

Systematic review of the literature on the clinical effectiveness of the cochlear implant procedure in adult patients

Revisione sistematica della letteratura sulla efficacia clinica della procedura di impianto cocleare nei pazienti adulti

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SUMMARY

The aim of this systematic review was to summarize the results of scientific publications on the clinical effectiveness of the cochlear implant (CI) procedure in adults. The members of the Working Group first examined existing research evidence from the national and international literature and main international guidelines. They considered as universally accepted the usefulness/effectiveness of unilateral cochlear implantation in severely-profoundly adult patients. Accordingly, they focused their attention on the systematic reviews addressing clinical effectiveness and cost/efficacy of CI procedures, with particular regard to the most controversial issues for which international consensus is still lacking. The following aspects were evaluated: monolateral CI in advanced-age adult patients; bilateral (simultaneous/sequential) CI vs. unilateral CI and vs. bimodal stimulation; benefits derived from the monolateral CI procedure in adult patients with prelingual deafness. With regard to CI in elderly patients, the selected studies document an improvement of the quality of life and perceptive abilities after CI, even if the benefits were found to be inferior in patients over 70 years at the time of surgery. Thus, from the results of the studies included in the review, advanced age is not a contraindication for the CI procedure. With respect to unilateral CI, bilateral CI offers advantages in hearing in noise, in sound localization and less during hearing in a silent environment. However, high interindividual variability is reported in terms of benefits from the second implant. With regard to CI in prelingually deaf adults, the selected studies document benefits deriving from the CI procedure in terms of improvement of perceptive abilities and in the quality of life after CI, as well as subjectively perceived benefits. However, there is high interindividual variability and the study sample is limited.

KEY WORDS: Cochlear implant • Bilateral cochlear implant • Prelingual deafened adults • Elderly patients

RIASSUNTO

L'obiettivo della revisione sistematica della letteratura è stato quello di sintetizzare i risultati degli studi scientifici pubblicati sull'efficacia clinica della procedura di impianto cocleare (IC) nell'adulto. I componenti del Gruppo di Lavoro, viste le evidenze della letteratura nazionale ed internazionale e analizzate le principali linee guida internazionali riguardanti la procedura in oggetto, decidono di considerare come universalmente accettata l'utilità/efficacia della procedura di IC unilaterale nelle sordità gravi/profonde dell'adulto e di focalizzare le reviews sistematiche sull'efficacia clinica e la costo-efficacia della procedura di impianto cocleare sulle tematiche più attuali e più discusse, per per le quali non esiste ancora un consenso internazionale. In particolare per la review riguardante l'efficacia clinica della procedura di IC nel paziente adulto, si è proceduto alla valutazione dei seguenti aspetti: IC monolaterale in pazienti adulti con età avanzata; IC bilaterale (sequenziale-simultaneo) vs. IC unilaterale e vs. stimolazione bimodale; beneficio derivato dalla procedura di IC monolaterale in pazienti adulti con sordità pre-linguale. Riguardo alla procedura di IC in pazienti adulti con età avanzata, gli studi selezionati nella review documentano un miglioramento della qualità della vita e delle abilità percettive. Negli studi in cui vengono presi in esame anche pazienti impiantati in età molto avanzata (oltre i 70 anni) si evidenzia un beneficio post-impianto inferiore in rapporto con l'età al momento dell'impianto. Dai risultati degli studi inclusi nella review emerge quindi che di per sé l'età avanzata non debba essere un fattore che controindica la procedura di impianto cocleare. Riguardo alla procedura di IC bilaterale, dagli studi selezionati emerge che l'IC bilaterale, rispetto all'IC unilaterale offre vantaggi nell'ascolto nel rumore, nella localizzazione sorgente sonora, durante l'ascolto nel silenzio. E' comunque riportata una elevata variabilità interindividuale nei benefici dal secondo impianto. Per quanto riguarda la procedura di IC in pazienti adulti con sordità pre-linguale, gli studi selezionati documentano benefici in termini di miglioramento delle abilità percettive, della qualità della vita post-IC e benefici soggettivi. I risultati riportati negli studi presentano comunque una alta variabilità interindividuale e il campione di studio è limitato.

PAROLE CHIAVE: Impianto cocleare • Impianto cocleare bilaterale • Pazienti adulti con età avanzata • Sordità pre-linguale

Introduction and aim

The aim of this systematic review of literature was to summarize the results of scientific publications on clinical effectiveness of the cochlear implant (CI) procedure in adults. The members of the Working Group first examined existing evidence from the national and international literature and main international guidelines. They considered as universally accepted the usefulness/effectiveness of unilateral cochlear implantation in severely-profoundly adult patients¹. They thus focused their attention on the systematic reviews addressing clinical effectiveness and cost/efficacy of cochlear implant procedures, with particular regard to the most controversial issues for which international consensus is still lacking.

Considering clinical effectiveness of CI in adult patients, the following aspects were evaluated:

1. monolateral CI in advanced-age adult patients;
2. bilateral (simultaneous/sequential) CI *versus* unilateral CI and *versus* bimodal stimulation;
3. benefits from a monolateral CI procedure in adult patients with prelingual deafness.

Methods

A systematic literature search was undertaken using an explicit and reproducible methodology aimed at minimizing any possible distortions, biases, or erroneous conclusions caused by the exclusion of important studies, according to the recommendations made by the *Systematic Reviews CRD's guidance for undertaking reviews in health care*².

Search strategy

An extensive review of literature was performed using the following databases: PubMed Medline and Cochrane Systematic Review Database. Furthermore, the major Internet sites and guidelines publications of national and international scientific societies dealing with the issue were consulted. Bibliographical research was completed by assessing the bibliographical entries of pertinent, previously selected publications.

Research issues

Bibliographical research performed on databanks using the *MeSH descriptor* or a combination of keywords was limited to articles published in English. The search in PubMed Medline was conducted on publications after the year 2000. Owing to the rapid progress of technology and the rapidly expanding indications to CI procedure, papers published before the year 2000 were excluded. The first bibliographical research was undertaken on 3 Sep 2009. At a later stage, bibliographic research was updated for the period of publication 3 Sep 2009-31 May 2010.

Bibliographical research characteristics

- PubMed Medline: "Cochlear Implants"[Mesh] AND

((("2000"[PDat]:"2009"[PDat]) AND (English[lang]) AND (adult[MeSH])) ⇒ 984 results

- Cochrane Systematic Review Database: MeSH descriptor cochlear implants explode all trees. A total of 107 results until 31/5/2010. All the studies retrieved by the Cochrane Systematic Review Database were also selected by PubMed Medline.

Outcomes assessed

Studies reporting one or more of the following outcomes were evaluated: audiological results and language and communication results.

Exclusion criteria

Articles which did not present the above-listed characteristics were not considered. Articles presented at congresses but not submitted to peer-review, as well as case reports, letters, commentaries and non-English studies published before the year 2000, were excluded. The inclusion criteria were applied by one reviewer and checked by a second. Any dissenting opinions were resolved through discussion.

Strategy to assess the quality of studies

The publications identified according to the search criteria described above were examined by two reviewers independently. Any dissenting opinions were resolved through discussion. A preliminary selection was made on the basis of the titles and abstracts. The works were then studied in full-text, and assessed in terms of methodological quality and usefulness of the reported results for the type of work to be conducted. Methodological quality was assessed using the available tools, according to the criteria specified in *Systematic Reviews CRD's guidance for undertaking reviews in health care*².

Strategy of data extraction

The data were extracted by a reviewer and checked by a second. Any dissenting opinions were resolved through discussion. Tables summarizing the main information on each study were produced, including authors' name, title, year of publication and title of journal, sample population and other data concerning methods, devices and results (Tables I-III).

Results

A total of 981 studies concerning clinical effectiveness of the CI procedure in adult patients were identified, using the research criteria listed in the "Aims". A preliminary evaluation was performed on the basis of the titles and abstracts, and 87 were selected and examined in full text. A total of 24 studies on the CI adult patient were chosen for the review. The principal documents containing the guidelines for the procedure of National and International CI were searched and examined.

A summary of the assessment of the literature studies is given in Figure 1. Bearing in mind the purpose of this review, the following articles were selected which concerned clinical effectiveness of the CI procedure in *adult patients*: 8 articles on “monolateral CI in advanced-age adult patients”; 13 articles on “Bilateral (sequential-simultaneous) CI in adult patients”; 3 articles on “Benefit derived from the monolateral CI procedure in adult patients with prelingual deafness”.

Tables I, II and III summarize the selected articles, subdivided according to subject with detailed information on the authors, title journal and year of publication, as well as sample features, most relevant data on the methods adopted, reported results and conclusions of the Authors.

With regard to the analysis of the results, it was not possible to perform a meta-analysis. Study design, type of comparison and results of the articles selected for inclusion in the review were different, and therefore it was difficult to define the features on which to base variations in outcome. The studies included in this review presented variability in terms of interventions and outcomes (clinical differences), as well as in study design and error risk (methodological differences).

The two most recent systematic reviews on CI procedure in adult patients^{3,4} showed the same difficulties with regard to the possibility of performing a meta-analysis, and are thus limited to a description of the work.

Results

Monolateral CI in advanced age adult patients

In the past, the CI procedure was not considered for advanced age adult patients, as the benefit was thought to be significantly inferior to that generally obtained in younger post-lingual adult patients. This was especially due to physiological deterioration of cognitive abilities which may have an impact on the capacities of speech perception with the CI, and to problems regarding tolerance of the surgical procedure, risk of post-operative complications and difficulties in manipulation of the external components of the device. More recently, however, some authors have demonstrated that not only young adults, but also adult patients in an advanced age benefit from the CI procedure in terms of improvement of speech perception; some studies have also demonstrated an improvement in quality of life. No relevant problems have been reported from the point of view of tolerance to medical procedures and post-operative complications. In 2004, the UK Cochlear Implant Study Group (UKCISG) established that the CI procedure is cost-effective even in patients implanted after the age of 70 years⁵.

A total of 8 articles were selected on “Monolateral CI in advanced age adult patients” (Table I).

In all selected studies, good post-CI results were reported in terms of improvement of perceptive abilities⁶⁻¹³. In 6 of

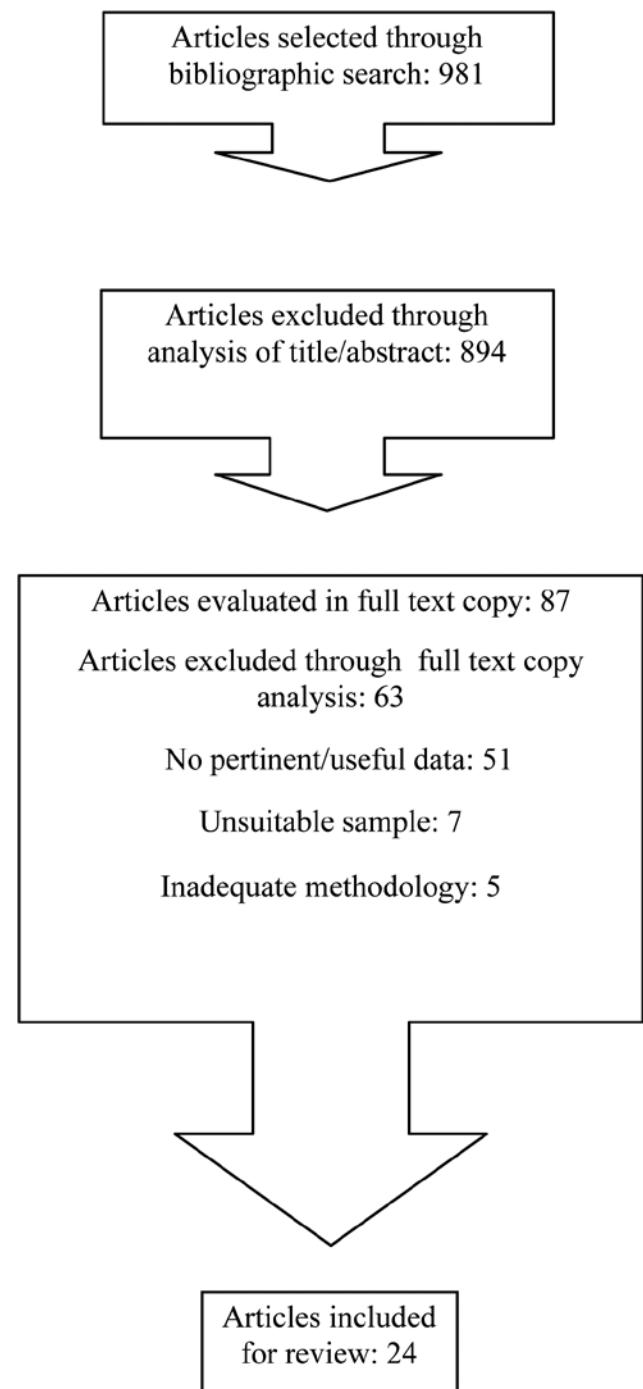


Fig. 1. Description of the selection of literature articles.

8 studies, no statistically significant differences were recorded between the results obtained in elderly and younger patients (a control group was used in four studies, while another reported on the results of a database for non-elderly implanted patients). Friedland et al.⁶, Chatelin et al.⁷ and Poissant et al.⁸ reported perceptive results that were slightly inferior in implanted elderly patients (statistically significant).

Statistically significant improvements in the quality of life of elderly patients were also documented in the study by

Table 1. Summary table of articles included for review on the issue "Monolateral CI in elderly patients".

Authors	Title	Journal, Year	Sample size and other methodology	Type of implant/processing strategy	Evaluated results	Conclusions/opinions
Friedland et al. ⁶	Case-control Analysis of cochlear implant performance in elderly patients	Arch Otolaryngol Head Neck Surg 2010	28 pts ≥ 65 yrs at CI. 28 younger implanted pts (control group). Follow-up at 1 year.	Not specified	Test of verbal perception: HINT-Q, HINT-N, CNC	Improvement with respect to pre-op condition in both groups. Elderly pts obtain inferior results in HINT-Q and CNC (statistically significant).
Williamson et al. ¹⁰	Auditory performance after cochlear implantation in late septuagenarians and octogenarians	Otol Neurotol 2009	28 adult pts post-CI users. Group 1: mean age at time of CI 80.7 years. Group 2 mean age at time of CI 71.6 yrs. Follow-up > 1 yr.	27 pts CI Nucleus, ESPRIT 36 processor, Freedom. 1 pt CI Clarion.	Comparison between results (verbal perception and questionnaire on pre- and post-CI satisfaction). HINT, CNC, questionnaire for satisfaction.	Post-CI benefits both in group 1 and group 2, with no significant differences in terms of age.
Noble et al. ¹¹	Younger and older age adults with unilateral and bilateral cochlear implants: speech and spatial hearing self-ratings and performance	Otolaryngol Head Neck Surg 2009	206 post-lingual adult pts. Unilat. CI users, bilat CI, CI and stim. Bimodal. Group 1 age at time of CI < 60 yrs, Group 2: age at time of CI > 60 yrs. Test administered 2 mths before CI and > 1 yr after CI.	Not specified	Hearing handicap Inventory for the Elderly, Hearing Handicap Questionnaire, Speech Spatial and Quality of Hearing Scale (SSQ), word recognition and localization test.	No statistically significant differences were observed in the two groups of pts (in terms of age).
Poissant et al. ⁸	Impact of cochlear implantation on speech understanding, depression, and loneliness in the elderly	J Otolaryngol Head Neck Surg 2008	Groups for which the results were compared: 9 pts who received CI ≥ 70 years, 8 pts received CI ≤ 60 yrs, 9 HA users ≥ 70 yrs.	Devices: Nucleus, Clarion, Medel	Outcomes: - verbal perception: recognition (CNC, CUNY, HINT) in quiet and noisy environment (HINT); - subjective perception of state of depression and loneliness: GDS (Geriatric depression scale) and UCLA (Loneliness scale version 3). Cf between pre- and post CI data.	No statistically significant differences were observed between pts implanted before and after 70 yrs of age, for the three tests. Pts who received CI after 70 yrs of age report improvement with respect to state of depression and loneliness.
Chan ¹²	Performance of older adult cochlear implant users in Hong Kong	Ear Hear 2007	14 elderly pts (56-77 yrs). 14 adult patients (18-53 yrs) (control group). All CI users. Test performed pre-op. and 6-12-24 mths post-op.	Not specified	Test of verbal perception. Hong Kong Speech Perception Test Manual.	Similar benefit reported in the two groups of pts, independent of age at implant. Deafness duration is reported to be more important. Cantonese.
Orabi et al. ⁹	Cochlear implant outcomes and quality of life in the elderly: Manchester experience over 13 years	Clini Otolaryngol 2006	34 pts > 65 yrs implanted from 1997 to 2002 (age CI 65-80 yrs). Test performed pre-op. 9 and > 21 mths post-CI.	IC Nucleus CI24/Nucleus CI22/Nucleus CI24 Contour/ Medel C40+/ Medel C40.	Auditory outcomes of verbal perception in silence and in noise - open set: BKB-sentences (Bench, Kowal and Bamford), AB-parole (Arthur Boothroyd), CUNY-sentences (The City University of New York). Subjective benefits and quality of life: Glasgow Health Status Inventory Questionnaire (GHSI), Glasgow Benefit Inventory Questionnaire (GBI).	Auditory outcomes post-CI significantly better than pre-op data. Patients' questionnaire replies reported improvement in quality of life. They compared the results with those of a database concerning implanted adults < 65 yrs and no statistically significant differences were found.

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Table 1. (follows)

Chatelain et al. ⁷	Cochlear implants outcomes in the elderly	Otolol Neurotol 2004	65 pts who received CI > 70 yrs. Control group 101 pts who received CI < 65 yrs. Follow up: 3-6-12 mths post-CI.	Clarion and Nucleus CI Devices	Outcomes: verbal perception test with CNC, CID and HINT.	Elderly groups also obtained considerable benefits from CI procedure, but outcomes were slightly inferior to those reached by younger pts (stat. sign. test CNC).
Labadie et al. ¹³	Cochlear implant performance in senior citizens	Otolaryngol head Neck Surg 2000	Study group of 16 post-lingual adult pts who received CI at ≥ 65 yrs. Control group: 20 post-ling. adult pts who received CI at 18-64 yrs.	Devices: Clarion Multi Strategy	Outcomes: evaluation of perceptive abilities. Recognition of sentences (CID) and bi-syllable words (CNC).	No statistically significant differences were observed in outcomes of the two groups.

Orabi et al.⁹. As far as subjective perception of state of depression and loneliness are concerned, Poissant et al.⁸ reported advantages in the group of adult patients implanted in an advanced age.

The studies selected for this review showed an improvement in the quality of life and perceptive abilities following cochlear implant surgery in advanced age patients. However, the various studies used different cut-off for age (in some 65 years, and in others 70, and even patients implanted after 80 years of age were included). These differences in age limits obviously affect outcomes.

In the studies taking into account elderly CI recipients (over 70 years), the benefit of post-cochlear implantation has been found to be inferior in relation to age at the time of implantation⁶⁻⁸. Thus, from the results of the studies included in the review, advanced age is not a contraindication for the CI procedure.

Bilateral (sequential-simultaneous) CI vs. unilateral CI and vs. bimodal stimulation in adult patients

A total of 13 articles were selected on “Bilateral (sequential-simultaneous) CI vs. unilateral CI and vs. bimodal stimulation” (Table II).

Improvements in the ability of localization of the sonorous source using two implants with respect to the monaural condition are reported in 6 studies¹⁴⁻¹⁹. Ten studies reported statistically significant improvements in terms of capacity of hearing in a noisy environment, deriving from the use of bilateral CI, compared to hearing with only one CI^{14 16 19 20-26}. Improvements in the capacity of hearing in a silent environment, deriving from the use of bilateral CI, with respect to listening with only one CI, are reported in 7 studies^{14 16 19 21 22 24 25}. In some studies, the outcomes were statistically significant.

The mechanisms underlying the benefit deriving from the use of two implants are, in most of the studies ($n \pm 5$), attributed to the *head shadow effect*^{19 21 23 24 26}, namely the possibility of hearing with the most favourable signal to noise ratio (SNR) ear. The studies by Eapen et al.²¹ and Ricketts et al.²³ also documented the benefits deriving from the effect of *binaural summation* and the *squelch effect*, which are linked to binaural integration. The benefits linked to *binaural summation* are also reported in the study by Schleich et al.²⁶.

The results obtained in patients with bilateral CI were compared with those obtained in patients with unilateral CI in only one study²⁰. The performance of the same patients with bilateral CI and with only one implant were compared in the other studies.

Concerning the possibility of receiving bilateral CI with a simultaneous or sequential procedure, 5 of the selected studies were on patients who received the two implants simultaneously, 5 in patients who received two implants by a sequential procedure, and 3 studies to a series of mixed case studies (simultaneous + sequential). None of

Table II. Summary table of articles included for review on “Bilateral (sequential-simultaneous) CI vs. unilateral CI and vs. bimodal stimulation” (in adult patients).

Authors	Title	Journal, year	Sample size and other methodology	Type of implant/ processing strategy	Evaluated results	Conclusions/Authors' opinions
Dunn et al. ²⁰	Bilateral and unilateral cochlear implant users compared on speech perception in noise	Ear Hear 2010	30 adult pts. Simultaneous bilateral CI. 30 adult pts with unilateral CI. Follow-up > 6 months.	Not specified	Results evaluated in terms of verbal perception in noise setting. - Cueing the listener. - Multiple-jammer test. Cognitive loading.	Outcomes of pts with bilateral CI were better (statistically significant).
Eapen et al. ²¹	Hearing in noise benefits after bilateral simultaneous cochlear implantation continue to improve 4 years after implantation	Otol Neurotol 2009	9 adult pts with bilateral simultaneous CI. Follow-up 4 yrs.	Devices: CI Medel Combi 40+, CIS strategy	Outcomes: - Perceptive abilities: identification in quiet (CNC), sentence recognition (CUNY) in noisy environment. Cf results with bilaterale vs. unilateral CI.	Identification with bilateral CI is better, bilateral CI recognition in the presence of noisy sources is better over the years and S/N diminishes. Authors reported benefit with bilateral CI derived from Head Shadow effect and summation; they also observed a squelch effect, which improves with the yrs. for improvement of the capacity of binaural integration.
Mosnier et al. ¹⁴	Speech performance and sound localization in a complex noisy environment in bilaterally implanted adult patients	Audiol Neurotol 2009	27 post-verbal deaf adults bilateral simultaneous CI.	Medel Combi40+ CIS strategy	Results evaluated with left-right-bilateral CI. Localization of speech in noisy environment (12 mths post-CI) and verbal comprehension (3-6-12 mths post CI), using lists of bi-syllable words in quiet and background noise (SNR +10+15).	Better (statistically significant) hearing in silent and in noisy environment with bilateral CI (compared to hearing with CI only). Localization of verbal material with background noise better than with CI only. 12/27 pts had no benefit with bilateral compared to unilateral CI in the localization task. Extreme interindividual variability of outcomes.
Tyler et al. ¹⁶	Speech perception and localization with adults with bilateral sequential cochlear implants	Ear Hear 2007	7 adults (6 post-verbal and 1 pre-verbal) sequential bilateral CI (delay 6 yrs 8mths - 17 yrs).	Device: Ineraid/Medel, Clarion HiRes 90K, Clarion Radial Bipolar 1.0, Clarion HiFocusII-CI, Nucleus 24M e R. Strategies: CIS, HiRes, ACE.	Outcomes: - Monosyllabic word recognition (CVC) in quiet and sentences (CUNY) with background noise. - Everyday sound localization.	They document benefit in hearing in quiet and with background noise and in 4/7 pts. Improvement in sonorous localization with bilateral CI vs. hearing with unilateral CI.
Wackym et al. ²²	More challenging speech-perception tasks demonstrate binaural benefit in bilateral cochlear implant users	Ear Hear 2007	7 adult pts with sequential and simultaneous bilateral CI. Follow-up: 4 m-4.6 yrs.	Devices: Nucleus 24 (strat ACE), HiRes90K (strat: HiRes), Medel Combi 40+ (strat CIS)	Comparison between outcomes with bilateral CI and unilateral CI (on one side with improved performance). - Recognition in <i>open set</i> in quiet and background noise environment (variable S/N). - APHAB.	They report a significantly better benefit with bilateral vs. unilateral CI (best side statistically significant).
Neuman et al. ¹⁵	Sound-direction identification with bilateral cochlear implants	Ear Hear 2007	8 adult pts (7 post-verbal, 1 pre-verbal). Test performed 5 and 11 mths post-CI.	Nucleus 24 Contour. Strategy of pr. ACE	Localization of sonorous source with verbal stimulus and pink noise.	Bilateral simultaneous CI for adults. Localization is statistically significantly better with bilateral CI than in the two monaural conditions.

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Table II. (*tbl/lovs*)

Ricketts et al. ²³	Speech recognition for unilateral and bilateral cochlear implant modes in the presence of uncorrelated noise sources	Ear Hear 2006	16 adult pts post-verbal. Simultaneous bil CI in most cases. Follow-up 4-7 mths. Follow-up at 12-17 mths for 10 pts.	Medel C40+.	Outcomes: verbal recognition in HINT (hearing in noise test), with varied SNR with adaptive system, CST (Connected Speech Test) with fixed SNR +10).	Adults: bilateral simultaneous and sequential CI. Better results in hearing with bilateral CI than in both monaural conditions, in both tests. Statistically significant. Attributed to both <i>binaural squelch</i> and <i>diotic summation</i> . In 10 pts they compared outcomes at 4-7 mths post-activation with those at 12-17 mths and observed improvement with statistically significant outcomes with bil CI, but the binaural advantage remains constant (improved bilateral CI - unilateral CI outcomes). In 6 pts they compared the influence of SNR variation: better outcomes in conditions with more favourable SNR. No statistical study performed on this test.
Litovsky et al. ²⁴	Simultaneous bilateral cochlear implantation in adults: a multicenter clinical study	Ear Hear 2006	34 post-lingual pts, bilateral simultaneous CI. Follow-up: 1-3-6 mths.	Nucleus 24 Contour (all). ESPRIT/SPRINT speech processor. ACE/SPEAK/CIS processing strategy.	Verbal perception in silence: HINT and CNC (speech 65 dB). Verbal perception in noisy environment: BKB-SIN Test (BKB-Research, 2005). They evaluated SRT (Speech Reception Threshold _SNR-50). Subjective collection of information: Abbreviated Profile of Hearing Aid Benefit (APHAB questionnaire).	All pts obtained benefit in at least one test. Many patients obtained benefit in all tests. Major benefit derived from head shadow effect (using the ear with > SNR), minimum benefit from squelch effect. They conclude that lack of synchronization between the two processors can negatively affect binaural integration. Subjective benefits reported in questionnaire.
Verschuur et al. ¹⁷	Auditory localization abilities in bilateral cochlear implant recipients	Otol Neurotol 2005	20 post-lingual adult pts: bilateral sequential CI: Follow-up 3-9 mths after second CI.	CI Nucleus 24M/K. Processing strategy: ACE/SPEAK.	Localization of sonorous source on horizontal plane with 1 CI (right and left) and with bilateral CI.	Better outcomes with bilateral CI in terms of monaural condition in all patients (statistically significant). No significant differences with regard to localization of sonorous source and type of stimulus.
Ramsden et al. ²⁵	Evaluation of bilaterally implanted adult subjects with the Nucleus 24 Cochlear Implant System	Otol Neurotol 2005	29 post-l. adults. Bilateral sequential CI (delay 1-7 years).	Device: Nucleus 24M and R	Evaluated results: Recognition of words (CNC) and sentences (CUNY) in silent and background noise environments.	1 patient does not use CI II, but only uses CI I with good results. They generally record advantages in hearing with bilateral CI with respect to unilateral CI. Considerably variable results, benefits not recorded in some patients.

(continues)

Table II. (follows)

Nopp et al. ¹⁸	Sound localization in bilateral users of MED-EL COMBI 40/40-cochlear implants	Ear Hear 2004	20 adult patients (19 post-lingual, 1 pre-lingual).	Ci: MED-EL COMBI 40/COMBI 40+. Processor: TEMPO+ Processing strategy CIS+.	Localization of sonorous source.	Adults: sequential bilateral CI. In 18/20 patients localization of sonorous source improves in statistically significant manner with bilateral CI compared to unilateral CI. The two subjects with modest outcomes had long deprivation (1 pre-lingual and the other deafness onset < 6 yrs). They found no correlation between results and interval duration between the two interventions and age of deafness onset.
Schleich et al. ²⁶	Head shadow, squelch, and summation effects in bilateral users of the MED-EL COMBI 40/40-cochlear implant	Ear Hear 2004	21 adult patients. (20 post-CI).	Medel Combi 40/COMBI 40+. Processor TEMPO +. Processing strategy CIS+.	Verbal perception in noisy environment.	Adults: sequential bilateral CI. 18/21 pts managed to perform the tests. There were statistically significant benefits obtained from the use of bilateral CI when hearing in noisy environment. They benefit both from head shadow effect, and binaural summation (statistically significant). Minor benefit by squelch effect. Data on squelch effect are attributed to limited number of pts.
Laszig et al. ¹⁹	Benefits of bilateral electrical stimulation with the nucleus cochlear implant in adults: 6-month postoperative results	Otol Neurotol 2004	37 post-CI adult pts, 15 with simultaneous implant, 22 with sequential implant.	Adults: bilateral simultaneous/sequential CI. Advantages in perception in quiet and noisy environment for one part of the pts. Advantages in localization for almost all pts. Head shadow demonstrated, summation and squelch were less evident.		

the studies compared the results of patients who received the two CIs by simultaneous intervention, with respect to those who received a sequential procedure.

No statistically significant correlations between benefits deriving from bilateral CI and delay between the two interventions, in patients who received the two implants by sequential procedure, are reported in a study by Nopp et al.¹⁸ An investigation by Wackym et al.²² described the subjective benefits from the use of bilateral vs monolateral CI, as reported in the APHAB questionnaire.

In summary, from the selected studies, bilateral CI with respect to unilateral CI offers advantages in hearing in noise (+++), sound localization (+++) and during hearing in a silent environment (++) . However, high interindividual variability is reported in terms of benefits deriving from the second implant.

Concerning simultaneous bilateral vs. sequential CI, no comparisons are reported between simultaneous vs. sequential bilateral post-CI outcomes.

Benefit derived from a monolateral CI procedure in adult patients with pre-lingual deafness

A total of 3 studies were selected on the issue “Benefits derived from monolateral CI procedure in adult patients with pre-lingual deafness” (Table III). Some publications on this subject were excluded as they present case studies that were not homogeneous, especially with regards to the rehabilitation method. Furthermore, some of the articles included adult patients with pre-lingual deafness, post-verbal adults or children. Additionally, these articles were excluded from the review as pre-lingual adult patients present particular features and problems.

All the selected studies²⁷⁻²⁹ reported that there were benefits from the cochlear implant procedure.

Two studies^{27,28} recorded post-cochlear implant benefits in perceptive abilities, in both *closed* and *open* sets. The study by Klop et al.²⁸ also documented an improvement in the quality of life after CI, while the study by Chee et al.²⁹ showed subjective benefits following CI, in the majority of patients evaluated, as a result of improvements in communicative abilities, awareness of the surrounding environment and increased independence.

Interindividual variability was present in the various studies, as is noted in the publication by Klop et al.²⁸.

In summary, the selected studies document the benefits deriving from the CI procedure in terms of improvement of perceptive abilities (identification in *closed* set and recognition in *open* set). Moreover, the studies report an improvement in the quality of life after CI as well as subjectively perceived benefits. However, the outcomes of these works present high interindividual variability and the study sample is limited.

Discussion and conclusions

The purpose of this report was to assess the clinical effectiveness of cochlear implants for adult patients. The members of the WG, after examining the existing national and international literature and main international guidelines, considered as universally accepted the usefulness/effectiveness of unilateral cochlear implantation in severely-profoundly deaf adults. Moreover, according to the only two systematic reviews on CI^{3,4}, there is consistent evidence that cochlear implantation is a safe, reliable and effective strategy for adults with severe to profound sensorineural deafness. As a consequence, the members of the WG focused their attention on clinical effectiveness of CI procedure, with particular regard to the most controversial issues for which international consensus is still lacking. With regard to hearing threshold levels, the available international guidelines indicate different levels of hearing over which CI is indicated. Some guidelines refer to the PTA (pure tone audiometry between 0.5-1-2 kHz), while others refer to the mean threshold between 2 and 4 kHz (UK)³⁰. Among the available international guidelines, the Food and Drug Administration (FDA) indicates that CI is indicated in adult patients with a PTA > 70 dB, while Belgian guidelines indicate the limit of a PTA > 85 dB associated with a auditory brainstem responses (ABR) threshold ≥ 90 dB HL³⁰. The British Cochlear Implant Group (BCIG) considers CI appropriate for adult patients with thresholds between 2 and 4 kHz > 90 dB. Italian guidelines allow CI in adult patients with a PTA > 75 dB¹.

Concerning hearing aid training and rehabilitative results with traditional hearing aids before implantation, the indications differ among the different national and international guidelines; Italian and British guidelines (BCIG), for example, consider CI appropriate in cases with an open set speech recognition score < 50%, the FDA in cases with an open set speech recognition score < 60% and Belgian guidelines in cases with an open set speech recognition score < 30%³⁰.

The WG of the present project considered the CI procedure appropriate for adult patients with bilateral severe to profound hearing loss (mean threshold between 0.5-1-2 kHz > 75 dB HL), with an open-set speech recognition score $\leq 50\%$ in the best aided condition without lip reading. In selected cases, CI is indicated if the open-set speech recognition score is $\leq 50\%$ in the best aided condition without lip reading with background noise (signal to noise ratio SNR + 10).

CI is allowed in selected cases with better residual hearing at low and middle frequencies and hearing threshold between 2 and 4 kHz ≥ 90 dB, with an open-set speech recognition score $\leq 50\%$ in the best aided condition without lip reading.

Another topic analyzed in the current review is *CI in adults with advanced age*. None of the published sys-

Table III. Summary table of articles included for review on "Benefit derived from monolateral CI procedure in adult patients with pre-lingual deafness.

Authors	Title	Journal, Year	Sample size and other methodology	Type of implant/processing strategy	Evaluated results	Conclusions/opinions
Santarelli et al. ²⁷	Cochlear implantation outcome in prelingually deafened young adults	Audiol Neurotol 2008	18 pre-ling adults who received CI at 13-30 yrs Follow-up: 3 yrs	Nucleus 24M/R. Clarion HiFocus CII/HiFocus 1.2/ HiRes90K Medel Tempo+/C40+ Processing strategies SPEAK/ACE/CIS/HiRes/SAS	Evaluation of perceptive abilities in closed and open set	Improvements in speech perception in closed and open set. Improvements also after 1 year post-implantation.
Klop et al. ²⁸	Cochlear implant outcomes and quality of life in adults with prelingual deafness	Laryngoscope 2007	8 implanted adults with prelingual deafness. Follow-up \geq 2 yrs	Device CII HI Focus I, HiRes90K, Hi Focus I	Evaluated results: Word recognition in <i>open</i> sets. (CVC monosyllables and phonemes). GoL (2 questionnaires Health Utility Index (HUJ-Mark2). Nijmegen Cochlear Implant Questionnaire (NCIQ) e VAS. Test performed pre-CI and 4-5 mths post-CI, then 12-30 mths post-CI	Statistically significant improvement of recognition of phonemes and words after implantation (statistically significant). The quality of life improves 4-5 months after implantation. It does not continue to improve after. Results are widely variable among patients.
Chee et al. ²⁹	Benefits of cochlear implantation in early-deafened adults: the Toronto experience	J Otolaryngol 2004	30 implanted pts with prelingual deafness Follow-up: 3-135 mths	Device not specified	Results: subjectively perceived benefits through questionnaire.	Most of the patients report benefits from CI procedure, as a consequence of improvements of communication, awareness of the surrounding environment and self-sufficiency.

tematic reviews have evaluated this issue. Generally an upper limit of age, over which CI is contraindicated, is not reported by the national and international guidelines on CI procedures. The WG of the present project drew the following conclusion: *CI in the elderly* is admitted, without any upper limit of age. General health problems and life expectancy should be taken into account, and the indications for CI should be considered on a case-by-case basis.

With regard to *bilateral CI in adult patients*, NICE guidance⁴ does not consider bilateral CI as a cost-effective procedure in adult patients. NICE guidance does not consider cost-effective a bilateral procedure even in cases of adults with post-meningitic deafness, as the probability of cochlear ossification occurring in adults with severe to profound deafness combined with failure of the unilateral implant and an inability to re-implant the first ear was considered likely to be very small. NICE guidance⁴ allows simultaneous bilateral CI in deaf-blind adult patients or in adult patients with additional disabilities; a sequential procedure is not admitted except for deaf-blind adult patients or adults with additional disabilities who previously received a unilateral CI. On the other hand, Bond et al.³ report that the evidence for clinical effectiveness of bilateral implantation suggests that there is additional gain from having two devices as these may enable people to hold conversations in social situations by being able to filter out voices from background noise and tell the direction that sounds are coming from.

The WG of the present project stated that bilateral CI in adult patients is indicated in the following conditions:

- patients with deafness and initial bilateral cochlear ossification (ex post-meningitic);
- deaf-blind patients or patients with multiple disabilities (that increase reliance on auditory stimuli as a primary sensory mechanism for spatial awareness);
- unsatisfactory results with unilateral CI if better results are achievable with a contralateral CI;
- patients with CI failure if reimplantation in the same ear is contraindicated.

Both simultaneous and sequential procedures are admitted, although the simultaneous procedure is recommended. In the case of sequential bilateral implantation, a short interval between surgeries is recommended.

The last topic analysed in the present review is *CI in adults with pre-lingual deafness*; this was not specifically assessed by either of the two existing systematic reviews on CI. The WG of the present project stated that the indications for CI in adults with pre-lingual deafness and prognostic factors should be analyzed on a case-by-case basis. Factors to be taken into account are mainly progression of deafness, use of hearing aids and rehabilitation (and in particular the methodology of rehabilitation), results with hearing aids, patient motivations and psychological aspects.

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