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Research Article

COMPARISON OF CARTILAGE TYPE IIIA AND IIIB TYMPANOPLASTY IN INDIAN PATIENTS WITH CHRONIC SUPPURATIVE OTITIS MEDIA

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ABSTRACT

Objective: This prospective comparative study determined the efficacy of type III tympanoplasty using homologous septal spur cartilage in patients with chronic otitis media (COM).

Methods: We selected patients by random sampling. Complete otolaryngological examination including otological examination, tuning fork tests, pure tone audiometry (PTA), and relevant investigations was done. Post-tympanoplasty residual air-bone gap (ABG) was graded. Type III tympanoplasty was done for all and followed up until month 6.

Results: Of 50 patients, 70.0% were men. Mean age was 27.72±10.81 years, 24 and 26 patients underwent type III-A and III-B tympanoplasty, respectively. Pre-operative mean PTA and ABG was 50.08 dB and 38.27 dB, respectively. Pre-operative ABG of 31–60 dB was seen in 41 patients while nine had an ABG of 0–30 dB. Overall, pre and post-operative PTA was 50.24 dB and 28.54 dB, respectively. Overall, pre- and post-operative ABG was 38.32 dB and 16.40 dB (III-A 36.92 dB and 14.79 dB; III-B 39.62 dB and 17.88 dB). Mean overall hearing gain postoperatively in PTA was 21.70 dB (type III A 22.33 dB, III B −21.115 dB). Overall, ABG closure was 23.53 dB (type III-A 22.333 dB, III-B −21.115 dB). None had failure (>30 dB). Good ABG of 10–20 dB was seen in 72% and 78% of patients at month 3 and 6, respectively.

Conclusion: Significant post-operative hearing improvement was seen in both types of tympanoplasty using homologous cartilage graft for ossicular reconstruction. Type III-A is better than type III-B as the stapes superstructure is vital for hearing.

Keywords: Air-bone gap, chronic suppurative otitis media, Hearing improvement, Pure tone audiometry, Tympanoplasty type III.

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INTRODUCTION

Tympanoplasty is a procedure for the eradication of middle ear diseases and reconstruction of the hearing mechanism by repairing the tympanic membrane with or without ossiculoplasty. Following the eradication of the disease, the reconstruction of the tympanic membrane and ossicles is a prerequisite to restoring hearing. Different materials, natural or bioinert, are used in the reconstruction and restoration of the hearing mechanisms. The materials used are refashioned ossicles, cartilage, cortical bone, titanium prosthesis, hydroxyapatite, and synthetic plastipore.

In surgical repair of hearing mechanism of the ear, several host factors come into play such as the size of perforation, Eustachian tube, function state of the middle ear mucosa, wound healing, the status of the ossicles, and degree of pneumatization of the mastoid [1]. Surgical consideration such as approaches (per meatal, end aural, and post aural), graft sources (temporalis fascia, a cartilage graft, and dura), placement of the graft, associated mastoid operation (intact canal wall and canal wall down), and ossiculoplasty also have a bearing on the success of the surgery. Hence, no single technique is best for all tympanoplasties.

In cases where there is an extensive loss of ossicles, the homologous septal spur cartilage is used for the reconstruction of ossicles to bridge the gap between the remnant of stapes and the neo tympanic membrane. In the evaluation of the surgical success of tympanoplasty, an assessment of various host and surgical factors has been a subject of interest for many years and continues to be a challenge.

The operational success of tympanoplasty can be evaluated in terms of the rate of graft uptake. However, to have a quantitative measurement of subject's hearing and to give scientific credibility to the results of the clinical tests, an audiometric evaluation of tympanoplasty can be done. Comparison of the pre and postoperative pure tone averages in speech frequencies and the air-bone gap (ABG) gives a complete picture of the improvement in hearing after surgery and also establishes a baseline for any changes (improvement/deterioration), which may occur as a result of treatment or due to the natural progression of disease.

Type III tympanoplasty has shown satisfactory outcomes in chronic otitis media [COM], both in experimental [2] and clinical studies [3]. It also has shown a lesser ABG apart from hearing outcome [4]. Data on clinical outcome of type III tympanoplasty in Indian patients are limited. Hence, we evaluated the degree of hearing improvement after type III tympanoplasty using homologous cartilage.

METHODS

This study was conducted at a government Ear, Nose and Throat (ENT) hospital located in South India, after obtaining Institutional Ethics Committee's review and approval. Our objective was to determine the efficacy of type III homologous septal spur cartilage in the improvement of hearing in cases of chronic suppurative otitis media by comparing the pre- and post-operative pure tone audiogram. We included patients who underwent type III Tympanoplasty done using homologous spur cartilage, selected by random sampling. Patients with the sensorineural hearing loss, only or significantly better hearing ear, any intracranial complications of the ear disease, malignant neoplasm of the external or middle ear and those with persisting ear discharge postoperatively were excluded from the study.

Patients who satisfied the criteria for selection were taken as subjects of the study after taking a written informed consent; for those aged <18, consent from the parents and assent from the patients were obtained. The data of the patient were collected in a case proforma. After taking a detailed medical history, complete ENT evaluation including otological examination, tuning-fork tests were done to rule out any source of infection. Pure tone audiometry (PTA), relevant haematological and radiological investigations to assess for fitness for surgery, culture, and sensitivity of ear discharge, and microscopic examination were done. Pure tone audiometric evaluation was done for all patients in a soundproof room with GSI 68 diagnostic audiometer, with standard procedures by the same audiologist both preoperatively and postoperatively. Audiometric testing was performed at 500, 1000, 2000, and 4000 Hz.

X-ray mastoids Schuller's view was taken for all. Patients were managed with type III tympanoplasty (Figs. 1 and 2), with cortical mastoidectomy or canal wall down mastoidectomy as indicated. In the postoperative period, all were followed up on an outpatient basis, once weekly in the first month, once a month later on and at third and sixth month to determine the hearing improvement. Post-tympanoplasty residual ABG was graded as per Kartush (1994) Classification [5].

Statistical analysis

We tested the null hypothesis that stated: "There is no significant difference in the mean values between the two groups, i.e., $\mu1=\mu2$." Our alternate hypothesis stated, "There is a significant difference in the mean values between the two groups, i.e., $\mu1\neq\mu2$." We kept the level of Significance: $\alpha=0.05$. Appropriate statistical tests were used (Student's t-test).

Decision criterion

We compared the p-value with the level of significance. We rejected the null hypothesis and accepted the alternate hypothesis, if p was <0.05. We accepted the null hypothesis when p≥0.05.

Results were interpreted in terms of frequency, mean, standard deviation, and range. Tables and figures were used to tabulate and depict the results.

RESULTS

We included 50 eligible patients meeting the selection criteria. There were 35 (70.0%) men and 15 (30.0%) women. Mean age of our study population was 27.72 years±10.81, range 12–56 years (Table 1). 33 (66.0%) patients were aged <30 years (Table 2).

Of 24 patients who underwent type III-A tympanoplasty, 14 (58.33%) were males and 10 (41.67%) were females; of 26 patients who underwent type III -B tympanoplasty, 21 (80.77%) were males and five (19.23%) were females. There was no significant association between type and gender (p>0.05).

Ear discharge (n=50, 100%) and hearing impairment (n=45, 90%) were the common complaints.

Right ear COM was seen in 24, left ear COM in 22 and 8 had bilateral involvement. Of the 50 cases, 26 were of mucosal type COM (52%) and 24 squamosal type (48%).

X-Ray mastoids (lateral oblique view) revealed sclerotic mastoid in 40 (80%) patients. Culture reports were sterile in 44 (88%); *Moraxella catarrhalis* in 3 (06%) among those with mucosal type COM and Saprophytes (n=3) and *Pseudomonas aeruginos*a (n=1) were reported in squamosal type.

Patients underwent Type III tympanoplasty with cortical mastoidectomy for mucosal type and canal wall down mastoidectomy for squamosal type, with ossiculoplasty using homologous cartilage graft. Of which 24 underwent Type III-A tympanoplasty and 26 underwent Type III-B tympanoplasty.

The preoperative mean PTA and ABG were 50.08 dB, and 38.27 dB, respectively. Preoperative ABG of 31–60 dB was seen in 41 patients while nine had a gap of 0–30 dB.

Post-operative audiometry was done at months 3 and 6 for all. In our study, the overall pre and post-operative PTA was 50.24dB and 28.54dB, respectively (Table 3).

Overall, pre and post-operative ABG was 38.32 dB and 16.40 dB, respectively. The pre and post-operative ABG was 36.92 dB and

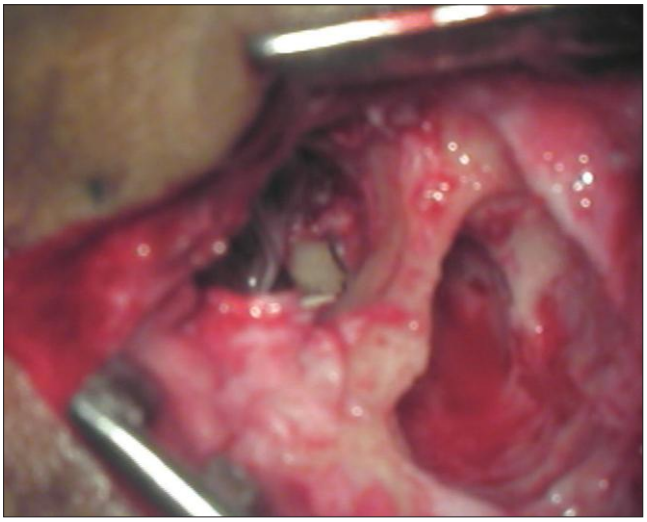

Fig. 1: Homologous spur cartilage placed in type III-A tympanoplasty

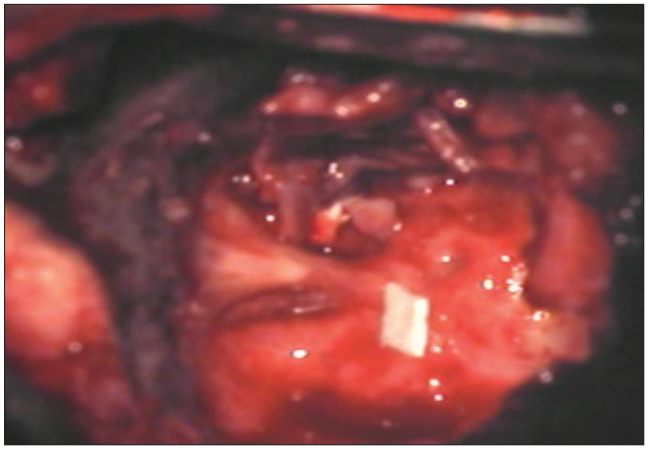

Fig. 2: Homologous spur cartilage placed in type III B tympanoplasty

Table 1: Mean age of the study population

Age (years)	n	Mean±SD	Median	Min	Max
Overall	50	27.72±10.81	24.5	12	56
Type 3A	24	28.83±12.17	23.5	15	56
Type 3B	26	26.69±9.50	26.0	12	45

SD: Standard deviation; Sample size - 50.

Table 2: Age distribution in the study

Age in years	n (%)
<20	15 (30.0)
21–30	18 (36.0)
31–40	8 (16.0)
41–50	8 (16.0)
>50	1 (02.0)

14.79 dB respectively, in type III-A tympanoplasty. In type III-B tympanoplasty, the pre and postoperative ABG was 39.62 dB and 17.88 dB, respectively (Table 4).

Overall, mean hearing gain postoperatively in PTA was 21.70 dB. In type III-A tympanoplasty, the hearing gain was 22.33 dB, and in type III-B tympanoplasty it was 21.115 dB. The overall ABG Closure was 23.53 dB. It was 22.333 dB in type III-A tympanoplasty and 21.115 dB in Type III-B tympanoplasty.

Post-tympanoplasty residual ABG was graded as per Kartush (1994) classification (Table 5).

Complications

At the end of 6 months all but two patients had ear dry; of the two patients who had ear discharge, one settled with oral and topical antibiotics. However, in the other patient, the ear discharge persisted due to infection. The tympanic graft was perforated. The patient was advised revision surgery at a later date.

DISCUSSION

The ultimate objective in treating COM is to clear infection by performing a proper cortical mastoidectomy in mucosal type and a modified radical mastoidectomy in Squamosal variety, thereby removing the pathology in total. The secondary aim was to improve hearing to the extent possible, with proper ossicular reconstruction. Tympanoplasty with canal wall up or down mastoidectomies has resulted in improvement in hearing loss in those with COM [6].

Although several new techniques and new implant materials have been developed since 1950, the search for the ideal implant is still on. We are yet to develop an entirely satisfactory method of reconstructing the ossicular chain. Homologous and autologous ossicles are in use for many years. However, the difficulty in procuring the ossicles and the fear of contracting diseases such as acquired immunodeficiency syndrome (AIDS) and hepatitis made surgeons look for other alternatives. Synthetic implants were devised for this purpose, but have a risk of inciting a foreign body reaction and become exposed through the tympanic membrane [7].

The analysis of success rates of various authors using autograft ossicles (69–70%) or homologous cartilage (78%) with that of other prostheses revealed similar success rate as with synthetic prostheses.

The most commonly used autograft material has been the incus body, which is often reshaped to fit between the manubrium of the malleus and the stapes capitulum. The homologous cartilage (septal spur and tragal cartilage) is used as an alternative if both malleus and incus are destroyed. Homologous cartilage is usually taken from thick septal spur during septoplasty and is preserved in 90% isopropyl alcohol. It is used as an effective ossicular reconstructive material without the risk of foreign body reaction or extrusion that is associated with synthetic materials [7]. This procedure is considered to have the advantage of very low extrusion rate, technically easy to perform with less risk of residual disease [8].

Age at surgery is an important determining factor for the outcome. Studies have suggested that patients with COM have to be operated at an early age to achieve a satisfactory surgical outcome [9]. Mean age of our patients was 27.72 years with a range of 12–56 years; 66.0% of our patients were aged <30 years. Adhikari *et al*. [10] reported a range of 15–65 years and those who underwent type III tympanoplasty had a mean age of 29.35 years. Higher mean age was noted by Küçükkavruk *et al*. (39 years) [11]. We observed male preponderance (70.00%), similar to the observations of Adhikari *et al*. Similar to our study, Gupta *et al*. [12] too observed the at majority of their patients were aged <30 years, mean age of 24 years, the age range of 13–55 years.

Table 3: Comparison of change in PTA (dB) and ABG (dB) from baseline within type 3A

Parameter	Time interval	Mean	SD	SEM	Mean difference		p-valuelue
PTA (dB)	Pre-operative	46.21	5.06	1.03	22.292	33.881	<0.001*
	3 months operative	23.92	4.66	0.95			
	Pre-operative	46.21	5.06	1.03	22.333	28.914	<0.001*
	6 months	23.88	4.76	0.97			
ABG (dB)	Pre-operative	36.92	5.27	1.07	22.208	31.757	<0.001*
	3 months operative	14.71	4.61	0.94			
	Pre-operative	36.92	5.27	1.07	22.125	28.588	<0.001*
	6 months	14.79	4.39	0.90			

*Statistically significant difference. PTA: Pure tone audiometry, ABG: Air-bone gap, SD: Standard deviation, SEM: Standard error of the mean; Sample size - 50.

Table 4: Comparison of change in PTA (dB) and ABG (dB) from baseline within type 3B

Parameter	Time interval	Mean	SD	SEM	Mean difference		p-valuelue
PTA (dB)	Pre-operative	53.96	8.33	1.63	20.462	16.188	<0.001*
	3 months operative	33.50	8.36	1.64			
	Pre-operative	53.96	8.33	1.63	21.115	17.244	<0.001*
	6 months	32.85	8.26	1.62			
ABG (dB)	Pre-operative	39.62	6.86	1.35	21.077	24.897	<0.001*
	3 months operative	18.54	5.58	1.09			
	Pre-operative	39.62	6.86	1.35	21.731	24.223	<0.001*
	6 months	17.88	5.78	1.13			

*Statistically significant difference. PTA: Pure tone audiometry, ABG: Air-bone gap, SD: Standard deviation, SEM: Standard error of the mean; Sample size - 50.

Table 5: Post- operative residual ABG

Post- operative residual ABG	No. of cases at 3 montpostoperativeive (%)	No. of cases at 6 montpostoperativeive (%)
Excellent - <10 dB	6 (12)	3 (6)
Good - 10–20 dB	36 (72)	39 (78)
Fair - 21–30 dB	8 (16)	9 (18)
Failure - >30 dB	-	-

ABG: Air-bone gap; Sample size - 50.

Table 6: Heating results using different materiacategorisedzed in 10 dB

Authors	Materials used	N	Excellent (10 dB) (%)	Good (11–20 dB) (%)	Fair (21–30 dB) (%)
Jackson *et al.* [16]	PORP (Proplast)	55	12 (22)	15 (27)	17 (31)
Berrenholz *et al.* [17]	PORSilastictic)	33	7 (21.2)	9 (27.7)	5 (15.1)
Batra *et al.* [1]	Hydroxylapatite	20	2 (10)	9 (45)	6 (30)
Dalchow *et al.* [19]	Titanium	790	340 (43)	261 (33)	111 (14)
Chole [7]	Cartilage	102	26 (25.5)	40 (39.2)	24 (23.3)
Harvey *et al*. [15]	Cartilage	20	2 (10)	8 (40)	3 (15)
RobertO'Reillylly [20]	Incus	137	35 (25.5)	56 (40.9)	23 (16.8)
Our results	Cartilage	49	3 (6)	38 (76)	9 (18)

The secondary goal of tympanoplasty is improving the hearing capacity, which, in turn, depends on the innate healing capacity, as well as on the perseverance of reconstruction. Wiatr *et al*. [13] analyzed the determinants of improvement in hearing after surgery in patients with COM. Presenre of granuoma related lesion in the middle ear, damage to ossicles, and closing ABG have been reported to be the significant determinants. Lee *et al*. [14] reported that PTA is essential in assessing the hearing capacity patient's subjective hearing is determined by the pre- and post-operative air conduction threshold of >10 dB and ABG decrement of >20 dB [14] Mean pre and postoperative ABG of 25.36 dB and 7.36 dB was noted by Küçükkavruk *et al*. [11]. In our study, a mean residual ABG of 21.62 dB at 3 months and 22.38 dB was attained at 6 months, post-surgery, which was statistically significant.

Hearing results in our study revealed a mean post-operative ABG of 22.38 dB which is comparable to previous studies (16.9±9.8 dB to 23.8 dB) [7,15]. Adhikari *et al*. [10] noted an improvement of 13.71%, from pre-operative air conduction threshold 51.05 dB to 44.05 dB in 6 month postoperative (p=0.0009). PTA ABG improvement was 14.4% with mean ABG 42.4 dB and 36.3 dB (p=0.0009), pre and postoperatively [10]. These results encourage us to opt for reconstruction of COM with easily available homologous cartilage.

Various studies have compared different implant materials, and hearing was better with cartilage (Table 6).

With the use of biological or synthetic implants, hearing results were good as Table 6. Post-operative residual ABG with titanium implants showed excellent results (43%) when patients were followed up for 6–12 months. As compared to other prostheses postoperative hearing results are equally good. Although the septal spur cartilage as the prosthesis, has given more or less the same results, to assess the long-term hearing results, a more extended follow-up period is required. We recommend a follow-up for 2 years for proper assessment of improvement in hearing as previous studies have noted satisfactory long-term improvement [21,22].

Shrestha *et al*. [23] concluded that type III tympanoplasty though showed varied hearing improvement results in significant improvement in PTA-ABG (range 15–61.2 dB). In their study, mean pre and postoperative ABG was 37.8 dB and 29.8 dB.

Babu *et al*. [8] compared the hearing outcome among those who underwent type III A and B tympanoplasty. They reported the average pre-operative mean ABG of 43.64 dB (type III-A 39.7 dB and type III-B 46.9 dB). The mean ABG at month 6 follow-up was 18.9 dB (type III-A 15.2 dB and type III-B 22.11 dB). In our study, the pre-operative mean ABG was 38.27 dB±5.82 (type III-A 36.92 dB±5.27 and type III-B 39.62dB, 6.86) and postoperative, the ABG was 16.34dB±5.13 III-A III A 14.79dB±4.39 and type III-B 17.88d B±5.78). Our results are comparable to that reported by Babu *et al*.

We graded post-tympanoplasty residual ABG as per Kartush Classification. None of our patients had failure (>30 dB). Good ABG of 10–20 dB was seen in 72% and 78% of patients at month 3 and month 6. Excellent results were seen in 12% and 6% of patients at month 3 and month 6. Type III-A showed better results than type III- B as the stapes superstructure is vital for hearing. Long-term follow-up would have helped us to assess the changes if any.

Two of our patients had ear discharge; one patient responded to treatment, while it persisted in other due to infection. The tympanic graft was performed. The patient was advised revision surgery at a later date.

Similar to our study, most of the studies on type III tympanoplasty had small number of patients. We limited our follow-up period to 6 months, as many patients drop out after this period; we did not evaluate the factors that contribute and influence the outcome. Comparison with other types would have given insight which surgery would be best suited for our patients.

CONCLUSION

Significant post-operative hearing improvement was seen in both type III-A and Type III-B tympanoplasty using homologous cartilage graft for ossicular reconstruction at 6 months post-operative follow-up. Our results showed that Type III-A is better option than type III-B as the stapes superstructure is vital for hearing.

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AUTHORS' CONTRIBUDrNS

Dr. Prashant R Reddy provided the design, intellectual content, innovations, protocol design for conducting the study and lead surgeon for the surgeries performed.

Dr. Rakesh Vuppala contributed to the study design, protocol design, interpreted the results, and prepared manuscript.

Dr. Supriya Bhat was responsible for the conduct of the study including assessments, patient follow-up, data collection, preparation, and the review of manuscript.

CONFLICTS OF INTEREST

The authors declare that there are no conflicts of interest regarding the publication of this article.

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