INTRODUCTION

Otosclerosis is a primary disease of the labyrinth bone capsule consisting of one or more localized foci in which bone resorption and deposition take place repeatedly. This focus may gradually invade the annular ligament and the stapes, causing bony ankylosis and deterioration of the air conduction of sound. It is a common entity that we encounter in our clinical practice. Treatment of otosclerosis can be medical, surgical or hearing aid support, but we preferred the surgical treatment for otosclerosis unless it is contraindicated. Sodium fluoride (NaF) is used substance as medical treatment of otosclerosis. In practice, an intervention should only be considered in cases with deafness over 30 dB and a Rinne value in this order, although the possibility of recovery by bone conduction (Carhart effect) can and should be taken into account [1]. Minor issues like post operative vertigo and tinnitus need to be adressed in detail during counselling for stapedotomy in order to provide comprehensive patient awareness in preparation for surgery. The short-term results are undoubtedly very good in the recent literature. Meticulous documentation of the audiological outcomes of stapedotomy and long term follow up of patients remains essential. Our institution has a large series of stapedotomy surgeries performed over a decade and the overall results have been gratifying. This study was aimed to sequentially document our patient's audiological improvement after stapedotomy as measured by pure tone audiometry.

STUDY METHOD

This prospective clinical study was performed in a total of 112 patients diagnosed with Primary Otosclerosis who underwent Stapedotomy from September 2010 to March 2012 at the Department of Otology, Madras ENT Research Foundation, Chennai, India after ethical commitee approval. All patients suspected to have Otosclerosis, were evaluated as per the candidacy criteriae for stapedotomy and selected patients underwent surgery during the study period. All surgeries were performed by the same senior most experienced surgeon of the institute and were followed up for a period of 2 years in the Otology clinic. Pre-operative and Post-operative audiometric evaluation was done using conventional pure tone audiometer with standard calibrations. Post-operative audiometry was sequentially performed at 6 months, 1 year and 2 years. Bone-conduction and air conduction thresholds and the Air-bone gap (ABG), were assessed at each schedule at 0.5 KHz, 1 KHz, 2 KHz and 4 KHz frequencies respectively. All the patients had significant audiological improvement as measured by their sequential pure tone audiometries. Overall, the frequency specific pre-operative mean average Air-Bone gap was 52.3dB at 500Hz, 36.5dB at 1KHz, 39.3dB at 2KHz, 38.7dB at 4KHz and the frequency specific postoperative mean average Air-Bone Gap closure was achieved by 27.8dB at 500Hz, 29.6dB at 1KHz, 13.6dB at 2KHz, 11.4dB at 4KHz, by the time of 2 years of follow up. A successful closure of AB gap >10dB was achieved in these speech frequencies in 80% of cases. The frequency specific bone-conduction thresholds were unchanged postoperatively. Two patients developed post-operative vertigo, out of which 1 developed SNHL after 3 weeks of surgery. The study confirms that stapedotomy is a safe and successful procedure in the hands of a well trained otologist, providing long-term hearing improvement to patients with otosclerosis.

Keywords: Otosclerosis, Pure Tone Audiometry, Air-Bone Gap, Carhart's Notch, Stapedotomy

Audiological Outcomes of Stapedotomy: Our Experience

Dr. Geetha Nair, Dr. Rabinindra B Pradhananga, Dr. S. Raghunandhan, Dr. Mohan Kameswaran
Madras ENT Research Foundation, Chennai, India

*Corresponding author
Dr. Geetha Nair
Email: drgeethaent@yahoo.com

Abstract: This study was aimed to sequentially document the patient's audiological improvement after stapedotomy as measured by pure tone audiometry. This prospective clinical study was performed in a total of 112 patients (age range: 20 - 63 years), diagnosed with Otosclerosis who underwent Stapedotomy at the Department of Otology, Madras ENT Research Foundation, Chennai between September 2010 to March 2012. Pre-operative and Post-operative audiometric evaluation was done using the same conventional pure tone audiometer with standard calibrations. Post-operative audiometry was sequentially performed at 6 months, 1 year and 2 years. Bone-conduction and air conduction thresholds and the Air-bone gap (ABG), were assessed at each schedule at 0.5 KHz, 1 KHz, 2 KHz and 4 KHz frequencies respectively. All the patients had significant audiological improvement as measured by their sequential pure tone audiometries. Overall, the frequency specific pre-operative mean average Air-Bone gap was 52.3dB at 500Hz, 36.5dB at 1KHz, 39.3dB at 2KHz, 38.7dB at 4KHz and the frequency specific postoperative mean average Air-Bone Gap closure was achieved by 27.8dB at 500Hz, 29.6dB at 1KHz, 13.6dB at 2KHz, 11.4dB at 4KHz, by the time of 2 years of follow up. A successful closure of AB gap >10dB was achieved in these speech frequencies in 80% of cases. The frequency specific bone-conduction thresholds were unchanged postoperatively. Two patients developed post-operative vertigo, out of which 1 developed SNHL after 3 weeks of surgery. The study confirms that stapedotomy is a safe and successful procedure in the hands of a well trained otologist, providing long-term hearing improvement to patients with otosclerosis.
Out of 112 patients 12 patients did not complete 2 year of follow up. Therefore the result of 100 patients were assessed.

The surgical technique used in all patients was reverse stapedotomy. The basic technique was performed by common transmeatal approach under local anaesthesia and sedation. The steps of the surgery included exposure of footplate and stapedial tendon at pyramid, perforation of the foot plate with a skeeter drill, incudo-stapedial disarticulation, cut of the stapes tendon, fracture of posterior crus of stapes, removal of stapes suprastructure and then crimping the prosthesis over long process of incus. Teflon pistons of size 0.6 X 4.25 mm were used as prosthesis in all cases. Fenestrum sealed with ear lobule fat autograft after the placement of the prosthesis.

The study was carried out after getting the approval from the ethical committee of the institution in September 2010. The results were recorded in an Excel spreadsheet which was then processed using the SPSS statistics package for Windows. The descriptive analysis of quantitative variables was performed by determining the mean and standard deviation for continuous variables and absolute and relative frequencies for categorical variables. The comparative analysis was performed using the nonparametric Friedman test (Friedman analysis of variance by ranks), taking into account the audiometric results in the 3 time periods. The accepted level of statistical significance in our work was \( P < 0.05 \).

**OBSERVATIONS AND RESULTS**

Out of 112 patients 12 patients were excluded as they did not complete 2 year of follow up. Hundred operated ears had been included in this study: 70 (70%) in women and 30 (30%) in men. The age range is 20-63 years with a mean of 36 years. 75% of patients were younger than 40, 15% were between 41 and 49, and 10% were over 50 years of age at the time of the intervention. The most common clinical presentation among our patients was hearing loss (80%), followed by a combination of hearing loss and tinnitus (17%). Less commonly, we encountered the combined presentation of hearing loss and vertigo (2%) or the combination of hearing loss, vertigo, and tinnitus, which was only observed in 1% of patients.

We noted that there were more operations on the right ear in 62 cases, (62%) than on the left 38 cases (38%). 1 Patient had monopodal stapes, 1 patient had laterally placed chorda tympani(fig.1) and 1 had persistent stapedial artery (fig.2) 10% of the patients had obliterative foci(fig.3) and next 10% were found to have biscuit footplate foci.

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**Fig-1: Monopodal stapes with lateralized chorda tympani**

(c=chorda tympani, i=rudimentary incus, fn=facial nerve, fp=footplate, p=postesior crus of stapes)

**Fig-2: Anomalous facial nerve course below footplate of stapes**

(i= incus, fp=footplate, fn=facial nerve)
Pre-operative and Post-operative (at 6 months, 1 year & 2 years) mean average air conduction thresholds were shown in table 1. Significant improvement in all frequency was noted in between preoperative and post operative mean air conduction threshold. (p=0.012). Though mild improvement in mean air conduction threshold was noted from 1st to 2nd year of follow up, it was not statistically significant (p=0.39).

Overall, the frequency specific pre-operative mean average Air-Bone gap was 52.3dB at 500Hz, 36.5dB at 1KHz, 39.3dB at 2KHz, 38.7dB at 4KHz and the frequency specific postoperative mean average Air-Bone Gap closure was achieved by 27.8dB at 500Hz, 29.6dB at 1KHz, 13.6dB at 2KHz, 11.4dB at 4KHz, by the time of 2 years of follow up (Table 2).

The frequency specific bone-conduction thresholds were unchanged postoperatively. A significant postoperative sensorineural hearing loss (SNHL) was seen in 1% and no improvement in 3% of cases in this series and one patient developed post op persistent vertigo.

**DISCUSSION**

As for the airborne route the short-term results are, without question very good. Birch et al [2] showed in their study a gain of between 25 and 35 dB on average for the air route. Previous reports of otosclerosis surgery have shown that stapedotomy gives better high-frequency gain and reduces the risk for sensorineural hearing loss (SNHL) [1, 2]. In a study presented by Spandow et al [3] the mean value of the averaged pure tone thresholds improved from 57 to 26 dB after 1 year of stapedotomy.

The symptom that most often affects patients with otosclerosis is hypoacusis, although the main reason for consultation is often tinnitus. In a study presented by del Bo et al [4], 56% of patients had tinnitus before surgery. In our study, the figures are somewhat lower, only 18% of our patients had tinnitus. Vertigo is a common symptom in patients operated on for otosclerosis. Our study found occasional vertigo in 1% of patients. Prosthesis dislocation, migration out of the oval window fenestra, and complete incus erosion were the most common causes for failure in this series. Several studies have commented on the variable of patient age at the time of stapes surgery [5, 6]. Stapedectomy in seniors is controversial. It is indicated to avoid the use of a hearing aid or to facilitate hearing aid fitting, when the association of otosclerosis and presbyacusis makes hearing aid provision unsatisfactory [7]. In a series of 154 cases of stapedectomy in the elderly, Lippy et al [8] stated that the percentage of patients (90.9%) having a successful surgical result (postoperative ABG within 10 dB) was similar to younger patients in the comparison group with a
successful surgical result (90%). Our results compare favorably with previous series, and our low rate of complications confirms that advanced age is not a contraindication to stapedectomy. Moreover, surgery will stop the progression of the disease and allow the patient better use of a hearing aid with an important improvement in sound discrimination [9].

Kazmierczak et al [10] had also analyzed the changes in air conduction, changes in bone-gap and changes in bone conduction threshold in 81 patients for the assessment of the result of stapedotomy. The improvement in air conduction threshold in all frequency was statistically significant (p= 0.012). But in subsequent follow up the changes in air conduction threshold were noted but statistically not significant. We infer that audiological improvement has sustained static overtime in our study group. (p=0.11 and 0.39). The frequency specific bone-conduction thresholds were unchanged in all postoperative audiometry.

However Sperling NM et al [11] found worsening of bone conduction threshold in early post operative period which might be due to cochlear trauma. Sperling NM et al [11] also had 91% of patients achieving an air-bone gap less than or equal to 10 dB by 6 months post operation which was 96% in our study.

In our study of 100 patients mean difference between pre and post operative air conduction threshold (dBHL) was 27.7dB, 28.6dB, 22.7 dB and 8.4 dB at 0.5, 1, 2 and 4 KHz respectively. (Table-3) In one study by Mair [12] mean difference between pre and post operative air conduction threshold (dBHL) was 32.1, 28.7, 22.7 and 14.7 at 0.5, 1, 2 and 4 KHz respectively. In another Study done by E A Myrvoll et al [13] mean difference between pre and post operative air conduction threshold (dBHL) was 29, 26.7, 19 and 12.7 at 0.5, 1, 2 and 4 KHz respectively. (Table-3) Our result is comparable with the previous results.

Table 3: comparison of the results of our study with others in mean difference between pre and post operative air conduction threshold (dBHL) at 2 years

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After the surgery 90.9% tinnitus pts reported improvement and 9.09% noted no change in tinnitus in a study conducted by Carlos A Oliveira [14]. While in our study 86% tinnitus pts reported improvement.

In a large series of patients studied by Robert Vincent et al.[15] the overall rate of failures was 6.6% and significant postoperative SNHL was seen in 0.7% which was mainly in senior patients. In our study failure rate was 3% while postop SNHL rate was 1%.

CONCLUSION

Our series confirms that stapedotomy for otosclerotic stapes fixation is a safe and successful treatment for long-term hearing improvement. Obliterative otosclerosis, biscuit footplate, monopodial stapes and persistent stapedial artery may be encountered during stapedotomy. Our study shows that judicious selection of cases for stapedotomy will result in high success rate in audiological outcomes in patients with otosclerosis. Stapedotomy surgery is safe and efficacious in the hands of an experienced otologist and audiological outcomes are often adjudged based upon this surgical acumen. Troublesome issues like post-op vertigo and tinnitus needs to be addressed during counselling for stapedotomy in order to provide optimal patient awareness in preparation for surgery.

REFERENCES


