

Hearing results in adults after stapedotomy

Emmanuel Sara Kolo, R. Ramalingam¹

Department of Otorhinolaryngology, Bayero University Kano/Aminu Kano Teaching Hospital, Kano, Nigeria, ¹K. K. Ramalingam Ear, Nose and Throat Hospital and Research Institute, Chennai, Tamil Nadu, India

ABSTRACT

Background: Although clinical otosclerosis is considered a rare disease, it is the common cause of hearing loss in patients with an intact tympanic membrane. Also, the hearing loss is amenable to other non-surgical remedies. However, stapes surgery is currently the preferred treatment modality. This study aimed to assess the short-term hearing results in adults after primary stapedotomy, and find, if any, the effects of some variables on post operative hearing. **Materials and Methods:** This was a retrospective review of the clinical records of all consecutive patients who had primary stapedotomy for otosclerosis at the K. K. Ramalingam Ear, Nose and Throat Hospital and Research institute, Chennai, India between October 2011 and December 2011. **Results:** A total of 31 adults were studied; 19 (61.3%) were males and 12 (38.7%) were females. Their ages were between 21 years and 69 years; the mean age was 43.67 years, standard deviation (SD) 11.859 (95% CI; 39.24-48.10). 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 (96.5%) and tinnitus (48.4%). The overall mean pre-operative pure tone average was 56.54 dB, SD 10.866 (95% CI; 52.55-60.52), while the overall mean post operative pure tone average was 33.75 dB, SD 15.577 (95% CI; 28.03-39.46). This difference was found to be statistically significant ($Z = -4.454$; $P = 0.000$). The overall mean pre-operative air bone gap was 43.14 dB; SD 6.824 (95% CI; 40.64-45.64) and the overall mean post operative air bone gap was 19.17 dB; SD 12.368 (95% CI; 14.63-23.70). This difference was found to be statistically significant ($Z = -4.701$). Nineteen patients (61.3%) had post operative air bone closure within 15 dB. The patient's age significantly correlated with the post operative pure tone average ($r = 0.443$; $P = 0.023$). There was no significant correlation between the duration of disease and the post operative pure tone average ($r = -0.034$; $P = 0.870$). **Conclusions:** Primary stapedotomy was effective in improving short term hearing outcome in adults with clinical otosclerosis. In addition, the post operative hearing outcomes were not affected by the duration of the disease; but by an increase in the patient's age.

Key words: Hearing loss, otosclerosis, pure tone audiometry, stapedotomy

Address for correspondence:

Dr. Emmanuel Sara Kolo,
Department of Otorhinolaryngology,
Bayero University Kano/Aminu
Kano Teaching Hospital,
Kano, Nigeria.
E-mail: emmyk90@yahoo.com

INTRODUCTION

Although clinical otosclerosis is considered a rare disease affecting 0.5-2% of the population, it is known to cause sensory neural hearing loss, mixed hearing loss, conductive hearing loss and vestibular abnormalities.^{1,2} In addition, it tends to be rare among the Negroid race: However, it is common in Europe, Middle East, North America, South America and India. In fact, it is the most common cause of

conductive hearing loss in patients 15-50 years with an intact tympanic membrane in these populations.³

The conductive hearing loss due to this disease is amenable to non-surgical and surgical remedies. However, stapes surgery is currently the preferred treatment modality.^{4,5} This involves replacement of all or part of the fixed stapes superstructure-stapedectomy and stapedotomy, respectively. Nevertheless, a recent trend has been in favour of stapedotomy; the rationale being that a limited opening of the vestibule in small fenestrae techniques reduces the risk of inner ear damage.^{6,7} Moreover, it gives similar and in some cases even better hearing results as compared to stapedectomy.^{7,8} In this paper, we share our experience in adults with otosclerosis who had primary stapedotomy in a developing country.

Previous studies have reported remarkable hearing improvement after primary stapedotomy in majority of

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patients who had otosclerosis.⁷⁻¹⁰ Even though, a small number of patients tend to experience unfavourable hearing outcomes; especially in those with advanced otosclerosis.¹¹

Otosclerosis is a primary disease of the otic capsule consisting of one or more localized foci in which bone resorption and deposition takes place repeatedly at predilection sites like the annular ligament and the stapes causing bone ankylosis and deterioration of air conduction of sound.⁴

This study aims to assess short term hearing results in adults after primary stapedotomy, and find if any, the effects of some variables on post operative hearing.

MATERIALS AND METHODS

This was a retrospective review of the clinical records of all consecutive patients who had primary stapedotomy for otosclerosis by the same author at a hospital and research institute in Chennai, India between October 2011 and December 2011. The study was approved by the Institutional Review Board of the hospital.

Patients were recruited into the study if they met the following inclusion criteria:

- Patients must have a clinical diagnosis of otosclerosis
- The surgical technique must be primary stapedotomy
- All the patients must have been operated by the same surgeon
- Patients must have records of their pre and post operative audiograms.

Those who had revision stapedotomy were excluded from the study, as well as those who had surgery for congenital fixation, tympanosclerosis and those with unreliable audiological data.

Study design

The case notes of all consecutive patients who had otosclerosis and underwent stapedotomy during the study period in our hospital were sort for and retrieved from the records department. Also, their respective pre and post operative audiograms were retrieved. Those who met the inclusion criteria above were recruited into the study. A proforma was designed and the following data were recorded: Bio-data, symptom history, examination findings, co-morbidity, pre and post operative audiograms and details of the surgical procedure.

All patients had pre-operative pure tone audiometry (PTA) shortly before surgery, and also at least 6 weeks post-operative. The test was carried out in a sound proof booth by a trained and experienced audiologist; and with the same audiometer (calibrated Kamplex AD 229 with TDH 39P headphones). A 5 dB step procedure

was employed, and a narrow band noise was used for masking.

The patients were all admitted a day before surgery. All stapedotomies were performed by the same surgeon under monitored sedation (phenergan and fortwin injections) with local anaesthetic blockage of the ear with 2% xylocaine and 1:200,000 adrenaline. A transcanal approach with a Rosen's incision was used in all cases and a tympanomeatal flap was raised medially. The chorda tympani nerve was retracted away from the field and the posterosuperior canal wall was curetted out. After adequate exposure, the stapes superstructure was inspected and palpated to confirm the diagnosis of otosclerosis. The mobility of the lateral ossicular chain was confirmed and the distance between the oval window and the long process of the incus was determined. The incudo-stapedial joint was disarticulated, the stapedial tendon was cut, the branches of the stapes were fractured and the foot plate perforated using a micro-motor and a tiny burr. Teflon prosthesis with a diameter of 0.4-0.6 mm were used in all cases and crimped to the long process of the incus, and the oval window was left unplugged. 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 an antibiotics soaked pack. Post operatively, the patients were positioned supine with the operated ears up and this position was maintained until they were discharged a day after.

Data analysis

Data obtained were recorded in an excel spreadsheet and were analysed using the Statistical Package for Social Sciences computer software program version 15. The air conduction, pure tone average and bone conduction thresholds were calculated for the frequencies 0.5, 1, 2 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 obtained on the same day. The main outcome measures were the post operative air bone gap and the post operative pure tone average. The paired sample *t*-test was used to compare differences in means. A *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 31 adults were studied; 19 (61.3%) were males and 12 (38.7%) were females. Their ages were between 21 years and 69 years; the mean age was 43.67 years, standard deviation (SD) 11.859 (95% CI; 39.24-48.10). 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 (96.5%) and tinnitus (48.4%). There were no vestibular complaints. The symptoms were bilateral in

majority of the cases (84%), however, only the worse ear was operated in each patient. Eighteen patients (58.1%) had 0.4 mm Teflon prosthesis inserted and 13 patients (41.9%) had the 0.6 mm prosthesis. There was no significant difference between the two groups ($X^2 = 13.204$; $P = 0.658$).

The overall mean pre-operative pure tone average was 56.54 dB, SD 10.866 (95% CI; 52.55-60.52), while the overall mean post operative pure tone average was 33.75 dB, SD 15.577 (95% CI; 28.03-39.46). This difference was found to be statistically significant ($Z = -4.454$; $P = 0.000$).

Table 1 shows the mean differences between the pre and post operative pure tone averages across four frequencies. These differences tended to decrease with increasing frequency and were all significant ($P = 0.000$).

The overall mean pre-operative air bone gap was 43.14 dB; SD 6.824 (95% CI; 40.64-45.64) and the overall mean post operative air bone gap was 19.17 dB; SD 12.368 (95% CI; 14.63-23.70). This difference was found to be statistically significant ($Z = -4.701$; $P = 0.000$). Nineteen patients (61.3%) had post operative air bone closure within 15 dB.

The mean pre and post-operative air bone gaps across the frequencies (0.5, 1, 2 and 4 kHz) are shown in Table 2.

Table 3 shows the mean difference between the pre-operative and mean post-operative air bone gap across four frequencies. They were all found to be statistically significant ($P = 0.000$). Before surgery, the mean pre operative air bone gap for those who had 0.4 mm and 0.6 mm Teflon prosthesis were 43.428 SD 7.183 (95% CI; 39.86-47.00) and 42.74 SD 6.560 (95% CI; 38.77-46.70), respectively. The mean difference was not significant (Mann-Whitney U test, $Z = -0.160$; $P = 0.873$). The mean post operative air bone gap in those who had the 0.4 mm Teflon prosthesis was 19.73 dB; SD 14.067 (95% CI; 12.74-26.73) and it was 18.38 dB; SD 10.047 (95% CI; 12.31-24.46) in those who had the 0.6 mm prosthesis. The mean difference was not statistically significant (Mann-Whitney U test, $Z = -0.402$; $P = 0.687$).

Spearman's rho test showed that patient's age significantly correlated with the post operative pure tone average ($r = 0.443$; $P = 0.023$). There was no significant correlation between the duration of disease and the post operative pure tone average ($r = -0.034$; $P = 0.870$).

There were no major vestibular complications in any of our patients, and none had persistent tinnitus post operatively.

DISCUSSION

Stapedotomy is currently the preferred technique in the surgical treatment of otosclerosis.⁸ Furthermore,

Table 1: Mean difference between pre and post operative pure tone averages

Frequency	Mean difference (dB)	95% Confidence interval	Z score	P value
0.5	25.48 (15.987)*	19.62-31.35	-4.548	0.000
1	24.68 (19.102)	17.67-31.68	-4.320	0.000
2	18.39 (17.483)	11.97-24.00	-3.979	0.000
4	14.52 (18.228)	7.83-21.20	-3.559	0.000

dB – Decibel; *Standard deviation

Table 2: Comparison of mean pre-operative and mean post-operative air bone gap

Frequency (kHz)	Mean pre-operative air bone gap (dB)	Mean post-operative air bone gap (dB)
0.5	44.63±10.371 (40.53-48.73)*	16.48±13.142 (11.28-21.68)
1	46.30±11.978 (41.56-51.03)	19.07±13.448 (13.75-24.39)
2	38.15±7.984 (34.99-41.31)	16.67±10.561 (12.49-20.84)
4	42.78±9.023 (39.21-46.35)	24.63±15.685 (18.42-30.83)

dB – Decibel; *95% confidence interval

Table 3: Mean difference between pre and post operative air bone gap

Frequency	Mean difference (Db)	95% Confidence interval	Z score	P value
0.5	28.23 (14.637)*	22.86-33.60	-4.750	0.000
1	26.61 (17.048)	20.36-32.87	-4.604	0.000
2	21.77 (13.137)	16.96-26.59	-4.599	0.000
4	18.15 (18.195)	10.95-25.35	-3.653	0.000

dB – Decibel; Standard deviation

several modifications exist today in the design of the stapes prosthesis all over the world. However, the Teflon piston-style prosthesis remains one of the most popular devices in use today. Possibly because Teflon is well-tolerated and it does not react with the tissues in the middle ear: And also depending on the study, the resultant hearing results are still comparable to those of other prosthesis.¹²⁻¹⁴ Likewise, due to the surgeon's personal preference and easy availability of this prosthesis in our setting, we used it to replace the stapes superstructure in all our patients. However, regardless of the technique or the kind of prosthesis used, the ability to hear without amplification still remains the ultimate goal of any surgery for hearing impairment.¹⁵

In this study, we found a remarkable improvement in the post operative hearing results after primary stapedotomy. In particular, we found a significant closure of the air-bone gaps within and across the frequencies 0.5, 1, 2 and 4 kHz. In addition, this study also found significant improvement in the post operative pure tone averages within and across the above stated frequencies. These improvements were

especially more pronounced at the lower frequencies. The post operative hearing results also remained good and comparable irrespective of the size of Teflon prosthesis used. These findings corroborate that of other researchers who also reported good post operative hearing results.^{7,9,10} On the other hand, the opinion of other researchers have been an unsatisfactory post operative hearing outcomes especially in those with advanced otosclerosis.^{1,11} Also, some workers have reported that the size of prosthesis inserted at the footplate is an important determinant of the post operative the hearing outcome.^{14,16} Even though, it is pertinent to realize that some of these researchers have used other types of prosthesis other than the Teflon piston. The perceived better post operative hearing outcomes at the lower frequencies might possibly be due to the fact that the higher frequencies are usually more affected by the disease process.¹

Furthermore, this study found that the post operative hearing outcomes were not affected by the duration of the disease. An increase, however, in the patient's age adversely affected the post operative hearing results. Hence, it is conceivable that some of the pathological changes that occur in the middle ear with advancing age could possibly play a role. On the other hand, the effect of the duration of the disease on post operative hearing was rather ironical. Since it is expected that the longer the duration of disease, the more the pathological process in the middle ear, and therefore, the more advance the disease, and the possibility that the post operative PTAs and air bone closure might be affected. Previous studies have observed poor post operative hearing results in those with prolonged disease.^{1,11}

Even though the authors admit that 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 multi-centre prospective study with a large sample size under standardised settings and with long follow up periods will probably yield more valid results.

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