

Prospective Assessment of the Sexual Function After Greenlight Endoscopic Enucleation and Greenlight 180W XPS Photoselective Vaporization of the Prostate

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PROSPECTIVE ASSESSEMENT OF THE SEXUAL FUNCTION AFTER GREENLIGHT[™] ENDOSCOPIC ENUCLEATION AND GREENLIGHT[™] 180W XPS PHOTOSELECTIVE VAPORIZATION OF THE PROSTATE

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Conflicts of interest

Benoit PEYRONNET and Sébastien VINCENDEAU are consultants for Boston Scientific

INTRODUCTION

Sexual dysfunction is commonly encountered in men with Low Urinary Tract Symptoms (LUTS) [1]. Probably underestimated, sexual activity was reported in 83% of men over 50 years old. LUTS due to Benign Prostate Obstruction (BPO) increases from 50% of men aged fifty to 80% of men over 70 years old. Many men with medical therapy require a surgical approach at some point due to prostatic volume progression and nature of the disease [2]. According to European Association of Urology and American Urology Association guidelines, Holmium Laser enucleation of the prostate (HoLEP) may be the preferred minimally invasive surgical treatment option for prostates larger than 80 g [3,4]. However, this surgical approach requires experience and relevant endoscopic skills that could explain its relatively slow widespread over the past decade [5]. Other minimally laser techniques have been developed, such as photoselective vaporization of the prostate (PVP) with Greenlight[™] laser 180W [6], whose safety and efficacy in prostates > 80 ml have been reported in expert medical centers [7,8]. Recently, endoscopic enucleation of the prostate with Greenlight[™] laser (GreenLEP) has been described as a possibly better approach than PVP 180W in larger prostates in terms of postoperative PSA decrease and risk of surgical re-treatment [9,10].

The effects of PVP 180W and GreenLEP on sexual function have never been assessed so far. Sexual impact of transuretral resection of the prostate (TURP) is controversial [11]. Regarding HoLEP, recent studies described a stable sexual function after surgery, despite high prevalence of ejaculatory dysfunction [12]. A maintained sexual function after PVP 80W and 120W was also reported using the International Index of Erectile Function (IIEF-5) [13].

The aim of this study was to assess the sexual impact (i.e. impact on ejaculatory and erectile functions (EF)) of PVP Greenlight[™] 180W and GreenLEP.

MATERIALS AND METHODS

Study design

Between January 2014 and September 2016, the data of 440 consecutive men with LUTS or complications related to BPO who underwent a PVP or GreenLEP at our

institution were prospectively collected. Surgical indications were based on guidelines of the European Association of Urology (EAU) [4]. Patients with prostate volume < 80 g on preoperative trans-rectal ultrasonography (TRUS) were excluded as well as patients with a post-operative follow-up < 12months, preoperative IIEF5 score < 5 (not sexually active), a history of neurological disorder or pelvic radiotherapy, untreated urinary tract infection, history of previous urethral surgery, prostate cancer (PSA > 4ng/ml and positive prostate biopsy or suspect digital-rectal examination), and procedures performed by low experienced surgeons (<100 procedures).

Interventions

Patients with antiplatelet therapy were operated under aspirin only (i.e. clopidogrel was always stopped during the perioperative period). Oral anticoagulation was bridged to low molecular weight heparin throughout the perioperative period in patients with high risk of thrombotic event and stopped in the others. PVP was performed with Greenlight[™] 180-W XPS (Boston Scientific System[™]; Inc. USA) and the MoXy laser fiber. Surgical technique was based on optimization of laser energy delivered to the prostatic tissue. After the completion of two channels at 5 and 7-o'clock with an energy setting of 80W, median lobe was first vaporized. Then, lateral lobes were removed using an energy setting of 80 to 140W towards the surgical capsule. The surgical objective was a widely open prostate cavity based with concomitant TRUS of the prostate during our initial experience [14].

GreenLEP was performed as previously described by Gomez-Sancha's using the HPS-120W fiber and 532nm 180W generator [9]. After a circonferential incision at the verumontanum, the adenoma at the apex was removed from the external sphincter. Then, the "en-bloc" enucleation was performed through a blunt dissection between the adenoma and the capsule with the tip of the scope from the apex to the bladder neck. Once removed, "en-bloc" adenoma was placed into the bladder and morcellated using Wolf[™] morcellator and Wolf Pyrana[™] endoscop (Richard Wolf GMbH[™], Knittlingen, Germany). At last, retrieved tissue were weighted and examined histologically.

Outcomes

The patients' characteristics, perioperative parameters and complications were prospectively collected. Postoperative complications were defined as any medical or surgical adverse event within the first 30 days following surgery using the Clavien-Dindo's classification modified according to the Greenlight[™] Users Group (GUGL) [15]. Sexual parameters involved antegrade ejaculation status (persistent or not) and International Index of Erectile Function-5 (IIEF5 score). Patients were evaluated at the third month after surgery and annually thereafter. Functional outcomes using questionnaires (IIEF5 score, IPSS score, QoL from IPSS scores and ICS male SF score), uroflowmetry and PSA were collected. Post-void residual (PVR) was assessed using supra-pubic ultra-sonography. Re-treatment was defined as any LUTS related to benign prostate obstruction (BPO) that required medical or surgical treatment.

The primary outcome was the change in erectile function (subjectively defined as any postoperative decline of IIEF5 \geq 5 points) [16]. The secondary outcomes were changes in voiding parameters (Δ Nocturia, maximum flow rate (Qmax), post-void residual urine volume (PVM), International Prostate Symptom Score (Δ IPSS score), Quality of Life question 8 (QoL) from IPSS, International Continence Society male SF score and urinary incontinence questions from the ICS male SF score.

Statistical analysis

Patients were matched in a 1:1 fashion according to the following variables: preoperative trans-rectal ultrasonography prostatic volume (PV) and cardiovascular risk factors (any of the following: smoking, diabetes and hypertension). Continuous variables were reported as mean and standard deviation (SD). Comparisons of continuous and categorical variables were performed using the Mann-Whitney U-test and χ^2 -square (or Fisher's exact test, as appropriate), respectively. Logistic regression analysis was used to assess predictive factors of Δ IIEF5 \geq -5. Spearman's rho assessed the correlation between continuous variables. Long term re-treatment rate free survival estimates were generated using Kaplan-Meier method; Log-rank was applied for pairwise comparison of survival. McNemar test assessed the paired variations of IIEF5 in each group. All p values were two-sided and statistical significance was defined as a p \leq 0.05. The statistical analysis was performed with JMPTM v.12.0 software (SAS Institute Inc, Cary, NC, USA).

RESULTS

Patient characteristics

The patient characteristics are summarized in table 1. Regarding ASA score, hypertension, smoking status, and history of diabetes, GreenLEP and PVP groups were comparable (p=0.28, p=0.90, p=0.79 and p=0.59, respectively). The mean age was 68 years (95%CI: 66-70) and 33/200 (17.7%) of patients were catheter-dependent before surgery.

Perioperative outcomes

The intraoperative data and postoperative results are shown in supplementary table 1. Mean preoperative prostate volume was 110 g (95%CI: 101-118) and 107 g (95%CI: 99-115) in the GreenLEP and PVP groups, respectively (p=0.68). Mean total energy delivered in the PVP group was 4.42 KJ/gram (4.2-4.6). Mean enucleation and morcellation times were 54 min (95%CI: 40-60) and 14 min (11-17), accounting for 63% and 16% of total operative time, respectively. Mean prostate tissue enucleated was 75.1 \pm 38.7 grams according to final pathology. Total operative time was significantly longer in the GreenLEP group compared to the PVP group (p=0.03). Irrigation, catheter and hospitalization times were comparable in both groups (p=0.79, p=0.32 and p=0.11, respectively). 98.9% of patients in GreenLEP group recovered spontaneous voiding after surgery vs. 88.5% in the PVP group (p=0.002). The rates of postoperative complications were comparable in the two groups (p=0.93).

Urinary and anatomical outcomes

Regarding baseline IPSS score, nocturia and Qmax, no statistically differences were observed between the two groups (p=0.33, p=0.29 and p=0.27, respectively). All urinary outcomes favored the GreenLEP group (supplementary table 2). IPSS score was significantly lower in the GreenLEP group than in the PVP group at 3, 12 and 24 months postoperatively (p<0.001). The postoperative IPSS-QoI evolution favored the GreenLEP group as well (p=0.003, p=0.007 and p<0.001 at 3, 12 and 24 months respectively). Compared to the GreenLEP group, nocturia evolution postoperatively in the PVP group was poorer with a mean variation of 0.5 ± 1.5 , 0.8 ± 1.6 and 0.9 ± 0.2

at 3, 12 and 24 months, respectively (p<0.05). The Qmax was significantly greater in GreenLEP group at each time point (p<0.001, p=0.003 and p=0.003).

Initial PSA levels were similar in the two groups (p=0.64) (supplementary table 3 and Figure 1). Mean reductions of PSA levels were 81.3% and 63.2% after 3 months, 73.4% and 54.4% after 12 months, 73.4% and 33.8% after 24 months, in the GreenLEP and PVP groups, respectively ((p<0.001, p=0.026 and p=0.004). After a mean follow up of 25.1 and 18.6 months, re-treatment rate was needed in nine patients (10.1%) in the PVP group vs. no patient in the GreenLEP group (log rank test: p=0.002).

Impact on sexual functions

Antegrade ejaculation was reported as being preserved in 24 patients (26.9%) in the PVP group *vs* one patient (1.2%) in the GreenLEP group at 12 months (p<0.001). Postoperative IIEF5 evolution was reported in Table 2. At baseline, IIEF5 scores were comparable in both groups (p=0.62). In the GreenLEP group, IIEF5 increased from 1.1 point, 1.3 and 0.7 point at 3, 12 and 24 months postoperatively. In the PVP group, IIEF5 remained stable after 3 months and decreased significantly after 12 and 24 months (p=0.031).

An IIEF5 decline \geq 5 points was observed in two and 19 patients in the GreenLEP and PVP groups, respectively (p<0.001). The mean postoperative change in IIEF5 favored GreenLEP at each time point, being +1.1 vs. -0.6 at 3 months (p<0.0001); +1.3 vs. -1.3 at 12 months (p<0.0001) and +0.8 vs. -1.3 at 24 months (p=0.008).

In multivariate analysis (adjusted to BMI, smoking, hypertension and diabetes status, Δ Nocturia>2 and Δ IPSS<5) age, history of coronary artery disease and surgical treatment with PVP (vs. GreenLEP) were independent predictors of IIEF5 decline over 5 points (Table 3).

Only the GreenLEP resulted in statistically significant improvement of IIEF5 at each postoperative assessment compared to baseline (p=0.002). Using Spearman correlation, we found a significant correlation between Δ Nocturia and Δ IIEF-5 (r=-0.574 p<0.0001) and between Δ IPSS and Δ IIEF-5 (r=0.273 p=0.0006) at 3 months.

DISCUSSION

The present study is the first prospective evaluation of sexual function after surgical treatment of BPO due to larger prostates. We observed an improvement of erectile function in the GreenLEP group while the erectile function worsened over time with recurring LUTS after PVP. PVP (vs. GreenLEP) was also a predictor of significant IIEF5 decrease posoperatively (≥5 points) in multivariate analysis. Surgical technique seemed to be an independent factor of the postoperative evolution of EF. Elshal et al. reported an improvement of EF compared to the control group with HoLEP in patients with a mean prostate volume of 132 ±54 grams [12]. However, in a subgroup of patients with a normal baseline IIEF5 score, EF had decreased at the 12th month of follow-up. The same author described in a previous study a decline of EF in 17.2% of HoLEP group vs 29.3% of patients in the PVP group [16]. Univariate analysis had identified baseline IIEF5 score as an independent factor of erectile function decline. In our study, two patients in the GreenLEP group and nineteen in the PVP group had a lowered postoperative EF score (p<0.001). Interestingly, mean initial IIEF5 in these patients was 19.7±4.8 vs 13.1±6.7 (p<0.001). With monopolar or bipolar TURP, Akman et al. also showed 17.0% of patients with worsening EF after surgery [17]. This finding has also been reported after PVP. Most studies showed a comparable baseline vs. postoperative EF [18]. However, Bruyere et al. and Kumar et al. reported a significant decrease in IIEF5 score in the sub-group of men with normal baseline EF [13,19]. Underlying assumptions were thermal damage to proximal cavernosal nerves during procedures, and the role of cardiovascular comorbidity such as diabetes [20]. We could easily explain a surgical stress in the early postoperative period in patients with normal initial EF, affecting their sexual life.

Erectile function remains a narrow vision of sexual life [21]. There is multidimensional aspects of the sexuality, desire or libido, orgasm, happiness, ejaculatory function that are not addressed by an erectile score such as the IIEF5 [22]. The present study reported a rate of antegrade ejaculation in 26.9% and 1.2% of patients in PVP and GreenLEP groups, respectively. Conversely the evolution of IIEF5 score postoperatively favored the GreenLEP group. For urologists, main objective in the management of LUTS due to larger prostates remains an anatomic treatment of the

adenoma to avoid the risk of recurring LUTS due to residual adenoma and a compromise with persistent antegrade ejaculation [9]. Since McVary's works, relationship between LUTS and ED are now acknowledged by all [23]. Nitric oxide (NO) decrease in prostate and penile smooth muscle remains the pharmacological target of PDE5-inhibotors in LUTS and DE medical treatments [24].

In our cohort, initial prostate volumes were comparable in both groups. Mean energy delivered in PVP group was 4.42 KJ/gram. In an international multicenter study, energy delivered over 3KJ/gram provided a PSA reduction over 50 percent. Higher energy > 7KJ/g seemed to reduce PSA up to 83%. Using high energy density was not associated with higher rate of perioperative complications [25]. The same rate of re-treatment was observed all groups. Postoperative PSA reduction is considered as a great surrogate of the prostatic volume treated for Greenlight users.

Actually, there are few studies showing the outcome of GreenLEP. Among them, GreenLEP seemed to have a superiority in term of re-treatment rate [26]. In our study, ten percent of patients in the PVP group required another medical or surgical treatment of LUTS after a median follow-up of 25.1 months. Using PVP 180W laser, Meskawi et al. recently reported in a multicenter study a re-treatment rate of 5.4% and 9.3% at 24 and 36 months, respectively [27]. Hueber et al. reported this rate from 1.0 to 1.2 at 12 and 24 months of follow-up, respectively, Calves et al., a rate of 4.8% with a mean follow-up of 57.4 \pm 6.8 months in smaller prostate volumes [7] [28]. Most of these re-treated patients experienced a lower energy delivered to the tissue, a lower postoperative PSA reduction and had a higher prostate volume. Our findings reinforce the existing evidence regarding the poor reliability of PVP in larger prostates with high retreatment rate in the medium to long run.

Our poorer outcomes regarding EF and IIEF-5 in the PVP group could be explained by this rate of re-treatment and recurring LUTS. This relationship was underlined with statically correlation between postoperative Δ Nocturia, Δ IPSS and Δ IIEF-5 (p<0.0001 and p<0.0006, respectively). This association between LUTS and EF is well depicted in many epidemiologic studies [1].

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Cardiovascular disease (CVD), age, hypertension and coronary disease, were also reported as predictive factors of worsening EF. Erectile dysfunction (ED) and CVD share common risk factors included diabetes, hypertension, age, obesity, metabolic syndrome hypercholesterolemia, sedentary lifestyle and depression [29]. They also share the same pathophysiology basis. Despite atherosclerotic burden, subclinical cavernosal inflammation, endothelial dysfunction and androgen deprivation interactions were clearly advocated. According to the "artery size" hypothesis, the smaller penile arteries suffer earlier than larger coronary arteries [30]. ED is now recognized as an early predictor of coronary artery disease [29].

The present study has several limitations that should be acknowledged. We evaluated the impact of modern and minimally laser treatments in BPO-related LUTS using PVP 180W and GreenLEP with a minimal erectile function score (IIEF-5) and ejaculatory status alone. Larger sexual function scores as IIEF-15 score, Danish Prostatic Symptom Score (Dan-PSS-Sex) or Ej-MSHQ (Ejaculation domain-male sexual health questionnaire) may have provided a more appropriate assessement of sexual function. Moreover, although statistically significant, the clinical significance of the difference in post-operative IEEF 5 evolution between the two groups could be called into question. Another possible shortcoming is that follow-up was not comparable in both groups with only 18.6 months in the GreenLEP group. A prospective controlled study could provide a more accurate comparative evaluation of the sexual impact of these two surgical procedures. The relatively limited number of events for the primary outcomes (21 patients had a decline of more than 5 points in the IIEF5) resulted in an underpowered multivariate assessment. Finally, owing to the increasing evidence on the poorer outcomes of PVP in larger glands, the two techniques compared herein (PVP and GreenLEP) could be seen as indicated for different patients' population and the clinical relevance of their comparison could therefore be regarded as debatable.

CONCLUSION

In this first prospective comparison of erectile function after surgical treatment of BPO due to larger prostates, we found a significant improvement of IIEF5

postoperatively in the GreenLEP group despite a poor rate of preserved antegrade ejaculation. Conversely erectile function slightly declined in the PVP group over time, concomitantly to recurring LUTS. Age, history of CAD, and surgical treatment of BPO with PVP (vs. GreenLEP) were independent predictors of significant IIEF5 decline (\geq 5). Further studies are needed to confirm our findings and the potential impact of recurring LUTS after PVP on erectile function.

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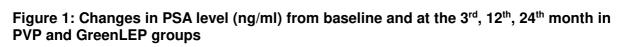
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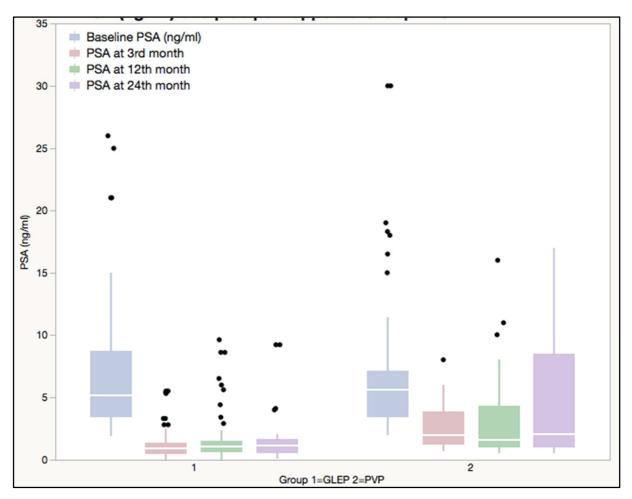


Table 1: Patients Characteristics

	GreenLEP n=100	PVP n=100	p value				
Age (years)	68 (66-69)	68 (67-70)	0.216				
ASA score							
1	41 (41.4)	26 (31.3)	0.279				
2	55 (55.6)	52 (62.6)					
3	3 (3.0)	5 (6.1)					
Hypertension	54 (54.0)	51 (53.1)	0.902				
Smoking	16 (16.0)	14 (14.6)	0.783				
Diabetes	14 (14.0)	11 (11.5)	0.593				
Preoperative							
indwelling	16 (16.2) 17 (19.5)		0.547				
catheter							
Alpha-blockers	70 (70.7)	55 (63.2)	0.278				
5-ARI	32 (32.3)	27 (32.1)	0.979				
Warfarin	1 (1.0)	3 (3.4)	0.253				
Aspirin	28 (28.3)	20 (25.8)	0.410				
n (%). data are mean (95%CI). p value : Mann-Whitney or Chi-							
2 Test							
GreenLEP: Greenlight Enucleation of the prostate. PVP: Photoselective Vaporization of the prostate. ASA score: American Society of Anesthesiology. 5-ARI: 5alpha reductase Inhibitor							

	Baseline (n=186)		3 months (n=151)		12 months (n=115)		24 months (n=89)	
	GLEP	PVP	GLEP	PVP	GLEP	PVP	GLEP	PVP
IIEF5 score <i>p value</i>	13.6 ±6.9	14.1 ±6.8 <i>0.619</i>	15.7 ±6.2	14.2 ±6.7 <i>0.123</i>	16.3 ±6.5	13.2 ±7.1 <i>0.009</i>	15.8 ±5.8	13.2 ±7.1 <i>0.061</i>
∆ IIEF5 <i>p value</i>	-	-	1.1 ±2.3	-0.6 ±3.1 <i><0.001</i>	1.3 ±2.2	-1.1 ±3.3 <i><0.001</i>	0.7 ±2.1	-1.0 ±3.3 <i>0.002</i>
n (%). data are mean (IC 95%). p value : Mann-Whitney between GLEP and PVP groups								
GreenLEP: Greenlight Enucleation of the prostate. PVP: Photoselective Vaporization of the prostate.								

Table 2: Changes in International Index of Erectile Fonction–5 (IIEF5 score) from baseline at the third, 12th and 24th month of follow-up.

Independent variable	Univariate				Multivariate		
	OR	(95% CI)	p value	OR	(95% CI)	p value	
Age	2.0 5	(1.11-2.15)	0.001	1.2 2	(1.04- 1.43)	0.007	
Hypertension	4.9 4	(1.05-23.3)	0.04	3.6	(0.9-14)	0.074	
Coronary artery disease	4.3	(1.03-18.3)	0.045	3.6	(1.7-74.4)	0.021	
Surgical technique PVP GLEP=Reference	15. 4	(1.9-121.5)	0.009	12. 3	(1.5- 101.9)	0.019	
Δ Nocturia >2	7.8	(1.9-31.7)	0.004	3.4	(0.7-15.2)	0.107	
Δ IPSS < 5	1.8 5	(0.51-6.75)	0.347		-		
Persistent antegrade ejaculation	2.2	(0.2-22.7)	0.499		-		
n (%). data are mean (95%CI). p value : Mann-Whitney between GLEP and PVP							
groups GreenLEP: Greenlight Enucleation of the prostate. PVP: Photoselective Vaporization of the prostate. IPSS: International Prostate Symptom Score. BMI: Body Mass Index							

Table 3: Univariate and multivariate logistic regression analysis for risk of postoperative IIEF5 decline \geq 5 points