Does Frailty or Age Increase the Risk of Postoperative Complications Following Cochlear Implantation?

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Abstract

Objective. To evaluate whether frailty or age increases the risk of postoperative complications following cochlear implant (CI) surgery.

Study Design. Retrospective cohort study.

Setting. Tertiary academic center.

Methods. An evaluation of all adult patients undergoing cochlear implantation between 2006 and 2020 was performed. The 5-item Modified Frailty Index (mFI-5, comprising preoperative history of pulmonary disease, heart failure, hypertension, diabetes, and partially/ totally dependent functional status) was calculated for all patients included in analysis in addition to demographic characteristics. The primary outcome was postoperative complications following CI within a 3-month period. Major complications included myocardial infarction, bleeding, and cerebrospinal fluid leak, among others. Predictors of postoperative complications were examined using multivariable logistic regression reporting odds ratios (ORs) and 95% CIs.

Results. There were 520 patients included for review with a median age of 68 (range, 18-94) years and a slight male predominance (n = 283, 54.4%). There were 340 patients (65.4%) who were robust (nonfrail) with an mFI of 0, while 180 (34.6%) had an mFI of ≥1. There were 20 patients who experienced a postoperative complication (3.85%). There was no statistically significant association between postoperative complications as a result of preoperative frailty (OR, 1.56; 95% CI, 0.98-2.48, P = .06) or age as a continuous variable (OR, 0.99; 95% CI, 0.97-1.02, P = .51).

Conclusions. CI is safe for elderly and frail patients and carries no additional risk of complications when compared to younger, healthier patients. While medical comorbidities should always be considered perioperatively, this study supports the notion that implantation is low risk in older, frail patients.

Keywords

cochlear implant, sensorineural hearing loss, frailty, frailty index, postoperative complications, older adults

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and not likely an adequate measure to predict patient morbidity and postoperative outcomes because it fails to capture other relevant factors that increase risk in all age groups. The use of frailty as a metric to determine surgical candidacy is expanding within the surgical literature. Frailty metrics attempt to quantify physiologic age based on comorbidities, rather than relying solely on chronologic age. Frailty is likely a more accurate metric than age in determining surgical candidacy because it summarizes in a single measure multiple common chronic conditions that affect resiliency. Increased physical frailty is associated with worse surgical outcomes across multiple surgical subspecialties.

The Modified Frailty Index (mFI) identifies medical comorbidities and information about the consequences of health on daily function. This index has been used in a variety of scenarios, including head and neck surgery, orthopedic surgery, neurosurgery, neurotology, and intensive care medicine, to predict patient outcomes. Despite frailty gaining increasing acceptance among physicians, there is much variation in how frailty is operationalized. The Canadian Study of Health and Aging developed a comprehensive 70-factor frailty index based on a patient’s history and physical exam. This metric was further reduced to an 11-item “modified index” (mFI-11) using factors available within the National Surgical Quality Improvement (NSQIP) database. Recently, the predictive power and usefulness of the mFI-5, comprising 5 of the original 11 items in the mFI-11 indicating the presence or absence of 4 chronic illnesses common in older individuals and the consequences of health status on daily function, were found to be equally effective in predicting mortality and postoperative complications in many subspecialties. As our health care system evolves, summary measures of health and wellness such as the mFI are being increasingly used to evaluate patients in an attempt to predict patient outcomes. The objective of this study was to evaluate whether the mFI-5 is predictive of complications following CI surgery.

**Methods**

**Study Design and Setting**

A retrospective chart review for all adult patients who underwent cochlear implantation between 2006 and 2020 at a single tertiary academic medical center was performed following institutional review board (IRB) approval (University of Utah IRB 00105049). Surgical implantation was performed by 2 experienced, fellowship-trained neurotologists at a high-volume (approximately 150 cochlear implants per year) CI center. To identify these patients, the University of Utah Enterprise Data Warehouse (EDW), which contains a longitudinal record of all data from the inpatient and outpatient electronic health records, as well as over 250 ancillary clinical, financial, and laboratory information systems, was used to include all patients age 18 years or older who received a CI. The Current Procedural Terminology (CPT) code 69930 (cochlear devise implantation, with or without mastoidectomy) was used to identify these patients.

**Measures and Outcomes**

Data extracted from the EDW included basic patient demographics, such as age at implantation, sex, race, and ethnicity. In addition, the preoperative items of the modified 5-item frailty index (mFI-5), which comprises history of pulmonary disease, heart failure, hypertension, diabetes, and partially/ totally dependent functional status, was calculated for all patients included in the analysis based on documentation prior to their date of surgery (see Appendix 1 in the online version of the article). Each variable was assigned 1 point, and the mFI-5 was calculated on a scale of 0 (i.e., no conditions present) to 5 (i.e., all conditions present). The primary outcome was postoperative complications following CI within a 3-month period using International Classification of Diseases, Ninth Revision (ICD-9) and International Classification of Diseases, Tenth Revision (ICD-10) codes (see Appendix 2 in the online version of the article). The complications included for analysis were the following: myocardial infarction (MI), congestive heart failure (CHF), cardiac arrest, stroke, cerebral edema, cerebral ischemia, need for reintubation, postoperative tracheostomy, pulmonary embolism, deep vein thrombosis (DVT), urinary tract infection (UTI), major and minor bleeding, cerebrospinal fluid leak, hydrocephalus, intraventricular hemorrhage, renal failure, wound infection, and sepsis. Preoperative medical evaluation is sought on all patients with medical comorbidities. This is typically done by sending patients to their primary care provider or cardiologist. In the authors’ experience, there are few medical conditions considered absolute contraindications to surgery, and patients are routinely optimized medically prior to surgery.

**Statistical Analysis**

The cohort was described using means and standard deviations or, alternatively, medians and ranges, as appropriate. Frailty was categorized based on mFI-5 score: nonfrail (mFI-5 = 0), prefrail (mFI-5 = 1), and frail (mFI-5 ≥2), and a χ² test was used to compare frailty with complications. Frailty was compared with the outcome of postoperative complication using a multivariable logistic regression model, where forward selection was used to select adjustment variables. We were limited in the number of available adjustment variables due to few complication events. Odds ratios (ORs), 95% CIs, and P values were reported. All tests were 2-tailed, and statistical significance was assessed at the .05 level. Statistical analysis was performed using STATA (16.1; StataCorp LLC).

**Results**

There were 520 adult patients who had cochlear implantation during our study period included for review (Table 1). The study population had a median age of 68 (range, 18-94) years and a slight male predominance. The racial makeup of the cohort is described in Table 1. There were 340 patients (65.4%) who were robust (nonfrail) with an mFI-5 of 0, compared to 126 prefrail patients (24.2%) and 54 (10.4%) total patients meeting criteria of frail. There was no statistical correlation between age and frailty (P = .08) (see Figure 1).
There were 20 patients who experienced postoperative complications (3.85%). The following complications were observed: 5 minor bleeding events, 2 postoperative arrhythmias, 2 acute kidney injuries, 2 urinary tract infections, 2 pneumonias, 2 surgical site infections, 1 DVT, 1 cerebral ischemia, 1 pressure sore ulcer, 1 myocardial infarction, 1 cardiac arrest, and no deaths. For the bivariate analysis, there was no statistically significant association between occurrence of complication and frailty as nonfrail patients had a complication rate of 3.2%, compared to preoperative frail at 4.8%, and 5.6% of frail patients ($P = .59$). Age and sex were selected as adjustment variables for multivariable analysis, although neither was associated with complication (both $P > .05$). Similarly, there was no association between postoperative complication and frailty in the multivariable analysis (OR, 1.56; 95% CI, 0.98-2.48; $P = .06$).

**Discussion**

Frailty has the potential to offer a simple yet accurate predictor of an individual patient’s surgical outcomes and risk for postoperative complications. Frailty metrics like the mFI-5 attempt to represent an individual’s overall health status rather than simply using chronological age as a metric to determine fitness for surgery. As a result, measuring a patient’s frailty index may be able to help identify more optimal surgical candidates. Although frailty can increase with chronological age, this is not a purely linear relationship, and up to 75% of those over the age of 85 may not meet many of the parameters for defining frailty. In this study, 58% of patients over the age of 85 had an mFI-5 of 0. Furthermore, to be useful, frailty should be objectively assessed and quantified; it is insufficient to judge the extent of frailty solely on functional status or physical appearance.

Increasing frailty has been demonstrated across a variety of surgical disciplines to be an independent risk factor for worse outcomes. This is the first reported study evaluating the effect of frailty as a predictor of complications following cochlear implantation. While the rate of postoperative complications appeared to increase with a mFI-5 >1, this did not reach statistical significance. However, this lack of significance could be potentially related to study design, rather than lack of effect due to the study’s retrospective nature. Similarly, chronological age at the time of implantation had no statistical effect on postoperative complications. These data demonstratively illustrate the safety of cochlear implantation regardless of age and potentially for those with mFI-5 >1.

These findings highlight the importance of frailty in predicting postoperative complications following cochlear implant surgery. Cochlear implant surgery is a safe and effective procedure, with a low risk of complications even in patients with increased frailty. While the risk of complications appeared to increase with increased frailty without reaching statistical significance, the overall complication rate remained clinically low compared to the positive benefits of cochlear implants in this older cohort. The potential impact cochlear implantation has on a patient’s quality of life is very high, especially for older adults who are at higher risk of functional decline. There is a growing body of evidence describing a direct connection between age-related hearing loss and cognitive decline in older adults. By restoring hearing via cochlear implant surgery, the negative consequences of profound hearing loss may be mitigated. This population of patients with severe-to-profound sensorineural hearing loss who do not derive sufficient benefit from a hearing aid are better served with a cochlear implant. This study helps

| Table 1. Demographic and Comorbidity Statistics for Older Cochlear Implant Recipients. |
|---------------------------------|-----------------|
| Factor                          | Value           |
| Age                             | 62.5 (0.9)      |
| Sex, No. (%)                    | Male 283 (54.4) |
|                                | Female 237 (45.6) |
| Race, No. (%)                   | White or Caucasian 468 (90) |
|                                | Hispanic/Latino 15 (2.9) |
|                                | Black/African American 1 (0.2) |
|                                | Asian 3 (0.6) |
|                                | American Indian/Alaska Native 3 (0.6) |
|                                | Unknown 30 (5.8) |
| Ethnicity, No. (%)              | Hispanic 15 (2.8) |
|                                | Not Hispanic 470 (90.4) |
|                                | Unknown 35 (6.7) |
| Preoperative comorbidities, No. (%) | Impaired functional status 9 (1.7) |
|                                | Heart failure 14 (2.7) |
|                                | Diabetes mellitus 79 (15.2) |
|                                | Hypertension 121 (23.3) |
|                                | Pulmonary disease 28 (5.4) |
| Five-item Modified Frailty Index, mean (SD) | 0.48 (0.77) |

Figure 1. Scatterplot of relationship between age and frailty. $P = .08$. 

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demonstrate that cochlear implantation can be done with low rates of complications, even in patients with increased frailty. There are 2 primary limitations to this study: its retrospective design and its small sample size. Any retrospective chart review is subject to several limitations. Importantly, retrospective designs demonstrate association without necessarily establishing a causal relationship. In addition, because the data were not collected in a controlled, prospective manner, it is possible that potential confounding variables may not have been considered. For instance, these variables are collected based on ICD-9 and ICD-10 codes to reflect specific clinical diagnoses. Often these diagnoses are based on clinical judgment and must be intentionally added to the electronic medical record to be effectively captured. However, the medical conditions in the mFI-5 are common elements documented in most patients’ charts. Therefore, it is likely that most of these elements were captured accurately in our review of records. We also recognize that additional factors not included in the mFI-5 could be important in predicting risk in presurgical patients. In this study, a presurgical assessment of cognition was not included, and postoperative delirium was not reliably assessed and therefore could not be included.

We also must consider whether these results can be generalized to the overall US population since the cohort in this study was relatively homogeneous. Utah has a 90% white population, and the Hispanic population appears underrepresented in this study based on the most recent census for Utah. One potential explanation for this discrepancy is that until only recently, the Spanish AZ-BIO sentence list to determine CI candidacy was not available at our institution. As a consequence, patients who are Spanish speaking only would need to be profoundly deaf in order to be implanted. For example, in a recent study from Dallas, Texas, with a Hispanic population of 38.3%, their cohort of CI recipients comprised 8.7% Hispanic patients and roughly 3% who were Spanish speaking only. This finding could offer an opportunity to increase health equity with outreach to overcome barriers to care.

The low value of the mFI-5, which in most cases was 0 or 1 in our patient population, limits the ability to relate frailty to outcomes. It is likely that referral for the procedure, self-selection, and mutual decision making with the surgeon already excluded many individuals who are frail with additional morbidities not captured by the mFI-5. Our findings do not substantiate the high level of concern that may be limiting access to CI from those who might benefit. Another possible limitation is that the low rate of major complications following CI surgery makes finding a clinically significant impact of frailty on postoperative complications more difficult. Overall, the published major complication rate for CI surgery in adults is between 1% and 5%. The low incidence of medical complications we observed may also be due to the high volume of cochlear implant surgeries at our institution performed by senior experienced surgeons with experienced anesthesia colleagues, factors well established in the literature to improve outcomes. Nevertheless, the low rate of complications only amplifies the safety and low risk of adverse events for older adults and even potentially more frail adults after cochlear implantation.

Future research should focus on the prospective analyses of physical frailty and its impact on patient outcomes. Prospective collection of data will allow a more thorough and consistent evaluation and provide an opportunity to assess how modification of the list of variables in the mFI-5 may affect surgical outcomes.

Conclusion

While there may be hesitation among patients and providers to proceed with cochlear implantation for older adults due to the risk of surgery and general anesthesia, this study suggests that age should not be the determining factor in making that decision. This study shows that the rate of postoperative complications is very low (3.85%), even for individuals with increased frailty based on the mFI-5. Neither age nor frailty predicted an increased rate of complications.

Author Contributions

Steven A. Gordon, lead author/writer of manuscript; Alana Aylward, coauthor/writer of manuscript; Neil S. Patel, co-lead editor, conceptual framework of manuscript, final approval of manuscript; Christian Bowers, conceptual framework of manuscript, editor, cowriter discussion; Angela P. Presson, editor, analysis of data, cowriter; Ken R. Smith, editor, analysis of data, cowriter; Norman L. Foster, editor, analysis of data, cowriter; Richard K. Gurgel, co-lead editor, lead of conceptual framework of manuscript, final approval of manuscript.

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