Quality of life in persons with hearing loss: The importance of psychological variables and hearing loss severity

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-University of Bergen, Faculty of Medicine, Department of Clinical Medicine.

-Haukeland University Hospital, Department of Head and neck Surgery.

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Abbreviations

APA: American psychiatric association

APHAB: Abbreviated Profile of Hearing Aid Benefit

CATS: Cognitive activation theory of stress

CBT: Cognitive behavioral treatment

DALY: Disability - adjusted years

dB: Decibel

DSM-5: Diagnostic and statistical manual of mental disorders, fifth edition

ENT: Ear, nose and throat

EORTC: European organization for research and treatment of cancer

EORTC QLQ C-30: EORTC Quality of life questionnaire Core 30

EPI: Eysenck personality inventory

GHQ: General health questionnaire

HA: Hearing aid

HL: Hearing loss

HRQoL: Health-related quality of life

ICD-10: International Classification of Diseases 10^{th} edition

ICF: International Classification of Functioning, Disability and Health

IDICH: International Classification of Impairment, Disability and Handicap

ISAD: Individual sound amplification device

kHz: Kilo hertz

PCA: Principal component analysis

PROM: Patient reported outcome measure

PTA: Pure tone average

SAC: Self-assessment of communication ability

SOC: Sense of coherence

SF-36: Medical outcome studies, short form 36

SNR: signal to ratio

SNHL: Sensorineural hearing loss

TOMCATS: Theoretically originated measure of the cognitive activation theory of stress

QoL: Quality of life

VS: Vestibular schwannoma

WHO: World health organization

Summary

Hearing loss (HL) is a prevalent condition, representing health and social challenges for a substantial number or of people globally. Up to 15% of the world's adult population is estimated to suffer from HL. As most people with HL suffers from age related HL, i.e. presbyacusis, the growing proportion of older people in the population, will lead to a substantial increase in the number of persons with hearing loss in the near future. In addition to the effect this will have on each individual's life, it also represents huge social consequences.

The overall objective of this thesis was to investigate the relationship between HL, general/generic and communication-specific (Health Related) Quality of Life ((HR)QoL). As supporting aims, distress, personality and choice of coping in HL patients was also investigated.

In paper I, we aimed to further develop the Abbreviated Profile of Hearing Aid Benefit (APHAB) questionnaire for the self-assessment of communication ability. We investigated the psychometric properties of the Norwegian version of the questionnaire applied to controls and a group of persons with various degrees of HL seeking HA. The findings indicate that the questionnaire is a valid measure of communication ability in both quiet and adverse listening conditions for participants with and without HL. This questionnaire was applied in paper III and paper IV.

Paper II presents a systematic literature review of studies investigating generic QoL in patients with HL. As an additional aim, we also included studies that addressed distress, mood, anxiety and HL. The findings in this review suggests that HL is associated with reduced generic QoL. However, the findings were equivocal, with some studies suggesting a strong relationship between HL and QoL, while others found no such relations. We also found that hearing aids (HA) seems to improve general QoL within the first year and that HL is a risk factor for distress. Conducting a systematic literature

review developed our understanding of the field, and the findings enabled us to develop methods and hypothesis applied in paper III and IV.

In the third paper we studied the relationship between general QoL, the APHAB response pattern and HL. The study found that the QoL level in persons with HL seems to be close to what seen in the general population, but higher than what is seen in many chronic serious diseases. Patients with unilateral HL reported slightly worse social function and more fatigue than patients with bilateral HL. Self- assessed communication ability correlated with general QoL scores. We also found that best pure tone average, but also cognitive and physical QoL function were associated to APHAB scores. This study concludes that general QoL scores among HL individuals seems to be relatively close to what have been reported in the general population.

In paper IV we investigated the importance of personality and choice of coping on QoL, distress and reported communication ability in persons with HL. Significant correlations were found between APHAB, HRQoL, distress scores on the one side and personality and coping style on the other side. The results suggests that employed coping style, distress/HRQoL and personality were closely associated to each other in this patient group. Patient-reported communication ability was associated to PTA (best ear) and personality.

In overall conclusion, general QoL among patients with HL seeking HA seems to be close to population levels. Distress scores may be slightly elevated compared to population norms. QoL and distress scores and interestingly APHAB scores seems also to depend on personality scores.

1. Introduction

The auditory system is useful to all species' ability to detect sound sources, and to interpret any information within the sound. Having these properties enables one e.g. to locate food, to avoid predators, to navigate and to communicate. Whenever surrounded by sounds, it is of importance to have the ability to identify and locate sound sources [1 p.1], and in modern peoples life, being able to communicate verbally is one of the main tasks for the auditory system [2].

Globally, hearing loss (HL) is a common sensory disease and represent a major health challenge for a large and constantly growing proportion of the population worldwide. World Health Organisation (WHO) estimated in 2018 that globally 466 million people are living with disabling HL. HL is considered to be the most prevalent sensory disease, affecting more than 5% of the world population and represent large economic costs [3]. Even if HL is most prevalent in the older part of the population, HL may occur in all ages of life [4]. Because of the HL, people are referred to ear, nose and throat (ENT) specialists and audiologists for hearing aids (HA) or other devices that amplify sounds. Despite of the disadvantages from the HL, and the benefits from using such devices, many are reluctant to use them [5].

Living with chronic disease or illness seems to affect Quality of Life (QoL) negatively [6, 7]. Gradually, there has been a growing attention to the effect of HL on people's QoL [8]. Even if HL to some degree affects people's life there seem to be no universal consensus whether HL cause reduced QoL. Different studies suggest different strength between HL and QoL. While some find strong associations [9], others find less strong [10] or no association [11] between HL and QoL. A proportion of older people that seems to grow quickly [12], imply a rapidly growing number of especially older adults with a HL. In order to provide patients with HL with adequate help, there is a need for more and specific knowledge about if, and to what extent the HL actually affect QoL, or if there is other influencing variables leading to reduced QoL.

The purpose of this dissertation was to investigate the relationship between physical HL, reported HL, QoL, reported neuroticism and choice of coping both in first time and experienced HA users both with bilateral and unilateral HL. The investigation aimed to answer 3 main questions: 1) what is the current knowledge on this field? 2) What is the relationship between physical and reported HL and QoL in adults seeking HA? 3) What is the importance of Personality and Choice of Coping on reported HL QoL and Distress in patients dependent on physical HL? To answer these questions, several methods were applied. First, we developed a questionnaire for self-assessment of communication ability; i.e. reported HL. Second, a systematic review was performed to synthesize empirical investigations on the relationship between HL and QoL, and between distress, mood and anxiety in persons with HL. Further, we conducted a cross- sectional study on the relationship between physical and reported HL and QoL. Finally, we performed a cross-sectional study on the importance of the physical HL, the personality trait neuroticism and reported choice of Coping on QoL, Distress and reported HL in adults seeking HA.

2. Hearing loss

2.1 Definitions

Peripheral hearing loss (HL) may be either sensorineural or conductive [13 p.261, 14], or a mix of these two. HL occurs either in one ear (unilateral HL) or in both ears (bilateral HL), with bilateral HL being the most prevalent condition. While sensorineural HL refers to cochlear or retro cochlear pathology, conductive HL refers to a mechanical impairment in the transmission of the sound travelling from the external ear to the internal ear [14].

Even if a unilateral HL may be understood as asymmetric, a HL is most commonly being defined as an asymmetric HL when the difference in the HL is exceeding 15 dB at frequencies 0.5, 1 and 2 kHz and 20 dB at frequencies 3, 4 and 6 kHz in a pure- tone audiogram in persons with bilateral HL [15].

According to the World Health Organization (WHO), HL is characterized by to which grade persons are hearing impaired (HL), made by pure tone audiometry in a quiet room. Hearing Loss may be graded from 0 to 4 [16]:

Grade 0: (no HL) 25 dB HL or less in the better ear. No, or very slight hearing problems. The person is able to hear whispering.

Grade 1: (slight HL) 26- 40 dB HL in the better ear. The person has some difficulty in hearing, but is able to hear and repeat what has been said in normal voice at a distance of 1 meter.

Grade 2: (moderate HL) 41- 60 dB HL in the better ear. The person is able to hear and repeat what has been said in raised voice at a distance of 1 meter.

Grade 3: (severe HL) 61- 80 dB HL in the better ear. The person is able to hear some words when shouted into the better ear.

2.2 Epidemiology of Hearing Loss

Even if the prevalence of HL in the adult population may be regarded as comparable in western countries there seem to be some vary between estimates. The prevalence of permanent HL in Norway estimated to be approximately 15% of the adult population [17]. In the U.S., the prevalence is estimated to be 7.2 % of the adult population, with mild unilateral HL as the most prevalent (5.7%). Moderate-or-worse unilateral HL is suggested to count for 1.5% of the U.S. population [18]. Sensory diseases have been suggested to be the world's second most common group of chronic disability when measured by years lived with disability [19].

HL may occur in all ages and stages in life [4] due to different reasons such as ear diseases [20], occupational noise exposure [21] and (specific) genetic diseases [22]. Also, comorbidity, e.g. hypertension and Diabetes mellitus and demographic variables, e.g. ethnicity, gender and education level may influence the prevalence of HL [23]. Thus, the prevalence of HL may be affected by a set of direct and underlying factors. Disabling HL is by the World Health Organization (WHO) estimated to affect around 360 million people, i.e. 5.3% of the world's population, while around 15% of the world's adult population is estimated to have some degree of HL [24].

Hearing loss (HL) is most prevalent in the elder population [25], and age related hearing loss, presbyacusis, may to some degree affect 70% of those aged above 70 years [26]. Presbyacusis typically causes a symmetric bilateral high frequency hearing loss sloping towards the higher frequencies. Presbyacusis causes reduced speech understanding in noisy environments, declined processing of acoustic information and impaired localization of sound sources [27]. As the parts of the human speech signal resides in higher frequencies, even a limited hearing loss at high frequencies, which is often the case with presbyacusis, may cause impaired speech recognition intelligibility [28]. Presbyacusis represents the sum of the environmental, sensory, genetic, metabolic and neural causes that to various extents are suggested to contribute to age-related

physiological hearing loss [14, 27, 29]. In the population of 80 years or older, the prevalence of HL seems to be as high as 55% in men and 45% in women [30]. With a Western world population that is getting older [31], HL will affect a growing number of persons in the future. HL is often not medically curable, but may be remedied with Hearing Aids (HA) or other individual sound amplification device (ISAD) [32]. Statistics Norway (SSB) have suggested that the proportion of the Norwegian population being 70 years or older, will rise from the current 12% to 21 % in year 2060. The increase is estimated to be greatest in the part of the population being 80 years or more, with a tripling of persons in this age category [33]. Thus, an increased need for hearing rehabilitation should be expected [25].

2.3 Hearing loss and cognitive function

Listening to speech with a HL seems to require the use of more cognitive resources which may increase cognitive stress and lead to changes in brain structure and function [34]. Untreated HL seems to increase the risk of developing dementia [35-37] and poorer cognitive function [37, 38]. This may to some extent be explained by both HL and dementia being more prevalent in the older population, since the proportion of HL is estimated to be as high as 60% of in people suffering from dementia [39]. Reduced social engagement caused by the HL may also lead to impaired cognitive function and dementia [40]. Still, even if there may be an association between HL and dementia, and HL seem to be associated with higher prevalence of dementia in older adults [41], it has not fully been determined whether HL is a marker for early-stage dementia or a modifiable risk factor for developing dementia [36].

2.4 Living with Hearing Loss

Cochlear HL includes loss of the function of the inner ear hair cells. This demands a signal-to-noise ratio greater than normal to communicate verbally effectively with others [42]. For adolescents, HL seems to increase risk for reduced social interaction,

reduced speech development and it has educational implications [4]. While sensorineural HL in most cases is not curable, HA and other individual sound amplification devices (ISADs) will often improve hearing function. Choice of treatment for patients with HL may rely on the type and severity of the HL [43].

HL is a condition that may be referred to as "the invisible disability of health care" [44]. Possibly, this is related to health professionals tendency to ignore HL in older patients, or due to the focus and higher priority of other health conditions and disabilities in the older population, rather than the HL [45]. In addition, many elderlies may regard their HL as a natural part of getting older, minimize it and consequently do not seek help for their HL.

One of the most important properties to all humans is the ability to be able to hear, listen and understand verbal communication. To hear clearly and living with a HL does not only have consequences for speech recognition, but maybe also affect the level of social function. Not hearing non-verbal sounds, such as not being able to hear the presence of other people in your surroundings have been suggested to cause tension, feelings of insecurity and loss of control of the situation. In studies where normal hearing persons were made "HL" by occluding the ear canal, the findings suggested similar psychological reactions as to persons with a genuine HL [46]. Thus, the HL together with other non-auditory characteristics such as general decline in physical abilities and function level due to normal ageing processes may lead to activity limitation and social isolation in daily life [47].

3. Hearing aids

The capacity to detect sounds, participate in social settings, and communicate with others seems to depend on the ability and degree of hearing. Thus, HL may cause multiple negative effects in the ability to participate and to communicate with the surroundings. Behind the use of HA, often lies a desire to correct or remedy the loss of hearing [48]. HA may to some extent help persons with HL to overcome the negative consequences of the HL, and the most important function for a HA is to amplify weak sounds from the surroundings, while at the same time avoid to amplify intense sounds [42].

The fitting of a HA is a complex procedure, from defining the nature of the HL, to obtaining a HA that fit and serve the individual well. There is no universal HA that fits everyone, but rather a selection of different HAs with different characteristics [49]. Stigmatization connected to having a HL, and the actual use of HA seems to have contributed to a demand for smaller and less visible sound amplifying devices, and the development in this field has been significant [50]. Factors such as denial of the HL and stigma related to the HL may result in not using the HA, despite an objective need for it. Stigma related to both HL and HAs also seems to be influenced by how their spouse or close relatives perceive these matters [48].

Studies have suggested that patients with a sensorineural HL (SNHL) experience improved QoL after receiving a HA by reducing psychological, social and emotional effects of the SNHL [51]. Still, some people seems to be reluctant to seek help for their HL, some because they sees the HL as a natural part of getting older, while others find using HAs stigmatizing [52]. Many who have received HAs may be use them to little or not at all may be due to various reasons such as lack of actively involving the HL patient in the rehabilitation process [43] or sufficient support to manage the practical use of HAs [53]. Even if people who are in need of a HA, neither do seek help, nor do use the HA, there seems to be little knowledge about why they fall out of the process from diagnosis to actually using the HAs [54]. Still, factors that makes people more likely to

seek help for their HL seem to be related to how they assess their hearing problems and to what extent significant others are supportive during the audiological rehabilitation [26]. Hence, the benefits from getting sound amplification must exceed the downsides of the HL. Nevertheless, it is pertinent to question if, and to what degree psychological and emotional conditions may affect whether people seek help for their HL, and if so, what is the benefit of help seeking [54].

Avoidance strategies might result in refusal to wear HAs or other ISADs and social isolation is suggested to cause to mental distress [55]. Adults with HL in general seem to suffer from activity limitation and participation restriction, but experienced HA users seem to have higher scores on these matters compared to non-experienced HA users. Level of function may vary from person to person, but younger persons in general seem to have less psycho-social problems as a consequence of the HL [56].

4. Quality of life

4.1 Historical development and definition

World Health Organization (WHO) suggests that: "Health as a concept is notoriously difficult to define, but no one disputes that health is both a matter of how long one lives and how well one lives (i.e. one's level of functioning)" [57]. Several definitions for QoL has been proposed during decades of focus on this concept, but an exact definition do not exist. Still, there seems to be consensus upon that QoL is a multidimensional construct [58].

The patient's well-being and psychological state have maybe not always been of great interest for medical doctors throughout history. The ethos of health care seems in the past to have changed from a paternalistic reduction view of illness and disease towards improving well-being of autonomous individuals [59]. Today, assessment of patients' QoL have become standard practice in clinical studies [58].Voltaire stated that "Doctors are men who prescribe medicine of which they know little, to cure diseases of which they know less, in human beings, of which they know nothing". Even since ancient Greece, Hippocrates (~460-377 BC) recognised that patient`s personal life satisfaction and psychological well-being are important for coping with illness [58].

Understanding of the term QoL has traditions back to Aristotle (384-322 BC), who used terms such as to conceive "good life", "doing well", and "being happy". What makes a person happy vary from person to person and may be a matter of dispute. Aristotle stated that happiness was a state of feeling or a kind of activity [60 p. 5-6]. In general, QoL is suggested to be the subjective perceptions of the positive and negative effects an illness has on life [61]. This suggests that even if a person, when observed from the outside, is expected to have poor QoL, he or she may well define their QoL as excellent. The opposite may also be possible.

The term QoL is a well-known concept, and most people may have a clear notion what the term means to themselves [62]. Still, factors such as satisfaction with life, well-being, happiness, meaning and functional status seems to be relevant to most people's perception of QoL [63]. The World Health Organisation (WHO) define QoL as "An individual`s perception of their position on life in the context of their culture and value systems in which they live and in relation to their goals, expectations, standards and concerns." This seems to be a fairly wide and general definition that is closely related to WHO`s definition of Health (1948), which describes health as "physical, mental and social well-being, and not merely the absence of disease or infirmity" [60].

4.2 Health related Quality of Life (HRQoL)

Closely related to the concept of QoL, we find Health-related QoL (HRQoL). This concept may be 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" [64]. At the same time as HRQoL to some degree overlap with the QoL concept it also emphasizes the influence of disease and the effect of treatment on general well-being [65]. HRQoL refers to how individuals assess how health status affects their daily function and well-being [51], and a meaningful change in HRQoL may be viewed upon by the patient, as one that results in a meaningful reduction in symptoms or improvement in function [66]. Disease-specific HRQoL questionnaires may be the most suitable measure of how the patients appraises responsiveness or changes to interventions. This should may be of interest for health professionals when there is need for information about how HL patients assess how HAs help to manage the HL [51, 67]. Since many disease specific instrument are designed for a narrow range of applicability, new instruments may be required to measure the effect a specific treatment on QoL [68].

4.3 Measurement of self-assessed Quality of Life

HRQoL refers to how the individual assess how and to what degree illness and disease affect physical, emotional and social components [69]. In the process of finding a suitable instrument, researchers should perhaps bear in mind that no single instrument represents a “gold standard”, neither as a standardized system of describing health, nor as a method of valuing them [69]. Because of the different properties in different HRQoL instruments, employed instruments should may be selected based upon its sensitivity to the health conditions that are being investigated [70].

There seems to be some advantages by using generic questionnaires. They may be suitable both to measure multiple aspects of QoL and they are applicable to different diseases. In addition, they may be suitable to compare patient groups, or even to compare patient groups with samples from the normal population [60, 71]. In addition to the purely generic QoL-questionnaires, several disease specific instruments contain questions about generic QoL. In the studies presented in this thesis (study 3&4), we have employed such an instrument, EORTC QLQ-C30 questionnaire, to measure QoL.

4.3.1 SF-36

The SF-36 seems to be one of the most commonly employed generic Health related QoL (HRQoL) questionnaires [72]. It has been translated into several languages [73]. The SF-36 serves as a multipurpose instrument containing 36 questions [73] assessing eight health concepts [74]. These eight concepts are:

- limitations in physical activities because of health problems
- limitations in social activities because of physical or emotional problems
- limitations in usual role activities because of physical health problems
- bodily pain
- general mental health (psychological distress and well-being)
- limitations in usual role activities because of emotional problems
- vitality (energy and fatigue)
- general health perceptions

This questionnaire, has been constantly developed from its original form in 1988, into a shorter form, the SF-12 (12 questions) [74]. As a generic instrument, the SF-36 is suitable to compare specific populations with normal population and the relative burden of diseases. It is also suitable to differentiate between health benefits of different treatments [73].

4.3.2 HUI3

The Health Utility Index Mark 3 (HUI3) is based on previous HUI versions; HUI and HUI Mark 2(HUI2) [64]. HUI3 is a generic instrument described as a within-the- skin instrument, which means that physical and emotional dimensions are included, but dimensions like social interaction are excluded. Several versions of this instrument are available. The difference between the versions lies in the time frame reflected in the questions [75]. This is an instrument that serves two main purposes; it is as a health-status classification system in addition to being a preference-based scoring function for valuing the health states described by that system [76]. The HUI3 consist of 15 items, each offering 4-6 response categories [70]. For example, emotion is categorized from “happy and interested in life” to “so unhappy that life is not worthwhile” [76]. The HUI3

is based on eight attributes that describes the individuals health status at a point in time; vision, hearing, speech, ambulation, dexterity, emotion, cognition and pain/discomfort [70, 76], and allows description of a vast number of health states [75].

4.3.3 EQ - 5 D

The EQ-5D instrument offers five items. Each item has three response categories. The five items measure mobility, self-care, usual activities, pain/discomfort and anxiety/depression [70]. These five items are divided into three categories of severity; No, moderate or extreme problems. As much as 243 different health states can be defined by this instrument. These health states can be converted into a single index score representing health utilities [59]. The EQ5-D has been further developed by the Euro QoL Group into a five level version (EQ-5D-5L) [77].

4.3.4 15D

The 15D is a 15- dimensional measure of health-related QoL. This instrument from the late 1970s subscribes to The World Health Organization definition of health (WHO). The 15D is suitable for calculating quality adjusted life years (QALY), which should reflect a reasonable balance between quality and length of life [69]. The 15-D instrument has proved more sensitive in finding significant relationships between HRQoL and several mental and somatic conditions, including HL, in individuals compared to the EQ-5D [59]. The 15D instrument consist of 15 items, each item representing one dimension. The 15 items offered in this instrument focus on impairment and disability, and includes mobility, vision, hearing, breathing, sleeping, eating, speech, elimination, usual activities, mental function, discomfort and symptoms, depression, distress, vitality and sexual function [70]. The 15D offers five grades of severity in each dimension [59].

5. Depression, Anxiety, Distress

There are two major classification systems for mental illness and diseases. The WHO's International Classification of Diseases (ICD) [78] and the Diagnostic and Statistical Manual of Mental Disorder (DSM) [79]. Where the ICD-system also contains a variety of other somatic conditions, the DSM- system, developed by the American Psychiatric association (APA), only apply to mental disorders.

Depression and anxiety may be defined and used as diagnostic criteria by international standardized classification manuals, such as ICD-10 or DSM-5. Distress, however, does not seem to have such a clear and unified definition. They seem to be closely connected to the construct of QoL, especially when QoL is measured as generic QoL, but also to some degree when measured as disease-specific QoL [80-82].

A study by Cetin (2010) claims that there is evidence for a relationship between depression, anxiety and QoL in patients with HL. Increased levels of both anxiety and depressive reactions has been reported in patients with HL. Another study by Carlson et al. (2015), states that persons with severe or profound HL, had higher levels of depression and anxiety, when compared to the general population [83]. The findings from both these studies suggest a need for professional help from psychologists or psychiatrics to minimize the negative sides of a HL [83, 84].

5.1 Depression

According to APA, depression is a common and serious medical illness. Prevalence is estimated to almost 7 % in adult persons. Almost 17 % of the population is expected to experience depression at some time in their life. Symptoms must last at least two weeks for a diagnosis of depression. Depression symptoms can vary from mild to severe [85] and can include:

- Feeling sad or having a depressed mood
- Loss of interest or pleasure in activities once enjoyed
- Changes in appetite — weight loss or gain unrelated to dieting
- Trouble sleeping or sleeping too much
- Loss of energy or increased fatigue
- Increase in purposeless physical activity (e.g., handwringing or pacing) or slowed movements and speech (actions observable by others)
- Feeling worth less or guilty
- Difficulty thinking, concentrating or making decisions
- Thoughts of death or suicide

According to the ICD-10 classification system, code F 32; depressive episodes are characterized by lowered mood, reduced energy and activity level. The ability to feel joy, concentration or interest is reduced. Physiological functions, such as sleep pattern, appetite and sexual needs may also be reduced. Being in this condition, self-esteem and self-confidence is usually lowered. Depending on the number of symptoms and severity, a depressive episode may be specified as mild, moderate or severe [78]. Depression does not seem to be equally distributed between genders: there seems to be an overweight of women suffering from depression. As much as one third of females are expected to experience a major depressive episode during lifespan.

5.2 Anxiety

In literature concerning the relationship between HL and anxiety, it does not seems to be any distinction between different types of anxiety in patients with HL. According to the ICD classification system, such distinction should be made. Generalized anxiety (F41.1) is a generalized and persistent form of anxiety. This disorder is not connected to any specific situation or circumstances but is rather free flowing. Symptoms of this disorder will often cause somatic manifestations, such as muscular tension or increased heartbeat. The ICD classification system also offers a diagnosis when a mix of the two disorders anxiety and depression appears (F41.2) [78].

In the DSM system, anxiety is present when at least three of the following symptoms are present at any given time:

- Restlessness or feeling keyed up or on the edge
- Being easily fatigued
- Irritability
- Muscle tension
- Sleep disturbance (difficulty falling or staying asleep, or restless unsatisfying sleep)

The symptoms should represent something new in addition to the patients normal function level, the last six months [79].

The state-trait theory of anxiety suggest that people who shows high trait anxiety (disposition to show anxiety in different situations) are having the greatest increase in state anxiety (moment-by-moment basis) under stress. According to the state-trait theory of anxiety, neuroticism is associated with increases in anxiety under stress. Also, neuroticism seem to affect coping abilities, with persons scoring high on neuroticism tend to cope ineffectively, and this will in turn lead to distress [86].

5.3 Distress

Even if it does not seem to be a unified definition for the concept of distress, Distress, as defined by [87] is “the degree of discomfort reported by patients in relation to their perceptions of the symptoms being experienced”. Rhodes and Watson [88] have defined distress as “the need to alter (restrain or reproduce) actions in response to subjective indication of disease or illness. Symptom distress is also the physical or mental anguish or suffering from the experience of symptom occurrence and/or feeling states”. As to psychological research, the concept of distress may be quantified as the sum of anxiety and lowered mood [89], and may be used as an indicator of mental disease [90]. In search for a definition of distress, the concept of psychological distress also occurs. Psychological distress may be explained as a unique discomforting, emotional state experienced by an individual that results in harm to the person, either temporarily or permanently [91].

The two concepts of distress and psychological stress are closely related to each other, and seem to be used interchangeably in the literature, alongside the concepts of strain and stress [91]. Psychological distress evolves from the individuals` perception of the situation. Hence, different individuals may perceive the same load differently. Ridner (2004) describe psychological distress as” the unique discomforting, emotional state experienced by an individual in response to a specific stressor or demand that result in harm, either temporary or permanent, to the person”. In this understanding, psychological distress, in contrast to psychological disorders, is short-lived [92]. The HL may cause elevated level of distress, which in the next run may influence and affect social engagement [93] and the patients’ health [55]. The strength of the relationship between HL and distress seem to be influenced by the presence of several mediating factors, such as avoidant coping strategies [55].

6. Personality

Personality is related to individual aspects. Still, some general, measurable characteristics exists. Personality traits seem to reveal themselves under stress, and personality and personality traits interact with coping [86].

Whereas personality may be defined as those characteristics of a person that account for consistent patterns of feelings, thinking and behavior [94 p. 8], personality traits refers to individual and internal characteristics that are presumed to predict a certain behavior [86]. The development of an organized classification of personality traits has a long history, originating in psychological theories. According to the psychoanalytic theory, first introduced by Freud [95], early experience, where early stages in life, and especially the first four-five years of a human's life is crucial, regarding developing personality in later life [94 p. 96].

One of the most influential persons in the work of using scientific approach and principles to construct a personality classification was the English scientists Raymond B. Catell [96]. In 1943, Catell tried to distinguish and classify different traits into clusters. He claims there are 171 different personality traits [96, 97]. In his effort to capture what he meant to be the most important personality traits, Catell condensed the 171 single traits into 60 personality clusters [97]. Still, even if different personality traits can be captured in clusters or models, one should bear in mind that internal individual differences within each subject in personality traits may occur during lifespan [98], and there may be individual differences between subjects [86] and genders [99].

In a study conducted by Cox et al. (2007), based on patient- reported data collected prior to hearing aid fitting, factors such as hearing problems and hearing aid expectations, was suggested to be more closely related to personality traits than to audiometric hearing loss [100]. These results suggests that patient-reported data merely concerning the HL may not provide enough data alone.

There are good models for organizing measures of temperament and personality [101], and The Big Five personality traits model is the most commonly used.

6.1.1 The Big five model

Based on the work of Catell (1943), several scientific papers have found that only five of the personality clusters have proved to be replicable [102] summarized in the five factor model, known as the Big five-model [103]. This model offers what have been suggested as the gold standard in a modern understanding of the personality trait concept [104]. The personality traits in The Big five are regarded as more or less stable, regardless of age groups and cultures [101]. The Big Five model, as described by Mc Crae & John (1992) consists of the following five factors:

1. Neuroticism: This personality trait is considered an emotional factor. High scores tend to be emotionally unstable people who are chronically anxious.

2. Extraversion: Extraversion refers to the quantity and intensity of interpersonal interaction, activity level, need for stimulation and capacity for joy, and is assessed and found to be high in these persons, who are often found to be person oriented, optimistic, fun-loving and affectionate. On the contrary, low scoring individuals are likely to be reserved, sober, task-oriented and quiet.

3. Openness to experience: This personality trait is linked to culture. High scoring individuals are curious, have broad interests and are creative and untraditional. Low scoring persons are conventional, with narrow interests and may be non-analytical.

4. Agreeableness: represents a positive attitude and compassion in thoughts, feelings and actions. High scores are very often person-oriented, optimistic, fun-loving and affectionate, good hearted, good-natured and helpful.

5. Conscientiousness: reflects the will and ability to achieve goals and to be responsible, hard-working, self-disciplined and ambitious.

The personality traits captured in this model are regarded as more or less stable, regardless of age groups and cultures [101].

6.1.2 Neuroticism

Neuroticism, labelled as a personality trait, was first described by Eysenck in 1947, were he made a distinction between this personally trait and the diagnoses of neurosis [105]. The personality trait of neuroticism may be defined as a tendency to experience negative emotions [106], and may also be described as an enduring personality trait [107] and a part of the spectrum that may be called emotional disorders [105].

Neuroticism refers to more or less stable pattern of responding with negative reactions to threat, frustration or loss, and not to be able to be in control when facing stressful situations [108]. Still, there are great variations in persons who have this personality trait. While low neuroticism together with high extraversion or high conscientiousness predicts low stress exposure and threat appraisal, high neuroticism together with low conscientiousness predicts high stress exposure and threat appraisal [109]. Individuals with high scores on neuroticism respond with intense emotional reactions to even minor challenges, while persons that score lower on neuroticism may have less emotional reactions to difficulties and challenges in life. Two of the most characteristic types of coping in persons high in neuroticism is wishful thinking (fantasies about escaping or avoiding the situation) and self- blame, which in the next turn predicts distress [86].

Personality traits have been suggested to explain vulnerability to mental disorders [110], and various mental disorders, such as depression, anxiety and schizophrenia seem to be associated to neuroticism [111]. Also, the risk of developing dementia seems to increase in those with high scores on neuroticism. A high score on conscientiousness, on the other hand, seems to reduce this risk [112]. In addition, even physical disorders seems to be predicted by level of neuroticism [107], with persons scoring high on more increased consumption of general health service use as a possible result [113]. Neuroticism seems to have a negative influence on subjective well-being, and

personality traits in general is a decisive factor for level of well-being. Hence, persons scoring high on neuroticism will have a poor score on well-being. This suggests that well-being is more related to internal factors in individuals, rather than external circumstances [114]. Neuroticism, as described in the literature, may be malleable over time by psychological interventions, but there is no diagnosis or treatment for this or any other traits described as emotional disorders [105].

Level of neuroticism seems to be correlated to the economic costs related to this personality trait, the higher degree of neuroticism the higher economic costs. With neuroticism, being a personality trait varying from person to person, also the economic costs will vary. The overall economic costs related to neuroticism is suggested to exceed the costs of common mental disorders, even when adjusted for these disorders when comorbidity is present [115].

Neuroticism has historically been viewed as a stable, genetically based trait [108]. In a study conducted by Nagel, Jansen [111], the authors suggests that the involvement of both specific neuronal cell types and genetic pathways influence the development of this personality trait. Recent understanding of this trait suggests a more complex etiology, influenced by both environmental and genetically dependent conditions. The presence of hereditary conditions seems to have less influence the older the persons gets [116]. Hence, neuroticism should not merely be seen as a predetermined trait that cannot be changed, but maybe rather a trait that may be modulated by environmental factors during a lifespan.

7. Stress and coping

7.1 Stress

Stress is an old English word, and in its original form, it refers to a physical stress, which may in turn will cause strain. Hans Selye is often called the father of the stress-concept [117]. He used the stress- concept to explain the response of the stress, rather than the load (stress). This forced him to invent a novel word or concept to explain the stimulus or load causing what he called stress, and he came up with the stressor- concept to explain what originally being called stress [118]. Today it is normal to define stress in the original form, as the load causing the strain. Stress is a natural part of life and most people will experience stressful events or periods. Therefore, stress is not necessarily something that one should seek to avoid [117].

7.2 Coping

Coping may be understood as a process explanation for differences in stress outcome [86]. Lazarus & Folkman (1984) has defined coping as cognitive and behavioral efforts made to manage demands that are appraised as taxing the resources of the person [119]. This is regarded as a transactional-relational model to explain the dynamic interplay between the person and the stressful situation. Thus, personality and the situational factors plays an important role in how the individual handle the challenge [120].

Factors like age and level of stress or stressors are strong predictors for which coping strategies individuals seek to choose [101]. In addition, the situational context in which stress occurs seems to influence coping and stress outcomes [121].

Coping strategies is together with defense strategies used to describe responses used when people face threatening situations. These two responses come from different psychological traditions. While coping strategies originate in the discipline of social psychology, defense strategies come from the psychoanalytic tradition. There has been

a long tradition of viewing these two concepts as very different from each other. Despite of this, a growing number of researchers now suggests that the interrelationship between the two is more significant than previous anticipated [122].

7.2.1 Coping strategies

People react to being under stress differently. In similar situations, some people become distressed or perform poorly, whereas others remain resilient [86]. Even though to reduce or remove the source of stress may be a good way to cope with stress [117], different coping strategies may be needed when expectations of a positive response outcome cannot be met. Several approaches to assess the coping have been proposed. Lazarus & Folkman [119] has proposed problem- and emotion-focused coping dichotomy. Endler & Parker [123] made an addition to Lazarus & Folkmans dichotomy, by introducing "escape-avoidance" coping. Another dichotomy was proposed by Mc Crae & Costa [124], namely "neurotic coping" as opposed to "mature coping".

Sense of humor is regarded as an important factor in coping with stress and stressors [125] and may serve as a moderator of the relation between stress and moods [126]. Abel (2002) found that persons who assess themselves to be high on humor are more likely to use positive reappraisal and problem-solving coping strategies, compared to those being low on humor. The results from this study suggests that humor may be useful in reconstructing a stressful situation into being less stressful [127].

Bandura [128] developed the concept of self-efficacy. When a person experience coping it makes the individuals believe in its own ability to cope with difficult and unexpected challenges also in the future. Bandura emphasizes four sources of efficacy beliefs: Mastery experiences, which refers to the persons own experience of mastering experiences when facing challenges. Vicarious experiences provided by social mode observing other persons similar to themselves succeed when putting an effort to it, strengthen the person's belief in having the capability to master comparable tasks. Social persuasion refers to individuals not being confident in that they have the ability to cope,

can be persuaded verbally that they have what it takes to master the situation. The fourth source of efficacy-beliefs is physiological and emotional states. This refers to an increase in physical status which leads to reduced stress and negative proclivities, and misinterpretation of physical status. Bandura claims that it is not the intensity of physical and emotional reactions that matters the most, but rather how they are being interpreted. People with high efficacy may interpret being emotionally aroused as an energizing facilitator of performance, whereas persons with self-doubt may interpret being emotionally aroused as a debilitation [129 p.3-5].

Antonovsky [130] has presented a theory that includes coping with stress or resisting illness. In his salutogenetic theory, Antonovsky focuses on sources of health, in contrary to a pathological orientation which focuses on sources to illness. This theory shows how a "sense of coherence" (SOC), or way of making sense of the world, is a major factor in determining how well a person manages stress and stays healthy. According to Antonovsky, SOC comprises three crucial components. The first component is comprehensibility, which refers to at what extent one perceives the stimuli being confronted to, as either coherent or structured, or as noise, chaotic or incomprehensible. Manageability refers to at what degree one can handle life events as manageable challenges. This brings a feeling of having enough recourses available. The third and last component is meaningfulness, which refers to at what extent one judge life as being understandable in an emotional sense. When problems or challenges occur, the person will try to find meaning in the challenge and do the best to manage in a dignified way [131].

7.3 The cognitive activation theory of stress (CATS)

CATS offer a general theory for the understanding of stress and coping. CATS offer formal definitions, and describe the process of coping and non-coping [117]. According to Ursin & Eriksen (2004), coping may be defined as positive outcome expectancies. This is a result from a learning process where positive experiences establish expectancies of coping (fig. 1). The expectancies does not necessarily reflect how the person objectively copes, but rather the subjective feeling of the ability of coping [117]. Thus, when facing challenges (stress or stressors) in life, such as illness or disease, how we employ available coping strategies may be more important than the challenge itself.

7.3.1 Four stress aspects

Stress stimuli

Stress stimuli refer to whether stimuli are regarded as harmless or harmful and depends on the person's appraisal of the situation. This evaluation is based on previous experiences and the person's expectations regarding the outcome. This includes that some stimuli is regarded as negative in most situations, while other stimuli may be perceived as positive by some individuals, whereas others may perceive the same stimuli as negative.

Stress experience

All stimuli seem, according to CATS, to be evaluated or filtered by the brain. Given that specific stimuli or a set of stimuli is perceived or considered threatening or negative, it may be described as stress. Humans are, in contrast to animals who "describe" their reaction to stress by withdrawal from an unpleasant situation, able to describe stress experience by being interviewed or by using questionnaires.

Stress response

The general response to stress stimuli is a non-specific alarm response, which may be regarded as a non-specific activation in arousal or wakefulness. This may be referred to as activation. Based on this, Ursin & Eriksen (2004), suggest that CATS is an activation theory.

Feedback from the stress response

According to the CATS theory (2004) the experience of the stress response, which adds to the feeling of being stressed, may be understood as a feedback loop from the peripheral changes back to the brain. This is referred to as the James-Lange principle, which proposes that a physiological arousal occurs when exposed to environmental stimuli. The interpretation of the physical response results in an emotional experience, which we react upon [132]. The specific coping attempts or strategies made by the individual, may change the stimulus situation, and will be stored as future response outcome expectancies.

7.3.2 When does the alarm occur?

Stress response may be regarded as a general, unspecific alarm that occur whenever any variable creates a mismatch between what is being expected (set value - SV) and what in fact happens (actual value – AV) (see table 1). In general, the alarm goes off in every situation where ones expectations are not met. The alarm continues until the mismatch between SV and AV has been eliminated, by changing the SV or, when possible changing the AV. The alarm is uncomfortable and is meant to drive the person into a correct decision. There are two kinds of alarms or activation responses (see fig.1): a short anabolic response, with no known pathophysiological effects (strain effect), and a sustained, catabolic response with adverse health effects (strain effect) [133]. The alarm may be regarded as a security system, which is supposed to guarantee priority to sudden and serious discrepancies [117].

7.3.3 Response outcome expectations

Expectations is, according to Ursin & Eriksen (2004), a cognitive function that registers, stores and uses specific information about how a specific stimulus leads to another stimulus, or how a certain response leads to a specific result. Positive response outcome expectations refer to an expectation to that the person's actions leads to a good result. This should, according to CATS, result in coping. No response outcome expectations,

on the other hand, refer to how the person does not know the results of their actions. According to CATS, this will lead to helplessness. Negative response outcome expectancies refer to how the person belief in that whatever they do, the result will be negative. This will lead to a feeling of hopelessness.

Fig. 1 The Cognitive Activation Theory of Stress

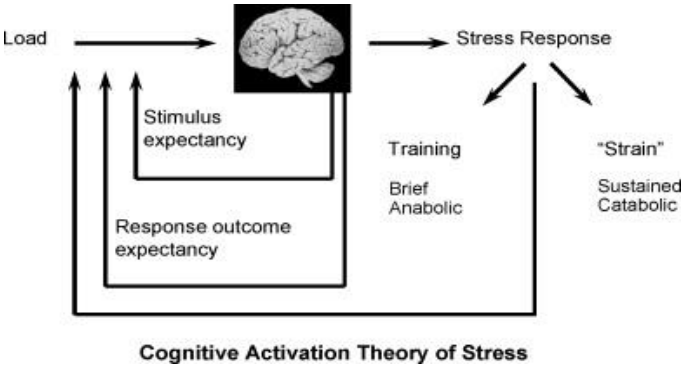

Figure 1: Schematic presentation of CATS, adapted from Eriksen, Murison [134]

Theories such as CATS seem to emphasize the individual's power to form a certain behavior. This perspective of coping does not seems to take in to account other factors, such as material factors, psychosocial resources, life events and lack of social support [135]. Also, genetic factors have been suggested to be linked to coping style [136, 137]. Even if there have been conducted several studies to explain and understand the nature of coping, there still seems to be many questions remaining to fully understand the exact nature of coping and the role of its biological, psychological and environmental determinants [138].

8. Patient Reported data

Involving patients in the process of rehabilitation and course of treatment seems to have become increasingly important, and patient reported outcome measures (PROMs) have moved from being an instrument for seeking patients' assessment of the care they received and the satisfaction with this, to being an instrument for the patients` assessment of their symptoms, their functional status, their well-being and their HRQoL. PROMs are usually standardized, validated questionnaires completed by the patient [139, 140].

PROMs were originally made for use in clinical research to gain information on patients` assessment of treatment effectiveness [140]. Gradually PROMs have been used in clinical settings to improve the clinical management of individual patients. In recent years, PROMs have increasingly been used by health professionals for comparing treatment outcomes [139, 140]. By using PROMs, one is able to measure both how the patient assess their general health (generic health status) and their health in relation to a specific disease or condition [140].

PROMs offer questions where the patient rate how they assess their own health, reflecting the severity or difficulty of the health. An overall sum score is calculated for each patient, which makes it possible to detect underlying constructs or phenomenon in individuals. By analyzing patients` sum score before and after an intervention, changes in patients` condition or general HRQoL are detectable [140].

8.1 Self-assessed hearing loss

How people assess their HL, and how communication problems influence daily life is typically measured using questionnaires such as the Abbreviated Profile of Hearing Aid Benefit (APHAB) [141]. This is a standardized self- report questionnaire used to quantify the impact of the HL on individuals everyday life [142]. By using PROMs such

as the APHAB, the patient's own perspective on functional status and symptoms can be captured.

The APHAB was originally a 66-item inventory called Profile of Hearing Aid Benefit (PHAB) [143]. A 24-item version based on the original version has later been developed to meet the need for a version more suitable in clinical settings [141]. This version consists of four subscales: Ease of communication (EC; strain of communicating under relatively favorable conditions), reverberation (RV; communicating in reverberant rooms), background noise (BN; communicating in noisy environments) and evasiveness (AV; unpleasantness of environmental sounds). Where RV, EC and BV describe speech communication in different listening environment, AV scores describes negative reactions to environmental sounds. A global score is calculated by averaging the scores of EC, RV and BN subscales. This should in total give an estimate of the overall communication problems [144]. The 24 items in the APHAB has been formed as statements, where the responder will decide how often the statement is true for him/her. The responder is offered seven alternatives, where the one that matches the everyday experience should be put a ring around [144].

With a growing number of available PROMs, choosing the right questionnaire is becoming increasingly more difficult. Still, the work of collecting valid data rely on choosing and using the correct PROM that address the proper functions and symptoms [145]. For clinicians, it is also pertinent that the PROM has a short administration time, and is straight forward and user-friendly to handle [146]. To ease the total burden of questionnaires for the responders when participating in surveys, questionnaires should follow the notion that "shorter is better" without losing accuracy and repeatability [147]. Hence, it could be argued that the APHAB is too extensive, and that there is need for an even shorter version. In the present version we have used the 24-item version of the APHAB. In addition, we have used a Likert response matrix with four response alternatives available as opposed to the original seven response alternatives.

8.2 Health Related Quality of Life Questionnaire (EORTC QLQ-C30)

The European Organization for Research of and Treatment of Cancer (EORTC) has developed a HRQoL questionnaire to measure QoL in cancer patients. The questionnaire contains a general part applicable in all cancer types. This part may also be suitable for other diseases, as well as the normal population, and allows to compare QoL in different diseases [71, 148]. The EORTC QoL questionnaire was originally developed in 1987 (QLQ-36). Later, additional versions have been developed, based on the same basic principles. This has culminated in the 30-item EORTC QLQ-C30 (version 3.0), which today is one of the most widely used HRQoL questionnaires [149]. The QLQ-C30 consists of 30 questions offering a global health scale, five functional indexes (physical, role, cognitive, emotional, and social), three symptom scales (fatigue, pain and nausea/vomiting) and six single items (dyspnea, insomnia, anorexia, constipation, diarrhea and financial difficulties). The answers are be given according to a four-point Likert format, with the exception of questions on general health and QoL, which are given according to a seven-point Likert format. All scores are linearly transformed such that they range from 0 to 100, in accordance with the EORTC Scoring Manual [149]. A higher global health score equates to better overall QoL and a higher score for functional scales corresponds to better functioning, whereas higher score for a symptom scale indicates more symptoms.

8.3 General Health Questionnaire (GHQ-12)

In paper IV we measured distress by employing The general health questionnaire (GHQ)-12 [150]. GHQ-12 is a versatile screening instrument designed for use in general practice. It has been shown to be a valid instrument for the detection of psychiatric morbidity in both general medical settings and in the community [151]. The GHQ-questionnaire consists of 12 questions where scores are given according to a standard 4-point response matrix. GHQ was analyzed with the responses calculated as Likert scores. The GHQ scores were also scored binomially denoting scores 1 & 2 as 1 and scores 3 & 4 as 2.

8.4 Personality inventory Questionnaire (EPQ)

The neuroticism scale consists of questions related to mental symptoms such as obsessive thoughts, anxiety, depression and low self-esteem, but also includes somatic symptoms like muscle pain, tachycardia and sleeplessness. The scale assesses adjustment versus emotional instability and identifies individuals prone to psychological distress, unrealistic ideas, excessive cravings or urges, and maladaptive coping responses. The low scorer is characterized as calm, relaxed, unemotional and self-satisfied [94]. Extroverted individuals are judged sociable, active, talkative and optimistic. The extroversion measure assesses quantity and intensity of interpersonal interaction, activity level, need for stimulation and capacity for joy. The low scoring individuals will be reserved, sober, task-oriented and quiet [94]. The lie scale is based on answers to nine questions with phrases like: “Have you ever stolen anything?” Although originally introduced as a lie score, it has later been suggested that the response pattern to this scale may be regarded as a measurement of a personality trait, possibly with a focus on handling on moral questions.

8.5 Coping Questionnaire (TOMCATS)

We have used the Theoretically Originated Measure of the Cognitive Activation Theory of Stress (TOMCATS) as to measure applied coping style. The TOMCATS questionnaire was employed to measure degree of generalized response outcome expectancies as described in the cognitive activation theory of stress (CATS) [117]. This questionnaire has been developed as a clinically and epidemiological suitable instrument. The TOMCATS-questionnaire consists of seven items. This makes it a short and practical supplement to traditional questionnaires used for testing coping styles in individuals [152]. Answers are given according to a four-point Likert format, rated from 1 (not true at all) to 4 (completely true) [152]. The TOMCATS measures three outcome expectancies dimensions from the CATS, categorized as either positive (coping), negative (hopelessness) or uncertain (helplessness) [152].

9. Aims of the thesis

9.1 Main aim

The main aim of this thesis is to study the relationship between physical and reported HL and QoL together with to study the importance of underlying potentially explaining variables.

9.2 Specific aims

9.2.1 Paper 1

The aim of the study was to study a four response-category as well as psychometrically validate the Norwegian version of the APHAB questionnaire for self-assessment of communication ability. We have also wanted to study if a cut-off score could be establish separating subjects with and without reported HL. In addition, we wanted to study how variables such as degree of physical HL, age and gender influence the APHAB response patterns.

9.2.2 Paper 2

In this study, we conducted a systematic literature review, and the main aim was to investigate the relationship between HL and generic QoL. We also performed an additional search, were the aim was to investigate any association between HL and distress.

9.2.3 Paper 3

In this study, we aimed to investigate whether general QoL is reduced among HA users compared to patients with head-and neck cancer and a population cohort. We included variables such as duration and causation, in addition to bilateral or unilateral HL and the

presence of co-morbidities. An additional aim was to study the relationship between general QoL, self-assessed communication ability and pure tone thresholds.

9.2.4 Paper 4

The main aim of the study was to study the relationship between QoL and distress among patients seeking HA fitting. A secondary aim was to investigate any relationship between reported and physical HL, reported HLQoL, reported choice of coping and reported personality in this patient group.

10. Design, materials and methods

10.1 Design

Data presented in this thesis was primary collected using a cross-sectional survey study design. In one of the studies (study II), a systematic review design was employed. The studies in this thesis were conducted at Haukeland University Hospital in Bergen, Norway.

10.2 Material paper I, III and IV

The patients included in paper I, III and IV represented two groups of patients seeking audiological rehabilitation. In total, we invited 301 adult patients (18-77 years) to participate in the study. 158 patients returned completed questionnaires yielding a response rate of 52.5%. The patients were either first time hearing aid users (n= 87) referred for their first hearing aid fitting or experienced HA users (n= 71) who had been referred for HA renewal. The first-time users had been referred to the ENT-department at Haukeland University Hospital in Bergen, Norway. The experienced users either were referred or had contacted the ENT-department themselves for HA renewal. Prior to being invited to participate, all patients had been scheduled with an appointment for hearing aid fitting. First-time users had been examined by an ENT-specialist. Years of living with a HL ranged from 0 to 76 years, with a mean of 22 years (SD±18). Most of the included patients suffered from sensorineural HL (n=144), while 13 patients had mixed types of HL. The three most prevalent diagnoses in this sample was noise induced HL (n=49), presbyacusis (n=42) and Hereditary related HL (n=20).

In paper I we excluded 23 patients with unilateral HL and 27 bilateral HL patients with a HL < 25 dB averaged over pure–tone frequencies of 0.5, 1, 2 and 4 kHz, leaving us with 108 included patients and 101 controls. The controls were adult subjects (aged 18≥ years) with self-reported normal hearing. This group served as controls. The controls were recruited among students and staff at a local University college. In paper III we

used previously collected data from patients with head and neck squamous cell carcinoma (HNSCC) [153], laryngectomized patients [154] and a randomly selected sample of 3000 persons from the General Norwegian population [155, 156] in addition to the patient group included in this study.

10.3 Methods paper I, III and IV

Demographic data such as education level, occupational, housing and family status were collected. Also, information regarding diagnosis and pure tone audiograms were collected from medical records. The authors inspected all patient records to control for correct diagnosis and audiogram-classifications. Any discrepancies between audiograms and recorded diagnosis were revised. Audiograms were recorded during regular visits to the clinic. All audiometers were calibrated according to ISO-389-1 (Article III [157]. Based on their most recent audiogram, patients were grouped by better ear pure tone average (PTA; frequencies 0.5, 1, 2 and 4 kHz) as having normal hearing (< 26 dB HL), slight/mild hearing loss (26-40 dB HL), moderate hearing loss (41-60 dB HL) or severe to profound hearing loss (61 dB HL or worse). Sensorineural hearing loss was defined by an average air-bone-gap (0.5, 1, 2 and 4 kHz) ≤ 10 dB HL. A conductive hearing loss was identified by an average air-bone gap ≥ 15 dB HL and average bone-conduction thresholds ≤ 25 dB HL (0.5, 1, 2 and 4 kHz). Average bone-conduction thresholds worse than 25 dB HL in combination with average air-bone gaps ≥ 15 dB HL, were categorized as a mixed hearing loss (0.5, 1, 2 and 4 kHz). Patients with bilateral (n = 135) and unilateral hearing loss (n = 23) were treated as separate groups in paper III and paper IV. A better ear with pure tone hearing thresholds equal or better than 25 dB HL at octave frequencies 0.125 to 8 kHz defined unilateral hearing loss. Experienced hearing aid users (n = 45) were currently fitted with a variety of HAs, in-the-ear (11.1 %), behind-the-ear (80%), or bi-CROSS systems (8.9%). A similar distribution of fittings was planned for the first-time HA users, with 19 % in-the-ear, 76.2 % behind-the-ear and 4.8 % bi-CROSS systems. All hearing aids were digital.

Patients with HL completed the questionnaires by pen and paper at home, and the questionnaires were delivered and returned by regular mail. Questionnaires were typically mailed to patients three to four weeks prior to the hearing aid fitting, and they were encouraged to return the questionnaires within one week. Thus, data was collected within one month prior to the hearing aid fitting. The controls in paper I were randomly recruited at the University campus and completed there and then by pen and paper and collected continuously.

10.4 Material and methods Paper II

A systematic literature search was performed, including journal articles published in the period from January 2000 to the 17th of March 2016. The search criterion applied were peer reviewed original research papers in English. We performed a primary search pertaining to the relationship between HL, HA and QoL. We used combination (AND) of the following keywords: *Hearing disorders OR deafness OR hearing loss/partial + OR hearing loss/ sensorineural + OR Tinnitus AND hearing aid OR hearing aid fitting AND hearing loss OR hard of hearing OR loss of hearing OR hearing impair* OR hearing disorder* OR deaf* OR hearing aid* OR hearing assistive technology.* A supporting search was performed pertaining to the relationship between distress/ mood/anxiety and HL. In this search we used the combination (AND) of the following keywords: *Quality of life + OR Quality of Life OR health-related Quality of Life OR HRQoL OR qol.*

As to meet the aims of this study and to limit the two searches, we excluded studies regarding the persons with HLs peers or family or other caregivers. We also excluded studies concerning deafness, patients with cochlea implants, dual or multi-sensorial loss, tinnitus, stigma and HL, assistive listening devices, bone-anchored hearing aids, HL and psychiatric diseases, hearing aids usage, sudden sensorineural HL, conductive HL and surgical interventions on HL. In addition to this, we also excluded concerning qualitative

studies as well as studies on psychiatric diseases, such as depression or anxiety prior to the HL.

By using critical appraisal tools (CATs) readers can appraise and rate relevant papers to be included in the review. However, many CATs are designed for appraisal of one research design only, which may require several CATs within the same systematic review [158]. We have used the Crowe Critical appraisal tool (CCAT) in the process of systematically assessing the quality of the journal articles to be included in the systematic review. This instrument, which consists of eight categories, allows for a wide range of qualitative and quantitative health research to be appraised using one tool. When using the CCAT the participants ticks off a score between 0 and 5. A 9th item that states the total score from the first eight items. Hence, a total score may range from 0 to 40 points [159].

After checking for duplications and screening the titles of the journal articles in the primary search (n=3280), we read the abstracts of the remaining journal articles. The most relevant papers were read thoroughly. We performed the same procedure in the supporting search (n=1157). This left us with 13 journal articles from the primary search and 7 studies from the supporting search that met the inclusion criteria. Thus, a total of 20 journal articles were to be included in the systematic review.

10.5 Statistics

The statistical program package SPSS Software for windows was employed (IBM Corp. Released 2016. IBM Statistics for Windows, version 23.0 and version 24.0. Armonk, NY: IBM Corp.), when performing the statistical analyses. Statistical significance was considered at $p < 0.05$.

Study I: We performed an exploratory factor analysis with Kaiser Normalization on results from the 12 candidate items to help explore the factor structure of the proposed questionnaire. Chronbach`s-α was used for testing internal consistency for the total

questionnaire. Pearson`s product-moment correlation coefficients (r) were used to investigate associations among HL variables, age, single items, and total score. Independent sample t tests with Bonferroni correction was used to investigate differences in single-items scores, total scale scores, subscale scores, age, and HL variables for different demographic groups (male/female, first-time users/ experienced users, controls/ HA users). Stepwise linear regression were calculated to help explore the associations among demographic variables and HL characteristics (independent variables) in addition to the mean sum score of the entire questionnaire (dependent variable). We also performed a one-way analysis of variance (ANOVA) and Bonferroni-corrected post hoc tests, to test whether the outcome was different between groups of persons with HL and the group of persons with normal hearing.

Study 3: In this study we included Cronbach's-α analyses, exploratory principal component analyses of variance (ANOVA) supplemented with least significant differences (LSD) post hoc analyses and Pearson`s correlation coefficients as indicated.

Study 4: In addition to descriptive Information for included subjects, we performed Correlations between reported expected coping and reported QoL and GHQ (distress). Pearson`s r correlations was conducted between reported coping expectations and neuroticism, gender, age and duration of hearing loss, as well as between APHAB, QoL, GHQ, expectancy coping, neuroticism and lie scores. Finally, we performed Cox stepwise regression analysis with APHAB, GHQ and QoL scores as dependent variables and levels PTA scores, expectancy coping and neuroticism/lie as independent variables.

10.6 Ethical approval paper I, III and IV

The study was approved by the Norwegian regional committees for Medical and Health Research Ethics in advance. Project reference: 2013/1302. All participants gave written consent in accordance with the Helsinki declaration before participation.

11. Results

11.1 Paper I

Inter-item correlations show that each item of the APHAB questionnaire correlated to all other items ($r \geq 0.563$, $p \leq 0.01$). With all the items having the same direction in response values, all correlations were, as expected positive. In patients with hearing loss, a Kaiser–Meyer–Olkin Test resulted in a value of 0.91, thereby confirming a sufficient sample size for factor analysis [160, 161]. The exploratory principal component analysis identified two factors formed by responses to the 12 candidate items in patients with hearing loss, with these factors accounting for 67.2% of the total variance.

A Varimax rotation was applied, and coefficients with absolute values lower than 0.5 were suppressed. The two factors were formed similarly to the APHAB subscales ‘‘ease of communication’’ and ‘‘background noise’’. The questionnaire seems to consist of two subscales ‘‘communication in quiet conditions’’ (items 2, 5, 6, 7, 8, 11, and 12) and ‘‘communication in adverse conditions’’ (items 1, 3, 4, 9, and 10).

Cronbach’s alpha (0.959) for all items suggest that the items measure the same basic construct. To assess each item’s contribution to the internal consistency of the scale, each item was deleted followed by a recalculation of Cronbach’s alpha. The deletion of any item did not increase the Cronbach’s alpha of the total scale (0.953–0.957) suggesting that each item is a valuable contribution to the questionnaire. Ranging from 0.735 to 0.851, the corrected item-total correlations show that each item contributes to the total scale.

Items in the subscale ‘‘communication in quiet situations’’ yielded a Cronbach’s alpha of 0.943. If any item was deleted, the Cronbach’s a ranged from 0.931 to 0.940, with the corrected item-total correlations ranging from 0.753 to 0.855. For items in the subscale, ‘‘communication in adverse situations,’’ a Cronbach’s alpha of 0.922 was found. The corrected item-total correlation and the Cronbach’s alpha any item was deleted ranged

from 0.765 to 0.825 and 0.903 to 0.911, respectively. Hence, both subscales show satisfactory psychometric properties when analyzed separately.

The averages of all candidate items were included in further analyses. The 90th percentile of scores in normal-hearing controls was 3.24 points. We used this score to calculate the sensitivity and specificity of the questionnaire in regard to separating patients from controls. The sensitivity was found to be 81%, with a specificity of 91%.

Responders were divided into four groups: slight/mild hearing loss (26–40 dB HL), moderate hearing loss (41–60 dB HL), severe-to-profound hearing loss (61 dB HL or worse), and normal hearing. The mean score of the total questionnaire, and for both subscales, decreases by hearing loss severity. This indicates that those with worse hearing experience more frequent difficulties with communication, both in quiet and adverse listening situations.

A one-way analysis of variance (ANOVA) was performed, and a significant difference in the mean total scale score between groups was found ($F(3.198) = 92.65$, $p < 0.000$). Following Bonferroni corrected post hoc t tests we found that the normal hearing controls had significantly ($p < 0.01$) higher scores than all three groups of hearing-impaired participants, while participants with slight-to-mild hearing loss had significantly ($p < 0.01$) higher scores than the two groups with poorer hearing loss. No significant ($p > 0.05$) difference in scores was seen between the groups with moderate and severe-to-profound hearing loss. These findings also suggest that the concurrent validity of the questionnaire is good.

Among patients with hearing loss, differences between males and females, and between first-time users and experienced users, were investigated. Total scale score, subscale scores, age, worse-ear PTA, better-ear PTA, and the duration of hearing loss were included in independent-sample t tests with a Bonferroni correction for multiple comparisons. No significant differences were found in any variable between first-time

users and experienced hearing aid users, or between male and female patients with hearing loss. No significant correlation was found between age and mean score.

For the patients with hearing loss, hearing loss variables that showed significant correlations in the correlation analysis were selected, and a stepwise linear regression was performed using these variables (better-ear PTA, worse-ear PTA, and duration of hearing loss) as independent values, and the mean score of the total scale as the dependent value. PTA in the worse ear was identified as a single predictor of the mean score of the questionnaire ($R^2 = 0.072$, $p = 0.01$, *beta* = -.290).

11.2 Paper II

This section presents main findings from the systematic literature review.

In the studies included in the two searches in this review, degree of HL was defined differently. Still, in most of the studies included in this review, the lower limit of hearing loss was defined by a mean hearing loss greater than 25 dB HL in the better ear at the octave frequencies from 0.5 to 4 kHz.

11.2.1 HA use and generic QoL

In the 13 studies included in the primary search self-report questionnaires was employed for persons with HL. The questionnaires used were either generic QoL questionnaires, disease- specific questionnaires or a combination of the two. There were differences in number of participants in the studies, varying from 30 to 2688 persons. Study design in the different studies varied. While some studies employed cross-sectional designs, others used longitudinal or prospective study designs. Only one of the included studies included both unilateral and bilateral HL patients. The remaining twelve studies either only included bilateral HL (3 studies) or presented no information on this matter (9 studies). There were variations between the included studies regarding when the participants have had their HA duration of HA use prior to participating in the study.

Five studies also measured QoL before the patients had their HA fitted [11, 32, 162-164].

The included studies in the systematic review had contradictory results regarding the HLs impact on QoL. Where some studies found a strong association [9, 165], other studies found weak [10, 56, 163, 164, 166] or no such correlation [11, 32, 162, 167, 168]. One of the studies [10] reported worse hearing at the high frequencies in males, compared to females. Despite this, the males reported higher scores on generic QoL. Hallberg and colleagues (2008) also found that males reported less use of non-verbal behavior that decreases consequences of the HL, such as pretending to hear or guessing what is being said in a conversation, or even avoiding social settings or interactions with others. This may lead to reduced coping skills, which in next run maybe lead to reduced QoL [166]. One study suggested that factors such as time of HL onset [83] was negatively correlated with QoL. Another study suggested that age in fact represent a decline in general health for most people [166]. With HL being most prevalent in older people, HL may just being one of other modulating factors that indirectly influence on QoL [164]. The latter point is also supported by another study that suggest that general life circumstances or comorbidities may influence, either alone or as a synergetic effect, on the general QoL scores [167].

By using HAs, people with HL alleviates the consequences of the HL and improve the quality of social relationships [164]. The use of HAs or other individual sound devices (ISADs) may improve QoL [166]. Still, both the degree of HL and the extent of HA use seem to be of importance for hearing-specific QoL [164]. In the studies where QoL was measured prior to and after three [32, 162, 164] or six [11, 163] months, the results were equivocal regarding the effect of HA on QoL.

11.2.2 Distress/ mood/anxiety and HL

The 7 studies included in the supplementary search had collected self- reported questionnaires from adult persons (≥ 18 years) with HL, concerning distress, anxiety or depression. There was great difference in the number of participants across the studies, varying from 90 [169] to 18,318 [170]. We found some small variations between genders. Still, the distribution was close to 50 % male/female. One study only included male participants [169]. None of the included studies reported on all the inclusion criteria. Where some of the included studies reported on distress and depression [171], other studies reported on anxiety and depression [83, 169, 170, 172, 173]. One studies reported on distress only [93].

The two studies that measured distress both reported a negative correlation between HL and distress. Distress score seem to increase 2 % for each dB increase in signal to ratio (SNR) [171]. The other study suggested that older adults with HL is more likely to experience emotional distress due to the HL [93]. Nachtegaal et al. (2009) also reported that the odds for developing moderate or severe depression increase with 5 % for each dB increase in SNR. These findings are supported by other studies where anxiety and mood were investigated, also when patients with HL were compared to reference population. One study suggested that when taking into consideration that some HL patients may have developed depression or anxiety prior to HL onset, the HL represent a risk factor for developing one of the two or both diseases [83]. The duration of the HL may be a risk factor, with increasing scores in depression and anxiety the longer the HL has been present [169], especially among younger individuals and females [171, 172].

The results from this study suggests higher prevalence of distress [93, 171] and anxiety [83, 169] in persons with HL. There also seem to be evidence for a strong association between HL and depression [170, 172, 173], particularly in females and younger individuals (≤ 70 years) [171, 172].

11.3 Paper III

The general QoL in the bilateral HL and unilateral HL groups were compared to the three other groups (one with HNSCC, one with laryngectomized patients and one cohort from the general Norwegian population). One-way ANOVA analyses followed by post hoc analyses were performed in order to study differences between groups.

Only significant post hoc results regarding the HL groups will be reported. Among these participants, "general QoL/health" was not scored dependent on group as measured by one-way ANOVA analysis ($F_{4,2286}$=1.0; p=0.407).

The "physical" function index was scored dependent on group ($F_{4,2231}$=14.8; p<0.001). Post hoc analyses showed that "physical" function was scored higher among both the bilateral (p<0.001) and the unilateral HL (p=0.02) patients compared to the laryngectomized patients. "Emotional" function index was scored significantly different between the groups ($F_{4,2234}$ =11.17; p<0.001). The score was higher among those with bilateral HL than in the population cohort, the HNSCC, the laryngectomized (all p<0.001) and with a trend towards the same among the unilateral HL (p=0.083). Furthermore, patients with unilateral HL scored higher than the laryngectomized group (p=0.044). Regarding "cognitive" function index, the scores were border-line significant dependent on group studied ($F_{4,2268}$=2.33; p=0.054). According to post hoc analyses patients with bilateral HL scored higher than the laryngectomized (p=0.029). We also found a weak trend towards the same compared to unilateral HL (p=0.099). Scores on the "role" function index were significantly different between groups ($F_{4,2257}$=3.20; p=0.013). The post hoc analyses showed that those with bilateral HL showed higher scores than the HNSCC group (p=0.019) and the laryngectomized group (p=0.002). The "social" function index was significantly different between groups ($F_{4,2246}$ =11.12; p<0.001). Patients with bilateral HL scored higher than the laryngectomized (p<0.001) as well as the unilateral HL (p=0.043) group. In addition, the unilateral HL group scored lower than the controls (p=0.009).

The ANOVA analyses were also adjusted for age. All functional indexes except the "cognitive" function index retained statistical significance.

Level of "fatigue" was scored dependent on group ($F_{4,2257}$=3.74; p=0.005). Patients with unilateral HL reported more "fatigue" than the patients with bilateral HL (p=0.033), and those with unilateral HL scored with a trend towards more fatigue than the controls (p=0.081). The groups did not differ significantly regarding reported level of "pain" ($F_{4,2255}$=1.91; p=0.106). On the other hand, the groups differed with regard to the level of "nausea and vomiting" ($F_{4,2258}$=8.90; p<0.001), level of "dyspnea" ($F_{4,2274}$=21.50; p<0.001), level of "appetite" ($F_{4,2269}$=5.54; p<0.001), level of "constipation" ($F_{4,2270}$=5.70; p<0.001) and level of "diarrhea" ($F_{4,2249}$=10.09; p<0.001). The post hoc analyses in general showed as expected that the HNSCC groups reported more severe symptoms than the controls and the HL groups. No difference was determined between the HL groups and the controls for these variables.

When comparing the first time HA candidates with those seeking HA renewal, the PTA values, but not the general QoL indexes, were lower in the renewal group compared to the first-time group. We investigated whether the type of hearing loss (hereditary/congenital, presbyacusis, noise-induced) influenced QoL. No difference was found caused between the groups dependent on QoL scores. No significant differences were observed (results not shown). The patients with HL also reported presence of some major co-morbidities (YES/NO) by a standard questionnaire [174]. No significant association was determined to the QoL scores (results not shown).

In patients with HL, age correlated to the functional QoL indexes, except for the "role function" index. APHAB scores were not associated with the age of the patients. Males and females scored QoL at equal levels except for "physical" QoL where males reported better scores than females.

Significant correlations were found between the APHAB sum scores and PTA in both the best and worst ear CV≈5.8%/ 9.% (r=- 0.24; p<0.01 / -0.31; p<0.001) respectively,

but not between the general QoL scores and PTA values. The APHAB sum score correlated with all the EORTC QLQ C30 sum scores ranging from CV≈3.2% (r=0.18; p<0.05) to CV≈ 6.8% (r=0.26; p<0.01). A Principal component analysis (PCA) was performed including the individual APHAB question responses, as well as sum scores derived from the QORTC QLQ C30 responses to identify the closest scored associations. This showed that the APHAB scores formed two components while the EORTC QLQ C30 responses formed separate components.

PTA in the best and worst ear, EORTC functional HRQoL indexes, level of fatigue, co-morbidities and bilateral or unilateral HL were included in a stepwise linear regression analysis as independent variables. APHAB sum score served as dependent variable. The first factor extracted was PTA in the best ear, the second extracted factor was "cognitive functioning" and the third extracted factor was "physical functioning".

11.4 Paper IV

11.4.1 Relations between personality and coping variables.

To measure response outcome expectancies, we have employed the TOMCATS questionnaire. Level of patient reported "positive" expectancy was negatively correlated to level of "negative" expectancy coping (r= -0.45; p<0.001) as well as to level of "no" expectancy (r= -0.53; p<0.001). Reported level of "no" versus "negative" expectancy coping was also correlated (r=0.72; p<0.001). We also found that neuroticism scores were also correlated to reported choice of expectancy coping; that is negative correlation to level of "positive" expectancy coping (r= -0.42; p<0.001) and positively to "no" expectancy coping (r= 0.47; p<0.001) as well as to "negative" expectancy coping (r= 0.40; p<0.001)

11.4.2 Associations between APHAB, QoL, GHQ scores and demographic variables

A positive association was found between lengths of formal education and QoL levels (General QoL: r=0.20; p<0.05, Functional QoL: r=0.18; p<0.05). Functional QoL (r=0.0.22; p<0.05) was *inversely* associated to not being employed. Whether living alone or number of children was not associated to QoL levels. The APHAB scores were not associated to any of these variables.

11.4.3 Associations between APHAB, QoL, GHQ scores versus neuroticism and choice of coping

APHAB scores (high score = good hearing) were correlated to scored level of "General health/QoL" (r=0.26; p<0.01), "general functional QoL" (r=0.31; p<0.001), GHQ (r= -0.18; p<0.05), PTA (best ear) (r= -0.38; p<0.001), "positive" expectancy (r= 0.26; p<0.001), "no" expectancy (r= -0.17; p<0.05), "negative" expectancy (r= -0.14; p<0.1), neuroticism (r= -0.19; p<0.05) and lie score (p= -0.24; p<0.01).

Regarding general QoL/health scores (high scores = good QoL), a positive correlation was found to functional QoL scores (r=0.79; p<0.001) and inverse correlation to distress levels (r= -0.50; p<0.001). A positive correlation was shown between general QoL levels and level of "positive" expectancy (r= 0.43; p<0.001), but inversely to "no" (r = 0.51; p<0.001) and "negative" (r = 0.39; p<0.001) expectancy. In addition, an inverse correlation was shown to reported level of neuroticism (r = -0.48; p<0.001) and the lie score (r= -0.23; p<0.01).

The sum functional score was also studied. A significant positive correlation was observed to "positive" expectancy (r=0.43; p<0.001), but inverse to "no" (r=-0.44; p<0.001) and "negative" (r=-0.39; p<0.001) expectancy (Table 3). In addition, inverse correlations were shown regarding level of neuroticism (r=-0.47; p<0.001) and lie score (r=-0.24; p<0.01). GHQ levels were correlated to reported levels of coping and personality. The GHQ level was inversely correlated to level of "positive" expectancy

(r=-0.39; p<0.001), but positively correlated to “no” (r=0.40; p<0.001) and “negative” (r=0.35; p<0.001) expectancy. Positive correlation was also observed to level of neuroticism (r=0.56; p<0.001) and lie score (r= 0.23; p<0.01).

The APHAB, GHQ, General health and the functional sum score variables were subsequently subject to stepwise linear regression analyses as dependent variables including measured coping and personality dimensions as well as PTA (both best and worst ear) scores as independent variables. Regarding the APHAB scores, the PTA score from the best ear (β=-0.36; p<0.001), then the neuroticism (β=-0.23; p<0.01) and the lie (β=-0.18; p<0.05) scores were uniquely associated. Concerning the General health/QoL scores were associated to “no” expectancy (β=-0.29; p=0.001), level of neuroticism (β=-0.28; p<0.001) and “positive” expectancy (β=0.17; p<0.05). In case of the functional sum score, neuroticism (β=-0.33; p<0.001) and “no” expectancy levels (β=-0.30; p<0.001) were uniquely associated. The GHQ scores were also studied by linear regression analysis in order to assess unique contribution to the GHQ score from explaining variables. Neuroticism (β=-0.46; p<0.001), “positive” expectancy (β=-0.25; p<0.001) and PTA from best ear (β=-0.19; p<0.01) turned out to be uniquely associated.

11.4.4 Scores dependent of specific diagnosis

The APHAB, QoL, distress, coping and personality levels were not scored dependent on diagnosis (results not shown). On the other hand, the correlations between in particular the coping score levels and QoL levels were scores with statistically significant higher common variance between patients with congenital or hereditable disease compared to in particular patients with presbyacusis or noise-induced HL In particular, correlations between choice of coping and general/functional QoL were statistically significantly stronger among the patients with hereditary and congenital cause versus patients with presbyacusis or noise-induced HL.

12. Discussion

12.1 Methodological considerations

12.1.1 Paper I

In this study we aimed to develop a questionnaire for the self-assessment of communication ability. Including novel candidate questions to be part of the factor analysis may have provided a more thorough tool. The number of included patients could have been higher. This could provide valuable information on the scores over different levels of HL severity, especially in the group with severe-to- profound HL which only counted eight participants.

It may also be relevant to discuss how accurately experienced HA users are able to evaluate their hearing in hearing scenarios without using their HA. Still, the lack of significant differences in the scores in first-time users and the experienced HA users imply that the experienced HA users can remember or at least imagine unaided performance in the various scenarios. This might be influenced by the daily use of HA in the experienced users. This information was not collected in the present study but should be included in future studies.

In the control group, we relied on that the subjects self-reported their hearing to be normal. Not testing the hearing in this group constitutes a possible methodological weakness. On the other hand, it allows us to collect data from a cohort that self-assesses their hearing to be normal. Still, including pure-tone audiometry and speech-in-noise tests would enable us to compare the two groups, even though previous studies have reported only weak correlations between speech-in-noise tests and the APHAB subscales being used as basis for the questionnaire we developed. The difference in age between the HA users and the control group was significant. Despite this, there was no correlation between age and outcome in the two groups. Nevertheless, future studies

should strive to collect data from a reference group comparable to the HA group regarding age and other demographic variables.

12.1.2 Paper II

When collecting data for this review we used three databases; Cinahl, Pub Med and Web of Science, including papers published in the period from January 2000 to March 2016. Additional papers could potentially have been found if we had performed a broader search, both for the timespan for publishing date and number of databases. However, after screening and reading a large number of papers (3280 papers in search # 1 and 1157 in search # 2) we possibly have found a representative selection of current knowledge on the fields. Also, we systematically scored the quality of the studies [159]. New knowledge is to some extent based on previous knowledge, and papers published in a timeframe of 16 years should be sufficient [175]. This suggests that the present systematic review also captures knowledge beyond the included timeframe.

In the present review we have included studies that have included adult persons with HL. QoL seem to be subject of change during different stages in life and difference in gender and age. Different methods in administering the questionnaires may influence the results, and should thus be taken into consideration [176]. HL seem to be more present in older persons and it is difficult to decide whether it is the HL or other confounding factors that affect QoL. When studying older adults by using self-reported questionnaires it is important to ensure that the participants have the cognitive capacity needed to understand and complete the questionnaire. We have not found studies in the present review that report on this matter. Most of the included studies, however, do not lend substantial support to the claim that demographic variables are of high importance concerning HL and QoL.

We did not systematically search the reference list of the included papers for additional papers. This could potentially have provided additional papers to this review. We acknowledge that this represents a weakness in our study design.

Differences in sample sizes, age of subjects, HL configurations and methodological presentations between studies made comparison of result between studies more complicated. In our systematic review we found different, and to some extent equivocal, trends in how HL affects QoL. These findings may suggest a need for more standardized instruments when measuring these matters. On the other hand, by having many instruments and methods available, researchers are given the opportunity to find the most suitable for the population being studied.

12.1.3 Paper III

Analyses were carried out in order to estimate the relative importance of included subjects' age on QoL. No clear pattern was found in the present data. Many studies concerning HL and general QoL have focused on studying elderly patients [165, 177, 178].

Presently, we have included subjects between 18 and 79 years primarily in order to minimize the influence of dement, or otherwise seriously ill patients. This may account for some of the discrepancies seen between our and other previously published findings. Gender is another example of demographic variables that may influence general QoL. Previous studies suggest no effect on general QoL in children with HL except in those with profound HL [179]. However, this changes in the adolescence, with a decline in general QoL for both genders but more pronounced in females [176]. This trend continues through adulthood for persons with a HL [177].

Many of the scientifically best-conducted studies regarding HL and general QoL have employed SF-36 as QoL measure. The SF-36 does not, however, cover a range of specific physical symptoms [167]. Other general QoL questionnaires could additionally be utilized in order to study whether HL affects a broader array of symptoms in persons with HL [164, 165, 167]. The presently employed general EORTC QoL questionnaire is an example of such a relatively broad questionnaire [180]. Despite this, no lowered general QoL was presently found among subjects with HL compared to a general control

group. It remains a possibility that general QoL instruments aimed to include variations within a relatively healthy population could have shown such differences.

Several studies concerning different diseases have shown a remarkably low impact of stable chronic disease or disability on perceived general QoL beyond two years observation [148, 181]. HL must be considered to be a chronic disability. Accordingly, this may also presently be the case as many patients had long duration of the HL. It is thus to some extent not surprising not to find reduced general QoL associated with HL. Therefore, a study of more recent HL onset and general QoL should be of interest. Furthermore, common co-morbidities may affect general QoL scores [174]. We have not determined any association between patient-reported common cardiovascular disease and diabetes on the one side and the general QoL scores on the other side. This further supports the definition of HL as a chronic disability in the present cohort.

HL may be unilateral or bilateral. Specific diseases that may cause unilateral HL are e.g. vestibular schwannoma [182] and chronic otitis media [183]. The present results suggest that reduced general QoL, e.g. social function, is associated with unilateral HL. Further analyses suggested that patients with vestibular schwannoma accounted for a substantial [182, 184], but not all of the shown differences in these patients. It should be of interest to study this more in detail.

As expected, internal associations in line with what is usually observed were determined between the different EORTC index responses adding to the validity of the study. In addition, strong internal associations were shown between the responses to the different items forming the APHAB score; also as expected. An association was determined between the APHAB scores and PTA scores, but not between the EORTC general QoL scores and the PTA scores. We have furthermore determined a present association between the reported APHAB scores and EORTC functional scores. Thus, as expected concerning the association between self-assessed communication ability as measured by the APHAB questionnaire and general QoL scores, an association was shown. Factor analyses, however, suggest that the APHAB and EORTC general QoL responses could

each be grouped according into separate factors. Thus, the content of the APHAB and the general QoL scores are mainly different. Stepwise regression analysis on the other hand showed that the PTA of the best ear together with the physical QoL scores best explained the APHAB scores. We cannot presently conclude about cause and effect of this association. It is generally best supported that the APHAB score is influenced by the perceived general QoL of the patient, but vice versa could also be possible. Thus, it is possible that, on an individual basis, there is a relation between self-assessed communication ability and general QoL.

Regarding justifying HL treatment, improvements in both general QoL and improved self-assessed communication ability are important outcome measures [80]. This constitutes an important challenge when baseline general QoL seems to be as close to the normal range at inclusion as presently determined. One suggestion to solve this problem is to use general QoL questionnaires with a so-called elevated ceiling where improved QoL beyond normal functioning may be measured. In any case, PROM questionnaires remain an important dimension of any patient treatment investigation. Previous studies have shown that psychosocial factors may be important determinants to individual general QoL scores [181] which should be further investigated. It is furthermore known that HL is associated with the level of distress [178]. Possibly, the adjustment by such factors will unravel underlying associations between HL and general QoL. This has been studied in paper IV.

We have used a general population control group studied by a previous version of the questionnaire [155, 156]. Some limitation can be stated because actual scoring was different regarding the functional scales going from two to four response alternatives in the two versions of the test used respectively. The scorings have, however, been re-calculated to percentages in both cases with the highest score being 100% and the lowest 0%. We have also previously published other patient group scores that validate the used control group scores comparing these two versions [148, 185]. In addition, the scoring concerning the “fatigue” index is identical in the two EORTC versions, which presently

yielded the same results as the functional scales. This also contributes to validity of the present calculations. We have also included two other former head and neck cancer patient groups who scored with four alternatives in order to validate the present QoL responses.

12.1.4 Paper IV

In the present study, both a limited number of respondents and low response rate should be taken into considerations when interpreting the results. With a larger number of representative subjects included in our sample together with multiple time points of data collection, some of the results might have been different. However, the findings in this study suggests strong correlation between psychological variables and QoL scores. We believe this add validity to the findings of this study. In a broader sense, the findings in the present study are being supported by equivalent results that have been presented in previous studies regarding other disabilities and QoL scores support that the present results are valid.

It is not surprising that psychosocial variables are associated to QoL scores. On the other hand, it is more surprising that the same is the case to some extent to the APHAB scores. Thus, in many instances the APHAB scores are generated similar to QoL. Obviously, this should be taken into consideration when interpreting APHAB scores, or the individual patient report about his or her perceived HL, as experienced in daily practice. Perceived hearing difficulties may be caused by more than mere auditory functioning.

When the questionnaire was designed to unravel direct consequences of reduced hearing, like the APHAB questionnaire, an association to reduced hearing has been shown. Intuitively the APHAB score should be dependent mainly on physical ability of hearing and the perceiving speech. As such, the APHAB score has also been shown to be associated with the PTA score. In addition, both neuroticism and lie personality traits were shown to be relevant as to the APHAB scores. This shows that speech perception

is more complexly generated than expected. These findings should be further investigated.

We have presently studied choice of coping by the TOMCATS questionnaire. The results show that higher reported use of "positive" expectancy was associated to lower distress and better QoL and APHAB scores, whereas reported more use of "no" or "negative" expectancy was related to lower QoL and more distress. We have, however, determined some overlap between the three defined choices of coping. Which coping strategy that is most strongly associated to the studied dependent variables is furthermore variable between the independent variables studied. In any case, the results show that emphasis on positive coping, and at the same time decreased passive or avoidant coping should be emphasized both regarding QoL, distress and as to understand of speech. This should be relevant among all HL-disabled individuals.

We have also shown that among patients with HL due to hereditary or congenital causes the associations between reported choices of coping and QoL scores are stronger than among patients with other causes of HL. This indicates that patients with early onset HL face more demanding tasks, and consequently should be more closely followed up in order to promote adequate coping.

One important issue that has been studied is whether psychosocial factor contribute to defer HL patients from seeking HA. This study has not been constructed to answer this question. Future studies need comparison possibilities to population scores of personality and preferred choice of coping. This should be a matter of future studies.

12.2 Summary of results and future research

12.2.1 Future studies

Our planned future studies will also include HRQoL data from other patient groups such as tinnitus patients, vestibular schwannoma and patients with cochlear implants (CI) in addition to the HL cohort presented in this thesis. Comparing different groups will contribute to more knowledge about HRQoL in these populations.

In the studies presented in this thesis, we have collected data from a single measure point. The findings suggest that there is no connection between duration of the HL and level of HRQoL. Still, we suggest that future studies should aim to have a longitudinal design, with measures before HA fitting and after e.g. six months, one year and after two years. This would provide more robust and valid data from this patient group.

In our studies, we included a limited number of HL patients. We also had a relatively low response rate. In order to get more robust data, we are planning to include a larger number of HL patients in our future studies, with a mix of patients with long duration of HL and patients with a more recent HL onset.

Our findings indicate that the revised version of the APHAB questionnaire is a valid measure self-assessed communication ability in quiet and adverse conditions. Even if this questionnaire may function well as a stand-alone questionnaire, we wish to perform further test of the questionnaire in order to investigate the potential as an outcome measure for HA fitting.

We have found that perceived stress and distress, psychological variables and coping style correlates to level of QoL. Some studies suggest that somatic and psychological states may improve by using psychological oriented actions, like cognitive behavioral treatment (CBT) [55]. Of interest is to investigate whether such actions may improve the use of HA. HL affects a considerable number of individuals, which implies that such actions must be easy to administer by health professionals.

Considering the difference between individuals as to how they perceive stress/distress, and how they respond to different situations or states, future studies should aim to cluster personality patterns or traits in the HL population, with the purpose to test different approaches to different groups or clusters. This may enable health professionals to provide a more tailored approach to persons suffering from HL, regarding use of HA and ISADs.

12.3 Implications for practice

As to how HL influence on QoL, we have presented findings suggesting that assessed QoL is related to personality. This suggest that a decline in QoL in HL patients may be co-explained by employed coping style and personality factors. These findings indicate a need for clinicians to collect PROMs data on these matters in addition to audiometric data. It may be difficult to predict how well people will react to amplification [186], and factors such as level of neuroticism may influence on how the patient explain or communicate the disease or illness being treated, which may influence on the quality of treatment given. Our results imply the need for other health professionals, such as psychologists, psychiatric nurses or psychiatrists in addition to ENT specialists and audiologists, to offer this patient group a more tailored treatment. Whether this results in increased QOL should be of interest for future clinical studies.

12.4 Ethical conciderations

The Norwegian Regional committees for Medical and Health research Ethics provided advance approval for the projects presented in this thesis. Project reference number have been provided in the papers were patient data were used (study I, III and IV). Throughout the work presented in this thesis, ethical aspects have been considered. When collecting data, we followed the research protocol, including that each patient could withdraw from the project at any time without justifying this, and without any consequences for their continued care at the hospital.

13. Conclusions

We have found that the revised and shortened version of the Norwegian translation of the APHAB questionnaire is a valid measure of self-assessed communication ability in both quiet and adverse listening conditions with and without HL. This questionnaire has potential as a stand-alone questionnaire, with subscales separately describing problems with communication in quiet and adverse situations.

In the systematic review we have performed, the findings were equivocal regarding the correlation between HL and generic QoL, and the effect of HA regarding improving generic QoL in HL patients. HL is a risk factor for distress. In those with severe or profound HL, there seems to be an elevated level of depression and anxiety.

We have found little difference in QoL scores in the HL population compared to those in the general population. The results from this study suggest there are little or no reduced QoL in those with a bilateral HL. Unilateral HL however, may be associated with reduced general QoL. An association was found between “physical” functioning QoL and perceived HL.

Psychological variables such as reported employed coping style, distress and personality/ HRQoL are closely, but complexly connected to each other. PTA from best ear predicted the APHAB score, as well as the GHQ score. We found that level of neuroticism was inversely associated to the outcome variables APHAB, GHQ, and QoL scores. Coping style was associated to the QoL and GHQ scores with “positive” expectations associated to better QoL and high scored “no” or “negative” expectations associated to lower QoL.

In overall conclusion, general QoL among patients with HL seeking HA seems to be close to population levels. Distress scores may be slightly elevated compared to population norms. QoL and distress scores and interestingly also APHAB scores seems also to depend on personality scores.

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RESEARCH ARTICLE Open Access

Generic quality of life in persons with hearing loss: a systematic literature review

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Abstract

Background: To the best of our knowledge, no empirically based consensus has been reached as to if, and to what extent, persons with hearing loss (HL) have reduced generic Quality of life (QoL). There seems to be limited knowledge regarding to what extent a hearing aid (HA) would improve QoL. The main aim of the present study was to review studies about the relationship between HL and QoL. A supporting aim was to study the association between distress and HL.

Methods: Literature databases (Cinahl, Pub Med and Web of Science) were searched to identify relevant journal articles published in the period from January 2000 to March 17, 2016. We performed a primary search pertaining to the relationship between HL, HA and QoL (search number one) followed by a supporting search pertaining to the relationship between distress/mood/anxiety and HL (search number two). After checking for duplications and screening the titles of the papers, we read the abstracts of the remaining papers. The most relevant papers were read thoroughly, leaving us with the journal articles that met the inclusion criteria.

Results: Twenty journal articles were included in the present review: 13 were found in the primary search (HL and QoL), and seven in the supporting search (HL and distress). The literature yields equivocal findings regarding the association between generic QoL and HL. A strong association between distress and HL was shown, where distressed persons tend to have a lowered generic QoL. It is suggested that QoL is lowered among HL patients. Some studies suggest an increased generic QoL following the use of HA, especially during the first few months after initiation of treatment. Other studies suggest that HA use is one of several possible factors that contribute to improve generic QoL.

Conclusions: The majority of the studies suggest that HL is associated with reduced generic QoL. Using hearing aids seem to improve general QoL at follow-up within the first year. HL is a risk factor for distress. Further research is needed to explore the relationship between HL and generic QoL, in addition to the importance of influencing variables on this relationship.

Keywords: Quality of life, Hearing loss, Impairment, Distress, Depression, Anxiety, Hearing aid

Background

In 2012, the World Health Organization (WHO) estimated that 360 million people, i.e. 5.3% of the world's population, were living with disabling hearing loss (HL), while around 15% of the world's adult population had some degree of HL [1]. Furthermore, sensory diseases have been estimated to be the world's second most common group of chronic disability when measured by years lived with disability [2]. HL increases with age, mostly because of age-related HL, generally referred to as presbyacusis. This term represents the sum of the environmental, sensory, metabolic and neural causes that to various extents are suggested to contribute to age-related physiological hearing loss [3, 4]. Presbyacusis cause reduced speech understanding in noisy environments, declined processing of acoustic information and impaired localization of sound sources [4]. Hearing loss is present in nearly two thirds of adults

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aged 70 years and older in the U.S. population [5]. Even though most people with HL suffer from presbyacusis, other factors such as other ear diseases [6], occupational noise exposure [7] and specific genetic diseases [8] may cause HL. Thus, HL may affect people at all ages and stages in life [9].

HL is often characterized by at which sound pressure level pure tones can be detected employing standard audiometric tests [3]. Presbyacusis typically causes a symmetric bilateral high frequency hearing loss. As human speech is related to relatively high frequencies, even a limited hearing loss at high frequencies may cause impaired speech intelligibility [10]. HL is often not curable, but hearing aids (HA) and other individual sound amplification devices (ISADs) may improve hearing function [11].

Patient reported outcome measures (PROMs), such as Quality of life (QoL) questionnaires, should ideally be systematically implemented in health care practices [12] as there seems to be a need for a more "holistic" approach within a modern view of health care. This calls for the inclusion of both disease-specific and generic QoL outcome measures [13]. QoL measures constitute important outcome- and state measures [14, 15], as well as an area of focus for research in its own right [14, 15]. However, there is no universally accepted definition for the concept of QoL [16, 17]. Even so, we all have a notion about what QoL is, and most people seem to have an intuitive understanding of their own QoL by referring to their own perception [16]. Thus, the concept QoL will hold different contents among different people [16].

WHO defines QoL as "An individual's perception of their position on life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards and concerns." This is a broad-ranging concept related to a person's physical health, psychological state, level of independence, social relationships, personal beliefs and their relationship to salient features of their own environment. The WHO QoL definition is closely related to the WHO's definition of health from 1948, which describes health as "physical, mental and social well-being, and not merely the absence of disease or infirmity" [16]. This is also a wide definition, in which in addition to a physical dimension, the WHO also includes well- being, environmental and psychological factors as part of health. Hence, both generic and disease-specific QoL become relevant as to disease and health [18].

Many different questionnaires have been developed with the intent of directly measuring the functional consequences of a disease; these may be termed "disease-specific" QoL questionnaires. Thus, QoL instruments intended to study the specific consequences of HL may be considered examples of such instruments [19]. The effect of HL on hearing function can usually be measured by hearing-specific questionnaires [20], but to what extent HL affects generic QoL is not well agreed upon and constitutes the main aim of this study.

The most commonly used generic QoL questionnaire is the SF- 36, with more than 13,000 "hits" on Pubmed as of 2016. The SF-36 measures functional status and wellbeing [21]. This questionnaire was first used in a provisional edition in 1988 and in a standard form in 1990 [22]. Shortened questionnaires have been developed from this original, i.e. the 12-item questionnaire SF-12 [23]. Another commonly used generic questionnaire is the Euro-QoL instrument (EQ-5D). This is a standardized questionnaire intended to measure generic QoL [24], and it may be utilized within a wide range of health conditions. The EQ-5D describes five dimensions: mobility, self-care, usual activities, pain/discomfort and anxiety/depression. An index value is calculated for each individual, ranging from 1, which indicates no problems in all five dimensions, to 15, which indicate severe problems in all five dimensions. Other generic questionnaires that may be used are the Health Utility Index (HUI) and the Sickness Impact Profile (SIP) [25, 26]. General parts of disease-related questionnaires, such as the European Organization for the Research and Treatment of Cancer (EORTC) Quality of Life Questionnaire (QLQ) may also be considered generic QoL instruments [27]. Disease specific questionnaires may also include some questions about generic QoL. However, generic QoL instruments measure many aspects of QoL, and are often intended for use over a wide range of diseases. Such questionnaires are often also applicable to healthy people. Thus, generic QoL questionnaires allow comparing QoL between patient groups, as well as to data from general populations [16, 28]. The specific main aim of the present study is to review the existing literature on generic QoL obtained by generic instruments among hearing-impaired patients.

In order to assess generic QoL within a disease context, important modulating factors known to contribute to QoL may be assessed alongside the QoL measure. This may include psychosocial factors [29], personality [30, 31] and factors related to activities of daily living [32]. To study potential modulating conditions in the relationship between HL and QoL has therefore been a supporting aim when reviewing the literature in the present study.

QoL as a construct seems to be closely associated with distress, anxiety, and mood, when measured primarily in generic, but also to some extent in disease-specific QoL questionnaires [20, 33–35]. Hence, it

should be of interest to study the impact of HL on distress, mood and depression. Anxiety and depression can be defined using standardized classification manuals such as the ICD-10 [36] or DSM-5 [37], while distress seems to have no such clear and universal definition. However, one may understand psychological distress as a unique discomforting, emotional state experienced by an individual that results in harm to the person, either temporarily or permanently [38]. In psychological research, distress is often quantified as the sum of anxiety and lowered mood [39]. Distress may also be utilized as an indicator of mental disease [39]. Thus, as QoL, distress, mood and anxiety are closely related concepts [40], we have conducted a search for the major publications on associations between HL and distress, anxiety and mood in order to present a more complete picture of the associations between HL and generic QoL.

Aim of this paper

So far, no empirically based consensus about if, and in case to what extent, HL patients have reduced generic QoL has been reached. The main aim of this study was to review studies on the relationship between HL and generic QoL published in the period 2000 to present day. As a supporting aim we have also determined noted psychological explaining factors reported in the above-identified publications. As an additional investigational tool, we have reviewed papers from the same period that study HL and distress, anxiety and mood. This was done because level of distress, anxiety and mood seems closely associated to generic QoL.

Method

Design

Data were collected using a systematized literature review design. We performed two separate searches for relevant papers. Search number one targeted HL, HA and QoL, whereas search number two targeted HL and distress, anxiety and depression. The Prisma 2009 checklist [41] was applied during the process of writing this paper, and is available as Additional file 1.

Searches

We suggest that literature produced over the past 15–16 years would contain most of the significant findings and results from prior studies [42]. Based on this, we set the time frame from the year 2000 up to the search date to obtain relevant literature. Moreover, we only included studies based on empirical data with an available abstract. To help narrow down the two searches in order to meet the specific aims of this study, we excluded studies concerning the hearing impaired peers or family or other caregivers. Other exclusion criteria were studies on deafness, persons with cochlea implants, dual or multi-sensorial loss, tinnitus, stigma and HL, assistive listening devices, bone-anchored hearing aids, HL and psychiatric disease, HA usage, sudden sensorineural HL, conductive HL and surgical interventions on HL. We also excluded qualitative studies as well as studies on psychiatric diseases and depression or anxiety prior to the HL.

Search number one - HL, HA and QoL

In the primary search, we included peer reviewed original papers in English published in the period from January 2000 to March 17, 2016 (search date). Studies on QoL or health-related QoL in adult persons with sensorineural hearing loss or presbyacusis were included.

To identify relevant studies, we performed a search in the databases Cinahl, Pub Med and Web of Science. We used combinations (AND) of the following keywords:

1. *Hearing disorders OR deafness OR hearing loss/ partial + OR hearing loss/sensorineural + OR Tinnitus AND hearing aid OR Hearing aid fitting AND hearing loss OR hard of hearing OR loss of hearing OR hearing impair* OR hearing disorder* OR deaf* OR hearing aid* OR hearing assistive technology.*
2. *Quality of life + OR Quality of Life OR health-related Quality of life OR HRQoL OR qol.*

A total of 3280 papers were found in the introductory search. After checking for duplications and screening the titles of the papers, 151 papers remained; Cinahl (n = 17), Pub Med (n = 43) and Web of Science (n = 91). After reading the abstracts, the remaining 35 papers were retained and thoroughly read. This left us with 13 journal articles that met the inclusion criteria (Fig. 1).

Search number two - HL and distress, anxiety and depression

From the supporting search we included peer-reviewed original papers in English published in the period from January 2000 to October 26, 2016 (search date). This search was aimed at studies on distress, depression and/or anxiety caused by the hearing impairment, in adults with sensorineural HL.

To identify relevant studies, we performed a search on October 26, 2016, using the databases Cinahl, Pub Med and the Web of Science.

A total of 1157 papers were found in the introductory search: Cinahl (n = 238), Pub Med (n = 325), Web of Science (n = 594). After checking for duplications, 908 papers remained. Screening the titles of the papers, reading abstracts and then thoroughly reading the most

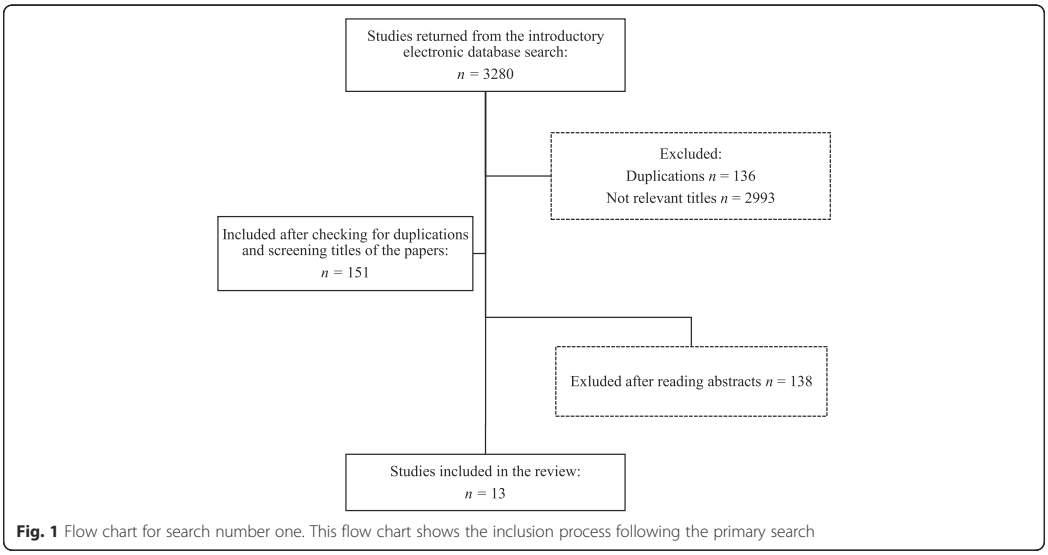

Fig. 1 Flow chart for search number one. This flow chart shows the inclusion process following the primary search

relevant papers left us with seven journal articles to be included in this review (Fig. 2).

Quality according to the Crowe critical appraisal tool (CCAT)

To assess the quality of the papers that met the inclusion criteria and thus were included in this review, we used the Crowe Critical appraisal tool (CCAT). The tool consists of a CCAT form and a CCAT user guide [43]. The CCAT form consists of nine category items. The first eight categories are scored from 0 to 5. The 9th item states the total sum score calculated from scores at categories 1 to 8. Thus, sum scores may range from 0 to 40 points. By using this tool, we had the opportunity to systematically assess the quality of the included papers. The sum score of the CCAT for each study is presented in Tables 1 and 2.

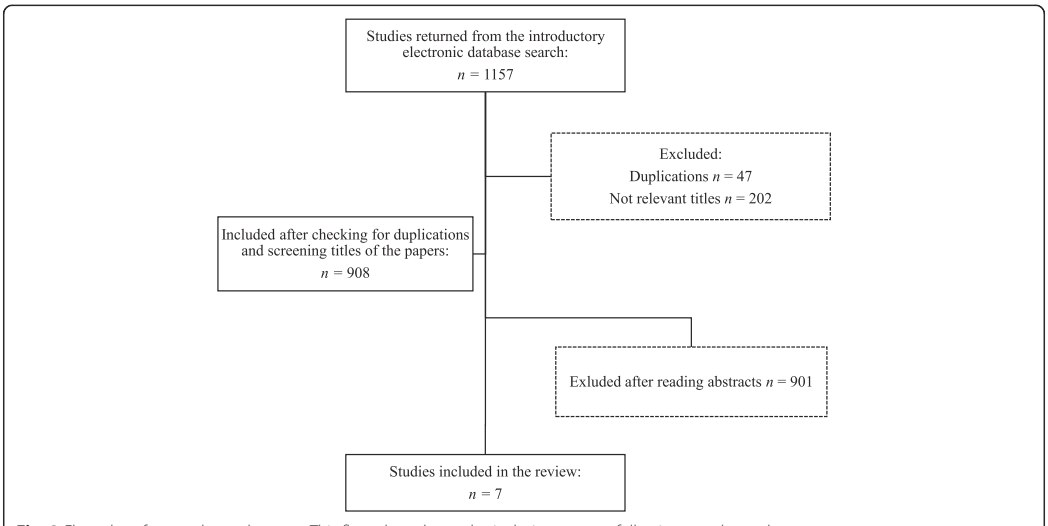

Fig. 2 Flow chart for search number two. This flow chart shows the inclusion process following search number two

Table 1 Included studies from the primary search

Study	Type of study	QoL Questionnaire used in study	First time/ experienced users?	Number of participants in study	Age	Unilateral or Bilateral HL	Range and character - HL	HA fitting	Results	CCAT score
Capoani Garcia Mondelli, M. F. and P. J. Soalheiro de Souza, 2012 [46]	Cross sectional/ Longitudinal	Generic WHOQOL - bref	First time	30 (57% male)	Range: 60–90 years, mean age 76.8 years	bilateral	Moderate hearing loss. No further definition.	Before HA fitting (ISAD) and after 3 months.	Using HA (ISAD) improved the overall QoL	25
Chew, H. S. and S. Yeak, 2010 [49]	Cross sectional	Generic: SF 36	First time	80 (41% male)	Range: 50 years and over. Median age 69 years	bilateral	>25 dB PTA in the better ear.	Not specified	SF-36 lacked specificity and sensitivity in assesing the impact on HL on QoL	21
Chia, E.-M., et al., 2007 [50]	Cross sectional	Generic: SF 36	Not specified	2431	Mean age: 67 years	Unilateral and bilateral	Unilateral HI defined as HI in one ear and no HI in the other ear. Bilateral HI defined as HI in both ears. HI defined as >25 dB PTA	Not specified	Unilateral HL: No significant difference in QoL than those whitout HL. Bilateral HL: Poorer QoL than those whitout HL.	27
Dalton, D. S., et al., 2003 [44]	5- year follow-up Longitudinal	SF-36 (Generic)	Not specified	2688, (42% male)	53–97 years, mean age 69 years	Not specified	Mild: 26–440 dB PTA HL in eighter ear. Moderate to severe: >40 dB PTA in eighter ear	Not specified	HL was associated with reduced QoL.	36
Espmark, A. K. K., et al., 2002 [47]	Cross sectional	HMS (26 questions, where 4 of 20 items where related to QoL)	First time	154 (38% male)	Born 1920 or earlier	Not specified	Three groups: Normal to slight HL: <30 dB PTA. Mild HL: 30–39 dB PTA. Moderate to severe HL: ≥ 40 dB PTA	Not specified	HL was significantly associated with reduced QoL in all four dimensions in females and in two of four in males.	27
Hallberg, L. R., et al., 2008 [51]	Cross sectional	PGWB	Mixed	79 (39% male)	48–92 years, mean age 68.7 years	Bilateral	PTA low at Freq. 0.5, 1 and 2 kHz was 39.6 dB. PTA high at Freq. 2,3,4 and 6 kHz was 55.5 dB	Not specified	HL was significantly associated with reduced QoL. Psychsocial consequenses of HI, such as lowered QoL, cannot be predicted from audiometric data alone.	33
Helvik, A. S., et al., 2006 [52]	Cross sectional	PGWB	Mixed, mean duration of the HI was 15.1 years	343 (55% male)	21–94 years, mean age 69 years	Not specified	Mean threshold of hearing for the total sample was 43.0 dB	Not specified	Psychological well-being was associated with activity limitation and participation restriction, but not with the degree of HL	28

Table 1 Included studies from the primary search *(Continued)*

Study	Type of study	QoL Questionnaire used in study	First time/ experienced users?	Number of participants in study	Age	Unilateral or Bilateral HL	Range and character - HL	HA fitting	Results	CCAT score
									and use of communication strategies	
Lotfi, Y., et al., 2009 [48]	Cross sectional/ Longitudinal	HHIE	First time users	207 (71% male)	*60 years, mean age 73.01 years	Not specified	Moderate HL: 56–70 dB Profound HL: 71–90 dB	Before HA fitting and after 3 months	Significant improvement in QoL after HA fitting	19
Meyer, J. M. and S. Kashubeck-West, 2013 [55]	Cross sectional	HHIA and The meassure of psychological well-being (generic)	Not specified	277 (25% male)	18–65 years Mean age 49 years	Not specified	Not specified	Not specified	Relationship between perceived severity and perceived disability acted as direct predictors to well-being and as a indirect predictors through their relationship with coping. No significant association between QoL and HL	30
Miyakita, T., et al., 2002 [54]	Cross sectional	Generic, LISZ, 13 questions about QoL	Not specified	210 retired workers, gender not specified	56–65 years, mean age 60.6 years	Not specified	Not specified	Not specified	Hearing disabillities was associated with deterioration in QoL. No significant association between QoL and HL	23
Niemensivu, R., et al., 2015 [45]	Prospective study Including control group	Generic 15D	First time HA	949 with HI (42% male), Control group 4685 persons	Mean age: 73.8 years	Not specified	Frequencies 0.5,1,2 and 4 kHz. Four categories of HL. Mild: 25–40 dB, moderate: 41–70 dB, Severe 71–95 dB and very severe: >95 dB.	Before HA fitting (in the better ear) and after six monthts	Significant improvement in QoL after unilateral HA fitting	29
Stark, P. and L. Hickson, 2004 [53]	Cross sectional/ Longitudinal	Generic SF- 36	First time HA	131 (67% male)	47–90 years, mean age 71.7 years	Not specified	Not devided in groups. PTA at 0.5, 1 and 2 kHz in the better ear.	Before HA fitting and after 3 months	No significant improvements in HRQoL after HA fitting.	30

Table 1 Included studies from the primary search *(Continued)*

Study	Type of study	QoL Questionnaire used in study	First time/ experienced users?	Number of participants in study	Age	Unilateral or Bilateral HL	Range and character - HL	HA fitting	Results	CCAT score
							25 dB or less: *n* = 18 26–35 dB: *n* = 44 36–46 dB: *n* = 23 46–55 dB: *n* = 8			
Vuorialho, A., et al., 2006 [56]	Cross sectional/ Longitudinal	Generic EQ-5D in combination with HHIE-S	First time HA	98 (50% male)	61–87 years (median 77 years)	Not specified	Not specified	Before HA fitting and after 6 months	No s ignificant QoL i mprovement after HA- fitting	30

EQ-5D EuroQol Group- 5 Dimensions
SF- 36 Medical Outcome Study (MOS) Short Form- 36 Health Survey Scale
15D 15 Dimension (a standardized self-administered measure of Health related Quality of Life)
LISZ Life Satisfaction Index, version Z
HMS Hearing Measurement Scale
PGWB Psychological General Well Being index
WHOQOL – bref Abbreviated version of the WHO QoL- 100 Quality of Life assessment
HHIE/HHIA Hearing Handicap Inventory for the Elderly/Adults
HHI-S HHIE - Screening version

Results

HL and generic QoL

The range of HL was presented differently in the included studies. Five studies presented HL in groups from mild to severe HL [44–48] and five presented the number of participants over different hearing range groups [49–53]. Three studies gave no information on this [54–56]. Still, it seems that in most of the included studies, the lower limit of hearing loss was defined by a mean hearing loss exceeding 25 dB HL in the better ear at the octave frequencies from 0.5 to 4 kHz [57] (Table 1).

The included studies have used self-report questionnaires concerning QoL in adult persons with HL. The number of participants varied from 30 to 2688 (Table 1). Of the 13 studies included, 11 studies were cross-sectional, one was longitudinal [44] and one was prospective [45]. Seven studies used a generic QoL questionnaire [45, 46, 49–52, 54]. Two used a disease-specific QoL questionnaire only [47, 48], while the remaining four studies used a combination of generic and disease-specific questionnaires (Table 1). Four studies used the SF-36 in order to measure generic QoL, of which three employed the SF-36 alone [44, 49, 50]. One study combined SF-36 and a disease-specific questionnaire, the Hearing Handicap Inventory for Elderly (HHIE) [53].

In general, two of the included papers concluded that HL is substantially associated with a reduced QoL [44, 54], whereas six claimed there is a weak correlation [47, 50–53, 56] and five no [45, 46, 48, 49, 55] significant correlation between HL and generic QoL.

One study investigated both unilateral and bilateral hearing loss (HL) [50], three studies reported bilateral HL only [46, 49, 51] while the remaining nine studies provided no information on this matter. In the study that reported both unilateral and bilateral HL, persons with unilateral HL did not report significantly lower generic QoL than persons without HL. In one study, worse hearing at the high frequencies in male patients than in female patients was reported [51]. Despite this, the males had significantly better scores on generic QoL compared to the females. Furthermore, non-verbal behavior that alleviates the consequences of HL on generic QoL, such as pretending to hear, guessing what was said and avoiding interactions, was reported less used by men than by women [51].

In one study, the disease-specific questionnaire (HHIE) and the SF-36 questionnaire were employed [49]. These authors suggests that the SF-36 form lacks sensitivity and specificity in assessing the impact of HL on QoL, and suggests that untreated HL results in a significant decline in QoL, as measured with the HHIE questionnaire.

A study based on a relatively small population of 30 individuals, suggested that Individual Sound Amplification Devices (ISADs) improved the overall QoL of the individuals assessed [50]. At the same time, poor social relationships and coping skills were risk factors for

Table 2 Studies included from search number two

Authors	Type of study	Hearing loss and Distress OR anxiety OR depression	Sample size and gender	Age	Results	CCAT score
Gopinath, B., et al. (2012) [62]	Survey	Distress	811 (control group = 687) No data on gender	≥ 55 years	Older patients with HL are significantly more likely to experience emotional distress directly due to their HL.	31
Nachtegaal, J., et al. (2009) [61]	Cross-sectional	Distress, depression	1511 No data on gender	18–70 years. Divided into 5 age strata (18–29, 30–39, 40–49, 50–59 and 60–70 years)	HL is negatively associated with higher distress, depression, somatization and lonliness in young and middle- aged groups.	33
Tseng, C. C., et al. (2016) [58]	Longitudinal	Depression	1717 (control group = 6868) 55% male	39–63 years. Median = 51 years	Patients with sudden sensorineural hearing loss (SSHNL) are 2.17 times more at risk for depressive disorders, compared to those without SSNHL. Especially in age groups ˂ 60 years.	29
Li et al. (2014)	Survey	Depression	18,318 Male = 48%	Adults 18 years or older. 18–44 years: 49.4% 45–69 years: 39.1% ≥ 70 years: 11.5%	HL is significantly associated with depression, particulary in women and those younger than 70 years.	25
Kramer, S. E., et al. (2002) [63]	Longitudinal (part of the LASA- study)	Depression and other chronic diseases	1506 (in the LASA- study)	55–85 years	Elderly with HL report significantly more depressive symptoms, in addition to negative association to other psychosocial variables.	20
Cetin, B., et al. (2010) [60]	Prospective	Depression and anxiety	90 (contol group = 90). All participants were male, military personel	21–30 years Mean age = 21.72 years	Higher level of depression and anxiety in the patient group, compared to the control group in the study. The duration of the HL was positevely correlated with anxiety and depression.	20
Carlsson, P.-I., et al. (2015) [24]	Retrospective	Depression and anxiety	1247 mean age = 67 years. Male = 51%	19–101 years, mean age 68 years	This study indicate greater levels of anxiety and depression among patients with severe or profound HL, than in the general population.	32

reduced QoL. The study suggested that HL is one of several reasons why the elderly have depression, anxiety or other noxious emotions.

The authors of a study that investigated the effect of age at HL onset suggested that late onset HL seem to be negatively correlated to QoL [24]. That is, people who are born with HL or acquire HL in younger years seem to adapt to their HL better, without the HL affecting their QoL in adult life. This study also found that the education level was lower in persons with HL, as only 14% of the participants had university-level education [24].

One study found that there probably is an indirect connection between HL and lower QoL. The authors explain this with a decline in general health that may occur with increased age [50]. This is supported by a study that included subjects with an average age of 71.7 years that found that older people have more health problems in general. Moreover, this study suggests that QoL has many modulating factors, with HL being one of those

factors [53]. Furthermore, this study suggests that it is important to understand the synergetic effect of present co-morbidities. This latter point is also addressed by a study that suggests that a varying perception of HL may be influenced by general life circumstances, and that one should not ignore the synergetic effect of multiple co-morbidities on the generic QoL scores [49].

HA use and generic QoL

Five studies measured QoL before the HA fitting, as well as after three [46, 48, 53] or six [45, 56] months following HA fitting. Four of these studies used generic questionnaires to measure QoL, while one used a disease-specific questionnaire [48]. There seems to be evidence that using HA alleviates HL and improves the quality of social relationships. The study conducted by Stark and Hickson [53] showed that the degree of HL, and extent of HA use, seems to be important for improved hearing-specific QoL. However, no significant improvement in generic QoL was reported in this study. The two other studies where QoL was measured after 3 months [46, 48], showed an improved QoL after using HA. In the two studies where QoL was measured after 6 months, one study reported that generic QoL measures yielded equivocal results [56], perhaps due to the sensitivity of the questionnaire being used. The other study [45] suggests a marginal improvement in generic QoL in adults with HL after using HA.

HL and distress, anxiety and/or depression

In the included studies, self-report questionnaires concerning distress, anxiety or depression were collected from participants who were adult persons over 18 years with HL. The number of participants in the studies varied from 90 to 18,318 (Table 2). The gender distribution reported varied from 48 to 55% male participants [24, 58, 59]. One of the studies only had male participants [60] (see Table 2). Three studies [59, 61, 62] used data collected from large population surveys, in which data on the correlation of HL and anxiety, depression and/or distress were available. Two of the studies were based on data collected from a national health register [24] or a database [58]. The remaining two studies had data collected from a prospective study [60] and a longitudinal study [63]. The study conducted by Nachtegaal et al. [61] presented results on both distress and depression, whereas Gopinath et al. [62] presented results from distress. The rest of the included studies presented results on anxiety and depression [24, 58–60, 63]. In these studies, associations between HL and distress, anxiety or depression were only part of the results and conclusions about factors negatively associated with HL.

Of the two included studies on distress, one study suggested that hearing loss is associated with higher distress and present depression. For every decibel increase in signal to noise ratio (SNR), the distress score increased by 2%, while the odds for developing moderate or severe depression increased by 5% [61]. The other study suggested that older HL adult patients are significantly more likely to experience emotional distress [62].

In a study conducted by Hallberg et al. [51], the authors suggest that the psychosocial consequences of the HL cannot be predicted from audiometric data alone, but must be seen in the context of coping strategies, such as communication strategies. In one of these studies, two of the exclusion criteria were dementia and psychiatric disease [49], while one study used limited psychiatric disease as an exclusion criterion [46].

In general, there seems to be significantly higher levels of both anxiety and depression in patients with severe or profound HL compared to a reference population. This seems to be the case even when taking into consideration that some of the patients may have developed anxiety or depression prior to the onset of HL [24]. The duration of HL seems to be positively correlated with anxiety and depression levels, thereby suggesting that the longer the amount of time with HL, the higher the levels of anxiety and depression [60]. However, many of the studies conclude that this conclusion is best supported among females and younger individuals [58, 61].

In conclusion, there seems to be a strong association between HL and depression [58, 59, 63], particularly in women and those younger than 70 years [58, 61]. Anxiety [24, 60] and distress [61, 62] also seem more prevalent among patients with HL. Thus, there is highly likely an association between distress and HL.

Discussion

The literature included in this review yield equivocal findings regarding the association between generic QoL and HL. Some authors argue that there are strong associations [44, 54], while others find less strong [47, 50–53, 56] or no relationships at all [45, 46, 48, 49, 55]. All the included studies on associations between distress and HL give firmly support to such a conclusion, in particular concerning depression among younger individuals [58, 59, 61].

One of the two studies with the highest number of subjects, supported an association between generic QoL and HL and focused on older adults [44]. These subjects showed more severe HL the older they were. The association between increased age and severity of the HL in this study makes it difficult to conclude whether the age or the HL caused the change in generic QoL. Furthermore, when studying older adults by the use of self- reported questionnaires like a QoL questionnaire, it is important to ensure that the informants have the

cognitive capacity needed to understand and complete the questionnaire. We have found no report concerning this matter in any of the published studies included in this survey. This should be a matter of future improvement of the investigational design.

Age is an example of a demographic variable that may influence generic QoL [32]. Therefore, such variables should be reported, and analyses carried out in order to estimate the relative importance of these variables. Furthermore, one should preferably adjust the QoL scores by these variables as additional analyses. This has to some extent been reported within the included papers, but no exhaustive study on this matter has been presented. Most of the included studies, however, do not lend any substantial support to the claim that demographic variables are of high importance concerning generic QoL and HL.

HL may be unilateral or bilateral. Standard procedure would be to report hearing levels from the least affected ear [64]. Nevertheless, to differentiate between the two conditions should be of importance and this was done in one investigation [50]. It should be of interest to study subjects with unilateral HL more extensively in order to acquire knowledge of any impaired QoL in this group.

Many of the studies yielding the highest CCAT-scores employed SF-36 as QoL measure, which only to some extent represents a generic HRQoL instrument. The SF-36 does not cover the full range of QoL. General symptoms are not covered [49]. More specifically health related QoL generic questionnaires could additionally be utilized in order to study whether HL affects a broader array of symptoms in persons with HL [44, 49, 53].

The associations between HL and distress, anxiety and depression are better documented than the general relationship between QoL and HL. Many factors may explain this relationship. HL may be the causative factor secondary to the social isolation caused by HL. Furthermore present comorbidity may explain both. This needs to be studied further. Distressed persons are expected to have lowered generic QoL [40]. Therefore, solely based on this association, generic QoL is suggested to be lowered among HL patients.

Regarding justifying HL treatment, improvements in both generic and disease-specific QoLs are important outcome measures, both clinically and for researchers [20]. To what extent individuals with untreated HL have lower generic QoL [49] is therefore interesting to study. A low generic QoL baseline subsequently improved after treatment constitutes an excellent HA treatment argument. A low baseline QoL among HL patients would also lend support to offering a larger range of treatments to this group beyond fitting a hearing aid [65]. The studies where generic QoL were measured following HA fitting after 3 months [46, 48, 53] or 6 months [45, 56] show equivocal findings. Some of these studies suggest increased generic QoL caused by the use of a HA, while other studies explain HA use as one of several possible factors that leads to better generic QoL. In conclusion, future generic QoL studies should be encouraged since a firm conclusion about HL and generic QoL has not yet been reached.

Despite the fact that HL may cause poorer generic QoL, and that using a HA may improve generic QoL, some studies suggest that many who are fitted with HAs, used their HA only to a limited degree [66]. This may be caused by the patients not receiving sufficient help and follow-up to master the HA [67]. Other studies on treatment show that HAs are an important contributor to increased QoL in HL patients [65]. Some studies suggest that using HAs over time seems to reverse the adverse effects of HL on QoL [62]. The process of HA fitting may also carry a placebo- effect. If so, this could also indicate that, as previously suggested [33, 68–70] concerning other diseases, generic QoL to a large extent mainly originates from the personality and thus stays more or less stable, regardless of the severity of HL.

We suggest a need for including both PROMs and physical measures in all hearing assessments [50]. Many modern HAs have the capability to log the actual use of the HAs in addition to the patient's self-reported use. By collecting both physical and QoL data repeatedly, more robust data would be available to evaluate the strength of the relationship between the actual use of HAs and eventual improvements in QoL. By including control groups within research, one could in addition obtain more conclusive answers as to whether an improved QoL following HA fitting may be considered a Hawthorne effect [71], i.e. if the QoL improvement during HA fitting is due to the attention in this period.

For researchers, it also seems reasonable to measure additional potentially explaining variables, at several time points, when trying to determine what affects the QoL in persons with HL. Such screening would provide the opportunity to unravel why and to what extent patients with HL has lowered QoL, or even psychiatric disease. This could provide important clues on how to better help these patients. Systematic studies of HL treatment, with this perspective included, could likely provide evidence on how to better the health care services for patients with HL.

Data were collected using a literature review design with the aim to identify relevant literature published from the timespan 2000–2016 concerning patients with HL and the evaluation of their generic QoL. When using a limited time span there will always be a risk of missing important publications. This represents a possible weakness in our study that could have been overcome by extending the timespan to include previous years.

Furthermore, we did not systematically search the reference list of the included papers for additional papers. This may have provided additional relevant papers and this represents a weakness in our design. Also, differences in sample sizes, age of subjects, hearing loss configurations and methodological presentations between studies complicated the comparison of results between studies.

Conclusions

The main aim of this study was to review studies about the relationship between HL and QoL. Results of our review show that the majority of such studies suggest that HL reduces QoL. Those studies that also measured QoL after fitting of HAs suggest that HA fitting to some degree improves generic QoL at follow-up within the first year. A supporting aim was to review studies on the relationship between HL and distress, anxiety and mood. Results of our review show that HL is a risk factor for distress. We suggest that systematic studies of HL treatment, with a QoL perspective included, could provide evidence on how to better the health care services for patients with HL. As a consequence of our findings we suggest a need for including both PROMs and physical measures in persons with hearing loss, both at baseline and as outcome measures. Further research is needed to explore the relationship between HL and generic QoL, as well as the importance of various influencing variables on this relationship.

Additional file

Additional file 1: PRISMA 2009 Checklist. (DOC 62 kb)

Abbreviations

HA: Hearing aids; HL: Hearing loss; ISAD: Individual sound amplification device; PROM: Patient reported outcome measure; QoL: Quality of life

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Availability of data and materials

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Authors' contributions

ØN performed the literature search and read all abstracts. ØN and PH read relevant papers to identify those that met the inclusion criteria. ØN wrote the initial results section. ØN and PH wrote an initial manuscript based on these results. JB, FV, AKA and HJA contributed substantially to the revision of all parts of the initial manuscript. All authors read and approved the final manuscript.

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