CREATING AND VALIDATING A PATIENT-REPORTED OUTCOME INSTRUMENT FOR WOMEN WITH VULVAR NEOPLASIA AFTER SURGICAL TREATMENT – A MIXED-METHODS PROJECT

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SUMMARY

In vulvar neoplasia, substantial improvements in therapy and care have been attained during the last decades.[1] Nevertheless even minor surgical interventions cause multiple symptoms and side effects that impact women's quality of life.[2] The term 'vulvar neoplasia' includes vulvar intraepithelial neoplasia (VIN) and vulvar cancer.[3, 4] Vulvar neoplasia is a rare condition with increasing incidence rates in the last 3 decades in Europe and the US.[5, 6] The incidence of vulvar neoplasia in Germany and Switzerland is about 2 to 7 per 100'000 women per year.[7, 8] Surgical treatment is the standard therapy for women with vulvar neoplasia.[9, 10] The prevalence of surgery related complications, such as wound infections, is estimated to be between 5% to 45%.[2, 11] Surgery-related complications are one type of adverse event and a substantial number of these complications are preventable.[12, 13] Surgery-related complications in women with vulvar neoplasia result in a variety of physical and psychosocial problems,[2, 14] and contribute to high health care costs.[15, 16] Modified surgical procedures such as the replacement of radical vulvectomy by less wide local excision often mean shorter hospitalizations.[17] Furthermore oncology care in general is shifting to the outpatient setting.[17] Thus, after discharge women with vulvar neoplasia and surgical treatment are confronted with the need to assess, evaluate and manage surgery-related symptoms without the support of the inpatient care team.

Symptoms are defined as patient's perceived changes in biopsychosocial functioning, sensations, or cognition,[18, 19] e.g. bleeding, shame, and fear. A patient's symptom experience includes 2 common dimensions with symptom occurrence, frequency and severity as the cognitive dimension, and symptom distress as the emotional dimension.[20] Dodd et al.[18] developed a generic symptom management model to understand how patients experience and manage symptoms, to provide health care professionals with direction for selecting clinical interventions, and to inform research. The model provides a framework for understanding the relationship between aspects of symptom experience, symptom management strategies and patient outcomes. In a patient-centred health care approach, this model provides appropriate guidance for treatment and care of patients with vulvar neoplasia. It is crucial to understand symptom experience in order to specify symptom assessment strategies and identify the focus for symptom management.[18]

Symptom assessment should be part of the general screening for adverse symptom events. This can be undertaken by collecting Patient-Reported Outcome (PRO) data.[21] A PRO is any report of the patient's health status that comes directly from the patient, such as his/her symptom experience.[22] The assessment of both objective and subjective data allows for better supportive care.[23]

In clinical practice complications and symptoms after vulvar surgical treatment are an immense challenge for affected women because they are often discharged before their surgical wound has healed. Despite this, for this patient population there is limited research about the prevalence and risk factors for different types of short-term wound complications and about women's experiences during the first 6 months following surgical treatment. Furthermore, no structured symptom assessment instrument is available and there is little guidance for the assessment of symptom experience in women with vulvar neoplasia and surgical treatment. To date, nursing care and research are hampered by effective symptom assessment following vulvar surgical treatment. An effective assessment will allow nurses to better assign management strategies and to be able to evaluate the improvement in assessed symptoms. With the goal of improving care of women with vulvar neoplasia and surgical treatment, this international, multicenter research project aimed to develop a symptom assessment instrument for patients with vulvar neoplasia who have undergone surgical treatment.

To address this aim we used a mixed-methods research approach and pragmatism guided this project.[24] This project consisted of a series of quantitative and qualitative studies with equal weighting of both methods using data of more than 180 women recruited from four Swiss (Zurich, Basel, Berne, St. Gallen) and four German University Hospitals (Berlin, Dusseldorf, Freiburg, Munich) from the years 1997 to 2011. The first study of the research project was a cross-sectional investigation focusing the clinical perspective. With a sequential exploratory two-phase strategy, in studies 2 to 5 we intended to give voice to the patients' experiences by the means of a qualitative approach in the first phase. Their experiences were then systematically analyzed in the quantitative component of the project (the second phase).

First, we conducted a cross-sectional study on the period prevalence and risk factors for postoperative short-term wound complications in vulvar cancer patients in Switzerland. Data were collected retrospectively from medical records from 2007 to 1997 using an investigator-developed data collection instrument to assess risk factors preoperatively and perioperatively, and wound complications that occurred within the first 30 postoperative hospital days. The period prevalence of wound complications was 45.4% (49/108), showing at least 1 of 8 assessed wound complications per patient within the median hospital duration of 11 days. The period prevalences for the wound complication were: 31.5% for dehiscence, 12% for hematoma, 6.5% for necrosis, 5.6% for infections, 4.6% for seroma, 1.9% for lymph cysts, 1.9% for malignant wounds, and 0% for disturbed tissue formation. Two of the 14 risk factors examined, the type surgical therapy (OR, 2.6; 95% confidence

interval [CI], 1.34-5.14) and inguinofemoral lymphadenectomy (OR, 3.0; 95% CI, 1.03-8.76) were significantly associated with short-term wound complications. The results of this retrospective study showed, that the high prevalence of short-term wound complications indicates a need for systematic wound assessment and early risk management, especially after hemivulvectomy, radical vulvectomy, and inguinal lymphadenectomy.[25]

Second, in order to understand the women's perspective, we conducted a qualitative study exploring the symptom experience in 20 women with vulvar precancer or cancer and surgical treatment in one Swiss and two German University Hospitals. Narratives showed eight key themes composing the essence of women's symptom experience: delayed diagnosis, disclosed disease, disturbed woman's self-image, changed vulva care, experienced wound-related symptoms, evoked emotions, affected interpersonal interactions and feared illness progression. The identified themes were consistent across different surgical procedures. The pattern present in all narratives was that women experienced a lack of information with regard to the above interrelated themes and that all of them used strategies to handle their situation, which affected their distress level. The communication, assessment and treatment of symptoms were hampered by the society's and the health system's tendency to overlook these symptoms and leave them in the realm of the unspeakable. We recommend that health care professionals need new strategies to support these women to recognize, assess and evaluate the seriousness of symptoms, and to communicate their symptom experience in order to minimize potentially preventable symptom-related distress.[26]

Third, we focused on the perspective of women with VIN during their illness trajectory by conducting a secondary data analysis of the qualitative study. Eight narratives showed women's experiences during their course of illness occurred in five phases: (1) There is something unknown; (2) One knows, what it is; (3) It is treated and should heal; (4) It has effects on daily life; (5) Meanwhile it works. These phases showed many women (1) had a late or incorrect diagnosis; (2) despite having a diagnosis women did not know what they suffered; (3) experienced a high uncertainty in decision-making during treatment, (4) VIN had an impact on the physical and psychosocial level; and (5) that the women learned over time to deal with their illness. Central for these women during their course of illness was a sense of 'Hope and Fear'. It reflects the fear of recurrence but also the trust in healing. 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 recommend that new models of counseling and providing information need to be developed and evaluated.

Fourth, a new Patient-Reported Outcome instrument for WOMen with vulvAr Neoplasia (WOMAN-PRO) was developed according to the PRO guidelines and based on literature searches, expert feedback (n=9) and patient interviews (n=20). Thirty-seven items were first pilot-tested by patients

(n=6) and experts (n=6). The revised 36 items were pilot-tested by patients (n=4). Participants were recruited from one Swiss and two German University Hospitals. To our knowledge, this is the first PRO measure designed specifically to assess post-vulvar-surgery symptoms, informational needs and related distress after hospital discharge. The revised WOMAN-PRO showed an excellent item and scale Content Validity Index (CVI=1.0) and has the potential to support women in recognizing, assessing, and evaluating the seriousness of post-surgical symptoms and in communicating their symptom experience to health care providers. This can decrease women's uncertainty about symptoms and reassure their decision-making about when to seek health care provider evaluation. It can provide clinical experts with systematic information about key symptoms from a patient perspective, and women's unmet informational needs.

In the fifth part of this research project, we identified the occurrence and distress associated with post-surgery symptoms of women with vulvar neoplasia measured with a Patient-Reported Outcome instrument (WOMAN-PRO). The study was a prospective cross-sectional survey conducted in 8 Hospitals in Switzerland and Germany. Outpatients (n=54) rated the occurrence of each of 31 symptoms, and the degree to which the symptoms distressed them. The average number of symptoms reported per patient was 20 (SD 5.02) with a range of 10 to 31 symptoms on a 0 to 3 scale. The 3 most prevalent wound-related symptoms were 'swelling' (n=46), 'drainage' (n=46) and 'pain' (n=43). The 3 most prevalent difficulties in daily life were 'sitting' (n=52), 'wearing clothes' (n=48) and 'carrying out my daily activities' (n=43). 'Tiredness' (n=51), 'insecurity' (n=44) and 'feeling that my body has changed' (n=42) were the 3 most prevalent psychosocial symptoms. The most distress symptoms were 'sitting' (Mean 1.98, SD 0.90), 'carrying out my daily activities' (Mean 1.79, SD 0.89), and 'open spot (e.g. opening of skin or suture)' (Mean 1.79, SD 0.92), which were on average reported to be 'quite a bit' distressing. In this study we also examined the reliability of the instrument using a Cronbach's alpha coefficient. For the items representing wound-related symptoms and difficulties in daily life alpha was 0.70, and it was 0.87 for items representing psychosocial symptoms. An alpha of 0.70 or above reflects adequate reliability.[27] The WOMAN-PRO data (1) show high symptom prevalence and distress, (2) call for a comprehensive symptom assessment, (3) may allow identification of areas for symptom management. If the results of further psychometric testing are promising, the WOMAN-PRO will provide an outcome measure for clinical trials.

The results of the research project contributed to the evidence on women with vulvar neoplasia and surgical treatment. First, it added knowledge to support nurses and physicians ability to identify patients at risk for post-surgical wound complications. Second, it provided, for the first time, a conceptual model of symptom experience in affected women. Third, it established, for the first time, evidence to help understand the VIN patient's experiences during her illness trajectory. Fourth, the development of the WOMAN-PRO instrument with a good content validity has the potential to contribute to a valid assessment of symptoms, informational needs and related distress in women

diagnosed with vulvar neoplasia and treated surgically. Fifth, WOMAN-PRO data showed a high symptom prevalence and distress, and provided preliminary evidence that the WOMAN-PRO instrument offers a feasible, targeted screening instrument to support systematic symptom assessment.

We conclude that our research project added to the existing knowledge on complications, symptoms and associated distress of women with vulvar neoplasia and surgical treatment, confirmed the given need for further research on (a) implementation strategies for comprehensive symptom assessment and (b) the identification of areas in symptom management to support early recognition of symptoms and decrease symptom related distress in women with vulvar neoplasia and surgical treatment.

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CHAPTER 1:

INTRODUCTION

INTRODUCTION

The following sections of this first chapter introduce the evidence concerning vulvar neoplasia (1.1), vulvar neoplasia treatment (1.2), post-surgical complications (1.3.), women's experiences following the diagnosis and treatment of vulvar neoplasia (1.4.), the concept of symptom experience (1.5), Patient-Reported Outcome instruments (1.6), challenges related to the care of patients with vulvar neoplasia (1.7), and the subsequent content of this research project (1.8).

1.1 Vulvar neoplasia

Vulvar intraepithelial neoplasia (VIN) and vulvar cancer are rare diseases, but show increasing incidence rates especially in young women[1, 2] and high recurrent rates.[3, 4] VIN refers to precancerous changes that occur in the skin that covers the female external genital organs (the vulva).[5] In the past, VIN was categorized as VIN 1, 2 and 3 according to the degree of abnormality. This classification was adapted by the International Society for the Study of Vulvar Disease in 2004. According to the new classification, VIN 1 is excluded from the classification and VIN includes lesions formally classified as VIN 2 or 3 or high grade VIN lesions. VIN is classified in two clinicopathologic subtypes. The usual VIN type is normally Human Papilloma Virus (HPV) related, while the differentiated type VIN is not associated with HPV in most cases.[6] Most people who are sexually active will have HPV at some time during their life. The vast majority of genital HPV infections are asymptomatic and clear within 1 to 2 years.[7] In Germany, the incidence rate of VIN in 2010 was estimated to be 7 per 100'000 women per year.[8] VIN incidence rate has increased in the last three decades in Europe and in the United States.[1, 9] The number of women with VIN tripled during 1985 and 1997 in a Central European sample.[2] VIN can affect women at any age, but it is more common under the age of 50.[10, 11] Reported risk factors are infection with HPV, smoking, and poor immunological status.[5, 11] VIN may be asymptomatic or may present with symptoms such as itching, discomfort, burning, and/or painful intercourse. The vulvar lesions may be red, brown, or white. A concern with VIN is the known progression to invasive cancer of the vulva.[11, 12]

Vulvar cancer usually develops slowly over several years.[13] Most vulvar cancers are squamous cell carcinoma (85% to 90%), although other histologic types such as adenocarcinoma, melanoma and Bartholin's gland cancers do occur.[14] The Federation Internationale de Gynecologie et Obstetrique (FIGO) and the American Joint Committee on Cancer (AJCC) classify the stages of vulvar cancer as 0 to 4.[15] Vulvar cancer incidence in Germany and Switzerland is between 1 and 7 cases per 100,000

women per year.[16, 17] The mean age of women with vulvar cancer is 72 years.[16] Reported risk factors for vulvar cancer are VIN, HPV infection, another anogenital intraepithelial neoplasia or carcinoma, syphilis, herpes genitalis, Acquired Immunodeficiency Syndrome (AIDS), smoking, lichen sclerosis, and squamous cell hyperplasia.[8, 18] VIN-related cancer recurs in 30% to 40% of patients.[3, 8]

1.2 Vulvar neoplasia treatment

VIN lesions are managed by surgical excision or laser treatment.[5, 19, 20] Surgery involves a wide local excision for focal lesions or a simple vulvectomy if the lesions are multifocal. It is estimated that after treatment of VIN by excision and/or laser vaporization 50% of women with positive surgical margins will required at least one additional treatment within 5 years.[10] Due to the high recurrence rate, the disfiguring nature of these procedures and the negative psychosexual impact on patients,[21] less invasive medical interventions have been developed and are still being evaluated. For example topical imiquimod cream appears to be effective in women with VIN, but its safety in view of the known progression of VIN to invasive disease needs further examination and more data on its adverse effects are required.[11]

Standard therapy for vulvar cancer is surgery.[22] In line with the FIGO guidelines, it consists of different surgical methods such as wide local excision, partial or radical vulvectomy and an inguinofemoral lymph node dissection depending on disease stage and lymph node involvement.[13] Based on tumor staging and patient factors, (neo-) adjuvant chemotherapy and radiation therapy may also be indicated.[23] Surgical reconstruction of the vulva may improve morbidity and quality of life after treatment.[24, 25] Generally, after minor surgical procedures an acute wound exists with good circulation and slight tissue damage and primary healing (per primam intentionem) generally occurs within three weeks.[26] However, even relatively small excisions are susceptible to post-surgical complications.[27] After major vulvar cancer surgery or in case of complications, delayed wound healing (per secundam intentionem) occurs.[28] Although surgical modifications have been made to reduce postoperative morbidity in women with vulvar neoplasia,[29] care for these patients is challenging with respect to post-surgical complications.

1.3 Post-surgical complications

Complications are defined as a medical problem that occurs during a disease or after a procedure or treatment.[13] Clinicians diagnose complications with clinical parameters. The main diagnostic criteria of a wound infection, for example, are fever, leukocytosis, positive blood cultures and serous or purulent discharge from the wound.[30] Most research published on complications following vulvar surgical treatment reflects the clinician perspective.[31] Reports of post-vulvar-surgery complications focus most often on physical and psychosexual effects.

Physical complications include wound dehiscence, wound infections, venous thrombosis, pulmonary embolism, pressure ulcers, introitale stenosis, urine incontinence/dysuria, rectocele, fecal incontinence, inguinal seroma, lymphedema, hernia, pain, scars, adhesions, and development of eschar.[5, 32-34] A recent randomized clinical trial included 30 women with VIN and reported no statistically significant differences in disease recurrence and adverse events in women treated with carbon dioxide laser (CO_2 laser) versus ultrasonic surgical aspiration (selective removal of diseased tissue) after one year follow-up. Several adverse events were reported: (1) pain (n = 30, 100%), (2) scars (n = 5, 16.6%), (3) dysuria or burning (n = 7, 23.3%), (4) adhesions (n = 1, 3.3%), (5) infection (n = 4, 13.3%), and (6) development of eschar (n = 4, 13.3%).[5] Three complications, lower extremity lymphedema (30% to 70%), wound dehiscence and infection (20% to 40%) were reported most frequently after surgical treatment in women with vulvar cancer.[35, 36] In a cross-sectional US study of 53 women whose vulvar cancer was treated surgically, lower-limb lymphedema was the most common complication and was experienced by 36% of the women.[36] Wound dehiscence and wound infection were reported in up to 85% of patients after radical vulvectomy and lymphadenectomy, depending on the definition of these wound complications, sampling strategies, measurement methods and wound complication assessment periods (ranged from 1 to 35 months).[17, 35, 37, 38] In a retrospective observational study of 101 patients after a modified radical vulvectomy and bilateral lymphadenectomy, Gaarenstrom et al.[39] reported that 9% to 17% of women had a wound dehiscence, 1% to 4% developed a hematoma, 9% to 39% had infections and there was a 40% lymph cyst rate. After less radical treatment, which disfigured the genitals to a lesser degree, post-surgical wound complications occurred less frequently.[35, 40, 41] For example, in a retrospective observational study examining complications after different types of vulvectomies in 149 patients, Leminen et al.[40] found that modified surgical techniques decreased dehiscence rates by 27% and infections by 28%.

Psychosocial complications have been addressed by most of the studies investigating sexual functioning.[5, 19, 21, 31, 42-45] Few studies focused on other psychosocial outcomes such as body image, partner relationships, and quality of life.[19, 43] A literature review of Graziottin & Serafini[46] reported that the psychosexual consequences in women with intraepithelial HPV-related neoplasia increases with the number of recurrences of HPV infection. The most frequently reported emotions in women with intraepithelial HPV-related neoplasia were depression, anxiety, and anger.[46] For example, Mc Fadden et al.[19] included seven women with VIN who had undergone surgical treatment in a two-year prospective study in Scotland. This study assessed depression and anxiety, quality of life, sexual functioning, and partner relationships every six-month with questionnaires. VIN had an adverse impact on quality of life and sexual functioning.[19] Another retrospective study in the US compared preoperative with postoperative sexual dysfunction and body image scores. The findings from this questionnaire telephone survey of 41 vulvar cancer patients showed significant sexual dysfunction ($P = 0.01$) and disturbed body image ($P = 0.004$) three months after surgical treatment.[43]

Overall, studies show evidence for high complication rates in women with vulvar neoplasia who undergo surgical treatment. Affected women have to assess and manage surgery-related problems and deal with emotional concerns after discharge. But how do women experience surgery-related complications and how do these complications impact their emotional and social lives?

1.4 Women's experiences following the diagnosis and treatment of vulvar neoplasia

This section includes qualitative research reporting on women's experiences concerning physical, emotional and social effects after vulvar surgical treatment from a patient perspective. Our literature search in 2009 identified three studies examining women's experiences following surgical treatment for vulvar neoplasia. One study focused on quality of life[47], one on women's experiences with VIN[48] and one on women's experiences with cancer of the vulva.[49] Based on their results, several symptoms and concerns were identified by women with vulvar neoplasia and surgical treatment.

Janda et al.[50] developed a vulvar cancer specific subscale to assess quality of life within the Functional Assessment of Cancer-General questionnaire (FACT-G). Instrument development was based on open-ended interviews with 15 patients 2 weeks to 39 months after surgery.[47] Results revealed reductions in several aspects of quality of life including physical, emotional and social functioning plus sexuality and body image. The vulvar cancer specific subscale included symptoms such as bleeding, odor, itching and burning in the vulva and a short vagina, as well as problems with swelling in the legs, sexual function, body appearance, urine control, and constipation. Likes et al.[48] utilized a qualitative focus group with six US women with VIN to explore patients' experiences with diagnosis and therapy. Participants reported symptoms of itching and pain. Shame, embarrassment and loss of control were reported as their most distressing experiences.[48] Jefferies and Clifford[49] described the experiences of 13 women in the UK with cancer of the vulva who were interviewed between 6 months and 5 years after surgery. Women's experiences were described as 'searching' to control their symptoms and emotions and emphasized their personal informational needs.[49]

Likes et al.[48] also explored emotional and social experiences in a group of women with VIN. The women feared infecting others with HPV. She found that for patients, sexually transmitted diseases had connotations of stigma, shame and impurity and caused problems in relationships with respect to loyalty and honesty. During the course of the illness, families and friends were perceived as either supportive or as a burden. Younger patients, in particular, felt that their peers often lacked the maturity to understand their experience.[48]

In summary, three qualitative studies showed that affected women reported several symptoms such as vulvar bleeding, odor and embarrassment. These studies rarely took the socio-cultural context influencing women's experiences into consideration. In conclusion, there is limited research on physical and emotional symptoms of affected women. No study could be identified that embedded

symptoms in a conceptual model of symptom experience in this patient population. It is crucial to understand women's symptom experiences in order to identify the symptom assessment strategies which are necessary to support symptom management.[51]

1.5 The concept of symptom experience

Symptoms are defined as a patient's perceived changes in biopsychosocial functioning, sensations, or cognition.[51, 52] Examples of common symptoms are pain and fatigue.[52] According to Dodd et al.,[51] the experience of symptoms may prompt patients to visit their health care providers. Symptoms also create distress and may disrupt social functioning. The management of symptoms generally becomes the responsibility of the patient. Health care providers often have difficulty proposing symptom management strategies that can be applied in acute and home care settings. To better understand how patients experience and manage symptoms, a generic symptom management model was developed by Dodd et al.[51] This model provides a framework for understanding the interrelatedness of three dimensions of symptom management, namely (1) symptom experience, (2) symptom management strategies and (3) outcomes. The model is designed to provide direction for health care professionals in selecting clinical interventions and informing research. Symptoms can help to bring problems to the attention of patients and clinicians. Dodd's model is based on the assumption that the gold standard for the study of symptoms is the perception of the individual experiencing the symptom and his/her self-report.

One dimension of the model is symptom experience, which contains the following three elements:

(1) An individual's perception of a symptom, i.e., perceived changes from the way the individual usually feels or behaves.
(2) The evaluation of the meaning of a symptom which entails the cause, frequency, temporal nature, severity, treatability of a symptom; the effect of the symptom on the individual's life and the threat posed by the symptom, for example, whether or not it is dangerous.
(3) The individual's response to a symptom which contains physiological, psychological, socio-cultural and behavioral components.[51]

Personal, environmental and health / illness components affect patient's symptom experience. For instance, a woman's symptom experience will vary by age, reproductive status, her current stage of disease, whether she is assessed in the clinic or at home, and her cultural beliefs about the meaning of a symptom.[52] Cultural components may cause distress especially in women with symptoms at the vulva, because in our socio-cultural context the vulva is known as a key element of eroticism,[46] and is strongly affected by taboo in Western society.[53] A patient's symptom experience includes two common dimensions with symptom distress as the emotional dimension, and symptom occurrence, frequency and severity as the cognitive dimension.[54] It is crucial to understand symptom experience

and the cultural aspects of a patient population in order to develop effective symptom assessment strategies. Symptom assessment, in turn, provide the basis for developing symptom management strategies to avert negative patient outcomes.[51, 55] Further supporting the importance of symptom assessment in women with vulvar neoplasia are studies that have shown that a significant proportion of cancer patients report severe symptoms that are not detected by clinicians during routine consultations.[56-58]

In literature searches in the Medline and CINAHL databases, Cochrane library and the Web of Science from 2000 to 2009, no studies focusing on symptom experience or symptom assessment in women with vulvar neoplasia and surgical treatment were found. Only one validated instrument measuring aspects of quality of life in vulvar cancer patients was identified, the Functional Assessment of Cancer Therapy-Vulvar (FACT-V).[50]

Summarizing the literature on complications, symptoms, and symptom experience of women with vulvar neoplasia, to date, most research on VIN and vulvar cancer patients has been restricted to retrospective observational studies, a few prospective studies and several randomized controlled trials examining specific treatment options for vulvar neoplasia. Many studies had small samples and data were primarily collected from the health care provider not the patient. Qualitative studies addressing symptoms, psychological and social problems related to a surgical treatment in these women are sparse. To date, little is known about how women experience symptoms after surgical treatment for vulvar neoplasia. Self-report instruments for assessing symptom experience are not available in this patient population. While current guidelines emphasize improving symptom assessment by providing written material for patients,[59, 60] such as Patient-Reported Outcome (PRO) instruments, nothing exists for women with vulvar neoplasia.

1.6 Patient-Reported Outcome instruments

PROs evolved from health-related quality of life tools that were becoming more disease-specific and symptom oriented.[61, 62] A PRO is any report of the status of a patient‘s health condition that comes directly from the patient, e.g. symptoms.[63] Systematic under-reporting and bias resulting for the use of standard summary methods have been described, potentially leading to treatment regimens appearing less toxic than they actually are.[62] Patient reporting is invaluable in detecting the severity of adverse symptoms and in allowing timely treatment. There are limitations to both clinically-reported outcomes and patient-reported outcomes. Therefore, assessment of both is the most accurate way to describe a patient’s status, rather than using traditional objective measurements alone. A combination of assessments allows for better supportive care.[64] A patient’s self-report captures important information that can only be assessed through a patient’s perception.[65, 66] Basch[67] emphasized the necessity of regularly including the patient’s voice by collecting PRO data as part of general screening for adverse

symptom events. As clinicians often underestimate the severity of a patient's symptoms, patient self-report can help to detect and prevent adverse events. When patient self-report of symptoms is standard practice, symptoms tend to be reported earlier in relation to their occurrence.[67] Thus, a PRO instrument can add important information about the patient's health status, the consequences of treatment, and the effectiveness of interventions.[65] The first three steps that the US Food and Drug Administration recommend in developing a PRO instrument are to: (1) identify concepts or domains that are important to patients and develop a conceptual model; (2) create and pilot test the instrument; and (3) assess its measurement properties.[68, 69]

1.7 Challenges for the care of patients with vulvar neoplasia

The decreasing length of post-surgery hospital stay has increased the responsibility for the patient to assess and manage symptoms.[60] Women with vulvar neoplasia are usually discharged before their surgical wound has healed. Follow-up visits are usually scheduled every three months for the first three years to detect recurrent cancer and to prevent predictable complications.[70] However, for this patient population there is limited research about the prevalence and risk factors for different types of short-term wound complications. Furthermore, evidence has shown that clinicians may underestimate the severity of a patient's symptoms that can, in turn, result in the occurrence of preventable adverse events.[71] Therefore research needs to focus on the patient perspective. Women need to assess and manage symptoms at home until they see their health care providers again.[48] Following surgery, women with vulvar neoplasia may not be able to identify complications such as wound infections. It is important to empower these women to recognize, assess and communicate symptoms, for example redness, that may indicate a complication. As symptoms vary over time, changes in the strategy to manage symptoms are required. Health care and especially nursing care should differ along an illness trajectory to meet patient and family needs.[72, 73]

In summary, published studies on this patient group are limited and showed weaknesses in design, sample size and analytical methods. No published studies based on a conceptual model and addressing the socio-cultural aspects of symptom experience of women with surgically treated vulvar neoplasia in Germany and Switzerland could be identified. Based on guidelines for the development of PRO measures, the wound complications and symptom experiences in women with surgically treated vulvar neoplasia need to be explored prior to developing a symptom assessment instrument.

Although an effective instrument collecting PRO data could support appropriate patient, nurse and physician decisions on symptom management following surgery, no instrument was found that assessed and quantified experienced symptoms and related distress in this patient population. A PRO instrument can support women with vulvar neoplasia in recognizing and evaluating the seriousness of symptoms so that appropriate treatment is sought in a timely fashion. In addition, such an instrument

can facilitate a woman's ability to communicate effectively with health care professionals by providing structured information on symptom occurrence and distress. This should facilitate targeted optimization of interventions to prevent and manage symptoms and their related distress, addressing patient needs as well as improving vulvar neoplasia treatment.

1.8 Subsequent content of this research project

Given the gaps in the evidence base on women with vulvar neoplasia and surgical treatment, this research project includes the following chapters. In **chapter 2** the aims and methods of this research project are described. **Chapter 3** is the publication "Period prevalence and risk factors for postoperative short-term wound complications in vulvar cancer – A cross-sectional study".[74] This chapter also synthesizes the limited evidence concerning risk factors and prevalence of post-surgery complications from a clinical perspective. In **chapter 4** the findings of the article "The unspoken disease: Symptom experience in women with vulvar neoplasia and surgical treatment - A qualitative study" are reported.[75] In this chapter, we suggest a conceptual model that may be useful in understanding the symptom experience of affected women from a patient perspective. In **chapter 5**, we focused on the patient perspective of women with vulvar intraepithelial neoplasia during their illness trajectory by conducting a secondary data analysis of the foregoing qualitative study. In **chapter 6** the development and content validity of a PRO instrument designed to self-monitor the post-surgery symptom experience and informational needs of WOMen with vulvAr Neoplasia (WOMAN-PRO) is reported. In **chapter 7** the initial findings of a cross-sectional survey using the WOMAN-PRO instrument to identify the occurrence and distress of post-surgery symptoms are presented. In **chapter 8** the key findings and research methods of the research project's studies are discussed. Furthermore suggestions for further research and clinical practice and conclusions are presented.

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CHAPTER 2:

AIMS AND METHODS

AIMS AND METHODS

Despite fundamental efforts to improve standard diagnostic, medical and surgical therapy for women with vulvar neoplasia,[1-3] adverse events such as surgery-related complications are common.[4-6] Given the gaps in the evidence regarding women with vulvar neoplasia and surgical treatment as discussed in the introduction section, health care professionals need new strategies to decrease adverse symptom events and symptom-related distress by focusing more intensively on patients' perspectives.

2.1 Aims

Therefore the aims of this research project were:

(1) To examine period prevalence and risk factors for postoperative short-term wound complications following surgical treatment of vulvar cancer in a cross-sectional study.

(2) To explore symptom experience, more specifically symptom occurrence and symptom distress in women with surgically treated vulvar neoplasia in a qualitative study.

(3) To explore women's experiences during their course of illness for vulvar intraepithelial neoplasia and its surgical treatment by carrying out a secondary data analysis of the forgoing qualitative study.

(4) To develop and pilot-test the self-administered WOMAN-PRO instrument for monitoring the post-vulvar-surgery symptom experience and informational needs of women with vulvar neoplasia.

(5) To examine the occurrence and distress related to post-surgery symptoms of women with vulvar neoplasia during the first week following hospital discharge following vulvar surgery in a cross-sectional study.

2.2 Methods

2.2.1 Design

To address these aims we used a mixed-methods research approach, which combined quantitative and qualitative methods with equal weighting of both methods. Mixed-methods research is a design with philosophical underpinnings and methods of inquiry.[7]

2.2.2 Methodology and methods of inquiry

As a methodology, mixed-methods research involves philosophical worldviews that guide the direction of the collection and analysis of data and the mixture of quantitative and qualitative approaches in several phases of the research process.[7] In the worldview of pragmatism, the actions taken are purposeful and aim at creating desired outcomes.[8] Pragmatism guided this mixed-methods research focusing on the primary importance of the research aims stated rather than the methods. Therefore this research project was oriented toward 'what works in clinical practice'. Both objective and subjective knowledge and combined deductive and inductive thinking were valued while analyzing data.

As a method of inquiry, mixed-methods research focuses on collecting and analyzing quantitative and qualitative data in a single study or series of studies.[7] The central premise of mixed-methods research is that the use of qualitative and quantitative approaches in combination provides a better understanding of research problems than either approach alone.[7] As the understanding of post-surgical complications and related symptom experience in women with vulvar neoplasia has received negligible research attention, a pluralistic approach was chosen. With such an approach we intended to give voice to the patients' experiences by the means of a qualitative approach. Their experiences were then systematically analyzed in the quantitative component of the project.

To address aim 1, the first study of the research project was a cross-sectional investigation exploring the prevalence and risk factors for postoperative short-term wound complications in women diagnosed with vulvar cancer at University Hospital Berne. Addressing the research problem from a patient perspective required adding a secondary form of data (qualitative data) to the first study.

To address aims 2 to 5, a sequential exploratory two-phase mixed-methods study (WOMAN-PRO) was conducted to explore symptom experience and illness trajectory in women with vulvar neoplasia and surgical treatment. The first phase of the WOMAN-PRO study included two qualitative studies with affected women recruited from the University Hospital Berne in Switzerland and two German University Hospitals in Freiburg and Munich. The use of interviews to explore important issues allowed us to discover the concerns of women diagnosed with vulvar neoplasia and treated with surgery. Heideggerian hermeneutics,[9] an approach to interpret and understand the meaning of people's lived experiences, provided the philosophical underpinning for the qualitative studies. According to Diekelmann et al.,[10] we used a critical hermeneutic approach to embed women's experiences in a wider socio-cultural context by relating the interpretation to additional literature, for example historical literature about the vulva in a German-speaking society.[11] Data analysis focused on the understanding of people, the language and the study of texts.[12] This process aims at uncovering meanings that may be hidden from social actors themselves,[13] and at generating knowledge, which contribute to empowerment and change.[14] This qualitative research enabled us to deconstruct initial

assumptions about patient experiences and showed us alternative ways in which they might be interpreted.[15] Findings from this qualitative study phase allowed us to formulate relevant instrument items and were used to develop the WOMAN-PRO instrument.

In the second phase of the WOMAN-PRO study, the pilot-tested instrument was administered to affected women from four Swiss Hospitals in the German speaking part of Switzerland and four University Hospitals in Germany. The data collected were used to examine the psychometric properties of the WOMAN-PRO and the prevalence of symptoms and their associated distress in women with vulvar neoplasia and surgical treatment during the first 7 days after discharge.

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CHAPTER 3:

PERIOD PREVALENCE AND RISK FACTORS FOR POSTOPERATIVE SHORT-TERM WOUND COMPLICATIONS IN VULVAR CANCER: A CROSS-SECTIONAL STUDY

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Modified version

Abstract

Background

Although clinicians recognize that postoperative wound management in patients with vulvar cancer (VC) is challenging, the prevalence and risk factors for different types of short-term wound complications (WC) remain unclear. The aims of this study were: (1) to determine the period prevalence of postoperative short-term WC and (2) to identify risk factors associated with short-term WCs in patients with VC.

Methods

In a cross-sectional study in a Swiss University Hospital, a sample of 108 patients with VC treated surgically (and free of WCs at the time of admission) was included. Data were collected retrospectively from 2007 to 1997 from medical records using an investigator-developed data collection instrument to assess risk factors preoperatively and perioperatively and WCs that occurred within the first 30 postoperative hospital days. The period prevalence of WCs was calculated, and logistic regression was used to identify risk factors for WCs.

Results

The median age was 69 years (interquartile range [IQR], 21 years). The period prevalence of WCs was 45.4% (49/108), showing at least 1 of 8 assessed WCs per patient within the median hospital duration of 11 days (IQR, 12 days). The period prevalence for each type of WC was 31.5% for dehiscence, 12% for hematoma, 6.5% for necrosis, 5.6% for infections, 4.6% for seroma, 1.9% for lymph cysts, 1.9% for malignant wounds, and 0% for disturbed tissue formation.

Two significant predictors of WCs were identified out of 14 risk factors examined ($P < 0.05$). The odds ratio (OR) for WC increased with the extent of surgical therapy, i.e. from excision to hemi-vulvectomy and to radical vulvectomy, by a factor of 2.6 (OR, 2.6; 95% confidence interval [CI], 1.34-5.14), and, in the case of inguinofemoral lymphadenectomy, by a factor of 3 (OR 3.0; 95% CI 1.03-8.76).

Conclusions

The high prevalence of short-term WCs (45.4%) indicates a need for systematic wound assessment and early risk-management - especially after hemivulvectomy, radical vulvectomy and inguinal lymphadenectomy.

3.1 Introduction

Although patients with vulvar cancer (VC) have different treatment options, care of these patients remains a challenge with respect to postoperative wound care. The incidence of VC in North America and Europe is about 1.6 per 100,000 women per year and is currently increasing in young women.[1] In line with the International Federation of Gynecology and Obstetrics (FIGO) and subject to the tumor stage, VC surgical treatment consists of wide excision, laser therapy, skinning vulvectomy, modified or radical vulvectomy.[2] Based on tumor staging, (neo-) adjuvant chemotherapy and/or radiation therapy may also be indicated. In the past 2 decades, several surgical modifications have been made to reduce postoperative morbidity, for example: (1) separate incision approach instead of en bloc radical vulvectomy and groin lymph node dissection, (2) radical local excision for the T1 lesion of the vulva instead of radical vulvectomy, and (3) modification of femoral lymphadenectomy, avoiding deep groin dissection and preservation of great saphenous vein.

Wound complications (WCs) after the surgical treatment of VC can be classified as dehiscence, hematoma, necrosis, infection, seroma, lymph cyst, disturbed tissue formation and malignant wounds.[3] Although WC in VC cause enormous physical and psychosocial problems and prolonged hospital stay as well as high health care costs,[4] information on prevalence and risk factors for wound complications is sparse. To identify previous studies on WCs in VC, we performed a literature search in MEDLINE, CINAHL and the Cochrane database, including all studies on patients with VC in the period between 1998 and 2008. The 11 studies identified examined WCs after a variety of surgical procedures and did not provide a definition of each WC.[4-14] Existing literature so far has focused on 2 types of WC, namely, wound infection and dehiscence in the region of the groin and genitalia.[4-14] Studies focusing on wound dehiscence and wound infections described rates from 5% to 85%, depending on the definition of the WC, the studied VC sample, and the assessment period of the WC.[5, 13] Only 5 of 9 observational studies and 2 randomized experimental studies described a VC sample with more than 100 patients.[6, 9, 11, 13, 14] Of these, only 1 study focused directly on different postoperative WCs after vulvectomy.[6] Gaarenstrom et al.,[6] in a retrospective observational study with a sample of 101 patients after a modified radical vulvectomy and bilateral lymphadenectomy, reported that 9% had vulvar wound dehiscence and 17% had groin wound dehiscence, 1% (vulvar) to 4% (groin) had hematomas, 9% (vulvar) to 39% (groin) had infected wounds, and 40% developed lymph cysts in their groin.

Gottrup et al.[15] reviewed risk factors associated with surgical site infections (SSIs) across surgical patients. The patient-related risk factors included diabetes, jaundice, chronic renal failure, poor physical condition, advanced age, alcoholism, smoking, obesity, poor nutrition, previous radiotherapy or chemotherapy, as well as medications. Assmussen et al.[16] and Lippert[17] reported that the risk of WCs was higher in patients on anticoagulants, immunosuppressants, cytostatics, antiphlogistics, and psychotropics as well as those with arterial and venous blood disorders.

In 149 patients with VC, Leminen et al.[9] identified bilateral tumor localization, a nonradical vulvectomy and a body mass index (BMI) over 25 as significant risk factors for wound infections in a retrospective observational study examining complications after different vulvectomies. In a recent prospective observational multicenter study examining the safety of sentinel node procedures, Van der Zee et al.[13] reported a decrease in the number of wound dehiscence inguinal from 34.0% to 11.7% and the number of wound infections from 21.3% to 4.5% after exclusive sentinel node dissection without inguinofemoral lymphadenectomy. Rouzier et al.[11] reported in a retrospective observational study with 194 patients that a BMI over 24 increased the risk of wound infection. They stated that age older than 70 years, BMI of more than 24, and the extent of lymphadenectomy increased the risk of wound dehiscence. Contrary to these results, Gaarenstrom et al.[6] and Carlson et al.[14] reported no increased risk in women older than 65 years. In a randomized clinical trial designed to compare the impact of vapor-heated fibrin sealant and sutured wound closure on lower extremity lymphedema after inguinal lymphadenectomies in 137 patients with vulvar malignancies, Carlson et al.[14] reported a significantly higher rate of vulvar infections in the vapor-heated fibrin sealent group. The use of a Blake drain was associated with an increase in vulvar and inguinal wound breakdown. There was no significant increased risk for WCs associated with a BMI of more than 30.

Other medical and patient-related risk factors for postoperative WCs that are crucial for identifying those at risk of possible WC and for initiating effective interventions in the future so far remain unmapped. Thus, prevalence and risk factors influencing the occurrence of WCs in patients with VC remains as two central, yet unresolved issues for health care professionals involved in post-surgical care of patients with VC.

The aims of the present study were to: (1) determine the period prevalence of WCs from the first to the 30th postoperative hospitalization day (short-term WC) in patients with VC and (2) identify medical and patient-related risk factors that were associated with short-term WCs.

3.2 Methods

3.2.1 Design, sample and setting

Using a retrospective cross-sectional design, the period prevalence of documented WCs and the associations between risk factors and short-term WCs were examined. Data were collected from the medical records of patients with VC in one Swiss University Hospital treated surgically between January 01, 1997 and December 31, 2007. On average, 14 patients with VC per year were operated on over the last 11 years in the designated hospital. The sample was comprised of all patients with VC meeting the inclusion criteria (Table 1).

Table 1. Inclusion and Exclusion Criteria

Inclusion criteria	Exclusion criteria
• Older than 18 years at the beginning of treatment	• Patients with VC treated exclusively with radiotherapy, chemotherapy, other gynecologic surgery
• Patients independent of FIGO stage or lymph node status treated surgically[a] in the time period of 1997-2007	• Patients with VC with pre-existing WCs at admission
• Stationary hospitalization and vulvar surgery on one of two gynecologic wards of the designated hospital	

FIGO, International Federation of Gynecology and Obstetrics; VC, vulvar cancer; WCs, wound complications

[a] Vulvar surgeries from 1997-2007 were performed by standardized methods according to the guidelines of German Society for Gynecology and Obstetrics.[18] Since 1997, VC surgeries have been carried out with sentinel lymph node dissection. Between 1997 and 2002, the surgery included the usual inguinofemoral lymphadenectomy with triple incision. Since 2003, a unilateral inguinofemoral lymphadenectomy was accomplished exclusively, depending on the lymph node status. During the survey period patients got routinely Redon drains after complete inguinofemoral lymphadenectomy (drain removal, if liquid flow rate <20mL).

3.2.2. Instrument, Variables and Measurement

A standardized data collection instrument was developed because no instrument for assessing short-term WCs based on medical record review was available.[15] For infections, the US Centers for Disease Control and Prevention suggests the use of the term 'surgical site infection' (SSI), which must meet specific criteria and occur within 30 days.[15] Because to date there is no standard definition of short-term WC, the definitions used in this study were based on the SSI criteria.

Documented demographic data, medical and patient-related risk factors and specific WCs were captured by this instrument. Development of this instrument was based on a literature review focusing on criteria, instruments, definitions of the risk factors, WCs and VC. Three wound healing experts, a professor of gynecology and 2 clinical nurse specialists, validated the criteria for each item according to the definitions (content validity). The first author (B.S.) conducted a pretest with the revised instrument with the first 10 medical records to determine if complete and accurate data could be

retrieved. If there were questions about information documented in the medical record, they were discussed with experts in the field. Intercoder reliability was tested by two authors (B.S. and M.E.) independently coding 5 medical records. Their coding resulted in a high intercoder agreement (Krippendorff's alpha = 1).

3.2.3 Demographic characteristics

In addition to the medical and patient-related risk factors, the following socio-demographic data were retrieved from medical records: civil status (married [1], single [2], widowed [3], divorced [4]), language (German [1], French [2], Italian [3], Spain [4], Others [5]), occupation (working [1], retired [2], housewife [3]), insurance (general [1], semiprivate [2], private [3]) and length of hospitalization (number of days [1-]).

3.2.4 Medical and patient-related risk factors

Six VC- and surgery-related characteristics were recorded: Diagnosis (primary tumor [1], recurrent tumor [2]), FIGO stage (I-IV [1-4]), surgical therapy (excision-including any kind of excision technique, skinning vulvectomy or laser therapy [1]; hemivulvectomy-including resection of one left, right, anterior, or posterior part of the vulva [2]; radical vulvectomy-radical resection or exenteration with or without flap reconstruction [3]), sentinel lymph node dissection (no [0]/ yes [1]), inguinofemoral lymphadenectomy (no [0]/ yes [1]/ others [2]) and number of eliminated lymph nodes (number of lymph nodes [1-]).

The following 16 patient-related characteristics were recorded: age (years), BMI (kg/m²), diabetes mellitus (type I, type II, no [0]/ yes [1],), liver disease (chronic hepatitis, cirrhosis or jaundice, no [0]/ yes [1]), kidney disease (kidney failure, hem dialysis or patients after kidney transplant; no [0]/ yes [1]), arterial disorders (atherosclerosis, peripheral arterial disease or arterial hypertension, no [0]/ yes [1]), venous disorders (venous insufficiency, varicose veins or heart failure with leg edema; no [0]/ yes [1]), general condition (good [0]/ reduced [1]), alcohol consumption (no [0]/ yes or sometimes [1]), smoking (no [0]/ yes or sometimes [1]), malnutrition risk (instrument 'Nutrition risk score'; no = <3 points [0]/ yes ≥3 points [1]), previous radiotherapy (up to 6 months before surgery, no [0]/ yes [1]), previous chemotherapy (up to 6 months before surgery, no [0]/ yes [1]), immunosuppressant medication (no [0]/ yes [1]), cytostatic medication (no [0]/ yes [1]) and psychotropic medication (no [0]/ yes [1]). During the survey period, all patients with VC underwent surgery routinely got antibiotics, anticoagulants and anti-inflammatory medication, so that these medications were not examined as potential risk factors.

Measurement of all 22 possible risk factors was based on information documented in the preoperative and perioperative records by physicians or nurses. Given that the influence of select medications on

WCs was also of interest with respect to the postoperative phase, data on medications were collected both preoperatively and postoperatively.

3.2.5 Short-term wound complications

Short-term WCs in the operative area were recorded as dichotomous dependent variables based on physician or nurse diagnosis. The WCs were operationalized as follows: wound dehiscence (presence [1] or absence [0] for each location of a level I, II, or III vulvar, inguinal and combined vulvar and inguinal dehiscence), hematoma (superficial or deep: no [0]/ yes [1]), necrosis (demarcated or wet border-necrosis or necrosis: no [0]/ yes [1]), infections (presence [1] or absence [0] for each location of superficial, deep or organ related vulvar, inguinal and combined vulvar and inguinal infection), seroma (serous exudates, ie, serum or lymph in cavities of the wound area: no [0]/ yes [1]), lymph cysts (well-defined amount of lymph in a cyst: no [0]/ yes [1]), malignant wounds (exulcerate or cicatricial malignant wound: no [0]/ yes [1]) and disturbed tissue formations (keloid, hypertrophic cicatricial tissue or cicatrice contracture: no [0]/ yes [1]).

Each short-term WC was classified as present or absent during the data collection period (first to 30th post-operative day). To indicate the association between risk factors and short-term WCs, the 8 WCs were combined in 1 variable ‘at least 1 of 8 WCs’.

3.2.6 Data collection

Data were selected from the medical and nursing records by the first author in the designated hospital and were directly coded into an electronic data file.

3.2.7 Data analysis

Descriptive data analyses were performed using SPSS 15.0 (SPSS, Inc., Chicago, IL) including measures of central tendencies, frequencies, distributions, medians and interquartile ranges (IQRs) depending on the measurement level of the variables. First the period prevalence was calculated to describe the proportion of patients with VC with at least 1 WC. Second period prevalences were calculated for each type of WC, considering the location of wound dehiscences and infections.

Inferential analysis was calculated using SAS 9.1.3., (SAS Institute, Inc., Cary, NC). Logistic regression was used to explore possible associations between risk factors and the dichotomy outcome variable ‘at least 1 of 8 WCs’, using generalized estimation equations to account for the fact that some patients had multiple hospitalizations during the data collection period of 11 years. The following risk factors were omitted from the model because of strong associations with other predictors in the model (based on a variance inflation factor of >2): general condition, liver disease, immunosuppressant medication, cytostatic medication, and the number of resected lymph nodes. The risk factors kidney disease, previous chemotherapy and malnutrition risk were excluded because of missing values. To avoid bias by misinterpreting the interrelationship between malignant wounds and tumor stage,

malignant wounds were excluded from the regression analysis. All remaining risk factors (n = 14) were tested separately in simple regression models. Because we expected FIGO to be confounded by a primary versus a recurrent tumor, we entered the interaction term of FIGO (I-IV) and diagnosis (primary and recurrent tumor) in the regression analysis, which allowed the effect of FIGO stage on WCs to be different for diagnosis (primary tumor / recurrent tumor). In a second step, all 14 risk factors were entered in a multiple regression model, which was purged by manual backward deletion.

The study was approved by the ethics committee of the canton Berne. The master list linking the study ID-number to VC patients was stored in a secure place separate from the study instruments in order to guarantee confidentiality.

3.3 Results

3.3.1 Sample characteristics

In total, 152 medical records of patients with VC were screened for eligibility. Seven medical records were missing and 37 patients did not meet eligibility criteria. A total of 108 patients with VC who were treated surgically were included in the calculation of WC period prevalence. In this sample, 74 patients were operated on once, 23 twice, 6 three times, 4 four times, and 1 five times. One patient with a missing BMI value and 2 patients with malignant wounds were excluded from the regression analysis. The sample for the regression was 105 patients (Figure 1).

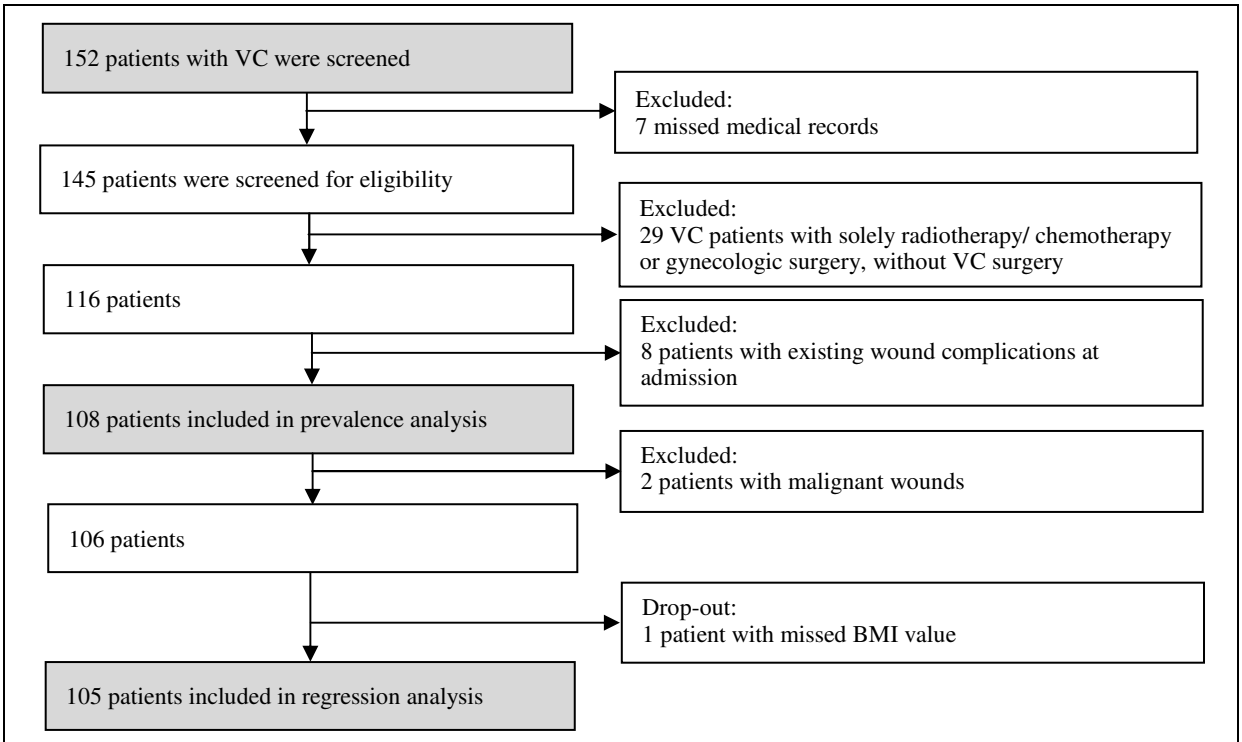

Figure 1. Flowchart: Numbers of Included and Excluded Patients with Vulvar Cancer.

VC, vulvar cancer; BMI, body mass index

The mainly German-speaking sample of 108 patients with VC had a median age of 69 years (IQR, 21). The median length of hospitalization was 11 days (IQR, 12). Approximately half of the cases had FIGO stage I tumors (44.5%) and half of them were FIGO stage II to IV (53.6%). The tumor was removed in 45.4% of the cases through excision and in 54.6% through hemivulvectomy or radical surgery. A similar proportion of cases received a sentinel lymph node dissection (47.2%) and inguinofemoral lymph node dissection (58.3%; Table 2).

Table 2. Demographics, Risk Factors and Medical Characteristics of the Sample (n = 108).

Variables	Frequency, Median	%, IQR
Civil state		
Married	45	41.7%
Single	12	11.1%
Widowed	32	29.6%
Divorced	3	2.8%
Not documented	16	14.8%
Language		
German	102	94.4%
French	2	1.9%
Italian	3	2.8%
Spain	1	0.9%
Occupation		
Working	12	11.1%
Retired	52	48.1%
Housewife	30	27.8%
Not documented	14	13.0%
Insurance		
General	60	55.6%
Semiprivate	19	17.6%
Private	10	9.3%
Not documented	19	17.6%
Length of hospitalization		
In days	11 (median)	12 (IQR)
Diagnosis		
Primary tumor	58	53.7%
Recurrent tumor	48	44.4%
Not documented	2	1.9%
FIGO stage		
Ia and Ib (primary tumor)	22	20.4%
II (primary tumor)	17	15.7%
III (primary tumor)	12	11.1%
IV (primary tumor)	7	6.5%
Ia and Ib (recurrent tumor)	26	24.1%
II (recurrent tumor)	12	11.1%
III (recurrent tumor)	9	8.3%
IV (recurrent tumor)	1	0.9%
not documented	2	1.9%

Table 2. (continued)	Frequency, Median	%, IQR
Surgical therapy		
Excision	49	45.4%
Hemivulvectomy	38	35.2%
Radical vulvectomy	21	19.4%
Lymph node dissection		
Sentinel	51	47.2%
Inguinofemoral	63	58.3%
Others	1	0.9%
Eliminated lymph nodes		
Number of lymph nodes	2 (median)	15 (IQR)
Age		
In years	69 (median)	21 (IQR)
BMI		
In kg/m²	27.9 (median)	7.3 (IQR)
Diabetes mellitus		
Type I	0	0%
Type II	16	14.8%
Arterial disorders		
Atherosclerosis, peripheral arterial disease or arterial hypertension	46	42.6%
Venous disorders		
Venous insufficiency, varicose or heart failure with leg edema	29	26.9%
Alcohol consumption		
Yes or sometimes	59	54.6%
Smoking		
Yes or sometimes	28	25.9%
Previous radiotherapy		
Up to 6 months before surgery	5	4.6%
Psychotropic medication		
Yes	32	29.6%

IQR, interquartile ranges; FIGO, International Federation of Gynecology and Obstetrics; BMI, body mass index

3.3.2 Period prevalence of short-term wound complications

The period prevalence for any short-term WC was 45.4% (49/108). These patients developed at least 1 of 8 WCs within a median hospital stay of 11 days (IQR, 12). The period prevalence for each type of WC was 31.5% for dehiscence (34/108), 12% for hematoma (13/108), 6.5% for necrosis (7/108), 5.6% for infection (6/108), 4.6% for seroma (5/108), 1.9% for lymph cyst (2/108), and 1.9% for malignant wounds (2/108). No patient had disturbed tissue formation. Dehiscences occurred twice as often in the vulva (n=20) as in the inguinal (n=10) region, and infections were more commonly located in the vulvar region (n=4) than in the inguinal region (n=1; Table 3).

Table 3. Period Prevalence of Short-term Wound Complications in Vulvar Cancer Patients (n = 108).

Variables	n	%
At least 1 WC[a] per patient		
Vulvar and/or inguinal	49	45.4%
Dehiscence		
Vulvar and/or inguinal	34	31.5%
Vulvar	20	18.5%
Inguinal	10	9.3%
Vulvar and inguinal	2	1.9%
Location not documented	2	1.9%
Hematoma		
Vulvar and/or inguinal	13	12.0%
Necrosis		
Vulvar and/or inguinal	7	6.5%
Infection		
Vulvar and/or inguinal	6	5.6%
Vulvar	4	3.7%
Inguinal	1	0.9%
Vulvar and inguinal	1	0.9%
Seroma		
Vulvar and/or inguinal	5	4.6%
Lymph cyst		
Vulvar and/or inguinal	2	1.9%
Malignant wound		
Vulvar and/or inguinal	2	1.9%
Disturbed tissue formation		
Vulvar and/or inguinal	0	0%

WC, wound complication

[a] Each short-term WC was documented as present or absent during the data collection period (1st to 30th post-operative day). The period prevalence was calculated to describe the proportion of vulvar cancer patients with at least one WC within a median hospitalization period.

3.3.3 Risk factors for short-term wound complications

In the uncontrolled simple regression analysis (Table 4), diagnosis, surgical therapy, sentinel lymph node dissection, and inguinofemoral lymphadenectomy were significant predictors of WCs. Two of them remained significant in the multiple model (Table 5): surgical therapy (P = 0.005) and inguinofemoral lymph node dissection (P = 0.044). Compared with patients who had an excision, those who had hemivulvectomy were 2.6 times more likely to have a WC. Compared further with patients who had a hemivulvectomy, those who had a radical vulvectomy were 2.6 times more likely to have a WCs (odds ration [OR], 2.6; 95% confidence interval [CI] 1.34-5.14). Patients receiving an inguinofemoral lymphadenectomy were 3 times more likely to have a WC compared with patients without an inguinofemoral lymphadenectomy (OR, 3.0; 95% CI 1.03-8.76). In simple logistic regressions, the interaction term of diagnosis and FIGO stage was significant (P = 0.004), suggesting that the association of FIGO and WC differ depending on the diagnosis. Indeed, a further exploratory analysis (Table 4) showed that the evidence of an association between WC and FIGO stage could exist

for patients who have a recurrent tumor, and not a primary tumor. This could not be corroborated on the multiple model.

Table 4. Risk Factors associated with Short Term Wound Complications after Vulvar Cancer Surgery: Simple Logistic Regressions (n = 105).

Variables	df	Odds ratios (95%CI)	Chi-Square	p value
Diagnosis				
Primary tumor, recurrent (1,2)	1	0.34 (0.16-0.72)	8.00	0.0047
FIGO stage				
Primary tumor (I-IV) (n = 58)	1	0.76 (0.45-1.30)	0.99	0.3209
Recurrent tumor (I-IV) (n = 47)	1	1.86 (0.96-3.61)	3.36	0.0667
Surgical therapy				
Excision, hemi-vulvectomy, radical vulvectomy (1-3)	1	3.62 (1.98-6.62)	17.51	<0.0001
Sentinel lymph node dissection				
No = 0, yes = 1	1	3.35 (1.59-7.06	10.14	0.0015
Inguinofemoral lymphadenectomy				
No = 0, yes = 1	1	5.98 (2.13-16.80)	11.54	0.0007
Diabetes mellitus				
Type II (no = 0, yes = 1)	1	1.31 (0.83-2.08)	1.36	0.2443
Arterial blood disorders				
Atherosclerosis, peripheral, arterial disease or arterial hypertension (no = 0, yes = 1)	1	1.25 (0.59-2.64)	0.33	0.5643
Venous disorders				
Venous insufficiency, varicose or heart failure with leg edema (no = 0, yes = 1)	1	0.90 (0.35-2.29)	0.05	0.8249
Age				
Years (1-)	1	1.02 (0.99-1.05)	1.07	0.3002
Alcohol consumption				
No = 0, yes or sometimes = 1	1	1.47 (0.68-3.21)	0.95	0.3298
Smoking				
No = 0, yes or sometimes = 1	1	0.71 (0.28-1.82)	0.51	0.4751
Previous radiotherapy				
Up to six months before surgery (no = 0, yes = 1)	1	0.82 (0.12-5.65)	0.04	0.8358
Body Mass Index				
In kg/m²	1	1.02 (0.96-1.09)	0.38	0.5397
Psychotropic medication				
No = 0, yes = 1	1	1.62 (0.72-3.63)	1.38	0.2396

CI, confidence interval; df = degree of freedom; FIGO, International Federation of Gynecology and Obstetrics

Table 5. Risk Factors associated with Short-term Wound Complications after Vulvar Cancer Surgery: Multiple Logistic Regression (n = 105).

Variables [a]	df	Adjusted odds ratios (95% CI)	Chi-Square	p value
Surgical therapy				
Excision, hemivulvectomy, radical vulvectomy (1-3)	1	2.62 (1.34 - 5.14)	7.89	0.005
Inguinofemoral lymphadenectomy				
No = 0, yes = 1	1	3.00 (1.03 - 8.76)	4.06	0.044

CI, confidence interval; df=degree of freedom; FIGO, International Federation of Gynecology and Obstetrics

[a] Model consisted of 14 risk factors: diagnosis, FIGO stage, surgical therapy, sentinel lymph node dissection, inguinofemoral lymphadenectomy, diabetes mellitus, arterial blood disorders, venous disorders, age, alcohol consumption, smoking, previous radiotherapy, Body Mass Index, psychotropic medication.

3.4 Discussion

This study is the first to report period prevalences for 8 short-term WC and risk factors for WCs in a Swiss sample. Owing to the definition of WCs used in this study and the consideration of 8 specific types of WCs the reported period prevalence (45.4%) is not directly comparable with reported WCs of about 40% in other western countries.[6, 9, 11, 13, 14] Furthermore, the relatively high prevalence of WCs may be related to the sample characteristics. Approximately 30% of the tumors in this study were stages III to IV. This explains the high proportion of women (58%) who had inguinofemoral lymph node dissection, which, in comparison with exclusive sentinel lymph node dissection, is accompanied with higher prevalence of WCs.[11, 13] Differences in the type of surgical intervention may explain differences in the prevalence rates of wound dehiscence and infection in different studies. For example, Van der Zee et al.[13] examined the prevalence of wound dehiscence and infection after sentinel node biopsy (SLN) dissection alone (n = 264) or SLN dissection with subsequent inguinofemoral lymphadenectomy (n = 47). The prevalence rates of wound infections and dehiscence in the total sample were 7% and 15%, respectively (infections, 4.5% and 21.3%, respectively, and dehiscence, 11.7% and 34.0%, respectively, in the SLN dissection alone group and in the SLN dissection with lymphadenectomy group). In comparison, the sample in this study showed more extensive surgeries. Thus, compared to Van der Zee et al.,[13] a higher WC prevalence could be expected.

In particular, this study demonstrates that the 3 most frequently observed short-term WCs were wound dehiscence, hematoma, and necrosis. With a prevalence of 31.5%, wound dehiscence was the most frequent WC in this study. This relatively high period prevalence falls within the range reported in other studies, which reported 9% to 47% wound dehiscence rates in patients with comparable surgeries.[6, 9, 13, 14] Yet, the definition used in this study covers each wound rupture (level I, II and III), irrespective of size.[17] Such definition is more encompassing than that used in the study by Gaarenstrom et al.[6] in which 17% of patients had a wound disruption over more than one third of the

length of the incision. Therefore, compared with that in Gaarenstrom et al., a higher prevalence could be anticipated in the current study.

In contrast to similar studies, the rate of documented wound infection (5.6%) was lower. Leminen et al.[9] reported that 47% of the patients in their study had wound infections, Gaarenstrom et al.[6] reported a 9% rate in vulvar region and 39% in the inguinal region, Van der Zee et al.[13] reported a rate of 4.5% after sentinel node procedure and 21,3% after lymphadenectomy, and Carlson et al.[14] a rate of 14% in vulvar region (33% in the fibrin sealant arm) and 35% in the inguinal region (36% in the fibrin sealant arm).[6, 9, 13] The low rate of infection in the current study may be related to the strict Centers for Disease Control and Prevention definition used. In contrast to the findings of Gaarenstrom et al.,[6] in the present study, both wound dehiscence and infection were more common in the vulvar than the inguinal region. Wound dehiscence and infection rates may have been related to the surgical techniques, the Redon drains and sutured closure after inguinal lymphadenectomy used in the participating hospital, or due to the differences in the prevalence of risk factors such as tumor localization, urine and fecal incontinence. These risk factors should be systematically recorded and examined in the future.

In this study, hematoma (12%) and necrosis (6.5%) were the second and third most frequent WCs. The prevalence of seroma was 4.6% in the current study. Lymph cysts (1.9%) were a relatively rare WC in the current study, in comparison with a 7% prevalence rate reported by Leminen et al.[9] and a 40% rate reported by Gaarenstrom et al.[6] Malignant wounds (1.9%) were rare in the current study which is consistent with the previously reported low prevalence (3%) of malignant wounds in the groin and genital region.[19] Interestingly, no other VC studies examining the prevalence of seroma and necrosis were found. Hematomas, malignant wounds, and lymph cysts have seldom been mentioned in other VC studies despite that they are well-known postoperative WCs and that they require additional therapies. Another WC, disturbed tissue formation, was not observed in this study sample. The absence of this wound complication was assuredly affected by the relatively short duration of hospitalization (median = 11 days) and the 30-day measurement period.

Two of the risk factors examined, the type surgical therapy and inguinofemoral lymphadenectomy, were significantly associated with short-term WCs in the current study. These findings are consistent with findings of other studies that reported a significant association between radical vulvectomy and inguinofemoral lymphadenectomy and WCs.[9, 11] Leminen et al.[9] reported that modified surgical techniques decreased wound dehiscence rates by 27% and infections by 28%. Recent studies suggest that sentinel node dissection in vulvar cancer is a safe alternative to inguinofemoral lymph node dissection and reduces the morbidity associated with surgical treatment.[13]

3.4.1 Limitations

Despite reviewing medical records of women who had been treated surgically for VC over an 11-year period, the low incidence of VC resulted in small sample of 108 women. The small sample limited the power to detect relationships that may have been evident with a larger sample.

Given that the data collection was limited to only 1 hospital, the results might not be representative of other hospitals. Owing to the retrospective data collection from medical records, mainly nominal variables were obtained with low information content (information bias). Nevertheless, a complete and accurate data collection was performed. An accurate recording of wound location was only possible in case of infection and dehiscence. The limited sample size allowed no regression analysis per WC type. Moreover, the study design did not allow for a description of causal relationships.

3.5 Conclusions

Acknowledging these limitations, the high prevalence of 45.4% short-term WC and 2 identified risk factors supported by findings in previous studies indicates that focused systematic wound assessments and early risk management are important components of the care for women with VC, especially patients with an increased risk after hemivulvectomy, radical vulvectomy, and inguinofemoral lymphadenectomy. The study results should enable clinicians to better identify patients with an increased risk for WCs and to provide appropriate interventions. In our hospital, we implemented a process guideline for regular postoperative multidisciplinary wound assessments performed by a physician, a nurse and a wound specialist in patients at risk. Further studies are being developed to enhance postoperative wound assessment for patients with vulvar cancer.[20]

Although other studies described several risk factors as predictors for WCs,[6, 9, 11, 14] this study found only 2 significant predictors, an aspect that requires further investigation. Given the rarity of VC, international, prospective multicenter studies are necessary[21] to clarify influencing factors on short-term and long-term WCs. Studies should examine additional risk factors and use uniform definitions and standardized survey instruments to provide the evidence base for systematic wound management.

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CHAPTER 4:

THE UNSPOKEN DISEASE: SYMPTOM EXPERIENCE IN WOMEN WITH VULVAR NEOPLASIA AND SURGICAL TREATMENT: A QUALITATIVE STUDY

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Modified version

Abstract

Background

Women with vulvar neoplasia often experience severe post-surgical complications. This study focuses on symptom experience of women during the first 6 months following surgical treatment for vulvar neoplasia considering their socio-cultural context.

Methods

In this qualitative study using a critical hermeneutic approach, narrative interviews were conducted. A purposeful sample of 20 patients was recruited from 1 Swiss and 2 German University Hospitals. Content analysis was employed to analyze the transcribed interviews considering women's experiences and social perceptions.

Results

Narratives showed eight interrelated themes: delayed diagnosis, disclosed disease, disturbed self-image, changed vulva care, experienced wound-related symptoms, evoked emotions, affected interpersonal interactions, and feared illness progression. The women experienced a general lack of information pertaining to above themes and all described strategies used to handle their situation, which affected their distress. The communication, assessment, and treatment of symptoms were hampered by the society's and the health system's tendency to overlook these symptoms and leave them in the realm of the unspeakable.

Conclusions

Health care professionals need new strategies to support these women to recognize, assess, and evaluate the seriousness of symptoms, and to communicate their symptom experience so that timely medical treatment is sought. This support may minimize potentially preventable complications and symptom-related distress.

4.1 Introduction

Women with vulvar neoplasia often experience severe post-surgical complications,[1] but there is limited research on their symptom experience. The term 'vulvar neoplasia' comprises the diagnosis of vulvar intraepithelial neoplasia (VIN)[2] and the diagnosis vulvar cancer.[3] VIN is the presence of abnormal keratinocytes in a woman's external genital that have the potential to develop into invasive carcinoma.[4] Human papilloma virus infection and older age can affect the risk of developing vulvar cancer.[5] About 30–50% of women with VIN or squamous cell carcinoma of the vulva will develop recurrent disease within 2 years of primary treatment.[4, 6] Surgery is the standard therapy for women with VIN and vulvar cancer.[4, 7] It consists of different surgical treatment methods such as local excision, laser vaporization, partial or radical vulvectomy and an inguinofemoral lymph node dissection depending on disease stage and the lymph node involvement. VIN is a premalignant skin condition and the majority of women with VIN require surgical treatment such as a local excision or a laser therapy.[8-10] Surgical interventions for VIN cause psychosexual morbidity and impact womens' quality of life.[8, 9] Even relatively small excisions are susceptible to post-surgical complications.[11] Although surgical modifications have been made to reduce postoperative morbidity in women with vulvar cancer,[12] the prevalence of complications, such as 30-70% rates of lower extremity lymphedema,[13-15] 20-40% wound complications[16-18] and psychosexual effects[19, 20] remain high.

Despite these reported complication rates, to date, little is known about the complication-related symptom experience of women and how socio-cultural aspects like stigma influence these experiences. Symptom experience is defined as patients' perceived indications of disease or changes in their biopsychosocial functioning and cognition.[21] Studies have shown that a significant proportion of cancer patients reported severe symptoms that were not detected by clinicians during routine consultations.[22, 23] Therefore the assessment of symptom experience is crucial in identifying immediate health care needs and in providing high-quality care.[24, 25] Three previous qualitative studies, showed that affected women reported symptoms such as vulvar bleeding, odor, pain, itching, burning, irritation, as well as problems with vulvar self-examination, leg swelling, sex, body appearance, loss of control, lack of information, shame, embarrassment, trouble controlling urine and constipation.[26-28] These studies rarely took the socio-cultural context influencing women's experiences into consideration. In summary, there is very limited research on the symptoms of affected patients. We found no published study that offered a conceptual framework and addressed the socio-cultural aspects of the symptom experience in these women in Germany and Switzerland. Therefore, this study will

contribute to a comprehensive understanding of the symptoms and symptom-related experiences by women during the first 6 months following surgical treatment within their socio-cultural context. The goal is to identify the main themes, and understand the meaning of symptoms from a patient perspective. This knowledge is crucial to improve communication about symptom experience, to assess symptom experience, to develop interventions to improve self-management of symptoms and to prevent symptom-related complications (e.g. wound infections) in the future.

4.2 Methods

This qualitative study is part of a larger mixed-methods research project (Clinical Trial ID: NCT01300663). We used a critical hermeneutic approach to identify the relevant individual themes of women with vulvar neoplasia embedded in a wider socio-cultural context.[29] Heideggerian hermeneutics, an approach to interpret and understand the meaning of people's lived experiences,[30] provided the philosophical underpinning. Diekelmann, Allen and Tanner[29] described the used critical hermeneutic process of data analysis, focusing on language and understanding of people as well as on the study of texts, in relation to wider socio-cultural aspects.[31] This process aims at uncovering meanings that may be hidden from social actors themselves,[32] and at generating knowledge, which contribute to empowerment and change.[33]

The study was approved by the ethical committees of Berne, Switzerland; Freiburg (No. 385-09) and Munich (No.412-09), Germany. A sample of affected women was recruited from gynecological wards or ambulatory clinics/facilities at 1 Swiss (Berne) and 2 German University Hospital's (Munich, Freiburg) based on the inclusion and exclusion criteria (Table 1).

Table 1. Inclusion and Exclusion Criteria.

Inclusion criteria	Exclusion criteria
• Older than 18 years	• Cognitive impairments which hinder to make an interview
• Able to read and write German	• Concurrently psychiatric treatment
• Diagnosis vulvar neoplasia (condyloma accuminatum, vulvar intraepithelial neoplasia pagetoid type, vulvar intraepithelial neoplasia, melanoma, squamous cell carcinoma)	• Terminal illness
• Vulvar surgical treatment in the last 6 months[a]	

[a] Surgeries were performed with standardized methods according the guidelines of German Society for Gynecology and Obstetrics.

To include a broad range of experiences, women were chosen purposefully considering variation in the following factors: diagnosis, age groups, time points after surgery, and surgical techniques.[1] They were contacted during hospitalization or after discharge and invited to participate in the study by a physician or a nurse. The first 2 authors contacted the women who agreed to participate and conducted 10 interviews each between September 2009 and March 2010. The 2 nurses, 1 with a Bachelor and 1 with a Master Degree, had experience in gynecological nursing care but neither was involved in direct clinical care when conducting the interviews. Both were educated in qualitative research and received extensive interview training and supervision by the senior researchers. All interviews were conducted in a private room, according to women's' preferences, in their homes or in the clinic. Interviews lasted 40-80 minutes (Table 2).

Table 2. Examples of interview questions.

Narrative interviews with open-ended and focused questions [a]
The interviews began by inviting women to tell their story:
'How are you at the moment?'
'How did you experience the time since your surgery?'
The Subsequent questions were guided by patients' answers, such as:
'Could you tell me more about your bleeding in the vulvar area?'
Finally the interviewer clarified any unresolved issues using focused questions, e.g.:
'How did you handle the vulvar bleeding?' or
'Which emotions did you experience during vulvar bleeding?' or
'You mentioned, not having spoken with others about your diagnosis, what type of communication was hampered?'

[a] Written informed consents were obtained prior to each interview.

Data collection and analysis occurred in parallel. This allowed revision of the interview guide as new themes emerged. For example, after the first 6 interviews, new questions were added about caring for the vulva. All women completed a socio-demographic data form. The interviewer contacted a physician or a nurse after the interview to gather medical information from medical records.

The data analysis was started after the first 2 interviews and it influenced further analysis. As some pre-surgical and post-surgical symptoms of participants were similar and pre-surgical symptoms affected women's symptom experience after surgery, this timeframe was included in further data analysis. All interviews were audio-recorded, transcribed verbatim, and organized in ATLAS.ti 5.6.3 (ATLAS.ti GmbH, Berlin, Germany). Pseudonyms have been used for participants. Data analysis was performed using a seven-stage process to identify categories, themes and constitutive patterns.[29] Critical hermeneutics allowed reflection and interpretation of the text and its language. By taking notes after each interview and by relating text interpretation to additional literature, socio-cultural aspects during conversation were considered (Table 3).

Table 3. Content analysis conducted in this study.

The seven stage process according to Diekelmann et al. (1989)
1. The first 2 authors read all the interview texts for an **overall understanding**
2. The first 2 authors summarized each interview and inductively identified **categories**. The first 2 authors and the fourth author with scientific and clinical expertise in gynecological oncology and experience in qualitative research analyzed selected transcribed interviews. Dialogue among team members clarified the analyses with group consensus as the goal.
3. The research team[a] (consisting of 4 members) with experience in qualitative research compared the interpretations of identified categories for similarities and differences. Discrepancies were clarified by referring to the text. The **socio-cultural context** was considered by relating interpretation to additional literature (historical, cultural literature, e.g. concerning the vulva in a German-speaking society within Europe).
4. The research team discussed similar and contradictory meanings of the categories, identified and documented **relational themes** (a theme cuts across all texts). Any disagreements in interpretation were resolved by going back to the text.
5. The research team discussed common meanings by comparing and contrasting the text as well as the relationships of the relational themes and identified **constitutive patterns** (present in all the documents).
6. An external expert in qualitative research reviewed the entire analysis.
7. Suggestions of the research team members regarding the draft of the final report using sufficient excerpts were incorporated into the final report.

[a] Five peer group meetings with four qualitative research members (B. Senn, D. Gafner, M. Eicher, R. Spirig) took place during data collection, to establish some degree of intersubjectivity.[31] Feedback on the research findings were obtained from six participants to ensure that participants' own meaning were represented.

As the translation of the interviews from oral into written text and the translation of quotes from German into English language were subject to interpretation, we tried to enhance trustworthiness of this analytical process. The first 2 authors conducted all interviews, read all transcripts, and individually analyzed the transcribed text to then identify and discuss categories. This process of data analysis was supervised by the fourth and last authors who are experienced qualitative researchers. The first author translated the entire analysis and specific excerpts illuminating the practices and concerns relevant to each woman and prepared a draft of the final report in English. Quotes were back translated. The first and third author, the latter is a native English-speaker, discussed the entire analysis word by word and the draft report during 3 personal meetings and online to enhance the representation of participants' own meaning in the translated text.

4.3 Results

4.3.1 Participants

Fifty-five women were screened for eligibility. Thirty-six were approached for study inclusion and 20 agreed to participate and were interviewed (11 in Berne, 6 in Freiburg, 3 in Munich). Primary reasons for not participating in the study were being too busy or too ill. Pattern recognition occurred after the 17th interview and no new themes were identified during the last 3 interviews; thus, sampling ceased. Characteristics of participants are listed (Table 4).

Table 4. Socio-demographic and Medical Characteristics (n = 20).

Variables	Frequency, Median	%, IQR
Age		
In years	55.5 (ME)	44.5-72.5 (IQR)
Marital status		
Single	4	20%
Married	7	35%
Widowed	6	30%
Divorced	3	15%
Nationality		
German	9	45%
Swiss	10	50%
Thai	1	5%
Educational level		
10 or less school years	5	25%
More than 10 years	15	75%
Employment status		
Working	12	60%
Not working	8	40%
Living arrangement		
Alone	8	40%
With the partner and / or children	12	60%
Help with wound management		
Without help	15	75%
Help of a health care professionals	3	15%
Help by a non-health care professionals	2	10%
Type of vulvar disease		
Condyloma accuminatum	3	15%
Vulvar intraepithelial neoplasia, pagetoid type	1	5%
Melanoma	2	10%
Vulvar intraepithelial neoplasia (II & III)	5	25%
Vulvar squamous cell carcinoma	9	45%
Stage of disease (International Federation of Gynecology and Obstetrics)		
0	9	45%
Ia and Ib	6	30%
II	1	5%
III	4	20%
Recurrent diagnosis	8	40%
Surgical therapy		
Local excision	2	10%
Laser-vaporization	9	45%
Partial vulvectomy (ant-, posterior or unilateral)	4	20%
Radical wide excision / vulvectomy (bilateral)	5	25%
Lymph node dissection		
Sentinel	9	45%
Inguinofemoral	4	20%
Removed lymph nodes	0 (ME)	0-3.5 (IQR)
Radiotherapy		
Adjuvant postoperative radiotherapy	1	5%
Length of hospitalization (in days)	6.5 (ME)	2-10.25 (IQR)

IQR, inter quartile range; ME, median

4.3.2 Symptom experience

Narratives showed key themes composing the essence of women's symptom experience focusing the postoperative phase: delayed diagnosis, disclosed disease, disturbed woman's self-image, changed vulva care, experienced wound-related symptoms, evoked emotions, affected interpersonal interactions, and feared illness progression. The identified themes were consistent across different surgical procedures. The pattern present in all narratives was that women experienced a lack of information with regard to the above interrelated themes and that all of them used strategies to handle their situation, which affected their distress level. Women's symptom experience was affected by the socio-cultural context and the health care system (Figure 1).

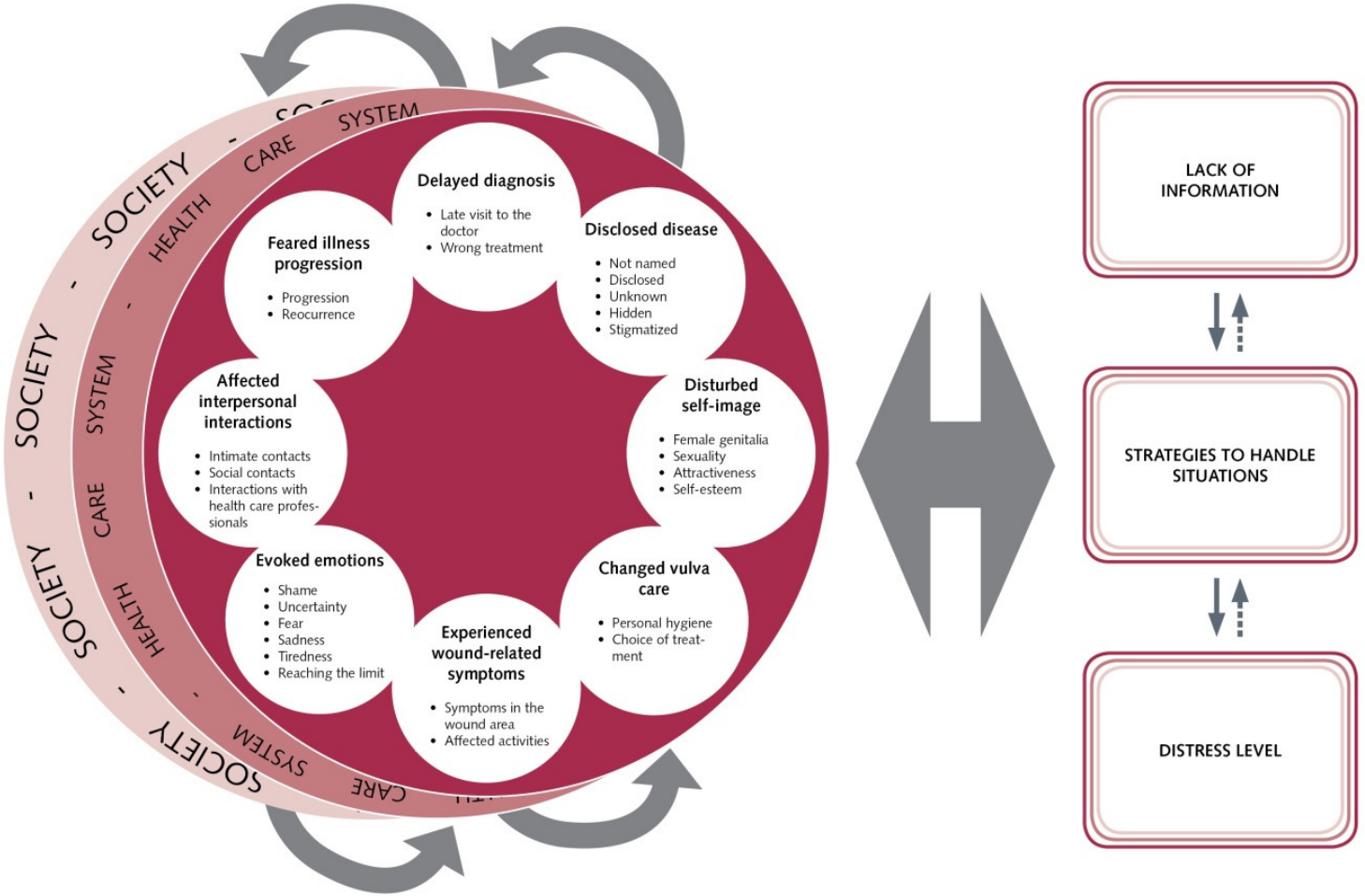

Figure 1. Symptom Experience in Women with Vulvar Neoplasia and Surgical Treatment: A Conceptual Model.[a]

[a] The conceptual model presents also the coding scheme, including the eight interrelated themes (headings in the white circles) with their subordinate categories (listing in the white circles). Women experienced a lack of information about the interrelated themes and all used strategies to handle their situation, which affected their distress. Women's symptom experience was affected by the socio-cultural context and the health care system.

4.3.3 Delayed diagnosis

Eleven of 20 women experienced a delayed diagnosis. The diagnostic delays formed the context for their experience of symptoms before surgical intervention. Some delayed visiting the doctor and others felt that they were misdiagnosed and treated inappropriately. Different reasons for a delayed diagnosis were mentioned. Most women were surprised that cancer can occur in the genital area. One mentioned that if she had known this fact she would have gone to the gynecologist earlier when symptoms such as swelling, pain, itching, pressure, open skin first occurred. Older participants often felt embarrassed and delayed visiting the doctor. Linda, an 80-year-old woman, with a vulvar intraepithelial neoplasia grade III stated:

> *The others are probably thinking I am crazy. What does she have down there? It is a stupid place, so that you sometimes have inhibitions. …I thought, now it's enough, I can't stand it any longer, I now have to look, if I can see anything… It looked strange, bumpy. Then I thought, now I have to go…, ashamed, but no choice.*

Younger women more often felt that they were treated inappropriately, e.g. for herpes for months, although they regularly went to their check-ups. They believed that clinicians ignored their symptoms. Two women changed doctors on their own initiative to obtain the correct diagnosis, because their clinicians had a lack of familiarity with the signs and symptoms of this rare disease.

4.3.4 Disclosed disease

The symptoms experienced by women with vulvar neoplasia and the location of neoplasia often remained unspoken. Nearly all women avoided and paraphrased the location of their disease with terms such as, 'down there', 'it' or 'thing'. Friends, colleagues and neighbors were only told it is a diagnosis in the 'lower body area'. Most women only revealed their diagnosis with information about the location to 1 close relative, usually a partner, a daughter or a sister. Linda said:

> *I have not told [my daughters] directly. I showed the medical report only to Sarah [one daughter] who said: 'This is something I have never heard of'.*

Vulvar neoplasia, an unknown and hidden disease in our society, has been attributed to stigmatized behaviors such as promiscuity. Women were concerned that others would attribute their disease to inadequate hygiene, promiscuity or deformities and they felt uncertain or ashamed. Kathrin, 58 years old reported:

> *I think it's somehow so hurtful. They [others] did not have an understanding at all... [They thought:] Does one get such a thing, if one has too much sex or does not wash oneself?*

Participants feared being stigmatized and were, therefore, reluctant to disclose the exact nature of their disease.

4.3.5 Disturbed self-image

The surgical intervention influenced participants' self-perception of being a woman in mainly 4 dimensions: the appearance of changed female genital, sexuality, attractiveness and self-confidence. Depending on the extent of surgery, the women's descriptions of surgery ranged from an embarrassing procedure to a disfiguring and mutilating surgery. Elisabeth, a 46-year-old woman, described her female genital after a vulvectomy using the words 'it looked totally disfigured… ugly' and mentioned feeling embarrassed when anticipating the situation of a partner who would see her vulva. Pamela, 80 years old, even used the strong metaphor of a 'bloody pig' to describe her feelings about the bleeding wound after vulvar cancer surgery:

> *I thought, now you're open, like when they kill a pig, but it later closed a little.*

Sandra, a 25-year-old woman, described her impression when she looked at her vulva after a laser vaporization with words as 'dirty' or 'unclean'. This impression affected her feelings of attractiveness and self-confidence:

> *[It] is not beautiful. It eats away a little bit at the self- esteem.*

Harriet, 55 years old even reported that her whole female self-image was changed:

> *When I walk through the city …. I have the feeling that I am surely the only woman running around here now with half a vulva. … I feel incomplete.*

4.3.6 Changed vulva care

Almost all women reported searching actively for information in order to perform adequate vulva care, even if they had not reported having a delayed or problematic wound healing process. Their personal hygiene took more time than before surgery. Caring for the female genitalia was done in a variety of ways and the choice of treatment was trial and error: Women washed their genitals with a washcloth, used only the shower, a Bidet or sits baths with various additives. Emilie, 67 years old, went through trial and error experiences related to recurrent vulvar cancer surgeries during the last 30 years, until she found out which kind of vulva care best supported the wound healing process after surgery. She got the additives from her daughter, who obtained them from her midwife. Even after her long illness trajectory, Emilie is not sure if she needs both additives (Tanolat and Calendula) in her sits bath:

> *I first made this with chamomile but chamomile tears it [the wound] open. [Afterwards] the Tanolat…, I put it into the sits bath, in warm water.... I put also a couple of drops [Calendula] into it. I do not know if I need both, in any case … it is very good.*

4.3.7 Experienced wound-related symptoms

The theme, wound-related symptoms, included symptoms in the wound area, the inter-relationships between emotions and other wound-related symptoms, symptom distress, activities affecting wound healing, and handling wound-related symptoms.

Women experienced and managed different symptoms in the wound area: bleeding, drainage (clear, cloudy, and purulent), warmth, swelling, redness, pain, itching, unusual odor, burning, altered sensation, pressure, hardness, open spot (skin or suture), scaring, and/or unusual skin color. These symptoms were affected by activities such as urination, bowel movements, sitting, wearing clothes, daily activities in the household and the workplace (Table 5). Pamela described her pain during urination after surgery, her symptom-related distress, the unexpected time frame of the symptom and how she handled this symptom:

> *You're passing water and you think that you are burning. It hurts so much! That is sheer madness, because one doesn't expect it. You think now that surgery is over, it will burn a little bit for a few days, but that was a pain. And now, the black tea helped [relieve the burning pain].*

Most women with vulvar intraepithelial neoplasia and vulvar cancer reported that symptoms occurred and were most distressing during the early post-discharge period. Some women had experienced symptoms and related difficulties in daily life over several months, especially women with progression of the disease, a recurrence of the neoplasia or a complication.

Table 5. Wound-related Symptoms in Women with Vulvar Neoplasia and Surgical Treatment.

Symptoms [a] in the wound area and affected activities	
Symptoms in the wound area	**Affected activities**
• bleeding • drainage (e.g. clear, cloudy, purulent) • warmth • swelling • redness • pain • itching • unusual odor • burning • altered sensation (e.g. numbness) • pressure • hardness open spot (skin or suture) • scaring • unusual skin color	• urination • bowel movement • sitting for a period of time • wearing clothes (e.g. underwear, trousers) • daily activities (e.g. walking) • activities in the household (e.g. cooking) • activities in the workplace

[a] Symptoms occurred and were most distressing during the early post-discharge period. Some women had experienced symptoms and related difficulties in daily life over several months, especially women with progression of the disease, a recurrence of the neoplasia or a complication.

4.3.8 Evoked emotions

The unknown diagnosis, the surgery, the location, the changed female genital and the experienced symptoms evoked feelings of embarrassment, uncertainty, fear, sadness, and tiredness bringing some women to the limit of their endurance. Seeing the vulva the first time after the surgical treatment evoked strong feelings. Amanda was 'shocked' the first time she saw the vulva during a follow-up visit. Most women did not know how to care for the vulva and the common postoperative symptoms to expect which resulted in fear. Susan diagnosed with vulvar intraepithelial neoplasia grade III stated:

> *The fact that passing urine can burn, or it is uncomfortable to sit, or wear pants or something... that you just want to know, if I have this, is it normal? Otherwise ... one may have fear and think that, I am not within the norm.*

4.3.9 Affected interpersonal interactions

For some women, the diagnosis, the surgical treatment and the postoperative symptoms affected their intimate and social contacts as well as interactions with health care professionals. Some women changed their perceptions about intimate contacts and their behavior in a partnership. Marianne, a single woman with a vulvar intraepithelial neoplasia grade II, reported:

> *There are some days where I would like to have a partner again, but I think I can't expect this of someone. With this mindset, I will withdraw completely.*

Mary, 37 years old with a vulvar intraepithelial neoplasia grade III treated with laser vaporization was living in a partnership. She asked herself why she was affected by the human papilloma virus and reported:

> *It is not easy to speak with the partner … I felt guilty …and somewhere you are always open [in the female genital] ... and the first times after surgery sexuality was not the same as before ... perhaps you were cramped and had not enjoyed [the sexual intercourse]… it is important to speak with the partner and he should be informed … yes one relationship [with another partner] was broken therefore [because of the disease].*

Some women minimized the frequency of their contacts with friends due to their symptoms experienced following the surgical treatment. Many women described the importance of social contacts such as with family members or colleagues at their working place. They described helpful and difficult situations. Most women felt uncertain about how to behave and how to speak about their disease and their symptom experience. Sandra went back to work 1 week after laser vaporization as her doctor had told her to and said:

> *I went to work after 1 week, that was really stupid. Working was sometimes difficult, because you don't want to do less than before. And nobody knew about it [the vulvar intraepithelial neoplasia]. Perhaps I should have said something [to my colleagues]. ... I have scars from this first surgery, they will never disappear... If you would have cared for it [the wound] better, rested, perhaps I would have no [scars]. … At that time I felt mentally not well … I think it is important that you explain it [the vulvar disease and surgical treatment] ... so that you would have been protected.*

Trying to behave as normally as possible and hiding the disease possibly influenced the development of complications and psychological well-being.

In relations with health care professionals such as nurses, clinical nurse specialists, physicians, and doctors women reported that some of them helped with clear advice about looking at the vulva for the first time. Not every woman was told to look at the vulva during her hospitalization and this discovery took place at different time points after surgery, sometimes after hospital discharge or at a follow-up visit. Sophia saw her vulva '…not until at home, then [I] just took a mirror and looked at the wound.' Some health care professionals gave helpful recommendations concerning the wound management (e.g. wound sprays); however, other health care professionals did not even assess the wound healing process during the hospital stay. Elisabeth reported, irritated:

> *The day, before I was discharged, I said I would really like to see what it looks like down there. No one has looked at me, other than where the drainage tube was lying, but no one ever looked at my vagina, after surgery.*

4.3.10 Feared illness progression

Many women reported fears about progression of the disease and recurrence of a precancer or cancer. Sandra, with vulvar intraepithelial neoplasia grade I diagnosis, said:

> *This may come back anytime. This is the silly thing. But, yes, so far I've hoped or feared a little that there is nothing bad.*

Other women associated the neoplasia with a disease progression, even if it was not yet a cancer diagnosis. Hannah with vulvar intraepithelial neoplasia grade III stated:

> *Yes, well, cancer, first comes radiation, then chemo, then death. So, these are the first 3 things that come to mind.*

When women first obtained their diagnosis vulvar surgical interventions helped to save their life, but many of them experienced the above mentioned symptoms and problems nobody told them before. Women with recurrent vulvar diseases usually treated with repeated surgical interventions described a illness journey over years. During this journey women took several efforts to deal with their problems.

4.3.11 A lack of information & strategies to handle situations to decrease distress

Every participant described information needs concerning diagnosis, prevention strategies, therapy procedures, anticipated symptoms, the meaning of symptoms, the wound healing process, strategies to handle symptoms, or the right time to contact a health care professional. Before discharge, Kathrin reported:

> *When I'm here [at the hospital], someone can always look at it. But when you get home, you are never able to evaluate it. Should I go to the doctor now or not?*

Affected women described a lack of information as very distressing, especially in the first days after discharge.

All women highlighted ineffective and effective ways to get the required information and strategies to handle their situations. They stated that the most effective factors were optimism, supportive social contacts and confidence to cope with difficult and sometimes overwhelming situations. Sophia found a way to get information:

> *I had many conversations with my daughter, she has a little idea; she is working in a cancer clinic and talking to her helped me a lot.*

4.3.12 The socio-cultural context and the health care system

Social values and norms affected women's concerns with regard to the above interrelated themes. Women for example felt embarrassed to talk about their sexual organs to others, especially to men. Sandra searched for an appropriate term to name her vulva and her disease:

> *To speak with another woman is easier anyway. But if there is a man, he has no idea what a uterus is. He is thinking, woman stuff. But, when I should have explained something more. What do I say? It is abnormal cells in the vagina? And afterwards, what will he have in his mind? … it is something that can be hard to imagine because you have not seen it. … You are simply ashamed.*

The diagnosis and treatment pushed women to break society's secrecy about vulvar diseases.

In addition healthcare values, norms, and power relations shaped concerns with regard to the above interrelated themes. For example, several women's wound assessments were discordant with health care professional's assessments. Kathrin was not educated to look at her vulva with a hand mirror. She recognized 2 weeks after vulvar surgery symptoms of infection, bad odor and pain, but her concerns were dismissed by nurses:

> *I feel quite misunderstood. ... So I thought it was very painful. It has now improved. So last Friday they began to treat these wounds. Before that, nothing had actually been done. ... If they checked it, they said: 'It really is not that bad and it will be all right'.*

Due to the disease it became necessary for women and health care professionals to look at this hidden part of the female body and to assess symptoms appropriately so that timely medical treatment was initiated.

4.4 Discussion

This multicenter study is the first to report knowledge about symptom experience of women with vulvar neoplasia focusing on the post-surgical phase while employing a critical hermeneutic approach and embedding the experiences of women within their socio-cultural context. The major issues that women faced after surgery were stigmatization related to the location of their disease, how to care for the vulva, and dealing with multiple symptoms. Assessment, communication and treatment of symptoms were hampered by social taboos which left vulvar symptoms in the realm of the unspeakable. The society and the health care system have the tendency to overlook these symptoms.

These findings are in line with Scholz's description that speaking about the vulva is taboo and evoked feelings of guilt.[34] The vulva is a neglected area of the skin, hidden away by ignorance, with the result that women with vulvar diseases, are desperate for help, suffer needlessly and waste money on inadequate treatment.[35] The visible parts of the female genitals have been described as linguistically invisible with no independent meaning.[36] The lack of common vocabulary among health care professionals and patients may make it more difficult for women to talk about the vulva, vulvar disease and care. Many of the medical terms used by clinicians may not be understood by women. For many women it is socially unacceptable to talk about problems 'down there'. In our society the social stigma of vulvar neoplasia threatens the identity of affected women and they fear discrimination. The control of information and techniques of deception are perceived as necessary to prevent discrimination. To protect one's identity, stigmatized people often use 1 of 2 techniques either hiding the problem or pointing it out.[37] Pamela for example pointed her problem out by using the metaphor of a 'bloody pig'.

Consistent with findings in previous studies,[19, 20, 38, 39] themes identified in this study included changes in self-image and concerns about sexuality. To improve care for affected women, health care professionals should explore these issues with them and give information on sexual activity or refer patients for counseling. Management of psychosexual effects of treatment should inform women on how the disease and treatment can affect their sexual self-concept, relationships, and functioning, as well as long-term consequences and how to overcome these alterations.[11, 40]

Patients need 3 fundamental resources to manage their symptoms and to avoid complications.[41] They need to be (1) informed about expected symptoms and effective strategies to prevent complications, (2) motivated to change and maintain daily health behaviors to self-manage their symptoms, and (3) prepared with behavioral skills to manage their symptoms at home.

Consistent with a recent published article,[28] many women in this study reported an information gap about what to expect and how to care for their vulva and to manage their surgical wound. This gap evoked negative emotional responses, affected relationships and caused potentially preventable distress. Jefferies and Clifford[28] described women's experiences as 'searching to control emotions' and emphasized their personal informational needs as well as a need to raise awareness of vulvar cancer through publicity for women in general and increased availability of relevant information. In this study affected women reported evoked emotions such as embarrassment throughout the course of their illness. This is probably due to the fact that VIN and vulvar cancer are rare diseases[42, 43] and knowledge about the disease in our society and in our health care system needs to be developed further.[26, 28, 44]

To enable patients to self-manage post-surgical care, health care professionals should encourage them to look at the vulva prior to discharge because this allows explanation of the changes that have occurred with surgery.[11] Self-assessment is necessary to evaluate symptoms and to prevent complications.[45-47] Systematic information is essential for patients[48, 49] to know which symptoms are part of a normal wound healing process, and which may indicate complications or may indicate reoccurrence of their cancer and the information should include guidelines for when the health care professional should be contacted. Without a clear understanding of wound healing-related symptoms, women may worry that many 'normal' or 'expected' postoperative symptoms mean that their cancer has reoccurred. Differentiated VIN diagnosis has been frequently missed and is associated with rapid progression to squamous cell carcinoma.[50] To date no standard screening programs exist to detect precursor lesions and, therefore, health care providers should be aware of the clinical features of vulvar neoplasia.[51, 52]

To date the consequences of delayed consultation in case of complications remain unknown, but it can be estimated that a delay in recognition of early symptoms of complications or complicated wound healing leads to a delay in seeking treatment and therefore results in complications that are more advanced, difficult and costly to treat. For example, Langbecker et al.[53] emphasized that the assessment, treatment and advice about lower limb lymphedema in cancer patients are important for early detection of lymphedema.

The study investigating the symptom experience of women with vulvar neoplasia and embedding these experiences in a wider socio-cultural context was subject to a number of limitations. Recruiting a small and purposeful sample of women at different tumor stages and undergoing radically different surgical treatments in university clinics limits the transferability of the findings to a larger population of patients and other settings.[54] As some women, who were considered as being too ill to participate in the study were excluded, selection bias might have affected the findings. Another limitation of the study is related to the formulation of the study goal and the method of data transcription and analysis

undertaken by qualitative researchers. The researchers, born and raised in Switzerland or Germany and the third author an American, have a background understanding as nurses and were trained in advanced practice nursing. Our background certainly influenced the formulation of the study goal and the data analysis. The experience of an interview is changed when translated to the written text. Furthermore language translation from German to English which is a form of interpretation could have influenced the data analysis process.

4.5 Conclusions

Despite the mentioned limitations, the experiences of the 20 women interviewed in this study are indicative of a need for action and change especially in postsurgical care. Women with VIN and vulvar cancer at different tumor stages and undergoing different surgical treatments experienced similar pre- and post-surgical symptoms, even after minimal invasive surgery. They handled diverse tasks and gained skills to deal with symptoms throughout the course of their illness. Health care professionals and the socio-cultural context enabled or complicated the handling of symptoms. Physical and psychosocial symptoms as well as informational needs seem to be apparent over months. In line with Jefferies and Clifford's findings,[28] even if diagnosis and appropriate treatment is found, it seems to be a lonely journey for women diagnosed with VIN or vulvar cancer.

This study is a first step in developing a conceptual framework of symptom experience of women with vulvar neoplasia. The data provide a foundation to develop a self-report measure to help women with vulvar neoplasia recognize, assess, and evaluate the seriousness of symptoms so that medical treatment is sought in a timely manner. This measure could be employed to monitor symptom experience in clinical studies and in the routine clinical follow-up of patients. Furthermore health care professionals should facilitate patients' ability to communicate tabooed symptoms by providing structured information on expected symptoms.

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CHAPTER 5:

BANGEN UND HOFFEN: ERFAHRUNGEN VON FRAUEN MIT VULVÄREN INTRAEPITHELIALEN NEOPLASIEN WÄHREND DES KRANKHEITSVERLAUFS: EINE QUALITATIVE STUDIE

[BETWEEN ANXIETY AND HOPE: THE EXPERIENCES OF WOMEN WITH VULVAR INTRAEPITHELIAL NEOPLASIA DURING THEIR ILLNESS TRAJECTORY: A QUALITATIVE STUDY]

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Abstract

Background

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, little is known about women's experiences throughout their course of illness. Therefore the aim of this study was to describe the experiences of women with VIN during their illness trajectory.

Methods

In a secondary data analysis of the foregoing qualitative study we analyzed eight narrative interviews with women with VIN. We used thematic analysis in combination with critical hermeneutics.

Results

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 narratives showed women's experiences during their illness occurred in five phases: (1) There is something unknown; (2) One knows, what it is; (3) It is treated and should heal; (4) It has effects on daily life; (5) Meanwhile it works. These phases showed many women (1) had a late or incorrect diagnosis; (2) despite having a diagnosis women did not know what they suffered from; (3) experienced a high uncertainty in decision-making during treatment, (4) VIN had an impact on their physical and psychosocial level; and (5) that the women learned over time to deal with their illness. Women's experiences were influenced twofold, by their feelings of 'embarrassment' and in 'dealing with health care professionals'.

Conclusions

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 counseling and providing information need to be developed and evaluated.

Zusammenfassung

Hintergrund

Die vulväre intraepitheliale Neoplasie (VIN) ist eine seltene chronische Krankheit, die zu einem invasiven Karzinom der Vulva fortschreiten kann. Symptome von VIN, negative Auswirkungen auf die Sexualität, die Ungewissheit der Krankheitsentwicklung und Körperbildveränderungen wurden von betroffenen Frauen als die schlimmsten Begleiterscheinungen benannt. Zum Erleben des Krankheitsverlaufes bei VIN ist jedoch wenig bekannt. Ziel dieser qualitativen Studie ist es, das Erleben von Frauen mit VIN während dem Krankheitsverlauf darzustellen.

Methoden

In einer Sekundäranalyse der qualitativen Daten der WOMAN-PRO Studie wurden acht Interviews mit Frauen nach chirurgischen Eingriffen bei VIN mittels thematischer Analyse und in Kombination mit kritisch hermeneutischer Reflexion ausgewertet.

Resultate

‚Bangen und Hoffen' stellt ein grundlegendes Muster dar und beinhaltet die stets vorhandene Angst vor Rezidiven sowie die Hoffnung, dass die Therapie wirkt. Es zeigte sich aufgrund der Analyse eine Darstellung des Krankheitsverlaufs in fünf Phasen: ‚Da ist etwas Unbekanntes', ‚Man weiss, was ES ist', ‚ES wird behandelt und soll heilen', ‚ES hat Auswirkungen' und ‚Mittlerweile geht es'. Diese Phasen beschreiben, dass viele Frauen (1) eine späte oder inkorrekte Diagnose erhielten, (2) trotz Diagnosestellung nicht wussten woran sie litten, (3) die Behandlung beschwerlich war, (4) VIN Auswirkungen auf der körperlichen und psychosozialen Ebene hatte und (5) die Frauen mit der Zeit lernten, mit ihrer Krankheit umzugehen. Der Krankheitsverlauf wurde durch das Gefühl der Frauen ‚Sich dafür schämen' beeinflusst, auch das Thema ‚Mit Fachpersonen umgehen' spielte eine massgebende Rolle.

Schlussfolgerungen

Die gegenwärtige Behandlung und Pflege scheint Frauen mit VIN nicht ausreichend zu unterstützen, um diese Phasen adäquat zu bewältigen. Wir empfehlen basierend auf Ergebnissen unserer Studie und der internationalen Literatur neue Modelle der Beratung und Information zu entwickeln und zu evaluieren.

5.1 Einleitung

Die vulväre intraepitheliale Neoplasie (VIN) ist eine seltene chronische Hautveränderung,[1] die zu einem invasiven Karzinom fortschreiten kann.[2] Die VIN stellt für die betroffenen Frauen ein einschneidendes Erlebnis dar und geht mit negativen Auswirkungen auf Lebensqualität und Sexualität sowie mit Schmerzen und Einschränkungen im Alltag einher.[2] Die Inzidenzrate von VIN hat seit den 1970er Jahren zugenommen und liegt derzeit bei 5 pro 100'000 Frauen.[3] VIN (ehemals VIN 2/3 genannt) wird in zwei Typen, die klassische und die differenzierte VIN, unterteilt.[3] Die klassische VIN ist mit 90-98% die häufigere Form und betrifft Frauen die durchschnittlich 30 Jahre alt sind. Zudem ist das Auftreten einer klassischen VIN mit dem Humanen Papilloma Virus (HPV) assoziiert, welches primär über Geschlechtsverkehr übertragen wird.[4] Die differenzierte VIN ist mit 2 bis 10% die seltenere Form. Ihr Auftreten ist nicht mit HPV assoziiert, betrifft mehrheitlich ältere Frauen und geht häufig aus einer vulvären Dystrophie (z. B. Lichen Sklerosus) hervor.[4, 5] Symptome, die auf einen der beiden VIN-Typen deuten, können Juckreiz, Schmerzen, Brennen, Pigmentstörungen und palpable Veränderungen sein. Rund 40% der Patientinnen sind jedoch beschwerdefrei.[4]

Die am meisten verbreiteten chirurgischen Behandlungen bei VIN sind die CO2-Laserevaporisation, die Skinning Vulvektomie und die lokale Exzision.[6] Pepas et al.[7] beschrieben in ihrer Meta-Analyse Hinweise, dass die Anwendung der Imiquimod-Crème (ein lokaler Immunmodulator) für die Heilung von VIN wirksam ist. Jedoch treten bei deren Anwendung Nebenwirkungen wie Schmerzen, Brennen, Juckreiz und Hautrötungen auf.[4] Innerhalb von 36 Monaten erleiden 30% der Frauen, nach einer Therapie bei der klassischen VIN einen Rückfall.[8] Die Kosten für einen einfachen chirurgischen Eingriff bei VIN in Deutschland betragen durchschnittlich 1560€.[9]

Herkunft, Übertragungsweise und mögliche Auswirkungen von HPV scheinen HPV-positiven Frauen nicht immer klar zu sein.[10] HPV-Infektionen lösen bei betroffenen Frauen Angst vor Krebs und vor Verlust der Fruchtbarkeit aus.[11] Die Art und Weise der Information durch Fachpersonen spielen bei der Entwicklung dieser Ängste eine massgebende Rolle.[12, 13] HPV-induzierte Krankheiten können einen bedeutenden Einfluss auf die Sexualität der Frauen haben, sind mit Stigmatisierung, Scham und Unreinheit konnotiert und können in der Partnerschaft Fragen nach Treue und Ehrlichkeit auslösen.[14] Nach chirurgischen Eingriffen an der Vulva haben die Frauen ein erhöhtes Risiko für eine Verminderung der Lebensqualität und der partnerschaftlichen Zufriedenheit. Sie leiden häufiger unter Depressionen und ihr Körperbild kann gestört sein.[13, 15-17]

Unter Einfluss christlicher Werte wurde die Sexualität lange Zeit nur innerhalb der Ehe und zur Zeugung eines Kindes gutgeheissen und ansonsten als Sünde bewertet.[18] Obwohl das 20. Jahrhundert eine Liberalisierung der Sexualethik in Europa mit sich brachte, sind die christlich geprägten Überzeugungen weiterhin wirksam.[19] Diese prägen die Bedeutungszuschreibungen der Vulva, die aus biologischen, emotionalen und symbolischen Gründen als Schlüsselorgan der Erotik und Sexualität gilt.[14] Im Rahmen religiöser Überzeugungen wurde und wird die Vulva als heiliger und heilender, aber auch als Ort der Sünde und des Bösen bezeichnet. Trotz diesen gewichtigen Bedeutungen ist die Vulva ein besonders stigmatisierter Bereich des weiblichen Körpers. Vielen Frauen ist die korrekte Bezeichnung ihrer Vulva unbekannt. In einer Schweizer Studie zur Prävention von sexuellem Missbrauch bei Kindern im Kindergartenalter im Jahre 1997 wurde festgestellt, dass die meisten Mädchen keine Bezeichnung für ihre Vulva kannten.[20]

Bisher wurde das Erleben einer VIN und deren Auswirkungen auf Lebensbereiche wie Arbeit, Freizeitaktivitäten oder Familie in drei qualitativen Studien beschrieben. Senn et al.[21] beschrieben das Erleben von Symptomen nach chirurgischen Eingriffen bei Frauen mit vulvären Neoplasien in der Schweiz und in Deutschland. Betroffene Frauen waren erstaunt über die Lokalisation der Krankheit und wussten nicht, wie sie Symptome handhaben und die Wunde pflegen sollten. Die Autoren schlussfolgerten, dass soziale Tabus die Kommunikation, die Diagnose und die Behandlung der vulvären Beschwerden erschwerten.[21] In einer US-amerikanischen Studie beschrieben Likes et al.,[13] dass betroffene Frauen die Diagnosestellung einer VIN als schockierend erlebten. Die Patientinnen erwähnten das Gefühl von Kontrollverlust, da sie weder den Virus, noch die (wiederkehrenden) Zellveränderungen beeinflussen konnten. Rückfälle und wiederholte Biopsien waren für die Frauen belastend.[13] Auftretende Symptome, negative Auswirkungen auf die Sexualität, die Ungewissheit der Krankheitsentwicklung und die Körperbildveränderungen wurden von betroffenen Frauen als die schlimmsten Begleiterscheinungen von VIN benannt.[2]

Weitere qualitative Studien, welche die Erfahrungen von Frauen mit VIN im zeitlichen Verlauf des Therapieprozesses darstellen, sind notwendig, um Betroffenen eine ganzheitliche, systematische und prozessorientierte Betreuung anzubieten. Eine solche Betreuung ermöglicht es, Frauen mit VIN während dem Krankheitsverlauf ihren Bedürfnissen entsprechend zu unterstützen. Ziel dieser Studie ist es, das Erleben von Frauen mit VIN in deren Krankheitsverlauf zu erforschen und darzustellen. Die Forschungsfrage lautet: Wie erleben Frauen mit chirurgischen Eingriffen bei VIN den Verlauf ihrer Erkrankung?

5.2 Methoden

5.2.1 Studiendesign

Bei dieser Studie handelt es sich um eine Sekundäranalyse der qualitativen Daten der WOMAN-PRO Studie (Klinische Studiennummer: NCT01300663). Die WOMAN-PRO Studie, welche einem sequentiell explorativen Mixed-Methods Design folgte, diente der Entwicklung eines konzeptuellen Modells zur Beschreibung von Symptom-Erfahrungen. In 20 narrativen Interviews wurden Frauen mit VIN oder Vulva Karzinom nach ihrem persönlichen Erleben der Krankheit und ihrer Behandlung befragt.[21] Die Analyse der Symptomerfahrungen machte deutlich, dass sich diese in Abhängigkeit des zeitlichen Verlaufs veränderten. Daher wurde entschieden, diesen Aspekt in einer Sekundäranalyse genauer zu analysieren. Acht der 20 interviewten Frauen hatten VIN. Deren Interviews wurden in die Sekundäranalyse einbezogen.

In dieser qualitativen Studie, wurden Interviews mittels thematischer Analyse in Kombination mit kritisch hermeneutischer Reflexion analysiert. Die thematische Analyse ist eine Methode zur Identifizierung, Analyse und Beschreibung von Themen und Mustern.[22] Die kritische Hermeneutik behält die Patientin im Fokus des Geschehens und reflektiert das gesprochene Wort sowie die daraus resultierenden Handlungen innerhalb des institutionellen und gesellschaftlichen Rahmens.[23, 24] Die kritisch hermeneutische Reflexion und Textanalyse lehnt sich an den hermeneutischen Zirkel an, einem methodologischen Prozess, bei dem zum Erreichen eines vertieften Verständnisses einzelne Textpassagen immer wieder mit dem gesamten Text verglichen werden.[24] Laut Berman et al.[25] wird mit dieser Methode Wissen mit Potential zu Veränderungen in der Praxis generiert. Die Kombination der thematischen Analyse mit der kritisch hermeneutischen Textanalyse nach Diekelmann et al.[23] ermöglicht es, die Analyseresultate systematisch darzustellen und die Daten in einem Forschungsteam kritisch hermeneutisch zu reflektieren.

5.2.2 Untersuchungsgruppe und -ort

Für die WOMAN-PRO Studie wurde eine zielgerichtete Untersuchungsgruppe von Frauen mit einem breiten Erfahrungshintergrund (verschiedene Altersgruppen, Diagnosen, operative Eingriffe und unterschiedliche Zeitpunkte nach dem chirurgischen Eingriff) bei vulvären Neoplasien gewählt. Die Rekrutierung fand in den ambulanten oder stationären Abteilungen eines Schweizer und eines Deutschen Universitätsspitals zwischen dem 1. September 2009 und dem 31. März 2010 statt. Ein- und Ausschlusskriterien für diese Sekundäranalyse sind in Tabelle 1 aufgelistet.

Tabelle 1. Ein- und Ausschlusskriterien für Teilnehmende der Folgestudie

Einschlusskriterien	Ausschlusskriterien
• Alter > 18 Jahre	• Kognitive Einschränkungen, die ein Interview verunmöglichen
• Deutsch mündlich und schriftlich beherrschen	• Aktuelle psychiatrische Behandlung
• Diagnose einer VIN	• Terminale Krankheitsphase
• Chirurgische Behandlungen einer VIN	

VIN, Vulväre intraepitheliale Neoplasie

5.2.3 Rekrutierung der Studienteilnehmerinnen

Pflegende und Ärzte der gynäkologischen Abteilungen beider Kliniken informierten die Patientinnen über die WOMAN-PRO Studie. Die Erst- und Letztautorin kontaktierten interessierte Patientinnen, instruierten diese über den Ablauf der Studie und die informierte Einwilligung. Anschliessend wurde ein Interviewtermin vereinbart.

5.2.4 Datensammlung

Insgesamt 8 Interviews der WOMAN-PRO Studie wurden für die Sekundäranalyse genutzt. Sechs führte die Erstautorin in der Schweiz durch. Zwei weitere Interviews führte die Letztautorin in Deutschland durch. Beide Interviewerinnen sind ausgebildet in qualitativer Forschung und diskutierten die Interviewtechniken mit erfahrenen Forschenden. Die Interviewerinnen hatten Erfahrung mit gynäkologischer Pflege, waren aber nicht in die Pflege der Interviewteilnehmerinnen involviert. Die Interviews fanden je nach Wunsch der Patientinnen bei ihnen zu Hause oder im Spital unter Beachtung der Intimsphäre statt. Der Interviewleitfaden wurde von der Letztautorin entwickelt, dessen Inhalt und Verständlichkeit von zwei Forschenden im Gebiet der gynäkologischen Onkologie beurteilt und wo nötig überarbeitet. Die Interviews umfassten Fragen zum aktuellen Befinden der Frauen sowie zu ihren Erfahrungen mit der Diagnose und der Behandlung. Eine Frage zum Krankheitsverlauf war nicht Bestandteil des Leitfadens. Bei inhaltlichen Unklarheiten wurde nachgefragt. Die Interviews wurden auf Tonband aufgenommen, Wort für Wort transkribiert und mit Hilfe von ATLAS.ti 6.2.26 (ATLAS.ti GmbH, Berlin) strukturiert. Alle Interviews dauerten 40 bis 80 Minuten. Anhand eines Fragebogens wurden soziodemographische Daten zu Alter, Zivilstand, Nationalität, Ausbildung und Berufstätigkeit erfragt. Aus den Patientenakten wurden Angaben zu Diagnose und Therapie erfasst.

5.2.5 Datenanalyse

Die acht Interviewtexte wurden thematisch analysiert[22] und kritisch hermeneutisch reflektiert.[23] Ziel der thematischen Analyse in Anlehnung an die kritisch hermeneutische Reflexion war, Kategorien, wiederkehrende Themen und grundlegende Muster zur Identifikation subjektiver Sichtweisen des

Krankheitsverlaufes sowie von Verhaltensweisen von Frauen mit VIN zu erkunden.[22, 23] Die Analyseschritte sind in Tabelle 2 dargestellt.

Die WOMAN-PRO-Studie und die Sekundäranalyse wurden von der Kantonalen Ethikkommission Bern und der Ethikkommission der Universitätsklinik in Freiburg im Breisgau (Nr. 385-09) gutgeheissen. Die Teilnehmerinnen wurden vor dem Interview über ihre Rechte aufgeklärt und unterzeichneten eine Einverständniserklärung. Personennamen und Ortsangaben wurden beim Transkribieren anonymisiert.

Tabelle 2. Die Analyseschritte nach Braun & Clarke (2006) in Anlehnung an das Vorgehen nach Diekelmann et al. (1989)

Phase	Prozessbeschreibung [a]
1. Bekanntmachung mit den Interviews	Die Erst- und Letztautorin lasen alle transkribierten Interviews mehrmals durch, um einen Überblick über die Interviewinhalte zu gewinnen.
2. Erarbeiten erster Kategorien	Die Erstautorin fasste besonders aussagekräftige Passagen aus den Interviews zusammen und identifizierte erste inhaltliche Kategorien. Das Forschungsteam, bestehend aus der Erst-, Dritt- und Letztautorin, diskutierte die Inhalte sowie die Bedeutungen dieser Kategorien und suchte im Dialog nach einem Konsens.
3. Suchen nach wiederkehrenden Themen	Die Erstautorin identifizierte, basierend auf den Kategorien, wiederkehrende Themen, die in allen Interviews auftraten. Die Mitglieder des Forschungsteams diskutierten Ähnlichkeiten und Widersprüche in den gefundenen Themen. Um soziokulturelle Hintergründe besser zu verstehen, wurde zusätzliche Literatur recherchiert.
4. Wiederkehrende Themen und grundlegende Muster identifizieren	Die Mitglieder des Forschungsteams ordneten und verglichen die wiederkehrenden Themen. Sie suchten nach Zusammenhängen zwischen den wiederkehrenden Themen und nach grundlegenden Mustern. Anschliessend überprüften sie die grundlegenden Muster wiederum durch Beiziehung der Interviewtranskripte.
5. Themen und grundlegende Muster definieren und benennen	Die Erstautorin benannte und definierte Themen und grundlegende Muster. Die Zweitautorin (Externe Expertin) prüfte die Analyseergebnisse und beurteilte das Verhältnis zwischen den wiederkehrenden Themen und grundlegenden Muster.
6. Verfassen des Manuskripts	Die Erstautorin verfasste einen Entwurf des Manuskripts mit Zitaten. Diesen sandte sie zur Begutachtung an die anderen Autorinnen. Kritische Kommentare wurden diskutiert und Ergebnisse daraus im Manuskript angepasst.

[a] Der Analyseprozess wurde in sechs Analysetreffen mit den Mitgliedern des Forschungsteams und in fünf Treffen mit fünf weiteren qualitativ Forschenden diskutiert. Letztere verglichen bei den Treffen jeweils ihre Analyseergebnisse mit derjenigen der Erstautorin und suchten dabei nach Ähnlichkeiten und Unterschieden.

5.3 Resultate

5.3.1 Demographische und medizinische Daten

Alle 8 Teilnehmerinnen wurden auf Grund einer VIN chirurgisch behandelt. Sechs Teilnehmerinnen stammten aus der Schweiz, zwei aus Deutschland. Die Frauen waren durchschnittlich 49 Jahre alt. Aus

den Interviews ging hervor, dass die Frauen zum Zeitpunkt des Interviews zwischen 3 Monaten und 9 Jahren an VIN litten. Weitere demographische und medizinische Daten sind in Tabelle 3 aufgelistet.

Tabelle 3. Demographische und medizinische Daten

Variablen	Häufigkeit
Alter (zwischen 25-80)	
In Jahren	49.25 (Median)
Zivilstand	
Ledig	1
Verheiratet	4
Geschieden	3
Leben in einer Partnerschaft	
Ja	7
Nein	1
Ausbildung	
Weniger als 10 Schuljahre	1
Mehr als 10 Schuljahre	7
Berufstätigkeit	
Ja	6
Pensioniert	2
Diagnose	
Klassische VIN	7
Differenzierte VIN	1
Rezidive von VIN	
Erstdiagnose	1
Rezidiv	7
Operation	
Laserevaporisation	6
Skinning Vulvektomie	2
Art der Hospitalisation	
Ambulant (< 24h)	2
Stationär (≥ 24h)	6
Hospitalisationsdauer stationär	
Tage (zwischen 1-3 Tage)	2 (Median)

5.3.2 Ergebnisse der Interviews

Basierend auf den Interviewtexten stellte sich heraus, dass das Gefühl ‚Bangen und Hoffen' für viele Frauen mit VIN immerwährend war, zumal sie stets mit der Angst lebten, ein Rezidiv zu erleiden, aber auch hofften, dass die Therapie wirke. ‚Bangen und Hoffen' als fortwährendes Gefühl ist ein grundlegendes Muster des Modells des Krankheitsverlaufs von Frauen mit VIN (Abbildung 1). Weiter zeigte sich aufgrund der Analyse eine Darstellung des Krankheitsverlaufs in fünf aufeinanderfolgenden, sich teilweise überlappenden Phasen: ‚Da ist etwas Unbekanntes', ‚Man weiss,

was ES ist‘, ‚ES wird behandelt und soll heilen‘, ‚ES hat Auswirkungen‘ und ‚Mittlerweile geht es‘. In diesen Phasen zeigt sich, dass Frauen mit VIN eine lange Krankheitsgeschichte beschreiben, bevor sie eine Diagnose erhielten. Trotz Diagnosestellung äusserten Frauen nicht gewusst zu haben, woran sie litten. Betroffene Frauen erlebten die Behandlung als beschwerlich und sie beschrieben, VIN hatte Auswirkungen auf der körperlichen und psychosozialen Ebene. In den Interviews kam auch zum Ausdruck, dass die Frauen mit der Zeit lernten, mit ihrer Krankheit umzugehen. Während des Krankheitsverlaufs wurden die Frauen vom Gefühl ‚Sich dafür schämen‘ begleitet und Fachpersonen beeinflussten den Krankheitsverlauf massgeblich. Die fünf Phasen des Krankheitserlebens stellen zusammen mit ‚Sich dafür schämen‘ und ‘Mit Fachpersonen umgehen‘ die wiederkehrenden Themen dar. Kategorien bilden die in Abbildung 1 dargestellten Subthemen der fünf Phasen.

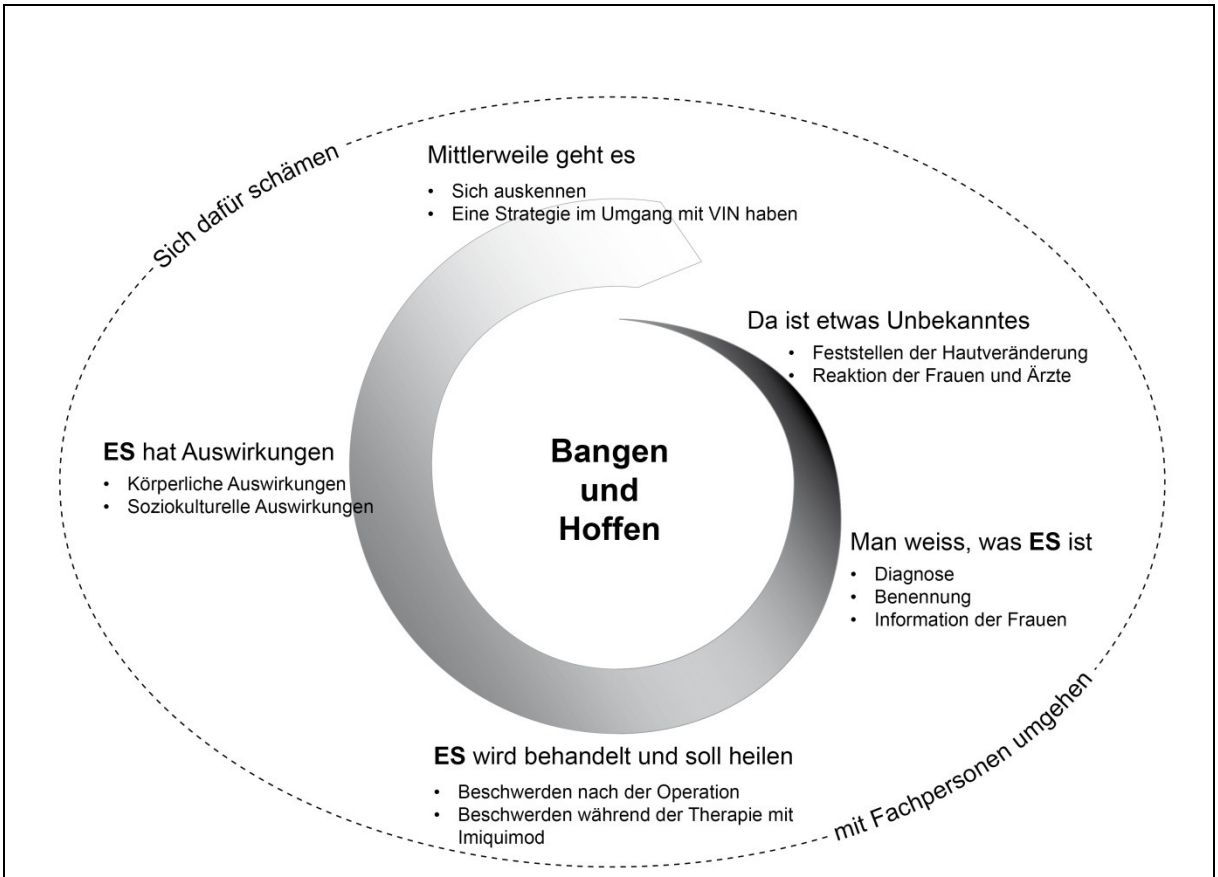

Abbildung 1. Erfahrungen von Frauen mit vulvären Neoplasien während des Krankheitsverlaufs. [a]

[a] Das grundlegende Muster ‚Bangen und Hoffen‘ beinhaltet die stets vorhandene Angst vor Rezidiven sowie die Hoffnung, dass die Therapie wirkt. Die fünf Phasen des Krankheitsverlaufes: ‚Da ist etwas Unbekanntes‘, ‚Man weiss, was ES ist‘, ‚ES wird behandelt und soll heilen‘, ‚ES hat Auswirkungen‘ und ‚Mittlerweile geht es‘ und die Themen ‚Sich dafür schämen‘ sowie ‚mit Fachpersonen umgehen‘ beschreiben die wiederkehrenden Themen. Kategorien bilden die Subthemen der fünf Phasen.

5.3.3 Bangen und Hoffen

‚Bangen und Hoffen' beschreibt ein zwiespältiges Gefühl, das den Krankheitsverlauf besonders prägt und während allen Krankheitsphasen immer vorhanden ist. ‚Bangen' beinhaltet die Angst vor Rezidiven, vor weiteren schmerzhaften Behandlungen, dass die VIN nicht heilt und zum Krebs fortschreitet, dass man stigmatisiert oder vom Partner verlassen wird. ‚Hoffen' beschreibt die Zuversicht, dass die angewandte Therapie nützt, dass die Krankheit mit der nächsten Behandlung bekämpft werden kann und dass keine weiteren Rezidive auftreten. Für Frau Jaun[1] lagen Bangen und Hoffen nahe beieinander. Aktuell hoffte sie, ihren guten Zustand möglichst beibehalten zu können und dass die Krankheit nicht fortschreitet. Sie bangte jedoch, dass Rezidive wieder auftreten können:

> *Jetzt geht es mir eigentlich gut, da ich weiss, dass soweit alles in Ordnung ist. [Aber] das kann immer wieder kommen. Das ist der Mist daran. … Bis jetzt habe ich schon gehofft, oder ein bisschen gebangt, dass es nichts Schlimmes ist.*

5.3.4 Die fünf Phasen des Krankheitserlebens

Die Phase ‚Da ist etwas Unbekanntes' beschreibt, wie die Frauen die Hautveränderungen feststellen, sich in ärztliche Behandlung begeben und wie die Ärzte darauf reagieren. Frau Jaun entdeckte eine Wucherung, die brannte, schmerzte und die ihrer Meinung nach „hässlich" und nach „Hautkrebs" aussah. Sie wandte sich mit ihrem Leiden an den Hausarzt. Dieser verwies sie an den Hautarzt, welcher sie wiederum ins gynäkologische Ambulatorium weiterwies. Frau Jaun erhielt relativ schnell eine Diagnose. Frau Beer, Frau Egger und Frau Sieber beschreiben hingegen eine lange Phase der Behandlung ohne dass die VIN erkannt worden wäre. Frau Beer wurde über mehrere Monate mit Antibiotika-Crèmes und Frau Egger zwei Jahre lang mit Antimykotika behandelt. Frau Sieber hatte vier Jahre lang eine wunde Stelle an der Vulva und wurde von ihrem Gynäkologen immer wieder mit verschiedenen Cremes vertröstet, die ihr nicht halfen. Frau Sieber sagte über ihren Gynäkologen:

> *Der wusste nicht, was das ist!*

Die Phase ‚Man weiss, was ES ist' beinhaltet den Zeitraum, in dem die Frauen die Diagnose erhalten und über ihre Krankheit informiert werden. Es kann sein, dass betroffene Frauen bis zu diesem Zeitpunkt bereits eine mehrjährige Leidensgeschichte hinter sich haben, die Diagnose bei Symptomen auf Anhieb korrekt gestellt wurde oder es sich um eine Zufallsdiagnose handelt. Trotz der Information über die Krankheit benutzten die Frauen die genaue Bezeichnung ihrer Krankheit VIN nicht. Frau Jaun sprach von ‚Zeug', ‚Veränderung der Haut' oder ‚Hautkrebs'. Frau Giger erläuterte, es seien ‚nicht gute Zellen mit verschiedenen Vorstufen' und dass sie an ‚der letzten Vorstufe' erkrankt sei. Die Bezeichnung ‚ES' in der Abbildung stellt diese Namenlosigkeit der Krankheit dar.

[1] Bei sämtlichen Patientinnennamen handelt es sich um Pseudonyme

Die meisten Frauen bemängelten, dass sie weder zur Krankheitsentstehung noch zum weiteren Verlauf genügend Informationen erhielten. Frau Giger hätte gerne gewusst, ‚was auf mich hätte zukommen können'. Frau Jaun ergänzte, dass die erhaltenen Informationen widersprüchlich und verwirrend waren:

> *Jedesmal wird irgendetwas anderes erzählt. Einmal ist die Ursache das, einmal das… Ich weiss gar nicht mehr, was richtig oder falsch ist.*

Die Phase ‚ES wird behandelt und soll heilen' erläutert Erfahrungen mit den operativen Behandlungen und der Therapie mit der Imiquimod-Crème. Symptome während der Heilungsphase nach operativen Behandlungen waren Schmerzen, Brennen, Wundsekrete, Blutungen, Entzündungen, offene Wundränder, Beschwerden während der Ausscheidung und ein Spannungsgefühl beim Sitzen. Einige Frauen fühlten sich psychisch geschwächt. Die Symptome wurden als sehr beschwerlich bezeichnet. Als eines der unangenehmsten Symptome, nannten mehrere Frauen das Brennen beim Wasserlösen. Frau Sieber bezeichnete diese Schmerzen als die schlimmsten ihres Lebens:

> *Wasser lösen, das war wirklich ganz, ganz schlimm. Solche Schmerzen hatte ich in meinem Leben noch nie!*

Frau Egger beschrieb Erfahrungen mit der Imiquimod-Crème und erzählte, dass sie nicht schlafen konnte und bei der Arbeit ‚böse und aggressiv' wurde. Die Crème brannte und juckte so stark, dass sie das Gefühl hatte, ‚die Hände auf den Rücken binden' zu müssen, um nicht alles wegzukratzen. Frau Jaun erläuterte, dass sie wegen der Crème an ‚Wahrnehmungsstörungen' in Form von Hypersensibilitäten litt. Kaltes Wasser fühlte sich eisig kalt an und Geräusche in normaler Lautstärke, nahm sie unangenehm laut wahr.

Die Phase ‚ES hat Auswirkungen' beschreibt die verschiedenen Auswirkungen der Erkrankung auf den Alltag von Frauen mit VIN. Die Krankheit hat Auswirkungen während der Behandlung, während der Heilungsphase und nach abgeschlossener Therapie. Nebst den Auswirkungen auf körperlicher Ebene (z.B. Schmerzen, Narben) gibt es auch Auswirkungen auf soziokultureller Ebene. Letztere treten im Bereich der Arbeit, der Hobbies, der Partnerschaft und der Lebensplanung auf. Auswirkungen auf die Arbeit äusserten sich beispielsweise durch lange Absenzen. Frau Egger störte bezüglich Hobbies, dass sie keinen Sport treiben konnte und dadurch ihre Kondition verlor:

> *Sport kannst du keinen [machen]. Du kannst nicht joggen gehen, nicht Fahrrad fahren, nicht Ski fahren. Du kannst nichts! … Man verliert in zwei Monaten die Kondition!*

Zu den Auswirkungen auf die Partnerschaft erzählte Frau Xantia, dass sich bei ihr die ‚sexuelle Lust ziemlich zurückgebildet' hatte. Wegen den Schmerzen beim Geschlechtsverkehr habe sie sich davon ‚distanziert'. Frau Egger berichtete, dass eine Partnerschaft an der Krankheit ‚zerbrochen ist'. VIN hatte für Frau Egger auch Auswirkungen auf ihre Lebensplanung. So waren die Krankheit und die Behandlungen für sie nicht mit der Gründung einer Familie vereinbar.

> *Ich finde, um ein Kind zu bekommen solltest du gesund sein.… Ich hatte immer das Gefühl, irgendwie in Behandlung zu sein … Ich hätte gar keine Zeit gehabt, mich auf eine Familie einzustellen.*

Die Phase ‚Mittlerweile geht es' stellt dar, wie Frauen mit VIN lernen, mit ihrer Krankheit umzugehen. Sie beschreiben gelernt zu haben, Symptome nach chirurgischen Eingriffen und bei Behandlungen mit Imiquimod zu handhaben und für sich eine Strategie im Umgang mit VIN gefunden zu haben. Frau Giger berichtete, wie sie feststellte, dass sie das Brennen reduzieren konnte, wenn sie im Stehen Wasser löste. Dank dem konnte sie das Symptom kontrollieren, was sie erleichterte:

> *Ich habe bemerkt, dass mir [beim Wasser lösen im Stehen] wohler ist. Wenn ich mich [dabei] nach vorne beuge, fliesst das Wasser nicht über die Wunde herab. … Jetzt kann ich wenigstens wieder Wasser lösen.*

Frau Hirt hatte lange Erfahrung mit VIN und wusste, dass ‚wenn es jucke oder brenne, dann soll ich es zeigen kommen'. Dieses Wissen erlaubte ihr ein weitgehend normales Leben zu führen, jedoch bei auftretenden Symptomen schnell und korrekt zu handeln. Trotz der immer bestehenden Ungewissheit sagte Frau Jaun, dass sie mit der VIN einigermassen zurechtkomme. Ihre Strategie im Umgang mit der Krankheit war die Ablenkung und die Hoffnung, dass sie wieder gesund wird:

> *Man weiss nicht, was jetzt noch alles kommt. … Aber mittlerweile ist es eigentlich gegangen. … Man lenkt sich ab, man macht etwas anderes [und] hofft auf das Beste.*

5.3.5 ‚Sich dafür schämen' und 'mit Fachpersonen umgehen'

Die zwei Themen begleiten die Phasen des Krankheitserlebens und können während dem gesamten Krankheitsverlauf immer wieder auftreten. Bezeichnend für die beiden Themen ist, dass sie mit zunehmender Erfahrung der Frauen mit VIN tendenziell an Bedeutung verlieren. ‚Sich dafür schämen' beinhaltet das von den Frauen geäusserte Schamgefühl. Es wird einerseits durch die Lokalisation, andererseits durch die Art der Übertragung der Krankheit hervorgerufen. Mehrere Frauen erwähnten, dass die Lokalisation der Krankheit ein ungutes Gefühl förderte, weil sie beim Erläutern der Krankheit gegenüber Mitmenschen über ihre Schamlippen sprechen mussten. Frau Beer schämte sich so, dass sie sich nicht wagte, zum Gynäkologen zu gehen. Erst als die Schmerzen unerträglich wurden, sagte sie sich ‚jetzt musst du dich nicht schämen, jetzt muss etwas gehen!' und vereinbarte einen Termin.

Die Tatsache, dass VIN durch HPV verursacht und somit durch Geschlechtsverkehr übertragen werden kann, löste Schamgefühle aus. Für Frau Egger war die Diagnose einer Geschlechtskrankheit etwas Schmutziges und Verrufenes. Sie befürchtete, dass andere sie deswegen verurteilen könnten und schämte sich, an VIN erkrankt zu sein:

> *Für mich ist das [die Geschlechtskrankheit] etwas Dreckiges, etwas Verrufenes. … Was denken die anderen? Am liebsten niemandem sagen, dass es eine Geschlechtskrankheit ist … Ich schäme mich, dass ich diese Krankheit habe.*

‚Mit Fachpersonen umgehen' beschreibt ein Kontinuum, nach welchem Frauen mit VIN die Qualität der Begegnungen mit Fachpersonen zwischen sehr schwierig und unterstützend erlebten. Viele Frauen sehnten sich nach einer Vertrauensperson. Jedoch gelang es ihnen durch die wechselnden Assistenzärzte und die kurz bemessene Zeit der Sprechstunden oft nicht, eine vertrauensvolle Beziehung mit dem Arzt aufzubauen und ihre Anliegen zu besprechen. Dazu erzählte Frau Giger:

> *Man hat jedes Mal einen anderen Ansprechpartner. Man kann kein Vertrauen zu einem Arzt aufbauen, weil jedes Mal jemand anderes da ist. Also das ist für mich eigentlich das Schlimmste gewesen… Ja, man fühlt sich nicht aufgehoben.*

Mehrere Frauen mit VIN fühlten sich durch pauschale Aussagen der Ärzte mit ihren Anliegen und Beschwerden nicht ernst genommen. Frau Egger vermisste das Einfühlungsvermögen in ihre Situation bei einer Verlaufskontrolle während der Therapie mit Imiquimod. Wegen starken Nebenwirkungen konnte sie die Crème nicht so lange wie vorgeschrieben auftragen und wurde deswegen von einer Ärztin getadelt. Das war für Frau Egger entmutigend, verletzend und löste Wutgefühle gegenüber der Ärztin aus:

> *Zeitweise haben sie mir gesagt: ‚Frau Egger, Sie müssen es [die Crème] mindestens sechs Stunden drauf haben.' Dann hätte ich am liebsten gesagt: ‚Haben Sie es auch schon mal drauf gehabt? Wissen Sie denn, wie das ist?'*

Im Gegensatz dazu erlebte Frau Sieber die Auskunft der Fachpersonen als sehr hilfreich. Sie wandte sich mit ihren Beschwerden telefonisch an die ambulante Gynäkologie, wo sie Auskunft darüber erhielt, wie sie das Brennen beim Wasser lösen reduzieren konnte:

> *Sie [das Personal im Spital] haben gesagt, man könne während dem Sitzbad Wasser lösen. … Das hat wirklich geholfen.*

5.4 Diskussion

Diese Studie beschreibt anhand einer thematischen Analyse unter Beachtung der soziokulturellen Hintergründe das Gefühl ‚Bangen und Hoffen' und welche Phasen Frauen während des Verlaufs einer VIN erlebten. Die Themen ‚Sich dafür schämen' und ‚Mit Fachpersonen umgehen' begleiteten das Erleben der Krankheitsphasen und spielten eine wichtige Rolle.

‚Bangen und Hoffen' und ‚Sich dafür schämen' vereinen drei psychosoziale Hürden von VIN. Erstens handelt es sich um eine Krankheit im Bereich der Vulva. Die Vulva ist für betroffene Frauen und für Fachpersonen nach wie vor ein Tabubereich und den Frauen fehlt eine umgangssprachliche Bezeichnung.[20, 21] Zweitens wird VIN zu einem grossen Teil durch Geschlechtsverkehr übertragen und ist dadurch bei den betroffenen Frauen mit Unreinheit und Scham konnotiert.[14] Drittens ist VIN eine Vorstufe invasiver Karzinome. Diese Information kann bei betroffenen Frauen Angst vor Krebs auslösen. ‚Krebs' geht für viele Menschen mit der Vorstellung von beschwerlichen Chemo- und Radiotherapien, einem langandauernden Leiden mit Metastasen und Schmerzen und schlussendlich einem qualvollen Tod einher.[12] Persönliche Überzeugungen, wie eine Krankheit zu Stande kommt und wie damit umgegangen wird, spielen dabei eine massgebende Rolle.[26] Durch die hohe Wahrscheinlichkeit eines Rezidivs kann die Angst vor Krebs immer wieder aufflammen.

Das Erleben der verschiedenen Krankheitsphasen von VIN sowie der Umgang mit Fachpersonen zeigen deutlich, dass VIN eine übersehene und unbekannte Krankheit ist, dass Frauen mit VIN ein Informationsdefizit haben und sie während dem Krankheitsverlauf eine konstante Ansprechperson benötigen. Die Hauptschwierigkeit in der Phase ‚Da ist etwas Unbekanntes', besteht darin, dass Ärzte die von den Frauen angegebenen Symptome nicht erkennen oder nicht ernst nehmen und Frauen diese aufgrund einer wahrgenommenen Stigmatisierung nicht ausreichend äussern. Mögliche Gründe dafür sind das ungenaue Hinschauen und das Übersehen der Vulva[1] oder, wie einige Frauen erläuterten, die Unkenntnis der Ärzte bezüglich der VIN Symptome. Das Informationsdefizit von Frauen mit VIN bezüglich ihrer Krankheit wird in der Phase ‚Man weiss, was ES ist' beschrieben. Laut der Association of Reproductive Health Professionals (ARHP) beträgt die Wahrscheinlichkeit einer HPV-Infektion während dem gesamten Leben 75-90%. HPV-Infektionen verlaufen meist ohne Symptome, heilen in rund 92% der Fälle innerhalb von zwei bis fünf Jahren spontan ab und werden meist nicht als Krankheit erfahren.[4, 27] Dieses Wissen kann die negative Bedeutung der Geschlechtskrankheit und die Angst vor der Weiterentwicklung zum Karzinom reduzieren.[14] Frauen mit VIN sollten demnach bei der Diagnosestellung über Herkunft und Bedeutung der Krankheit informiert werden, um Gefühle wie Scham und Angst vor Krebs oder Stigmatisierung gering zu halten. Braun und Gavey[28] beschrieben, dass das ‚Konzept' der Krankheitsentstehung für Frauen mit zervikalen intraepithelialen Neoplasien anhand angepasster Information normalisiert werden kann. Das ‚sich normalisieren' scheint ein wichtiger Schritt im Verlauf der Krankheit zu sein. Ziel ist es, dass diese Normalisierung möglichst

schnell nach der Diagnosestellung eintritt, um betroffene Frauen im Umgang mit ihrer Krankheit zu bestärken und sie zur Phase ‚mittlerweile geht es' zu führen. Nebst dem Informationsdefizit bezeichneten es einige Frauen als etwas vom Schlimmsten, keine vertrauensvolle Beziehung zu den Fachpersonen zu haben. Sie wünschten sich, dass Fachpersonen Bezugspersonen darstellten, die sich mit der Krankheit auskennen und mit welchen offen gesprochen werden kann. Wie auch in der Studie von Likes et al.,[13] waren sich Fachpersonen dieser Rolle oft nicht bewusst und bagatellisierten beispielsweise Symptome. An dieser Stelle wäre ein Beratungskonzept mit einer Advanced Practice Nurse (APN) nach Hamric et al.[29] denkbar, die sich in ihrem Arbeitsbereich auf HPV und VIN spezialisiert hat und wissenschaftlich ausgebildet ist. Eicher et al.[30] beschrieben in einer systematischen Review, dass das Konzept einer Breast Care Nurse positive Auswirkungen auf das physische und psychosoziale Wohlbefinden von Frauen mit Brustkrebs haben kann. Dies könnte auch bei einer APN spezialisiert auf HPV und VIN der Fall sein. Jedoch muss der wissenschaftliche Hintergrund dazu erst erarbeitet und die Informationsbedürfnisse von Frauen mit VIN, um sie in all ihren Krankheitsphasen angepasst unterstützen zu können, anhand weiterer Studien in Erfahrung gebracht werden.

Im Rahmen dieser Studie entstanden zahlreiche Fragen, die nicht beantwortet werden konnten. So stellt sich aus historischer Sicht die Frage, inwiefern die Stigmatisierung weiblicher Geschlechtsmerkmale, insbesondere der Vulva beim Nicht-Erkennen, Übersehen oder Bagatellisieren von Symptomen von VIN durch Fachpersonen eine Rolle spielt. Aus gesundheitspolitischer Perspektive wäre interessant zu untersuchen, in wie weit ein föderalistisches und dezentrales Gesundheitssystem, wie jenes der Schweiz, die Erkennung und korrekte Behandlung von seltenen Krankheiten wie VIN beeinflusst. Auch wäre es interessant, den Einfluss des in den letzten Jahren vermehrt aufgekommenen Diskurses bezüglich der HPV-Impfungen auf die Wahrnehmung des HPV als Geschlechtskrankheit näher zu betrachten. Diese Fragen stellen Inhalte für weitere Studien dar.

Limitationen dieser Studie sind die kleine Untersuchungsgruppe und die Tatsache, dass es sich um eine Sekundäranalyse von bereits bestehenden Interviews handelt. Die Sekundäranalyse bringt mit sich, dass einseitige Aussagen und Verzerrungen nicht ausgeschlossen und nicht weiter elaboriert werden können. Zudem enthielt der Interviewleitfaden keine spezifischen Fragen zum Erleben des Krankheitsverlaufes. Weiter wurden Frauen mit VIN ohne chirurgischen Eingriff, ausgeschlossen.

5.5 Schlussfolgerungen

Trotz den genannten Limitationen zeigen die Erfahrungen von Frauen mit VIN während dem Krankheitsverlauf einen Verbesserungsbedarf in der Versorgung. Das Erleben von VIN basiert auf dem Grundgefühl ‚Bangen und Hoffen'. Wesentliche Aspekte zum Krankheitsverlauf wurden in fünf Phasen zusammengefasst, welche von den Themen ‚Sich dafür schämen' und ‚Mit Fachpersonen umgehen' begleitet werden. Die gegenwärtige Behandlung und Pflege scheint Frauen mit VIN nicht ausreichend zu unterstützen, um diese Phasen adäquat zu bewältigen. Daher empfehlen wir basierend auf der internationalen Literatur und unseren Studienergebnissen neue Modelle der Beratung und Information zu entwickeln und zu evaluieren. Weitere Studien können dazu beitragen, die Bedeutung von VIN innerhalb des soziokulturellen, gesundheitspolitischen und historischen Kontextes detaillierter zu beschreiben.

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CHAPTER 6:

SELF-MONITORING THE POST-SURGERY SYMPTOM EXPERIENCE AND INFORMATIONAL NEEDS OF WOMEN WITH VULVAR NEOPLASIA: DEVELOPMENT AND CONTENT VALIDITY OF A PATIENT-REPORTED OUTCOME INSTRUMENT (WOMAN-PRO)

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Modified version

Abstract

Objectives

The aims of this study were to (1) develop a WOMen with vulvAr Neoplasia – Patient-Reported Outcome (WOMAN-PRO) instrument to measure women's post-vulvar-surgery symptom experience and informational needs, (2) examine the content validity of the newly developed WOMAN-PRO instrument, (3) describe modifications based on pilot-testing, and (4) examine the content validity of the revised instrument.

Methods

In a mixed-methods research project (Clinical Trial ID: NCT01300663) a new instrument was developed according to the PRO guidelines, as no self-report instrument assessing women's symptom experience and informational needs after surgical treatment of vulvar neoplasia (vulvar intraepithelial neoplasia and vulvar cancer) is available. Participants were recruited from 1 Swiss and 2 German University Hospitals. The instrument was developed based on literature searches, expert feedback (n=9) and patient interviews (n=20). Thirty-seven items were first pilot-tested by patients (n=6) and experts (n=6). The revised 36 items were pilot-tested by patients (n=4). The content validity index (CVI) for each item and for the entire instrument was calculated. Content validity for the WOMAN-PRO instrument is defined as the extent to which items on the scale represent the symptom experience and informational needs of patients with vulvar neoplasia.

Results

The initial pilot test showed an excellent scale CVI based on patient (CVI = .98) and expert feedback (CVI =.92). After revising 6 items based on low individual item CVI's and participant comments, the revised WOMAN-PRO showed excellent item and scale content validity (CVI=1.0).

Conclusions

The newly developed patient reported outcome instrument has the potential to guide patients and clinicians in assessing symptoms, informational needs and related distress. Use of the WOMAN-PRO instrument in clinical practice can offer patients guidance in self-assessment and early recognition of symptoms. This can decrease women's uncertainty about symptoms and reassure their decision-making about when to seek health care provider evaluation. It can provide clinical experts with systematic information about key symptoms from a patient perspective, and women's unmet informational needs. If the results of further psychometric testing are promising, the WOMAN-PRO will provide an outcome measure for clinical trials.

6.1 Introduction

The term vulvar neoplasia includes vulvar intraepithelial neoplasia (VIN)[1] and vulvar cancer.[2] Vulvar neoplasia is an uncommon disease with increasing incidence rates in Europe and in the United States.[3, 4] In Germany the incidence rate of VIN was estimated to be 7 per 100'000 women per year and vulvar cancer occurs at a rate of 2.5 per 100'000 women per year.[3] VIN can affect women at any age, however it is more common under the age of 50.[5, 6] High grade VIN is associated with human papilloma virus (HPV) infection and may progress to invasive disease.[6] The mean age of vulvar cancer diagnosis is 72 years.[7] Women with VIN and vulvar cancer have a high recurrence rate of 30-40%.[3, 8]

Although vulvar neoplasia includes different diseases, surgical treatment is the standard therapy for women with VIN and vulvar cancer.[9, 10] Different surgical treatment methods are used for the treatment of vulvar neoplasia such as local excision, skinning vulvectomy, laser vaporization, partial or radical vulvectomy and inguinofemoral lymph node dissection depending on disease stage and the lymph node involvement. Based on tumor staging, medical interventions, (neo-) adjuvant chemotherapy and radiation therapy may be indicated.[6, 9]

Studies investigating clinician-reported outcomes in vulvar neoplasia showed that recent surgical modifications have reduced postoperative morbidity in women with vulvar cancer,[11] but the rates of the post-surgery complications such as lower extremity lymph edema (30-70%),[12-14] wound dehiscence (10-30%), infections (5-40%)[15-17], and psychosexual effects[18-20] remain high.

Even minor surgical interventions for VIN caused physical and psychosexual morbidity and impacted women's quality of life.[21, 22] One randomized clinical trial included 30 women with VIN and reported no statistically significant differences in disease recurrence and adverse events in women treated with carbon dioxide laser (CO2 laser) versus ultrasonic surgical aspiration (selective removal of diseased tissue) after 1 year follow-up. Eleven of 30 women had disease recurrence after 1 year. Several adverse events were reported: (1) pain (all participant), (2) scars (n=5), (3) dysuria or burning (n=7), (4) an adhesion (n=1), (5) infections (n=4), and eschars (n=4).[21] A 2-year prospective study included 7 women after surgical treatment for VIN. Women scored poorly on quality of life and sexual functioning scores.[22]

Despite these complication rates, to date little is known about patients' complication-related symptom experience (e.g. odor as a symptom of a possible wound infection) and their informational needs. Symptoms are defined as patients' perceived indications of disease or changes in their biopsychosocial

functioning, sensation or cognition.[23] Symptom experience includes 2 common dimensions with symptom occurrence (frequency and severity) as the cognitive dimension, and symptom distress as the emotional dimension.[24]

The main challenge in understanding the symptom experience of women with vulvar neoplasia is the absence of a conceptual and psychometrically sound post-vulvar-surgery instrument specifically designed to assess the full range of key symptoms, informational needs and related distress. Patient reported outcome (PRO) data on post-surgical symptoms are important since patients may use different criteria than clinical experts[25] to assess the surgical wound healing process and the treatment efficacy with respect to improvements in co-morbidities and, therefore, may disregard potentially serious symptoms. An inadequate assessment of symptoms and informational needs may impair patient self-management and influence health care decisions and the use of health care services.[26] Consequently, the assessment of symptom experience and informational needs is crucial to identify patients' immediate health care needs in the provision of high-quality care.[27, 28] The aims of this study were (1) to develop a Patient Reported Outcome instrument for WOMen with vulvAr Neoplasia (WOMAN-PRO), (2) to examine the content validity of the newly developed WOMAN-PRO, (3) to describe modifications based on pilot-testing, and (4) to examine the content validity of the revised instrument.

6.2 Methods

6.2.1 Study design

This study is part of a larger mixed-methods research project (Clinical Trial ID: NCT01300663). The development of the WOMAN-PRO closely followed the PRO guidelines with 4 phases: A-D.[29] A qualitative study describing symptom experience and needs considered important by patients with vulvar neoplasia, based on interviews with 20 patients, informed the instrument development.[30] This article will focus on the development processes of phases A and B, while phases C and D including psychometric testing are ongoing.

6.2.2 Development of the WOMAN-PRO

The development process (Figure 1) followed the predefined phases, process steps and procedures recommended in the PRO guidelines. During the project updated guidelines were published.[31] We adopted our project to this new version where possible, e.g. defining a primary endpoint for the research application and documentation of the preliminary instrument development.

6.2.2.1 Phase A: Identify concepts & develop a conceptual framework

Process step 1: Determine intended population & research applications. The reason for developing a WOMAN-PRO assessing symptom experience of women after vulvar surgical treatment was two-fold. On one hand, the instrument was developed to be used in clinical practice. The goal is to use it to inform

patients about expected symptoms following vulvar surgery, to improve patient-health care provider communication about women's symptom experience, informational needs and to prevent surgery-related complications (e.g. wound infections) during clinical follow-up by supporting self-management and by influencing health care decisions and the use of health care services. On the other hand, the WOMAN-PRO - if the psychometric properties prove to be acceptable - can be used in clinical trials that chose the post-surgical symptom experience in women with vulvar neoplasia as a primary endpoint.

Process step 2: Identify concepts and domains that are important to patients (literature review, patient interviews). Relevant symptoms and assessment instruments for these patients were identified by literature searches undertaken by 2 authors (B.S., M.E.) from January 2009 to April 2009 in the Medline and CINAHL databases, Cochrane library and the Web of Science with the search terms combined and formulated as appropriate for each data base: 'vulvar neoplasia' OR 'genital neoplasia, female' OR 'ovarial neoplasia' OR 'cervix neoplasia' AND 'needs' OR 'assessment' OR 'gynecologic surgical procedures' OR 'signs and symptoms' OR 'quality of life' OR 'wounds and injuries' OR 'nursing evaluation research' OR 'experience'. An additional hand search was performed within references of identified studies. The literature search returned 957 citations which were screened for eligibility by title. Thirty-one were assessed by full text based on inclusion criteria (peer reviewed German and English publications from 2000 to 2009). A total of 9 studies were included in this review: two qualitative studies addressing experiences of women with vulvar neoplasia[32, 33] and 7 describing instruments assessing quality of life for gynecological cancer patients,[34-36] adverse events,[37] and general symptoms.[38-40] Since no instrument focusing on the symptom experience and needs of women with vulvar neoplasia and surgical treatment was identified, a qualitative study was undertaken to provide a basis for generating items for a new post-vulvar-surgery specific PRO instrument. We used information from retrieved studies to develop an interview guide for use in interviews with patients following vulvar surgery.[30]

Process step 3: Hypothesize expected relationships among concepts. Based on twenty open-ended patient interviews conducted 1 to 6 month after surgical treatment, 46 categories, 8 themes, and 3 patterns were identified and presented in a conceptual model. Narratives showed 8 key themes composing the essence of women's symptom experience: delayed diagnosis, disclosed disease, disturbed woman's self-image, changed vulva care, experienced wound-related symptoms, evoked emotions, affected interpersonal interactions, and feared illness progression. The identified themes were consistent across different surgical procedures. The pattern present in all narratives was that women experienced a lack of information with regard to the above interrelated themes and that all of them used strategies to handle their situation, which affected their distress level.[30]

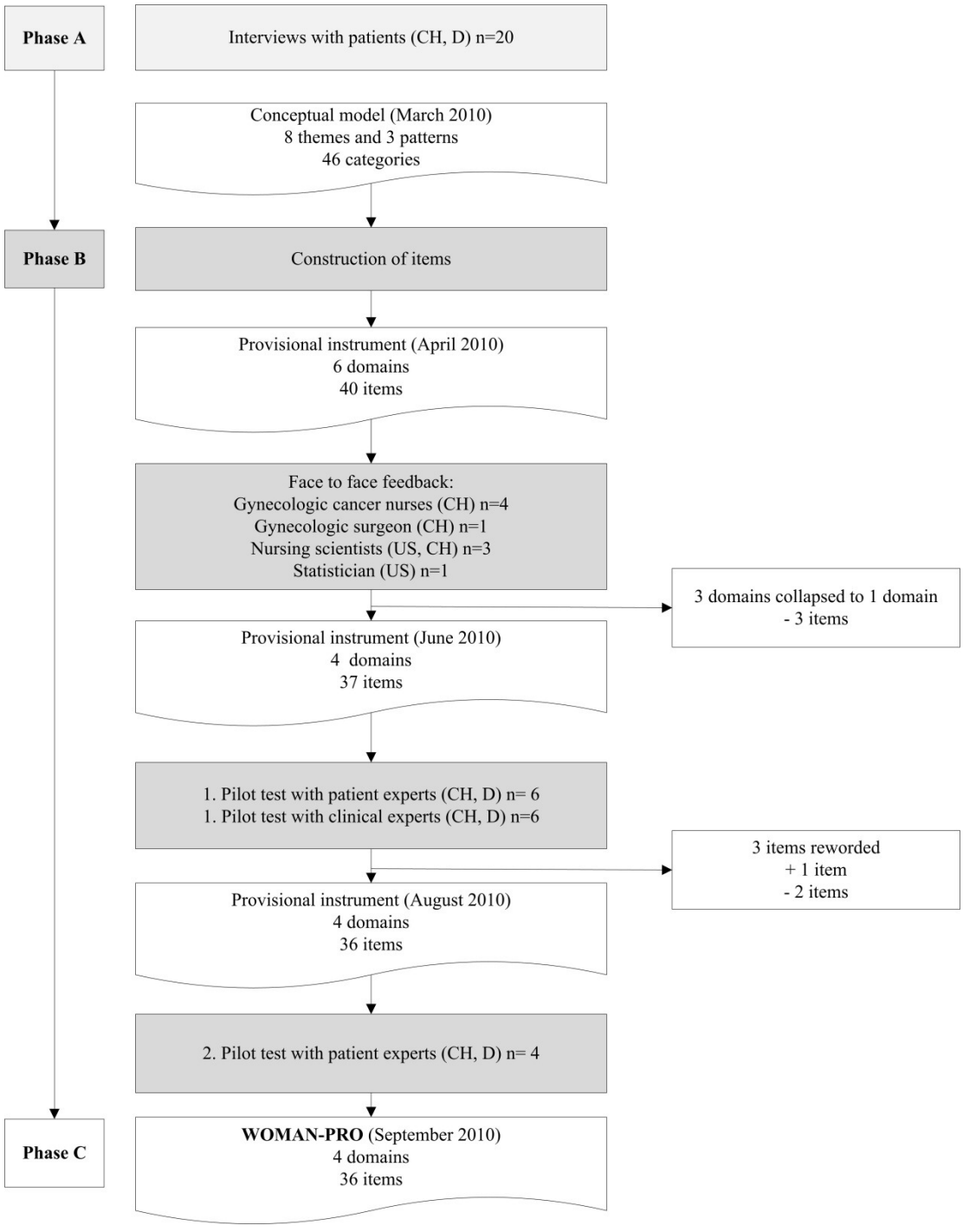

Figure 1. Development Process of the WOMAN-PRO

CH refers to Switzerland; D refers to Germany; US refers to the United States

6.2.2.2 Phase B: Create the instrument

Process step 4: Generate items. Based on this qualitative data, a preliminary conceptual framework with items (based on categories) and domains (based on themes and patterns) was developed. Direct patient input into PRO item generation was assured by validating the items with patients who

participated in the qualitative part of the study. Item wording and completeness was confirmed by going back to the coded transcriptions and was performed with ATLAS.ti 5.6.3 (ATLAS.ti GmbH, Berlin, D).

Process step 5: Choose administration method, recall period, and response scales. A paper-based data collection method and a self-administered approach were selected to include all age groups (20-80) of the target patient population. As participants in the qualitative study described a lack of information as very distressing in the first days after discharge and symptoms occurring during the first weeks following discharge are central in preventing complications related to wound healing, the WOMAN-PRO instrument should be completed for the first time 7 days after discharge. To consider patient burden, minimize recall bias and give patients the opportunity to react in a timely manner when symptoms occurred, a 7-day recall period was selected. Likert scale scoring options were developed.

Process step 6: Draft instructions. Patients' instructions for self-administration as well as instructions for health care provider-supervising self-administration were drafted in written form.

Process step 7: Format instrument. The new provisional post-vulvar-surgery specific PRO instrument was formatted, based on the final item selection criteria (see 'Data analysis') by the first author.

Process step 8: Draft procedures for scoring and administration procedures. Draft procedures for scoring and administration were defined. This provisional instrument was shown to 9 experts in April 2010: four Swiss gynecologic cancer nurses, 1 Swiss gynecologic surgeon, 2 US and 1 Swiss nursing scientists and 1 US statistician. A total of 32 face-to-face meeting with one or more of these experts took place. Expert feedback was utilized to ensure that the questionnaire captured clinically relevant items and was usable in clinical practice. The provisional instrument (April 2010) covered 6 dimensions of women's experiences following surgery for vulvar neoplasia with 40 items. Based on experts' face-to-face feedback 3 dimensions (emotions, female genitalia and social contacts) were collapsed to 1 domain (psychosocial aspects) and 3 items were deleted to minimize redundancies in the instrument.

Process step 9 and 10: Pilot test the draft instrument and refine instrument. The provisional instrument was pilot-tested in 2 phases. The quality of the provisional instrument was assessed in June 2010 by patient and clinical experts. The instrument was revised based on the first pilot test and was pilot-tested again in August 2010 by patient experts as they were the target group for the instrument (see 'Pilot-testing of provisional instrument'). The provisional self-report instrument (June 2010) included:

- General information (explanations about: terms such as symptom experience, vulva, anatomical components of the female genital, medical diagnoses, normal wound healing process; and how this instrument and a hand mirror can help assess symptoms)

- Personal information to support decision making (space to list the contact person and his/her telephone number, individual information about normal expected symptoms, warning symptoms, and recommendations concerning behavior after surgical treatment)
- Instructions on how to fill out the symptom list (e.g. when and how to mark the appropriate box)
- Symptom list (items with answer categories for the occurrence of each item and its related distress)
- Need list (items with answer categories for the occurrence of each item and its related distress)
- Individual symptom list (space for 3 other items with answer categories covering the occurrence of each item and its related distress)
- Individual prioritization of 3 to 5 experienced symptoms (issues which women wanted to discuss at the next appointment with their health care provider)
- Invitation to note 3 individual strategies (which could help during this time of changes)

The provisional instrument (June 2010) covered 37 items representing symptom experience and informational needs following surgery for vulvar neoplasia within the following 4 dimensions: (1) sixteen items asked about wound-related symptoms; (2) five items addressed difficulties in daily life; (3) twelve items focused on psychosocial feelings, thoughts or activities; and (4) the informational needs list covered 4 items.

- For the symptom list the occurrence of each item was measured on a 5-point Likert scale [0-4]. For the wound-related symptoms and difficulties in daily life, women were asked to rate how frequent they experienced the symptom during the first 7 days after discharge (answer categories: never [0], 1-2 days [1], 3-4 days [2], 5-6 days [3], or daily [4]). Women were asked to assess the severity of psychosocial symptoms (answer categories: not at all [0], a little bit [1], somewhat [2], quite a bit [3], very much [4]).
- Four response options assessed the degree of informational needs (answer categories: not existing [0], a little [1], moderate [2], large [3]).
- The distress associated with each item was measured on a 5-point Likert scale (answer categories: not at all [0], a little bit [1], somewhat [2], quite a bit [3], and very much [4]).

6.2.3 Pilot testing of provisional instrument

6.2.3.1 Sample and setting

This study was approved by the ethical committees of Berne, Switzerland; Freiburg (no. 385-09) and Munich (no.412-09), Germany. All participants (n=20) from a previously conducted qualitative study were invited to participate in pilot-testing.[30] They were originally recruited from gynecological wards or ambulatory facilities at 1 Swiss (Berne) and 2 German University Hospitals (Munich, Freiburg).

Eligible patients were (a) older than 18 years, (b) able to read and write German, (c) diagnosed with vulvar neoplasia, and (d) treated with vulvar surgery during the prior 6 months. Excluded patients were (a) cognitively impaired (b) concurrently under psychiatric treatment or (c) terminally ill. The purposeful sample represented a variety of vulvar neoplasia-related diagnoses, age groups, time points after surgery, and surgical techniques. All 20 women consented after the qualitative interviews to participate in pilot-testing of the content validity of the instrument. Ten were invited to participate in the first pilot test and the other 10 to participate in the evaluation of the revised instrument. Participants were purposefully allocated to each group to represent a comparable variety of the above mentioned sampling criteria. In addition, 16 clinical experts were invited to participate to ensure that the WOMAN-PRO would be useful to clinicians and that all clinically relevant aspects of each domain were captured in the instrument. Eligible clinical experts were (1) graduated nurses and physicians working in the participating units/facilities, (2) working directly with patients with vulvar neoplasia, and (3) working for at least 1 year in the gynecology setting with a work load of at least 50%.

6.2.3.2 Content Validity Instrument

The patients and clinical experts were asked to rate the relevance of each item on the provisional instrument on a content validity index (CVI) rating form.[41] The question to patients was: 'Please rate the relevance of this item to your experiences following vulvar surgery'. The question to clinical experts was: 'Please rate the extent to which this item is relevant to symptoms / needs that you see in women who have had vulvar surgery'. The instrument contained 37 items rated on a 4-point Likert scale (1 = not relevant, 2 = somewhat relevant, 3 = quite relevant, 4 = highly relevant). After rating the items, patients and clinical experts were asked whether all significant aspects of symptoms / needs had been included and to identify any important aspects of women's experiences that were missing. They were asked, 'From your perspective, are there other symptoms / needs that should be added or any that should be removed from the symptom diary? If so, please write your suggestions below'.

All participants were also asked if they had any concerns about the following aspects (yes / no) and if so, how they would revise the issue of concern: (1) layout, (2) introduction, (3) instructions for self-administration, (4) clarity and correctness of item wording, and (5) response-options for the scales. The last question asked if study participants had further comments / suggestions to improve the provisional instrument.

6.2.3.3 Data collection

Questionnaires were sent out between June and September 2010 by the first author. Paper and pencil questionnaires for CVI-rating were sent out to patients to be completed at home. All patients completed the CVI-rating once between 3 and 12 months following their surgery. Clinical experts were provided with an online version of the questionnaire for CVI-rating. Data collection procedures were identical for patients in both rounds of pilot-testing. All patient participants received a cover

letter, an information letter, an informed consent, a provisional instrument, a content validity form, and a socio-demographic data form. This paper based survey packet included 2 pre-addressed stamped envelopes, 1 for the signed consent and 1 for the questionnaires. Telephone reminders were carried out by the first author 1 to 5 weeks after sending the questionnaires to the patients, depending on their availability. Upon return of the questionnaires, they were checked for completeness and if there was any missing data, patients were telephoned. Clinical experts received an e-mail reminder 5 weeks after receiving the online questionnaire. If they did not respond following the reminder, they were considered non-responders. Informed consent of clinical experts was implied by completion of questionnaires.

6.2.3.4 Data analysis

Data analysis procedures were identical for both rounds of pilot-testing. The CVI for each item was calculated by summarizing the number of patients/clinical experts giving a 3 (quite relevant) or 4 (highly relevant) rating divided by the total number of patients/clinical experts who completed the item. The CVI for the entire instrument was calculated by summing all items rated as 3 or 4 and dividing the total score by the number of items. We followed the guidelines recommended by Polit and Beck when evaluating the content validity of individual items[41] and the entire questionnaire.[42] They recommend that at least 3 experts complete the CVI instrument and that individual items be considered as having good content validity if their mean CVI score is at least .78, while a mean CVI score of .90 on the total questionnaire represents excellent content validity. The item and total questionnaire CVIs were calculated separately for the patient and clinical experts. Additional written text was summarized and all results were discussed and evaluated by the research group (co-authors M.M., M.E., S.E., R.S.) to determine which questions met the criteria for final selection. The following 3 predefined criteria were considered for selection of the final items:

(1) Symptoms / needs that were most distressing for patients
(2) Symptoms / needs that are clinically meaningful in predicting complications
(3) The length of the instrument.

6.3 Results

6.3.1 Participants

Eight of 10 patient experts (Table 1) and 6 of 16 clinical experts (Table 2) completed the first pilot test. Two content validity forms of the patients were excluded because of invalid data (contradictory answers). Four of 10 patient experts completed the second pilot test (Table 1). Reasons for not replying to the survey were being too busy or too ill. Table 1 summarizes the characteristics of the patients and Table 2 presents those of the clinicians.

Table 1. Patients' Socio-demographic and Medical Characteristics of the Pilot Test.

Characteristics	Pilot 1 N=6	Pilot 2 N=4
Age (in years); median (IQR)	52 (43.75;64.75)	75 (65.25;80.25)
Marital status (n, %)		
Single	2 (33.3%)	1 (25%)
Married	3 (50%)	0
Widowed	1 (16.7%)	2 (50%)
Divorced	0	1 (25%)
Nationality (n, %)		
German	3 (50%)	2 (50%)
Swiss	3 (50%)	2 (50%)
Educational level (n, %)		
10 or less school years	6 (100%)	3 (75%)
More than 10 years	0	1 (25%)
Current employment status (n, %)		
Working	4 (66.7%)	1 (25%)
Not working	2 (33.3%)	3 (75%)
Living arrangement (n, %)		
Alone	1 (16.7%)	3 (75%)
With the partner and/or children	5 (83.3%)	1 (25%)
Wound management (n, %)		
Without help	5 (83.3%)	2 (50%)
Help of health care professionals	1 (16.7%)	1 (25%)
Help by non-health care professionals	0	1 (25%)
Type of vulvar disease (n, %)		
Condyloma accuminatum	1 (16.7%)	0
VIN, pagetoid type	1 (16.7%)	0
Melanoma	0	1 (25%)
VIN (II & III)	1 (16.7%)	0
Vulvar squamous cell carcinoma	3 (50%)	3 (75%)
Stage of disease - AJCC Groupings (n, %)		
0	3 (50%)	0
Ia and Ib	2 (33.3%)	3 (75%)
II	1 (16.7%)	0
III	0	1 (25%)
IV	0	0
Recurrent diagnosis (n, %)	5 (83.3%)	0
Surgical therapy [a] (n, %)		
Local excision	1 (16.7%)	0
Laser-vaporization	3 (50%)	0
Partial vulvectomy [b]	0	2 (50%)
Radical wide excision/vulvectomy [c]	2 (33.3%)	2 (50%)
Lymph node dissection (n, %)		
Sentinel	2 (33.3%)	3 (75%)
Inguinofemoral	1 (16.7%)	1 (25%)
Removed lymph nodes; median (IQR)	0 (0;3.75)	1 (0.75;3.5)
Adjuvant postoperative therapy [d]	0	0
Length of hospitalization (in days); median (IQR)	3.5 (1.25;8.75)	9,5 (8;11.25)

IQR, interquartile range; VIN, vulvar intraepithelial neoplasia; AJCC stage groupings, American Joint Committee on Cancer's

[a] Surgeries were performed at all three hospitals according to the guidelines of the German Society for Gynecology and Obstetrics. [b] Partial vulvectomy means an ant-, posterior or unilateral surgical treatment; [c] Radical wide excision/vulvectomy incorporates a bilateral surgical treatment; [d] Adjuvant postoperative therapy means chemo- or radiotherapy.

Table 2. Clinical Experts' Socio-demographic Characteristics of the first Pilot Test.

Characteristic	Pilot 1 N = 6
Age; median (IQR)	
In years	47.5 (35.75; 49.5)
Marital status (n, %)	
Single/divorced	3 (50%)
Married/cohabiting	3 (50%)
Nationality (n, %)	
German	2 (33.3%)
Swiss	4 (66.7%)
Profession (n, %)	
Nurse	4 (66.7%)
Physician	2 (33.3%)
Working place (n, %)	
Ward	2 (33.3%)
Ambulatory	3 (50%)
Not documented	1 (16.7%)
Working status (n, %)	
60%	1 (16.7%)
80%	2 (33.3%)
100%	3 (50%)
Working experience [a] (n, %)	
1-2 years	1 (16.7%)
3-4 years	1 (16.7%)
> 10 years	4 (66.7%)

IQR, interquartile range (1.quartile; 3.quartile)
[a] Working experience means years after finishing professional training.

6.3.2 Content validity of the provisional WOMAN-PRO

Content validity of the WOMAN-PRO instrument is the extent to which items on the scale represent the symptom experience and informational needs of patients with vulvar neoplasia. The provisional instrument (June 2010) had a scale CVI of .98 based on 6 patients' ratings and a scale CVI of .92 based on 6 clinical experts' assessments. Clinical experts' assessments of 34 items showed excellent CVI ranging from .83 (15 items) to 1.0 (19 items). The remaining 3 items ('release clear fluid', 'warmth' and 'burning') had a lower CVI of .66. Patients' assessment of 36 items showed excellent item CVIs of .83 (3 items) to 1.0 (33 items). The remaining item, 'release clear fluid', had a lower CVI of .66.

6.3.3 Modifications based on pilot-testing

Based on the CVI and the comments from the initial piloting of the provisional instrument, a decision was made to delete 2 items, revise 3 items, add 1 item (Table 3) and reduce the response options from 5 to 4 categories. Two of the symptom frequency response options ('5 to 6 days' and 'daily') were collapsed into '5 to 7 days'. The 'somewhat' response option for the psychosocial items and distress items was deleted.

Table 3. Items revised on the provisional instrument based on the first pilot test.

Items	Revision	Reason
'Release clear fluid'	Deleted	CVI patient experts .66 CVI clinical experts .66
'Release clear fluid'& 'Release cloudy fluid'	Renamed as 'drainage' (e.g. clear, cloudy)	One patient suggested to reword the items to 'drainage'
'Warmth'	No revision	Item CVI clinical experts .66, but the patient item CVI was 1.0 and warmth is a cardinal symptom of infection
'Burning'	No revision	Item CVI clinical experts =.66, but the item CVI of patients was 1.0 and it was a very distressing and an often mentioned symptom in patient interviews
'Scar'	Renamed as 'scarred skin'	One clinical expert mentioned 'irritated word for a symptom'
'Dissolving urine' (Swiss expression)	Renamed as 'passing urine'	One clinical expert mentioned 'an understandable expression for Swiss and German speaking patients is needed'
'Difficulties talking about the disease'	Deleted	One patient mentioned 'redundant or obsolete question' by filling out the instrument
'Need for more information about daily activities (e.g. wearing underwear, hobbies, sexuality)'	New	One clinical expert mentioned the question on the need for more information about 'sex, swimming, wearing underwear' is missing

6.3.4 Content validity of the revised WOMAN-PRO

The revised instrument (August 2010) had a scale CVI of 1.0 based on 4 patients rating. Patients' assessment of 36 items showed excellent CVI of 1.0. There were no suggested changes to the content of this version. Patients completed the revised instrument within 20 minutes (Figure 2). Figure 2 presents the hypothesized conceptual framework and items included in the final version of the instrument (Appendix).

6.4 Discussion

The WOMAN-PRO is the first instrument to focus on post-vulvar-surgery symptoms, informational needs and related distress during the first week after hospital discharge in women at different tumor stages and undergoing different surgical treatments. The content of the measure was determined by reviewing international literature; involving US, German and Swiss physicians and nurses; and most importantly, by interviewing patients from 2 European Countries.

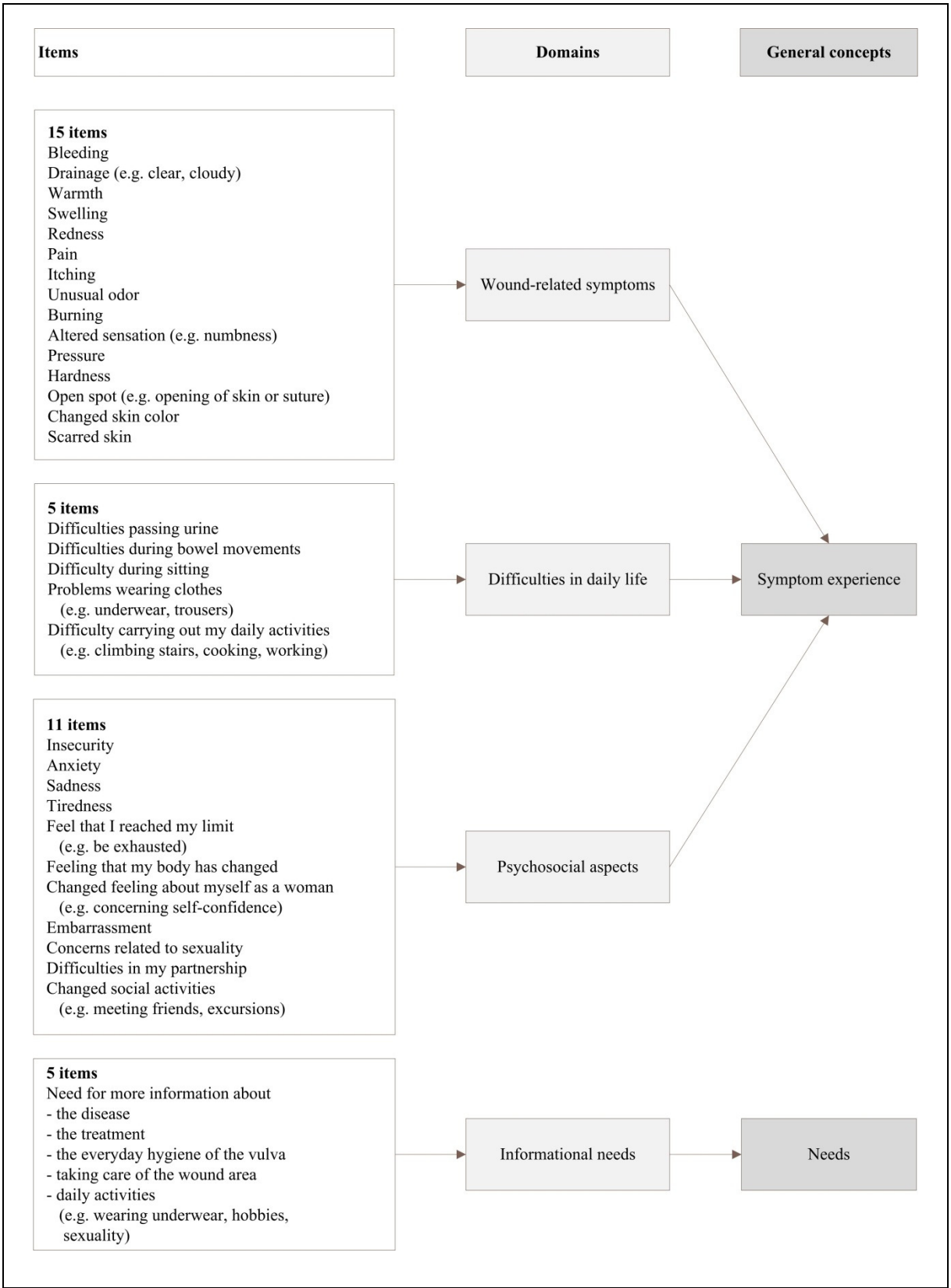

Figure 2. Hypothesized Conceptual Framework of the WOMAN-PRO (September 2010).

If subsequent studies support the reliability and validity of this instrument, it has the potential to be of value in research and clinical practice. It may be useful in evaluating the benefits of new and existing treatments for vulvar neoplasia as well as other aspects of patient care. Such data would support health outcomes research,[43] and evidence-based practice.[44] Furthermore, collection of PRO data during routine clinical follow-up may help patients and experts to identify problems, facilitate communication, and direct appropriate treatment of underappreciated symptoms.[44] Using a PRO can help inform the patients' decision-making process about when to seek health care provider evaluation,[45] and may also play an important role in creating realistic expectations about post-surgical symptoms.[44] Using the WOMAN-PRO, patients may recognize symptoms of complicated wound healing early enough to prevent complications. Clinical experts e.g. may be able to reliably measure informational needs concerning daily behaviors such as condom use after treatment.

This study has several limitations. Recruiting a small and purposeful sample of patients without adjuvant chemo-radiation and a convenience sample of clinical experts in University clinics limits the generalization of the findings. The experiences of women who declined to participate in the qualitative interviews may have been different than those of the women who consented to participate. As a result, the findings may not be generalizable to this patient population. Despite efforts to allocated participants to the 2 groups to represent a comparable variety of the sampling criteria, the patient expert group in pilot 1 and pilot 2 differed in relation to demographic variables. The women in pilot test 2 were older, had a longer hospital stay, were more likely to be single and living alone, thereby needed more help. This could have had an impact on the reported CVI.

6.5 Conclusions

In conclusion, content validity of the WOMAN-PRO is strong, making it a promising instrument to assess the occurrence of symptoms, informational needs and the self-reported distress experienced by women with vulvar neoplasia. Further examination of psychometric properties of the WOMAN-PRO is still needed and the instrument should be also tested in future studies to assess late effects in patients after vulvar surgery.

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CHAPTER 7:

A PATIENT-REPORTED OUTCOME MEASURE TO IDENTIFY OCCURRENCE AND DISTRESS OF POST-SURGERY SYMPTOMS OF WOMEN WITH VULVAR NEOPLASIA (WOMAN-PRO): A CROSS-SECTIONAL STUDY

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Modified version

Abstract

Objectives

To describe the (1) symptom experience of women with vulvar neoplasia (vulvar intraepithelial neoplasia and vulvar cancer) during the first week after hospital discharge, and (2) associations between age, type of disease, stage of disease, the extent of surgical treatment and symptom occurrence.

Methods

This cross-sectional study was conducted in eight Hospitals in Germany and Switzerland. Symptom experience after surgical treatment in women with vulvar neoplasia was measured with our newly developed WOMAN-PRO instrument. Outpatients (n=54) rated the frequency / severity of 31 symptoms and the degree to which the symptoms distressed them. We used descriptive statistics and regression analysis.

Results

The average number of symptoms reported per patient was 20 (SD 5.02) with a range of 10 to 31 symptoms. The three most prevalent wound-related symptoms were 'swelling' (n=46), 'drainage' (n=46) and 'pain' (n=43). The three most prevalent difficulties in daily life were 'sitting' (n=52), 'wearing clothes' (n=48) and 'carrying out my daily activities' (n=43). 'Tiredness' (n=51), 'insecurity' (n=44) and 'feeling that my body has changed' (n=42) were the 3 most prevalent psychosocial symptoms. The most distress symptoms were 'sitting' (Mean 1.98, SD 0.90), 'carrying out my daily activities' (Mean 1.79, SD 0.89), and 'open spot (e.g. opening of skin or suture)' (Mean 1.79, SD 0.92), which were on average reported to be 'quite a bit' distressing. No associations were found between symptom occurrence and age, type of vulvar disease, stage of disease and the extent of surgical procedures.

Conclusions

WOMAN-PRO data showed a high symptom prevalence and distress, call for a comprehensive symptom assessment, and may allow identification of areas in symptom management.

7.1 Introduction

Even minor surgical interventions for women with vulvar neoplasia cause physical and psychosocial morbidity and impact women's quality of life.[1, 2] However, little is known about women's symptom experience after surgical treatment for vulvar neoplasia. Vulvar neoplasia includes vulvar intraepithelial neoplasia (VIN)[3] and vulvar cancer.[4] Vulvar neoplasia has an incidence of 2 to 7 per 100,000 women per year,[5, 6] with increasing incidence rates especially in young women and high recurrence rates.[7, 8]

Surgical removal of visible lesions is the standard therapy for women with VIN and vulvar cancer.[9, 10] High grade VIN lesions are usually managed by surgical excision or laser-vaporization.[1, 2, 11] Vulvar cancer is normally treated by local excision, partial or radical vulvectomy and inguinofemoral lymph node dissection depending on disease stage and lymph node involvement. Depending on tumor staging, medical interventions, (neo-) adjuvant chemotherapy and radiation therapy may be indicated.[10, 12]

Although treatment for vulvar neoplasia has become more individualized and less radical in recent years,[13] women still experience symptoms related to wound complications and other adverse events.[14] The symptoms include bleeding, pain, odor, itching, burning, as well as problems with sexual dysfunction, loss of urine control and constipation.[15-17] Despite the fact that investigators have identified the occurrence of multiple symptoms in women with vulvar neoplasia, little is known about their self-reported symptom experience after surgical treatment.

According to Dodd et al. (2001), symptoms are defined as patients' perceived changes in the biopsychosocial functioning, sensations, or cognition.[18] There are two interrelated components of the symptom experience: symptom occurrence (frequency or severity) and symptom distress, the subjectively perceived burden of a symptom.[19] The newly developed WOMAN-PRO instrument measures symptom experience in this patient population includes wound-related symptoms, difficulties in daily life, psychosocial symptoms, and related distress. Understand the individual's symptom experience is crucial for effective symptom management.[20]

As clinicians often underestimate symptom severity or even miss side effects associated with preventable adverse events during clinical assessment, patient self-report is the gold standard for measuring symptoms and tends to lead to earlier recognition and reporting.[18, 21] Basch (2010)

emphasized the necessity of regularly including the patient's voice by collecting Patient-Reported Outcome (PRO) data as part of general screening for adverse symptom events. A PRO is any report of the status of a patient's health condition - such as symptoms - that comes directly from the patient.[22] Symptom assessment is essential for effective symptom control.[23] In oncology, application of PRO measures in clinical practice improved professional-patient communication and patient well-being.[24] PRO data can help to identify cancer patients' most bothersome symptoms.[25] Furthermore, PRO instrument can add important information for assessing consequences of treatment and for decision making.[26] To have more valid and patient-oriented information for clinical decision-making and for setting research priorities, PRO data on patients' post-vulvar-surgery symptom experience are needed. Therefore the aim of this study was to determine the prevalence of wound-related symptoms, difficulties in daily life, psychosocial symptoms and related distress experienced during the first 7-days after discharge in a German-speaking sample of women with surgically treated vulvar neoplasia.

Research questions were:

(1) How prevalent are symptoms during the first 7-days following hospital discharge following the surgical treatment of vulvar neoplasia?
(2) What is the mean number of symptoms and their distress level perceived by women with vulvar neoplasia?
(3) Which are the most prevalent and distressing symptoms?
(4) Are there associations between age, type of vulvar disease, stage of disease, and/or the extent of surgical treatment and symptom occurrence?

7.2 Methods

7.2.1 Study design

This cross-sectional study is the quantitative part of an international multicenter mixed-methods study (Clinical Trial ID: NCT01300663). This article focuses on women's symptom experience during the first 7 days following hospital discharge after the surgical treatment of vulvar neoplasia.

7.2.2 Sample and setting

Consecutive eligible women were recruited from gynecological wards or ambulatory facilities at four Swiss Hospitals (University Hospitals Basel, Berne, Zurich & Cantonal Hospital St. Gallen) and four German University Hospitals (Berlin, Dusseldorf, Freiburg, Munich). Women were eligible to participate in the study if they were older than 18 years, able to read and write German, diagnosed with vulvar neoplasia, and treated with vulvar surgery. Women who were cognitively impaired, had co-morbid severe psychiatric illnesses or were terminally ill were excluded from the study.

7.2.3 Variables and measures

We measured socio-demographic and medical variables, as well as symptom experience. Socio-demographic variables included age, marital status, nationality, educational level, current employment status, and living arrangement. Medical data included type of vulvar disease, stage of disease and therapy (Table 1 and 2).

Women's symptom experience after surgical treatment of vulvar neoplasia was measured with our newly developed WOMAN-PRO. This self-report instrument covers 31 symptoms occurring following surgery for vulvar neoplasia. The physical component assessed 15 wound-related symptoms and 5 difficulties in daily life. The psychosocial component has 11 items that inquire about psychosocial feelings, thoughts or activities. The response option for each item is a 4-point Likert scale [0-3]. For the wound-related symptoms and difficulties in daily life women were asked to rate how frequent they experienced the symptom / difficulty during the first 7 days after discharge (never, for 1 to 2 days, 3 to 4 days, or 5 to 7 days). For the psychosocial symptoms, women were asked to assess the severity of symptoms (not at all, a little bit, quite a bit, very much). For each reported symptom, associated distress was scored on a 4-point Likert scale [0-3] ranging from 'not at all' to 'very much distressing'. We developed the WOMAN-PRO instrument, according to the PRO guidelines, based on literature searches, expert feedback (n=9) patient interviews (n=20), and 2 pilot tests of the newly developed instrument with patients (n=10) and experts (n=6). The revised WOMAN-PRO showed an excellent item and scale content validity index (CVI=1.0). In this study we also examined the reliability of the instrument using a Cronbach's alpha coefficient. For the items representing wound-related symptoms and difficulties in daily life alpha was 0.70, and it was 0.87 for items representing psychosocial symptoms. An alpha of 0.70 or above reflects adequate reliability.[27] Prior to calculating Cronbach's alpha, we examined its appropriateness using inter-item and item-to-total correlations.

7.2.4 Data collection

Data collection occurred between October 1, 2010 and August 31, 2011. Trained nurses and physicians informed all eligible patients about the study. Hospitalized women who were interested in participating received a study package (containing study information, the informed consent and two questionnaires: WOMAN-PRO and the socio-demographic form) to complete at home. To ensure subject confidentiality, women were asked to return the signed consent form and completed questionnaires in separate pre-addressed stamped envelopes. The first author called up all women once one week following discharge to remind them filling out the questionnaires and return them to the center. Women who did not return the questionnaire were considered as non-responders. Returned questionnaires were checked for completeness and women were called to obtain missing responses. Clinical information was collected from patients' medical files by the first author.

7.2.5 Data analysis

We randomly selected and double entered 30% of the questionnaires to ensure data quality. The data entry error rate was less than 1%. Socio-demographic, medical, and WOMAN-PRO data were analyzed descriptively using means, frequencies and proportions. Missing responses are declared in the Tables and Figures. In the Scatterplot we used mean symptom frequency / severity scores (y-axis) and mean symptom distress scores (x-axis). Mean scores were calculated per item over all patients. We also examined to what extent the physical and psychosocial dimensions of symptom frequency / severity could be explained by the variables age and type of vulvar disease, stage of vulvar disease, and the extent of vulvar surgery using two different multiple linear regression analyses. The first regression model was with physical and the second with psychological mean frequency / severity symptom scores across all items as the outcome variable. The distress domain was not taken into account. Predictors were entered in the regression analysis simultaneously as continuous variables. Analyses were performed in SAS 9.1.3. (SAS Institute, Inc., Cary, NC).

7.2.6 Ethical considerations

This study was approved by the ethics committees of Berne, Basel (no.17/11), St. Gallen (no. 10/123/1B), and Zurich (no. 2010-0467/0) in Switzerland and Berlin, Dusseldorf (no. 3505), Freiburg (no. 385-09) and Munich (no.412-09), Germany. The master list linking the study ID number to the women was stored in a locked cabinet separate from the study data to guarantee confidentiality.

7.3 Results

7.3.1 Sample characteristics

Across the setting, 117 women had vulvar surgery during the study period; 15 declined to be assessed for eligibility and 35 did not meet eligibility criteria (Figure 1). Of the 67 eligible patients, 13 women (19.4%) refused to participate. Tables 1 and 2 summarize the sample's socio-demographic and medical characteristics (N = 54).

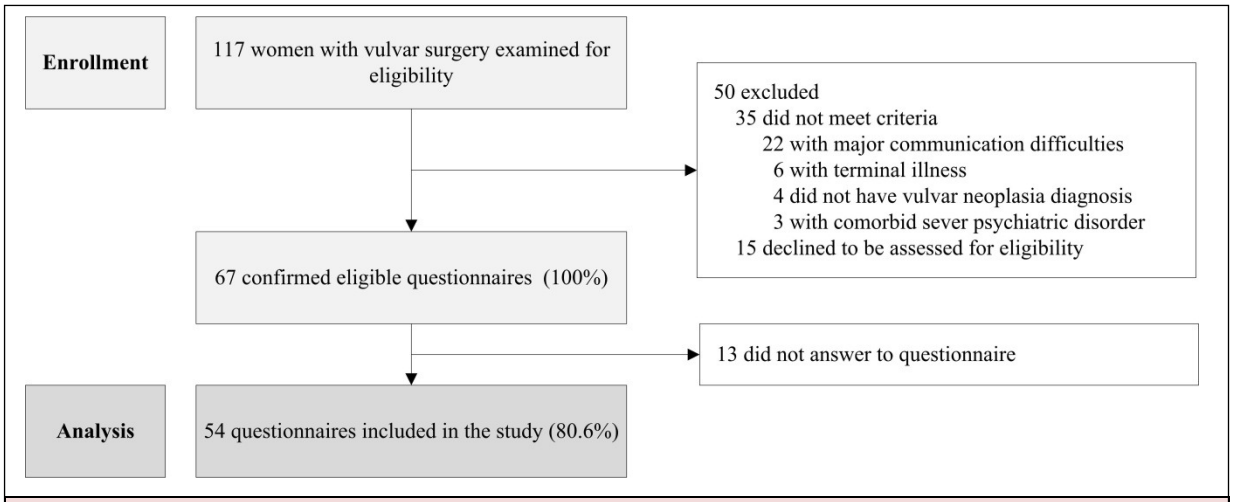

Figure 1. Flowchart of Sample (80,6% participant rate).

Table 1. Sample's Socio-demographic Characteristics (N=54).

Characteristics	No. (%)
No of patients per country (n, %)	
Germany	28 (51.9%)
Switzerland	26 (48.1%)
Age; median (IQR)	
In years	54 (44; 66)
Marital status (n, %)	
Married	20 (37.0%)
Single / widowed / Divorced	33 (61.1%)
Missing	1 (1.9%)
Nationality (n, %)	
German	31 (57.4%)
Swiss	19 (35.2%)
Others	3 (5.6%)
Missing	1 (1.9%)
Educational level (n, %)	
10 or less school years	18 (33.4%)
More than 10 years	34 (63.0%)
Missing	2 (3.7%)
Current employment status (n, %)	
Working	35 (64.8%)
Not working	19 (35.2%)
Health insurance (n, %)	
General	43 (79.6%)
Half private / private	10 (18.5%)
Missing	1 (1.9%)
Living arrangement (n, %)	
Alone	24 (44.4%)
With the partner or others	28 (51.9%)
Missing	2 (3.7%)
Wound management (n, %)	
Without help	35 (64.8%)
Help of a health care professionals	13 (24.1%)
Help by a non-health care professionals	4 (7.4%)
Missing	2 (3.7%)

IQR, interquartile range (1.quartile; 3.quartile)

Table 2. Sample's Medical Characteristics (N=54).

Characteristics	No. (%)
Type of vulvar disease (n, %)	
Condyloma accuminatum	5 (9.3%)
VIN (II & III)	12 (22.2%)
Vulvar squamous cell carcinoma	31 (57.4%)
Melanoma	2 (3.7%)
Other vulvar carcinoma	2 (3.7%)
Missing	2 (3.7%)
Stage of disease (AJCC Groupings) (n, %)	
0	17 (31.5%)
Ia and Ib	28 (51.9%)
II	1 (1.9%)
III	1 (1.9%)
IV	5 (9.3%)
Missing	2 (3.7%)
Previous diagnosis with VIN or VC (n, %)	
Yes	11 (20.3%)
Missing	2 (3.7%)
Surgical therapy [a] (n, %)	
Local excision	6 (11.1%)
Laser-vaporization or skinning vulvectomy	14 (25.9%)
Partial vulvectomy [b]	26 (48.2%)
Radical wide excision/vulvectomy [c]	6 (11.1%)
Missing	2 (3.7%)
Lymph node dissection (n, %)	
Sentinel	21 (38.9%)
Inguinofemoral	14 (25.9%)
Removed lymph nodes; median (IQR)	2 (0; 7)
Missing	2 (3.7%)
Adjuvant postoperative therapy (n, %)	
Chemo- or radiotherapy during hospitalization	2 (3.7%)
Length of hospitalization (days); median (IQR)	9 (3.5; 12.5)
Missing	2 (3.7%)
Filling out the diary; median (IQR)	
Days after discharge	7 (7; 8)

IQR, interquartile range (1.quartile; 3.quartile); VIN, vulvar intraepithelial neoplasia; VC, vulvar cancer;
AJCC stage groupings, American Joint Committee on Cancer's

[a] Surgeries were performed at all hospitals according to the guidelines of the German Society for Gynecology and Obstetrics.

[b] Partial vulvectomy means an ant-, posterior or unilateral surgical treatment.

[c] Radical wide excision/vulvectomy incorporates a bilateral surgical treatment.

7.3.2 Symptom prevalence and distress

The mean number of symptoms per woman was 20 (SD 5.02) with a range of 10 to 31 symptoms. Table 3 presents the number and proportion of women reporting each symptom along with the mean frequency / severity and distress scores for individual items. The three most prevalent wound-related symptoms were 'swelling' (n=46), 'drainage' (n=46) and 'pain' (n=43). The three most prevalent difficulties in daily life were 'sitting' (n=52), 'wearing clothes' (n=48) and 'carrying out my daily activities' (n=43). 'Tiredness' (n=51), 'insecurity' (n=44) and 'feeling that my body has changed' (n=42) were three most prevalent psychosocial symptoms. Based on mean scores of all 31 assessed items, 'sitting' (2.67), 'wearing clothes' (2.33) and 'swelling' (2.20) were the most frequent symptoms. On average, women reported that they occurred for 3 to 4 days. The most distress symptoms were 'sitting' (1.98), 'carrying out my daily activities' (1.79), and 'open spot (e.g. opening of skin or suture)' (1.79) which were on average reported to be 'quite a bit' distressing. Figure 2 shows the classification of items into four categories: (1) frequent / severe and distressing (n=5), (2) infrequent / not severe but distressing (n=14), (3) frequent / severe but not distressing (n=6), and (4) not frequent / severe and not distressing (n=6). 'Sitting', 'wearing clothes' and 'carrying out my daily activities' were the three most distressing and most common difficulties. The two least severe but still distressing psychosocial symptoms were 'embarrassment' and 'sadness'.

Table 3. Symptom Prevalence in descending Order with Number and Percentages of Women experiencing a Symptom, mean Symptom Frequency/Severity and Distress Scores[a] (N=54).

Symptom	No. (%) of patients with a symptom	Symptom frequency/ severity Mean (SD)[a]	Symptom distress Mean (SD)
Wound-related symptoms			
Swelling	46 (85.2%)	2.20 (1.14)	1.39 (0.95)
Drainage (e.g. clear, cloudy)	46 (85.2%)	2.13 (1.13)	1.26 (0.80)
Pain	43 (79.7%)	1.78 (1.19)	1.42 (0.91)
Bleeding	41 (75.9%)	1.70 (1.25)	1.27 (0.90)
Altered sensation (e.g. numbness)	36 (66.7%)	1.81 (1.39)	1.53 (0.97)
Redness	35 (64.8%)	1.59 (1.34)	0.94 (0.94)
Burning	32 (59.3%)	1.39 (1.34)	1.52 (0.85)
Unusual odor	31 (57.4%)	1.43 (1.37)	1.50 (0.98)
Hardness	30 (55.6%)	1.41 (1.39)	1.47 (0.97)
Pressure	30 (55.6%)	1.28 (1.29)	1.30 (0.79)
Open spot (e.g. opening of skin or suture)	28 (51.9%)	1.20 (1.28)	1.79 (0.92)
Changed skin color	26 (48.2%)	1.13 (1.32)	0.85 (0.88)
Itching	24 (44.4%)	0.94 (1.22)	1.38 (0.88)
Warmth	23 (42.6%)	0.76 (1.04)	0.61 (0.78)
Scarred skin[b]	19 (35.9%)	0.87 (1.29)	1.35 (0.93)
Difficulties in daily life			
During sitting	52 (96.3%)	2.67 (0.73)	1.98 (0.90)
Wearing clothes (e.g. underwear, trousers)	48 (88.9%)	2.33 (1.08)	1.69 (0.90)
Carrying out my daily activities (e.g. climbing stairs, cooking, working)	43 (79.6%)	2.07 (1.24)	1.79 (0.89)
During bowel movements	32 (59.3%)	1.13 (1.17)	1.63 (0.94)
Passing urine	29 (53.7%)	1.06 (1.19)	1.69 (0.81)
Psychosocial symptoms			
Tiredness	51 (94.4%)	1.54 (0.82)	1.04 (0.92)
Insecurity	44 (81.4%)	1.31 (0.91)	1.50 (0.82)
Feeling that my body has changed	42 (77.8%)	1.46 (1.09)	1.57 (0.97)
Feel that I reached my limit (e.g. be exhausted)	39 (72.2%)	1.30 (1.00)	1.61 (0.82)
Concerns related to sexuality	37 (68.5%)	1.30 (1.08)	1.66 (0.91)
Anxiety	36 (66.7%)	1.04 (0.95)	1.67 (0.83)
Changed social activities (e.g. meeting friends, excursions)	34 (63.0%)	1.04 (0.97)	1.50 (0.71)
Sadness	34 (63.0%)	0.94 (0.88)	1.45 (0.79)
Changed feeling about myself as a woman (e.g. concerning self-confidence)	30 (55.6%)	1.04 (1.12)	1.73 (0.91)
Embarrassment	23 (42.6%)	0.69 (0.93)	1.50 (0.93)
Difficulties in my partnership	18 (33.3%)	0.54 (0.91)	1.25 (1.07)

[a] Symptom frequency/severity mean scores refers to: (1) symptom frequency for the wound-related symptoms and difficulties in daily life (0 = never; 1 = 1-2 days; 2 = 3-4 days; 3 = 5-7 days), as well as to (2) symptom severity for psychosocial symptoms (0 = not at all; 1 = a little bit; 2 = quite a bit; 3= very much). Symptom distress mean scores ranged from 0 = not at all, 1 = a little bit, and 3 = quite a bit, to 4 = very much distressing.

[b] For the symptom 'scarred skin', data from 53 patients were available due to missing values.

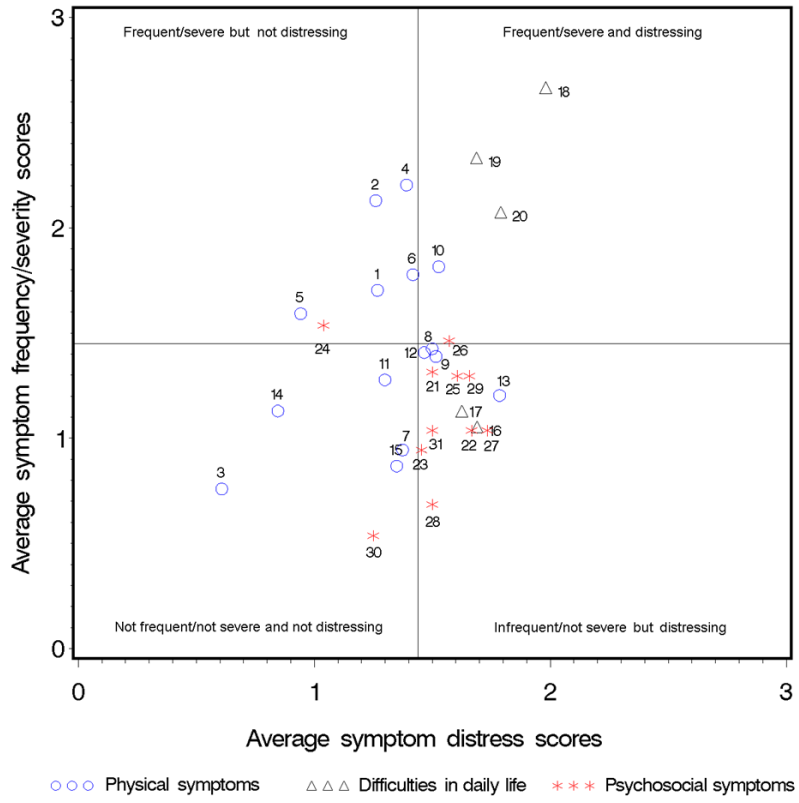

Figure 2. Scatterplot: Ranking of Average Symptom[a] Frequency / Severity and Distress Scores (mean scores per item over all patients, N=54).

[a] Legend:

Wound-related symptoms	Difficulties in daily life	Psychosocial symptoms
1 = Bleeding 2 = Drainage (e.g. clear, cloudy) 3 = Warmth 4 = Swelling 5 = Redness 6 = Pain 7 = Itching 8 = Unusual odor 9 = Burning 10 =Altered sensation (e.g. numbness) 11 = Pressure 12 = Hardness 13 = Open spot (e.g. opening of skin or suture) 14 = Changed skin color 15 = Scarred skin [b]	16 = Difficulties passing urine 17 = Difficulties during bowel movements 18 = Difficulty during sitting 19 = Problems wearing clothes (e.g. underwear, trousers) 20 = Difficulty carrying out daily activities (e.g. climbing stairs, cooking, working)	21 = Insecurity 22 = Anxiety 23 = Sadness 24 = Tiredness 25 = Feel that I reached my limit (e.g. be exhausted) 26 = Feeling that my body has changed 27 = Changed feeling about myself as a woman (e.g. concerning self-confidence) 28 = Embarrassment 29 = Concerns related to sexuality 30 = Difficulties in my partnership 31 = Changed social activities (e.g. meeting friends, excursions)

[b] For the symptom 15 'scarred skin', data from 53 patients were available due to missing values.

7.3.3 Relationship between variables and symptom occurrence

In our linear regression analysis the average frequency / severity of physical (wound-related and daily life) and psychosocial symptoms were not significantly related to the subjects' ages or to the disease- and treatment-related factors examined (i.e. type of vulvar disease, stage of disease and the extent of surgical procedures, Table 4).

Table 4. Symptom Occurrence and its Relationship to Age and Disease- and Treatment-related Variables (N=52).

Outcome variable: Mean frequency/severity score over all wound-related and daily life symptoms (Model 1)	df	Wald (95%CI)	Chi-Square	p value
Age				
Years (1-)	1	0.00 (-0.01 - 0.01)	0.29	0.5873
Type of vulvar disease				
VIN (incl. condylomata), Vulvar cancer (1,2)	1	0.04 (-0.36 - 0.44)	0.04	0.8452
Stage of vulvar disease				
AJCC Groupings (0-IV)	1	0.03 (-0.12 - 0.17)	0.16	0. 6892
Surgical therapy				
Excision, laser-vaporization or skinning vulvectomy, partial vulvectomy, radical wide excision (1-4)	1	0.09 (-0.83 - 0.27)	1.05	0.3065
Outcome variable: Mean frequency/severity score for all psychosocial symptoms (Model 2)	**df**	**Wald (95%CI)**	**Chi-Square**	**p value**
Age				
Years (1-)	1	-0.01 (0.01- -0.02)	1.42	0.2328
Type of vulvar disease				
VIN (incl. condylomata), Vulvar cancer (1,2)	1	0.34 (0.19 - 0.87)	1.56	0.2115
Stage of vulvar disease				
AJCC Groupings (0-IV)	1	-0.06 (-0.26 - 0.13)	0.41	0.5225
Surgical therapy				
Excision, laser-vaporization or skinning vulvectomy, partial vulvectomy [a], radical wide excision [b] (1-4)	1	0.03 (-0.20 - 0.27)	0.08	0.7736

CI=confidence interval; df=degree of freedom; AJCC stage groupings, American Joint Committee on Cancer's
[a] Partial vulvectomy means an ant-, posterior or unilateral surgical treatment.
[b] Radical wide excision/vulvectomy incorporates a bilateral surgical treatment.

7.4 Discussion

To our knowledge this is the first study exploring self-reported symptom frequency / severity and distress during the first week after hospital discharge in women with vulvar neoplasia and surgical treatment. In addition to objective measures such as wound complications, this PRO data allow evaluation of symptoms and symptom-related distress from women's perspective, which provide relevant additional information for researchers and clinical practitioners. The high participation rate among women invited to participate in the study (80.6%) suggests that symptom assessment with the self-report WOMAN-PRO instrument is feasible.

Women in this study experienced a high number of symptoms (mean 20, SD 5.02, range 10-31). This number is larger than previously reported in studies with surgical or advanced cancer samples where the mean or median number of symptoms per patient ranged from 2 to 13.[28, 29] Differences may be related to the different sample characteristics, use of different measures, or assessing a variable number of symptoms, as well as different data collection time points.

In this study, 80% or more of the women experienced the wound-related symptoms 'swelling', 'drainage', and 'pain'. We were unable to identify other studies that examined the prevalence of swelling and drainage in this patient population in the last ten years. Other studies have examined the prevalence of pain and consistent with our findings, reported that it was the most prevalent adverse event associated with the treatment of vulvar neoplasia.[1, 30] Kaushik et al.[1] described the prevalence of adverse events in a randomized clinical trial comparing carbon dioxide laser (CO2 laser) and ultrasound surgical aspiration (selective removal of diseased tissue) in 30 women with VIN. One week after surgery, patients completed a postoperative pain assessment by using a visual analog pain scale and all experienced pain. Other adverse events were evaluated once 2 to 4 weeks after surgery and included scars (n = 5, 16.6%), dysuria or burning (n = 7, 23.3%) [1]. Comparable prevalence data was not found for other assessed symptoms.

In the current study, the three most prevalent psychosocial symptoms were 'tiredness' (94.4%), 'insecurity' (81.4%) and 'feeling that my body has changed' (77.8%). This is consistent with previous studies which reported that tiredness[31] and changed body image[32] were reported by women with vulvar neoplasia during the course of their therapy.

Surprisingly, we found that 'sitting', 'wearing clothes' and 'carrying out my daily activities' were the 3 most common and most distressing problems identified by the women in this study. In fact, these items were, on average, rated considerably higher in both their occurrence and distress dimensions than most wound-related and psychosocial symptoms. Three previous qualitative studies reported that they were distressing for women with vulvar neoplasia.[16, 20, 33]

The evaluation of distress provides relevant additional information on patients' symptom experience. We found that 'embarrassment' was a less common (42.6%) and less severe (0.69) symptom in our sample, but still distressing for the women who experienced it (distress score 1.50). This is similar to previous qualitative studies that found that embarrassment was a distressing problem for women with vulvar neoplasia.[15, 34] Attention should be given to symptoms associated with high distress because such symptoms are linked to poor quality of life.[35] Women with vulvar neoplasia should, therefore, be asked about both common and distressing symptoms.

The Scatterplot (Figure 2) allows clinicians to identify the relationship between frequency / severity and distress of all symptoms. Whereas physical symptoms may occur more frequent, in this sample

they were less distressing than psychosocial symptoms and difficulties in daily life. Symptoms that were neither frequently occurring nor distressing such as 'warmth' could be left out of the instrument to diminish the burden of completing a long questionnaire. The findings of this and future studies can provide more balanced information for affected women and their families about what to expect most frequently as well as the symptoms that may be most distressing after discharge.

We studied a heterogeneous study sample of women that included two types of vulvar diseases and different tumor stages, ages[36] and surgical treatments[37] which are known to effect the risk for short-term complications (e.g. wound breakdown) after vulvar surgery. In our study we did not find a significant relationship between the average symptom severity / frequency and the above mentioned variables. As the small sample limited the power to detect relationships that may have been evident with a larger sample, these relationships should be examined in future studies.

In summary, women with vulvar neoplasia (33-96%) seem to experience significant number of symptoms and many of those symptoms are distressing. However, it is still unclear if and which type of intervention may benefit these women. The findings of this study support the necessity to monitor short-term symptoms carefully in all women with vulvar neoplasia after surgical treatment and to investigate treatment and supportive care options. An assessment of symptom experience from the individual's perspective can support the goal to avert negative outcomes. It should be followed by identifying appropriate intervention strategies.[18]

The findings of this trial need to be interpreted in light of potential limitations: The sample size was small, which limited the power of detecting relationships between variables. To reduce patients burden for a new measure, women were asked to complete the WOMAN-PRO instrument only once after discharge. We were unable to measure differences between responders and non-responders. Further examination of psychometric properties of the WOMAN-PRO is still needed and the instrument should be also tested to demonstrate its ability to detect outcome changes over time. To address some of these limitations, in further trials we would include a larger sample, compare responders and non-responders, evaluate addition psychometric properties of the WOMAN-PRO and / or examine its ability to detect changes in women's symptom experience over time following surgery.

7.5 Conclusions

This trial provides preliminary evidence that the WOMAN-PRO instrument for women with vulvar neoplasia and surgical treatment who attend cancer centers offers a feasible, targeted screening measure to support systematic symptom assessment. WOMAN-PRO data focusing on patients' post-vulvar-surgery symptom experience (1) showed high symptom prevalence and distress, (2) calls for a comprehensive symptom assessment, (3) may allow identification of areas for symptom management. Where difficulties with symptom control exist, WOMAN-PRO data may allow clinicians to identify symptoms that need to be the focus of care because they are distressing, and to evaluate the impact of patient-centered care on the occurrence of symptoms and their associated distress.

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CHAPTER 8:

DISCUSSION

DISCUSSION

In this final chapter the key findings of the research project's studies are summarized and discussed (8.1) and the limitations and strengths of research methods are described (8.2). Further, implications for research (8.3) and practice (8.4) are suggested while also outlining further perspectives. This chapter ends with conclusions (8.5).

Our research project added to the existing knowledge on complications, symptoms and associated distress of women with surgically treated vulvar neoplasia. Using quantitative and qualitative research methods made it possible to focus on both the clinician and the patient perspective. Therefore both perspectives will be discussed in this chapter.

8.1 Discussion of key findings

This discussion will focus on the following three key findings across the research project: post-vulvar-surgery complications identified by clinicians (8.1.1), post-vulvar-surgery experiences reported by women with vulvar neoplasia (8.1.2), and the new WOMAN-PRO instrument for patients and clinicians (8.1.3).

8.1.1 Post-vulvar-surgery complications identified by clinicians

The results of the first cross-sectional study of this thesis showed a high prevalence of short-term wound complications of 45.4% (49/108), indicating a need for systematic wound assessment. Wound assessment is necessary especially for women at high risk for wound-related complications after hemi- and radical vulvectomy (OR, 2.6; 95% confidence interval [CI], 1.34-5.14) and inguinofemoral lymphadenectomy (OR, 3.0; 95% CI, 1.03-8.76).[1] This research study generated knowledge about post-vulvar surgery wound complications utilizing two approaches, a literature search and a cross-sectional study. The literature search, as described in the introduction section of the cross-sectional article (Chapter 3), revealed that previous research focused on a limited selection of wound complications such as wound dehiscence and infections. The full range of wound complications was not fully summarized.[2] The findings of the literature search guided us in the development of a data collection tool utilized to collect medical record information about eight short-term wound complications. This retrospective study showed that women, particularly after hemivulvectomy, radical vulvectomy, and inguinal lymphadenectomy, are at higher risk of developing complications.

Better risk management including systematic wound assessment and early risk management may contribute to lowering these risks.[1] Although other studies described several risk factors for wound complications,[3-6] this study with a small sample of 108 patients found only two significant predictors, hemi- and radical vulvectomy and inguinofemoral lymphadenectomy. Addition research is needed to clarify the risk factors for wound complications following the surgical treatment of vulvar cancer. Secondary to the rarity of vulvar cancer, international multicenter studies will be necessary to provide an adequate sample to identify these risk factors.

Despite study limitations, our and other studies confirm that the wound complications are a frequent problem in patients who have had surgical treatment of vulvar neoplasia.[3-5] Furthermore, these complications lead to substantial patient morbidity,[7-9] prolonged hospital stay and cause considerable costs.[10-12] The results of these studies have provided the evidence-base for a multidisciplinary team of the Department of Obstetrics and Gynecology, University Hospital Berne, Switzerland to develop and implement an evidence-based guideline for wound management for patients after hemivulvectomy, radical vulvectomy, and inguinal lymphadenectomy. The guideline describes a clinical pathway for care which should contribute to prevention, recognition and treatment of wound complications.[13]

Current evidence on complication rates and our experience in clinical practice show that further research and practice development are needed. The evaluation of implemented guidelines and the development of effective wound management interventions remain a central issue that nurses have to focus on in the future.[14, 15] In addition, interventions are needed to address the assessment and management of other common post-surgical complications such as lymphedema,[6] depression,[16] sexual dysfunction,[17] and the negative impact of this intimate condition on women's lives.[18]

8.1.2 Post-vulvar-surgery experiences reported by women with vulvar neoplasia

The results of our qualitative study provided a conceptual model to inform nurses and physicians about the perceptions that women with vulvar neoplasia have about their post-surgical symptom experiences and management. Narratives showed that vulvar neoplasia is considered an unspoken disease. Women experienced a lack of information from different health professionals that might be related to the stigmatization of the vulva. They expressed many difficulties in communicating about their disease, caring for their vulva and dealing with symptoms. This information gap and the difficulties evoked negative emotional responses, affected interpersonal interactions and caused potentially preventable distress.[19] These findings are consistent with other qualitative research findings.[15, 18, 20, 21]

Our qualitative findings revealed, that women experience similar symptoms 'prior to their diagnosis' and 'during their postoperative wound healing process'. They seemed not to have a clear understanding of wound healing-related symptoms. Some women worried that many 'normal' or

'expected' postoperative symptoms were a sign that their cancer has reoccurred. These issues appear to increase women's uncertainty and their distress level. Further aspects discussed in the literature call for action in clinical practice: (1) early and differentiated VIN diagnosis is frequently missed by physicians and such a delayed diagnosis can be associated with rapid progression to squamous cell carcinoma,[22] and (2) the lack of a standard screening program to detect precursor lesions.[23] Additionally, recent qualitative research has illustrated that most women were unfamiliar with vulvar cancers symptoms.[24, 25] Therefore, we recommend that health care providers educate women about symptoms that may indicate vulvar neoplasia.

Another two questions arose out of the qualitative portion of this dissertation that need investigated in the future, the clinician-patient collaboration and socio-cultural aspects. Clinicians' recommendations were perceived as either enablers or barriers to managing of vulva care and the symptoms that occurred. Clear advice concerning symptom management was given to some patients. Other clinicians, however, did not even assess symptoms during the hospital stay. Women described several issues related to obtaining professional support during the follow-up, e.g. changing physicians, not having a trusting physician-patient relationship and time pressure of nurses and physicians. Further, socio-cultural factors added to women's experience of distress,[19, 26] e.g. communication about an unspoken disease and the non-recognition of symptoms by patients and clinicians. The current debate about Human Papilloma Virus (HPV) vaccine and its related discourse that links HPV with sexually transmitted diseases[27-29] may enhance the stigmatization of this rare disease. The in-depth analysis of women's experiences showed a gap in the level of information concerning the above mentioned aspects. Further detailed insights into the care needs of women with vulvar neoplasia are necessary. For example, which information can be provided in written form and which information needs to be shared during personal appointments with nurses.[15, 20, 21]

In summary, women's experiences, clinician's evaluation and socio-cultural aspects all play a key role in decision-making regarding communication, symptom assessment and its management during vulvar neoplasia treatment. Consequently, including patient self-reporting as a major element in follow-up care has the potential to enhance the quality of supportive care.

8.1.3 The new WOMAN-PRO instrument for patients and clinicians

We developed a WOMen with vulvAr Neoplasia–Patient Reported Outcome (WOMAN-PRO) instrument to fill the void between complications identified by clinicians and symptoms reported by patients with vuvlar neoplasia (Appendix). The WOMAN-PRO content is described in detail in chapter 6. The self-report WOMAN-PRO showed excellent item and scale content validity (CVI=1.0) and adequate reliability (Cronbach's alpha≥0.70). In a prospective cross-sectional survey in eight Hospitals in Switzerland and Germany, outpatients (n=54) rated the occurrence of each of 31 symptoms, and the degree to which the symptoms distressed them during the first 7 days after

discharge following surgical treatment for their vulvar neoplasia (Chapter 7). WOMAN-PRO data showed high symptom prevalence and distress. The average number of symptoms reported per patient was 20 (SD 5.02, range 10-31 symptoms). In addition, the survey provided preliminary evidence that the WOMAN-PRO instrument offers a feasible, targeted screening instrument to support systematic symptom assessment. The new WOMAN-PRO provides (1) women with written information and (2) a list to assess the symptom experience, informational needs and associated distress of women with surgically treated vuvlar neoplasia. The symptom list in the new PRO measure supports systematic symptom assessment which has the potential to be used as an outcome measure in future research.

According to Dodd et al.,[30, 31] symptom assessment leads to the identification of the symptoms that need to be the focus for symptom management. Given that women in our qualitative study reported using a number of self-management strategies to manage their symptoms after vulvar surgery, we also included space for women to record these strategies in the WOMAN-PRO symptom diary. Clinicians can also use the Diary to provide individualized information for women about which symptoms are expected and which should prompt contact with the clinician based on the type of surgical procedure or other pertinent clinical information. For instance, after vulvar excision expected symptoms during the first four days after discharge include swelling, warmth and redness. This information should increase the capacity of women to perceive such symptoms as part of normal wound healing. Therefore, we consider the WOMAN-PRO instrument not only as a clinical instrument for health professionals but as guide for women to enhance their self-assessment, early recognition and evaluation of symptoms and their related distress. Our assumption is that such an approach may decrease women's uncertainty about symptoms and reassure their decision-making about when to seek health care provider evaluation. It can also provide clinicians with systematic information about key symptoms from a patient perspective, the impact of those symptoms on women's daily lives, and their unmet informational needs. In addition, women are given an opportunity to prioritize the three most important issues that they would like to address during their next appointment with their clinician. This personal preparation should facilitate communication and self-tailored action plans to manage symptoms.

However, the WOMAN-PRO instrument was not designed to address all of the complexity associated with effective self-management skills as proposed by Lorig (2002).[32] Self-management involves people taking responsibility for their own health and wellbeing, as well as learning to behave in a manner that promotes health and manages their illnesses.[32, 33] Lorig et al. (2002) described six self-management skills (1) problem solving, (2) decision making, (3) resource utilization, (4) the formation of a patient-provider partnership, (5) action planning, and (6) self-tailoring.[32] Evidence from clinical trials in patients with diverse chronic conditions suggests that supporting patient self-management positively impacts clinical outcomes, reduces health care costs and lowers the use of health care

services over the course of illness.[34-40] Given the WOMAN-PRO instrument content discussed above, we believe that this instrument has the potential to improve self-management following surgical treatment of vulvar neoplasia by assisting patients with problem solving, decision making, action planning, and individualized reporting of symptoms and needs during the immediate post-discharge period. Additional research is needed to determine the usefulness of the WOMAN-PRO beyond the initial post-discharge period. In addition, there is a gap in the evidence base concerning (1) the comprehensive self-management support needs of women with vulvar neoplasia with and without surgical treatment, and (2) the health care providers' implementation of evidence based and individualized intervention strategies to improve health outcomes. Both aspects will be further elaborated below (see 'implications for future research and practice')

8.2 Limitations and strengths of research methods

Study 1 of this research project was a cross-sectional study exploring the period prevalence and risk factors for postoperative short-term wound complications in vulvar cancer which also summarized the literature from a clinical perspective. Studies 2 to 5 were guided by an sequential exploratory two-phase mixed-methods approach with equal weighting of qualitative and quantitative data.[41] Our intent in the first phase was to conduct an interview study to explore the symptom experience in women with surgically treated vulvar neoplasia from a patient perspective. In the second phase, findings from this qualitative interview study were used to develop the WOMAN-PRO instrument for quantitative studies and for clinical purposes.

The research project has three main methodical limitations. First, not all aspects of the updated patient-reported outcome guidelines published during our ongoing project could be addressed. For example we did not select, translate and test items from the Common Terminology Criteria for Adverse Events (CTCAE) - PRO item bank, which contains symptoms related to adverse events of cancer treatment.[42] Second, a limitation in the prospective cross-sectional survey was that we only assessed one measurement time point. As a result, we were not able to capture changes in symptoms over time. Third, the limited timeframe for data collection in the survey restricted the sample size and only permitted us to partly test the psychometric properties of the WOMAN-PRO instrument.

Utilization of a mixed-methods approach in this research project had several methodical strengths. The interview data broadened understanding of experienced symptoms and their related distress, as well as providing insights into problems that women experienced during the course of their illness. Second, the new conceptual model developed from the qualitative study enabled us to formulate items for the new WOMAN-PRO instrument. Therefore, we believe that the sequential exploratory mixed-method design was vital to the development of knowledge from a patient perspective, and that this comprehensive and differentiated information would not have been arisen from an approach that was

purely quantitative. Third, based on the qualitative and quantitative study results we were able to develop a new PRO measure and collect initial evidence about symptom prevalence and related distress in two European countries.

8.3 Implications and perspectives for future research

Based on our findings, further studies need to include a larger sample so that addition psychometric properties of the WOMAN-PRO can be examined. We only examined women's symptom experiences and distress during the first 7 days after discharge following vulvar surgery. Future studies should examine the ability of the WOMAN-PRO to detect changes in women's symptom experience over time following surgery.

In general, nursing research needs to progress from descriptive to intervention studies to be more useful to clinicians and patients.[43-46] It is important for intervention studies to include PRO self-reporting measures to monitor subjective adverse events and assess specific treatment benefits from the patient perspective.[47, 48] This may improve the quality and completeness of disease specific intervention outcome data, provide a more comprehensive picture of the patient experience, and improve the efficiency of clinical operations.[49] Based on the evidence discussed above, we plan (1) to develop and test a patient self-management support intervention for women with vulvar neoplasia, and (2) continue to test the psychometric properties of the WOMAN-PRO instrument in future studies. Guided by the United Kingdom Medical Research Council's Complex Intervention Framework,[50] development and testing a patient self-management support intervention requires the following three steps:

(1) First, a meta-synthesis of qualitative studies describing aspects of self-management in women with vulvar neoplasia needs to be conducted.[51] This should result in a comprehensive understanding of informational and educational needs, self-management tasks and skills needed by affected women and their families. Then it is necessary to decide which needs could be translated into a self-management support intervention for women with different disease stages, therapies and co-morbidities.

(2) Second, a systematic literature review needs to elaborate the most effective self-management support intervention in terms of improving patient outcomes in the field of gynecologic oncology since based on our knowledge; no such interventions exist in the vulvar neoplasia literature. In addition current evidence about the effective implementation of research interventions in clinical practice should be considered.[52, 53]

(3) Third, the new developed self-management support intervention with a specified dose and duration should be tested in a pilot study to assess its effectiveness and feasibility as well as to understand the change process.[50]

To allow the simultaneous (1) examination of the newly developed self-management support intervention and (2) the psychometric testing of the WOMAN-PRO instrument, validated tools should be included in the planed pilot study to measure symptom occurrence and distress. In addition, to recruit a large enough sample size to ensure acceptable statistical power to perform analyses on subgroups, e.g. women with different disease stages, therapies and co-morbidities, a multicenter study will be required.

8.4 Implications and perspectives for practice

In addition to the implications for future research, we believe that this study also has implications for clinical practice. The high prevalence of symptoms and the finding that symptoms that are less common may, nonetheless, be distressing for the women who experience them, support the need for the systematic assessment of symptoms and their related distress in patients follow surgical treatment of vulvar cancer. Given this, we recommend that clinicians use and evaluate the new PRO self-report instrument as a major element of follow-up care in women with vulvar intraepithelial neoplasia (VIN) and vulvar cancer.

The shift of care to outpatient settings, the short hospital stays after surgical treatment, and the treatment by different players present challenges for health care.[54] The shorter hospital stays reduced the counseling time and inconsistent health care providers make the systematic assessment of symptoms and their related distress important.[54, 55] While research supports the importance of including patient reports when assessing symptoms of adverse events,[56-58] there is also some research to suggest that there is better agreement between nurse and patient-reported adverse event symptoms than between patient and physician reports. These findings suggest that nurses could play an important role in collecting symptom data related to adverse treatment events.[59] In our German-speaking context, interdisciplinary follow-up visits may improve recognition of early signs of recurrence and adverse events. Nurses and physicians play a key role in symptom assessment and management in women with vulvar neoplasia and their families. Based on our research and that of others,[56, 58, 60] we recommend the incorporation of PRO self-reports into the follow-up care in this patient population to facilitate communication, decision-making, symptom assessment and management. Clinicians should be educated in the delivery of individualized evidence-based care based on PRO data. The synthesis of PRO information with clinician's objective observations will result in better care for women who have vulvar neoplasia and surgical treatment. We suggest nurse-led follow-up consultations complementary to physician appointments to allow adverse symptom event monitoring. Whether vulvar-specific instruments will improve the completeness or interpretability of adverse symptom event data will be evaluated and reported in the future.[47]

8.5 Conclusions

We conclude that the results of this research project narrowed the gap in existing knowledge on women with vulvar neoplasia and post-surgical care. It added data to support nurses' and physicians' ability to identify patients at risk for post-surgical wound complications. Furthermore, it provided the first conceptual model of symptom experience in affected women. In addition, it added evidence on VIN patients' experiences during their illness trajectory. Furthermore, the development of the WOMAN-PRO instrument with a good content validity and reliability has the potential to contribute to the valid assessment of symptoms, informational needs and related distress in women with vulvar neoplasia who have undergone surgical treatment. Moreover, WOMAN-PRO data showed a high symptom prevalence and distress, and provided preliminary evidence that the WOMAN-PRO instrument offers a feasible, targeted screening instrument to support systematic symptom assessment.

The study results confirmed the need for further research on (1) implementation strategies for comprehensive symptom assessment and (2) identification of areas in symptom management. Clinicians should focus on the early recognition of symptoms and interventions to decrease symptom related distress in women with surgically treated vulvar neoplasia.

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APPENDIX:

DAS SYMPTOM-TAGEBUCH

Mein Symptom-Tagebuch

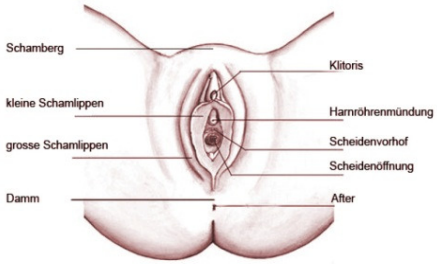
WOMAN-PRO Studie

2

Das Symptom-Tagebuch informiert Sie...

über zu erwartende Symptome nach einem chirurgischen Eingriff auf Grund vulvärer Zellveränderungen. Es bietet Ihnen die Möglichkeit zu prüfen, ob und welche Symptom-Erfahrungen bei Ihnen in den letzten sieben Tagen aufgetreten sind und welche dieser Erfahrungen belastend für Sie waren. Symptome sind Erfahrungen (z.B. körperliche Signale, Gefühle, Gedanken, Verhaltensweisen, Bedürfnisse). Symptom-Erfahrungen umfassen die Häufigkeit, Stärke, Dauer eines Symptoms und die daraus resultierende persönliche Bedeutung.

Die äusseren weiblichen Geschlechtsteile bezeichnen Fachpersonen als Vulva. Die Vulva umfasst die grossen und kleinen Schamlippen, den Schamberg, die Klitoris, den Scheidenvorhof, die Scheidenöffnung und die Harnröhrenmündung. Der Begriff vulväre Zellveränderung umfasst verschiedene Erkrankungen im Bereich der Vulva. Zum Beispiel handelt es sich um Zellveränderungen die in der Medizin als: vulväre intraepitheliale Neoplasien (VIN), Melanome oder Plattenepithelkarzinome bezeichnet und üblicherweise mit einem chirurgischen Eingriff behandelt werden. Die Wundheilung wird durch viele Faktoren beeinflusst und kann Tage bis Wochen in Anspruch nehmen. So sind in den ersten vier Tagen nach einem chirurgischen Eingriff Symptome wie Wärme, Schwellung, Rötung, Wundschmerz und der Austritt von Flüssigkeit normal.



Ihr persönliches Symptom-Tagebuch unterstützt Sie...
darin beeinflussbare Symptome zu erkennen, sie einzuschätzen und Ihre erlebten Symptome Fachpersonen mitzuteilen. Eventuell kann Ihnen ein Handspiegel helfen Ihre Vulva zu beobachten und Symptome einzuschätzen. Die Einschätzung der persönlich empfundenen Belastung auf Grund eines Symptoms kann Sie in der Entscheidung unterstützen, welche Symptome Sie beim nächsten Termin mit Ihrer Fachperson besprechen möchten.

Bitte notieren Sie...

zu erwartende Symptome über die Sie Ihre Fachperson vor der Entlassung informiert oder bitten Sie Ihre Fachperson diese zu notieren. Beispielsweise erhalten Sie Informationen über Symptome der Wundheilung und weitere Empfehlungen zum Verhalten nach der Operation (z.B. Bad nehmen, Schwimmbad- und Saunabesuch, Geschlechtsverkehr, Kondome benutzen).

Datum der Entlassung: .....

Ihre Ansprechperson bei Fragen (Name, Tel. Nr.): .....

Harmlose Symptome, die in den nächsten Tagen auftreten können:

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Warnsymptome, bei denen Sie sich umgehend bei einer Fachperson melden sollten:

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Hier ist Platz für Ihre persönlichen Notizen zum Verhalten nach der Operation:

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In der Regel füllen Sie das Symptom-Tagebuch am 7. Tag nach der Entlassung aus und bringen es zur ambulanten Kontrolle mit.

Ein Beispiel wie Sie Ihr Symptom-Tagebuch ausfüllen:

Schritt 1: Lesen Sie zuerst, um welches Symptom es sich handelt.
Schritt 2: Kreuzen Sie dann an, ob dieses Symptom bei Ihnen auftrat.
Schritt 3: Wenn das Symptom bei Ihnen auftrat kreuzen Sie an, wie belastend oder störend dies für Sie war.

1. Aufgabe lesen

2. Frage ankreuzen

3. Zweite Frage **NUR** ankreuzen, wenn das Symptom auftrat

Aufgabe:
Bitte kreuzen Sie an, wie oft jedes dieser Symptome im Wundgebiet in der letzten Woche bei Ihnen auftrat und wenn es auftrat, wie belastend es für Sie war.

	Wie oft haben Sie das Symptom erlebt?				**WENN das Symptom auftrat, wie stark hat Sie das belastet?**			
	nie	1-2 Tage	3-4 Tage	5-7 Tage	gar nicht	ein wenig	ziemlich stark	sehr stark
Blutung	☐	☒	☐	☐	☐	☐	☒	☐

Dieses Kreuz bedeutet, eine Blutung im Wundgebiet trat in der letzten Woche während 1-2 Tagen auf.

Dieses Kreuz bedeutet, die aufgetretene Blutung im Wundgebiet belastete Sie ziemlich stark.

Bitte informieren Sie ihre Fachperson über Ihre Symptom-Erfahrungen. Dies unterstützt die Auswahl und Weiterführung einer geeigneten Behandlung.

5

Datum des chirurgischen Eingriffs: .....

Datum, an dem Sie das Symptom-Tagebuch ausfüllen: .....

Bitte kreuzen Sie an, wie oft jedes dieser Symptome im Wundgebiet in der letzten Woche bei Ihnen auftrat und wenn es auftrat, wie belastend es für Sie war.

	Wie oft haben Sie das Symptom erlebt?				**WENN das Symptom auftrat, wie stark hat Sie das belastet?**			
	nie	1-2 Tage	3-4 Tage	5-7 Tage	gar nicht	ein wenig	ziemlich stark	sehr stark
Blutung	☐	☐	☐	☐	☐	☐	☐	☐
Austritt von Flüssigkeit (z.B. klar, trüb, eitrig)	☐	☐	☐	☐	☐	☐	☐	☐
Wärme	☐	☐	☐	☐	☐	☐	☐	☐
Schwellung	☐	☐	☐	☐	☐	☐	☐	☐
Rötung	☐	☐	☐	☐	☐	☐	☐	☐
Schmerzen	☐	☐	☐	☐	☐	☐	☐	☐
Juckreiz	☐	☐	☐	☐	☐	☐	☐	☐
Ungewöhnlicher Geruch	☐	☐	☐	☐	☐	☐	☐	☐
Brennen	☐	☐	☐	☐	☐	☐	☐	☐
Veränderte Empfindung (z.B. Taubheit)	☐	☐	☐	☐	☐	☐	☐	☐
Druck	☐	☐	☐	☐	☐	☐	☐	☐
Verhärtung	☐	☐	☐	☐	☐	☐	☐	☐
Offene Stelle (z.B. Haut oder Naht geht auf)	☐	☐	☐	☐	☐	☐	☐	☐
Veränderte Hautfarbe	☐	☐	☐	☐	☐	☐	☐	☐
Vernarbte Haut	☐	☐	☐	☐	☐	☐	☐	☐

Bitte kreuzen Sie an, wie oft jede dieser Schwierigkeiten in der letzten Woche bei Ihnen auftrat und wenn sie auftraten, wie belastend diese für Sie waren.

	Wie oft haben Sie die Schwierigkeiten erlebt?				**WENN die Schwierigkeiten auftraten, wie stark hat Sie das belastet?**			
	nie	1-2 Tage	3-4 Tage	5-7 Tage	gar nicht	ein wenig	ziemlich stark	sehr stark
Schwierigkeiten beim Wasserlassen	☐	☐	☐	☐	☐	☐	☐	☐
Schwierigkeiten beim Stuhlgang	☐	☐	☐	☐	☐	☐	☐	☐
Schwierigkeiten beim Sitzen	☐	☐	☐	☐	☐	☐	☐	☐
Schwierigkeiten, Kleider zu tragen (z.B. Unterwäsche, Hosen)	☐	☐	☐	☐	☐	☐	☐	☐
Schwierigkeiten, alltägliche Handlungen auszuführen (z.B. Treppen steigen, kochen, Arbeit im Büro)	☐	☐	☐	☐	☐	☐	☐	☐

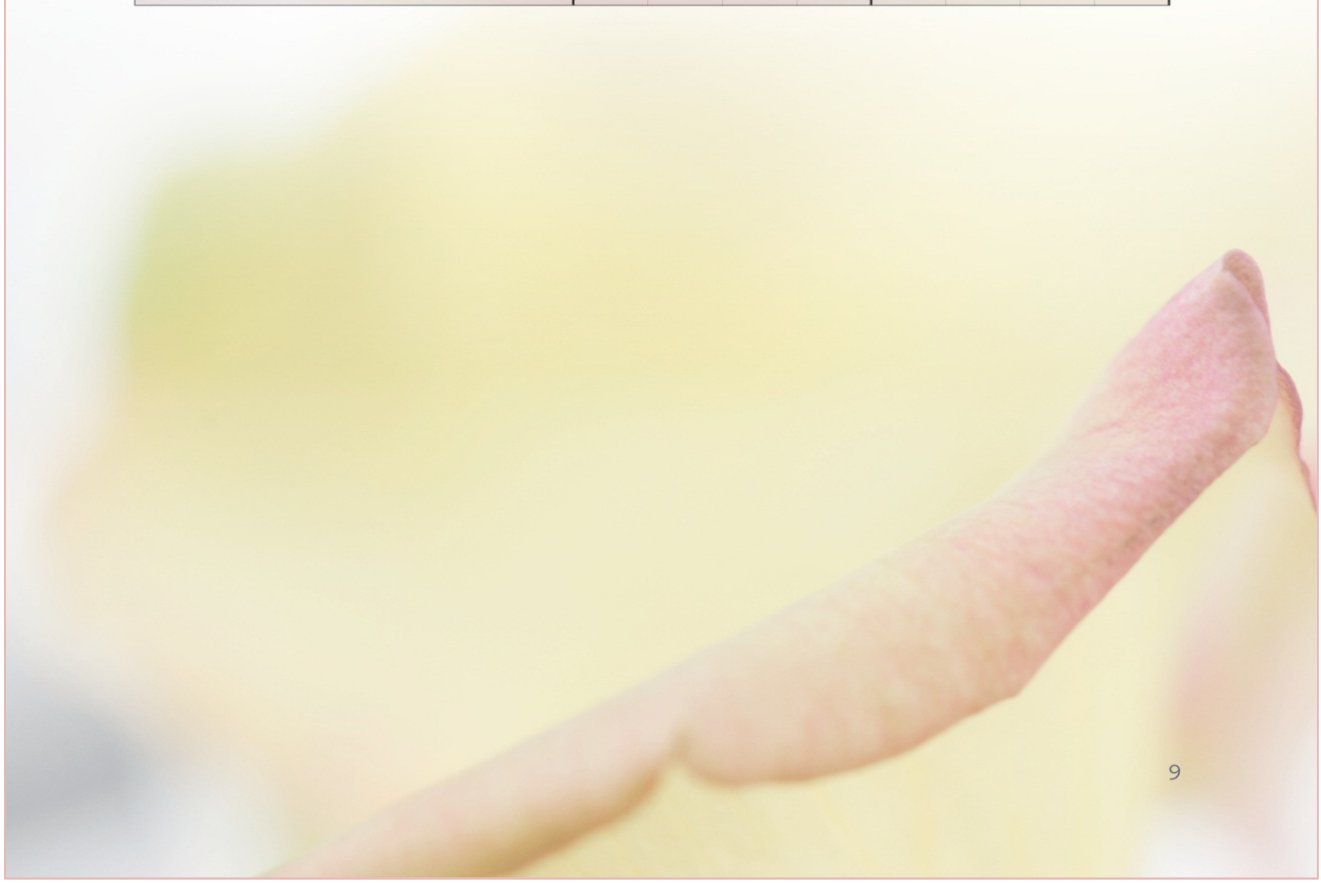
7

Bitte kreuzen Sie an, wie stark folgende Gefühle, Gedanken oder Verhaltensweisen durch die Erkrankung, den chirurgischen Eingriff oder durch das Wundgebiet in der letzten Woche beeinflusst wurden und wie belastend dies für Sie war.

	Wie stark erlebten Sie die Gefühle, Gedanken oder Verhaltensweisen?				**WENN die Gefühle, Gedanken oder Verhaltensweisen auftraten, wie stark hat Sie das belastet?**			
	gar nicht	ein wenig	ziemlich stark	sehr stark	gar nicht	ein wenig	ziemlich stark	sehr stark
Unsicherheit	☐	☐	☐	☐	☐	☐	☐	☐
Angst	☐	☐	☐	☐	☐	☐	☐	☐
Traurigkeit	☐	☐	☐	☐	☐	☐	☐	☐
Müdigkeit	☐	☐	☐	☐	☐	☐	☐	☐
Gefühl, an die eigenen Grenzen zu stossen (z.B. erschöpft sein)	☐	☐	☐	☐	☐	☐	☐	☐
Gefühl, einen veränderten Körper zu haben	☐	☐	☐	☐	☐	☐	☐	☐
Verändertes Gefühl, eine Frau zu sein (z.B. in Bezug auf das Selbstwertgefühl)	☐	☐	☐	☐	☐	☐	☐	☐
Gefühl, sich zu schämen	☐	☐	☐	☐	☐	☐	☐	☐
Bedenken in Bezug auf die Sexualität	☐	☐	☐	☐	☐	☐	☐	☐
Schwierigkeiten in der Partnerschaft	☐	☐	☐	☐	☐	☐	☐	☐
Verändertes Verhalten in Bezug auf soziale Aktivitäten (z.B. Freunde treffen, Spaziergänge)	☐	☐	☐	☐	☐	☐	☐	☐

Bitte kreuzen Sie an, wie gross ihr Bedürfnis nach weiteren Informationen zu den nachfolgenden Themen in der letzten Woche war und wie belastend dies für Sie war.

	Wie gross war ihr Bedürfnis nach weiteren Informationen?				**WENN ein Bedürfnis nach weiteren Informationen vorlag, wie stark hat Sie das belastet?**			
	nicht vorhanden	gering	mässig	gross	gar nicht	ein wenig	ziemlich stark	sehr stark
Bedürfnis, mehr Informationen über die Erkrankung zu haben	☐	☐	☐	☐	☐	☐	☐	☐
Bedürfnis, mehr Informationen über die Behandlung zu haben	☐	☐	☐	☐	☐	☐	☐	☐
Bedürfnis, mehr Informationen über die tägliche Hygiene der Vulva zu haben	☐	☐	☐	☐	☐	☐	☐	☐
Bedürfnis, mehr Informationen über die Versorgung des Wundgebiets zu haben	☐	☐	☐	☐	☐	☐	☐	☐
Bedürfnis, mehr Informationen über das Verhalten im Alltag zu haben (z.B. Unterwäsche tragen, Hobbys, Sexualität)	☐	☐	☐	☐	☐	☐	☐	☐



9

Falls Sie andere Symptome hatten, bitte notieren Sie diese in den leeren Feldern. Kreuzen Sie an wie stark ein Symptom durch die Erkrankung, den chirurgischen Eingriff oder durch das Wundgebiet in der letzten Woche beeinflusst wurde, und wie belastend dies für Sie war.

	Wie stark erlebten Sie das Symptom?				Wie stark hat Sie das Symptom belastet?			
	gar nicht	ein wenig	ziemlich stark	sehr stark	gar nicht	ein wenig	ziemlich stark	sehr stark
	☐	☐	☐	☐	☐	☐	☐	☐
	☐	☐	☐	☐	☐	☐	☐	☐
	☐	☐	☐	☐	☐	☐	☐	☐

Hier ist Platz für Ihre persönlichen Anliegen:
Über welche 3-5 Symptome (körperliche Signale, Gefühle, Gedanken, Verhaltensweisen, Bedürfnisse) möchten Sie beim nächsten Termin mit ihrer Fachperson sprechen?

.....

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.....

.....

.....

Überlegen Sie sich, was Ihnen in dieser Zeit der Veränderung gut tun könnte.
Haben Sie Lust sich drei Wünsche aufzuschreiben?

1. .....

.....

2. .....

.....

3. .....

.....

Wir wünschen Ihnen
alles Gute!

11

Version September 2010

WOMAN-PRO Studie

CURRICULUM VITAE

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EDUCATION

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05.2001 – 09.2005	**LECTURER ASSISSTANT** School of Nursing, Ausbildungszentrum Insel, Berne, Switzerland.
05.1999 – 05.2001	**STAFF NURSE** Surgical and geriatric care unit, Zieglerspital, Berne, Switzerland.
10.1993 – 04.1994	**STAFF NURSE** Acute geriatric care unit, Hüttenhospital, Dortmund, Germany.

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2001	Nursing License Switzerland / Registered Nurse AKP 20012101
1993	Nursing License Germany

MEMBERSHIP IN PROFESSIONAL AND SCIENTIFIC SOCIETIES

2009 – present	**EUROPEAN ACADEMY OF NURSING SCIENCE** (EANS) Member of the International Fellowship Program for Young Nursing Researchers
2007 – present	**SWISS ASSOCIATION OF NURSING SCIENCE** (VFP) Professional Association for Graduated Nurses Member of the Interest Groups Agogic & Oncology
2005-present	**SWISS ONCOLOGY ASSOCIATION** (ONKOLOGIEPFLEGE SCHWEIZ) Member of the Professional Association for Oncology Nurses

RESEARCH GRANTS

Mueller MD, Senn B, Eicher M, Engberg S, Spirig R. Creating and validating a patient-reported instrument to assess symptom experience related to surgical wounds in women with vulvar neoplasia - A mixed-methods study. 2009-2011, Krebsforschung Schweiz KFS 02456-08-2009: Direct costs 116.500 CHF. Role: Co-Investigator

RESEARCH AWARDS

EONS NOVICE RESEARCH AWARD 2010

Senn B. Creating and validating a Patient-Reported Instrument to assess symptom experience related to surgical wounds in women with vulvar neoplasia - A mixed-methods study. European Oncology Nursing Society, The Hague, Netherlands, April 15-16, 2010.

PUBLICATIONS

PEER REVIEWED JOURNALS

Senn B, Gafner D, Happ MB, Eicher M, Mueller MD, Engberg S, Spirig R. The unspoken disease: Symptom experience in women with vulvar neoplasia and surgical treatment - A qualitative study. Eur J Cancer Care (Engl) 2011; DOI: 10.1111/j.1365-2354.2011.01267.x.

Senn B, Kirsch M, Sanz CC, Karlou C, Tulus K, De Leeuw J, Ringnér A, Goossens GA, & Cleary V. How cancer research could benefit from the Complex Intervention Framework: students' experiences of the European Academy of Nursing Science summer school. Eur J Cancer Care (Engl) 2011; 20: 1-4.

Senn B, Mueller MD, Cignacco EL, Eicher M. Period prevalence and risk factors for postoperative short-term wound complications in vulvar cancer: a cross-sectional study. Int J Gynecol Cancer 2010; 20: 646-654.

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Eicher M, Senn B. [Oncology Nursing Research in Switzerland] Onkologiepflegeforschung in der Schweiz. Schweizer Krebsbulletin 2011; 2:124-126.

Senn B. Research flash: [Swiss Cancer League communication skills training programme for oncology nurses: an evaluation.] Ein Schulungsprogramm der Krebsliga Schweiz für Onkologiepflegende zur Förderung ihrer Kommunikationsfähigkeiten: Eine Evaluation. Onkologiepflege 2010; 2: 38-41.

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BOOKS / CHAPTERS IN BOOKS

Senn B, Gaertner B, Haldemann G, Walther Nufer T. [Guidance for evidence based education] Leitfaden für eine evidenzbasierte Unterrichtspraxis. Schriftenreihe Praxiswissen. hep Verlag. 2010; 1-52.

THESIS

MASTER THESIS

Institute of Nursing Science, University of Basel, Switzerland, 2008

Period prevalence and risk factors for postoperative short-term wound complications in vulvar cancer: A cross sectional study.

PUBLISHED ABSTRACTS

Senn B, Eicher M, Mueller, M., Engberg, S., & Spirig, R. The Post-surgery symptom experience of women with vulvar neoplasia: Development and content validity of a Patient-Reported Outcome (PRO) Instrument. Poster presentation at the European Multidisciplinary Cancer Congress ECCO 16, ESMO 36, ESTRO 30, Stockholm, Sweden, 2011, September 23-27. Abstract in European Journal of Cancer Abstract Book. Vol. 47, Suppl.1, p. 563-564.

Senn B. [Needs-oriented care in gynecology: a symptom diary for women after vulvar surgery] Bedürfnisgerecht pflegen in der Gynäkologie: ein Symptom-Tagebuch für Frauen nach vulvären chirurgischen Eingriffen. Oral presentation at the 14th International Seminar: Oncology Nursing - Advanced Practice of the German-speaking European School for Oncology (deso). St. Gallen, Switzerland, 2011, August 25-26. Abstract in Onkologische Pflege-Fortgeschrittene Praxis. List 23.

Senn B, Eicher M, Mueller, M., Engberg, S., & Spirig, R. Creating and validating a Patient-Reported Outcome instrument to assess symptom experiences related to surgical wounds in women with vulvar neoplasia – a mixed-methods study. Oral presentation at the 7th European Oncology Nursing Society (EONS) Spring Convention, The Hague, The Netherlands, 2010, April 15-16. Abstract in conference booklet.

Senn, B., Eicher, M., Mueller, M., Engberg, S., & Spirig, R. The unspoken disease: Symptom experiences after surgical treatment in women with vulvar neoplasia – a qualitative study. Oral presentation at the 8th Congress and Postgraduate Course of the European College for the study of vulval disease (ECSVD), Munich, Germany, 2010, September 16-18. Presentation in Vulvar Diseases online booklet.

PRESENTATIONS

INTERNATIONAL

Senn B, Eicher M, Mueller MD, Engberg S, Spirig R. The post-surgery symptom experience of women with vulvar neoplasia: Development and content validity of a Patient-Reported Outcome (PRO) instrument. 16th European Multidisciplinary Cancer Congress of the European CanCer Organisation ECCO 16, ESMO 36, ESTRO 30. 2011, September 23-27, Stockholm, Sweden (poster presentation).

Senn B. [Needs-oriented care in gynecology: a symptom diary for women after vulvar surgery] Bedürfnisgerecht pflegen in der Gynäkologie: ein Symptom-Tagebuch für Frauen nach vulvären chirurgischen Eingriffen. 14th International Seminar: Oncology Nursing - Advanced Practice of the German-speaking European School for Oncology (deso). 2011, August 25-26, St. Gallen, Switzerland (oral presentation).

Senn B, Eicher M, Mueller MD, Engberg S, Spirig R. The post-surgery symptom experience of women with vulvar neoplasia: Development and content validity of a Patient-Reported Outcome (PRO) instrument. 9th European Academy of Nursing Science Summer School. 2011, July 4-8, Lund University, Sweden (poster presentation).

Senn, B., Eicher, M., Mueller, M., Engberg, S., Spirig, R. Self-monitoring the post-surgery symptom experience of women with vulvar neoplasia: Development and content validity of a Patient-Reported Outcome instrument (WOMAN-PRO). 4th Vorarlberger Interdisciplinary Vulva Workshop. 2011, May 13-14, Feldkirch, Austria (poster presentation).

Senn, B., Eicher, M., Mueller, M., Engberg, S., Spirig, R. The unspoken disease: Symptom experiences after surgical treatment in women with vulvar neoplasia – a qualitative study. 8th Congress and Postgraduate Course of the European College for the study of vulvar disease (ECSVD). 2010, September 16-18, Munich, Germany (oral presentation).

Senn, B., Eicher, M., Mueller, M., Engberg, S., Spirig, R. Creating and validating a Patient-Reported Outcome instrument to assess symptom experience related to surgical wounds in women with vulvar neoplasia – a mixed-methods study. 7th European Oncology Nursing Society (EONS) Spring Convention. 2010, April 15-16, The Hague, The Netherlands (oral presentation).

Senn B, Walther T, Gaertner B. [Guidelines for the implementation of evidence-based practice at the Nursing School in Berne]. "Simplicity, or diversity? Interdisciplinary and Intraprofessional." 9. International Scientific Meeting for Health Education Lernwelten. 2009, September 3-5, Winterthur, Switzerland (oral presentation).

Senn B, Eicher M, Mueller MD, Engberg S, Spirig R. Creating and validating a Patient-Reported Outcome instrument to assess symptom experience related to surgical wounds in women with vulvar neoplasia – a mixed-methods study. 7th European Academy of Nursing Science Summer School. 2009, June 22- July 3, University of Turku, Finland (poster presentation).

Senn B, Mueller M, Cignacco E, Eicher M. Period prevalence and risk factors for postoperative short-term wound complications in vulvar cancer patients. Joint Annual Meeting of Hematology and Oncology DGHO, ÖGHO, SGH, SGMO. 2008, October 10-14, Vienna, Austria (oral presentation).

NATIONAL

Senn B, Mueller MD, Cignacco EL, Eicher M. Prävalenz und Risikofaktoren postoperativer Wundkomplikationen bei Patientinnen mit Vulvakarzinom: Eine Querschnittstudie. Fachtagung für Gesundheitsberufe Evidence-based Practice – was bringt die Zukunft. 2010, March 5th, University Hospital Berne Inselspital, Berne, Switzerland (oral presentation).

Senn B, Eicher M, Mueller MD, Engberg S, Spirig R. Entwicklung und Prüfung eines Instruments für Frauen mit vulvären Neoplasien zur Erfassung ihrer Symptomerfahrungen nach chirurgischen Eingriffen. Comprehensive Cancer Center Freiburg symposium. 2010, October 16, Freiburg, Germany (oral presentation).

LOCAL

Senn B, Eicher M, Mueller MD, Engberg S, Spirig R. Entwicklung und Prüfung eines Instruments für Frauen mit vulvären Neoplasien zur Erfassung ihrer Symptomerfahrungen nach chirurgischen Eingriffen. Jour fixe advanced training, Department of Gynecologic Oncology, Women's Health Hospital, University Hospital Basel. 2011, February 28, Basel, Switzerland (oral presentation).

Senn B, Eicher M, Mueller MD, Engberg S, Spirig R. Entwicklung und Prüfung eines Instruments für Frauen mit vulvären Neoplasien zur Erfassung ihrer Symptomerfahrungen nach chirurgischen Eingriffen. Department of Gynecologic Oncology Conference. Women's Health Hospital. University Hospital Zurich. 2010, December 22th, Zurich, Switzerland (oral presentation).

Senn B, Eicher M, Mueller MD, Engberg S, Spirig R. Entwicklung und Prüfung eines Instruments für Frauen mit vulvären Neoplasien zur Erfassung ihrer Symptomerfahrungen nach chirurgischen Eingriffen. Department of Gynecologic Oncology Conference. Women's Health Hospital, University Hospital Berline, Charité. 2010, November 5th, Berline, Germany (oral presentation).

Senn B, Eicher M, Mueller M, Engberg S, Spirig R. Entwicklung und Validierung eines Patient-Reported Outcome Instruments - Eine Mixed-Method Studie. Haute Ecole de Santé advanced research training. 2010, May 4, Fribourg, Switzerland (oral presentation).

Senn, B., Eicher, M., Mueller, M., Engberg, S., Spirig, R. Creating and validating a Patient-Reported Outcome instrument to assess symptom experience related to surgical wounds in women with vulvar neoplasia – a mixed-methods study. Oncology Nurse Research Group Meeting, School of Nursing, University of Pittsburgh. 2010, April 5, Pittsburgh, Pennsylvania, US (oral presentation).

Senn B, Mueller MD, Cignacco EL, Eicher M. Prävalenz und Risikofaktoren postoperativer Wundkomplikationen bei Patientinnen mit Vulvakarzinom: Eine Querschnittstudie. Extra-Impuls Conference, Institute of Nursing Science, University of Basel. 2009, September 29th, University Hospital Basel, Basel, Switzerland (oral presentation).

Senn B, Mueller MD, Eicher M. Practice Development Project – Wound management in vulvar cancer patients – a guideline for nurses. Department of Gynecologic Oncology Conference. University Hospital Berne Inselspital. 2007, June 25th, Berne, Switzerland (oral presentation).

TEACHING

MASTER OF NURSING SCIENCE, UNIVERSITY OF BASEL, COURSES TAUGHT

2010 – present	Qualitative research: Proposal Writing Course Co-teacher, seminars, student advisor and mentor
2009 – present	Qualtitative Research: Master's thesis Course Student advisor and mentor

BACHELOR'S NURSING SCIENCE, UNIVERSITY OF BASEL, COURSES TAUGHT

2009 – present	Research Methods I: Qualitative Research Part Co-teacher, lectures, seminars
2008 – 2009	Advanced Nursing Practice Course Co-teacher, action learning group seminars

OTHER EDUCATIONAL ACTIVITIES

SCHOOL OF NURSING, AUSBILDUNGSZENTRUM INSEL / BERNER BILDUNGSZENTRUM PFLEGE,

COURSES TAUGHT

2005 – 2010	Nursing Research, Literature Search, Primary Nursing Teacher
2002 – 2005	Gerontology / Geriatrics, Public Health, Gynecology Co-teacher
2001 – 2002	Nursing Strategies (e.g. prophylaxis, bedding), Co-teacher

SCHOOL OF NURSING, AUSBILDUNGSZENTRUM INSEL / BERNER BILDUNGSZENTRUM PFLEGE,

FURTHER ACTIVITIES

2005 – 2010	Advanced training for teachers, consulting of teachers Teacher
2001 – 2010	Development of two curricula, exams, evaluation reports Collaborator