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ARTICLE

Nerve-spring technique could achieve a functional trifecta outcome of robotic intracorporeal studer's orthotopic neobladder in the male

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Abbreviations used: RISON, robotic intracorporeal studer's orthotopic neobladder; PET/CT, Positron Emission Tomography-Computed Tomography; NVB, prostatic neurovascular bundle; CCI, Charlson Comorbidity Index; ERAS, enhanced recovery after surgery

Ethical Approval: This study was approved by the ethics committee of the Chinese PLA General Hospital Third Medical Centre (2018-P2-081-04).

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ABSTRACT

Objectives: To summarize some key steps of functional improvement in robotic intracorporeal studer's orthotopic neobladder (RISON) of males, especially for nerve-spring technique. We also presented the result of 1-year follow-up aimed to illustrate its functional trifecta outcomes.

Methods: Robotic radical cystectomy with intracorporeal studer's orthotopic neobladder was performed on 33 male patients by the same surgeon from April 2018 to March 2019. Nerve-sparing technique had been used in 11 of the 33 patients. A prospectively maintained dataset was retrospectively searched and the related perioperative and follow-up data were analyzed. The functional trifecta outcomes referred to the freedom from recurrence, urinary continence and sexual function recovery after one year.

Results: A total of 33 males were included in our study. All perioperative information was recorded in detail. Thirty-two cases were confirmed to have negative surgical margin, except one pT3a case. And another case of incidental prostate cancer was diagnosed pathologically. All patients (100%) were recurrence-free one year after the operation. Eleven patients underwent nerve-sparing surgeries, including inter-fascial techniques or intra-fascial techniques. All these patients attained daytime continence (0 pad) at 1 month. With the nighttime continence, nerve-sparing group (2, 2 ,1) used fewer pads than other 22 cases (3, 3 ,2) at 1, 6 or 12 month(s) respectively. We defined urinary continence as 0 pad in daytime and no more than 1 pad in nighttime. The median preoperative score of International Index of Erectile Function (IIEF-6) in the 11 cases was 24. The sexual function recovery was defined as IIEF-6 > 20. The final trifecta rate was 54.5% and the median follow-up time lasted 17 months (range, 12 to 22 months).

Conclusions: RISON could be a safe and feasible choice of urinary diversion. Nerve sparing techniques might help the patients achieve a relatively higher functional trifecta rate.

Keywords: Intracorporeal studer's orthotopic neobladder; Nerve sparing techniques; Functional trifecta outcomes

INTRODUCTION

Classic radical cystectomy for male involves bladder, surrounding adipose tissue, distal ureter, prostate and seminal vesicles, and tends to affect the sexuality of patients [1]. Thanks to the advances in the robotic precision surgery technology in recent years, the sexual ability of some patients receiving the operation can be preserved. The indication is less stringent for intracorporeal orthotopic neobladder. Marc A *et al*. found that patients with nerve-sparing intracorporeal orthotopic neobladder accomplished better long-term continence after surgery, and this superiority became more apparent over time [2]. Although young

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male patients tend to have high demand for the preservation of sexual function and protecting the neurovascular bundle could preserve sexual function in some patients [3,4], the differences in outcomes between inter-fascial and intra-fascial techniques have seldom been reported in robotic intracorporeal studer's orthotopic neobladder (RISON). Besides, some available pentafecta criteria neglected functional outcomes [5,6]. Some available pentafecta definitions included negative soft tissue surgical margins, lymph node yield ≥ 16, absence of major (grade III-IV) complications at 90 days, absence of UD-related long-term sequelae and freedom from clinical recurrence at ≤ 12 months [1, 2].

On the other hand, we defined trifecta as the recurrence-free status, urinary continence (0 pad in daytime and less than 1 pad in nighttime) and sexual function recovery (IIEF-6 > 20), which, we believe, may better serve to indicate the functional outcomes of intracorporeal studer's orthotopic neobladder. In this study we aimed to summarize some key steps to achieve functional improvement in RISON of males, especially nerve-spring. We also presented the results of a 1-year follow-up to show the functional trifecta outcomes of RISON, with the inter-fascial or intra-fascial techniques in RISON being preliminarily discussed.

PATIENTS AND METHODS

Study Population

A total of 33 male patients underwent RISON and standard lymph node dissection performed by the same surgeon (Dr. HZ Li) from April 2018 to March 2019. A retrospective analysis was conducted on the basis of an institutional database on these patients. The sexual function and urinary control were preoperatively evaluated. Among the 33 patients, 11 were selected strictly against our criteria to undergo nerve-sparing surgeries. This study was approved by the ethics committee of the Chinese PLA General Hospital Third Medical Centre, Beijing, China. All patients provided written informed consent and all the relevant details had been obtained. The approval number was 2018-P2-081-04.

Indications

Indications for RISON included: (1) having intact urethra and well-functioning external sphincter, (2) having negative urethral resection margin; (3) having good renal function; (4) having no obvious intestinal tract diseases. Besides, patients with relatively better preoperative erectile function and expressing strong desire in maintaining potency were indicated/selected for nerve-sparing without age restriction.

Perioperative care and surgical technique

A routine cystoscopy or even biopsy was performed to exclude the subjects contraindicated for the operation. Positron emission tomography-computed tomography (PET/CT) was performed conditionally, which could help diagnose lymph node metastasis. Port placement and patients' position were comparable to those of the robotic prostatectomy. The difference was that all trocars moved 2 cm to cranial side when patient's build was relatively small. And we additionally employed a 12 mm and a 5 mm trocar at the opposite McBurney's point and the midpoint between the pubis to the navel, respectively, for inserting Endo-GIA stapler and placing single-J stents.

Effort was made to preserve the supporting ligaments of the urethra as much as possible, especially with the bilateral total intra-fascial technique. More supporting tissues could be conserved without opening the intra-pelvic fascia. Moreover, cutting off the pubis prostatic ligament closely adjacent to the pubis could fully expose the apex of prostate, which could minimize bleeding and maintain the fixation of urethra. In addition, care should be exercised to protect the nerve tissues located at two and ten o'clock in the urethra which are also critical for continence maintenance [7].

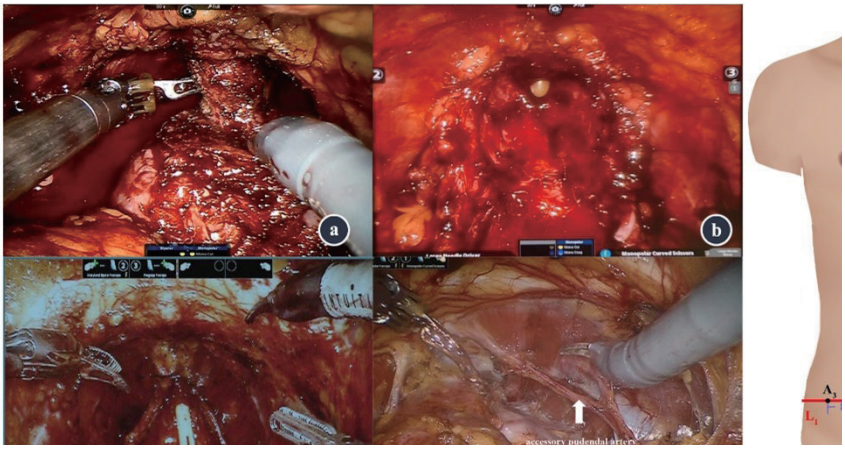


Figure 1 a. Retention of "tubular urethra"; b–c. Preservation of the NVB by intra-fascial or inter-fascial technique; d. Preservation of the accessory pudendal artery; e. Distribution of ports (L1: Umbilical level L2: Midline of abdomen L3: Pubic level A1: Monopolar scissor A2: Bipolar Maryland A3: Cardiere Grasper As1: the 12 mm trocar As2: the opposite McBurney point, the 12 mm trocar As3: the 5 mm trocar)

Both sides of prostate were separated sufficiently, with urethra left intact, and then the prostate could be turned over 180°. At this point, we had a "tubular urethra" by dissecting the prostate from left to right and free a longer segment of urethra (**Fig. 1a**). The dorsal vascular complex should be conserved whenever possible. The urethra should be anastomosed first with the guidance of a urinary duct, so that an effective length of urethra could be fully utilized due to a good view. Pre-fixation could shorten the time for suturing the bladder and the neobladder was shaped in line with the shape of pelvic cavity.

The prostatic neurovascular bundle (NVB) was preserved by intra-fascial or inter-fascial technique (**Fig. 1b-c**). The intra-fascial technique included not cutting open the Denonvilliers' fascia, dissecting the layer on the back of the prostate between the prostatic fascia and the prostatic capsule (the layer on both sides was inside the prostatic fascia). Blunt dissection was extended to the apex of prostate along the prostate capsule. The surface of prostate was not covered by any fascia. The inter-fascial technique was the most commonly used nerve-sparing method. The layer on the back of prostate was dissected between prostatic fascia and the Denonvilliers' fascia, and the layer on both sides of prostate was between the prostatic fascia and the pelvic fascia. Great care should be taken not to excessively dissect the apex and bilateral neurovascular bundles. What is more, thermal damage and excessive pulling of the NVB should also be avoided. The specific choice of nerve-sparing during operation should depend on the status of adhesion, but intrafascial technique should be used if the dissection layer was clear. The accessory pudendal artery should be preserved (**Fig. 1d**). And the distribution of ports is shown in **Figure 1e**.

Follow-up

Patients were encouraged to engage in exercise of levator at the early stage, which is very conducive to the quick recovery of patients' urinary continence. In addition, intermittent clipping of the duct to gradually protract the patient's micturition interval could expand the capacity of neobladder in a week before removal of the urinary duct. Follow-up was conducted in strict compliance with NCCN/EAU Guidelines [8,9]. Given that good postoperative rehabilitation is also important, we set up a communication platform (WeChat) to facilitate communication among patients and with doctors.

Trifecta definition

The functional trifecta outcomes were defined as the freedom from recurrence, urinary continence (0 pad during daytime and less than 1 pad during night time) and sexual function recovery (IIEF-6 > 20).

Statistical Analysis

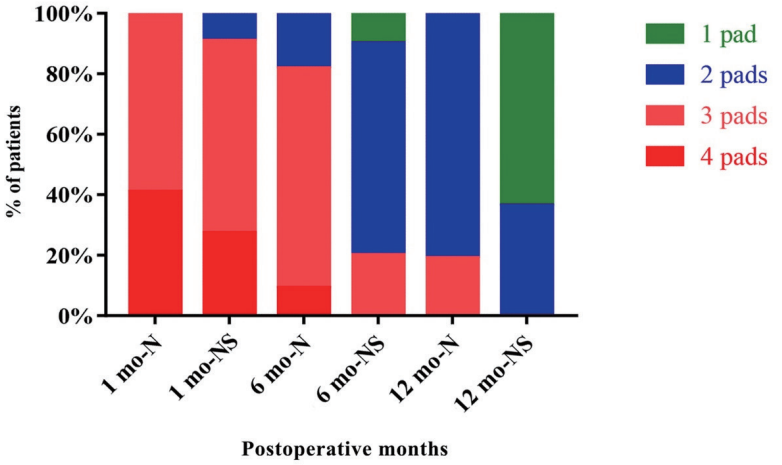
All related information was recorded in detail, including age, BMI, Charlson Comorbidity Index (CCI), neoadjuvant chemotherapy, preoperative continence, preoperative IIEF-6 score, indwelling gastric tube time, tolerance time, operating time, blood loss, postoperative hospital stay and complications. We kept good contact with every single patient to guide their rehabilitation and to follow them up. Postoperative continence was evaluated 1, 3 and 12 month(s) after surgery. Daytime continence was defined as 0 pad per day and night continence ability was measured in terms of the count of pads used. Erectile function was questionnaire-evaluated on the IIEF-6 scale 3, 9 and 12 months after the surgery. All postoperative early (≤ 30 days) and late (> 30 days) complications were graded by Clavien-Dindo system and the details of complications were recorded. All therapeutic procedures followed the conception of the enhanced recovery after surgery (ERAS) [10]. Patients who had local more severe lesions or developed positive surgical margin were administered adjuvant chemotherapy.

Continuous data were presented as the median and the interquartile range and categorical data were given as frequencies and proportions. The relevant non-parametric test, Wilcoxon rank sum test and chi-squared test were conducted for different kinds of variables when necessary. Our data were analyzed by using IBM SPSS Statistics package (Version. 25.0).

RESULTS

All 33 patients received RISONs successfully without open conversion or death. The median age and body mass index were 56 years (IQR 50–62) and 25.4 kg/m^2 (IQR 23.8–26.8), respectively. One group with 22 patients did not receive nerve-sparing surgery and the other group containing 11 patients had their nerve conserved. Some related data are shown in **Table 1**. Both groups had 2 patients who were put on neoadjuvant chemotherapy. All patients had normal preoperative urinary continence. The median preoperative IIEF-6 score was 19 and 24 respectively. Ten patients (30.3%) developed early complications (≤ 30 days). Except for 2 patients who received postoperative blood transfusion, the complications were mainly gastrointestinal and infection-related diseases. All complications were no more than Degree II. Late complications (after 30 days) developed in 16 patients (48.5%), and were mostly of gastrointestinal nature and infection-related. Only one patient with pelvic cavity effusion (Degree III) was treated with interventional ultrasound (**Table 2**). The oncologic and continence results are given in **Table S1**. All 33 patients survived up to now without recurrence. Among them, 32 had bladder cancer with stage no higher than T2N0M0. Only 1 patient was diagnosed with T3aN0M0 pathologically. Positive lymph nodes were not found in any case. One positive soft tissue surgical margin and one incidental prostate cancer were confirmed pathologically. The positive patients were given adjuvant chemotherapy. The stage and Gleason's score of the incidental prostate carcinoma was T2aN0M0 and 3+3, respectively. Since the tumor was at relatively early stage, no adjuvant

therapy was administered. All of 11 (100%) nerve-sparing patients attained daytime continence (0 pad) at 1 month, the other 20 of 22 (90.9%) achieved daytime continence (0 pad) at 12 months. As for the night time continence, nerve-sparing group (2, 2, 1) needed fewer pads than other 22 cases (3, 3, 2) at 1, 6 or 12 month(s) respectively (**Fig. 2**). Seven out of eleven (63.6%) patients required no more than 1 pad during night time. And the median bladder capacity for each group was 300 (243.75–300) mL and 350 (300–350) mL. No patients needed catheterization and no one had increased post-void residual urine. Eight out of eleven (72.7%) patients in the nerve-sparing group scored no less than 20 on IIEF-6 scale (International Index of Erectile Function). As for different kinds of nerve-sparing techniques, patients in the intra-fascial group (n=5) achieved continence recovery faster than their counterparts in the inter-fascial group (n=6) (**Table S2**, **Fig. 3**). The rate of night time continence was 5/5 (100%) and 2/6 (33.3%), in the intra-fascial and inter-facial group, respectively. The median preoperative IIEF-6 score of these two groups was 24 and 24.5 respectively. The selection of nerve-sparing technique completely depended on the specific situation during operation. Patients in the intra-fascial group (20, 21, 23) attained better erectile function (without taking Tadalafil) than those in the inter-fascial group (13.5, 15.5, 19) at 3, 9 or 12 months respectively. All 11 patients accomplished sexual function recovery at 12 months, but no one recovered to the preoperative level (**Table S2**). The rate of sexual function recovery was 5/5 (100%) and 3/6 (50%), respectively. The median follow-up time in the 33 patients was 17 months (range 12 to 22). Thus, the final functional trifecta rate of nerve-sparing was 6/11 (54.5%). The preliminary rate in the intra-fascial and inter-fascial groups was 5/5 (100%) and 1/6 (16.7%) (**Table 3**).



	4 pads	3 pads	2 pads	1 pad
1 mo-N	9 (40.9%)	13 (59.1%)	0	0
1 mo-NS	3 (27.3%)	7 (63.6%)	1 (9.1%)	0
6 mo-N	2 (9.1%)	16 (72.7%)	4 (18.2%)	0
6 mo-NS	0	3 (27.3%)	7 (63.6%)	1 (9.1%)
12 mo-N	0	5 (22.7%)	17 (77.3%)	0
12 mo-NS	0	0	4 (36.4%)	7 (63.6%)

N: Normal NS: Nerve-sparing

Figure 2 Night time continence in the normal group and nerve-sparing group

DISCUSSION

Nerve sparing technique has been verified to be advantageous in the preservation of continence or erectile function of patients receiving orthotopic neobladder [2,7,11,12]. Most techniques originated from radical prostatectomy. And a trifecta outcome has been seen as a hallmark of success with prostatectomy: *i.e.*, tumor control, continence preservation, and erectile potency. As this type of surgery is performed at the relatively early stage of the tumor, it tends to yield relatively more favorable oncologic results [5,6]. Besides, early complication rate in our series was 30.3%, which was consistent with the rate of 30–31.4% reported in literature, whereas the late complication rate in this study was 48.5%, marginally higher than the rate of 18.6–32.5% reported in literature [7,11]. Nonetheless, our late complications were mostly mild. Therefore, we put forward a new functional trifecta of RISON since this operative technique also requires criteria

for continence and erectile function.

Table 1 Baseline and Perioperative Data

Complications	No nerve-sparing	Nerve-sparing	Treatment	*P*
Early (< 30 days, *n* and grade)				
Gastrointestinal complications	4, I	1, I	Oral medications or observation	
Infectious complications	1, II	1, II	Intravenous antibiotics	
Bleeding requiring transfusion	1, II	2, II	Transfusion	
Total	6/22 (27.3%)	4/11 (36.4%)	1	1.000
	10/33 (30.3%)			
Late (> 30 days, *n* and grade)				
Gastrointestinal complications	3, I	1, I	Oral medications or observation	
Infectious complications	4, I	2, I	Oral antibiotics	
Infectious complications	3, II	2, II	Intravenous antibiotics	
Pelvic cavity effusion	1, III	0	Interventional ultrasound	
Total	11/22 (50.0%)	5/11 (45.5%)		1.000
	16/33 (48.5%)			

Note: IQR means Interquartile range; Normal: no need of pads

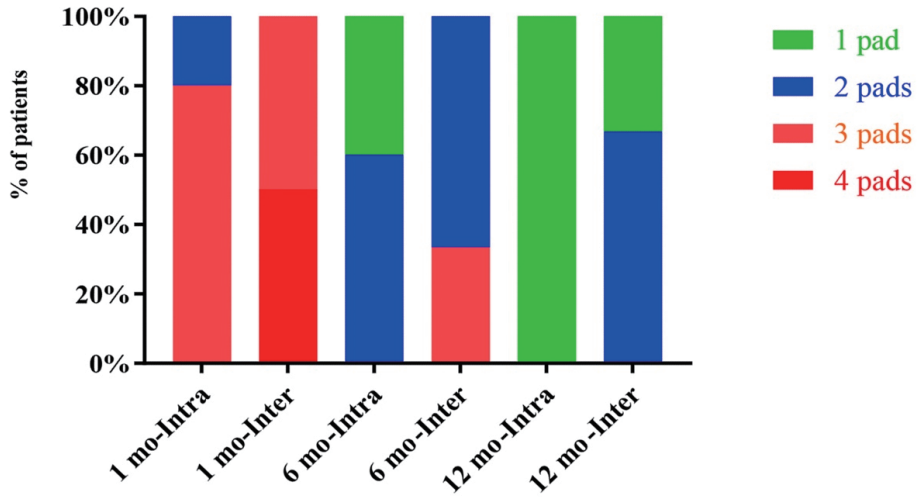
Table 2 Complications

Characteristics	No nerve-sparing	Nerve-sparing	*P*
Total, *n*	22	11	
Age (year), Median (IQR)	58 (50–63)	53 (49–57)	0.089
BMI, Kg/m^2, Median (IQR)	25.5 (20.3–33.8)	24.8 (22.9–33.7)	< 0.001
Charlson Comorbidity Index, *n*			0.081
0–2	5 (22.7%)	1 (9.1 %)	
3–5	17 (77.3%)	9 (81.8%)	
6–8	0	1 (9.1%)	
>8	0	0	
Neoadjuvant Chemotherapy, *n*			1.000
Presence	2 (9.1%)	2 (18.2%)	
Absence	20 (90.9%)	9 (81.8%)	
Preoperative Continence	Normal	Normal	
Median Preoperative IIEF-6 score (IQR)	19 (18–20.2)	24 (24–25)	< 0.001
Indwelling Gastric Tube, Days, Median (IQR)	3 (3–4)	3 (2–3)	< 0.001
Tolerance Time, Days, Median (IQR)	4.5 (3.75–5.25)	4 (3–6)	0.029
Operation Time, Hours, Median (IQR)	7 (5.38–8.5)	5 (4.5–7)	< 0.001
Blood Loss, ml, Median (IQR)	250 (200–500)	200 (150–300)	< 0.001
Postoperative Hospital Stay, Days, Median (IQR)	9 (8–10.25)	7 (7–12)	< 0.001

Table 3 Tifecta outcomes of RISON

Groups	Nerve-sparing	Intra-fascial	Inter-fascial
Functional trifecta rate	54.5%	100%	16.7%

First and foremost, the oncological control should be the *sine qua non* for using nerve sparing. Furthermore, preoperative imaging couldn't accurately diagnose the stage of bladder tumor: The diagnostic accuracy for outward tumor growth was 55%–92%, and the size-based diagnostic sensitivity for lymph node metastasis was only 48%–87% [13-15]. Hong K *et al*. reviewed 14 studies involving 785 patients and found that F-18 FDG PET/CT had a low sensitivity and high specificity for the detection of lymph node metastasis of bladder cancer. The sensitivity was 0.57 (95% CI: 0.49–0.64) and the specificity was 0.92 (95% CI: 0.87–0.95). Although true positive rate was not very high, higher true negative rate was still of diagnostic value [16]. Craig L *et al*. retrospectively examined 357 patients who underwent radical cystectomy and orthotopic bladder without intraoperative frozen biopsy and found that urethral recurrence rate (1.6%) was not higher in patients with a positive urethral margin and recurrence-free survival was not significantly worse in terms of lymph node stages, suggesting that a frozen biopsy was not essential [17]. On the other hand, this study was of retrospective nature and when we examined a positive urethral margin by frozen biopsy, the urinary diversion was often altered. We believe further studies are warranted to confirm aforementioned conclusion. Therefore, combining preoperative examination even PET/CT may be essential to decreasing the positive rate of surgical margin and to the diagnosis of lymph node metastasis.



	4 pads	3 pads	2 pads	1 pad
1 mo-Intra	0	4 (80.0%)	1 (20.0%)	0
1 mo-Inter	3 (50.0%)	3 (50.0%)	0	0
6 mo-Intra	0	0	3 (60.0%)	2 (40.0%)
6 mo-Inter	0	2 (33.3%)	4 (66.7%)	0
12 mo-Intra	0	0	0	5 (100.0%)
12 mo-Inter	0	0	4 (66.7%)	2 (33.3%)

Intra: intrafascial technique **Inter: interfascial technique**

Figure 3 Night time continence in the intrafascial group and interfascial group

Maximal preservation of urethral length has been verified to be beneficial for continence in prostatectomy [18-20]. A meta-analysis confirmed that membranous urethral length had a significant positive effect on continence at 3 months, 6 months and 12 months after surgery and concluded that each extra millimeter of length was associated with a significantly greater odds for continence (OR: 1.09, 95% CI: 1.05–1.15, $P < 0.001$) [21]. The same may also be true for RISON. Prostate-sparing cystectomy should not have this problem. However incidental prostate cancer is a potential risk factor for prostate-sparing cystectomy in spite of its

ability to improve continence. Yaw A *et al*. reported a technique modification of apex-preserving cysto-prostatectomy which kept a millimeter longer prostatic urethra without any destruction of urethra and left a robust plate for ureterovesical anastomosis. All patients achieved daytime urinary continence with no pad usage [22]. Besides, urethral sphincter and its length may be influenced by the shape of the apex. If the segment of the distinct striated and smooth muscles of the sphincter was dissected inside the apex the colliculus seminalis was found, full-length preservation of the urethral sphincter could be accomplished [23]. However, use of all these methods is premised on the exclusion of prostate cancer, especially in apex tissues. Ganzer *et al*. demonstrated that 37% and 30% of the cross-sectional urethral sphincter area was laterally covered by the DVC at the apex and 5 mm distal to the apex respectively. If the DVC was completely ligated horizontally, some functions of the urethral sphincter may be lost [24], which might explain why intra-fascial group attained a better continence recovery than inter-fascial group in our study. The advantages of intra-fascial vs. inter-fascial nerve-sparing techniques in terms of continence and erectile function after prostatectomy have been intensively studied [25,26] but reports on the post-RISON differences between them have been scanty. We found the same results as those obtained with prostatectomy: intra-fascial techniques may provide more favorable outcomes than inter-fascial ones in terms of both continence and erectile function. The results can be attributed to the fact that the two procedures were anatomically based on the same mechanism as that of prostatectomy [27].

Disagreements remain with respect to the preservation of the accessory pudendal artery. Stephen B *et al*. retrospected a total of 880 consecutive patients who underwent robotic prostatectomy. A multivariate analysis demonstrated that age (confidence interval [95% CI]: 0.94, 0.99) and baseline IIEF-5 (95% CI: 1.15, 1.26) bore a strong relationship with erectile function rather than the preservation of the accessory pudendal artery but the study gave no anatomical explanation [28]. Henry BM *et al*. conducted a meta-analysis and examined the prevalence and variations of the accessory pudendal artery [29]. They found that the penile blood supply partially originated from an accessory pudendal artery in more than a third of their cases. The research recommended that the accessory pudendal artery should be preserved whenever possible . This study statistically analyzed the significance of preservation of the accessory pudendal artery from an anatomical perspective and provided a basis for our research.

Our study was not devoid of limitations. The sample of our research was still relatively too small to reach any definitive conclusions, especially for different kinds of nerve-sparing techniques. We lost some data due to the retrospective nature of the study, and a prospective research is needed to make the results more convincing. Moreover, since it was a single-center series and involved only one single surgeon, its generalizability is limited and the conclusion should be applied with caution. At last, a long-term analysis is still warranted to verify our conclusion.

CONCLUSION

RISON is a safe and feasible choice of urinary diversion. Nerve-sparing techniques have wide indications for intracorporeal orthotopic neobladder. It may benefit patients on continence rehabilitation. Besides, intra-fascial techniques may produce more favorable outcomes than inter-fascial techniques in terms of both continence or erectile function. Intra-fascial techniques in RISON may be the best choice if possible. In summary, our preliminary study showed that nerve-spring technique may achieve a functional trifecta outcome with the robotic intracorporeal studer's orthotopic neobladder in the male.

Author Contributions

Study conception and design: Hongzhao Li.

Acquisition of data: Qiang Cheng, Liangyou Gu, Wenzheng Chen.

Statistical analysis: Xupeng Zhao, Xin Ma, Xiao Chang, Qing Ai.

Drafting and editing of the manuscript: Qiang Cheng, Liangyou Gu, Wenzheng Chen.

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Availability of data and materials

All the data used to support the findings of this study are included within the article.

Ethics approval and consent to participate

The study was approved by the Ethics Committee of the Chinese PLA General Hospital Third Medical Centre. All patients provided written informed consent and all the details had been obtained regarding the consent of the patients. The ethical approval number is 2018-P2-081-04.

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Supplementary information

Supplementary information of this article can be found online at https://polscientific.com/bladder/index.php/bladder/article/view/850/130.