The Journal of Laryngology & Otology

cambridge.org/jlo

Outcomes in paediatric patients undergoing stapedotomy

David Lehmann[1], Ewen Chao[1], Robert Saadi[2], Madelyn Wang[1] and Huseyin Isildak[1]

[1]Stony Brook University Hospital, New York, USA and [2]Arkansas Children's Hospital, Little Rock, Arkansas, USA

Main Article

Huseyin Isildak takes responsibility for the integrity of the content of the paper

Presented as a poster at the Combined Otolaryngology Spring Meetings (COSM), 3–7 May 2023, Boston, Massachusetts, USA.

Cite this article: Lehmann D, Chao E, Saadi R, Wang M, Isildak H. Outcomes in paediatric patients undergoing stapedotomy. *J Laryngol Otol* 2025;1–3. https://doi.org/10.1017/S0022215124001580

Received: 10 April 2024
Revised: 13 June 2024
Accepted: 27 June 2024

Keywords:
hearing loss; otology; middle ear surgery; otosclerosis; audiology

Corresponding author:
Huseyin Isildak;
Email: mdhuseyin@gmail.com

Abstract

Objectives. This study aimed to describe outcomes of paediatric stapes surgery at an academic tertiary care centre.

Methods. Electronic medical records of patients younger than 21 years who underwent stapedotomy between September 2013 and July 2020 were reviewed.

Results. A total of 17 patients (7 male, 10 female) were included in our study; 14 underwent surgery on one ear while 3 underwent surgery on both ears (20 ears total). Mean pre-operative air-bone gap was 34.5 dB (standard deviation, 11). At three months, the mean post-operative air-bone gap was 20.6 dB (standard deviation, 10.2), with a mean improvement of 17 dB (standard deviation, 12.1). Sixty-four per cent of patients had closure of their air-bone gap to 20 dB or less. A negative correlation between pre-operative body-mass index and post-operative air-bone gap was statistically significant (n = 14, $p = 0.03$, r = -0.57 [95% confidence interval -0.85, -0.04]).

Conclusion. Paediatric stapedotomy can be effective and safe. In this cohort, age was not correlated with improvement in air-bone gap; pre-operative body mass index was significantly correlated with post-operative air-bone gap.

Introduction

Conductive hearing loss (CHL) in children is most commonly secondary to middle ear effusion; however, a subset of paediatric CHL stems from ossicular chain abnormalities, including juvenile otosclerosis (JO), congenital stapes fixation (CSF), tympanosclerosis, round window atresia and osteogenesis imperfecta.[1] Stapedectomy using an artificial prosthesis was first done in 1956 and has since been extensively studied in adult patients.[2] In contrast, due to the relative rarity of paediatric ossicular chain pathology, most cohorts that have been studied vis-à-vis stapes surgery are relatively small, although these have been incorporated into systematic reviews and meta-analyses in recent years. Additionally, there has been some hesitancy, historically, to perform stapes surgery on children due to the risk of other congenital abnormalities, like facial nerve anomalies, as well as poorer post-operative outcomes, particularly in patients with CSF.[3] Despite this, recent studies have demonstrated clinically significant reductions of the air-bone gap (ABG) after stapes surgery in CSF and JO patients.[4,5] Schwam et. al found that the presence of concomitant ossicular abnormalities such as malleus fixation did not make a significant difference in outcomes.[6] However, further investigation is warranted given the heterogeneity of available data. In this study, we sought to describe the outcomes for a cohort of paediatric patients who underwent stapes surgery at our institution.

Materials and methods

Institutional Review Board (IRB) approval at Penn State Hershey Medical Center was obtained (STUDY00014969), and eligible patients were identified via the electronic medical record system at Penn State Hershey Medical Center in Hershey, PA. Patients were included in the study if they were younger than 21 years old at the time of surgery and had undergone stapedotomy with perichondral graft and bucket handle prosthesis placement between September 2013 and July 2020. Age inclusion criteria encompass patients who were diagnosed with otosclerosis as children and are in line with other studies of paediatric stapedotomy in the literature.[7,8] All patients were operated on by the same senior author. Demographic data were then collected and organised using Microsoft Excel (version 16.66.1, Redmond, WA). Statistical analyses, including testing for normality, correlations, and t-tests, were performed using Prism 9 (version 9.4.1, Boston, MA).

The following demographic and clinical comorbidities were documented: age, sex, body mass index (BMI), family history of hearing loss, history of chronic otitis media (COM) or mastoiditis, history of otologic procedures (not including previous stapes surgery), history of previous stapes surgery, history of tympanic membrane perforation and pre-operative tinnitus or vertigo. All of these were documented as binary variables, except age and BMI, which were continuous variables. Post-operative complications were collected, including sensorineural hearing loss (SNHL), infection, bleeding, persistent vertigo, facial nerve injury and need for revision surgery.

The audiometric evaluation included pre-operative and post-operative audiogram data obtained three months following surgery (Table 1). Variables collected included laterality of ear involved (unilateral vs. bilateral), pre-operative and post-operative pure-tone averages (PTAs) in air conduction and bone conduction, pre-operative and post-operative ABG and successful closure of the ABG. PTA thresholds were used as a surrogate for overall hearing and were calculated from 0.5, 1, 2, and 3 kHz frequencies. The hearing threshold was calculated by averaging the mean thresholds across all frequencies in the affected ear. ABG was calculated from the air- and bone-conduction thresholds obtained at the same test interval by taking the difference of the bone conduction PTA (PTA-BC) and air conduction PTA (PTA-AC).

Results

A total of 17 patients (7 male, 10 female) were included in our study; of these patients, 14 underwent surgery on one ear while 3 underwent surgery on both ears (20 ears total). Median days of follow-up after surgery, which included ears with audiograms performed beyond three months post-op, was 121 (n = 18, interquartile range [IQR] 279.5). Median age was 16 years (n = 20, IQR 11), and median BMI was 20.5 (n = 20, IQR 10.3). One patient had a family history of hearing loss. Eight ears had a history of COM/mastoiditis, 13 had a history of a previous otologic procedure (including 1 which had a previous stapes surgery), and 1 ear had a history of semicircular canal dehiscence syndrome. One patient did not have a pre-operative or post-operative audiogram, and five ears did not have a post-operative audiogram at three months (i.e., 19 ears with pre-operative data available and 14 ears with three-month post-operative data available). Mean pre-operative ABG, PTA-AC and PTA-BC were 34.5 dB (SD 11), 52.4 dB (SD 13.2) and 17.8 dB (SD 8.8), respectively. At three months, the mean post-operative ABG, PTA-AC and PTA-BC were 20.6 dB (SD 10.2), 35.4 dB (SD 14) and 16.6 dB (SD 10.4), respectively. Mean improvement in ABG was 17dB (n = 14, SD 12.1). Of ears with audiograms done at three months post-operatively, 9 (64%) had a closure of their ABG to 20 dB or less. Age was not significantly correlated with any pre- or post-operative audiologic parameters. BMI was significantly correlated with post-operative ABG ($n = 14$, $p = 0.03$, $r = -0.57$ [95% confidence interval {CI} -0.85, -0.04]). Patients with previous otologic surgery had a mean ABG improvement of 14.1 (SD 13.0), while those who had no history of otologic surgery had a mean ABG improvement of 20.8 (SD 10.6), though this difference was not statistically significant ($p = 0.32$). Complications included one patient with an intra-operative tempanic membrane (TM) perforation, one patient with severe post-operative vertigo and one patient requiring revision surgery for adhesions. No patients had profound SNHL in the operative ear after surgery. There were no cases of perilymph 'gusher' or facial nerve injury.

Table 1. Demographics of cohort as well as pre- and post-operative audiogram findings

Gender (n = 17)	Male 7, Female 10
Age (n = 20, years)	Median 16 (IQR 8-19)
BMI (n = 20, kg/m^2)	Median 20 (IQR 17.3-27)
Family history of hearing loss (n = 17)	Yes 1, No 16
History of otologic procedures (n = 20)	Yes 13, No 7
History of COM (n = 20)	Yes 8, No 12
Laterality of disease (n = 17)	Unilateral 10, bilateral 7
Pre-op PTA-AC (n = 19, dB)	Mean 52.4 (SD 13.2)
Pre-op PTA-BC (n = 19, dB)	Mean 17.8 (SD 8.8)
Pre-op ABG (n = 19, dB)	Mean 34.5 (SD 11)
Post-op PTA-AC (n = 14, dB)	Mean 35.4 (SD 14)
Post-op PTA-BC (n = 14, dB)	Mean 16.6 (SD 10.4)
Post-op ABG (n = 14, dB)	Mean 20.6 (SD 10.2)
Improvement in ABG (n = 14, dB)	Mean 17.0 dB (SD 12.1)
Duration of follow-up (n = 18, days)	121 (IQR 80.5-360)

ABG = air-bone gap; BMI = body mass index, COM = chronic otitis media; dB = decibels, IQR = interquartile range, PTA-AC = pure-tone average-air conduction, PTA-BC = pure-tone average-bone conduction; SD = standard deviation.

Discussion

Although stapedotomy is a well-established treatment for CHL related to ossicular chain abnormalities in adults, it is less well-studied in children, given such pathologies are rarer in this population. For instance, one study notes a JO incidence of 0.8 per 100,000 person-years, whereas incidence of otosclerosis in the general population is 3.2 per 100,000 person-years.[9] As a result, much of what is known about managing this entity is built on data compiled from multiple small cohort studies which are then incorporated into larger systematic reviews or meta-analyses. The aim of our study was to add the experiences from our institution to this greater pool of data. A recent meta-analysis of studies that includes 810 ears found a mean pre-operative ABG for JO and CSF of 31.8 (SD 5.2) and 39.4 (SD 10), respectively; they found a mean post-operative ABG for JO and CSF of 9.6 (SD 6) and 19.2 (SD 12.5), respectively.[4] This is roughly in line with the findings in our cohort. Eighty-one per cent of JO ears and 41 per cent of CSF ears had successful outcomes in that study, which was defined as post-operative ABG < 10 dB.[4] Two ears in our study (14%) met this criteria. However, other studies have defined post-operative ABG of ≤ 20 dB as successful, and 64 per cent of ears in our study met this benchmark.[10,11] Because many of the studies included in Daniel et al. did not include statistical analysis of ABG gain, this was not incorporated into their main results although they did perform a meta-analysis of available data which demonstrated an ABG gain of 24.8 dB for JO and 22.6 dB for CSF which is similar to the findings in our cohort.[4] This improvement can be clinically significant in that it may reduce the need for hearing aids in these patients.

One advantage of our cohort is that we incorporated data on previous otologic surgery; although there was no statistically significant difference in ABG gain between those who did and did not undergo surgery previously, this may be due to the small size of our cohort and suggests further investigation into the possibility that this may confound stapes surgery outcomes. In our previous study, which included patients 21 years and older, we did find a significantly lower ABG gain in patients who had previous otologic surgery.[12] Another advantage is that we were able to investigate the relationship between history of COM and post-operative hearing in our cohort and found no significant difference in post-operative

https://doi.org/10.1017/S0022215124001580

audiometric data (PTA-AC, PTA-BC and post-op ABG) between those who did and did not have a history of COM; moreover, none of our patients had post-operative SNHL during the follow-up time period of our study. This is reassuring, since previous literature has established that COM increases risk of SNHL and our data suggest that stapes surgery may not impact this risk.[13]

Our finding that higher BMI—which may make for a more difficult procedure given the patient's body habitus—is significantly associated with lower post-operative ABG is provocative given our previous study did not find a relationship between BMI and post-operative hearing outcomes.[12] Another study, which analysed BMI as a categorical variable, also did not find any significant impact of this demographic aspect on operative outcomes.[14] That said, neither of the aforementioned studies focused exclusively on paediatric patients. Additionally, prior research has shown that the role of BMI is not as clear cut in predicting tissue adiposity in children as it is in adults.[15] Therefore, further study regarding the impact of BMI on audiometric outcomes of paediatric stapes surgery is warranted.

Our study does have certain limitations, including a small cohort size, limited generalisability—given that all these patients underwent surgery with one provider at one institution, and short follow-up (median 121 days). Additionally, we do not have data available to determine the underlying diagnosis that led to stapes surgery in these patients (i.e., JO vs. CSF vs. stapes fixation with other ossicular chain abnormality). Typically, patients with CSF have a more significant pre-operative hearing loss, undergo surgery at a younger age, and have worse outcomes.[3,4,6] We also do not have data on duration of hearing loss nor on the kind of non-stapes otologic surgery done previously, which may have offered further insight into our cohort's outcomes. Nevertheless, our findings are suggestive of areas that warrant further investigation vis-à-vis paediatric stapedotomy while simultaneously contributing to the growing pool of data on stapedotomy outcomes in this cohort.

In conclusion, paediatric stapedotomy can be effective and safe. Unlike our previously published results, age within the paediatric population did not show correlation to improvement in ABG. Also, in contrast with our previous study, increased BMI was significantly associated with smaller post-op ABG. Patients with previous otologic surgery may have had a worse outcome, although our small sample size was unable to show significance for this.

Financial support. This research received no specific grant from any funding agency, commercial or not-for-profit sectors.

Competing interests. The authors declare none.

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https://doi.org/10.1017/S0022215124001580