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The Impact of Cochlear Implantation on Health-related Quality of Life in Older Adults, Measured with the Health Utilities Index Mark 2 and Mark 3

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Abstract

Purpose: To determine the usefulness of the Health Utilities Index (HUI) in older Cochlear Implant (CI) recipients, the primary aims were: (1) to assess Health Related Quality of Life (HRQoL), measured with HUI, in older CI candidates while comparing with age-and gender-matched normal-hearing controls; (2) to compare HRQoL after CI with the preoperative situation, using HUI and the Nijmegen Cochlear Implant Questionnaire (NCIQ) . The difference between pre- and postoperative speech intelligibility in noise (SPIN) and in quiet (SPIQ) and the influence of preoperative vestibular function on HRQoL in CI users were also studied.

Methods: Twenty CI users aged 55 years and older with bilateral severe-to-profound postlingual sensorineural hearing loss and an age- and gender-matched normal-hearing control group were included. HRQoL was assessed with HUI Mark 2 (HUI2), HUI Mark 3 (HUI3) and NCIQ. The CI recipients were evaluated preoperatively and 12 months postoperatively.

Results: HUI3 Hearing ($p = 0.02$), SPIQ ($p < 0.001$), SPIN ($p < 0.001$) and NCIQ ($p = 0.001$) scores improved significantly comparing pre- and postoperative measurements in the CI group. No significant improvement was found comparing pre- and postoperative HUI3 Multi-Attribute scores ($p = 0.07$). The HUI3 Multi-Attribute score after CI remained significantly worse ($p < 0.001$) than those of the control group. Vestibular loss was significantly related to a decrease in HUI3 Multi-Attribute ($p = 0.037$) and HUI3 Emotion ($p = 0.021$) scores.

Conclusion: The HUI is suitable to detect differences between normal-hearing controls and CI users, but might underestimate HRQoL changes after CI in CI users over 55.

Keywords: Health-related Quality of Life, Cochlear Implantation, Health Utilities Index, Older Adults, Cost-utility

Declarations

Funding

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Conflict of Interest Statement

The authors have no conflicts of interest to declare.

Ethics approval

The study was carried out in conformity with the recommendations of the ethics committee of the University of Antwerp, Antwerp, Belgium and he University Hospital Antwerp, Antwerp, Belgium and the Declaration of Helsinki. The protocols for the control group and the CI users were approved on November 21, 2016 (protocol number: 16/43/450) and June 15, 2015 (protocol number: 15/17/181) respectively.

Consent to participate

All participants gave written informed consent prior to participation in accordance with the Declaration of Helsinki.

Consent for publication

Patients signed informed consent regarding using their data to write and publish this article.

Availability of data and material

To protect study participant privacy, data cannot be shared openly. The public availability of data was not included in the ethics approval of this study. The datamanagement part of the study protocol states that raw participant data can only be accessed by the principal investigators and cannot be shared or given to anyone outside the study team.

Code availability

Not applicable

Authors' Contributions

EA undertook data collection and analysis and drafted the manuscript. AG, VT, OV, PVDH, VVR and GM critically revised the manuscript. All authors read and approved the final manuscript.

1. Introduction

Older adults make up an increasing proportion of the growing world population. Since aging is one of the main causes of progressive postlingual sensorineural hearing loss (SNHL), the prevalence of hearing impairments is expected to rise as well [1]. As a result, there will be a growing need for hearing care and hearing rehabilitation [1]. Persons with mild to moderate SNHL could benefit from hearing aids, while cochlear implantation (CI) has become standard care for persons with a severe-to-profound SNHL. However, awareness amongst patients and CI health care professionals remains a key barrier to access for potential candidates, with alarmingly low rates of penetration [2].

Cochlear Implantation is increasingly performed in older adults due to the rising life expectancy of the world population [1]. Several risk factors, including prolonged duration of deafness, age-related changes in the auditory system, decreased communication abilities, co-existing health issues (multimorbidity), vestibular loss, cognitive decline and psychological problems could negatively impact CI outcomes in older adults [3-5]. Despite these constraints, several studies have shown that CI outcomes of healthy older adults are comparable to those of younger adults and that CI has a significantly positive impact on audiological performance and QoL measures in both groups [6,7]. Moreover, multiple studies have demonstrated an improvement of cognitive functioning in older adults after CI [5,8-11]. Overall, these findings and risk factors cause a growing interest in the cost-utility of CI in older adults, which is linked to CI candidacy and reimbursement .

To be able to estimate the cost-utility of any intervention, the change in perceived health state of participants needs to be evaluated by instruments measuring health-related quality of life (HRQoL), utility and/or activities in daily life. Theofilou (2013) defined HRQoL as: "*Optimum levels of mental, physical, role (e.g. work, parent, carer, etc.) and social functioning, including relationships, and perceptions of health, fitness, life satisfaction and well-being" [12].* HRQoL can be assessed using several instruments, including disease-specific and generic questionnaires. Disease-specific questionnaires evaluate particular diagnostic groups or patient populations. An example of a disease-specific HRQoL questionnaire developed and validated for CI users is the Nijmegen Cochlear Implant Questionnaire (NCIQ) [13]. Generic questionnaires, on the other hand, are broadly applicable across various diseases, interventions and populations, but are less able to detect subtle but possibly important outcome changes than disease-specific questionnaires [14-16]. However, utility can only be assessed with a limited number of generic questionnaires, including the Health Utilities Index (HUI) and the EuroQoL (EQ)-5D-5L [17,18].

The HUI is a validated and standardized generic questionnaire system, developed to measure HRQoL and health states in a wide variety of subjects, diseases, interventions and therapies [17]. The instrument has been used to conduct large general and clinical population health studies in several countries, of which population reference data are publically available [19]. The first version of HUI, the HUI Mark 1 (HUI1), was developed to monitor the health-related outcomes of infants with very low birthweights [20,21]. Based on the most important attributes of HUI1, the HUI Mark 2 (HUI2) has subsequently been developed, specifically for the evaluation of treatment outcomes after childhood cancer [17]. However, the instrument turned out to be much more widely applicable than originally envisaged and was applied in various groups of patients with a wide range of disabilities [22,23]. The HUI Mark 3 (HUI3) is the latest and most extended version of HUI. It is considered as the measure for primary analysis because of its detailed descriptive system, the availability of population norms and its structural independence [17,24]. In the field of CI, HUI3 is generally considered as the most sensitive and consistent instrument for studies evaluating health utility according to Crowson et al. (2018) [25]. However, HUI2 and HUI3 are complementary as HUI2 includes attribute levels for fertility and self-care, which are not covered by HUI3. Therefore, HUI currently consists of HUI2 and HUI3 classification systems, which are jointly able to determine approximately 1.000.000 health states [17]. Attribute levels, single-attribute scores and multi-attribute scores can be derived and calculated from HUI questionnaires [17]. Multi-attribute scores provide an overall HRQoL measure and can be utilized to estimate cost-utility using Quality Adjusted Life Years (QALYs) [26]. QALYs are the main internationally recognized metrics to evaluate cost-utility of medical interventions. QALYs are calculated by multiplying the time spent in a health state with the utility score of that health state in order to weigh up the costs of an intervention against its benefits.

HUI has previously been assessed in an elderly population, but limited studies have been conducted using HUI to evaluate HRQoL and cost-utility in older CI users [7,27-29]. Focused studies on HUI in older CI users are needed as the HUI items related to communication might be impacted by hearing performance before and after CI. In addition, the great variety of HRQoL questionnaires available for CI users cause a lack of consensus regarding HRQoL measurement in the field of CI. HUI and other generic HRQoL measures are neither developed nor validated to be used in a CI population. This raises questions whether those instruments alone are sufficiently sensitive to detect differences in HRQoL before and after CI, especially because cost-utility calculations are based on the outcomes of these measures [30]. It would be interesting to see if changes in HUI scores are equivalent to changes in scores of CI-specific questionnaires such as NCIQ. Therefore, this study includes the following two primary aims: 1) to assess HRQoL, measured with HUI, in older adult CI candidates while comparing with age-and gender-matched normal hearing controls; 2) to compare HRQoL after CI with the preoperative situation, using HUI and NCIQ. The following two secondary aims are also studied: 1) to evaluate the difference in best-aided speech intelligibility in noise (SPIN) and in quiet (SPIQ) between

CI users before and after CI. In addition, the association between the difference in self-perceived hearing loss (HUI3 Hearing score) and the difference in SPIN and SPIQ results will be investigated in the CI group; 2) to study the influence of vestibular function on HRQoL in CI users preoperatively.

2. Materials and Methods

2.1 Ethics

This longitudinal prospective controlled study was carried out in conformity with the recommendations of the ethics committee of the University of Antwerp, Antwerp, Belgium and he University Hospital Antwerp, Antwerp, Belgium. The protocols for the control group and the CI users were approved on November 21, 2016 (protocol number: 16/43/450) and June 15, 2015 (protocol number: 15/17/181) respectively. All participants gave written informed consent prior to participation in accordance with the Declaration of Helsinki.

2.2 Participants

A consecutive sample of 20 adults (10 males, 10 females) aged 55 years and older with a bilateral postlingual severe-to-profound SNHL were included in the study between November 2016 and January 2019. The age cut-off of 55 years was chosen based on a neurologic perspective on aging, as Gallacher et al. (2012) found that this age is the youngest mean age in which presence of HL was shown to increase dementia [31]. Hence, in this study the term “older adults” or “older CI users’” reflects the oldest group of patients in the spectrum of CI recipients, as persons of all ages (from babies to elderly) can be CI candidates. The participants were all scheduled for their first unilateral cochlear implantation with a multi-electrode CI at the Department of Otorhinolaryngology, Head and Neck Surgery of the Antwerp University Hospital (UZA), Antwerp, Belgium. Every subject was eligible for the reimbursement of a CI according to the National criteria in Belgium at the time of enrollment: (1) the hearing threshold in the ear with the best pure tone average (PTA) is at least 85dB HL at 500, 1000 and 2000 Hz, (2) speech recognition scores are 30% or less for Dutch open-set monosyllabic words presented at 70dB SPL in quiet in best-aided condition and (3) in brainstem evoked response audiometry, peak V thresholds are at least 90dB nHL. All patients had a thorough multidisciplinary evaluation before surgery, including a consultation with a psychologist and comprehensive counseling about their expectations towards the CI outcomes and the rehabilitation process. The speech processor was activated approximately four weeks postoperatively and its settings were optimized during regular fitting appointments. The CI recipients were evaluated one month preoperatively and 12 months postoperatively. Table 1 presents more information on the demographics of the CI group.

In addition, a population-based sample of 103 participants aged 50 – 89 years was recruited by advertising in the hospital, by means of the population registries made available by the local city councils in Antwerp (Belgium) and by approaching family, friends and acquaintances. The participants had normal hearing thresholds according to age between 250 Hz and 8kHz according to BS 6951:1988, EN 27029:1991, and ISO 7029-1984 standards. Out of this sample, twenty controls were matched to the CI group according to age and gender.

Overall, subjects were excluded if they had a history of any neurological disease (e.g. Parkinson's Disease, dementia, cerebrovascular accident, etc.) and/or if their Dutch language skills were limited. CI users with bilateral vestibulopathy (BVP) or other vestibular disorders were not excluded. The mean age of the CI recipients at implantation and the control group was 69 years (range: 55 – 82 years).

2.3 HRQoL assessment

2.3.1 Health Utilities Index

HUI is a standardized and validated 17-item questionnaire system including two complementary classification systems, HUI2 and HUI3. HUI3 is defined as the outcome measure for primary analysis. HUI2 and HUI3 each consist of three different types of outcome measures: attribute levels, single-attribute utility scores and multi-attribute utility scores. Attribute levels represent health states of participants, ranging from 1 (no disability) to 6 (severe disability). Single- and multi- attribute scores vary from dead (0.00) to perfect health (1.00) and are calculated using scoring functions based on community preference measures for health states. Single-attribute scores describe HRQoL per attribute level, while multi-attribute scores provide a general HRQoL value. As a result, the HUI3 multi-attribute score was used as the measure for primary analysis in this study. In Table 2, the attributes of HUI2 and HUI3 are presented. HUI2 Fertility was not included in the statistical analyses because it was considered irrelevant for the older adult population in this study. HUI was assessed approximately two weeks preoperatively and 12 months postoperatively in CI users. The control group did not receive an additional follow-up HUI assessment.

2.3.2 Nijmegen Cochlear Implant Questionnaire

The NCIQ is a 60-item disease-specific measure for QoL and focuses on the needs of CI recipients [13]. It is categorized in the following 6 subdomains, each containing 10 items: 1) Basic sound perception; 2) Advanced sound perception; 3) Speech production; 4) Self-esteem; 5) Activity; 6) Social interactions. The first 55 items are formulated as statements with 5 answer categories to indicate the degree to which the statement is true: never, sometimes, often, mostly, and always. The other 5 items will be answered according to the CI user's ability to perform the action in question: no, poorly, moderate, adequate, and good. If a statement does not apply to a patient, a sixth answer can be given: "not applicable." Scores vary from 0 to 100, with higher scores indicating better HRQoL. The CI users filled in the NCIQ preoperatively and 12 months postoperatively.

2.4 Speech audiometry assessment

The Nederlandse Vereniging voor Audiologie (NVA) lists were used to quantify speech recognition in quiet and the Leuven Intelligibility Sentences Test (LIST) was performed to assess speech perception in noise [32,33] in best-aided condition in the CI users pre- and postoperatively. Both tests were performed according to current clinical standards (ISO 8253-1, 2010). Preoperatively, the best-aided condition could be either unaided or aided with uni- or bilateral hearing aid(s), while postoperatively, it could be either with unilateral CI or with unilateral CI and contralateral hearing aid. The NVA lists were performed at 65 dB SPL in quiet in free field, with the participant sitting in front of the loudspeaker, positioned at ear level, at a one-meter distance in a sound treated booth. The percentage of correctly identified phonemes represented the speech perception score in quiet. The LIST was performed with a noise level fixed at 65 dB SPL and the speech level adapted to the participants' responses. If participants were able to identify all bold keywords of the current sentence correctly, the speech level of the next sentence was reduced with 2 dB SPL. If not, the speech level of the next sentence was increased with 2 dB SPL. The Speech Reception Threshold (SRT) was calculated by averaging the level of the last 5 sentences together with the level of the imaginary 11th sentence of the list.

2.5 Vestibular function evaluation

Vestibular function was assessed preoperatively in the CI group with the rotatory chair test (Nystagliner Toennies, Germany) and bithermal caloric tests. Electronystagmography (ENG) was used to perform nystagmus recordings during these tests. The rotatory chair test was performed using sinusoidal rotation (0.05 Hz) with a peak velocity of 60°/sec. More detailed methodology and norm values have been described by Van der Stappen et al. (2000) [34]. Bithermal (30°/44°) caloric irrigation was performed with patients in supine position with a head-incline of 30°.

2.6 Data management

All data were acquired and analyzed by an ICH-GCP accredited researcher and stored in an OpenClinica (OpenClinica LLC, Waltham, MA) database, an online application designed for electronic data collection and management in clinical studies.

2.7 Statistics

IBM SPSS Statistics version 21 (IBM Corp., New York, NY) was used to perform the statistical analysis. The HUI3 multi-attribute score was regarded as the measure for primary analysis. All other HUI3 and HUI2 scores, NCIQ scores, speech audiometry and vestibular function test results were considered as secondary outcome measures in this study. HUI scores of the control group were compared with the scores of the CI users, both pre-and postoperatively. Additionally, the HUI, NCIQ, SPIQ and SPIN results of the CI users before implantation were compared with the postoperative situation. The non-parametric Wilcoxon signed-rank test and the Mann-Whitney U test were used to carry out the pairwise comparisons between CI users pre- and postoperatively and the unpaired comparison between the control group and the CI users pre-and postoperatively, respectively, due to the small sample size (n = 20). In addition, Bonferroni correction was applied by adjusting the significance level ($\alpha_{original} = 0.05$) to correct for multiple HUI3 Multi-Attribute score comparisons ($\alpha_{corrected} = 0.05 / 3 = 0.017$). For the secondary outcome measures, no corrections were applied ($\alpha = 0.05$). The non-parametric Spearman rank-order correlation between the CI users' preoperative HUI scores and preoperative vestibular test results (rotatory chair gain, caloric right sum, caloric left sum) and between the difference in HUI3 Hearing score (∆ HUI3 Hearing) and the difference in speech intelligibility results (∆ SPIN and ∆ SPIQ), both after CI compared to preoperatively, were also calculated.

3. Results

As shown in Table 3, there is a statistically significant difference between HUI3 Multi-Attribute scores of normal hearing controls and the CI users, both pre- ($|x| = 0.30$; $p < 0.001$) and postoperatively ($|x| = 0.22$; $p < 0.001$). Normal hearing controls showed significantly higher HUI3 Multi-Attribute scores than the severely hearing-impaired participants, regardless of their CI. Further statistical analyses showed that CI users preoperatively had significantly lower HUI2 Sensation ($p < 0.001$), HUI2 Multi-Attribute ($p = 0.01$), HUI3 Hearing ($p <0.001$) and HUI3 Emotion ($p = 0.04$) scores than normal hearing controls. CI users postoperatively only obtained significantly lower scores for HUI3 Hearing compared to normal hearing controls ($p < 0.001$). Moreover, no significant difference was found between the pre- and postoperative HUI3 Multi-Attribute scores in the CI group ($|x| = 0.08$; $p = 0.07$). Preoperatively, CI users demonstrated significantly lower scores on HUI3 Hearing ($p = 0.020$), HUI3 Speech ($p = 0.02$) and HUI2 Sensation scores ($p = 0.03$) than postoperatively. HUI3 Vision, HUI3 Ambulation, HUI3 Dexterity, HUI3 Cognition, HUI3 Emotion, HUI3 Pain, HUI2 Mobility, HUI2 Emotion, HUI2 Cognition, HUI2 Self-Care and HUI2 Pain did not differ significantly after CI compared to preoperatively. Figure 1 presents the most striking results. NCIQ results are presented in Figure 2. NCIQ data was missing for one CI user. Overall, both the NCIQ total score and the subdomain scores improved significantly after CI. For example the median total score was 42.08 [31.91; 48.48] preoperatively and increased to a median total score of 55.51 [48.31; 75.47] 12 months postoperatively ($p = 0.001$).

A significant improvement of SPIQ ($|x| = 66$ dB; $p < 0.001$), as well as SPIN ($|x| = 16.16$ dB SNR; $p < 0.001$), was observed after CI compared to preoperatively, as depicted in Figure 3. There was a significant negative correlation between △ HUI3 Hearing and △ SPIN ($r_s = -0.564$; $p = 0.01$), but no correlation between △ HUI3 Hearing and △ SPIQ ($r_s = 0.177$; $p = 0.454$) after CI compared to the preoperative situation. Furthermore, preoperative ENG tests were performed in 15 out of 20 patients. Two out of the remaining five patients underwent video Head Impulse Testing (vHIT), which was introduced to our CI program in a later stage. The other three patients received their vestibular assessment postoperatively rather than preoperatively. Three out of 15 patients suffered from Bilateral Vestibulopathy (BV). There was a significant positive correlation between the preoperative rotatory chair gain and both the preoperative HUI3 Multi-Attribute score ($p = 0.037$) and HUI3 Emotion score ($p = 0.021$) in the CI users. There was no significant correlation between the rotatory chair gain and the remaining HUI scores, as well as between the results of the caloric tests and the HUI scores in the CI group before implantation. The Spearman correlation coefficients are presented in Table 4.

4. Discussion

This study aimed to assess the impact of cochlear implantation on HRQoL, measured with HUI, in older adults comparing the results with age-and gender-matched normal hearing controls in order to evaluate the usability of HUI in CI recipients. In general, the results suggested that normal-hearing controls have a better overall HRQoL than CI users pre- as well as postoperatively. More detailed analyses pointed out that the CI users' self-perceived hearing-impairment could have mainly caused their reduced HUI HRQoL scores compared to the control group. The difference between the perceived hearing loss of CI users, measured with HUI, before implantation compared to after CI was statistically significant, which is in line with the outcomes of Francis et al. (2002) Arnoldner et al. (2014) and Zwolan et al. (2014) [29,27,7]. Nevertheless, CI users postoperatively still reported a significantly greater hearing loss severity than the control group, while objective speech intelligibility significantly improved after implantation compared to preoperatively. A possible explanation for these findings might be that only two questions about hearing loss are included in HUI, including one question concerning speech understanding in a group conversation which still poses a problem after implantation for most CI users. Hence, HUI might be missing other important abilities and disabilities that contribute to hearing-related HRQoL of CI users such as communication abilities and social and psychosocial functioning, which are included in NCIQ. Furthermore, CI users could under- or overestimate their hearing loss, which was clearly the case in one of the CI users in this study who indicated not perceiving any hearing impairment preoperatively. Another possible explanation concerns the great variety in outcomes after CI, which depends on several other important factors besides hearing loss. Lazard et al. (2012) demonstrated that duration of deafness and preoperative hearing aid use have a significant effect on speech perception with CI, while level of education, gender and the ear of implantation (based on best or worse PTA) show no significant impact [35]. Additionally, lack of auditory stimulation could accelerate cognitive decline according to several studies [5,9-11,8]. Hence, prevention of auditory deprivation partially determines CI outcomes and could partially explain the difference with the control group. Vestibular disorders such as BVP are strongly related to severe-to-profound SNHL and could also have a considerable impact on the HRQoL scores of the CI patients before and after implantation, without affecting the HRQoL of the control group [36,4]. In addition, HL is generally associated with a higher prevalence of anxiety and depression in older adults, which would imply that the CI group possibly showed more anxiety and depression symptoms than the NH control group [37,38]. These findings were partially confirmed in our study, with HUI3 Emotion significantly deferring between the CI users preoperatively and the NH control group, but not between the CI users postoperatively and the NH controls.

Contrary to expectations, general HRQoL did not significantly improve after implantation compared to HRQoL before implantation in the primary outcome measure of the study (HUI3 Multi-Attribute score). This finding is contrary to the outcomes of Francis et al. (2002), Arnoldner et al. (2014) and Lenarz et al. (2017), who did establish a significant difference ($p < 0.001$) on overall HRQoL, measured with HUI, comparing the postoperative situation with the preoperative measurement in the CI group [39]. NCIQ scores, on the other hand, improved considerably after CI compared to preoperatively which is consistent with recent literature [5,40]. According to our findings, HUI underestimates changes in overall HRQoL induced by cochlear implantation, which supports the results of Zwolan et al. (2014) and confirms the findings regarding generic questionnaires of Patrick (1989) and Lin (2012) Andries et al. (2020) and McRackan et al. (2018) [30]. These results may be explained by the fact that HUI includes topics unrelated to CI, such as dexterity, ambulation or vision. Therefore, a large amount of health factors could have had an influence on the HUI3 Multi-Attribute score, especially in older CI recipients. Older participants often suffer from health issues associated with ageing such as arthritis, rheumatism, etc., which could have had a negative impact on the HUI3 Multi-Attribute score [41]. The discrepancy between the results of this study and the study of Arnoldner et al. (2014) could therefore be attributed to the fact that Arnoldner et al. (2014) also included younger participants and did not divide their participants in age groups. Hence, age-related health issues might have had no impact on the HUI3 Multi-Attribute score in Arnoldner et al.'s (2014) study but might have influenced the HUI3 Multi-Attribute score in our study. However, if age-related health ailments were the only influencing factor of overall HRQoL, this would imply that the control group's overall HRQoL results presumably would not significantly differ from those of CI recipients postoperatively. Therefore, another possible explanation for the lack of significant difference between pre- and postoperative HRQoL in the CI group would be a negative impact of hearing loss comorbidities such as vestibular loss on HRQoL, which might have been present in the participants with severe to profound SNHL but not in the control group, as mentioned. Reduction or loss of vestibular function was significantly related to a decrease in overall HRQoL and utility indices for emotion, which is in line with the findings of Agrawal et al. (2018) who compared HUI scores of patients with vestibular loss to a matched healthy control group. Agrawal et al. (2018) also reported significantly negative associations between vestibular loss and vision, dexterity and speech utility indices. However, our vestibular evaluation was limited to the lower frequencies functioning of the lateral semi-circular canals and did not assess all six semicircular canals and higher frequencies functioning. More elaborate vestibular assessments can be performed using vHIT, but this test was only recently introduced to our CI program, after the start of the study. Hence, further research should be undertaken to investigate the association between vestibular loss and HRQoL in CI users. Lenarz et al. (2017) also demonstrated a significant negative influence of hearing loss comorbidities, dizziness and tinnitus on HUI scores in their study. They reported that comorbidities were absent in the vast majority of their participants, while Francis et al. (2002) did not report comorbidities in their study. Possibly, the participants in our study had more comorbidities than those of Francis et al. (2002) and Lenarz et al. (2017), leading to a less pronounced overall HRQoL difference. HUI does not include items specifically addressing HL comorbidities as it is a generic questionnaire, developed to be applicable in a large variety of health conditions. Therefore, potentially important factors influencing the HRQoL of individuals with SNHL cannot be deduced from HUI results only.

An appropriate supplement to generic questionnaires, such as HUI, would be disease-specific questionnaires or in this case hearing specific and CI-specific questionnaires. Hearing-specific instruments, e.g. the Speech Spatial and Qualities of Hearing questionnaire (SSQ) or the Abbreviated Profile of Hearing Aid Benefit (APHAB), are developed and validated to be used specifically in hearing-impaired subjects to assess self-perceived sound quality, sound localization, speech perception, etc. [42-44]. These instruments provide an overview of the communication issues persons with hearing loss could experience in daily life in addition to objective tests, such as pure tone and speech audiometry. In our study, the difference in objective SPIN results was significantly associated with the difference in self-perceived hearing impairment in the CI group postoperatively compared to the preoperative situation, but the difference in objective SPIQ results and the difference in self-perceived hearing impairment were not. Current objective speech audiometry tasks alone are, therefore, often not fully representative for complex real-life communication. Nevertheless, hearing-specific instruments are validated primarily in persons with mild to moderate hearing loss and / or hearing aids and not particularly in CI recipients. Hence, these instruments possibly do not capture the whole spectrum of hearing-related problems CI recipients perceive [40,45]. On the other hand, CI-specific questionnaires, such as the NCIQ, are developed and validated for use in CI recipients [13]. In our study, the NCIQ scores showed a greater impact of CI on HRQoL than HUI results. This might be caused by the fact that the NCIQ, on the one hand, more elaborately assesses sound perception in various situations and, on the other hand, includes factors relevant for CI users that are not or only conditionally included in the HUI such as psychological and social functioning. Hence, the NCIQ focuses more on domains of significance for HRQoL in CI users and might, therefore, be more useful in this population compared to the HUI. The main limitation of NCIQ is the lack of involvement of CI recipients in the establishment of the instruments' item bank, which could lead to relevant items not being included in the final version of the questionnaire [45]. The new CI-specific Cochlear Implant Quality of Life questionnaire developed by McRackan et al. (2019), which is based on a new HRQoL item-bank for CI users, seems promising in this regard but is not translated or validated in Dutch and was not released before the start of our study [46]. In addition, caution is needed to not overestimate the estimated effect of cochlear implantation when using hearing-specific or CI-specific questionnaires [13,47]. Moreover, disease-specific questionnaires cannot be an alternative to generic questionnaires in terms of cost-utility estimation. A careful selection of HRQoL questionnaires based on the research aim and the study design is therefore recommended. Future studies should use a HRQoL assessment protocol including adequate utility, HRQoL and daily life performance measures.

Francis et al. (2002) and Arnoldner et al. (2014) found that utility indices for emotion of CI users postoperatively were significantly higher than those of CI users preoperatively. Francis et al. (2002) reported that this increase in emotion utility scores could be attributable to the significant improvement in speech intelligibility after cochlear implantation. They found a significant correlation between speech recognition scores and HUI emotion utility scores. However, the speech intelligibility scores of our participants also improved significantly before compared to after CI, but no significant difference in emotional state was demonstrated. Hence, our participants might have had better psychological counseling before implantation or might have been more emotionally stable than the participants of Francis et al. (2002) and Arnoldner et al. (2014). Furthermore, HUI scores for cognition did not significantly differ between all groups, while several large studies demonstrated that cochlear implantation generally improves cognitive abilities [9,5,8,10,11]. The reason for this could be that the participants' perceived cognitive functioning might not correspond with their actual cognitive abilities. Supplementary cognitive tests adjusted for hearing loss need to be administered to assess cognition in more detail. Interestingly, the results suggested that CI users preoperatively could supposedly produce less understandable speech than CI users postoperatively. The two speech questions of HUI concern the degree to which relatives and strangers are able to understand the participant. Persons with hearing impairment often have problems following conversations and could therefore sometimes answer or react beside the point. Hence, their conversation partners might not react as expected, giving the impression that they did not understand them. In addition, it seems plausible that this result could be due to a misinterpretation of the two speech questions by the CI users. In Dutch, these questions are formulated in passive voice (e.g. was understood) which might have confused them. Furthermore, the small sample size of our study did not allow Bonferroni correction to be applied on the secondary outcome measures such as HUI3 Hearing. Future research is required to establish these results with certainty. No statistical model could be applied to determine the influence of hearing loss comorbidities and other mentioned factors on HRQoL in CI users due to the small sample size. Further research is therefore recommended to develop a full picture of the factors affecting HRQoL in older CI users. In addition, the large age range (55 – 82 years) of the participants in this study could have caused variability in HUI scores. Zwolan et al. (2014) found that the preoperative HUI3 Multi-Attribute score of CI users aged 65 years and older did not differ significantly from the 6 or 12 month post CI scores, while this was the case in their CI users aged under 65. In our study, the sample size was too small to divide our participants in age groups to provide an estimation of the effect of age on our measurements. Hence, future studies are needed to clarify if HUI might be more appropriate in a subgroup of CI users, based on age at implantation.

5. Conclusion

The HUI is a suitable instrument for the evaluation of HRQoL differences between normal hearing controls and CI users, but may underestimate the positive impact of CI on HRQoL in CI users over 55. A complex array of difficulties including psychosocial factors and HL comorbidities might have an influence on CI outcome, which can be difficult to identify with HUI only. Therefore, adding hearing-specific and/or CI-specific questionnaires is recommended to obtain additional and more detailed information about the HRQoL of CI users. Further research is needed to generate a HRQoL assessment protocol, including generic and disease-specific HRQoL and daily life performance questionnaires to evaluate HRQoL comprehensively in this population.

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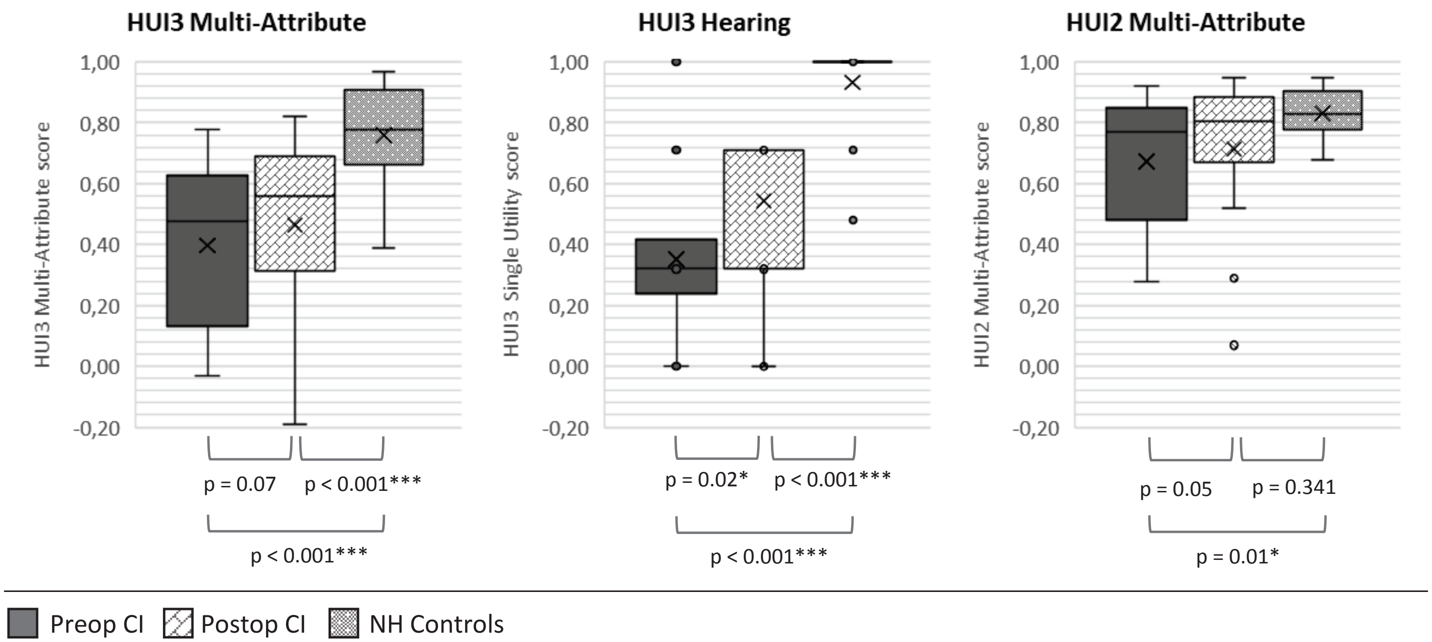
Figure 1

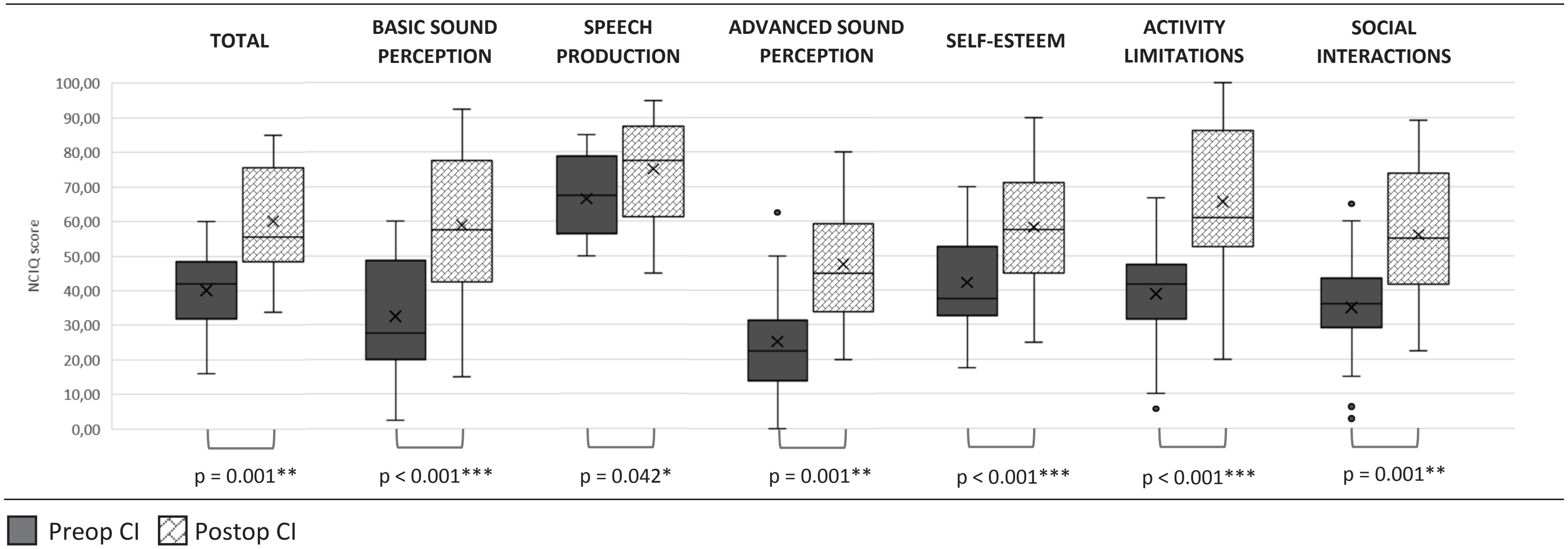
Figure 1. Overview of HUI3 Multi-Attribute, HUI3 Hearing and HUI2 Multi-Attribute scores (n = 20)



Notes: ** indicates p < 0.05; ** indicates p < 0.01; *** indicates p < 0.001*

Figure 2

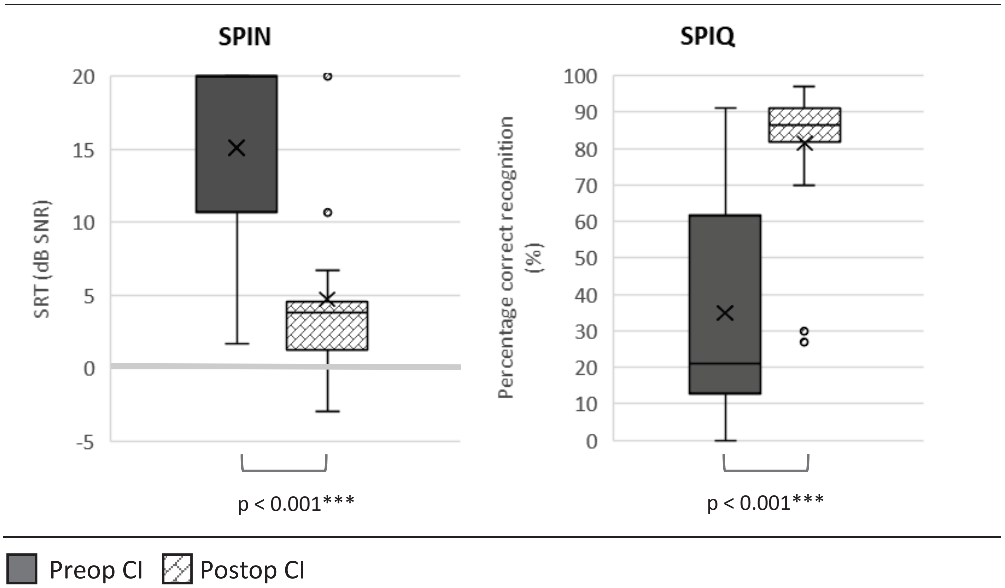
Figure 2. NCIQ results in CI users (n = 19)



Notes: ** indicates p < 0.05; ** indicates p < 0.01; *** indicates p < 0.001*

Figure 3

Figure 3. Overview of speech audiometry results in quiet and in noise in CI users (n = 20)



Notes: ** indicates p < 0.05; ** indicates p < 0.01; *** indicates p < 0.001*

Table 1

Table 1. Demographics CI group

	Sex	Age at implantation (yr)	Duration HL right (yr)	Duration HL left (yr)	Cause HL	HA use preop	Duration HA use preop (yr)	Side of implantation	CI and electrode	Speech processor	Contralateral HA use after CI
1	f	63	20	2	Menière	Bilateral	2	Right	Synchrony flex28	SONNET	Yes
2	m	67	20	11	Hereditary	Unilateral (left)	8	Left	Synchrony flex28	SONNET	No
3	m	76	0,3	0,3	Trauma	No	0	Right	Synchrony flex28	SONNET	No
4	m	56	26	26	Unknown	Bilateral	12	Right	Synchrony flex28	SONNET	Yes
5	m	66	30	30	Unknown	Bilateral	6	Right	Synchrony flex28	SONNET	Yes
6	f	74	20	20	Hereditary	Bilateral	18	Right	Synchrony flex28	SONNET	Yes
7	m	81	26	26	Unknown	Bilateral	25	Right	Synchrony flex28	SONNET	No
8	m	72	67	15	Meningitis right, Sudden left	Unilateral (left)	15	Left	Synchrony flex28	SONNET	No
9	f	59	30	0,8	Otosclerosis	Bilateral	7	Right	Synchrony flex28	SONNET	Yes
10	f	56	17	17	Unknown	Bilateral	10	Left	Synchrony flex28	SONNET	Yes
11	m	82	38	38	Unknown	Unilateral (left)	10	Left	Synchrony flex24	SONNET	No
12	m	72	3	3	Unknown	Unilateral (right)	1	Left	Synchrony flex28	SONNET	No
13	m	55	12	12	Hereditary	Bilateral	10	Left	Slim Modiolar	CP1000	No
14	f	67	29	29	Otosclerosis	Bilateral	27	Right	Synchrony flex28	SONNET EAS	Yes
15	f	72	7	7	Hereditary	Unilateral (left)	5	Right	Synchrony flex28	SONNET	No
16	f	77	7	7	Unknown	Bilateral	10	Right	Synchrony flex28	SONNET EAS	Yes
17	m	78	32	32	Unknown	No	0	Right	Synchrony flex28	SONNET EAS	No
18	f	63	24	24	Hereditary	Bilateral	18	Right	Synchrony flex28	SONNET EAS	Yes
19	f	59	Unknown	Unknown	Otosclerosis	Bilateral	4	Left	Synchrony flex28	RONDO 2	Yes
20	f	63	56	56	Unknown	Unilateral	53	Right	Synchrony flex28	SONNET DL	No

Table 2

Table 2. HUI2 and HUI3 attributes

HUI3 attributes	**HUI2 attributes**
Vision	Sensation
Hearing	
Speech	
Ambulation	Mobility
Dexterity	
Emotion	Emotion
Pain	Pain
Cognition	Cognition
	Self-Care
	Fertility

Table 3

Table 3. Overview HUI2 and HUI3 scores (n=20) and p-values of pairwise comparisons

	Preop CI	**Postop CI**	**NH Controls**	**Preop CI vs Postop CI**	**Preop CI vs NH controls**	**Postop CI vs NH Controls**
HUI3 Multi-Attribute[l]	0.48 [0.13 – 0.62]	0.56 [0.32 – 0.68]	0.78 [0.67 – 0.91]	0.07	< 0.001***	< 0.001***
HUI3 Vision	0.95 [0.95 – 0.95]	0.95 [0.95 – 0.95]	0.95 [0.95 - 0.95]	0.32	0.82	0.64
HUI3 Hearing	0.32 [0.24 – 0.32]	0.71 [0.32 – 0.71]	1.00 [1.00 – 1.00]	0.02*	< 0.001***	< 0.001***
HUI3 Speech	1.00 [0.78 – 1.00]	1.00 [1.00 – 1.00]	1.00 [1.00 – 1.00]	0.02*	0.05	0.78
HUI3 Ambulation	1.00 [0.96 – 1.00]	1.00 [0.83 – 1.00]	1.00 [1.00 – 1.00]	0.13	0.60	0.27
HUI3 Dexterity	1.00 [1.00 – 1.00]	1.00 [1.00 – 1.00]	1.00 [1.00 – 1.00]	0.46	0.76	0.58
HUI3 Emotion	0.91 [0.91 – 1.00]	0.92 [0.91 – 1.00]	1.00 [0.91 – 1.00]	0.05	0.04*	0.20
HUI3 Cognition	1.00 [0.92 – 1.00]	1.00 [0.91 – 1.00]	1.00 [0.92 – 1.00]	0.57	0.08	0.70
HUI3 Pain	0.92 [0.77 – 1.00]	0.92 [0.77 – 1.00]	0.92 [0.77 – 0.92]	0.25	0.50	0.76
HUI2 Multi-Attribute	0.77 [0.48 – 0.85]	0.81 [0.67 – 0.88]	0.83 [0.78 – 0.90]	0.05	0.01*	0.34
HUI2 Sensation	0.65 [0.49 – 0.65]	0.87 [0.65 – 0.87]	0.87 [0.87 – 0.87]	0.03*	< 0.001***	0.15
HUI2 Mobility	1.00 [0.98 – 1.00]	1.00 [0.92 – 1.00]	1.00 [1.00 – 1.00]	0.25	0.60	0.28
HUI2 Emotion	1.00 [0.86 – 1.00]	0.86 [1.00 – 1.00]	1.00 [1.00 – 1.00]	0.20	0.31	0.18
HUI2 Cognition	1.00 [0.86 – 1.00]	1.00 [0.86 – 1.00]	1.00 [0.86 – 1.00]	0.06	0.16	0.80
HUI2 Self-Care	1.00 [1.00 – 1.00]	1.00 [1.00 – 1.00]	1.00 [1.00 – 1.00]	0.11	0.78	0.57
HUI2 Pain	0.95 [0.95 – 1.00]	0.98 [0.75 – 1.00]	0.95 [0.75 – 1.00]	0.71	0.70	0.62

Notes: All scores denote median [inter-quartile range]; [l]Measure for primary analysis, significance level α=0.017 (the other reported measures are secondary outcome measures, significance level α=0.05); * indicates p < 0,05; ** indicates p < 0.01; *** indicates p < 0,001

Table 4

Table 4. Correlation coefficient ENG results and HUI23 scores in CI candidates preoperatively (n=15)

	Rotatory chair gain	Caloric right sum	Caloric left sum
HUI3 Multi-Attribute	0.54*	0.35	0.38
HUI3 Vision	0.29	0.31	0.24
HUI3 Hearing	0.31	0.10	0.13
HUI3 Speech	0.27	0.39	0.49
HUI3 Ambulation	0.12	-0.03	0.17
HUI3 Dexterity	0.31	0.35	0.37
HUI3 Emotion	0.59*	0.43	0.47
HUI3 Cognition	-0.08	0.18	0.16
HUI3 Pain	-0.03	0.03	-0.01
HUI2 Multi-Attribute	0.10	-0.08	-0.14
HUI2 Sensation	0.28	0.14	0.18
HUI2 Mobility	0.12	-0.03	0.17
HUI2 Emotion	0.15	-0.15	-0.15
HUI2 Cognition	-0.16	0.12	0.07
HUI2 Self-Care	-	-	-
HUI2 Pain	-0.30	-0.16	-0.27

Notes: ** indicates $p < 0.05$; - indicates that the HUI2 Self-Care score is constant and r could not be calculated*