
Best Evidence Statement (BEST)

Date: June 9, 2011

Quality of Life in Children with Sequential Bilateral Cochlear Implants

Clinical Question

P (population/problem)	Among children with permanent hearing loss
I (intervention)	does sequential bilateral cochlear implantation
C (comparison)	versus unilateral cochlear implantation
O (outcome)	improve quality of life?

Topic and/or question originally asked

Does a sequential cochlear implant improve the quality of life in children?

Target Population

Inclusion: Children, age 0-21, with permanent bilateral hearing loss who do not benefit from conventional amplification (i.e hearing aids)

Exclusion: Children with simultaneous bilateral cochlear implants

Definitions:

Cochlear Implant (CI): A medical device that substitutes for damaged (dead) hair cells of the inner ear. It consists of an electrode array that is surgically implanted in the cochlea. It delivers electrical signals to the auditory nerve from an external processor, enabling people with severe to profound hearing loss to perceive sound again.

Bilateral Cochlear Implant (BICI): one implant in/on each ear

Sequential Bilateral Cochlear Implant: a CI device is implanted in one ear and then subsequently a second CI is implanted in the other (contralateral) ear at a later date.

Simultaneous Bilateral Cochlear Implant: one CI device surgically implanted in each ear during the same surgery.

Binaural/bilateral hearing: coordination of inputs from both ears by the nervous system

Quality of Life (QoL): physical functioning, emotional functioning, social functioning and school functioning. Other important indicators of QoL in the CI population include hearing in noise, localization, communicative intent and behavior, nature of interpersonal relationships and involvement in recreational activities.

Recommendation (See Table of Recommendation Strength following references)

There is insufficient evidence and a lack of consensus to make a recommendation on the use of sequential bilateral cochlear implants rather than a unilateral cochlear implant to improve the quality of life in children with hearing loss.

Discussion/summary of evidence

Bilateral cochlear implantation (BICI) is considered an accepted medical practice in clinically appropriate adults and children (*Balkany, Hodges, Telischi, Hoffman, Madell, Parisier, Gantz, Tyler, Peters, Litovsky 2008,[5b], Eapen & Buchman 2009, [5b]*) and, among some groups, is considered the standard of care for children with bilateral sensorineural hearing loss (*Papsin & Gordon,[5b] 2008*).

Several studies have successfully documented improvements in functional hearing abilities in the pediatric population which may influence a child's quality of life (*Johnston, Durieux-Smith, Angus, O'Connor, Fitzpatrick 2009 [1b], Beijen, Snik, Mylanus, 2007, [4b], Bichey & Miyamoto, 2008 [4b], Galvin, Hughes, Mok 2010 [4b], Lovett, Kitterick, Hewitt, Summerfield, 2010, [4b], Scherf, Van Deun, van Wieringen, Wouters, Desloovere, Dhooge, Offeciers, Deggouj, DeRaeve, Wuyts, Van de Heyning, 2009,[4b]*). Professionals have also qualitatively observed positive effects of bilateral implantation on children's communication behaviors (*Galvin, Hughes, Mok 2010, [4b], Kuhn-Inacker, et. al.,[4b], Scherf et al. 2009 [4b]*). Unfortunately, these anecdotal reports and other functional benefits are not consistently measured during the pre implant or the post implant evaluation process for pediatric bilateral implantation.

Only one study to date measured an improvement in the quality of life (QoL) of pediatric BICI recipients by using a generic QoL scale (*Bichey & Miyamoto 2008, [4b]*). However, the sample of 6-79 year old post-lingually deafened individuals is not reflective of the sample of interest. Two other studies found no improvement in the QoL of pediatric BICI recipients using a generic QoL measures (*Beijen, Snik, Mylanus, 2007, [4b], Lovett, et. al.,[4b], and Summerfield, Lovett, Bellenger, Batten, [4b], 2010*).

Proposed Research Agenda

It is clear that well designed and controlled studies that explore a variety of outcomes including cost-effectiveness, quality of life, speech, language, and psycho-educational measures related to bilateral cochlear implants should be further explored in order to provide additional support for parents and clinicians as well as to inform health policy (*Dowell, Galvin, Dettman, Leigh, Hughes, van Hoesel, 2011,[1b], Johnston, et. al., 2009 [1b], Murphy & O'Donoghue, 2007, [1b], Bichey & Miyamoto, 2008, [4b]*). In addition, future studies should include a control group of children with only unilateral cochlear implants as well as children with a unilateral cochlear implant and a contralateral hearing aid (*Sparreboom, et. al., 2010, [1b]*).

There is a significant need for a sensitive and specific quality of life measure for BICI patients. Since QoL questionnaires allow comprehensive insight into patient's daily life and activities they are an essential addition to speech perception tests to quantify outcome after cochlear implantation. QoL measures may provide the family perspective which is crucial in guiding clinical and policy decisions (*Lin & Niparko, 2006, [1b], Murphy & O'Donoghue, 2007, [1b], Sparreboom, et al. 2010 [1b], Huttunen, Rimmanen, Vikman, Virokannas, Archbold, Lutman, 2009, [4b], Loy, Warner-Czyz, Tong, Tobey, Roland, 2010, [4b], Loeffler, Aschendorff, Burger, Kroeger, Laszig, Arndt, 2010, [5b]*).

Health Benefits, Side Effects and Risks

The objective benefits of BICI correspond with the primary benefits of bilateral hearing, which include improved speech perception in noise and localization abilities (*Murphy & O'Donoghue, 2007, [1b], Sparreboom, van Schoonhoven, van Zanten, Scholten, Mylanus, Grolman, Maat, 2010, [1b], Kuhn-Inacker, Shehata-Dieler, Muller, Helms 2004, [4b], Litovsky, Johnstone, Godar, Agrawal, Parkinson, Peters, Lake, 2006, [4b]*).

Arguments against bilateral cochlear implantation note the need to preserve the contralateral ear for future technology and rehabilitative methods and potential damage to residual hearing, as the internal placement of CI's destroy the hair cells in the cochlea (*Galvin, Leigh, Hughes, 2009, [5b] and Offeciers, Morera, Muller, Huarte, Shallop, Cavalle 2005, [5b]*). In addition, the use of additional anesthesia and potential harm to the vestibular system were once thought to be areas of concern and have been studied in depth. Subsequently, several authors have concluded that cochlear implantation in children continues to be reliable and safe in experienced hands, with a low percentage of severe complications (*McJunkin Jeyakumar, 2010, [4b], Buchman, Joy, Hodges, Telishi, Balkany, 2004, [4a], and Das & Buchman, 2005, [5b]*). It is also important to note, the financial costs accrued by the hospital (i.e. surgical costs, anesthesia costs, physicians costs) and the family (i.e. cost of device and accessories, follow up programming appointments, follow up therapy sessions) for lifelong support of bilateral cochlear implants need continued consideration and warrants further investigation (*Bichey & Miyamoto 2008, [4b], Summerfield, et. al., 2010, [4b]*).

References (evidence grade in []; see *Table of Evidence Levels following references*)

- Balkany, T., Hodges, A., Telischi, F., Hoffman, R., Madell, J., Parisier, S., Gantz, B., Tyler, R., Peters, R., Litovsky, R. (2008). William House Cochlear Implant Study Group: Position Statement on Bilateral Cochlear Implantation. *Otology and Neurotology*, 29 (2), 107-108 [5b]
- Beijen, J.W., Snik A.F.M., Mylanus E.A.M. (2007). Sound Localization Ability of Young Children with Bilateral Cochlear Implants. *Otology and Neurology*, 28, 479-485[4b]
- Bichey, B, & Miyamoto, R. (2008). Outcomes in Bilateral Cochlear Implantation. *Otolaryngology Head and Neck*, 138, 655-661 [4b]
- Buchman, C., Joy, J., Hodges, A., Telishi, F., Balkany, T. (2004). Vestibular Effects of Cochlear Implantation. *The Laryngoscope*, 114, 1-22 [4a]
- Das, S., Buchman, C. (2005). Bilateral Cochlear Implantation: Current Concepts. *Current Opinions in Otolaryngology and Head and Neck Surgery*, 13, 290-293 [5b]
- Dowell, R., Galvin, K., Dettman, S., Leigh, J., Hughes, K., van Hoesel, R. (2011). Bilateral Cochlear Implants in Children. *Seminars in Hearing*, 32, 53-72[1b]
- Eapen, R., Buchman, C. (2009). Bilateral Cochlear Implantation: Current Concepts. *Current Opinion in Otolaryngology and Head and Neck Surgery*, 17, 351-355 [5b]
- Galvin, K, Leigh, J., Hughes, K. (2009). How we do it: Clinical management of the child receiving a second, bilateral cochlear implant. *Cochlear Implants International*, 10, 84-91 [5b]
- Galvin, K., Hughes, K., Mok M. (2010). Can adolescents and young adults with prelingual hearing loss benefit from a second sequential cochlear implant. *International Journal of Audiology*, 49, 368-377[4b]
- Huttunen, K., Rimmanen, S., Vikman, S., Sorri, M., Archbold, S., Lutman, M.E. (2009). Parent's Views on the quality of life of their children 2-3 years after cochlear implantation. *International Journal of Pediatric Otorhinolaryngology*, 73,1786-1794 [4b]
- Johnston, J., Durieux-Smith, A., Angus, D., O'Connor, A., Fitzpatrick, E. (2009). Bilateral pediatric cochlear implants: A critical review. *International Journal of Audiology*, 48,601-617 [1b]
- Kuhn-Inacker, H., Shehata-Dieler, W., Muller, J., Helms, J. (2004). Bilateral cochlear implants: a way to optimize auditory perception abilities in deaf children? *International Journal of Pediatric Otorhinolaryngology*, 68, 1257-1266 [4b]

- Lin, F., Niparko, J. (2006). Measuring Health-Related Quality of Life after Pediatric Cochlear Implantation: A systematic review. *International Journal of Pediatric Otorhinolaryngology* 70, 1695-1706 [1b]
- Litovsky, R., Johnstone, P, Godar, S., Agrawal, S, Parkinson, A, Peters, R, Lake J (2006). Bilateral cochlear implants in children: Localization and acuity measured with minimum audible angle. *Ear and Hearing*, 27, 43-59 [4b]
- Loeffler, C., Aschendorff, A., Burger, T., Kroeger, S., Laszig, R., Arndt, S. (2010). Quality of Life Measurements after Cochlear Implantation. *The Open Otorhinolaryngology Journal*, 4, 47-54 [5b]
- Lovett, R.E.S., Kitterick, P.T., Summerfield, A.Q. (2010). Bilateral or Unilateral Cochlear Implantation for deaf children: An observational study. *Archives of the Disabled Child*, 95,107-112 [4b]
- Loy, B., Warner-Czyz, AD, Tong, L., Tobey, EA, Roland, PS. (2010). The children speak: An examination of the quality of life of pediatric cochlear implant users. *Otolaryngology Head and Neck Surgery*, 142, 247-53 [4b]
- McJunkin, J, Jeyakumar, A. (2010). Complications in pediatric cochlear implants. *American Journal of Otolaryngology – Head and Neck Medicine and Surgery* 31, 110-113 [4b]
- Moog, J.S., Geers, A.E. (1999). Speech and language acquisitions in young children after cochlear implantation. *Otolaryngology Clinical North American*, 32, 6-18 [4b]
- Murphy, J., O'Donoghue, G. (2007). Bilateral Cochlear Implantation: An Evidence-Based Medicine Evaluation. *The Laryngoscope* , 117, 1412 [1b]
- O'Donoghue, G., Nikolopoulos, T., Archbold, S., Tait, M. (1998). Congenitally deaf children following cochlear implantation. *Acta Otolaryngologica*, 52, 111-114 [4b]
- Offeciers, E., Morera, C., Muller, J., Huarte, A., Shallop, J., Cavalle, L. (2005). International consensus on bilateral cochlear implants and bimodal stimulation. Second Meeting Consensus on Auditory Implants, 19-21 February 2004, Valencia, Spain. *Acta Oto-Laryngologica*, 125: 918-919 [5b]
- Papsin, B., Gordon, K. (2008). Bilateral cochlear implants should be the standard for children with bilateral sensorineural hearing loss. *Current Opinion in Otorology and Head and Neck Surgery*, 16, 69-74[5b]
- Peters, R., Wyss, J., Manrique M. (2010). Worldwide Trends in Bilateral Cochlear Implantation. *The Laryngoscope*, 120, S17-S44 [4b]
- Scherf, F., Van Deun, L., van Wieringen, A., Wouters, J., Desloovere, C., Dhooge, I., Offeciers, E., Deggouj, N., De Raeve, L., Wuyts, F., Van de Heyning, P. (2009). Subjective Benefits of Sequential Bilateral Cochlear Implantation in Young Children after 18 months of Implant Use. *Journal of Oto-Rhino-Laryngology and its Related Specialties*, 71, 1112-1212 [4b]
- Scherf, F., van Deun, L., van Wieringen, A., Wouters, J., Desloovere, C., Dhooge, I., Offeciers, E., Deggouj, N., De Raeve, L., De Bodt, M., Van de Heyning, P. (2009). Functional outcome of sequential bilateral cochlear implantation in young children: 36 months postoperative results. *International Journal of Pediatric Otorhinolaryngology* , 73, 723-730 [4b]
- Sparreboom, M., van Schoonhoven, J., van Zanten, B., Scholten, R., Mylanus, M., Grolman, W., Maat, B. (2010). The Effectiveness of Bilateral Cochlear Implants for Severe-Profound Deafness in Children: A Systematic Review. *Otology and Neurology* , 00, 1-10 [1b]
- Summerfield, A, Lovett, R., Bellenger, H., Batten, G., (2010). Estimates of the Cost-Effectiveness of Pediatric Bilateral Cochlear Implantation. *Ear and Hearing*, 31, 611-624 [4b]

Note: Full tables of evidence grading system available in separate document:

- [Table of Evidence Levels of Individual Studies by Domain, Study Design, & Quality](#) (abbreviated table below)
- [Grading a Body of Evidence to Answer a Clinical Question](#)
- [Judging the Strength of a Recommendation](#) (abbreviated table below)

Table of Evidence Levels (see note above)

<i>Quality level</i>	<i>Definition</i>
1a† or 1b†	Systematic review, meta-analysis, or meta-synthesis of multiple studies
2a or 2b	Best study design for domain
3a or 3b	Fair study design for domain
4a or 4b	Weak study design for domain
5 or 5a or 5b	Other: General review, expert opinion, case report, consensus report, or guideline

†a = good quality study; b = lesser quality study

Table of Recommendation Strength (see note above)

<i>Strength</i>	<i>Definition</i>
“Strongly recommended”	There is consensus that benefits clearly outweigh risks and burdens (or visa-versa for negative recommendations).
“Recommended”	There is consensus that benefits are closely balanced with risks and burdens.
No recommendation made	There is lack of consensus to direct development of a recommendation.

Dimensions: In determining the strength of a recommendation, the development group makes a considered judgment in a consensus process that incorporates critically appraised evidence, clinical experience, and other dimensions as listed below.

1. Grade of the Body of Evidence (see note above)
2. Safety / Harm
3. Health benefit to patient (*direct benefit*)
4. Burden to patient of adherence to recommendation (*cost, hassle, discomfort, pain, motivation, ability to adhere, time*)
5. Cost-effectiveness to healthcare system (*balance of cost / savings of resources, staff time, and supplies based on published studies or onsite analysis*)
6. Directness (*the extent to which the body of evidence directly answers the clinical question [population/problem, intervention, comparison, outcome]*)
7. Impact on morbidity/mortality or quality of life

Supporting information

Introductory/background information

Since the acceptance of cochlear implants (CIs) by the United States Food and Drug Administration in 1990 (FDA, 2008), CI's have become the standard of care for children with severe to profound hearing loss as it has proven to significantly improve speech, language and communication outcomes (*Moog & Geers, 1999, [4b], and O'Donoghue, Nikolopoulos, Archbold, Tait, 1998, [4b]*). Over the years, candidacy criteria for cochlear implantation have expanded substantially. Additionally, a more recent trend is bilateral cochlear implantation (BICI); which involves the simultaneous or sequential insertion of a cochlear implant in each ear. Although unilateral implants provide considerable benefits, normal hearing is not restored, even in the implanted ear. Unilateral CI recipients still suffer a significant auditory deficit because of the profound hearing loss in their contralateral ear. Bilateral cochlear implantation has the ability to provide the recipient with binaural auditory abilities not achieved with unilateral cochlear implantation (specifically summation, squelch and localization). Worldwide experience with BICI includes approximately 8,000 adult and pediatric patients as of December 2008; 70% of these recipients are children (*Peters, Wyss, Manrique, 2010, [4b]*). Results of BICI studies clearly demonstrate benefit; however, it is of a varying degree. Therefore, as bilateral cochlear implantation becomes increasingly available to children, it is prudent that up to date

research be available to clinicians and families regarding various outcomes, including speech, language, education and quality of life.

Group/team members

Group/Team Leader: Christine Eby Fishman, AuD, FAAA, Operations Coordinator, Cochlear Implant Team. Cincinnati Children's Hospital Medical Center, Division of Audiology

Other group/team members: Barbara K. Giambra, MS, RN, CPNP, Evidence-based Practice Mentor, Center for Professional Excellence, Research and Evidence-based Practice

Search strategy

Databases: PubMed, Medline/OVID, Google Scholar, CINAHL and hand searching.

National Association of Children's Hospitals and Related Institutions (NACHRI) electronic mailing list and Benchmarking with other established CI programs: inquiry included patient population size, cochlear implant team members, and subjective and objective evaluations pre and post implantation, as well as their recommended follow-up time intervals

Keywords: Bilateral Cochlear Implants (BICI) , sequential cochlear implants (CI) , subjective benefit of bilateral CI , qualitative benefit of bilateral CI, perceptual benefit of cochlear implantation, psychosocial development (of pediatric CI users), benefits of BICI, BICI candidacy, Quality of Life with BICI's/CI's

Limits: English language, pediatrics (age 0-21), sequential bilateral cochlear implantation; all dates included Retrieved: July 29, 2010 – December 31, 2010

Known conflicts of interest

No financial conflicts of interest were found

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Note

This Best Evidence Statement addresses only key points of care for the target population; it is not intended to be a comprehensive practice guideline. These recommendations result from review of literature and practices current at the time of their formulation. This Best Evidence Statement does not preclude using care modalities proven efficacious in studies published subsequent to the current revision of this document. This document is not intended to impose standards of care preventing selective variances from the recommendations to meet the specific and unique requirements of individual patients. Adherence to this Statement is voluntary. The clinician in light of the individual circumstances presented by the patient must make the ultimate judgment regarding the priority of any specific procedure.

Reviewed against quality criteria by two independent reviewers.