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Avancerad nivå

Titel
Nytta samt hälsorelaterad livskvalitet hos vuxna patienter med konduktiv eller kombinerad hörselnedsättning som använder benlednings hörselimplantat eller konventionell hörapparat

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Sammanfattning
Syfte: Syftet med denna studie var att undersöka graden av nytta och hälsorelaterad livskvalitet hos vuxna patienter med konduktiv/kombinerad hörselnedsättning som använder benlednings hörselimplantat eller konventionell hörapparat.
Metod: Datainsamlingen utfördes via enkäterna Abbreviated Profile of Hearing Aid Benefit (APHAB) och Health Utilities Index Mark 3 Inc (HUI3). APHAB analysen utgick ifrån 33 respondenter ifrån respektive grupp och HUI3 analysen ifrån 32 respondenter ifrån varje grupp.
Resultat: Resultaten visade på att patienter med konduktiv/kombinerad hörselnedsättning som använder benlednings hörselimplantat eller konventionell hörapparat erhöll liknande grad av nytta i olika vardagliga situationer och inga signifikanta skillnader påvisades mellan grupperna. Båda grupperna erhöll generellt signifikant högre grad av nytta med benlednings hörselimplantat eller konventionell hörapparat jämfört med utan. Den övergripande hälsorelaterade livskvaliten var ungefär lika mellan de båda grupperna och inga signifikanta skillnader observerades.
Slutsats: Benlednings hörselimplantat och/eller konventionell hörapparat är goda lösningar för att behandla patienter med konduktiv/kombinerad hörselnedsättning.
Nyckelord: Konduktiv/kombinerad hörselnedsättning; benlednings hörselimplantat; konventionell hörapparat; nytta; hälsorelaterad livskvalitet

University of Gothenburg
The Sahlgrenska Academy
Institute of Neuroscience and Physiology
Unit of Audiology

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MASTER RESEARCH THESIS IN AUDIOLOGY, 30 ECTS

Advanced level

Title
Benefit and health-related quality of life in patients with conductive or mixed hearing loss using bone conduction hearing implants or conventional air conduction hearing aids

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Objective: The aim of this study was to investigate the degree of benefit and health-related quality of life (HRQL) in adult patients with conductive or mixed hearing loss that use bone conduction hearing implants or conventional air conduction (AC) hearing aids.
Design and study sample: Data were collected from the questionnaires Abbreviated Profile of Hearing Aid Benefit (APHAB) and Health Utilities Index Mark 3 Inc. (HUI3). The APHAB analyses consisted of responses from thirty-three respondents from each group and the HUI3 analyses from thirty-two respondents from each group.
Results: Both groups obtained a similar degree of benefit in different everyday hearing situations and no significant differences were found. Both groups received, in general, a significantly higher degree of benefit with a hearing device than without. The overall HRQL of life was similar between both groups and no significant differences were observed.
Conclusion: Both of the hearing devices are good solutions in the rehabilitation of patients with conductive or mixed hearing loss.
Key Words: Conductive/mixed hearing loss; bone conduction hearing implant; conventional hearing aid; benefit; health-related quality of life

Abbreviations

AC: Air Conduction

APHAB: Abbreviated Profile of Hearing Aid Benefit

BCHI = Bone Conduction Hearing Implant

dB HL: decibel Hearing Level

HA: Hearing Aid

Hz: Hertz

HL: Hearing Loss

HRQL: Health-related Quality of Life

HUI3: Health Utilities Index Mark 3 Inc.

kHz: kiloHertz

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INTRODUCTION

Hearing loss

Hearing loss can be divided into three generally different types, depending on where the impairment is located. Conductive hearing loss arises from impairment in the ear canal or middle ear and results in sound waves not reaching the inner ear in the normal way due to conducting problems and affects the ability to hear lower sound levels (Roeser et al., 2007). Sensorineural hearing loss is the most common type of hearing loss with the impairment occurring in the inner ear, somewhere in the cochlea, auditory nerve pathways or in the cortex. This type of hearing loss also decreases the ability to hear lower sound levels and also the ability to recognize speech can be affected and sound will be unclear. Mixed hearing loss can be defined as a combination of both conductive hearing loss and sensorineural hearing loss and the impairment can, for example, be in both the middle and inner ear (Roeser et al., 2007). The etiology of hearing loss can be caused by or be a combination of different factors such as age-related hearing loss, prolonged exposure to noisy environments, infections/inflammations that can also be chronically, congenital aural malformations, genetic factors and ototoxic drugs (Arlinger et al., 2008). Hearing loss can vary in degree and the table below illustrates the different degrees (Clark, 1981).

Degree of hearing loss	**Hearing loss range (dB HL)**
Normal	-10 to15
Slight	16 to25
Mild	26 to 40
Moderate	41 to 55
Moderately severe	56 to 70
Severe	71 to 90
Profound	91+

Hearing instruments

At the beginning of the 1900s, a new era of analogue technology in hearing devices began. Over the years the technology has progressed and the very first hearing aid of a digital character was introduced in 1987, after which digital technology has progressed quickly (Mudry & Dodelè, 2000). The idea of hearing via bone conduction is very old and was already known in antiquity. The construction of the bone conducted vibrator placed behind the ear on the processus mastoideus area, aided, for example, by eyeglasses was developed in the 20th century and the first bone conduction hearing implant was implanted in 1977 (Mudry & Tjellström, 2011).

Hearing instruments can be divided into two main groups: those that amplify, which are conventional air conduction (AC) hearing aids and middle ear implants, and those that replace a function of the body, which are bone conduction hearing implants, cochlear implants and brainstem implants (Centers for Medicare & Medicaid Services, n.d.). The bone conduction hearing systems can be divided into two major sub-categories: conventional bone conductors - mainly used on band and implantable bone conduction hearing implants. The implantable bone conduction hearing implants can be percutaneous with no skin in between or with a magnetic connection, which are based on a magnetic coupling using magnets on both sides of the skin.

The direct connection option consists of a transducer (sound processor) connected to an osseo-integrated titanium implant situated in the temporal portion of the mastoid bone. A skin-penetrating abutment attaches the sound processor to the implant, and the acoustic signal is consequently transmitted to the inner ear(s) directly through the skull bone, bypassing the tympanic membrane and the ossicular chain (Håkansson et al., 1985; Håkansson et al., 1994). Since the end of the 1970's, the percutaneous option widely known as Baha, has proved to be a good treatment for patients with hearing loss who couldn't benefit from a conventional AC hearing aid (Lustig et al., 2001; Mylanus et al., 1998; Tjellström & Håkansson, 1995; Tjellström et al., 1983; Snik et al., 1995).

The audiological indication for bone conduction hearing implants includes patients with conductive or mixed hearing loss or single-sided sensorineural deafness (Hagr, 2007). The medical indications include patients with chronically draining ears due to inflammation/infection or congenital aural malformations (Hagr, 2007; Lustig et al., 2001). Individuals with single-sided deafness caused by, for example, acoustic neuroma or sudden deafness can also be candidates for bone conduction hearing implants (Hol et al., 2005; Snik et al., 2005). The most common type of hearing device is the conventional AC hearing aid, which transmits the amplified sound the normal way (Hagr, 2007). The ear canal directs processed sound to the eardrum and makes it vibrate. Subsequently, vibrations are transferred through the auditory ossicles to the inner ear, converting vibrations into electrical impulses and then sent to the cortex via auditory nerve pathways (Roeser et al., 2007).

Transmitting sound via a bone conduction hearing implant can give patients with conductive or mixed hearing loss more benefit by better speech perception than a conventional AC hearing aid (Hol et al., 2005; Mylanus et al., 1998; Flynn et al., 2009; de Wolf et al. 2010). An explanation for this is that such patients, when using a conventional AC hearing aid, are in need of more amplification due to mixed hearing loss. This can mean that even powerful conventional AC hearing aids are not sufficient. The need for more amplification will often result in more distortion, saturation and feedback problems and less natural sound. The bone conduction hearing implant compensates for the sensorineural element of the hearing impairment and bypasses the conductive loss (Flynn et al., 2009). The bone conduction hearing implant is a reliable solution in hearing rehabilitation since it can improve the hearing thresholds for individuals with conductive or mixed hearing loss who couldn’t benefit from conventional AC hearing aids (Lustig et al., 2001).

de Wolf et al. (2010) has investigated the differences in speech understanding between patients with mixed hearing loss who use bone conduction hearing implants or conventional AC hearing aids by using aided thresholds and speech recognition tests. The outcomes from the audiometric evaluations showed that patients with air-bone gaps that exceeded 35 dB showed better audiometric and speech perception results with bone conduction hearing implants compared to conventional AC hearing aids.

The authors also used the Abbreviated Profile of Hearing Aid Benefit (APHAB) questionnaire to consider the patients' opinions, which showed that patients with an average air-bone gap less than 45 dB rated the conventional AC hearing aid higher than the bone conduction hearing implant. The study also emphasized that bone conduction hearing implants should be a more common selection for patients with mixed hearing loss having significant air-bone gaps, who couldn't use or benefit from conventional AC hearing aids (de Wolf et al., 2010).

Mylanus et al. (1998) compared patients who had previously used conventional AC hearing aids with their bone conduction hearing implants through audiometric tests including e.g., speech recognition in noise and an ENT outpatient clinic questionnaire concerning different hearing-related issues. The results showed that the larger the air-bone gap, the greater the benefit from a bone conduction hearing implant compared to a conventional AC hearing aid. Furthermore, a bone conduction hearing implant is a good alternative for patients with chronic ear problems or if a conventional AC hearing aid cannot be used.

Studies have also shown ambiguous results in the comparisons between bone conduction hearing implants and conventional AC hearing aids, evaluated with audiometric measurement such as speech recognition tests and questionnaires (Snik et al., 1995; Snik et al., 2004; Mylanus et al., 1995). Nevertheless, the bone conduction hearing implant was still described as a notable solution for patients who cannot benefit from conventional AC hearing aid (Snik et al., 1995; Mylanus et al., 1995).

Bance et al. (2002) has compared the function of bone conduction hearing implants with conventional AC hearing aids through different objective audiometric tests in both quiet and noise and also included a comparison group of subjects with normal hearing. The subjective quality of life was also studied by the questionnaires, Sanders' Profiles and Medical Outcomes Study, MOS SF-36. The outcomes reported no significant differences between bone conduction hearing implants and conventional AC hearing aids in objective measurements (sound field audiogram and different speech discrimination tests) and in quality of life.

Health-related quality of life

Previous studies have shown that an untreated hearing loss can have a range of consequences which lead to among other things communicative disabilities and affect the health-related quality of life (HRQL). HRQL is a broad term defined as *"the value assigned to duration of life as modified by the impairments, functional states, perceptions, and social opportunities that are influenced by disease, injury, treatment, or policy"* (Patrick & Erickson, 1993).

Tatović et al. (2011) has studied the association between hearing loss and HRQL using the Hearing Handicap Inventory for the Elderly-Screening (HHIE-S) questionnaire. The study emphasized that hearing impairment can affect physical and psychological health in adults, which can also affect the quality of life. Furthermore, HRQL is an important factor to consider in individuals with hearing loss. Similar outcomes were also reported in elderly individuals (Mulrow et al., 1990; Mulrow et al., 1990; Ciorba et al., 2012; Dalton et al., 2003). Previous studies have shown that hearing devices can also have an effect on the quality of life. Öberg et al. (2012) has investigated self-reported hearing difficulties and the use of hearing aids and their relationships to among other things psychosocial and health variables in elderly individuals by using questionnaires such as the EuroQol-5D (EQ-5D), the International Outcome Inventory for Hearing Aids (IOI-HA) and home visits. The outcomes showed that elderly people with hearing loss and hearing difficulties who do not use hearing aids can have poorer physical health and quality of life than elderly people with hearing difficulties who use hearing aids (Öberg et al., 2012).

Cacciatore et al. (1999) has among other things investigated hearing loss, cognition and HRQL aspects in elderly people in a cross-sectional study of a random sample of elderly individuals by using questionnaires such as the Geriatric Depression Scale (GDS) and Activities of Daily Living (ADL). The outcomes reported that hearing aids could improve the HRQL in the elderly and help prevent disabilities of cognitive character. An untreated hearing impairment can result in less social activity, isolation, depression and a sense of exclusion which can affect the HRQL (Arlinger, 2003).

Several studies have also shown that a bone conduction hearing implant can improve the user's overall wellbeing and quality of life. Arunachalan et al. (2000) investigated quality of life aspects in patients with conductive hearing loss who use a bone conduction hearing implant by using the Glasgow Benefit Inventory (GBI) questionnaire. The authors concluded that a bone conduction hearing implant can significantly improve the user's quality of life. Similar outcomes were also reported from other studies that have also used, among other things, the GBI questionnaire (Arunachalan et al., 2001; Gillett et al., 2006; de Wolf et al., 2010; Dutt et al., 2002).

Furthermore, McDermott et al., (2002) concluded that patients' satisfaction with bone conduction hearing implants can be significantly better than their previously used conventional AC hearing aids by using the Nijmegen group questionnaire. On the contrary, Hol et al. (2004) could not report any significant differences in HRQL in patients with bone conduction hearing implants who had previously used conventional AC hearing aids measured by, among other things, the EuroQol-5D (EQ-5D) and the Hearing Handicap and Disability Inventory (HHDI) questionnaires.

The previous studies mentioned above lead to the hypothesis that patients with bone conduction hearing implants, having conductive or mixed hearing loss, will probably get similar benefits and HRQL as patients with conventional AC hearing aids.

Study motivation

The motivation of this study is based on the following:

1. Highlighting the HRQL in patients with conductive or mixed hearing loss, since this might affected by the degree of benefit the patients received from their bone conduction hearing implants or conventional AC hearing aids.
2. Several studies have investigated quality of life aspects from hearing with a bone conduction hearing implant (Arunachalan et al., 2001; Gillett et al., 2006; de Wolf et al., 2010) or a conventional AC hearing aid (Öberg et al., 2012; Cacciatore et al., 1999).

Fewer studies have compared differences between the hearing devices regarding quality of life aspects. Previous studies such as McDermott et al. (2002) and Hol et al. (2004) have focused on dependent groups when comparing satisfaction/HRQL between the devices, while this study focuses on two independent groups that do not seem to have been studied, as does the Health Utilities Index Mark 3 Inc. (HUI3) questionnaire.

3. Contributing more knowledge regarding benefit and HRQL aspects, which can be necessary for the improvement of subjective evaluations in the rehabilitation of these patient groups and providing more material for further research.

AIM OF THE STUDY

The aim of this study was to investigate the degree of benefit and HRQL in adult patients with conductive or mixed hearing loss who use bone conduction hearing implants or conventional AC hearing aids.

RESEARCH QUESTIONS

- Do patients with bone conduction hearing implants or conventional AC hearing aids get the same level of benefit in different everyday hearing situations?
- Are there any differences between aided and unaided conditions for patients using bone conduction hearing implants and conventional AC hearing aids in different everyday hearing situations?
- Are there any differences in HRQL between patients with bone conduction hearing implants or conventional AC hearing aids?

MATERIALS AND METHODS

Participants

Respondents were included in this study based on the following criteria:

1. Mixed or conductive hearing loss
2. Used a bone conduction hearing implant or a conventional AC hearing aid for at least 6 months
3. Over 18 years of age

For the purpose of this study, the type of hearing loss was defined as:

1. Conductive hearing loss: Bone conduction thresholds ≤20 dB HL and an air-bone gap ≥15 dB HL averaged over 0.5, 1 and 2 kHz (Stephens, 2001).
2. Mixed hearing loss: Bone conduction thresholds ≥20 dB HL and an air-bone gap ≥15 dB HL averaged over 0.5, 1 and 2 kHz (Stephens, 2001).

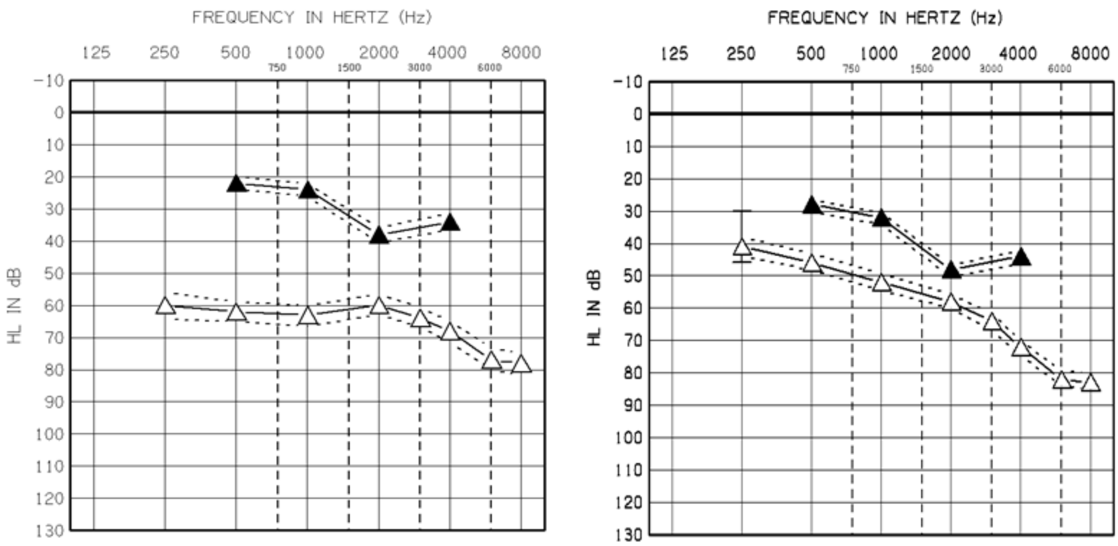
The respondents' background data are presented in table 1 and the audiological data in figure 1. Based on the type of hearing device, they were divided into two groups. Group 1: respondents with bone conduction hearing implants (BCHI) and group 2: respondents with conventional AC hearing aids (HA). In total, 173 questionnaires were sent out and 81 of the 173 respondents (47%) returned the questionnaires, including 41 patients with bone conduction hearing implants and 40 patients with conventional AC hearing aids.

Table 1. Descriptive Population Data

Group	**Type of HL**	**Mean age in yrs. (SD / range)**	**Male n (%)**	**Female n (%)**	**Unilateral device n (%)**	**Bilateral device n (%)**	**Duration BA/HA usage 6 mos - 19 yrs n (%)**	**Duration BA/HA usage 20 - >39 yrs n (%)**
BCHI	Mixed/ Conductive	65 (14 / 29-83)	15 (44)	19 (56)	26 (81)	6 (19)	17 (50)	17 (50)
HA	Mixed/ Conductive	74 (10 / 42-87)	17 (47)	19 (53)	9 (26)	25 (74)	31 (86)	5 (14)

BCHI = bone conduction hearing implant, HA = conventional AC hearing aid, HL= hearing loss

A. Bone conduction hearing implant **B. Conventional AC hearing aid**



▲ Bone conduction threshold △ Air conduction threshold

Figure 1. Mean baseline audiograms of combined ears of 34 patients with bone conduction hearing implants (A) and 36 patients with conventional AC hearing aids (B). Dotted lines represent ±1 standard error of the mean.

This study was approved by the Central Ethical Review Board in Gothenburg, Sweden.

Procedure

A grant application for use of the HUI3 questionnaire was submitted to the Health Utilities Index (HUInc.). The application was approved by the HUInc Grant Review Committee, which allowed the author of this study to use the Swedish version of HUI3 questionnaire. The Swedish version of the APHAB questionnaire was obtained through Hearing Aid Research Laboratory University of Memphis - USA.

The study subjects were obtained through the following sources in Sweden.

Source 1: Files from Sahlgrenska University Hospital Gothenburg, Sweden.

Source 2: Files from Hearing Center, Kungsgärdets Center Uppsala, Sweden

Source 3: Files from Hearing Center, Västmanlands Hospital Västerås, Sweden.

Source 4: Files from Hearing Center, Gävleborg Hospital Gävle, Sweden.

Source 5: An inquiry was sent to 10 audiology clinics in Sweden. The clinics were asked to mediate contact between the authors of this study and their patients who fulfilled the criteria to be included in the study.

The questionnaires were sent in paper format together with an information letter and informed consent form. After two-four weeks a reminder letter was sent out to respondents that had not answered or returned the questionnaires. All answered questionnaires were sent back to Gothenburg University individually inside the accompanying envelope in order to preserve secrecy, confidentiality, and to avoid middlemen (Holme & Solvang, 1997). A copy of the signed informed consent, together with a letter of appreciation was also sent out to all participating respondents (34 respondents from the bone conduction hearing implant group and 36 from the conventional AC hearing aid group).

Questionnaires

The following questionnaires were used in our evaluation.

1- *Abbreviated Profile of Hearing Aid Benefit (APHAB)*

The APHAB assesses auditory functioning in daily life and is a hearing disability–specific questionnaire. A reduction in hearing disability achieved by fitting a hearing aid is measured by 24 questions subdivided into 4 subscales: ease of communication (EC), reverberation (RV), background noise (BN), and aversiveness (AV) to sound. The questions in the EC subscale are related mainly to listening difficulties in quiet situations and the questions in BN to listening difficulties in the presence of background noise. The questions in the RV are related to listening difficulties in reverberant situations and the AV subscale relates to high sound levels in different everyday hearing situations that might be perceived as uncomfortable.

The APHAB measures frequency of listening difficulties with and without the use of a hearing device and the benefit in different everyday hearing situations. The APHAB can also compare other fittings and measure benefit over time. The APHAB has a scoring scale from 1 to 99, with a higher score indicating more frequent listening difficulties. The APHAB questionnaire is regarded as a valued instrument for clinical uses (Cox & Alexander, 1995) and has been used in several earlier studies (Gstoettner et al., 2011; Plyler et al., 2008; Johnson et al., 2010; Moore et al., 2005).

2- Health Utilities Index Mark 3 Inc. (HUI3).

The HUI-3 is a generic, multi-attribute, preference-based questionnaire used to measure overall HRQL. This is one of the few general questionnaires that is able to capture changes in quality of life as a result of a change in hearing status. The HUI-3 consists of the following eight subdomains: vision, hearing, speech, ambulation, dexterity, emotion, cognition, and pain. In the HUI-3, there are 2 types of scores: the single-attribute utility and the multi-attribute utility. The single-attribute utility score varies from 0 (highest degree of impairment or disability) to 1.00 (no impairment). The multi-attribute utility score varies from −0.36 (most disabled) to 1.00 (perfect health), whereas 0 corresponds to death.

The HUI3 questionnaire is often used in clinical studies and is seen as a reliable and valued instrument (Horsman et al., 2003). The HU3 questionnaire has shown to be a useful instrument for evaluating HRQL in populations with hearing loss (Janneke et al., 2007). General demographic questions were placed at the end of the questionnaire, allowing respondents to start as quickly as possible with the main questions and to avoid tiredness and reduced concentration (Trost, 2007).

Analysis

The results from the APHAB questionnaire were analysed according to Instructions for Manual Scoring of the APHAB (Instructions for Manual Scoring of the APHAB, n.d.). Analyses were done regarding aided and unaided conditions for every item and with both scores for each subscale. The subjective benefit was calculated by subtracting aided scores from unaided ones. Data from questions 1, 9, 11, 16, 19, 21 were coded as reversed. Each APHAB subscale must require at least four responses of six to be valid. Four patients, 1 with a bone conduction hearing implant and 3 with conventional AC hearing aids, were not included in APHAB analyses due to insufficient response in the questionnaire.

The HUI3 questionnaire was analysed according to Health Utilizes Index Procedures Manual for Self-Administered questionnaires (Health Utilities Index procedures manual, n.d.). The HUI3 attributes were calculated from level codes in different tables and all level codes were then used to obtain scores from tables that provide single or multi-attribute data.

To calculate the overall HRQL, the obtained scores for each of the eight attributes from the multi attribute data table were put in the formula, Dead - Perfect Health Scale ($u^* = 1.371 \times b_1 \times b_2 \times b_3 \times b_4 \times b_5 \times b_6 \times b_7 \times b_8) - 0.371$). Six patients, 2 with bone conduction hearing implants and 4 with conventional AC hearing aids, were not included in the HUI3 analyses due to insufficient response in the questionnaire. Respondents with insufficient responses from the APHAB or HUI3 questionnaires were not totally excluded from this study, since they had completed responses from one of the two questionnaires.

The statistical analyses were performed using the Statistical Package for the Social Sciences (SPSS), version 21. Descriptive statistics were used to calculate data from questionnaires. A t-test for independent groups was performed to investigate statistical differences between the groups in both questionnaires. A paired sample t-test was performed to calculate statistical differences between unaided and aided conditions in APHAB for each group. Alpha level <0.05 was used to establish statistical significance.

RESULTS

In total, 81 respondents returned the questionnaires, 41 using bone conduction hearing implants and 40 using conventional AC hearing aids. In total eleven respondents were excluded. Seven of those excluded were in the group with bone conduction hearing implants due to the use of both a bone conduction hearing implant and a conventional AC hearing aid in unison. Four respondents in the group with conventional AC hearing aid were excluded due to the following:

- One of the respondents returned the questionnaire with the information ‘Did not want to participate’.
- Two respondents had used hearing aids for less than 6 months.
- One respondent used both a bone conduction hearing implant and a conventional AC hearing aid.

APHAB responses

Sixty-six patients, 33 from each group, were included in the analyses here.
Scores from the APHAB are demonstrated as benefit scores and the percentage of listening difficulties from unaided and aided conditions.

Figure 2 presents values for benefit distribution scores in each APHAB subscale for the groups with bone conduction hearing implants and conventional AC hearing aids, where larger numbers indicate better performance.

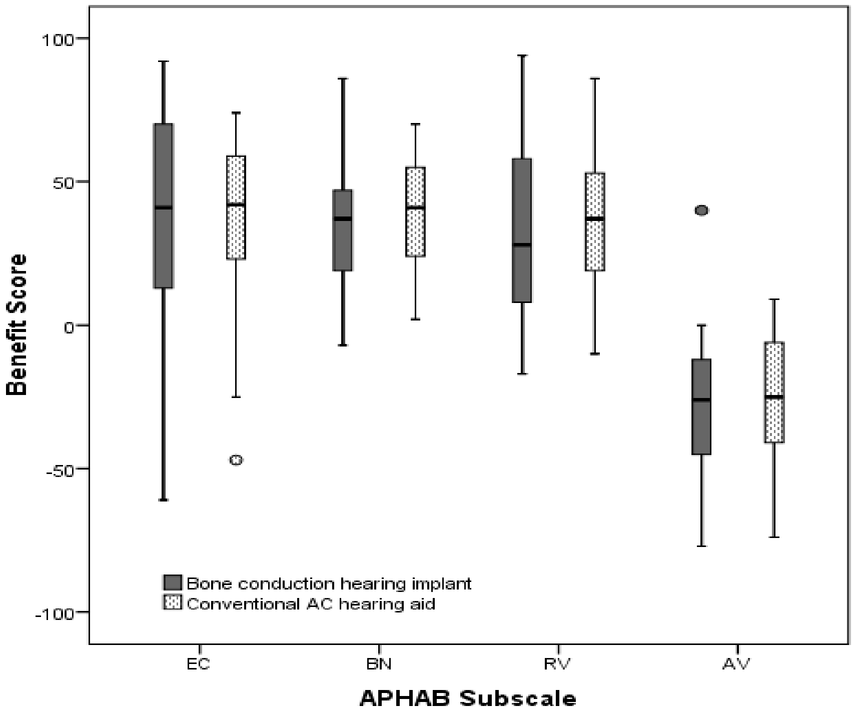


Figure 2. The statistical distribution for benefit scores in each APHAB subscale for the groups with bone conduction hearing implants and conventional AC hearing aids (horizontal stripes: median). EC= Ease of Communication, BN= Background Noise, RV= Reverberation, AV= Aversiveness.

These results indicate that patients in both groups receive a relatively similar degree of benefit in each subscale using two types of devices. Assessment of statistical analyses of the APHAB results is presented in table 2. No statistically significant differences between the groups were found in each subscale and thus it failed to reject the null hypothesis.

Table 2. Results from independent sample t tests comparing benefit scores for each APHAB subscale between the groups with bone conduction hearing implants and conventional AC hearing aids.

APHAB Subscale	Bone conduction hearing implant Mean (SD)	Conventional hearing aid Mean (SD)	t	df	p
EC	33.70 (44.04)	36.91 (28,14)	.353	54.4	.725
BN	35.94 (25.96)	39.39 (18,58)	.622	64	.536
RV	34.82 (32.10)	36.36 (23,10)	.224	58.1	.823
AV	-28.55 (24.01)	-26.09 (22,86)	.425	64	.672

Figure 3 displays the frequency of perceived listening difficulties with and without each device, where larger numbers indicate more listening difficulties and lower numbers indicate lesser listening difficulties.

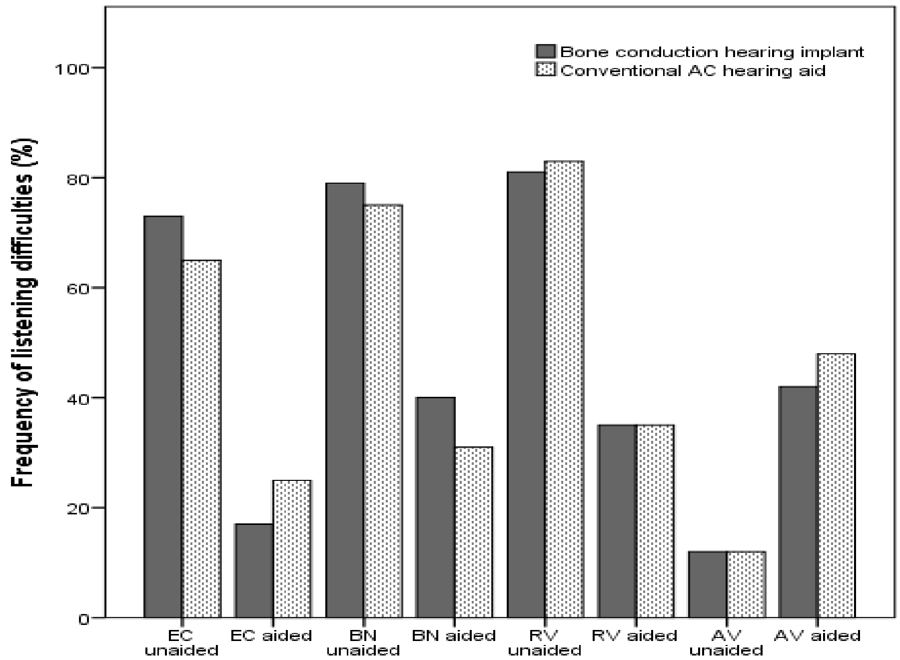


Figure 3. Median values for unaided and aided conditions in each APHAB subscale for the groups with bone conduction hearing implants and conventional AC hearing aids. EC= Ease of Communication, BN= Background Noise, RV= Reverberation, AV= Aversiveness.

Table 3 illustrates the results of statistical analyses of the APHAB subscales with and without devices. Statistically significant differences were observed with and without devices for both groups in each subscale.

Table 3. Results from paired samples t tests comparing the percentage of listening difficulties in each APHAB subscale between with and without BCHI and HA.

APHAB Subscale	BCHI Mean (SD)	t	df	p	HA Mean (SD)	t	df	p
EC unaided	64.39 (31.74)	4.396	32	.000	64.52 (23.56)	7.534	32	.000
EC aided	30.70 (26.98)				27.61 (13.14)			
BN unaided	75.79 (18.81)	7.954	32	.000	74.42 (15.90)	12.18	32	.000
BN aided	39.85 (19.72)				35.03 (16.10)			
RV unaided	73.21 (23.27)	6.230	32	.000	73.97 (19.06)	9.044	32	.000
RV aided	38.39 (24.25)				37.61 (18.94)			
AV unaided	17.48 (20.75)	-6.831	32	.000	21.36 (20.10)	-6.557	32	.000
AV aided	46.03 (25.05)				47.45 (23.03)			

HUI3 responses

Sixty-four responses, 32 from each group were analysed here.

Scores from HUI3 are presented as single attributes and overall HRQL. Figure 4 shows HUI3 scores as mean values for all eight attributes and overall HRQL for the group with bone conduction hearing implants and conventional AC hearing aids. The HUI3 scores are approximately similar between the groups with both devices.

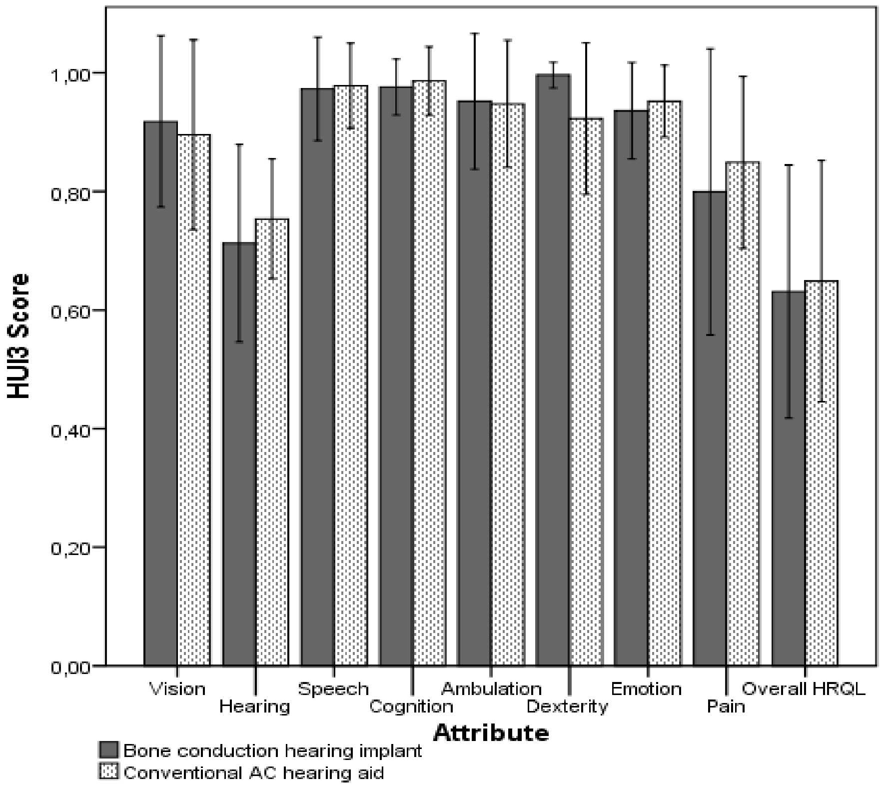


Figure 4. HUI3 scores as mean values for all eight attributes and overall HRQL for the groups with bone conduction hearing implants and conventional AC hearing aids. Error bars indicate ± 1 standard deviation.

Table 4 illustrates the results of statistical analyses between the two groups for each attribute and overall HRQL. No statistically significant differences between the groups were found in each HUI attribute and overall HRQL, and thus it failed to reject the null hypothesis.

Table 4. Results from independent- samples t tests comparing HUI3 scores for all eight attributes and overall HRQL between the groups with bone conduction hearing implants and conventional AC hearing aids.

HUI3 Attribute	Bone conduction hearing implant Mean (SD)	Conventional hearing aid Mean (SD)	t	df	p
Vision	.91 (.14)	.90 (.16)	-.396	65	.693
Hearing	.72 (.17)	.75 (.10)	.890	65	.377
Speech	.97 (.09)	.98 (.07)	.275	63	.785
Cognition	.98 (.05)	.99 (.06)	.671	65	.505
Ambulation	.94 (.12)	.95 (.11)	.162	64	.872
Dexterity	.98 (.10)	.93 (.12)	-1.959	61.87	.055
Emotion	.92 (.13)	.95 (.06)	1.235	64	.222
Pain	.79 (.24)	.86 (.15)	1.420	52.35	.162
Overall HRQL	.64 (.21)	.65 (.20)	.210	62	.834

DISCUSSION

Method discussion

Since we in this study wanted to obtain a wide range of respondents and get access to as many users as possible, factors that might have had an impact on this study's results, such as the degree of hearing loss and air-bone gaps, were not considered. Another factor that could have had an impact on the results was the age differences between the two groups; for example, a lower mean age in the bone conduction hearing implant group could explain the almost significant differences in the dexterity attribute in the HUI3 questionnaire. Since most of the respondents in the conventional AC hearing aid group used bilateral devices and the majority in the bone conduction hearing implant group used unilateral devices, both groups were not matched and this could affect the results. As the audiological data presented in figure 1 show, the groups were not well matched, which has probably influenced the results and made the outcomes more of a descriptive nature rather than indicating differences between the two groups.

An additional factor that might have affected responses from the APHAB or HUI3 questionnaires is reduced concentration and tiredness, which may have caused respondents to answer hesitantly and complete the questionnaires quickly without reflecting on the questions. Other causes might depend on self-reporting factors. For example, respondents may understand the questions differently and respond from their own interpretations and not from the described situation.

Since the questionnaires have been returned by post there is a risk that some might not have arrived at Gothenburg University and been lost. Also, some of the respondents might not have received the questionnaires due to incorrect addresses or other postal factors.

A disadvantage with APHAB is that if a subject has not experienced the situations that the questions pertain to, the subject may have to imagine a similar situation, which might affect the responses. The results from APHAB were not normally distributed, and display a wide distribution of benefit scores in each APHAB subscale for both groups, which can also be seen from the quite large standard deviations. One outlier was observed from the group with conventional AC hearing aids in the EC subscale and one from the group with bone conduction hearing implants in the AV subscale. Other factors that might have affected the results are when adjustments have been made in the hearing devices or other fitting factors, since APHAB also considers different fitting adjustments and not only subjective benefit (Gstoettner et al., 2011).

The HUI3 questionnaire is described as an insensitive instrument to measure differences between hearing devices and it requires great differences in sound quality between hearing devices to show any effects (Persson et al., 2008). Non-adequate amplification in the respondents' hearing devices may also have affected the HUI3 results. There was quite a wide range of responses in some of the HUI3 attributes and overall HRQL in both of the groups. This indicates that it's not easy to measure HRQL and that it can vary greatly at the individual level and probably over time.

Results discussion

APHAB

Earlier studies have concluded that bone conduction hearing implants can give patients with conductive or mixed hearing loss more benefit than conventional AC hearing aids, especially if the air - bone gaps are significantly large (Mylanus et al., 1998; Flynn et al., 2009; de Wolf et al., 2010). This study's results showed that the subjective benefit for both groups was approximately similar in each APHAB subscale and that there were no statistical differences between the groups, supporting the hypothesis and failed to reject the null hypothesis.

However, this study's results confirm an earlier study from Bance et al. (2002), which showed no significant differences in objective measurements between bone conduction hearing implants and conventional AC hearing aids.

The results from unaided and aided conditions illustrated significant differences between hearing with and without bone conduction hearing implants or conventional AC hearing aids in each APHAB subscale. This shows that both types of hearing devices increase the degree of benefit that the respondents obtain from the EC, BN, RV subscales but not AV. Both groups experienced more listening difficulties in the AV subscale with hearing devices than without. This indicates that amplified sounds from different everyday hearing situations with high sound levels can be perceived as uncomfortable and problems regarding amplification of loud sound remain. The results of this study emphasize that both bone conduction hearing implants and conventional AC hearing aids are good solutions in hearing rehabilitation for individuals with conductive or mixed hearing loss. It is also important to consider the type and degree of hearing impairment plus individual needs and conditions during the assessment of the hearing device type. Furthermore, the present results in agreement with earlier studies show that bone conduction hearing implants are a good alternative and a reliable solution for patients with conductive or mixed hearing loss who are unable to use or get benefit from conventional AC hearing aids (de Wolf et al., 2010; Lustig et al., 2001; Snik et al., 1995; Snik et al., 2004). The results on the individual level varied considerably within and between both groups, which makes the results more varied and ambiguous. Conclusions from the comparison between the hearing devices have also been reported as ambiguous in previous studies (Snik et al., 1995; Snik et al., 2004).

HUI3

The results from HUI3 showed that the overall HRQL was approximately similar between the group with bone conduction hearing implants and conventional AC hearing aids and that no statistical differences between the groups were observed, verifying the hypothesis and failing to reject the null hypothesis.

The overall HRQL outcomes from this study both partially confirm and not confirm some of the earlier studies. The results partially confirm a previous study from Hol et al. (2004), which emphasized that HRQL in general couldn't be affected significantly by bone conduction hearing implants in patients who had previously used conventional AC hearing aids. The results do not confirm McDermott et al. (2002), which showed that patients' satisfaction with bone conduction hearing implants can be significantly better than with the conventional AC hearing aids that had previously been used. However, it is difficult to compare with some of the previous studies because they have focused on subjects in dependent groups while this study focused on subjects in independent groups. The overall HRQL results although confirmed Bance et al. (2002), which reported no significant differences in quality of life between individuals who use bone conduction hearing implants and conventional AC hearing aids.

Several of the earlier studies have emphasized that a bone conduction hearing implant can improve the patient's satisfaction and HRQL (Arunachalan et al., 2000; Arunachalan et al., 2001; Gillett et al., 2006; de Wolf et al., 2010; Dutt et al., 2002). Similar results have also been shown in patients with conventional AC hearing aids (Öberg et al., 2012; Cacciatore et al., 1999). The HUI3 results from this study confirm the earlier studies regarding the ability of a bone conduction hearing implant or a conventional AC hearing aid to enhance the user's HRQL. The majority of the HUI3 single-attribute scores for both groups were quite high, close to one for all attributes except the hearing attribute, and decrease when it comes to the overall HRQL scores. The hearing attribute scores probably had an effect on the reduced overall HRQL scores. In general, this indicated that both groups experienced a quite good HRQL. On the other hand, it is difficult to determine whether this is due to the hearing devices or other psychosocial, psychological and medical factors. Since the HUI3 results have not been measured from pre- or post-usage of hearing devices, it's difficult to determine how much influence the hearing devices had on the HRQL.

CONCLUSION

Patients with bone conduction hearing implants or conventional AC hearing aids who have conductive or mixed hearing loss obtain a similar degree of benefit in different everyday hearing situations and no significant differences were found. In general, both groups obtained a significantly higher degree of benefit with bone conduction hearing implants or conventional AC hearing aids than without aid in different everyday hearing situations. The overall HRQL was similar between the groups with bone conduction hearing implants and conventional AC hearing aids and no significant differences were observed. Bone conduction hearing implants or conventional AC hearing aids are good solutions for the rehabilitation of patients with conductive or mixed hearing loss.

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APPENDIX

GÖTEBORGS UNIVERSITET

SAHLGRENSKA AKADEMIN

Institutionen för neurovetenskap och fysiologi

Enheten för audiologi

Information och inbjudan till deltagande i studien: Nytta samt hälsorelaterad livskvalitet hos vuxna patienter med konduktiv eller kombinerad hörselnedsättning som använder benförankrad implantat eller konventionell hörapparat

Du tillfrågas härmed om du vill delta i ett projekt som vi bedriver vid enheten för audiologi vid Sahlgrenska akademin. Denna information beskriver varför och hur studien genomförs samt tänkbara risker och nytta. Dessutom beskrivs hur insamlade uppgifter kommer att behandlas. Ta god tid på dig att läsa informationen och ställ gärna frågor om något är oklart.

Undertecknad är en student som studerar vid enheten för audiologi på Göteborgs Universitet och arbetar nu med sin magisteruppsats. Projektet har sin grund i två frågeformulär som skickas ut till totalt 120 patienter i Sverige, varav 60 till patienter med benförankrad hörapparat (Baha) och 60 med konventionell hörapparat.

Bakgrund och syfte

Tidigare studier har visat att nyttan samt taluppfattningsförmågan kan påverkas beroende på om patienten med konduktiv eller kombinerad hörselnedsättning använder benförankrad hörapparat (Baha) eller konventionell hörapparat. Vidare kan användandet av benförankrad eller konventionell hörapparat ge upphov till ökad hälsorelaterad livskvalité. Projektet syftar till att undersöka graden av nytta hos vuxna patienter med konduktiv eller kombinerad hörselnedsättning som använder benförankrad hörapparat (Baha) eller konventionell hörapparat samt deras hälsorelaterade livskvalitet.

Förfrågan om deltagande
Dina kontaktuppgifter har erhållits genom din lokala hörcentral/audiologiskmottagning. Du tillfrågas deltagande eftersom du antingen använder benförankrad hörapparat (Baha) eller konventionell hörapparat samt har konduktiv (ledningshinder) eller kombinerad typ av hörselnedsättning.

Hur genomförs studien?
Vid besvarande av APHAB (Abbreviated Profile of Hearing Aid Benefit) formuläret ska du tänka utan eller med hörapparat i nutid samt ringa in ett svar vid respektive svarsalternativ (se vidare instruktioner på frågeformuläret). I frågeformuläret används begreppet ”hörapparat”. För dig som använder benförankrad hörapparat föreställ dig ”benförankrad hörapparat (Baha)” istället.
Vid HUI3 (Health Utilities Index Mark 3) formuläret ska du ringa in ett svarsalternativ som bäst beskriver din vanliga funktionsförmåga (se vidare instruktioner på frågeformuläret).
Det kommer att ta ca 15-20 minuter att besvara frågeformulären.

Detta samtycke och ifyllda frågeformulär returneras i bifogat svarskuvert till:
Armen Eskandari
C/o Andrè Sadeghi
Institutionen för neurovetenskap och fysiologi
Enheten för audiologi
Box 452
40530 Göteborg

Vilka är riskerna?
Det finns inga tänkbara risker med att delta i projektet. Du ska endast på hemmaplan fylla i frågeformulären.

Finns det några fördelar med att delta?
Det finns inga direkta fördelar för dig med att delta i studien. Dock kommer din medverkan hjälpa oss att lyfta fram mera kunskaper kring nytta samt hälsorelaterad livskvalitet hos patienter med benförankrad eller konventionell hörapparat.

Hantering av data och sekretess
Alla dina personuppgifter och svar kommer att markeras med en kod och är sekretesskyddade. Ingen obehörig kommer att kunna ta del av dina personuppgifter i denna studie. Dina personuppgifter kommer att behandlas i enlighet med personuppgiftslagen (SFS 1998:204). Besvarade frågeformulär kommer att bearbetas med statistiskt analysprogram via dator och enskilda svar kommer inte att kunna identifieras. Inte heller i publikationen kommer enskilda patienter att kunna identifieras eftersom data kommer att presenteras som gruppdata. Data från studien kommer att sparas i 10 år.

Ansvarig för behandling av dina personuppgifter är Göteborgs Universitet. Du kan vända dig till Kristina Ullgren om du önskar utdrag över de personuppgifter som finns registrerade på dig och ev. hjälp till rättelse (Adress: Universitetsledningens kansli, Box 100, 405 30 Göteborg, telefon 031-786 10 92).

Hur får jag information om studiens resultat?
Publiceringen av arbetet beräknas äga rum under slutet av 2013. Du kan informeras om resultaten om du så önskar. Kontakta i så fall André Sadeghi, Tlf: 031-786 57 86, Email: andre.sadeghi@neuro.gu.se

Vem har godkänt studien?
Denna studie är granskad och godkänd av Etikprövningsnämnden i Göteborg.

Frivillighet
Studien är frivillig, dvs. du kan välja att inte skriva på detta samtycke. Beslutar du dig för att delta kommer du att få skriva under ett samtyckesformulär (du kommer dessutom att få en kopia av detta formulär). Du kan när som helst under studiens gång avbryta ditt deltagande. Framkommer det under studiens gång ny information som kan tänkas påverka ditt beslut att delta i studien kommer du att informeras om detta.

För att skapa en god tillförlitlighet på studien är vi i behov av så många svar som möjligt.

Kontaktinformation

Har du frågor om studien, kontakta: Armen Eskandari, Projektutförare
guseskanar@student.gu.se eller 073- 899 56 58.
Har du frågor om personuppgiftslagen (PUL), kontakta: Kristina Ullgren, Universitetsledningens kansli, Box 100, 405 30 Göteborg eller 031-786 10 92.
Har du frågor om behandling av personuppgifter, kontakta:
Personuppgiftsansvarig för studien, André Sadeghi, 031-786 57 86 eller andre.sadeghi@neuro.gu.se

Nytta samt hälsorelaterad livskvalitet hos vuxna patienter med konduktiv eller kombinerad hörselnedsättning som använder benförankrad implantat eller konventionell hörapparat

Samtyckesformulär

Jag har läst igenom denna information. Jag har fått möjlighet att ställa frågor om studien genom att kontakta ansvariga för studien. Jag samtycker till:

* Att delta i studien

* Att mina personuppgifter får behandlas så som det är beskrivet i denna information

Jag är medveten om att mitt deltagande är helt frivilligt. Väljer jag att inte delta i studien kommer detta inte att påverka mitt framtida omhändertagande.

Jag är medveten om att jag skall få en kopia av denna information och det undertecknade samtycket.

______________________________ ___________________________________

Datum Underskrift

____

Namnförtydligande

APHAB– FORMULÄR

Välj det svar som ligger närmast Din egen upplevelse.
Om Du inte har erfarenhet av exakt den beskrivna situationen,
föreställ Dig en liknande situation.

A	Alltid (99%)
B	Nästan Alltid (87%)
C	Ofta (75%)
D	I hälften av fallen (50%)
E	Ibland (25%)
F	Sällan (12%)
G	Aldrig (1%)

		Utan min hörapparat	**Med** min hörapparat
1.	När jag befinner mig i en mataffär full med folk kan jag uppfatta vad kassörskan säger.	A B C D E F G	A B C D E F G
2.	Jag missar mycket information när jag lyssnar på föredrag.	A B C D E F G	A B C D E F G
3.	Oväntade ljud, t ex från brandlarm, är obehagliga.	A B C D E F G	A B C D E F G
4.	Jag har svårt att uppfatta orden i ett samtal med en familjemedlem hemma.	A B C D E F G	A B C D E F G
5.	Jag har svårt att följa en dialog på svenska på bio eller på teater.	A B C D E F G	A B C D E F G
6.	När jag lyssnar på nyheterna på bilradion och familjen pratar samtidigt, har jag problem att höra nyheterna.	A B C D E F G	A B C D E F G
7.	När jag sitter vid ett middagsbord med flera personer och försöker samtala med en av dem, är det svårt att uppfatta vad som sägs.	A B C D E F G	A B C D E F G
8.	Trafikljud är för starka.	A B C D E F G	A B C D E F G
9.	När jag pratar med en person som befinner sig i andra änden av ett stort, tomt rum, kan jag uppfatta orden.	A B C D E F G	A B C D E F G
10.	När jag är i ett litet kontorsrum och intervjuar någon eller själv blir intervjuad, är det svårt att följa med i samtalet.	A B C D E F G	A B C D E F G
11.	När jag är på bio eller på teater, kan jag följa dialogen även om folk omkring mig viskar och prasslar med karamellpapper.	A B C D E F G	A B C D E F G
12.	När jag samtalar lågmält med en vän, har jag svårt att uppfatta vad som sägs.	A B C D E F G	A B C D E F G

HARL
Hearing Aid Research Lab.

A	Alltid (99%)
B	Nästan Alltid (87%)
C	Ofta (75%)
D	I hälften av fallen (50%)
E	Ibland (25%)
F	Sällan (12%)
G	Aldrig (1%)

		Utan min hörapparat	**Med** min hörapparat
13.	Ljud från spolande vatten, t ex från toaletten eller duschen, är obehagligt starka.	A B C D E F G	A B C D E F G
14.	När en föreläsare talar till en liten grupp människor och de övriga lyssnar lugnt, måste jag anstränga mig för att uppfatta vad som sägs.	A B C D E F G	A B C D E F G
15.	När jag samtalar i lugn och ro med min läkare i ett undersökningsrum, är det svårt för mig att följa samtalet.	A B C D E F G	A B C D E F G
16.	Jag kan uppfatta samtal även då många människor pratar samtidigt omkring mig.	A B C D E F G	A B C D E F G
17.	Ljud från byggplatser är obehagligt starka.	A B C D E F G	A B C D E F G
18.	Det är svårt att uppfatta vad som sägs på föredrag eller gudstjänster.	A B C D E F G	A B C D E F G
19.	När jag befinner mig i en folksamling kan jag samtala med andra.	A B C D E F G	A B C D E F G
20.	Ljud från sirenen på en brandbil i närheten är så starkt att jag får hålla för öronen.	A B C D E F G	A B C D E F G
21.	Jag kan uppfatta orden i predikan vid gudstjänsten.	A B C D E F G	A B C D E F G
22.	Ljudet av tjutande däck är obehagligt starkt.	A B C D E F G	A B C D E F G
23.	Jag måste be folk upprepa vad de säger när vi samtalar på tu man hand i ett tyst rum.	A B C D E F G	A B C D E F G
24.	Jag har svårt att uppfatta vad som sägs, om en fläkt eller ventilationsanläggning är på.	A B C D E F G	A B C D E F G

HUI3 Multi-Attribute Health Status Classification System

Attribute	Level	Description*
Vision	1	Able to see well enough to read ordinary newsprint and recognize a friend on the other side of the street, without glasses or contact lenses.
	2	Able to see well enough to read ordinary newsprint and recognize a friend on the other side of the street, but with glasses.
	3	Able to read ordinary newsprint with or without glasses but unable to recognize a friend on the other side of the street, even with glasses.
	4	Able to recognize a friend on the other side of the street with or without glasses but unable to read ordinary newsprint, even with glasses.
	5	Unable to read ordinary newsprint and unable to recognize a friend on the other side of the street, even with glasses.
	6	Unable to see at all.
Hearing	1	Able to hear what is said in a group conversation with at least three other people, without a hearing aid.
	2	Able to hear what is said in a conversation with one other person in a quiet room without a hearing aid, but requires a hearing aid to hear what is said in a group conversation with at least three other people.
	3	Able to hear what is said in a conversation with one other person in a quiet room with a hearing aid, and able to hear what is said in a group conversation with at least three other people, with a hearing aid.
	4	Able to hear what is said in a conversation with one other person in a quiet room, without a hearing aid, but unable to hear what is said in a group conversation with at least three other people even with a hearing aid.
	5	Able to hear what is said in a conversation with one other person in a quiet room with a hearing aid, but unable to hear what is said in a group conversation with at least three other people even with a hearing aid.
	6	Unable to hear at all.

Speech	1	Able to be understood completely when speaking with strangers or people who know me well.
	2	Able to be understood partially when speaking with strangers but able to be understood completely when speaking with people who know me well.
	3	Able to be understood partially when speaking with strangers or people who know me well.
	4	Unable to be understood when speaking with strangers but able to be understood partially by people who know me well.
	5	Unable to be understood when speaking to other people (or unable to speak at all).
Ambulation	1	Able to walk around the neighbourhood without difficulty, and without walking equipment.
	2	Able to walk around the neighbourhood with difficulty, but does not require walking equipment or the help of another person.
	3	Able to walk around the neighbourhood with walking equipment, but without the help of another person.
	4	Able to walk only short distances with walking equipment, and requires a wheelchair to get around the neighbourhood.
	5	Unable to walk alone, even with walking equipment. Able to walk short distances with the help of another person, and requires a wheelchair to get around the neighbourhood.
	6	Cannot walk at all.
Dexterity	1	Full use of two hands and ten fingers.
	2	Limitations in the use of hands or fingers, but does not require special tools or help of another person.
	3	Limitations in the use of hands or fingers, is independent with use of special tools (does not require the help of another person).
	4	Limitations in the use of hands or fingers, requires the help of another person for some tasks (not independent even with the use of special tools).
	5	Limitations in the use of hands or fingers, requires the help of another person for most tasks (not independent even with the use of special tools).
	6	Limitations in the use of hands or finders, requires the help of another person for all tasks (not independent even with the use of special tools).
Emotion	1	Happy and interested in life.
	2	Somewhat happy.
	3	Somewhat unhappy.
	4	Very unhappy.
	5	So unhappy that life is not worthwhile.

Cognition	1	Able to remember most things, think clearly and solve day to day problems.
	2	Able to remember most things, but have a little difficulty when trying to think and solve day to day problems.
	3	Somewhat forgetful, but able to think clearly and solve day to day problems.
	4	Somewhat forgetful, and have a little difficulty when trying to think or solve day to day problems.
	5	Very forgetful, and have great difficulty when trying to think or solve day to day problems.
	6	Unable to remember anything at all, and unable to think or solve day to day problems.
Pain	1	Free of pain and discomfort.
	2	Mild to moderate pain that prevents no activities.
	3	Moderate pain that prevents a few activities.
	4	Moderate to severe pain that prevents some activities.
	5	Severe pain that prevents most activities.

Bakgrundsfrågor

Är du man eller kvinna?
Man ☐
Kvinna ☐

Vilket år är du född? 19..........

Använder du
Vanlig hörapparat? ☐
Benförankrad implantat (Baha)? ☐

Använder du vanligtvis
En hörapparat eller benförankrad implantat (Baha)? ☐
Två hörapparater eller benförankrade implantat (Baha)? ☐
Hörapparat på ena örat och benförankrad implantat på det andra (Baha)? ☐

Hur länge har du använt hörapparat/benförankrad implantat (Baha)?
Mindre än 6 mån ☐
6 mån - 4 år ☐
5-9 år ☐
10-19 år ☐
20-29 år ☐
30-39 år ☐
39 eller mer ☐

Tack för ditt deltagande