



# Global Greenlight Group: largest international Greenlight experience for benign prostatic hyperplasia to assess efficacy and safety

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## Abstract

**Introduction** Greenlight photo-selective vaporization of the prostate (GL-PVP) has gained international acceptance as a safe and effective alternative procedure for the treatment of benign prostatic hyperplasia (BPH), especially in anticoagulated men. This descriptive analysis aims to characterize the current state of GL-PVP, pooling data from international centers.

**Methods** Data from 3627 patients who underwent GL-PVP with the XPS-180 W system in seven international centers performed by eight expert surgeons between 2011 and 2019 were retrospectively analyzed. Demographic, perioperative, and postoperative data were collected, including IPSS, QoL, Qmax, PVR, and PSA, and complications.

**Results** At baseline, median age, prostate volume, PSA, and IPSS were 70 years (interquartile range 64–77), 64 (47–90), 3.1 ng/mL (1.8–6), and 22 (19–27), respectively. Median lasing and operative time were 34 (23–48) and 62 min (46–85), respectively. Median energy use was 250.0 kJ (168.4–367.9), with 92.6% of procedures being completed with one laser fiber. In 60.1% of cases, catheter was removed on postoperative day 1 with median length of 2 days. All-cause mortality within 30 days was 0.3%. Median PSA reduction at 3 months and 60 months compared to baseline was 43.9 and 46.4%, respectively ( $p < 0.001$ ). All functional outcomes (IPSS, QoL, Qmax, and PVR) were significantly improved across study period when compared to baseline ( $p < 0.001$ ). For those men with longer follow-up available, the observed surgical BPH retreatment rate was 1.5%

**Conclusion** Using the largest multi-user, international database of GL-PVP, Greenlight XPS laser treatment in experienced hands is a safe, effective, and durable BPH treatment option.

**Keywords** BPH · BPE · Prostate · Photovaporization · Greenlight PVP

## Introduction

Lower urinary tract symptoms (LUTS) are common in the aging population of men and are often a result of benign prostatic hyperplasia (BPH) [1]. In cases where medical management fails to adequately address LUTS or urinary retention caused by BPH, surgical intervention is recommended. Transurethral resection of the prostate (TURP) remains the surgical standard in prostates between 30 and 80 cc [2] given its established success rate and global availability. However, TURP has been associated with noticeable morbidity such

as bleeding [3]. Consequently, efforts have been made to develop technologies with superior hemostatic properties.

Greenlight photo-selective vaporization of the prostate (GL-PVP) is an established alternative to TURP and has demonstrated that it is a safe option in men requiring anti-coagulation therapy. In addition, current EAU guidelines provide a strong recommendation for PVP as a safe alternative for TURP in prostate volumes between 30 and 80 cc [1].

To ascertain the global state of GL-PVP in the wide array of available BPH surgical modalities, the Global Greenlight Group (GGG) database was created through the collaboration of eight experienced surgeons in seven international centers within North America, South America, and Europe. The aim was to provide a well-represented real-world characterization of the safety and effectiveness of GL-PVP.

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Herein, through retrospective review of a pooled international database, we provide a descriptive analysis of preoperative, perioperative data, surgical complications, and functional outcomes found within the GGG database.

## Methods

### Study population

Between February 2011 and October 2019, men with LUTS secondary to BPH underwent GL-PVP with the XPS-180 W laser system, performed by one of eight high-volume surgeons at seven international centers in Canada, France, Germany, Italy, Mexico, Brazil, and Argentina. Patients with history of prostate cancer ( $n=24$ ), previous TURP ( $n=158$ ), pelvic radiation ( $n=4$ ), or neurological disorders ( $n=2$ ) were excluded from the study. After institutional board review approvals, 3627 men were included for analysis. Indications for surgery in respective countries were based on guidelines established by the CUA, AUA, and EAU on BPH management [1, 2, 4]. Given the retrospective nature of this patient database, a shared protocol for prostate cancer screening was not applicable. However, all men were evaluated and appropriately counseled according to national protocols.

### Surgical procedure

All patients underwent GL-PVP using the XPS-180 W system and MoXy laser fiber. Procedures were performed in accordance to published International Greenlight User guidelines, [5] incorporating personalized experience by the operating surgeon [6]. Procedures were performed under general or spinal anesthesia. Prophylactic antibiotic treatment and antithrombotic therapy was administered according to local guidelines.

### Study parameters

Age at surgery, American Society of Anesthesiologists score (ASA), and use of BPH or antithrombotic medication was collected. Preoperatively, patients completed the International Prostate Symptom Score (IPSS) and quality of life (QoL) questionnaire and underwent uroflowmetry and post-void residual measurements (PVR). Baseline PSA levels were established, preoperative prostate size was estimated through transrectal ultrasound (TRUS). Operative time, hospital length of stay (LOS), duration of catheterization, and Clavien–Dindo complications were collected. IPSS, QoL, Qmax, PVR, and PSA were collected at 3, 6, 12, 24, 36, 48, and 60 months, according to local surgeon/clinic preferences.

## Statistical analyses

Data were analyzed with SPSS, version 23 (Chicago, Illinois, USA). Descriptive statistics are presented as percent, mean, and median. Normally distributed data are presented as mean (SD), non-normally distributed data are presented as a median (IQR), and categorical data are presented as proportions. The Kruskal–Wallis test was used to compare median PSA, IPSS, QoL, Qmax, and PVR at all follow-up time points. Pairwise comparison was completed using the Dunn–Bonferroni approach. In exploratory analyses, we examined the effect of age on postoperative incontinence adjusting for baseline IPSS using a multivariable logistic regression model. A  $p$  value less than 0.05 was considered statistically significant.

## Results

### Baseline demographics, Supplemental Table 1

A total of 3627 men underwent GL-PVP of the prostate with the XPS-180 W system. Median age was 70 years (64–77). Median preoperative prostate volume was 64 cc (IQR 47–90), with 38% of prostates presenting with a median lobe. Preoperatively, 35.5 and 78.0% of patients were using 5-ARIs and alpha-blockers. 34.3% of patients were receiving antithrombotic therapy other than aspirin. 28.5% of patients had an ASA score of 3 or higher. Median preoperative PSA levels were 3.3 (1.7–6.0) with an IPSS score of 22 (19–27).

### Operative characteristics, Supplemental Table 2

Median vaporization time was 34 (23–48) min with an operative time of 62 (46–85) min. Overall, the mean laser energy delivered was 250.0 (168.4–367.9) kJ, with 44.1% of cases using greater than 4 kJ/cc of prostate. 92.5% of cases required one MoXy laser fiber. Perioperative blood transfusion was required in 23 (0.8%) patients, of which 11 were receiving antithrombotic therapy preoperatively. Median postoperative catheter time was 1 (1–2) day. Median LOS in North American, South American, and European centers was 0 (0–1), 1 (0–1), and 2 (1–2) days, respectively. 47 cases (2.8%) were converted to TURP due to operative complications. Prostatic capsule perforation occurred in 21 (1.4%) patients. Prostatic adenocarcinoma was observed on tissue pathology in 14 (1.7%) cases with a mean of 4.7 g (5.9) of tissue (vaporization incision technique) [6].

### Postoperative complications, Table 1

Median follow-up time was 6 months (0–12). The majority of postoperative complications were Clavien–Dindo grade I and II, while 26 (1.7%) patients experienced major

complications (Grade III–IV–V). The 30-day readmission rate was 13.2%, for which the majority were visits to the emergency department for Grade I hematuria. 244 patients (10.5%) had reported incontinence within 30 days of the surgery, of which 61% were greater than 70 years old. 500 patients (22.6%) experienced LUTS such as dysuria, frequency, and urgency. At 3-month follow-up, LUTS and incontinence was reported in 7.9 and 5.4% of patients, respectively. At 6-month follow-up, LUTS and incontinence was reported in 2.8 and 0.7% of patients, respectively. Major cardiovascular events (myocardial infarction, stroke, deep vein thrombosis, pulmonary embolism, congestive heart failure exacerbation) and death occurred in 0.8 and 0.3% of cases, respectively. In a single institution, bladder neck contracture (BNC) and urethral stricture was seen in 11 (1.9%) and 5 (0.9%) patients at 60 months. Within 60 months, BPH recurrence requiring surgical reintervention was seen in 10

(1.5%) patients and 19 patients (3.3%) were restarted on BPH medications.

### Functional outcomes, Table 2

Using the Kruskal–Wallis test, we found that there was a significant change in median PSA, IPSS, QoL, Qmax, and PVR across all time points ( $p < 0.05$ ). We then performed pairwise comparison using the Dunn–Bonferroni approach and found that PSA was significantly decreased at all follow-up time points (6, 12, 24, 36, 48, and 60 months) compared to baseline ( $p < 0.001$ ). Similarly, median IPSS, QoL, Qmax, and PVR all significantly improved when comparing to baseline at all follow-up time points ( $p < 0.001$ ). For patients with data up to 60 months, median change of PSA was 46.6% and median IPSS score and QoL was 5 (3–8) and 1 (0–2), respectively, from a baseline of 22 (19–27) and 4 (3–5). Median

**Table 1** Perioperative, early postoperative (< 30 days), and long-term complications

Complication	Clavien–Dindo grade	Number of patients (%)	Sample size
<b>Perioperative</b>			
Prostatic capsule perforation	IIIa	21 (1.4%)	1471
Conversion to TURP	IIIa	47 (2.8%)	1659
<b>Early postoperative (&lt; 30 days)</b>			
30-day readmission	–	192 (13.3%)	471
# On anti-coagulants	–	58 (30%)	192
Fever	I	62 (4.0%)	2158
UTI	I	118 (5.3%)	2219
LUTS*	I	500 (22.6%)	2217
OAB	I	6 (1.1%)	555
Incontinence	I	232 (10.5%)	2217
Retention	I	164 (7.4%)	2217
Hematuria	I	219 (9.9%)	2217
Paraphimosis	I	1 (0.2%)	555
Hematuria	II	32 (4.3%)	746
Osteitis pubis	II	1 (0.2%)	555
Urosepsis	II	8 (0.5%)	1471
Stenosis (urethra, meatus, bladder neck)	IIIb	1 (0.1%)	1471
Arrhythmia	IVa	6 (0.4%)	1471
Major cardiac event**	IVb	12 (0.8%)	1471
Respiratory distress (desaturation)	IVb	3 (0.2%)	1471
Death	V	4 (0.3%)	1471
<b>Long term at 5-year follow-up</b>			
Bladder neck contracture	IIIb	11 (1.93%)	569
Urethral stricture	IIIb	5 (0.89%)	569
BPH recurrence requiring medical reintervention	II	19 (3.34%)	569
BPH recurrence requiring surgical reintervention	IIIb	10 (1.5%)	569

\*Dysuria, frequency, urgency

\*\*Angina, myocardial infarction, transient ischemic attack, stroke, deep-vein thrombosis, pulmonary embolism, congestive heart failure exacerbation

**Table 2** Long-term GL-PVP functional outcomes at up to 5-year follow-up

Functional outcomes									
Outcome	Baseline	Months							<i>p</i> value*
		3	6	12	24	36	48	60	
<b>PSA ng/mL</b>									
Mean (SD)	6.5 (22.9)		3.5 (28.4)	2.2 (2.4)	3.1 (5.6)	3.01 (5.32)	2.9 (3.44)	2.8 (3.4)	
Median (IQR)	3.3(1.7–6)		1.7 (0.8–3.1)	1.5 (0.7–2.8)	1.7 (0.7–3.7)	1.7 (0.7–3.6)	1.7 (0.7–3.6)	1.5 (0.6–3.5)	
PSA change	–		43.9%	45.0%	51.7%	45.8%	46.7%	46.4%	
No. pts	<i>n</i> =3432		<i>n</i> =1652	<i>n</i> =162	<i>n</i> =500	<i>n</i> =364	<i>n</i> =254	<i>n</i> =136	
<b>IPSS</b>									
Mean (SD)	22.8 (6.7)	7.1 (4.4)	6.6 (4.3)	5.2 (4.2)	5.3 (4.3)	5.3 (4.0)	5.3 (4.2)	6.1 (5.4)	
Median (IQR)	22 (19–27)	6 (4–9)	5 (4–9)	4 (2–7)	4 (3–7)	4 (3–7)	4 (3–7)	5 (3–8)	
No. pts	<i>n</i> =2482	<i>n</i> =1013	<i>n</i> =1906	<i>n</i> =1587	<i>n</i> =512	<i>n</i> =374	<i>n</i> =251	<i>n</i> =176	
<b>QoL</b>									
Mean (SD)	4.1 (2.5)	1.4 (1.2)	1.0 (1.1)	0.9 (1.1)	0.9 (1.1)	0.9 (0.9)	0.9 (1.0)	1.2 (1.4)	
Median (IQR)	4 (3–5)	1 (1–2)	1.0 (1.1)	1 (0–1)	1 (0–1)	1 (0–1)	1 (0–1)	1 (0–2)	
No. pts	<i>n</i> =1011	<i>n</i> =53	<i>n</i> =439	<i>n</i> =433	<i>N</i> =364	<i>n</i> =249	<i>n</i> =170	<i>n</i> =148	
<b>Qmax (mL/s)</b>									
Mean (SD)	7.5 (10.8)	19.4 (6.6)	18.7 (6.8)	18.9 (6.8)	19.0 (7.1)	25.1 (113.2)	17.8 (6.1)	20.1 (25.5)	
Median (IQR)	6.3 (4–9)	19 (16–22)	18 (15–22)	18 (15–22)	19 (15–23)	18 (15–22)	17 (14–22)	17 (14–21)	
No. pts	<i>n</i> =1441	<i>n</i> =1008	<i>n</i> =1004	<i>n</i> =854	<i>n</i> =444	<i>n</i> =312	<i>n</i> =229	<i>n</i> =123	
<b>PVR (mL)</b>									
Mean (SD)	220.5 (341.6)	38.7 (60/8)	30.3 (54.3)	32.8 (61.4)	33.9 (69.1)	37.4 (73.1)	40.4 (94.7)	46.6 (91.2)	
Median (IQR)	122 (32–291)	17 (0–50.0)	15 (0–36.3)	15 (0–40)	10 (0–34)	10 (0–40)	13 (0–50.0)	46.6 (91.2)	
No. pts	<i>n</i> =2129	<i>n</i> =1051	<i>n</i> =1062	<i>n</i> =938	<i>n</i> =514	<i>n</i> =338	<i>n</i> =239	<i>n</i> =129	

\**p* value obtained using Kruskal–Wallis test

Qmax was 17 (14–21) mL/s compared to 6.3 (4–9) mL/s at baseline.

## Discussion

To the best of our knowledge, this is the largest international database evaluating the use of GL-PVP in men with the XPS-180 W system. Our study demonstrated durable, safe, and effective results up to 60 months postoperatively. Notably, in this series of men treated by high-volume surgeons, the observed BPH surgical revision was 1.5% of those men with 60-month follow-up. Given the comparable functional outcomes to the reference standard TURP, GL-PVP is known to be a safe alternative for the surgical management of LUTS secondary to BPH [2]. Nonetheless, there remains limited clinical data on the outcomes of GL-PVP. The GOLIATH trial demonstrated the non-inferiority of GL-PVP to TURP at 24 months based on IPSS assessment [7]. However, the trial included only 281 patients and excluded patients with prostate volume greater than 100 cc.

The median operative time was 62.0 min in our sample, which is greater than that seen in the GOLIATH trial

(median 49.6 min) [8]. The difference in operative time is likely attributable to increased prostate volumes. Our study included 551 patients with prostates larger than 100 cc as measured by TRUS, an exclusion criterion in the GOLIATH trial. In support of our findings, Campobasso et al. have previously demonstrated a median operative time of 75 min in prostates between 100 and 130 cc [9].

The median energy used per case was 250 kJ, resulting in a median energy density of 3.9 kJ/cc, while 43% of our patients had an energy density superior to 4 kJ/cc. We have previously estimated that an energy density of at least 4 kJ/cc may be associated with lower rates of retreatment: the average energy used in patients who required retreatment was 2.1 kJ/cc, compared to 4.4 kJ/cc in patients who did not [10]. The median LOS was 2 (1–3) days. Given the likely geographical impact on reimbursement, LOS was longer in European centers, as opposed to centers within countries such as Canada, where GL-PVP is treated as a same-day surgery. In addition, 60.2% of patients had their catheter removed within postoperative day 1, further suggesting that GL-PVP provides an accelerated course of discharge.

Regarding safety, 34.3% of men required antithrombotic therapy other than aspirin at the time of surgery.

Unfortunately, whether antithrombotic therapy was continuous or stopped prior to operation was not documented. Overall, 0.8% of men required perioperative red blood cell transfusion, 50% of which were receiving antithrombotic therapy. While GL-PVP is considered an effective option for patients undergoing antithrombotic therapy, only a few retrospective studies have reported on its ongoing use during surgery [11, 12]. The Stop or Ongoing Oral Anticoagulation in Patients Undergoing PVP (SOAP) phase 3 trial is a multicentre RCT evaluating safety and efficacy of PVP in patients using anticoagulation therapies, the results of which may guide future management [13].

2.8% of GL-PVP cases required conversion to TURP, due to failure to progress or bleeding complications. Notably, a previous RCT comparing PVP with the HPS 120 W system to HoLEP demonstrated that 22% of PVP cases were converted to TURP or HoLEP due to bleeding complications or inadequate tissue removal [14], a stark difference to our findings. The improved maximum power output of the XPS-180 W system may have contributed to improved tissue removal and coagulation ability. In addition, the potential impact of learning curves during the use of the previous generation (HPS system) may have also resulted in poorer surgical performance and outcomes at that time.

The majority of postoperative complications in patients treated with GL-PVP were Clavien–Dindo grade I or II. The most common complications within 30 days were lower urinary tract symptoms (dysuria, frequency, urgency), incontinence, and grade I hematuria at 22.6, 10.5, and 9.9%, respectively. At 6 months, LUTS and incontinence was reported in 2.8 and 0.7% of patients, respectively. Within the group of patients who experienced incontinence postoperatively, 61% were greater than the age of 70 years old. Furthermore, when adjusting for categories of baseline IPSS, compared to patients a year younger, patients a year older were more likely to be incontinent (OR 1.03, 95% CI 1.02–1.05,  $p < 0.001$ ), translating to a 16% increase in the odds of being incontinent for every 5-year increase in age. Unfortunately, subtypes of incontinence were not documented. 4.3% of men experienced grade II hematuria requiring postoperative blood transfusion related to bleeding events. Death and major cardiovascular events such as myocardial infarction, or congestive heart failure exacerbation occurred in 0.3 and 0.8% of patients, respectively. Three of four patients who died and seven of 12 patients who experienced major cardiovascular events within 30 days of operation were receiving antithrombotic management preoperatively.

Given the retrospective nature of our study, long-term follow-up regarding retreatment rates was limited. This reduction of follow-up is related to the return of patients to their primary care physician or community urologist coupled with the lack of post-BPH surgery guidelines follow-up. Amongst those with long-term assessments, an observed

1.9% of men were found to have BNC within 60 months, of which all underwent direct vision internal urethrotomy for management. Furthermore, 3.34% of men were observed to have LUTS secondary to BPH recurrence, treated with medical reintervention (5-ARI, alpha-blockers). Interestingly, this contrasts to the previously reported rate of 13.8% of men requiring medical retreatment for LUTS at 12-month follow-up post-TURP or open prostatectomy [15]. Although it was a secondary endpoint, we wished to report on it as it is often not included with other BPH surgical outcome publications. However, our reduced long-term follow-up assessments may have played a role. In addition, among those men with 60-month assessment, an observed 1.5% of men required repeat surgical BPH intervention. In an RCT comparing TURP to GL-PVP, however, with the lower power HPS 120 W system, GL-PVP was associated with a significantly higher reoperation rate (11% vs. 1.8%) [16]. Since these results were obtained from a single institution with an experienced surgeon, the generalizability of these results must be taken into account. The learning curve to achieve adequate tissue removal should not be overlooked simply due to its hemostatic features. Beginner surgeons should aim for proper patient selection (30–80 cc), and a minimum of 4 kJ/cc to achieve sustainable results. Despite substantial loss to follow-up within the GGG database, our findings are notable when considering previously reported retreatment rates. Taken together, GL-PVP appears to be a safe and effective intervention with minimal perioperative and postoperative complications, as well as minimal surgical failure rates.

When analyzing functional outcomes after GL-PVP, men showed significant improvements in IPSS, and QoL as well as uroflowmetry parameters such as Qmax, and PVR, at all follow-up time points when compared to baseline. Furthermore, PSA was significantly decreased at all follow-up time points. Specifically, there was a 43.9% decrease in median PSA at first follow-up (3 months), which was maintained at 60 months (46.4% decrease). These results have been corroborated by previous studies, including a recent multicenter Italian cohort study including 1077 men who underwent GL-PVP. They demonstrated significant improvements in Qmax and IPSS at 6 and 12 months [17]. Thus, results from the GGG database provide compelling evidence of the durability of GL-PVP.

To the best of our knowledge, this is the largest retrospective study of PVP using the Greenlight XPS system. Among the strengths of GGG database is the large number of patients ( $n = 3627$ ) who were treated across multiple international centers. Furthermore, the surgeons performing the procedures were all experts in their field. The retrospective nature of our study may have introduced bias due to substantial patient loss during follow-up, which lead to a reported median of 6 months of follow-up. Many patients



were treated in tertiary care centers and discharged to be followed by their primary care physicians, thus long-term data collection was not uniform. Furthermore, due the retrospective nature of the study, important parameters such as ejaculation/erectile function, and subcategories of incontinence were not captured. Finally, we could not account for heterogeneity in the experience and techniques implemented by the surgeons, as well as heterogeneity in the reporting of complications.

In conclusion, our multicenter experience demonstrated very few major operative complications and low reintervention rate. GL-PVP using the XPS-180 W system is a safe and effective treatment for LUTS secondary to BPH and can provide durable outcomes.

**Supplementary Information** The online version contains supplementary material available at <https://doi.org/10.1007/s00345-021-03688-4>.

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## Declarations

**Conflict of interest** Consultants and proctors for Boston Scientific for Greenlight: KZ, DSE, VM, ER, and HC. Investigators and consultants for PROCEPT BioRobotics: VM, TB, NB, and KZ. Surgical tutors for Greenlight Xcelerated Performance System (American Medical System-AMS, Minnetonka, MN) and received honoraria for their tutorship: GF and LC. All the other authors do not report any relevant conflicts of interest.

**Ethics approval** All the procedures performed in this study were in accordance with the ethical standards of the institutional research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standard.

**Informed consent** Formal consent is not required for this type of study (retrospective).

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