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Original Article

Neobladder long term follow-up

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KEYWORDS

Ileocecal bladder;
Indiana pouch;
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Abstract One of the commonest forms of orthotopic bladder substitution for bladder cancer survivors, used in our institute, is the use of ileocecal segment. Sometimes, the need for Indiana pouch heterotopic continent diversion arises.

Aim: To compare the long-term effect of orthotopic ileocecal bladder and heterotopic Indiana pouch following radical cystectomy in bladder cancer patients.

Patients and methods: Between January 2008 and December 2011, 91 patients underwent radical cystectomy/anterior pelvic exenteration and orthotopic ileocecal bladder reconstruction (61 patients) and Indiana pouch (30 patients), when orthotopic diversion could not be technically or oncologically feasible.

Results: Convalescence was uneventful in most patients. All minor and major urinary leakage cases, in both diversions groups, were successfully conservatively treated. Only one patient in the ileocecal group with major urinary leak required re-exploration with successful revision of uretero-colonic anastomosis. Only one patient in the Indiana pouch group had accidentally discovered sub-centimetric stone, which was simply expelled. The overall survival proportion of ileocecal group was 100% compared to 80% in the Indiana pouch group ($p < 0.001$). The disease free survival proportion of ileocecal group was 90.8% compared to 80% in the Indiana pouch group ($p = 0.076$). Effective comparative daytime and nighttime urinary continence as well as renal function deterioration were not statistically significant between both reconstruction types.

Conclusion: Both ileocecal bladder and Indiana pouch are safe procedures in regard to long-term effects over kidney function following radical cystectomy.

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Introduction

In Egypt, bladder cancer reflects a major health problem as it is the most common cancer seen in males (14% of all cancers) [1]. Bladder cancer survivors, face a multitude of health-related consequences following cystectomy. These are mostly related to urinary diversion and reconstruction. While improvements in perioperative care have decreased the surgical morbidity following cystectomy, the complications and

functional consequences associated with urinary diversion remain problematic [2].

The Fourth International Consensus Conference on bladder cancer endorsed orthotopic bladder reconstruction as the procedure of choice in properly selected patients [3]. The risk of urethral recurrence after radical cystectomy for transitional cell carcinoma is reported between 4% and 18% in the literature [4]. Multifocal bladder tumors, diffused carcinoma in situ, cancer at the bladder neck and prostatic involvement are the most important risk factors for predicting urethral recurrence [5–8]. In such circumstances, the need for heterotopic continent diversions arises as *kokh* an Indiana pouches. Nevertheless, a critical evaluation of the kidney function is mandatory in all patients when any continent diversion is considered [9,10].

Several techniques are available for orthotopic bladder substitution, one of the commonest forms used in our institute are the use of ileocecal segment as an orthotopic bladder substitute which has been used by Khafagy using the ileocecal region as an artificial bladder because of its valve that would protect the kidneys from the back pressure exerted by the external urethral sphincter, which theoretically prevents urine reflux. The other form for orthotopic bladder substitution is the use of the cecal segment as a low pressure reservoir [11].

Aim of the study

In this study we compare the long-term effect of two forms of urinary diversion (orthotopic ileocecal bladder and heterotopic Indiana pouch) following radical cystectomy in patients with bladder cancer as regarding: continence, frequency of voiding, postoperative kidney function, back pressure changes, reflux, and pouch related complications.

Patients and methods

Ninety-one patients underwent radical cystectomy or anterior pelvic exenteration and urinary diversion in the form of orthotopic ileocecal bladder reconstruction (61 patients) and Indiana pouch (30 patients) between January 2008 and December 2011.

All patients presented with invasive carcinoma of the bladder. Indiana pouch was adopted in patients to whom orthotopic diversion could not be performed due to:

- Basal tumor involving prostatic urethra in males or membranous urethra in females.
- Severe inflammatory bowel disease.
- Too short mesocolon that prevents the cecum to reach the urethra.

Preoperative medical assessment included complete, routine, laboratory tests in addition to cardiological assessment. Cystoscopy was done for all patients to take a biopsy from the lesion and to localize the site of the tumor and its distance from membranous urethra, mainly to exclude patients with any lesions close to – or less than – 2 cm, or an invaded membranous urethra. The stage of the disease was evaluated by clinical assessment, computerized tomography, routine plain chest X-ray and metastatic work-up, as indicated. Liver function was considered adequate when serum albumin was

> 3 gm/dl and prothromb in concentration > 75%. Creatinine clearance < 50 ml per min was considered a contraindication for ileocecal orthotopic neobladder.

Only patients with tumors classified as T1–T3 were included in this study. An informed consent was provided by all patients preoperatively, in which the possibility of an alternate reconstruction or urinary diversion in relation to possible adverse intraoperative findings, was explained and documented.

Indiana pouch reconstruction used the ileocecal part of the gut, using a segment, starting from a point in the ileum 10–12 cm proximal to the ileocecal valve down to another point 30–35 cm down the right colon. Following appendectomy, the cecum is opened, both ureters tunneled in its mucosa, and then the colon re-sutured. An ileal tube in then tapered over a catheter and extubated through the abdominal wall, preferably at the umbilicus.

All intra-operative and post-operative data were recorded, including duration of operation, intraoperative blood loss, the duration of indwelling catheter, and postoperative pouch-related complications. All our patients were evaluated postoperatively every 3 months by clinical examinations (voiding frequency, the ability to maintain continence, and urination), laboratory assessment (including renal profile, serum electrolytes and blood picture), and radiological investigations using ultrasonography, and chest X-rays. Computerized tomography was done every 6 months. Urodynamic study was done between 6 and 8 months postoperatively. The least period of follow up was 36 months.

Continence was strictly defined as excellent if the patient was completely dry at all times, good if there were occasional or sporadic episodes of leakage but no need for protection, fair if no more than a single pad was required for 24 h, and unsatisfactory if more than one pad was required within 24 h. Incontinence was further divided into nocturnal or daytime. Excellent, good and fair grades were considered as effective continence.

Statistical methods

Data was analyzed using IBM SPSS Advanced Statistics version 20.0 (SPSS Inc., Chicago, IL). Numerical data were expressed as mean and standard deviation. Qualitative data were expressed as frequency and percentage. Chi-square test (Fisher's exact test) was used to examine the relation between qualitative variables. For quantitative data, comparison between two groups was done using independent sample *t*-test survival analysis was done using Kaplan–Meier method and comparison between two survival curves was done using log-rank test. A *p*-value < 0.05 was considered significant.

Results

The mean age of all patients was 55.2 ± 5.5 years (range: 32–66 years). The mean age of patients in ileocecal bladder group was 56.3 ± 5.8 , while it was 54.4 ± 4.8 years in Indiana pouch group (*p* = 0.125). All patients were males except for only 4 females who underwent Indiana pouch. Pathological evaluation of all patients is presented in Table 1. The two groups were comparable pathologically in cell type (*p* = 0.737), stage (*p* = 0.460) and lymph node status (*p* = 0.402).

Pathological criteria	Ileocecal bladder (<i>n</i> = 61) No. (%)	Indiana pouch (<i>n</i> = 30) No. (%)	Total No. (%)	<i>p</i> -Value
<i>Cell type</i>				
TCC	31 (50.8)	19 (63.3)	50 (54.9)	0.737
SCC	29 (47.5)	11 (36.7)	40 (44.0)	
Adenocarcinoma	1 (1.6)	0 (0.0)	1 (1.1)	
<i>Pathological stage</i>				
pT2	16 (26.2)	6 (20.0)	22 (24.2)	0.460
pT3	43 (70.5)	24 (80.0)	67 (73.6)	
pT4	2 (3.3)	0 (0.0)	2 (2.2)	
<i>Nodal status</i>				
LN's negative patients	42 (68.9)	18 (60.0)	60 (65.9)	0.402
LN's positive patients	19 (31.1)	12 (40.0)	31 (34.1)	

Complications	Ileocecal bladder (<i>n</i> = 61) No. (%)	Indiana pouch (<i>n</i> = 30) No. (%)	<i>p</i> -Value
A. Early complications	20 (32.8)	7 (23.3)	0.353
<i>Reconstruction related</i>			
Minor urinary leak	8 (13)	2 (6.7)	0.197
Major urinary leak	2 (3)	0 (0)	
<i>Non-reconstruction related</i>			
Chest infection	1 (1.6)	5 (16.6)	0.975
Wound sepsis	9 (14.8)	0 (0)	*
Burst abdomen	0 (0.0)	4 (13.3)	0.856
Rectal tear & fecal fistula	1 (1.6)	2 (6.7)	*
		1 (3.3)	*

* *p* Value is not calculated owing to small number of cases.

Indiana pouch procedure was lengthier and accompanied with significantly more blood loss. The mean duration of the surgical procedure in the ileocecal group was 4.3 ± 0.4 h compared to 5.3 ± 0.2 h in the Indiana pouch group ($p < 0.001$). The mean intraoperative blood loss in the ileocecal group was 625.5 ± 194.6 in comparison to 1160.6 ± 344.2 in the Indiana pouch group ($p < 0.001$).

Early postoperative complications

Convalescence was uneventful in most patients, except for some complications detailed in Table 2. Chest infections were treated by proper antibiotics and chest exercise. All cases with wound infection were controlled by repeated dressings, only one case in each group developed systemic manifestations [medium grade fever, leukocytosis and elevated C-reactive protein (CRP)] controlled by additional oral antibiotics for 5 days. Two cases with burst abdomen were treated by re-exploration and closure by tension sutures. The two cases with rectal tear were treated by primary closure, with only one of them (in the ileocecal group) required a covering temporary loop colostomy, to avoid recto-pouch fistula, which was closed 2 months later.

All minor and major urinary leakage cases, in both diversions groups, where successfully conservatively treated through delayed intra-abdominal drains removal, until the leakage stopped; usually by the 11th–12th postoperative day for the minor and 21th postoperative day for one of the major leakage cases. One patient in the ileocecal group with major urinary leak, in whom the CT with contrast revealed complete

disruption of uretero-colonic anastomosis, required re-exploration on the 14th postoperative day with successful revision of uretero-colonic anastomosis.

Late postoperative complications

During the follow up period, only one patient in the Indiana pouch group had accidentally discovered sub-centimetric stone during self-catheterization 9 months postoperatively, which was simply expelled with no further stone formation during the follow up period.

After a median follow up period of 40.7 months (range: 10–46 months), no disease-related mortality was observed in the ileocecal bladder group; overall survival proportion 100% at 3 years. The overall survival proportion of the Indiana pouch group was 80% ($p < 0.001$, Fig. 1). Four cases (6.6%) of ileocecal bladder group developed local recurrence; one of them (1.6%) also developed chest metastases. Three cases (10.0%) of Indiana pouch group developed local recurrence. These were among 6 cases (20.0%) who developed distant metastases and eventually died. The disease free-survival (DFS) proportion was 90.8% in ileocecal bladder group and 80.0% Indiana pouch group ($p = 0.076$, Fig. 2).

Postoperative urinary continence

Urinary continence results for both reconstructions are detailed in Table 3. There was no significant difference between

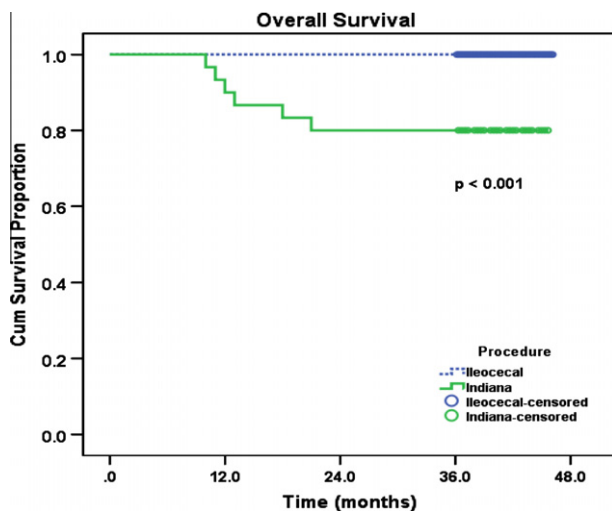


Figure 1 Overall survival curve of the two studied groups.

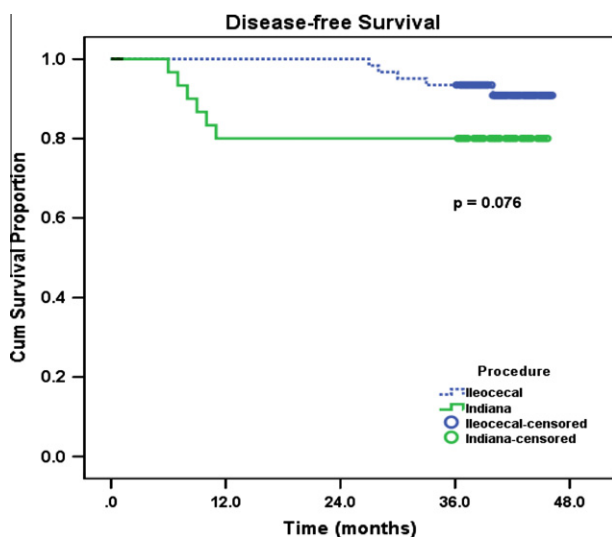


Figure 2 Disease-free survival curve of the two studied groups.

the two groups in daytime continence ($p = 0.263$) and nighttime continence ($p = 0.369$).

Six to eight months postoperatively, urodynamic studies were done. Table 4 shows the urodynamic values of the two

groups. All of the 4 tests yielded higher values in the ileocecal group. Maximum capacity of the neobladder and the mean pressure at full capacity were significantly higher in the ileocecal bladder group ($p = 0.001$). Also, the mean filling volume at first contraction and mean maximum reservoir pressure during contraction were significantly higher in the ileocecal bladder group ($p < 0.001$).

Postoperative renal status

Renal function was evaluated both laboratory and radiologically. These were always compared to the pre-operative status. Values within normal level both pre- and post-operative were considered as “Unchanged”. Rising levels of blood urea nitrogen (BUN) or serum creatinine (s. creat.), calceal cupping or its ballooning, increased dilatation of the pelvicalceal system in the postoperative period, when compared to preoperative measurements, were all classified as “deteriorated”. The values of BUN: 7–20 mg/dl, s. creatinine: 0.6–1.2 mg/dl were considered as “normal”. Renal status results for both reconstructions are detailed in Table 5. The two groups were comparable regarding the proportion of deterioration of renal laboratory function ($p = 0.481$) and renal radiological appearance ($p = 0.736$).

Discussion

When deciding how to create a urinary reservoir, one must choose a design that provides characteristics similar to those found in the normal bladder; including orthotopic bladder substitute, whenever possible, having a low pressure pouch with adequate compliance and capacity, preservation of the upper tracts by avoiding reflux and obstruction of the ureters, the ability to empty and daytime and nighttime continence. Clearly, no single technique is ideal for all patients and clinical situations [12]. However we may be obligated to perform urinary diversions, due to oncological or patient general factors.

In this study, two continent urinary reconstructions, namely, the orthotopic ileocecalneo-bladder and the non-orthotopic Indiana pouch were studied and compared regarding their long term effects on renal functions.

The mean age in our study was 55 years which is younger than the mean age of American and European bladder cancer patients [13–15]. This may be due to higher incidence of bladder cancer in Egypt due to schistosomal infestation and its predisposition to bladder cancer at younger age [16], as demonstrated by the high incidence of SCC (47.5%).

Table 3 Continence status achieved at 3 years post-operatively.

Time	Continence grade	Ileocecal bladder ($n = 61$) No. (%)	Indiana pouch ($n = 30$) No. (%)	p-Value*
Daytime	Excellent	20 (32.8)	4 (13.3)	0.263
	Good	30 (49.2)	21 (70.0)	
	Fair	4 (6.6)	4 (13.3)	
	Unsatisfactory	7 (11.5)	1 (3.3)	
Nocturnal	Excellent	4 (6.6)	1 (3.3)	0.369
	Good	20 (32.8)	18 (60.0)	
	Fair	25 (41.0)	8 (26.7)	
	Unsatisfactory	12 (19.7)	3 (10.0)	

* Comparing satisfactory grades vs. unsatisfactory grade. Excellent, good and fair grades were all considered as satisfactory.

Table 4 Urodynamic study results after 6–8 months.

Variable	Ileocecal bladder (<i>n</i> = 61) mean ± SD	Indiana pouch (<i>n</i> = 30) mean ± SD	<i>p</i> -Value
Maximum capacity (ml)	527.4 ± 50.2	481.9 ± 73.0	0.001
Mean pouch pressure at full capacity (cm H ₂ O)	20.0 ± 9.1	13.8 ± 2.7	0.001
The mean filling volume at first contraction (ml)	215.0 ± 15.2	174.2 ± 39.9	< 0.001
The mean maximum reservoir pressure during contraction (cm H ₂ O)	38.5 ± 4.6	31.4 ± 8.5	< 0.001

Table 5 Follow up of renal status after 2 years.

Renal status	Ileocecal bladder (<i>n</i> = 61) No. (%)	Indiana pouch (<i>n</i> = 30) No. (%)	<i>p</i> -Value
<i>Renal laboratory functions</i>			
Improved	2 (3.3)	0 (0.0)	0.481
Stationary	35 (57.4)	20 (66.7)	
Deteriorated	24 (39.3)	10 (33.3)	
<i>Renal radiological appearance</i>			
Improved	4 (6.6)	3 (10.0)	0.736
Stationary	49 (80.3)	22 (73.3)	
Deteriorated	8 (13.1)	5 (16.7)	

Most of our patients (54.9%) had transitional cell carcinoma (TCC), while only (44%) had squamous cell carcinoma (SCC); when compared to previous Egyptian distribution, this is approaching the values of the western series, where transitional cell carcinoma, together with undifferentiated cell carcinoma, predominated [17]. This is believed to be due to the cumulative success of the national anti-bilharzial campaign with the subsequent decrease of the squamous metaplasia following bilharzial infestation [11].

The early reconstruction related postoperative complications (minor and major urinary leaks) occurred in 16% and 7% in ileocecal and Indiana patients, respectively ($p = 0.353$). Figures are comparable to other series ranging from 16% to 30% [18].

In all continent reservoirs, daytime continence is achieved earlier than nighttime continence since it improves quickly, as nighttime continence improves with increasing volume and compliance of the reservoir which occurs after months [19]. Excellent, good or fair daytime continence is achieved in 88–95% of patients in different series [19–23], as well as in our study where 54 (88.5%) in the ileocecal group and 29 (96.7%) in the Indiana pouch group, with no statistical value ($p = 0.263$).

In our study, 49 (80.3%) ileocecal and 27 (90%) Indiana pouch patients experienced good nighttime continence, with no statistical value ($p = 0.369$). This is in concordance to the different series published, reporting satisfactory nighttime continence rates in the range of 66–93% [21,24–27].

The urodynamic study demonstrated that the means of the volumes of each construction were within the ranges mentioned in the literature by other authors for both of them [28,29]. The statistically significant higher both “bigger maximum capacity” (527.4 ± 50.2 ml) ($p = 0.001$) and “mean filling volume at first contraction” (215.0 ± 15.2 ml) ($p < 0.001$) for the ileocecal neobladder group can be explained by the fact that the ileocecal neobladder is tubularized while the Indiana pouch is detubularized. This technical differ-

ence explains the statistically significant higher “mean pouch pressure at full capacity” (20.0 ± 9.1 cm H₂O) ($p = 0.001$) and “the mean maximum reservoir pressure during contraction” (38.5 ± 4.6 cm H₂O) in the ileocecal neobladder group ($p < 0.001$) which leads to noticed reservoir dilatation with time.

The functional outcomes of the upper urinary tract after urinary diversion were assessed, in this study, using serum blood urea nitrogen (BUN), serum creatinine level, renal ultrasonography and IVU. An increase in serum creatinine level in patients with a solitary functioning kidney is a suitable tool to determine renal function [30] while others [31] reported that evaluation of postoperative renal function by serum creatinine and radiological examination are not always adequate for proper assessment. In our study there was no statistical difference regarding renal functions affection between the ileocecal bladder, and the Indiana pouch.

Though one third of our patients had Indiana pouch, none of our patients developed severe metabolic acidosis, compared to other studies reporting a rate up to 33.3% of occurrence. We think this may be attributed to the strict routine use of sodium bicarbonate therapy after surgery in our patients in addition to the high oral fluid intake [32,33].

Normal renal functions were preserved in 57% and 66% of orthotopic ileocecal and Indiana pouch patients, respectively, with no statistical difference between the two techniques ($p = 0.481$). As for radiological pelvic/cecal system configuration, they remained stationary in 80% of orthotopic ileocecal and 73% in Indiana pouch, while deterioration occurred only in 16% and 13% of patients, respectively ($p = 0.736$). These results are comparable to those recorded in other series [11,34,35].

Urinary calculus formation is a well-known late complication of continent urinary diversion [36]; however, stone formation in the Indiana pouch has not been regarded as a significant problem due to the absence of foreign material (such as exposed staples). Western experience mentioned a rate

of 2.3–13% [37,38] of stone formation, similar to this study which was 3%.

In this study, Indiana pouch patients demonstrated no significant difficulty with self-catheterization, other than that experienced at the beginning of its usage. No difference was recorded between the two tapering techniques used: tapering the ileum with Lambert suture or with a linear stapler. This is much better than other series which recorded up to 15% stomal stenosis [39].

Koch reported that there is a progressive risk of chronic diarrhea, vitamin B12 or folic acid deficiency with the terminal ileal resection [40]. The present study did not show such complications. This may be due to regular replacement therapy of vitamin B complex.

In this study, most of tumors were T3 (73.6%), similar to other Egyptian colleagues figures [11]. When comparing these results to those of Studer and colleagues [17] T3 tumors were present in only 42% of his patients. This may be due to the late presentation of Egyptian patients.

The statistically worse survival in the Indiana pouch group 80% ($p < 0.001$) and the causative statistically worse disease-free survival (80.0%) Indiana pouch group in the same group, though not statistically ($p = 0.076$), significant, can be explained by the higher number of pT3 and LN positive patients among this group, indicating more advanced and aggressive tumors, even though it has no statistical significant ($p = 0.402$).

Regular follow-up is essential for all patients who have an orthotopic ileal neobladder substitute. It is necessary to assess and assure optimal reservoir function and prevent potential complications. As a well-functioning bladder substitute should have no or minimal post-void residual urine, no infection, no incontinence, no acidosis, and no obstructed upper urinary tracts [19].

Conclusion

Both ileocecal bladder and Indiana pouch are safe procedures in regard to long-term effects over kidney function following radical cystectomy.

We recommend both types as bladder substitutes, Indiana pouch being a continent substitute of choice when orthotopic continent diversion is not feasible for oncological and patient factors, since in our study they had nearly similar results regarding continence and renal functions affection.

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