EUROPEAN UROLOGY 82 (2022) 295–302

available at www.sciencedirect.com
journal homepage: www.europeanurology.com

European Association of Urology

Surgery in Motion

Preliminary Functional Outcome Following Robotic Intracorporeal Orthotopic Ileal Neobladder Suspension with Round Ligaments in Women with Bladder Cancer

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Article info

Article history:
Accepted November 10, 2021

Associate Editor:
Alexandre Mottrie

Keywords:
Robotic surgery
Radical cystectomy
Intracorporeal
Neobladder
Emptying dysfunction
Round ligaments

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Abstract

Background: Chronic urinary retention (CUR) is a frequent complication after orthotopic neobladder (ONB) reconstruction in women. To decrease CUR, several open surgical modifications to provide back support to the ONB have been established on the basis of pelvic anatomical differences between females and males.
Objective: To illustrate our technique for robotic intracorporeal reconfiguration of ONB as integrated into our open surgical approach to provide back support to the ONB with round ligaments in women.
Design, setting, and participants: From November 2017 to April 2021, 28 patients underwent robotic intracorporeal ONB with a minimum of 6 mo of follow-up at a single centre.
Surgical procedure: We performed robotic radical cystectomy, pelvic lymphadenectomy, and a complete intracorporeal ONB suspended with round ligaments (rONB). Our surgical procedure is demonstrated in the accompanying video.
Measurements: Demographics and clinical and pathological data were collected. Perioperative and 90-d complications and 6-mo functional outcomes were compared for the rONB group (n = 12) and the patients receiving a traditional ONB (tONB; n = 16).
Results and limitations: The median total operative time was 305 min (interquartile range [IQR] 270–370) for tONB and 303 min (IQR 287–330) for rONB. The median estimated blood loss was 325 ml (IQR 200–700) for tONB and 350 ml (IQR 262–600) for rONB. Some 50% of the tONB group and 41.7% of the rONB group experienced low-grade complications. A total of 12.5% tONB and 8.3% rONB patients experienced high-grade complications with neobladder-vaginal fistula. The cumulative risk of CUR was 37.5% in the tONB group and 16.7% in the rONB group. This study is limited by the small sample size and the short follow-up period.
Conclusions: We established a feasible surgical technique for a robotic intracorporeal ONB configuration suspended with round ligaments. This may prevent the occurrence of emptying dysfunction in women.
Patient summary: We describe our stepwise technique for creating a new bladder within the body that is suspended with round ligaments. Patients undergoing removal

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https://doi.org/10.1016/j.eururo.2021.11.012

of the bladder for bladder cancer may benefit from this technique in terms of better urinary function and the advantages of a robotic surgical approach.

1. Introduction

The gold standard treatment for patients with muscle-invasive and high-risk recurrent bladder cancer is radical cystectomy (RC) with urinary diversion [1]. Orthotopic neobladder (ONB) is thought to be the optimal form of urinary diversion because it most closely resembles the native bladder. However, ONB is still associated with a substantial risk of urinary complications that significantly affect patient quality of life. In addition, patients receiving an ONB have a higher risk of long-term major complications and reoperation in comparison to those receiving an ileal conduit [2]. Women in this setting experience different complications to men, generally related to voiding dysfunction, and chronic urinary retention (CUR) is a significant functional complication of ONB that develops in 31–61% of cases in the long term [3–8].

The local anatomy and nerves contribute to possible causes of voiding dysfunction [9,10]. Concerning the pelvic anatomical differences between women and men, some surgeons and investigators have attributed CUR to a lack of posterior support of the neobladder leading to its downward migration, resulting in posterior kinking of the neobladder-urethral anastomosis. Therefore, certain surgical modifications have been introduced to provide back support to the neobladder and significantly decrease the rate of CUR [3,11–13]. We developed an open approach for surgical modification in which the posterior ileal neobladder is suspended with round ligaments, and obtained better functional outcomes in a single-centre trial conducted in 2011 [14]. However, in the era of robotic surgery it has been confirmed that intracorporeal ONB reconstruction is safe and feasible. Especially in women, specimens can be extracted through the vagina without making an additional incision in the abdominal wall. On the basis of our novel open approach and experience, the advantages of robotic intracorporeal RC and urinary diversion in women encouraged us to explore integration of robotic intracorporeal ONB reconfiguration in our open approach to provide back support to the ONB using round ligaments in female patients. The objective of this study was to describe our intracorporeal technique and initial functional outcomes in comparison to patients without back support of the ONB.

2. Patients and methods

From November 2017 to April 2021, robot-assisted RC, standard or extended pelvic lymph node dissection (PLND), and intracorporeal ONB (Hautmann pouch) were performed by a single surgeon in 33 female patients with bladder cancer. Among these, 28 were followed up for at least 6 mo. Two ONB reconstruction approaches were described to the patients and they were allowed to select one. Twelve patients accepted the procedure in which the ONB is suspended with round ligaments (rONB), and 16 underwent the traditional procedure (tONB). All data were consecutively entered prospectively into our institutional review board–approved database and queried retrospectively. Our inclusion criteria for RARC were identical to those for open cystectomy. The indications and contraindications for orthotopic reconstruction in this cohort conformed to the criteria set by the European Association of Urology guidelines on bladder cancer [1].

2.1. Surgical technique

With the patient in the steep Trendelenburg position, a six-port transperitoneal approach similar to that described by Goh et al [15] was used (Fig. 1). Traditional RC techniques in women are performed with anterior pelvic exenteration, which includes RC, anterior vaginectomy, hysterectomy, and bilateral salpingo-oophorectomy. In this cohort, we used partial sparing of the anterior vagina close to the urethral stump of 2 cm, and the ovaries were spared in patients younger than 60 yr. The technique for RC together with PLND is well described in the literature. The urethra was transected just distal to the bladder neck. Frozen sectioning was performed to exclude carcinoma in situ and overt carcinoma. After RC, we isolated the posterior peritoneum from the posterior wall of the vagina and the uterus with a layer of thick extraperitoneal tissue. The flap was then sutured circumferentially to the pelvic fascia and to the vaginal wall just below the ventral urethral margin with 3-0 Vicryl (Fig. 2B). Our refined technique for intracorporeal W-shaped ONB reconstruction using a 40-cm length of ileum was previously described [16]. Therefore, here we mainly focus on critical points of the procedure for intracorporeal ONB suspension with round ligaments.

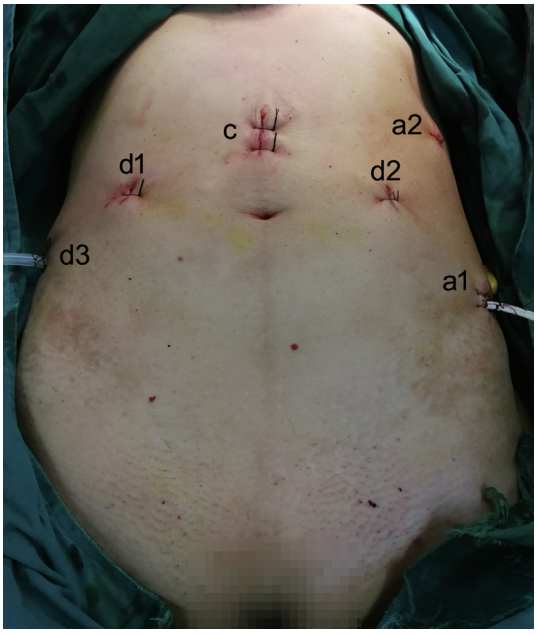

Fig. 1 – Port positioning. Point c denotes the placement for the camera trocar, and points d1, d2, and d3 are the positions for the other three robotic trocars. The assistant uses one 12-mm trocar (a1) and one 5-mm trocar (a2).

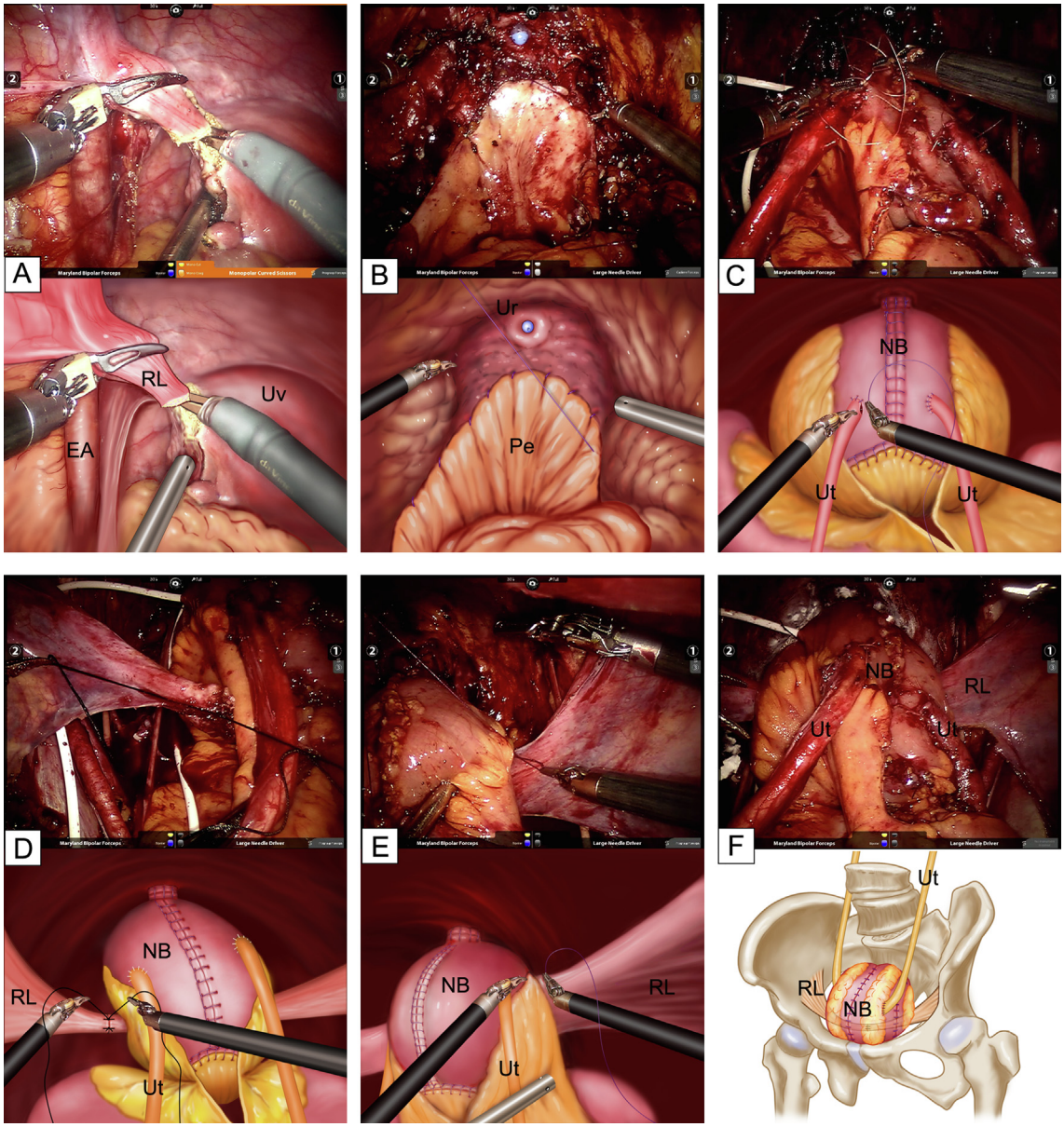

Fig. 2 – The critical steps in reconfiguration of a neobladder with round ligaments. (A) The round ligaments are cut close to the uterus and preserved early before pelvic lymphadenectomy. (B) To reconstruct the pelvic floor, the flap, which was isolated from the posterior peritoneum from the posterior wall of the vagina and the uterus with a thick layer of extraperitoneal tissue, was sutured circumferentially to the pelvic fascia and to the vaginal wall just below the ventral urethral margin with 3-0 Vicryl. (C) A Hautmann neobladder was reconstructed and the ureters were anastomosed directly to the lateral wall of the neobladder with 4-0 monofilament sutures. (D) The stumps of the round ligament were sutured with 2-0 polyester sutures behind the neobladder. (E) The bilateral sides of the neobladder were sutured to the round ligament using 3-0 Vicryl. (F) Completion of the ONB reconfiguration. EA = external iliac artery; RL = round ligament; Uv = uterus; Ur = urethra; Pe = peritoneum; Ut = ureter; NB = neobladder.

The round ligaments were cut close to the uterus and preserved early in the operation before PLND (Fig. 2A). The stumps of the round ligaments were sutured with 2-0 polyester sutures. In contrast to the open approach, this step was performed after intracorporeal anastomosis of the urethra pouch and ONB reconstruction (Fig. 2C,D). The bilateral sides of the pouch were sutured to the round ligament using 2-0 Vicryl (Fig. 2E) so that the posterior part of the pouch was suspended from the round ligament. The ligament provides back support to the ONB and prevents its downward migration after resection of the uterus (Fig. 2F).

An enhanced recovery after surgery protocol was followed for most patients when applicable [17]. The pelvic drain was removed when the output was <100 ml/d and fluid biochemistry excluded the presence of urine. The ureteral catheters were removed during the hospital stay at 10–12 d after surgery. The urethral Foley catheter was removed at 2 wk if no leakage was confirmed.

2.2. *Follow-up*

Scheduled follow-up visits occurred at 3, 6, 12, 18, and 24 mo, and annually thereafter. Each follow-up visit included history, voiding function questionnaires on daytime and nighttime continence, a physical examination, laboratory work, and a radiological evaluation (chest computed tomography, computed tomographic urography; Fig. 3). Urodynamic evaluations were performed at 3, 6, and 12 mo when applicable. Voiding radiography and cystoscopy were routinely used to check for ONB outlet

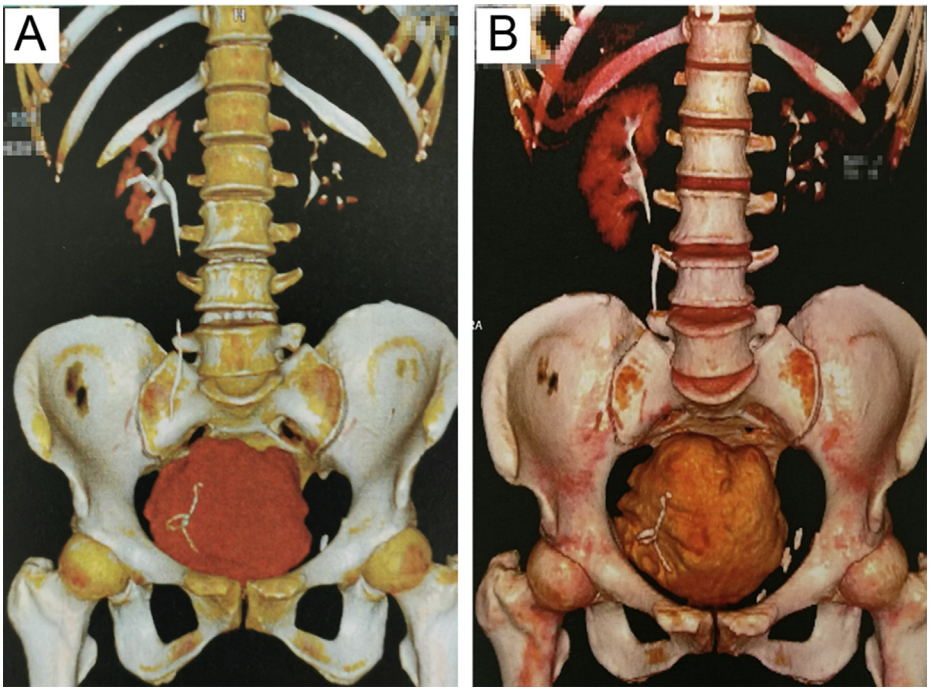

Fig. 3 – Computed tomographic urography imaging of an orthotopic neobladder suspended with round ligaments at (A) 6 mo and (B) 12 mo.

obstruction when patients presented with incomplete emptying. CUR was defined as a persistent residual urine volume greater than 100 ml. Additional ultrasonography or urodynamic measurements were conducted if the patient presented with a change in urination pattern. Continence was investigated using a questionnaire with the continence definition as previously described [16]. The 90-d postoperative complications were categorised according to the Clavien-Dindo classification [18].

2.3. Statistical analysis

The two ONB types were compared using the Mann-Whitney *U* test for continuous data and Pearson's χ^2 test or Fisher's exact test for categorical data. A Kaplan-Meier curve was used to compare the cumulative incidence of CUR over time. The difference between the study groups was assessed using the log-rank test. All analyses were performed using the SPSS version 19.0 (SPSS Inc., Chicago, IL, USA).

3. Results

The patient demographics and clinical parameters are shown in Table 1. Robotic intracorporeal ONB was successfully completed in all 28 patients without open conversion. The baseline and intraoperative characteristics of the two groups were similar (Table 1). The median operative time was 305 min (interquartile range [IQR] 270–370) for tONB and 303 min (IQR 287–330) for rONB. The median estimated blood loss was 325 ml (IQR 200–700) for tONB and 350 ml (IQR 262–600) for rONB. All baseline parameters were not different between tONB and rONB, except the number of dissected lymph nodes was larger in rONB than in tONB.

Results for complications are presented in Table 2. Overall, 50.0% of tONB patients (eight of 16) and 41.7% of rONB patients (five of 12) experienced low-grade complications, with no significant differences observed between the treatment groups. Two of 16 tONB patients and one of 12 rONB patients experienced high-grade complications with neobladder-vaginal fistula (NVF). NVF was secondary to a pelvic abscess in one case. These patients with NVF recovered after reoperation with transvaginal repair.

Follow-up for the overall cohort ranged from 6 mo to 40 mo. Twenty-three patients (13 tONB and 10 rONB) were fol-

Table 1 – Clinical patient characteristics

Parameter	tONB	rONB	*p* value [a]
Number of patients	16	12	
Median age, yr (IQR)	58 (50–66)	60 (48–70)	0.689
Median body mass index, kg/m^2 (IQR)	24.2 (21.6–26.1)	23.1 (20.2–26.4)	0.545
ASA score (*n*)			1
1–2	16	12	
3–4	0	0	
Lymphadenectomy (*n*)			0.560
Standard	15	10	
Extended	1	2	
Median number of lymph nodes, *n* (IQR)	18 (13–20)	23 (16–30)	0.045
TNM stage, *n* (%)			
pT1	4 (25.0)	2 (16.7)	0.669
pT2	8 (50.0)	8 (66.7)	
pT3	4 (25.0)	2 (16.7)	
pN0	14 (87.5)	12 (100)	0.492
pN1–2	2 (12.5)	0 (0)	
Neoadjuvant chemotherapy (*n*)	1	1	1
Adjuvant chemotherapy (*n*)	3	1	0.61

ASA = American Society of Anesthesiologists; IQR = interquartile range; rONB = orthotopic neobladder suspended with round ligaments; tONB = traditional orthotopic neobladder.
[a] Fisher's exact test for categorical variables and Mann-Whitney *U* test for continuous variables.

Table 2 – Early and late complications stratified by Clavien classification

	Patients, *n* (%)		Treatment	*p* value [a]
	tONB	rONB		
Early complications (≤90 d)	10 (62.5)	6(50)		0.702
Clavien grade I–II	8 (50)	5 (41.7)		0.718
Paralytic ileus	1 (6.3)	1 (8.3)	Conservative	
Pneumonia	0 (0)	1 (8.3)	Antibiotics	
Prolonged urine leakage	1 (6.3)	1 (8.3)	Prolonged drainage	
Pelvic abscess	1 (6.3)	0 (0)	Transvaginal drainage	
Lymphatic leakage	2 (12.5)	1 (8.3)	Prolonged drainage	
Anaemia requiring transfusion	2 (12.5)	1 (8.3)	Transfusion	
Diarrhoea	1 (6.3)	0 (0)	Conservative	
Clavien grade III–IV	2 (12.5)	1 (8.3)		1
Neobladder-vaginal fistula	2 (12.5)	1 (8.3)	Transvaginal repair	
Late complications (>90 d)				
Clavien grade I–II	1 (6.3)	1 (8.3)		1
Chronic pyelonephritis	1 (6.3)	1 (8.3)	Antibiotics	
Clavien grade III–IV	0 (0)	0 (0)		

rONB = orthotopic neobladder suspended with round ligaments; tONB = traditional orthotopic neobladder.
[a] Fisher's exact test.

lowed for more than 1 yr. The median follow-up time was 24.0 mo (IQR 18.5–33) for the tONB group and 19.5 mo (IQR 12–33 m) for the rONB group. The preliminary functional outcomes are shown in Fig. 4. To evaluate continence, the questionnaires were analysed at 6 mo postoperatively. In the tONB group, continence was rated as good, satisfactory, and unsatisfactory by 56%, 38%, and 6% of patients during the day, and 31%, 38% and 31%, respectively, at night. In the rONB group, continence was rated as good, satisfactory, and unsatisfactory by 75%, 17%, and 8% of patients during the day, and 25%, 50%, and 25%, respectively, at night. There were no significant differences in continence between the groups during the day ($p = 0.60$) or night ($p = 0.80$). In addition, there were no significant differences in urodynamic parameters, including peak flow rate, functional urethral length, capacity, neobladder pressure at maximum cystometric capacity, and compliance, between the tONB and rONB groups (Table 3). Six of the 16 tONB patients and two of the 12 rONB patients experienced CUR. The cumulative risk of CUR was 37.5% in the tONB group and 16.7% in the rONB group. However, Kaplan-Meier curves showed that the cumulative incidence of CUR did not significantly differ between the tONB and rONB groups according to a log-rank test ($p = 0.199$).

One patient in the tONB group died of a lung metastasis at 12 mo postoperatively. Two patients in the rONB group died of liver and bone metastasis at 12 mo and 18 mo postoperatively, respectively.

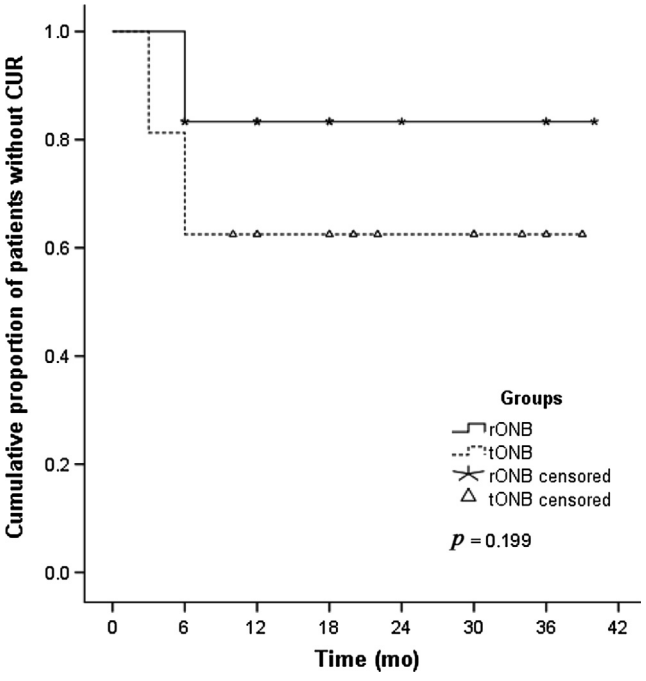

Fig. 4 – Cumulative proportion of patients without significant chronic urinary retention (CUR). rONB =orthotopic neobladder suspended with round ligaments; tONB = traditional orthotopic neobladder.

Table 3 – Urodynamic parameters and continence at 6 mo after surgery

	tONB (*n* = 16)	rONB (*n* = 12)	*p* value
Urodynamic parameters, median (interquartile range)			
Peak flow rate (ml/s)	13(8–18)	11 (7–13)	0.21
Functional urethral length (mm)	22 (20–25)	22 (16–25)	0.45
Maximal urethral closure pressure (cm H_2O)	59 (46–70)	56 (35–65)	0.24
Neobladder neck pressure (cm H_2O)	35 (30–43)	34 (22–35)	0.22
Neobladder pressure at maximum cystometric capacity (cm H_2O)	10 (6–17)	12 (9–23)	0.16
Compliance (ml/cm H_2O)	24 (22–29)	28 (23–36)	0.64
Capacity (ml)	291 (230–320)	300 (235–348)	0.84
Continence at 6 mo, *n* (%)			
Daytime			0.60
Good	9 (56)	9 (75)	
Satisfactory	6 (38)	2 (17)	
Unsatisfactory	1 (6)	1 (8)	
Nighttime			0.80
Good	5 (31)	3 (25)	
Satisfactory	6 (38)	6 (50)	
Unsatisfactory	5 (31)	3 (25)	

rONB = orthotopic neobladder suspended with round ligaments; tONB = traditional orthotopic neobladder.

4. Discussion

In the era of robotic surgery, worldwide cumulative data for RC and urinary diversion have shown that intracorporeal urinary diversion (ICUD) has dramatically increased since the previous decade [19,20]. ICUD provides potential benefits in terms of a minimally invasive technique, including smaller incisions, less pain, less bleeding, a lower rate of bowel-related complications, a lower risk of "third space" losses and fluid imbalance, and no need for extensive ureteric dissection, which may cause ureteric strictures [21–23]. However, the proportion of intracorporeal neobladders for all ICUDs is still low owing to technical challenges, including a longer operation time and learning curve. In the present study, we established a surgical technique for a robotic intracorporeal ONB suspended with round ligaments. The technique replicates the principles of our original open surgery approach in women. In contrast to the open approach, which uses 50 cm of ileum in a Studer manner, the intracorporeal ONB is reconstructed using 40 cm of ileum in a Hautmann manner. Both reconfigurations are in accordance with the "double-folding" principle, and the long-term functional outcome after the open approach is promising worldwide [24,25]. In addition, urinary function after our robotic intracorporeal ONB is comparable to that after open surgery [16].

ONB creation after RARC is considered the most challenging part of the surgical procedure, and most complications associated with RARC are related to the ONB. Likewise, the prolonged operation time is also a factor in the higher rate of complications. A prolonged operation time has always been a concern with RARC and ICUD, especially for totally intracorporeal ONB. In our series, the operation time ranged from 230 to 450 min. We observed that the operation time reached a plateau of 300 min after the first 20 cases (15 male and five female patients) since 2017. It should be noted that our team has ONB experience of more than 600 cases, including open, laparoscopic, and robotic approaches for extracorporeal reconstruction. Thus, the learning curve for the intracorporeal ONB technique should be shorter in high-volume centres [26].

Safety issues related to perioperative complications are a concern for this new modified surgical technique. We found no difference in total complication rates between the tONB and rONB groups or between the robotic intracorporeal approach and the previous open approach. However, the occurrence of ileus (a gastrointestinal complication) was 6.3% in the tONB group and 8.3% in the rONB group, and seemed to be lower than for patients undergoing the open approach [14]. This reflects the advantages of the intracorporeal ONB approach. Another specific complication of concern is neobladder-vaginal fistula (NVF) related to ONB in women. NVF is an uncommon complication occurring in 5.0–11% of women undergoing RC with orthotopic urinary diversion [27–29]. The NVF incidence of 10.7% (three of 28) in the current series is slightly higher than the average rate reported for other series using the open approach. Regarding possible causes of NVF, our first NVF case occurred within the five initial patients. To achieve neobladder-urethral anastomosis, the initial procedure involved anastomosing the most dependent part of the posterior plate of the neobladder in these patients. The affected patient presented with prolonged anastomotic leakage after the operation, caused by a tension connection between the urethral and posterior urethral plates of the neobladder. The second NVF case presented with an abscess behind the posterior plate of the neobladder due to inadequate drainage. The final NVF case did not present with any symptoms. We believe that the rate of NVF will decrease with maturation of the intracorporeal technology for women.

To the best of our knowledge, the current study is the first description of a robotic intracorporeal technique to provide back support for ONB in women. The intracorporeal approach replicates our open technique using a Hautmann pouch instead of a Studer pouch. Our preliminary data on the functional outcome show that intracorporeal rONB also effectively improves neobladder emptying. The incidence of CUR was 37.5% in the tONB group and 16.7% in the rONB group. The functional outcome in the present study compares favourably with results for our open approach [14] and data reported by Zahran et al [13] of CUR incidence of 45.9% and 39.7% for the groups without surgical modifications, and 23.1% and 18.8% for the group with surgical modifications, respectively. Puppo et al [12] reported that the creation of posterior support for the neobladder by harvesting a thick flap completely avoided CUR. Taken together, these data indicate that anatomical or mechanical alterations, including configuration of the reservoir and an acute neocystourethral angle due to downward migration of the ONB, are important causes of incomplete emptying. A hammock-like structure created using a ligament suspended posterior to the Hautmann pouch could maintain the anatomical ONB configuration at an adequate neocystourethral angle. Nevertheless, this surgical modification cannot prevent CUR in all cases. We cannot deny that alteration of the nerves is another important factor contributing to CUR. Ali-El-Dein et al [30] reported that among female patients who underwent genital-sparing cystectomy and orthotopic diversion for bladder cancer, daytime continence was achieved in 13/13 (100%) and nighttime continence in 12/13 (92%), without any CUR in the long term. It has been suggested that ideal functional outcomes contribute to further preservation of the physical structure, including the anatomy and nerves. In addition, Gross et al [31] found that hypercontinence with CUR was related to a hypertonic urethra with very high maximal urethral closing pressure (UCP), and they assumed that these patients were unable to relax the proximal part of the urethra because of intraoperative damage to the parasympathetic nerves and overstimulation by sympathetic nerves. In our series, two rONB patients experienced CUR, of whom one had a hypertonic urethra with very high maximal UCP at rest of approximately 86 cm of H_2O. Therefore, identification of individual potential aetiologies may provide assistance in planning a urinary diversion.

This report is limited by the small sample size, selection bias, and short follow-up. Although our indications for intracorporeal ONB were the same as those for the open approach in women, patients were allocated to two types of ONB procedure according to their own choice without

randomisation. Although the rate of CUR in the tONB group was double that in the rONB group, the difference did not reach statistical significance owing to the small sample size. Corroboration of both the better emptying function and the benefits of robotic intracorporeal ONB reconstruction with this integrated surgical technique is required in more cases and over the long term.

5. Conclusions

We established a surgical technique for robotic intracorporeal ONB reconfiguration suspended with round ligaments that is based on our open surgical approach. This integrated technique is feasible and safe. The technique not only potentially prevents the occurrence of emptying dysfunction but also benefits from being a minimally invasive intracorporeal surgical approach.

Author contributions: Zhiwen Chen 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: ZW Chen.
Acquisition of data: ZW Chen, P He, XZ Zhou, P Li, QW Li, J Zheng.
Analysis and interpretation of data: P He, XZ Zhou.
Drafting of the manuscript: ZW Chen.
Critical revision of the manuscript for important intellectual content: P He, XZ Zhou, ZW Chen.
Statistical analysis: XZ Zhou.
Obtaining funding: ZW Chen.
Administrative, technical, or material support: XM Li. P Li.
Supervision: ZW Chen, ZS Zhou.
Other (*sketching*): ZW Chen.

Financial disclosures: Zhiwen Chen certifies that all conflicts of interest, including specific financial interests and relationships and affiliations relevant to the subject matter or materials discussed in the manuscript (eg, employment/affiliation, grants or funding, consultancies, honoraria, stock ownership or options, expert testimony, royalties, or patents filed, received, or pending), are the following: None.

Funding/Support and role of the sponsor: This study was supported by Clinical Innovation Funding from the Third Military Medical University (grant number 2012XLC02) to Zhiwen Chen. The sponsor played a role in review and approval of the manuscript.

Acknowledgments: We acknowledge Ms Hanzhi Chen from the University of Florida for her contribution to video production.

Supplementary data

The Surgery in Motion video accompanying this article can be found in the online version at doi: https://doi.org/10.1016/j.eururo.2021.11.012 and via www.europeanurology.com.

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