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Audioogical Outcome of Stapedotomy for Primary Otosclerosis

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Abstract:

Introduction: To find out the audiometric outcome after stapedotomy patients with clinical diagnosis of otosclerosis.

Methods: This prospective observational study was performed in a total of 142 patients diagnosed with primary Otosclerosis, who underwent Stapedotomy at the Department of ENT & Head-Neck Surgery, Combined Military Hospital, Dhaka between January 2013 to January 2018. All patients were evaluated as per the candidacy criteria for stapedotomy and selected patients underwent surgery during the study period and were followed up for a period of 12 months in the Otology clinic. Pre-operative and Post-operative audiometric evaluation were done using conventional pure tone audiometry with standard calibrations. Post-operative audiometry was performed at 03 month, 06 month and 12 month.

Results: Overall, the frequency specific pre-operative mean average Air-Bone gap was 51.6 dB at 500Hz, 35.7 dB at 1000 Hz, 40.5 dB at 2000 Hz, 38.9 dB at 4000 Hz and the frequency specific postoperative mean average Air- Bone Gap closure was achieved by 28.1 dB at 500Hz, 30.3 dB at 1000 Hz, 12.5 dB at 2000 Hz, 10.8 dB at 4000 Hz, by the time of 1 years of follow up. The difference was statistically significant ($p<0.05$) between pre-operative Air-Bone gap and post operative Air-Bone gap. After the surgery 88.7% tinnitus patients reported improvement and 11.3 % noted no change in tinnitus. Postoperative sensorineural hearing loss (SNHL) was seen in 1.4 %, failure rate was found 3.8% and 1.4% patients developed post-operative persistent vertigo.

Conclusion: Most of the audiometric results reveal excellent hearing improvement after stapedectomy surgery and worsened bone conduction (postoperative threshold shifts) for primary otosclerosis. It is safe and successful procedure providing long-term hearing expansion in primary otosclerosis with minimum failure rate.

Key words: Primary Otosclerosis, Stapedotomy, Teflon piston, Carhart's notch.

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Introduction:

Otosclerosis is a common cause of progressive hearing impairment that causes fixation of the stapes.[1] 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.[2] Generally, bone growth may disrupt the ability of the acoustical signal to travel from the middle ear to the inner ear in an effective manner, which may result in hearing impair-ment. This hearing impairment can be manifested as conductive, sensorineural, or mixed hearing loss de-pending on the extent and the progress of the disease.[3] Surgical intervention is the preferred treatment approach to ameliorate the conductive hearing loss associated with stapedial otosclerosis. It mainly affects the ossicular chain and can be treated surgically by removing (part of) the stapes and replacing it with a prosthesis: stapedotomy and stapedectomy, respectively. There is a small risk of permanent sensorineural hearing loss (SNHL) of less than 1%.[4,5] Other complications associated with stapes surgery include failure to close the air-bone gap, postoperative vertigo, and tinnitus.

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Materials and Methods:

This prospective observational study was performed in a total of 142 patients diagnosed with Primary Otosclerosis, who underwent Stapedotomy at the Department of ENT & Head-Neck Surgery, Combined Military Hospital, Dhaka between January 2013 to January 2018. All patients were evaluated as per the candidacy criteria for stapedotomy and selected patients underwent surgery during the study period and were followed up for a period of 12 months in the Otology clinic. Pre-operative and Post-operative audiometric evaluation were done using conventional pure tone audiometry with standard calibrations. Post-operative audiometry was performed at 03 month, 06 months and 12 months. All surgeries were performed by the two most experienced surgeon of the institute and were followed up for a period of one year in the Otology clinic. Pre-operative and post-operative audiometric evaluation was done using conventional pure tone audiometry. Post-operative audiometry was performed at 3, 6 and 12 month respectively. The bone-conduction and air conduction thresholds and the Air-bone gap (ABG), were assessed at 0.5 KHz, 1 KHz, 2 KHz and 4 KHz frequencies respectively. The surgical technique used in all patients was reverse stapedotomy. The basic technique was performed by common transmeatal approach under local anaesthesia with 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 crimpping 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 results were recorded in spreadsheet which was then processed using the SPSS statistics package for ver-23. 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.

Results:

Out of 142 patients, majority 55(38.7%) patients belonged to age 30-40 years with mean age was 38.5±13.7 years (Table I).

Table-I

Age distribution of the study patients (n=142)

Age group (years)	Frequency	Percentage
≤20	5	3.5
21-30	27	19.0
30-40	55	38.7
41-50	32	22.5
>50	23	16.2
Mean±SD	38.5±13.7	

Males were predominant (57.7%) and female was 60(42.3%). Male: female ratio was 1.36:1 (Figure I).

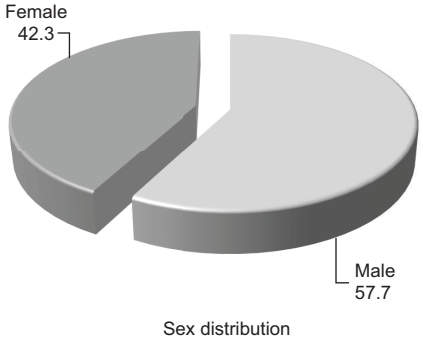

Fig.-1: *Pie chart showing sex distribution of the study patients (n=142)*

Majority 117(82.4%) patients had hearing loss, 65(45.8%) had hearing loss and tinnitus, 6(4.2%) had hearing loss & giddiness and 4(2.8%) had giddiness & tinnitus (Figure II).

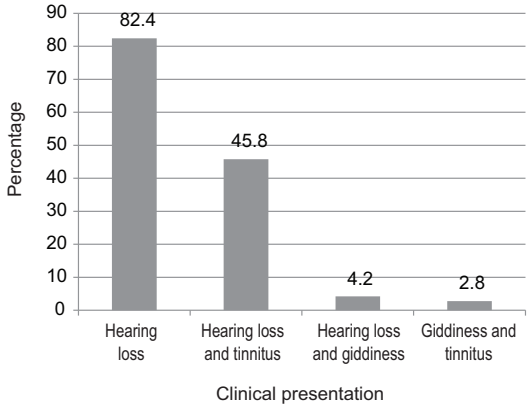

Fig.-2: *Bar diagram showing clinical presentation of the study patients (n=142)*

93(65.5%) patients had right site of operation and 49(34.5%) patients had left site of operation (Figure III).

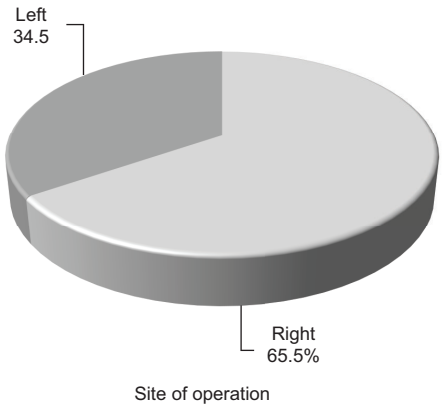

Fig.-3: *Pie chart showing site of operation of the study patients (n=142)*

Pre-operative and Post-operative (at 3 months, 6 months and 12 months) mean average air conduction thresholds were shown in Table II. Significant improvement in all frequency was noted in between preoperative and post operative mean air conduction threshold. (p=0.001) (Table II).

Overall, the frequency specific pre-operative mean average Air-Bone gap was 51.6 dB at 500Hz, 35.7 dB at 1000 Hz, 40.5 dB at 2000 Hz, 38.9 dB at 4000 Hz and the frequency specific postoperative mean average Air-Bone Gap closure was achieved by 28.1 dB at 500Hz, 30.3 dB at 1000 Hz, 12.5 dB at 2000 Hz, 10.8 dB at 4000 Hz, by the time of 1 years of follow up. The difference was statistically significant ($p<0.05$) between pre-operative Air-Bone gap and post- operative Air-Bone gap (Table III).

Regarding outcome of the surgery, most of the (88.7%) tinnitus patients was reported improve and 11.3 % was noted no change of tinnitus. Postoperative sensorineural hearing loss (SNHL) was seen in 1.4 %, failure rate was found 3.8% and 1.4% patients developed post-operative persistent vertigo (Table IV).

Table-II

Mean average Air Conduction Thresholds pre-op and post-op at 3 month, 6 month and 12 months (n=142)

PTA	Pre-op (dBHL) Mean±SD	Post-op 3 month (dBHL) Mean±SD	P value	Post-op 6 month (dBHL) Mean±SD	P value	Post-op 12 month (dBHL) Mean±SD	P value
500 Hz	61.4±21.5	47.5±17.2	0.001[s]	36.2±16.5	0.001[s]	33.6±17.8	0.001[s]
1 KHz	58.6±14.7	37.9±15.6	0.001[s]	30.2±13.7	0.001[s]	26.3±11.3	0.001[s]
2 KHz	54.3±15.3	35.8±13.4	0.001[s]	33.1±14.5	0.001[s]	30.7±12.5	0.001[s]
4 KHz	43.8±16.5	32.3±14.7	0.001[s]	33.7±12.8	0.001[s]	31.4±13.4	0.001[s]

s=significant; P value reached from paired t–test

Table-III

Pre-op A-B gap and post-op A-B closure on 1yr follow up (n=142)

PTA	Pre-op ABG (dBHL) Mean±SD	Post-op ABG (dBHL) Mean±SD	P value
500 Hz	51.6±5.7	28.1±10.3	0.001[s]
1000 Hz	35.7±7.6	30.3±11.1	0.001[s]
2000 KH	40.5±6.4	12.5±8.7	0.001[s]
4000 Hz	38.9±7.1	10.8±7.5	0.001[s]

s=significant; P value reached from paired t–test

Table IV

Distribution of the study patients by outcome (n=142)

Outcome	Frequency	Percentage
Improvement	126	88.7
No changes	16	11.3
Postoperative sensorineural hearing loss (SNHL)	2	1.4
Failure rate	5	3.8
Postoperative persistent vertigo	2	1.4

Discussion:

In current study observed that the majority 55(38.7%) patients belonged to age 30-40 years with mean age was 38.5±13.7 years. Alzhrani et al.[1] reported the mean (standard devia-tion) age of patients at intervention was 37(17) years, with a range of 19 to 69 years. Nair et al.[2] also supported similar observation they reported 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. Parida et al.[6] reported that mean age of the study population was 31 6 6.025 years (range, 23-47 years). Most patients were in the age group of 25 to 29 years.

In current study showed males were predominant (57.7%) and female were 60(42.3%). Male: female ratio was 1.36:1. Similar observation was found Alzhrani et al.[1] they showed the remaining 53 patients were 24 (45.3%) females and 29 (54.7%) males. Nair et al.[2] reported different observation 70 (70%) in women and 30 (30%) in men.

In this study showed that the majority 117(82.4%) patients had hearing loss, 65(45.8%) had hearing loss and tinnitus, 6(4.2%) had hearing loss & giddiness and 4(2.8%) had giddiness & tinnitus. Nair et al.[2] reported that 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. Alzhrani et al.[1] reported that mixed hearing loss was 52.8% and conductive was 47.2%.

In this study showed that 93(65.5%) patients had right site of operation and 49(34.5%) patients had left site of operation. Alzhrani et al.[1] reported right side operation was 31(58.5%) and left side was 22(41.5%). Nair et al.[2] also noted that there were more operations on the right ear in 62 cases, (62%) than on the left 38 cases (38%).

In this study showed pre-operative and post-operative (at 3 month, 6 month and 12 month) mean average air conduction thresholds were shown in table II. Significant improvement in all frequency was noted in between preoperative and post operative mean air conduction threshold. (p=0.001). Alzhrani et al.[1] reported stapedotomy yielded significant improvements in mean (SD) postoperative air-conduction thresholds of about 18.7 (11.7) dB (*P*<.0001) and mean (SD) postop-erative bone-conduction thresholds of about 2 (7.2) dB (*P*<.05). In one study by Kolo and Ramalingam[7] mean difference between pre and post op air conduction threshold (dbHL) was 28.4, 24.6, 18.4, and 14.52 at 0.5, 1, 2 and 4 KHz respectively. In another Study done by Myrvoll et al.[8] mean difference between pre and post op air conduction threshold (dbHL) was 29, 26.7, 19, 12.7 at 0.5, 1, 2 and 4 KHz respectively. Nair et al.[2] reported significant improvement in all frequency was noted in between preoperative and post operative mean air conduction threshold (p=0.012). In Nair et al.[2] 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. In one study by Mair[9] 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 Myrvoll et al.[8] 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. Our result is comparable with the previous results.

In this study overall, the frequency specific pre-operative mean average Air-Bone gap was 51.6 dB at 500Hz, 35.7 dB at 1000 Hz, 40.5 dB at 2000 Hz, 38.9 dB at 4000 Hz and the frequency specific postoperative mean average Air- Bone Gap closure was achieved by 28.1 dB at 500Hz, 30.3 dB at 1000 Hz, 12.5 dB at 2000 Hz, 10.8 dB at 4000 Hz, by the time of 1 years of follow up. The difference was statistically significant (p<0.05) between pre-operative Air-Bone gap and post operative Air-Bone gap. Nair et al.[2] observed 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. Alzhrani et al.[1] showed that Stapedotomy yielded significant improvements in mean (SD) postoperative air-conduction thresholds of about 18.7 (11.7) dB (*P*<.0001) and mean (SD) postop-erative bone-conduction thresholds of about 2 (7.2) dB (*P*<.05). Additionally, a significant correlation was found between improvement

in air-conduction thresholds and the size of preoperatve air-bone gap ($P<.01$). In a study presented by Spandow et al.[10] the mean value of the averaged pure tone thresholds improved from 57 to 26 dB after 1 year of stapedotomy. Sperling 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 their study.

In study by Vincent et al.[12] the overall rate of failures was 6.6%. There were 7.8% cases of severe postoperative SNHL. Comparison with present study observed that the most of the (88.7%) tinnitus patients was reported improve and 11.3 % was noted no change of tinnitus. Postoperative sensorineural hearing loss (SNHL) was seen in 1.4 %, failure rate was found 3.8% and 1.4% patients developed post op persistent vertigo.

Conclusion:

Common clinical presentation was found hearing loss and tinnitus in primary otosclerosis. Most of the audiometric results reveal excellent hearing improvement after stapedectomy surgery and worsened bone conduction (postoperative threshold shifts). Significant improvement was in post operative mean air conduction threshold in comparison to preoperative all frequencies. It is also more safe and successful procedure providing long-term hearing expansion in primary otosclerosis and minimum failure rate.

Conflict of interest: Nothing to declare

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