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[Intervention Review]

Conservative versus interventional management for primary spontaneous pneumothorax in adults

Michael Ashby¹, Greg Haug², Pete Mulcahy³, Kathryn J Ogden⁴, Oliver Jensen⁵, Julia AE Walters⁶

¹Launceston Clinical School, Northern Integrated Care Service, Launceston General Hospital, South Launceston, Australia. ²Department of Medicine, Launceston General Hospital, Launceston, Australia. ³Launceston General Hospital, DHHS, Mt Nelson, Australia.

⁴Launceston Clinical School, University of Tasmania, Launceston, Australia. ⁵Launceston Clinical School, University of Tasmania Medical Faculty, South Launceston, Australia. ⁶La Trobe University, Melbourne, Australia

Contact: Michael Ashby, Launceston Clinical School, Northern Integrated Care Service, Launceston General Hospital, 41 Frankland St, South Launceston, Tasmania, 7250, Australia. michael.d.ashby@gmail.com.

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ABSTRACT

Background

Primary spontaneous pneumothorax is widely managed according to size with interventional techniques based on practice guidelines. Interventional management is not without complications and observational data suggest conservative management works. The current guidelines are based on expert consensus rather than evidence, and a systematic review may help in identifying evidence for this practice.

Objectives

The objective of the review is to compare conservative and interventional treatments of adult primary spontaneous pneumothorax for outcomes of clinical efficacy, tolerability and safety.

Search methods

We searched the Cochrane Central Register of Controlled Trials (CENTRAL), (*The Cochrane Library*, Issue 6, 2014); MEDLINE via Ovid SP (1920 to 26th June 2014); EMBASE via Ovid SP (1947 to 26th June 2014); CINAHL via EBSCO host (1980 to 26th June 2014); and ISI Web of Science (1945 to 26th June 2014). We searched ongoing trials via the relevant databases and contacted authors. We also searched the 'grey literature'.

Selection criteria

We included randomized controlled trials (RCTs) and we accepted quasi-RCTs if a systematic method of allocation was used. Participants were limited to adults aged 18 to 50 years, with their first symptomatic primary spontaneous pneumothorax with radiological evidence and no underlying lung disease.

Data collection and analysis

Two of five authors independently reviewed all studies in the search criteria and made inclusions and exclusions according to the selection criteria. No statistical methods were necessary as there were no included trials.

Main results

We identified 358 studies with duplicates removed. There were three potentially relevant studies that we excluded as they were not randomized controlled trials. There was one ongoing trial that was relevant and we contacted the authors and confirmed the study is ongoing at June 2014. We will update this review when this ongoing study is completed.

Authors' conclusions

There are no completed randomized controlled trials comparing conservative and interventional management for primary spontaneous pneumothorax in adults. There is a lack of high-quality evidence for current guidelines in management and a need for randomized controlled trials comparing conservative and interventional management for this condition.

PLAIN LANGUAGE SUMMARY

Observation alone versus drain tube or needle insertion (interventional) for primary spontaneous pneumothorax in adults without previous lung disease.

Review question: A primary spontaneous pneumothorax (PSP) is a collection of air in the lining of the lung that occurs on its own or without a traumatic event. When this occurs, people can have chest pain and shortness of breath. Most of the time, the air in the lung is absorbed by the body and slowly decreases with time. Most of the guidelines in managing this condition recommend draining the air by sucking it out with a small needle, or placing a larger tube into the chest that drains the air over a period of time (both called 'interventional' management'). We aimed to examine the evidence for the recommendation.

Background: Interventional management can have side effects, such as causing more pain, infection, and potentially damaging nearby structures. The other way of treatment is called observational or conservative, where pain relief and extra oxygen are given until the lung re-inflates and the air is absorbed by the body on its own. Studies that look back on how patients were managed (retrospective studies) and personal experience of the authors with these patients show that managing them by observation alone can work well.

Review findings: The authors of this review searched for studies that compared interventional management with observational management but found no completed studies, although there is one study in progress. This means that there is a lack of high-quality evidence about the best way to manage a primary spontaneous pneumothorax in adults aged over 18 without previous lung disease; further studies are needed. The evidence is current to 26th June 2014.

BACKGROUND

Description of the condition

A pneumothorax is defined as air in the pleural space, that is, air between the lung and the chest wall. A primary spontaneous pneumothorax (PSP) is a pneumothorax that occurs in a person without a precipitating event (including iatrogenic causes) or known underlying lung disease. Secondary spontaneous pneumothorax occurs as a result of known underlying lung disease, most commonly in persons suffering from chronic obstructive pulmonary disease (COPD) (Light 2007).

The most widely accepted mechanism for pneumothorax in cases of primary spontaneous pneumothorax is rupture of sub-plural bullae. Bulla formation is thought to be secondary to inflammatory change at a cellular level, most likely as a result of inhaled tobacco smoke (Sahn 2000). Other mechanisms include small airways inflammation and emphysematous changes. Spontaneous pneumothorax is a relatively common pathology, with studies suggesting 18 to 28 cases per 100,000 population in men and two to six per 100,000 population in women (Gupta 2000; Melton 1979). Smoking has been implicated in the pathogenesis of PSP, and is associated with up to 22 times the risk of developing a first PSP in moderate smokers (up to 22 cigarettes per day) (Bense 1987).

Description of the intervention

Primary spontaneous pneumothorax can be treated either conservatively or by intervention. Interventional treatment options, which have been popular in the last 40 to 50 years, include simple fine needle aspiration, large- or small-bore intercostal tube drainage, thoracotomy and thoracoscopy. Conservative management, which involves observing the patient, giving appropriate analgesia and oxygen therapy, and only treating interventionally in rare cases, is the focus of this review.

How the intervention might work

The treatment principles for primary spontaneous pneumothorax are to remove the air from the pleural space, and to decrease the chance of recurrence (Light 2007). Lung physiology dictates a lung will inflate with inspiration and that the air in the pleural space will be reabsorbed. The rate of reabsorption is estimated at 1.25% of the volume of the hemithorax each 24 hours (Kircher 1954). Many of the initial studies favouring interventions focused on the speed of normalization of x-ray findings or length of stay in hospital, which was determined by normalization of x-ray findings rather than clinical endpoints such as frequency of complication, analgesic requirements, and recurrence risk (Romanoff 1968). In 1966 Stradling and Poole, in a large observational study, reported on the efficacy and safety of conservative management. They expressed concern that interventional management would be practised on the basis of rapid radiological resolution (Stradling 1966).

Current guidelines on the management of primary spontaneous pneumothorax (Baumann 2001; De Leyn 2005; Henry 2003; MacDuff 2010) largely ignore the practice of conservative management, despite the earlier evidence of its efficacy and safety, and recommend intervention in all but the smallest PSPs. We believe that the evidence for this recommendation is limited, and clinical experience has suggested that conservative management can be effective and safe even in large PSPs.

Why it is important to do this review

Currently there are three major published guidelines outlining treatment options for PSP. The British Thoracic Society (Henry 2003; MacDuff 2010) and the Belgian Society of Pneumology (De Leyn 2005) both state simple aspiration to be the first line treatment for all PSPs requiring intervention (Henry 2003; MacDuff 2010). In contrast to this, the American College of Chest Physicians consensus guidelines state there is no role for simple aspiration, and recommend the insertion of an intercostal catheter as first-line therapy in large pneumothoraces (Baumann 2001). This highlights the disagreement between current guidelines and the lack of clarity in recommendations and practice regarding interventional management as first-line treatment for most PSPs. There is no recommendation for even a trial of a conservative approach in anything but the smaller PSPs, defined by: 1) the British Thoracic Society as a rim of less than two centimetres of air in the pleural space, 2) the American College of Chest Physicians as three centimetres or less, and 3) the Belgian Society of Pneumology as "small and minimally symptomatic" (De Leyn 2005, p. 266). The major published guidelines cite the limited relevant evidence and low levels of evidence, and disagree on which pneumothoraces can be managed conservatively.

Literature currently exists comparing the interventional methods of management, including a Cochrane Review (Wakai 2007) comparing simple aspiration versus intercostal drainage, finding that there is no difference between the two interventions with regard to immediate successful resolution.

PSP is a condition that should have a near 100% survival rate, occurring as it does in people with no underlying lung disease. However, complications of intervention do occur, with rates of up to 30% with chest tube insertion. Interventions can impact adversely on morbidity, mortality, and other outcomes such as pain and length of stay (Ball 2007; Vedam 2003),.

The somewhat contradictory published guidelines (Baumann 2001; De Leyn 2005; Henry 2003; MacDuff 2010), along with the lack of a firm evidence base, has led to wide variations in the management of PSP, reflecting local preferences and expertise rather than an evidence-based approach. A systematic review of the literature, including literature which examines the use of a conservative approach to PSP, will help to create an evidence-based background for future treatment recommendations.

OBJECTIVES

The objective of the review is to compare conservative and interventional treatments of adult primary spontaneous pneumothorax for outcomes of clinical efficacy, tolerability and safety.

METHODS

Criteria for considering studies for this review

Types of studies

We planned to include randomized controlled trials (RCTs) and to accept quasi-RCTs if a systematic method of allocation was used, such as alternation, assignment based on date of birth, case record number and date of presentation. We planned to include studies

reported in abstract form (e.g. conference presentations) if data were available from the investigators.

Types of participants

We planned to include adults (aged 18 to 50 years) with a first episode of symptomatic primary spontaneous pneumothorax (PSP) as identified by radiographic evidence, where there was no underlying lung disease. We planned to exclude: adults with lung disease such as chronic obstructive pulmonary disease; asthma; interstitial lung disease; cystic fibrosis; trauma; any other secondary causes or recurrent pneumothorax; and adults with an iatrogenic pneumothorax. Adults over 50 were also to be excluded due to the increased likelihood of smokers over 50 having COPD changes.

Types of interventions

We planned to compare observational/conservative management with interventional management.

We defined observational/conservative management as:

- Oxygen therapy
- Analgesia

Interventional management strategies included:

- Intercostal or thoracic drainage
- Simple, manual needle aspiration
- Thoracotomy or thoracoscopy
- Chest tubes, suction, catheterization

Chest tube size was to be documented where available.

Types of outcome measures

Primary outcomes

1. Immediate success - defined as clinical resolution with substantial radiological improvement of pneumothorax within 28 days without complications
2. Failure of treatment - defined as need for a secondary intervention within 28 days
3. Mortality - all causes within 28 days
4. Duration of hospitalization - measured in nights in hospital from first presentation

Secondary outcomes

1. Immediate recurrence: 24 to 48 hours
2. Early recurrence: one to two weeks
3. Intermediate recurrence: two to four weeks
4. Late recurrence: more than four weeks
5. Complications: including of interventional and conservative management

Outcomes did not form part of the study eligibility assessment, so that studies that met the participant, intervention and comparison criteria were to be included in the review even if they reported no relevant outcomes. Time-to-event data were to be interpreted with care and in light of the duration of studies, in order to ensure that censoring was properly dealt with.

Search methods for identification of studies

Electronic searches

We conducted electronic searches of the Cochrane Central Register of Controlled Trials (CENTRAL), (*The Cochrane Library*, Issue 6, 2014); MEDLINE via Ovid SP (1920 to 26th June 2014); EMBASE via Ovid SP (1947 to 26th June 2014); CINAHL via EBSCO host (1980 to 26th June 2014); and ISI Web of Science (1945 to 26th June 2014). We did not apply any language restrictions. The development of our final search strategy was an iterative process, and we employed strategies to maximize the sensitivity of the search as outlined in Chapter 6.4 of the *Cochrane Handbook of Systematic reviews of Interventions* (Higgins 2011). Given we were interested in quasi-randomized as well as randomized trials, we did not limit the search to RCTs. We initially used the MEDLINE search strategy identified in [Appendix 1](#), but refined our terms by assessing retrieved studies for unidentified search terms. We used both MeSH terms and free text as appropriate, given issues of precision and sensitivity.

We developed the search strategy in conjunction with the Cochrane Anaesthesia Review Group's Trials Search Co-ordinator.

Searching other resources

In addition we searched relevant ongoing trials registers and relevant conference proceedings.

We scanned the references of primary sources and we searched any other unpublished sources known to the authors, including 'grey literature' (reports that are produced by all levels of government, academics, business and industry in print and electronic formats but that are not controlled by commercial publishers). We sought information about, and raw data from, published trials where it was appropriate.

Data collection and analysis

Selection of studies

We combined the results of all studies and deleted duplicates. Two of five authors (PM, OJ, MA, KO, JW) independently reviewed all studies identified to assess whether they met the inclusion criteria, and reviewed the abstract and retrieved the full text of the article if insufficient information was available from the abstract. We screened studies for eligibility based on whether: it was a controlled trial; involved participants aged 18 and over; spontaneous pneumothorax was the condition under study; and one intervention involved conservative management as defined in the protocol (screening form [Appendix 2](#)). We resolved any disagreements between authors by discussion with all authors present and the involvement of a sixth author (GH) if they remained unresolved. If a study satisfied all of these criteria, or it was unclear from the title and abstract, we retrieved the full text and determined inclusion of the study based on the criteria described in addition to identified inclusion and exclusion criteria. Once again, two authors independently determined exclusion, and resolved disagreements by discussion with all authors.

Data extraction and management

We planned to extract data from the included studies using an appropriately modified version of the Cochrane Anaesthetic Review Group's Data Collection Form ([Appendix 3](#)). Two authors were to independently extract the data and to resolve disagreements by

discussion with all authors. If we needed further information from the authors of the trial, we planned to contact them and request the information or data.

Assessment of risk of bias in included studies

Assessment of risk of bias is a domain-based critical evaluation of included studies. Three authors (PM, OJ, MA) planned to independently assess the risk of bias using The Cochrane Collaboration's tool for assessing risk of bias (Higgins 2011, Chapter 8). We planned to assess each study according to the following domains: random sequence generation; allocation concealment; blinding of participants and personnel; blinding of outcome assessment; incomplete outcome data; selective reporting; and any other bias. A copy of the risk assessment form that we planned to use is attached (Appendix 4). We planned to assess trials as having low risk of bias if all identified domains were assessed to be satisfactory, and a high risk of bias if one or more domains were assessed as being at high risk or unclear risk. All authors were to jointly discuss and resolve disagreements in any classification.

If relevant studies were identified, we planned to include the risks of bias for each study in a table of included study characteristics and to explore the impact of risk of bias by graphing results according to risk of bias and, if appropriate, to perform sensitivity analyses excluding studies assessed as having high or uncertain risk of bias, to determine whether their inclusion altered the results of a meta-analysis.

Measures of treatment effect

We planned to make a descriptive or quantitative comparison of outcomes depending on the characteristics of the studies identified for inclusion (heterogeneity, comparability of outcomes, the presence of serious publication or reporting bias).

We planned analyses to contrast the intervention effect of the outcomes between the two groups with respect to the direction and size of the effect, consistency across studies and strength of evidence.

We planned to perform pair-wise comparisons (see: Data synthesis) and to calculate a treatment effect for dichotomous outcomes (immediate success, early and late recurrence rates, complications, 28-day all-cause mortality, etc) using risk ratios with a 95% confidence interval.

For continuous variables (length of hospital stay) we planned to calculate the difference in means as an estimate of effect size, using fixed-effect mean difference with a 95% confidence interval. Where there were continuous variables measured on different scales, we planned to use a standardized mean difference for analysis.

For time-to-event outcomes we planned to calculate log hazard ratios and standard errors from results of Cox proportional hazards regression models, and to pool using the generic inverse-variance method.

Unit of analysis issues

The unit of analysis was the individual participant for dichotomous outcomes.

Dealing with missing data

If not all intended outcomes were reported we planned to contact the authors of the study and gather the relevant outcome data. If summary data were not available we planned to contact authors to obtain the relevant summary statistics. Where this was not possible we planned to employ imputation methods if possible (Higgins 2011 section 16.1), or to determine and discuss the implications of exclusion from the analysis.

We planned to examine each study to determine how the authors dealt with missing data. If intention-to-treat (ITT) analyses were not performed and the data were available to perform them, we planned to do so (Higgins 2011 section 16.2). In the case of large numbers of incomplete data we planned to perform sensitivity analyses using 'best-case' and 'worst-case' scenarios (Higgins 2011 section 16.2.2). We made explicit the assumptions of whatever method we used to cope with missing data.

Assessment of heterogeneity

We planned to assess heterogeneity for outcomes using the Chi² test in Review Manager 5 (RevMan 5.3), with the null hypothesis being no heterogeneity for treatment effect (Higgins 2011). The Chi² test measures the deviation of observed effect sizes from an underlying overall effect. This test has low power to detect true heterogeneity when studies have small sample sizes or are few in number, hence we will use a P value of 0.01 (Higgins 2002). The I² statistic assesses the impact of heterogeneity on the meta-analysis (Higgins 2002). The magnitude is roughly interpreted as:

1. 0% to 40%: might be unimportant;
2. 30% to 60%: may represent moderate heterogeneity;
3. 50% to 90%: may represent substantial heterogeneity; and
4. 75% to 100%: may represent considerable heterogeneity.

Assessment of reporting biases

We attempted to avoid publication bias by ensuring that we closely examined all potential sources of unpublished studies. In particular we examined the 'grey literature', trial registers, and conference proceedings.

We planned to use a funnel plot of the effect estimate of each study plotted against a measure of their size or precision, to assess publication bias where 10 or more studies were included and provided outcome data. We planned to visually examine the funnel plot for symmetry, with asymmetry alerting us that there may be a problem that needs consideration.

Data synthesis

Depending on the studies identified for inclusion, we planned to produce a descriptive or a quantitative comparison of outcomes. The authors planned to determine whether it was appropriate to proceed with quantitative analyses (meta-analysis) based on:

- Heterogeneity of studies, in particular with respect to the interventions examined
- Comparability of outcomes measured
- The presence of serious publication or reporting bias

If we identified heterogeneity between studies, we planned to investigate possible causes, perform prespecified subgroup

analyses and consider whether pooling was appropriate. if there was unexplained heterogeneity we planned to pool with a random-effects meta analysis.

When we considered meta-analysis was appropriate, we planned to use pair-wise comparisons focused on the intervention of interest (conservative/non-interventional treatment) compared to one or more different interventional treatments, logically grouped where appropriate. In addition we compared conservative/non-interventional treatment to all interventional treatments, grouped as one. We planned to perform meta-analyses in Review Manager 5 software ([RevMan 5.3](#)).

Results of quantitative analyses were to be assessed with respect to: the direction of the effect, the size of the effect, consistency across studies, and the strength of evidence for the effect. We planned to prepare a 'Summary of findings' table consistent with recommendations in the *Cochrane Handbook for Systematic Reviews of Interventions* ([Higgins 2011](#)), using the GRADE software to assess the quality of the body of evidence for the primary and other important outcomes.

Subgroup analysis and investigation of heterogeneity

We prespecified a subgroup analysis of smokers to examine differences in outcome effect size in smokers versus non-smokers,

in order to determine if the intervention works differently in these two populations.

Sensitivity analysis

We prespecified sensitivity analyses for the following:

1. Studies identified as having a high risk of bias are excluded from analyses to determine if this alters the results.
2. Imputation of missing data to determine 'best-case' and 'worst-case' scenarios.
3. Where significant heterogeneity exists, random-effects versus fixed-effect models are compared.

RESULTS

Description of studies

Results of the search

We conducted a search on 26th June 2014, using our search terms outlined in [Appendix 1](#), and returned 359 studies with duplicates removed. The databases searched were the Cochrane Central Register of Controlled Trials (CENTRAL), MEDLINE, EMBASE, CINAHL, and Web of Science. There were three potentially relevant studies ([Figure 1](#)).

Figure 1. Study flow diagram.

We excluded the three potentially relevant studies because they were not randomized controlled trials ([Brown 2014](#); [Massongo 2014](#); [Schramel 1996](#)). Examination of ongoing trials registries revealed one trial which was relevant and satisfied our inclusion criteria ([ANZCTR336270](#)).

Included studies

We found no studies which satisfied our inclusion criteria for this review.

Ongoing studies

We found one ongoing study ([ANZCTR336270](#)). We contacted the trialists. Their target number of participants is 274, with 100 recruited as of the 9th of June 2014 ([Characteristics of ongoing studies](#)). The trial will likely run for 18 to 24 months. We will update this review when this ongoing study is completed.

Excluded studies

[Brown 2014](#) conducted a retrospective analysis of emergency presentations for pneumothoraces and compared their outcomes in terms of management, conservative or drainage. There were 225 patients with combined PSP and secondary spontaneous pneumothorax (SSP), 150 (67%) PSPs and 82 (84%) SSPs were managed with intervention. Of note, the complication rate was 11% and recurrence rate 17% in the interventional group, compared with a recurrence rate of 5% in the conservative group. There was no progression to clinical tension pneumothorax with hypotension, and hypoxaemia (haemoglobin oxygen saturation measured by pulse oximetry $\leq 92\%$) was only observed in patients with SSP or in PSP patients aged > 50 years.

We excluded this study because it was a retrospective analysis, not a randomized controlled trial. The results, however, suggest conservative management in patients with PSP is a safe and potentially superior management option in terms of patient outcomes.

[Massongo 2014](#) describes a prospective study of PSPs managed conservatively or with small-bore drain, allocated based on size and clinical tolerance of pneumothorax. The main aim was to evaluate the safety of outpatient management for PSP, with the main outcome being lung re-expansion. The patient numbers were small (60), and patients were not randomized; however the 83% success rate (no recurrence at one year), and no major complications support outpatient management.

[Schramel 1996](#) compares video-assisted thoracoscopic surgery (VATS) and conservative treatment for cost effectiveness in a retrospective review. Conservative management in this study involved pleural drainage and observation. In this conservative group, only 10 out of 113 pneumothoraces were managed with observation alone. The primary outcome was recurrence rate. Video-assisted thoracoscopic surgery is favoured in this study over 'conservative' management, with lower recurrence rate, complications, shorter drainage and hospitalization time than pleural drainage or observation ([Schramel 1996](#)).

Not only is this study not randomized, but the 'conservative' management group encompasses interventional management under our definitions, with true observational management in only 10 of 113 patients. The lower recurrence rate with VATS confirms that this is a definitive treatment, albeit an overtreatment in as

many as 89% of people who would not have had a second PSP ([Stradling 1966](#)).

Risk of bias in included studies

There were no included studies on which to conduct a 'Risk of bias' assessment.

Allocation

There were no included studies on which to assess allocation.

Blinding

There were no included studies on which to assess blinding.

Incomplete outcome data

There were no included studies on which to assess incomplete outcome data.

Selective reporting

There were no included studies on which to assess selective reporting.

Other potential sources of bias

There were none.

Effects of interventions

There were no included studies upon which to calculate effects of the interventions of interest.

DISCUSSION

Summary of main results

We identified no randomized or quasi-randomized clinical trials which compared conservative management with interventional management for the treatment of primary spontaneous pneumothorax (PSP). We have therefore confirmed our hypothesis that there is no strong evidence base for interventional management of PSP, despite widespread practice and recommendation. We identified one ongoing trial, which is an encouraging sign that those working in the area have identified this as a gap in the evidence base for the treatment of PSP.

Overall completeness and applicability of evidence

The one study which we identified from the ongoing trials register (Australia and New Zealand Clinical Trials Registry), 'A randomized controlled trial of conservative versus interventional treatment of primary spontaneous pneumothorax', may provide data in the future for analysis ([ANZCTR336270](#)). However, currently there are no randomized trials examining the conservative management of PSP.

Several retrospective case studies exist that include conservative management. [Stradling](#) and [Poole](#) describe an observational study that shows an 80% expansion without intervention and an 11% relapse rate over six years without discriminating for size ([Stradling 1966](#)). [Kelly 2007](#) confirms the success of conservative management in a review of 154 people with PSP, with 91 treated conservatively, 82 (79%) of whom were successfully managed without further intervention. [Cliff 1957](#) also describes 147 PSPs managed conservatively with a 12.1% recurrence rate. The results

from [Brown 2014](#), as described above, suggest conservative management is potentially a superior option with a lower recurrence rate and no adverse outcomes.

Studies also exist that advocate interventional treatment. [Ruckley 1966](#) describes 11 out of 119 people with PSP managed 'conservatively', made up of six PSPs treated with fine needle aspiration and five with observation only, without mentioning success rates for conservative management. [O'Rourke 1989](#) presents 130 people with spontaneous pneumothorax, of whom 40 were managed conservatively with nine requiring chest tubes and a 32.5% recurrence rate; however, primary and secondary pneumothoraces are not differentiated in the results. [Seremetis 1970a](#) also advocates interventional management for the benefit of shorter length of stay and lower recurrence rate with chest tube.

Overall, observational data demonstrate a good success rate with minimal relapse, and suggest a place for observational management for large PSPs in clinical practice. Evidence from randomized trials is needed to confirm this.

Quality of the evidence

There were no included studies on which to comment.

Potential biases in the review process

There were no included studies reviewed.

Agreements and disagreements with other studies or reviews

There have been no other reviews on conservative versus interventional management of PSP.

AUTHORS' CONCLUSIONS

Implications for practice

We found no completed randomized controlled trials involving conservative management of primary spontaneous pneumothorax (PSP) to include in this review. There is a lack of evidence comparing the effects of conservative management with interventional management for this condition.

Implications for research

The lack of studies comparing conservative management of primary spontaneous pneumothorax with interventional management highlights the lack of high-quality evidence in the current treatment guidelines of PSP. Although some observational data may suggest a clinical benefit for conservative management, there is a requirement for randomized controlled trials to be performed that include conservative management in order to strengthen practice guidelines.

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We would like to thank Ronan O'Sullivan (content editor) and Andrew MacDuff (peer reviewer) for their help and editorial advice during the preparation of the systematic review.

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CHARACTERISTICS OF STUDIES

Characteristics of excluded studies [ordered by study ID]

Study	Reason for exclusion
Brown 2014	Not a randomized controlled trial.
Massongo 2014	Not a randomized controlled trial.
Schramel 1996	Not a randomized controlled trial.

Characteristics of ongoing studies [ordered by study ID]

ANZCTR336270

Trial name or title	A study to investigate the treatment of pneumothorax (collapsed lung)
Methods	Randomized controlled parallel-group non-inferiority trial; Participants will be randomized using a secure, centralized web-based randomization system. Participants will be randomized in real time by computer, stratified by study site, using an adaptive biased coin (Urn) technique. The group allocation will only be revealed when the investigator confirms inclusion criteria have been met and enters the participant's details. Study in Australia (Perth) and New Zealand (4 sites).
Participants	<p>Inclusion: Primary spontaneous pneumothorax that is 32% or larger, 14 - 50 years old.</p> <p>Exclusion:</p> <ol style="list-style-type: none"> 1. Secondary pneumothorax, defined as pneumothorax occurring in the setting of acute trauma (including iatrogenic) or underlying lung disease including but not limited to COPD, pulmonary fibrosis, tuberculosis, cystic fibrosis, lung cancer and asthma that requires regular preventative medication or has been symptomatic within the last 2 years 2. Previous spontaneous pneumothorax on the same side 3. Coexistent haemothorax (i.e. spontaneous haemopneumothorax)

ANZCTR336270 (Continued)

	<p>4. Bilateral pneumothorax</p> <p>5. Instability at any stage suggesting tension pneumothorax; systolic BP (SBP) < 90 mmHg, mean arterial pressure (MAP) < 65 mmHg or heart rate (HR) > SBP</p> <p>6. Pregnancy at time of enrolment</p> <p>7. Social circumstances whereby the patient either does not have adequate support after discharge to re-attend hospital if required, or is unlikely to present for study follow up.</p> <p>8. Air travel within the next 12 weeks if this cannot be deferred, should the pneumothorax be slow to resolve"</p>
Interventions	<p>Intervention:</p> <p>Conservative management of primary spontaneous pneumothorax. Participants will be observed for 4 hours in the emergency department and a repeat x-ray taken. If they are clinically stable and able to mobilize comfortably they will be discharged home and followed as an outpatient with a review at 24 - 72 hours, and at 2, 4 and 8 weeks.</p> <p>Comparator:</p> <p>Standard interventional treatment of primary spontaneous pneumothorax. An attempted air aspiration procedure will be performed. If unsuccessful, the participant will have an intercostal chest drain inserted and be admitted to hospital. Further management, including the use of suction or need for surgery, will be at the discretion of the treating physician.</p>
Outcomes	<p>Primary:</p> <p>Proportion of subjects with complete lung re-expansion on chest x-ray at 8 weeks; time in days to symptomatic recovery, defined as: discharge from hospital; resolution of symptoms (chest pain score of 0 on a 1 - 10 visual analogue scale; shortness of breath score of 0 on the Borg scale); cessation of analgesic medication; predefined complication of interventional treatment; proportion of participants with persistent air leak, defined by the presence of a chest drain/catheter in situ for 3 days or longer at 8 weeks.</p> <p>Secondary:</p> <p>Proportion of participants with pneumothorax recurrence at 12 months.</p>
Starting date	14th July 2011; proposed sample size 342
Contact information	Dr Kyle Perrin, Medical Research Institute of New Zealand Level G, CSB Wellington Hospital Riddiford Street Newtown Wellington 6242. +64 4 8050232 . kyle.perrin@mrnz.ac.nz
Notes	<p>www.anzctr.org.au/Trial/Registration/TrialReview.aspx?id=336270</p> <p>Trial report on 9th June 2014: "Thus far none of the patients randomized to conservative management have needed to cross over into the interventional arm".</p>

COPD: chronic obstructive pulmonary disease

APPENDICES

Appendix 1. CENTRAL (*The Cochrane Library*) search strategy

#1 MeSH descriptor: [Pneumothorax] explode all trees
#2 pneumothorax
#3 #1 or #2
#4 MeSH descriptor: [Thoracotomy] explode all trees

#5 MeSH descriptor: [Thoracostomy] explode all trees
 #6 MeSH descriptor: [Chest Tubes] explode all trees
 #7 MeSH descriptor: [Drainage] explode all trees
 #8 MeSH descriptor: [Suction] explode all trees
 #9 (aspiration or thoraco?tom* or suction):ti,ab or chest tube* or (drain* near/3 (chest or intercostal or thoracic))
 #10 #4 or #5 or #6 or #7 or #8 or #9
 #11 #3 and #10

Appendix 2. MEDLINE (Ovid SP) search strategy

1. exp Pneumothorax/ or pneumothorax.af.
2. exp Thoracotomy/ or exp Thoracostomy/ or exp Chest Tubes/ or Drainage/ or Suction/ or (aspiration or thoraco?tom* or suction).ti,ab. or chest tube*.mp. or (drain* adj3 (chest or intercostal or thoracic)).mp.
3. 1 and 2
4. ((randomized controlled trial or controlled clinical trial).pt. or randomized.ab. or placebo.ab. or clinical trials as topic.sh. or randomly.ab. or trial.ti.) not (animals not (humans and animals)).sh.
5. 3 and 4

Appendix 3. EMBASE (Ovid SP) search strategy

1. exp pneumothorax/ or pneumothorax.af.
2. thoracotomy/ or thorax drainage/ or chest tube/ or suction/ or (aspiration or thoraco?tom* or suction).ti,ab. or chest tube*.ti,ab. or drain* adj3 (chest or intercostal or thoracic).ti,ab.
3. (placebo.sh. or controlled study.ab. or random*.ti,ab. or trial*.ti,ab. or ((singl* or doubl* or trebl* or tripl*) adj3 (blind* or mask*)).ti,ab.) not (animals not (humans and animals)).sh.
4. 1 and 2 and 3

Appendix 4. CINAHL (EBSCOhost) search strategy

S1 (MM "Pneumothorax") OR "Pneumothorax"
 S2 ((MM "Thoracotomy") OR (MM "Chest Tubes") OR (MH "Drainage") OR (MH "Suction")) OR AB (aspiration or thoraco?tom* or suction) OR TI (aspiration or thoraco?tom* or suction) OR TX chest tube* OR ((drain* N3 (chest or intercostal or thoracic)))
 S3 ((MM "Randomized Controlled Trials") OR (MM "Random Assignment") OR (MM "Prospective Studies+") OR (MM "Clinical Trial Registry") OR (MM "Double-Blind Studies") OR (MM "Single-Blind Studies") OR (MM "Triple-Blind Studies") OR (MM "Multicenter Studies") OR (MM "Placebos")) OR (random* or placebo*)
 S4 S1 AND S2 AND S3

Appendix 5. ISI Web of Science search strategy

#1 TS=pneumothorax
 #2 TI=(aspiration or thoraco?tom* or suction) or TS=chest tube* or TS=(drain* SAME (chest or intercostal or thoracic))
 #3 TS=(random* or ((controlled or clinical) SAME trial*) or placebo* or multicenter or prospective) or TS=((blind* or mask*) SAME (single or double or triple or treble))
 #4 #3 AND #2 AND #1

Appendix 6. Screening form

Author	Title	Journal	Date vol page	Controlled/RCT	Pneumothorax	Conservative treatment	Exclude	Get full refer- ence
				2 author consensus	2 author consensus	2 author consensus		

Appendix 7. Data Extraction Form

CARG

Data collection form

Intervention review

Notes on using a data extraction form:

- Be consistent in the order and style you use to describe the information for each report
- Record any missing information as unclear or not described, to make it clear that the information was not found in the study report(s), not that you forgot to extract it.
- Include any instructions and decision rules on the data collection form, or in an accompanying document. It is important to practice using the form and give training to any other authors using the form.

Review title or ID

Study ID (*surname of first author and year first full report of study was published e.g. Smith 2001*)

Report IDs of other reports of this study (*e.g. duplicate publications, follow-up studies*)

Notes:

1. General Information

Date form completed (*dd/mm/yyyy*)

(Continued)

Name/ID of person extracting data
Report title
(title of paper/ abstract/ report that data are extracted from)
Report ID
(ID for this paper/ abstract/ report)
Reference details
Report author contact details
Publication type
(e.g. full report, abstract, letter)
Study funding sources
(including role of funders)
Possible conflicts of interest
(for study authors)
Notes:
2. Study Eligibility

Study Characteristics	Eligibility criteria	Yes	No	Unclear	Location in text
	(Insert eligibility criteria for each characteristic as defined in the Protocol)				(pg & ¶/fig/table)
Type of study	Randomized Controlled Trial				
	Controlled Clinical Trial				
	(quasi-randomized trial)				
Participants					

(Continued)

Types of intervention

**Types of outcome mea-
sures**

INCLUDE

EXCLUDE

Reason for exclusion

Notes:

DO NOT PROCEED IF STUDY EXCLUDED FROM REVIEW

3. Population and setting

Description

Include comparative information for each group (i.e. intervention and controls) if available

Location in text

(pg & ¶/fig/table)

Population description

(from which study participants are drawn)

Setting

(including location and social context)

Inclusion criteria
Age ≥ 18
1st episode of spontaneous pneumothorax
Radiological evidence

Exclusion criteria
Underlying lung disease
Trauma

(Continued)

Other secondary cause
Recurrence
Informed consent obtained

Yes No Unclear

Notes:

4. Methods

Descriptions as stated in report/paper
Location in text

(pg & ¶/fig/table)

Aim of study
Design (e.g. parallel, crossover, cluster)

Unit of allocation

(by individuals, cluster/ groups or body parts)

Start date
End date
Total study duration
Ethical approval needed/ obtained for study

Yes No Unclear

Notes:

5. Risk of Bias assessment

See Chapter 8 of the [Higgins 2011](#)

Domain	Risk of bias			Support for judgement	Location in text (pg & ¶/fig/table)
	Low risk	High risk	Unclear		
Random sequence generation (selection bias)					
Allocation concealment (selection bias)					
Blinding of participants and personnel (performance bias)				Outcome group: All/	
(if required)				Outcome group:	
Blinding of outcome assessment (detection bias)				Outcome group: All/	
(if required)				Outcome group:	
Incomplete outcome data (attrition bias)					
Selective outcome reporting? (reporting bias)					
Other bias					
Notes:					

6. Participants

Provide overall data and, if available, comparative data for each intervention or comparison group.

	Description as stated in report/paper	Location in text (pg & ¶/fig/table)
Total no. randomized		
<i>(or total pop. at start of study for NRCTs)</i>		
Clusters		
<i>(if applicable, no., type, no. people per cluster)</i>		
Baseline imbalances		
Withdrawals and exclusions		
<i>(if not provided below by outcome)</i>		
Age		
Sex		
Race/Ethnicity		
Size of pneumothorax		
Co-morbidities		
<i>(should be excluded if co-existent lung disease)</i>		
Other treatment received	<i>(additional to study intervention)</i>	
Other relevant sociodemographics		
Subgroups measured		
Smoking		
Other		
Subgroups reported		
Smoking		
Other		
Notes:		

(Continued)

7. Intervention groups

Copy and paste table for each intervention and comparison group

Intervention Group 1

	Description as stated in report/paper	Location in text (pg & ¶/fig/table)
Group name		
Conservative or Interventional		
No. randomized to group (specify whether no. people or clusters)		
Theoretical basis (include key references)		
Description of intervention (include sufficient detail for replication, e.g. Type of supportive therapy - oxygen, analgesia etc; or type of intervention – chest tube, needle aspiration etc)		
Duration of treatment period		
Timing (e.g. frequency, duration of each episode)		
Delivery (e.g. mechanism, medium, intensity, fidelity)		
Providers (e.g. type of hospital, specialty, training etc)		
Co-interventions		
Economic variables (i.e. intervention cost if available)		
Notes:		

8. Outcomes

Copy and paste table for each outcome.

Early recurrence

	Description as stated in report/paper	Location in text (pg & ¶/fig/table)
Outcome name		
Recurrence - early		
Time points measured		
Time points reported		
Outcome definition (with diagnostic criteria if relevant)		
Person measuring/reporting		
Imputation of missing data (e.g. assumptions made for ITT analysis)		
Assumed risk estimate (e.g. baseline or population risk noted in Background)		
Power		
No. with data in conservative mx group		
N. with data in interventional group		
Notes:		

Repeat for late recurrence

Mortality

	Description as stated in report/paper	Location in text
--	--	------------------

(Continued)

(pg & ¶/fig/table)

Outcome name
Mortality

Time points measured

Time points reported

Person measuring/reporting

Imputation of missing data

(e.g. assumptions made for ITT analysis)

Assumed risk estimate

(e.g. baseline or population risk noted in Background)

Power
No. with data conservative
No. with data interventional

Notes:

Length of hospital stay

**Description as stated
in report/paper**
Location in text
(pg & ¶/fig/table)

Outcome name
Length of hospital stay

Outcome definition

Person measuring/reporting

Unit of measurement

Imputation of missing data

(e.g. assumptions made for ITT analysis)

(Continued)

Assumed risk estimate

(e.g. baseline or population risk noted in Background)

Power Number of participants with Data:

Conservative group

Interventional group

Notes:

Pleurectomy or pleurodesis

	Description as stated in report/paper	Location in text (pg & ¶/fig/table)
Outcome name		
Pleurectomy or pleurodesis		
Time points measured		
Time points reported		
Outcome definition		
Person measuring/reporting		
Imputation of missing data (e.g. assumptions made for ITT analysis)		
Assumed risk estimate (e.g. baseline or population risk noted in Background)		
Power		
No. with data conservative		
No. with data interventional		
Notes:		

Complications

	Description as stated in report/paper	Location in text (pg & ¶/fig/table)
Outcome name		
Complications		
Time points measured		
Time points reported		
Outcome definition		
Person measuring/reporting		
Imputation of missing data (e.g. assumptions made for ITT analysis)		
Assumed risk estimate (e.g. baseline or population risk noted in Background)		
Power		
No. with data conservative		
No. with data interventional		
Notes:		

9. Results

Copy and paste the appropriate table for each outcome, including additional tables for each time point and subgroup as required.

Dichotomous outcome – Early recurrence

Description as stated in report/paper	Location in text
---------------------------------------	------------------

(Continued)

(pg & ¶/fig/
table)

Comparison
Outcome
Subgroup
Timepoint

(post onset of pneumothorax)

Results
Conservative treatment
Interventional treatment

No. events

No. participants

No. events

No. participants

No. missing participants and reasons
No. participants moved from other group and reasons
Any other results reported
Unit of analysis (by individuals, cluster/groups or body parts)

Statistical methods used and appropriateness of these methods (e.g. adjustment for correlation)

Reanalysis required? (specify)

Yes No Unclear

Reanalysis possible?

Yes No Unclear

Reanalysed results
Notes:

Repeat for late recurrence

Mortality

Description as stated in report/paper		Location in text (pg & ¶/fig/table)												
Comparison														
Outcome														
Subgroup														
Timepoint (time from onset of pneumothorax)														
Results	<table border="1"> <thead> <tr> <th colspan="2">Intervention</th> <th colspan="2">Comparison</th> </tr> <tr> <th>No. events</th> <th>No. participants</th> <th>No. events</th> <th>No. participants</th> </tr> </thead> <tbody> <tr> <td colspan="4"> </td> </tr> </tbody> </table>	Intervention		Comparison		No. events	No. participants	No. events	No. participants					
Intervention		Comparison												
No. events	No. participants	No. events	No. participants											
No. missing participants and reasons														
No. participants moved from other group and reasons														
Any other results reported														
Unit of analysis (by individuals, cluster/groups or body parts)														
Statistical methods used and appropriateness of these methods (e.g. adjustment for correlation)														
Reanalysis required? (specify)														
Yes No Unclear														
Reanalysis possible?														
Yes No Unclear														
Reanalysed results														
Notes:														

Pleurectomy or pleurodesis

Description as stated in report/paper		Location in text (pg & ¶/fig/table)								
Comparison										
Outcome										
Subgroup										
Timepoint (from onset of pneumothorax)										
Results	<table border="1"> <thead> <tr> <th colspan="2">Intervention</th> <th colspan="2">Comparison</th> </tr> </thead> <tbody> <tr> <td>No. events</td> <td>No. participants</td> <td>No. events</td> <td>No. participants</td> </tr> </tbody> </table>	Intervention		Comparison		No. events	No. participants	No. events	No. participants	
Intervention		Comparison								
No. events	No. participants	No. events	No. participants							
No. missing participants and reasons										
No. participants moved from other group and reasons										
Any other results reported										
Unit of analysis (by individuals, cluster/groups or body parts)										
Statistical methods used and appropriateness of these methods (e.g. adjustment for correlation)										
Reanalysis required? (specify)										
Yes No Unclear										
Reanalysis possible?										
Yes No Unclear										
Reanalysed results										
Notes:										

Complications

Description as stated in report/paper				Location in text (pg & ¶/fig/table)
Comparison				
Outcome				
Subgroup				
Timepoint (from onset of pneumothorax)				
Results	Intervention		Comparison	
	No. events	No. participants	No. events	No. participants
No. missing participants and reasons				
No. participants moved from other group and reasons				
Any other results reported				
Unit of analysis (by individuals, cluster/groups or body parts)				
Statistical methods used and appropriateness of these methods (e.g. adjustment for correlation)				
Reanalysis required? (specify)				
Yes No Unclear				
Reanalysis possible?				
Yes No Unclear				
Reanalysed results				
Notes:				

(Continued)

Length of hospital stay

Description as stated in report/paper				Location in text (pg & ¶/fig/table)		
Comparison						
Outcome						
Subgroup						
Timepoint (from admission)						
Post-intervention or change from baseline?						
Results	Intervention			Comparison		
	Mean	SD (or other variance)	No. participants	Mean	SD (or other variance)	No. participants
No. missing participants and reasons						
No. participants moved from other group and reasons						
Any other results reported						
Unit of analysis (individuals, cluster/ groups or body parts)						
Statistical methods used and appropriateness of these methods (e.g. adjustment for correlation)						
Reanalysis required? (specify)						
Yes No Unclear						

(Continued)

Reanalysis possible?

Yes No Unclear

Reanalysed results

Notes:

10. Applicability

Have important populations been excluded from the study? (*e.g. smokers*)

Yes No Unclear

Is the intervention likely to be aimed at disadvantaged groups? (*e.g. lower socioeconomic groups*)

Yes No Unclear

Does the study directly address the review question?

(*any issues of partial or indirect applicability*)

Yes No Unclear

Notes:

11. Other information

**Description as stated
in report/paper**

Location in text
(*pg & ¶/fig/table*)

Key conclusions of study authors

References to other relevant studies

Correspondence required for further study information (*from whom, what and when*)

Notes:

Risk of Bias Table

Unique ID	ISDN	First author	Journal / conference	Year	Reviewer
-----------	------	--------------	----------------------	------	----------

(Continued)

Domain	Description of what was done	Risk of bias judgement		
Sequence generation (How were patients allocated into intervention groups)		Low	High	Unclear
Allocation concealment (Was allocation list concealed prior to allocation)		Low	High	Unclear
Blinding of participants and personnel (Bias due to knowledge of allocation by participant or personnel).		Low	High	Unclear
Blinding of outcome assessment - objective outcomes (knowledge of the allocation by outcome assessor)		Low	High	Unclear
Blinding of outcome assessment – subjective outcomes (knowledge of the allocation by outcome assessor)		Low	High	Unclear
Incomplete outcome data (attrition due to amount, nature or handling of incomplete outcome data)		Low	High	Unclear
Selective reporting (Are all pre-specified outcomes reported)		Low	High	Unclear
Other potential source of bias		Low	High	Unclear
Other potential source of bias		Low	High	Unclear
Other potential source of bias		Low	High	Unclear

Risk of Bias Table

Unique ID	ISDN	First author	Journal / conference	Year	Reviewer

Appendix 8. Risk of Bias Tool

Risk of Bias Table

Unique ID	ISDN	First author	Journal / conference	Year	Reviewer
<hr/>					
<hr/>					
<hr/>					
Domain	Description of what was done			Risk of bias judgement	
Sequence generation (How were patients allocated into intervention groups)				Low	High Unclear
Allocation concealment (Was allocation list concealed prior to allocation)				Low	High Unclear
Blinding of participants and personnel (Bias due to knowledge of allocation by participant or personnel).				Low	High Unclear
Blinding of outcome assessment - objective outcomes (knowledge of the allocation by outcome assessor)				Low	High Unclear
Blinding of outcome assessment – subjective outcomes (knowledge of the allocation by outcome assessor)				Low	High Unclear
Incomplete outcome data (attrition due to amount, nature or handling of incomplete outcome data)				Low	High Unclear
Selective reporting (Are all pre-specified outcomes reported)				Low	High Unclear
Other potential source of bias				Low	High Unclear
Other potential source of bias				Low	High Unclear
Other potential source of bias				Low	High Unclear

(Continued)

WHAT'S NEW

Date	Event	Description
20 December 2018	Amended	Editorial team changed to Cochrane Emergency and Critical Care

CONTRIBUTIONS OF AUTHORS

Michael Ashby (MA), Pete Mulcahy (PM), Kathryn J Ogden (KO), Greg Haug (GH), Oliver Jensen (OJ), Julia Walters (JW).

Conceiving the review: GH

Co-ordinating the review: MA

Undertaking manual searches: MA, OJ, PM

Screening search results: MA, OJ, PM, KO

Organizing retrieval of papers: KO

Screening retrieved papers against inclusion criteria: MA, PM, KO, GH

Appraising quality of papers: MA, OJ, PM, GH

Abstracting data from papers: MA, KO

Writing to authors of papers for additional information: KO

Providing additional data about papers: KO

Obtaining and screening data on unpublished studies: KO, MA

Data management for the review: KO, MA, JW

Entering data into Review Manager 5 ([RevMan 5.3](#)): MA, PM

RevMan statistical data: KO, JW

Other statistical analysis not using RevMan: KO, JW

Interpretation of data: KO, GH, MA, OJ, PM, JW

Statistical inferences: KO, JW

Writing the review: MA, KO, GH, PM

Securing funding for the review: N/A

Guarantor for the review (one author): MA

Person responsible for reading and checking review before submission: KO

DECLARATIONS OF INTEREST

Michael Ashby: none known

Greg Haug: none known

Pete Mulcahy: none known

Kathryn J Ogden: none known

Oliver Jensen: none known

Julia Walters: none known

SOURCES OF SUPPORT

Internal sources

- Department of Medicine, Launceston General Hospital, Australia.

Home Institute

- University of Tasmania, Australia.

Launceston Clinical School

External sources

- No sources of support supplied

DIFFERENCES BETWEEN PROTOCOL AND REVIEW

We planned to include a 'Summary of findings' table and to include the following outcomes: immediate success, failure of treatment, mortality, early and late recurrence, complications and length of hospital stay. Given there were no included studies in this review, we were unable to create a 'Summary of findings' table ([Ashby 2013](#)), but we plan to include one when we update the review.

INDEX TERMS

Medical Subject Headings (MeSH)

Pneumothorax [*therapy]

MeSH check words

Adult; Humans