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OTOLOGY

Cross-cultural adaption and validation of the Chronic Otitis Media Questionnaire 12 (COMQ-12) in the Italian language

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Abstract

Purpose The evaluation of Health-Related Quality of Life (HRQoL) in patients with chronic otitis media COM has gained attention over the past years and several questionnaires have been developed to evaluate it in affected patients. The Chronic Otitis Media Questionnaire 12 (COMQ-12) is a widely used disease-specific tool that evaluates the severity of symptoms, the specific impact on work and lifestyle, the effects on the health service, and general impact of the disease in patients with COM. The COMQ-12 questionnaire has been translated and validated into different languages; however, an Italian version is not yet available. The aim of this original study was to translate the COMQ-12 questionnaire into the Italian language and validate this new Italian language version in Italian-speaking patients with COM.

Methods The COMQ-12 was translated into Italian (COMQ-12-It) following international guidelines. Validation was performed comparing and correlating COMQ-12-It with (1) a question that addresses HRQoL, and (2) the results of a generic questionnaire assessing HRQoL, namely the EQ-5D-5L questionnaire.

Results Forty-eight patients with COM were included in the study. Cronbach's alpha was 0.80 indicating a high reliability. There was a strong positive correlation between the question that directly addressed HRQoL and total score (correlation coefficient = 0.62), while the regression analysis between total score of COMQ-12-It and EQ-5D-5L showed a positive relation but only a weak positive correlation (correlation coefficient 0.36).

Conclusions Our study showed evidence that the Italian version of the COMQ-12 questionnaire is a valid and reliable tool to evaluate HRQoL in Italian-speaking patients with COM.

Keywords Chronic otitis media · Cholesteatoma · Health-related quality of life · Italian · COMQ-12

Introduction

Chronic otitis media (COM) is a chronic infection of the middle ear with or without perforation [1]. Prevalence of COM ranges between < 1% in industrialized countries to > 4% in low-income countries [2–4].

COM has a serious impact on quality of life (QoL) of affected patients following hearing loss, persistent infection, and frequent malodorous discharge from the ear [5–10]. The evaluation of Health-Related Quality of Life (HRQoL) in COM has gained increasing attention over the past years [6–8, 11–15], and several questionnaires have been developed to evaluate it in affected patients. They include the Chronic Otitis Media Questionnaire 12 (COMQ-12) [16], the Chronic Ear Survey (CES) [17], the Chronic Otitis Media Outcome Test 15 (COMOT-15) [18], the Zurich

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Chronic Middle Ear Inventory (ZCMEI-21) [19], and the Chronic Otitis Media 5 (COM-5) [9].

The COMQ-12 questionnaire was developed by Phillips et al. [16] to evaluate QoL in patients with COM based on three COM-related quality of life questionnaires—the CES [17], the COMOT-15 [18], and the COM-5 [9]. The COMQ-12 questionnaire is composed of 12 questions in 4 different categories: severity of symptoms, specific impact on work and lifestyle, impact on the health service, and general impact of the disease on the patient. Based on the degree of inconvenience or frequency of symptoms, questions are scored on a six-point scale from 0 (no impact) to 6 (most severe impact).

The COMQ-12 questionnaire has been translated and validated into Portuguese [20], Serbian [21], Kannada [22], Russian [23], Dutch [24], and Turkish [25]. The aim of this study was to translate the COMQ-12 questionnaire into the Italian language and validate this new Italian language version in Italian-speaking patients with COM.

Materials and methods

This study included patients suffering from COM recruited in the University Hospital of Bari. The inclusion criteria were a diagnosis of COM with or without cholesteatoma, age > 12 years, and sufficient Italian language skills. The study was approved by the local Ethic Committee (University of Bari) and was performed in accordance with the Helsinki declaration and its amendments. Informed consent was obtained from all the participants. Further details on the study design are provided in Fig. 1.

Translation of the COMQ-12 into Italian and cross-cultural adaptation

The process of translation and adaptation of COMQ-12 was performed based on the Principles of Good Practice for the Translation and Cultural Adaptation Process for Patient, Reported Outcomes Measures, according to the

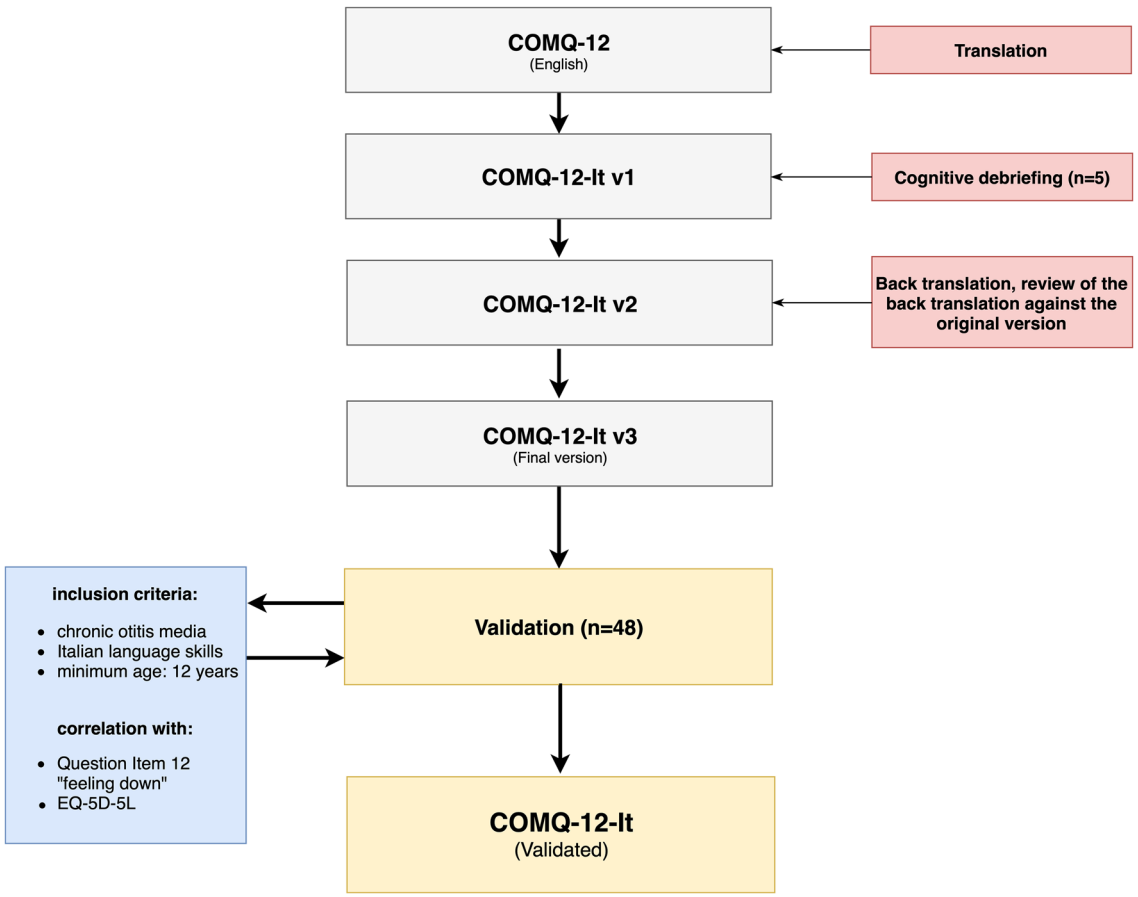

Fig. 1 Study design for the translation of the Chronic Otitis Media Questionnaire 12 (COMQ-12) into the Italian language (COMQ-12-It) and validation of the COMQ-12-It

recommendations of the International Society for Pharmacoeconomics and Outcomes Research Task Force [26].

Two forward translations were performed by two translation experts. Then Italian-speaking clinicians merged the two translations into one translation (COMQ-12-It, v1). This version was used for a first pilot test in five patients to highlight the potential difficulties in understanding the questions; minor revisions followed the pilot test. The modified questionnaire (COMQ-12-It, v2) was back translated into English from a third translation expert. The back translation was then compared with the English version and the COMQ-12-It, v2 underwent additional minor modifications to provide an equivalent Italian translation (COMQ-12 It) that was used for the validation process (Supplementary Appendix).

Validation process

A printed version of the COMQ-12-It questionnaire was administered to patients with COM during ambulatory visits regardless of the status of their otitis (active, inactive) or the presence or absence of previous ear surgery. To validate the COMQ-12-It questionnaire, responses were correlated with two items aimed at measuring the overall HRQoL: the first was question 12 of the COMQ-12-It; the second was the EuroQol 5D questionnaire (EQ-5D) in its 5-level version (EQ-5D-5L), an instrument for a meaningful description and measurement of HRQoL. The EQ-5D-5L questionnaire investigates mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. The EQ-5D-5L questionnaire has been previously validated in the Italian language [27]; however, the value sets for comparison are only available in the English language [28].

Statistical analysis

Values are reported as mean ± SD or as absolute number and percentage. To assess the internal consistency of the construct, the reliability coefficient (Cronbach's alpha) was reported for the 12 items of the questionnaire. To check the relevance of individual items, item to total correlation was calculated. Moreover, partial reliability coefficient was calculated by excluding one item at a time. Concurrent validity was assessed by calculating Spearman correlation between 12 item questions and 5D question. Concurrent validity was determined by comparing the total scores of COMQ-12-It and subscores to the EQ-5D-5L descriptive system and VAS scores using Spearman rank correlation and linear regression analysis including mean prediction intervals. Statistical analyses were performed using Prism (version 7 for Apple Macintosh, GraphPad Software). The significance level was set to $p < 0.05$.

Results

Forty-eight patients with COM completed the Italian version of the COMQ-12-It; 22 were males and 26 were females. Mean age was 49.6 years (12–78), with no significant differences between sex [males: 49.9 years (12–78); females: 49.4 years (14–77); $p = 0.92$]. COM without cholesteatoma was found in 20 (41.7%) patients; cholesteatoma was present in 28 (58.3%) patients. COM was unilateral in 44 patients (91.7%) and bilateral in 4 patients (8.3%). Twenty-five patients (52.1%) already had surgery at the time of questionnaire administration; 23 (47.9%) never had surgery for COM.

Mean total COMQ-12-It score was 27.3 (6–53). Table 1 shows mean, median, standard deviation, and variance for each of the 12 items of the COMQ-12-It questionnaire. Among the 12 questions, most had a mean score between 2 and 3. The mean score of individual items resulted inferior to 2 for 5 items, and above 3 for 3 items.

Figure 2 shows the average score of each item based on the status of COM. The average score for inactive mucosal COM (with previous surgery) was lower compared to other categories in most of the individual items whereas the average score for patients with active mucosal COM (wet perforation, without previous surgery) had a higher value compared to other categories. Differences between subgroups were not statistically significant.

Table 2 shows item to total correlation analysis. The overall reliability coefficient alpha found in our sample was 0.80

Table 1 Descriptive statistics of Chronic Otitis Media Questionnaire 12-Italian (COMQ-12-It) question responses with mean, median, standard deviation, and variance for each of the 12 items of the COMQ-12-It

	Q1	Q2	Q3	Q4	Q5	Q6	Q7	Q8	Q9	Q10	Q11	Q12
Mean	2.50	1.98	2.94	3.04	1.79	1.71	2.35	2.06	2.04	1.81	1.77	3.29
Median	2.00	2.00	3.50	4.00	1.00	1.50	3.00	1.50	2.00	2.00	1.00	4.00
SD	1.61	1.72	1.77	1.84	1.75	1.65	1.83	1.99	1.84	1.45	1.70	1.76
Variance	2.60	2.96	3.12	3.40	3.06	2.72	3.34	3.97	3.40	2.11	2.90	3.10

Among the 12 questions, most had a mean score between 2 and 3. The mean score of individual items resulted inferior to 2 for 5 items, and above 3 for 3 items

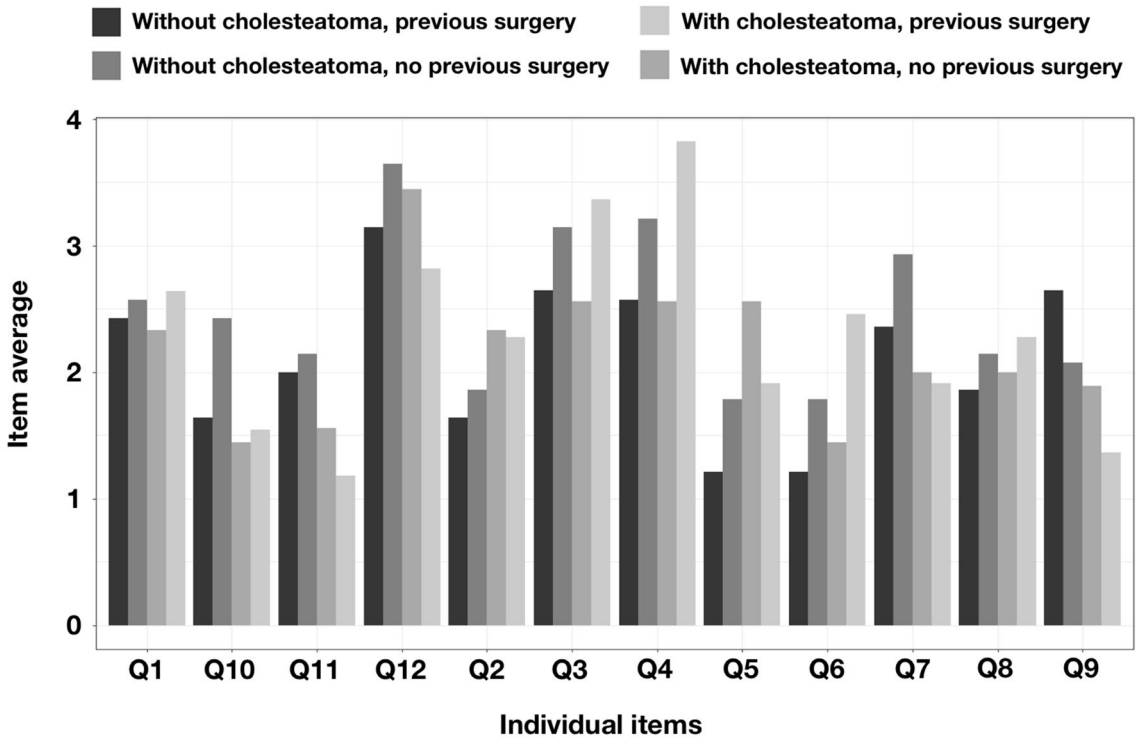

Fig. 2 Average score of each item based on the status of chronic otitis media (COM). The average score for inactive mucosal COM (with previous surgery) was lower compared to other categories in most of the individual items whereas the average score for patients with active mucosal COM (wet perforation, without previous surgery) had a higher value compared to other categories. Differences between subgroups were not statistically significant

Table 2 Item to total correlation

	Item total correlation	Alpha without single item	Sample size
Q1	0.55	0.77	48
Q2	0.39	0.79	48
Q3	0.52	0.77	48
Q4	0.51	0.77	48
Q5	0.39	0.79	48
Q6	0.38	0.79	48
Q7	0.48	0.78	48
Q8	0.36	0.79	48
Q9	0.30	0.79	48
Q10	0.38	0.79	48
Q11	0.41	0.78	48
Q12	0.62	0.76	48

The overall reliability coefficient alpha is 0.80, indicating a very good level of internal consistency. The correlation between each of the individual item to the total score is equal or greater than 0.3, indicating the importance of each individual item to the final underlying construct

indicating a very good level of internal consistency. The correlation between each of the individual item to the total score showed values equal or greater than 0.3, indicating the importance of each individual item to the final underlying construct.

Figure 3a shows the distribution of the total COMQ-12-It score between patients who underwent surgery and those who did not. Patient with no previous surgery for COM showed skewed distribution where median value of the total score was closer to third quartile whereas the median score was closer to the first quartile for those patients who had previous surgery. Moreover, the distribution of total score for the patients who had surgery showed symmetric pattern compared to the distribution of total score of patients who did not have surgery. The median score of patients who did not undergo surgery was higher than the median score of the patients who were surgically treated.

Figure 3b shows the distribution of the total score between patients with and without cholesteatoma. The variation of the total score was slightly higher in patients without cholesteatoma compared to patients with cholesteatoma. In addition, the median score of patients without cholesteatoma was higher than in patients with cholesteatoma. The difference was not statistically significant.

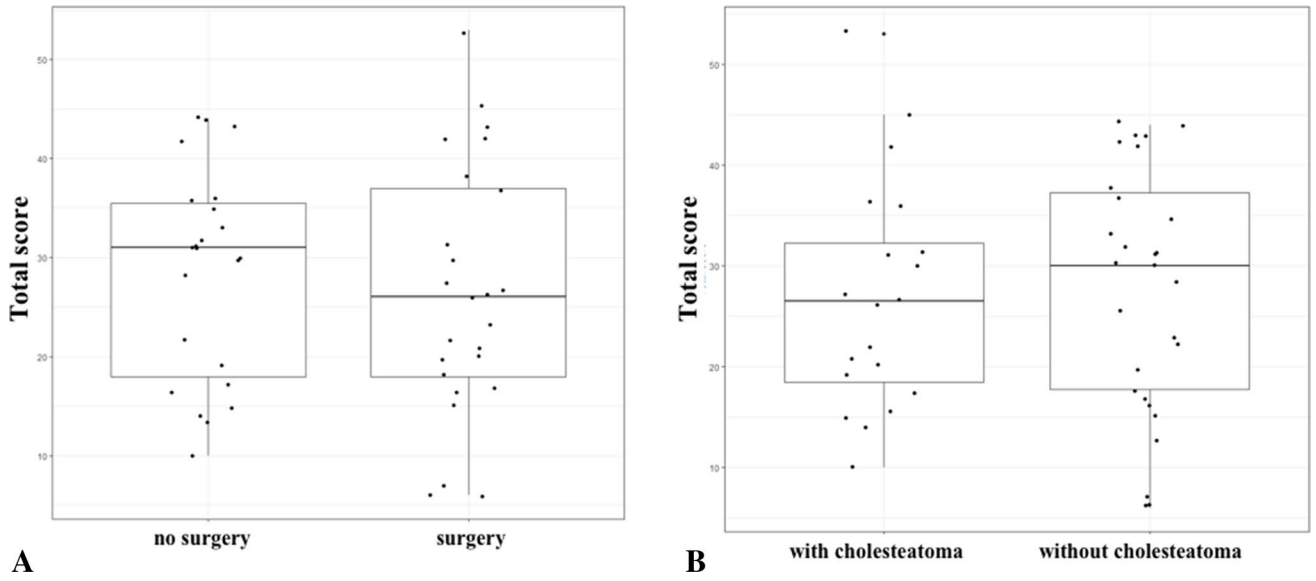

Fig. 3 **a** The distribution of the total Chronic Otitis Media Questionnaire 12-Italian (COMQ-12-It) score between patients who underwent surgery and those who did not. **b** Distribution of the total score between patients with and without cholesteatoma

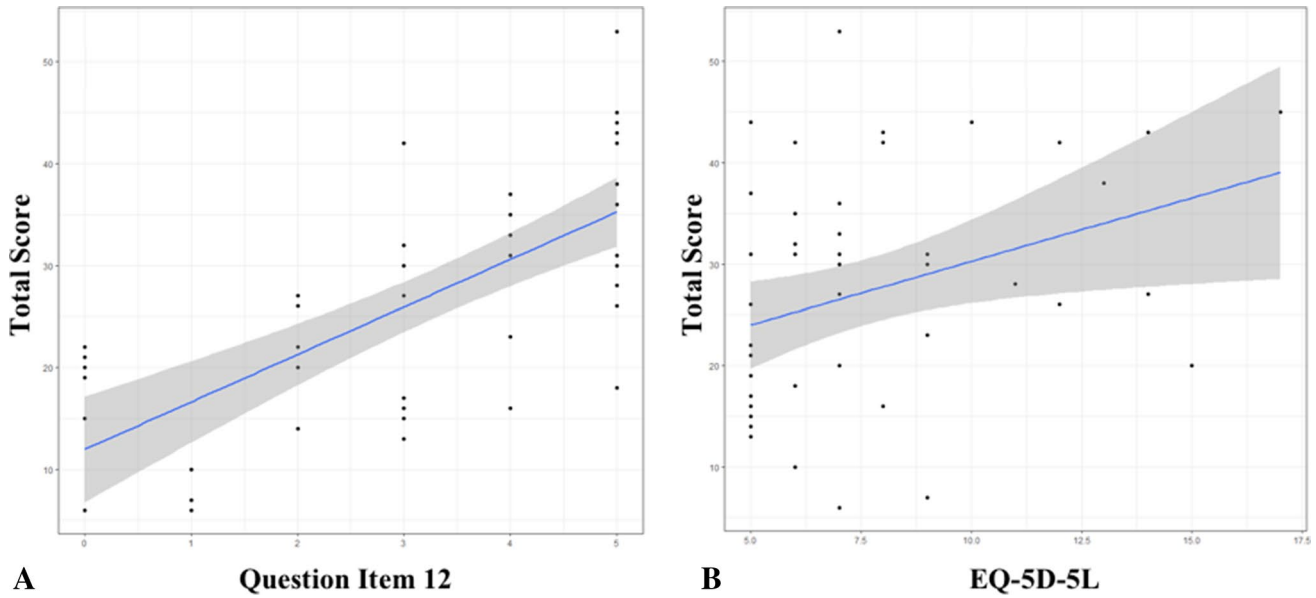

Fig. 4 Regression analysis results for total score of Chronic Otitis Media Questionnaire 12-Italian (COMQ-12-It) and **a** Item 12 and **b** EQ-5D-5L questionnaire. There was a strong positive correlation between item number 12 and total score (correlation coefficient = 0.62), while the regression analysis between total score of COMQ-12-It and EQ-5D-5L showed a positive relation but only a weak positive correlation (correlation coefficient 0.36)

Figure 4 shows regression analysis results. There was a strong positive correlation between item number 12 (the question used to measure QoL) and COMQ-12-It total score (correlation coefficient = 0.62; $p < 0.01$). The fitted regression line also showed a positive correlation between Item 12 and the COMQ-12-It total score. This result indicates that item number 12 "feeling down" is highly correlated with the total score; therefore, it could be assumed that this individual item can measure the underlying construct with a high reliability (Fig. 4a).

The regression analysis between total score of COMQ-12-It and EQ-5D-5L showed a positive relation but only a weak positive correlation based on correlation coefficient (correlation coefficient 0.36; $p < 0.05$) (Fig. 4b).

Discussion

In the last decades, patient-reported outcomes on HRQoL have become important endpoints to assess the individual impact on general health, social interaction, and psychological status of several pathological conditions [6–8, 11–15]. However, it is of utmost importance to develop HRQOL measures in patients' and caregivers' native languages. The present study translated the COMQ-12 questionnaire into Italian and validated the new Italian version in patients with COM to allow the use of this questionnaire in the Italian population.

To date, two questionnaires to evaluate QoL in patients with COM have been translated in the Italian language and validated in the Italian population, the CES-I [29] and the ZCMEI-22-It [30]. The CES-I focuses on disease-specific health but does not investigate the impact of specific symptoms on patients' QoL. The ZCMEI-22-It provides a comprehensive assessment of relevant dimensions of HRQoL in Italian patients with COM. In addition, the Short Form 36 Health Survey Questionnaire in its Italian version (SF-36-It) is commonly used for this purpose although it is a generic questionnaire that has not proven to be sensitive enough for COM [31]. The COMQ-12 questionnaire is slightly different from the other questionnaires as it evaluates QoL in patients with COM into four different domains; its use in the Italian language may be a useful tool to evaluate QoL in Italian-speaking patients also in conjunction with the two other specific questionnaires.

The translation of the COMQ-12 questionnaire in the Italian language was performed following a standardized approach to guarantee maximum reliability. No major difficulties were found in the translation or in the cultural adaptation of the questionnaire. The results showed that the Italian version of COMQ-12 has good internal consistency and item-total correlations. The overall reliability coefficient alpha found in our sample was 0.80; this value indicates a very good level of internal consistency and is in line with the original English version and recent validation studies in other languages [20, 22–25]. This overall value of reliability coefficient is indicating that the 12-item questions measure the same underlying construct consistently. All item-to-total correlation values are greater than or equal to 0.3 and this indicates the importance of each individual item to the final underlying construct.

In the validation study, we found a strong positive correlation between item number 12 (an item that evaluated overall QoL) to total score. This confirms the success of the validation process demonstrating that Italian-speaking individuals with COM have significant impairment in their HRQoL measures and that this individual item can measure the underlying construct with a high reliability. Interestingly, we did not find a significant correlation with the ED-5D-5L questionnaire; this may be due to the limited size of our sample or to the fact that the EQ-5D-5L is a generic HRQoL questionnaire that does not meet the requirements to assess QoL in specific conditions such as COM.

Conclusions

Our study showed evidence that the Italian version of the COMQ-12 questionnaire is a valid and a reliable tool to evaluate HRQoL in Italian-speaking patients with COM.

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Compliance with ethical standards

Conflict of interest The authors declare that they have no conflict of interest.

Research involving human participants and/or animals All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional research committee of the University of Bari (2018) and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Informed consent Informed consent was obtained from all individual participants included in the study.

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