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ORIGINAL ARTICLE

Multicenter international experience of 532 nm-laser photovaporization with Greenlight XPS in men with large prostates (prostate volume > 100 cc)

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Abstract
Purpose To evaluate the outcomes and durability of photoselective vaporization of the prostate (PVP) using the XPS-180 system in patients with a large prostate volume (PV) > 100 cc at 4 years of follow-up in a large, multicenter experience.
Methods 438 men with pre-operative transrectal ultrasound (TRUS) PV > 100 cc were treated in eight experienced centers in Canada, USA, and in France with the Greenlight XPS laser using PVP for the treatment of symptomatic BPH. IPSS, Qmax, postvoid residual (PVR), and prostate-specific antigen (PSA) were measured at 6, 12, 24, 36, and 48 months. Durability was evaluated using BPH retreatment rate at 12, 24, and 36 months.
Results Median PV and PSA were 121 cc and 6.3 ng/dl. Indwelling catheter at the time of surgery was observed in 37% of men. Median operative, laser time, and energy applied were 90 min, 55 min, and 422 kJ, respectively. Median energy delivery was 3.4 kJ/cc of prostate per case. Outpatient surgery was feasible with median length of stay at 24 h. IPSS, Qmax and PVR were significantly improved at all endpoints including at 48 months. Moreover, surgical BPH retreatment rates were 5.4 and 9.3% at 24 and 36 months. Interestingly, characteristics of retreated men include: energy delivery 2.4 vs. 3.4 kJ/cc of prostate ($p = 0.02$) and PSA reduction at 12 months 26 vs. 51% ($p = 0.02$).
Conclusions PVP using Greenlight XPS-180W can potentially provide durable improvements with regard to functional outcomes at 4 years. However, rising retreatment rates after 3 years is of concern. This highlights the imperative need of utilizing a standardized surgical technique (enucleation-like-defect) and an optimal energy density >3KJ/cc.

Keywords Photoselective vaporization of the prostate · XPS · Greenlight · Large prostate · >100 cc · Benign prostate hyperplasia

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Introduction

Endoscopic management of large prostate volumes (PV) > 80–100 cc remains a clinical scenario with limited available treatment options. According to European association of urology (EAU) and American association of urology (AUA) guidelines, other than open retropubic prostatectomy, Holmium laser enucleation of the prostate (HoLEP) is the preferred treatment options in patients with

large prostates [1, 2]. HoLEP has been well established as size-independent procedure with durable long-term results compared to open prostatectomy [3]. Unfortunately, due to a difficult learning curve, access to additional surgical materials, and use of intra-vesicle morcellation, the penetration of HoLEP in the urological community over the past two decades has been limited [4].

In the pursuit of other endoscopic, minimally invasive laser technologies, increasing evidence has emerged regarding the efficacy and safety of Greenlight photoselective vaporization (PVP) as a feasible option in patients with larger prostate volume by surgeon with expertise [5–7]. Unfortunately, robust, long-term data to support Greenlight PVP as a primary treatment for men with large gland volume are lacking. Furthermore, an increased risk of retreatment is of concern.

Based on these considerations, the purpose of this study was to examine the mid-term outcomes of Greenlight PVP in patients with a PV > 100 cc in a large multiinstitutional cohort. Particularly, durability and potential factors associated with higher retreatment rate were analyzed.

Materials and methods

Patient population

We conducted a multiinstitutional, retrospective study of prospectively collected data for patients treated with Greenlight laser PVP for benign prostate hyperplasia (BPH) using the XPS-180W system. Treatment indications were in accordance with the American, Canadian, and European clinical practice guidelines [1, 2, 8]. Surgeries were performed at eight sites in three different countries: Canada (University of Montreal Health center, University of Toronto), United States (Colombia, Cornell and Hackensack), and France (Toulouse, Tours and Brest) between years 2010 and 2015. Only patients with a PV > 100 cc identified on pre-operative transrectal ultrasound (TRUS) were included in the study. Patients with a prostate cancer diagnosis were excluded from the analyses ($n = 10$). Similarly, patients with missing pre-operative characteristics were also excluded. Institutional review board approval was obtained.

Surgical procedure

All patients underwent PVP performed as previously described using the XPS-180W system [9–12]. The procedures were performed according to published International Greenlight use (IGLU) guidelines and incorporated surgeon's own technique and experience [13]. All procedures were performed under general or spinal anesthesia. Pre-operative antibiotic prophylaxis was administered to all patients, according to local practice guidelines. All surgeons utilized the three lobes approach for PVP. In short, the vaporisation procedure starts with the creation of a working space with 80-W power at 5 and 7 o'clock. The reminder of the prostate was vaporised in circumferential manner with respect to the following anatomic landmarks: prostate capsule, bladder neck, and verumontanum, using a maximum power of 180 W, adjustable in 10–20 W steps with the XPS system. For coagulation, the TruCoag feature pulse modulated at 12 Hz and 5–40 W was used. A 23F continuous-flow cystoscope was used. The MoXy fibers were utilized with the XPS system and irrigated with cooled or room temperature saline irrigation.

Variables

Pre-operative variables were collected. Age was coded as a continuous variable. Medical history was abstracted from patients' charts. It included comorbidity score stratified according to the American society of anesthesiology (ASA), antiplatelet medication, as well as anticoagulant medication. The previous BPH medical and surgical history was also abstracted from the data: history of the previous TURP, history of catheterization/retention, and use of BPH medications (alpha-blocker and inhibitors of 5-alpha reductase).

Pre-operative symptoms index score [international prostate symptoms score (IPSS)], uroflowmetry [Qmax and post-voiding residual (PVR)] parameters, as well as prostate-specific antigen level (PSA: ng/dl) were also included and coded as continuous variables.

Finally, operative characteristics were also collected. This included total operative time, lasing time, energy use (kJ), number of fibers, and energy density delivery (kJ/cc). The latter was calculated by dividing energy use per prostate volume as measured by pre-operative TRUS [14].

Outcomes

Patients were followed post-operatively at 6, 12, 24, 36, and 48 months. During follow-up visit, symptoms score (IPSS), uroflowmetry (Qmax and PVR) parameters, and PSA level were recorded. In addition, PSA decrease was calculated by subtracting pre-operative PSA by PSA at specific follow-up. Follow-up was calculated as time from surgery to last visit.

Peri-operative and post-operative complications were also prospectively recorded. Peri-operative complications included complications that happened intra-operatively and during hospitalization: bleeding, capsular perforation, conversion to monopolar TURP, failure to remove catheter, and hospital stay. Post-operative complications included

complications after hospital discharge. It was recorded between discharge and 6 months after surgery. All complications were graded according to the Clavien-Dindo classification [15]. Finally, retreatment rate was also evaluated at 12, 24, 36, and 48 months following PVP surgery.

Statistical analyses

Descriptive statistics focused on frequencies and proportions for categorical variables. Means, medians, and interquartile ranges were reported for continuous variables. In addition, post-operative outcomes were stratified according to energy use using a previously defined cutoff. The Mann–Whitney test and Chi-square test were used to compare statistical significance of differences in medians and proportions, respectively. All statistical tests were performed using R software environment for statistical computing and graphics (Vienna, Austria, version 3.0.1). All tests were two-sided with a significance level set at $p < 0.05$.

Results

Baseline characteristics

Descriptive statistic of patients demographic is summarized in Table 1. Overall, 438 patients were treated with Greenlight 180 W XPS PVP for BPH. The median follow-up was 24 months (range 1–60 months). The mean and median TRUS PV were 135 and 121 cc, respectively (range 100–300 cc). Median age at surgery was 72 years (range 50–96). The majority of men had low comorbidity score (ASA I–II 66%) and did not use aspirin (71%), antiplatelet (91%), or anticoagulant therapy (88%). Regarding BPH history, alpha-blockers and 5 alpha reductase inhibitors were used in 83 and 46% of patients, respectively. The previous TURP was performed in 8% of patients and 37% had an indwelling urinary catheter at the time of surgery.

Peri-operative characteristics are described in Table 2. The median lasing time was 55 min with a median total energy of 422 kJ. This was corresponding to median Energy/PV ratio of 3.4 KJ/cc energy density. The majority of cases (61%) used only 1 MoXy fiber per case.

Efficacy

Following PVP, IPSS was significantly decreased compared baseline at all follow-up endpoints including at 48 months after surgery (Fig. 1a). Similarly, uroflowmetry parameters (Qmax and PVR) were also significantly improved after surgery at all endpoints (All $p < 0.001$; Fig. 1b, c). PSA significantly decreased after surgery compared to baseline at

Table 1 Descriptive characteristics of 438 patients treated with XPS Greenlight for larger prostate (prostate volume > 100 g)

Variables	*n* (%)
Age	
Mean (median)	72 (72)
IQR	65–78
ASA score	
I	83 (19)
II	207 (47)
III–IV	132 (30)
Unknown	16 (4)
Aspirin use	
No	310 (71)
Yes	128 (29)
Antiplatelet use	
No	400 (91)
Yes	38 (9)
Anticoagulant use	
No	385 (88)
Yes	53 (12)
5-ARI use	
No	238 (54)
Yes	200 (46)
Alpha-blockers use	
No	76 (17)
Yes	362 (83)
Previous TURP	
No	405 (92)
Yes	33 (8)
Indwelling catheter	
No	222 (51)
Yes	163 (37)
Unknown	53 (12)
TRUS prostate volume, cc	
Mean (median)	135 (121)
IQR	107–150
PSA, ng/mL	
Mean (median)	9.5 (6.4)
IQR	4–10.7
IPSS	
Mean (median)	23 (23)
IQR	17–29
Qmax	
Mean (median)	7 (6)
IQR	4–9
PVR	
Mean (median)	260 (160)
IQR	70–380

IQR interquartile range, *ASA* American society of anesthesiology, *5-ARI* 5 alpha reductase inhibitors, *TURP* transurethral resection of the prostate, *TRUS* transrectal ultrasound, *PSA* prostate-specific antigen, *IPSS* international prostate symptom index, *PVR* postvoid residual

Table 2 Operative characteristics of 438 patients treated with XPS Greenlight for larger prostate (prostate volume > 100 g)

Variables	*n* (%)
Lasing time	
Mean (median)	60 (55)
IQR	40–74
Operative time	
Mean (median)	98 (90)
IQR	69–120
Energy use (KJ)	
Mean (median)	467 (422)
IQR	321–572
Number of fibers	
1	268 (61)
2	132 (31)
3+	38 (9)
Energy density (KJ/cc)	
Mean (median)	3.5 (3.4)
IQR	2.5–4.4
Energy density (KJ/cc)	
≤3	177 (40)
>3	261 (60)
Hospital stay (h)	
Mean (median)	38 (24)
IQR	24–48
Catheterization time (h)	
Mean (median)	36 (24)
IQR	24–48

IQR interquartile range, *KJ* Kilo Joules

all endpoints including 48 months (overall PSA decrease was 49% at 6 months; Fig. 1d).

Adverse events

Intra-operative complications were observed in 9.3% of men at PVP (Table 3). Conversion to standard TURP was noted in 6.5% of cases, related to bleeding and capsular perforation in 3.5 and 3%, respectively. While the median length of stay and catheterization time was 24 h (for both). 10% of patients failed the first void trial after surgery, which were a majority (66%) of men with indwelling catheter.

For post-operative complications, the overall complications rate at 0–6 months was 34.1% (Table 3). The majority of adverse events were Clavien-Dindo grade I (22%). Complications requiring intervention under regional or general anesthesia (Clavien-Dindo III) were recorded in 3.9% of patients.

More specifically, hematuria and irritative symptoms were the most common Clavien-Dindo grade I/II complications, while stricture was the most common Clavien-Dindo grade III. With regard to the severe adverse events, one patient developed decompensated heart failure 4 weeks following PVP and died thereafter from this pre-existing cardiac complication (Clavien IV).

Retreatment

The retreatment rates per year were less than 1, 5.4, 9.3, and 2.4% between 0–12, 12–24, 24–36, and 48 months, respectively (Fig. 2). The baseline and operative characteristics of men retreated patients are summarized in Table 4. Retreated patients were more likely to have larger PV (median 150 vs. 120 cc; $p = 0.002$), treated with less energy density (median 2.4 vs. 3.4 KJ/cc; $p = 0.02$) and experienced a lower PSA reduction at 6 months post PVP (median 35 vs. 55%; $p = 0.01$).

Discussion

In the current unique study, only men with PV > 100 cc were included, with a median PV among 438 patients of 120 cc. Not surprisingly, such challenging cases in experienced surgeon hands required longer operative time [median operative time of 90 min (range 35–220 min)] and energy usage. Similarly, the number of fiber per case was higher than usual with 40% of cases used more than two MoXy fibers (range from 2 to 7) [5]. Nevertheless, intra-operative complications were rather low and acceptable with capsular perforation rate of 3% and conversion to TURP seen in 6.5% of cases, respectively. In terms of complications between 0 and 6 months, they were similar to the previously published literature including the GOLIATH study in which patients had mean prostate volume ≈50 cc (48.6 cc) with exclusion of patients with TRUS PV > 100 cc, urinary retention, anticoagulation, or those with the previous TURP [16, 17]. Similarly, hospital stay and catherization time were not increased and equivalent to the previous report [18]. Safety and complications are also consistent with other reported XPS Greenlight series that appear to be size-independent [18].

Urinary symptoms (IPSS, QoL) and uroflow parameters (Qmax, PVR) were all significantly improved compared to baseline and this including at 4 year follow-up. These data show the potential of PVP to successfully treat patients with large glands with a durable outcome. However, non-statistically significant changes towards deterioration were observed between 3 and 4 years after surgery: slight IPPS increase and Qmax decrease. Similarly, serum PSA also follows this trend with incremental rise between years 3 and 4. Conversely, retreatment rate, which remained low after 1 year (<1%), increased to 5.4% at 2 years and

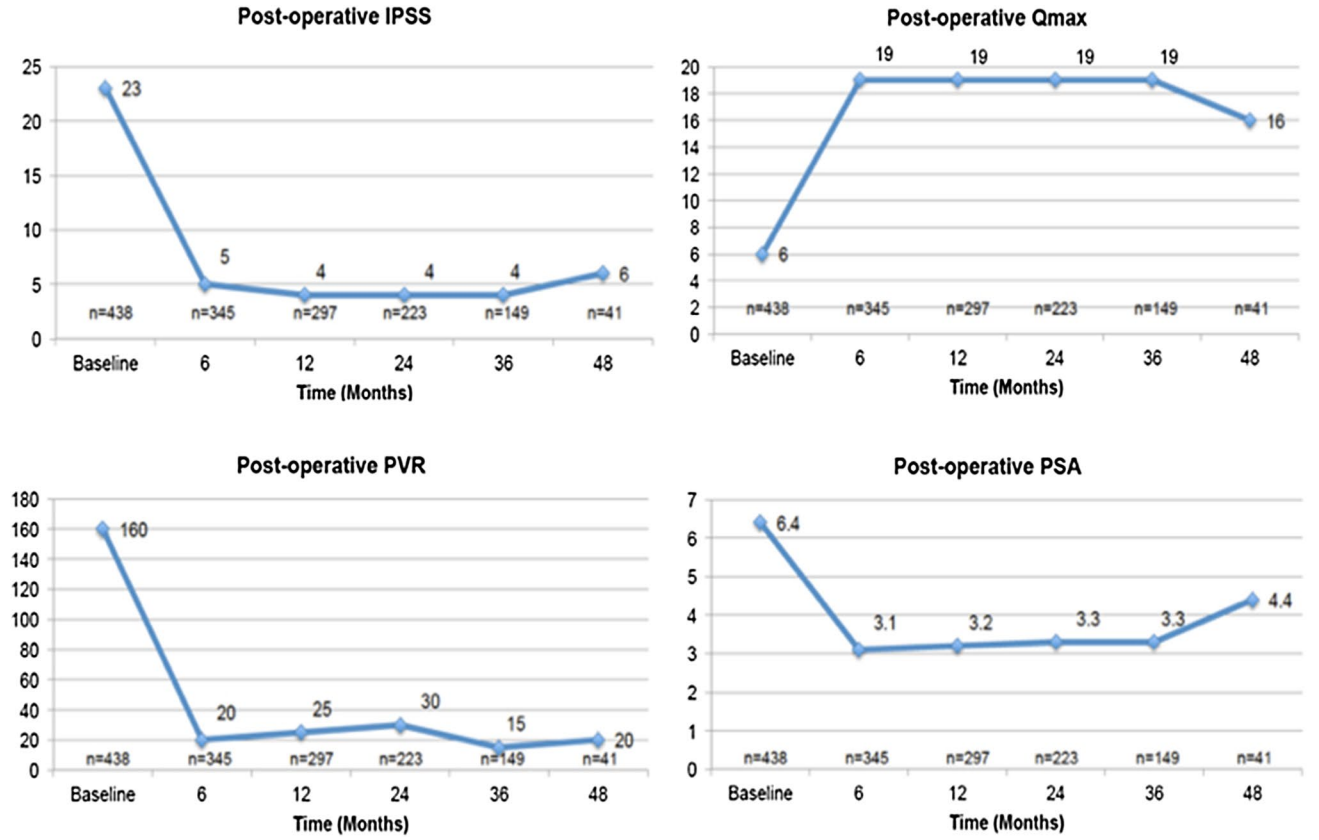

Fig. 1 Post-operative outcomes of patients with large prostate (>100 cc) treated with GreenLight XPS 180 system for symptomatic benign prostate hyperplasia, **a** International prostate symptom score (IPSS), **b** Qmax, **c** postvoid residual (PVR), **d** prostate-specific antigen (PSA) level

leaped to 9.3% at 3 years. Moreover, these retreatment rates could be higher if patient with lost of follow-up were considered. Retreatment procedures generally include PVP for recurring LUTS due to adenoma (residual or regrowth) and open prostatectomy for 3 cases of retention with catherization. Patients retreated had a median TRUS of 150 cc (100–252) and were treated with a reduced median energy density of 2.4 kJ/cc. Similarly, in a previous study, retreatment rate was 0.9% (4/462) at 12 months and 1.2% (5/411) at 24 months and retreated case was likely to be caused by undertreatment [5]. Ideally, in smaller prostate (<100 cc), a 5 KJ/cc energy delivery is required to achieve an 80% PSA reduction at 2 years. However, achieving this energy level (5 KJ/cc) in larger prostate could be time- and fiber-consuming. Although, the optimal energy density use in prostate larger than 100 cc is not known, a 3-4kJ/cc cutoff has been proposed as minimum threshold to achieve complete adenoma vaporization in most of the cases [14].

In addition, retreatment rates were higher than those recorded after HoLEP where retreatment ranged between 2.7 and 5% [3, 19]. The previous reports have suggested that the amount of tissue removed during PVP is significantly less than that removed during a HoLEP [20]. Objective measurements of prostate volume change were not performed in the current study. However, serum PSA decline and nadir were statistically different in the retreated patient. This difference in PSA decrease likely reflects the lesser adenoma removal that underlies the risk of a higher rate of treatment failure in the long term. PSA decrease of a minimum of 50% should be observed at 6 months [21, 22].

The precise amount of tissue necessary to be removed to alleviate patients with durable improvements is unknown; Enucleation or creation of enucleation-like defect may certainly be the ideal surgical goal. The latter could be measured by an 80% PSA reduction at 6 month follow-up [23]. However, achieving this by PVP (within our cohort PSA, reduction was 50% at 6 months) can be time-consuming with large prostate and requires both patience and expertise. Thus, residual adenoma after PVP could result in patient with large prostate and could explain the increased retreatment rates compared to HoLEP. In consequence, PVP is not a size-independent procedure in contrast to HoLEP where treatment efficiency increases with prostate size [3]. Alternatively, 532 nm Green Laser enucleation of the prostate

Table 3 Peri-operative and post-operative complications of patients treated with XPS Greenlight for larger prostate (prostate volume > 100 g)

Outcomes	*n* (%)
Peri-operative complications	
Intra-operative complications	37 (9.3)
Bleeding	14 (3.5)
Capsular perforation	12 (3)
Conversion to standard TURP	26 (6.5)
First voiding trial failure	44 (10%)
Post-operative complications (0–6 months)	
Clavien-Dindo grade I	
Hematuria	33 (8.6)
Irritative symptoms	42 (10.9)
Urinary incontinence	16 (4.2)
Urinary retention	6 (1.6)
Others	4 (1)
Total	84 (22)
Clavien-Dindo grade II	
Hematuria	19 (4.9)
UTI	11 (2.8)
Irritative symptoms	8 (2)
Stricture	4 (1)
Urinary incontinence	3 (0.8)
Urinary retention	11 (2.9)
Others	4 (1)
Total	49 (12.8)
Clavien-Dindo grade III–IV	
Hematuria	3 (0.8)
Stricture	8 (2)
Urinary retention	1 (0.3)
Others (ACS)	4 (1)
Total	16 (4.2)
Total overall grades	131 (34.1)

ACS acute coronary syndrome

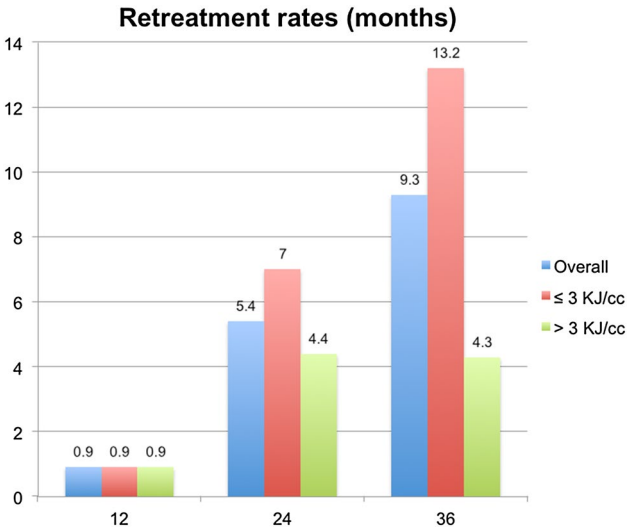

Fig. 2 Retreatment rates at 12, 24, and 36 months following photoselective vaporization of the prostate using GreenLight XPS 180 system stratified according to energy delivery (≤3 Kj/cc vs. >3 KJ/cc)

Table 4 Characteristics of retreated patients compared to their counterparts

Characteristics	Retreated (*n* = 22)	Non-retreated (*n* = 163)	*p* value
Age			0.7
Mean (median)	73 (73)	72 (72)	
TRUS prostate volume, cc			0.002
Mean (median)	147 (150)	135 (120)	
Retention with catheter, *n* (%)			0.8
No	13 (59%)	102 (63%)	
Yes	9 (41%)	61 (37%)	
Baseline PSA (ng/dl)			0.2
Mean (median)	7.2 (6.6)	9.9 (6.3)	
Energy delivery, KJ/cc			0.02
Mean (median)	2.8 (2.4)	3.6 (3.4)	
% of PSA decrease at 6 months			0.01
Mean (median)	35 (35)	54 (55)	
% of PSA decrease at 12 months			0.02
Mean (median)	17.5 (26)	51.3 (51)	

TRUS transrectal ultrasound, *PSA* prostate-specific antigen, *KJ* Kilo Joules

(GreenLEP) technique may be used, but the benefits in terms of learning curve compared to HoLEP remain to be determined [11].

Cost analysis was not performed in this study. Hospital stay and catherization were short and similar to those reported in studies with smaller prostate [16, 18]. However, the cost of additional fiber often required in patients with large gland (40% of patients in our series) has to be taken into consideration.

Limitations of this study include its retrospective nature and the lost of follow-up. Heterogeneity between centers in terms surgeon's techniques and assiduity of follow-up are inherent bias but may be also reflective of real clinical practice.

Conclusions

Greenlight PVP using the XPS-180W is safe and effective in treating patients with prostate >100 cc in the hands of an experienced surgeon. It can potentially provide durable

symptoms improvements at 4 years if treated with sufficient energy density (3-4kJ/cc) and adequate adenoma removal reflected by PSA decrease of at least 50% at 6 months. However, rising retreatment rates after 3 years is of concern. In consequence, PVP in patients with large gland requires expertise and diligence to ensure durable outcomes.

Compliance with ethical standards

Ethical standards The current study involved human participants and were in accordance with institutional and national ethical standards.

Conflict of interest The authors declare that they have no conflict of interest.

Informed consent All participants have given written consent before inclusion in this study.

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