e-ISSN: 0976-822X, p-ISSN:2961-6042

Available online on http://www.ijcpr.com/

International Journal of Current Pharmaceutical Review and Research 2024; 16(5); 793-797

Original Research Article

A Prospective Randomized Study to Assess the Efficacy of Endoscopic Stapedotomy in Comparison to Traditional Microscopic Stapedotomy

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Received: 13-03-2024 / Revised: 20-04-2024 / Accepted: 24-05-2024
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Conflict of interest: Nil

Abstract

Aim: The aim of the present study was to assess the efficacy of endoscopic stapedotomy in comparison to traditional microscopic stapedotomy.

Methods: This prospective randomized study applied on 40 patients (40 ears) presented to Department of ENT, Government Medical College and Hospital, Bettiah, Bihar, India for one year and diagnosed clinically and audiologically as stapedial otosclerosis. These patients divided randomly into two groups, 20 patients (20 ears) operated using the traditional microscopic stapedotomy procedure and 20 patients (20 ears) underwent endoscopic stapedotomy procedure.

Results: The right ears of 7 (35%) of group A and 12 (60%) of group B were stapled. The left ears of 13 patients (65%) of group A and 8 patients (40%) of group B were operated on. No difference was statistically significant. Group A had a much shorter operational time than group B. All patients in both groups had their mean preoperative air-bone gap (ABG) measured at 500, 1000, 2000, and 4000 Hz. It was 30–58dB. The mean ABG in group A was 40 ± 7.5, with a median of 39.5, whereas group B had a mean of 38 ± 7.6. The difference is not statistically significant. At 4 months postoperatively, both groups' patients' mean ABG at 500, 1000, 2000, and 4000 Hz was assessed. From 3 to 45 dB. Group A had a mean postoperative ABG of 7.75 ± 11.5, whereas group B had 10.5 ± 10.2. Bony curettage and CTN modification differed significantly.

Conclusion: Postoperative hearing is better than preoperarive one in both groups. Postoperative complications such as CTN injury and taste disturbance were less in endoscopic than microscopic stapedotomy.

Keywords: endoscopic; microscopic; stapedotomy; chorda tympani nerve; taste, air bone gap

Introduction

Since the introduction of modern stapes surgery by Shea, [1,2] there has been a significant improvement in hearing outcome, minimizing the complication rate. [3,4] The clinical outcomes mainly depend on the crucial steps in the stapes surgery, that is, making a fistula over the footplate. Different surgical methods have been developed to make the fenestra over the stapes footplate for a better hearing outcome with minimal damage to the surrounding soft tissue. [5] Based on the above facts, the CO2 laser has been increasingly used in microscopic and endoscopic stapedotomy. [6] With the advancement in endoscopic ear surgery, endoscopic stapedotomy is often preferred to the standard microscopic stapedotomy by providing a wide field of visualization and minimizing injury to the chorda tympani nerve. [7-9]

In addition, subluxation of the ossicular chain may result from removal of the posterior part of the bony canal. [10,11] Endoscopes in middle ear surgery have made it possible to reach certain remote areas which were otherwise inaccessible via the straight axis vision of microscopes. [12] The use of the endoscope would offer much benefits, such as good panoramic view and easy accessibility to the oval window niche, stapes and facial nerve. Also, with this technique, removal of the scutum and manipulation of the chorda tympani are less frequent. On the other hand, endoscopic ear surgery has some limitations, such as one hand operation and the needed learning and experience. [13,14] Alterations in taste sensation are frequently reported by patients undergoing stapes surgery. This is directly related to the extent of manipulation of the chorda tympani nerve during surgery. This may

range from minimal handling to even severing the nerve in difficult anatomical situations for the sake of access to the footplate area. [15]

The aim of the present study was to assess the efficacy of endoscopic stapedotomy in comparison to traditional microscopic stapedotomy.

Materials and Methods

This prospective randomized comparative study applied on 40 patients (40 ears) presented to Department of ENT, Government Medical College and Hospital, Bettiah, Bihar, India for one year and diagnosed clinically and audiologically as stapedial otosclerosis. These patients divided randomly into two groups, 20 patients (20 ears) operated using the traditional microscopic stapedotomy procedure and 20 patients (20 ears) underwent endoscopic stapedotomy procedure. Adult patients with progressive hearing loss, intact tympanic membrane, Conductive hearing loss & air bone gap (ABG) > 25 dB were included in the study. Pregnant females, patients with Ménière's disease & active otosclerosis were excluded. All patients were submitted to history taking, general examination & ENT examination e.g.otoscopy & tunning fork tests. Pure tone audiometry & ABG for every patient was measured at frequencies 500, 1000, 2000 & 4000 Hz. Tympanometry & acoustic reflex were also measured.

Microscopic Technique

Under hypotensive general anaesthesia, using Leica M 320 HD microscope Transcanal horizontal incision performed by round knife 6-7 mm lateral to tympanic annulus from 7 -1 O'clock. Tympanomeatal flap (TMF) was elevated (Fig.1) & the annulus also was elevated using the round knife to inter the middle ear. Identification of the chorda tympani nerve under the tympanic membrane. The tympanomeatal flap was reflected anteriorly to demonstrate the ossicular chain. Curetting of posterosuperior meatal wall (Fig.3), may be needed, to avoid chorda tympani & ossicular injury, using an ear curette of House (Fig.2) to show the stapes footplate. Stapes fixation is ensured by testing ossicular mobility. Incudostapedial joint separation, cutting the stapedial tendon using angled needle or microcessor, fracture & then removal of stapes superstructure (head, neck, anterior & posterior crura). Stapes footplate fenestration was made using a 0.6 mm stapedial perforator or 0.5- 0.7 mm diamond burr. Teflon piston, was put in this Footplate orifice and the other end linked to the incus long process with crimping. Ossicular mobility was tested after prosthesis application. Footplate fenestration was sealed using ear lobule piece of fat. Finally, repositionning of tympanomeatal flap and then gelfoam and antibiotic soaked gauze application in the external auditory canal.

Endoscopic Stapedotomy

The same surgical steps of the microscopic technique, the same instruments in addition to video monitoring system, with 0°, 4 mm diameter and 17 cm long endoscope may be used when the EAC is wide enough. With narrow EAC, 3 mm diameter and 17 cm long endoscope can be used. TMF elevation (Fig.6), posterosuoerior Curettage of bony meatal wall & manipulation of CTN was done in some patients for better vision of tympanic cavity& ossicles. Ossicular mobility is tested for insurance of Foot pate fixation & stapedial tendon cutting by fine needle. Incudostapedial joint separation by straight needle & stapes superstructure fracturing & removal. A hole was made in the stapedial footplate by stapedial perforator. Teflon piston prosthesis is placed in the Footplate hole and the other end linked to the Long process of incus with crimping. After sealing the footplate hole with fat, tympanomeatal flap was repositioned and antibiotic soaked pack was put in the External auditory meatus.

Postoperative PTA was performed for all patients either microscopic (Group A) or endoscopic (Group B) at 4 months and an ABG was measured at frequencies 500, 1000, 2000 & 4000 Hz. Comparison of the two groups as regard the following parameters:

Preoperative: clinically, PTA, AR.

Operative: time of each procedure in minutes, Accessibility and visibility of the field of surgery & intraoperative complications

Postoperative: hearing, tinnitus, vertigo, subjective taste disturbance, pain and other complications. PTA, AR. Data were analyzed using Statistical Program for Social Science (SPSS) version 20 (USA). P-value < 0.05 was considered significant.

Results

Table 1: Comparison of side of surgery and operative time in studied groups

		Group A (20)		Group B (20)		P-value
Side of surgery	Right stapedotomy	7	35%	12	60%	0.342
	Left stapedotomy	13	65%	8	40%	
		Group A (N = 20)		Group B (N = 20)		P-value
Operative time (min)	Mean ±SD	70 ± 11.2		85 ± 8.8		0.001
	Median	70.5		85.5		

Stapedotomy was performed on the right ear of 7 patients (35%) of group A and 12 patients (60 %) of group B. It was performed on the left ear of 13 patients (65 %) of group A and 8 patients (40 %) of group B. There was no statistically significant difference. There was statistically significant decreased operative time in group A when compared with operative time in group B.

Table 2: Comparison of pre-operative ABG in studied groups

Pre-operative		Group A (N = 20)		Group B (N = 20)		P-value
ABG	Mean ±SD	40 ± 7.5		38 ± 7.6		0.604
	Median	39.5		37.5		
ABG	30 - 40 dB	11	55%	13	65%	0.778
	41- 50 dB	7	35%	5	25%	
	51 - 60 dB	2	10%	2	10%	

The mean preoperative air- bone gap(ABG) at frequencies 500, 1000, 2000 & 4000 Hz for all patients of both groups was measured. It ranged from 30 - 58dB. The mean ABG in group A was 40 ± 7.5 with median ABG of 39.5 while the mean ABG in group B was 38 ± 7.6. There is no statistically significant difference.

Table 3: Comparison between studied groups as regarding post-operative ABG

Post-operative		Group A (20)		Group B (20)		P-value
ABG	Mean ±SD	7.75 ± 11.5		10. 5 ± 10.2		0.429
	Median	4		6.5		
ABG	0 - 10 dB.	17	85%	15	75%	0.719
	11- 30 dB.	2	10%	3	15%	
	31 - 50 dB.	1	10%	2	5%	

The mean postoperative ABG at frequencies 500, 1000, 2000 & 4000 Hz. for all patients of both groups was measured, at 4 months Postoperatively. It ranged from 3 to 45 dB. The mean postoperative ABG in group A was 7.75 ± 11.5 while in group B it was 10. 5 ± 10.2. There was no statistically significant difference between studied groups.

Table 4: Comparison between studied groups as regarding bony curettage and CTN manipulation

		Group A (20)		Group B (20)		P-value
Bony work	done	15	75%	4	20%	0.0004
	Not done	5	25%	16	80%	
		Group A (N20)		Group B (20)		P-value
CTN manipulation	Manipulated	17	85%	5	25%	0.0001
	Not manipulated	3	15%	15	75%	

Bony work on posterosuperior bony meatal wall, for good demonstration of the stapes footplate region, was done in 15patients (75 %) of group A and 4 patients (20%) of group B and was not performed in 5 patients (25%) of group A and 16 patients (80%) of group II. It shows high statistically significant difference. Chorda tympani was manipulated, for better visualization of the stapes footplate & oval window region, in 17 patients (85 %) of group A & 5 patients (25%) of group B. It was not manipulated in 3 patients (15%) of group A & 15 patients (75 %) of group B. It was statistically significant difference.

Table 5: Post-operative complications in studied groups

Post-operative complications	Group A (20)		Group B (20)		P-value
No	17	85%	14	75%	0.256
Dizziness	2	10%	3	15%	0.632
Tinnitus	0	0%	1	5%	0.311

Two patients (10%) of group A & 3 patients (15%) of group B suffered from dizziness up to 2 days post-operatively which was managed conservatively until improvement & discharge. Tinnitus was present in one patient (5%) of group B.

Discussion

Stapedotomy has been practiced as a surgical modality for the treatment of stapedial otosclerosis. The conventional tool for the surgery has been the operating microscope. The operating microscope renders the surgeon the advantage of use of both

hands for instrumentation and hence greater stability which is of utmost importance in a surgery as delicate as stapes surgery. However, it has certain limitations. The field of view through an operating microscope is narrower as compared to an endoscope. This is because the focal length of the operating microscopes commonly used in otology is around 250 mm. This essentially has a number of implications. Certain working areas that do not lie directly in the line of our visual axis cannot be readily visualized by microscope. This means any tissue lying in front has to be repositioned or removed to ensure adequate visualization. This adds to the operative morbidity and longer operating times. [16,17] Furthermore, this surgery may become technically difficult with hidden stapes and oval window or narrow external auditory canal. Removal of the scutum may be needed for better exposure of the stapes and oval window, and consequently there is a risk of damage to the chorda tympani nerve. Postoperative taste disorders are encountered in 20–60% of patients after stapes surgery. [18,19]

Stapedotomy was performed on the right ear of 7 patients (35%) of group A and 12 patients (60 %) of group B. It was performed on the left ear of 13 patients (65 %) of group A and 8 patients (40 %) of group B. There was no statistical significant difference. There was statistically significant decreased operative time in group A when compared with operative time in group B. The mean preoperative air- bone gap(ABG) at frequencies 500, 1000, 2000 & 4000 Hz for all patients of both groups was measured. It ranged from 30 - 58dB. The mean ABG in group A was 40 ± 7.5 with median ABG of 39.5 while the mean ABG in group B was 38 ± 7.6. There is no statistical significant difference. The mean postoperative ABG at frequencies 500, 1000, 2000 & 4000 Hz. for all patients of both groups was measured, at 4 months Postoperatively. It ranged from 3 to 45 dB. Surmelioglu et al., reported that the postoperative ABG was 9.3 dB in the endoscopic group and 13.5 dB in the microscopic group, and there was no statistically significant difference between the two groups. [20] In contrast to this study, the mean postoperative ABG in our study was 7.75 ± 10.2 in the endoscopic group B and 10.1 ± 11.5 in the microscopic group A, which was statistically significant. Naik and Nemade, had not reported any postoperative complications as taste failure, facial nerve paralysis and tympanic membrane perforation. [21]

The mean postoperative ABG in group A was 7.75 ± 11.5 while in group B it was 10. 5 ± 10.2. There was statistically significant difference in bony curettage and CTN manipulation. Two patients (10%) of group A & 3 patients (15%) of group B suffered from dizziness up to 2 days post-operatively which was managed conservatively until improvement & discharge. Tinnitus was present in one patient (5%) of group B. In Q Yang et al study, a mean operative time of endoscopic stapes surgery was (74.1±26.0) minutes While that of microscopic approach was (66.5±15.9) minutes & Statistical difference was evident. The average operative time of endoscopic surgery became shorter as the cases increased. [22] Bhardwaj et al study on 40 (20/20) patients showed that mean operative time was 50.25 and 76.05 minutes in the microscopic and endoscopic groups respectively. [23] These results were consistent with our study. Endoscopic stapedotomy has the advantages of good visualization, less bony work in posterosuperior deep meatal wall and easy accessibility to the stapes, oval window niche and facial nerve [24] which is in agreement with our study in which bony work was performed in 15 patients (75 %) of group A and 4 patients (20 %) of group B which was significant statistically. Surmelioglu et al., reported that the incidence of CTN injury was more in the microscopic group than the endoscopic group which is in agreement with our study but, impaired taste sensation was noticed in 33% in the microscopic group and in 4.5% of the endoscopic group which is in contrast to our study as only 2 patients (10%) of the endoscopic group developed impaired taste sensation and no patients (0%) of the microscopic group developed impaired taste sensation but, this was a subjective complaint. [24]

Conclusion

Microscopic stapedotomy is the traditional method for surgical treatment of otosclerosis. Curettage of posterosuperior meatal wall, increased possibility of CTN injury and taste affection which is more common with microscopic technique. Endoscopic stapedotomy has become very common with easy accessibility to the stapes. Curettage of posterosuperior bony meatal wall, CTN manipulation & injury are less common with the endoscopic technique. Postoperative complications such as CTN injury and taste disturbance were more in endoscopic than microscopic stapedotomy. Endoscopic stapes surgery has some limitations such as one-handed surgery, loss of binocular vision, difficult haemostasis with repeated suctioning of the operative field that leads to more operative time. Endoscopic stapedotmy is more difficult technique than microscopic surgery specially with beginners due to absent stereoscopic view and difficult one handed surgery.

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