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CLINICAL INVESTIGATION **Quality of Life**

DEVELOPMENT OF A EUROPEAN ORGANIZATION FOR RESEARCH AND TREATMENT OF CANCER MODULE TO ASSESS THE QUALITY OF LIFE OF PATIENTS WITH PROCTITIS AFTER PELVIC RADIOTHERAPY FOR MALIGNANCY

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Purpose: To describe the development of a proctitis-specific quality-of-life module to supplement the European Organization for Research and Treatment of Cancer Quality of Life Questionnaire (EORTC QLQ-C30).
Methods and Materials: The module was developed according to EORTC guidelines, which consisted of an extensive literature review to identify previously described issues and interviews conducted with seven health professionals and 10 patients to rationalize the item list for construction into a provisional module. The module developed was then pretested with 28 patients and five health professionals.
Results: The final module contains 21-items that are suitable to obtain information about the patients' quality of life after high-dose pelvic irradiation. The questionnaire has now been translated into four languages and commenced field testing in late 2007.
Conclusions: The EORTC QLQ-C30, supplemented by EORTC QLQ-PRT21, will enable health professionals to more accurately monitor the side effects that patients experience after pelvic irradiation. **© 2008 Elsevier Inc.**

Radiotherapy, proctitis, quality of life, pelvic cancer, rectal bleeding, treatment side effects.

INTRODUCTION

Radiotherapy is commonly used to treat cancers in the pelvic region. Radiation proctitis, one of the side effects experienced by patients after receiving radical doses of pelvic irradiation (50–70 Gy), is an unpleasant recurrent clinical syndrome characterized by bouts of anorectal pain, profuse rectal bleeding or blood clots, explosive bowel urgency, frequent diarrhea, profuse mucous discharge, and fecal and/or mucous incontinence (1, 2). The most common presenting complaint is adverse rectal bleeding (3–7). Approximately 85% of patients who experience radiation proctitis develop symptoms within the first 2 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 reported incidence of chronic radiation proctitis ranges between 2% and 20% in retrospective studies of varying sample size, radiation doses, and types of pelvic malignancy treated (2, 3). However, the true incidence of radiation proctitis is likely to be underestimated because most reports rely on medical practitioner–based evaluation of symptoms, often utilizing toxicity scales that focus on rectal bleeding and do not include assessment of urgency or defecation and/or mucous/fecal incontinence. The move to conformal radiation techniques and intensity-modulated radiotherapy has helped to reduce toxicity of pelvic treatment (10). However, more recently there has been an increase in the range of indications for pelvic radiation (e.g., use of neoadjuvant bowel radiotherapy and postprostatectomy radiotherapy) (11), and there has also been a trend toward dose-escalation studies (12). 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 unrecognized and managed in the future. Prospective

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trials are needed to establish the true incidence of the condition and the effect it has on patients' quality of life and to 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 (13).

Quality-of-life instruments provide a reliable and valid method of assessing the impact of treatment on patients' lives and evaluating topical, medical, nutritional, and surgical options (14). Recent research by Olopade *et al.* (15) reported that the Vaizey incontinence questionnaire and a modified inflammatory bowel disease questionnaire can be used to assess patients' gastrointestinal chronic toxicity and disability experienced after pelvic radiotherapy. Although the combined questionnaires ask patients about side effects after pelvic irradiation they do not focus on determining the severity of radiation proctitis and how this is impacting on the patients' quality of life. To date, there has been only one questionnaire developed to measure the quality of life of patients with radiation proctitis (8). However, this questionnaire does not cover all issues related to proctitis or allow easy comparison with other measures of core quality of life issues, because it is a stand-alone instrument. Therefore, there is a need to develop a questionnaire that can be used to adequately and reliably measure the severity of proctitis and other side effects after pelvic irradiation.

The European Organization for Research and Treatment of Cancer (EORTC) has developed a standard 30-item questionnaire, the EORTC QLQ-C30, which can be used to assess the quality of life of cancer patients. This questionnaire includes a total of nine multi-item scales: five functional scales (physical, role, cognitive, emotional, and social); three symptom scales (fatigue, pain, and nausea and vomiting); and a global health and quality-of-life scale (16). It is designed to be used in conjunction with specific modules that focus on the patient's diagnosis and symptoms. Quality-of-life modules have previously been developed for cervical cancer (CX24) and prostate cancer (PR25). The cervical cancer module has already been validated, and the module for prostate cancer is in its final phase of development and is already being used to assess quality of life in some prostate studies (17, 18). Although these modules are useful for identifying disease-specific issues, they fail to adequately cover the problems associated with radiation proctitis. Currently there is no specific questionnaire that comprehensively assesses the quality of life concerns of patients who are experiencing proctitis. The aim of this study was to develop and test a proctitis-specific quality-of-life module that can be used in conjunction with the EORTC QLQ-C30 quality-of-life questionnaire. The proposed proctitis module has the potential to enable health professionals to identify issues that can easily be overlooked in a busy clinic situation and act as a measure to record change and provide a robust outcome measure in this neglected area.

METHODS AND MATERIALS

Ethics approval was gained from Edith Cowan University and the hospitals involved. All participants were provided with a relevant information sheet, and written informed consent was obtained.

Guidelines for the development of EORTC modules (19) were followed. However, the module development process was interrupted because of resource constraints, during which time the EORTC substantially changed the module development process to improve the robustness of the procedure (20). Nonetheless, the EORTC Quality of Life Executive Committee guided our latter development of the questionnaire and enabled us to incorporate our earlier work into the phases that are recommended for module development. The EORTC guidelines on module development recommend that the following phases be used: Phase 1: generation of quality-of-life issues; Phase 2: construction of items for the provisional module; Phase 3: pretesting; and Phase 4: field testing (20).

Phase 1a: generation of quality-of-life issues

A list of relevant quality-of-life issues was developed by (*1*) conducting a literature search, (*2*) interviewing health professionals, and (*3*) conducting patient interviews as recommended by the EORTC guidelines for module development (20).

The literature was searched for quality-of-life issues after pelvic irradiation and for existing questionnaires on proctitis using two databases: MEDLINE from January 1966 to June 2000 and PSYCHINFO from January 1992 to June 2000. The following key words were used: rectal bleeding, proctitis, quality of life, radiotherapy side effects, pelvic irradiation, and bowel dysfunction. A provisional list of items was developed.

Phase 1b: interviews with health professionals and patients

The provisional list and core instrument were presented at the ''Radiation Induced Rectal Injury Scientific Workshop'' held in Port Douglas, Queensland, Australia, in June 2000, and participants were invited to provide feedback on the appropriateness of content and breadth of coverage. Health professionals were also asked to identify any other issues that they thought should be included and which items they thought should be rephrased or removed. Finally, health professionals were invited to indicate the five most important items they believed should be included.

Radiation oncologists in Western Australia and South Australia recruited patients. Patients were eligible if they had been experiencing proctitis symptoms for more than 1 year. The provisional list of issues and the QLQ-C30 were discussed with each patient on an individual basis. Patients were asked whether they understood the questions, how relevant the issues were to them, whether they felt any additional issues should be included, and which five symptoms were most relevant to them and therefore should be included in the questionnaire

Phase 2: construction of items for the provisional module

Phase 2 began in 2005 and followed the 2002 EORTC revised guidelines for module development (20). First, an additional literature search was conducted to ensure that no new articles on radiation proctitis measurement had been published between June 2000 and June 2005. Next the EORTC QLG Item Bank (21) was consulted to determine whether any of the items already existed. Finally, new items were constructed to be consistent with the Item Bank, and a revised questionnaire was developed. Questions were designed so that they were compatible with the response categories of the EORTC QLQ-C30, relevant to patients within a 1-week time frame, not too confronting or upsetting to patients, requiring patients to consider experiences of stress rather than just change in behavior, and finally, worded positively when referring to patients' experiences of receiving support.