Clinical and audiological aspects of stapes surgery otosclerosis

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Chapter 7


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ABSTRACT

This study reports the evaluation of the results of 80 stapedotomies in patients with bilateral otosclerosis. All preoperative and postoperative audiologic data, together with all relevant information of the operations, were stored in a database and analysed retrospectively. A new approach has been developed in order to evaluate the benefit of second ear stapes surgery in a more disability-orientated way using the criteria of the American Medical Association (AMA) in the Guides to the Evaluation of Permanent Impairment. In all patients the percentage of Binaural Hearing Impairment (BHI) and the percentage of Impairment of the Whole Person (IWP) were determined according to the AMA-criteria. In patients who had both operations at the Academic Medical Center it was found after the first operation that there was an important decrease for the BHI-percentage (from 26% to 10%) as well as for the IWP-percentage (from 9% to 4%). In addition, the percentages dropped significantly after the second operation (from 11% to 7% and from 4% to 2%, respectively). During follow-up there were no serious complications. It is concluded that bilateral stapedotomy is a safe procedure with good results.

INTRODUCTION

There is still controversy regarding the decision to perform bilateral stapes surgery in patients with significant bilateral conductive hearing losses due to otosclerosis. There is, of course, a risk of immediate or delayed sensorineural hearing loss (SNHL) which can, very rarely, be bilateral. This problem can occur even many years after the operation. The policy of the Academic Medical Center is to offer a second operation on the contralateral side to patients who had a good result after the first stapes operation without any specific technical problems. Patients are fully counselled about the potential risks of bilateral surgery.

Usually the surgical success has been described with reference to the improvement in air-conduction (AC) thresholds, closure of the air-bone gap (ABG) and achieving socially acceptable hearing in the operated ear. It is well recognised that the patient’s disability is mainly determined by the hearing thresholds in the better hearing ear. However, the patient’s disability is also influenced in a positive way by an improvement of the hearing in the poorer hearing ear after a second stapes operation. To gain a better understanding of the benefits of a second stapes operation the authors determined the percentage of Binaural Hearing Impairment (BHI) and the percentage Impairment of the Whole Person (IWP) according to the international AMA-criteria\(^1\) in order to study the impairment of binaural hearing and the degree of disability caused by the hearing loss before and after stapes surgery. In this way the authors hope to achieve a more disability-orientated method to evaluate the benefit of second side surgery.
SUBJECTS AND METHODS

From 1983 to 1996 80 operations were performed in 44 patients with bilateral otosclerosis at the Academic Medical Center by the second author. Of these 44 patients, 8 had their first stapes operation at another hospital. All clinical information from these first operations was traced. The patient group consisted of 17 men and 27 women with a median age of 33 years (range 12-65) at the time of their first operation. The surgical approach to the middle ear was in all cases transcanal. In all cases the micro-pick technique described by Marquet\(^2\) was used to create a small fenestra in the stapes footplate. During the operation the clinical otosclerosis grade was estimated by the surgeon (according to the grade system of M. Portmann \& Y. Guerrier\(^3\)) and a choice was made of different prostheses depending on the anatomical situation and grade of otosclerosis. Oral antibiotic prophylaxis was given during surgery to all patients.

Conventional air-bone pure tone and speech audiometry was performed before every operation and 2 to 3 months after the operation in all patients who underwent surgery in our hospital. In some patients additional audiological data were available 12 months or more after the second operation. All audiograms were performed by classified personnel according to the ISO 1975 standard.

In order to analyse the percentage BHI according to the Guides to the Evaluation of Permanent Impairment\(^1\) a modification was applied to determine the "Decibel Sum of the Hearing thresholds Levels (DSHL)". Originally the DSHL was determined by totalling the decibel hearing levels at the following frequencies: 0.5, 1, 2 and 3 kHz. Because the AC threshold at 3 kHz is not routinely measured in The Netherlands, we interpolated between 2 kHz and 4 kHz. In this way the MDSHL (Modified DSHL) was determined by totalling the AC thresholds at 0.5, 1, 2 and the mean thresholds at 2 and 4 kHz. The same guide lines from the AMA were used to determine the percentage of monaural hearing loss. To determine the percentage BHI the following formula was used:

\[
\text{binaural hearing loss (\%)} = \left( \frac{(5 \times \% \text{ hearing loss better ear}) + \% \text{ hearing loss worse ear}}{6} \right)
\]

According to the AMA-criteria the IWP index can be derived as different categories of percentage of BHI are corresponding to a certain percentage of IWP. In this way an impairment percentage is intended to represent an informed estimate of the degree to which an individual's capacity to carry out daily activities has been diminished.

All data were stored into a database (Microsoft Access\(^*\)). These data, together with the audiological data, were further analysed using a spreadsheet program (Microsoft Excel\(^*\)).

For statistical analysis the Student \(t\)-test for independent variables was used as well as analysis of variance tests. All tests carried out were two-tailed. \(P\)-values of less than 0.05 were considered as statistically significant.
RESULTS

For analysis of the results the patient population was divided into two cohorts of patients: (1) group A: those who had both operations at the Academic Medical Center (n = 36); and (2) group B: those who had the first operation in another clinic but the second operation in our institution (n=8).

Table 1 shows the data regarding the number of right and left ears, the degree of otosclerosis, the type of prosthesis that has been used, and the mean, minimum, and maximum duration of follow-up in months. The mean time between the operation on the first side and the second side was 27 months (range 7-123) in group A and 34 months (range 11-96) in group B. In group A there were five revision operations in patients who had the first operation elsewhere. Of these five patients three had a poorly fitting prosthesis and this had to be replaced by a new prosthesis. In one patient who was operated elsewhere the attempt to insert a prosthesis was not successful because of a protruding facial nerve. In another patient a mobilisation of the incus/stapes joint was performed without inserting a prosthesis. In both these patients a prosthesis could be placed successfully. In group B there were two patients who had an operation on both ears elsewhere. In one of these two patients a dislocation was found of the prosthesis in one of the ears, while in another patient a prosthesis could not be placed because of unknown technical reasons. A new prosthesis was also placed successfully in these two patients.

Table 1. Data of patient population.

<table>
<thead>
<tr>
<th></th>
<th>First side*</th>
<th>Second side*</th>
<th>Second side**</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>(n = 36)</td>
<td>(n = 36)</td>
<td>(n = 8)</td>
</tr>
<tr>
<td>Affected side</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Left ear</td>
<td>20</td>
<td>16</td>
<td>3</td>
</tr>
<tr>
<td>Right ear</td>
<td>16</td>
<td>20</td>
<td>5</td>
</tr>
<tr>
<td>Degree of otosclerosis</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Grade 1</td>
<td>7</td>
<td>5</td>
<td>-</td>
</tr>
<tr>
<td>Grade 2</td>
<td>12</td>
<td>17</td>
<td>4</td>
</tr>
<tr>
<td>Grade 3</td>
<td>14</td>
<td>13</td>
<td>3</td>
</tr>
<tr>
<td>Grade 4</td>
<td>1</td>
<td>1</td>
<td>-</td>
</tr>
<tr>
<td>Unknown</td>
<td>2</td>
<td>-</td>
<td>1</td>
</tr>
<tr>
<td>Type prosthesis</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Teflon loop 0.4 mm</td>
<td>25</td>
<td>25</td>
<td>3</td>
</tr>
<tr>
<td>Teflon loop 0.3 mm</td>
<td>4</td>
<td>3</td>
<td>2</td>
</tr>
<tr>
<td>Teflon loop 0.6 mm</td>
<td>3</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>K-piston</td>
<td>1</td>
<td>8</td>
<td>3</td>
</tr>
<tr>
<td>Shea cup small</td>
<td>3</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Follow-up in months</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean</td>
<td>52</td>
<td>28</td>
<td>34</td>
</tr>
<tr>
<td>Minimum</td>
<td>15</td>
<td>6</td>
<td>6</td>
</tr>
<tr>
<td>Maximum</td>
<td>147</td>
<td>99</td>
<td>63</td>
</tr>
</tbody>
</table>

* = Group A patients (who had both operations at our institution; ** = Group B patients (who had their first operation elsewhere).
In the group of patients who had both operations in our clinic (group A) the state of otosclerosis was known for both operations. There were no clear differences in the grade of otosclerosis between the first and the second operation. First operation: average grade 2.26; SD 0.8; second operation: average grade 2.27; SD 0.7 (grade 2: small focus of ankylosis; grade 3: large focus of ankylosis, ≥ 50% of footplate).

Of all the evaluated patients it was necessary to perform revision surgery 7 months after the operation on the second side in one patient from group A because of persistent conductive hearing loss which occurred 5 months after operation. During the revision operation there was a dislocation of a golden K-piston which apparently was bent due to many adhesions in an ear with active otosclerosis. A 0.4 mm Teflon piston was placed successfully and this resulted in a clear improvement in hearing. During evaluation of the audiological data for this patient only the pre- and postoperative audiograms from the second operation in which a golden K-piston was placed were taken into account and not the pre- and postoperative audiograms of the revision operation.

For evaluation of the audiological data the hearing losses were averaged. In patients from group B, who had their first operation elsewhere, the pre- and postoperative audiograms were not complete. All patients in group A had an audiogram more than 1 year after the operation on the first side (often this was the preoperative audiogram of the operation on the second side), while in 11 patients audiological data were present more than 1 year after the operation on the second side. The mean time of these audiograms after the first and second operation in group A was 38 months (range 12-144) and 21 months (range 12-82), respectively. In group B there were 6 patients whose audiological data was available more
than 1 year after the operation on the second side. The mean time of these audiograms after the second operation was 23 months (range 14-63).

Figure 1 gives the results of the mean AC thresholds at 0.5, 1 and 2 kHz (PTA) pre- and postoperatively and at least 1 year after the operation on the second side. There was no serious SNHL (dead ear) in either group A or group B and there was no decline in speech discrimination. However, in one of the patients in group A, there was a SNHL of 25 dB directly after the revision operation. Postoperatively the ABG was closed from 42 to 5 dB and the mean AC thresholds at 0.5, 1, and 2 kHz (PTA) in this patient improved from 55 to 42 dB. No patients suffered from persistent vertigo.

Table 2 shows the results with regard to the ABG closure. In group A a closed ABG (conductive component of less than 10 dB) was achieved in 86.1% (31/36) after the first operation and in 80.5% (29/36) after the second operation. In group B this result was achieved in 62.5% (5/8). After more than 1 year of follow-up a closed ABG was retained in 83.3% (30/36) after the first operation and in 72.7% (8/11) after the second operation in group A, while in group B this was in 66.6% (4/6).

After the first operation 80.5% of patients (29/36) had normal hearing (defined as mean AC thresholds at the frequencies 0.5, 1, and 2 kHz of ≤ 30 dB) on the operated side, and after the second operation this was also true of 80.5% (29/36) in the contralateral ear in group A. After bilateral stapedotomy socially acceptable hearing in both ears was achieved in 75% (27/36) of the patients in group A. In group B, 87.5% (7/8) had normal hearing after the operation on the second side, while 75% (6/8) had socially acceptable on both sides.

<table>
<thead>
<tr>
<th>Air-bone gap (dB)</th>
<th>First side*</th>
<th>Second side*</th>
<th>Second side**</th>
</tr>
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<tbody>
<tr>
<td></td>
<td>pre (n=36)</td>
<td>post (n=36)</td>
<td>&gt;1 year (n=36)</td>
</tr>
<tr>
<td>0-10</td>
<td>-</td>
<td>31</td>
<td>30</td>
</tr>
<tr>
<td>11-20</td>
<td>4</td>
<td>4</td>
<td>6</td>
</tr>
<tr>
<td>21-30</td>
<td>14</td>
<td>1</td>
<td>-</td>
</tr>
<tr>
<td>31-40</td>
<td>12</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>41-50</td>
<td>5</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>51-60</td>
<td>1</td>
<td>-</td>
<td>-</td>
</tr>
</tbody>
</table>

* = Group A patients (who had both operations at our institution); ** = Group B patients (who had their first operation elsewhere).

In all patients the percentage BHI and the percentage IWP according to the AMA criteria could be determined before and after the operation. Figure 2 shows the reduction of the mean percentages of BHI and IWP at different times during follow-up. There was an obvious reduction in both BHI and IWP after the first operation in group A (from 26% to 10% and from 9% to 3%, respectively). These differences were highly significant ($p < 0.001$ for BHI and $p < 0.01$ for IWP; 2-tailed Student $t$-test). Between the first and second operations the
Bilateral Stapedotomy in Patients with Otosclerosis

BHI and IWP increased slightly (differences were not significant). After the second operation there was a further decline in both BHI and IWP (from 11% to 5% and from 4% to 2%, respectively). These differences were also significant for both parameters ($p < 0.05$). The same percentages increased slightly at the time of audiometry more than 12 months after the second operation in group A (differences not significant). Also in group B there was a clear reduction of both BHI and IWP after the second operation (from 17% to 9% and from 6% to 3%, respectively). These differences were, however, not significant.

Fig. 2. Percentages Binaural Hearing Impairment (BHI) and Impairment of the Whole Person (IWP) according to the AMA criteria.

** = $p < 0.001$; *** = $p < 0.01$; * = $p < 0.05$ (two-tailed Student t-test).

DISCUSSION

It is important that the surgeon be aware of his individual results so that he can obtain truly informed consent to the patient especially when he considers a procedure in which serious complications can occur. The purpose of this study was the evaluation of the results in patients after bilateral stapes surgery. On both sides there was an obvious hearing improvement in every frequency except 8000 Hz. This improvement of the hearing was also measured greater than one year postoperatively for the same frequencies in both ears.

Whether one should offer a second operation to patients with bilateral otosclerosis remains a point of discussion. There is a risk of immediate or delayed SNHL, which in the case of bilateral surgery can occur at both sides. Vestibular damage can also occur with permanent loss of balance. The advantages of bilateral stapes surgery, if it is successful, are the improvement of binaural hearing and consequently the ability to localise the direction from which sound is coming. Different publications on this subject are in favour of$^{7,11,12}$ or
against, the policy of performing a second stapes operation. Zeittoun et al. established by a questionnaire that 41% of British consultants perform bilateral stapes operations, while 58% do not. Many surgeons, especially those who do not specialise in the surgical treatment of otosclerosis, feel that the patient should be allowed the safeguard of being able to wear a hearing aid in the second ear if necessary.

Socially acceptable hearing after stapes surgery depends of course on the preoperative cochlear hearing loss which can be severe in otosclerosis. It is therefore clear that in these cases of severe cochlear hearing loss even a technically perfect operation can appear unimpressive in outcome. Nevertheless 75% of our patients achieved socially acceptable hearing in both operated ears. This means that these patients have more symmetrical hearing which also improves the directional hearing ability. Porter et al. described in a series of bilateral operated patients in whom 35% had a BC threshold above 30 dB which resulted in 65% socially acceptable hearing in both operated ears. These patients achieved a so-called category “a” result according to the criteria of the Glasgow Benefit Plot (category “a” result means socially acceptable hearing defined as an AC threshold of ≤ 30 dB in both ears).

The AMA-criteria are widely used by law in worker’s compensation cases. The growing emphasis on worker’s compensation claims and litigation makes it important to use more objective criteria to establish the degree of impairment. Disability in this way is defined as an alteration of an individual’s capacity to meet personal, social or occupational demands because of an impairment of a human organ system. Even though rating or estimating impairments cannot be totally objective, use of the “Guides to the Evaluation of Permanent Impairment” from the AMA increases objectivity and enables physicians to evaluate and report medical impairment in a standardised manner, so that reports from different observers are more likely to be comparable in content and completeness.

The BHI and the degree of disability due to the hearing loss (IWP) declined significantly after the first operation in patients who had both operations in our hospital. The benefit of a second stapes operation appears from a further statistical significant decline of both the BHI and the degree of disability. Because it was not possible to determine the DSHL in all patients a modified DSHL (MDSHL) was calculated as an alternative by taking the mean AC thresholds at the frequencies 2000 and 4000 Hz in to account instead of the threshold at 3000 Hz. There were no statistical differences (2 tailed Student-t test) if the AC threshold at 4000 Hz had been taken into account to determine the MDSHL in stead of the mean thresholds at 2000 and 4000 Hz at any measured point during follow-up in figure 2. Our approach of data analysis is a useful method to gain a better impression of the patients benefit after such a procedure of bilateral surgery.

During the follow-up period it was necessary to do revision surgery in one patient out of a total of eighty operations and it appeared that there was a dislocated prosthesis which had to be replaced (see results). During the same follow-up period there were no perilymph fistulas or serious SNHL (dead ears).

The results from this study justify our policy of offering a second operation to patients with bilateral otosclerosis. It appears that this procedure improves the chance of achieving normal and symmetrical hearing and that patients who had a good result from the first opera-
tion almost always may expect a good result from their second operation. An important factor in achieving good results is extensive surgical experience in performing stapes surgery and therefore we think that some centralisation of these operations is appropriate.

REFERENCES

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