Pitfalls and Complications of Stapedectomy: A Prospective Study

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Abstract

Introduction: Stapedectomy is now one of the most popular and common surgeries done worldwide. Otosclerosis remains the most common single cause of conducting hearing loss in adult population. Females are more frequently affected than males with an approximate 2:1 ratio.

Materials and Methods: This study consists of 94 patients who underwent stapedectomy for otosclerosis. This study was conducted at Government Theni Medical College Hospital, Theni, during the period of 3-year (2013-2016). Patients were evaluated and operated. The various anatomical variations, diagnostic dilemmas, intraoperative complications, its management and follow-up were done systematically.

Results: Age of patients included in this study ranged from 14 to 58 years. Youngest patient was a 14-year-old girl. Surgery was done commonly in the age group between 31 and 40 years. Out of 94 patients, 46 (48.9%) were males and 48 (51.1%) were females. The family history of otosclerosis was noted in 48 patients (51.1%). Positive family history in females was about 56.3%, and positive family history in males was 43.7%. The most common symptom was hard of hearing followed by Paracusis willisi and tinnitus. In this study, 50% of the patients initially had noticed onset of conductive hearing loss during 2nd pregnancy and also aggravation of hearing loss during subsequent pregnancies. Bilateral otosclerosis was commonly encountered than unilateral involvement. The ratio was found to be higher in females. In cases of bilateral equal conductive hearing loss weber test was done to select the ear for surgery. In this study, 52% of patients had air-bone gap between 41 and 60 dB.

Conclusion: The common problems encountered during stapedectomy are (1) excessive posterosuperior overhang, (2) narrow external auditory canal, and (3) narrow oval window niche. Surgical skills, tissue respect, experience, and aseptic surgical technique are essential to perform stapedectomy with least complications. Adequate postoperative care and proper instruction of the patient are mandatory for a good hearing result.

Key words: Floating footplate, Otosclerosis, Stapedectomy

INTRODUCTION

The advent of microscope has revolutionized the treatment of the patients suffering from otosclerosis. Stapedectomy is now one of the most popular and common surgeries done worldwide. It is a rewarding surgery for both the patient and the surgeon. It gives relief for patients who are socially handicapped.¹⁻⁶

Otosclerosis is a primary and exclusive disease of the otic capsule. Although a number of plausible causes of otosclerosis have been suggested, genetic, racial, hormonal, metabolic, viral, pregnancy, infection, vascular and traumatic and more recently autoimmune disorders, its etiology remains unknown. Otosclerosis remains the most common single cause of conducting hearing loss in adult population.

Females are more frequently affected than males with an approximate 2:1 ratio. Otosclerosis occurs far more commonly in persons of European origin and Indians than Africans. Family history is positive in 50% of cases. Pregnancy, puberty, menopause has been thought to stimulate the activity of otosclerosis.³⁻¹³
Surgeons have recognized the mechanical impediment to sound transmission caused by otosclerosis since the last 19th century. John Shea in 1956, revived stapedectomy and also introduced prosthetic restoration of ossicular continuity from incus to tissue covering oval window. Other than stapedectomy, treatment options available are hearing aids and fluories. Although indications for stapedectomy and hearing aid are the same, stapedectomy is usually preferred by the patient because hearing aid is not acceptable socially and cosmetically. Today, the properly selected patient in the hands of an experienced otologic surgeon has a better than 95% chance of closure of the air-bone gap with a low incidence of complications. Stapedectomy usually results in restoration of normal hearing with air-bone gap closure to <10 dB.14-19

Complications commonly encountered during surgery include tympanic membrane perforation, injury to chorda tympani nerve, ossicular dislocation, floating footplate and perilymph gusher and sensorineural hearing loss. Hence, the proper selection of patients should be done very carefully. Although complications are rare, counseling of the patient should be done regarding the treatment modalities available and results of surgery.20-24

MATERIALS AND METHODS

This study consists of 94 patients who underwent stapedectomy for otosclerosis. This study was conducted at Government Theni Medical College Hospital, Theni, during the period of 3-year (2013-2016).

In this study, all the selected patients were subjected to a thorough ear, nose and throat clinical examination including tuning fork tests. Pure tone audiogram and impedance audiometry were done for all the patients. Speech audiometry was done selected number of patients (30%). The intra- and post-operative complications encountered during surgery were recorded. Congenital anomalies and variations were also recorded.

Patient Selection Criteria
1. Patients with otosclerosis with positive family history of otosclerosis with moderate to severe conductive hearing loss (air conduction level 45-65 dB at speech frequencies with bone conduction level 0-25 dB at speech frequencies)
2. Also patients with unilateral otosclerosis with good cochlear reserve
3. Age of the patients should be more than 12 years
4. Patients with mixed hearing loss with speech discrimination score of more than 90%.

Exclusion Criteria
1. Patients with Meniere’s disease were excluded from the study
2. Patients with chronic suppurative otitis media and otitis externa were also excluded from the study
3. Patients with only on hearing ear
4. Those patients with cochlear otosclerosis
5. Age more than 60 years
6. Patients with conductive hearing losses from other causes such as tympanosclerosis causing stapes fixation and secretory otitis media
7. Patients with active otosclerosis (Schwartzte sign positive).

Those patients who are willing for surgery after proper counseling were selected (this includes those not willing for hearing aid and fluocrine therapy). Patients with otosclerosis with conductive hearing loss with air-bone gap of more than 30 dB with good cochlear reserve were selected for stapedectomy.

Surgical Technique
Stapedectomy was done in all cases as following.

Anesthesia
Stapedectomy was done under local anesthesia with 2% xylocaine with adrenaline. Before surgery, injection fortwin and injection phenergan, injection atropine given as premedication 45 minutes before surgery. Local anesthesia is safer and associated with less bleeding than general anesthesia. Intraoperative improvement in hearing can be tested under local anesthesia. Injury to facial nerve in case of prolapsing and bare facial nerve can be detected under local anesthesia intraoperatively. There is some belief that the patient’s ability to report intraoperative vertigo may help the surgeon to avoid injury to the saccule.

Before starting the surgery, auricle and the external auditory canal are cleaned with betadine (povidone iodine).

The ear canal is washed with warm saline solution to remove the povidone iodine, and local infiltration is with 2% xylocaine with adrenaline (1 in 20,000). The initial injections are made with a 30-gauge needle around the periphery of the entrance to the ear canal (3 o’, 6 o’, 9 o’, 12 o’ clock positions of the external auditory canal). Approximately, 2.5-3 ml of this solution is injected. Several sizes of era speculums should be available on the tray, and the largest one that can be seated into the canal is used commonly. A fixed speculum holder is not used. The advantage of not using a fixed speculum holder is flexibility of the speculum for viewing purposes and for allowing the patient to move his or her head if desired.
**Division of the Stapedius Tendon**

The tendon of the stapedius muscle is cut with microscissors (or) using sickle knife.

**Removal of the Stapes Suprastructure**

Before fracturing the suprastructure, a control hole is made in the posterior half of the footplate with a perforator in some cases. Then, the next step is the fracture of the stapes suprastructure from the footplate of stapes. A fine incision knife is applied from the side of the facial nerve that is immediately above the footplate, to the base of the posterior crus of the stapes, and the stapedial crus is fractured by applying gentle pressure toward the promontory. This must be carried out carefully to prevent the footplate from being mobilized at this time.

Enlargement of the control hole made in the footplate is usually done with perforators of increasing size. In many cases, a fenestra is made in the footplate using perforator. Usually, a 0.6 m fenestra is the ideal size for 0.5 mm diameter prosthesis. Small fenestra stapedectomy results in less post-operative vertigo and better high-frequency hearing than total footplate removal.

The distance from the inferior surface of the long process of incus and to the fenestra made in the footplate of stapes is measured using house measuring stick. The measurement is usually 4.5 mm but may vary from 3.5 mm to as much as 5.5 mm. One-half of a millimeter is added to this distance to determine the prosthesis length.

Usually, Teflon piston is used. Preoperatively autoclaving of the Teflon piston is done as a method of sterilization. Teflon piston of variable sizes (0.4 mm, 0.5 mm, and 0.6 mm) is usually kept in separate bottles.

The Teflon piston is spread open and gasped with alligator forceps; in such a way that the forceps and the long axis of prosthesis form an obtuse angle. The prosthesis is now introduced into the vestibule and snapped onto the incus. Because Teflon has memory, the ring tends to close without crimping. The prosthesis position can be adjusted easily. Gelfoam is placed around the prosthesis.

Hanging test and bending test are done to test the placement of the prosthesis. If hanging test is positive, then Teflon piston should be replaced by another piston of adequate length because the piston is not fitting properly into the fenestra made in the footplate.

Crimping of the piston is usually done if bending test is positive. It occurs because the piston is not fitting properly in the long process of incus.

Intraoperative hearing improvement is checked by asking the patient to repeat numbers, sentences and also by asking questions, in whispering voice and also in normal conversational voice.
The tympanomeatal flap is then gently returned to its normal position with a blunt instrument. The meatus is packed from the tympanic membrane to the junction of the inner and middle thirds of the meatus using pieces of gelfoam soaked in antibiotic solution. Medicated canal packing was done afterward. A cotton ball is placed in the ear, and the patient is awakened from surgery.

RESULTS

The observation of 94 patients who underwent stapedectomy during the period of 3-year (2013-2016) is as follows.

Age Incidence
Age of patients included in this study ranged from 14 to 58 years. Youngest patient was a 14-year-old-girl. Surgery was done commonly in the age group between 31 and 40 years (Table 1).

Sex Incidence
Sex incidence of the patients is as follows.

Out of 94 patients, 46 (48.9%) were males and 48 (51.1%) were females (Table 2).

Family History
Patients with the family history of otosclerosis are as follows.

The family history of otosclerosis was noted in 48 patients (51.1%). Positive family history in females was about 56.3% and positive family history in males was 43.7% (Table 3).

Pre-operative Symptomatology
The most common symptom was hard of hearing followed by Paracusis willisi and tinnitus (Table 4).

Role of Pregnancy in Otosclerosis
In this study, 50% of the patients initially had noticed onset of conductive hearing loss during 2nd pregnancy and also aggravation of hearing loss during subsequent pregnancies (Table 5).

Unilateral Versus Bilateral Involvement
Bilateral otosclerosis was commonly encountered than unilateral involvement. The ratio was found to be higher in females. In cases of bilateral equal conductive hearing loss Weber test was done to select the ear for surgery (Table 6).

In this study, 52% of patients had air-bone gap between 41 and 60 dB (Table 7).

Difficulties Encountered During Stapedectomy
During surgery, it was observed that 40.4% of patients had excessive posterosuperior bony overhang, 20.2% of patients had narrow external auditory canal, 10.6% of patients had narrow oval window niche. Obliterative otosclerosis was observed in 2.1% of patients (Table 8).

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<th>Table 4: Pre-operative symptomatology</th>
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P. willisi: Paracusis willisi

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Microscopic Appearance of Footplate Types of Footplate
In this study, 80% of patients had thick chalky footplate and 10% had thin footplate with a milky opalescence (Table 9).

Congenital Anomalies and Variations
During the study, it was observed that 5.3% of patients had bare facial nerve, 3.2% of patients had bare facial nerve hanging over the oval window, 2.1% of patients had persistent stapedial artery, and 1.1% of patients had congenital anomalies of the ossicular chain (Table 10).

Intraoperative Complications
During surgery, it was observed that 4.25% of patients had an injury to chorda tympani nerve, 2.1% of patients had tear in the tympanic membrane, 1.1% of patients had perilymph gusher (Table 11).

Post-operative Complications
During surgery, it was observed that 4.2% of patients had taste disturbance, 4.2% of patients had persistent conductive hearing loss, and 3.2% of patients had sensorineural hearing loss (Table 12).

DISCUSSION
This study consists of 94 patients from 2000-2002, included 46 males and 48 females. A maximum number of patients belonged to the age group of 31-40 years.

Stapedectomy was done under local anesthesia. Surgery done under local anesthesia was useful to prevent general anesthetic complications and to know hearing improvement intraoperatively. Intraoperative vertigo was detected during surgery under local anesthesia.

In this study, the most common difficulty encountered during surgery was excessive posterosuperior bony overhang in 40.4% of patients. House curette was used carefully to curette excessive posterosuperior bony overhang. Curetting should be done from medial to lateral direction and also from superior to inferior direction.25-27

It was done carefully to avoid dislocation of incus and injury to the horizontal portion of the facial nerve. Excessive curetting of the overhang can cause problems in reposition of the tympanomeatal flap. It was not reported in our study.

This was followed by narrow external auditory canal in 20.2% of patients, narrow oval window niche in 10.6% of patients. The surgeon should always look for prominent or bare facial nerve in these cases. Hoard P. House in his...
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study reported few cases of narrow oval window niche. They used cutting burr to enlarge the control hole made in the oval window region instead of perforator.²⁹⁻³¹

In our study, obliterator otosclerosis was reported in 2.1% of patients. Obliterator otosclerosis was managed as follows.

After removal of the suprastructure of the stapes, hand burrs were used to define the footplate region (preferably in posteroinferior portion of the footplate). It was identified by a blue area and seepage of perilymph. Prosthesis introduced after obtaining an adequate opening (twice the width of the 0.6 mm PTFE piston) in the oval window region using perforators. The piston in these cases must extend about 0.5 mm beyond the inner edge of the footplate opening. Gelfoam placed around the prosthesis. Hand burring should be done very slowly and meticulously to avoid perilymph fistula.

Amedee and Miles L. Lewis, during a 25 year period study in 3000 patients reported obliterator otosclerosis in 4% of patients. The technique followed by them was as follows. After drilling to convert the obliterator footplate to a blue footplate from one-third to half of the entire footplate, it was removed by hook. Gelfoam was used to cover the open oval window. In their study, they reported 20 patients with obliterator otosclerosis had a progressive sensorineural hearing loss and 10 had a progressive mixed (or) conductive hearing loss. 7 patients had complete sensorineural hearing loss.³²⁻³⁵

In one of the studies reported diffuse obliterator otosclerosis in 2.1% of patients. Ugo Fisch, in his study reported obliterator otosclerosis in 13.7% of patients.

In our study round, window otosclerosis was reported in 1.1% of patients. The patient had partial obliteration of the round window niche. Surgery was done in the usual way (burring of the round window otosclerosis may result in sensorineural hearing loss). In a study conducted by Peter S. Ronald and William L. Meyerhoff reported about 30% of patients had round window otosclerosis, but complete closure of the niche is very uncommon. The study conducted 1989 reported closure of round window in 9 patients out of 1040 patients (0.87%).

In our study, bleeding during elevation of the tympanomeatal flap was controlled using cotton ball soaked in 4% xylocaine with adrenaline. It has both analgesic and vasoconstriction effect. Shea in his study reported 6.3% of patients had excessive bleeding during surgery, which can cause further cochlear hearing loss after 1 year of surgery. In one study has reported mucosal trauma with disruption of the capillary of the footplate as the cause of bleeding.

In our study, the most common congenital anomaly encountered was bare facial nerve in 5.3% of patients. This was followed by bare facial nerve overhanging the oval window in 3.2% of patients. The facial nerve taking an anomalous course was reported in 1.1% of patients. In those cases were bare facial nerve hanging over the oval window, perforator was used to make control hole in the posteroinferior quadrant to avoid injury to the facial nerve. This was done meticulously. In our study, facial paralysis was not reported. In these cases, surgery was not abandoned.

In our study, persistent stapedial artery was reported in 2.1% of patients. Bleeding from persistent stapedial artery was managed conservatively. Surgery was done without any difficulty.

Congenital anomalies of the ossicular were reported in our study to be 1.1%. The patient had malformed incus. The PTFE piston was placed in between the handle of malleus and footplate of stapes. Wiet et al. reported about 1% incidence of incus malleus fixation and malformed or short long process of incus was reported in 14% of patients.

In our study, fixed malleus was reported. Wiet et al. in his study reported about the incidence of malleus fixation as 1%. Causse and Causse in their study reported about 10.6% of patients had malleus fixation. Manubrium of the malleus was palpated during surgery to identify malleus fixation.

High jugular bulb was reported in 1.1% patients in our study. In our study, stapedectomy was done in the usual way without causing injury to the high jugular bulb. Mas Takashima in his study reported jugular bulb as rare.

In our study, the most common intraoperative complication was an injury to chorda tympani nerve in 4.2% of cases. In our study, routinely chorda tympani nerve was preserved to avoid taste disturbances postoperatively. In a few cases, chorda tympani nerve was kept as a support for PTFE piston. Chorda tympani nerve was cut deliberatively in two cases to visualize the footplate of stapes.

In our study, we used curette to remove bony overhang. Careful delineation of the nerve was also done to avoid injury. A network of Florida Otolaryngologists reported loss of taste sensation in 5-10% of patients. Zoran Becvarovski reported injury to chorda tympani nerve in 5-10% of patients.

In our study, tear in the tympanic membrane was encountered during the elevation of the tympanomeatal flap in 2.1% of patients. To prevent tear, the tympanomeatal flap...
In our study, the most common post-operative complication reported was tasted disturbance due to chorda tympani nerve injury in 4.2% of patients. Permanent taste disturbances occurred in 5% of patients in a study conducted by Wiet et al. In our study, taste disturbances following stapedectomy was reduced because of careful separation of the chorda tympani nerve. It was usually pushed anteriorly to avoid injury to chorda tympani nerve.

In our study, the persistent conductive hearing loss was reported in 4.2% of patients. In four patients, one patient developed fracture of the long process of incus. In our study, it was reduced because of proper selection of patients, correct technique, and crimping the prosthesis. Kacker et al. reported few patients of persistent conductive hearing loss. It was commonly encountered due to adhesions in the middle ear. The necrosis of the long process of incus was also mentioned as a cause of persistent conductive hearing loss in their study. Hildmann, Steinbach in 1989 reported about 11% patients of persistent conductive hearing loss in their study. It was reported due to adhesions in the middle ear.

Otitis media was reported in 2.1% of patients. These patients were treated aggressively with higher antibiotics because to avoid the risk of developing sensorineural hearing loss, labyrinthitis, and meningitis. John W. House in his study reported middle ear infections very rarely. Victor Goodhill, Irwin Harris in their study reported few patients of otitis media due to concomitant upper respiratory tract infections. These patients were treated with decongestants and intravenous antibiotics.

About 87% of hearing improvement was reported in a study conducted by Mathews and Rasgon in 1994. Shea Jr. reported 95% of hearing improvement in his study. David M. Vernick reported 78% of hearing improvement in 1984. Coker and Duncan reported hearing impairment in 75% of patients. Peter S. Roland, William L. Meyerhof reported hearing impairment in about 90% of cases. Hough, Michael McGee reported closure of the air-bone gap to within 10 dB in 90-95% of patients. Paparella in his study reported hearing improvement in 90% of cases. In our study, about 90% of cases showed improvement in hearing.
In our study, the sensorineural hearing loss was reported in 3.2% of patients. One patient had obliterative otosclerosis. He developed dead ear intraoperatively due to injury to vestibule during hand burring. One patient developed sensorineural hearing loss about 6 months after surgery. The one patient developed perilymph gusher and fistula postoperatively. Goodhill and Harris in their study reported 1-2% of severe sensorineural hearing loss. Cause in his series reported 2% patients of sensorineural hearing loss following surgery.

Austin in his study reported 1% of the sensorineural hearing loss. The factors proposed by him was bone chips in the vestibule, irrigation with an open oval window, trauma with instruments to the vestibular contents, too violent or rapid aspiration of perilymph, middle ear infections.

Hughes in 1987 in his study of 75 patients reported severe sensorineural hearing loss in 1 patient. Pederson and Felding have reported in their study of 1111 patients, about 2 patients of partial sensorineural hearing loss. Jean Marquet in his study of 2919 patients reported sensorineural loss in 0.91% of patients. Kacker et al. reported 1-2% of sensorineural hearing loss. Mathews and Rason, in 1994, in their study of 71 patients reported high severe sensorineural hearing loss in 3 patients. Wiet et al. in his study of stapedectomy reported 1-3% of patients had sensorineural loss following surgery.

The duration of surgery is very important in stapedectomy because the results of surgery vary depending on the duration of surgery. Duration of surgery is always proportional to the post-operative sensorineural hearing loss. The time taken for surgery after making control hole in the footplate is very important because of continuous perilymph leak and also exposure of the vestibule which causes sensorineural hearing loss postoperatively. Continuous suctioning of the blood in the vestibule should not be done because of the risk of post-operative sensorineural hearing loss. The incidence of post-operative tinnitus also depends on the duration of surgery, so it is very important for the surgeon to finish the surgery as quickly as possible.

In our study, persistent tympanic membrane perforation was not reported. 2.1% of patients had small perforation of the tympanic membrane during surgery. They healed very well because of the proper approximation of the edges of the tympanic membrane and also due to sterile aseptic technique. Cause and Cause reported tympanic membrane perforation as 1.9% in their study. Myringoplasty was done to repair the defect after 2-3 months of surgery.

In our study, external canal granulation was reported in 1.1% of patients and it was managed conservatively.

In our study, facial palsy and suppurative labyrinthitis were not reported. Shambaugh in his study reported 1 patient of partial facial paralysis. Shea in his study reported five and one-half day post-operative facial palsy after stapedectomy and reported an incidence of 0.1%. Smith et al. reported an incidence of 0.5% of facial palsy.

CONCLUSION

Surgical skills, tissue respect, experience, and aseptic surgical technique are essential to perform stapedectomy with least complications. Adequate postoperative care and proper instruction of the patient are mandatory for a good hearing result.

REFERENCES

10. Pederson CB, Felding JU. Stapes surgery; Complications and airway infection. p. 54-6.