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Surgery in Motion

Robotic Intracorporeal Padua Ileal Bladder: Surgical Technique, Perioperative, Oncologic and Functional Outcomes

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Abstract

Background: Robot-assisted radical cystectomy (RARC) with intracorporeal neobladder reconstruction is a challenging procedure. The need for surgical skills and the long operative times have led to concern about its reproducibility.
Objective: To illustrate our technique for RARC and totally intracorporeal orthotopic Padua ileal bladder.
Design, setting, and participants: From August 2012 to February 2014, 45 patients underwent this technique at a single tertiary referral centre.
Surgical procedure: RARC, extended pelvic lymph node dissection, and intracorporeal partly stapled neobladder. Surgical steps are demonstrated in the accompanying video.
Measurements: Demographics, clinical, and pathological data were collected. Perioperative, 2-yr oncologic and 2-yr functional outcomes were reported.
Results and limitations: Intraoperative transfusion or conversion to open surgery was not necessary in any case and intracorporeal neobladder was successfully performed in all 45 patients. Median operative time was 305 min (interquartile range [IQR]: 282–345). Median estimated blood loss was 210 ml (IQR: 50–250). Median hospital stay was 9 d (IQR: 7–12). The overall incidence of perioperative, 30-d and 180-d complications were 44.4%, 57.8%, and 77.8%, respectively, while severe complications occurred in17.8%, 17.8%, and 35.5%, respectively. Two-yr daytime and night-time continence rates were 73.3% and 55.5%, respectively. Two-yr disease free survival, cancer specific survival, and overall survival rates were 72.5%, 82.3%, and 82.4%, respectively. The small sample size and high caseload of the centre might affect the reproducibility of these results.
Conclusions: Our experience supports the feasibility of totally intracorporeal neobladder following RARC. Operative times and perioperative complication rates are likely to be reduced with increasing experience.
Patient summary: We report the outcomes of our first 45 consecutive patients who underwent robot-assisted radical cystectomy with intracorporeal neobladders. Perioperative, oncologic, and functional outcomes support this technique as a feasible and safe surgical option in tertiary referral centres.
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1. Introduction

Radical cystectomy (RC) is the standard treatment for muscle-invasive bladder cancer. It is a complex and morbid procedure performed predominantly in elderly patients [1]. Robot-assisted RC (RARC) with intracorporeal urinary diversion (ICUD) has recently emerged as a minimally invasive alternative to open RC (ORC) that replicates open surgical principles with encouraging oncologic and functional outcomes [2,3]. Several revisions of standard open reservoir configurations have been proposed to shorten the operative time of the robotic technique [2,4–6]. Such revisions improved ICUD efficiency, but the relatively long operative time and the complexity of the pouch configuration still raise concerns about wide reproducibility.

In this article, we describe our technique for the completely intracorporeal Padua ileal bladder (PIB) configuration using titanium staples to configure part of the neobladder, and we report perioperative, 2-yr oncologic and functional outcomes of our first 45 patients.

2. Patients and methods

Between August 2012 and February 2014, 45 consecutive patients with high-grade urothelial carcinoma underwent RARC and complete ICUD. All data were entered prospectively into an institutional review board-approved database and queried retrospectively. Inclusion criteria were muscle-invasive or recurrent high-grade urothelial carcinoma of the bladder refractory to intravesical immunotherapy. Severe cardiovascular diseases with an ejection fraction < 36%, retinal vascular diseases, and the presence of a ventriculoperitoneal shunt were the only contraindications to robotic surgery.

2.1. Port placement and patient positioning

Port placement is shown in Figure 1. An additional suprapubic miniport was placed to introduce double-J stents. Motorized articulated EndoGIA staplers (Covidien, Dublin, Ireland) were used through the 12-mm midclavicular ports. After RC and extended pelvic lymph node dissection, Trendelenburg position was reduced from 45° to 20°.

2.2. RC and pelvic lymph node dissection

RARC was performed according to the technique described by Desai et al [7]. Distal ureters were cut between Hem-o-lok clips (Teleflex, Wayne, PA, USA) and sent for frozen section. The urethra was incised and the Foley catheter retracted in tight conjunction with the bladder neck and secured with a Hem-o-lok clip to avoid urine spillage. A meticulous *separate package* extended pelvic lymph node dissection including obturator, internal, external, common iliac, and presacral nodes was performed as described for open surgery [8].

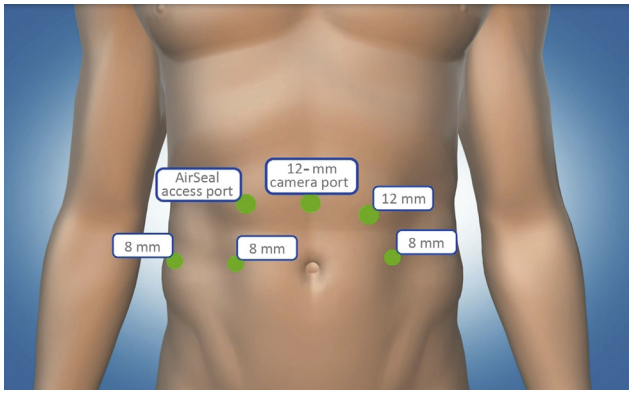

Fig. 1 – Port placement.

2.3. Choice of ileal segment to construct the neobladder

To select the ileal segment for the neobladder configuration, we chose the most sloped part of the ileum at a variable distance (minimum 20 cm) from the ileocecal valve in relation to the mesentery structure of each patient. Approximately 42 cm of ileum was used (Fig. 2A).

The division of the proximal ileum was made using only one stapler load (60 mm). Isolation of the distal extremity of the ileal segment was carried out with a 6- to 8-cm deep section of the mesentery using two consecutive stapler loads (60 mm and 45 mm).

The optimal point of the selected bowel loop to create the neobladder neck was identified about 12–14 cm proximal to the distal ileal section edge after ensuring a tension-free approach to the urethral stump (Fig. 2B). The proximal half of the loop was used to configure the left base and the dome of the neobladder.

The following ileal segments were used to construct the neobladder (Fig. 2C):

- 8 cm for the right plate
- 10 cm for the neck configuration
- 8 cm for the left plate
- 16 cm folded in a "U" configuration to create an 8-cm dome

2.4. Detubularisation and configuration of the neobladder

A 10-cm inverted U-shaped neobladder neck was created with a stay suture approximating the ileum segment at 8 cm and 18 cm from the distal ileum border. After detubularising the 8 cm of distal ileum along the antimesenteric border, motorised stapler arms were introduced through the two branches of the inverted U to approximate them and create the neobladder neck (Fig. 2B).

One 60-mm or two sequential 45-mm stapler loads were applied to detubularise and simultaneously suture 10 cm (5 cm + 5 cm) of ileum, creating the neck of the neobladder. The remaining 24 cm of the ileum were subsequently detubularised starting at the proximal ileal edge (Fig. 2D). The neobladder was then shaped as a triangle with 8-cm sides and the vertex at the inverted U-shaped neobladder neck (Figs. 2E and 2F).

The 16-cm folded segment at the left horn was finally approximated to the proximal ileal cut point (right neobladder horn) with a transverse fold, and the inner borders of the created pouch were hand-sewn, completing the posterior aspect of the neobladder (Figs. 2G and 2H).

2.5. Urethroneoneck anastomosis

After cutting the reservoir at the most sloped part of the neoneck, the urethroileal anastomosis was performed with two end-knotted 2-0 Monocryl Visi-Black running sutures. A 22-French haematuria catheter was used, and the balloon was inflated with 5 ml of saline solution.

2.6. Ureteroileal anastomoses

Ureters were passed through the posterior aspect of the neobladder and spatulated. Ureteroileal anastomoses were performed according to the modified split-nipple technique with 4-0 Monocryl (Ethicon, Somerville, NJ, USA) interrupted sutures. Guidewires and 6/7-French double-J stents

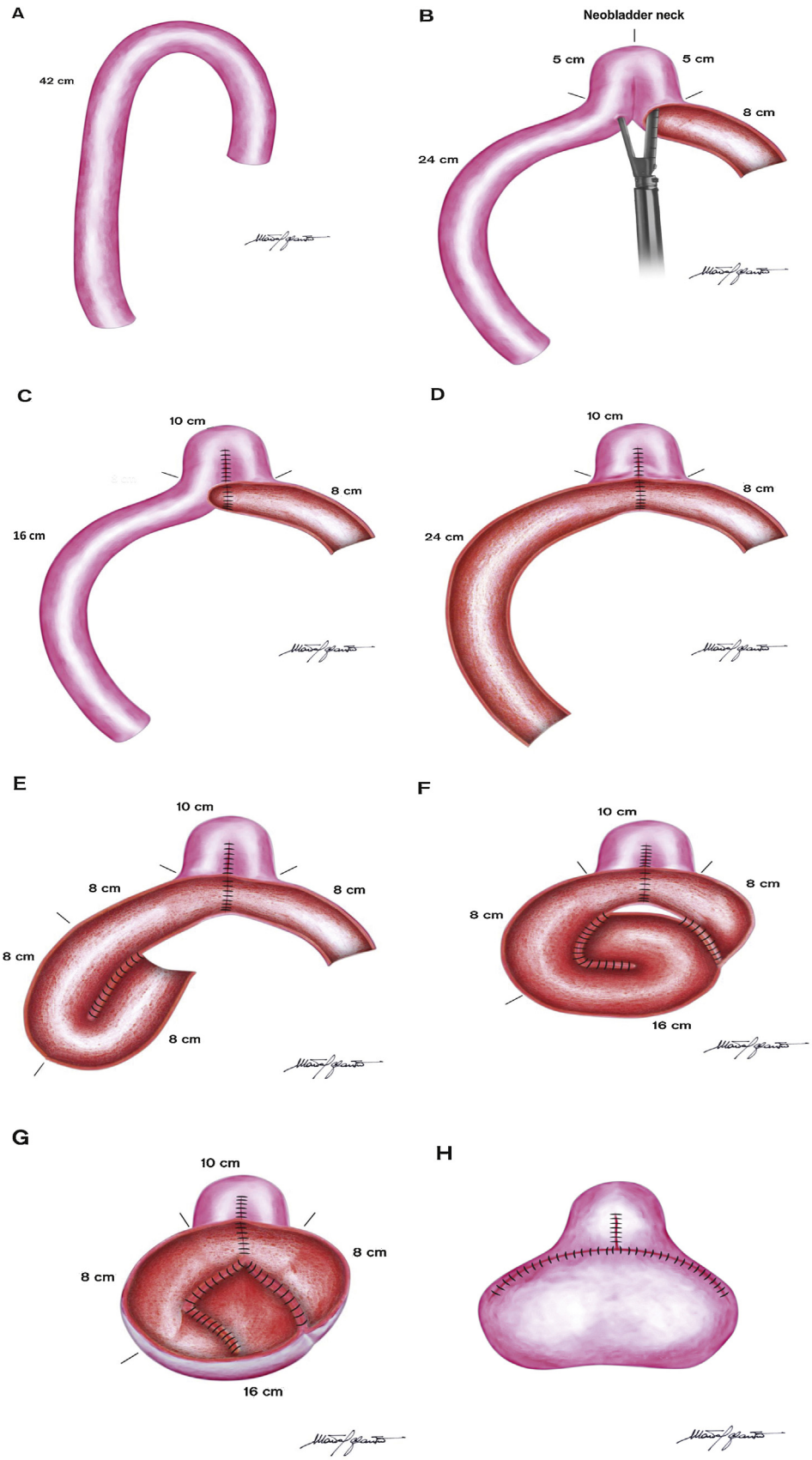

Fig. 2 – Neobladder configuration. (A) Ileal segment used to configure neobladder. (B) Detubularisation of the right horn (8 cm) and incision of the left horn to insert motorized staplers. (C) Configuration of the neobladder neck with motorised titanium staplers. (D) Detubularisation of the proximal part of ileum (24 cm). (E) First folding of the proximal ileal segment, approximating two 8-cm segments that will configure the neobladder dome with the subsequent folding. (F) Second folding and configuration of the posterior plate. (G) Completion of the posterior plate of neobladder. (H) Closure of the anterior neobladder wall and final shape of Padua ileal bladder.

were inserted through a prepubic miniport trocar (Minisite MiniPort 2 mm; Covidien).

2.7. Completion of the neobladder

The anterior aspect of the neobladder was hand-sewn with two 2-0 barbed running sutures. A serous–serous suture was performed with the intent of intussuscepting mucosal layers.

2.8. Statistical methods

Median, range, and proportion were used to report continuous and categorical data. Continuous and discrete variables were compared with Student t test and the χ^2 test, respectively. Survival analysis was performed using the Kaplan–Meier method. Survival rates were computed at 1 yr, 2 yr, and 3 yr after surgery for the entire cohort; subsequently, a stage-specific analysis was performed, and the log-rank test was applied to assess statistical significance between groups. All p values <0.05 were considered statistically significant. Statistical analysis was performed using SPSS v24 (IBM Corp., Armonk, NY, USA).

3. Results

RARC with intracorporeal PIB was successfully completed in all 45 patients without open conversion. Median operative time (console time) was 305 min (interquartile range: 282–345 min). Median estimated blood loss was 210 ml (range: 50–250 ml), median time to regular diet was 6 d (range: 5–21 d), and median length of hospital stay was 8 d (range: 6–45 d; Table 1). Pathologic reports confirmed organ-confined disease in 25 patients. The mean number of removed nodes was 35 (range: 14–56), and 13 patients had pathologic nodal metastases (Table 2).

Twenty patients (44.4%) experienced perioperative complications, and severe complications (Clavien grade $\geq$ 3) occurred in eight patients (17.8%; Table 3). A detailed report of perioperative complication events is provided in Supplementary Table 1.

A significant decrease ($p < 0.003$) of mean operative times was observed in the last tertile compared with the first one and a trend towards significance was observed also for overall complications ($p = 0.065$), high grade complications ($p = 0.068$) and duration of hospital stay ($p = 0.06$; Supplementary Table 2).

Complications recorded after discharge are listed in Supplementary Table 3. The overall incidence of 180-d severe complications (Clavien grade $\geq$ 3) was 35.5% (16 patients); 10 patients (22.2%) did not experience any complications.

Regarding functional outcomes, two patients experienced 1-cm neobladder stone formation, and both were successfully treated with an outpatient endoscopic procedure. Overall, 2-yr daytime and night-time continence rates were 73.3% and 55.5%, respectively (Table 4).

At a median follow-up of 24 mo (interquartile range: 19.0–29.5), 14 patients (31.1%) had experienced disease recurrence, seven patients (15.5%) were deceased from disease, the remaining 38 had a minimum follow-up of 2 yr. The 2-yr rates of disease-free survival (DFS), cancer-specific survival (CSS), and overall survival (OS) were 72.5%, 82.3%, and 82.4%, respectively (Supplementary Fig. 1).

The 2-yr DFS, CSS, and OS rates of patients with organ-confined disease (lower than pT3N0) were significantly higher (88.2%, 100%, 100%, respectively) compared with those of patients with locally advanced disease (pT3–4N0: 67.5%, 78.8%, and 78.8, respectively) and nodal disease

Table 1 – Demographic and perioperative data

Demographic and perioperative data	Median (IQR range) or n (%)
Age, yr (IQR)	65 (61-70)
BMI, kg/m^2 (IQR)	27 (24.4-30)
Male, n (%)	32 (71.1)
ASA score, n (%)	
2	36 (80)
3	9 (20)
Smokers, n (%)	23 (51.1)
Cardiac disease, n (%)	9 (20)
Diabetes, n (%)	6 (13.3)
Neoadjuvant chemotherapy, n (%)	15 (33.3)
Clinical stage, n (%)	
Ta-is-1	8 (17.8)
T2	28 (62.2)
T3	9 (20)
N0	41 (91.1)
N2-3	4 (8.9)
Previous intravesical BCG therapy, n (%)	10 (22.2)
Preop Hb, g/dl (IQR)	14.4 (13.9–15.2)
Estimated blood loss, ml (IQR)	210 (50–250)
Intraoperative trasfusion rate, n (%)	0 (0)
Postop Hb, g/dl (IQR)	12.3 (11.5–13.2)
Preop creatinine, mg/dl (IQR)	0.86 (0.75–0.99)
24-h postop creatinine, mg/dl (IQR)	1.34 (1.1–1.8)
Preop e-GFR, ml/min/1.73m^2[a] (IQR)	93 (76–98.8)
24-h postop e-GFR ml/min/1.73m^2 (IQR)	58 (36.5–70.7)
Operative time, min (IQR)	305 (282–345)
Time to flatus, d (IQR)	3 (3–5)
Time to bowel, d (IQR)	6 (5–8)
Time to regular diet, d (IQR)	5 (4–7)
Length of hospital stay, d (IQR)	8 (6–13)

ASA = American Society of Anesthesiologists; BMI = body mass index; BCG = acillus Calmette–Guérin; e-GFR = estimated glomerular filtration rate; aaqHb = haemoglobin; IQR = interquartile range;
[a] According to the Modification of Diet in Renal Disease formula.

Table 2 – Pathologic data

pT-N Stage	n (%) or median (IQR)
pT0, n (%)	13 (28.8)
pTis, n (%)	4 (8.9)
pT1, n (%)	2 (4)
pT2a, n (%)	3 (6.7)
pT2b, n (%)	3 (6.7)
pT3a, n (%)	4 (8.9)
pT3b, n (%)	9 (20)
pT4a, n (%)	7 (15.5)
pN0, n (%)	32 (71.1)
pN1, n (%)	7 (15.5)
pN2, n (%)	4 (8.9)
pN3, n (%)	2 (4.4)
No. of nodes removed, median (IQR)	35 (26–40)
Incidental prostate cancer, n (%)	10 (30.3)
Positive surgical margins, n (%)	0 (0)

IQR = interquartile range.

Table 3 – Perioperative and overall complication rates

Perioperative complications	
Clavien grade	*n* (%)
Clavien grade I	9 (20)
Clavien grade II	11 (24.4)
Clavien grade IIIa	6 (13.3)
Clavien grade IIIb	0 (0)
Clavien grade IVa	1 (2.2)
Clavien grade IVb	1 (2.2)
Clavien grade V	0 (0)
Overall complication rate	
Patients experiencing a perioperative complication of any grade, *n* (%)	20 (44.4)
Patients experiencing a perioperative severe complication (Clavien grade ≥ 3), *n* (%)	8 (17.8)
Overall incidence of complications of any grade at 180-d evaluation, *n* (%)	35 (77.8)
Overall incidence of severe complications (Clavien grade ≥ 3) at 180-d evaluation, *n* (%)	16 (35.5)

Table 4 – Two-yr functional outcomes

2-yr functional outcomes		
Median serum creatinine, mg/dl (IQR)	1.20 (0.98–1.59)	
CKD Stages, *n* (%)		
CKD Stage 1	3/45 (6.7)	
CKD Stage 2	18/45 (40)	
CKD Stage 3A	15/45 (33.3)	
CKD Stage 3B	7/45 (15.6)	
CKD Stage 4	2/45 (4.4)	
CKD Stage 5	0/45 (0)	
Neobladder stones, *n* (%)	2 (4.4)	
Continence rate		
	Day-time continence[a], *n* (%)	Night-time continence[a], *n* (%)
Men	27/32 (84.4)	20/32 (62.5)
Women	6/13 (46.1)	5/13 (38.5)
Overall	33/45 (73.3)	25/45 (55.5)

CKD = chronic kidney disease; IQR = interquartile range.
[a] No pad use.

(any pTN+: 25.4%, 48.5%, and 49.4%, respectively, all p values < 0.001; (Supplementary Fig. 2).

4. Discussion

RARC is a challenging and technically demanding procedure. The primary aim of this procedure is the achievement of negative surgical margins (SMs) with lymph node (LN) yields comparable to open series [9]. These goals are mandatory to consider this procedure oncologically effective.

In 2015, Raza et al [10] reported the long-term oncologic outcomes from a multi-institutional series including 702 patients who underwent RARC with a median follow-up of 67 mo. Pathologic organ-confined disease was found in 62% of patients, and SMs were positive in 8%. Median LN yield was 16, and 21% of patients had positive LNs. The 5-yr recurrence-free survival, CSS, and OS rates were 67%, 75%, and 50%, respectively.

In a cumulative analysis of 105 papers on oncologic and functional outcomes after RARC, positive SMs rates were 5.6% (1.0–1.5% for pT2 or lower; 0–25% for pT3 or higher), with a median of LN yield of 19 (range: 3–55) and an LN-positive rate of 22% [11].

Our data compare favourably with the literature with a positive SM rate of 0% and a median number of 35 retrieved nodes (range: 14–56); the 2-yr DFS and CSS rates were 68.9% and 84.4%, respectively. These outcomes should not be considered biased by strict selection criteria because the incidence of locally advanced disease and pathologic nodal metastasis was 44.4% and 28.9%, respectively. Despite the small sample size and the short follow-up of our series, 2-yr oncologic outcomes were found to be an adequate surrogate and predictor of long-term oncologic outcomes, since most recurrences happen in the first 2 yr after RC [12].

Robotic intracorporeal neobladder was first described in 2003 by Beecken et al [13]. They performed an intracorporeal Hautmann pouch with an operative time of 8.5 h. In the majority of reports, ICUDs were associated with long operative time regardless of the type of reservoir performed [4,6,14,15]. Nevertheless, with increasing experience, the operative times for ICUD decreased [14]. Operative times affect diffusion of RARC; however, high-volume centres reported a stepwise reduction of operative times with good outcomes, tracking a step-by-step standardised technique [2,16]. In our series, the median operative time was 305 min (interquartile range: 282–345 min) and was likely positively affected by a standardised use of the staplers to configure the neobladder neck and the posterior left aspect of the neobladder.

Regarding the safety and reproducibility of this technique, RARC with ICUD is a technically demanding procedure, and extracorporeal urinary diversion (UD) remains the preferred approach at most centres [3].

Different from other minimally invasive urologic procedures, discussion about the reproducibility of RARC with ICUD must take into account the high morbidity of RC itself, regardless of surgical approach. Open RC is associated with a high risk of complications (> 60%), a considerable risk of high-grade complications (13–40%), and 90-d mortality up to 7% [17]. Moreover, orthotopic UD is associated with higher risks of perioperative complications [18]. Based on these data, a panel of experts recently recommended selecting patients as candidates for ileal conduit at the beginning of RARC learning curve to keep the perioperative complication rates at the minimum [9]. Notably, the only prospective randomised trial on RARC versus ORC that aimed to compare the perioperative outcomes of these approaches, although performed at a tertiary referral centre, has a large bias due to the accomplishment of extracorporeal UD in the robotic arm [19].

RARC studies with standardised reporting of complications were recently published with overall 90-d complication rates of 48% and 52%, respectively [20,21]. Our perioperative outcomes are comparable to other RARC and ICUD reports, with a 30-d incidence rate of severe complications at a reasonable 17.8%, significantly lower than the 30% threshold supported as a benchmark by the Pasadena consensus

panel [9]. Despite the small sample size of this initial series, we demonstrated a significant decrease of operative time and a trend towards a significant decrease ($p = 0.06$) of complications, severe complications, and duration of hospital stay after the first 30 cases. Our series also highlighted the need for strict follow-up after discharge because of a significant risk of developing complications in the 1st 6 mo after treatment, some of which can be potentially life threatening. Of 16 severe complications that occurred after discharge, eight (50%) required readmission and treatment.

Several neobladder models have been described, but all should have the following features: high capacity, low pressure, absence of reflux, and complete voiding by abdominal straining and perineal relaxation [22]. Our ICUD, the PIB, first described in 1990 by Pagano et al [23], accomplishes the required symmetry of the pouch and is perfectly allocated in the small pelvis in a *true orthotopic* position. The double sequential orthogonal folding of the ileal segment generates a low-pressure, high-capacity, spheroidal reservoir that maintains stable volume and maximal capacity at long-term urodynamic evaluation [24].

Robotic ICUD was performed with the intent of exactly reproducing the surgical steps of open vescica ileale Padovana. Staplers were used to configure the neobladder neck and to suture the left aspect of the neobladder, as is conventionally done in open surgery [24]. The use of the staplers contributed to reduced operative times; however, the main concern regarding widespread use of nonabsorbable materials inside the urinary tract is the increased risk of stone formation [25].

Fontana et al [26] reported a 6% rate of stone formation in their titanium stapled ileal neobladder series, comparable to the 5.0% incidence of stone formation within conventionally hand-sewn reservoirs [27]. We previously reported 9% incidence of stone formation in a series of 445 patients treated with ORC and stapled PIB at a median follow-up of 41 mo and successful endoscopic treatment in all patients (34 performed as outpatient procedures) [28]. More recently, Muto et al [29] reported a 4.5% incidence of neobladder stone formation at a median follow-up of 36 mo in 606 patients treated with ORC and stapled Camey II neobladders. Preliminary results of our series are in line with the literature, with only two neobladder stone occurrences at a median follow-up of 24 mo (4.4%), and those were successfully treated endoscopically.

Finally, recovery of urinary continence after RC and ICUD is one of the main goals potentially affecting quality of life of patients. Even if very limited data are available about functional outcomes of RARC with ICUD, Tyritzis et al [30] reported 12-mo daytime continence rates of 88% in men and 67% in women and 12-mo night-time continence rates of 76% (continence defined as no pad use). In our series, 1-yr daytime and night-time continence rates were 73.3% (84.4% in men, 46.1% in women) and 55.5% (62.5% in men, 38.5% in women), respectively. These data, based on a strict definition of continence (no pad use) seem comparable to the previous report by the Karolinska Institute [30].

Our results are affected by biases and limitations. Firstly, the choice of orthotopic neobladder model is based essentially on surgeon preference, experience, and practice. Similarly, the use of titanium staplers to reduce operative times might be associated with higher incidence of neobladder stones; however, this event can be successfully treated endoscopically as an outpatient procedure with minimal impact on patient quality of life. Finally, reproducibility of RARC with ICUD remains a matter of debate. Regardless of surgical approach, RC with orthotopic neobladder is a technically demanding procedure that should be performed in tertiary referral centres to minimise the incidence of perioperative complications and to treat potentially life-threatening complications promptly in the 1st 6 mo after treatment.

5. Conclusions

We described our step-by-step technique for robot-assisted intracorporeal partly stapled PIB, exactly replicating open surgical principles. Use of a standardised technique and titanium staplers can contribute to improved efficiency and minimal perioperative complications. Further studies are required to evaluate long-term outcomes of intracorporeal vescica ileale Padovana.

Author contributions: Giuseppe Simone had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

Study concept and design: Simone, Papalia.
Acquisition of data: Misuraca, Tuderti, Minisola, Ferriero, Vallati, Guaglianone.
Analysis and interpretation of data: Simone, Papalia.
Drafting of the manuscript: Simone, Papalia.
Critical revision of the manuscript for important intellectual content: Gallucci.
Statistical analysis: Simone.
Obtaining funding: None.
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Other: None.

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Appendix A. Supplementary data

The Surgery in Motion video accompanying this article can be found in the online version at http://dx.doi.org/10.1016/j.eururo.2016.10.018 and via www.europeanurology.com.

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