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Patient-reported barriers to vibrating vaginal wand therapy post-radiation: implications for improving adherence

Abstract

Purpose: Vaginal dilator therapy is commonly used for the prevention of vaginal stenosis after radiation therapy among women with gynecologic cancers, facilitating more comfortable and feasible pelvic exams and improved sexual function. While adherence to dilator therapy is a known barrier, few data exist regarding factors contributing to non-adherence. Fewer data exist regarding the use of vibrating vaginal wands (VVW), which are increasingly utilized in this setting. Our objective was to determine adherence to VVW and patient-reported barriers to the use of VVW therapy.

Methods: A prospective cohort study was performed between September 2017 and December 2019 among women receiving radiation therapy for gynecologic cancers. Participants were provided with a VVW after radiation therapy and asked to record usage frequency and barriers to use in a study diary for up to 16 weeks. Patient-reported health-related quality of life and sexual health outcomes were evaluated at baseline and follow-up time points for up to 16 weeks.

Results: Among 51 enrolled participants, the overall adherence rate was 66% (95% CI:51.7 – 77.8%). The most frequently cited barriers were: 1) being too tired to use the vaginal wand; 2) thinking of the vaginal wand as a sex toy; 3) being reminded of their treatment and cancer; 4) being sick of using the vaginal wand; and 5) not being able to use the wand in the shower. Higher barrier scores were associated with decreased VVW usage. Increased patient-reported pain interference and lower sexual interest were significantly correlated with lower frequency of use.

Conclusion: Most patients adhere to VVW for up to 4 months following radiation therapy, however, barriers to use exist. Routine follow-up, support, and patient-oriented pre-emptive counseling by providers may improve adherence to VVW therapy among gynecologic cancer survivors.

Keywords: patient-reported barriers, vaginal dilator therapy, adherence, radiation

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Introduction

Women undergoing radiation treatment for gynecologic cancers experience vaginal mucosal changes which may result in vaginal fibrosis, vaginal stenosis, dyspareunia, and lymphedema.[1] These changes can lead to sexual dysfunction or the inability to undergo adequate surveillance pelvic exams.[2–5]

Vaginal dilator therapy is widely recommended by providers following pelvic radiotherapy to prevent vaginal stenosis and agglutination despite a lack of high-quality data.[6–9] Recent data indicate low adherence with therapy.[10] Qualitative studies report barriers to dilator use include viewing usage as a negative experience, thinking of the dilator as an embarrassing sex toy, and the use of a dilator causing a relived experience of invasive treatment.[11,12]

Vibrating vaginal wands (VVW) have recently become commonly prescribed for the prevention of vaginal stenosis. VVW therapy is thought to stimulate vaginal tissue and increase vaginal blood flow to a greater degree than static dilators.[13] The vibration is thought to create shear stress on endothelial capillaries, thus increasing blood flow and vaginal lubrication.

Data regarding the use of VVW among women treated for gynecologic cancer are limited. Based on prior data regarding barriers to vaginal dilator use, VVW may present a unique set of barriers secondary to the element of vibration. The primary objective of this study was to determine adherence to VVW therapy, identify barriers to use, and to identify demographic, health-related quality of life, and sexual function measures associated with adherence to VVW therapy among women with gynecologic cancer undergoing pelvic radiotherapy.

Methods

Participants

A prospective cohort study of patient-reported adherence and barriers to VVW among women with gynecologic cancers undergoing pelvic radiotherapy was conducted at a university-based academic medical practice. Women ≥18 years of age with a diagnosis of gynecologic malignancy undergoing any radiation treatment were included. Demographics and clinical characteristics were abstracted from patients' electronic medical records. All patients were prescribed a VVW following radiation treatment. Participants were invited to participate in the study at the time they were provided with the VVW. Participants were given standard institutional instructions on usage of the VVW in addition to unstructured, standard in-office counseling regarding use. They were asked to complete a diary tracking their usage and barriers to use. Adherence was defined as VVW use ≥ 4 times per week for > 50% of each patient's follow-up period of up to 16 weeks after radiation therapy completion. The definition of adherence for this study was chosen based on our institution's

standard recommendations. The study was approved by the University of Wisconsin-Madison Institutional Review Board (IRB). Informed consent was obtained from all participants as outlined in the IRB-approved protocol. Guidelines outlined in the Declaration of Helsinki were followed. Preliminary data from this work was previously published as an abstract from conference proceedings.[14]

Patient-reported measures

Participants completed measures related to sexual function – Patient Reported Outcomes Measurement Information System (PROMIS) at the time of enrollment (baseline) and at each follow-up visit.[15,16] Follow-up assessments were completed at the time of standard-of-care surveillance visits for participants' gynecologic malignancy, at three to five weeks after enrollment, and again at two to four months after enrollment. At the last follow-up appointment, participants rated sixteen pre-specified barriers to use on a five-point Likert scale with respect to how much each barrier interfered with use. Barriers were developed in collaboration with experts from our cancer center's longstanding sexual health program (Women's Integrative Sexual Health Program) as well as expert opinion, prior data, and feedback from patients undergoing active treatment at our Cancer Center.

Statistical considerations

Demographic characteristics were summarized with frequencies and percentages or with medians and the interquartile range (IQR; central half-sample from 25th to 75th percentile). Negative binomial regression was used to explore the association between total VVW usage frequency over 16 weeks and demographic characteristics, endorsement of individual barriers, PROMIS and FACIT scores; models include length of follow-up as an offset to yield estimates of usage per week. The degree to which each barrier affected use (five levels from 'not at all' to 'very much') was reported with frequencies and percentages. Barriers were then sorted according to their Kendall-Wei rank.[15,16] Analyses were conducted using R v.3.5.1.[17]

Results

Fifty-one participants (median age 65.8 years) were enrolled (Table 1). The majority (84%) had uterine cancer and Stage I disease (61%). Twelve percent received both external beam radiation therapy (EBRT) and vaginal brachytherapy; 88% received vaginal brachytherapy alone. Thirty-nine percent received chemotherapy.

Table 1 Demographic and clinical characteristics of N=51 patients with gynecologic malignancy undergoing radiation therapy[a]

Characteristic	Median (Interquartile range)
Age (years), n=49	65.8 (57.9 – 71.6)
BMI (kg/m2)	34.0 (27.1 – 38.8)
	Frequency (%)
Malignancy type	
Uterine	43 (84)
Cervix	6 (12)
Vulva	2 (4)
Cancer stage	
I	28 (61)
II	7 (15)
III	11 (24)
Chemotherapy	
No	31 (61)
Yes	20 (39)
External Rradiation	
No	45 (88)
Yes	6 (12)
Brachytherapy	
No	6 (12)
Yes	45 (88)
Vulvar/Vaginal	
No	48 (98)
Yes	1 (2)
Relationship status	
Married	24 (49)
Single	11 (22)
Divorced	6 (12)
Widowed	8 (16)
Children at home	
No	39 (80)
Yes	10 (20)
Education	
Some high school	1 (2)
High school graduate	9 (18)
Trade school	2 (4)
Some college	20 (41)
College graduate	11 (22)
Post graduate degree	6 (12)
Income	
< $10,000	2 (4)
$10,001 – 25,000	3 (6)
$25,001 – 40,000	9 (18)
$40,001 – 55,000	9 (18)
$55,001 – 70,000	13 (27)
$70,001 – 85,000	4 (8)
$85,001 – 100,000	4 (8)
> $100,000	5 (10)
Religious	
No	9 (18)
Yes	40 (82)

[a] Missing values may reduce sample size for some variables.

Of the 51 participants, 47 provided information regarding the frequency of VVW use for at least 5 weeks of follow-up. Average VVW use was 4.19 (95% CI: 3.57–4.92) times per week across the 16-week follow-up period. The adherence criteria were met by 31(66%) of 47 women (95% CI: 51.7— 77.8). The most frequently cited barriers were:

1) Being too tired to use the vaginal wand
2) Thinking of the vaginal wand as a sex toy
3) Being reminded of their treatment and cancer
4) Being sick of using the vaginal wand
5) Not being able to use the wand in the shower (Table 2).

No demographic characteristics were found to be significantly associated with frequency of VVW use over the 16-week follow-up period. Though not significant, average usage frequency increased 13% (95% CI: 1-27, p = 0.063) with each additional decade of age.

Associations between VVW use and health-related quality of life dimensions (anxiety, depression, pain, sexual function, fatigue, and physical function) were evaluated. A second set of models was

performed to adjust for age, given the previously noted association between age and VVW use. Without accounting for age, women reporting greater anxiety and pain interference had approximately 25% less overall use (ROM=0.74, p=0.045). However, in models adjusting for age, the association between anxiety and VVW use was diminished (ROM=0.83, p=0.256), while the association between pain interference and VVW was stronger (p=0.030 [unadjusted], p= 0.015 [adjusted]) (Table 3). Sexual interest was not related to VVW usage in the unadjusted model (ROM=1.18, p=0.222), but greater interest was strongly associated with increased use after adjusting for age (ROM=1.45, p=0.006). Weekly usage was 45% greater for women at the 75th percentile of sexual interest as compared to those at the 25th percentile (95% CI: 11–91). No other quality-of-life dimension was associated with VVW use. Other patient-reported barriers included physical discomfort/fatigue, social obligations, having a caregiver role, time/forgetfulness, travel/vacation, treatment days, and personal reasons.

Table 2 Patient-reported barriers to use of vibrating vaginal wands among women with gynecologic cancer

Barrier	Not at all	A little bit	Somewhat	Quite a bit	Very much	Kendall-Wei Rank
I was too tired to use the vibrating vaginal wand.	18 (44%)	12 (29%)	5 (12%)	3 (7%)	3 (7%)	0.39
The vibrating vaginal wand is like a sex toy.	22 (54%)	7 (17%)	4 (10%)	5 (12%)	3 (7%)	0.37
Using the vibrating vaginal wand reminds me of my treatment and cancer.	21 (51%)	12 (29%)	4 (10%)	2 (5%)	2 (5%)	0.32
I was sick of using the vibrating vaginal wand.	21 (52%)	11 (28%)	4 (10%)	-- (--)	4 (10%)	0.32
I am not able to use the vibrating vaginal wand in the shower.	23 (66%)	1 (3%)	2 (6%)	2 (6%)	7 (20%)	0.31
I had vaginal soreness.	28 (68%)	7 (17%)	3 (7%)	2 (5%)	1 (2%)	0.24
Using the vibrating vaginal wand was messy because of the lube.	24 (60%)	11 (28%)	3 (8%)	1 (2%)	1 (2%)	0.23
I was not able to travel with the vibrating vaginal wand.	32 (86%)	-- (--)	2 (5%)	1 (3%)	2 (5%)	0.22
The vibrating vaginal wand is too loud.	35 (90%)	3 (8%)	-- (--)	-- (--)	1 (3%)	0.2
I did not have batteries for the vibrating vaginal wand.	38 (97%)	-- (--)	-- (--)	-- (--)	1 (3%)	0.19
Using the vibrating vaginal wand is a negative psychological experience.	29 (71%)	9 (22%)	1 (2%)	1 (2%)	1 (2%)	0.18
I did not use the vibrating vaginal wand because I was nauseated.	35 (88%)	2 (5%)	2 (5%)	-- (--)	1 (2%)	0.18
I was told not to use the vibrating vaginal wand because I had low blood counts.	39 (98%)	-- (--)	-- (--)	-- (--)	1 (2%)	0.17
I did not have a timer to keep track of how long I was using the vibrating vaginal wand.	38 (93%)	-- (--)	2 (5%)	-- (--)	1 (2%)	0.17
Using the vibrating vaginal wand conflicted with my religious beliefs.	38 (95%)	-- (--)	2 (5%)	-- (--)	-- (--)	0.15
I did not want to have to clean the vibrating vaginal wand.	39 (98%)	1 (2%)	-- (--)	-- (--)	-- (--)	0.15

A Kendall-Wei rank was used because not all participants responded to the questionnaire and to avoid ties among discrete responses.

Table 3 Relative change in mean weekly frequency of vibrating vaginal wand use adjusted for age

Variables (IQR)	Crude association (ignoring age)		Association (adjusted for age)	
	ROM (95% CI)	p-value	ROM (95% CI)	p-value
Depression (39.5-53.9)	0.90 (0.65, 1.23)	0.507	0.90 (0.65, 1.26)	0.544
Anxiety (43.5-57.0)	0.74 (0.55, 0.99)	0.045	0.83 (0.60, 1.15)	0.256
Fatigue (46.5-56.9)	0.90 (0.74, 1.09)	0.272	0.90 (0.74, 1.11)	0.322
Pain Interference (40.7-57.0)	0.73 (0.56, 0.97)	0.03	0.71 (0.54, 0.94)	0.015
Physical Function (27.4-34.1)	0.98 (0.84, 1.16)	0.842	0.99 (0.85, 1.17)	0.914
Sexual Interest (33.4-45.3)	1.18 (0.90, 1.56)	0.222	1.45 (1.11, 1.91)	0.006

Ratio of means (ROM) is the relative change in mean weekly frequency of use over one IQR from the 25th to the 75th percentile of the indicated PROMIS T-score. ROMs are shown without covarying for age (unadjusted) and also after covarying for age (adjusted).

Discussion

Vaginal dilator therapy is an important component of survivorship care for women with gynecologic cancers undergoing pelvic radiotherapy. Providers caring for women with gynecologic cancers are increasingly recommending the use of VVW; however, there are few data regarding adherence to therapy or barriers to use for this type of vaginal dilator.

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Previous studies report variable adherence rates to vaginal dilator use, typically less than 50%. Hanlon et al, in a study of 42 women with endometrial cancer, reported that 64% of women were adherent to vaginal dilator use at least once per week at 6 weeks, but only 16% were adherent to use at 6 months.[10] Our study demonstrates a generally higher adherence rate (66%) than previous studies over a four month period. One of the most cited barriers to use in our study was being tired of using the wand. It is unclear whether adherence rates would remain stable if the duration of the study was increased, given this cited barriers. This is an important limitation of this study, as prevention of vaginal agglutination and stenosis is a long-term issue that requires consistent dilator use. Future studies should seek to evaluate longer duration of use in this population.

Not surprisingly, women who reported more barriers to VVW used it less frequently. Preemptively discussing common barriers at initiation of VVW therapy and during routine follow-up may provide an opportunity to improve use. Sooner follow-up with providers shortly after initiating VVW could create opportunities to troubleshoot barriers for patients sooner after initiation of therapy to increase adherence over time. In our study, follow-up was three to five weeks after enrollment. Follow-up in the first month following initiation of VVW may be an ideal timeframe. Telehealth or patient navigation support could be utilized to follow patients more closely to identify and remedy barriers to prevent patient discontinuation of dilator therapy.

Fatigue was the most significant cited barrier. Therapy-related fatigue typically decreases over months following completion of therapy, though initiation of dilator therapy occurs immediately following treatment to prevent vaginal stenosis and agglutination. This study highlights fatigue as an important cancer-treatment-related symptom that can impact not only adherence to VVW but also overall quality of life. Additional counseling and cancer fatigue-related support may be warranted at specific time points to improve continued use, particularly in the time period immediately following treatment. Partnering with other local cancer-survivorship resources, such as integrative health programs, may be helpful in this situation.

Aversion to VVW therapy due to the similarities of the VVW with a sex toy was an elicited barrier. Normalization of dilator therapy in this clinical context is an important aspect of preemptive counseling. Based on our data, directly addressing and normalizing this barrier may be an important aspect of counseling. A stronger emphasis on the clinical need for adequate surveillance exams rather than on impacts to sexual health may be helpful in this scenario. For patients expressing this barrier at initiation or during follow-up, use of a static dilator could be offered as an alternative if it is perceived as more of a therapeutic device than the VVW.

Women experiencing pain interfering with daily activities were less likely to regularly use the VVW. Pain is a known side effect of cancer treatment that can be multifactorial and rooted in biopsychosocial factors. It is unclear based on our data how this directly impacts adherence to VVW, though pain with sexual activity is a widely known issue facing cancer survivors and could be another confounding issue. Providers need to elicit a wide review of systems and barriers in follow-up to best troubleshoot barriers to use.

Women who reported a higher level of sexual interest were more likely to adhere to VVW therapy, likely due to greater motivation to maintain sexual function. For women with lower sexual interest, an emphasis regarding the importance of vaginal patency to facilitate and increase comfort of surveillance exams may improve adherence.

To our knowledge, this is the first study to identify barriers to VVW therapy among women with gynecologic cancer. Identification of barriers aids providers with specific areas to focus counseling efforts regarding dilator therapy. Many barriers identified in our study may be improved with more extensive pre-emptive counseling and sooner follow-up to review and support ongoing use. Future interventional studies are needed to evaluate the impact of patient education, counseling, and/or lifestyle modifications on vaginal wand compliance.

There are several limitations to this study. This is a relatively small single-institution cohort, the majority of whom were patients with early-stage endometrial cancer who underwent vaginal brachytherapy alone. Because of this, our data may not be as applicable to other gynecologic cancers or those undergoing pelvic radiation. Those undergoing more extensive radiation therapy and/or chemotherapy may have different or greater barriers based on increased toxicity that were not fully addressed by this study. Participation in this study was voluntary, and those enrolled may have been more motivated for this reason. This is a possible explanation of our higher adherence rate compared to prior studies. We also used patient self-reported adherence, which could have falsely increased reported use. Among those not completing all questionnaires, non-response bias is possible.

Most women with gynecologic cancers undergoing pelvic radiotherapy are adherent to VVW therapy but have identifiable barriers to use. Knowing barriers allows providers to better target their counseling efforts to promote continued use, giving women the best chance at maintaining vaginal and sexual health following treatment for gynecologic cancers.

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Author contributions

Janelle N. Sobecki: Resources, Methodology, Writing – Original Draft, Review & Editing, **Mary J. Kao:** Conceptualization, Methodology, Data Curation, Writing – Review & Editing, Project administration, **Grace Blitzer:** Writing – Original Draft, Review & Editing, **Margaret Straub:** Conceptualization, Methodology, Investigation, Resources, Writing – Review & Editing. **Kristin A. Bradley:** Conceptualization, Methodology, Investigation, Resources, Writing – Review & Editing. **Erin S. Costanzo:** Conceptualization, Methodology, Resources, Writing – Review & Editing. **Michael R. Lasarev:** Formal analysis, Resources, Data Curation, Writing – Review & Editing. **Joanne Rash:** Conceptualization, Methodology, Writing – Review & Editing. **David M. Kushner:** Conceptualization, Methodology, Writing – Review & Editing, Supervision.

Availability of data and material (data transparency)

Research data are stored in an institutional repository and will be shared upon request to the corresponding author.

Disclosure

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Conflicts of interest

Kristin Bradley receives royalties from Up-to-date as an author on radiation therapy for gynecologic cancers. The remainder of the authors have no conflicts of interest.

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