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Dutch health-related quality of life measure for chronic otitis media

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Abstract. *Dutch health-related quality of life measure for chronic otitis media*. *Objective*: Chronic otitis media (COM) describes a variety of symptoms and physical findings that result from prolonged damage to the middle ear by infection and inflammation. The Health-Related Quality of Life measure for COM (COMQ-12) is a new questionnaire for the assessment of COM that evaluates the overall burden of disease from the patient's perspective. The aim of this study was to develop and appraise the psychometric properties of the Dutch version of the COMQ-12.
Materials and methods: The Dutch version of the COMQ-12 was obtained through translation and back-translation. Fifty adult patients with a history of active COM completed the Dutch version of the COMQ-12. The internal consistency of this questionnaire was evaluated using Cronbach's alpha coefficient.
Results: The average COMQ-12 score was 22.4 (SD 11.9). The internal consistency of the Dutch version of the COMQ-12 was high, with a Cronbach's alpha value of 0.833.
Conclusions: The Dutch version of the COMQ-12 provides appropriate health-related quality of life outcome measures in patients with a history of COM. This questionnaire is a useful tool to evaluate the overall burden of disease from the patient's perspective.

Introduction

Chronic otitis media (COM) describes a variety of symptoms and physical characteristics that result from prolonged damage to the middle ear by infection and inflammation. Different forms of COM exist, for example, retraction or perforation of the tympanic membrane, chronic drainage from the ear, and the presence of cholesteatoma.[1] Symptoms than can be caused by COM include otorrhea, hearing loss, otalgia, tinnitus, and vertigo. Approximately 2% of the population is affected by COM and it can be associated with significant morbidity.[2] The World Health Organization (WHO) estimates COM to affect between 65 and 350 million individuals globally; thus, it is a leading cause of health care visits and drug prescriptions.[3]

The Health-Related Quality of Life Measure for COM (COMQ-12) is a new questionnaire for the assessment of active COM.[4] This questionnaire was developed to evaluate the overall burden of disease from the patient's perspective. Measures of health-related quality of life (HRQoL) allow a systematic assessment of the need for treatment and the resulting benefit. From both a clinical and a research perspective, it is important to assess the impact of disease on HRQoL. Patient-reported outcome measures (PROMs) are instruments that allow the assessment of outcome for specific interventions, and are useful to compare different types of surgical and nonsurgical interventions.[5] The HRQoL measures, such as the COMQ-12, can be employed as PROMs once they are appropriately evaluated for this purpose.

The original English version of the COMQ-12 was developed by Phillips *et al*.[4] The construction of this questionnaire was based on three other pre-existing questionnaires: the Chronic Ear Survey (CES),[2] the Chronic Otitis Media Outcome Test 15 (COMOT-15),[6] and the Chronic Otitis Media 5 (COM-5).[7] The initial validation of the original English version was completed by Phillips *et al*., with a Cronbach's alpha value of 0.889, which demonstrates a high internal consistency.[4] The aim of this study was to validate the Dutch version of the COMQ-12 in a group of COM patients.

Materials and methods

The questionnaire

The Dutch questionnaire, like the original English questionnaire, consists of 12 self-rating questions. The patient has to answer these questions using a six-point scale. Eight questions (1-7, 12) ask about the severity of complaints; whereas, the other four questions (8-11) are about the frequency of acts concerning the ear problems. In these 12 questions, 10 different topics are covered: water exposure, hearing, tinnitus, ear pain or discomfort, medications, restrictions of daily living, discharge, dizziness or vertigo, doctor visits, and global quality of life or distress.

The translation process

The Dutch version of the COMQ-12 was obtained by translation and back-translation.[8] The Dutch version was back-translated to English by an independent native English-Dutch speaker. The term "general practitioner" was changed to "doctor" because, unlike in the United Kingdom, the otorhinolaryngologist might serve as the first-line physician for cases of COM. This difference is the result of the country's specific health care organization. The final version of the Dutch COMQ-12 is shown in Appendix 1.

Ethics

The study was designed and conducted according to the Declaration of Helsinki (1996). Ethic committee approval was obtained to audit our patients' data.

Subjects

Dutch speaking patients, with a history of active COM, who visited the ENT department at the University Hospital in Antwerp between February and July 2014, were asked to complete the Dutch version of the COMQ-12. A total of 50 patients, with different types of COM. completed the questionnaire.

Psychometric assessment

Questionnaire reliability was assessed on the basis of internal consistency by calculating Cronbach's alpha. This index is used as an internal consistency estimate of the reliability of test scores by assessing the degree of correlation between the individual components of a questionnaire. Coefficients greater or equal to 0.70 are defined as acceptable; while, those greater than or equal to 0.80 are defined as good. The data were analyzed using SPSS (SPSS Inc. Chicago, IL, USA).

Results

This group of participants consisted of 32 (64%) men and 18 (32%) women, with a mean age of 53 years (range 15-82 years). These 50 patients presented with different forms of COM, at different stages of disease activity. We divided the patients in five different subgroups, based on their type of COM (Table 1). Almost 50% of our patients belonged to the healed COM group (E), the other half presented with more active pathologies. The COMQ-12 scores ranged overall from 2 to 51, out of a maximum score of 60. The average COMQ-12 score was 22.4 (SD 11.9). For the Dutch version of the COMQ-12, the Cronbach's alpha value was 0.833, indicating that the internal consistency of this questionnaire was high. This means that there is a high degree of correlation between the individual items of the questionnaire.

Discussion

Approximately 2% of the population is affected with COM, which is associated with significant morbidity.[2] The COMQ-12 was developed by Phillips *et al*.[4] for the assessment of COM. This questionnaire is an evaluation tool that assesses the impact of disease on HRQoL from the patient's own perspective as part of the Ear Audit.[9,10] The aim of this study was to appraise the psychometric properties of the Dutch version of the COMQ-12. Therefore, the questionnaire was translated into Dutch and an assessment of its validity was performed based on the internal consistency. The study population represented a heterogeneous group of COM patients, aged between 15 and 82 years, all with different disease presentations and activities. The internal consistency of the original English questionnaire was already shown to be high, with a Cronbach's alpha value of 0.889.[4] Our study confirmed the high internal consistency of the Dutch version of the COMQ-12, with a Cronbach's alpha value of 0.833.

Table 1
Description of Patient Groups

Group	Description	Total	Postoperative (%)
A	inactive mucosal COM (dry perforation)	9	0
B	active mucosal COM (wet perforation)	3	0
C	inactive squamous epithelial COM (retraction, atelectasis, epidermosis)	7	2 (28.6)
D	active squamous epithelial COM (cholesteatoma)	7	0
E	healed COM (intact tympanic membrane, covered perforation, tympanosclerosis)	24	23 (95.8)

To adequately interpret the COMQ-12 scores, it is important to have a reference point to start from. A study by Phillips *et al*.[11] determined normal values for the COMQ-12 scores in an adult population without active COM. Seventy healthy volunteers filled in the English version of the COMQ-12. The overall COMQ-12 scores ranged from 0 to 41 with a mean score of 3.4 (SD 6.1). The median score was 2 and the modal score was 0. The results from this study indicate that the majority of patients in an adult population without active COM would have a score of 5 or less. Phillips *et al*.[11] recommended considering these normal values in the preoperative setting when patients with COMQ-12 scores of 5 or less are considered for surgery. For the Dutch version of the COMQ-12, normal values are not yet determined; although, this is a goal for future work that is necessary for a more specific interpretation of the Dutch questionnaire results.

Fully appraising the psychometric properties of a HRQoL questionnaire involves documenting the development of the measure over a period of time; in addition, both the reliability and validity must be assessed. This study presents preliminary data to support further assessment of the Dutch version of the COMQ-12. Once patient data and instrument scores are acquired and pre-intervention and post-invention results are compared, the COMQ-12 can be further evaluated as a valid tool to assess patient outcome in the form of a PROM.

Conclusion

In conclusion, the Dutch version of the COMQ-12 provides an appropriate measure of HRQoL in patients with a history of COM. This questionnaire is a useful tool to evaluate the overall burden of disease from the patient's perspective.

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APPENDICES

Appendix 1. Chronische Middenoorontsteking Vragenlijst – 12

Met volgende vragen willen we evalueren hoe ernstig uw oorproblemen u beïnvloeden. We verwachten dat deze vragenlijst ons kan helpen te begrijpen welke oorklachten het belangrijkst zijn voor u.

Lees elke vraag aandachtig, beantwoord de onderstaande vragen door het cijfer aan te duiden dat het meest van toepassing is. De cijfers verwijzen telkens naar een specifieke omschrijving. Elke vraag dient u te beantwoorden rekening houdend met de situatie van de afgelopen 6 maanden.

Voor de volgende vragen mag u aanduiden hoe ernstig de verschillende elementen u beïnvloeden. Hierbij maakt u gebruik van de onderstaande schaal en kan u het juiste cijfer aanduiden als antwoord op de vraag.

0 Stoort me absoluut niet
1 Beperkte last
2 Matige last
3 Belangrijke last, maar ik kan ermee omgaan
4 Belangrijke last, en ik kan er moeilijk mee omgaan
5 Het ergste dat me ooit heeft getroffen

Ernst van de klachten:

1.	Oorloop of loopoor	0	1	2	3	4	5
2.	Een slechte geur uit het oor	0	1	2	3	4	5
3.	Gehoorproblemen thuis, bv. luider zetten van radio of TV	0	1	2	3	4	5
4.	Gehoorproblemen tijdens gesprekken in groep of in rumoerige omgeving	0	1	2	3	4	5
5.	Ongemak in en/of rond het oor	0	1	2	3	4	5
6.	Duizeligheid of het gevoel uit balans te zijn	0	1	2	3	4	5
7.	Oorsuizen of geluiden in het oor	0	1	2	3	4	5

Voor de volgende vragen mag u aanduiden hoe vaak de verschillende elementen u beïnvloeden. Hierbij maakt u gebruik van de onderstaande schaal en kan u het juiste cijfer aanduiden als antwoord op de vraag.

0 Minder dan 1 keer elke 6 maanden
1 Minstens 1 keer elke 6 maanden
2 Minstens 1 keer elke 3 maanden
3 Minstens 1 keer elke maand
4 Minstens 1 keer per week
5 Meerdere dagen per week

Levensstijl en werk
Hoe vaak bent u niet in staat geweest om:

8. Uw normale dagelijkse activiteiten uitvoeren thuis / op werk?	0	1	2	3	4	5
9. Wassen of douchen of baden zoals u wenste? Hoe vaak hebt u schrik dat dit een oorontsteking zou kunnen doen ontstaan?	0	1	2	3	4	5

Gezondheidszorg:

10. Hoe vaak bent u bij een arts geweest voor uw oorproblemen?	0	1	2	3	4	5
11. Hoe vaak moet u geneesmiddelen gebruiken voor uw oorprobleem (bv. ook oordruppels)?	0	1	2	3	4	5

Voor de volgende vraag mag u aanduiden hoe slecht uw situatie is op een schaal van '0' tot '5'. '0' betekent niet, en '5' betekent het ergste wat u zich kan voorstellen.

Algemeen:

12. In welke mate maken uw oorproblemen u 'depri'?	0	1	2	3	4	5