Prospective Health-related Quality of Life Analysis for Patients Undergoing Radical Cystectomy and Urinary Diversion

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OBJECTIVE To better define health-related quality of life (HRQOL) for patients undergoing radical cystectomy (RC) and urinary diversion.

MATERIALS AND METHODS Patients undergoing RC and urinary diversion for urothelial carcinoma by 1 of 2 surgeons (G.D.S. or N.D.S.) had a HRQOL assessment at baseline and at follow-up using the validated, bladder cancer–specific Functional Assessment of Cancer Therapy–Vanderbilt Cystectomy Index questionnaire. The primary outcome was change in HRQOL between baseline and follow-up.

RESULTS From September 15, 2011, to July 23, 2012, 74 of 103 eligible patients were enrolled, and all but 1 completed the baseline Functional Assessment of Cancer Therapy–Vanderbilt Cystectomy Index leaving 73 patients in the study. Median age was 68 years (interquartile range, 60-74 years), 58 (78%) were Caucasian, 53 (73%) were ≥cT2, 45 (62%) underwent incontinent diversion, and the mean age-adjusted Charlson Comorbidity Index score was 2.4 ± 1.8, with no significant differences among the 73 participants and 30 nonparticipants. The median time from surgery to response was 175 days (interquartile range, 102-232 days), and the response rate was 67%, with 9 deaths during follow-up. Baseline HRQOL scores did not significantly differ between respondents and nonrespondents or between those living vs deceased. Overall, RC-specific, physical, social, and functional HRQOL scores did not differ from baseline to follow-up, whereas emotional HRQOL scores were significantly improved (15.7 ± 5.8 vs 18.1 ± 3.9, $P = .03$). Overall or domain-specific HRQOL measures did not differ significantly between patients undergoing incontinent (n = 27) vs continent (n = 16) diversions.

CONCLUSION Overall, HRQOL scores did not statistically differ from baseline to the median 6-month follow-up for patients undergoing RC and urinary diversion for urothelial carcinoma. Patients undergoing continent vs incontinent urinary diversions had similar overall HRQOL scores at follow-up. UROLOGY 84: 808–814, 2014. © 2014 Elsevier Inc.

A major impetus for the development of continent urinary diversion is to improve the health-related quality of life (HRQOL) of patients undergoing radical cystectomy (RC). Although the first continent urinary diversion was performed more than 150 years ago,[1] the last 50 years have witnessed a blossoming of diversion types and techniques.[2-7] The perioperative and long-term complication of several continent urinary diversions have been well described, but the HRQOL of those patients has not been adequately studied.[8,9]

A review of the post-RC HRQOL literature by Porter and Penson[10] in 2005 revealed that only 1 of 15 eligible studies were of a prospective design. Since that time, there has been increased interest in the subject along with the development of 2 bladder cancer–specific, validated HRQOL questionnaires.[11,12] The European Organization for Research and Treatment of Cancer (EORTC) is in the process of validating a third group of bladder cancer-specific HRQOL instruments, the EORTC QLQ-BLS24 and QLQ-BLM30.[13] In this study, we have used the validated, bladder cancer–specific Functional Assessment of Cancer Therapy–Vanderbilt Cystectomy Index (FACT-VCI). The absolute and change in HRQOL from baseline to follow-up were compared across patients undergoing RC and continent vs incontinent diversions. Preoperative and postoperative characteristics were assessed alongside diversion type in a multivariate fashion to study the effect of diversion on HRQOL.

MATERIALS AND METHODS

From September 15, 2011, to July 23, 2012, patients undergoing RC and urinary diversion by 1 of 2 surgeons (G.D.S. or N.D.S.)

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Table 1. Demographics of trial participants vs nonparticipants

Variables	Participant (n = 73)	Nonparticipant (n = 30)	*P* Value
Age median (IQR), y	68 (60-74)	69 (65-80)	.22
Gender, No.			
Male	57	21	.45
Female	16	9	
Race, No.			
Caucasian	57	23	.88
Non-Caucasian	16	7	
Diversion type			
Incontinent	45	18	1.00
Continent (ONB + IP = sum)	19 + 9 = 28	11 + 1 =12	
Preoperative chemotherapy or radiotherapy, No. (%)	22 (30)	10 (33)	.82
BMI median (IQR), kg/m^2	28 (24-32)	27 (23-29)	.08
Pathologic tumor stage, No. (%)			
≤pT2	37 (50.7)	18 (60)	.39
pT3/T4	36 (49.3)	12 (40)	
Pathologic node positive, No. (%)	20 (27.4)	8 (26.7)	.94
Age-adjusted Charlson Comorbidity Index, mean ± SD	2.4 ± 1.8	2.2 ± 1.5	.62
Clavien complications, No. (%)			.38
Class 1-2	30 (41)	15 (50)	
Deep venous thrombus	7 (9.6)	1 (3.3)	
Infectious	10 (13.7)	4 (13.3)	
Cardiac	4 (5.5)	0	
Ileus/GI related	4 (5.5)	8 (26.7)	
Blood transfusion	5 (6.8)	2 (6.7)	
Class ≥3	22 (30)	8 (27)	
GI bleeding	2 (2.7)	1 (3.3)	
Wound dehiscence	4 (5.5)	2 (6.7)	
Intra-abdominal abscess	6 (8.2)	2 (6.7)	
Myocardial infarction	1 (1.4)	0	
Sepsis	3 (4.2)	2 (6.7)	
Acute renal failure	1 (1.4)	1 (3.3)	
Death	5 (6.8)	0	

BMI, body mass index; GI, gastrointestinal; IP, Indiana pouch; IQR, interquartile range; ONB, orthotopic neobladder; SD, standard deviation.

were approached by a member of the clinical research staff for enrollment into this institutional review board–approved study. All patients underwent RC for oncologic indication. Both operating surgeons are senior faculty with expertise in the management of bladder cancer. Of 103 eligible patients, 74 consented for participation. Once consented, patients completed a preoperative HRQOL assessment using the validated FACT-VCI questionnaire and provided baseline education level, marital status, and income data. The FACT-VCI is a validated tool that includes the 27-item FACT-General (G) questionnaire and 17 urology-specific questions. All items are scored on a Likert scale of 0-4, with higher scores indicating higher HRQOL. Ten questions are reverse-ordered. The FACT-G questionnaire is divided into 4 domains: physical, social, emotional, and functional well-being. The questions, "I am able to have and maintain an erection," and "I am satisfied with my sex life," were studied separately from the overall HRQOL scores because the first was for men only and the second was optional.

A follow-up FACT-VCI questionnaire was mailed 2 months or more postoperatively to the 64 patients who were living. We waited 2 months to allow the patients to recover completely from surgery and minimize the effect of convalescence on HRQOL. Patients who failed to initially respond were contacted by a member of the research team and encouraged to complete the follow-up FACT-VCI. The tool has a reported correlation between first and second completions of 0.79, with a Cronbach α of >0.70 for internal consistency.[11] The primary outcomes were overall HRQOL and the change in HRQOL at baseline vs follow-up. The patient completed both questionnaires in the absence of a physician.

A comprehensive, prospectively maintained database was queried for all clinical, pathologic, and outcome data. All complications were graded according to the Clavien classification system.[14] Charlson Comorbidity Index scores were age-adjusted, with 1 point added per decade beyond 50 years. The online Social Security Death Index was queried when necessary.

Statistical analysis was performed using STATA 12 software (StataCorp LP, College Station, TX). Continuous and categoric variables were compared using 2-sided *t* tests and χ^2 tests, respectively. Univariate and multivariate analyses of HRQOL end points were performed using linear regression. A *P* value of <.05 was considered statistically significant.

Using a paired 2-sample *t* test to examine a difference in mean overall HRQOL between baseline and follow-up, with 43 subjects at significance level (α) of 0.05 and standard deviation of the difference of 24.5, we have 80% power to show a difference of 11 in overall HRQOL. Comparing adjusted overall HRQOL (follow-up − baseline) for continent vs incontinent patients, with 16 and 27 patients and standard deviation of the mean difference of 19.2, we have 80% power to show a difference of 20 with significance level of 0.05.

RESULTS

Of the 103 consecutive, eligible patients, 74 enrolled, and 73 completed the baseline FACT-VCI and were included