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# Spherical Ileocecal Neobladder and Proximal Urethral Sparing: Extended Qualified Evaluation

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## Abstract

**Background:** long-term review of the functional sufficiency and safety of an innovative modified ileocecal neobladder (IC) after proximal urethral sparing cystectomy (PUS) post neoadjuvant down staging chemotherapy.

**Materials and methods:** (2000-2016), 126 participants (55 females) with bladder and uterine cervix cancers underwent cystectomy / anterior pelvic resection. 51% had cisplatin-based neoadjuvant chemotherapy. Entirely open IC was implanted to PUS in 61 patients (24-females). Another 65 (31-females) underwent classical non PUS cystectomy. Continence progress and morbidity were evaluated over 68 month (m).

**Results:** PUS improved day time continence and stress drips significantly vs. non PUS both for males and females besides increased bladder neck and voluntary urethral median pressures (27.6 & 102 cm H2O vs. 20.4& 71 for non PUS p .0141). Capacities and voiding volumes significantly increased 6 to 12 m post surgery; but residual volume & compliance didn't. Females had lower bladder neck and urethral pressures than males even PUS and day& night continence were delayed significantly.

Male total 24 hour control was (36, 59, 73& 70%) after 6, 12 & 24- m until 5-years respectively. Ladies continence was (0, 12.5, 33 & 30%) for the similar times. Stress incontinence at 2-m was 84% (grade II & III), dropped to 49% (grade I) after 5-years. Early complications (17.5%) were mostly Clavien-grade I-III with 2-mortality and 5 reoperations. Late complications (13.5%) were grade II & III including 4 reoperations without rediversion.

**Conclusions**: IC with PUS is nearly uncomplicated technique with adequate compliance and offers consistent rising continence rates for both sexes with prolonged intact renal function.

**Keywords:** Continent Urinary Diversion; Orthotopic Neobladder; Ileocecal Pouch; Prostate Sparing Radical Cystectomy; Neobladder Urodynamic Study; Neobladder Morbidity; Female Neobladder

## Introduction

Radical cystectomy and orthotopic diversion is a major surgical technique liable to early and delayed morbidity as results of abolished sensations and reflexes. Neoadjuvant chemo-radiation increased the scope of conservative resection in muscle invasive bladder cancer [1-3]. Several technical modifications have evolved to improve continence and decrease pouch related drawbacks including prostate sparing cystectomy, skipping anti reflux and modifying the intestinal pouch configuration [4-11]. Completely detubularized

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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 and PUS impact on voiding.

## Materials and Methods

November 2000 started an institutional study on referred patients with (T1-3) bladder cancer as well as cancer of the cervix; engaged for radical cystectomy or anterior pelvic resection with orthotopic IC neobladder at the Surgical Oncology unit of the National Cancer Institute, Cairo University. Inclusion Criteria are: (1) Tumours ≥ 2 cm bladder neck & No insitu. (2) No previous incontinence, diabetes or urethral stricture. (3) Creatinine ≤ 150umol/l & normal liver function (4) Average BMI with adequate mental and intellectual condition. (5) Informed consent. Till January 2016,126 patients (55 females) have been enrolled in the series (Table 1). Proximal urethra sparing is operated in 61 patients (48%) including 24females. Former 65 (31 females) underwent classical resection without PUS.

### Technical modifications:

- Prostate sparing cystectomy partially if enlarged or entirely for tumour ≥3cm of bladder neck , Likewise in females 2-cm perisphincter was kept back after frozen section 5, 11
- 15-20 cm both ileocolonic segments, totally detubularized including the valve and end to side spatulated ureteric implantation over stents without submucosal tunnelling followed by pouch to the abdominal wall fixation (Figure 1a,b,c,d).

Surveillance: includes the oncologic status of the patients besides upper and lower urinary functional sequences by regular imaging, serum labs &questionnaire (Figure2 a, b, c).

Continence is assisted starting with the 2nd month by detailed patient voiding history and pad free time is considered true continence even associated with stress drips or urgency. Urodynamic evaluation is advised at the 6th and 12th month to bypass the maximum morbidity time (Figure 3).

**Data analysis**: applied SPSSwin statistical package version-12.

**Table 1:** Clinical & pathological features of 126 patients (55 female) and postoperative complications* (Clavien-Dindo grade) + oncologic outcome

| Clinical& pathological features | Early complications (90 days) | No. (%) | Time | CDC | Delayed complications | No. (%) | Time | CDC |
|---|---|---|---|---|---|---|---|---|
| **Age** | - Wound infection | 11(8.7) | 6-21 | I | | | | |
| Male 53(30- 72) | -Leakage | | | II | | | | |
| Female 48(33 - 69) | Urine | 7(5.5) | 7-22 | II | -Ureteric stricture | 5 (4) | | |
| **Tumor Site** | Urine+ fecal | 5(4) | 5-10 | III | - Urinary retention | 4 (3.2) | 14-40 | III |
| Bladder - 107 | -Prolonged ileus | 13(10.3) | 8-13 | II-III | - Over distension | 8 (6.3) | 12-22 | III |
| Cervix - 18 | -recto-urinary fistula | 3(2.4) | 12 | III | - Pouchocele | non | 10-26 | III |
| Vagina - 1 | -Mortality | 2 (2) | | IV/V | -Reflux | 7 (5.5) | - | |
| **Tumor type#** | -Sepsis | | | | - Upper UTI | 22(17.5) | 10-23 | II |
| Non muscle Invasive TCC 26 | -Renal failure | | 35 | | -Stone (Pouch) | 1 | 11-54 | II-III |
| Muscle Invasive TCC 71 | **Total*** | **22(17.5)** | 64 | | (Renal) | 1 | 18 | II |
| Squamous Ca 25 | **Early reoperation** | **5** | | | - Acidosis | 15(12) | 45 | II |
| Adeno Ca 4 | **Recurrence ± mortality & timing** | | | | mild | -11 | 3-11 | |
| **Pre-operative treatment** | **- Tumor cumulative relapse** | | 27(21) 18-65 month | | sever – | - 4 | | II |
| Neoadjuvant Chemo | **- Tumor cumulative mortality** | | 23(18.3) 27-78 month | | -Persistent diarrhea | non | | II |
| 64- (3/4 cisplatin-based) | **- Nonspecific cumulative mortality** | | 10(8) 9-89 month | | **Total*** | **17(13.5)** | | - |
| Pelvic Radiotherapy-36 | | | | | **Reoperation** | 4 | | |
| **Renal US& CT** | | | | | | | | |
| Normal – 116 & Dilatation-10 | | | | | | | | |

*= more than one complication in a patient, Timing- starting & 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

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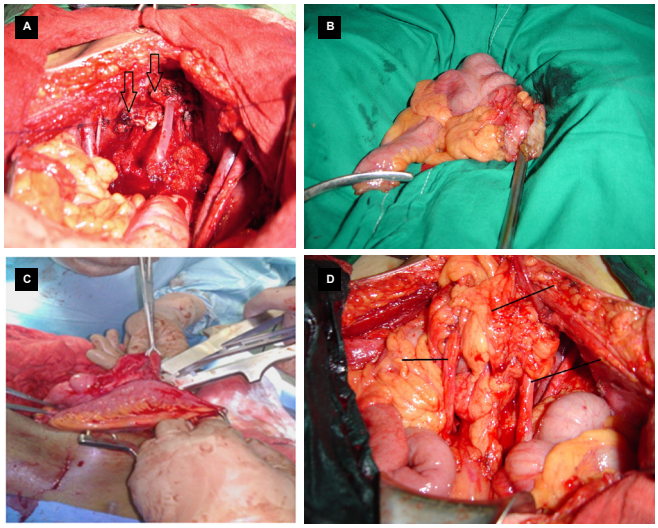


**Figure 1** – (A) Female anterior pelvic resection with preservation of 2cm around bladder neck and closed vaginal stump. (B) Isolated (15-cm each) ileo colonic segment with appendectomy. (C) Two steps sequential stapler total detubularization. (D) Tension-free pouch urethral and ureteric implantations plus anterior rectus sheath fixation (arrows: IC, RT & Lt ureters).

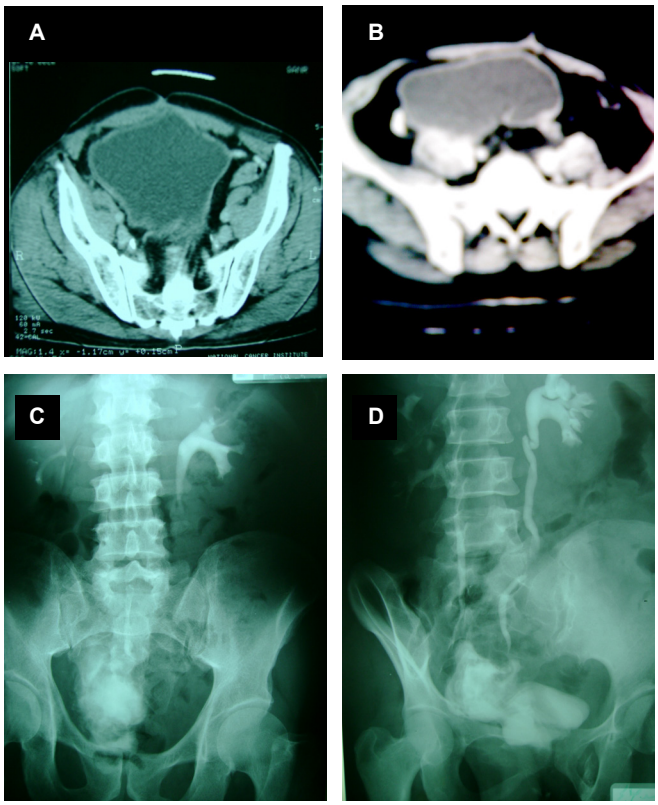


**Figure 2** - (A) A 57-year male pelvic CT (2-year) →spherical IC without posterior sag together with 566 ml capacity and 40 cm$H_2O$ maximum pressures. (B) Post evacuation pouch size. (C) Same patient 6-year without over distension and intact renal units. (D) Male patient 32 month with 3cm left ureteroenteric stricture and back pressure treated by open repair.

Time to full daytime voiding control is short for males compared to females. PUS shortens this time period compared to non-PUS either for males or females. All UDS tested candidates had delayed sensation, void by abdominal straining with average day voiding frequencies every1-4 hours increasing nocturnal to 3-5. Abdominal leak point pressures determined at 6th-m revealed that all females leaked at pressure ≥ 80 cm H2O; while, 58 males didn't leak urine even up to 200 cm H2O intra-abdominal pressure. Fifteen patients (6-PUS) had 150 ml or more residual at one time. Perioperative morbidities were mostly grade I & II and reoperation was needed for 5 cases without rediversion. Leak in PUS was 3% in contrast to 22% for the others but bladder neck strictures were 6.3% equal for both. Mean pre & post diversion serum creatinine levels are not diverse (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 3-8 m.

### Delayed sequels:

Bacteriuria was noticed in all patients up to 22 m. but only 12 symptomatic infections manifest associated with refluxes and ureteric strictures.

Pouch cystoscopy for 49 patients after variable time (5-60 m.) diagnosed one pouch stone without suture line encrustation. Random mucosal biopsies didn't notice dysplastic or metaplastic changes and colonic mucosal lining reserved columnar epithelium over prolonged periods (Figure 4). [10, 13]

Serial liver investigates spotted 6 patients with raised AST & ALT and 5 cirrhotic changes (24 -48 m.) and all proved virus C hepatitis. Further 56 patients (≥ 5 year report on) have average liver function.

Ca2, Vit.D and B12 levels monitored transient lower levels in 23 participants (8 to 20 m.) and 22 ladies had lower bone density.

For 2-3 m. nearly all complained of soft to watery bowel motions that persisted ≤1 m but no noted delayed persistent watery diarrhea.

Median follow-up is 68 m. (16 - 183). Disease free survival estimates 57.7% 5-year survival and median recurrence time is 26 m. Local recurrence involved lateral pelvic wall without central or urethral relapses in males or females coupled with 22-distant metastases (lungs mainly).

## Discussion

Bladder cancer is numerous in our population and orthotopic diversion for male candidates was mainly by

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## Results

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

| Time (evaluable No.) * | Continents (%) Day | night | 24hours | Stress grade (%) (Total cases) | | |
|---|---|---|---|---|---|---|
| **2- month (M:71)** | (41.7) | (8) | (0) | I- (19) | II (22) | III (43) |
| **(F: 55)** | (44) | (0) | (0) | | (84%) | |
| **6-month (M: 64)** | (59) | (45.8) | (35.6) | I (41) | II (26) | III (12) |
| **(F: 53)** | (66.7) | (0) | (0) | | (79%) | |
| **12- month (M: 60)** | (88.8) | (59) | (59) | I (45) | II (19) | III (12) |
| **(F: 50)** | (62.5) | (43.8) | (12.5) | | (76%) | |
| **24- month (M: 53)** | (92.8) | (80) | (73) | I (45) | II (12) | III (4) |
| **(F: 41)** | (71) | (41.7) | (33) | | (61%) | |
| **5-year (M: 44)** | (89.3) | (84) | (70) | I (39) | II (10) | - |
| **(F: 37)** | (60) | (45) | (30) | | (49%) | |

Factors affecting time period to true day-time continence

I) - Urethral sparing effect
Male patients: PUS 6 (1-10) non-PUS 8 (4-17) p-0.02 (s)
Females: PUS 8 (3-19) non-PUS 12(1-36) p-0.001 (s)
Total series: PUS 6 (1-12) non-PUS 11(2-36) p-0.0150 (s)
II)- Sex (Males) 6.4 (1- 17) (Females) 10.5 (1-36) p < 0.0312 (s) & 95% CI 1.07-8.9)

| **III) -Adjuvant Rth.** | **IV) -Morbidity** | V) - Age |
|---|---|---|
| **Yes** 8(3-36) | **Yes** 12.7 (5-36) | < 50 6 (3-23) |
| **Non** 6.7(1-25) P: 0.09 | **Non** 7.3 (1-12) P: 0.046. (s) | ≥ 50 6.4(1-36) P- 0.41, |

* Number of patients excluding mortalities and lost follow-up cases
**Grading of stress urinary incontinence:**
I: urine loss during coughing, sneezing and pressure
II: loss during lifting, running and climbing stair
III: loss during standing without physical activity
Significant effect on continence

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

| | | | | 12-months | | |
|---|---|---|---|---|---|---|
| | **6-months** (78) | **12-months** (64) | | ***Males (53)*** | ***Females (39)*** | |
| ***- Cystometry*** | | | | | | |
| · maximum capacity(ml) | 413(335-590) | 533(362-626) | .045 s | 482(362-610) | 519 (377-596) | 0.251 |
| · Residual (ml) | 36(0-285) | 45(0-347) | 0.056 | 36(0-347) | 45(16-120) | 0.411 |
| · Basal pressure(cm $H_2O$) | 18 (9.1-23.5) | 16(9-24.3) | 0.63 | 17.6(13.7-24.3) | 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) | .0321s |
| · 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) | .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) | .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 no PUS*** | | | | | | |
| · Bladder neck (cm $H_2O$) | 22.5(9-30) | 20.4(15.5-36) | | 23.5(15.5-36) | 11.5(9-21) | .002 s |
| · Voluntary urethral (cm $H_2O$) | 66 (51-119) | 71 (30-123) | | 81(48-123) | 52.5( 30-85) | .001s |
| ***-Urethral pressure for PUS*** | | | | | | |
| · Bladder neck | - | 27.6(11-40) | .0215 s | 34(22-40) | 15.5(11-21) | .0001s |
| · Voluntary urethral | - | 102 (39-119) | . 0141 s | 102(51-119) | 83(39-111) | .0052s |

# UDS-600 software and standard water-filled external transducer-type device
Results in median (range)
S significant

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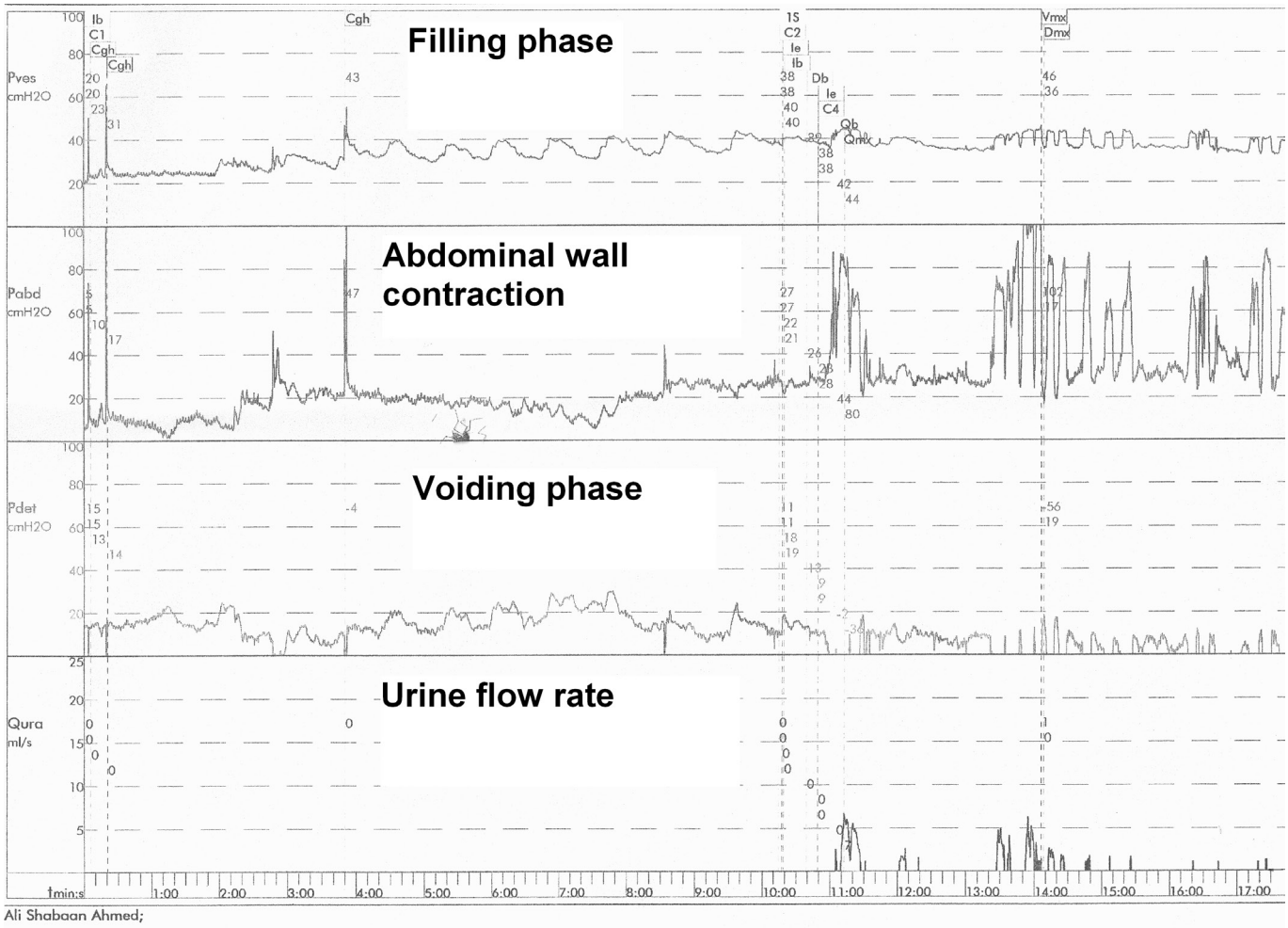


**Figure 3-** UDS 39 year male after USC (12 month) →delayed sensation, 481 ml pouch capacity, no contraction during filling phase or during voiding. Patient voids by abdominal contraction (6.7ml/s max flow rate), 3.2ml/s average rate and 210 ml post voiding residual urine.

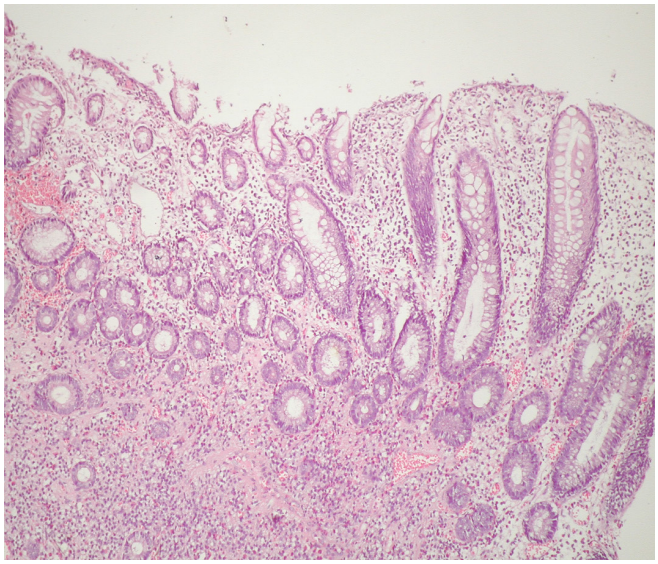

**Figure 4-** 7-years mucosal biopsy of IC pouch with persistent colonic pattern, excess lymphocytic infiltration without metaplasia or dysplasia.

tubularized ileocoecal pouch with low incidence of early and delayed morbidity as electrolyte changes, over distension plus residual urine but with high incidence of night and stress incontinence with frequent renal backpressure.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 voiding intervals (4 vs. 2.5 hours at 1year); however, detubularization prompted also to raised residual volume (25% vs. 0% at 1-year). PUS is more frequent now following the encouraging results of tumor downstaging by neoadjuvant treatment 3 to 4 courses of cisplatin-based for muscle invasive and also the inclusion of T1 lesions (21% of this series) [ 2, 3, 16] Long term serial urethroscopy plus cystoscopy didn`t find recurrence in both sexes.

Spherical IC offered our series a 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

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pelvic floor, which are able to maintain resistance pressure across the urethral continence zone that exceeds the pressure generated within the pouch. [17-22] Additional factors that may influence continence include urethral length and sensitivity, patient age and mental status, intact pelvic nerve supply to the rhabdomyosphincter, completeness of voiding, and presence or absence of bacteriuria. [17-20] In this comparative study urethral length together with bladder neck sphincter improved significantly continence both subjective and UDS finding in both sexes. This series time (11 m.) to achieve night-time control is equal to that reported for ileal pouches. [4, 7, 18, 21] Nevertheless, continence improved with time in a good percentage of cases by pelvic floor training and decreasing fluid intake before bedtime. [18] Night control reports for variable ileal neobladders also required 6 to12 m. to reach maximum levels as the capacity and compliance increase nevertheless; nighttime leakage was 20- 30%. [17-23] 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. 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. [17-23]

Females had significantly lower total day rate, although reservoir capacities and compliance are 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.

## Morbidity

Low pressure reservoirs reflux has not the same impact on the kidney parenchyma as high pressure reservoirs and antireflux procedures may have no such expected benefit and on the reverse increase uretero-intestinal stricture risk demanding sometimes open repair. [ 9, 16, 27] 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 4% in contrast to10% reported in similar series. [1, 4, 7, 9, 15, 19, 21, 23] Prostate sparing modification and bladder neck preservation for ladies improved postoperative care. Pouch mobilization to the pelvis was effortless and omentoplasty together with pouch stitch to the rectus sheath precluded pouchocele or hypercontinence. [21, 22] Ileal pouches enthusiasm attributes to their distensibility and lower rate of metabolic changes. Nevertheless; the higher ability to accommodate pressure seems to be unlimited 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 [24, 25]

Pouch related early and late complication rates (17.5 and 13.5% in that order) are average morbidities and could be managed with achievement in spite of 2% mortalities and 9 (7%) early and delayed reoperations. Over 11-years follow up of W-pouch reported 3% perioperative deaths while, neobladder related early and late complications appeared in (15.4%) and (23.4%) as well as 0.3 & 4.4%, early and late abdominal reoperation rates.4 Other study reporting on serous lined W-neobladder holds 9% early including urinary leaks, besides 9% late including pouch stones and uretero-ileal strictures. [1, 17, 2, 22] Using Studer ileal neobladder pouch, nearly all patients demonstrated early metabolic acidosis and received sodium bicarbonate 2 - 6 g/ day for 3 -6 weeks. [23] Successive random biopsies of our pouch mucosa in 63% over the study time showed continual colonic pattern; nevertheless, the metabolic disturbances are mostly limited to the first year signifying that not only the absorptive ability is responsible for the acidosis but the time of urine storage. [4, 5, 17-20, 23, 26, 27] Ileal neobladder avoid use of terminal ileum, and the theoretical problems of vitamin B12 deficiency and bile salt malabsorption besides diarrhea due to ileocoecal valve disturbance. [1, 4, 5, 23, 26, 28] In this study only transient but non persistent diarrhea is noticed. Comparative studies in-betweens ileal conduit and ileocoecal pouch had an increased stool frequency and softer consistency but, no difference in stool continence [18, 26, 28]

## Conclusions

IC plus PUS has acceptable continence and complication rates to further use after cystectomy with oncological safety. Females have lower early continence rates with this type of neobladders; but improve after the first year.

## Availability of Data and Materials

The original series characteristic data within this article including figures are available on reasonable authorized request from the corresponding author.

## Conflict of interest and Funding statements

The corresponding author discloses no external funding or personal relationship with other people or organizations that can influence this study.

## Author Contribution

The authors designed the research study, performed the research, collected follow up data and analysed them. Authors are responsible for the wright and read of this manuscript and decision to submit the final one for publication.

## Ethics approval and consent participate

This research was approved by the Surgical Oncology

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department at the National Cancer Institute, Cairo University as an Ethical Institutional Review Board. Patients provided informed consent and agreed to publication of the details of this research.

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