Surgery for tympanic membrane retraction pockets (Review)

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[Intervention Review]

Surgery for tympanic membrane retraction pockets

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ABSTRACT

Background

Tympanic membrane retractions are commonly managed by ENT surgeons. There is currently no consensus as to the indications, timing and options for management of this condition.

Objectives

To study the effectiveness of different surgical options in the management of tympanic membrane retractions.

Search methods

We searched the Cochrane Ear, Nose and Throat Disorders Group Trials Register; the Cochrane Central Register of Controlled Trials (CENTRAL) (*The Cochrane Library*, 2010 Issue 1); PubMed (1950 to 2010); EMBASE (1974 to 2010); CINAHL (1982 to 2010); BIOSIS Previews; ISI Web of Science; CAB Abstracts; LILACS; KoreaMed; IndMed; PakMediNet; China National Knowledge Infrastructure; ISCTRN; UKCRN; ICTRP and Google. The date of the search was 17 March 2010.

Selection criteria

Randomised controlled trials (RCTs) of the surgical management of tympanic membrane retraction pockets in adults or children. Staging of the retraction using a known system must have been performed. Studies of cholesteatoma or perforations were excluded.

Data collection and analysis

Two authors independently collected and analysed data to minimise the effects of selection and reporting bias.

Main results

Two RCTs were included, involving 71 participants. The first study showed no statistically significant benefit of cartilage graft tympanoplasty over a watch and wait policy for either disease progression or hearing outcome. The second showed no additional benefit from the insertion of ventilation tubes over cartilage tympanoplasty alone with regards to hearing outcome.

Authors' conclusions

No evidence currently exists to either support or refute the role of surgery in the management of tympanic membrane retractions. Higher quality studies are much needed to ascertain this.

PLAIN LANGUAGE SUMMARY

Surgery for tympanic membrane retraction pockets

The tympanic membrane, or eardrum, is a thin piece of tissue that separates the external ear from the middle ear. Its main function is to transmit sound from the air to the three small bones of the middle ear. A retraction of the tympanic membrane happens when all or a segment of the membrane collapses inwards towards the middle ear. Tympanic membrane retractions are commonly managed by ENT surgeons but there is currently no consensus as to the indications, timing and options for management of this condition. We identified only two randomised controlled trials, involving 71 participants, which could be included in this review. One was a small study which showed no statistically significant benefit of cartilage graft tympanoplasty over a watch and wait policy, either for disease progression or hearing. The other showed no additional benefit from the insertion of ventilation tubes ('grommets') over cartilage tympanoplasty alone for patients' hearing. Further high quality studies are much needed.

SUMMARY OF FINDINGS FOR THE MAIN COMPARISON *[Explanation]*

Study	Number of patients	No. of patients with disease progression	Audiological outcome	Relative risk (95% CI)	Absolute risk reduction (95% CI)
Barbara 2008	25	0/15 in surgery group 3/10 in control group	No hearing deterioration in any patient	0.11 (0.01 to 1.93)	0.27 (-0.03 to 0.57)
Elsheikh 2006	46	0/23 in cartilage tympanoplasty alone group 0/23 in cartilage tympanoplasty plus ventilation tube group	Both groups showed a statistically significant increase in air conduction thresholds. No difference was found between the 2 groups	Unable to calculate	Unable to calculate

BACKGROUND

Description of the condition

The tympanic membrane, or eardrum, is a thin piece of tissue that separates the external ear from the middle ear, acting to transmit sound from the air to the three ossicles of the middle ear. A retraction of the tympanic membrane occurs when all or a segment of the membrane collapses inwards towards the middle ear.

Tympanic membrane retractions may be asymptomatic and therefore picked up incidentally by the examining clinician. In symptomatic patients, the commonest symptoms are recurrent ear discharge and hearing loss. The hearing loss is typically conductive in nature, and may be as a result of a middle ear effusion, splinting of the tympanic membrane or erosion of the ossicular chain. Otalgia is occasionally a feature and is due to changes in middle ear pressure or infection.

Retractions can be stable or unstable, the latter implying the formation of a cholesteatoma; that is the retraction has begun to hinder the normal migration of epithelial cells and to trap this keratin in the middle ear (Sudhoff 2000; Wells 1983). Potential complications of cholesteatomas include hearing loss, vertigo, facial nerve injury and intracranial complications (although these latter two are rare). It is still not possible to predict the likely course of a retraction reliably; namely those that will go on to form cholesteatoma, those that will remain stable and safe, and those that may even resolve. For this reason the timing and nature of any intervention remains unclear.

The point prevalence of tympanic membrane retractions in healthy children aged 5 to 16 years has been reported to be 14% to 26% in pars flaccida (the smaller more lax segment lying superiorly) and 0.3% to 3.7% in pars tensa (the larger 'tense' segment lying inferiorly) (Stangerup 1994). More recent data will be added by a current study looking at the prevalence of retractions of the tympanic membrane in children within the Avon Longitudinal Study of Parents and Children (ALSPAC). This is likely to be published in 2010 by one of the review authors (D Pothier).

Several factors are thought to be important in the formation of tympanic membrane retractions, including Eustachian tube dysfunction (Danner 2006) and structural changes to the membrane secondary to repeated bouts of inflammation (Ruah 1992). One of the determinants of middle ear pressure is the balance between the rate of oxygen and nitrogen absorption from the middle ear space into the bloodstream (Cantekin 1980a) and the reciprocal movement of carbon dioxide (Bylander 1985). The rate of diffusion is dependent on a number of factors, including the condition of the mucosa and the ventilation of the tympanomastoid system. It has recently been demonstrated that middle ear pressure decreases if the Eustachian tube does not open (Pau 2009). Eustachian tube dysfunction affects the normal flow of gas through the Eustachian tube thereby affecting its ability to help regulate middle ear pressure. If a negative middle ear pressure develops, the tympanic membrane may become medialised into the middle ear space and onto the ossicles (Sadé 2000). The insertion of ventilation tubes may also increase the rate of retraction (Maw 1994), however the size of any effect is unclear. When one is considering this process in the pars tensa, the terms atelectasis and retraction can be used interchangeably, however for pars flaccida pathology only the term retraction is used. For the purposes of this review, to avoid confusion, only the term retraction will be used.

Diagnosis is entirely clinical and requires a visual examination of the tympanic membrane using an auroscope, microscope or even otoendoscope (which can be coupled to an image capture system). The most commonly used staging systems are the Tos classification for pars flaccida retractions (Tos 1980) and the Sadé classification for pars tensa retractions (Sadé 1979), although others have been reported. Both have four grades depending on how far medially the retraction has progressed, and whether there is involvement of other middle ear structures.

The staging systems are defined as:

Sadé I: retracted tympanic membrane;

Sadé I: retraction with contact onto incus;

Sadé III: middle ear atelectasis (tympanic membrane on to the promontory, but mobile);

Sadé IV: adhesive otitis media (tympanic membrane on to the promontory, but fixed).

Tos I: pars flaccida not in contact with malleus head;

Tos II: pars flaccida in contact with malleus head;

Tos III: limited outer attic wall erosion;

Tos IV: severe outer attic wall erosion.

A further 3 stage classification system was proposed by Charachon et al (Charachon 1992):

Stage 1: mobile retraction pocket;

Stage 2: fixed and controllable retraction pocket;

Stage 3: fixed and uncontrollable retraction pocket.

In addition to their clinical use, staging/classification systems of retractions are useful for research, where the behaviour of retractions can be studied. It is important to note, however, that any system used must be validated and reproducible, and recent work has suggested that both systems suffer from poor reproducibility both by an individual and between individuals, i.e. low intra- and inter-rater reliability (Pothier 2006). Despite the potential difficulties with these grading systems they remain the most widely utilised method for the sequential recording of tympanic membrane atelectasis over time. Studies that have used them to assess the outcome of surgical intervention will therefore be included in the review, however, their results should be viewed with caution.

One alternative to these grading systems is the use of image capture from otoendoscopic assessment. Whilst a potential disadvantage of this is the two-dimensional nature of the image gained, the use of digital photography to record pathology of the tympanic membrane eliminates the need to rely on the interpretations and descriptions of another clinician when sequential assessments are required.

Regular observation is important to assess disease progression and monitor for complications, such as cholesteatoma formation. As part of an assessment of a patient with a tympanic membrane retraction, audiometric evaluation with a pure tone audiogram and tympanometry is usually performed.

Description of the intervention

There is no consensus amongst otologists as to the indications, timing and options for management of tympanic membrane retractions. A conservative 'watch and wait' policy is commonly adopted as a first-line strategy (Saffer 2000) as early retractions may resolve spontaneously in a proportion of patients. This policy is often coupled with medical therapies aimed at improving Eustachian tube function (i.e. nasal decongestant sprays, oral antihistamines and steroids) (Cantekin 1980b; Silverstein 2003), or inflation devices (i.e. the Otovent® balloon) (Blanshard 1993). Surgical management of this condition is varied. Options include the insertion of a ventilation tube such as a grommet or T-tube which may be done alone or in combination with some form of mastoid exploration or tympanic membrane reconstruction (Elsheikh 2006). The affected segment of tympanic membrane can also be excised and either left or replaced with a fascial graft or with a stronger graft such as cartilage harvested from the pinna or tragus (Blaney 1999; Dornhoffer 2003; Sharpe 1992). Adenoidectomy for adenoidal hypertrophy may improve Eustachian tube function, however there are conflicting reports on this (Bluestone 1975; Dempster 1989; Honjo 1985).

Why it is important to do this review

There is clearly controversy and wide variation between clinicians in the management of this common condition. It is for this reason that the review was undertaken by the authors, in an attempt to guide this clinical uncertainty with the best available evidence on the subject.

OBJECTIVES

To study the effectiveness of different surgical options in the management of tympanic membrane retractions in both adults and children.

METHODS

Criteria for considering studies for this review

Types of studies

Randomised controlled trials in which tympanic membrane retractions have been managed by any method of surgical intervention.

Types of participants

Inclusion criteria

- Patients of all ages (adult and child data may be analysed separately).
- Clinically diagnosed retraction segments.

Exclusion criteria

- Any non-hospital setting for the study.
- Retractions which have not been assessed, so as to allow change post-intervention to be accurately recorded.
- Any patient with cholesteatoma or perforation.

Types of interventions

Insertion of ventilation tubes (alone or combined with another procedure, such as excision of retracted tympanic membrane segment or mastoidectomy). We also included tympanoplasty, with or without re-enforcement with cartilage, and removal of adenoidal tissue.

Types of outcome measures

Primary outcomes

- Clinical monitoring of the retraction, for example looking for resolution, cessation of progression, no effect or even continued progression of the disease. This is complicated by the fact that there is no validated staging system.
- Adverse events.

Secondary outcomes

Whether the intervention has any effect on those things noticeable to the patient:

- improvement in hearing thresholds;
- reduction in ear discharge;
- improvement in otalgia;
- improvement in quality of life scores.

Search methods for identification of studies

We conducted systematic searches for randomised controlled trials. There were no language, publication year or publication status restrictions. We contacted original authors for clarification and further data where trial reports were unclear and planned to arrange translations of papers where necessary. The date of the last search was 17 March 2010.

Electronic searches

We searched the following bibliographic databases from their inception: the Cochrane Ear, Nose and Throat Disorders Group Trials Register; the Cochrane Central Register of Controlled Trials (CENTRAL) (*The Cochrane Library*, 2010 Issue 1); PubMed; EMBASE; CINAHL; BIOSIS Previews; ISI Web of Science; CAB Abstracts; LILACS; KoreaMed; IndMed; PakMediNet; China National Knowledge Infrastructure; ISCTRN; UKCRN; ICTRP and Google.

Subject strategies for databases were modelled on the search strategy designed for CENTRAL. Where appropriate, we combined subject strategies with adaptations of the highly sensitive search strategy designed by the Cochrane Collaboration for identifying randomised controlled trials and controlled clinical trials (as described in *The Cochrane Handbook for Systematic Reviews of Interventions* Version 5.0.2, Box 6.4.b. (Handbook 2009)). Search strategies for the major databases are shown in Appendix 1.

Searching other resources

We scanned the reference lists of identified publications for additional trials and contacted authors where necessary. We searched PubMed, TRIPdatabase, NHS Evidence - ENT & Audiology and Google to retrieve existing systematic reviews possibly relevant to this systematic review, so that we could scan their reference lists for additional trials. We contacted authors of published trials and other experts in the field.

Data collection and analysis

Selection of studies

The two authors independently reviewed all the abstracts of studies found with the above search strategy, after any duplicate records had been removed using reference management software, with any obviously irrelevant reports excluded at this stage. We sought the full text of any relevant reports and also in cases where it was not possible to assess suitability for study selection based on the abstract alone. We made attempts to identify multiple reports from the same study, which could then be merged. We then applied the inclusion/exclusion criteria after assessment of the full-text reports. Any differences in opinion between the two authors were resolved by discussion and consensus.

Data extraction and management

The two authors then independently assessed each study and extracted the data using an adapted form from the Cochrane ENT Group. This form was pre-piloted and assessed by a consensus between the authors. Any alterations to the form were made and re-tested before being used for the actual data extraction of the reports. If there were multiple reports for a study, we planned to extract data from each report separately, then combine the information across multiple data collection forms. Any discrepancies in data extracted by the two authors were to be settled by a consensus meeting. If this was not possible, the study author was to be contacted for clarification, and if an agreement was still not reached this was to be made clear in the final report.

Assessment of risk of bias in included studies

To ensure any bias in the studies selected was detected and no bias was introduced when reviewing, the two authors (PCN and DDP) independently assessed the studies and then agreed on the study quality using the Cochrane Collaboration's recommended 'Risk of bias' tool, in which critical assessments are made separately for six different domains: sequence generation, allocation concealment, blinding of participants, personnel and outcome assessors, incomplete outcome data, selective outcome reporting and other sources of bias (Handbook 2009).

For each domain, we made a description to provide a succinct summary from which judgements of risk of bias could be made, with the aim of ensuring transparency in how these judgements are reached. For each description, we made a judgement. The judgement for each entry involved answering a question, with an answer of 'yes' indicating low risk of bias, 'no' indicating high risk of bias and 'unclear' indicating either lack of information or uncertainty over the potential for bias.

Data synthesis

We analysed the data on an intention-to-treat basis, using Review Manager 5.0 (RevMan 2008). If comparable between studies, we had planned to pool and analyse data statistically. If data were missing, we intended to contact the original authors. If adequate data were available, we planned to perform subgroup analysis of adults versus children, stage of retraction and site of retraction pocket. Outcome measures were likely to be either related to the presence or absence of improvement (dichotomous) or reported as change in stage on a recognised staging system (this can be nominal or ordinal data). We planned to calculate pooled risk ratio estimates (random-effects), their 95% confidence intervals, the Chi^2 test for heterogeneity and the I^2 statistic for each outcome. An I^2 figure of > 50% would preclude pooling as this implies marked differences between the studies (Hardy 1998).

RESULTS

Description of studies

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

Results of the search

We retrieved 97 references on implementation of the search strategy. This number reduced to 69 once duplicate references were removed, and then to 42 once a further 27 studies which were clearly not relevant to this systematic review were removed. We examined these remaining 42 studies in detail and found only two studies to be eligible for inclusion (Barbara 2008; Elsheikh 2006). Of the studies rejected, 37 were not randomised controlled trials. Three studies were randomised trials, however they did not study atelectasis. One randomised controlled trial was excluded as there was no suitable control group.
We found no other systematic reviews on the topic.

Included studies

Barbara 2008 was a prospective randomised controlled trial with sequential randomisation of 30 consecutive patients. The setting was a university hospital (tertiary referral centre). Patients were randomised to one of two arms: 15 patients in the active treatment arm underwent lateral attic reconstruction surgery (LAR) with tragal cartilage (including perichondrium) graft. Follow up was at 15 days, then one, two, six and 12 months with otoscopy, pure tone audiometry and tympanometry. The control group underwent the same follow-up regime but without any active intervention.The study outcome measures were otoscopic appearance of tympanic membrane, pure tone audiometry and tympanography.
Elsheikh 2006 was a prospective randomised controlled trial with randomisation of 46 consecutive patients. The setting was a university hospital. Patients were randomly assigned in to two treatment groups. Twenty-three underwent reconstruction of the atelectatic tympanic membrane using the perichondrium/cartilage graft, performed with concomitant intraoperative T-tube insertion (group 1). Twenty-three patients underwent the same reconstruction with perichondrium/cartilage grafting, with no T-tube insertion (group 2). The shortest follow-up period was 13 months. Outcome measures were Eustachian tube function, audiometry at one year and clinical inspection at three, six and 12 months.

Risk of bias in included studies

We assessed the included studies (Barbara 2008; Elsheikh 2006) using the the Cochrane Collaboration's tool for assessing risk of bias (Handbook 2009). Both were found to have a potentially significant risk of bias. In Barbara 2008 the randomisation method was only sequential allocation to one of the two arms. However, the author does stipulate that this was on a consecutive cohort. It was performed by a single investigator, who undertook the randomisation, intervention and all follow-up assessments with no evidence of blinding. The only objective measurements were taken with audiological assessments, however no actual data are presented in the publication. Finally, monitoring of tympanic membrane retraction was performed subjectively by the investigator alone.
The randomisation method was not specified by Elsheikh 2006. Despite this, the cohort characteristics of the two study groups (age, sex, degree of retraction and middle ear risk index scores) are well-matched. There is no description as to whether any of the investigators were blinded to the allocation of the patients at any point in the trial. No patients were lost to follow up and all undertook postoperative testing to give complete outcome data. There is no description of whether the audiological assessments were undertaken independently or by the investigators themselves. One of the primary outcome measures was graft success (i.e. no perforation, recurrence of atelectasis, or lateralisation within 12 months). The only result presented for this outcome measure is a single statement that the tympanic membranes had returned to "near normal" in all patients. This introduces a potentially high risk of reporting bias. Furthermore, three patients in the group not receiving T-tubes developed a conductive hearing loss with two of these patients subsequently receiving myringotomies. It is unclear if the audiological data was recorded on these patients before or after this second intervention.

Effects of interventions

See: **Summary of findings for the main comparison**
We assessed the effects of interventions using the primary and secondary outcome measures described previously.

Primary outcome measures

Clinical observation/assessment of the retraction

Barbara 2008: There was no evidence of epitympanic membrane retraction in the treatment arm at 12 months (0/15). Five patients underwent revision procedures for possible residual or recurrent disease on the evidence of CT scanning showing hypodense areas in the epitympanum. Surgical findings were negative in all five cases. Three of 10 patients in the control arm showed disease progression. Two patients had widening of the epitympanic erosion and one developed cholesteatoma. All three were due to undergo lateral attic reconstruction surgery (LAR).
Elsheikh 2006: Although the degree of tympanic membrane retraction was assessed using the Sadé classification pre-operatively, there are no results reported postoperatively. The only results are a statement that the tympanic membranes had returned to "near normal" in all patients.

Adverse events

Barbara 2008: One patient in the active treatment arm had a postoperative infection at day 15. This required systemic and topical antibiotics and resolved completely.
Elsheikh 2006: No postoperative complications are recorded.

Secondary outcome measures

Improvement in hearing

Barbara 2008: All patients in the study had normal hearing at the beginning and end of the study at 12 months, irrespective of which intervention they had received.
Elsheikh 2006: Both intervention groups showed a statistically significant increase in pure tone air-conduction thresholds and air-bone gap averages. There was no significant difference between the two groups however.

Reduction in ear discharge

Reduction in ear discharge was not assessed in either study.

Improvement in otalgia

Improvement in otalgia was not assessed in either study.

Quality of life

No quality of life assessment was carried out in either study.
In the Barbara 2008 study, calculating the relative risk of progression of the retraction pocket to either a worse stage or cholesteatoma formation gives a value of 0.11 (95% confidence interval of 0.01 to 1.93). This is not statistically significant.
No data are presented in the Elsheikh 2006 study on stage of retraction or progression to cholesteatoma and therefore relative risk of progression cannot be calculated.

DISCUSSION

Retraction of the tympanic membrane is a common otological condition, with a variety of strategies employed in its management. Despite this, a search of the literature has yielded only two randomised controlled trials with a very low number of cases. The findings from the first study (Barbara 2008) do suggest that surgical intervention with a tragal cartilage reconstruction of the lateral attic wall reduces the risk of progression of the retraction pocket. The numbers were too small, however, and statistical significance was not achieved. Furthermore, whilst the investigator has attempted to select a homogenous cohort of patients, there are several aspects of the study design that expose it to a high potential risk of bias.

The second included study was Elsheikh 2006. Although pre-operative stage of retraction is documented in this study, there are no postoperative data given for the stage of retraction, merely a comment that "The TM had returned from a collapsed state to near normal in all patients". There was no difference in hearing outcomes between the two groups, suggesting no additional benefit with the insertion of ventilation tubes. This is only applicable to patients having undergone cartilage tympanoplasty at the same time, however, and cannot be extrapolated to the use of ventilation tubes alone.

The other studies identified by the search were excluded principally on design (mostly being retrospective case series) and because they did not study the process of interest, namely retraction pockets.

One interesting aspect that affects the risk of bias in both the included studies and all those that were excluded for other methodological reasons, is the reliability of repeated grading of retraction pockets using a staging system. None of the various staging systems in widespread use have been validated, and indeed some as yet unpublished work by one of this review's authors has highlighted their high inter and intra-rater variability. This makes interpretation of any studies performed using these systems difficult. However, because of their widespread use, and the fact no other method has been shown to be superior at charting the course of retractions, studies have not been excluded on the basis of use of these grading systems. It is clear that a more reliable and reproducible method of assessing tympanic membrane retractions is required in the future.

AUTHORS' CONCLUSIONS

Implications for practice

There is currently no good evidence for the role of any individual surgical intervention for the management of atelectasis of the tympanic membrane. The only randomised controlled trials (RCTs) included in this review failed to show any statistical benefit of surgical intervention versus a watch and wait policy. This review does not make any comment on the role of surgery in pockets that have begun to progress to cholesteatoma.

Implications for research

It is obvious from the findings of this review that better studies are much needed to ascertain the optimal management of tympanic membrane retractions. This is a problem commonly encountered by ENT surgeons and considerable variability in the management strategies currently employed still exists. Several key aspects will need to be addressed by any future studies to clarify this. The first is trial methodology. Robust randomised controlled trials are essential to remove the element of potential bias affecting most studies to date (being retrospective case series). The second is the inclusion of a control arm of no surgical intervention in any future RCT.

The natural history of these atelectatic segments is not clear and therefore comparing two surgical interventions alone may assume falsely that intervention is a pre-requisite. The other arms would be one or more of the surgical interventions of interest, such as ventilation tubes, T-tubes, segment excision and grafting or cartilage tympanoplasty. The final aspect that will need to be considered in any future trial is how to stage an atelectatic tympanic membrane reliably. This is fundamental, not only for the ability to monitor individual patients' progress through a trial period accurately, but also to be able to compare the results of different studies. There are currently no validated methods of achieving this, however, and for the results of any future studies to be meaningful this is one problem that will necessarily require a solution. One way of approaching this aspect, before a validated system is available, would be to rank studies by the quality of the methodology employed to record pre- and post-intervention appearance of the atelectasis. An example would be to score a study as grade 1 if the microscopic appearance of the tympanic membrane was agreed by more than one blinded expert reviewer using an accepted grading system, grade 2 if assessment was only by a single blinded reviewer, and grade 3 if assessment was by a single non-blinded reviewer.

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* *Indicates the major publication for the study*

CHARACTERISTICS OF STUDIES

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

Barbara 2008

Methods	Sequential randomisation of 30 consecutive patients to active treatment and control arms Inclusion criteria: • Type II retraction pocket (Charachon staging system) • Presence of an epitympanic pocket, with a posterior or central localisation, fixed and fully visible under microscopic otoscopy • Absence of accumulating material within the pocket • Normal audiogram • CT scan ruling out any other pathology behind the retraction pocket
Participants	Initially 30 patients, 15 in each arm. However, 5 patients were lost to follow up in the control arm (personal communication with author) The remaining 25 patients consisted of 13 men and 12 women, with an age range of 29 to 63 years
Interventions	15 patients in active treatment arm underwent lateral attic reconstruction surgery (LAR) This surgical technique consisted of: • general anaesthesia • post-auricular approach • tragal cartilage (with perichondrium) graft • exposure of the posterior epitympanic ossicular content • half-moon shaped graft inserted • tympanomeatal flap replaced and secured with antibiotic soaked Gelfoam Follow up at 15 days, then 1, 2, 6 and 12 months with otoscopy, pure tone audiometry and tympanometry The control group underwent the same follow-up regime
Outcomes	Otoscopic appearance of tympanic membrane: No evidence of epitympanic membrane retraction in the treatment arm at 12 months (0/15). 5 patients underwent revision procedures, however as CT had shown hypodense area in epitympanum. Surgical findings were negative in all 5 cases 3/10 patients in the control arm showed disease progression. 2 patients had widening of the epitympanic erosion, and one developed cholesteatoma. All 3 were due to undergo LAR Pure tone audiometry: All patients in the study had normal hearing at the beginning and end of the study at 12 months, irrespective of which intervention they had received Tympanometry: No tympanometry results are given for the patients on entering the trial. In the active treatment group, at 12 months, there were 60% with type A, 20% with type As and 20% with type B tympanograms No tympanometry data are recorded for the control group

Notes	One patient in the active treatment arm had a complication. This presented as a post-operative infection at day 15 requiring systemic and topical antibiotics Relative risk was calculated using a correction value of 0.5 in the cells containing 0

Risk of bias

Item	Authors' judgement	Description
Adequate sequence generation?	No	Sequential allocation on a consecutive cohort
Allocation concealment?	No	Sequential allocation to each of the treatment arms would allow the investigator to know which arm the subsequent patient would be allocated to
Blinding? All outcomes	No	The study is performed by a single investigator. No blinding took place
Incomplete outcome data addressed? All outcomes	No	5 patients from the control group were not included in the analysis as they were lost to follow up
Free of selective reporting?	Unclear	All outcome measures only assessed by the investigator (i.e. otoscopic progression and hearing assessment)
Free of other bias?	Unclear	Single investigator who performed the randomisation, treatment and assessment at follow up

Elsheikh 2006

Methods	Prospective randomisation of consecutive patients into 2 treatment groups Inclusion criteria: • Any degree of atelectasis Exclusion criteria: • Patients with ossicular disruption, cholesteatoma and previous tympanoplasty The shortest follow-up period was 13 months. Outcome measures were Eustachian tube function, audiometry at 1 year and clinical inspection at 3, 6 and 12 months
Participants	23 patients in group 1 consisting of 15 males and 8 females with a mean age of 27. 15 patients had Sadé grade 2 retractions and 8 had grade 3 retractions 23 patients in group 2 consisting of 14 males and 9 females with a mean age of 29. 16 patients had Sadé grade 2 retractions and 7 had grade 3 retractions No patients were lost to follow up and all patients completed the required postoperative testing

Elsheikh 2006 (*Continued*)

Interventions	Group 1: All underwent reconstruction of the atelectatic tympanic membrane using a perichondrium/cartilage graft performed with concomitant intraoperative T-tube insertion Group 2: All patients underwent the same reconstruction with perichondrium/cartilage grafting with no T-tube insertion Outcome measures were Eustachian tube function, audiometry at one year and clinical inspection at 3, 6 and 12 months
Outcomes	Clinical inspection: Although the degree of tympanic membrane retraction was assessed using the Sadé classification pre-operatively, there are no results reported postoperatively. The only results are a statement that the tympanic membranes had returned to "near normal" in all patients Pure tone audiometry: Both intervention groups showed a statistically significant increase in pure tone air conduction thresholds and air-bone gap averages. There was not significant difference between the 2 groups, however Eustachian tube function: No statistically significant differences were found in Eustachian tube function between the 2 groups
Notes	Recurrent conductive hearing loss was reported in 2 patients in group 1 and 3 patients in group 2

Risk of bias

Item	**Authors' judgement**	**Description**
Adequate sequence generation?	No	No description of randomisation protocol
Allocation concealment?	No	No evidence of allocation concealment
Blinding? All outcomes	No	No comment that the authors were blinded to patient allocation or outcome measures
Incomplete outcome data addressed? All outcomes	Yes	No patients lost to follow up
Free of selective reporting?	Unclear	Unclear who performed the postoperative otoscopic assessment or audiological testing. No grading given for postoperative results
Free of other bias?	Yes	-

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

Study	Reason for exclusion
Anderson 2004	ALLOCATION: Not randomised
Cassano 2010	ALLOCATION: Not randomised
Caye-Thomasen 2009	ALLOCATION: Not randomised
Charachon 1988	ALLOCATION: Not randomised
D'Eredita 2009	ALLOCATION: Randomised PARTICIPANTS: Perforations not atelectasis
Dornhoffer 2003	ALLOCATION: Not randomised
Duckert 1995	ALLOCATION: Not randomised
Elluru 2001	ALLOCATION: Not randomised
Eviatar 1978	ALLOCATION: Not randomised
Gerber 2000	ALLOCATION: Not randomised
Grewal 2003	ALLOCATION: Not randomised
Gurgel Testa 2002	ALLOCATION: Randomised PARTICIPANTS: Study of perforations only
Harner 1995	ALLOCATION: Not randomised
Johnston 2004	ALLOCATION: Randomised PARTICIPANTS Study of otitis media with effusion not retractions/atelectasis

(*Continued*)

Kalcioglu 2003	ALLOCATION: Not randomised
Kemaloglu 2000	ALLOCATION: Not randomised
Khullar 2000	ALLOCATION: Not randomised
Kujawski 2004	ALLOCATION: Not randomised
Kuttner 1996	ALLOCATION: Not randomised
Lancaster 2002	ALLOCATION: Not randomised
Lazard 2007	ALLOCATION: Not randomised
Lee 2009	ALLOCATION: Not randomised
Liu 2005	ALLOCATION: Not randomised
Mackle 1995	ALLOCATION: Not randomised
Roger 1997	ALLOCATION: Not randomised
Sadé 1981	ALLOCATION: Not randomised
Sadé 2001	ALLOCATION: Not randomised
Shin 2007	ALLOCATION: Not randomised
Sudhoff 2000	ALLOCATION: Not randomised
Tarabichi 2004	ALLOCATION: Not randomised
Tekin 2000	ALLOCATION: Not randomised

(*Continued*)

Truy 1994	ALLOCATION: Not randomised
Ueda 2001	ALLOCATION: Not randomised
Uslu 2010	ALLOCATION: Not randomised
Uzun 2003	ALLOCATION: Not randomised
Walker 2003	ALLOCATION: Not randomised
Yoon 2007	ALLOCATION: Not randomised
Yung 1999	ALLOCATION: Not randomised
Yung 2004	ALLOCATION: Not randomised
Zanetti 2001	ALLOCATION: Not randomised

DATA AND ANALYSES

This review has no analyses.

APPENDICES

Appendix 1. Search strategies

CENTRAL	PubMed	EMBASE (Ovid)	BIOSIS Previews (Ovid)
#1 MeSH descriptor Tympanic Membrane explode all trees #2 ((tympanic OR retrotympanic OR epitympanic) AND membrane) #3 (eardrum* OR (ear* AND drum*)) #4 (#1 OR #2 OR #3) #5 (retract* OR collaps* OR atelectas* OR atelectat*) #6 (#4 AND #5) #7 MeSH descriptor Surgical Procedures, Operative explode all trees #8 (surg* OR excis* OR reconstruct*) #9 (ventilation OR grommet* OR mastoidectom* OR tympanoplast* OR myringotom* OR tube* OR tympanostom*) #10 (#7 OR #8 OR #9) #11 (#6 AND #10)	#11 #6 and #10 #10 #7 OR #8 OR #9 #9 (ventilation [tiab] OR grommet* [tiab] OR mastoidectom* [tiab] OR tympanoplast* [tiab] OR myringotom* [tiab] OR tube* [tiab] OR tympanostom* [tiab]) #8 (surg* [tiab] OR excis* [tiab] OR reconstruct* [tiab]) #7 "Surgical Procedures, Operative"[Mesh] #6 #4 AND #5 #5 (retract* [tiab] OR collaps* [tiab] OR atelectas* [tiab] OR atelectat* [tiab]) #4 #1 OR #2 OR #3 #3 (eardrum* [tiab] OR (ear* [tiab] AND drum* [tiab])) #2 ((tympanic [tiab] OR retrotympanic [tiab] OR epitympanic [tiab]) AND membrane [tiab]) #1 "Tympanic Membrane"[Mesh]	1 Eardrum/ 2 ((tympanic or retrotympanic or epitympanic) and membrane).tw. 3 (eardrum* or (ear* and drum*)).tw. 4 1 or 3 or 2 5 (retract* or collaps* or atelectas* or atelectat*).tw. 6 4 and 5 7 exp Surgery/ 8 (surg* or excis* or reconstruct*).tw. 9 (ventilation or grommet* or mastoidectom* or tympanoplast* or myringotom* or tube* or tympanostom*).tw. 10 8 or 7 or 9 11 6 and 10 12 eardrum/su 13 12 and 5 14 11 or 13	1 Eardrum/ 2 ((tympanic or retrotympanic or epitympanic) and membrane).tw. 3 (eardrum* or (ear* and drum*)).tw. 4 1 or 3 or 2 5 (retract* or collaps* or atelectas* or atelectat*).tw. 6 4 and 5 7 exp Surgery/ 8 (surg* or excis* or reconstruct*).tw. 9 (ventilation or grommet* or mastoidectom* or tympanoplast* or myringotom* or tube* or tympanostom*).tw. 10 8 or 7 or 9 11 6 and 10 12 [eardrum/su] 13 12 and 5 14 11 or 13
CINAHL (EBSCO)	**Web of Science**	**CAB Abstracts (Ovid)**	**ISCTRN (mRCT)**
S1 (MH "Tympanic Membrane") S2 TX (tympanic OR retrotympanic OR epitympanic) and TX membrane S3 TX eardrum S4 TX ear and TX drum S5 S1 or S2 or S3 or S4	#1 TS=(eardrum* OR (ear AND drum*)) #2 TS=((tympanic OR retrotympanic OR epitympanic) AND membrane) #3 #2 OR #1 #4 TS=(retract* OR collaps* OR atelectas* OR atelectat*)	1 Eardrum/ 2 ((tympanic or retrotympanic or epitympanic) and membrane).tw. 3 (eardrum* or (ear* and drum*)).tw. 4 1 or 3 or 2 5 (retract* or collaps* or atelec-	(retract* OR collaps* OR atelectas* OR atelectat*) AND (eardrum OR tympanic)

(*Continued*)

S6 retract* OR collaps* OR atelectas* OR atelectat* S7 S5 and S6 S8 (MH "Surgery, Operative") S9 TX surg* OR excis* OR reconstruct* S10 TX ventilation OR grommet* OR mastoidectom* OR tympanoplast* OR myringotom* OR tube* OR tympanostom* S11 S8 or S9 or S10 S12 S7 and S11	#5 #4 AND #3 #6 TS=(surg* OR excis* OR reconstruct*) #7 TS=(ventilation OR grommet* OR mastoidectom* OR tympanoplast* OR myringotom* OR tube* OR tympanostom*) #8 #7 OR #6 #9 #8 AND #5	tas* or atelectat*).tw. 6 4 and 5 7 exp Surgery/ 8 (surg* or excis* or reconstruct*).tw. 9 (ventilation or grommet* or mastoidectom* or tympanoplast* or myringotom* or tube* or tympanostom*).tw. 10 8 or 7 or 9 11 6 and 10 12 [eardrum/su] 13 12 and 5 14 11 or 13	

HISTORY

Protocol first published: Issue 3, 2009

Review first published: Issue 7, 2010

CONTRIBUTIONS OF AUTHORS

Paul Nankivell - protocol development, co-ordinating the review, data collection, quality assessment, analysis of data, writing the review.

David Pothier - paper collection, data collection, quality assessment, analysis of data.

DECLARATIONS OF INTEREST

None to declare.

INDEX TERMS

Medical Subject Headings (MeSH)

*Tympanic Membrane; Cartilage [transplantation]; Ear Diseases [*surgery]; Middle Ear Ventilation [methods]; Randomized Controlled Trials as Topic; Tympanoplasty [*methods]

MeSH check words

Adult; Child; Humans