

International recognition of the Chronic Otitis Media Questionnaire 12

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Abstract

Objective: The Chronic Otitis Media Questionnaire 12 was developed initially in the UK to assess patient-reported health-related quality of life associated with chronic otitis media. This study aimed to determine whether this tool is applicable to the Russian population, which has a materially different healthcare system.

Method: A total of 108 patients with different forms of chronic otitis media completed the Russian Chronic Otitis Media Questionnaire 12.

Results: The average Russian Chronic Otitis Media Questionnaire 12 score was 19.4 (standard deviation = 8.3). The internal consistency of the Russian Chronic Otitis Media Questionnaire 12 was high, with a Cronbach's alpha value of 0.860.

Conclusion: The Russian version of the Chronic Otitis Media Questionnaire 12 was found to be a reliable tool for the assessment of health-related quality of life in patients with chronic otitis media. This sets the scene for international collaboration, using this tool to assess the effectiveness of surgical treatments even amongst countries with different healthcare systems.

Key words: Otitis Media; Quality Of Life; Questionnaires; Chronic Disease; Surveys And Questionnaires; Translations

Introduction

Chronic otitis media is a widespread disease that affects up to 2 per cent of the population.¹ There are several forms of chronic otitis media, each of which is characterised by peculiarities of courses and outcomes. Some forms of chronic otitis media, given their asymptomatic courses, may not cause concern initially and, therefore, often remain undiagnosed for years. Other forms of chronic otitis media occur with a vivid clinical picture expressed by the complaints of the patient and decrease in their quality of life (QoL). Patients in this second group are much more likely to seek medical care, require active treatment and may well have high expectations of treatment.

A patient's expectations can be greater than the initial forecasts of the surgeon. In such situations, an objective tool is required to evaluate the relationship between the pattern of disease perceived by the patient and the pattern of disease based on objective data. An important objective of surgical intervention in patients with chronic otitis media is to meet the expectations of the patient. Inevitably, perfectly

executed surgery does not always provide a corresponding improvement in QoL for the patient.

The relationship between patient expectations and surgical expectations has been demonstrated through the use of the health-related QoL questionnaires. The Chronic Otitis Media Questionnaire 12 was devised in the UK to assess patient-reported QoL associated with chronic otitis media.² The original English version of the Chronic Otitis Media Questionnaire 12 was developed by Phillips *et al.*^{2,3} It compares favourably when compared with other similar health-related QoL questionnaires.⁴ The Chronic Otitis Media Questionnaire 12 is gaining international recognition, and has been translated and evaluated in Dutch.⁵

This study aimed to determine whether the Chronic Otitis Media Questionnaire 12 can be truly internationally adaptable, by identifying whether it can be satisfactorily applied to the Russian population, which has a different healthcare system. Superficially, this exercise provides supportive data to instruct the application of the Chronic Otitis Media Questionnaire 12 in Russia. However, of greater academic interest, the

administration of the Chronic Otitis Media Questionnaire 12 into a healthcare system that differs in many fundamental ways to that of the UK and Western Europe provides great insight into how socio-economic and cultural factors can affect patient-reported QoL in chronic otitis media.

Materials and methods

The Russian Chronic Otitis Media Questionnaire 12 was developed from the original English version of the Chronic Otitis Media Questionnaire 12. The utilisation of an established and well-constructed item list allowed consequent adoption of a validated list of 12 questions characterising all essential experiences of a patient with chronic otitis media. Each item is assessed on a five-point scale. Eight questions (numbers 1–7 and 12) describe the severity of the disease, whereas the remaining four questions (numbers 8–11) describe the frequency of their occurrence. The minimum score possible is 0 and the maximum score possible is 60. To allow comparison with other studies that have translated the Chronic Otitis Media Questionnaire 12 into another language, a consistent approach was employed with respect to the translation and psychometric evaluation processes.⁵

This study was designed and conducted according to the Declaration of Helsinki (1996). The study methodology was approved according to local ethics guidelines. Informed consent was obtained from all individual participants included in the study.

The Russian Chronic Otitis Media Questionnaire 12 was translated and evaluated in collaboration with the original authors of the Chronic Otitis Media Questionnaire 12. The Russian Chronic Otitis Media Questionnaire 12 was obtained by an established process of translation and back-translation.⁶

A total of 108 Russian-speaking patients with a history of active chronic otitis media were asked to complete the Russian Chronic Otitis Media Questionnaire 12. In addition, the Russian Chronic Otitis Media Questionnaire 12 was given to 60 healthy volunteers without chronic otitis media.

Questionnaire reliability was assessed on the basis of internal consistency by calculating Cronbach's alpha. This index is used as an internal consistency estimate of the reliability of test scores by assessing the degree of correlation between the individual components of a questionnaire. Coefficients greater than or equal to 0.70 are considered to be acceptable; those greater than or equal to 0.80 are considered to be good. All data were analysed using Statistica and GNU R (version 10.0.1011.6; StatSoft, Tulsa, Oklahoma, USA).

Results

The study included 108 patients, 49 men (45 per cent) and 59 women (55 per cent), ranging in age from 16 to 84 years. Patients were classified according to their form of chronic otitis media and whether previous surgery had been undertaken. Four groups of patients

TABLE I
DISTRIBUTION OF PATIENTS AND QUALITY OF LIFE SCORES FOR EACH CHRONIC OTITIS MEDIA GROUP

COM type	COM patients (n (%))	Score average (range)*
Perforated eardrum	58 (54)	18.5 (4–43)
Cholesteatoma	21 (19.4)	21.2 (6–41)
Open mastoid cavity	18 (16.6)	21.8 (5–37)
Adhesive otitis media & fibrosis	11 (10)	16.6 (5–28)

*Obtained for the Russian Chronic Otitis Media Questionnaire 12. COM = chronic otitis media

were defined: perforated eardrum patients, cholesteatoma patients, patients after previous surgery (open mastoid cavity), and patients with adhesive otitis media and fibrosis. The distribution of the patients and the QoL scores for each group are shown in Table I.

The Russian Chronic Otitis Media Questionnaire 12 scores ranged from 4 to 43 amongst all respondents. The average score was 19.4 (standard deviation = 8.3). The median Russian Chronic Otitis Media Questionnaire 12 score overall was 20. Ninety-one per cent of respondents achieved a score of 30 or less; 55 per cent of respondents achieved a score of 20 or less. For the Russian Chronic Otitis Media Questionnaire 12, Cronbach's alpha was equal to 0.860.

Sixty healthy volunteers without chronic otitis media were asked to complete the Russian version of the Chronic Otitis Media Questionnaire 12. The scores overall ranged from 0 to 14 amongst all respondents, with a mean score of 3.55. The median Russian Chronic Otitis Media Questionnaire 12 score overall was 2.5 and the modal score was 0, with 19 participants (31.7 per cent) achieving this score. Seventy-five per cent of respondents achieved a score of 5 or less; 95 per cent of respondents achieved a score of 10 or less.

Discussion

Health-related QoL measurements reflect the overall burden of disease from the perspective of the patient rather than the clinician. This makes the acquisition of this kind of data particularly pertinent in otology, where clinical, radiological and audiological findings may inter-relate poorly, and therefore poorly predict health-related QoL. The use of health-related QoL measures has been shown to aid both the patient's prioritisation of their symptoms⁷ and the management of their individual expectations.⁸

One problem with any health-related QoL tool is related to its ability to allow acceptability, reliability and validity across different, internationally diverse populations. Patient perception and prioritisation of health can be influenced by many factors. The healthcare system in Russia is different to that in the UK, in both the manner it is funded and the manner in which it is administered. This has implications for access to healthcare. More privileged patients may

seek intervention at an earlier stage, and are likely to have greater expectations for outcome than those who are less privileged.

In Russia, healthcare is funded via a mixed public and private system. Since 1996, the Constitution of the Russian Federation has provided all citizens with the right to free healthcare under Mandatory Medical Insurance. State hospitals have been allowed to offer private services, but since 2011 some private providers have been providing services to the state-insured. Healthcare costs per capita in Russia are much lower than those in Europe, including Eastern Europe. According to the most recent published figures from the Organisation for Economic Co-operation and Development, expenditure on healthcare in 2012 was 6.3 per cent of gross domestic product, compared to 9.3 per cent in the UK.⁹ About 5 per cent of the population, mostly in major cities, have health insurance.¹⁰

In 2012, the Russian Federation had 4.9 physicians per 1000 population, a much higher number than the Organisation for Economic Co-operation and Development average of 3.2.⁹ In addition, the number of hospital beds in the Russian Federation was 9.3 per 1000 population in 2012, almost two times greater than the Organisation for Economic Co-operation and Development average (4.8 beds) in 2012. However, compared with Organisation for Economic Co-operation and Development countries, the Russian Federation has very high levels of mortality and shorter life expectancy. In 2012, life expectancy at birth in the Russian Federation was 70.2 years, 10 years lower than the Organisation for Economic Co-operation and Development average (80.2 years).

Much has changed since the break-up of the former Soviet Union. As is universal around the world, different healthcare systems face their own particular challenges. An excellent history of how healthcare has evolved in Russia is detailed by Barr and Field.¹¹

The level of primary healthcare development in Russia is low compared to secondary and tertiary care. The healthcare model in Russia is such that the requirement for surgical treatment has implications that are not only financial. Russia is a huge country; therefore, the population density is lower than in Europe. A large number of people live in small towns and villages where there are no specialists and limited emergency care. It is often the case that the nearest major city is hundreds of miles away. This means that hospital admission requires travelling to a major centre, which necessitates taking leave from work and family for many weeks. Furthermore, the duration of hospitalisation in Russia is much longer than in European countries. The numbers of doctors in hospitals and clinics in Russia per patient exceed those for European countries. However, because of reduced efficiency, hospital departments are less able to meet demands.

The Chronic Otitis Media Questionnaire 12 was developed to assess the impact of disease on health-related QoL

TABLE II
INTERNAL CONSISTENCY FOR DIFFERENT CHRONIC
OTITIS MEDIA QUESTIONNAIRE 12 VERSIONS

Questionnaire version language	Participants (n)	Cronbach's alpha
English	50	0.889
Dutch	50	0.833
Russian	108	0.860

from the patient's perspective.² The Russian version of the Chronic Otitis Media Questionnaire 12 had a Cronbach's alpha of 0.860; this confirms high internal consistency of the questionnaire and a high degree of correlation between its individual components. This index is used to measure the reliability of test scores: a factor greater than or equal to 0.70 is defined as acceptable and those equal to or more than 0.80 are defined as good. This compares well with the original English version² and the Dutch version⁵ of the Chronic Otitis Media Questionnaire 12. Table II compares the key reliability characteristics of the English, Dutch and Russian versions of the Chronic Otitis Media Questionnaire 12.

The acquisition of data in a healthy population without chronic otitis media is of great importance for interpreting Chronic Otitis Media Questionnaire 12 scores in the context of inactive disease. A study by Phillips *et al.* determined normal values for the Chronic Otitis Media Questionnaire 12 scores in an adult population without active chronic otitis media.³ We replicated this study for our population. The results of both studies demonstrated that Chronic Otitis Media Questionnaire 12 scores of 5 or less are characteristic in a healthy population. This finding is interesting from the perspective of evaluating a health-related QoL assessment tool for chronic otitis media. Furthermore, it suggests that, despite the many cultural differences in Russian and UK populations, when assessing otological and audiological symptoms in healthy populations, outcome scores are comparable. The health and societal implications of this finding reach further than the initial intended objectives of this study; they are interesting and worthy of reflection within disciplines outside of otolaryngology.

Questionnaire development is not achieved by a single study in a single population. A great deal can be achieved via question development across many different centres and across different countries. This process requires the translation from the original questionnaire language to the native language for each individual country, whilst allowing any nuances in language to be interpreted correctly. Having the Chronic Otitis Media Questionnaire 12 in different languages provides an opportunity to evaluate the course of the disease and its outcomes in different social and cultural conditions all around the world. This allows us to obtain a more complete and objective picture of both the studied disease and the instrument employed to compare disease severity and outcome. Robust,

valid and reliable questionnaires evolve via a disseminated process that involves many different patient populations over a number of years. Furthermore, there are a multitude of contemporary techniques available to perform psychometric appraisal. The current study represents an important step for the development of the Chronic Otitis Media Questionnaire 12 in the Russian population and complements ongoing work regarding its development as a global tool to assess QoL in patients with chronic otitis media.

- **Patient and surgeon expectations regarding quality of life (QoL) outcomes do not always correspond**
- **The Russian Chronic Otitis Media Questionnaire 12 can reliably assess health-related QoL in chronic otitis media patients**
- **This study investigated whether the questionnaire could be applied to the Russian population, which has a different healthcare system**
- **The findings suggested comparable outcome scores for Russian and UK healthy populations**
- **The study represents an important step for questionnaire development for the Russian population**
- **It also supports its use as a global tool to assess QoL in chronic otitis media patients**

In conclusion, the Russian version of the Chronic Otitis Media Questionnaire 12 is a reliable tool for assessing health-related QoL in patients with chronic otitis media. Russian Chronic Otitis Media Questionnaire 12 scores vary amongst different types of chronic otitis media. Now that the preliminary appraisal of the Russian Chronic Otitis Media Questionnaire 12 has been completed, this tool can be employed to acquire further data to support its role in the planning of surgical treatments and assessment of treatment outcomes in the Russian population. The successful

employment of Western European health-related QoL instruments in populations that are distinctively different in terms of social, economic and cultural makeup provides support for using these tools in an 'international' manner for the acquisition of international clinical audit datasets.

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