

Original Article

Validity and Test-Retest Reliability of the Dutch Version of the Chronic Otitis Media Benefit Inventory

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OBJECTIVES: We aimed to test the validity and test-retest reliability of the Dutch translation of the Chronic Otitis Media Benefit Inventory (COMBI) questionnaire.

MATERIALS and METHODS: In total, 30 chronic otitis media (COM) patients with a previous ear surgery completed the questionnaire; 30 patients with a negative medical history of COM complaints and with previous non-otologic surgery as the control group completed the questionnaire. For estimating the test-retest reliability, patients of the COM group completed the questionnaire twice; the scores were compared to those of the control group to test the validity.

RESULTS: The overall COMBI score ranged as 32-60 in the patient test group, 32-60 in the patient retest group, and 35-40 in the control group. A mean (standard deviation) score of 43.87 (6.81) in the patient test group, 44.4 (6.83) in the patient retest group, and 36.7 (1.29) in the control group was noted. Post-intervention, the COM patients had a significantly higher absolute COMBI score compared to the control group. The diagnostic accuracy was investigated, and a cut-off score of 38.5 was found to have a high sensitivity and specificity in distinguishing a significant positive change from an insignificant change after the intervention. The average-measures intra-class correlation coefficient for absolute agreement (ICC-AA) was 0.985 (95% confidence interval: 0.969-0.993), indicating an excellent test-retest reliability in the control group.

CONCLUSION: The Dutch version of the COMBI questionnaire has a good validity, diagnostic accuracy, and test-retest reliability.

KEYWORDS: COMBI, chronic otitis media, validity, test-retest reliability, quality of life

INTRODUCTION

Chronic otitis media (COM) is a prevalent disease with a serious impact on patient's overall health status, which affects approximately 2% of the population ^[1]. The assessment of the physical and psychosocial impact of a disease from patients' perspective has gained interest in recent years. Hence, health-related quality of life (HRQoL) measures and patient-reported outcome measures (PROM) have been developed, although they are not interchangeable terms. HRQoL measures are used to assess the patient's overall health status, whereas the PROM is used for disease-specific items in addition to QoL items, thereby creating the ability to monitor the outcome of interventions.

In otology, single clinical, radiological, and audiology findings may inter-relate poorly and may also predict the HRQoL poorly. It has been shown that the use of HRQoL measures aids the patient to prioritize their symptoms and subsequently direct them to the clinical management of their individual expectations ^[2,3]. In 2014, Philips et al. ^[4] developed the Active COM Questionnaire 12 (COMQ-12) as a mixed generic and specific PROM. A Dutch version was developed and validated in 2015. In this study, a cut-off value between normal individuals and COM patients was established. A good validity, diagnostic accuracy, and test-retest reliability was achieved, making the COMQ-12 a useful tool in clinical evaluation studies to assess the impact of surgery on patient's complaints ^[5]. However, one shortcoming of COMQ-12 was its inability to evaluate the "responsiveness" after treatment as reported by Philips in 2016 in the systematic review on the role of PROM in the assessment of chronic ear diseases ^[6]. Therefore, in 2017, the

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COM Benefit Inventory (COMBI) questionnaire was developed and validated by Philips as its dynamic equivalent [7].

In analogy with our previous study, the aim of the present study was to culturally adapt the COMBI to Dutch and to obtain measures of the validity and test-retest reliability of the Dutch translation [5]. The diagnostic accuracy or the ability of the COMBI to discriminate between significant alteration and no significant alteration of a disease-specific burden (after surgical intervention) was also investigated.

MATERIALS AND METHODS

Firstly, the original COMBI developed by Phillips was translated by both first authors. The translation was sent to a native English-speaking person who has lived in Flanders for more than 40 years and is fluent in both English and Dutch. Secondly, this person translated the Dutch version back into English. Both original and translated English versions of the COMBI were then compared by the first authors. As no substantial differences between the two English versions were noted, it was decided to adopt the Dutch version for further scientific and clinical use (Appendix A).

The questionnaire consists of 12 questions divided into 2 categories to compare the diseasespecific burden with the pre-intervention status. The first category focuses on the severity of symptoms, whereas the second category focuses on the psychosocial impact on the lifestyle and work. The initial validation of the questionnaire has been completed, and it provides a useful dynamic tool for the assessment of COM [7]. As in the original COMBI, COM patients and the control group patients (i.e., patients without ear problems) were asked to rate the level of inconvenience or frequency of the complaints they experienced compared with the preoperative status. Each question is provided with five response options ranging between maximal amelioration and maximal deterioration, namely "much worse," "a little or somewhat worse," "no change," "a little or somewhat better," and "much better" as scores 1-5, respectively.

Study Population

In total, 60 individuals were asked to complete the Dutch version of the COMBI. All the participants provided written consent. The patient group consisted of 30 patients who underwent COM surgery (such as primary or revision myringoplasty and tympanoplasty for non-cholesteatoma and cholesteatoma ears). This group comprised 15 females with a mean age of 47.2 years (standard deviation [SD]=15.0; range=21-72) and 15 males with a mean age of 46.0 years (SD=16.0; range=18-71). The patients completed the questionnaire twice at an interval of approximately 2 weeks. The first completion was achieved 6 to 12 months after the surgery. The dataset of the first completion of the COMBI (i.e., test) was called "patient test group." The dataset from the second completion was referred to as "patient retest group."

The control group consisted of 30 patients. They were selected based on a negative medical history of COM complaints and recent non-otologic surgery, such as rhinoplasty, septoconchoplasty, functional endoscopic sinus surgery, parotidectomy, tonsillectomy, or thyroidectomy. They were administered the questionnaire 2-6 months after the surgery. This group included 11 females with a mean age of 47.2 years (standard deviation [SD]=19.1; range=24-82) and 19 males with a mean age of 42.8 years [SD=16.6; range=17-72]. Patient information was de-identified for the data analysis.

Statistical Analysis

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

First, the normality of the data distribution was investigated using the one-sample Kolmogorov-Smirnov test, which showed a skewed distribution for the questionnaire scores; therefore, the non-parametric Mann-Whitney U test was used to assess the validity of the questionnaire.

To examine the diagnostic value of COMBI, several estimates of diagnostic precision were calculated: sensitivity, specificity, and the area under the receiver operating characteristics curve (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 COMBI scores, a threshold score for distinguishing patients without a significant change after intervention from those with improvement after intervention was derived from the ROC curve.

Finally, to assess test-retest reliability, the average-measures type A intra-class correlation coefficient using an absolute agreement definition (ICC_{AA}) was calculated. Similar to other reliability coefficients, the ICC_{AA} ranged 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_{AA} , a general guideline states that values above 0.75 correspond good to excellent reliability, and values below 0.75 correspond to poor to moderate reliability [8].

An ethics committee approval was received for this study from the ethics committee of the Sint-Augustinus Hospital, GZA Antwerp. (BUN nr: B099201732917)

RESULTS

Study Population

The overall COMBI score in the patient test group ranged as 32-60, with a mean value of 43.87 (SD=6.81). The overall COMBI score in the patient retest group ranged as 32-60, with a mean value of 44.4 (SD=6.83). The median score of the COMBI was 43 in the patient test group and 43.5 in the patient retest group. Data of both patient groups showed a normal distribution (test group: Kolmogorov-Smirnov $Z=0.144$; $p=0.116$; retest group: Kolmogorov-Smirnov $Z=0.132$; $p=0.195$). In the control group, the overall COMBI score ranged as 35-40, with a mean value of 36.7 (SD=1.29). The median score of the COMBI was 36 in the control group. The distribution of the control group data was not normal (Kolmogorov-Smirnov $Z=0.280$; $p=0.000$). Non-parametric statistical methods were chosen based on the abnormal distribution of the data of the control group (Table 1).

Validity

When the absolute COMBI scores of both patient groups (patient test group and patient retest group) was compared with that of the control group using the Mann-Whitney U test, the COMBI score of the COM patient was found to be significantly different from the control participants ($U=110.00$; $p=0.000$).

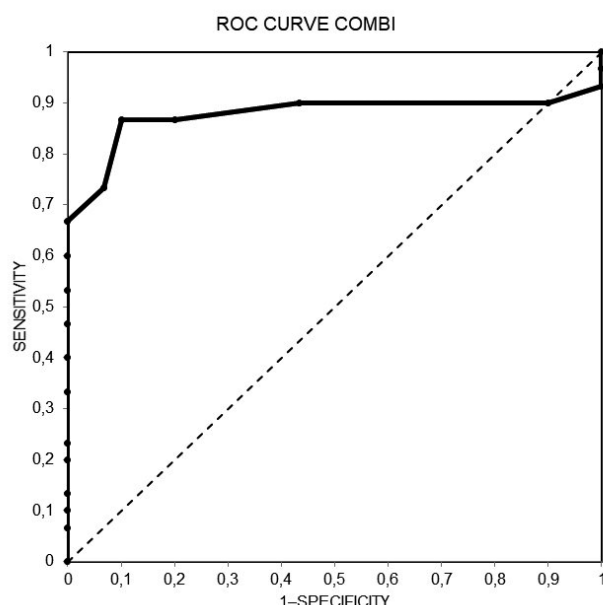


Figure 1. ROC curve. The ability of COMBI to discriminate between a significant change post-intervention from an insignificant change is represented by AROC. To facilitate the clinical interpretation of COMBI scores, a threshold of 38.5 was derived from the ROC curve. AROC: area under the receiver operating characteristics curve; COMBI: Chronic Otitis Media Benefit Inventory

To determine the diagnostic accuracy of COMBI and its ability to distinguish between patient without COM and COM patients, an ROC curve was constructed (Figure 1). The value of A_{ROC} with COMBI scores as the test variable and the group (i.e., patient group=1 and control group=0) as the state variable was 0.878, which revealed high discriminatory power to distinguish significant change after intervention from insignificant change (with a statistical significance at $p<0.001$). The ROC curve-based Youden index was also used to identify the cut-off point that achieved the best balance between sensitivity and specificity and would provide optimal discrimination between the experimental and control groups. In this regard, a COMBI cutoff score of 38.5 produced estimates of sensitivity and specificity of 0.867 and 0.933, respectively. Therefore, using this threshold, 87% of patients were correctly classified as having a significant change, whereas 93% of patients were correctly categorized as having insignificant change (Figure 2).

Test-Retest Reliability

The average-measures of ICC_{AA} was 0.985 (95% confidence interval=0.969–0.993), which clearly exceeds the ICC threshold of 0.75 and confirms that there was excellent test-retest reliability within the control subjects.

DISCUSSION

The measurement of patient-based perception of QoL due to their illness has become very important in healthcare. COMBI is a patient-re-

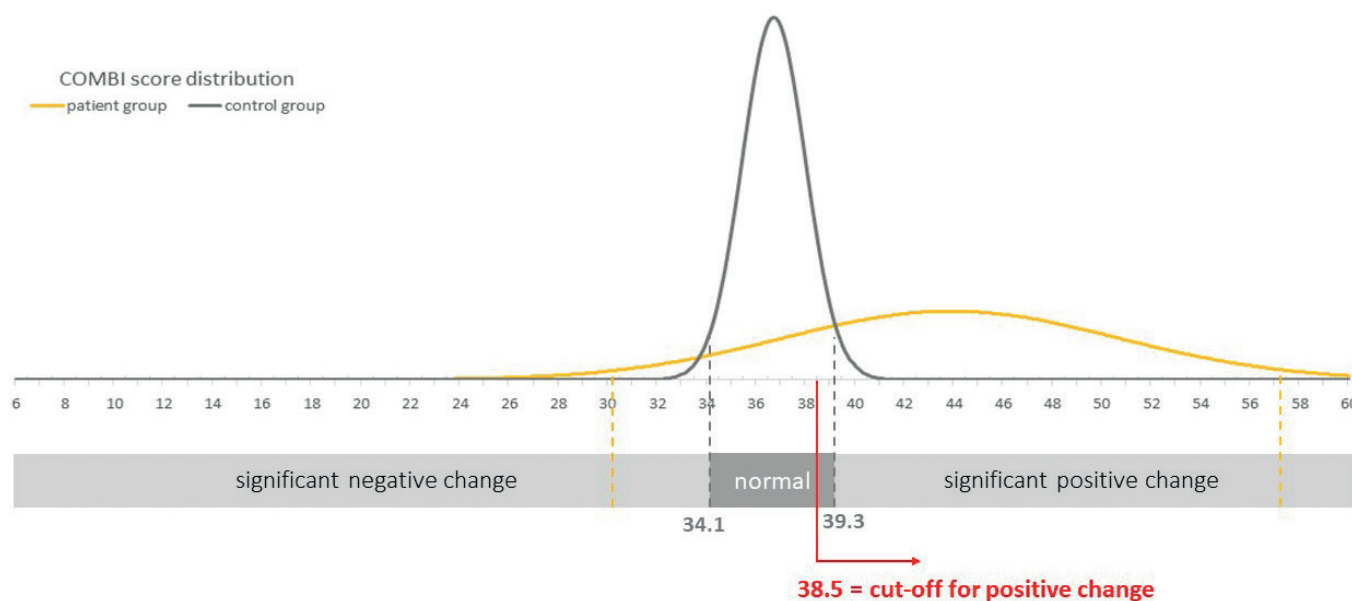


Figure 2. The COMBI score normal distribution. The overall COMBI score in the patient group (mean=43.8; SD=6.81) is significantly different from that in the control group (mean=36.7; SD=1.29). Normal scores ranged from 34.1 to 39.3 (i.e., the 95% confidence interval deducted from the data of the control group). The cut-off score for positive change is 38.5.

COMBI: Chronic Otitis Media Benefit Inventory; SD: standard deviation

Table 1. Descriptive statistics

	Number (n)	Min	Max	Range	Median	Mean	SD	SE
Patient test group	30	32	60	28	43	43.87	6.81	1.24
Patient retest group	30	32	60	28	43.5	44.40	6.83	1.25
Control group	28	35	40	5	36	36.7	1.29	0.24

Patient test group and retest group consist of patients who underwent a previous COM surgery. The control group consists of patient who underwent a non-otologic surgery. COM: chronic otitis media; Min: minimum score; Max: maximum score; SD: standard deviation; SE: standard error

lated outcome questionnaire that has been constructed to obtain information regarding the dynamic change in the physical and psychosocial burden post-intervention. It allows a clinician to get rapidly yet a general idea of the impact of the intervention and the residual complaints that need to be managed. Therefore, its implementation is of great use in a patient follow-up setting. We translated the original COMBI into Dutch and tested it for validity, diagnostic accuracy, and test-retest reliability.

The scores for the control group varied from 35 to 40, with a mean score of 36.7 (SD=1.29) and a median score of 36. A score of 36 is obtained when “zero change” is the response to all questions. Whenever responses were different from “zero change,” they were most frequently seen with the second category of questions regarding the psychosocial impact, lifestyle, and work. This can be attributed to the generic quality of the questions.

The analysis of the diagnostic accuracy and the ability to distinguish COM from normal participants produced a cut-off score of 38.5 with reasonable sensitivity and specificity. Scores higher than 38.5 indicate a significant positive alteration post-intervention. Unfortunately, it was not possible to determine a cut-off score to indicate a significant negative alteration post-intervention because all individuals in the patient group reported an overall positive change.

The questionnaire used in this study was a Dutch translation of the original COMBI questionnaire. Although an expansion to seven response options was suggested by Phillips et al.^[7] for avoiding bias in answers due to the observed ceiling effect, we chose to use a translation of the original questionnaire with five response options. Through this approach, we contributed to the ambition of multiple studies with a larger number of participants in distinct clinical populations for achieving the psychometrical appraisal of a QoL instrument^[7].

CONCLUSION

The COMBI questionnaire is a patient-reported measurement tool with a good validity and test-retest reliability, which aims at obtaining a dynamic evaluation of physical and psychosocial impact in COM patients after intervention. A cut-off score to distinguish a significant positive change from an insignificant change post-intervention was determined. A cut-off score to distinguish a negative change could not be determined in our study. The COMBI questionnaire is a useful tool complementary to the COMQ-12 in daily clinical practice.

Ethics Committee Approval: Ethics Committee approval was received for this study from the Ethics Committee of the Sint-Augustinus Hospital, GZA Antwerp (BUN nr: B099201732917).

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

Peer-review: Externally peer-reviewed.

Author Contributions: Concept – G.D.G., J.v.D.; Design – G.D.G., J.v.D.; Supervision – J.v.D.; Materials – G.D.G., J.v.D.; Data Collection and/or Processing – G.D.G., J.v.D.; Analysis and/or Interpretation – G.D.G., J.v.D., Y.M., R.V.; Literature Search – G.D.G., J.v.D.; Writing – G.D.G., J.v.D.; Critical Reviews – Y.M., R.V., A.Z., E.O.

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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. Nies C, Celik I, Lorenz W, Koller M, Plaul U, Krack W, et al. [Outcome of minimally invasive surgery. Qualitative analysis and evaluation of the clinical relevance of study variables by the patient and physician]. *Chirurg* 2001; 72: 19-28; discussion 28-9. [\[CrossRef\]](#)
3. Koller M, Lorenz W, Wagner K, Keil A, Trott D, Engenhardt-Cabillic R, et al. Expectations and quality of life of cancer patients undergoing radiotherapy. *J R Soc Med* 2000; 93: 621-8. [\[CrossRef\]](#)
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. van Dinther J, Droessaert V, Camp S, Vanspauwen R, Maryn Y, Zarowski A, et al. Validity and Test-Retest Reliability of the Dutch Version of the Chronic Otitis Media Questionnaire 12 (COMQ-12). *J Int Adv Otol* 2015; 11: 248-52. [\[CrossRef\]](#)
6. Phillips JS, Yung MW. A systematic review of patient-reported outcome measures for chronic suppurative otitis media. *Laryngoscope* 2016; 126: 1458-63. [\[CrossRef\]](#)
7. Phillips JS, Haggard M, Spencer H, Yung M. The Chronic Otitis Media Benefit Inventory (COMBI): Development and Validation of a Dynamic Quality of Life Questionnaire for Chronic Ear Disease. *Otol Neurotol* 2017; 38: 701-7. [\[CrossRef\]](#)
8. Portney LG, Watkins MP. Foundations of clinical research: applications to practice. 2nd ed. ed. Upper Saddle River, NJ: Prentice Hall; London: Prentice-Hall International; 2000.

Appendix A

Onderstaande vragen zijn om te achterhalen hoe erg uw oorproblemen u beïnvloeden in vergelijking met de situatie voor de operatie/ behandeling. Geen enkele machine kan dit voor u doen: enkel u kan ons dit vertellen. Wij verwachten dat de resultaten van deze vragenlijst ons helpen om te begrijpen welke klachten voor u onvoldoende positief gewijzigd zijn. Deze wetenschap zal ons helpen om de wijze waarop patiënten met oorproblemen worden verzorgd te verbeteren.

Beantwoord alstublieft onderstaande vragen zorgvuldig door elke gestelde vraag te overwegen en vervolgens het geschikte cijfer te omcirkelen. De cijfers verwijzen elk naar een bepaalde beschrijving die eronder vermeldt staat. Er zijn geen juiste of foute antwoorden, maar probeert u alstublieft goed na te denken over elke vraag voordat u het geschikte cijfer omcirkelt.

Ernst van de symptomen

1. Sedert uw operatie/behandeling, is uw oorloop of drainage van uw oor verbeterd of verslechterd?

5	4	3	2	1
Veel beter	Een beetje beter	Onveranderd	Een beetje slechter	Veel slechter

2. Sedert uw operatie/behandeling, hoe zou u de verandering beschrijven in het hebben van een 'slecht ruikend oor'? Is dit verbeterd of verslechterd?

5	4	3	2	1
Veel beter	Een beetje beter	Onveranderd	Een beetje slechter	Veel slechter

3. Sedert uw operatie/behandeling, is uw gehoor thuis (bijv. de televisie of de radio luider moeten zetten) verbeterd of verslechterd?

5	4	3	2	1
Veel beter	Een beetje beter	Onveranderd	Een beetje slechter	Veel slechter

4. Sedert uw operatie/behandeling, is uw gehoor wanneer u met anderen in groep spreekt (of wanneer u in een lawaaierige omgeving bent) verbeterd of verslechterd?

5	4	3	2	1
Veel beter	Een beetje beter	Onveranderd	Een beetje slechter	Veel slechter

5. Sedert uw operatie/behandeling, is het discomfort in en/of rond het oor verbeterd of verslechterd?

5	4	3	2	1
Veel beter	Een beetje beter	Onveranderd	Een beetje slechter	Veel slechter

6. Sedert uw operatie/behandeling, is uw duizeligheid of uw gevoel van 'instabiliteit' verbeterd of verslechterd?

5	4	3	2	1
Veel beter	Een beetje beter	Onveranderd	Een beetje slechter	Veel slechter

7. Sedert uw operatie/behandeling, is uw tinnitus of lawaai in het oor verbeterd of verslechterd?

5	4	3	2	1
Veel beter	Een beetje beter	Onveranderd	Een beetje slechter	Veel slechter

Gevolgen voor levensstijl, werk en gezondheidszorg

8. Betreffende uw gewone dagelijkse activiteiten thuis en op het werk, zou u zeggen dat u meer problemen of minder problemen ondervindt, sedert uw operatie/behandeling?

1	2	3	4	5
Veel meer problemen om activiteiten uit te voeren	Meer problemen om activiteiten uit te voeren	Onveranderd	Meer problemen om activiteiten uit te voeren	Veel minder problemen om activiteiten uit te voeren

9. Betreffende de mogelijkheid om u te wassen of te douchen of te baden zoals u zelf zou willen sedert uw operatie/behandeling, hebt u dan meer angst of minder angst om een oorontsteking te krijgen door deze activiteiten?

1	2	3	4	5
Veel meer angst dat het oor nat wordt	Meer angst dat het oor nat wordt	Onveranderd	Minder angst dat het oor nat wordt	Veel minder angst dat het oor nat wordt

10. Sedert uw operatie/behandeling, bent u vaker of minder vaak naar uw huisarts gegaan omwille van uw oorproblemen?

1	2	3	4	5
Veel vaker	Vaker	Onveranderd	Minder vaak	Veel minder vaak

11. Sedert uw operatie/behandeling, heeft u vaker of minder vaak medicijnen (met inbegrip van oordruppels) moeten nemen voor uw oorprobleem?

1	2	3	4	5
Veel vaker	Vaker	Onveranderd	Minder vaak	Veel minder vaak

Algemeen

12. Sedert uw operatie/behandeling, bent u meer of minder 'onderuit gehaald' door uw oorprobleem dan ervoor?

1	2	3	4	5
Veel meer dan voorheen	Meer dan voorheen	Onveranderd	Minder dan voorheen	Veel minder dan voorheen

Heel erg bedankt om deel te nemen.