

OTOLOGY

Cross-cultural adaptation and Italian validation of chronic otitis media outcome test 15 (COMOT-15)

Adattamento culturale e validazione in italiano del questionario COMOT-15 nella valutazione degli outcomes del trattamento dell'otite media cronica

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SUMMARY

Objective. Chronic suppurative otitis media (CSOM) may result in a serious impairment of the quality of life (QoL). The most relevant characteristics of CSOM are well represented in the "Chronic Otitis Media Outcome Test 15" questionnaire (COMOT-15). The aim of the study was to translate and adapt the COMOT-15 questionnaire into Italian.

Methods. This is a prospective study conducted on 52 Caucasian Italian-speaking patients with CSOM and 52 controls. The linguistic adaptation of the COMOT-15 consisted of the translation of the English version into Italian and reliability assessment of the translation. Psychometric measurements included internal consistency and test-retest reliability.

Results. Cronbach's α was 0.95. The test-retest reliability showed a strong positive correlation for total score and all subscales. Age and gender had no influence on the scores. The correlation between the COMOT-15 and the pure tone average showed a significant association for the scale "Hearing Function".

Conclusions. The Italian COMOT-15 questionnaire provides good internal consistency and is suitable for QoL evaluation in Italian-speaking patients suffering from CSOM. In addition, it is able to evaluate the subjective symptoms perceived by patients.

KEY WORDS: QoL, chronic otitis, COMOT 15, hearing loss, ear discharge

RIASSUNTO

Obiettivo. L'otite media cronica suppurativa (OMCS) può determinare una grave compromissione della qualità della vita (QoL) dei pazienti. Gli aspetti clinici più rilevanti dell'OMCS sono rappresentati nel questionario "Chronic Otitis Media Outcome Test 15" (COMOT-15). Scopo dello studio è tradurre e adattare alla lingua italiana il questionario COMOT-15.

Metodi. Abbiamo effettuato uno studio prospettico di validazione arruolando 52 pazienti con diagnosi di OMCS e 52 controlli. Il processo di adattamento linguistico del questionario è consistito nella traduzione della versione originale inglese in italiano e nella misura dell'affidabilità della stessa. Le misure psicometriche che abbiamo preso in considerazione includevano coerenza interna e affidabilità test-retest.

Risultati. Il Cronbach α era pari a 0,95. Abbiamo riscontrato una forte correlazione positiva sia per il punteggio totale che per tutte le sottoscale. Età e sesso non hanno influenzato i punteggi. L'analisi delle correlazioni tra COMOT-15 e soglia uditiva per la via aerea ha mostrato un'associazione significativa per la sottoscala "Funzione uditiva".

Conclusioni. Sulla base dei nostri risultati è stato possibile dimostrare che la versione italiana del questionario COMOT-15 da noi proposta ha una buona coerenza interna ed è particolarmente adatta per la valutazione della QoL nei pazienti di lingua italiana affetti da otite media cronica suppurativa. Inoltre, esso è in grado di valutare i sintomi soggettivi percepiti dai pazienti.

PAROLE CHIAVE: QoL, otite cronica, COMOT-15, ipoacusia, otorrea

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Conflict of interest

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Introduction

Otitis media (OM) includes various subtypes of pathologies characterised by middle ear mucosa inflammation such as acute otitis media (AOM), otitis media with effusion (OME), chronic suppurative otitis media (CSOM), mastoiditis and cholesteatoma. CSOM (with or without cholesteatoma) affects approximately 2-4% of the general population and is defined as a chronic inflammation of the middle ear and mastoid cavity with or without tympanic membrane perforation¹⁻³. It is characterised by recurrent ear discharge and hearing loss, and, less frequently, otalgia, fever, vertigo and tinnitus¹.

CSOM may be associated with significant limitation of hearing function that may result in communication problems impairing social interaction and professional life. Conductive hearing loss is considered a serious disability, contributing to a significant disease burden worldwide^{4,5}. In addition, persistent discharge from the ear, pain or frequent physician visits may result in a serious impairment of patients' quality of life (QoL)^{4,5}. In case of CSOM with cholesteatoma, complications such as facial nerve paralysis, Bezold's, Luc's, Citelli's abscesses, meningitis or encephalitis, may develop and potentially threaten the patient's life⁶.

QoL measures are clinically important to determine the impact of the disease, as well as the effectiveness of different types of treatment, and assessment of objective parameters does not mirror the subjective experiences of patients. Health-related QoL is particularly important in chronic health conditions, such as CSOM, requiring long-term treatment and life-long care. Generally, hearing levels measured by pure tone audiometry have been used to define and quantify CSOM-related QoL. However, disabling hearing loss on audiometric data may not correlate with QoL⁷. Assessing subjectively QoL with a specific questionnaire is steadily increasing in clinical medicine and, in particular, in different otorhinolaryngological diseases as rhinosinusitis, several studies have reported that physicians' ratings of the QoL in patients with chronic illness were significantly different from patients' self-rated QoL^{5,7}. Currently, in clinical practice, there are a large number of questionnaires that can measure QoL^{5,7}. However, not all questionnaires are able to evaluate the subjective symptoms, functional outcomes and the psychological aspects of CSOM^{4,6}.

Generic questionnaires, as the Short Form 36 Health Survey (SF-36), can be used to assess CSOM-related discomfort, but they are not disease-specific and can, therefore, underestimate the impact of the disease on patients' QoL. Hence, disease-specific measures are more sensitive than generic measures⁵. So far, the most relevant characteristics of CSOM, including clinical symptoms and functional

and psychological impairments, are well represented in the COMOT-15 questionnaire⁶. However, it is crucial to develop questionnaires in native languages and ensure they are appropriate to the culture of the country so that they can be used on larger groups of the population. Thus, we developed an Italian COMOT-15 questionnaire, which subjectively assesses disease-specific QoL.

The aim of this study was to linguistically and culturally adapt the COMOT-15 questionnaire into Italian and to obtain measures of its internal consistency and test-retest reliability.

Materials and methods

Study population and study design

This is a prospective instrument validation study that was conducted on 52 Caucasian Italian-speaking patients affected by CSOM who were diagnosed and followed at our institution. Patients were enrolled between January 2018-December 2018 at ENT section of Department of Neuroscience, Reproductive and Odontostomatological Sciences, University "Federico II" of Naples, Italy. We enrolled as controls 52 Caucasian Italian-speaking healthy volunteers. A diagnosis of CSOM was obtained from the patient's medical history, ENT examinations, including otomicroscopy and oto-endoscopy, pure tone audiometry and computed tomography (CT) scans. All subjects were asked to fill in the translated COMOT-15 questionnaire on their own during their first visit to the outpatient clinic and again one month after their first visit for retest evaluation.

The linguistic adaptation process of the Italian version of the COMOT-15 questionnaire consisted of two phases: the first phase was translation of the original English version into Italian, and the second consisted of measuring the reliability of the translation obtained.

Pure-tone audiometry for testing conventional frequency range (0.125 to 8 kHz), was performed using an Amplaid 319 audiometer (Amplaid Inc., Milan, Italy) in a double-walled, soundproof room. Pure-tone average values were calculated in dB from the air conduction hearing loss as the mean of 0.5, 1, 2 and 4 kHz thresholds (pure tone average, PTA).

Subjects signed an informed consent form before participating in the study. All procedures performed in studies were in accordance with the ethical standards of the institutional research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. Local Board of Medical Ethics number 339/20.

COMOT-15 questionnaire

The COMOT-15 consists of 3 subscales, categorised as ear symptoms (questions 1-6), hearing function (questions 7-9)

and mental health (questions 10-13), which form the overall score. In addition to questions from 1 to 13, the COMOT-15 contains two other questions: a general evaluation of the impact of CSOM on QoL (question 14) and a question on the frequency of ENT visits as a result of CSOM in the previous 6 months (question 15). The total score and the 3 subscales were transformed into a 0-100 score by dividing the sum of the raw scores of the items by the sum of spans of the items, followed by multiplying this number by 100⁴.

Linguistic adaptation process of the Italian version of the COMOT-15

The linguistic adaptation was obtained by translation of the original version in English into Italian and back-translation into English again. Two native Italian otolaryngologists and one bilingual expert whose mother tongue was Italian independently translated the questionnaire. The 3 versions were unified by consensus between the translator and researchers. The bilingual translator back-translated this final version. After the back-translation, the two otolaryngologists and the bilingual expert adapted the Italian questionnaire in order to improve the semantic equivalence of meaning between the two English versions. After these steps had been completed, the first version of the Italian COMOT-15 questionnaire was conceived. This version was initially pilot-tested on a sample of 25 healthy volunteers to determine whether the questions could be clearly understood. The pilot test was performed by a single investigator (EC) through a direct interview to assess possible difficulties in understanding the questionnaire. After some words were modified to facilitate comprehension, the Italian translation was finalised (Fig. 1).

Measuring the reliability of the cross adapted Italian version of COMOT-15

In a second phase of this study, we compared patients diagnosed with CSOM with healthy volunteers. Exclusion criteria were as follows: age < 18, lack of full legal capacity, inability to read and understand Italian, immunodeficiency, diabetes, heart, oncological, immunological, malformations, neuropsychiatric diseases and previous ear surgery.

Data analysis

The data were analysed with SPSS 19 for Windows (IBM Corp., Armonk, NY). Continuous baseline characteristics were presented as the mean and standard deviation. The internal consistency of the test was determined using Cronbach's α . The test-retest reliability was assessed by exploring the correlation between the COMOT-15 scores obtained during the first visit at the outpatient clinic (test) and those obtained one month after the first visit (retest) by using the Pearson correlation coefficient.

COMOT-15 (chronic otitis media outcome test)						
Considerato quanto sia grave il problema, quando si verifica e quanto spesso accada, si prega di valutare ogni elemento sotto riportato su quanto invalidante possa essere per lei cercando il numero corrispondente						
	Nessun problema	Molto lieve	Lieve/leggero	Moderato	Severo	Insoportabile
1. Otorrea (fuoriuscita di liquido dall'orecchio)	0	1	2	3	4	5
2. Mal d'orecchio	0	1	2	3	4	5
3. Pressione all'orecchio/sensazione di orecchio pieno	0	1	2	3	4	5
4. Acufeni (fischio nell'orecchio)	0	1	2	3	4	5
5. Mal di testa	0	1	2	3	4	5
6. Abbassamento dell'udito	0	1	2	3	4	5
7. Difficoltà a comprendere una persona che parla a distanza	0	1	2	3	4	5
8. Difficoltà a comprendere qualcosa in ambiente rumoroso	0	1	2	3	4	5
9. Difficoltà a comprendere quando più persone parlano contemporaneamente	0	1	2	3	4	5
10. L'abbassamento dell'udito mi fa sentire depresso/triste	0	1	2	3	4	5
11. A causa della mia perdita uditiva temo di fraintendere le altre persone	0	1	2	3	4	5
12. La mia perdita uditiva può causare situazioni imbarazzanti	0	1	2	3	4	5
13. Ho paura che i miei problemi uditivi possano peggiorare in futuro	0	1	2	3	4	5
14. Valutazione complessiva dell'impatto della patologia uditiva sulla qualità della vita	0	1	2	3	4	5
15. Frequenza di visite specialistiche legate alla patologia dell'orecchio negli ultimi sei mesi	0	1	2	3	4	5

Figure 1. The Italian version of COMOT-15 questionnaire.

The absolute scores of the healthy participants and patients were analysed with the non-parametric Mann-Whitney U-test to assess the validity of the questionnaire. Statistical significance was achieved for a p inferior to 0.05.

Results

We recruited 52 Caucasian Italian-speaking patients (mean age was 48.3 ± 16.1 SD, range 18-64 years; 28 females) diagnosed with CSOM and 52 Caucasian Italian-speaking healthy volunteers (mean age 42.6 ± 10.1 SD, range 19-62; 29 females). The male/female ratio was 0.8 in the investigational arm and 0.7 in the control arm.

We found a bilateral CSOM in 13/52 subjects (25% of cases) and 38/52 (73%) CSOM with cholesteatoma. Pure tone average (PTA) [dB] calculated from air conduction hearing loss at 0.5, 1, 2 and 4 kHz in CSOM patients showed a value of $55[\text{dB}] \pm 10.2$ SD. The opposite ear showed a healthy aspect in 39/52 (75 %) patients.

The total score of the Italian version of COMOT-15 was 36.76 ± 13.1 (mean \pm SD). The mean scores of the subscales of COMOT-15 were 11.05 ± 4.45 (mean \pm SD) for ear symptoms, 13.48 ± 5.83 (mean \pm SD) for hearing function and 9.69 ± 4.65 (mean \pm SD) for mental health

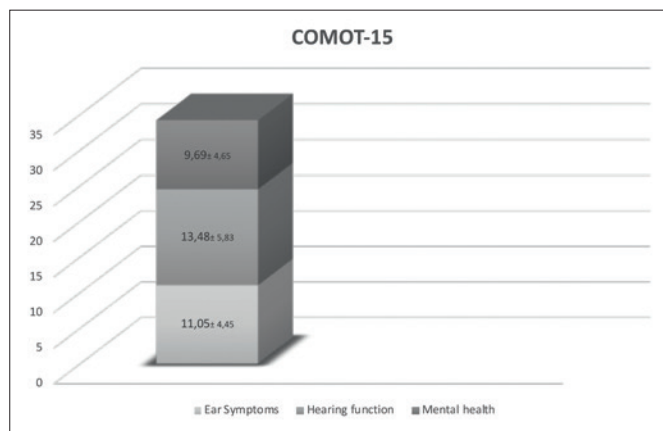


Figure 2. Mean scores of the Italian version of COMOT-15. The mean total score of the Italian version of COMOT-15 was 36.76 ± 3.1 . The mean scores of the subscales of COMOT-15 were 11.05 ± 4.45 for ear symptoms, 13.48 ± 5.83 for hearing function, and 9.69 ± 4.65 for mental health (mean \pm SD).

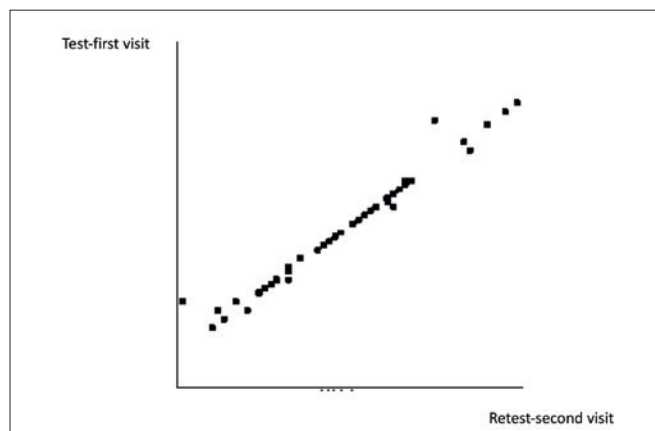


Figure 3. Test-retest reliability. The test-retest reliability showed a strong, positive Pearson correlation coefficient ($r = 0.98$, $p = 0.00001$) for total score and all subscales: ear symptoms $p < 0.01$, hearing function $p < 0.01$, mental health $p < 0.01$.

(Fig. 2). The mean scores of subgroups, CSOM with/without cholesteatoma, are reported in Table I.

The Mann-Whitney U-test showed that the COMOT-15 scores were significantly higher in patients with CSOM than in control subjects ($U = 68.5$, $p = 0.0001$).

The internal consistency was supported by a Cronbach’s α of 0.95. The test-retest reliability showed a strong, positive Pearson correlation coefficient ($r = 0.98$, $p = 0.00001$) for total score and all subscales: ear symptoms $p < 0.01$, hearing function $p < 0.01$ mental health $p < 0.01$ (Fig. 3). Age and gender had no influence on the evaluation of the scores of COMOT-15 ($p > 0.05$).

The analysis of correlations between the scales of the COMOT-15 and the pure tone average showed a significant association for the scale “Hearing Function”, $p < 0.008$.

Discussion

The present study aimed to translate the COMOT-15 into the Italian language. The translated version was administered to a large study population.

The results showed that the Italian COMOT-15 provides good reliability as well as internal consistency, suggesting its suitability in determining the QoL of Italian-speaking individuals suffering from CSOM. The mean total score of

the Italian COMOT-15 (36.76 ± 13.1 , mean \pm SD) suggested a deterioration of QoL in patients affected by CSOM. In addition, the mean scores of the subscales pointed out that ear symptoms were the major cause of reduced QoL in Italian-speaking individuals with CSOM.

QoL measurements in CSOM subjects assess the impact of the disease on patient’s overall health, social interaction and psychological status⁶. The most common CSOM QoL questionnaires, although each with some limitations, are: the Glasgow Benefit Inventory (GBI), Glasgow Health Status Inventory (GHSI), Chronic Ear Survey (CES)⁸, Chronic Otitis Media Questionnaire 12 (COMQ-12), Otitis Media-6 questionnaire (OM-6) and the health-related QoL (HRQoL)^{5,6,9-11}. The GBI was designed to evaluate changes in QoL following surgery, whereas the GHSI measures the impact of a health problem on the QoL and provides information about the physical health subscale. Although the GBI and GHSI have been commonly used for ear, nose and throat diseases, they do not give enough information about the hearing function and mental health of the patient⁵. The CES questionnaire includes some single items evaluating the frequency of symptoms or medical problems, but it does not include a subjective assessment of their severity as perceived by the patients^{4,7,8}. It does not seem to adequately cover the subjective point of view of the patients^{4,8}.

Table I. Mean scores of the Italian version of COMOT-15 in subgroups (CSOM with cholesteatoma and without cholesteatoma). Differences between total cases scores and subgroups (CSOM with/without cholesteatoma) scores are not statistically significant (mean \pm SD).

	No.	Overall score	Ear symptoms	Hearing function	Mental health
Total cases	52	36.76 ± 13.1	11.05 ± 4.45	13.48 ± 5.83	9.69 ± 4.65
CSOM with cholesteatoma	38	37.02 ± 13.43	11.41 ± 4.19	13.92 ± 5.49	10.01 ± 4.38
CSOM without cholesteatoma	14	36.07 ± 12.76	10.08 ± 4.64	12.29 ± 6.07	8.84 ± 4.84

The COMQ-12 consists of 12 questions grouped into four categories on severity of symptoms, impact on lifestyle, work and the health service, as well as general impact on the patient's QoL. However, like the GBI and GHSI it does not give information about hearing function and mental health of the patient^{1,4,6}.

Lastly, the OM-6 and the HR QoL are intended exclusively for paediatric use^{12,13}.

However, the most relevant characteristics of CSOM^{14,15}, including clinical symptoms and functional and psychological impairments, are well represented in the COMOT-15^{4,6}. The COMOT-15 seems to represent a well-conceived synthesis of the most important items affecting patients' quality of life, representing the impact of the disease and of its therapy.

Indeed, the 15 questions of COMOT-15 consist of three subscales, categorised as ear symptoms, hearing function and mental health. In addition, the COMOT-15 contains a question on the general evaluation of the impact of CSOM on QoL and a question about the frequency of ENT visits^{4,6}.

The COMOT-15 is currently the only questionnaire that evaluates the frequency of ENT visits, which represents an indirect measure of QoL^{4,6}. For these reasons, it seems to be the most suitable questionnaire to evaluate CSOM. Furthermore, the COMOT-15 questionnaire assesses the impact of CSOM on the patient's overall health, social interaction and psychological status⁶.

Given the usefulness of QoL questionnaires, in our opinion it is essential to develop QoL measures in native languages and appropriate to the culture of the country. There has been growing literature exploring tools that are able to assess clinical patient-based outcomes, or rather, outcomes as experienced by the patients. In addition, a subjective way of investigation, like a questionnaire, can reflect QoL much more closely than exclusive clinician-rated outcomes. Furthermore, it is crucial to develop native-languages questionnaires that can be used on larger groups of patients⁷.

Conclusions

This study confirmed the importance of using validated translations of QoL questionnaires, which, by giving the possibility to compare populations from different countries and with different cultures, represent a valid tool to establish clinical protocols for global health systems. Our study showed that the Italian COMOT-15 questionnaire has good internal consistency and validity, and can be successfully applied to Italian-speaking patients. Given that the COMOT-15 is a quick, easy-to-use instrument to determine the QoL of subjects with CSOM, it is strongly advisable that further translations in other different languages will follow.

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