Original Research

AMERICAN ACADEMY OF OTOLARYNGOLOGY–HEAD AND NECK SURGERY FOUNDATION

OTO Open
2021, Vol. 5(3) 1–5

DOI: 10.1177/2473974X211044084
http://oto-open.org
SAGE

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

Steven A. Gordon, MD, MPH[1], Alana Aylward, MD[1], Neil S. Patel, MD[1], Christian Bowers, MD[2], Angela P. Presson, PhD[1], Ken R. Smith, PhD[1], Norman L. Foster, MD[1], and Richard K. Gurgel, MD, MSCI[1]

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 $\geq$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

Received August 5, 2021; accepted August 14, 2021.

Sensorineural hearing loss in the older adult population is increasing in frequency and represents an important treatment challenge. Worldwide, 8.5% of the population is over the age of 65 years and is expected to double by the year 2050 to nearly 1.6 billion people.[1] The prevalence of hearing loss for individuals aged 60 to 69 years stands at 43.8% and is nearly ubiquitous by the time they reach their 80s.[2] Cochlear implantation provides the opportunity to restore hearing and attenuate the potential negative consequences of profound hearing loss such as cognitive decline.[3] Yet, despite this proven efficacy, roughly 5% of adults who meet candidacy criteria for cochlear implantation (CI) proceed with surgery.[4]

One hypothesis for this low utilization is a reluctance in performing a surgical procedure in older adults for fear of increased complications. However, the safety and efficacy of cochlear implantation in older adults is well documented.[5-8] As more literature has been devoted to the topic of cochlear implantation in older adults, using chronological age alone as a determinant of surgical candidacy is arguably too simplistic

[1]Division of Otolaryngology–Head and Neck Surgery, University of Utah, Salt Lake City, Utah, USA
[2]Department of Neurosurgery, University of New Mexico School of Medicine, Albuquerque, New Mexico, USA

Corresponding Author:
Steven A. Gordon, MD, MPH, Division of Otolaryngology–Head and Neck Surgery, University of Utah, 50 North Medical Dr, SOM 3C-120, Salt Lake City, UT 84132, USA.
Email: Steven.Gordon@hsc.utah.edu

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.[9,10] Frailty metrics attempt to quantify physiologic age based on comorbidities, rather than relying solely on chronologic age.[11] 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.[12-14]

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.[9,15-18] 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.[19] 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.[17] 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 $\geq$2), and a χ^2 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.[20] 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 infection, 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, .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.[11,21,22] 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.[13] 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.[3,23] 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)

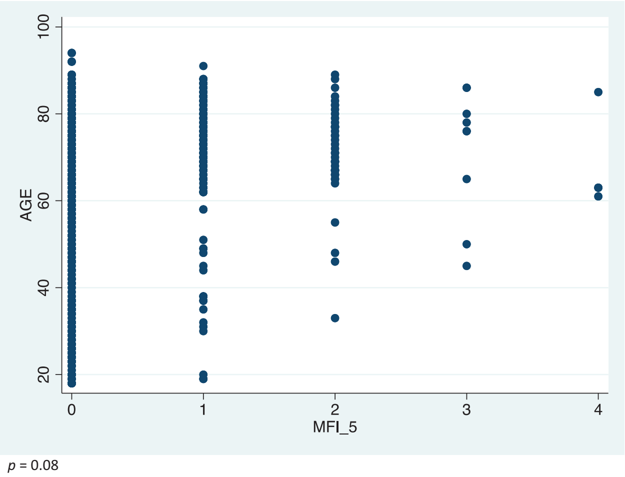

Figure 1. Scatterplot of relationship between age and frailty. $P = .08$.

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.[24] 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%.[25-27] 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.[28,29] 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,

Disclosures

Competing interests: None.

Sponsorships: None.

Funding source: Funding from NIA/NIH R21 AG067403-01A1.

ORCID iD

Steven A. Gordon https://orcid.org/0000-0001-9656-8730

Supplemental Material

Additional supporting information is available at http://journals.sagepub.com/doi/suppl/10.1177/2473974X211044084

References

1. Wan He DG, Kowal P. *An Aging World: 2015*. US Government Printing Office; 2015.
2. Cruickshanks KJ, Wiley TL, Tweed TS, et al. Prevalence of hearing loss in older adults in Beaver Dam, Wisconsin: the Epidemiology of Hearing Loss Study. *Am J Epidemiol*. 1998; 148:879-886.
3. Panza F, Lozupone M, Sardone R, et al. Sensorial frailty: age-related hearing loss and the risk of cognitive impairment and dementia in later life. *Ther Adv Chronic Dis*. 2019;10: 2040622318811000.
4. Sorkin DL. Cochlear implantation in the world's largest medical device market: utilization and awareness of cochlear implants in the United States. *Cochlear Implants Int*. 2013;14(suppl 1):S4-S12.

5. Carlson ML, Breen JT, Gifford RH, et al. Cochlear implantation in the octogenarian and nonagenarian. *Otol Neurotol*. 2010;31: 1343-1349.
6. Forli F, Lazzerini F, Fortunato S, Bruschini L, Berrettini S. Cochlear implant in the elderly: results in terms of speech perception and quality of life. *Audiol Neurootol*. 2019;24:77-83.
7. Manrique-Huarte R, Calavia D, Huarte Irujo A, Giron L, Manrique-Rodriguez M. Treatment for hearing loss among the elderly: auditory outcomes and impact on quality of life. *Audiol Neurootol*. 2016;21(suppl 1):29-35.
8. Sanchez-Cuadrado I, Lassaletta L, Perez-Mora RM, et al. Is there an age limit for cochlear implantation? *Ann Otol Rhinol Laryngol*. 2013;122:222-228.
9. Casazza GC, McIntyre MK, Gurgel RK, et al. Increasing frailty, not increasing age, results in increased length of stay following vestibular schwannoma surgery. *Otol Neurotol*. 2020;41:e1243-e1249.
10. Smart R, Carter B, McGovern J, et al. Frailty exists in younger adults admitted as surgical emergency leading to adverse outcomes. *J Frailty Aging*. 2017;6:219-223.
11. Fried LP, Tangen CM, Walston J, et al. Frailty in older adults: evidence for a phenotype. *J Gerontol A Biol Sci Med Sci*. 2001; 56:M146-M156.
12. Kojima G, Iliffe S, Walters K. Frailty index as a predictor of mortality: a systematic review and meta-analysis. *Age Ageing*. 2018;47:193-200.
13. Wahl TS, Graham LA, Hawn MT, et al. Association of the Modified Frailty Index with 30-day surgical readmission. *JAMA Surg*. 2017;152:749-757.
14. Yagi M, Michikawa T, Hosogane N, et al. The 5-Item Modified Frailty Index is predictive of severe adverse events in patients undergoing surgery for adult spinal deformity. *Spine (Phila Pa 1976)*. 2019;44:E1083-E1091.
15. McIntyre M, Gandhi C, Dragonette J, et al. Increasing frailty predicts worse outcomes and increased complications after angiogram-negative subarachnoid hemorrhages. *World Neurosurg*. 2020;134:e181-e188.
16. Pazniokas J, Gandhi C, Theriault B, et al. The immense heterogeneity of frailty in neurosurgery: a systematic literature review. *Neurosurg Rev*. 2021;44(1):189-201.
17. Subramaniam S, Aalberg JJ, Soriano RP, Divino CM. New 5-factor Modified Frailty Index using American College of Surgeons NSQIP data. *J Am Coll Surg*. 2018;226:173-181.e178.
18. Zampieri FG, Iwashyna TJ, Viglianti EM, et al. Association of frailty with short-term outcomes, organ support and resource use in critically ill patients. *Intensive Care Med*. 2018;44:1512-1520.
19. Velanovich V, Antoine H, Swartz A, Peters D, Rubinfeld I. Accumulating deficits model of frailty and postoperative mortality and morbidity: its application to a national database. *J Surg Res*. 2013;183:104-110.
20. Vittinghoff E, McCulloch CE. Relaxing the rule of ten events per variable in logistic and Cox regression. *Am J Epidemiol*. 2007;165:710-718.
21. Iqbal J, Denvir M, Gunn J. Frailty assessment in elderly people. *Lancet*. 2013;381:1985-1986.
22. Song X, Mitnitski A, Rockwood K. Prevalence and 10-year outcomes of frailty in older adults in relation to deficit accumulation. *J Am Geriatr Soc*. 2010;58:681-687.
23. Gurgel RK, Ward PD, Schwartz S, Norton MC, Foster NL, Tschanz JT. Relationship of hearing loss and dementia: a prospective, population-based study. *Otol Neurotol*. 2014;35:775-781.
24. Tolisano AM, Schauwecker N, Baumgart B, et al. Identifying disadvantaged groups for cochlear implantation: demographics from a large cochlear implant program. *Ann Otol Rhinol Laryngol*. 2020;129:347-354.
25. Farinetti A, Ben Gharbia D, Mancini J, Roman S, Nicollas R, Triglia JM. Cochlear implant complications in 403 patients: comparative study of adults and children and review of the literature. *Eur Ann Otorhinolaryngol Head Neck Dis*. 2014;131:177-182.
26. Petersen H, Walshe P, Glynn F, et al. Occurrence of major complications after cochlear implant surgery in Ireland. *Cochlear Implants Int*. 2018;19:297-306.
27. Stamatiou GA, Kyrodimos E, Sismanis A. Complications of cochlear implantation in adults. *Ann Otol Rhinol Laryngol*. 2011;120:428-432.
28. Hatch JL, Bauschard MJ, Nguyen SA, Lambert PR, Meyer TA, McRackan TR. Does hospital volume affect outcomes in patients undergoing vestibular schwannoma surgery? *Otol Neurotol*. 2018;39:481-487.
29. Rezaii E, Li D, Heiferman DM, et al. Effect of institutional volume on acoustic neuroma surgical outcomes: state inpatient database. 2009-2013. *World Neurosurg*. 2019;129:e754-e760.