Urinary function following radical cystectomy and orthotopic neobladder urinary reconstruction

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Abstract

Introduction: An orthotopic neobladder urinary diversion aims to minimize the physical and psychological effects of radical cystectomy through avoidance of a stoma and maintenance of urethral voiding. Neobladder function reported in the literature ranges widely due to differences in patient selection and method of assessment. The objective of the study was to characterize functional outcomes of consecutive patients treated at a tertiary care hospital.
Methods: A historical cohort of patients who underwent radical cystectomy with a neobladder diversion performed at The Ottawa Hospital between January 2006 and December 2014 were reviewed. Outcomes of interest were urinary continence, use of clean intermittent catheterization (CIC), post-void residual volume, and uroflowmetry at three, six, and 12 months following cystectomy.
Results: During the study period, 158 neobladder diversions were performed. The mean age of patients was 63.1 years (standard deviation [SD] 8.1), and 81.7% were male. Significant daytime incontinence (>1 pad) three months following surgery was common (65%), but decreased to 8.6% by 12 months. Nighttime incontinence was also common at three months (54%) and improved at 12 months (20%). While no appreciable differences between men and women were observed for continence, more women performed CIC at 12 months post-surgery (59% of women; 9% of men; relative risk [RR] 0.15; 95% confidence interval [CI] 0.07–0.30). Among patients who did not catheterize, uroflowmetry and post-void residual volume parameters were stable between three and 12 months postoperative.
Conclusions: Daytime and nighttime incontinence is common in neobladder patients following surgery, but improves considerably with time. Correspondingly, many female neobladder patients at our institution use CIC.

Introduction

Bladder cancer is the fifth most common cancer in Canada. Approximately 8300 Canadians are diagnosed with bladder cancer annually, and 2300 die from the disease yearly.[1] Approximately one-third of patients with non-metastatic bladder cancer develop muscle-invasive disease,[2] where neoadjuvant chemotherapy and radical cystectomy remain the standards of care.[3,4]

Maintaining quality of life following radical cystectomy is an important consideration when choosing the method of urinary diversion. While an ileal conduit is the traditional form of urinary diversion, an orthotopic continent diversion (neobladder) is preferred by some patients, with an aim to achieve a better postoperative quality of life.[5-9] Creation of a neobladder allows patients to avoid a stoma and permits urethral voiding.[10] Patients who receive a neobladder often have better physical function and improved psychological well-being compared to patients with an ileal conduit.[9-11] Neobladders ideally function as a continent reservoir that allows for efficient urethral emptying. However, patients must be aware of the potential for both incontinence and urinary retention.[12] Currently, an accurate expectation of neobladder function is limited because studies have reported vast differences in risk. For example, the prevalence of complete day and night continence one year following surgery has been reported as low as 22% and as high as 63%.[13]

To adequately counsel patients, accurate data are needed to characterize postoperative function and adverse events of each type of diversion. In the U.S., 20% of patients receive a continent urinary diversion,[14] with high case volume hospitals performing a higher proportion of continent diversion compared to low case volume hospitals.[15] It is possible that some centres offer neobladders only to the healthiest patients and achieve superior functional outcomes compared to centres that endorse more liberal eligibility criteria. The purpose of this study was to evaluate the functional outcomes in patients receiving orthotopic neobladders at The Ottawa

Hospital, where approximately 50% of patients receive this form of lower urinary tract reconstruction.

Methods

After institutional research ethics board approval, a historical cohort study was conducted with consecutive patients from The Ottawa Hospital who underwent an open radical cystectomy with neobladder diversion from January 2006 to December 2014. All neobladders were created by surgeons who had fellowship training in urological oncology. At our centre, continent diversion options are presented to all patients without medical contraindications. While no strict eligibility criteria are used, in general, neobladder diversion is advocated for patients with good physical, cognitive, and renal function. Alternative forms of diversion (ileal conduit or continent catheterizable pouches) are offered to patients who are not neobladder candidates due to other medical conditions (e.g., renal dysfunction), pre-existing urinary incontinence, urethral strictures, or anterior urethral tumours.

Medical records were reviewed to capture baseline patient and tumour information. In all cases, an orthotopic neobladder (Studer method) was created with ureteral stents tethered to a 24 French urethral catheter. Ureteral stents were not routinely externalized, nor were suprapubic catheters routinely used. Patients received similar perioperative care based on a standardized institutional care pathway. The urethral catheter and ureteral stents were removed three weeks following surgery. Neobladder patients participate in teaching sessions and are taught to void using Credé's manoeuvre every hour during the day, extending the interval between voids by 10 minutes every week until they reach three hours between each voiding attempt. At night, patients were counselled to wake at least once to empty their neobladder.

Postoperative assessments

Postoperative neobladder function was assessed and documented during followup clinic visits. In general, patients were followed at least three, six, and 12 months following surgery, with further followup based on the intensity of cancer surveillance required. At each assessment, patients were asked to characterize their daytime and nighttime urinary function, including use of incontinence products. If incontinence products (pads) were used, patients were asked how many pads they used, regardless of type of pad or how saturated they became. The use of clean intermittent catheterization (CIC) was documented. In general, CIC is recommended at our centre when patients have complete urinary retention or if they have partial urinary retention and secondary signs and symptoms of retention (e.g., persistent urinary tract infection, overflow incontinence, or worsening renal function). Uroflowmetry and post-void residual volume via bladder ultrasound were performed by clinic nurses and documented in the medical record.

Using a standardized data collection form, severity of incontinence during the day and night was categorized as: fully continent (no use of pads); mild incontinence (one pad per day or night); or incontinent (two or more pads per day or night). Peak urinary flow, mean urinary flow, and post-void residual urine volume was abstracted. For all time points, the closest predefined period was used. For example, if a patient was seen in followup two months or four months postoperative, the corresponding data was used to populate the three-month post-surgery outcomes. If a patient was not assessed, that time point was documented as "missing." For patients who died during followup, functional information prior to their death was used and was censored after death.

Analysis

Given previous reports of differences in neobladder function between men and women, information was summarized and tabulated stratified by sex. Patient-reported continence, uroflowmetry characteristics, and post-void residual volume were presented for each postoperative time point. Univariable analysis was performed using t-tests or Chi-squared tests as appropriate. No correction was made for multiple testing and $p \leq 0.05$ was considered statistically significant. Analyses were performed using SAS (SAS Institute Inc., Cary, NC, U.S.).

Results

Cohort characteristics

A total of 158 patients underwent a radical cystectomy with neobladder diversion from 2006–2014. Mean patient age at surgery was 63.1 years (standard deviation [SD] 8.41), and the majority of patients were male (81.7%). Baseline characteristics of the cohort are presented in Table 1. Prior to cystectomy, there were no differences in baseline characteristics between male and female patients, with the exception of more men receiving neoadjuvant chemotherapy. Nine patients had prior pelvic radiation (five had previous chemoradiation to the bladder with curative intent, three received radiation for conditions other than bladder cancer, and one received palliative radiation for recalcitrant hematuria). Less than 10% of patients reported urinary incontinence prior to surgery. In all cases, preoperative incontinence was described by patients as mild or attributed to severe cancer-related bladder overactivity.

Neobladder functional data were not available for 17 patients at followup for the following reasons: five died before the three-month followup, seven patients had cancer

Table 1. Baseline patient characteristics

	Overall (n=158)	Male (n=129)	Female (n=29)	p
Demographics				
Age in years, mean (SD)	63.1 (8.4)	62.8 (8.8)	64.2 (6.6)	0.4
Cardiovascular disease, n (%)	35 (22.2)	31 (24.0)	4 (13.8)	0.2
Diabetes mellitus, n (%)	21 (13.3)	20 (15.5)	1 (3.5)	0.1
Hypertension, n (%)	71 (44.9)	56 (43.4)	15 (51.7)	0.4
Smoking history, n (%)	96 (61.2)	78 (60.9)	18 (62.1)	0.9
Neoadjuvant chemotherapy, n (%)	30 (19.0)	29 (22.5)	1 (3.5)	0.02
Pathology characteristics from cystectomy specimen				
AJCC T stage, n (%)				
CIS/T0/T1	81 (52.9)	67 (53.2)	14 (51.9)	0.7
T2	43 (28.1)	34 (27.0)	9 (33.3)	
T3/T4	29 (19.0)	25 (19.8)	4 (14.8)	
WHO grade, n (%)				
Low	13 (9.4)	11 (9.6)	2 (8.7)	1.0
High	125 (90.6)	104 (90.4)	21 (91.3)	
Tumour histology, n (%)				
Urothelial carcinoma	143 (93.5)	116 (92.8)	27 (96.4)	0.7
Variant histology	10 (6.5)	9 (7.2)	1 (3.6)	
Preoperative continence, n (%)				
Continent	148 (93.6)	122 (94.6)	26 (89.7)	0.4
Occasional incontinence	10 (6.4)	7 (5.4)	3 (10.3)	

AJCC T: American Joint Committee on Cancer Tumour stage; CIS: carcinoma in situ; SD: standard deviation; WHO: World Health Organization.

progression and were followed by medical oncology where functional data was not captured, four patients were lost to followup, and one patient was converted to an ileal conduit four weeks post-neobladder creation due to multiple medical conditions and complications, including wound and neobladder dehiscence.

Functional outcomes

Daytime and nighttime incontinence was common in the early postoperative period, but decreased substantially over time. By one year followup, approximately 70% of men and women did not use pads in the daytime, and less than 10% used more than one pad per day (Table 2). Long-term nighttime incontinence was more prevalent, with 60% requiring pads at night and 25% using more than one pad per night. While risk of incontinence was similar between men and woman, a larger proportion of women used CIC. At one year post-surgery, 59% of women used CIC compared to 9% of men (Table 2).

Uroflowmetry measurements and post-void residual volumes are presented in Table 3. Urine flow parameters did not change during followup. Women had higher flow rates, but this difference was not statistically significant. Median post-void residual volumes of patients who did not catheterize increased slightly over time, from 14 cc (interquartile range [IQR] 0–60) to 31 cc (IQR 0–87). At one year followup, there were significantly more women with high residual volumes using CIC.

Table 2. Daytime and nighttime incontinence

	Overall	Male	Female	p[a]
Total n	**158**	**129**	**29**	
Daytime incontinence				
3 months, n (%)[b]				0.9
No pads	45 (34.6)	35 (34.0)	10 (37.0)	
1 pad	44 (33.9)	36 (35.0)	8 (29.6)	
>1 pad	41 (31.5)	32 (31.0)	9 (33.4)	
Missing	28 (17.7)	26 (20.2)	2 (6.9)	
6 months, n (%)[b]				0.2
No pads	58 (47.9)	46 (47.4)	12 (50.0)	
1 pad	41 (33.9)	36 (37.1)	5 (20.8)	
>1 pad	22 (18.2)	15 (15.5)	7 (29.2)	
Missing	37 (23.4)	32 (24.8)	5 (17.2)	
12+ months, n (%)[b]				0.4
No pads	83 (70.9)	70 (71.4)	13 (68.4)	
1 pad	24 (20.5)	21 (21.4)	3 (15.8)	
>1 pad	10 (8.6)	7 (7.2)	3 (15.8)	
Missing	41 (25.9)	31 (24.0)	10 (34.5)	
Nighttime incontinence				
3 months, n (%)[b]				0.1
No pads	22 (16.7)	14 (13.3)	8 (29.6)	
1 pad	39 (29.5)	33 (31.4)	6 (22.2)	
>1 pad	71 (53.8)	59 (55.3)	13 (48.2)	
Missing	26 (16.5)	23 (17.8)	2 (6.9)	
6 months, n (%)[b]				0.2
No pads	35 (29.0)	25 (26.0)	10 (40.0)	
1 pad	43 (35.5)	38 (39.6)	5 (20.0)	
>1 pad	43 (35.5)	33 (34.4)	10 (40.0)	
Missing	37 (23.4)	33 (25.6)	4 (13.8)	
12+ months, n (%)[b]				0.2
No pads	48 (41.4)	37 (38.1)	11 (57.8)	
1 pad	45 (38.8)	41 (42.3)	4 (21.1)	
>1 pad	23 (19.8)	19 (19.6)	4 (21.1)	
Missing	42 (26.6)	32 (24.8)	10 (34.5)	
Intermittent catheterization				
3 months, n (%)	7 (5.1)	3 (2.7)	4 (14.8)	0.03
6 months, n (%)	10 (7.9)	5 (5.0)	5 (19.2)	0.03
12+ months, n (%)	22 (17.3)	9 (8.6)	13 (59.1)	<0.0001

[a]p corresponds to the comparison between male and female. [b]Proportions for continence status correspond to total number of patients with functional data.

Associations between patient characteristics and neobladder function

With the exception of sex, few baseline parameters were associated with neobladder function. In some cases, clinically significant associations were observed, but the cohort was underpowered to determine if the findings were due to chance. Patients who received neoadjuvant chemotherapy were more likely to experience daytime incontinence (relative risk [RR] 1.55; 95% confidence interval [CI] 0.85–2.85; p=0.15). Nighttime incontinence was more common in patients with diabetes (RR 1.41; 95% CI 1.04–1.91; p=0.03). While not sta-

tistically significant, older patients were more likely to experience daytime and nighttime incontinence (Table 4). Patients with a smoking history were more likely to perform CIC (RR 2.31; 95% CI 0.91–5.87; p=0.08), as did older women (Table 4). Patients who received chemotherapy were less likely to require CIC (RR 0.31; 95% CI 0.09–1.85; p=0.24), however, none of these associations were statistically significant.

Discussion

An orthotopic neobladder is an established urinary diversion option for patients who require a radical cystectomy. At our centre, we have adopted fairly liberal eligibility criteria for neobladder and approximately 50% of patients choose a neobladder diversion. These data show that most patients experience acceptable functional outcomes. Daytime and nighttime incontinence in neobladder patients is common following surgery, but improves considerably over time. By one year post-radical cystectomy, 71% and 40% use no pads during the day and night, respectively. Using current selection practices, it was found that continence was similar between men and women. Conversely, over time, the use of CIC increases following surgery, especially in women.

Previous publications report continence is achieved in 85–100% of patients during the day, and between 60–95% at night.[11,16] However, there have been reports of an even wider range of continence, with some overall continence rates as low as 18% and as high as 92% at followup periods beyond one year.[17,18] The definition of continence differs between studies, and variations in patient reporting makes it difficult to compare continence outcomes among institutions. For example, in this cohort, 20% of patients used one pad during the day and 40% used one pad at night. Often, the pad was described by patients as a "security pad" because of rare and minor incontinence. Similarly, Ahmadi et al reported 47% of patients use at least one pad during the day and 72% wear pads at night, but 47% of pad users were essentially dry.[19] It is clear that pad use may not always reflect the level of continence or patient satisfaction. A complete representation of patient continence should include not only number of pads, but also size of pads, degree of wetness, frequency of incontinence episodes, and most importantly, patient bother. There is a need for a validated neobladder-specific patient-reported outcome instrument to help inform future patients and to compare between surgical techniques.

Nighttime incontinence is more prevalent than daytime incontinence for both men and women. This difference is thought to be due to the absence of a "guarding" reflex, increased dwell time of concentrated urine that is diluted via osmosis through the neobladder mucosa, and potentially due to increased nocturnal urine production.[20] We observed that patients with diabetes have an increased risk of nighttime incontinence, consistent with previous publications.[19,21] It has been hypothesized that diabetic neuropathy may affect autonomic innervation of the urethral sphincter and urethral sensation has been suggested to contribute to incontinence.[21]

We observed that partial or complete urinary retention increased over time. In the present study, more than half

Table 3. Uroflowmetry and post-void residual urine measurements

	Overall	Male	Female	p[a]
Peak flow (cc/s)				
3 months, mean (SD)	16.1 (9.7)	15.3 (8.7)	22.1 (14.5)	0.2
6 months, mean (SD)	17.5 (10.3)	16.5 (9.5)	23.7 (13.4)	0.05
12 months, mean (SD)	18.0 (12.5)	17.6 (12.6)	21.7 (11.8)	0.4
Mean flow (cc/s)				
3 months, mean (SD)	7.4 (3.3)	7.3 (3.4)	8.3 (2.9)	0.5
6 months, mean (SD)	8.6 (5.7)	8.0 (5.1)	11.4 (7.8)	0.1
12 months, mean (SD)	7.9 (4.8)	7.9 (5.0)	8 (1.8)	0.9
Post-void residual volume (cc)				
3 months, median (IQR)[b]	14 (0,60)	17 (0,60)	2.5 (0,45)	0.4
<100 cc, n (%)	86 (75.4)	71 (77.2)	15 (68.2)	
100 cc–<500 cc, n (%)	19 (16.7)	16 (17.4)	3 (13.6)	0.2
≥500 cc or CIC, n (%)	9 (7.9)	5 (5.4)	4 (18.2)	
6 months, median (IQR)[b]	20 (0.56)	18.5 (0.57)	20 (0.40)	0.8
<100 cc, n (%)	75 (72.8)	60 (74.1)	15 (68.2)	
100 cc–<500 cc, n (%)	15 (14.6)	13 (16.0)	2 (9.1)	0.2
≥500 cc or CIC, n (%)	13 (12.6)	8 (9.9)	5 (22.7)	
12 months, median (IQR)[b]	31 (0.87)	31.5 (2.91)	0 (0.64)	0.1
100 cc, n (%)	79 (65.8)	69 (71.9)	10 (41.6)	
100–<500 cc, n (%)	17 (14.2)	16 (16.7)	1 (4.2)	<0.001
≥500 cc or CIC, n (%)	24 (20)	11 (11.4)	13 (54.2)	

[a]p corresponds to the comparison between male and female. [b]Median values presented exclude patients who performed CIC. CIC: clean intermittent catheterization; IQR: interquartile range; SD: standard deviation.

Table 4. Comparison of age group and neobladder function at 12 months stratified by sex

Age group	Male			Female		
	No pads	Pads	p	No pads	Pads	p
Daytime incontinence, n (%)			0.25			0.47
Age ≤60	32 (80)	8 (20)		8 (20)	1 (20)	
Age 60–70	29 (67.4)	14 (32.6)		14 (32.6)	5 (41.7)	
Age 70–80	9 (60)	6 (40)		6 (40)	0 (0)	
Nighttime incontinence, n (%)			0.09			0.41
Age ≤60	20 (51.3)	19 (48.7)		2 (40)	3 (60)	
Age 60–70	13 (29.6)	31 (70.5)		7 (58.3)	5 (41.7)	
Age 70–80	4 (28.6)	10 (71.4)		2 (100)	0 (0)	
Intermittent catheterization, n (%)	No CIC	CIC	0.57	No CIC	CIC	0.14
Age ≤60	38 (90.5)	4 (9.5)		4 (80)	1 (20)	
Age 60–70	43 (89.6)	5 (10.4)		5 (33.3)	10 (66.7)	
Age 70–80	15 (100)	0 (0)		0 (0)	2 (100)	

CIC: clean intermittent catheterization.

of women were self-catheterizing by one year following surgery. The proportion of patients in this study using CIC is at the upper end of what is reported in the literature.[22-25] Differences between institutions may be due to our routine use of post-void ultrasound and liberal recommendation of CIC for patients who do not completely empty their neobladder and have other symptoms, such as incontinence. It has been our observation that patients with retention have more incontinence episodes, which improves with the use of CIC. Many of our patients report better quality of life with CIC to avoid incontinence. Certainly, chronic urinary retention following neobladder diversion in women is prevalent, and women considering neobladder construction should be informed about the strong possibility of CIC.

There are several potential limitations to this study that should be considered when interpreting the results. Since this was a retrospective review, the timing of followup was not consistent for every patient and some patients had incomplete documentation of uroflow, post-void residual volume, or urinary function. Methods to document urinary function were consistent, but were not based on validated instruments. Associations between baseline patient characteristics and postoperative urinary function were limited due to a relatively small sample size. Despite these limitations, we have reported the functional outcomes of a reasonably large cohort. We have shown that continent urinary diversion is feasible in a substantial proportion of radical cystectomy patients with acceptable urinary function for most patients. Future prospective studies with validated and standardized outcome measures will be helpful to improve the precision of postoperative estimates of function.

Conclusion

Daytime and nighttime continence in neobladder patients improves during the first year following surgery. Correspondingly, post-void residual volumes increase and many female neobladder patients at our institution use CIC to avoid incontinence and prevent complications of retention. Goals of neobladder diversion include avoidance of a stoma, maintenance of continence, and urethral voiding. While some of these goals are frequently achieved, patients should be provided with detailed information to help them make an educated decision regarding treatment preferences.

Competing interests: Dr. Cagiannos has attended advisory boards for AbbVie and Ferring; and has received speaker honoraria from AbbVie, Acerus, and Ferring. Dr. Lavallée has attended advisory boards for Ferring and Sanofi; and has received a grant from Sanofi. Dr. Morash has attended advisory boards for AbbVie, Astellas, Ferring, Janssen, and Sanofi; and has participated in a clinical trial supported by AbbVie. Dr. Hickling has attended advisory boards for Pfizer; has been a speaker for Allergan, Astellas, and Pfizer; and has participated in a clinical trial supported by Astellas. The remaining authors report no competing personal or financial interests related to this work.

This paper has been peer-reviewed.

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