Lower Urinary Tract Reconstruction Following Radical Cystectomy Using Ileal Neobladder with Studor Technique; 3 Years Experience

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ABSTRACT
Between April 1997 and March 2000, 29 men underwent lower urinary tract reconstruction by means of the ileal neobladder of Studor with a modification. All operations were done after radical cystectomy for bladder carcinoma. The median age was 48.5 years. There was 2 perioperative deaths with an operative mortality rate of (6.8%). The early complication rate for issues indirectly related to the neobladder was (13.7%) compared to a (34.4%) directly neobladder-related complication rate. Neobladder-related late complications have been acceptable including urinary retention (11.1%), metabolic acidosis (7.4%). Through March 2000, (11.1%) of the patients died of metabolic disease and (3.7%) of unrelated medical problem. Eight patients (29.6%) suffered pelvic recurrence. Diurnal continence was achieved in 85.2%, while the nocturnal continence rate was 48.1%. Two patients (7.4%) required intermittent catheterization because of inability to void. The median neobladder capacity was 447 ml. The upper tract remained stable in (59.2%) of the patients, improved in (11.1%). Dilatation either unilateral or bilateral occurred in (29.6%) of the patients; however, the renal function remained good in (18.1%) and impaired in (11.1%).

Key Words: Cystectomy - Urinary reservoir - Continent.

INTRODUCTION
The last decade has witnessed a surge of creativity by urological surgeons in the use of bowel segments for total replacement of the native bladder, either as a bladder substitute that empties via the urethra or as a continent reservoir that drains by a catheterizable stoma [6,14,23,25]. These neobladders ideally share several characteristics with normal bladder, including a continence mechanism, adequate capacity at low intravesical pressure and antireflux mechanism capable of preventing upper tract deterioration [1]. The successful creation by Cavney and Le Duc [4] of a neobladder from small intestine with preservation of the urethral sphincter mechanism during cystectomy confirmed that such a procedure was technically feasible using readily available materials and had an acceptable complication rate. A variety of technical innovations for neobladder creation followed their original work [14,17]. Since 1985 Studor et al. [27] designed an orthotopic double crossfolded ileal low pressure reservoir in conjunction with an afferent tubular isoperistaltic segment. The initial urodynamic assessment confirmed the low pressure characteristics of the ileal reservoir. Furthermore, postoperative videourodynamics showed that the peristaltic force of the ureters and the afferent tubular ileal segment (analogous to the Goodwin ileal ureter) [7] were sufficient to protect the upper urinary tract and no reflux occurred while emptying the reservoir. In this work, we report on our experience with the ileal neobladder as originally described by Studor et al. [28] with a modification. The results of 29 patients who underwent this procedure at our institution were analyzed with respect to continence, upper tract preservation and complications.

PATIENTS AND METHODS
From April 1997 through March 2000, 29 men underwent bilateral pelvic lymph node dissection with en bloc radical cystoprostatectomy together with urinary diversion by ileal neobladder of Studor [28] with a modification for management of invasive bladder cancer. Preoperative evaluation included serum chemistry studies, CBC, chest radiography, excretory
Cystoscopy and bimanual examination under anaesthesia, biopsy of the bladder cancer along with biopsies of the prostatic urethra were performed in each patient. A positive biopsy for cancer in the prostatic urethra was considered an indication for en bloc urethrectomy and so these patients were excluded from the study; while the presence of carcinoma in situ within the bladder was not a contraindication. The presence of pelvic nodal disease (N₁) or peri-vesical fat involvement (stage T₃b) away from the prostate did not preclude an ileal neobladder. Patients with extensive pelvic disease (stage 4, N₂) involving the prostate or extension close to the pelvic floor found at operation were also excluded. All patients were continent preoperatively with no penile or bulbular urethral stricture. Seven patients had bilateral upper tract dilatation preoperatively but non had abnormal serum creatinine or electrolyte levels. Other contraindications for the procedure included severely compromised renal function (creatinine of 2.5 mmol/L or more) and lack of patient compliance. Follow-up evaluation: postoperative follow-up ranged from 5 to 36 months (median 22 months). Patients were seen at 3 months intervals for 2 years, 6 months intervals thereafter. All patients were evaluated for tumor progression, continence, renal function, upper tract status and metabolic status. Urodynamic flow studies were recommended for all patients and have been completed in 11. Continence was evaluated one year postoperatively. Diurnal continence was defined as normal if the patient was completely dry or required only one pad daily. Nocturnal continence was present when patient were dry throughout the night whether or not they had to wake up by alarm to void. Hyperchloremic acidosis was diagnosed when serum electrolytes revealed increased chloride (greater than 106 mEq/L), decreased bicarbonate (carbon dioxide less than 24 mEq/L) and normal or low potassium levels (3.5 mEq/L or less). Follow-up consisted of abdominal ultrasound, chest X-ray and relevant serum determinations. Excretory urogram and urodynamic studies were done after 1 year for the surviving patients and when indicated.

Surgical technique:
Pelvic lymphadenectomy and cystoprostatectomy were performed according to standard procedure. The urethra was transected as close as possible to the apex of the prostate. For the construction of the reservoir, an ileal segment 45-50 cm long was isolated approximately 25 cm proximal to the ileocecal valve and bowel continuity was restored. To construct the reservoir itself, the distal end of the ileal segment (approximately 35-40 cm long) was opened along its antimesenteric border except the most distal 2 cm Fig. (1-A). The 2 medial borders of the U-shaped opened distal part of the ileal segment were over sewn with a single layer seromuscular continuous 3/0 polyglycolic acid suture (Fig. 1-B). The bottom of the U was folded over between the 2 ends of the U (Fig. 1-C) thus resulting in a spherical reservoir. The distal tubular limb was anastomosed to the urethra over 22, 3 way silicone urethral catheter (Fig. 1-D). Six polyglycolic acid 2/0 seromuscular suture were placed between the urethra and the distal tubular segment. After transposition of the left ureter to the right side, the ureters were split and anastomosed by running sutures using the Nesbit Technique in an end to end or end to side fashion to the proximal unopened part of the ileal segment to form the afferent tubular segment which was 15 to 20 cm long (Fig. 1-E). The ureters were stented with 8 F catheters which passed to the outside through a separate stab incision in the afferent tubular segment. Two suction drains were inserted to drain the pelvic, two other Penrose drains were put into both paracolic gutters.

Post-operatively, the pouch is rinsed every 4 hours with saline through the 3 way indwelling catheter; mucus clots must be aspirated. Between tenth and twelfth postoperative days the ureteric stents are removed. After exclusion of a fistula by a cystogram on the fourteenth day, the indwelling catheter is removed. After catheter removal, the patients were instructed to void every 2 hours, first by sitting, by relaxing the pelvic floor, if necessary, by abdominal straining. The patients were encouraged to drink 2-3 L fluid per day and to take additional dietary salt. The reservoir will secrete sodium and chloride because the urine will be hypoosmolar and the additional salt intake prevents a salt-losing syndrome and acidosis [29]. Body weight and blood gases were examined regularly. Residual urine was repeatedly excluded and any bacteriuria was treated. Patients without metabolic acidosis or with metabolic acidosis compensat-
ed by oral intake of sodium bicarbonate were thereafter instructed to retain the urine 3 and later 4 hours until the maximal voiding volume was increased to 500 ml. Thereafter, the patients were followed up every 3-6 months.

RESULTS

In this study, 29 ileal low pressure bladder substitute as described by Studor with a modification were performed at NCI, Cairo University from April 1997 to March 2000. All patients were males with a median age of 48.5 years (range from 39-61). All operations were done for bladder carcinoma (Table 1). The median operating time required to perform the entire procedure was 6 hours 20 minutes with a range of 4.5 to 7 hours. However, this included our initial cases. The median estimated blood loss was 1,350 ml (range 750 to 2500 ml). A median of 2 units of blood was transfused (range from 0-4). Five patients did not require transfusion. The median postoperative hospital stay for these patients was 21 days (range 17-60).

There was no operative mortality related to the procedure. However, there have been 2 perioperative deaths, with an operative mortality rate of 6.9%. A 58-years old man suffered a myocardial infarction 14 days postoperatively (2 days before his scheduled discharge from the hospital). The other patient was 51 years old and had adult respiratory distress syndrome after the development of pelvic abscess and massive pulmonary embolism and died 17 days postoperatively. Complications of the procedure were divided into those directly related to the urinary reservoir construction and those indirectly related to the ileal neobladder. Four patients (13.7%) suffered neobladder unrelated and general early complications that must be expected after any major operation including deep venous thrombosis in one patient (3.4%), wound infection in 2 patients (6.8%) and pneumonia in one patient (3.4%). Specific early complications directly related to the reservoir construction were prolonged ileus (7-10 days) in six patients (20.6%) which was treated conservatively and urinary extravasation from the pouch through the drain sites in 2 patients (6.8%) which ceased after 6 and 7 weeks of bladder drainage with a urethral catheter. Diarrhea developed in two patients (6.8%) after ileal resection that lasted 3 to 7 weeks postoperatively and ultimately responded to antispasmodic agents. Once subsided, the diarrhea did not recur. Late complications (occurring greater than 2 months postoperatively) included urinary retention, metabolic disturbances and disease recurrences. Three patients (11.1%) complained of excessive mucus in the urine causing urinary retention and required rehospitalization for catheter insertion for irrigation. Although sodium bicarbonate substitution could be stopped within 3 months postoperatively in most patients, mild clinically asymptomatic temporary metabolic acidosis has been noted in 10 patients (37%), whereas 2 patients had severe metabolic disturbance requiring rehospitalization within the first year postoperatively and were treated with alkalinizing agents. None of our patients had megaloblastic anaemia nor neuropathy. Through March 2000, Twelve patients (44.4%) died: 3 (11.1%) died of metabolic disease, 1 (3.7%) of unrelated medical problem, and 8 (29.6%) suffered disease recurrence.

Daytime continence was achieved in 23 patients (85.2%), while the nighttime continence was (48.5%). Most patients who were dry woke up to void 2 to 4 times during the night, usually by alarm. The median time to achieve continence was 4 months (range from 1.5 to 12 months). Two patients (7.4%) required intermittent catheterization because of the inability to void or to maintain a post-void residual urine of less than 100 cc after 6 months.

Urodynamic studies showed basal pressures of less than 20 cm water from the 6th month postoperatively onwards (Fig. 2), that is after increasing the reservoir functional capacity to more than 300 ml. Filling was begun at a median rate of 53 ml fluid/minute (range from 1-95) and the urodynamic parameters are illustrated in Table (2). Excretory urograms showed that the upper urinary tract have remained stable in 16 patients (59.2%) (Fig. 3) and improved in 3 (11.1%). In 8 patients the upper tract deteriorated; however, the renal function remained good in 5 and was impaired in 3.
Table (1): Patient characteristics.

<table>
<thead>
<tr>
<th></th>
<th>Age mean 48.5 ys median</th>
<th>(39-61)</th>
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**Clinical stage:**
- II: 3
- III: 26

**Pathological stage:**
- P2: 3
- P3a: 9
- P3b: 17

**Histopathology:**
- SCC: 19
- TrCC: 8
- Adenocarcinoma: 2

**LN involvement:**
- LN-ve: 25
- LN +ve: 4

**Tumor site:**
- Anterior wall: 3
- Posterior wall: 11
- Right lateral: 4
- Left lateral: 8
- More than one site: 3
- Associated bilharziasis: 23/29

Table (2): Ileal neobladder; urodynamic parameters.

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Median (range)</th>
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<tbody>
<tr>
<td>Capacity (ml)</td>
<td>447 (215-635)</td>
</tr>
<tr>
<td>Peak pressure (cm water)</td>
<td>39 (13-52)</td>
</tr>
<tr>
<td>Max. flow rate (ml/sec)</td>
<td>13 (4.2-27)</td>
</tr>
<tr>
<td>Average flow rate (ml/sec)</td>
<td>9.8 ml (5.3-17.8)</td>
</tr>
<tr>
<td>First sensation to void (ml)</td>
<td>217 ml (211-379)</td>
</tr>
<tr>
<td>Strong desire to void (ml)</td>
<td>416 (283-543)</td>
</tr>
<tr>
<td>Post-void residual (ml)</td>
<td>50 (0-200)</td>
</tr>
<tr>
<td>Flow-time (sec)</td>
<td>52 (39-73)</td>
</tr>
</tbody>
</table>

Fig. (1-A): Excision of 50 cm ileal segment approximately 25 cm before ileo caecal valve. The distal 30 cm segment is opened along the antimesenteric border except the most distal 2 cm.

Fig. (1-B): Closure of the posterior wall of the pouch by oversewing the two medical borders.

Fig. (1-C): The bottom of the U is folded over between the 2 ends of U, resulting in a spherical reservoir.

Fig. (1-D): Anastomosis of the distal tubular segment of the ileal segment to the membranous urethra over silicone urethral catheter.
Fig. (1-E): The ureters are split and anastomosed to the proximal unopened ileal segment. The ureters were stented with 8F catheters which passed to outside through a separate stab in the afferent tubular.

Fig. (2): Ileal neobladder urodynamic curve one year postoperative showing basal pressure less than 20 cm H2O, with maximum cystometric capacity 406 ml.

Fig. (3, A&B): Showing preoperative IVP (A) and one year postoperative (B) showing no appreciable change.

**DISCUSSION**

There is no perfect substitute for the normal bladder. Nearly a century and a half after the first reported urinary diversion [24], many ingenious procedures have been devised to channel the urine directly to the outside of the body or to store the urine temporarily before expelling it. Bricker [2] popularized the ileal conduit in 1950s and this has remained the gold standard of urinary diversion to which all others must be compared. However, many researchers [5,21,22] reported a late complication rate ranging between 28 and 49%. Progressive renal damage
was noted to occur in 6% of the renal units at 5 years and 35% at 16 to 20 years. This damage was secondary to ureteroileal obstruction in 45%, calculi in 31% and reflux with infection in 24%. These complications combined with the psychological problems associated with an appliance have led others to consider continent cutaneous diversion and orthotopic neobladder reconstruction as reasonable alternatives. The ideal urinary reservoir should be designed to have characteristics similar to those found in the normal bladder, including a low pressure pouch with adequate compliance and capacity, preservation of the upper tracts by avoiding reflux with adequate compliance and capacity, the normal bladder, including a low pressure sphincter as described by Lilien and Camey [16,32]. Skinner et al. [25] had 22% late complication rate with 10 to 15% of the patients eventually requiring reoperation. This complication rate is likely to be higher in patients who have this diversion performed by surgeon with less experience. The technique for creating an ileal neobladder described by Studor et al. [27] is reliable and relatively simple. It is essentially a composite of several techniques already familiar to most urologists. A satisfactory reservoir for urine storage at a relatively low pressure with the shortest length of ileum is achieved by following the principle of detubularization and reconfiguration described by Kock [14]. Antireflux of urine and preservation of the upper urinary tracts are maintained by an isoperistaltic afferent limb of ileum along with low pressure achieved during physiological filling of the reservoir. During voiding, abdominal straining produces an equal pressure on the pouch and afferent limb, so that no differential pressure is created that would drive reflux. The ureters are implanted in a direct end to end fashion, with low risk of obstruction [2]. Urinary continence relies upon preservation of the external urinary sphincter as described by Lilien and Camey [18] and to the compliant and low pressure nature of the pouch.

We have made only minor modifications to the technique as it was described by Studor et al. [1]. The ureters are anastomosed to the afferent limb after the pouch is in place [2]. We did not insert a suprapubic tube and relayed on a single urethral balloon catheter [3]. We left a very short (most distal 2 cm) tubular ileal segment between the pouch and the urethra. This modification was suggested not only to decrease the possibility of stricture from the triangular suture of the pouch-urethral anastomosis but also to provide wide more vascular anastomotic suture line covered by mucosal rim. This construction may have contributed to the zero percent incidence of anastomotic stricture in this study. Studor et al. [31] reported 2% incidence of ileourethral anastomotic stricture, while in Rogers et al. series [23] the incidence was 10%. In Hautmann et al. [10] study which included 211 consecutive patients the incidence was 7%. In Studor et al. [28] series they left 5 cm tubular segment between the pouch and the membranous urethra in 4 patients; 2 of whom underwent later resection of this segment due to the presence of intermittent incontinence from pressure peaks (due to peristalsis) within this segment. The other 2 patients were doing well during follow-up. We did not find any pressure peaks within the very short tubular segment together with excellent continence especially during the day.

Making the reservoir from 40 cm ileum, 25 cm apart from ileocecal junction as suggested by Studor et al., has many advantages over the reservoir made of 60 cm ileal segment, 15 cm from the ileocecal junction as described by others [11,23]: (1) It avoids a floppy bag with low intraluminal pressure that increases the risk of chronically infected residual urine or even the need for life long intermittent selfcatheterization. (2) It decreases the risk of so called spontaneous rupture of the reservoir as the tension on the reservoir for large pouch when filled with urine is significantly higher than in small reservoir with the same intraluminal pressure [13]. (3) The functional capacity of reservoir made of 40 cm ileum increases within weeks or months in most patients from 150 to 450-500 ml in different series [6,15,26]. In this study the functional capacity 6 to 12 months postoperatively ranged from (215-635 ml) with median reservoir capacity of 447 ml. (4) It decreases the incidence of postoperative electrolyte disturbance or metabolic acidosis due to the limited storage time and increased voiding
that the antireflux properties of an intestinal segment used in the urinary tract depend upon the length of the segment, that is the longer the ileal segment, the greater the resistance to reverse flow. Gregoir [9] made simultaneous bladder and renal pelvis pressure recordings in patients with an ileal ureter. The renal pelvis pressure measured through a nephrostomy tube was significantly lower than bladder pressure and remained low even when the bladder was filled. The urodynamic studies by Studor et al. [29] in patients with ileal bladder substitutes and afferent tubular segments confirmed this finding. They added that unlike the action of a normal bladder, there is no coordinated contraction of the reservoir to cause an isolated intravesical pressure increase and possible reflux during micturition. Voiding is achieved primarily by relaxation of the urethral sphincter mechanism and then by an increase in abdominal pressure, which also acts equally on the ureters and on the renal pelvis. The lack of any pressure difference makes reflux impossible. Moreover, in the event of a major pressure peak in the ileal bladder for any reason, the membranous urethra would act as a safety valve.

Continence is determined by the external sphincteric competence, volume and low pressure nature of the reservoir [3].

Preservation of the maximum length of functioning membranous urethra and preservation of the neurovascular bundles responsible for erection have been suggested to increase continence rate [8,33]. However, we did not try to preserve the neurovascular bundle as it compromise radical resection specially in patients with T3 lesion (which constitute more than 90% of our study group).

The unidirectional peristalsis of the ureters and afferent tubular ileal segment has the advantage of being a dynamic antireflux system under low pressure conditions as first described by Mann and Bollman [19]. Hinman [11] showed frequency which shorten the time for reabsorption of urinary solutes [13]. Jagenburg et al. [12] noted reabsorption of acids by the ileal reservoir and also found that iso-osmolality between urine and serum was established within 2 to 6 hours. This is mainly achieved by transmucosal shift of free water into the pouch. This explains why the patient should be advised to drink 2-3 litres of water each day. The rapid shift of free water into the pouch is the reason why those patients have to void 1 to 1.5 litres of urine per night, resulting in nocturia.

Melchior et al. [20] reported the death of a patient from acidosis 3 months postoperatively, while 50% of their patients required alkalinizing treatment for acidotic imbalance. Hautmann et al. [10] reported that 47% of 211 patients had mild acidosis and 3% required hospitalization for severe metabolic rearrangements. One patient of 32, in the Benson et al. [1] study had metabolic acidosis. Studor et al. [28] did not find significant acidosis or electrolyte disturbances. In this study two patients developed metabolic acidosis and required hospitalization during the first postoperative year and 3 patients died later from metabolic acidosis; which emphasizes that long-term monitoring for electrolyte disturbances in patients with urinary reservoir is needed.

By preservation of the most distal part of the terminal ileum, the resorption of vitamin B12, folic acid and biliary acids should be compromised less, so resulting in a decrease of postoperative diarrhea and B12 deficiency. In Rogers et al. [23] study which used 60 cm ileal segment, 15 cm from ileocecal junction for ileal neobladder construction, they found significant diarrhea in 20% of patients and 20% developed low serum level of vitamin B12, one of whom had frank B12 deficiency within relatively short follow-up of the study. Others [1,30] did not find any significant B12 deficiency and none of their patients required permanent replacement therapy. In this study mild diarrhea was encountered in 2 patients which responded rapidly to constipating drugs. Also, no frank megaloblastic anaemia or neuropathy were found.

The unidirectional peristalsis of the ureters and afferent tubular ileal segment has the advantage of being a dynamic antireflux system under low pressure conditions as first described by Mann and Bollman [19]. Hinman [11] showed
When the reservoir is full, it also stimulates bladder afferents which wake the patient. Moreover, feedback to the brain increases in response to an increased pressure of the reservoir. The daytime continence in this study was 85.2% which is nearly similar to that reported by Studor [31] and others [1,23]. However, the nighttime continence rate is lower which may be attributed to the strict criteria we used for the definition of night continence and the relatively short follow-up period.

Also, the absence of detrusor-sphincter reflex resulting in the sphincter tone does not increase in response to an increased pressure of the reservoir. Moreover, feedback via the brain stem through the bladder afferents which awake the patient when the reservoir is full, is also missing [23]. Therefore, until the new sensation of fullness awakens the sleeping patient, we recommend the use of an alarm clock for the first 2 postoperative years instead of having the patients either continued to use the alarm clock or wore a safety pad at night more than 2 years postoperatively.

Conclusion:

The initial results in this study with ileal low pressure reservoir are promising. The favorable preliminary data regarding reservoir function and preservation of the upper tract together with the low rate of pouch urethral anastomosis have been reproduced by others [1,23,30]. The procedure has the advantage of technical simplicity with an acceptable complication rate. However, it must be emphasized that the favorable initial results were influenced by careful patient selection, postoperative voiding re-education and meticulous follow-up.

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