COMPARATIVE STUDY OF TYMPANOPLASTY WITH CONVENTIONAL TEMPORALIS FASCIA GRAFT VERSUS TRAGAL CARTILAGE PERICHONDRIUM GRAFT

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ABSTRACT

The study was carried out on 50 patients with central perforation in tympanic membrane (dry & inactive stage). The study was done in the department of OTORHINOLARYNGOLOGY of BURDWAN MEDICAL COLLEGE AND HOSPITAL over a period of one year. The study was done on comparison between tympanoplasty procedure using temporalis fascia as graft versus cartilage composite graft. Precise history was taken from respective patients in detail and were examined clinically. Patients with dry perforation with good cochlear reserve, intact and mobile ossicular chain, functioning Eustachian tube were selected randomly for the operation. Tympanoplasty procedure using temporalis fascia as graft was done in 50% (n=25) patients and tympanoplasty procedure using cartilage composite graft was done in 50% (n=25) patients. In this study the age range of patients were from 13 to 50 years, the mean age was 26.62 years, the number of male and female was equal. Right sided disease was predominant in our study and the mean duration of symptom was 11.24 months. The mean pre-operative hearing loss (pure tone average by pure tone audiometry) was 37.84 ± 4.65 dB and mean pre operative airborne gap was 22.84 ± 4.65 dB. Post operative Mean air conduction was 23.48 ± 5.54 dB among them 24.2 ± 6.26 dB in the fascial group and 22.76 ± 4.73 dB in the cartilage group. This result is not statistically significant. Post operative mean air-bone gap was 13.84 ± 5.94 dB among them 14.76 ± 5.6 dB in fascial group and 12.92 ± 6.23 dB in the cartilage group which is not significant statistically. Successful graft take-up rate of 88.00% (n=44). The overall success rate among tympanoplasty using temporalis fascia graft (GROUP A) and tympanoplasty using composite cartilage graft (GROUP B) technique were 84.00% (n=21) and 92.00% (n=23) respectively. 12.00% (n=6) patients were marked as failure cases during postoperative follow up period. The overall failure rate among tympanoplasty using temporalis fascia graft (GROUP A) and tympanoplasty using composite cartilage graft (GROUP B) technique were 16.00% (n=4) and 8.00% (n=2) respectively. So the distribution of surgical outcome in terms of success rate or failure rate was statistically insignificant in the two study groups (p= 0.384). So the distribution of surgical outcome in terms of success rate or failure rate cartilage composite graft gives a definitely better result than temporalis fascia graft. However, the two method did not differ significantly in terms of hearing improvement.

KEYWORDS

Tympanoplasty, Temporalis fascia, Tragal cartilage, Pure tone audiometry.

INTRODUCTION :

Chronic suppurative otitis media is a very common condition in the practice of otolaryngology both in developed as well as developing countries. Perforation of the tympanic membrane which results in recurrent otorrhea and hearing loss. It affects both sexes and all age groups. The incidence of CSOM continues to be high in developing countries because of poor socio-economic standards, poor nutrition, lack of health education etc. and so the demand for corrective surgery is ever-increasing. Tympanoplasty refers to any operation involving reconstruction of the tympanic membrane and/or the ossicular chain. It is performed to eradicate disease from the middle ear and to reconstruct the sound transmission mechanism of the middle ear. Type I Tympanoplasty is a procedure by which defect of tympanic membrane is repaired by using a Graft (commonly graft of temporalis fascia or sometimes perichondrium).^{2,3} This will check repeated infection from the external ear canal. A commonly used graft is the temporalis fascia which may be used in an underlay or onlay technique.⁴ In current surgical practice, the tragal cartilage with perichondrium graft has gained popularity, more so after the technique was described by Eavey.⁵ However, the introduction of cartilage as a graft for tympanoplasty debuted almost at the same time as temporalis fascia. The cartilage tympanoplasty offers an otologist another reliable material in his armamentarium for tympanic membrane reconstruction.⁶ However, in our patients we used neither skin nor any other graft over the cartilage. This context will analyze the postoperative results of graft acceptancy and hearing improvement between tympanoplasty.

AIMS AND OBJECTIVES :

AIMS:

The Aims of the study is to find out the alternative graft material for

tympanioplasty other than the conventional temporalis fascia and the hearing improvement of the patients.

OBJECTIVES:

1. Evaluation of success rate in term of graft acceptancy in patients undergoing tympanoplasty using temporalis fascia graft and cartilage composite graft.
2. To estimate the level of hearing improvement in patients undergoing tympanoplasty using temporalis fascia graft and cartilage composite graft.

MATERIALS AND METHODS :

STUDY AREA : Burdwan Medical College & Hospital, Burdwan

STUDY POPULATION: Data for the study will be collected from the patients undergoing middle ear surgery in the Department Of Otorhinolaryngology at Burdwan Medical College & Hospital, Burdwan.

STUDY PERIOD: August 2014 to July 2015

SAMPLE SIZE: 50 cases ,aged ≥ 10 yrs, ≤ 50 yrs Group A (N= 25) temporalis fascia graft Group B (N=25) tragal cartilage with perichondrium graft

SAMPLE DESIGN/PROCEDURE: A predesigned proforma will be used to record the relevant information (patient's data, clinical findings, and investigation reports) from the individual patient selected with inclusion and exclusion criteria.

STUDY DESIGN: A single-blind, randomized, hospital based study.

Submitted :

Accepted :

Publication : 01st March, 2020

PLAN FOR ANALYSIS OF DATA: data will be entered in MS EXCEL data sheet & checked thoroughly. Data will be analyzed using standard statistical techniques with the help of statistical software.

METHODOLOGY/STUDY TECHNIQUE:

All these 50 patients who underwent operation in the ENT OT of BMC Hospital were followed up for this study. The patients are selected consecutively as and when they are presented during the study period considering the inclusion and exclusion criteria's upto the study population is achieved i.e. 50 patients. Every patient is called for follow up at one week postoperation for stitch removal and graft uptake assessment again after 3 month post-operation for audiometric assessment considering improvement in pure tone threshold only as compared to presurgery status. The patients are again called for follow up at 6 month post-operation to compare audiometric status with that of 3 month postoperation.

SURGICAL APPROACH:

Through post aural approach, under local anaesthesia tragal cartilage was harvested by keeping one side perichondrium intact on the cartilage. A slit was cut over the cartilage graft to accommodate the handle of the malleus. Tympanomeatal flap was then raised in the usual manner. Thereafter, the tragal cartilage graft was placed medial to annulus and the handle of malleus. The tympanomeatal flap was then repositioned back over the cartilage graft. Temporalis fascia also placed in the same manner medial to annulus and the handle of malleus. After placing the graft in position and stabilizing it with placement of gel foam the wound was then closed. In post aural route wound was closed in two layers. The last part of the operation is putting a pressure bandage over the mastoid area for proper hemostasis especially in post aural approaches.

FIG 1: TEMPORALIS FASCIAGRAFT

FIG2: AFTER REPOSITIONING OF POSTERIOR MEATAL WALL

FIG 3: HARVESTING TRAGAL CARTILAGE

FIG 4: CARTILAGE PERICHONDRIMUM GRAFT

Post operatively the patients were put on a course of antibiotic, analgesics, antihistamines and nasal drops. Mastoid bandage and dressings were removed next day of operation (24-48 hrs). Stitches were removed after 6-7 days later. Patients were discharged after 2 days. Patients were called up for first follow up at the end of 1st week post operatively, then at three weekly interval for six months. Pure tone audiogram (PTA) was carried out in each patient postoperatively at 12th week of follow-up visit. The preoperative audiogram was compared with the final postoperative audiogram. Otoscopic examination of the operated ears was carried out at 10th week of follow-up visit to assess the graft uptake and complications that would have occurred in the follow-up period.

RESULTS:

Fifty consecutive patients fulfilling the inclusion criteria underwent ear operation. Among these patients Tympanoplasty using temporalis fascia as graft was done in 50% (n=25) patients and Tympanoplasty using composite cartilage graft was done in another 50% (n=25) patients. During preoperative examination of middle ear cavity, intact & mobile ossicular chain was found in all cases. So no patient required ossiculoplasty. Various data and their analysis as obtained are given below. The statistical software SPSS version 20 has been used for the analysis. An alpha level of 5% has been taken, i.e. any p value is less than 0.05 it has been considered as significant. In table and diagram the procedures are termed as GROUP A (tympanoplasty using temporalis fascia as graft) and GROUP B (tympanoplasty using composite cartilage graft).

In our study the youngest patient was of 13 years age and the oldest was of 50 years of age. The mean age was 26.62 years (± 11.14 years). The mean age of patients who underwent tympanoplasty using temporalis fascia as graft and tympanoplasty using composite cartilage graft was 28.04 years and 25.20 years respectively. The differences among the two groups are statistically insignificant ($p = 0.311$). Most patients age was from 13-20 years (44.00%).

TABLE 1: MEAN AGE DISTRIBUTION BETWEEN TWO GROUP

	GROUP			
	GROUP A	GROUP B		
	Mean $\pm$ Std. Deviation	Mean $\pm$ Std. Deviation	p Value	Significance
Age (in years)	28.04 $\pm$ 12.42	25.2 $\pm$ 9.73	0.515	Not Significant

Mann-Whitney U test, p value less than 0.05 is considered as significant. In our study 50.00% (n=25) were female and 50% (n=25) were male. Female: Male ratio was 1:1. The sex ratio did not have statistical significance among the two groups.

TABLE 2: COMPARISON OF TWO GROUP ON THE BASIS OF SEX DISTRIBUTION

		GROUP		Total		
		GROUP A	GROUP B		p Value	Significance
Sex	MALE	14(56)	11(44)	25(50)	0.396	Not Significant
	FEMALE	11(44)	14(56)	25(50)		
Total		25(100)	25(100)	50(100)		

Pearson's Chi Square test, p value less than 0.05 is considered as significant. In our study post operative Mean air conduction was 23.48 $\pm$ 5.54 dB among them 24.2 $\pm$ 6.26 dB in the fascial group and 22.76 $\pm$ 4.73 dB in the cartilage group. This result is not statistically significant.

TABLE 3: COMPARISON BETWEEN PRE OP PURE TONE AVERAGE AND POST OP PURE TONE AVERAGE

	GROUP			
	GROUP A	GROUP B		
	Mean $\pm$ Std. Deviation	Mean $\pm$ Std. Deviation	p Value	Significance
Pre OP Pure-Tone Average(dB)	38.56 $\pm$ 4.09	37.12 $\pm$ 5.13	0.301	Not Significant
GROUPS	24.2 $\pm$ 6.26	22.76 $\pm$ 4.73	0.489	Not Significant

Mann-Whitney U test, p value less than 0.05 is considered as significant

FIG 5: PRE AND POST OPERATIVE HEARING GAIN

In our study post operative mean air-bone gap was 13.84 ± 5.94 dB among them 14.76 ± 5.6 dB in fascial group and 12.92 ± 6.23 dB in the cartilage group which is not significant statistically.

TABLE 4: COMPARISON BETWEEN PRE OP AIR-BONE GAP AND POST OP AIR-BONE GAP

	GROUP			
	GROUP A	GROUP B	p Value	Significance
	Mean $\pm$ Std. Deviation	Mean $\pm$ Std. Deviation		
Pre OP Air-Bone gap(dB)	23.56 $\pm$ 4.09	22.12 $\pm$ 5.13	0.301	Not Significant
Post OP Air-Bone gap(dB)	14.76 $\pm$ 5.6	12.92 $\pm$ 6.23	0.278	Not Significant

Mann-Whitney U test, p value less than 0.05 is considered as significant

FIG 6: PRE AND POST OPERATIVE CLOSURE OF AIR-BONE GAP

OVERALL SUCCESS RATE:

In our study 88.00% (n=44) patients had overall successful result. The overall success rate among tympanoplasty using temporalis fascia graft (GROUP A) and tympanoplasty using composite cartilage graft (GROUP B) technique were 84.00% (n=21) and 92.00% (n=23) respectively. 12.00% (n=6) patients were marked as failure cases during post operative follow up period. The overall failure rate among tympanoplasty using temporalis fascia graft (GROUP A) and tympanoplasty using composite cartilage graft (GROUP B) technique were 16.00% (n=4) and 8.00% (n=2) respectively. So the distribution of surgical outcome in terms of success rate or failure rate was statistically insignificant in the two study groups (p=0.384).

TABLE 5: COMPARISON BETWEEN TWO GROUP ON THE BASIS OF SUCCESS AND FAILURE RATE

		GROUP		Total	p Value	Significance
		GROUP A	GROUP B			
Surgery Result	SUCCESS	21(84)	23(92)	44(88)	0.384	Not Significant
	FAILURE	4(16)	2(8)	6(12)		
Total		25(100)	25(100)	50(100)

FIG 7: COMPARISON BETWEEN SUCCESS AND FAILURE RATE

DISCUSSION:

The Tympanic Membrane (TM) 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 for millions of patients.⁷ There are a number of materials for closure of TM perforations like skin,⁸ perichondrium,^{9,10} vein,¹¹ temporalis fascia,¹² dura¹³ and cartilage.^{14,15} The most frequently used technique for the repair of tympanic membrane perforations is underlay grafting of temporalis fascia.

In the cases of subtotal and total perforations, atelectatic ear, retraction pocket, long term results of temporalis fascia graft may not be very satisfactory.^{16, 17} to overcome this, perichondrium and/or cartilage grafts are used with good results. Four techniques have been described for cartilage tympanoplasty, namely the Inlay butterfly graft, cartilage-perichondrium island flap, palisade flap, and cartilage shield tympanoplasty. In our study, we used cartilage-perichondrium island flap technique for type-1 tympanoplasty using tragal cartilage of full thickness (1mm). In our study the minimum pre-operative pure tone average was 30 dB and maximum pure tone average was 48 dB. The mean was 37.84 ± 4.65 . All patients had negative Rinne's test and ABC test not reduced pre operatively. Distribution of preoperative hearing loss in the two study groups was not statistically significant (p=0.301). Shrestha S et al,¹⁸ in her study found preoperative A-B gap of around 30 dB in 76% of her patients.

In another study by Ashifaque Ahmed Shaikh et al,¹⁹ showed mean pre operative air conduction of 40 dB and A-B gap of around 25 dB. So most cases of TM perforation have mean A-B gap of around 30 dB.

In our study post operative Mean air conduction was 23.48 ± 5.54 dB among them 24.2 ± 6.26 dB in the fascial group and 22.76 ± 4.73 dB in the cartilage group. This result is not statistically significant.

El-Hennawi(2001) reported mean air conduction gain was 20 ± 11 dB in the fascial group, and 21 ± 11 dB in the cartilage group.²⁰

Chouhan, A (2015) Post-operatively mean air conduction was 27.4 dB with standard deviation of 11.5 dB.²¹

In our study post operative mean air-bone gap was 13.84 ± 5.94 dB among them 14.76 ± 5.6 dB in fascial group and 12.92 ± 6.23 dB in the cartilage group which is not significant statistically.

The mean air bone gap pre-operative was 22.84 dB which was reduced to 13.84 dB post-operatively thus giving improvement in hearing of 9 dB. Among the fascial group mean air-bone gap was 23.56 dB pre operatively and 14.76 dB post operatively. And improvement in hearing of 8.8 dB. On the other hand the cartilage group mean air-bone gap was 22.12 dB pre operatively and 12.92 dB post operatively, and improvement in hearing of 9.20 dB.

Mahadevaiah A et al. in which they achieved difference of mean pre-and post-surgery air bone gap of 13 decibels.²²

Chouhan, A (2015) the mean air bone gap pre-operative was 26.4 decibels which was reduced to 18 decibels post-operatively thus giving improvement in hearing of 8.4 decibels.²¹

In our study, when success rate of the tympanic membrane perforation closure at the end of 1-year with different graft materials was compared, successful graft take-up rate of 88.00% (n=44) patients had overall successful result. The overall success rate among tympanoplasty using temporalis fascia graft (GROUP A) and tympanoplasty using composite cartilage graft (GROUP B) technique were 84.00% (n=21) and 92.00% (n=23) respectively. 12.00% (n=6) patients were marked as failure cases during post operative follow up period. The overall failure rate among tympanoplasty using temporalis fascia graft (GROUP A) and tympanoplasty using composite cartilage graft (GROUP B) technique were 16.00% (n=4) and 8.00% (n=2) respectively. So the distribution of surgical outcome in terms of success rate or failure rate was statistically insignificant in the two study groups (p=0.384). Our results are comparable with the study of Strahan et al. in which take-up rate of 87.5% was achieved using temporalis fascia and 86% by tragal perichondrium by underlay technique.²³ Singh et al. had recorded a graft success rate of 95% for temporalis fascia and 90% for tragal perichondrium.²⁴ Sprem et al.,¹⁹ had reported a graft take-up rate of 91% with temporalis fascia and

92% using tragal perichondrium.²⁵ When success rate of the tympanic membrane perforation closure at the end of 1-year with different graft materials was compared, successful graft take-up rate of 92.31% was achieved for temporalis fascia (Group A), while for tragal cartilage-perichondrium composite graft (Group B) it was 96.92%. El-Hennawi (2001) reported good anatomical results in 88 ears out of 90 (97.7%), compared with 281 ears out of 290 (96.9%).²⁰ Sapci et al. (2006), at the end of the 1st year of observation, graft survival was 92% in the cartilage group and 85% in the fascia group.²⁶

CONCLUSION :

This study found alternative graft material for tympanoplasty which is beneficial in terms of graft uptake and hearing improvement over a short term follow-up period.

The degree of post-operative hearing improvement in both our treatment groups was dependent on pre-operative hearing status; the larger the pre-operative air-bone gap, the poorer the reduction in post-operative air-bone gap.

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Conflict of interest: None declared

Ethical approval:

The study was approved by the Institutional Ethics Committee

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