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Intraoperative Audiometry in Primary Stapes Surgery

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Objective: This study evaluates the feasibility and predictive value of intraoperative pure tone audiometry (PTA) during primary stapes surgery. As a secondary aim, we explored whether preoperative air conduction (AC) thresholds and air-bone gap (ABG) values may influence intraoperative and postoperative hearing outcomes.

Study design: Retrospective case series.

Setting: "Ramazzini" Hospital, Carpi (Modena), Italy.

Patients and interventions: Patients consecutively undergoing primary stapes surgery for otosclerosis between November 2022 and June 2023 were included. All surgeries were performed microscopically under local anesthesia.

Main outcome measures: A correlation analysis was performed between intraoperative and postoperative AC PTA to evaluate the predictive value of intraoperative testing. As a secondary analysis, the potential influence of preoperative hearing status on intraoperative and postoperative outcomes was evaluated by correlating preoperative AC PTA and ABG with AC gain. Predicted AC gain was defined as the difference between intraoperative and preoperative AC PTA, whereas effective AC gain was defined as the difference between postoperative and preoperative AC PTA.

Results: Twenty-eight patients were included. Significant improvements in AC thresholds for single frequencies and PTA were observed both intraoperatively and postoperatively compared with preoperative values. A strong positive correlation emerged between intraoperative and postoperative AC PTA ($r = 0.76$, $P < 0.005$), indicating the predictive value of intraoperative testing. Importantly, postoperative AC thresholds improved by an average of 0.73 dB compared with intraoperative measurements. As a secondary finding, preoperative ABG, but not preoperative AC PTA, was observed to have an association with intraoperative and postoperative outcomes.

Conclusions: Intraoperatory AC PTA was shown to predict with a good approximation postoperative audiometric outcomes of primary stapedoplasty and is a simple, rapid, and cost-effective method for immediate functional assessment.

Keywords: Audiometry, Stapedoplasty, Stapedotomy, Stapes surgery

Recent literature has extensively focused on hearing outcomes and complication rates of primary stapes surgery comparing different devices,[1–5] crimping techniques,[6] type and material of prostheses,[7,8] and endoscopic versus microscopic techniques.[9,10]

A discrete number of studies have been published over the past decades regarding the advantages and disadvantages of the type of anesthesia on stapes surgery outcomes, as well, with no study proving the superiority of one over the other in terms of both hearing outcomes and patient's distress.[11–14] Nonetheless, a tendency for general anesthesia to replace local anesthesia in most otologic surgeries, including stapes surgery, can be observed nowadays among most centers.

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This might be the reason why intraoperative pure tone audiometry as an objective method to intraoperatively assess hearing outcomes during middle ear surgery has been recently abandoned in favor of other tools, including electrocochleography (ECochG), auditory brainstem responses (ABRs), auditory steady state responses (ASSRs), and distortion product otoacoustic emissions (DPOAEs), which can be performed under general anesthesia, even though none of them are routinely employed up to date.[15] As a matter of fact, these tests require trained personnel, increase operative times and thus the length of anesthesia, and their cost-effectiveness has not been measured yet.[16] A few attempts have been made in the past at validating the role of intraoperatory pure tone audiometry during stapes surgery, but they only report results from small series of patients.[17,18]

At our center, we still routinely perform primary stapes surgery under local anesthesia, and we feel that the opportunity to perform intraoperatory pure tone audiometry in this setting could be an adjunct benefit to this technique, given that it is an easy, rapid, inexpensive, and noninvasive test.

Therefore, the aim of this study was to validate the feasibility of intraoperatory pure tone audiometry and its potential role in predicting postoperative hearing results after primary stapes surgery.

Materials and methods

Patients subjected to primary stapes surgery between November 2022 and June 2023 at "Ospedale Ramazzini di Carpi," Carpi

(MO), Italy, were retrospectively analyzed. All surgeries were performed by a single senior surgeon (M.N.). Patients were included in the study if surgery had been performed with the classic microscopic technique and under local anesthesia. Patients subjected to revision surgery were excluded. Cases where a malleo-stapedoplasty was performed were also excluded. Data regarding patients' demographic characteristics and audiometric tests were retrospectively collected and tabulated using Microsoft Excel 2002 (Microsoft Corp.).

Surgical technique

All surgeries have been performed under local anesthesia (2% Lidocaine with 1:100,000 epinephrine). A transcanal approach was used. After harvesting an anteriorly-based tympanomeatal flap, the oval window region was exposed, and the ossicular chain was tested for mobility. When necessary, bone was removed from the scutum to improve visibility. The stapedius muscle and posterior crus of the stapes were cut with microscissors. The stapes was disarticulated from the incus, and the superstructure was removed. The remaining footplate was perforated in its posterior third with a microdrill. A Teflon-platinum prosthesis was cut to the necessary size, inserted into the platinotomy, and crimped around the long process of the incus. The oval niche was sealed with reabsorbable material. The tympanomeatal flap was repositioned, and pure tone average (PTA) air audiometry was performed. Finally, the ear canal was plugged with resorbable hemostatic material. No revision of the prosthesis positioning was performed after audiometry, even if it showed poor results.

Patients were generally discharged from the hospital the day after surgery, if bone conduction was maintained with respect to the preoperative audiometry.

Audiometric tests

Audiometric results were analyzed and reported according to the guidelines of the Committee on Hearing and Equilibrium.[19] Preoperative and postoperative hearing tests, including air-conduction (AC) and bone-conduction (BC) thresholds, were performed in soundproof chambers using standard equipment. Intraoperatively, only the AC threshold was measured, using a portable audiometer (Amplifon Amplaid A 137) and trying to reduce background noise to a minimum.

Preoperative audiometry was performed on average one week before surgery, postoperative audiometric outcomes were derived from the latest available follow-up audiometry.

PTA for both AC and BC was calculated on 500, 1000, 2000, and 3000 Hz. Air-bone gap (ABG) was calculated preoperatively and postoperatively on the same frequencies. ABG closure was defined as postoperative ABG <10 dB.

Statistical analysis

We performed a descriptive analysis by calculating mean and SD for continuous variables and absolute frequency and percentage for categorical variables. A correlation analysis was performed, using Pearson correlation coefficient r for continuous variables, between intraoperative and postoperative AC PTA to determine if intraoperative AC PTA was predictive of postoperatory audiometric results. Correlation was considered very high with $r > 0.9$, high with r between 0.7 and 0.9, moderate with r between 0.5 and 0.7, and low with $r < 0.5$.

In addition, the same analysis was performed between preoperative AC PTA and AC gain (predicted and effective), and between preoperative ABG and AC gain (predicted and effective), to understand whether the preoperative hearing status may influence intraoperative and/or postoperative results. Predicted AC gain was defined as a measure of improvement as the difference between intraoperative and preoperative AC PTA. Similarly, we defined effective AC gain as the difference between postoperatory and preoperatory AC PTA.

Finally, we applied a linear regression analysis to describe the relationship between intraoperative and postoperative AC PTA.

Wilcoxon matched pairs signed rank test was used to compare preoperative with intraoperative and postoperative audiometric test results.

Statistical analysis was performed using STATA 18 (Stata 18 Base Reference Manual). We considered a P-value <0.05 as statistically significant.

Ethical statement

This study was conducted in accordance with the Helsinki Declaration and approved by the Local Ethical Committee (CE Emilia Romagna 6052).

Results

A total of 28 patients (9 males and 19 females) were eventually included in the study. Among them, 15 stapedotomies were performed on the left ear and 13 on the right ear. The mean age of the study cohort was 57.3 years with a SD of 12.2 (range: 33 to 79). Four patients had already been subjected to stapes surgery on the contralateral ear. In none of the cases a switch to general anesthesia was required during the course of the procedure. No patient experienced vertigo or tinnitus during surgery. In 2 patients, a small intraoperative footplate fracture was observed. It was repaired with tragal pericondrium and a steroid bolus was administered at the end of surgery. In one case, the pyramidal eminence and stapedius muscle were found to be absent.

The average time point for postoperative audiometry was 142 days after surgery (range: 26 to 377 d).

Preoperative, intraoperative, and postoperative AC and preoperative and postoperative BC thresholds for all the analyzed frequencies, and relative PTA are detailed in Table 1. Overall, there was a significant improvement in both AC thresholds for single frequencies and AC PTA from the preoperative to the intraoperative audiometry and from the preoperative to the postoperative audiometry. Mean AC threshold improvement from preoperative to postoperative audiometry was higher at lower frequencies (-28.1 dB at 500 Hz vs -17.2 dB at 3 kHz). A similar trend was observed regarding mean AC threshold improvement from preoperative to intraoperative audiometry (-16.8 dB at 500 Hz vs -6.6 at 3 kHz).

Mean preoperative ABG was 25.5 dB (SD: 9.7), while mean postoperative ABG was 12.7 dB (SD: 8.4). Mean ABG improvement was 12.8 dB. A total of 28% of patients achieved ABG closure, while the proportion of postoperative ABG <20 dB was 89.3%.

A significant high positive correlation was found between intraoperative and postoperative AC PTA ($r = 0.79$, $P < 0.005$) as seen in Figure 1, even though we observed that intraoperative AC thresholds and AC PTA were overall higher than their postoperative counterpart. From the regression analysis, an average decrease of 0.73 (95% CI: 0.47-0.98) in postoperative

Table 1

Air and bone conduction thresholds for single frequencies and PTA val

	500 Hz; Mean (SD)	1000 Hz; Mean (SD)	2000 Hz; Mean (SD)	3000 Hz; Mean (SD)	PTA; Mean (SD)
Air conduction (dB)					
Preoperative	60.4 (9.2)	59.5 (11.3)	60.2 (13.4)	63.5 (14.7)	60.5 (9.5)
Intraoperative	43.6 (10.4)	44.8 (12.7)	53 (15.4)	56.9 (16.3)	46.4 (11.9)
Postoperative	32.3 (11.8)	36.4 (13.3)	41.1 (15)	46.3 (16.1)	36.4 (11.3)
Predicted gain	16.8[a]	14.6[a]	7.1[a]	6.6[a]	14.1 (8.8)[a]
Effective gain	28.1[a]	23.1[a]	19.3[a]	17.2[a]	24 (10.1)[a]
Bone conduction (dB)					
Preoperative	23.9 (9.2)	27.3 (10.6)	41.3 (14)	37.9 (13.4)	25.8 (8)
Postoperative	20 (9.5)	23.2 (10)	31.3 (13.7)	33.6 (13.5)	22.9 (8.3)
Difference between postoperative and preoperative	3.9	4.1	10	−4.3	2.9 (3.5)

[a]Statistically significant at Wilcoxon matched pairs signed rank test. Significance set at $P < 0.05$.PTA indicates pure tone average.Predicted gain: difference between intraoperative and preoperative results. Effective gain: difference between postoperative and preoperative results. Predicted and effective gain are expressed in absolute value.

AC PTA was estimated for a one-unit decrease in intraoperative AC PTA.

No correlation was observed between preoperative AC PTA and AC gain (both predicted and effective, $r = 0.22$ and 0.31, respectively) as seen in Figure 2. In contrast, preoperative ABG showed a moderate correlation with both predicted gain ($r = 0.66$, $P < 0.005$) and effective gain ($r = 0.63$, $P < 0.005$; Fig. 3).

Discussion

Our results show that intraoperatory AC PTA predicts with a good approximation postoperative audiometric outcomes of primary stapedoplasty. Likely due to intraoperatory bleeding and the impossibility of completely canceling background noise, intraoperative results appear ~0.73 times lower than postoperative results.

From the authors' experience, intraoperative PTA is easy to perform, it does not add much to operating room (OR) occupation times, does not affect the cost of the procedure itself, and does not require additional personnel in the OR, as the results of the test can be easily interpreted by the surgeon.

Given that intraoperatory PTA can only be performed under local anesthesia, in light of the above results, it could be worth to reexplore the role of local anesthesia in stapes surgery, which also gives the advantage to live-monitor vestibular function, reduce OR occupation times and waiting lists, and was found comparable to general anesthesia in terms of postoperatory outcomes and complication rates.[13,20,21]

Other methods to assess stapes surgery success intraoperatively under local anesthesia have been described in the past, including intraoperative tuning fork test and whisper hearing test. However, the results of these subjective tests were not confirmed at postoperative audiometry. More in detail, a number of patients who reported subjective hearing improvement at the end of the procedure had poor results on postoperative PTA.

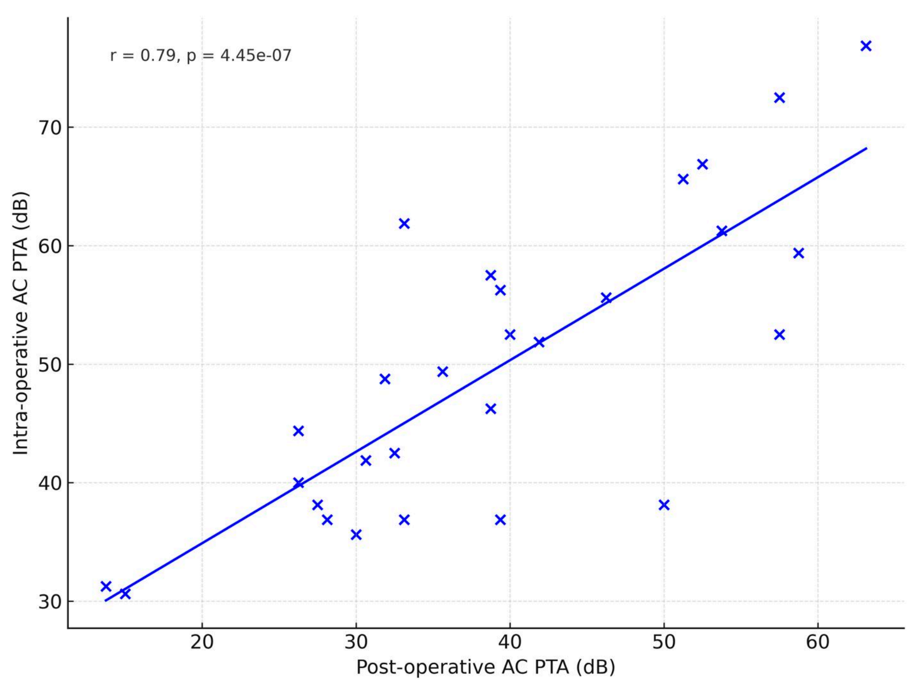

Figure 1. Scatter plot of intraoperative and postoperative AC PTA. AC PTA indicates air conduction pure tone average.

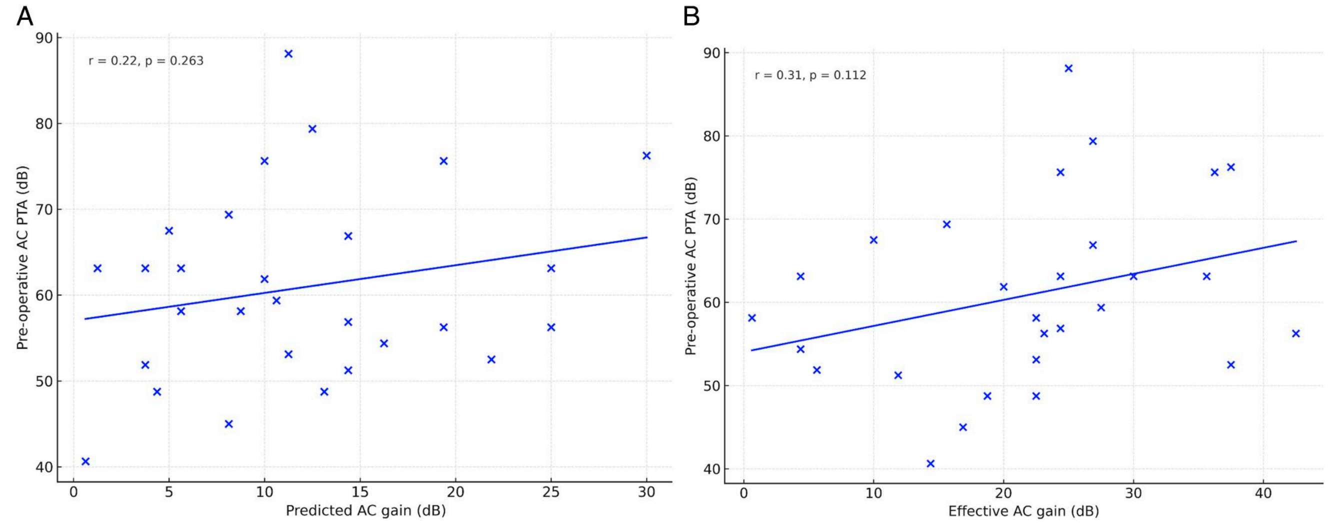

Figure 2. Scatter plot of AC PTA and predicted gain (*A*) and effective gain (*B*). Predicted gain: difference between intraoperatory and preoperatory AC PTA. Effective gain: difference between postoperatory and preoperatory AC PTA. AC PTA indicates air conduction pure tone average.

Ren and colleagues hypothesized 2 main reasons for this discrepancy: patients had strong willingness of hearing improvement and/or background noise might have interfered with the results.[15,22]

Of course, a number of methods have been described for intraoperatory hearing monitoring during middle ear surgery under general anesthesia. To make a few examples, ABR monitoring has been employed since the late 80s with this particular aim. Actually, ABRs are essentially unaffected by the patient's cognitive conditions, such as sleep, sedation, or attention, and, therefore, could be employed both under general and local anesthesia. The main disadvantages of this technique, which are probably the reasons why it is not routinely employed in everyday practice, are that it requires additional OR staff members and additional operating room time. Furthermore, no data are available from the current literature regarding its cost-effectiveness.[16,23,24] In addition, ABR sensitivity in predicting low-frequency (< 2 kHz) hearing thresholds is reported to be inadequate.[15]

There have been some attempts over the past years at exploiting ECochG, an electrophysiological test which is normally employed for hearing monitoring during surgery for cerebello-pontine angle tumors, for intraoperatory monitoring during stapes surgery. However, results from these studies are controversial: Freeman et al[25] found a significant correlation between improvement in ECochG thresholds following piston insertion and improvement in air conduction thresholds measured at 6 weeks postoperatively at all frequencies except 6 and 8 kHz, while no clear correlation was found in other series.[26,27] ECochG has the advantage to detect damage to the inner ear as it occurs during the course of surgery, however, it was found unable to predict whether or not it will be

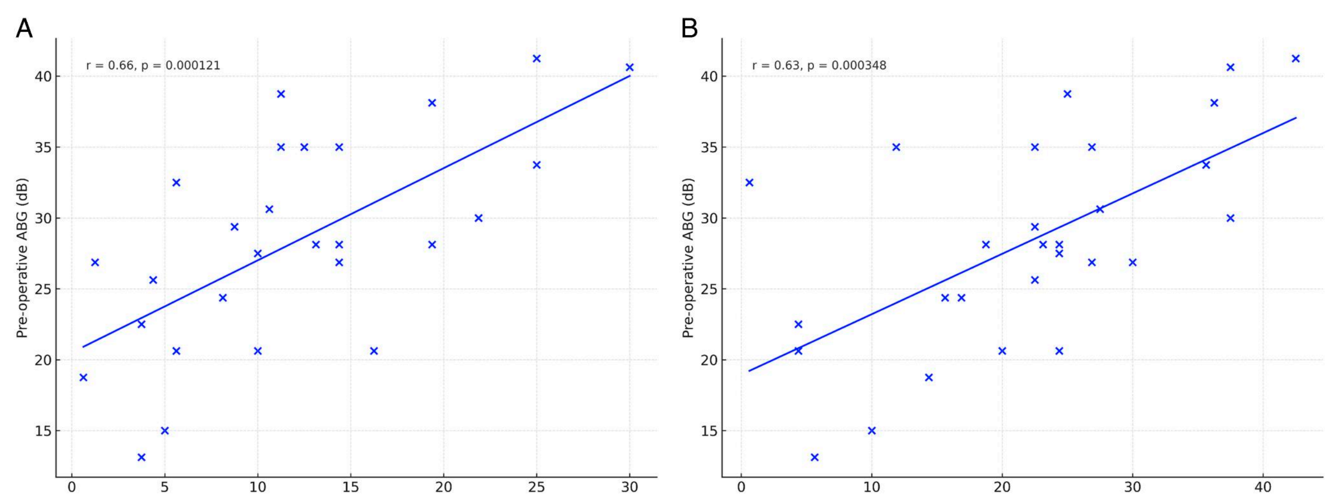

Figure 3. Scatter plot of ABG and predicted gain (*A*) and effective gain (*B*). Predicted gain: difference between intraoperatory and preoperatory AC PTA. Effective gain: difference between postoperatory and preoperatory AC PTA. ABG indicates air-bone gap; AC PTA, air conduction pure tone average.

permanent, and, therefore, it cannot be relied upon to provide protection.[25]

It should be emphasized that in this case series, no intraoperative adjustments were made based on intraoperative PTA results, as the primary objective was to assess whether this test could reliably predict postoperative hearing outcomes. The next step will be to implement intraoperative audiometry as an active feedback tool to guide intraoperative decision-making, allowing the surgeon to refine the procedure in real time when suboptimal results are detected.

As a secondary outcome of our study, we observed that preoperatory AC thresholds did not correlate with postoperative AC improvement, while preoperative ABG showed a weak correlation with postoperative AC PTA gain. According to other published series, AC gain and ABG reduction were higher the more severe the degree of preoperatory hearing impairment, suggesting that patients with an ABG lower than 20 dB should be referred to other methods for hearing improvement.[28–30] In contrast, a few more reports have found large ABGs (> 34.5 dB) and low air conduction thresholds to be negative prognostic factors for surgical success.[31] These conflicting results may stem from different studies employing different outcome measures (preoperatory ABG versus preoperatory AC PTA and ABG gain versus AC gain). To make an example, Bittermann et al found that a smaller preoperative ABG (≤ 30 dB) could lead to a better postoperative ABG (≤ 10 dB), while a large preoperative ABG (> 30 dB) and preoperative AC (> 50 dB) could lead to a better AC (> 20 dB).[32] It has been previously pointed out that the use of different audiologic parameters may affect reported success rates of stapes surgery, for instance postoperatory ABG may be affected by the phenomenon of overclosure, that is, improved bone conduction (BC) thresholds and the inability to recognize postoperative changes in BC, or it may be affected by the inclusion of higher frequencies in the calculation.[33]

In our series, only a handful of patients had a preoperatory ABG higher than 35 dB, and none had an ABG lower than 20 dB, which might explain why, in this homogeneous cohort, no clear correlation between preoperatory hearing levels and surgical success could be appreciated.

Our study is surely limited by a small sample size. In addition, the time range for postoperative audiometry was wide on this cohort (26 to 377 d) and should be more clearly defined in further studies. In contrast, all procedures were performed by a single surgeon with a standardized technique and the same prosthesis type, which strengthens our conclusion regarding the reliability of intraoperatory audiometry in predicting postoperative hearing outcomes after primary stapes surgery.

In conclusion, intraoperatory AC PTA predicts with a good approximation postoperative audiometric outcomes of primary stapedoplasty and is a simple, rapid, and cost-effective method for immediate functional assessment.

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