

CLINICAL STUDY ON POSTOPERATIVE OUTCOME OF OSSICULOPLASTY IN CHRONIC SUPPURATIVE OTITIS MEDIA.

Otorhinolaryngology

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ABSTRACT

Introduction: Chronic Suppurative otitis media is an inflammatory disorder of middle ear cleft which also causes ossicular erosion leading to functional impairment of ear. Ossiculoplasty aims to restore hearing to an extent by replacing the damaged ossicle by prosthesis and thus rebuild the ossicular coupling mechanism of middle ear. This study is aimed at analyzing the hearing outcome post ossiculoplasty. **Materials and Method:** A prospective longitudinal study done on 250 cases of CSOM with ossicular erosion leading to conductive deafness. They all were investigated preoperative and their audiometry was documented. After ossiculoplasty they were followed up for period of 6 months postoperatively and the hearing was analyzed and compared with the pre-operative level. **Results and Observation:** It was seen that about 67% cases had improved hearing post ossiculoplasty. This depended on number of factors like the type of prosthesis used, the preoperative status of ossicles, presence of cholesteatoma, surgical skill and post-operative patient's compliance. **Conclusion:** Ossiculoplasty is an emerging technology with variety of techniques mentioned in literature. Success of ossiculoplasty depends on many factors related to prosthesis used, patient and the surgeons. Ossiculoplasty when performed well keeping all ideal conditions in vicinity yields a very good result and helps patients overcome their hearing handicap thus reducing economic and social burden.

KEYWORDS

ossiculoplasty, autologus, COM

INTRODUCTION

Chronic Suppurative Otitis Media is a common disease in developing countries with prevalence of 2%¹. Chronic otitis media (COM) is an inflammatory process in middle ear with erosion initially involving ossicular chain followed by scutum, tegmen and fallopian canal.

Common ossicle to be eroded is long process of incus which causes discontinuity in ossicular chain leading to conductive hearing loss.

Surgical treatment of CSOM aims at eradication of disease, prevention of recurrence and preservation/restoration of hearing by removing the disease and restructuring middle ear through ossicular reconstruction. Ossiculoplasty is done along with all types of middle ear surgeries (tympanoplasty to canal wall down procedures). Type of reconstruction depends on intra-operative status of ossicles, middle ear and risk benefit ratio of patient. Ossiculoplasty can be done for ossicular fixation too. Ossiculoplasty is an emerging field with advancements being made towards a better functional and structural outcome of middle and outer ear. Even after excellent surgical work, few factors are essential for desired outcome like: pre-operative hearing level, pre-operative status of ossicles and middle ear tissue, Eustachian tube function, type of prosthesis and post-operative care.

Aims and Objectives

To evaluate hearing outcome after ossiculoplasty in CSOM by comparing pre and 6 months postoperative hearing, while studying techniques of and factors affecting successful outcome of ossiculoplasty.

MATERIALS AND METHODS

Longitudinal, randomized, interventional study including 250 cases of CSOM with ossicular erosion from April 2016 to April 2017 at KKR HOSPITAL AND RESEARCH CENTRE. All underwent surgical management for disease clearance with ossiculoplasty.

Inclusion Criteria: Patients of age between 5 -70 years, of CSOM with conductive loss of > 25 dB and compliant to long term follow up.

Study Tool: A study proforma which included patient's details, chief complaints and its duration, pre-operative audiogram, status of ear pre-operatively, type of ossicular defect and disease seen intra-operatively, surgery performed, material used for reconstruction and postoperative follow up at 3rd month and 6th month in terms of hearing status, dry ear, presence of any complications.

Ethical Committee And Scientific Approval: Protocol submitted to and approved by institutional scientific and ethical committee.

METHODOLOGY

All individuals reporting to OPD with signs and symptoms of COM were assessed and ones satisfying inclusion criteria were taken up for study. They were informed in detail about disease, treatment options, nature of study, their role in study and consequences of study. Detailed informed, written consent was taken from patients. Detailed history and clinical examination including otoscopy was done for all. They underwent Pure tone Audiogram and X-Ray mastoid. HRCT temporal bone was reserved for cases with atticointral disease and revision surgery. After Pre-operative investigations and anesthetic check-up surgery was planned. On surgery day, patients underwent surgery depending on pre-operative hearing status, disease extent and intra-operative status of ossicles. Patients were retained in hospital for one day after operation and were advised 24 hours strict bed rest. Post-operatively patients were observed for vitals, soakage of dressing, facial palsy and lateralization of Weber. Patients were called for review on post-operative Day 7 for suture removal and given antihistaminic and multivitamin for one month. Patients were called for post-operative review on 1st month, 3rd month and 6th month. During 3rd and 6th month, post-operative audiogram was done and documented and were examined for status of ear (wet/dry), presence of any complications/cavity problems. Data were collected and entered on Microsoft excel spreadsheet. Association between surgery and post-operative findings were assessed with Ction of resuhi square analysis and mean PTA and mean ABG were compared using paired "t" test.

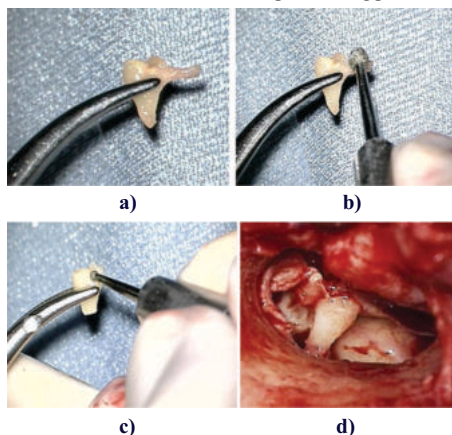


Figure: 1: A) Incus Held By Its Body. B) Long Process Of Incus Removed . C) Articular Surface Shaped For Handle Of Malleus Accommodation D) Incus Transposition Over Head Of Stapes.

RESULTS AND OBSERVATION

This was a prospective study in which 250 cases were studied. Results of study are as follows: In 250 patients there were 148 male and 102 females with male: female ratio of 1.45:1. Laterality of ear ratio left: right being 1.29:1. Both values were not statistically significant ($p=0.8$) inferring that disease has no gender or direction preponderance. Patients reported with varied symptoms most common being discharging ear, 78% cases followed by decreased hearing (68%) followed by ear pain, ear block and other miscellaneous symptoms

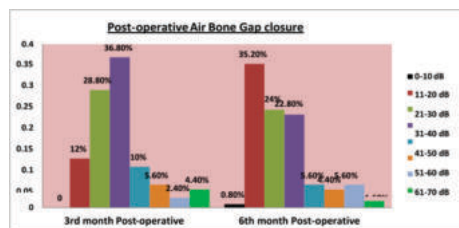
Patients underwent otoscopic examination and categorized into three categories: tubotympanic (22.4%), atticotympanic (40%) and both (37.6%) for proper surgical management. Pre-operative hearing was grouped into range of 10 dB. Most common hearing defect fell in range of 51-60dB (23.6%), followed by 41-50dB (22.8%), 31-40dB (20%), 61-70dB (14.4%), 21-30dB (11.2%) and >70dB (8%). Surgery was planned depending on intraoperative status of ossicles. They were classified on basis of Austin's classification.

Of 250 cases, 146 cases underwent Canal Wall Up, 43 Canal Wall Down, 61 cases underwent tympanoplasties without mastoid exploration (Wullstein Tympanoplasty type III -46 cases; Wullstein Tympanoplasty type IV- 15 cases). Ossicular reconstruction was done using bones (autologous/homologous) and cartilage.

In majority of cases bones [ossicles (autologous/homologous)] were used harvested and refashioned to be transposed between remnant structures in middle ear. For others, cartilage harvested from ipsilateral concha for ossiculoplasty.

Post-operative Follow Up

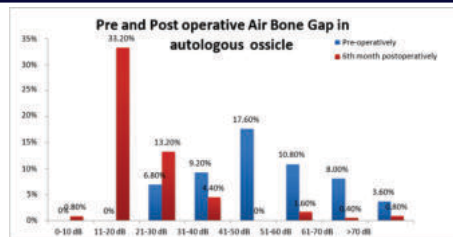
Hearing outcome: Here, success rate of ossiculoplasty was judged by gain in post-operative Air Bone Gap closure of 20-30 dB, which means that if patient had an improvement of more than 20 dB in post-operative Air bone gap closure, it was successful surgery. Post-surgery patients were followed at 3rd month and 6th month post-operatively to assess hearing status. After 3rd month follow up improvement in majority patients fell into group of 31-40 dB (36.8%) followed by 21-30dB (28.8%) and least group of 61-70dB (2.4%). 6th month post-operative follow up showed further closure of AB gap by majority of patients falling into group of 11-20dB (35.2%) and least into 71-80dB (1.6%). (Graph: 1)



Graph 1: Post-operative Air Bone Gap Closure

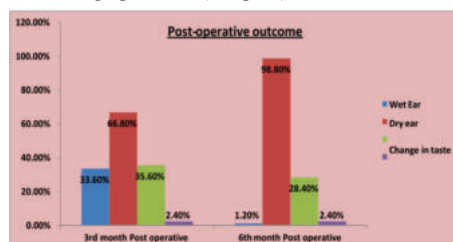
Mean Pre-operative Air Bone gap and Air Conduction threshold was 49.3 dB and 48.4dB respectively in 6th month post-operative period was 31.07dB and 34.07dB respectively. Gain in AB gap at end of 6th month post-operative was 18.22 dB and gain of Air Conduction Threshold was 14.32dB. This was statistically significant (p value=0.001)

Here, it was seen that hearing improvement at end of 6th month period was seen in almost all 97.7% cases (133 out of 136 cases) having autologous ossicle grafting. Remaining 3 cases showed worsening of hearing by increase in Air bone gap by 10 dB. In cases with homologous ossicle transposition this was seen in about 90.8% cases (80 out of 91 cases). Almost very little to no improvement was seen in patients having autologous cartilage, although none of cases had worsened hearing. Hence, autologous ossicle gave maximum hearing improvement with an Air Bone Gap Closure between 21-30 dB. Preoperatively maximum number of cases fell into hearing group of 41-50 dB (17.6% cases) followed by 51-60dB (8%) with minimum number in group of > 70 dB (3.6%). Post-operatively maximum cases had an Air Bone Gap of 21-30 dB (13.2% cases) and minimum in 61-70 dB (0.8%). Thus, showing that maximum cases achieved good hearing post-operatively with an Air Bone Gap closure within 20 dB. Hence, a significant improvement in hearing was noted on use of autologous material (Graph 2)



Graph 2: Pre And Postoperative Air Bone Gap In Autologous Ossicle

On analyzing Homologous ossicle, it was seen that there was an overall improvement in hearing outcome with majority cases having Air Bone Gap range of 31-40 dB. This could be attributed to worsening seen in few cases in later period of follow up due to resorption of homologous cartilage. Overall gain in Air Bone Gap Closure for homologous graft was within 10dB. For autologous cartilage improvement in Air Bone Gap closure was about 20dB. In this study, stapes suprastructure was found intact 46% and absent in 34% cases. Status of stapes effected post-operative hearing outcome. Intact stapes suprastructure had better hearing outcome post-operatively with ABG closure up to 30 dB than absent stapes suprastructure (10 dB only). Among 250 cases there were 14 cases of revision middle ear surgery with ossiculoplasties. Study showed that revision cases had little improvement in terms of hearing outcome post-surgery. 8 out of 14 cases underwent ossicular reconstruction with auto cartilage and remaining 6 had autologous (3) and homologous (3) ossicle transposition. 6 cases showed AB gap closure within 10 dB, 4 within 11-20 dB, 2 within 21-30 dB and remaining 2 had worsened hearing. Here, Post-operative air bone gap closure varied with disease, as on 6th month post-operative follow up cases having cholesteatoma had maximum number with air bone gap closure within 21-30dB (12.4%) and for attic disease without cholesteatoma and for tubotympanic disease it was within 0-10 dB (0.4% and 16.8% respectively) Other characteristics were also studied in postoperative period, prevalence of which is shown in graph below. (Graph:3)



Graph 3: Post Operative Outcome Of Other Parameters.

DISCUSSION

Chronic Otitis Media is an inflammatory disorder of middle ear which causes permanent changes in tympanic membrane and erosion of bony areas of ear including ossicles. Ossicular erosion causes functional impairment due to loss of both ossicular and acoustic coupling causing hearing disability in individuals. In such a scenario patients' treatment aims at dual goals. Firstly, to achieve a dry, disease free ear and secondly, to have an ear with a better functional outcome via ossiculoplasty. Present Study included both males and females within a wide range of age group from years to 70 years with a mean age of 35.08 years with male:female ratio of 1.45:1. This was similar to study conducted by Chivan et al². Main complaint of patients was discharging ear (78%) followed by decreased hearing (68%), finding were similar to study of Chivan et al² where 100 % cases reported decreased hearing and 97.5% with discharging ear. Otomicroscopic examination findings were broadly grouped into categories depending on site of involvement as: Atticotympanic seen in 100, Tubotympanic in 56 and both in 144 cases. Most common finding was central perforation seen in 127 cases, followed by cholesteatoma (42.4%), retraction pocket (38.8%), chronic adhesive process (8.4%) and attic granulations (3.2%) in decreasing order. (Mohammad Ajalloueyan³). Different surgical procedure was done. Canal wall up done for disease (cholesteatoma/granulations) limited to epitympanum, attic and aditus with mastoid antrum involvement. Canal wall down was done for extensive disease involving entire mastoid cavity along with tip, with erosion of surrounding bony structures and for revision cases. Few cases which had only central perforation with varied degree of

ossicular degradation cases were treated with tympanoplasty type III or IV.

In the study, common technique was transposition of autologous/homologous ossicle onto head of stapes in cases with an intact stapes suprastructure (46 %). Cases having an intact stapes suprastructure with intact malleus technique of malleostapediopexy was performed (30% cases of 37.6% cases having Austin A type ossicular defect). In remaining 7.6% due to non-availability of incus or long defect which hindered use of cartilage reconstruction, autologous malleus/homologous ossicle was directly placed on head of stapes in direct contact with tympanic membrane. 54 % cases of 250 cases which lacked stapes suprastructure but had mobile footplate were also considered for ossicular reconstruction. Here, autologous/homologous ossicle or autologous cartilage was transposed onto mobile footplate. Literature describes various methods for gaining stability of prosthesis at footplate region^{4,5}. Most common material used for reconstruction was autologous ossicle (54.4%) similar to study Wehr⁵, Austin⁶ and Glasscock⁷. Post-operative Outcome: Hearing: Recent literature emphasizes that, ideal reflector of hearing outcome is change in Air Bone Gap, measured by difference between pre-operative and post operative parameters; calculated as Air Bone Gap Closure (Harder et al¹⁸ because:

1. AB Gap gives better idea about chances of hearing improvement.
2. Air Conduction threshold may give false interpretation. Cases of small cholesteatoma may have ossicular erosion not be reflected in air conduction threshold. As a result both pre and post operatively hearing remains good and outcome is assessed as no change in hearing outcome, whereas actually with ossicular reconstruction a definite Air Bone Gap closure exists.
3. Helps in overcoming confounding factor of presbycusis in long term follow up.

In study a 6 month postoperative follow up was done and success rate was decided by change in Air Bone Gap attained by an individual at end of 6th month. Patients with Air Bone Gap Closure within 25 dB had successful ossiculoplasty, which was 60% in present study. This was comparable to or studies documented in literature^{9,10,11}. Mean gain in ABG was 18.22 dB similar to study by Chavan et al² Post-operative outcome of other parameters. Patients were also followed up after 6 months of operation to assess status of reconstructed ear, presence of tinnitus, facial palsy,

At end of 6th month dry ear was achieved in 247 cases (98.8%). At 3rd month post-about 84 cases had discharging ear. These had granulations were over neotympanum or in post-operative cavity which were treated with application of 2% acetic acid drops and were reviewed after 2 weeks and 6th month at which dry status was achieved. Remaining 3 cases presented with wet ear at end of 6th month (2 had granulations and 1 recurrent central perforation). Pre-operative tinnitus was seen in 6 cases of study. No improvement in tinnitus was observed. This was in contrast to study of Zeman et al,¹² Around 71 cases at 6th month post operative follow up had change in taste. The number was more at 3rd month and improvement occurred due to compensatory action from contralateral nerve (Philip Michael et al¹³). There were no cases of post-operative facial palsy and sensorineural hearing loss.

Factors affecting Outcomes of ossiculoplasty: Success of ossiculoplasty in terms of hearing gain was assessed by measuring Air Bone gap closure. Any closure above 20 dB was taken as a successful outcome. In present study overall improvement was seen in 42.4 % with ABG > 20 dB. Around 36.4% cases had ABG closure within 0-10 dB. Worsening i.e. decrease in ABG closure was seen in 5.6% cases while remaining 15.6% cases showed no change.²

1. Surgical Skill of operating surgeon: In present study cases were operated by three different operating surgeons. Results did not have any statistical significance.²
2. Status of middle ear: Presence/absence of cholesteatoma or preoperative ear is dry or discharging. In this study it was seen that ossiculoplasty done in ears without cholesteatoma (21% with ABG>20 dB) had a better ABG closure than with cholesteatoma (14.8% with ABG> 20dB).² In Contrast to present study, Dornhoffer reported that pathological condition of ear has little or no affect over postoperative hearing status. Result of study is contradictory to fact mentioned in literature. As per documented text it is said that pre-operative ear is divided into 4 groups depending on severity of discharge.¹⁴

Belluci Classification:

- Group 1: No discharge –excellent prognosis of ossiculoplasty
 - Group 2: Intermittent discharge- fair prognosis of ossiculoplasty
 - Group 3: Profuse discharge – poor prognosis of ossiculoplasty
 - Group 4: Cleft palate and nasopharyngeal abnormalities-very poor prognosis of ossiculoplasty.
3. As per Black, who gave SPITE score, ossiculoplasty post-operative results will depend upon following factors: Surgical, Prosthesis, Infection, Tissue and Eustachian tube factors.¹⁵ In discharging, infected middle ear outcome is not as good as expected due to increased propensity for fibrosis and formation of adhesions in between tympanic cavity structures and reconstructed ossicles thus leading to dampening of vibrations and hence post-operative failure.
 4. Status of stapes suprastructure: It was seen that cases with intact stapes supra structure had success rate of 32.4% cases while ones lacking only 18 %.indicates presence of stapes suprastructure gives better outcome (p=0.001). Brackmann et al¹⁶ and Goldenberg¹⁷
 5. Ossicular material used: Here, most common ossicular material used was autologous ossicle>homologous ossicle> autologous conchal cartilage. It was seen that a successful ABG closure was in 36.8% cases of transposed autologous ossicle. 5.6% cases of homologous ossicle while none in cartilage interposition. For cartilage reconstructed ossicle borderline success was seen in 9.2% cases. Literature shows varied results. Jha et al¹⁸ found that cartilage bone, and gold are better and more cost effective alternatives to plastipore and titanium. In contrast to present study Yung et al¹⁸ found no difference between different types of prosthesis used. Jackson et al¹⁹ achieved better results with Teflon TORP than PORP in his study of 141 cases of ossiculoplasty.²⁰ (Table:1)

Table 1 : Comparative Studies For Different Materials For Ossicular Reconstruction

Author (year)	Materials	Postop. ABG (>20dB) PORP	Postop. ABG (>20dB) TORP
Wehr (1978)	Homologous ossicle	90%	76%
Austin (1972)	Autologous and Homologous ossicle	83%	71%
Vartiainen (1985)	Autologous ossicle and cortical bone	50%	35%
Glasscock (1975)	Autologous and homologous ossicle	65%	
Penington (1978)	Autologous, homologous ossicle and cortical bone	Combined PORP and TORP 85%	
Gersdorff (1989)	Homologous ossicle and cortical bone	78%	56%
Vercruyysse (2002)	Homologous ossicle		81%
Siddiq (2004)	Autologous ossicle	65%	88%

As study period was only till 6th month post-operative follow up, none of cases came with extrusion of prosthesis. So extrusion rate of reconstructed ossicles could not be assessed.

CONCLUSION

Ossiculoplasty improves functional role of ear by providing better hearing. Its success, though, depends on factors like material, technique, pre-operative status of ossicle and middle ear and patient's postoperative compliance. Still, when performed meticulously keeping all factors under vision ossiculoplasty gives a very good functional outcome.

REFERENCES

1. Adkins wy (1990) composite autograft for Tympanoplasty & Tympanomastoid surgery. Laryngoscope 100, 244-247.
2. Shrinivas Shripatrao Chavan et al. Ossiculoplasty: A Prospective Study of 80 Cases. Iranian Journal of Otorhinolaryngology, Vol.26(3), Serial No.76, Jul 2014
3. Mohammad Ajalloueyan. Experience With Surgical Management of Cholesteatoma; Arch Otolaryngol Head Neck Surg. 2006;132:931-933
4. Fisch U, May J. Tympanoplasty, Mastoidectomy and Stapes Surgery. New York: Thieme; 1994
5. Fisch U, May J, Linder T, Naumann IC. A new L-shaped titanium prosthesis for total reconstruction of the ossicular chain. Otol Neurotol. 2004; 25(6):891-902.
6. Jovanovic S, Schonfeld U (1995) Application of the CO2 laser in stapedotomy. Adv Otorhino-Laryngol 49:95-100
7. Jovanovic S, Anft D, Schonfeld U, Berghaus A, Scherer H (1995) Tier experimentelle Untersuchungen zur CO2-Laser-Stapedotomie. Laryngo-Rhino-Otol 74:26-32
8. Harder h., Jerlvall L., Kyle n P. et al. (1982) Calculation of hearing results after tympanoplasty. Clin. Otolaryngol. 7, 221±229

9. Yung M. Long-term results of ossiculoplasty: reasons for surgical failure. *Otology and Neurotology* 2006; 27: 20–26.
10. Athanasiadis- Sismanis A, Poe DS. *Ossicular Chain Reconstruction* in: Gulya AJ, Minor LB, Poe DS Glasscock- Shambaugh Surgery of the Ear. 6th Ed. Connecticut: People's Medical Publishing House. 2010: 489-99.
11. Eleftheriadou A, Chalastras T, Georgopoulos S, Yiotakis J, Manolopoulos L, Iliadis I, Charalabopoulos K, Kandiloros D. Long-term results of plastipore prostheses in reconstruction of the middle ear ossicular chain. *ORL J Otorhino- laryngol Relat Spec.* 2009; 71(5): 284-8.
12. Alexander Fernandez de Azevedo, Anna Bárbara de Castro Soares, Henrique Queiroz Correa Garchet, and Nicodemos José Alves de Sousa: Tympano-mastoidectomy: Comparison between canal wall-down and canal wall-up techniques in surgery for chronic otitis media. *Int. Arch. Otorhinolaryngol.*, São Paulo - Brazil, v.17, n.3, p. 242-245, Jul/Aug/September – 2013.
13. Zeman F, Koller M, Figueiredo R. Tinnitus Handicap Inventory for evaluating treatment effects: which changes are clinically relevant *Otolaryngol Head Neck Surg.* 2011; 145(2): 282-287
14. Bellucci RJ. Selection of cases and classification of tympanoplasty. *Otolaryngol Clin North Am.* 1989; 22(5): 911-26.
15. Black B. Ossiculoplasty prognosis: the SPITE method of assessment. *AmJ Otol.* 1992; 13(6): 544-51.
16. Brackmann DE, Sheehy JL, Luxford WM. TORPs and PORPs in tympanoplasty: a review of 1042 operations. *Otolaryngol Head Neck Surg* 1984; 92: 32–7.
17. Goldenberg RA. Hydroxylapatite ossicular replacement prostheses: preliminary results. *Laryngoscope* 1990; 100(7): 693–700
18. Jha S, Mehta K, Prajapati V, Patel D, Kharad P. A comparative study of ossiculoplasty using various graft materials. *NJIRM* 2011; 2(4): 53-56
19. Yung M. Long terms results of ossiculoplasty: reasons for surgical failure. *Otology and Neurotology.* 2006 : 27: 20-26
20. Gary Jackson C, Glasscock ME, Schwaber MK, nissen AJ, Christiansen SG, Smith PG. Ossicular chain reconstruction: the TORP and PORP in chronic ear disease *Laryngoscope* 1983; 93 (8): 981-8