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Assessment of Patient-Reported Measures of Bowel Function Before and After Pelvic Radiotherapy: An Ancillary Study of the North Central Cancer Treatment Group Study N00CA

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Abstract

Purpose—The Bowel Function Questionnaire (BFQ) has been used in clinical trials to assess symptoms during and after pelvic radiotherapy (RT). This study evaluated the importance of symptoms in the BFQ from a patient perspective.

Methods—Patients reported presence or absence of symptoms and rated importance of symptoms at baseline, 4 weeks after completion of pelvic RT, and 12 and 24 months after RT. The BFQ measured overall quality of life (QOL) and symptoms of nocturnal bowel movements, incontinence, clustering, need for protective clothing, inability to differentiate stool from gas, liquid bowel movements, urgency, cramping, and bleeding. Bowel movement frequency also was recorded. A content validity questionnaire was used to rate symptoms as "not very important," "moderately unimportant," "moderately important," or "very important."

Results—Most of the 125 participating patients rated all symptoms as moderately or very important. Generally, patients gave similar ratings for symptom importance at all study points, and ratings were independent of whether the patient experienced the symptom. Measures of greatest importance (moderately or very important) at baseline were ability to control bowel movements (94%), not having to wear protective clothing (90%), and not having rectal bleeding (94%). With the exception of need for protective clothing, the presence of a symptom at 4 weeks was associated with significantly worse QOL (*P*<.01 for all).

Conclusions—The BFQ has excellent content validity. Patients rated most symptoms as moderately or very important, indicating the BFQ is an appropriate tool for symptom assessment during and after pelvic RT.

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Keywords

bowel function; content validity; pelvic radiotherapy; quality of life

Introduction

Pelvic radiotherapy is commonly used for patients with gastrointestinal, gynecologic, genitourinary, or other pelvic cancers. Rectal dysfunction is the major form of symptomatic toxicity in these patients [1–6]. Randomized trials have been conducted previously by the North Central Cancer Treatment Group (NCCTG) to examine the mitigative effects of several pharmacologic agents on rectal toxicity during radiotherapy [1–4].

A bowel function questionnaire (BFQ) was used in several of these studies to assess the impact of the pharmacologic agents on bowel function [1, 3, 4]. The BFQ, developed and created by Mayo Clinic physicians, is based on a method used to assess bowel function of patients with resected rectal cancer [7]. The BFQ identifies patient-reported problems with various aspects of bowel function (yes or no response) to help evaluate how bowel dysfunction affects normal activities and quality of life (QOL). The primary purpose of the questionnaire is to identify patient-perceived problems with bowel function; this is considered more relevant and precise than collecting incidence measures that were assessed by clinicians. If the patient perceives that bowel function is a problem, then it is a problem [8]. Face validity of this instrument is derived from a content analysis of the literature and the framework used in the application of the original questionnaire [8–20].

N00CA was a randomized clinical trial comparing the effectiveness of depot octreotide versus placebo for prevention of diarrhea during pelvic radiotherapy. Details regarding patient eligibility, conduct of the study, and the lack of benefit of octreotide in the reduction of acute treatment-related diarrhea have been reported previously [4]. As part of that study, the importance of the various symptoms assessed by the BFQ was evaluated by patients. Here, we report the results of this secondary analysis and the long-term results of bowel function in the 2 treatment groups.

Methods and Materials

Written informed consent and institutional review board approval was required prior to entry of any patients onto NCCTG protocol N00CA [4]. During the course of the study, the BFQ and a content validity questionnaire (CVQ) were administered at baseline, 4 weeks after completion of radiotherapy, and at 12 and 24 months after radiotherapy. Assessed symptoms included nocturnal bowel movements, incontinence, clustering, protective clothing, stoolgas confusion, liquid bowel movements, urgency, cramping, and rectal bleeding. Brief descriptions of each symptom are shown in Table 1. The BFQ score, calculated with every assessment, represented the total number of symptoms experienced by the patient (eg, a patient reporting incontinence, clustering, and protective clothing would have a score of 3). The frequency of bowel movements also was recorded.

A QOL measure (the Uniscale questionnaire) was included in the BFQ [21]. With this tool, patients rated their overall QOL on a 0-to-10 scale, in which 0 indicated a QOL "as bad as it can be" and 10 indicated a QOL "as good as it can be". The overall QOL score was not converted to a 0-to-100 scale (as is standard practice) because there were no between-assessment comparisons. Patients were categorized by QOL status (ie, score of 5 [considered clinically deficient QOL] vs >5) [22, 23].

Patients also completed a CVQ with each BFQ assessment. For the CVQ, patients rated each BFQ symptom on a 5-point scale corresponding to "not very important," "moderately unimportant," "moderately important," or "very important" (with 5 being "very important"). Ratings were averaged to determine an overall importance score.

Basic summary statistics and frequencies of study end points were compiled for each time point. Fisher exact, χ^2 , and Wilcoxon statistical tests were used to compare results. Correlation analysis was completed to compare the average importance rating to patient QOL. P values less than .05 were considered statistically significant.

Results

This study was open for accrual between May 10, 2002 and October 28, 2005. It accrued 125 patients and all patients were eligible for these analyses. Patient characteristics have been reported previously [4]. Briefly, patients had a mean age of 62.6 years, most were men (58.4 %), and patients had cancer of the rectum (36 %), prostate (30.4 %), gynecologic organs (28.8%), or other organs (4.8%). No cytotoxic chemotherapy was allowed during radiotherapy except for 5-fluorouracil or cisplatin. 5-Fluorouracil was administered to 39.2 % of patients (4.8 % by bolus and 34.4 % by continuous infusion). Sixteen percent of patients received cisplatin. The numbers of patients who completed the BFQ were as follows: baseline, n=124; 4 weeks, n=114; 12 months, n=94; and 24 months, n=74. The numbers of patients who completed the CVQ (rating the importance of various measures of bowel function) were as follows: baseline, n=124; 4 weeks, n=106; 12 months, n=94; and 24 months, n=73.

Primary results of the octreotide trial showed that the study agent did not prevent acute diarrhea [4]. Baseline BFQ scores for both treatment arms were 1.3 (P=.63). Long-term (12-month) results showed that octreotide-treated patients had significantly higher overall BFQ scores (2.9 vs 1.9; P=.04). Octreotide-treated patients had more problems with clustering (P=.05) and a significantly greater need for protective clothing (P=.04) (Table 2). By 24 months, there were no significant differences in BFQ scores between treatment arms (2.2 [octreotide] vs 1.9 [placebo]; P=.58).

We next examined the relationship between mean overall QOL score and presence or absence of BFQ symptoms (Table 3). At week 4, QOL was significantly lower for patients for each symptoms except need for protective clothing (P<.01). At subsequent time points, the number of symptoms significantly associated with lower overall QOL progressively decreased (six symptoms at 12 months; two symptoms at 24 months). Greater than two bowel movements per day was associated with significantly decreased overall QOL at 4

weeks (P=.046) and 24 months (P=.02) but not at 12 months (P=.17). Further, when comparing patients with a QOL score of greater than 5 with patients with clinically deficient QOL (score 5), the latter group had a significantly higher number of symptoms at baseline (mean BFQ score, 2.3 vs 1.1; P=.02) and at 4 weeks (mean BFQ score, 5.1 vs 2.7; P<.01). Clinical deficiency in overall QOL was not significantly associated with the number of symptoms experienced at 12 or 24 months (data not shown).

Using data from the CVQ for all time points, the average importance patients placed on any bowel function symptom was 4.1, which corresponded to "moderately important" on the content validity descriptive scale. Detailed results of the content validity analysis are shown in Table 4. At baseline, all measures of bowel function were rated as moderately important or very important by the majority of patients (range, 54%–94%). The most important measures at baseline were ability to control bowel movements, not having to wear protective clothing, and not having rectal bleeding; these measures were rated as moderately important or very important by 94%, 90%, and 93% of patients, respectively. In general, the percentage of patients that ranked a symptom as moderately important or very important was similar for all time points. For example, the proportion of patients that rated ability to control bowel movements as moderately important or very important was 94%, 94%, 86%, and 96% at baseline, 4 weeks, 12 months, and 24 months, respectively.

CVQ ratings were independent of whether the patient experienced the symptom. Table 5 details how patients with or without a specific symptom rated the importance of that symptom. For example, 100% of the patients who experienced incontinence at 4 weeks rated this symptom as moderately or very important, and 84% of patients who did not have incontinence also rated it as moderately or very important.

An exploratory analysis was conducted to determine whether the BFQ score was associated with overall QOL. This analysis used all QOL and BFQ scores from all time points in the study. Pearson correlation analysis showed a moderate correlation (r=-0.41; *P*<.001) between the overall QOL and total BFQ scores.

Discussion

The results of the N00CA bowel function assessment are similar to those reported elsewhere from randomized studies [24–29] and nonrandomized studies [7, 16, 30]. All have shown significantly worse outcomes for bowel function after pelvic radiotherapy.

The present study sought to determine the importance of commonly used measures of bowel function from a patient perspective, which then allowed us to determine content validity of the BFQ. All symptoms measured by the BFQ were rated by patients as being either moderately important or very important. At 4 weeks, all symptoms except for need for protective clothing were significantly associated with worse QOL. Progressively fewer symptoms were associated with worse QOL at 12 and 24 months, suggesting that patients may have the ability to adapt to bowel function problems caused by pelvic radiotherapy (PR). The analyses comparing patients with and without clinically deficient QOL also

supports this interpretation of the data; in our cohort, a worse QOL score did not necessarily indicate increased incidence of symptoms.

The findings of this study have important implications for informed consent before PR and for counseling after treatment. In the informed consent process, particular emphasis should be placed on symptoms that patients regard as most important (eg, incontinence). An awareness of symptoms that are most important to patients can also facilitate counseling after radiotherapy. For example, bleeding is often encountered during and after a course of PR [1, 3, 4, 16, 28, 29], and the present study shows that most patients consider this an important symptom that may also be associated with diminished QOL. If serious other causes of rectal bleeding have been excluded, clinicians will be in a better position to provide reassurance to patients with regard to the clinical significance of this symptom.

The findings of this study also have important research implications. Symptoms in the BFQ are important to patients and are therefore appropriate targets for studies aimed at mitigating toxicity caused by PR. In particular, efforts to reduce incontinence, rectal bleeding, and the need for protective clothing should be emphasized in future clinical trials. The total BFQ score is significantly correlated with QOL, indicating that it is a valid measure of global bowel function. Furthermore, the content of the BFQ has been validated by the patients in this study. Thus, the BFQ can be used as a support measure to aid symptom awareness.

Conclusion

The BFQ has excellent content validity. Patients rated most BFQ symptoms as moderately important or very important, indicating that it is an appropriate tool for symptom assessment during and after PR. Our results also suggest that symptomatic problems after radiotherapy may adversely affect QOL. These criteria make them appropriate targets for future research to mitigate radiation-related bowel dysfunction.

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Abbreviations

BFQ Bowel function questionnaire
CVO Content validity questionnaire

NCCTG North Central Cancer Treatment Group

PR Pelvic Radiotherapy

QOL Quality of life

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Definition of Terms in the BFQ

Table 1

2

BFQ Symptom	Definition
Nocturnal bowel movements	Nocturnal bowel movements Needing to get up at night for bowel movements
Incontinence	Loss of control of bowel movements
Clustering	Needing to have a bowel movement within 30 minutes of a prior bowel movement
Protective clothing	Need for protective clothing or a pad
Stool-gas confusion	Unable to differentiate between stool and gas
Liquid bowel movements	Having liquid bowel movements
Urgency	Inability to delay bowel movements at least 15 minutes
Cramping	Cramping with bowel movements
Rectal bleeding	Blood with bowel movements

BFQ, bowel frequency questionnaire.

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Table 2

Bowel Function at 12 and 24 Months After Radiotherapy

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	1	12 Months		2	24 Months	
BFQ Symptom ^a Oc	ctreotide (n=44)	Placebo (n=50)	P Value	Octreotide (n=44) Placebo (n=50) P Value Octreotide (n=36) Placebo (n=38) P Value	Placebo (n=38)	P Value
Nocturnal bowel movements	20.5	22.0	98.	11.1	23.7	.16
Incontinence	15.9	8.2	.25	16.7	13.2	.67
Clustering	56.8	36.7	.05	41.7	39.5	.85
Protective clothing	23.3	8.2	.04	16.7	7.9	.25
Stool-gas confusion	32.6	24.5	.39	19.4	31.6	.23
Liquid bowel movements	27.3	14.6	.13	16.7	18.4	.84
Urgency	62.8	48.9	.19	58.3	43.2	.20
Cramping	34.1	18.4	80.	22.2	7.9	.08
Rectal bleeding	16.3	10.4	.41	17.1	5.4	.11

BFQ, bowel frequency questionnaire.

 $^{\it a}$ Complete description of symptoms is shown in Table 1.

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Table 3

Effect of BFQ Symptom on QOL Scores

				00	QOL Score, mean ^b	eanp			
		4 Weeks			12 Months			24 Months	
	BFQ Symptom	mptom		BFQ Sy	BFQ Symptom		BFQ Symptom	mptom	
BFQ Symptom ^a	Present	Absent	P Value	Present	Absent	P Value	Present	Absent	P Value
Nocturnal bowel movements	5.9	8.1	<.01	7.2	8.5	.01	7.9	8.7	.05
Incontinence	6.3	7.6	<.01	7.4	8.3	.03	8.6	8.5	86:
Clustering	8.9	8.0	<.01	7.8	8.6	.01	8.1	8.8	<.01
Protective clothing	7.4	7.1	.63	7.0	8.4	.01	8.4	8.5	.73
Stool-gas confusion	0.9	8.1	<.01	7.5	8.5	<.01	8.1	8.7	.13
Liquid bowel movements	6.4	7.8	<.01	7.3	8.5	<.01	8.2	8.6	.35
Urgency	8.9	8.1	<.01	8.1	8.5	.53	8.2	8.9	.00
Cramping	6.5	8.0	<.01	7.8	8.4	90.	8.0	8.6	.15
Rectal bleeding	6.4	7.7	<.01	7.9	8.3	.45	8.0	9.8	.13

BFQ, bowel frequency questionnaire; QOL, quality of life.

 $^{\it a}{\rm Complete}$ description of symptoms is shown in Table 1.

 $^{b}\mbox{Possible}$ scores ranged from 0–10 (higher values indicate better QOL).

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Table 4

Patient-Assessed Measures of Bowel Function Before and After Pelvic Radiotherapy^a

		Pati	Patients, %	
Bowel Function Measure	Baseline (n=124)	4 Weeks (n=105)	12 Months (n=92)	24 Months (n=73)
Not having to get up at night to have a bowel movement				
Not very important or moderately unimportant	17	19	20	11
Neutral	23	15	111	25
Moderately important	30	26	33	33
Very important	30	40	35	31
Able to maintain control of bowel movement				
Not very important or moderately unimportant	1	3	3	1
Neutral	ĸ	3	6	3
Moderately important	10	12	12	21
Very important	84	82	74	75
Not having a bowel movement within 30 minutes of a previous bowel movement				
Not very important or moderately unimportant	15	14	20	14
Neutral	31	27	25	30
Moderately important	27	31	30	34
Very important	27	27	25	22
Not having to wear protective clothing or a pad				
Not very important or moderately unimportant	4	5	35	∞
Neutral	9	7	8	10
Moderately important	15	21	18	10
Very important	75	89	69	73
Able to tell the difference between stool and gas				
Not very important or moderately unimportant	4	5	4	3
Neutral	13	10	111	7
Moderately important	30	25	34	34
Very important	53	09	51	26
Neutral	31	27	25	30
Not having liquid bowel movements				

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		Patie	Patients, %	
Bowel Function Measure	Baseline (n=124)	4 Weeks (n=105)	12 Months (n=92)	24 Months (n=73)
Not very important or moderately unimportant	4	9	4	4
Neutral	16	12	12	18
Moderately important	31	29	37	34
Very important	48	53	47	44
Able to delay having a bowel movement for at least 15 minutes				
Not very important or moderately unimportant	9	9	7	7
Neutral	15	6	16	13
Moderately important	40	37	40	44
Very important	39	49	37	37
Not having cramping with bowel movements				
Not very important or moderately unimportant	5	S	14	∞
Neutral	15	17	15	15
Moderately important	33	30	31	38
Very important	48	48	40	38
Not having blood in bowel movements				
Not very important or moderately unimportant	-	1	4	1
Neutral	9	4	9	S
Moderately important	10*	17	7	11
Very important	83**	78	82	82

^aAll percentages were rounded to the nearest whole number. Some percentage totals are slightly more or less than 100% because of rounding.

Table 5

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Importance of Individual BFQ Symptoms for Patients With and Without the Symptom

			Pati	Patients, $\%^b$		
	Symptom	Symptom at 4 Weeks	Symptom	Symptom at 12 Months	Symptom a	Symptom at 24 Months
${\rm BFQ}{\rm Symptom}^a$	Present	Absent	Present	Absent	Present	Absent
Nocturnal bowel movements	62	61	65	69	54	64
Incontinence	100	84	91	87	100	94
Clustering	57	51	53	99	50	59
Protective clothing	19	84	62	06	99	85
Stool-gas confusion	83	92	88	98	68	68
Liquid bowel movements	75	77	74	98	62	08
Urgency	42	77	84	70	76	81
Cramping	75	69	58	75	82	71
Rectal bleeding	81	06	92	06	100	92

 $^{^{\}it a}{\rm Complete}$ description of symptoms is shown in Table 1.

b Patients rated the symptom as "moderately important" or "very important."