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ORIGINAL ARTICLE

Comparision of Allogenic Cartilage and Autologous Cortical Bone in Ossicular Reconstruction: A Comparative Study

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Abstract Ossicular discontinuity is the most common cause of conductive hearing loss. The use of ossicular graft material in ossicular chain reconstruction significantly improves the result in hearing. This study was conducted to compare and analyze the outcome of ossicular reconstruction using allogenic septal spur cartilage and autologous cortical bone in terms of hearing results and graft uptake rates. Study design: randomized clinical trial. Study included 112 patients visiting our ENT department. Patients between 16 and 50 years of age with history of chronic ear discharge and air–bone–gap (ABG) of > 35 dB and ossicular involvement were included in the study. The patients underwent detailed ENT examination, audiological and radiological assessment of temporal bone and those patients with evidence of ossicular erosion were subjected to ossiculoplasty with allogenic septal spur cartilage (group I) and autologous cortical bone (group II) randomly. The patients were followed up to 6 months to analyze functional and anatomical results. 50 patients out of 56 patients (90%) from group I who underwent allogenic septal cartilage ossicular reconstruction showed significant improvement in hearing as assessed by pure tone audiogram after 3 months and 6 months. Remaining 10% of patients who did not show hearing improvement on PTA were reopened after 6 months. It was observed that the stapes head got necrosed in them. 40 patients (72%) out of 56 patients (50%) from group II who underwent autologous cortical bone reconstruction showed hearing improvement. Remaining 16 patients (28%) showed no hearing improvement. They were reopened and ankylosis, dislocation of ossicle and extrusion were noted. In our study, graft uptake rates, formation of retraction pockets, and hearing improvements were analyzed. Complications like ankylosis formation, dislocation of ossicle and extrusion rates were more in the group II compared to group I. Hearing results of group I are better compared to group II and the allogenic septal cartilage being readily available is a good option for ossicular reconstruction.

Keywords Ossiculoplasty · Allogenic septal spur cartilage · Autologous cortical bone

Introduction

Reconstruction of the conductive mechanism is one of the most interesting topics in middle ear surgery. Ever since Matte's first myringostapediopexy there has been an extensive search for the ideal middle ear implant with the understanding that the middle ear environment in chronic ear disease is probably the main factor in determining treatment success [1, 2].

A moderate conductive hearing loss of > 35 dB, can indicate ossicular (Malleus, Incus, Stapes) discontinuity-commonly from the erosion of long process of incus or stapes suprastructure. Loss of ossicles or discontinuity of

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the ossicular chain is the most common cause of conductive hearing loss in adults [3, 4]. Definitive treatment includes primary clearance of the disease from the middle ear cleft and ossicular reconstruction.

Outcome of ossiculoplasty are affected by many factors. Eustachian tube function, adhesions and the status of the residual ossicular chain are some of the intrinsic factors, while the extrinsic factors are the surgical technique and the design and composition of the prosthesis used [5, 6].Over the years, various grafts (auto grafts/allografts) have been used for ossicular reconstruction. Homograft and autograft ossicles, cartilage, alloplastic ossicular prostheses like Total or Partial Ossicular Replacement Prosthesis, ceramic implants, hydroxyapatite, bone cements, titanium, gold etc. are being used [7]. Some studies have reported that equally good results maybe achieved with autograft, homograft or alloplastic partial prosthesis [8].

Hearing improvement varies depending up on several factors like the material used, the stage of the disease, degree of destruction, state of middle ear mucosa, eustachian tube function and the degree of pre-operative hearing loss. The ENT surgeons are still confronted with problems of ossicular reconstruction regarding the surgical procedure to be done, type of graft to be selected especially in low and poor socioeconomic population. Thus, there is a need to comprehensively and holistically evaluate the outcome of ossiculoplasty using homologous graft ossicles versus autologous graft ossicles.

In our study, we have compared the results of ossiculoplasty in terms of hearing improvement and graft acceptance rates postoperatively by using allogenic septal cartilage and autologous cortical bone.

Materials and Methods

This study was conducted in patients of age group between 16 and 50 years attending the tertiary health care center with adequate outpatient, inpatient, and diagnostic capabilities during the period July 2017 to August 2019. Patients with chronic suppurative otitis media (CSOM) with an air–bone–gap (ABG) of > 35 dB and ossicular involvement were included in the study.

Patients who suffered from complications of CSOM, mixed hearing loss, acute suppurative otitis media, otosclerosis, cholesteatoma were excluded from the study. All the patients underwent detailed ENT examination followed by audiological and radiological assessment of temporal bone and those patients with evidence of ossicular erosion were subjected to ossiculoplasty with allogenic septal spur cartilage (group I) and autologous cortical bone (group II).

Compliance with Ethical Standards

All the authors declare that they have no conflict of interest. Ethical clearance was obtained from appropriate ethical committee for research on human subjects. Written informed consent was obtained from all the subjects using the standard consent form approved by the ethical committee.

Surgical Technique

Among 112 patients included in the study, 56 patients underwent ossiculoplasty with allogenic septal spur cartilage and 56 patients with autologous cortical bone. All patients underwent canal wall up cortical mastoidectomy.

The operation was done under general anaesthesia by postaural route in all cases. Autologous Cortical bone was procured from the patient intraoperatively and shaped accordingly. Fig. 1 shows drilling the cortical bone. Similarly the Homograft Septal Cartilage was procured from vomero-chondrine groove during septoplasty and preserved in 70% absolute alcohol. Fig. 2 shows cartilage refashioning. When cartilage was needed for reconstruction, it was washed in saline for 1 h in the operating room. It was shaped using a 15 number blade such that the length just protrudes through the neotympanic membrane. Further the superior contact surface of the cartilage/bone should be sloping to have enough contact area (at least 52 mm) and the margins made smooth so that there were no sharp edges against the tympanic membrane. To keep it on the stapes head, the inferior portion of the cartilage/bone was drilled using 0.6 mm diamond burr to form a socket and a groove for stapedius tendon was designed using 15 number blade.

After securing the temporalis fascia graft and tympanomeatal flaps in the anterior sulcus with underlay

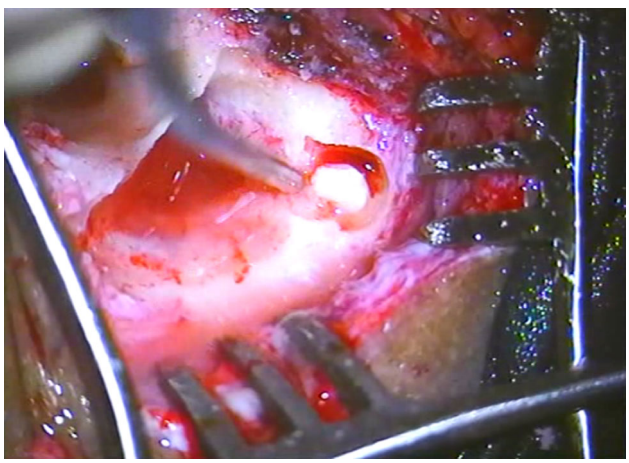


Fig. 1 Drilling the cortical bone

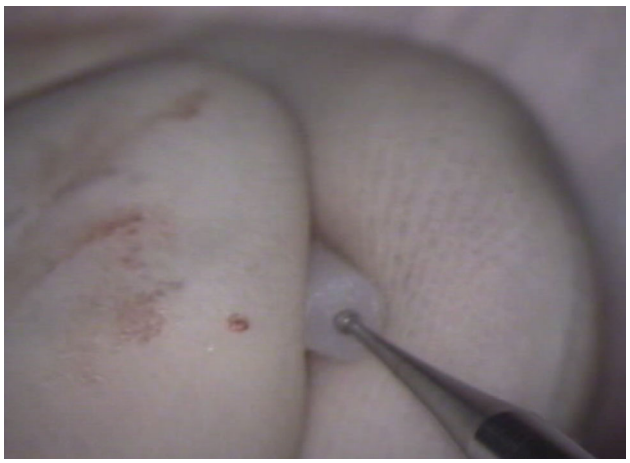
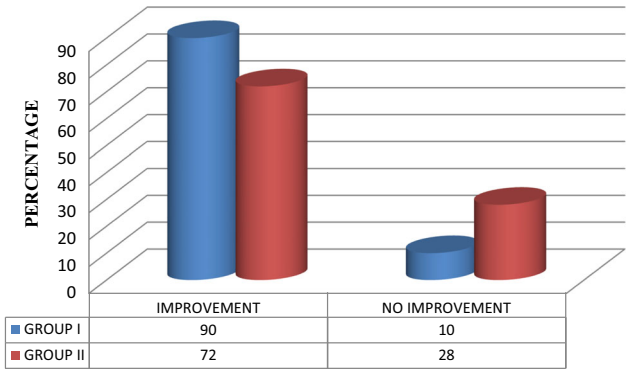


Fig. 2 Cartilage refashioning

technique (in closed cavity procedure), the temporalis fascia graft was gently elevated posteriorly till the oval window area was visualized. The graft was placed over the stapes head using a 22 gauge suction cannula and smooth curved pick. After placing the cartilage/bone its stability over the stapes was confirmed. Figure 3 shows cartilage placed on stapes head.

The newly placed cartilage/bone was temporarily supported by gel foam soaked in antibiotic eardrops. Care was taken to prevent contact between newly placed cartilage/bone and surrounding structures (posterior bony rim, lateral attic wall, facial canal, promontory or conchal cartilage). The temporalis fascia graft was repositioned. The external auditory canal was filled with antibiotic solution and the cotton ball covered with antibiotic ointment kept over it.

Fig. 3 Cartilage placed on stapes head



Graph 1 Comparision of hearing outcome between Group I AND Group II

Outcome Measures

PTA was done 3 months and 6 months post operatively and the values were taken for calculation. In our study the outcome in terms of graft uptake rates, and hearing improvements were analyzed

Results

A total of 112 patients were included in the study, of which 56 patients underwent ossiculoplasty with allogenic cartilage and 56 patients with autologous cortical bone from July 2017 to August 2019. Postoperatively PTA was done at 3 months and 6 months. 50 patients (90%) out of 56 patients from group I who underwent allogenic septal cartilage ossicular reconstruction showed significant improvement in hearing as assessed by pure tone audiogram after 3 months and 6 months in comparison to 40 patients (72%)out of 56 patients from group II post op hearing results are shown in Graph 1. Who showed hearing improvement after undergoing autologous cortical bone reconstruction. Complications like ankylosis formation, dislocation of ossicles and extrusion rates were more in the group II compared to group I. Hearing results of group I are better compared to group II and the allogenic septal cartilage being readily available is a good option for ossicular reconstruction. Average post op ABG closure of less than 20 dB were considered as hearing improvement.

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

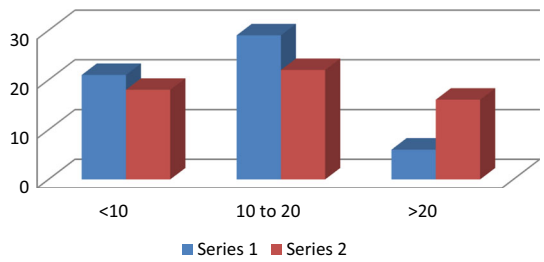
both sexes and all age groups. In India prevalence rate is more in rural than in urban population and is the single most important cause for hearing impairment in rural population.

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.

Current techniques of ossiculoplasty have evolved empirically as a result of trial and error. With the evolution of newer surgical techniques and advances in the instrument armamentarium available to the otologist, the hearing outcome of ossiculoplasty has shown a noticeable improvement over recent years.

In our study, a total of 112 cases of chronic otitis media were enrolled and divided into two groups. The patients underwent detailed ENT examination, audiological and radiological assessment of temporal bone and those patients with evidence of ossicular erosion were subjected to ossiculoplasty with allogenic septal spur cartilage (group I) and autologous cortical bone (group II) randomly. The patients were followed up to 6 months to analyze functional and anatomical results. Out of 56 patients from group I who underwent allogenic septal cartilage ossicular reconstruction 50 patients (90%) showed significant improvement in hearing as assessed by pure tone audiogram after 3 months and 6 months. Remaining 10% of patients who doesn't show hearing improvement on PTA were reopened after 6 months. It was observed that the stapes head got necrosed in them. In comparison to 56 patients (50%) group II who underwent autologous cortical bone reconstruction 40 patients (72%) showed hearing improvement. Remaining 16 patients (28%) had no hearing improvement. Post op hearing results are shown in Graph 1. They were reopened and we noted ankylosis, dislocation of ossicle and extrusion.

Postoperative ABG, was < 20 dB in 90% cases in group I and 72% in group II (Graph 2). This is in accordance with a study showing Postoperative ABG within 20 dB in 74% at latest follow-up [9]. In another study by Sendra et al. [10] in which homologous cartilage was used for ossicular reconstruction, closure of the ABG to within 20 dB was achieved in 10 of 20 patients (50%). Post operative air–bone–gap results are shown in Table 1.



Graph 2 Comparision of post operativehearing results in allogenic-septal spur and autologous cortical bone

Table 1 Comparison of postoperative hearing results with allogenic cartilage graft and autologous cortical bone graft

Postoperative AB closure gap	Allogenic cartilage (%)	Autologous cortical bone (%)
< 10	21 (38)	18 (33)
10–20	29 (52)	22 (39)
> 20	6 (10)	16 (28)

AB = air–bone–gap

Table 2 Comparison of groups of patients who underwent ossiculoplasty with allogenicseptal spur and autologous cortical bone

Parameters	Allogenicseptal cartilage	Autologus cortical bone
Male:female	26:30	27:29
Ankylosis	0	5
Extrusion	0	6
dislocation of ossicles	0	5
Necrosis of stapes head	6	0
Graft rejection with residual perforation	Nil	Nil

In our study the outcome in terms of graft uptake rates, extrusion, dislocation and necrosis of ossicles and hearing improvements were analyzed. The data for the above outcome are shown in Table 2. Average post op ABG closure of less than 20 dB were considered as hearing improvement. Complications like ankylosis formation, dislocation of ossicle and extrusion rates were more in the group II compared to group I. Hearing results of group I are better compared to group II.

Conclusion

Ossiculoplasty with cartilage offers a good alternative with minimal complications and extrusion rates. Moreover autografts have some disadvantages like lack of availability in chronically diseased ears, bone may not be available in extensive cholesteatoma extending up to mastoid cortex, prolonged operation time to obtain and reshape the material and/or loss of rigidity. On the other hand cartilage is easily available and stored in absolute alcohol thus convenient for otologists. Conclusion is that readily available homologous cartilage graft do compete with the well established choice of autograft cartilage and can be used for ossicular reconstruction with good results without any risk of

complications. Theoretically it is shown that the main disadvantage of these grafts are transmission of prions however there is no such evidence of prions transmission using septal cartilage. It is worthwhile to conclude that there is a need for many clinical trials with larger sample size and longer follow up period to standardize the ossiculoplasty techniques.

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Author Contributions KP Contributed to the design of study, collected samples, did data analysis and drafted the manuscript. Corresponding author of the manuscript. KCP Contributed to the design of study, data analysis, helped to frame the manuscript. MBS Contributed to the design of study, data analysis and reviewed the manuscript and helping me in editing the article. PKA Contributed to the design of study, data analysis and reviewed the manuscript. IG Contributed to the design of study, data analysis and reviewed the manuscript and helping me in editing the article. All authors read and approved the final manuscript.

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Compliance with Ethical Standards

Conflict of interest Authors declare no conflict of interest

Ethical Approval Taken from the Sridevaraj medical college ethical committee.

Human and Animal Rights All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional committee, Institutional ethical committee approved it.

Informed Consent Approval for the study was obtained from the Institutional Ethics Committee. Informed consent was required for this study.

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