

ORIGINAL ARTICLE

Operative profile, safety and functional outcomes after GreenLight laser prostate surgery: results from a 12 months follow-up multicenter Italian cohort analyses

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ABSTRACT

BACKGROUND: Over the two past decades, GreenLight laser therapy has been considered a valid alternative for the treatment of lower urinary tract symptoms (LUTS) associated with benign prostatic hyperplasia/benign prostatic obstruction (BPH/BPO). However, the debate on the effectiveness of laser therapy compared to conventional techniques is still open. The aim of our study is to analyze and describe the use of GreenLight laser prostate surgery in Italy, with regard to the surgical techniques performed and the surgical and functional outcomes at mid-term follow-up.

METHODS: From March 2012 to July 2018, patients who underwent GreenLight laser prostate surgery for LUTS due to BPH/BPO from 19 Italian centers were included. The following parameters were evaluated in the population: age, prostate volume, prostate adenoma volume, PSA tot, Q_{max} at uroflowmetry (UFM), International Prostatic Symptoms Score

(IPSS), previous therapy for LUTS, use of anticoagulants and antiplatelet drugs. We recorded also the kind of anesthesia, mean laser time (min), mean irradiation time (min), TURP conversion/completion rate, postoperative day of catheter removal, postoperative acute urinary retention (AUR), hospital stay, variation of hematocrit (Ht) and hemoglobin levels (Hb). Early complications were classified according to the Clavien-Dindo classification, the re-operation rate within 30 days and after 30 days, the late complications and the Patient Global Impression of Improvement were also collected. Changes over time in terms of blood loss and functional outcomes (IPSS and Q_{max} at the UFM at 6 and 12 months) were tested with Student's test for paired samples. We assumed $P \leq 0.05$ as level of statistical significance.

RESULTS: Overall, 1077 were enrolled in the study, 554 (56.4%) were treated with standard vaporization and 523 (48.6%) with anatomical vaporization. Student's *t*-test for paired samples showed no statistically significant differences in terms of reduction of Ht preoperative vs. Ht postoperative (42.80 ± 3.91 vs. 39.93 ± 5.35 95% CI $P=0.3$) and preintervention and postintervention Hb levels (14.28 ± 1.46 vs. 13.72 $P=0.35$). Compared with the preoperative Q_{max} (8.60 ± 2.64), the 6- and 12-month UFM showed a significant improvement [19.56 ± 6.29 , $P < 0.01$ and 19.99 ± 5.92 $P < 0.01$]. In terms of IPSS variation, compared to the baseline level (22 ± 5.51) the 6- and 12-month follow-up confirmed a significant reduction (8.01 ± 4.41 $P < 0.01$ and 5.81 ± 4.12 $P < 0.01$ respectively). Postoperative complications were CD0, CD1, CD2, CD3, CD4 in 33.0%, 35.3%, 2.9%, 0.3%, and 0.6%.

CONCLUSIONS: To the best of our knowledge, this is one of the most numerous surgical series of GreenLight laser vaporization and with the longest follow-up. This technique should be considered as a safe and effective alternative in the treatment of secondary LUTS to BPH.

(Cite this article as: Reale G, Marchioni M, Altieri V, Greco F, De Nunzio C, Destefanis P, *et al.* Operative profile, safety and functional outcomes after GreenLight laser prostate surgery: results from a 12 months follow-up multicenter Italian cohort analyses. *Minerva Urol Nefrol* 2020;72:622-8. DOI: 10.23736/S0393-2249.20.03597-3)

KEY WORDS: Lasers; Prostatic hyperplasia; Urinary tract infections.

Benign prostatic hyperplasia (BPH) is a disease that occurs mainly in men over 50,¹ with lower urinary tract symptoms (LUTS). Besides worsening the quality of life of patients, it can result in various complications such as recurrent UTIs, hematuria, bladder stones, bladder diverticulosis up to obstructive uropathy with bilateral hydroureteronephrosis and chronic kidney disease (CKD).² The most widely used surgical approach for prostatic volumes between 30 g and 80 g, in the twentieth century, was certainly the trans urethral resection of prostate (TURP), a valid technique with a low learning curve but however not lacking in adverse events, such as bleeding requiring transfusions, capsular perforations and TUR syndrome.³ Therefore, over the past 20 years, alternative methods have been developed with the aim of reducing adverse events, reaching anyway valid functional outcomes. One of these techniques, the laser photovaporization, was introduced in clinical practice about twenty years ago. The GreenLight laser 180W allows three main techniques, standard and anatomical vaporization⁴ or enucleorection.⁵

The aim of our study is to analyze and describe the use of GreenLight laser prostate surgery in Italy, with particular regard to the surgical techniques performed and surgical and functional outcomes at mid-term follow-up.

Materials and methods

From March 2012 to July 2018, 1077 consecutive patients were enrolled in the survey in 19 Italian centers for lower urinary tract symptoms (LUTS) associated with benign prostatic hyperplasia (BPH) and treated with GreenLight laser with long follow-up (12 months). The data's obtained were collected retrospectively by each center involved in the study and finally collected by two urologists (L.C. and M.M). Intra- and perioperative parameters were extracted from the medical records and operating registers. The functional parameters were obtained from the check-ups that the patients underwent. All patients completed 12-month follow-up. The first author (G.R) elaborated the data's and performed all the statistical analysis.

A total of twenty-nine experienced surgeons performed all the GreenLight laser procedures. The following parameters were evaluated in the population: mean age, mean prostate volume, mean prostate adenoma volume, PSA tot, Q_{max} a UFM, IPSS, previous therapy for LUTS, anticoagulants and antiplatelet drugs. We also evaluated the kind of anesthesia used, mean operative time (min), mean irradiation time (min), the TURP conversion/completion rate, the postoperative day of bladder catheter removal, postoperative

RAU, length at hospital stay. Early complications were classified according to the Clavien-Dindo classification, the re-operation rate within 30 days and after 30 days, the late complications and the Patient Global Impression of Improvement were also collected. "Patient Global Impression of Improvement" is a validated self-administered patient questionnaire about their postoperative condition compared to the preoperative condition and evaluated with the following answers: very much better, much better, a little better, no change, a little worse, much worse, very much worse. It is a very simple and intuitive questionnaire that allows the patient to identify his own postoperative condition with respect to the preoperative condition. This tool is useful for assessing the degree of patient satisfaction after surgery.

Statistical analysis

For the assessment of blood loss and for the assessment of functional outcomes (IPSS and Q_{max} at the UFM at 6 and 12 months), a T Student test

for paired samples was used. We have assumed $P=0.05$ as level of statistical significance. All the statistics were performed using SPSS 20 for Windows.

Results

Complete population characteristics and surgical details are described in Table I. Altogether, the patients enrolled in the study were 1077, with a mean age of 69.32 ± 8.26 years. At the trans rectal ultrasound (TRUS) median prostate volume (mL) was 64.07 ± 29.08 mL with an ultrasound evaluation of the median prostate adenoma volume (mL) of 36.00 ± 22.28 mL. Preoperative PSA was 3.16 ± 4.0 ng/mL. In the cohort examined, patients who did not perform any therapy for LUTS prior to surgery were 185 (17.2%), 482 (44.8%) performed therapy with alpha-blockers alone 58 (5, 4%) only with 5 ARI and 286 (26.6%) performed therapy with combination therapy with alpha-blockers + 5ARI. Besides, 789 (73.3%) patients did not perform therapy with phytotherapy vs.

TABLE I.—*Baseline characteristics.*

Characteristics	Median (IQR)	Standard deviation
Age (year)	69.00 (64.00-76.00)	8.269
Follow-up duration (months)	18.00 (12.00-26.00)	11.925
Prostatic volume TRUS (mL)	60.00 (45.00-75.00)	29.083
Prostatic adenoma volume TRUS (mL)	36.00 (25.00-50.00)	22.286
Energy supplied (Kj)	220.00 (144.42-330.00)	148.78
Irradiation time (min)	25.00 (18.00-36.00)	14.020
Operating time (min)	60.00 (42.00-75.00)	23.046
Postop day CB removal (d)	1.00 (1.00-2.00)	1.474
Day of definitive removal of CB (d)	2.00 (1.00-2.00)	2.100
Postop day of discharge (d)	2.00 (1.00-3.00)	1.64
Ht pre	43.00 (41.00-45.00)	3.911
Hb pre	14.00 (14.00-15.00)	1.464
Ht post	40.00 (38.00-43.00)	5.359
Hb post	14.00 (13.00-15.00)	2.893
PSA-pre (ng/mL)	3.00 (2.00-4.00)	4.051
PSA-post 3 months (ng/mL)	1.00 (1.00-2.00)	1.456
PSA-post 6 months (ng/mL)	1.00 (1.00-2.00)	1.375
PSA-post 12 months (ng/mL)	1.00 (1.00-2.00)	1.460
UFM pre (mL/s)	8.00 (7.00-10.00)	2.640
UFM post 6 months (mL/s)	19.00 (16.00-22.00)	6.291
UFM post 12 months (mL/s)	19.00 (16.00-22.00)	5.923
IPSS pre	23.00 (19.00-26.00)	5.516
IPSS post 6 months	8.00 (5.00-10.00)	4.414
IPSS post 12 months	6.00 (3.00-8.00)	4.129
Patient Global Impression of Improvement	1.00 (1.00-2.00)	0.887

TRUS: Trans Rectal Ultra Sound; Kj: kilo-joule; min: minutes; CB: bladder catheter; d: day; Ht: hematocrit; Hb: hemoglobin; PSA: prostatic specific antigen; UFM: uroflowmetry; IPSS: International Prostatic Symptom Score.

108 (10%) who performed the aforementioned therapy, while 837 (77.7%) did not perform therapy with PDE5 inhibitors for LUTS.

Among the evaluated patients 607 (56.4%) did not perform any anticoagulant/antiplatelet therapy at the time of surgery and 470 (43.6%) patients were treated. In the specific subgroup analysis, 27.6% of patients performed treatment with cardioaspirin. Functional parameters (uroflowmetry, IPSS) will be discussed in the comparison with postoperative parameters. Concerning the operative parameters, 554 (56.4%) patients were subjected to laser vaporization and 523 (48.6%) were subjected to anatomical vaporization. 856 (79.5%) spinal/peridural anesthesia was performed and 152 (14.1%) patients underwent to general anesthesia. In most patients (874, 81.2%) there were no pre-existing urethral strictures and in a minority of cases penile urethra strictures (46 4.3%), bulbar urethral strictures (22 2.0%) and membranous (9 0.8%) urethral strictures were present 826 (76.7%) did not have a catheter after surgery.

All pre and peri/postoperative characteristics collected are described in Table II, III. The mean operative time (min) was 59.26 ± 23.04 min and the irradiation time (min) of 28.18 ± 14.02 min. Conversion or completion with TURP (necessary for bleeding or for reduction of the urethral lumen during surgery) was necessary only in 34 (3.2%) patients and the postoperative removal of

the bladder catheter occurred in the first postoperative day in 543 (50.4%) patients, in the second in 310 (28.8%) patients, in third in 143 (13, 3%). Acute retention episodes of postoperative urine (AUR) did not occur in 835 (77.5%) patients vs. 87 (8.1%). The length at hospital stay was: 2 (498 patients, 46.2%), 1 (294 patients, 27.3%), 3 (164 patients, 15.2%), 4 (48.4.5%) days. Postoperative complications, categorized according to Clavien Dindo classification (Table IV), occurred in the following percentages: no complication in 355 (33.0%) patients, CD 1 in 380 (35.3%), CD 2 in 31 (2.9%), CD 3rd in 3 (0.3%), CD 3b in 3 (0.3%), CD 4 in 7 (0.6%). The rate of blood transfusion in the cohort was 0.4% (4 patients). Reintervention rate or within 30 days 0.6% (6 patients) due to hematic clots retention, reoperation rate over thirty days 2.9% (31 patients) due to hematic clots retention and bladder neck stenosis. Among the early complication 114 patient had temperature $\geq 38^\circ\text{C}$

TABLE II.—Preoperative characteristics (N.=1077).

	N.	Percentage (%)
Previous BPH therapy		
No therapy	185	17.2
Alpha-blockers	482	44.8
5 ARI	58	5.4
Alpha-blockers + 5 ARI	286	26.6
Phytotherapy		
No	789	73.3
Yes	108	10.0
No anticoagulant/antiplatelet therapy	607	56.4
Anticoagulant/antiplatelet therapy	470	43.6
Anesthesia		
Spinal/peridural	856	79.5
General	152	14.1
Urethral stricture		
No pre-existing	874	81.2
Penile urethra	46	4.3
Bulbar urethra	22	2.0
Membranous urethra	9	0.8

TABLE III.—Peri- and postoperative characteristics.

Postoperative characteristics	N.	Percentage (%)
Patients enrolled	1077	-
No catheter after surgery	826	76.7
Conversion or completion with TURP	34	3.2
Postoperative removal bladder catheter		
1 st postop day	543	50.4
2 nd postop day	310	28.8
3 rd postop day	143	13.3
Acute retention episodes of postoperative urine (RAU)		
Not occur	835	77.5
Occur	87	8.1
The length hospital stay (days)		
2	498	46.2
1	294	27.3
3	164	15.2
4	48	5.0
Blood transfusion	4	0.4
Reintervention rate or within 30 days	6	0.6
Reintervention rate over 30 days	31	2.9

TABLE IV.—Postoperative complications according to Clavien Dindo Classification (N.=1077).

	N.	Percentage (%)
No complication	355	33.0
CD 1	380	35.3
CD 2	31	2.9
CD 3rd	3	0.3
CD 3b	3	0.3
CD 4	7	0.6

and $45 < 38^{\circ}\text{C}$. One hundred and thirty eight patients had dysuria, 141 patients had urinary urgency and 62 patients had urinary frequency. The most prevalent late complications occurred in the population were LUTS persistence in 45 patients (4.2%), stress incontinence in 30 patients (2.8%) and bladder sclerosis in 14 patients (1.3%). The Patient Global Impression of Improvement administered to patients showed the following scores: 1 in 529 patients (49.1%), 2 in 314 patients (29.2%), 3 in 76 patients (7.1%), 4 in 29 patients (2.7%), 5 in 8 patients (0.7%), 6 in 4 patients (0.4%), 7 in one patient (0.1%). The analysis of the sample averages with the Student's *t*-test for illustrated samples showed no statistically significant differences in terms of reduction of Ht preoperative vs. Ht postoperative (42.80 ± 3.911 vs. 39.93 ± 5.359 95% CI $P=0.3$) and preintervention and postintervention Hb (14.28 ± 1.464 vs. 13.72 $P=0.35$) (Figure 1).

The differences in terms of improvement of the preoperative Q_{\max} (8.60 ± 2.640) were found to be statistically significant at 6 months follow-up (19.56 ± 6.291 , $P<0.01$) and at 12 months follow-up (19.99 ± 5.923 ; $P<0.01$). Also the differences in terms of preoperative IPSS reduction (22.63 ± 5.516) at 6 months follow-up (8.01 ± 4.414 ; $P<0.01$) and at 12 months follow-up (5.81 ± 4.129 ; $P<0.01$) (Figure 2).

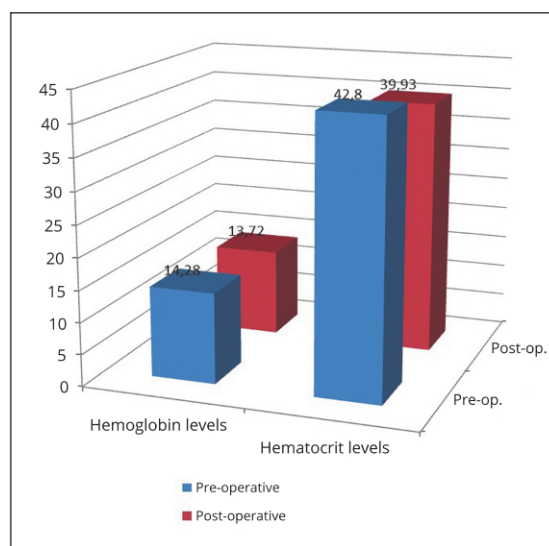


Figure 1. Preoperative and postoperative hematocrit and hemoglobin levels of the sample (%).

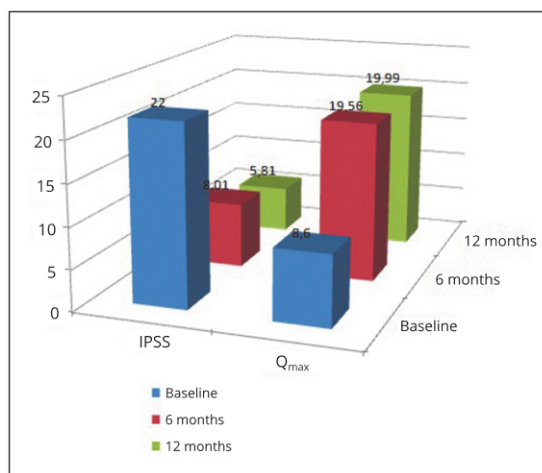


Figure 2. IPSS and Q_{\max} evaluation at baseline, after 6 and 12 months.

Discussion

The GreenLight laser technique in our series has proven to be an effective technique in terms of functional and safe outcomes for patients who are subjected to various procedures. To avoid sampling and selection bias we wanted to emphasize that all patients treated had LUTS secondary to BPH as almost all the population at the time of treatment performed a pharmacological or phytotherapeutic therapy for LUTS and because at cystoscopy prior to treatment 874 patients (81.4%) had no presumed urethral strictures that could be a confounding factor. The results obtained are similar to the results of a large multicenter randomized trial with a six-month,⁶ 12 months⁷ and 24 months follow-up.⁸ In particular the GOLIATH Study with 24 months follow-up⁸ showed how the vaporessection with GreenLight laser actually proved to be not inferior than the gold standard TURP in terms of IPSS (6.9 ± 6.0 vs. 5.9 ± 6.1 difference 1.0 [CI-0.5, 2.5]), and of Q_{\max} 21.2 ± 10.7 vs. 22.9 ± 9.3 difference -1.3 [CI-4.0, 1.4], with the advantage of minor length hospital stay and minor catheterization time.

And these parameters were also similar in our series, considering postoperative day of discharge (day) 2 ± 1.64 (1.00-3.00) and postoperative day of bladder catheter removal (day) 1 ± 1.474 (1, 00-2.00)). In terms of median energy delivered by the device in (Kj) 220.00 ± 148.78 (144.42-330.00) were disbursed with a median

irradiation time (min) of 25 ± 14.020 ($18.00-3.6.00$), amount of energies and irradiation time that allows a use of a low number of fibers and therefore a saving on the material, considering, above all, that Valdivieso *et al.*⁹ have shown how the functional outcomes after treatment with GreenLight Laser 180W, after two years of follow-up, do not change in relation to the amount of energy delivered.⁹

Although ours is not a study of non-inferiority or comparison with other techniques, we reported the results in terms of functional outcomes in our series that were statistically significant at both 6- and 12 months of follow-up and we have demonstrated that all the functional parameters highlighted had a statistically significant improvement compared to the baseline. Among the most interesting data recorded in the postoperative period, we report that 76.7% of patients didn't need a bladder catheter after the procedure, that episodes of acute retention occurred in only 8.1% of patients and that only 34 patients (3.2%) needed a conversion or completion with TURP. To this regard Ajib *et al.*¹⁰ in their 120-month follow-up series documented a similar conversion to TURP rate with 10 patients (2.7%) converted to treatment. Similar results were also described in a review by Rapisarda *et al.*¹¹ that highlighted, in terms of reoperation rate, no statistically significant difference. In addition to recording objectively the functional improvement we also have inserted a validated self-administered patient questionnaire about their postoperative condition compared to the preoperative condition (Patient Global Impression of Improvement), with the following answers: very much better, much better, a little better, no change, a little worse, much worse, very much worse. We noticed that about half of the sample (49.1%) described the postoperative condition as "Very much better". Particularly interesting is also the topic on the safety of the technique in patients using anticoagulant/antiplatelet therapy. In clinical practice, each urologist must deal with the problem of stopping/bridging therapy of anticoagulant/antiplatelet therapy prior surgery. Both anatomical and standard vaporization have proved to be safe techniques in these typologies of patients¹² and, as shown in Table

I, in our series 470 patients (43.6%) continued the use of anticoagulant/antiplatelet therapy with low blood transfusion rate (0.4%) and without statistically changes in the postoperative Hb and Ht parameters. The topic on the perioperative bleeding risk after GreenLight laser surgery in patient using anticoagulant / antiplatelet therapy is still open. Naspro *et al.*¹³ demonstrated the safety of using GreenLight laser in terms of postoperative bleeding (with a low transfusion rate) but a correlation of the anticoagulant/antiplatelet therapy with a greater catheterization and irrigation time and higher late complications rate. However, further studies of correlation with the different anticoagulant/antiplatelet therapy and the use of the GreenLight 180W are necessary. We have documented that postoperative complications have been minor, as complications have occurred in Clavien-Dindo 3b in 0.3% of the sample and in Grade IV in 0.6% of the sample and these data are in accordance with the authors of the GOLIATH study (CD3 1 pts and CD4 no patient in the GreenLight group with follow-up at 24 months).⁸ In terms of re-intervention we also found low reoperation rates (Reintervention rate within 30 days 6pts (0.6%) and over 30 days 31 pts (2.9%) and these data, if compared in the literature, are similar to some papers where the re-operation rate after GreenLight reaches 0.7% with a follow-up of 120 months,¹⁰ 2.4% (2/84)¹⁴ up to 9.0% reported by the authors of the GOLIATH with a 24-month follow-up.⁸

Limitations of the study

The primary limitation of this study is the retrospective nature; second the lack of a comparison with existent techniques; third short follow-up duration (12 months).

Conclusions

To the best of our knowledge, this is one of the most numerous and with a longer follow-up surgical series of GreenLight laser vaporization in Italy. Standard and anatomic technique should be considered as a safe and effective alternative for the treatment of LUTS secondary to BPH, in particular for patient with anticoagulant/antiplatelet therapy. All the evaluated functional

outcomes demonstrate a statistical improvement in the LUTS due to BPH/BPO and a good patient satisfaction after GreenLight laser surgery. However further papers on different aspect of the treatment are needed.

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Conflicts of interest.—Paolo Destefanis, Lorenzo Ruggera, Claudio Dadone, Giovanni Ferrari and Luca Cindolo did surgical tutorship for AMS and they received honoraria for their tutorship. All other authors have no conflicts of interest to declare.

Authors' contributions.Giulio Reale had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis. Luca Cindolo and Michele Marchioni: study concept and design. Giulio Reale and Michele Marchioni: statistical analysis. All authors read and approved the final version of the manuscript.

History.—Article first published online: April 10, 2020. - Manuscript accepted: April 1, 2020. - Manuscript revised: February 20, 2020. - Manuscript received: July 31, 2019.