COMPLICATIONS OF ORTHOTOPIC ILEAL W-NEOBLADDER WITH SEROUS LINED EXTRAMURAL TUNNEL IN 520 PATIENTS

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Objective To report on the complications following orthotopic ileal W-neobladder with serous lined extramural antireflux ureteral implantation.

Patients and Methods The records of 520 patients that had undergone one-stage radical cystectomy and orthotopic ileal neo-bladder were reviewed retrospectively including the follow-up files. Special attention was directed towards the mortality, morbidity and late complications recorded during the follow-up evaluation.

Results Hospital mortality was reported in 5 cases. Eighty-one early complications were observed in 60 patients (11.5%), including GIT complications in 13, wound infection in 22 and pouchovaginal fistulae in 3. Out of 520 patients 400 were evaluable (308 men and 92 women). Tumor recurrence was documented in 101 patients (20%) including 5 with isolated urethral recurrence (0.9%). Late complications included pouch stones

in 13, outflow obstruction in 12, mucus retention in 4 and adhesive bowel obstructtion in 5. Urinary incontinence was found in 9% and 18% of patients during the day and night times, respectively. Hypercontinence was documented in 9 females. Upper tract deterioration was observed in 36 out of 785 renal units (4.5%) due to anastomotic stricture in 32 and chronic pyelonephritis in 4. Poucho-ureteral reflux was seen in 28 units (3.6%). Bacteria were isolated in the urine of 32% of 316 examined patients. Serum creatinine was normal in all but 4 patients and 44 patients (11%) suffered from subclinical chemical metabolic acidosis.

Conclusion The incidence of complications following ileal W-neobladder is low and amenable to treatment in most of the patients. Furthermore, the technique has proved its efficacy and durability.

Keywords Orthotopic, ileal neobladder, serous lined tunnel, complications

INTRODUCTION

Radical cystectomy and orthotopic bladder substitution is currently the most acceptable treatment for invasive bladder cancer, whenever possible 1-4. Although the functional and oncological outcome following these procedures is satisfactory, nevertheless some important complications do exist. The reported complication rate following orthotopic bladder substitution ranges from 9% to 50% 1-5. These include both early and late surgical and/or urological complications. In this report a retrospective review of patients' records was conducted to define the incidence of postoperative problems and how they were treated.

PATIENTS AND METHODS

From January 1992 through January 2001, orthotopic bladder substitution with an ileal W-

neobladder was performed in 520 patients, including 411 males and 109 females. The mean age was 47 ± 7 years. Cystectomy for invasive bladder cancer was the indication in all patients.

The operated patients were fit or became fit enough to withstand prolonged surgery. Adequate liver functions were important prerequisites. A serum albumin \geq 3gm/dl and a prothrombin time greater than 75% were essentially required. The serum creatinine should be \leq 1.6mg/dl or chemical creatinine clearance \geq 50ml/min.

The exclusion criteria for orthotopic bladder replacement included diffuse carcinoma in situ and/or tumor involvement of the posterior urethra in males. Tumor extension to the bladder neck or anterior vaginal wall and sphincteric deficiency were among the contraindications in female patients.

Table 1: Early Complications of the Ileal W-Neobladder (520 Patients)

Complication	No.	%
Mortality	5	1.0%
lleus	8	1.5%
Jaundice	2	0.4%
Haematemesis	3	0.6%
Wound infection	14	2.7%
Deep venous thrombosis	8	1.5%
Urinary leakage	16	3.1%
Lymphatic collection	22	4.2%
Poucho-vaginal fistula	3	2.8%*

^{*} in 109 female patients

Table 2: Current Status of Patients with Ileal W-Neobladder

Status	No.
Postoperative mortality	5
Death from cancer	90
Living with disease	11
Death from unrelated cause	12
Lost to follow-up	2
Available for evaluation	400*
Total	520

Preoperative patient preparation, surgical technique and postoperative care were the subject of previous publications⁵⁻⁷. All patients were kept on prophylactic low molecular weight heparin for 10 days. After hospital discharge the follow up visits were scheduled every month for the first 6 months, then every 3 months thereafter. The operated patients were followed up from 14-108 months with a mean of 42 ± 23 months.

During each visit, a symptom analysis including daytime continence and enuresis was done as well as a clinical assessment for evidence of local tumor recurrence. Office abdominal sonography was obtained routinely

during each visit. Intravenous urography was done at 6 months postoperatively and repeated when indicated. Gravity ascending pouchography with voiding studies was carried out at least once for each patient at 6-12 months and repeated every two years thereafter. Serum creatinine, electrolytes (Na, K, Cl) and arterial acid base profile were obtained every 3 months or when indicated. Urine cultures and sensitivity tests were performed in symptomatic patients and in those who had evidence of reflux and/or upper tract abnormallities. Bone scan, computerized tomography or magnetic resonance studies were performed when local or distant tumor recurrence was suspected.

RESULTS

Mortalities:

Five patients died in the hospital due to fatal pulmonary embolism in 3 and extensive myocardial infarction in two.

Early complications:

Early complications are those observed within one month postoperatively. A total of 81 complications developed in 60 patients (11.5%) (Table 1).

Urinary leakage was observed in 16 patients. The site of urine leak was at the urethro-ileal junction in 15 and from the pouch wall at the suture line in one. All were treated by prolonged urethral drainage but one patient required placement of bilateral nephrostomy tubes to ensure adequate dryness of the pouch. None of the patients required open surgery for urinary leakage. Pelvic lymphocele was observed in 22 patients (4.2%). It was symptomatic in 8 and required percutaneous ultrasound-guided drainage. In the remaining 14 patients the collections were asymptomatic and were treated conservatively.

Two patients developed postoperative jaundice which resolved spontaneously after exclusion of calculous obstructive biliary disease. Haematemesis and melena were observed in 3 patients; in one patient they were due to bleeding varices and were treated by injection sclerotherapy, while in the two remaining patients they were due to stress peptic ulcer and were treated conservatively.

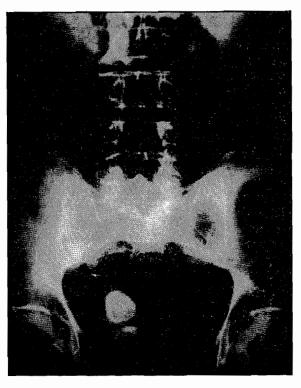


Fig. 1: Plain radiograph showing two pouch stones. They were treated with lithoclast

Wound infection was seen in 14 patients, 9 were females. All were treated conservatively but two required secondary sutures due to an impending burst abdomen.

Eight patients suffered from painful swelling in one or the other lower limb. Deep venous thrombosis (DVT) was confirmed by Doppler ultrasound in 6 but two were negative although they had the classic signs and symptoms of DVT. All patients were treated conservatively.

Three females among the initial 20 cases suffered from persistent vaginal urinary leakage. The diagnosis of poucho-vaginal fistula was confirmed. All were successfully repaired three months postoperatively using the transvaginal route.

Oncological failures and patients available for evaluation

Currently, 400 patients are available for evaluation (308 men and 92 women) (Table 2). One hundred and one patients (25%) had

Table 3: Late Complications of the Ileal W-Neobladder (400 Patients)

Complication	No.	%
Pouch stones	13	3.2%#
Urethral strictures	4	1.3%*
Urethro-ileal stenosis	8	2.6%*
Mucus retention	4	1.3%*
Bowel obstruction	5	1.3%#
Hypercontinence in female	9	9.7%◆

^{* 308} male patients; # 400 patients; • 92 female patients

tumor recurrence, 90 died and 11 are still living with the disease. The pattern of oncological failure consisted of 54 local pelvic recurrences, 37 distant metastases and 10 due to both. Four men and one woman had an isolated urethral recurrence. Total urethrectomy with an adequate safety margin was performed. The orthotopic neobladders were converted into continent cutaneous reservoirs. The surgical technique was described in a previous publication 15.

Late Complications:

Out of all patients available for evaluation 40 patients had 43 complications (10%) (Table 3). Pouch stones were observed in 13 patients (3.2%). The stones were treated by visual litholapaxy in 11, while the remaining two patients required open poucholithotomy (Fig. 1).

Outflow obstruction in 12 male patients was due to anastomotic urethro-ileal narrowing in 8 and urethral stricture in 4. The former cases were treated by intermittent dilatation and the latter were treated by visual urethrotomy. Acute mucus retention was observed in 4 patients, one had urethro-ileal stenosis. Pouch irrigation and temporary catheterization were necessary. Adhesive bowel obstruction was observed in 5 patients, 3 were treated conservatively and 2 required open surgery.

Urinary incontinence:

During the day time 364 patients (91%) were completely continent. The remaining 36 had various degrees of incontinence: total incontinence in 16, stress incontinence in 10,

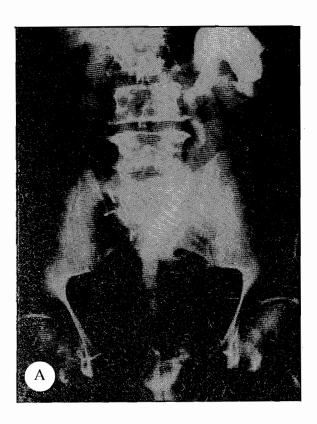
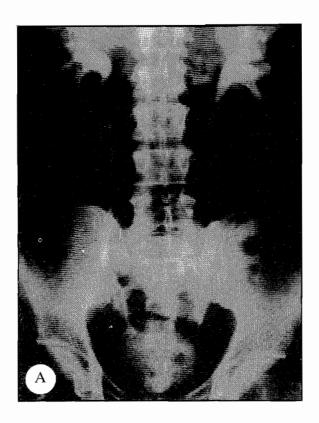






Fig. 2: A: Intravenous urogram 2 years postoperative showing hydronephrosis of a solitary left kidney. B: Plain radiograph showing an internal stent following retrograde balloon dilatation and laser ureterotomy. C: Intravenous urogram 6 weeks after removal of the stent showing an improved configuration



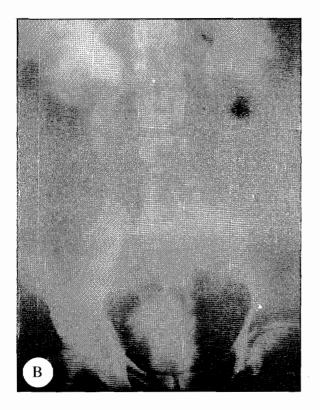




Fig. 3: A: Preoperative intravenous urogram. B: Intravenous radiograph showing bilateral ureteral strictures after failure of endoscopic dilatation. C: Intravenous radiograph showing an improved upper tract after open surgical revision.

Table 4: Treatment of 32 Renal Units with Uretero-Ileal Anastomotic Stricture

	No.	
Successful endoscopic treatment	14*	
Open surgical revision	15#	
Double-J stent (regular exchange)	2	
Nephrectomy	1	
Total	32	

^{*} was attempted in 22 patients

Table 5: Types of Isolated Microorganisms from Pouch Urine Samples

Microorganism	%
E. Coli	40%
Klebsiella	19%
Proteus	11%
Pseudomonas	6%
Enterobacter	4%
Others	20

unidentified diurnal wetting in 8 and the remaining two preferred to use prophylactic protective pads during the prayer. During the night time 328 patients (82%) were dry without medication. Overall 304 patients (76%) were continent during the day and dry at night with a voiding frequency of 3-5 times and 0-2 times during day and night times, respectively.

Overcontinence:

Nine patients out of the evaluable 92 females (9.7%) reported some degree of retention with a significant residual urine ≥ 150 ml. Seven patients practiced self intermittent catheterization, while the remaining 2 preferred to void in the squatting sitting position for adequate pouch emptying.

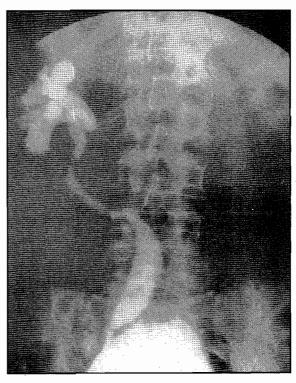


Fig. 4: A gravity ascending pouchogram showing right poucho-ureteral reflux

Upper tract status:

Upper tract evaluation using both ultrasonography and IVU showed a stable and/or improved configuration of 753 out of 785 reimplanted ureters (96%). Anastomotic ureteroileal stricture was the cause of renal deterioration in 32 implanted ureters (4%). Endoscopic treatment through a retrograde or antegrade approach was attempted in 22 units and was successful in 14 (63%) (Fig. 2). Open surgical revision was required in 15 units including those with endoscopic failure (Fig. 3). Nephrectomy was performed in one patient due to poor kidney function (Table 4). Surgical revision entailed exposure of the ileal tunnel from within the pouch. A pull-through procedure was then performed. The strictured segment was excised and the spatulated healthy distal ureter was re-implanted within the tunnel.. This was feasible in 11 units. Direct uretero-ileal re-implantation was performed in 4 ureters due to long segment stricture. Two renal units in two patients were managed by placement of double J stents and exchanged

[#] including the failures of endoscopy

every 4 months since the patients refused further surgical intervention.

Reflux and bacteriuria:

Gravity ascending pouchgraphy showed evidence of reflux in 22 patients (28 units or 3.6%) (Fig. 4). The reflux was of grade II in 20 units and of grade III in the remaining 8. It was bilateral in 6 patients (12 units). In four patients recurrent pyelonephritis was reported. All the refluxing patients were kept on antibiotic therapy.

Urine culture was obtained from 316 patients. Bacteriuria was observed in 101 patients (32%). The types of micro-organisms are illustrated in Table 5.

All patients with positive urine cultures were treated with the proper antibiotics. Repeated cultures showed persistent bacteruria in 30 patients including those with reflux.

Pyelonephritis:

Four patients suffered from recurrent attacks of acute pyelonephritis. All had poucho-ureteral reflux and two of them were diabetics.

Metabolic and nutritional complications:

Serum creatinine was within a normal range in 99% of the followed patients (0.6-1.2 mg/dl). Four patients (1%) had a serum creatinine ranging between 2.3 to 8 mg/dl. Serum electrolytes including Na, K and Cl were within normal limits. Estimation of arterial blood gases demonstrated a normal acid base profile in 89% of the patients. A chemical sub-clinical compensated mild metabolic acidosis with hyperchloraemia was observed in 44 patients (11%).

None of the patients had abnormal gastrointestinal problems or clinical evidence of nutritional deficiencies.

DISCUSSION

Orthotopic bladder substitution is currently the method of choice for urinary diversion following cystectomy. Although the procedure needs a long operative time and some technical demands, the rate of morbidity and/or mortality is acceptable 1-5. Improved techniques of anaesthesia, a better pre- and postoperative care, the availability of broad-spectrum antibiotics and prophylactic anticoagulation therapy have all resulted in a low mortality rate. The mortality rate reported in the literature is less than 2% 1-3. In this series, five patients (1%) did not leave the hospital alive; the cause of death was pulmonary embolism in three and extensive myocardial infarction in two. The young age of our cancer patients (47 years) was an additional factor for the low mortality rate.

The construction of an ileal neobladder from a 40 cm long segment would result in an adequate capacity (500 ml at 6 months) without further dilatation with a longitudinal follow-up. Furthermore the nutritional or metabolic consequences were minimal^{1,5,8}.

A controversy still exists with regard to the method of implanting the ureters to the reservoir, whether it is necessary to use an antireflux procedure or not in the so-called low-pressure reservoirs. To answer this question a prospective controlled randomized study of a large number of patients with long-term follow up is required. So far, such a critically evaluated study does not yet exist.

It is important to mention that the directly refluxing uretero-intestinal anastomosis has a risk of stenosis of 4%⁹⁻¹¹. Furthermore, evidence was provided that the refluxing ureters were associated with bacteriuria in the upper tract as well as with pyelonephritis¹². The high incidence of bacteriuria (32%) in this series and other series reporting on ileal orthotopic reservoirs¹³ together with the high pressure exerted during voiding would carry the risk of regurgitation of the infected urine up to the kidneys.

The conventional wisdom suggests that if an antireflux procedure with a low stricture rate providing the potential advantage of protection of the upper tract does exist, it is welcome. These data support our view to maintain the use of the serous lined extramural technique as an antireflux mechanism^{6,7,14}.

The early complication rate in this series was 11.5%. It is important to emphasize that all these complications were treated conservatively. One patient required bilateral nephro-

stomy tubes to stop a significant urine leakage. Percutaneous tube drainage of a sizable symptomatic lymphocele was required in 8 patients (1.5%). Three patients out of 109 (2.6%) females developed poucho-vaginal fistula. These were among the initial 20 cases in the early experience before the use of omentum interposition between the vaginal stump and the urethro-ileal junction. A successful vaginal repair was feasible in all.

The incidence of oncological failure was 25% during the mean follow-up of 42 months. An isolated urethral recurrence without associated local pelvic or distant metastases was observed in 5 patients (4 males and one female). All were subjected to total urethrectomy with an adequate safety margin via a combined abdomino-perineal approach. The orthotopic bladders were converted to continent cutaneous reservoirs using a serous lined ileal valve. The surgical technique was the subject of a previous publication 15.

The incidence of late complications was 10%. Forty-four complications were observed in 40 patients. The non-urologic surgical complications namely late bowel obstruction and wound complications were similar to those reported for other orthotopic urinary reservoirs 16,17.

Pouch stones appeared less frequently than in the urethral hemi Kock's pouch (3.2% vs. 32%)^{13,18,19}. This low incidence is mostly due to the absence of foreign material used for the nipple fixation in the hemi Kock reservoir. Most of the stones were treated by visual litholapaxy, but two required open poucholithotomy. These two patients were lost for two years during the follow up program.

Outflow obstruction is an important complication, and significant attention should be paid in this respect during the follow-up visits. Although the incidence is low, nevertheless it carries the risk of pouch decompensation. Local recurrence in the urethra or at the poucho-urethral anastomosis should be expected in every case until proved otherwise. The incidence of outflow obstruction was 3%. Visual internal urethrotomy or repeated cold dilatation of the urethro-ileal stenosis was satisfactory in all patients. This low incidence may be due to a careful urethro-ileal anastomosis and the eversion of the pouch mucosa similarly as in the vesico-urethral anastomosis following radical prostatectomy.

We routinely use a 20 Fr. non-irritant silicon urethral catheter for 3 weeks, therefore a low rate of urethritis and consequently a minimal risk of stricture would be expected.

Urinary incontinence in patients with orthotopic bladder substitution ranges between 7-15% during day time and 20-25% during night time. Many factors are responsible for a satisfactory urinary continence including the age, reservoir compliance, fine urethral stump dissection and surgical handling. The overall day and night continence in this series is 91% and 82%, respectively. Similar results have been observed by other authors^{5,10,13,17}. In female patients it was 93% during daytime and 79% during nighttime. Among 92 females available for evaluation, 9 showed some degree of urine retention or significant residual urine ≥ 150 ml. Video-urodynamic studies proved that the cause of overcontinence was due to mechanical fact s rather than neurogenic reasons²⁰. Unless the body of the pouch is supported posteriorly, an acute angle develops at the poucho-urethral junction on abdominal straining during voiding. Several technical modifications have been advocated to avoid this problem including an omental packing to support the back of the ileal pouch. fixation of the vaginal stump to the peritoneal flap at the anterior aspect of the rectum and hanging up the angles of the vaginal vault bilaterally to the preserved round ligaments and, finally, the fixation of the anterior aspect of the pouch near its dome to the anterior abdominal wall to prevent its descent during straining. Following these modifications the overcontinence rate decreased from 17% to 9%. Patients with significant residual urine were advised to use regular self-catheterization.

The need for intermittent self-catheterization was rare in our male patients. It is usually due to outflow obstruction resulting from urethral stricture or stenosis at the urethro-ileal junction. Comparable low rates were noted by Elmajian¹⁷ and Hautmann et al². Nevertheless, Steven and Poulson reported an increase of the prevalence of patients requiring intermittent self-catheterization from 15.4% at 6 months to 43.2% at 5 years¹³.

Serum creatinine and electrolytes were within the normal range in 99% of the followed patients. Four patients (1%) suffered chronic renal impairment due to recurrent pyelonephritis; two of them were diabetics, and so

far only one has started regular haemodialysis. An estimation of the acid base profile showed a normal range in all patients, but a chemical sub-clinical compensated metabolic acidosis was observed in 44 patients (11%). Therefore, we advise these patients to take sodium bicarbonate 8-10 gms daily.

Although the ureters were re-implanted using an antireflux serous lined technique, the spatulated end of the ureter is anastomosed to the intestinal mucosa near the distal end of the trough by a mucosa-to-mucosa technique. Accordingly, the incidence of anastomotic stricture is low (4%). This result compares favourably with those reported after a direct anastomotic technique^{9,11}. Most anastomotic strictures were amenable to treatment. Retroor antegrade endourologic treatment was successful in 63% of cases. Open surgical revision was successful in the remaining cases including those with initial endoscopic failure. One renal unit out of 785 re-implanted units was lost due to a delayed patient presentation.

The incidence of reflux as demonstrated by ascending studies was 3.6%. The reflux was of intermediate grade (grade II) in most cases. All were kept on prophylactic antibiotics according to culture sensitivity tests. Four patients developed acute pyelonephritis. Revisional surgery was not performed in any of the refluxing patients.

In conclusion, ileal W-neobladder with a serous lined extramural tunnel as an antireflux technique is associated with excellent functional results and has proved its efficacy and durability. The complication rate is low and amenable to treatment in most of the patients. Currently, this technique is the standard procedure whenever orthotopic bladder substitution is required. Furthermore, similar results have been reported by other authors²¹⁻²⁴.

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RESUME

Complications de la Neo-Vessie par Anse Iléale en W avec Réimplantation Urétérale Extramurale sous Sereuse chez 520 Patients

Objectif Rapporter les complications de la néo-vessie iléale en W avec réimplantation urétérale antireflux. Patients et Méthodes II s'agit d'une étude rétrospective portant sur une série de 520 patients ayant bénéficié d'une iléo-cystoplastie de substitution après cystectomie radicale. Les données du suivi ont été analysées avec une attention spéciale pour la mortalité, la morbidité et les complications tardives. Résultats Une mortalité hospitalière a été reportée dans 5 cas. Quatre vingt et une complications précoces ont été observées chez 60 patients (11,5%), incluant des complications GIT dans 13 cas, une infection de la plaie opératoire dans 22 cas et une fistule vagino-néo-vésicale dans 3 cas. Sur les 520 patients, 400 étaient évaluables (308 hommes et 92 femmes). Une récidive tumorale documentée a été retrouvée chez 101 patients (20%) dont 5 avec une récidive urétrale isolée (0.9%). Les complications tardives incluaient des lithiases dans la néo-vessie dans 13 cas, une obstruction à l'écoulement des urines dans 12 cas, une rétention de mucus dans 4 cas, et une occlusion intestinale par brides dans 5 cas. Une incontinence urinaire a été retrouvée dans 9% et 18% des cas respectivement diurne et nocturne. Une vessie rétentioniste a été retrouvée chez 9 patientes. Une détérioration du haut appareil urinaire a été notée dans 36 des 785 unités rénales (4,5%) due à une sténose anastomotique dans 32 cas et une pyélonéphrite chronique dans 4 cas. Une bactériurie a été isolée dans 32 % des 316 patients qui ont bénéficié d'un ECBU. A l'exception de 4 patients, la créatininémie était normale chez tous les autres, tandis que 44 patients avaient une acidose métabolique infra-clinique. Conclusion L'incidence des complications après néo-vessie intestinale en W est faible et traitables chez la plupart des patients. De plus, la technique a prouvé son efficacité et la stabilité de ces résultats dans le temps.

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