Determining treatment choices after the cochlear implant evaluation process

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Abstract
Objectives
- Determine the proportion of patients starting the cochlear implant evaluation (CIE) process proceeding to cochlear implantation.
- Determine which patient factors are associated with undergoing cochlear implantation

Methods: Retrospective case series of all patients scheduled for a CIE within a tertiary academic neurotology practice between January 1, 2014 and April 30, 2016. Management pathways of patients undergoing CIE were examined.

Results: Two hundred thirty-seven adult patients were scheduled for CIE during the study period. Two hundred twenty-six patients started the evaluation process, and 203 patients completed full evaluation. Of patients that completed CIE, 166/203 (82%) met criteria for implantation and 37/203 (18%) did not meet criteria. Fifty-nine patients out of 166 patients (36%) meeting criteria did not receive implants and 107/166 (64%) underwent implantation, yielding an overall implantation rate of 47% (107/226) among patients scheduled for CIE. Common reasons for deferring CI among candidates included failure to show up for preoperative appointment (24%), choosing hearing aids as an alternative (22%), patient refusal (21%) and insurance issues (17%). Overall, CIE led to a new adjunctive hearing device (CI or hearing aid) in 113 (113/203, 56%) cases.

Conclusion: Fifty-six (113/203) percent of patients who underwent CIE at an academic medical center underwent CI surgery or received an adjunctive hearing device, but 36% (59/166) of candidates did not receive a CI. Patients who forewent CI despite meeting candidacy criteria did so due to cost/insurance issues, or due to preference for auditory amplification rather than CI.

Level of evidence: 4.

Keywords
cochlear implants, evaluation process, treatment pathways
1 | INTRODUCTION

Cochlear implants (CI) are the most successful implantable device for restoration of hearing loss. To date, close to 350,000 ears have been implanted around the world. Research has shown that the benefits of CI include improved speech recognition, improved quality of life, improved economic status, and decreased stress. Due to these results, CI is considered the standard of care for patients with hearing loss who have minimal benefit from traditional hearing amplification. Despite the clear benefits of CI and excellent cost-effectiveness profile, fewer than 10% of adults meeting audiologic criteria are evaluated for possible implantation. Commonly cited reasons for this low implant rate include a lack of education among patients, audiologists, and physicians, difficulties in maintaining financially viable CI programs and socioeconomic disparities. Achieving a clearer understanding of the evaluation process is important to sustain CI centers and individual providers who provide implant-related services. Despite this, little is known about the final decisions of patients after they are initially referred for a cochlear implant evaluation (CIE).

With this in mind, we sought to investigate the CIE at our institution. This process includes a comprehensive audiologic evaluation, as well as questions regarding a variety of factors relating to implantation success, including matters of personal preference (aversion to implantation of a foreign body), financial concerns (lack of or inadequate insurance), and potential gaps in patient understanding of implant outcomes (benefits, risks, and alternative treatment options). Although many CI centers have established CIE pathways, there are no published studies that have explored the effect of CIE on likelihood of implantation. In view of this, the goal of our study was to evaluate the outcomes of CIE at our institution.

2 | METHODS

2.1 | Study design

We reviewed the medical records of all patients older than 18 years of age who were scheduled for CIE on one or both ears from January 1, 2014 to April 30, 2016. This study was approved by our institutional review board. CIE began with patients or a referring physician contacting a centralized call center with a request to be evaluated for CI. Patients were then scheduled for a CIE visit. All CIEs were performed by one of two audiologists (LH, TH) in a 90-minute visit, during which patients underwent standard pure tone and speech audiometry as well as aided speech testing with AzBio sentence and consonant-nucleus-consonant (CNC) word lists. This information was used to determine if patients were audiologic candidates for CI. Following this component of the evaluation, the audiologists administered a questionnaire to evaluate patient motivation to proceed with CI. Consensus regarding appropriate candidacy for CI was based on results of the CIE together with discussion between both audiologists and the patient's neurotologist. Information from all CIEs was recorded in a centralized database. If patients were not candidates for CI, alternative hearing rehabilitation options were given at the time of the initial CIE.

Patient data was then obtained from the CIE database, including information pertaining to demographics, insurance status, etiology of hearing loss, medical comorbidities, referral source, outcome of CIE (candidate or not a candidate for CI), and final disposition (CI or other hearing device). With respect for reason for not obtaining CI in candidates, the medical record was reviewed for the audiology notes, which specifically detail the reason for not undergoing implantation. With respect to those who were considered poor surgical candidates, this was based on discussion with the implant team with the patient and the anesthesia service to determine if the risk of surgery outweighed the potential benefit of CI.

2.2 | Statistical analysis

Descriptive statistics were presented as mean and standard deviations for continuous variables, and categorical data were expressed as numbers and percentages. Outcome measures included percentage of patients completing CIE, percentage of patients proceeding to CI, and percentages of patients not proceeding to CI. Normality of continuous distributions was determined via the Kolmogorov-Smirnov test. Comparisons of categorical variables were performed using the Fisher exact test. Comparisons of continuous variables with normal distributions were performed with paired or unpaired, two-tailed student t-tests. Similar comparisons of non-normal distributions were performed with the Mann-Whitney sum ranks test. A P value of <.05 was considered statistically significant. All analyses were performed using SAS version 9.4 (Cary, North Carolina).

3 | RESULTS

Of the 237 patients who were scheduled for CIE, 226 presented for their visit. Of these 226 patients, 120 (53%) were male, and the mean age was 64 years. Two hundred-six (91%) were white, 13 (6%) were black, 4 (2%) were Hispanic, and 3 (1%) were of another ethnicity. As shown in Table 1, the most common reasons for hearing loss cited by the referring provider or the patient (if self-referral) were presbyscusis (29%) and infectious etiologies (24%). One hundred twenty-seven patients (56%) had commercial insurance and 75 (33%) were covered by Medicare. One hundred eighty-four patients (81%) used a hearing aid prior to CIE, 8 patients trialed hearing aids prior to any planned CI, 9 did not choose to participate with any type of hearing rehabilitation, and 25 elected to proceed directly to CI without trialing hearing amplification (these patients were audiologic candidates for CI).

Of the 226 patients who presented for CIE, 203/226 (89%) completed CIE (Figure 1). The two most common reasons given for not completing CIE (n = 23) were refusal to undergo the required...
audiologic testing (n = 12) and having already received a CI (n = 8). Of the 203 patients who completed the CIE, 166/203 (73%) met criteria for CI. Of these candidates, 107/166 patients (64%) received a CI, and 59/166 patients (36%) did not receive a CI. An additional 6/203 patients (3%) received either a new conventional hearing aid, bone-anchored hearing aid, or Bi-CROS hearing aid. Overall, 113/203 (56%) patients who completed CIE received an assistive hearing device.

Table 2 shows associations of various factors on progression to CI among the 166 patients who met criteria for CI. As shown, there was no significant difference in the percent of patients who underwent implantation based on age, sex, race, referral source, etiology of hearing loss, and insurance status.

Table 3 shows the outcomes of the 59 patients who met the criteria for CI but did not receive implants. The most common reasons for not receiving a CI were failure to return for preoperative appointment (24%), choosing a hearing aid as an alternative treatment (22%), patient refusal to undergo surgery (21%) and insurance denial/financial concerns (17%). Of note, of those who expressed that they would like a hearing aid as an alternative, 6/13 actually received a hearing aid, and 7/13 did not end up obtaining a hearing aid.

4 | DISCUSSION

The overall goal of our study was to describe the current status of the CIE process at our institution. With this in mind, we reviewed the medical records of patients who were scheduled for CIE and subsequently assessed their pathway through the CIE process and their clinical outcomes. We found that 56% of patients who completed CIE received an assistive hearing device (CI or new hearing aid)—suggesting that the CIE led to a change in audiological management for more than half of patients who underwent CIE. Our data also indicate a need to improve the efficiency of the CIE process, particularly for patients who do not trial hearing aids prior to CIE and for CI candidates who do not follow through with CI. These findings suggest that patients who do not undergo CI often do so based on a preference for a hearing aid as an alternative treatment. In part, this may be attributed to a limited understanding by patients of the benefits of CI. The impact of insurance status on deciding whether or not to undergo CI may also play a role, as 17% of appropriate candidates who did not proceed with CI chose to avoid this procedure primarily due to financial concerns.

Most importantly, our study provided feedback regarding our centralized scheduling system. Many patients without a history of hearing aid use were incorrectly routed to a CIE at their initial contact point with a centralized call center. Thus, it may be a better use of resources to triage patients who have not trialed hearing aids to a standard 60-minute hearing loss evaluation visit as opposed to a lengthy CIE. Of the 237 patients in our study who were scheduled for a 90-minute CIE, 8 were found to have already undergone a CI at
another institution. All 8 patients were self-referred and incorrectly routed by the call center to a CIE, indicating another aspect requiring improvement in the triage process. To address this problem, Lorens et al has recommended creating standardized pathways for CI referrals, working on best practice guidelines for each step of the CIE process, and ensuing post-implant care.13 To best act on these suggestions and formulate best practice guidelines, a baseline understanding of what is currently occurring in the CIE process is necessary. Our data provide a starting point from which to build potential interventions, such as education of call center staff or pre-screening of potential CIE candidates by audiology and surgical staff.

Limitations of this work include an inability to generalize our findings to other institutions and being unable to evaluate if patients presenting to our institution went elsewhere for CI. Our intention was to describe the current status of the CIE process at our institution, and as such, we did not ask patients more in-depth questions regarding why or why not they chose to proceed with CI, which would be beneficial in designing future interventions to improve implantation rates. In addition, there may be some patients who go onto receive a CI at a later date, for whom the CIE was valuable despite not immediately leading to a CI after CIE. In addition, there are other variables that we did not examine that may influence rates of implantation (socioeconomic status, education, proximity to hospital) which we were unable to examine with our data. In addition, we are unable to discern if this study is underpowered, as there is little baseline data in this field, and conducting a power analysis is thus difficult. Finally, due to the time period of the data collection, unilateral deafness was not used as a criteria for implantation, so the inclusion of this new indication may skew the results.16 Despite these limitations, our study provides a better understanding of the outcomes and inefficiencies of the CIE process at a major CI center. We ascertained specific reasons why patients chose to defer CI and identified points of attrition throughout the CIE. It is our hope that our experience paves the way for future quality improvement projects.

### TABLE 2
Association of demographics, referral source, etiology of hearing loss, and insurance status on CI implantation among candidates

|                  | CI implantation |   |   | P-value |
|------------------|-----------------|---|---|---------|
|                  | Yes (N = 107)   | No (N = 59)   |   |         |
| Age, Mean (SD)   | 62.7 (15.9)     | 64.1 (18.6)   | .62 |
| Sex (%)          |                 |               | .22 |
| Female           | 56 (52.3)       | 25 (42.4)     |   |
| Male             | 51 (47.7)       | 34 (57.6)     |   |
| Race (%)         |                 |               |   |
| White            | 99 (92.5)       | 52 (88.1)     | .34 |
| Black            | 6 (5.6)         | 4 (6.8)       |   |
| Hispanic         | 2 (1.9)         | 1 (1.7)       |   |
| Other            | 0               | 2 (3.4)       |   |
| Referral (%)     |                 |               | .47 |
| Self             | 9 (8.4)         | 7 (11.9)      |   |
| Other            | 98 (91.6)       | 52 (88.1)     |   |
| Etiology of hearing loss (%) | | | | |
| Presbycusis      | 38 (35.5)       | 13 (22.0)     | .32 |
| Infectious       | 27 (25.2)       | 15 (25.4)     |   |
| Noise            | 14 (13.1)       | 11 (18.6)     |   |
| Congenital       | 13 (12.1)       | 12 (20.3)     |   |
| Traumatic        | 6 (5.6)         | 3 (5.1)       |   |
| Surgical/Iatrogenic | 5 (4.7)   | 2 (3.4)       |   |
| Medication/Ototoxicity | 4 (3.7) | 3 (5.1)       |   |
| Insurance (%)    |                 |               |   |
| Commercial       | 58 (54.2)       | 38 (64.4)     | .2 |
| Medicare         | 38 (35.5)       | 14 (23.7)     |   |
| Self-pay         | 8 (7.5)         | 4 (6.8)       |   |
| Medicaid         | 1 (0.9)         | 3 (5.1)       |   |
| Other Govt/VA    | 2 (1.9)         | 0             |   |

Approximately half of patients who underwent CIE received a CI. Thirty-six percent of patients who were appropriate candidates for CI did not undergo implantation, most commonly due to a failure to return for a pre-op visit, or patient preference for a hearing aid as an alternative treatment, regardless of recommendation for CI. Further research into the effects of standardized pathways in the future may improve efficiencies and decrease inappropriate referrals.

### TABLE 3
Outcomes of patients meeting criteria for CI but who did not undergo this procedure

|                  | N = 59 (%) |
|------------------|-----------|
| Did not return for pre-op visit | 14 (23.7) |
| Chose hearing aids instead | 13 (22.0) |
| Patient declined | 12 (20.3) |
| Insurance | 10 (16.9) |
| Not a good surgical candidate | 6 (10.2) |
| Had stapedectomy instead | 1 (1.7) |
| Went elsewhere | 2 (3.4) |

## 5 | CONCLUSIONS

Approximately half of patients who underwent CIE received a CI. Thirty-six percent of patients who were appropriate candidates for CI did not undergo implantation, most commonly due to a failure to return for a pre-op visit, or patient preference for a hearing aid as an alternative treatment, regardless of recommendation for CI. Further research into the effects of standardized pathways in the future may improve efficiencies and decrease inappropriate referrals.

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### CONFLICT OF INTEREST

Dr. Samy receives research funding from Cochlear Corporation. The remaining authors have no conflicts of interest to disclose.

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