The Bone-Anchored Hearing Aid

Quality-of-Life Assessment

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Objectives: To assess the impact of a bone-anchored hearing aid (BAHA) on the quality of life (QOL) of adults and to test the hypothesis that a BAHA improves QOL because otorrhea and/or skin irritations decrease.

Design: Prospective postal-based questionnaire study using validated health-related QOL instruments, combined with hearing-aid–related questions.

Patients and Methods: The study included 56 consecutive adult patients with acquired conductive or mixed hearing loss who were scheduled for BAHA implantation at the University Medical Centre Nijmegen, Nijmegen, the Netherlands. All 56 patients completed the 36-Item Short-Form Health Survey (SF-36), the EuroQol-5D (EQ-5D), and the Hearing Handicap and Disability Inventory (HHDI); 36 patients had been using an air-conduction hearing aid (ACHA) and 20 patients a conventional bone-conduction hearing aid (CBHA). Questionnaires were filled out before surgery and after 6 months of experience with the BAHA.

Results: In the SF-36 group, there was significant improvement in the scores of the mental health domain (P = .02). When the SF-36 patients were classified according to previous hearing aid, there was no statistically significant change in the scores in any of the domains. In the EQ-5D group and in its ACHA and CBHA subgroups, there were no important differences in the results before and after the patients received their BAHAs. In the HHDI group, the handicap and disability scales showed significant improvement (P < .01) irrespective of the type of previously worn hearing aid.

Conclusions: Overall, generic health-related QOL was not influenced significantly by the use of a BAHA according to the SF-36 and the EQ-5D. The more disease-specific scales (HHDI) did show improved QOL with a BAHA.

Arch Otolaryngol Head Neck Surg. 2004;130:394-399

Several clinical studies have evaluated surgical and audiometric outcomes with the bone-anchored hearing aid (BAHA). It has been shown that the percutaneous coupling of the BAHA to the skull is safe and stable over time. Furthermore, these studies have consistently shown that the audiological results are superior to those obtained with conventional bone conductors and, although less convincingly, with air-conduction hearing aids (ACHAs).

Because a surgical procedure is involved, and the financial costs are relatively high, it seems more important to evaluate subjective appraisals in studies in which conventional hearing aids were replaced with a BAHA. Most studies that reported subjective assessments of patients fitted with a BAHA used questionnaires with items concerning the patient’s attitude toward the new hearing aid itself or the patient’s performance in various listening situations and conditions. The questionnaires compared the BAHA with conventional hearing aids, and, again, the results favored the use of the BAHA.

The importance of patient outcome research is becoming increasingly recognized, and a number of recent studies have focused on quality-of-life (QOL) issues. Instruments used to obtain outcome measurement after hearing aid fitting vary in length and internal structure. Use of an appropriate instrument is essential to obtain valid and clinically meaningful measurement of outcome. Frequently used instruments quantify disability and handicap as well as benefit and health status. In most studies, a significant reduction in hearing disability and handicap was noted, while Dutt et al and other authors reported improved QOL. All data collection in these studies can be
classified as retrospective, as measurements were only performed after implantation of the BAHA.

The aim of this prospective postal-based questionnaire study was to quantify the impact of hearing rehabilitation with a BAHA on the QOL of adults; 3 different validated instruments were used. The patients answered questions about their QOL with their previous hearing aid (before BAHA) and after 6 months of experience with their new BAHA (after BAHA).

As ACHAs or conventional bone-conduction hearing aids (CBHAs) can be contraindicated because of persistent otorrhea or severe skin irritations caused by the transducer pressing against the skin of the temporal bone, we also tested the hypothesis that a BAHA improves QOL if otorrhea and/or skin irritations decrease. Patients were therefore asked about the prevalence and, if present, the frequency of these hearing-aid–related complaints.

**METHODS**

**PATIENT GROUPS**

Fifty-six consecutive adult patients with acquired conductive or mixed hearing loss and listed for BAHA surgery participated in this prospective questionnaire study. The mean age (and age range) of the patients at implantation and the mean air- and bone-conduction thresholds are listed in Table 1.

Most patients (n=51) received a BAHA Classic (Entific Medical Systems, Go¨teborg, Sweden), while a small proportion (n=5) were fitted with a BAHA Cordelle (a more powerful BAHA with a body-worn amplifier) (Entific Medical Systems) because of their sensorineural hearing loss. Carlsson and Hakanssøn12 have shown that, theoretically, it is possible to virtually close the air-bone gap with the BAHA Classic. Also, it is possible to compensate 15 to 20 dB of the sensorineural hearing loss component with the more powerful BAHA Cordelle. As part of the regular evaluation procedure, aided sound-field measurements were performed to see whether these theoretical targets were met. This criterion was fulfilled within 10 dB (at 1, 2, and 4 kHz) in all 56 patients, so the fitting of the BAHAs was considered adequate.

All patients had been using hearing aids before implantation: 36 of the 56 patients had been using an ACHA, and 20 had been using a CBHA. Table 1 shows that hearing loss was somewhat more profound in the CBHA group than in the ACHA group. The audiometric data listed in Table 1 refer to the ear ipsilateral to the side of implantation, which was always the ear with the best cochlear reserve.

**QOL INSTRUMENTS**

Generic QOL (or health status) instruments measure basic concepts (eg, psychological, physical, and social functioning) that are always relevant to health status. Generic instruments are not disease specific and thus enable comparison of health status across the borders of any specific diseases. For this study, we selected the self-report 36-Item Short-Form Health Survey (SF-36) and the self-report EuroQol-3D (EQ-5D), both of which seem capable of measuring health-related QOL.13 As a more disease-specific instrument, we selected the Hearing Handicap and Disability Index (HHDI).

Patients were asked to fill out these instruments on 2 occasions: (1) with their previous hearing aid before surgery and (2) after 6 months of experience with the BAHA. The SF-36 was developed in the United States from the Medical Outcome Study General Health Survey Instrument.14 The SF-36 consists of 36 items with the following domains: physical functioning, role limitations (physical problems), role limitations (emotional problems), vitality, mental health, social functioning, pain, and general health perception. The number of response categories per item ranges from 2 to 6; better functioning leads to a higher score on a specific item. The end score is an 8-dimensional profile. The Dutch version used in this study was developed to translate, validate, and normalize the self-report SF-36 in a range of languages and cultural settings.15 The self-report SF-36 is an internally consistent and valid measure of health status.16-18

The EQ-5D is a generic health-related QOL instrument that consists of 5 domains: mobility, self-care, usual activities, pain/discomfort, and anxiety/depression.16 Three response alternatives are available for each domain (1, no problems; 2, some problems; and 3, severe problems). The EQ-5D utility index is obtained by applying predetermined weights to the 5 domains. This EQ-5D utility index ranges from 0 (worse than death) to 1 (perfect health status) and is a societal-based numerical quantification of a patient’s health status. The EQ-5D instrument has been developed specifically to generate a generic cardinal index of health, thus giving it considerable potential for use in health care evaluation.16 Also, patients were asked to rate their own state of health on an EQ-5D visual analogue scale (VAS), made up of a vertical line ranging from 0 (worst imaginable state of health) to 100 (best imaginable state of health). The EQ-5D VAS appears to have good test-retest reliability, is easily self-administered, and has been standardized for use in the Netherlands.13,20

Because the SF-36 and the EQ-5D are generic instruments, they need to be supplemented with a disease-specific QOL questionnaire. Therefore, we appended the HHIDI (a hearing handicap inventory for the elderly) to establish an inventory for hearing handicap and hearing disability.11 Hearing handicap refers to disadvantages imposed by impairment or limitations on an individual’s psychological or social functioning. The short version of the HHIDI deals with 3 items: emotional response, social withdrawal, and reactions of others.11 Therefore, these questions represent the nonauditory problems that are caused by hearing impairment or disability and are tailored to investigate the degree of hearing disability. The Dutch equivalent inventory, which has equal validity, internal consistency, and reliability, was used in our study.24

In the case of missing data, aggregated domains were not computed (at most, this reduced the overall number of patients from 56 to 51). To avoid “enthusiasm bias” or bias that could be caused by possible initial problems with the fitting of

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**Table 1.** Characteristics of the Patients Classified According to Previous Hearing Aid*  

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Group</th>
<th>N = 56</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, y</td>
<td>ACHA</td>
<td>47.9 (24-73)</td>
</tr>
<tr>
<td>Sex, % male</td>
<td></td>
<td>33</td>
</tr>
<tr>
<td>Hearing loss</td>
<td></td>
<td>63.2 (30-103)</td>
</tr>
<tr>
<td>(0.5, 1, and 2 kHz, dB HL)</td>
<td></td>
<td>26.8 (9-51)</td>
</tr>
<tr>
<td>Air-bone gap, dB</td>
<td></td>
<td>36.4 (16-60)</td>
</tr>
</tbody>
</table>

Abbreviations: AC, air conduction; ACHA, AC hearing aid; BC, bone conduction; CBHA, conventional BC hearing aid; HL, hearing level.

*Values are expressed as mean (range) unless otherwise indicated.

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the implant, the questionnaires were filled out again after the patients had 6 months of experience with the BAHA.

The patients were asked to answer several hearing-aid-related questions to gain insight into the number of hours of daily BAHA use and the number of visits to an otolaryngologist because of otorrhea or skin irritations. They were also asked about the frequency of episodes of otorrhea and about the prevalence of skin irritations with their conventional hearing aid and with the BAHA.

ANALYSIS

The Wilcoxon test was used to compare the results of the ACHA with those of the CBHA group (data in nonparametric scales) for statistical analyses. Difference scores, which were used to compare presurgery and postfitting results, were analyzed with the t test; \( P<.05 \) was chosen as the level of significance. However, calculating statistical significance is highly dependent on the sample size and does not reflect the clinical relevance of measured differences. Thus, besides difference scores, effect sizes were estimated. Effect sizes are standardized measures and are therefore appropriate to assess the magnitude of changes in health-related QOL.25 The effect size shows the absolute clinical effect of the difference between the previous hearing aid and the BAHA on a certain question, irrespective of the number of patients. A small effect is given by an effect size of 0.2 to 0.5, a moderate effect by an effect size of 0.5 to 0.8, and a large effect by an effect size of more than 0.8. The effect can be negative or positive.25 The results were computed using an SPSS software package (Version 10; SPSS Inc, Chicago, Ill). The results of the total study group were used to construct box and whisker plots: the whiskers show the standard error of the mean. To answer the question about the possible influence of the previous hearing aid on outcome measures with the BAHA, we separately analyzed the results for the whole group (irrespective of their previous hearing aid) and for the patients with the 2 different types of previous hearing aids. The likelihood of limitations due to ceiling effects was low, as none of the subscales had a mean score that approached the extremes of the response range in any of the 3 response instruments.

RESULTS

SF-36 SCORES

In the total group, there was very little difference in any of the domains. Only the scores in the mental health domain improved significantly (\( P=.02 \)). However, the effect size was small (−0.30). A slight, statistically nonsignificant improvement was seen in the social functioning and pain domains (\( P=.30 \)), and a very small improvement was seen in the vitality domain. Slight deterioration was seen in the physical functioning, role limitations (physical and emotional problems), and general health perception domains (Figure 1).

Differences in the ACHA group were smaller than those in the CBHA group; there were no statistically significant changes in any of the domains. In the CBHA group, role limitations (emotional) deteriorated after implantation of the BAHA, which means that these patients seem to spending less time on work or daily habits as a result of (increased) emotional problems. However, the change was not significant (\( P=.19 \)). The scores on the pain domain were also slightly lower (\( P=.30 \)), which means that patients were experiencing slightly more pain. Effect sizes showed that the clinical effect was small in all SF-36 domains. Table 2 gives an overview of all these changes, classified according to previous hearing aid.

EQ-5D SCORES

There were no important differences between the presurgery and postfitting results in the EQ-5D group. In the group as a whole, the patients’ scores on the mobility, pain/discomfort, and anxiety/depression domains were slightly poorer after implantation of the BAHA. The total
group showed a small, nonsignificant increase in scores on the other domains (Figure 2).

The ACHA group showed slightly increased scores on the mobility and anxiety/depression domains, which means that these patients were slightly less mobile and much more anxious/depressed after implantation. Anxiety/depression increased significantly in this specific group (P < .01), but the effect size (−0.30) (eg, the clinical effect of increased anxiety/depression) was small. The slight decrease in the scores on the usual activities and pain/discomfort domains showed that patients were doing somewhat better (P > .05). In the CBHA group, there was a small improvement on the self-care, usual activities, and anxiety/depression domains. This means that these patients were less anxious/depressed, although this difference was not statistically significant (P > .05). The scores on the mobility and pain/discomfort domains were increased (P = .26), which means that the patients were slightly less mobile and experienced more pain/discomfort. The effect size for all of these domains was small (<0.30). Table 3 gives an overview of the changes, classified according to previous hearing aid.

Scores on the EQ-5D VAS did not change significantly after implantation. Before surgery, the total group scored 74 on the EQ-5 VAS compared with a score of 73 six months after implantation. Both of these scores were lower than the general population mean of 82.5.20

HHDi Scores

Figure 3 shows significant improvement (P < .01) not only on the disability scale but also on the handicap scale.

Several studies1-4 have reported patients' opinions on the BAHA, as it is becoming increasingly acknowledged that the benefits of the BAHA extend beyond the boundaries of audiological tests. In general, patient outcome research has consisted of questionnaire studies involving domains dealing with hearing, sound quality, comfort, cosmetic appearance, practical arrangement, and utilization time (ie, the amount of time hearing aids are turned on). Either the patients were asked about hearing aid preference or they had to rate a specific hearing aid on a numerical scale. Mostly, questionnaires were administered after the patient had been using the BAHA for a while. Reference data consisted of the patients' opinions about their previous hearing aid. Most studies reported that the patients considered their BAHA to be an im-

TABLE 3. Scores of the Total Group of Patients Classified According to Previous Hearing Aid on the 5 Domains of the EuroQol-5D, EuroQol-5D Utility Index, and EuroQol-5D Visual Analogue Scale Before and After Receiving a Bone-Anchored Hearing Aid (BAHA)

<table>
<thead>
<tr>
<th>Domain</th>
<th>ACHA* After BAHA</th>
<th>CBHA* After BAHA</th>
<th>Mean Differences</th>
<th>Effect Size</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mobility</td>
<td>1.29 (0.46)</td>
<td>1.31 (0.47)</td>
<td>1.35 (0.49)</td>
<td>1.50 (0.51)</td>
</tr>
<tr>
<td>Self-care</td>
<td>1.03 (0.17)</td>
<td>1.03 (0.17)</td>
<td>1.20 (0.41)</td>
<td>1.10 (0.31)</td>
</tr>
<tr>
<td>Usual activities</td>
<td>1.47 (0.66)</td>
<td>1.44 (0.50)</td>
<td>1.60 (0.68)</td>
<td>1.55 (0.60)</td>
</tr>
<tr>
<td>Pain/discomfort</td>
<td>1.49 (0.51)</td>
<td>1.47 (0.51)</td>
<td>1.70 (0.57)</td>
<td>1.85 (0.49)</td>
</tr>
<tr>
<td>Anxiety/depression</td>
<td>1.26 (0.44)</td>
<td>1.42 (0.60)</td>
<td>1.26 (0.45)</td>
<td>1.20 (0.41)</td>
</tr>
<tr>
<td>Utility</td>
<td>0.79 (0.17)</td>
<td>0.77 (0.17)</td>
<td>0.71 (0.23)</td>
<td>0.70 (0.19)</td>
</tr>
<tr>
<td>Visual analogue scale</td>
<td>76.1 (14.1)</td>
<td>73.4 (17.1)</td>
<td>74.0 (16.0)</td>
<td>72.4 (17.4)</td>
</tr>
</tbody>
</table>

Abbreviations: See Table 1.
*Values are expressed as mean (SD).
†P < .01.

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improvement with regard to speech recognition, quality of sound, and user comfort.\textsuperscript{5,6,7} On a numerical scale, the improvement in speech recognition in quiet and in noise was statistically significant and agreed with the audiological results.\textsuperscript{3} Two smaller studies\textsuperscript{28,29} reported a statistically significant improvement in questionnaire results with the BAHA compared with the CBHA, a finding that was not reflected by the results on speech discrimination tests. In patients who changed from an ACHA to the BAHA, the reduction of ear infections was a clear improvement in some studies.\textsuperscript{5,27} In other studies, the majority of patients reported subjective improvement with the BAHA, irrespective of the type of hearing aid they had previously been using.\textsuperscript{6,8}

The studies mentioned above discussed satisfaction with, and/or the performance of, the BAHA in comparison with a previous hearing aid in different situations. However, performance measures cannot adequately characterize the actual impact on a patient's well being. Therefore, questionnaires have been developed to characterize health status and any changes after intervention. Recent articles\textsuperscript{9-11} on QOL have made use of the Glasgow Benefit Inventory. This validated, generic, health-related QOL inventory is a patient-orientated questionnaire that is designed for measuring outcomes after an otorhinolaryngological intervention. These retrospective studies found significant improvement in the patients’ QOL after they received a BAHA, an improvement that is comparable to the result obtained with middle ear surgery.\textsuperscript{11} However, the Glasgow Benefit Inventory is a measure of patient benefit and not of health status per se.\textsuperscript{10}

In our study, the possible gain in health-related QOL was assessed by comparing a baseline measurement taken before surgery to a follow-up measurement taken 6 months after implantation. The SF-36 and the EQ-5D were directly related to the BAHA. The scores improved considerably only on the mental health domain of the SF-36 health survey, but this effect disappeared when the patients were classified into groups according to their previous hearing aid. On the EQ-5D, scores on the anxiety/depression domain deteriorated significantly in the ACHA group (P=.01), which means that these patients had become more anxious/depressed after receiving a BAHA. However, the effect size (ie, the clinical effect) was small (−0.30).

It has been suggested that general (age-related) satisfaction with life is independent of satisfaction with hearing.\textsuperscript{30} Other more recent studies, however, have found good reason to believe that hearing aids do improve QOL.\textsuperscript{9,11,31} It can therefore be hypothesized that the currently available general health status instruments lack the appropriate sensitivity to assess the gain in health-related QOL as a result of an alteration in hearing aids\textsuperscript{31,32} or that the change in general health status is too small for them to detect. Considering the significant effect of cochlear implantation on the general health of previously deaf persons,\textsuperscript{33} it may be argued that just changing from one hearing aid to another (ie, from a conventional hearing aid to a BAHA) does not have a great impact. This theory was possibly reflected by the observation within our study that the EQ-5 VAS did not show a statistically significant change between the presurgery and postfitting measurements.

In contrast, the more disease-specific HHDI reflected that the alteration of hearing aids did have a significantly positive effect, irrespective of the type of previous hearing aid; eg, the patients had to consult their otolaryngologist much less frequently after receiving a BAHA. The ACHA group demonstrated overall improvement with regard to hearing aid–related questions, especially in regard to the frequency of otorrhea, while the CBHA group also showed overall improvement, particularly in the prevalence of skin irritations. Because all 56 patients reported that they were using their BAHA for 8 or more hours a day, it can be assumed that these effects were directly related to the BAHA.

According to the outcome measures used in this study, the general health status of the patients did not change significantly after they received a BAHA. However, a hearing-specific QOL instrument showed significant improvement not only in disability but also in handicap (P<.01). Furthermore, the hearing-aid-related questions showed that all our patients were using their BAHA for at least 8 hours a day and that the number of visits to their otolaryngologist had decreased. These findings are helpful in our preoperative counseling and encourage the con-

![Figure 3. Mean (SEM) scores of the total group of patients on the 2 domains of the Hearing Handicap and Disability Inventory before and after implantation of a bone-anchored hearing aid (BAHA).](image)

<table>
<thead>
<tr>
<th>Table 4. Scores of the Total Group of Patients Classified According to Previous Hearing Aid on the Hearing Handicap and Disability Inventory Before and After Receiving a Bone-Anchored Hearing Aid (BAHA)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>ACHA</strong>\textsuperscript{*}</td>
</tr>
<tr>
<td><strong>Disability</strong></td>
</tr>
<tr>
<td><strong>Before BAHA</strong></td>
</tr>
<tr>
<td><strong>Handicap</strong></td>
</tr>
</tbody>
</table>

Abbreviations: See Table 1.
\textsuperscript{*}Values are expressed as mean (SD).
\textsuperscript{†}P<.01.
Table 5. Number of Otolaryngology Visits by Patients Classified According to Previous Hearing Aid Before and After Receiving Bone-Anchored Hearing Aid (BAHA)

<table>
<thead>
<tr>
<th>Group</th>
<th>No. of Patients</th>
<th>No. of Visits, Mean (SD)</th>
<th>Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACHA</td>
<td>Before BAHA</td>
<td>32</td>
<td>12.7 (10.5)</td>
</tr>
<tr>
<td></td>
<td>After BAHA</td>
<td>33</td>
<td>3.3 (4.8)</td>
</tr>
<tr>
<td>CBHA</td>
<td>Before BAHA</td>
<td>19</td>
<td>5.4 (4.9)</td>
</tr>
<tr>
<td></td>
<td>After BAHA</td>
<td>20</td>
<td>1.5 (2.1)</td>
</tr>
<tr>
<td>Total</td>
<td>Before BAHA</td>
<td>51</td>
<td>9.96 (9.5)</td>
</tr>
<tr>
<td></td>
<td>After BAHA</td>
<td>53</td>
<td>2.66 (4.1)</td>
</tr>
</tbody>
</table>

Abbreviations: See Table 1.

Figure 4. Number of patients who preferred the bone-anchored hearing aid (BAHA) or their previous hearing aid (left, air-conduction hearing aid [ACHA]; right, conventional bone-conduction hearing aid [CBHA]) in regard to otorrhea and skin irritations. The number of patients who experienced no difference is not shown.