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Satisfaction evaluation between digisonic sp monaural vs binaural

Abstract

Introduction: Satisfaction questionnaires are efficient means to assess whether the device dispensed to the patient met their expectations and improved their quality of life. They reveal what is beyond the hearing aid performance. They reveal what is beyond the hearing aid performance showing the patient's perceptions of the device use in everyday communication situations, social life return, self-esteem improvement and overall health.

Objective: To evaluate and compare the satisfaction level of patients implanted with Neurelec Digisonic ® SP ® Monaural and Binaural cochlear implants devices.

Methods: Patients implanted with NEURELEC ® (SP Digisonic ® Monaural and Binaural devices) brand from a Cochlear Implant Program of a tertiary hospital were evaluated concerning the clinical and demographic variables, pre and post-operative audio logical data and personal satisfaction with the use of the cochlear implant device.

Results: In overall score mark and two subscales binaural patients were more satisfied compared to monaural (positive effect, and services and cost). However, the statistical analysis comparing both groups showed a non-significant difference between them. Regarding the activation time of the cochlear implant, the better positive effects tend to be for the binaural implant group ($p = 0.08$).

Conclusion: It is not possible to state that patients implanted with Neurelec® *Digisonic SP*®Binaural have grater overall level of satisfaction than the ones implanted with the monaural. However, the research shows that the positive effects tend to be superior in the first group.

Keywords: cochlear implantation, patient satisfaction, hearing loss, questionnaires, hearing tests

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Introduction

Hearing loss in their varying degrees affects thousands of people every year in Brazil. In response to this demand the Brazilian Ministry of Health developed a public health policy regulated by ordinance GM/MS No. 3,762, of October 20, 1998 and subsequently extended by Ordinance No. 1.278/MS of October 20, 1999, which Instituted programs of hearing devices (hearing aids) concession and public policies of cochlear implants.[1,2]

They reveal what is beyond of the hearing aid performance showing the patient's perceptions of the device use in everyday communication situations, social life return, self-esteem improvement and overall health.[3–6]

Quality of life is a comprehensive term and involves various aspects of people's life. For the World Health Organization this term refers to "the individual's perception of their position in life in the context of culture and value systems in which they live and in relation to their goals, expectations, standards and concerns".[7] This World Health Organization Quality of Life (WHOQOL) definition indicates the subjective nature of the quality of life assessment, since it does not reflect objective issues about the environment, functional or psychological health or even though how a health professional or a relative evaluate these dimensions, but only the patient's perception is measured.[8]

The adaptation of hearing aids and cochlear implant involves many subjective and psychosocial factors and when the professionals Involved know how to evaluate and validate them, the adaptation becomes easier and faster for the users. The patient must be informed that the device will not restore normal hearing, but it will support the acquisition of more acoustic information and that the hearing rehabilitation activities should be introduced at the same time as the use of the device starts. The positive impact of the use of cochlear implants in the life of hearing impaired people is demonstrated in several studies and satisfaction questionnaires have been included as one of the variables to be considered.[9–14]

The benefit of binaural hearing is well described in the literature. The better performance of sound localization in bilateral cochlear implant users depends on the head shadow effect, the effect "squelch" and the effect of binaural sum. The head shadow effect occurs due to the head's obstruction of the sound arrival to the stimulated ear and the improvement of the relation of signal-noise (SNR). The binaural sum is the result of central auditory processing and demonstrates the ability of the central auditory nervous system to integrate and use the information from both ears. The "squelch" effect is the ability of the auditory system to use information from both ears when speech and noise are spatially separated.[15–23]

Although unilateral cochlear implant provides good speech understanding in background noise conditions, with no implanted hearing device patients often reports difficulties in speech understanding when exposed to noise and in the sound location perception, since these two functions require binaural stimulation. Therefore, it is not surprising the increasing interest in binaural cochlear implants. Bilateral cochlear implants can increase the quality of life through better hearing, especially in noisy environments and

the improved sound localization, compared with unilateral cochlear implants.[24] However a systematic review of cost-benefit of bilateral cochlear implantation in adults with profound to severe hearing loss, showed that bilateral implantation is probably worthwhile considering the cost-benefit limit in a willingness to pay up to £ 62,000 per quality adjusted by year life.[25]

This indicates that despite the benefits of bilateral cochlear implantation due to high costs he has a good cost-benefit ratio for adults from the standpoint of public health. Whereas the cost of binaural cochlear implant is close to the cost of a single monaural and much less than the cost of two monaural cochlear implant cochlear implants. So it is not surprising that there is a growing interest in the study of binaural cochlear implants.

This research focused on the cochlear implanted patient satisfaction, evaluating and comparing the satisfaction level of patients implanted with Neurelec ® Digisonic SP ® Monaural implant device and Neurelec Digisonic ® SP Binaural implant device.

Materials and methods

Clinical evaluation was conducted with patients implanted with NEURELEC ® brand (Digisonic SP ® Monaural and DigisonicSP ® Binaural) of the Cochlear Implant Program from a tertiary hospital. It was assessed different clinical and demographic variables and reviewed the medical records of all patients. All pre and post-operative information were tabulated and the most recently acquired patients' data were used in the analysis. The analysed variables were age, sex, initial stage of hearing loss (congenital, childhood, adolescence or adult), pregnancy, perinatal an genetic antecedents as well as the electrophysiological tests.

Satisfaction questionnaire

The questionnaire SADL (Satisfaction with Amplification in Daily Life) was selected to evaluate this sample. It was translated into Portuguese and adapted to our cultural aspects by Mondelli et al.,[26] and validated by the study of Danieli et al.,[27] (Table 1). The questionnaire results in an overall satisfaction score and a profile of subscales that address positive effects, service and value, negative characteristics and personal image.

All answers are computer for the global satisfaction; a conventional score scale was used for questions 1, 3, 5, 6, 8, 9, 10, 11, 12, 14, e 15 and a reversed score scale was used for questions 2, 4, 7 e 13, as shown in Table 2. In Table 3 is presented the score of the questions used for the subscales.

Table 1 Possible answers the SADL questionnaire

A	Not a little
B	Little
C	Somehow
D	Kind of
E	Pretty
F	Very
G	Very much

Table 2 Detailing the SADL questionnaire

SADL Answers	Convencional Points	Inverted Points
Not a little	1	7
Little	2	6
Somehow	3	5
Kind of	4	4
Pretty	5	3
Very	6	2
Very much	7	1

Table 3 Scores of the SADL questionnaire

Positive Effects	1 ,3, 5, 6, 9, 10
Service and Cost	12, 14, 15
Negative Factors	2, 7, 11
Personal Image	4, 8, 13

Implanted devices

The NEURELEC ® provides for our cochlear implant program two types of internal devices: Digisonic SP ® Monaural and Digisonic SP ® Binaural.

The Digisonic ® SP Monoaural cochlear implant system comprised of Digisonic SP implant and Digi SP ou Digi SP'K speech processors was released by French Company Neurelec S.A in 2004. This device corresponds to the latest version of the implantable component developed by the company and presents several improvements in relation to the previous versions.

The increment in the beam's electrodes number allowed: greater number of active channels for stimulation and spectral representation inside the cochlea; the receiver-stimulator fixation system using two titanium screws; and the increasing in the stimulation rate with the inclusion of sound processing strategy "Mean Peak Interleaved Sampling" (MPIS). The internal component developed by Neurelec the Digisonic ® SP is shown in Figure 1.[28] French company Neurelec SA in 2006 developed the Digisonic SP ® Binaural device. It comprises of a single receiver-stimulator connected to two electrodes beams responsible for stimulating simultaneously and synchronously the remaining nerve fibres in both cochleae (Figure 2).

The receiver-stimulator presents the same characteristics of the conventional Digisonic SP monaural, with the fixation system using titanium screws and its compact structure and in monoblock format allows faster and less invasive insertion. Each beam has 12 electrodes connected to a grounding electrode, totaling 24 active stimulation channels and speed up to 24,000 pulses per second.

A contralateral microphone is connected to a conventional speech processor Digi ® SP or Saphyr ® SP, which analyses separately the entry signals originated from the two ears and send them synchronously to the electrodes located in the different cochleae providing, in this way, a binaural hearing (Figure 3). The contralateral microphone used for the system operation is Widex CROS (Widex Corp., Denmark).

Inclusion and exclusion criteria

The research's analysis included UNICAMP's patients implanted with Neurelec® Digisonic SP® Monoaural and Digisonic SP® Binaural devices from 2011 until 2013. Patients with incomplete records or who do not want to take part in the evaluation were excluded from the protocol.

Audiological evaluation

Audiological tests including impedanciometry, tonal and vocal audiometry were performed. The tests were executed with an audiometer AC30-SD25, calibrated according to ISO 389 standards / 64.

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For ABR, which were repeated at least twice, it was used the AT-235 device (Interacoustics).

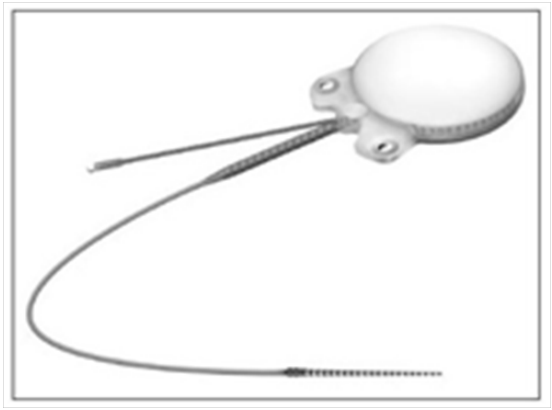

Figure 1 Digisonic®SP monoaural - Illustration shows the internal component receiver stimulator and a small region magnetic structure in a sealed ceramic titanium base. Observe the lateral niche for the two set the crews.

Figure 2 Neurelec Digisonic SP Binaural model.

Figure 3 Scheme demonstrating the sounds captured by the microphone of the speech processor and the conventional contralateral microphone connected to it. Both are processed by the speech and sent to a single implanted receiver-stimulator, responsible for transmitting information to both beams ipsilateral and contralateral electrodes processor, so that they promote synchronous pacing in the remaining nerve fibers in both cochlea.

SADL (satisfaction with amplification in daily life)

The questionnaire SADL (Satisfaction with Amplification in Daily Life) was prepared in order to assess overall patient satisfaction with the use of a hearing aid. By identifying the factors that contribute to satisfaction and to try to confirm these attributes to the processes involved, has the potential to qualify more health services.[29]

The SADL has 15 questions, divided into 4 subscales, reflecting overall satisfaction.

1. Positive effects: Six items related to acoustic and psychological benefit.
2. Service and value: Three items related to professional competence, product price and number of repairs.
3. Negative factors: three items relating to environmental noise amplification and phone use.
4. Personal image: Four items related to aesthetics and the stigma of hearing aid use.[3] Items are rated such that satisfaction is reflected by the high score. A score is generated for each of the four subscales and each subscale score is computed from the average of the answers to your questions.

To answer 15 questions a scale of 7 points from the same period, which corresponded to a categorical scale from "not at all" to "very much" satisfied was used. For 11 questions, "very much" and indicated total satisfaction was scored 7 as "not at all" indicated complete dissatisfaction and was scored 1.

The other four questions were inverted, where " very much" indicated complete dissatisfaction, and scored 1 and "not at all" indicated overall satisfaction, and scored 7.[30]

Statistical analysis

The research's data were analysed using descriptive and comparative statistical analyses, calculating averages, medians, standards deviations and applying T test for the two samples. The Sigma XL version 6.2 program was used for statistical tests.

Ethical aspects

All standards of the institution's Committee of Ethics were complied with the approval protocol number: CAAE:24802914.8.0000.5404.

Results

The research analysis was composed of 12 patients divided in two groups: 7 patients implanted with Digisonic SP ® Monoaural (Group A); and 5 patients implanted with Digisonic SP ® Binaural (Group B).

The participants in group A were 4 female and 3 male patients. The age average was 42.7years ad average activation time of 27.7months. All of the 7 patients were Saphir speech processor users. Three of the patients were implanted on the right side and 4 of them on the left side. Six participants were classified as post-lingual and one as pre-lingual. Group B was composed of 3 male and 2 female patients. Their age average was 46.8 years and activation time average of 12months. All of the 5 patients were Saphir speech processor users (Charts 1 & 2).

Satisfaction questionnaires (SADL) were applied to all patients of both groups. Chart 3 presents the global average score and 4 subscales of the monaural and binaural implanted patients. Figure 3 demonstrates the mean global scores and the four subscales of the monaural and binaural implanted subjects. The overall score and two subscales showed that binaural users were more satisfied if compared to the monaural (positive effects, services and cost). However, in the statistical analyses comparing both groups there was no statistical significance between them. It was observed that regarding the CI activation time the tendency was a better positive effects for the binaural implanted group (p= 0.08).

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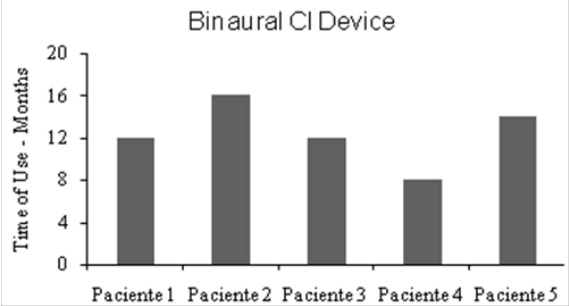

Chart 1 Activation time Binaural Cochlear Implant device.

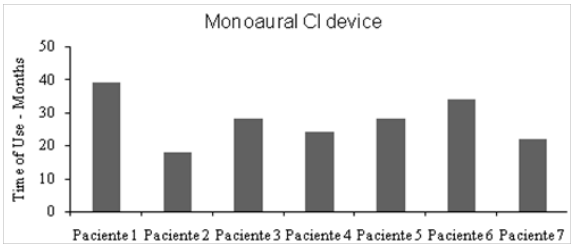

Chart 2 Activation time Monoaural Cochlear Implant device.

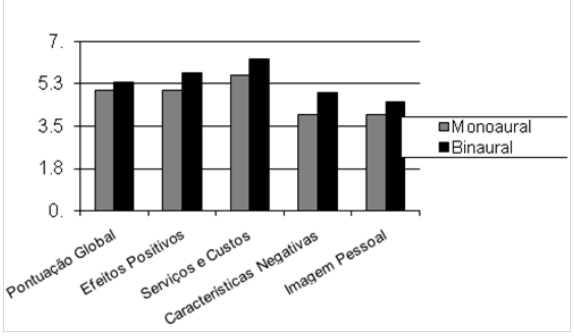

Chart 3 Results SADL in both groups.

Discussion

The patients' satisfaction level with their devices use, either monaural or binaural, is extremely important for their quality of life. In this sense, the SADL scale is short and brief but at the same time comprehensive enough to allow a valid evaluation of a multidimensional variable. Nevertheless, as Cox et al.,[3] point out, further researches are needed to refine the understanding and properties in test and retest and determine the clinical, scientific and administrative applicability of results.[6] Although there is no statistical significance in the comparative analysis between the groups of users monaural and binaural devices, it was observed that the individually, for both groups, the level of satisfaction was good. Besides, the lack of statistical significance in the results may be explained by the relatively small number of individuals in the sample studied.

In a study of Marki-Torkko et al, pre-operative expectations and the post-operative experiences related to cochlear implants were analysed using a questionnaire. Patients described their satisfaction as having living in two different worlds (one with the auditory stimulation and one without), showing importante increasing in well-being and satisfaction with their devices. A large part of living social life was improved by communication and results showed that the satisfaction was not limited only to the users, but also to their significant others.[31]

Another study, by Nardo et al.,[31] used two questionnaires to evaluate the health status (SF-36), CI-related effects on daily activities and personal satisfaction (Questionnaire for self-evaluation of CI benefit with SADL scale modification), to compare the benefits of unilateral cochlear implant in patients over 60 with a control group of younger CI recipients. Although there were some different responses to the questionnaire between groups, both showed very good result and satisfaction with CI. Results obtained in terms of auditory perception, general health and perceived benefit showed that advanced chronological age could not be considered as major factor limiting the effectiveness of CI.[32]

Cochlear implantation is a safe surgical technique for rehabilitation of severe to profound sensorineural hearing loss but not free of complications, although the complication rate is low. These complications have been a reason for concern in health care centers during the implementation of new surgical approaches and can be divided into minor and major complications.[23,33]

The minor complication rate is significantly higher in the adult population, but major complication rate is similar both for children or adults. Minor complications include transient peripheral facial palsy, posterior meatal wall injuries, annulus and tympanic membrane injuries, perilymphatic fistula, bleeding, corda tympani nerve injuries, and hematoma. Major complications include electrodes problems (misplacement, damage, inserting problems compression of electrodes, dislocation), flap dehiscence or infection, cholesteatoma, otomastoiditis, facial palsy with sequela, CSF leak, meningitis and incapacitating otological symptoms.[23,33]

The follow-up time of these patients becomes a bias, since the introduction of the Digisonic SP Binaural device is more recent; patients implanted with it had a shorter follow-up. Nonetheless, it was possible to observe that the positive effects of the use of this CI in patients were better than patients using monaural devices.

Conclusion

This research presented a comparison of satisfaction level between patients implanted with Neurelec ® Digisonic SP ® Monaural and Neurelec ® Digisonic SP ® Binaural devices. It is not possible to state that patients implanted with binaural devices were more satisfied that the monaural ones, since there is no statistical significance in the comparative analysis between the groups. However, the results showed that there is a tendency that the positive effects were better in patients implanted with binaural device, despite the shorter introduction time.

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Conflicts of interest

Author declares there are no conflicts of interest.

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