



Mid-term functional outcomes of extraperitoneal robot-assisted simple prostatectomy: a single centre experience

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Abstract

For large prostate volume, open simple prostatectomy (OSP) or holmium laser enucleation are the gold standard surgical treatment medical therapy failure. Robot-assisted simple prostatectomy (RASP) has recently been proposed as an alternative to OSP and endoscopic techniques. Our objective was to describe our extraperitoneal RASP technique for patients with benign prostate obstruction (BPO), and to report on perioperative and mid-term functional outcomes. Data were collected prospectively for all consecutive patients who underwent RASP in our high-volume tertiary hospital over a 6-year period. International Prostate Symptom Score (IPSS), International Index of Erectile Function-5 (IIEF-5) and uroflow findings were compared before and after surgery. Intraoperative and postoperative outcomes were also assessed. Forty-seven patients were included in the study. There was no intraoperative incident and no blood transfusion was needed after surgery. Median time to bladder catheter removal was 4 days and patients were discharged the day after. Within 90 postoperative days, 6 patients (12%) experienced at least one complication, all low-grade except one (2.1%) which was Clavien IIIa grade. By univariate analysis, the only risk factor for postoperative complications was the Charlson comorbidity index (OR = 2.1, 95% CI = [1.1–4.7], $p = 0.04$). At 12 months, a significant improvement IPSS and uroflow rate was observed. No patient reported stress urinary incontinence. Extraperitoneal RASP appears to be a safe and effective technique for men with LUTS related to large BPO. RASP is less invasive than OSP and wide diffusion of the robot-system could lead to the rapid implementation of RASP as a treatment for large prostate.

Keywords Benign prostatic hyperplasia · Functional urology · Lower urinary tract symptoms · Surgical treatment · Robot-assisted laparoscopy

Introduction

Lower urinary tract symptoms (LUTS) are associated with impaired quality of life (QoL) in men, and their prevalence reaches 45% in those aged > 70 years [1, 2]. Benign prostatic obstruction (BPO) is the main cause of LUTS in men and

medical oral therapy is the primary treatment of choice [3]. In the case of treatment failure, urinary retention, impaired renal function secondary to obstructive uropathy, recurrent urinary tract infections, recurrent haematuria, bladder diverticula and bladder stones, a surgical procedure is recommended. In accordance with European Association of Urology guidelines, the best surgical approach should be proposed based on prostate volume. In the case of a large prostate gland, with a volume > 80 mL, open simple prostatectomy (OSP) or holmium laser enucleation of the prostate (HoLEP) are the gold standard [4].

OSP has been the reference procedure for decades but it carries significant peri- and postoperative morbidity, mostly due to bleeding. HoLEP has been shown to result in excellent functional outcomes with reduced morbidity and hospital stay compared to OSP. Thus, it has largely replaced the open approach [5, 6]. Other techniques described to provide

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good functional outcomes include greenlight PVP, ThuLEP, aquablation and GreenLEP [7, 8].

Robot-assisted simple prostatectomy (RASP) was first proposed by Sotelo et al. in 2008 as an alternative to OSP and endoscopic procedures [9]. RASP is performed mainly in high-volume hospitals with broad experience in robotic surgery, and different techniques with corresponding outcomes have been described [10].

The aim of this study was to describe our RASP technique and to report on its functional outcomes.

Patients and methods

Data were collected prospectively from all consecutive patients who underwent extraperitoneal RASP in our academic hospital over a 6-year period (2013–2019). All procedures were performed with either the Da Vinci Si or Xi Surgical Systems (Intuitive Surgical, Sunnyvale, CA, USA) by one expert robotic urology surgeon with a high level of experience (> 10-year experience and > 100 procedures).

Each patient with a prostate volume > 80 mL was offered RASP after a shared decision on the surgical approach. Patients who previously underwent a BPO surgical treatment were excluded from the study. All patients gave their written consent for inclusion and the study was approved by our local ethics committee.

Preoperative workup and data collection

Preoperative baseline characteristics (age, body mass index (BMI), ASA score, Charlson comorbidity index, use of prostate medications and use of anticoagulant and/or antiaggregant therapy) were collected by a single investigator that was not involved in the treatment. A digital rectal examination and ultrasound of the urinary system was performed, as well as a flexible cystoscopy (to eliminate bladder tumor in case of hematuria or to eliminate urethral stricture), transrectal ultrasound, prostate magnetic resonance imaging and/or biopsy when indicated or necessary.

The following factors were also evaluated: operative time (OT); estimated blood loss (EBL); intra-operative complications according to the Intraoperative Adverse Incident Classification (EAUiaIC) by the European Association of Urology ad hoc Complications Guidelines Panel [11]; time to catheter removal; length of stay (LOS); postoperative complications according to the Clavien–Dindo classification; enucleated prostate volume; and changes in haemoglobin levels or renal function perioperatively) The quality of complications reporting was assessed using Martin's criteria as recommended by the EAU Guidelines office panel [12].

The following data were collected before surgery, as well as at 12 months postoperatively to assess functional

outcomes: uroflowmetry; post-void residual volume; prostate specific antigen (PSA) level; International Prostate Symptoms Score (IPSS); quality of life (QoL) score; and International Index of Erectile Function-5 (IIEF-5) questionnaire.

Surgical technique

All procedures were performed under general anaesthesia with the patient placed in the lithotomy position at 20° of Trendelenburg. A single perioperative dose of antibiotic prophylaxis and pharmacological and mechanical thromboembolic prophylaxis were administered. In our extra-peritoneal technique, we place 4 robotic-arm trocars and one AirSeal trocar for the assistant (Fig. 1). The camera trocar was placed sub-umbilically. For the development of the Retzius space, an oval-shape balloon dilator trocar was used under direct vision. Thereafter, under optical control, two latero-umbilical robotic trocars were placed at 8 cm from the camera port, one robotic trocar 2 cm up from the iliac crest on the left side and the AirSeal trocar 2 cm up from the iliac crest on the right side.

Monopolar curved scissors, fenestrated bipolar forceps, ProGrasp™ forceps and 2 large needle drivers were used.

Opening of the prostate capsule

After defatting the anterior surface of the prostate and bladder, pre-emptive haemostatic control was assured by an uninterrupted 2–0 V-Lock barbed suture on both sides of the prostatic capsule (Fig. 2). A longitudinal incision of the prostate capsule and the anterior bladder wall was performed to access the bladder neck and prostatic adenoma.

Adenoma enucleation

Localisation of ureteral orifices and incision of the bladder mucosae between the 5- and 7-o'clock positions over the adenoma were performed. The plane between the adenoma and the peripheral zone of the prostate was developed with a combination of blunt, sharp and electrocautery dissection on both side of the prostate. In this phase, ProGrasp™ forceps were used to create traction on the adenoma to facilitate development of the correct plane (Fig. 3). Dissection was carried out up to the apex with particular attention to the sphincter complex. An anterior commissurotomy was created to free the prostatic apex via a precise dissection. The prostatic urethra was divided with cold scissors.

Re-trigonalization and closure

Prostatic bed bleeding was controlled with bipolar forceps. A running suture from the bladder neck mucosae to the urethra was performed to re-trigonalize the prostatic fossa with



Fig. 1 Trocar placement. 4 robotic-arm trocars and one AirSeal trocar for the assistant were placed in our technique

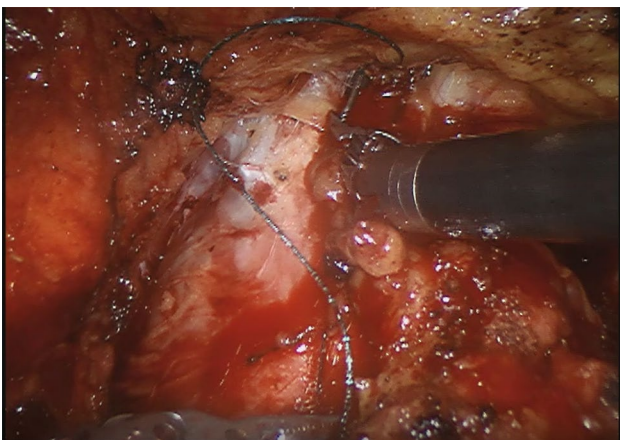


Fig. 2 Prostatic capsule haemostatic control. To avoid bleeding at the opening of the prostatic capsule, an uninterrupted 2-0 V-Lock barbed was sutured on both sides of the prostatic capsule

a 4–0 V-Loc (Covidien) barbed suture. Whenever possible, a mucosal flap over the median lobe was usually used for the re-trigonalization to avoid to pull down the ureteral orifices and the re-trigonalization suture was only performed posteriorly. A 20 French 3-way urinary catheter was inserted

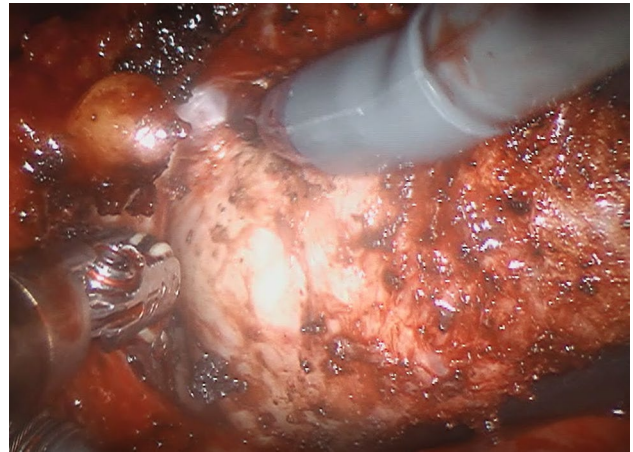


Fig. 3 Adenoma enucleation. ProGrasp™ forceps were used to create traction on the adenoma in order to facilitate development of the correct plane

under direct vision and its balloon inflated in the prostatic fossa. Double layer closure of the anterior bladder wall and prostatic capsule was performed with a V-Loc 3–0 barbed suture and checked for water tightness with 180 cc of water. The prostatic adenoma was placed in an endoscopy bag and retrieved through the Airseal trocar. Surgical drainage was left in place at surgeon's discretion depending on intra-operative bleeding.

Postoperative management

Continuous bladder irrigation (CBI) was maintained for at least 2 days under standard conditions. The bladder catheter was removed the day after discontinuation of CBI if the urine did not present hematuria and the patient was discharged after spontaneous miction. Paracetamol-based painkillers were used if needed.

Statistical analysis

Continuous variables are presented as median and inter-quartile range and qualitative variables as frequency and percentage.

The Wilcoxon test was used to compare the preoperative and postoperative data. Predictive factors for postoperative complications were analysed by univariate logistic regression analysis that was performed on all preoperative variables. A *p* value of 0.05 was chosen to determine statistical significance.

Table 1 Baseline patient characteristics

Variable	Study cohort (N=47)
Age (years)	70 (65–75)
ASA score	2 (0)
Charlson comorbidity index	3 (3–4)
BMI (kg/m ²)	26 (24.8–28)
Prostate-specific antigen (ng/mL)	9.4 (6–16.1)
Prostate volume (mL)	131.5 (100–180)
Median protruding lobe, n (%)	32 (68%)
IPSS QoL	3 (3–4)
Indwelling urethral catheter before surgery, n (%)	20 (43%)

Values shown are median (IQR) unless indicated otherwise

IQR interquartile range, ASA American Society of Anaesthesiologists score, BMI body mass index, IPSS International Prostate Symptom Score, QoL quality of life

Results

Study population

A total of 47 patients underwent RASP and were included in the study. No patients were excluded from the study or lost to follow-up. The preoperative baseline characteristics of the patients are shown in Table 1. Thirty-six patients (77%) were receiving alpha blocker medication at the time of surgery six patients were receiving 5 AR inhibitors alone (13%) and three patients (6%) were receiving alpha blockers and 5 AR inhibitors. Of the patients, two (4%) did not have medical treatment because of prior side effects.

The intraoperative characteristics of the study population are shown in Table 2. Median OT was 110 min (IQR: 92.5–120) and median EBL was 200 mL (IQR: 150–400). Two patients had intraperitoneal procedures due to unpredicted peritoneal opening with no consequence on the surgical outcome (EAUiaic—grade 0). No other intraoperative adverse event was reported.

Outcome measures

The median time to bladder catheter removal was 4 days. No blood transfusions were needed. On the pathology report, median specimen weight was 73.3 g (IQR: 54.6–108.9). In our cohort, four patients (8%) had an incidental adenocarcinoma of the prostate. Two of these were considered clinically significant (Gleason ≥ 7): one was placed under active surveillance protocol with no increased in PSA and the second was treated with radiotherapy and hormone therapy.

The main surgical outcomes and postoperative complications are described in Table 2. At 90-day post-surgery, six patients (12%) experienced at least one complication. Of them, two needed readmissions for hematuria whom one was

Table 2 Perioperative outcomes

Variable	Study cohort (N=47)
Operative time (min)	110 (92.5–120)
Intraoperative blood loss (mL)	200 (150–400)
Catheterisation duration (days)	4 (3–4)
Surgical drain, n (%)	16 (32%)
Time to drain removal (days)	2 (2–2)
Length of hospital stay (days)	4 (4–5)
Preoperative haemoglobin (g/dL)	15 (14.2–15.7)
Postoperative haemoglobin (g/dL)	13.3 (12.5–14)
Specimen weight (g)	73.3 (54.6–108.9)
Volume enucleated of total prostate volume, %	58.9% (45.0–67.4%)
Postoperative complications, n (%)	6 (12%)
Clavien 1	4 (8)
Clavien 2	1 (2)
Clavien 3a/3b	1/0 (2/0)
Clavien 4	0 (0)
Clavien 5	0 (0)

All values are median (IQR) unless indicated otherwise

on curative anticoagulation for arrhythmia. Only one patient suffered a severe complication defined as Clavien–Dindo > II (haematoma of the Retzius space requiring radio-guided drainage (Clavien IIIa)). No grade IV or V complications occurred.

On univariate analysis, the only risk factor for postoperative complications was the Charlson comorbidity index (OR = 2.1, 95% CI = [1.1–4.7], $p = 0.04$).

The functional outcomes of the patients are shown in Table 3. Twelve months after surgery patients experienced a significant improvement in flow rate and IPSS. No patient had acute urinary retention during the study period and no patient has reported stress urinary incontinence (SUI) to date.

Discussion

More than 1000 cases of RASP, performed using different techniques, have been described over the past 12 years. This high number of procedures is an indication of the efficacy and safety of this surgical intervention [10]. In our study, we confirmed the feasibility of an extra-peritoneal approach with acceptable morbidity and promising mid-term functional results. For OSP, the extra-peritoneal approach is the gold standard, while for RASP, both the trans- and extra-peritoneal routes have been performed. The background to the use of the trans-peritoneal approach is its similarity to robot-assisted radical prostatectomy (RARP), which is usually performed in cases of prostate

Table 3 Evolution of functional outcomes

Variable	Preoperative	12-month postoperative	<i>p</i> -value
IPSS	24.5 (18.7–27.0)	2 (1–4)	<0.001
Maximum flow rate (mL/s)	8.8 (6.7–11.8)	24.0 (12.1–32.0)	<0.001
Void volume (mL)	140 (121–179)	139 (94–318)	1
Post-void residual volume (mL)	150 (93.3–248.8)	0 (0–30)	<0.001
Indwelling urethral catheter before surgery, <i>n</i> (%) ^a	20 (43%)	0 (0)	<0.001

All quantitative values shown are median (IQR)

IPSS International Prostate Symptoms Score

^aAfter alpha-blocker failure

cancer [13]. However, centres with experience in extra-peritoneal radical prostatectomy have also proposed the same approach for RASP with good results.

Our centre has a long experience with both the trans- and extra-peritoneal RARP approaches and previously proposed the second approach to reduce the risk of ileus and to shorten the LOS.

In our series, OT and EBL were consistent with literature. Autorino et al., in a European–American multi-institutional analysis, reported that the median OT was 154 min and EBL was between 100 and 400 mL in a series of 487 RASP procedures [14]. In the analysis of Cockrell and Lee, the OT ranged from 90 to 228 min [15]. In our study, the OT and EBL did not differ between the first case and the last, probably due to our experience in robotic prostate surgery. In the literature, the OT for endoscopic enucleation was reported to be between 67 and 72 min for a prostate between 80 and 150 mL with an increase of around 20 min for bigger prostates [7]. In our series, median prostate volume was 131.5 mL with a median OT of 100 min, which is comparable to that of endoscopic procedures for prostates bigger than 150 mL.

In this study, the mean urethral catheter removal was at day 4. These results are greater when compared with literature and are mainly explained by precautionary measures at the beginning of our RASP experience and they should be lower in the future days. Although, endoscopic enucleation techniques focus on the need for prolonged catheter duration post-operatively, initial results of single-port RASP seem to show improvement in initial day or next day voiding trial and in pain management. In their initial study reporting single port RASP, Steinberg et al. showed a mean catheter duration of 1.9 days for a mean prostate volume of 104 mL [16]. Moreover, in a recent propensity matched cohort of patients who underwent single-port RASP, Ganesan et al. showed a 50% decrease in post-operative narcotic when compared with multi-port RASP [17]. Single-port RASP still needs face-to-face comparative trials with endoscopic and multi-port procedures to confirm these preliminary results.

Bleeding is the main consequence of OSP with a transfusion rate of 20–25% [18]. RASP seems to provide a solution to this problem with a transfusion rate between 0 and 5% [15]. In our series of 47 patients fulfilling the inclusion criteria, there was no any blood transfusion postoperatively.

One advantage of RASP in comparison with endoscopic procedures is the absence of urethral passage of instruments. Transurethral enucleation or resection of the prostate accounts for urethral stricture in up to 4% and SUI, because of sphincter damage, in up to 1.5% of cases [19]. In our series, no patients developed a symptomatic urethral stricture and none reported SUI at 12-month follow-up. In addition, patients with unhealthy urethra could also benefit this procedure as it is preserved during the surgery. Further sub-group study could refine patient selection.

At 12 months, we observed a significant decrease for IPSS, and a significant increase for Qmax. After OSP and laser enucleation the benefit in terms of IPSS and Qmax were similar to our group [8, 20].

Our study has several limitations. First, it was a retrospective analysis of a prospective cohort. Second, there was no comparison with OSP and/or endoscopic techniques and no randomized comparison with other techniques. Moreover, there might be a patient selection bias regarding the high mean BMI (26 kg/m²), even if the eligible patients were included consecutively. A robotic surgeon with a high level of experience is needed to obtain these results. The analysis of costs was not an objective of our study. Nevertheless, despite its limitations, our paper describes the real-life treatment of BPO in a main urological robotic centre.

Conclusion

Extraperitoneal RASP is a safe and effective technique for men with LUTS related to large benign prostatic hyperplasia. The use of RASP in experienced centres could add to the surgical armamentarium for large BPO management, given these encouraging results.

Author contributions AP: Participated in research design, data collection, writing of the paper, performance of the research, data analysis. DB: Participated in research design, writing of the paper, performance of the research, data analysis. UP: Participated in writing of the paper, performance of the research and data analysis. ID: Participated in research design and data analysis. DB: Participated in research design and data analysis. JP: Participated in writing of the paper and data collection. CV: Participated in writing of the paper and data collection. EC-K: Participated in research design, writing of the paper and data collection. TS: Participated in research design, writing of the paper and data collection. MR: Participated in research design, writing of the paper, performance of the research, data analysis.

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Availability of data and materials Not applicable.

Code availability Not applicable.

Declarations

Conflict of interest The authors declare no conflict of interest.

Informed consent For this study oral consent was obtained for every patient.

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