ORIGINAL ARTICLE

Comparison of half-thickness tragal cartilage graft to temporalis fascia graft Tympanoplasty Type I: A randomized control trial

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Abstract

Objective: To compare half-thickness tragal cartilage graft with temporalis fascia graft in terms of graft take-up and acoustic outcomes in type-I tympanoplasty.

Methods: The randomised control trial was conducted at Lady Reading Hospital, Peshawar, Pakistan, from January to December 2017, and comprised patients aged 16-60 years undergoing tympanoplasty. The patients were divided into two equal groups using systemic random sampling method. In Group A, tympanoplasty type-I was done using half-thickness tragal cartilage graft, while in Group B, it was done using temporalis fascia graft. Data was analysed using SPSS20.

Results: Of the 40 patients, there were 20(50%) in each of the two groups. Overall, there were 24(50%) males and 16(40%) females. The mean age of Group A was 28.57±8.00 years, and in Group B it was 27.14±6.18 years. The graft success rate in Group A was 19(95%) and in Group B it was 18(90%) (p>0.05).

Conclusion: The graft success rates for half-thickness tragal cartilage and temporalis fascia were statistically non-significant.

Keywords: Cartilage, Graft, Fascia, Tympanoplasty, Hearing loss. (JPMA 70: 602; 2020) **https://doi.org/10.5455/JPMA.16032**

Introduction

Tympanic membrane (TM) forms the lateral wall of the middle ear cleft which separates the middle ear from the external auditory canal. It is made of three layers except in the upper part called Pars Flaccida. The outerlayer of TM is made up of epithelium, the middle layer is fibrous tissue, and the inner layer is mucosal lining. The thickness of TM measures 0.1mm, having a diameter of 7-10mm, weighing approximately 14mg.[1] The function of TM is to assist in hearing and in the protection of the middle ear from infection. Perforation in TM means loss in the continuity of TM layers. The causes of TM perforation may be trauma, like blast, accident and firearm, or infection of the middle ear, like acute or chronic suppurative otitis media. It can also be iatrogenic, as in case of placement of grommet for glue ear.[2] The purpose of tympanoplasty is to reconstruct TM perforation and to restore the sound conducting mechanism.[3] In 1955, Zoellner and Wullstein used different types of graft materials for tympanoplasty. Later, Heermann introduced cartilage palisade graft labelled as Simmering Technique. Goodhill introduced the first cartilage perichondrium composite graft material. Different graft materials can be used to close the TM defect. Some of these materials are temporalis fascia, tragal cartilage, perichondrium and fat.[4] Temporalis fascia and tragal perichondrium had more anatomic proximity, compliance and translucency. The mode of action of these biological graft materials is the provision of support for the membrane remnant to proliferate and to heal the defect. Temporalis fascia is thin, translucent and available in sufficient amount, but due to its close resemblance with tympanomeatal flap in colour it may be displaced unintentionally during handling. However, the reported success rate of temporalis fascia graft in literature varies from 93% to 97%.[2]

On the other hand, cartilage is middle ear-friendly and survives for comparatively longer due to the fact that its nourishment is based on diffusion process. Due to the rigid nature of cartilage, it prevents medialisation of the graft to promontory in case of severe eustachian tube dysfunction.[1] Cartilage graft is used in cases of chronically malfunctioning eustachian tube, adhesive otitis media, recurrent perforation and large TM perforation. But its demerits include its thickness which hinders sound conduction and its limited size. The success rate of the cartilage graft tympanoplasty varies in literature from 43%to100%.[5]

Chronic suppurative otitis media (CSOM) is an endemic health problem in our society. The reasons could be probably low literacy level, communities situated in far flung areas away from health facilities, lack of specialist

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services to the public in outreach area, and inappropriate treatment of the middle ear infections. A large number of patients suffering from inactive mucosal chronic otitis media (COM) with decreased hearing present to otolaryngology units. Tympanoplasty is the surgery of choice for chronic otitis media inactive mucosal type.[2]

The current study was planned to compare the graft success rate of cartilage graft versus temporalis fascia in tympanoplasty type-I at our institution. The hypothesis was that cartilage graft tympanoplasty was more successful than temporalis fascia tympanoplasty.

Patients and Methods

The randomised control trial (RCT) was conducted at the Department of Ear, Nose and Throat (ENT), Head and Neck Surgery, Medical Teaching Institute (MTI), Lady Reading Hospital (LRT), Peshawar, Pakistan, from January to December 2017, and comprised patients undergoing tympanoplasty.

After obtaining approval from the institutional ethics board, the sample size was calculated using OpenEpi software while keeping exposure at 43%.[6] Those included were patients of either gender aged 16-60 years with inactive mucosal COM having remained dry for at least one month, and conductive hearing loss with minimum air-bone gap (ABG) of 10 decibell (dB), with the middle ear being free of disease.

Those excluded were patients with attic and/or posterior retraction pocket along with cholesteatoma; ossicular chain dysfunction and associated otogenic complication; and active mucosal COM.

The sample was raised using convenience non-probability sampling technique. After getting written informed consent from all the patients, they were divided into two equal groups using systemic random sampling method. In Group A, tympanoplasty type-I was done using half-thickness tragal cartilage graft, while in Group B, it was done using temporalis fascia graft.This trial has been registered with Clinical Trial.gov on January 25, 2019 bearing its registration No. ClinicalTrials.gov identifier (NCT number): NCT03817242 (https://clinicaltrials.gov/ ct2/show/NCT03817242). Assessment of all the patients was carried out comprising detailed history, thorough examination focussing on ENT findings, relevant investigations, surgery and follow-up. Ear was evaluated for side, size, site, margins of perforation, ear drum remnants, middle ear mucosal status and aural discharge. Any septic focus in the rest of ENT zone was addressed before surgery. Pre-operative pure tone audiometry (PTA) and tympanometry was carried out by the same senior audiometrician using standard two channel clinical audiometer (Amplaid 455; Italy). PTA was performed on frequencies 500 to 8000Hz. Hearing loss was calculated considering selected frequencies of 0.5, 1, 2, and 4kHz. All patients were subjected to tympanoplasty type-I under general anaesthesia, using a surgical microscope (Takagi OM-5-, Japan). Local anaesthesia was injected in a concentration of 2% lidocaine with 1:100,000 adrenaline at anterior, posterior, inferior and superior quadrants of the external auditory canal. In most cases end-aural approach was adopted. After deepening the end-aural incision to the bone, self-retaining ear retractor was applied. Margins of the TM perforation were freshened. Tympanomeatal flap was elevated approximately 6mm away from the tympanic annulus between 7 and 1 O'clock level. After examining the middle ear cleft, few pieces of gelfoam were placed to create bed for graft. The graft was placed and the tympanomeatal flap was brought back to its position. The ear canal was packed with an antibiotic-soaked pack. Incision was closed and aseptic aural dressing was applied.

In case of cartilage tympanoplasty in Group A, tragal cartilage was obtained. A small incision was given on medial aspect of tragus sparing 2mm of cartilage at the top to maintain the contour of tragus. The incision of tragus was closed with prolene 3/0. Then perichondrium was removed from one side of the cartilage, while holding in proper position the cartilage was thinned out with the help of size 15 surgical blade. Then the half-thickness cartilage graft was finalised according to the perforation size.

In case of Temporalis fascia tympanoplasty in Group B, the end-aural incision was extended superiorly. After dissection, temporalis fascia was visualised and then normal saline was injected into fascia such that bleb was formed by elevation of the fascia from underlying muscles. Then the required amount of fascia was excised and spread over a glass slide. Fascia graft was placed over a bed formed by gelfoam pieces. Tympanomeatal flap was repositioned. Canal was packed with antibiotic-soaked pack. Wound was closed with prolene 3/0 and aseptic dressing was performed.

Post-operatively, all patients were given injectable antibiotics, oral analgesics and oral antistamines. Mastoid dressing was removed after 24 hours while skin stitch and aural pack were removed on the 10th post-operative day. Patients were instructed to avoid exertion and do sneezing with open mouth if it occurs.

All the patients were assessed at 1st, 3rd and 6th month follow-up. On follow-up visits, autoscopy and PTA were performed. ABG closure on PTA was checked during the follow-up and was taken as an indication of hearing improvement. PTA and otoscopic examination of TM were done pre-operatively and post-operatively to look for the graft take-up. Subjective hearing improvement of the individuals was assessed post-operatively by PTA and whisper test. All these findings were recorded on a predesigned proforma.

Data were analyzed using SPSS 20. Mean ± standard deviation (SD), and frequencies and percentages were calculated for quantitative and qualitative data respectively. Independent samples t test was used keeping confidence interval (CI) at 95%. P<0.05 was considered significant.

Results

Of the 40 patients, there were 20(50%) in each of the two groups. Overall, there were 24(50%) males and 16(40%) females in an age range of 16-41 years. The mean age of Group A was 28.57±8.00 years, and in Group B it was 27.14±6.18 years. TM perforation was on the right side in 11(27.5%) in Group A and 13(32.5) in Group B (Table-1).

Pre-operative and post-operative air conduction and ABG values were not significantly different in the two groups (p>0.05) (Table-2). The graft success rate for Group A was 19(95%) and in Group b was 18(90%). No statistically significant difference was observed between the groups in terms of correlation between age and ABG closure (p>0.05).

Table-1: Demographic Data and characteristics.

Demographic Data	Group A (Half Thickness Cartilage Graft)	Group B (Temporalis Fascia Graft)
Age Groups (years)		
Mean ± SD	28.57± 8.00	27.14±6.18
< 20	5(12.5)	3(7.5)
21-30	11(27.5)	6(15)
31-40	3(7.5)	11(27.5)
>41	1(2.5)	Nil
Gender	**n (%)**	**n(%)**
Male	13(32.5)	11(27.5)
Female	7(17.5)	9(22.5)
Side of Ear	**n (%)**	**n(%)**
Right Side	11(27.5)	13(32.5)
Left Side	8(20)	5(12.5)
Both Side	1(2.5)	2(2.5)
Site of Perforation	**n (%)**	**n(%)**
Anterio-superior	5(12.5)	3(7.5)
Anterio-inferior	7(17.5)	16(40)
Posterio-superior	2(2.5)	1(2.5)
Posterio-inferior	6(15)	Nil
Size of perforation	**n (%)**	**n(%)**
Medium	15(37.5)	11(27.5)
Large	3(7.5)	8(20)
Total perforation	2(5)	1(2.5)

SD: Standard deviation.

Table-2: Comparison of pre- and post-operative audiometry findings between the groups (n=40).

Audiometry Finding	Group A (Half Thickness Cartilage Graft) Mean ± SD (dB)	Group B (Temporalis Fascia Graft) Mean ± SD (dB)	P-Value
Pre-Op Air Conduction	49.00±8.52	50.00±12.97	
Post-Op Air Conduction	23.25±14.16	21.00±11.19	p-0.637
Pre-Op Air Bone gap	34.25±10.29	35.00±11.47	
Pos-Op Air Bone Gap	8.50±14.51	7.50±11.41	p-0.702

The difference in outcome between the two groups was statistically non-significant (p>0.05). The overall significant subjective hearing improvement was in 20(67.5%) individuals, while mild subjective hearing improvement was in 7(17.5%). Significant subjective hearing improvement in Group A was 13(65%) and in Group B it was 14(70%) (p>0.05).

Discussion

The patients in the current study were mostly in the second decade of life, which was similar to earlier studies.[7,8] The second decade of life is more active and the patient is more concerned about health, and that explains why tympanoplasty was commonly performed in this age. In the current study the male:female ratio was 1.5:1, which was similar to the reported ratio of 1.3:1, but differed from other studies.[1,9,10] In the current study, TM perforation was more on the right side (27.5%), mainly at the anterio-inferior site (17.5%) and was of medium size (37.5%), and all these elements were in line with earlier studies.[1,11]

There was statistically non-significant reduction in ABG in Group B, while the graft success rates in Group A and Group B were 95% and 90% respectively. The difference was statistically non-significant. These results were consistent with a study which reported a success rate of 85% in full-thickness tragal cartilage group and 70% in temporalis fascia tympanoplasty group, and the difference was statistically non-significant (p>0.05).[11]

In the current study, overall significant subjective hearing improvement was 67.5%, while significant subjective hearing improvement was 65% and 70 % in Group A and Group B respectively, which is a bit low from a study

Table-3: Comparison of air-bone gap (ABG) closure, graft success rate of current study with other studies.

Author of study	Year of Study	Total No. of Patients	CARTILAGE GRAFT				FASCIA GRAFT			
			Pre-Op ABG mean ±SD	Post-OP ABG mean ±SD	P-Value	Success rate	Pre-Op ABG mean ±SD	Post-OP ABG mean ±SD	P-Value	Success rate
Kumar[9]	2017	60	43.24±12.15	27.16±10.54	---	93.33%	44.44±8.66	24.48±6.13	---	86.66%
Yegin[10]	2014	78	35.68±12.94	26.113±12.87	0.001	92.1%	33.68±11.44	24.25±12.68	0.001	65.0%
Kadah[11]	2016	60	26.75±11.39	12.25±7.69	<0.001	85%	23.50±8.90	12.50±7.69	<0.001	70%
Gun[12]	2013	27	25.48±3.69	16±10.22	<0.001	96.7%	22.26±2.86	12.68 +4.81	<0.001	79.2%
Sood[13]	2012	40	14.98±9.915	11.55±8.173	---	(95%	11.41±8.288	10.49±9.069	---	90%
Vadiya[14]	2015	142	32.69±7.0	22.46±7.0	0.0001	98.46%	32.33±7.0	17.66±7.0	0.341	89.61%
Yegin[15]	2014	247	22.43±8.07	14.93±8.69	0.001	91.3%	22.28±8.76	17.60±10.96	0.001	68.9%
Guindi[16]	2015	30	30.15±5.42	20.44 ±5.34	<0.0001	93.33%	30.22±6.49	10.74 ±4.29	<0.0001	93.33%
Ozdamar[17]	2011	60	28.2±9.3	17.3±10.5	0.000	96% i	27.9±9.6	19.1±7.6	0.000	92%
Vijay Kumar[18]	2014	60	26.01 ± 9.17	12.32 ± 8.38	---	---	22.69 ± 12.43	12.36 ± 12.40	---	---
Zeeshan[19]	2015	100	33.3	21.0	0.0001	88.0%	33.4	20.5	<0.001	84.0%
Khan[20]	2011	28	32.46±5.02	9.2131±3.28	<0.05	92.4 %	32.46±5.02	9.6429±2.65	<0.05	84.3 %
Pradhan[21]	2015	60	29.06 ± 7.2	17.40 ±6.4	0.512	96.66%	30.23 ±7.77	14.60 ± 4.6	0.982	80%
Current Study	2017	40	34.25±10.29	8.50±14.51	.012	95	35.00±11.47	7.50±11.41	.702	90

where hearing improvement was 86.5% and 82.9% for fascia and cartilage graft respectively. The difference in subjective hearing improvement between the two groups was non-significant (p>0.05).[8] The mean ABG closure and graft success rates of the current study are comparable to other studies (Table-3).[9-21]

The current study has its limitation in terms of its small sample size. Further studies are needed with larger samples to find more information regarding graft success rate, hearing improvement and complications.

Conclusion

The difference in the air-conduction and reduction in ABG between half-thickness tragal cartilage and temporalis fascia tympanoplasty groups was statistically non-significant. The graft success rate for half-thickness tragal cartilage and temporalis fascia tympanoplasty was also non-significant.

Disclaimer: The study has been registered with clinicaltrial.gov.

Conflict of Interest: None.

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