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Quality of Life after Intervention with a Cochlear Implant or Hearing Aid

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Abstract

Objective—To investigate the impact of hearing aid and cochlear implant use on quality of life in adults.

Study Design—Prospective observational cohort study.

Methods—113 adults aged 50 years with post-lingual hearing loss receiving routine clinical care at a tertiary academic medical center were evaluated with the Medical Outcome Study Short Form-36 before and 6 and 12 months after intervention with hearing aids or cochlear implants. Change in score was assessed using linear mixed effect models adjusted for age, gender, education, and history of hypertension, diabetes, and smoking.

Results—A significant increase in mental component summary score was observed in both hearing aid and cochlear implant users from baseline to 12 months, with cochlear implant users increasing nearly twice that of hearing aid users (hearing aid: 2.49 [95% confidence interval 0.11, 4.88], $P=.041$; cochlear implant: 4.20 [95% confidence interval 1.85, 6.55], $P<.001$). The most substantial increases were observed in individuals with the lowest baseline scores. There was no significant difference in physical component summary score from baseline to 12 months.

Conclusions—Treatment of hearing loss with hearing aids and cochlear implants results in significant increases in mental health quality of life. The majority of the increase is observed by 6 months post-treatment and we observed differential effects of treatment depending on the level of baseline quality of life score with the greatest gains observed in those with the lowest scores.

Keywords

Quality of life; mental health; hearing impairment; hearing aid; cochlear implant

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INTRODUCTION

Nearly two-thirds of adults 70 years of age have hearing loss.^{1,2} Individuals with hearing impairment have poorer cognitive,^{3–5} physical,^{6,7} and mental function^{8,9} as well as lower health-related quality of life.^{10,11} Hearing aids (HA) and cochlear implants (CI) are the most common devices used for the treatment of hearing loss. Although these interventions result in improvements in speech perception^{12,13} and even *disease-specific* quality of life, the impact on generic *health-related* quality of life is unclear.^{14–18}

Health-related quality of life is a broad multi-dimensional concept that includes both physical and mental well-being. Since its introduction in 1992, the 36-question Medical Outcomes Study Short-Form Questionnaire (SF-36) has become the primary instrument for evaluating generic health-related quality of life.¹⁹ CI and HA could plausibly improve quality of life through improvements to speech and noise understanding,²⁰ social interaction,⁹ or cognitive function.³ No study to date has found statistically significant improvements in SF-36 summary scores after hearing aid use,^{17,21} although one study did report increases in the social function domain.²² Studies examining change in SF-36 after cochlear implantation have been more extensive;^{15,23} however, only one study of 22 Dutch adults has found improvements in SF-36 summary measures.²⁴

The Studying Multiple Outcomes after Aural Rehabilitative Treatment (SMART) Study evaluated adults before and after receiving routine clinical care with a hearing aid or cochlear implant at a tertiary academic medical center. In this prospective, observational cohort study, we investigated whether quality of life, measured by the validated SF-36, changed within one year of receiving a CI or HA. We hypothesized that mental health-related factors of quality of life would improve from baseline to 6 and 12 months post-intervention.

MATERIALS AND METHODS

Study Participants

The design of the SMART Study has been previously described.²⁵ We recruited patients from the Johns Hopkins Department of Otolaryngology-Head and Neck Surgery who presented for evaluation for hearing aids or cochlear implants from 2011 to 2014. Patients who fulfilled the following criteria were eligible for the study: (1) 50 years of age, (2) English-speaking, (3) receiving a hearing aid for the first time (or <1 hour/day of prior use) or receiving a first cochlear implant, (4) diagnosed with post-lingual hearing loss, and (5) aural-oral verbal communication as primary communication modality.

Participants completed 3 study visits: (1) Baseline evaluation before receiving the intervention, (2) 6-month post-intervention follow-up evaluation, and (3) 12-month post-intervention follow-up evaluation. 145 patients, out of 564 eligible patients, agreed to participate in the study. The most common reasons for not participating in the study included lack of interest, time constraints, transportation limitations, and feasibility of returning for follow-up visits. All study participants were provided with a parking voucher (\$8 value) and a meal voucher (up to \$10 value) at each study visit. Study participants also received an

additional 1 year extended warranty on their hearing device, provided by the respective hearing aid (Phonak, Oticon, Starkey, Unitron, Widex) or cochlear implant (Cochlear America, Med-El Corp., Advanced Bionics) companies. Of the 145 individuals consented, 32 individuals (22%) dropped out of the study for various reasons: 10 individuals could not be reached, 8 individuals provided personal reasons, 6 individuals reported device issues, 4 individuals reported illness, and 4 individuals returned their hearing aids. The remaining 113 individuals make up our analytic cohort. Participants who were included in our analytic cohort did not significantly differ from individuals not included in our analytic cohort in terms of baseline mean MCS scores (analytic cohort: 54.9, non-analytic cohort: 52.7, $P=.581$) or PCS scores (analytic cohort: 54.3, non-analytic cohort: 50.9, $P=.5026$). Written informed consents were obtained from participants by the clinical research coordinator and other trained research personnel. All study procedures were reviewed and approved by the Johns Hopkins Institutional Review Board (Baltimore, Maryland).

Treatment of Hearing Loss

Study participants received hearing aids or cochlear implants according to routine clinical care at Johns Hopkins. For individuals fitted with hearing aids, decisions as to type of technology, unilateral vs. bilateral fitting, hearing aid features, and fitting procedures were determined by the individual audiologist and patient. Cochlear implantation surgeries and pre- and post-operative fitting and programming were performed by the staff of the Johns Hopkins Listening Center. Decisions as to which cochlear implant technology to use and fitting procedures were made individually between the implant audiologist and the patient.

Covariates

Data on demographic variables, medical history, and history of noise exposure were obtained by a trained research coordinator during interviews. Race/ethnicity was grouped as Non-Hispanic White or Caucasian, Non-Hispanic Black or African-American, Hispanic or Latino, Asian or Pacific Islander, American Indian or Alaskan Native, or Native Hawaiian or Other Pacific Islander. Household information was determined by the number of individuals living in the participants' current households. Education was collapsed into a 3-level variable. Variables related to medical history included diabetes (based on self-reported diagnosis), smoking (current/former/never), and hypertension (told by healthcare professional on two or more visits about hypertension diagnosis and/or current use of prescribed hypertension medication). Audiometric assessments were performed during participants' clinical visits and abstracted from the audiometric database at Johns Hopkins.

Quality of Life

The Medical Outcome Study Short Form-36 survey is arguably the most widely used tool for evaluating health-related quality of life.¹⁹ It was administered to participants at baseline, 6 months, and 12 months post-intervention. The SF-36 is a multi-level scale that assesses mental and physical health function. The mental component summary (MCS) and physical component summary (PCS) are global assessments derived from 8 individual health domains: 1) physical function, 2) role limitations due to physical problems, 3) social functioning, 4) bodily pain, 5) general mental health perception, 6) role limitations due to emotional problems, 7) emotional wellbeing, and 8) general health perception. Each domain

is evaluated on a range of 0 (worst) to 100 (best) with a global median of 50. The MCS measure is composed of vitality, social function, role limitations due to emotional problems, and general mental health perception domains. The PCS is composed of physical functioning, role limitations due to physical problems, bodily pain, and general health perception score domains. We assessed changes in both MCS and PCS at 6 months and 12 months post-treatment. In addition, two individual domain scores, emotional wellbeing and physical function, were evaluated because they are made up of the largest quantity of SF-36 questions (5 and 10, respectively).

Statistical Analysis

Demographic and clinical characteristics were compared across the treatment groups using the Wilcoxon rank sum and Fisher's exact test where appropriate. Linear mixed effects models were used to model the longitudinal trajectories of (outcome) before and after CI or HA fitting, accounting for the repeated measurements within individuals using random intercepts. Contrasts between the time $\times$ treatment interaction were used to assess the difference between groups at each visit, the differences within groups across time, and the changes between consecutive visits by group. All models were adjusted for age, gender, education, and history of hypertension, diabetes, and smoking as time-fixed covariates. Effect size was estimated using mean change in a group divided by the baseline standard deviation of the group. Residual diagnostic plots were used to assess residual autocorrelation, the linearity of associations, variance homogeneity, and normality of the residuals and predicted random effects. Sensitivity analysis included stratification by treatment group to determine if there is effect modification and if pooling of the groups was appropriate. Analysis of influential points identified using residual diagnostics was conducted for the MCS model. Participants were excluded if they were missing any covariates or were missing the outcome at baseline. All covariates associated with the likelihood of a missed study visit were included in outcome models, with the assumption that outcomes were missing at random (MAR). Significance testing was performed using two-sided tests with a type I error rate of 0.05. All analyses were conducted in R (R Foundation for Statistical Computing, Vienna, Austria).

RESULTS

The demographic characteristics of the SMART study analytic cohort are summarized in Table I. 50 individuals received HAs and 63 received a CIs. Individuals receiving a CI were more likely to have greater hearing impairment (70.0 vs. 37.5, $P<.001$) and lower educational attainment. CI and HA recipients were not different in terms of age, gender, race, smoking status, history of hypertension or diabetes. Missingness at 1 year follow-up was not associated with age, gender, race, education, smoking status, history of diabetes, or hypertension, but was associated with treatment. HA users were more likely to miss their 1 year follow-up (results not shown) as it was not part of their standard of care, as it is for CI users.

The change in quality of life score pre- and post- hearing loss treatment was investigated through linear mixed effects models adjusted for age, gender, race, education, and history of

hypertension, diabetes, and smoking (Table II). On average, HA participants scored 2.43 points higher at baseline relative to CI patients (95% Confidence Interval [CI]: -0.56, 5.41), although this difference was not statistically significant ($P=0.111$). An increase in MCS score was observed in both HA and CI users from baseline to 12 months, with CI users increasing nearly twice that of HA users (HA: 2.49 [95% CI: 0.11, 4.88], $P=.041$; CI: 4.20 [95% CI: 1.85, 6.55], $P<.001$). This equates to a 0.29 standard deviation change from baseline for HA users and a 0.53 standard deviation change from baseline for CI users. CI users, but not HA users, experienced significant increases in MCS score after 6 months (HA: 1.93 [95% CI: -0.16, 4.03], $P=.070$; CI: 3.17 [95% CI: -0.93, 5.42], $P=.006$, 0.40 standard deviation change). Figure 1 depicts the distribution of MCS scores at 12 months vs. baseline. The most substantial increases in MCS were observed in individuals with the lowest baseline MCS (Fig. 2). For the PCS, there was no significant score difference from baseline to 12 months for HA or CI users (HA: 1.01 [95% CI: -1.28, 3.31], $P=.338$; CI: 0.33 [95% CI: -1.92, 2.58], $P=.775$). Figure 3 depicts the distribution of PCS score at 12 months vs. baseline.

In addition to the SF-36 summary scores, 2 domain scores were assessed. For the emotional wellbeing domain, HA users did not experience a statistically significant increase in scores from baseline to 12 months (3.04 [95% CI: -1.13, 7.21], $P=.153$). However, we did observe a significant increase in emotional wellbeing domain for CI users after 6 months (4.02 [95% CI: 0.31, 7.73], $P=.034$, 0.25 standard deviation change) and 12 months (5.98 [95% CI: 1.78, 10.18], $P=.005$, 0.37 standard deviation change). For physical function domain scores, we did not observe a significant difference in scores from baseline to 6 or 12 months for HA and CI users.

Sensitivity analysis included stratification of the treatment groups. We found that the associations between education and hypertension differed by treatment arm, but the estimated change from baseline was nearly identical between the pooled model and each stratified model. Upon stratification, the estimated change in score from baseline to 12 months were as follows: PCS: HA 1.02 (95% CI: -1.11, 3.16), $P=.387$, CI 0.37 (95% CI: -2.14, 2.88), $P=.777$; MCS: HA 1.88 (95% CI: 0.25, 3.50), $P=.024$, CI 4.87 (95% CI: 1.52, 6.78), $P=.002$; emotional wellbeing domain: HA 2.30 (95% CI: 0.19, 3.45), $P=.051$, CI 5.99 (95% CI: 0.84, 11.15), $P=.023$; physical function domain: HA 3.36 (95% CI: -0.20, 6.93), $P=.064$, CI -2.01 (95% CI: -8.74, 4.70), $P=.556$. Two influential points were identified in the analysis of MCS from baseline to 12 months. Exclusion of these values resulted in minimal change in the estimates (HA: 2.03 [95% CI: -0.18, 4.25], $P=.072$; CI: 4.87 [95% CI: 2.69, 7.05], $P<.001$).

DISCUSSION

Our results demonstrate that treatment of hearing loss with HAs and CIs result in significant increases in mental health quality of life. The majority of these score increases are observed at 6 months, but continue to rise up to 12 months. While CI users started out with lower scores, the average increase in MCS for CI users was nearly twice that for HA users. Our results were robust to adjustment for multiple potential confounders and are based on one of

the largest prospective studies to date analyzing SF-36-measured quality of life after hearing loss treatment.^{14,18}

To our knowledge, no study to date has identified improvement in SF-36 MCS with HA use. This may be attributable to previous studies' follow up times being less than 6 months. We found no significant improvements in either emotional wellbeing or physical function domains. By comparison, the largest study to date examining pre- and post-HA intervention actually found decreases in general health after 3 months in a sample of 93 Australians.¹⁷ In contrast, a prospective study of 56 HA recipients in Brazil demonstrated improvements in general health perception and physical function domains after 4 months.²¹ Finally, Joore et al. found improvements in SF-36 social functioning domain 5 months post-HA fitting in a population of 80 hearing impaired adults in the Netherlands.²² These differences in findings may be attributable to different sample sizes and baseline quality of life scores.

Prior studies examining the impact of cochlear implantation on SF-36-measured quality of life have been more extensive. We found increases in MCS and emotional wellbeing domains at both 6 and 12 months. Damen et al. found similar increases in MCS in a group of 22 Dutch adults with hearing loss up to 6 years after cochlear implantation.²⁴ The largest study to date of 283 CI recipients in Canada found increases in 5 of the 8 SF-36 domains, including emotional wellbeing, physical role functioning, mental health, emotional role functioning, and social functioning.¹⁵ Similarly, Arnolder et al. found improvements in emotional wellbeing, social functioning, and mental health domains in 32 CI recipients after 1 year.²³ Neither of these studies examined MCS or PCS. Our results seem to contrast with smaller studies which did not observe a difference in SF-36 pre- and post-CI.^{16,26,27} As such, we recommend future studies investigating quality of life following hearing loss treatment obtain adequate sample sizes for observing differences. Of note, we did not observe improvement in either PCS or physical function domain for CI users. This is consistent with prior research, suggesting treatment of hearing loss does not significantly improve physical quality of life.²⁴

We found that individuals with hearing impairment who received a CI had twice the gain in MCS scores on average than HA recipients. This may be related to the relative magnitude of improvement in access to auditory information provided by a CI vs HA which is clearly related to the severity of the underlying hearing loss. Alternatively, this finding could be the result of more CI recipients having low MCS scores at baseline (Fig. 1) and hence having the greatest room for improvement. Randomized controlled trials would be necessary to determine what factors predict improvements in quality of life and if individuals with similar levels of hearing impairment would experience greater improvements from CI use than from HA use.

Several explanations could account for the improvement in mental health quality of life after intervention with HAs and CIs. Hearing impairment has long been associated with lower quality of life in adults,^{10,11} with some cross-sectional studies demonstrating that this association is reduced or absent in individuals using HAs.²⁸ The increase observed in MCS score could be the result of reductions in depression^{29,30} and anxiety^{31,32} symptoms associated with hearing loss. Multiple demographic characteristics³³ and cardiovascular risk

factors³⁴ could impact outcomes, although models were adjusted for age, gender, race, education, and history of hypertension, diabetes, and smoking. Alternatively, individuals participating in the study could have experienced improvements in mental health due to increased interactions with health care providers during the follow up period. However, a previous study examining a control population of untreated hearing-impaired adults actually observed decreases in quality of life similar in magnitude to the improvements experienced by treated individuals.²⁴

Our study has limitations. Because we did not include randomization or an untreated control arm, we are unable to definitively say increases in quality of life were directly caused by HA or CI use. We also are not able to investigate the role of determinants of CI and HA effectiveness such as hours of use, assistive listening device use, or unilateral vs. bilateral device use.³⁵ Selection bias and external validity warrant consideration, although this study was completed in a relatively diverse population. Our analysis was posited on the assumption that data were missing at random (MAR), but it is possible that those who experienced declines in the quality of life were less likely to attend follow-up visits, or that those who did not attend follow-up visits differed with respect to other potential confounding factors. HA recipients were more likely to miss a follow-up visit, since they do not have regularly scheduled visits as with CI recipients. 32 individuals dropped out of the study. This is consistent with the response rates of previous studies examining the SF-36 in older adults^{36,37} and is an inherent limitation of observational studies' dependence on patient's willingness to return for study visits. Future research will require greater resources to ensure complete data collection, such as funding transportation costs for participants to return for study visits and other study retention incentives. Alternative tools for measuring generic health-related and disease-specific quality of life exist, such as the Health Utilities Index (HUI3)³⁸ and Nijmegen Cochlear implant Questionnaire (NCIQ),³⁹ respectively. We chose to use the MOS SF-36 due its widespread utility across disciplines, but it is possible other tools would have had greater sensitivity in measuring changes in quality of life.^{40,41}

CONCLUSION

Our observations demonstrate that intervention with HAs and CIs is associated with increases in mental health quality of life in adults with post-lingual loss. To our knowledge, this was the longest prospective study of HA recipients, and the first to demonstrate significant improvements in MCS score. As the global population ages and the importance of mental health is recognized, future randomized trials are needed to elucidate the impact of hearing rehabilitative therapies on quality of life and the factors affecting potential benefit.

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Fig. 1.
Short Form-36 mental component summary score at 12 months vs. baseline with LOESS fit and 95% confidence bands.

Fig. 2.
Change in Short Form-36 mental component summary score from baseline to 12 months by
baseline mental component summary score with LOESS fit and 95% confidence bands.

Fig. 3. Short Form-36 physical component summary score at 12 months vs. baseline. Shaded area equal 95% confidence intervals.

TABLE I

Baseline Characteristics of Participants

Characteristics	All (n=113)	Hearing Aid (n=63)	Cochlear Implant (n=50)
Age, mean [IQR]	69.6 [63.5, 77.4]	71.0 [63.4, 75.5]	69.2 [62.9, 78.5]
Gender, n (%)			
Female	46 (40.7)	25 (39.7)	21 (42)
Race, n (%)			
White	102 (90.0)	57 (90.5)	45 (90.0)
Education, n (%)			
High school or less	16 (14.2)	4 (6.3)	12 (24.0)
College or associates	48 (42.5)	26 (41.3)	22 (44)
Postgraduate	49 (43.4)	33 (52.4)	16 (32)
Smoking status, n (%)			
Former or Current	56 (49.6)	26 (41.3)	30 (60.0)
Hypertension, n (%)	62 (55)	35 (56)	27 (54)
Diabetes mellitus, n (%)	24 (21)	17 (27)	7 (14)
PTA [IQR]	46.2 [36.0, 65.6]	36.2 [27.5, 42.5]	69.4 [64.4, 81.6]

IQR = Interquartile range

TABLE II

Change in Quality of Life Score after Hearing Loss Treatment

Short Form-36 Assessment	Baseline to 6 Months		Baseline to 12 Months	
	Hearing Aid (n=63)	Cochlear Implant (n=50)	Hearing Aid (n=63)	Cochlear Implant (n=50)
Mental Component Summary	1.93 (−0.16, 4.03)	3.17 [*] (0.93, 5.42)	2.49 [*] (0.11, 4.88)	4.20 [*] (1.85, 6.55)
Physical Component Summary	−0.14 (−1.90, 1.62)	0.64 (−1.25, 2.52)	1.01 (−1.28, 3.31)	0.33 (−1.92, 2.58)
Emotional Wellbeing Domain	3.01 (−0.42, 6.44)	4.02 [*] (0.31, 7.73)	3.04 (−1.13, 7.21)	5.98 [*] (1.78, 10.18)
Physical Function Domain	−3.31 (−8.77, 2.15)	−1.04 (−6.90, 4.82)	3.00 (−8.78, 2.15)	−2.19 (−7.73, 3.35)

The data represent mean estimate (95% confidence interval) from linear mixed effects models adjusted for age, gender, education, and history of hypertension, diabetes, and smoking.

^{*} Indicates statistical significance ($p < .05$)