

Ossiculoplasty using autologous incus in patients of chronic suppurative otitis media (CSOM): a prospective observational study

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Abstract

Background: CSOM and associated hearing loss is significant in our society and an effort directed towards the assistance of those who are afflicted is indeed worthwhile. The problem of ossicular reconstructions for CSOM in difficult chronic ears however continues to represent a major rehabilitation challenge. Various materials have been used in reconstruction of middle ear including synthetic, bony and cartilaginous materials.

Methods: The present study was prospective observational study of 50 cases who underwent ossiculoplasty for middle ear surgery over the period of 2 and half years. CSOM patients with hearing loss >40 dB were included and patients with sensorineural hearing loss were excluded out from the study. Otoscopic examination, tuning fork tests, and examination under microscope were done in all the patients.

Results: A total number of 50 patients were included in the study. Graft was taken up in 90% cases and rejected in 5% subjects after 3 months postoperatively. The average pre-operative air-bone gap was 45 ± 3.60 dB while the average post-operative air-bone gap was 25.66 ± 9.25 dB. The average hearing gain was 19.34 dB which was statistically significant ($p=0.000$).

Conclusions: This study concluded that ossiculoplasty with an autologous incus graft is safe surgical approach with good results for reconstructing the ossicular chain due to lower extrusion rate with good post-operative hearing gain.

Keywords: Ossiculoplasty, air-bone gap, chronic suppurative otitis media, hearing gain

Introduction

Chronic suppurative otitis media (CSOM) is typically a persistent, potentially dangerous disease often capable of causing severe destruction and irreversible sequel such as; fatal intracranial complications leading to undue burden on the patient, family and society ^[1].

A person with hearing loss or without speech is deprived of vital communication in the present day industrial world. It also results in reduction of academic achievement and disturbance in social and emotional development. In adults it produces psychosocial complications and affects the quality of individual's daily living activity. They have reduced mobility, fewer interpersonal contacts and it poses a significant economic burden, as few deaf people are employed in professional, technical and managerial position ^[2].

CSOM and associated hearing loss is significant in our society and an effort directed towards the assistance of those who are afflicted is indeed worthwhile. The consistent achievement of good hearing results in presence of CSOM is still one of most difficult challenges of otologic surgery. Smyth observed that the overall objective of the treatment of CSOM in children is to ensure functional restoration by surgery, with minimal delay after treatment of any upper respiratory problems, so that normal development of speech continues especially in bilateral disease ^[3].

The debate as to whether the open types of mastoidectomy with tympanoplasty are good or worse than the closed types will continue. There is no short cut to the successful excision of disease and the operation of choice must be that in which all the disease can be excised. Once this is achieved the surgeon can decide on the type of middle ear and /or mastoid reconstruction procedure, to be used, whether this should be staged or not, and what the reconstruction should ultimately be achieved. The consequences of surgical decision can be appreciated only over time, through the proper study of surgery done and its outcome and therefore each surgeon should analyse his results continuously and in relationship to the principles used in his surgical problem solving.

The problem of ossicular reconstructions in difficult chronic ears however continues to represent a major rehabilitation challenge. Various techniques have been used for treatment of ossicular erosion in chronic otitis media, but there are still controversies in choosing the best method for ossicular reconstruction. In recent years, numerous techniques and materials have been used for reconstructing the ossicular chain. Various prosthetics or autologous or homologous bone or cartilage can be used for the ossicular reconstruction ^[4]. Replacement of incus by its own transposition was reported in 1957 for the first time and polypropylene tube was used on incus and under tympanic membrane ^[5]. Later, incus replacement between malleus and stapes or tympanic membrane was used but had disadvantage of incus translocation which was solved by forming and drilling the incus bone. More recently, various materials have been used in reconstruction of middle ear including synthetic, bony, and cartilaginous materials, hydroxylapatite and plastipore ^[6]. The use of sculpted autologous or homologous incus interposition results in higher hearing success than current allograft prosthetics, has a low extrusion rate, and is stable over time. Only a few studies were found on literature search from this part of India. Hence the present study was undertaken in Rajasthan to assess the graft uptake rate, to gauge the success and complications after ossiculoplasty with autologous incus in patients of CSOM.

Methods

This prospective observational study was conducted in all the patients who were admitted in the department of Otorhinolaryngology of a tertiary care teaching hospital, Udaipur, Rajasthan for a period of two and half years from June 2018 to December 2021. Total 50 patients of chronic suppurative otitis media patients with hearing loss >40 db who underwent middle ear surgery were included in this study and patients with sensorineural hearing loss and who were unfit for surgery were excluded out from the study.

Procedure

Informed consent was taken from all the patients. Institutional ethics committee permission was taken before commencement of the study. An elaborate history was taken from all the patients who were enrolled in the study. History was taken to determine the onset, duration and cause of the hearing loss. A thorough Otomicroscopic assessment was done to study the status of middle ear and external ear along with tuning fork test. All patients underwent routine blood investigations and investigations related to ear examination like pure tone audiometry, impedance audiometry and X-Ray mastoids, HRCT temporal bone, CT Brain if required.

The various parameters were noted like age, gender, duration of deafness, type of ossicular reconstruction, and classification of the deafness. The patients were selected for ear surgery along with ossicular reconstruction. Autologous ossicle (incus) was used for ossiculoplasty. Sutures were removed on 7th day. Every patient was evaluated in an outpatient sitting after 15 days, one month, one and half month, two and three month and watched for the development for any complications. Pure tone audiometry (PTA) was done for hearing improvement before surgery and also postoperatively at 3 and 6 months in every patient.

Statistical analysis

Chi-square test was used to analyse categorical variables which were summarized as frequency and percentage. Continuous variables were summarized as mean and standard deviation and for pre and post-op comparison with the same group, paired sample t-test was used. A p value <0.05 was taken as statistically significant.

Results

A total of fifty patients were enrolled in the study. Maximum number of patients (50%) belonged to 15-24 years. Females (58%) were more in present study. In present study right ear (66%) was commonly affected than left ear (34%). In present study ear discharge was present in 78% cases. In present study earache was present in 22% cases. In present study tinnitus was present in 14%. Subtotal perforation (30%) was most commonly encountered perforation and least common was marginal perforation (2%). In the present study 46% of patients presented with granulation tissue in mastoid and middle ear exploration and 22% of patient affected by cholesteatoma. In this study Type 3 tympanoplasty (48%) was commonly done procedure. (Table 1)

In present study, graft was taken up in 90% cases and rejected in 5% subjects after 3 months postoperatively. (Table 1)

Table 1: Distribution of study patients with different parameters (n=50)

		Frequency	Percentage
Age (in years)	15-24	25	50.0
	25-34	19	38.0
	35-44	6	12.0
Sex	Male	21	42.0
	Female	29	58.0
Ear involved	Right	33	66.0
	Left	17	34.0
Ear discharge	Present	39	78.0
	Absent	11	22.0
Ear ache	Present	11	22.0
	Absent	30	78.0

Tinnitus	Present	7	14.0
	Absent	43	86.0
Ear complaints	Hearing difficulty	50	100.0
	Discharge	39	78.0
	Earache	11	22.0
	Tinnitus	7	14.0
Tympanic membrane status	Central perforation	9	18.0
	Large central perforation	13	26.0
	Subtotal perforation	15	30.0
	Attic perforation/retraction	9	18.0
Cholesteatoma	Present	11	22.0
	Absent	39	78.0
Granulation tissue	Present	23	46.0
	Absent	27	54.0
Procedure	MRM with Type 3 tympanoplasty	16	32.0
	Antrostomy with Type 3 tympanoplasty	10	20.0
	Type 3 tympanoplasty	24	48.0
Graft Status	Taken up	45	90.0
	Rejected	5	10.0

Table 2 shows the average pre-operative air-bone gap was 45 ± 3.60 dB while the average post-operative air-bone gap was 25.66 ± 9.25 dB. The average hearing gain was 19.34 dB which was statistically significant ($p=0.000$).

Table 2: Comparison between preoperative and postoperative air-bone gap

	Air-bone gap (dB) Mean \pm SD	P value
Preoperative	45.00 ± 3.60	0.000*
Postoperative	25.66 ± 9.25	
Hearing gain (Pre-Post)	19.34 ± 7.00	

*Significant

Discussion

Chronic suppurative otitis media with or without cholesteatoma frequently results in disruption of ossicular chain. In otorhinolaryngology, ossicular chain reconstruction is still an emerging surgical discipline. The tympanic membrane and ossicular chain are reconstructed when disease and pathology are removed from the tympanum after operation [7].

The present study was done to find the success of ossicular reconstruction using autologous incus. The goal was to get the optimum long-term hearing result by establishing a secure and reliable link between the tympanic membrane and the moveable stapes footplate.

In present study most of the patients (50%) were in age group between 15-24 years. One study done in 2002 by Gulathi *et al.* also showed 76% patients were between 15-25 years of age group [8]. In the present study, females (58%) were affected more often than men. There was also female domination in one study done by Basaket *al.* In which females were 1.2 times more than [9]. This suggests that chronic suppurative otitis media most commonly affect females of early age group. In present study right ear (66%) was most commonly affected than left ear. In present study chief complaint was hearing difficulty (100%), followed by ear discharge (78%), ear ache (22%) and tinnitus (14%). In present study subtotal perforation (30%) was most common tympanic membrane pathology and least was marginal perforation (2%). In present study 22% of patients had cholesteatoma and 46% of patient had granulation tissue. Similar complaints have been reported by various studies [10].

In present study graft success rate after ossiculoplasty using autologous incus was 90%. A

study done by Gouda *et al.* In 2019 had shown 83.3 graft success rates ^[11]. Success rate of ossiculoplasty depends upon various factors and it also depends upon local factors like granulation tissue and cholesteatoma which were found less in present study as well Gouda *et al.* study.

In present study, the average preoperative air-bone gap was 45 ± 3.60 dB and it reduced to 25.66 ± 9.25 dB after surgery. The average hearing gain was 19.34 dB and it was found significant ($p=0.000$). These results are very much similar to results reported by O'Reilly *et al.*, Wehrs, Desaulty *et al.* and Zheng *et al.* ^[12-15] O'Reilly *et al.* reported that 27% of patients who underwent ossiculoplasty achieved an air-bone closure within 10 dB, and 66.4% within 20 dB ^[12]. Desaulty *et al.* reported that 78% of patients who underwent an autologous incus reconstruction had a final air-bone gap less or equal to 30 dB ^[14]. One study has also reported satisfactory results in 83% of patients after using an autologous incus to reconstruct the ossicles ^[13]. The study done by Zheng *et al.* also showed that the residual air-bone gap was less than 20 dB in 86.1% of cases after two months of surgery ^[15]. These all studies reported excellent results with autograft.

In present study autologous incus was used for ossiculoplasty and showed good results. Earlier one study has also reported that among the ossiculoplasty materials (autologous cartilage, autologous incus and partial ossicular replacement prosthesis), autologous incus gives best postoperative hearing gain and lowest extrusion rate^[16].

Conclusions

This study concluded that ossiculoplasty with an autologous incus graft is safe surgical approach with good results for reconstructing the ossicular chain due to lower extrusion rate with good post-operative hearing gain. Furthermore, single-stage ossicular restoration has the potential to reduce patient hospitalisation time while also improving the cost-effectiveness of medical services.

References

1. Morris P. Chronic suppurative otitis media. *BMJ ClinEvid.*, 2012, 05-07.
2. Luft P. Communication barriers for deaf employees: needs assessment and problem-solving strategies. *Work.* 2000;14(1):51-9.
3. Van der Veen EL, Schilder AGM, Van Heerbeek N, Verhoeff M, Zielhuis GA, Rovers MM. Predictors of chronic suppurative otitis media in children. *Arch Otolaryngol Head Neck Surg.* 2006;132(10):1115-8.
4. Sharma K, Gururani P, Arora A, Singh G. Role of autologous versus homologous cartilage in ossicular reconstruction: a comparative study. *Indian J Otolaryngol Head Neck Surg.* 2017;69(2):137-41.
5. Mudhol RS, Naragund AI, Shruthi VS. Ossiculoplasty: revisited. *Indian J Otolaryngol Head Neck Surg.* 2013;65(3):451-4.
6. Mocanu H, Mocanu AI, Drago AM, Radulescu M. Long-term histological results of ossicular chain reconstruction using bioceramic implants. *Experimental and Therapeutic Medicine.* 2021;21:260.
7. Varshney S, Nangia A, Bist SS, Singh RK, Gupta N, Bhagat S. Ossicular chain status in chronic suppurative otitis media in adults. *Indian J Otolaryngol Head Neck Surg.* 2010;62(4):421-6.
8. Gulati SP, Sachdeva OP, Kumar A, Chanda R, Sachdeva A. Audiological profile in chronic suppurative otitis media. *Indian Journal of Otology.* 2002;8(1):24-8.
9. Basak B, Gayen GC, Das M, Dhar G, Ray R, Das AK. Demographic profile of CSOM in a rural tertiary care hospital. *ISOR Journal of Pharmacy.* 2014;4(6):43-6.

10. Chavan SS, Jain PV, Vedi JN, Rai DK, Kadri H. Ossiculoplasty: a prospective study of 80 cases. *Iran J Otorhinolaryngology*. 2014;26(76):143-150.
11. Gouda MI, Mohammad MA, Mohammad HS, Ghany MAHA. Assessment of Cartilage Strip and Bone Cement in Ossiculoplasty. *ZUMJ*. 2019;25(5):595-600.
12. O'Reilly RC, Cass SP, Hirsch BE, Kamerer DB, Bernat RA, Poznanovic SP. Ossiculoplasty using incus interposition: hearing results and analysis of the middle ear risk index. *Otology & Neurotology*. 2005;26(5):853-8.
13. Wehrs RE. Ossicular reconstruction in ears with cholesteatoma. *Otolaryngology*. 1989;22(5):1003-13.
14. Desaulty A, Shahsavari S, Pasquesoone X. Ossicular reconstruction with autograft in Type 3 tympanoplasty. *Otorhinolaryngology*. 2005;126(1):19-23.
15. Zheng C, Guyot JP, Montandon P. Ossiculoplasty by interposition of a minor columella between the tympanic membrane and stapes head. *Am J Otol*. 1996;17:200-2.
16. Mahanty S, Maiti AB, Naskar S, Das SK, Mandal S, Karmakar M. A comparative study of outcome of ossiculoplasty using cartilage graft, bone and different alloplasts in chronic otitis media. *Indian J Otol*. 2015;21:144-8.