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Implementation of uHear™ - an iOS-based application to screen for hearing loss - in older patients with cancer undergoing a comprehensive geriatric assessment

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ABSTRACT

Objective: Validation of uHear™ as a screening tool to detect hearing loss in older patients with cancer without a known diagnosis of presbycusis, as part of a Comprehensive Geriatric Assessment (CGA).

Materials and methods: Patients (≥ 70 years) with a histologically confirmed diagnosis of cancer, were enrolled at the time of CGA screening. Patients were evaluated by uHear™, which was compared to conventional audiometry as gold standard. We defined a pure-tone average (PTA) of ≥ 40 dB HL as the pass or fail screening cut-off. Validation of uHear™ was defined in terms of diagnostic accuracy through Receiver Operating Characteristics (ROC)-analysis. To accept uHear™, we estimated that the Area Under the ROC-curve (AUC) had to differ significantly from 0.50 with an AUC of at least 0.70. The Whispered Voice Test and Hearing Handicap Inventory for the Elderly were also administered.

Results: Thirty-three patients consented for participation. In one patient, the results of one ear were excluded from the analysis as the patient was documented with a known hearing disorder in that ear. Significant hearing loss, defined by a PTA of ≥ 40 dB HL calculated from the air conduction thresholds at 0.5, 1.0 and 2.0 kHz, was found in 15.4% of tested ears. uHear™ showed excellent diagnostic accuracy with an AUC $\pm$ SE of 0.98 ± 0.14 . It provided maximum sensitivity (100.0%) but poor specificity (36.4%) at our predefined cut-off score of ≥ 40 dB HL.

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Conclusion: uHear™ can be implemented as a screening tool to detect hearing loss in older patients with cancer within a CGA.

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1. Introduction

The cancer incidence is 11-fold higher in patients aged 65 or more than in their younger counterparts¹. Some older patients may tolerate treatment as well as younger patients, although others might suffer from severe toxicity and may require treatment modifications. For this reason, it is crucial to identify those patients who have an increased risk of developing toxicities². Selecting proper treatments solely based on the information the physician retrieved during the appointment is a very difficult task. Therefore, a comprehensive geriatric assessment (CGA) has been the key to individualized care in older patients with cancer^{3,4}. A CGA is a multidisciplinary evaluation assessing medical, psychosocial and functional capabilities and limitations in older patients with cancer. It aims at predicting the functional age of patients including the risk on morbidity and mortality through assessing a wide range of domains such as functional status, cognition, nutrition, emotional status, polypharmacy, comorbidities and sensory dysfunctions including vision and hearing^{5–8}.

Presbycusis is a common problem among older people, affecting 90% of the people aged 80 and older⁹. It is estimated that at least 40% of people aged 65 years and older present with a hearing loss important enough to impair communication¹⁰. Acoustic deterioration can lead to social isolation¹¹, seriously affecting patients' ability to function properly whilst difficulties with communication can lead to a significant reduction in quality of life. In addition, poor hearing reflects whether the patient is able to hear instructions regarding potential adverse events, supportive care medications and indications of when to seek medical care^{12,13}. A formal audiogram has been proposed as the gold standard to define patients' hearing status¹⁴. However, such assessment is time-consuming and requires additional appointments, which may be cumbersome for patients with cancer who already need to spend a lot of time in the hospital. Further, many physicians have little or no time to screen for hearing loss, which urges the necessity of a quick and simple screening tool¹⁵.

The content of a CGA is mainly based on the National Comprehensive Cancer Network (NCCN) Guidelines in Older Adult Oncology⁸. As mentioned, NCCN recommends to assess not solely functional domains, but they state that it is also important to take sensory dysfunctions such as vision and hearing, into account. To screen for hearing loss, NCCN advises a whispered voice test in which patients need to occlude an ear while the investigator whispers following sentence: "What is your name?". The patient passes if he hears the sentence and is able to answer it. He fails when he doesn't succeed in this task. The test is repeated for the contralateral ear⁸. In this paper, we will use the validated Whispered Voice Test (WVT) as screening tool recommended by NCCN. The WVT has been validated in several studies in non-cancer subjects, and thus not in our target population, but has shown a good sensitivity, specificity and Area Under

the Receiver Operating Characteristics (ROC) - Curve (AUC)¹⁶. However, various outcomes have been reported especially due to the inter-rater reliability, possibly caused by differences in loudness of the whispering, and thus decreasing the usability of the WVT in clinical practice¹¹.

The last decade, the use of multimedia applications has increased dramatically. More than six billion cell phones have been sold globally. This consumer-driven demand has led to changes in the society where almost everyone can afford a hand-held computer and communication device. With this growing technology, there are many cultural and infrastructural reasons to adopt cell phones as a vehicle to improve health care¹⁷. uHear™ was designed by Don Hayes and runs on iOS devices such as iPod, iPad and iPhone. It is easily accessible, free and fast to assess. uHear™ is an ear-level pure-tone hearing test designed to determine air conduction thresholds in each ear independently. The app has been validated for use in a general population and has shown good performance scores in ruling out moderate hearing loss^{18,19}. In this trial, we aimed at validating uHear™ as a screening tool for hearing loss specifically in older patients with cancer as part of a CGA.

2. Materials and Methods

2.1. Patient Selection

The registered UHEAR-trial was conducted in older patients with cancer at the radiotherapy and oncology departments of the General Hospital Groninge (Kortrijk, Belgium) from December 2014 till June 2015 (UHEAR-trial; clinicaltrials.gov identifier: NCT02381782). An ethics committee approval was obtained from the ethics committee of the General Hospital Groninge. Patients were recruited upon presentation at the geriatric oncology clinic, where we try to evaluate all patients with newly diagnosed cancer, when they received a CGA as part of routine clinical practice^{7,20,21}. Eligible patients were at least 70 years old at time of enrolment and needed to have a histologically confirmed diagnosis of a solid cancer or hematologic malignancy. Any type of treatment and any type of stage were allowed. Patients had to be cognitively able to perform assessments. Ears of patients with a known hearing loss, fitted with hearing aids, clinically diagnosed with Meniere's disease, retrocochlear hearing loss, autoimmune inner ear disease, fluctuating hearing loss or a history of sudden sensorineural hearing loss were excluded from analyses.

2.2. Comprehensive Geriatric Assessment

Hearing tests were assessed as part of a CGA. In routine practice, patients are screened with the Geriatric-8 questionnaire (G-8). A cut-off of ≤ 14 was applied²². Patients who screen negative are deemed fit and are not assessed with

a full CGA. However, for uniformity purposes, we aimed at assessing all negative screening patients with a complete assessment in this trial.

The CGA comprises following standardized measures asides to specific questions regarding social status: functional status (Activities of Daily Living, Instrumental Activities of Daily Living^{23,24}), physical status (number of falls), nutrition (Mini Nutritional Assessment - Short Form²⁵), emotional status (Geriatric Depression Scale - 15²⁶), cognition (MMSE or Freund CDT^{6,27,28}), polypharmacy (number of drugs) and comorbidities (Charlson Comorbidity Index²⁹). Patients were deemed vulnerable if they presented with impairments in two or more domains within the CGA^{20,30,31}.

2.3. Audiologic Evaluation

All audiologic measures were performed by a trained and certified audiologist.

2.3.1. Immitance Measurement and Pure Tone Audiometry

A 226 Hz tympanometry was performed with an 85 dB sound pressure level probe tone (Zodiac 901 Middle-ear Analyzer, Madsen Electronics). Pure tone audiometry was conducted in a sound booth by use of a recently calibrated Interacoustics AC3 audiometer. The Hughson-Westlake technique was applied. Air conduction thresholds were established for conventional octave frequencies ranging from 0.25 kHz to 8.0 kHz.

2.3.2. uHear™

uHear™ (version 2.0, Unitron, Victoria, BC, Canada) was performed by use of an iPod touch (iOS version 8.1.2, Apple Inc., Cupertino, California, USA). Standard iPod touch ear buds were used. Testing took place in a quiet hospital room or physician's office. The application contains three modules. In this trial, we used the sensitivity test to determine air conduction thresholds at 0.5, 1.0, 2.0, 4.0 and 6.0 kHz, measured in each ear separately. uHear™ uses a 267 ms pulse duration and employs a simple 10 dB down and 5 dB up approach. The lowest threshold with two responses out of three excursions is recorded as the hearing sensitivity¹⁸.

2.3.3. Whispered Voice Test

The WVT was performed by the audiologist when standing behind the patient in a quiet hospital room or physician's office. The patient had to repeat a set of three different numbers at four decreasing levels of loudness per ear: conversational voice at six inches and at two feet from the ear, and whispered voice at six inches and at two feet from the ear while the patient occluded the external auditory canal of his non-tested ear. The investigator exhaled completely prior to testing in order to ensure an equal intensity level in all assessments. A pass was given if the patient could repeat all three numbers correctly at each level of loudness or if he achieved greater than 50% success over three successive triplet sets. Failure to pass at each level of voice testing is considered indicative for hearing impairment¹⁶.

2.3.4. Hearing Handicap Inventory for the Elderly

The Hearing Handicap Inventory for the Elderly (HHIE) has been developed as a self-assessment tool to assess the impact of hearing loss on the emotional and social adjustment of older patients. It consists of a 13-item subscale based on emotional side effects and a 12-item subscale exploring social and situational consequences. The HHIE score ranges from 0 to 100 with a cut-off score of ≥ 43 indicating a significant perceived handicap. Scores ranging from 17 to 42 indicate a mild to moderate perceived handicap^{32,33}.

2.4. Statistical Analyses

Statistical analyses were conducted by use of SPSS software (version 22; IBM SPSS Statistics, Chicago, IL) and Prism® software (GraphPad Prism 5, Inc., La Jolla, CA). Descriptive statistics were performed to present patient and tumor characteristics. Descriptive statistics were further conducted to present assessment results of both CGA and hearing tests. The Pure-Tone Average (PTA) was calculated as the average air conduction threshold found at 0.5 kHz, 1.0 kHz and 2.0 kHz. We defined a PTA of ≥ 40 dB HL as the pass or fail screening cut-off as this was proposed by Ventry and Weinstein for individuals aged 65 years or older³⁴. Since data did not meet the criteria of normality, Wilcoxon matched-pairs signed-ranks test was used to compare uHear™ and conventional audiometry thresholds. A priori sample size calculations were based on literature review and following assumptions^{9,10}. We assumed that conventional audiometry was the gold standard against which uHear™ was compared. A diagnostic test with an AUC of 0.50 has no diagnostic value (comparable to tossing a coin). We would therefore only accept uHear™ if the AUC significantly differed from 0.50 at the 5% significance level. We aimed to include 63 eligible ears. A sample of 25 from the positive group and 38 from the negative group would achieve 80% power to detect a difference of 0.20 between the AUC under the null hypothesis of 0.50 and an AUC under the alternative hypothesis of 0.70 using a two-sided z-test at a significance level of 0.05. The data are discrete (rating scale) responses. The AUC is computed between false positive rates of 0.00 and 1.00. The ratio of the standard deviation of the responses in the negative group to the standard deviation of the responses in the positive group is 1.00. Sensitivity (Se) and specificity (Sp) with 95% confidence intervals (95%CI) were calculated at our predefined cut-off score. Positive and negative predictive values were also determined (PPV and NPV, respectively).

3. Results

3.1. Patient Characteristics

In total, 34 patients consented for participation. One patient withdrew during the testing phase due to deterioration of the overall condition. Of the remaining 33 patients or 66 ears, the results of one ear were excluded from the analyses as the patient presented with a known hearing disorder in that ear.

Patients had an average age of 76.4 years (range 70–85). The majority of patients were males (69.7%). Patients presented with a cancer diagnosis of following sites: hematologic malignancy (33.3%), genitourinary (27.3%), gastro-intestinal (15.1%), breast (9.1%), head and neck (9.1%), gynecologic (3.0%) and thoracic sites (3.0%). Most patients received systemic treatment (51.5%) and were treated with palliative intent (57.6%) (Table 1).

Patients presented with a mean G-8 score of 14.2 (range 7.0–17.0). The majority of patients (57.5%) screened negative on the G-8 and were considered 'fit'. In all but two patients, cognition was assessed through either MMSE or Freund CDT. All of those (100%) were considered as cognitively adequate. One patient participated in a trial by our group in which a full neuropsychological evaluation is performed. He showed good cognitive functioning (data not shown). One patient did not undergo any form of cognitive screening as he screened negative on the G-8 and no full CGA data were obtained.

3.2. Conventional Audiometry vs. uHear™

Tympanometry results were not obtained in five ears since occlusion of the ear canal failed. Most patients presented with normal tympanograms (Table 2). Mean pure-tone air conduction thresholds per frequency as measured by conventional audiometry and uHear™ are presented in Fig. 1. Fig. 1 further shows the average difference between both tests at 0.5, 1.0, 2.0 and 4.0 kHz. Wilcoxon matched-pairs signed-ranks test indicated a statistical significant difference between thresholds found at 0.5, 1.0 and 2.0 kHz ($p < 0.001$). No difference was found between uHear™ and conventional audiometry thresholds at 4.0 kHz ($p = 0.327$).

Conventional audiometry indicated 15.4% of tested ears as having a clinically significant hearing loss with a PTA ≥ 40 dB HL. uHear™ found a PTA of 40 dB HL or more in 69.2% of cases. As mentioned above, power analysis was based on a ROC-curve

Table 2 – Tympanometry results.

Type (n = 60)	n (%)
A	48 (80.0)
Ad	7 (11.7)
As	2 (3.3)
B	2 (3.3)
C	1 (1.7)

in which uHear™ is compared to conventional audiometry, the gold standard. ROC-curve analysis showed an excellent AUC $\pm$ SE of 0.98 ± 0.14 (Fig. 2). It provided high Se of 100.0% (95%CI [65.5–100.0]), but poor Sp of 36.4% (95%CI [24.1–50.5]). The PPV and NPV were 22.2% (95%CI [11.7–37.5]) and 100.0% (95%CI [80.0–100.0]), respectively (Table 3). When excluding all ears without a tympanogram, or those with a type B or type C tympanogram, uHear™ showed similar results in terms of Se (100.0% (95%CI [65.5–100.0])) and Sp (38.3% (95%CI [65.5–100.0])), indicating its value in detecting sensorineural hearing loss.

Since the cut-off of ≥ 40 dB HL resulted in a poor Sp of uHear™, exploratory analyses were performed in order to look at other cut-off scores. Results indicated that a cut-off of ≥ 55 dB HL would be more optimal to detect a PTA of ≥ 40 dB HL with conventional audiometry in this population (Fig. 3). Although 4 kHz had the highest correlation between both hearing tests, including this frequency in the PTA calculation did not improve the diagnostic accuracy (data not shown).

3.3. Whispered Voice Test

The WVT showed a positive test result in 4.6% of tested ears. Se of the WVT was calculated as 30.0% (95%CI [8.1–64.6]). Its Sp was 100.0% (95%CI [91.9–100.0]) (Table 3).

3.4. Hearing Handicap Inventory for the Elderly

The HHIE was recorded per patient, and not per ear, as with other results described in this paper. Pass or fail results from both ears, obtained through PTA calculation, were put together for this analysis. A fail was given to patients who presented with a PTA of ≥ 40 dB HL in both ears.

The HHIE showed a mean score of 9.2 (0–32). No patient stated that they believed they had a significant hearing handicap. Seven patients (21.2%) showed scores between 17 and 42, indicating a perceived mild to moderate handicap. HHIE-results showed low Se (0.0%, 95%CI [0.0–53.7]), but maximum Sp (100.0%, 95%CI [85.0–100.0]) when using the cut-off of ≥ 43 . The HHIE indicated a high AUC $\pm$ SE when compared to conventional audiometry (0.88 ± 0.06) (Table 3).

Table 1 – Patient characteristics.

Characteristics (n = 33)	Mean (range) n (%)
Age (years)	76.4 (70–85) n (%)
Sex	
Male	23 (69.7)
Female	10 (30.3)
Cancer site	
Hematologic malignancy	11 (33.3)
Genitourinary	9 (27.3)
Digestive	5 (15.1)
Breast	3 (9.1)
Head and neck	3 (9.1)
Gynecologic	1 (3.0)
Thorax	1 (3.0)
Treatment type	
Systemic	17 (51.5)
Radiotherapy	6 (18.2)
Targeted therapy	6 (18.2)
Combination	3 (9.1)
Other	1 (3.0)
Treatment intent	
Curative	14 (42.4)
Palliative	19 (57.6)

4. Discussion

Hearing loss is widespread in older patients and can result in reduced communication and cognitive performance, reduced functionality and poor quality of life³⁵. Therefore, NCCN Guidelines in Older Adult Oncology recommend an assessment of sensory functions such hearing, as part of a CGA. The NCCN proposes a screening tool that is similar to the WVT⁸. In previous reports, the WVT showed good diagnostic accuracy,

Fig. 1 – Mean air conduction thresholds measured by conventional audiometry and uHear™. HL: hearing level.

although problems were found when accounting the inter-rater reliability^{11,16}. In our trial, we aimed to validate uHear™, an iOS-based application which is freely available in the iTunes store, to screen for hearing loss in older patients with cancer within a CGA.

uHear™ was compared to conventional audiometry, which is considered to be the gold standard. We stated that we would accept uHear™ if we found an AUC of at least 0.70. Results showed an excellent AUC of 0.98, indicating that we can use uHear™ as a screening tool for hearing loss within the CGA. A good screening tool needs a high Se and high NPV as it reduces the number of false negative cases. uHear™ showed perfect Se and NPV scores of 100.0%. On the contrary, we found poor Sp (36.4%) and poor PPV (22.2%). Exploratory analyses suggested that a cut-off of ≥ 55 dB HL may be more suited to detect a hearing loss with a PTA of ≥ 40 dB HL with conventional audiometry in this population. The poor Sp and PPV results can be attributed to the overestimation of air conduction thresholds as measured by uHear™ when compared to conventional audiometry. Wilcoxon matched-pairs

Fig. 2 – Receiver operating characteristics (ROC) curve of uHear™ compared with conventional audiometry as gold standard.

signed-ranks test detected significant statistical differences between thresholds at 0.5, 1.0 and 2.0 kHz, whereas no difference was found at 4.0 kHz. Increased uHear™ thresholds in lower frequencies have also been noted in previous studies and may be ascribed to following factors^{18,36}. First, uHear™ was administered in a quiet room and not in a sound booth as with conventional audiometry. Although ambient noise was reduced to a minimum, it could not be excluded completely. Second, the average age of patients included in this trial was 76.4 years. Some patients were familiar with touch screens, whereas others had never worked with this type of device. Therefore, the tapping on the screen had to be learned upon assessment of uHear™. uHear™ demands an immediate tap when a sound is heard. When this does not happen, it registers the sound as 'not heard by the patient' and would therefore thus unwantedly elevate the threshold. However, if this effect would be present in some patients, there would be no difference between the results of both ears since frequencies are assessed alternately. Third, both uHear™ and the standard iPod touch ear buds had not been calibrated. Therefore, it is impossible to ensure that the level and frequency of the auditory stimulus are exactly as it should be³⁶. Nonetheless, having to calibrate the device and its ear buds would lower the easy accessibility of this screening tool.

When comparing uHear™ to the WVT, the screening tool proposed by the NCCN, WVT showed worse sensitivity results (30.0%). It did show excellent Sp (100.0%). However, as mentioned above, a good screening tool needs a high Se and high NPV as it reduces the number of false negative cases, favoring the use of uHear™ instead of the WVT. The low sensitivity can be explained by a number of factors. To start, the PTA in older patients can be slightly elevated due to poor attention, delayed response, interference from tinnitus and other neurophysiologic problems³⁷. Therefore, patients' speech reception could better than their PTA results indicate. Last, it is known that the WVT has a low test-retest reliability. One investigator may have a louder whisper of another, and thus leading to other results¹⁶.

The HHIE also did not outstand uHear™ with a lower AUC of 0.88. No patient declared that they believed to have a significant hearing handicap which resulted in a Se of 0.0%. This is in line with previous reports in which was stated that patients want to postpone the acquisition of hearing aids as long as possible³⁸. The HHIE did reach a high Sp 100.0%, although its clinical value is rather redundant for screening purposes.

We have already covered in part the limitations in this study. We can summarize them as follow. First, uHear™ overestimated air conduction thresholds resulting in a poor Sp. The lower the frequency, the higher the difference compared to conventional audiometry. Explanations may be found in the ambient noise level that was present in the testing room and the age of the population under study resulting in an unfamiliarity with touch screen devices. Exploratory analyses further indicated that a cut-off score of ≥ 55 dB HL could be more suited in this population. However, this needs to be confirmed through further research, which we are planning in the future. Second, we found a rather low proportion of patients presenting with a significant hearing loss since we did not include patients with a known hearing loss. This resulted in poorer performance scores of uHear™,

Table 3 – Audiologic evaluation: performance measures and predictive values. a, b

	Conventional audiometry (n = 65)	uHear™ (n = 65)	Whispered voice test (n = 65)	Hearing handicap inventory for the elderly (n = 33)
Vulnerability (%)				
PTA ≥ 40 dB	15.4	69.2	^a	^a
Screening failure	^a	^a	4.6%	0%
Performance measures				
Se[95%CI]	^a	100.0 [65.5–100.0]	30.0 [8.1–64.6]	0.0 [0.0–53.7]
Sp[95%CI]	^a	36.4 [24.1–50.5]	100.0 [91.9–100.0]	100.0 [85.0–100.0]
AUC ± SE	^a	0.98 ± 0.14	^b	0.88 ± 0.06
Predictive values				
PPV[95%CI]	^a	22.2 [11.7–37.5]	100.0 [31.0–100.0]	^b
NPV[95%CI]	^a	100.0 [80.0–100.0]	88.7 [77.5–95.0]	84.8 [67.3–94.3]

PTA: Pure Tone Average, Se: Sensitivity, Sp: Specificity, AUC: Area Under the ROC-Curve, PPV: positive predictive value, NPV: negative predictive value, CI: confidence interval.

^a not applicable.

^b cannot be calculated.

WVT and HHIE. Third, since patients were recruited on one site of the hospital, we did not find a normal distribution of cancer sites. However, we feel that this did not influence results. Last, the time needed to assess uHear™ and conventional audiometry did not significantly differ. Although recommended by the NCCN, screening for hearing loss is not always incorporated in a CGA as it increases total assessment time. Nevertheless, looking at the patient's hearing status is a crucial element of the CGA as it provides useful information for health care providers.

Although uHear™ has some limitations, it also brings many advantages. Firstly, in the population under study, despite not being documented, we feel that the assessment time of uHear™ and conventional audiometry did not differ significantly since most patients were not familiar with touch screens and training was necessary. However, uHear™ does lead to profit in time since patients do not have to be transferred to the audiology department. Further, in future, training will be redundant since more patients will be familiar with touch screens. Secondly, having an idea of the patient's hearing is crucial to health care providers. Certainly for those who have to explain the risk and benefits of the treatment and have to ensure that patients know what to do in case of adverse events. A patient with an unknown hearing disorder could feel uncomfortable to ask to repeat sentences over and

over again. When health care providers would know that the patient has a hearing problem, adequate measures can be taken such as improvement in signal to noise ratio, written instructions, etc.

We want to emphasize that in patients with cancer, it is not the main goal to diagnose patients with a hearing loss, but we rather want to be able to give physicians a complete view of the patients' capabilities so that tailored care can be implemented. Based on the results of this trial, we can conclude that uHear™ is usable as a screening tool for older patients with cancer within a CGA and that it is more favorable to use when compared to the NCCN's proposed WVT or to the HHIE.

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Fig. 3 – Sensitivity and specificity of uHear™ according to different cut-off scores based on the pure tone average.

Disclosures and Conflict of Interest Statements

The authors declare to have no conflict of interest.

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