International Journal of Technology Assessment in Health Care, **16:3** (2000), 864–873.

THE EFFECT OF COCHLEAR IMPLANT USE IN POSTLINGUALLY DEAF ADULTS

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Abstract

Objective: To assess the effect of the use of cochlear implants (CI) on the health status of postlingually deaf adults.
Methods: Participants comprised 45 postlingually deaf adult multichannel CI users and 46 deaf candidates on the waiting list for a CI. The latter group acted as control subjects to corroborate the validity of retrospective completion of the questionnaires by the CI recipients. Three HRQOL instruments were used: a) a specially developed CI questionnaire (NCIQ); b) a generic HRQOL questionnaire (SF-36); and c) a health-state classification system (HUI-2) suited to estimate single preference scores.
Results: Retrospectively estimated pre-implant scores in the CI user group corresponded very well with the scores in the control group. Postimplant scores in the CI users were substantially higher in all six domains ($p < .001$) of the NCIQ than the scores in the control group. Effects due to a CI were also observed with the SF-36 in five of the seven domains ($p < .01$). Statistically significant differences between the two groups ($p = .001$) were observed in two of the six domains of the HUI-2.
Conclusions: All three questionnaires detected improvements in HRQOL due to CI use. To make a detailed assessment of the effect of a CI on functional outcomes and well-being, a special purpose HRQOL instrument is far more adequate than a general HRQOL instrument. This study also showed that a CI affects several other health domains besides auditory performance. The effect of CI use on general functioning and well-being proved to be considerable.

Keywords: Health-related quality of life, Cochlear implantation, Treatment effect, Outcome measurement

Cochlear implantation in profoundly deaf people is a relatively new medical technology that partially restores auditory perception. The obvious benefits of this technique are enhancement of sound and speech perception and speech production. Owing to the technological development of cochlear implants (CI), the results of this medical intervention have improved over the past few decades (4;9). Besides the re-establishment of sound perception and the resulting improvement in speech production, the use of a CI may also have a positive impact on other health domains.

We would like to thank all the participants in this study who filled out the questionnaires and provided valuable comments. We also thank our colleagues at the Institute for the Deaf in St. Michielsgestel for sharing their experience with us.

Clinicians and policy makers have recognized that changes in a patient's health status are the primary outcome of medical interventions. Subsequently, the World Health Organization has extended the definition of health with psychological and social domains. More and more medical interventions are being evaluated in a comprehensive manner by looking at a broad range of health domains that can be affected by deterioration in a person's general health status. The paradigm that is focused on the comprehensive measurement of health outcomes on the subjective level of the patient is referred to as health-related quality of life (HRQOL). In the case of a CI, this means that evaluations should also extend to general aspects such as self-esteem, daily activities, and social functioning.

So far, most of the reports on HRQOL aspects in CI users have generally been based on the use of open-ended questionnaires or on interviews with patients (10;13;23;26;30). Only one study on the impact of CI use made use of closed-set questionnaires, which were built up in a systematic manner and provided quantifiable scores (19). Although this questionnaire encompassed the psychological and social domains of the HRQOL concept, it lacked the physical component. In addition, the psychological and social domains were not dealt with separately but were aggregated into one composite score.

Some studies attempted to measure and quantify HRQOL effects in CI users with "generic" HRQOL instruments or preference-based HRQOL systems designed to evaluate different types of medical intervention. Wyatt et al. (27;28) used the Health Utilities Index (HUI, version 2). Harris et al. (16) used the Quality of Well-Being Scale (QWB) to measure improvement in quality of life and psychological well-being in CI users. The HUI-2 and QWB were specifically developed to produce a single preference score or value (technical term: utility), in order to merge HRQOL values with survival data to calculate quality-adjusted life years (QALYs). However, these types of instrument cannot be used to make detailed subjective evaluation of outcomes or HRQOL changes induced by CI use, because they are not sensitive or comprehensive enough.

To assess the effect of CI use, we have used three conceptually different HRQOL questionnaires. The first instrument can be classified as a disease-specific HRQOL questionnaire for self-report use, specifically developed for the evaluation of CI user populations. In addition, two generic HRQOL questionnaires were used that are not restricted solely to the evaluation of CI user populations and can therefore be used to compare the effect of CI use on HRQOL to the results of other medical interventions. The primary aim of this study was to assess the effect of CI use on the perceived health status of adults with profound sensorineural hearing loss.

METHODS

Quality of Life Measures

The Nijmegen Cochlear Implantation Questionnaire (NCIQ) is a disease-specific instrument based on the conventional approach to measuring HRQOL (17). Three general domains are distinguished: physical, psychological, and social functioning. The following subdomains are specified: sound perception-basic, sound perception-advanced, and speech production in the physical domain, while activity and social functioning are specified in the social domain. The domain psychological functioning consisted of only one subdomain, self-esteem. Each domain consists of 10 items, formulated as a statement with a five-point response scale to indicate the degree to which the statement applies to the respondent. There is also a sixth response category if the item is not considered relevant. Scores range from 0 to 100 (optimal).

The Medical Outcome Study Short-Form 36 (SF-36) health survey was developed in the United States on the basis of the large battery of health status and HRQOL instruments employed in the Medical Outcomes Study (25). This generic (e.g., non–disease-specific)

HRQOL questionnaire consists of 36 items. These items are organized into eight domains: physical functioning (10 items), social functioning (2 items), problems with role functioning due to physical problems (4 items), problems with role functioning due to emotional problems (3 items), pain (2 items), mental health (5 items), vitality (4 items), and an overall domain, general health perception (5 items). The number of response choices per item ranges from two to six. The SF-36 yields an eight-dimensional profile, in which each domain has a range from 0 to 100 (optimal). The Dutch version of the SF-36, employed in the current study, was developed as part of the International Quality of Life Assessment Project (1). Psychometric properties of this instrument have been studied in detail and are considered adequate (5;14;24;29).

At present the Health Utility Index, Mark II (HUI-2) is probably the most comprehensive multi-attribute health-state classification system (22). It is focused on the more functional concepts of HRQOL, such as disabilities (dysfunction) and resulting dependencies. The HUI-2 encompasses seven domains (sensation, mobility, emotion, cognition, self-care, pain, and fertility). Obviously, the last domain can safely be omitted if it is not relevant. Three to five levels of functioning are defined in each domain (also called attributes). Any specific combination of the applicable number of domain levels constitutes a unique health state. Values for the attributes range from 0 to 100 (optimal). A distinguishing feature of the HUI-2—as opposed to, for example, the SF-36 and the NCIQ—is the potential to assign a numerical value (or utility) to any health status of a particular participant based on the HUI-2 classification. Each attribute has an associated weight that indicates the subjective assessment of the attribute in question. This utility, on a scale from 0 to 1.0 (0 = death, 1.0 = perfect health), is obtained by applying a predetermined multi-attribute utility function. Utility data express the overall assessment of a specific health status, and these can be merged together with expected life years to compute QALYs. QALYs are appealing because they provide a relatively simple means of reflecting the HRQOL effects of medical interventions and enable comparisons with interventions that have very different types of outcome (e.g., in cost-effectiveness analysis).

Study Population and Design

In April 1998 the NCIQ was sent to 60 adult subjects who had received a CI during the period 1989–97 under the supervision of the Nijmegen/St. Michielsgestel CI team, with a letter explaining the purpose of the study. All the subjects were using oral-aural communication. The selection and implantation procedures have been described previously (7).

Thirteen of the 60 subjects were excluded from the study: 10 of these subjects were prelingually deaf and 3 were postlingually deaf but had been fitted with a single-channel implant. The remaining 47 postlingually deaf adult participants have been fitted with a multichannel implant, using advanced speech encoding strategies (MPEAK, SPEAK, CIS). They have been using their implant for at least 1 year.

The three questionnaires were administered twice to the CI users in a crossover design: once in the past tense to obtain retrospective information and once in the present tense to evaluate the current HRQOL. Half of the CI users filled out the retrospective version first (CI-pre), while the other half filled out the standard (present tense) version (CI-post). Two weeks after completing and returning the first questionnaire, the other version was sent to the CI users. Results from both versions are presented. The retrospective answers of the CI users were compared with those from the control group (baseline) of postlingually deaf candidates on the waiting list for a CI at our institute.

Statistical Analysis

Descriptive statistics of the two study groups were computed for the main characteristics: age, age at cochlear implantation, age at onset of deafness, sex, paid employment, education, and living situation. Scores on the three questionnaires were declared as missing values if nothing was filled in or if ambiguous information was provided. On the NCIQ, missing values and the response category “not applicable” were both treated as not completed. The maximum permitted number of incomplete answers for a specific subdomain was set at three items per subject; above this number the subject was excluded.

Since the distribution of the scores on the majority of separate domains was highly skewed (as evidenced by the results of Kolmogorov-Smirnov tests), nonparametric tests were used to analyze whether the scores of the two groups were significantly different. Wilcoxon’s signed rank test was used to compare the dependent scores of the CI group. The Mann-Whitney U test was applied to test the two assessments of the CI group against the response of the control group. To avoid the effect of multiple testing, $p < .01$ was regarded as statistically significant. As the sample size largely determined whether an effect would be statistically significant, we employed an estimator of effect size d for continuous variables (8). Effect sizes were calculated by dividing the means of the two measures by the deviation in that scale.

RESULTS

Respondent Characteristics

A total of 45 (95%) CI users returned both the standard and the retrospective version of the NCIQ, the SF-36, and the HUI-2. In the control group, 46 subjects (87%) completed the standard and the adapted (CI-post) version of the three questionnaires. Demographic and clinical characteristics of the two groups were very similar (Table 1).

NCIQ. Table 2 shows the mean scores on the six domains of the NCIQ together with their standard deviations. On the NCIQ, scores were substantially higher on all six domains during CI use. Differences between the CI-pre and CI-post scores were all statistically significant ($p < .001$). The largest difference between CI-post and CI-pre (and the control group)

Table 1. Demographic and Clinical Characteristics of CI Users and the Candidates for a CI on the Waiting List (Control Group)

Characteristic	CI (n = 45)	Control subjects (n = 46)
Sex		
Male	46%	60%
Female	54%	40%
Paid employment		
Yes	43%	38%
No	57%	62%
Education level		
Lower	32%	27%
Secondary	50%	57%
Higher	18%	16%
Living situation		
Alone	20%	16%
With others (partner, children)	80%	82%
Care center	0%	2%
Age (mean yrs ± SD)	50 ± 16	51 ± 16
Age of onset of deafness (mean yrs ± SD)	31 ± 18	37 ± 20
Duration of deafness (yrs ± SD)	13 ± 12	16 ± 14
Age CI (mean yrs ± SD)	44 ± 16	—
CI use (yrs ± SD)	5 ± 2.8	—

Table 2. Mean Scores (SD in Parentheses) on the Six Domains of the NCIQ of CI Users (Retrospective Version = CI pre, Standard Version = CI post) and the Control Group (Baseline Measurement)

Domain	Control group (n = 46)	CI group (n = 45)		CI post − CI pre (n = 45)		
		CI pre	CI post	Change (SD)	*p* Value[a]	Effect size[b]
Sound perception-basic	11.6 (14.4)	3.2 (5.8)	64.1 (23.5)	61.3 (23.9)	<.001	3.56
Sound perception-advanced	19.6 (13.4)	14.4 (11.4)	53.8 (19.6)	40.5 (16.7)	<.001	2.46
Speech production	64.6 (18.8)	59.8 (20.1)	81.7 (17.8)	22.2 (21.2)	<.001	1.15
Self-esteem	44.8 (20.1)	42.0 (19.6)	66.7 (16.4)	25.6 (17.3)	<.001	1.37
Activity	45.6 (23.0)	49.0 (21.0)	72.9 (15.9)	24.7 (15.6)	<.001	1.28
Social interactions	46.7 (19.8)	52.1 (17.2)	71.9 (14.5)	20.1 (11.0)	<.001	1.24

[a] Nonparametric testing: Wilcoxon signed rank test (2-tailed Monte Carlo sampling).
[b] Effect size: $d \leq 0.2$ indicates a small effect; $d \cong 0.5$, a medium effect; and $d \geq 0.8$, a large effect.

was observed for the domains sound perception-basic and sound perception-advanced. Differences were smaller for all other four domains, although the overall improvement owing to the CI was still more than 30%. Moreover, the effect sizes were large for all six domains ($d > 0.8$). CI-pre and control scores were very similar, except for sound perception-basic.

SF-36. Higher scores for the CI-post period were also observed on three domains of the SF-36 (Table 3). These domains were: social functioning, the two role functioning domains (physical and emotional), and the mental health domain. Except for the domains pain and vitality, all the differences between the CI-pre and CI-post scores were statistically significant ($p \leq .01$). The effect of a CI on physical functioning was negative and the effect size was small ($d = 0.27$). CI-pre and control scores on the SF-36 were fairly similar, but

Table 3. Mean scores (SD in Parentheses) on the Eight Domains of the SF-36 Instrument of CI users (Retrospective Version = CI pre, Standard Version = CI post) and the Control Group (Baseline Measurement)

Domain	Control group (n = 46)	CI group (n = 45)		CI post − CI pre (n = 45)		
		CI pre	CI post	Change (SD)	*p* Value[a]	Effect size[b]
Physical functioning	79.2 (24.8)	89.7 (17.1)	84.5 (21.5)	−3.7 (10.5)	.010	0.27
Social functioning	72.8 (29.6)	58.6 (27.4)	84.7 (20.2)	26.5 (27.3)	<.001	1.08
Role functioning (physical)	60.2 (41.5)	60.6 (40.1)	80.0 (35.6)	19.9 (40.2)	.002	0.51
Role functioning (emotional)	72.7 (35.6)	64.4 (38.3)	85.2 (32.2)	20.9 (40.5)	.003	0.59
Pain	77.2 (25.8)	88.7 (17.3)	83.2 (17.1)	−5.3 (17.8)	NS	0.32
Mental health	71.0 (21.0)	61.6 (18.9)	77.3 (17.9)	15.8 (19.9)	<.001	0.85
Vitality	66.4 (20.2)	67.9 (18.6)	71.5 (18.7)	3.4 (18.5)	NS	0.19
General health perception	68.7 (21.5)	—[c]	72.3 (19.8)	—	—	—

[a] Nonparametric testing: Wilcoxon signed rank test (2-tailed Monte Carlo sampling).
[b] Effect size: $d \leq 0.2$ indicates a small effect; $d \cong 0.5$, a medium effect; and $d \geq 0.8$, a large effect.
[c] Not measured.

Table 4. Mean Scores (SD in Parentheses) on the Six Domains of the HUI-2 of CI Users (Retrospective Version = CI pre, Standard Version = CI post) and the Control Group (Baseline Measurement)

Domain	Control group (n = 46)	CI group (n = 45)		CI post − CI pre (n = 45)		
		CI pre	CI post	Change (SD)	*p* Value[a]	Effect size[b]
Sensation	14.5 (18.2)	3.0 (9.6)	48.8 (23.1)	46.4 (24.2)	<.001	2.59
Mobility	92.4 (17.4)	97.8 (9.0)	97.8 (9.0)	0.0 (5.4)	NS	0.00
Emotion	89.1 (13.6)	79.5 (19.6)	90.6 (13.4)	10.5 (17.5)	.001	0.66
Cognition	83.8 (19.8)	93.2 (13.8)	95.5 (13.7)	1.6 (12.5)	NS	0.17
Self-care	97.1 (11.9)	99.2 (5.1)	98.5 (7.1)	−0.7 (5.1)	NS	0.11
Pain	88.6 (18.8)	90.3 (13.4)	88.3 (16.5)	1.7 (15.8)	NS	0.13
HUI-2 utility	0.62 (0.16)	0.55 (0.11)	0.82 (0.14)	0.28 (0.15)	<.001	2.08

[a] Nonparametric testing: Wilcoxon signed rank test (2-tailed Monte Carlo sampling).
[b] Effect size: $d \leq 0.2$ indicates a small effect; $d \cong 0.5$, a medium effect; and $d \geq 0.8$, a large effect.

the differences between the two groups were greater than they were for the NCIQ. There was no systematic effect between the control group and the CI-pre assessments.

HUI-2. The HUI-2 domains (Table 4) showed less significant results than those of the other two HRQOL questionnaires. Only two of the six domains showed statistically significant differences between the CI-pre and CI-post scores: sensation (partially comprising hearing functioning) and emotion. The effect size observed for sensation was large ($d > 0.8$). Utilities obtained with the HUI-2 increased from 0.55 (CI-pre) to 0.82 (CI-post), which is a large effect ($d = 2.08$).

Generally, the standard deviations for the 20 domains of the three HRQOL questionnaires were moderate. Relatively large standard deviations were observed for two SF-36 domains (role functioning domains), whereas the smallest standard deviations were observed for the HUI-2 weights.

DISCUSSION

Our study showed that a CI led to a significant improvement in HRQOL of postlingually deaf adults. We used three HRQOL questionnaires, each of them based on a different HRQOL measurement approach. The disease-specific NCIQ measured important improvements on six health domains between the CI-pre and CI-post situation. As expected, major improvements were observed on the three domains focused on sound and speech functionality. Moreover, an average increase in scores of 30% was observed on the psychological domain and the two social domains. The generic SF-36 questionnaire reflected significant effects on four of its seven domains: social functioning, role functioning (physical and emotional), and mental health. The more crude classification system of the HUI-2 showed great improvement in sensation (comprising vision, speech, and hearing) and a slightly smaller improvement in emotion. Standard deviations of the HUI-2 classification were smaller than those of the two questionnaires, which is basically an intrinsic feature of any concise instrument.

There was a strong agreement between the retrospective answers of the CI users regarding their pre-implant HRQOL and the HRQOL perceived by the deaf candidates on the waiting list for a CI. This agreement between the CI users and the control subjects provides strong support for the validity of interpreting retrospective information from CI users. Differences between the CI-pre scores and the scores of the control subjects may be attributed to different aspects. It is well known that valuation of health states may differ according to illness experience (11;15). People with a disability sometimes manage to adapt in such a way that their HRQOL assessments of their own health status exceed those of healthy control subjects. This phenomenon has been the subject of study in the social sciences under the heading of cognitive dissonance and valuation or response shift (6). A similar process may also be applicable to the responses of the non-CI users (control subjects). If the differences between the CI-pre scores and the scores of the control group were largely thought to originate from adaptation effects, then we may consider the CI-pre scores in this retrospective study as more precise HRQOL estimates than the scores of the control subjects. Another possible explanation is that the retrospective answers to the CI questionnaires may have been confounded by inaccurate memory, although this would probably only have led to an increase of the unreliability of the scores but not to systematically biased responses (2). Although an adaptation effect may partially explain the differences between the CI-pre and control scores, the differences may reflect genuine differences (e.g., background characteristics) between the two groups. A moderate number of cases participated in this study, and data were obtained via retrospective measurements. Nevertheless, the differences observed between the CI-pre and CI-post situation are fairly substantial. Therefore, these limitations do not preclude us from drawing valid conclusions. However, further research is necessary to evaluate the validity and reliability of the NCIQ questionnaire.

SF-36 scores of the CI study group were compared with the norm scores ($n = 2{,}474$) from a Canadian study (24). Canadian scores were very similar to the norm scores ($n = 1{,}063$) of a Dutch population sample (29). Table 5 shows that the CI-post scores were very similar with the norm scores on all eight domains. Compared with the CI group and the general population-based norm scores, postlingually deaf adults without a CI had substantially poorer scores on the domains of social functioning, role functioning (physical and emotional), and mental health. Especially for policy makers, it may be more informative to compare the effect of CI with other medical interventions. Therefore, results of two transplant studies using the SF-36 are also summarized in Table 5. However, when these instruments are used in different types of disease or medical interventions, one should be cautious about the influences of age on the general health status and the influence of comorbidity conditions. Khan et al. (18) compared three groups of patients using the SF-36: patients with renal failure undergoing hemodialysis, patients receiving peritoneal dialysis, and patients who had undergone a renal replacement therapy (transplant). The perception of health in the hemodialysis and peritoneal dialysis patients was significantly poorer than that in the transplant patients and healthy control subjects. Part of the effect, however, was explained by differences in age and comorbidity. Rector and Kubo (21) used the SF-36 to evaluate the impact of a heart transplant on the perceived quality of life. A considerable difference was found between the patients receiving transplants and the patients on the waiting list for a heart transplant. The average age of the patients on the waiting list and the patients receiving transplants was 51 years and 53 years, respectively.

Table 5 clearly indicates that a CI has a considerable impact on the perceived HRQOL. On some of the domains, the impact was comparable to that of renal transplantation and heart transplantation. In terms of social functioning, for example, the health perception of profoundly deaf patients can be compared with those of patients receiving hemodialysis or patients awaiting a heart transplant. The greatest improvements due to a CI were found for the domains social functioning and role functioning. Not surprisingly, renal or heart transplantation mainly affects physical parameters, but these interventions also have a considerable effect on social functioning, comparable with that of a CI. Apparently, deafness has a greater association with emotional problems than renal or cardiac pathology: a CI had a strong positive effect on emotional problems.

Several studies have made use of the HUI-2 to evaluate quality of life and calculate utilities for different types of condition. Neumann et al. (20) used the instrument on patients suffering from different stages of Alzheimer's disease (moderate 0.53, mild 0.69). Not

Table 5. Mean Scores (SD in Parentheses) of the CI Study Group (Retrospective Version = pre, Standard Version = post) on the Domains of the SF-36 Instrument, Norm Scores of the SF-36, and Scores Obtained with the SF-36 for Other Diseases

		CI								
		CI study group (n = 45)			Renal replacement therapy[a]			Heart transplantation[b]		
Domain	Norm scores general population (n = 2,474)[a]	Postlingually deaf adults (pre)	Adult CI users (post)	Mean change (post – pre)	Hemodialysis (n = 43)	RTx (n = 102)	Mean change (Rtx – hem.)	Waiting list (n = 42)	HTx (n = 143)	Mean change (Htx – waiting list)
Physical functioning	84	90	85	–5	46	68	22	36	71	35
Social functioning	83	59	85	26	54	80	26	63	85	22
Role functioning (physical)	81	61	80	19	51	63	12	27	62	35
Role functioning (emotional)	81	64	85	21	75	80	5	71	77	6
Pain	75	89	83	–6	82	78	–4	60	69	–9
Mental health	75	62	77	15	66	79	13	75	77	2
Vitality	61	68	72	4	41	63	22	39	62	23
General health perception	72	—[c]	72	—	42	64	22	33	70	37

[a] Data from Khan et al. (18).
[b] Data from Rector and Kubo (21).
[c] Not measured.

unexpectedly, the average age of these patients was relatively high (63 years). Bartman et al. (3) found an HRQOL utility of 0.70 in older patients with intermittent claudication. The mean utility of a group of adult survivors of brain tumors was 0.78. Due to the heterogeneity in this group, utilities ranged from 0.2 to 1. Wyatt et al. (28) found utilities of 0.59 and 0.79 in profoundly deaf adults and in patients fitted with a CI, respectively. These results are in agreement with our own findings.

The main disadvantage of generic quality of life instruments is their relative insensitivity to some specific health-related aspects of illness. Rector and Kubo (21), for example, found that the SF-36 missed items for health-related distress, sexual dysfunction, problems with sleep, and self-image. Dougherty et al. (12) also found that the SF-36 was relatively insensitive to some clinically important changes in cardiac status and recommended the use of a disease-specific measure such as the Seattle Angina Questionnaire. Similarly, the SF-36 and especially the HUI-2 are insensitive to small changes in the hearing abilities of CI patients. Thus, they are unable to evaluate the effect of different types of CI or speech-coding strategy, even in the same group of patients. Therefore, we stress the importance of using a comprehensive disease-specific quality of life instrument, such as the NCIQ, in combination with generic instruments.

POLICY IMPLICATIONS

The improved health-related quality of life due to a CI is substantial and will last from the time of implantation until death. Therefore, we conclude that the benefits of a CI expressed in terms of the number of QALYs gained may be even greater than those associated with numerous other medical treatments for (nonlethal) diseases.

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