Original Article

Comparison of tympanic membrane grafting medial or lateral to malleus handle

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Abstract

Background: To compare two methods of tympanic membrane (TM) grafting when graft materials medial or lateral to malleus, this study have been done.

Materials and Methods: In this clinical trial which was conducted in Alzahra and Kashani hospitals, between June 2010 and February 2012, 56 patients with chronic otitis media and perforated TM entered the study in two groups. The inclusion criteria consisted of patients who were at least 15-years-old without history of smoking, diabetes mellitus or autoimmune disease. Exclusion criteria of the study: No compliance for follow up, post-surgical ear trauma or any infective pathology that directly affects the ear. In Group A patients, the graft material is pierced in near central part of the graft and they lodged so that the malleus handle projects through the graft perforation. Group B had grafting in the lateral side of the malleus. Three month after surgery both groups examined and tested by audiometry. Success of surgery is defined as complete repair of TM, without lateralization, atelectasis, blunting or retraction pocket.

Results: This study contained 28 patients in Group A and 28 in Group B. Overall success rate was 94.64% that was 96.42% in Group A, and 92.85% in Group B. Differences of air-bone gap in each group before and after surgery was 16.10 (±4.89) in Group A, and 15.78 (±3.40) in Group B. Improvement of hearing level was not significant between two surgical methods ($P = 0.442$).

Conclusions: Both techniques (medial and lateral to malleus handle) of TM grafting are effective with success rates 96.42% and 92.85% respectively.

Key Words: Chronic otitis media, tympanoplasty, tympanic membrane perforation

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INTRODUCTION

Tympanoplasty is a surgical method, to eradicate middle ear infection and improve its function.[1] A main part of tympanoplasty is repair of perforated tympanic membrane (TM) which results mainly from chronic otitis media (COM). Other etiologies include traumatic or neoplastic defects on the TM.[2] Ventilation tube insertion is reported the most common surgical cause of TM perforation.[3-5]

Prevalence of COM is estimated to be 0.5-30% in different population and there are about 120 million patients with COM around the world. Essential treatment of COM is by surgical procedures to eliminate

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disease, prevention of recurrence and maintain or improve hearing. About 70000 "tympanoplasty" and "mastoidectomy" operations have been performing annually in United States.[6]

Modern tympanoplasty was introduced in 1950s by Zollner and Wullstein, since then different techniques were evolved for repair of TM.[2,7-9] Tabb and Shea first innovated medial positioning of grafting tissue to malleus and residue of TM.[7,10-12]

Nowadays, two classic methods are applied in tympanoplasty which includes underlay and overlay techniques. In the underlay method which is used more frequently, the graft sits medial to malleus and residue of tympan. In overlay technique after the elevation of squamous tissue, the graft is positioned lateral to annulus and fibrotic layer of TM residue. The underlay technique is generally more recommended for posterior perforations. It has less risk for lateralization, and more acceptable success rate, even in the hands of less experienced surgeons. Overlay technique, is not only proper for all types of perforations but also saves the middle ear volume. It also has a good success rate especially in large and anterior perforation.[13]

Otologic surgeons may choose either method depending on the characteristics of the defect.[14]

In underlay technique the fascial graft is pierced in order to make a hole for the malleus handle to pass through it. At first, the hole is passed through the tip of malleus handle and then the graft is stretched over it to fit around the neck of malleus so that the graft lodges medial to malleus.[15] In this study these two TM grafting methods have been compared.

MATERIALS AND METHODS

This single-blinded clinical trial which was conducted in Alzahra and Kashani hospitals, from June 2010 to February 2012, began with 56 COM patients with perforated TMs. Those patients with at least 15-year-old, dry ear, no history of diabetes mellitus, autoimmune disease, and smoking, were included in the study. Exclusion criteria were: No compliance for follow up, beginning of active otorrhea, ear trauma, and upper airway infection.

Patients were selected by simple randomized method. 28 patients were allocated in Group A and 28 patients in Group B by random 2 column tables.

All of the patients assigned informed consent. The study was approved by Isfahan University of Medical Sciences ethics committee, Isfahan, Iran. There was no financial conflict of interest.

At the beginning, demographic data (age, sex, past medical history), physical examination and otoscopic parameters were registered in a form.

Group A patients had tympanoplasty by TM grafting medial to malleus. Group B had graftings in the lateral side of the malleus. Surgery was done under general anesthesia, and the graft tissue was harvested from temporalis fascia in both groups.

All the patients were referred to the Otorhinolaryngology clinic for follow up. Three months after the surgery both the groups were examined and tested by audiometry. Success of surgery is defined as complete repair of TM, without lateralization, atelectasis, blunting or retraction pocket. Mean air-bone gap before and after tympanoplasty and success rate of tympanoplasty were analyzed with SPSS version 18 by independent *T*-test, Ki-square, ANCOVA. $P > 0.05$ considered as significant.

RESULTS

This study contained 28 patients in Group A and 28 in Group B. Patients were 16-62 years old. Mean (± standard deviation) of age was 33 (±12) years old. 21 operations were performed on right ear, and others were on the left ear. Baseline characteristics had no statistical significant difference between groups ($P > 0.05$).

In Groups A and B, 26 patients (92.9%) had conductive hearing loss, and 2 patients had mixed hearing loss (two groups were the same). Mean air-bone gap of two groups, before and after the tympanoplasty is described in Table 1.

Overall success rate was 94.64% (96.42% in Group A, and 92.85% in Group B).

There was one perforation in Group A, and one perforation and one blunting in Group B. Fisher Exact test did not show any difference between success rates of two groups ($P = 0.33$).

Table 1: Audiometry of group A and B, before and after surgery

	Before treatment	After treatment	*P* value (before and after treatment)[¥]
Air bone gap			
Group A	24.42 (±8.50)	8.32 (±6.78)	<0.001
Group B	25.35 (±6.12)	9.57 (±5.20)	<0.001
P value (between group A and B)*	0.641	0.777	

[¥]By paired sample *T*-test,*by Independent sample *T*-test

Difference of air-bone gap in each groups before and after surgery was 16.10 (±4.89) in group A, and 15.78 (±3.40) in Group B. Improvement of hearing level was not significant between two surgical methods (P = 0.442).

DISCUSSION

Different techniques in tympanoplasty have implemented, with different success rate in different settings, and studies. The difference between success rates of different studies can be attributed to their follow up schedule that is between 3 and 21 months.

In underlay method which is used more frequently, the graft is located medial to malleus and residue of TM. This clinical trial study was done to compare the two methods of TM grafting by graft medial or lateral to malleus. In both methods the margin of the graft was located medial to annulus and TM remnant. Indeed these are two modalities of underlay technique.

There is no previous study that compares these two methods in a single clinical trial. We found no difference between success rates of both groups in this study. Overall success rate was 94.64%. The success rate of medially grafting group was 96.42% (with one perforation) and the success rate of laterally grafting group was 92.85% (with 1 perforation and 1 blunting).

Air-bone gap improvement was 16.10 (±4.89) in medial to malleus grafting group, and 15.78 (±3.40) in lateral to malleus group. Improvement of hearing level was not significant between 2 surgical methods.

In a retrospective study in Turkey, a total of 104 patients underwent tympanoplasty, via underlay technique in 46 patients and over-under technique in 58 patients. The mean follow-up period was 11 months. In the first group of patients with underlay technique (the graft was placed medial to the remaining drum and the manubrium), the success rate was 91.5%. In the second group with over-under technique (the graft was placed under the remaining drum and over the malleus), the success rate was 94.9%. In the patients operated by the underlay technique, the air-bone gap decreased 16.55 db. This rate was 16.96 db in those operated via the over-under technique.[16]

In another study in Michigan Ear Institute, the chosen technique had been over-under tympanoplasty which was performed by placing the graft over the malleus and under the annulus. All their 120 patients had successful grafts. Lateralization of the grafted drum did not occur. Seventeen patients had late atelectasis, and 12 patients had late perforations; nearly all of these were noted more than 1 year after surgery and were attributed to persistent Eustachian tube dysfunction or infections. Average improvement in air-bone gap for all patients was 5.3 db, whereas speech reception threshold improved by 5.9 db.[13]

In another study by Fiorino in Italy, 78 umbus-anchored over-under myringoplasties were performed. They used a large graft with a radial slit distended under the TM and annulus, and the two tongues were positioned to surround the umbus area and overlapped under a non-perforated portion of the TM. Graft take was obtained in 91% of cases and the auditory result showed an average residual air-bone gap of 6.7db.[17]

In Ryan study on 147 patients, overlay graft technique was highly successful for TM repair which was 98.75%, even in difficult cases.[18]

The study of Jung concluded medial graft tympanoplasty is suitable for posterior TM perforation, and medio-lateral graft method is an excellent for the reconstruction of large anterior or subtotal TM perforation.[19]

On the basis of our study data, short-term outcomes of both techniques were good and there was no significant difference between their graft take and audiometric results. It seems that good performance of any technique by the surgeon is the more important factor in success of surgery than the type of technique. Also noteworthy to mention there are no absolute indications for any of these techniques.

There were some confounding factors in our study that include: Eustachian tube function status, size and location of the TM perforation. Although this study has evaluated the short-term results of these two tympanoplasty methods, for assessment of long-term outcomes or complications such as atelectasis, retraction pockets or perforations long-term follow up is necessary. Further study with longer follow up and more detailed localization of perforation site may reveal some preference for each technique.

CONCLUSION

Both techniques of tympanoplasty by placing the graft medial to malleus or lateral to it are effective with success rate 96.42% and 92.85%, respectively. Air-bone Gap improvement was 16.10 (±4.89) in graft medial to malleus group, and 15.78 (±3.40) in graft lateral to malleus group and there is no significant difference between them.

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