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ORIGINAL PAPER

The safety and feasibility of the simultaneous use of 180-W GreenLight laser for prostate vaporization during concomitant surgery

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Summary *Objectives: To explore the safety and feasibility of photo-selective vaporization of the prostate (PVP) with GreenLight XPS 180 Watt laser (GL-180-W XPS) combined with other surgical procedures.*
Material and methods: Data on patients in whom GL-180-W XPS was performed to relieve lower urinary tract symptoms/ benign prostatic hyperplasia (LUTS/BPH) symptoms were extracted from a multi-institutional database (2011-2016). Patients were stratified into two groups. In the first all patients who had GL-180-W XPS with a concomitant procedure during the same surgical session were included as cases while those who underwent GL-180-W XPS PVP only were included as control.
Results: A total of 487 patients were included. Fifty-eight (11.9%) patients underwent concomitant procedures. Multivariable linear regression models failed to find an association between concomitant procedures and longer laser time (p = 0.4). Similarly, multivariable linear regression models failed to find an association between concomitant procedures and laser time even when the analyses were repeated and stratified into endoscopic (p = 0.6) and open/laparoscopic (p = 0.4) procedures. Multivariable logistic regression models failed to demonstrate any association between concomitant procedures and early complications (OR:1.39, CI: 0.379-2.44, p = 0.2), late complications (OR:1.84, CI:0.78-3.98; p = 0.1) and acute urinary retention (OR:1.84, CI:0.78-3.98; p = 0.1). When the analyses were repeated and the concomitant procedures stratified into endoscopic and open/laparoscopic ones, they yielded virtually the same results.
Conclusions: GL-180-W XPS PVP could be safely performed in concomitant endoscopic or open/laparoscopic surgery. These results should be taken into consideration in the counseling of the patient who might choose to undergo simultaneous procedures.

KEY WORDS: *GreenLight laser; Concomitant procedures; LUTS/BPH; Simultaneous surgery.*

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INTRODUCTION

Lower urinary tract symptoms (LUTS) are strongly associated with ageing (1) and might be the most evident consequence of *benign prostatic hyperplasia* (LUTS/BPH). LUTS/BPH, when related to *bladder outlet obstruction* (BOO), are often caused by *benign prostatic enlargement* (BPE) (2). A surgical treatment is often necessary in LUTS/BPH patients who experience low efficacy of pharmacological therapies or want to discontinue these therapies (3). Moreover, some patients may have already progressed and/or experienced LUTS/BPH complications, such as bladder diverticula or vesical calculi before surgery (4). Furthermore, since patients with LUTS/BPH are usually aged, other conditions such inguinal hernia may require supplementary surgical treatment (4).
Nowadays, *photoselective vaporization of the prostate* (PVP) with *GreenLight XPS 180 Watt laser* (GL-180-W XPS) (*American Medical Systems, Minnetonka, Minnesota, USA*) is considered a valid alternative to TURP, thanks to its safeness and efficacy (5). Moreover, the GL-180-W XPS PVP guarantees an early discharge and limits the need for blood transfusion (6-8). Currently, little evidence on the safety, efficacy and feasibility of PVP with other concomitant procedures are available. This evidence derived mostly from single center or case series reports (9, 10).
The aim of this study is to evaluate the safety and feasibility of GL-180-W XPS PVP combined with other surgical procedures. Moreover, we aim to test the effect of simultaneous procedures on perioperative outcomes, functional outcomes and complication rates.

MATERIALS AND METHODS

Data on patients in whom PVP was performed to relieve LUTS/BPH symptoms were abstracted from a multi-institutional database (2011-2016). Patients were stratified into two groups. In the first group, all patients who had PVP with a concomitant procedure during the same surgical session were included as cases. In the second group,

L. Cindolo and G. Ferrari do surgical tutorship for AMS and received honoraria for their tutorship.

all patients who underwent only simple PVP were included as controls. PVP procedures were performed according to the techniques previously described by Gomez-Sancha and following the surgeons' preferences (11).
The characteristics of patients collected at the time of surgery were age, LUTS/BPH drug therapy, antiplatelet/anticoagulant therapy, ASA score. Moreover, prostate volume, PSA levels, *International Prostate Symptom Score* (IPSS), maximum urinary flow (Q_{max}) and indwelling catheter history before surgery were recorded. Intra- and perioperative data, including anesthesia type, laser time, energy used, catheterization time and postoperative stay were noted. The laser time referred only to the time from the beginning to the end of laser prostate vaporization. All the patients underwent an outpatient clinic visit at least after 3 months and then annually. During the follow-up visit, IPSS, Q_{max}, and PSA levels were recorded.
The *Patient Global Impression of Improvement* (PGI-I) was evaluated with the PGI-I scale (12). Complications were collected and classified as early (within 30 post-operative days) or late (after 90 days). Early complications were classified according to the Clavien-Dindo system (13, 14).
Our study has been reported in line with the STROCCS criteria (15). Written informed consent was obtained from all subjects and for this study ethical committee approval was given.

Statistical analysis

Descriptive statistics relied on median and interquartile ranges for qualitative covariates and on count and percentages (%) for categorical variables. Differences between groups were assessed with the chi-square test for categorical variables and the Mann-Whitney U test for continuous variables. Three sets of analyses were performed. First, multivariable linear regression models examined the effect of concomitant procedures on the laser time. Second, separate multivariable logistic regression models tested the effect of concomitant procedures on the rates of early complications, late complications and acute urinary retention. Third, all the analyses were repeated after using a different coding that stratified the concomitant procedures into endoscopic versus open/laparoscopic ones. All the multivariable models were adjusted for age and prostate volume. All statistical tests were two-sided. The level of significance was set at $p < 0.05$. Analyses were performed using the R software environment for statistical computing and graphics (*version 3.4.3; http://www.r-project.org/*).

Results

Preoperative and post-operative descriptive analyses

In total 487 patients were included. Out of them 58 (11.9%) underwent a PVP and a concomitant procedure during the same anesthesia. Twenty-nine endoscopic and 29 open/laparoscopic concomitant procedures were performed (Table 1). Patients who underwent concomitant procedures had a more frequent history of an indwelling catheter (36.2 *vs.* 21.2%, p = 0.02). Moreover, patients with concomitant procedure were more frequently treated for LUTS/BPH symptoms (31 *vs.* 18.4%, p = 0.02) (Table 2). Patients who underwent PVP in association with other endoscopic procedures were more frequently diagnosed with smaller prostate glands (median volume 50.0 *vs.* 60.0 mL; p = 0.020) and had more frequently an history of indwelling catheter (41.4 *vs.* 21.2%, p = 0.012 (Supplementary Table 1).
After the surgery, significant statistical differences were found for the indwelling catheter time which was longer in patients who underwent concomitant procedures (2 *vs.* 1 day, p = 0.006). Moreover, the ΔIPSS was slightly wider for patients who underwent concomitant procedures (-20 *vs.* -18, p = 0.03) than in those who underwent simple PVP (Table 3). No differences between the two groups were found in terms of an early and late complication rate (p = 0.3 and p = 0.07 respectively) (Table 3).
Acute urinary retention occurred in 8.4 and 15.5 patients after simple PVP and PVP with concomitant procedure, respectively (p = 0.1). ΔUFM was not statistically significant different between two groups (p = 0.4). Most of the patients (56.7%) had no complications at all; among patients with complications the wide majority was graded as Clavien-Dindo I (40.7%) (Tables 3, 4). Consistently we found no statistically significant differences in terms of

Table 1.
Concomitant procedures.

Concomitant procedure	Numbers of procedures	Kind of surgery
Vescical lithotripsy	13	Endoscopic
Internal Urethrotomy	8	Endoscopic
TURB	5	Endoscopic
Vescical botulinum	3	Endoscopic
Inguinal hernia repair	24	Laparoscopic/open
Colecistectomy	2	Laparoscopic/open
Hydrocelectomy	2	Laparoscopic/open
Laparoscopic bladder diverticulectomy	1	Laparoscopic/open

Table 2.
Demographic and clinical characteristics of patients before photo-selective vaporization of the prostate stratified according to the surgical procedure (PVP vs PVP + concomitant procedures). Quantitative variables are reported as median and interquartile ranges (IQR). Qualitative variables are reported as count and percentages (%).

	Overall (n = 487)	PVP (n = 429)	PVP + Concomitant procedures (n = 58)	p-value
Preoperative parameters				
Age, years	70 (64-76)	70 (64-77)	70.5 (65.2-76)	0.8
Follow-up duration, months	17 (11-23,5)	18 (11-24.6)	14.5 (8-19.8)	**< 0.001**
Prostate volume, mL (missing = 3)	60 (43.8-80)	60 (45-80)	52 (40-74)	0.05
PSA, ng/mL (missing = 58)	2.7 (1.3-4.5)	2,7 (1.3-1.4)	2.5 (1-5.1)	0.7
Q_{max}, mL/s (missing = 116)	8 (6-10)	8 (6,1-10)	7.6 (6.3-10)	0.2
IPSS (missing = 118)	25 (21-28)	25 (21-28)	26 (20.5-33.5)	0.05
ASA score				0.05
1-2	259 (53.2)	220 (51.3)	39 (67.2)	
3-4	93 (19.1)	83 (19.3)	10 (17.2)	
Unknown	135 (27.7)	126 (29.4)	9 (15.5)	
History of catheterization	112 (23)	91 (21.2)	21 (36.2)	**0.02**
BPH therapy				**0.02**
5-ARI	15 (3.1)	12 (2.8)	3 (5.2)	
Alfa-blocker	236 (48.5)	207 (48.3)	29 (50)	
Combination therapy	139 (28.5)	131 (30.5)	8 (13.8)	
None	97 (19.9)	79 (18.4)	18 (31)	

Supplementary Table 1.
Demographic and clinical characteristics of patients before photoselective vaporization of the prostate stratified according to the surgical procedure (PVP vs PVP + other endoscopic procedures). Quantitative variables are reported as median and interquartile ranges (IQR). Qualitative variables are reported as count and percentages (%).

	PVP (n = 429)	PVP + Other endoscopic procedures (n = 29)	p-value
Age, years	70.0 (64.0, 77.0)	72.0 (67.0, 76.0)	0.546
Prostate volume, mL	60.0 (45.0, 80.0)	50.0 (35.0, 67.2)	**0.020**
PSA, ng/mL	2.7 (1.3, 4.4)	1.4 (1.0, 3.6)	0.133
Qmax, mL/s	8.0 (6.1, 10.0)	8.6 (7.0, 11.0)	0.573
IPSS	25.0 (21.0, 28.0)	23.0 (20.0, 30.0)	0.954
ASA score			0.477
- 1-2	220 (51.3%)	17 (58.6%)	
- 3-4	83 (19.3%)	3 (10.3%)	
- Unknown	126 (29.4%)	9 (31.0%)	
History of catheterization	91 (21.2%)	12 (41.4%)	**0.012**
BPH therapy			0.163
- 5-ARI	12 (2.8%)	3 (10.3%)	
- Alfa-blocker	207 (48.3%)	14 (48.3%)	
- Combination therapy	131 (30.5%)	8 (27.6%)	
- None	79 (18.4%)	4 (13.8%)	

Supplementary Table 2.
Demographic and clinical characteristics of patients during and after photoselective vaporization of the prostate stratified according to the surgical procedure (PVP vs PVP + other endoscopic procedures). Quantitative variables are reported as median and interquartile ranges (IQR). Qualitative variables are reported as count and percentages (%).

	PVP (n = 429)	PVP + Other endoscopic procedures (n = 29)	p-value
Laser time (min)	27.0 (18.0, 38.2)	20.5 (17.0, 33.5)	0.250
Energy used (Kj)	247.1 (157.1, 360.0)	193.0 (148.8, 337.7)	0.442
Discharge day	2.0 (1.0, 2.0)	2.0 (1.0, 2.0)	0.838
Catheter removal day	1.0 (1.0, 2.0)	2.0 (1.0, 3.0)	0.079
Δ PSA, ng/mL	-1.3 (-2.9, -0.2)	-0.7 (-1.8, -0.3)	0.207
Δ Q_{max}, mL/s	11.0 (7.0, 14.0)	8.2 (1.8, 12.8)	0.076
Δ IPSS	-18.0 (-23.0, -14.0)	-16.0 (-25.0, -13.0)	0.691
Acute urinary retention	36 (8.4%)	5 (17.2%)	0.106
Late complications	73 (17.0%)	8 (27.6%)	0.149
Early complication	182 (42.4%)	12 (41.4%)	0.912
Satisfaction			0.617
Not satisfied	16 (3.7%)	2 (6.9%)	
Satisfied	388 (90.4%)	26 (89.7%)	
Unknown	25 (5.8%)	1 (3.4%)	
Clavien-Dindo classification			0.356
0	247 (57.6%)	17 (58.6%)	
1	170 (39.6%)	11 (37.9%)	
2	2 (0.5%)	0 (0.0%)	
3a	2 (0.5%)	1 (3.4%)	
4a	8 (1.9%)	0 (0.0%)	

main postoperative outcomes when PVP patients were compared to those who had PVP in association with other endoscopic procedures (Supplementary Table 2).

Multivariable linear regression models

Multivariable linear regression models failed to find an association between concomitant procedures and longer laser time (coefficient 1.59, -1.90 to 5.08; p = 0.4).

Table 3.
Demographic and clinical characteristics of patients during and after photoselective vaporization of the prostate stratified according to the surgical procedure (PVP vs PVP + concomitant procedures). Quantitative variables are reported as median and interquartile ranges (IQR). Qualitative variables are reported as count and percentages (%).

	Overall (n = 487)	PVP (n = 429)	PVP + Concomitant procedures (n = 58)	p-value
Peri- and post-operative features				
Laser time (min) (missing = 26)	27 (18-37)	27 (18-38.2)	25 (18.4-34.2)	0.6
Energy used (Kj) (missing = 5)	246.6	247.1 (157.1-360)	242.4 (169.0-336.1)	0.7
Discharge day	2 (1-2)	2 (1-2)	2 (1-2)	0.7
Catheter removal day	1 (1-2)	1 (1-2)	2 (1-2,8)	**0.006**
Δ PSA, ng/mL	-1.3 (-3 to -0.3)	-1.3 (-2.9 to -0.2)	-1.1 (-3.0 to -0.5)	0.5
Δ Q_{max}, mL/s	11 (7-14)	11 (7-14)	12.6 (8.6-13.7)	0.4
Δ IPSS	-18 (-24 to -14)	-18 (-23 to -24)	-20 (-27.5 to -14)	**0.03**
Acute urinary retention	45 (9.2)	36 (8.4)	9 (15.5)	0.1
Late complications	89 (18.3)	73 (17)	16 (27.6)	0.07
Early complication	211 (43.3)	182 (42.4)	29 (50)	0.3
Satisfaction				0.5
Not satisfied	20 (4.1)	16 (3.7)	4 (6.9)	
Satisfied	439 (90.1)	388 (90.4)	51 (87.9)	
Unknown	28 (5.7)	25 (5.8)	3 (5.2)	
Clavien-Dindo classification				0.4
0	276 (56.7)	247 (57.6)	29 (50)	
1	198 (40.7)	170 (39.6)	28 (48.3)	
2	2 (0.4)	2 (0.5)	0 (0)	
3a	3 (0.6)	2 (0.5)	1 (1.7)	
4a	8 (1.6)	8 (1.9)	0 (0)	

Table 4.
Early and late complications according to the surgical procedure (PVP vs PVP + concomitant procedures). Qualitative variables are reported as count and percentages (%).

Early complications	Overall	PVP	PVP + Concomitant procedures
Fever (< 38°C)	13 (2.7)	12 (2.8)	1 (1.7)
Fever (≥ 38°C)	15 (3.1)	11 (2.6)	4 (6.9)
Burning urination	74 (15.2)	61 (14.2)	13 (22.4)
Bladder tenesmus	37 (7.6)	32 (7.5)	5 (8.6)
Urge	42 (8.6)	36 (8.4)	6 (10.3)
Urge incontinence	47 (9.7)	37 (8.6)	10 (17.2)
Stress incontinence	36 (7.4)	30 (7)	6 (10.3)
Capsule perforation	6 (1.2)	5 (1.2)	1 (1.7)
Hematuria	16 (3.3)	16 (3.7)	0 (0)
Acute urinary retention	45 (9.2)	36 (8.4)	9 (15.5)
Urinary tract infections	7 (1.4)	7 (1.6)	0 (0)
Blood transfusion	3 (0.6)	3 (0.7)	0 (0)
Cardiovascular acute event	13 (2.7)	13 (3)	0 (0)
Minor cardiovascular event	5 (1)	5 (1.2)	0 (0)
Major acute cardiovascular event	8 (1.6)	8 (1.9)	0 (0)
Late complications			
Urethral stenosis	14 (2.9)	11 (2.6)	3 (5.2)
Bladder neck contracture	18 (3.7)	14 (3.3)	4 (6.9)
Prostatic fossa sclerosis	8 (1.6)	8 (1.9)	0 (0)
Urinary stress incontinence	27 (5.5)	23 (5.4)	4 (6.9)
Re-intervention	10 (2.1)	7 (1.6)	3 (5.2)
Persistent irritative symptoms	28 (5.7)	22 (5.1)	6 (10.3)
Urethral stenosis	14 (2.9)	11 (2.6)	3 (5.2)
Bladder neck contracture	18 (3.7)	14 (3.3)	4 (6.9)

Similarly, multivariable linear regression models failed to find an association between concomitant procedures and

Table 5.
Multivariable logistic regression (adjusted for prostate volume and patient age), concomitant procedures endoscopic and other vs. standard.

Outcomes		Odds ratio (95% confidence interval)			
		Univariable	p-value	Multivariable	p-value
Early complications					
	Standard	Reference		Reference	
	Endoscopic	0.96 (0.44-2.04)	0.9	0.99 (0.45-2.16)	0.9
	Laparoscopic/open	1.92 (0.90-4.22)	0.09	1.91 (0.89-4.21)	0.09
Late complications					
	Standard	Reference		Reference	
	Endoscopic	1.86 (0.75-4.21)	0.15	1.95 (0.77-4.49)	0.1
	Laparoscopic/Open	1.86 (0.75-4.21)	0.15	1.85 (0.75-4.20)	0.2
Acute urinary retention					
	Standard	Reference		Reference	
	Endoscopic	2.27 (0.73-5.89)	0.1	1.91 (0.60-5.11)	0.2
	Laparoscopic/open	1.75 (0.49-4.81)	0.3	1.76 (0.49-4.97)	0.3

laser time even when the analyses were repeated and the concomitant procedures stratified into endoscopic (coefficient 1.21, -3.50 to 5.92, p = 0.6) and open/laparoscopic (coefficient 1.99, -2.88 to 6.85, p = 0.4) ones.

Multivariable logistic regression models

Multivariable logistic regression models failed to demonstrate any association between concomitant procedures and early complications (OR: 1.39, CI: 0.38-2.44, p = 0.2), late complications (OR: 1.84, CI: 0.78-3.98; p = 0.1) and acute urinary retention (OR: 1.84, CI: 0.78-3.98; p = 0.1). When the analyses were repeated and the concomitant procedures were stratified into endoscopic and open/laparoscopic ones, they yielded virtually the same results (Table 5).

Discussion

We hypothesized that PVP combined with other surgical procedures is feasible and safe. To test our hypothesis, we compared functional and surgical outcomes of patients who underwent PVP combined with other surgical procedures, with those who underwent PVP only. Data were abstracted from a large multi-institutional database. Our analyses showed several important findings.

First, the proportion of patients with a history of catheterization was higher in the concomitant procedure group compared to the standard procedure group (36.2 *vs.* 21.2%). However, the proportion of patients not pharmacologically treated was also higher in the concomitant procedure compared to the standard procedure (31.0 *vs.* 18.4%). This finding is of interest because suggests that patients undergoing concomitant procedures could be less compliant to chronic treatments or physicians less prone to prescribe medications in those who are candidate to combination surgery with an history of indwelling catheter. It is worth of consideration the fact that in patients with a history of an indwelling catheter, the use of an alpha-blocker reduces the risk of acute retention after catheter removal (16). Moreover, the use of combination therapy in LUTS/BPH patients reduces the risk of complications (17). Taken together these observations suggest that it might be of importance for more complex patients, such as those candidates for concomitant procedures, to continue or start LUTS/BPH therapy in order to reduce the risk of complications after surgery. Unfortunately, the granularity of our dataset do not allow to specifically investigate this hypothesis, thus larger and prospective studies investigating the effect of LUTS/BPH treatment in concomitant procedure candidates are warrant.

Second, in a multivariable linear regression model no statistically significant differences were found in laser time between the concomitant procedure and standard procedure groups. We relied on this parameter as a surrogate of surgical difficulties that may occur when more than one procedure is performed. Indeed, when concomitant procedures are performed before the PVP, especially for endoscopic treatments (i.e. vesical lithotripsy or internal urethrotomy), bleeding or access difficulties are always a possibility. Moreover, it is worth of consideration that in our study the two groups (simple PVP and concomitant procedure) had similar prostate size. In consequence, our findings suggest that the most important predictor of laser time is the prostate size. Thus, physicians should not worry to perform concomitant procedures, that do not affect the effectiveness of PVP. The latter is confirmed again by our results, which also showed no detrimental effect of concomitant procedures on overall early complications, late complications or acute urinary retention in multivariable logistic regression models. Results were virtually the same even when all the multivariable models were adjusted to the different nature of concomitant surgical procedures (standard, endoscopic and laparoscopic/open) in specific analyses.

Our findings suggest that PVP performance is not affected by other surgical procedures. Such evidence is clinically meaningful considering that almost 10% of patients need more than one treatment, according to our series. This finding corroborates those of smaller and/or more historical series. *Patel et al.* in a smaller single institutional series (N = 372, 38 underwent concomitant procedures) also showed no enucleation and morcellation time differences in patients who underwent HOLEP with concomitant procedures (4). Similarly, the feasibility of GL-180-W PVP in combination with various other procedures was shown in small series or case reports (9, 10, 18, 19).

More specifically, *De la Torre et al.* explored the feasibility of Green Light laser 80 or 120 W prostate vaporization and bladder lithotripsy with holmium laser in 19 patients. The authors showed that there was a significant improvement in terms of Q_{max}, post-micturition residual volume, and IPSS after surgery with no intra- o post-operative complications (10). In a similar study *Hora et al.* reported no peri- or post-operative complications in 8 patients who underwent laparoscopic bladder diverticulectomy and Green Light Laser HPS 120 W or XPS 180 W vaporization of prostate in one operative session (19). Taken together, our study as well as those previously discussed, show the feasibility of laser surgery and more specifically of GL-180-W PVP concomitantly with other procedures (9, 10, 18-20).

Third, despite the fact that preoperative IPSS was similar in a concomitant procedure compared to the standard, ΔIPSS was wider in the concomitant procedure compared to the standard procedure (-20 *vs.* -18). This finding corroborates the results of previous investigators that showed a larger improvement in terms of IPSS in patients who underwent

a concomitant procedure compared to a standard procedure (4). This finding is a novelty in the field of GL-180-W XPS PVP. Indeed, to the best of our knowledge no previous studies have investigated functional outcomes after GL-180-W XPS PVP with concomitant not urological surgical procedures. For example, *De la Torre et al.* related the use of Green Light laser 80 or 120 W prostate vaporization and bladder lithotripsy with holmium laser, *Hora et al.* Green Light Laser HPS 120 W or XPS 180 W with bladder diverticulectomy and Cindolo et al related the feasibility of GL-180-W XPSPVP associated to robot-assisted laparoscopic diverticulectomy (9, 10, 19).
It might be hypothesized that in patients with concomitant pathological conditions the relief from multiple comorbidities may exert a positive effect also on IPSS, which is wider than in patients with LUTS/BPH only.
Nevertheless, this study has several limitations. The major limitations are related to its retrospective study and the fact that non-randomized design and different surgical experience could not be controlled in the analytic phase. Further limitations included the not standardized pre- and post-operative patient management. Similarly, the assessment and management of the complications may vary according to the different centres.

Conclusions

Our study underlines how GL-180-W XPS PVP could be safely performed in concomitant endoscopic or open surgery. These results should be taken into consideration in the counseling of the patient who might choose to undergo simultaneous procedures. Further studies are warranted to confirm our results.

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