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Impact of Obesity on Peri-Operative and Long-Term Functional Outcomes after Robotic Assisted Simple Prostatectomy

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Abstract: Obesity represents a worldwide epidemic disorder, increasing the overall morbidity and mortality rate. In this study we investigated the impact of obesity on peri-operative and long-term functional outcomes of Robotic assisted simple prostatectomy (RASP). Baseline flowmetry parameters and validated questionnaires' scores were prospectively recorded. Follow-up assessments included Flowmetry and validated questionnaires. Composite outcomes (Trifecta) was defined as combination of: post-operative Q-max>15 ml/sec, IPSS score<8 and absence of complications. Pentafecta included also post-operative ejaculation persistence (MSHQ score>0) and the Erectile function maintenance (ΔIEEF<6). Data were stratified by BMI (<30 or ≥30). 81 patients underwent RASP in our Institution. Baseline demographics and clinical features, questionnaires score and baseline flowmetry results were comparable between obese and non-obese cohorts. At follow-up, obese patients reported lower subjective improvement in IPSS (p=0.02) and OABQ scores (p<0.001) and higher incidence of stress incontinence requiring Duloxetin (p<0.001). Flowmetry outcomes, were also worse in this cohort (p=0.02 and p=0.03, respectively). At comprehensive outcomes assessment, obese patients had comparable Trifecta (67% vs 54%, p=0.39) and pentafecta achievement rate (p=0.76). Our prelimirary results proved that obesity is associated with worse functional outcomes (storage LUTS and incontinence rate) after RASP, but doesn't affect trifecta and pentafecta achievement rate.

Keywords: robot-assisted simple prostatectomy; obesity; BMI; benign prostatic obstruction; functional outcomes; trifecta; pentafecta

1. Introduction

Benign prostatic hyperplasia (BPH) is the most common cause of bladder outlet obstruction (BOO) and lower urinary tract symptoms (LUTS) in elderly men [1,2]. It is predicted that over 90% of men will experience at least one episode of LUTS, and up to 25% of them will undergo surgical treatment to alleviate symptoms [2,3].

Surgical intervention is considered the cornerstone treatment in complicated LUTS or ineffective medical therapy [4]. The EAU Non-neurogenic Male LUTS Guidelines recommend open simple prostatectomy (OSP) or laser enucleation techniques in males with large prostate adenomas (>80g) [4]. More recently, due to its feasibility and reproducible technique, Robotic-assisted simple prostatectomy (RASP) has obtained widespread acceptance in the scientific community as an alternative treatment for BOO [5]. Robotic, compared with OPS, offers lower postoperative complications, a shorter length of hospitalization, and lower estimated blood loss and transfusion rates [5,6].

Obesity represents a major health problem, with numbers abruptly increasing in the last years [7]. Several studies correlate obesity with a higher risk of intra and postoperative complications as

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well as functional outcomes impairment, while other studies claim obesity does not affect treatment outcomes [8–10]. We, therefore, analyzed the impact of body mass index (BMI) on peri-operative and long-term functional outcomes of patients undergoing RASP in our center.

2. Materials And Methods:

This is a retrospective study of a prospectively maintained Institutional Review Board-approved database of RASP conducted between June 2012 and May 2020. The research protocol was approved by the local Research and Institutional Ethics Committee. All procedures contributing to this work comply with the ethical standards of the relevant national and institutional guidelines on human experimentation and with the Helsinki Declaration of 1975, as determined in 2008.

Demographic data included age, American Society of Anesthesiology classification status (ASA), BMI, and history of prior pelvic and/or abdominal procedures. Patients were divided into two groups depending on BMI: <30 kg/m^2 and ≥ 30 kg/m^2.

Baseline functional parameters related to LUTS were registered, including International Prostate Symptom Score (IPSS) and quality of life (QoL), post-void residual volume, maximum flow rate (Qmax), and prostate-specific antigen (PSA). Other relevant questionnaires included the International Index of Erectile Function (IIEF) score, Male Sexual Health Questionnaire (MSHQ), International Consultation on Incontinence Questionnaire (ICIQ), and Overactive bladder questionnaire (OABQ). These variables were also analyzed in the postoperative, with a follow-up period encompassed from the surgical date to the last time of patient contact.

Exclusion criterions included individuals with a prior history of bladder or prostate cancer, urethral stricture, neurological disease, and a prostate volume (PV) < 80cc. PV was measured by transrectal ultrasound, using the ellipsoid formula: height x width x length of the prostate x 0.523.

We tested composite outcomes (Trifecta) defined as a combination of post-operative Q-max >15ml/sec, IPSS score <8, and absence of complications [11]. Likewise, pentafecta outcomes which add into account the persistence of antegrade ejaculation (MSHQ>0), and Erectile function maintenance (ΔIEEF <6) were recorded [12].

Perioperative results included surgical approach, operative time (ORT), catheterization time, blood loss, and length of stay. Post-operative complications within the first 90 days were graded according to the Clavien-Dindo classification (CDC) [13]. All surgeries were conducted by one surgeon (GS) with a Da Vinci Si Surgical System (Intuitive Surgical, Sunnyvale, CA, USA). Indications for each surgical approach were outside the scope of this study and can be reviewed in the series by Bove et al [14].

Outcomes were analyzed and compared between groups retrospectively. Continuous and categorical variables were compared using Mood's median test and the Chi-square tests, respectively. $P < 0.05$ was considered statistically significant. A descriptive statistic was performed with the Statistical Package for the Social Sciences (SPSS version 23, IBM, Chicago, IL, USA).

3. Results:

The characteristics of the 81 individuals who underwent RASP for LUTS/BPO at our institution are depicted in Table 1. The median length of follow-up was 36 months. Preoperative LUTS features and patient demographics were substantially comparable between predefined cohorts. As expected, median BMI was significantly different between the two cohorts with 66 patients having a BMI <30 kg/m^2 compared to a BMI ≥30 kg/m^2 in 15 patients (P<0.01).

Table 1. Baseline and Peri-Operative Outcomes.

Variable	Overall *N=81*	BMI<30 *N=29 (64%)*	BMI≥30 *N=15 (36%)*	*p*-value
Age (y)	69 (63 – 74)	69 (64 – 74)	67 (62- 72)	0.56
ASA ≥ 3 (%)	12 (15%)	10 (15%)	2 (13%)	0.86
BMI	25 (23-29)	24 (22-27)	31 (30-32)	<0.01

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Prostate volume (g)	90 (80 – 116)	90 (79 – 116)	90 (80-117)	0.84
Indwelling catheter (%)	31 (38)	28 (42)	3 (20)	0.10
PSA pre (ng/dl)	5 (3.6 – 8.8)	5 (3.3-8.6)	6 (4-10)	0.40
IPSS pre	25 (20 – 28)	25 (21 – 28)	20 (17-26)	0.08
QoL index PRE	5 (4-5)	4.5 (4-5)	5 (4-5)	0.65
IIEF-5 pre	19 (11.5 – 23)	20 (12 – 23)	18 (9 – 21)	0.40
MSHQ pre	11 (8 – 15)	10 (8 – 15)	11 (8-15)	0.69
ICIQ pre	1 (1 – 4)	1 (1 – 5)	1 (0-2)	0.10
OABQ-SF pre	44 (37 – 55)	42 (34 – 52)	45 (38-58)	0.21
Q-MAX (ml/sec) pre	8 (5 – 10)	8 (5 – 10)	6 (4-8)	0.08
Operative time (min)	116 (92-135)	120 (95-136)	110 (90-126)	0.39
Surgical technique (%)				0.77
- **FREYER**	26 (32)	20 (30)	6 (40)	
- **MILLIN**	37 (46)	31 (47)	6 (40)	
- **MADIGAN**	18 (22)	15 (23)	3 (20)	
Length of stay (days)	3 (3-4)	3 (3-4)	3 (3-5)	0.73
Peri-op complication (%)	8 (9)	7 (11)	1 (7)	0.64

BMI: body mass index; ASA: America Society of Anesthesiologist score; IPSS: international prostate symptoms score; IEEF: Index of Erectile Function; MSHQ: Male Sexual Health Questionnaire; ICIQ: International Consultation on Incontinence Questionnaire; OABQ: Overactive bladder questionnaire; Q-MAX: peak flow; QoL: Quality of life;

All surgeries were performed with an intraperitoneal approach. Freyer, Millin, and Madigan techniques were performed in 26 (32%), 37 (46%), and 18 (22%) cases, respectively.

Perioperative and long-term functional outcomes were reported in Table 2. The median ORT, defined as console time, was longer in the non-obese patients, but without reaching statistical significance (120 minutes vs 110 minutes, P=0.39). No differences were found in terms of peri-operative complications (p=0.64). Concerning immediate postoperative variables, there was also no difference in terms of catheterization time (P=0.42) and hospital stay (P=0.73). Blood loss was negligible with every approach (<50ml).

LUTS were assessed four weeks after surgical treatment during follow-up visits and improved in both cohorts. Median IPSS decreased by 21 points in the non-obese population compared to 14 points in obese patients (p<0.02). A significant improvement in QoL was also recorded, albeit without significant differences between groups (p<0.47). Postoperative median Qmax was statistically improved in the former cohort (22 ml/sec vs. 20 ml/sec, p<0.02). Median postvoid residual volume was lower in non-obese individuals (0ml vs 10ml p<0.03). A significant decline was found in the PSA values in both cohorts, 86% and 93.4%, respectively.

Regarding sexual function, no significant difference was found postoperatively between the two cohorts in terms of IEEF -5 score (p<0.41) or MSHQ score (p<0.65). Likewise, no significant difference was noted in the ICIQ scores (p<0.08).

On the other hand, a statistically significant difference was found in the OABQ SF score (median19 points vs median 36 points p<0.01) between groups. Likewise, a higher incidence of stress incontinence requiring duloxetine was found in the obese cohort (2 vs 5 patients p<0.01).

Trifecta was achieved in 36 (54%) patients in the non-obese cohort compared to 10 (67%) patients in the obese population. No significant differences were observed between the "trifecta achieved" and the "trifecta not achieved" groups for baseline BMI (P<0.39). Only 11 (17%) individuals achieved pentafecta outcome in the non-obese cohort compared to 3 (20%) patients in the other group. Similarly, no statistical difference was noted between groups (p=0.76).

Table 2. peri-operative and long-term functional outcomes.

Variable	Overall *N=81*	BMI<30 *N=29 (64%)*	BMI≥30 *N=15 (36%)*	*p*-value
Time to catheter removal (days)	7 (6-8)	7 (7-9)	7 (5-8)	0.42

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Follow-up (moths)	37 (22-66)	38 (24-66)	33 (14-69)	0.30
PSA post	0.7 (0.4-1.2)	0.7 (0.4-1.2)	0.4 (0.2-0.8)	0.04
IPSS post	5 (3 – 9)	4 (2-9)	6 (5 – 9)	0.02
QoL post	1 (0 – 1)	1 (0-1)	0 (0 – 1)	0.47
IIEF-5 post	18 (9 – 22)	18 (11- 23)	18 (6 – 20)	0.41
MSHQ post	4 (1 – 5)	3 (1-5)	5 (1 – 11)	0.65
ICIQ post	1 (1 – 1)	1 (0-1)	1 (1 – 5)	0.08
OABQ-SF post	20 (19 – 26)	19 (19-21)	36 (24 – 58)	<0.01
QoR – VAS (%)	90 (70-100)	90 (70-100)	90 (60-100)	0.78
Q-MAX post (ml/sec)	21 (18 – 26)	22 (18 – 28)	20 (16- 21)	0.02
PVR (ml)	0 (0-14)	0 (0-10)	10 (0-20)	0.03
Tamsulosin post (%)	12 (15)	9 (14)	3 (20)	0.53
Duloxetin post (%)	7 (9)	2 (3)	5 (33)	<0.01
TRIFECTA (%)	46 (57)	36 (54)	10 (67)	0.39
PENTAFECTA (%)	14 (17)	11 (17)	3 (20)	0.76
Delayed complications (%)	2 (2.5)	0 (0)	2 (13)	<0.01
Antegrade ejaculation (%)	24 (30)	20 (30%)	4 (27%)	0.78

IPSS: international prostate symptoms score; IEEF: Index of Erectile Function; MSHQ: Male Sexual Health Questionnaire; ICIQ: International Consultation on Incontinence Questionnaire; OABQ: Overactive bladder questionnaire; Q-MAX: peak flow; QoL: Quality of life; PVR: Post-Void Residue; QoR: Quality of recovery

4. Discussion:

To our knowledge, this work represents the first reported comparative study on long-term functional outcomes and perioperative complications in patients with a BMI < 30 kg/m² versus those with a BMI ≥30 kg/m² undergoing RASP as a surgical treatment of BOO due to BPH. After a median follow-up of 36 months, obese patients reported significantly lower subjective improvements in IPSS ($p=0.02$) and OABQ scores ($p<0.001$) and higher incidence of stress incontinence ($p<0.001$). Likewise, objective outcomes, namely Q-max and post-void residual volume, were also worsened in this cohort ($p=0.02$ and $p=0.03$, respectively [Table 2]).

Obesity represents a major clinical issue in many countries, with a 3 - 6-fold increase over the last decade [15]. Besides having a detrimental effect on patient health, the odds of developing complications are increased [8]. Moreover, men with overweight and abdominal adiposity are predisposed to a higher prevalence of LUTS [16,17]. Fowke et al. found a strong correlation between prostate size volume with BMI, waist-hip ratio, abdominal circumference, and total fat mass [18]. Kim et al. evidenced strong correlations between BMI, IPSS score, and prostate enlargement among Korean men [19]. Giovannucci et al. showed that patients were 38% ($p< 0.0001$) more likely to have surgery for LUTS secondary to BPO with a waist circumference (>109cm) compared to those with waist circumferences (<89 cm) [16].

Considering the aforementioned evidence, LUTS/BOO will become increasingly prevalent in the next years, posing as a major risk factor when assessing surgery for LUTS/BOO. Admittingly, multiple centers have demonstrated the reproducibility, safety, and efficacy of RASP; nonetheless, the impact of obesity on functional and perioperative outcomes is of utmost importance and may even add to its economic burden on society.

The patient populations in both study cohorts are comparable to those described elsewhere in this setting, comprising severely symptomatic individuals (median IPSS: 25 for non-obese and 20 for obese patients) with severe BOO (median Qmax: 8mL/ second for non-obese and 6 mL/second for obese patients mL/second) and enlarged prostate glands (median prostate volume: 90 ccs for both groups). ASA profile scores did not differ between our patient cohorts, as previously reported in other series [20]. The analysis of post-operative outcomes elicits few comments. To begin with, several studies demonstrate that obesity prolongs ORT and, as a result, perioperative mortality and morbidity increase in an already high-risk patient population [9,10,21]. Hypothetically, increased retropubic and periprostatic fat may alter the structural anatomy of the lower urinary tract posing a

more challenging approach to the surgeon. Contrary to this, Singh et al. found no statistically significant difference in mean ORT and perioperative complications among obese and non-obese patients undergoing radical prostatectomy [22]. Likewise, we did not find a significant difference in our study with both procedures performed within acceptable ORTS (120 min vs. 110 min, p=0.39). The average ORT looks certainly shorter than reported in other series [11,23], probably due to the surgeons' technical maturity at the time of our study.

Our overall complication rate was 9.0%, most of which were low-grade (Clavien 1 - 2), which usually have no major impact on post-operative recovery. Compared with the data reported by Pavan et al., within a CDC rate of 17.7%, our population had few operative complications. There were no grade V complications. Only 1.2% (1/81 patients) of all complications was CDC grade III, corresponding well with the complication rate of 1.1% for CDC grade III reported by Autorino et al. [11]. There were no grade IV -V complications. No significant difference was seen among our patient population.

In addition, PSA levels decreased significantly in both groups, and this report provides indirect evidence of the treatment's success, because RASP allows for complete enucleation of the adenoma, duplicating the established fundamentals of open surgery even in obese individuals.

In terms of length of stay (LOS) this was similar for both groups (median LOS: 3 days) and less when contrasted to the OSP series [24], but considerably longer compared with laser and bipolar energy surgeries [20]. In this regard, LOS might be affected by nonmedical factors based on the healthcare system where treatment is conducted. For instance, RASP series from the USA have recorded significantly shorter LOS (1-2 days) [25]. Consequently, these results can be viewed in different ways. This is likely not true for catheterization time as RASP does not provide the same results as endoscopic procedures [20].

Holmium laser enucleation of the prostate (HOLEP), is less invasive than RASP and suitable for prostates of any size, unlike transurethral resection of the prostate. To date, HOLEP is the only laser treatment endorsed by both the American Urological Association (AUA) and European Association of Urology (EAU) guidelines, as there is level 1 evidence that it provides functional outcomes comparable to those of OSP in men with large prostates. However, a recent retrospective study comparing functional outcomes of RASP vs Holep, showed that Trifecta achievement was significantly higher in the RASP group compared to HOLEP [30].

As with any other surgical technique for BOO/BPE, subjective (IPSS, QoL score) and objective parameters (Qmax, PSA) are valuable proxy metrics for therapeutic efficacy. Gacci et al. depicted an association between obesity, metabolic syndrome, and poor relief of LUTS after OP and TURP [26]. After surgical treatment, incomplete recovery of both total IPSS and storage IPPS was associated with subjects having a waist circumference > 102 cm [26]. In our study, the greater improvement for non-obese individuals in terms of Qmax and lower IPPS, albeit statistically significant, a 2 mL/second difference between groups is not clinically relevant. The same holds true for the better improvement in the IPSS for non-obese individuals since the median postoperative IPPS score for both groups remained within the "low symptoms" score range.

Although there was a statistically significant improvement in terms of quality of life (QoL) in both groups after RASP, a significant difference was found concerning the OABQ score (19 vs. 36 $p<0.01$). In a prospective trial, Sener et al. correlated abdominal obesity with a detrimental effect on QoL mainly due to the persistence of storage symptoms after surgical treatment [27]. McVary et al., in a recent pooled data analysis, evidenced that improvement in storage symptoms has a more positive impact on QoL and urinary bothersomeness compared to voiding symptoms [28]. Moreover, in a systemic review comprising seven RCTs Simon et al. demonstrated that age and BMI were the most significant risk factors for incontinence after prostatectomy regardless of the surgical approach [29]. This correlates with our results, where a higher number of obese patients (5 vs 2 $p<0.01$) required duloxetine after surgical treatment to manage stress incontinence.

Recently, trifecta and pentafecta composite outcomes have been introduced as markers of surgical quality for simple prostatectomy procedures [11]. At multivariable analysis, BMI was not a significant factor predictive of favorable trifecta outcome in Autorino's paper [11]. Whereas, in the

series of Pavan et al., age (p=.03) and BMI p=.03) predicted a favorable outcome [23]. In our study, at comprehensive outcomes assessment, obese patients had comparable trifecta (67% vs. 54%, p=0.39) and pentafecta achievement rate (20% vs. 17%, p=0.76).

Our study is not devoid from limitations. First of all, the retrospective design carries some inherited bias, including possible inaccuracies in data reporting. The analysis was restricted to parameters that were available and of appropriate quality for a reliable assessment. Secondly, only BMI was used to define obesity. In patients with large muscle mass, BMI may not distinguish pure adipose tissue from lean body mass. Thus, other obesity parameters, such as waist circumference or waist-to-hip ratio, were not assessed. Ultimately, how RASP compares to other established endoscopic procedures for BPE remains to be determined. In this respect, still limited evidence exists. In a large-retrospective cohort, holmium enucleation of the prostate had comparable short-term functional outcomes and complication rates among obese and non-obese individuals [20]. This topic certainly warrants further investigation.

5. Conclusions:

Despite the recognized limitations of this analysis, the present findings confirm that RASP offers comparable long-term functional outcomes and perioperative complications among obese and non-obese patients. Ultimately, obese patients should be counseled regarding the risk of post-prostatectomy storage LUTS and urinary incontinence.

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Institutional Review Board Statement: The study is a retrospective analysis, therefore it did not involve human participants and/or animals. The research protocol was approved by the local Research and Institutional Ethics Committee. All procedures contributing to this work comply with the ethical standards of the relevant national and institutional guidelines on human experimentation and with the Helsinki Declaration of 1975, as determined in 2008.

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.

Availability of data and material: The datasets generated during this study are available from the corresponding author on reasonable request.

Conflicts of Interest: The authors declare no conflict of interest.

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