# Patient-Reported Outcomes During Pelvic Radiation Therapy: A Secondary Analysis on Sexual Function From NRG-RTOG 1203

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## ABSTRACT

**PURPOSE** NRG-RTOG 1203 reported that intensity-modulated radiation therapy (IMRT) reduced patient-reported GI toxicities in patients with cervical/endometrial cancer receiving postoperative RT, compared with 3-dimensional conformal radiation therapy (3DRT). We conducted a secondary analysis of patient-reported sexual function (PR-SF) among treatment groups to identify factors associated with sexual dysfunction.

**METHODS AND MATERIALS** Patients on NRG-RTOG 1203 were randomly assigned to 3DRT versus IMRT and completed Patient-Reported Outcomes (PRO)-Common Terminology Criteria for Adverse Events (CTCAE) and FACT-Cx surveys at baseline, week 5 of RT, and at 4-6 weeks, 1 year, and 3 years after RT. Patient responses to FACT-Cx sexual function questions were analyzed. The between-arm frequency and severity of responses and their comparison with PRO-CTCAE GI toxicity were tested using chi-square tests. A repeated-measures logistic regression model was used to determine the impact of clinical and treatment factors on PR-SF.

**RESULTS** Two hundred thirty-six patients completed PR-SF questions; 125 (53%) received 3DRT and 111 (47%) IMRT. There were no significant differences in PR-SF between groups ($P > .05$). After RT, responses to "I am afraid to have sex" and "I am interested in sex" significantly improved over time ($P = .007$ and $P = .03$, respectively). At 1 year after RT, women with interference from abdominal pain were more bothered by odor from the vagina versus women with no interference of abdominal pain (5% *v* 0%, $P = .006$). Additionally, at 1 year after RT, women with no severity of abdominal pain or no interference from abdominal pain liked their body appearance more versus women with at least some abdominal pain or some interference from abdominal pain (34% *v* 13%, $P = .003$ and 32% *v* 6%, $P = .001$, respectively).

**CONCLUSION** PR-SF was similar between treatment groups. After RT, fear of sex declined and interest in sex improved over time. Women with GI toxicity after RT completion are at risk for worse sexual function.

ACCOMPANYING CONTENT

- Appendix
- Data Sharing Statement
- Protocol

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## INTRODUCTION

Patients with gynecologic cancer undergoing pelvic radiation therapy (RT) experience toxicities affecting the GI (GI) and genitourinary (GU) systems. Historically, standard RT consisted of 4-field RT (three-dimensional [3D]) to the 3-dimensional conformal radiation therapy (3DRT) resulting in a large volume of the pelvis receiving high radiation doses and leading to significant toxicities.[1,2] Intensity-modulated radiation therapy (IMRT) offered promise as it allowed for highly conformal radiation volumes with sparing of normal tissue. Retrospective studies analyzing pelvic RT showed lower bowel dose and lower rates of acute and chronic GI toxicity with IMRT versus 3DRT.[1,3] Subsequently, the NRG-RTOG 1203 trial was initiated as the first prospective study to compare the efficacy

## CONTEXT

**Key Objective**

What is the impact of intensity-modulated radiation therapy (IMRT) versus 3-dimensional conformal radiation therapy (3DRT) on sexual function in women with cervical or endometrial cancer, and do any additional clinical or treatment factors affect sexual function?

**Knowledge Generated**

There was no difference in sexual function in women who received postoperative 3DRT versus IMRT, and a majority of sexual function outcomes returned to baseline levels within 1 year after RT. GI toxicity after RT may exacerbate sexual function issues, highlighting a population who may benefit from referrals for abdominal pain, diarrhea, incontinence, or for sexual function interventions.

**Relevance *(F. Rubagumya)***

This study demonstrates that regardless of the radiotherapy technique used—IMRT or 3DRT—patient-reported sexual dysfunction (PR-SF) and GI toxicities are at their highest during the course of treatment and improve over time after treatment completion. Importantly, the findings reveal no significant difference in terms of toxicities between the two approaches. GI toxicity was associated with worse PR-SF.*

**Plain Language Summary *(M. Lewis)***

In women receiving radiation for cervix or uterus cancer, the type of radiation (whole pelvic *v* intensity-modulated) did not make a difference in effects on sexual function, which sometimes overlapped with GI toxicities.†

*Relevance section written by *JCO Oncology Advances* Associate Editor Fidel Rubagumya, MD, MMed, MPH.
†Plain Language Summary written by *JCO Oncology Advances* Associate Editor Mark Lewis, MD.

and toxicity of IMRT with 3DRT as postoperative treatment in patients with cervical or endometrial cancer.

The primary end point of NRG-RTOG 1203 was acute GI toxicity evaluated by the National Cancer Institute Common Terminology Criteria for Adverse Events (CTCAE) physician-graded toxicity scale and by patient-reported outcomes (PROs). The study showed that IMRT was associated with significantly less acute and late patient-reported GI toxicity and less late GU toxicity compared with 3DRT.[4,5] Interestingly, in 2020, a secondary report showed that physician-graded outcomes underestimated patient GI symptoms and showed no difference in toxicity between the two treatment groups.[6]

Pelvic RT, which includes vaginal and paravaginal tissues in the target for gynecologic cancer, may lead to sexual dysfunction; however, the increased conformality of IMRT may reduce dose to other pelvic soft tissues, which may lessen the impact on sexual function. However, the prevalence and severity of sexual dysfunction in women receiving pelvic RT is not well established in the modern era. Sexual function was not directly investigated in NRG-RTOG 1203; but, the PRO instruments included sexual function. Thus, we performed a secondary analysis of patient-reported sexual function (PR-SF) from NRG-RTOG 1203 to compare dysfunction between treatment arms and investigate factors associated with sexual dysfunction.

## METHODS AND MATERIALS

### Study Design

The study design, patient eligibility, and interventions were previously described.[4] Briefly, patients with cervical or endometrial cancer requiring postoperative RT were randomly assigned to 3DRT versus IMRT. Patients were treated to 45 or 50.4 Gy with or without concurrent cisplatin. The study protocol describes the RT setup, contours, dosing, plan, and quality assurance.[4] The primary end point was change in patient-reported acute GI toxicity from baseline to 5 weeks after starting RT. Secondary end points included change in GU toxicity from baseline to 5 weeks and assessment of toxicities and quality of life (QOL) at 1 and 3 years of follow-up. The study protocol was approved by the institutional review board of each participating center and was registered at ClinicalTrials.gov (identifier: NCT01672892).

### Measures

Patients completed the PRO-CTCAE[7] for GI toxicity and the Functional Assessment of Cancer Therapy Cervical Cancer Subscale[8] (FACT-Cx) at baseline, week 5 after starting RT, and at 4-6 weeks, 1 year, and 3 years after RT. For both instruments, patients reported toxicity on a 5-point Likert scale as follows: none or not at all to very severe or almost constantly for severity questions; not at all to very much or

almost constantly for interference questions; and, never or not at all to very much or almost constantly for frequency questions. A score of zero indicated a patient response of none, not at all, or never.[7,8] Patient responses to the following FACT-Cx questions were included for analysis of sexual function:

- "I am bothered by discharge or bleeding from my vagina"
- "I am bothered by odor coming from my vagina"
- "I am afraid to have sex"
- "I feel sexually attractive"
- "My vagina feels too narrow or short"
- "I have concerns about my ability to have children"
- "I am interested in sex"
- "I like the appearance of my body"

### Statistical Analysis

NRG Oncology statisticians performed this analysis using SAS Version 9.4. Patient characteristics were compared between treatment arms. *T*-tests, or Wilcoxon testing for non-normally distributed data, were used for comparing continuous variables. Chi-square tests, or Fisher's exact test if sample sizes were small, were used for comparing categorical variables. The frequency and severity of responses to sexual function questions were compared by arm and at each time point using chi-square testing. Sexual function responses were compared with GI PRO-CTCAE toxicity responses using chi-square testing. Holm's procedure was used to adjust for multiplicity. A repeated-measures generalized linear mixed-effects regression model with a logit link function was used to determine the impact of treatment arm, time point, the interaction between treatment arm and time point (to determine if the impact of treatment varies across time), baseline sexual function, stratification factors (primary cancer site, total RT dose, and use of chemotherapy), and relevant covariates (age, race, and Zubrod performance status) on postbaseline sexual function. These models analyzed the probability of a negative response to each sexual function question: "Quite a bit or very much" for negatively worded questions and "Not at all, a little bit, or somewhat" for positively worded questions. This dichotomy was chosen to identify significant negative concerns for each sexual function question. Global F-tests within the model were used to determine the improvement of PR-SF over time and the significance of the interaction term. Because of the small sample sizes, no statistical tests were performed for survey responses at 3 years after RT except within the framework of a repeated-measures model due to the inclusion of data at all time points and adjustment for patient characteristics.

## RESULTS

### Patient-Reported Sexual Function

Of the 279 patients included for the primary NRG-RTOG 1203 analysis, 236 (85%) consented to complete PR-SF questions. One hundred-twenty (96%), 111 (89%), 110 (88%), 94 (75%), and 25 (20%) patients in the 3DRT group and 101 (91%), 92 (83%), 90 (81%), 85 (77%), and 24 (22%) patients in the IMRT group completed surveys at baseline, week 5 during RT, 4-6 weeks after RT, 1 year after RT, and 3 years after RT, respectively. There were no significant differences in baseline demographic or clinical characteristics between treatment groups in the current analysis (Table 1). There was no significant difference in FACT-Cx survey completion by rates of sexual, GI, and/or GU adverse events at any time point.

There were no significant differences in PR-SF between treatment groups ($P > .05$, Appendix Table A1). In all patients, at baseline, week 5 during RT, 4-6 weeks after RT, 1 year after RT, and 3 years after RT, the following number (percentage) of patients reported a negative response to each sexual function question. "I am bothered by discharge or bleeding from my vagina": baseline seven patients (3%), during RT three (2%), 4-6 weeks after RT one (1%), 1 year after RT two (1%), and 3 years after RT 0. "I am bothered by odor coming from my vagina": baseline five (2%), during RT one (1%), 4-6 weeks after RT three (2%), 1 year after RT two (1%), and 3 years after RT 0. "I am afraid to have sex": baseline 30 (15%), during RT 35 (19%), 4-6 weeks after RT 23 (12%), 1 year after RT 22 (13%), and 3 years after RT three (6%). "I feel sexually attractive": baseline 157 (75%), during RT 148 (78%), 4-6 weeks after RT 153 (81%), 1 year after RT 129 (75%), and 3 years after RT 36 (77%). "My vagina feels too narrow or short": baseline 12 (6%), during RT 15 (8%), 4-6 weeks after RT 17 (9%), 1 year after RT 19 (11%), and 3 years after RT five (11%). "I have concerns about my ability to have children": baseline two (1%), during RT two (1%), 4-6 weeks after RT 0, 1 year after RT one (1%), and 3 years after RT 0. "I am interested in sex": baseline 159 (76%), during RT 165 (86%), 4-6 weeks after RT 151 (79%), 1 year after RT 133 (78%), and 3 years after RT 38 (81%). "I like the appearance of my body": baseline 155 (70%), during RT 152 (77%), 4-6 weeks after RT 144 (73%), 1 year after RT 129 (73%), and 3 years after RT 34 (71%).

PR-SF numerically improved for both treatment groups after RT and approached/exceeded baseline sexual function over time for most questions; however, responses to "my vagina feels too narrow or short" numerically worsened after RT for all patients regardless of radiation modality or primary cancer type (Fig 1). Additionally, there were significantly more positive responses to "I am afraid to have sex" and "I am interested in sex" across time ($P = .007$ and $P = .03$, respectively).

### Sexual Function Association With GI Toxicity

At baseline, women with at least some pain or interference of pain in the abdomen were more likely to fear sex versus women with no pain or interference of pain in the abdomen (23% *v* 4%, $P = .0001$ and 27% *v* 7%, $P = .0001$, respectively, Table 2, Fig 2).

**TABLE 1.** Baseline Characteristics of Included Patients (N = 237)

| Patient Characteristic | IMRT Pelvic Radiation Treatment (n = 111) | 3-Dimensional Conformal Radiation Therapy (3DRT) (n = 125) | Total (N = 237) | P[a] |
|---|---|---|---|---|
| Age, years | | | | |
| Median | 63 | 60 | 62 | .18 |
| Range | 28-82 | 29-83 | 28-83 | |
| Quartile 1-quartile 3 | 55-70 | 53-67 | 54-68 | |
| Race, No. (%) | | | | |
| Black | 13 (11.7) | 10 (8.0) | 23 (9.7) | .51 |
| White | 83 (74.8) | 101 (80.8) | 185 (78.1) | |
| Other | 15 (13.5) | 14 (11.2) | 29 (12.2) | |
| Ethnicity, No. (%) | | | | |
| Hispanic or Latino | 7 (6.3) | 8 (6.4) | 15 (6.3) | .98 |
| Not Hispanic or Latino | 104 (93.7) | 117 (93.6) | 222 (93.7) | |
| Zubrod performance status, No. (%) | | | | |
| 0 | 85 (76.6) | 90 (72.0) | 175 (73.8) | .42 |
| 1-2 | 26 (23.4) | 35 (28.0) | 62 (26.2) | |
| Surgical resection, No. (%) | | | | |
| TAH | 46 (41.4) | 54 (43.2) | 100 (42.2) | .95 |
| Radical hysterectomy | 23 (20.7) | 26 (20.8) | 49 (20.7) | |
| Vaginal hysterectomy/laparoscopic-assisted vaginal hysterectomy | 42 (37.8) | 45 (36.0) | 88 (37.1) | |
| RT dose, Gy,[b] No. (%) | | | | |
| 45 | 68 (61.3) | 75 (60.0) | 143 (60.3) | .84 |
| 50.4 | 43 (38.7) | 50 (40.0) | 94 (39.7) | |
| Disease site,[b] No. (%) | | | | |
| Endometrium | 95 (85.6) | 105 (84.0) | 201 (84.8) | .74 |
| Cervix | 16 (14.4) | 20 (16.0) | 36 (15.2) | |
| Chemotherapy,[b] No. (%) | | | | |
| No chemotherapy | 78 (70.3) | 91 (72.8) | 170 (71.7) | .67 |
| Five cycles of cisplatin delivered once per week at 40 mg/m$^2$ | 33 (29.7) | 34 (27.2) | 67 (28.3) | |

Abbreviations: IMRT, intensity-modulated RT; RT, radiation therapy; TAH, total abdominal hysterectomy.
[a]Chi-square test for all except *t*-test for age.
[b]Stratification factor.

At 4-6 weeks after RT, women with no loss of bowel control were less bothered by odor coming from the vagina versus women with at least some loss of bowel control (100% *v* 95%, $P = .007$, Table 2, Fig 2).

At 1 year after RT, women with no interference of pain in the abdomen were less likely to report bother from odor from the vagina versus women with at least some interference of pain in the abdomen (100% *v* 95%, $P = .006$, Table 2, Fig 2). Women with no pain severity or interference of pain in the abdomen were more likely to like the appearance of their bodies versus women with at least some pain or interference of pain in the abdomen (34% *v* 13%, $P = .003$ and 32% *v* 6%, $P = .001$, respectively, Table 2, Fig 2).

## Linear Mixed-Effects Models

There was no statistically significant impact of treatment arm, time point, baseline sexual function, and relevant covariates on responses to the following sexual function questions: "I feel sexually attractive"; "My vagina feels too short or narrow"; and "I have concerns about my ability to have children" ($P > .05$ for all, Appendix Table A2).

Women with greater age and at 3 years after RT versus at baseline were less bothered by discharge or bleeding from the vagina (odds ratio [OR], 0.92 [95% CI, 0.86 to 0.98], $P = .01$ and OR, 0.003 [95% CI, 0 to 0.559], $P = .03$, respectively, Table 3). Women who received chemotherapy were more bothered by odor from their vagina (OR, 2.36 [95% CI 1.24-4.48, $P < .01$, Table 3). Women at 3 years after RT versus at baseline were less afraid of sex (OR 0.09, 95% CI, 0.02 to 0.40], $P < .0001$, Table 3). Additionally, women with greater age and who received 50.4 Gy versus 45 Gy were less afraid of sex (OR, 0.94 [95% CI, 0.90 to 0.99], $P = .03$ and OR, 0.34 [95% CI, 0.13 to 0.87], $P = .02$, respectively). Women with older age and at 4-6 weeks after RT versus at baseline were less interested in sex (OR, 1.10 [95% CI, 1.04 to 1.16],

 

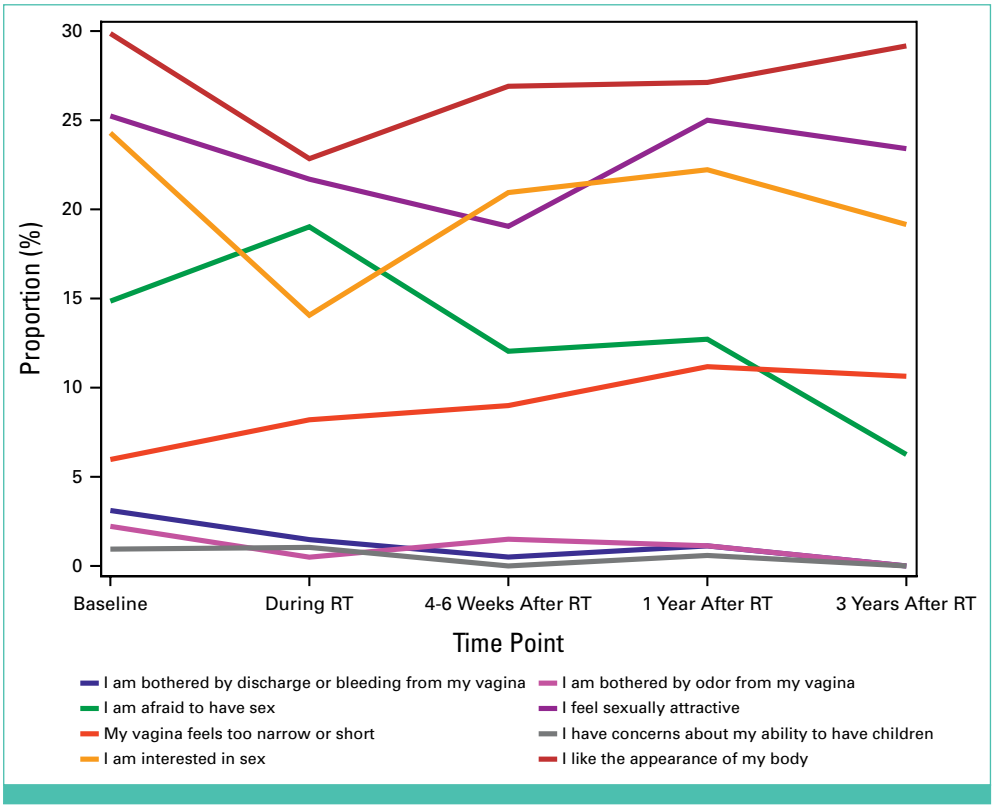


**FIG 1.** Longitudinal trajectory of reporting "very much" or "quite a bit" to questions related to sexual function or body image from the FACT-Cx instrument by women with cervical or endometrial cancer requiring postoperative RT. FACT-Cx, Functional Assessment of Cancer Therapy Cervical Cancer Subscale; RT, radiation therapy.

$P$ = .001 and OR, 1.77 [95% CI, 0.88 to 3.54], $P$ = .03, respectively, Table 3).

## DISCUSSION

In this analysis of PR-SF from the NRG-RTOG 1203 phase III randomized controlled trial, we found no significant differences in PR-SF between patients with cervical or endometrial cancer receiving postoperative 3DRT versus IMRT. Among all women, interest in sex was lowest and fear of sex was greatest during RT; however, responses to both improved over time after RT completion. Perceived vaginal shortening worsened across the study period after RT and, importantly, no differences were seen between 3DRT versus IMRT. The similarity in outcomes between these radiation modalities is unsurprising, given that the treatment approach was focused on minimizing bowel radiation exposure whereas vaginal tissues and other sexual organs were not prioritized for sparing with IMRT. GI toxicity, including abdominal pain and loss of bowel control, was associated with worse PR-SF across the study period. Our findings suggest that, despite worsening of PR-SF during and shortly after RT, long-term PR-SF improves back to baseline in women with cervical or endometrial cancer receiving postoperative pelvic RT.

Limited prospective evidence exists regarding sexual function in women with cancer, with the current study being one of the first reports of PR-SF in this patient population during the past 10 years. The EMBRACE-I prospective study analyzed PR-SF in women with gynecologic cancer who received definitive RT at higher doses than the radiation doses received by patients on our study. EMBRACE-I showed that, while rates of sexual activity improved after RT completion, the proportion of patients with vaginal dysfunction was greater than the general population, and issues with vaginal dryness and shortening were associated with dyspareunia and sexual dysfuction.[9] Another study of PR-SF in patients with cervical cancer receiving definitive RT corroborated these findings.[10] Other prospective analyses of PR-SF in women who received pelvic RT exist, all in the anorectal cancer population, and similarly showed vaginal shortening after RT with dyspareunia at 1-year post-treatment.[11-13] Although our study confirmed the persistence of vaginal shortening after pelvic RT, our long-term follow-up also demonstrated a return to baseline for other sexual function outcomes by 1 year after RT. Our study protocol did not mandate the use of a vaginal dilator after treatment, which may minimize vaginal shortening in these patients and should be investigated in future studies. Finally, some PR-SF measures in our study, such as "I am bothered by discharge/

**TABLE 2.** Association Between FACT-Cx Sexual Function Survey Responses With PRO-CTCAE Toxicity Grading

| PRO-CTCAE Toxicity Responses Stratified by Each FACT-Cx Question | Baseline, No. (%) | | | Week 5 During RT, No. (%) | | | 4-6 Weeks After RT, No. (%) | | | 1 Year After RT, No. (%) | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | Not at all, A Little Bit, Somewhat | Very Much, Quite a Bit | *P* | Not at all, A Little Bit, Somewhat | Very Much, Quite a Bit | *P* | Not at all, A Little Bit, Somewhat | Very Much, Quite a Bit | *P* | Not at all, A Little Bit, Somewhat | Very Much, Quite a Bit | *P* |
| "I am bothered by odor from my vagina" | | | | | | | | | | | | |
| Severity of pain in the abdomen | | | .31 | | | .15 | | | .048 | | | .041 |
| No toxicity | 94 (99) | 1 (1) | | 65 (99) | 1 (2) | | 109 (100) | 0 | | 118 (100) | 0 | |
| Some toxicity | 126 (97) | 4 (3) | | 133 (100) | 0 | | 82 (97) | 3 (4) | | 55 (96) | 2 (4) | |
| Interference of pain in the abdomen | | | .08 | | | .33 | | | .13 | | | **.0060*** |
| No toxicity | 130 (99) | 1 (1) | | 96 (100) | 0 | | 139 (99) | 1 (1) | | 138 (100) | 0 | |
| Some toxicity | 89 (96) | 4 (4) | | 102 (99) | 1 (1) | | 52 (96) | 2 (4) | | 35 (95) | 2 (5) | |
| Frequency of diarrhea | | | .90 | | | .67 | | | .087 | | | .17 |
| No toxicity | 125 (98) | 3 (2) | | 31 (100) | 0 | | 95 (100.0) | 0 | | 85 (100) | 0 | |
| Some toxicity | 94 (98) | 2 (2) | | 167 (99) | 1 (1) | | 96 (97) | 3 (3) | | 88 (98) | 2 (2) | |
| Frequency of loss of bowel control | | | .44 | | | .22 | | | **.0068*** | | | .29 |
| No toxicity | 199 (98) | 4 (2) | | 119 (100) | 0 | | 137 (100) | 0 | | 139 (99) | 1 (1) | |
| Some toxicity | 21 (96) | 1 (5) | | 79 (99) | 1 (1) | | 54 (95) | 3 (5) | | 34 (97) | 1 (3) | |
| Interference of loss of bowel control | | | .47 | | | .25 | | | .15 | | | .37 |
| No toxicity | 198 (98) | 4 (2) | | 114 (100) | 0 | | 137 (99) | 1 (1) | | 133 (99) | 1 (1) | |
| Some toxicity | 22 (96) | 1 (4) | | 84 (99) | 1 (1) | | 54 (95) | 2 (5) | | 40 (98) | 1 (2) | |
| Frequency of antidiarrhea medication | | | .79 | | | .41 | | | .15 | | | .74 |
| Never/0-1 times daily | 217 (98) | 5 (2) | | 117 (99) | 1 (1) | | 173 (99) | 2 (1) | | 163 (99) | 2 (1) | |
| ≥2 times daily | 3 (100) | 0 (0) | | 79 (100) | 0 | | 17 (94) | 1 (6) | | 9 (100) | 0 | |
| "I am afraid to have sex" | | | | | | | | | | | | |
| Severity of pain in the abdomen | | | **.0001*** | | | .12 | | | .11 | | | .02 |
| No toxicity | 81 (96) | 3 (4) | | 50 (88) | 7 (12) | | 96 (91) | 9 (9) | | 105 (91) | 10 (8) | |
| Some toxicity | 91 (77) | 27 (23) | | 96 (78) | 27 (22) | | 67 (84) | 13 (16) | | 44 (79) | 12 (21) | |
| Interference of pain in the abdomen | | | **.0001*** | | | .27 | | | .05 | | | .06 |
| No toxicity | 110 (93) | 8 (7) | | 71 (85) | 13 (16) | | 121 (91) | 12 (9) | | 121 (90) | 14 (10) | |
| Some toxicity | 61 (74) | 22 (27) | | 75 (78) | 21 (22) | | 42 (81) | 10 (19) | | 28 (78) | 8 (22) | |
| Frequency of diarrhea | | | .13 | | | .73 | | | .63 | | | .20 |
| No toxicity | 103 (89) | 13 (11) | | 25 (83) | 5 (17) | | 83 (89) | 10 (11) | | 76 (90) | 8 (10) | |
| Some toxicity | 69 (81) | 16 (19) | | 121 (81) | 29 (19) | | 80 (87) | 12 (13) | | 73 (84) | 14 (16) | |
| Frequency of loss of bowel control | | | .42 | | | .35 | | | .68 | | | .40 |
| No toxicity | 157 (86) | 26 (14) | | 86 (79) | 23 (21) | | 118 (89) | 15 (11) | | 120 (88) | 16 (12) | |
| Some toxicity | 15 (79) | 4 (21) | | 60 (85) | 11 (16) | | 45 (87) | 7 (14) | | 29 (83) | 6 (17) | |
| Interference of loss of bowel control | | | .98 | | | .51 | | | .063 | | | .14 |
| No toxicity | 155 (85) | 27 (15) | | 81 (79) | 21 (21) | | 120 (91) | 12 (9) | | 116 (89) | 14 (11) | |
| Some toxicity | 17 (85) | 3 (15) | | 65 (83) | 13 (17) | | 43 (81) | 10 (19) | | 33 (80) | 8 (20) | |

(continued on following page)

**TABLE 2.** Association Between FACT-Cx Sexual Function Survey Responses With PRO-CTCAE Toxicity Grading (continued)

| PRO-CTCAE Toxicity Responses Stratified by Each FACT-Cx Question | Baseline, No. (%) | | | Week 5 During RT, No. (%) | | | 4-6 Weeks After RT, No. (%) | | | 1 Year After RT, No. (%) | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | Not at all, A Little Bit, Somewhat | Very Much, Quite a Bit | *P* | Not at all, A Little Bit, Somewhat | Very Much, Quite a Bit | *P* | Not at all, A Little Bit, Somewhat | Very Much, Quite a Bit | *P* | Not at all, A Little Bit, Somewhat | Very Much, Quite a Bit | *P* |
| Frequency of antidiarrhea medication | | | .36 | | | .63 | | | .50 | | | .061 |
| Never/0-1 times daily | 170 (85) | 29 (15) | | 87 (82) | 19 (18) | | 148 (88) | 20 (12) | | 142 (88) | 19 (12) | |
| ≥2 times daily | 2 (67) | 1 (33) | | 57 (79) | 15 (21) | | 15 (94) | 1 (6) | | 6 (67) | 3 (33) | |
| "I feel sexually attractive" | | | | | | | | | | | | |
| Severity of pain in the abdomen | | | .087 | | | .29 | | | .26 | | | .49 |
| No toxicity | 59 (69) | 27 (31) | | 49 (83) | 10 (17) | | 86 (84) | 16 (16) | | 87 (74) | 30 (26) | |
| Some toxicity | 98 (79) | 26 (21) | | 96 (76) | 30 (24) | | 63 (78) | 18 (22) | | 42 (79) | 11 (21) | |
| Interference of pain in the abdomen | | | .96 | | | .95 | | | .89 | | | .32 |
| No toxicity | 90 (75) | 30 (25) | | 68 (78) | 19 (22) | | 107 (82) | 24 (18) | | 101 (74) | 35 (26) | |
| Some toxicity | 67 (75) | 22 (25) | | 77 (79) | 21 (21) | | 42 (81) | 10 (19) | | 28 (82) | 6 (18) | |
| Frequency of diarrhea | | | .44 | | | .81 | | | .63 | | | .53 |
| No toxicity | 87 (73) | 32 (27) | | 24 (80) | 6 (20) | | 72 (80) | 18 (20) | | 62 (74) | 22 (26) | |
| Some toxicity | 70 (78) | 20 (22) | | 121 (78) | 34 (22) | | 77 (83) | 16 (17) | | 67 (78) | 19 (22) | |
| Frequency of loss of bowel control | | | .66 | | | .51 | | | .37 | | | .76 |
| No toxicity | 142 (74) | 49 (26) | | 86 (77) | 26 (23) | | 108 (83) | 22 (17) | | 101 (75) | 33 (25) | |
| Some toxicity | 15 (79) | 4 (21) | | 59 (81) | 14 (19) | | 41 (77) | 12 (23) | | 28 (78) | 8 (22) | |
| Interference of loss of bowel control | | | .22 | | | .056 | | | .63 | | | .96 |
| No toxicity | 139 (74) | 50 (27) | | 77 (73) | 28 (27) | | 107 (82) | 23 (18) | | 98 (76) | 31 (24) | |
| Some toxicity | 18 (86) | 3 (14) | | 68 (85) | 12 (15) | | 42 (79) | 11 (21) | | 31 (76) | 10 (24) | |
| Frequency of antidiarrhea medication | | | .75 | | | .76 | | | .23 | | | .02 |
| Never/0-1 times daily | 155 (75) | 52 (25) | | 86 (79) | 23 (21) | | 136 (82) | 29 (18) | | 124 (78) | 36 (23) | |
| ≥2 times daily | 2 (67) | 1 (33) | | 57 (77) | 17 (23) | | 12 (71) | 5 (29) | | 4 (44) | 5 (56) | |
| "My vagina feels too narrow or short" | | | | | | | | | | | | |
| Severity of pain in the abdomen | | | .01 | | | .28 | | | .17 | | | .06 |
| No toxicity | 87 (99) | 1 (1) | | 55 (95) | 3 (5) | | 97 (93) | 7 (7) | | 103 (92) | 9 (8) | |
| Some toxicity | 102 (90) | 11 (10) | | 109 (90) | 12 (10) | | 69 (87) | 10 (13) | | 46 (82) | 10 (18) | |
| Interference of pain in the abdomen | | | .01 | | | .23 | | | .01 | | | .91 |
| No toxicity | 115 (98) | 3 (3) | | 81 (94) | 5 (6) | | 125 (94) | 8 (6) | | 116 (89) | 15 (11) | |
| Some toxicity | 73 (89) | 9 (11) | | 83 (89) | 10 (11) | | 41 (82) | 9 (18) | | 33 (89) | 4 (11) | |
| Frequency of diarrhea | | | .59 | | | .71 | | | .89 | | | .02 |
| No toxicity | 111 (93) | 8 (7) | | 28 (93) | 2 (7) | | 81 (91) | 8 (9) | | 69 (83) | 14 (17) | |
| Some toxicity | 78 (95) | 4 (5) | | 136 (91) | 13 (9) | | 85 (90) | 9 (10) | | 80 (94) | 5 (6) | |
| Frequency of loss of bowel control | | | .29 | | | .50 | | | .096 | | | .65 |
| No toxicity | 173 (94) | 12 (7) | | 102 (93) | 8 (7) | | 120 (93) | 9 (7) | | 119 (88) | 16 (12) | |
| Some toxicity | 16 (100) | 0 (0) | | 62 (90) | 7 (10) | | 46 (85) | 8 (15) | | 30 (91) | 3 (9) | |

(continued on following page)

**TABLE 2.** Association Between FACT-Cx Sexual Function Survey Responses With PRO-CTCAE Toxicity Grading (continued)

| PRO-CTCAE Toxicity Responses Stratified by Each FACT-Cx Question | Baseline, No. (%) | | | Week 5 During RT, No. (%) | | | 4-6 Weeks After RT, No. (%) | | | 1 Year After RT, No. (%) | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | Not at all, A Little Bit, Somewhat | Very Much, Quite a Bit | *P* | Not at all, A Little Bit, Somewhat | Very Much, Quite a Bit | *P* | Not at all, A Little Bit, Somewhat | Very Much, Quite a Bit | *P* | Not at all, A Little Bit, Somewhat | Very Much, Quite a Bit | *P* |
| Interference of loss of bowel control | | | .99 | | | .35 | | | .02 | | | .16 |
| No toxicity | 173 (94) | 11 (6) | | 97 (93) | 7 (7) | | 121 (94) | 8 (6) | | 112 (87) | 17 (13) | |
| Some toxicity | 16 (94) | 1 (6) | | 67 (89) | 8 (11) | | 45 (83) | 9 (17) | | 37 (95) | 2 (5) | |
| Frequency of antidiarrhea medication | | | .66 | | | .96 | | | .66 | | | .98 |
| Never/0-1 times daily | 186 (94) | 12 (6) | | 96 (91) | 9 (9) | | 150 (91) | 15 (9) | | 140 (89) | 18 (11) | |
| ≥2 times daily | 3 (100) | 0 (0) | | 66 (92) | 6 (8) | | 16 (94) | 1 (6) | | 8 (89) | 1 (11) | |
| "I like the appearance of my body" | | | | | | | | | | | | |
| Severity of pain in the abdomen | | | .41 | | | .54 | | | .01 | | | **.0033*** |
| No toxicity | 68 (73) | 25 (27) | | 50 (79) | 13 (21) | | 71 (66) | 36 (34) | | 79 (66) | 40 (34) | |
| Some toxicity | 87 (68) | 41 (32) | | 98 (75) | 32 (25) | | 69 (82) | 15 (18) | | 49 (88) | 7 (13) | |
| Interference of pain in the abdomen | | | .45 | | | .43 | | | .05 | | | **.0012*** |
| No toxicity | 92 (72) | 35 (28) | | 69 (74) | 24 (26) | | 95 (69) | 42 (31) | | 94 (68) | 45 (32) | |
| Some toxicity | 63 (68) | 30 (32) | | 79 (79) | 21 (21) | | 45 (83) | 9 (17) | | 34 (94) | 2 (6) | |
| Frequency of diarrhea | | | .016 | | | .64 | | | .17 | | | .094 |
| No toxicity | 80 (64) | 45 (36) | | 22 (73) | 8 (27) | | 64 (69) | 29 (31) | | 58 (67) | 28 (33) | |
| Some toxicity | 75 (79) | 20 (21) | | 126 (77) | 37 (23) | | 76 (78) | 22 (22) | | 70 (79) | 19 (21) | |
| Frequency of loss of bowel control | | | .78 | | | .74 | | | .25 | | | .017 |
| No toxicity | 139 (70) | 60 (30) | | 88 (76) | 28 (4) | | 95 (71) | 39 (29) | | 96 (69) | 43 (31) | |
| Some toxicity | 16 (73) | 6 (27) | | 60 (78) | 17 (22) | | 45 (79) | 12 (21) | | 32 (89) | 4 (11) | |
| Interference of loss of bowel control | | | .17 | | | .08 | | | .29 | | | .016 |
| No toxicity | 136 (69) | 62 (31) | | 80 (72) | 31 (28) | | 96 (71) | 39 (29) | | 92 (69) | 42 (31) | |
| Some toxicity | 19 (83) | 4 (17) | | 68 (83) | 14 (17) | | 44 (79) | 12 (21) | | 36 (88) | 5 (12) | |
| Frequency of antidiarrhea medication | | | .16 | | | .60 | | | .077 | | | .66 |
| Never/0-1 times daily | 154 (71) | 64 (29) | | 87 (76) | 28 (24) | | 129 (75) | 43 (25) | | 121 (73) | 44 (27) | |
| ≥2 times daily | 1 (33) | 2 (67) | | 60 (79) | 16 (21) | | 10 (55) | 8 (44) | | 6 (67) | 3 (33) | |

NOTE. *P* values represent chi-square testing of the association of GI toxicity with a negative response to each sexual function question: "Quite a bit or very much" for negatively worded questions and "Not at all, a little bit, or somewhat" for positively worded questions. Percent is the proportion of patients reporting positive and negative sexual function by PRO-CTCAE toxicity. Holm's procedure by time point by FACT-Cx question was used to adjust for multiplicity. Significant *P* values are shown in bold with an asterisk representing the adjusted value.

Abbreviations: FACT-Cx, Functional Assessment of Cancer Therapy Cervical Cancer Subscale; PRO-CTCAE, Patient-Reported Outcomes-Common Terminology Criteria for Adverse Events; RT, radiation therapy.

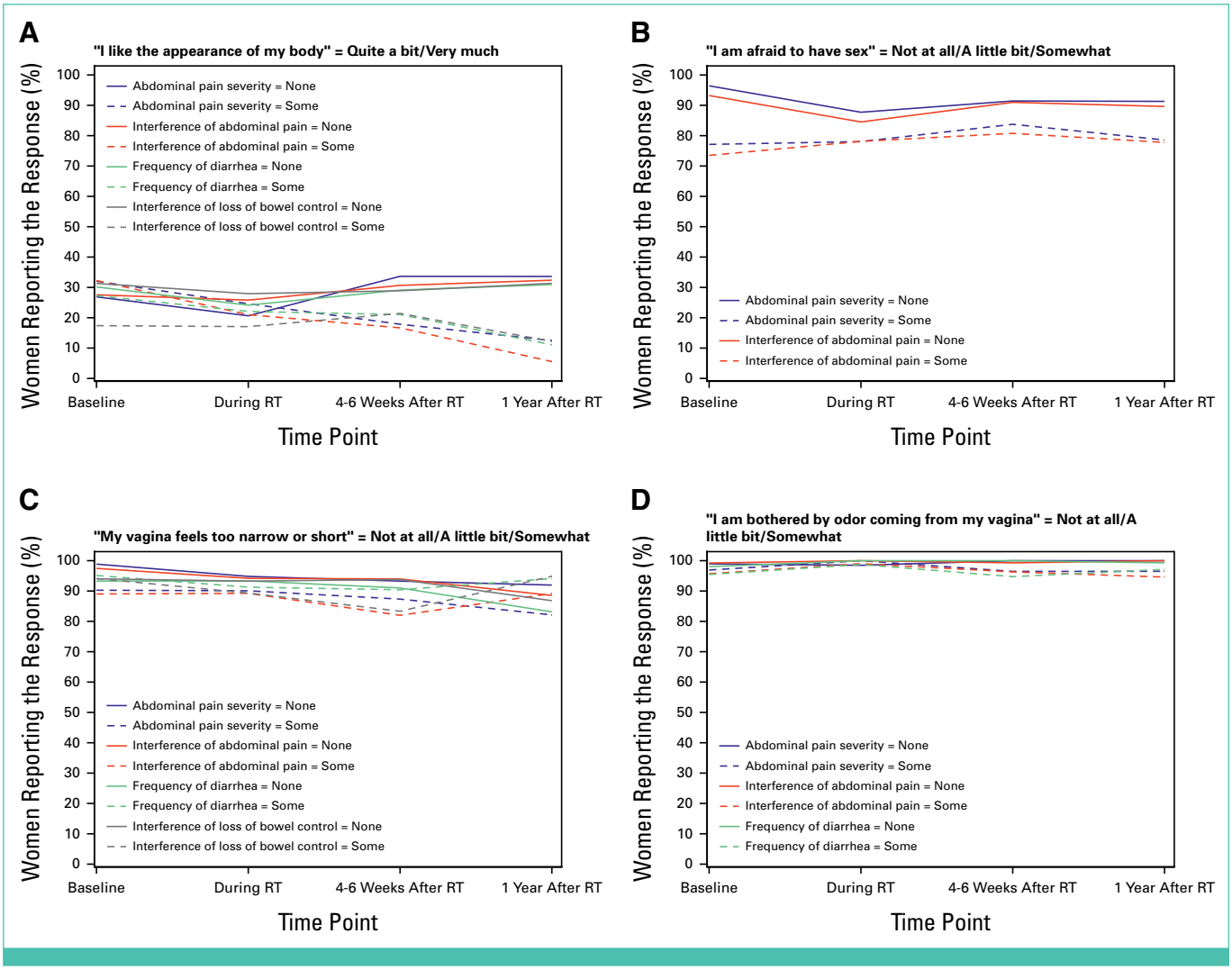


**FIG 2.** Longitudinal trajectory of responses to questions related to sexual function or body image stratified by responses to GI PRO-CTCAE toxicity scales at each time point. PRO-CTCAE, Patient-Reported Outcomes Common Terminology Criteria for Adverse Events; RT, radiation therapy.

bleeding from my vagina," had low rates of negative responses (<5%), indicating better-than-expected sexual function in these areas. Altogether, these findings add value to the current literature base and can help counsel women who require pelvic RT.

On the basis of our literature search, the limited evidence for PR-SF in females with any cancer receiving pelvic RT is in stark contrast to the many prospective and retrospective studies evaluating PR-SF in males with prostate cancer receiving pelvic RT. One study comparing PR-SF collection in females with cervical cancer versus males with prostate cancer receiving pelvic RT found that males were more often asked about sexual function during their appointments and more frequently assessed with a PR-SF instrument compared with females.[14] A better understanding of sexual function after pelvic RT and the drivers of sexual dysfunction in females is warranted, especially considering the high proportion of young women with cervical cancer and the increasing incidence of young women with rectal cancer who may seek counseling regarding the long-term impact of pelvic RT on sexual function or management of sexual dysfunction after RT.[15-17] Oncologists, particularly those involved in clinical trial design and PRO implementation, should advocate for inclusion of PR-SF instruments in protocols involving women with cancer receiving RT. Additionally, since this study did not find any differences in PR-SF between radiation modalities, potential radiation drivers of worse PR-SF, such as dosimetric predictors, should be evaluated, and is an ongoing analysis in our cohort of women from NRG-RTOG 1203. Finally, similar to the standard-of-care PR-SF collection in males with prostate cancer,[18] oncology and survivorship clinics should consider screening for and/or collecting PR-SF in female patients, such as through the European Organisation for Research and Treatment of Cancer Sexual Health Questionnaire or the Female Sexual Function Index,[19,20] to better understand the trajectory of sexual function in women after pelvic RT.[21]

**TABLE 3.** Generalized Linear Mixed-Effects Models Examining the Association of Clinical and Treatment Factors With FACT-Cx Sexual Function Survey Responses in Women With Cervical or Endometrial Cancer Requiring Postoperative RT

| Effect | Reference Level | OR (95% CI) | *P* |
|---|---|---|---|
| A. "I am bothered by discharge or bleeding from my vagina"[a] | | | |
| Treatment arm | IMRT | 0.657 (0.195 to 2.212) | .4972 |
| Time[b] | | | .0650 |
| Time point: week 5 after RT start | Baseline | 0.444 (0.093 to 2.110) | |
| Time point: weeks 4-6 after RT end | Baseline | 0.142 (0.013 to 1.592) | |
| Time point: year 1 | Baseline | 0.353 (0.056 to 2.220) | |
| Time point: year 3 | Baseline | 0.008 (0.000 to 0.455) | |
| Disease site | Endometrium | 2.041 (0.266 to 15.66) | .4919 |
| Age | | 0.930 (0.873 to 0.991) | .0243 |
| RT dose | 45 Gy | 1.465 (0.358 to 6.006) | .5949 |
| Chemotherapy | No chemotherapy | 0.498 (0.111 to 2.228) | .3610 |
| Zubrod | 0 | 4.498 (1.178 to 17.17) | .0279 |
| Race | White | 3.432 (0.898 to 13.11) | .0713 |
| B. "I am bothered by odor coming from my vagina"[c] | | | |
| Treatment arm | IMRT | 1.202 (0.706 to 2.046) | .4967 |
| Time[b] | | | .1393 |
| Time point: week 5 after RT start | Baseline | 1.184 (0.698 to 2.009) | |
| Time point: weeks 4-6 after RT end | Baseline | 0.799 (0.455 to 1.403) | |
| Time point: year 1 | Baseline | 0.721 (0.397 to 1.309) | |
| Time point: year 3 | Baseline | 0.131 (0.017 to 1.024) | |
| Disease site | Endometrium | 0.408 (0.144 to 1.157) | .0916 |
| Age | | 0.986 (0.958 to 1.015) | .3476 |
| RT dose | 45 Gy | 0.658 (0.379 to 1.144) | .1377 |
| Chemotherapy | No chemotherapy | 2.357 (1.231 to 4.513) | .0098 |
| Zubrod | 0 | 1.212 (0.666 to 2.205) | .5278 |
| Race | White | 1.080 (0.565 to 2.062) | .8156 |
| C. "I am afraid to have sex"[a] | | | |
| Treatment arm | IMRT | 4.666 (1.798 to 12.11) | .0016 |
| Time[b] | | | .0068 |
| Time point: week 5 after RT start | Baseline | 1.475 (0.712 to 3.055) | |
| QOL time point: weeks 4-6 after RT end | Baseline | 0.681 (0.299 to 1.553) | |
| QOL time point: year 1 | Baseline | 0.686 (0.287 to 1.639) | |
| QOL time point: year 3 | Baseline | 0.087 (0.018 to 0.417) | |
| Disease site | Endometrium | 0.923 (0.174 to 4.890) | .9249 |
| Age | | 0.950 (0.905 to 0.997) | .0380 |
| RT dose | 45 Gy | 0.333 (0.132 to 0.843) | .0203 |
| Chemotherapy | No chemotherapy | 1.478 (0.467 to 4.675) | .5052 |
| Zubrod | 0 | 1.241 (0.434 to 3.551) | .6871 |
| Race | White | 2.955 (1.065 to 8.201) | .0375 |
| Treatment/time interaction[b] | | | .0566 |
| Treatment/time interaction: 3DRT: week 5 after RT start | Baseline, IMRT | 1.090 (0.368 to 3.223) | |
| Treatment/time interaction: 3DRT: time point: weeks 4-6 after RT end | Baseline, IMRT | 0.595 (0.160 to 2.208) | |
| Treatment/time interaction: 3DRT: time point: year 1 | Baseline, IMRT | 0.476 (0.116 to 1.955) | |
| Treatment/time interaction: 3DRT: time point: year 3 | Baseline, IMRT | 0.008 (<0.001 to 0.097) | |
| D. "I am interested in sex"[d] | | | |
| Treatment arm | IMRT | 1.420 (0.425 to 4.747) | .5682 |
| Time[b] | | | .0338 |
| Time point: week 5 after RT start | Baseline | 3.726 (1.601 to 8.676) | |

(continued on following page)

**TABLE 3.** Generalized Linear Mixed-Effects Models Examining the Association of Clinical and Treatment Factors With FACT-Cx Sexual Function Survey Responses in Women With Cervical or Endometrial Cancer Requiring Postoperative RT (continued)

| Effect | Reference Level | OR (95% CI) | *P* |
|---|---|---|---|
| Time point: weeks 4-6 after RT end | Baseline | 1.675 (0.831 to 3.374) | |
| Time point: year 1 | Baseline | 1.509 (0.673 to 3.384) | |
| Time point: year 3 | Baseline | 2.392 (0.634 to 9.018) | |
| Disease site | Endometrium | 2.597 (0.380 to 17.75) | .3299 |
| Age | | 1.117 (1.051 to 1.186) | .0003 |
| RT dose | 45 Gy | 0.620 (0.209 to 1.839) | .3884 |
| Chemotherapy | No chemotherapy | 0.443 (0.108 to 1.814) | .2573 |
| Zubrod | 0 | 4.196 (1.095 to 16.07) | .0364 |
| Race | White | 2.341 (0.635 to 8.635) | .2012 |
| Treatment/time interaction[b] | | | .0330 |
| Treatment/time interaction: 3DRT: week 5 after RT start | Baseline, IMRT | 3.839 (1.446 to 10.19) | |
| Treatment/time interaction: 3DRT: time point: weeks 4-6 after RT end | Baseline, IMRT | 1.088 (0.409 to 2.893) | |
| Treatment/time interaction: 3DRT: time point: year 1 | Baseline, IMRT | 1.322 (0.483 to 3.617) | |
| Treatment/time interaction: 3DRT: time point: year 3 | Baseline, IMRT | 14.02 (1.843 to 106.6) | |
| E. "I like the appearance of my body"[d] | | | |
| Treatment arm | IMRT | 0.860 (0.334 to 2.215) | .7539 |
| Time[b] | | | .2952 |
| Time point: week 5 after RT start | Baseline | 2.017 (1.073 to 3.793) | |
| Time point: weeks 4-6 after RT end | Baseline | 1.349 (0.709 to 2.567) | |
| Time point: year 1 | Baseline | 1.419 (0.721 to 2.794) | |
| Time point: year 3 | Baseline | 1.206 (0.360 to 4.038) | |
| Disease site | Endometrium | 0.701 (0.147 to 3.332) | .6544 |
| Age | | 0.971 (0.922 to 1.023) | .2645 |
| RT dose | 45 Gy | 1.225 (0.462 to 3.250) | .6828 |
| Chemotherapy | No chemotherapy | 1.131 (0.394 to 3.242) | .8187 |
| Zubrod | 0 | 0.665 (0.215 to 2.052) | .4771 |
| Race | White | 1.202 (0.396 to 3.644) | .7450 |

NOTE. These models analyzed the probability of a negative response to each sexual function question: "Quite a bit or very much" or "A little bit, somewhat, very much, quite a bit" for negatively worded questions and "Not at all, a little bit, or somewhat" for positively worded questions. Age is analyzed continuously.

Abbreviations: 3DRT, three-dimensional conformal radiation therapy; FACT-Cx, Functional Assessment of Cancer Therapy Cervical Cancer Subscale; IMRT, intensity-modulated RT; RT, radiation therapy.

[a]Modeling likelihood of "Very much, quite a bit."

[b]Global F-test.

[c]Modeling likelihood of "A little bit, somewhat, very much, quite a bit."

[d]Modeling likelihood of "Not at all, a little bit, somewhat."

Pelvic RT not only leads to physical changes that affect sexual function, but also mental changes that affect sexual health.[22] In this study, patient-reported fear of sex and interest in sex were worse during RT. These psychological determinants of sexual health are just as important for maintaining sexual function as are the physical components,[23] and likely contribute to the lower levels of sexual activity during pelvic RT.[9] Impairment in the psychological aspects of sex has been associated with worse mental health in patients with cancer.[24] Fortunately, in this study and EMBRACE-I, levels of psychological sexual distress decreased over time after RT.[25] Sexual function should be monitored in women during and after pelvic RT to trigger the appropriate interventions, such as vaginal dilators, and referrals, such as to body image counselors, pelvic floor physical therapists, or mental health specialists.

To our knowledge, this is the first prospective report showing the association of patient-reported GI toxicity with worse PR-SF. Specifically, abdominal pain was associated with fear of sex, worse body appearance, and bother from vaginal odor at multiple time points. The presence of diarrhea or loss of bowel control was associated with worse body appearance and bother from vaginal odor. Although the etiologies of these associations warrant further investigation, these results suggest that GI toxicity represents

another component of the multifactorial interplay of factors affecting sexual function. Previous studies of patients with inflammatory bowel disease, who experience similar bowel symptoms as cancer survivors with treatment toxicity, have also shown associations of GI symptoms with sexual dysfunction.[26] These studies agree that, along with management of other detriments in physical and mental health that affect PR-SF, treatment of GI symptoms is needed to optimize sexual function. Prompt management of abdominal pain and diarrhea or fecal incontinence through medications, diet changes, procedures, or referrals to specialty services is needed during all stages in treatment.[27] Additionally, pelvic floor rehabilitation focusing on strengthening the pelvic musculature involved in bowel movements and sexual arousal, which may be damaged by pelvic RT, may benefit patients.[21,28,29] Finally, as GI toxicity after treatment may prompt feelings of embarrassment, depression, or anxiety,[30] which may affect sexual function, patients with GI symptoms after pelvic RT should be considered for mental health referrals.

Many studies have shown suboptimal communication regarding sexual function between oncologists and females with cancer.[22] PROs may be a useful tool to initiate dialogue about sexual concerns and align patient visits with ASCO's practice guideline for assessing sexual problems in patients with cancer.[31] PR-SF instruments may be necessary for comprehensive evaluation of sexual function in patients with gynecologic cancer, providing a more accurate representation of symptom burden and QOL than provider-reported outcomes.[32] In our previous analysis of patient-reported versus clinician-reported GI toxicity in the NRG-RTOG 1203 study population, clinicians underreported symptomatic GI toxicity compared with patients.[6] Given this and our results showing an association between GI toxicity and worse PR-SF, using patient-reported instruments for monitoring GI toxicity and sexual function is essential in patients with gynecologic cancer. Finally, our study showed that younger age was associated with greater fear of sex, which represents an area of concern for young patients that deserves further study. There is a paucity of studies analyzing PROs in young adults with cancer who received RT[33]; thus, an opportunity exists for using PROs in young adults to further investigate their unique toxicity profile.

This study has several limitations. We did not collect information regarding sexual activity levels, so we were unable to track sexual activity or analyze the association of PR-SF with sexual activity. However, the EMBRACE-I study collected sexual activity information and showed that sexual activity returned to baseline and exceeded baseline levels after RT, which is a helpful benchmark for our study population.[9] Additionally, patient compliance for completion of survey questions related to sexual function worsened over time. This may have biased our sample and resulted in an underrepresentation of sexual function outcomes. However, our survey completion rates were similar to previous analyses studying PR-SF in women who received pelvic RT.[10,25,34,35] Finally, we did not use a PRO instrument specifically validated for sexual function and instead selected questions targeting sexual function from a validated instrument that measures QOL in patients with cancer. Despite these limitations, the findings from this study are important to recognize, given the lack of studies analyzing sexual function in women with cancer. Future investigations are warranted to more comprehensively capture PR-SF after pelvic RT and identify interventions to mitigate sexual dysfunction.

In summary, our findings showed no difference in PR-SF in women with cervical or endometrial cancer receiving postoperative 3DRT versus IMRT. PR-SF worsened during and shortly after RT; however, many PR-SF outcomes returned to baseline levels by 1 year after RT. Specifically, fear of sex declined and interest in sex improved over time. Additionally, we identified that GI toxicity after RT completion may be a risk factor for worse PR-SF, highlighting a patient population who may benefit from early referrals for abdominal pain or diarrhea/incontinence or for sexual function interventions. Overall, this study was one of the first prospective analyses of PR-SF in women who received pelvic RT; much is yet to be discovered, and future studies are warranted.

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## APPENDIX

**TABLE A1.** Comparison of FACT-Cx Sexual Function Survey Responses in Women With Cervical or Endometrial Cancer Requiring Postoperative RT Who Received 3DRT Versus IMRT

| FACT-Cx Question and Responses | Baseline, No. (%) | | | Week 5 During RT, No. (%) | | | 4-6 Weeks After RT, No. (%) | | | 1 Year After RT, No. (%) | | | 3 Years After RT, No. (%) | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | IMRT | 3DRT | *P* | IMRT | 3DRT | *P* | IMRT | 3DRT | *P* | IMRT | 3DRT | *P* | IMRT | 3DRT | *P* |
| "I am bothered by discharge or bleeding from my vagina" | | | | | | | | | | | | | | | |
| Not at all, a little bit, somewhat | 102 (97) | 116 (97) | .99 | 90 (98) | 110 (99) | .59 | 89 (99) | 110 (100) | .45 | 83 (99) | 93 (99) | .99 | 24 (100) | 25 (100) | — |
| Very much, quite a bit | 3 (3) | 4 (3) | | 2 (2) | 1 (1) | | 1 (1) | 0 | | 1 (1) | 1 (1) | | 0 | 0 | |
| "I am bothered by odor from my vagina" | | | | | | | | | | | | | | | |
| Not at all, a little bit, somewhat | 103 (98) | 117 (97) | .99 | 92 (100) | 110 (99) | .99 | 90 (100) | 107 (97) | .25 | 84 (100) | 91 (98) | .50 | 24 (100) | 25 (100) | — |
| Very much, quite a bit | 2 (2) | 3 (3) | | 0 | 1 (1) | | 0 | 3 (3) | | 0 | 2 (2) | | 0 | 0 | |
| "I am afraid to have sex" | | | | | | | | | | | | | | | |
| Not at all, a little bit, somewhat | 80 (85) | 92 (85) | .99 | 68 (85) | 81 (78) | .22 | 76 (89) | 92 (87) | .58 | 72 (90) | 79 (85) | .32 | 24 (100) | 21 (87) | .23 |
| Very much, quite a bit | 14 (15) | 16 (15) | | 12 (15) | 23 (22) | | 9 (11) | 14 (13) | | 8 (10) | 14 (15) | | 0 | 3 (13) | |
| "I feel sexually attractive" | | | | | | | | | | | | | | | |
| Not at all, a little bit, somewhat | 69 (72) | 88 (77) | .38 | 64 (76) | 84 (80) | .53 | 71 (84) | 82 (79) | .42 | 60 (76) | 69 (74) | .79 | 18 (75) | 18 (78) | .79 |
| Very much, quite a bit | 27 (28) | 26 (23) | | 20 (24) | 21 (20) | | 14 (16) | 22 (21) | | 19 (24) | 24 (26) | | 6 (25) | 5 (23) | |
| "My vagina feels too narrow or short" | | | | | | | | | | | | | | | |
| Not at all, a little bit, somewhat | 85 (92) | 104 (95) | .37 | 77 (92) | 91 (92) | .95 | 76 (92) | 96 (91) | .81 | 73 (90) | 78 (88) | .61 | 21 (88) | 21 (91) | .99 |
| Very much, quite a bit | 7 (8) | 5 (5) | | 7 (8) | 8 (8) | | 7 (8) | 10 (9) | | 8 (10) | 11 (12) | | 3 (13) | 2 (9) | |
| "I have concerns about my ability to have children" | | | | | | | | | | | | | | | |
| Not at all, a little bit, somewhat | 95 (99) | 115 (99) | .99 | 88 (99) | 102 (99) | .99 | 83 (100) | 108 (100) | — | 79 (99) | 90 (100) | .47 | 23 (100) | 23 (100) | — |
| Very much, quite a bit | 1 (1) | 1 (1) | | 1 (1) | 1 (1) | | 0 | 0 | | 1 (1) | 0 | | 0 | 0 | |
| "I am interested in sex" | | | | | | | | | | | | | | | |
| Not at all, a little bit, somewhat | 74 (77) | 85 (75) | .67 | 74 (87) | 91 (85) | .69 | 71 (84) | 80 (75) | .17 | 64 (81) | 23 (25) | .35 | 18 (75) | 20 (87) | .46 |
| Very much, quite a bit | 22 (23) | 29 (25) | | 11 (13) | 16 (15) | | 14 (16) | 26 (25) | | 15 (19) | 69 (75) | | 6 (25) | 3 (13) | |
| "I like the appearance of my body" | | | | | | | | | | | | | | | |
| Not at all, a little bit, somewhat | 72 (71) | 83 (70) | .89 | 71 (79) | 81 (76) | .60 | 66 (75) | 78 (72) | .59 | 24 (29) | 24 (26) | .68 | 18 (75) | 16 (67) | .53 |
| Very much, quite a bit | 30 (29) | 36 (30) | | 19 (21) | 26 (24) | | 22 (25) | 31 (28) | | 60 (71) | 69 (74) | | 6 (25) | 8 (33) | |

Abbreviations: 3DRT, three-dimensional conformal radiation therapy; FACT-Cx, Functional Assessment of Cancer Therapy Cervical Cancer Subscale; IMRT, intensity-modulated radiation therapy; RT, radiation therapy.

**TABLE A2.** Generalized Linear Mixed-Effects Models Examining the Association of Clinical and Treatment Factors With FACT-Cx Sexual Function Survey Responses in Women With Cervical or Endometrial Cancer Requiring Postoperative RT

"I Feel Sexually Attractive"

| Effect | Reference Level | OR (95% CI) | *P* |
|---|---|---|---|
| Treatment arm: 3DRT | IMRT | 1.222 (0.535 to 2.788) | .6340 |
| Time point: week 5 during RT | Baseline | 1.476 (0.751 to 2.899) | .3353 |
| Time point: 4-6 weeks after RT | Baseline | 1.810 (0.978 to 3.349) | |
| Time point: 1 year after RT | Baseline | 1.031 (0.528 to 2.015) | |
| Time point: 3 years after RT | Baseline | 1.204 (0.384 to 3.769) | |
| Disease site: cervix | Endometrium | 0.440 (0.116 to 1.675) | .2283 |
| Age | | 0.981 (0.938 to 1.026) | .4051 |
| RT dose: 50.4 Gy | 45 Gy | 1.690 (0.695 to 4.105) | .2464 |
| Chemotherapy | No chemotherapy | 1.461 (0.530 to 4.026) | .4626 |
| Zubrod | 0 | 1.236 (0.467 to 3.271) | .6694 |
| Race | White | 1.729 (0.631 to 4.742) | .2866 |

Age is analyzed continuously
Modeling likelihood of "not at all, a little bit, or somewhat"

"My Vagina Feels Too Short or Narrow"

| Effect | Reference Level | OR (95% CI) | *P* |
|---|---|---|---|
| Treatment arm: 3DRT | IMRT | 1.287 (0.494 to 3.354) | .6046 |
| Time point: Week 5 during RT | Baseline | 1.676 (0.617 to 4.548) | .5311 |
| Time point: 4-6 weeks after RT | Baseline | 1.814 (0.610 to 5.390) | |
| Time point: 1 year after RT | Baseline | 2.768 (0.861 to 8.893) | |
| Time point: 3 years after RT | Baseline | 2.792 (0.580 to 13.44) | |
| Disease site: cervix | Endometrium | 0.269 (0.036 to 2.002) | .1993 |
| Age | | 0.980 (0.927 to 1.037) | .4913 |
| RT dose: 50.4 Gy | 45 Gy | 1.146 (0.432 to 3.039) | .7839 |
| Chemotherapy | No chemotherapy | 2.181 (0.671 to 7.091) | .1945 |
| Zubrod | 0 | 0.879 (0.302 to 2.559) | .8126 |
| Race | White | 1.794 (0.597 to 5.398) | .2975 |

Age is analyzed continuously
Modeling likelihood of "quite a bit or very much"

"I Have Concerns About My Ability to Have Children"

| Effect | Reference Level | OR (95% CI) | *P* |
|---|---|---|---|
| Treatment arm: 3DRT | IMRT | 0.467 (0.073 to 2.964) | .4184 |
| Week 5 during RT | Baseline | 1.047 (0.122 to 9.004) | .3829 |
| Time point: 4-6 weeks after RT | Baseline | 0.002 (0.000 to 6.909) | |
| Time point: 1 year after RT | Baseline | 0.591 (0.046 to 7.613) | |
| Time point: 3 years after RT | Baseline | 0.017 (0.000 to 7.765) | |
| Disease site: Cervix | Endometrium | 3.594 (0.426 to 30.35) | .2394 |
| Age | | 1.032 (0.936 to 1.139) | .5255 |
| RT dose: 50.4 Gy | 45 Gy | 0.000 (0.000 to 906E3) | .4618 |
| Chemotherapy | No chemotherapy | 1.276 (0.208 to 7.813) | .7917 |
| Zubrod | 0 | 3.450 (0.538 to 22.13) | .1913 |
| Race | White | 1.891 (0.278 to 12.85) | .5141 |

Age is analyzed continuously
Modeling likelihood of "quite a bit or very much"

NOTE. These models analyzed the probability of a negative response to each sexual function question: "Quite a bit or very much" for negatively worded questions and "Not at all, a little bit, or somewhat" for positively worded questions.
Abbreviations: 3DRT, three-dimensional conformal radiation therapy; FACT-Cx, Functional Assessment of Cancer Therapy Cervical Cancer Subscale; IMRT, intensity-modulated RT; OR, odds ratio; RT, radiation therapy.