

Translation and validation of the Indonesian version of the chronic otitis media questionnaire-12

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ABSTRACT

Chronic suppurative otitis media (CSOM) is a pathological disorder affecting the ear, characterized by a persistent and long-lasting middle ear infection accompanied by the absence of an intact tympanic membrane. Multiple measures can be employed to evaluate the quality of life among patients with CSOM. One such instrument is the chronic otitis media questionnaire-12 (COMQ-12), which has demonstrated satisfactory levels of validity and reliability. The utilization of the COMQ-12 questionnaire has the potential to improve the quality of life experienced by CSOM patients. This study aimed to evaluate the validity and reliability of the Indonesian adaptation instrument of the COMQ-12 in patients with CSOM in the Otorhinolaryngology department of multiple hospitals in Yogyakarta. The study was conducted from February to July 2023. The study comprised 48 participants, consisting of 16 males and 32 females. The adapted Indonesian version of the COMQ-12 instrument demonstrates validity and reliability in assessing patients' quality of life with CSOM, as evidenced by a statistically significant r-value of 0.2353. The internal consistency analysis reveals that Cronbach's α coefficient is 0.868. The Indonesian adaptation of the COMQ-12 demonstrates validity and reliability as an assessment tool for measuring the health-related quality of life in patients diagnosed with CSOM.

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1. INTRODUCTION

Chronic suppurative otitis media (CSOM), commonly referred to as chronic otitis media, is a medical condition that affects the ear [1], [2]. Typically, it presents as long-lasting ear discharge, known as otorrhea, lasting 2 to 6 weeks. Subsequently, it leads to a perforated tympanic membrane, ossicular chain disruption, and bone resorption [3]–[7]. CSOM can be categorized into two different subtypes: CSOM without the presence of cholesteatoma and CSOM with the presence of cholesteatoma [8].

Chronic suppurative otitis media is a globally prevalent condition, affecting a substantial population of 65 to 330 million individuals, which accounts for 0.45% to 2.6% of the total population [9], [10]. The global disease burden from CSOM exhibits variation across different regions, with prevalence rates ranging from less than 1% in high-income countries to 4% in low-income countries [11]. CSOM also remains highly prevalent in

various regions of Indonesia, with documented rates of 3.1% between 2006 and 2009. This number suggests that approximately 6.6 million individuals in Indonesia were affected by CSOM during that period [10].

Chronic suppurative otitis media significantly impacts patients' health-related quality of Life (HRQoL) by causing hearing loss, persistent infection, and foul-smelling ear discharge [12]–[16]. Recently, several studies have been conducted to examine the effects of chronic otitis media (COM) on daily living and to assess the HRQoL of patients with this condition. These studies have led to the creation of several questionnaires for evaluation uses [15]–[18].

The chronic otitis media questionnaire-12 (COMQ-12) is a specific tool developed by Dr. John S. Phillips to assess the quality of life in individuals diagnosed with CSOM [19], [20]. Thus far, the questionnaire has undergone the necessary procedures of translation and validation in many languages, enabling its utilization in assessing HRQoL within diverse cultural contexts. The main objective of this research was to translate the COMQ-12 into Indonesian and evaluate its validity and reliability for individuals diagnosed with CSOM.

2. METHOD

2.1. The questionnaire

We initially obtained permission from Dr. John S. Phillips to start the validation procedure. The initial version of the COMQ-12 is a self-evaluation survey comprising 12 questions, categorized into four distinct sections. Symptom intensity is the focus of questions 1 through 7. Questions 8 and 9 pertain to the implications of the disease on work and lifestyle. The quality of life (QoL) is assessed using a Visual Analogue Scale in Question 12, and Questions 10 and 11 inquire about the evolution of COM in health services. Each item is given a numerical rating between 0 and 5 based on the patient's reported level of discomfort [19].

2.2. Translation process

The English translation of the COMQ-12 in Indonesia was conducted by two native Indonesian speakers who were fluent in English and worked independently. A qualified expert, knowledgeable in both cultural contexts, critically evaluated the two translated versions of the questionnaire and produced the final version. The Indonesian version was then translated back into English once again by an individual fluent in English. In contrast to the initial revision, the back-translation did not reveal any substantial conceptual differences. After that, the authors comprehensively evaluated both questionnaire versions and merged the findings to produce an integrated and final design.

2.3. Ethical considerations

The present study (No. 040/EC-KEPK FKIK UMY/XII/2022) received approval from the Health Research Ethics Committee at the Universitas Muhammadiyah Yogyakarta. The ethics declaration applies until December 30, 2023. Informed consent was obtained from all participants.

2.4. Study participants

The study identified people who spoke Indonesian and had documented histories of chronic otitis media (COM). These participants were invited to participate in the assessment by completing the Indonesian chronic otitis media questionnaire-12 (COMQ-12). The study participants were required to meet specific inclusion criteria, which included being older than 12 years and having a documented history of active chronic otitis media. The questionnaire was distributed to 48 participants. Additionally, clinical and demographic data were collected for each participant in our study.

2.5. Data analysis

The data was analyzed using the following methodologies: Adapting cross-cultural (transcultural) questionnaires was performed following the methods developed by the World Health Organization (WHO). The collected data underwent computational analysis using a computer program to conduct research. The data analysis procedure included multiple assessments to evaluate the internal validity and reliability of the adapted version of the COMQ-12 questionnaire in the Indonesian language. The validity assessment utilized the Pearson correlation test to examine the relationship between the individual question items and the overall questionnaire score. The internal consistency of the data was assessed through reliability analyses, which involved the computation of Cronbach's alpha coefficients. An alpha (α) value above 0.7 is widely accepted as indicative of reliability.

3. RESULTS AND DISCUSSION

3.1. Characteristics of study participants

The study included 48 patients diagnosed with chronic otitis media (COM) who met the specified eligibility criteria. Most of the participants are female, as shown in Table 1. Specifically, there are 16 male participants, comprising 33% of the total sample, while the remaining 32 participants are female, accounting for 67% of the sample. The mean age of the participants is 39.8 years, ranging from 12 to 76 years. The age group of 21-30 years was the most prevalent, including 13 individuals, making up 27% of the total sample.

In terms of education, the most common level among participants in this study is undergraduate, with 19 individuals (40%) having attained this qualification. Moreover, most participants, precisely 14 individuals (29%), were employed in the private sector. Most participants, precisely 34 individuals or 71%, reported no smoking history. Additionally, ten respondents (20.8%) reported experiencing ear discharge, while seven (14.6%) reported decreased hearing. Furthermore, 31 participants (64.6%) reported experiencing a combination of ear discharge, decreased hearing, and ear pain.

The left ear was the auditory organ that elicited the most problems for participants, with 21 individuals (43%) reporting this problem. Furthermore, 20 patients (42%) experienced complaints lasting over three years. Central perforation of the tympanic membrane was identified in 42 patients (88%). Remarkably, among the 48 patients, cholesteatoma was diagnosed in only one person (2%). In contrast, 11 participants (23%) had a history of atopy.

Table 1. The participants' demographic and clinical characteristics

Variable	N=48	Percentage (%)	Variable	N=48	Percentage (%)
Age			The history of smoking		
11-20	5	10%	Yes	14	29%
21-30	13	27%	No	34	71%
31-40	9	19%	Which ear has the symptom?		
41-50	8	17%	Right	19	40%
51-60	7	15%	Left	21	43%
>60	6	13%	Both	8	17%
Gender			Duration of symptoms		
Male	16	33%	Less than three months	6	13%
Female	32	67%	3 to 6 months	10	21%
Educational level			6 to 12 months	4	8%
Primary education	3	6%	1 to 3 years	8	17%
Secondary education	3	6%	More than three years	20	42%
High school	20	42%	Type of tympanic membrane perforation		
Undergraduate degree	19	40%	Central	42	88%
Diploma degree	3	6%	Subtotal	5	10%
Occupation			Total	1	2%
Teacher	2	4%	Cholesteatoma		
Housewife	10	21%	Yes	1	2%
Private employee	14	29%	No	47	98%
Student	11	23%	The history of atopy		
Retired	1	2%	Yes	11	23%
Civil servants	2	4%	No	37	77%
Self-employed	8	17%	No	37	77%
			No	37	77%

3.2. Validity and reliability of the Indonesian COMQ-12

In the current study, a validity test was conducted on 48 participants, resulting in an R-value of 0.2353. The gathered R-values indicate that all questions in the Indonesian COMQ-12 questionnaire exhibit higher R-values, suggesting the questionnaire's validity for use. Additionally, the study determined that the Cronbach α coefficient for the Indonesian COMQ-12 questionnaire was 0.868, indicating a satisfactory level of reliability (Cronbach α coefficient > 0.7). The study employed the 2-way mixed model, rank average (k=2), and absolute consistency to determine the intraclass correlation coefficient (ICC). The analysis was carried out using the Pearson correlation coefficient test. The findings reveal that a significance value of 0.00 or ≤ 0.05 indicates a correlation between the two variables.

3.3. Discussion

This study aimed to translate and validate the COMQ-12 questionnaire in Indonesian for patients previously diagnosed with chronic otitis media. We encountered no significant challenges during the translation and cultural adaptation process. This study included 48 participants, with a gender distribution of 16 males and 32 females. This total number of participants aligns with the findings of a previous study by Quaranta *et al.*

which adapted the COMQ to Italian, with 48 participants consisting of 22 males and 26 females [21]. The questionnaire was administered to individuals aged 12 years and older. While the initial study primarily focused on adult participants, the COMQ-12 can also be applied to younger patients [11].

The education levels among individuals with CSOM vary. In the present study, we observed an increased prevalence of CSOM among individuals enrolled in high school. In various regions of Indonesia, approximately 29.3% of individuals diagnosed with CSOM in Medan and Bandung are predominantly those who have completed primary education. It is important to note that individuals with lower levels of education often require more information about nutrition and adopting a healthy lifestyle [5]–[27].

Our study observed a high prevalence of central tympanic perforation (88%) among participants, consistent with the findings reported by Taoussi [9]. Subsequently, subtotal tympanic perforation occurred in 10% of cases (five cases). CSOM has the potential to spread to the contralateral ear over time, indicating a delay in the management of CSOM in developing countries. In our study, only 2% (one patient) had cholesteatoma, contrasting with some literature suggesting complications of CSOM with cholesteatoma occur in most of cases [28]. Cholesteatoma is typically observed around the perforation, particularly in the attic or posterosuperior region, and is often associated with erosion of the external ear canal bone [29].

The initial version of the COMQ questionnaire, developed by Phillips, underwent translation and adaptation for different languages and cultural contexts [19]. After the initial iteration, several modifications were made in other languages. The languages include Dutch [30], Italian [21], Kannada [31], Korean [32], Portuguese [11], Russian [33], Spanish [34], [35], Arabic [36], Turkish [37], Mexican Spanish [38], Slovenian [39], Armenian [40], and French [41]. The questionnaire has consistently shown validity across all versions.

The internal consistency is assessed using Cronbach's alpha coefficient. This statistical indicator quantifies the level of consistency within the components that constitute a test. The Cronbach's Alpha coefficient for the Indonesian version of the COMQ-12 questionnaire is 0.86, aligning with the results from two previous validation studies. Table 2 summarizes internal consistency measures obtained using Cronbach's Alpha for various language versions of the COMQ-12 [34]. Certain specialists in psychometrics claim that elevated values of Cronbach's alpha may result, particularly when it is exclusively used as the primary criterion for evaluating homogeneity [42]–[44].

Furthermore, a specialized tool such as the COMQ-12, explicitly designed for assessing quality of life (QoL), contributes to including a diverse range of individuals within the sample group. It is essential to acknowledge that the alpha coefficients for the various questionnaire items, ranging from 0.82 to 0.86, indicate an acceptable level of internal consistency. This observation underscores the questionnaire's reliability and validity, rendering it suitable for application in clinical settings [34].

The translation and validation of the COMQ-12 questionnaire into Indonesian followed a systematic methodology to ensure optimal dependability. Remarkably, no significant challenges were encountered during the translation or cultural adaptation. The findings from the validation process indicated that the internal consistency and item-total correlation of the Indonesian version of COMQ-12 were satisfactory. The reliability coefficients suggest that all 12 question items consistently assess the underlying construct. Importantly, all item-total correlations are equal to or greater than 0.3, indicating the significance of each question item. This questionnaire is a valuable tool for objectively assessing the quality of life associated with auditory health. Its high level of utility makes it well-suited for evaluating the quality of life in standard clinical practice, extending its applicability beyond clinical trials and observational studies.

Table. 2 Internal consistencies for different COMQ-12 versions

Questionnaire language	Participants with COMQ	Cronbach Alpha
Dutch	35	0.83
English	50	0.89
Italian	48	0.80
Kannada	80	0.88
Korean	106	0.94
Portuguese	100	0.85
Russian	108	0.86
Serbian	60	0.82
Spanish	200	0.86
Turkish	50	0.81

4. CONCLUSION

The research findings indicate that the Indonesian version of the COMQ-12 scale has shown high reliability and validity. This term is used for individuals diagnosed with chronic suppurative otitis media. Employing this tool in both clinical and research on the health-related quality of life in patients diagnosed

with chronic suppurative otitis media will lead to developments in healthcare in Indonesia. However, additional assessment is required in a more extensive sample, ideally employing factor analysis and investigating the stability of the results over time.




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