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Research Article

Reconsideration of Ileocoecal Pouch as a Neobladder Post Cystectomy with Proximal Urethra Sparing: Extended Evaluation of Continence and Morbidity in 97 Patients

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ABSTRACT

Purpose: To reconsider safety and functional sufficiency of ileocoecal pouch (IC) as a neobladder post urethral sparing cystectomy (USC) in a prolonged series. Secondary aim is male to female voiding control.

Materials and methods: From 2000-2016, 97 participants (36 females) with bladder and uterine cervix cancer underwent cystectomy/anterior pelvic resection. Entirely open IC was used with modifications to add urethral length. Continence progress and morbidity were evaluated over 68 month (m). Pad-free candidate in-between voiding times beside candidates' satisfaction were a real continence.

Results: Male total 24-hour control was (36, 59, 73 70%) after 6, 12 and 24 month and 5-years respectively. Ladies continence was (0, 12.5, 33 and 30%) for the similar time. Stress incontinence was 84% (grade II and III) at 2-min decreased to 49% (grade I) after 5-years. Capacities and voiding volumes significantly elevated 6 minutes-12 minutes; but residual volume and compliance didn't. Females had lower bladder neck and urethral pressures than males even USC and dayand night continence were delayed significantly. Female sex and comorbidity were the main factors to delay continence while age and USC were non-significant.

Early complications (20%) were mostly Clavien-grade I and II with 2-mortality and 3-reoperation. Leak was less for USC. Late complications (17.5%) were grade II and III including 4-reoperation without rediversion.

Conclusions: IC is still a safe straightforward technique with adequate compliance and offers consistent rising continence rates with average morbidity and renal preservation. Females may not benefit control for this diversion as males and USC has no significant impact.

Key Words: continent urinary diversion, orthotopic neobladder; ileocoecal pouch, prostate sparing radical cystectomy, neobladder urodynamic study, neobladder morbidity, female neobladder

Abbreviations: (IC) ileocoecal pouch, (USC) urethral sparing cystectomy, (m) month, (UDS) Urodynamic Study

INTRODUCTION

Radical cystectomy and orthotopic diversion is a major surgical technique. Specific urinary diversions should be based on three important parameters. First is the mental status of the patient to accommodate the disturbed physiological anatomy, then his renal function plus the overall health, and thirdly bladder disease and its precautions. Regardless the type of urinary diversion, the procedure should not compromise cancer control, and should have acceptable complications and reoperation rates [1-3].

Several technical modifications have evolved to improve continence and decrease pouch related drawbacks including prostate sparing cystectomy, omitting ante reflux and modifying the intestinal pouch configuration [4-11].

Completely detubularized IC is technically simple and attains semispherical shape with adequate compliance nevertheless, pouch over distension is less frequent and residual urine post micturition is generally small in amount [6-10].

Primary aim investigates morbidity and voiding control over extended period and secondary aim compares male to female results.

MATERIALS AND METHODS

In November 2000 we started an institutional review board approved study at the surgical oncology unit of the National

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Cancer Institute, Cairo University, Egypt on consecutive patients with (Tables 1-3) bladder cancer as well as cancer of the cervix; engaged for radical cystectomy or anterior pelvic resection with orthotopic IC neobladder. Inclusion Criteria were: (1) Tumors ≥ 2 cm bladder neck and No *in situ*. (2) No previous incontinence, diabetes or urethral stricture. (3) Creatinine ≤ 150 umol/l and normal liver function (4) Average BMI with adequate mental and intellectual condition. (5) Informed consent. Till January 2016, 97 patients (36 females) have been enrolled in the series (Table 1). Proximal urethra sparing was used in 61 patients (63%) including 24females. Other 36 (12 females) underwent classical resection.

Technical modifications

1. Prostate sparing cystectomy partially (enlarged) or entirely for tumor ≥ 3cm bladder neck, likewise in females 2-cm perisphincter was kept back after frozen section [5,11]. 2.15 cm to 20 cm ileocolonic segments, totally detubularized including the valve and end to side ureteric implantation over stents without submucosal tunneling followed by pouch to the abdominal wall fixation (Figure 1).

Follow up

Includes the oncologic status of the patients besides upper and lower urinary functional sequences by regular imaging, serum labs and questionnaire (Figure 2). Once the indwelling catheter was removed, patients initiate spontaneous Valsalvas' voiding in a sitting position/2 hours and encouraged to avoid going longer than 4 hours between evacuations and to set an alarm to awaken once during the night to urinate. Intermittent self-catheter was advised for cases with post voiding US residual more than 150 ml and difficult spontaneous evacuation of mucous. Regular blood gases/4 days and on suspecting acidosis or base defect ≥ 2.5 mEq/L alkalinizers was indicated. Continence was assisted starting with the 2nd month by detailed patient voiding history and pad free time was considered true continence even associated with stress drips or urgency. Urodynamic evaluation was advised at the 6th and 12th month to bypass the maximum morbidity time (Figure 3). Cystoscopy was performed to determine causes of difficult voiding or for unsatisfactory continence. Adjuvant irradiation was indicated for ≥ pT3, perivesical invasion and nodal invasion. Data analysis applied SPSS win statistical package version-12, numerical data as mean± standard deviation (SD), median (minimum-maximum) and qualitative as frequency (%). Multivariate analysis used Cox-regression for the significant factors affecting time to complete continence and survival analysis used Kaplan-Meier method.

Table 1: Clinical and pathological features of 97 patients and postoperative complications* (Clavien-Dindo grade)+oncologic outcome.

*=more than one complication in a patient, Timing- starting and utmost-day for early complication and month for delayed

CDC=Clavien-Dindo Complications grades [12].

I-Complication requiring allowed therapeutic regimens without surgical, endoscopic or radiological interventions.

II-More therapeutic regimens ± blood transfusions ± parenteral nutrition.

III-Required surgical, endoscopic or radiological interventions.

IV-Life threatening complication requiring IC/ICU management.

V-Death

Clinical and pathological features	Early complications (90 days)	No. (%)	Time	CDC	Delayed complications	No. (%)	Time	CDC
Age								
Male 51 (30-62)	Wound infection	11 (11)	6-21	I	Ureteric stricture	5 (5.1)	14-40	III
Female 43 (31- 69)								
	Leakage			II	Urinary retention	4 (4)	14-22	III
	Urine	7 (7.2)	Jul-22	II	Over distension	4 (4)	Oct-22	III
Tumor Site	Urine+fecal	3 (3)	05-Oct	III	Pouchocele	non	-	
Bladder-91	Prolonged ileus	11 (11.3)	Aug-13	II-III	Reflux	7 (7.2)	Oct-23	II
Cervix-5	Recto-urinary fistula	1(1)	12	III	Upper UTI	12 (12.4)	Nov-54	II-III
Vagina-1	Mortality	2 (2)		IV/V	Stone (Pouch)	0		
Tumor type#	Sepsis		35		(Renal)	1	45	II
Non muscle Invasive 6								
Muscle Invasive TCC 73					Acidosis	15(15.5)	11-Mar	
Squamous Ca 14								
Adeno Ca 4	Renal failure		64					
					mild	-11		II
					severe	-4		II
					Persistent diarrhea	non		-
Pre-operative treatment	Total*	20(20.6)			**Total***	17 (17.5)		

Neoadjuvant Chemo-34				
Pelvic Radiotherapy-6				
	Early reoperation	3	**Reoperation**	4
Renal US and CT	**Recurrence ± mortality and timing**			
Normal-87 and Dilatation-10				
	Tumor cumulative relapse 27 (28.1)			
	18-65 month			
	Tumor cumulative mortality 23 (24)			
	27-78 month			
	Nonspecific cumulative mortality 6 (6.3)			
	9-89 month			

Note:*= more than one complication in a patient, Timing- starting and utmost-day for early complication and month for delayed

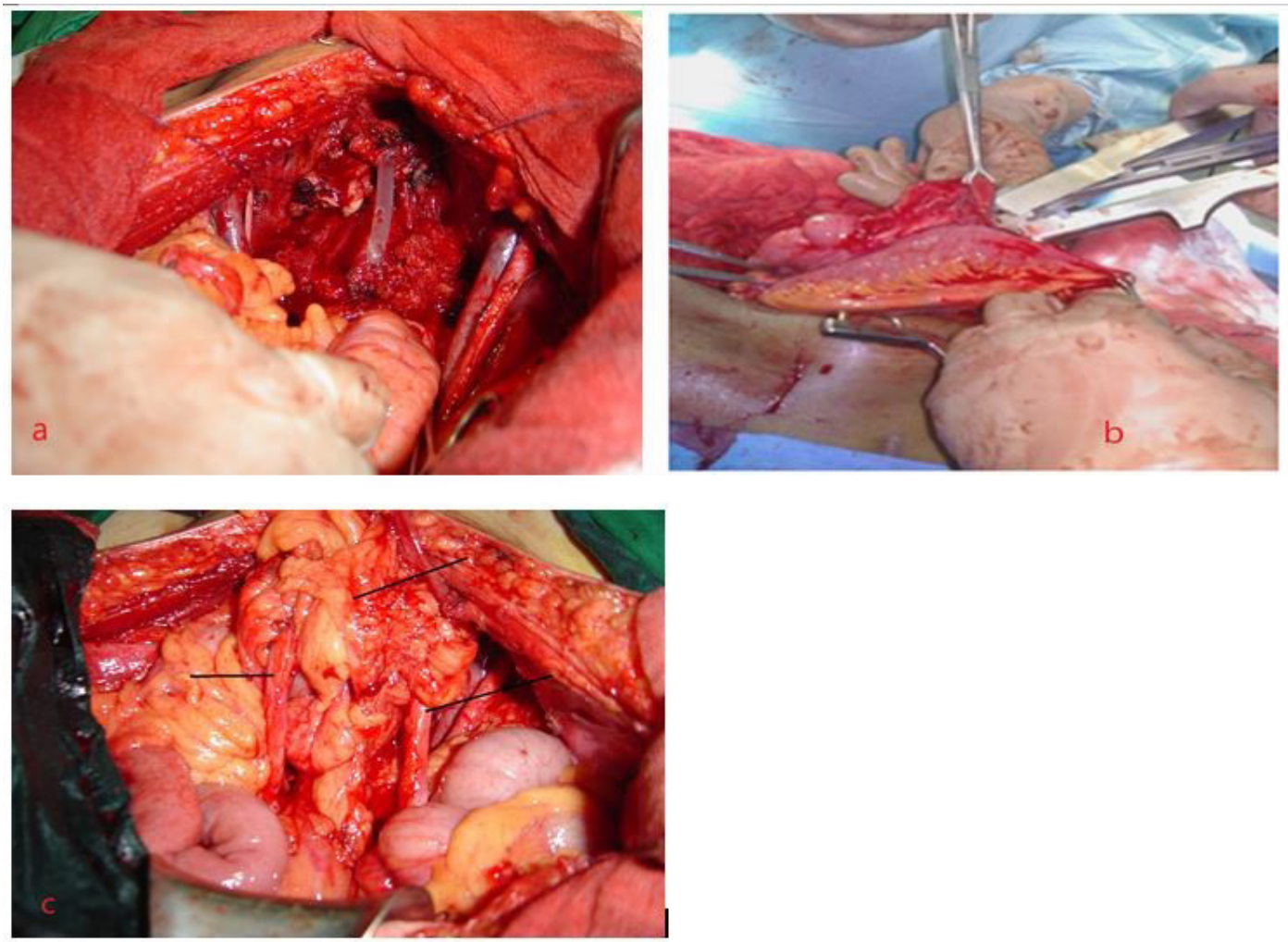

Figure 1: (a) Radical prostate-sparing cystectomy, (b) isolated (15-cm each) ileo colonic segment with appendectomy, two steps sequential stapler total detubularization and (c) tension-free pouch urethral and ureteric implantations plus anterior rectus sheath fixation (arrows: IC, RT & Lt ureters).

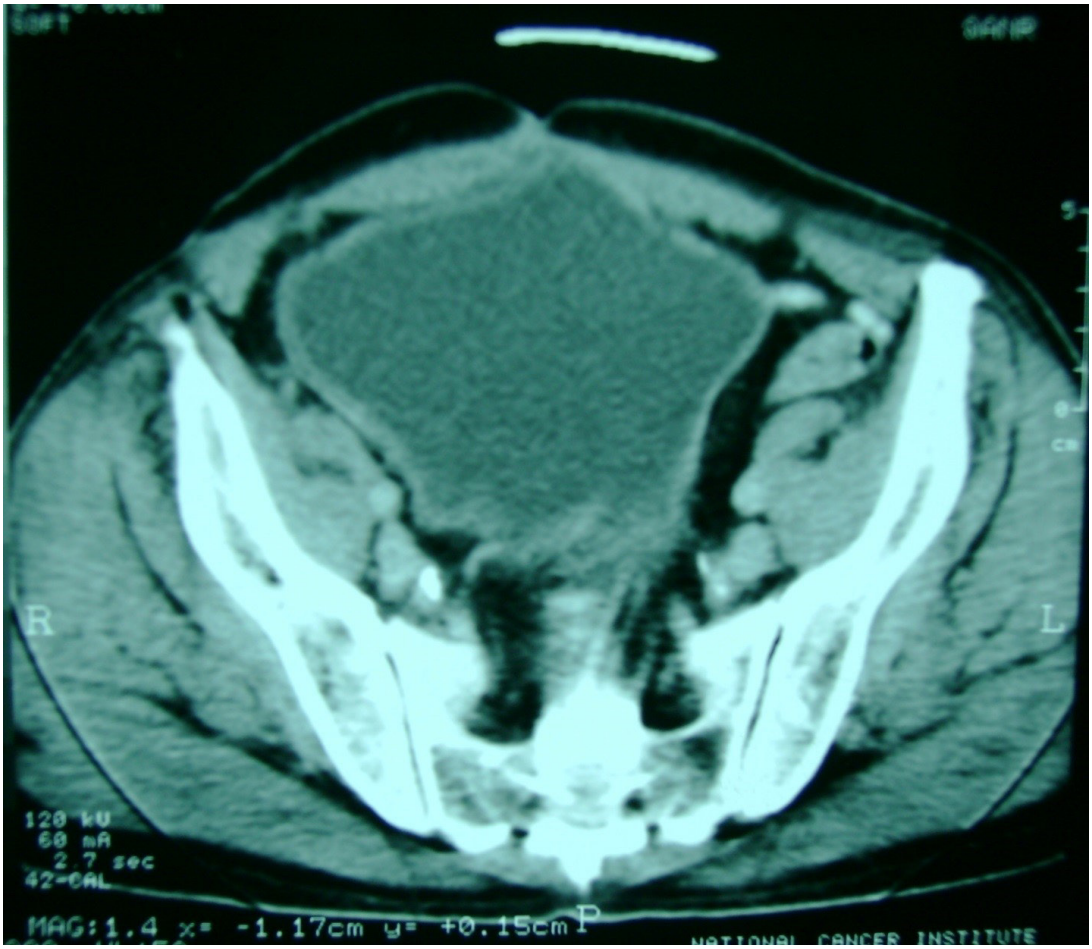

Figure 2: A 57-year male pelvic CT (2-year) → spherical IC without posterior sag together with 566 ml capacity and 40 cm H_2O maximum pressures.

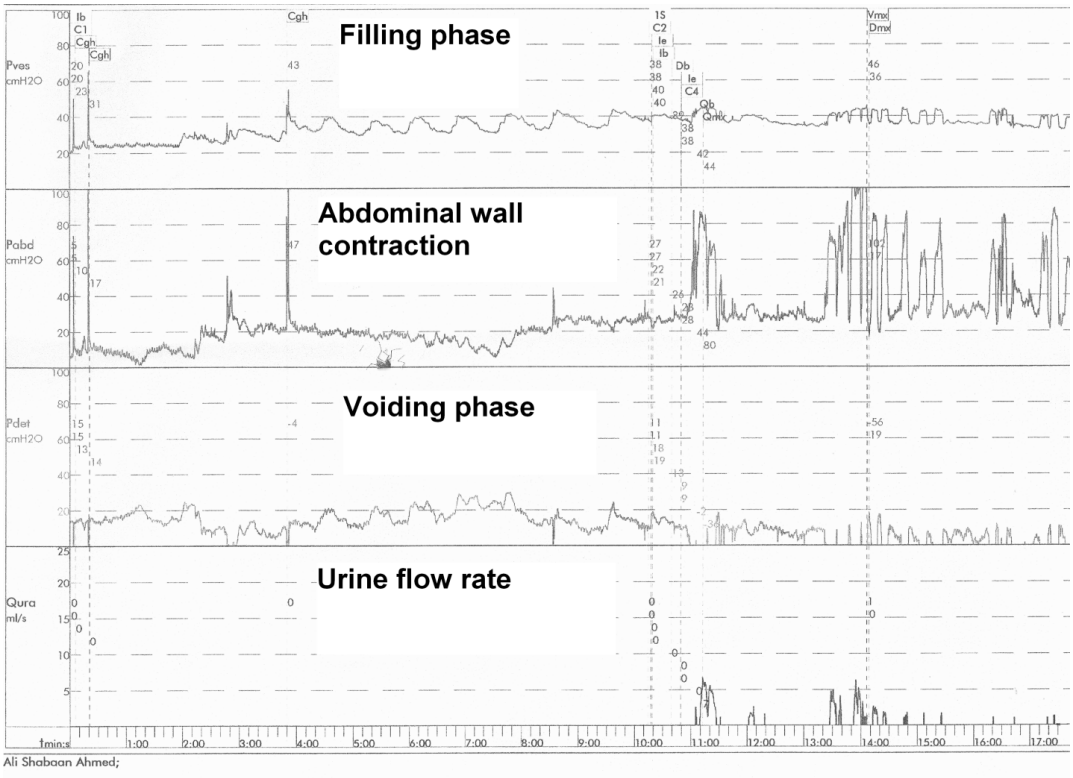

Figure 3: UDS 39 year male after USC (12 month) → delayed sensation, 481 ml pouch capacity, no contraction during filling phase or during voiding. Patient voids by abdominal contraction (6.7 ml/s max flow rate), 3.2 ml/s average rate and 210 ml post voiding residual urine.

RESULTS

Cystectomy and diversion time averaged 185 minutes (147-380), 35 minutes shorter with stapler (15- 60) and blood loss 550 ± 460 ml with 2 (0-3) transfuse units. In-patient stay for the total was 14 days (10-56) and 10-12 for the non-morbid and 51 (54%) patients had adjuvant irradiation. Median follow-up was 68 mins (16-183) and 4 were lost for records after 18 minutes (18-27). Disease free survival estimates 57.7% 5-year survival and median recurrence time is 26 minutes. Local recurrence involved lateral pelvic wall without central or urethral relapses in males or females coupled with 22-distant metastases (lungs mainly). USC had no central or urethral recurrences.

Morbidity

Perioperative morbidities were mostly grade I and II (16/20) and reoperation was needed for 3 cases without rediversion. USC leak was nearly 3% in contrast to 22% for the others but bladder neck strictures were 8% equal for both. Mean pre and post serum Creatinine levels made no difference 100 ± 35 versus 130 ± 50 umol/l. Serial estimates after 5-years follow-up show only age-related ascent. Pre and postoperative bicarbonate levels maximum differences were (28 *vs.* 26 mEq/L). Excess base defect ≥ -2.5 mEq/L plus CL ≥ 110 mEq/L were found for first 3 minutes to 8 minutes. Bacteriurias take on in all patients up to 22 minutes. but 12 symptomatic infections went together with refluxes and ureteric strictures. Pouch cystoscopy for 49 patients after variable time (5 minutes to 60 minutes) remarked no pouch stone or suture line encrustation. Random mucosal biopsies didn't note dysplastic or metaplastic changes and colonic mucosal lining reserved columnar epithelium over prolonged periods [10,13].

Serial liver investigates spotted 6 patients with raised AST and ALT and 5 cirrhotic changes (24 minutes to 48 minutes) and all proved virus C hepatitis. Further 56 patients (≥ 5 year report on) have average liver function. Ca^{2}, Vitamin D and B_{12} levels monitored transient lower levels in 23 participants (8 minutes to 20 minutes) and 22 ladies had lower bone density. For 2-3 months, nearly all majorities of patients have complained of soft to watery bowel movements that persisted ≤ 1 month, but no instances of prolonged watery diarrhea were noted.

Continence

All UDS tested candidates had delayed sensation, void by abdominal straining with day voiding frequencies/1-4 hours with an increase in nocturnal voiding to every 3 to 5 hours. Abdominal leak point pressures determined at 6 minutes revealed that all females leaked at pressure ≥ 80 cm H_2O; while, 48 males didn't leak urine even up to 200 cm H_2O intra-abdominal pressure (Figure 3).

About 27% had ≥ 150 ml residual urine. Repetitive large residual over long times (2mins to 21mins) occurred in 20 males associated with night incontinence and stress drips. Variables affecting time to full day voiding control revealed two significant factors namely sex and associated morbidity (Tables 2-3).

Table 2: Continence progression in between evaluable males (M) and females (F) and factors affecting.

*Number of patients excluding mortalities and lost follow-up cases

Grading of stress urinary incontinence [1].

I: urine loss during coughing, sneezing and pressure

II: Loss during lifting, running and climbing stair

III: Loss during standing without physical activity

Time (evaluable No.) *	Continents (%)			Urgency ± stress incontinence grade (%) (Total cases)
	Day	night	24hours	
2- month (M:60) (F:36)	(41.7) (44)	(8) (0)	(0) (0)	I- (19) II (22) III (43) (84%)
6-month (M:60) (F:30)	(59) (66.7)	(45.8) (0)	(35.6) (0)	I (41) II (26) III (12) (79%)
12- month (M:58) (F:32)	(88.8) (62.5)	(59) (43.8)	(59) (12.5)	I (45) II (19) III (12) (76%)
24- month (M:46) (F:24)	(92.8) (71)	(80) (41.7)	(73) (33)	I (45) II (12) III (4) (61%)
5-year (M:36) (F:20)	(89.3) (60)	(84) (45)	(70) (30)	I (39) II (10)- (49%)
Variables *vs.* median time (month) up to complete day continence		Sex (M) 6.4 (1-17) (F) 10.5 (1-36) p < 0.0312 and 95% CI (1.07-8.9)		Urethral saving Preserved 6 (1-12) Resected 8 (2-36) P:0.0550
Adjuvant Rth. Yes 8(3-36) Non 6.7(1-25) P:0.09		Morbidity Yes 12.7 (5-36) Non 7.3 (1-12) P:0.046 and 95% CI (1-4.8).		Age <50 6 (3-23) ≥ 50 6.4 (1-36) P:0.41

Note:*= Number of patients excluding mortalities and lost follow-up cases

Table 3: Urodynamic results # for total participant patients plus male to female.

#UDS-600 software and standard water-filled external transducer-type device

Results in median (range)

[s] **significant**

	6-months (78)	12-months (64)		12-months		
				Males (43)	Females (21)	
- Cystometry				482 (362-610)		
• Maximum capacity(ml)	413 (335-590)	533 (362-626)	0.045[s]	36 (0-347)	519 (377-596)	0.251
• Residual (ml)	36 (0-285)	45 (0-347)	0.056	17.6 (13.7-24.3)	45 (16-120)	0.411
• Basal pressure (cm H_2O)	18 (9.1-23.5)	16 (9-24.3)	0.63	13.5 (9-16.5)	13.5 (9-16.5)	0.311
• Maximal pressure (cm H_2O)	39 (14-45)	38 (19-48)	0.711	40 (30.7-48)	20 (11.2-36)	0.0321[s]
• Compliance (ml/cm H_2O)	20.2 (19.4-27.3)	22.4 (16.9-38.4)	0.512	22.4 (16.9-25.3)	28.4 (20-38.4)	0.061
-Uroflowmetry						
• Max. voiding volume (ml)	210 (120-388)	346 (255-642)	0.001[s]	-	-	-
• Voiding time (sec.)	30 (21-55)	35 (22-90)	0.58	32 (22-56)	40 (32-90)	0.531
• Maximum flow rate (ml/sec.)	7.8 (2.5-29)	14.3 (4.4-41)	0.321	11 (4.4-22.5)	23 (9-34)	0.001[s]
• Average flow rate (ml/sec.)	3.2 (1.3-11.5)	4.6 (2.1-19.5)	0.413	4.6 (3.6-12.4)	7.5 (2.1-11)	0.17
-Urethral pressure						
• Bladder neck (cm H_2O)	22.5 (9-30)	28.4 (15.5-36)	0.215	30 (15.5-40)	11.5 (9-21)	0.002[s]
• Voluntary urethral (cm H_2O)	66 (51-119)	78 (30-123)	0.411	81 (48-123)	52.5 (34-85)	0.001[s]
-Urethral pressure for USC	-	27.6 (18-36)		34 (22-40)	15.5 (11-21)	0.0001[s]
• Bladder neck	-	102 (45-119)		102 (51-119)	53 (39-85)	0.0052[s]
• Voluntary urethral						

Note:[s] =significant

DISCUSSION

Bladder cancer is frequent in Egypt and for a long time cystectomy was the standard of care. Urethral sparing cystectomy is frequently performed as a result tumor regression by neoadjuvant chemotherapy. Orthotopic diversion for male candidates in this Institute started mainly by tubularized ileocoecal pouch with high incidence of night and stress incontinence and ileal conduit was the diversion in ladies [14,15].

Detubularization substantially enhanced reservoir capacity, and delayed onset plus reduced the amplitude of pressure rise by contractions, markedly improved nocturnal continence (80% *vs.* 17% at 2 years) and delayed voiding intervals (4 *vs.* 2.5 hours at 1year); however, detubularization prompted also to raised residual volume (25% *vs.* 0% at 1-year).

Morbidity

Because low pressure reservoirs reflux has not the same impact on the kidney parenchyma as high pressure reservoirs and ante reflux procedures may have no such expected benefit and on the reverse increase uretero-intestinal stricture risk demanding open repair [16]. We omitted this measure in this sequential series. Delayed reflux developed in 7% associated with neck stricture and over distension. Uretero-enteric stricture risk was 5% in contrast to10% reported in similar series [1-3,13].

Technique wise, ongoing series operative time was short devoid of extra blood loss. Stapler shortens time further without continence or morbidity consequences. Prostate sparing modification and bladder neck preservation for ladies improved postoperative care but for continence there was no significant improve in comparison to the classical resection group. Pouch mobilization to the pelvis was effortless and omentoplasty together with pouch stitch to the rectus sheath precluded pouchocele or hypercontinence [17,18].

Ileal pouches enthusiasm attributes to their distensibility and lower rate of metabolic changes. Nevertheless; the higher ability to accommodate pressure seems to be limitless in addition to the delayed or lost neo-vesicles sensation, leading to over distension and sometimes spontaneous rupture. Delayed ruptures have been reported on top of acute or chronic over distention observed with long-term follow-up, as ileal pouch capacity enlarges and the efficiency of voiding by Valsalvas straining reduces with one case report of IC rupture [19,20].

Pouch related early and late complication rates (20.6% and 17.5% in that order) are average morbidities and could be managed with achievement inspite of 2% mortalities and 6 (6.1%) early and delayed reoperations. W-pouch early study reported 3% perioperative deaths over 11-years follow up of 263 patients while, neobladder related early and late complications appeared in 56 (15.4%) and 85 (23.4%) as well as 0.3% and 4.4%, early and late abdominal reoperation rates. This Later study reporting on 450 patients with serous lined W-neobladder holds 9% early including urinary leaks, besides 9% late including pouch stones and uretero-ileal strictures [17]. Using Studer ileal neobladder pouch, nearly all patients demonstrated early metabolic acidosis and received sodium bicarbonate 2-6 g/day for 3-6 weeks. Random biopsies of our pouch mucosa in 63% over the study time showed continual colonic pattern; nevertheless, the metabolic disturbances were mostly limited to the first-year signifying that not only the absorptive ability is responsible for the acidosis [10,15,21].

Ileal neobladder avoid use of terminal ileum, and the theoretical problems of vitamin B_{12} deficiency and bile salt malabsorption besides diarrhea due to ileocoecal valve disturbance [22,23]. In this study only transient but non persistent diarrhea was noticed. Comparative study in-betweens ileal conduit and ileocoecal pouch had an increased stool frequency and softer consistency but, no difference in stool continence [24].

Continence

In general, IC offered our series slow but progressive continence rate with a reasonable early high stable compliance, elucidating the low over distension rate. Continence is dependent on capacity besides intact urethral sphincter and pelvic floor, which are able to maintain resistance pressure across the urethral continence zone that exceeds the pressure generated within the pouch [25-28]. Additional factors that may influence continence include urethral length and sensitivity, patient age and mental status, intact pelvic nerve supply to the rhabdosphincter, completeness of voiding, and presence or absence of bacteriuria [25,27,28].

In this study the 11 mins time to achieve night-time control was equal to that reported for ileal pouches. Nevertheless, continence improved with time in a good percentage of cases by pelvic floor training and decreasing fluid intake before bedtime [26].

Night control reports for variable ileal neobladders also required 6 minutes to12 minutes. to reach maximum levels as the capacity and compliance increase nevertheless; nighttime leakage was 20%-30% [16-18,22,23]. Nocturnal incontinence is not pouch specific and reflects the loss of normal reflex rise in urethral pressure during reservoir filling as a result of afferent input loss after detrusor resection [28]. As well, nocturnal urine input exceeds the reservoir capacity since more water is shifted by the intestine to render the concentrated nocturnal urine iso-osmolar. Water shift decreases with time together with mucosal atrophy and adaptation, improving continence through time [2,22,23].

Females had significantly lower total day rate, although reservoir capacities and compliance were similar to males. UDS shows that reservoir basal pressure is on average lower than bladder neck and voluntary urethral pressures in males; whereas, in females it is similar and in a small group higher describing the higher stress dripping.

CONCLUSION

IC has acceptable continence and complication rates to further use post cystectomy. Long term follow-up revealed few pouch over distension, no rupture complication, small though repetitive residual urine volume, preserved upper urinary tract integrity with low incidence of transient metabolic acidosis. Females have lower continence rates with this pouch.

Authors' Contribution Statement

Nassar OAH – Kamal A- Fahim M

a. Nassar O, Kamal A, Fahim M→ Protocol design, selection of patients, performing the surgical operation, postoperative care guidance and follow-up of cases.

b. Nassar O and Fahim M → Collection, analysis and interpretation of data.

c. Kamal A → Drafting the article and revising data critically.

d. Nassar O → Final writing of the manuscript to be published

Disclosure of potential conflicts of interest

Examples of Conflict of Interest:

(a) Source of Funding

(b) Paid consultant to Sponsor

(c) Study Investigator Funded by Sponsor

(d) Employee of Sponsor

(e) Board Membership with Sponsor

(f) Stock Holder for Mentioned Product/Company

(g) Patent Inventor for Mentioned Product

(h) Any Financial Relationship to Competitors of Mentioned Product

1) Nassar O has no conflict of interest with any of the above listed examples

2) Kamal A has no conflict of interest with any of the above listed examples

3) Fahim M has no conflict of interest with any of the above listed examples

Disclaimers: no one has the right except the authors to publish this manuscript. Manuscript has not been presented in meetings.

This research involves Human participants with documented informed consents

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