Factors Affecting the Outcome of Stapes Surgery

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Abstract To study the outcome of stapes surgery based on the Clinical, Audiometry, and Surgical pre- and postoperative factors. This study is a prospective study of factors affecting the outcome of stapes surgery in otosclerosis patients. From February 2010 to June 2011, 57 patients of confirmed clinical otosclerosis were analysed. Out of them, 31 patients were included in our study as were available for follow-up. Clinical, audiometry and surgery-related parameters were included to assess the surgery outcome. Results were reported as suggested by AAO-HNS (American Association of Otolaryngology and Head and Neck Surgery) guidelines for stapes surgery, 1995. The paired t-test and analysis of variables test (ANOVA) were used to evaluate the results. A *p* value of <0.05 was considered significant. There was statistically significant improvement in ABG (air bone gap) closure at 3 months of surgery (*p* value <0.001). Among all cases, PTA BC (pure tone average bone conduction) at 3 months of surgery was found in the range of 7.5 dB to 43.75 dB. ABG closure was achieved in the range of 0 dB to 27.5 dB among all cases. Variables like gender, degree of hearing loss, type of footplate, sealing material, and piston diameter were definitely predicting the outcome of stapes surgery. Pure tone audiometry plays an important role to diagnose the otosclerosis, to evaluate degree and type of hearing loss and to assess hearing outcome after surgery. Our results may improve knowledge of predictive factors, providing the

surgeon with useful information to plan surgery with a better case selection as well as to counsel the patient on the likelihood of success of the procedure.

Keywords Stapes surgery · Factors · Hearing outcome

Introduction

The era of modern stapes surgery began in 1956, when Shea successfully removed stapes and reconstructed the ossicular chain with Teflon prosthesis after sealing the oval window with a thin skin graft [1].

Reporting methods have also changed making direct comparisons difficult. Most of the studies have used preoperative bone conduction to assess postoperative ABG (air bone gap) closure in stapes surgery and 0.5, 1, and 2 kHz frequencies were used to calculate pure tone average, so comparison is not possible. Furthermore, several series have quoted converting approximately 20 percent of stapedotomies into stapedectomies because of technical difficulties. This may introduce further bias as the results of stapedotomy are made to appear worse as they reflect difficult cases.

Surgical procedure and intra-operative findings may influence the functional outcome of stapes surgery. Very few series have investigated the study of preoperative variables on the postoperative hearing gain. The interest was mainly focused on the preoperative audiometry features. Surgical parameters like type and diameter of piston, type of footplate, technique, and tissue seal may be useful in determining candidacy for revision and therefore may lead to a more successful outcome. So we have included clinical, audiometry and surgical parameters to assess success of stapes surgery. Knowledge of the factors

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affecting the hearing outcome may help predict hearing results in stapes surgery and is important in patient counselling.

Material and Method

This study is a prospective study of factors affecting the outcome of stapes surgery in otosclerosis patients. From February 2010 to June 2011, 57 patients of confirmed clinical Otosclerosis were treated by Stapes surgery in the Otorhinolaryngology Department of Apollo Main Hospital, Chennai (India). Out of them, 31 patients came for follow-up at 3 months, so were included in our study.

Diagnosis of Otosclerosis was based on clinical history, otoscopy, pure tone audiometry (air conduction, bone conduction, air-bone gap) and impedance audiometry findings.

Surgery was indicated as per AAO-HNS guidelines, 1995 [2]. All patients were explained for hearing aid and hearing outcome as per their preoperative bone conduction thresholds. Primary Stapes surgery for confirmed otosclerosis cases was done. Patients of revision stapes surgery, stapes fixation other than otosclerosis were excluded.

Variables to Assess the Outcome

Clinical

Age, gender, occupation, hearing impairment, tinnitus, vertigo, family history, medical history of associated comorbidities like Hypertension, Diabetes Mellitus.

All patients with vertigo were investigated to rule out Meniere's syndrome before surgery.

Audiometry Related

Pre- and postoperative pure-tone average air conduction (PTA AC), pre- and postoperative pure-tone average bone conduction (PTA BC), preoperative air-bone gap (ABG), postoperative air-bone gap closure, postoperative air conduction gain (AC gain).

All audiograms were performed by senior audiologist according to the ANSI 3.6/ISO-389 (1975) standard by Hughson-Westlake method with GSI-61 Clinical audiometer. Pure tone audiometry was done in all cases. PTA AC and PTA BC were calculated from average of 0.5, 1, 2 and 3 kHz frequencies as per AAO-HNS guidelines. ABG closure was calculated from postoperative PTA AC minus postoperative PTA BC. Impedance audiometry was done using 226 Hz probe with GSI-61 tympanostar. Impedance audiometry was done in 28 patients.

Surgical

Type of footplate, fenestration size, Teflon piston diameter, fenestration seal, fenestration technique.

Types of Footplate [3]

(1) *Anterior or posterior lesion (thin)* if anterior or posterior otosclerotic focus with rest of footplate-normal. (2) *Thick* otosclerotic focus circumferentially involving entire footplate but annular ligament is free. (3) *Obliterative* lesion of otosclerotic focus completely obliterating oval window niche.

Surgical Technique

All cases were done by Rosen's approach under local or general anaesthesia with standard surgical technique by senior consultants. The posterosuperior bony overhang was curetted to expose the stapes bone, oval window, facial nerve and the base of the pyramid. Preliminary fenestration was made posteroinferiorly in the central footplate region. We used original Shea Teflon piston in all cases. Fenestration was widened up to 0.6, 0.7, 0.8, or 0.9 mm as per the piston diameter to be used. Two cases of stapedotomy were converted to partial stapedectomy as footplate was fractured. Fenestration was created nonmanually (with skeeter drill or graduated perforator) or manually. Length of the piston was calculated 0.25 mm longer than the distance from underside of incus to footplate, resulted in 3.75, 4, 4.25, or 4.5 mm. After opening the loop of piston outside on needle, it was encircled over long process of incus, crimped and interpositioned in footplate fenestration. Fenestration seal was done with gelfoam, fat, blood or perichondrium. On table, subjective hearing was checked.

Follow Up

All patients were asked for follow-up after 3 months. Pure-tone audiometry was done in all patients on follow-up to assess the hearing level. Patients were given instructions to avoid heavy weight lifting, flight journey, strenuous exercises, and not to blow nose vigorously for 1 month.

Statistics

All calculations were performed with statistical software (SPSS; SPSS, Inc., Chicago, IL, USA). The paired t-test and Analysis of variables test (ANOVA) were used to evaluate the results. A *p* value of <0.05 was considered significant.

Table 1 Degree of hearing loss affecting the hearing outcome

Mean Audiometry Levels (dB)	Moderate (N = 11)	Moderate to severe (N = 15)	Severe (N = 5)
Preoperative PTA AC	50	62	72.0
AC Gain at 3 months	19.77	29.33	28.75
Preoperative PTA BC	14.10	22.25	30.25
PTA BC at 3 months	19.32	21.75	32.25
Preoperative ABG	35.91	37.75	41.75
ABG at 3 months	10.91	10.92	11.0

PTA AC pure tone average air conduction, PTA BC pure tone average bone conduction, ABG air-bone gap, AC gain air conduction gain, *p* value <0.05 was significant

AAO-HNS Committee on Hearing and Equilibrium (CHE) Guidelines (1995) [2]

The mean preoperative PTAs of AC, BC, and ABG at 0.5, 1, 2 and 3 kHz were compared with corresponding postoperative values. Postoperative BC values were used to calculate postoperative ABG. For reporting overclosure or presumed operative damage, the postoperative values were measured six or more weeks after surgery.

The number of decibels of closure of the air-bone gap was determined as the preoperative minus the postoperative air-bone gap. This was a continuous variable from negative values (worse gap after treatment) to positive values (less gap).

The Committee recommended reporting the mean, standard deviation, and range of the postoperative air-bone gap and the number of decibels of change (level). For convenience, committee recommended to report summaries of the air-bone gap in bins constructed as follows: 0–10, 11–20, 21–30, and >30 dB. To comply with level 1 of these guidelines, investigators should report the mean, standard deviation, and range of change in high tone bone conduction level in decibels of hearing loss for each case if reporting the results at six or more weeks after treatment. Investigators may wish to report early postoperative data in a study like comparing technical hearing improvement with two types of prosthetic stapes. When clinical hearing improvement was being addressed, however, the post treatment interval should be 1 year or longer.

Results

Total 57 patients were operated for stapes surgery during our study period. Among them, 3 months follow-up was available in 31 cases. Total 31 cases were included in our study. Surgical parameters were available in all cases (*n* = 31). Special focus was given to surgical parameters.

PTA AC and PTA BC at 0.5, 1, 2, and 3 kHz were calculated as per AAO-HNS guidelines. Mean values of all

audiometry parameters were used to assess the hearing results. ABG closure was calculated from postop PTA AC minus postop PTA BC. *p* value <0.05 was taken as statistically significant.

The overall female to male ratio was 1.38:1. 83.9% cases were of less than 50 years of age and 16.1% cases were of more than 50 years. Other than hearing loss, most common symptoms were tinnitus (58.1%), Paracusis of Willis (22.6%) and vertigo (2.9%) among all cases. 22.6% Cases had positive family history. There were 48% severe, 36% moderate and 16% very severe degree of hearing loss cases (Table 1).

Thin, thick and obliterative footplates were in 51, 39 and 10% of cases respectively. We used 0.5 mm diameter Teflon piston in 55% cases, 0.4 in 32% and 0.6 in 13% cases. Partial stapedectomy was done in 2 cases (6.45%).

To seal fenestration, different types of sealing materials were used as per surgeon's choice. Gelfoam sealing material was used in 65% cases, fat in 29% cases, blood and perichondrium in 3.22% cases each.

ABG closure was significantly better in females (Mean = 8.89 dB) compared to male patients (Mean = 13.75 dB) as *p* value was 0.022. AC Gain was significantly better in >50 dB hearing loss cases (*p* value = 0.013, Table 1).

Obliterative footplate cases had less bone conduction severity than other footplate cases. AC Gain was better in thick footplate cases as compared to thin and obliterative footplate cases but it was statistically insignificant as *p* value = 0.718. ABG Closure at 3 months was statistically better in thin and thick footplate than obliterative footplate cases as *p* value = 0.010 (Table 2).

There was bone conduction improvement in 0.6 mm piston cases while it was worsened in 0.4 mm piston cases (Table 3). PTA BC threshold at 3 months was not significantly different among both gelfoam and fat sealing material cases (Table 4). One case developed sensorineural hearing loss >15 dB in which gelfoam was used for sealing the footplate fenestration.

Bone conduction is the indicator for acoustic damage. According to AAO-HNS guidelines, bone conduction and

Table 2 Footplate type affecting the hearing outcome

Mean audiometry levels (dB)	Thin (n = 16)	Thick (n = 12)	Obliterative (n = 3)
Preoperative PTA AC	59.84	59.27	57.08
AC Gain at 3 months	25.16	29	23.33
Preoperative PTA BC	22.97	22.08	12.5
PTA BC at 3 months	24.61	22.18	13.33
Preoperative ABG	36.88	37.19	44.58
ABG at 3 months	10.08	9.69	20.41

PTA AC pure tone average air conduction, PTA BC pure tone average bone conduction, ABG air-bone gap, AC Gain air conduction gain, p value <0.05 was significant

Table 3 Teflon Piston diameter affecting the hearing outcome

Mean audiometry levels (dB)	0.4 mm (N = 10)	0.5 mm (N = 17)	0.6 mm (N = 4)
Preoperative PTA AC	59.88	59.12	59.06
AC Gain at 3 months	27.63	24.71	26.25
Preoperative PTA BC	19	22.28	25.31
PTA BC at 3 months	23.13	22.35	22.19
Preoperative ABG	40.88	36.84	33.75
ABG at 3 months	9.13	12.06	10.63

PTA AC pure tone average air conduction, PTA BC pure tone average bone conduction, ABG air-bone gap, AC gain air conduction gain, p value <0.05 was significant

air bone gap mean and standard deviation to be reported at 6 weeks or later. Among all cases, PTA BC at 3 months of surgery was found in the range of 7.5–43.75 dB. ABG Closure was achieved in the range of 0–27.5 dB among all cases (Table 5).

ABG closure ≤ 20 dB was achieved in 93.6% of cases. Socially acceptable hearing was achieved in 41.9% cases after surgery. Statistically significant improvement in ABG closure was found at 3 months of surgery (p value < 0.001). Mean AC Gain was 25.85 dB at 3 months of surgery (Table 6).

Table 4 Sealing material affecting the hearing outcome

Mean audiometry levels (dB)	Gelfoam (n = 20)	Fat (n = 9)	Blood (n = 1)	Perichondrium (n = 1)
Preoperative PTA AC	58.44	61.39	53.75	65
AC Gain at 3 months	24.81	27.92	27.50	26.25
Preoperative PTA BC	21.44	23.33	7.5	23.75
PTA BC at 3 months	22.25	23.19	20	26.25
Preoperative ABG	37	38.06	46.25	41.25
ABG at 3 months	11.38	10.28	6.25	12.5

PTA AC pure tone average air conduction, PTA BC pure tone average bone conduction, ABG air-bone gap, AC gain air conduction gain, p value <0.05 was significant

PTA AC was significantly better at 3 months of surgery (Mean of preoperative PTA BC = 59.35 dB and postoperative = 33.51 dB; p value < 0.001). There was definite improvement in ABG Closure at 3 months of surgery (Mean of preoperative PTA BC = 37.74 dB and postoperative = 10.93 dB; p value < 0.001). PTA BC was slightly worsened after 3 months of surgery compared to preoperative findings, but it was not statistically significant (Mean of preoperative PTA BC was 21.61 dB and at 3 months of surgery was 22.58 dB with p value = 0.4).

In our study, 58% cases had tinnitus and 12.9% cases had vertigo preoperatively. 50% cases with tinnitus and 75% with vertigo had improvement in their symptoms at 3 months of surgery.

Most of the cases (77.42%) had transient vertigo postoperatively and was improved with labyrinthine sedatives. Other complications were like discomfort to sound, alteration of taste, sensorineural hearing impairment.

Discussion

Reporting methods for stapes surgery have been changed over the time. Previously preoperative bone conduction was used to assess postoperative ABG closure after surgery and 0.5, 1 and 2 kHz frequencies were used to calculate pure tone average. AAO-HNS [2] had suggested 0.5, 1, 2 and 3 kHz frequencies to calculate pure tone average and postoperative bone conduction to assess postoperative ABG closure after surgery for reporting results of surgery for uniform reporting. Surgical techniques have changed from total stapedectomy, then partial stapedectomy and recently stapedotomy. A direct comparison with previous studies was difficult as difference in reporting methods, surgery techniques, piston and grafting materials.

Very few studies have investigated the effects of preoperative variables on the postoperative hearing gain. The interest was mainly focused on the preoperative audiometry findings. The role of clinical and surgical parameters was not mentioned in many studies.

Table 5 Level 1 summary data of primary surgery according to the guidelines of the AAO-HNS committee on hearing and Equilibrium in conductive hearing loss (dB)

Mean audiometry levels (dB)	Mean	SD	Min–max (range)
PTA BC at 3 months	22.58	8.76151	7.5–43.75
Postoperative ABG	10.93	5.95091	0–27.5

PTA BC pure tone average bone conduction, *ABG* air-bone gap, *SD* standard deviation

Table 6 Summary

	Findings
AC PTA $\leq$ 30 dB at 3 months (%)	31 cases (41.9%)
ABG closure $\leq$ 10 dB at 3 months (%)	19 cases (61.3%)
ABG closure $\leq$ 20 dB at 3 months (%)	29 cases (93.6%)
Mean preoperative ABG (dB)	37.74 dB
Mean ABG at 3 months (dB)	10.93 dB
Mean gain in AC at 3 months (dB)	25.85 dB
Mean preoperative BC PTA (dB)	21.61 dB
Mean BC PTA at 3 months (dB)	22.58 dB
BC PTA elevation $>$ 15 dB at 3 months (%)	1 case (3.2%)

PTA AC pure tone average air conduction, *PTA BC* pure tone average bone conduction, *ABG* air-bone gap, *AC gain* air conduction gain, *p* value <0.05 was significant

We have used AAO-HNS [2] guidelines for reporting the outcome to maintain uniform reporting of the surgery.

The Committee on Hearing and Equilibrium (CHE) concluded that for basic reporting, the following parameters are required:

1. Mean, SD, and range of the postoperative ABG (PTA of 0.5, 1, 2, and 3 kHz);
2. The change in high-frequency BC level (PTA of 1, 2, and 4 kHz) at 6 weeks or more.

When comparing the percentage of ABG closure within 20 dB or less in primary surgery, we observed slightly better percentage of hearing outcome in our data (93.6%) compared to reported by Vincent [4] (92%) and Hausler (92%) [5].

When comparing the percentage of ABG closure within 10 dB or less after surgery, we observed less percentage in cases (61.3%) in our study compared to reported by Vincent [4] (63.6%) and Hausler [5] (79%).

In our study, 41.9% cases had socially acceptable hearing at 3 months of surgery while Vincent [4] reported slightly better results (44.2%). In our study bone conduction was worsened slightly and Vincent [4] reported slight improvement in bone conduction at 3 months.

83.9% cases were in less than 50 years of age group in our study while 90% cases were reported by Ophir Handzel

[6]. In our study, overall female to male ratio was 1.38:1 and study done by Emmett [7] found female to male ratio of 2:1. This difference could be because of small number of cases in our study.

ABG closure was significantly better in female patients compared to male patients. Marchese [8] noticed no gender-related differences in ABG closure.

Ophir Handzel has reported that positive family history in otosclerosis represents 50% of all clinical cases [6], while in our study, 22.6% of all clinical cases had positive family history. There was no significant difference in the degree of clinical severity between sporadic and familial cases same as reported by Morrison AW [9]. Anyway, a family history of otosclerosis did not play a predictive role in functional results after stapedotomy supporting study done by Marchese [8].

In our study, 96.8% cases had bilateral otosclerosis and 3.2% cases had unilateral otosclerosis. Merchant [3] quoted incidence of involving both ears in 85–90% cases and Smyth [10] had reported involving unilaterally in 15% cases.

AC gain was statistically better in patients with severe and very severe degree of hearing impairment than moderate type of hearing impairment group. These findings were supporting as reported by Kisilevsky [11] (32 dB, severe to profound; 28.75 dB, mild to moderate hearing loss).

In our study, 9.7% cases had Obliterative footplate, Hausler [5] mentioned an incidence of 3–10%. ABG closure was significantly better in thin and thick footplate groups compared to obliterative footplate group, which was in agreement with study conducted by Vincent [12].

We found >57 dB degree of mean conductive hearing impairment in all types of footplate. Schuknecht [13] had reported that diffuse bony ankylosis involving entire circumference of the annular ligament will result in conductive loss >40 dB and localized bony fixation of the anterior footplate will result in 30–40 dB.

Clinical severity of bone conduction was less in obliterative footplate group compared to other footplate groups, but it was statistically insignificant. AC Gain was good in thick footplate group compared to thin and obliterative footplate groups, but it was statistically insignificant.

Comparing our results with the review made by Teig [14], we observed no significant difference in AC gain among 0.4 and 0.6 mm piston diameter groups. In our study, Bone conduction showed improvement in 0.6 mm and worsening in 0.4 mm piston diameter group, but it was statistically insignificant.

The use of connective tissue seals increase the surface area to transmit energy, may prevent perilymph leakage, and restore the stiffness of the annular ligament in theory. We used mostly gelfoam or fat as sealing material. There

was no significant difference in the hearing outcome among the two groups.

In our study, bone conduction worsening of >15 dB (17.5 dB) occurred in 3.2% cases while Vincent [4] reported in 1.5% cases. This case had a thick footplate. We used 0.4 mm piston diameter sized Teflon piston for interposition, gelfoam for sealing fenestration and suctioning was done over footplate area as was having troublesome bleeding.

The incidence of preoperative tinnitus in 58% cases and momentary vertigo in 12.9% cases were comparable to the results of Merchant [3] and Hausler [5]. 50% of cases with tinnitus and 75% with vertigo had improvement in their symptoms.

As per our study, gender, degree of hearing loss, Type of footplate, sealing material, and piston diameter were definitely predicting the outcome of stapes surgery. Occupation and fenestration size were not much predicting the outcome of surgery. Other variables like age, family history, medical history, compliance, fenestration technique, and type of anaesthesia were not affecting the outcome of stapes surgery.

We observed transient vertigo in most of cases (77.42%) after surgery, alteration of taste in 19.35% cases, discomfort to loud sound in 6.45% cases. Merchant [3] reported transient vertigo in most of cases, alteration of taste in 30% cases, and discomfort to loud sound in 35–41% cases.

Conclusion

We can conclude that pure tone audiometry plays an important role to diagnose the otosclerosis, evaluate degree and type of hearing loss and to assess hearing outcome after surgery. Our results may improve knowledge of predictive factors, providing the surgeon with useful information to plan surgery with a better case selection as well as to counsel the patient on the likelihood of success of the procedure.

Compliance with Ethical Standards

Conflict of interest There is no conflict of financial interest.

Informed consent Informed consent was obtained from all individual participants included in the study.

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