

Outcome of classical and reversal stapedotomy in otosclerosis

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Abstract

Classical and reversal stapedotomy both are exclusively done in otosclerosis but definite information regarding surgical advances, postoperative results, complications and information about how and in which patients these surgical techniques should exclusively be used are a source of continuous discussions. This prospective observational study was conducted in the Department of Otolaryngology-Head & Neck Surgery, Bangabandhu Sheikh Mujib Medical University, Shahbagh, Dhaka from July 2019 to December 2020 to compare the outcomes of classical and reversal stapedotomy in patients with otosclerosis. Total 28 cases of otosclerosis who underwent stapedotomy were divided into two groups i.e. Group A (classical stapedotomy) & Group B (reversal stapedotomy) with 14 patients in each group. All patients were followed up post-operatively up to 3 months with Pure-tone audiometry (PTA). There is no significant difference between classical and reversal stapedotomy approach in terms of hearing improvement and complications. Chorda tympani injury was the main complication in both the groups. Regarding hearing gain and complications there was no significant difference between classical and reversal stapedotomy approach.

Introduction:

Otosclerosis, also known as otospongiosis, is a primary localized disease of bony otic capsule that leads to stapes ankylosis.¹

It develops due to destruction of normal bone by osteoclasts and replacement of new spongy bone by osteoblasts and ultimately results in stapes fixation.² It is clinically characterized by a slow progressive conductive hearing loss, tinnitus, vertigo and paracusis willisii.³ Mixed or sensorineural type of deafness may also occur in a few patients.^{4,5}

The disease is more commonly seen in women of childbearing age and Caucasians.^{2,5} The onset of otosclerosis is usually around the third or fourth decade of life. It is predominating in females and is autosomal dominant, with a 20–40% penetrance.^{5,6} It can occur in both ears about 80% of patients.⁷ It most commonly involves the cochlear wall anterior to the oval window, followed by the round window niche and the cochlear apex.⁸ The definite diagnosis can only be made preoperatively by observing the mechanical fixation of the stapes.

The available treatments of otosclerosis are surgery, hearing aid and medical therapy with fluoride.² Surgery has been developed over time and therapy is mainly surgical. Due to the development of the stapes mobilization technique, proposed by Rosen, and fenestration of the oval window, proposed by Shea in 1958, otosclerosis surgery has constantly improved, the techniques being standardized, and a significant decrease in failures. The current trend is to replace total stapedectomies with stapedotomies, with reports of better air-bone (ABG) gap closure at high frequencies, and better speech recognition after the procedure. Although some authors have found similar results with the techniques.^{4,9,10}

There are different sequence of surgical steps. The choice is limited to two options. In classic procedure placement of the prosthesis following stapes suprastructure removal and in reversal procedure placement of prosthesis preceded stapes suprastructure removal are done.¹¹ Performing of classical stapedotomy causes loss of rigidity of mechanical transmission system unlike the reversal technique.⁴



Fenestration of footplate prior to removal of stapes arch reduce the incidence of floating footplate or footplate avulsion and application of prosthesis before removal of stapes superstructure decrease incidence of incus subluxation/luxation.¹² Thus, the reversal technique maintain a more rigid mechanical system which makes it possible to measure the force necessary to correctly position the prosthesis without significant trauma to inner ear as well as to minimize the risk of incus subluxation/luxation and footplate avulsion. Sometimes reversal technique cannot be performed due to the narrow space between facial nerve and posterior crura (narrow oval niche) where a modified reversal technique involves removing the posterior crura early to achieve a better access to the stapes footplate keeping the suprastructure intact.¹³ Fisch's exclusion criteria for reversal stapedotomy are otosclerosis obliterans and otosclerosis with narrow oval window niche.^{14,15}

However, different techniques are being used in stapedotomy now-a-days. To perforate the stapes footplate micro-drills or various lasers can be used. But no significant difference was found between laser-assisted, microdrill and manual microsurgical stapedotomy in regards with hearing outcome^{5,16}. Not only surgical techniques, but also prostheses available to the surgeon have continued to evolve since the teflon prosthesis developed by Treace. Besides teflon, various other materials such as titanium, gold, platinum or special steel have been used.^{4,17}

However both classical and reversal stapedotomy are being done worldwide now-a-days. Both the technique has some advantages and complications. However, definite information regarding surgical advances, perioperative complications, postoperative results and information about how and in which patients this surgical technique should be exclusively used are a source of continuous discussions. Therefore the present study has been designed to assess and compare audiometric results, perioperative and postoperative complications after classic and reversal techniques when performed with microdrill.

Methods

This prospective observational study was carried out on diagnosed cases of otosclerosis in the department of Otolaryngology-Head & Neck Surgery, Bangabandhu Sheikh Mujib Medical University (BSMMU), Dhaka from July 2019 to December 2020. Patients were selected purposively according to selection criteria. A total number of 28 patients were divided purposively into two groups (14 patients in each group). After selection of the subjects, the nature, purpose and benefit of the study were explained to each patient of in details. They were encouraged for voluntary participation. They were allowed to withdraw their name from the study whenever they feel like. Informed written consent was taken

from the participants. Ethical clearance was obtained from the Institutional Review Board (IRB) of BSMMU.

Patients aged from 18 to 50 years, clinically diagnosed as otosclerosis with normal otoscopic finding with conductive hearing loss not more than 70 and 30 dB in air and bone conduction respectively were included in this study. Patients with tympanic membrane perforation, obliterative otosclerosis, cochlear otosclerosis, active disease and only hearing ear were excluded from this study. All patients attended first in outpatient department, where a detailed history was taken and a thorough general & ENT examination were performed. Microscopic & otoendoscopic examinations were performed in indoor setup. PTA, impedance and SRT for subjective assessment of hearing loss was performed in all cases. Hearing loss was calculated by averaging the threshold of hearing at 500, 1000 & 2000 Hz from PTA.

Steps of Classical Stapedotomy

The procedure was carried out under general anesthesia. Local anesthetic (2% lidocaine with 0.0005% adrenaline) infiltration in the canal was done before procedure. Position was supine with head rotated to opposite shoulder. Surgery was performed through a purely permeal approach under microscope. In permeal approach a tympanomeatal flap was elevated from 7 o'clock to 12 o'clock position. Chorda tympani nerve was freed from mucosal fold. Posterosuperior bony annulus was curetted enough to adequate release of chorda tympani, expose of stapes, oval window, facial nerve and base of pyramid. Diagnosis was established by palpation of handle of malleus and stapes suprastructure to check fixation of footplate. Assessment of length of prosthesis was done by measuring from the undersurface of incus to stapes footplate. Extra 0.25 mm was taken for the hole. House measuring rod and zig was used for prosthesis measurement. Fixed diameter (6 mm x 0.6 mm) Teflon piston (Grace surgical) prosthesis was used in all cases. Disarticulation of incudostapedial joint was done in posterior to anterior direction. Division of stapedius tendon was done by micro scissor. Posterior crura of stapes was excised by skeeter drill with 0.7mm diamond burr and down fracture and removal of stapes superstructure was done. Stapedotomy hole was made by skeeter drill with 0.7 mm burr at posterior third of footplate. Placement of teflon stapes piston prosthesis between oval window and long process of incus. Crimping of loop was done for proper fixation. Sealing around the footplate hole by fat graft harvested from ear lobule. Repositioning of tympanomeatal flap in its original position. Packing the external acoustic canal by gelfoam and sofra tulle was done.

Steps of Reversal Stapedotomy

The procedure was carried out under general anesthesia. Local anesthetic (2% lidocaine with .0005% adrenaline) infiltration in the canal was done before procedure. Position

was supine with head rotated to opposite shoulder. Stapes surgery is usually performed through a purely permeal approach under microscope. In permeal approach a tympanomeatal flap was elevated from 7 o'clock to 12 o'clock position. Chorda tympani nerve was freed from mucosal fold. Posterosuperior bony annulus was curetted enough to adequate release of chorda tympani, expose of stapes, oval window, facial nerve and base of pyramid. Diagnosis was established by palpation of handle of malleus and stapes suprastructure to check fixation of footplate. Assessment of length of prosthesis was done by House measuring rod and zig from the undersurface of incus to stapes footplate. Extra 0.25 mm taken for the hole. Stapedotomy hole was made by skeeter drill with 0.7 mm burr at posterior third of footplate. Placement of teflon stapes piston prosthesis between oval window and long process of incus. Crimping of loop was done for proper fixation. Disarticulation of incudostapedial joint was done in posterior to anterior direction. Division of stapedius tendon done by microseissor. Posterior crura of stapes was excised by skeeter drill with 0.7mm diamond burr and down fracture and removal of stapes superstructure done. Sealing around the footplate hole by fat graft harvested from ear lobule. Repositioning of tympanomeatal flap in its original position. Packing the external acoustic canal by gelfoam and sofra tulle was done.

Hearing outcome was assessed preoperatively and postoperatively at 6 weeks and 3 months with Pure-tone audiometry (0.5, 1 and 2 kHz). Audiological evaluation was done according to guidelines of the Committee on Hearing and Equilibrium of the American Academy of Otolaryngology-Head and Neck Surgery Foundation. Postoperative ABG to within 10 dB was defined as surgical success and within 20 dB was considered satisfactory.^{4,18} Peroperative complications (incus luxation and footplate avulsion) and postoperative complications (perilymph fistula, dysgeusia/chorda tympani injury, facial nerve injury, TM perforation, vertigo and dead ear) was also assessed. Taste abnormalities was investigated as presence or absence of a subjective abnormal taste sensation. All the data were compiled and sorted properly and the numerical data were analyzed statistically by using Statistical Package for Social Sciences (SPSS-26). A *p*-value of less than 0.05 was considered statistically significant.

Results

Age of the patients ranged from 18 to 50 years. The Mean \pm SD age was 35.93 \pm 10.62 and 35.86 \pm 12.9 years respectively in classical and reversal stapedotomy group. No significant differences were observed between the groups. Majority of the patients were female & was comprising 10 (71.4%) in both the groups. Most patients were housewife & constituting 9(64.3%). Right ear was operated more in both groups. Most of the patients had bilateral otosclerosis 9(64.3%) in both groups.

Only 4 (28.6%) and 5 (35.7%) study subjects had family history of otosclerosis present in both groups respectively.

Mean \pm SD pre and post-operative air conduction was 54.88 \pm 3.43 dB and 29.52 \pm 3.16 dB ingroup A and 54.29 \pm 4.27 dB and 27.62 \pm 2.83 dB in group B. This difference was statistically significant. Mean \pm SD pre and post-operative bone conduction was 23.33 \pm 3.98 dB and 21.55 \pm 3.10 dB in group A and 24.05 \pm 4.12 dB and 22.62 \pm 3.56 dB in group B. This difference was not statistically significant. Mean \pm SD pre and post-operative air bone gap was 31.55 \pm 5.49 dB and 7.48 \pm 4.61 dB in group A and 30.24 \pm 4.79dB and 6.19 \pm 3.61 dB in group B. This difference was statistically significant but postoperative hearing outcome was not statistically significant between the groups. Mean hearing outcome was 24.10 \pm 3.32 dB group A and 25.36 \pm 3.34 dB in group B. Postoperative hearing outcome was not statistically significant between the groups.

After stapedotomy pre and postoperative airborne gap difference of final follow-up at 3months was \leq 10 dB in 12(85.71%), 11-20 dB in 1(7.14%) and $>$ 20 dB in 1(7.14%) case in group A and \leq 10 dB in 13(92.86%) and 11-20 dB in 1(7.14%) case in group B. No one have pre and postoperative air bone gap difference $>$ 20 dB ingroup B. (Table-I,II & Figure-1)

Table-I			
Mean pure tone audiometry of study subjects in both groups (N=28)			
Pure tone audiometry	Preoperative	Post-operative	^b p value
Air conduction (dB)			
Group A (n=14)	54.88 \pm 3.43	29.52 \pm 3.16	<0.001 ^s
Group B (n=14)	54.29 \pm 4.27	27.62 \pm 2.83	<0.001 ^s
^a p value	0.812ns	0.247ns	
Bone conduction (dB)			
Group A (n=14)	23.33 \pm 3.98	21.55 \pm 3.10	0.196 ^{ns}
Group B (n=14)	24.05 \pm 4.12	22.62 \pm 3.56	0.298 ^{ns}
^a p value	0.644ns	0.408ns	
Air-bone gap (dB)			
Group A (n=14)	31.55 \pm 5.49	7.48 \pm 4.61	0.001 ^s
Group B (n=14)	30.24 \pm 4.79	6.19 \pm 3.61	0.019 ^s
^a p value	0.513ns	0.185ns	

Table-II			
Hearing outcome of the study subjects in both groups (N=28)			
Variable	Group A (n=14)	Group B (n=14)	p value
Hearing outcome (dB)	24.10 \pm 3.32	25.36 \pm 3.34	0.326ns

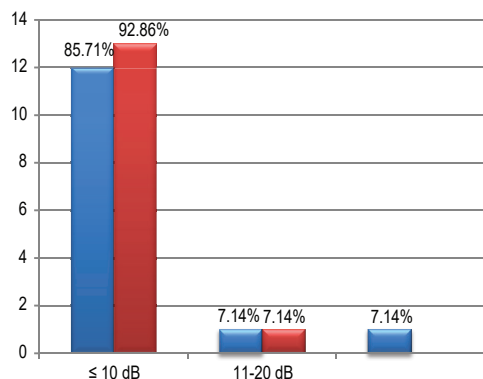


Figure - 1: Distribution of study subjects according to ABG in both groups (N=28) at 3 months

During the course of the study only 1(7.14%) case in both the groups developed postoperative temporary vertigo that was subsequently relieved. Only 3(21.4%) case in Group A and 2(14.3%) case in Group B developed taste disturbance/chorda tympani injury. No patient developed postoperative perilymph fistula, facial nerve palsy, TM perforation, incus luxation or dead ear. On the other hand, 11(74.6%) and 12(85.7%) patients had no complication in both groups respectively. No significant differences were observed between the groups. (Table - III)

Table-III			
Continued: Distribution of study subjects according to complications (N=28)			
Variable	Group A (n=14)	Group B (n=14)	p value
At 3 months			
No Complications	11 (78.6%)	12 (85.7%)	0.769ns
Complications	3 (21.4%)	2 (14.3%)	
Incus luxation	0 (0%)	0 (0%)	
Footplate avulsion	0 (0%)	0 (0%)	
Chorda tympani injury	3 (21.4%)	2 (14.3%)	
Facial nerve palsy	0 (0%)	0 (0%)	
Perilymph fistula	0 (0%)	0 (0%)	
Permanent Vertigo	0 (0%)	0 (0%)	
TM perforation	0 (0%)	0 (0%)	

Discussion

In this study, mean age was 35.93 years in classical and 35.86 years in reversal stapedotomy. The youngest and eldest patients were 18 and 50 years respective. Almost similar findings were observed by Bulgurcu et al.¹¹ Majority (71.4%) of the subjects were female. Male and female ratio was 1:2.5.

Our findings are almost similar to Lang et al.¹⁹; Souza et al.¹ and Bulgurcu et al.¹¹ But Fakir et al.²⁰ found that male (68.75%) was affected more by otosclerosis than female (31.25%) which was dissimilar to our finding. This difference may be due to lack of medical facilities in the remote part of the country. In the present study, 35.71% population was student, 35.71% was service holder and 64.28% was housewife in their occupations. Fakir et al.²⁰ found in his study that 31.25% was student, 15.62% was service holder and 25% was house wife.

Only few study subjects had family history of otosclerosis. No study was found to compare these demographic variables due to different in methodology.

In the present study, otosclerosis patients presented with hearing loss, tinnitus and dizziness. Among them bilateral otosclerosis was common. Almost similar finding was observed by Xie J et al.²¹ Fakir et al.²⁰ found deafness (100%), tinnitus (75%) and vertigo (25%) in their study which was almost similar to our study. Souza et al.¹ reported that unilateral (71.2%) otosclerosis was more common than bilateral which was dissimilar to our finding.

Postoperative air conduction, bone conduction and air bone gap were decreased at 3 months of follow-up from 6 weeks follow-up values in both groups. This difference was statistically significantly ($p < 0.05$) in case of air conduction in both the groups. In case of bone conduction and air-bone gap, the differences are not significant ($p > 0.05$) between the two groups. Almost similar findings were observed by Freni et al.⁴ where at 6 weeks, mean \pm SD of air-bone gap was 13.03 ± 7.78 (dB) in classical group and 11.78 ± 5.62 (dB) in reversal group and at 4 months, air-bone gap was 9.54 ± 6.07 (dB) and 8.09 ± 3.72 (dB) respectively which was not statistically significant between the groups.

In the present study, mean hearing outcome was increased more in reversal group than classical group both at 6 weeks after surgery and 3 months after surgery. This difference was not statistically significantly ($p > 0.05$) between the groups. But significant ($p < 0.05$) difference was found within both the groups. Almost similar findings were observed by Freni et al.⁴

At final follow-up of 3 months, all the subjects obtained ABG < 20 (dB) in reversal group but only 7.14% case had ABG > 20 (dB) in classical group. Almost similar finding was observed by Freni et al.⁴ Lang et al.¹⁹ found no significant differences in auditory outcomes of both groups. After 3 months of post-operative follow up bone conduction values at 2 kHz was decreased in 9 (64.28%) cases in Group A and in 8 (57.14%) cases in Group B. No statistically significant difference ($p > 0.05$) was observed between the groups in pre and postoperative bone conduction at 2 kHz.

After 3 months of post-operative follow up average air-bone gap values at 2 kHz was decreased from 15.57±7.79 dB to 6.43±4.13 dB in classical group and 15.36±8.43 dB to 5.36±4.58 dB in reversal group B. No statistically significant difference ($p>0.05$) was observed between the groups in pre and postoperative air-bone gap at 2 kHz. Almost similar finding was observed by Xie J et al.²¹

In term of post-operative complications, only chorda tympani injury were found after operation at final follow-up of 3 months. No permanent vertigo was found but immediate post operative vertigo was seen in few cases. The rate of development of postoperative complication was lower in reversal group than classical group. But this difference was not statistically significant. Szyman'ski et al¹² found SNHL, dead ear and occasional vertigo as postoperative complications in classical group probably due to too long prosthesis which was eventually removed. Freni et al⁴ found no important complications in both groups, seemingly due to the aid of CO2 laser used for crus vaporization and footplate fenestration. Haque MN et al³ found chorda tympani nerve injury (taste disturbance) in 3 (8.82%), TM perforation in 1 (2.94%) and FN palsy in 1 (2.94%) patient. Hossain MD et al²² found only 1 (2%) case developed postoperative hearing loss or SNHL. Postoperative persistent vertigo developed in only 1 (2%) case which relieved over time.

Fiorino and Barbieri¹³ and Szyman'ski et al¹² reported that the implementation of a classic stapedotomy causes the loss of rigidity of the mechanical transmission system in contrast to the reversal technique. Therefore, to avoid inner ear trauma, incus subluxation and reduced risk of persistent hearing loss; self-crimping prosthesis is necessary in classic stapedotomy. The same type of prosthesis was used successfully in reverse stapedotomy group. Szyman'ski et al¹² and Lang et al¹⁹ reported that the reversal approach is considered safer than the classic procedure due to less complications; especially, floating footplate and incus subluxation. In our study no such complications were observed which may be due to small number of cases in this study.

Conclusion

There is no significant difference between classical and reversal stapedotomy approach in terms of hearing improvement and complications. Chorda tympani injury is the main complication in both the groups. Although optimal care had been taken by the researcher in every step of the study, there were some limitations. The study was conducted in a selected hospital. So the study population might not represent the whole community. The sample was taken purposively. So there may be chance of bias which can influence the results. The study and follow-up period was short in comparison to other studies. Moreover the sample

size was small. Similar type of study should be done with large sample size and long period of follow-up.

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