A Prospective Study of the Cost-Utility of the Multichannel Cochlear Implant

Cynthia S. Palmer, MS; John K. Niparko, MD; J. Robert Wyatt, MD; Margaret Rothman, PhD; Gregory de Lissovoy, PhD

Context: Prior clinical studies have indicated that cochlear implantation provides benefits to individuals with advanced sensorineural hearing loss who are unable to gain effective speech recognition with hearing aids.

Objective: To determine the cost per quality-adjusted life-year (QALY) for adults receiving multichannel cochlear implants.

Design: Prospective 12-month multicenter study using preference-based quality-of-life measures and total cost determinations, comparing profoundly hearing-impaired adult subjects with and without cochlear implants.

Setting: Hospital-based and patient-resource clinics.

Patients: Severely to profoundly hearing-impaired adult recipients of a cochlear implant and adults eligible for the device who had not yet received it.

Main Outcome Measure: Clinical assessment of implant participants included medical and audiologic (speech understanding) data at the time of enrollment, 6 months, and 12 months. All participants' health-utility was assessed at the time of enrollment, 6 months, and 12 months using the Health Utility Index. One-year medical resource utilization and cost data included bills related to implants, patient diaries, charge estimates from clinical sites, and published literature. A decision model was developed to determine cost per QALY.

Results: Of the 84 enrolled adults, 62 (75%) completed the study. Mean health-utility scores at the time of enrollment were identical between groups. The marginal 12-month health-utility gain for implant recipients was 0.20; 90% of this improvement was achieved within 6 months. For patients with a mean 22-year life expectancy, the marginal cost per QALY was $14,670.

Conclusions: Overall, multichannel cochlear implants significantly improved recipients' performance on measures of speech understanding and ratings of health-utility within 6 months of implantation. The multichannel cochlear implant yielded a very favorable cost per QALY.


Epidemiologic studies in the United States indicate that approximately 9% of all adults self-report hearing impairment that affects speech comprehension on a daily basis. A more recent study employing audiometric testing within communities indicated that the prevalence of significant hearing impairment may be as much as 5 times greater than this. An estimated 10% of individuals with sensorineural hearing loss experience impairment so advanced that conventional amplification provides little benefit; thus, these individuals are considered profoundly hearing impaired. Because the severity of sensorineural hearing loss accelerates with age, changing demographic characteristics in the United States will considerably increase the prevalence of profound hearing impairment. The public health concern entailed by the growing prevalence of deafness is underscored by observations of consequences, including constrained access to general medical and mental health services.

See also page 1214

Since the mid-1980s, multichannel cochlear implants have been available as a treatment for profound sensorineural hearing loss. The device uses advanced microcircuitry to restore responsiveness to the auditory periphery. Cochlear implants are now firmly established as an option for the (re)habilitation of advanced hearing impairment to enable environmental and voiced sound awareness and speech comprehension. The implant system consists of external components (microphone, speech processor, battery) and
SUBJECTS, MATERIALS, AND METHODS

This study was approved by the institutional review boards of the participating institutions. All study participants gave informed consent.

STUDY POPULATION

Sixty-six adults scheduled for a Nucleus 22-channel cochlear implant (Cochlear Corp, Englewood, Colo) were enrolled at 17 implantation centers (16 US, 1 Canadian) from October 1994 through February 1996. Eligibility criteria were as follows: 18 years or older; postlingual deafness; aided discrimination of less than 30% of CID (Central Institute of the Deaf) sentences in the better-hearing ear at the time of presentation; no medical, surgical, or cognitive contraindications to implantation; and no prior cochlear implantation. During this same period, 56 comparable individuals were identified who had been evaluated but not scheduled for cochlear implantation pending third-party insurance coverage; 24 were enrolled in the study. Some were referred by organizations that assist hearing-impaired persons to obtain insurance benefits. During the enrollment period, 12 comparison group members received a Nucleus 22-channel cochlear implant and were then included in the implant group.

CLINICAL EVALUATION

All implant and nonimplant participants who were enrolled at clinical sites provided a medical history including internal components (receiver-stimulator implanted in the mastoid process, electrode array in the cochlea) that can restore responsivity to the auditory pathway.

Despite their demonstrated capacity to provide communicative benefits, cochlear implants have been systematically assigned to existing diagnosis related groups that often fail to cover the costs of the new technology.9 Such negative payment incentives may influence clinical considerations when hospitals and clinicians prioritize the use of new medical technologies.

Cochlear implants belong to a unique class of medical technologies that ostensibly have little effect on survival, but may confer benefits in enhanced quality of life inherent in improved social and environmental contact. Are cochlear implants a worthwhile intervention in light of associated costs? We address this question using a generic measure of health status and determined costs to yield a cost-utility ratio for cochlear implants. Cost-utility analysis is a method used to assess the societal value of such interventions relative to other therapies, including those with impact on survival.10,11 Quality-adjusted life-years (QALYs) are a standard measure of utility. Utility, a term borrowed from economics, describes an individual’s strength of preference for a health state on a scale ranging from 0 for death to 1 for perfect health.12 Quality-adjusted life-years are calculated as time in a health state weighted by the utility of the state.13 A cost-utility analysis of alternative health technologies entails (1) specification of the period affected by the intervention, cause, duration and family history of hearing loss, active medical problems, prior surgery, history of treatment for depression or other psychological problems, and current medications. Audiologic assessment at the time of enrollment, 6, and 12 months minimally included Northwestern University 6-word test (NU-6) and CID sentence recognition in the participant’s best hearing-aided or implanted condition. Speech recognition capabilities are routinely assessed with these standardized tests. Nonimplant participants who were not enrolled through participating clinics were unable to provide medical history and audiologic data.

For subjects in the implant group, the surgeon recorded clinical features (ie, ossification, fibrosis) and any other operative factors that could affect implant placement and function. All medical complications were recorded at the time of the 6- and 12-month follow-up visits.

HEALTH UTILITY ASSESSMENT

Results of a pilot study of the health-related quality-of-life assessment method have been previously reported.23 Utility was measured using the Health Utility Index (HUI).26 Unlike other widely used instruments, such as the Quality of Well-being Scale,27 the HUI incorporates domains related to spoken communication and hearing. With the approval of the developers of the HUI, questions that mention hearing aids were expanded to read “hearing aid or cochlear implant.” For members of the implant group, the HUI was self-administered at the time of enrollment (presurgery) and at 6 and 12 months postsurgery. Comparison group members completed the mailed self-
administered HUI at the time of enrollment and at 6 and 12 months following enrollment.

MEASUREMENT OF COSTS

For the implant group, medical resource utilization was allocated to 3 phases of the course of treatment: (1) implant perioperative; (2) 1-year postsurgical follow-up; (3) second and subsequent years. Implant perioperative resources and costs were documented by obtaining copies of hospital and physician bills. Procedures listed on bills were compared with a checklist of expected treatment events as recorded in the study case report forms. Missing charges for services known to have been performed were imputed. Resource use and costs during the 1-year follow-up period were determined in several ways. Study participants who had received an implant were asked to submit copies of all bills for hearing-related care, including prescription and nonprescription medication, and received a nominal cash reward for doing so. All participants (with or without implants) were requested to record in a diary any medical care received. The diary was reviewed at the study’s conclusion to identify hearing-related care (and compared with bills in the case of participants who received cochlear implants).

Resource use related to the implant during the second and subsequent years was estimated based on descriptions of follow-up care developed by several of the clinical sites. These costs are typically nominal and include an annual clinic visit and 1 (rechargeable) AA battery per day. Also included were all medical care and other charges related to device failure and replacement.

The economic value attributed to a course of therapy can vary depending on the perspective of the analysis. We included all direct costs for cochlear implantation, including patient-borne costs such as extended warranties, insurance, and batteries. Resources were valued based on actual charges as recorded on the hospital and physician bills that were obtained from study participants. It is likely that the use of billed charges overstates the amounts actually paid.

Billed charges for preoperative, audiologic, and surgical assessments typically predated participant identification and enrollment and were difficult to obtain. Thus, median charges for these assessments were estimated using data collected from participating clinical sites. Resource items imputed for the implant perioperative and 1-year follow-up phases were priced using the mean charge observed for other bills obtained from study participants at that clinical site. Hearing-related medical encounters recorded in participant diaries but without corresponding submitted bills were assigned a Current Procedural Terminology (CPT) code and priced based on the 1996 Medicare maximum allowable charge. Medication costs were based on the Red Book wholesale drug price with an assumed 30% retail markup. Although not all implant recipients choose to pay for annual insurance against loss, theft, or damage to external parts of the cochlear implant or for the available extended service warranty after expiration of the manufacturer’s 3-year device warranty, these costs were included for all implant recipients.

Study participants in the nonimplant group had minimal contact with the clinical sites. The participant diary was the primary means of documenting their use of medical resources.

CLINICAL ASSESSMENTS

Fifty-nine percent of the 46 implant recipients had been deaf for less than 10 years, while 32% were deaf for more than 20 years. Baseline comorbid conditions reported by implant recipients were typical of older adults and included hypertension (20%), coronary artery disease (11%), osteoarthritis (11%), and thyroid disease (9%). Ten (63%) of the 16 nonimplant participants were enrolled through a nonclinical site and thus provided no medical or audiologic history. Surgery was unremarkable for 44 of 46 members of the implant group. In 2 cases, prior stapedectomies for otosclerosis precluded full insertion of active electrodes.

Implant recipients were assessed at the time of their 6- and 12-month clinic visits. Among the 43 participants (93%) who returned for 6-month follow-up, 6 (14%) reported 1 or more minor complication, including 2 local flap-related infections, 5 instances of temporary or intermittent vertigo, and 2 cases of tinnitus. Three of the 7 reports of vertigo or tinnitus predated the implantation procedure. At 12 months, 32 participants (70%) returned for scheduled follow-up and 9 (28%) reported 1 or more complication. Most complaints predated surgery or occurred during the initial 6-month follow-up period. One patient reported “pinging” in the implanted ear that was unrelated to device activation. Another experienced facial nerve stimulation that was corrected by deactivating the specific electrodes causing stimulation.

Audiologic mean scores at the time of enrollment for the implant group were 6% for CID sentence and 2% for NU-6 word recognition. By 6 months, highly significant (P<.001) improvement was recorded in scores on speech recognition tests using CID sentence (mean gain ± SD, 56% ± 5%) and NU-6 word lists (mean gain ± SD, 30% ± 4%). Further significant gains in CID sentence recognition were made from 6 to 12 months (P<.01).

HUI SCORES

The mean ± SD HUI scores at the time of enrollment for the implant group (0.58 ± 0.17) and nonimplant group (0.58 ± 0.20) were virtually identical. Figure 1 indi-
cates that HUI scores were significantly greater for the implant group than for the nonimplant group at 6 months (0.76 ± 0.18 vs 0.57 ± 0.18; P < .001) and at 12 months (0.78 ± 0.17 vs 0.58 ± 0.23; P < .01). These results were confirmed in a statistical procedure (analysis of variance) that controlled for age, sex, and duration of hearing impairment. For the cost-utility analysis, we assumed that health-utility scores would remain stable in both the implant and nonimplant groups during subsequent years.

Subscale scores of the HUI for the 2 groups were compared using the Fisher exact test. At the time of enrollment, only one subscale (mobility) was significantly different (P = .05), with a lower mean score for the implant group. At 6 months, the implant group displayed significantly higher scores for hearing (P < .001) and sensation (P < .01), while other subscales remained unchanged. At 12 months, significantly greater scores were observed in the implant group for hearing (P < .001), sensation (P < .01), and speech (P < .01).

**TREATMENT COSTS**

For implant recipients, charges for the implant/perioperative phase and 1-year follow-up included 6 components: assessments prior to surgery, facility charge (inpatient or day surgery), cochlear implant device, surgery professional fee, anesthesiology professional fee, and 12-month follow-up care. Billing data were unavailable for 5 implant recipients from Canada and 1 implant recipient who was treated at a Veterans Affairs facility. Of the remaining 40 implant participants, 35 (88%) submitted complete or partial billing data for each of the 6 charge components.

Table 3 gives the mean and range of derived and billed charges for each component of the implant/perioperative phase and 1-year follow-up as well as the corresponding mean charge after imputation of missing data. Although mean and median billed charges were similar (≤10% difference), the range of each component was broad, with the highest charge representing approximately 3 to 9 times the lowest charge. The billed charge for the multichannel cochlear device itself ranged from $14 027 to $37 572. The highest charge representing approximately 3 to 9 times the lowest charge. The billed charge for the multichannel cochlear device itself ranged from $14 027 to $37 572. The highest charge representing approximately 3 to 9 times the lowest charge. The billed charge for the multichannel cochlear device itself ranged from $14 027 to $37 572. The highest charge representing approximately 3 to 9 times the lowest charge. The billed charge for the multichannel cochlear device itself ranged from $14 027 to $37 572. The highest charge representing approximately 3 to 9 times the lowest charge. The billed charge for the multichannel cochlear device itself ranged from $14 027 to $37 572.

Figure 1. Mean Health Utility Index (HUI) scores at baseline, 6 months, and 1 year.
persons generally use more medical resources than those without impairment, the type and severity of hearing impairment does not appear to have a consistent effect on medical resource utilization. Therefore, we assumed that both implant and nonimplant subjects would receive equivalent periodic follow-up care for severe to profound deafness; this cost was excluded from analysis. Additional annual costs for implant recipients were projected to include loss/damage insurance for the external device components ($135), extended warranty after year 3 ($248), and rechargeable battery replacement ($10).

Although no device malfunction was observed in the study population, we projected long-term costs associated with internal component failure and replacement. The internal device failure rate was derived by fitting a survival curve to 11-year data on multichannel cochlear implants where the actual cumulative failure rate was 5.3% (Cochlear Corp, unpublished data, 1997). We assumed a 99% internal component replacement rate. Reimplantation included estimated rates of minor (3%) and major (6%) complications of cochlear implantation, with previously estimated mean respective costs of $863 and $9943. Cost-utility is measured as the incremental cost per QALY for the cochlear implant relative to no implant, based on the cumulative stream of costs and benefits over the period affected by the intervention. We used life tables and the mean ± SD age (56 ± 15 years) of implant recipients enrolled in the study to project a 22-year period of use.

Results of cost-utility analysis are presented in Table 4. All costs and benefits are discounted at a rate of 3%. The base case, representing the most likely scenario, yields a mean incremental cost of $14 670 per QALY for cochlear implant vs nonimplant recipients. To establish a confidence interval on this point estimate, we employed a bootstrapping procedure that generated 1000 predicted values for the cost-utility ratio. The distribution of these values is plotted in Figure 2. In the base case, there is a 95% likelihood that cost per QALY falls between $8241 and $30 347.

### Sensitivity Analysis

Sensitivity analyses assess the robustness of findings with respect to assumptions, such as the stability of utility over time, cost associated with cochlear implantation, and the period of use following the 12-month study period. Specification of the period of use is particularly critical when an intervention has a substantial up-front cost because this expenditure must be amortized over the duration of effect. Longer duration of use substantially mitigates costs.

**Table 3. Implant-Related and 1-Year Follow-up Charges per Patient**

<table>
<thead>
<tr>
<th>Type of Service</th>
<th>No. of Cochlear Implantees</th>
<th>Range of Submitted Charges, $</th>
<th>Mean Charges, $ (% of Total)</th>
<th>Mean Imputed Charges, $ (% of Total)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Preoperative assessment†</td>
<td>NA</td>
<td>NA</td>
<td>1200 (3.2)</td>
<td>NA</td>
</tr>
<tr>
<td>Audiologic assessment†</td>
<td>NA</td>
<td>NA</td>
<td>1027 (2.7)</td>
<td>NA</td>
</tr>
<tr>
<td>Surgical assessment†</td>
<td>NA</td>
<td>NA</td>
<td>150 (0.4)</td>
<td>NA</td>
</tr>
<tr>
<td>Anesthesiologist‡</td>
<td>23</td>
<td>246-1616</td>
<td>1110 (2.0)</td>
<td>1051 (2.9)</td>
</tr>
<tr>
<td>Surgeon‡</td>
<td>24</td>
<td>2410-5875</td>
<td>4492 (12.0)</td>
<td>4694 (12.7)</td>
</tr>
<tr>
<td>Inpatient or day-surgery stay‡</td>
<td>23</td>
<td>1274-11 094</td>
<td>5758 (15.4)</td>
<td>5666 (15.4)</td>
</tr>
<tr>
<td>Implant device‡</td>
<td>23</td>
<td>14 027-37 572</td>
<td>22 516 (60.2)</td>
<td>21 598 (58.6)</td>
</tr>
<tr>
<td>Follow-up (1-year)‡</td>
<td>27</td>
<td>56-4215</td>
<td>1152 (3.1)</td>
<td>1451 (3.9)</td>
</tr>
<tr>
<td>Total</td>
<td>NA</td>
<td>NA</td>
<td>37 405 (n = 35)</td>
<td>34 460</td>
</tr>
</tbody>
</table>

*NA indicates not applicable.
†Mean charges calculated from estimates provided by participating clinical sites.
‡The number varies for charges submitted by cochlear implantees because of missing bills; all charges were inflated to 1996 dollars.

**Table 4. Cost Utility: Base Case and Sensitivity Analyses**

<table>
<thead>
<tr>
<th>Variable</th>
<th>Base Case</th>
<th>Range of Estimates</th>
<th>Corresponding Range in Cost-Utility</th>
</tr>
</thead>
<tbody>
<tr>
<td>Base case analysis, $</td>
<td>14 670</td>
<td>Low High</td>
<td>Low High</td>
</tr>
<tr>
<td>Increase in health utility for implant recipient</td>
<td>0.20</td>
<td>0.20 0.20 + 0.5%/y</td>
<td>$11 645 $16 895</td>
</tr>
<tr>
<td>Discount rate</td>
<td>3%</td>
<td>0% 5%</td>
<td>11 823 19 718</td>
</tr>
<tr>
<td>Charge for implant device, $</td>
<td>22 516</td>
<td>14 027 37 572</td>
<td>13 972 15 134</td>
</tr>
<tr>
<td>Surgeon's fee, $</td>
<td>4492</td>
<td>2410 5875</td>
<td>13 173 16 459</td>
</tr>
<tr>
<td>Anesthesiologist's fee, $</td>
<td>1110</td>
<td>246 1616</td>
<td>14 380 14 840</td>
</tr>
<tr>
<td>Hospital charge, $</td>
<td>5758</td>
<td>1294 11 094</td>
<td>13 173 16 459</td>
</tr>
<tr>
<td>Year 1 follow-up charges (no complications), $</td>
<td>1152</td>
<td>960 3428</td>
<td>14 609 15 394</td>
</tr>
<tr>
<td>Annual insurance and batteries only, $</td>
<td>443</td>
<td>145 443</td>
<td>13 446</td>
</tr>
</tbody>
</table>

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per year. Figure 3 illustrates the effect of varying this between 1 year and the projected “best case” 37-year period of use. Because about 80% of lifetime costs are incurred in the first year, cost per QALY decreases rapidly as the period of use is extended.

There is evidence that benefits of the cochlear implant improve with continued use, while advances in sound-processing technology continue to enhance the effectiveness of the device. We performed a sensitivity analysis under the assumption that utility scores improved for implant recipients by 0.5% per year over the lifetime of the individual, increasing utility from 0.78 postimplant in year 1 to a maximum of 0.87 at (base case) year 22. This resulted in a $14 251 cost per QALY (Table 4). Variation in the discount rate from 0% to 5% resulted in costs per QALY of $11 645 to $16 895, respectively (Table 4). Charges for the implantation and perioperative procedures were also varied across the interval defined by the lowest and highest billed or site-estimated charges per charge component, resulting in costs per QALY ranging from $11 823 to $19 718.

In this study, self-reported measures of health indicated that the preimplant experimental group and comparison group, both with severe to profound deafness, suffered a measurable burden of morbidity greater than that of individuals without hearing impairment. Recipients of cochlear implants rated their health-related quality of life as significantly improved following implantation. The measures employed in the study probed attributes of the intervention that extended beyond sensory restoration and thus provide a unique assessment of the effects of implantation in ameliorating profound hearing loss.

Health utility measures the value of medical interventions from the patient perspective by assigning a numerical value to states of health with and without the intervention. This metric is particularly valuable in the case of treatment that improves quality of life but may have little or no impact on survival. The 12-month HUI scores recorded in this study (means for the implant vs comparison groups, 0.79 and 0.59, respectively) were consistent with previous results obtained using cross-sectional data. Our findings were also consistent with previous studies in the United Kingdom and the United States indicating that mean loss of health-utility ranges from about 0.37 for “deafness” to about 0.40 for “profound bilateral postlingual hearing loss in adults.” Further, observed gains in health-utility were consistent with health-utility gains of 0.10 to 0.30 with multichannel cochlear implantation derived by other methods. Although previous studies have indicated that long duration of deafness can have a negative impact on degree of improvement with implantation, no significant relationship between duration of hearing loss and HUI at either 6- or 12-month follow-up was noted in the current study.

Links between hearing impairment and cognitive, emotional, and physical comorbid conditions have been reported. Although it is likely that the link between hearing impairment and reduced health is multifactorial, one hypothesis suggests that effective interaction...
Conclusions

This prospective 12-month study indicates that severely to profoundly hearing-impaired individuals achieve significantly improved HRQL within a relatively brief period following multichannel cochlear implantation. The base case cost per QALY determined by this study was highly favorable for adults implanted in the United States and Canada. The multichannel device has an impressive cost-utility ratio compared with the average cost per QALY of a wide variety of existing medical interventions. Longer-term work is needed to demonstrate how HRQL may change over protracted periods for implant recipients.