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Original paper

The Romanian Version of Health-Related Quality of Life Questionnaire 12 for Chronic Otitis Media. The Socio-Economic Status Impact Significance

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Abstract

Objective: Our primary objective was to translate and validate Chronic Otitis Media (COM) Questionnaire-12 (COMQ-12) in Romanian. The secondary objective was to investigate the effect of the socioeconomic status on the preoperative COMQ-12 scores in individuals with a similar stage of disease.

Methods: This was a cross-sectional study. Patients diagnosed with different stages of (COM) with cholesteatoma, scheduled for the first surgery, filled in the Romanian translated version of the COMQ-12. The patients were divided according to the stage of the disease and the environment of origin: rural versus urban areas.

Results: The internal consistency of the Romanian COMQ-12 proved excellent, with a Cronbach’s alpha equal to 0.959. The correlation of the 24 randomly split-half reliability analysis varied from 0.904 to 0.917, with a mean of 0.908. Significantly higher COMQ-12 scores are obtained by patients from urban (mean = 42.14, SD =9.04) as compared to those from rural (mean = 30.44, SD = 5.88) only for those with stage III disease (P-value=0.0292).

Conclusions: Romanian version of COMQ-12 proved to be a valid instrument that can be use in clinical practice to provide suitable information in COM patients, which contributes to the development of an international common otology dataset. Patients from rural areas tend to disregard their symptoms, being more predisposed to potential complications related to COM rather than urban patients at the same stage of the disease.

Keywords

Chronic otitis media, Quality of life, Questionnaires, Translation, Validation.

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Introduction

Chronic suppurative otitis media (CSOM) is defined as ‘a chronic inflammation of the middle ear and mastoid cavity, which presents with recurrent ear discharge through a tympanic perforation [1]. The prevalence of the disease varies widely worldwide, but it is estimated to be higher (4%) in developing countries than in high-income countries (<1%). In addition, CSOM has been reported to be more prevalent among the rural population, presumptively due to the lower standard of living and the poor education level compared to those of urban areas [2].

Different nomenclatures and classifications are used in the literature for this disorder; to that end, the terms COM (chronic otitis media) and CSOM (chronic suppurative otitis media) can be considered similar [3]. The most valid classification today considers two categories of disease: CSOM with or without cholesteatoma. CSOM without cholesteatoma can be further divided into active and inactive forms [4, 5]. Both conditions are characterized by symptoms that include otorrhea and hearing loss of varying severity, but other unpleasant symptoms, such as otalgia, tinnitus, and vertigo, may be present [6]. These conditions affect the patient’s quality of life (QoL) [3]. The chronically draining ear in CSOM can be difficult to treat.

Although CSOM without cholesteatoma is considered a safe condition and cured by medical treatment, there are some particular granulated forms in which complications may occur, and surgery is required [7]. CSOM with cholesteatoma is a non-neoplastic, keratinizing lesion characterized by intense cell proliferation within the middle ear and mastoid, bone erosion, and recurrence that can lead to intracranial complications (*e.g.*, brain abscess, meningitis). Surgery is the only effective treatment for cholesteatoma [8].

Surgical treatment has the ideal goal of the patient achieving complete eradication of the disease, a dry ear free of recurrence, and preserved or improved hearing. In some individual cases, these objectives cannot be achieved, even in the case of a very correctly performed surgery. Inherent in these situations, the patients and the surgeons have different opinions regarding what constitutes success with the surgery [9]. QoL assessments have been implemented to evaluate the results of treatments from the patient’s perspective. In addition, for a distinct category of diseases, PROMs (specific patient-reported outcome measures) were developed [10]. The most recognized and accepted PROM for CSOM is the COMQ-12 (The Chronic Otitis Media Questionnaire–12), developed by Phillips *et al.* [11]. This instrument shows sufficient consistency and preliminary validity after being translated and validated in different languages (Dutch, Serbian, Russian, Portuguese, Canada, and Turkish) [12–17]. The international assimilation of the COMQ-12 allows the opportunity to assess the effectiveness of surgical treatments even among countries with different social and economic statuses and different

healthcare systems. However, the social domain of QoL in patients with COM has never been fully assessed in the literature [13].

One weakness of the initial COMQ-12 investigation was that the study population included a heterogeneous group of patients with different stages of the disease [11].

The primary objective of our study was to assess the validity of the Romanian version of the COMQ-12, taking into account that there is no literature on health-related quality of life measurements in Romanian-speaking individuals with CSOM.

The secondary objective was to test whether the different socioeconomic statuses of the patients had any impact on the preoperative COMQ-12 scores in individuals with a similar stage of the disease.

Materials and Methods

The COMQ-12 was translated with the permission of the original authors and followed the standardized process for PROM translation. The English version of COMQ-12 was translated independently by two native Romanian-speaking otolaryngologists with proficient knowledge of English. A bicultural expert compared the two translated questionnaires and produced a final version. The Romanian version was then translated back into English by one native English-speaker. There were no conceptual differences in the back-translation compared to the original version. The authors then approved the final Romanian version of the COMQ-12 in format and content. A cross-sectional study underwent in the Otorhinolaryngology Department University Hospital of Cluj-Napoca was made. All eligible patients referred from January 2017 to December 2018 for evaluation were invited to participate. The following eligibility criteria were applied: age ≥ 11 years old, no mental illness, no congenital ear malformations, and Romanian native speakers, patients diagnosed with different stages of chronic otitis media with cholesteatoma, scheduled for the first surgery. All patients included in the study were asked to fill the Romanian translated COMQ-12 questionnaire, and they were assisted by an ENT Resident Doctor if needed.

Furthermore, for patients younger than 18, the questionnaire was completed in the presence and with the help of younger patients’ legal guardians.

Supplementary pieces of information were extracted from the patient’s medical record. These pieces of information included general patients’ conditions, age, origin, and profession (education level), clinical findings and symptoms, and the auditory status on both ears based on audiograms.

All audiograms were performed by specialized personnel according to the ISO -389 (1975) standard. Audiometric evaluation included preoperative ABG, AC and BC thresholds.

The American Speech–Language–Hearing Association (ASHA) guide-lines was taken into consideration when the degrees of hearing loss were evaluated [18].

We consider contralateral ear status pathological if the degree of hearing loss to the other ear was at least moderate (below 41dB), regardless the pathology.

The patients were divided into two categories according to the environment of origin (rural versus urban area). We consider rural areas those localities inhabited by less than 10.000 people, with limited or no access to public utilities such as sewage systems and modernized roads. We excluded patients from rural areas surrounding big cities [19, 20].

Another criteria for inclusion in the rural patients group was the salary record included in the hospital admittance chart, and it was between the limits of the minimum wage/household in Romania, which is around 300 euro, 12% less than the minimum wage in urban areas. [21]

The stage of the disease was established after the surgery following the recent SAMEO-ATO staging classification for cholesteatoma [22], and the data has been added.

In addition, twenty-nine healthy volunteers, with a negative medical history of COM complaints and with previous non-otologic surgery, were enrolled in the study as a control group.

Statistical analysis

Statistical analysis was done with the Statistica program (v. 13, StatSoft, USA) at a significance level of 5% for comparison of two groups and an adjusted significance level according to the number of compared groups otherwise.

Cronbach's alpha was calculated to assess the internal consistency of the Romanian COMQ-12. A split-half design was done in the reliability analysis with the correlation of the subtotals for 6 and 5 of the 11 scoring items. Three strategies were applied: e.g., first vs. second half, odd- v. even-numbered items, and 24 randomly determined split. A Cronbach's alpha higher than 0.9 is associated with an almost perfect consistency, while a value between 0.8 and 0.9 as a strong consistency [23].

The normality of quantitative data was tested with the one-sample Kolmogorov-Smirnov test. Data were reported as mean and standard deviation (SD) and compared with Student t-test whenever proved to follow the normal distribution; otherwise, median and (Q1 to Q3) – where Q is the quartile – and comparison with Mann-Whitney test was used. Kruskal-Wallis test was applied to compare the class of hearing among the patients. The box and whisker plot was used to illustrate the differences in COMQ-12 score among different groups, the x representing the value of the mean, the horizontal line

in the box the value of the median, the box representing the 1st and respectively the 3rd quartile and the whiskers the minimum and maximum; the o indicate an outlier. The qualitative data were reported as number and percent and comparison between groups done with Chi-square test or Fisher exact test according to the expected values.

Results

One hundred and thirteen patients with ages ranging from 11 to 83 were included in the study. Eighty-three patients were assigned to the CSOM (Chronic Suppurative Otitis Media) group and twenty-nine to the control group. The gender was balanced among participants (Women: Men = 61:51), without significant differences among groups ($\chi^2 = 0.12$, P-value = 0.7307). The patients in the CSOM group proved significantly older compared to those in the control group (CSOM: median = 34 years (27 to 49), control: median = 28 (26 to 32), Mann-Whitney test: Z statistic = 2.19, P=0.0286.

The Romanian COMQ-12 score ranged from 0 to 58 on all participants to the study, with a median of 28 and an interquartile range from 10.50 to 36.00, and a mean 25.20 (SD=15.59). On the whole investigated sample, 69 patients (62%) had a COMQ-12 score ≤ 30 , with 32 patients (28%) COMQ-12 score ≤ 20 . The Romanian COMQ-12 score ranged from 0 to 22 amongst participants in the control group, with a mean of 2.93 (SD=4.13).

The Romanian COMQ-12 score ranged from 12 to 58 amongst participants in the CSOM group with a mean of 32.98 (SD=9.68), with 40 patients (48%) having a COMQ-12 score ≤ 30 and only 4 patients (5%) with a score ≤ 20 . The internal consistency of the Romanian COMQ-12 proved excellent, with a Cronbach's alpha equal to 0.959. The correlation on the first vs. second half split lead to a correlation of 0.905 and the odd- vs. even-numbered items was 0.903. The correlation of the 24 randomly split-half reliability analysis varied from 0.904 to 0.917, with a mean of 0.908.

The COMQ-12 score proved significantly higher on the CSOM group as compared to the control group (Mann-Whitney test: Z statistic = 7.95, P<0.0001): median = 31 (26.75 to 37.25) for CSOM and 2 (0 to 4) for the control group.

In the case group, no significant difference regarding the COMQ-12 score were observed when women were compared to men (Mann-Whitney Test: Z-stat = 1.58, P-value = 0.1151), considering that the age of women was significantly higher (median = 40 years, (32 to 59)) compared to men (median = 31 years (22 to 44); Mann-Whitney Test: Z-stat = 2.79, P-value = 0.0053).

No differences were observed when characteristics of subjects with CSOM from rural areas were compared with those from urban area (Table 1).

Table 1. Characteristics of the CSOM group by the living area.

Characteristic	All sample (n=83)	Rural (n=38)	Urban (n=45)	Stat. (P-value)
Age, years ^a	38.38 (16.51)	35.9 (15.1)	40.3 (17.7)	-0.91 (0.3607)
Sex, Men ^b	46 (54.8)	20 (51.3)	26 (57.8)	0.36 (0.5506)
Educational level ^b				
1. None	7 (8.3)	4 (10.3)	3 (6.7)	
2. Primary education (1-4 years)	11 (13.1)	10 (25.6)	1 (2.2)	
3. Secondary education (5-8 years)	14 (16.7)	5 (12.8)	9 (20.0)	
4. Highschool (9-12 years)	24 (28.6)	12 (30.8)	12 (26.7)	
5. Vocational education	20 (24.9)	7 (18.4)	13 (28.8)	
7. College education	7 (8.3)	0 (0.0)	7 (15.6)	
The degree of the hypoacusis ^b				n.a. (0.3015)
mild	10 (11.9)	3 (7.7)	7 (15.6)	
moderate	54 (65.1)	28 (73.7)	26 (57.8)	
severe	10 (11.9)	2 (5.1)	8 (17.8)	
profound	9 (10.7)	5 (12.8)	4 (8.9)	
Contralateral ear status pathological ^b	29 (34.9)	14 (36.8)	15 (33.3)	0.11 (0.7384)
Stage ^b				n.a. (0.3948)
I	3 (3.6)	2 (5.3)	1 (2.2)	
II	64 (77.1)	27 (71.1)	37 (82.2)	
III	15 (18.1)	9 (23.7)	6 (13.3)	
IV	1 (1.2)	0 (0.0)	1 (2.2)	
COMQ-12 score	31 (27 to 37)	30 (25 to 35)	34 (28 to 39)	-1.60 (0.1087)

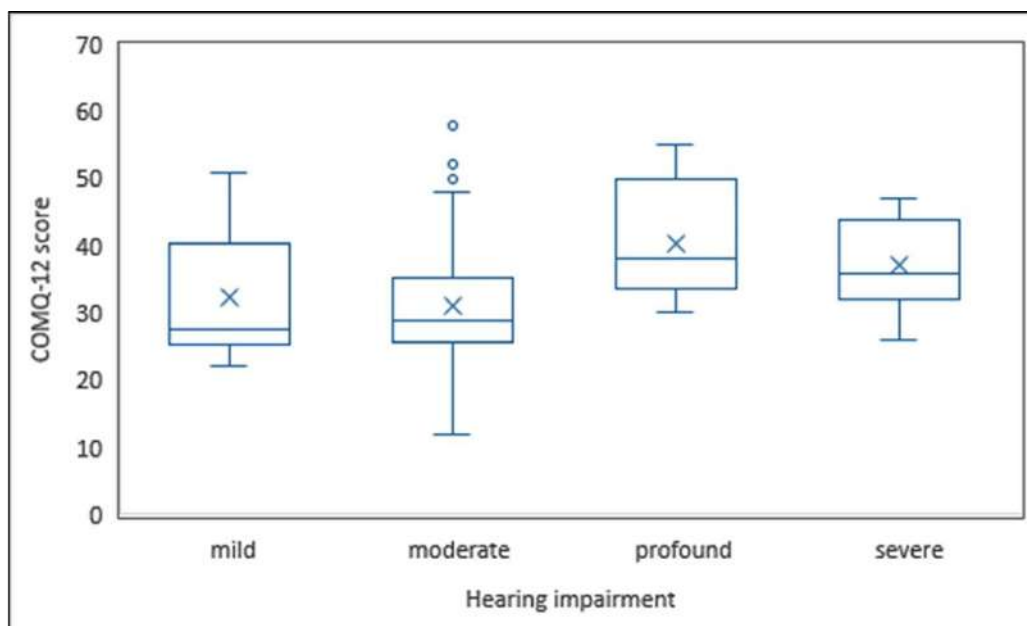
^amean (standard deviation); Student t-test for independent samples;

^bno. of cases (%), Chi-square test or Fisher exact test (when Fisher exact test has applied the statistic of the test is not available – n.a.);

^cmedian (Q1 to Q3), where Q1 is the 25th percentile, and Q3 is the 75th percentile; Mann-Whitney test.

The COMQ-12 score proved significant differences among the classes of hearing loss; Kruskal-Wallis test: H-statistics=12.57, P-value=0.0057), with significantly

higher scores amongst those with profound hearing loss as compared to those with moderate hearing loss (post-hoc analysis: P-value = 0.0130) (Fig. 1).

**Figure 1.** COMQ-12 score according to hearing loss score

The COMQ-12 score proved significantly higher on patients with pathology on the contralateral ear as compared to those without (Mann-Whitney Test: Z-stat = -2.71, P-value = 0.0068) (Fig. 2).

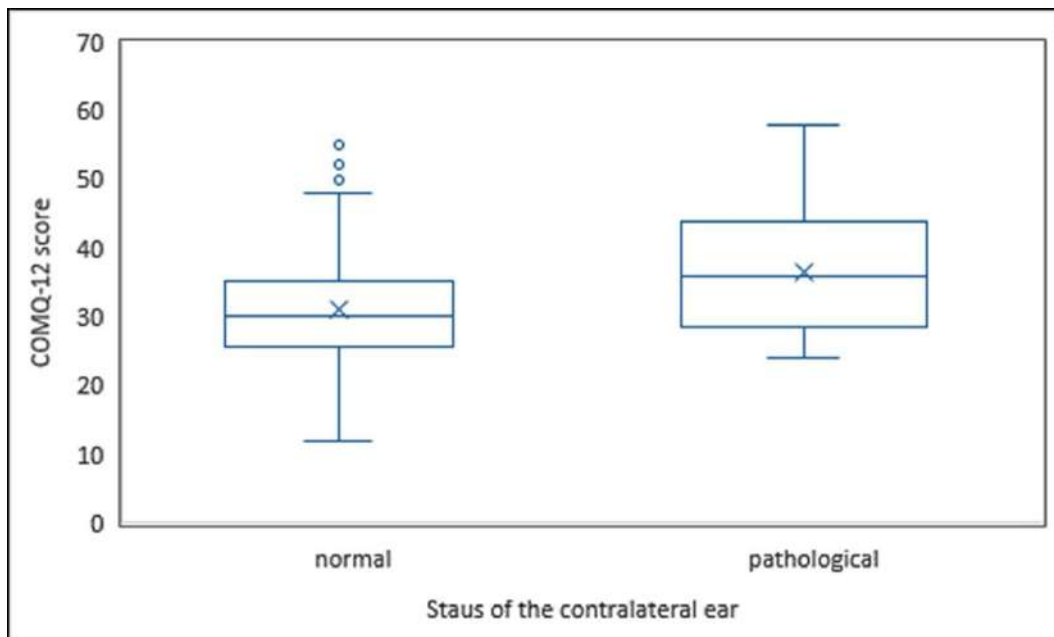


Figure 2. Variability of COMQ-12 score among patients with and without normal contralateral ear.

The COMQ-12 score had similar values amongst patients with different stages of the disease (Kruskal-Wallis test: H-statistics = 3.65, P-value = 0.3015).

The COMQ-12 score proved higher on women

(mean = 35.57, SD=9.97) compared to men (mean = 30.25, SD=7.78) for stage II (Mann-Whitney test: Z-statistic= 2.00, P-value=0.0459; but not for stage III (Mann-Whitney test: Z-statistic=-0.06, P-value=0.9539) (Fig. 3).

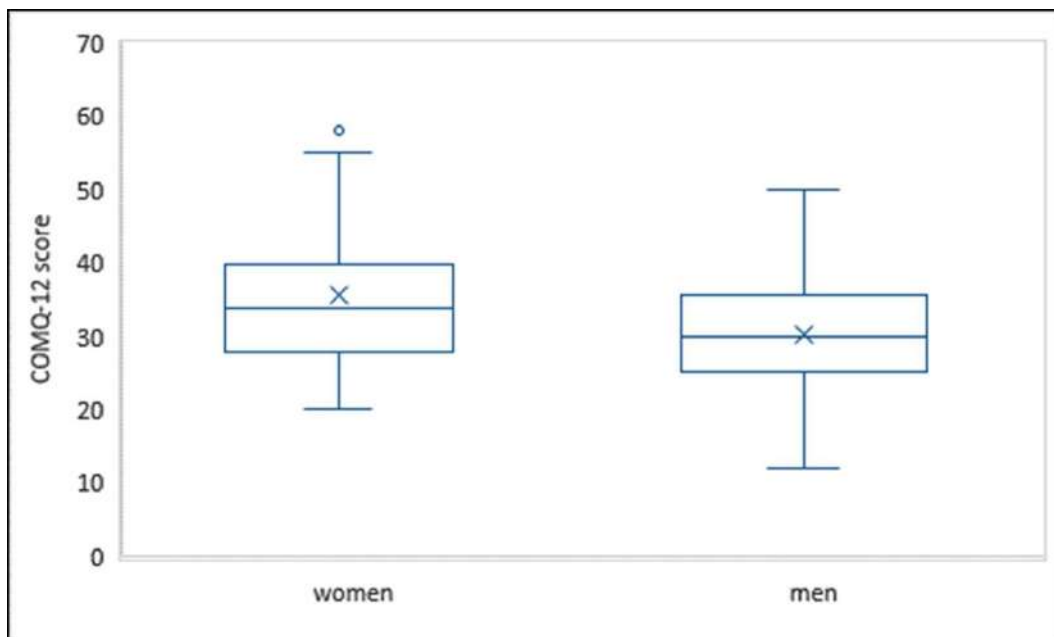


Figure 3. COMQ-12 score by gender for patients with stage II of disease

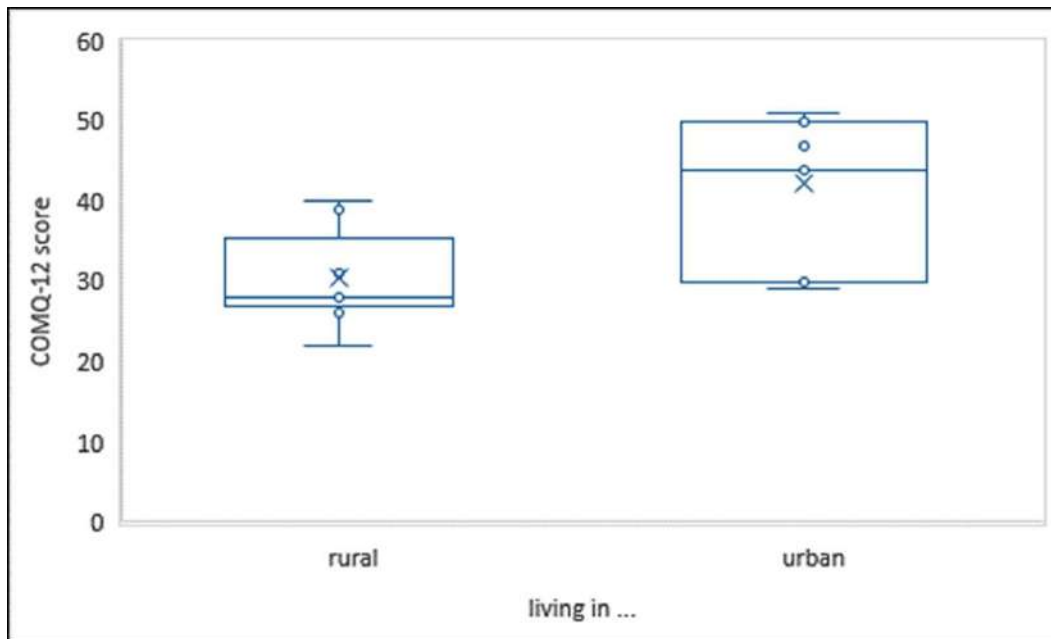


Figure 4. COMQ-12 score by rural or urban settlement

Significantly higher COMQ-12 scores are obtained by patients from urban (mean = 30.44, SD = 5.88) as compared to those from rural (mean = 42.14, SD = 9.04) only for those with stage III disease Mann-Whitney test: Z-statistic=2.18, P-value=0.0292) (Fig. 4).

Patients with pathological contralateral ear had significantly higher COMQ-12 scores (mean = 35.77, SD = 8.14) as compared to those with normal function (mean = 30.90, SD = 9.26) only for those with stage II disease (Mann-Whitney test: Z-statistic=2.33, P-value= 0.0201; Fig. 5).

Patients with pathological contralateral ear had

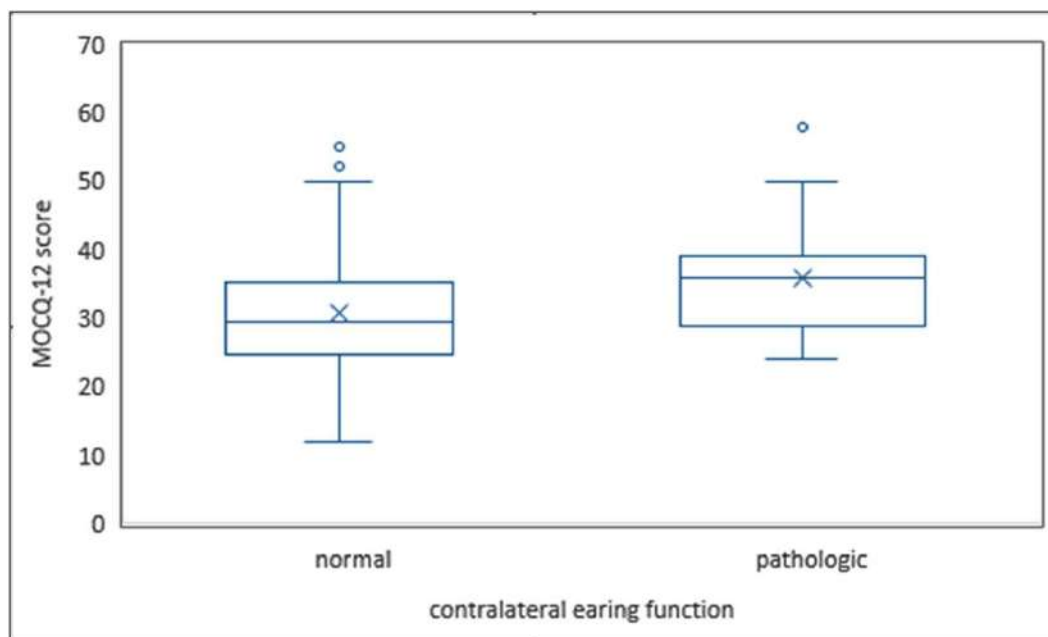


Figure 5. COMQ-12 score by contralateral ear for patients with stage II of disease

Discussion

The Chronic Otitis Media Questionnaire-12 (COMQ-12) translation into Romanian proved internal consistency (Cronbach's alpha of 0.959) and reliability, evaluated by how well the individual component questions of a questionnaire correlate with each other. This result is in agreement with the original English questionnaire report, with a Cronbach's alpha value of 0.889 [11], and previously validated studies, which also confirmed a high internal consistency for the COMQ-12, well above the conventional threshold of acceptability (0.7) [12- 17]. The limitations of the original study, noticed even by the authors, were the absence of a normal score in individuals unaffected by CSOM and that the original study population included a heterogeneous group of patients with different stages of disease presentations, as well as its inability to evaluate the "responsiveness" after treatment [11].

The problem with the absent 'reference or normal point' to adequately interpret the COMQ-12 results was successfully solved later by Phillips et al., who determined that the COMQ-12 scores less than or equal to 5 is characteristic of an adult without active COM [24]. In the present study, the Romanian COMQ-12 score ranged from 0 to 22 among participants in the control group, with a mean of 2.93 (SD=4.13). The results conformed with data presented by Korsakov et al. (mean equal to 3.55) [14], Doruk et al. (mean equal to 3.60) [17], and Fonseca et al. (median equal to 2) [15] as a reference point and validated our results.

CSOM has been reported to be more prevalent among the rural population, presumptively due to the lower standard of living and the poor education level compared to urban areas [2], but the social domain of QoL in patients with COM has never been fully assessed in the literature [13].

Some studies revealed that Romania has approximately 2.5 doctors and 5.8 nurses per 1,000 inhabitants; nevertheless, these numbers are low compared to other European countries. Moreover, some rural and remote villages, where poverty rates can be twice as high as in urban areas, do not have a full-time medical assistant/nurse or a doctor [25]. Several socioeconomic groups such as a large share of the rural unemployed population, self-employed workers in agriculture, rural Roma population, casual and seasonal workers without any health insurance. These groups also have a low level of education [26]. Because of the abovementioned factors, the CSOM group of patients (n=83) was further divided into two sub-groups based on the environment of origin: rural (n=38) and urban (n=45) areas (Table 1). In addition, we staged the cholesteatoma in both groups according to the new EAONO/JOS staging system and applied four types of middle ear cholesteatoma [22].

Although we had assumed that we would find rural patients to have a lower quality of life compared to the urban area patients, this was not the case in our study. Furthermore, patients from urban areas reported higher COMQ-12 scores than rural area patients, but this was

statistically significant only for stage III disease. According to these results, patients in urban areas are most likely more distressed and disturbed concerning their symptoms than patients from rural areas at the same stage of the disease. This finding suggests the presence of individual differences in the perception of patients to disease and whether they seek medical care [27], which can be related to educational level and social and economic status. In fact, it was obvious that the rural patients from our investigation had a lower educational level; only 7 (18.4%) of them attended vocational training courses after graduating from high school, compared to 20 (44.2%) patients from urban areas.

Furthermore, a higher number of patients from rural areas (23.7%) presented with stage III disease compared with patients from urban areas (13.3%) (Table 1).

However, as a whole, all patients from the CSOM group reported a significantly low level of quality of life, highlighted by the Romanian COMQ-12 score with a mean of 32.98 (SD=9.68). The total score has a higher value than the total scores from other studies, a result that could be explained by the inclusion of patients with inactive forms of the disease [11-14]. However, the values corresponded with the sub-scores evaluated for the cholesteatoma category from other analyses [13, 14]. According to recent data, patients with COM seem to have a poorer quality of life, which is most likely related to hearing loss, rather than some accompanying and disturbing complaints, including tinnitus or ear discharge. [28] Concerning hearing level, there are some controversies in the literature. Yung et al. [11] found no correlations between hearing level and COMQ-12 scores, while Prabhu et al. [16], in a very recent Canadian publication, showed that the scores were poorer for a higher degree of hearing loss. Similar results have also been indicated by Oorts et al. [16] in the Dutch adaptation and validation of the COMQ-12. This current study showed that the COMQ-12 score proved to be significantly different among the classes of hearing loss (Fig. 2, P-value<0.005), with significantly higher scores among those with severe hearing loss than among those with moderate hearing loss (post hoc analysis: P-value < 0.02). When we compared the scores between patients with hearing loss on both sides versus patients with unilateral hearing loss, the scores were significantly higher in the first group, showing a poorer quality of life in these subjects. Nevertheless, since normal hearing is binaural, it seems only logical that in assessing surgical attempts to improve quality of life, the function of both ears should be evaluated. This conclusion supports the Steward's results [29] that although bilateral hearing loss is not a prognostic factor for QoL measures, it affects mental well-being more than unilateral cases. Although the scores of the patients with first-stage cholesteatoma (cholesteatoma localized in the primary site) were lower than the scores of the patients with second-stage (cholesteatoma involving two or more sites) and third-stage (cholesteatoma with extracranial complications or pathologic conditions), the difference does not reach the statistical significance

(P-value > 0.25). This reflects the fact that in patients with cholesteatoma, the QoL is affected from early stages.

A significant difference of COMQ-12 means score was observed in women as compared with men for stage II (P-value=0.0459; Fig. 3) but not for stage III (P-value=0.9539). This result support the hypothesis that sex may be one of the factors that can influence patient perception and prioritization of health, even though other studies did not report similar results [16].

Nevertheless, this study has some limitations. Firstly, the number of patients with a different stage of the disease was unequal, with most of the patients with stage II cholesteatoma (cholesteatoma involving two or more sites).

Furthermore, the inclusion of patients under the age of 18 in the study can be considered a bias factor for the educational level evaluation. However, the validation of the questionnaire was not based on this assessment.

Second, no comparison of score preoperative and postoperative was made, but this is our future intention. We also plan to introduce the COM Benefit Inventory complementary [30] to the COMQ-12 in Romania for quality assessment of surgical results in CSOM.

The results of our study confirmed sufficient consistency and validity to justify international adaptation of the COMQ-12 questionnaire, without the restrictions imposed by language or a different healthcare system in a country such as Romania. International collaboration regarding the surgical outcome of ear surgery is mandatory to make better decisions and to enable comparisons of provider's performances to stimulate improvement services [31].

Another clinical importance of the study is that for daily practice, otolaryngologists should anticipate greater health care demands from rural populations, promoting healthy behaviors and educational programs. Patients who come from a particular (inferior, squatter) socioeconomic environment with a low educational level are less aware of the possible complications related to the evolution of CSOM, underestimating the symptoms. Finally, hearing loss remains among the most important factors with a negative impact on the quality of life of patients with CSOM.

This information helps understand the personal impact of CSOM on an individual's life and may be beneficial in preoperative selection and counseling.

It is tempting to conclude which of the two, hearing loss or the environment of origin, is more important to QoL, but there is simply too much variability in an individual's perception of his/her condition to draw any specific conclusions regarding this. Thus, further studies are essential/required in this field.

Conclusions

The Romanian version of the COMQ-12 showed good validity and high reliability, allowing its clinical use as a health-related QoL questionnaire for the assessment of COM. Hearing loss remains among the most important factors with a negative impact on the quality of life of patients with COM. These patients' quality of life is

impaired regardless of the disease stage. Patients with a low educational level, who come from rural areas with low socioeconomic status, tend to neglect their symptoms and are more prone to the complications that may occur in the evolution of CSOM.

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Conflict of Interest

The authors have no conflict of interest to declare.

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