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Prospective study of vaginal dilator use adherence and efficacy following radiotherapy

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Abstract

Background and purpose—Vaginal stenosis (VS) after pelvic radiotherapy can impair long-term quality of life. We prospectively assessed adherence and efficacy of VD use as the primary and secondary objectives, respectively.

Material and methods—Women with gastrointestinal (n=63) and gynecologic (n=46) cancers self-reported use and VD size in monthly diaries for 12 months after radiotherapy. Adherence was measured as actual VD use out of recommended times over 12 months (3×/week × 52 weeks = 156).

Results—Among 109 participants, aged 28–81 years (median, 58 years), mean percent adherence over 12 months was 42% (95% confidence interval [CI], 36%–48%). Adherence was highest in the first quarter (56%), but fell to 25% by the fourth. Disease type, treatment sequence, and chemotherapy were predictors of adherence (all $P<.05$). Eighty-two percent maintained pre-RT VD size at 12 months; of 49% with decrease in VD size at 1 month post-RT, 71% returned to pre-RT VD size at 12 months. Disease type, younger age, and increased adherence at 6 months were associated with maintaining or returning to pre-RT size at 12 months (all $P\leq.05$).

Conclusions—VD use is effective in minimizing VS, but adherence at 12 months was poor. Studies evaluating methods of improving adherence and determining the optimal frequency and duration of use are needed.

Keywords

Pelvic radiotherapy; Sexual function; Late effects; Gastrointestinal cancers; Vaginal dilator

Pelvic radiotherapy (RT) plays an integral role in managing gynecologic and pelvic gastrointestinal (GI) malignancies. This has been shown to reduce local recurrence, but can lead to long-term side effects, particularly vaginal stenosis (VS), shortening and narrowing of the vagina. Prevalence of radiation-induced VS after pelvic RT for gynecologic

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Conflict of Interest Statement

The authors have no potential conflicts of interest.

malignancies varies widely [1–3]. However, impact of VS has been well documented, with increased rates of dyspareunia, leading to diminished frequency of, and satisfaction with, sexual intercourse [4, 5] and pain on vaginal examination, potentially impairing thorough and adequate pelvic assessment [3].

In a previous study [6] examining sexual intercourse compared with vaginal dilator (VDs) in minimizing VS, 57% of women relying on sexual intercourse alone developed VS versus 11% for VDs. Based on these data, the best practice guidelines from the National Forum of Gynecological Oncology Nurses in 2005 recommended patients use the dilator three times per week for 10 minutes. This regimen is to continue for the duration of the patients' lives after pelvic radiation to decrease adhesions and minimize stenosis, regardless of sexual activity [7].

Studies have found low adherence with VD use [8–10], but were limited to endometrial and cervical cancers, and sample sizes were small, limiting generalizability. There are limited data confirming the efficacy of VD use in minimizing VS, or in establishing timing, frequency, and duration for gynecologic and GI malignancies. To collect evidence to establish best practices, we prospectively investigated adherence to use of a VD to determine effectiveness in minimizing VS after pelvic RT during a 12-month trial.

Patients and methods

This study was approved by the Memorial Sloan Kettering Cancer Center Institutional Review Board in November 2008.

Eligibility

Women ≥21 years, with histologically confirmed, nonmetastatic cervical, endometrial, rectal, or anal cancer treated with definitive or adjuvant pre- or postoperative external beam pelvic radiation or brachytherapy were eligible. Exclusion criteria included prior pelvic radiation and prior mental or physical handicap.

Patient recruitment

Eligible patients were identified and approached in radiation oncology clinics at the Memorial Sloan Kettering Cancer Center Manhattan campus and its four regional sites in New York and New Jersey. Between January 2009 and June 2012, 116 patients were recruited. All study participants gave written informed consent.

Study Intervention

Before starting radiation, participants were provided with dilator kits, containing 4 dilator tubes of increasing sizes and lubricating jelly. After the nurse demonstrated the equipment and supplies and reviewed the content of a uniform patient-education fact card, each patient was instructed to use the VD 3 times/week, regardless of sexual intercourse frequency. Patients were taught how to determine their baseline VD size, specifically the largest dilator that could be tolerably inserted and kept in place for 10 minutes without vaginal pain, tightness, and/or bleeding.

The start date for VD use was determined by participants' RT treatment sequence:

- Preoperative RT patients (rectal): 12–14 weeks post-RT (6–8 weeks after pelvic surgery)
- Postoperative RT patients (cervical and endometrial) and those undergoing RT alone (anal): 4–6 weeks post- RT.

When initiating VD use, patients received additional instruction on when and how to increase the size of the VD for optimal benefit. Patients were also given a diary to record the date of each dilator use and the size of the dilator.

Data collection

During enrollment, patients completed a demographic questionnaire, including age, medical history, sexual history, and lifestyle factors. Patients are initially instructed in VD use prior to RT treatment to determine their VD size and record their baseline measurements in their diaries. One month (median, 31 days) after RT, patients again use the VD to determine a post-treatment baseline. During regular use, patients recorded dilator size (i.e., size 1–4) for each date of use in their weekly diary. The study team made scripted monthly phone calls to remind each participant to mail in their diaries. This was further facilitated by providing MSKCC stamped envelopes at the end of each month. In addition, the study primary investigator called participants at 3, 6, and 12 months to collect current VD size. Study duration was 12 months (Supplemental Fig. 1). The study was designed to determine the level of self-adherence of patients to VD use based on the weekly diary entries.

Study outcome/end points

Dilator Adherence—Patients' adherence to weekly VD regimen was measured by 1) summarizing the number of times the VD was used per week based on the weekly diaries, 2) calculating overall percent adherence from the number of 156 possible times each patient used the VD during the 52 weeks on study (3×/week × 52 weeks = 156), and 3) calculating percent adherence from the number of times each patient used the VD each quarter (3×/week × 13 weeks = 39). Adherence was calculated for all patients eligible for the study. If a patient withdrew early from the study due to non-adherence or other non-medical reasons, the patient was assumed to have not used the dilator after withdrawal and the full denominator of 156 was used to calculate overall percent adherence. However, if a patient did not finish the study due to advanced disease, death, or medical reasons to discontinue VD use, the denominator for percent adherence was reduced to the total number of times the patient could have used the dilator while on the study (<156 times).

Vaginal Dilator Efficacy—The efficacy of VD use was defined as ability to maintain or return to pre-RT baseline size with the dilator in place for a full 10 minutes; this was evaluated in patients completing the 3-, 6-, and 12-month assessments. We also examined ability to return to pre-RT baseline VD size in patients with decreased dilator size at 1 month post-RT.

Data analysis

Group comparisons were evaluated using Fisher's exact test for categorical variables and the Wilcoxon rank sum test or Kruskal-Wallis test for continuous variables. $P<.05$ was considered statistically significant. Computations were performed using SAS version 9.2 (SAS Institute, Cary, NC).

Results

Study sample

116 patients were enrolled; 7 were ineligible and removed due to distant metastases or medical condition incompatible with VD use. Data analysis was thus performed on 109 participants (Supplemental Fig. 2). There was only 1 cervical cancer patient. This patient was included in all analyses, except those examining the effect of disease diagnosis.

Patient characteristics

Table 1 describes patient characteristics. Median age was 58 years (range, 28–81 years); endometrial cancer patients were older (median age, 60 years) than rectal (54 years) or anal (55 years) cancer patients and had more comorbidities, in particular hypertension. History of tobacco use was more common in anal cancer patients. Rectal and anal cancer patients reported more sexual activity at baseline than endometrial cancer patients (64%, 69%, and 41%, respectively; $P=.03$). Most endometrial patients (84%) were post-menopausal compared with rectal (57%) and anal (71%). All endometrial patients had total hysterectomy pre-radiation.

Cancer treatment modality

Forty-six patients had gynecologic cancers. The 45 endometrial cancer patients were treated with total abdominal hysterectomy and bilateral salpingo-oophorectomy, followed by adjuvant RT [11]. Of these, 7 received external beam RT (EBRT) alone (median dose, 50.4 Gy) and 38 intravaginal RT (median dose, 21 Gy; range, 18–25 Gy, in 3–5 fractions), 2 of whom also received EBRT to 45 Gy. The target volume treated was one-half to two-thirds the vagina length. Treatment was delivered using a cylinder connected to an after-loading HDR ^{192}Ir source. Cylinder diameter ranged from 2 to 3 cm (median, 3 cm). The dose was prescribed to a depth of 0.5 cm from the vaginal surface. The 1 cervical cancer patient was treated with EBRT alone to 50.4 Gy.

Anal cancer patients (n = 35) were treated with concurrent chemotherapy (5-fluorouracil and mitomycin C) and EBRT in 5–6 weeks with intensity-modulated radiation therapy to a total of 50–56 Gy (median dose, 56Gy) using a 1.8–2 Gy daily fraction) [12]. Rectal cancer patients (n = 28) were treated with concurrent 5-fluorouracil-based chemotherapy and EBRT for 5–6 weeks pre- or postoperatively with either a 3-field plan or intensity-modulated radiation to a median dose of 50Gy using a 1.8–2 Gy daily fraction; patients also received postoperative chemotherapy [13].

Table 2 displays treatment modality, total radiation dose, and vaginal dose. Median vaginal maximum dose and mean vaginal dose were significantly higher for anal cancer patients than rectal or endometrial cancer EBRT patients.

Adherence to VD use

Percent adherence was calculated for all patients, regardless of whether they finished the study; however, we adjusted the total number of times the dilator could be used for five patients to account for these patients not finishing the study (due to advanced disease, death, or medical reasons to discontinue VD use). Weekly adherence rates using VD for 3×/week versus 1x/week were compared across groups (Fig. 1). At 4 weeks after initiation of use, the adherence rate for 3×/week was 45% (49/108), declining to 20% (21/106) at 35 weeks and 5% (5/104) at 52 weeks. Adherence to VD only once/week was 69% (74/108) at 4 weeks after initiation, 34% (35/104) by 48 weeks, and 12% (12/104) at 52 weeks.

Mean percent adherence across all groups over the 1-year period was 42% (95% CI, 36%–48%). Mean percent adherence was also examined quarterly, and declined across all groups from 56% in the first quarter (95% CI, 49%–63%) to 46% in the second quarter (95% Cl, 39%–53%), 41% in the third quarter (95% CI, 34%–49%), and 25% in the fourth quarter (95% CI, 20%–31%).

Adherence was lowest among patients with rectal cancer, pre-op RT, and those receiving chemotherapy (all $P<.05$; Table 3).

Effectiveness of VD use

Effectiveness of VD use was measured by maintaining or returning to pre-RT dilator size and was calculated in patients who provided measurements. Effectiveness for all groups at 6 and 12 months after VD start was 73% (66/90) and 82% (66/81), respectively (Fig. 2). At 1 month post-RT, 51 of 105 patients (49%) had a decrease in VD size from pre-RT; of these, 52% (24/46) reported return to baseline by 6 months and 71% (29/41) by 12 months after VD start. Of those who had a decrease in VD size at 1 month post-RT, 22% (2/9) and 63% (5/8) were able to return to pre-RT size at 6 and 12 months, respectively, in the rectal cancer group; 54% (14/26) and 68% (15/22), respectively, in the anal cancer group; and 73% (8/11) and 82% (9/11), respectively, in the endometrial group (Supplemental Table 1).

There was a strong association between adherence to VD use by 6 and 12 months and maintaining or returning to pre-RT size at 12 months. Mean percent adherence by both 6 months (68% vs. 45%, respectively, $P=.03$) and 12 months (57% vs. 39%, respectively, $P=.05$) was higher in patients who maintained or returned to pre-RT dilator size at 12 months compared with those who did not. Baseline characteristics associated with maintaining or returning to pre-RT dilator size at 12 months include disease group (endometrial cancer; $P=.05$) and younger age ($P=.05$) (Table 4).

Study attrition and nonadherence

Of the 109 participants, 24% (n = 26) requested to withdraw over the course of 12 months due to (a) nonadherence with VD use (n = 10); (b) progression of disease (n = 3); (c)

personal reasons (n = 8); and (d) treatment-related side effects (n = 5). The most common reasons for nonadherence were lack of understanding of VD utility (not enough time, not in the mood, sexually active or inactive, vacation); vaginal symptoms associated with VD use (primarily bleeding and discomfort), and medical reasons (postchemotherapy fatigue, rehospitalization, and urinary tract infection).

Discussion

Vaginal stenosis is a significant long-term effect of pelvic RT in patients with gynecologic and GI cancers. Our prospective study of VD use suggests that adherence results in maintaining or returning to baseline VD size in 82% overall. In those who had a decrease in VD at 1 month post-RT, 71% returned to baseline (endometrial, 82%; anal, 68%; rectal, 63%).

This is the first prospective study to report on the incidence of VS in women treated for GI malignancies. However, in women with gynecologic malignancies, prevalence has been reported from 1.6% to 88% [1–3, 14–17]. Factors accounting for the wide variation may include RT techniques, treatment planning differences, sequence and combination of modalities, over- or underreporting, and lack of valid measurement tools [1, 4, 15, 16, 18–20]. Onset of VS was evident as early as 1 month post-RT in 77%, 42%, and 30% of anal, rectal, and endometrial patients, respectively, in this sample. Our findings were consistent with studies showing that VS develops early, even during the course of intracavitary RT and within 1 month after EBRT in cervical and endometrial cancers [20, 21]. Development of VS has also been attributed to the cumulative effect of radiation, which produces adhesions and circumferential fibrosis in vaginal epithelium. This could significantly diminish blood flow to the vaginal tissues, causing loss of elasticity and sensation [5, 21, 22]. Our study demonstrated adherence to VD use at 6 months was important for recovery to pre-RT vaginal size; thus, early intervention may reduce long-term consequences.

To date, no studies have prospectively evaluated adherence with VD use in women with GI cancers. Unfortunately, mean percent adherence for dilator use 3×/week for the 12 months on study was only 42%. The subgroup of patients with rectal cancer and those undergoing pre-operative RT had the lowest adherence to VD use, likely due the subsequent surgical resection, either a low anterior resection or abdominal perineal resection with construction of permanent colostomy. In addition, patients receiving chemotherapy were less adherent with VD use, likely related to the on-going symptoms from their therapy that may prevent patients from focusing on long-term preventative measures.

Some studies [4, 8] report adherence rates of only 6% at 12 months for endometrial or cervical cancers. A recent study of gynecologic cancer patients who received an educational intervention reported adherence to 2–3×/week VD use of 35% at 12 months, using patient recall [3]. Our findings are based on real-time documentation at time of VD use. Measurement of adherence over a certain timespan may better represent overall adherence since there were various reported practices for VD use.

In our study age was less of a factor than in previous studies, which found higher adherence in older women [3, 8, 23]. We found that the main predictors of low adherence were disease type, treatment sequence, and chemotherapy. Patients with rectal cancer who needed postoperative chemotherapy were less likely to adhere, most likely due to treatment-related side effects, such as bowel dysfunction, fatigue, and neutropenia related to surgery and adjuvant chemotherapy. Their longer treatment course [24] with more acute side effects may have lessened the priority of long-term health maintenance.

Adherence is a complex phenomenon, and ensuring regular VD use may require more than education. Additional psychoeducational interventions to ameliorate fears about sexuality following RT led to better adherence than basic instruction alone in one study (44% versus 5.6%, respectively) [8]. However, there is a lack of evidence on the optimal timing, frequency, and duration of VD use.

Duration of VD use is a significant question. At 12 months, 82% of patients maintained their pre-RT size, with persistent VS in 18%. Previous studies indicated that VS was present 2 years post-RT, with decreased vaginal length >1–2 cm in endometrial cancer patients [25] without VD use. We believe that the positive effects from VD use to minimize VS should be available to patients for as long as necessary, especially beyond 1 year.

Our results highlight the need for methods to improve adherence. Recent studies offer some ideas: women tend to be more motivated to use VDs if they believe pelvic exams will be more comfortable [10].

Limitations

Our 24% attrition rate at 12 months fell within the 16%–45% range of similar prospective studies [3, 4, 9]. To maintain data integrity and avoid overestimating adherence, all patients were included in the calculation of adherence rates.

Although psychological barriers to VD use exist, we studied only physical factors. We did not explore positive influences, or “facilitators,” to adherence. One qualitative study of 15 participants [26] originally identified barriers and facilitators of VD use. The lack of standardized VS measures and methods of addressing VS makes it difficult to correlate results from different studies. In addition, due to the different disease types included in the study, there was not a uniform start time for VD use. Also complicating the assessment is the inability to obtain consistent vaginal length and caliber due to patients’ varying ages and physical characteristics, which alter the anatomic structure of vaginal tissues [27]. Shortening of the apex and decreased caliber can contribute to the inability to insert the dilator beyond the distal vagina. Further, we realize that without randomizing participants to 2x/week, 1x/week, and <1x/week, differing thresholds for pain tolerance, variations in vaginal symptoms, and effectiveness with varying frequent use of VD would not be accounted for. Thus, we obtained the pre-RT VD sizes, allowing us to compare and measure effectiveness post-RT. We consider our pre-RT measurement effort to be a strength of the study, and we believe the use of self-report to be the best method of collecting data without standardized measurement instruments. Our study was not designed to attempt to impute

effectiveness of VD use but to assess patients' pattern of adherence and secondarily to evaluate the effectiveness of VD use.

The study was designed to include patients who were either sexually active or not There were not any preconceived expectations or attempts to predict outcomes, only to learn whether patients adhered to VD use. The inconsistent sexual activity of our patients made it impossible to ascertain whether sexual activity was a determining factor.

Future implications

A goal for future studies is to improve the patient self-reporting tools. Informal conversations with patients indicated that over- and under-recording resulted from the desire to avoid embarrassment or fear of rejection from her caregiver. Future studies should examine whether sexual activity is a predictor of adherence of VD use. Finally, randomized controlled trials in a homogeneous patient population are needed to determine if timing and frequency of VD use affect efficacy.

Conclusions

Our study reported on the adherence and effectiveness of VD use in reducing the effects of VS for patients receiving pelvic radiation for anal and rectal cancers not previously studied prospectively, and included gynecologic cancers. We demonstrated benefit of VD adherence, specifically by minimizing VS following pelvic RT. These results will serve as a significant foundation for future studies determining the optimal frequency and duration of VD use and for improving quality of life post-RT.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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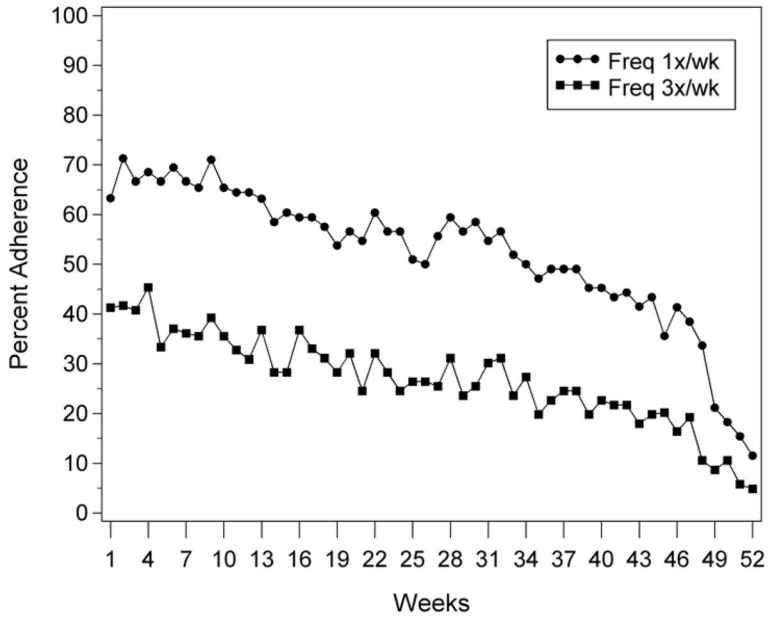

Fig. 1.
Adherence of vaginal dilator at 3×/week versus 1×/week in all groups.

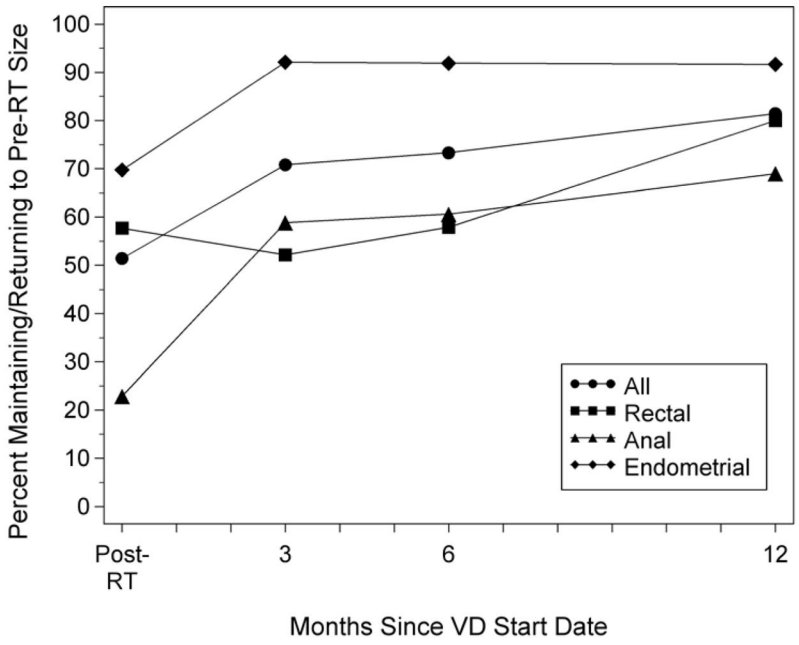

Fig. 2.
Effectiveness of vaginal dilator use.

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Table 1

Patient Characteristics

Variable	Category	Total (n = 109)	Rectal (n = 28)	Anal (n = 35)	Endometrial (n = 45)	*P*
Age	Median (range)	58 (28–81)	54 (28–78)	55 (44–77)	60 (44–81)	0.06
Race	White	82 (75%)	18 (64%)	26 (74%)	37 (82%)	0.14
	Asian	9 (8%)	5 (18%)	1 (3%)	3 (7%)	
	Black/African- American	7 (6%)	1 (4%)	2 (6%)	4 (9%)	
	Hispanic	7 (6%)	2 (7%)	4 (11%)	1 (2%)	
	Other	4 (4%)	2 (7%)	2 (6%)	0	
Education level	Post-graduate degree	33 (31%)	5 (18%)	13 (37%)	15 (34%)	0.25
	College degree	33 (31%)	13 (46%)	11 (31%)	9 (21%)	
	Some college	21 (19%)	6 (21%)	4 (11%)	11 (25%)	
	High school or less	21 (19%)	4 (14%)	7 (20%)	9 (21%)	
	Missing	1	0	0	1	
Marital status	Married	75 (69%)	22 (79%)	25 (71%)	27 (60%)	0.06
	Divorced	13 (12%)	2 (7%)	5 (14%)	6 (13%)	
	Single	9 (8%)	1 (4%)	5 (14%)	3 (7%)	
	Widowed	12 (11%)	3 (11%)	0	9 (20%)	
Gravida	No children	19 (17%)	3 (11%)	7 (20%)	9 (20%)	0.59
	Children	90 (83%)	25 (89%)	28 (80%)	36 (80%)	
Menopausal status at diagnosis	Pre-menopausal	18 (17%)	8 (29%)	5 (14%)	5 (11%)	0.10
	Post-menopausal	80 (73%)	16 (57%)	25 (71%)	38 (84%)	
	Peri-menopausal	11 (10%)	4 (14%)	5 (14%)	2 (4%)	
Using topical estrogen	No	105 (96%)	28 (100%)	32 (91%)	44 (98%)	0.22
	Yes	4 (4%)	0	3 (9%)	1 (2%)	
Sexually active (baseline)	No	48 (44%)	10 (36%)	11 (31%)	26 (59%)	0.03
	Yes	60 (56%)	18 (64%)	24 (69%)	18 (41%)	
	Missing	1	0	0	1	
Smoking History	No	59 (54%)	20 (71%)	14 (40%)	25 (56%)	0.05
Comorbidities	Yes	50 (46%)	8 (29%)	21 (60%)	20 (44%)	
	0	77 (71%)	23 (82%)	29 (83%)	24 (53%)	0.03

Variable	Category	Total (n = 109)	Rectal (n = 28)	Anal (n = 35)	Endometrial (n = 45)	*P*
	1	24 (22%)	4 (14%)	5 (14%)	15 (33%)	
	2+	8 (7%)	1 (3%)	1 (3%)	6 (13%)	
Diabetes	No	98 (90%)	25 (89%)	34 (97%)	38 (84%)	0.17
	Yes	11 (10%)	3 (11%)	1 (3%)	7 (16%)	
Hypertension	No	81 (74%)	25 (89%)	29 (83%)	26 (58%)	0.005
	Yes	28 (26%)	3 (11%)	6 (17%)	19 (42%)	
Vascular Insufficiency	No	107 (98%)	28 (100%)	35 (100%)	43 (96%)	0.51
	Yes	2 (2%)	0	0	2 (4%)	

Table 2

Treatment Modality and Radiation Doses

Variable	Category	Total (n = 109)	Rectal (n = 28)	Anal (n = 35)	Endometrial (n = 45)
Surgery	No	32 (29%)	4 (14%)	28 (80%)	0
	Yes	77 (71%)	24 (86%)	7 (20%)	45 (100%)
Radiation	Preoperative RT	28 (26%)	25 (89%)	3 (9%)	0
	Postoperative RT	51 (47%)	2 (7%)	4 (11%)	45 (100%)
	RT with no surgery	30 (28%)	1 (4%)	28 (80%)	0
RT modality	EBRT	71 (65%)	28 (100%)	35 (100%)	7 (16%)
	Intravaginal	38 (35%)	0	0	38 (84%)
Mean EBRT dose	Median (range)	5000	5000	5400	5040 (4320–5040)
Mean IVRT dose	Mean IVRT dose				2100 (1800–2500)
Chemotherapy	No	32 (29%)	0	0	32 (71%)
	Yes	77 (71%)	28 (100%)	35 (100%)	13 (29%)

Abbreviations: EBRT, external beam radiotherapy; IVRT, intravaginal radiotherapy; RT, radiotherapy.

Table 3

Factors Associated with Mean Percent Adherence

Variable	Category	N	Mean (std)	*P* value
Disease group	Rectal	28	0.24 (0.30)	.002
	Anal	35	0.51 (0.28)	
	Endometrial	45	0.47 (0.34)	
Age	<65	78	0.44 (0.33)	.34
	≥65	31	0.37 (0.33)	
Race	Non-white	27	0.42 (0.27)	.84
	White	82	0.42 (0.35)	
Education	College degree or higher	66	0.47 (0.32)	.10
	Less than college degree	42	0.36 (0.33)	
Marital status	Married	75	0.43 (0.33)	.77
	Other	34	0.4 (0.33)	
Menopausal	Post	80	0.43 (0.33)	.82
	Pre	29	0.4 (0.31)	
Sexually active (baseline)	No	48	0.41 (0.33)	.75
	Yes	60	0.43 (0.33)	
Smoking history	No	59	0.42 (0.34)	.95
	Yes	50	0.42 (0.31)	
Comorbidities	No	77	0.4 (0.33)	.32
	Yes	32	0.46 (0.32)	
Radiation	Preop	28	0.26 (0.29)	.004
	Postop	51	0.45 (0.34)	
	RT with no surgery	30	0.53 (0.29)	
RT modality	EBRT	71	0.39 (0.33)	.14
	Intravaginal	38	0.48 (0.32)	
Chemotherapy	No	32	0.52 (0.33)	.04
	Yes	77	0.38 (0.32)	

Abbreviations: EBRT, external beam radiotherapy; RT, radiotherapy.

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Table 4

Factors Associated with Effectiveness by 12 Months

Variable	Category	12 month denominator	Do not maintain or return to pre-RT size at 12 months	Maintain or return to pre-RT size at 12 months	*P* value
Disease group	1 Rectal	15	3 (20%)	12 (80%)	0.05
	2 Anal	29	9 (31%)	20 (69%)	
	3 Endometrial	36	3 (8%)	33 (92%)	
Age	<65	60	8 (13%)	52 (87%)	0.05
	≥65	21	7 (33%)	14 (67%)	
Race	Non-white	21	5 (24%)	16 (76%)	0.52
	White	60	10 (17%)	50 (83%)	
Education	Less than college degree	31	9 (29%)	22 (71%)	0.08
	College degree or higher	50	6 (12%)	44 (88%)	
Marital status	Married	56	7 (13%)	49 (88%)	0.06
	Other	25	8 (32%)	17 (68%)	
Menopausal	Pre	21	2 (10%)	19 (90%)	0.33
	Post	60	13 (22%)	47 (78%)	
Topical estrogen	No	79	15 (19%)	64 (81%)	1.0
	Yes	2	0	2 (100%)	
Sexually active (baseline)	No	34	8 (24%)	26 (76%)	0.39
	Yes	47	7 (15%)	40 (85%)	
Smoking history	No	41	7 (17%)	34 (83%)	0.78
	Yes	40	8 (20%)	32 (80%)	
Comorbidities	No	55	11 (20%)	44 (80%)	0.76
	Yes	26	4 (15%)	22 (85%)	
Radiation	Pre-operative	15	3 (20%)	12 (80%)	0.28
	Post-operative	41	5 (12%)	36 (88%)	
	RT with no surgery	25	7 (28%)	18 (72%)	
RT modality	EBRT	49	12 (24%)	37 (76%)	0.14
	Intravaginal	32	3 (9%)	29 (91%)	
No Chemotherapy	No	54	14 (26%)	40 (74%)	0.02
	Yes	27	1 (4%)	26 (96%)	

Variable	Category	12 month denominator	Do not maintain or return to pre-RT size at 12 months	Maintain or return to pre-RT size at 12 months	*P* value
Vaginal moisturizer (3 months)	No	62	13 (21%)	49 (79%)	0.50
	Yes	19	2 (11%)	17 (89%)	
Vaginal moisturizer (6 months)	No	60	15 (25%)	45 (75%)	0.009
	Yes	21	0	21 (100%)	
Vaginal moisturizer (12 months)	No	58	12 (21%)	46 (79%)	0.54
	Yes	23	3 (13%)	20 (87%)	
Compliance rate by 6 months	Mean (std)	-	45% (34%)	68% (28%)	0.03
Compliance rate by 12 months	Mean (std)	-	39% (31%)	57% (27%)	0.05

Abbreviations: EBRT, external beam radiotherapy; RT, radiotherapy.