Ossiculoplasty with autologous incus and autologous cortical bone: A retrospective analysis

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Abstract
Aim: To compare and analyse the outcome of ossiculoplasties with autologous incus and autologous cortical bone.

Study Design: Retrospective study

Materials and Methods: Patients between the age group of 15 to 60yrs with a history of chronic suppurative otitis media with moderate conductive hearing loss (>35dB), who underwent ossiculoplasties with either autologous incus or autologous cortical bone from 2015 to 2017 were included in the study. The outcomes in terms of Graft uptake, the formation of retraction pockets, hearing improvements and rate of recurrence were analysed and included for a period of 6months post-surgery.

Results: A total of 42 patients with ossicular chain dysfunction were included in the study, in which 24 patients underwent ossiculoplasty with autologous incus and 18 patients with autologous cortical bone. Post operatively hearing evaluation by Pure Tone Audiometry was done after 6months, which showed similar improvement in both groups. Complications and extrusion rate were also absent in both the groups.

Conclusion: There is no significant difference in the outcomes following ossiculoplasties with autologous incus or autologous cortical bone in terms of graft uptake rates, the formation of retraction pockets, recurrence rates and hearing improvements.

Keywords: chronic suppurative otitis media; ossiculoplasty; pure tone audiometry; air bone gap

1. Introduction
The tympanic membrane and the middle ear space were first introduced by the early Greek Physicians in the 5th century B.C. and they considered middle ear space as the seat of hearing. By 29th century investigators provided the basic concept of hearing and the notable among them were the studies of Noble Laureate Van Bekesy. A sound is a form of energy transmitted from the external ear (pinna, external auditory canal and the tympanic membrane) to the middle ear (ossicles) into the inner ear [1].

The ossicles are the smallest bone in the body and are functionally most complicated. They are in the form of acicular chain across the tympanic cavity from the tympanic membrane to the fenestrae vestibule. Loss of ossicles or discontinuity of the acicular chain is the most common cause of conductive hearing loss in adults [2,3].

Middle ear composed of three ossicles-malleus, incus and stapes. Malleus has 2 main parts manubrium, with the anterior and lateral process, attached to the tympanic membrane and head which is attached to the incus. Incus has a head, body, long process and short process. Head of incus articulates with the head of the malleus. At the end of the long process is a small region called the lenticular process which articulates with the head of the stapes. While stapes has a footplate, two crura and a head. The footplate of the stapes covers the oval window. All 3 form the incudomalleal joint and incudostapedial joint at the point of their articulation. Axis of rotation of ossicles and axis of suspension by their ligaments coincide with their centre of rotational inertia hence bones are able to vibrate with very little loss through the suspending ligament at lower frequencies where mass effects are small, ligaments play important role in maintaining the position of ossicles [2].

Chronic suppurative otitis media (CSOM) is the term used to describe a variety of symptoms and signs that result from long term damage to the middle ear from infection and its incidence is progressing in our population. Because of its varying presentations, each case adds
a new challenge for the clinician and there is no routine treatment for the same. This can include: severe retraction or perforation of tympanic membrane, erosion of the ossicles of the middle ear, chronic or recurrent discharge from the ear, the presence of cholesteatomas, or any of its complications—Intracranial and Intertemporal [2].

CSOM begins with an episode of acute otitis media especially during childhood mostly due to upper respiratory tract infections and is characterized by persistent discharge from the middle ear through a tympanic membrane perforation. This perforation can be small, medium and large or can be central, marginal, subtotal and total. It can also be either pars tensa or attic perforation. Patients who had continued discharge from the ear along with tympanic membrane perforation for a period of 6 weeks to 3 months, despite of the medical treatment, is regarded as CSOM. And is one of the preventable causes of hearing loss especially in developing countries like India [2, 3].

The progression and end of the disease is difficult to define. Healing can be seen in patients in long term but they can develop either recurrent bouts of ear otorrhea (active CSOM) or a dry but permanent tympanic membrane perforation (inactive CSOM) without the probability of resumption in near future. Or the perforation heals imperfectly with areas of retraction and scarring in the tympanic membrane and won’t vibrate adequately or not to the sound [2, 3].

CSOM can present as an early acute phase with reversible mucosal and bony changes but in late chronic phase with recurrent episodes of otorrhea and mucosal changes it can result in osteoneogenesis, bony erosions and osteitis of the temporal bone (Mastoid) and the ossicles. This is followed by accicular destruction and or Ankylosis of the ossicles. Hearing loss occurs in patients due to the combined effect of tympanic perforation and changes in the bony pathology, there will be reduced or absent vibration of the sound conducting mechanism [2, 3].

Complications of CSOM are not uncommon. It produces chronic mastoiditis by contiguous spread, erosion of walls of the middle ear and mastoid cavity leads to exposure of the facial nerve, jugular bulb, lateral sinus, membranous labyrinth and the temporal lobe dura. Which can lead to facial nerve paralysis, lateral sinus thrombosis, labyrinthitis, meningitis and brain abscess. Hematogenous spread of infection to the brain can also produce the complications [3]

A moderate conductive hearing loss of >35dB, can indicate ossicular (Malleus, Incus, Stapes) discontinuity- commonly from the erosion of long process of incus or stapes superstructure. Definitive treatment includes primary clearance of the disease from the middle ear cleft and ossicular reconstruction. For the reconstruction, various grafts, autografts/allografts can be used. Auto grafts include ossicular bones (auto incus mainly), cortical bone, tragal or septal cartilages and certain prosthesis like Total/Partial ossicular replacement prosthesis can be used [3].

Middle ear can be approached either postaurally, anteriorly and endaurally. Middle ear mucosa, ossicular status and round window reflex is assessed after elevating the tympanomeatal flap. If any discontinuity is noticed, mostly necrosis of the lenticular process of the incus, it is dismantled from the joints. Either it is taken out drilled or reshaped or other grafts is remodelled for the better anchorage and placed back. The patients with Austin type a (Erosion of incus with intact malleus and stapes) and type C (erosion of stapes superstructure with intact malleus) ossicular defects were considered for ossiculoplasty [4, 5].

In our present study, patients who underwent ossiculoplasty with autologous incus and autologous cortical bone have been taken and compared the outcomes in terms of graft taken up rates, the formation of retraction pockets, recurrence rates and hearing improvement postoperatively.

2. Materials and Methods

Patients in the age group between 15 and 60yrs who underwent ossiculoplasties with autologous incus and autologous cortical bone from 2015 to 2017 in R J Jalappa Hospital were included in the study. Patients with the mixed hearing loss, CSOM with complications and extensive cholesteatoma cases were excluded from the study.

3. Surgical techniques

Among 42 patients included in the study, 24 patients underwent ossiculoplasty with autologous incus and 18 patients with autologous cortical bone. All patients underwent canal wall up cortical mastoidectomy.

In group 1 incus with the necrosed long process was taken from the incudomalleal joint. It was held using Derlacki’s ossicle holding forceps and the body of incus is drilled and reshaped using 0.6mm diamond burr under the microscope. The remnant long process was drilled into a cylindrical shape with a flat base. A socket was made in the undersurface of a remodeled long process for engaging the head of stapes. Part of the short process was removed and a notch was drilled in the undersurface of the long process to engage the handle of malleus. The incus is then placed between the handle of malleus and stapes superstructure (if present) or on to the stapes footplate.

In group II before cortical mastoidectomy, a segment of a cellular cortical bone harvested mostly from the Mc Evan’s area for ossiculoplasty. It is then drilled and reshaped using 0.6mm diamond burr under the microscope. Then is placed between the handle of malleus and stapes superstructure (if present) or on to the stapes footplate. Crushed soft tissues are placed over the cortical bone to prevent its extrusion [6].

After checking for the round window reflex, temporalis fascia graft which was harvested before surgery was placed. A bed of gel foam soaked with an antibiotic is made in the middle ear before placement of the graft. The slit is made in the graft for the accommodation of handle of malleus and handle of the malleus is exteriorized.

4. Results

A total of 42 patients were included in the study, of which 24 patients underwent ossiculoplasty with autologous incus and 18 patients with autologous cortical bone from 2015 to 2017. Postoperatively for a period of 6months the outcomes in terms of graft uptake rates, the formation of retraction pockets, recurrence rates and hearing improve ments were analysed. Average post op ABG closure of less than 20dB were considered as hearing improvement.

5. Discussion

Chronic suppurative otitis media is a long standing infection of a part or whole of the middle ear cleft. Incidence of chronic suppurative otitis media is higher in developing countries because of poor socioeconomic standards, poor nutrition and lack of proper health education. It can affect both sexes and all age groups. In India prevalence rate is more in rural than
in urban population and is the single most important cause for hearing impairment in rural population. Chronic suppurative otitis media can be of two types, Tubotympanic [safe or benign] and Atticoantral [unsafe or dangerous] types. Tubotympanic type remain localized to the mucosa of the middle ear cleft and the ossicular chain is usually intact and mobile but may show some degree of necrosis particularly long process of the incus. While in atticoantral type, it involves posterosuperior part of middle ear cleft namely attic, antrum, posterior tympanum and mastoid. It is associated with Cholesteatoma. Acicular chain necrosis is common in this type. Destruction may be limited to the long process of incus or may involve the stapes superstructure, handle of malleus or the entire ossicular chain [6, 7].

In all the cases patients have to undergo Tympanoplasty that includes repair of tympanic membrane plus the ossicular chain reconstruction. Austine Kartush made a classification for ossicular status. It has four different groups:- Group A is Malleus and Stapes present (common) because of precarious vascularity of incus. Group B- Malleus and footplate of stapes present Group C-Malleus absent and stapes present Group D- Malleus and stapes superstructure absent [8].

The most common ossicular chain dysfunction encountered is the necrosis of the long process of the incus, the malleus and the stapes being normal and is one of the main cause for moderate hearing loss in cases of CSOM. In others, there is additional loss of stapes superstructure, leaving only a mobile footplate and malleus. Yet in others only the footplate is left, all other ossicles, the malleus, incus and the stapes superstructure are destroyed. Various materials have been tried for ossicular chain reconstruction since many years and no ideal material is still standardized for the same. A wide range of prostheses, autologous and synthetic are available for use these days. Ideally, the ossicular reconstruction prosthesis should be bio compatible, safe, easy to handle and capable of efficient sound transmission. The materials used today are autograft, homograft and allograft. Irradiated homograft ossicles and cartilage were first introduced in the 1960s in an attempt to overcome some of the disadvantages of autograft implants. In the late 1970s, a high-density polyethylene sponge (HDPS) that had nonreactive properties was developed. The original form was a machined-tooled prosthesis (Plasti-Pore). A more versatile manufactured thermal-fused HDPS (Polycel) arrived later. Autograft materials include ossicles (malleus, incus), cartilages (septal, conchal cartilages) or cortical bone. They are all easy to harvest with less chance of extrusion rate, biocompatible, no risk of transmitting disease and no necessary for reconstitution. Disadvantages of autograft ossiculoplasty are: prolonged operative time, possible displacement or resorption, possibility of the autograft harboring microscopic cholesteatoma, poor fit if the stapes superstructure is absent. Allograft materials include those synthetic materials made of hydroxyapatite, titanium or glass ceramics. These are readily available and is pre-sculptured [8]. In our present study, outcomes of surgery with two autografts (Autoincus and autocortical bone) have been compared. In those patients with history of chronic suppurative otitis media with considerable hearing loss are taken up for surgery, and hose with necrosed lenticula process of incus underwent ossiculoplasty with either auto incus or auto cortical bone. With the usage of auto incus bone the availability and acceptance by the patient postoperatively will be better, but there will be restriction of modification of its size and shape for reconstruction. In case of using cortical bone it is easily available in the operative field and is similar to the ossicles and to any shape it can be reconstructed. According to a study by Berkowitz in 1978, a hollow drill is designed for harvesting bone graft. A report of Creutzfeldt-Jacob disease and a case of HIV infection was quoted following bone graft in JAMA update, 1987 and Centre for Disease Control 1988 [9]. In our study the outcome in terms of graft uptake rates, formation of retraction pockets, recurrence rates and hearing improvements were analysed. Average post op ABG closure of less than 20dB were considered as hearing improvement. And find no difference in the outcomes in the ossiculoplasties with autologous cortical bone and autologous incus with a follow-up period of six months in the patients.

6. Conclusion
Ossiculoplasties in cases of chronic suppurative otitis media with considerable hearing loss can be done with either autologous incus or autologous cortical bone with no significant difference in the outcomes following ossiculoplasties with either autologous incus or autologous cortical bone in terms of graft uptake rates, formation of retraction pockets, recurrence rates and hearing improvements.

7. Statement of author contributions
Indu Varsha Gopi: Contributed to the design of study, collected samples, did data analysis and drafted the manuscript. Corresponding author for the manuscript. KC Prasad: Contributed to the design of study, data analysis, helped frame and edited the manuscript; Balan Ashok Contributed to the design of study, data analysis and reviewed the manuscript. Anjali P K: Contributed to the design of study, data analysis and reviewed the manuscript. All authors read and approved the final manuscript. Conflict Of Interest The authors declare no conflict of interest or commercial affiliation related to this study.

8. Acknowledgements
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9. Legends to Figures
Fig 1: Figure 1a. Shows remodeling of the auto incus using 0-5mm diamond burr. Figure 1b. Shows ossiculoplasty with autologous incus and Figure 1c. Shows ossiculoplasty with autologous cortical bone.
10. Legends to Tables

Table 1: Comparison of groups of patients who underwent ossiculoplasty with autologous incus and autologous cortical bone.

<table>
<thead>
<tr>
<th>Parameters</th>
<th>Auto Incus</th>
<th>Auto cortical bone</th>
</tr>
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<tbody>
<tr>
<td>Age group (years)</td>
<td>33.2±5</td>
<td>33.3±5</td>
</tr>
<tr>
<td>Male:female</td>
<td>11:13</td>
<td>09:09</td>
</tr>
<tr>
<td>Graft rejection with residual perforation</td>
<td>Nil</td>
<td>Nil</td>
</tr>
<tr>
<td>Retraction pocket formation</td>
<td>Nil</td>
<td>Nil</td>
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<tr>
<td>Post of ABG closure (dB)</td>
<td>81% [n=18]</td>
<td>83% [n=15]</td>
</tr>
<tr>
<td>Type of assembly</td>
<td>Malleus to stapes superstructure</td>
<td>Malleus to stapes footplate</td>
</tr>
<tr>
<td></td>
<td>19 (79%)</td>
<td>16 (88.8%)</td>
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<tr>
<td></td>
<td>(20.8%)</td>
<td>(11.1%)</td>
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11. Research involving human participants

All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional committee Institutional ethical committee approved and information waivers for retrospective study of remaining samples.

12. Informed Consent

Approval for the study was obtained from the Institutional Ethics Committee. Informed consent was not required for this study.

13. References