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Vaginal and Sexual Health Treatment Strategies within a Female Sexual Medicine Program for Cancer Patients and Survivors

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Abstract

Purpose—We sought to evaluate patient adherence and response to simple vaginal and sexual health treatment strategies in female cancer patients receiving treatment at a female sexual medicine and health program, and identify improvements of physical symptoms, per patient and clinical evaluation.

Methods—Evalubility criteria included gynecologic exam at initial visit; at least one follow-up with gynecologic exam within 8 months of initial visit; and all consecutive follow-ups <6 months apart. Demographics, medical information, and clinical assessments from 175 evaluable patients with at least 1 follow-up from 09/12–10/14 were analyzed. The majority of patients were being treated for or had a history of breast (n=90, 53%), gynecologic (n=54, 32%), or colorectal/anal (n=15, 9%) cancers. An assessment form included a clinician evaluation, Vaginal Assessment

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Compliance with Ethical Standards

Conflict of Interest: The authors have no conflicts of interest to disclose.

Ethical approval: All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Informed consent: Data for this study was collected under an Institutional Review Board waiver.

Scale (VAS), Vulvar Assessment Scale (VuAS), and patient-reported outcomes. Compliance with treatment recommendations were summarized, and changes over time were compared for clinical outcomes.

Results—Mean number of visits was 3.43. Mean age was 55.4 years; 92% (n=155/169) were in menopause. Treatment strategies included rationale and instruction for use of vaginal moisturizers, lubricants, pelvic floor exercises and dilator therapy, in addition to psychosexual education regarding sexual changes (response, anatomy and function) associated with cancer treatment and support. At last assessment, 89% had complied with the clinical recommendation (moisturize 2–5+ times/week). Vaginal pH scores >6.5 declined over time (p=0.03). VAS scores improved by last assessment (p<0.001), as did VuAS scores (p=0.001). Sexual function scores significantly improved (p<0.001), confidence about future sexual activity increased (p=0.004), and sexual/vaginal health concerns decreased (p=0.00003).

Conclusion—Significant changes were observed in women using treatment strategies, with improvement in vulvovaginal symptoms, a decrease in elevated vaginal pH and pain with exams, enhanced sexual function, and intimacy confidence.

Implications for Cancer Survivors—These findings have high clinical relevance for symptom management with improvement of sexual function using simple strategies and clinical tools in the oncology setting.

Keywords

cancer; survivorship; female sexual health; quality of life; vaginal health

Introduction

Recent surveys of patients' needs have revealed the need for information and strategies, as well as the development of programs, to address vulvovaginal health concerns and sexual function in cancer patients and survivors [1-4]. While the natural progression of aging and initiation of menopause can result in vulvovaginal atrophy for women, cancer and its associated treatment can often trigger and/or worsen vulvovaginal and sexual issues. Vaginal and vulvar dryness, irritation, and loss of genital tissue elasticity caused by a reduction in estrogen can lead to pain and discomfort with standard gynecologic examinations, as well as with sexual activity [5-11]. The Female Sexual Medicine and Women's Health Program (FSMWHP) at Memorial Sloan Kettering Cancer Center was established to address the negative effects of cancer and cancer treatment on vulvovaginal health and sexuality. The FSMWHP is a multi-disciplinary program using a psychosexual education model. The goals of the program are to provide information, simple strategies, and support to improve symptoms and enhance confidence about sexual/vaginal health while simultaneously promoting evidence-based research.

The objective of this evaluation was to examine patient adherence and response to simple sexual/vaginal health treatment strategies in female cancer patients/survivors receiving treatment at the FSMWHP. Clinical tools were developed to summarize changes over time and to identify improvements of physical symptoms as reported by patients and observed on clinical evaluation. Demographics, medical information, clinical findings (as per

gynecologic exams), vulvovaginal symptoms, adherence to treatment recommendations, and patient-reported outcomes (PROs) were analyzed for patients who had a gynecologic exam during their baseline visit and at last follow-up (during the 2-year study period) to assess whether the changes over time were statistically significant. Simple, time-efficient strategies in this setting are lacking, and these findings have high clinical relevance and can be easily applied within the clinical setting.

Materials and Methods

Setting

A limited waiver of authorization was obtained to access new-visit data collected on FSMWHP clinical assessment forms from 9/26/2012–10/31/2014 to evaluate the program. Evaluability criteria for this program analysis included gynecologic exam at initial visit; at least one follow-up visit with a gynecologic exam within 8 months of initial visit; and all consecutive follow-up appointments had to be less than 6 months apart. Of 400 new-visit patients, 175 were considered evaluable, totaling 601 visits. Upon completion of an initial visit at the FSMWHP, women were strongly encouraged to make a follow-up appointment if significant symptoms were reported on assessment or noted on exam, and/or if it appeared the patient would benefit from additional support with sexual/vaginal health concerns. In a case in which a patient's symptoms or concerns were minimal or the visit was considered a prevention visit (e.g., a pre-treatment visit), follow-up, as needed, was recommended at an initial consult. Ultimately, follow-up was determined by the patient's preference.

Intervention

The FSMWHP is designed as a two-clinician program consisting of a PhD clinical psychologist (certified sexual therapist) and a nurse practitioner (NP). This model enables the provision of comprehensive, quality care addressing both the emotional and physical effects of cancer and cancer treatment in a clinically feasible and timely manner. Women were predominately referred to the program by their oncologist or another member of their clinical team, although a few made an appointment via self-referral. Referrals were made if a patient was expressing psychosexual distress and/or self-reported vaginal issues such as pain, dyspareunia, loss of libido, dryness, or discomfort with their gynecologic examinations. The FSMWHP uses a psychosexual education model with the initial visit including information about possible changes to the body secondary to cancer treatment, assessment of vulvovaginal symptoms, sexual function, previous strategies used to address symptoms and sexual concerns, and provision of the rationale and instruction for treatment recommendations to address motivation, set realistic expectations, enhance compliance, and support. Follow-up visits consisted of review/documentation of compliance, with recommendations and re-education if needed, adjustment of treatment strategies based on symptom assessment, gynecologic exam and support regarding confidence about future intimacy (self-efficacy items) and managing sexual concerns. Of note, follow-up visits generally included visits with both the NP and PhD (separately); however, further follow-ups could were with either clinician based on the patient's need (e.g., more psychological support with the PhD or symptom(s) management with the NP). In our cohort, the majority of the patients preferred to attend their appointments individually.

Measures

The FSMWHP clinical assessment form, which incorporates clinician and patient input, was completed for all attendees. The initial part of the form is an assessment of vaginal/vulvar symptoms. The Vaginal Assessment Scale (VAS) and Vulvar Assessment Scale (VuAS) are each 4-item measures in which the clinician asks the patient to quantify and rate (none, mild, moderate, or severe) their perception of dryness, soreness, irritation without sexual activity, and pain with sexual activity (i.e., dyspareunia/painfulness of the external tissues during stimulation) in these anatomical areas (Appendix 1). Each item is assessed on a numeric scale (0=None to 3=Severe) – a lower score indicates fewer symptoms. The VAS and VuAS composite scores (both range 0-3) equal the mean of the item scores and are calculated when ≥2/4 items are not missing. Lower scores indicate better functioning. In previous studies, the VAS has been shown to be sensitive to change [12]. The VuAS is a modification of the VAS, targeting vulvar symptoms. Internal consistency reliability (Cronbach's alpha) of the VAS and VuAS composite scores at the baseline visit were 0.70 and 0.68, respectively. VAS and VuAS correlations with pelvic exam outcomes and PROs were calculated to confirm validity.

The clinician also uses the assessment form to document patient-reported frequency of use of vaginal/vulvar health promotion strategies (vaginal lubricant, internal and external moisturizers, pelvic floor exercises, and dilators) and to identify the strategies recommended at the visit (Appendix 1).

The pelvic exam checklist on the clinical assessment form was developed based on the Common Terminology Criteria for Adverse Events (CTCAE) and multidisciplinary discussions (psychologist, NPs, general gynecologist, radiation oncologist, and gynecologic oncologists) and modified in conjunction with feedback from our patients and clinical team. The pelvic exam checklist assesses 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). Lower scores indicate fewer symptoms. The rest of the assessment form is completed by the patient and includes the following validated PRO measures:

Female Sexual Function Index (FSFI)—a brief self-report instrument of female sexual function [13] recently validated in cancer survivors [14]. Its 19 items assess six domains of sexual function: desire, subjective arousal, lubrication, orgasm, satisfaction, and pain/discomfort. A higher score is indicative of better sexual function, and a total score greater than 26.55 indicates no sexual dysfunction.

Sexual Activity Questionnaire (SAQ)—a 14-item self-report instrument assessing whether women are engaging in sexual activity with someone, reasons for any reported inactivity, and sexual feelings and experiences over the previous month [15]. Section III of the SAQ produces two multi-item scale scores: discomfort during sexual intercourse (dryness and pain) and pleasure from sexual intercourse (desire, enjoyment, satisfaction) [16]. A higher score indicates more difficulties with sexual function. For this program

evaluation, we classified women as sexually active if they answered, “Yes” to SAQ item #3: “Do you engage in sexual activity with anyone at the moment?”

Sexual Self-Schema Scale (SSS)—a self-rated assessment regarding aspects of one's sexual self [18,18]. It contains 26 scored trait adjectives (e.g., cautious, loving, open-minded) plus 24 adjective fillers (e.g., generous, practical, kind) rated from 0 (not at all descriptive of me) to 6 (very descriptive of me). The items produce three dimension scores (loving-romantic, direct-open, and embarrassment-conservatism) and a total score. Scores of a 57 or greater in the cancer patient population indicates a positive sexual schema, while a score lower than 57 a more negative sexual self-view.

Exploratory items addressing self-efficacy and sexual/vaginal health were also included—Examples include: “Do you feel confident about sexual activity in the future?” (Yes/No), “How confident are you in using vaginal health promotion strategies?” (0-10 visual analogue scale with anchors at 0=Not at all, 5=Somewhat, and 10=Very), “How confident are you in managing sexual health/vaginal health issues in the future?” (0-10 visual analogue scale with anchors at 0=Not at all, 5=Somewhat, and 10=Very), and “How concerned or worried are you about your sexual function and vaginal health?” (0-10 visual analogue scale with anchors at 0=Not at all, 5=Somewhat, and 10=Very). A higher score indicates more confidence in sexual activity.

Statistical analyses

Demographics, medical information, clinical exam findings, and PROs were analyzed for evaluable patients. Data from baseline and last assessment during the 2-year time period for each patient were separately summarized using frequencies and percentages for categorical variables and means and standard deviations for continuous variables. Changes on categorical variables (e.g., clinical exam ratings) were investigated by crosstabulating responses from first with last visit and using McNemar's chi-squared tests for paired proportions to assess for statistically significant changes. Continuous measures (e.g., PRO scale scores) from first to last assessment were examined for statistical significance using paired t tests. Internal consistency reliability coefficients (Cronbach's alpha) of the VAS and VuAS composite scores were calculated using inter-item polychoric correlations to account for their ordinal nature. To evaluate change in overall vaginal health, a vaginal health improvement index was calculated by subtracting baseline symptom scores on the pelvic exam from those at last assessment, then summing individual symptom change scores. Similar to other studies [19], the following 8 symptoms contributed to the vaginal health improvement index: pH, moisture, rugosity, elasticity, length, thickness, epithelial integrity, and vascularity. Women were grouped as “improved” if this index was <0, indicating a net improvement in symptomatology, or as “not improved” if this index was ≥ 0. Chi-squared and Fisher's exact tests assessed the statistical significance between these groups on categorical variables, and two-sample t tests were used to assess differences on continuous variables. Correlations between pain with exam (a four-category ordinal variable), FSFI pain (continuous), and FSFI total score (continuous) were calculated using polychoric correlations between ordinal variables, polyserial correlations between ordinal and continuous variables, and Pearson correlations between continuous variables. Significance

tests with $p<0.05$ were considered statistically significant. All statistical analyses were conducted in R 3.1.1 [20].

Results

Patient Characteristics

Mean number of visits was 3.43 (SD=1.5). Maximum number of visits was 11. Mean age at initial consult was 55.4 years (SD=10.7; range, 22.85-79.15). Although 31% of the patients were younger than age 50, 92% (n=155/169) were menopausal. Sixty-one percent (n=107) reported a current intimate relationship. Attendees were predominantly white (n=155, 89%), and the majority had a history of breast (n=90, 53%), gynecologic (n=54, 32%), or colorectal/anal (n=15, 9%) cancer. Forty-nine percent (n=83) were receiving treatment (Table 1).

Adherence to sexual/vaginal health promotion strategies

Participants demonstrated adherence to the recommended sexual/vaginal health strategies (at last assessment), with 95% (n=139/147) reporting regular use of a vaginal lubricant with sexual activity or dilators, 89% (n=143/161) administering moisturizer consistently, 69% (n=111/162) performing pelvic floor exercises regularly, and 41% (n=50/122) compliant with recommended dilator therapy.

Vaginal health assessment

Vaginal (VAS) symptoms improved from first to last assessment (mean, 1.09 [SD 0.65] to 0.55 [SD 0.5]; $p<0.001$), as did the Vulvar (VuAS) symptoms (mean, 0.79 [SD 0.67] to 0.59 [SD 0.55]; $p<0.001$). FSFI total mean scores increased from 12.53 (SD 7.68) to 16.18 (SD 9.30) ($p<0.001$), indicating improvement in sexual function. Significant improvement was noted for all subdomains (desire, arousal, lubrication, orgasm, satisfaction, and pain) of the FSFI from first to last assessment (Table 2). Findings on the SAQ also showed increased pleasure (mean, 5.96 [SD 4.45] to 7.74 [SD 5.42]; $p<0.001$) and less discomfort (mean, 1.35 [SD 1.93] to 2.78 [SD 2.12]; $p<0.001$).

At Visit 1, 43% (n=66/152) of the women reported current sexual activity with a partner, which increased to 55% at last assessment (n=83/152; p=0.004). The number of women falling in the range of sexual dysfunction on the FSFI decreased from 96% (n=136/141) to 85% (n=121/141) by last assessment. Confidence about future sexual activity increased from 47% (n=65/139) to 61% (n=85/139) (p=0.004). Concerns about sexual/vaginal health (scale of 0-10) decreased over time, with 52% (n=74/143) rating their concern at 9-10 at first visit and 30% (n=43/143) by last assessment ($p<0.001$). FSFI arousal mean scores improved from first (mean, 2.15; SD=1.77) to last assessment (mean, 2.73; SD=1.89) ($p<0.001$), and urinary incontinence rates declined from 59% (n=61/104) to 33% (n=33/104), which could be connected to high adherence rates with pelvic floor exercises of a few times per week to daily (69%; n=111/162).

Pelvic exam clinical outcomes

At Visit 1, 80% (n=81/101) experienced pain with pelvic exam, which decreased to 64% (n=65/101) by last assessment (p=0.006). Vaginal pH of greater than 6.5 declined from 28% (n=46/164) to 20% (n=32/164) (p=0.03). The rate of vulvar atrophy decreased from 73% (n=71/97) to 59% (n=57/97) (p=0.01). Vulvar irritation rates decreased from 72% (n=76/105) to 57% (n=60/105) (p=0.007). Eighteen percent of women (n=30/165) had normal vaginal moisture at first visit, which increased to 28% (n=46/165) at last assessment (p=0.03; Table 3)

Overall, 48% (n=82/171) of patients were classified as “improved” according to the vaginal health improvement index. Improvement was associated with age (81% of patients who improved compared with 60% who did not improve were 50 years of age or older; p<0.01), a higher number of clinic visits (mean, 3.95 [SD=2.01] versus 3.28 [SD=1.71]; p=0.02), and higher adherence at last assessment to recommended use of dilators (p=0.02) and more frequent use of moisturizer (p=0.01). Lubrication adherence at last visit was not associated with improvement, but women who were adherent to lubrication recommendations for at least half of their follow-up visits were more likely to have improved vaginal health (52%) compared with those who were not as consistent with lubrication use (28%) (p=0.03).

VAS and VuAS

Correlations at baseline between VAS and VuAS items and composite scores, clinical exam outcomes, and PRO variables were calculated to assess whether the VAS and VuAS correlated with other related variables. The VAS and VuAS were correlated with gynecologic outcomes; the strongest associations were between the VAS total and scarring on exam (−0.37) and VuAS total with vulvar irritation (0.35) seen on exam. VAS dryness was associated with SAQ discomfort (−0.38) and FSFI lubrication (−0.25). VAS dyspareunia was correlated with FSFI pain (−0.56), SAQ discomfort (−0.45), and FSFI lubrication (−0.26). VuAS external discomfort was correlated with FSFI Desire (−0.32).

Associations between outcomes

Correlations of pain (pain severity during pelvic exam and FSFI pain) and sexual function with clinical exam outcomes and PROs at baseline are listed in Table 4. Sexual Functioning: FSFI total score was strongly associated with SAQ pleasure (0.77) and moderately with SSS passionate score (0.31). Epithelial integrity (−0.40) and elasticity (−0.32) were negatively associated with FSFI total scores. Pain as measured by FSFI: was positively associated with SAQ pleasure (0.45) and negatively associated with elasticity (−0.46), epithelial integrity (−0.59), vulvar irritation (−0.32), and VAS dyspareunia (−0.56). Pain on exam: was moderately correlated with pelvic exam signs of vestibular irritation (0.49), vulvar irritation (0.44) and vulvar atrophy (0.33), vaginal tissue factors of vascularity (0.30), elasticity (0.31), and reported vaginal (VAS) (0.34) and vulvar symptoms (VuAS) (0.27).

Group comparisons

An analysis was conducted to examine potential group differences between evaluable and inevaluable women. Of the 400 women seen for a new visit, 225 did not have a follow-up within 8 months of initial consult with a gynecologic exam. The findings revealed that

compared with the evaluable cohort (n=175), women with no follow-up were on average 3.4 years younger (p=0.001), and on gynecologic exam noted to have better vaginal elasticity, vaginal length, vascularity, less pain, and less vulvar atrophy. FSFI pain scores were significantly better in the no follow-up group. Responses to the VAS pain item also differed between the groups, but follow-up analysis indicated more evaluable women (34%, n=60/175) reporting “no attempt” compared with inevaluable women (22%). On the SAQ, more women with no follow-up reported being in a current relationship (84%, n=190/225) compared with evaluable women (77%, n=134/175). Inevaluable women also had higher scores on the SSS embarrassed-conservative subscale.

Discussion

Although the normal aging process prompts physical changes that influence sexual function and vaginal health, vulvovaginal atrophy in the setting of cancer compounds these symptoms or induces them earlier [5-11]. Our FSMWHP evaluation demonstrated positive changes over time for both objective and subjective measures. Female cancer patients and survivors reported improvement in vulvar/vaginal symptoms, enhanced sexual function, increased sexual activity and confidence in future intimacy, and were also seen to have a decline in severely elevated vaginal pH and decreased pain with gynecologic exams. Older women attending the FSMWHP improved more and were more likely to follow-up compared with younger women, possibly due to the severity of their symptoms or more flexibility with time (younger women are more likely to have small children or work constraints). Regardless, our sample was predominantly menopausal despite age, and as vulvovaginal changes can be cumulative [21-23], these findings highlight the importance of getting information and time-efficient strategies to women as soon as possible.

Other factors such as motivation should be addressed, and the rationale for adherence with strategies and consistency should be clearly discussed. Clinically, we observed that women were generally unaware of the natural aging process and its impact on tissue quality and comfort. The loss of genital tissue elasticity and lubrication often causes vulvovaginal dryness and discomfort, and can lead to pain with gynecologic examinations, dyspareunia, and changes in sexual function [5-7]. If women are provided with this basic information, moisturizers can be extremely helpful for overall women's health when used at the frequency needed to address their symptoms (usually greater than the products’ recommendations), consistently for sustained benefit and applied both internally and to the external tissues of the lower genitals. Our results demonstrated improvement not only in vaginal, but vulvar, symptoms. Additionally, the study sample exhibited adherence to treatment recommendations and significant improvement on all domains of the sexual response, as per the FSFI. Although many women may not have time to attend or access a female sexual medicine clinic, basic guidelines (moisturizers and lubricants) can be offered, with frequency and consistency in mind for ideal benefit.

There are several noted limitations of this study. The program evaluation could only be conducted with women with follow-up in order to assess the recommended strategies and the effectiveness of the FSMWH by determining if changes were noted over time. Our examination of potential differences between evaluable and inevaluable patients revealed

that the latter were younger, less symptomatic, and more likely to already be on local estrogens. There are many possible reasons that could explain a lack of follow-up: these women received information to address their concerns at initial consult and felt follow-up was not necessary; they were recommended to “return as needed”; or they did not view the resources or strategies feasible at that point in their cancer experience. Our findings were also based on PROs, attendees’ perception of vaginal/vulvar symptoms, and reported adherence with recommended strategies, which could be subject to bias. However, these were examined and compared with pelvic exam outcomes and correlations between the clinical outcomes and PROs to support our study findings.

The authors recognize the absence of a control group to demonstrate efficacy and assist in attributing the results directly to the program. Though comparability between patients in the program and a control group cannot be demonstrated, the notable improvements and satisfaction in the patients who attended the program have built a foundation for future study of its effectiveness in treating this population of cancer patients and survivors. Our results demonstrate that simple, non-hormonal strategies can be helpful to female cancer patients and survivors. However, it is understood that these findings were observed in women attending a program designed to provide support and clinical care targeting these issues. As such, more time and attention was allocated to address these concerns than may be available or feasible at other oncology clinics. We also acknowledge that these results were observed in women with follow-up, which may reflect a greater motivation and/or commitment to the sexual/vaginal rehabilitation process.

Regardless, we feel that certain elements of the FSMWHP can be easily translated into clinical care in several ways, e.g., by providing simple information and education on vulvovaginal health strategies, including guidelines for product application. Based on our findings, vulvovaginal symptoms, sexual function, and comfort with exams are likely to improve, although information needs to be tailored based on symptoms and treatment history. For example, in breast cancer patients treated with aromatase inhibitors, vaginal atrophy is often more severe. Moisturizing frequency may vary (3-5 times per week) from that of the recommended product dose [24], and applying to the internal vaginal tissues and external lower genital area (vulva, clitoral area, and vestibule) may be beneficial. However, patient adherence is key. We also found the VAS and VuAS to be a reliable, accurate, and time efficient clinical tool that could be used to identify and monitor troublesome vulvovaginal symtoms. These symptoms were also correlated with clinical exam outcomes and PROs. The VAS and VuAS are brief and could be easily incorporated into general assessment forms. Additionally, simple screening tools have been developed [25-27] for those interested in addressing these concerns more routinely or in-depth within clinical practice for intervention (patient education materials or referral to specialist).

Vulvovaginal health and tissue quality are crucial for comfort with gynecologic examinations—an essential component of cancer surveillance. Although sexuality is a priority for many, for those unclear about this issue, vulvovaginal health should remain a priority. As the US population of cancer survivors continues to grow, expected to be 18 million by 2020 [28], quality of life, including vulvovaginal health and sexual function, will require more attention [29-31].

The findings of this program evaluation have substantial clinical relevance. Our program examined simultaneously the emotional and physical implications of the changes to vulvovaginal health and sexual functioning in the setting of coping with a cancer experience, in order to identify simple, time efficient strategies and tools that could be offered as frontline treatment and used within a busy clinical practice. Many interventions have been shown to be effective in addressing these issues but tend to be costly, time intensive, and require administration by a sexuality expert. We believe that our findings demonstrate the benefit of information addressing prominent physical symptoms (vulvovaginal dryness, irritation, discomfort) and instruction for strategies to improve tissue quality (moisturizers) and pelvic floor function (awareness and control), as well as promoting circulation and addressing pain with exams or penetration (dilators), which are associated with positive benefits to symptom management, confidence about future sexual activity, and improvement in sexual function (as per PROs). Within the oncology setting, based on the described model, patients could be screened easily using the VAS/VuAS, and these women can be routinely offered patient education materials (Appendix 1) addressing these noted areas of concern. However, follow-up discussions are crucial to re-assess symptoms, re-educate as needed, and for referrals (e.g., mental health professional, gynecologist, pelvic floor physical therapist) for additional support, when appropriate.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

Acknowledgments

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Table 1

Patient characteristics

Characteristic	N (%)
	N=175
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 (62%)
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	
No	86 (51%)
Yes	83 (49%)
Endocrine therapy (AI, Tamoxifen)	62 (75%)
Chemo/biological therapy	10 (12%)
Radiation therapy	3 (4%)
Utilizing Hormonal Supplementation (e.g., Vagifem)	17 (21%)
Prior Radiation Therapy	97 (57%)
Upper RT (i.e., chest)	61 (63%)
Lower RT (i.e., pelvic, abdominal)	36 (37%)
Other	1 (1%)

AI, aromatase inhibitor; RT, radiation therapy

Table 2

Comparison of VAS, VuAS, and PRO Scale Scores at First and Last Assessments

Variable	N	First Assessment Mean (SD)	Last Assessment Mean (SD)	t	df	p
VAS Composite	173	1.09 (0.65)	0.55 (0.50)	10.46	172	<0.001
VuAS Composite	168	0.79 (0.67)	0.59 (0.55)	3.68	167	<0.001
FSFI Total Score	141	12.53 (7.68)	16.18 (9.30)	−5.75	140	<0.001
FSFI Desire	150	2.47 (1.14)	2.74 (1.28)	−2.88	149	0.005
FSFI Arousal	151	2.15 (1.77)	2.73 (1.89)	−4.05	150	<0.001
FSFI Lubrication	149	1.80 (1.76)	2.56 (1.97)	−5.22	148	<0.001
FSFI Orgasm	149	2.14 (2.13)	2.89 (2.26)	−3.96	148	<0.001
FSFI Satisfaction	137	2.45 (1.45)	3.02 (1.76)	−4.42	136	<0.001
FSFI Pain	139	1.37 (1.81)	2.29 (2.31)	−5.63	138	<0.001
SAQ Pleasure	146	5.96 (4.45)	7.74 (5.42)	−4.43	145	<0.001
SAQ Discomfort	104	1.35 (1.93)	2.78 (2.12)	−5.90	103	<0.001
SSS Total Score	145	62.10 (15.23)	61.76 (15.32)	0.53	144	0.60
SSS Passionate-Romantic	147	44.58 (8.00)	43.51 (8.73)	2.71	146	0.008
SSS Open-Direct	148	38.08 (7.19)	38.61 (6.94)	−1.45	147	0.15
SSS Embarrassed-Conservative	145	20.87 (6.20)	20.41 (6.19)	1.29	144	0.20

FSFI, Female Sexual Function Index, SAQ, Sexual Activity Questionnaire; SSS, Sexual-Self Schema Scale; VAS, Vaginal Assessment Scale; VuAS, Vulvar Assessment Scale

Table 3

Comparison of Clinical Outcomes at First and Last Assessments

Clinical Assessment	First Assessment n (%)	Last Assessment n (%)	p
Pain (n=101)			p=0.006
Yes	81 (80.2%)	65 (64%)	
No	20 (19.8%)	36 (36%)	
Vaginal pH (n=164)			p=0.03
6.5+	46 (28.1%)	32 (19.5%)	
Vaginal Moisture (n=165)			p=0.03
Normal	30 (18.2%)	46 (28%)	
Minimal/None	135 (81.8%)	119 (72%)	
Vestibular Irritation (n=100)			p=0.50
Yes	48 (48.0%)	44 (44%)	
No	52 (52.0%)	56 (56%)	
Vulvar Atrophy (n=97)			p=0.01
None	26 (26.8%)	40 (41%)	
Mild/Moderate/Severe	71 (73.2%)	57 (59%)	
Vulvar Irritation (n=105)			p=0.007
None	29 (27.6%)	45 (43%)	
Mild/Moderate/Severe	76 (72.4%)	60 (57%)	
Rugosity (n=162)			p=0.81
Good [thick rugated folds]	144 (88.9%)	146 (90%)	
Minimal [poorly rugated]	18 (11.1%)	16 (10%)	
Elasticity (n=164)			p=0.002
Excellent [fully distensible]	133 (81.1%)	149 (91%)	
Fair [moderate loss of distensibility]	31 (18.9%)	15 (9%)	
Length of Vagina (n=164)			p=0.13
>6 cm	132 (80.5%)	139 (85%)	
4-6 cm	26 (15.9%)	22 (13%)	
<4 cm	6 (3.7%)	3 (2%)	
Fecal Incontinence (n=103)			p=0.02
Yes	15 (14.6%)	6 (6%)	
No	88 (85.4%)	97 (94%)	
Urinary Incontinence (n=104)			P<0.001
Yes	61 (58.7%)	33 (32%)	
No	43 (41.3%)	71 (68%)	
Pad Use (n=97)			p=0.07
Pads	31 (32.0%)	23 (24%)	
No Pads	66 (68.0%)	74 (76%)	

Table 4

Correlations of Pain with Exam, FSFI Pain, and FSFI Total Score with Clinical and Patient-Reported Outcomes, at First Assessment

		Pain w/Exam (4-cat)		FSFI Pain		FSFI Total Score	
Variable Group	**Variable**	**N**	**Correlation**	**N**	**Correlation**	**N**	**Correlation**
VAS/VuAS Composites	**VAS Composite**	113	0.34**	159	−0.16*	161	−0.05
	VuAS Composite	108	0.27**	155	−0.18*	157	−0.19*
VAS Items	**VAS 1 (Dryness)**	113	0.32**	160	−0.15^	162	−0.08
	VAS 2 (Soreness)	113	0.22	159	−0.19	161	−0.08
	VAS 3 (Irritation)	113	0.19	158	−0.13	160	−0.18^
	VAS 4 (Dyspareunia)	72	0.35**	110	−0.56**	109	−0.25*
VuAS Items	**VuAS 1 (Dryness)**	108	0.30**	154	−0.09	156	−0.14
	VuAS 2 (Soreness)	108	0.22^	154	−0.16	156	−0.17^
	VuAS 3 (Irritation)	108	0.11	154	−0.26**	155	−0.17^
	VuAS 4 (Painful to Touch)	84	0.12	132	−0.19^	134	−0.18^
Pelvic Exam Checklist	**Pain with Exam (4-cat)**	−-	−-	108	−0.22*	108	−0.08
	Scarring	111	0.11	151	−0.25^	153	−0.22^
	pH	110	0.33**	154	−0.15^	156	−0.17^
	Moisture	112	0.28*	156	−0.29**	158	−0.15^
	Elasticity	110	0.31*	155	−0.46**	157	−0.32**
	Length	111	0.22	155	−0.42**	157	−0.24*
	Thickness	113	0.20	158	−0.02	160	−0.02
	Integrity	109	0.20	151	−0.59**	153	−0.40**
	Vascularity	112	0.30*	155	−0.28*	157	−0.20^
	Vulvar Atrophy	78	0.33**	94	−0.23*	95	−0.07
	Vulvar Irritation	78	0.44**	97	−0.32**	98	−0.23*
	Vestibular Irritation	78	0.49**	95	−0.21^	96	−0.11
	Urinary Incontinence	78	−0.08	95	0.10	96	−0.04
	Fecal Incontinence	78	0.08	95	−0.13	96	−0.17
	Pad Use	78	−0.20	92	0.08	93	0.05
FSFI Scales	**FSFI Total Score**	108	−0.08	160	0.70**	−-	−-
	FSFI Desire	110	0.00	158	0.18*	161	0.53**
	FSFI Arousal	111	0.00	160	0.45**	162	0.90**

		Pain w/Exam (4-cat)		FSFI Pain		FSFI Total Score	
Variable Group	**Variable**	**N**	**Correlation**	**N**	**Correlation**	**N**	**Correlation**
	FSFI Lubrication	110	−0.13	161	0.56**	163	0.82**
	FSFI Orgasm	108	0.00	157	0.48**	160	0.87**
	FSFI Satisfaction	105	−0.01	153	0.40**	155	0.73**
	FSFI Pain	108	−0.22*	−-	−-	160	0.70**
SAQ Scales	**SAQ Pleasure**	105	−0.14	152	0.45**	153	0.77**
	SAQ Discomfort	89	−0.28*	127	0.11	127	−0.08
	SAQ Habit	97	−0.01	139	0.12	141	0.20*
	SAQ Too Tired	106	−0.06	151	−0.07	152	0.06
SSS Scales	**SSS Total**	106	−0.07	153	0.18*	156	0.30**
	SSS Passionate-Romantic	106	−0.15	154	0.14^	157	0.31**
	SSS Open-Direct	107	0.04	155	0.10	158	0.17*
	SSS Embarrassed-Conservative	106	0.01	153	−0.17*	156	−0.15^

FSFI, Female Sexual Function Index, SAQ, Sexual Activity Questionnaire; SSS, Sexual-Self Schema Scale; VAS, Vaginal Assessment Scale; VuAS, Vulvar Assessment Scale

^ $p < 0.10$

* $p < 0.05$

** $p < 0.0$