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

Revisioni 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 adult patients, 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 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

Acta Otorhinolaryngol Ital 2011;31:299-310
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 patients. 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.

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.

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 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 years.

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 abilities. In 6 of 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., Chatelin et al. and Poissant et al. 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...
| Authors          | Title                                                                 | Journal, Year          | Sample size and other methodology                                                                 | Type of implant/processing strategy | Evaluated results                                                                                           | Conclusions/opinions                                                                 |
|------------------|----------------------------------------------------------------------|------------------------|-----------------------------------------------------------------------------------------------------|-------------------------------------|-------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------|
| Friedland et al. | Case-control Analysis of cochlear implant performance in elderly     | 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.| 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 3G 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.     | 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. Follow-up > 1 yr. | 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.  | 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 yrs, 8 pts received CI ≤ 60 yrs, 9 HA users ≥ 70 yrs. Test administered 2 mths before CI and > 1 yr after CI. | 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             | 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.     | Cochlear implant outcomes and quality of life in the elderly: Manchester experience over 13 years | Clin 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: BRB-sentences (Bench, Kowal and Bamford), AS-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. |
Post-CI benefits both in group 1 and group 2, with no significant differences in terms of age. Elderly pts obtain inferior results in HINT-Q and CNC (statistically significant).

Williamson et al. compared between results (verbal perception and questionnaire on pre- and post-CI satisfaction). HINT, CNC, questionnaire for 28 pts ≥ 65 yrs at CI. 28 younger implanted pts (control group). Follow-up at 1 year.

Summary table of articles included for review on the issue “Monolateral CI in elderly patients”.

| Authors | Title | Journal | Sample size and other methodology |
|---------|-------|---------|----------------------------------|
| Noble et al. | 3G processor, Freedom. 1 pt CI Clarion. | | |
| Chatelin et al. | Auditory performance after cochlear implantation in late septuagenarians and octogenarians | Otolaryngol Head Neck Surg 2008 | 27 pts CI Nucleus, ESPRIT satisfaction. |
| Poissant et al. | Otolaryngol Head Neck Surg 2009 | | 65 pts who received CI > 70 yrs. Control group 101 pts who received CI < 65 yrs. Follow up: 3-6-12 mths post-CI. |
| Labadie et al. | 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-lingual adult pts who received CI at 18-64 yrs. |
| | | | 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 CNQ). |
| | | | No statistically significant differences were observed in outcomes of the two groups. |

Table I. (follows)
### 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.        | 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.       | 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. CI 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.     | 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 sets 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.       | 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/Model, Clarion HiRes 90K, Clarion Radial Bipolar 1.0, Clarion HiFocus-II, 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.      | 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 AC8), HiRes90K (strat, HiRes), Medel Combi 40+ (strat OIS) | Comparison between outcomes with bilateral CI and unilateral CI (on one side with improved performance). - Recognition in open set 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.      | 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. |
### Table II. (follows)

| Authors | Title | Journal, Sample size and other methodology | Outcomes: verbal recognition in HINT (hearing in noise test), with varied SNR with adaptive system, CST (Connected Speech Test) with fixed SNR +10. |
|---------|-------|-------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------|
| Ricketts et al. | 21 | Speech recognition for unilateral and bilateral cochlear implant modes in the presence of uncorrelated noise sources | Medel C40+. |
| Dunn et al. | 20 | Bilateral sequential CI (delay 6 yrs 8mths - 17 yrs). | Ear Hear 2007 16 adult pts post-verbal. Simultaneous bilateral CI in most cases. Follow-up 4-7 mths. Follow-up at 12-17 mths for 10 pts. |
| Verschuur et al. | 17 | Auditory localization abilities in bilateral cochlear implant recipients | Nucleus 24 Contour (all). ESPRIT/SPRINT speech processor. ACE/SPEAK/CS processing strategy. |
| Ramsden et al. | 25 | Evaluation of bilaterally implanted adult subjects with the Nucleus 24 Cochlear Implant System | Cochlear implant in adults (continues) |
| | | Otol Neurotol 2006 20 post-lingual adult pts: bilateral sequential CI. Follow-up 3-9 mths after second CI. CI Nucleus 24 MK. Processing strategy: ACE/SPEAK. | Localization of sonorous source on horizontal plane with 1 CI (right and left) and with bilateral CI. |
| | | Otol Neurotol 2005 29 post-l. adults. Bilateral sequential CI (delay 1-7 years). | Recognized results: Recognition of words (CNC) and sentences (CUNY) in silent and background noise environments. |

**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 binaural squelch and diotic summation. 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 bilateral 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. 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. 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. 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.
| Study                  | Title                                                                 | Journal                  | Year | Patients | CI Model | Processing Strategy | Outcome/Results                                                                 |
|------------------------|----------------------------------------------------------------------|--------------------------|------|----------|----------|--------------------|---------------------------------------------------------------------------------|
| Nopp et al. [18]       | Sound localization in bilateral users of MED-EL COMBI 40/40- cochlear implants | Ear Hear 2004            | 2004 | 20 adult patients (19 post-lingual, 1 pre-lingual) | CI: MED-EL COMBI 40/40+. Processor: TEMPO+. Processing strategy CIS+. | Localization of sonorous source. 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, squeich, and summation effects in bilateral users of the MED-EL COMBI 40/40- cochlear implant | Ear Hear 2004            | 2004 | 21 adult patients (20 post-CI). | Medel Combi 40/COMBI 40+. Processor TEMPO+. | 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 squeich effect. Data on squeich 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        | 2004 | 37 post-CI adult pts, 15 with simultaneous implant, 22 with sequential implant. | 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 squeich 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. An investigation by Wackym et al. 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 studies reported that there were benefits from the cochlear implant procedure. Two studies recorded post-cochlear implant benefits in perceptive abilities, in both closed and open sets. The study by Klop et al. also documented an improvement in the quality of life after CI, while the study by Chee et al. 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. 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, 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). 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 auditory brainstem responses (ABR) threshold ≥ 90 dB HL. 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 dB.

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%.

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 ≤ 50% in the best aided condition without lip reading. In selected cases, CI is indicated if the open-set speech recognition score is ≤ 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 ≤ 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.  | 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.        | Cochlear implant outcomes and quality of life in adults with prelingual deafness | Laryngoscope 2007   | 8 implanted adults with prelingual deafness Follow-up ≥ 2 yrs                                    | Device CII Hi Focus I, HiRes90K, Hi Focus I                                                       | Evaluated results: Word recognition in open sets. (CVC monosyllables and phonemes), QoL, 2 questionnaires Health Utility Index (HUI-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.        | 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 guidance 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 guidance 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. 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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Received: August 22, 2011 - Accepted: October 25, 2011

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