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Research Article

Impact on Daily Life of an Active Middle Ear Implant

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Abstract

Objective: The aim of this study was to evaluate the effect of a totally implantable active middle ear implant in quality of life of the implanted patients taking into account their hearing performance.

Methods: Retrospective observational nonrandomized group study. Settings: Private hospital. From March 2018 and September 2019, all the participant with minimum 6 months' experience with the Carina system were evaluated. The evaluation was performed using the Abbreviated Profile of Hearing Aid Benefit (APHAB) questionnaire.

Results: Nine patients complete the entire questionnaire. A reduction of difficulties was seen in quiet environments/ease of communication (32.8% vs 54.3%), in background noise environments (42.8% vs 62.3%) and in environments with reverberation (38.7% vs 63.9%) in the patient with the active middle ear implant when compared to the unaided condition. In what concerned the trouble caused by unpleasant sounds/Aversiveness, an increased discomfort was described with de middle ear implant compared to the unaided condition (50.3% vs 32.8%).

Conclusion: Active middle ear implants seem to improve auditory perception in daily activities, even in difficult conditions like background noise or reverberation environments, although statistically significant conclusions cannot be achieved due to the small sample size. APHAB demonstrated to be a potential useful tool in this evaluation.

Keywords: Active Middle Ear Prosthesis; Carina Implant; Middle Ear Transducer; Quality of Life; Hearing

Abbreviations

APHAB: Abbreviated Profile of Hearing Aid Benefit; AMEI: Active Middle Ear Implants; HRQoL: Health-related Quality of Life; SP: Sickness Impact Profile; HUI3: The Health Utilities Index Mark 3; SF-36: 36-Item Short Form Survey

Introduction

In recent years different technologies have been developed trying to solve some of the limitations of hearing aids technology. Active middle ear implants (AMEI) are one of these examples. New totally implantable devices also added the effect of comfort and aesthetics to these technological improvements.

In spite of the progressively higher use of these devices there aren't yet enough studies to analyze the improvement expected in patients' quality of life and the impact in the daily life [1,2].

The middle ear implants benefit evaluation is usually done by comparing the results of pure tone or speech audiometry before and after the implantation. However, audiometric results do not always reflect the real daily difficulties felt by the patients.

The concepts of quality of life and health-related quality of life (HRQoL) try to measure the impact of a disorder and treatment on several attributes that are thought to constitute the self-perceived health status of an individual. HRQoL specifically related with hearing loss include different dimensions, as limitation of general activities, social and emotional problems, communication impairment, physical symptoms and cognitive impairments [3-6].

The assessment of quality of life can be performed with different methods: questionnaires, looking at changes in person's overall wellbeing, measuring economic and social development and, in the particular case of hearing loss, patients' speech discrimination evaluation and its influence in social life. The majority of the existing instruments include items related to the major health domains of physical, social, and mental health. Short Form (36) Health Survey (SF-36) or Health Utilities Index (HUI) are some of the examples [7,8].

A significantly smaller number of questionnaires access the problem of hearing loss and the various systems of hearing rehabilitation. One of the examples is the Abbreviated Profile of Hearing Aid Benefit (APHAB), which is an adaptation of Profile of Hearing Aid Benefit 66-item inventory which was designed for a hearing aid wearer. All of the items are related to communication abilities or perception of sound in daily life situations. Other example to evaluate individual's perceived level of hearing handicap is The Hearing Handicap Inventory for Elderly (HHIE), that measure the effect of hearing loss on social/situational functioning and the emotional impact of the hearing loss. Both of these instruments have been shown to be responsive to hearing aid intervention [9-12].

Till now, as far as the authors are aware, there are no questionnaires directed specifically to the evaluation of the benefit of a middle ear implant.

The aim of this study was to evaluate the impact of an AMEI in quality of life of their recipients having in mind the hearing performance and the daily life difficulties experienced.

Material and Methods

The CUF Porto Hospital Ethics Committee approved this retrospective mono-center, nonrandomized group study and authorized the use of the patients' clinical information (reference number of ethical committee approval: HCP/CES-009/18). The procedures followed were in accordance with the tenets of the Helsinki Declaration as revised in 2013. Informed consent was obtained from all patients who participated in the study.

Patients implanted with an AMEI Carina® were selected. No patients implanted with another type of middle ear implant were included, trying to limit the bias of the results. The study was performed between March 2018 and September 2019. All the participant were 14 years of age or older with a minimum of 6 months' experience with the Carina system; moderate to severe sensorineural hearing loss (SNHL) with actuator coupled to the incus (standard approach) or moderate to severe mixed hearing loss (MHL) with the actuator coupled to the head of stapes.

The Abbreviated Profile of Hearing Aid Benefit (APHAB) was used to analyze pre- and postoperative hearing benefit. This is a 24-item questionnaire composed of situational-specific questions that are classified into one of four categories: (1) ease of communication, which examines the communication effort under favorable conditions; (2) reverberation, which studies communication in reverberant environments such as lecture halls or a classroom; (3) background noise, which look at the capacity of communication in high levels of background noise; and (4) aversiveness of sound, which evaluate the discomfort to unpleasant environmental sounds. Aided (with AMEI) and unaided (without AMEI) conditions were compared. Each question is scored in a 7-categories scale from 1% to 99%, related with the frequency of occurrence. Some questions are scored in a reversed way [11,12].

The patients were requested to fill in the questionnaire previous to the implant surgery and 3-6 months after surgery. All patients were assessed pre- and postoperatively with tonal and speech audiometry. The results of this evaluation have already been published and can be accessed in Peixoto., *et al*. 2021 [13].

Results

Eighteen patients were included. These patients were surgically implanted between December 2014 and October 2019. Fifty nine per cent of patients were male. The mean (SD) patient age was 59 (±15.55) years old at the time of the intervention, and the mean duration of hearing loss was 15.6 (±13.69) years. In this study, 65% of the subjects were implanted in the right ear, and 60% had SNHL type of hearing loss.

Nine patients complete the entire questionnaire in both moments of the evaluation.

APHAB tries to assess patients' difficulties in diverse day-to-day situations in different hearing environments. Figure 1 to 3 present the report (in percentage) of the difficulties of the patients in quiet environments/Ease of Communication (EC), in background noise environments' (BN) and in environments with reverberation (RV), with and without AMEI. Figure 4 present the discomfort caused by unpleasant sounds/Aversiveness (AV).

Figure 1: Ease of Communication: difficulties with and without AMEI (in percentage).

Figure 2: Background Noise: difficulties with and without AMEI (in percentage).

Figure 3: Reverberation: problems with and without AMEI (in percentage).

Figure 4: Aversiveness: discomfort with and without AMEI (in percentage).

In ordinary situations with quiet surroundings as when the patient is with one family member (4), in a small room (10), when he is talking quietly with a friend (12), in a small group (14), talking to a doctor in the exam room (15), talking in a quiet environment (23) there was a reduction in the difficulties and a need for repetition presented by the patients with AMEI comparing with no AMEI (Figure 1).

In circumstances with background noise as in the supermarket, talking to the cashier (1), listen the news in the car radio with other people talking (6), in a dinner with several people (7), other situations with several people talking at the same time (16), in a crowd (19) or with other noises as the air conditioner on (24) there was a decrease of the troubles percentage expressed by patients with AMEI (Figure 2).

The same difficulties' reduction was seen in all conditions where there is reverberation, as in a class room (2), in a movie or theater (5) with people whispering (11), in a large empty room (9), in lectures or in churches (18) or in at the Mass or worship service (21) (Figure 3).

When analyzed the discomfort conditioned by ambient noises, such as a car alarm (3), traffic (8), running water in a kitchen sink or in a bathroom (13), construction sounds (17), a siren (20) or a car break (22), it was found that in all these conditions a greater discomfort was reported by the patients with AMEI (Figure 4).

In spite of the differences found in the different categories/ environments there were no statistically significative differences found between the aided and unaided condition (Table 1).

	Mean	Std. Dev	Asymp. Sig. (2-tailed)[a]
EC_NOAMEI	54,28	27,95	0,90
EC_ AMEI	32,83	22,64	
BN_ NOAMEI	62,29	22,25	0,063
BN_ AMEI	42,84	23,34	
RV_ NOAMEI	63,91	23,58	0,063
RV_ AMEI	38,68	24,47	
AV_ NOAMEI	32,81	26,88	0,205
AV_ AMEI	50,28	34,36	

Table 1: Mean values comparations in Ease of Communication (EC), Background Noise (BN), in Reverberation (RV) and Aversiveness (AV) with and without AMEI.

a. Wilcoxon Signed Ranks Test.

Discussion

Despite the improvements in conventional hearing aid technology in the last few decades, there are still some limitations. AMEI have been developed to overcome such problems and, in recent years, an increasing number of these devices have been implanted. In the specific case of the Carina device all the components are implanted under the scalp skin. Two groups of patients can theoretically benefit of this totally implantable device: those patients who cannot use a conventional hearing aid, with the improvement expected of hearing levels, speech comprehension in quiet and noisy environments, communication and socialization; and those who are hearing aid users answering to technical problems like feedback, occlusion effect and sound distortion and allowing sports and aquatic activities, as well as esthetic concerns and lifestyle due to an invisible solution [1,2].

At this point it is also important to remember that AMEI were initially indicated patients with moderate to severe sensorineural hearing loss, but in recent years extended for patients with mixed hearing loss with ossicular defects in whom conventional ossiculoplasty itself would not restore properly hearing function [2].

At the current moment there are no formal instruments other than pure tone and speech audiometry to assess the real benefit of these implants. And for a long time, audiometric results were seen as the most reliable way of assessing the auditory benefit obtained with implants, but actually there was often no clinical correspondence between what was observed during the audiometric assessment and what the patient reported as daily difficulties and limitations. In order to answer and evaluate these difficulties, other assessment instruments were created. Speech discrimination in noise or assessment of quality of life/hearing improvement through questionnaires were some of the developed instruments.

In the particular case of questionnaires different enquires were developed or used, however, the majority of them is not specific for hearing loss and include a diversity of physical functions, such as mobility, performance of activities of daily living, absence or presence of pain, social interaction, or mental acuity. Common examples included Sickness Impact Profile (SIP), the Health Utilities Index Mark 3 (HUI3) or 36-Item Short Form Survey (SF-36) [14-16]. Only a few address hearing impairment difficulties and hearing impaired patient's quality of life. One example is APHAB. APHAB is a questionnaire for hearing aids users. The answers are given in a dichotomous way opposing "with hearing aid" and "without hearing aid", considering the advantages and disadvantages experienced with hearing aid use. Four different subgroups are considered in a global set of 24 questions. For each subgroup, the individual performance itself and the benefits of amplification, both with hearing aid and no hearing aid are measured on the rating scale [11,12].

The aim of this study was to evaluate the impact of a totally implanted AMEI in daily activities related with patients´ hearing performance. To analyze this problem authors choose the APHAB questionnaire due to its simplicity and short duration, and due to the fact that it is totally focus on hearing and allows comparison between unaided and aided performance. The authors had already previous experience of using other questionnaires through The Cochlear ™ Implanted Recipient Observational Study (IROS) in patients with cochlear implants. The long extension of this assessment severely limited its routine use and a limited assessment of everyday auditory impact.

APHAB presents statements about communication abilities or perception of sound in daily life situations, as hearing in noisy environments or communication in reverberant environments, and the respondents' task is to indicate how frequently each statement is true.

In a previous work, the authors were able to observe an increasing satisfaction and improvement in the sound perception with consequent improvement inquality of life in some patients with Carina, but in an informal manner [17].

Carina should allow ambient sounds recognition and speech perception improvement. Can APHAB be capable to show these expected benefits?

In quiet situations, as a small room or when talking quietly with a friend, all the patients presented a reduced degree of difficulties during a conversation in these environments using the implant. These results are consistent with the improvement in speech discrimination observed in speech audiometry with Carina [17].

Hearing impaired patients have frequent complaints in noisy environments. The same is true for patients with hearing aids. What is the behavior with AMEI?

In background noise conditions as in a supermarket, with several people talking, in a crowd or with other environment noises, patients demonstrated with APHAB less difficulties with Carina. This is in line with what had been demonstrated in 2019 and 2021 by another's studies, in which there was an improvement in speech discrimination in noise in patients implanted with the Carina device [13,17].

Other problematic condition for hearing loss patients is when they are subject to reverberation. Reverberation occurs when some waves of acoustic energy are reflected from features of an environment, like a wall, and reach the ear after waves of energy that have moved through a direct path. This delay in acoustic energy interrupts speech recognition [18]. This is an acoustic phenomenon present in many everyday hearing environments as in a class room, in a cinema or theater, in a large empty room or in churches (all conditions assessed by APHAB). In this study Carina seems to improve de hearing understanding in reverberant environments reducing difficulties felt in these kind of environments.

In what concerns with loud noises, an increasing discomfort was seen with the AMEI, when compared to the condition with no AMEI, as was expected. Higher-pitched sounds are usually lost in gradual hearing loss and may seem abnormally sharp when amplified.

The small size of the sample limits the conclusions and no statistically significant differences were found in the four subgroups of questions between pre- and post-implanted condition. Also it is difficult to compare these conclusions with other studies because few studies address this theme.

Savas., *et al*. presented no significant differences between Carina implant and conventional hearing aids. Patients with AMEI showed clinical improvements in quality of life questionnaire scores, using the Glasgow Benefit Inventory [2].

Pulcherio., *et al*. in a systematic review, using APHAB scale and comparing between unaided and aided conditions with Esteem, Carina and conventional hearing aids found benefit with these AMEI, contributing this way for an improvement of quality of life [19].

An interesting future study will be the comparison between hearing aids and Carina, using APHAB.

In conclusion, we can say that the AMEI appears to improve auditory perception in daily activities, even in difficult conditions, as with background noise or reverberation, although statistically significant conclusions cannot be drawn due to the small sample size.

Conclusion

The APHAB seems to be a potentially useful clinical tool for measuring the outcome of AMEI fittings, allowing comparison with other sound amplifiers as hearing aids and the follow-up of the success of a fitting over time. It could thus be potential usefully for AMEI as well as hearing aids evaluations. Larger studies are needed. Conclusion should reflect and elucidate how the results correspond to the study presented and provide a concise explanation of the allegation of the findings.

Conflict of Interest

No financial interest or any conflict of interest exists.

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