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INVITED ARTICLE

Management of Retraction Pockets of Pars Tensa and Pars Flaccida: A Systematic Review of Literature

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Introduction: The treatment of retraction pockets and atelectatic tympanic membrane, both surgical and non-surgical, is highly variable amongst otologists and not always supported by good quality evidence. We undertook a systematic review of evidence to assess the quality of available evidence with the purpose of informing clinical practice.

Materials and Methods: The following databases were systematically searched: PubMed, Embase , Centre for Reviews and Dissemination (DARE, NHS EED, INAHTA), NICE, Cochrane Database of Systematic Reviews , Cochrane Economic Evaluations, Cochrane Technology Assessment and Cochrane Central Register of Controlled Trials. The date of the last search was 07/03/2012 and no language limitation was applied. The identified studies were screened independently by the two reviewers using pre-defined inclusion criteria and validated quality assessment instruments. Randomised controlled trials and comparative studies were considered for inclusion.

Results: The scoping search identified 589 papers which were screened for relevance. A number of 66 papers were judged potentially eligible and were analysed independently by the authors. Two randomised controlled trials and one cohort study met the inclusion criteria. The quality of studies and standard of reporting were poor.

Discussion: The literature published on the management of retraction pockets and tympanic atelectasis is of low level of evidence and suffers from poor reporting standard. The studies reviewed were small and suffered from many methodological flaws. In the absence of high level of evidence, the authors propose to undertake a consensus exercise amongst experts using the Delphi technique.

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Introduction

The European Academy of Otology and Neurotology wishes to produce guidelines on a number of otological and neurotological conditions, one of which is on 'Cholesteatoma'. It was recognized that producing a guideline on any surgical condition based on high level of evidence is difficult if not impossible. There are many problems in designing a high quality randomized controlled study comparing different surgical techniques, as it is almost impossible to control the surgical skill of a surgeon, and it is difficult to eliminate observer bias. Some designs of RCTs in the past may not even pass the stage of the ethics committee [Thomsen et al., 1981]. The purpose of this systematic review on surgical and non-surgical interventions for retraction pockets and atelectasis is to identify if any high level of evidence exists that could be used for guideline development.

Material and methods

Data sources:, PubMed (1950 to 2012), Embase (1980 to 2012), Centre for Reviews and Dissemination (DARE, NHS EED, INAHTA), NICE, Cochrane Database of Systematic Reviews , Cochrane Economic

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Evaluations, Cochrane Technology Assessment and Cochrane Central Register of Controlled Trials were systematically searched. The date of the last search was 07/03/2012. A search strategy was developed based on MESH terms identified in the scoping search: tympanic membrane, ear drum, epitympanic, retrotympanic, collaps*, atelectas*, atelectat* combined with tympanoplast*, myringotom*, tympanostom*, mastoidectom*, surg*, excis*, reconstruct*, ventilation or grommet*

Bibliographies of identified studies were manually searched for relevant references. No language limitation was applied and papers in foreign languages were translated. Citations were exported to Reference Manager 12 and duplicates removed. Only published data was used as time and resource limitation did not allow for contacting authors for unpublished data.

Study selection

The inclusion/exclusion criteria were piloted on 10 papers and refined by discussion between reviewers.

The following inclusion/exclusion criteria were applied:

Study Design: randomised or non-randomised controlled trials. Non-comparative studies such as case series, cohorts and narrative reviews were excluded. Conference proceedings were also excluded as the limited information available would make the quality assessment impossible.

Population: studies including patients of all ages with retraction pockets or atelectatic tympanic membrane. If a study reported on patients with other ear pathology (such as cholesteatoma or perforation), the study was included in the review only if the outcomes were reported separately on the disease of interest.

Intervention: surgical intervention for retraction pockets/atelectasis.

Comparator: surgical or non-surgical intervention, including watchful waiting.

Outcome: Primary outcome was the clinical description of tympanic membrane such as resolution, cessation of progression, no effect or progression of disease. The secondary outcome of interest was audiological result. Only studies with a follow-up period of minimum a year were included.

Data extraction and quality assessment

The quality assessment and data extraction were undertaken by two independent reviewers in order to determine a minimum quality threshold for selection of studies; to explore quality differences as an explanation for heterogeneity of results; to guide interpretation for findings and aid in determining the strength of inferences and to guide recommendation for future. The forms used for data extraction and quality assessment were piloted on 10 studies and refined after discussion between reviewers.

In assessing the RCT's we used the Cochrane Collaboration 'Risk of Bias' tool as described in the Handbook [2011]. The risk of bias was assesses in six main areas: sequence generation, allocation concealment, blinding of participants, personnel and outcome assessors, incomplete outcome data, selective outcome reporting. Other potential sources of bias were also considered.

The criteria suggested by the NHS Centre for Reviews and Dissemination[2009] were used for the quality assessment of non-randomised studies.

1. Is there sufficient description of groups and distribution of prognostic factors such as age, site and extent of retraction pocket/atelectasis, ossicular chain status, audiometric data, and infection status?

2. Are groups comparable on all confounding factors?

3. Is the intervention reliably ascertained? Is the surgical technique described in sufficient details? Is tympanoplasty performed and what materials are used? Any additional procedures such as Silastic insertion, ventilation tubes, etc given?

4. Is the comparator surgical technique/non-surgical treatment reliably described?

5. Is the follow-up periods long enough for residual/recurrent diseases to manifest itself? Are the results presented at similar post-operative intervals for the two groups compared? How is the outcome ascertained (i.e. otoscopy, audiometry, tympanometry, imaging)?

6. What proportion of cohort of followed up in each group?

7. Are there similar drop-out rates and reason for drop-out rates between groups?

8. Is surgical expertise of operators similar between groups?

Data synthesis

The search resulted in 589 papers after de-duplication and the abstracts were screened for relevance independently by the two reviewers. Where sufficient information was available, for example if it was clear that they did not meet one of the inclusion criteria, papers were excluded at this stage. We analysed the full text of papers considered potentially eligible for inclusion, or if the information in the abstract was not enough to make a judgment. A number of 66 full text papers were independently assessed by two reviewers using clearly defined inclusion/exclusion criteria. Their references were screened for relevant studies but this search yielded no additional studies.

Where disagreement existed it was resolved by discussion. A third reviewer was available for consultation if agreement could not be reached, but adjudication was not necessary. The selection process is illustrated using the PRISMA [2012] diagram (figure 1).

One systematic review of surgery for tympanic membrane retraction pockets published by the Cochrane collaboration was identified [Nankivell and Pothier, 2010]. We also identified two RCTs[Barbara, 2008;Elsheikh et al., 2006] comparing surgical techniques for retraction pockets, both studies being included in the Cochrane review [Nankivell and Pothier, 2010]. One non-randomised controlled study [Cassano and Cassano, 2010] published after the Cochrane review was included. After closer scrutiny for quality assessment, we decided to exclude this study as the many sources of bias and confounding factors made the interpretation of results impossible. Details of this study, along with its quality assessment and reasons for exclusion, are presented below

Results

Two randomised trials [Barbara, 2008;Elsheikh et al., 2006] satisfied the inclusion criteria and quality assessment.

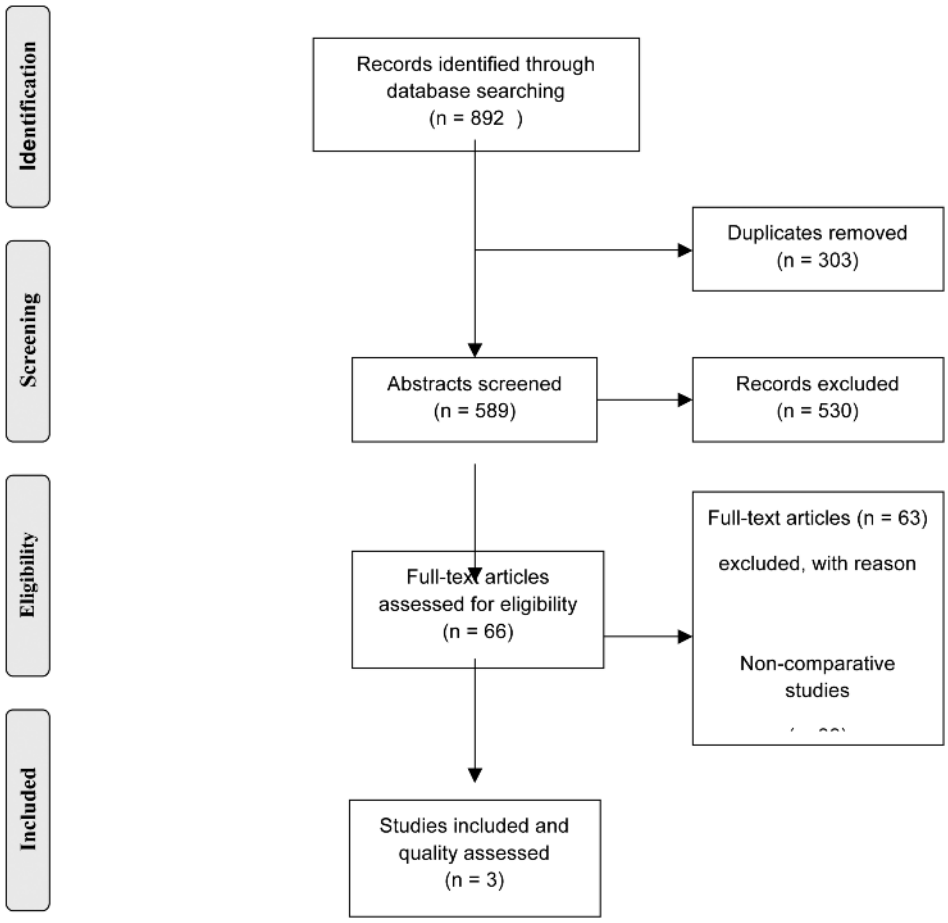

Figure 1. PRISMA diagram for studies selection

Barbara 2008 was a prospective randomised trial assigning adults with grade IICharachon retraction pocket(fixed and controllable retraction pocket) by sequential consecutive randomisation to either lateral attic reconstruction with tragal cartilage and perichondrum graft (15 patiens) or watchful waiting (15 patients). The follow up regime was similar for both groups at 15 days, 1, 2, 6 and 12 months. The outcomes of interest were otoscopic appearance of tympanic membrane, pure tone audiometry and tympanometry.

Elsheikh 2006 was a prospective randomised study assigning adults with Sade grade 2 (tympanic membrane touching long process of incus) and 3 (tympanic membrane touching long process of incus and promontory) retraction pocket to either tragal cartilage and perichondrum tympanoplasty plus T tube insertion (23 patients) or tympanoplasty alone (23 patients). The outcomes assessed were clinical inspection at 3, 6 and 12 months and Eustachian tube function and audiometry at one year. The shortest follow-up period was 13 months.

Risk of bias

We assessed the risk of bias using the Cochrane Collaboration Risk of Bias tool Handbook [2011]. Both studies had a high risk of bias.

In Barbara 2008 the randomisation was sequential allocation on a consecutive cohort, with no allocation concealment or blinding (single investigator undertaking randomisation, surgery and outcome assessment). Although pure tone audiometry was undertaken no data is presented in the paper. The baseline tympanometry data is not presented for either group but the author report the tympanogram results for the intervention group. The clinical appearance of the tympanic membrane was assessed by one investigator alone introducing potential for bias. Five out of the initial 15 patients allocated to the control group were lost to follow up (high risk of attrition bias). Three patients from the control group demonstrated progression of disease (2 had widening of bony erosion and 1 had accumulation of keratin in the pocket) and required surgical intervention eventually.

In Elsheikh 2006 the randomisation method was not specified but the two groups were comparable on all prognostic factors. No allocation concealment or blinding for assessors was reported either. Three patients from the initial 49 recruited were lost to follow up but it is not reported from which group. The primary outcome measure was the status of the tympanic membrane postoperatively. Although pre-operatively the Sade grading for retraction was used there is no clinical staging reported postoperatively. Authors report only that the tympanic membrane has return to "near normal" in all patients and that is likely to introduce reporting bias, especially if the assessors were not blinded. In the group not receiving T tubes, 3 patients developed conductive hearing loss and two of them required myringotomy.

Summary of effects of intervention

a. Appearance of the tympanic membrane and Imaging

Barbara 2008: No evidence of retraction of tympanic membrane at 12 months in the active treatment group (0/15). Five patients underwent CT scanning demonstrating hypodense area in the epitympanum and underwent revision with negative findings in all cases.

In the control group 3/10 showed disease progression with widening of the bony erosion in two patients and keratin accumulation in one patient. They all underwent surgery subsequently.

Elsheikh 2006: Sade grading used pre-operatively but not for post-operative results. Authors just stated that the tympanic membrane returned to "near normal" in all participants.

b. Audiometry

Barbara 2008 report that all participants had normal hearing at the beginning of the study and at 12 months follow up, irrespective of treatments received but no data is presented.

Elsheikh 2006 report that pure tone average (0.5, 1, 2 and 3 KHz) and air-bone gap average improved in both groups postoperatively but there was no significant difference between the two groups ($p>0.05$). There was no significant difference between pre- and postoperative word discrimination scores in any group. The authors reported recurrent conductive hearing loss in 2 patients in group 1 (tympanoplasty and T tube - 8.69%) and 3 patients in group 2 (tympanoplasty - 13%).

c. Complications

Barbara 2008: one patient in the active treatment group had an infection on day 15 that required topical and systemic antibiotics and resolved completely.

Elsheikh 2006: no complications reported.

One retrospective cohort [Cassano and Cassano, 2010] study satisfied the inclusion criteria but failed the quality assessment.

Cassano 2010 treated 45 ears in 37 children in the intervention group. The pathology included otitis media with effusion, recurrent infections, polyps, perforations and major bilateral hearing loss.

The pockets were described as 22 postero-superior, 8 postero-inferior, 2 antero-superior, 2 antero-inferior, 11 postero-superior and inferior. The severity of retraction was classified as follows: Sade grade 1 (annular retraction) and 2 (tympanic membrane touching long process of incus) 16 cases, grade 3(tympanic membrane touching long process of incus and promontory) 24 cases, grade 4(tympanic membrane adherent to promontory) 5 cases. Twenty eight children were younger than 8 years of age, while 17 ears were older than 8 years of age. No audiological data was presented.

In the control group the authors included 40 ears but did not report how many patients were involved. The reasons for not treating these patients were very variable: treatment 'deemed unnecessary' in 5 cases of Sade grade 1-2 and 3 cases of grade Sade 3 'as condition mild, did not progress and/or no hearing loss was observed'. Treatment was not performed in 25 cases grade 3 and 7cases grade 4 either because it was contra-indicated by co-morbidity (6 cases) or parental refusal of treatment in 26 cases. There was no information on the control group site of retraction or about infection, perforation and age distribution. There was no attempt by authors to perform statistical analysis for distribution of prognostic factors in the two groups.

A number of surgical intervention were employed in the intervention group and they not uniformly applied, but chosen tailored to the severity of retraction and therefore biasing results. Patients with grade 1-2 Sade retraction (16 cases) underwent: toilet of nasal cavity, systemic or topical steroids, antibiotics, decongestants, tubotympanic insuflation and autoinsuflation and ventilation tubes in cases refractory to treatment. Patients with grade 3 retraction (24 cases) underwent: endaural incision, myringoplasty with composite tragal cartilage-perichodrum graft, some requiring scutum reconstruction, Silastic was used in 4 cases with adhesion to promontory and ossiculoplasty was performed in 7 cases, with cartilage (2 cases) and ceramic or titanium (5 cases).Ventilation tube insertion alone was performed in 8 cases.

In the control group the authors give no detail on what treatment, if any, was adopted, apart from regular follow-up with hearing tests. No details are given about follow-up intervals or audiological data.

It is unclear when the results presented occurred and whether the same observer examined the child at all visits or whether another observer was available for verification. The authors give no details on how the results were documented (ie clinical pictures, drawings, clinical notes, etc). No information about losses to follow-up or surgical expertise of the operator is presented.

This is a study of low quality and no meaningful comparison can be made although authors claim that there is a significant anatomical improvement in the treatment group when compared with controls.

Discussion

The treatment of retraction pockets is highly variable amongst otolaryngologist and there is no consensus as to the indication, timing and type of intervention used in its treatment. We set out to search for the highest level of evidence in an attempt to answer this important clinical dilemma. The scoping search identified a limited number of randomised controlled studies on this condition and also one systematic Cochrane review [Nankivell and Pothier, 2010]. Due to the paucity of data, we decided to widen the search and look for good quality comparative studies to ensure that good evidence that may be available is not overlooked due to over stringent inclusion criteria. The majority of studies identified were non-comparative and most of them were retrospective. The low level of evidence and poor reporting standards made this type of evidence not suitable for the purpose of this review.

In the light of the finding of this review there is no high level of evidence to support any surgical intervention over watchful waiting in the management of mild to moderate degrees of retraction pockets (grade II Charachon and Grade 2 and 3 Sade) as there is also no good evidence to favour one particular treatment over the others.

Although a randomised controlled trial is the highest level of evidence for testing the efficacy of one form of treatment over another for retraction pocket or atelectasis, it may maybe not be the most suitable or practical way of answering this particular clinical dilemma. There is no universally accepted staging system for retraction pockets. All the currently used systems all suffer from a high degree of inter-observer and intra-observer variability[Pothier DD, 2009]. This in turns raises the difficulty in recruiting patients with comparable staging and assessing the tympanic membrane postoperatively. Surgical interventions for atelectasis or retraction pockets are very variable and the surgical skills of the surgeons also vary, thus introducing a number of confounding factors. Also, recurrence of retraction pockets could take several years to manifest [Yung, 1997] and long-term follow up may be necessary for the comparative studies.

In the light of the problems likely to be encountered in setting up a high quality comparative study we feel that the otological community may be better served by obtaining a consensus on the management of retraction pockets from experts in the field. We plan to use the Delphi method for obtaining census from the members of the European Academy of Otology and Neurotology and this will be presented in another paper.

Conflicts of interest: none

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