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Original Paper

Development of an EORTC Questionnaire Module to be Used in Quality of Life Assessment for Patients with Oesophageal Cancer

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Quality of life (QOL) assessments in patients with oesophageal cancer should provide clinically meaningful data that can assist management decision making. This study describes the development of a specific module for oesophageal cancer to use with the European Organisation into Research and Treatment of Cancer (EORTC) QOL questionnaire, the EORTC QLQ-C30. Relevant QOL issues were generated from a literature search and interviews with patients and oesophageal cancer specialists. Issues were formulated into items compatible with those of the EORTC QLQ-C30. The provisional module was pretested in patients from the United Kingdom, Spain and Sweden. The resulting module, the QLQ-OES 24, includes 24 items conceptualised as containing six scales and five single items. The addition of an oesophageal cancer-specific module to the core questionnaire should improve the sensitivity and specificity of the core instrument to allow detection of even small benefits accrued from new treatment modalities. Copyright © 1996 Elsevier Science Ltd

Key words: oesophageal neoplasms, quality of life, EORTC, questionnaire

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INTRODUCTION

PATIENTS WITH oesophageal cancer can be treated in many different ways and choice depends in part on such factors as disease stage and the general health of the patient. Efforts to improve survival have included better pretreatment staging procedures, improved supportive care and the introduction of multimodality therapies. Although there are some encouraging results, the benefits gained in terms of impact on disease-free survival may potentially be at the expense of treatment-related toxicity [1, 2]. These considerations and the knowledge that the overall outcome of patients with oesophageal cancer is poor, have logically led to major advances in treatment evaluation. This now extends beyond standard endpoints of disease-free survival time, morbidity and relief of dysphagia to include a measure of the impact of this treatment and condition on the patients' health-related quality of life (QOL) [3, 4].

Little is known about QOL measurement in patients with oesophageal cancer. A recent literature review, using Medline, identified 33 original articles published in English that incorporated QOL in the evaluation of treatment for oesophageal neoplasms [5]. Only three of these utilised generic validated QOL instruments [6–8]. Most of the other studies measured QOL by a dysphagia score, with or without a simple measure of the patient's performance status. Conclusions from this review were that QOL research in patients with cancer of the oesophagus was lagging behind other areas of oncology and that current instruments were not optimal in the assessment of these patients [5].

A generic questionnaire for assessing QOL in patients with cancer, the EORTC QLQ-C30, has been published by the European Organization for Research and Treatment of Cancer (EORTC) Quality of Life Study Group [9]. This instrument has been recently evaluated in patients with oesophageal cancer with promising results [10]. It was easily

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Table 1. Phases of development of the EORTC QLQ-OES24, the oesophageal cancer module for use with the EORTC QLQ-C30

Phase I	Generation of quality of life issues -Literature search -Detailed interviews with patients and specialists -Semi-structured interviews with patients and specialists This produces a list of potential QOL issues
Phase II	Construction of issues into a provisional questionnaire -The items are worded to synchronise with other questionnaire modules -The items are worded to be compatible with the QLQ-C30 response categories The provisional questionnaire is then ready for pre-testing
Phase III	Testing of the questionnaire for acceptability and relevance -Patients complete the questionnaire and are interviewed -Results are analysed according to response prevalence and variance -Results are discussed with the EORTC QOL Study Group The whole process is reviewed by two members of the Study Group
Phase IV	Field testing in an international group of patients -The module is tested for reliability, validity and cross-cultural application The module should now be valid and ready for use in clinical trials

completed by most patients and the reported QOL scores in the functional and symptom scales and items reflected the expected clinical findings. Dysphagia grade, however, as graded by an independent observer, did not significantly correlate with the QOL scores and it would appear that problems with dysphagia do not overwhelm all aspects of QOL, and functional and other physical symptoms need to be measured separately. These data support the view that a new QOL instrument for patients suffering from cancer of the oesophagus, incorporating a suitable dysphagia scale, is required.

The EORTC QLQ-C30 questionnaire was designed to be supplemented by questionnaire modules specific to a particular cancer or treatment [11]. Such modules should improve the sensitivity and specificity of the core instrument to allow detection of very small beneficial or detrimental effects accrued from potentially curative, palliative and adjuvant treatments. Modules should be developed according to guidelines published by the EORTC Quality of Life Study Group [12], to ensure that high quality questionnaires will be produced, suitable for QOL assessments alongside the EORTC QLQ-C30. Currently, only one such module has been published after international field testing, for patients with lung cancer [11], but modules for breast and head and neck cancer are undergoing international validation [13, 14].

This study describes the development of an EORTC questionnaire module for patients with oesophageal cancer. The oesophageal cancer module is designed to be suitable for QOL assessments before, during and after any single treatment, or combination of treatments including chemotherapy, external beam radiotherapy, oesophagectomy, intubation, laser treatment, tumour necrosis with ethanol or diathermy, or brachytherapy.

MATERIALS AND METHODS

The module development process

Module development has four strict and distinct phases, published in detail by the EORTC QOL Study Group [12]. Each phase is summarised in Table 1. Phase IV, an international validation study, is currently being completed and will be the subject of a future paper.

RESULTS

Phase I: Generation of QOL issues

An exhaustive list of potential issues was produced from a literature review and from in-depth interviews with patients and specialists. To ensure all pertinent QOL issues were identified, three large databases were examined. Medline was searched from January 1966 to February 1994; Psychinfo from January 1992 to February 1994; and Embase from January 1980 to February 1994. The major subject headings were oesophageal neoplasms and QOL. This identified 45 articles. Eight papers incorporated oesophageal cancer-specific questionnaires to assess the outcome of treatment [15–22]. Very little information is available about the construction of these questionnaires and only one of the eight had undergone careful development and psychometric testing [22]. Detailed interviews were undertaken with an oesophageal cancer surgeon, a medically qualified epidemiologist with an interest in health outcomes research and 10 patients with oesophageal cancer. The literature search was discussed and additional issues added to produce

Table 2. The nine broad categories of relevant QOL issues abstracted from the literature and interviews with patients and specialists (after elimination of the issues covered by the EORTC QLQ-C30)

Description	No. of issues
Dysphagia	6
Pain	4
Gastrointestinal symptoms	3
Eating-related issues	14
Respiratory symptoms	5
General symptoms not in the EORTC QLQ-C30	6
Specific emotional issues	3
Eating-related social function	1
Satisfaction with care	4
Total	46

*Table 3. Content of the 32-item pre-testing module and final EORTC QLQ-OES24**

Items in pre-testing module Phase III	Items in EORTC QLQ-OES24
Dysphagia	Dysphagia
Eating solid food	Eating solid food
Eating soft foods	Eating soft foods
Drinking liquids	Drinking liquids
Deglutition	Deglutition
Being able to swallow saliva	Being able to swallow saliva
Choking when swallowing	Choking when swallowing
Eating related items	Eating related items
Enjoying eating	*Two items were combined to:*
Enjoying drinking	Enjoying meals
Feeling a blockage when eating	
Troublesome eating	Troublesome eating
Troublesome eating in front of others	Troublesome eating in front of others
Trouble with taste	Trouble with taste
Feeling full up too quickly	Feeling full up too quickly
Indigestion	Indigestion
Troublesome belching	Troublesome belching
Trouble with indigestion	Trouble with indigestion
Trouble with acid or bile	Trouble with acid or bile
Pain	Pain
Pain when swallowing	Pain when eating
Chest pain	Chest pain
Abdominal pain	Abdominal pain
Side-effects of treatment	Single symptom items
Having a dry mouth	Having a dry mouth
Trouble with bending forwards	
Troublesome coughing	Troublesome coughing
Troublesome talking	Troublesome talking
Hair loss	Hair loss
Sleeping propped up	
Emotional items	Emotional items
Worry about weight loss	Worry about weight loss
Burden of treatment	Burden of treatment
Burden of illness	Burden of illness
Worry about family	
Worry about future health	Worry about future health
Clinical problems	Clinical problems
Weight loss	*All were deleted*
Bed sores	
Using a feeding tube	

* The EORTC QLQ-C30 is protected by international copyright and the EORTC QLQ-OES24 is not in the public domain while under development. Use of these questionnaires is prohibited without prior written consent of the Study Group. Enquiries should be addressed to Dr G. Kiebert, EORTC Data Centre, Quality of Life Unit, Avenue E. Mounier 83, Bte 11, 1200 Brussels, Belgium. Enquiries on the use of the EORTC QLQ-OES24 should be addressed to the first author of this paper.

a provisional list of 76 QOL issues. Thirty generic issues found in the EORTC QLQ-C30 were eliminated from this list. The remaining 46 issues were divided into nine broad categories, as detailed in Table 2.

Semi-structured interviews

The list of 46 QOL issues produced from the literature review and in-depth interviews was then reduced by presenting it in a semi-structured format to 10 specialists and 22 British patients who were asked to rate each issue with regard to its relevance to a QOL questionnaire. Relevance was defined by the frequency and amount of trouble caused by each issue. Issues were deleted if 25% or more patients considered them irrelevant [12]. Issues were added if patients or specialists considered them important. Generic issues found in the EORTC QLQ-C30 were also deleted from the list. The specialists were two oesophageal surgeons, two oncologists, two general practitioners, a palliative care nurse, a nutrition nurse, a senior ward nurse and a district nurse. The patients were selected to represent a range of disease stages and treatments.

Based on the quantitative results of the semi-structured interviews, 20 issues were deleted from the list of 46. Patients found nine issues irrelevant. Seven issues were removed because of content overlap, and four issues focusing on satisfaction with care were removed because a separate module was concurrently being developed to measure satisfaction.

Six of seven issues volunteered during these interviews were added: enjoyment of drinking, the burden of treatment, the burden of illness, worry of weight loss, worry regarding future health and hair loss. Sexual problems, volunteered as important by one patient, were not added

because other patients and specialists thought it would not be relevant to most patients.

Phase II: Construction of a provisional module, list of items

A list of items (specific questions) were constructed from the list of QOL issues generated during Phase I. Items were compatible with the EORTC QLQ-C30 response categories and time frame of one week. The items conformed to recognised principles of questionnaire construction. Of the 32 issues generated following Phase I, 27 were constructed into new items and five issues were found to be similar to items in both the EORTC Breast and Head and Neck QOL modules. The wording of these latter five issues was made synchronous with the other modules. Phase II produced a provisional questionnaire for pretesting, expected to form eight multi-item scales (see Table 3).

Phase III: Pre-testing of the provisional module

Phase III was designed to identify problems with specific items and to ensure the module adequately covered QOL experiences in a larger sample of patients. Patients completed the EORTC QLQ-C30, the provisional module, a debriefing questionnaire and then underwent a structured interview. The results were summarised according to response prevalence (range and mean score) and variability. Items with low frequency (mean score < 1.5) and/or low variability (range <2) were considered for exclusion. The qualitative results extracted from the patients' interviews were used to help decide which items should be included in the module for larger scale field testing.

Pretesting was performed in a total of 132 patients, 105 from the United Kingdom, 17 from Spain and 10 from Sweden. Patients undergoing six different types of treatment were studied. Details are summarised in Table 4. Data from the United Kingdom were analysed separately from data from Spain and Sweden. Spanish and Swedish data were analysed as one group.

No additional items were added to the module and a total of eight items were deleted.

In the British sample, two items had mean scores of less than 1.5: 'problems with bed sores', and 'troublesome talking'. Patients from Spain and Sweden also reported few problems with bed sores; thus this item was removed from the module. The item concerning troublesome talking was retained because this was considered important to patients with a recurrent laryngeal nerve palsy.

Table 4. Details of patients interviewed during Phase III: pre-testing

	Phase III pre-testing
No. of patients from each country	
United Kingdom	105
Spain	10
Sweden	17
Total	132
Sex (male/female)	92/40
Mean age (range) in years	67 (51–88)
Karnofsky performance status [25]	
100	2
90	18
80	22
70	29
60	21
50 or less	13
Total*	105
Dysphagia grade	
1. Able to eat all or most solid food	29
2. Able to eat only soft foods	43
3. Able to drink liquids only	46
4. Complete dysphagia	14
Total	132
Treatment	
Before oesophagectomy	16
<8 months since oesophagectomy	17
>8 months since oesophagectomy	17
2–8 months since oesophagectomy and adjuvant treatment	16
Before intubation	16
1–8 months since intubation	15
2–8 months since laser treatment	8
2–8 months since chemo/radiotherapy	27
Total	132

* Not rated in patients from Spain or Sweden.

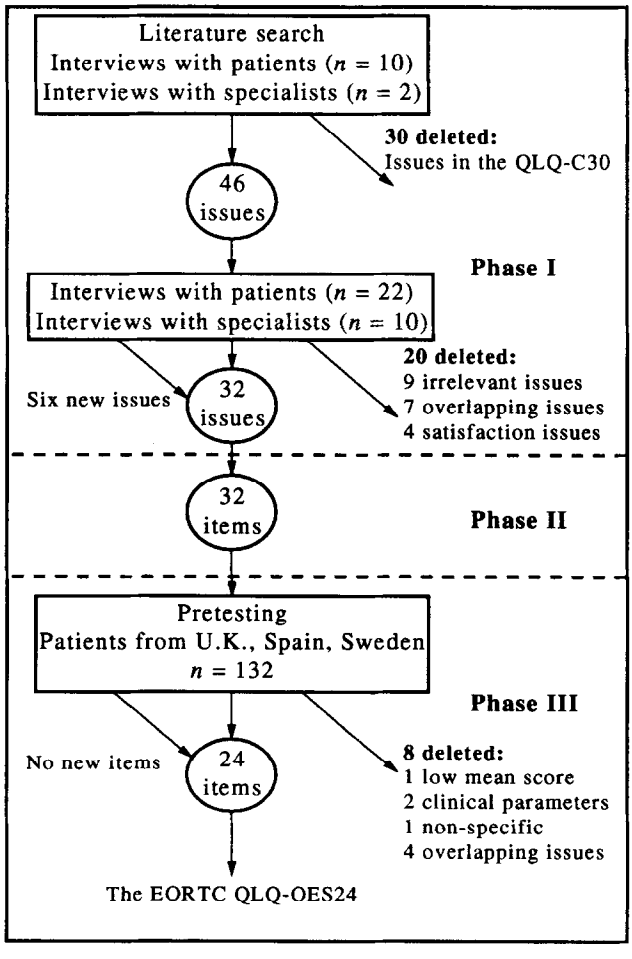

Figure 1. Development of the EORTC QLQ-OES24

Two items were deleted because they were considered to be clinical parameters that could be recorded elsewhere: 'use of a feeding tube' and 'weight loss'.

The item: 'worrying about family or friends' was deleted because it was felt to be non-specific to patients with oesophageal cancer.

Four items were deleted because patients from all three countries thought their content overlapped. The items, 'trouble with bending forwards' and 'having to sleep propped up' were deleted and the question about acid and bile reflux was retained instead. The item, 'feeling a blockage when swallowing' was deleted because of overlap with the dysphagia scale. Two items were merged into one: thus, 'enjoyment of eating' and 'enjoyment of drinking' were merged to 'enjoying meals'.

The resulting EORTC oesophageal cancer module (QLQ-OES24) includes 24 items, conceptualised as consisting of six scales and five single symptom items (Table 3). The wording of the final English version was modified slightly to clarify the meaning of some items. The module will be translated according to the guidelines for questionnaire translation written by the Study Group. Phases I–III of the development of this module have been reviewed and accepted by two members of the Study Group who were not involved in the development process [23]. Figure 1 summarises the module development.

DISCUSSION

In 1977, Stoller and colleagues published a new proposal for the evaluation of treatment for carcinoma of the oesophagus, which considered four domains of QOL: swallowing ability, work habits, the enjoyment of leisure and sleeping habits [15]. Since this original work, few papers have measured these broader aspects of patients' QOL. Although survival is an important goal, the influence of major surgery, adjuvant therapy or palliation of malignant dysphagia on patients' QOL should be an integral part of management decision making. Precise, valid, reliable and sensitive QOL instruments should, therefore, be developed.

The EORTC QLQ-OES24 has been methodically developed to ensure that, when used with the EORTC QLQ-C30, it will be able to assess all major dimensions of health-related QOL in patients with oesophageal cancer. The content has been based not only on literature and clinicians' assessment, but also on issues volunteered by patients receiving a variety of treatments themselves. The composition and design of this module has been examined in over 100 patients from three European countries.

In the few previous studies that have measured QOL in patients with oesophageal cancer, a variety of instruments has been used [7, 22, 24]. This creates difficulties in cross-study comparisons. Contrasts between studies can only be made by using standardised instruments. The EORTC Quality of Life Study Group approach, with a combination of a general cancer questionnaire and a diagnosis-specific module, allows for such comparisons.

This approach also allows other studies that have additional research questions (e.g. about the impact of the patients' illness on the family) to be added after the core questionnaire and diagnosis-specific module. This will allow clinicians greater flexibility to tailor the system to their requirements at the same time as maintaining standardisation for cross-study comparisons.

The EORTC QLQ-OES24 and the EORTC QLQ-C30 will now be tested in an international field study (Phase IV), to ensure that it is an appropiate and psychometrically tested instrument to assess QOL of patients with oesophageal cancer in clinical trials.

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