

## Early Audiometric Evaluations May Predict Cochlear Damage After Stapes Surgery

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**OBJECTIVES:** We evaluated early and late improvements in postoperative air-bone gap in patients following stapes surgery and sought correlations between postoperative cochlear symptoms and early postoperative audiometric test results.

**PATIENTS AND METHODS:** Clinical and surgical records of 91 patients (29 men, 62 women; mean age 48 years; range 18 to 82 years) with otosclerosis were reviewed following stapedotomy with the small fenestra technique without interposition. The same Teflon-platinum piston was used in all the patients. Audiometric tests were performed within a week before the operation, 5 to 7 days (early evaluation) and at least three months after surgery (late evaluation). The air-bone gap and air conduction thresholds were measured at 4 and 8 kHz. The presence or absence of cochlear symptoms (tinnitus, fullness) were evaluated with the use of a questionnaire preoperatively and in the early and late postoperative periods.

**RESULTS:** Complete air-bone gap closure or a closure to less than 20 dB were obtained in 65 patients (71.4%) in the early postoperative period, and in 87 patients (95.6%) in the late period ( $p < 0.001$ ). Sensorineural deterioration at 4 kHz was found in 24 patients (26.4%), 21 of whom had an air-bone gap of varying degrees in the early postoperative period. Preoperatively, 66 patients (72.5%) had tinnitus and 30 patients (33.0%) had fullness. Tinnitus disappeared in 26 patients (39.4%,  $p < 0.001$ ) and in eight patients (12.1%,  $p = 0.073$ ), fullness disappeared in eight patients (26.7%,  $p = 0.004$ ) and in nine patients (30%) in the early and late postoperative evaluations, respectively. Newly developed tinnitus and fullness were seen in three patients (3.3%) and in another three patients, respectively. All the patients in whom cochlear symptoms (tinnitus and fullness) disappeared after surgery had either a complete air-bone gap closure or a closure 10 to 20 dB in the early postoperative period, and a complete closure in the late postoperative period. However, none of the patients with newly developed cochlear symptoms exhibited closure in the early postoperative period.

**CONCLUSION:** Early audiometric evaluations can help identify patients at risk for postoperative cochlear symptoms, such as tinnitus, fullness, and sensorineural hearing loss. For these patients, a careful postoperative follow-up including a longer bed rest after surgery may be beneficial.

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Hearing loss caused by otospongiosis usually responds to standardized technical procedures, such as stapedectomy or stapedotomy.<sup>[1]</sup> Otosclerotic patients may also present with other symptoms (tinnitus, high-frequency loss) that arise from the beginning, or develop as the disease progresses. The functional results after surgery for otosclerosis are usually assessed by the improvement in pure tone average (PTA) and air-bone gap (ABG) closure. Although these methods provide reliable data, they sometimes give limited information on the quality of patient's hearing, which may be altered by symptoms that could follow the operation.<sup>[2]</sup> In fact, after surgery, symptoms related to inner ear impairment, such as tinnitus, fullness or high-frequency sensorineural hearing loss that do not exist preoperatively may develop despite a good functional outcome and a symptom-free postoperative course.<sup>[3-5]</sup>

Although the guidelines proposed in 1995 by the American Academy of Otolaryngology-Head and Neck Surgery (AAO-HNS) outline the best method for obtaining uniform data after stapes surgery,<sup>[6]</sup> they offer no precise indications as to the proper timing of the postoperative audiometric evaluation. There is consensus that, to have the first definitive hearing result after stapes surgery, audiograms should be postponed until one month after surgery<sup>[7]</sup> and should be considered stable at the third postoperative month.<sup>[8,9]</sup> In a previous paper, it was shown that hearing results obtained shortly after surgery, i.e. after 3 and 5 days, corresponded fairly well (with no differences) with the final outcome only in a limited percentage of patients.<sup>[10]</sup>

This study was designed to evaluate early and late hearing improvements in postoperative ABG in a group of patients who underwent stapes surgery and had similar patterns of conductive hearing loss. In particular, postoperative cochlear symptoms and correlation of these symptoms with early postoperative audiometric tests were investigated.

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#### PATIENTS AND METHODS

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We reviewed clinical and surgical records of 91 patients (29 men, 62 women; mean age 48 years; range 18 to 82 years) who underwent stapedotomy with the small fenestra technique without interpo-

sition for clinically documented otosclerosis between 1997 and 2002 at the Otolaryngology Clinic of the University "La Sapienza" of Rome. In all surgeries, the same Teflon-platinum piston (Audio Technologies®, Gossolengo-Piacenza, Italy) was used. Particular care was taken to ensure that the tip of the prosthesis went beyond 0.25 mm of the footplate plane. Selection of the patients was made according to the following criteria: primary operation for stapedotomy (revision excluded); pure tone average (PTA) threshold obtained within a week before the operation, 5 to 7 days after surgery (early evaluation), and at least three months after surgery (late evaluation, the time considered suitable for a final hearing result after surgery).<sup>[8]</sup> Data regarding onset, persistence or disappearance of cochlear symptoms (tinnitus, fullness) were reviewed preoperatively and for the two postoperative periods. Conclusive data were collected by a phone interview 90 days postoperatively.

Audiometric tests were performed with an Amplaid 297 audiometer, calibrated according to ISO 389, with headphones TDH-39 and Mx 41 AR cushions. The air-bone gap and air conduction thresholds were measured at 4 and 8 kHz to assess functional outcome. The former was calculated as pure tone threshold averages at 0.5, 1, and 2 kHz. The following audiometric variables were considered: early and late hearing thresholds; the difference between postoperative air conduction and preoperative bone conduction; and pure tone thresholds at 4 and 8 kHz. The patients were assigned to one of the three classes according to early and late postoperative ABG evaluations: class A= ABG <10 dB (ABG closure); class B= 10 to 20 dB; and class C= >20 dB. Sensorineural hearing loss over 4 kHz was defined according to the AAO-HNS classes: class I (< 10 dB), class II (11-20 dB), class III (21-30 dB), and class IV (>30 dB).<sup>[11]</sup> The presence or absence of cochlear symptoms (tinnitus, fullness) were evaluated with the use of a questionnaire during each selected period.

Statistical analyses were made on SPSS 9.0 software for Windows, using the chi-square test, and Fisher's exact test, when necessary. The Friedman test was used to compare repeated measures. Statistical significance was set at  $p < 0.05$ .

The study was conducted in accordance with the ethical standards of the responsible committee on

**Table 1. Air-bone gap measured after postoperative 7 days and 12 weeks**

|                         | Pure tone average   |      |                    |      |
|-------------------------|---------------------|------|--------------------|------|
|                         | Early postoperative |      | Late postoperative |      |
|                         | No. of patients     | %    | No. of patients    | %    |
| Air-bone gap closure    | 26                  | 28.6 | 81                 | 89.0 |
| Air-bone gap (<10 dB)   | 14                  | 15.4 | –                  |      |
| Air-bone gap (10-20 dB) | 25                  | 27.5 | 6                  | 6.6  |
| Air-bone gap (>20 dB)   | 40                  | 40.0 | 4                  | 4.4  |

institutional human experimentation and with the Helsinki Declaration (JAMA 2000;284:3043-3049).

### RESULTS

Of 91 patients who underwent stapes surgery with the small fenestra technique, a closed or <20 dB of ABG was obtained in 65 patients (71.4%) in the early postoperative period, and in 87 patients (95.6%) at least three months after surgery (Friedman test,  $p < 0.001$ ) (Table 1).

Sensorineural deterioration at 4 kHz was found in 24 patients (26.4%): being class I in eight patients (8.8%), class II in nine patients (9.9%), class III in two patients (2.2%), and class IV in five patients (5.5%). Of these 24 patients, 21 had an open ABG in the early postoperative period.

Before surgery, 66 patients (72.5%) had a complaint of tinnitus on the affected side; this symptom disappeared five days after surgery in 26 patients (39.4%,  $p < 0.001$ ) and after 12 weeks in eight patients (12.1%,  $p = 0.073$ ). On the other hand, three patients described tinnitus that developed postoperatively (3.3%,  $p = 0.234$ ); of these, tinnitus was present in two patients in the early postoperative period.

Thirty patients (33.0%) complained of fullness preoperatively. Of these, eight patients (26.7%,  $p = 0.004$ ) and nine patients (30%) became free of this symptom in the early and late postoperative periods, respectively. Three patients (3.3%) experienced newly developed fullness immediately after surgery ( $p = 0.234$ ) (Table 2).

All the patients in whom cochlear symptoms (tinnitus and fullness) disappeared after surgery had an

ABG closure of 10 to 20 dB in the early postoperative evaluations, and a complete ABG closure after three months. However, none of the patients with newly developed cochlear symptoms exhibited ABG closure in the early postoperative period.

### DISCUSSION

Stapes surgery with the small fenestra technique or total stapedectomy generally provide an optimal recovery from the hearing deficit, especially when the treatment takes place at the early stages of the disease, i.e. at a time before bone conduction is compromised.<sup>[12]</sup> In this study, in a group of patients with pure conductive hearing loss of similar degree, stapes surgery with the small fenestra technique without interposition resulted in a complete or <20 dB of ABG closure in a great majority of the patients (95.6%).

In 39.5% of the patients, routine assessments of the auditory function performed 5 to 7 days after surgery failed to detect hearing improvement. However, assessment of the auditory thresholds three months after surgery showed a satisfying surgical outcome, with only 4.4% lacking hearing improvement. These findings are in agreement with those reported in previous studies,<sup>[10]</sup> suggesting that early auditory assessment might indicate, but not reliably predict the definitive successful hearing outcome after stapes surgery.

The results also showed that a significant correlation existed between the persistence of an ABG in early audiometric evaluations and the course of associated cochlear symptoms, such as tinnitus, aural fullness, or high-frequency hearing loss. Indeed, oto-

**Table 2. Course of tinnitus and fullness after postoperative 7 days and 12 weeks**

|          | Preoperative    |      | Early postoperative |      | Late postoperative |      |
|----------|-----------------|------|---------------------|------|--------------------|------|
|          | No. of patients | %    | No. of patients     | %    | No. of patients    | %    |
| Tinnitus | 66              | 72.5 | 40                  | 44.0 | (32+3)=35          | 38.5 |
| Fullness | 30              | 33.0 | 22                  | 24.2 | (13+3)=16          | 17.6 |

spongiosis usually not only causes hearing loss, but it is often associated with other cochlear disorders. In a series of 142 patients who underwent stapes surgery, Aarnisalo et al.<sup>[3]</sup> found no relationship between labyrinthine symptoms (loud noise intolerance, tinnitus) and the surgical technique, and attributed these symptoms to the natural course of the disease. Moreover, the inner ear may also be affected by the pathological process during the natural course of the disease, resulting in sensorineural, high-frequency hearing loss. It is important to note that tinnitus, fullness, or high-frequency hearing loss may also develop after surgery, and in some patients, these symptoms may culminate in such a degree that they may overshadow the actual benefits of a good functional outcome.

All the patients in this study underwent stapedotomy without interposition. According to this technique, restoration of the conductive system is due to the direct contact of the tip of the prosthesis with the perilymphatic fluids which, in order to guarantee a satisfying transmission effect, should involve covering the prosthesis tip with the vestibular endosteum, which at the same time seals the labyrinthine opening. A variable functional behavior was, however, experienced in an early postoperative auditory evaluation, and one may hypothesize that this phenomenon might be associated with individual reactions to minimal differences in a standardized technique, which may end up with a delayed healing process between the labyrinthine fluids and the tip of the prosthesis.

Of note, cochlear symptoms developed only in those patients in whom ABG was more than 10 dB; they never appeared in patients in whom ABG was closed or remained below 10 dB. Furthermore, recovery from symptoms was seen only in patients in whom ABG was less than 10 dB. These findings may suggest that persistence of ABG in the early postoperative period may be associated with an increased likelihood of postoperative clinical sequelae in the form of persistent or newly developed cochlear symptoms during the late postoperative course.

Why these symptoms develop is difficult to explain. Surgical trauma, as well as the existence and the location of the otospongiotic focus – despite a properly performed surgery – could lead to labyrinthine irritation by means of intoxication of the labyrinthine fluids by enzyme release into the vestibule or may result in

induction of a temporary endolymphatic hydrops.<sup>[13]</sup> In addition, introduction of air into the vestibule (pneumolabyrinth) and its delayed reabsorption may play a role in certain cases.<sup>[14]</sup> It is, therefore, reasonable to extrapolate that these complications, which are usually transient, might become permanent unless they are properly treated.

In 26.4% of the patients, sensorineural deterioration at 4 and 8 kHz was detected. This finding suggests that, contrary to what is commonly known,<sup>[15,16]</sup> surgery using the small fenestra technique does not preclude the possibility of high-frequency hearing loss. There was a close correlation between this sensorineural deterioration and incomplete ABG closure detected at early assessments. As a comparison, of 65 patients in whom early audiometric assessments showed ABG closure, this high-frequency loss was detected in only three patients. Thus, early evaluations could help throw more light on patients at risk for developing cochlear symptoms and sensorineural hearing loss. Patients at risk could benefit from a more accurate postoperative care, which may include a longer bed rest and combined use of corticosteroids and vasodilators (e.g. carbogen).

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