

**Stapedial Otosclerosis and Evaluation of Small Fenestra Stapedotomy**Sreejith M K<sup>1</sup>, Sunil Kumar K P<sup>2</sup>, Binchu P Babu<sup>3</sup><sup>1</sup>Assistant Professor of ENT, Government Medical College, Kozhikode, Kerala<sup>2</sup>Sunil Kumar K P, Professor of ENT, Government Medical College, Kozhikode, Kerala<sup>3</sup>Government Medical College, Kozhikode, Kerala

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**Abstract:**

**Background:** Otosclerosis is a non-infective slowly progressive disease of unknown aetiology primarily involving the otic capsule where the normal enchondral bone is replaced with spongy vascular bone causing ankylosis of footplate of stapes resulting in acquired conductive or mixed deafness in adults. Small fenestra stapedotomy with prosthesis is the most accepted form of present treatment to overcome the deafness.

**Aims and Objectives:** To study the clinical and audiological findings of stapedial otosclerosis and to study the outcome and complications of small fenestra stapedotomy in a cohort of 55 patients during February 2019 to July 2020.

**Methods:** A cohort study was conducted between February 2019 and July 2020 on 55 consecutive patients diagnosed with stapedial otosclerosis who underwent small fenestra stapedotomy at the Department of ENT, Government Medical College, Kozhikode, a tertiary care centre. Patients were followed up for a minimum period of 3 months. 4 patients lost follow up during the study period.

**Results:** A total of 55 patients were considered for the study, there were 36 females and 19 males. The age of patients varied from 17-60 years and the mean age was 33 years. Majority of patients were in 3rd and 4th decades (83.6%). Hearing loss was the most common symptom reported by all the patients. Other associated symptoms were tinnitus (56.3%) and vertigo (21.8%). Majority of the patients (94.5%) presented within 8 years after the onset of symptoms. 83.6% patients had bilateral symptoms. 12.7% patients had family history of similar disease. Most of the patients had normal tympanic membrane. Majority of the patients (89.1%) had moderate to moderately severe hearing loss. 92.7% of the patients were having air-bone gap between 31dB-50dB. Majority of patients (54.5%) had a type A tympanogram. Most common type of otosclerotic foci found during stapedotomy was anterior focus type (54.5%) and least common was posterior focus type. A piston length ranging from 4.25mm to 4.5mm was used intra-operatively. Facial nerve abnormality was the commonest (10.9%) complicating factor found intra-operatively. Vertigo was the most common complaint of patients postoperatively. There was significant improvement in the A-B gap 3 months after surgery, with 76.4 % patients having an A-B gap of less than 10 dB and rest of them had it between 11dB and 20dB.

**Conclusion:** The result supports the role of small fenestra stapedotomy with maximal effectiveness and least complications. Mean post-operative A-B gap 3 months following surgery was 8.47 dB, which substantiates that small fenestra stapedotomy is an ideal procedure for correcting the conductive component of hearing loss in otosclerosis.

**Keywords:** Otosclerosis; small fenestra; stapedotomy, conductive deafness and audiometry.

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**Introduction**

The commonest non-infective cause of acquired conductive deafness in adult is otosclerosis. The term 'otosclerosis' is derived from 'oto' meaning "of the ear" and 'sclerosis' meaning "abnormal hardening of body tissue". The disease is characterized by alternate phases of bone resorption and formation. The term 'clinical otosclerosis' denoted, the site of bony changes in the otic capsule with clinical manifestations. The term 'histological otosclerosis' was used when only histological change present without clinical

manifestations. In 1735 Antonio Valsalva gave first description of ankylosis of stapes to margins of oval window. [1] In 1881 Von Troltsch coined the term "otosclerosis". [2] Politzer in 1893 referred to the fixation of stapes as otosclerosis and first described otosclerosis as a primary disease of otic capsule. [3] The prevalence of Otosclerosis was around 0.5%- 1% of the 1 lakh population occurring with varying degrees. [4] The clinical diagnosis of otosclerosis, as clarified by Bezold in 1908, requires a careful history, physical

examination, ENT examination, tuning fork tests and audiometric testing. Radiographic examinations can be done adjuncts if needed. [5] Kessel in 1878 employed the first stapes mobilization. (6) In 1892, the procedure of extracting the stapes for the entity was first performed by Jack of Boston but was troubled with obvious difficulties because he lacked proper magnification and antibiotic coverage. [7] Dr. John Shea revived the stapedectomy operation for otosclerosis and replaced the stapes bone with a polyethylene tube prosthesis and vein graft in 1956. [8] Small fenestra stapedotomy is a more accurate method of creating a hole in footplate rather than total footplate removal. It provides less post-operative vertigo and better high frequency hearing compared to total footplate removal. [9] First microscopic proof of stapedial ankylosis has been credited to Katz in 1890 (Bezold and Siebenmann 1894) and it was Haberman (1894) according to Mayer (1917), first demonstrated that more than one focus may occur. [10] Prevalence of clinical otosclerosis has been reported by many investigators to be higher in women: 72.5% (Schmidt, 1933), 68% (Shambaugh, 1952), 67% (Cawthorne 1955). Since otosclerosis is not a genetically sex linked characteristic, one would expect a sex ratio prevalence of 1:1. [11] Ugo Fisch in 1980 suggested changes in the steps of the procedure. He advocated creating a 0.6 mm fenestra in the footplate with an intact incudostadial joint and stapes suprastructure, followed by the incudostadial joint disjunction and suprastructure removal before inserting the prosthesis. [12]

**Aims and Objectives:** To study the clinical and audiological findings of stapedial otosclerosis. To study the outcome and complications of small fenestra stapedotomy.

#### Methods:

**Study Period:** February 2019 to July 2020

**Study Design:** Cohort study

A cohort study was conducted during the period of February 2019 to July 2020 in the department of ENT, Govt. medical college, Kozhikode. This study was conducted, by using the data from the department. An institution Ethics committee approval was obtained and proforma was used. Inclusions Criteria: Patients with a diagnosis of conductive deafness caused by otosclerosis were included. Patients of both the genders were included. Patients aged above 12 years of age were included. Patients with purely stapedial otosclerosis were included. Exclusion Criteria: Patients aged below 12 years were not included. Patients with mixed or cochlear type of otosclerosis were not included. Patients with second ear surgery were not included. Patients undergoing second time stapes surgery were not included. Patients with sensory

type of deafness were not included. Patients with tinnitus were not included. Patients with co-morbid conditions like diabetes mellitus, renal diseases and hypertension were not included. Patients with immune-compromised diseases were not included.

**Sample Size:** Sample size was calculated based on previous study by the formula, Sample size  $(n) = 4pq/d^2$ , where  $p$ =Prevalence,  $q=100-p$  and  $d$ =precision of the study(10% of  $p$ ). In a study conducted by Ahamad Nauphal Pullarat et al on pre and post-operative evaluation of small fenestra stapedotomy in stapedial otosclerosis, the prevalence ( $p$ ) was 88%. Applying that into equation  $n = 4 \times 88 \times 12 / (8.8)^2$ ; Sample size ( $n$ ) = 55.

**Study Setting:** Department of ENT, Government Medical College, Kozhikode.

#### Objectives:

1. To studies the clinical and audiological findings of stapedial otosclerosis.
2. To study outcome and complications of small fenestra stapedotomy.

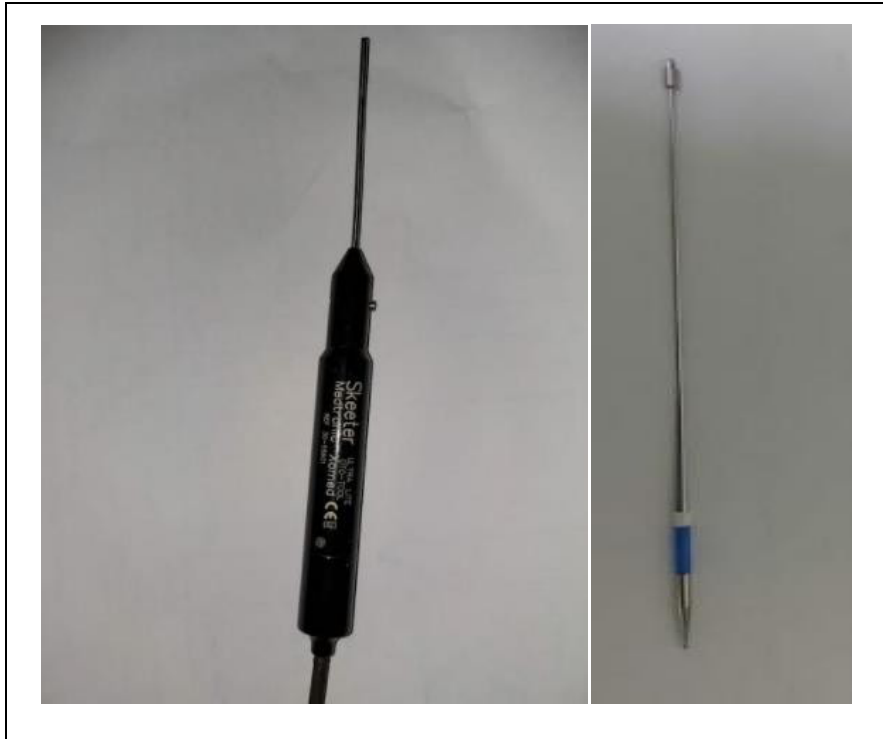
**Method of Data Collection:** After obtaining approval from IEC, a thorough clinical history was taken after obtaining demographic data. The onset of the symptoms, their duration, progression of hearing loss and associated symptoms such as vertigo, tinnitus were elicited. Otoscopic examination was done to evaluate tympanic membrane status. Tuning fork test was done using 256, 512, and 1024 Hz. Complete audiometry including air and bone thresholds, speech discrimination and acoustic reflexes, tympanometry were done preoperatively. Hematological investigations, chest X-ray and ECG were taken. An informed written consent was taken explaining all the possible complications of surgery.

Steps of small fenestra stapedotomy: All surgeries were done under local anaesthesia. All patients were given premedication 30-45minutes before the procedure. An adequate size speculum placed in the external auditory canal, local infiltration given in four quadrants of cartilaginous canal with 2% lignocaine with 1: 100000 adrenaline. 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 incisions joined approximately 5-6mm from the annulus.

The tympanomeatal flap is elevated up to annulus and folded anteriorly. The chorda tympani nerve is identified and preserved to gain exposure to the oval window region. Postero-superior 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. Oval window niche is examined for otosclerotic foci. Mobility of ossicular chain assessed. The malleus

and incus are palpated to assess their mobility. The movement of stapes superstructures examined. A small (approximately 0.6mm in diameter) fenestra is put in the posterior half of the footplate using a skeeter (Fig 1). 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. The Incudo-stapedial joint disarticulated. The stapedial tendon

is divided with scissors. The stapes superstructure is removed. Inj. Hydrocortisone 100 mg IV and Inj. Phenergan 25 mg IV were given intra-operatively. Ointment cotton kept in external auditory canal. In case of facial nerve abnormalities and thick posterior crura, the IS joint is dislocated and stapes superstructure is removed first, followed by fenestrarction, insertion and crimping of piston, with rest of steps being the same.



**Fig 1: Medtronic skeeter drill**

**Post-operative care:** Postoperatively patient was continued on broad spectrum antibiotics with analgesic, and systemic decongestant. Patients without any complications were discharged on first postoperative day. On discharge, oral form of antibiotic was given with systemic decongestant for next one week. Prochlorperazine was given for patients with postoperative vertigo. Follow up: Patients were advised to attend the outpatient department on sixth postoperative day and ear was examined. Antibiotics were continued for another two weeks.

During the third postoperative visit at 4 weeks, the status of tympanic membrane was assessed. External ear canal and tympanic membrane was especially looked for any granulation tissue formation. Any other complaints if present were tackled accordingly. Patients were advised to come at three months. During this visit status of tympanic membrane was again assessed by otoscopy. Pure tone audiogram was done and the results were

compared with preoperative audiogram. Four patients didn't attend the visit at three months.

**Data Analysis:** Data was entered in MS EXCEL and analysis was done using SPSS 18 software. Qualitative variables were expressed in percentages and quantitative variables were expressed as mean. T test was performed to find the relationship between preoperative and postoperative A-B gap.

### Results

study included 55 patients who were diagnosed to have stapedial otosclerosis and underwent small fenestra stapedotomy in Department of ENT, Medical College, Kozhikode. There were 18/55 (32.7%) patients in the age group of 31 to 40 years, 15/55 (27.3%) in the age group of 21 to 30 years and 13/55 (23.6%) in the age group of 41 to 50 years (Table 1). Majority of patients were in 3rd and 4th decades (83.6%). Most commonly affected age group was 31- 40 years (32.7%). The mean age was 33 years.

**Table 1: Shows the Age incidence among the study group (n-55)**

Age Group	Number	Percentage
<20	7	12.7
21-30	15	27.3
31-40	18	32.7
41-50	13	23.6
51-60	1	1.8
>60	1	1.8

There were 36/55 (65.5%) females and 19/55 (34.5%) males with a male to female ratio of 1: 1.89 (Table 2).

**Table 2: Distribution of subjects in terms of gender (n-55)**

Gender	Number	Percentage
Female	36	65.5
Male	19	34.5

Among the total 55 patients, 52/55 (94.5%) attended the OPD for treatment within 08 years after the onset of symptoms. Shortest duration was 1 year and longest was 12 years (Table 3).

**Table 3: Distribution of patients in terms of duration of symptoms (n-55)**

Duration	No	Percentage
<4years	22	40
5-8	30	54.5
9-12	3	5.5
13-16	0	0
17-20	0	0

In this study 46/55 (83.6%) patients had bilateral symptoms and only 16.4% had unilateral symptoms (Table 4).

**Table 4: Show the distribution in terms of side of ear affected (n-55)**

Side Affected	Number	Percentage
Bilateral	46	83.6
Left	4	7.3
Right	5	9.1

Correlating the age of the patients and the onset of their symptoms, it was observed that the mean age of onset was 28 years.

**Table 5: Distribution in terms of age of onset of hearing loss (n-55)**

Age Of Onset	Number	Percentage
<10	0	0
11-20	13	23.6
21-30	16	29.1
31-40	24	43.6
41-50	1	1.8
>50	1	1.8

Correlating the family history of otosclerosis among the patients, it was observed that there was absent history in 87.5% and present in 12.7% which was significantly against the usual reporting (Table 6).

**Table 6: Shows the distribution of patients in terms of their family History (n-55)**

Family History	No	%
Absent	48	87.3
Present	7	12.7

Among the various symptoms that otosclerosis patients present with, the Hearing loss was seen in all the patients (100%). Other associated symptoms were tinnitus and vertigo. None of the patient had vertigo or tinnitus as the only symptoms (Table 7).

**Table 7: Shows the distribution in terms of presenting complaint (n-55)**

Presenting complaint	Number	Percentage
Deafness	55	100
Deafness + Tinnitus	31	56.3
Deafness + Vertigo	12	21.8
Deafness + Tinnitus + Vertigo	6	10.9

The appearance of the tympanic membrane in all the patients was examined and found that 72.7% had normal appearance, 18.2% had retracted membrane and 09.1% had myringosclerosis (Table 8).

**Table 8: Shows the distribution of patients in terms of appearance of their tympanic membrane (n-55)**

Tympanic membrane	No	%
Normal	40	72.7
Retracted	10	18.2
Myringosclerosis	5	9.1

Pure tone audiometry showed that pure tone Average (PTA) was Approximately 89.1% of the patients had moderate to moderately severe hearing loss. None of the patients were having minimal or profound hearing loss (Table 9).

**Table 9: Shows the distribution of patients in terms of preoperative PTA**

PTA	Number	Percentage
15-25 (Minimal)	0	0
16-40 (Mild )	2	3.6
41-55 (Moderate)	22	40.0
56-70 (Moderately severe)	27	49.1
71-90 (Severe)	4	7.3
>90( Profound)	0	0

Air bone gap (a-b gap) was noted in all the patients and it was observed that 92.7% of the patients were having air-bone gap between 31-50dB. None of them had air bone gap more than 55dB or <20dB (Table 1).

**Table 10: Shows the distribution of patients in terms of preoperative air-bone gap (n-55)**

A-B gap	Number	Percentage
0-10	0	0
11-20	0	0
21-30	2	3.6
31-40	27	49.1
41-50	24	43.6
>50	2	3.6

The commonest type of tympanogram was Type 'A' followed by type 'As' in this study (Table 11).

**Table 11: Shows the Distribution of patients in terms of type of tympanogram observed (n-55)**

Type	Number	%
A	30	54.5
As	23	41.8
B	2	3.6

Intra operative site of otosclerotic focus noted showed that in 54.5% of the patients it was anterior footplate type, circumferential type in 23.6% a distribution in terms of type of otosclerotic foci found during stapedotomy and it was oblitative type in 10.9% of the patients (Table 12).

**Table 12: Shows the type of otosclerotic focus noted intra-operatively (n-55)**

Type of otosclerotic foci	Number	Percentage
Anterior Focus	30	54.5
Biscuit Type	4	7.3
Circumferential Type	13	23.6
Oblitative Type	6	10.9
Posterior Focus	2	3.6

During the small fenestration stapedotomy in 92.7% of the patients 04.25 mm size Teflon piston was used. Only in 07.3% of the patients 4.5 mm piston length was used (Table 13).

**Table 13: Shows the distribution of patients in terms of length of piston used (n-55)**

Piston Length	Number	Percentage
4.25	51	92.7
4.5	4	7.3

Distribution in terms of complicating factors found during Small fenestra stapedotomy in the present study was tabulated in Table 14. Facial nerve abnormalities were the commonest being 6/55 (10.9%) in the study.

**Table 14: Shows the complication encountered in the study (n-55)**

Complicating factor	Number	Percentage
High jugular bulb	0	0
Facial nerve abnormalities(Dehiscence/Overhanging)	6	10.9
Persistent stapedial Artery	0	0
Fixed malleus	0	0
Perilymph leak	0	0
Floating footplate	0	0
Fracturing of incus	0	0
Vertigo	0	0
Tympanic membrane tear	0	0

The postoperative air-bone gap was noted within 10dB in 76.4% of the patients and within 20dB in all patients. The p value comparing preoperative and postoperative air- bone gap was 0.004. By conventional criteria this difference is considered to be statistically significant. The mean postoperative A-B gap was 08.47 dB. (n-55), (Table 15).

**Table 15: Distribution of patients in terms of postoperative air-bone gap (n-55)**

A-B Gap	No.	%
0-5	28	50.9
6-10	14	25.5
11-15	4	7.3
16-20	5	9.1
>20	0	0

Symptomatic complication of vertigo found in 32.7% of the patients and no other symptoms was complained of by the patients (Table 16).

**Table 16: Shows the symptomatic complications in the study group (n-55)**

Complicating Factor	Number	Percentage
Vertigo	18	32.7
SNHL	0	0
Injury to chorda Tympani	0	0
Injury to facial Nerve	0	0
Perilymph leak	0	0
Tympanic membrane tear	0	0
Acute otitis media	0	0
Labrynthitis	0	0
Meningitis	0	0

The vertigo lasted for two to three days only in all these patients. All patients were treated successfully by conservative methods.

### Discussion

In the present study 55 patients with stapedial otosclerosis who underwent small fenestra stapedotomy were studied to assess the demographic features, clinical, audiological, per operative findings, outcome and complications of small fenestra stapedotomy. Although the sample size was small, the results obtained were comparable to those in other studies conducted by eminent otologists as described in the literature. The mean age of patients included in the study was 33 years. Mean age of male patients was 33 and female patients was 33. Quaranta et al (2005), (13) in a study of 151 patients with otosclerosis observed that the mean age of patients was 46 years. Thus patients in this study presented about 13 years earlier than the patients of that study. The mean age of onset of symptoms in the present study was 28 years. Average age of onset has been

reported to be 33 (Panama, 1987), (14), 29 (Minnesota), (15), 24 (Chile, 1987), (16) and 23 (Brazil), (17). This study included 65.5% females 34.5% males. Male: female ratio was 1:89. The prevalence of clinical otosclerosis has been reported by many investigators to be higher in women: 72.5% (Schmidt, 1933), (11) 68% (Shambaugh, 1952), (11) and 67% (Cawthorne 1955), (12) 83.6% of patients had bilateral ear symptoms. The incidence of bilaterality was 72% (Glasscock 1995), (20) 80% (Ginberg et al, 1978), (21) and 62% (Lavy et al, 1990), (22) in other studies. The main symptom in otosclerosis was slowly progressive hearing loss.

The magnitude of hearing loss was directly related to the degree of stapes footplate fixation and the duration of hearing loss. Majority of the patients presented within 08 years of onset of symptoms. The duration of hearing loss was studied by Lippy et al (1999), (23) (who compared the trend of disease in the 1960's, 1970's, 1980's and 1990's) and was found 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. Tinnitus was seen in 56.3% of patients. It was associated with vertigo in 10.9%. In a study conducted by Piotr Henryk, (24) preliminary results showed that 107 of 157 patients with otosclerosis (68.2%) had preoperative tinnitus. Of them, 51 (47.7%) had unilateral tinnitus (in the ear that qualified for stapes surgery), and 56 (52.3%) had bilateral tinnitus. A positive family history was found in 12.7% of patients in this study. However, Wager (1939) (25), reported a positive family history in 58%, Cawthorne (12) (1955), in 54.5% and Larsson (1960) (26), in 49%. The physical appearance of tympanic membrane was normal in most patients with otosclerosis. In this study 72.7% patients had a normal intact tympanic membrane, 18.2 % had mild retraction and 09.1% had myringosclerosis. The key objective measurement in otosclerosis is the pure tone audiogram. In this study 89.1% of the patients had moderate to moderately severe hearing loss pre operatively and 92.7% had an air - bone gap between 31 dB-50 dB. None of the patients had air-bone gap less than 20 or less than 55 dB. 54.5% of patients had type A tympanogram and 41.8% had 'As' type. The distinguishing factors of the type A curve is a clearly defined peak, which occur in the range of + or -100 da Pa. In later stages of stapes fixation and 'As' type is obtained. The transcanal approach was used in 100% of small fenestra stapedotomy cases. Endaural or post-aural approaches were not used in any of the patients. Types of footplates with otosclerotic foci were studied intra-operatively. The commonest type found was footplate with anterior focus of otosclerosis in 54.5% followed by circumferential type in 23.6% and oblitative type in 10.9%, biscuit type in 07.3% and posterior focus in 03.6%. Lippy et al (24) study done over 04 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. Smyth and Hazard (1978), (27) in a study of 655 cases had noticed 64% circumferential type, 28% biscuit footplate and 08% oblitative otosclerosis. Various types of pistons were preferred by different authors. Teflon piston of 0.4 mm diameter was used in this study. The length of the piston depended 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 of the case and the length of the piston was cut to size. Most commonly used length was 04.25 mm (92.7%), followed by 04.5mm (7.3%). The commonest complicating factor that we found during small fenestra stapedotomy was facial nerve abnormalities (dehiscent and overhanging facial canal) which occurred in 06 patients (10.9%). None had floating footplate, persistent stapedia artery and tympanic membrane tear, high jugular bulb, fixed malleus, perilymph gush, fracture of long

process of incus or per-operative vertigo. Postoperative pure tone audiogram was taken at 03 months and postoperative air - bone gap were assessed. 76.4 % of the patients had air - bone gap within 10 dB and rest had within 20 dB. None had an air - bone gap of more than 20 dB. The mean postoperative air-bone gap was 08.47 dB in this study which was considered as a good result. The p value comparing preoperative and postoperative air-bone gap was 0.004. By conventional criteria this difference was considered to be statistically significant. Quaranta et al (2005), (28) reported 84.8% of small fenestra stapedectomy had a postoperative air - bone gap within 10 dB and mean postoperative air - bone gap as 06 dB. The commonest postoperative complication which occurred in this study was postoperative vertigo in 32.7% patients. None of the patients had sensory neural hearing loss, facial nerve or chorda tympani injury, Perilymph gush, acute otitis media, labyrinthitis or meningitis. Palva et al (1977), (29) observed in his study of 456 ears (360 patients) of three drum perforation, one infected and two dry, perilymph fistula in 07 and sensorineural hearing loss in 06 patients. Salvinelli et al (2004), (30) reported delayed facial palsy in 07 out of 706 stapedectomy operations.

They suggested a viral origin and suggested prophylactic therapy with acyclovir during the whole perioperative period in all patients with history of HSV reactivation. Hannley et al (1993), (31) reported a 02.8% sensorineural hearing loss after stapedectomy. Lippy et al (1999), (15) observed in 02 patients sensori-neural hearing loss and in 06 patients tympanic membrane tear. Surgical approaches in treating otosclerosis should be individualized. It is possible to use a diversity of techniques, depending on the pathologic conditions and anatomic characteristics encountered during stapes surgery.

The major aim is to improve hearing significantly, with or without a hearing aid and to avoid complications. The demerits of this study are that the number of patients is relatively less than that required for an effective epidemiological study. Moreover the duration of follow up is short and no long term analysis of disease progression or the need for subsequent procedures has been made.

### Conclusion

Otosclerosis is commonly seen in 3rd to 4th decades of life and females are affected twice as males. Majority of patients presented with bilateral hearing loss of moderate to moderately severe degree. Most common type of tympanogram was type A followed by As. Most common type of otosclerotic lesion found was anterior focus followed by circumferential type. Commonest complicating factor found during stapedotomy was facial nerve abnormalities. Commonest

complication found following small fenestra stapedotomy was postoperative vertigo. Mean postoperative air-bone gap following small fenestra stapedotomy was 08.47 dB which proves this surgery to be very effective procedure in correcting the conductive component of hearing loss occurring in otosclerosis.

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