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# Translation and Linguistic Validation of the Albanian Version of Eortc Qlq Bn-20 Questionnaire

**Original Article**

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**Abstract:** **Background:** Brain tumors and their treatments decrease the quality of life. The assessment of patient-reported outcomes, and more specifically health-related quality of life, is an important aspect of clinical care. EORTC QLQ BN20 and Functional Assessment of Cancer Therapy-Brain (FACT-BR) are the most used tools to assess QoL. In Albania, there is very little information available about the quality of life of cancer patients. The aim of this study was to describe the translation process and linguistic validation of the EORTC QLQ-BN20 questionnaire into Albanian.

**Patients and methods:** According to the EORTC standard guidelines, there was a backward and forward translation procedure to generate the Albanian language version of the QLQ-BN20. The linguistic validation process included a pilot study of ten patients. Face-to-face interviews were conducted to detect any difficulty encountered while completing the questionnaire.

**Results:** Four female and six male patients with an average age of 58.4 participated in the pilot study. There was no need for changes to be incorporated into the final Albanian BN–20 questionnaire.

**Discussion:** The pilot validation showed that the Albanian translation of the EORTC BN-20 nearly replicated its English counterpart. The final version of the Albanian BN-20 has received EORTC approval, and it is available on the EORTC website for academic or commercial use in clinical practice and studies for patients with primary brain tumours.

**Keywords:** *Albanian • Brain Tumour • HRQOL • linguistic validation • QLQ-BN20• translation*

## 1. Introduction

Brain and central nervous system (CNS) cancers represent a significant global public health challenge due to their high mortality rates, substantial financial burden on individuals and society, poor survival outcomes, and profound impact on patients' quality of life (QoL).[1,2] According to the 2020 Global Cancer Observatory statistics, brain and CNS cancers rank as the 19th most common malignancy, accounting for 1.9% of all cancers, and the 12th leading cause of cancer-related deaths, representing 2.5% of all cancer fatalities.[1] The relative survival rate at 5 years is 35.7%.[3] In Albania, brain cancer is the seventh most prevalent malignancy, with an annual incidence rate of about 7.7 per 100,000 in males and 4 per 100,000 in females.[4] Patients with primary brain tumors (PBTs) often experience a range of distressing symptoms, including physical, emotional, and cognitive impairments. These challenges may include sensory deficits, physical disability, loss of independence, and significant changes to personal and professional lives, compounded by societal stigma.[5] Despite progress, many brain tumor treatments are not curative, and their primary goals consist in extending the patient's life and relieving their symptoms.[6] The impact of brain tumors on patients' cognitive function and behavior is multifactorial, influenced by the tumor itself, treatment regimens, and individual patient characteristics. The gold standard therapy for most brain tumors consists of neurosurgery, followed by adjuvant radiotherapy, chemotherapy, or combined chemoradiotherapy.[7] Cancer treatments may have a neurotoxic side effect, which has a detrimental impact on the patients' health-related quality of life (HRQoL).[8] The term HRQoL refers to a multidimensional notion covering physical, psychological, and social aspects, in addition to symptoms induced by the disease and its treatment.[9] These include both positive changes that are anticipated to enhance HRQoL and negative ones like symptom experience and influencing factors. Patients with PBTs have a decreased QoL because of

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mental health outcomes, particularly depression.[11] Therefore, to select the best treatment for a specific patient, it is necessary to take into consideration the stage of the disease, any risk associated with the given treatment, and the patient's general health.[12-14] Besides the standard biomedical criteria, QoL has been included in the evaluation criteria for cancer therapy, and it has emerged as an increasingly important outcome in clinical neuro-oncology.[10] Evaluating patient-reported outcomes, especially HRQoL, is of significant importance in this context. In Albania, there is a lack of sufficient data on QoL for cancer patients. Most HRQoL tools were developed in English, targeting primarily English-speaking populations. Two widely recognized generic questionnaires used to assess HRQoL in cancer patients, regardless of cancer type, are the European Organization for Research and Treatment of Cancer Core Questionnaire (EORTC QLQ-C30) and the Functional Assessment of Cancer Therapy-General (FACT-G).[15,16] The EORTC and FACT systems have each developed brain cancer-specific questionnaires: the European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Brain Cancer Module (EORTC QLQ-BN20) and the Functional Assessment of Cancer Therapy-Brain (FACT-BR), respectively. EORTC QLQ-BN20 primarily assesses the physical limitations experienced by patients, while FACT-BR focuses more on the emotional and social aspects of their QoL. Both instruments have previously been tested in English-speaking patients and were found to have adequate psychometric properties.[17-19]

Very modest work has been done on the QoL issues in Albania and wherever there are Albanian-speaking patients, especially in oncology.[20] Although it is difficult to select the tool in the routine clinic, we decided to explore the translation of the EORTC QLQ-BN20 instrument. Although the EORTC QLQ-C30 and EORTC QLQ-BN20 English version questionnaires are overall valid instruments, their implementation within a new country requires translation and cultural adaptation. The variation in languages and cultures worldwide has prompted the translation of these questionnaires into numerous languages. Administering questionnaires in English in a region where Albanian is the primary language would likely be ineffective, as it could exclude individuals who are not fluent in English. According to Article 14 of the Albanian Constitution, Albanian is the official language of the country.[21] Moreover, patients with PBT visiting the University Hospital Center "Mother Theresa," a national referral center for cancer treatment in Albania, come from various geographic regions and represent diverse socioeconomic and educational backgrounds. Therefore, to ensure inclusivity and accurate data collection, it is essential to administer questionnaires in the Albanian language.[22]

This study outlines the translation and linguistic validation of QLQ-BN20 into Albanian, aiming to provide medical professionals and academics with a suitable instrument for assessing the QoL of Albanian patients in both clinical practice and research.

# 2. Patients and Methods

## 2.1. Instrument

The aim of the QLQ-BN20 questionnaire is to assess how the tumor and its therapy affected the symptoms, signs, and HRQoL of patients with brain tumors in both clinical trials and real-world scenarios, over the past week. In addition to the Brain Cancer module, it is advisable to use the QLQ-C30 questionnaire to capture disease-specific psychosomatic functions and symptoms. QLQ-BN20 comprises 20 items, divided into four multi-item scales that evaluate communication deficit, visual impairment, motor difficulties, and uncertainty about the future, and seven additional single-item questions: weakness in the legs, headache, seizures, drowsiness, hair loss, itchiness, and bladder control.[23] Each item has four ratings on a Likert-type scale: "not at all," "a little," "quite a bit," and "very much." These ratings are subsequently transformed into a 0–100 scale, with higher scores reflecting greater severity of symptoms.[24] EORTC QLQ-BN20 was designed for self-administration, though it is also advisable to be administered by an interviewer.

The entire process of translation of the QLQ-BN20 module was done according to the suggested guidelines as given by the European Organization for Research and Treatment of Cancer (EORTC).[24] In the beginning, one of the authors played the role of project leader by enabling communication with the EORTC translation unit (TU) and coordinating the work of the translators during each phase. Firstly, formal approval to translate and validate QLQ-BN20 in Albanian language was obtained from the EORTC Quality of Life Group (a group in Brussels, Belgium), which is available upon request. EORTC QLQ-BN20 in English, along with EORTC translation and pilot testing guideline, and the scoring manual were graciously provided to us. The standard procedure recommended by the EORTC Quality of Life Group was followed.

## 2.2. Phase 1

Two Albanian native speakers who are also fluent in English were responsible for translating the BN20

questionnaire from the English version into Albanian during the first phase. The project coordinator was able to create the best version by combining the first two forward translations after talking through each query with the translators.

### 2.3. Phase 2

The second phase involved translating the original version back into English. It was completed by two separate translators with an excellent command of English and with Albanian as their mother tongue. They had not previously seen the questionnaire. A third person, a proficient English speaker, created a new version of the questionnaire based on the two versions that were collected at this point. The EORTC TU received both the English and Albanian versions of the materials along with any pertinent remarks.

### 2.4. Phase 3

During the third phase, the EORTC TU reviewed and compared the English version sent by us with the original questionnaire. The second intermediate version of the questionnaire which was used for the pilot study was developed following consensus within EORTC.

### 2.5. Linguistic validation

The final phase involved pilot testing of the translated BN20 module. This study used a prospective, descriptive cross-sectional design. According to the EORTC guidelines, linguistic validation was conducted in 10 patients diagnosed with PBTs and referred to the University Hospital Center "Mother Teresa." These facilities serve as national referral centers for cancer treatment in Albania. Nonprobability consecutive sampling was used for recruiting participants. The nursing personnel approached brain tumor patients visiting the surgical/oncology clinic of "Mother Teresa" University Hospital Center in Tirana as per their scheduled appointments. Potential participants were screened for eligibility by the research group. Eligible participants were required to be native Albanian speakers, over 18 years old, have a histologically confirmed brain cancer diagnosis, have never seen the questionnaire before, and provide written informed consent. Only patients who were able to follow the questions and give answers were interviewed. All participants signed the consent form. There were no exclusions in patient selection in terms of disease stage, age, and the type of treatment at the time of the interview. Considering the noninterventional design of the study, formal approval was granted by the University Hospital Center "Mother Teresa" (Prot. No. 2264/1), which is available upon request. The study adhered to the ethical standards for human subject protection outlined in the Declaration of Helsinki and in compliance with the legal requirements of the country. Anonymity and confidentiality of the data were assured according to Albanian Law no. 9887, dated 10.03.2008, "Protection of personal data."[25]

Initially, participants completed the questionnaire. This was followed by an interview, where they shared their feedback on the clarity and comprehensibility of the translation. All comments were recorded and compiled into a pilot test report, which was forwarded to TU for evaluation. After reviewing and discussing the feedback, the TU finalized the translation and concluded the project.

## 3. Results

The following is the outcome of the use of the aforementioned methods in our testing and linguistic validation process.

The primary objective of the initial phase was to translate BN20 into Albanian, ensuring that the version produced was conceptually as close as possible to the original questionnaire. The two translators were handed the English version of the instrument. Translator I was an imaging technician with a strong proficiency in English and native fluency in Albanian. The second translator was a family physician with exceptional English proficiency and native Albanian language skills. Then, a third person reconciled the two forward translations into a single Albanian version by selecting the most appropriate wording from each translation or combining elements of both. The first intermediate Albanian questionnaire included relevant questions from both translations, showing which translation came closest to matching the questions from the original English questionnaire.

### 3.1. Difficulties encountered

The project coordinator reviewed both versions of the questionnaires. No significant differences were observed in questions 1, 4, 6, 8, 11, 12, 13, 14, 15, 16, 17, 18, and 19. However, in question 2, although both versions conveyed similar meanings, the word "dukur" translates to "seem," whereas "ndjerë," as used by

Translator II, means “felt.” In addition, “pasur” translates to “have,” while “hasur” means “face”. Since there is no word for “setbacks” in Albanian, the second translation was considered by changing the word “setbacks” into “obstacles”. In question 3, the first translation was chosen. Since there is no Albanian word to translate “disruption” in this context, its meaning was given with a group of words. In question 7, the version given by the project coordinator was a combination of the two translations. In question 9, both translators used a term whose meaning is difficult to understand by the patients. Therefore, the coordinator translated “seizures” into a common phrase of the spoken language “kriza me dridhje trupi,” which means “a sudden attack of illness manifested with body tremors”. For question 10, the wording proposed by the second translator was selected for the first intermediate Albanian version because it was considered more comprehensive than that proposed by the first translator. In question 20, the first translation was chosen, but the meaning of the query was explained in brackets for a better understanding by a patient with any level of education. The two translators for the back translation phase were unfamiliar with the original EORTC-BN20 questionnaire. They were informed about the purpose of the questionnaire, which is to assess the QoL of individuals with brain tumors, and were instructed to phrase the questions in clear and simple English, ensuring the questions would be easily understood by all readers. The first translator was an English teacher, while the second was an imaging technician fluent in both Albanian and English. The two back translations were reviewed in comparison to the original questionnaire and to each other. Every question from both translators was comparable to every other question on the original questionnaire. Following discussion with EORTC TU, it was decided that the second question of the first intermediate Albanian questionnaire should be changed to “A ju është dukur sikur gjendja juaj nuk po përmirësohet ose po përkeqësohet?,” meaning “Did you feel that your condition has worsened or not improved?” The preliminary translation underwent external proofreading by a translator from a chosen agency, and all suggestions and corrections were analyzed and discussed. Upon reaching a consensus, the translation proceeded to linguistic validation, sometimes referred to as pilot testing.

## 3.2. Linguistic validation

The second version of the Albanian questionnaire was administered to 10 patients diagnosed with PBTs over 2 days, from June 22, 2023 to June 23, 2023. The patient group consisted of six males and four females, with an average age of 58.4 years (ranging from 31 to 79 years). The histopathologic subtypes of brain tumors included three grade 3 gliomas, two glioblastomas, two low-grade gliomas, two pituitary adenomas, and one meningioma. The native language of all patients was Albanian. Educational levels varied: one patient had completed elementary school, three had attended lower secondary school, four had completed high school, and two had vocational secondary or higher education. The sociodemographic data of our study participants are presented in Table 1.

Table 1: Sociodemographic characteristics of our study participants.

| Demographic characteristics | Number (*N* = 10) | Percentage |
|---|---|---|
| **Gender** | | |
| Female | 4 | 40 |
| Male | 6 | 60 |
| **Age, years** | | |
| Average age (SD), range | 58.4 (16.01), 31–79 | |
| **Educational level** | | |
| Elementary school | 1 | 10 |
| Lower secondary school | 3 | 30 |
| High school | 4 | 40 |
| Vocational school | 2 | 20 |
| **Marital status** | | |
| Single | 1 | 10 |
| Married | 6 | 60 |
| Divorced | 1 | 10 |
| Widowed | 2 | 20 |
| **Type of tumor** | | |
| Grade 3 gliomas | 3 | 30 |
| Glioblastoma | 2 | 20 |
| Low-grade glioma | 2 | 20 |
| Pituitary adenoma | 2 | 20 |
| Meningioma | 1 | 10 |
| **Surgical intervention** | 10 | 100 |

All patients had undergone some form of surgery for their brain tumors. After completing the questionnaire, each patient was interviewed to assess their experience with the questions, focusing on aspects such as difficulty in answering, confusion, comprehension issues, whether any questions were upsetting, and if they would have phrased any questions differently.

### 3.3. Difficulties encountered in pilot testing

In question 6, three patients encountered difficulty in understanding the word "double," but TU recommends changes in wording if more than half of the patients had issues during the pilot study. After the report, the TU finalized the Albanian BN20 questionnaire and made it accessible for use on the EORTC website.

### 3.4. Bias

The patients were exclusively selected from the oncology clinic of University Hospital Center "Mother Teresa," the only public hospital offering radiation therapy services in Albania. Thus, the sample may not reflect the broader population of brain cancer patients. For example, patients from specialized centers may be healthier or have better access to treatment than those from less specialized centers or rural areas. However, "Mother Teresa" University Hospital Center manages 90% of all cancer cases and is considered the national referral center for cancer treatment.

The small sample size of 10 participants was deemed adequate according to the EORTC guidelines for the linguistic validation phase of the questionnaire. Formal psychometric validation and reliability testing of the Albanian versions of EORTC QLQ-C30 and EORTC QLQ-BN20 are currently being conducted in a separate study involving 60 patients with PBTs of varying severity grades.

## 4. Discussion

QoL is a crucial outcome measure, particularly for brain tumor patients, and is increasingly utilized in clinical trials. EORTC QLQ is the most commonly used QoL questionnaire, with the core C30 and BN20 modules being administered to assess the QoL in patients with brain cancer. Since Albanian is the official language, it can be difficult for many Albanians to fully understand English. Therefore, it was essential to translate the brain cancer module into Albanian to ensure that clinicians can use the questionnaire in clinical studies and for Albanian-speaking patients abroad. Therefore, it is very important to have the questionnaire in the patient's own language, so that they can understand and answer in a better way. Having the questionnaire in the patient's native language is crucial for ensuring they understand it fully and can provide more accurate answers. It is also important to use culturally adapted and equivalent questionnaires. Cultural adaptation of QLQ is a detailed and intricate process. The final version must be linguistically and conceptually precise, easy to understand for people from different educational backgrounds, culturally sensitive, nonoffensive, and closely aligned with the original text's wording and format. EORTC QLQ-C30 has already been translated into Albanian and is commonly used in research and clinical trials in Albanian-speaking communities.[20] Translation of EORTC QLQ-BN20 was performed following EORTC's translation guidelines. The final translation was submitted to EORTC for evaluation, where its accuracy and translation method were assessed. Based on the feedback given by EORTC TU, pilot testing of the Albanian QLQ-BN20 questionnaire did not require significant modifications. In contrast, a similar study on the Hindi version of QLQ-BN20 identified difficulties in three questions, which were subsequently adjusted to better align with the spoken language. [26] The Albanian version of BN20 has now been approved by EORTC and can be used in clinical trials involving brain tumors, as well as in routine QoL assessments, with permission from the EORTC QLQ unit (http://www.eortc.be/home/qol). This translation effort is a significant milestone in assessing the QoL for Albanian-speaking brain cancer patients. Further studies should be conducted to assess the reliability and validity of the Albanian version of EORTC QLQ-BN20. Utilizing a standardized and validated tool can facilitate comparison of outcomes across different studies and enhance patient care.

## Conflicts of Interest

Each author declares that he or she has no commercial associations (e.g., consultancies, stock ownership, equity interest, patent/licensing arrangement, etc.) that might pose a conflict of interest in connection with the submitted article.

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