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ORIGINAL ARTICLE

Green light laser enucleation of the prostate with early apical release is safe and effective: single center experience and revision of the literature

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ABSTRACT

BACKGROUND: Green Light laser enucleation of the prostate (GreenLEP) is an endoscopic treatment to treat bladder outlet obstruction in men with large prostate (>100 cc). Herein, we describe our GreenLEP series and describe its safety and efficacy.

METHODS: Between February 2014 and April 2019, 120 patients from a single center underwent *en-bloc* GreenLEP with early apical release. All procedures were performed with the AMS XPS laser generator (set: 120 W for vaporization and 20 W for coagulation). Morcellation was carried out with the Wolf Piranha morcellator. Data concerning the pre-, intra- and postoperative outcomes were prospectively collected. The follow-up data at 6, 12 months and at the last control were collected.

RESULTS: The median age was 66.0 (IQR: 61.0-71.0) years; 37.5% of the patients were under antiplatelet/anticoagulant therapy, 15.0% had indwelling catheter history. The median prostate volume and the baseline PSA value were 98.5 mL (IQR 83.0-130.0) and 4.2 ng/mL (IQR: 3.2-6.8), respectively. The median operative and lasing time were 65.0 (IQR: 51.0-83.5) and 6.0 (IQR: 6.0-10.0) minutes, respectively. In the postoperative period 1 patient was transfused. The median follow-up was 18.0 (IQR: 12.0-39.5) months. All patients had significant improvement in terms of improvement of uroflowmetry (median from 9 mL/sec [IQR 7.8, 11.0] to 20.0 [IQR 18.0, 22.0], P<0.001) and symptoms control (IPSS median score from 26.0 mL/sec [IQR 22.0, 28.0] to 7.0 [IQR 6.0, 8.0], P<0.001]) over time. After 12 months 1 patient complained of stress incontinence (1 pad/day) and 1 of "de novo" wet urgency.

CONCLUSIONS: *En-bloc* GreenLEP with early apical release is a safe and effective procedure even for large volume prostates. It allows us to limit the use of laser energy and shorten the operating times with stable and satisfactory long-term outcomes.

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KEY WORDS: Lasers; Prostate; Endoscopy.

Lower urinary tract symptoms (LUTS) have a high prevalence in men over 50 years of age, bring about a noticeable worsening of the quality of life and a considerable health expenditure.[1] The European Association of Urology (EAU), as well as the American Urological Association (AUA) guidelines suggest that transurethral resection of the prostate (TURP) is one of the gold

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standards for the treatment of bladder outlet output (BOO) /benign prostatic hyperplasia (BPH) associated LUTS.[2, 3] TURP is characterized by excellent surgical and functional results, however relatively high comorbidity rates have been reported when this approach is used in patients with larger glands.[4]

Since 2016, the Endoscopic Enucleation of the Prostate (EEP) has been supported as one possible gold standard in the treatment of BPO in patients with middle and large prostatic adenomas, safely and efficiently replacing the open adenectomy.[2-5] EEP can be performed with bipolar plasmakinetic energy as well as with all the available laser sources (holmium YAG [HoLEP], thulium [ThuLEP] and Green light [GreenLEP]), with durable efficacy outcomes (IPSS and Qmax), and safety profiles (transfusion, infection, stricture, etc.). Even if the functional data and the objective success rate seem to be equivalent, unfortunately the scientific evidence is still limited with regard to direct comparison of the different power sources, especially for the new ones.[6, 7]

In particular, the Green Light Laser is easily absorbed by the hemoglobin of the soft tissues, which leads to a better coagulation, optimal hemostasis and limited deep tissue injuries.[8] Gomez-Sancha has explored the possibilities of the Green Light Laser in depth, considering its versatility and by describing different techniques.[8] As part of a gradual learning curve, it has the potential to be developed in three stages from standard vaporization to anatomical vaporization and finally to enucleation. In different studies we had already demonstrated the flexibility of this energy source by highlighting the interesting and durable results in different patient populations.[8-11] Benefits of GreenLEP include: clearer definition of the surgical capsule (lack of disruption with mechanical peeling), minimal transfer of thermal energy to the capsule (decreased dysuria), and a shorter surgical learning curve (ability to transition to vapoenucleation/vaporization during surgery).[12]

Nowadays, there is a growing body of literature focusing on GreenLEP, however most of the available studies are limited by the small cohorts and the relatively short follow-up.[12]Taking all this into consideration, we aimed to systematically describe midterm functional outcomes after GreenLEP.

Materials and methods

After the approval of the local ethical committee, we carried out a retrospective analysis of the institutional, prospectively-maintained database of all patients who underwent *en-bloc* GreenLEP for refractory LUTS caused by medically treated BPH of any volume. Surgical procedures were completed from February 2014 to April 2019 at the Urology Department of Hesperia Hospital of Modena. Patients with missing preoperative data were excluded from the analyses. All procedures were performed under general or spinal anesthesia by three experienced surgeons (defined as surgeons who had done more than 300 Green Light Laser procedures). Preoperative antibiotic prophylaxis was administered to all patients, according to local practice guidelines.

The preoperative variables of age, medical history, American Society of Anesthesiology score (ASA Score), antiplatelet and anticoagulant medication, previous medical history of LUTS/BPH (use of alpha-blockers and/or inhibitors of 5-alpha reductase), IPSS score, uroflowmetry (Q_{max}) and post void residual with serum prostate-specific antigen level (PSA) were collected. The intraoperative characteristics, total operative time, lasing time, energy use (kJ) and number of fibers used were also recorded as well as the amount of morcellated tissue and the final histopathological report. The surgical armamentarium was AMS XPS Laser (Boston Scientific Corporation, Marlborough, MA, USA), Laser Fiber 2090 (set: 120 W for vaporization and 20 W for coagulation), with a dedicated 30° Wolf 24.5Ch double-flow steel tip endoscope. The morcellator Piranha (Richard Wolf GmbH, Knittlingen, Germany) was used in all cases.

The surgical strategy of *en-bloc* GreenLEP with early apical release technique was clearly defined[13] and applied in all the procedures. After sterilization of the skin and surgical draping, with the patient in the lithotomy position, a sterile lubricant gel is instilled into the urethra.[6, 13] A diagnostic cystoscopy is performed to exclude

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urethral stricture or other bladder diseases and to recognize ureteral orifices and the anatomical landmarks (cranial urethral sphincter and verumontanum caudally). The procedure begins by marking circumferential limits between the adenoma and sphincter with the use of coagulation. After this first gentle incision, maintaining a safe distance from the external sphincter, the groove is progressively deepened upwards to establish a clear separation between the sphincter and the prostatic apex, sparing the urethral crest.

Moving from the lateral part of the verumontanum, the combined use of a laser fiber and the mechanical action of a resectoscope tip allows for a surgical plane. These incisions are joined to the previously made anterior incision until the prostate apex is completely released and starts retracting.

The enucleation continues with the retrograde development of a plane between the adenoma and the prostatic capsule starting in the direction of the bladder neck, with a progressive coagulation of vessels and fibrous bridges. The access to the bladder is done at the level of the bladder neck, which is incised circumferentially, taking care to protect the ureteral orifices and the posterior lip of the bladder neck (avoiding major disconnection between the prostate capsule and bladder wall).

The adenoma is then separated from the prostatic capsule up to the bladder. Lastly, the urethral crest is incised. Once the enucleation is completed the prostatic adenoma is pushed into the bladder and a good hemostasis is reached by laser coagulation of small vessels until the outflow is clear. The Piranha morcellator is inserted and carefully used to extract the adenoma chips. In order to minimize the bleeding due to the decompression of the bladder during insertion of the morcellator, the change of the optic and the insertion of the morcellator should be performed only after the addition of a second irrigation tube for adequate bladder distension. At the end of the procedure a 3-way Dufour catheter is left in situ and the bladder gently irrigated for 24 hours. The patients were then discharged when the clinical conditions made it possible without a catheter (trial without a catheter usually on the 2nd postoperative day).

Follow-up visits were performed every 6 months, collecting both subjective (International Prostate Score System, IPSS) and objective (PSA and peak flow (Q_{max}) and postvoid residual) parameters.

Complications were classified as "early" (within 30 postoperative days) or as "late" (after 90 days). Early complications were catalogued according to Clavien-Dindo system.[12, 13] Urinary incontinence was defined as the reported incontinence of any degree and type (stress or urge incontinence) if bothersome and impairing the patient's quality of life.

Statistical analysis

Since Shapiro-Wilk Test showed a non-normal distribution of quantitative variables, non-parametric analyses were conducted. Descriptive statistics relied on median and interquartile range (IQR) for continuous variables and on absolute and relative frequencies for categorical variables. Boxplots graphically depicted changes in IPSS, Q_{max} and PSA from the baseline to 6 and 12 months of follow-up. To assess statistically significant changes in functional parameters and PSA over time, the Friedman test was performed. All statistical analyses were performed using R Statistical Software (version 3.6.2; R Foundation for Statistical Computing, Vienna, Austria). All tests were two-tailed, and a P value <0.05 was considered indicative of a statistically significant association.

Results

A total of 120 patients were enrolled in this study (median age: 66 years). Among these patients, 37.5% were under anticoagulant/antiplatelet drugs, 80% of them took alpha blockers or 5-alpha reductase inhibitors or both; 15% had an indwelling catheter. All patients' baseline characteristics were reported in Table I. The preoperative median IPSS was 26.0 (IQR: 22-28). The median prostate volume was 98.5 mL (≥100 cc: 48.3%). The median overall operating and lasing time were 65 and 6 min, respectively. The average number of fibers used per patient was 1. The median catheterization time was 2 days and the median length of stay was 2 days. The median

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TABLE I.—*Descriptive preoperative characteristics of the study cohort.*

Characteristics	Overall (N.=120)
Age (years) median (IQR)	66.0 (61.0, 71.0)
Volume median (IQR)	98.5 (83.0, 130.0)
Prostate volume (cc)	
<100 (cc)	62 (51.7%)
≥100 (cc)	58 (48.3%)
Prostate adenoma volume (cc) median (IQR)	77 (65.2, 110.8)
PSA (ng/mL) median (IQR)	4.2 (3.3, 7)
Preoperative anticoagulants	
None	75 (62.5%)
Antiplatelet	34 (28.3%)
Anticoagulant	11 (9.2%)
Anticoagulants	
None	75 (62.5%)
Acetilsalicilic Acid	29 (24.2%)
Clopidrogrel	5 (4.2%)
New Oral Anticoagulants	2 (1.6%)
Eparine LMW	1 (0.8%)
BPH therapy	
Alpha-blockers	63 (52.5%)
Combination therapy	30 (25.0%)
None	24 (20.0%)
5-ARIs	3 (2.5%)
History of indwelling catheter	18 (15.0%)

TABLE II.—*Descriptive perioperative characteristics.*

Characteristics	Overall (N.=120)
Anesthesia	
Loco-regional	118 (98.3%)
General	2 (1.7%)
Laser time median (IQR) (min)	8.0 (6.0, 10.0)
Operative time median (IQR) (min)	65.0 (51.0, 83.5)
Day of discharge median (IQR) (day)	2.0 (2.0, 3.0)
Urethral catheter removal median (IQR) (day)	2.0 (2.0, 3.0)
Early complications rate	37 (30.8%)
Late complications rate	2 (1.6%)

TABLE III.—*Descriptive early and late complications.*

Complications	Early	Late
Fever <38 °C (%)	4 (3.3%)	-
Fever >38 °C (%)	4 (3.3%)	-
Burning urination (%)	11 (9.2%)	-
Urinary frequency (%)	11 (9.2%)	-
Urge (%)	6 (5.0%)	-
Urge incontinence (%)	1 (0.8%)	1 (0.8%)
Stress incontinence	3 (2.5%)	1 (0.8%)

weight of morcellated tissue was 67.5 g (IQR: 55.0-87.5). The histopathological report confirmed: 116 (96.6%) benign prostatic hyperplasia, 3 (2.5%) incidental prostate cancer (Gleason score 3+3) and one case (0.8%) of malacoplakia associated with benign prostatic hyperplasia. The peri-operative outcomes are shown in Table II.

Intraoperative complications included 1 case of bladder perforation during morcellation and 1 case of cardiac arrest for which cardiopulmonary resuscitation was necessary. The first occurrence was managed by maintaining the catheter *in situ* for 4 days without sequelae. The second occurrence was conservatively managed.

In the immediate postoperative period 1 patient was transfused because of symptomatic anemia secondary to hematuria (Hb lower level 8.8 g/dL with dyspnea).

According to the Clavien-Dindo system, the most common postoperative early complications were graded as I-II (>92%). The most frequent event was burning urination and urinary frequency (9.2%) (Table III). On the other hand, after 12 months only one patient suffered from persistent stress urinary incontinence (1 pad/day) and 1 had de novo wet urgency (Table III). None of the patients needed a surgical revision for urethral stricture or residual adenoma.

The median follow-up was 18.0 (IQR: 12.0-39.5) months, with the minimum follow-up of 8.0 months. When analyzing functional results after surgery, statistically significant differences were found for all three parameters (IPSS, PSA, Qmax and PVR) which improved over time (Table IV; Figure 1, 2, 3).

Discussion

Herein, we describe the midterm functional outcomes after prostate *en-bloc* enucleation with early apical release using the Greenlight XPS 180W generator. The increased availability of this energy source has boosted the range of surgical strategies possible for BOO/BPH, allowing for ablative techniques like anatomic vaporization, vapoenucleation and enucleation of the prostate.[7] This last option can be achieved with two techniques: the *en-bloc* and the three-lobe. Considered the most challenging in terms of learning curve, the *en-bloc* enucleation has been proven to be feasible and safe, with potential technical advantages over the classic three-lobe procedure.[13, 14]

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TABLE IV.—*Functional results.*

	Baseline (N.=120)	6 Month (N.=120)	12 Month (N.=120)	P value
IPSS				<0.001
Median (IQR)	26.0 (22.0, 28.0)	7.0 (6.0, 9.0)	7.0 (6.0, 8.0)	
UFM				<0.001
Median (IQR)	9.0 (7.8, 11.0)	20.0 (18.0, 22.0)	20.0 (18.0, 22.0)	
PSA				<0.001
Median (IQR)	4.2 (3.2, 6.8)	1.5 (1.0, 2.2)	1.2 (0.9, 2.0)	
PostVoid Residual				<0.001
Median (IQR)	119 (69, 220)	36 (11, 90)	43 (17, 79)	

Q_{max} is maximum urinary flow rate calculated with uroflowmetry in mL/s. PostVoid Residual is measured in mL. IPSS The International Prostate Symptom Score is a question written screening tool used to screen for benign prostatic hyperplasia (BPH). A score between 0 to 7 is correlated with mild symptoms, from 8 to 19 with moderate symptoms, from 20 to 35 with severe symptoms. P value with Friedman Test.

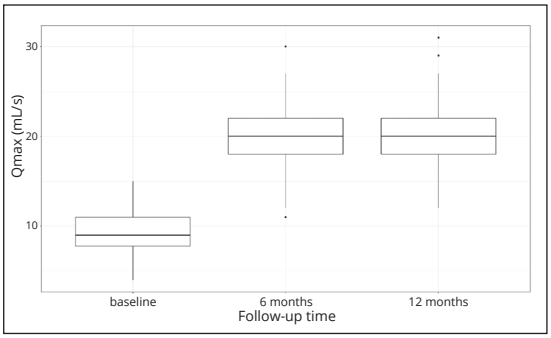

Figure 1.—The median Qmax increase from baseline (9.0; IQR: 7.8-11.0 mL/sec, missing =8) at 6 months (20.0; IQR: 18.0-22.0 mL/sec, missing =2) and remained stable at last control (20.0; IQR: 18.0-22.0, missing=35) after *en-bloc* Green Light Laser Enucleation (Friedman's Test P value <0.001).

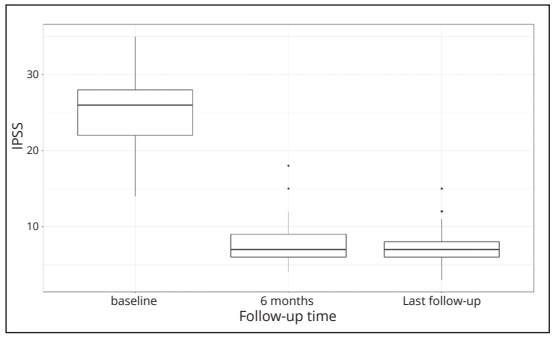

Figure 2.—The median International Prostatic Symptoms Score improved from baseline (26.0; IQR: 22.0-28.0) at 6 months (7.0; IQR: 6.0-9.0) and remained stable at last control (7.0; IQR: 6.0-8.0, missing= 33) after *en-bloc* Green Light Laser Enucleation (Friedman's Test P value <0.001).

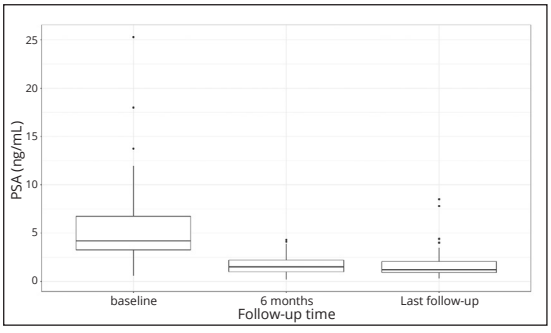

Figure 3.—The median Prostate Specific Antigen decreased from baseline (4.2; IQR: 3.2-6.8 ng/mL) at 6 months (1.5; IQR: 1.0-2.2 ng/mL, missing=33) and remained stable at last control (1.3; IQR: 0.9-2.0 ng/mL, missing=41) after *en-bloc* Green Light Laser Enucleation (Friedman's Test P value <0.001).

In this study, we assessed the operative and postoperative outcomes with a median follow-up of 18 months. We showed that both urinary symptoms and uroflow parameters significantly improved compared to the baseline. These results confirm the potential for *en-bloc* GreenLEP with early apical release for successfully treating patients with BOO/BPH, irrespective of prostate volume.

Our results corroborate those of previous series which showed similar operative and lasing times, morcellated tissue volumes and similar functional outcomes.[15-18] In addition, the duration of the catheterization and length of postoperative stay duplicates those previously reported (Table V).[15-18]

Misrai *et al.* retrospectively compared the results of open prostatectomies with GreenLEP[15] and found that the GreenLEP had a clearly better perioperative profile with lower morbidity. Our results further support these findings, particularly considering our maximized use of the fiber (18 *vs.* 8min), a higher rate of morcellated tissue (60 *vs.* 71 g) and a longer follow-up (7 *vs.* 18 months) (Table V).

Panthier *et al.* also reported on their initial

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TABLE V.—*Comparison with other single center studies evaluating GreenLEP procedures.*

Studies	Technique	Number of patients	Prostate volume (g)	Laser time (min)	Operative time (min)	Morcellated tissue (g)	Follow-up length (months)	Q max variation	IPSS changes	Stress definitive incontinence
Misrai[15]	*En-bloc* early apical release	204	100	18	60	60	7.5	Missing	Missing	1.4%
Panthier[16]	*En-bloc* early apical release	100	84	16	85	45.5	9.3	+22.46	-15.86	1%
Bajic[17]	Enucleation lobe-by-lobe	108	77	24	Missing	44	10.3	+17.7	Missing	0%
Huet[18]	*En-bloc* early apical release	100	110	Missing	68	75.1	18.5	Missing	Missing	Missing
Current study	*En-bloc* early apical release	120	98.5	8	65	71.8	18	+21	-19	0.8%

surgical series regarding 100 *en-bloc* GreenLEP procedures.[16] Their results largely overlapped ours and Misrai's findings, confirming the safety and the efficacy of the early apical release *en-bloc* enucleation. Moreover, our data relied on a higher ratio of large glands (33% prostate volume ≥90 mL *vs.* 48% of prostate volume ≥100 mL) and a shorter operative time (85 *vs.* 65min) yet the same rate of postoperative stress urinary incontinence (Table V).

Bajic *et al.* also obtained similar results in terms of obstruction relief and complication rate, despite their use of the "lobe-by-lobe" simplified enucleation technique, a recorded longer lasing time (24 min) and, most likely, a longer operative time (data not reported).[17] Huet *et al.* described functional results consistent with the others, even when focusing on a different target (sexual function)[18] (Table V).

The feasibility of the *en-bloc* GreenLEP technique, originally described, was dependent on the learning curve of each surgeon and on his endoscopic experience.[7] There is general agreement on the complexity of this procedure, especially at the beginning of the learning curve, where spatial recognition is not a common skill and is still unfamiliar to many urologists. We acknowledge that mastery of this technique requires a good spatial understanding of prostatic anatomy, allowing orientation and choice of the proper enucleation plane.

Drawing on the standardized technique we used, we have become convinced that surgeons should mirror the following crucial steps: incision of the mucosa in critical landmarks; gentle lateral tilts of the tip of the scope; creation and development of the enucleation space between the adenoma and the surgical capsule; early apical release that helps to ensure the integrity of the external sphincter.[14]

Only by following these steps did we finally achieve optimal obstruction relief with a limited use of energy (the shortest lasing time) and a reasonable incontinence rate (Table V).

Choosing the Green Light Laser source is justified as it allows the surgeon to switch between resection and vaporization at any time during the procedure, and to use all the emission modalities (coagulation and vaporization) in different phases of the surgery at whatever stage of the surgeon's learning curve.[19] With respect to the balance of costs, a recent study has confirmed that laser procedures (PVP and HoLEP/ThuLEP) are associated with a shorter hospitalization and a better cost profile compared to open prostatectomy.[20]

Limitations of the study

This study has several limitations. First, its retrospective nonrandomized design, non-differentiation into groups of the variable "prostate volume" and the selection of patients.

Second, the assessment of postoperative events (such as incontinence) which was only based on a clinical interview; and the importance of this issue cannot be neglected and should be resolved in future studies. Third, the patients' sexual function and the surgeons' experience and learning curve were not evaluated.

However, despite all these limitations, our

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study 1) confirms the safety, effectiveness and reliability of *en-bloc* GreenLEP with early apical release for the surgical management of prostatic obstruction, ensuring early and stable benefits for the patients;[21] 2) corroborates the versatility of the GreenLight Laser system;[22] 3) demonstrates, across surgical series and different institutions, consistency of results; 4) highlights that a surgical program following a standard technique allows for a safer procedure.[14, 19]

Conclusions

Our study shows that, in the mid-term time frame, the *en-bloc* GreenLEP with early apical release is a safe and effective procedure for the control of bothersome LUTS in men with BOO/BPH and large adenomas, with a short hospital stay and catheterization time. It allows for the preservation of the external sphincter, and minimizes the risk of postoperative stress incontinence. Long term follow-up is required to better evaluate the risk of reintervention and the benefits on the bladder function.

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Authors' contributions.—Giovanni Ferrari: protocol/project development, data management, manuscript writing/editing; Salvatore Rabito: protocol/project development, data collection or management, manuscript writing/editing; Lorenzo Gatti: protocol/project development; Nicolas N. Ntep: data collection; Ferdinando D. Vitelli: data collection or management; Michele Marchioni: data analysis, manuscript review; Riccardo Ferrari: data collection; Luca Cindolo: protocol/project development, data collection or management, data analysis, manuscript writing/editing; Bernardo M. Rocco: manuscript writing/editing; Salvatore Micali protocol/project development. All authors read and approved the final version of the manuscript.

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