Estimated Cost-effectiveness of Active Middle-Ear Implantation in Hearing-Impaired Patients With Severe External Otitis

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Objective: To determine the cost-effectiveness of middle-ear implantations in hearing-impaired patients with severe external otitis in the Netherlands.

Design: Cost-effectiveness analysis, using single-subject repeated measures of quality of life and total cost determinations.

Setting: Hospital based.

Patients: Moderately to severely sensorineurally hearing-impaired patients (n=21) with severe chronic external otitis, eligible to receive a middle-ear implant.

Main Outcome Measure: Cost per quality-adjusted life-year (QALY), based on scores of the Medical Outcomes Study Short-Form Health Survey (SF-36) generic quality of life questionnaire. Only direct costs were included in cost calculation of middle-ear implantation.

Results: Mean health utility gain was 0.046 (0.012-0.079) (P=.01) measured at the mental component of the SF-36. With a mean profitable time of 19.4 years and an overall cost of €14 354, minimal cost-effectiveness of middle-ear implantation was €16 085/QALY.

Conclusion: Based on the cost per QALY, middle-ear implantation proved to be a cost-effective and justified health care intervention in the Netherlands.

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In patients with moderate to severe sensorineural hearing loss, conventional hearing aid fitting may be troublesome owing to chronic external otitis. Although some patients benefit from vented or silver- or gold-coated ear molds, others continue to experience pain or itching when the ear canal is occluded, which leads to nonuse of the hearing aid. In these patients, the electronic middle-ear implant may form a solution, because the device does not block the ear canal. At present, 2 types of middle-ear implants are commercially available: the Vibrant Soundbridge (Med-El, Innsbruck, Austria)1-3 and the Otologics MET device (Otologics LLC, Boulder, Colo).4-6

Compared with conventional hearing aids, the application of the middle-ear implant involves surgery and higher financial cost, which has led to health care policy questions regarding treatment effectiveness and cost-benefit analyses. Cost-effectiveness of a treatment can be determined by combining the qualitative and quantitative health benefit with the cost of the treatment.

To assess the health benefit of a medical intervention, generic health-related quality of life (HR-QOL) instruments are often used. These questionnaires are not disease specific and can therefore be applied to areas not directly affected by a specific disorder. Improvement in quality of life (QOL), also called health utility gain, is expressed on a linear scale from 0.00 (death) to 1.00 (perfect health).7 Unfortunately, several studies have shown only small changes in generic HR-QOL questionnaire scores after hearing aid fitting.8 An example is the general Medical Outcomes Study Short-Form Health Survey (SF-36) questionnaire that assesses various aspects from physical as well as mental health.9,10 Although various studies assessing the benefit of hearing aid fitting showed marginally better mental health status, no improvements were noted, and sometimes negative changes were seen in some aspects of physical health, for example physical functioning and bodily pain.10,12 This is not in accordance with the results of disability and handicap-specific questionnaires that have shown significant improvements in hearing aid

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benefit in hearing-impaired subjects. It has been concluded that a major problem with generic HR-QOL questionnaires is their insensitivity to problems concerning audition and communication. Barton et al reported low benefit scores but marked differences between the outcomes of 3 different HR-QOL instruments, which indicates that cost-effectiveness depends on the questionnaire used. The BAHA system (bone-anchored hearing aid), a semi-implantable bone-conduction device, was not found to have any significant effect on QOL when generic instruments were used, whereas disability-specific questionnaires showed significant improvements. In contrast, significant changes in HR-QOL questionnaires were reported in postlingually deafened adults after cochlear implantation. The relative insensitivity of existing HR-QOL questionnaires to audition and communication problems has led to the development of several new instruments to assess health benefit after hearing aid fitting. The Glasgow Benefit Inventory (GBI) is an HR-QOL questionnaire that was specially developed to measure outcomes of otolaryngologic interventions. It examines how the health status of the patient has been affected by the intervention, including psychological, social, and physical well-being. The GBI has been used successfully to evaluate the Vibrant Soundbridge, the BAHA system, and recently, cochlear implants in a large population of recipients. The Nijmegen Cochlear Implant Questionnaire (NCIQ) is an HR-QOL questionnaire that was specially developed to assess health status after cochlear implantation. It comprises questions in communicative, psychological, and social domains. Although the NCIQ has not yet been used widely, it has proven to be reliable and sensitive to clinical changes.

Up to now, none of the HR-QOL questionnaires has received a general recommendation. Therefore, it remains advisable to use several instruments in parallel to determine postintervention health status.

After the health utility gain has been determined, the number of quality-adjusted life-years (QALYs) can be calculated. A QALY is designed to aggregate the total health improvement in a group of individuals, while capturing improvements in QOL (health utility) and quantity of life. It is calculated by multiplying the life expectancy after the intervention (years) by the health utility gain due to that intervention. However, the assumption that a subject will benefit from the intervention until death is unrealistic in case of middle-ear implant application. In any subject, hearing can be expected to deteriorate with age, which makes every hearing aid less effective and eventually ineffective at some stage in life. Therefore, life expectancy after the intervention should be replaced by profitable years, ie, the number of years of effective middle-ear implant use.

In the United States, England, and Canada, health interventions with a cost-utility ratio of less than about $10,553/QALY are considered to be acceptable cost-effective. This (the assumed US exchange rate, as of October 10, 2005, for determination of this figure was $1.00=€0.825929.) is comparable with the ratios of €18.150/QALY and €20,000/QALY calculated in the Netherlands. One exception is the British Cochlear Implant Study Group who use an upper limit of acceptability of £50,000/QALY.

Several cost-effectiveness studies have been performed on hearing devices, especially on cochlear implants. Cochlear implantation was shown to be a cost-effective treatment, with cost-utility ratios that ranged from €10,553 and €12,107/QALY to €22,283/QALY. At a mean cost of €13,933 and €15,807/QALY, conventional hearing aid fitting was also considered to be cost-effective in elderly patients. However, to our knowledge, no research has been done on the cost-effectiveness of middle-ear implantations. The aim of the present study was to determine the cost-effectiveness of middle-ear implantations in patients with sensorineural hearing loss. It was expected that this treatment would be cost-effective in terms of cost per QALY.

**METHODS**

The study had a prospective, single-subject, repeated-measures design in which each patient served as his or her own control subject in the QOL reports. Early in the selection phase, prior to being selected for middle-ear implantation, patients filled out 2 HR-QOL questionnaires, the SF-36 and the NCIQ. The same 2 questionnaires were also filled out 6 and 12 months after the middle-ear implant audio processor had been fitted. The GBI questionnaire was added to the protocol later and was filled in by the patients at 6 to 24 months of follow-up. As it concerns a retrospective questionnaire, this change in protocol was not seen as a problem. To minimize enthusiasm bias in the patients who received implants, all the questionnaires were sent by mail, and a relatively long evaluation period was chosen. The QALYs were calculated based on the health utility gain reflected in the questionnaires.

To assess whether the audio processor fittings were adequate while dealing with the nonlinear amplification of the audio processors, it was decided to measure amplification for normal speech levels (speech gain) and to compare this gain with target gain values obtained with the well-validated National Acoustic Laboratories (NAL) nonlinear rule, which prescribes desired gain as a function of input level based on hearing thresholds alone. Speech gain was defined as the shift between the unaided and aided speech audiograms (speech recognition intensity graph) at the 65-dB sound pressure level input. Mean NAL target gain values at frequencies of 0.5, 1.0, and 2.0 kHz for an input level of 65 dB sound pressure level were used to compare with measured speech gain.

Differences between baseline and implant-aided scores were analyzed using a paired t test; 2-sided comparisons were considered statistically significant at P<.05. Data are expressed as mean±SD, while hearing differences between post–middle-ear implantation and baseline are expressed as means (95% confidence intervals [CIs]). SPSS statistical software, version 12.0, was used to make the calculations (SPSS Inc, Chicago, Ill).

**STUDY POPULATION**

The study population comprised 21 middle-ear implant users who had been operated on between January 2000 and May 2004 at the Department of Otorhinolaryngology, University Medical Center St Radboud, Nijmegen, the Netherlands. In 13 patients, the Vibrant Soundbridge had been implanted, fitted with the 404 audio processor, and 8 patients received the Otologics Implant Study Group who use an upper limit of acceptability of €50,000/QALY.
MENTAL HEALTH, 2 overall scores should be determined.10 The
costs may not have any direct effect on physical health but may affect
quality of life and general health perceptions. Because hearing device fitting
problems, vitality, mental health, social functioning, bodily pain,
functioning, role limitations due to physical and emotional prob-
lems, vitality, mental health, and social functioning. The SF-36
questionnaire assesses 8 different health concepts: physical func-
tioning, role limitations due to physical and emotional prob-
lems, vitality, mental health, social functioning, bodily pain,
functioning, role limitations due to physical and emotional prob-
lems, vitality, mental health, and social functioning. The physical and mental component summary mainly contains physical func-
tioning, role limitations due to physical problems, bodily pain,
and general health perceptions. The mental component summary
mainly is composed of role limitations due to emotional prob-
lems, vitality, mental health, and social functioning. The physical and mental component summary scores are ex-
pressed as a value between 0 and 1.

QOL SCALES

SF-36 Questionnaire

The SF-36 is a multidimensional outcome instrument to mea-
sure QOL. It has been designed to prospectively monitor pa-
tient outcomes in medical and clinical research settings.9 The
questionnaire assesses 8 different health concepts: physical func-
tioning, role limitations due to physical and emotional prob-
lems, vitality, mental health, social functioning, bodily pain,
and general health perceptions. Because hearing device fitting
may not have any direct effect on physical health but may affect
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lems, vitality, mental health, and social functioning. The physical and mental component summary scores are ex-
pressed as a value between 0 and 1.

Nijmegen Cochlear Implant Questionnaire

The NCIQ is a prospective questionnaire used to measure QOL.
It was specially developed to evaluate how cochlear implanta-
tion affects health status.20 The general physical domain con-
ists of 3 subdomains (basic and advanced sound perception
and speech production) and mainly focuses on communica-
tion (referred to as NCIQ communication). The psychological
domain (NCIQ psychological) contains mainly self-esteem ques-
tions, while the social domain (NCIQ social) addresses activ-
ity limitations and social interactions. Because our subjects had
acquired hearing loss, 6 questions on deaf speech and sign lan-
guage were deleted (questions 8, 15, 33, 39, 56, and 57; see
questionnaire in Hinderink et al20). Scores can range from 0 to
100 based on a 5-point scale that indicates the degree of abil-
dy in different situations.

GBI Questionnaire

The GBI is a retrospective standardized questionnaire that ex-
amines the impact of an otologic treatment, such as middle-
ear implantation, on the health status of the patient.22 Scores
can range from −100 to +100 on the basis of 5-point scales that
measure from severe deterioration to great improvement in health status.

COST PER QALY

The QALYs were calculated from the health utility gain scores
obtained with the QOL questionnaires. The hearing of every
subject will deteriorate over time, and any middle-ear implant
will eventually become ineffective. Snik et al6 estimated
the maximum hearing loss for proper middle-ear implant applica-
tion: 70 dB hearing loss for the Vibrant Soundbridge
and 80-dB hearing for the Otologics MET (average at 0.5, 1.0,
and 2.0 kHz). Individual profitable usage periods in years can be
calculated by subtracting the average hearing loss from the
maximum hearing loss and dividing this by an assumed deteri-
oration of 1 dB per year (average at 0.5, 1.0, and 2.0 kHz).27
The formula would be expressed as follows: profitable years
Vibrant Soundbridge = 70 dB–average hearing loss in decibels
(0.5, 1.0, and 2.0 kHz)/1 dB per year and profitable years
Otologics MET = 80 dB–average hearing loss in decibels (0.5,
1.0, and 2.0 kHz)/1 dB per year.

A QALY was calculated by multiplying the number of prof-
itable years with a middle-ear implant by the health utility gain
from that specific middle-ear implant.

Treatment cost was calculated according to the methods de-
scribed by Severens et al20 and only included the direct cost of
middle-ear implantation, ie, during the phases of selection,
implantation, rehabilitation, and aftercare. It was assumed that
the cost of long-term aftercare for today’s semi-implantable de-
vices is comparable to that for conventional hearing aid fit-
tings. The cost of personnel was made up of 3 parts: the gross
salary of the employee, a 21% raise for the social liabilities paid
by the employer, and a 37% raise by the hospital for the facili-
ties and equipment. Reimplantations were not taken into ac-
count because these were assumed to be the result of “grow-
ing pains” of the new device and expected to become insignificant
in number as experience increases. On the basis of the total cost
of middle-ear implantation and the value of 1 QALY, we cal-
culated the cost per QALY.

FITTING AUDIOPROCESSORS

The mean ±SD difference between the measured gain and
target gain estimated by the NAL rule was 2.4 ± 6.4 dB
(range, −11.5 to 7.6 dB); thus, measured gain was a little
higher than NAL target gain. This suggests that the audio-
processor fitting can be considered as adequate.

QOL SCALES

All 21 patients completed the SF-36 and NCIQ preop-
eratively and postoperatively, but only 17 patients (81%)
returned the retrospective GBI questionnaire. Table 1
lists the overall results of the SF-36 and the NCIQ at
baseline and after middle-ear implantation. Because GBI scores
implicate effectiveness by definition, only health utility
gain is shown for this questionnaire.

Significant differences were found in the physical and
mental components of the SF-36 between post–middle-
ear implantation and baseline (P = 0.05 and P = 0.01, re-
spectively, for the mean individual difference scores). The mental component summary had higher scores after
middle-ear implantation. Social functioning was the only underlying health concept with significantly higher scores after middle-ear implantation ($P = .01$). Surprisingly, the physical component summary was significantly poorer after middle-ear implantation. Bodily pain was the only subdomain that had just significantly lower scores compared with baseline ($P = .05$). The communication-related physical, psychological, and social domains of the NCIQ were significantly higher after middle-ear implantation than at baseline ($P = .002$, $P = .01$, and $P = .001$, respectively). All of the underlying subdomains of the NCIQ showed significantly higher scores after middle-ear implantation than at baseline ($P \leq .01$ for all subdomains). The mean GBI score was highly significant ($P < .001$).

Because the SF-36 is the only questionnaire that is widely accepted as a health utility instrument, QALY and cost per QALY values are given only for this questionnaire, using the SF-36 mental component summary score as the health utility gain measure.

**COST PER QALY**

The mean±SD estimated profitable period of middle-ear implant use was 19.4±9.0 years. Multiplying this estimate by the health utility gain score obtained with the mental component of the SF-36 questionnaire produced a QALY value of 0.89.

The overall cost of middle-ear implantation was estimated to be €14 354, based on the costs listed in Table 2. Dividing this amount by the value of 1 QALY, cost per QALY for middle-ear implantation was €16 085 according to the SF-36.

**COMMENT**

The present prospective study addressed the cost-effectiveness of middle-ear implantation in hearing-impaired patients with severe external otitis and is the first to our knowledge to show the cost-effectiveness of middle-ear implantation, although the treatment has been applied for almost a decade. These results can be expected to encourage approval and justification of middle-ear implantation in the future.

Since no other QOL and cost-effectiveness data were available on middle-ear implantation, comparisons were made with studies on cochlear implants. It must be noted that the target populations for the 2 hearing aids are not equal. The middle-ear implant is used in subjects with sensorineural hearing loss, while the cochlear implant is offered to deaf subjects. When we compared the present SF-36 (mental component score) and NCIQ results obtained after middle-ear implantation with those after cochlear implantation in adults at the same research institute,11,20 improvement with cochlear implantation was found to be from about 2 to 2.5 times higher than that with middle-ear implantation (Table 3) (the SF-36 physical summary score was not considered because no change in physical functioning was expected to occur as a re-

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**Table 1. Health-Related Quality of Life Questionnaire Results at Baseline and After Middle-Ear Implantation**

<table>
<thead>
<tr>
<th>Questionnaire†</th>
<th>Baseline</th>
<th>After Implantation</th>
<th>Individual Change Mean (95% CI)</th>
<th>$P$ Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>SF-36, physical</td>
<td>0.512 ± 0.087</td>
<td>0.479 ± 0.100</td>
<td>–0.033 (–0.063 to –0.002)</td>
<td>.05</td>
</tr>
<tr>
<td>SF-36, mental</td>
<td>0.488 ± 0.099</td>
<td>0.534 ± 0.071</td>
<td>0.046 (0.012 to –0.079)</td>
<td>.01</td>
</tr>
<tr>
<td>NCIQ, communication</td>
<td>61.7 ± 13.6</td>
<td>71.7 ± 11.0</td>
<td>9.7 (3.8 to 15.5)</td>
<td>.002</td>
</tr>
<tr>
<td>NCIQ, psychological</td>
<td>60.2 ± 13.9</td>
<td>71.3 ± 13.1</td>
<td>10.5 (2.8 to 18.2)</td>
<td>.01</td>
</tr>
<tr>
<td>NCIQ, social</td>
<td>62.2 ± 15.9</td>
<td>70.0 ± 12.4</td>
<td>13.6 (6.4 to 20.7)</td>
<td>.001</td>
</tr>
<tr>
<td>GBI</td>
<td>NA</td>
<td>NA</td>
<td>33.9 (27.3 to 41.4)</td>
<td>&lt;.001</td>
</tr>
</tbody>
</table>

*Abbreviations: CI, confidence interval; GBI, Glasgow Benefit Inventory; NA, not applicable; NCIQ, Nijmegen Cochlear Implant Questionnaire; SF-36, Medical Outcomes Study Short-Form Health Survey.

†There were 21 respondents to each questionnaire except GBI, which had 17.

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**Table 2. Estimation of the Overall Cost of Middle-Ear Implantation**

<table>
<thead>
<tr>
<th>Treatment Component</th>
<th>Cost, €*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Selection phase</td>
<td></td>
</tr>
<tr>
<td>ENT specialist</td>
<td>276</td>
</tr>
<tr>
<td>Audiologist</td>
<td>188</td>
</tr>
<tr>
<td>Administration</td>
<td>86</td>
</tr>
<tr>
<td>Assistant</td>
<td>137</td>
</tr>
<tr>
<td>Total</td>
<td>687</td>
</tr>
<tr>
<td>Surgery</td>
<td></td>
</tr>
<tr>
<td>ENT specialist</td>
<td>553</td>
</tr>
<tr>
<td>Surgical nurse</td>
<td>531</td>
</tr>
<tr>
<td>Anesthesiologist</td>
<td>357</td>
</tr>
<tr>
<td>Assistant</td>
<td>158</td>
</tr>
<tr>
<td>Total</td>
<td>1 599</td>
</tr>
<tr>
<td>Hospital stay of 2 d</td>
<td>1 135</td>
</tr>
<tr>
<td>Follow-up care</td>
<td></td>
</tr>
<tr>
<td>ENT specialist</td>
<td>107</td>
</tr>
<tr>
<td>Audiologist</td>
<td>642</td>
</tr>
<tr>
<td>Assistant</td>
<td>282</td>
</tr>
<tr>
<td>Total</td>
<td>1 031</td>
</tr>
<tr>
<td>Materials</td>
<td></td>
</tr>
<tr>
<td>Middle-ear implant†</td>
<td>9 500</td>
</tr>
<tr>
<td>Surgery material</td>
<td>402</td>
</tr>
<tr>
<td>Total materials</td>
<td>9 902</td>
</tr>
<tr>
<td>Total cost</td>
<td>14 354</td>
</tr>
</tbody>
</table>

*Abbreviation: ENT, otolaryngologist.

*The US exchange rate on October 10, 2005, the relevant time period, was €1.00 = $0.825292.

†The implant used in this estimate was the Otologics MET device (Otologics LLC, Boulder, Colo); the Vibrant Soundbridge (Med-El, Innsbruck, Austria) would have been about €500 cheaper.
We report that after cochlear implantation, someBAHA-treated in other studies. After cochlear implantation, GBI should be clarified to diminish this adverse effect.

Regarding the choice of the HR-QOL questionnaires in the present study, most of the HR-QOL questionnaires are insensitive to audition and communication problems that are often present as a result of diminished hearing or hearing aid fitting. Therefore, we decided to use the additional NCIQ and GBI questionnaires, which include questions on these topics. A disadvantage of these questionnaires is that they were not designed to calculate the cost per QALY in that an overall utility score has not yet been defined for these questionnaires.

In conclusion, this study was the first to our knowledge to address cost-effectiveness of middle-ear implantation.
tation. With an estimated cost of €16 085/QALY according to the SF-36 QOL questionnaire, middle-ear implantation proved to be a cost-effective and justified health care intervention for the treatment of hearing-impaired patients with severe external otitis. Additional support came from a comparison with a previous study on QOL in cochlear implant users; middle-ear implantation was 2 to 2.5 times less effective but more than 3 times cheaper than cochlear implantation, resulting in a more favorable cost-effectiveness ratio.

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