Pharmacoeconomics

Translation and Validation of COST - FACIT (Version 2) Questionnaire into Hindi and Marathi to Assess Financial Toxicity in Indian Cancer Patients

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Abstract

Background Cancer is one of the most expensive and exhaustive medical conditions with a huge impact on the financial condition of the patient and their family members. A lot of advancements have led to improvement in the survival of the patients but at a raised cost. Comprehensive Score for financial Toxicity - Functional Assessment of Chronic Illness Therapy (COST - FACIT Version 2) is one such validated and widely used tool. Assessing the financial burden in our country is still far more challenging as COST - FACIT is available in the English language but not in any regional language. Hence, we decided to validate this tool in Hindi and Marathi languages.

Material and Methods A single-center, cross-sectional study was conducted in the Department of Uro-Oncology at the Tata Memorial Hospital. The original version of the COST - FACIT (Version 2) was translated from English into Hindi and Marathi languages, following the FACIT translation method and tested for content validity that included two forward translations, followed by reconciliation and a backward translation. The questionnaires were then approved by the FACIT team, and pilot testing was done for 20 patients (10 for each Hindi and Marathi language). Each of these 20 patients, after filling up the questionnaire themselves, was interviewed for any difficulty encountered during answering the questionnaire. Based on the suggestions or interpretations of this pilot testing, the necessary changes were incorporated in the final Hindi and Marathi questionnaires.

Results A total of 20 patients (10 each for Hindi and Marathi) were included for pilot testing of the questionnaire. The median age of the entire cohort was 61 years (27–79). The questionnaires showed good content and face validity and demonstrated a high internal consistency (Cronbach’s α: 0.85 for Hindi, 0.89 for Marathi).

Conclusion The questionnaire COST - FACIT (Version 2) has been approved and validated in Hindi and Marathi languages by the FACIT team for use in clinical practice and studies.

Keywords
► cancer
► COST FACIT
► financial toxicity
► translation
► validation

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Introduction

Cancer comes under one of the most expensive and exhaustive medical conditions. Treatment of cancer involves multiple treatment modalities, including surgery, radiation therapy, and systemic chemotherapy. During the course of the treatment, patients might get hospitalized for supportive care as well. Treatment cost along with supportive care cost further increases the financial toxicity of the patient. In low-middle income countries, patients undergoing cancer treatment often experience severe financial distress as a significant amount of their saving is spent on their ongoing treatment. Financial consequences of cancer treatment include significant out-of-pocket costs, loss of income, and caregiver burden.

The term financial toxicity/stress refers to the various problems faced by the patients related to the cost of medical care. Financial toxicity has not only affected patients in cost-related issues but it also affects patients’ quality of life and access to medical care. Such as, a patient may avoid visiting the hospital or may not take a medicine prescribed by the doctor, due to cost constraints. Due to the high cost associated with cancer treatment, cancer patients are at increased risk of financial toxicities.

In the last two decades, major advances have been made in preventing, diagnosing, and treating various cancers with the use of newer targeted therapies, immunotherapies, and CAR-T cell therapies across multiple tumor types. This has not only led to improvement in the overall survival but also improvement in the quality of life of patients. However, all these advancements come at the increasing cost of the treatment. As the health cost increases, which leads to an increase in the financial burden, further resulting in higher out-of-pocket expenses.

Patients and their family members bear the impact of rising healthcare expenditures. Although the new targeted therapies have proved to benefit from a medical point of view, it comes along with a high treatment cost leading to greater financial toxicity and increased financial distress, reduced quality of life, and subsequently poorer outcomes.

Financial stress due to cancer is multifactorial. This includes the cost of cancer treatment consisting of chemotherapy, radiation, and surgery, travel cost to treatment centers. Moreover, there is a chance of temporary loss of productivity at work, or permanent termination from the job can be noticed in patients who are employed. All these factors add to the financial stress on the patient and also affects the quality of life of the patients.

According to a new study from Virginia Commonwealth University, almost one-third of cancer survivors experience financial problems due to their diagnosis and/or treatment. Most of the patients especially the survivors, who have trouble paying the cost of the treatment are more likely to stop or delay medical care such as by delaying the prescriptions.

Cancer survivors faces more financial problems which leads to further deterioration of their mental health-related quality of life.

Financial stress has cancer-related psychosocial effects which are understudied and the degree to which cancer-related monetary costs affect an individual’s overall quality of life has not been fully described.

Nowadays, patient-reported outcome measures are becoming an integral part of the clinical trial outcome and also in the routine care of cancer patients. FACIT questionnaires are widely used as a measure to assess patient-reported outcomes. When it comes to assessing financial toxicity in patients, there is no such tool available to evaluate financial toxicity in patients, specifically in India. Comprehensive Score for financial Toxicity - Functional Assessment of Chronic Illness Therapy (COST - FACIT Version 2) is such a tool available in various languages but not in Hindi and Marathi. India, being a lower-middle-income country with a large population, has very low health-related insurance coverage. As a result, the majority of health-related expenses in India are Out of pocket (OOP) expenses. A study was conducted in north India on OOP expenses reported that the total mean expenditure was 10 times the per capita income and also, indirect costs were significantly higher than direct costs. Therefore, the current study was undertaken to translate the FACIT-COST questionnaire into Hindi and Marathi languages so that there will be a patient-reported outcome to assess the financial toxicity among the patients in our country.

Methods

Study Design

The study is a single-center, cross-sectional study, conducted in the Department of Uro-Oncology at the Tata Memorial Hospital, a tertiary cancer center in Mumbai, India. The original version of the COST - FACIT (Version 2) was translated from English into Hindi and Marathi languages, following the FACIT translation guidelines and was also tested for content validity.

Formal permission for using a FACIT questionnaire from the FACIT Measurement System Web site (http://www.facit.org) was taken for developing the Hindi and Marathi versions of the FACIT-COST through iterative forward–backward translation sequences.

After taking permission from the FACIT, ethical approval was obtained from the Institutional Ethics Committee of the Tata Memorial Hospital on February 27, 2020. The trial was registered on the Clinical Trial Registry of India (http://ctri.nic.in) on June 9, 2020.

Questionnaire

The COST - FACIT questionnaire consists of 12 questions (Fig. 1). It was developed by De Souza et al and was validated to assess the degree of financial stress experienced by patients with cancer. The COST questionnaire has 12 items that have been officially coded sequentially from FT1 to FT12. Items 2, 3, 4, 5, 8, 9, and 10 of the questionnaire are reverse scored. The responses vary from 0 (not at all), 1 (a little bit), 2 (somewhat), 3 (quite a bit), and 4 (very much). The score ranges between 0 and 44, and a higher score implies better financial well-being. D’Rummo et al used a grading system with Grade 0 (COST score ≥26), Grade 1 (14–25), Grade 2 (1–13), and Grade 3 (0) for the FACIT-COST.
The guidelines for the process of translation and validation were provided by the FACIT team. The steps included:

**Forward Translation**
The English COST - FACIT questionnaire was translated into Hindi and Marathi languages, as appropriate, as possible to the original English COST - FACIT (Version 2) by two translators, who were fluent in the target languages, i.e., Hindi or Marathi and English.

**Reconciliation**
The two forward translations were reconciled by a third translator, who was fluent in both Hindi or Marathi and English Language.

**Back Translation**
The reconciled version of the questionnaire was then back-translated to English by a translator, fluent in English and the native language (Hindi or Marathi).

All translations were then sent to the FACIT team for review. A few comments raised by the FACIT representative were resolved and the final questionnaire in Hindi and Marathi languages was then tested among the population.

**Pilot Testing and Study Population**
After getting the questionnaire approved by the FACIT team, the Hindi and Marathi questionnaires were then administered to 20 patients (10 each for Hindi and Marathi versions) who visited the Uro-Oncology department at our hospital.
and were reading the questionnaire for the first time. Participants included in this study were patients who were fluent in Hindi and Marathi for the Hindi and Marathi versions, respectively.

**Statistics**
Demographic analysis was performed for age, education, performance status, income, and category of the patients (general or private as per the hospital policy). A correlation was performed using Pearson’s test for correlation using IBM SPSS Statistics for Windows, Version 22.0 IBM Corp Armonk.

**Results**

**Forward Translations (Hindi and Marathi)**
The English COST - FACIT questionnaire was given to two translators for translating it into Hindi and Marathi languages. For Hindi translation, translators I and II were SA and DV, respectively. Both the translators had a good command of English and Hindi. For the Marathi version, translator I was RB, and translator II was DB.

**Difficulties Encountered During Translations**
The Hindi and Marathi questionnaires were then evaluated by one of the investigators of the study. No significant differences were found between the two forward Hindi and Marathi questionnaires prepared by the translators. Both Hindi and Marathi forward translations were finalized after a round of due discussion between the translators and investigators.

**Reconciliation**
The Hindi and Marathi forward translations were reconciled into a single questionnaire by SD and PD, respectively, after due discussions with one of the investigators of the study.

**Back Translations**
The Hindi and Marathi reconciled questionnaires were then given to two translators for each Hindi and Marathi who did not know about the original COST - FACIT questionnaire in the English language. The translators were informed that the questionnaire is a tool to evaluate the financial toxicity in patients. They were requested to back translate the Hindi and Marathi questionnaires into the English language in simple and easily understandable language. For the Hindi version, the translator was NS. For the Marathi version, the translator was KA. The Hindi and Marathi back-translated questionnaires were then compared with the original English version of the questionnaire and were found to be similar.

The complete report was then sent to the FACIT team and after sorting out the comments raised by the FACIT team, the final questionnaires were considered to be used for pilot testing (Figs. 2 and 3).

**Pilot Testing**
The approved Hindi and Marathi questionnaires were then distributed to 20 patients (10 each for Hindi and Marathi versions) who visited the Uro-Oncology department at our hospital and who had never seen the questionnaire before. The study population comprised participants who were native speakers of Hindi and Marathi, for the Hindi and Marathi versions, respectively. The median age of the entire cohort was 61 years (27–79). Nine out of the 20 participants (45%) had completed secondary school education, and 8 out of 20 (40%) had completed college and above education (= Table 1).

A correlation was observed between the monthly income of the patients and the COST score.

The mean COST score of 20 patients included in this study was 18.23 (range 4–33). Most of the patients, i.e., 45% experienced mild impact (Grade 1) financial toxicity, while 30% of the patients suffered moderate impact (Grade 2) financial toxicity (= Fig. 4).

**Reliability Analysis**
The questionnaires demonstrated good content and high internal consistency (Cronbach’s $\alpha$: 0.85 for Hindi, 0.89 for Marathi) (=Tables 2 and 3).

**Discussion**
Our study provides various desirable evidence to support the validity and reliability of the Hindi and Marathi versions of the FACIT-COST (version-2) to measure financial toxicity in cancer patients.

The guidelines provided by the FACIT team were adopted for translating and validating the FACIT-COST (version-2) questionnaire into Hindi and Marathi languages. The final translated questionnaires were then submitted to the FACIT team for their comments. A few queries were raised by the FACIT team, which were discussed by the investigators with the translators. The changes suggested by them were incorporated into the final questionnaires, which have now been approved by the FACIT team, some of them, such as FT2 in Hindi was initially translated as “Mere ilaaj ke liye mere jeb se hone wala kharch, mere anumaan se adhik hai” but after receiving comments by the FACIT team it was changed to “Mere ilaaj ke liye mere jeb se hone wala kharch, jitna maine socha tha usse adhik hai.” In Marathi FT2 was changed after comments from “Majhya vaidkiye kharch ha mee jikta vichar kela hota tyapeksha jast ahae” to “majha khishatun honara vaidkiye kharch ha mee jikta vichar kela hota tyapeksha jast ahae,” also FT5 was modified from “mee nirash ahae ki mee kaam kru shakt naahi v majhe purn yogdaan deu shakt nahi” to from “mee nirash ahae ki mee kaahi kaam kru shakt naahi kiva je yogdan mee nehmi krto te kru shakt nahi.”

The Cronbach’s $\alpha$ value for testing the reliability was 0.85 and 0.89 for Hindi and Marathi languages, respectively, indicating comparability to that of the original version. The value obtained was above 0.7, i.e., the reference value, which implied that the questionnaire had a high internal consistency and homogeneity. Also, high accuracy was observed in Hindi and Marathi languages.

Financial toxicity is one of the most common issues faced by patients while undergoing cancer treatments. Most of the patients who were interviewed during the process of
validation reported that the source of financial support for their cancer treatment was their personal savings or the financial support from the government in case they were government employees. In short term, the majority of the patients were able to manage the cost of the treatment but they expressed their concern for the long-term cost of their treatment as their savings will get depleted on long-term treatment.

Thus, there is a paucity of literature on the financial toxicity incurred by Indian patients. Some studies have been conducted in India that have indicated financial toxicity as one of the major problems amongst the cancer patients undergoing treatment that further affects the quality of life of patients. The majority of the studies, conducted in Indian patients, such as those by Wajid, Alexander, and Pati et al, used a self-constructed questionnaire to assess financial toxicity in patients.11–13 Hence, there is a need for a validated tool in local languages to assess the financial toxicity in patients.

The translated questionnaire will help in assessing the financial toxicity that Indian patients encounter. The study had its limitations. The study included only a small section of the population (patients diagnosed with urological cancers of various stages). For a better understanding of the financial...
stress faced by the patients, a study can be planned in the future considering a large cohort of patients.

With the availability of translated and validated versions of the FACIT-COST questionnaire in Hindi and Marathi, financial toxicities associated can be assessed in patients undergoing cancer treatment and appropriate measures can be taken in the future to reduce this.

**Conclusion**

The questionnaire COST - FACIT (Version 2) has been approved and validated in Hindi and Marathi languages by the FACIT team and has been incorporated on their website (www.facit.org) for use in clinical practice and studies.
Institutional Review
The ethical clearance was obtained from the Institutional Ethics Committee at Tata Memorial Hospital, Mumbai, India.

Confl icts of Interest
None declared.

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Table 1 Baseline characteristics

| Characteristics       | Value |
|-----------------------|-------|
| Age (y)               | Range 27–79 |
|                       | Median 61 |
| ECOG PS               | Category 0: 3 (15) |
|                       | Category 1: 17 (85) |
| Category              | General 9 (45) |
|                       | Private 11 (55) |
| Income                | Range 500–800000 |
|                       | Median 23500 |
| Diagnosis             | Yes 14(70) |
|                       | No 6(30) |

Table 2 Cronbach’s reliability test for Hindi

| Question | Mean | Std. deviation | Cronbach’s alpha |
|----------|------|----------------|------------------|
| FT1      | 1.67 | 1.414          | 0.823            |
| FT2      | 1.56 | 1.509          | 0.823            |
| FT3      | 0.67 | 1.414          | 0.818            |
| FT4      | 0.67 | 1.323          | 0.859            |
| FT5      | 1.56 | 1.509          | 0.834            |
| FT6      | 1.67 | 1.323          | 0.811            |
| FT7      | 1.89 | 1.453          | 0.826            |
| FT8      | 2.44 | 1.424          | 0.848            |
| FT9      | 1.22 | 1.481          | 0.824            |
| FT10     | 1.33 | 1. | 0.829            |
| FT11     | 2.56 | 1.59           | 0.927            |

Table 3 Cronbach’s reliability test for Marathi

| Question | Mean | Std. deviation | Cronbach’s alpha |
|----------|------|----------------|------------------|
| FT1      | 1.6  | 0.966          | 0.885            |
| FT2      | 1.4  | 1.578          | 0.894            |
| FT3      | 1    | 1.155          | 0.877            |
| FT4      | 0.8  | 1.033          | 0.894            |
| FT5      | 2.4  | 1.578          | 0.888            |
| FT6      | 1.5  | 1.08           | 0.877            |
| FT7      | 1.4  | 1.265          | 0.876            |
| FT8      | 1.3  | 1.418          | 0.894            |
| FT9      | 1.8  | 1.619          | 0.875            |
| FT10     | 1.3  | 1.16           | 0.875            |
| FT11     | 1.6  | 1.506          | 0.874            |
| FT12     | 3.4  | 0.966          | 0.936            |

Fig. 4 Patient distribution by FT grade; COST score ≥ 26 (Grade 0), 14–25 (Grade 1), 1–13 (Grade 2), and 0 (Grade 3).

Conflicts of Interest
None declared.
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