Direct comparison of Green Light Laser XPS Photoselective Vaporization of the Prostate (PVP) and Green Laser En Bloc enucleation of the prostate (GreenLEP) in enlarged glands > 80 ml: A study of 120 patients

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Running head: PVP versus GreenLEP in larger prostates

ABSTRACT

Purpose: To compare patient outcomes after 180 W XPS Greenlight photoselective vaporization of the prostate (PVP) and Green laser enucleation of the prostate (GreenLEP) used to surgically manage benign prostatic obstruction (BPO).

Materials and Methods: Two groups of 60 consecutive patients with enlarged glands (>80 mL) underwent either GreenLEP or PVP (performed by the same surgeon and including his learning curve) and were retrospectively evaluated. Perioperative data from both groups were compared.

Results: Operative time was significantly shorter in the GreenLEP group (60 vs 82 min, $p<0.0001$). The complication rates were comparable between the groups. At 2 months, urinary incontinence was significantly higher in the GreenLEP group (25% vs. 3.4%, $p<0.0001$) but incontinence rates were similar at 6 months (3.4 % vs. 0%, $p=0.50$). At 6 months, the I-PSS, QOL and PVR had similarly decreased in the two groups after the procedure (compared to baseline), whereas the Qmax value had greatly improved, significantly favoring the GreenLEP group (+78% vs. +64%, $p<0.0001$). The prostate size and PSA level reductions were significantly higher in the GreenLEP group (74% vs. 57%, $p<0.0001$ and 67% vs. 40%, $p=0.007$). The unplanned readmission rates were similar in both groups (16.7% vs. 6.7%, $p=0.16$).

Conclusions: PVP and GreenLEP were safe and provided satisfactory short-term functional outcomes in patients with a prostate volume over 80 mL. However, the surgical time was longer in the PVP group, which also had a higher rate of unplanned readmission and lower decreases in the PSA level and prostate size.

INTRODUCTION

Lower urinary tract symptoms caused by benign prostatic obstruction (BPO) are highly prevalent in men older than 50 years of age. Surgery is indicated in cases of complicated BPO or moderate-to-severe symptoms with insufficient drug treatment efficacy, according to European guidelines.[1] Greenlight photoselective vaporization of the prostate (PVP) has been emphasized in recent years as a viable alternative to transurethral resection of the prostate, with comparable short-term functional outcomes[2,3] for small- to medium-sized prostates. However, in recent years, several studies have raised concerns regarding the efficacy of photoselective vaporization of the prostate (PVP) with 80 W and HPS-120 W Greenlight laser in larger glands with high long-term reoperation rates,[4] and evidence supporting the use of the GreenLight XPS 180 W for PVP in larger prostates is limited.

When prostate volumes exceed 80 mL, enucleation techniques using open prostatectomy or holmium-laser enucleation of the prostate (HoLEP) are currently the most established available options.[1] HoLEP has significantly lower perioperative morbidity rates and shorter hospital stays, and it has favorable outcomes compared to open prostatectomy and transurethral resection of the prostate.[1,2,5] However, to date, this technique has failed to spread widely in current clinical practice[6] because it is technically demanding and has a long learning curve.[7–9]

Green-laser enucleation of the prostate (GreenLEP) has recently been advocated as a new endoscopic enucleation procedure to excise the transitional zone as a single piece “en-bloc” using a Greenlight™ laser with a 120-W side firing fiber.[10]

However, in the literature, there is a lack of clinical data supporting GreenLEP. The aim of this study was to compare the efficacy of the XPS 180 W Greenlight PVP and Green laser “en-bloc” enucleation of the prostate (GreenLEP) procedures in relieving BPO in enlarged prostate volumes > 80 ml.

MATERIALS AND METHODS

Population. Between April 2011 and March 2014, men who were referred for lower urinary tract symptoms related to BPO and who underwent surgery were retrospectively reviewed. The first 120 consecutive patients with a TRUS prostate measurement >80 mL who underwent either PVP (as previously described[11]) or a GreenLEP procedure were included in the present single-center study. There were two distinct eras during the study period: during the first era (2011-2012) PVP was used for all patients, regardless of the prostate volume. During the second era (2013-2014), we started to perform GreenLEP procedure and this technique was used in all patients with prostate> 80 mL. Hence, the choice between the two surgical techniques did not depend on patients' characteristics. The patients provided informed consent to undergo enucleation with the Greenlight™ laser. All men who underwent prostate cancer, and pelvic radiotherapy were excluded from the analysis.

Surgical techniques. A Greenlight XPS 532-nm laser generator (American Medical Systems, Minnetonka, MN, USA) was used for all cases. The type of laser fiber used depended on which technique was utilized. For pure PVP, the MoXy fiber was utilized. For the GreenLEP group, the HPS 2090 fibers were used, along with the 120 W system. The HPS fiber was chosen for enucleation because it is more solid than the Moxy fiber, which allowed mechanical dissection of adenoma with the end of the fiber. GreenLEP was conducted with a Wolf™ double-flow endoscope 24.5-Fr, with continuous irrigation of the bladder with saline. At the end of the procedure, a morcellator with a single-use, Wolf-Piranha blade was used in all cases. All procedures were performed by a single surgeon (VM) with no previous enucleation experience. The 60 GreenLEP cases presented here indicate his learning curve. He learnt GreenLEP by watching videos of a proctor who had a large experience of this enucleation technique.[10] The PVP included in this study were his first cases with prostates>

80 ml.

All PVP procedures were performed as previously described with wattage from 120 to 180W [9]. The first step of the procedure was to identify the striated sphincter, the verumontanum, prostatic lobes and ureteral orifices through regular urethrocystoscopy. Then, using coagulation, a horizontal mark (security line) was created at the anterior part, clearly above the urinary sphincter. To perform 'en-bloc' enucleation of the prostate, the capsular plane was then found posteriorly, laterally to the verumontanum, through coagulation of the mucosa and then vaporization of the tissue. After the first contact with the prostatic capsule on the right side, enucleation was conducted from the apex and then laterally and anteriorly, primarily using mechanical energy by pushing the lobe towards the bladder. Occasionally, hemostasis (coagulation mode, power setting: 40W) or vaporization (power setting: 80W) were performed during this step. After the enucleation was completed laterally and anteriorly, the adenoma was detached in one piece and pushed into the bladder. Hemostasis was then performed before conventional morcellation. Only laser coagulation was routinely used. Electrocautery was used only in cases of uncontrolled bleeding and these procedures were then considered as conversion to TURP.

Data collection. The perioperative datas were retrospectively reviewed and recorded by a single person (VM) using patients' charts. Postoperative complications were also graded according to the Clavien–Dindo classification.[12] Urinary incontinence was defined as any postoperative urine leakage reported by the patient.

Postoperative follow-up assessments were scheduled postoperatively at 2, 6 and up to 12 months. The median follow-up times were 16 [8.7; 24.7] and 6 [2.5;12] months in the PVP and GreenLEP groups, respectively. Hence, to make the two groups comparable (especially for time-dependent variables) we truncated the follow-up at 6 months.

Statistics. Data are presented as the medians and interquartile range or mean (sd) for continuous variables and frequencies and percentages for qualitative variables. The Fisher exact test was used to compare qualitative variables, and the Wilcoxon rank-sum test was used to compare continuous variables, as appropriate. All tests were two-sided, and $p < 0.05$ was considered to be statistically significant. Statistical analyses were performed using R (version 3.1.1).

RESULTS

Population.

Overall, 120 patients were included in the analysis. The median patient age, prostate volume and preoperative PSA were 69 range 64-76 years, 100 range 80-110 ml and 4.4 range 3-7.3 ng/dl, respectively. The patient's baseline characteristics are summarized in Table 1. The baseline clinical features were comparable between both groups, except for a significantly higher Qmax value, a lower PVR and a higher proportion of 2 and 3 ASA scores in the PVP group. No patient had undergone previous surgical treatment for BPO. One patient had bladder stones that were treated during the enucleation procedure (vaporization using an Holmium laser).

Perioperative parameters.

PVP surgery was successfully performed in all cases, with a median of 1.12 fibers per patient (vs. 1.02 in the GreenLEP group, p=0.03). More than one laser fiber per procedure was required in 7 PVP cases due to exceeding energy limits in 3 cases and fiber damage in 4 cases. GreenLEP surgery was performed successfully in all cases, but one patient required conversion to open surgery for adenoma and clot removal after the enucleation technique (Table 2) had been performed. The median energy, energy/ml of prostate, lasing time and

intraoperative time were significantly higher in the PVP group (p<0.0001). The median time to catheter removal was significantly shorter in the PVP group (p<0.0001). However, both groups were comparable in terms of capsular perforation, early postoperative complications (25% vs. 16.6%, p=0.46) or median length of hospital stay (Table 2). There were 2 major complications in each group (Clavien IIIb). Conversion to TURP was needed in 10 and 5 patients in the GreenLEP and the PVP group respectively (16.6% vs. 8.3%; p=0.16).

Functional outcomes.

At 2 and 6 months, the I-PSS, QOL and PVR had similarly decreased in the two groups after the procedure (compared to baseline), whereas the Qmax value had greatly improved, significantly favoring the GreenLEP group (+78% vs. +64%, p<0.0001). The median enucleated tissue weight was 63 gr [45;88], and the residual prostate volume was 23 ml [20;30] in the GreenLEP group. The median percent reduction of the TRUS estimated prostate size was significantly higher in the GreenLEP group (-74% vs. -57%, p<0.0001). Two cases (3.4%) of incidental Gleason 6 (3+3) low-grade prostate cancer of less than 5% (T1a) of the processed tissue were detected in patients undergoing GreenLEP. They opted for active surveillance (Table 2). The median percent reduction in the PSA level was 49% vs. 82%, p<0.0001 at 2-months and 40% vs. 67%, p=0.006 at 6-months in the PVP and GreenLEP groups, respectively (Table 3). Postoperative urinary incontinence, which necessitated one or two pads/day, occurred significantly more frequently in the GreenLEP group at 2 months (25% vs. 3.4%, p<0.0001), but this difference was not longer significant postoperatively at 6 months (3.4% vs. 0%; p=0.15). Mean number of pads per day for patients with urinary incontience was 1.3 in the GreenLEP group and 1.5 in the PVP group (p=0.73). Physiotherapy was used in most patients with postoperative urinary incontinence in both groups (66.7% vs. 50%; p=0.99). When comparing the first 30 GreenLEP cases to the last 30 cases, the rate of transient SUI was significantly lower in the latter group (11/30, i.e., 37% vs.

4/30 i.e., 13.3%; p=0.04).

At 6 months, unplanned readmission rates were similar in both groups (16.7% vs. 6.7%, p=0.16).

DISCUSSION

Recently, the use of GreenLight™ PVP has increased widely in Western countries but the evidence supporting the use of PVP for large prostates is limited.[2,3] In addition, PVP has already been compared with Holmium enucleation, suggesting earlier improvements in storage symptoms after HoLEP[13]. This study is the first to report the clinical outcomes of the GreenLEP technique. Obviously, the use of Greenlight PVP for large glands is still controversial because of the high intraoperative time and the limited amount of tissue removed during the procedure, even when using the latest 180_W XPS device.[14,15] Interestingly, we found that GreenLEP procedure was near 1.5-fold faster compared to PVP in large glands. Not surprisingly postoperative prostate volume (74 vs 57%; p <0.001) and PSA reduction (67 vs 40%; p = 0.007) was higher with GreenLEP than with PVP respectively and similar to that obtained after HoLEP.[16] This difference reflects the larger amount of adenoma removed with enucleation compared to pure vaporization. In the current study, we found a better Qmax improvements at 2 and 6 months after GreenLEP which is consistent with the recent report of Elshal et al. who compared HoLEP with an hybrid PVP enucleation procedure in a randomized trial and showed a greater percent reduction in PSA (82.6 -90% vs. 45.9 - 48%), and a greater percent reduction in TRUS volume (74 - 82% vs. 43.1 -52.5%) after HoLEP. They also observed a better Qmax improvement (24.9 -31.1 ml/s vs. 18.3 - 18.5 ml/s) at 12 months in the enucleation arm.[17] Despite its difference in Qmax, IPSS score and PVR were equivalent between the procedures. There was a trend towards higher conversion to TURP rate in the GreenLEP group, which could be related to a higher rate of intraoperative

bleeding compared to PVP during the initial cases.

Several series have suggested higher long-term reoperation rates with PVP compared to those reported in large open prostatectomy series,[4] but these series were published in the KTP-80 W and HPS-120 W era. In the largest multicenter retrospective study published to date,[15] Hueber et al. have reported only 2% 2-yrs retreatment rates for prostate volumes > 80 ml after using Greenlight 180_W XPS PVP, but reports describing the long-term outcomes of 180 W XPS PVP on larger prostates are still lacking.

Despite a well-established reputation supported by RCT trials and guidelines, the use of HoLEP among urologists remains rather low. One of the most important arguments advanced to explain this paradox has been the long learning curve of the technique. Long operating times, difficulty of the enucleation and incomplete morcellation were the most important factors encountered by beginner surgeons.[18] The feasibility of Greenlight laser enucleation has been tested in a pilot study in which the authors tried to imitate the HoLEP technique.[19] However, while the description of the technique seemed straightforward, the authors treated 21 patients with rather medium-sized prostates (75 mL), and the energy used was 233 kJ, which was somewhat higher than that used in our experience and was close to what is required to perform regular PVP. According to our experience, the use of mechanical energy for enucleation, once the capsule has been reached, is the cornerstone of the enucleation technique with the Greenlight laser, and it explains the difference in the energy level used between PVP and GreenLEP. En bloc Green laser enucleation of the prostate has been previously described, and its learning curve could be shorter than the Holep one but is still under evaluation.[10] Holep remains the only enucleation technique supported by high level of evidence studies.[1]

Our 25% rate of transient urinary incontinence in the GreenLEP group was similar to the rates reported in the literature with HoLEP (1.4–44%)[2,20], and physiotherapy led to complete

symptom resolution. Among the 15 patients who experienced postoperative SUI, 11 cases occurred in the first 30 procedures, thereby suggesting a learning curve effect. The transient SUI rate observed during the last 30 GreenLEP (13 %) is roughly similar to that reported in PVP series (e.g., 11% at 6 month in the Goliath study).[3] Based on our results, the transient SUI rate may be the major concern related to GreenLEP; therefore, further assessment of this parameter should be performed after more experience using this technique to determine whether our findings are only related to a steep learning curve or if they are indeed attributable to the GreenLEP technique.

This study has several limitations that should be acknowledged. The major shortcomings of the current study, mostly related to its retrospective non-randomized design, are the learning curve assessment for the PVP and GreenLEP procedures (for the large glands), the short follow-up period and the lack of cost evaluations. The assessement of post-operative incontinence was based only on clinical interview, which is an important drawback, and the validity of this endpoint could therefore be called into question. The sexual function was not evaluated which could be regarded as a flaw. Despite the different distributions of ASA scores between both groups was a coincidence, it could have influenced the results observed, especially concerning complications. Different lasers have been used in the two groups and follow-up was longer in the PVP group. A longer follow-up is required to accurately assess the functional outcomes and reoperation rates.

CONCLUSION

PVP and GreenLEP were safe and provided satisfying short-term functional outcomes in patients with enlarged prostates. However, the operative time could be longer in the PVP group, with possibly lower decreases in the PSA level and prostate size. In contrast, GreenLEP could be associated with a longer catheterization time and a higher rate of transient

SUI.

Conflict of interest:

Vincent Misrai and Kevin Zorn are proctors for American Medical System

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Table 1 Preoperative baseline characteristics of patients (n=120)

	PVP (n=60)	**GreenLEP (n=60)**	***p-value***
Age at the time of surgery (years)	70 [65 ; 77]	68 [63 ; 74]	*0.11*
ASA score			
1	3 (5%)	24 (40%)	
2	45 (75%)	30 (50%)	*< 0.0001*
3	12 (20%)	6 (10%)	
Preoperative PSA (ng/dl)	4.3 [2.8 ; 7.5]	4.6 [3.0 ; 7.0]	*0.67*
Preoperative Prostate volume (ml)	100 [85 ; 110]	100 [80 ; 120]	*0.56*
I-PSS	18 [14 ; 21]	17 [14 ; 20]	*0.34*
I-PSS question 8 (QOL)	5 [4.0 ; 5.0]	4 [4.0 ; 4.2]	*0.01*
Qmax (ml/sec)	6.5 [4.9 ; 8.0]	5.2 [4.0 ; 6.0]	*0.005*
PVR (ml)	50 [0 ; 150]	100 [100 ; 200]	*0.01*
Number of patients with indwelling catheter	11 (18.3%)	12 (20%)	*0.99*
Preoperative prostate medications			
Alpha blockers	55 (91.7 %)	56 (93.3 %)	*0.99*
5ARIs (alone or combined with alpha blockers)	20 (33.3%)	23 (38.3 %)	*0.7*
Patients on ongoing			
Aspirin	16 (26.6%)	27 (45%)	*0.056*
Clopidogrel	2 (3.3%)	2 (3.3%)	*0.99*
Anti vitamin K	5 (8.3%)	2 (3.3%)	*0.44*

Abbreviations: PSA: Prostate specific Antigen; I-PSS: International Prostate Symptom Score; QOL: quality of life; Q max: maximum urinary flow rate ;PVR: post-void residual volume ; 5ARIS. 5 alpha-reductase inhibitor Data are given by number and percentage, n (%); median and [1^{rst};3rd quartile]

Table 2 Perioperative parameters of patients (n=120)

	PVP (n=60)	**GreenLEP (n=60)**	***p-value***
Total energy (KJ)	490 [360 ; 580]	65 [47 ; 95]	*<0.0001*
Lasing time (min)	58 [45 ; 68]	20 [15 ; 25]	*<0.0001*
Energy/ml prostate (KJ/ml)	4.6 [3.6 ; 5.7]	0.7 [0.5 ; 0.98]	*<0.0001*
Intraoperative time (min)	82 [65 ; 110]	60 [55 ; 70]	*<0.0001*
Lasing time/operative time (%)	67 [61 ; 73]	29 [25 ; 36]	*<0.0001*
Conversion to monopolar TURP	5 (8.3%)	10 (16.6%)	*0.16*
Reason of TURP conversion			
For haemostasis	4 (6.7%)	6 (10%)	*0.74*
For residual prostatic tissue	1 (1.6%)	4 (6.7%)	*0.36*
Number of laser fibre per procedure*	1.12 (0.32)	1.02 (0.13)	*0.03*
Catheterization (days)	1.5 [1 ; 2]	2 [2 ; 2]	*<0.0001*
Early postoperative complications	15 (25%)	10 (16.6%)	*0.37*
Clavien-Dindo classification			
I	5 (8.3%)	3 (5%)	
Fever resolving spontaneously	*4*	*0*	
Confusion	*1*	*1*	
Gross hematuria	*0*	*2*	
II	8 (13.3%)	5 (8.3%)	
Acute urinary retention	*3*	*4*	
Gross hematuria	*2*	*1*	*0.99*
Urinary tract infection	*3*	*0*	
IIIa	0	0	
IIIb	2 (3.3%)	2 (3.3%)	
Conversion to open simple prostatectomy	*0*	*1*	
Two stages morcellation due to bleeding	*0*	*1*	
Reoperation for blood clots removal	*2*	*0*	
Capsular perforation	6 (10%)	7 (11.6%)	*0.84*
Blood transfusion	1 (1.6%)	1 (1.6%)	*0.99*
Length of stay (days)	2 [2 ; 4]	2 [2 ; 4]	*0.58*
Weight of specimen (gms)		63 [45 ; 88]	
Histopathology			
BPH	-	58 (96.6%)	
BPH with focal Gleason 6 (3+3) prostate cancer	-	2 (3.4%)	

Abbreviations: TURP: Transurethral Resection of the Prostate; BPH: Benign Prostatic Hyperplasia. Data are given by number and percentage, n (%); median and [1^{rst};3rd quartile] or mean* (sd)

Table 3: Postoperative parameters

	PVP (n=60)	GreenLEP (n=60)	*p-value*
2 months outcomes			
I-PSS	4 [3 ; 6]	4.5 [3 ; 6]	*0.84*
Reduction rate of I-PSS (%)	70 (23)	71 (16)	*0.62*
IPSS question 8 (QOL)	1 [1 ; 2]	1 [0 ; 2]	*0.83*
Qmax	19 [16 ; 23]	25 [23 ; 27]	*<0.0001*
Increasing rate of Qmax (%)	64 (16)	78 (8.7)	*<0.0001*
PV (ml)	40 [30 ; 60]	23 [20 ; 30]	*<0.0001*
Reduction rate of PV (%)	57 (16)	74 (11)	*<0.0001*
PVR (ml)	0 [0 ; 1.5]	0 [0 ; 5]	*0.97*
PSA (ng/dl)	1.7 [1.4 ; 3.0]	0.64 [0.3 ; 1.0]	*<0.0001*
Reduction rate of PSA (%)	49 (29)	82 (17)	*<0.0001*
Urinary incontinence (%)	2 (3.4%)	15 (25%)	*<0.0001*
6 months outcomes			
PSA (ng/dl)	1.6 [1.0 ; 2.5]	0.66 [0.4 ; 1.9]	*0.006*
Reduction rate of PSA	40 (77)	67 (46)	*0.007*
Urinary incontinence	0	2 (3.4%)	*0.15*
6 months-Unplanned readmissions	10 (16.7%)	4 (6.7%)	*0.16*
Cause of readmission			
Acute urinary retention	2 (20%)	1 (25%)	
Gross hematuria	2 (20%)	0	
2 stages morcellation	0	1 (25%)	
Uretral stricture	2 (20%)	0	
Bladder neck stricture	1 (10%)	0	
Urinary infection	3 (30%)	1 (25%)	
Cystoscopy (persistent overactive bladder)	0	1 (25%)	

Abbreviations: I-PSS: International Prostate Symptom Score; QOL: Quality Of Life; PSA: Prostate Specific Antigen ;PV: prostate volume ; 5ARIS: 5-alpha reductase inhibitor. Data are given by number and percentage, n (%); median and [1^{rst};3rd quartile] or mean* (sd)

Key definition for abbreviations

PVP : photoselective vaporization of the prostate
Greenlep : Green laser enucleation of the prostate
IPSS: International Prostate Symptom Score
PVR : Post-Void Residual volume
Q max : maximum urinary flow rate
PSA : Prostate Specific Antigen level
BPO : Benign Prostatic Obstruction
Holep : Holmium laser enucleation of the prostate
ASA : American Society of Anesthesiology score
PAI: Platelet-aggregation inhibitors
AUR : Acute Urinary Retention
SUI : stress urinary incontinence