

ORIGINAL RESEARCH

Candidacy for Cochlear implantation: Validating a novel Cochlear implant candidacy calculator against gold-standard, in-clinic audiometric assessments

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Abstract

Objectives: Cochlear implants (CI) are reliable implantable devices that are highly cost-effective in reducing the burden of hearing loss at an individual and societal scale. However, only 10% of CI candidates are aware of their candidacy and receive a CI. A web-based screening tool to assess CI candidacy may make many more individuals aware of their candidacy for cochlear implantation. The objective of this study was to validate and optimize the online Cochlear Implant Candidacy Calculator against in-clinic audiometric testing.

Methods: Audiogram data and word discrimination scores for 132 patients who underwent initial CI consultation at the Johns Hopkins Cochlear Implant Center in 2020 were inputted into the calculator. Candidacy results from the calculator were compared against formal clinical diagnoses provided by the audiologist at the time of visit. Receiver Operating Characteristic (ROC) and Area Under the Curve (AUC) analyses were performed to identify optimal diagnostic thresholds.

Results: Of the resulting 132 patients, 54 presented with single-sided deafness (SSD), and 114 were clinically determined to be CI candidates. ROC AUC analyses identified optimal thresholds of high-frequency PTA ≥ 65 dB and word discrimination score $\leq 50\%$. To maximize sensitivity at the expense of specificity, diagnostic thresholds of high-frequency PTA ≥ 65 dB and word discrimination score $\leq 70\%$ were chosen, which yielded accuracy, sensitivity, specificity, and ROC AUC of 0.90, 0.94, 0.82, and 0.88, respectively.

Conclusion: The novel online CI Candidacy Calculator exhibits high sensitivity and accuracy, and moderate specificity. The calculator may thereby be useful in increasing awareness of potential CI candidacy, increasing prevalence of CIs, and decreasing the burden of hearing loss.

KEYWORDS

audiogram, calculator, candidacy, cochlear implant

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1 | INTRODUCTION

Hearing loss is extremely prevalent with increasing age, affecting 25% of patients older than 50 years, and over 50% of patients older than 80 years of age.¹ This disabling condition causes a significant personal, social, and economic burden.² In particular, costs to the health care sector for moderate-to-profound hearing loss, not including costs for providing hearing devices, are estimated to be in the range of \$67–107 billion; loss of productivity due to unemployment and premature retirement among people afflicted with hearing loss is estimated to cost \$105 billion annually.³

A cochlear implant (CI) is a reliable implantable device that has been shown to be highly cost-effective at an individual and societal scale as measured by quality-adjusted life years gained in both children and adults.⁴ FDA guidelines for CI candidacy include air conduction thresholds from moderate to profound levels, and aided sound-field speech recognition scores $\leq 50\%$ in the ear to be implanted or $\leq 60\%$ in the best binaurally aided condition (when presentation level is 60 dB SPL). Medicare guidelines require $\leq 40\%$ speech discrimination scores obtained using sentence material.

Despite strong evidence of the value of this device, only 10% of cochlear implant candidates receive a CI.^{5,6} A primary reason for lack of adoption of this very effective technology is lack of awareness of candidacy criteria in practices and communities outside major academic settings. Moreover, audiometric testing and subsequent follow-up visits to assess cochlear implant candidacy are time-consuming, resource-intensive, and expensive. These barriers were exacerbated with the closure of many outpatient audiology and otolaryngology offices during the COVID-19 pandemic.⁷ A web-based screening tool to assess potential cochlear implant candidacy using only standard audiometry results may help to raise awareness of cochlear implant candidacy in a convenient format that could be accessed by practitioners (e.g., providers, audiologists), patients, and the public.

The primary aim of this study was to validate and optimize a novel online Cochlear Implant Candidacy Calculator developed by the Johns Hopkins Cochlear Implant Center against the gold-standard, in-clinic audiometric testing.

2 | MATERIALS AND METHODS

Approval for this study was obtained through the Johns Hopkins School of Medicine Institutional Review Board. Informed consent was not required due to the retrospective nature of this study.

2.1 | Standard in-clinic testing for cochlear implant candidacy

An in-clinic evaluation is the current gold-standard protocol for assessing cochlear implant candidacy. Patients who are potential cochlear implant candidates undergo two stages of diagnostic evaluation (Figure 1). First, patients receive a standard audiometric evaluation to assess normal

hearing and speech discrimination function. A traditional audiometric evaluation does not include aided sound-field air conduction thresholds, nor aided sound-field speech discrimination testing at a fixed amplitude (i.e., volume), which is the cornerstone of establishing CI candidacy. Rather, the standard diagnostic audiogram includes unaided, ear-specific pure-tone threshold and speech discrimination testing assessed using recorded voice delivered via insert or circum-aural headphones. The following components are conducted as part of the audiometric evaluation:

- Unaided testing of air and bone conduction thresholds for each individual ear, with masking of the contralateral side when clinically appropriate.
- Unaided assessment of the speech reception threshold (SRT) for each individual ear, with masking of the contralateral side when clinically appropriate. As poor speech discrimination may elevate the SRT, a clinician may opt for assessment of speech detection thresholds (SDT) using monitored live-voice presentation.
- Unaided testing of speech discrimination function with monosyllables presented at 40 dBHL above the ear's SRT or SDT, with masking of the contralateral side when clinically appropriate. If +40 dBHL goes beyond comfortable loudness for the patient, testing is performed with speech presentation at the most comfortable level (MCL) for the subject.

Patients with poor hearing and speech discrimination function are fitted with hearing aids. Patients who report limited benefit from amplification after a 30-day trial are referred for a formal CI candidacy consultation. During this visit, the patient's hearing aids are evaluated electro-acoustically to ensure proper function and amplification levels close to the NAL-NL2 prescriptive targets. Patients whose hearing aids fail to reach target levels are re-fitted with new hearing aids. Patients with bilateral sensorineural hearing loss undergo:

- Assessment of aided sound-field thresholds at 250, 500, 1000, 2000, 4000, and 8000 Hz for each ear, with masking of the contralateral side when clinically appropriate.
- Aided speech discrimination testing with presentation of CNC words and AZBio Sentence material, in both quiet and noise environments, per specifications outlined in the "Minimal Speech Test Battery (MSTB) for Adult Cochlear Implant Users 2011," with masking of the contralateral side when clinically appropriate.

As most patients with single-sided deafness (SSD) at our institution utilize traditional CROS amplification models, during their CI candidacy consultation visit, these patients are fitted with a unilateral behind-the-ear hearing aid programmed using NAL-NL2 prescriptive guidelines.

SSD patients then undergo:

- Assessment of aided sound-field thresholds at 250, 500, 1000, 2000, 4000, and 8000 Hz in the candidate ear, with the contralateral ear masked via an insert headphone presenting narrow-band noise.
- Aided speech discrimination testing in the candidate ear with presentation of CNC words and AZBio Sentence material, in both

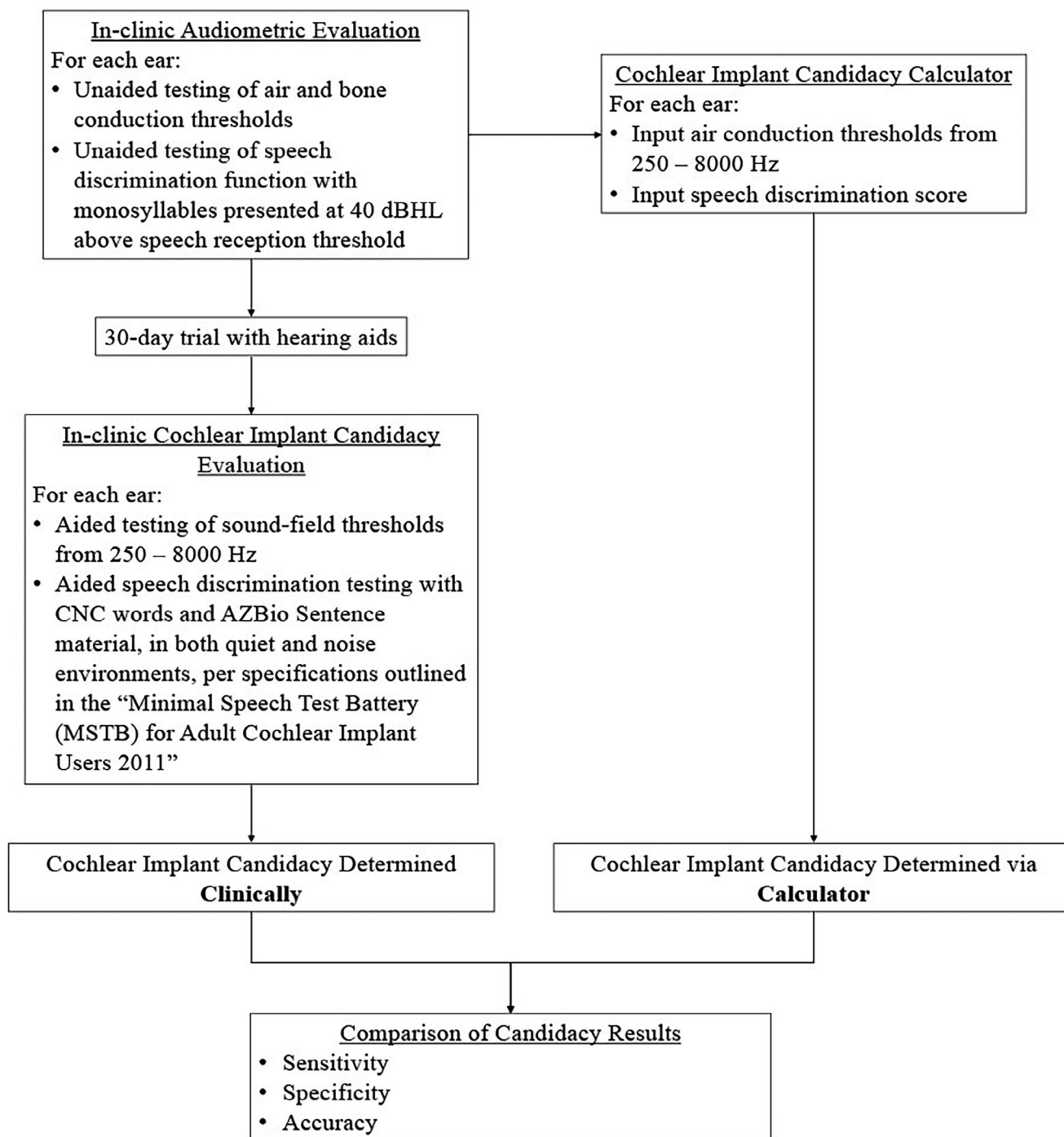


FIGURE 1 Evaluation of the performance of the Cochlear Implant Candidacy Calculator against in-clinic assessments.

quiet and noise environments, per specifications outlined in the “Minimal Speech Test Battery (MSTB) for Adult Cochlear Implant Users 2011,” with the contralateral ear masked via an insert headphone presenting speech-masking noise.

As CI eligibility requirements vary by insurance, patients deemed clinically to be CI candidates are those who meet their own insurance requirements for reimbursement. In particular, a patient with Medicare was considered a clinical candidate for a cochlear implant if their aided sentence discrimination score was < 40%. A patient with Medicaid was

considered a clinical candidate if their aided sentence discrimination score was < 50%. A patient with Blue Cross Blue Shield was considered a clinical candidate if their aided speech discrimination score was < 50%.

2.2 | Development of the diagnostic criteria

Previous studies have shown that audiometric results may correlate with in-clinic CI evaluation results.^{8,9} In order to “cross-walk” the

results of routine audiometry with the formal test results used to establish CI candidacy, we chose a high-frequency pure-tone average (PTA) at 1, 2, and 4 kHz of ≥ 70 dB, and word discrimination score of $\leq 70\%$ correct as our CI candidacy criteria for the initial iteration (prior to any optimization) of the calculator, which calculates and outputs CI eligibility for each ear independently. A high-frequency PTA threshold of 70 dB was chosen as a high-frequency PTA of 70 dB is considered the lower bound of the “severe” category in traditional hearing loss descriptors (i.e., mild, moderate, severe, and profound).^{10,11} A word discrimination score threshold of 70% was chosen to yield high sensitivity, which is the goal of a screening tool, and capture more potential CI candidates.^{12,13} Additionally, a word discrimination score of 70% has been used in several studies as a threshold of “good” and “socially useful” hearing.^{14,15}

We sought to more rigorously identify numerical thresholds to improve performance of the calculator. To this end, medical records from 132 adult patients who underwent audiometric evaluation and subsequent CI candidacy consultation between January 2020 and January 2021 at the Johns Hopkins Outpatient Center, Green Spring Station, and Suburban Outpatient Center were analyzed. Unaided air conduction thresholds (250, 500, 1000, 2000, 4000, 6000, and 8000 Hz), unaided word discrimination scores, and CI clinical eligibility were collected. Unaided audiometry results and unaided speech discrimination scores were inputted into the calculator, and eligibility assessed by our screening tool was noted and compared to CI candidacy determined via in-clinic testing. Performance of the calculator was assessed by computing sensitivity, specificity, and accuracy relative to the gold-standard clinical assessment. Sensitivity was the proportion of clinically determined CI candidates who were deemed eligible for a CI by the calculator. Specificity was the proportion of patients clinically ineligible for a CI who were likewise deemed ineligible by the calculator. Accuracy was the proportion of all cases that were correctly assessed by the calculator. Receiver operating characteristic (ROC) and area under the curve (AUC) analyses were performed to iterate through all numerical combinations of high-frequency PTA and speech discrimination score thresholds. The diagnostic criteria that yielded the highest AUC score were selected.

3 | RESULTS

3.1 | Development and optimization of the diagnostic criteria

The initial iteration of the online CI candidacy criteria was developed using the audiometric criteria of both high-frequency (1, 2, 4 kHz) PTAs of ≥ 70 dB and word recognition/discrimination scores of $\leq 70\%$ correct. The online CI candidacy calculator is displayed in Figure 2.

To optimize the above criteria, we investigated a total of 132 patients who underwent initial CI candidacy consultations between January 2020 and January 2021. The mean age of these patients was 65.7 years, and the sex ratio (male 63: female 69) was 1: 1.1. Of the 132 patients, 54 presented with single-sided deafness (SSD), and 114 were clinically

Cochlear Implant Candidacy Calculator

Please fill in the spaces below with your corresponding hearing threshold and word discrimination score values.

Audiogram data:

Frequency (Hz)	250	500	1000	2000	4000	6000	8000
Hearing Level (dB) Left	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Hearing Level (dB) Right	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

Word Recognition/Discrimination Score data:

Word Recognition/Discrimination Score (%), Left Ear:

Word Recognition/Discrimination Score (%), Right Ear:

Check eligibility

FIGURE 2 Cochlear implant candidacy calculator

determined to be CI candidates (including 54/54 patients with SSD and 60/78 of all other patients). The sensitivity, specificity, accuracy, and AUC of our novel CI candidacy calculator (with initial thresholds of high-frequency PTA ≥ 70 dB and word discrimination score $\leq 70\%$) were 89%, 90%, 89%, and 90%, respectively. We then iterated through all combinations of high-frequency PTA and speech discrimination score thresholds to identify the diagnostic criteria most optimal for the calculator's performance. ROC AUC analyses yielded optimal diagnostic thresholds of high-frequency PTA ≥ 65 dB and word discrimination score $\leq 50\%$. Resulting accuracy, sensitivity, specificity, and AUC were 92%, 91%, 92%, and 92%, respectively. However, to achieve higher sensitivity, although at the expense of specificity, screening boundaries of high-frequency PTA ≥ 65 dB and word discrimination score $\leq 70\%$ were chosen, and yielded accuracy, sensitivity, specificity, and ROC AUC of 90%, 94%, 82%, and 88%, respectively.

4 | DISCUSSION

Although there exists strong evidence of the value of CIs in alleviating the medical, social, and economic burden of hearing loss, only 10% of eligible candidates receive a CI. This is due in part to a lack of awareness of candidacy criteria in many communities outside major academic or metropolitan settings. In this study, novel diagnostic criteria for CI candidacy were developed using results from routine audiometric testing. Audiometric results from 132 patients were used retrospectively to validate a novel CI candidacy calculator against formal clinical candidacy determinations. As the purpose of the calculator is to increase awareness and referrals for CI evaluation, we chose to maximize sensitivity at the expense of specificity of the calculator. To this end, diagnostic thresholds of high-frequency PTA ≥ 65 dB and word discrimination score $\leq 70\%$ were chosen, which yielded high accuracy (90%) and sensitivity (94%), and moderate specificity (88%).

False-positive results ($n = 16$; clinical: not a CI candidate; calculator: CI candidate) were found in patients with poor unaided

audiological results (both high-frequency PTA \geq 65 dB and word discrimination score \leq 70%) but clinically acceptable performance (based on insurance guidelines) under best-aided listening conditions. Likewise, false-negative results ($n = 11$; clinical: CI candidate; calculator: not a CI candidate) were found in patients deemed eligible for a CI based on poor aided discrimination scores, although it was moderate unaided air-conduction thresholds (40–60 dB) that provoked ineligibility in the calculator. It may be advisable for a future version of the calculator to weigh discrimination scores and moderate air conduction thresholds as “potential CI candidate requiring additional clinical testing.” Future iterations of the calculator may also incorporate information about patient age and insurance status to help tailor diagnostic criteria.

Our study was subject to one main limitation. As subjects were pooled from the Johns Hopkins Outpatient Center, Green Spring Station, and Suburban Outpatient Center, results may not be representative, and should be further validated using a broader patient population.

5 | CONCLUSION

The novel online CI Candidacy Calculator exhibits high accuracy and sensitivity, and moderate specificity. The calculator may be useful in increasing awareness of potential CI candidacy, increasing prevalence of CIs, and thereby decreasing the burden of hearing loss.

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CONFLICT OF INTEREST

The authors have no conflicts of interest to declare.

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