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A comparative study of results of stapedotomy and neo-stapedotomy as a surgical treatment for otosclerosis

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ABSTRACT

Background: The aim of the study was to establish the usefulness of preservation of the stapedius tendon and the incudo-stapedial joint during the surgical procedure for the treatment of otosclerosis, to find out the advantages of neo-stapedotomy over standard stapedotomy and to compare the hearing improvement in neo-stapedotomy and stapedotomy.

Methods: A prospective, randomised, controlled study with a sample size of 150 patients (ears) presented with pure conductive deafness, paracusis willisii and tinnitus was done. The patients were divided in to group A (n=60) & and group B (n=90), where neo-stapedotomy and standard stapedotomy procedure were performed respectively. Pure tone audiometry and tympanometry were done both pre and postoperatively. Speech discrimination score (SDS) and loudness discomfort levels (LDL) were measured at 3 months postoperatively.

Results: Postoperative hearing improvement in both groups was almost identical. Improvement in middle ear compliance was marginally more in group A patients. Stapedial reflex could be elicited in 72 % of the patients in group A, but remained absent in group B, at 3 month post-operatively. The SDS became worse with more than 20 dB suprathreshold sounds in group B patients whereas it was maintained even with 80 dB in most patients of group A. Post-operative mean LDL for both pure tone and speech frequency in group A patients were higher than those in group B.

Conclusions: The difference of SDS and LDL between two groups were statistically significant. Hence, neo-stapedotomy is a better procedure, as no postoperative pseudo-recruitment 'rollover' observed and also dynamic range of hearing increased.

Keywords: Neo-stapedotomy, Stapedotomy, Stapedial reflex, Speech discrimination score, Loudness discomfort level

INTRODUCTION

Otosclerosis is a primary progressive focal disease of the labyrinthine capsule characterised by ankylosis of the footplate of the stapes by the formation of new spongy bones. The prevalence of otosclerosis has been estimated to be 0.2 to 1.0 % in Caucasians and rarely in Africans, Asians and Amerindians. A higher incidence to the extent of 17% & 10% has been reported in the Todas tribal population from Nilgiri, South India, most likely due to the endogamous marriages within the tribal population. However, no such study of prevalence of otosclerosis in

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India or in eastern region is found even with extensive search of the literature.

The surgical treatment for hearing loss due to otosclerosis was attempted by Kessel in 1878, although Prosper Meniere had advocated stapes mobilisation for hearing loss as early as 1842. At the end of the nineteenth century, many attempts either to mobilise or to remove the stapes were described but the good results were short lived and many patients had no hearing after surgery.⁴

The surgical management switched to fenestration of the lateral semicircular canal in order to bypass the fixed ossicular chain and allow free movement of the inner ear fluids in response to sounds. Lempert's operation in 1938 became the first commonly performed surgical procedure for otosclerosis.⁵

The emphasis then returned to the stapes, with the stapes mobilisation of Rosen and closure of the air- bone gap, but this was liable to short term refixation and the consequent recurrence of hearing loss.⁶

Then came the era of replacement of stapes by artificial prosthesis i.e. stapedoplasty operation, which can be of different types: stapedectomy, stapedotomy and stapedotomy with preservation of stapedius tendon (neostapedotomy). Shea first described and later modified Stapedectomy operation in 1963, in which complete removal of footplate of stapes with reconstruction of the ossicular chain by artificial prosthesis was carried out.⁷

For the past 40 years, since Shea (1958) introduced the procedure, the results of the stapes surgery have been excellent. Since then otosclerosis related conductive hearing impairment has been treated with the intent of normalising the function of the middle ear conductive apparatus. Many of the techniques described differ only in how and where the new window be formed on the oval window, how large it should be, the diameter and the material of the piston used and what type of tissue should be used for closing the window.

Surgery for otosclerosis has evolved from total stapedectomy to partial stapedectomy and then to stapedotomy, a small fenestra technique, where less than 25% of the footplate of the stapes is removed followed by application of artificial prosthesis. Colletti et al have opined that small fenestra techniques show a lower incidence of perilymphatic fistulas and immediate or delayed sensorineural hearing loss, better high frequency hearing and speech discrimination scores and fewer complications in the middle ear (slipping prosthesis, loose prosthesis etc.).8

In all these techniques, the stapedial tendon is routinely sectioned, thus reducing the protecting function of the middle ear.

Acoustic reflex might provide a mechanism for constantly changing the auditory input, which may aid in either auditory analysis or the maintenance of attention, without sacrificing transmission sensitivity. Also, stapedius muscle modulates the acoustic system and provide a means by which an auditory signal can be separated from background noise and allow maintenance of attention to a continuous sound. 10

McCandless and Schumacher found that the patients with facial nerve paralysis proximal to the stapedius branch experienced reduced tolerance for loud sounds and a reduction of speech discrimination at high intensity levels 'rollover'. 11

Reduced loudness discomfort levels for speech, distortion and pseudo-recruitment 'rollover' were reported by McCandless et al after stapedectomy and they ascribed them to the cutting of the stapedius tendon.¹²

Chadwell et al found that speech intelligibility was significantly poorer in the stapedectomised ear than in the unoperated ear at all intensity levels and they considered the acoustic reflex as a general aural overload regulator.¹³

Girgis et al summarised the effects of cutting the stapedius muscle as: a drop of high tones, lowered speech discrimination, hyperacusis and susceptibility to sensorineural damage. He advocated for the preservation of the stapedius tendon during stapes surgery.¹⁴

Though preservation of the stapedius muscle during the surgery for otosclerosis have been reported in the literature, yet the references available are not too many.

According to Roychaudhuri et al. 'neo-stapedotomy' is the stapes surgery in otosclerosis with anatomical preservation of stapedius tendon and incudo-stapedial joint. In the cases on which it is possible to preserve both the structures, it is named as "classical neo-stapedotomy". 15

The aim of the study was to establish the usefulness of preservation of the stapedius tendon and the incudo-stapedial joint during the surgical procedure for the treatment of otosclerosis, to find out the advantages of neo-stapedotomy over standard stapedotomy and to compare the hearing improvement in neo-stapedotomy and stapedotomy.

METHODS

This prospective randomised controlled study was done in the Department of E.N.T. and Head- Neck Surgery, Ramakrishna Mission Seva Pratishthan, Vivekananda Institute of Medical Sciences, Kolkata & Sri Aurobindo Seva Kendra, Kolkata for a period of 4 yrs. from January '2016 to December '2019.

A simple random sampling technique was adopted and the patients attending OPD with history of bilateral, progressive hearing loss, a normal otoscopic examination, pure conductive deafness with normal bone conduction values at 500 Hz, 1 & 2 KHz and absent stapedial reflex, were included in the study. The patients with a history or clinical evidence of middle ear disease or surgery, mixed hearing loss or patients with only one hearing ear were excluded.

A detailed history of each case was taken, which included the chief complaints, history of present illness, history of past illness, family history and personal history and the data was recorded in a proforma. The onset, duration and the progress of the disease symptoms were enquired for, which included deafness, tinnitus, vertigo, ear blockage and ear discharge, if any.

Otoscopic examination of the external auditory canal and tympanic membrane was done and the mobility of the tympanic membranes was assessed. Tuning fork tests (Rinne, Weber, Gelle and Absolute bone conduction test) were performed in all the cases. The pre-operative clinical assessments were confirmed by routine pure tone audiometry and tympanometry including middle ear compliance and stapedial reflex.

The patients were divided randomly in to two groups (n=75 in each group initially) for the comparative study after taking written informed consent. During operation, 15 patients, who were kept for neo- stapedotomy technique had to undergo standard stapedotomy operation due to anatomical variations and underlying pathological condition. Hence, group A (n=60) comprised patients where preservation of stapedius tendon and incudo-stapedial joint was done and group B (n=90) comprised patients where standard stapedotomy procedure was followed.

All the patients were operated under local anaesthesia using either operating microscope or 0-degree otoendoscope. Each subject was placed supine on the operating table with the head slightly rotated away from the ear to be operated on. The ear was prepared with sterile draping. Local anaesthetic was injected in to the ear canal with 2% xylocaine with adrenaline.

A posterior tympanomeatal flap was created in the canal skin by endomeatal incision from approximately 7 to 1 O'clock in the right ear and 5 to 11 O' clock in the left ear, 12-14 mm lateral to the tympanic annulus. The flap was gently raised in the subperiosteal plane. The annulus was detached from the bony sulcus and then elevated, care was taken so that the tympanic membrane was not perforated and the chorda tympani nerve was not cut. The tympanomeatal flap was then placed anteriorly over the handle of malleus. The chorda tympani nerve was mobilised and pushed downwards out of the field of operation. Posterosuperior bony overhang was then removed with the curette and/or micro drill until the

horizontal part of facial nerve could be seen superiorly and the base of the pyramid posteriorly. Ossicular mobility was then tested. The lenticular process was gently palpated to confirm the fixation of the movement of stapes.

The distance from medial surface of the incus to the footplate was measured with the help of a Shea's teflon piston depth measuring gauge. The fenestra was made preferably at the centre of the footplate with intact stapes, stapedius tendon and incudo-stapedial joint in all the patients. Measured teflon piston was inserted in to the fenestra and hooked with the distal part of the long process of the incus. Crurotomy was done after the insertion of the teflon piston. In group-B patients, the stapedius tendon was cut close to the pyramid and then the superstructure of the stapes was removed (Figure 1 and 2).



Figure 1: Neo-stapedotomy (with preserved stapedius tendon and incudo-stapedial joint).



Figure 2: Standard stapedotomy operation.

The tympanomeatal flap was restored to its anatomical position. Subjective hearing improvement was noted thereafter using whispered voice. The gelfoam layers were placed over the tympanomeatal flap. Antibiotic, decongestant, analgesic and vestibular sedative as and when necessary were prescribed to all patients post-

operatively. The gelfoams in the ear canal were cleaned after third post-operative week.

Pure tone audiometry was carried out at three months after surgery. Air bone gap (ABG) at 0.5, 1 and 2 KHz were considered. Results were reported as successes when ABG was less than 10 dB (Figure 3).

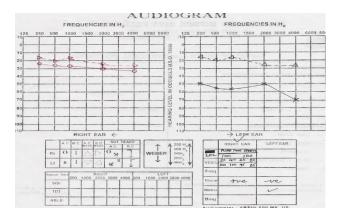


Figure 3: Post-operative pure tone audiometry with SDS% and LDL (neo-stapedotomy, right).

Tympanometry including middle ear compliance and stapedial reflex were measured and compared in both the groups after three month post-operatively (Figure 4).

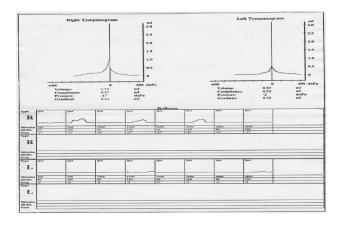


Figure 4: Post-operative tympanometry (neostapedotomy, right).

Speech discrimination score (SDS) with suprathreshold sound intensities and loudness discomfort level (LDL) for both pure tone and speech frequencies were measured 3 months after surgery in both the groups. The results of the speech discrimination score and loudness discomfort level were compared and statistically analysed with the help of student's t-test.

RESULTS

All the patients presented with progressive deafness (100%) of gradual onset as their chief complaints. Tinnitus (66%), paracusis willisii (76%) and vertigo (2%) were other associated complaints.

Ten percent of the patients had history of stapedotomy done in one of the ears, 4% patients presented with past history of neo-stapedotomy in one ear. No history of any ear surgery was present in 86% cases. The patients with a history of ear surgery were operated in the other diseased ear.

On otoscopic examination, no significant abnormality was found in external auditory canal. The tympanic membrane was normal and mobile in 82% of the cases. In 18% cases, tympanic membrane was dull and mobile.

On Pure Tone Audiometry, 80 % patients presented with moderate conductive loss i.e. with 30-45 dB of Air Bone Gap at frequency 0.5, 1 and 2 KHz. Severe conductive loss was present in 16% cases and mild in 4% cases.

Tympanometry was done in all patients to evaluate middle ear compliance, stapedial reflex, middle ear pressure and tympanic curves. The stapedial reflex was absent by ipsilateral and contralateral stimulation. Middle ear pressure was normal in all the patients.

Thirty patients of group A showed type A tympanometry curve and the other thirty had type as curve while tympanometry curve was of type A in 50 cases of group-B and type as in 40 cases.

Pure tone audiometry conducted at 3 months postoperative revealed that closure of A-B gap to less than 10 dB were achieved in 95% patients of group A and 90 % patients of group B.

In the study, pre-operative middle ear compliance in group A patients was 0.28 ml which increased to 0.75 after 3 months of operation while in group B patients, it improved from 0.30 ml to 0.71 ml. Middle ear compliance was found to be increased in both the study groups after operation but improvement was marginally more in group A.

Stapedial reflex could be elicited in 42 patients of group A (72% cases) after 3 months of operation, while it could not be elicited in any of the patients of group B.

Mean speech discrimination score at 20 dB suprathreshold sound intensity was 100% in both the study groups. The score was 100%, 93.5% and 86.58% at suprathreshold sound intensities of 40 dB, 60 dB and 80 dB respectively in group A patients. It became poorer in group B patients when the sound intensity was increased further from 20 dB; it was 93.06%, 82.72% and 71.89% (Table 1).

The statistical difference between the two groups at 40 dB, 60 dB and 80 dB suprathreshold sound intensities were highly significant (Table 1).

The mean LDL value in group A patients was 94.67 dB and 85.17 dB with pure tone and speech frequency

respectively while in group B patients, the results were 80.11 dB and 70.44 dB. Thus, group A patients had higher mean LDL value compared to group B (Table 1).

The statistical difference for LDL value for both pure tone and speech frequencies between the two groups was highly significant (Table 1).

Table 1: Mean values of SDS % (at different supra threshold sound intensity levels in dB) & LDL (pure tone and speech frequency) postoperatively with statistical analysis.

| Parameters / Group | | Group A | Group B | P value | Remarks |
|-----------------------------------|-----------|----------|----------|---------|-------------|
| Speech Discrimination score | 20 dB | 100% | 100% | - | |
| | 40 dB | 100% | 93.06% | < 0.001 | III: . 1.1 |
| | 60 dB | 93.5% | 82.72% | < 0.001 | Highly |
| | 80 dB | 86.58% | 71.89 | < 0.001 | Significant |
| LDL | Pure Tone | 94.67 dB | 85.17 dB | < 0.001 | Highly |
| | Speech | 80.11 dB | 70.44 dB | < 0.001 | Significant |

DISCUSSION

In our study, all the patients presented with progressive deafness, 66% presented with tinnitus, 76% with paracusis willisii and 2% with occasional vertigo. Rasmy (1986) observed chief complaints being deafness in 100%, tinnitus in 80% and occasional vertigo in 5% cases. The results were almost comparable to the present study. 16

Silverstein et al reported the average preoperative airbone gap for group A as 22.8 dB and 25.2 dB for group B. The higher mean values for the preoperative air –bone gap in the present study might be attributed to the late presentation of the patients in this part of country in both the study groups.¹⁷

Roychaudhuri et al observed the mean middle ear compliance in both pre- and post-operative period as 0.34 ml and 0.72 ml in group A while in group B as 0.36 ml and 0.64 ml respectively. Rasmy also showed an increase in mean middle ear compliance from 0.47 ml to 0.72 ml at 3 months post operatively in group A patients. The results of Roychaudhuri et al and Rasmy conform to the present study.

Gros et al got stapedial reflex in 61.8% patients at onemonth post-operative and 94.1% patients at 3-month post-operative in group A, while Roychaudhuri et al reported the same in 75% and 90% patients at 1 and 3 post-operative months, respectively. None of the authors could elicit it in patients of group B where stapedial tendon was transected. Therefore, the return of the stapedial reflex in group A patients in the present study nearly corroborated with the findings of Gros et al and Roychaudhuri et al.¹⁸

In some patients of group, A with intact stapedius muscle, no stapedial reflex was evoked post-operatively in the present study, which was at par with the opinion of Meurman et al and Karjalainen et al.^{19,20}

The absent stapedial reflex post operatively in some patients of group A was probably due to the insufficient stimulus intensity levels in the contralateral ear (Meurman et al.)

Karjalainen et al opined that the absence of stapedial reflex in group A was probably due to the pressure exerted by the stapedius muscle on to the incus instead of on to the stapes due to detached crurae (Crurotomy). They concluded that the preservation of stapedius tendon required more revision surgery. They further reported that the blood circulation to the stapes and the long process of incus was better maintained with preservation of stapedius tendon and incudo-stapedial joint.

Causse, reported that 75% of the patients regained stapedial reflex when tested 1 year. After surgery he found that in 30% of the patients, the stapedius tendon was anatomically perpendicular to a line drawn from incus to footplate. In these cases, the tendon could be preserved and not needed to be reconstructed. In 70% of the patients, the tendon was at an angle with the line drawn from incus to the footplate, that would pull the prosthesis in to the vestibule when contracted. The tendon needs to be reconstructed in these cases, making sure that the reconstructed tendon lies perpendicular to the piston.²¹

Causse (loc cit) believed that the benefits of the patients were that the inner ear was protected from acoustic trauma, patients heard better in a noisy situation and that they heard their own voice normally. Revision surgery was not found to be necessary in any of the patients in the present study, might be due to shorter duration of post-operative follow up.

It is presumed, that the reason for the absence of stapedial reflex in some of the group A patients of the present study could be due to the reasons ascribed by Gros et al (2000), Meurman et al, Karjalainen et al.

Rasmy et al observed air-bone gap closure to less than 10 dB in 22 cases out of 25 and 10-20 dB in 2 cases after 3 months of the procedure; one of their patients did not

improve after surgery. Silverstein et al reported improvement in air bone gap less than 10 dB in 88 % cases and 10-20 dB in 12 % cases of group A, while the same in group B was 77 % and 23 % cases respectively. The hearing improvement was similar in both the groups. Roychaudhuri et al also concluded that post-operative hearing improvement was identical in both the groups. So, the post-operative improvement in hearing in the present study conforms to the studies of Rasmy, Silverstein et al, Roychaudhuri et al.

Roychaudhuri et al reported mean SDS% with suprathreshold sound intensities in both the groups. It was 100% in both the groups for 20 dB of sound intensity. With further increase in sound intensities, the deterioration in group B patient was worse than group A. The findings in the present study were comparable to the study by Roychaudhuri et al.

The absence of stapedial muscle action might result in auditory overload resulting in distortion of sound in the operated ear particularly to loud sounds and reduced speech discrimination (rollover) at high intensity levels (McCandless et al). They observed curious loudness changes 'pseudo-recruitment' at suprathreshold sound levels unlike the typical recruitment patterns recognised in cochlear disorder in which recruitment were seen at all intensity range. In all their cases, the intensity increments were linear at lower intensity levels with an abrupt change in loudness perception occurring between 65-90 dB of suprathreshold sound intensity.

Lowered speech discrimination score in patients with sectioned stapedius tendon can be explained by a drop of high tones which causes diminution of hearing of consonants, distortion of frequency, distortion of phase, distortion of harmonics and the masking effect of low tones on the high tones (Girgis). So, the preservation of the stapedius tendon is essential for better speech discrimination and no pseudo-recruitment 'rollover'.

The pure tone hearing threshold level and the hearing level where the patient felt the sound uncomfortably loud were measured in all the patients 3 month postoperatively. The gap between the threshold level and loudness discomfort level is the 'dynamic range' of ear. Dynamic range of ear decreases with increase in recruitment.

Gros et al reported mean LDL for speech frequency in both the groups as 114.1 dB and 98.0 dB respectively. Roychaudhuri et al observed the mean LDL for both pure tone and speech frequencies in group A as 95 dB and in group B as 83 dB and 79 dB respectively. The results in the present study almost corroborated with the study of Gros et al and Roychaudhuri et al.

The contraction of the restored stapedius muscle in patients of group A with preserved tendon increases the middle ear compliance, which is responsible for the

higher LDL value (Gros et al). They suggested that increase in LDL with preservation of stapedius tendon, supported the protective function of stapedius tendon. The higher LDL for both pure tone and speech frequencies increased the dynamic range in group A patients.

Silverstein et al opined that the stapedial reflex extends the dynamic range of hearing and protects the ear against fatigue and damage from exposure to high intensity sounds.

The stapedial reflex reduced the temporary threshold shift caused by fatigue and thereby increased the dynamic range of hearing. (Hilding). Therefore, the preservation of stapedius tendon was beneficial in improvement of LDL and thereby lengthening of the dynamic range.²²

Preservation of the incudo-stapedial joint was beneficial by maintaining better blood supply to the lenticular process of incus and head of the stapes, thereby preventing necrosis of the long process of incus and slipping of prosthesis. Further, mechanical slipping of the prosthesis was prevented by intact stapedius tendon. Moreover, application of the prosthesis was easier with stiff and intact ossicular chain (Silverstein et al).²³

Limitations

Neo-stapedotomy technique has many advantages over the standard stapedotomy technique for otosclerosis. It is also, not a difficult procedure but, it may not be possible to preserve the stapedius tendon in all the cases due to anatomical aberrations and pathological conditions. A larger sample size and a long term follow up will definitely show light on the topic.

CONCLUSION

Post-operative hearing improvement was found to be similar in both the study groups. The middle ear compliance improved in both the groups postoperatively, but the improvement is marginally more with preservation of stapedial tendon (neo-stapedotomy). Also, the stapedial reflex is regained in most of the patients after neo-stapedotomy.

Speech discrimination score is poorer in stapedotomy patients with more than 20 dB suprathreshold sounds whereas it is maintained even with 80 dB suprathreshold sound in patients with preservation of stapedius tendon thereby no pseudo-recruitment 'rollover' is observed. Post-operative loudness discomfort level is elevated in neo-stapedotomy patients, hence 'dynamic range' of hearing is found to be increased.

Preservation of stapedius tendon in neo-stapedotomy technique provides blood supply to the incudo-stapedial joint, preventing necrosis of the long process of incus and slipping of prosthesis and hence it is useful in prevention of hyperacusis and protection of inner ear from acoustic and barotrauma. It is also concluded that application of prosthesis is easier in neo-stapedotomy technique.

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Institutional Ethics Committee

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