Bilateral Cochlear Implantation (CI) in Children

SBU ALERT REPORT NO 2006-01 • 2006-01-25 • WWW.SBU.SE/ALERT

Summary and Conclusions

TECHNOLOGY AND TARGET GROUP: Among the 100 000 (approximate) children born in Sweden each year, between 1 and 2 per 1 000 have a hearing loss that requires some form of habilitation. Also, some children who can hear at birth may lose their hearing at an early age, eg, resulting from severe infection or head trauma. In most cases, conventional hearing aids, other devices, and psychosocial and communicative support are helpful in habilitating these children. Cochlear implantation (CI) is an option if conventional hearing aids do not yield satisfactory results in habilitating children with profound hearing loss or deafness.

This assessment assumes that a decision has been made to use cochlear implantation. Hence, the aim is not to compare the value of cochlear implantation versus other aural habilitation methods, but to compare a single (unilateral) implant versus dual (bilateral) implants.

Cochlear implants are devices that electrically stimulate the auditory nerve, and potentially allow people with profound hearing loss or deafness to recognize sounds. A cochlear implant consists of an internal component with a receiver and electrodes, and an external component with a microphone, speech processor, and transmitter. The internal component is implanted in the ear during a surgical procedure that lasts several hours. Following insertion of a cochlear implant, the patient begins a lifelong habilitation process. In children who previously have been unable to hear, the brain must learn to interpret sound, ie, the children must be given opportunities to learn listening skills and train their hearing. Also, the implant itself must be checked and maintained. Cochlear implants enable children to develop speech communication skills, depending on individual abilities. Maintaining sign language in these children, and in their environment, is important since the outcome of implantation varies by individual and because implants cannot be used in some situations (eg, while bathing or during a technical malfunction). Earlier, the devices were implanted in only one ear (unilateral cochlear implantation). Implanting devices in both ears (bilateral cochlear implantation) is being introduced to help children improve speech perception, primarily in complex listening situations, and to develop directional hearing. This assessment focuses on a potential target group of approximately 60 children per year diagnosed with congenital, or early acquired, profound hearing loss or deafness.

PRIMARY QUESTION: Is there scientific evidence to show that patients benefit more from bilateral CI than from unilateral CI? This assessment is based on a systematic review of the literature.

PATIENT BENEFIT: Only a few scientific studies (none of which included a control group) have assessed bilateral cochlear implants. Studies using children as their own controls have reported improvements in speech perception and directional hearing when children used both implants instead of only one. However, these studies provide only low-quality evidence because of their design. Results from clinical studies on complications of unilateral CI in children showed that complication rates varied from 2 percent to 16 percent. A second cochlear implant would double the risk for complications. No studies have specifically investigated the complications or side effects from bilateral cochlear implantation.

ECONOMIC ASPECTS: A single cochlear implant costs approximately 220 000 Swedish kronor (SEK). The total cost for unilateral cochlear implantation is estimated to be around 350 000 SEK, including evaluation, surgery, fitting of the speech processor, and followup visits for the first year. Insertion of two implants during a simultaneous operation would add the cost of the second device, but the associated costs would not increase substantially. Hence, the total cost for bilateral implantation would be approximately 600 000 SEK. If the two devices were implanted sequentially, with an interval of several months, the cost would be higher (at least 700 000 SEK). No studies were identified that addressed the cost effectiveness of bilateral CI in children.

SBU's appraisal of the evidence

Scientific documentation on the benefits of bilateral cochlear implantation in children is insufficient*. Well-designed, scientific studies are needed to determine whether the method yields positive effects that outweigh the increased risk for complications. Given the uncertainty of current knowledge, there is an urgent need to systematically compile national data on clinical experience.

Criteria for Evidence Grading SBU's Conclusions, see page 2

Criteria for Evidence Grading SBU's Conclusions

Evidence Grade 1 – Strong Scientific Evidence. The conclusion is corroborated by at least two independent studies with high quality and internal validity, or a good systematic overview.

Evidence Grade 2 – Moderately Strong Scientific Evidence. The conclusion is corroborated by one study with high quality and internal validity, and at least two studies with medium quality and internal validity.

Evidence Grade 3 – Limited Scientific Evidence. The conclusion is corroborated by at least two studies with medium quality and internal validity.

Insufficient Scientific Evidence – No conclusions can be drawn when there are not any studies that meet the criteria for quality and internal validity.

Contradictory Scientific Evidence – No conclusions can be drawn when there are studies with the same quality and internal validity whose findings contradict each other.

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The complete report is available only in Swedish.