison 2 Needle aspiration (needle or angiocatheter left in situ) vs. intercostal tube drainage, Outcome 6 Number of chest drain insertions.

APPENDICES

Appendix 1. Cochrane Neonatal standard search strategy

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 randomized [tiab] OR placebo [tiab] OR drug therapy [sh] OR randomly [tiab] OR trial [tiab] OR groups [tiab]) NOT (animals [mh] NOT humans [mh]))

Embase: ((exp infant) OR (infan* OR newborn or neonat* OR premature or very low birth weight or low birth weight or VLBW or LBW).mp 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).mp

CINAHL: (infan* OR newborn OR neonat* OR premature OR low birth weight OR VLBW OR LBW) 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: (infan* or newborn or neonat* or premature or preterm or very low birth weight or low birth weight or VLBW or LBW)

Appendix 2. Risk of bias tool

We used the standard methods of Cochrane and Cochrane Neonatal to assess the methodological quality of the trials. For each trial, we sought information regarding the method of randomisation, blinding and reporting of all outcomes of all the infants enrolled in the trial. We assessed each criterion as being at a low, high, or unclear risk of bias. Two review authors separately assessed each study. Disagreements were resolved by discussion. We added this information to the table [Characteristics of included studies](#). We evaluated the following issues and entered the findings into the 'Risk of bias' table:

1. Sequence generation (checking for possible selection bias). Was the allocation sequence adequately generated?

For each included study, we categorized the method used to generate the allocation sequence 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); or
- unclear risk.

2. Allocation concealment (checking for possible selection bias). Was allocation adequately concealed?

For each included study, we categorized the method used to conceal the allocation sequence 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); or
- unclear risk

3. Blinding of participants and personnel (checking for possible performance bias). Was knowledge of the allocated intervention adequately prevented during the study?

For each included study, we categorized the methods used to blind study participants and personnel from knowledge of which intervention a participant received. Blinding was assessed separately for different outcomes or class of outcomes. We categorized the methods as:

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

4. Blinding of outcome assessment (checking for possible detection bias). Was knowledge of the allocated intervention adequately prevented at the time of outcome assessment?

For each included study, we categorized the methods used to blind outcome assessment. Blinding was assessed separately for different outcomes or class of outcomes. We categorized the methods as:

- low risk for outcome assessors;
- high risk for outcome assessors; or
- unclear risk for outcome assessors.

5. Incomplete outcome data (checking for possible attrition bias through withdrawals, dropouts, protocol deviations). Were incomplete outcome data adequately addressed?

For each included study and for each outcome, we described the completeness of data including attrition and exclusions from the analysis. We noted 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 re-included missing data in the analyses. We categorized the methods as:

- low risk (< 20% missing data);
- high risk ($\geq$ 20% missing data); or
- unclear risk.

6. Selective reporting bias. Are reports of the study free of suggestion of selective outcome reporting?

For each included study, we described how we investigated the possibility of selective outcome reporting bias and what we found. For studies in which study protocols were published in advance, we compared prespecified outcomes versus outcomes eventually reported in the published results. If the study protocol was not published in advance, we contacted study authors to gain access to the study protocol. We assessed the methods as:

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

7. Other sources of bias. Was the study apparently free of other problems that could put it at a high risk of bias?

For each included study, we described any important concerns we had about other possible sources of bias (for example, whether there was a potential source of bias related to the specific study design or whether the trial was stopped early due to some data-dependent process). We assessed whether each study was free of other problems that could put it at risk of bias as:

- low risk;
- high risk;
- unclear risk

If needed, we explored the impact of the level of bias through undertaking sensitivity analyses.

WHAT'S NEW

Date	Event	Description
4 June 2018	New search has been performed	We updated searches in 2018 and found one new eligible study for inclusion
4 June 2018	New citation required and conclusions have changed	We included one new study and made changes to the main conclusions

CONTRIBUTIONS OF AUTHORS

MB and OR reviewed the literature and wrote the review.

SZ and MGC assisted in the review of literature and in writing of the review.

COD commented on the review.

DECLARATIONS OF INTEREST

MB, OR, SZ, COD and MGC declare having no competing financial conflict of interest.

SOURCES OF SUPPORT

Internal sources

- Institute for Clinical Sciences, Lund University, Lund, Sweden.

MB and OR are employed by this organisation

- Istituto Giannina Gaslini, Genoa, Italy.

MGC is employed by this organisation

External sources

- Vermont Oxford Network, USA.

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DIFFERENCES BETWEEN PROTOCOL AND REVIEW

We added the methodology and plan for 'Summary of findings' tables and GRADE recommendations, which were not included in the original protocol (see [Summary of findings for the main comparison](#)).

We have specified two separate comparisons, i.e. needle removal immediately after aspiration; needle left in situ.

INDEX TERMS

Medical Subject Headings (MeSH)

*Chest Tubes [statistics & numerical data]; *Needles; Device Removal; Hemorrhage [etiology]; Hospital Mortality; Pneumothorax [mortality] [*therapy]; Randomized Controlled Trials as Topic; Risk; Suction [instrumentation] [methods] [mortality]; Thoracentesis [instrumentation] [*methods] [mortality]; Thoracostomy [adverse effects] [methods]

MeSH check words

Humans; Infant, Newborn