Original Research Article

DOI: http://dx.doi.org/10.18203/issn.2454-5929.ijohns20183455

Comparison of otological and audiological outcome of type-I tympanoplasty using composite tragal perichondrium and temporalis fascia as graft

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Received: 28 July 2018 Revised: 12 August 2018 Accepted: 14 August 2018

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ABSTRACT

Background: The most frequently used technique for the repair of TM perforation is underlay grafting of temporalis fascia in normally ventilated middle ears. In advanced middle ear pathology, large perforations, at electatic drum or retraction pockets, temporalis facia may cause higher failure rates. In such cases, a more rigid grafting material such as cartilage is preferred because of its increased stability and resistance to middle ear pressure even in cases with chronic eustachian tube dysfunction.

Methods: This is a prospective randomized study design on comparison of temporalis fascia and cartilage as graft in patients of CSOM with subtotal perforation. 80 patients, divided randomly into two groups with equal patients, with tragal cartilage (group 1) and temporalis fascia (group 2) as graft. Follow up done at post-operative 3rd week and 3rd month for graft acceptance as well as graft health. Audiometric evaluation was conducted at 3rd month. The data obtained was subjected to appropriate statistical analysis using SPSS version 20.

Results: Graft uptake rate in group1 and 2 was 93.75% and 90%. The mean AB gap improved in group1from 36.38±6.10 dB to 18.13±5.84 dB. Similarly in group 2 it improved from 28.73±5.82 dB to 15.23±8.14 dB; showed statistically highly significance in both groups (p<0.001).

Conclusions: Composite tragal perichondrium graft delivers an excellent audiologic outcome comparable to temporalis fascia graft specially where medialization of graft is expected. It gives ENT surgeons a reliable armamentarium in tympanoplasties for subtotal perforation.

Keywords: Tympanoplasty, Cartilage, Temporalis fascia, Composite tragal perichondrium

INTRODUCTION

According to WHO survey in 2001, hearing loss is a global problem with 275 million of the world's population suffering from moderate or greater degrees of decreased hearing acuity. The disease is more commonly seen in developing countries.

TM perforation is one of the common clinical conditions encountered in ENT practice. Tympanic Membrane plays

a significant role in the physiology of hearing as well as in the pathophysiology of chronic inflammatory middle ear diseases. The TM perforations significantly impair the quality of life in millions of patients.

Various materials are available for closure of TM perforations like skin, perichondrium, vein, temporalis fascia, dura and cartilage. The most frequently used technique for the repair of tympanic membrane perforations is underlay grafting of temporalis fascia due

to the ease of its accessibility at the surgical site and the successful closure of the tympanic membrane in most of the normally ventilated middle ears. However, in situations such as advanced middle ear pathology, large perforations, atelectatic ears or retraction pockets, temporalis facia may cause higher failure rates regardless of the surgical technique used. This is because the post-operative dimensions of the temporal facia are unpredictable as it is composed of irregularly arranged elastic fibres and fibrous connective tissue. In such cases, a more rigid grafting material such as cartilage is preferred because of its increased stability and resistance to middle ear pressure even in cases with chronic eustachian tube dysfunction.

Cartilage contributes minimally to an inflammatory tissue reaction and is well incorporated with tympanic membrane layers. It also provides firm support to prevent retraction. Cartilage graft has very low metabolic rate. It receives its nutrients by diffusion, is easy to work with because it is pliable, and it can resist deformation from pressure variations. Perichondrium and cartilage share with fascia the quality of being mesenchymal tissue, but they are thicker and stiffer. They mechanically reduce the vibratory pattern of the tympanic membrane, contributing to some impairment in functional results, especially in the higher tones. The mass effect of the cartilage over the prosthesis is always a concern. Cartilage has lower compliance than fascia and hence, sudden pressure variations may not be well regulated with a more rigid tympanic membrane.

The mechanical characteristics of cartilage offer the advantage of high resistance to retraction and reperforation. Cartilage has a constant shape, firmer than fascia and also lacks fibrous tissues, so that the post-operative dimensions remain the same and it is also nourished by diffusion and shows great adaptation with tympanic membrane.⁴ Although a significant conductive hearing loss might be anticipated with cartilage owing to its thickness and rigidity, several studies suggest hearing results with cartilage to be no different than those for facia.⁵⁻⁸ It has also been suggested that acoustic benefit may be obtained by thinning the cartilage.

METHODS

It was a prospective randomized clinical study conducted in the department of ENT, Geetanjali Medical College and Hospital, Udaipur, Rajasthan from January 2016 to June 2017. The aim of this study were to assess and compare, graft acceptance rate, the improvement in hearing outcomes and the air-bone gap closure after type-I tympanoplasty using composite tragal perichondrium and temporalis fascia as graft.

Eighty patients with dry subtotal tympanic membrane perforation due to chronic otitis media, in which ossicular chains were intact and mobile were taken up for study.

Inclusion criteria

All the patients diagnosed with dry subtotal tubotympanic perforation (involving 50% or more of tympanic membrane) with intact and mobile ossicular chain,

Exclusion criteria

Exclusion criteria were patients who do not follow up as stated above; patients who are suffering from sensory neural hearing loss; patients with attico-antral type of CSOM; ossicular chain discontinuity; eustachian tube dysfunction; past history of tympanoplasty; comorbidities like malignancy, diabetes mellitus, immunocompromised state due to any cause, etc.

After randomization 80 patients was divided into two groups of 40 patients. A detailed clinical history and examination was recorded on specific proforma designed for the study. All patients were subjected to pre-operative audiometric evaluation i.e. pure tone audiometry (PTA). Impedence Audiogram was done to access status of ossicular chain and Eustachian tube function preoperatively. In all patients a subtotal TM perforation was detected by otoscopy and examination under microscope. Necessary preoperative investigations were performed. Patients were taken for surgery under GA.

A total of 40 patients (Group 1) went under a tympanoplasty using composite tragal perichondrial cartilage while in the other 40 patients (Group 2) temporalis fascia was used as a graft material to close the TM perforation.

Postoperative follow up comprise of otoscopic examination at postoperative 3rd week and 3rd month. Assessment of the graft acceptance as well as graft health was done at both the visits. Audiometric evaluation (Post op PTA) was conducted at 3rd month.

Technique of surgery

Post aural Wilde's incision was made. Posterior tympanomeatal flap was elevated up to the fibrous annulus which was detached from the bony sulcus and positioned anteriorly thus exposing the middle ear. Status of the middle ear structures was then assessed. Adequate size of Temporalis fascia or composite tragal cartilage graft was harvested. Once harvested, the tragal cartilage was sliced to appropriate thickness (around 1 mm) using cartilage slicer. Type 1 tympanolasty via underlay technique was done using Temporalis fascia or composite tragal cartilage of adequate thickness after making crisscross incision to release the springicity. Gel foams were kept in middle ear. Flap was then repositioned back and canal was filled with gel foam. Closure was done in two layers (subcutaneous and skin). Mastoid dressing was given for 2 days followed by simple dressing for 5 days. Suture removal was done at 7 post-operative day. Patients were given antibiotic cover for 3 weeks.

Follow up was done at 3 weeks, 6 weeks and 3 months. At each follow up the complaints of the patients were noted. Microscopic examination was done to see the condition of the canal and graft. Pure tone audiometry was done at 3 follow-up.

The data obtained was subjected to appropriate statistical analysis using SPSS version 20. The following tests were applied suitably, such as, Chi square test, Paired and unpaired t-test and Analysis of Variance (ANOVA).

RESULTS

This is a prospective randomized study design on comparison of graft used in tympanoplasty, using temporalis fascia and cartilage as graft in patients of chronic otitis media with tympanic membrane perforation.

Maximum number of patients 25 (31.25%) were between 31-40 years. The mean age of patient was 30.25 yrs. (Table 1).

Table 1: Age distribution of patients.

Age (years)	No. of patients	Percentage (%)
≤20	21	26.25
21-30	20	25.00
31–40	25	31.25
41–50	12	15.00
≥51	02	02.50
Total	80	100

Table 2: Sex distribution of patients.

Sex	No. of patients	Percentage (%)
Male	53	66.25
Female	27	33.75

There were 27 (33.75%) females and 53 (66.25%) males and female to male ratio 1:1.96 showing females were almost double the number of males (Table 2).

Commonest complaint in our study was ear discharge (100%), followed by hearing impairment in 76 (95%), tinnitus 5 (6.25%) and ear ache 3 (3.75%). None had vertigo (Table 3).

Table 3: Presenting complaints of patients (n=80).

Presenting complaint	No. of patients	Percentage (%)
Ear discharge	80	100
Hearing impairment	76	95
Tinnitus	05	6.25
Ear ache	03	3.75
Vertigo	00	00

There were very low postoperative complications with only 6 (8%) had ear ache, 5 (6%) complained of pus discharge, 2 (2.5%) had vertigo (Table 4).

Table 4: Postoperative complications.

Postoperative complications	No. of Patients	Percentage (%)
Ear ache	6	8
Pus discharge	5	6
Vertigo	2	2.5
Others	0	0

Table 5: Graft uptake at 3 months of follow up.

Status of graft	Group 1 (%)	Group 2 (%)	Total (%)
Accepted	39 (97.50)	36 (90)	75 (93.75)
Rejected	1 (2.50)	4 (10)	5 (6.25)
Total	40 (100)	40 (100)	80 (100)

The successful graft uptake was seen in 75 patients (93.75%) at the end of third post-operative month, while in 5 patients (6.25%) had graft rejection (Table 5).

Table 6: Postoperative hearing improvement.

Hearing	Grou	ıр 1	Grou	ıp 2
improvement (pre– post op)	No.	%	No.	%
1–10 dB	4	10.26	9	25.00
11-20 dB	20	51.28	19	52.78
21-30 dB	13	33.33	7	19.44
≥31 dB	2	5.13	1	2.78
Total	39	97.50	36	90

In group 1, at the end of third post-operative month, when improvement in hearing in terms of AB gap was observed it shows that 4 (10.26%) patients had improvement from 1 to 10 dB, 20 (51.28%) patients had 11 to 20 dB improvement, 13 (33.33%) patients had 21 to 30 dB improvement and 2 (5.13%) patients had >30 dB improvement while 1 patient with unsuccessful graft take up had no improvement in hearing. In the group 2, 9 (25%) patients presented with 1 to 10 dB improvement, 19 (52.78%) patients presented with 11 to 20 dB improvement, 7(19.44%) patients presented with 21 to 30 dB improvement and 1(2.78%) patients presented with >30 dB improvement while 4 patients with failure to graft uptake showed no change in their audiogram (Table 6).

Preoperative PTA was done for all the patients. In group 1, 29 patients presented with AB gap between 26-40 dB, 10 patients with >40 dB and 1 patient with 16-25 dB. In group 2, 24 patients presented with AB gap between 26-40 dB, 15 patients with 16-25 dB and 1 patient with >40 dB preoperatively. Again AB gap was observed postoperatively and was reduced. In group 1, 24 patients

had AB gap between 16-25 dB, 12 patients had < 15 dB and only 4 had AB gap between 26-40 dB. While in group 2, 22 patients had <15 dB, 14 patients had AB gap between 16-25 dB, 3 had between 26-40 dB and 1 had AB gap >40 dB (Table 7).

Table 7: Pre and postoperative air bone gap.

	Preoperative air bone gap		Postoper bone gap	
Air bone gap (dB)	Group 1	Group 2	Group 1	Group 2
≤15	-	-	12	12
16–25	1	15	24	14
26-40	29	24	4	3
>41	10	1	0	1
Total	40	40	40	40

Table 8: Comparison of pre and post-operative hearing results.

Hearing result (AB gap)		Postoperative (Mean±SD)	P value
Group 1	36.38±6.10	18.13±5.84	<0.001 (HS)
Group 2	28.73±5.82	15.23±8.14	<0.001 (HS)

The mean AB gap measured preoperatively in group 1was 36.38±6.10 which improved to 18.13±5.84 dB post operatively. Similarly group 2 also showed improvement from 28.73±5.82 to 15.23±8.14 dB postoperatively. Results were statistically highly significant which showed both techniques are equally effective (Table 8).

Maximum acceptance of 100% patients was in 41-50 years and >50 years of age group (Table 9).

Table 9: Graft uptake rate with age of the patient.

Age group	No.	Percentage (%)
≤20	18/21	85.71
21–30	19/20	95.00
31–40	24/25	96.00
41–50	12/12	100
≥51	2/2	100
Total	75/80	93.75

Table 10: Graft uptake rate with sex of the patient.

Sex	No.	Percentage (%)
Male	51/53	96.23
Female	24/27	88.89
Total	75/80	93.75

Females had better acceptance rate (96.23%) than males (88.89%) (Table 10).

DISCUSSION

Tympanoplasty not only gives the patient a dry ear but also improves hearing. Lot of graft materials have been used by various surgeons for covering the perforation in the ear drum. The most commonly used graft material is temporalis fascia.

Cartilage is a reliable graft for TM reconstruction as it is nourished by diffusion and becomes well incorporated in the TM. The advantage of the cartilage over temporalis fascia cannot be overlooked as its toughness prevents the retraction of the neotympanic membrane. Two main reasons why many otologists prefer fascia rather than cartilage are the easier technique of fascia harvesting and the postoperative hearing improvement.

Cartilage tympanoplasty is said to prevent retraction pockets in the TM because of its firm support. There is some resistance to infection with cartilage during the healing period. Thus, the risk of recurrent perforation is reduced. In cases of severe Eustachian tube dysfunction, cartilage maintains its integrity and resists resorption as well as retraction. Cartilage graft has been thought to have a very low metabolic rate, a factor helpful in maintaining intactness of the graft. Cartilage receives its blood supply by diffusion from the surface with help of the perichondrium. Failure rate of cartilage graft was 2.50% due to infection and inadequate postoperative antibiotic therapy in comparison to temporalis fascia group in which failure rate was 10% due to mediallization of graft and infection. Large tympanic membrane perforations are relatively more difficult to treat because of less tympanic membrane margin to support the graft to survive and less tension to resist the tympanic retraction, decreased blood supply of graft and Eustachian tube dysfunction postoperatively.

Jansen and Salen reported the use of cartilage-perichondrial composite graft for tympanic membrane reconstruction. ^{9,10} It has also been described for the management of retraction pockets and more recently for the reconstruction of the tympanic membrane in cases of recurrent perforation with encouraging results. ^{2,5,11}

Desarda et al conducted study of 600 ear operations of varied middle ear pathology. The technical advantage of tragal perichondrium graft in myringoplasty, ossiculoplasty and mastoid cavity obliteration were discussed and concluded that tragal perichondrium and cartilage is an ideal graft material for reconstructive tympanoplasty.¹²

Kazikdas et al compared the graft take rates and hearing results of primary type 1 cartilage tympanoplasty operations with palisade technique with those of primary tympanoplasty using temporalis fascia in a homogenous group of patients. Mean speech reception threshold, airbone gap and pure-tone average scores comparing the

gain between both techniques showed no significant changes in the threshold (p>0.05). 13

Khan et al concluded that cartilage was a promising graft material to close TM perforations. Acoustic benefit may be obtained by thinning the cartilage. They described preparation of the graft by slicing it and presented 3 years' experience of shield cartilage type tympanoplasty using sliced tragal cartilage perichondrium composite graft. ¹⁴

Mohamad et al concluded that Tympanoplasty using cartilage with or without perichondrium has better morphological outcome than tympanoplasty using temporalis fascia. However, there was no statistically significant difference in hearing outcomes between the two grafts. ¹⁵

Shreeya et al conducted a study on cartilage support for fascia graft in type I tympanoplasty. This technique is working well and can be considered as good alternative method in tympanoplasty for large or subtotal central perforations. ¹⁶

In the present study maximum number of patients 25 (31.25%) were between 31-40 years, Range was 9 to 65 years. The mean age of patient was 30.25 yrs, which was quiet similar to the study of Verma et al. ¹⁷ In a study by Shishegar et al, patients age range was 10-50 years with mean age of 30 years. ¹⁸ In a study by Kyrodimos et al, the mean age was 32.4 years (range 7 to 72 years). ¹⁹

In the present study there were 27 (33.75%) females and 53 (66.25%) males and female to male ratio was 1: 1.96 showing more active females participation and is seen in other studies also. 16,17,20

All patients in our study (100%) had ear discharge followed by hearing impairment in 76 (95%), tinnitus 5 (6.25%) and ear ache 3 (3.75%). None had vertigo. This finding is similar to those of Sirena et al and Singh et al in which the chief presenting symptom of the patient was otorrhea found in all of the cases. ^{21,22}

There were very low postoperative complications with only 6 (8%) complained about ear ache, 5 (6%) complained of pus discharge and 2 (2.5%) had vertigo. Immediate surgical complications reported in literature include wound infection, haematoma formation and facial nerve injury. Sikander et al reported vomiting in 10% and vertigo in 6% cases post operatively.²² Gamra et al reported single case of postoperative local infection out of 23 cases.⁸

In group 1 there was 97.50% graft uptake and in group 2 it was 90%. Successful graft uptake was seen in 75 patients (93.75%), while in 5 patients (6.25%) had graft rejection. Verma et al reported that in 27 (90%) patients the TM graft was intact and 3 (10%) patients had residual perforations. ¹⁷ In group 1, after 3 months follow up, 29 (96.67%) patients had intact TM and residual perforation

was seen in one (3.33%) patient. These reports compare well with similar study conducted by Dabholkar whose postoperative graft uptake rate with temporalis fascia was 84% and tragal perichondrium showed 80%. ²³ Parida found 80% uptake rate with temporalis fascia. ²⁴

Quraishi et al reported success rate of 94% in primary myringoplasty with tragal perichondrium. Most of graft failures were due to infection probably transmitted either along Eustachian tube or along external auditory canal. ¹⁵ Cavaliere et al reported graft uptake was achieved using tragal cartilage in 99.35% patients and there were no immediate post-operative complications. ²⁵

Improvement in hearing in terms of AB gap was tabulated in Table 6. Our study compares well with Chhapola et al whose postoperative hearing assessed after 6 months of surgery, with temporalis fascia graft showed air bone gap of less than 10 dB in 82% of patients and more than 10 dB in 18% patients, air bone gap closure with tragal perichondrium was less than 10 dB in 78% patients and more than 10 dB in 22% of patients.²⁶

In a study by Kumar, 77.5% of cases showed improvement in hearing, while 22.5% of them showed no improvement. About 80% cases operated with temporalis fascia showed hearing improvement, while similar percentage (75%) of cases who were operated using tragal perichondrium showed improvement in hearing (p> 0.05). Similar results were achieved by Dabholkar et al. 23

In group 1, the mean AB gap measured preoperatively was 36.38±6.10 which improved to 18.13±5.84 dB post operatively. Similarly it also improved from 28.73±5.82 to 15.23±8.14 dB postoperatively in group. Both were statistically highly significant which showed both techniques are equally effective.

In study by Ozbek et al postoperative air-bone was 10.33±1.87 dB in cartilage and 11.25±9.5 dB in fascia group. No significant difference in hearing was observed.²⁷

Gamra et al showed successful closure of the tympanic membrane perforation was achieved in 97% of the cartilage group as compared 94% of the facia group. The average gain was 21±11 dB in cartilage group and 20±22 dB in fascia group. With an average follow–up of 2 years, residual perforation was observed in 2.2% in cartilage group. Re–perforation of fascia graft and retraction were noted in 2.1 and 1% respectively. Results were comparable with our study.⁸

Above discussion proves that cartilage tympanoplasty provides excellent audiologic outcome comparable to temporalis fascia graft. The grafts whose material properties (mass, stiffness, damping) differ significantly from the properties of TM can alter the impedance of the TM and contribute to acoustic transmission losses. A

thick cartilage disk has excellent stability but will reflect most of the incoming sound.

Though the choice of graft material is dependent on the surgeon's skill and experience, cartilage tympanoplasty gives ENT surgeons a reliable armamentarium in tympanoplasties. Despite its rigid nature, cartilage tympanoplasty delivers an excellent audiologic outcome comparable to temporalis fascia graft specially where medialization of graft is expected.

Funding: No funding sources

Conflict of interest: None declared

Ethical approval: The study was approved by the

Institutional Ethics Committee

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Cite this article as: Sharma N, Sharma P, Sharma P, Gourav K, Goyal VP. Comparison of otological and audiological outcome of type-I tympanoplasty using composite tragal perichondrium and temporalis fascia as graft. Int J Otorhinolaryngol Head Neck Surg 2018;4:1182-7.