International Cross-Cultural Field Validation of an EORTC Questionnaire Module for patients who may be experiencing radiation proctitis

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BACKGROUND

Proctitis is an unpleasant recurrent clinical syndrome that is manifest by bouts of the following symptoms: anorectal pain, profuse rectal bleeding or blood clots, explosive bowel urgency, frequent diarrhoea, mucous discharge, faecal and/or mucous incontinence [1, 2]. Increasing use of radiation therapy in pelvic malignancy has led to an increase in the incidence of acute and chronic radiation proctitis, with the most common presenting complaint being rectal bleeding [3-7]. Approximately 85% of patients develop symptoms within the first two years after treatment [3]. These symptoms may persist in some patients and therefore have profound social and psychological consequences for the patient and their family [8, 9].

The incidence of radiation proctitis in retrospective studies of varying sample size, radiation doses and types of pelvic malignancy treated, ranges between two percent and 20% [2, 3, 10]. However, the true incidence of radiation proctitis is likely to be underestimated because most reports rely on medical practitioner based evaluation of symptoms, often utilising toxicity scales which focus on rectal bleeding and do not include assessment of urgency or defaecation and or mucous/faecal incontinence. It is estimated that approximately 5% of patients develop chronic complications including fistulae, stricture and disabling faecal incontinence [10].

The move to conformal radiation techniques and intensity modulated radiotherapy has helped to reduce toxicity of pelvic treatment [11]. However, more recently, there has been an increase in the range of indications for pelvic radiation (e.g. use of neo-adjuvant bowel radiotherapy and post-prostatectomy radiotherapy) [12] and there has also been a trend towards dose escalation studies [13]. Given that the diagnosis of radiation proctitis has traditionally been made reluctantly, there is a risk that radiation proctitis will become a bigger issue for patients, particularly if it continues to be unrecognised and managed in the future. Prospective trials are needed to establish the true incidence of the condition, the effect it has on patients' quality of life and determine the best forms of treatment. These should include valid QoL scales to reliably assess the effectiveness of treatment in patients incapacitated by the condition [14].

To date, there is only one questionnaire developed to measure the quality of life of patients with radiation proctitis [8]. However, this questionnaire did not cover all issues related to proctitis and employed focus groups for generation and coverage of items. There are also EORTC QOL modules that have been developed for cervical cancer (CX24) and prostate cancer (PR25). However, although these modules are useful for identifying disease-specific issues, they fail to adequately cover the problems associated with radiation proctitis.

RESEARCH TO DATE

The research team has already pre-tested the module in Australia (n=28), Norway (n=15), Germany (n= 15) and France (n=11). Table 1 summarises the participants in each country. ▶

Table 1: Comparison between Australian and European data

Patient characteristics	Australia	Norway	Germany	France
Number of patients	28	15	15	11
Mean age in years (SD)	72.03 (8.85)	66.71 (8.957)	69.67 (6.894)	64 (8.246)
Range in years	58-87	48-79	56-79	49-79
Percent Male	78.6%	69%	100%	91%
Diagnosis				
Prostate	18	8	14	8
Bladder	3			
Rectal cancer	2	5		2
Anal Canal	3	1	1	
Endometrial Cancer				1
Hodgkin's Lymphoma	1			
Non-Hodgkin's Lymphoma	1	1		
Currently on treatment	13	15	15	2

From left to right: Dickon Hayne, Georgia Halkett, Nigel Spry, Samar Aoun

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Individual items in the module were modified slightly following analysis of the data collected in Australia and Europe. Two additional items were also added to the questionnaire to address urgency experienced by patients and their ability to completely empty their bowels. Please refer to our published article to view the results of the data collected in Australia [15]. A copy of the revised questionnaire can be obtained from the EORTC or the authors.

The questionnaire is now currently being tested in Italy.

LAUNCHING OF PHASE IV OF PROJECT IN 2009

We have funding to undertake this project and plan for accrual to commence in 2009. The primary objective of Phase IV of the study will be to test the scale structure, reliability and validity and cross-cultural applicability of the proctitis module to be used alone or together with the EORTC Quality of Life Questionnaire (EORTC QLQ-C30) in patients who are currently receiving radiation therapy to their pelvic region and likely to be experiencing acute radiation proctitis.

CROSS-CULTURAL SAMPLING

Patients will be recruited from collaborating hospitals in Australia, Norway, Germany, France and Italy. This will enable the testing of the questionnaire in Anglo-Saxon countries, Northern Europe and Southern Europe. This sample will enable the researchers to increase the generalisibility of the findings and show that the proctitis module is a reliable and valid instrument that can be used in the countries where it is tested.

ELIGIBILITY CRITERIA

We aim to recruit patients who have received a curative dose of radiation therapy to their pelvic region (greater than 50 Gy). This will include tumours located in the following sites: prostate, cervix and rectum.

Participants will be eligible for the study if:

1. They have a tumour located in their pelvis (e.g. prostate, cervix, rectum, bladder, anal canal, endrometrium)
2. They are receiving a radical course of pelvic irradiation (greater than 50 Gy)
3. Are able to converse freely in the language that the questionnaire is written.

Participants will be ineligible for the study if:

1. They have previously received radiation therapy,
2. The radiation dose prescribed is less than 50 Gy
3. They are participating in other Quality of Life trials.

TRIAL DESIGN

This is a cross-sectional longitudinal descriptive study, which collects Quality of Life data alongside socio-demographic and clinical background data at three time points during the patients' radiation therapy treatment. The following time points will be used: baseline (during first week of treatment); completion of treatment; and three months post completion of treatment. Administration of the questionnaire at these time points will facilitate evaluation of how the patients' experiences of acute proctitis change as they proceed through treatment. Socio-demographic details collected will include age, geographical location, education and clinical background data will include diagnosis, tumour site and radiation dose prescribed. Patients will be stratified by treating centre and tumour site.

Patients who participate in the study will be asked to complete a demographics questionnaire, the EORTC QLQ-C30 and the proctitis module. Patients will be asked to complete the first questionnaire when they are seeing their clinician during a routine visit. On subsequent occasions the questionnaire will be either provided when they present for treatment or alternatively posted to them with reply paid envelopes so that patients can post these questionnaires back to them.

The clinicians involved in treating these patients and identifying them for the study will be asked to complete the EORTC/RTOG classification system for each patient at each time point.

SAMPLE SIZE REQUIREMENTS

We will initially be aiming for a sample size of at least 270 patients to enable us to evaluate the scale structure of the proctitis module.

DATA ANALYSIS

Descriptive statistics will be used to describe the sociodemographic and clinical data of participants. The questionnaire will then be assessed for both reliability and validity.

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COLLABORATORS ARE WELCOME, PLEASE CONSIDER PARTICIPATING

If you are interested in using this proctitis module, we would like to invite you to participate in the Phase IV testing of this module.
We also intend to conduct a subsequent study involving patients who are suffering with chronic proctitis.

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