The Process of Translation and Linguistic Validation of the Functional Assessment of Cancer Therapy-Brain Quality of Life Instrument from English to Malayalam: The Challenges Faced

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Abstract

Aim: Both brain tumors and their treatments have a major negative impact on the quality of life (QoL). EORTC BN20 and Functional Assessment of Cancer Therapy-Brain (FACT-BR) are the most commonly used tools to assess QoL. The FACT-BR is a 23-item questionnaire, especially about the psychosocial aspects of QoL. This paper describes the challenges we faced during the process of translation and validation of the FACT-BR into Malayalam. **Methods:** We first screened the patients to ensure their mental status was satisfactory and that they could communicate well in both languages. According to the Functional Assessment of Chronic Illness Therapy methodology, there were two forward translations from English to Malayalam by two independent translators, a reconciliation of the two forward translations, a back-translation into English, a review/finalization by a fifth translator, proofreading, and then testing on a small cohort of patients. **Results:** The whole process of translation was fraught with small and large hurdles – from small technical issues to the gaps in sociocultural norms. The sub item BR 7, due to the lack of an exact equivalent word, had issues that persisted up to the validation phase. The postquestionnaire debriefing interviews confirmed that the translations were well understood and conceptually equivalent to the original English one. **Conclusions:** Translation of the FACT-BR into Malayalam nearly completely reproduced the concepts of the original English questionnaire, as proved in the subsequent validation process.

Keywords: Functional Assessment of Cancer Therapy-Brain, Malayalam, translation, validation

INTRODUCTION

Brain tumors - The burden of disease

Brain tumors comprise roughly 1.8% of the total cancer burden globally and 1.9% in India. In 2012, the global incidence of primary central nervous system (CNS) tumors was 3.4 per 100,000, age-adjusted using the world standard population. The incidence rates in males were 3.9 per 100,000 and among females, 3.0 per 100,000. Thus, an estimated total of 256,123 individuals were diagnosed, including 139,608 males and 116,605 females. The incidence was higher in the developed nations (5.1 vs. 3.0 per 100, 000 population).[1]

According to unpublished data (hospital cancer registry) from our institute, CNS tumours comprised 3.4% of the total tumors in males and 3.1% in females. However, in the age group of 0–14 years, it was 18.3% and 25.8%, respectively. Again, in the 15–34 years' age group, this was 11% and 8.3%. Thus, brain tumors occur more commonly in the younger patients in whom the quality of life (QoL) issues are of paramount importance.

Quality of life in neuro-oncology

The brain can harbor tumors that cover a wide spectrum from the truly benign, indolent tumors to one of the most malignant and aggressive ones. Even a tiny tumor in an eloquent area could be catastrophic as compared to a large tumor in a relatively noneloquent region. The most common symptoms include fatigue, headache and seizures followed by sleep disturbances, cognitive issues, focal neurologic deficits, and behavioral problems. Both surgery and radiation therapy that

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form the backbone of treatment add to the insult. Moreover, like in any other subsite of oncology, as the survival gets better with the availability of better treatment modalities, the QoL issues gain more prominence.

Quality of life assessment

There are no well-established tools to assess the QoL in neuro-oncology practice. Too short questionnaires may not yield much information, too long and complicated questionnaires lead to a lack of compliance. Finding the right instrument to measure QoL is probably a challenge in itself.[2]

The most commonly used questionnaires are the EORTC BN20 and the Functional Assessment of Cancer Therapy-Brain (FACT-BR),[3] although both may be difficult to use in the setting of recurrent tumors. The EORTC BN 20 looks more at the physical disabilities of patients while the FACT-BR is focused more on emotional and social aspects [Table 1]. Since it is not easy to pick up these subtle concerns in the routine clinic, we decided to explore the translation of FACT-BR.

Functional Assessment of Cancer Therapy-Brain

The principles of test construction and evaluation have been utilized in the development of the FACT scale, and it has undergone thorough psychometric testing for validity and reliability.[4] FACT-BR was developed as a newly combined brain subscale questionnaire and checked for validation and reliability in 1995.[5]

It is a 23-item questionnaire with disease-specific questions pertaining to brain neoplasms,[6] usually used along with the core questionnaire that has 27 items. Patients rate all 5 items using a five-point Likert scale ranging from 4 "very much" to 0 "not at all." The higher the ratings, the better the QoL. The FACT-BR can be filled out in a few minutes and is written at the 4th grade reading level.

Indian scenario

Very modest work has been done on QoL issues in India, especially in neurooncology[7] primarily because we are a vast diverse nation and questionnaires developed in the West have little relevance in our context. This article outlines our experience in translating and validating the FACT-BR questionnaire into Malayalam[8] – the official language of Kerala which is spoken by nearly 38 million people, including in the union territories of Lakshadweep and Puducherry.

Process of translation and linguistic validation: Need for a culturally adapted tool

Each culture is unique due to economic, demographic, political, geographic, and sociologic differences. Thus, even linguistic and conceptual equivalence between questionnaires cannot guarantee the general applicability of results.

A number of outcome based assessment tools that are sensitive across cultures have been developed that help clinicians to better understand the factors that affect QoL and associated well-being. Many instruments have been translated, adapted, and validated in non-English-speaking people.[9-11]

Translation methodology

The suitability of the instrument to the target language is mainly ensured by the process of translation. Local dialects,

Table 1: The FACT BR questionnaire

	Additional concerns	Not at all	A little bit	Some-what	Quite a bit	Very much
Br1	I am able to concentrate	0	1	2	3	4
Br2	I have had seizures (convulsions)	0	1	2	3	4
Br3	I can remember new things	0	1	2	3	4
Br4	I get frustrated that I cannot do things I used to	0	1	2	3	4
Br5	I am afraid of having a seizure (convulsion)	0	1	2	3	4
Br6	I have trouble with my eyesight	0	1	2	3	4
Br7	I feel independent	0	1	2	3	4
NTX6	I have trouble hearing	0	1	2	3	4
Br8	I am able to find the right word (s) to say what I mean	0	1	2	3	4
Br9	I have difficulty expressing my thoughts	0	1	2	3	4
Br10	I am bothered by the change in my personality	0	1	2	3	4
Br11	I am able to make decisions and take responsibility	0	1	2	3	4
Br12	I am bothered by the drop in my contribution to the family	0	1	2	3	4
Br13	I am able to put my thoughts together	0	1	2	3	4
Br14	I need help in caring for myself (bathing, dressing, eating etc.)	0	1	2	3	4
Br15	I am able to put my thoughts into action	0	1	2	3	4
Br16	I am able to read like I used to	0	1	2	3	4
Br17	I am able to write like I used to	0	1	2	3	4
Br18	I am able to drive a vehicle (my car, truck, etc.)	0	1	2	3	4
Br19	I have trouble feeling sensations in my arms, hands, or legs	0	1	2	3	4
Br20	I have weakness in my arms or legs	0	1	2	3	4
Br21	I have trouble with coordination	0	1	2	3	4
An10	I get headaches	0	1	2	3	4

idioms, and subtle variations in which words and terms are used and meant in common parlance lead to qualitative issues as well. A comprehensive translation methodology helps avoid all conceptual or semantic concerns.

The cultural adaptation of a QoL questionnaire is achieved by: (1) Translation: To ensure the linguistic validity and (2) psychometric validation: To evaluate the psychometric properties. Both are complementary and mandatory to demonstrate the equivalence of the questionnaires.[7]

Conceptual match among the adapted versions is essential since minor deviations in the intended meaning would lead to changes in perception of the item.[12] The intent could be very well understood, but the perception may be different from the original source in English. Thus, linguistic nuances cause conceptual inequalities that may not get detected easily. This is especially likely to happen if there are significant cultural differences or differences in qualifying symptoms between both groups.[11,13]

Functional Assessment of Chronic Illness Therapy translation system

Functional Assessment of Chronic Illness Therapy (FACIT) translation measurement system makes use of experts, both health care and language, to develop linguistically and culturally appropriate translations.[14] The protocol also includes a pilot testing to ensure that patients with dissimilar backgrounds but with similar symptoms understand the terms consistently.

We translated the FACT-BR QoL Questionnaire into Malayalam and then conducted a linguistic validation as per the FACIT Methodology. The purpose is to ensure that the concepts of the original English questionnaire is adequately captured by the Malayalam translation and is readily understood by patients with brain tumors in Kerala.

METHODS

Translation of Functional Assessment of Cancer Therapy-Brain

The entire process of translation of the FACT-BR into Malayalam was done according to the FACIT translation methodology[6,15] which is somewhat complex. It requires two forward translations from English to Malayalam by two translators working independently from one another, a

reconciliation of the two forward translations provided by a third translator, a back-translation into English performed by a fourth translator, a review/finalization by a fifth translator (a Malayalam speaking health care expert), proofreading and then testing on a small cohort of patients who are familiar with both languages and who complete the test version of the questionnaire and then answer questions from a cognitive debriefing script that was prepared by the FACIT team.

During the initial translation, a grammatically correct translation of the meaning of each question was the priority and not translating each word. This was reviewed by the FACIT team and then by a group of bilingual health care experts to ensure a harmonized translation. The participants were then chosen from among patients receiving treatment for brain tumors at the authors' institution. Cognitive debriefing interviews were used to test the translated questionnaire. A trained interviewer carried out a standardized process following a participant's review, and completion of a patient reported outcome tool.

Linguistic validation

As per the FACIT validation methodology, ten participants were recruited from among the patients undergoing treatment for brain tumors. Participants were eligible if Malayalam was their first language, could understand and use English well, and had a brain tumor that had not impaired their cognitive ability. They also had to be 18 years or older and Eastern Cooperative Oncology Group Performance Status 2 or above and able to provide a written informed consent. Details collected include the age, gender, educational qualification, diagnosis, and functional performance status [Table 2].

Procedure

The participants were first screened to ensure that their mental status was satisfactory and that they could communicate well in both languages. A field tester (medical social worker) supervised the process, and then the subjects completed the FACT-BR in both English and Malayalam. Later, each person underwent the cognitive debriefing interview to ensure that none of the terms used was difficult to understand, offensive, or irrelevant. The interviewer aimed to assess both the individual and cultural relevance and the participants' total understanding of the item, and also to check whether any of the translations were poorly phrased.

Table 2: Patient characteristics					
Gender	Age	Education	PS	Diagnosis	On treatment?
M	39	BA	0	Left Pterional Meningioma	Y
M	25	M Tech	1	Neurofibromatosis 2 with bilateral acoustic schwanoma	Y
F	57	BA BEd	0	Recurrent Left Temporal Oligo-Astrocytoma WHO Grade II	Y
F	24	B Sc	0	Right Temporal Astroblastoma-Anaplastic variant	Y
M	57	MA	0	Right parietal AVM	Y
F	61	XII	1	Invasive Pituitary Macroadenoma	Y
M	29	BA	1	Non Functioning Pituitary Macroadenoma	Y
F	19	XII	0	GH secreting pituitary macroadenoma.	Y
F	33	BA	1	Recurrent Right splenial Oligodendroglioma WHO Gr III	Y
F	68	MD	1	Right sphenoid wing atypical meningioma	Y

The interview began with this text that was read out: "A questionnaire for brain tumor patients is being tested. We would like to know if it can be readily understood. Were there any items which were difficult to understand? Would you please tell me which items were difficult to understand and why they were difficult? Furthermore, could you suggest a better way to phrase these items?"

The interviewer decided whether the paraphrasing of the items was correct and recorded any issues with the understanding or suggested wording changes on a data collection form.

The debriefing results were evaluated by the original translator, back translators, language coordinator, and the survey research expert. There were multiple harmonized translations of problem words/sentences with new back translations that were reviewed by the survey research expert. The final forward and backward translations were created once all the issues were resolved [Figure 1].

RESULTS

Participants

The age ranged from 19 to 68 years, with a mean age of 41.2 years. There were 4 males and 6 females and most had

FACT-Br (Version 4)

കഴിഞ്ഞ 7 ദിവസങ്ങളിൽ അനുഭവമായ നിങ്ങളുടെ പ്രതികരണത്തെ സൂചിപ്പിക്കാൻ ഒരോ വരിയിലേയും ഒരു സംഖ്യയിൽ ദയവായി വൃത്തം വരയ്ക്കുകയോ അടയാളപ്പെടുത്തുകയോ ചെയ്യുക.

	ഇതര ഉത്കണ്ഠകൾ	ഒട്ടും തന്നെ ഇല്ല	ഒരൽപ്പം കുറച്ച്	വല്ലപ്പോഴും	കുറച്ചധികം	വളരെ അധികം
Br1	എനിക്ക് ശ്രദ്ധിക്കാൻ കഴിയുണ്ട്................................	0	1	2	3	4
Br2	എനിക്ക് അപസ്മാരം വന്നിട്ടുണ്ട്...............................	0	1	2	3	4
Br3	എനിക്ക് പുതിയ കാര്യങ്ങൾ ഓർമിക്കാൻ കഴിയും........	0	1	2	3	4
Br4	ചെയ്തിരുന്ന കാര്യങ്ങൾ ഇപ്പോൾ ചെയ്യാൻ സാധിക്കാത്തതിൽ എനിക്ക് മോഹഭംഗം ഉണ്ടാകുന്നു	0	1	2	3	4
Br5	അപസ്മാരം ഉണ്ടാകുമോ എന്നെനിക്കു പേടിയുണ്ട്........	0	1	2	3	4
Br6	എനിക്ക് കാഴ്ചക്ക് ബുദ്ധിമുട്ടുണ്ട്................................	0	1	2	3	4
Br7	ഞാൻ മറ്റുള്ളവരെ ആശ്രയിക്കുന്നില്ല എന്ന് തോന്നുന്നു...	0	1	2	3	4
NTX6	എനിക്ക് കേൾക്കുന്നതിന് ബുദ്ധിമുട്ടുണ്ട്.......................	0	1	2	3	4
Br8	എനിക്ക് ഉദ്ദേശിച്ചത് പറയാൻ ഉചിതമായ വാക്കു(കൾ)കണ്ടുപിടിക്കാൻ കഴിയുന്നു.....................	0	1	2	3	4
Br9	എനിക്ക് എന്റെ ചിന്തകൾ പ്രകടിപ്പിക്കാൻപ്രയാസം ഉണ്ട്................	0	1	2	3	4
Br10	എന്റെ വ്യക്തിത്വത്തിലെ മാറ്റം എന്നെ അലട്ടുന്നു..........	0	1	2	3	4
Br11	എനിക്ക് തീരുമാനങ്ങൾ എടുക്കാനും ഉത്തരവാദിത്വം ഏറ്റെടുക്കാനും കഴിയുന്നു...................	0	1	2	3	4
Br12	കുടുംബത്തിലേക്കുള്ള എന്റെ സംഭാവന കുറഞ്ഞത് എന്നെ അലട്ടുന്നു	0	1	2	3	4
Br13	എനിക്ക് എന്റെ ചിന്തകൾ ഏകീകരിക്കാൻ കഴിയുന്നു ...	0	1	2	3	4
Br14	എനിക്ക് എന്റെ സ്വന്തം കാര്യങ്ങൾ ചെയ്യാൻ (കുളിക്കാൻ, വസ്ത്രം ധരിക്കാൻ, കഴിക്കാൻ തുടങ്ങിയവ) സഹായം ആവശ്യമാണ്	0	1	2	3	4
Br15	എന്റെ ചിന്തകൾ പ്രവൃത്തിയിലാക്കാൻ എനിക്ക് കഴിയുന്നു	0	1	2	3	4
Br16	എനിക്ക് വായിച്ചിരുന്ന പോലെ വായിക്കാൻ കഴിയുന്നു	0	1	2	3	4
Br17	എനിക്ക് എഴുതിയിരുന്ന പോലെ എഴുതാൻ കഴിയുന്നു..	0	1	2	3	4
Br18	എനിക്ക് വാഹനമോടിക്കാൻ (കാർ തുടങ്ങിയവ) കഴിയുന്നു	0	1	2	3	4
Br19	എനിക്ക് കൈകാലുകളുടെ സംവേദനം അറിയാൻ ബുദ്ധിമുട്ടുണ്ട്	0	1	2	3	4
Br20	എനിക്ക് കൈകാലുകളിൽ ബലക്കുറവ് ഉണ്ട്.................	0	1	2	3	4
Br21	എനിക്ക് ചലനങ്ങളുടെ ഏകോപനത്തിൽ ബുദ്ധിമുട്ടുണ്ട്	0	1	2	3	4
An10	എനിക്ക് തലവേദന ഉണ്ടാകാറുണ്ട്	0	1	2	3	4

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Figure 1: Functional Assessment of Cancer Therapy-Brain Martin Marietta Materials (original)

benign brain tumors [Table 2]. The level of education ranged from Pre- to postgraduation. We had two bright young people as participants – an engineer and a speech therapist; also a senior pediatrician and a newspaper editor. The rest of the participants were doing clerical jobs.

Translation

The whole process of translation was fraught with small and large hurdles– from small technical issues to the gaps in sociocultural norms. The sub item BR 7, due to the lack of an exact equivalent word, had issues that persisted up to the validation phase. BR 3 and BR 19 were other items where the approximate words had to be substituted.

Cognitive debriefing

During the process of linguistic validation, we tried to ensure that the desired intent was communicated by the translated items using the "Patient Interview Form" provided by FACIT. The debriefing process exposed the confusion due to the double negative used in subitem Br 7 ("I feel independent"). Five patients provided comments consistent with their answer choices on the questionnaire. The other five seemed to give good explanations, but their response choice of 0 or 1 was not a match with that explanation. These same five patients gave an accurate explanation for the question "What does the term "independent" mean in this item?" The answers ranged from "not dependent" to "not expecting help." This showed that the participants understood the meaning correctly, but the question seemed to have derailed due to the double negative. Hence, after multiple rounds of discussions, it was decided to change the phrase to "I feel I am self-sufficient" that is nearer in meaning and less confusing.

Overall, the participants found the Malayalam FACT-BR easy to complete, relevant, and definitely appropriate. The postquestionnaire debriefing interviews confirmed that except for BR 7, the translations were well understood and conceptually equivalent to the original English one.

DISCUSSION

Translation of a QoL questionnaire is a very labor intensive process. Hence, there has not been much attempt (other than those driven by the industry) to translate QoL questionnaires. It involves hard work from individuals as well as lengthy group discussions.[16] From technical issues with the Malayalam font used to subtle nuances in ensuring the content equivalence, the entire process was challenging and involved multiple rounds of discussions and scores of E-mails to reach the final version.

Semantic equivalence is probably the biggest hurdle in translating QoL questionnaires.[17] This means making sure each statement retains its original meaning and was our biggest challenge.

Content equivalence denotes whether the concept of each item is relevant to the cultural setting where it is used. For example, driving a vehicle is probably too rare skill at least in

the middle aged and above, to be even considered a significant issue among our population.

Due to the colonial heritage, many English words are commonly used, sometimes more than their Malayalam counterparts. However, except for BR 7, we were spot on about all the other items, and they could all be very well understood by the target population. We thus conclude that, despite the occasional glitches and small approximations, the FACT-BR was well translated to Malayalam.

It is important to use questionnaires that are equivalent and culturally adapted. This effort of translation is an important step toward this goal, and use of a standardized and validated tool may help compare outcomes between different studies as well as improve patient care.

For us, the entire process was an uphill task but very exhilarating because this work can be carried out only by medical personnel who not only understand what the patient is going through but also have a deep interest in the literary aspect of both languages – for us it was a hitherto uncharted territory and we thoroughly enjoyed the experience.

Translation - Challenges

The test of the quality of translation was the process of establishing semantic and content equivalence. Apart from sociocultural implications (driving a vehicle), many English words are commonly integrated into everyday speech. This difficulty has been already noted by translators working with other tools of health-related QoL (HR-QoL).[17]

The sub item BR-7 posed the most difficult problem since there is no equivalent Malayalam term for independence in a person. We finally had to settle for a double negative that was, however, proved to be too complicated to understand during the validation phase.

The word "frustrated" in subitem BR-3 was another difficult item, for which semantic equivalence could not be achieved. "Arms, hands and legs" in BR-19 and 20 were shortened to "arms and legs" which is a more common usage in Malayalam.

The Malayalam words for "difficulty," "trouble" and "problem" are used interchangeably in the day today conversation. For the purpose of this translation, we decided to be consistent and substituted the words used in FACT-general version. There were also issues with using the noun form of a word in place of a verb.

One major worry we had was that the questionnaire may remind the patient of unpleasant problems. However, we finally decided that venting their emotions would help the patient face their issues better and also make our bond stronger. We were indeed proved right.

Study limitations

Apart from the literary issues *per se*, the most important limitation was probably that we included patients with all kinds of brain tumors. However, this was also a good opportunity to test the questionnaire among different kinds of participants

from the ones that have indolent tumors like pituitary adenoma, where the patient has a very positive outlook to ones like recurrent glioma that have a dismal outcome.

The small number of ten participants was adequate according to the FACIT organization. All participants had a preserved cognition and were familiar with both languages.

CONCLUSIONS

Translation of the FACT-BR into Malayalam nearly completely reproduced the concepts of the original English questionnaire, as proved in the subsequent validation process. For us, the entire process was challenging but very rewarding. The evolution of the FACT-BR Malayalam using the FACIT translation methodology and involving translation experts has provided a very promising tool to assess the HR-QoL of Malayalam speaking patients with brain tumors. These methods and the current study has opened the gates to the world of HR-QoL in neuro-oncology in Malayalam.

Conflicts of interest
There are no conflicts of interest.

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