Original Article

Comparison of the quality of life between ileal conduit and orthotopic neobladder in post radical cystectomy bladder cancer male patients using the FACT-BL questionnaire

Napat Ditchaiwong[1], Supon Sriplakich[1], Thanakorn Booranachon-apha[2], Wasana Khampiwmar[2]

[1]Division of Urology, Department of Surgery, Faculty of Medicine, Chiang Mai University, Chiang Mai, [2]Division of Urology, Department of Surgery, Buddhachinaraj Hospital, Phitsanulok, Thailand

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Abstract

Objective: Radical cystectomy (RC) is standard treatment for bladder cancer. Removal of the bladder requires reconstruction of the lower urinary tract, a procedure that also has impact on the patient's quality of life (QoL). In Thailand, information pertinent to the level of the quality of life between ileal conduit and orthotopic neobladder is still limited. The objectives of this study are to evaluate the quality of life (primary outcome) and oncologic outcome (secondary outcome) of patients who underwent an Ileal Conduit (IC) or Orthotopic Neobladder (NB) using FACT-BL, a bladder-cancer-specific questionnaire.

Materials and Methods: One hundred and forty six patients underwent radical cystectomy and urinary diversion for bladder cancer from 2009 to 2019 at our institution. Out of these, 61 (42%) patients were asked to participate in this study. All 61, who were divided into two groups, 34 IC and 27 NB, completed the questionnaire, a survey response rate of 100%. Mean follow-up was 7 years 3 months.

Results: There were no statistically significant differences in ll FACT-G categories (PWB, SWB, EWB and FWB) between the two groups. Patients with neobladder had reported that they urinated more frequently than usual. Mean interest in sex was 49% in all patients and capability of maintaining an erection was 23%.
The mean total values of FACT-BL in IC and NB patients were 128.51 ± 15.51 and 126.70 ± 17.35, showing no significant difference.

Conclusion: Prinary diversion type does not appear to be associated with differential post-operative QoL and sexual satisfaction. There is a possibility that patients with neobladder urinate more frequently than before surgery but this did not reach statistical significance.

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Corresponding author: Supon Sriplakich

Address: Division of Urology, Department of Surgery, Faculty of Medicine, Chiang Mai University, Maharaj Nakorn Chiang Mai Hospital, 110 Intawaroros Road, Sriphum, Muang, Chiang Mai 50200, Thailand

E-mail: ssriplak@hotmail.com

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Introduction

The 10th most common cancer in the world is bladder cancer. Bladder cancer is over four times more common in men than women and the sixth most frequent and ninth most deadly neoplasm.[1] Radical cystectomy (RC) is the standard treatment for localized muscle-invasive bladder cancer, high-risk non-muscle invasive cancers, or cancers resistant to intravesical chemotherapy.[2]

Once a patient has had a cystectomy, a urinary reconstruction is needed which may have specific problems related to the surgery, such as urine leakage, change of body image and loss of sexual interest. All prospective studies published after 2011 have shown neobladder to have superior QoL outcomes compared to other urinary diversion types. NB is more successful than IC in terms of physical functioning, role functioning, social functioning, global health status/QoL and financial expenditure.[3,4]

FACT-BL, the Functional Assessment of Cancer Therapy – Bladder, is a 39 item instrument developed to measure five domains in bladder cancer patients. This tool has recently become available for use in conjunction with FACT-G, and its coefficients of reliability and validity are uniformly high. The ability of this scale to discriminate patients on the basis of stage of disease, performance status rating (PSR), and hospitalization status supports its high level of sensitivity.[5]

Although these validated instruments are assumed to be useful, few studies in Thailand have compared the QoL of patients with an ileal conduit (IC) or an orthotopic neobladder (NB), using the FACT-BL questionnaire.[6]

In this study, we assessed the QoL of patients who underwent different forms of urinary diversions, using the Thai version of the FACT-BL questionnaire. We examined differences in Quality of Life between Ileal Conduit and Orthotopic Neobladder in post radical cystectomy bladder cancer male patients by using the FACT-BL questionnaire that assesses specific symptoms, such as trouble controlling urine, body image appearance, sexual function and interest.

Materials and Methods

Study design

One hundred and forty-six patients underwent radical cystectomy and urinary diversion for bladder cancer from 2009 to 2019 at our institution. Out of these, 85 (58%) patients were deceased at the time of this study and the remaining 61 were asked to participate in this study. All 61 patients answered the questionnaire giving a survey response rate of 100%. 18 (30%) patients answered the questionnaire at OPD and 43 (70%) patients answered the questionnaire by phone. Each patient completed a consent form. These patients included 34 with IC and 27 with NB. Mean follow-up was 86.9 months.

QoL was assessed using FACT-BL. This score was calculated from physical, social, emotional, and functional well-being, and a bladder cancer subscale. Higher FACT scores indicated a higher level of QoL. The questionnaire was translated into Thai by FACIT.org. Napat Ditchaiwong ("Investigator") has been granted license to use the Thai version of the FACT-Bl.

The medical records of each patient were reviewed. Clinical and demographic parameters including age, time after the procedure at survey, time in surgery, type of diversion, and final pathological status, were recorded.

The Research Ethics Committee of the Faculty of Medicine, Chiang Mai University approved this study (study number: SUR 2562-06927) (Figure 1).

Study setting

This study is a double-center study carried out at Maharaj Nakorn Chiang Mai Hospital (Chiang Mai University Hospital) and Buddhachinaraj Hospital, Thailand. These are teaching and referral hospitals.

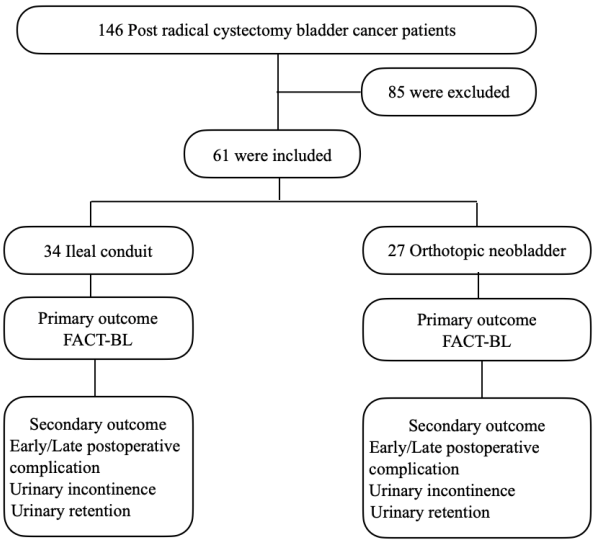

Figure 1. Flow diagram

Data collection and definitions

All data was collected from the hospital digital database, the Chiang Mai University registry database and the Buddhachinaraj Hospital database.

The 10-year data (2009-2019) was evaluated.

The primary outcome of the study, the quality of life, was calculated from the FACT-BL questionnaire.

The secondary outcome assessed the early/late postoperative complications, urinary incontinence and urinary retention

Statistical analysis

The categorical data is shown as number and percentage and is analyzed using Fisher's exact test. The continuous data (baseline characteristics) are shown as mean and standard deviation or median and interquartile range and are analyzed using Chi-square test for categorical variables. A p-value < 0.05 was used to denote statistically significant. The analysis was performed using STATA program version 14.0 (STATA corp, CS, TX, USA).

Results

Demographic and clinical features

The 61 patients who met the inclusion criteria were stratified into an IC group (n = 34) and an NB (n = 27) group (Table 1). There were significant differences in the numbers undergoing each operation type. Comparisons between the two groups showed no significant differences in age at surgery and survey, underlying disease and the follow up period. Patients undergoing NB were statistically significantly at a lower stage than IC (85.19% vs 58.82%).

12 (35%) of the 34 patients who underwent IC compared to 5 (18%) of the 27 patients with NB received systemic chemotherapy. There were no significant differences between these numbers.

Only one patient with IC had radiation therapy. Both groups of patients had different types of questionnaires due to COVID-19 situation. Most hospitals had preventative methods such as postponing follow up for disease stable patients.

Primary outcome

FACT-BL scores are shown in Table 2. Overall mean ± SD of FACT-BL was 127.71 ± 16.24. The mean ± SD of FACT-G in patients with IC and NB was 94.11 ± 12.87 and 93.49 ± 13.29, respectively, showing no significant differences. Both patient groups had high scores for EWB (25.20 ± 3.69 of total 28 points) and there was no significant difference between the groups. Total scores of bladder-cancer subscales were similar between each group.

The results of the bladder-cancer subscale questionnaire are shown in table 3 and table 4.

There were no significant differences in controlling urine between IC and NB. However, 22 (81%) out of 27 patients with NB reported that after surgery they urinate more frequently than usual, in comparison to 18 (52%) out of 34 patients with IC. 5 (15%) out of 34 and 8 (30%) out of 27 patients with IC and NB, respectively, feel it burns when they urinate these results were not significantly different. Half (50.8%) of post radical cystectomy patients have no interested in sex at all. 85% of IC and 67% of NB reported an inability to maintain an erection.

Feelings about the appearance of their bodies were not significantly different.

The questions, "I am embarrassed by my ostomy appliance" and, "caring for my ostomy appliance is difficult", was only on the questionnaire for IC patients. 70% of IC reported that they were not embarrassed by their ostomy appliance. Caring for their ostomy is found difficult in 73% of IC patients.

Secondary outcome

Oncological scores are shown in table 5.83% and 51% of patients had no early or late postoperative complications, respectively. There were no significant differences in early and late complications in both groups. Urinary incontinence and retention were reported only for NB.

68% and 96% of NB patients had no urinary incontinence or retention, respectively (Table 5).

Discussion

In this study, we used the Thai version of the FACT-BL for which we received licensure from FACIT.org. FACT-BL is a well-known respected questionnaire to assess differences in QoL among bladder cancer patients subjected to different types of urinary diversion.[7]

Dutta et al. used FACT-G in 72 patients with IC or NB and found no significant differences in total FACT-G scores between the groups which was the same as this study.8 However, they found

Table 1. Demographic and clinical features

Parameters	Total N=61	Type of diversion		P-value
		Ileal conduit (n=34)	Neobladder (n=27)	
Operation type n (%)				
Open RC	31 (50.82)	11 (32.35)	20 (74.07)	0.002
Lap RC	30 (49.18)	23 (67.65)	7 (25.93)	
Mean age at survey ± SD (years)	68.61 (8.82)	70.07±9.0	66.74±8.39	0.143
Mean age at surgery ± SD (years)	61.70 (9.40)	62.33±9.89	60.93±8.88	0.568
Median month at Follow up (IQR)	86.89 (62.27)	94 (56)	67(110)	0.135
U/D n (%)				0.204
0 = No	18 (29.63	10 (31.25)	8 (29.63)	
1 = DM	2 (7.41)	1 (3.13)	2 (7.41)	
2 = HT	7 (25.93)	7 (21.88)	7 (25.93)	
3 = Anemia	0 (0.00)	2 (6.25)	0 (0.00)	
5 = CVD	0 (0.00)	1 (3.13)	0 (0.00)	
7 = Renal disease	1 (3.70)	5 (15.63)	1 (3.70)	
10 = Previous Surgery	0 (0.00)	2 (6.25)	0 (0.00)	
12 = Multiple diseases	9 (33.33)	4 (12.50)	9 (33.33)	
PT stage n (%)				
0	1 (1.64)	0 (0.00)	1 (3.70)	0.443
1 = < T2	18 (29.51)	14 (41.18)	4 (14.81)	0.046
2 = T2	16 (59.26)	13 (38.24)	16 (59.26)	0.126
3 = T3	5 (18.52)	2 (5.88)	5 (18.52)	0.224
4 = T4	1 (3.70)	5 (14.71)	1 (3.70)	0.214
PN stage n (%)				
0 = N0	54 (88.52)	31 (91.18)	23 (85.19)	0.689
1 = N1	6 (9.84)	3 (8.82)	3 (11.11)	1.000
3 = N3	1 (1.64)	0 (0.00)	1 (3.70)	0.443
PM stage n (%)				-
M0	61 (100.00)	34 (100.00)	27 (100.00)	
M1	0 (0.00)	0 (0.00)	0 (0.00)	
Systemic chemo n (%)				0.064
0 = No	44 (72.13)	22 (64.71)	22 (81.48)	
1 = Neoadjuvant	10 (16.39)	9 (26.47)	1 (3.70)	
2 = Adjuvant	7 (11.48)	3 (8.82)	4 (14.81)	
Post op radiation therapy n (%)				1.000
0 = No	60 (98.36)	33 (97.06)	27 (100.00)	
1 = Yes	1 (1.64)	1 (2.94)	0 (0.00)	
Questionnaire n (%)				0.046
1 = Paper	18 (29.51)	14 (41.18)	4 (14.81)	
2 = Phone call	43 (70.49)	20 (58.82)	23 (85.19)	

RC = radical cystoprostatectomy, IC = ileal conduit, NB = neobladder, DM = diabetes mellitus, HT = hypertension, CVD = cardiovascular disease, multiple disease = more than 1 disease

that patients with NB had significantly better EWB and FWB than IC. In contrast to our study in which there were no differences between the groups in any domains of FACT-G.

Mansson et al. compared the QoL of 64 patients with a continent reservoir or NB using FACT-BL and observed no differences in any domain of FACT-G between the two groups.[6]

In their study, patients with a continence reservoir had significantly less trouble controlling urine and patients with NB had a significantly better appreciation of their body appearance. In our series, both groups of patients had no differences in controlling their urine and appreciation of their body appearance.

Table 2. Primary outcome (FACT-BL in the diversion groups)

Function (maximum)	Total N=61	Type of diversion		P-value
		Ileal conduit (n=34)	Neobladder (n=27)	
PWB (28)				0.819
Mean (SD)	25.20 (3.69)	25.29 (3.82)	25.07 (3.59)	
Median (p25, p75)	27 (24, 28)	27 (24, 28)	26 (23, 28)	
SWB (28)				0.509
Mean (SD)	22.80 (4.79)	23.17 (4.42)	22.34 (5.27)	
Median (p25, p75)	23.30 (20, 26.8)	23.65 (21, 26.8)	23 (18, 26.8)	
EWB (24)				0.641
Mean (SD)	22.36 (3.42)	22.18 (3.51)	22.59 (3.35)	
Median (p25, p75)	23 (21, 24)	22.5 (21, 24)	23 (21, 24)	
FWB (28)				0.993
Mean (SD)	23.48 (4.49)	23.47 (4.49)	23.48 (4.57)	
Median (p25, p75)	24 (22, 28)	24.5 (20, 28)	24 (22, 28)	
FACT-G (108)				0.855
Mean (SD)	93.84 (12.95)	94.11 (12.87)	93.49 (13.29)	
Median (p25, p75)	95 (86, 102)	96.5 (86, 101)	94 (84, 105)	
Bladder-specific subscale (48)				0.415
Mean (SD)	33.87 (5.62)	34.40 (5.32)	33.21 (6.01)	
Median (p25, p75)	34.8 (31, 38)	35 (32, 38)	33.6 (28.8, 37.2)	
FACT-BL TOI (104)				0.616
Mean (SD)	82.54 (10.73)	83.16 (10.64)	81.76 (10.99)	
Median (p25, p75)	84 (75, 91)	86.5 (75, 92)	80.8 (75, 90.2)	
FACT-BL (156)				0.6693
Mean (SD)	127.71 (16.24)	128.51 (15.51)	126.70 (17.35)	
Median (p25, p75)	129.2 (119, 139)	131 (119, 138)	128.2 (115.6, 142.4)	

PWB = physical well-being, SWB = social/family well-being, EWB = emotional well-being, FWB = functional well-being, FACT-G = functional assessment of cancer therapy – general, FACT-BL = functional assessment of cancer therapy – bladder

We found that our NB patients urinated significantly more frequently than usual.

Urinary incontinence following orthotopic NB replacement is a common finding in NB patients.[9] In contrast to stoma patients, IC patients easily manage their urine by using a urine bag for diversion all the time. This situation makes control of urine more easily manageable in comparison to NB patients.

With regard to external body scores, Bjerre BD et al. and Kikuchi et al. found that IC patients had a significantly poorer body image than those with NB.[10,11] This was in contrast to our study which found that both groups had no differences in their perception of body image.

Erectile dysfunction and sexual dysfunction in men are common after cystectomy and urinary diversion. Radical cystectomy without nerve sparing surgery also causes other factors that affect sexual function such as psychological issues, age, and health-related competing risks for ED. However, body image, partner response, and change in life course and sexual priorities, have received less attention.[12] Our study found that half of our patients were not interested in sex and a small majority of them were unable to maintain an erection. It may be important to counsel the patient about their sexual life after radical cystectomy.

Daytime and nighttime incontinence is common in NB patients following surgery, but improves considerably with time.[13] In our study, 32% of NB (median time at follow up 7 years 3 months) experienced urinary incontinence.

In males undergoing radical cystectomy with NB, retention requiring catheterization to void is uncommon. Freedom from any catheterization or retention at 5 years after RC was 77% and 88%, respectively.[14] In our study, 3.7% of NB (median month at follow up 7 years 3 months) had urinary retention.

Table 3. Answer to bladder-cancer subscale question

Bladder-specific subscale	Total N=61 n (%)	Type of diversion	
		Ileal conduit (n=34) n (%)	Neobladder (n=27) n (%)
BL1 I have trouble controlling my urine			
0 = Not at all	24 (39.34)	16 (47.06)	8 (29.63)
1 = A little bit	9 (14.75)	5 (14.71)	4 (14.81)
2 = Somewhat	12 (19.67)	6 (17.65)	6 (22.22)
3 = Quite a bit	10 (16.39)	3 (8.82)	7 (25.93)
4 = Very much	6 (9.84)	4 (11.76)	2 (7.41)
BL2 I urinate more frequently than usual			
0 = Not at all	21 (34.43)	16 (47.06)	5 (18.52)
1 = A little bit	15 (24.59)	8 (23.53)	7 (25.93)
2 = Somewhat	8 (13.11)	4 (11.76)	4 (14.81)
3 = Quite a bit	9 (14.75)	2 (5.88)	7 (25.93)
4 = Very much	8 (13.11)	4 (11.76)	4 (14.81)
BL3 It burns when I urinate			
0 = Not at all	48 (78.69)	29 (85.29)	19 (70.37)
1 = A little bit	6 (9.84)	2 (5.88)	4 (14.81)
2 = Somewhat	2 (3.28)	1 (2.94)	1 (3.70)
3 = Quite a bit	2 (3.28)	1 (2.94)	1 (3.70)
4 = Very much	3 (4.92)	1 (2.94)	2 (7.41)
BL4 I am interested in sex			
0 = Not at all	31 (50.82)	20 (58.82)	11 (40.74)
1 = A little bit	6 (9.84)	3 (8.82)	3 (11.11)
2 = Somewhat	18 (29.51)	7 (20.59)	11 (40.74)
3 = Quite a bit	3 (4.92)	3 (8.82)	0 (0.00)
4 = Very much	3 (4.92)	1 (2.94)	2 (7.41)
BL5 I am able to have and maintain an erection			
0 = Not at all	47 (77.05)	29 (85.29)	18 (66.67)
1 = A little bit	6 (9.84)	0 (0.00)	6 (22.22)
2 = Somewhat	4 (6.56)	2 (5.88)	2 (7.41)
3 = Quite a bit	4 (6.56)	3 (8.82)	1 (3.70)
4 = Very much	0 (0.00)	0 (0.00)	0 (0.00)
C7 I like the appearance of my body			
0 = Not at all	3 (4.92)	3 (8.82)	0 (0.00)
1 = A little bit	(0.00)	0 (0.00)	0 (0.00)
2 = Somewhat	10 (16.39)	7 (20.59)	3 (11.11)
3 = Quite a bit	19 (31.15)	11 (32.35)	8 (29.63)
4 = Very much	29 (47.54)	13 (38.24)	16 (59.26)
C8 I am embarrassed by my ostomy appliance			-
0 = Not at all	24 (70.59)	24 (70.59)	
1 = A little bit	2 (5.88)	2 (5.88)	
2 = Somewhat	5 (14.71)	5 (14.71)	
3 = Quite a bit	1 (2.94)	1 (2.94)	
4 = Very much	2 (5.88)	2 (5.88)	
C9 Caring for my ostomy appliance is difficult			-
0 = Not at all	9 (26.47)	9 (26.47)	
1 = A little bit	11 (32.35)	11 (32.35)	
2 = Somewhat	10 (29.41)	10 (29.41)	
3 = Quite a bit	3 (8.82)	3 (8.82)	
4 = Very much	1 (2.94)	1 (2.94)	

Table 4. Bladder-cancer subscale question (Yes vs No)

Bladder-specific subscale	Total N=61 n (%)	Type of diversion		P-value
		Ileal conduit (n=34) n (%)	Neobladder (n=27) n (%)	
BL1 I have trouble controlling my urine				0.196
0 = Not at all	24 (39.34)	16 (47.06)	8 (29.63)	
1 - 4	37 (60.66)	18 (52.94)	19 (70.37)	
BL2 I urinate more frequently than usual				0.030
0 = Not at all	21 (34.43)	16 (47.06)	5 (18.52)	
1 - 4	40 (65.57)	18 (52.94)	22 (81.48)	
BL3 It burns when I urinate				0.212
0 = Not at all	48 (78.69)	29 (85.29)	19 (70.37)	
1 - 4	13 (21.31)	5 (14.71)	8 (29.63)	
BL4 I am interested in sex				0.202
0 = Not at all	31 (50.82)	20 (58.82)	11 (40.74)	
1 - 4	30 (49.18)	14 (41.18)	16 (59.26)	
BL5 I am able to have and maintain an erection				0.126
0 = Not at all	47 (77.05)	29 (85.29)	18 (66.67)	
1 - 4	14 (22.95)	5 (14.71)	9 (33.33)	
C7 I like the appearance of my body				0.248
0 = Not at all	3 (4.92)	3 (8.82)	0 (0.00)	
1 - 4	58 (95.08)	31 (91.18)	27 (100.00)	

Neobladder patient did not answer for C8, C9 question

Table 5. Bladder-cancer subscale question (Yes vs No)

Oncological outcome	Total N=61 n (%)	Type of diversion		P-value
		Ileal conduit (n=34) n (%)	Neobladder (n=27) n (%)	
Early complication				0.974
0 = No	51 (83.61)	28 (82.35)	23 (85.19)	
2 = Bowel ileus	1 (1.64)	1 (2.94)	0 (0.00)	
3 = Bowel injury	2 (3.28)	1 (2.94)	1 (3.70)	
6 = Bowel obstruction	1 (1.64)	1 (2.94)	0 (0.00)	
7 = Wound Complication	3 (4.92)	1 (2.94)	2 (7.41)	
8 = Multi	3 (4.92)	2 (5.88)	1 (3.70)	
Late complication				0.225
0 = No	47 (77.05)	26 (76.47)	21 (77.78)	
1 = Parastromal hernia	3 (4.92)	3 (8.82)	0 (0.00)	
2 = Stone	2 (3.28)	0 (0.00)	2 (7.41)	
3 = UTI	3 (4.92)	2 (5.88)	1 (3.70)	
6 = Anastomatic stricture	4 (6.56)	1 (2.94)	3 (11.11)	
7 = Bowel obstruction	1 (1.64)	1 (2.94)	0 (0.00)	
8 = Multi	1 (1.64)	1 (2.94)	0 (0.00)	
Urinary incontinence				-
0 = No	17 (68.00)	0 (0.00)	17 (68.00)	
1 = Yes	8 (32.00)	0 (0.00)	8 (32.00)	
Urinary retention				-
0 = No	26 (96.30)	0 (0.00)	26 (96.30)	
1 = Yes	1 (3.70)	0 (0.00)	1 (3.70)	

UTI = urinary tract infection

In one study it was shown that in contrast to males, females undergoing continuous urinary diversion had worse FACT-BL scores in comparison with those with a neobladder.[15]

One point to mention is that the diapers necessary for neobladder patients are personal expenses while the ostomy bag in an ileal conduit patient is sponsored by the government.

There are several limitations of this study including firstly it was a cross-sectional study. The decision to perform any type of urinary diversion depends upon many considerations, including patient factors such as co-morbidity, age, body build and surgeon preferences. 32 (72%) out of 44 Maharaj Hospital patients underwent IC while 15 (88%) out of 17 Buddhachinaraj Hospital patients underwent NB. The type of surgery was dependent on the surgeon's decision. However, there were no differences in demographic and clinical features between groups, with the exception of operation type (open or laparoscopic). All radical cystectomy performed at Buddhachinaraj Hospital is by open procedure, therefore 74% of NB are open surgery.

Second, both groups of patients had different methods of completion of the questionnaires. Due to the COVID-19 situation, most hospitals had preventive methods of postponing follow up for disease stable patients, and answering the FACT-BL questionnaire face to face or by phone call may alter the results.

Third, this study was only reported for male patients and other studies have found that interest in sex and body appearance may differ in female patients.

Conclusions

In conclusion, based on data from this cross-sectional, non-randomized study with a small sample size, males treated with Ileal Conduit or Neobladder do not appear to experience differential post-operative QoL or sexual satisfaction. However, Neobladder patients seem to complain that they urinate more frequently than before surgery. Further randomized prospective studies are needed.

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Conflict of Interest

The authors declare no conflict of interest.

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