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A Retrospective Study: Good Functional Outcomes are Independent of Pre-Operative Factors in Stapes Surgery for Otosclerosis

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Abstract

Context: Stapes surgery is the mainstay of treatment for otosclerosis. Reported success rates of stapes surgery for otosclerosis vary widely, ranging from 63.6% to 94%. The pre-operative prognostic factors of hearing outcomes after surgery are not well studied.

Objective: To determine the hearing results after stapes surgery and analyze the prognostic role of pre-operative factors on hearing outcomes.

Design: Retrospective study.

Setting: Tertiary referral center.

Patients: 90 cases of otosclerosis operated on in our institute from 2006 to 2016 were included into the study.

Interventions: Stapes surgery was performed for 90 cases of otosclerosis (77 stapedotomies, 13 stapedectomies).

Main outcome measures: Audiograms performed just before and six months after operation were used. We selected several pre-operative variables for analysis- age, gender, unilateral/bilateral disease, air (AC) and bone conduction (BC) thresholds, air-bone gap (ABG). Our outcomes measured were post-operative AC, ABG and percentage improvement in air-bone gap (ABGi). The associations between these pre-operative predictors and outcomes were then analyzed.

Results: We report 80% (n=72) and 84.7% (n=76) of cases achieving ideal ABG (≤ 10 dB) and AC outcomes (gain in ≥ 20 dB), respectively. The mean post-operative ABG was 8.8 dB. The mean ABGi, was 78.8% with 78.9% (n=71) of cases attaining ideal ABGi (≥ 70%). Pre-operative variables did not significantly influence post-operative AC and ABG results. However, patients with larger pre-operative ABG (>30 dB) had greater ABGi (85.7 vs. 72.5%, p<0.001).

Conclusion: Stapes surgery provides good and predictable results independent of disease severity or patient profile. Consequently, patients with larger hearing impairment are likely to benefit relatively more from surgery.

Keywords: Otosclerosis; Stapes surgery; Outcome; Prognostic factors; Stapedectomy; Stapedotomy

Introduction

Otosclerosis is a disease of the temporal bone that affects the inner and middle ear. It is characterized by a pathological pleomorphic replacement of normal bone with spongiotic or sclerotic bone [1]. Otosclerosis has traditionally been presumptively diagnosed by characteristic clinical findings on medical history, physical examination and audiology testing [2]. However, final intraoperative assessment of stapes footplate fixation is required to confirm otosclerosis. Stapes surgery has become the mainstay of primary treatment of conductive hearing loss in otosclerosis [3]. Otosclerosis is relatively rare and hence understudied in the Asian population compared to Caucasians. Lee et al. [2] reported that only 1.13% of patients treated for impaired hearing in Taiwan had the disease. Due to rarity of the disease in the population, reports on outcomes of stapes surgery among Asians are scarce and low-powered. Nevertheless, success rates reported from existing Western studies are varied, with reported air-bone gap (ABG) closure (closed to ≤ 10 dB) ranging from 94% to 63.6% [4,5]. Given the heterogeneity of reported results among patients from current literature, it would be beneficial if surgeons were able to prognosticate the success of surgery using pre-operative clinical data. However, there is a paucity of information about the prognostic factors affecting post-operative outcome in stapes surgery in current literature. In our review of the existing literature, the few studies that attempted to investigate the impact of some pre-operative or intra-operative factors failed to reach a common consensus [6,7]. Studies conducted by demonstrated that a smaller preoperative ABG increases the chance of better postoperative closure but [8] identified no variables that were prognostic among the factors they studied. The success of ear surgery is conventionally measured by post-operative ABG and gain in AC thresholds. These are considered objective outcomes that reflect the absolute gain in hearing threshold of the individual after the surgery. However, they do not factor in the individual's pre-operative hearing thresholds into the equation. Therefore, this overlooks the fact that the patient with a larger ABG prior to surgery has benefited more compared to another for the same post-operative ABG achieved. In this study, we included the percentage improvement in ABG as an additional outcome measure in attempt to reflect the relative gain in hearing after stapes surgery. In summary, the aim of this paper is to report the post-operative outcomes of stapes surgery in our population and to determine the prognostic significance of various pre-operative factors on post-operative hearing outcomes.

Methods

We performed a retrospective study of all consecutive cases of primary stapes surgery performed in our institution (Tan Tock Seng Hospital, Singapore) from January 2006 to June 2016. The diagnosis of oteosclerosis was based on a clinical history of progressive hearing loss with normal oteoscopic findings, an audiogram showing conductive hearing loss and subsequently confirmed by decreased mobility of ossicular chain intra-operatively. Only cases with complete clinical, surgical and demographic data were included for this retrospective study. Patients with known congenital malformations, a history of chronic ear infections, previous operation, or sudden sensorineural hearing loss of the affected ear were excluded. For patients in whom both ears met inclusion criteria, each ear was included and analyzed separately. Patient demographical data extracted from case notes included age at surgery, sex, race, unilateral or bilateral disease and side of ear affected.

Surgical Procedure

The surgery was done under general anaesthesia, via a transcanal approach. The stapes footplate was tested for fixation to confirm the diagnosis of otosclerosis. The prosthesis we used was a Teflon-wire piston design where both the diameter and length could be selected. The distance between the underside of the incus and surface of the footplate was measured, to assist in the selection of a prosthesis which was 0.25 mm longer than this measured distance. Using a Skeeter microdrill (Medtronic, Xomed, Jacksonville, FL, USA), a stapedotomy fenestration was created on the footplate of 0.2 mm greater diameter than the intended piston diameter. If for any reason a larger fenestration had been created on the stapes footplate, for example when a fragment of footplate removed along with the base of a crura, the fenestration is described as a partial stapedectomy rather than a stapedotomy.

Pre-operative and post-operative audiometric assessment

Audiological evaluation was carried out using pure-tone audiometry (PTA) which was performed in accordance to the standards set by American Academy of Otolaryngology- Head and Neck Surgery Foundation [9]. Pre-operative results were based on the most recent audiogram performed prior to surgery. The post-operative results used for analysis were based on the pure-tone audiogram results that were routinely performed 6 months after surgery in our institute. PTA was calculated for air-conduction (AC), bone-conduction (BC), air-bone gap (ABG) using the mean of 0.5, 1.0 and 3.0 kHz thresholds in accordance to the new and revised reporting guidelines from the Committee on Hearing and Equilibrium [9]. Our three main measured outcomes were post-op ABG, improvement in AC thresholds and percentage improvement in ABG (ABGi). ABGi is calculated by the percentage improvement in ABG based on the original ABG.

Ethics

Ethical approval was obtained from National Healthcare Group (NHG) Institutional Ethics Review Board (IRB). Collection of data from this study was entirely through operative notes and clinical data found in medical records and therefore no direct patient contact was required.

Statistics

Statistical analysis was performed with IBM SPSS Statistics Version 21.

Based on existing data in the literature, we selected and investigated the effect of multiple pre-operative factors on our measured outcomes. Independent variables measured using quantitative data (age, pre-operative ABG, AC and BC thresholds) were dichotomised into two groups based on the median value of the dataset. As mentioned, our primary outcomes measured were post-operative ABG levels, improvement in AC thresholds and ABGi. Each of these outcomes was categorized into 'ideal' and 'not ideal' subgroups, with cut-offs decided with reference to existing literature. The pre-operative predictors selected in our analysis included: Age at surgery (50 years or less/greater than 50 years), sex (male/female), unilateral/bilateral disease, pre-operative ABG (≤ 30 dB/>30 dB), AC (≤ 70 dB/>70 dB) and BC thresholds (≤ 30 dB/>30 dB). The association between these pre-operative predictors and outcomes were analyzed using $\chi 2$ test for categorical data and Mann-Whitney U test for quantitative data, with p value of ≤ 0.05 considered to be statistically significant.

Results

Seventy-six patients with oteosclerosis underwent primary stapes surgery from January 2006 to June 2016. A total of 90 stapes surgery was performed. Seventy-seven (85.6%) were stapedotomies and the remaining 13 were stapedectomies (14.4%). The demographics of the cases can be summarized in **Table 1**.

The mean age at time of surgery was 50.4 years and ranged from 41-73 years, with an equal distribution of males and females. The side of operated ears comprised 43.3% (n=39) left ears and 56.7% right ears (n=51). In terms of race, the majority of the operated ears belonged to Chinese (67.8%, n=61), followed by Indian (21.1%, n=19), Malay (7%, n=6) and others (4%, n=4). Most ears that were operated on had bilateral disease

(72.2%). Only 28.9% (n=26) of patients had underwent a trial of hearing aids prior to operation.

Table 1 Clinicopathological data of cases (n=90).

	n	%
Gender		
Male	45	50
Female	45	50
Age		
≤ 50 years	51	56.7
>50 years	39	43.3
Mean	50.4 (41-73)	
Operation side		
Left	39	43.3
Right	51	56.7
Race		
Chinese	61	67.8
Malay	6	6.7
Indian	19	21.1
Others	4	4.4
Bilaterality of disease		
Unilateral	16	17.8
Bilateral	74	72.2
Trial of hearing aid		
Yes	26	28.9
No	64	71.1
Surgery		
Stapedotomy	77	85.6
Stapedectomy	13	14.3

Pre-operative hearing

The pre-operative audiometry results are summarized in **Table 2**. The mean pre-operative ABG was 35 dB (range 18.0-60.0). The cases were divided into two groups based on median pre-operative ABG of 30 dB. Thirty (33.3%) of cases had a pre-operative ABG level of 30 db or less, while the remaining 60 (66.7%) had levels of more than 30 dB. The mean pre-operative BC thresholds were 34.4 dB (range 16.7-66.7). The number of cases that had pre-operative BC that were 30 dB and less was 41 (45.6%) while the rest (54.4%, n=49) had BC levels of greater than 30 dB. The mean pre-operative AC threshold was 69 dB (range 27.7-108.7). The cohort was divided into 2 groups based on the median pre-operative AC threshold of 70 dB. Fifty-four (60.0%) of cases had pre-operative AC levels of 70 dB and less; the remaining 36 (40.0%) cases had pre-operative AC levels greater than 70 dB.

Table 2 Pre-operative audiometry results.

	n	%
ABG		
≤ 30 dB	30	33.3
>30 dB	60	66.7
Mean	35 (18-60)	
Pre-op BC		
≤ 30 dB	41	45.6
>30 dB	49	54.4
Mean	34.4 (16.7-66.7)	
Pre-op AC		
≤ 70 dB	54	60
>70 dB	36	40
Mean	69 (27.7-108.7)	

Post-operative results

Table 3 Post-operative audiometry results.

	n	%
ABG		
≤ 10 dB (excellent)	72	80
10.1-20 dB (good)	16	17.8
>20 dB (poor)	2	2.2
Mean	8.8 (0-28.3)	
Post-op gain in AC		
≥ 20 dB (ideal)	76	84.4
<20 dB (not ideal)	12	15.6
Mean	31.6 (6.4-63.4)	
ABGi		
≥ 70% (ideal)	71	78.9
<70% (not ideal)	19	21.1
Mean	78.8 (21.1-100)	

Table 3 summarizes the post-operative audiometry outcomes at 6 months. Out of the 90 ears that were operated on, 80.0% (n=72) had excellent post-operative ABG results (post-operative ABG of 10 dB or less), 17.8% (n=16) had good results (post-operative ABG of 10.1-20 dB) and only 2.2% (n=2) had poor results (post-operative ABG of >20 dB). The mean post-operative ABG was 8.8 dB (range 0-28.3). The two patients who had 'poor results' had a post-operative ABG of 22.6 and 28.3 dB. In terms of post-operative gain in AC, 84.7% (n=76) achieved a gain of ≥ 20 dB with a mean gain of 31.6 dB (range 6.4-63.4

dB).The mean ABGi was 78.8% with a range from 21.1-100%. 78.9% (n=71) of cases achieved an ideal ABGi of ≥ 70%.

Impact of pre-operative variables on outcome

We studied the impact of several pre-operative variables (including age at surgery, sex, unilateral/bilateral disease, pre-operative ABG, AC and BC thresholds) on post-operative outcomes, as measured by post-operative ABG, gain in AC and ABGi.

Post-operative ABG

We considered a post-operative ABG of 10 dB or less as 'ideal' and ABG greater than 10dB as 'not ideal'. Our results on the effect of pre-operative variables studied on post-operative ABG can be summarized in **Table 4**.

Table 4 Impact of pre-operative variables on post-operative ABG.

	≤ 10 dB, n=(%)	>10 dB, n=(%)	Significance ,p=	Odds Ratio (95% CI)
Age				
≤ 50 (n=51)	40 (78.4)	11 (21.6)	0.44	0.795 (0.277-2.286)
>50 (n=39)	32 (82.1)	7 (17.9)		
Gender				
M (n=45)	33 (73.3)	12 (26.7)	0.093	0.423 (0.143-1.251)
F (n=45)	39 (86.7)	6 (13.3)		
Biaterality of disease				
Unilateral (n=16)	11 (68.8)	5 (31.2)	0.182	0.469 (0.633-7.188)
Bilateral (n=74)	61 (82.4)	13 (17.6)		
Pre-operative AC				
>70 (n=36)	34 (94.4)	2 (5.6)	0.348	7.158 (0.497-11.031)
≤ 70 (n=54)	38 (70.4)	16 (29.6)		
Pre-operative BC				
>30 (n=49)	45 (76.3)	14 (23.7)	0.435	0.476 (0.244-3.516)
≤ 30 (n=41)	27 (87.1)	4 (12.9)		
Pre-operative ABG				
>30 (n=60)	46 (76.7)	14 (23.3)	0.174	0.505 (1.626-7.037)
≤ 30 (n=30)	26 (86.7)	4 (13.3)		

We found no significant difference in the attainment of ideal post-operative ABG based on the pre-operative variables studied.

Post-operative gain in AC

We set the threshold for gain in AC at 20 dB; cases that resulted in a gain in AC thresholds of 20 dB or more were considered to have an ideal outcome. Once again, none of the variables analyzed was significant for affecting post-operative improvement of AC thresholds. The results are further elaborated in **Table 5**.

Table 5 Impact of pre-operative variables on post-operative AC gain.

	≥ 20 dB, n=(%)	<20 dB, n=(%)	Significance, p=	Odds Ratio (95% CI)
Age				
≤ 50 (n=53)	41 (78.4)	9 (21.6)	0.467	0.246 (0.051-1.243)
>50 (n=39)	37 (82.1)	2 (17.9)		
Gender				
M (n=45)	37 (73.3)	8 (26.7)	0.098	0.330 (0.017-2.329)
F (n=45)	42 (86.7)	3 (13.3)		
Biaterality of disease				
Unilateral (n=16)	13 (68.8)	3 (31.2)	0.304	0.525 (0.445-8.150)
Bilateral (n=74)	66 (82.4)	8 (17.6)		
Pre-operative AC				
>70 (n=36)	33 (94.4)	3 (5.6)	0.139	1.913 (0.017-1.143)
≤ 70(n=54)	46 (70.4)	8 (29.6)		
Pre-operative BC				
>30 (n=49)	43 (76.3)	6 (23.7)	0.626	0.995 (0.283-3.566)
≤ 30 (n=41)	36 (87.1)	5 (12.9)		
Pre-operative ABG				
>30 (n=60)	57 (76.7)	3 (23.3)	0.174	6.909 (0.822-7.037)
≤ 30 (n=30)	22 (86.7)	8 (13.3)		

Post-operative ABGi

In terms of outcome as measured by ABGi, we arbitrarily defined a percentage improvement in ABG (ABGi) of 70% or more as an ideal result. This study found that the group with larger pre-operative ABG had a higher mean post-operative ABGi and this was statistically significant (mean of 85.7 versus 72.5%, p<0.001). We similarly found that cases with a pre-operative ABG of >30 were more likely to achieve a post-operative ABGi that was ideal (p=<0.001; or 4.26 95%

CI=1.91-20.01). However, none of the other variables analyzed significantly affected post-operative ABGi outcomes **(Table 6)**.

Table 6 Impact of pre-operative variables on post-operative ABGi.

ABGi			ABGi grouped into ideal vs. non-ideal outcomes			
	Mean ABGi (%)	Significance, p=	≥ 70%, n=(%)	<70%, n=(%)	Significance, p=	Odds Ratio (95% CI)
Age						
≤ 50 (n=51)	75.8	0.362	38 (74.5)	13 (25.5)	0.542	0.531 (0.173-3.346)
>50 (n=39)	82.3		33 (84.6)	6 (15.4)		
Gender						
M (n=45)	75.8	0.308	32 (71.1)	13 (28.9)	0.103	0.379 (0.113-1.267)
F (n=45)	81.9		39 (86.7)	6 (13.3)		
Biaterality of disease						
Unilateral (n=16)	71.7	0.21	12 (75.0)	4 (25.0)	0.542	0.763 (0.376-5.344)
Bilateral (n=74)	80.4		59 (79.7)	15 (20.3)		
Pre-operative AC						
>70 (n=36)	82.3	0.326	30 (83.3)	6 (16.7)	0.052	1.585 (0.255-3.231)
≤ 70(n=54)	76.7		41 (75.9)	13 (24.1)		
Pre-operative BC						
>30 (n=49)	79.6	0.325	40 (81.6)	9 (18.4)	0.266	1.434 (0.150-2.817)
≤ 30 (n=41)	78		31 (75.9)	10 (24.4)		
Pre-operative ABG						
>30 (n=50)	85.7	<0.001	52 (86.7)	8 (13.3)	<0.001	3.763 (1.905-8.008)
≤ 30 (n=30)	72.5		19 (63.3)	11 (36.7)		

Conclusion

Stapes surgery is an established primary treatment for conductive hearing loss in oteosclerosis. Reported successful air-bone gap (ABG) closure (closed to ≤ 10 dB) results in current literature range from 95.5% to 63.6% [4,5,7,10]. To our knowledge, there is currently no large-scale published data reporting the results of stapes surgery in the Asia-pacific region to date. In this study conducted in an Asian population, 80.0% of cases achieved excellent 6 months post-operative ABG levels of ≤ 10 dB and up to 97.8% achieved at least good results (ABG ≤ 20 dB). We have reported higher rates of ideal ABG results attained post-stapes surgery compared to some of the existing studies. For example, Bittermann et al. [6] and Kisilevsky et al. [4] reported a mean post-operative ABG of 10 dB or less in 72.1% and 75.2% of their patients respectively. However, the mean follow-up time period was 3 months in the study by Bittermann et al. [6] and 16.4 months in Kisilevsky et al. [4], compared to the longer follow-up period of 6 months in our series. [11] published results of as high as 95.6% (n=800) of patients achieving post-operative ABG of 10 dB or less at a mean follow-up period of 1 year, which is one of the highest success rates in the existing literature. The large variability in surgical outcomes after stapes surgery may be partially explained by differences in surgical experience and technique as suggested by [12-14]. In addition to measuring post-operative results based on the standard 'absolute' post-operative audiometry parameters such as ABG levels, AC and BC thresholds used in most studies, we incorporated ABGi as an alternative outcome measure. Based on the logic that given the same post-operative ABG outcomes attained, patients who had a larger pre-operative ABG benefited relatively more compared to those with a smaller pre-operative ABG. ABGi reflects the relative gain in hearing function by expressing the gain in ABG closure as a percentage of the pre-operative value. Therefore, we believe that this better reflects the individual 'relative' benefit from the surgery. Our current study reports a mean ABGi gain after surgery of 78.8% with 78.9% (n=71) patients achieving an ABGi of ≥ 70%. The only other study that incorporated measurement of percentage improvement in ABG levels was by Koopmann et al. [15] who reported a mean ABGi of about 53%. He also encouraged the incorporation of "relative gain" in pre-operative counselling for patient and supported the role of ABGi as such a measure. This is further supported by Caylakli et al. [16] who reported that patients with the largest pre-operative ABG had the greatest increase in post-operative speech discrimination score.

However, more studies specifically looking at the relationship between ABGi and improvement in subjective hearing after surgery are required to validate the use of ABGi as an accepted outcome measure. In the second part of our study, we aimed to investigate the role of pre-operative clinical and audiological factors in predicting surgical success. Compared to ossiculoplasty [17-20], there is currently a paucity of information and a lack of consensus with regards to prognostic factors relating to stapes surgery [6-8,15,21,22]. Studies found that a smaller pre-operative ABG had better closure of post-operative ABG. In addition, the study by Bittermann et al. [6] also demonstrated that older patients were more likely to achieve a post-operative ABG of 10 dB or less. In contrast to Bittermann et al.'s results [6], Marchese et al. [22] reported that older patients in fact had a poorer outcome after stapedotomy. In this study, we investigated the impact of age, sex, unilateral versus bilateral disease, as well as pre-operative ABG, AC and BC thresholds on post-operative outcomes. We found that ideal post-operative ABG (≤ 10 dB) and improvement in AC thresholds (≥ 20 dB) was not influenced by any of the pre-operative variables studied. In other words, ideal post-operative outcomes can be achieved regardless of the severity of pre-operative hearing deficits or other factors such as age, gender or bilateralism of disease. In terms of outcome measured by ABGi, this study reports that cases with larger pre-operative ABG (>30 dB) are statistically more likely to achieve better ABGi in terms of mean ABGi and probability of achieving ideal ABGi (≥ 70%). This suggests that patients who have a more significant conductive hearing loss or larger ABG benefit relatively more from surgery compared to those with a smaller ABG. This is in agreement with our finding that the achievement of ideal post-op ABG is independent of the magnitude of pre-operative ABG. These findings are consistent with the recent study by Koopman et al. [15] who similarly could not demonstrate any pre-operative factors that significantly influences post-surgical ABG outcome. He also reported a greater ABGi in patients with higher pre-operative ABG (≥ 29 dB). However, he reported that cases with higher AC threshold also had statistically significant higher post-operative ABGi. This trend was noted in our study but fell just short of achieving statistical significance (p=0.052 or 1.585) and this may be possibly explained due to our smaller sample size.

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