Gynecologic Oncology xxx (2017) xxx–xxx

Contents lists available at ScienceDirect

Gynecologic Oncology

journal homepage: www.elsevier.com/locate/ygyno

# The impact of written information and counseling (WOMAN-PRO II Program) on symptom outcomes in women with vulvar neoplasia: A multicenter randomized controlled phase II study

Silvia Raphaelis [a,*], Hanna Mayer [a], Stefan Ott [b], Michael D. Mueller [c], Enikö Steiner [d], Elmar Joura [e], Beate Senn [f,g]

[a] Department of Nursing Science, University of Vienna, Alser Strasse 23, 1080 Vienna, Austria
[b] Lecturer for Business Mathematics and Statistics, University of Applied Sciences FHS St. Gallen, Rosenbergstrasse 59, 9001 St. Gallen, Switzerland
[c] Department of Obstetrics and Gynecology, Inselspital, University Hospital Bern, Effingerstrasse 102, 3010 Berne, Switzerland
[d] Department of Obstetrics and Gynecology, Vienna General University Hospital, Währinger Gürtel 18-20, 1090 Vienna, Austria
[e] Department of Obstetrics and Gynecology and Comprehensive Cancer Center, Medical University of Vienna, Spitalgasse 23, 1090 Vienna, Austria
[f] Institute for Applied Nursing Sciences IPW-FHS, University of Applied Sciences FHS St. Gallen, Rosenbergstrasse 59, 9001 St. Gallen, Switzerland
[g] Sydney Nursing School, The University of Sydney, Mallett Street 88, 2050 Camperdown, NSW, Australia

## HIGHLIGHTS

- This is the first study testing support programs in women with vulvar neoplasia.
- Symptom prevalence decreased in women with counseling by a clinical relevant degree.
- The results justify testing counseling in a phase III trial.

## ARTICLE INFO

*Article history:*
Received 25 February 2017
Received in revised form 28 April 2017
Accepted 30 April 2017
Available online xxxx

*Keywords:*
Vulvar neoplasms
Randomized controlled trials
Symptoms
Oncology nursing
Advanced practice nursing
Patient education as topic

## ABSTRACT

*Objective.* To determine whether written information and/or counseling based on the WOMAN-PRO II Program decreases symptom prevalence in women with vulvar neoplasia by a clinically relevant degree, and to explore the differences between the 2 interventions in symptom prevalence, symptom distress prevalence, and symptom experience.

*Methods.* A multicenter randomized controlled parallel-group phase II trial with 2 interventions provided to patients after the initial diagnosis was performed in Austria and Switzerland. Women randomized to written information received a predefined set of leaflets concerning wound care and available healthcare services. Women allocated to counseling were additionally provided with 5 consultations by an Advanced Practice Nurse (APN) between the initial diagnosis and 6 months post-surgery that focused on symptom management, utilization of healthcare services, and health-related decision-making. Symptom outcomes were simultaneously measured 5 times to the counseling time points.

*Results.* A total of 49 women with vulvar neoplasia participated in the study. Symptom prevalence decreased in women with counseling by a clinically relevant degree, but not in women with written information. Sporadically, significant differences between the 2 interventions could be observed in individual items, but not in the total scales or subscales of the symptom outcomes.

*Conclusions.* The results indicate that counseling may reduce symptom prevalence in women with vulvar neoplasia by a clinically relevant extent. The observed group differences between the 2 interventions slightly favor counseling over written information. The results justify testing the benefit of counseling thoroughly in a comparative phase III trial.



## 1. Introduction

The term vulvar neoplasia includes high-grade squamous intraepithelial lesions of the vulva (vulvar HSIL) as a precancerous

* Corresponding author.
*E-mail address:* silvia.mona.raphaelis@univie.ac.at (S. Raphaelis).

http://dx.doi.org/10.1016/j.ygyno.2017.04.024
0090-8258/

condition and vulvar cancer as an invasive malignant disease [1,2]. Vulvar neoplasms are rare diseases with a worldwide increase in incidence over the past decades [3–5]. In European countries, the annual incidence of 1 to 7 per 100,000 women [6,7] is increasing in women younger than 60 years old [4,8,9] and has a high recurrence rate [10,11].

Vulvar neoplasms are primarily treated using surgical procedures and fundamental improvements have been achieved in the last decades with minimally invasive surgery [12,13]. However, complete excision of lesions may require extensive resections and sometimes excision of the clitoris hood [12,14] and are experienced by affected women as disfiguring interventions [15]. Moreover, even minimally invasive interventions may cause numerous biopsychosocial symptoms [16], as was recently shown in a cross-sectional study in which 65 women with vulvar neoplasia had on average 20 wound-related symptoms, psychosocial symptoms, or difficulties in daily life 1 week post-surgery [17]. In addition, minimally invasive surgery leads to short hospitalizations; thus, women need to assess and treat their symptoms on their own.

Because of high symptom prevalence and necessary self-care after discharge, symptoms represent pivotal problems that should be addressed in clinical practice. However, a review of qualitative studies indicates that affected women see themselves as insufficiently informed and counselled about potential symptoms, the meaning of the symptoms, and self-care interventions, such as vulvar self-examination and alarm signs that require immediate professional support [15,18–20]. Moreover, affected women have difficulties learning more about their symptoms in a proactive and personally initiated manner [19] and do not completely understand that these symptoms are treatable [18]. The relevant literature emphasizes the necessity of special evidence-based care [15,19,20], and the women surveyed recommended implementing special consultations with oncology nurses [18]. In summary, this indicates that women with vulvar neoplasia need more support in how to prevent, recognize, and manage their symptoms. However, in this patient group, supporting interventions have yet to be tested.

Concerning the question of which supporting interventions may improve symptom outcomes in women with vulvar neoplasia, research in women with other gynecologic cancers indicates that counseling has the potential to reduce symptom severity [21] and symptom distress [21,22]. Moreover, it appears that information-based interventions show rather short-term [23] and sporadic [24] effects. However, despite the rather unfavorable results concerning written information, there remains uncertainty about its definite benefit. Therefore, a set of written information and a counseling program (WOMAN-PRO II Program) [25] has been developed for women with vulvar neoplasia. The next step is to determine whether the interventions yield a clinically important improvement in a primarily symptom outcome and to initially explore possible intervention differences. Thus, this study aims to:

(1) Examine whether women's symptom prevalence reduces with each intervention by a clinically relevant degree. A mean number of 4 or more decreased symptoms within each intervention measured between 1 week post-surgery and 6 months post-surgery was defined as a clinically important improvement, based on the reported symptom scores of a previous study [17] and clinical expertise representing both established methods for determining clinical relevance [26].
(2) Explore whether written information or counseling is more likely to reduce symptom prevalence, symptom distress prevalence, or symptom experience between 1 week post-surgery and 6 months post-surgery.

## 2. Methods

### 2.1. Study design

This study is part of the mixed-methods project WOMAN-PRO II, consisting of a quantitative study and a qualitative sub-study (clinical trial ID: NCT01986725). The primary outcome of the quantitative study was symptom prevalence. The secondary outcomes were defined as symptom distress, symptom experience, women's informational needs, uncertainty, quality of life, quality of care, economic evaluation, and process outcomes. This paper focuses on the symptom outcomes of the quantitative study. Results of the qualitative sub-study and the other outcomes are currently published [27–29] or will be published elsewhere. For the quantitative study, a multicenter randomized controlled parallel-group phase II design with 2 intervention arms and repeated measures was conducted. Because both interventions were newly developed and scheduled to be tested for the first time, a phase II design was selected. Therefore, it is typical to determine whether a desirable response rate becomes obvious within an intervention and to add a randomization where appropriate to determine potential group differences that will, in turn, inform a strictly comparative phase III trial [30].

### 2.2. Interventions

#### 2.2.1. Written information (intervention I)

This intervention consisted of standard care and written information. Standard care refers to patient care during hospitalization and follow-up according to local standards and existing guidelines [31]. Written information developed by a group of clinical experts and administered to women in the early treatment phase included a set of leaflets concerning wound care after discharge and healthcare services available in the hospital and the community (for example, a psycho-oncologist or smoking-cessation counseling).

#### 2.2.2. Counseling based on the WOMAN-PRO II Program (intervention II)

This intervention was in addition to standard care and written information. Counseling was delivered 5 times for 10 to 50 min after initial diagnosis, 1 week post-surgery, 2 weeks after discharge, 3 months post-surgery, and 6 months post-surgery. The counseling was a follow-up appointment to physician appointments and was conducted by an APN or a nurse with an equivalent education (for example, a nurse consultant with extended expertise in clinical practice). The structure and content of the intervention was based on an evidence-based counseling guideline [25] that consisted of recommendations for information materials (for example, leaflets concerning wound care, diagrams of the vulva), utilization of healthcare services, health-related decision-making, symptom self-assessment with the WOMAN-PRO Symptom Diary [17], simple interventions for symptom relief, coordination of care, and multi-professional cooperation. Based on the women's entries in their symptom diary, counseling focused on a maximum of 3 to 5 symptoms. These symptoms were selected by the women and were supplemented by the APN where necessary, based on clinical expertise. For example, wound-related symptoms were added by the APN to the counseling agenda if the women's entries pointed to inflammatory reactions (for example, pain, redness, swelling, and warmth). Although the intervention had a clear structure and content as described in the guideline, it was tailored to women's needs in terms of mode of delivery (face-to-face and/or phone), intensity, involvement of partners or family members, and the materials provided. To guarantee adequate implementation, the APNs attended a 12-hour training program that focused on the recommendations of the counseling guideline [25], the application of various tools such as the WOMAN-PRO Symptom Diary [17], and practical exercises. During the complete study, the APNs had the opportunity to receive supervision on any questions that might have been evoked during the counseling process.

### 2.3. Sample and setting

The sample size calculation was based on the symptom scores observed in a previous study [17] and yielded a required total sample of 90 women with a power of 80% by a randomization ratio of 1:2 (written

Please cite this article as: S. Raphaelis, et al., The impact of written information and counseling (WOMAN-PRO II Program) on symptom outcomes in women with vulvar neoplasia: A mult..., Gynecol Oncol (2017), http://dx.doi.org/10.1016/j.ygyno.2017.04.024