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Sexual Function After Intracavitary Vaginal Brachytherapy for Early-Stage Endometrial Carcinoma

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Abstract

Objective—To describe the effects of intracavitary brachytherapy (IVB) on sexual function and quality of life of women with early-stage endometrial cancer.

Methods—Women with International Federation of Gynecology and Obstetrics stage I to stage II endometrial cancer treated surgically with or without IVB were identified and mailed questionnaires. Quality of life and sexual function were measured using the European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Core 30 and the cervical cancer disease-specific module. Pertinent data from prior surgery and radiation treatments were abstracted retrospectively. Linear transformation of the survey subscale scores was conducted per European Organization for Research and Treatment of Cancer guidelines.

Results—Sixteen women in the IVB arm and 53 in the surgery-alone group completed the survey. Of the sexually active patients, 33% of the IVB patients and 42% of the surgery-alone patients felt their vagina was dry during sexual activity ($P = 0.804$) and 17% versus 20% felt their vagina was short ($P = 0.884$). Seventeen percent of patients in the IVB group felt their vagina was tight compared to 29% in the surgery-alone group ($P = 0.891$) and 0% versus 14% of patients reported pain during intercourse ($P = 0.808$). There was no statistically significant difference in sexual/vaginal functioning, sexual worry, or sexual enjoyment between the 2 groups.

Conclusions—Although both groups report vaginal changes that may affect sexual function, the patients treated with IVB reported similar outcomes on a sexual function questionnaire compared to patients treated with surgery alone.

Keywords

Sexual function; Endometrial cancer; Intracavitary brachytherapy; Quality of life

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Endometrial cancer is the fourth most common malignancy in women and the most common gynecologic malignancy. Approximately 40,000 new cases will be diagnosed each year. The standard of care for most women with endometrial cancer is surgical resection.¹ After surgery, external beam radiation to the pelvis with or without intracavitary vaginal brachytherapy (IVB) is typically used for patients with certain risk factors based on age, stage, depth of invasion, and tumor grade.² Three phase 3 randomized trials have shown improved local regional control but no overall survival benefit with postoperative external beam radiation for patients with intermediate-risk endometrial cancer.^{3–5} Despite these trials, postoperative treatment remains controversial and diverse among institutions.¹

Most women with endometrial cancer will be diagnosed with FIGO stage I disease. The overall prognosis is excellent and approximates 80% to 90% after definitive therapy.⁴ Because these women have long overall and disease-free survival, many will have long-term toxicities from treatment that affect their overall quality of life (QOL). Previous studies have found that radiation therapy for gynecologic malignancies results in sexual dysfunction owing to multiple physical and psychological factors.^{6–11} Most studies have been conducted in patients with cervical cancer or in patients who have received pelvic external beam radiation. To our knowledge, no studies have evaluated the effects of IVB without external beam radiation for patients with endometrial cancer.

MATERIALS AND METHODS

After obtaining Institutional Review Board approval, we recruited women who underwent surgical treatment for the management of endometrial cancer at the James Cancer Hospital at the Ohio State University Medical Center from January 2002 to December 2007. Eligibility criteria included patients aged 20 to 75 years with International Federation of Gynecology and Obstetrics (FIGO) stage I to stage II endometrial adenocarcinoma, adenosquamous carcinoma, papillary serous carcinoma, and clear cell carcinoma treated with surgery or surgery and intracavitary vaginal brachytherapy (IVB). White, African American, Hispanic, and Asian/Pacific Islander ethnicities were included. Patients were excluded if they received external beam radiation, had been diagnosed with persistent or recurrent disease before study enrollment, or had severe mental or physical handicap.

A total of 595 patients with early-stage endometrial cancer were identified from the hospital cancer registry. Of 76 patients who received surgery and IVB, 43 patients (57%) met the study inclusion criteria. Because of a significantly higher portion of patients treated with surgery alone, 3 patients treated with surgery alone were recruited for every one surgery and IVB patient. Patients were matched by age in 5-year intervals and by the year of diagnosis (2002–2004 and 2005–2007). One hundred-fifteen of 129 patients identified in the latter group were eligible for study enrollment.

From January 2009 to September 2009, a cross-sectional study was conducted by mailing a questionnaire to eligible patients (Supplemental Digital Content 1, <http://links.lww.com/IGC/A84>). Informed consent was implied by the completion of the survey. If patients did not return the questionnaire within 4 weeks, a second questionnaire was sent and the patients were contacted by phone by an investigator to encourage submission. The patients were also given the option of completing the survey over the phone. After return of the survey, data were retrospectively obtained from their previous treatment records, including age at the time of treatment, ethnicity, treatment dates, type of surgery and status of lymph node dissection, surgical stage, tumor histology and grade, use of chemotherapy, disease status, and radiation parameters including dose, number of fractions, and dose per fraction.

The purpose of the mailed questionnaire was to assess the sexual function and vaginal problems of women who were treated with surgery with or without IVB for early-stage endometrial cancer using the European Organization for Research and Treatment of Cancer (EORTC) cervical cancer disease-specific module (QLQ-CX24). This module was designed to supplement the core QOL questionnaire, the EORTC Quality of Life Questionnaire Core 30 (QLQ-C30), to assess disease- and treatment-related effects on QOL in patients with cervical cancer.¹² The Sexual function–Vaginal changes Questionnaire (SVQ) was developed for patients with gynecological malignancies to assess sexual problems.¹³ In addition, information regarding the overall QOL for both groups was obtained using the EORTC QLQ-C30, which was developed to specifically assess QOL in patients with cancer.¹⁴ No questions from the survey were modified, with the exception that not all the questions from the SVQ were used owing to overlap with questions from the EORTC QLQ-CX24. Several additional questions were placed in our questionnaire for data collection purposes, including the use of hormone replacement therapy, vaginal estrogens and dilators, marital status, socioeconomic status, smoking history, and disease status.

The EORTC QLQ-C30 has been validated as a tool to evaluate health-related QOL in patients with cancer. It is a 30-item Likert scale survey including functional and symptom subscales and a global health status QOL scale. Linear transformation of the mean score was used to convert the scores to a 0-to-100 scale. A high score represented a higher (healthy) level of functioning and QOL and a higher (worse) level of symptoms. This questionnaire has a high internal consistency with a median κ of 0.85.¹⁴ At the time of this study, no disease-specific module existed for endometrial cancer; and therefore, the supplemental cervical cancer module (EORTC QLQ-CX24) was used to assess sexual function. The EORTC QLQ-CX24 is a 24-item questionnaire that is a disease-specific module designed to supplement the EORTC QLQ-C30 and demonstrates a high internal consistency with a Cronbach α coefficient of 0.87 for the sexual/vaginal functioning items.¹² Additionally, the EORTC QLQ-CX24 has been demonstrated to be valid and reliable.¹² Questions 50 to 53 comprise the sexual/vaginal functioning scale. Linear transformation of the mean score was used to convert the scores to a 0-to-100 scale. Questions regarding sexual worry (item 48), sexual activity (item 49), and sexual enjoyment (item 54) are scored separately and linearly transformed to a 0-to-100 scale. A high score is equivalent to worse symptoms or problems, except for sexual activity and sexual enjoyment, where a higher score indicates fewer symptoms or problems. Although there is not a score that specifically defines sexual dysfunction, the scores between the 2 groups can be compared. A scale difference of at least 10 is considered to be clinically relevant.¹⁵ The SVQ consists of 20 core questions, measuring items such as sexual activity, interest, satisfaction, and body image; and 7 questions regarding sexual and vaginal problems compared to precancer diagnosis. This questionnaire has been previously validated in the medical literature for patients with gynecologic malignancies. Psychometric analyses confirmed the internal consistency of the scales used to assess vaginal changes and sexual functioning based on Cronbach α values of 0.76 to 0.83.^{13,16} Because many of the core questions from the SVQ were similar to the EORTC QLQ-CX24 questionnaire, only the final 7 questions of the SVQ were used. The items of the SVQ are scored individually, making it possible to use these questions, which deal specifically with pretreatment sexual function, separately with the EORTC QLQ-CX24.

All statistical tests were 2 sided. Given the explorative nature of this study, no adjustments for multiple comparisons were used. Categorical patients' characteristic and demographic variables were compared between the 2 groups (IVB vs surgery) using the Fisher exact test owing to the small cell counts (Tables 1 and 2). Continuous patient characteristic variables were compared using *t* tests (Table 1). All the survey results were originally compared between the 2 groups using the Fisher exact test. One-way analysis of variance models were

used to compare the linear transformations of the survey question results between the 2 groups (Tables 3 and 4).

RESULTS

One hundred fifty-eight patients were eligible for the study. Eighty-seven patients returned the survey (55% response rate). Patients had the option of completing the survey for participation in the study or returning the survey blank to be removed from the study. Seventeen patients returned the survey but refused to participate in the study. Eleven patients (15%) who did not return the questionnaire had invalid addresses or phone numbers and could not be located. One patient was ineligible because of recurrent disease. Sixty-eight eligible patients completed the survey: 16 treated with IVB and 53 in the surgery-alone group.

Patients' characteristics are presented in Table 1, and patients' demographics are presented in Table 2. Most of the patients were white with adenocarcinoma of the endometrium. More patients in the surgery-alone arm had FIGO stage IA to IB disease ($P < 0.001$) and grade 1 disease ($P = 0.018$). All patients underwent total abdominal hysterectomy with bilateral salpingo-oophorectomy, and all but 11 patients from the surgery-alone group had a lymph node dissection ($P = 0.054$). One patient in the IVB arm and 3 in the surgery group received chemotherapy. All patients treated with IVB received 2100 cGy in 3 fractions. One patient in the surgery group with stage IB disease was also found to have a synchronous ovarian primary that did not require additional therapy. Demographics were similar among the patients, except household income.

QOL Outcomes

There was no statistically significant difference in the overall QOL for patients treated with surgery alone or IVB. Most of the patients in both groups reported excellent global health status. There were also no statistically significant differences in physical, emotional, cognitive, or social functioning. Symptoms scales according to the QLQ-C30, including fatigue, pain, and diarrhea, were similar between the 2 groups (Table 3). However, a higher number of women reported difficulty controlling their bowels a little to very much on the QLQ-CX24 in the IVB group (60%) compared to the surgery-alone group (15%; $P = 0.038$). This question was included in 1 of 11 questions in the symptoms experience scale of the QLQ-CX24. When linear transformation of this scale's score was performed, there was no difference between the 2 groups.

Sexual Functioning Outcomes

A total of 37 patients (63% in the IVB group and 52% in the surgery group) were not sexually active, but there was no difference between the 2 groups ($P = 0.643$). Of the sexually active patients, 33% of the patients in the IVB group and 42% of the patients in the surgery-alone group felt their vagina was quite a bit to very much dry during sexual activity ($P = 0.804$) and 17% versus 20% felt their vagina was short ($P = 0.884$). Seventeen percent of the patients in the IVB group felt their vagina was tight compared to 29% in the surgery-alone group ($P = 0.891$) and 0% versus 14% of the patients reported pain during intercourse ($P = 0.808$). Fifty percent of the patients in the IVB group and 61% of the patients in the surgery-alone group reported sexual activity as enjoyable ($P = 0.737$). When the scores from the QLQ-CX24 were linearly transformed, there was no difference in the sexual/vaginal functioning scale, sexual worry, or sexual enjoyment between the 2 groups (Table 4).

There was no statistically significant difference between the groups on the SVQ for changes in interest in sexual activity ($P = 0.108$), dryness of the vagina ($P = 0.347$), size of the vagina

($P = 0.487$), and pain with intercourse since cancer diagnosis ($P = 0.999$). However, 50% of the patients in the IVB group versus 31% of the patients in the surgery-alone group were less interested in sexual activity, and 50% versus 71% reported increased dryness of the vagina compared to before their diagnosis of cancer. Fifty percent versus 36% felt their vagina was smaller and 50% versus 53% have more pain with intercourse now than before their diagnosis.

DISCUSSION

Intracavitary brachytherapy alone is frequently used instead of external beam radiation for management of early-stage endometrial cancer. Post Operative Radiation Therapy in Endometrial Carcinoma and Gynecologic Oncologic Group 99 studies showed that most recurrences after surgery for patients with intermediate-risk endometrial cancer occurred in the vaginal vault and failed to demonstrate an overall survival benefit for adjuvant external beam radiation.^{17,18} Many patients with intermediate-risk disease either receive no adjuvant therapy or are treated with IVB alone.² Multiple non-randomized studies have shown excellent local control, disease-free survival, and overall survival with IVB alone as adjuvant treatment for women with intermediate-risk endometrial cancer.^{2,3,19–21} Intracavitary brachytherapy also spares the patient from the genitourinary, gastrointestinal, and additional toxicities of whole-pelvis radiation.^{3,5,17,20} In addition to retrospective studies, the Post Operative Radiation Therapy in Endometrial Carcinoma (PORTEC) 2 prospective trial was recently published. This study randomized patients with high- to intermediate-risk endometrial cancer to IVB or whole-pelvis external beam radiation after surgery. They demonstrated that vaginal cuff brachytherapy is effective in decreasing vaginal recurrence and is associated with a better QOL than external beam therapy.²² However, sexual functioning was similar in both groups.²³ Additional data comparing the 2 treatments will be obtained with Gynecologic Oncologic Group 249, which is randomizing patients with high-risk early-stage endometrial cancer to adjuvant pelvic radiation therapy versus IVB and chemotherapy.

Whereas several studies have shown that women with endometrial cancer who receive external beam radiation therapy after surgery have impaired QOL,^{8,10,24} there are few data regarding the long-term sexual adverse effects from treatment for women specifically with early-stage endometrial cancer treated with brachytherapy alone. Women with cervical cancer have been found to have persistent sexual dysfunction and vaginal changes up to 2 years after external beam radiation with IVB¹⁶ and also may experience sexual adverse effects from surgery alone.²⁵ Bruner et al⁹ evaluated the sexual adverse effects for women with endometrial and cervical cancer who received IVB, but most of these patients also received external beam radiation. This study demonstrated that IVB with or without external beam radiation results in vaginal stenosis, decreased sexual satisfaction, and dyspareunia.⁹ Katz et al²⁶ reviewed 41 patients treated with adjuvant brachytherapy for patients with cervical or endometrial cancer, and 32 patients also received external beam radiation. All patients received 2 low-dose rate vaginal cylinder insertions to 30 Gy, and the degree of vaginal shortening was recorded at each treatment. A significant difference in vaginal length occurred between the first and second treatment for patients treated with external beam and brachy-therapy but not with brachytherapy alone.²⁶

Our results revealed similarly reported outcomes between the 2 groups in all areas of QOL, including sexual functioning. However, both groups report sexual and vaginal changes; and many patients in both groups were not sexually active. Whether the lack of sexual activity is due to treatment effects or other factors is not known. Overall health status and QOL was excellent in both treatment groups. Although no control population of women was used, the primary aim of the study was to determine if IVB contributes any additional toxicity to

surgical management of endometrial cancer, and therefore, the control group was not necessary for the study.

The strengths of our study include the use of previous validated and reliable questionnaires. The EORTC QLQ-C30 and its subscales are commonly used to assess the QOL of cancer survivors in clinical studies. In addition, our patient group was matched in age and year since treatment to ensure a balanced population. There was a difference in the stage and grade of patients included in the study based on treatment group, which is expected because patients with low-risk endometrial cancer, based on depth of invasion and grade, are typically treated with surgery alone. The limitations of our study include the lack of a pretreatment questionnaire to determine baseline sexual activity and functioning and the low survey response rate. In addition, the data were collected in a cross-sectional manner as opposed to a longitudinal study. Additional factors other than surgery and/or radiation, including age, hormone replacement therapy, and use of vaginal estrogens, may affect sexual functioning. We obtained this information from all patients to account for these possible confounders. In addition, 4 patients received chemotherapy, 3 patients in the surgery alone group and one in the IVB group, which may also be significant confounder when evaluating QOL and sexual function. The study was also biased by the subjective nature of the symptoms and by patient recall, particularly for the SVQ. Although limited conclusions can be drawn regarding a comparison between cohorts, the survey responses reflect our patients' perceptions regarding sexual function and QOL after treatment, which may be helpful when counseling patients regarding expected treatment adverse effects.

In conclusion, we report that patients who were treated with IVB report similar outcomes on a QOL and sexual function questionnaire compared to patients treated with surgery alone for early-stage endometrial cancer; however, our study did not have enough power to detect a difference if one existed and is subject to multiple confounding factors and effect modification. Prospective studies should be conducted to evaluate the sexual and additional long-term toxicities of vaginal brachytherapy. Knowledge regarding the sexual function of these women will guide physicians on appropriate counseling for patients and may result in future research for management and prevention of symptoms. Although limited conclusions can be drawn regarding a comparison between cohorts, the survey responses reflect our patients' perceptions regarding sexual function and QOL after treatment, which may be helpful when counseling patients regarding expected treatment adverse effects.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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TABLE 1

Patients' characteristics

	Surgery	Surgery + IVB	P
No. patients	53	16	
Age			
Mean	60	58	0.407
Range	30–75	36–74	
Race			
White	53	15	0.232
Asian/Pacific Islander	0	1	
FIGO stage			
IA	37	1	<0.001
IB	14	2	
IC	1	5	
IIA	1	3	
IIB	0	5	
FIGO grade			
1	42	7	0.018
2	10	7	
3	1	2	
Histology			
Adenocarcinoma	52	15	0.413
Clear cell/papillary serous	1	1	
Chemotherapy			
Yes	3	1	0.661
No	50	15	
Use of HRT			
Yes	8	0	0.183
No	45	16	
Use of vaginal estrogens			
Yes	4	0	0.566
No	49	16	
Use of vaginal dilator			
Several times a week	1	1	<0.001
Less than once a week	1	9	
Never	49*	6	

* Two patients did not answer.

TABLE 2

Patients' demographics

	Surgery	Surgery + IVB	<i>P</i>
Education			
High school or less	16	7	0.826
Some college	15	4	
College degree	15	4	
Graduate degree	7	1	
Marital status			
Married	34 [*]	9	0.436
Single with partner	11	6	
Single with no partner	7	1	
Annual income			
<\$25,000	15 [*]	5 [*]	0.048
\$25,000–\$49,999	8	7	
\$50,000–\$100,000	21	2	
>\$100,000	8	1	

* One patient did not answer.

TABLE 3

Sexual functioning of endometrial cancer survivors by treatment based on EORTC QLQ-CX24 scores

EORTC QLQ-CX24	Surgery n = 53		Surgery + IVB n = 16		P
	Mean	SD	Mean	SD	
Symptom experience *	11.6	12.5	13.3	15.6	0.665
Body image *	21.2	25.1	17.4	18.6	0.576
Sexual/vaginal functioning *	30.1	29.2	22.2	26.7	0.548
Menopausal symptoms *	21.4	30.7	25.0	31.0	0.682
Sexual worry *	13.7	27.6	12.5	24.0	0.874
Sexual activity †	21.8	26.3	18.8	27.1	0.689
Sexual enjoyment †	59.3	29.7	61.1	32.8	0.893
Lymphedema *	20.8	25.5	22.9	37.9	0.793

* Higher scores indicate higher level of symptoms or problems.

† Higher scores indicate higher/healthy functioning.

TABLE 4

Quality of life of endometrial cancer survivors by treatment based on EORTC QLQ-C30 scores

EORTC QLQ-C30	Surgery n = 53		Surgery + IVB n = 16		P
	Mean	SD	Mean	SD	
Functioning scales [*]					
Physical functioning	85.0	21.8	92.5	11.6	0.194
Role functioning	91.8	19.0	94.8	8.0	0.546
Emotional functioning	73.6	25.4	80.2	21.3	0.348
Cognitive functioning	80.2	24.5	84.4	18.7	0.531
Social functioning	90.3	24.1	95.8	9.6	0.371
Global health status/QOL [*]					
Overall QOL	79.7	17.5	78.7	15.8	0.827
Symptom scales [†]					
Fatigue	18.9	21.9	21.5	17.9	0.659
Nausea and vomiting	3.9	13.9	6.25	14.6	0.552
Pain	11.3	23.3	12.5	18.8	0.854
Dyspnea	12.0	21.8	6.25	13.4	0.326
Insomnia	25.2	32.0	16.7	24.3	0.331
Appetite loss	4.4	13.1	4.2	11.4	0.949
Constipation	20.1	27.2	14.6	21.0	0.457
Diarrhea	8.8	23.7	10.4	16.0	0.800
Financial difficulties	14.5	30.3	16.67	29.8	0.799

* Higher scores indicate higher/healthy functioning/better QOL.

† Higher scores indicate higher level of symptoms or problems.