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Analysis of Outcome Domains in Adult Cochlear Implantation: A Systematic Review

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Abstract

Objectives: To determine the breadth of outcome domains used in the reporting of adult cochlear implant (CI) surgery for the purpose of registry and quality measure development.

Data Sources: Systematic review of randomized, controlled trials.

Review Methods: In consultation with a medical librarian, search strategies were constructed to identify randomized controlled trials (RCT) studying adults undergoing cochlear implantation. MEDLINE, EMBASE, Scopus, CINAHL, Cochrane Database of Systematic Reviews, Cochrane Central Register of Controlled Trials, and the Database of Abstracts of Reviews of Effects were searched from database inception to July 2015. Studies were evaluated for level of evidence and risk of bias using the Cochrane Collaboration's risk of bias tool, and outcome domains were extracted from each study.

Results: Of 4,473 unique citations found, eight studies were included in this review. All eight trials were evidence level 1B. Risk of bias was low in two trials, and high in the other six. Reported outcome domains included speech perception in quiet and noise, speech tracking, quality of life, timbre perception, hearing preservation, vestibular function, electrode insertion technique, functional measures, functional imaging, fitting time, and tinnitus.

Conclusions: An analysis of randomized, controlled trials studying cochlear implantation in adults yielded a wide spectrum of outcome domains. This is the first study to comprehensively describe the breadth of outcome domains in adult cochlear implantation. Validated instruments from these domains could be considered for potential inclusion as quality measures and registry use.

Keywords

cochlear implant; hearing loss; deafness; outcome assessment; treatment outcome

INTRODUCTION

Since obtaining Food and Drug Administration (FDA) approval in 1984, over 58,000 adults and 38,000 children have received a cochlear implant in the United States.¹ Thus, outcomes

research in cochlear implantation is a topic remarkably deserving of scientific interest, given the high priority assigned by the Institute of Medicine,² the detailed process involved in obtaining an implant, and the cost of roughly \$60,000 for one implant. We have previously described why quality measures should be developed for cochlear implant centers,³ and the demand for this type of work is high among the otologic community.⁴

Many studies have evaluated the impact of cochlear implants in adults, and have primarily focused on objective measures assessed by audiologists such as speech perception scores. It is widely accepted that cochlear implant “performance” is measured using open-set speech recognition. Additional outcomes have been studied as well, including health-related quality of life,^{5,6} music perception,^{7,8} and hearing preservation.^{9,10}

Though such studies have eloquently shown the improvements possible with a cochlear implant in various outcome domains, none have attempted to comprehensively assemble the range of domains affected by cochlear implantation. As part of a research effort to develop quality measures for adult cochlear implant centers, we undertook this study. Because children are usually attempting to acquire language and attend school at the same time, and have a much higher incidence of otitis media leading to potential infectious complications with the implant, this adds multiple layers of complexity and other outcomes that are not shared in adults. Thus, we first chose to focus on adults, and the analogous review for children is currently under development. Our main objective in this study was to explore and compile the various outcome domains used in the reporting of adult cochlear implant surgery in randomized, controlled trials.

METHODS

Search Strategy

No review protocol was published for this study. Using the PICOS format for this systematic review, the population and intervention of interest was adults aged greater than 18 years undergoing cochlear implantation, the comparison was deaf adults aged greater than 18 years without a cochlear implant, the reported outcome from the included study was the main question of interest, and the study design was randomized clinical trials, meta-analyses, and systematic reviews. The published literature was searched using strategies created by a medical librarian. Using a combination of standardized terms and natural language terms collected from on topic articles, these strategies were then implemented in Ovid Medline, Embase, Scopus, Cumulative Index of Nursing and Allied Health Literature (CINAHL), Cochrane Database of Systematic Reviews, Cochrane Central Register of Controlled Trials, Database of Abstracts of Reviews of Effects, and clinicaltrials.gov. Databases were searched from database inception to July 2015. Full search strategies are provided in the Appendix. This study was conducted as part of a larger study to develop quality measures for adult cochlear implant centers, using methods adapted from the American College of Cardiology/American Heart Association.¹¹

Study Selection

As recommended by the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-analyses) statement,¹² two authors (PV, JL) reviewed the abstracts. At the abstract review level, studies were excluded if they were 1) not randomized, controlled trials, 2) focused exclusively on children, 3) not focused specifically on cochlear implantation, and 4) animal or cadaver studies. Full texts were then screened, and excluded if they 1) were published prior to 2001, 2) were not truly randomized, controlled trials, 3) included less than 10 patients in the study, 4) used non-English speech perception tests, 5) were not focused specifically on cochlear implantation, or 6) did not differentiate between adults and children in the results (Figure 1).

Data Extraction

Outcome measures used in each study were extracted from the methods and results sections, by listing the measure and domain being studied. The required data for completing a modified version of the Cochrane Collaboration's Risk of Bias Tool was also extracted, including information on random sequence generation, allocation concealment, and blinding, for example.¹³ In the case where this information was not available in the manuscript, corresponding authors were contacted via e-mail.

Analysis

The Cochrane Collaboration's Risk of Bias template was used for reporting the risk of bias for each study, and outcome domains were summarized by including the measure used in the study. Due to the innate heterogeneity of the data in this systematic review, a meta-analysis was not performed.

RESULTS

There were 4,473 unique citations, and of 26 full texts screened, 8 were included for analysis (Figure 1).^{14–21} All 8 studies were evidence level 1B. Overall risk of bias was high in 6 of 8 studies, most commonly due to lack of blinding of participants and/or personnel (4 of 8), one due to enrollment being terminated early for concerns about differences among treatment groups, and one due to selective reporting (Table 1).

In total, 228 participants were included in this systematic review. The participants studied were of mean age 58.3 years (range 18–87), and of studies that reported the participants' gender, 62% were female (5 of 8 studies, 103 of 165 participants). Of studies that reported the implant manufacturer (n=208 implants), 64% were made by Cochlear Corporation, 27% by Advanced Bionics, and 8% by MED-EL. Mean follow-up time was 5.3 months.

The most common outcome domains examined in randomized, controlled trials of adult cochlear implantation were speech perception (4 of 8 studies), timbre perception (3 of 8 studies), and quality of life (2 of 8 studies). Additional domains included pitch perception, speech tracking, fitting time, electrode impedance, functional imaging, functional measures, vestibular function, and hearing preservation (Table 2). Most studies examined more than one domain (Mean = 2.3 domains per study).

DISCUSSION

In this systematic review of randomized, controlled trials in adults, we found a core set of outcome domains that are impacted by restoring hearing in postlingually deafened adults through cochlear implantation (Table 2). While commonly discussed domains such as speech perception and quality of life were included, additional domains such as fitting time, pitch, and timbre perception were also studied. Risk of bias was high in the majority of studies included, most commonly due to lack of blinding.

Based on our analysis, we believe that the results represent a broad selection of outcome domains, which can (and in some cases should) be captured in registries and could be used for quality measure development for adult cochlear implant centers. Though this study was not designed to capture the ideal measure to use for each outcome domain, there are many publicly available validated measures that should be used for this purpose in the future. For example, health-related quality of life improvements post-cochlear implantation have been previously shown with the Health Utilities Index Mark III (HUI3).²² In addition, the Minimum Speech Test Battery, including the Consonant-Nucleus-Consonant (CNC) test, has been recommended for measuring speech perception in implantees.²³ We recommend that validated measures be used if the outcome domains described in this study are to be measured in the future in a registry or other prospective study. An assessment of instruments used for the various outcome domains measured in cochlear implantation in the included studies is provided in Table 3. It is important to note that there are many instruments not included in this assessment, as this we only included instruments used in the included studies. A more complete description of all the available instruments is beyond the scope of this paper.

One of the challenges in developing quality measures for a procedure with a delayed outcome is that the outcome must be measured at an appropriate time. Several landmark studies have shown that implantees take several months to show improvements in speech perception,²⁴ and that benefits from bilateral hearing such as squelch and localization peak at around 12 months.^{25,26} Thus, for the measurement of outcomes such as speech perception and quality of life, we believe it would be reasonable to wait until 12 months to have a final measurement of impact. Other process-based quality measures should be able to be measured either at or near the time of surgery.

Though we sought to find a comprehensive list of outcome domains in adult cochlear implantation, many domains studied have not been subject to randomized, controlled trials, and thus were not included in this analysis. This obviously relates to the nature of surgery as a therapeutic intervention and the ethics of randomly allocating patients. This is a limitation of this study, and if we had included systematic reviews or observational studies, we would have found a larger collection of outcome domains. However, we believe that by focusing on randomized, controlled trials, we limited the studies to those done with a minimum level of rigor, requiring prospective trial design and a clear causal explanation for the outcome studied. Similar studies have been done in other fields, such as orthopedics, where the researchers used a summary of randomized trials to study patient-reported outcomes.²⁷ Others in otolaryngology have systematically reviewed observational studies,²⁸ and

described outcome domains such as postoperative infection rates and explants due to infection,^{29,30} in addition to speech perception. Additional observational studies have described improvements in depression and cognitive function in the elderly.³¹ Future research could examine the impact of a cochlear implant on the ability to return to the workforce and other markers of social functioning to fully capture the broad and lasting impact of cochlear implantation in adults.

CONCLUSION

This study serves as a starting point for registry development and quality improvement research in cochlear implantation. Future researchers should consider these various domains affected by cochlear implantation in adults.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Figure 1.
Flow of Studies Through Systematic Review.

Table 1.

Risk of Bias Summary from Included Studies.

Reference	Overall Risk of Bias	Random sequence generation	Allocation concealment	Blinding of participants and personnel	Incomplete outcome data	Selective reporting	Other sources of bias	Used Validated Instruments
Battmer 2015 ¹⁴	high	low	high	high	high	low	high	partially
Buchman 2014 ¹⁵	high	low	low	low	low	low	high	yes
Driscoll 2012 ¹⁶	high	low	high	high	unclear	unclear	unclear	no
Enticott 2011 ¹⁷	low	low	low	low	unclear	low	low	yes
Gfeller 2002 ¹⁸	high	low	low	high	low	low	low	partially
Quentin Summerfield 2006 ¹⁹	high	low	unclear	high	low	low	low	yes
Ramos 2015 ²⁰	low	low	low	low	low	low	low	yes
Tobey 2005 ²¹	high	unclear	unclear	low	low	high	unclear	partially

Table 2.

Summary of Outcome Domains From Included Randomized Controlled Trials.

Reference	Clinical Question	Outcome Domains										
		Speech Perception	Speech Tracking	Timbre Perception	Pitch Perception	Fitting Time	Functional Imaging	Electrode Impedance	Functional Measures	Quality of Life	Vesti-bular Function	Hearing Preser-vation
Battmer 2015 ¹⁴	Can a new programming technique improve postoperative implant mapping?	AB, BKB				Required time to complete fitting						
Buchman 2014 ¹⁵	Does electrode insertion depth affect individual performance?	HINT, CNC		MuSIC	MuSIC				HDSS, APHAB			
Driscoll 2012 ¹⁶	Can postoperative focused training improve music perception?			Instrument recognition test								
Enticott 2011 ¹⁷	Does topical dexamethasone applied to the round window at the time of surgery reduce postoperative dizziness?							Common ground impedance		DHI, ABC, caloric testing, cVEMP	PTA	
Gfeller 2002 ¹⁸	Can postoperative focused training improve music perception?	IAC, HINT, CNC		Timbre recognition test, Timbre appraisal test								
Quentin Summerfield 2006 ¹⁹	Does the timing of the second implant (simultaneous vs. sequential) in postlingually deafened adults lead to a difference in outcomes?								SSQ	GHSI, HUI3, VAS, EQ-5D, tinnitus annoyance		
Ramos 2015 ²⁰	Does topical dexamethasone with or without hyaluronic acid applied to the middle ear cavity at the time of surgery improve the chances of hearing preservation?											PTA
Tobey 2005 ²¹	Does amphetamine administered during aural rehabilitation improve speech perception and speech tracking?	HINT	Video and audio tracking				SPECT rCBF					

Abbreviations: AB = Arthur Boothroyd, BKB = Bamford-Kowal-Bench, HINT = Hearing in noise test, CNC = Consonant-nucleus-consonant, MuSIC = Musical Sounds In Cochlear Implants, HDSS = Hearing Device Satisfaction Survey, APHAB = Abbreviated Profile of Hearing Aid Benefit, DHI = Dizziness Handicap Inventory, ABC = Activities-specific Balance Confidence, cVEMP = cervical vestibular evoked myogenic potential, PTA = pure tone audiometry, IAC = Iowa Consonant Test, HINT = Hearing in Noise Test, SSQ = Speech,

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Spatial, and Qualities of Hearing Scale, GHSI = Glasgow Health Status Index, HUI3 = Health Utilities Index Mark 3, VAS = Overall Quality of Life Visual Analog Scale, EQ-5D = EuroQol-5D, SPECT rCBF = Single photon emission computed tomography regional cerebral blood flow

Table 3.

Assessment and Recommendations for Measuring Cochlear Implant Outcomes.

Outcome Domain	Instrument(s)	Advantage(s)	Disadvantage(s)
Speech Perception	AB, BKB, HINT, CNC, IAC	Ease and speed of administration, many word lists have been validated, audiologists very familiar with these, used for determination of implant candidacy	Negatively affected by cognitive difficulties, Ceiling effect observed with HINT
Speech Tracking	Video and audio tracking	Validated test, widely studied by audiologists	Requires extra equipment, correlates closely with speech perception tests, stressful to patients with poor speech perception
Timbre Perception	MuSIC, Instrument recognition test, Timbre recognition test, Timbre appraisal test	Many available validated tests, well replicated	Long testing time, varies with musical training
Pitch Perception	MuSIC	Validated test, measures more than one domain	Long testing time, varies with musical training
Fitting Time	Required time to complete fitting	Relevant to all cochlear implant patients, easy to measure	Not validated, highly subjective
Functional Imaging	SPECT rCBF	Not reliant on subjective patient response	Not extensively studied in cochlear implantation, expensive
Electrode Impedance	Common ground impedance	Can be measured intraoperatively	Varies between devices, precluding comparison between devices
Functional Measures	SSQ	Extensively studied, abbreviated version available and validated for use	Affected by cognitive status
Quality of Life	HDSS, APHAB, GHSL, HUI3, VAS, EQ-5D, Tinnitus annoyance	Extensively studied, many available validated tests, directly relevant to patients	Disease-specific instruments and general quality of life instruments may not correlate, tinnitus not well correlated with implant performance
Vestibular Function	DHI, ABC, Caloric testing, cVEMP	Well understood tests, may improve patient expectations by testing	Expensive to measure, requires extra equipment
Hearing Preservation	PTA	Widely used, easily understood	Difficult to preserve hearing in all cases

Abbreviations: AB = Arthur Boothroyd, BKB = Bamford-Kowal-Bench, HINT = Hearing in noise test, CNC = Consonant-nucleus-consonant, MuSIC = Musical Sounds In Cochlear Implants, HDSS = Hearing Device Satisfaction Survey, APHAB = Abbreviated Profile of Hearing Aid Benefit, DHI = Dizziness Handicap Inventory, ABC = Activities-specific Balance Confidence, cVEMP = cervical vestibular evoked myogenic potential, PTA = pure tone audiometry, IAC = Iowa Consonant Test, SSQ = Speech, Spatial, and Qualities of Hearing Scale, GHSL = Glasgow Health Status Index, HUI3 = Health Utilities Index Mark 3, VAS = Overall Quality of Life Visual Analog Scale, EQ-5D = EuroQol-5D, SPECT rCBF = Single photon emission computed tomography regional cerebral blood flow