

Original Research Article

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Single centre experience of ossiculoplasty using different materials: a subjective and objective evaluation

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ABSTRACT

Background: Chronic otitis media has serious impact over the ossicular integrity in middle ear resulting in ossicular necrosis and various grades of hearing loss along with other associated symptoms. Tympanomastoidectomy with ossicular reconstruction using various materials can improve the symptoms.

Methods: A retrospective study of 50 patients underwent tympanomastoidectomy with ossiculoplasty in Department of ENT and Head and Neck Surgery at AIIMS Patna from April 2017 to 2018. Patients with chronic otitis media having ossicular necrosis with ABG (air bone gap) more than 25 dB were included in this study. PORP (partial ossicular reconstruction prosthesis) and TORP (total ossicular reconstruction prosthesis) were used as ossicular reconstruction after clearance of disease. This study was expressed as subjective and objective evaluation following ossiculoplasty.

Results: Fifty patients having chronic otitis media with decreased hearing and other associating symptoms were included in this study. Preoperative air conduction threshold was 55.32 dB with preoperative ABG was 44.24 dB. Postoperative result was summarised as postoperative AC threshold was 32.72 dB with gain of 22.60 dB with ABG 25.45 dB.

Conclusions: Chronic otitis media may lead to ossicular necrosis and various grade of hearing loss. A proper technique and skilled tympanomastoidectomy with ossiculoplasty can improve the symptoms of chronic otitis media.

Keywords: Air bone gap, Air conduction, Bone conduction, Decibel, Partial ossicular reconstruction prosthesis, Pure tone audiometry, Total ossicular reconstruction prosthesis,

INTRODUCTION

Ossicular integrity is an integral aspect of middle ear conductive mechanism. Discontinuity of ossicular integrity may lead to moderate to severe conductive hearing loss. Ossicular discontinuity can occur as a sequel of chronic otitis media or due to trauma. 60 to 70% otology patients suffer from conductive hearing loss due to ossicular defect.^{1,2} Ever since Matte's first myringostapediopexy in 1901, there has been a quest for the ideal middle ear implant with the understanding that middle ear environment in chronic ear disease is probably the main factor in determining treatment success.³

Ossiculoplasty is done using either biological or alloplastic materials.⁴

Earlier the most common and accepted material used for ossicular reconstruction were auto grafts and allograft but it fell out of repute because of fear of prion diseases. Due to potential risk of prion diseases and various disadvantages of autograft and allograft material, biomaterial scientists and otologists were concerned for material having least potential for infection and accommodative for middle ear environment. Over the last several decades there has been a major shift of most widely used autograft to different prosthesis. With

numerous prostheses available, the otologist has a wide array from which to choose, but may find it difficult to know which middle ear implant works best.⁵ In the last 10 years, proponents of utilizing titanium as the ideal middle ear implant have reported their results in numerous reviews.⁶ Alloplastic materials includes metals (titanium and gold), plastics (plastipore, proplast, polyethylenes, polytetrafluoroethylene, or Teflon) and biomaterials (ceramics and hydroxyapatite).⁷ Combined efforts of both biomaterial scientists and otologists have led to manufacture of various alloplastic materials. Most commonly used materials are teflon and titanium. The role of cartilage in the field of hearing reconstructive surgery can never be overlooked even today.

The aim of this study was to focus on the results of different ossiculoplasty materials used to do ossiculoplasty in ear surgeries in terms of objective hearing gain and subjective improvement of patient's symptoms.

METHODS

This was a retrospective study is based upon a series of 50 patients who underwent ossiculoplasty in Department of ENT of All India Institute of Medical Sciences, Patna over the period of one year from April 2017 to April 2018.

Inclusion criteria

Patients between age group between 12-42 years; hearing loss with air bone gap (ABG) more than 25 dB; and both squamous and mucosal disease were included.

Exclusion criteria

Any patient having complication other than hearing loss; revision surgery, patients with fixed stapes foot plate due to either otosclerosis or tympanosclerosis were excluded.

All the patients were evaluated in detail first using otoendoscopy and then under microscope in the outpatient department. This was also followed by tuning fork tests after which pure tone audiogram (PTA) was done. HRCT temporal bones were done for all these patients who we were planning to operate for ear pathology. HRCT temporal bones was much superior than x-ray mastoid and gives excellent view of the extent of middle ear disease, ossicular chain status, status of erosion of scutum and other vital structures. Fistulas are best assessed on CT scans. HRCT also helps in decision making about the extent of surgery and proposed plan for ossiculoplasty. Ossicular necrosis is suspected in patients having ABG more than 25 dB.

In this study we included patients where allografts titanium and Teflon PORP and TORP were used. The other material used was autologous cartilage (tragal or chonchal).

Ossiculoplasty was done in three different scenarios viz tympanoplasty, intact canal wall/canal wall up mastoidectomy (CWU), canal wall down mastoidectomy (CWD).

The decision of surgery was based on the extent of middle ear disease. Partial ossicular reconstruction prosthesis (PORP) was used when the stapes suprastructure was intact and mobile and total ossicular reconstruction prosthesis was used when stapes suprastructure was absent and only a mobile stapes footplate was present. We used Teflon TORP in 10 cases, Teflon PORP in 9 cases, titanium TORP in 7 cases and titanium PORP in 11 cases. Refashioned tragal cartilage of the patient was used as a strut on the stapes footplate (TORP) in 4 cases and cartilage over stapes head (PORP) in 9 cases.

A piece of cartilage was always placed above the prosthetic material to prevent extrusion. Temporalis fascia graft was placed over the cartilage for reconstruction.

Postoperative period was uneventful and none of the patient complains about the postoperative dizziness and facial palsy. Stitches removal done on day 7 and aural wick removal done on day 14. All patients followed precaution against water entry, nose blowing and upper respiratory tract infection for three weeks duration. Otoendoscopy was done on day 15 and at one-month duration. Repeat audiogram was performed at three months of follow up. Objective improvement in hearing was recorded. Subjective improvements of symptoms was assessed from a questionnaire routinely filled by patients which records attributes of decrease hearing, tinnitus, heaviness, itching and pain apart from intermittent ear discharge. Success of surgery was depending upon the subjective and objective improvement.

RESULTS

50 case of ossiculoplasty were studied in this retrospective study. Out of 50 patients 30 patients (60%) were male and 20 patients (40%) were female. The mean age at which they were operated was 23.46 years for male and 25.7 years for female and overall mean age was 24.36 years. Most of the patients presented with intermittent ear discharge followed by decrease hearing. Out of 50 patients cholesteatoma was present in 40 patients (80%) with involvement of mastoid antrum, aditus and attic along with ossicular involvement. In 20% of patients mastoid air cell was well pneumatized but presented with ossicular erosion. Long process of incus was the most commonly involved part of ossicular chain and involved in almost all cases studied in this descriptive study. Stapes super structure was the second most common involved ossicles. Stapes superstructure necrosis along with necrosis of incus was present in 29 (58%) patients. Intact superstructure was present in 21

(42%) patients. Malleus involved in 30% of cases. Impairment of hearing was tested with pure tone audiometry (PTA) and each patient included in study had conductive or mixed hearing loss. Average of AC (air conduction) was 55.32 dB and BC (bone conduction) was 15.62 dB. Mean of air bone gap (ABG) was 44.24 dB. All cases underwent ear surgery and out of 50 patients, canal wall up mastoid exploration with type 3

tympanoplasty was done in 22 patients (44%). Canal wall down mastoid exploration with type 3 tympanoplasty was done in 18 (36%) patients and simple tympanoplasty with ossicular 9676 c9c-9 reconstruction was done in 10 patients (20%). Temporalis fascia was used as graft material in all cases. Teflon, Titanium and Autologous Tragal cartilage was used as an ossicular reconstructive material after proper length measurement in this study.

Table 1: CWD (canal wall down), CWU canal wall up), PORP (partial ossicular reconstruction prosthesis), TORP (total ossicular reconstruction prosthesis).

| Procedure | No. | PORP | TORP | Preoperative PTA | Postoperative PTA | Average gain |
|-------------------------------------------------|-----|------|------|------------------|-------------------|--------------|
| CWD mastoidectomy + type 3 tympanoplasty | 18 | 7 | 11 | 54.85 dB | 34.31 dB | 17.51 dB |
| CWU mastoidectomy + type 3 tympanoplasty | 22 | 12 | 10 | 53.61 dB | 37.23 dB | 16.38 dB |
| type 3 tympanoplasty | 10 | 8 | 2 | 52.46 dB | 29.84 dB | 22.62 dB |

Table 2: Preoperative ABG with SD (standard deviation), post-operative ABG with SD, average gain of ABG with SD or reduced ABG are summarized in chart.

| Types of prosthesis | Pre-operative ABG | Post-operative ABG | Average gain ABG |
|-----------------------|-------------------|--------------------|------------------|
| | Mean±SD | Mean±SD | Mean±SD |
| Teflon TORP | 48.10±8.90 | 25.49±10.14 | 22.61±1.24 |
| Teflon PORP | 44.88±23.77 | 24.36±7.26 | 20.52±16.51 |
| Titanium TORP | 45.85±11.18 | 26.42±5.53 | 19.43±5.65 |
| Titanium PORP | 43.33±5.77 | 23.01±4.06 | 20.32±1.71 |
| Cartilage TORP | 52.08±11.01 | 28.83±7.54 | 23.75±3.47 |
| Cartilage PORP | 40.07±8.59 | 19.98±13.61 | 20.09±5.02 |

Out of 50 patients Teflon TORP was used in 10 cases (20%), Teflon PORP was used in 9 cases (18%), titanium TORP was used in 7 cases (14%), titanium PORP was used in 11 cases (22%), fashioned cartilage TORP was used in 4 cases (8%) and fashioned cartilage PORP was used in 9 cases (18%). Hearing assessment of each post operated patient was done on three month of follow up period and post-operative mean air conduction threshold was 32.72 dB. Average of hearing gain of postoperative patients was 22.60 dB. Preoperative air bone gap (ABG) of each 50 patients was calculated and the mean value of air bone gap (ABG) was 44.24 dB. On the three month of postoperative period, hearing assessment was done and the excellent air bone gap was achieved. Average value of postoperative air bone gap (ABG) was reduced and the value was 25.45 dB. Gain of air bone gap was (ABG) was 18.79 dB. Assessment of subjective improvement in the postoperative period was done by analyzing the answers of a questionnaire related to patient symptoms

given to them at three month follow up visit. Out of 50 patients only 4 patients (8%) complained about persistence of heaviness in ear following surgery. Tinnitus persisted in 5 (10%) patients. Out of 50 patients 2 (4%) patients had postoperative residual perforation with persistence of mucopurulent discharge, and out of these two, one has extrusion of prosthesis (Teflon TORP). Out of 50 patients, 49 (98%) patients had improvement of hearing following ossiculoplasty and only 1 (2%) patient has worsening of hearing postoperatively. Postoperative pain persisted in 2 (4%) patients. None of the patient complained of vertigo following ossiculoplasty.

DISCUSSION

Current techniques of ossiculoplasty have generally evolved empirically as a result of trial and error. The first correction of ossicular defect was done by Zollner in 1955.⁸ With the evolution of newer surgical techniques and advancement in the operative instruments armamentarium, hearing outcome of ossiculoplasty has shown a noticeable improvement over the recent years.⁹

Much of the variability in the literature concerning hearing results after ossiculoplasty is due to lack of understanding and uniform reporting of those middle ear factors that influence the results.¹⁰

The otologic surgeon does not easily control certain variables such as middle ear fibrosis, adhesive otitis, and significant eustachian tube dysfunction. However, two variables that can be controlled by the surgeon are the type of prosthesis used and the manner in which the prosthesis is used.¹¹

Success of ossiculoplasty depends upon the following factors, otologist skill with technical ability, quality and

stability of ossicular replacement materials and favourable middle ear environment.

The actual challenge during ossiculoplasty was how to achieve a stable and proper connection between stapes footplate (with or without stapes superstructure) and tympanic membrane for a good and satisfactory hearing result. There is a need of proper disease free middle ear environment with good eustachian tube function for sound stability of ossicular replacement in chronically infected ear. Chronically infected ears have potency to resorption and extrusion of prosthesis.

In this retrospective study, 50 patients were taken up for evaluation. They were presented with ear discharge and decrease hearing. Age ranged from 14 to 42 years for male and 12 to 37 years for female. Male female ratio was 3:2 with male predominance.

This study assessed both subjective and objective improvement after ossiculoplasty. Subjective improvement is defined as improvement of symptoms of chronic otitis media after surgical management that patients expressed at time of clinical examination. Most common symptoms associated with chronic otitis media in this study were decrease hearing, tinnitus, heaviness, itching and pain apart from intermittent ear discharge.

Out of 50 patients only 4 patients (8%) complained about persistence of heaviness in ear following surgery. Tinnitus persisted in 5 (10%) patients. Postoperative residual perforation with persistence of mucopurulent discharge was present in 2 (4%) patients and out of these two, 1 (2%) has extrusion of prosthesis (Teflon TORP). Out of 50, 49 (98%) patients had improvement of hearing following ossiculoplasty and only 1 (2%) patient has worsening of hearing postoperatively. Postoperative pain persisted in 2 (4%) patients. None of the patient complained of vertigo following ossiculoplasty.

Objective improvement is defined as assessment of improvement with help of specific investigation. In this study specific investigation for hearing assessment was PTA (pure tone audiometry). Preoperative air conduction (AC) threshold of all patients were measured and the mean value was 55.32 dB with maximum loss was 75 dB and minimum loss was 26.66 dB. Postoperative mean value for air conduction (AC) was 32.7 dB and the resulting hearing gain was 22.6 dB. These values indicate that there was a definite and positive improvement of hearing in 98% of patients.

Preoperative ABG (air bone gap) was 44.24 dB and postoperative ABG following ossiculoplasty was 25.45 dB. Out of 50 patients 32 (64%) patients had ABG below 25 dB following ossiculoplasty and that indicate success of ossiculoplasty. In this study autologous fashioned tragal cartilage and prosthesis (titanium and Teflon) were employed for the reconstruction of ossicular chain. Out of 50 patients maximum gain of ABG with excellent

improvement of hearing was seen in cartilage TORP applied in 4 (8%) patients and Teflon TORP applied in 10 (20%) with average gain of 23.25 dB and 22.61 dB respectively. There was one case of Teflon TORP extrusion.

Table 3: Types of prosthesis employed with average gain of ABG (air bone gap).

| Types of prosthesis | Average gain of ABG |
|---------------------|---------------------|
| Teflon TORP | 22.61 dB |
| Teflon PORP | 20.52 dB |
| Titanium TORP | 19.43 dB |
| Titanium PORP | 20.32 dB |
| Cartilage TORP | 23.25 dB |
| Cartilage PORP | 20.09 dB |

Hillman reviewed 84 patients who underwent tympanoplasty using plastipore prosthesis and 53 who used titanium. There was 1 extrusion in the titanium group. There was one incidence of prosthesis failure in the titanium group. 60% of patients had postoperative air-bone gap of 20 dB or less in the plastipore group. In the titanium group, 45.3% achieved a 20 dB or less air-bone gap.¹²

Naragund et al showed average postoperative ABG closure of less than 20 dB in 7 cases (58%) with autologous incus and 4 cases (33.3%) with titanium prosthesis.¹³ The ideal prosthesis for ossiculoplasty should be compatible, stable, safe, readily available, easily insertable and capable of yielding optimal sound transmission.

Jha et al conclude that cartilage; bone and gold are better and more cost effective alternatives to plastipore and titanium.¹⁴ Jackson et al achieved better results with Teflon TORP than PORP in his study of 141 cases of ossiculoplasty.¹⁵

Gardner et al published a retrospective study comparing the success results of PORP and TORP showing 48% in case of PORP and 24% in case of TORP when polyethylene base reconstruction was done.¹⁶

Zakzouk et al, in 2015, had 49 total ossicular reconstructions (titanium prosthesis, 40 patients; autologous incus, 9 patients) and mean air-bone gap at 2 years after surgery for the titanium prosthesis (21 dB) and autologous incus group (31 dB).¹⁷

Cholesteatoma had significant effect on the outcome of Ossiculoplasty in our study. Out of 50 patients, mastoid cellularity and middle ear cleft were affected with cholesteatoma in 40 patients with involvement of long process of incus and stapes superstructure. Postoperative hearing gain in these patients was 16.94 dB compared to 10 patients without cholesteatoma having hearing gain of 22.62 dB. Mastoid cellularity had a significant effect on

the outcome of the surgery. In the presence of cholesteatoma, poor results were seen when the stapes suprastructure or malleus handle were affected (55.6% and 40.0% respectively). It was the effect of cholesteatoma on ossicles rather than the cholesteatoma itself that affected the result of Ossiculoplasty.⁹

The presence or absence of cholesteatoma had significant effect on the results of ossiculoplasty. Cholesteatoma is an ectopic effect of squamous keratinizing epithelium in the middle ear that can cause hearing loss, otorrhoea and intracranial complication.¹⁸ Mastoidectomy with intact canal wall and canal wall down has significant effect on the outcome of ossiculoplasty. In this study postoperative hearing gain of intact canal wall and canal wall down was 16.38 dB and 17.51 dB respectively.

Dornhoffer et al stated that the type or complexity of the surgical procedure had a significant impact on the hearing results, both in the performance of a mastoidectomy with the surgical procedure and more importantly, in the removal of the canal wall.^{19,20} He advocated partial mastoid obliteration and reconstruction of the tympanic ring with cartilage when performing canal-wall-down surgery in an attempt to deepen the middle ear cleft, and reported encouraging hearing results.

Hazarika et al stated that MRM tympanoplasty was done in 19 cases with granulation and cholesteatoma and average preoperative and postoperative hearing loss was 49.5 and 32.8 dB respectively.²¹ Average percentage change of hearing loss was -32% with SD $\pm 14.5\%$. Tympanoplasty was done in 56 cases and average change of hearing loss was -26.1% with SD $\pm 17.3\%$. The combination of CWD and TORP gave significant inferior hearing thresholds as compared to TORP/CWU and PORP/CWD combinations.²²

The study limitation encountered is being retrospective in nature the sample size and sufficient representation could not be ensured.

CONCLUSION

Chronic otitis media causes necrosis of ossicles, which leads to disruption of ossicular assembly further leading to various degrees of conductive hearing loss. A skilled and proper technique of ear surgery with ossicular reconstruction imparts definite improvement of symptoms subjectively and objectively. Types of prosthesis and nature of surgery have impact over the improvement of hearing. Placing a piece of cartilage between prosthesis and temporalis fascia can prevent extrusion of the prosthesis.

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Conflict of interest: None declared

Ethical approval: The study was approved by the Institutional Ethics Committee

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