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

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Abstract

Introduction—Healthcare professionals can play a pivotal role in promoting vulvovaginal health through assessment and appropriate intervention.

Aim—The development and validation of brief clinical measures to facilitate the identification of vulvovaginal symptoms in cancer patients/survivors is warranted.

Methods—175 female cancer survivors attending a Female Sexual Medicine and Women's Health Program from 9/26/2012–10/31/2014 completed the Vaginal Assessment Scale (VAS) and Vulvar Assessment Scale (VuAS)—a modified version of the VAS that targets vulvar symptoms. Pelvic exam results were recorded using a clinical exam checklist. Internal consistency of both scales was assessed using Cronbach's alpha, and correlation between scales and other outcomes was reported.

Results—The internal consistency measures of the VAS and VuAS at first visit were 0.70 and 0.68, which decreased to 0.53 and 0.66 at last visit. The VAS composite and VuAS composite scores were moderately correlated with one another (0.42 and 0.45 at first and last visit, respectively). Strong correlation was observed between VAS pain with intercourse and Female Sexual Function Index (FSFI) pain with intercourse (−0.63 and −0.71 at first and last visit, respectively). Worse pain with exam, worse functioning on the FSFI pain, lubrication and total

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scales, and worse vulvar irritation were correlated with more severe symptoms on the VAS and VuAS.

Conclusions—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. Future validation across diverse settings and groups of women are needed.

Keywords

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 impacted by reduced 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 in order to assess and treat difficulties of tissue quality. These symptoms can negatively impact sexual function as well as comfort with gynecologic exams.

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 patients or women receiving endocrine therapy. With feasible clinical tools, healthcare professionals can play a pivotal role in promoting vulvovaginal health by easy identification, provision of information, and appropriate intervention/treatments.[4,5]

The Vaginal Assessment Scale (VAS) has been utilized to assess vaginal symptoms in the general population,[6] but the measure has never been validated in the female cancer population. Additionally, validated measures 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 via a written questionnaire, and validation of this method of administration was one of the aims of this study. This paper describes and presents the preliminary validation analysis of two novel tools, the VAS and Vulvar Assessment Scale (VuAS), which can be used in the clinical setting to assess symptoms of vaginal and vulvar tissue quality and function in female cancer patients/survivors.

Methods

A limited waiver of authorization was obtained to access new-visit data collected on clinical assessment forms at the XXX from 9/26/2012–10/31/2014. Women were referred to the XXX by their clinical team for assistance with sexual/vaginal/vulvar health concerns.

The FSMWHP clinical assessment form consists of a clinician evaluation, the VAS, the VuAS, and patient-reported outcomes (PROs). At each visit, a member of the clinical team (PhD/NP) administers the VAS and VuAS in an interview-style format. The clinician uses the assessment form to identify appropriate treatment strategies (e.g., vaginal lubricants, internal and external moisturizers, pelvic floor exercises, and dilators) and to document patient-reported frequency of these strategies. Findings on the pelvic exam are recorded on a checklist assessing the physical vaginal characteristics (agglutination, scarring/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/gynecological exam by the NP (Appendix 1). At these visits, patients also complete PROs, including the Female Sexual Function Index (FSFI), and supplemental questions about confidence (e.g., "Are you confident about sexual activity in the future").

The VAS and VuAS

The VAS and VuAS are each 4-item measures 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 both the vaginal and vulvar areas. In previous studies, the VAS has been shown to be sensitive to change as a self-report measure. In a randomized trial of vaginal tablets of estradiol or hyaluronic acid sodium salt in women with symptoms of atrophic vaginitis, the instrument was able to detect a significant reduction in symptoms following 8 weeks of treatment.[6] The authors developed the VuAS by modifying the VAS in order to target vulvar symptomatology. The VuAS focuses on the external genitalia, including the tissue surrounding the vaginal opening, the labia minora, labia majora, clitoral hood, clitoris, and perineum. A diagram may 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 if they experienced specific symptoms (yes/no) in the past 4 weeks and rate each symptom as mild, moderate, or severe. Items 1–3 assess vaginal and vulvar dryness, soreness, and irritation during routine activities outside of the setting of intimacy. Item 4 assesses discomfort/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. The patient is then asked, "Do you have vulvar soreness?" Soreness can be defined as pain or discomfort with walking/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?" Finally, the patient is asked, "Do you experience discomfort/pain in the tissue surrounding or outside of the vagina during or after sexual activity or touch?" If the patient was not sexually active within the 4 weeks, she indicates that "no attempt" was made. The clinician provides these explanations for each of the questions 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 (both with a range of 0–3) are calculated by taking the mean of the items when at least 2 of 4 items are not missing. Lower scores indicate better function. For Item 4 of each instrument, "no attempt" is considered missing. Since we believe Item 4 of each instrument may represent a different dimension (i.e., sexuality), whereas the first 3 represent vaginal/vulvar health and may be independent of sexuality, an alternative composite score based on only Items 1–3 was created for both the VAS and VuAS.

FSFI

The FSFI is a brief self-report measure of female sexual function developed by Rosen and colleagues[7] and recently validated for use in female cancer survivors.[8] It is a 19-item questionnaire assessing six domains of sexual function in women: 1) desire, 2) arousal, 3) lubrication, 4) orgasm, 5) satisfaction, and 6) pain/discomfort. While the FSFI is primarily used in sexually active women, it has been psychometrically validated for use among female cancer survivors (FSFI Scoring-http://www.fsfiquestionnaire.com/FSFI%20Scoring %20Appendix.pdf).[8]

Gynecologic Exam

At visits in which a gynecologic evaluation was performed, the clinician completed a checklist with 14 Likert items and 5 binary items related to vaginal and vulvar physical presentation and risk factors for vaginal and vulvar conditions.

Study sample

Data were collected from 175 women receiving care at the FSMWHP from 9/26/2012– 10/31/2014 who were seen as a new visit with a gynecologic exam with at least one follow- up (with gynecologic exam) within 8 months of the initial visit and a consecutive visit less than 6 months apart. Data were collected for 601 exams, and data from first and last visits that included a gynecologic exam were used for this analysis.

Statistical Methods

The VAS and VuAS are both based on 4 items. We explored the properties of each score and also the properties of each score if you were to leave out Item 4. This was done because we believed that Item 4 may represent a different underlying construct. To confirm that each score consisted of similar, inter-correlated items we calculated the correlation between each item and the composite score excluding that item ("corrected item-total correlation"). Internal consistency of composite scores was assessed using Cronbach's alpha. Because the item scores are ordinal, polychoric correlation, which is appropriate for ordinal outcomes, was used in the calculation of Cronbach's alpha.

Change over time for each item was assessed by cross-tabulating the responses from the first visit with those from the last, and the Stuart Maxwell test was used to assess whether the change on each item was statistically significant. Change in the composite scores from first to last visit was assessed for statistical significance using paired t-tests.

Polychoric correlation (which is appropriate for ordinal measures) was used to assess the correlation between items, and polyserial correlation (which is used for measuring correlation between an ordinal measure and a continuous measure) was used to assess the correlation between items and multi-item scales. Pearson correlation was used to assess correlation between composite scores. Correlations between composite scores based on Items 1–4 and composite scores based on Items 1–3 did not exclude overlapping items.

To understand the clinical importance of the VAS and VuAS, we investigated whether VAS/VuAS composite scores and items were correlated with clinical features, including clinical exam and FSFI outcomes. Polychoric, polyserial, or Pearson correlation was used as appropriate. In order to assess the responsiveness to change of the VAS and VuAS, we examined correlations of the change in VAS/VuAS composite with the change in clinical features using Pearson correlation. All statistical analysis was done in R 3.1.1 (R Foundation, Vienna, Austria) using the *polycor, psych* and *DescTools* packages.

Results

VAS composite scores at first and last visit were available for 173 and 175 women, respectively. VuAS composite scores at first and last visit were available for 168 and 175 women, respectively. Patient characteristics are listed in Table 1.

The internal consistency reliability (Cronbach's alpha) of the VAS was 0.70 at the baseline visit. Further analysis indicated that omitting Item 4 (pain with intercourse) increased the reliability to 0.73. Similar results were observed for the VuAS, which had a reliability of 0.68. Omitting Item 4 (pain with touch) increased the reliability to 0.75. At the last visit, the VAS reliability was 0.53 (reliability omitting Item 4, 0.64), and the VuAS reliability was 0.66 (reliability omitting Item 4, 0.60).

The VAS composite improved from a mean of 1.09 (SD=0.65) at baseline to 0.55 (SD=0.51) at the last visit (t=10.5; df=172; p<0.001). At baseline, 66% of patients had moderate/severe VAS dryness (Item 1) compared with 27% at the last visit (p<0.001). There were low rates of VAS soreness and irritation (Items 2 and 3) at both time points (Table 2). VAS pain with intercourse (Item 4) was only rated if the patient had recently attempted intercourse. Among the 114 patients who had recently attempted intercourse at the baseline visit, 79% reported moderate/severe pain with intercourse compared with 46% of the 89 women who had recently attempted intercourse at the last visit (p<0.001).

The VuAS composite improved from a mean of 0.79 (SD=0.67) at baseline to 0.56 (SD=0.55) at the last visit (t=3.7; df=167; p<0.001). At baseline, 51%% of patients had moderate/severe VuAS dryness (Item 1) compared with 28% at the last visit (p<0.001l Table 2). Compared with the VAS there were somewhat higher rates of VuAS soreness and irritation (Items 2 and 3) at both time points. VuAS pain with touch (Item 4) was only rated if the patient had recently attempted sexual activity. Among the 141 patients who had recently attempted sexual activity at the baseline visit, 25% reported moderate/severe pain with touch at baseline compared with 14% of 121 patients who had recently attempted sexual activity the last visit (p=0.2263).

Table 3 shows correlations between VAS and VuAS items and composite scores at first visit. High correlations between each composite score and the same score excluding Item 3 are expected due to the fact that the same three items go into each score. We were interested to see which items seemed to be associated with one another. The largest correlations tended to be between corresponding items on the VAS and VuAS, i.e., between VAS dryness and VuAS dryness (correlation=0.53), between VAS soreness and VuAS soreness (correlation=0.36), between VAS irritation and VuAS irritation (correlation=0.61), and between VAS dyspareunia and VuAS pain to touch (correlation=0.32). The VAS composite and VuAS composite scores were moderately correlated with one another (correlation=0.42).

VAS and VuAS composite and item correlations with pain with exam were generally small to moderate (i.e., 0.10–0.30) and positive, while correlations with FSFI pain, lubrication, and total score were small to moderate and negative, as expected (for FSFI domains, higher scores indicate better function). Strong correlations were observed between VAS dyspareunia (Item 4) and FSFI pain (−0.63), and correlation between VAS dyspareunia and pain with exam was 0.35 at baseline. Correlations of change in VAS and VuAS composite scores from first to last visit with change in pain with exam, FSFI pain, and FSFI total were moderate and in the expected direction (Table 4).

At first visit, VAS items tended to be correlated with higher pH, and the correlation between the VAS composite score and pH was 0.15 (Table 5). These correlations were attenuated at last visit. Vulvar irritation on exam and VuAS irritation (Item 3) had a moderate positive correlation (0.44), and vulvar irritation on exam and VuAS composite had a moderate positive correlation (0.36). Vulvar irritation was also correlated with VuAS dryness and soreness. Less moisture was correlated with more severe symptoms on VAS and VuAS items at first visit (correlation with VAS and VuAS composites were 0.25 and 0.18, respectively). The correlations were smaller at last visit, likely partially due to fewer patients with no moisture. There was a moderate positive correlation between change in VAS and VuAS composites and change in moisture (0.24 and 0.21, respectively), indicating that patients whose VAS/VuAS scores decreased from first to last visit (symptom severity lessened) tended to have changes in moisture level towards normal.

The VAS and VuAS had adequate internal consistency at baseline, with Cronbach's alpha of 0.70 for the VAS and 0.68 for the VuAS. The reliabilities were lower at the last visit (0.53 and 0.66, respectively). This could potentially be due to a statistical phenomenon known as the "floor effect," which occurs when scores fall within a small range (in this case, the women reported few or no symptoms on the items at their last visit, because their symptoms had improved during the course of their treatment in the program). When scores fall into a small range, alpha becomes deflated. Of note, the VAS had a larger decrease in reliability from first to last visit than the VuAS, and also had a corresponding larger improvement in symptoms (overall score dropped by 0.539 compared with 0.204 for the VuAS). Both VAS and VuAS total scores improved significantly between first and last visit, and there was significant improvement on the following individual symptom items: VAS and VuAS dryness and VAS pain. The higher internal consistency values achieved when Item 4 (pain with intercourse on the VAS and pain with touch on the VuAS) was omitted indicate that

these items may measure a different underlying construct than Items 1–3; specifically, we believe this could be a dimension related to the impact of tissue quality specifically on sexual function instead of overall symptoms.

We found large correlations between the conceptually related items of VAS pain with intercourse and FSFI pain with intercourse (correlation = −0.63). Worse pain with exam and worse functioning on the FSFI pain and total scales were correlated with more severe symptoms on the VAS and VuAS. The instruments appeared to be responsive to change in that change in VAS/VuAS composite from first to last visit was moderately correlated with pain with exam, FSFI pain, FSFI lubrication, FSFI total score, and moisture in the expected directions.

Discussion

Assessment of vaginal and vulvar symptoms are crucial for intervention. Various treatments for dryness can be implemented to improve vaginal and vulvar health, including moisturizers (nonhormonal and horomonal [topical vaginal estrogen and hormone therapy]) and lubricants for sexual activity.[5] Although there are many common over-the-counter products available to treat vulvovaginal atrophy in the general population, women tend to be unfamiliar and uninformed about treatment options, are often dissatisfied with the available treatments, or are not compliant with treatment.[1,2]

Our study was limited by the minimal information we had on premenopausal women, which hampered our ability to compare scores between pre- and post-menopausal women. In addition, our study consisted of women with dysfunction who were actively seeking treatment at a female sexual medicine program; therefore, the VAS and VuAS will require validation in a less symptomatic population to ensure generalizability for use in the general population. Our sample was also predominantly white and consisted of highly educated women of high socioeconomic status; therefore, future studies should examine these tools across more diverse populations. Lastly, this validation study did not assess the test–retest reliability or the divergent validity of the VAS and VuAS. Future studies should assess this in order to determine the stability of the scores in the same patient over a short period of time and the consistency of scores when administered by different clinicians.

In this study, we assessed the psychometric properties of the 4-item VAS and VuAS scales, as well as a 3-item version of each scale, omitting the last question (pain with intercourse/painful to touch). Overall, we recommend the use of the 4-item versions of the scales for several reasons. The correlation between VAS Item 4 and the VAS composite based on Items 1–3 was 0.32, and the correlation between VuAS Item 4 and the VuAS composite based on Items 1–3 was 0.22, which we feel supports the inclusion of the fourth item for patients who find it relevant (that is, women who have been sexually active in the last 4 weeks) despite the increase in Cronbach's alpha that was generally seen when Item 4 was omitted. In addition, these items facilitate discussion between the patient and the clinician about important aspects of well being. Lastly, both the VAS and VuAS composites can be scored as long as at least 2 of the items on the given composite are completed, so inclusion of the fourth item will not lead to missing composite score data among sexually inactive women.

Clinical Relevance

Vulvovaginal atrophy is a chronic and progressive condition after menopause,[1,2] which can negatively impact intimacy, enjoyment of sexual intercourse, and sexual spontaneity. Often cancer patients/survivors to need to apply non-hormonal moisturizers at a greater frequency (3–5 times per week) than what is recommended on the product, as well as apply the moisturizers to the external vulvar tissues to alleviate their symptoms. As female cancer patient/survivor symptoms tend to be more acute, methods to identify and address their symptoms are needed for successful intervention, and the VAS and VuAS can be easily used in the clinical setting to assist with this process. For example, breast cancer patients treated with aromatase inhibitors are at risk for vulvovaginal tissue quality changes, which can contribute to painful intercourse and uncomfortable gynecologic exams.[9] In the clinical setting of a busy oncology practice, the VAS and VuAS would be a feasible strategy to identify these issues and provide simple solutions to improve tissue quality. Targeting these symptoms is important, as they can be cumulative and negatively impact comfort, quality of life and intimacy, and they can also influence compliance with endocrine therapy. This could also be the case for women have undergone radiation therapy, who may not be compliant with dilators due to discomfort connected with poor tissue quality.[10]

Conclusions

Vulvovaginal atrophy is underdiagnosed and undertreated, calling for more discussion between clinicians and women regarding associated symptoms and their impact on quality of life, sexual health, and comfort with gynecologic exams. In the cancer setting, these issues are more profound due to the nature of cancer treatment. We found the VAS and VuAS to be simple, feasible clinical tools that can be used in the oncology setting to efficiently assess and help clinicians address vulvovaginal/sexual health concerns of female cancer patients and survivors.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

Acknowledgments

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Table 1

Participant and visit characteristics (N=175)

Characteristic	Number of patients (%)
Mean Age, years (SD)	55.4 (10.7)
Age <50	55 (31%)
Age 50	120 (69%)
Menopausal *	
No	14 (8%)
Yes	155 (92%)
Race	
White	155 (89%)
Black	11 (6%)
Asian	6 (3%)
Other/Refused	3 (2%)
Marital Status	
Single	46 (26%)
Married /Partnered	107 (61%)
Divorced/Separated/Widowed	22 (13%)
Type of Cancer * ^	
Breast	90 (53%)
Gynecologic	54 (32%)
Colorectal/Anal	15 (9%)
Gastric/Genitourinary	6 (4%)
Skin	5 (3%)
Hematologic	3 (2%)
Other (Sarcoma, Head/Neck, Liver, Lung, High-risk *BRCA*, non-cancerous conditions)	12 (7%)
Actively on Treatment *	83 (49%)
Endocrine therapy (AI, Tamoxifen)	62/83 (75%)
Chemo/biological therapy	10/83 (12%)
Hormonal (e.g., estradiol vaginal tablets)	17/83 (20%)
Radiation therapy	3/83 (4%)
Prior Radiation Therapy *#	97 (57%)
Upper radiation therapy (i.e., chest)	61/97 (63%)
Lower radiation therapy (i.e., pelvic, abdominal)	36/97 (37%)
Palliative radiation therapy	1/97 (1%)
Total Number of Visits at Time of Analysis	
2	51 (29%)
3	37 (21%)

Characteristic	Number of patients (%)
4	33 (19%)
5	15 (9%)
6+	39 (22%)
Median time from first to last visit, months (IQR)	4.1 (2.3, 6.0)

AI, aromatase inhibitor

*
Data missing for 6 patients.

^
Percentages may not add up to 100 as patients can have more than one diagnosis/response.

#
One patient received both upper and lower radiation therapy

Table 2

Vaginal Assessment Scale (VAS) and Vulvar Assessment Scale (VuAS) item scores for first versus last visit

Item	First visit N	Last visit N	First visit N (%)	Last visit N (%)	p
VAS – Dry	174	174			<0.001
none			36 (21)	82 (47)	
mild			23 (13)	46 (26)	
moderate			35 (20)	37 (21)	
severe			80 (46)	9 (5)	
VuAS – Dry	167	173			<0.001
none			60 (36)	77 (45)	
mild			22 (13)	48 (28)	
moderate			45 (27)	37 (21)	
severe			40 (24)	11 (6)	
VAS – Sore	173	175			0.5467
none			146 (84)	156 (89)	
mild			17 (10)	12 (7)	
moderate			6 (4)	5 (3)	
severe			4 (2)	2 (1)	
VuAS – Sore	167	175			0.1275
none			119 (71)	134 (77)	
mild			25 (15)	25 (14)	
moderate			17 (10)	15 (9)	
severe			6 (4)	1 (1)	
VAS – Irritation	172	172			0.1156
none			125 (73)	141 (82)	
mild			27 (16)	18 (10)	
moderate			14 (8)	10 (6)	
severe			6 (3)	3 (2)	
VuAS – Irritation	167	175			0.7106

Item	First visit N	Last visit N	First visit N (%)	Last visit N (%)	p
none			104 (62)	119 (68)	
mild			34 (20)	28 (16)	
moderate			22 (13)	20 (11)	
severe			7 (4)	8 (5)	
VAS – Pain	174	173			<0.001
none			11 (10)	24 (27)	
mild			13 (11)	24 (27)	
moderate			27 (24)	25 (28)	
severe			63 (55)	16 (18)	
no attempt			60	84	
VUAS – Pain	166	165			0.2263
none			86 (61)	80 (66)	
mild			20 (14)	24 (20)	
moderate			26 (18)	12 (10)	
severe			9 (6)	5 (4)	
no attempt			25	44	

Table 3

Inter-item correlation of the Vaginal Assessment Scale (VAS) and Vulvar Assessment Scale (VuAS) at first and last visit[*]

	VA S1	VA S2	VA S3	VAS 4	VAS composite	VAS composite items 1–3 only	Vu AS 1	VuA S2	VuA S3	VuAS 4	VuA S composite	VuAS composite items 1–3 only
VAS 1	1	0.39	0.34	0.43	0.40	0.29	0.53	0.21	0.08	0.40	0.37	0.32
VAS 2		1	0.71	0.21	0.56	0.66	0.30	0.36	0.34	0.20	0.47	0.46
VAS 3			1	0.09	0.47	0.53	0.37	0.38	0.61	0.20	0.55	0.56
VAS 4				1	0.32	0.32	0.05	−0.14	0.15	0.32	0.17	0.03
VAS composite					1	0.92	0.45	0.27	0.30	0.36	0.42	0.39
VAS composite Items 1–3 only						1	0.50	0.38	0.36	0.35	0.48	0.46
VuAS 1							1	0.60	0.37	0.32	0.49	0.46
VuAS 2								1	0.52	0.11	0.57	0.64
VuAS 3									1	0.11	0.48	0.46
VuAS 4										1	0.22	0.22
VuAS composite											1	0.94
VuAS composite Items 1–3 only												1

[*]
(The top number represents first visit and the bottom number represents last visit.) For correlation between composite score and individual items included in that score, correlation is based on the score excluding that item.

Table 4

Correlations between Vaginal Assessment Scale (VAS) and Vulvar Assessment Scale (VuAS) items and composite and pain with exam, Female Sexual Function Index (FSFI) pain, and FSFI total

Variable Group	Variable	Pain with Exam (4 cat)		FSFI Pain		FSFI Total Score		FSFI Lubrication	
		N First visit	Correlation First visit	N First visit	Correlation First visit	N First visit	Correlation First visit	N First visit	Correlation First visit
VAS/VuAS Composites	VAS Composite	113	0.35	159	−0.16	161	−0.05	167	−0.14
	VuAS Composite	108	0.27	155	−0.18	157	−0.19	162	−0.18
VAS Items	VAS 1 (Dryness)	113	0.32	160	−0.15	162	−0.07	168	−0.25
	VAS 2 (Soreness)	113	0.22	159	−0.18	161	−0.12	167	−0.18
	VAS 3 (Irritation)	113	0.19	158	−0.13	160	−0.18	166	−0.18
	VAS 4 (Dyspareunia)	72	0.35	110	−0.63	109	−0.24	112	−0.26
VuAS Items	VuAS 1 (Dryness)	108	0.29	154	−0.08	156	−0.13	161	−0.18
	VuAS 2 (Soreness)	108	0.22	154	−0.15	156	−0.15	161	−0.08
	VuAS 3 (Irritation)	108	0.10	154	−0.24	155	−0.17	161	−0.20
	VuAS 4 (Painful to Touch)	84	0.12	132	−0.16	134	−0.16	138	−0.09
		Change in Pain with Exam (4-cat) from first to last visit		Change in FSFI Pain from first to last visit		Change in FSFI Total Score from first to last visit		Change in FSFI Lubrication Score from first to last visit	
		N	Correlation	N	Correlation	N	Correlation	N	Correlation
	Change in VAS composite from first to last visit	82	0.18	137	−0.22	139	−0.09	147	−0.11
	Change in VuAS composite	78	0.21	135	−0.11	136	−0.10	143	−0.12

Variable Group	Variable	Pain with Exam (4 cat)		FSFI Pain		FSFI Total Score		FSFI Lubrication	
		N First visit	Correlation First visit	N First visit	Correlation First visit	N First visit	Correlation First visit	N First visit	Correlation First visit
from first to last visit									

Table 5

Correlations at first and last visit of Vaginal Assessment Scale (VAS) and Vulvar Assessment Scale (VuAS) items and composites with clinical exam outcomes

Variable Group	Variable	pH		Vulvar irritation		Moisture	
		N First visit	Correlation First visit	N First visit	Correlation First visit	N First visit	Correlation First visit
VAS/VuAS Composites	VAS Composite	165	0.15	104	0.11	168	0.25
	VuAS Composite	159	0.04	106	0.36	162	0.18
VAS Items	VAS 1 (Dryness)	165	0.16	105	0.04	168	0.31
	VAS 2 (Soreness)	165	0.08	104	0.03	168	0.05
	VAS 3 (Irritation)	164	0.12	104	0.21	167	0.20
	VAS 4 (Dyspareunia)	110	0.26	69	0.22	111	0.26
VuAS Items	VuAS 1 (Dryness)	159	0.05	106	0.27	162	0.01
	VuAS 2 (Soreness)	159	−0.06	105	0.27	162	0.20
	VuAS 3 (Irritation)	158	0.03	105	0.44	161	0.31
	VuAS 4 (Painful to Touch)	134	0.10	87	0.06	136	0.08

		Change in pH from first to last visit		Change in Vulvar irritation from first to last visit		Change in moisture from first to last visit	
		N	Correlation	N	Correlation	N	Correlation
Change in VAS composite from first to last visit		163	0.12	103	−0.03	164	0.24
Change in VuAS composite from first to last visit		157	0.02	105	0.23	158	0.21

*
Higher scores are worse for clinical exam outcomes.