Robot-assisted-radical-cystectomy with total intracorporeal Y neobladder: Analysis of postoperative complications and functional outcomes with urodynamics findings

Robot-Assisted-Radical-Cystectomy with total intracorporeal Y neobladder: analysis of postoperative complications and functional outcomes with urodynamics findings

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ABSTRACT

Objectives: To describe our robotic Y intracorporeal neobladder (ICNB) technique and to report its post-operative complications and urodynamics (UD) findings.

Subjects and Methods: In this prospective study we enrolled patients affected by MIBC (T1-T4N0-N1M0) from 01/2017 to 06/2021 at our Centers. All the patients underwent robotic radical cystectomy (RARC) with Y-ICNB reconfiguration. Early and late complications were collected and classified according to Clavien-Dindo. Continence and potency at 1, 3, 6 and 12 months were evaluated. At the 3rd month of follow-up patients underwent UD. Finally, in a retrospective match paired analysis the functional outcomes of Y RARC patients were compared with a cohort of open Y radical cystectomy.

Results: 45 patients were enrolled. Overall 30-day complications were observed in 25 (55,5%) patients and 30 to 90-days complications in 4 (8,9%). 9 patients (20%) had Clavien $\geq$ 3 complications. UDs revealed median neobladder capacity of 268 cc, with a median compliance of 13 ml/cm H20; the voiding phase showed a voiding volume and a post void residual (PVR) of 154 cc and 105 cc respectively. At 12 months of follow-up 4.4%, 15.5% and 4.4% of the patients experienced urge, stress and mix urinary incontinence respectively. The comparison between Y RARC and Y open RC revealed a higher neobladder capacity with open approach (p=0.049) with subsequent better findings during the voiding phase in terms of maximum flow (p= 0.002), voiding volume (p= 0.001) and PVR (p= 0.01). Focusing on continence recovery, a slight trend in favor of RARC was shown without reaching the statistical significance.

Conclusions: Robotic Y-ICNB is feasible and safe as shown by the low rate of postoperative complications. Satisfying UD functional outcomes are achievable, both during filling and voiding phase.

1. INTRODUCTION

In case of organ confined muscle invasive bladder cancer (MIBC), the best treatment solution is still represented by radical cystectomy (RC) associated to pelvic lymph-node (LND) dissection and urinary diversion [1].

Aiming to decrease the impact of this procedure on patients' quality of life and aesthetics, when feasible, the replacement of the bladder with a urinary diversion allowing to void through the native urethra is very attractive [2].

Over the years, the ever wider use of robotic surgery has allowed to furtherly seek this result while preserving oncological and safety outcomes comparable with the open approach [3, 4]. Moreover, possible advantages in terms of estimated blood losses (EBL), time to regular diet and length of stay (LOS) were recorded in favor of robot assisted radical cystectomy (RARC) [5]. Multiple approaches for intracorporeal neobladder (ICNB) reconstruction have been reported, emulating the steps of open surgery or attempting to simplify them [6].

The ideal characteristics of neobladders are: appropriate capacity, low-pressure storage in order to avoid ureteral reflux, high compliance to promote continence, voluntary voiding at acceptable intervals with scarce post void residual and low reabsorption capacity.

Among the multiple ICNB options, the Y neobladder, firstly described by Fontana et al. [7], still represents only 5% of robotic procedures [6], and hasn't been deeply investigated, especially in terms of functional outcomes [8, 9].

In this prospective study we described our robotic Y-ICNB technique and we reported hereafter the results concerning post-operative complications and urodynamics findings. Finally, we compared the functional outcomes of robotic and open approach by using a propensity score match analysis.

2. MATERIALS AND METHODS

a. Study population

In this prospective study we enrolled patients affected by MIBC (T1-T4N0-N1M0) from January 2017 to June 2021 at San Luigi Gonzaga Hospital – Orbassano, Turin (IT) and IRCCS Candiolo Cancer Institute, (IT) by the same surgical equipe. The exclusion criteria were: pathological confirmation of tumor in the prostatic urethra, indication to treatment without curative intent (cT4b, salvage or palliative cystectomies), presence of urethral strictures.

All patients were submitted to RARC with transperitoneal approach. A highly experienced surgeon in both pure and robot-assisted laparoscopic surgery for prostate and bladder cancer (F. P.) carried out all the procedures. All suitable patients were offered to undergo neoadjuvant cisplatin-based chemotherapy before the surgical procedure.

b. Surgical technique

i. Patients positioning, trocar placement and demolitive phase with LND

The patient was placed in a 27° Trendelenburg position and six ports (four 8 mm ports for the optic and robotic instruments, and both 12 mm and 5 mm ports for the assistant) were introduced and placed in a classical fan configuration and the daVinci surgical system (X or Xi based on the availability in operative room) was docked.

Radical cystectomy was performed with posterior approach reproducing the steps of open technique [6] and in selected cases, a nerve sparing procedure was carried [10]. After bladder removal, the posterior reconstruction was performed in a double layer using a 3-0 barbed suture; firstly, the needle was passed into the cranial portion of the previously sectioned Denonvilliers' fascia and the median raphe from right to left; then the previously sectioned peritoneum of Douglas pouch was sutured with the median raphe, to obtain a peritoneal flap.

An extended modified pelvic lymph node dissection was performed in all cases with the removal of obturator, internal iliac, external iliac and presacral lymph nodes.

Finally, using the suction device, a peritoneal washing cytology was obtained inside the pelvic cavity and the obturator fossa bilaterally, with the aim to record any spreading of tumoral cells.

ii. Total intracorporeal Y neobladder configuration

The ileum was marked by placing a 3/0 monofilament stay suture 15 to 20 cm proximally to the ileocecal valve. Holding the suture on the right side with the IV robotic arm, the surgeon pulled the ileum caudally towards the urethral stump paying attention to the tissue traction on the mesentery. With this maneuver the ileal segment took a U-shaped configuration. Then, on the left side, the length of the ileal segment was determined with the same concepts ensuring to be long enough to anchor the ileum to the parietal peritoneum in a tension-free manner. Here, a second 3/0 monofilament stay suture was passed. At the end the isolated U-shaped ileal segment had two central portions of 15 to 20 cm each and two limbs of 5 cm each (Figure 1).

A third 3/0 monofilament stay suture was placed to mark the most distal portion of the U-shaped loop close to the urethral stump. An opening was made close to the stay suture for the urethroileal anastomosis. The posterior aspect of the urethroileal anastomosis was sutured using a 3-0 barbed suture over a 20F Foley catheter. The proximal and distal ends of the 40 to 60-cm ileal segment, previously marked with the 3/0 monofilament stay sutures, were transected using an Endo-GIA stapler. The bowel continuity was restored performing an anatomical side-to-side anastomosis using a 12 mm endo GIA stapler (Covidien, Ireland) with 60 mm medium/thick reload. The two central segments were detubularized at the antimesenteric borders, maintaining intact the two limbs. The posterior plate of the two central detubularized segments was sutured using 3-0 barbed sutures in a running fashion. The anterior plate was then sutured in a similar fashion, also completing the anterior aspect of the urethroileal anastomosis. Leakage test was made at the end of the procedure filling the neobladder with 60 ml of saline solution. The ureters were spatulated anteriorly and reimplanted on 7-9 Ch Bracci ureteral stents, using the direct Nesbit technique, to the dorsal aspect of each limb with 4-0 polydioxanone sutures. Ureteral stents were brought out through the distal portions of each limb and then through the anterior abdominal wall. The two limbs were then fixed to the psoas muscles. An independent Jackson-Pratt drainage was inserted through the skin for the fourth robotic arm. The specimen was retrieved through the skin from a widening of the incision for the optic trocar. At the end of the procedure, the skin wounds were sutured. The steps of this reconstructive phase of the intervention were illustrated in Figure 2.

c. Postoperative care, pathological findings and follow-up

After the procedure we thoroughly applied the enhanced recovery after surgery (ERAS) protocol [11]. Final pathology was reviewed in accordance with the revised WHO 2016 classification [12]

and the rate of positive surgical margin (PSM) was assessed. The planned follow-up included visits at 1, 3, 6 and 12 months; blood tests and CT scan performed at three months and afterwards every 6 months until the third year after surgery and then annual imaging, as advised by EAU guidelines [13].

d. Perioperative data collection and analysis of the complications

We collected patient demographics and peri- and postoperative outcomes such as operative time, conversion rate, complication rate, blood loss, length of stay and final pathology.

Regarding postoperative complications, we distinguished early (30 days) and late (90 days) complications, including gastrointestinal, infectious, haematologic and genitourinary ones. Complications were classified in accordance with the Clavien-Dindo classification [14].

e. Functional outcomes and urodynamics evaluation

After the removal of the catheter patients were instructed to train the pelvic floor and void the neobladder every 2-3 hours during both day and night.

We evaluated continence at 1, 3, 6 and 12 months. We defined day and night continence as the necessity of up to one pad per day or night, respectively.

Furthermore, in men, at the same time-points, we assessed sexual potency, defined as the ability to obtain an erection adequate for sexual intercourse or masturbation, with or without the use of PDE-5 inhibitors (score >2 at question 32 of the EPIC questionnaire: 'How would you describe the usual quality of your erections during the last 4 weeks?') [15].

Finally, at 3 months, patient underwent urodynamic studies, including cystometry and uroflowmetry.

f. Comparison of functional outcomes with open Y neobladder

In a matched pair analysis, the data of the patients treated with RARC an Y ICNB were compared to those of patients underwent open radical cystectomy from 2007 until today by the same surgical team. "Inclusion" and "exclusion" criteria were the same, the patients in the open group were treated by using previously described technique [7]. All the data were extracted from our Institutional, prospectively maintained, IRB approved "San Luigi Hospital" database.

In order to optimize the nature of comparison with the control group (open RC), we relied on 1:1 propensity score (PS) matching according to the nearest neighbor [16] with a calliper of 0.2. The

PSMATCH procedure by SAS® Statistics Software was used. The 1:1 PS-matched cohorts (RARC vs open RC) were balanced according to age, sex, body mass index (BMI), clinical stage, age adjusted Charlson index and pathological stage (Supplementary Table 2).

g. Statistical analysis

Data were reported using median and interquartile ranges (IQR) or frequencies and proportions for continuous or categorical variables, as appropriate. To verify the comparability between Y RARC and open RC groups, baseline and urodynamics variables were evaluated, testing the differences of quantitative and categorical variables with nonparametric Mann–Whitney and chi-squared tests, respectively. Kaplan-Meier survival curves were design with the log rank test to assess the cancer specific survival (CSS) and the recurrence-free survival (RFS) rates of the cohort, stratified in localized (≤T2) and locally-advanced (≥T3a) tumor and according to the nodes status (N0 vs N+). Statistical significance was set at $p<0.05$. Statistical analysis were performed using SAS® Statistics Software.

3. RESULTS

a. Baseline characteristics and perioperative outcomes

Forty-five patients were included in the study. Baseline characteristics were summarized in Supplementary Table 1.

The median operative time was 287 mins (263 – 315), of which 115 mins (109 – 133) and 165 mins (151 – 182) for demolitive and reconstructive phase, respectively. In 26 (57,8%) of the male patients a nerve-sparing approach was performed. Median EBL was 549 cc (410 – 687).

Focusing on postoperative data, median catheterization and hospitalization time were 15 (13 – 18) and 17 (15 – 23) respectively, whilst the median time for ureteral stent removal was 14 (12 – 15) days (see Table 1).

b. Analysis of the complications

Complications are listed in Table 1. Overall 30-day complications were observed in 25 (55,5%) patients and 30 to 90-days complications in 4 (8,9%).

Rate of Clavien grade I, II, IIIa, IIIb, IVa, IVb and V complications within 30 days were 4 (8,9%), 12 (26,7%), 4 (8,9%), 3 (6,7%), 1 (2,2%), 1 (2,2%) and 0 respectively.

The highest-grade complications were hematologic in 16 (35.6%), gastrointestinal in 14 (31.1%), infectious in 8 (17.8%), genitourinary in 7 (15.5%) and miscellaneous in 7 (15.5%) cases (fever in all the cases). One bowel anastomotic leak (2,2%), 2 benign uretero-enteric anastomotic strictures (that not required any surgical approach) (4,4%) and 4 lymphoceles (8,9%) were recorded. Uretero-enteric strictures surgically treated were noticed in 1 of 45 patients undergoing temporary nephrostomies and double J that was removed after 30 days. No neobladder-to-conduit diversions reconfigurations was needed.

c. Pathological and oncological outcomes

Forty-four cases revealed transitional cell carcinoma, whilst in 1 case a squamous carcinoma was registered. pT stage was shown in Table 2. The median number of lymph-nodes removed was 18 (IQR: 16 – 24) and 36 (80%) patients had pN0 disease. Focusing on oncological outcomes (Tables 2), median follow-up time was 14 (IQR: 12-18) months. In 4 (8,9%) and 2 (4,4%) cases local or distant recurrences were registered, respectively. The most frequent sites of distant metastasis were lung in 2 patients and liver in 2 patients.

Four (8,9%) patients underwent a Cisplatin-Gemcitabine adjuvant chemotherapy and one (2,2%) received a Carboplatin-based adjuvant therapy. No patient developed urethral recurrence or bone recurrence 16 months after RARC.

Kaplan Meier curves for CSS and RFS, stratified for pT and pN stage, are depicted in Fig. 3A and Fig 3B, respectively. At twelve months 2 patients died (4.4%), among them only 1 (2.2%) for bladder cancer.

d. Y robotic neobladder functional outcomes

Evaluating the filling phase, at three months the median neobladder capacity was 268 cc (IQR: 244 -321), with a median compliance of 13 ml/cm H20 (IQR: 9-23). Urinary incontinence after provocative maneuvers (Valsalva) was registered in 2 (4.4%) patients. The study of the voiding phase at three months revealed a voiding volume and a post void residual (PVR) of 154 cc (IQR: 90 – 230) and 105 cc (IQR 33 – 160) respectively.

Daytime continence was achieved in 28 (62,2%), 33 (73,3%), 34 (75,5%) and 34 (75,5%) patients at 1, 3, 6, 12 months of follow-up; whilst the night-time continence rates recorded were 53,3%, 64,4%, 71,1% and 71.1% at the same time-points. At 12 months, the type of incontinence was urge incontinence in 2 (4,4%) patients, stress incontinence in 7 (15,5%) patients and mixed incontinence in 2 (4,4%) cases.

Among the 23 patients underwent NS RARC, 6 (23,0%), 9 (34,6%), 13 (50%) and 16 (61,5%) were potent at 1, 3, 6 and 12 months of follow-up (see Table 3).

e. Y RARC vs Y open radical cystectomy: analysis of functional outcomes

The comparison between Y RARC and Y open RC prior to any matching relied on 45 (16%) and 225 patients (84%). After retrospective matched pair analysis, 45 patients with same preoperative and pathological characteristics who underwent open RC were selected (Supplementary Table 2). Considering the filling phase, a higher maximum neobladder capacity was recorded with open approach (268 vs 299 cc for robotic and open approach; p=0.049). It translated into better findings during the voiding phase for open approach in terms of maximum flow (9.2 vs 13.7 cc; p= 0.002), voiding volume (154 vs 236 cc; p= 0.001) and PVR (105 vs 54 cc; p= 0.01). Focusing on continence recovery, a slight trend in favor of the robotic approach was shown without reaching the statistical significance (Table 3).

4. DISCUSSION

To the best of our knowledge herein we report the largest series of patients who underwent total Y-ICNB during RARC.

Our findings reveal that the Y-ICNB with robotic approach is feasible and safe, allowing to limit the occurrence of severe postoperative complications: nine patients (20%) only had Clavien grade $\geq$ 3 adverse events.

This finding is particularly encouraging, especially in the light of the results of a recently published systematic review [4], revealing an overall complication rate ranging from 10% to 82%, with Clavien $\geq$ 3 complications rate between 12% and 37%. Also

This goal was achieved thanks to the adoption in our Institution of the ERAS protocol that seems to reduce the risk of readmission at 30 days and decrease the days of hospitalization by 1-2 days [17]. Moreover, the adoption of the total intracorporeal approach allowed to record only 11% of gastrointestinal complications (excluding constipation) and 17% of infectious ones: these results are in accordance with the International Radical Cystectomy Consortium (IRCC), which revealed that patients who had intracorporeal diversion had a significantly lower risk of postoperative gastrointestinal and infectious complications [18].

Rate of lymphocele was 8.9%; even if slightly higher than other series [19], only 3 patients required needle aspiration. Even if haematologic complications (anemia) represented 35% of the entire adverse events recorded in our series, our mean EBL was 549 (410 – 687) cc, in line with the current Literature, that already demonstrated the advantages of robotics compared to the open approach [20]. Paying particular attention to some technical details of our Y-RARC, focusing on demolitive phase we should underline the importance of robotic approach that allow to maximize the urethral length preservation and to perform a more precise nerve-sparing approach as already demonstrated in the Literature [21]. Secondly, looking to the reconstructive phase, the suture between the peritoneal flap and the median raphe, reproducing the concept of the posterior reconstruction of our total anatomical reconstruction technique described for robotic prostatectomy [22-24], covers and fills the space between the rectum and the neobladder, avoiding the creation of a posterior funnel, and allows to lay down and allocate the neobladder in a more physiological manner. Moreover, this additional layer helps to avoid the risk of neobladder-rectal fistulae.

Thirdly, we noticed that no cases of neobladder stones was recorded thanks to the use of barbed sutures instead of metallic staplers for the reservoir reconfiguration.

Finally, the final configuration of Y-neobladder doesn't require ureteral transposition allowing to leave the ureters aligned in their natural position, avoiding traction, kinking, or crossing and preserving their vascularization. The ureter-neobladder anastomosis is therefore tension-free, reducing the incidence of strictures.

Focusing on functional aspects, starting to speak about continence recovery, in our series day-time continence rate, defined as the use of 0-1 pads/day, was good since the beginning of the follow-up overcoming 60%, reaching more than 75% after twelve months. Similar findings were recorded for night-time continence, with 71% of continent patients at the end of the follow-up. In current Literature, data on postoperative continence are very heterogeneous [25]: if the most recently published FLORIN technique reported similar continence outcomes [26], the Karolinska-modified Studer ICNB showed 90% of continence after 12 months (0 or 1 pad per day) [27], whilst with the U-shaped neobladder only 65% of patients used less than one pad during the day and 18% at night after a short median follow-up of 6.3 months [25]. It's interesting to denote that the group of Asimakopoulos et al. [9] described stunning findings on a small series of 40 highly selected young men with localized bladder cancer (T2 or less) submitted to nerve-sparing surgery and Y-shaped neobladder. At 12 months, they reached 100% of no-pad daytime continence and 72.5% night-time continence.

On the other side, among the 26 patients who had benefit of nerve sparing approach in our series, 13 (50%) and 16 (61.5%) were potent after 6 and 12 months of follow-up. Karolinska group reported a 19% of potency [27], whilst in the selected population presented by Asimakopoulos et al. [9] all the patients returned to preoperative erectile function. Regarding women, two out of three evaluable female patients included in our study stayed sexually active after the procedure (66%): our results are in line with Karolinska's institute data.

Another strength of our study is represented by a detailed analysis of urodynamics findings, covering a lacking field of the current Literature for ileal neobladder. Few studies focused on this aspect in the past. The USC group [28], reproducing Studer technique and using 60 cm of ileum, had a median neobladder capacity of 514 ml (330–1001 ml). This determined a normal compliance (median 33 ml/cmH2O) without neobladder overactivity, but is related to high PVR (mean PVR = 268 ml). On the contrary, the U-shaped neobladder described by the Japanese group [29] using only 40 cm of ileum, had a capacity of only 285 ml after 12 months. The maximum neobladder

pressure was 26.5 cmH2O, translating into a poorer compliance and PVR was low (median 29 ml). Our findings are in line, considering that we used 40-50 cm of ileum as well, with 268 cc (IQR: 244 - 321) of neobladder capacity, and a median compliance of 13 ml/cm H20 (IQR: 9-23). We would underline the advantage of measuring the length of the ileal segments based on the traction exercised on the mesentery, respect to the standard methods with the ruler, that allow us to have a tension free reservoir configuration, tailored on patient's specific anatomy.

Regarding continence, two over 12 (16%) [28] patients from the USC group had urinary incontinence during provocative maneuvers (coughing or Valsalva) related to an abdominal leak point pressure of 40 cmH2O and 50 cmH2O. A lower rate equal to 4.4% was recorded in our series.

Concerning the voiding phase, the inability to void completely was noted in many published studies, with PVR requiring clean intermittent catheterization (CIC) ranging from 0 to 11%. Again, our findings correctly fit in this context revealing a post void residual of 105 cc (IQR 33 – 160) with no need for CIC.

Finally, we focus on the comparison with our open Y RC. As shown in Table 3, the open approach allowed a significant higher maximum neobladder capacity (268 vs 299 cc; p= 0.0049), translating into better voiding results such as maximum flow, voiding volume and PVR. The reason could be an easier management of the bowel with the open approach that allows to measure more precisely the distance among the intestinal loops with a subsequent more voluminous reservoir. However, this objective urodynamics findings did not translate into an advantage in terms of continence recovery. On the contrary a slight trend in favor of robotics emerged, proven again the importance of the preservation of the anatomical structures (such as urethral length) and of the posterior reconstruction for continence mechanisms.

As regards the oncological outcomes, our findings confirming the oncological safety of the robotic approach as already demonstrated [30]. Moreover, it is interesting to denote that in any case the selective cytologic sampling performed after the demolitive phase revealed the presence of tumoral cells. With the limit of a short follow-up statistically significant differences were found for CSS and PFS according to the stratification for pT and pN respectively (Figure 3).

As already reported by other groups, the robotic approach seems to achieve survival outcomes comparable with those of open approach. Current evidence highlights that the most important factors predicting disease recurrence are pathological stage, lymph-node invasion and surgical experience [4].

Our study is not devoid of limitations, in particular the short follow-up, the huge experience of the surgeon – that may limit the reproducibility of the data in real life practice, and lack of late urodynamics findings. Furthermore, the issues of open approach related with the adoption of a detubularized neobladder instead of a reconfigured one (delay in the maturation of the reservoire), and with the use of Nesbit anastomosis technique (reflux), were replicated in robotics. However, despite these limitations, we report the largest series so far evaluating complication, oncologic and functional outcomes after RARC and Y-ICNB. Concluding, a last consideration should be made: due to the higher costs of robotics and its limited access, an accurate and tailored patients' selection for robotic approach is essential [31], and specifically for this kind of surgery the ideal candidates should be younger patients or those highly motivated to preserve sexual function.

5. CONCLUSIONS

Our findings reveal that total intracorporeal Y neobladder is feasible and safe with the robotic approach. Moreover, some technical tips and tricks allow to reduce the occurrence of postoperative complications. Finally, this kind of reconfiguration is characterized by satisfying urodynamics functional outcomes as proven by the adequate neobladder capacity, low-pressure storage and high compliance during the filling phase and low post void residual after the voiding phase.

CONFLICT OF INTEREST:

All the authors have nothing to declare.

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None

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FIGURE LEGENDS:

- Figure 1: Surgical steps of the isolation of the ileal segment for the reservoir and bowel continuity restoration. a) The first ileal segment was isolated 20 cm proximal to ileocecal valve; b) the ileal loop was pushed down up to the urethral stump; c, d) the length of the ileal segment was determined ensuring to be long enough to anchor the ileum to the parietal peritoneum in a tension-free manner, and then the proximal and distal end of the isolated ileal segment were transected using an Endo-GIA stapler; e) the left ileal segment previously marked with 3/0 monofilament stitch was anchored to the parietal peritoneum; f) the bowel continuity was restored by performing anatomical side-to-side anastomosis using an Endo-GIA stapler
- Figure 2: Surgical steps of Y neobladder reconfiguration. a) Peritoneal flap was sutured with median raphe covering the rectum; b) The posterior aspect of the urethroileal anastomosis was sutured by using a 3-0 barbed suture over a 20F Foley catheter; c, d) The two central segments were detubularized at the antimesenteric borders; e) The posterior plate of the two central detubularized segments was sutured using 3-0 barbed sutures in a running fashion; f, g) The anterior plate was then sutured in a similar fashion, also completing the anterior aspect of the urethroileal anastomosis; h, I, l) The ureters were spatulated anteriorly and reimplanted on 7 Ch Bracci ureteral stents, using the direct Nesbit technique, to the dorsal aspect of each limb with 4-0 polydioxanone sutures. Ureteral stents were brought out through the distal portions of each limb and then through the anterior abdominal wall. The two limbs were then fixed to the psoas muscles; m, n) final results of our Y-ICNB.
- Figure 3: A) Kaplan-Meier curves depicting cancer specific survival (CSS) stratified according pT and pN stage; B) Kaplan-Meier curves depicting recurrence free survival (RFS) stratified according pT and pN stage

Y RARC	0-30 days	30-90 days	Total
N° Gastrointestinal, number (%)			
• Bowel obstruction	1 (2,2)	0	1 (2,2)
• Bowel leak	1 (2,2)	0	1 (2,2)
• Constipations	9 (20)	0	9 (20)
• Ileus	0	0	0
• Neobladder-bowel fistula	3 (6,7)	0	3 (6,7)
• Total	14 (31,1)	0	14 (31,1)
N° Infectious, number (%)			
• Sepsis	1 (2,2)	3 (6,7)	4 (8,9)
• Urinary tract infection	3 (6,7)	1 (2,2)	4 (8,9)
• Intra abdominal ascess	0	0	0
• Epidydimitis	0	0	0
• Total	4 (8,9)	4 (8,9)	8 (17,8)
N° Hematologic, number (%)			
• Anemia	7 (15,5)	1 (2,2)	8 (17,8)
• Anemia requiring transfusion	8 (17,8)	0	8 (17,8)
• Hematoma/bleeding	0	0	0
• Total	15 (33,3)	1 (2,2)	16 (35,6)
N° Genitourinary, number (%)			
• Acute urinary retention	0	1 (2,2)	1 (2,2)
• Urine leak	0	0	0
• Ureteroenteric stricture	0	0	0
• Hydronephrosis	1 (2,2)	1 (2,2)	2 (4,4)
• Reservoir stones	0	0	0
• Bladder neck contracture	0	0	0
• Neobladder-vaginal fistula	0	0	0
• Lymphocele	1 (2,2)	3 (6,7)	4 (8,9)
• Totals	2 (2,2)	5 (11,1)	7 (15,5)
N° Others, number (%)			
• Acute renal failure	0	0	0
• Fever	4 (8,9)	3 (6,7)	7 (15,5)
• Compartment syndrome	0		0
• Nerva palsy	0	0	0
• Arhithmya	0	0	0
• Deep vein thrombosis	0	0	0
• Total	4 (8,9)	(6,7)	7 (15,5)

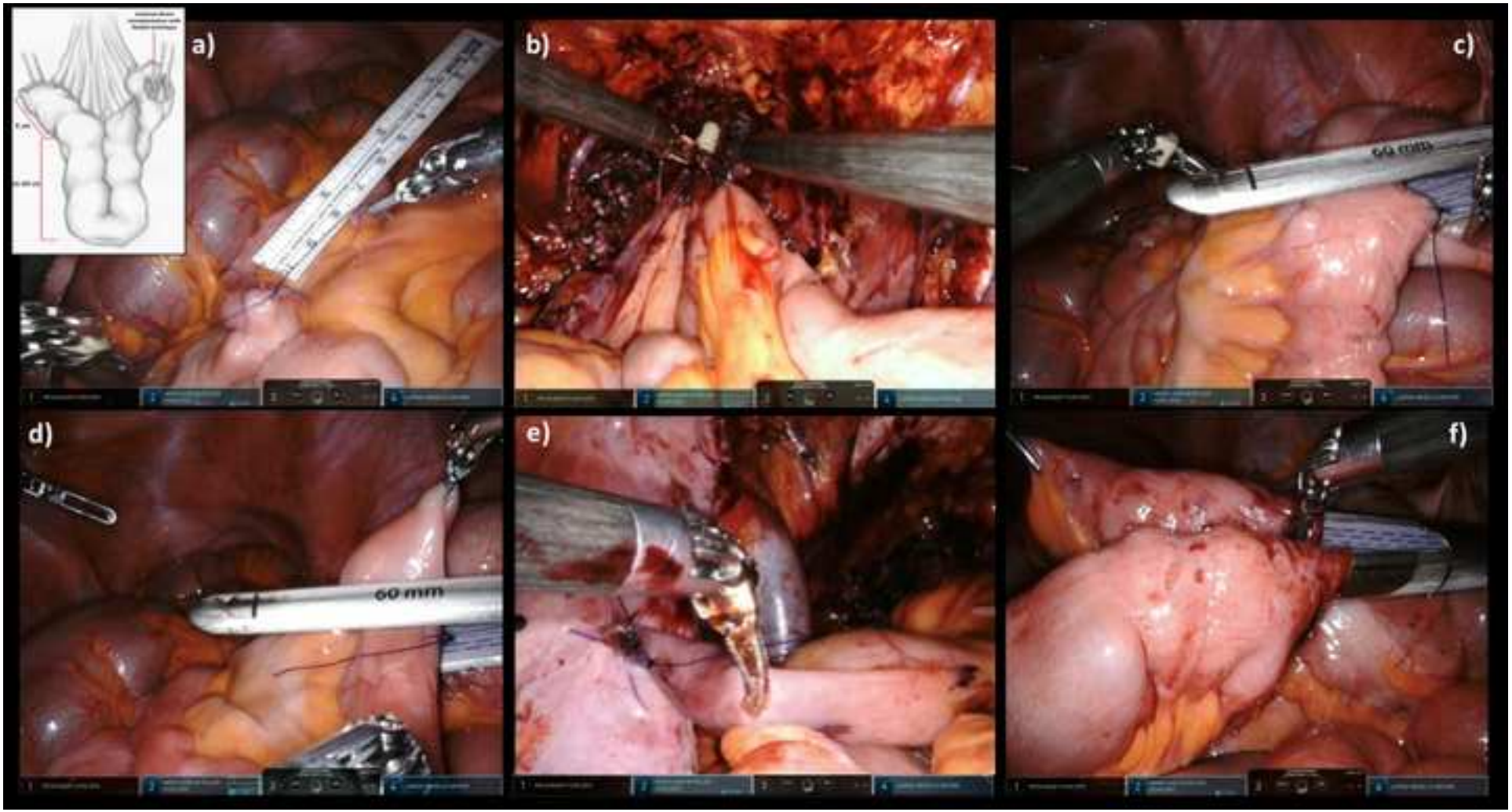
Table 1: Summary of early (30 days) and late (90 days) complications

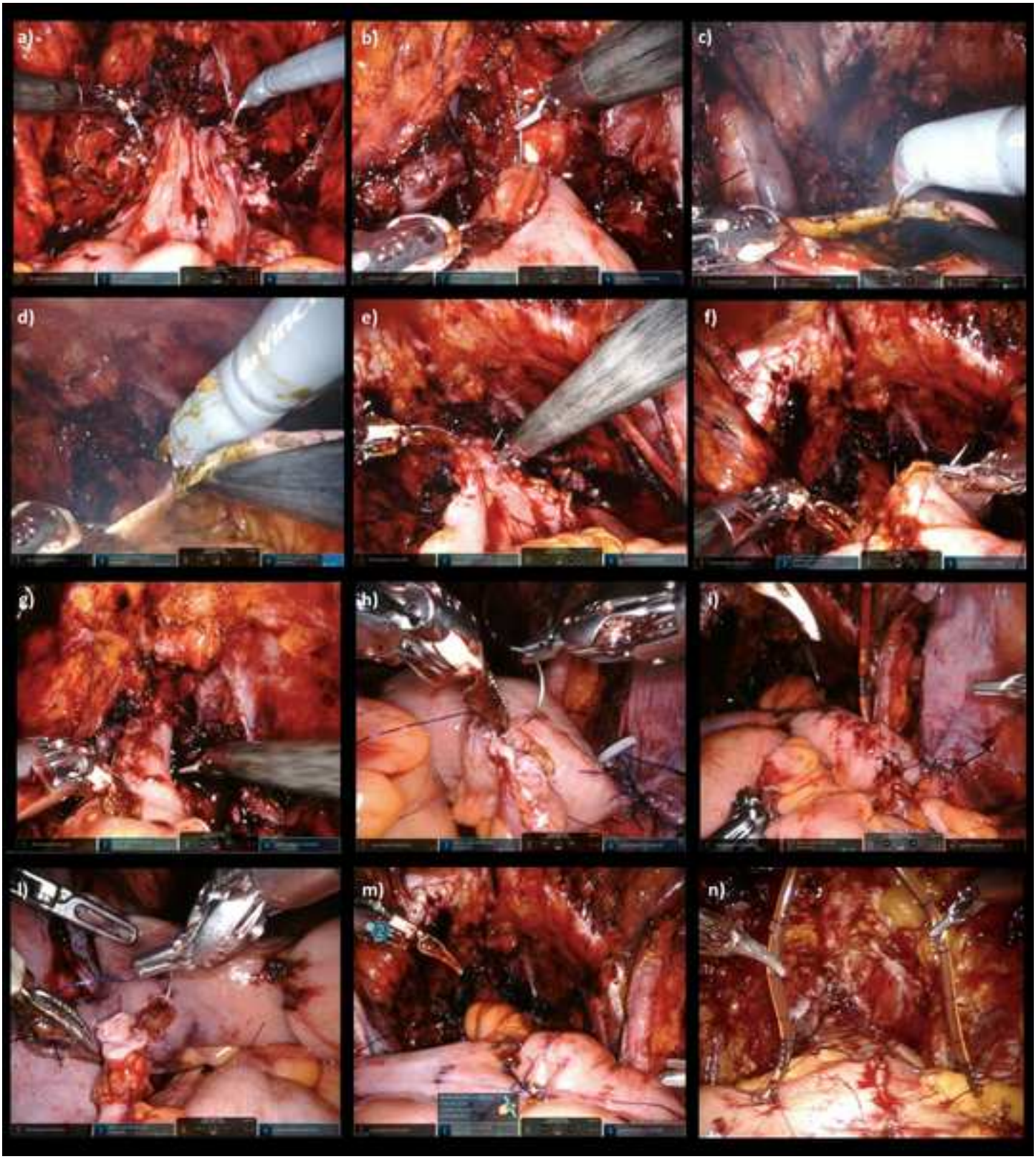
Y RARC	DATA
Type of histology, number (%) • Transitional cell Carcinoma • Others	 44 (97,8) 1 (2,2)
Concomitant carcinoma in situ, number (%)	14 (31,1)
PSM, number (%)	0 (0)
Lymphonode removed, median (IQR)	18 (16 – 24)
Final pathological stage, number (%) • pTa • pT0 • pT1 • pT2 • pT3 • pT4	 0 16 (35,6) 14 (31,1) 4 (8,9) 9 (20.0) 2 (4,4)
Pathological N stage, number (%) • pNx • pN0 • pN1 • pN2	 0 36 (80%) 5 (11,1%) 4 (8,9%)
Mean follow-up, months; median (IQR)	14 (12-18)
Recurrence, number (%)	5 (11.1)
Overall mortality, number 12 months (%)	2 (4,4)
Cancer specific mortality, number 12 months (%)	1 (2,2)

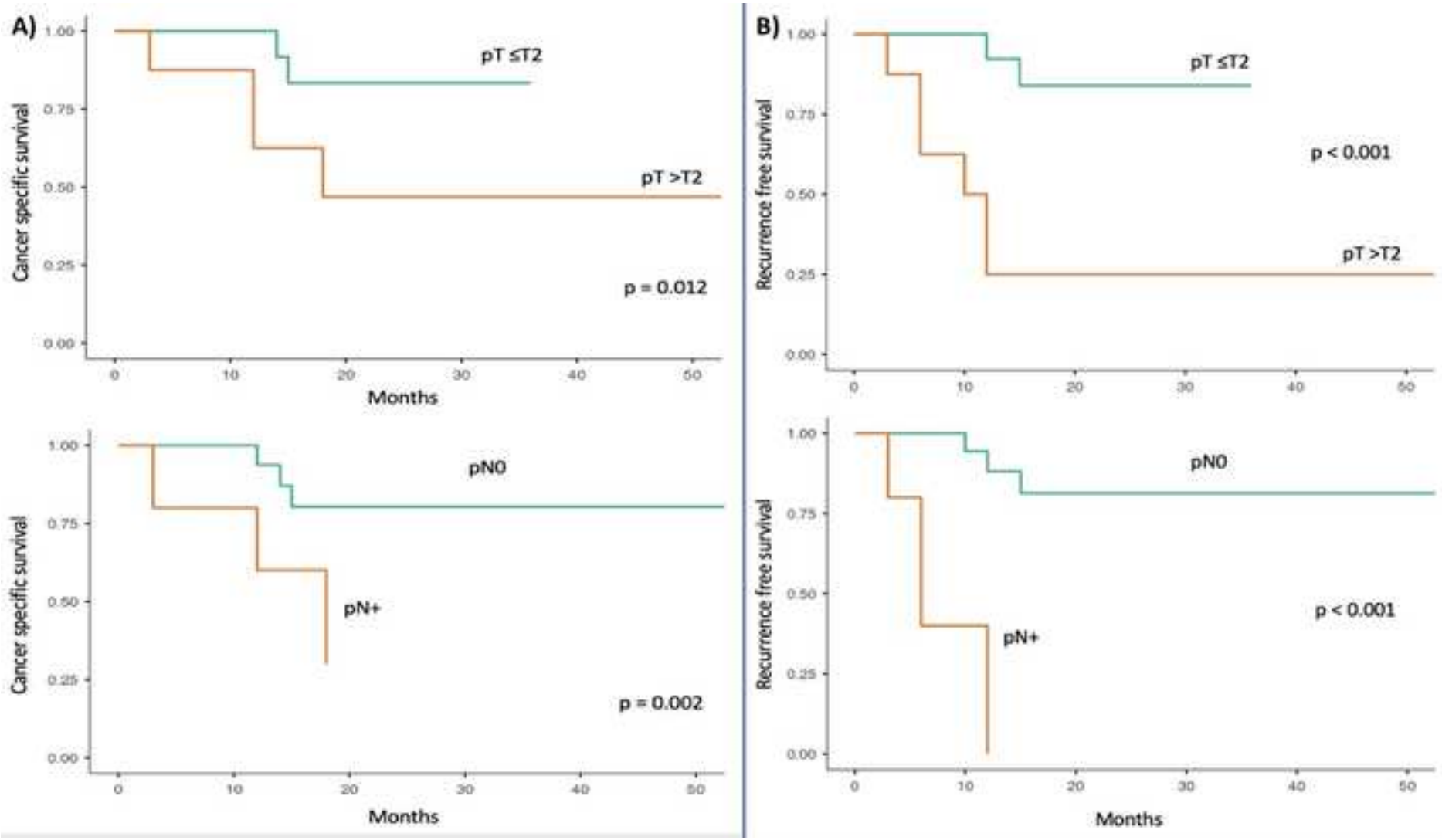
Table 2: Pathological and oncological follow-up (PSM: positive surgical margin; IQR: interquartile range)

	Y RARC	Y open RC	p-value
Filling phase			
Compliance (ml/cm H20), median (IQR)	13 (9-23)	19,9 (8-25)	0.08
Maximum neobladder capacity (ml), median (IQR)	268 (244 -321)	299,7 (250-315)	0.049
Neobladder pressure at maximum filling (ml/cm H20), median (IQR)	25 (15 – 34)	19,3 (17-33)	0.02
Urinary incontinence provocative manouvres, number (%)	2 (4.4)	6 (14)	0.2
Voiding phase			
Maximum flow (ml/s), median (IQR)	9,2 (5 – 11)	13,7 (3-17)	0.002
Voiding volume (ml), median (IQR)	154 (90 – 230)	236,1 (123-246)	0.001
Post voiding residual (ml), median (IQR)	105 (33 – 160)	54,7 (50,7)	0.01
Qmax neobladder pressure (ml/cm H20), median (IQR)	13 (10 – 24)	19,5 (10-32)	0.35
Functional outcomes			
Continence at 1 month, number (%)			
• diurnal	28 (62,2)	24 (53.3)	0.52
• nocturnal	24 (53,3)	22 (48.8)	0.82
Continence at 3 months, number (%)			
• diurnal	33 (73,3)	29 (64.4)	0.49
• nocturnal	29 (64,4)	26 (57.7)	0.66
Continence at 6 months, number (%)			
• diurnal	34 (75,5)	30 (66.6)	0.48
• nocturnal	32 (71,1)	28 (62.2)	0.81
Continence at 12 months, number (%)			
• diurnal	34 (75,5)	31 (68.8)	0.63
• nocturnal	32 (71,1)	30 (66.6)	0.81
Type of incontinence at 12 months of FU:			
• UUI	2 (4,4)	3 (6.6)	0.99
• SUI	7 (15,5)	8 (17.7)	0.99
• Mixed UI	2 (4,4)	3 (6.6)	0.99
Potency (for men), number (%)			
• 1 month	6 (23,0)	3 (12.5)	0.55
• 3 months	9 (34,6)	5 (20.8)	0.44
• 6 months	13 (50)	10 (41.6)	0.75
• 12 months	16 (61,5)	14 (58.3)	0.95
NS approach, number (%)	26 (57.7)	24 (53.3)	0.83

Table 3: Urodynamics findings and functional outcomes (IQR: interquartile range; Qmax: maximum flow; UUI: urge urinary incontinence; SUI: stress urinary incontinence; UI: urinary incontinence; NS: nerve-sparing)







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Declaration of interests

☒ The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

☐The authors declare the following financial interests/personal relationships which may be considered as potential competing interests:

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