CLINICAL RESEARCH

e-ISSN 1643-3750 © Med Sci Monit, 2016; 22: 3035-3042 DOI: 10.12659/MSM.896869

Received: Accepted: Published:	2015.11.26 2016.01.26 2016.08.28		Cochlea Quality	r Impla of Life	ants in e and /	Sub Audi	ojects Over Age 65: ological Outcomes		
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Background: Material/Methods: Results:		Cochlear implants (CIs) have been recognized as a safe and effective means for profound hearing loss rehabil- itation in children and adults and recently their use has been extended to subjects over 65 years of age. The aim of this paper was to assess indices related to changes in the quality of life (QoL) in elderly CI recipients. A case-control paradigm was used to assess the effects of CIs on the QoL. Forty-two subjects were assigned to the Case group and 15 subjects to the Control group. All 57 subjects were affected by profound hearing loss and had received a CI. Audiological data were collected from both groups at: (i) 1 month pre-implantation [T1]; (ii) 1 day pre- implantation [T2]; (iii) 30 days post-implantation, with CI used in free field [T3]; and (iv) 12 months post-implantation, with CI used in a free field [T4]. The QoL was assessed via a Glasgow Benefit Inventory (GBI) questionnaire, adapted to otolaryngology. To compare subjects across different ages with varying degrees of speech development, a perception parameter was used from the Speech Perception Categories test developed by Geers and Moog. Hearing performance was considerably improved after CI. In relation to the hearing performance at time T1, statistically significant threshold gains were observed in both groups in the T3 and T4 observation windows. At time T4, a threshold gain of 70 dB HL in the Case group and a gain of 84 dB HL in the Control group were observed. With speech therapy rehabilitation, a perception level of 6 was reached by 80.0% of patients in the Case group and by 100% of patients in the Control group. In terms of QoL, both groups showed improved post- CI scores. Statistical differences were observed between the 2 groups, with the Control group outperforming the Case group in all but the social section. Describe age replayed chappend aparing degrivation.							
								Conclusions:	
MeSH Keywords:			Cochlear Implants • Health Services for the Aged • Quality of Life						
	Full-t	ext PDF:	http://www.medscimonit.com/abstract/index/idArt/896869						
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MEDICAL SCIENCE MONITOR

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Background

Hearing loss is considered one of the most prevalent disabilities in the modern world and has been estimated to affect up to 30% of the adult population in developed countries [1–3]. This figure means that approximately 70 million people have already have severe hearing loss and that at least 900 million people will be affected by age-induced hearing losses by 2050 [1]. Studies on the European prevalence of hearing loss confirm that most elderly subjects are affected by a hearing deficit. In particular, data in the literature suggest that 30% of men over age 60 years, 20% of women over age 70 years, and 55% of men and 45% women over age 80 years have hearing problems [2,3].

Traditionally, hearing loss in the elderly is addressed with conventional hearing aids. In recent years, cochlear implants (CIs) have been proposed for treating these patients, who usually present severe and/or profound sensorineural hearing losses [4–9]. The latter are caused mainly by presbycusis/age-induced hearing loss, noise trauma, ototoxicity induced by specific drugs, autoimmune inner ear disease, Meniere disease, and various ear infections such as meningitis or labyrinthitis [10].

Despite the fact that CI services have been extended to the elderly population worldwide, the available clinical data do not show whether older patients can perform as well as younger CI recipients. Numerous factors can influence hearing performance in the elderly, including age-related auditory-processing problems, long history of hearing deprivation, difficulties in handling new technological devices, and properly following rehabilitative processes [11,12]. The cost-utility ratio of CIs in the elderly is reported to be another concern, as some authors argue that the total cost of the procedure may not be justified by the results achieved in elderly patients [11,12].

The purpose of this study was to evaluate, via a case-control study design, the effectiveness of CIs in older adults presenting profound/severe sensorineural hearing loss, using as indices audiological data and information from quality of life (QOL) questionnaires. Data were collected post-operatively from the audiological archives of our institute. Conducting a retrospective study provided the advantage of using larger datasets with an improved statistical significance. Unfortunately, the choice of investigated variables had to be restricted, since not all patients were assessed with the same clinical procedures.

Material and Methods

Patients

Fifty-seven patients with severe/profound sensorineural hearing loss who received a cochlear implant between January 2006 and December 2011 were enrolled in this study. All subjects presented a post-lingual hearing loss. For each patient, audiometric data and information from QOL questionnaires were collected. All enrolled patients provided informed consent prior to the cochlear implant surgical procedure, according to European laws.

Forty-two (42) subjects (23 females and 19 males) ages 65–86 years (mean 75.5 ± 5.7 y), were assigned to the Case group. Fifteen (15) subjects (8 males and 7 females) ages 40–59 years (mean 49.5±5.9 y), were assigned to the Control group. The difference between the sample sizes was part of the statistical design, since the Control group was very homogenous. It was considered advantageous, in accordance to the objectives of the study, to better explore the Case group properties via a larger sample.

Data

For each patient, the following data were collected: age at the implantation time; sex; family history of hearing loss; presence of tinnitus and/or dizziness; previous use of conventional hearing aids; implanted ear; type of cochlear implant; and hearing threshold level at the following times: (i) 1 month pre-implantation [T1]; (ii) 1 day pre-implantation [T2]; (iii) 30 days post-implantation, with CI used in free field [T3]; and (iv) 12 months post-implantation, with CI used in free field [T4]).

Each patient underwent neuroradiological evaluation (CT and MRI scans) before the CI surgical procedure, in order to evaluate the petrous bone, the inner ear, and, particularly, the cochlea, the internal auditory canal, and the cerebral structures.

To compare subjects across different ages with varying degrees of speech development, a perception parameter was calculated for each patient. This parameter was derived from the Speech Perception Categories test by Geers and Moog [13]. A scheme with 6 levels of speech perception was used; these levels are presented in Table 1. The speech therapy evaluation was performed 3 times at: 1 m pre-implantation (T1); at 30 d post-implantation (T3); and at 12 m post-implantation. (T4).

The assessment of how the CI affected the quality of life of each subject was conducted via a Glasgow Benefit Inventory (GBI) questionnaire, adapted to otolaryngology [14]. This questionnaire was administrated 12 months post-implantation, during a patient interview with an ENT specialist, allowing evaluation of how the cochlear implant affected patient health status. Each questionnaire contained 18 questions (see the Appendix) divided into 3 sections: (i) a general section with 12 questions; (ii) a social-support section with 3 questions; and (iii) a physical-health section with 3 questions. The total from the 3 individual section scores (ranging in values from -100 to 100) was considered the global GBI score.

 Table 1. Perceptive categories according to the Geers and Moog scale.

Table 2.	Number of participants, in the age sub-classes, for the
	case and control groups.

0 = no detection of speech sounds		Number of patients
1 = simple detection	Case group	
2 = pattern perception	65–69 years	29
3 = inconsistent closed set word recognition	70–79 years	10
4 = consistent closed set word recognition between words	≥80 years	3
that only differ for a vowel	Case group 65–69 years 70–79 years ≥80 years Control group 40–49 years 50–60 years	
5 = consistent closed set word recognition between words that only differ for a consonant	40–49 years	8
6 = open set word recognition	50–60 vears	7

Table 3. Percentage of hearing aid use, pre- and post-operatively, in the Case and Control groups.

Percentage of hearing aid use	Case group	Control group
Overall percentage	56.0%	87.0%
Percentage of hearing aid use in the implanted ear (before CI)	36.6%	73.3%
Percentage of hearing aid use in the contra-lateral ear (before CI)	19.5%	87.0%
Percentage of hearing aid use in the contra-lateral ear (after CI)	19.5%	87.0%

Characteristics of the patient groups

Of the 57 study participants, 31 received an implant in the right ear and 26 in the left ear. The age classes of the Case and Control groups are shown in Table 2.

Of the 57 patients, 65% declared that had been using a hearing aid (either in the implanted or in the contralateral ear) before the CI surgery. Subjects from both groups had also been using hearing aids in the contralateral ear after the CI; however, as described in Table 3, the use of hearing aids in the Control group was higher.

In terms of past medical history, 41% of the 57 patients declared a family history of hearing loss. Nineteen percent of the Case group subjects presented other complications, such as diabetes mellitus and cardiovascular diseases. In contrast, in the Control group only 2/15 patients (13%) showed an association with diabetes mellitus and none with cardiovascular diseases.

The etiology of hearing loss in the Case and Control groups is shown in Table 4. Vertigo and tinnitus were associated to sensorineural hearing loss in both groups. For tinnitus, 16 patients in the Case group and 6 patients in the Control group presented bilateral tinnitus, while 2 patients from the Control group and 2 from the Case group presented tinnitus on the CI side.

Table 4. Etiology of hearing loss within the Case and Control groups.

Etiology	Percentage
Otosclerosis	11.9%
Presbycusis	39.1%
Acoustic trauma	2.4%
Sudden sensorineural hearing loss	9.5%
Meniere syndrome	7.1%
Autoimmune hearing loss	16.7%
Ototoxicity	2.4%
Unknown	10.9%

Statistical analysis

A Case-Control design was used to assess the effects of CIs on the QoL. To compare the case and control subjects, analyses of variance with non-parametric tests was used. The audiometric data were condensed by calculating, for each ear, a pure tone average (PTA) threshold estimate at 0.5, 1, and 2 kHz. All statistical tests with p values less than 0.05 were considered statistically significant. The statistical analyses were performed with SPSS 16.0. Table 5. Mean pure tone average audiometric thresholds (PTA: 0.5, 1, and 2 kHz) of the Case and Control groups at times: T1=1month pre-op, T2=1 day pre-op, T3=1 month post-op, and T4=12 months post-op. For the measurements at T3 and T4 the Clswere used in free field. The time T1 (blue columns) was considered the point or reference for the statistical assessments (nosignificant differences with the T2 measurements). The last 2 columns refer to the threshold gain between the periods T1–T4and T1–T3. Asterisks denote significant gain differences at p=0.05.

Time	Т1	Т2	Т3	T4	T1-T4	T1-T3
Case Group						
PTA implanted ear (dB HL)	97	106	47	36	61*	50*
PTA contralateral ear (dB HL)	93	95	96	98		
PTA implanted ear with hearing aid (dB HL)	65	66	-	-		
PTA contralateral ear with hearing aid (dB HL)	64	65	52	60		
Control Group						
PTA implanted ear (dB HL)	108	119	45	35	73*	63*
PTA contralateral ear (dB HL)	90	100	95	90		
PTA implanted ear with hearing aid (dB HL)	66	65	-	-		
PTA contralateral ear with hearing aid (dB HL)	52	49	46	47		



Figure 1. Mean pure tone average audiometric thresholds (PTA: 0.5, 1, and 2 kHz) of the Case (A) and Control (B) groups at the different studied times. T1=1 month pre-op, T2=1 day pre-op, T3=1 month post-op, and T4=12 months post-op.

Results

Audiological data

As expected, the mean threshold value of the implanted ear was greater than the mean threshold of the contralateral ear, since in both groups the "worst" ear had been selected for a cochlear implant. For both groups, the average threshold values at time=T1 (1 month pre-implantation) and T2 (1 day pre-implantation) were slightly different, but no statistically significant differences were observed. Therefore, for the threshold analyses, the time T1 was considered as the reference time.

As expected, hearing performance was considerably improved with the cochlear implant and significant threshold gains were observed in both groups. In particular, at time=T4, a threshold gain of 70 dB HL was observed in the Case group and a gain of 84 dB HL in the Control group. At time=T3 (1 month post-implantation) we found a gain of 59 dB HL in the Case group and a gain of 74 dB HL in the Control group. There were additional threshold gains improvements from T3 to T4, but these were not significant and are not reported. Analyses of variance on the impact of the CI brand (Advanced Bionics, Medel, Cochlear) on the threshold data did not find any statistically significant effects. The data are summarized in Table 5 and Figure 1.

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Figure 2. Perceptive categories assignment at times T1 (1 month pre-op), T3 (1 month post-op) and T4 (12 months post-op) for the Case and Control groups. At time =T2 (1 day pre-op) no measurements were taken. (A) Data from the Case group. (B) Data from the Control group. The perceptive category levels range from 0 to 6 and their values are described in Table 1.

Perceptive category levels

The analysis of perceptive category data showed that at time=T1, 57.0% of patients in the Case group and 20.0% of patients in the Control group were initially assigned to perceptive category 0 (i.e., no detection of speech sounds; for the category details see Table 1). Prior to implantation at time=T2, no speech measurements were taken.

At time=T3 (1 month post-implantation), 47.6% of the Case group and 46.6% of the Control group patients were assigned to perceptive category 2 (i.e., pattern recognition).

At time=T4 (12 months post-implantation) and after speech therapy rehabilitation, 80.0% of patients in the Case group and 100% of patients of the Control group were assigned to perception level 6 (i.e., open set word recognition). The data are summarized in Figure 2.

Quality of life (QOL)

The results concerning quality of life were obtained from a total of 53 patients, because 4 patients from the Case group were not available for an interview. Statistical differences were observed between the GBI scores from the 2 groups, with the Control group outperforming the Case group in almost all sections. In terms of the global GBI score, both groups showed improvement, but the Control subjects showed a higher mean GBI score value than the subjects in the Case group (48.3 vs. 33.5). For the general GBI section, statistical differences were also observed between groups (59.5 vs. 42.3). For the social support section, both groups showed a similar and not statistically significant performance (19.5 vs. 20.5). The largest difference was observed in the physical health section (32.5 vs. -0.5). The data are depicted in Figure 3.



Figure 3. G.B.I. average score results for the Case and Control groups. The asterisks denote statistical significance at p=0.05. The acronym "ns" denotes a non-significant difference. The Control group shows better scores in all sections except the social support section. The largest difference was observed in the physical health section. The probable causes for the latter are addressed in the Discussion section.

Discussion

Cochlear implant programs worldwide have been gradually extended to elderly individuals, mainly due to the increased life expectancy in the developed world and to the increased prevalence of hearing loss with age. The majority of the data in the literature reporting on the quality of life in the implanted subjects comes from studies on adults and young adults [4–9]. Very few studies reported data from elderly implant recipients [4,5,7,9–16].

The assessment of QOL in CI recipients is important because it is becoming more evident that CI affects not only hearing abilities, speech perception, and speech production, it also has a significant effect on social life, activities, and self-esteem [17–22]. It remains difficult to predict how an elderly subject will perform after receiving a CI. Studies in the literature have verified that duration of deafness prior to CI and pre-operative speech perception performance are important factors that can significantly affect elderly speech perception scores after CI. Other factors that have been claimed to impact CI-mediated hearing performance include: CI electrode array design; CI speech processing strategy; and, most importantly, any degree of residual hearing [17–32].

Several indirect instruments have been developed to assess the QOL in patients with a cochlear implant and various validation schemes have been presented in the literature [29,30]. Generic instruments to assess the Quality of Life, such as the SF-36 questionnaire, have already been used to assess CI performance. However, specific instruments, such as the GBI questionnaire, which evaluates health-changes after surgery, allow a more precise assessment of QOL [17–27]. GBI is a subjective, patient orientated, post-interventional questionnaire, especially developed to evaluate any otorhinolaryngological surgery and therapy and has been used to assess various outcomes of audiological interventions [14,28].

The results of the present study suggest that the audiological skills of implanted subjects are considerably improved in both groups. The objective of this study was to assess the possibility that after a cochlear implant, the quality of life in the elderly can be improved. Specific factors, including the use and duration of hearing aids and the total duration of the speech therapy sessions, were not investigated, although it is plausible that they contribute to the overall QOL index. These parameters and the complex interactions with audiological data can be the topic of future investigations using a larger group of elderly subjects.

The analysis of perceptive status (Table 1) demonstrated the success of the cochlear implant. At time=T1 (1 month pre-implantation) the majority of patients were assigned to perceptive category 0, but 12 months later (t=T4) almost all patients reached the best value (i.e., 6) of the perceptive category scale. These data show that CI is not only an effective tool for adults, it also is an effective hearing restoration strategy for the elderly.

Data from administration of the GBI questionnaire suggest patients in both the Case and Control groups consider that they have good QOL, although QOL is rated higher by Control group patients, particularly in the general and in the physical health sections. This could be attributable to the younger age of those in the control group, leading to better performance. Also, Control group patients generally had better perceptive categories score prior to CI than those in the Case group. The observed large difference in the physical health section scores was probably caused by the presence of certain diseases (i.e., diabetes mellitus and cardiovascular disease) in the Case group. The anamnesis data show that these two diseases are present in 8 patients (19%) in the Case group but only in 2 patients (13%) of the Control group. In this context, the health status of the Case group patients was conditioned by factors independent of the proper functionality of the cochlear implant.

Scores obtained with the GBI are similar to those reported by other authors, with improved QOL perception in the general subscale [14,19,33]. Although the GBI data show that elderly subjects can be successfully assessed, it is important to emphasize that data derived from questionnaires tend to be subjective because they reflect the emotional status of the subject during the interview. Any factor which influences the physical or the emotional status of the subject can bias the acquired responses. To improve the validity of the data, a repeated-measures procedure is required (i.e., more than 1 interview every × months), but in clinical terms this is often not possible.

This study had a retrospective design to evaluate the largest possible sample size of elderly implanted subjects in our Institute. A retrospective design offers good control of the variance of the examined data (caused by the larger sample size), but it suffers in terms of flexibility and number of investigated variables; fewer variables are analyzed because fewer variables are available for the whole sample. Due to incomplete data, some important variables were not considered: (i) use and duration of hearing aids, (ii) total duration of the CI, (iii) etiology of hearing loss, (iv) age-induced CI performance, and (v) total duration of the speech therapy sessions. These factors should be explored and additional studies are needed to elucidate their role in performance of CI in elderly patients.

Conclusions

The present study shows that CIs improve QOL and audiological skills in elderly patients. Our data suggest that these advantages are comparable to the benefits in younger implanted adults. Although the data suggest that the GBI global score can effectively assess QOL in the elderly, larger samples of patients need to be tested with a repeated-measures statistical model.

Conflict of interest statement

The authors have no conflicts of interest to declare.

Financial disclosure

The authors have no financial relationships relevant to the content of this article. This study received no financial support.

Appendix

The Glasgow Benefit Inventory (GBI) questionnaire adapted to otolaryngology (11) was administrated post-operatively, during a patient interview, to evaluate how the cochlear implant affected patient health status. The questions in English language appear below, and the questions in Italian can be found at: https://www.ihr.mrc.ac.uk/projects/gbi.

- 1. Has the result of the ear operation affected the things you do?
- 2. Have the results of the ear operation made your overall life better or worse?
- 3. Since your ear operation, have you felt more or less optimistic about the future?
- 4. Since your ear operation, do you feel more or less embarrassed when with a group of people?

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- 5. Since your ear operation, do you have more or less self-confidence?
- 6. Since your ear operation, have you found it easier or harder to deal with company?
- 7. Since your ear operation, do you feel that you have more or less support from your friends?
- 8. Have you been to your family doctor for any reason, more or less often, since your ear operation?
- 9. Since your ear operation, do you feel more or less confident about job opportunities?
- 10. Since your ear operation, do you feel more or less self-conscious?
- 11. Since your ear operation, are there more or fewer people who really care about you?
- 12. Since you had the ear operation, do you catch colds or infections more or less often?
- 13. Have you had to take more or less medicine for any reason, since your ear operation?
- 14. Since your ear operation, do you feel better or worse about yourself?
- 15. Since your ear operation, do you feel that you have had more or less support from your family?
- 16. Since your ear operation, are you more or less inconvenienced by your ear problem?
- 17. Since your ear operation, have you been able to participate in more or fewer social activities?
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