

# The Continent Aspect of Orthotopic Neobladder

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**Annotation:** Radical cystectomy (RC) remains the reference standard treatment for patients with muscle-invasive bladder cancer and the success of orthotopic urethral anastomosis surgeries has been demonstrated throughout time, thus these options should be presented to all patients who qualified. To evaluate the timing of neobladder continence post-operatively for both diurnal and night continence. During the period from JULY 2019 to OCTOBER 2021, a total of 20 patients with muscle invasive transitional cell carcinoma (TCC) of bladder (15 males and 5 females) who underwent radical cystectomy with orthotopic neobladder, their age between (35-70) years who fulfilled the inclusion criteria and completed at least 1year of follow up. This survey, the diurnal continence rate was 85% 12 months after surgery. The highest rate of nocturnal continence was achieved during follow up at 12 months after surgery is 60%.The mean age of patients who had urine continence was significantly lower than incontinent patients. Diabetes is associated with a poor prognosis for daytime and nighttime continence. RC and orthotopic urine diversion have a very good rates of daytime continence. It's important to focus on resolving nighttime incontinence, which may take more time to be improved. A good,

satisfactory functional continence results are achieved after orthotopic urine diversion, and this may be efficiently monitored with a validated questionnaire.

**Keywords:** Radical cystectomy, orthotopic neobladder, diabetes, satisfactory.

## Introduction

Radical cystectomy (RC) remains the reference standard treatment for patients with muscle-invasive transitional cell carcinoma (TCC) of the bladder<sup>(1)</sup>. The first reported urinary diversion into a segment of bowel was by Simon in 1852.<sup>(2)</sup> In 1950, Bricker refined and popularized the ileal conduit form of urinary diversion.<sup>(3)</sup> The ileal conduit introduced by Seiffert and popularized by Bricker has been used for half a century, and it is still considered a standard form of urinary diversion following cystectomy for bladder cancer<sup>(4)</sup>. One of the earliest continent cutaneous diversions in humans was described by Gilchrist et al. in 1950 incorporating the ileocecal valve as the continence mechanism and the distal ileum as a catheterizable stoma. However, this innovation attracted little attention at that time.<sup>(5)</sup> In 1982, Kock et al. subsequently reintroduced the concept of a continent cutaneous diversion with a technique that was originally developed for a continent ileostomy by incorporating an intussuscepted nipple valve to maintain continence and avoid reflux.<sup>(6)</sup> In animal experiments and then in humans, Kock demonstrated the importance of complete detubularization of the bowel segment and the double-folding technique that creates the most spherical shape possible and these concepts are the cornerstone of current cutaneous and orthotopic reservoirs.<sup>(6,7)</sup> Lemoine in 1913 performed the first orthotopic reconstruction in a human subject, converting a patient from a ureterosigmoidostomy to an orthotopic diversion by transposing a segment of sigmoid to the urethral stump<sup>(8)</sup>. Initially these techniques were applied only to male patients but in the mid 1990s, it was discovered through anatomic dissections and initial clinical experience that women could remain continent with a low-pressure reservoir and preservation of only the urethra itself.<sup>(9-11)</sup>

In the series from Ulm, Germany, only 16% of the patients undergoing cystectomy had medical contraindications to orthotopic diversion, and another 2% refused<sup>(12)</sup>. It was noted that residents in most residency programs do not get much practice with these operations.<sup>(13)</sup> In the United States, many cystectomies are done by surgeons who only conduct a few of the procedures per year<sup>(14)</sup>

All orthotopic reconstruction methods share three fundamental principles that are critical to their success. The patient must first have a functioning external sphincter mechanism and an unobstructed urethra. Second, to maintain a low pressure throughout the filling process, the reservoir must be suitably compliant. Finally, the reservoir must have adequate volume to allow for reasonable voiding intervals, in general, this should be at least 300 to 500 mL once the pouch is mature.<sup>(15)</sup>

The urethral sphincter is composed of both smooth and striated muscles in both males and females. The pudendal nerve innervates the striated rhabdosphincter, which appears to be the most important for continence. The architecture of the urethral sphincter mechanism has been described by careful neuroanatomic dissections and three-dimensional reconstructions of male and female cadavers.<sup>(16)</sup> In the female cadavers, the major portion of the striated muscle that makes up the rhabdosphincter is located on the ventral and lateral aspects of the urethra. No clearly defined line could be identified between the transverse smooth muscle cranially and the striated muscle caudally.<sup>(16)</sup> There are delicate fibers from the perineal portion of the pudendal nerve course underneath the urogenital diaphragm, entering the caudal portion of the urethra laterally.<sup>(17)</sup> The rhabdosphincter is a distinct, striated muscle that is not in direct touch with the

fibers of the levator ani muscle in male cadavers. These dissections proved that the male sphincter does not create a muscular ring that is horizontally positioned around the membranous urethra. Instead, the male rhabdosphincter is also "omega-shaped," principally ventral and lateral to the membranous urethra and prostate.<sup>(16)</sup> The innervation of the male rhabdosphincter was also found to originate from fine branches that arise off the pudendal nerve.

### **Patients and Method:**

A prospective study conducted at AL.SADER Medical City in Al-Najaf province during the period from July 2019 to October 2021. A total of **20** patients with muscle invasive TCC of bladder (15 males and 5 females) who underwent RC with ONB, their age ranges from (35-70) years who fulfilled the inclusion criteria and completed at least 1 year of follow up. Preoperative evaluation included Patient characteristics, history, clinical evaluation, urinalysis, full blood count, renal function test, liver function test, US, abdominal and pelvic CT, urethroscopy was performed preoperatively before going to RC with ONB in all patients. All surgeries were done by the same surgical team. Before any information was collected, we made sure to have each patient's verbal approval. Patients were told that their information would remain private throughout the study, and that it would be used solely for research purposes.

### ***Inclusion criteria:***

Patients documented by histopathology to have invasive bladder cancer who are surgically fit and accept all complications, and were totally continent preoperatively.

### ***Exclusion criteria:***

1. Those with impaired continence preoperatively.
2. History of radiotherapy.
3. Neurological problems.

## **SURGICAL TECHNIQUES FOR CONTINENCE PRESERVATION DURING RADICAL CYSTECTOMY**

### **Anterior Apical Dissection in the Male Patient**

During a typical cystectomy, the bladder and prostate will both be completely separated from the rectum before the urethral dissection is performed. The prostatic apex should not be reached through posterior dissection distally. The posterior pedicles detached at the end, and after that, the prostate was dissected retrogradely from the rectum. The endopelvic fascia cutted immediately close to the prostate, and the levator muscles were gently swept away from the lateral and apical regions of the prostate. Under the pubis and to the side of the deep dorsal venous complex, the puboprostatic ligaments were noted and slightly separated. In the control the DVC absorbable suture were used to avoid the risk for erosion of suture, clips, or staples into the urethral anastomosis. The venous complex was separated towards the apex of the prostate after it has been ligated. Deep suture bites into the complex or levator muscles were avoided since they may impair the continence mechanism. The anterior urethra was then incised slightly beyond the apex of the prostate. Before complete urethral division, six 2-0 absorbable polyglycolic acid sutures were placed circumferentially in the urethra under direct vision, carefully integrating just the urethral wall and avoiding the levator muscles.

The urethral catheter was clamped and distally divided. Two further sutures were subsequently used to include the rectourethralis muscle and the caudal portion of the Denonvilliers fascia. The specimen is then extracted when the posterior urethra is separated. To identify their position, the urethral sutures were labeled and covered with a towel until the urethroenteric anastomosis is conducted.

## Urethra Preservation in a Female Patient

The uterus, cervix, and ovaries were all removed during a standard female cystectomy (anterior exenteration). After the posterior pedicles had been divided, the bladder was carefully dissected away from the anterior vaginal wall. Caudal dissection was performed to reach the vesicourethral junction. Tugging on the Foley catheter balloon to place it at the bladder neck aids in locating this juncture. Sharp dissection was performed to remove the bladder neck and the first 0.5 cm of the urethra from the vagina. At this time, the specimen was attached only by the urethra itself. After marking the incision site just distal to the vesicourethral junction, the Foley catheter could be withdrawn and a pedicle clamp applied across the bladder neck to avoid tumor spillage when the urethra is transected. Individual 2-0 absorbable sutures were put circumferentially into the urethra, labeled, and set aside in 8 to 10 locations. After that, the vagina closed at the apex using absorbable suture and suspended to the Cooper ligament or preserved cut ends of the round ligaments, to avoid postoperative vaginal prolapse.

## Bowel Segment Selection

Reservoirs made of detubularized ileum and the ureters implanted directly into a small tabularized chimney on a standard **W** ileal neobladder without antireflux mechanisms.

## Ileal Neobladder (Hautmann Pouch)

This neobladder is a spherical (**W** design) ileal reservoir with a high capacity, 40 cm of ileum is used. A traction suture placed along the antimesenteric boundary to designate the most easily accessible ileal region. The isolated bowel segment was then arranged in a **W** shape and opened along the antimesenteric border, except for a 5-cm section at the traction suture, where the incision was arched to form a U-shaped flap. The four **W** limbs were then sutured together with a continuous absorbable suture. In the location for the urethral anastomosis, a tiny full-thickness section of bowel is removed, and the sutures are knotted from inside the neobladder. The ureters were implanted from inside the neobladder through a tiny incision in the ileum at a suitable spot after the ileal neobladder is placed in the pelvis and the urethral sutures are knotted. The remaining anterior wall was subsequently sutured with a running absorbable suture. After that drain left in place, closure of layers done, and the patient discharged with a 16 Fr. Foley catheter and 20 Fr. SPC.

A CBC, RFT, electrolyte, and serum protein level were all examined in the first few postoperative days. The patient was instructed to remain NPO for the first few days post-operatively after which oral liquids and food were gradually introduced. To reduce the possibility of intestinal paralysis, morphine and its derivatives were used with caution.

The reservoir was irrigated with 0.9% NaCl and mucus was aspirated every 8 hours and as necessary. Patient discharged home between 7-10 days.

On the next visit, after (3-4) weeks postoperatively, checking of pouch by pouchogram, and then foley removed after few days, then SPC removal was done. After foley removal, observation of urination – stop test, cystogramic urination done, and patient followed by pad usage questionnaire (Figure 1). in first 3,6, and 12-months post-op. Cystoscopic assessment of the anastomosis site and the pouch at time of DJ removal at (4) weeks post operatively. After the urethral catheter was removed, patients are given the opportunity to fill out a questionnaire about their continence (**Figure 1**). The questionnaires inquire how often the pads were utilized (day, night, or both) and the total number of pads employed. In addition, patients were asked to provide ratings for how moist their pads are both during the day and at night. Patients are also questioned about their daily catheterization habits.

Patients were judged to be continent if they were not using pads at all during a given time period or if they reported their pads to be "totally dry" (day or night). In order to further interpret the data, questionnaires were done on regular visits in less than 3-, 6-, and 12-months following

surgery. Patients who were undergoing clean intermittent catheterization (CIC) were not excluded from participation.

Structural alterations in continence mechanisms are a part of urinary diversion with ONB. Timed voiding using voluntary sphincter relaxation, Valsalva procedures, and postural strategies is necessary for individuals who have lost bladder stretch reflexes and filling feeling. Our study is to employ a validated questionnaire to prospectively assess continence outcomes in RC patients with ONB.

### Statistical analysis:

Statistical analysis was performed using IBM® SPSS® version 23 for Windows. Chi-square test was used to analyze the association between categorical variables, Fisher's Exact test was used instead of the former when needed. Independent Samples T-test was used to test the statistical significance of the difference between two variable or more, respectively. P-value less than 0.05 was considered significant throughout the study.

### Results

There were 20 patients enrolled in this study who underwent open RC and ONB. There have been 15(75%) males and 5(25%) females. Their mean age was  $51.0 \pm 10.24$  years (range 35-70 years). The mean BMI was  $27.6 \pm 6.22$  kg/m<sup>2</sup>- (range, 18-40) kg/m<sup>2</sup>. Three (15%) patients were diabetic. The variables taken into analysis were age and diabetes.

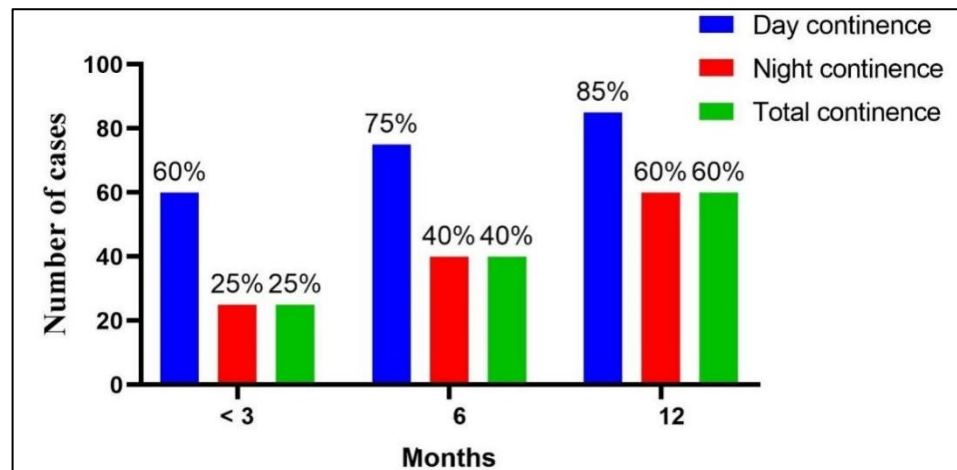
**Table-1: Basic characteristics of the study group**

Study variables		
Age (years) Mean± SD		51.0± 10.24
Gender	Male Number (%)	15 (75.0)
	Female Number (%)	5 (25.0)
BMI (kg/m <sup>2</sup> ) Mean± SD		27.6± 6.22
Diabetes Number (%)		3 (15.0)
Total number (%)		20 (100.0)

This survey was taken within three months following surgery, 60% of patients reported continence during the day. The diurnal continence rate hit its highest point 12 months after surgery (which is the maximum follow up period of our study) is 85%. Within three months of surgery, 25% of patients reported overnight continence. The highest rate of nocturnal continence was achieved during follow up at 12 months after surgery is 60%. The percentage of patients who reported having daytime and overnight continence increased from 25 % at three months after surgery to 60% at 12 months post-surgery. As shown in Table-2 and Figure-2.

**Table-2: Continence rates according to time and postoperative interval**

Postoperative Interval	Day time continent		Night time continent		Totally continent		P-value
	Number	%	Number	%	Number	%	
<3 months	12	60	5	25	5	25	0.905.
6 months	15	75	8	40	8	40	
12 months	17	85	12	60	12	60	



**Figure-2: Bar chart showing the distribution of continence according to postoperative duration**

The mean age of patients who had urine continence was significantly lower than incontinent patients throughout the study period as shown in Table-3.

**Table-3: Distribution of mean age according to continence status postoperatively**

Postoperative Interval		Age in the Continent group (year)	Age in the incontinent group (year)	P-value
		Mean± SD	Mean± SD	
Day time	<3 months	44.25±5.36	61.13±6.64	<0.001
	6 months	46.33±6.47	65±5	<0.001
	12 months	47.94±7.59	68.33±2.08	<0.001
Night time	<3 months	39±2.35	55±8.49	<0.001
	6 months	41.38±4.1	57.42±7.6	<0.001
	12 months	43±5	59±7.4	<0.001

After the operation, we kept track of the number of pads that were utilized both during the day and at night. The number of patients who required three or more pads on a daily basis dropped from 20% during the first three months after surgery to 10% at 12 months after surgery.

**Table-4: Distribution of pad use during the day time according to postoperative Interval**

Postoperative Interval	No pad		One pad		Two pads		Three pads		P-value
	No.	%	No.	%	No.	%	No.	%	
<3 months	4	20	7	35	5	25	4	20	0.326
6 months	9	45	4	20	4	20	3	15	
12 months	12	60	3	15	3	15	2	10	

Throughout the different postoperative time periods the amount of wetness was measured. One patient stated that pads were "wet" and one report that it was soaked during the peak period of daytime continence (12 months). This was a considerable improvement as during the first three months postoperatively 25% and 12.5% of pad users during the day reported having their pads wet or soaked, respectively. As shown in Table-4

**Table-5: Distribution of pad wetting during the day time according to postoperative Interval**

Postoperative Interval	Number of patients	Almost dry		Wet		Soaked		P-value
		No.	%	No.	%	No.	%	
<3 months	16	10	62.5	4	25	2	12.5	0.973

6 months	11	8	72.7	2	18.2	1	9.1	
12 months	6	4	66.7	1	16.7	1	16.7	

## Discussion

The use of orthotopic bladder replacement as a method of urinary diversion after cystectomy has become increasingly common.<sup>(21)</sup> The mortality rate following surgery is estimated to be somewhere around 2%, according to the majority of publications.<sup>(22)</sup>

Depending on the definition of continence that is used, there is a significant amount of variation in the daytime continence rates that have been reported in the research. These percentages range from 80% to 98% in (4-11) years follow up period in multiple studies<sup>(23)</sup>. In the literature on this group, total dryness without the need for protection is a typical descriptor.<sup>(24)</sup> Another definition is the objective loss of 1 gram of urine or less during 40 minutes of provoking incontinence testing, while others include not needing to use pads, catheters, or any other kind of prophylaxis<sup>(25)</sup>

The data that we obtained demonstrate a trend that is fairly similar for daytime continence, with a maximum value of 85% occurring between 6 and 12 months following surgery (Table 1) and (Figure-2). In contrast to the fact that more than half of patients achieve daytime continence by 3 months, the overnight continence rate appears to peak later, which may indicate that neobladder stretching and compliance contribute to the establishment of nighttime continence. In addition, in each time period, fewer patients report having complete bladder control both during the day and at night. Our rates peak is 60% at 12 months postoperatively. In contrast Abol-Enein et al. claims 80% nightly continence by 38 ± 25 months after RC, and in multiple other studies, night time continence was about 72-80% over different follow up periods<sup>(26)</sup>. Variations in the documentation of nocturnal voiding may account for some of the discrepancies in reported overnight continence. Although we did not ask about midnight awakenings in our survey, Studer et al. found that 79% of patients who set an alarm were able to maintain their continence during the night<sup>(15)</sup>. Steven et al. defined continence as no urine leak with no more than 2 to 3 nightly awakenings to urinate as part of their subjective assessment<sup>(27)</sup>.

Further, employing specified, standardized criteria for continence and a validated questionnaire, may aid to discover sources of bias unrecognized in prior retrospective research that depended on surgeon reported evaluations.<sup>(19,36,39)</sup>

In contrast to studies that only do a single evaluation, the research that we are conducting is a prospective evaluation of continence in all of the neobladder patients who are scheduled for follow-up. We were able to establish when individuals become continent by having a group of questionnaire responses from each patient during the course of their ongoing care. This strategy is similar to the existing researches on continence after radical prostatectomy.<sup>(28-30)</sup>

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