

Audiological Outcome of Endoscopic Stapedotomy in Nepalese population

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ABSTRACT

Background

Otosclerosis is a complex disease of otic capsule that mainly affects the stapes footplate causing conductive hearing loss, sometimes mixed hearing loss. Microscope stapes surgery was used traditionally but endoscopic stapedectomy has ushered a new revelation.

Objective

To report the audiological outcome of solely endoscopic trans canal stapedotomy surgery for otosclerosis in Nepalese population.

Method

This retrospective case series study analysed pre and post operative pure tone average of air conduction (AC) and bone conduction (BC) threshold and air bone gap (ABG) at 0.5, 1, 2 and 4 kHz. Postoperative ABG ≤ 10 dBHL (decibels hearing level) and ABG ≤ 20 dBHL was used to consider surgical success and improvement respectively. Paired t-test was used to test the significance of the audiological outcome of the study group pre and post operatively.

Result

The study included 9 patients, 10 operated ears with male to female ratio of 1:2. Mean age was 37.60 ± 9.28 years and mean postoperative air bone gap was $19.00 (\pm 5.89)$ and gain in air bone gap $18.75 (\pm 8.70)$ which was found to be statistically significant ($p < 0.000$). Audiological outcome in each of the four frequencies, 500 Hz, 1000 Hz, 2000 Hz and 4000 Hz was also found to be statistically significant.

Conclusion

This limited series study concludes that because of its favourable audiological gain and closure of the air bone gap postoperatively and better intraoperative view, it can uplift other surgeons to choose this as preferred technique.

KEY WORDS

Audiological outcome, Endoscopic stapedotomy, Otosclerosis, Stapes surgery

INTRODUCTION

Otosclerosis is a complex and progressive disease of pathological bone remodeling that mainly affects the stapes footplate, and in more advanced stages the otic capsule of the temporal bone.¹ Most common symptom is a conductive hearing loss but may also present with mixed hearing loss depending upon the location and extent of disease.¹ Clinical otosclerosis is relatively common in White Europeans with a reported frequency of 0.1-2.1%, and is also common among individuals of Indian extraction.² Traditionally the most widely accepted treatment for otosclerosis is microscopic stapes surgery.

Endoscopic otologic surgery has been increasingly applied in the surgical treatment of otosclerosis, with potential advantages over standard microscopic surgery. Several studies have mentioned better visualization, lower chance of damaging periauricular structures, lower chance of chorda tympani injury, and minimal scutum drilling, with low postoperative complications, such as changes in the sense of taste, auricular numbness, pain, short operative time and expanded teaching experience for surgical trainees.³⁻⁵ Endoscopic stapes surgery can also facilitate trans canal surgery where microscopic trans canal approach is inconvenient in cases of anatomical variations of the external auditory canal, the stapes position, a hidden oval window, and the facial nerve bulging over the oval window.⁶

Endoscopic stapedectomy ushered a revolution as a new technique with less complications.⁷ In a systematic review including 12 studies showed that the audiological outcomes rate of ABG closure less than 20 dB for endoscopic stapedotomy was 94.04%, and that of less than 10 dB was 76.2% and the gain in air-bone gap ranged from 9 dB to 16 dB.⁷ Committee on Hearing and Equilibrium guidelines 1995 recommend to take mean of the thresholds at frequencies 0.5, 1, 2 and 3kHz to form four tone pure tone average as they believe to include 3 kHz that reflects the importance of higher frequencies in the understanding of speech. In the past there also has been a common practice to use the frequencies of 0.5, 1, and 2 kHz or 0.5, 1, 2, and 4 kHz to calculate a pure-tone average.⁸

Unlike medicines whose introduction and evaluation into clinical practice is highly regulated, new surgical procedures and devices are yet to have such standardization, and in turn at risk of establishing potentially harmful interventions into clinical practice. Therefore standardized and transparent measurement are needed and reporting of outcomes to safely evaluate and introduce surgical innovation into clinical practice.⁹ This study aims to report on the audiological outcome of solely endoscopic trans canal stapedotomy surgery for otosclerosis, which is fairly a new surgical technique. Therefore, contributing to the pool of data and information to lead forward similar other

studies by becoming the first of its kind done in Nepal.

METHODS

This is a retrospective case series study done by extracting information from the computerized medical records and audiogram reports of the patients who were diagnosed with otosclerosis clinically, audiological and underwent solely endoscopic transcanal stapes surgery (stapedotomy) from the year August 2019 to May 2024 A.D at the Department of ENT and Head & Neck surgery at Dhulikhel Hospital, Kavre Nepal. Surgeries were performed by a single senior consultant ENT surgeon in the department of ENT and Head and Neck Surgery at Dhulikhel Hospital. Ethical approval was taken from the institutional review committee (IRC).

Inclusion criteria:

Diagnosed with otosclerosis

Conductive hearing loss involving both ears with air-bone gap larger than or equal to 30 decibels (dB), absent stapedius reflex

Came for at least 6 months of postoperative follow-up

Exclusion criteria:

History of past middle ear infections with tympanic membrane perforation

Otosclerosis with coexisting ossicular chain anomalies

Patients with retrocochlear pathology

Audiometry showing conductive hearing loss with an air-bone gap less than 30 dB.

Surgery

The Hopkins Telescope with features of 4 mm diameter, 18 cm length and 0 degree angulation was used. Teflon stapes prosthesis (TSP) was used in all the patients, with 0.4 mm diameter and 4 mm length which was adjusted to variable lengths according to the distance between long process of incus and stapes footplate. Surgeries were done under general anesthesia in transcanal approach. After proper positioning, dressing and draping, ear to be operated was infiltrated with 1:2,00,000 adrenaline. Canal incision at 6 and 12 O clock position was given and two incisions joined. Then tympanomeatal flap was elevated, after entering middle ear landmarks were identified. Incudostapedial joint disarticulated, mobility of incudomalleolar joint and stapes was checked, confirming the stapes fixation, stapedial tendon was cut, posterior crurotomy performed and anterior crura down fractured. Piston length measured from footplate to medial surface of long process of incus. After fenestration was performed, piston was kept in the oval window and lateral end kept on the long process

of incus. Oval window sealed with connective tissue, tympanomeatal flap repositioned. External auditory canal packed with gelfoam.

Audiological Outcome

To assess the hearing outcome the medical records with pre and post operative pure tone audiogram results were analysed retrospectively. Pre operative audiometry was done within 1 month before surgery and post operative audiometry was done 6 months following surgery. Pre and post operative pure tone average of AC, BC and ABG at four frequencies 0.5, 1, 2 and 4 kHz were analysed as recommended by WHO 2020. Surgery was considered successful if the postoperative audiogram showed reduced ABG to less than or equal to 10 (ABG ≤ 10 dBHL) and it was considered as an improvement if the postoperative ABG was lesser than 20 dB (≤ 20 dBHL).⁵ In this study pre and post operative audiological report with postoperative ABG was constructed as ≤ 10 dBHL, ≤ 20 dBHL and > 20 dBHL. Improvement or gain in ABG after subtracting post operative ABG from pre operative ABG in each of the four frequencies 500, 1000, 2000 and 4000 Hz was also estimated.

Statistical Analysis

For data analysis we used IBM® SPSS® 25 software (IBM Corp, Armonk, NY). Standard descriptive statistical calculations was used for categorical values such as mean, standard deviation (SD), expressed in numbers and percentages. Quantitative variable such as numerical values of hearing thresholds in dBHL were analysed using the parametric paired t-test to test the significance of the audiological outcome of the study group pre and post operatively. All statistical analyses were performed with a 95% confidence interval (95% CI) and p value of < 0.05 was considered statistically significant.

RESULTS

The study includes nine patients who underwent 10 consecutive solely endoscopic transcanal stapes surgeries (stepedotomy) where one patient received surgery for both ears in different times. Among nine patients there were 3 (33.33%) male and 6 (66.67%) female patients with male to female ratio of 1:2. Age of the patients ranged from 24 - 48 years old with mean age ± S.D of 37.60 ± 9.28. Among 10 operated ears, 4 (40%) was operated on right side and 6 (60%) was operated on left side. Demographics of study population is shown in table 1.

Audiological Outcome:

Preoperative mean (± S.D) AC threshold was 56.88 (± 8.38) dBHL, BC threshold was 19.13 (± 5.78) dBHL and ABG was 37.75 (± 8.05); Postoperative mean (± S.D) AC threshold was 36.63 (± 6.38) dBHL, BC threshold was 16.50 (± 5.74)

dBHL and ABG was 19.00 (± 5.89). Improvement or gain in AC threshold was 20.25 (± 10.25) dBHL, BC threshold was 2.63 (± 5.51) dBHL.

Table 1. Demographic characteristics of the study population

Demographic Characteristics	Values (N/%) (Numbers/Percentages)
Total patients	9
Total Ears	18
Total Operated Ears	10
Male	3 (33.33%)
Female	6 (66.67%)
Male: Female	1:2
Age Range	24-48
Mean age ± S.D	37.60±9.28
Side of Surgery	
Right	4 (40%)
Left	6 (60%)

Gain or closure of ABG 18.75 (± 8.70) which was found to be statistically significant (p < 0.000), the rate of which is further distributed as gain of ABG to > 20 dB was 70%, <20 dB was 10% and < 10 dB was 20%. We also found that the postoperative ABG ≤ 20 dB was found in 8 operated ears (80%) and > 20 dBHL was found in 2 operated ears (20%) as shown in table 2.

Table 2. Post operative Air Bone Gap

Postoperative ABG	Frequency	Percentage
≤ 10 dBHL	0	0%
≤ 20 dBHL	8	80%
> 20 dBHL	2	20%

In our assessment of audiological outcome of each of the four frequencies i.e, 500 Hz, 1000 Hz, 2000 Hz and 4000 Hz, it emerged that postoperative gain in ABG was also statistically significant in all the frequencies as shown in table 3.

Table 3. Gain in Air Bone Gap on the basis of four frequencies at 500, 1000, 2000 and 4000 Hz

Frequency (Hz)	Pre-Op ABG (Mean ± S.D)	Post-Op ABG (Mean ± S.D)	ABG Gain (dBHL)	Significance (p<0.005)
500 Hz	46.50 ± 11.79	25 ± 9.12	21.50±11.06	0.000
1000 Hz	43.50 ± 11.55	20 ± 7.81	23.5 ± 13.34	0.000
2000 Hz	25.5 ± 9.26	13 ± 8.23	12.5 ± 9.20	0.002
4000 Hz	32.5 ± 6.85	24.5 ± 7.97	11.00 ± 9.94	0.007

DISCUSSION

Otosclerosis has traditionally been regarded as a middle-ear disease, but the inner ear can also be affected.² Outbreaks start at the front part of the oval window, and immobilization of the stapes base occurs, leading to conductive hearing loss (Bezold-Siebenmann type).¹⁰ It is characterized by a progressive adult-onset hearing loss that is usually bilateral (70-85%) and asymmetrical, developing initially in one ear, as well as tinnitus and sometimes vertigo.¹⁰ The microscope is used as a conventional tool of choice for stapes surgery with reliable outcomes. Despite of its binocular vision, freedom of both hands it has some disadvantages such as, it requires unobstructed direct view of the operating area, endaural incision, drilling of the bony auditory canal, and regular repositioning of the patient. In contrast, the endoscope has become the modern way to visualize middle ear structures paving its way into the surgical realm.¹¹

In our study age of the study population ranged from 24-48 years old with mean age \pm S.D was 37.60 ± 9.28 which is comparable with study from Abdullah et al.¹² where mean age of presentation was 30.6 ± 7 SD years and also with Darjazini et al.¹⁰ with mean age of 38.2 years old. In our study male to female ratio was found to be 1:2, which is comparable with a British cohort, where females to males ratio of 1.9 was found in keeping with previous reports of a gender bias of 1.5-2:1.² This could be explained by the hypothesis that oestrogen may play a role in the aetiology of the disorder.¹³ Also supported by a cohort study where of 186 female study participants 69.4% had been pregnant, 83.1% had breastfed and 39.8% had noticed a deterioration in hearing during or shortly after their pregnancy.¹⁴

In our study improvement or gain in AC threshold was $20.25 (\pm 10.25)$, BC threshold was $2.63 (\pm 5.51)$ and gain in ABG was $18.75 (\pm 8.70)$ which was found to be statistically significant ($p < 0.000$). Comparable with study by Abdullah et al. where hearing results showed mean AC gain of 18.3 dB, ABG gain of 23.3 dB and a statistically significant BC gain was reported.¹² The present ABG gain is comparable to other studies also as summarized in the table 4. In a systematic review by Koukkoullis et al. concluded that the hearing outcomes of the endoscopic approach are similar to those of the microscope with no statistical significance.¹¹

In this study postoperative ABG ≤ 20 dBHL was found in 80% and > 20 dBHL was found in 20%. This means that post surgery improvement in audiological outcome was 80%. Similarly, Iannella et al. claimed that the percentage of ears with a postoperative air bone gap < 20 dB was 93.3%, showing no difference from the percentage in the microscopic group (97.5%).²⁰ However a meta-analysis revealed a statistically significant difference in hearing

Table 4. Postoperative ABG gain comparison with other studies

Author	Stapes Surgery	ABG Gain (dBHL)
Lin et al. ¹⁵	79, microscopic	21.21
Alzharani et al. ¹⁶	45, microscopic	17
Sarkar et al. ¹⁷	32, endoscopic	31.4
Elzayat et al. ¹⁸	80, microscopic	23.48
Xei et al. ¹⁹	28, microscopic	23.4
Current Study	10, endoscopic	18

improvement with endoscopic stapes surgery with gain in air-bone gap ranged from 9dB to 16dB which is similar to our study and mean of gain in postoperative ABG in each of the four frequencies at 500 Hz, 1000 Hz, 2000 Hz and 4000 Hz also emerged to be statistically significant.⁷ This emphasizes that there is an improvement in the patient's ability to understand speech, as these four frequencies are often regarded as important speech frequencies.

Small number of study population need more cases in the future for relevance with the population. Hearing outcome was not compared from short term to long term, longer follow up of 1 year, 5 years are needed in the future. Did not mention about the challenges or difficulties faced during surgery that might have role in audiological outcome.

CONCLUSION

This present limited series study culminates that by performing solely endoscopic transcanal stapedotomy surgery, favourable postoperative audiological outcome can be achieved. The main advantage of a fully endoscopic stapes surgery is better intraoperative view of the middle ear anatomical structures, particularly the stapes footplate however it is subjected to the flaw such as lack of 3-D vision, requirement of experience, prolonged learning curve compared to the microscopic technique, and necessity of performing single-handed surgery.⁶ Despite that as a result of better audiological gain and closure of the ABG postoperatively with endoscopic stapedotomy can motivate otologists to choose this as preferred technique.

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