

# Translation and validation of the EORTC QLQ-PAN26 quality of life questionnaire for patients with pancreatic cancer

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**Background.** The aim of this report was to describe the validation and translation of the European Organization for Research and Treatment of Cancer (EORTC) QLQ-PAN26 questionnaire into Lithuanian and to test its reliability by estimating the internal consistency of the questionnaire.

**Materials and methods.** The forward and back translation procedure was performed from November 2002 to October 2003 following the EORTC guidelines given in the literature. The source instrument was translated from English into Lithuanian. The translation process was strictly documented and supervised by the Translation Coordinator, Quality of Life (QoL) Unit, EORTC (European Organization for Research and Treatment of Cancer).

**Results.** The semi-final version was tested on 13 patients (9 male and 4 female) with pancreatic cancer. The final report was sent to EORTC. After approval of the supervising organization the translation was approved. The internal consistency, QoL numerical representation of the questionnaire and the scales were calculated.

**Conclusions.** The EORTC QLQ-C30 questionnaire and the supplementary module QLQ-PAN26 have been successfully and legally translated into Lithuanian. The Lithuanian version of the questionnaire is correct, reliable, easily understandable and readily available for use to appropriate patients. The pilot testing has revealed a good internal consistency of the module.

**Key words:** quality of life, questionnaire, pancreatic cancer

## INTRODUCTION

The fast development of the new technologies in contemporary medicine and surgery in particular makes it possible to revise the methods of treatment of some diseases. Surgery has become more aggressive achieving higher radicalism in gastrointestinal cancers. Whether the patient enjoys a good quality of life following extended surgery remains a matter of debate. There is a growing interest to assessing the impact of a disease and the effect of a treatment on a patient's life (1). The patients experience problems with work and social activities, finances, family and sexual life as well as disturbances of emotional functioning. Such subjective aspects of the patient's health are referred to as quality of life. Quality of life measurements have become increasingly important in surgical research and, beside the more established outcome measures such as morbidity, mortality and survival rates, are one of the endpoints of

clinical trials (2–5). Valuable clinical and cultural information can be obtained by comparing the results of such measurements with those reported from other countries with different cultures and languages, which may also have consequences for health policy (6). Worldwide application of the standardized questionnaires results in obtaining comparable QoL scores and improved interpretation of the data. To achieve these goals, the QoL instruments must be reliable and valid in spite of their multilingual character. Instruments previously developed in another language must be translated and validated in a systemic way in order to overcome conceptual, semantic and linguistic differences between cultures (7). Such a procedure should be followed for each country and language involved (8).

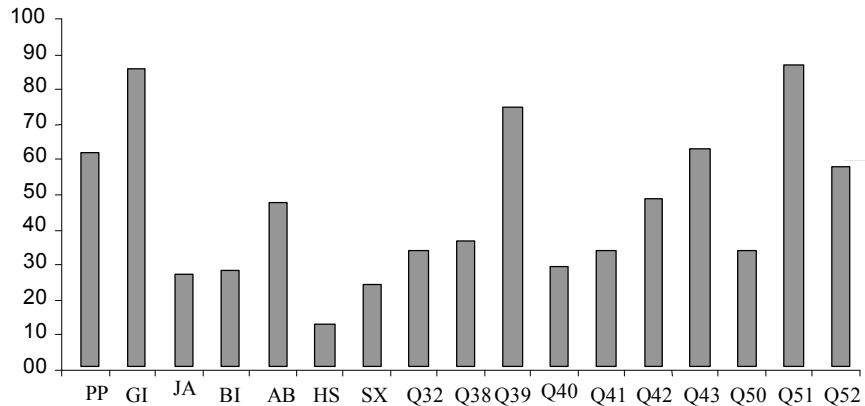
A disease-specific quality of life questionnaire for pancreatic cancer patients, the EORTC QLQ-PAN26, has recently been developed by the European Quality of Life in Pancreatic Adenocarcinoma (EQoLiPA) study group on behalf of the EORTC study group on quality of life (9). It has been developed using EORTC guidelines for module development (10). The module is designed for use in a wide range of patients with pancre-

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atic cancer varying in disease stage and treatment modality, including single and multi-modality treatment, definitive and palliative surgery, chemo- and radiotherapy, and endoscopic palliation. It is used in conjunction with the QLQ-C30 questionnaire. The module comprises 26 questions assessing disease symptoms, side effects of treatment and some specific psychosocial issues of importance in pancreatic cancer. The questionnaire consists of symptom scales such as pancreatic pain symptom scale, upper gastrointestinal symptom scale, jaundice scale, body image scale, altered bowel habit scale, health satisfaction scale and sexuality scale. The module is currently available in Chinese (Taiwan), Danish, Dutch, English, American English, French, German, Swiss German, Hungarian, Italian, Spanish and Swedish, and, finally, in Lithuanian. The aim of this report was to describe the translation and validation procedure of the EORTC QLQ-PAN26 questionnaire into the Lithuanian language and to test its reliability estimating the internal consistency of the questionnaire.

## MATERIALS AND METHODS

The forward and backward translation procedure of the original EORTC module QLQ-PAN26 was performed from November 2002 to October 2003 following the EORTC guidelines given in the literature (11). The translation procedure was strictly documented and supervised by the Translation Coordinator, QoL Unit, EORTC. The source instrument was translated from English into Lithuanian by two independent translators, native Lithuanian speakers with a high level of fluency in English. The translation team compared the versions of the translations and discussed the differences. The differences were insignificant. After the two versions of the translation have been compared, discussed and adjusted, a preliminary Lithuanian version was agreed upon. It was followed by a back-ward translation of the preliminary Lithuanian version into English by two independent professional translators both fluent in Lithuanian and with English as their mother tongue, both of them being unfamiliar with the background objectives of the study. Both versions of the backward translation were compared with each other and after minor adjustments a final English version was agreed upon. There were no unresolved differences between the translations. All versions of the forward and back-ward translations, as well as the final Lithuanian version were sent to EORTC had been reviewed. The final English version was compared with the original questionnaire by the



The symptom scales: PP – pancreatic pain (Q 31, 33, 34, 35), GI – gastrointestinal (Q 36, 37), JA – jaundice (Q 44, 45), BI – body image (Q 48,49), AB – altered bowel habit (Q 46, 47), HS – health satisfaction (Q 53, 54), SX – sexuality scale (Q 55, 56), separate questions – Q.

**Figure.** Quantitative data on quality of life in pilot testing group

responsible staff of the QoL Unit, EORTC. A few minor differences between the backward translation and the original questionnaire were not significant and were solved after consultation between the EORTC and the translation team in Lithuania. The translation was afterwards considered a semi-final, i.e. ready for pilot testing. The aim of the pilot testing was to identify and solve any potential problems of comprehension by the pancreatic cancer patients. The pilot testing was started after the permission from the EORTC was obtained. The semi-final Lithuanian version of the EORTC module QLQ-PAN26 was tested on 13 patients (9 males and 4 females) with pancreatic cancer, managed at the Department of Surgery, Kaunas University of Medicine Hospital. The questionnaire was delivered prior to surgery or palliative treatments. After the pilot study was accomplished, the final report was originated and sent to the EORTC. The report included a procedure following the account of the pilot testing containing the characteristics of the patient cohort, qualitative and quantitative data (Figure). Afterwards the internal consistency (Cronbach's alpha) of the questionnaire and of the separate scales was calculated.

## RESULTS

All the patients analyzed were native Lithuanian speakers aged from 32 to 82 years (mean, 60.62). Among them, there were six pensioners, two workers, one farmer, three employees, one owner of a company. It took 7 to 15 minutes to complete the questionnaire. All the patients stated the questionnaire to be not too long, it was relevant to their condition, and it was easy to understand as well as to answer the questions. Four patients asked about the period of the time they had to refer: the last seven days including the day of the interview or the last calendar week. Because of the age and cultural traditions, four patients had problems with answering the questions about their sexual activity. One

Table. The internal consistency of the questionnaire

The specific symptom scale	Pancreatic pain, PP	Upper gastrointestinal, GI	Jaundice, JA	Body image, BI	Altered bowel habit, AB	Health satisfaction, HS	Sexuality, SX	The entire questionnaire
Questions	31, 33, 34, 35	36,37	44,45	48,49	46,47	53,54	55,56	
Cronbah's alpha	0.87	0.27	0.61	0.94	0.86	0.27	0.96	0.89

male and one female patients thought it was inappropriate to speak about it. One female patient didn't answer these questions because "all this was in the past". One male patient when answering question 56 asked how he could measure sexual enjoyment. He suggested an alternative wording: "Have you felt sexual enjoyment?". One obese male patient was wondering why he should worry about the weight being too low, while he was worried of his weight being too high. He suggested an alternative wording: "Have you worried about your weight being too high?". One male patient could not evaluate his physical attraction. He thought his partner should answer this question instead. The alternative wordings of these questions were not better apprehensible than the original version, so it was concluded that the translation required no further changes. The calculated internal consistency of the questionnaire was 0.89, of pancreatic pain and specific symptom scale PP (questions 31, 33, 34, 35) 0.87, upper gastrointestinal symptom scale GI (questions 36, 37) 0.27, jaundice scale JA (questions 44, 45) 0.61, body image scale BI (questions 48, 49) 0.94, altered bowel habit scale AB (questions 46, 47) 0.86, health satisfaction scale HS (questions 53, 54) 0.27, sexuality scale SX (questions 55, 56) 0.96 (Table).

Subsequently the Lithuanian version of the EORTC module QLQ-PAN26 was validated by the QoL Unit, EORTC and is now ready for use in Lithuanian-speaking periampullary cancer patients.

## DISCUSSION

Although the outcomes of surgical treatments have been measured primarily in terms of morbidity and mortality for many years, it is now increasingly acknowledged that the Quality of Life evaluation is an important additional outcome measure. There are two main uses of Quality of Life measurements. Knowledge of the effects of illness on the health and wellbeing of patients and of how they cope with their disease can help to advance our understanding of pancreatic cancer. Most interesting to clinicians at present is measuring Quality of Life as an outcome of a clinical intervention or trial (9). Using the QLQ-C30 and QLQ-PAN26 in future studies will allow accurate and standardized cross-study comparisons of different treatment interventions, particularly in randomized clinical trials. This will enable justification of the benefit of any intervention for quality of life to be based on evidence rather than on "expert" speculation (9). Approximately 50–60 patients with pancreatic cancer (from definitive surgery to palliative management)

are being treated annually at the Department of Surgery, Kaunas University of Medicine Hospital. It is very important to understand the subjective wellbeing of these patients.

Prospective studies undertaken at three institutions of Capetown, Southampton and Magdeburg have shown that Quality of Life assessment system designed for pancreatic cancer patients works effectively also in patients with chronic pancreatitis (12). So the translation will also be useful here. The internal consistency of the questionnaire is good when Cronbach's alpha exceeds 0.7. Our results showed a good internal consistency of the Lithuanian QLQ-PAN26 questionnaire and the symptom scales. We have obtained a slightly lower consistency in the upper GI symptom and health satisfaction scales. Taking into account the small number of patients and the small number of questions in these scales, deviations of Cronbach's alpha were regarded as insignificant. There was no need for the cultural adaptation, because Lithuanian as the mother tongue is spoken only in Lithuania, and in general the patients found the questions relevant and appropriate. When the translation process was under way, the EORTC QLQ-PAN26 was a phase III module, which means it was under development, however, thus it was being shared only with the groups willing to provide data relevant to evaluating its psychometric properties. Now it is the phase IV module. In the future, we shall collaborate with EORTC and participate in the development process of this questionnaire.

## CONCLUSIONS

The EORTC QLQ-C30 questionnaire module QLQ-PAN26 has been successfully and correctly translated into Lithuanian. The Lithuanian version of the questionnaire is accurate, reliable, easily understandable and readily available for use to appropriate patients. The pilot testing has revealed good internal consistency of the module.

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**PACIENTŲ, SERGANČIŲ KASOS VĖŽIU,  
GYVENIMO KOKYBĖS KLAUSIMYNO VERTIMAS  
IR ĮTEISINIMAS****S a n t r a u k a**

Šio darbo tikslas yra EORTC QLQ-PAN26 klausimyno vertimo į lietuvių kalbą ir įteisinimo proceso aprašymas, taip pat klausimyno patikimumo nustatymas įvertinus vidinį nuoseklumą. Vertimas iš anglų kalbos į lietuvių ir atgal buvo atliekamas nuo 2002 m. lapkričio iki 2003 metų spalio pagal EORTC metodus nurodymus. Vertimo procedūra buvo griežtai dokumentuojama ir prižiūrima EORTC Gyvenimo kokybės padalinio vertimų koordinatoriaus. Preliminari versija buvo išbandyta su 13 pacientų (9 vyrais ir 4 moterimis), sirgusių kasos vėžiu. Vėliau buvo nusiųstas galutinis pranešimas į EORTC. Gautas atsakymas, kad vertimas yra įteisintas. Buvo apskaičiuotas klausimyno ir atskirų jo skalių vidinis nuoseklumas ir gyvenimo kokybės skaitmeninė išraiška. EORTC QLQ-C30 klausimyno modulis QLQ-PAN26 yra sėkmingai legaliai išverstas į lietuvių kalbą. Klausimyno modulio lietuviška versija yra legali, patikima, lengvai suprantama ir prieinama naudojimui atitinkamiems pacientams. Pirminis bandymas parodė gerą vidinį modulio nuoseklumą.

**Raktažodžiai:** gyvenimo kokybė, klausimynas, kasos vėžys