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Original Article

Comparison of Pure Tone Audiograms before and after Stapedotomy for Otosclerosis in a Tertiary Care Hospital

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ABSTRACT

Objective: To study the mean improvement in Air-Bone gap after stapedotomy.
Study Design: Quasi Experimental study
Place and Duration of Study: Combined Military Hospital, Lahore and Rawalpindi Pakistan, from Jul 2020 to Jul 2021.
Methodology: A total of 33 patients having diagnosis of otosclerosis undergoing stapedotomy in age range 15 to 40 years of either gender was included. Patients with revision stapedotomy, Air -Bone gap less than 10dB, only hearing ear and chronic ear disease were excluded. All stapedotomies were performed under general anesthesia. Pure Tone Audiometry and Tympanometry were performed in all cases shortly before surgery and six weeks postoperatively.
Results: In this study range of age was from 15-40 years with the mean age of 29.91±5.25 years. Out of these 33 patients, 11(33.33%) were male and 22(66.67%) were female with male to female ratio of 1:2. Most female patients 17(51.52%) were between 31-40 years of age. In my study, Air-Bone gap preoperatively was 42.15±3.88 and Air-Bone gap postoperatively was 20.0±2.95 with *p*-value of 0.0001.
Conclusion: This study concluded that patients who underwent stapedotomy showed improvement in post-operative mean Air-Bone gap.

Keywords: Air-Bone Gap (ABG), Hearing Loss, Otosclerosis, Stapedotomy.

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INTRODUCTION

Otosclerosis is an autosomal dominant disorder causing progressive hearing loss mostly conductive type due to fixation of footplate of stapes.[1] This disease is more common in women and pregnancy is associated with worsening of the symptoms.[2]

Otosclerosis affects 0.5-2.0% of population in Africa but according to statistics this disease is more common in America, Europe and Asia.[3] It is the most frequent cause of conductive hearing loss behind an intact ear drum in 15-50 years of age group.[3] The hearing loss can be managed by applying hearing aid and surgical methods but currently the treatment of choice for otosclerosis is stapes surgery.[4,5] In 60% of the patients with otosclerosis, the disease is present in both ears.[3] In majority of patients, the diagnosis is made on the basis of conductive hearing loss on history that is usually progressive and audiometric analysis.[3] Pure tone audiometry shows gap between air and bone conduction threshold with carhart's notch while temporal bone high resolution computerized tomographic scan is more specific but not sensitive.[6] With the help of a needle or a laser, a small fenestra is made in the stapes footplate and prosthesis is inserted connecting footplate of stapes to long process of incus. The improvement in outcome of stapes surgery is dependent upon the familiarity with the procedure and skill of surgeon.[7] Stapes surgery comprises of either stapedotomy or stapedectomy. Recently, studies have shown better results with stapedotomy as compared to stapedectomy, with lesser complications making it the preferred surgical procedure.[8]

In patients with advanced otosclerosis, the hearing outcome is unfavourable when stapedotomy is done but a few studies showed remarkable hearing results after stapedotomy.[5,9] Adedji *et al.*, in an article showed that average Air-Bone gap (ABG) postoperatively for 500, 1000, 2000 and 4000 Hz frequency had less than 10dB ABG closure in 61.1% of patients as compared to 1.6% preoperatively and in 85.2% of patient's closure of ABG was <20dB as compared to 4.7% preoperatively (t − 13.89, *p*=0.000). Hearing was improved in 94% of patients and 81.5% had ABG closure greater than 10dB after stapedotomy (mean gain 23.38±12.37, t =13.89, *p*=0.000).[10]

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Our study aims at improvement in hearing resulting in improvement in quality of life as well in management of cases. This mode of treatment is not very popular in Pakistan and therefore no local article has been cited. Patients will be reviewed to see closure of air bone gap following stapedotomy and management may be recommended in future accordingly.

METHODOLOGY

This Quasi experimental study was done in Combined Military Hospital, Lahore and Rawalpindi Pakistan, from Jul 2020 to Jul 2021. Approval of study was taken from ethical review board (327/2021).

Inclusion Criteria: Patients aged 15-40 years who presented with decreased hearing and characteristic pure tone audiogram findings of otosclerosis i.e. Air-Bone gap of 15-20dB or more and presence of Carhart's notch were included in this study. A proforma was made to record following data and maintained as the patients record: Patient`s profile, findings of examination, pre-operative audiogram at first visit and post-operative audiograms six weeks after stapes surgery.

Exclusion Criteria: Patients having chronic ear disease, Air-Bone gap less than 10dB, Revision stapedotomy and patients with only hearing ear were excluded from the study.

In our study 33 patients who had diagnosis of otosclerosis were evaluated. The sample size was calculated using the WHO sample size calculator using the population proportion of otosclerosis as 2.0%.[11] Patients planned for stapedotomy were admitted one day before the surgery and all the cases were done under general anesthesia. In all cases, transcanal approach was used with a standard Rosen's incision and tympanomeatal mucosal flap was raised anteriorly. The chorda tympani nerve was moved away from surgical field. The bony overhang of postero superior canal wall overhang was curetted out. Diagnosis of otosclerosis was confirmed by checking mobility of stapes suprastructure. Approximate distance between the stapes footplate and long process of incus was measured. Incudostapedial joint was disengaged followed by removal of suprastructure of stapes. Using a tiny needle, foot plate of stapes was perforated. Teflon prosthesis of appropriate length was used in all surgeries. One end of this prosthesis was crimped to the incus and the other end to hole in stapes foot plate. The raised tympanomeatal flap was fashioned back and remaining cavity was filled with gel foam. All patients were nursed post operatively with their operated ear facing the roof and this ear up position was kept until the patient was discharged from hospital.

Study cases were those patients who had record of pre and 6 weeks' postoperative audiometry (PTA). PTA was done in a sound attenuated room with the same audiometer (Interacoustics calibrated audiometer AD 226 with headphones). A 5dB increase in frequency was done for all patients with appropriate masking.

Data was analyzed using Statistical Package for the social sciences (SPSS) version 23.00. Tables were constructed with Microsoft Excel (Microsoft Corp, Redmond, WA, USA). Paired sample t-test and independent sample t test were applied to analyze findings of audiogram. A *p*-value of ≤0.05 was considered significant.

RESULTS

Out of 33 patients, 22(66.67%) were females and 11(33.33%) were males with female to male ratio of 2:1. The range of age was from 15-40 years with the mean age of 29.91±5.25 years. In this study, majority of the females 17(51.52%) were between 31-40 years of age. Table-I shows that majority of patient who underwent stapedotomy had right sided disease 18(54.55%) as compared to left sided disease 15(45.5%) concurring with the findings by Kolo *et al.*[11] Mean air bone gap in our study was 42.15±3.88 before surgery and mean Air-Bone gap was 20.0±2.95 after surgery with *p*-value of less than 0.0001 as shown in Table-I.

Table-I: Mean Improvement in ABG in Patients Undergoing Stapedotomy (n=33)

	Air-Bone gap Mean±SD	*p*-value
Pre-operative	42.15±3.88	0.0001
Post-operative	20.0±2.95	

Comparison of mean air bone gap considering age as shown in Table-II demonstrated that patients age significantly correlated with post-operative Air-Bone gap with younger patients having better outcome.

Table-II: Comparison of Improvement in Mean Air Bone Gap with respect to Age Groups (n=33)

Age groups	Air-Bone gap Mean±SD	*p*-value
15-30	19.31±2.98	0.0001
31-40	20.65±2.85	

Results of Table-III showed that female gender demonstrated improved mean Air-Bone gap as compared to male gender.

Table-III: Comparison of Improvement in Mean Air Bone Gap with respect to Gender (n=33)

Gender	Air-Bone gap Mean±SD	*p*-value
Male	20.18±2.48	0.0001
Female	19.91±3.21	

Table-IV demonstrated that patients having right sided disease showed better outcome after surgery as compared to left sided disease.

Table-IV: Comparison of Improvement in Mean Air Bone Gap with respect to Laterality (n=33)

Laterality	Air-Bone gap Mean±SD	*p*-value
Right	19.83±2.81	0.001
Left	20.20±3.19	

DISCUSSION

Conductive hearing loss due to stapes footplate fixation is caused mainly by otosclerosis or congenital malformation of stapes. Otosclerosis is more prevalent in Asians & Caucasians as compared to Africans. If no treatment is done for otosclerosis, there will be progressive conductive deafness. It is an established fact that pregnancy worsens or triggers otosclerosis. Another causative factor for otosclerosis is measles virus. With the introduction of measles vaccine, incidence of otosclerosis decreased. Vasalava first described Otosclerosis in 1735 as fixation of stapes footplate to the oval window.[12]

The incidence of this autosomal dominant disease is about 2% with male to Female ratio of 1:2. It is usually a bilateral disease in 60% of the cases. Predilection for age is 15 to 50 years. The surgery for clinical otosclerosis is either Stapedectomy or stapedotomy. In stapedectomy, stapes suprastructure and footplate are removed and replaced with an appropriate size prosthesis. This surgery was first done by Dr. John J. Shea.[12] As compared to stapedectomy in stapedotomy, a small fenestra is drilled in the footplate of stapes with aid of an operating microscope. A piston prosthesis connects long process of incus to stapes footplate hole. Stapedotomy was first described by Professor Henri André Martin. Various methods can be used to make this tiny hole including perforator, needle, laser and microdrill.[13]

In research by Kolo *et al.,*[11] 31 patients having clinical diagnosis of otosclerosis who underwent stapes surgery were studied; 12(38.7%) were females and 19(61.3%) were males. Their age range was 21-69 years with age mean of 43.67 years (SD) 11.859 (95% CI; 39.24-48.10). It showed that overall mean pure tone average before surgery was 56.54 dB, SD 10.866 (95% CI; 52.55-60.52), while it was 33.75 dB, SD 15.577 (95% CI; 28.03-39.46) after surgery. Difference in pure tone average was noted to be significant statistically (Z= −4.454; *p*=0.000). Mean ABG before stapes surgery was 43.14 dB; SD 6.824 (95% CI; 40.64-45.64) and after stapes surgery the mean ABG was 19.17 dB; SD 12.368 (95% CI; 14.63-23.70). This difference in ABG before and after surgery was found to be statistically significant (Z= −4.701). As per the results, post-operative ABG closure to within 15dB was seen in 19 patients (61.3%). There was a strong correlation between age of patient and pure tone average after surgery (r=0.443; *p*=0.023).[13]

54 stapedotomies[10] (52 unilateral and 1 bilateral) were evaluated in a retrospective review. Average ABG after stapedotomy revealed that 61.1% patients had complete ABG closure to less than 10% as compared to 1.6% pre-operatively. Closure of ABG to within 20dB was seen in 85.2% as compared to 4.7% pre-operatively (t–13.89, *p*=0.000). Hearing was improved in more than 94% and greater than 10dB Air-Bone gap closure was seen in 81.5% after stapedotomy (mean gain 23.38±12.37, t=13.89, *p*=0.000). Tympanic membrane perforation (10%) was the commonest complication seen in this study.[10]

Another study[14] comparing conventional stapedotomy vs diode laser stapedotomy for Otosclerosis was reviewed. A total of 60 Stapes surgeries (30 in each group) were done with female (n=18) and male (n=42). Air-Bone gap mean before stapes surgery in the diode laser stapedotomy was 38.51±8.643 dB & in conventional stapedotomy groups was 36.42±8.678 dB. After 6 months of stapes surgery, Air-Bone gap mean was 10.86±5.383 dB in the conventional stapedotomy and 11.05±5.236 dB in diode laser stapedotomy groups. In the diode laser stapedotomy group mean air conduction improvement was seen by 24.98±5.348 dB and in conventional stapedotomy it was 24.08±5.911 dB at 6 months. No difference was found in the hearing gain at 6 months between two groups (*p*=0.05). However, with diode laser stapedotomy, a reduced severity and rate of intraoperative bleeding, vertigo after surgery,

vomiting were seen (0%, 6.6%, and 10%) compared to conventional laser stapedotomy (16.7%, 16.7%, and 16.7%). This difference was not statistically significant (p=0.05).[14]

A prospective study was performed by Vincent *et al.*,[15] over a period of 14 years in the analysis of 3050 stapedotomies. The mean ABG before stapes surgery was 25.6 and after stapes surgery was 1.7 dB. Mean ABG was less than 10dB in 94.2% of cases. A study of 256 stapedotomies was published by Oeken *et al.*,[16] in which the ABG after surgery was reduced to 10 dB or less in 220 patients (86%). Same result was reproduced by Ataide *et al.*,[17] in 75.8% of patients.

Nguyen *et al.*,[18] found the Air-Bone gap before laser diode stapedotomy was 29±0.8 dB & at one-year 9±0.6 dB with Air-Bone gap closure 20±0.2 dB. The mean air conduction threshold was improved by 22±1.7 dB after one-year. Air-Bone gap before conventional laser stapedotomy was 32±0.9 dB & at one-year 10±0.6 dB after conventional laser stapedotomy with Air-Bone gap closure 22±0.3 dB. At one-year, improvement in Air conduction threshold was 25±1.1 dB. However, after one-year, no difference was observed in hearing gain between the conventional laser and diode laser group. Comparison of small fenestration stapedotomy using microdrill and diode laser was done by Feng *et al.*[19] Diode laser was used in 29 ears and microdrill was used in 21 ears. Statistically significant difference was not noted in the speech frequency after surgery and high frequency ABG closure between the two groups. However, Diode laser stapedotomy had better closure of ABG.

Surgical outcome after stapedotomy was extensively discussed.[20-25] Surgical outcomes were less favourbale in revision stapedotomy as compared to primary one.[25] In a study titled "Long term result after stapedectomy versus stapedotomy" by Kursten *et al.*,[22] concluded that stapedotomy had superior outcome and is the preferred surgical treatment for management of otosclerosis.

The outcome of this study showed that there is statistically significant improvement in mean Air-Bone gap i.e. 20.0±2.95 dB after surgery with p-value of less than 0.05 as compared to study by Adedji *et al.*,[10] showing mean gain 23.38±12.37 dB with p-value of 0.000. In our study, greater than 10dB Air-Bone gap closure was seen in 85% of patients after stapedotomy as compared to 81.6% reported by Adedji *et al.*[10] We also report 95% preservation of chorda tympani and tympanic membrane perforation 8% similar to study by Adedji *et al.*[10] Mean improvement in Air-Bone gap after diode laser stapedotomy was 24.98±5.348 dB[14] compared to our study showing that no difference was found in hearing gain between both studies.

CONCLUSION

Stapedotomy is a safe and effective surgical procedure with favourable hearing results and quality of life. So, we recommend that stapedotomy should be used routinely for treating otosclerosis to improve hearing and decrease morbidity.

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Authors' Contribution

Following authors have made substantial contributions to the manuscript as under:

MM & SNR: Data acquisition, data analysis, critical review, approval of the final version to be published.

AA & UR: Study design, data interpretation, drafting the manuscript, critical review, approval of the final version to be published.

KAK & AJ: Conception, data acquisition, drafting the manuscript, approval of the final version to be published.

Authors agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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