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ORIGINAL ARTICLE

Efficacy and safety profile of GreenLight laser photoselective vaporization of the prostate in ≥ 75 years old patients: results from the Italian GreenLight Laser Study Group

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Abstract

Background Benign Prostatic Obstruction (BPO) is the most common non-malignant urological condition among men and its incidence rise with age. Among prostate treatments, GreenLight laser seems to reduce bleeding and would be safer in the aging population.

Aims We aimed to compare the functional outcomes and safety profile of < 75 years old (Group A) and ≥ 75 years old (Group B) patients.

Methods In a multicenter setting, we retrospectively analyzed all the patients treated with GreenLight Laser vaporization of the prostate (PVP).

Results 1077 patients were eligible for this study. 757 belonged to Group A (median age 66 years) and 320 to Group B (median age 78 years). No differences were present between the two groups in terms of prostate volume, operative time, hospital stay, PSA decrease over time after surgery, complications and re-intervention rate with a median follow-up period of 18 months (IQR 12–26). Nevertheless, focusing on complications, GreenLight laser PVP demonstrated an excellent safety profile in terms of hospital stay, re-intervention and complications, with an overall 29.6% complication rate in older patients and only two cases of Clavien III. Functional outcomes were similar at 12 month and became in favor of Group A over time. These data are satisfactory with a Qmax improvement of 111.7% and an IPSS reduction of 69.5% in older patients.

Discussion and conclusions GreenLight laser photoselective vaporization of the prostate is a safe and efficient procedure for all patients, despite their age, with comparable outcomes and an equal safety profile.

Keywords Elderly · GreenLight laser · Photoselective vaporization of the prostate · Outcomes · Complications

Background

Lower urinary tract symptoms (LUTS) related to benign prostatic obstruction (BPO) are age dependent, with more than 38% of patients above 80 years [1]. With the evolution of medical knowledge and the improvements in social and economic conditions, life expectancy in high-income countries has increased from approximately 45 years in 1850 to almost 80 years today [2]. This increase in aging populations results in a growing need to manage fragile and older patients. Patients unresponsive to medical therapies for LUTS are a candidate for surgical treatment. Currently, the physician managing these patients has two questions to answer to: 'is it better to operate or not?" and "how safe and minimally invasive is the proposed procedure?". When treating older patients, we should take into consideration a balance between safety, invasiveness and functional outcomes [3–5]. Nowadays, minimally invasive surgical therapies (MISTs) are emerging in BPO treatment due to their safety [6]. However, further studies are needed to provide more information on their effectiveness [7, 8]. Laser

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technologies are safer and guarantee the same functional results compared to open prostatectomy and transurethral resection of the prostate (TURP) [9, 10]. A recent systematic review and meta-analysis reported that endoscopic enucleation techniques are associated with a higher operative time and Clavien I and II complication rate, especially regarding blood transfusion rate, compared to the vaporization techniques [11]. With its new 532 nm wavelength, metal-capped and liquid-cooled irrigated fiber (Moxy TM fiber), the last generation of GreenLight laser, the 180-W LBO crystal Green Light Xcelerated Performance System (XPS)TM (American Medical System-AMS, Minnetonka, Minnesota) has emerged as a versatile laser technology with excellent hemostatic property [12, 13].

We compared the efficacy and safety profile of GreenLight laser photoselective vaporization of the prostate (PVP) in < 75-year-old and ≥ 75-year-old patients in our large multicenter cohort of patients.

Methods

Study design

A retrospective evaluation of prospectively collected data of real-life patients affected by BPO and treated with the 180-W XPS GL system, in a multi-institutional, prospectively collected database performed in 20 Italian centers was conducted from September 2011 to April 2021. Surgeons with consolidated experience in GreenLight PVP performed all considered procedures.

All patients signed an informed consent before data collection.

Baseline assessment

A complete medical anamnesis for preoperative factors, including age, body mass index (BMI), American Society of Anesthesiology (ASA) score was recorded. In particular, the use of anticoagulants or antiplatelets was recorded, together with the type of anesthesia and antibiotic prophylaxis. In addition, a comprehensive assessment of LUTS burden was collected for each patient and included International Prostate Symptom Score (IPSS) and IPSS quality of life (QoL), history of catheterization or urinary retention, digital rectal examination (DRE), total serum PSA, prostate volume measured with transrectal prostate ultrasound (TRUS), uroflowmetry (UFM).

Exclusion criteria were age < 18 years, previous prostate surgery, follow-up ≤ 12 months and absence of informed consent to participate. Patients were then divided into 2 groups: < 75 years (Group A) vs ≥ 75 years old (Group B) based on the fact that the World Health Organization highlighted that people aged more than 75 years have much more disability and need for assistance than younger persons. (World Health Organization. Significant loss of functional ability, and care dependence. World Report on Aging and Health. http://apps.who.int/iris/bitstream/handle/10665/186463/9789240694811_eng.pdf;jsessionid=2342855AC115632C5C15C1B21BAC57F9?sequence=1).

GreenLight procedure

Surgical procedures comprised standard and anatomical PVP, the type of procedure was performed according to the surgeon's preferences. For each patient, delivered energy (measured in Joule) and time of energy delivered (measured in minutes) were recorded. Intraoperative data included surgical time, number of fibers used and conversion or completion with TURP. Perioperative data recorded were also complications, recorded according to Clavien-Dindo classification, hemoglobin drop, blood transfusions, hospital staying, day of bladder removal and acute urinary retentions.

Outcomes assessment

Complications, evaluated according to Clavien–Dindo classification, were collected as early (within 30 postoperative days) or late (at the latest follow-up consultation) to report the incidence of the post-operative bladder neck and urethral stenosis. We considered post-operative dysuria and incontinence as complications when they prompted additional medical examination or bothered patients. Fever > 37.5 °C for less than 24 h and hematuria requiring application of bladder catheter and irrigation or re-intervention were also reported. Post-operative assessments were recorded at 6 and 12 months and then yearly for each patient and comprised PSA, validated questionnaires collected at baseline, flowmetry and re-interventions. Moreover, the subjective satisfaction of patients who underwent GreenLight was measured through Patient's Global Impression of Improvement (PGI-I) [14].

Statistical analysis

Continuous variables were reported as the median and interquartile range (IQR) and categorical variables as absolute number and percentage. Statistical comparisons between Group A and Group B were conducted at baseline, surgery and follow-up through Mann–Whitney test and Chi-squared test as appropriate, with statistical significance set at $p < 0.05$.

We also conducted a One-Way Analysis of Variance (ANOVA) statistical analysis and a multinomial logistic regression to explore if age > 75 years was a predictor of worst outcomes or higher complication rate.

Data analysis was conducted with IBM SPSS 28.0.1.0 (IBM Corp., Armonk, N.Y., USA).

Ethics

The ethical appraisal was obtained for the current study as previously reported (protocol number: 1550/2017 SS Annunziata Hospital, "G. D'Annunzio" University of Chieti, Chieti, Italy) [15]. Data sharing between centers was conducted according to EU privacy regulations, with anonymized data to safeguard patients' privacy.

Results

A total of 1077 patients across all the centers were considered eligible for this study, respected all inclusion criteria, including at least 12 months of follow-up and were thus enrolled. Overall, patients had a median age of 69 (64–76) years and a median follow-up of 18 (12–26) months and had anatomical PVP or PVP in 554 (51.4%) and 523 (48.6%) cases, respectively. In addition, 170 patients (17.1%) had an indwelling catheter in place due to AUR. When divided according to age, 757 (70.3%) patients belonged to Group A, while 320 belonged to Group B (29.7%). When we compared Groups at baseline, they differed for antiplatelet and anticoagulants therapies ($p < 0.001$), ASA score ($p < 0.001$), hemoglobin ($p < 0.001$), BPO medical treatment ($p = 0.003$) and indwelling bladder catheter ($p < 0.001$) in a statistically significant way. Previous history of urethral stenosis treatment had a higher incidence in Group B ($p = 0.039$). However, no cases of urethral strictures were observed during the procedures. Data are reassumed in Table 1.

When we compared intraoperative characteristics between Group A and Group B, we did not find any statistically significant differences, as reported in Table 2. Early reinterventions were clot removal by endoscopic surgery in Group B, while it happened 3 times in Group A. Other reported early reintervention which occurred all in Group A were bladder neck stricture requiring retreatment and one bladder wall lesion occurred which required conversion to open surgery.

When we analyzed follow-up, regarding post-operative stress urinary incontinence (SUI), they were self-limited, with a complete resolution in the post-operative period within 30 days, except one of a Group B patient, who required a urethral sling. All other interventions were re-treatments for bladder neck stricture, which occurred in both groups without any statistically significant difference. In addition, the incidence of urethral stricture was

Table 1 Baseline comparison of < 75 years old vs ≥ 75 years old patients submitted to GreenLight treatment due to bladder prostatic obstruction

	Group A (< 75 years old) $N = 757$	Group B (≥ 75 years old) $N = 320$	*P* value
Age, years	66 (62–70)	78 (76–81.5)	
Follow up period, months	18 (12–27)	17 (12–23)	0.570
Prostate volume, mL	59 (45–75)	60 (45–77)	0.835
BPO treatment			
Alpha-blocker	366 (48.3%)	116 (36.3%)	**0.003**
5-ARI	42 (5.5%)	16 (5%)	
Combination	181 (23.9%)	105 (32.8%)	
PDE5-I	66 (8.7%)	20 (6.3%)	
Antiplatelet therapies	27.5%	43.4%	**< 0.001**
Anticoagulant therapies	6.7%	13.9%	**< 0.001**
ASA score, %			
1	120 (15.9%)	21 (6.3%)	**< 0.001**
2	474 (62.6%)	132 (41.4%)	
3	158 (20.9%)	166 (51.9%)	
4	5 (0.6%)	1 (0.4%)	
Hemoglobin, g/dl	14.6 (13.7–15.4)	14.0 (12.8–14.8)	**< 0.001**
PSA, ng/mL	2.90 (1.60–4.80)	2.90 (1.64–5.10)	0.941
IPSS	23 (19–26)	23 (19–27)	0.307
Qmax, mL/s	8,6 (7.0–10.4)	8.5 (6.6–10.0)	0.897
Indwelling Bladder Catheter	91 (12.0%)	79 (24.6%)	**< 0.001**
Previous urethral stenosis	48 (6.3%)	30 (9.4%)	**0.039**

Bold highlights the statically significant values

Values are expressed as *n* (%) or median (IQR)

Table 2 Comparison of intraoperative data and perioperative outcomes between < 75 years-old vs ≥ 75 years-old patients

	Group A (< 75 years-old) *N* = 757	Group B (≥ 75 years-old) *N* = 320	*P* value
Anatomic PVP	372 (49.1%)	151 (47.2%)	0.558
Delivered energy, KJ	220 (145–320)	225 (140–355)	0.821
Time energy delivering, minutes	25 (19–35)	26 (18–37)	0.557
Surgical time, minutes	60 (42–75)	55 (43–75)	0.494
Number of fibers used	1 (97.9%)	1 (98.2%)	0.339
	2 (2.1%)	2 (1.8%)	
Conversion to TURP	29 (3.8%)	8 (2.5%)	0.258
Anesthesia			
Spinal	652 (86.1%)	262 (81.9%)	0.099
General	105 (13.9%)	58 (18.1%)	
Delta Hemoglobin	0.5 (0–1.1)	0.5 (0.1–1.1)	0.870
Blood transfusion	2 (0.3%)	2 (0.6%)	0.376
Bladder catheter removal, days	2 (1–2)	2 (1–2)	0.935
Acute urinary retention	60 (7.9%)	27 (8.4%)	0.537
Hospital staying, days	2 (1–3)	2 (1–3)	0.648
Post-operative complications			
Fever > 37.5°	71 (9.4%)	22 (6.9%)	0.299
UTI	25 (3.3%)	17 (5.3%)	
Dysuria	59 (7.8%)	25 (7.8%)	
Relevant hematuria	10 (1.3%)	5 (1.6%)	
SUI	19 (2.5%)	10 (3.1%)	
UUI	21 (2.8%)	17 (5.3%)	
MACE			
Myocardial infarction	3 (0.3%)	1 (0.3%)	
Angina	2 (0.2%)	1 (0.3%)	
DVT	3 (0.3%)	0	
Clavien-Dindo			
I	59 (7.8%)	25 (7.8%)	0.546
II	158 (20.9%)	68 (21.2%)	
III	6 (0.8%)	2 (0.6%)	
Early reintervention	5 (0.7%)	1 (0.3%)	0.546

SUI stress urinary incontinence, *UUI* urge urinary incontinence, *MACE* major acute cardiovascular events, *DVT* deep venous thrombosis

not statistically different between Group A and B (2.4% versus 2.9%, respectively). When we compared other variables, PGI-I was higher in younger patients ($p = 0.008$), while maximum flow and IPSS where comparable at 12 months but different at month 6 and at the last follow-up ($p < 0.005$). These results are summarized in Table 3 and in Fig. 1, 2 and 3.

According to ANOVA univariate analysis, we found out that the Elderly was not associated with a different surgical approach ($p = 0.558$), but that differed on Maximum Flow at each follow-up, with $p = 0.030$ at month 6, $p = 0.041$ at month 12 and $p = 0.003$ at last follow-up, while IPSS was affected only at last follow-up ($p < 0.001$) similarly to PGI-I ($p = 0.012$). Early and late complications were also similar ($p = 0.183$ and $p = 0.572$). When we conducted multivariate logistic regression, none of these variables reached statistical significance, as reported in Table 4

Discussion

As reported by several articles, systematic reviews and meta-analyses, laser surgeries (Holmium, Thulium and GreenLight laser) for BPO guarantee shorter hospital length of stay and catheterization time, with minor comorbidity, especially for bleeding complications, with the same functional results as the traditional transurethral resection of the prostate (TURP), even in high-risk patients [9, 16].

Table 3 Long term outcomes of GreenLight treatment comparing < 75 years-old vs ≥ 75 years-old patients

	Group A (< 75 years-old) *N* = 757	Group B (≥ 75 years-old) *N* = 320	*P* value
PGI-I	1 (1–2)	2 (1–2)	**0.008**
PSA, ng/ml			
6 months	1.5 (0.8–2-4)	1.5 (0.8–2.9)	0.970
12 months	1.4 (0.8–2.3)	1.4 (0.8–2.6)	0.975
Last follow-up	1.5 (0.8–2.4)	1.5 (0.8–2.6)	0.984
Maximum flow, ml/s			
6 months	19.8 (16.8–23.6)	17.8 (15.0–20.9)	**< 0.001**
12 months	19.5 (15.8–23.5)	18.0 (15.7–21.8)	0.078
Last follow-up	19.4 (16.2–23.2)	18.0 (15.0–21.0)	**0.008**
IPSS			
6 months	7 (5–10)	8 (5–11)	**0.032**
12 months	6 (3–8)	6 (3–9)	0.788
Last follow-up	6 (4–8)	7 (5–10)	**0.007**
Long term reintervention	24 (3.2%)	7 (2.2%)	0.458

Bold highlights the statically significant values

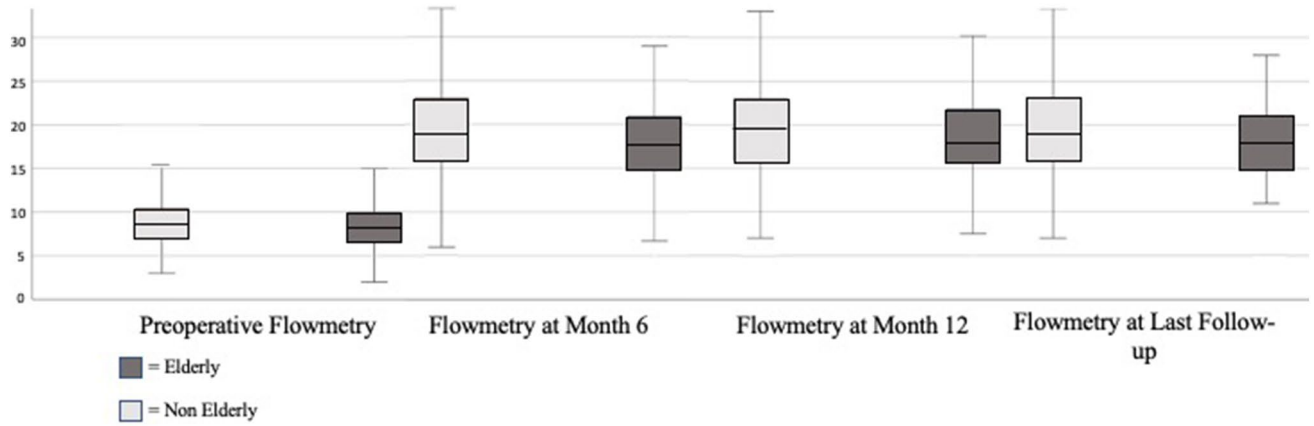

Fig. 1 Flowmetry change over time stratified according to the age

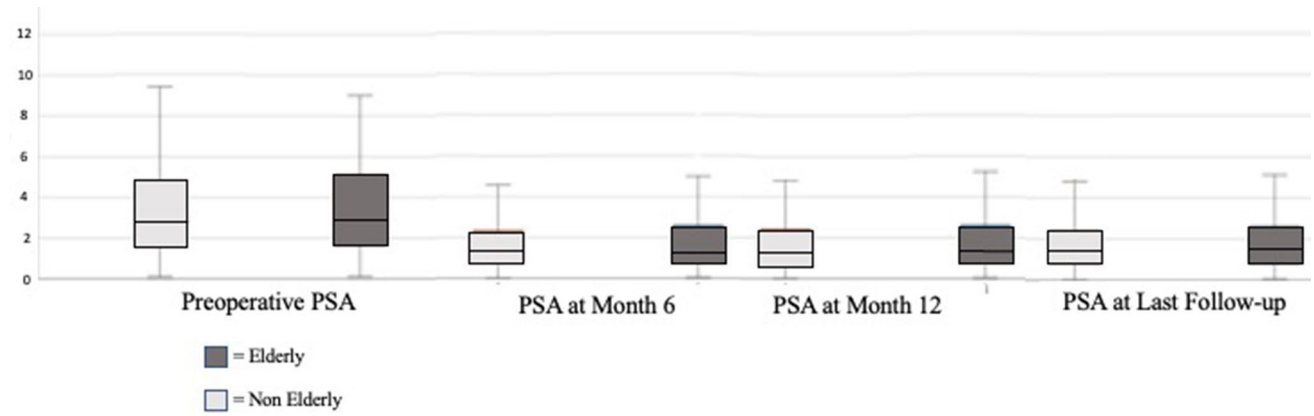

Fig. 2 PSA change over time stratified according to the age

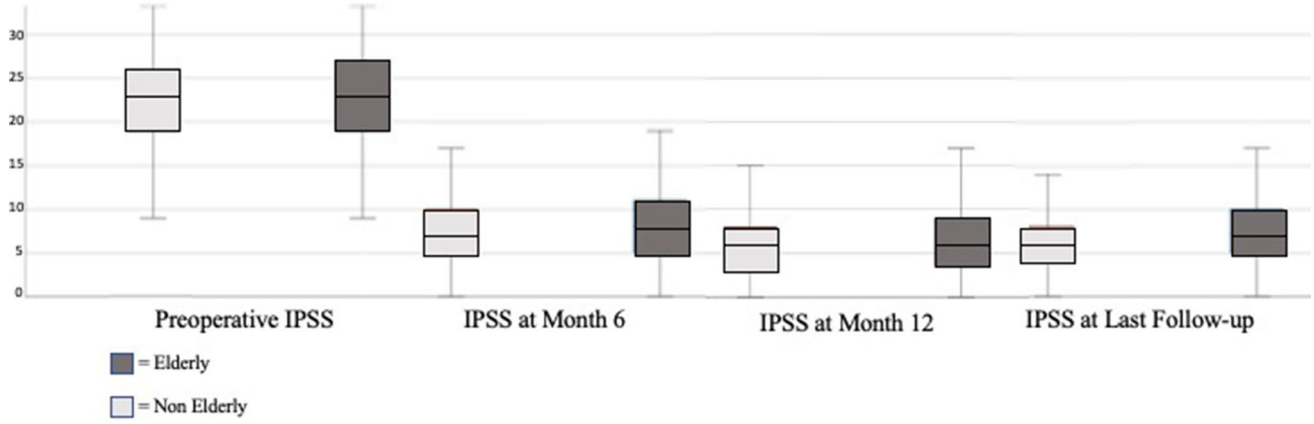

Fig. 3 IPSS change over time stratified according to the age

Table 4 Multinomial logistic regression on patients ≥ 75 years-old impact on GreenLight treatment outcomes and complications

	Odds Ratio	Confidence Interval (5–95%)	*P* value
Anatomic PVP	0.92	0.508–1.666	0.782
Early Complications	0.522	0.090–3.034	0.469
Late Complications	1.497	0.386–5.801	0.559
Maximum Flow, ml/s			
6 months	0.957	0.882–1.037	0.284
12 months	0.923	0.763–1.116	0.407
Last follow-up	1.060	0.888–1.266	0.516
IPSS			
6 months	1.014	0.916–1.123	0.787
12 months	1.020	0.737–1.411	0.905
Last follow-up	1.005	0.734–1.377	0.974
PGI-I	1.048	0.744–1.477	0.788

PVP photoselective vaporization of the prostate; *IPSS* International Prostate Symptom Score; *PGI-I* Patient Global Impression of Improvement

More than other lasers for BPO, GreenLight laser has demonstrated both effectiveness and safety in different scenarios, such as large prostate, especially for patients at high risk of bleeding, with good mid- and long-term functional results [13, 17–19].

These characteristics are linked to the excellent haemostatic property of the GreenLight and its versatility to shift from enucleation to vaporization technique with excellent functional results [20]. As reported by a recent meta-analysis the enucleation techniques correlate with a major risk of complications Clavien I–II and transfusion, but have shown superior functional outcomes. However, in the studies analysed in this meta-analysis the peak flow at the latest follow-up consultation in the PVP patients was always over 16 ml/s, unfortunately the authors did not report on the percentage of improvement to better clarify this aspect [11]. The greater risk of complications with the enucleation technique may explain the preference for standard vaporization in Group B (52.8%, $p < 0.001$) in our series.

Three recent papers reported the experience of octogenarians undergoing the Holep procedure [21–23]. The Authors did not find any differences in terms of complications [21–23] and functional outcomes at 1 month [22] and at 6 months [23] in any of the series. However, the absence of a longer follow-up period is a limitation for all of them. Recently, two papers on thulium laser vapoenucleation of the prostate (ThuVEP) also reported their results in ≥ 75-year-old patients [24, 25]. The first one reported a propensity score comparison between patients older than 75 years undergone ThuVEP and TURP. The Authors found a difference in terms of peak flow in favour of the ThuVEP group, but a greater IPSS reduction in the TURP group, with no differences in terms of complication, hospital length of stay (median 3 days) or catheterization time. The difference in IPSS score in favour of the TURP group was supposed by the Authors to be due to a higher grade of persistent/de novo storage LUTS after ThuVEP [24]. In the second paper, Bertolo et al. performed a propensity score analysis stratifying the patients who underwent ThuVEP according to the 75 years old cut-off point. After three months of follow-up, the Authors did not find any differences in IPSS and peak flow values, complications and readmission [25]. For both Authors, ThuVEP showed excellent functional results in men aged ≥ 75 years.

Only two papers reported on the experience with GreenLight XPS 180-W in older patients [26, 27]. Liu et al. described their experience in 150 octogenarian patients undergone PVP, with improvement in all functional outcomes (Peak flow, IPSS, PVR and QoL questionnaire) with a rate of intraoperative, early and late postoperative complications of 0.7%, 29.8%, and 13.3%, respectively [26].

Conversely, in the study by Moiroud, the Authors divided the patients into 3 groups (younger than 70, 70–80, and older than 80 years) and they found a higher rate of complications and worse QoL and peak flow improvement in patients older than 80 years. They concluded that octogenarian patients had more morbidity and worse functional outcomes than younger patients [27].

In our study, we compared the functional results and the safety profile of PVP in patients under and below 75 years of age. In our analysis we did not find any differences in terms of complications in older patients, with only 0.6% of Clavien III and an overall complications rate of 29.6%, with one case of early re-intervention, despite an ASA score ≥ 3 and use of antiplatelet and/or anticoagulant therapies in 52.3% and 57.3% of patients, respectively. These data are similar to those by Liu and the HoLEP and ThuVEP series, and better than data from Moiroud, who reported a complications rate of 45% in octogenarians [21–27]. Regarding functional outcomes, our data are in line with others studies on GreenLight in older patients, with amelioration of all parameters from the baseline, with 111.7% of improvement of peak flow and 69.5% of IPSS reduction at the latest follow-up consultation. Despite these excellent mid-term functional results, with no statistical differences between the two groups at 12 months in terms of IPSS and peak flow ($p = 0.788$ and $p = 0.078$), by extending the study period up to a median of 18 (12–26) months, this uniformity tends to disappear. At the latest follow-up consultation, younger patients had better outcomes in terms of IPSS and peak flow ($p = 0.007$ and $p = 0.008$), particularly with regard to the PGI ($p = 0.008$). These aspects may be in part explained by muscle loss, axonal degeneration, and ischemic fibrosis of the bladder in older patients, which might be the reason for worsening results over time rather than ineffective treatment. These aspects may result in disappointed expectations possibly explaining the lower PGI in older patients [28]. In fact, in our study, we did not find any difference in PSA value after surgery between younger and older patients ($p = 0.984$), with a PSA reduction of 48.2% in both groups. As reported in the literature, a PSA reduction of approximately 50% is considered the surgical goal to reduce re-treatment risk [29].

Opposed to previously reported papers, in our study we analysed the same surgical procedure (GreenLight laser PVP) in two different age groups with mid-term follow-up. These differences should be considered when evaluating the worse functional outcomes [21–23, 25].

Differently from the results by Moiroud about the indwelling bladder catheter after surgery, all of our patients are catheter free at the latest follow-up, in spite of a 24.6% of pre-operative history of urinary retention and an 8.4% rate of acute urinary retention after surgery in older patients, with no differences with younger patients. This is confirmed by our recent article, showing that only low adenoma volume and lasing time, pre-operative IPSS ≥ 19 and 5-ARI intake, and not age, are predictive factors of post-operative acute urinary retention [30].

The retrospective nature and the multi-centre experience are well-known limiting factors of our study. Nevertheless, the numerous study population, with a median study period of 18 months, including at least 12 months of follow-up, and the comparison between two different populations undergoing the same surgical procedure are the major strengths of our work to better define the real limits of GreenLight laser PVP in ≥ 75-year-old patients.

Despite the statistical difference at the latest follow-up visit in terms of urinary outcomes between the two groups, the 111.7% improvement of peak flow and the 69.5% reduction of IPSS should not be considered a treatment failure or a reason not to treat older patients.

Conclusion

GreenLight laser PVP is a safe procedure for ≥ 75 years old as well as for younger patients. We did not find any differences in mid-term (12 months) functional results. However, over the course of time younger patients maintain their improvement more than older patients, who nevertheless maintain a relevant improvement compared to their baseline.

Author contributions Conceptualization, Methodology, Writing—original draft preparation: DC; Methodology, Writing—original draft preparation, Formal analysis: SM; Material preparation, data collection: FG, PD, GF, FV, SV, GR, TC, RO, AT, LR, AL, CD, PG, GD, LP, MC, FM, SR, RM, LS, AF; Supervision: CD, GF, SM; Conceptualization, Methodology, review and editing: LC.

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Data availability The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request.

Declarations

Conflict of interest P.D., L.R., C.D., G.F., and L.C. do surgical tutorship for AMS and received honoraria for their tutorship. All other authors have no competing financial interests that exist.

Human and animal rights All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional research committee and with the 1964 Helsinki Declaration and its later amendments.

Ethical approval Ethical approval was waived by the local Ethics Committee of the University of Chieti in view of the retrospective nature

of the study and all the procedures being performed were part of the routine care.

Informed consent Informed consent was obtained from all individual participants included in the study.

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