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Surgery in Motion

Urethra and Ejaculation Preserving Robot-assisted Simple Prostatectomy: Near-infrared Fluorescence Imaging-guided Madigan Technique

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Abstract

Background: With the increasing adoption of novel technologies and anatomical techniques, surgical management of benign prostatic hyperplasia (BPH) provides significant benefits in terms of obstruction relief, early urethral catheter removal, and faster return to daily activities. However, the main pitfall of BPH surgery in sexually active men remains ejaculatory dysfunction (EjD), which permanently affects quality of life.

Objective: To detail a novel technique for marking the intraprostatic urethra through a retrograde injection of indocyanine green to enhance selective dissection of prostatic lobes during urethra-sparing robot-assisted simple prostatectomy (US-RASP) with the use of near-infrared fluorescence imaging (NIFI).

Design, setting, and participants: Between January and September 2017, 12 consecutive male patients, who had BPH, were sexually active, and were motivated to preserve ejaculatory function, underwent US-RASP.

Surgical procedure: US-RASP with NIFI to enhance the identification and preservation of the prostatic urethra.

Measurements: Clinical data were prospectively collected in our institutional RASP dataset. Perioperative and functional outcomes of US-RASP were both graded, and assessed according to Clavien grading system and validated questionnaires postoperatively (International Prostate Symptom Score [IPSS]; Male Sexual Health Questionnaire on EjD [MSHQ-EjD] Short Form) at 3 and 12 mo.

Results and limitations: Median preoperative prostate size was 102 cc (interquartile range [IQR] 88–115). Median operative time was 150 min (IQR 145–170). Median estimated blood loss was 250 (IQR 200–350). Continuous bladder irrigation was avoided in 83.4% of patients. Median time to catheter removal was 7 d (IQR 7–7) with a median hospital stay of 3 d (IQR 2–3). At 1-yr follow-up, median IPSS score, International Index of Erectile Function score, and MSHQ-EjD Short Form score were 5 (IQR 4–8), 26 (IQR 26–28), and 12 (IQR 1–14), respectively. Satisfactory antegrade ejaculation was reported in eight patients (66%).

Conclusions: We described a novel NIFI-guided technique to perform US-RASP. This technique showed promising early functional results, suggesting a significant role of intraprostatic urethral integrity for the preservation of ejaculatory function.

Patient summary: We developed a novel robotic technique to perform simple prostatectomy with integral preservation of the prostatic urethra. This technique provided a high rate of ejaculatory function preservation.

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1. Introduction

According to European Association of Urology (EAU) guidelines, for patients affected by significant bladder outlet obstruction or lower urinary tract symptoms not responsive to medical therapy secondary to benign prostatic hyperplasia (BPH), endoscopic techniques represent the first choice in the urological armamentarium [1]. Standard transurethral resection, enucleation, laser, or minimally invasive techniques share all similar indications, with prostatic adenoma size representing a critical factor for optimizing the surgical outcomes [2–6]. Open or minimally invasive simple open prostatectomy is traditionally offered in patients with larger prostatic glands (≥ 80 ml) or wherever the endoscopic treatment is not available, with the transprostatic (Millin) or transvesical (Freyer) approaches representing the mostly used approaches [1,7,8].

In recent years, robot-assisted simple prostatectomy (RASP) has gained popularity due to decreased blood loss, faster recovery, and potential avoidance of continuous bladder irrigation in the postoperative setting [9]. Despite the wide range of surgical options actually available for the management of BPH, ejaculatory dysfunction (EjD) still represents an unmet need among BPH functional outcomes, which significantly affects quality of life in sexually active men [10,11].

The pathogenesis of EjD after surgery remains unclear, with several studies identifying the lack of bladder neck closure, which is traditionally incised in all endoscopic approaches, a critical factor [12,13]. To date, several alternative techniques for limiting EjD rates after surgery have been proposed with contrasting evidence [14–16].

The aim of this current series with the enclosed video is to detail the surgical steps of a novel technique of near-infrared fluorescence imaging (NIFI)-guided urethra-sparing robot-assisted simple prostatectomy (US-RASP), and to report 1-yr surgical, perioperative, and functional outcomes.

2. Patients and methods

Baseline, perioperative, and follow-up data were recorded in a prospectively collected RASP database; all eligible patients provided written informed consent to both robotic procedure and a planned early postoperative endoscopic control (flexible cystoscopy at 30 d after surgery) to evaluate the full integrity of the prostatic urethra.

2.1. Inclusion and exclusion criteria

Between January and September 2017, 12 consecutive sexually active male patients with BPH were candidates for US-RASP. Inclusion criteria were failure of alpha-blocker and 5-alpha reductase inhibitors, a prostate gland volume of ≥ 80 m, and interest in preserving ejaculatory function (EF). Initial clinical work-up included medical history, physical examination, flow rate evaluation including peak flow rate (Q_{max}) measurement, voided volume, postvoiding residual volume assessed by transabdominal ultrasound, renal tract ultrasound, transrectal ultrasound (TRUS), prostate volume measurement, prostate-specific antigen (PSA) testing, International Prostate Symptom Score (IPSS), 15-item

International Index of Erectile Function questionnaire (IIEF-15) assessment, and an abridged version of the 25-item Male Sexual Health Questionnaire to assess EjD (MSHQ-EjD Short Form) [17–19]. Exclusion criteria were coexistent bladder stones or bladder diverticula requiring treatment, prostate volume < 80 ml, median lobe > 10 ml, IIEF score < 17 , and contraindications to robotic surgery with a steep Trendelenburg position.

2.2. Surgical technique

All the procedures were performed using Da Vinci Si Surgical System (Intuitive Surgical, Sunnyvale, CA, USA) by two surgeons (G.S. and M.G.) in a three-arm configuration with a transperitoneal approach.

2.2.1. Patient positioning and port placement

All patients received prophylactic antibiotic treatment before starting the surgical procedure. After induction of general anesthesia, an indwelling 18 Fr urethral catheter is positioned and the patient is placed in the lithotomy position with a steep Trendelenburg angle; a transperitoneal five-port access was performed using a 0° scope. The camera port was placed through the umbilicus, and two 8-mm robotic ports were placed midline between the iliac crest and the main trocar. Two 12-mm ports for the assistant surgeon were placed at the midline, between the camera and the robotic ports. A three-arm configuration was used; Hot Shears monopolar curved scissors (Intuitive Surgical), Pro-Grasp forceps (Intuitive Surgical), and a large needle driver were used to perform sutures. The two 12-mm assistant ports allowed the introduction of a disposable suction/irrigation and a 10 mm Ligasure Atlas (Covidien, Mansfield, MA, USA) device.

2.2.2. NIFI-guided urethra-sparing robot-assisted Madigan prostatectomy

Once the Retzius space was developed through an inverted U-shaped anterior peritoneal incision, the bladder neck was meticulously isolated in order to expose the proximal prostatic urethra. The 18 Fr urethral catheter was retracted into the navicular fossa with the balloon inflated with 3 ml of saline solution, and 50 ml of indocyanine green (ICG) was injected. With the use of NIFI, prostatic adenoma dissection started initially from the right lobe, developing a dissection plane from the base and progressively moving toward the 12 o'clock position. Sharp and blunt dissections were combined to enucleate the right lobe, continuously switching from conventional light to near-infrared fluorescence to ensure selective control of the intraprostatic urethra. In the case of a median prostatic lobe, NIFI was used to improve the visualization of the bladder neck and to avoid any unintended violation of the urinary tract. Finally, the dissection was completed toward the prostate apex. Retrograde dissection was completed to remove “en bloc” the right lobe. Blunt dissection and NIFI were mostly used when proceeding medially in proximity to the prostatic urethra. The same procedure was performed contralaterally. The prostatic lobes were collected in an Endo Catch bag (Covidien). Hemostasis was ensured. Any remnant of distal paraurethral tissue in the prostatic fossa was dissected under NIFI, avoiding any dissection at the distal urethra and at the posterior side of the urethra. A minimal bladder neck incision was performed to ensure complete resection only in case of a median prostatic lobe. In case of any violation of urinary tract integrity, the urethra was sutured with an interrupted 3/0 Monocryl suture.

After the completion of the resection, a definitive indwelling 20 Fr Foley catheter was introduced and inflated in the bladder with 10 ml saline solution. The integrity of ejaculatory ducts can be confirmed with both TRUS and NIFI. Finally, the bladder neck was approximated to the ventral prostatic rim with a running Monocryl 3/0 or barbed suture (V-loc 3/0; Covidien). Watertightness was confirmed by irrigating the bladder with 150 ml of saline solution. A drain was left in the Retzius space.

Table 1 – Baseline demographic and clinical characteristics

Patients (n)	12
Age (yr)	63 (60–67)
BMI	24.4 (23.8–27.3)
ASA score	2 (2–3)
Prostate volume on TRUS (cc)	102 (88–115)
Hemoglobin (g/dl)	13.5 (12.8–15.2)
Indwelling catheter, n (%)	2 (16.6)
ASA = American Society of Anesthesiologists; BMI = body mass index; TRUS = transrectal ultrasound. Data reported as median values (interquartile range).	

2.3. Postoperative management and follow-up

Continuous bladder irrigation was intentionally avoided whenever feasible. Urethral catheter was removed conventionally on the 7th postoperative day. Deep vein thrombosis prophylaxis and early ambulation were pursued. The drain was removed if the 24-h output was lower than 100 ml and the patient was usually discharged the day following flatus recovery with 21 d of subcutaneous low-weight molecular heparin injections. Follow-up consisted of scheduled visits at 3 and 12 mo after surgery including complete biochemical blood tests, physical examination, uroflowmetry, abdominal ultrasound, PSA dosage, IPSS, and IIEF-15 and MSHQ-EjD scores. Furthermore, a 16 Fr flexible cystoscopy was performed 4 wk postoperatively.

2.4. Endpoints

Collected demographic parameters were age, body mass index, comorbidities, American Society of Anesthesiologists score, pre- and postoperative PSA, pre- and postoperative hemoglobin, uroflowmetry, preoperative prostate size (TRUS estimated), history of acute urinary retention, pre- and postoperative IPSS, pre- and postoperative IIEF-15 score, and pre- and postoperative MSHQ-EjD Short Form score. Main surgical outcomes were reported, including operative time, estimated blood loss, length of hospital stay, mean catheterization time, length of hospital stay and perioperative complications according to the Clavien-Dindo system [20], and pathological findings.

Primary endpoints were surgical feasibility of US-RASP assessed by complete preservation of the intraprostatic urethra, perioperative morbidity, and complications. Secondary endpoints were represented by early functional outcomes (IPSS, and IIEF-15, and MSHQ-EjD Short Form scores) assessed at 3 and 12 mo postoperatively.

2.5. Statistical analysis

Descriptive analyses were used. Frequencies and proportions were reported for categorical variables. Medians and interquartile ranges (IQRs) were reported for continuously coded variables. Differences between continuous variables assessed at baseline, 3-mo and 1-yr follow-up were assessed with Wilcoxon test. All *p* values of <0.05 were considered statistically significant. Statistical analysis was performed using SPSS v24 (IBM Corp., Armonk, NY, USA).

3. Results

Baseline demographic and clinical data are summarized in Table 1. All patients were sexually active (IIEF score >17) and interested in preserving antegrade ejaculation. The median preoperative MSHQ-EjD Short Form score was 9 (IQR 7–11), due to effects of alpha-blockers. No intraoperative complications occurred, and the procedure was successfully

Table 2 – Perioperative and pathological outcomes

Patients (n)	12
Operative time (min)	150 (145–170)
Estimated blood loss (ml)	250 (200–350)
Continuous bladder irrigation, n (%)	2 (16.6)
Time to catheter removal (d)	7 (7–7)
Length of stay (d)	3 (2–3)
Conversion to standard technique, n (%)	0 (0)
Urethral reconstruction, n (%)	2 (16.6)
Clavien-Dindo complications, n (%)	
Grade 1	2 (16.6)
Grade 2	1 (8.3)
Grade 3a	0 (0)
Grade 3b	0 (0)
Adenoma weight (g)	78 (61–84)
Incidental prostate cancer, n (%)	0 (0)
Continuous data are reported as median values (interquartile range).	

completed in all patients. Unintentional violation of urinary tract occurred in two patients (16.6%). Overall, 25% of patients experienced perioperative complications, including fever (grade 1), wound infection (grade 1), and anemia requiring a single blood transfusion (grade 2). On pathological examination, the median weight of excised adenomas was 78 g (IQR 61–84); no incidental prostate cancer was found. Perioperative and pathological data are reported in Table 2. Three-month and 1-yr functional outcomes are given in Table 3. No urethral strictures were reported. Complete recovery of EF was achieved in eight patients (66%) with a median 1-yr MSHQ-EjD Short Form score of 12 (IQR 3–14). Median IPSS and Qmax improved significantly at 3 mo, from 33 to 6 (*p* < 0.001) and from 7.7 to 18.6 ml/s (*p* < 0.001), respectively. Median postvoid residual volume improved from 175 ml preoperatively to 30 ml at 3-mo evaluation (*p* < 0.001). No patient reported urgency or stress urinary incontinence during follow-up.

4. Discussion

The main goal of BPH surgery is represented by the urethral obstruction relief [1]. In recent years, different endoscopic techniques have been introduced with the aim of decreasing intraoperative complications such as bleeding in high-risk patients and reducing perioperative morbidity [21]. Irrespective of the surgical technique and the energy source used, EjD represents one of the major pitfalls of BPH surgery, significantly affecting quality of life, especially in young and sexually active men [10].

Several techniques have been described in order to decrease the postoperative EjD rates, but unfortunately, due to the lack of validated tools and questionnaires for assessing EF after surgery, available data in literature are undoubtedly scanty and controversial [10,22].

The exact mechanism involved in the pathogenesis of postoperative EjD remains unclear. It has been suggested that EjD is caused by the impaired closure mechanism of the bladder neck. Indeed, complete preservation of the bladder neck together with the paracollicular area represents critical factors that are advocated when an

Table 3 – Functional outcomes

	Baseline	3 mo	1 yr	Baseline vs 3 mo ^a	Baseline vs 1 yr ^b	3 mo vs 1 yr ^c
IIEF-15	27 (26–28)	27 (26–28)	27 (26–28)	0.51	0.64	0.67
IPSS	33 (27–34)	6 (5–8)	5 (4–8)	<0.001	<0.001	0.001
MSHQ-EjD Short Form	9 (7–12)	11 (4–14)	12 (3–14)	0.07	0.06	0.9
Maximum flow rate (ml/s)	7.7 (6.3–8.3)	18.6 (16.4–24.9)	21.8 (18.6–27.3)	0.001	<0.001	0.56
Voided volume (ml)	169 (127–213)	262 (192–350)	249 (177–318)	<0.001	<0.001	0.003
Postvoid residual volume (ml)	175 (125–190)	30 (25–57)	22.5 (20–42)	<0.001	<0.001	<0.001
PSA total (ng/ml)	5.6 (4.3–6.4)	1.6 (0.8–2.5)	2 (1.1–2.7)	<0.001	<0.001	<0.001

IIEF = International Index of Erectile Function; IPSS = International Prostate Symptom Score; MSHQ-EjD = Male Sexual Health Questionnaire to assess ejaculatory dysfunction; PSA = prostate-specific antigen.
Continuous data are reported as median values (interquartile range).
^a Comparison of *p* values between baseline and 3-mo data.
^b Comparison of *p* values between baseline and 1-yr data.
^c Comparison of *p* values between 3-mo and 1-yr data.

“ejaculation-sparing technique” is endoscopically attempted [23]. Notably, endoscopic enucleation techniques aimed at preserving ejaculation share the same intrinsic limitation, as the prostatic urethra cannot be preserved; besides, all are affected by a significant risk of residual adenoma [24].

According to EAU guidelines, simple open prostatectomy is traditionally reserved for larger adenomas (≥ 80 ml) or situations when endoscopic techniques are not available [1]. With the increasing adoption of robotic surgery, RASP has progressively been standardized and it may actually be considered an alternative to standard open simple prostatectomy [25]. The main advantage of robotic surgery in this context may be represented by the meticulous hemostasis during the development of a dissection plane between adenoma and prostatic capsule, and the improved dexterity in the prostatic capsule reconstruction [26]. In this report, we also highlight the significant benefits provided by NIFI to enhance visibility, identification, and consequently preservation of the prostatic urethra.

The concept of preservation of the prostatic urethra (Madigan technique) was initially described by Dixon et al. [27] in open surgery. More recently, several authors attempted to duplicate this approach in the minimally invasive setting, reporting significant advantages in terms of less residual adenoma and shorter catheterization time [28,29]. However, this suggestive technique has never gained a wide consensus, and it has been progressively abandoned due to the significant complexity in avoiding unintentional violation of urinary tract.

Urethral preservation remains a critical factor, not only to achieve complete recovery of EF, but also to minimize surgical trauma and perioperative morbidity. If the urethra is completely preserved, postoperative bladder irrigation can be avoided and consequently the length of stay can significantly be reduced. More interestingly, integrity of ejaculatory ducts is mandatory to guarantee preservation of antegrade ejaculation. NIFI provides significant support in this specific field also, thanks to a transurethral ICG reflux through ejaculatory ducts that appear as a green structure in close proximity to the distal urethra; integrity of ejaculatory ducts can also be confirmed with real-time TRUS.

As previously demonstrated by robotic surgery in other surgical procedures, NIFI itself has also contributed to improvement in surgical outcomes in several urological procedures [30]. In this report, we sought to reproduce surgical steps of Madigan prostatectomy with the use of NIFI to enhance visualization of the prostatic urethra and to avoid any unintentional violation of the urinary system, making the classic Madigan procedure feasible and more reproducible.

We believe that this technique may represent an alternative option to standard endoscopic ejaculation sparing techniques that usually fail to achieve the expected outcomes.

Intraurethral delivery of ICG provided significance enhancement in the identification of the prostatic urethra. In addition, in two cases of our series, where a medium lobe was present, unintentional violation of the urinary tract occurred; NIFI provided immediate identification of the injury and consequently the opportunity to promptly repair it before proceeding with dissection.

Despite advancement and simplification provided by both robotic platform and NIFI, this procedure remains technically challenging: in patients with large lateral lobes and/or medium lobe protruding into the bladder neck, the risk of missing the proper dissection plane can turn into an incomplete resection with a potential risk of long term recurrence of obstructing symptoms related to BPH.

Our series is not devoid of limitations. First of all, the small sample size, strict inclusion/exclusion criteria, and lack of a standardized comparison cohort preclude definitive conclusions about the superiority of this technique over the available alternative options. Certainly, the presence of a huge median prostatic lobe significantly affects the reproducibility of this technique, limiting the indications for this approach to a select cohort of patients. Preservation of antegrade ejaculation was obtained in 66.6% of patients; therefore, when this outcome is not achieved, benefits of this procedure remain unclear. There are also valid ejaculation-preserving endoscopic techniques to be considered as alternative options, especially for smaller glands or for those with a huge median lobe. The need for robotic surgical skills and costs of robotic surgery should also be considered as potentially main drivers in a decision-making

process. Finally, larger series and longer follow-up are needed to confirm our findings and durability over time of both obstruction relief and preservation of EF.

Our report also has several strengths: basically, this technique is aimed at “preserving” the urethra and EF, while providing relief to obstruction symptoms. Despite the potential impact of the learning curve on outcomes, it was successful in two-thirds of cases; this result compared favorably with the outcomes of endoscopic ejaculation-preserving techniques in prospective randomized trials, where the reported success rate ranged between 46% and 66% [14,16].

Today, preservation of the EF remains an unmet need of BPH surgery, irrespective of the surgical approach chosen. In this context, US-RASP may be considered a feasible and reasonable option, and a potential “early” option in patients with BPH and significant side effects of alpha-blockers on EF.

5. Conclusions

We report feasibility, and perioperative and 1-yr outcomes of US-RASP in 12 consecutive patients. In this preliminary experience, all patients had complete relief of obstructive symptoms, urinary tract integrity was maintained in 83.4%, and two-thirds of patients reported antegrade ejaculation at 1-yr follow-up. NIFI-guided US-RASP should be considered as an option when counseling patients about BPH surgery who are motivated in preserving antegrade ejaculation.

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.

Acquisition of data: Tuderti, Minisola, Ferriero, Guaglianone.

Analysis and interpretation of data: Simone, Tuderti, Anceschi, Misuraca.

Drafting of the manuscript: Anceschi, Simone.

Critical revision of the manuscript for important intellectual content: Simone, Gallucci.

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Appendix A. Supplementary data

The Surgery in Motion video accompanying this article can be found in the online version at <https://doi.org/10.1016/j.eururo.2018.11.051> and via www.europeanurology.com.

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