Abstract

Purpose: To develop an evidence-based guideline for nurses and other health care professionals involved in pre- and postsurgical care of women with vulvar cancer (VC) or vulvar intraepithelial neoplasia (VIN).

Methods: This evidence-based guideline was developed according to six domains of the methodological framework AGREE II. Literature research with focus on cancer care, symptom management and self-management/counselling was conducted from April to August 2013 in the databases CINAHL, Cochrane Library, PsycINFO, PubMed as well as in 14 international guideline databases. Interdisciplinary experts (n=14) were involved in the development of the guideline from December 2013 to January 2014. This guideline is currently tested in the WOMAN-PRO II RCT (Clinical Trial No: NCT=1986725).

Results: For the definition of recommendations, five guidelines, one meta-analysis, two systematic reviews and two randomized controlled trials were included. In total, 24 recommendations were formulated to answer 22 clinical questions based on patients' perspective and experts' opinion. Evidence ranged from 3.5 to 5 (3.5 = weak evidence and/or clinical relevance, 5 = best evidence and/or clinical relevance). The recommendations were subsumed under different themes regarding physical, psychological and psychosocial aspects.

Conclusions: The clinical practice guideline developed in this study firstly provides recommendations for symptom management issues focusing on self-management interventions for women with VC or VIN. As an interdisciplinary guideline it should be used in addition to the existing medical guideline in the German speaking context.

Keywords: Evidence-based guideline; vulvar cancer; vulvar intraepithelial neoplasia; symptoms and distress; self-management; symptom-management

Introduction

An annual incidence of two to seven per 100,000 women has been reported for vulvar neoplasms (VN) in the United States and Europe (Hampl et al., 2011). The term “vulvar neoplasms” comprises vulvar intraepithelial neoplasia (“premalignant lesions”, VIN) and vulvar cancer (VC) (Sideri et al., 2005). One predisposing factor for VIN mostly seen in younger patients is Human Papilloma Virus (HPV). VC is more widespread in elderly women and its cause is almost unknown (Alkatout et al., 2015). It is the fourth most common gynaecologic cancer comprising several histological types, with squamous cell carcinoma being the most common category. The gold standard for treating VC and high-grade VIN is surgery (Alkatout et al., 2015). After vulvar surgical therapy women often experience symptoms and related distress. Symptoms may be categorized into three types: wound-related symptoms (e.g. swelling), psychosocial symptoms (e.g. tiredness) and difficulties in daily life (e.g. during sitting) (Senn et al., 2013). Even minimal surgical treatment causes a variety of symptoms and postsurgical complications (Baker-Glenn et al., 2011). Women´s symptom experience can vary depending on the FIGO stage (International Federation of Gynaecology and Obstetrics [Belhadj et al., 2014]) as well as on the type of treatment and may affect the perceived quality of life (Novackova et al., 2015).

Due to reduced hospital length of stay after vulvar surgical therapy, women`s self-management of challenging situations has become a high priority in order to prevent negative outcomes (Humphreys et al., 2008). Self-management can be defined as tasks undertaken by individuals to deal with medical, role and emotional management of their health condition (McCorkle et al., 2011). The three types of symptoms (wound-related, psychosocial and difficulties in daily life) can be allocated to the tasks of self-management. To support self-management, verbal and written information provide a basis for educating patients about their condition and care (Silva, 2011). Structured counselling, including identification of pre-surgical risks for complications and planning of post-surgical interventions can lower patient morbidity (Senn et al., 2015). However, women report a lack of pre- and postsurgical counselling (Jefferies and Clifford, 2011). They described receiving

limited information from health care professionals with regard to symptom management (Senn et al., 2011). To achieve effective symptom management, it is essential to understand the individual's symptom experience (Senn et al., 2011). According to Dodd et al. (2001), symptom management may be understood as a dynamic process with the aim of preventing negative outcomes. Given et al. (2004) developed a nurse-delivered intervention to reduce the severity of physical and psychological symptoms in patients receiving chemotherapy. For this purpose, standardized information and approaches to problem solving were used to reduce symptom severity. To implement self-management interventions and to develop care plans, a patient-provider partnership is important (McCorkle et al., 2011). As Allen (2003) stated in her study, women with VC need high-quality information delivered in an appropriate environment by a clinical nurse specialist as part of a multidisciplinary team.

The current guideline for diagnosis and management of VC proposes an integrative approach to caring for women with VC, including a skilled nurse as a key factor for patient management in coordination with medical treatment (Royal College of Obstetricians and Gynaecologists [RCOG], 2014).

Offering support provided by skilled nurses during treatment is a first step to put into practice guideline recommendations. Nurses and other health care providers need evidence-based guidelines for symptom management in order to support women systematically and comprehensively in their symptom management. It can be expected that evidence-based guidelines promote positive treatment outcomes (Puhan et al., 2014). In this context the German Society for Gynaecology and Obstetrics (DGGG) (Working Group of Gynaecological Oncology, 2009) developed guidelines for the treatment of vulvar premalignant and malignant lesions, targeting surgery, radio- and chemotherapy. However, there remains a shortage of recommendations concerning symptom management. To our knowledge, a guideline containing recommendations focusing on the most prevalent physical and psychosocial symptoms in women with VIN and VC does not yet exist. Consequently, it is difficult for nurses and other health care providers to support symptom management in a systematic and comprehensive manner. In response to an absence of synthesized evidence,

we developed a guideline for health care professionals with a focus on the most prevalent postsurgical symptoms described in a previous study (Senn et al., 2013). Professionals can use this guideline in counselling for women with VC or VIN after surgical treatment.

Therefore, our main research question was: Which recommendations are appropriate to support symptom self-management with regard to the most prevalent postsurgical symptoms/problems in women with VIN and VC?

Based on results from Senn et al. (2013), which focused the most prevalent postsurgical symptoms, the main research question was operationalized into 22 clinical questions shown in table 1.

[**table 1:** Clinical questions]

Methods

The development of this guideline is based on the six domains of AGREE II, an instrument internationally acknowledged for (I) assessing quality of guidelines, (II) providing a methodological strategy for the development of guidelines and (III) supporting authors with regard to reporting information in guidelines (Brouwers et al., 2010). Domains 1 to 4 are defined 'scope and purpose', 'stakeholder involvement', 'rigour of development' and 'clarity of presentation'. The last two domains consist of 'applicability' and 'editorial independence'. A nursing counselling concept was developed according to the PEPPA framework (Bryant-Lukosius and Dicenso, 2004), including a clinical pathway. According to the six domains of AGREE II (Brouwers et al., 2010) we developed a draft of the guideline in December 2013. A group of six experts, consisting of physicians, specialist nurses and nursing scientists, assessed this draft. We incorporated the experts' comments in our guideline which is currently tested in the WOMAN-PRO II randomized controlled trial (Clinical Trial No: NCT01986725).

Domain 1: Scope and Purpose

The target population of the guideline includes women with VC or VIN and surgical treatment with a curative and not a palliative intention. Results of previous studies in patients with VC or VIN undergoing surgery have shown that patients suffer from a high number of postsurgical symptoms (Senn et al., 2011; Senn et al., 2013). Affected women mentioned on average 20 symptoms, comprising wound-related symptoms, psychosocial issues and activities of daily living (Senn et al., 2012). Based on these results, we determined the primary and secondary outcomes.

Domain 2: Stakeholder Involvement

In order to assess views and preferences of the target population, we conducted semi-structured interviews with patients with VC or VIN and surgical treatment. These interviews focused on the experience of postsurgical symptoms and resulting constraints to which women are exposed. Furthermore, we assessed the women`s needs and investigated which improvements they regard as necessary for their care. Target users of the guideline are advanced practice nurses. Therefore, a gynaecologic-oncology nurse was part of the group of four experts who formulated and rated the guideline's recommendations.

Moreover, physicians and other health care professionals focusing on care of this specific patient population may apply the guideline too. To assess the view of these stakeholders, experts from different areas (gynaecology, oncology, radiology, nursing science) were involved in the development of the counseling intervention as well as in the review of the guideline.

Domain 3: Rigour of Development

Criteria for selecting evidence: To identify current guidelines and studies focusing on care for women with VC or VIN undergoing surgery, we conducted a literature review guided by the 22 clinical questions shown in table 1. Inclusion criteria for guidelines were (1) description of the methodological approach, (2) at least partly designed for nursing, (3) publication date from 2003 to 2013, (4) guidelines focusing on symptoms due to an oncological disease and (5) English or German language. Exclusion criteria for guidelines were (1) thematic focus on

palliative care and end-of-life care, (2) guidelines in terms of guidebooks and (3) guidelines concerning chronic oncological symptoms.

Inclusion criteria for studies were (1) studies focusing on oncological symptoms, (2) randomized controlled trial, systematic review, meta-analysis, (3) publication date from 2003 to 2013 and (4) English language. Exclusion criteria for studies were focus on patients in a palliative or end-of-life situation.

We searched the following guideline-specific databases: American Cancer Society, Working Group Supportive Care in Oncology, Rehabilitation and Social Medicine of The German Cancer Society, Association of the Scientific Medical Societies in Germany, BC Cancer Agency, EONS, European Society for Medical Oncology, GIN, Multinational Association of Supportive Care in Cancer, NCCN, National Guideline Clearinghouse, NICE, New Zealand Guidelines Group, ONS and SIGN. To identify meta-analyses, systematic reviews or randomized controlled trials we selected the databases CINAHL, Cochrane Library, PsycINFO and PubMed. Furthermore, we also checked reference lists of all included studies for additional literature.

Based on the 22 clinical questions (table 1) thematic focuses were given. The thematic focuses comprised Advanced Practice Nursing, assessment, counseling, information, self-management and symptom management. For each thematic focus we developed questions according to PICO which supported the identification of relevant search terms. The search term used for each thematic focus are shown in table 2.

[**table 2:** search terms]

The search terms were adapted for each database. An example for a search string for the database PubMed is as follows: ((("Advanced Practice Nursing"[Mesh]) OR "Nurse Clinicians"[Mesh])) AND ((((("Vulvar Neoplasms"[Mesh]) OR vulvar intraepithelial neoplasia) OR "Genital Neoplasms, Female"[Mesh]) OR "Carcinoma in Situ"[Mesh]) Filters: Meta-Analysis; Randomized Controlled Trial; Systematic Reviews; Publication date from 2003/01/01 to 2013/07/30; English.

One person conducted the research between April and August 2013. The flowcharts of the literature search are shown in figure 1 and 2.

[**figure 1:** Flowchart of literature search to identify guidelines]

[**figure 2:** Flowchart of literature search to identify studies]

Strengths and limitations of the body of evidence: Two authors independently assessed the methodological quality of all included studies. Guidelines were evaluated using the DELBI instrument for methodological guideline appraisal (Association of the Scientific Medical Society in Germany and Agency for Quality in Medicine, 2008). Meta-analyses, systematic reviews and randomized controlled trials were appraised according to the FIT Nursing Care tool (Panfil and Ivanovic, 2011) which was developed according to the guidelines of the Cochrane Collaboration (Higgins and Green, 2011) and GRADE (Puhan et al., 2014). As in the Swiss/German speaking context the FIT Nursing Care tool is well known, it has been chosen in order to enhance the transparency of our approach especially for our target users.

We formulated the recommendations on the basis of the identified literature. In a voting procedure of four experts with clinical and scientific expertise, each recommendation has been discussed with regard to available evidence, health benefits, side effects and risks. Eight external experts reviewed the guideline. An update is planned for 2018.

Domain 4: Clarity of Presentation

For optimal visibility, the recommendations are presented in a blue box. A list of all recommendations can be found in the front section of the guideline.

Domain 5: Applicability

In the methodological part of the guideline, we named facilitators and barriers possibly having an impact on the application of the recommendations. Furthermore, structure criteria (e.g. ensuring that a specialized nurse is available for counselling in patients with vulvar neoplasms), process criteria (e.g. providing contact with other healthcare services involved in

caring and treatment) and outcome criteria (e.g. pain level) were determined (Donabedian, 2008).

Domain 6: Editorial Independence

The Federal Office of Public Health (Switzerland) and the University of Applied Sciences St. Gallen (Switzerland), funded the guideline. All persons involved in developing the guideline made their contribution within their institutional work. The members of the development group had no competing interests to declare.

Results

To determine the recommendations, we included five guidelines, one meta-analysis, two systematic reviews and two randomized controlled trials.

Table 3 shows the results of the methodological guideline appraisal.

In figure 3 and figure 4, the results of the methodological appraisal of the remaining studies are visible.

[**table 3:** Methodological guideline appraisal, DELBI]

[**figure 3:** Methodological appraisal of systematic reviews and meta-analyses]

[**figure 4:** Methodological appraisal of randomized controlled trials]

In the domain “methodological rigour of purpose” four of the included guidelines reached a percentage of 52% or more (Cruickshank M.E., 2011; Mitchell et al., 2007; Poage et al., 2008; Scottish Intercollegiate Guidelines Network [SIGN], 2008). Only one guideline achieved 48 % but could nevertheless be included because of its clinical relevance (Sheldon et al., 2008). Three guidelines (Mitchell et al., 2007; Poage et al., 2008; Sheldon et al., 2008) achieved rather low scores in the domain “stakeholder involvement”. Reasons were that they missed to report or did not involve key stakeholders, especially patients in the guideline’s development. Low scores in the domain “general applicability” (e.g. Cruickshank M.E., 2011; Mitchell et al., 2007; Sheldon et al., 2008) can be explained by the fact that guidelines failed to report barriers and facilitators to implementation of the guideline as well as resource

implications for applying the guideline. Within the domain 8 “methodological rigour of development when using existing guidelines” especially in three of the included studies (Mitchell et al., 2007; Poage et al., 2008; Sheldon et al., 2008) there was a lack of description how the search for already existing guidelines was conducted, if included guidelines were critically appraised and how the content of the guideline has influenced the recommendations.

With regard to the included studies the meta-analysis was of good methodological quality except for the domain “description of selection process of included studies” (McNeely et al., 2011). Both systematic reviews had methodological weaknesses, e.g. in the domain “literature research” or “assessment of included studies” (Luckett et al., 2009; Ridner et al., 2012).

The randomized controlled trials had adequate research questions, recruitment and equal treatment but nevertheless the sample size was too small (Beatty et al., 2010; Thomas et al., 2012).

In total, it was possible to formulate 24 recommendations on the basis of 22 clinical questions which were categorized into the following themes: *symptom self-assessment, surgical wound and vulva care, postsurgical pain, postsurgical tiredness, postsurgical urinary symptoms, lymphedema, difficulties concerning sitting, wearing clothes and activities of daily living, uncertainty* and *body image.* The recommendations for symptom management in women with VC or VIN and surgical treatment are visible in table 4. The source of evidence and grades of recommendations are included.

[**table 4:** Recommendations, including time, source of evidence and grade of recommendation]

The grades of recommendations range from 3.5 to 5 (3.5 = weak evidence and /or clinical relevance, 5 = best evidence and / or clinical relevance). For each recommendation the literature source and the time are listed (table 3). Eleven recommendations were classified

as grade 4, three were classified as grade 3.5, 3.75 and 4.25, and two as grade 4.75 or 5. For each recommendation a maximum of three external sources were identified.

Discussion

Within the framework of this study we developed an evidence-based guideline focusing for the first time on symptom management in women with VC or VIN after surgical treatment. The development was based on the methodological principles of AGREE II (Brouwers et al., 2010). As described in the domains of AGREE II, stakeholder involvement and the rigour of development are essential parts of a guideline's development. Current approaches for guidelines development recommend an even stronger focus on different sources of knowledge (e.g. including quantitative and qualitative research, contextual information and expert practical and experience knowledge). The consideration of different sources of knowledge should strengthen the guideline's relevance, applicability and practicability for target users (Lukersmith et al., 2016). Therefore, besides the inclusion of the current best external evidence, we included patients, experts in gynaecologic oncology and gynaecologic-oncology nurses as target users in the guideline's development. Especially patient engagement is strongly recommended before and during the guideline's development as well as in the phase of dissemination and implementation (Armstrong et al., 2016). Thus semi-structured interviews were conducted with women with VC or VIN and surgical treatment. The women's opinion has been incorporated in framing the clinical questions, conducting the review and the development of the recommendations. It is important to bear in mind that stakeholders, including patients and health care professionals, should not only be included in the developmental phase but also informed about the presence of such guidelines. Studies have shown that, especially in patients, the awareness of guidelines is low but they have a wish to be informed in order to be supported when choosing between different treatment options (Fearns et al., 2016). We try to enhance the dissemination of our guideline by making it accessible online for free and providing institutions with information about the guideline. To support the guideline's applicability in clinical practice, the recommendations have been

formulated in an easily accessible, patient-centered and comprehensive manner (Allen, 2003; National Institute for Health and Care Excellence [NICE], 2012).

Strengths and limitations

This guideline was developed according to stringent methodological principles, systematically considering all six steps of the AGREE II guideline (Brouwers et al., 2010). The available literature was rated independently by two persons using internationally accepted checklists. However, the literature search was conducted by only one researcher, due to limited resources. To define recommendations, we included five guidelines, one meta-analysis, two systematic reviews and two randomized controlled trials. As the literature offered only a limited number of interventions supporting women in their management of VC or VIN after surgical treatment, we extended our research on women with other gynaecological tumours, e.g. breast cancer. Due to limited external evidence, seven recommendations are based on expert opinions.

Conclusions

This clinical practice guideline for symptom management in women with vulvar neoplasms is the first interdisciplinary guideline focusing on self-management. It should be used in addition to the existing medical guideline developed by the DGGG (Working Group of Gynaecological Oncology, 2009) and the new medical guideline of the NCCN (National Comprehensive Cancer Network, 2016). Our guideline supports early detection and assessment of postsurgical symptoms on predefined timeframes, the use of evidence-based symptom-relieving interventions and interdisciplinary decisions regarding therapy by systematically involving the patient as well as the medical perspective. The application of this guideline should be tailored to the individual patient's needs with regard to treatment history, risk factors, comorbidities and lifestyle. By using the WOMAN-PRO symptom diary, women can be actively involved in symptom management. Empowerment concerning their self-management can be strengthened.

The development of this guideline has been conducted systematically in cooperation with all

relevant stakeholders (NICE, 2012) and on the basis of currently available evidence (Association of the Scientific Medical Society in Germany and Agency for Quality in Medicine, 2008; Royal College of Obstetricians and Gynaecologists, 2014; Working Group of Gynaecological Oncology, 2009). Further research is required to test the guideline's effectiveness and feasibility in home care settings. Future guideline development should consider also additional postsurgical symptoms as well as side effects of adjuvant therapies, such as chemotherapies and radiotherapies, in women with VIN and VC.

Conflict of interest

The authors declare no conflict of interest.

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