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Validation of Clinical Tools for Vaginal and Vulvar Symptom Assessment in Cancer Patients and Survivors

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ABSTRACT

Introduction: Health care professionals can play a pivotal role in promoting vulvovaginal health through assessment and appropriate intervention.

Aim: To develop and validate brief clinical measurements to facilitate the identification of vulvovaginal symptoms in patients with and survivors of cancer.

Methods: One hundred seventy-five women survivors of cancer attending a Female Sexual Medicine and Women's Health Program from September 26, 2012 through October 31, 2014 completed the Vaginal Assessment Scale (VAS) and the Vulvar Assessment Scale (VuAS)—a modified version of the VAS that targets vulvar symptoms. Pelvic examination results were recorded using a clinical examination checklist.

Main Outcome Measures: Internal consistency of the two scales was assessed using Cronbach α, and the correlation between scales and other outcomes was reported.

Results: The internal consistency measurements of the VAS and VuAS at the first visit were 0.70 and 0.68, which decreased to 0.53 and 0.66 at the last visit. The VAS composite and VuAS composite scores were moderately correlated with each other (0.42 and 0.45 at first and last visits, respectively). A strong correlation was observed between VAS pain with intercourse and Female Sexual Function Index (FSFI) pain with intercourse (-0.63 and -0.71 at the first and last visits, respectively). Worse pain with examination, worse functioning on the FSFI pain, lubrication, and total scores, and worse vulvar irritation were correlated with more severe symptoms on the VAS and VuAS.

Conclusion: The VAS and VuAS are simple tools that can be used by clinicians to assess health concerns in women diagnosed with and treated for cancer. Validation is needed across diverse settings and groups of women.

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Key Words: Cancer; Cancer Survivorship; Sexual Health; Vaginal Health; Vulvar Health; Symptom Assessment

INTRODUCTION

Vulvar and vaginal atrophy are common issues affecting women in the general population,[1,2] but they can be more acute in cancer populations.[3] Vulvovaginal health is affected by decreased estrogen and results in symptoms of dryness, decreased lubrication and elasticity, irritation, and discomfort of the vaginal and vulvar tissues.[1,2] Unfortunately, there are a lack of clinical tools that effectively address vulvovaginal health concerns beyond the realm of sexual activity. Symptoms of vulvar and vaginal dryness, soreness, irritation, and pain require clinical inquiry to assess and treat difficulties of tissue quality. These symptoms can negatively affect sexual function and comfort with gynecologic examinations.

Women with vaginal and/or vulvar dryness should be encouraged to discuss their symptoms openly with their oncology clinical team, and health care providers should proactively raise this topic, particularly with menopausal women or women receiving endocrine therapy. With feasible clinical tools, health care professionals can play a pivotal role in promoting vulvovaginal health by easy identification, provision of information, and appropriate intervention/treatments.[4,5]

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The Vaginal Assessment Scale (VAS) has been used to assess vaginal symptoms in the general population,[6] but the scale has never been validated in the female cancer population. In addition, validated measurements to specifically target vulvar symptoms are lacking. In this study, the instruments were administered by a dialogue with the health care provider; the psychometric properties of the instruments could be different than if they were administered by a written questionnaire, and validation of this method of administration was one of the aims of this study. This article describes and presents the preliminary validation analysis of two novel tools, the VAS and the Vulvar Assessment Scale (VuAS), which can be used in the clinical setting to assess symptoms of vaginal and vulvar tissue quality and function in women with and survivors of cancer.

METHODS

A limited waiver of authorization was obtained to access new-visit data collected on clinical assessment forms at the Female Sexual Medicine and Women's Health Program (FSMWHP) at the Memorial Sloan Kettering Cancer Center from September 26, 2012 through October 31, 2014. Women were referred to the FSMWHP by their clinical team for assistance with sexual, vaginal, and vulvar health concerns.

The FSMWHP clinical assessment form consists of a clinician evaluation, the VAS, the VuAS, and patient-reported outcomes. At each visit, a member of the clinical team (PhD or nurse practitioner) administers the VAS and VuAS in an interview-style format. The clinician uses the assessment form to identify appropriate treatment strategies (eg, vaginal lubricants, internal and external moisturizers, pelvic floor exercises, and dilators) and to document patient-reported frequency of these strategies. Findings from the pelvic examination are recorded on a checklist assessing physical vaginal characteristics (agglutination, scarring or adhesions, pH, moisture, rugosity, elasticity, length, thickness, epithelial integrity, vascularity, and irritation) and physical vulvar characteristics (vulvar atrophy, irritation, and vestibular irritation) based on the clinical pelvic-gynecologic examination by the nurse practitioner (Appendix 1). At these visits, patients also complete patient-reported outcomes, including the Female Sexual Function Index (FSFI), and supplemental questions about confidence (eg, "Are you confident about sexual activity in the future?").

VAS and VuAS

The VAS and VuAS each are four-item measurements administered to the patient by a health care provider in the clinical practice setting to quantify and rate (none, mild, moderate, or severe) their perception of dryness, soreness, irritation, and pain (dyspareunia or painfulness to touch with external stimulation) for the vaginal and vulvar areas. In previous studies, the VAS has been shown to be sensitive to change as a self-report measurement. In a randomized trial of vaginal tablets of estradiol or hyaluronic acid sodium salt taken by women with symptoms of atrophic vaginitis, the instrument detected a significant decrease in symptoms after 8 weeks of treatment.[6] Those researchers developed the VuAS by modifying the VAS to target vulvar symptomatology. The VuAS focuses on external genitalia, including tissue surrounding the vaginal opening, labia minora, labia majora, clitoral hood, clitoris, and perineum. A diagram can be used to educate patients and help patients identify areas of concern (Appendix 2).

Typically, the VuAS has been used in conjunction with the VAS. Patients are asked to recall whether they experienced specific symptoms (yes or no) during the past 4 weeks and rate each symptom as mild, moderate, or severe. Items 1 to 3 assess vaginal and vulvar dryness, soreness, and irritation during routine activities outside the setting of intimacy. Item 4 assesses discomfort or pain in the context of sexual activity (vaginal intercourse or external [vulvar] manual stimulation with or without a partner). For example, the clinician first asks the patient, "Do you have vulvar dryness?" Dryness can be described as a lack of moisture or a feeling as if the tissues are sticking together. Then, the patient is asked, "Do you have vulvar soreness?" Soreness can be defined as pain or discomfort with walking or exercise, wiping with toilet tissue, or with certain clothing. To assess for itching or burning of the vulva, the patient is asked, "Do you experience vulvar irritation?" Then, the patient is asked, "Do you experience discomfort or pain in the tissue surrounding or outside the vagina during or after sexual activity or touch?" If the patient was not sexually active within the past 4 weeks, then she indicates that "no attempt" was made. The clinician provides these explanations for each question during the initial administration and offers additional clarification at follow-up administrations, if necessary. A similar dialogue is conducted for the assessment of vaginal symptoms.

Each item in the VAS and VuAS is scored from 0 (none) to 3 (severe). The VAS composite and VuAS composite scores (range = 0−3) are calculated by taking the mean of the items when at least two of four items are not missing. Lower scores indicate better function. For item 4 of each instrument, "no attempt" is considered missing. Because we believe item 4 of each instrument might represent a different dimension (ie, sexuality), whereas the first three represent vaginal and vulvar health and might be independent of sexuality, an alternative composite score based on only items 1 to 3 was created for the VAS and VuAS.

Female Sexual Function Index

The FSFI is a brief self-report measurement of female sexual function developed by Rosen et al[7] and recently validated for use in women survivors of cancer.[8] It is a 19-item questionnaire assessing six domains of sexual function in women: (i) desire, (ii) arousal, (iii) lubrication, (iv) orgasm, (v) satisfaction, and (vi) pain or discomfort. Although the FSFI is used primarily in sexually active women, it has been psychometrically validated for use in women survivors of cancer (FSFI scoring; http://www.fsfiquestionnaire.com/FSFI%20Scoring%20Appendix.pdf).[8]