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ROBOT-ASSISTED VERSUS STANDARD LAPAROSCOPY FOR SIMPLE PROSTATECTOMY: MULTICENTER COMPARATIVE OUTCOMES

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Abstract

Objective. To report a comparative analysis of laparoscopic simple prostatectomy (LSP) versus robot assisted simple prostatectomy (RASP).

Methods. Consecutive cases of LSP and RASP done between 2003 and 2014 at 3 participating institutions were included in this retrospective analysis. The effectiveness of the two procedures were determined by performing a paired analysis of main functional and surgical outcomes. A multivariate analysis was also conducted to determine the factors predictive of "trifecta" outcome (combination of IPSS score <8, Q_{max}>15 mL/sec and no perioperative complications).

Results: A total of 319 patients underwent minimally invasive simple prostatectomy at the participating institutions over the study period. Total prostate volume was larger in the RASP group (median 118.5 mL versus 109 mL, p=0.02). Median EBL tended to be higher for LSP (300 ml versus 350 ml, p=0.07). There was no difference in terms of catheterization time (p=0.3) and hospital stay (p=0.42). A higher rate of overall postoperative complications was recorded in the RASP group (17.7% versus 5.3%), but rate of major complications was not significantly different between the two techniques (2.3 versus 2.1, p=0.6). Subjective and objective parameters significantly improved for both LSP and RASP. On multivariable analysis, only two factors were associated with likelihood of obtaining a favorable (trifecta) outcome: age (OR: 0.94; p=0.03) and BMI (OR: 0.84; p=0.03).

Conclusions. Both LSP and RASP can be regarded as safe and effective minimally invasive surgical treatments for bladder outlet obstruction due to large prostate glands.

INTRODUCTION

Bladder outlet obstruction (BOO) associated with benign prostatic enlargement (BPE) represents one of the most frequent causes of lower urinary tract symptoms in men[1]. For decades, open simple prostatectomy (OSP) has represented the standard surgical treatment of complicated BOO associated with a large prostate volume[2,3]. Given the high surgical morbidity of this procedure[4], other minimally invasive surgical options have been explored[5]. Among these options, laser-based enucleation techniques have become largely popular, given the demonstrated efficacy[6]. More recently, bipolar energy based endoscopic procedures have been implemented as another “size independent” surgical treatment for BPE[7].

Since first series reported by Mariano et al. in 2002[8], laparoscopic simple prostatectomy (LSP) has also been explored as another potential minimally invasive surgical treatment for the management of BPE in case of large volume prostate glands. More recently, robot assisted laparoscopic simple prostatectomy (RASP) has also been implemented[9]. Overall, large dataset analysis shows that both techniques can be safely and effectively performed in a variety of healthcare settings in which specific surgical expertise and technology is available[10].

The aim of this study was to compare the outcomes of LSP to those of RSP in Centers that have matured experience with both techniques.

PATIENTS AND METHODS

Study Design

Consecutive cases of LSP and RASP performed between 2003 and 2013 at 3 teaching hospitals were included in this retrospective multicenter study. Each group performed the procedure according to their own surgical indication, technique and follow-up protocol. The data had been collected in a de-identified and standardized data-file, which was specifically built for a larger multi-institutional study whose findings have been already reported[10]. For the purpose of the present analysis only Centers which had provided both laparoscopic and robotic cases were considered. Institutional Review Board approval/waiver was obtained at participating centers.

Parameters

Demographic data included age, body mass index (BMI), Charlson Comorbidity Index (CCI) and history of prior abdominal/pelvic surgery. Baseline functional parameters related to lower urinary tract symptoms were collected, including International Prostate Symptom Score (IPSS) and Quality of Life (QoL) score, maximum flow rate (Q_{max}), prostate specific antigen (PSA) and Sexual Health Inventory for Men (SHIM) score. These variables were also assessed in the postoperative period with a follow-up calculated from the date of surgery to the date of the last contact with the patients. Other relevant parameters related to BOO were registered (indwelling catheter, related bladder disease, total prostate and adenoma volume).

Perioperative outcomes included surgical approach, operative time, estimated blood loss (EBL), intra-operative complications classified according to Satava[11], catheterization time, length of hospital stay (LOS) and pathological assessment of prostate and weight. Postoperative complications occurring in the 90-day post-surgery were also recorded and graded according to the standardized Clavien Dindo system[12].

Statistical Analysis

Descriptive statistics was used to summarize patients' baseline characteristics. Median and interquartile range (IQR) were reported for continuous variable, and the frequency and percentage for categorical variables. Perioperative and postoperative continuous variables were compared using the Wilcoxon matched-pairs signed rank test.

A multivariate analysis was also conducted to determine the factors predictive of trifecta outcome, previously defined as a combination of IPSS score < 8, Q_{max} > 15 mL/sec and no perioperative complications[10]. The following clinically relevant parameters were included in the multivariable model: age at surgery, BMI, prostate gland volume, ORT, EBL, technique (laparoscopic vs robotic) and previous abdominal surgery. On the multivariate analysis, results were provided as odds ratios (ORs) with their 95% confidence intervals (CIs). Significance was defined as p<0.05. Data were analyzed using SPSS v.21 software (IBM Corp., Armonk, NY, USA).

RESULTS

Demographics

A total of 319 patients underwent minimally invasive simple prostatectomy at the participating institutions over the study period. **Figure 1** shows that, since its introduction, the robotic technique has been preferred over the laparoscopic one.

The characteristics of the 189 (59.25%) men who underwent LSP and 130 (40.75%) men who underwent RASP are shown in **Table 1**. At baseline, there was no difference between the groups in terms of age, BMI, CCI. RASP group presented a higher proportion of patients with history of previous surgery (32% vs. 21%, p=0.02). Moreover, they presented higher scores on IPSS (median 23 vs. 17, p<0.001) and QoL (median 6 vs. 5, p=0.001). Total prostate volume was larger in the RASP group (median 118.5 mL vs. 109 mL, p = 0.02).

Surgical Outcomes

Surgical outcomes have been summarized in **Table 2**. In the LSP group, all the surgeries were performed with an extra-peritoneal approach, whereas in the RASP group, 31.5% of the cases were performed with transperitoneal approach (p<0.001). The median

ORT was longer in the RASP group, but without reaching statistical significance (150 min versus 120, p=0.07). Median EBL tended to be higher for LSP (300 ml vs. 350 ml, p=0.07). No difference was found in terms of intraoperative complications (p=0.55) and conversion rate (p=0.81). Regarding immediate postoperative variables, there was also no difference in terms of catheterization time (p=0.3), time to drain removal (p=0.3), and hospital stay (p=0.42).

A higher rate of postoperative complications was recorded in the RASP group, where 14.6% patients developed a minor postoperative complication and 2.3% had a major one, compared to 3.17% and 2.1% in the LSP group , respectively (p<0.001). No grade 5 complication was recorded in either group.

Functional outcomes

The mean length of follow up was 6 (0.1) months for the LSP group and 10.3 (3) months for the RASP group. A significant improvement was recorded in terms of IPSS (-90% for LSP and -64% for RASP, <0.001) (**Figure 2a**). Also, postoperative Q_{max} was significantly improved postoperatively for both LSP and RASP (100% and 142% respectively) [**Figure 2b**]. A significant decline was found in the PSA values for LSP (91% reduction) and RASP (64% reduction) [**Figure 2c**]. Also Postoperative SHIM score was higher in the LSP group (24 versus 17, p=0.01) (**Figure 2d**).

Trifecta

On multivariable analysis, only two factors were associated with higher likelihood of obtaining a favorable (trifecta) outcome: age (OR: 0.94; 95% CI, 0.89-0.99, p=0.03;) and BMI (OR: 0.84; 95% CI, 0.71-0.99, p=0.03). On the other hand, history of previous abdominal surgery (p=0.74;), prostate volume (p=0.23), ORT (p=0.83) and EBL (p=0.92) were not significantly associated with the trifecta. Similarly, the outcome was not influenced by the type of procedure (RASP vs. LSP, OR: 0.44; 95% CI: 0.17-1.12, p=0.09).

DISCUSSION

To our knowledge, this work represents the first reported comparative study of robot-assisted versus standard laparoscopic simple prostatectomy involving urological Centers having significant experience with both techniques. This multi-institutional "real-life" data analysis provides further evidence on the reproducibility, safety and efficacy of these techniques.

In the past two decades, substantial progress has been made in the surgical treatment of BOO due to BPE. However, despite recent advances in endourological techniques[5], OSP remains a largely used surgical procedure for large prostate adenomas[13], given its established efficacy and minimal cost. Nevertheless, this procedure carries a high morbidity, specifically perioperative bleeding[4]. This limitation prompted the development of laparoscopic approach for the simple prostatectomy procedure with the aim of duplicating the principles of open surgery, above all the "enucleation" of the adenoma, while limiting the surgical invasiveness. In few small single-center analyses, LSP seemed to offer shorter length of stay, lower blood loss and shorter catheter time compared to OSP[14-16]. This was also confirmed in a recent systematic review of 14 studies including a total of 626 patients[17]. As for any other laparoscopic procedure[18], the application of robotics has been explored for simple prostatectomy, likely facilitated by the maturing experience with radical prostatectomy[19]. Since the first pioneering series of transperitoneal[20] and extra-peritoneal[21] RASP, multiple RASP series have been reported[22]. However, by 2012, it has been estimated that only 5% of the procedures were performed using a minimally invasive approach[23].

As previously demonstrated in a larger analysis[10], it was not surprising to discover that in our series robot-assisted laparoscopy surpassed standard laparoscopy over time at participating institutions, as shown in **Figure 1**. As simple prostatectomy is a technically demanding procedure, encompassing both extirpative and reconstructive steps, the addition of robotic technology has been regarded as a helpful tool for physicians embarking on this surgical endeavor. As RASP seems to be usurping LSP in recent years, one might argue whether LSP can still have a role in this setting. We believe that LSP remains a viable option in Centers where robotic surgery is not yet in place, mainly because of cost issues, but where there is sufficient aparoscopic expertise to effectively perform LSP.

Owing to the experience developed with robotic radical prostatectomy[24], the majority (almost 80%) of RASPs in our study were performed using transperitoneal approach. On the other hand, the laparoscopic cases were performed via an extraperitoneal approach, as done for laparoscopic radical prostatectomy[25]. It remains to be determined how these two approaches compare in terms of outcomes of simple prostatectomy. A recent meta-analysis done for robotic radical prostatectomy suggests that perioperative parameters may be more favorable for the extra-peritoneal approach[26].

The patient populations in both study groups are similar to those reported elsewhere in this setting, consisting of severely symptomatic patients (median IPSS: 17 for LSP and 23 for RASP) with severe BOO (median Qmax: 5 ml/sec for LSP and 9 ml/sec for RASP ml/s) and large prostate glands (median prostate volume: 100 cc for LSP and 118.5 cc for RASP).

The analysis of surgical outcomes elicits few comments. Both procedures were conducted within acceptable operative times, with LSP having shorter duration (median 120 minutes versus median 150 minutes, p=0.07), which can be explained by the time necessary for robot docking. It should be also assumed that in teaching institutions trainees might have participated in the procedures to some extent, and this should be taken into consideration. In addition, the “learning curve” effect should also be considered as early cases were also included in the present analysis. Nevertheless, average operative time looks certainly longer than that reported for holmium enucleation[27] or OSP[2-4].

Notably, the estimated blood loss was quite limited in both groups (median 300 ml for LSP and 250 ml for RASP), without a significant difference between them. This finding confirms previous one suggesting an advantage over OSP[14-16]. Intra-operative complication rates were quite low for both techniques, whereas the 10-11% conversion to OSP seems relatively high. As shown in the table 2, conversion rates were 11.6% in the LSP group and 10.8% in the RASP group (p=0.81). The two main reported reasons for conversion were “bleeding” and “inability to progress due to technical difficulty”. However, both these findings (low intraoperative complication rate and relatively high conversion rate to open) can be interpreted as surrogates of safety measures for surgeons embracing minimally invasive simple prostatectomy.

In terms of hospital stay, this was similar for both techniques and, again, shorter if compared to OSP series[2-4,] but much longer if compared to laser and bipolar energy procedures[6-8]. To this regard, it needs to be pointed out that hospital stay can be influenced by non-medical factors depending on the health care system and country where the procedure is performed. RASP series from the USA, for example, have reported a much shorter hospital stay (1-2 days)[13]. Therefore this study finding can be interpreted in different ways. This is probably not the case for the catheterization time, as neither LSP nor RASP compare favorably with that of endoscopic procedures[6-9].

Most of the postoperative complications in the series were low grade (Clavien 1 and 2), which usually have minimal impact on the postoperative course. Overall, the complication rate was significantly higher for RASP (17.7% versus 5.3%, <0.001), but this difference was not significant when considering only major events (Clavien 3 and 4). In addition, one might argue that RASP cases were more recent, which might account for a more accurate report of postoperative events, especially minor ones. In a recent analysis of 10-year data from the National Inpatient Sample, including over 35,000 patients who had simple prostatectomy for BPE, Pariser et al found that use of a minimally invasive approach was associated with a decreased risk of complications[23].

As for any other surgical procedure for BOO/BPE[6], subjective (IPSS, QoL score) and objective parameters (Qmax, PSA) are important proxy measures for treatment efficacy. For all of them a significant improvement was recorded after surgery for both LSP and RASP. The higher improvement for LSP in terms of Qmax, although statistically significant, does not translate in clinically significant difference with only 2 ml/sec difference between groups. The same can be said for the higher improvement in terms of IPSS for the RASP group, as for both LSP and RASP the median postoperative IPSS value was within the “mild symptoms” score range.

To note, minimal difference between preoperative and postoperative SHIM scores was found for both techniques, which confirm the minimal impact of the procedure on sexual function. Recently, we also proposed a “trifecta” of outcomes for minimally invasive SP, comprising of a combination of IPSS score < 8, Q_{max} > 15 mL/sec and no perioperative complications[13]. In the present analysis, age (p=0.03; OR: 0.94; 95% CI, 0.89-0.99) and BMI (p=0.03; OR: 0.84; 95% CI, 0.71-0.99) predicted a favorable “trifecta” outcome. External validation of this composite outcomes measure is awaited. The finding that increasing BMI has a negative impact on outcome mirros previous studies on robotic radical prostatectomy[28].

Main limitations of this study needs to be acknowledged. First, its retrospective design, which might account for inaccuracies in data reporting, and which necessarily limited the analysis to the parameters that were of sufficient quality. Moreover, the two study groups were not matched. On the other hand, a multivariate analysis was performed to better clarify the independent value of each of the techniques. Also, a cost analysis was outside the scope of this study. It remains to determine how minimally invasive prostatectomy compares to endoscopic techniques. In this respect, still limited data exist. Matei et al. reported lower costs for RASP compared to OSP, mainly due to the shorter hospital stay[29]. In a small case-control study, holmium enucleation of the prostate was found to provide similar short term functional results and complication rates compared to LSP with the advantage of less catheterization time, reduced costs and shorter hospital stay[30]. This issue certainly needs further investigation.

In conclusions, both LSP and RASP can be regarded as safe and effective minimally invasive surgical treatments for BOO due to large prostate glands. The outcomes of robotic surgery have the potential to improve with maturing surgical experience. The implementation of laparoscopic versus robotic approach in this setting is likely to be mainly influenced by surgeon's preference, availability of instrumentation, and cost issues.

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LEGENDS TO FIGURES

Figure 1. Number of cases during the study period

Figure 2. Plots of pair analysis (preoperative versus postoperative value) for relevant parameters: (a) IPSS, (b) Qmax; (c) PSA; (d) SHIM. P values of the difference between preoperative and postoperative values for each parameter are indicated for both LSP (Laparoscopic Simple Prostatectomy) and RASP (Robot assisted Simple Prostatectomy).

Table 1: Overview of study population, procedures and techniques

	LSP (n=189)	RASP (n=130)	p value
Age, year, median (IQR)	68 (62.6, 73)	67.4 (63, 73)	0.71
BMI, kg/m^2, median (IQR)	26.5 (25, 29)	26 (24, 28)	0.30
Charlson index, median (IQR)	2 (1,2)	2 (1,2)	0.46
Prior Abdominal/Pelvic Surgery, n (%)	40(21.2)	42(32.3)	**0.02**
Baseline IPSS, median (IQR)	17(13, 21)	23 (19, 27)	**<0.001**
Baseline QoL, median (IQR)	5 (4, 6)	6 (5,6)	**0.001**
Baseline Qmax, ml/sec, median (IQR)	5 (5, 10)	9 (7, 12)	**0.001**
Baseline PSA median (IQR)	6 (3.2, 9.1)	6.1 (3.6, 9.7)	0.61
Baseline SHIM score, median (IQR)	21(14, 24)	18 (12, 22)	0.25
Indwelling Foley, n (%)	24 (12.7)	21 (16.3)	0.37
Bladder stone, n (%)	5 (2.6)	4 (3.1)	1.00
Bladder diverticulum, n (%)	12 (1.4)	6 (1.3)	0.85
Prostate volume overall, ml, median (IQR)	109 (90, 129.5)	118.5 (100, 140)	**0.02**
Adenoma volume, ml, median (IQR)	70 (70, 80)	77.5 (77.5, 108)	0.44

LSP= Laparoscopic simple prostatectomy; RASP= Robotic simple prostatectomy; BMI=Body mass index; Hb=Hemoglobin; PSA=Prostate specific antigen; IPSS=International Prostate Symptom Score; PVR=Post void residual urine; SHIM=Sexual Health inventory for men

Table 2: Main surgical outcomes

	LSP (n=189)	RASP (n=130)	p value
Approach, n (%)			
Transperitoneal	0 (0)	41 (31.5)	**<0.001**
Extraperitoneal	189 (100)	89 (78.5)	
ORT, min, median (IQR)	120 (90-180)	150 (98-180)	0.07
EBL, ml, median (IQR)	300 (200-500)	250(127-450)	0.07
Intraoperative complications*, n (%)	10 (5.3)	5 (3.8)	0.55
Conversions, n (%)	22 (11.6)	14 (10.8)	0.81
Time to Foley removal, median (IQR)	5 (4-5)	5 (4-6)	0.30
LOS days, median (IQR)	5 (5-6)	5 (5-6)	0.42
Pathology, n (%)			0.45
BPH	184 (97.4)	129 (99.2)	
Adenocarcinoma	5 (2.6)	1 (0.8)	
Specimen weight, grs, median (IQR)	94 (58-115)	77 (58-101)	0.23
90day post-op. complications, n (%)			
Minor (grade 1-2)	6 (3.2)	19 (14.7)	**<0.001**
Major (Grade 3-4)	4 (2.1)	3 (2.3)	**0.60**
Overall	10 (5.3)	23 (17.7)	
Postop PSA, ng/dl, median (IQR)	0.3 (0.1-2)	2 (0.5-3.1)	**0.002**
Δ% Postop PSA, ng/dl, mean	- 91	-56	**0.005**
Postop Qmax, ml/sec, median (IQR)	20 (17-23)	22 (18-28)	**0.02**
Δ% Postop Qmax, ml/sec, mean	+100	+142	**0.03**
Postop IPSS, median (IQR)	2 (1-2)	5 (4-10)	**<0.001**
Δ% IPSS, mean	- 90	- 64	**<0.001**
Postop. SHIM, median (IQR)	24 (12-25)	17 (10-23)	**0.01**
Δ% Postop. SHIM, mean	+13	-3	**0.01**

LSP=Laparoscopic simple prostatectomy; RASP= Robotic simple prostatectomy; ORT=Operative time; BL=estimated blood loss; LOS=length of stay; BPH=Benign prostatic hyperplasia; PSA=Prostate specific antigen; IPSS=International Prostate Symptom Score; SHIM=Sexual Health inventory for men
*All Satava grade 2 for both groups