Candidacy and Outcomes for CIs and Hybrids

Holly Teagle, AuD, Associate Professor
University of North Carolina – Chapel Hill
Historical Expansion of FDA Guidelines

• Manufacturers submit technology for approval to the FDA - must be safe and effective
• Clinical outcomes support these claims
• Patient success encourages expansion in technology and practices
Criteria in 1985

- Adults 18 yrs+
- ONSET of hearing loss
  Post linguistic
- DEGREE of hearing loss
  Profound
- WORD RECOGNITION
  0%

Pre-Operative
Aided Speech Testing
Word Test
Hearing Aid: 0%

$A_B$ = Hearing Aid Both Ears
Criteria in 1990

- Adults 18 yrs+
- Children 2 yrs+
- **ONSET** of hearing loss
  - Post linguistic adults
  - Pre & Post Linguistic kids
- **DEGREE** of hearing loss
  - Profound
- **WORD RECOGNITION**
  - 0%

Pre-Operative

Aided Speech Testing

Word Test

Hearing Aid: 0%

$A_B$ = Hearing Aid Both Ears
Criteria in 1998

- Adults 18 yrs+
- Children 18 mos+
- ONSET OF HEARING LOSS Pre & Post Linguistic
- DEGREE OF LOSS Severe to Profound Adults Profound Children
- WORD RECOGNITION 40% or less

Pre-Operative
Aided Speech Testing
Word Test

Hearing Aid: 38%

A_B = Hearing Aid Both Ears
Criteria in 2000

- Adults 18 yrs+  Children 12 mo+

- ONSET OF HEARING LOSS
  Pre & Post Linguistic

- DEGREE OF LOSS
  Severe to Profound Adults
  Profound Children

- WORD RECOGNITION
  Sentences s core 50% or less in ear to be implanted,
  < 60% in best aided condition

Pre-Operative
Aided Speech Testing

Sentence Test

Hearing Aid: 46%

$A_B = \text{Hearing Aid Both Ears}$
Criteria in 2014

- Adults only for Hybrid
- DEGREE OF LOSS
  Hybrid/Electro-Acoustic: Normal to Moderate in low frequencies
  S/P mid to high frequencies
  (2 devices: Cochlear and MED-EL)
- WORD RECOGNITION
  CNC word score >10% but less than 60% in ear to be implanted;
  <80% CNC words in contralateral ear

Pre-Operative
Aided Speech Testing

Word Test
Hearing Aid:  
54% LE
72% RE
Why have FDA Guidelines expanded?

• CI technology and clinical outcomes improved
• Adults and children with S/P hearing loss have better outcomes with CIs than with hearing aids
• Testing previously only used sentence scores; now increasingly using single word test scores and hearing in noise (more people are candidates)
• Research demonstrates candidates do better with more residual hearing and shorter periods of deafness
Med El EAS

Cochlear Nucleus Hybrid
Why was this expansion appropriate?

• FDA approval of a hybrid device signifies recognition that:
  • CI Hybrid electrode more likely to result in more preserved residual hearing than traditional CI electrode
  • Opened door for patients with greater pre-operative hearing to receive Hybrid CI
  • Studies show hybrid hearing provides improved speech recognition in noise compared to traditional CIs, leading to greater attention being paid to testing in noise
CI Outcomes

• Tremendous variability in outcomes due to heterogeneous population
  
  Based on a published meta-analysis (Gaylor, et al., 2013)

• Statistically significant improvement in mean speech scores as measured by open-set sentence or multi-syllable word tests;

• Significant improvement in QOL after unilateral implantation

• Bilateral implantation showed improvement in communication-related outcomes compared with unilateral implantation

• Bilateral implantation provides additional improvements in sound localization compared with unilateral device use.
Pre-Operative Aided Speech Testing

Word Test

Hearing Aid: 16%

$A_B = \text{Hearing Aid Both Ears}$

Post-Operative Aided Speech Testing

Word Test

CI Right 80%
CI Left 84%

$C_R = \text{Cochlear Implant Right Ear}$
$C_L = \text{Cochlear Implant Left Ear}$
• EAS Outcomes – Single Center Study

Adunka et al (2013)
Pre-Operative
Aided Speech Testing
Word Test
Hearing Aid: 26%

$A_L =$ Hearing Aid Left Ear

Post-Operative -2 years
Aided Speech Testing
Word Test
EAS 90%
$C_L =$ Cochlear Implant Left Ear
Medicare and Cochlear Implants
Medicare and Cochlear Implantation

• Federally funded health insurance program for people 65+

• Medicare has it’s own criteria for CI Coverage
  • Limited benefit from hearing aids with 40% or less words in sentences in best aided in ear to be implanted

• Clinical trial allows up to 50% in ear to be implanted and 60% bilaterally
Research Project: Medicare CED

- ACIA sponsored development of Coverage with Evidence Development study approved by Medicare
- Study is registered on clinicaltrials.gov
- https://clinicaltrials.gov/ct2/show/NCT02075229
- Purpose: To evaluate safety and efficacy of CIs for older adults using expanded CMS criteria
- If approved, CMS and FDA guidelines will be more equivalent
Centers involved in the Medicaid Study
Patient Eligibility Medicare Expansion Study

- 65 years of age or older
- Bilateral moderate-to-profound sensorineural hearing loss in low frequencies (up to 1000 Hz) and profound sensorineural hearing loss in high frequencies (3000 Hz and above)
- Best aided sentence score in quiet between 40 - 60% correct on recorded HINT sentences
- Scores exceed current Medicare guideline but meet FDA
- Spoken English as primary language
- Cognitive ability to use auditory clues and willingness to undergo rehabilitation
- No medical contraindications for surgery
Evaluation of Revised Indications for Cochlear Implant Candidacy for the Adult CMS Population: Results to date
How to go forward if you think you may be a candidate for the Medicare Clinical Trial

• Many audiologists are hesitant to refer based on early candidacy criteria and unfamiliarity w/ CI

• Your candidacy is unknown until you’ve been tested at a CI center

• Study audiologists will review your audiogram before the apt to determine if an evaluation is recommended

• Typically people are happy they went for an evaluation, even if they are not a candidate, as they receive information

• Unlike a hearing evaluation, testing for CI candidacy is typically covered by health insurance (including Medicare)
Have you been told you’re “not deaf enough” even though you have difficulty hearing?

• We can review your audiogram and give you an idea if you might want to explore candidacy at a center near you
• Study personnel can review your most recent audiogram prior to visiting
• Insurance coverage is the same as under Medicare (though it will not cover travel)
• May return to a local CI center after first year
Benefits Reported by Patients

• Richer relationship with family and friends
• Increased confidence and ease of communication at home and work
• More social opportunities
• Greater employment opportunities
• Improvement in quality of life
Why is it wrong to wait?

• Too many people are waiting...the average delay between onset of severe/profound hearing loss and CI is 10 years

• Duration of deafness is one of the most significant predictors of outcomes with a CI: shorter duration of deafness results in better outcomes
References


• CMS STUDY INFORMATION CONTACT: Donna Sorkin / dsorkin @acialliance.org