

ORIGINAL PAPER

Safety profile of treatment with greenlight versus Thulium Laser for benign prostatic hyperplasia

Davide Campobasso^{1,2}, Antonio Barbieri², Tommaso Bocchialini², Gian Luigi Pozzoli¹, Francesco Dinale², Francesco Facchini¹, Marco Serafino Grande¹, Jean Emmanuel Kwe^{1,3}, Michelangelo Larosa¹, Giulio Guarino^{1,3}, Davide Mezzogori⁴, Elisa Simonetti¹, Francesco Ziglioli², Antonio Frattini¹, Umberto Vittorio Maestroni²

¹ Department of Urology, Ospedale Civile di Guastalla and Ospedale Ercole Franchini di Montecchio Emilia, Guastalla, Italy;

² Department of Urology, University Hospital of Parma, Italy;

³ Urological Residency School Network, Department of Urology, University Hospital of Modena and Reggio Emilia, Modena, Italy;

⁴ Department of Engineering and Architecture, University of Parma, Italy.

Summary

Objective: The major strengths of surgical treatment of benign prostatic hyperplasia

with laser are reduced morbidity compared to endoscopic resection. No studies analysed the different risk of intra/peri-operative events between patients undergoing Thulium and GreenLight procedures.

Materials and methods: We retrospectively reviewed 100 consecutive cases undergoing GreenLight vaporization and Thulium procedures performed during the learning curve of two expert endoscopic surgeons. Pre-operative data, intra and post-operative events at 90 days were analysed.

Results: Patients on antiplatelet/anticoagulant therapy were predominant in the Green group ($p < 0.0001$). Rates of blood transfusion ($p < 0.0038$), use of resectoscope ($p < 0.0086$), and transient stress urinary incontinence were statistically higher in the Thulium group. On the contrary conversions to TURP ($p < 0.023$) were more frequent in GreenLight patients.

Readmissions were more frequently necessary in GreenLight group (24%) vs. Thulium group (26.6%). The overall complication rate in GreenLight and Thulium groups were 31% and 53% respectively; Clavien 3b complications were 13% in Thulium patients versus 1% in GreenLight patients.

Conclusions: GreenLight and Thulium treatments show similar safety profiles. Randomized controlled trial are needed to better clarify the rate of major complications in Thulium group, and the incidence of post-operative storage symptoms in these patients' populations.

KEY WORDS: Benign Prostatic Hyperplasia; Complications; GreenLight Laser; Learning curve; Safety; Thulium Laser.

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INTRODUCTION

Benign prostatic obstruction (BPO) due to benign prostatic hyperplasia (BPH) is the most common disease causing Lower Urinary Tract Symptoms (LUTS) in men. Up to 50% of men over the age of 50 report some degree of LUTS. Medical therapies, apart from lifestyle modifications, are the first line choice. In case of medical combination therapies failure, surgical management is the solution. Transurethral resection of the prostate (TURP) and open prosta-

tectomy have long been considered the historical gold standard for BPO with prostate volume less and over 80 mL, respectively. Despite the excellent long-term functional results of these procedures, new technologies are being developed to reduce the hospital stay, the catheterization time, the haemorrhagic risk and the complication rate. At present, 3 types of laser technologies [Holmium, 180W LBO crystal Green Light Xcelerated Performance System (XPS), Thulium] are considered by treatment guidelines for medically-refractory LUTS at the same level as TURP with comparable short- and mid-term results, but with less morbidity and invasiveness (1). Nowadays data about long term results are emerging (2-4). At present, the focus about the different laser technologies is not on functional results. The real questions are about which laser has the best safety profile and which laser for which patients should be used. One of the arguments against the widespread use of the holmium laser in BPO treatment is due to the fact that only enucleation procedures can be performed, which are characterized by a long learning curve (5). Differently, Greenlight and Thulium laser are more versatile allowing a change in surgical technique (pure enucleation versus standard or anatomical vaporization) during the same procedure without modifying the functional outcomes and the complication rates (6, 7). In this study, we analysed the different intra and peri-operative events between patients undergoing Thulium vs. Greenlight procedure for benign prostatic obstruction in two centers.

MATERIALS AND METHODS

In this study, we retrospectively reviewed 100 consecutive cases undergoing Greenlight standard *photoselective vaporization of the prostate* (PVP) and 100 consecutive cases undergoing *Thulium VapoEnucleation of the Prostate* (ThuVEP) or *Thulium Laser Enucleation of the Prostate* (ThuLEP) at the beginning of the learning curve of two expert endoscopic surgeons. This study and all related procedures were performed in accordance with the Declaration of Helsinki. Informed consent was obtained from all individual participants included in the study.

We considered only Greenlight procedures performed by a single surgeon (AF) at the *Urology Department of Ercole Franchini Hospital in Montecchio Emilia, AUSL-IRCCS of Reggio Emilia*, from 2014 to 2016, with the 180W LBO crystal Green Light *Xcelerated Performance System (XPS)™ (American Medical System-AMS, Minnetonka, Minnesota)* and a 532 nM fiber (Moxy TM fiber). Instead, all the procedures with Thulium were performed by an expert endoscopic surgeon (AB) at the *Urology Department of the University Hospital of Parma*, from 2015 to 2018, with the Thulium laser (*Cyber TM 200 W, Quanta System Spa, Varese, Italy*) and a 1000 micron, reusable, front-firing laser fiber. Standard Greenlight PVP and ThuVEP/ThuLEP procedures were performed as previously described (4, 8). Examined pre- and post-operative factors and intra- and peri-operative data included age, *American Society of Anesthesiology (ASA)* score, prostate volume evaluated with *trans-rectal ultrasound (TRUS)*, use of antiplatelet and anticoagulant medications, history of catheterization or retention, conversion to TURP, capsular perforation, use of the resectoscope for haemostasis and other intra-operatively recorded events, catheterization time and length of hospital stay. Complications were classified according to Clavien-Dindo classification (9). Complications and post-operative events, such as access to hospital for consultation/readmission, incontinence, and erectile dysfunction were collected and classified as early (within 30 post-operative days) or late (31-90 days). LUTS such as dysuria, urinary frequency or urgency, and urinary incontinence, of any degree and type (stress or urge incontinence), were considered as post-operative complications when they required additional medical examination or therapy and negatively impacted on patient's quality of life. Application of bladder catheter and irrigation or re-intervention or medical examination for haematuria were also reported as a complication. All patients underwent an outpatient clinic evaluation at 1 and 3 months. In all cases, antiplatelet therapies (such as glycoprotein IIb/IIIa receptor inhibitors or adenosine diphosphate -ADP- inhibitors), and anticoagulant therapies were stopped before surgery and bridging was done based on medical history. Conversely, COX inhibitors (aspirin) were not stopped before surgery. Antibiotic and antithrombotic prophylaxis were administered to all patients according to local practice protocols. In all cases, at the end of surgery, a three-way bladder catheter was placed with continuous bladder irrigation for at least 12 hours.

Statistical analyses

The Anova test and chi-square tests were used for statistical analysis. A $p < 0.05$ was considered to assess statistical significance. Values were presented as n (%) or mean \pm SD.

RESULTS

A standard PVP was performed in all 100 patients in the Greenlight group, on the contrary 20 patients underwent ThuVEP and 80 patients ThuLEP in the Thulium group. Age, ASA score, and prostate volume were similar between the two groups. All data are reported in Table 1. Patients on antiplatelet/anticoagulant therapy were pre-

dominant in the Green group ($p < 0.0001$). A history of indwelling catheter history was more represented in the Thulium group ($p = 0.002$). Interestingly, considering intra-operative data, the use of resectoscope for haemostasis was more frequent in patients undergoing Thulium procedures ($p = 0.008$), but patients in the Greenlight group had a higher conversion rate to TURP (5% versus 0%, $p = 0.023$). No statistical difference was found in capsular perforation rate between Thulium and Greenlight ($p = 0.13$), despite an incidence of 12% versus 4%, respectively. No major differences were observed between the two groups in the following post-operative data: hospital stay, catheterization time, early acute urinary retention (AUR), erectile dysfunction, post-operative storage symptoms and de novo urgency. Blood transfusion rate ($p = 0.003$) and stress urinary incontinence (SUI) three months post-operatively ($p = 0.002$) were lower in Greenlight group. In particular, none of the patients undergoing Greenlight PVP needed blood transfusion against 8% in the Thulium group. The overall complication rate in Greenlight and Thulium groups were 31% versus 53% respectively ($p < 0.0001$) (Table 2). The majority of complications in Thulium group were Clavien grade II (22%), whereas in the Greenlight group they were Grade I (25%). Thirteen patients needed a second operation for complications in the Thulium series (Clavien 3b), 84.6% (11 pts) of these being endoscopic revision for haematuria. In 5 cases endoscopic revision for haematuria was performed during the same admission. One patient of Greenlight series required open surgery for bladder perforation with extraperitoneal fluid collection. The patient came to our attention after one month for haematuria and blood clots retention, during endoscopic revision a bladder perforation was discovered. In our series, 25% of patients needed an unplanned outpatient's evaluations after discharge in the Greenlight

Table 1.
Characteristics of study population.

	Greenlight group	Thulium group	P value
Age (years)	70.81 \pm 7.56	70.73 \pm 7.88	0.9
ASA score	2.33	2.09	0.1
Prostate Volume (ml)	50.25 \pm 16.67	68.6 \pm 35	0.49
Indwelling Catheter (%)	12%	29%	0.002
Antiplatelet and Anticoagulant Medications (%)	59% Antiplatelet 9% Anticoagulant	34% Antiplatelet 6% Anticoagulant	< 0.0001
Capsular Perforation (%)	4%	12%	0.13
Conversions to TURP	5%	0%	0.023
Hemostasis with resectoscope	9%	28%	0.008
Hospital Stay (days)	2.07 \pm 0.6	2.82 \pm 1.5	0.6
Catheterization time (days)	1.98 \pm 1.3	1.95 \pm 1.4	0.88
Blood Transfusion (%)	0%	8%	0.003
Early Urinary retention - AUR (%)	12%	8%	0.75
Storage symptoms and de novo urgency (%)	27% (27 pts)	39% (39 pts)	0.07
At 1 months	88.8% (24/27)	38.4% (15/39)	
At 3 months	66.7% (15/27)	5.1% (2/39)	
SUI at three months (%)	7%	18%	0.0029
Erectile Dysfunction (%)	5%	8%	0.38

AUR = Acute Urinary Retention; SUI = Stress Urinary Incontinence.

Table 2.
Overall complication rate.

	Greenlight	Thulium
Complications according to Clavien-Dindo Classification (%)	Clavien I 25% 12 AUR 6 Hematuria without blood clot retention 5 Urinary tract infection without signs of bacteremia 2 Fever	Clavien I 18% 8 AUR 4 Urinary tract infection without signs of bacteremia 3 Hematuria without blood clot retention 3 Fever
	Clavien II 5% 3 Urinary tract infection with signs of bacteremia 1 Pulmonary embolism 1 Heart Failure	Clavien II 22% 14 Urinary tract infection with signs of bacteremia 8 Blood transfusion
	Clavien IIIb 1% 1 endoscopic revision with bladder perforation and open conversion	Clavien IIIb 13% 11 endoscopic revision for hematuria 1 endoscopic revision for bladder neck contracture 1 stenting for ureteral orifice damage

AUR = Acute Urinary Retention.

Table 3.
Association between PPLA score and risk factors for kidney stones or stone recurrence.

Group	Complications		
	Peri-operative	Early (30 days)	Late (31-90 days)
Greenlight	6 Acute Urinary Retention 2 Fever 1 Urinary tract infection without signs of bacteremia 2 Hematuria without blood clot retention	4 Acute Urinary Retention 1 Endoscopic revision with bladder perforation and open conversion 1 Pulmonary embolism 4 Hematuria without blood clot retention 1 Heart Failure	2 Acute Urinary Retention 3 Urinary tract infection with signs of bacteremia 4 Urinary tract infection without signs of bacteremia
Thulium	5 Acute Urinary Retention 1 Fever 5 Urinary tract infection with signs of bacteremia 8 Blood transfusion 5 Endoscopic revision for hematuria 1 Stenting for ureteral orifice damage	3 Acute Urinary Retention 2 Fever 9 Urinary tract infection with signs of bacteremia 4 Urinary tract infection without signs of bacteremia 6 Endoscopic revision for hematuria 3 Hematuria without blood clot retention	1 Endoscopic revision for bladder neck contracture

group with 24% (6 pts) readmissions (one patient for heart failure and one for pulmonary embolism one month post-operatively). Similarly, in the Thulium group 30% of patients needed re-evaluation with 26.6% (8 pts) readmission. Haematuria, requiring endoscopic revision was the most common cause of readmission (75% - 6 pts). Complications divided by time of onset are reported in Table 3.

DISCUSSION

In recent years, with the development of laser technologies, overcoming the well-known complications and morbidity rates, TURP procedures have decreased (1, 10). The necessity to find less invasive procedures is linked to two aspects. The prevalence of BPH increases with advancing age in a linear fashion, and obesity and metabolic syndrome are two risk factors for this condition. All these aspects are prevalent in Western countries. Nowadays procedures are required to guarantee good functional results, low complications rates, short hospitalization with fast return to normal activity and safety in high-risk patients or patients under anticoagulant or antiplatelet therapy. In the literature, several papers reported data about safety and good results of Thulium

and Greenlight (1, 11, 16, 17). Only two papers compared the results of Thulium and Greenlight for the treatment of BPO (17-19). In the first (17, 18), the Authors compared 116 and 118 patients undergone Thulium and 120W *high-performance system* (HPS)TM *Lithium Triborate* (LBO) vaporization, respectively. The Authors did not find statistically significant differences in term of complications, with readmission, transfusion, and re-operation rates of 2.6 vs 1.7%, 2.6% vs 0% and 1.7 vs 5.1%, respectively. No major details are available on these aspects. In the second paper (19), the Authors analysed the results of ThuVEP performed in one center (158 pts) and standard Greenlight PVP in 3 centers (93 pts), with no significant differences in term of complications, only hemoglobin drop was in favor of PVP. In the PVP group, 66.7% developed a complication versus the 15.2% of the ThuVEP group. On the contrary in our series the Greenlight group developed an overall complication rate of 31% versus 55% in the Thulium group. However, in the study by Castellani and colleagues, Clavien grade I was the most common complication grade in PVP and ThuVEP (95.1 versus 35.1%), in line with our experience (80.6% versus 32.7%). The Authors reported a reoperation rate after 30 days of 8.6% and 7% in patients undergoing PVP and ThuVEP, respectively, but they did not specify the cause

of the second procedure (haematuria, urethral/bladder neck stenosis etc). Unfortunately, the two papers did not focus on safety profile and complications. The Authors did not specify how many surgeons and how experienced performed the procedures, the type of complications and the reasons for readmission and re-operation. Our study is based on collection of cases of patients treated by two surgeons at the beginning of their learning curve in GreenLight PVP and ThuVAP/ThuVEP procedures. In particular, in our Thulium series, the 5 cases of re-operation for haematuria in the post-operative period occurred in the first 50 procedures, and in 4 cases a capsular perforation was reported during the first enucleation procedures. These patients had a prostate volume < 80 cc (means 56.6 cc) and they were not on anticoagulant or antiplatelet therapies. Also, the case of stenting for superficial ureteral orifice lesion occurred during the first 50 procedures. In the remaining 6 cases of re-operation for haematuria described in the post-discharge period for Thulium series, one occurred during the first 50 procedures, the other 5 cases were high-risk patients with ASA score 3 and prostate volume > 80 cc (mean 109.8 cc) and/or with antiplatelet or anticoagulant therapies. Definitely, the 60% of complications Clavien grade IIIb occurred in the first 50 procedures with Thulium, and these issues must be considered when analysing our data. Also, the 8% of transfusion rate, which directly correlates with the endoscopic revision rate in the first 50 procedures, must be correctly interpreted. Moreover, despite the conversion to TURP being more frequent in the Greenlight group, all the cases happened in the first 20 procedures and our rate was in line with other series (3). An additional aspect to consider was the higher number of enucleation procedures in the Thulium series (80% vs 0%). In fact, the higher resectoscope use in the Thulium group is linked to the need for an optimal endoscopic vision before morcellation. Also, the 12% of capsular perforation in Thulium group is linked to the enucleation procedures. The re-admission rate at 3 months is comparable between Thulium and Greenlight group (8% and 6%, respectively), with a higher incidence of further urgent medical examination in the patient undergoing Greenlight PVP (25% versus 16%). Concerning the urinary symptoms, our data on storage symptoms and de novo urgency are in line with the literature and do not differ between the two groups ($P = 0.07$) (20, 21). However, some differences are present in the time necessary to resolve these symptoms (Table 1). In the Thulium group, only two patients described persistence of storage symptoms at 3 months versus 15% in the Greenlight group. Moreover, in our series patients undergone Greenlight PVP needed one further medical evaluation for post-operative LUTS and storage symptoms more frequently than in the Thulium group (16% versus 9%). On the contrary, the incidence of transient postoperative urinary stress incontinence is more frequent in the Thulium group (18% vs 7%, $p = 0.0029$). These data are in line with a recent review of the literature regarding ThuLEP procedures, which reported transient irritative symptoms and incontinence between 6.7% and 18.5% (21). Furthermore, the risk of incontinence was higher in enucleation than in resection methods and correlates with the

learning curve (4). Moreover, our study reported the functional results at 3 months. Several papers describe a reduction of stress incontinence at 12 months in ThuLEP series (21). Some limitations are present in our study, first of all its retrospective nature and the presence of enucleation procedures in the Thulium group compared to PVP Greenlight group (80% versus 0%). Otherwise, the choice to consider the first 100 Thulium procedures by a single surgeon, including his learning curve, and 100 consecutive standard Greenlight PVP by a surgeon during his learning curve are strengths of this paper. With careful data analysis we found a higher risk of Clavien grade IIIb complications and blood transfusion in the peri-operative period in the first 50 procedures of ThuLEP. No patients required blood transfusion in the following 50 Thulium procedures, despite the prostate volume and the enucleation procedure had increased. In these sub-groups of patients, the risk of endoscopic revision for haematuria was higher in patients with prostate volume > 80 cc and under antiplatelet/anticoagulant therapies. In our real-life setting with Thulium and Greenlight lasers, both laser systems were documented to be equally safe for patients affected by BPO, also at the beginning of the learning curve. We could not find any significant difference in terms of complications after the first 50 procedures. Future prospective randomized studies are needed to confirm this conclusion on both techniques.

CONCLUSIONS

GreenLight and Thulium treatments show similar safety profiles. The higher rate of transient IUS in Thulium patients is linked to the use of enucleation technique in contrast to vaporization technique with GreenLight. Furthermore, the higher use of resectoscope for haemostasis during Thulium enucleation is needed to perform a safety morcellation procedure. Larger study population reflecting multicentred experience would be necessary to better clarify the rate of major complications in Thulium group, and the grade and durability of post-operative storage symptoms in these patients' populations.

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Correspondence

Davide Campobasso, MD (Corresponding Author)
d.campobasso@virgilio.it

Gian Luigi Pozzoli, MD
pozzolig@ausl.re.it

Grancesco Facchini, MD
facchinifrancesco@yahoo.it

Marco Serafino Grande, MD
marcogrande2@yahoo.it

Jean Emmanuel Kwe, MD
jeanemmanuelk@yahoo.fr

Michelangelo Larosa, MD
larosam@ausl.re.it

Elisa Simonetti, MD
elisasimonetti88@gmail.com

Antonio Frattini, MD
antonio.frattini@ausl.re.it

Urology Unit, Civil Hospital of Guastalla,
Azienda USL-IRCCS di Reggio Emilia
Via Donatori di Sangue 1, Guastalla 42016 (RE) (Italy)

Antonio Barbieri, MD
barbio68@icloud.com

Tommaso Bocchialini, MD
tommaso.bocchialini@libero.it

Francesco Dinale, MD
ceciadinale@gmail.com

Giulio Guarino, MD
giulio.guarino3@gmail.com

Francesco Ziglioli, MD
ziglioli@hotmail.it

Vittorio Maestroni, MD
umaestroni@ao.pr.it

Department of Urology, University Hospital of Parma
Viale Antonio Gramsci, 14, 43126 Parma (Italy)

Davide Mezzogori, MD
davide.mezzogori@unipr.it

Department of Engineering and Architecture, University of Parma
Parco Area delle Scienze, 59, 43124 Parma (Italy)

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