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Transvesical open prostatectomy for benign prostatic hyperplasia in the era of minimally invasive surgery: Perioperative outcomes of a contemporary series

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ABBREVIATIONS

OP, open prostatectomy;
MIS, minimally invasive surgery;
HOLEP, holmium laser enucleation of the prostate

Abstract ***Objective:*** To assess the perioperative morbidity of transvesical open prostatectomy (OP) and its predictors as a treatment for benign prostatic hyperplasia (BPH), and to update knowledge about the morbidity of OP using a standardised morbidity scale (Clavien), thus providing a platform for comparison with the newly developed techniques.

Patients and methods: We retrospectively review men with BPH who were treated with transvesical OP between April 2002 and December 2012. Preoperative patients' data were reviewed for relevant variables. Operative details, the postoperative course, and 30-day relevant data were assessed. The study cohort was stratified based on the resected prostate weight, with group 1 having a resected weight of $\leqslant$120 g and group 2 $>$120 g.

Results: The review identified 163 patients. The mean (SD, range) duration of catheterisation after OP was 7.9 (2.2, 5–20) days and the duration of hospitalisation after OP was 8.1 (1.8, 5–15) days; both were significantly longer in group 2. All patients were able to void spontaneously by the first follow-up visit. Of 163 OP procedures, there were 106 perioperative complications in 69 (42.3%). Low-grade

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complications (grade $\leqslant 2$) included 38 (45.2%) and 53 (67%) in groups 1 and 2, respectively ($P = 0.8$). High-grade complications ($\geqslant 3$) included 3 (3.5%) and 12 (15.1%) in groups 1 and 2, respectively ($P = 0.02$). The blood transfusion rate was 24.5%, the perioperative mortality rate was 1.2% and the re-admission rate within the first 30 days after OP was 1.2%. High-grade complications were significantly associated with a greater resected prostate weight (odds ratio 1.08, 95% CI 1.001–1.17, $P = 0.046$).

Conclusion: The OP procedure is associated with a significant perioperative morbidity that correlated significantly with the resected prostate weight, especially for high-grade complications.

Introduction

The surgical treatment of BPH began in the late 19th century. In 1884, the first complete suprapubic removal of a prostatic adenoma was performed by Eugene Fuller [1]. However, the procedure was associated with a high mortality rate (18%). In 1900, Peter Freyer reported the first prostatectomy with a 5% mortality rate [1]. The operation was deemed successful and carried his name as the standard surgical treatment of BPH for 50 years. In 1951, Hryntschack described the transvesical open prostatectomy (OP), with the principles and steps that are now followed in most urological centres [1]. Then, after the development of TURP, it became the standard method for treating small and moderate-sized prostate for many years. As resecting a large prostate adenoma with TURP is associated with a significant increase in the perioperative morbidity, this limits its role for larger glands [2]. Thus in most of the current guidelines, OP is still an option when the prostate size limits a conventional TURP [3]. Moreover, OP is described as the most effective and durable treatment option [3].

Recently, two factors have affected the trends in the surgical management of BPH. The first is the change in the target population for surgery, after improvements in medical treatment, i.e. older patients are presenting for surgery with more morbidities and larger prostates. The second is the advent of minimally invasive surgery (MIS), where relevant parties are promoting the use of laser prostatectomy, i.e., the media, industry and patients themselves. Even laparoscopy and robotic surgery are starting to be influential in this decision.

The new laser techniques, especially holmium laser enucleation of the prostate (HOLEP), seem to be promising competitors for both approaches, TURP and OP, in treating BPH in men with large glands [4]. Other methods include bipolar TURP and the 532 nm laser (Greenlight™, AMS, Minnetonka, MN, USA).

To assess the surgical outcome standardised validated tools should be used for better reporting and comparison of the outcomes. Despite better reporting of the efficacy outcomes using symptom scores and urinary flow rates, the reporting of negative outcomes in previous different series of OP lacked any use of a standard assessment tool [1].

The work of Dindo et al. [5] in improving the quality of the reporting of negative outcomes from different surgical procedures, through their updated Clavien scale, and with wide acceptance of this scale in the urological community [6] induced us to use this modified scale to report on a contemporary series of OP in a tertiary referral centre. The predictors of the negative outcome events were also analysed.

Patients and methods

We retrospectively review our electronic database for all patients with a diagnosis of BPH who were treated surgically between April 2002 and December 2012. Men who were treated with OP were identified. Patients with previous prostate or urethral surgery, voiding disorders not related to BPH (e.g. neurogenic bladder disorder), and those with a preoperative histological diagnosis of prostate cancer were not included in the analysis. The study cohort was stratified based on the resected prostate weight, with group 1 having a resected weight of $\leqslant 120$ g and group 2 of > 120 g.

Transvesical OP was performed in the standard fashion, as described previously [1] with an initial cystoscopy at the time of OP. The patient was placed supine and the pre-vesical space exposed. A longitudinal incision was made. The bladder cavity was explored and the ureteric orifices identified. The appropriate plane between the adenoma and the prostate capsule was developed and the adenoma gently dissected from the capsule. The dissection was completed using the index finger until only the distal urethra attachment remained; this was finally cut using curved scissors and the adenoma freed. A 22 F three-way urethral catheter was placed transurethrally so that the tip of the catheter and the balloon remained in the bladder. In addition, a 20 F Nelaton suprapubic tube was placed into the dome of the bladder

and secured with a 4–0 chromic purse-string suture. The suprapubic tube exited the bladder through a separate stab incision at the lateral aspect of the dome, avoiding the peritoneal cavity.

Once the urine was clear, the irrigation was stopped and the suprapubic catheter clamped and removed after the urethral catheter and successful voiding on the fifth day. A senior resident assisted by an attending urologist performed most of the cases. Patients were followed after discharge in an outpatient setting for 2–4 weeks after discharge.

Preoperative patient data were reviewed for relevant variables, with operative details, the postoperative course, and 30-day relevant data assessed. Perioperative changes in the blood biochemistry were assessed. The baseline and immediate postoperative laboratory data were reviewed for blood haemoglobin, haematocrit value, blood sodium and serum creatinine levels. The perioperative complications were graded using the Clavien scale (Appendix).

The results are presented as a percentage or mean (SD) and analysed statistically using Fisher's exact test and the chi-square test for categorical variables, and Student's *t*-test for continuous variables. A paired *t*-test was used to compare continuous variables at different sample times of the study. In all test, $P < 0.05$ was considered to indicate statistically significant differences. A multivariate binary regression was analysed, with the potentially confounding variables associated with a negative outcome.

Results

The review process identified 169 patients; only 163 met the inclusion criteria. The baseline criteria of the patients are given in Table 1. There was a significantly higher morbidity index and preoperative needle biopsy rate in group 2 ($P < 0.05$). The perioperative data are also summarised in Table 1. The mean (SD) resected weight of the adenoma was 99.8 (21.4)g. A concomitant cystolithotomy was performed in 41 men (25.1%). There was a significant change in the mean blood haemoglobin level, haematocrit and mean serum creatinine level between the baseline (13.7 g, 40.9% and 1.1 mg/dL, respectively) and immediately after OP (10.9 g, 33.1% and 1.55 mg/dL, respectively; $P = 0.001$, < 0.001 and 0.002, respectively). However, there was no significant difference in both groups for blood haemoglobin or haematocrit deficits (Table 2). Postoperative continuous bladder irrigation for more than one night was indicated in more than half of the men, with no statistically significant difference between the groups. The mean (SD, range) duration of catheterisation after OP was 7.9 (2.2, 5–20) days and the duration of hospitalisation after OP was 8.1 (1.8, 5–15) days, and both were significantly longer in group 2 (Table 1). All patients were able to

Table 1 The baseline and perioperative variables.

Mean (SD) or *n* (%) variable	Group 1	Group 2	*P*
Number	84	79	
Age at surgery (years)	68.2 (6.9)	68.7 (7.1)	0.600
Body mass index (kg/m^2)	28.2 (5.4)	29 (6.3)	0.470
N patients with ASA score $\geqslant 2$	28 (33.3)	41 (51.8)	0.002
Diabetes mellitus, no	39 (46.4)	35 (44.3)	0.480
N patients for each indication			
LUTS refractory to medical therapy	48 (57.1)	39 (49.3)	0.720
Urine retention and failed TOV	25 (29.7)	26 (32.9)	
Haematuria	11 (13.2)	14 (17.8)	
Preoperative:			
PSA level (ng/mL)	12.1 (11.8)	15.2 (11.1)	0.106
TRUS prostate size (mL)	123.2 (39)	167 (62.8)	0.026
Needle biopsy	47 (55.9)	59 (74.6)	0.016
Positive urine culture	27 (36.5)	36 (46.2)	0.250
Haemoglobin deficit (g/dL)	2.7 (1.7)	2.8 (1.4)	0.700
Haematocrit deficit (%)	9.1 (7.6)	8.6 (4.5)	0.830
Resected weight (g)	94.6 (19.3)	146.6 (26.2)	< 0.001
Histopathology of resected tissue			
BPH	64 (76.1)	63 (79.7)	0.800
BPH with prostatitis	17 (20.2)	14 (17.7)	
Prostate cancer	3 (3.7)	2 (2.6)	
Postop continuous irrigation > one night	55 (65.7)	57 (72.1)	0.120
Duration of postop catheterisation (days)	7.8 (2.2)	8.8 (3.2)	0.040
Duration of postop hospitalisation (days)	8.05 (1.7)	8.9 (3.4)	0.038

TOV, trial of voiding; ASA, American Society of Anesthesiologists.

Table 2 The perioperative (first 30 days) complications according to the modified Clavien scale [5].

Grade	Graded complications	Group, *n* (%)			
		1	2	*P*	Management
I	Transient elevation of serum creatinine	7 (8.3)	9 (11.4)	0.60	Monitoring + fluid balance + stop nephrotoxic medications
	Fever	5 (6)	8 (10.1)	0.20	Fomentations + antipyretics
	Subcutaneous haematoma	1 (1.2)	–	0.50	Observation
II	Capsular violation	–	1 (1.3)	0.50	Prolonged catheterisation
	Urethral trauma/catheter-induced injury	–	1 (1.3)	0.50	Prolonged urethral catheterisation
	TUR syndrome	–	–	–	–
	Anaemia necessitating transfusion	16 (19)	24 (30.4)	0.10	Blood transfusion
	Secondary haemorrhage	–	1 (1.3)	0.50	Urethral catheter + antibiotics ± bladder irrigation ± blood transfusion
	Epididymo-orchitis	2 (2.4)	1 (1.3)	1.0	Antibiotics + anti-inflammatory + lead-subacetate foments
	Urine leak/extravasation	5 (6)	3 (3.8)	0.70	Prolonged catheter drainage
	Wound infection	2 (2.4)	5 (6.3)	0.20	Wound care
IIIa	Wound dehiscence	–	2 (2.5)	0.23	Secondary sutures
	Bleeding necessitating cystoscopic haemostasis	–	3 (3.8)	0.05	Cystoscopic haemostasis
	Pelvic collection	–	1 (1.3)	0.48	Percutaneous tube drain
	Migrated ureteric stent	–	1 (1.3)	0.50	Delayed antegrade removal
IIIb	Bleeding necessitating exploration	–	2 (2.5)	0.23	Abdominal exploration and haemostasis ± packing
IVa	Deep vein thrombosis/pulmonary embolism	1 (1.2)	–	1.0	Thrombolytic and anticoagulants therapy
	Acute lower-limb ischaemia	1 (1.2)	–	1.0	Limb revascularisation and embolectomy
	Acute right-sided heart failure	–	2 (2.5)	0.23	Intensive care unit
IVb	–	–	–	–	–
V	Perioperative mortality	1 (1.2)	1 (1.3)	0.80	Massive pulmonary embolism

void spontaneously within 2–4 weeks after OP, at the first follow-up clinic visit.

The perioperative negative events are listed in Table 2, following the modified Clavien scale, with details of their management. Of 163 OP procedures, there were complications in 69 (42.3%), including 106 complications in 69 patients. Low-grade complications (grade $\leqslant 2$) included 38 (45.2%) and 53 (67%) in groups 1 and 2, respectively ($P = 0.8$). The most frequent low-grade complications were perioperative bleeding requiring a blood transfusion, and a transient elevation of the serum creatinine level. High-grade complications (grade $\geqslant 3$) included three (3.5%) and 12 (15.1%) in groups 1 and 2, respectively ($P = 0.02$). Bleeding necessitating active intervention in the perioperative period is the commonest high-grade complication. The perioperative mortality rate was 1.2%, and the re-admission rate within the first 30 days after OP was 1.22%.

Perioperative complications (low and high grades) were significantly associated with a higher preoperative serum creatinine level on a univariate analysis Table 3, which was not statistically significant in a multivariate analysis (odds ratio 4.5, 95% CI 0.904–22.6, $P = 0.066$). On a subgroup analysis, high-grade complications were significantly associated with a greater resected prostate weight (odds ratio 1.08, 95% CI 1.001–1.17, $P = 0.046$). A preoperative estimate on TRUS of the volume of the prostate had no statistical significance as a predictor of perioperative morbid events, neither overall nor for any grade of complication.

The final pathological examination of the resected prostate showed prostatic adenocarcinoma in three and two specimens in groups 1 and 2, respectively ($P = 0.8$). A watchful-waiting strategy was adopted in three patients with prostate cancer, and delayed hormonal therapy was offered to the others. The pathological findings are also shown in Table 1.

Discussion

The introduction of new surgical techniques is often confronted by the need to challenge more easily and clearly accessible procedures. Recently, laser prostate surgery, a newly introduced alternative to OP, is challenged as being superfluous in developing countries [7]. What is really needed is a comparison of procedure outcomes based on standardised measures, where a comparison of graded outcomes could help in defining the new standard of care. Here we report on the perioperative morbidity of OP in a contemporary series, using standardised tools for reporting. In the current patients, the commonest grade 1 complication was transient ele-

Table 3 Possible variables influencing the complications: univariate analysis.

Mean (SD) Perioperative or *n* (%) variable	No Complications	Complications	*P*
No. of patients	94	69	
Age at surgery (years)	67.3 (6.1)	69.9 (7.8)	0.019
Body mass index (kg/m^2)	28.7 (5.4)	28.6 (5.8)	0.920
Indications (indwelling catheter)	30 (31.9)	21 (30.4)	0.770
Morbidity index (ASA $\geqslant$ 2)	34 (36.1)	35 (50.7)	0.129
Diabetes mellitus, No	39 (41.4)	35 (50.7)	0.080
Preoperative:			
Positive urine culture	38 (40.4)	25 (36.2)	0.618
Haemoglobin level (g/dL)	13.8 (1.7)	13.6 (1.6)	0.560
Serum creatinine level (mg/dL)	1.03 (0.25)	1.21 (0.43)	0.003
PSA level (ng/mL)	13.3 (11.2)	14.03 (12)	0.740
TRUS volume of prostate (mL)	151.6 (61)	148 (56)	0.860
Preoperative prostate needle biopsy, No	56 (59.5)	50 (72.4)	0.165
Volume of the attending urologist (high), No	19 (20.2)	12 (17.3)	0.690
Weight of resected prostate adenoma (g)	118.9 (32)	121 (38)	0.700
Pathology findings of the resected tissue			
BPH	76 (80.8)	53 (76.8)	0.680
BPH + prostatitis	16 (17)	13 (18.8)	
Prostate cancer	2 (2.2)	3 (4.4)	

ASA, American Society of Anesthesiologists.

vation of the serum creatinine level (10%). As shown in Table 2, the spontaneous normalisation of serum creatinine level with no need for proximal renal drainage was the usual course of this event. Trigonal oedema is a possible explanation. In this cohort, one of the four patients undergoing OP required a blood transfusion, perioperative blood loss being the commonest low-grade (grade $\leqslant$ 2) complication. Re-intervention (endoscopic or open) under regional or general anaesthesia to control postoperative bleeding was the commonest high-grade complication (Table 2).

Table 4 summarises the perioperative outcomes for different reports of transvesical OP [8–16]. It is apparent that the standardised reporting of the morbidity of OP is lacking. Millin's retropubic prostatectomy is another option and it is the operation which was associated with a relative reduction in the morbidity of OP since its introduction in 1946. However, it remains limited in the presence of associating vesical stones, a narrow pelvic cavity and a large median lobe with significant intravesical protrusion [1]. Furthermore, it is also associated with significant perioperative morbidity (43.2%) and mortality (1.7%) [17].

The new competitors to OP are transurethral enucleation techniques, laparoscopic simple prostatectomy and robotic-assisted simple prostatectomy. The data support HOLEP, in contrast to the other techniques, to challenge and even replace OP. In a large series of HOLEP, the perioperative complication rate was 2.3% [18], with a transfusion rate of 0.5%, a mean hospital stay of 31.6–32 h and a mean catheter duration of 19.1–33.6 h [18].

In a multicentre feasibility study for robotic-assisted simple prostatectomy, a 7.6% complication rate and zero transfusion rate were reported, but the authors did not use a standardised reporting system for the neg-

Table 4 Perioperative outcome (first 30 days) in different series of OP.

Variable	Study									
	Present	[15]	[14]	[8]	[9]	[16]	[12]	[10]	[11]	[13]
No. of patients	163	70	34	201	151	60	1602	32	200	249
Mean (SD):resected weight (g)	99.8 (21)	115.4	116.8 (33)	63.5	nr	96.4 (36)	nr	63 (39)	nr	61
Complications (%)	42.3	30	23.5	21.8	12.7	33.3	36.9	15.6	14	19.6
Low-grade (%)	85.4	nr	nr	nr	nr	nr	nr	nr	nr	nr
High-grade (%)	14.6	nr	nr	nr	nr	nr	nr	nr	nr	nr
Blood transfusion (%)	24.5	8.6	11.7	18.9	6.8	13.3	8.2	100*	1	4.6
Mortality (%)	1.2	–	0	nr	0	0	0.055	0	1	nr
Mean (SD) (days):										
Hospital stay	8.1 (1.8)	6.9	9.2 (3.4)	11.5 (5)	6 (0.9)	10.4 (1.89)	6.9	6.2 (2.1)	6.2	9
Catheter duration	7.9 (2.2)	5.8	7.5 (1.6)	6.4 (3)	5 (0.9)	8.1 (0.83)	5.5	5.4 (2.6)	nr	nr

* Autologous; nr, not recorded.

ative events. The mean catheter duration was 8.8 days and the mean hospital stay was 2.7 days [19]. Another report on the 'single port transvesical enucleation prostatectomy' showed an 11% conversion rate to OP, a low-grade complication rate of 22%, a transfusion rate of 12.5%, with a mean duration of catheterisation of 8.6 days and a hospital stay of 7 days [20].

Despite the relatively high perioperative morbidity rate of transvesical OP, it remains the treatment that provides the most durable functional outcome [3]. The exceptionally long hospital stay of the present patients adds significantly to the cost of the procedure. Recently, after the world economic crisis, healthcare resources are limited and all national health systems have been forced to reconsider an allocation of resources, with an inevitable trend towards reducing the number of inpatient beds, increasing day-case surgery and lowering treatment costs, thus favouring alternative surgical techniques.

Despite many new publications on laser prostate surgery there are few up-to-date reports on the widely practised OP in developing countries.

Standardisation of the classification of complications for an intervention is necessary to allow a valid comparison among different institutes, within an institute over time, or among operators. Also, this allows a fair comparison of newly developed surgical techniques to the standard ones. Moreover, it allows better weighting of the influence of different risk factors on the outcome of a procedure. Since the introduction of the modified Clavien system, there is a growing body of knowledge, with standard reporting of different urological procedures [6]. Ou et al. [14], in their randomised controlled trial comparing transvesical OP with TURP, reported a higher perioperative safety profile for transvesical OP than for TURP for the patient with BPH whose prostate volume was >80 mL.

We did not use the preoperative TRUS-estimated prostate size as a differentiating factor, as this was done at different times, with more than one ultrasonographer performing TRUS, so we adopted a more objective method by using the resected adenoma weight. A threshold of 120 g resection weight was chosen, based on the agreement of most guidelines that beyond this limit of prostate size, unless HOLEP is available, OP should be used. According to the available evidence, other new MIS techniques could be used to treat a prostate of 80–120 g [3], and thus we used this stratification to offer a platform for comparing different limits to OP.

The main limitation of this work was that it is retrospective, where subjective symptom scores and objective functional outcome variables were not reported. However, in a large contemporary cohort of patients, standardised reporting of the perioperative outcome would significantly affect the reporting of results for the newly developed techniques. This study offers a recent basis for further comparison and reporting of all surgical treatment alternatives for BPH. We have recently introduced HOLEP to our institute, with the expectation that it might replace OP, with an expected cost saving based on reduced perioperative morbidity and hospital stay. The present report would enhance the ability to assess all these new alternatives.

In conclusion, we validated the use of the modified Clavien scale for assessing the morbidity of transvesical OP. OP is associated with significant perioperative morbidity that correlates significantly with resected prostate weight, especially for high-grade complications. We suggest that it would be valid to assess graded outcomes when assessing new less-invasive tools for treating large prostates, particularly when comparing these tools to the standard procedures. Furthermore, the preoperative TRUS-estimated prostate size is not as accurate as resected prostate weight in predicting the outcome of prostatic resection procedures.

Conflict of interest

None.

Source of funding

None.

Appendix A.

The classification of surgical complications according to the Modified Clavien system [5].

Grade	Definition
Grade I	Any deviation from the normal postoperative course with no need for pharmacological treatment or surgical, endoscopic, and radiological interventions
Grade II	Complications requiring pharmacological treatment. Blood transfusions and total parenteral nutrition are also included
Grade III	Complications requiring surgical, endoscopic, or radiological intervention
Grade IIIa	Intervention not under general anaesthesia
Grade IIIb	Intervention under general anaesthesia
Grade IV	Life-threatening complications requiring intensive care unit stay
Grade IVa	Single organ dysfunction (including dialysis)
Grade IVb	Multi-organ dysfunction
Grade V	Death of the patient
Suffix (d) ('disability')	The patient has a complication at the time of discharge; suffix (d) is added to the respective grade of complication

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