

Short term hearing results in patients with otosclerosis after stapedotomy in a tertiary care center.

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Abstract

Introduction: Stapedotomy done for otosclerosis is one of the finest middle ear surgery and needs great expertise. The present study is done to evaluate the short-term hearing results in patients with otosclerosis and treated with primary stapedotomy.

Methods: A retrospective chart review of patients after stapedotomy surgery was done from April 2011 to October 2016. Stapedotomy was performed under local anesthesia using a Teflon piston under local anesthesia. The patients were followed up after 6 weeks for the assessment of the hearing status. The hearing assessment was done using the Air Bone gap improvement and Air Bone gap closure (AB gap closure) pre and postoperatively.

Results: Total of 73 cases were retrieved from hospital database. 3 cases were excluded and analysis of only 70 cases was done. Among the total patients 85.71% of the patients had bilateral involvement of the disease. The overall mean pre-operative pure tone Air conduction average was 55.66 dB, SD 11.576 (95% CI; 52.57-59.212), while the overall mean post-operative pure tone average was 17.63 dB, SD 11.958 (95% CI; 14.70-21.57). This difference was found to be statistically significant ($p = 0.000$). The overall mean pre-operative air bone gap was 37.65 dB and the overall mean post-operative air bone gap was 18.47dB. This difference was found to be statistically significant ($p = 0.000$).

Conclusion: This study confirms that stapedotomy for clinical otosclerosis is a safe and successful treatment for short-term hearing improvement. Both the AC threshold and AB gap closure showed significant improvement postoperatively.

Key Words: otosclerosis, stapedotomy, air-bone gap, air conduction threshold, air bone gap closure, pure tone audiogram.

Introduction

Otosclerosis is a localized hereditary disorder that affects the endochondral bone of the otic capsule with disordered resorption and deposition of bone. It is characterized by area of bone resorption, new bone formation, vascular proliferation & connective tissue stroma.¹⁻⁴ The location of the otosclerotic foci determines the symptomatology. The site anterior to the oval window 'fissula ante fenestrum' is affected in 90% of the patients, leading to the fixation of the stapes causing conductive hearing loss in most of the

patients.^{5,6} Mixed or sensorineural cases may also be observed in cases of extensive disease or cochlear otosclerosis. The clinical otosclerosis disease affects between 0.3% to 0.4% of the world's population⁷ and commonly affects the Caucasians.^{8,9} It is common in Europe, Middle East, North America, South America, India and rare in African people.

It is twice as more common in females than in males. It is the most common cause of conductive hearing loss in patients of age groups 15-50 years with an intact tympanic membrane; with the bilateral involvement in

70% to 85% of the cases.¹⁰ As per the symptomatology, the most common symptom is hearing loss followed by tinnitus. The other symptoms like aural fullness and vertigo can also be associated in some patients. Around 60% of the patients also have the positive family history of otosclerosis.¹¹

The conductive hearing loss in this disease is amenable to non-surgical and surgical remedies. The main goal in the treatment of otosclerosis is to improve patient's hearing. This goal can be achieved by fitting patients with hearing aids or through otological microsurgery. Stapes surgery is currently the preferred treatment modality. Since the first stapedectomy with vein graft interposition described by Shea in 1956¹² and stapedotomy in 1960.¹³ The surgical technique for otosclerotic stapes fixation has undergone many modifications. During the last two decades, the technique has evolved from stapedectomy to stapedotomy the rationale being that a limited opening of the vestibule in small fenestrae techniques reduces the risk of inner ear damage.

Many studies on large series of stapedectomies demonstrated excellent results, with air-bone gap (ABG) closure of 10 dB or more in greater than 90 per cent of patients. ABG closure was calculated by comparing postoperative pure tone average (PTA) thresholds for air conduction with pre-operative bone conduction thresholds.

The incidence of otosclerosis in Nepal has not been studied so far though the disease is seen more often in the southern part of the country. This study done in a tertiary care center aims to assess the short term hearing improvement in stapedotomy.

Methods

The retrospective study of the patients who had undergone stapedotomy was conducted in the department of ENT and Head & Neck Surgery, Ganeshman Singh Memorial Academy of ENT-HNS (GMSMA-ENT), Institute of Medicine, Tribhuvan University Teaching Hospital. The surgeries done between April 2011 to October 2016. This study was approved by Institutional Review Board of the hospital. The patients fulfilling the inclusion criteria of age >15 years, clinically confirmed cases of otosclerosis, stapedial otosclerosis with the air bone gap of at least 30dB⁷ were included in the study. Patients with revision stapedotomy, cochlear otosclerosis were excluded from the study.

The case records of all the patients with otosclerosis who underwent stapedotomy in the above mentioned duration was retrieved from the records department of GMSMA of ENT-HNS. Their respective pre and post-operative audiograms were recorded. A proforma was designed and the following data were recorded: Bio-data, symptom history, examination findings, comorbidity, pre and post-operative audiograms and details of the surgical procedure.

Pre-operative pure tone audiometry (PTA) done within one month before surgery and post-operative PTA within 6-8 weeks were recorded. The audiogram was done in a sound treated room by trained and experienced audiologists by Huggan and Westlake technique with 5dB intensity interval. Air conduction included 250, 500, 1000, 2000, 3000, 4000 and 8000 Hz frequencies and bone conduction frequencies included 250, 500, 1000, 2000, 3000 and 4000 Hz. Average was calculated from 500, 1000, 2000, 3000 and 4000 Hz frequencies. The tympanometry performed was also recorded.

The patients were admitted a day prior to the surgery. All stapedotomies were done under sedation (50mg pethidine + 25mg promethazine) intramuscular injection ½ hour before surgery with local anaesthetic blockage of the ear with 2% xylocaine and 1:200,000 adrenaline (maximum of 7mg/kg). A tympanomeatal flap was raised medially and the posterosuperior canal wall was curetted to visualize the pyramid and the stapedial tendon. After adequate exposure, the ossicular chain mobility was assessed and the stapes was inspected and palpated to confirm the diagnosis of otosclerosis. Once the mobility of the stapes superstructure was diagnosed to be absent the incudo-stapedial joint was disarticulated, the stapedial tendon was cut, the crura of the stapes were fractured and removed. The distance between the footplate and the undersurface of the long process of the incus was determined. The piston was then cut at the length 0.25mm more than the distance measured from the footplate and the undersurface of the incus. The foot plate was perforated using a Skeeter drill with a microburr. Teflon prosthesis with a diameter of 0.4-0.6 mm x 3.75-4.5 mm were used according to the measurement done and crimped to the long process of the incus. In all the cases fat sealant was used around the piston base. Subsequently, after confirming the position of the prosthesis and subjective hearing improvement on the operating table, the tympanomeatal flap was replaced and secured with gel foam and BIPP soaked pack. Post operatively, the

patients were positioned supine with the operated ears up for 24 hours with gradual increment of mobility until they were discharged after 3rd to 5th postoperative day. Postoperative antibiotics (Tab Ciprofloxacin 500mg twice a day) were given for 7 days and pack removed on the 7th day postoperatively.

After 6-8 weeks the patients were followed up for hearing evaluation. The air conduction, pure tone average and bone conduction thresholds were calculated for the frequencies 0.5, 1, 2, 3 and 4 kHz. The air-bone gap was calculated as the difference between the pre-operative bone conduction and the post-operative air conduction thresholds. The main outcome measures were the post-operative air bone gap and the post-operative air bone gap closure. Thus, the pre and postoperative audiometry test results were compared according to the criteria published by the Committee on Hearing and Equilibrium if the American Academy of Otolaryngology – Head and Neck Surgery Foundation.¹⁰ The data was entered and analysed using SPSS 20. The paired sample t-test was used to compare the differences in means. $P < 0.05$ was considered statistically significant. The association between age, duration of disease and the post-operative pure tone averages were tested using the Spearman's rho test.

RESULTS

A total of 73 adults were taken for the study and 3 cases were excluded due to absence of post-operative audiogram. Thus, total of 70 patients were finally taken for study. 39 (55.7%) were females and 31 (44.3%) were males as shown in figure I.

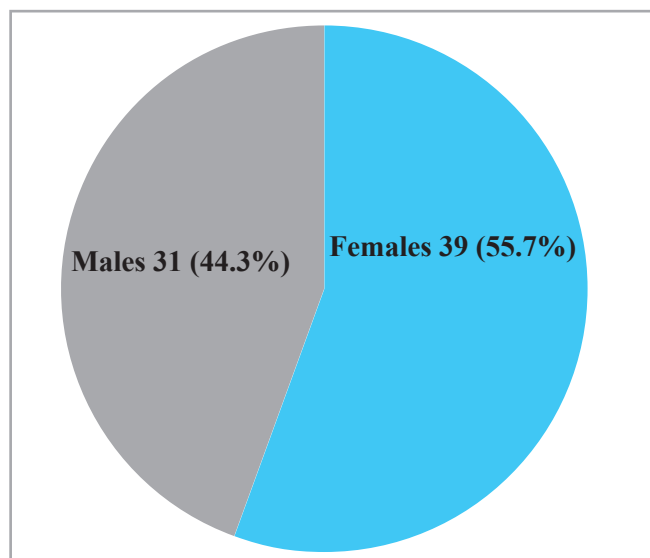


Figure I: Gender distribution of the patients

Among the total patients 59 (84.3%) of them had right sided stapedotomy and the remaining 11 (15.7%) had on the left side. The age of the patients ranged from 21 years to 50 years and the distribution was as shown in figure II. The majority of the patients were in the age group of 15-30 years of age forming 68.6% of the total followed by 28.6% in the age range of 31-45 years and 2.8% in the age range of 41- 60 years of age as shown in figure II. The mean age was 29.90 years, standard deviation (SD) 8.69 (95% CI; 26.40-31.40).

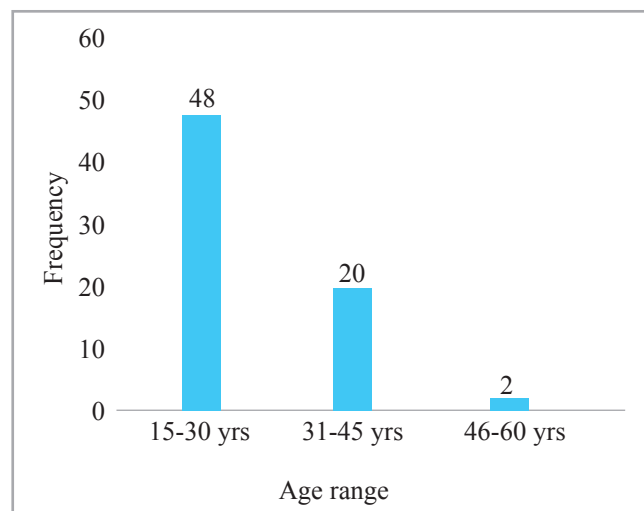


Figure II: Age distribution (n=70)

The mean duration of symptom was 5.96 years; SD 6.188 (95% CI; 3.65-8.27). The commonest presenting symptoms were hearing loss with tinnitus in 38 (54.3%) followed by only hearing loss in 22 (31.4%), hearing loss with tinnitus with ear fullness in 9 (12.9%) and hearing loss with tinnitus with vertigo in 1 (1.4%) as shown in figure III.

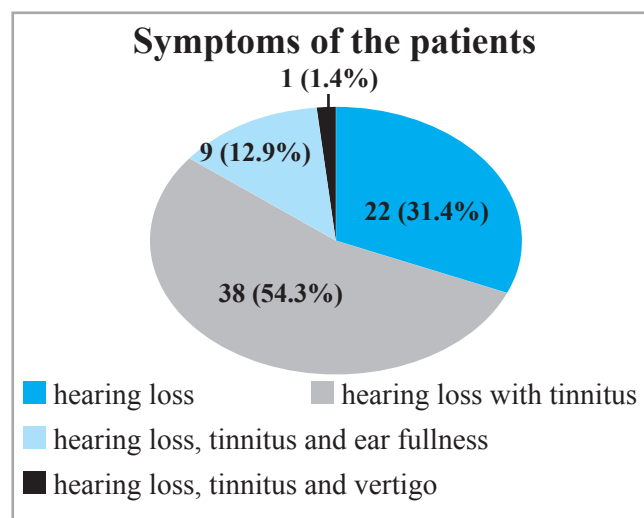


Figure III: Presenting symptoms of the patients (n=70)

Among the total patients, 85.71% of the patients had bilateral involvement of otosclerosis. The ear with the larger AB gap was operated first. All the patients were operated under local anesthesia and all of them had on-table subjective hearing improvement. 38 (54.3%) patients had Teflon piston size more than 4.25 mm used as prosthesis and 32 (45.7%) had piston of size less or equal to 4.25 mm. There was no significant difference between the two groups ($p = 0.445$). Postoperatively, one patient developed delayed high frequency sensorineural hearing loss after 4 weeks and one other developed decrease loss of taste sensation in the side of the operation done.

Regarding the hearing status, it was assessed after 6 weeks by repeating the pure tone audiogram. The overall mean pre-operative pure tone average was 55.66 dB, SD 11.576 (95% CI; 52.57-59.212), while the overall mean post-operative pure tone average was 17.63 dB, SD 11.958 (95% CI; 14.70-21.57). This difference was found to be statistically significant ($p = 0.000$). Table 1 shows the mean differences between the pre and post-operative Air Bone Gap (ABG) across four frequencies. These differences tend to decrease with increasing frequency except in 2 KHz where it was increased and were all significant ($P = 0.000$).

Table 1: Mean difference between pre & post-operative air bone gap

Frequency (KHz)	Mean difference (dB)	Standard Deviation	95% confidence interval	p- value
0.5	26.122	14.407	21.984-30.261	0.000
1.0	21.939	11.493	18.637-25.240	0.000
2.0	14.184	12.597	10.565-17.802	0.000
4.0	14.490	14.406	10.352-18.628	0.000

The overall mean pre-operative air bone gap was 37.65 dB and the overall mean post-operative air bone gap was 18.47dB. This difference was found to be statistically significant ($p = 0.000$). There was improvement in the mean postoperative AB closure after stapedotomy as shown in the table 2.

Table 2: Mean pre and postoperative AB gap

Frequency (KHz)	Mean pre-operative Air Bone Gap (dB)	Standard Deviation	Mean post-operative Air Bone gap (dB)	Standard Deviation
0.5	46.63	11.788	20.51	15.621
1.0	42.45	9.581	20.51	12.000
2.0	24.18	11.150	10.00	11.180
4.0	37.35	14.401	22.86	13.129

Similarly, on assessing the ABG closure postoperatively, 23 (32.6%) patients were within 10dB. Similarly, 26 (37.1%) cases were within 20dB and 21 (30.3%) patients within 25dB as shown in Table 3.

Table 3: Postoperative ABG closure

ABG Closure within (dB)	Cases	Percentage
10 dB	23	32.6%
20 dB	26	37.1%
25 dB	21	30.3%

Discussion

Otosclerosis is a common disease affecting the otic capsule causing hearing loss, usually bilateral. The diagnosis is mainly done by clinical evaluation and audiological tests. The relatively normal looking

tympanic membrane with the conductive hearing loss is seen in stapedial otosclerosis. The pure tone audiometry done shows conductive hearing loss with the Carhart's notch at 2KHz and the tympanometry usually shows the As type of curve. There is a growing use of CT scan¹⁴ of the temporal bone for surgical planning and assess the risk of complications, but it was not done in our study.

Various literatures mention the female predominance in otosclerosis with the ratios of 2:1 to 3:1.¹⁰ In our study, we also found the female predominance though the ratio was less. This co-related with the findings of other studies.^{15,16} But the less female predominance in our study maybe due to our small sample size and

social factors of male dominance. Our study showed the maximum number of patients in the age of 15-30 years with the average age of 29.9 years of age. This is comparable to the other studies in the literature.¹⁰ This is the commonest age group when the patients become clinically symptomatic and seek for surgical intervention too.

All of our patients were counselled regarding the options of hearing aid and stapes surgery both. Once the patients were convinced for surgery they are dated. The present study in accordance with many other literatures highlighted the relevance of stapes surgery especially on its role in significant hearing improvement in otosclerosis.^{17,18} All of our surgeries were done under sedation and local anesthesia thus making it easier for the peroperative assessment of the patients also. This is supported by other literatures where all the surgeries were performed under local anesthesia irrespective of the modality of making the fenestra in the stapes footplate like the use of perforator, Skeeter drill or lasers.^{7,10,19} There are many choices of piston used for stapes surgery like titanium, teflon, gold, platinum, nitinol etc. Many authors have described about the superiority of the titanium prosthesis but due to the cost issue we have been exclusively using the Teflon piston.^{10,20,21} The various diameter of the Teflon piston used in our study and few other literatures were 0.4mm, 0.5mm and 0.6mm. The present study hasn't explored on the comparison of the difference of hearing improvement based on the prosthesis diameter. The various authors mention that the advantage of using the smaller diameter is the lower risk of inner ear damage²², but other studies have mention the significantly better hearing gain on using the prosthesis with the larger diameter.^{23,24}

Our study we have found a remarkable improvement in the post-operative hearing results after primary stapedotomy at all four frequencies. The hearing improvement were especially more pronounced at the lower frequencies of 0.5, 1 and 2 KHz but less improvement at 4 KHz. These finding is well co-related with findings of most other studies.^{25,26} Improvement of bone conduction thresholds at 0.5, 1 and 2 kHz may be presumed to be influenced by the Carhart effect, and unchanged bone conduction at 4 kHz might be due to the effect of restored ossicular chain mobility, while worsening of bone conduction thresholds indicates sequelae of surgical trauma to the inner ear.

The success of the stapes surgery is defined as a closure of the AB gap of 10dB or better. In our study the mean

AB gap closure was within 10dB in 32.6%, within 20dB in 37.1% of the patients. This is comparable to the study done by Farid et al²⁷ where 32.1% of their patients had AB gap closure within 10dB. But some other authors take AB gap closure within 20dB as satisfactory.²⁸

Taiwo et al in their study showed 61.1% of their patients had AB gap closure within 20dB which is comparable to our study.¹⁹

Though our relatively small sample population could possibly have introduced bias in our findings, we conclude that primary stapedotomy was effective in the short term in improving hearing outcome in adults with clinical otosclerosis. A prospective study with a large sample size with long follow up periods will probably yield more valid results.

Conclusion

The short term hearing improvement after stapedotomy showed significant hearing improvement as assessed by AB gap closure. 69.7% of our patients had postoperative AB gap closure within 20dB which is comparable to most of the literatures around the world.

Recommendation

Long term study and the assessment of the surgery done by a single surgeon would be recommended as it leads to more consistent results.

Conflict of interest: None declared

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