Original Research Article

Comparison of Results of Myringoplasty with Temporalis Fascia and Perichondrial: Cartilage Composite Graft in High Risk Perforations

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Abstract

Background: The objectives of this study were to compare the graft uptake and post-operative hearing results of underlay myringoplasty with temporalis fascia and perichondrial-cartilage composite graft in high risk perforations.

Materials & Methods: Patients of ages of 13 years and above with diagnosis of chronic otitis media – mucosal type with high risk perforations undergoing myringoplasty were included. Criteria of high risk were >50% perforation of tympanic membrane, revision cases, absent/eroded handle of malleus, oedematous/unhealthy middle ear mucosa and marginal perforation of any size. Pure tone audiometry was done within 1 week before surgery. Seventy cases included for myringoplasty were randomly allocated by lottery method into two groups with 35 cases each in temporalis fascia group and perichondrial - cartilage composite graft group. After 6 weeks graft uptake results were assessed and post-operative hearing was evaluated and compared within and between the groups.

Results: Graft uptake rates in temporalis fascia group and perichodrial - cartilage composite graft group were 88.57% and 91.43%, respectively with no statistically significant difference between the groups (p = 0.69). The mean pre- and post-operative air bone gaps in temporalis fascia group were 31.81 ± 10.49 dB and 17.87 ± 7.96 dB. The mean pre- and post-operative air bone gaps in perichondrial - cartilage composite group were 35.19 ±7.26 dB and 22.62 ± 8.77 dB. These differences in both the groups were statistically highly significant (p < 0.001) showing improvement in the hearing after surgery. The mean post-operative ABG gains were 13.94 ± 8.36 dB and 12.57 ± 8.21 dB in temporalis fascia and perichondrial - cartilage composite groups respectively.

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Conclusion: The graft uptake rates and hearing results after perichondrial - cartilage composite graft are similar to those of temporalis fascia graft. Perichondrial- cartilage composite graft even though more rigid and thicker than temporalis fascia did not affect post-operative hearing results adversely.

Keywords: Myringoplasty, chronic otitis media, high risk perforation, temporalis fascia, perichondrium - cartilage, pure tone audiometry.

Introduction

Mucosal type of chronic otitis media (COM) is a common disease worldwide. There is no uniformity regarding nomenclature of this disease. Terms like chronic otitis media tubotympanic or non cholesteatoma type are also used synonymously.[1, 2] The mucosal type of disease may pass through acute, inactive, quiescent or healed stages. There is discharge in middle ear and external auditory canal with congestion of middle ear mucosa in acute stage. Absence of otorrhoea and normal looking middle ear mucosa are seen in inactive stage.[3]

Oral antibiotics and/or ototopical antibiotics mixed with steroid are prescribed to stop otorrhoea which may take a period of days to weeks.[4] Small perforation may heal by this treatment only while others may need surgical intervention. Surgical treatment of chronic otitis media-mucosal type is myringoplasty wherein the closure of perforation of pars tensa is done mainly to prevent recurrent ear discharge and to improve hearing.[5]

Success of myringoplasty is related to the intactness of pars tensa and improvement in hearing after operation. Hearing improvement is assessed either in terms of closure of air bone gap (ABG) or improvement in threshold of air conduction. There are various factors responsible for success of myringoplasty like experience of surgeon, size of perforation, status of middle ear (dry or wet), presence of infection in perioperative period, technique (underlay or overlay), and status of opposite ear etc.[6]

Currently indications of cartilage tympanoplasty include all revision cases as well as certain high risk primary tympanoplasties, which include a subtotal perforation, a perforation in a patient with previously repaired cleft palate, and an ear draining at the time of surgery. Use of cartilage in these cases is also supported by the findings of others.[7] So, there was the necessity of a prospective study regarding the comparison of results of myringoplasty using temporalis fascia and tragal perichondrial - cartilage composite graft in high risk perforations. This is the first study of its kind in the country.

Materials & Methods

It was a prospective, comparative, randomized study at Ganesh Man Singh Memorial Academy for ENT-Head and Neck Studies, Institute of Medicine, Tribhuvan University, Kathmandu, Nepal.

Inclusion criteria:

- Both gender
- Age : 13 years & above
- Chronic otitis media - mucosal with >50% perforation of TM
- Chronic otitis media - mucosal with <50% perforation of TM with one or more of the following situations:
  - ⇒ Revision surgery
  - ⇒ Absent/eroded handle of malleus
  - ⇒ Oedematous/unhealthy middle ear mucosa
- Any size with margin involvement

Exclusion criteria:

- Frank otorrhea at the time of surgery
- Patients with sensorineural hearing loss

Non probability convenient sampling method was applied. With the confidence level of 95% and confidence interval of 5%, the sample size calculated was 70. Detail history, general physical examination, ear examination with otoscope and tuning fork test with 512 Hz was done and confirmed by faculty if done by resident. Examination under microscope was done before surgery.

Pure tone audiometry test was performed within 1 week before surgery and at 6-8th week after surgery by trained audiometrician. It was tested in sound treated room. Hugson and Westlake technique was

used for audiometric evaluation. Test was performed through air conduction and bone conduction. Air conduction included the frequencies 250, 500, 1000, 2000, 3000, 4000 and 8000 Hz and bone conduction included 250, 500, 1000, 2000, 3000 and 4000 Hz. Four frequencies pure tone average was calculated from 500, 1000, 2000 and 3000 Hz.

Air Bone Gap (ABG) was measured by the difference of average of air conduction and bone conduction threshold done at the same time. It was documented both pre- and post-operatively. Examination under microscope was done before surgery. Both type of myringoplasty were performed by the faculty. Informed consent was taken from all the patients' pre-operatively after explaining the procedure.

Study population was randomly divided into two groups by lottery method.

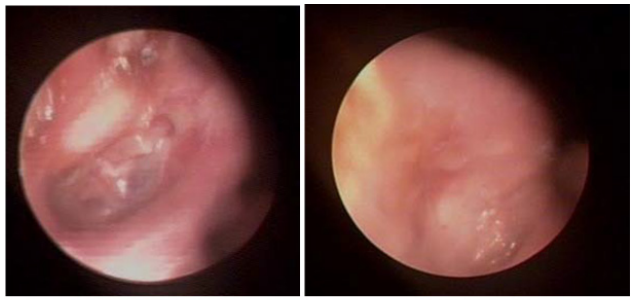
A: Tragal Perichondrial - Cartilage Composite grafting – 35

B: Temporalis fascia grafting – 35

Either permeatal, postauricular or endaural approach was used to access the tympanic membrane and middle ear according to necessity or convenience of the surgeon.

Follow-up

Patients were given oral antibiotics (ciprofloxacin 500 mg 12 hourly) for 10 days and antihistamines fexofenadine in post-operative period. Follow up was done in 6th postoperative day and after 6-8th weeks after surgery. In 6th post-operative day, suture and pack were removed. Topical antibiotic and steroid ear drops were given for 2 weeks. Patients were followed at or after 6th to 8th weeks. Graft uptake results were noted (Fig. 1 A & B) and PTA was performed. Any residual perforation from pin point to total rejection was reported as failure. Pure tone audiometry was done only for successful graft uptake cases at 6-8th week.



A B

Figure 1: Post-operative graft status A) temporalis fascia graft B) perichondrial - cartilage composite graft

Results were analysed as graft uptake rate and change between pre- and post-operative hearing. Data were analyzed using Fisher's exact test, Chi square test, dependent and independent '*t*' test on a SPSS statistical package version 16.0. The level of statistical significance was set at the $p < 0.05$.

Results

Ages of the patient ranged between 13 to 53 years in temporalis fascia group (Group A) with mean age of 28.2 years and 15 to 55 years in cartilage composite group (Group B) with mean age of 29.48 years. The most common age group was 21-30 year (34.28 % in each group), which was followed by 13-20 year age group (28.58 % in group A and 25.72% in group B), 31-40 year age group (22.85 % in each group) and >41 year age group (14.29 % in group A and 17.15 % in group B).

Table 1: Clinical outcomes in Group A (temporalis fascia) and Group B (cartilage composite)

Characteristics	Group A (Temporalis fascia) (n=35)	Group B (Cartilage composite) (n = 35)
Frequency of bilateral disease	U/L 19 (54.28 %) B/L 16 (45.72 %)	U/L 17 (48.58 %) B/L 18 (51.42 %)*
Post-operative graft status	Uptake 31 (88.6%) Failure 4 (11.4%)	Uptake 32 (91.4%) Failure 3 (8.6%)**

*Chi-square test: $p = 0.632$ - statistically not significant

**Fisher's Exact test (p = 0.690) – Statistically not significant

Sixteen (45.72%) patients of temporalis fascia group (Group A) had bilateral disease while 18 (51.42%) patients of composite cartilage group (Group B) had bilateral disease, no statistically significant difference in frequency of disease distribution. In temporalis fascia group (Group A), there was graft uptake in 31 (88.6%) cases and failure in 4 (11.4%) cases whereas in cartilage composite group (Group B), graft uptake was observed in 32 (91.4%) cases and failure in 3 (8.6%) cases (Table 1).

Comparison of pre- and post-operative hearing in between two groups

The mean preoperative air bone gap was 31.81 dB (SD = 10.48) and post-operative air bone gap was 17.87 dB (SD = 7.96). Hearing improvement after surgery was found to be statistically highly significant. ($p < 0.001$). For the comparison of hearing results in this group, only 32 cases with graft uptake were taken. The mean pre-operative air conduction threshold was 51.06 dB (SD = 8.281) and post-operative air conduction threshold was 36.69 dB (SD = 9.845). The mean preoperative air bone gap was 35.19 dB (SD = 7.26) and post-operative air bone gap was 22.62 dB (SD = 8.77). Hearing improvement after surgery was found to be statistically highly significant ($p < 0.001$) (Table 2).

Table 2: Comparison of pre- and post-operative hearing in temporalis fascia group (Group A) and Group B (n = 31)

Group A	Mean (Db) Std.	Deviation Std.	Error of Mean
Pre-operative PTAAC threshold	48.45	14.413	2.589
Post-operative PTAAC threshold	33.52	14.962	2.687
Pre-operative PTAAB Gap	31.81	10.489	1.884
Post-operative PTAAB Gap	17.87	7.961	1.430*
Group B			
Pre-operative PTAAC threshold	51.06	8.281	1.464
Post-operative PTAAC threshold	36.69	9.845	1.740
Pre-operative PTAAB Gap	35.19	7.267	1.285
Post-operative PTAAB Gap	22.62	8.772	1.551**

Paired T-test

*PTA-AC threshold: t = 8.828, df = 30, p < 0.001 – Statistically highly significant.
*PTA-AB Gap: t = 9.283, df = 30, p < 0.001 – Statistically highly significant
Paired T-test -
**PTA-AC threshold: t = 9.550, df = 31, $p < 0.001$ – Statistically highly significant.
**PTA-AB Gap: t = 8.659, df = 31, $p < 0.001$ – Statistically highly significant.

Comparison of pre- and post-operative hearing between two groups

The mean pre-operative PTA-AC threshold were 48.45 dB and 51.06 dB and postoperative PTA-AC threshold were 33.52 dB and 36.69 dB in temporalis fascia group (Group A) and cartilage composite group (Group B) respectively. Similarly, preoperative PTA-ABG were 31.81 dB and 35.19 dB and post-operative PTA-ABG were 17.87 dB and 22.62 dB in temporalis fascia group (Group A) and cartilage composite group (Group B) respectively. Mean AB gain was 13.94 dB in temporalis fascia group (Group A) and 12.57 dB in cartilage composite group (Group B). Applying independent T-test, the difference in means between the groups in each category was found to be not significant statistically (Table 3).

Table 3: Comparison of pre- and post-operative hearing between two groups

Mean	Group A Temporalis fascia (n = 31)	Group B Cartilage composite (n = 32)	***p* value**
Pre-operative PTA-AC threshold (dB)	48.45	51.06	0.324
Post-operative PTA-AC Threshold (dB)	0.276	36.69	0.276
Pre-operative PTA-AB Gap (dB)	35.19	35.19	0.141
Post-operative PTA-AB Gap (dB)	17.87	22.62	0.074
ABG gain (dB)	13.94	12.57	0.513

Comparison of pre- and post-operative hearing in terms of percentage of ABG closure in two groups

ABGs were divided into different bins of 0-10 dB, 0-20 dB, 0-30 dB and >30 dB. It was noted that 41.93 % in temporalis fascia group (Group A) and 43.75 % in cartilage composite group (Group B) had ABG closure within 10 dB. 67.74% of temporalis fascia group (Group A) and 84.37% of cartilage composite group (Group B) had ABG closure within 20 dB and 100% of temporalis fascia group (Group A) and 96.87% of cartilage composite group (Group B) had ABG closure within 30 dB (Table 4).

Table 4: Comparison of pre- and post-operative hearing in terms of percentage of ABG closure in two groups

ABG closure within	**Group A (Temporalis fascia)(n = 31)**	**Group B (Cartilage composite) (n =32)**
0-10 dB	13 (41.93%)	14 (43.75%)
0-20 dB	21 (67.74%)	27 (84.37%)
0-30 dB	31 (100%)	31 (96.87%)
>30 dB	31 (100%)	32 (100%)

Discussion

In the present study, underlay technique was used in all cases. It is acknowledged that underlay technique remains the most common technique nowadays. It has advantages of ease of assessment the middle ear cavity including ossicular chain and its mobility. Underlay technique is easier and is less time consuming. It avoids anterior blunting and lateralization of graft.[9, 10]

The patients were of in between 13 to 53 years of age in temporalis fascia group (Group A) with the mean age of 28.2 years and were of 15 to 55 years of age in cartilage composite group (Group B) with mean age of 29.48 years. The most common age group was 21-30 year with 12 patients (34.28%) in each group. This group of patient is probably very much concerned about the nuisance created by ear discharge and decrease in hearing and is willing to undergo surgery with ease. There was almost homogenous distribution of the patients in both the groups. The most common age groups undergoing myringoplasty are similar in other studies also.[11, 12] There were 16 (45.72 %) cases of bilateral disease in temporalis fascia group (Group A) and 18 (51.42 %) cases in cartilage composite group (Group B). There was no statistically significant difference in frequency of bilateral disease in both the groups. (p = 0.632) Status of contralateral ear is a negative prognostic factor in some studies and especially in children.[13, 14]

In our study, we included only high risk perforations, that is >50% perforation of tympanic membrane, perforation underwent revision surgery, perforation with absent/eroded handle of malleus, oedematous/unhealthy middle ear mucosa but not actively discharging and perforation with margin involvement. This is a slight modification of high risk criteria used by Dornhoffer.[15]

There was almost equal distribution of high risk criteria in both the groups, the criteria of >50% TM perforation being the commonest. Out of 35

patients in each group, in group A, 27 cases had >50% TM perforation and in group B, 23 cases had >50% perforation of TM. Both the groups had 5 cases each of oedematous/unhealthy middle ear. Status of middle ear at surgery is one of the important factors that influences graft uptake in myringoplasty.[6] Graft uptake was assessed after 6 weeks of surgery. By this time, Gel foam is expected to have dissolved completely. Prasad *et al.*[16] had also used 6 weeks as the minimum postoperative follow up period after myringoplasty, the time required for complete healing and good hearing results. Brown *et al.*[6] used minimum of 4 weeks from the date of operation to assess the results. A short period of follow up is the limitation of our study. Uptake rate of myringoplasty using temporalis fascia as graft was 88.6% and with tragal perichondrial - cartilage composite graft it was 91.4%. This observed difference was not statistically significant (p= 0.690). Our results are similar to those of Ulku[17] who had found graft uptake rate of 88.2% with temporalis fascia and 91.3% with perichondrium cartilage in subtotal perforations in his retrospective study. Also, Ozbek *et al.*[18] reported graft uptake rate of 70.2% in temporalis fascia group and 100% in cartilage group in >50% TM perforation but this study was done in children. Kazikdas *et al.*[19] achieved graft uptake rate of 75% in temporalis fascia and 95.7% in perichondrium cartilage group in subtotal perforations with palisade technique.

Among failure cases, 5 cases had unilateral disease whereas 2 cases had bilateral disease in our study. Out of 5 cases with unilateral disease, one was revision surgery and in one, middle ear was unhealthy and oedematous at the time of surgery. This is in contrary to the findings of other authors who had concluded that diseased contralateral ear is associated with poor surgical outcome.[6] Caylan observed success rate of surgery in the bilateral diseased group to be 10/18 (55%) and in unilateral group 32/33 (96.9%).[14]

Pure tone audiometry was done in sound treated room with calibrated equipment. Although environmental noise was minimum in our set up, sound proof room would have been ideal. Four frequencies pure tone average was calculated from 500, 1000, 2000 and 3000 Hz. Same frequencies were used by Kazikdas *et al.,*[19] Cabra *et al.*[20] and Brown C *et al.*[6] These four frequencies are the speech frequencies that keep the importance of subjective hearing. Use of only 3 frequencies 500, 1000 and 2000 Hz for measurement is also common.[21]

Conclusion

The graft uptake rates and hearing results after perichondrial - cartilage composite graft are similar to those of temporalis fascia graft. Perichondrial-cartilage composite graft even though more rigid and thicker than temporalis fascia did not affect post-operative hearing results adversely. Therefore, we recommend the use of perichondrial - cartilage composite graft for tympanic membrane reconstruction in high risk perforation.

Conflict of Interest: None

Ethical clearance: Ethical approval was taken from Institutional Review Board of TUTH, IOM.

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