

ISRG Journal of Multidisciplinary Studies (ISRGJMS)



ISRG PUBLISHERS

Abbreviated Key Title: isrg j. multidiscip. Stud.

ISSN: 2584-0452 (Online)

Journal homepage: <https://isrgpublishers.com/isrgjms/>

Volume – III, Issue -II (February) 2025

Frequency: Monthly



Translation and cross-cultural adaptation of the EORTC BIL21 questionnaire in Albanian language for the assessment of QoL in patients with BTC

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| **Received:** 13.01.2025 | **Accepted:** 15.01.2025 | **Published:** 01.02.2025

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Abstract

Introduction: Advanced biliary tract cancer is associated with a poor prognosis, with a median survival of less than a year. The disease is often diagnosed at an advanced stage when treatment options are limited. These patients have a reduced health-related quality of life, which is a crucial factor in the decision-making for treatment options, especially in novel therapies. Although for the assessment of quality of life in medicine are available well-established and validated tools in BTC patients, in Albania, studies assessing the quality of life for this target group of patients haven't been conducted yet.

Aim: Translation and cross-cultural adaptation of the EORTC BIL21 questionnaire into Albanian language.

Methodology: After obtaining permission from the EORTC team, the questionnaire was translated following their translation guidelines. Then, the questionnaire was pilot-tested in a group of 10 patients over 18 years old, with a confirmed diagnosis of biliary tract cancer.

Results: All steps of the EORTC translation guidelines have been rigorously and successfully followed. 10 patients were included in the study of the first phase, of which 6 males (60 %) and 4 females (40 %).

Conclusion: The final version of the BIL-21 for the Albanian language approved by the EORTC can be used for research purposes by researchers in all Albanian-speaking countries in clinical practice. The conclusions reached will be an added value to clinicians, in the recognition and management of these symptoms in the early stages.

Keywords: biliary tract cancer, EORTC, QoL, questionnaire

Introduction

Forms of biliary tract cancer constitute epithelial malignancies of the biliary tree and include gallbladder cancer (GBC), ampulla of Vater cancer (AVC), (extra-hepatic [EHC], and intrahepatic [IHC] bile ducts). Biliary tract cancer accounts for approximately 3% of all gastrointestinal malignancies and is the most common hepatobiliary cancer after hepatocellular carcinoma. Unfortunately, the mortality rate (3.58 per 100,000) is very high (Tariq NU, 2019).

Advanced biliary tract cancer is associated with a poor prognosis, with a median survival of less than one year (Anderson CD, 2004). The disease is often diagnosed at an advanced stage when treatment options are limited. These patients have a reduced health-related quality of life, which is a decisive factor in decision-making about treatment modalities, especially novel therapies (Hunter LA, 2021).

WHO defines quality of life as a person's perception of his place in life within the context of the culture and value systems in which he lives and in relation to his goals, expectations, standards and concerns (S., 2010).

Recently, special attention has been given to the instruments used to evaluate the quality of life on a multidimensional level, especially in cancer patients. One of the instruments widely used to assess this health indicator in cancer patients are the questionnaires of the European Organization for Research and Treatment of Cancer (EORTC) (Arraras Urdaniz JI, 2008). The most frequently used questionnaire in oncology practice is the EORTC-QLQ-C30, which is very broad and not focused on specific symptoms related to a certain region, such as in the case of biliary tract tumors. The EORTC Core Quality of Life questionnaire (EORTC QLQ-C30) is a reliable and valid instrument, designed to measure cancer patients' physical, psychological, and social functions. The questionnaire consists of a combination of single items and multi-item scales. The quality of life of patients with this form of cancer can be significantly affected by several factors, including its stage, the effectiveness of treatment, the presence of symptoms, and its general physical and emotional state (Davda J, 2021). Coping with the diagnosis and treatment of cancer can have a significant emotional and psychological impact. Anxiety, depression, fear, and uncertainty are common feelings experienced by individuals with cancer, which can affect their overall quality of life (Niedzwiedz, 2019).

It is important that health care providers address these factors and provide a comprehensive approach to care that focuses on improving the quality of life for people with biliary tract cancer. This may include a combination of medical treatments, symptom management, emotional support and rehabilitation services. (Hunter LA S. H., 2021).

Although well-defined and validated tools are available in healthcare for the assessment of the quality of life for patients with biliary tract cancer, no studies have yet been conducted in Albania to assess the quality of life for this target group of patients.

This study describes the steps followed for the translation and cross-cultural adaptation of the EORTC BIL21 version questionnaire in Albanian language for the assessment of QoL in patients with biliary tract cancer.

Aim

The aim of this study is the translation and transcultural adaptation of the EORTC BIL21 questionnaire in the Albanian language, as evidenced by the fact that no equivalent instrument was able to be used.

Methodology

Translation procedure

The translation of the questionnaire was based on the protocol recommended by the translation unit at the EORTC.

The translation process started with a request to the EORTC and after receiving the approval, the following steps were followed, according to the guidelines of the translation unit (TU) (Dagmara Kuliś, 2017).

First, the final version was translated from English to Albanian by two freelance translators, Albanian citizens with very good knowledge of Albanian and English. An intermediate translation was then made based on the two translations, carried out by a third person, who reviewed the two translations and selected the most appropriate grammatical and linguistic variant.

The revised material was then translated into English. This was carried out once again by two additional independent translators who were native Albanians and had excellent knowledge of both English and their native language.

All these findings are put together into a report that is returned to the EORTC translation unit. This allows the unit to assess and analyze each step that has been taken, supported by relevant input from both parties involved.

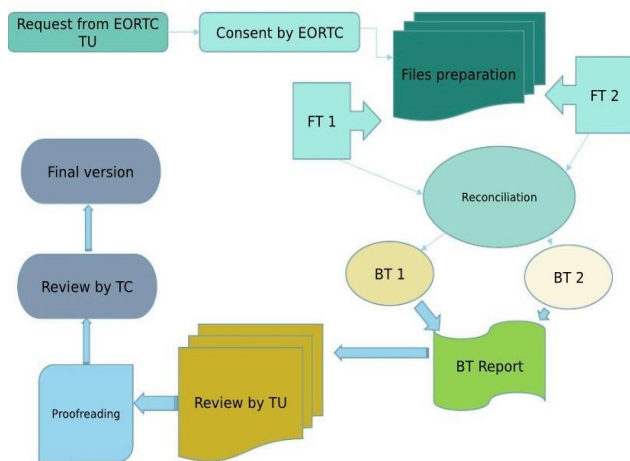
After reviewing the report and resolving unclear issues, the preliminary translation was reviewed by an external translator of an agency chosen by the translation unit, and after agreeing to the suggestions made by them; the questionnaire was subjected to linguistic validation or as it is otherwise known test- piloting.

The pilot test was carried out at "Mother Teresa" University Hospital Center, which is a center that offers medical services at a national level in Albania and is the largest Hospital Center in our country, having the highest number of patients who receive various

medical services and more specifically oncological ones. The reason for choosing this center is due to the fact that the oncology department is the largest in the country and has the entire range of services and treatments that oncology patients can undergo such as chemotherapy, external radiotherapy through 3D and VMAT techniques, surgery, etc. Before starting the pilot test, administrative permission was obtained from the head of the department, and it was informed about the content of the questionnaire, the steps that were followed to obtain the final version of the questionnaire, and the steps that would be followed in the future.

A graphical illustration of each step conducted in accordance with the EORTC translation unit's recommendations is presented in Figure 1.

Fig. 1 Diagram of the translation steps of the EORTC BIL21 questionnaire in the Albanian language



The EORTC QLQ-BIL21 questionnaire consists of 21 questions in total: 3 single questions about side effects of treatment, difficulties with drainage bags/tubes and concerns about weight loss, 18 questions grouped into 5 proposed scales: symptoms of eating (4 questions); symptoms of jaundice (3 questions), fatigue (3 questions), pain symptoms (4 questions) and anxiety symptoms (4 questions). The response format was constructed through a four-point Likert scale, with response options classified as “not at all”, “a little”, “quite a bit” and “very much” (Kaupp-Roberts SD, 2016).

After receiving the administrative approval for conducting the pilot test, then continued with the identification of patients with bile duct cancer in the chemotherapy department, as one of the basic lines of treatment of these tumors before or after surgery. In addition to the administration of the EORTC BIL21 questionnaire, some demographic data related to age, gender, education, marital status, and occupation were obtained. The study included all patients over the age of 18, with a confirmed diagnosis of biliary tract cancer, who were able to sign the consent. All patients included in this stage were asked in advance if they agreed to participate in the study, after explaining the purpose of the study, respecting their right to refuse based on their general physical condition.

The questionnaire was administered by the authors of the study by performing the questions in order and at the same time seeing if there was anything unclear to make relevant changes in the final version.

Results

After carefully following all the steps and agreeing on the final version, the last step followed, conducting the pilot test in patients with the aforementioned characteristics of inclusion in the study. The questionnaire was administered to 10 adult patients with a confirmed diagnosis of biliary tract cancer, of whom 60% were men (n=6) and 40% were women (n=4). 70% of them lived in urban areas (n=7). In general, the limit we encountered during the pilot testing was the general physical condition of the patients, rather than the difficulties in understanding the questions. Their psycho-emotional state was also affected and most of them felt hopeless about their future, based on the information they had received as well as the lack of psychological counseling (since none of them reported having committed or was conducting psychological counseling sessions).

Following the pilot test results, a table summarizing the patient interviews was created. Out of the overall 21 questions, question 39 - Have you felt “slower”-was found to be the most challenging. When the phrase “slower” was added to the explanation, the patients' initial unwillingness to respond-“in carrying out your daily activities”- was dispelled, and they were able to respond.

However, while only three patients out of ten shown it, the EORTC translation process guidelines state that there is no need to modify the questions considering that the number of patients demonstrating a lack of comprehension of the existing translation should be greater than five (Dagmara Kuliś, 2017)

After agreeing to the suggestions that were made, the full version translated into the Albanian language of the EORTC BIL21 questionnaire may be accessible for use by researchers, different professionals, or even patients. This version can easily be found on the website of the European Organization for Research and Treatment of Cancer (EORTC).

Conclusion

In recent years, there has been increasing focus on quality of life in oncology clinical practice, as it is a vital indicator of a patient's overall health status. This emphasis has led to the creation of tools designed to effectively assess this aspect of life. Additionally, international support for scientific research on the quality of life of cancer patients plays a crucial role, with studies being conducted worldwide.

After completing all the necessary stages of translation and transcultural adaptation of the questionnaire for assessing the quality of life of patients with biliary tract cancer (EORTC BIL21), a standardized questionnaire in the Albanian language was obtained, which will be able to be used by the scientific community and the general public. This questionnaire will serve as an instrument to evaluate the quality of life of patients with biliary tract cancer at different stages of their treatment, making it possible to evaluate the efficacy of treatments and at the same time to measure the factors related to treatment reliability, thus bringing about an increase in factors related to the quality of life.

This instrument will help to improve the aspects related to the quality of life in this target group of patients, as during the pilot phase, a sense of pessimism and uncertainty about the future was observed in each participant who was interviewed, leading to the necessity of the implementation of psychological support during the treatments.

This study presents all the steps and data obtained from the translation and transcultural adaptation of the EORTC BIL21 questionnaire from English to Albanian. This validated questionnaire is currently available in 49 languages, recently adding the final version in Albanian. It will serve as an instrument for measuring and evaluating the quality of life in Albanian patients with a confirmed diagnosis of biliary cancer accessible for research purposes by the scientific community, without having to ask for permission from the relevant EORTC department.

References

1. Tariq NU, McNamara MG, Valle JW. Biliary tract cancers: current knowledge, clinical candidates and future challenges. *Cancer Manag Res.* 2019;11:2623-2642. Published 2019 Mar 29. doi:10.2147/CMAR.S157092
2. Hunter LA, Soares HP. Quality of Life and Symptom Management in Advanced Biliary Tract Cancers. *Cancers (Basel).* 2021 Oct 11;13(20):5074. doi: 10.3390/cancers13205074. PMID: 34680223; PMCID: PMC8533827.
3. Hunter LA, Soares HP. Quality of Life and Symptom Management in Advanced Biliary Tract Cancers. *Cancers (Basel).* 2021 Oct 11;13(20):5074. doi: 10.3390/cancers13205074. PMID: 34680223; PMCID: PMC8533827.
4. Vahedi S. World Health Organization Quality-of-Life Scale (WHOQOL-BREF): Analyses of Their Item Response Theory Properties Based on the Graded Responses Model. *Iran J Psychiatry.* 2010 Fall;5(4):140-53. PMID: 22952508; PMCID: PMC3395923.
5. Arraras Urdaniz, J. I., Villafranca Iturre, E., Arias de la Vega, F., Domínguez Domínguez, M. A., Lainez Milagro, N., Manterola Burgaleta, A., Martínez López, E., Romero Rojano, P., & Martínez Aguillo, M. (2008, October). The EORTC quality of life questionnaire QLO-C30 (version 3.0): Validation study for spanish prostate cancer patients. *Archivos Españoles De Urología* (Ed. Impresa), 61(8). <https://doi.org/10.4321/s0004-06142008000800017>
6. Davda J, Kibet H, Achieng E, Atundo L, Komen T. Assessing the acceptability, reliability, and validity of the EORTC Quality of Life Questionnaire (QLQ-C30) in Kenyan cancer patients: a cross-sectional study. *J Patient Rep Outcomes.* 2021 Jan 7;5(1):4. doi: 10.1186/s41687-020-00275-w. PMID: 33415528; PMCID: PMC7790948.
7. Niedzwiedz, C.L., Knifton, L., Robb, K.A. *et al.* Depression and anxiety among people living with and beyond cancer: a growing clinical and research priority. *BMC Cancer* **19**, 943 (2019). <https://doi.org/10.1186/s12885-019-6181-4>
8. Hunter LA, Soares HP. Quality of Life and Symptom Management in Advanced Biliary Tract Cancers. *Cancers (Basel).* 2021 Oct 11;13(20):5074. doi: 10.3390/cancers13205074. PMID: 34680223; PMCID: PMC8533827.
9. Dagmara Kuliś, Andrew Bottomley, Galina Velikova, Eva Greimel, Michael Koller, EORTC QUALITY OF LIFE GROUP TRANSLATION PROCEDURE Fourth Edition 2017, Brussels, D/2017/6136/001 ISBN 978-2-930064-44-4
10. Kaupp-Roberts SD, Yadegarfar G, Friend E, O'Donnell CM, Valle JW, Byrne C, Bahar I, Finch-Jones M, Gillmore R, Johnson CD, Pereira SP, Wiggers JK, Pinto M, Al-Sarireh B, Ramage JK. Validation of the EORTC QLQ-BIL21 questionnaire for measuring quality of life in patients with cholangiocarcinoma and cancer of the gallbladder. *Br J Cancer.* 2016 Oct 25;115(9):1032-1038. doi: 10.1038/bjc.2016.284. Epub 2016 Sep 27. PMID: 27673364; PMCID: PMC5117782
11. Anderson, C. D., Pinson, C. W., Berlin, J., & Chari, R. S. (2004). Diagnosis and treatment of cholangiocarcinoma. *The oncologist*, 9(1), 43–57. <https://doi.org/10.1634/theoncologist.9-1-43>