OBJECTIVE:

The aim of the study was to describe the (a) symptom experience of women with vulvar intraepithelial neoplasia and vulvar cancer (vulvar neoplasia) during the first week after hospital discharge, and (b) associations between age, type of disease, stage of disease, the extent of surgical treatment and symptom experience.

METHODS:

This cross-sectional study was conducted in eight hospitals in Germany and Switzerland (Clinical Trial ID: NCT01300663). Symptom experience after surgical treatment in women with vulvar neoplasia was measured with our newly developed WOMAN-PRO instrument. Outpatients (n=65) rated 31 items. We used descriptive statistics and regression analysis.

RESULTS:

The average number of symptoms reported per patient was 20.2 (SD 5.77) with a range of 5 to 31 symptoms. The three most prevalent wound-related symptoms were ‘swelling’ (n=56), ‘drainage’ (n=54) and ‘pain’ (n=52). The three most prevalent difficulties in daily life were ‘sitting’ (n=63), ‘wearing clothes’ (n=56) and ‘carrying out my daily activities’ (n=51). ‘Tiredness’ (n=62), ‘insecurity’ (n=54) and ‘feeling that my body has changed’ (n=50) were the three most prevalent psychosocial symptoms/issues. The most distressing symptoms were ‘sitting’ (Mean 2.03, SD 0.88), ‘open spot (e.g. opening of skin or suture)’ (Mean 1.91, SD 0.93), and ‘carrying out my daily activities’ (Mean 1.86, SD 0.87), which were on average reported as ‘quite a bit’ distressing. Negative associations were found between psychosocial symptom experience and age.

CONCLUSIONS:

WOMAN-PRO data showed a high symptom prevalence and distress, call for a comprehensive symptom assessment, and may allow identification of relevant areas in symptom management.
Development of a postsurgical patient-reported outcome instrument for women with vulvar neoplasia.

Senn B¹, Mueller MD, Hasenburg A, Blankenstein T, Kammermann B, Hartmann A, Donovan H, Eicher M, Spirig R, Engberg S.


Abstract

PURPOSE/OBJECTIVES: To (a) develop the Women With Vulvar Neoplasia-Patient-Reported Outcome (WOMAN-PRO) instrument as a measure of women's post-vulvar surgery symptom experience and informational needs, (b) examine its content validity, (c) describe modifications based on pilot testing, and (d) examine the content validity of the revised instrument.

DESIGN: Mixed-methods research project.

SETTING: One Swiss and two German university hospitals.

SAMPLE: 10 patients and 6 clinicians participated in the pilot test.

METHODS: The instrument was developed based on literature searches, clinician feedback, and patient interviews. Thirty-seven items were first pilot tested by patients and clinicians. The revised 36 items were pilot tested by patients. The content validity index (CVI) for each item and the entire instrument was calculated.

MAIN RESEARCH VARIABLES: Symptom experience and informational needs of patients with vulvar neoplasia.

FINDINGS: The initial pilot test showed excellent scale CVI based on feedback from patients (CVI = 0.98) and clinicians (CVI = 0.92). After revising six items based on low individual CVIs and participant comments, the revised WOMAN-PRO showed excellent item and scale content validity (CVI = 1).

CONCLUSIONS: The newly developed WOMAN-PRO instrument can guide patients and clinicians in assessing symptoms, informational needs, and related distress.

IMPLICATIONS FOR NURSING: Use of the WOMAN-PRO instrument in clinical practice can offer patients guidance in self-assessment and early recognition of symptoms. The instrument also can provide clinicians with systematic information about key symptoms from a patient perspective, as well as women's unmet informational needs. If the results of additional psychometric testing are promising, the WOMAN-PRO tool may provide an outcome measure for clinical trials.
THE IMPACT OF THE SELF-MANAGEMENT INTERVENTION ‘WOMAN-PRO II PROGRAM’ ON PATIENTS WITH VULVAR NEOPLASIA TO MINIMIZE POST-SURGICAL SYMPTOM PREVALENCE: A MIXED METHODS PROJECT

Abstract

Background
In vulvar neoplasia, even minor surgical interventions cause multiple symptoms, symptom related distress and complications, which have an impact on a woman’s quality of life and contribute to high health care costs. For the majority of the patients, symptom and distress reduction can be obtained if adequate treatment is provided. However, symptoms remain often undertreated in patients with cancer. Patient self-management skills are influenced by patients’ knowledge, activities and attitude to manage symptoms. This study aims to test possible differences between the impact of standard care (intervention I) and the WOMAN-PRO II program (intervention II) on symptom prevalence in women with vulvar neoplasia after surgical treatment across time.

Methods
In a sequential explanatory mixed-methods project, a randomized phase II study will be followed by a qualitative sub-study. Ninety patients with vulvar neoplasia treated surgically will participate in the randomized trial in four Swiss hospitals, one Austrian and one Australian hospital. This international multicenter approach enables a higher generalizability of the study results. After stratification by precancer /cancer, women will be randomly assigned (1:2 ratio) to intervention I (n=30) and intervention II (n=60). The primary outcome of this study is symptom prevalence. Secondary outcomes will be collected for explorative reasons and include symptom distress, uncertainty, quality of life, social support, resilience, quality of care, post-surgical complications, and functional status. Cost evaluation, process outcomes, socio-demographic and medical data will also be assessed. Quantitative data for intervention I and intervention II will be collected at the counseling points of time and analyzed by using mixed linear regression analysis. Twenty interviews will be conducted with women of the WOMAN-PRO II program group (ten women from Switzerland/Austria, ten women from Australia). A focus-group interview will be conducted with twelve gynecology-

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oncology nurse specialists in order to better understand to which degree the interventions meet individual needs as well as to identify remaining barriers and enablers for the implementation of symptom self-management. Qualitative data will be analyzed by using thematic analysis according to Braun and Clarke (2006) and a critical hermeneutic reflection according to Diekelman et al. (1989).

**Discussion**
This study will (1) evaluate the impact of the WOMAN-PRO II program on symptom prevalence, patient-reported outcomes and clinical parameters, and (2) inform the design of a possible phase III study on the clinical efficacy of the program.

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Between anxiety and hope: the experiences of women with vulval intraepithelial neoplasia during their illness trajectory - a qualitative approach.

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Abstract

The vulvar intraepithelial neoplasia (VIN) is a rare chronic skin condition that may progress to an invasive carcinoma of the vulva. Major issues affecting women's health were occurring symptoms, negative influences on sexuality, uncertainty concerning the illness progression and changes in the body image. Despite this, there is little known about the lived experiences of the illness trajectory. Therefore, the aim of this study was to describe the experiences of women with VIN during the illness trajectory. In a secondary data analysis of the foregoing qualitative study we analysed eight narrative interviews with women with VIN by using thematic analysis in combination with critical hermeneutics. Central for these women during their course of illness was a sense of "Hope and Fear". This constitutive pattern reflects the fear of recurrence but also the trust in healing. The eight narratives showed women's experiences during their course of illness occurred in five phases: "there is something unknown"; "one knows, what IT is"; "IT is treated and should heal"; "IT has effects on daily life"; "meanwhile it works". Women's experiences were particularly influenced by the feeling of "embarrassment" and by "dealing with professionals". Current care seems to lack adequate support for women with VIN to manage these phases. We suggest, based on our study and the international literature, that new models of counselling and providing information need to be developed and evaluated.