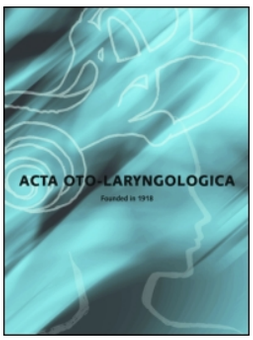

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RESEARCH ARTICLE

Adaptation and validation of the chronic otitis media questionnaire 12 (COMQ-12) in the Mexican Spanish language (COMQ-12-Mx)

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ABSTRACT

Background: Chronic otitis media (COM) questionnaire 12 (COMQ-12) is a specific-disease tool that evaluates COM patients.

Objective: To validate COMQ-12 in the Mexican Spanish language (COMQ-12-Mx).

Materials and methods: Mexican Spanish-speaking healthy volunteers and COM patients who attended a Secondary Care Center from May 2019 to October 2019. The COMQ-12 in Mexican Spanish was obtained by translation and back translation from an English-Spanish translator. All participants completed the COMQ-12-Mx questionnaire. COM patients were included regardless of their COM status. Control group completed the questionnaire twice. Participants were categorized into three groups: group 1 (COM), group 2 (volunteers first test) and group 3 (volunteers retest). Cronbach's alpha was used for internal consistency, Spearman's rank correlation coefficient was used for test-retest reliability and Mann–Whitney U test compared groups.

Results: We included 78 Mexican Spanish-speaking participants (COM $n = 37$, healthy volunteers $n = 41$), 51 females and 27 males, mean age was 39.67 years (SD ± 18.32). Group 1 COMQ-12-Mx score was 22.108 ± 11.79, group 2 score was 3.561 ± 4.399 ($p \leq .001$) and group 3 score was 3.683 ± 4.435. Cronbach's alpha was 0.828 and test-retest reliability achieved a 0.928 outcome.

Conclusions: COMQ-12-Mx is a valid and reliable tool to evaluate quality life in Mexican Spanish-speaking patients with COM.

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Otitis media; suppurative otitis media; quality of life; health-related quality of life

Introduction

Chronic Otitis Media (COM) is not uniformly defined in the literature. World Health Organization defines this disease as chronic inflammation of the middle ear and mastoid cavity, with recurrent ear discharges or otorrhea through a tympanic perforation. The disease usually begins in childhood as a spontaneous tympanic perforation due to acute otitis media (AOM) [1]. Complications such as hearing loss, are described globally in over 30.32/10,000 COM patients [2]. Several forms of COM are recognized, from active (cholesteatoma with or without otorrhea, or otorrhea without cholesteatoma) to inactive status (retraction pocket, perforation or ossicular resorption or fixation) [3]. Other authors still consider COM only if the symptoms persist for more than three months after an AOM episode.

COM has a high global prevalence, countries with the highest rates of COM (>4% of population) are African and Asian, where COM represents a massive public health problem. In Latin America, there is no accurate data on the prevalence and incidence of this disease. Furthermore, the World Health Organization reports a 2.94% prevalence in America [1]. Chronic suppurative otitis media is a major cause of disabling hearing loss, particularly in developing countries. Additionally, there are other factors that could affect the quality of life (QoL) of COM patients, such as chronic ear discharge, discomfort and disturbance of balance. Additionally, in some cases, complications such as facial paralysis and intracranial sepsis can have devastating consequences [4].

As a result, there has been an urge to be able to measure the self-perception of health in order to assess the benefit of health care interventions and target services [5]. With this purpose Phillips et al. [6] in 2014 in the United Kingdom described the COM questionnaire-12 (COMQ-12), in an effort to create an instrument for evaluation of health-related QoL (HRQoL) in patients with COM. Additionally, other tests have been created (CES [7], COMOT-15 [8], COM-5 [9] and the ZCMEI-21 [10]) to evaluate COM. COMQ-12 is a specific-disease tool that evaluates the severity of symptoms, the specific impact on work and lifestyle, the effects on health service, and the general impact of the disease in patients with COM [11].

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COMQ-12 has been translated and validated into Portuguese, Turkish, Russian, Serbian, Kannada, Dutch and Italian [11–18], thus far not in Spanish language. Therefore, the aim of this study is to adapt the COMQ-12 questionnaire into the Mexican Spanish language and to validate this questionnaire in the Mexican Spanish-speaking patients with COM. Thus, to be used for clinicians to measure the impact in QoL of patients with COM either in preoperative or postoperative evaluation. The Spanish translation of this instrument can overcome geographic barriers and, in this manner, become available to other Latin Spanish countries in America and Spanish-speaking patients worldwide.

Materials and methods

Subjects

This study was performed at the Department of Otorhinolaryngology and Head and Neck Surgery of a Secondary Care Center in patients diagnosed with COM from May 2019 to October 2019. The protocol was conducted with previous approval of the Research Committee of this Center. Informed consent was obtained from all patients.

A total of 78 patients (41 healthy volunteers and 37 with COM diagnosed) completed the Mexican Spanish version of the COMQ-12 questionnaire. Inclusion criteria required COM diagnosis regardless of the etiology or actual COM status, there were no restrictions on age or gender. Exclusion criteria were: no native Mexican Spanish-speaking patients, patients with insufficient language skills who were unable to give proper answers and those who declined to participate. Three groups were allocated: group 1 with 37 patients with COM and a control group with 41 healthy volunteers. These 41 participants were also asked to complete the questionnaire for a second time for further evaluation. The retest was applied 7 d after initial test. The control group was divided into group 2 and group 3 according to their first test and their retest, respectively. Healthy volunteers confirmed the absence of middle ear disease by clinical history.

Questionnaire

The COMQ-12 questionnaire assesses three different aspects of the patient's symptoms along with 12 questions (answers scale from 0 to 5). The first seven questions evaluate the intensity of symptoms, question 8 and 9 evaluate the impact on patient's life, and the impact on public health is appraised in question 10 and 11. The last question evaluates the emotional distress of the patient [12]. The minimum score possible is 0 and the maximum is 60. 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 QoL or distress [6].

Translation process into Mexican Spanish

Prior e-mail authorization of an only Mexican Spanish version by Phillips et al. two independent forward translations were performed by two Mexican Spanish-speaking clinicians of the Otorhinolaryngology Department competent in English language. Afterward, both clinicians reached a consensus and merged the two translations into one questionnaire (COMQ-12-Mx, version 1). COMQ-12-Mx version 1 was back translated into English by an English-Spanish translator. The back translation was then compared with the original English version. This English translated version was once again translated into Spanish by a second translator (COMQ-12-Mx, version 2), for a posterior comparison with the COMQ-12-Mx-version 1. The COMQ-12-Mx-version1 underwent additional minor modifications to provide an equivalent Spanish translation of the original. The final result (COMQ-12-Mx) was then used for the validation process.

Validation process

A printed version of the COMQ-12-Mx questionnaire was applied to patients with COM during ambulatory visits in the Department of Otorhinolaryngology and Head and Neck Surgery, regardless of the COM status or the presence of previous otological surgery. The COMQ-12-Mx questionnaire was also applied to healthy volunteers in two different evaluations as mentioned previously. The validation process is described in Figure 1.

Statistical analysis

To compare the demographic characteristics of the population the χ^2 test was used. Cronbach's alpha was used to assess the internal consistency of the instrument and determine the item-total correlation. Spearman's rank correlation coefficient value (Spearman's Rho) was measured to show the test-retest reliability. A value of ≥ 0.7 was established as acceptable reliability.

Mann–Whitney *U* test measured whether there was a difference between the group 1 scores and the control group 2 scores. The diagnostic value of the instrument was assessed using receiver operating characteristics (ROC) curve and the area under the curve was drawn (A_{ROC}). The cut-off score was chosen for the diagnosis of COM according to the best specificity and sensitivity values.

Continuous variables were reported as mean and standard deviation and ANOVA test for the comparison of continuous variables in >2 groups. For categorical variables, absolute number and percentage were used. Significance level was set to $p \leq .05$.

The Statistical Package for the Social Sciences (SPSS) version 21 (IBM Corp., Armonk, NY) was utilized to perform the statistical analysis.

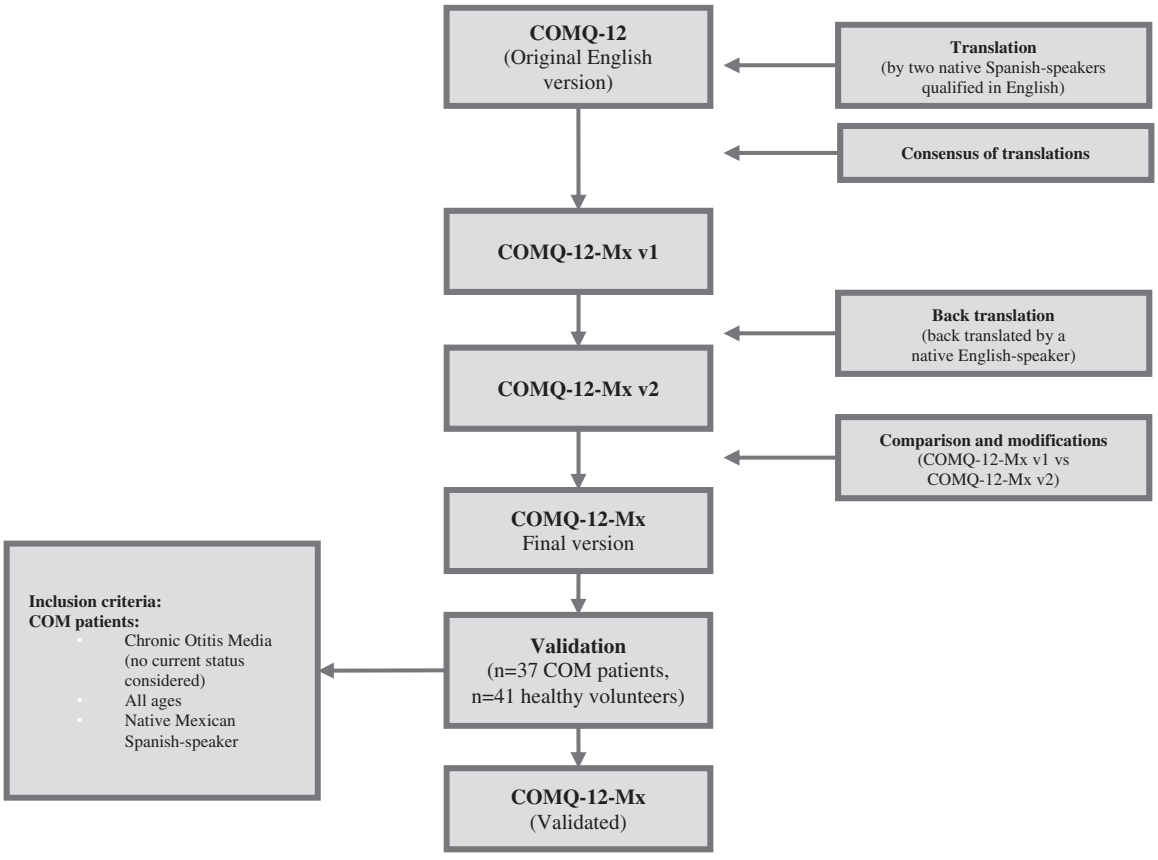

Figure 1. Validation process of the Chronic Otitis Media Questionnaire (COMQ-12) in the Mexican Spanish language (COMQ-12-Mx).

Results

Seventy-eight patients (51 females, 27 males), 37 with COM and 41 healthy volunteers. Mean age 39.67 ± 18.32 years (range: 15–89). In group 1 the right ear was affected in 45.9% ($n = 17$), left ear in 37.8% ($n = 14$) and both ears in 16.2% ($n = 6$).

Previous ear surgery was present in 64.86% ($n = 24$) of group 1, 66.66% ($n = 16$) were subject to more than one surgery (ranging from 2 to 4). Radical mastoidectomy was performed in 41.66% ($n = 10$) of COM patients, cortical mastoidectomy in 41.66% ($n = 10$) and 16.66% ($n = 4$) had other forms of ear surgeries. The remaining 35.13% ($n = 13$) participants had no previous surgeries. The demographic characteristics are shown on Table 1. Age between COM group and control group was significant ($p < .001$).

The overall COMQ-12-Mx scores was 12.359 ± 12.72, with a range from 0 to 52 amongst all participants. In order to see each item and mean scores of COMQ-12-Mx questionnaire applied to all participants ($n = 78$) see Table 2.

The average score of COMQ-12-Mx test was 22.108 ± 11.79 for group 1 (range 7–52). For the subgroup with radical mastoidectomy ($n = 10$) the mean score was 21.90 ± 12.82, for the cortical mastoidectomy ($n = 10$) was 20.80 ± 8.12, and for other surgeries ($n = 4$) (e.g. tympanoplasty or ventilation tube) was 19.75 ± 11.38. COM patients with no surgeries ($n = 13$) obtained a mean score of 24.00 ± 13.12.

For the control group (test and retest) the mean score was 3.62 ± 4.39 (range 0–15). Group 2 had a mean score of 3.561 ± 4.399) and group 3 had a mean score of 3.683 ± 4.435 (group 1 *vs.* group 2, $p < .001$). Table 3 shows each item separately.

Table 1. Demographic characteristics of the population.

	Group 1 ($n = 37$)	Group 2 ($n = 41$)	p Value
Age	49.432 ± 17.85	30.878 ± 13.84	.003
Sex			.813
Females ($n = 51$)	25	26	–
Males ($n = 27$)	12	15	–
Affected ear			
Right	17	0	–
Left	14	0	–
Both	6	0	–
Previous surgery	24	0	–
Number of surgeries			
1	8	0	–
2	12	0	–
3	3	0	–
>3	1	0	–
Type of surgery			
Mastoidectomy	20	0	–
Cortical	10	0	–
Radical	10	0	–
Others	4	0	–

Table 4 shows item to total correlation analysis (group 1, 2 and 3). The overall Cronbach's alpha found in the COMQ-12-Mx study was 0.908. The Cronbach's alpha comparing group 1 and 2 was 0.902. The analysis of test and retest was 0.842. Analyzing exclusively the COM group the outcome was 0.828. In all situations, the Cronbach's alpha remained consistent and significant.

Table 2. Descriptive statistics of COMQ-12-Mx on the overall population.

	Q1	Q2	Q3	Q4	Q5	Q6	Q7	Q8	Q9	Q10	Q11	Q12
Mean	0.667	0.449	1.167	1.308	0.654	0.705	0.987	0.782	1.974	1.231	1.269	1.167
Median	0.000	0.000	1.000	1.000	0.000	0.000	0.000	0.000	0.000	0.500	0.000	0.000
SD	1.3355	1.1007	1.2318	1.3799	1.1146	1.2803	1.3043	1.6007	2.3957	1.3857	1.9318	1.7464
Variance	1.784	1.212	1.517	1.904	1.242	1.639	1.701	2.562	5.740	1.920	3.732	3.050

Q: question; SD: standard deviation.

Table 3. Descriptive statistics of each group's scores on the COMQ-12-Mx.

	Q1	Q2	Q3	Q4	Q5	Q6	Q7	Q8	Q9	Q10	Q11	Q12
Group 1												
Mean	1.324	0.892	1.703	1.757	1.108	1.135	1.514	1.378	4.108	2.432	2.514	2.243
Median	0.2796	0.2413	0.2288	0.2696	0.2252	0.2661	0.2470	0.3319	0.2996	0.1668	0.3586	0.3274
SD	0.000	0.000	1.000	1.000	1.000	0.000	1.000	0.000	5.000	3.000	2.000	2.000
Variance	1.7006	1.4679	1.3917	1.6399	1.3700	1.6187	1.5023	2.0187	1.8224	1.0149	2.1810	1.9917
Group 2												
Mean	0.073	0.049	0.683	0.902	0.244	0.317	0.512	0.244	0.049	0.146	0.146	0.195
Median	0.0412	0.0341	0.1280	0.1474	0.0909	0.1073	0.1358	0.1248	0.0341	0.0746	0.0659	0.0798
SD	0.000	0.000	0.000	1.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000
Variance	0.2637	0.2181	0.8197	0.9435	0.5823	0.6870	0.8695	0.7994	0.2181	0.4775	0.4220	0.5109
Group 3												
Mean	0.098	0.098	0.732	0.829	0.220	0.317	0.537	0.244	0.024	0.146	0.146	0.293
Median	0.0469	0.0469	0.1106	0.1302	0.0820	0.1073	0.1264	0.1248	0.0244	0.0746	0.0746	0.1003
SD	0.000	0.000	1.000	1.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000
Variance	0.3004	0.3004	0.7080	0.8337	0.5250	0.6870	0.8092	0.7994	0.1562	0.4775	0.4775	0.6420

Q: question; SD: standard deviation.

Table 4. Item total correlation (groups 1, 2 and 3).

	Item total correlation	Alpha without single item
Q1	0.626	0.895
Q2	0.630	0.896
Q3	0.554	0.898
Q4	0.534	0.899
Q5	0.746	0.891
Q6	0.555	0.898
Q7	0.728	0.890
Q8	0.524	0.900
Q9	0.673	0.897
Q10	0.719	0.890
Q11	0.625	0.896
Q12	0.822	0.883

The Spearman's rank as correlation coefficient was 0.928 when comparing control group 2 and 3.

Mann–Whitney *U* test was used to evaluate the difference between mean scores from group 1 and control group 2, the outcome was $p < .001$.

An ROC curve was constructed. The best balance between sensitivity and specificity was defined as 9 as shown on Figure 2.

The complete COMQ-12-Mx is provided (see Supplementary Appendix A).

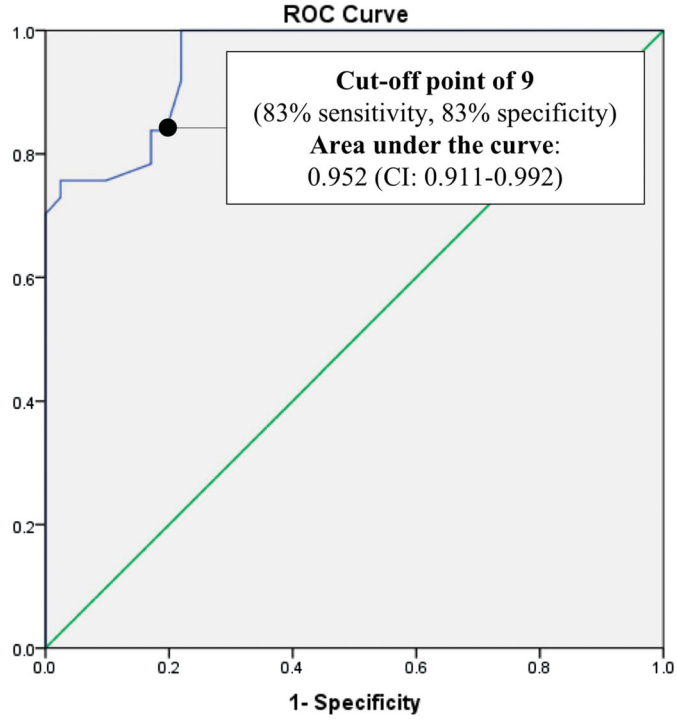

Figure 2. The COMQ-12-Mx ROC curve.

Discussion

Back in 2014 Phillips, et al. [6] created an instrument for the assessment of HRQoL for patients with COM. At that time there were no sufficient QoL instruments for patients with COM, in this manner, COMQ-12 flourished as a good alternative and several translations of this instrument were published [11–18], unfortunately, there is no, at this moment, a Spanish translation. Furthermore, studies have shown that previous translations have proved with significant internal consistency. Nonetheless, these studies have included diverse inclusion criteria, including exclusively COM patients [11–15], or both healthy and unhealthy subjects [12,16–18]. Our study was designed with a methodology similar to the Turkish, Russian, Serbian and Dutch validation. The internal consistency of some of these translations overpassed the value of 0.80, therefore achieving good outcomes. Cronbach's alpha for the COMQ-12-Mx at 0.828 adequately compares to values reported by other languages validations: Dutch (0.833), Kannada (0.880), Portuguese-Brazilian (0.850), Russian (0.860), Turkish (0.810) and Italian (0.800).

The overall mean score of COMQ-12-Mx participants (12.34 ± 12.72) can be explained due to the fact that healthy volunteers represented a larger sample and that their scores ranged from 0 to 15. The maximum and mean scores of the control group (test: 3.561 and retest: 3.683) was unexpectedly high, this aspect has been reported also in the study by Doruk et al. [12] and Van Dinther et al. [16]. The questions that most frequently showed a higher score were numbers three and four. These items evaluate hearing loss both in a noisy environment and when listening to radio or television. Those findings were similar to the studies previously mentioned. In our study, nonetheless, two participants achieved scores of 12 and 15 points. The mean scores of groups 2 and 3 are also similar to other validating studies.

On the other side, data reported by other adaptations [11–13,16] had obtained higher mean scores than our study. We assume that our mean COM group score could have achieved a higher total sum, if their condition had not been surgically treated. In this study, mastoidectomy subgroups (radical or cortical) scored lower than those patients not surgically treated. This hypothesis could be answered with longitudinal studies where preoperative and postoperative evaluations are compared.

The sensitivity and specificity found in our study were lower than previous research [12,16]; this might be due to the high maximum score obtained by the control group both in the test and in the retest. Additionally, the sensitivity (83%) and the specificity (83%) were set at a cut-off point of 9. We decided this cut off value due to the fact that a lower result (<80%) in either sensitivity or specificity is dubious. If we reduce the cut-off point to 6, the instrument reaches 100% of sensitivity but lowers specificity (78%). According to the character of this disease, we have considered capital the sensitivity due to the important complications COM can produce or predispose to.

The overall Cronbach's alpha was 0.908 for the total of participants but the final value selected was 0.828 considering only the COM group, according to the methodology of the original article by Phillips et al. [6]. Nevertheless, either analysis may prove the consistency of the instrument.

Phillips and Yung [19] in 2015 compared the existing Patient-Reported Outcome Measures (PROMs): CES [7], COMOT-15 [8], COM-5 [9] and COMQ-12 [6], in an effort to verify the diversity of the individual questionnaire items. The results proved that only COM-5 [9] and COMQ-12 [6] include the three domains defined by Koller and Lorenz in 2012 [20] according to the WHO definition of 'health and QoL'.

Moreover, there is a lack of information about the OMC burden in America itself, since most of the reports center in AOM. The broad spectrum of complications (either intratemporal or intracranial) of an untreated otitis media can impact quality life or even threaten the patient's life. Thus, the urge of measurement tools and instruments to evaluate the clinical evolution and quality of life in patients with COM.

The adequacy of this instrument allows the physician to use it on a daily basis to evaluate not only the evolution of the COM spectrum but the efficacy of the treatments employed. When non-invasive COM treatment has failed and the resources left are surgical, the patient's perception of surgery and its results are crucial for the surgeon. The goal is to obtain the greatest degree of satisfaction both for the patient as for the surgeon with respect to the therapeutic process and final outcome. A model where patients participate in their own care through the use of PROMs is receiving increasing attention worldwide and was the main reason for the intention to adapt this low-cost instrument for COM population for Latin American countries and Spanish speaking countries.

The Mexican Spanish version of the COMQ-12 is valid and a reliable tool to evaluate HRQqL in Mexican Spanish-speaking patients with COM and even COM patients from other Spanish-speaking countries. It is practical in the clinical field, as well as it is for research. Furthermore, it represents a potential tool to evaluate surgical therapeutic outcomes in patients with COM.

Methodological consideration/limitations

Cronbach's alpha was 0.828 for the COMQ-12-Mx with 83% of sensitivity and specificity at cut-off point of 9.

Informed consent

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

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Disclosure statement

No potential conflict of interest was reported by the author(s).

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