

Critical Review:

Based on health related quality of life (HRQoL) outcome measures, are cochlear implants (CIs) a suitable treatment option for adults with profound post-lingual deafness?

Pheba Ninan, M.Cl.Sc (AUD) Candidate
University of Western Ontario: School of Communication Sciences and Disorders

This purpose of this critical review is to provide clinicians with an evidence-based answer regarding the possible benefits of CIs on HRQoL. Study designs include four single groups with repeated measures, one case-control and randomized control study. Overall, evidence suggests that HRQoL is improved with the use of CIs in adults with post-lingual deafness. However, the benefits of CIs are dependent on length of deafness and other factors that warrants further investigation. Moreover, clinicians need to be mindful of possible methodological flaws in these studies when considering the results.

Introduction

Patients with severe and profound hearing impairments have been recommended for cochlear implants (CIs) after repeated attempts with hearing aids. Unlike traditional amplification devices, CIs are surgically implanted into the cochlea and have been a means of reproducing a sense of sound awareness and physical hearing for some patients. CIs have been proven successful in terms of speech perception in quiet and noisy situations and speech production (Klop, et al. 2008).

While considering factors of speech perception, speech production and physical hearing, it is important to consider the patient's satisfaction with life and their psychological and social well-being before and after receiving the implants. In addition to hearing loss, hearing impaired individuals who have had limited success with traditional amplification also experience deterioration in general health status, social isolation, anxiety, depression, loss of relationships with family and friends and general dissatisfaction with life (Maillet et al. 1995; Klop, et al. 2008; Cohen et al., 2004). It is important to examine whether CIs improve these aspects in addition to providing speech perception. These aspects are important indicators in evaluating the benefits of CIs and can provide essential information about the effectiveness of CIs. Health-related quality of life (HRQoL) measures have been used to quantify the psychological and social domains of patients before and after cochlear implantation. Research studies use HRQoL as a common term to refer to one's physical, social, emotional and psychological domains (Cohen et al., 2004). Evaluating these measures goes beyond merely examining the acoustic and perceptual changes that may have occurred after receiving CIs. Speech production and perception scores are measured in the sound booth and do not capture how the patient copes in the real world with the CIs. On the other hand, HRQoL measures evaluate the benefit of CIs on psychological and social domains and provide a real-life picture of how the patient copes outside the sound booth after cochlear implantation.

Currently, closed-set questionnaires such as the Nijmegen Cochlear Implantation Questionnaire (NCIQ),

the Quality of Well-Being Scale (QWB), Patient Quality of Life Form (PQLF), and Assessment of Quality of Life (AQoL), to name a few are used to evaluate HRQoL measures before and after implantation. Closed-set questionnaires provide a more systematic basis of evaluation and quantifiable scores for the use of analysis (Krabbe et al., 2000).

Objectives

The objective of this paper was to outline and critically evaluate whether CIs are advisable for adults with post-lingual deafness based on HRQoL measures before and after cochlear implantation. This review examines selected studies that have considered the effect of CIs on the health status of adults with severe to profound post-lingual deafness.

Methods

Search Strategy

Computerized databases including PubMed, CINAHL, SCOPUS, PsycINFO, and Google Scholar were searched using: [(cochlear implants) OR (cochlear implantation) AND [(health-related quality of life) OR (quality of life)] AND [(adult)]. The search was limited to peer-reviewed studies, in English, conducted on adult human subjects with CIs versus no CIs. Reference sections in the obtained articles were reviewed to locate additional relevant articles.

Selection Criteria

Studies selected for this critical review were required to investigate the effect of cochlear implantation on the HRQoL of post-lingually deafened adults. No limit was set on HRQoL questionnaires used, the type of implanted device or demographics of the adult participants (age, race, gender or socioeconomic status). Studies from Europe, North America and Australia were included.

Data Collection

A review of the literature yielded six original articles consistent with the above selection criteria. The retrieved articles included four single group or case-series with

repeated measures, which provided a grade 3 level of evidence. One randomized control trial that provided a grade 1 level of evidence. The final article is a matched control study that provided a grade of 2b level of evidence (Dolloghan, 2007). There is variety in the research groups represented as all the studies are from different research departments.

Results

Single group with repeated measures

Harris, Anderson & Novak (1995) used a single group with repeated measurements to investigate and quantify the emotional and HRQoL changes before and after cochlear implantation. A group of nine adults from California with severe to profound post-lingual deafness between the ages of 23 and 59 underwent audiological assessment and was administered four socioeconomic scales. The QWB questionnaire was used to evaluate HRQoL changes before and after implantation. The Centre of Epidemiologic Studies–Depression Scale (CES-D) and Satisfaction with Life Areas Scale (SLA) was used to quantifiably measure depression and happiness, respectively. The researchers also assessed personal income during the study. Cost-benefit/utility ratio was calculated based on the cost of the implantation, the average increase in income over the period of the study, and the average number of work years (well years) of a CI recipient. This ratio is based on an assumption that the patients will experience an increased QoL as years progress. Audiological measurements and the aforementioned questionnaires were completed before and after (at 6 months, 1, 2, 2½ and 3 years) following cochlear implantation. In the study, two out of nine patients experienced some surgical complications (unexpected facial nerve paralysis). As a result, the QoL of these two patients did not improve.

The results and data analysis were based on the remaining seven patients. The patients had better thresholds following implantation than before. On the QWB questionnaire, the patients showed an overall improvement of 7.2% in mobility, physical well-being and social activity over the course of the study. The difference scores remained significant during follow-up appointments. At baseline, the patients mentioned having social limitations and attributed these to their hearing loss. On the SLA scale (scored on a 0-6 scale; higher indicating better), the patients scored a mean of 3.72 at baseline. However, after implantation, the mean gradually increased to 5.43 by the 3rd year. A paired *t*-test revealed that the differences between the measures were significant. Similarly, the participants' personal income increased to a mean of 11.4 (\$12,500 to \$14,999) after three years following implantation from a mean of 8.9 (\$9000 to \$9999) at baseline. This increase during the study correlates with the improvements seen on the QWB scale. After receiving CIs, the patients were more willing to work and/or return to school for additional training.

The researchers did not use a systematically accepted scale to assess income. They developed income interval categories and asked patients to provide approximate ranges of their income. On the CES-D scale, before implantation, the group mean was 14.78 and it declined to 6.50 after the first year of receiving CIs. This shows that depression decreased in the first year. However, the scores increased to 11.7 and 20.3 in the second and third years after receiving CIs, respectively. The reason for this increase is not explained in the article. Harris et al., (1995) presents that cochlear implantation is a cost efficient medical intervention when compared to other surgical interventions based on the cost per well year.

The authors clearly outlined the purpose of the study and described the participant eligibility criteria allowing this research to be replicated by others. However, the authors' assume that HRQoL will continue to increase regardless of additional factors that can affect one's general health (e.g., age-related ailments). This ultimately influences the data analysis and explanation of the presented results. Appropriate baseline measures were taken and the study design allowed each patient to be their own control. This provided certainty and included individual differences when analyzing the benefits of CIs. Harris et al. (1995) provides sufficient evidence that CIs positively affect the HRQoL in post-lingually deafened adults.

Hawthorne et al. (2004) completed a prospective study using the same design as Harris et al. (1995) and evaluated HRQoL and social participation benefits of 34 adults with the mean age of 49 receiving CIs in Australia and New Zealand. The authors clearly outline their participation selection criteria and document any missing data that has occurred during the study period. Technical details about CI devices were not included. The patients in this study were assessed using the AQoL, which evaluates independent living, social relationships, mental senses along with psychological well-being and the Hearing Participation Scale (HPS), which measures social interaction in relation to hearing. These measures were obtained before and at 3 and 6 months after cochlear implantation. Either scale is scored from 0.00 to 1.00 with a low score indicative of poorer performance. The post-operative results at 3 and 6 months from either questionnaire were compared to the norms generated from a healthy population and hospital outpatients. These norms were provided from another study completed by the first author of this article. AQoL results were significantly different at baseline and 3 months and at 3 and 6 months. Prior to implantation, the patients reported scores below the normative values of the general population. During follow-up appointments, the AQoL scores converged with the norms obtained from hospital outpatients. An analysis of each component of the AQoL was not conducted due to the small sample size. The same results were seen with the scores obtained with the HPS.

Hawthorne and colleagues (2004) presented data analyses that prove their initial purpose of the study. However, they do not provide a reason for selecting the two aforementioned scales even though they admit that some invalidity of the questionnaires could affect the study outcomes. Since the AQoL was developed by the first author and her research team, their decision to use this questionnaire would be biased to this effect. There is proper documentation of effect sizes and its influences on the data analyses. Since a repeated-measures design was utilized, a clear pattern of HRQoL improvement over the study period can be seen with following implantation. The study should have been continued over 6-months as the long-term benefits of cochlear implantation could have been examined. The present results are convincing, however, it is possible that the participants were over-reporting any HRQoL changes due to their expectations that change should occur. The authors present additional factors such as socioeconomic status (SES) and degree of hearing loss that can influence the results. These results should be cautiously interpreted, as there are factors that are identified but not examined in detail that could affect the benefits presented.

Klop and colleagues (2008) evaluated the benefits of CIs in post-lingually deaf Dutch adults and quantified the clinical relevance of these benefits. Forty-four adults were recruited before and followed until 12 months after implantation. The adults received their implant devices in the study and they all attended a rehabilitation program that commenced immediately following the surgery. Participants were assessed for speech perception and QoL throughout the study period. The NCIQ, Ontario Health Utilities Index (HUI2 and 3) and cost-utility ratios were calculated to quantify the HRQoL benefits of CIs. The utility ratios, similar to the cost-benefit scores in the Harries et al. (1995) study are a measure of quality-adjusted life years (QUALs) and were calculated from the patient's life expectancy at the time of surgery, the cost of the surgery and any follow-up expenses. QUALs are used to measure the cumulative increase in QoL following implantation surgery (Summerfield et al., 2002). Unlike Harris et al. (1995), the patient's entire lifetime was taken into consideration in estimating the individual QUAL gain. The authors did not provide any detailed description of deriving these values for the expected gain. They conclude that the cost of the implant is acceptable based on a rule of thumb obtained from another study. It is not clear whether this rule of thumb is generally accepted in literature or merely used as a point of reference particularly in this study. On the NCIQ and HUI2, the patients obtained significant improvements in self-esteem, communication ability, and social functioning. Data analysis for the pre- and post-operative data was performed using paired *t*-tests. Since the sample size was relatively large, the effect seen within this group was significantly different. Multivariate linear

regression analysis was used to analyze any factors that could influence in the speech perception and HRQoL scores. This study, unlike others previous discussed, considered the clinical relevance of the benefits of CIs based on effect size (ES) and minimally clinically important difference (MID). MID is the smallest difference in measurements which patients would perceive as benefit or change (Klop et al. 2008). Typically, a change of 0.5 SD from the baseline is accepted in current literature as a value for MID. However, the authors argue that this standard cannot be applied to assess the effectiveness of CIs, as the patient's perception of change was larger than predicted. The research study does not continue to explain their viewpoint in this aspect but abruptly concludes the paper with a statement that MID in CIs requires further investigation. MID is a relevant clinical aspect, however, there are limitations in quantifying it and the authors did not recognize it in this study. Although, this study involves concepts that requires future research, Klop et al. (2008) presents evidence that CIs improve the HRQoL of adults with post-lingual deafness with the data analyses, its valid design, widely accepted questionnaires and a relatively large sample.

Similar to the previously mentioned studies, Mo, Lindbæk & Harris (2005) also used a single subject design to evaluate the changes in HRQoL following cochlear implantation. Twenty-nine post-lingually deaf adults were recruited at the beginning of the study and were mailed the PQLF, Index Relative Questionnaire Form (IRQF) and Short Form 36 (SF-36) to complete and return back prior to the surgery. These adults were evaluated at 12 and 15 months following the surgery. The IRQL evaluates domains similar to the PQLF (communication, social activities, and isolation) and it was administered to the CI user's close relative to assess their perspective of the adult with hearing impairment. The SF-36 was used to measure general health and assesses overall QoL changes. Two patients did not respond, therefore, the total number of participants in the study and the corresponding data analysis was $n=27$. In the PQLF, the differences in HRQoL were significant with the Bonferroni correction in all domains especially in categories that reflect how communication and hearing affects life and family relationships. A similar analysis of the IRQF scores also revealed statistically significant differences. In this study, the SF-36 scores before and after implantation showed significant differences particularly in the area of general health. Therefore, this study showed that the patients who received CIs showed significant improvements in their ability to communicate, felt less isolated and were able to maintain healthy relationships with family and friends. In essence, their HRQoL improved after receiving implants.

One of the limitations in this study is that the researchers did not control for any extraneous variables

such as other illnesses that could affect how the patients reported any HRQoL change. As a result, these effects could confound the results presented. The authors do not provide their rationale in administering these HRQoL questionnaires and their lack of providing a clear outline of how their participants were recruited for the study. This limits the ease of replicating this research and the credibility in the results provided. Even though, the evidence presented suggests HRQoL changes in post-lingually deaf adults after implantation, the results cannot be generalized and should be interpreted with caution.

Case-Control Study

Krabbe, Hinderink & van den Broek (2000) completed a case-control retrospective study, which included 45 postlingually deaf adult CI users and a control group of 46 deaf adults waiting for an implant. Three HRQoL questionnaires (NCIQ, SF-36 & HUI-2) were administered to all the participants involved in the study. The adults who completed and returned the questionnaires *and* who met the eligibility criteria of postlingual deafness were included in the study. The implanted adults had been using their devices for about a year. These adults received the HRQoL questionnaires twice using a crossover design: once to assess retrospectively their experience without CIs and presently to evaluate their current HRQoL. The answers provided by the control group on the HRQoL questionnaires were used to validate the retrospective information obtained from the CI users. Nonparametric tests (Wilcoxon's signed rank test and Mann-Whitney U test) were used to analyze the scores from the treatment and control groups. There was strong corroboration between the retrospective information obtained from CI users and that from the control group. Improved scores for HRQoL were also seen during CI use on all the questionnaires (NCIQ: $p < .001$; SF-36: $p \leq .01$). On the HUI-2 questionnaire, the scores increased from 0.55 (pre-CI) to 0.82 (post-CI). These are based on results obtained from the CI users. Effect size was also included during analysis and it was significant in all three questionnaires ($d \geq 0.8$). In essence, CI use improved HRQoL in adults with post-lingual deafness. In addition to speech perception, improvements were also seen in social functioning, self-esteem, social interactions and mental health.

The authors used clear eligibility criteria and provided detailed information about their recruitment process that easily allows this study to be replicated. The evidence provided is compelling as the data analysis was appropriate and included a large sample size. However, the analysis was limited in that it did not include factors such as length of deafness or other physical ailments that could have affected the results presented here. Regardless, a clear rationale was provided and the design that was suitable to study the purpose. Unlike other studies, the researchers also used a control group of adults waiting for CIs. In addition, the use of a crossover design reveals

consistent changes that provide some basis to infer causality. This study was conducted in an adequate fashion and reveals evidence that CIs can improve one's HRQoL.

Randomized Control Trial (RCT)

Maillet, Tyler & Jordan (1995) conducted a study using a RCT design to evaluate the changes in HRQoL in adults with post-lingual deafness before and after cochlear implantation. Eighty-two adults were recruited as part of a cooperative studies program and randomly placed into one of three CI groups (Nucleus 22-channel CI, Ineraid 4-channel CI and 3M/Vienna single-channel CI). Most of the adults had been profoundly deaf for about 15 years and the participants were asked to complete three HRQoL questionnaires (PQLF, IRQF and Performance Inventory for Profound Hearing Loss (PIPHL)). These surveys were administered along with other audiological tests before implantation, during the stimulation (turning on the device) phase and at 3, 12, and 24 months following the surgery. The article includes detailed information about each questionnaire, the manner of administration and scoring. The data analysis only compared the scores obtained before implantation and at 24 months following the surgery. After 24 months of implantation, a paired *t*-test analysis revealed a statistical significant improvement in the PQLF ($t = 5.14$; $p < .0001$; $N = 71$); IRQF ($t = 5.25$; $p < .0001$; $N = 62$) and PIPHL ($t = 6.70$; $p < .0001$; $N = 72$). The adults in this study reported improved HRQoL after 24 months after implantation. The researchers do not provide any explanation for the discrepancy observed in the original number of participants recruited and the present numbers of respondents seen for each questionnaire. Significant improvement was seen because of CIs by both the patients *and* their relatives. Unlike, previously mentioned studies in this review, these researchers also examined the influence of other factors such as length of deafness, patient's age and speech perception ability on HRQoL. A Pearson correlation coefficient was used to analyze patient's age and length of deafness with the results obtained from the three questionnaires. The degree of improvement in HRQoL was dependent on the length of deafness. Adults who were deaf for a shorter period (in years) perceived significantly more improvement after the surgery.

In considering the evidence presented, one should be mindful of the possible limitations in this study. For instance, analysis was not conducted on the data obtained at 3 and 12 months following the surgery. Evaluation of this data would have provided an understanding of degree of HRQoL changes that may have occurred after the surgery. The authors did not explain the participant recruitment process nor did they provide information about any missing data. Although similar results were obtained from the three groups of CI users, there was no comparison in examining the degree

of HRQoL present across the different devices. The data analysis and design of the study was satisfactory and the evidence shows that there is improvement in HRQoL of adults with post-lingual deafness after receiving CIs.

Discussion

The purpose of this critical review was to evaluate whether CIs should be considered as a treatment option for adults with post-lingual deafness based on HRQoL measures before and after implantation.

Six articles were reviewed and the results were consistent across the studies. Each article in this critical review revealed compelling evidence that post-lingually deafened adults with CIs experience positive HRQoL changes. Although each study was unique in its research design and use of HRQoL questionnaires (e.g. NCIQ, IRQF, PQLF, AQoL) similar results were present. The research studies used a through selection criteria for their participants, valid design in their respective study and appropriate data analysis to examine their purpose. In addition to improved speech perception, implanted participants reported increased mobility, independence, high self-esteem, better social relationships with family and/or friends, increase in personal income, improved general functioning, and less isolation and withdrawal from society.

There were minor methodological and reporting errors that may have influence the results. Limited explanation regarding missing data or lack of analysis on collected data could bias how the results were presented (Harris et al., 1995; Hawthorne et al., 2004; Maillet et al., 1995). Klop et al. (2008) introduced MID to evaluate clinical differences, however, they did not explain its usefulness to CIs nor did they integrate this concept into explaining their results, although it was part of their initial purpose. Exploring these aspects in addition to replicating each study in this review while controlling for extraneous variables (e.g. other illnesses) would be suitable recommendation for future research. General health status can change with the presence of health problems and the HRQoL could be inadvertently affected, with or without CIs being present.

Cochlear implants are an expensive treatment option; however, the long-term improvements in HRQoL and speech perception abilities outweigh the initial costs, as demonstrated by Klop et al., (2008) and Harris et al. (1995) in their study about QALs and cost-benefit ratios, respectively (Summerfield et al., 2002). The research groups assessed their participants over different lengths of time after the implantation surgery. While Hawthorne et al. (2004) continued to examine their subjects for 6 months following the surgery; other studies continued to evaluate their participants' performance for above 2 years after cochlear implantation (Maillet et al., 1995; Harris et al., 1995). This reveals that the HRQoL improvements after implantation extend beyond the first few months after surgery and it is a cost-efficient option

for post-lingually deafened adults who have had limited success with traditional amplification.

Maillet et al. (1995) study considered length of deafness as part of their analysis and integrated this factor in providing the HRQoL changes after implantation. This aspect was not considered by the other articles examined in this review. This study found that individuals with longer duration of deafness (in years) before the surgery perceived limited improvement in their HRQoL after receiving CIs. This does not imply that these adults perceived *no* improvement in their QoL after cochlear implantation. Rather, the degree of HRQoL change that these adults perceived was less compared to individuals who were deaf for a shorter period. The difference perceived could be attributed to the plasticity of the brain and the lack of auditory stimulation over a longer period (Fallon et al., 2008). Does that mean that after a certain number of years of prolonged deafness (e.g. >15 years), CIs may not improve one's HRQoL? Further research in this area is required to answer this question. One should be mindful of this aspect and other factors (i.e. higher auditory systems) while considering CIs as a treatment option.

Clinical Implications and Conclusions

The evidence presented is clinical relevant and provide clinicians with a compelling evidence-based answer when their patients with post-lingual deafness contemplate the possibility of receiving CIs after failure with traditional hearing instruments. This review revealed that CIs provide better HRQoL in addition improved sense of sound and speech perception.

Although, this review did not include an extensive evaluation of HRQoL questionnaires, it provided clinicians with an awareness of these surveys and their possible usefulness in measuring HRQoL in CI use. These HRQoL questionnaires can be utilized in clinical practice to counsel, evaluate and demonstrate the HRQoL changes prior to and after the surgery. Cochlear implants, therefore, can be considered as a treatment option in adults with post-lingual deafness. However, the duration of deafness and other variables such as already existing illnesses and health complications are to be evaluated before recommending an adult with post-lingual deafness for cochlear implantations.

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