Original Article

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Hearing outcome following ossicular reconstruction for incus defects using partial ossicular replacement prosthesis

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Abstract

Background: Situation of incus erosion is common while performing tympanoplasties for cases of chronic otitis media. As none of the available techniques is said to be gold standard, a cost effective and easily available partial ossicular replacement prosthesis is employed and the postoperative hearing outcome is presented.

Objectives: To assess the hearing results of ossiculoplasty using partial ossicular replacement prosthesis during tympanoplasty.

Methodology: A descriptive cross-sectional study was carried out in a tertiary referral hospital of Nepal from June 2018 to September 2019. Twenty-eight consecutive patients who underwent tympanoplasty for chronic otitis media (inactive/mucosal) with incudostapedial discontinuity were operated using polytetrafluoroethylene partial ossicular replacement prosthesis without removing the incus. Pure tone averages, air-bone gap and air conduction gain were calculated pre and post-operatively.

Results: There was no extrusion of prosthesis. The post-operative air-bone gap less than 20 dB was achieved in 23 (77%) cases. All the patients had post-operative air-bone gaps of ≤25dB. There were no major complications.

Conclusion: Polytetrafluoroethylene partial ossicular replacement prosthesis is a safe, reliable and efficient alternative for ossiculoplasty during tympanoplasty surgery.

Key words: Incudostapedial discontinuity; Ossiculoplasty; Partial ossicular reconstructive prosthesis; Tympanoplasty.

INTRODUCTION

Chronic otitis media (COM) is the leading cause of conductive hearing impairment secondary to damage of the tympanic membrane and/or middle ear ossicles. The aim of the tympanoplasty surgery is to eradicate the disease and restore the hearing mechanism. It is common to find situations of incus erosion even while operating for mucosal COM. Reconstruction of such defects to restore the conductive mechanism of the middle ear is one of the most intriguing topics in middle ear surgery.

The most common cause for the ossicular chain discontinuity in COM is erosion of lenticular or long processes of incus with intact malleus and stapes[1]. Various options available for ossicular reconstruction for such defects are biological materials like autograft or homograft, cortical bone, cartilage and alloplastic materials like polytetrafluoroethylene (PTFE), silastic, proplast, titanium or gold[2].

The ideal prosthesis for ossicular reconstruction should be biocompatible, stable, safe, light weight,

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easily insertable and capable of yielding optimal sound transmission. Among the biological materials, sculptured incus interposition was the first and most widely used technique pioneered by Hall and Rytzner in 1957[3]. Partial necrosis and ankylosis of the bony walls are the recognizable complications of this technique. The next option after this is the use of partial ossicular replacement prosthesis (PORP), which is cost effective and easily available. Here, we present an early result of hearing outcome following ossicular reconstruction for incus defects using polytetrafluoroethylene PORP during tympanoplasty surgeries in COM inactive mucosal.

METHODOLOGY

With the approval from the Institutional Review Committee (Ref. no:0106201801), a descriptive cross-sectional study was carried out in the Department of Otolaryngology Head and Neck Surgery at Kathmandu Medical College Teaching Hospital, Kathmandu, Nepal from June 2018 to September 2019. All the cases destined for tympanoplasty due to chronic otitis media inactive mucosal having air-bone gap (ABG) > 25 dB and lenticular or long process of incus erosion who gave informed consent were included in the study. Patients having cholesteatoma, stapes fixation, sensorineural hearing loss, ossicular chain defect other than incus or previous same ear surgery were excluded. The sample size was calculated by using the formula,

$$n = Z^2 \times p \times q/e^2$$
$$= (1.96)^2 \times 0.077 \times 0.923 / 0.1^2$$
$$= 27.55$$
$$\sim 28$$

Where, n = sample size,

Z = 1.96 at 95% confidence level,

p= prevalence (0.077)[4],

q = 1-p,

e = margin of error (10%).

The surgery was performed under local anesthesia via post aural route. Margin of the perforation was freshened and temporalis fascia graft harvested. After the elevation of the tympanomeatal flap, the middle ear was exposed and the ossicular chain was inspected under microscope for its integrity and mobility. Only the cases with lenticular or long processes of incus erosion were selected for the study. The defective incus was gently pushed up into the attic region but not discarded. The malleus handle was denuded from the tympanic membrane and was gently retracted posteriorly with the help of 90-degree hook until it came to lie directly over the stapes head. Special attention was given not to violate the superior ligament of the malleus. The PTFE PORP (EON Meditech Pt. Ltd., Surat, India) was trimmed to an appropriate length, inserted into the stapes head and the flat prosthesis head rested directly medial to malleus handle without tension. The extra stability to the prosthesis head was provided by a cartilage support harvested from the concha through the same post auricular incision. The malleus handle was fitted into a small groove made in the same piece of cartilage as suggested by Baylancicek et al[5]. The temporalis fascia graft was placed medial to tympanic membrane remnant but lateral to handle of malleus (over-underlay technique). Middle ear and external auditory canal were packed with pieces of gelfoam to support the graft. The wound was closed in layers and the patients were discharged on the same day of surgery with a course of antibiotic, anti-inflammatory and systemic decongestant. Sutures were removed on the sixth post-operative day and regular follow-up was done.

Audiometric assessment was done before, at three months of surgery, then biannually. Air conduction (AC) and bone conduction (BC) pure tone averages (PTAs) were measured at 500, 1000, 2000 and 3000 Hz according to the Committee on Hearing and Equilibrium of the American Academy of Otolaryngology - Head and Neck Surgery guideline[6]. Pre-operative and post-operative PTAs and air-bone gap (ABG); post-operative AC gain were measured. The procedure was said to be successful when there was a closure of ABG within 20 dB in post-operative audiogram.

Statistical analysis was done using the IBM Statistical Package for the Social Sciences (SPSS) Statistics for Windows, version 20 (IBM Corp., Armonk, N.Y., USA). Descriptive statistics was presented including mean, standard deviation, frequency and percentage. p-value less than 0.05 was considered significant.

RESULTS

Out of all the tympanoplasties performed by the first investigator during the study period, 28 cases which fit into the inclusion criteria of this research design were analysed. Descriptive parameters like age, sex and audiological findings are presented in Table 1. Post-operative ABG less than 20 dB was achieved in 23 (77%) cases. The worst post-operative air bone closure was 25 dB in our series. Extrusion of the prosthesis or granulation tissue was not seen in any of the cases. Except for two post-operative reperforations, there were no other complications. There was no significant difference in Bone conduction Pure Tone Average before and after surgery. However there was a significant difference in Air conduction Pure Tone Average and Air-bone gap before and after surgery.

Table 1: Demographic variables and comparison of preoperative and post-operative hearing outcome

Characteristics	Findings	P value
Age in years (Mean ± SD)	33 ± 15	
Sex n (%)		
Male	17 (61)	
Female	11 (39)	
Bone conduction Pure Tone Average (PTA) in dB		
Preoperative (Mean ± SD)	5.80 ± 5.54	>0.05
Post-operative (Mean ± SD)	5.07 ± 4.47	
Air conduction Pure Tone Average (PTA) in dB		
Preoperative (Mean ± SD)	42.03 ± 6.21	<0.001
Post-operative (Mean ± SD)	21.08 ± 7.07	
Air-bone gap (ABG) in dB		
Preoperative (Mean ± SD)	35.90 ± 7.16	< 0.001
Post-operative (Mean ± SD)	16.01± 4.86	
Post-operative air conduction gain in dB (Mean ± SD)	21.55 ± 6.05	

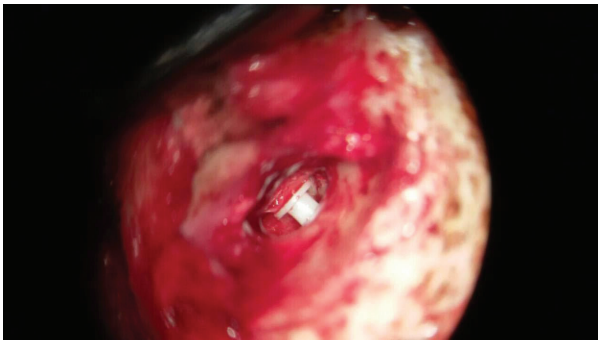

Figure 1: Intraoperative photo using PORP

DISCUSSION

Tympanoplasty is one of the most commonly performed otological procedures. Whenever the air-bone gap exceeds 25dB in a case of mucosal COM, the operating surgeon should consider possible ossicular chain defects apart from tympanic membrane perforation. The most frequently encountered ossicular defect during tympanoplasty is the erosion of long process or the lenticular process of incus[7]. It is common to encounter incus erosion during tympanoplasty even for mucosal COM. The incidence of such situations varies as stated in the literature from 5.5% to 24.1%[4].Varieties of surgical techniques and reconstruction prosthesis are available to repair this kind of ossicular defect, each having its own advantages and disadvantages.

Hall and Rytzer, using an incus autograft, performed the first ossicular reconstruction[3]. The advantages of autograft were easy availability, low cost, low extrusion rate and biocompatibility. Even though it is still the most widely used technique, it has disadvantages like necrosis, displacement, difficult and time consumption while shaping and vascular compromise due to drill burn. Autograft materials may not be available or the cholesteatomatous ossicle may have microscopic foci that preclude their use. Because of this, alcohol preserved or irradiated homograft ossicles and cartilage were first introduced in 1960. House, Patterson and Linthicum were the first to introduce homologous incus for ossiculoplasty in 1966[3]. However, this technique also carried potential risks of infection. This is why combined efforts between biomaterial scientists and surgeons led to the manufacture of different alloplastic materials for implantation.

Synthetic prosthesis made from plastic, metal or ceramic has been used as a PORP for incus erosion. This type of prosthesis has gained popularity because of its easy availability and ease of application. However, it also inherits potential disadvantages like extrusion or displacement, particularly when the middle ear is infected or the eustachian tube function is poor[5]. This extrusion can be minimized by the placement of a cartilage between the prosthesis and the graft[8].

The success of the ossiculopalsty is defined by the closure of the post-operative air-bone gap (ABG). The standard guideline[5] has given the cutoff point of 20 dB. A success rate of 77% (n=23) was achieved in the present study which is in accordance with other reports[9,10,11]. Hess-Erga et al[10]. reported a success rate of 82% in 44 PORP with a mean 5.2 years follow-up. Extrusion rate in this series was 5%. Berenholz et al[11]. in a similar study reported a success rate of 81.2% with PORP in 4.3 years with only one extrusion.

The presence and position of malleus is a key factor affecting ossiculoplasty result because of better hearing

and low rate of extrusion. The ideal ossiculoplasty happens when the malleus is positioned directly over the stapes[12,13]. The same concept was adopted in current study using a 90-degree hook during its dissection and retraction of the malleus posteriorly. The PORP was nicely fitted at the medial surface of the malleus without tension and was supported by cartilage. These might be the main causes for non-extrusion of prosthesis in any of the cases in our series. In contrast, Brackmann et al. and Goldenberg found the contribution of the malleus handle to be insignificant[14,15].

We did not discard the remnant of the incus as described in most of the literature. Rather, it was mobilized superiorly into the attic region with a hope to reuse it as an autoplastic material for revision surgery if the prosthesis extruded. A small number of patients and the shorter follow-up periods (maximum 22 months to minimum six months) are the main limitations of this study.

CONCLUSION

Polytetrafluoroethylene PORP is an easy, safe and effective material for the management of incus erosion during tympanoplasty and shows a significant change in Air-conduction Pure Tone Average and Air-bone gap before and after surgery. A larger series with longer follow up is recommended.

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