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Original Paper

Development of a Disease Specific Quality of Life (QoL) Questionnaire Module to Supplement the EORTC Core Cancer QoL Questionnaire, the QLQ-C30 in Patients with Pancreatic Cancer

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There is overwhelming consensus that quality of life assessment is urgently required in pancreatic cancer, yet little research has been conducted. We report on the development of a disease specific questionnaire module to supplement the EORTC core cancer module, the QLQ-C30 in patients with pancreatic cancer, using EORTC quality of life study group guidelines for module development. Relevant QoL issues were generated from literature searches and interviews with health professionals and patients with pancreatic cancer. Issues were constructed into items and provisionally translated. The provisional module was pretested in patients in 8 European centres. The resulting module the QLQ-PAN26 includes 26 items related to disease symptoms, treatment side-effects and emotional issues specific to pancreatic cancer. This should ensure that the module will be sensitive to assess the small but important disease and treatment related QoL changes in pancreatic cancer. The use of the QLQ-C30 and QLQ-PAN26 will provide a comprehensive system of QoL assessment in international trials of pancreatic cancer.

Key words: pancreatic neoplasm, quality of life, EORTC QLQ-C30, questionnaire
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INTRODUCTION

THE OUTLOOK for a patient diagnosed with pancreatic adenocarcinoma remains gloomy in terms of prognosis and survival, with over 90% dying within a year of diagnosis [1]. Treatment options remain limited. Only 20% of patients may be suitable candidates for a 'curative resection', with only 15–20% of these patients surviving beyond 5 years. The majority of patients receive palliative surgical or medical interventions. The roles of chemotherapy and radiotherapy remain a source of debate within the literature [2] and any benefit in terms of gain in survival time and alleviation of symptoms must be balanced against the costs of treatment toxicity and any deterioration in quality of life (QoL). There is overwhelming consensus that QoL assessment is urgently required in pancreatic cancer [3–5]. However, little research has been published and to our knowledge no disease specific questionnaire has been described in the literature.

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The EORTC Quality of Life study group have developed a modular approach to the development of QoL questionnaires specifically designed for the clinical trial situation [6]. A 30 item core cancer questionnaire, the QLQ-C30 has been developed. This is intended to be supplemented by additional modules to assess specific disease and treatment related QoL issues, in particular patient subgroups. This approach facilitates generalisability of results across studies and the sensitivity to detect small but clinically meaningful differences in QoL to address specific research questions. To ensure scientific rigour, detailed guidelines for module development have been published [7], and recently updated [8]. We describe the first three phases of the development of a pancreatic cancer specific module to supplement the EORTC QLQ-C30.

PATIENTS AND METHODS

The EORTC guidelines for module development were followed (Figure 1). Phase 1 was conducted in the U.K. This involved extensive literature searches, using MEDLINE, EMBASE, CANCERLIT and CINAHL databases and qualitative interviews with 29 patients and 6 multi-disciplinary health professionals with experience in pancreatic cancer to generate relevant QoL issues in pancreatic cancer. Purposive sampling allowed a cross section of patients to be identified across the spectrum of disease stage and treatment intervention. The grounded theory method of data collection and analysis [8] was used to produce an exhaustive list of issues. A description of the methods used has been published elsewhere [12]. This initial list of issues was then reduced using the EORTC criteria for item deletion: items already covered in the QLQ-C30; items difficult to operationalise into health related QoL items; and issues which could be obtained by other means, for example patient medical records. This list of issues was then given to a new set of 5 patients and 12 pancreatic cancer specialists, to rate the importance of each item, and ensure no significant omissions. This list of issues was then constructed into items using the same format and time frame employed in the QLQ-C30 (phase 2). Where possible, issues which had been constructed into items in a previous module were used or adapted (with the permission of relevant module developers) to provide consistency and clarity across modules. This provisional module and a report of phases 1 and 2 was then reviewed by two members of the Module Development Committee (MDC). After revision, this module was provisionally translated into 10 European languages (Dutch, French, German, German (Swiss), Greek, Italian, Hungarian, Portuguese, Spanish, Swedish) using the EORTC translation procedure [9]. The provisional module and the QLQ-C30 were pretested in 76 patients (Table 1) in 8 European countries through the European Quality of Life in Pancreatic Cancer (EQoLiPA) study group (U.K., 25; Sweden, 7; Germany and Switzerland, 10; Italy, 13; Greece, 6; Spain, 8; Hungary, 7), followed by a structured interview. This was directed at patients responses to each individual item to assess patient acceptability; and two questions directed at the entire questionnaire (QLQ-C30 and provisional pancreatic cancer module), to check for irrelevant items and any significant omissions.

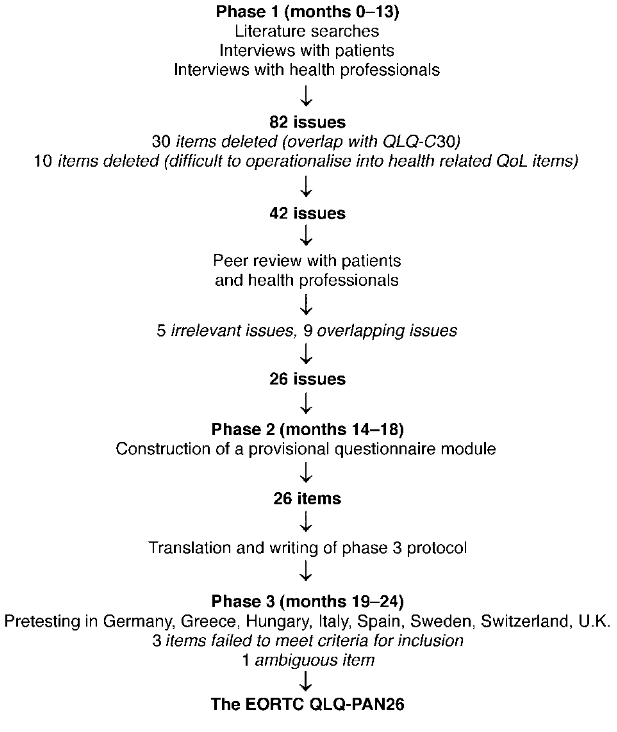

Figure 1. Phases and time frame of the development of the EORTC, QLQ-PAN26.

RESULTS

The development of the EORTC pancreatic cancer module was undertaken in 2 years (Figure 1). The initial literature search was largely unproductive and only 26 published papers were identified as relevant [10]. 24 potentially relevant QoL issues were generated, covering symptoms of pancreatic cancer and treatment side effects. No study described QoL from the patients' perspective. No other pancreatic cancer specific questionnaire was identified. The initial grounded theory study of patients and professionals identified 82 issues. This initial list of issues was then reduced following EORTC module guidelines to 42 issues. Examples of items deleted included; nausea, fatigue, depression (already covered by the QLQ-C30); self esteem, hope (difficult to operationalise into health related QoL items); and analgesia consumption (could be gathered from patients, records). Peer review with a further population of patients and specialists, and the MDC produced a list of 26 issues which were constructed into items. A provisional 26 item module was initially constructed

Table 1. *Sociodemographic and clinical features of patients in phase* 1 *and* 3

	Phase 1 ($n = 34$)	Phase 3 ($n = 76$)
Age, mean and range	67.4 years (49–85 years)	65.7 years (43.8–86.6 years)
Sex (M:F)	22:12	38:38
Marital Status		
Married	23	60
Widowed	9	8
Single/divorced	2	8
Disease duration: (mean and range)	4.5 months (0–60 months)	2.75 months (0–18.25)
Primary Treatment		
Surgical resection	12	24
Surgical palliation	6	22
Stent placement	11	14
Palliative chemotherapy	5	16

Table 2. Content of the EORTC QLQ-PAN26

Pain	Body Image
Abdominal discomfort	Physical attractiveness
Back pain	Satisfaction with body
Position related pain	
Night time pain	
Eating related items	Side effects
Restriction of diet intake	Burden of treatment
Restriction of food types consumed	Dry mouth
	Taste changes
Indigestion	Fear of future health
Flatulence	Ability to plan future
Cachexia	Health care satisfaction
Loss of muscle strength	Information
Weight loss	Support
Hepatic	Altered bowel habit
Jaundice	Frequency of elimination
Pruritus	Urgency of elimination
Ascites	Sexuality
Swollen abdomen	Sexual interest
	Sexual enjoyment

in English and then translated into the relevant languages prior to pretesting.

The median time for patient self completion of the QLQ-C30 and provisional pancreatic module was 12 min (range 5–25 min). 23 of 26 items met the criteria for inclusion when stratified into groups by treatment intervention (surgical resection, surgical palliation, endoscopic palliation and chemotherapy only), and geographic location (U.K., Southern Europe and North Europe). Three items (bone pain, stomatosis and family support), failed to meet the criteria and were deleted. An item related to coping with illness was deleted due to a high ceiling effect and many patients felt this question was difficult to understand. An additional issue, sexuality, was identified in Southern European patients. Also, many patients felt that the item related to diarrhoea in the QLQ-C30 did not adequately cover the problems of steatorrhea experienced. These additional issues were constructed into four new items. This resulted in a 26 item pancreatic cancer module covering disease and treatment related symptoms, and additional emotional consequences of pancreatic cancer (Table 2). A full report and the final module was peer reviewed by the MDC and accepted as being developed in accordance with module guidelines. The module has been termed the EORTC QLQ-PAN26.

DISCUSSION

The QLQ-PAN26 is one of a series of disease or treatment specific modules developed by the EORTC QoL study group to supplement the QLQ-C30, using standard guidelines for module development. The use of literature searches, interviews with patients and health professionals and rigorous peer review provides high content validity of the QLQ-PAN26. The study generated specific disease and treatment related symptoms, and issues related to the emotional and social well-being in patients with pancreatic cancer which are not covered comprehensively in previous quality of life questionnaires. Consequently, this should ensure that the module will be sensitive to assess the small but important disease and treatment related QoL changes in clinical trials for pancreatic cancer.

Our initial qualitative approach to develop a quantitative questionnaire allowed the patients to generate relevant quality of life issues from their own experience and has provided a unique insight into the pancreatic cancer patients perception of their quality of life. This has been reported elsewhere [12].

The EORTC QLQ-PAN26 is now undergoing final translation using the EORTC translation procedure. It has been incorporated into a large international field study and several clinical trials to assess the reliability, validity and clinical responsiveness of the EORTC QLQ-C30 and QLQ-PAN26 in pancreatic cancer patients.

1. Carter D. Cancer of the Pancreas. *Gut* 1990, **31**, 494–496.
2. Lionetto R, Pugliese V, Bruzzi P, Rosso R. No standard treatment is available for advanced pancreatic cancer. *Eur J Cancer* 1995, **31A**, 882–887.
3. Alexandre JH, Bouilot JL. Quality of life assessment in pancreatic surgery. *Theoretical Surgery* 1992, **7**, 18–20.
4. Ahlgren JD. Chemotherapy for pancreatic carcinoma. *Cancer* 1996, **78**, 654–663.
5. Rothenberg ML, Abbruzzese JL, Moore M. A rationale for expanding endpoints in clinical trials in advanced pancreatic carcinoma. *Cancer* 1996, **78**, 627–632.
6. Aaronson NK, Ahmedzai S, Bergman B, *et al.* on behalf of the EORTC Quality of Life Study Group. The European Organisation for Research and Treatment of Cancer QLQ-C30: a quality of life instrument for use in international clinical trials in oncology. *J Natl Cancer Inst* 1993, **2**, 319–325.
7. Sprangers MAG, Cull A, Bjordal K, Groenvold M, Aaronson NK on behalf of the EORTC Quality of Life Study Group. The European Organisation for Research and Treatment of Cancer. Approach to quality of life assessment: guidelines for developing questionnaire modules. *Qual Life Res* 1993, **2**, 287–295.
8. Sprangers MAG, Cull A, Groenvolf K, Bjordal J, Blazeby J, Aaronson NK for the EORTC Quality of Life Study Group. The European Organisation for Research and Treatment of Cancer approach to developing questionnaire modules; an update and overview. *Qual of Life Res* 1998, **7**, 291–300.
9. Strauss A, Corbin J. *Basics of Qualitative Research. Grounded Theory Procedures and Techniques*. Sage Publications, London. 1990.
10. Cull A, Sprangers MAG, Bjordal K, Aaronson NK on behalf of the EORTC Quality of Life Study Group. Translation Procedure. 1994. EORTC internal document.
11. Fitzsimmons D, Johnson CD. Quality of life after treatment of pancreatic cancer. *Lagenbeck's Archives of Surgery* 1998, **398**(2), 145–151.
12. Fitzsimmons, D., George, S., Payne, S.A. and Johnson, C.D. Differences in perception of quality of life issues between health professionals and patients with pancreatic cancer. *Psycho Oncol* 1999, in press.

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