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Significant Hearing Threshold Gain through Stapedotomy in Patients with Otosclerosis at Indorewala ENT Hospital, India

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Abstract: Otosclerosis is a mysterious disease that has confused and interested clinicians and researchers for centuries and despite intensive research, etiologic and pathophysiologic mechanisms remain unknown. This study was embarked upon to determine whether there would be hearing threshold gain among patients with otosclerosis who underwent stapedotomy and also to ascertain whether the threshold gained would be significant or not. A retrospective study of 128 patients who underwent stapedotomy between 2008 – 2013 at Indorewala ENT Hospital, Nashik, India. Medical records, including preoperative and postoperative audiograms were reviewed. A comparative study of pre and postoperative hearing thresholds was done. Analysis of data was done through descriptive statistics and t-test. Comparing pre and post-operative audiometric thresholds, (N = 128, youngest = 16 years, oldest = 72 years, mean age = 41.70, SD = 12.86), our results showed significantly bilaterally 17dB hearing threshold gain. Right ear - (t=7.209, df=254, p=0.000), Left ear - (t=7.353, df=254, p=0.000). There were successful improvement in all ears (100%) and there was no single patient with surgery-related sensorineural hearing loss. Our conclusion is that competent hands (Audiologists and ENT surgeons) are very pivotal to improved hearing and stem otosclerotic progression.
Keywords: Indorewala, otosclerosis, stapedotomy, pure tone audiometry, threshold gain**.**

INTRODUCTION

There are two main causes of conductive hearing loss due to fixation of stapes footplate: deposition of spongy bone around the footplate (otosclerosis) and congenital malformation of stapes [1]. Before, the ankylotic stapes was generally regarded as a complication of catarrhal inflammation of the middle ear and the hearing loss was considered a nervous deafness because the tympanic membrane was intact [2]. The etiologic and pathophysiologic mechanisms remain unknown despite intensive research. Different theories have been postulated; they include viral [3,4], endocrine, hormonal [5] and autoimmune factors [6]. Genetic factors appear to play a vital role, and several genes have been localized, but no true candidate gene has yet been identified [7]. It is still not known whether the postulated autosomal dominant inheritance with reduced peneterance is the only mode of transmission because approximately half of cases appear to be sporadic [8] and since the cause of otosclerosis is unknown, the disease remains incurable.

In 1950, Carhart reported bone conduction threshold elevation of approximately 2000Hz (2kHz) among patients with otosclerotic lesion induced stapes ankylosis that disappeared after stapes surgery. Since then, this deceptive 2kHz bone conduction threshold dip (2kBD) or Carhart notch without inner ear damage has become a well-known indicator of stapes fixation [9]. However, results of studies have suggested that elevation in bone conduction thresholds between 1kHz and 4kHz can be caused by various factors that affect the conductive mechanism of the middle ear. In fact, it is not uncommon to encounter cases of Carhart notch in which hearing loss is caused by detachment of the incudostapedial joint. For Carhart to be used as a preoperative predictor of stapes fixation, it should be shown that the notch exists with stapes fixation but not with other ossicular chain disorders such as disconnection [10-12]. The treatments that can be implemented are symptomatic: hearing aids or surgery to compensate for hearing loss and medical treatment

with sodium fluoride or bisphosphonates to reduce the progression of cochlear otosclerosis [13].

There are 360 million persons in the world with disabling hearing loss (5.3% of the world's population) out of which 328 million (91%) of these are adults (183 million males, 145 million females) and 32 (9%) millions of these are children. The prevalence of disabling hearing loss for adults and children is greatest in South Asia followed by Asia Pacific and Sub-Saharan Africa [14]. Otosclerosis has a prevalence of approximately 0.3% in Western countries [15], Caucasians are the most affected race, with the prevalence of 0.3-0.4% and about 4 times the prevalence compared to Asians [16], with a peak onset in the third decade. Clinical otosclerosis is twice common in women. It has traditionally been regarded as a middle ear disease, and during the past 50 years, the development of surgical methods has been successful.

Stapedotomy is a procedure in which a small hole is performed in the fixed footplate under microscope magnification and piston prosthesis is inserted in the hole and connected to the long process of the incus from the other side. It was first performed by Professor Henri André Martin. The tiny hole is made by needle, perforator, microdrill or laser [17] as opposed to stapedectomy whereby the stapes suprastructures and footplate are removed and replaced by prosthesis. In 1959, stapedectomy was introduced by Shea [18]. Later, many modifications were made, and stapedotomy is now the most widely used technique [19]. Many studies have shown good surgical results, including closure of the air-bone gap (ABG), on both a short- and long-term basis (up to 32 years) [20,21]. The inner ear component in otosclerosis has been extensively studied and debated. Histologic studies have questioned the relationship between histologic cochlear otosclerosis and sensorineural hearing loss [22,23]. Audiological studies have reported various results. Several studies have reported a stable bone conduction (BC) threshold, that is, a normal bone conduction threshold which is less than or equal to 25dB with or without carhart notch on the audiogram, whereas others have demonstrated a sensory hearing loss progression of various degrees. The sensorineural hearing loss has been interpreted as being age-related in the majority of cases [24]. In contrast, a 2006 study by Topsakal et al. demonstrated a preoperative sensorineural hearing loss disproportionate to age [25]. The term cochlear otosclerosis, which was previously used to describe histologic otosclerosis with the repalecement of the endosteal layer of the cochlea, has subsequently been used in conjunction with clinical otosclerosis to refer to sensorineural hearing loss that is presumably caused by otosclerosis, in contrast to age-related hearing loss, that is, the term cochlea otosclerosis refers to sensorineural hearing loss disproportionate to age in patients with otosclerosis. However, the nature of sensorineural hearing loss in patients with otosclerosis is still in the dark, and as there is a long lifetime expectancy with the disease, it is vital to purse long-term follow up studies of audiological function. This study aimed to determine whether or not there would be improvement in the hearing thresholds among patients with otosclerosis who underwent stapedotomy and also to ascertain whether the threshold gained (if there were) be significant or not.

MATERIALS AND METHODS

Methods

This is a retrospective study of 128 patients who underwent stapedotomy between 2008 – 2013 at Indorewala ENT Hospital, Nashik, India.

Patient Selection

The study included all the patients who had stapedotomy performed on them. Also, it included those patients whose medical records with their pre and post-operative audiograms could be retrieved. The study population consisted of 68 women (53.1%) and 60 men (46.9%). The mean age as at the time of surgery was 42 years (youngest 16 years; oldest 72 years, SD 12.9 years).

Mode of Data Collection

The patients' medical records were retrieved and bio-data and other infomation such as age, sex, diagnosis, pre and post-surgery audiograms were collected. Pure Tone Audiometry was done 3 months prior to surgery and 15 months after surgery. Frequencies from 250Hz to 8000Hz were tested for air conduction (AC) and frequencies from 500Hz to 4000Hz for bone conduction (BC). Pure tone averages were calculated at 0.5, 1, 2, and 4KHz. Analysis of data was done through descriptive statistics and t-test.

RESULTS

Demographic data

Table-1: Age of the patients

N	Youngest	Oldest	Mean age	SD
128	16	72	41.70	12.86

Table-2: Gender of the patients

Gender	Frequency	Percent
Male	60	47
Female	68	53
Total	128	100

Research Question 1: How many patients presented with Carhart Notch?

Table 3 reveals that 83 (64.8%) of the patients had Carhart notch while the remaining 45 (35.2%) did not have.

Table-3: Table showing numbers of patient with Carhart Notch

Carhart Notch	Frequency	Percent
Yes	83	64.8
No	45	35.2
Total	128	100

Research Question 2: How many patients underwent unilateral and bilateral stapedotomy?

Table 4 reveals that out of the 128 ears operated, 57 (44.53%) were right ears, 52 (40.63%) were left ears while the remaining 19 (14.84%) were bilaterally operated.

Table-4: Table showing the ears operated

Operated Ear(s)	Frequency	Percent
R	57(Right ears)	44.53
Unilateral L	52 (Left ears)	40.63
Bilateral	19(both ears)	14.84
Total	128	100

Hypotheses

H_1: There would be no hearing threshold gain after stapedotomy.

H_2: There would be no significant difference between pre and post-operative audiometric hearing thresholds among patients who underwent stapedotomy.

Table-5: Table showing threshold gained and the significance

Variable	N	Mean±SD	Mean diff	t value	df	p value
Pre-Op Right Ear	128	54.40±18.32	16.63	7.209	254	0.000*
Post-Op Right Ear	128	53.45±18.55	16.62	7.353	254	0.000*
Pre-Op Left Ear	128	36.84 ±17.60				

*significant at $p<0.05$

Comparing pre and post-operative audiometric thresholds, table 5 shows a significant mean difference of 16.63 in the right ears of 128 patients that underwent stapedotomy (t=7.209, df=254, p=0.000). On the left ears, table 5 also shows a significant mean difference of 16.62 (t=7.353, df=254, p=0.000). The result did not support hypotheses 1 and 2, and therefore were rejected.

DISCUSSION

This study reveals that 83 (64.8%) of the patients had Carhart notch while only 45 (35.2%) did not have it. Carhart notch is a typical sign seen on the audiometric configurations of patients with otosclerosis, it is a dip on the audiogram at 2kHz on bone conduction test. However, Carhart notch reported in this present study is higher than the study by Manuele *et al*. which comprised of 213 patients with an average age of 46 years (102 men and 111 women). Only 46 patients (27.7%) had Carhart notch on their audiometry [26]. In otosclerosis, conductive loss of about 40 dB in the low frequencies with a reduction of the gap towards 2 kHz is typical, because stapes fixation reduces the elasticity of the ossicular chain. An interesting finding in otosclerosis is the deterioration of bone conduction thresholds at middle to high frequencies, which sometimes disappears after successful surgery: the so-called Carhart notch, which can reach up to 25 dB at 2 kHz. A possible cause is the absence of middle ear resonance, in humans at 2000 Hz, together with reduced perilymph oscillation due to the immobile footplate [27].

Table 4 revealed that out of the 128 ears operated, 57 (44.53%) were right ears, 52 (40.63%) were left ears while the remaining 19 (14.84%) were bilaterally operated. Stapedotomy was only performed on ears with air conduction thresholds that were above 30 dBHL. In other words, we employed conservative therapeutic management of otosclerosis when air conduction thresholds are lower than or equal to 30 dBHL rather than taking a surgical option.

In comparing the pre and post-operative audiometric thresholds, we found significant differences in both left and right ears pre and post-operative AC thresholds. Right ear pre – operative AC threshold was 54.40±18.32, post-operative AC threshold was 37.77±18.60 with a mean difference of 16.63dB. In the left ear also, pre-operative AC threshold was53.45±18.55 while the post-operative AC threshold

was 36.84 ±17.60 with a mean difference of 16.62dB. This is approximately a hearing threshold gain of 17dB bilaterally which was highly significant. Hence, hypotheses 1 and 2 were rejected. That is, there is a hearing threshold gain and there is a significant difference between pre and post-operative audiometric thresholds among patients who underwent stapedotomy. In other words, the hearing thresholds of patients that we operated upon for stapes surgery due to otosclerosis have a significant improvement in their hearing when we compared the hearing thresholds prior to surgery and after the surgery.

Our study corroborates with the study by Manuele *et al*. who also compared pre and post AC-PTA thresholds. They reported a statistically significant improvement (Pre-op: 59.1 dB ± 14.4; Postop: 33.8 dB ± 12.98 p< 0.05), this is a significant gain of 25.3dB.The evaluation of pre and post-op PTA BC thresholds also showed a statistically significant improvement (Pre-op: 29.1 dB ± 10.49); Postop: 22.1 dB ± 10.74; p< 0.05) with a significant gain of 7dB [26]. Our study also agreed with another study of 20 consecutive stapes surgeries by Ho-seob *et al*. [27], which were conducted between 2011 and 2014, patient age ranged from 20 to 64 years, representing 5 males and 12 females. Mean audiologic follow-up duration was 11 months. Pre-operative threshold frequency for BC and AC were 39.8±15.8 and 66.4±15.3 dB HL, respectively. After the stapes surgery, the thresholds for BC and AC were 36.8±16.3 and 42.0±16.2 dB HL, respectively (3dB and 24.4dB gain respectively).

Similarly, the results of our study is in line with the study by Ghonim *et al*. which was conducted on 65 patients operated upon for otosclerosis at Otolaryngology Department Mansoura University Hospital, Egypt and Otolaryngology Department Aarhus University Hospital, Denmark between 1987 and 1999 with bilateral hearing loss in all cases. 37 patients were operated at Mansoura University Hospital and 28 at Aarhus University Hospital. The mean age as at the time of surgery was 68.5 years with a range from 65 to 77 years. There were 30 males (46%) and 35 females (54%). The mean preoperative air conduction (500-4000Hz) was 69.1 dB and the mean preoperative bone conduction (500 - 4000Hz) was 36.3dB. The mean postoperative air conduction (500-4000Hz) was 41.3 dB and the mean postoperative bone conduction (500-4000Hz) was 31.1dB. Hearing gain were 27.8dB and 5.2dB respectively [28].

Lastly, our study corroborates with a retrospective study by Merán-Gil *et al*. [29], they conducted their study on patients operated for stapetodomy between the period 1993-1997 in Spain. A total of 46 operated ears were included in their study: 34 (74%) women and 12 (26%) men.

The age range was 36 – 81 years as at the time of intervention with a mean of 52.04 years. They found an improvement after surgery (pre-operative mean 51.45dB and early post-operative mean 26.71dB) 24.74dB gain, which is a statistically significant change (p<.005).

CONCLUSION

Stapedotomy is one of the standard techniques for the treatment of otosclerosis. There were successful improvement in all ears (100%) and there was no single patient with surgery-related sensorineural hearing loss. In other words, this study reported a significant improvement in the hearing thresholds of patients with otosclerosis who underwent stapedotomy. We conclude that pure tone audiometry in the hands of competent Audiologists and stapedotomy in the hands of competent ENT surgeons guarantee improved hearing and stem otosclerotic progression.

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