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Original Article

Validity and Test–Retest Reliability of the Dutch Version of the Chronic Otitis Media Questionnaire 12 (COMQ–12)

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OBJECTIVE: To test the validity and test–retest reliability of the Dutch translation of the Chronic Otitis Media Questionnaire 12 (COMQ-12).

MATERIALS and METHODS: Thirty-five healthy individuals with no history of chronic otitis media (COM) received the questionnaire as well as a group of 35 patients with complaints of COM. The healthy participants had to complete the questionnaire twice (control group 1 and control group 2) to estimate the test–retest reliability, and their scores were compared with those of the patients (group 3) to test the validity.

RESULTS: The overall COMQ-12 score in control group 1 ranged from 0 to 11, in control group 2 from 0 to 6, and in group 3 from 7 to 46. The mean score in control group 1 was 1.43 [standard deviation (SD) 2.30], 1.34 in control group 2 (SD 2.06), and 27.80 in group 3 (SD 10.51). A comparison of the absolute COMQ-12 scores of the two control groups and the patient group showed a significantly higher COMQ-12 score in patients with COM than in controls. The diagnostic accuracy was investigated, and a COMQ-12 cut-off score of 8 was found to have a near-perfect sensitivity and specificity in distinguishing between the presence and absence of COM. The single-measures intraclass correlation coefficient for absolute agreement (ICCAA) was 0.859 (with a 95% confidence interval from 0.738 to 0.926). This clearly exceeded the ICC threshold for acceptable reliability (ICC≥0.75) and therefore confirmed that there was reasonable test–retest reliability when applying the questionnaire to control subjects.

CONCLUSION: The Dutch version of the COMQ-12 has good validity, diagnostic accuracy, and test–retest reliability.

KEYWORDS: COMQ-12, chronic otitis media, test-retest reliability, quality of life

INTRODUCTION

Chronic otitis media (COM) remains a common disease that has a serious health impact on up to 2% of the population [1]. In the assessment of healthcare, patient-based measuring instruments regarding the quality of life and perceived handicap have become increasingly important. Combining three COM-related quality of life questionnaires—the Chronic Ear Survey [1], the Chronic Otitis Media Outcome Test 15 (COMOT-15) [2], and the Chronic Otitis Media 5 (COM-5) [3] —the Chronic Otitis Media Questionnaire 12 (COMQ-12) is a disease-specific tool that was recently developed by Phillips et al. [4] to meet that purpose. The COMQ-12 consists of 12 questions grouped in four categories regarding the severity of symptoms, impact on lifestyle and work, impact on the health service, and general impact on the patient. Each question needs to be scored on a six-point ordinal scale from 0 (i.e., no impact) to 5 (i.e., most severe impact), depending on the level of inconvenience or frequency of symptoms. Initial validation has been completed, and this provides a useful clinical tool for the assessment of active COM [4]{Formatting Citation}. In 70 subjects without active chronic middle-ear disease, the overall mean score was 2, the modal score was 0 in 39% of participants, and the majority of participants had a total COMQ-12 score of 5 or less [5].

The purpose of the present study was to culturally adapt the COMQ-12 to Flemish Dutch and to obtain measures of the validity and test–retest reliability of this Dutch translation of the original COMQ-12. The scores of controls were compared with those of patients to test the validity. The diagnostic accuracy or the ability of COMQ-12 to discriminate between normal subjects and subjects with chronic middle-ear pathology was investigated. Finally, the test–retest difference between two repeated administrations was assessed.

MATERIALS and METHODS

Firstly, the original COMQ-12 that was developed by Phillips et al. [4] was translated by the first three authors. The translation was sent to a native English-speaking person who has lived in Flanders for more than 40 years and speaks fluent Dutch. Secondly, this person

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translated the Dutch version back into English. Both the original and retranslated English versions of the COMQ-12 were then compared by the first three authors. There were no substantial differences between these two English versions; therefore, it was decided to adopt the Dutch version for further scientific and clinical use (Appendix A). As in the original COMQ-12, controls as well as patients were asked to rate the severity or frequency of their symptoms on a six-point equal-appearing interval scale from 0 (i.e., "this doesn't bother me at all or less frequently than once every 6 months") to 5 (i.e., "the worst thing that has ever affected my life or most days in the week").

Study Population

In total, 70 individuals were asked to complete a Dutch version of the COMQ-12. The control group consisted of 26 women with a mean age of 41.6 years [standard deviation (SD)=10.8; range=24–65] and nine men with a mean age of 40.9 years (SD=11.3; range=24–67) without a history of COM. These were healthy volunteers who were selected randomly from hospital staff (i.e., medical doctors, nurses, and administrative staff members) and among relatives and friends of the authors.

In addition to completing the COMQ-12, control subjects were also asked for their age and the presence of ear-related problems such as acute ear infections or previous ear surgery. One separate episode of infection was accepted; only a history that was consistent with COM led to exclusion. The dataset from the first completion (i.e., test) by the control subjects was called "control group 1." The dataset from their second completion of the COMQ-12 questionnaire (i.e., retest) was referred to as "control group 2."

The study group comprised 19 female subjects with a mean age of 36.2 years (SD=19.8; range=8–78) and 16 male subjects with a mean age of 41.7 years (SD=20.2; range=7–68) with COM. They visited our clinic in July 2015 with complaints of COM. The dataset from their completion of COMQ-12 was called "group 3."

All data were analyzed anonymously.

Statistics

Statistical analysis was performed with the Statistical Package for the Social Sciences (SPSS) Statistics version 20 (IBM; Armonk, NY, USA). For each analysis, a significance level of 5% was adopted. Various tests were used.

Firstly, the normality of the data distribution was investigated with the one-sample Kolmogorov–Smirnov test.

Secondly, the absolute scores of healthy participants and patients were analyzed with the non-parametric Mann–Whitney U-test to assess the validity of the questionnaire.

Thirdly, to examine the diagnostic value of COMQ-12, several estimates of diagnostic precision were calculated: sensitivity, specificity, and the area under a receiver operating characteristics curve (i.e., A_{ROC}). The A_{ROC} statistic is interpreted as a score between 1.0 (for perfect discrimination between cases and non-cases) and 0.5 (for chance-level diagnostic accuracy). To facilitate the clinical interpretation of COMQ-12 scores, a threshold score for distinguishing normal from abnormal subjects was derived from the ROC curve.

Fourthly, to assess test–retest reliability, the single-measures type A intraclass correlation coefficient using an absolute agreement definition (i.e., ICC_{AA}) was calculated. Similar to other reliability coefficients, the ICC ranges from 0.00 (i.e., total absence of reliability) to 1.00 (i.e., perfect reliability). Although there are no standard criteria for the interpretation of ICC, a general guideline suggests that values of above 0.75 indicate good to excellent reliability, and values below 0.75 correspond to poor to moderate reliability [6].

Ethics committee approval was received for this study from the ethics committee of the Sint-Augustinus Hospital, GZA Antwerp.

RESULTS

Study Population

In the control group of 35 healthy individuals, one participant reported a history of ear disease. This participant had undergone an ossiculoplasty for traumatic luxation of the incus. The overall COMQ-12 score in control group 1 ranged from 0 to 11, with a mean score of 1.43 (SD=2.30). In control group 2, the overall COMQ-12 scores ranged from 0 to 6, with a mean of 1.34 (SD=2.06). The COMQ-12 scores of the individual who reported an ear problem were 3 (test) and 6 (retest). The median COMQ-12 score overall was 0 in control groups 1 and 2, and the modal (or most prevalent) score was 0 in 18 participants (51.4%) in control group 1 and 21 participants (60%) in control group 2 (see Table 1). The distribution of control group 1 data was not normal (Kolmogorov–Smirnov Z=1.584; p=0.013). The distribution of control group 2 data was not normal (Kolmogorov–Smirnov Z=2.029; p=0.001).

The overall COMQ-12 scores in the patient group (group 3) ranged from 7 to 46, with a mean score of 27.80 (SD=10.51). The median overall COMQ-12 score was 28 (Table 1).

The distribution of group 3 data was normal (Kolmogorov–Smirnov Z=0.085; p=0.200). Non-parametric statistical methods were chosen based on the abnormal distribution of the data of the control subjects.

Validity

A comparison of the absolute COMQ-12 scores of the two control groups (control group 1 and group 2) with that of the patient group

Table 1. Descriptive statistics

	Number (n)	Min	Max	Range	Mean	SD	SE
Control group 1	35	0	11	11	1.43	2.30	0.39
Control group 2	35	0	6	6	1.34	2.06	0.35
Patient group	35	7	46	39	27.80	10.51	1.78

Control groups 1 and 2 are healthy participants who completed the COMQ-12 twice with a mean interval of 2 weeks. The third group consists of patients with a history of chronic otitis media.
Min: lowest COMQ-12 score; Max: highest COMQ-12 score; SD: standard deviation; SE: standard error

using the Mann–Whitney U-test showed that the COMQ-12 score was significantly higher in patients with COM than in control subjects (U=2.00; p=0.000).

To determine the diagnostic accuracy of COMQ-12 and its ability to distinguish normal from COM subjects, an ROC curve was constructed (Figure 1). The value of A_{ROC}, with COMQ-12 scores as the test variable and the group (i.e., control group 1 versus group 3) as the state variable, was 0.998, which revealed very high discriminatory power to distinguish subjects with normal middle ears from those with chronically abnormal middle ears (with statistical significance at p<0.001). The ROC curve was also used to identify which cutoff point achieved the best balance between sensitivity and specificity and would provide optimal discrimination between experimental and control groups. In this regard, a COMQ-12 cutoff score of 8 produced estimates of sensitivity and specificity of 1.00 and 0.97, respectively. Therefore, using this threshold, 100% of patients were correctly classified as having COM, whereas 97% of non-cases were correctly categorized as normal.

Test–Retest Reliability

The single-measures ICC_{AA} was 0.859 (with a 95% confidence interval from 0.738 to 0.926), which clearly exceeds the ICC threshold of 0.75 and confirmed that there was acceptable test–retest reliability with the control subjects.

DISCUSSION

The measurement of patient-based perception of the quality of life and handicaps has become very important in healthcare. The COMQ-12 is a patient-related outcomes questionnaire that is constructed to obtain information about the symptoms that are most important for the patient. It allows the clinician to get an idea of the expectations of patients regarding therapy and to choose an adequate management strategy that is consistent with these expectations [7]. We translated the original COMQ-12 into Dutch and tested it for validity, diagnostic accuracy, and test–retest reliability.

The scores for normal subjects, which varied from 0 to 11 and from 0 to 6 with mean scores of 1.43 and 1.34 as well as modal scores of 0 in 51.4% and 60% of the control participants for completion and recompletion, respectively, are comparable to the values for normal subjects calculated by Phillips et al. [5]

A cutoff value of 8 was determined to distinguish between the absence and presence of COM, although in the control group one 44-year-old patient had a COMQ-12 score of 11 (test) and 6 (retest) in the absence of COM. This can be explained by a high score for the questions regarding hearing, which can be diminished in the absence of COM. Also, two patients reported COMQ-12 scores of 7 and 9. One had COM for years and had undergone several operations for this problem. Because the COMQ-12 is a patient-based measurement, the subjective inconvenience is assessed, and this patient was probably able to cope very well with his COM. The other patient had a small attical cholesteatoma in the absence of otorrhea and with good hearing, which was discovered because of a sensation of ear fullness and tinnitus.

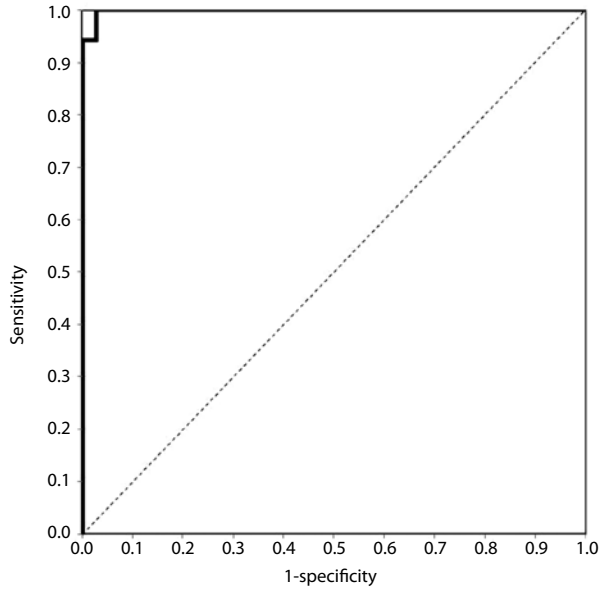

Figure 1. ROC curve. The ability of COMQ-12 to discriminate between normal and chronic middle-ear infection is represented by AROC. To facilitate the clinical interpretation of COMQ-12 scores, a threshold score of 8 for distinguishing normal from abnormal subjects was derived from the ROC curve.

The Dutch version of the COMQ-12 has good reproducibility and high diagnostic accuracy for detecting COM and can be used in clinical evaluation studies to assess the impact of surgery on patients' complaints.

Ethics Committee Approval: Ethics committee approval was received for this study from the ethics committee of Sint-Augustinus Hospital, GZA Antwerp.

Informed Consent: Informed consent was obtained from patients who participated in this study.

Peer-review: Externally peer-reviewed.

Author Contributions: All authors contributed equally to this study.

Conflict of Interest: No conflict of interest was declared by the authors.

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REFERENCES

1. Nadol JB, Staecker H, Gliklich RE. Outcomes assessment for chronic otitis media: the chronic ear survey. Laryngoscope 2000; 110: 32-5. [CrossRef]
2. Baumann I, Kurpiers B, Plinkert PK, Praetorius M. Development and validation of the Chronic Otitis Media Outcome Test 15 (COMOT-15). Measurement of health-related quality of life in patients with chronic otitis media. HNO 2009; 57: 889-95. [CrossRef]
3. Vlastos IM, Kandiloros D, Manolopoulos L, Ferekidis E, Yiotakis I. Quality of life in children with chronic suppurative otitis media with or without cholesteatoma. Int J Pediatr Otorhinolaryngol 2009; 73: 363-9. [CrossRef]
4. Phillips JS, Haggard M, Yung M. A new health-related quality of life measure for active chronic otitis media (COMQ-12): development and initial validation. Otol Neurotol 2014; 35: 454-8. [CrossRef]
5. Phillips JS, Yung MW. COMQ-12 scores in adult patients without chronic middle ear disease. Clin Otolaryngol 2014; 39: 362-7. [CrossRef]
6. Portney LG, Watkins MP. Foundations of clinical research: applications to practice (2nd edition). Upper saddle River, NJ: Prentice-Hall; 2000.
7. Koller M, Lorenz W, Wagner K, Keil A, Trott D, Engenhart-Cabillic R, et al. Expectations and quality of life of cancer patients undergoing radiotherapy. J R Soc Med 2000; 93: 621-8.

APPENDIX A. Translated version of COMQ-12

Chronic Otitis Media Questionnaire–12 (COMQ-12):

Chronic Otitis Media Questionnaire–12 (COMQ-12):

Deze vragen zijn om te achterhalen hoe erg uw oorproblemen u beïnvloeden. Geen enkele machine kan dit voor u doen: enkel u kan ons dit vertellen. Wij verwachten dat de resultaten van deze vragenlijst ons helpen te begrijpen welke van uw oor symptomen het meest belangrijk voor u zijn. Deze wetenschap zal ons helpen om de wijzen waarop patiënten met oorproblemen worden verzorgd te verbeteren.

Beantwoord alstublieft onderstaande vragen door zorgvuldig elke gestelde vraag te overwegen en vervolgens het geschikte cijfer te omcirkelen. De cijfers verwijzen elk naar een bepaalde beschrijving. Er zijn geen juiste of foute antwoorden, maar probeert u alstublieft goed na te denken over elke vraag voordat u het geschikte cijfer omcirkelt. Overweeg alstublieft elk probleem zoals het in de voorbije 6 maanden geweest is.

VOORBEELD:

Duid voor de volgende vraag alstublieft aan hoe vaak u deze activiteit uitvoert, gebruik makende van de onderstaande schaal en door het geschikte cijfer te omcirkelen:

0 Nooit
1 Minstens éénmaal per drie maanden
2 Minstens éénmaal per maand
3 Minstens éénmaal per week
4 De meeste dagen in de week
5 Heel de tijd

Hoe vaak eet u toast voor ontbijt? 0 1 2 3 <u>4</u> 5

Een persoon die zodanig antwoordt, geeft aan dat hij/zij gewoonlijk toast eet als ontbijt doch niet altijd.

Als u enig probleem ondervindt bij het beantwoorden van de vragen, vraag dan hulp aan een lid van de klinische staf. Dank U.

Duid voor de volgende vragen alstublieft aan <u>hoe ernstig</u> de verscheiden beschreven elementen u beïnvloeden, gebruik makende van de onderstaande schaal door het geschikte cijfer te omcirkelen.

0 Stoort me helemaal niet
1 Een beperkt ongemak
2 Een matig ongemak
3 Een groot ongemak maar ik kan er mee omgaan
4 Een groot ongemak en ik vind het zwaar om ermee om te gaan
5 Het ergste dat mijn leven ooit heeft getroffen

Symptoom ernst:

1. Lopend oor of drainage van het oor	0 1 2 3 4 5
2. Een 'slecht ruikend oor' hebben	0 1 2 3 4 5
3. Gehoorproblemen thuis, bv vereisend dat het volume van de TV of radio wordt opgedreven	0 1 2 3 4 5
4. Gehoorproblemen wanneer men spreekt met mensen in groepen of in lawaaierige omgevingen	0 1 2 3 4 5
5. Discomfort in en/of rondom het oor	0 1 2 3 4 5
6. Duizeligheid of gevoel van "instabiliteit"	0 1 2 3 4 5
7. Tinnitus of lawaai in het oor	0 1 2 3 4 5

Duidt u voor de volgende vragen alstublieft aan <u>hoe vaak</u> de verscheiden beschreven elementen u beïnvloeden, door gebruik te maken van de onderstaande schaal en door het geschikte cijfer te omcirkelen.

0 Minder frequent dan eenmaal per 6 maanden
1 Minstens eenmaal per 6 maanden
2 Minstens eenmaal per 3 maanden
3 Minstens eenmaal per maand
4 Minstens eenmaal per week
5 De meeste dagen in de week

APPENDIX A. Translated version of COMQ-12 (Continuous)

Levensstijl en werk impact:

Hoe vaak bent u NIET in staat geweest om:

8. Uw normale dagelijkse activiteiten thuis/op het werk uit te voeren 0 1 2 3 4 5
9. U te wassen, te douchen of te baden zoals u zou willen

bv. Hoe vaak bent u angstig geweest dat deze activiteiten een oorontsteking veroorzaken? 0 1 2 3 4 5

Gezondheidszorg impact

10. Hoe vaak bent u langsgegaan bij uw huisarts omwille van uw oorproblemen? 0 1 2 3 4 5
11. Hoe vaak bent u genoodzaakt medicijnen in te nemen (inclusief oordruppels) voor uw oorprobleem? 0 1 2 3 4 5

Voor de volgende vraag, duid alstublieft aan hoe erg de dingen zijn, schaal van '0' tot '5'. '0' betekent helemaal niet erg, '5' betekent het ergste dat u zich ooit kan inbeelden:

Algemeen:

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

Controleert u alstublieft dat u een antwoord heeft geformuleerd op elke vraag en vraag om hulp indien u dit moeilijk vindt.

Heel erg bedankt om deel te nemen.