

OTOSCLEROSIS - AN EVALUATION OF CLINICAL AND AUDIOLOGIC FINDINGS; OUTCOME AND COMPLICATIONS OF SMALL FENESTRA STAPEDOTOMY

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ABSTRACT: INTRODUCTION: Otosclerosis is one of the commonest non infective causes of acquired deafness in adults'. 'Otosclerosis' literally means hardening of the ear. It is a primary and exclusive disease of otic capsule of human temporal bone. Otosclerosis is characterised by alternate phases of bone resorption and formation. If the location of bony changes produces evident clinical manifestations term "Clinical Otosclerosis" is used. If bony changes are not translated into clinical manifestations, the term used is "histological Otosclerosis". Antonio Valsalva in 1735 gave first description of ankylosis of stapes to margins of oval window. Von Troltsch in 1881 coined the term 'Otosclerosis'. Politzer in 1893 first described Otosclerosis as a primary disease of otic capsule. Although the clinical course of the disease is well documented, its aetiology remains unclear; thus, multiple theories are available. But none of them has established a definite cause. Otosclerosis usually manifests as a progressive conductive or mixed hearing loss occurring clinically to varying degrees in 0.5% - 1% of the general population. The clinical diagnosis of Otosclerosis, as clarified by Bezold in 1908, requires a careful history, physical examination, tuning fork evaluation and audiometric testing. Radiographic examinations can be done as adjuncts when needed. Therapeutic options for Otosclerosis include medical, surgical and use of hearing aids, alone or in combination. Stapes surgery is an effective treatment for hearing loss and tinnitus of Otosclerosis and stapedectomy is the current treatment of choice for conductive component of Otosclerosis. The first stapes mobilization was employed by Kessel in 1878. The procedure of extracting the stapes for Otosclerosis was first performed by Jack of Boston in 1892 but was beset with obvious difficulties because he lacked proper magnification and antibiotic coverage. In 1956 Dr. John Shea revived the stapedectomy operation for Otosclerosis and replaced the stapes bone with a polyethylene tube prosthesis and vein graft. Small fenestra stapedectomy is a more precise method of creating a hole in footplate rather than total footplate removal. It gives less post-operative vertigo and better high frequency hearing compared to total footplate removal. The present study is a longitudinal clinical study on Otosclerosis with emphasis on clinical and audiological features, per operative findings, outcome and complications of stapedectomy. The objective is to study the demographic and clinical features of Otosclerosis in this part of Kerala; to analyze the results of audiometry and operative notes of Otosclerosis; to describe the outcome and incidence of complications of small fenestra stapedectomy in Otosclerosis.

KEYWORDS: Otosclerosis, a-b Gap, Stapedotomy, Stapedectomy, Small fenestra, SN loss and Conductive deafness.

ORIGINAL ARTICLE

INTRODUCTION: MATERIALS AND METHODS: 43 patients attending the department of ENT, Govt Medical College, Kozhikode between October 2007 and October 2009 are included in the present study. Among these 6 patients underwent surgery in both ears, hence totally 49 ears are operated upon.

INCLUSION CRITERION:

1. Patients with Stapedial Otosclerosis.
2. Patients above 12 years.
3. Patients of both sexes.

EXCLUSION CRITERIA:

1. Patients with pure sensorineural hearing loss (cochlear Otosclerosis).
2. Patients undergoing revision Stapedectomy.
3. Patients aged below 12 years.

Clinical Evaluation: After recording demographic data, a thorough clinical history is taken. The onset, duration, progression of hearing loss is recorded. History of vomiting and tinnitus are elicited. Otosopic examination to observe the Tympanic membrane is done. Tuning fork tests with 256, 512 and 1024 Hz are done. Haematological investigations and investigations for CVS and Rs are done. An informed consent is taken explaining all the possible complications associated with the surgery. Patients are kept on empty stomach overnight. A day before thorough shampoo head bath is advised in all the patients. Premedication is given by Inj Pentazocine 30mg and Promethazine 25 mg intramuscular route. Inj Atropine 1 amp is given I.M.

Technique of Operation: Local infiltration of the EAM with 1% xylocaine with 1:2000 adrenaline injected in 6 points of EAM is used. All the patients are operated upon by the first author of the paper.

Steps of Small Fenestra Stapedectomy: Vascular strip is carefully injected with 2% Lignocaine with adrenaline (1 in 1 lakh units). A tympanomeatal flap is then developed by making a vertical incision from 12'o clock position and by a curvilinear incision from the 6'o clock position. These two incisions are joined approximately 5 to 6 mm lateral to the annulus. The tympanomeatal flap is elevated; the chorda tympani nerve is identified and preserved to gain exposure to the oval window region. Posterior bony overhang, if present, is curetted until the tip of the pyramidal process and the horizontal portion of facial canal over the oval window are seen. The Stapedial tendon is divided sharply. The stapes superstructure is removed. A small (approximately 0.8mm in diameter) fenestra is made in the posterior half of the footplate using a pick or hand drill. The Teflon piston (0.4 mm diameter) is then inserted through the fenestra to a depth of about 0.25mm in the vestibule. It is then crimped to the long process of Incus. A tissue seal is made around the piston with fat, blood clot or gel foam.

Post-operative Care: Post operatively patients were continued on broad spectrum antibiotics with analgesic, antihistamine and systemic decongestant. Patients without any complications are

ORIGINAL ARTICLE

discharged on second post-operative day. Patients are advised to avoid sneezing and sudden movement of the head and neck for 48 hours. On discharge, oral form of antibiotic was given with antihistamine and prochlorperazine for next one week.

Follow up: Patients are advised to attend the outpatient department on sixth post-operative day and ear was examined. Antibiotic and antihistamine were continued for another two weeks. During the third post-operative visit at 4 weeks, the gel foam, if remaining, was removed and status of tympanic membrane checked. External ear canal and tympanic membrane is especially looked for any granulation tissue formation. Any other complaints if present are tackled accordingly. Patients are advised to come after three months. During this visit status of tympanic membrane is again assessed by otoscopy. Pure tone audiogram is done and the results compared with pre-operative audiogram. Five patients did not attend the visit at three months. Regarding ethical point of view no patients are subjected to any further risk during the study. No further investigations are done. No new methods were tried during this study.

Observations: The study included 43 patients who are diagnosed to have Stapedial Otosclerosis. They underwent small fenestra stapedectomy in the Department of ENT, Government Medical College, Kozhikode. Among them six patients underwent bilateral small fenestra stapedectomy at an interval of 6 months. Thus totally 49 ears affected by Otosclerosis are studied.

Age distribution of patients: The ages of patients varied from 18-60 yrs.

Age group	Number	Percentage %
< 20	3	6.98
21 – 30	13	30.23
31 – 40	18	41.86
41 – 50	7	16.28
>50	2	4.65

Table 1: showing Age distribution of the patients (n=43)

Majority of patients were in 3rd and 4th decades (72.09%). Most commonly affected age group is 31-40 years (41.86%).

Sex	Number	Percentage %
Male	14	32.6
Female	29	67.4

Table 2: showing Sex distribution of the patients (n=43)

In the present study the female to male preponderance is seen in the ratio of 1: 2.1.

ORIGINAL ARTICLE

Side of ear affected:

Side affected	Number	Percentage (%)
Both sides	36	83.7
Right only	4	9.3
Left only	3	7

Table 3: showing the side of involvement (n=43)

83.7% patients presented with bilateral symptoms and 16.3% had unilateral symptoms.

Analysis of symptoms:

Symptoms	Number	Percentage (%)
Deafness	43	100
Deafness + tinnitus	25	58.1
Deafness + vertigo	5	11.6
Deafness + tinnitus + vertigo	4	9.3
Paracusis	5	11.6

Table 4: showing the incidence of symptoms (n=43)

Hearing loss was present in all the patients. Other associated symptoms were tinnitus and vertigo. None of the patients presented with vertigo or tinnitus as the only symptom.

Age of onset of hearing loss: The present study showed the patients of age group of 31 to 40 years are most affected (41.86%). The next commonest age group is 21 to 30 years.

Age of onset	Number	Percentage (%)
<10yrs	2	4.65
11 – 20	9	20.93
21 – 30	10	23.26
31 – 40	18	41.86
41 – 50	3	6.98
>50	1	2.33

Table 5: Showing the age of onset of symptoms (n=43)

Duration of symptoms:

Duration of Symptoms	Number	Percentage (%)
<4 yrs	23	53.49
5 – 8 yrs	11	25.58
9 – 12 yrs	5	11.63

ORIGINAL ARTICLE

13 – 16 yrs	2	4.65
17 – 20 yrs	2	4.65

Table 6: Showing the duration of symptoms (n=43)

Majority of the patients (53.49%) presented with loss of hearing for less than 4 years after the onset of symptoms. 4.65% of the patients in the present study gave history of loss of hearing for more than 20 years. Aggravation of hearing loss during pregnancy is seen in 3 (12.5%) out of 24 female patients showed aggravated hearing loss during pregnancy (12.5%).

Family history:

Family history	Number	Percentage (%)
Present	5	11.6
Absent	38	88.2

Table 7: Showing incidence of family history in Otosclerosis patients (n=43)

The incidence of family history is seen in 5 (11.62%) patients in the present study.

Tympanic membrane: Otoscopy of the patients in the present study showed normal appearance in 35 patients, myringosclerosis in 4 and retraction in 10 patients.

TM Finding	Number	Percentage (%)
Normal	35	71.43
Retraction	10	20.41
Myringosclerosis	4	8.16

Table 8: Showing the status of TM (n=43)

Preoperative pure tone average:

PTA	Number	Percentage (%)
Minimal (15-25)	0	0
Mild (16-40)	1	2.04
Moderate (41-55)	20	40.82
Moderately severe(56-70)	24	48.98
Severe (71-90)	4	8.16
Profound (>90)	0	0

Table 9: Showing Pre-operative PTA (n=43)

Approximately 90% of the patients presented with moderate to moderately severe hearing loss. There are no patients with minimal or profound hearing loss. 23 (46.94%) out of 49 audiograms studied showed Carharts notch.

ORIGINAL ARTICLE

Preoperative Air-Bone gap:

A-B Gap	Number	Percentage (%)
0-10	0	0
11-20	0	0
21-30	1	2.04
31-40	27	55.10
41-50	20	40.82
>50	1	2.04

Table 10: Showing a-b gap (n=43)

96% of the patients showed air-bone gap between 31-50 dB.

Tympanogram:

Type	Number	Percentage (%)
A	26	55.08
As	21	42.86
B	2	4.08

Table 11: showing type of Tympanogram in Otosclerosis patients (n=43)

The study showed as type of curve in (26) 42.86% of the patients.

Commonest type of Tympanogram is A type followed by 'As' type.

Types of Otosclerosis foci found during tympanotomy:

Type	No.	%
Anterior focus	25	51.02
Posterior focus	3	6.12
Circumferential type	12	24.49
Biscuit type	4	8.16
Obliterative type	5	10.2

Table 12: showing Types of Otosclerosis foci on Tympanotomy (n=43).

On Tympanotomy 51.02% of the patients showed an anterior focus of Otosclerosis focus. Circumferential type of Otosclerosis type is seen in 24.49% of the patients. Biscuit type is seen in 8.16% of the patients.

Length of piston used in the present study: Piston length of 4.25 mm is used in 53.06%, and 4.5 mm size is used in 20.41% of the patients.

ORIGINAL ARTICLE

Length (mm)	Number	Percentage (%)
3.75	4	8.16
4	9	18.37
4.25	26	53.06
4.5	10	20.41

Table 13: Showing the length of the piston used (n=43)

Complicating factors found during small fenestra stapedectomy:

Complicating factors	Number	Percentage (%)
High jugular bulb	0	0
Facial nerve abnormalities (dehiscence & overhanging)	5	10.2
Persistent Stapedial artery	1	2.04
Fixed Malleus	0	0
Perilymph leak	0	0
Floating footplate	3	6.98
Fracture of incus	0	0
Vertigo	0	0
Tympanic membrane tear	1	2.04

Table 14: Showing the Intra-operative complications (n=43)

The present study showed facial nerve overhanging stapes footplate in (10.2%), floating foot plate in 6.98% and persistent Stapedial artery in 2.04% of the patients.

Post-operative Air-Bone Gap: 72.72% of the patients showed closure of a-b Gap to within 10dB. The P value calculated comparing the pre and post-operative results is <0.0001 and significant.

Post op ABG (dB)	Number	Percentage (%)
0-5	23	52.27
6-10	9	20.45
11-15	7	15.92
16-20	5	11.36
>20	0	0

Table 15: Showing post-operative closure of a-b Gap (n=43)

Complications following small fenestra stapedectomy: During the post-operative period 26.53% of the patients presented with the complaints of vertigo. This complaint lasted for three to five days and treated conservatively.

ORIGINAL ARTICLE

Complications	Number	Percentage (%)
Vertigo	13	26.53
SNHL	0	0
Injury to chorda tympani	0	0
Injury to facial nerve	0	0
Perilymph leak	0	0
Tympanic membrane tear	1	2.04
A/C otitis media	0	0
Labyrinthitis	0	0
Meningitis	0	0

Table 16: Showing the incidence of post-operative symptoms and complications.

DISCUSSION: In the present study 43 patients underwent small fenestra stapedectomy for Stapedial Otosclerosis, their demographic data, clinical findings, audiological assessment are recorded and analyzed. Anatomical abnormalities encountered during the surgery, complications following small fenestra stapedectomy are also analyzed. Although the sample size was small, the results obtained are compared to similar studies in the literature. The mean age of patients included in the study is 34 years. Mean age of male patients is 36 and female patients is 33. In the present study younger female patients are found with Otosclerosis than Male patients.¹ In 2005 Quaranta et al in a study of 151 patients with Otosclerosis, found the mean age to be 46 years. The mean age of onset of symptoms in this study is 28 years. In a similar study the mean age of onset in different countries is found to be; in Panama 33, in Minnesota 29, in Chile 24 and in Brazil 23. In the present study the female preponderance is 1:2 which is similar to other studies by Schmidt in 1933 (72.5%), by Shambaugh in 1952 (68%) and by Cawthorne in 1955 (67%).² Comparison of studies for bilateral involvement with the present study (83.7%); in Glasscock study 72%, Ginsberg et al 80% and in Levy et al study it was 66%. The primary symptom in Otosclerosis is gradually progressive hearing loss. The magnitude of hearing loss is directly related to the degree of fixation of stapes footplate and the duration of hearing loss. 90% of the patients presented within 12 yrs of onset of symptoms. The duration of hearing loss was studied by³ Lippy et al in 1999 compared the trend of disease in the 1960's, 1970's, 1980's and 1990's and found that incidence to decrease from 18.3 years in 1960's to 14.6 years in 1970's, 16.3 years in 1980's and 11.1 years in 1990's. 25% of the patients in this study gave history of Tinnitus. History of vertigo is elicited in 9.3% of the patients.⁴ Goodhill proposed that tinnitus in Otosclerosis was a class of 'unmasked visceral tinnitus' which could be a feature of any pathology associated with conductive deafness and is due to normally sub audible tympanic and peritympanic vascular and muscular noises that are unmasked by the conductive deficit. A positive history of Paracusis Willis was found in 11.6% of patients. Wager in 1939 showed familial incidence in 58% of patients in his study. Cawthorne showed the incidence to be 54.5% and Larsson in 49% of his patients. Aggravation of hearing loss during pregnancy is seen in 12.5% of the patients in this study. Worsening of hearing is noted in 60% of his patients by Panama in

ORIGINAL ARTICLE

1987. Similarly clinical onset of Otosclerosis is reported in 16.6% of the patients of Brazil, 14% of Puerto Rico and 10% of Minnesota patients in his study. The physical appearance of tympanic membrane is usually normal in most patients with Otosclerosis. In about 10% a positive Schwartz's sign is identifiable. In this study 71.43% patients had a normal intact tympanic membrane, 20.4% had mild retraction and 8.16 % had myringosclerosis. The key objective measurement in Otosclerosis remains the pure tone audiogram. 89% of the patients had moderate to moderately severe hearing loss pre operatively and 96% had an a-b gap of 31dB to 50 dB. Air bone gap below 20dB and above 55dB is not seen in the present study. Type A Tympanogram is found in 55.08% of the patients and As type of Tympanogram is seen in 42.86% of the patients.⁵ As the middle ear aeration is un-affected in Otosclerosis Type Tympanogram is seen usually and As Type of Curve is seen in later stages. In the present study all the patients are operated through transcanal approach. Anterior focus Otosclerosis is seen in 51.02% of the patients, followed by circumferential type in 24.49%, Obliterative type in 10.2% and biscuit type in 8.16%. Posterior focus Otosclerosis is seen in 6.12 % of the patients. In a study published in 1999 by Lippy et al over 4 decades (1999) reported 28% solid or obliterated footplates in the 1960's, 10% in the 1970's, 4% in the 1980's and 6% in the 1990's.⁶ Smyth and Hazzard (1978) in a study of 655 cases found an incidence of 64% in circumferential type, 28% in biscuit footplates and 8% in Obliterative Otosclerosis. Various types of pistons are preferred by different authors. In the present study Teflon piston of 0.4 mm diameter is used in all the patients. The length of the piston depends on the distance from the incus to the stapes footplate. This distance together with an extra 0.25mm (extra length is the depth to be inserted into the vestibule) is measured in each case and the length of the piston was cut to size with measuring jig. Most commonly used length was 4.25mm (53.06%), followed by 4.5mm (20.41%), 4mm (18.37%) and 3.75mm (8.16%). The commonest post-operative complicating factor found during the surgery in the present study is facial nerve abnormalities like dehiscence and overhanging facial canal. It occurred in 5 patients (10.2%). Floating footplates is found in 3 patients (6.98%). Persistent Stapedial artery is found in 1(2.04%) and tympanic membrane tear in 1 (2.04%) of the patients. Post-operative Pure Tone Audiogram is taken at 3 months. Post-operative a-b Gap recorded in all the patients is analyzed. 72.72 % of the patients showed a-b gap within 10 dB and the rest showed within 20 dB. There are no patients with a-b gap more than 20 dB in this study. The mean post-operative a-b gap is 9.2 dB in this study. The Pre-Operative and Post-Operative results of closure of a-b gap is statistically significant with P value <0.001. By conventional criteria this difference is considered to be extremely statistically significant. Quaranta et al in 2005 reported 84.8% of small fenestra stapedectomy had a post-operative a-b gap within 10 dB and mean post-operative a-b gap as 6 dB. The commonest post-operative complication which occurred in our study is post-operative vertigo (26.53%). Tympanic membrane tear occurred in one case (2.04%). During Post –Operative follow up with audiogram, evidence of SNHL is not found in the present study.⁷ Palva et al reported in his study of 456 ears (360 patients) of three drum perforations – one infected and two dry, Perilymph fistula in 7 and sensorineural hearing loss in 6.⁸ Larsson et al reported delayed facial palsy in 7 out of 706 stapedectomy operations. They proposed a viral origin and suggested prophylactic therapy with acyclovir during the whole perioperative period in all patients with history of HSV reactivation.⁹ Hannley et al in 1993

ORIGINAL ARTICLE

reported a 2.8% rate of sensorineural hearing loss after stapedectomy. Lippy et al in 1999 encountered 2 cases of sensorineural hearing loss and 6 cases of tympanic membrane tear in their study. Surgical approaches in treating Otosclerosis need not be stereotyped. It is possible to use a variety of techniques, depending on the pathologic conditions and anatomic characteristics encountered during stapes surgery. The major objective is to improve hearing significantly, with or without a hearing aid and to avoid complications. This is a limited study with 43 patients insufficient to give a significant epidemiological record. The duration of the study and follow up period is also not sufficient to give long term effects of small fenestra Stapedectomy response. Stapes surgery is indicated in a patient with socially unacceptable hearing threshold (30dB or worse), a negative Rinnes at three consecutive lower frequencies of 256, 512 and 1024. The speech discrimination if found good is an added benefit of predicting favourable prognosis.¹⁰ Stapes should be firmly fixed and when there is very early partial fixation, stapes surgery is best delayed until fixation is more complete because there is only a little hearing improvement to be gained and much to be lost in case of severe cochlear reaction.¹¹ Fully successful stapes surgery not only corrects the entire conductive component of loss but it also removes the variable Carhart's notch with over closure of the pre-operative air-bone gap. Thus stapes surgery can be used for improving the hearing aid usage in presence of stapes fixation and a profound hearing loss, provided there is good speech discrimination.

CONCLUSIONS: Present study shows incidence of Otosclerosis similar to the literature reviewed world over; Females are commonly affected and the age group is between 3rd and 4th decades. Bilateral involvement is present with unequal progression of the disease in each ear. Aggravated loss of hearing in pregnancy is found in the study, even though in a small percentage of patients. Otosclerosis focus is found to be in anterior in nature in large numbers. Typical As curve of Tympanogram is not seen in the present study. Facial nerve course anomalies are the commonest among the anatomical surprises. Small fenestra Stapedotomy is an ideal method of surgical intervention in the Indian Scenario as it is devoid of major post-operative complications or vertigo. Small fenestra Stapedotomy results showed mean closure of a-b gap to be 9.2dB in the study which is significant statistically and a recommended choice of surgery in Indian Scenario.

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