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# Long-Term Quality of Life after Radiation Therapy for Treatment of Anal Cancer

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#### **Abstract**

**Background:** Radiation therapy is the current standard of care for localized squamous cell anal carcinoma. Our goal was to evaluate long-term quality of life in patients after this treatment.

**Methods:** Questionnaires were mailed to 80 patients treated with definitive radiation therapy, with or without concurrent chemotherapy for anal cancer, with a minimum 2-year interval after completion of radiotherapy. The questionnaire included the Functional Assessment of Cancer Therapy-Colorectal (FACT-C), the Medical Outcomes Study (MOS) Sexual Problems Scale, and questions on demographic characteristics and co-morbidities.

**Results:** Thirty-two patients (40%) completed the questionnaire. There were no significant differences in clinical and demographic characteristics between the survey respondents and non-respondents. Among the 32 respondents, the median dose of radiotherapy was 55 Gy, and 97% had received concurrent chemotherapy. The median interval between radiotherapy and survey participation was 5 years (range 3–13 years). The median total FACT-C score was 108 (range 47–128), out of a maximum (best possible) score of 136. Patients who reported depression or anxiety and younger patients had significantly lower total FACT-C scores. The median scores on the physical, social/family, emotional, functional and colorectal subscales of FACT-C were 20, 23, 21, 22, and 21, out of maximum (best possible) scores of 28, 28, 24, 28, and 28, respectively. The median score on the MOS Sexual Problems Scale was 67 (range 0–100), out of a maximum (worst possible) score of 100.

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**Conclusion:** Patients treated with radiation therapy for anal cancer reported acceptable overall quality of life scores, but poor sexual function scores.

#### **Condensed Abstract:**

This study evaluated long-term quality of life in patients treated with radiation therapy for anal cancer, using the Functional Assessment of Cancer Therapy-Colorectal and the Medical Outcomes Study Sexual Problems Scale instruments. Patients reported acceptable overall quality of life scores, but poor sexual function scores.

#### Keywords

Quality of Life; Anal Cancer; Radiotherapy; Chemotherapy; Sexual Dysfunction

#### INTRODUCTION

Radiation therapy with concurrent chemotherapy is the current standard of care for patients with localized squamous cell carcinoma of the anal canal <sup>1–4</sup>. Chemoradiation serves as definitive treatment and allows sphincter preservation. Most patients treated with chemoradiation have excellent outcomes, with 5-year overall survival around 75% <sup>4</sup>. However, pelvic radiation therapy could potentially cause late toxicity, adversely affecting quality of life <sup>5–12</sup>. Limited information is currently available regarding long-term quality of life in patients treated with radiotherapy or chemoradiation for anal cancer <sup>13–15</sup>.

The goal of this study was to evaluate long-term quality of life in patients treated with definitive radiotherapy or chemoradiation for squamous cell anal cancer. Questionnaires were mailed to patients treated with radiotherapy or chemoradiation at a single institution, with a minimum of 2-year follow-up after completion of treatment. The study was based on the Functional Assessment of Cancer Therapy-Colorectal (FACT-C) instrument and the Medical Outcomes Study (MOS) Sexual Problems Scale.

#### **METHODS**

#### **Patient Selection**

Eligibility criteria for this study included the following: patients treated with radiation therapy for non-metastatic squamous cell carcinoma of the anal canal, between January 1993 and December 2003, at the University of Texas M.D. Anderson Cancer Center, and alive at the time of study. Exclusion criteria were age < 18 years and those that could not read English at the seventh grade level. Patients initially treated with radiotherapy who subsequently had salvage surgery were included. Patients had a minimum 2-year interval from completion of radiotherapy to the time of the study.

#### **Survey Method**

Eligible patients were identified using hospital and radiation oncology departmental records, and the M.D. Anderson Tumor Registry, which includes survival information from the Bureau of Vital Statistics. Mailing addresses of eligible subjects were verified by phone calls, and subjects with verified addresses were mailed the study questionnaire. Subjects

were asked to return the questionnaire by mail. If a response was not obtained, subjects were contacted up to two more times by mail or telephone to request participation in the study.

#### **Quality of Life Instrument**

The study used the Functional Assessment of Cancer Therapy-Colorectal (FACT-C) instrument to assess quality of life. FACT-C has been shown to be both a reliable and valid measure of quality of life in patients with colorectal cancer<sup>16–19</sup>. Since no instrument exists to specifically assess quality of life in anal cancer, and since anal and colorectal cancers have similar symptomatology and treatment related side effects, we used the FACT-C instrument for this study. FACT-C is a self-administered questionnaire that consists of 34 items covering four domains of quality-of-life: physical, social/family, emotional and functional, as well as a colorectal cancer subscale that is specific to the concerns of patients with colorectal cancer. Each item is rated on a scale from 0 to 4. The maximum score is 136, with higher scores indicating better quality of life. In addition, the questionnaire included the Medical Outcomes Study (MOS) Sexual Problems Scale, a 4-item instrument having a maximum score of 100, with higher scores indicating worse sexual function<sup>20–22</sup>. Furthermore, the questionnaire had 13 questions on demographic characteristics and co-morbidities.

### Statistical Analysis

Chi-square tests were used to compare demographic and clinical characteristics between respondents and non-respondents. Standard descriptive statistics, including mean, median, range and 95% confidence interval, were calculated for the total FACT-C score, the physical, social/family, emotional, functional, and colorectal cancer subscale scores, and the MOS Sexual Problems Scale. The Wilcoxon Rank Sum and Kruskal-Wallis tests were used to evaluate the effect of demographic, pathologic and treatment factors on the quality of life scores. A P value less than 0.05 was considered statistically significant.

#### **RESULTS**

#### **Patient and Treatment Characteristics**

Eighty patients met the eligibility criteria for this study and had verifiable mailing addresses; these patients were mailed the questionnaire. Of these 80 patients, 32 (40%) provided informed consent and completed the questionnaire. There was no significant difference in the demographic, clinical and treatment characteristics between the survey responders and non-responders (Table 1). There was also no significant difference in the rate of local failures or colostomies between the survey responders and non-responders (Table 1). All cases of colostomies were performed for recurrent or residual disease.

Patients were staged based on physical examination including digital rectal examination, proctoscopy, chest X-ray, and computed tomography (CT) scan. Among the 32 survey responders, the T classification was T1 in 7 (22%), T2 in 15 (32%), T3 in 6 (32%), and T4 in 4 (12%) patients<sup>23</sup>. The N classification was N0 in 23 (72%), N1 in 5 (16%), N2 in 3 (9%) and N3 in 1 (3%) of the patients. All patients underwent CT-simulation and were treated with 6–18 megavolt photons, along with electron fields when appropriate. Among the responders, 30 (94%) patients underwent radiotherapy initially with anterior and posterior

fields, followed by a three-field technique with posterior, right lateral and left lateral fields; this technique has been previously described in detail<sup>24</sup>. Among the responders, the median dose of radiotherapy was 55 Gy, with 30 (94%) patients receiving a dose 55 Gy and 31 (97%) receiving concurrent chemotherapy. The concurrent chemotherapy regimen was 5-fluorouracil (5-FU) and cisplatin in 23 (72%) patients, of whom 2 (6%) also received induction 5-FU and cisplatin. The concurrent chemotherapy regimen was 5-FU and mitomycin C in 2 (6%) patients, and capecitabine and cisplatin in 6 (19%) patients. The median interval between radiotherapy and survey participation was 5 years (range 3–13 years).

#### **Quality of Life Scores**

Table 2 shows the mean, median, range and confidence intervals for the total FACT-C, the FACT-C subscales and the MOS Sexual Problems Scale scores. On the FACT-C scale and subscales, higher scores indicate better quality of life. The median total FACT-C score was 108, out of a maximum (best possible) score of 136. The median scores on the physical, social/family, emotional, functional and colorectal subscales of FACT-C were 20, 23, 21, 22, and 21, out of maximum (best possible) scores of 28, 28, 24, 28, and 28, respectively. On the MOS Sexual Problems Scale, higher scores indicate worse quality of life. The median score on the MOS Sexual Problems Scale was 67, out of a maximum (worst possible) score of 100.

We evaluated the specific responses to all questions; items are presented below if >20% patients reported a score in either of the two most unfavorable categories, and percentages are expressed in terms of the number of patients who answered that particular item. On the FACT-C questionnaire, 16 (55%) patients reported that they were "not at all" or "a little bit" satisfied with their sex lives, 7 (23%) patients reported having "not at all" or "a little bit" control of their bowels, 10 (31%) patients reported "quite a bit" or "very much" diarrhea, and 8 (25%) patients reported "not at all" or "a little bit" liking the appearance of their bodies. On the MOS Sexual Problems questionnaire, 17 (65%) patients reported that lack of a sexual interest was "somewhat" or "very much" of a problem, 17 (71%) patients reported that inability to relax and enjoy sex was "somewhat" or "very much" of a problem, and 18 (72%) patients reported that difficulty in becoming sexually aroused was "somewhat" or "very much" of a problem. Among 6 men, 4 (67%) reported that difficulty getting or keeping an erection was "somewhat" or "very much" of a problem. Among 20 women who answered that question, 14 (70%) reported that difficulty in having an orgasm was "somewhat" or "very much" of a problem.

#### Factors Associated with Quality of Life Scores

We evaluated the effect of various demographic, pathologic and treatment factors on the quality of life scores. The age at diagnosis was significantly associated with the total FACT-C score (Table 3). The median total FACT-C score was 106 for patients with age < 51 years at the time of treatment and 114 for those with age 51 years (P=0.033). A history of depression or anxiety was also significantly associated with the total FACT-C score. The median total FACT-C score was 92 for patients who reported depression or anxiety and 109 for those who did not report depression or anxiety (P=0.006). Moreover, patients who

reported depression or anxiety had significantly lower scores for the physical subscale (median score 17 vs. 22, P=0.005), functional subscale (median score 20 vs. 25, P=0.011) and colorectal subscale (median score 18 vs. 22, P=0.012). Patients who reported a history of other cancers had a significantly lower score for the physical subscale (median score 17 vs. 21, P=0.044). No other factors were significantly associated with the FACT-C total or subscale scores. No factors were significantly associated with the MOS Sexual Problems Scale scores (Table 4). However, there was a trend towards lower MOS Sexual Problems Scale score in those with age 51 years compared with those with age < 51 years (median score 29 vs. 79, P=0.107) and in those with a colostomy (median score 0 vs. 67, P=0.056). Time from treatment was not significantly associated with any of the scores.

#### DISCUSSION

While chemoradiation is the current standard of care for patients with squamous cell cancer of the anal canal, limited information is available about long-term quality of life of these patients. Since patients treated for anal cancer have high survival rates, long-term quality of life is an important clinical issue. This study shows that patients treated with radiation therapy or chemoradiation have acceptable overall quality of life scores, but poor sexual functioning scores.

The mean total FACT-C score in this study was 104, out of a maximum (best possible) score of 136. In comparison, a study on 903 patients with stage II and III colon cancer undergoing chemotherapy with 5-FU and leucovorin showed mean total FACT-C scores of 83 and 87 during chemotherapy and about 6 months after completion of chemotherapy, respectively<sup>18</sup>. A study on 201 patients who underwent surgery for colorectal cancer showed a mean total FACT-C score of 80 at six-week follow-up<sup>25</sup>. A study on 173 colorectal cancer survivors showed mean total FACT-C scores of 111, 112 and 115, 25–36 months, 37–60 months and > 60 months after diagnosis, respectively<sup>26</sup>. Hence, the total FACT-C score reported in the current study compares favorably to that reported by colorectal cancer patients undergoing treatment, and appears similar to that reported by colorectal cancer survivors in long-term follow-up.

The mean MOS Sexual Problems Scale score in the current study was 51, out of a maximum (worst possible) score of 100. In comparison, the mean Sexual Problems Scale score was reported to be 24 in patients with a major medical condition and 41 in patients with depression<sup>20</sup>. A randomized study comparing total abdominal hysterectomy and supracervical hysterectomy in 135 women showed mean Sexual Problems Scale scores of 20 in the total abdominal hysterectomy arm and 18 in the supracervical hysterectomy arm (scores rescaled to be consistent with the current study)<sup>27</sup>. Thus, the Sexual Problems Scale scores in this study compare unfavorably to that reported in studies on other high-risk groups. Moreover, a large proportion of patients reported unfavorable scores on each of the items on the Sexual Problems Scale, such as lack of sexual interest, inability to relax and enjoy sex, difficulty in becoming sexually aroused, difficulty getting or keeping an erection, and difficulty having an orgasm. Of note, these poor sexual function scores were reported by a population of relatively young patients, with a median age of 51 at cancer diagnosis. We hypothesize that the sexual dysfunction in these patients are a result of late radiation damage

to the internal and external genitalia. Studies are warranted to further characterize the prevalence and etiology of sexual dysfunction after radiation therapy for anal cancer.

Although the total FACT-C scores and subscale scores appear favorable in this study, the responses on certain items give cause for concern. Specifically, 31% of patients reported difficulty with diarrhea, 23% reported difficulty with bowel control and 55% reported difficulty with their sex lives. The responses regarding sexual function are consistent with the findings from the Sexual Problems Scale. The long-term gastrointestinal symptoms could be a consequence of radiation damage to the small and large bowel, rectum and anal canal.

A number of dosimetric studies have recently demonstrated that intensity modulated radiation therapy (IMRT) can reduce radiation dose to the genitalia in patients undergoing radiotherapy for anal cancer<sup>28–31</sup>. In addition, IMRT can reduce radiation dose to the bowel, which may potentially reduce the rate of long-term diarrhea and difficulty with bowel control<sup>29–31</sup>. However, the long-term gastrointestinal symptoms could partly be due to the effects of either the tumor or radiotherapy on the anal canal; IMRT will not be able to ameliorate anal canal related-toxicity, since the anal canal will be part of the target volume even with IMRT. A number of clinical studies have recently evaluated IMRT for anal cancer; however, further follow-up will be required from these studies to determine whether IMRT can help reduce the risk of long-term sexual or gastrointestinal problems<sup>30–32</sup>.

In this study, younger patients were found to have significantly lower total FACT-C scores. Moreover, there was a trend towards worse Sexual Problems Scale scores in younger patients. Younger patients may have higher expectations regarding quality of life and sexual functioning, which may have led worse self-reported quality of life scores in these patients.

Our study indicates that more emphasis needs to be placed on identifying and addressing treatment-related symptoms after chemoradiation for anal cancer. Long-term follow-up of these patients is necessary to identify and treat consequences of successful cancer therapy. Recent articles have reviewed appropriate management of gastrointestinal and sexual dysfunction after pelvic radiation therapy<sup>5</sup>, 33–35. Opiate agonists such as loperamide, bulking agents, and low fiber diet can help decrease gastrointestinal symptoms<sup>5</sup>, 33. Phosphodiesterase inhibitors, such as sildenafil, can help improve sexual function in men, while topical estrogen, vaginal moisturizers, lubricants and vaginal dilators can help improve sexual function in women<sup>34</sup>, 35.

Previous studies have evaluated quality of life after radiotherapy for anal cancer. Tournier-Rangeard et al. conducted a prospective study of quality of life among 119 patients in a randomized controlled trial, using the EORTC QLQ-C30 questionnaire<sup>36</sup>. This study showed that quality of life scores improved 2 months after chemoradiation, compared to prior to treatment; however, this study did not provide any information about long-term quality of life. Vordermark et al. reported a study on 22 colostomy-free anal cancer survivors, using the Gastrointestinal Quality of Life Index, which showed a mean score of 114, compared to a mean score of 121 in healthy volunteers<sup>14</sup>. However, this study did not evaluate non-gastrointestinal aspects of quality of life. Allal et al. evaluated long-term

quality of life in 41 patients, using the European Organization for Research and Treatment of Cancer (EORTC) QLQ-C30 and QLQ-CR38 questionnaires<sup>13</sup>. Their study reported acceptable scores, except for a high symptom score for diarrhea and a low sexual functioning score, which are consistent with the findings of our study. Jephcott et al. compared quality of life scores in 50 long-term anal cancer survivors and 50 matched volunteer controls, using the EORTC QLQ-C30 and QLQ-CR38 questionnaires<sup>15</sup>. Anal cancer survivors had significantly lower scores for overall quality of life, as well as for the physical functioning and sexual functioning scales. Moreover, anal cancer survivors had significantly poorer scores for a number of symptom scales, including fatigue, nausea, diarrhea, gastrointestinal symptoms, defecation problems and sexual problems. While the findings in our study are broadly consistent with those in previous studies, our study uses a different questionnaire (FACT-C) for assessing quality of life, and also evaluates sexual function in greater detail, using the MOS Sexual Problems questionnaire.

This study has several limitations. The sample size was small; however, we believe that the study represents a significant contribution, given that squamous cell anal cancer is a relatively rare malignancy. The response rate was only 40% and it is possible that quality of life scores could have been different between survey responders and non-responders. However, there were no significant differences in demographic, clinical and treatment characteristics between survey responders and non-responders. Information was not available regarding quality of life, gastrointestinal function and sexual function at baseline among these patients. Patients may have had some gastrointestinal or sexual dysfunction at baseline, and we were unable to account for these potential baseline deficits. Moreover, we evaluated quality of life at a single time-point and were, therefore, unable to assess changes in scores for individual patients over time. For the overall group of patients, the time from treatment was not significantly associated with any of the scores. We evaluated the relationship between a number of factors and a number of scores, and these analyses were not corrected for multiple comparisons.

In conclusion, patients treated with radiation therapy or chemoradiation for squamous cell anal cancer reported acceptable overall long-term quality of life scores, but poor sexual function scores. Moreover, the survey responses indicated that a significant proportion of patients had difficulty with diarrhea, bowel control and different aspects of sexual function. Younger patients reported worse quality of life scores. Clinicians need to identify and address treatment-related symptoms after radiation therapy for anal cancer. Modern techniques of radiation therapy, such as IMRT, could potentially reduce toxicity by reducing radiation dose to the bowel and genitalia. However, studies with prolonged follow-up will be needed in patients treated with IMRT in order to determine whether IMRT mitigates against long-term gastrointestinal and sexual dysfunction.

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 Table 1:

 Demographic, Clinical and Treatment Characteristics among Survey Responders and Non-Responders

Characteristic	Responders No. of Patients (%)	Non-Responders No. of Patients (%) 48	
N	32		
Median Age at Diagnosis (yrs)	51	54	0.64
Gender			
Male	6 (19%)	11 (23%)	0.65
Female	26 (81%)	37 (77%)	
Race			
White	29 (91%)	42 (88%)	0.36
Black	2 (6%)	3 (6%)	ĺ
Hispanic	0 (0%)	3 (6%)	
Others	1 (3%)	0 (0%)	
HIV Status			
Negative	30 (94%)	48 (100%)	0.15
Positive	2 (6%)	0 (0%)	
T Classification			
T1	7 (22%)	8 (17%)	0.30
T2	15 (47%)	15 (31%)	İ
T3	6 (19%)	17 (35%)	
T4	4 (12%)	8 (17%)	
N Classification			
N0	23 (72%)	31 (65%)	0.56
N1	5 (16%)	5 (10%)	
N2	3 (9%)	7 (15%)	
N3	1 (3%)	5 (10%)	
Radiotherapy Dose			
< 55 Gy	2 (6%)	4 (8%)	1.00
55 Gy	26 (81%)	39 (81%)	İ
> 55 Gy	4 (12%)	5 (10%)	
Radiotherapy Technique			
AP/PA, then 3 field	30 (94%)	45 (94%)	1.00
Other	2 (6%)	3 (6%)	
Concurrent Chemotherapy			
5-FU/ cisplatin	23 (72%)	36 (75%)	0.28
5-FU/ mitomycin C	2 (6%)	7 (15%)	
Capecitabine/ cisplatin	6 (19%)	3 (6%)	

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Characteristic Responders No. of Patients (%) Non-Responders No. of Patients (%) P 5-FU 0 (0%) 1 (2%) 1 (3%) None 1 (2%) Locoregional Failures 3 (9%) 6 (13%) 0.734 Colostomy 3 (9%) 6 (13%) 0.734 Page 11

HIV: Human Immunodeficiency Virus, AP: Antero-posterior, PA: Postero-anterior, 5-FU: 5-fluorouracil

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 Table 2:

 Quality of Life Scores in Patients Treated with Radiation Therapy for Anal Cancer

	Maximum Possible	Mean	Median	Range	95% CI
FACT-C, Total Score*	136	104	108	47–128	60–124
Physical Subscale	28	20	20	3–24	9–24
Social/Family Subscale	28	22	23	13–28	13–28
Emotional Subscale	24	20	21	5–24	13–24
Functional Subscale	28	22	22	5–28	12–28
Colorectal Subscale	28	20	21	10–27	12–26
MOS Sexual Problems Scale **	100	51	67	0–100	0–100

FACT-C: Functional Assessment of Cancer Therapy – Colorectal

MOS: Medical Outcomes Study

CI: Confidence Interval

<sup>\*</sup>Higher scores indicate better quality of life for the FACT-C total score and subscale scores

<sup>\*\*</sup>Higher scores indicate worse sexual function for the MOS Sexual Problems Scale

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Table 3:

Total FACT-C Scores in Different Subgroups of Patients Treated with Radiation Therapy for Anal Cancer

Factor	Median Score*	P
Age at Treatment		
< 51 yrs	106	0.033 **
51 yrs	114	
Time from Treatment		
< 5 yrs	108	0.485
5 yrs	106	
Gender		
Female	108	0.790
Male	107	
Race		
White	105	0.796
Non-white	108	
T Classification	1	1
T1	108	0.690
T2	108	
T3	110	
T4	109	
N Classification		
N0	107	0.198
N1	108	
N2	123	
N3	81	
Radiation Dose		1
55 Gy	108	0.494
> 55 Gy	113	
Concurrent Chemotherapy		1
5-fluorouracil/ cisplatin	109	0.321
Other	98	
Colostomy		
Yes	121	0.332
No	108	
History of Other Cancers		
Yes	110	0.795
No	108	

Factor	Median Score*	P	
History of Gastrointestinal Problems			
Yes	94	0.185	
No	108		
History of Depression/ Anxiety			
Yes	92	0.006**	
No	109		

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 $<sup>{}^{\</sup>ast}$  Higher scores indicate better quality of life for the FACT-C total score

<sup>\*\*</sup> P < 0.05

Table 4:

MOS Sexual Problems Scale Scores in Different Subgroups of Patients Treated with Radiation Therapy for Anal Cancer

Factor	Median Score*	P
Age at Treatment		<u> </u>
< 51 yrs	79	0.107
51 yrs	29	
Time from Treatment		
< 5 yrs	54	0.848
5 yrs	71	
Gender		
Female	71	0.539
Male	54	
Race		
White	67	0.693
Non-white	33	
T classification		
T1	83	0.273
T2	42	
Т3	50	
T4	4	
N classification		
N0	67	0.881
N1	0	
N2	42	
N3	83	
Radiation Dose		
55 Gy	67	0.104
> 55 Gy	4	
Concurrent Chemotherapy		
5-fluorouracil/ cisplatin	67	0.762
Other	67	
Colostomy	1	
Yes	0	0.056
No	67	
History of Other Cancers	1	
Yes	25	0.616

Factor  $\mathbf{Median\ Score}^*$ No 67 History of Gastrointestinal Problems Yes 25 0.791 67 No History of Depression/ Anxiety 83 0.282 Yes 37 No

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 $<sup>^{*}</sup>$  Higher scores indicate worse sexual function for the MOS Sexual Problems Scale