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Robotic simple prostatectomy vs HOLEP, a 'multi single-center' experiences comparison

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Introduction The aim of this study was to compare peri-operative and mid-term outcomes of patients who underwent robot-assisted simple prostatectomy (RASP) vs holmium laser enucleation of the prostate (HOLEP). RASP and HOLEP are the treatments of choice for men with symptomatic benign prostatic obstruction (BPO) and a prostate ≥80 g, achieving comparable short and mid-term efficacy. No randomized controlled studies have proved the superiority of one technique over the other.

Material and methods The prospectively maintained databases of the participating institutions were queried for patients with a prostate volume (PV) ≥80 g, who underwent surgery for BPO between 2011 and 2021. The study population was divided into two subgroups based on surgical approach. Demographics, baseline characteristics, and 12 months outcomes were compared between groups: χ^2 and Student t-tests were used for categorical and continuous variables, respectively. The Trifecta composite outcome (post-operative Q-max >15 ml/sec, International Prostate Symptom Score (IPSS) <8 and absence of complications) was used to define surgical quality and the two groups were compared accordingly. Logistic regression analyses investigated predictors of Trifecta achievement.

Results We included 97 patients with comparable pre-operative features (all p >0.30): 43 underwent RASP, 54 HOLEP. Median PV was 102 g (IQR 89–120) and Q-max was 7.2 ml/s (IQR 5.4–9.0). The Trifecta rate was 43% overall, higher in the RASP subgroup (56% vs 33%; p = 0.02). The endoscopic approach was its only independent predictor (OR 0.5; 95% CI 0.28–0.88; p = 0.016).

Conclusions At univariable regression analysis, surgical approach was the only independent predictor of Trifecta achievement, which was significantly higher in the RASP group compared to HOLEP.

Key Words: robot-assisted simple prostatectomy ‹› HOLEP ‹› benign prostatic obstruction ‹› functional outcomes ‹› Trifecta

INTRODUCTION

In the last years, a considerable number of minimally invasive treatment strategies for benign prostatic obstruction (BPO) have been proposed, with promising functional outcomes and limited complication rates [1–5]. Regardless of its non-negligible morbidity, open simple prostatectomy (OSP) has represented, for decades, the best treatment option for patients affected by BPO caused by large adenomas and refractory to medications or complicated by urinary retention, recurrent urine infections, bladder stones or diverticula [6]. With the introduction of surgical robots in this field, we have witnessed a significant reduction of perioperative complications and ambitious functional outcomes, such as ejaculatory function preservation, have become attainable [7–10]. Meanwhile, holmium laser enucleation of the prostate (HOLEP)

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is rapidly becoming the new gold standard for the treatment of BPO, being less invasive than robot-assisted simple prostatectomy (RASP) and suitable for prostates of any size, unlike transurethral resection of the prostate [11]. Up to today, despite recent technological innovations, HOLEP is the only laser treatment endorsed by both the American Urological Association (AUA) and European Association of Urology (EAU) guidelines [12], as there is level 1 evidence that it provides functional outcomes comparable to those of OSP in men with large prostates [13]. When treating such patients, the goal is to achieve complete removal of the prostatic adenoma through any enucleation technique available: RASP, OSP, HOLEP, or mono-/bipolar transurethral enucleation of the prostate (mTUEP and b-TUEP) [14]. However, due to the lack of comparative clinical trials, the optimal management option is yet to be determined [15]. In the present study, we compared peri-operative and mid-term outcomes of patients with lower urinary tract symptoms (LUTS)/BPO due to large adenomas who underwent RASP vs HOLEP.

MATERIAL AND METHODS

Once the Internal Review Board (IRB) approval was obtained, the prospectively maintained databases of the participating institutions on BPO surgery were merged and retrospectively queried for patients who presented with a PV ≥80 g at the time of treatment. All the patients suitable for surgery, presenting with LUTS/BPO and large prostates (≥80 g), refractory to medical therapy or associated with urinary retention, recurrent urinary tract infections, secondary renal function impairment, were offered both RASP and HOLEP [16]. Robot-assisted and endoscopic procedures were performed by different surgeons experienced in the specific field (>50 cases), according to the already published techniques [17, 18].

The following data were extracted for the purpose of the study:

1) demographic and anthropometric characteristics: age, body mass index (BMI), American Society of Anesthesiologists (ASA) score
2) operation time (OT) and length of hospital stay (LOS)
3) postoperative and 90-days complications (graded according to the Clavien-Dindo classification system) [19]
4) scores obtained at different validated questionnaires assessing LUTS: International Prostatic Symptom Score (IPSS) and its Quality of Life (QoL) index, and erectile function: International Index of Erectile Function short form (IIEF-sf), administered at baseline and at 12 months follow-up
5) uroflowmetry parameters, recorded at baseline and 1 year after surgery.

The study population was split into two subgroups based on the surgical approach and patients' baseline features were compared: χ^2 and Student t-tests were used for categorical and continuous variables, respectively. The Trifecta composite outcome proposed by Autorino et al. (post-operative maximum flow rate [Q-max] >15 ml/sec, IPSS score <8 and absence of complications) was used to assess surgical quality in the two cohorts [10]. Predictors of Trifecta achievement were investigated by logistic regression analyses. Data were analyzed using the Statistical Package for Social Science v. 25.0 (IBM, Somers, NY, USA).

RESULTS

Between January 2011 and March 2021, 106 patients underwent RASP and 230 underwent HOLEP. Based on their prostate size (≥80 g), a total of 97 patients were included in this study: 43 (44%) underwent RASP and 54 (56%) underwent HOLEP. Demographics are reported in Table 1. The median interquartile range (IQR) age was 70 years (65–75). Baseline characteristics were statistically comparable within the whole series (all p >0.3). Overall, 17 patients (17%) were ASA 3–4. The median (IQR) BMI was 26 (24–28), the median prostate volume was 102 g (89–120), the median prostate-specific antigen (PSA) was 5.1 (3.2–8.3) and the median uroflowmetry assessed Q-max was 7.2 (5.4–9). Pre-operative serum sodium was within the normal range in every patient. Renal function and electrolytes were checked daily until the hospital discharge and remained stable. Patients with catheter dependent urinary retention in the RASP and in the HOLEP cohort were 20 (46%) and 16 (30%) respectively. Peri-operative and post-operative outcomes are reported technique-by-technique as following (Table 1).

Robot-assisted simple prostatectomy cohort

Pre-operative median (IQR) IPSS score, QoL-index, and IIEF score were 20 (17–21), 3 (3–4) and 16 (10–18) respectively, comparable between groups (all p >0.3). The median operative time, was 111 min, significantly longer compared to the HOLEP group (p <0.01). The median (IQR) length of hospital stay was significantly shorter in this cohort: 3 days (3–4) (p <0.01). Four patients were receiving anticoagulants pre-operatively. Anticoagulation therapy was discontinued 24 hours prior to the operation and resumed on post-operative day (POD) 2. Also 3 patients were receiving antiplatelet therapy which was

discontinued 7 days prior to surgery and switched over to low molecular weight heparin until 6 days after surgery. Antiplatelet medications were restored on the 7th day after surgery. Median time to catheter removal was 7 days. Three patients (7%) experienced peri-operative complications, represented by urinary tract infections (UTI) complicated by fever (Clavien 2). None of the patients in this cohort experienced clot retention.

Holmium laser enucleation of the prostate cohort

In this group, pre-operative median (IQR) IPSS score, QoL-index and IIEF were: 20 (15–23), 3 (3–4) and 12 (5–19) respectively. The median (IQR) operative time was 70 minutes (50–86) and the median length of hospital stay was 7 days (6–8). Median time to catheter removal was 5 days, significantly shorter than in the RASP cohort (p <0.01). A total of 6 patients received anticoagulants pre-operatively. Anticoagulation therapy was maintained throughout the admission. Overall, 12 (22%) patients experienced complications. In particular: 6 patients experienced UTI complicated by fever (Clavien 2), and 6 patients presented with acute clot retention within 7 days from the catheter removal (Clavien 1). After excluding those patients on anticoagulant therapy from the analysis, clot retention incidence slightly decreased from 6 (11%) to 4 (8%). The overall complication rate was significantly higher in this group (p = 0.03).
At follow-up, median (IQR) PSA, Q-max, IPSS and QoL-index were: 0.8 (0.4–1.3); 21 ml/sec (16–25), 5 (3–9.5) and 1 (0–2) respectively. No statistically significant differences were found in these variables between groups (all p >0.2). Patients manifesting stress incontinence post-operatively were 3 (7%) in the RASP cohort and 5 (9%) in the HOLEP group. This difference was not statistically significant. Median IIEF remained unchanged pre- and post-operatively in both groups. Delta PSA, delta IPSS and its QoL index, and delta Q-Max were not significantly different between groups as well (all p >0.09) (Table 1). At their last follow-up, none of the patients required re-treatment.

Table 1. *Baseline characteristics and outcomes – Median (IQR)*

Variables	Overall N = 97	HOLEP N = 54 (56 %)	RASP N = 43 (44 %)	p-value
Age (y)	70 (65–75)	70 (66–74)	72 (64–75)	0.57
BMI	26 (24–28)	26 (24–28)	25 (22–28)	0.34
ASA 3–4 N. (%)	17 (17.5%)	8 (15.0%)	9 (21.0%)	0.30
Prostate volume (g)	102 (89–120)	102 (88–116)	105 (90–125)	0.46
Pre-operative PSA (ng/ml)	5.1 (3.2–8.3)	5.1 (3.0–7.4)	4.9 (3.6–9.7)	0.90
Pre-operative Q-Max (ml/sec)	7.2 (5.4–9.0)	7.0 (6.0–9.0)	7.0 (4.0 – 10.0)	0.39
Pre-operative IPSS	20 (17–22)	20 (15–23)	20 (17–21)	0.89
Pre-operative Qol index	3 (3–4)	3 (3–4)	3 (3–4)	0.46
Pre-operative IIEF	15.0 (6.5–18.5)	12.0 (5.0–19.0)	16.0 (10.0–18.0)	0.30
Operative time (min)	85 (60–111)	70 (50–86)	111 (90–135)	**<0.01**
Lenght of Hospital Stay (days)	6 (4–8)	7 (6–8)	3 (3–4)	**<0.01**
Time to catheter removal (days)	7 (5–8)	5 (4–6)	7 (7–9)	**<0.01**
Post-operative PSA (ng/ml)	0.8 (0.4–1.3)	0.8 (0.5–1.3)	0.7 (0.4–1.4)	0.57
Δ PSA (ng/ml)	4.0 (2.5–6.8)	4.0 (2.4–6.7)	4.0 (3.0–7.2)	0.57
Post-operative Q-Max (ml/sec)	21 (16–25)	22 (15–25)	20 (17–26)	0.77
Δ Q-Max (ml/sec)	13.6 (8.7–18.0)	13.0 (7.0–18.0)	14.0 (11.0–16.0)	0.31
Post-operative IPSS	5.0 (3.0–9.5)	6.0 (3.0–10.0)	5.0 (2.0–9.0)	0.20
Δ IPSS	13 (9–16)	13 (8–16)	15 (9–17)	0.09
Post-operative QoL index	1 (0–2)	1 (0–1)	1 (0–1)	0.42
Δ QoL index	2 (1–3)	2 (1–3)	2 (1–3)	0.79
Post-operative IIEF	15 (6–20)	12 (5–19)	18 (10–20)	0.10
Post-operative stress incontinence (%)	8.0 (8.2%)	5.0 (9.3%)	3.0 (7.0%)	0.68
Peri-operative complications	15 (15%)	12 (22%)	3 (7%)	**0.03**
TRIFECTA N. (%)	42 (43.3%)	18 (33%)	24 (56%)	**0.02**

BMI – body mass index; ASA – American Society of Anesthesiologists score; IPSS – International Prostate Symptoms Score; IIEF – Index of Erectile Function; Q-Max – peak flow; Qol – quality of life; PSA – prostate-specific antigen; n – number of patients

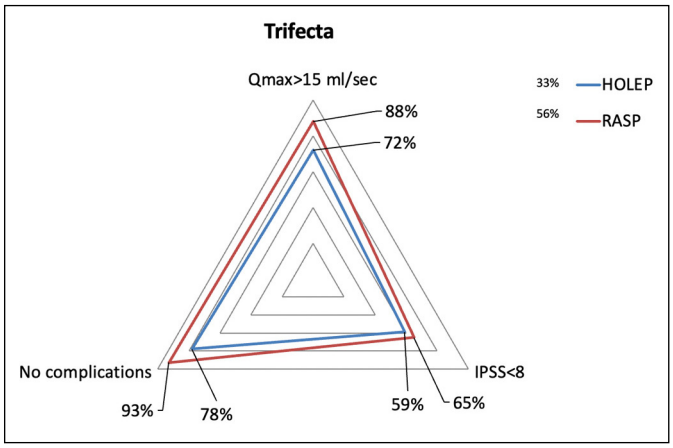

Figure 1. *Trifecta rates in HOLEP and RASP groups.*
Trifecta was definied as Qmax >15 ml/sec, absence of complications and IPSS <8
RASP – robot-assisted simple prostatectomy; HOLEP – holmium laser enucleation of the prostate

Table 2. *Univariable logistic regression analyses to identify predictors of Trifecta achievement*

Variables	OR	95% CI		p-value
		Lower	Higher	
Age	1.029	0.973	1.088	0.313
BMI	0.924	0.815	1.048	0.219
ASA score ≥3	1.333	0.466	3.819	0.592
Prostate volume	1.006	0.992	1.021	0.395
Pre-operative PSA	0.997	0.925	1.075	0.935
Pre-operative Q-Max	1.074	0.947	1.217	0.268
Pre-operative IPSS	0.978	0.893	1.070	0.626
Pre-operative QoL index	0.957	0.634	1.443	0.832
Pre-operative IIEF	1.034	0.978	1.092	0.237
Endoscopic approach	0.500	0.284	0.880	0.016

BMI – body mass index; ASA – American Society of Anesthesiologists score; IPSS – International Prostate Symptoms Score; IIEF – Index of Erectile Function; Q-Max – peak flow; Qol – quality of life; PSA – prostate-specific antigen; n – number of patients; OR – odds ratio; CI – confidence intervals

Trifecta rate was 43% overall but it was significantly higher in the robotic subgroup (56% vs 33%; p = 0.02) (Figure 1). At univariable regression analysis, surgical technique was the only independent predictor of Trifecta achievement (OR 0.500; 95% CI 0.284–0.880; p = 0.016) (Table 2).

DISCUSSION

The significant improvements provided by robotic technology in terms of functional outcomes combined with the benefit of a minimally invasive technique, led to a worldwide adoption of RASP [20–26].

HOLEP is also being increasingly adopted as an alternative to simple prostatectomy for a few paramount reasons documented by randomized controlled trials, systematic reviews and meta-analyses. First of all, HOLEP proved durable functional outcomes, comparable to those of OSP while reducing the complication rate [27, 28, 29]. Secondly, its effectiveness is independent from the prostate size [15]. Thirdly, HOLEP is a suitable option for patients on anticoagulant medications or with high cardiovascular risk [28, 30]. In our series those patients on anticoagulant medications undergoing HOLEP maintained their anticoagulant therapy throughout the admission.

The first study comparing functional outcomes between HOLEP and RASP was published by Zhang et al. In their study both techniques proved to be safe and equally proficient [14]. However, the number of patients in their series was heavily unbalanced (32 RASP vs 600 HOLEP). In our series, the two cohorts (43 RASP and 54 HOLEP) were homogeneous for demographics (age, BMI, ASA score, prostate volume), pre-operative PSA, baseline IPSS and its Quality of Life index, baseline IIEF and uroflowmetry assessed Q-Max.

At follow-up, IPSS and Qol-index were comparable between groups, confirming that both techniques are equally time-efficient in removing as much prostatic tissue as possible [31]. In terms of length of hospital stay, Jones et al. reported significant advantages of HOLEP when compared to open prostatectomy [32]. We believe that these advantages are not strictly provided by just the HOLEP procedure, but also by any minimally invasive approach. In our series, the hospital stay was shorter in the RASP cohort: 3 days vs 7 days in the HOLEP cohort since the two hospitals adopted different clinical care pathways: HOLEP patients were discharged only after catheter removal, whereas RASP patients followed an enhanced recovery (ERAS) protocol, therefore they were discharged home with the catheter still in place. Urethral catheter and skin stitches were removed in an outpatient setting. In terms of median operative time, Umari et al., reported comparable surgery duration (105 min) in their series of 81 RASP and 45 HOLEP [33]. In our series, despite the fact that the overall median operative time was similar to those reported in literature, a statistically significant difference was found comparing the two groups, predictably in favor of HOLEP. These results are in line with those of other authors such as: Zhang et al., who showed that the median operative time for HOLEP was reduced in comparison to RASP, even when the size of enucleated adenomas was similar [14]. Few reasons can explain this finding: on one hand, in trans-peritoneal operations, a preliminary

adhesiolysis is often required. On the other hand, in the robotic technique, docking, undocking and the cystorrhaphy, represent additional and time-consuming surgical steps. Umari et al. adopted the same surgical technique for every patient scheduled for RASP (modified Freyer), using a four rather than three arms configuration. Undoubtedly the use of all robotic arms translates into a costlier procedure, but the increased dexterity may translate into a shorter median operative time. Umari et al. also reported comparable peri-operative complication incidence (29%) between groups [33]. The complications incidence in our RASP series was significantly lower (10% vs 22%). In particular, peri-operative complications in the HoLEP cohort were: UTI (11%) and acute clot retention (11%). These results seem to be in line with those reported in literature: a recent systematic review reported hematuria requiring catheterization incidence ranging from 0 to 12% in different series; and UTI ranging from 0 to 14.8% [34]. The difference in acute clot retention rate between groups may be explained by the fact that HoLEP patients maintained their anticoagulant therapy during the whole hospital time. After excluding those patients on anticoagulant drugs from the analysis, clot retention incidence dropped only slightly in the HOLEP cohort from 11% to 8%.

The 'Trifecta' reporting system is a method based on three reproducible variables to report the global results achievable by a surgical technique, identify its predictors. In the last decade many minimally invasive techniques have been proposed to treat both benign and malignant conditions, all of them presenting particular strength and weakness points. Therefore, comparing different techniques by their Trifecta achievement rate can help the Urologist to choose the most suitable approach for each single patient. We successfully adopted this standardized parameters-based outcome reporting system for different procedures such as: robot-assisted radical cystectomy with intracorporeal orthotopic neobladder and robot-assisted partial nephrectomy, also to evaluate improvements in surgical proficiency along the learning curve [35–37]. In this study we adopted the Trifecta proposed by Autorino et al., based on the following three standardized parameters: Q-max >15 ml/sec, IPSS <8 and absence of complications, to assess composite outcomes and compare the Trifecta achievement's rate between the two cohorts [10]. The Trifecta achievement rate was significantly higher in the RASP group compared to the HOLEP group: 56% vs 33% (Figure 1). Although both approaches were effective in achieving durable obstructive symptoms relief, there were undeniable differences when dissecting this outcome into subcategories: RASP performed better than HOLEP in both post-operative IPSS (<8) and Q-max (>15 ml/sec): 65% vs 59% and 88% vs 72% respectively. In terms of peri-operative complications, both techniques showed very low complication incidence. Interestingly, at univariable regression analysis, surgical approach was the only independent predictor of Trifecta achievement, with odds ratio of 50%, suggesting that, RASP represents a more suitable option for patients affected by BPO refractory to medical treatments and sustained by a prostate gland larger than 80 g, and fit for a robotic-assisted operation. In our opinion HOLEP represents an excellent alternative option if the Da Vinci robot is not available or if the patient cannot undergo a laparoscopic procedure due to individual cardiovascular risks.

This is the first study comparing composite (Trifecta) outcomes between the RASP and HOLEP to orient urologists in choosing the best treatment for patients affected by BPO caused by large (≥80 g) prostates, and this is the strength of our study. The limitations of this study include: the small number of patients and the retrospective nature. Also, patients underwent HOLEP and RASP at separate institutions adopting slightly different post-operative clinical care pathways. This can explain the difference in terms of length of hospital stay particularly favorable in the RASP cohort. HOLEP patients were discharged only after urethral catheter was removed and the patient voided multiple times spontaneously and without any problem. This limitation may represent a bias in the peri-operative data interpretation, however, the hospital stay was never intended as one of the study endpoints as it is not included in the Trifecta parameters. Furthermore, we adopted ASA score as a predictor of anesthetic risks related to the operation, which in turn, can reflect the odds of perioperative complication. However, ASA is not an appropriate measure of medical comorbidity. Finally, to be sure that different centers do not influence the outcomes, the techniques should have been switched between the two hospitals, and the results re-analyzed. This was not possible at the time of the results analysis because the Da Vinci surgical platform was available only in one institution, in which holmium laser was not available. Nonetheless, this represents a goal for further studies needed to corroborate our conclusions.

CONCLUSIONS

By comparing different techniques with a standardized metric system, this study provides important insights which may assist in counseling patients undergoing surgery for BPO and a large prostate.

RASP performed better than HOLEP in both postoperative IPSS and Q-max. In terms of perioperative complications, both techniques showed very low complication incidence.
At univariable regression analysis, surgical approach was the only independent predictor of Trifecta achievement, which was significantly higher in the RASP group compared to the HOLEP group: 56% vs 33% respectively. Nonetheless, HOLEP represents an excellent alternative option if the Da Vinci robot is not available or if patients are unfit for a robotic-assisted procedure.

CONFLICTS OF INTEREST

The authors declare no conflicts of interest.

INFORMED CONSENT

For this study, written consent was obtained from every patient to use their deidentified data. The authors confirm that an Institutional Review Board approved the study and informed consent for this retrospective study was waived according to the national laws.

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