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TYMPANOPLASTY TYPE I USING TRAGAL CARTILAGE AS GRAFT: OUR EXPERIENCE.

Fazal-I-Wahid[1], Sajid Rashid Nagra[2]

1. MBBS, FCPS,
Assistant Professor
Department of ENT, Head and Neck Surgery
Medical Teaching Institute (MTI),
Lady Reading Hospital (LRH),
Peshawar –Khyber Pakhtunkhwa-Pakistan.
2. MBBS, MCPS, FCPS
Associate Professor
Department of ENT
Rai Medical College Sargodha, Punjab

Correspondence Address:
Dr. Fazal-I-Wahid
C-19, Khushal Medical Center,
Dabgari Garden Peshawer.
drfazal 58@yahoo.com

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ABSTRACT… Objectives: To determine the efficacy of tragal cartilage graft in tympanoplasty type I. **Study Design:** Quasi-experimental study. **Setting:** Department of ENT, Head and Neck Surgery, Medical Teaching Institute (MTI), Lady Reading Hospital (LRH), Peshawar, Pakistan. **Period:** From Jan. 2017 to Dec. 2017 (One Year). **Material & Methods:** A total of forty four patient fulfilling inclusion criteria were included in this study. All the patients were assessed in terms of detail history, thorough examination focusing on ENT findings. Pure Tone Audiometry (PTA) was performed pre-operative and post-operative at 3 and 6 months interval for the frequencies of 0.5, 1, 2,4 Hz. Data were analyzed using SPSS (version 16). Paired sample t-test of significance was used. The confidence interval was set to 95% and P-value <0.05 was considered significant. **Results:** Out of 44 patients males were 24 (54.54%), female 20 (45.45%) with Male: Female ratio of 1.2:1. Mean age of the patients was 28. 47 + SD 7.26 Years. There was statistically significant difference between the pre and post-op air conduction ($p<.001$), and pre-op and post-op air bone gap ($p<.001$).There was subjectively significant hearing improvement in 31 patients (70.5%). Cartilage graft was taken in 43 patients with success rate of 97.7%. **Conclusion:** Tragal cartilage is an effective graft material, which yields good results in terms of graft take up, hearing improvement and minimum complication, postoperative healing and acoustic properties.

Key words: Tragal Cartilage, Graft, Tympanoplasty.

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INTRODUCION

Tympanic membrane(TM) perforation is the defect produced in the ear drum due to trauma or infection, which leads into otorrhea and reduced hearing. Tympanoplasty is the surgical procedure performed to reconstruct the perforated tympanic membrane, deal with middle ear pathology and restore middle ear sound conducting mechanism.[1] Chronic Otitis Media (COM) can be classified into mucosal (active or inactive) and squamous types (active or inactive). Tympanoplasty Type I is performed in case of inactive mucosal COM.[2] The mechanism of biological graft materials is that they act as scaffold of tissue matrix to seal the perforation which subsequently revascularises and migration of fibroblast and epithelium takes place. The commonly used autologous graft materials are vein, fat, fascia lata, temporalis fascia, tragal perichondrium and cartilages.[3] Temporalis facia and tragal perichondrium are most commonly used due to their anatomic proximity, compliance and translucency. To get closure of perforation and restore hearing caused by chronic suppurative otitis media, several trials were carried out since the 1600s. In 1952 Zollner and Wllestein introduced tympanoplasty using various graft materials and prosthesis for closure of TM and as ossicular substitute respectively. Salen from Sweden was probably the first surgeon who used cartilage as graft material for myringoplasty with acceptable good results.[4] He used septal cartilage with intact mucoperichondrium on one side. Thus he obtained 92% success rate of closing the perforation with good hearing result. Later Heermann et al, introduced cartilage palisade graft for tympanoplasty labeled as Simmering Technique.[3] The same time, Goodhill introduced the first cartilage perichondrium composite graft for closing TM perforation. In 1998, Eavey introduced another technique of

using tragal cartilage with intact perichondrium on both side with good results. In the literature reported success rate of temporalis facia is 93 -97%.[5] While cartilage has been proved to be middle ear friendly and survives for long time because it is nourished mainly by diffusion. Thus it maintains its rigid quality resisting resorption and retraction even in case of severe Eustachian Tube malfunction.[4] The use of cartilage has been established in cases of chronically dysfunction eustachian tube, adhesive otitis media, draining ears with large perforation and recurrent perforation of TM. In the literature reported successful take rate and improvement of hearing for cartilage tympanoplasty varies from 43% to 100%.[5]

Such study has never been conducted in our institute before. Moreover this study was aimed to test the effectiveness of tragal cartilage as graft in tympanoplasty type I in terms of graft take rate and postoperative audiometric results.

MATERIALS AND METHODS

This quasi-experimental study was conducted at the department of E.N.T, Head and Neck Surgery, Medical Teaching Institute (MTI), Lady Reading Hospital (LRH), Peshawar, Pakistan from Jan. 2017 to Dec. 2017. Sample size was calculated using G-Power software, considering α as 0.05, β as 0.1 and effect size 8.5, thus sample size was 44. Convenient (Non-probability) sampling technique was adopted. This study was approved from Hospital Ethical Board. A well informed consent was taken from all the patients explaining them the procedure, its benefits, risks and outcomes.

Inclusion Criteria

1. All patients of both genders in the age range 16 – 60 years.
2. Inactive mucosal COM remained dry for at least one month.
3. Conductive hearing loss with minimum Air-Bone Gap (ABG) of 10 dB.
4. Middle ear is free of disease.

Exclusion Criteria

1. Attic and / or posterior retraction pocket with cholesteatoma.
2. Ossicular chain dysfunction and associated otogenic complication.
3. Patients under 16 years or above 60 years.
4. Active mucosal COM.

All the patients were assessed in terms of detail history, thorough examination focusing 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 was addressed before surgery. Pure Tone Audiometry (PTA) was performed pre-operative and post-operative at 3 and 6 months interval. All PTAs were performed by same senior audiometrician using standard two channel clinical audiometer Amplaid 455 made Italy. PTA was performed for the frequencies of 0.5,1,2,4 kHz. Pre- and postoperative thresholds at 0.5, 1, 2, 4 kHz were recorded. The ABG was calculated in both pre- and postoperative PTA. Success of the procedure was characterized in terms of graft take, closure in AB-Gap and subjective hearing improvement. Tragal cartilage with intact mucoperichondrium on one side was used as graft material for tympanoplasty. All patients were followed up for at least 6 months and any complication encountered was recorded. The data were recorded on predesigned proforma.

Data were analyzed using SPSS (version 16). Quantitative data were expressed as mean ± standard deviation (SD). Qualitative data were expressed as frequency and percentage. Paired sample t-test of significance was used when comparing between related samples. The confidence interval was set to 95% and the margin of error accepted was set to 5%. So, the p-value was considered significant as the following: P-value <0.05 was considered significant. P-value <0.001 was considered as highly significant. P-value >0.05 was considered insignificant.

All tympanoplasties were performed by the author following well-established principles of ear surgery. Proper position of the patient was obtained after general anesthesia. Aseptic cleaning and draping carried out. The tragus was infiltrated with 2% lidocaine with 1:100,000

epinephrine. An incision through the skin and cartilage was made on the medial side of the tragus, leaving at least 2 mm of cartilage in the dome of tragus to maintain its contour for cosmesis. The tragal cartilage with its perichondrium was harvested. Tragal cartilage is ideal one as it is thin, flat, easily and sufficiently available. The tragal cartilage was thinned out to 0.5 mm thickness using No.15 surgical blade. Perichondrium is left intact on side of the cartilage. A V-shaped notch is excised from the cartilage to accommodate the handle of malleus. End-aural approach to the middle ear with inlay technique of graft placement was adopted. After denuding the remnants of margins of perforation tympanomeatal flap was elevated starting 6 mm lateral to the margin from 3 to 9 O'clock position. The middle ear was meticulously examined and any pathological material was addressed. The cartilage graft was placed on a bed formed by putting few pieces of Gelfoam to avoid medialization of graft. The cartilage graft was placed in the plane medial to the remnant of TM. No space is left between posterior canal wall and the reconstructed TM. Tympanomeatal flap was repositioned. Gelfoam pieces were placed to stabilize the graft. Routine postsurgical care was exercised and antibiotic + steroid containing drops were prescribed in case of any suspicion of infection. All patients were called for follow –up visits on 1st, 3rd and 6th months' interval. During follow up visit PTA, Otoscopic examination of TM and subjective hearing improvement were recorded.

RESULTS

Total 44 patients were enrolled in this study; Male 24(54.54%), Female 20(45.45%) with Male: Female ratio of 1.2:1. Mean age of the patients was 28. 47 + SD 7.26 (Min. 16, Max. 40) years. Patients in 3rd decade of life dominated (36%) followed by 1st and 2nd decade. Tympanic membrane perforation was more common on right side involving 25 patients (56.8%), anterio-inferior site was involved in 26 patients (59.1%) with predominantly medium sized perforation found in 28 patients (63.6%) (Table-I). The mean and Standard deviation of PTA finding was calculated and there was no difference between mean and SD of Pre-op and post-op Bone Conduction on PTA i.e. there was no effect of cartilage tympanoplasty on bone conduction of sound transmission. The pre-op mean air-conduction 49.65 + 11.53 dB was reduced to post-op mean air-conduction of 22.27 + 12.22 dB. There was statistically significant difference between the pre and post-op air conduction ($p<.001$). The pre-op mean air bone gap (PTA- ABG) was 34.31 + 10. 95 dB, which was also reduced to post-op mean air bone gap (PTA- ABG) of 7.34 + 5.82 dB. By applying Paired Samples Test there was statistically significant difference between pre-op and post-op air bone gap ($P<.001$) (Table-II). Thus cartilage graft tympanoplasty produced good results in term of closure of air-bone gap. There was subjectively significant hearing improvement in 31 patients (70.5%), while mild hearing improvement was observed in 9 cases (20.5%). Cartilage graft was taken in 43 cases (97.7%), while graft failure was noticed in one case (2.3%). Graft infection was observed in 3 cases (6.8%) that responded to antibiotics.

Side of Ear		
Side of Ear	**Frequency**	**Percent**
Right Side	25	56.8
Left Side	16	36.4
Both side	3	6.8
Total	44	100.0
Site of Perforation		
Site of Perforation		
Anterio-superior	8	18.2
Anterio-inferior	26	59.1
Posterio-superior	3	6.8
Posterio-inferior	7	15.9
Total	44	100.0
Size of Perforation		
Size of Perforation		
Small	1	2.3
Medium	28	63.6
Large	11	25.0
Total perforation	4	9.1
Total	44	100.0

Table-I. Characteristics of tympanic membrane perforation (n- 44).

	Pre-Op (Mean+ SD)	Post-Op (Mean+ SD)	P-Value
Air Conduction on PTA	49.65+11.53	22.27+12.22	<.001
Air-Bone Gap(ABG) on PTA	34.31+10.97	7.34+5.82	<.001

Table-II. Mean + SD of Pre-Operative and Post-Operative Air Conduction and Air- Bone Gap on PTA and P- Value.

DISCUSSION

In this study 44 patients were enrolled; Male 24 (54.54%), Female 20 (45.45%) with Male: Female ratio of 1.2:1, that is in accordance with study of Myla, who also carried out tympanoplasty on 60 patients; male 25 and female 22 with male: female ratio of 1.1: 1.[6]

Similarly Khan studied total 80 patients, of which male 54%, female 46% with male: female ratio of 1.1: 1.[7] However this male: female ratio differs from others studies where female dominate.[8,9] The patients include in this study had mean age of 28. 47 + SD 7.26 (> 16 < 40) years and patients in 3rd decade of life dominated (n-16, 36%). This simulates to study of Shanmugam, who reported mean age of patient was 28.6 years with majority of patients belonged to 3rd decade of life.[10] Similarly Ocak from turkey also found that mean age of patient was 31.1 years.[6]

I observed that tympanic membrane perforation was more common on right side (56.8%), at anterio-inferior site (59.1%) with predominantly medium sized perforation (63.6%). This is in agreement with Khan's study, where majority of patient had TM perforation on right side (61.25%), followed by left side (38.75%) and medium size perforation was most common (42.5%).[7]

Similarly Myla noted that majority of patient had TM perforation in anterior quadrant (38.7%), followed by posterior quadrant of TM (8.3%).[6] Yegin from Brazil also carried out study on cartilage tympanoplasty in 2016 and found that right ear was commonly involved (n-17, 44.7%) and medium sized perforation was common one (n-18, 47.4%).[11]

The success of tympanoplasty was determined by closure of air-bone gap (ABG) on post-operative PTA, healing of the membrane perforation with tragal cartilage graft and subjective improvement of the patient's hearing. The mean and Standard deviation of PTA finding was calculated and there was no difference between mean and SD of pre-op and post-op Bone Conduction on PTA i.e. there was no effect of cartilage tympanoplasty on bone conduction of sound transmission. Similarly Dabhekar, Kadah and Guind also calculated mean + SD of the PTA finding to get results of their studies.[9,12,13]

In this study the mean pre-operative Air-bone Gap (ABG) and mean post-operative ABG on PTA was calculated and there was statistically significant closure in air-bone gap which is comparable to other studies. In current study there was subjectively significant hearing improvement in 31 patients (70.5%), while mild hearing improvement was observed in 9 cases (20.5%). Similarly in Myla's study there was significant hearing improvement in 65% patients and mild hearing improvement in 20% patients.[6] Sood from India also reported that subjective hearing improvement was occurred in thirty five out of 40 patients (87.5%).[4]

In Kumar's study hearing improvement accounted 50%.[14] Graft infection was observed in 3 cases (6.8%) that responded to antibiotics and no other serious complication was recorded in this study which comparable to study of Shrikrishna, who also encountered infection of graft in one case (3.33%).[5] Cartilage graft was taken in 43 cases (97.7%) in this study, which is comparable to other studies as listed in table below (Table-III).[1-3,7,10-18]

CONCLUSION

Tragal cartilage is an effective graft material, which yields acceptable results in terms of graft take up rate and hearing improvement, because tragal cartilage gives greater stability to remnants of tympanic membrane perforation and resistant to negative middle ear pressure.

Author of Study	No. of Patients	Year of Study	Pre-Op ABG mean +/-SD	Post-OP ABG mean+/- SD	Graft	P-Value	Success Rate
Hosam [1]	25	2016	22.4+/-6.14	14.8+/-10.2	Butterfly cartilage	<0.001	7 6%.
Chouhan[2]	100	2013	26.4+/- 10	18+/- 9	Tragal Cartilage	<0.00003	90%
Ozdamar[3]	40	2011	28.2+/-9.3	17.3+/-10.5	Tragal Cartilage	<0.000	96%
Khan[7]	80	2015	32.464+/-5.0220	9.2131+/-3.2823	Sliced Tragal Cartilage	<0.008	100 %
Shanmugam [10]	25	2017	37.00 +/-4.33013	25.80+/-6.23832	Tragal cartilage	<0.001	92%
Yegîn [11]	247	2014	22.43+/-8.07	14.93+/-8.69	Full-thickness cartilage	<0.001	91.3%
Kadah [12]	60	2017	26.75+/-11.39	12.25+/-7.69	Full ThicknessTragal Cartilage	<0.001	85%
Guind[13]	30	2015	30.15±5.42	20.44 ±5.34	Full Thickness Cartilage		(93.33%
Kumar [14]	60	2017	43.24+/-12.15	31.8+/-10.55	Tragal cartilage perichondrium	<0.0001	93%
Gun [15]	27	2013	25.48+/-3.69	16 +/- 10.22	Cartilage Palisades	<0.001	96.7%.
Siddique [16]	35	2015	39.00+/-7.526	30.94+/-11.308	Tragal cartilage	<.000	97.6%
Kaya [17]	93	2014	22.1+/-7.1	13.3+/-5.9	Butterfly Cartilage	<0.05	94.6%
Yegin [18]	78	2014	35.68 +/-12.94	26.113+/-12.87	Full-thickness cartilage	<0.001	92.1%
Current Study	44	2017	34.3182+/-10.975	7.340+/-5.826	Tragal Cartilage	<.001	97.7%

Table-III. Comparison of success rate of cartilage graft of our study with other studies.

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AUTHORSHIP AND CONTRIBUTION DECLARATION

Sr. #	Author(s) Full Name	Contribution to the paper	Author(s) Signature
1	Fazal-I-Wahid	Conceived, designed and prepared the manuscript.	
2	Sajid Rashid Nagra	Did statistical analysis and critically reviewed manuscript.