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SCIENCE DIRECT

Gynecologic Oncology 97 (2005) 568–575

Gynecologic Oncology

www.elsevier.com/locate/ygyno

The functional assessment of cancer-vulvar: Reliability and validity

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Received 19 November 2004
Available online 23 March 2005

Abstract

Objectives. To assess the reliability and validity of the Functional Assessment of Cancer Therapy-Vulvar (FACT-V).

Methods. Seventy-seven patients treated between January 1996 and January 2001 for cancer of the vulva completed the FACT-V, the Eastern Cooperative Oncology Group Performance Status Rating (ECOG-PSR) and the Hospital Anxiety and Depression Scale (HADS) once, 20 consecutive patients treated between February 2001 and October 2001 completed the questionnaires twice, once before surgery and at 2 months follow-up. The FACT-V scores were compared by patients' performance status, FIGO stage, recurrence, and age, and correlated to the HADS scores. Changes in the FACT-V from baseline to 2 months follow-up were evaluated to establish FACT-V's responsiveness to change.

Results. The FACT-V's internal consistency was adequate (Chronbach's alpha range, 0.75 to 0.92). Patients with lower performance status, higher FIGO-stage or recurrent disease received lower FACT-V scores, indicating discriminant validity. The correlation between the FACT-V and the HADS were in the expected direction, indicating convergent and divergent validity. From pre- to post-surgery, scores in nine out of fifteen items of the vulvar cancer-specific subscale improved, while those of five items declined, indicating sensitivity of the vulvar cancer specific items to changes in patients' well-being.

Conclusions. The newly developed FACT-V provides a reliable and valid assessment of the quality of life of women with vulvar cancer. It can be used as a short measure of quality of life within research studies, and to facilitate communication about quality of life issues in clinical practice.
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Keywords: Vulvar cancer; Quality of life questionnaire

Introduction

About 3900 women are diagnosed with vulvar cancer each year in the United States [1]. It is a relatively uncommon cancer, with only 3 to 5% of all gynecologic malignancies originating from the vulva [2]. Surgery and radiotherapy are the standard treatments and while effective, the treatment for vulvar cancer still imposes disfigurement and mutilation to the external genitals of patients likely to be associated with significant impairment of patients' quality of life (QOL). During the last 15 to 20 years, more conservative surgical techniques were developed and individualized patient management is desirable in order to retain patients' QOL without diminishing survival [3].

At diagnosis, patients with gynecologic cancer report high levels of anxiety, depression and social isolation [4]. Once treated, a significant proportion of gynecologic cancer patients experience fatigue, emotional distress, reduced social functioning, bladder and vaginal dysfunction [5]. Reductions in global QOL and emotional functioning were observed during and up to 24 months after treatment [6,7]. However, only few or no patients with vulvar cancer were included in studies investigating QOL in gynecologic malignancies [4,7–9], and only a handful of studies

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0090-8258/$ - see front matter © 2005 Elsevier Inc. All rights reserved.
doi:10.1016/j.ygyno.2005.01.047

reported on QOL or psychosocial well-being associated with vulvar cancer so far [10–14]. The main focus of these studies was on sexual functioning, and patients with vulvar cancer frequently experience significant reductions in this domain of QOL. After treatment, patients may experience vulva pain or numbness, and lymphedema of the legs [15], which may diminish other aspects of their functioning and QOL.

One of the most widely utilized QOL questionnaires is the Functional Assessment For Cancer General (FACT-G), developed by Cella et al. [16]. The FACT-G can be accompanied by cancer-site- and symptom-specific subscales such as those developed for breast cancer [17], ovarian cancer [18] and anemia [19].

The purpose of the current study was to perform the initial psychometric evaluation of a vulvar cancer subscale (VCS) measuring concerns of patients with cancer of the vulva and to establish its reliability and validity in combination with the FACT-G.

Materials and methods

Item generation

We reported on this process in detail elsewhere [15]. Briefly, during semi-structured interviews, 15 patients with a mean age of 68.8 years (range 52 to 85 years) and a mean time since surgery of 13.7 months (range 2 weeks to 36 months) were asked to describe their experience with vulvar cancer and the effect of illness and treatment on their QOL. All patients received treatment at the Queensland Center of Gynecological Cancer in Brisbane, Australia. These semi-structured interviews were structured according to guidelines provided by the Centre on Outcomes, Research and Education (CORE) [19]. Five experts in the treatment of women with vulvar cancer were also interviewed. Items were collated and redundant items and items idiosyncratic to individual patients were excluded. This process yielded the first version of the VCS (15 items), which together with the FACT-G comprises the FACT-V.

Participants

Patients for the present study came from two sources: group one consisted of patients who had surgery for vulvar cancer at the Queensland Center of Gynecological Cancer between January 1996 and January 2001. One hundred and forty-five patients were identified and received the assessment package by mail in March 2001. Thirteen patients had left the address, 3 patients had died, one patient refused participation, no response was received from 51 patients and 77 (59.7%) patients agreed to participate and returned completed questionnaires. No significant difference with respect to age ($P = 0.10$), FIGO Stage ($P = 0.59$), or treatment ($P = 0.11$) between responding and non-responding patients was observed.

Group two (longitudinal sample) consisted of 20 consecutive patients who had surgery for vulvar cancer between February 2001 and October 2001. These patients completed the assessment package twice, once before surgery and again 2 months thereafter. The second assessment of these 20 patients was considered eligible for the cross-sectional analysis resulting in a sample of 97 patients for this analysis.

Patient characteristics

For patients with squamous cell carcinoma (SCC), tumor stage was recorded using the 1988 International Federation of Gynecology and Obstetrics (FIGO) Stage classification. Patient's treatment and time since diagnosis was also summarized. All information was extracted from the hospital charts. Eighty-six patients (88.6%) had a radical local excision/radical vulvectomy or a wide local excision as primary treatment. Of these, 63 patients (64.9%) had a groin node dissection. The groin node dissection was bilateral except in those patients with stage 1 disease who had unilateral lesions. Postoperative radiotherapy to the groins and the pelvis was given to patients with positive groin nodes and local radiotherapy to patients with close or positive margins at the vulva ($n = 7$). Primary chemo-radiation ($n = 3$) or primary radiotherapy ($n = 1$) was given to patients with unresectable disease/or unfit for surgery. Detailed patients characteristics are given in Table 1.

Assessment package

The participating patients completed the FACT-G and the newly developed VCS, the Eastern Cooperative Oncology Group Performance Status Rating (ECOG-PSR) and the Hospital Anxiety and Depression Scale (HADS) [20]. The FACT-G is a self-report scale and allows patients to rate their current physical, functional, social/family and emotional well-being on 5-point Likert scales ranging from "not at all" to "very much" [16]. The FACT-G has well established psychometric properties and is sensitive to changes in cancer patients' well-being. The ECOG-PSR scale allows patients' to rate their subjective performance status on a 5-point scale (0 = no symptoms, 1 = some symptoms, but do not require bedrest during the waking day, 2 = require bedrest for less than 50% of the waking day, 3 = require bedrest for more than 50% of the waking day, 4 = unable to get out of bed). The HADS is a widely used self-assessment scale to assess emotional distress, specifically anxiety (HADS-A, 7 items) and depression (HADS-D, 7 items) on a scale ranging from 0 (no problem) to 3 (maximum distress). Patients are grouped into non-cases (scores up to 10) or cases (scores 11 or above). [20] The HADS is generally well accepted by patients and various studies reported good reliability and validity [21].

Statistical analysis

Means, SDs and percentages of extreme response were calculated to describe the item characteristics of the VCS.

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