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Pilot Testing and Preliminary Psychometric Validation of the Polish Translation of the EORTC INFO25 Questionnaire

Validation of the Polish version of INFO25—pilot study

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Abstract The quality of information that oncological patients receive from health care professionals is an underestimated issue in Poland and Eastern European countries. There is lack of sufficient data on this subject. The European Organization for Research and Treatment of Cancer (EORTC) supplies a new tool for measuring the quality of information provided to cancer patients. The purpose of the study is the translation into Polish, pilot testing and preliminary validation of the EORTC information module (INFO25). Following the EORTC translation procedures, forward and back translations of the questionnaire were performed (English→Polish, Polish→English). The intermediate version of the INFO25 was pilot-tested together with the general questionnaire of quality of life (EORTC QLQ-C30). Reliability, validity and known-group comparison tests were performed. A total of 21 patients with different cancer diagnoses were recruited into the study (7 women and 14 men; mean age of 60,2 years, age range 25–73 years). Apart from filling out the INFO25, patients were interviewed about the difficulties with answering every questionnaire item. Patients' comments were analyzed and minor language changes were made to the initial translation. The internal consistency of the INFO25 showed a reliability of 0,78. The final version of the Polish

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translation of the INFO25 module was obtained and approved by the EORTC Quality of Life Department. It can now be used in clinical setting and for scientific purposes.

Keywords Cancer · EORTC · INFO25 · Quality of information · Quality of life

Introduction

Information Received by Cancer Patients

The quality and quantity of information received by patients is an increasingly important issue in oncology (Arraras et al. 2010; Rehnberg et al. 2001; Singer et al. 2013). We still lack data concerning this matter, especially in Central and Eastern Europe. Medical staff receives training in breaking bad news procedures (Kotlinowska and Wilusz 2010). However, the type, quantity and quality of information the patients receive during the diagnostic process and treatment is rarely investigated (Butow et al. 1997). There are numerous benefits that may be related to providing adequate information, among them: improvement of patient satisfaction, compliance and relations with medical staff as most complaints received by health care professionals are caused by lack of proper communication. Additionally, proper transmission of information may diminish the distress accompanying cancer treatment and improve cooperation with the patient and their family (Butow et al. 1996; Degner et al. 1998; Kotlinowska and Wilusz 2010; Mesters et al. 2001). It remains unclear if patient satisfaction is linked to the amount of information received, although there are data supporting this thesis (Butow et al. 1997). If the physicians were to receive feedback on the topic of provided information, it could also facilitate communication. Polish doctors seem to shy away from informing the patients of the diagnosis and treatment options, finding it easier to talk to the family, which often leaves them with a feeling of guilt and helplessness. This attitude has been recently changing, also in other European countries, especially among younger professionals, although communication skills are not included in postgraduate medical training (Arraras et al. 2011; Bracci et al. 2008; Degner et al. 1998; Kotlinowska and Wilusz 2010). There is a need to adapt shared information depending on the recipient (eg. his/her age). Senior patients in Poland are accustomed to receiving a very limited amount of information regarding their health status. It is not known whether, and to what extent, the population of these patients would benefit from a significant change of this situation. At the same time, it seems that younger patients do not agree with such paternalism in medicine and probably more commonly would like to be involved in the decision making processes.

This topic requires further exploration as many cancer patients are still not satisfied with the information provided (Montomery et al. 1999; Passalacqua et al. 2009; Repetto et al. 2009). What is more it stays unclear if factors such as patient's gender or education status should influence the way of patient-doctor communication.

EORTC Information Module

The INFO25 information module is meant for use among cancer patients in different disease sites and stages, in any moment of the treatment and in follow-up periods, as

well as for research or daily clinical purposes. The module can be presented on its own or together with other EORTC questionnaires, for assessing the quality of life dimensions (Arraras et al. 2010; Singer et al. 2013).

The INFO25 module is not the first one created to measure the information provided to patients with cancer. However, the existing ones are focused mainly on patients' satisfaction or needs (Arraras et al. 2011; Bonevski et al. 2000; Degner et al. 1998; Mesters et al. 2001; Thomas et al. 2004).

As EORTC recommends linguistic and cultural adaptation to be performed in every country the questionnaire would be used, we attempted formulating a correctly translated and culturally adequate INFO25 questionnaire in Polish. We plan to perform further studies with psychometric validation as it was done previously with the EORTC QLQ-OG25 and the QLQ-OPT30 modules

(Chmielowska et al. 2013; Tomaszewski et al. 2013).

Patients and Methods

Patients

The patients were recruited prospectively between October and November 2012 at the Department of Clinical Oncology of the University Hospital in Krakow, Poland. Patients were eligible if they had a histologically confirmed diagnosis of a malignant tumour. Study exclusion criteria were lack of consent to participate in the study and being unable to fill out or understand the questionnaire. There were no restrictions as to the gender, age or type of malignancy.

The research protocol was approved by the Jagiellonian University Ethics Committee (registry KBET/253/B/2011). The study was performed in accordance with the ethical standards laid down in the 1964 Declaration of Helsinki and its later amendments.

Interview procedure

The patients were approached during their stay at the inpatient clinic and informed about the study. After informed consent, they were interviewed by trained staff members. Each patient completed the Polish version of the EORTC QLQ-C30, the INFO25 module and a personal questionnaire. The total time for completion of questionnaires and interview was approximately 25 min. Information about every participant's clinical history and physical examinations was taken from patient records.

Questionnaire

The INFO25 is a 25-item module comprised of four multi-item scales: information about the disease (4 questions), information about medical tests (3 questions), information about treatment (6 questions) and information about other services (4 questions). In addition to the four multi-item scales, the EORTC INFO25 has 8 single items regarding different places of receiving care, self-help attempts, receiving written and digital information, satisfaction with the information received, wish to receive more information, wish to receive less information, and helpfulness of the information obtained.

A global score can be computed by averaging the scores from the 12 scales. Higher scores indicate higher levels of information. Twenty-one out of twenty-five INFO25 questions are scored on a 1 to 4 point Likert scale (“not at all”, “a little”, “quite a bit”, “very much”). Four questions (50, 51, 53, 54) are answered by either “yes” or “no”. Questions 53 and 54 have an extra sub-question for patients who have replied “yes”, in which they are invited to specify the topics in which they would like to have received more or less information. Detailed information on how to score the EORTC INFO25 questionnaire can be found in the EORTC QLQ-C30 scoring manual and its later addendum (Fayers et al. 2001).

Translation procedure

The translation process of the EORTC INFO25 Polish version was authorized by the EORTC Quality of Life Department. The translation was completed in accordance with the EORTC translation procedure (Dewolf et al. 2009). The EORTC QLQ item bank was searched for existing translated items but no such items were found.

First, two independent forward translations were made (English→Polish) by two medical professionals, Polish native speakers (both holders of the Cambridge Certificate of Proficiency in English). From the two translations a unified, preliminary Polish version of the INFO25 questionnaire was created, aided by discussion between the translators and the project manager. This version was then translated back into English by two independent English native speakers, both professional translators fluent in Polish. The two obtained back translations were compared with the original English version of the INFO25 questionnaire. This was done by the project manager. Since no significant differences were noted between the original version and the two back translations, all the translation process documentation was sent to EORTC for approval, before beginning the pilot testing phase. Based on the documentation, EORTC approved the preliminary Polish version of the INFO25 and sent back the intermediate Polish version of the INFO25, ready for pilot testing.

Pilot testing

The intermediate version of the INFO25 was pilot-tested in 21 Polish cancer patients (14 men and 7 women). Patients were asked whether they had any difficulty answering the questions, whether they found any of the questions confusing, upsetting or containing difficult vocabulary. When a patient reported having trouble answering any of the questions, they were asked to suggest an alternative way to formulate it. None of the question was found problematic, confusing or offensive. However, in case of question 46: ‘During your current disease or treatment, how much information have you received on: Aspects of managing your illness at home?’ a single respondent suggested inserting additional information. It has to be noted that the question was said to be understood even without these supportive information. In case of question 34: ‘During your current disease or treatment, how much information have you received on: Whether the disease is under control?’ one patient reported that it needs to be made more specific, but did not elaborate in what way. One respondent advised replacing the words ‘written information’ by the word ‘brochure’ in question

50. Another patient suggested that some may think that questions ‘Do you wish to receive more information? If yes, please specify on which topics?’ (question 53b) and ‘Do you wish that you had received less information? If yes, please specify on which topics?’ (question 54b) ask about the same thing. What is important, when asked to suggest an alternative way to phrase the questions all patients decided to leave the primary version of the questions.

Patients’ comments were analyzed and minor language changes were made to the initial translation.

After this phase the final translation of the Polish version of the EORTC INFO25 questionnaire was obtained and approved by the EORTC Quality of Life Department.

Statistical analysis

Statistical analysis was conducted using computer software Statistica 10.0 PL by StatSoft Poland. Scores for multi-item scales and for single items were calculated by linear transformation of raw scores into a 0–100 score (Fayers et al. 2001). To analyze the data, descriptive statistics (mean, standard deviation, percentage distribution) were used.

Convergent validity was assessed by correlating each item with its own scale. Discriminant validity was assessed by correlating each item with any other scale. Evidence of item-convergent validity was defined as a correlation of 0,40 or greater between an item and its own scale (corrected for overlap) (Arraras et al. 2010). A scaling success for an item was seen when the correlation between an item and its own scale was significantly higher than its correlation with other scales (Arraras et al. 2010; Fayers and Machin 2007). Cronbach alpha coefficient was calculated to assess the internal consistency of the Polish version of the EORTC INFO25 questionnaire. Internal consistency estimates of a magnitude of $>0,70$ were considered acceptable (Fayers and Machin 2007).

Clinical validity was assessed using known-group comparisons. This assesses if the questionnaires could be used to discriminate between subgroups of patients differing in clinical status. The known groups used in this study were age (>60 or ≤ 60), gender and current treatment (potentially curative vs. palliative) (Caruso et al. 2000; Friedemann-Sanchez et al. 2007). Differences between groups were tested with the Mann–Whitney test. The significance level was set at $p \leq 0,05$.

Results

A total of 21 patients were recruited into the study—7 women and 14 men. Patients’ clinical and demographic data are presented in [Table 1]. Nine patients had colorectal cancer, four had gastric cancer, four suffered from head & neck malignancies, one had breast cancer, one had gastric lymphoma, one had testicular cancer and one had an astrocytoma.

Thirteen (62 %) patients said that they had received written information from their physicians and seven (33 %) had reported obtaining such information on a CD. Nineteen (90 %) patients wished they had received more information from their doctors and only two (10 %) people wanted to receive less information.

Table 1 Patients' clinical and demographic data

| | Total (n=21) | Women (n=7) | Men (n=14) |
|--|--------------|-------------|-------------|
| Age (SD) | 60,2 (10) | 53,4 (13,5) | 63,6 (5,8) |
| Education level | | | |
| Elementary | 4 (19 %) | 2 | 2 |
| High school | 3 (14 %) | 1 | 2 |
| Vocational | 8 (38 %) | 2 | 6 |
| University | 6 (29 %) | 2 | 4 |
| Working status | | | |
| Employed | 16 (76 %) | 6 | 10 |
| Unemployed | 1 (5 %) | 0 | 1 |
| Retired/Pensioner | 3 (14 %) | 0 | 3 |
| Student | 1 (5 %) | 1 | 0 |
| Treatment option (more than one treatment option possible) | | | |
| Chemotherapy | 13 (62 %) | 3 | 10 |
| Radiotherapy | 1 (5 %) | 1 | 0 |
| Chemoradiotherapy | 8 (38 %) | 4 | 4 |
| Hormonal therapy | 1 (5 %) | 1 | 0 |
| Underwent previous surgical treatment | 17 (81 %) | 5 | 12 |
| Current treatment | | | |
| Curative | 13 (62 %) | 4 | 9 |
| Palliative | 8 (38 %) | 3 | 5 |
| Zubrod scale (SD) | 0,67 (0,73) | 1,14 (0,90) | 0,43 (0,51) |

SD – standard deviation

Reliability, convergent and discriminant validity of the Polish version of the INFO25 are presented in [Table 2]. The internal consistency estimate of the full questionnaire showed a reliability of 0,78.

Known-group comparison by age (>60 or ≤60), gender and current treatment (potentially curative vs. palliative) is presented in [Table 3].

Table 2 EORTC INFO25: reliability, convergent and discriminant validity of multi-item scales

| | Item correlation within scale* | Item correlation with other scales* | Cronbach alpha |
|----------------------------------|--------------------------------|-------------------------------------|----------------|
| Information about the disease | 0,62–0,78 | –0,12–0,87 | 0,71 |
| Information about medical tests | 0,45–0,74 | –0,35–0,67 | 0,68 |
| Information about treatment | 0,43–0,56 | –0,35–0,70 | 0,62 |
| Information about other services | 0,64–0,95 | –0,56–0,51 | 0,73 |

Single items not included in this table

* Spearman correlation coefficients

When the INFO25 Global Score was calculated by gender it showed that when comparing information obtained by men ($49,7\pm 15,6$) to information obtained by women ($55,7\pm 11,5$) there were no statistically significant differences ($p=0,31$).

When the INFO25 Global Score was calculated by current treatment it showed that when comparing information obtained by patients from the potentially curative group ($48,3\pm 15,4$) to information obtained by patients from the palliative treatment group ($57,2\pm 11,1$) there were no statistically significant differences ($p=0,29$).

Discussion

The original version of the INFO25 module has been checked for validity and reliability in multicenter studies (Arraras et al. 2010; Singer et al. 2013). This manuscript presents results from the translation, pilot testing and preliminary psychometric validation of the INFO25 information module. The module has been also translated and tested in Spain (Arraras et al. 2011); however, to the best of our knowledge, our study has been the first to perform a preliminary validation and linguistic adaptation of the INFO25 questionnaire in Central and Eastern Europe.

There are data suggesting the existence of relationship between the quality of information received and the quality of life. In fact, some reports speculate that what is most relevant is not the amount of information provided, but the influence it has on the patient's quality of life (Annunziata et al. 1998; Mallinger et al. 2005). Currently, HRQoL in cancer patients has become an important outcome measurement also in clinical trials (Blazebly et al. 2006). Therefore, any factors possibly influencing HRQoL need valid measuring instruments. It has been shown that the cultural aspect influences the relationship between the overall HRQoL and its components score (Scott et al. 2008). Probably, the same statement is valid for quality of information assessment.

Cross-cultural and proper linguistic adaptation was essential because we did not want our results to be misleading. It has been shown that omitting parts of the adaptation processes may result in future studies bias. Incorrectly or carelessly translated and adapted questionnaires would not measure what they intend to assess (De La Rosa et al. 2007). We managed to create a user-friendly Polish version of the information module. The patients were willing to answer all questions, not finding them awkward or inappropriate. It may seem surprising that also the question considering sexual activity (question 43) was accepted and answered by all patients as, unfortunately, in Poland it is still beyond everyday clinic practice to offer support in the field of sexology. To the contrary, most of the patients wished to receive more information not only on the causes of their disease or on further treatment, but also on the impact the disease and its treatment might have on their sexual activity.

Cultural barriers and difficulties, occasionally found during pilot studies of the EORTC modules in other countries, have been suggested for example in elderly patients' population (Wadasadawala et al. 2008). Also in post-communist countries of Central and Eastern Europe cultural adaptation is essential. These countries have experienced significant changes in the last four decades. This also relates to the

Table 3 Known-group comparison: Age, gender and current treatment

| Scale/item | Gender (SD) | | p-value | Current treatment (SD) | | p-value | Age (SD) | | p-value |
|---|-------------|--------------|-------------|-----------------------------|------------------|---------|-------------|-------------|---------|
| | Male (n=14) | Female (n=7) | | Potentially curative (n=13) | Palliative (n=8) | | >60 (n=9) | ≤60 (n=12) | |
| Information about the disease | 53,6 (17,2) | 69,5 (11,5) | 0,05 | 57,1 (18,6) | 61,5 (14,7) | 0,61 | 57,4 (13,5) | 59,7 (19,7) | 0,77 |
| Information about medical tests | 62,7 (20,7) | 71,5 (18) | 0,33 | 63,2 (22,4) | 69,4 (15,4) | 0,63 | 66,7 (13,6) | 64,8 (24,1) | 0,84 |
| Information about treatment | 48 (17,7) | 54,8 (15,2) | 0,33 | 50,9 (16,6) | 49,3 (16,9) | 0,91 | 53,7 (16,9) | 47,9 (16,2) | 0,44 |
| Information about other services | 31 (23,4) | 26,2 (14,8) | 0,74 | 23,1 (19,3) | 39,6 (19,8) | 0,06 | 25,9 (22,2) | 31,9 (20,1) | 0,53 |
| Information about different places of care | 33,3 (29,2) | 14,3 (17,8) | 0,14 | 20,5 (21,7) | 37,5 (33) | 0,23 | 25,9 (27,8) | 27,7 (27,8) | 0,89 |
| Information about self-help | 42,9 (27,5) | 38,1 (23) | 0,61 | 38,5 (26,7) | 45,8 (24,8) | 0,54 | 33,3 (23,6) | 47,2 (26,4) | 0,23 |
| Satisfaction with the information received | 61,9 (25,7) | 76,2 (16,3) | 0,03 | 61,5 (23) | 75 (23,6) | 0,22 | 55,6 (16,7) | 75 (25,1) | 0,06 |
| Overall helpfulness of the information received | 64,3 (24,3) | 95,2 (12,6) | 0,01 | 71,8 (26,7) | 79,2 (24,8) | 0,54 | 66,7 (23,6) | 80,6 (26,4) | 0,23 |

Single items with a “yes” or “no” answer are not included in this table

Statistically significant data presented in bold

SD—standard deviation

field of health care system that, in most ex-Eastern Bloc countries, stays badly organized with limited access to psychological and social care for patients, as well as poorly funded and underestimated position of family medicine (Oleszczyk et al. 2012).

In our study, the majority of patients wished they had received more information. There are some reports claiming the important role of providing the patient with full information or proving that there is a connection between patients' satisfaction and the amount of information provided. However, these reports do not focus on the type of information given to the patients, and the data they present seem vague, which means they require further testing and, in fact, they will be a topic of our ongoing studies (Butow et al. 1997; Fujimori and Uchitomi 2009; Gysels and Higginson 2007; Innes and Payne 2009).

The internal consistency of 0,78 suggests that all items can be added to generate a score on perceived information provision. Two scales did not reach the required Cronbach alpha value of >0.7 . These were the Information about medical tests (0.68) and Information about treatment (0.62). We recognise that our values are very close to the required Cronbach alpha, and also that these are only guidelines, rather than simple cut off or threshold scores. The other scales proved to have appropriate Cronbach alpha values.

INFO25 multi-item scales show good convergent validity. According to our preliminary results, women are more satisfied with the information they receive, finding it more helpful. The gender differences in information needs have already been mentioned in several reports (Friedemann-Sanchez et al. 2007; Fujimori and Uchitomi 2009). Also, the data considering validation of the original INFO25 version showed that the satisfaction-with-the-received-information scale differentiated between genders in the known-group comparison test, while such differences were not found in the overall-helpfulness-of-the-information scale (Arraras et al. 2010).

Insufficient discriminant validity may be related to the fact that the group was small or, less likely, to the stress accompanying the breaking bad news procedure, insufficient training of health care professionals, patients' inability to discriminate whether they are informed about the disease itself, the diagnostic and therapeutic procedures or other medical activities they are involved in.

As for known-group comparison, our results are largely consistent with the English version (Arraras et al. 2010). Because of the small number of participants in this pilot study many statistically significant differences could not have been seen. However some trends could be detected. Taking into account the current treatment intention, one can see that the "Information about current treatment" scale is a potentially good candidate for a discriminator between patient differing in treatment option. The same goes for the "Satisfaction with the received information" item when one considers patients age.

These results show that INFO25 is a promising tool in performing research on information quality and quantity received by cancer patients.

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