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Efficacy and safety of photoselective vaporization of the prostate using the Greenlight XPS 180W laser and simple prostatectomy for high-volume prostate hypertrophy: a comparative analysis

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Introduction This study aimed to compare the safety and efficacy of treatment using simple prostatectomy (SP) and using photoselective vaporization of the prostate (PVP) with a 180W GreenLight XPS laser in patients with high-volume prostate hypertrophy.

Material and methods The study included 120 patients with LUTS symptoms caused by prostatic enlargement of more than 80 ml; 79 patients were treated with SP, while 41 were treated with PVP. The analysis included subjective the International Prostate Symptom Score (IPSS) and Quality of Life (QoL), and objective (Qmax), (Qave), and post-void residual volume (PVR) parameters before treatment and at an average of 38 months after surgical treatment. Early and late adverse effects and length of hospitalisation were assessed. Complication reports were performed according to the modified Clavien-Dindo system.

Results The analysis independently showed the effectiveness of both methods. Subjective parameters (IPSS, QoL), showed no significant differences. Patients treated with SP scored slightly better on objective parameters (Qmax, Qave, and PVR). Analysis of adverse effects and hospitalisation time were more favourable after PVP.

Conclusions SP and PVP were found to be comparable and highly effective in treating benign prostatic hyperplasia in terms of IPSS and QoL. Patients treated with the SP method obtained slightly better results of objective parameters such as Qmax, Qave, and PVR. Compared with SP, PVP has a more favourable safety profile.

Key Words: minimally invasive ‹› benign prostatic hyperplasia (BPH) ‹› greenlight 180W XPS laser ‹› PVP ‹› surgical treatment ‹› safety profile ‹› lower urinary tract symptoms (LUTS)s ‹› simple prostatectomy ‹› C-D Clavien-Dindo Classification System

INTRODUCTION

Modern therapeutic technology is rapidly evolving, with particular focus on the active development of minimally invasive methods for treating patients with benign prostatic hyperplasia (BPH). This has led to the systematic introduction of more innovative technologies into everyday life. The same is true for photoselective vaporization of the prostate (PVP).

The introduction of the Greenlight 180W XPS next-generation laser, which utilizes increased power

by using advanced fibre technology, has significantly improved treatment results. However, given the high power of the device, it is crucial to evaluate the safety of this new method.

Surgical treatment of BPH with a volume greater than 80 ml involves the removal of the prostatic adenoma using an open method – simple prostatectomy (SP) – with either a transvesical or prevesical access. Absolute indications for surgical treatment of lower urinary tract symptoms (LUTS) in patients with BPH are mainly recurrent urinary retention, bladder stones, haematuria, recurrent urinary tract infections (UTI), and urinary stasis with or without comorbid renal failure during subvesical obstruction. In addition, patients whose LUTS worsens despite pharmacological treatment, whose quality of life deteriorates steadily, and those who cannot tolerate pharmacotherapy are qualified for surgical treatment [1]. This study aims to determine the effectiveness of BPH treatment with SP and PVP treatment and with the GreenLight XPS laser, and to compare the safety profiles of both methods.

The purpose of this work included the following:

To perform a comparative analysis of the efficacy and safety of SP and PVP GreenLight XPS treatment in patients with BPH.

To perform a comparative evaluation of subjective parameters extracted from the International Prostate Symptom Score (IPSS) and Quality of Life (QoL) questionnaires.

To comparatively evaluate objective parameters on the basis of the results of uroflowmetry studies involving the analysis of parameters, including Qmax, Qave, and PVR.

To perform a comparative evaluation of the side effects and complications in patients undergoing BPH treatment using both methods.

Complication reports were performed according to the modified Clavien-Dindo Classification System, which was published in 2004, was recommended in 2012, and was validated in 2017 by many scientific societies of urology for post-operative complications reports. It is a simple and objective diagnostic tool for the postoperative condition of patients. This modified system is divided into 7 classes, which are presented below [2, 3, 4].

Grade I: Any deviation from normal postoperative course without the need for pharmacological treatment or surgical, endoscopic, or interventional radiology. The accepted therapies are drugs such as antiemetic, antipyretics, analgesics, diuretics, and electrolytes, as well as physiotherapy.

Grade II: Complications requiring pharmacological treatment with drugs other than those used in Grade I complication (including haematuria requiring blood transfusion)

Grade III: Complications requiring surgery, endoscopy, or interventional radiology

Grade IIIa: Intervention carried out under any form of anaesthesia other than general anaesthesia (including performing a cystostomy)

Grade IIIb: Intervention performed under general anaesthesia

Grade IV: Life-threatening complications (including central neurological complications)

Grade IVa: Dysfunction of a single organ, including renal failure supported by dialysis

Grade IVb: Multiple organ dysfunction with intensive care unit admission

Grade V: Death of the patient

MATERIAL AND METHODS

The present study used retrospectively collected data including the medical histories of patients operated from 1 January 2012 to 31 December 2017, as well as the results of postoperative examinations performed during the observation period.

Study design and participants

The study participants include patients treated for BPH at 2 centres: patients in the Department of Urology, Oncological and Functional Urology of the Military Institute of Medicine – National Research Institute, who received treatment using SP and a GreenLight XPS 180W PVP, and patients treated using SP during the same period at the Department of Urology of St. Padre Pio Regional Hospital in Przemyśl. The study included 79 patients who underwent SP and 41 patients who underwent PVP. Patients treated with the aforementioned methods were then followed up for an average of 38 months after the procedure. Patients were eligible for both PVP and SP according to similar indications, i.e. patients with increased LUTS, caused by an enlarged prostate measuring more than 80 ml on ultra-sound, and others in whom treatment methods did not produce the expected favourable results. All eligible patients, in the preoperative period, were examined according to the recommendations of the European Association of Urology (EAU). The study centred around medical history, physical examination, and laboratory and imaging studies. For the purposes of this study and analysis, each patient underwent an ultrasound examination prior to surgical treatment, with a focus on prostate volume, and patients were included in the study on this ba-

sis. During the medical interview with the patient, the nature and severity of LUTS was assessed. The patients were presented with all therapeutic options related to the treatment of BPH. An integral part of the patients' examination was the completion of an IPSS and QoL questionnaire by each patient who did not experience urinary retention.

A digital rectal examination (DRE) of the prostate was performed, as well as a panel of standard tests necessary to perform the procedure under anaesthesia. In addition, tests were ordered as part of the evaluation of prostatic and urinary tract disorders: prostate-specific antigen (PSA) levels, microbiological and general urinalysis, and evaluation of renal function and haemoglobin levels, as well as ultrasound evaluation of the upper urinary tract with calculation of prostate volume (Pvol) and urine volume retained after micturition (post-void residual volume – PVR) were assessed.

Prior to surgical treatment, each patient underwent a uroflowmetry examination. This examination was waived before surgery only in patients who had urinary retention, because in this group, ad hoc protection of the urinary tract with a Foley catheter was used. This group included 25 patients who subsequently underwent adenomectomy and 4 patients in the PVP group. Uroflowmetry is one of the basic tests used in the diagnosis of lower urinary tract abnormalities. It is a completely painless, non-invasive, short, and simple to perform test. The volume of urine expelled per unit time was measured, including the rate of maximal urethral flow (Qmax) and the average rate of urethral flow (Qave). The volume of urine retained after micturition (PVR) was then assessed using ultrasound.

Bacteriuria can increase the risk of infection during medical procedures. An especially important procedure was the identification of bacteriuria before the planned procedures to reduce the risk of infectious complications. Patients qualified for surgery, who were found to have a urinary tract infection in the laboratory tests performed, were separated from the respective patient groups. If an acute urinary tract infection was found, the decision to perform surgery was postponed until the patient was successfully treated. The patients were treated using the appropriate pharmacotherapy according to the urine culture result obtained. This group comprised 10 patients who underwent SP and 3 patients who underwent PVP. It should also be noted that a negative urine culture is not always an indicator of the absence of bacteria, because the lower genitourinary tract is colonized by microflora belonging to the microbiome.

In the group of patients qualified for the study, a separate group also included patients who experienced urinary retention. In this group, no uroflowmetry examination was performed before the procedure. Because the urinary tract was secured with a Foley catheter, in this group of patients, in addition to the routinely performed DRE tests, the following were performed: PSA tests, urinalysis and determination of blood creatinine levels, and transabdominal ultrasound (TAUS) with assessment of the volume of the prostate and bacteriological examination of the urine, with particular attention to the antibiotic sensitivity of the bacteria found.

Before surgery, if a positive urine bacteriological culture was obtained, antibiotic therapy was administered, and hospitalisation was postponed for approximately 2 weeks. In the preoperative and perioperative period, they were administered antibiotic therapy according to the antibiogram obtained. Furthermore, these patients underwent additional bacteriological tests after the surgical procedure.

The next group identified from among those qualified for the study were patients with abnormalities on DRE examinations and/or patients who had an increase in serum PSA levels, and who underwent additional testing due to suspected prostate cancer. Based on this, these patients underwent transrectal ultrasound (TRUS) followed by a multisite core biopsy performed with a Tru-Cut needle (18 G) under TRUS guidance (TRUScoreBx).

The evaluation scheme for groups of patients undergoing surgical treatment for BPH is shown in Figure 1.

During follow-up visits, all patients who underwent PVP using the 180W GreenLight XPS laser and SP received a comprehensive evaluation, including uroflowmetry (to measure urethral flow) and ultrasound of the prostate. Additionally, urine retention after micturition was evaluated, along with laboratory tests, such as PSA and general urinalysis. Patients also completed the IPSS questionnaire and the QoL questionnaire, while possible complications of the treatment were assessed.

A flow chart showing the examination of patients who were eligible for surgery is shown in Figure 2.

Surgical methods

Photoselective vaporization of the prostate – surgical procedure scheme

Laser vaporization of the prostate is performed using a device that uses a lithium triborate (LBO) crystal, which emits a 532-nm wave with a power of 180 watts (i.e. an XPS laser). An Nd-YAG laser

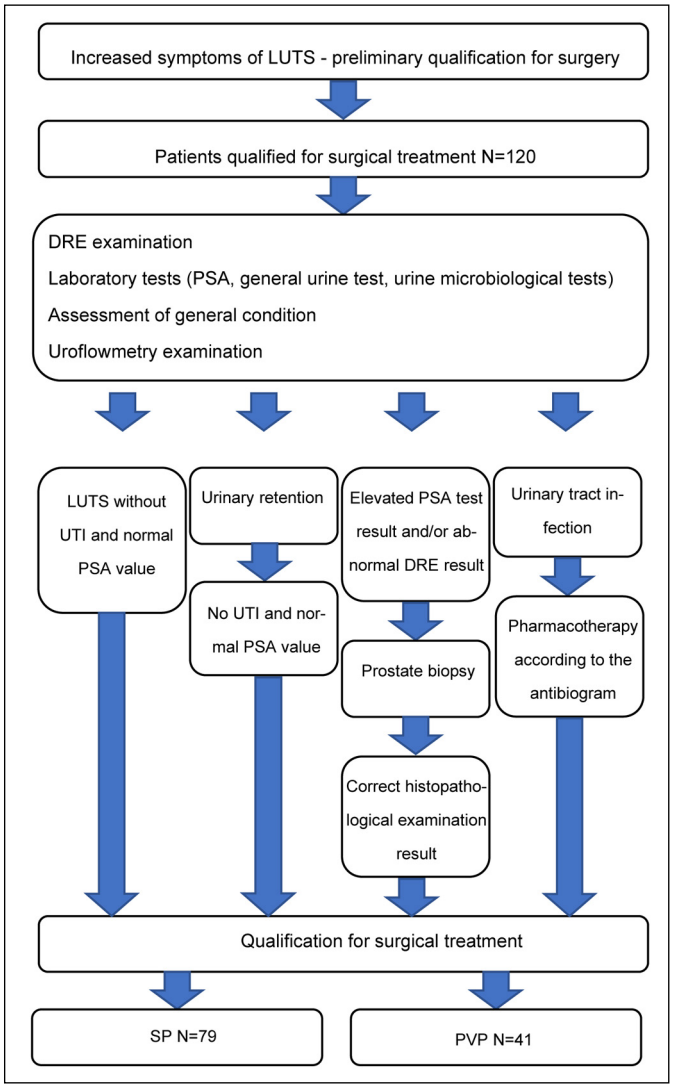

Figure 1. *Scheme for evaluating groups of patients receiving benign prostatic hyperplasia surgery.*

DRE – digital rectal examination; LUTS – lower urinary tract symptoms; N – number of patients; PSA – prostate-specific antigen; PVP – photoselective vaporization of the prostate; SP – simple prostatectomy; UTI – urinary tract infections

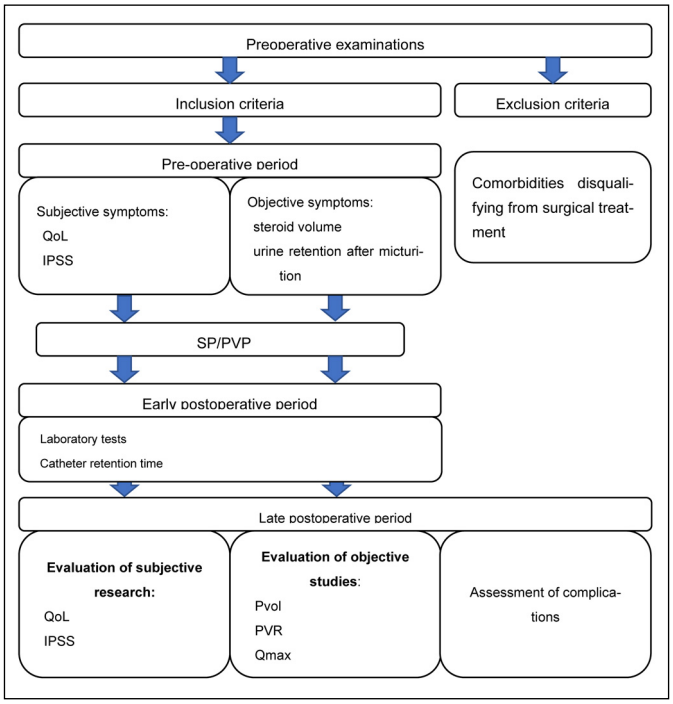

Figure 2. *Study pattern of patients undergoing surgical treatment for benign prostatic hyperplasia between 2012 and 2017.*

IPSS – International Prostate Symptom Score; Qmax – maximal urethral flow; QoL – quality of life; Pvol – prostate volume; PVP – photoselective vaporization of the prostate; PVR – post-void residual volume; SP – simple prostatectomy

wave of 1064 nm is passed through this crystal. This wave is selectively absorbed by haemoglobin; furthermore, it is transmitted through water and penetrates cells without energy loss. Absorption of this wave leads to the immediate removal of glandular tissue by rapid photothermal vaporization of heated intracellular water. Hence the name photoselective vaporization of the prostate [5].

In addition, this laser features an innovative system for controlling the emitted energy from the fibre. GreenLight™ MoXy™ delivers laser light to the tissue with a maximum power of 180 watts and a wavelength of 532 nm during PVP treatment. The MoXy™ Liquid Cooled Fibre with Active Cooling Cap™ technology used in this device ensures the flow of fibre salt solution around the fibre, which has a cooling effect and minimizes devitrfication of the fibre tip. The device is equipped with a vision track with a light source, camera, monitor, and a 24F continuous flow rigid cystoscope.

Simple prostatectomy – scheme of operational procedure

The SP procedure with various modifications (including Hryntschak) is still commonly per-formed using various types of haemostatic nipples. Extirpation of the adenoma is performed prepubescently by inserting the index finger into the prostatic portion of the urethra, after which the finger is moved to its anterior wall to break the prostatic urethra. By moving the finger laterally, the lateral lobes of the adenoma are separated from the prostatic capsule. Afterwards, a Foley or Dufour catheter (22–24 F) is inserted into the bladder through the urethra, and a temporary haemostatic suture is also placed to control frequent bleeding from the site of the prostatic adenoma. The next step is to insert a cystostomy catheter into the bladder. After controlling haemostasis, the urinary bladder is sutured in 2 layers using a continuous suture.

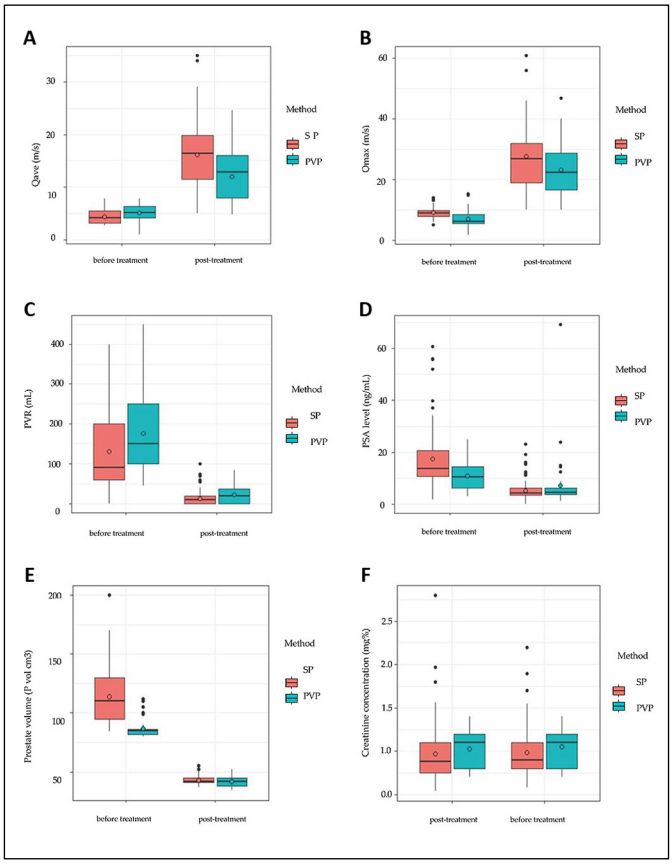

Figure 3. *Plot of mean, median, and first and third quartile values for objective parameters by SP and PVP 31 treatment method and time of measurement (before and after treatment):* **A** *– average flow rate (Qave);* **B** *– maximum flow rate (Qmax);* **C** *– post-voiding residual urine (PVR);* **D** *– PSA level;* **E** *– prostate volume (P vol);* **F** *– Creatinine concentration.*

Statistical analysis

For quantitative characteristics, one-way analysis of variance (ANOVA) was used as a method to evaluate the effectiveness of treatment methods. For objective parameters (Qmax, Qave, PVR, prostate volume, and creatinine and PSA concentrations), the analysis of the effectiveness of the 2 BPH treatment methods, as well as the comparative analysis of these methods, was performed using a one-factor ANOVA. When evaluating the effectiveness of the application of each treatment method, i.e. SP or PVP GreenLight XPS, the ranking factor was the time of measurement of the analysed parameters before and after the application of treatment. Statistically significant differences between group values were determined based on a p-value of less than 0.05. Polychoric correlation analysis was used to assess the co-variance of quantitative characteristics expressed as ordinal variables (this applies to IPSS and QoL scores). Underlying the use of the polychoric correlation index is the assumption that both parameters, IPSS and QoL, are continuous variables that have been "simplified" to an ordinal scale. A given subjective parameter (IPSS, QoL) and the time at which it was measured (before and after treatment) were put to test. The higher the absolute value of the correlation index, the stronger the implied relationship between a given subjective parameter and time. If the correlation index had a negative value, it meant that after treatment with a particular method, the value of the analysed subjective parameter decreased after the use of the given approach. If the correlation index had a positive value, the treatment would be accompanied by an increase in the value of this parameter.

RESULTS

In the present study, the parameters that support the effectiveness of the method were evaluated for an average of 38 months after treatment, which was a sufficient duration that allowed for an effective and accurate assessment of distant treatment results. Patients had their LUTS complaints assessed using the IPSS and QoL sheets. On the other hand, functional evaluation of the lower urinary tract was performed using uroflowmetry (Qmax, Qave), and assessment of post-voiding residual of urine was performed using ultrasound.

The patients' age range in group 1 (SP) was 51 to 86 years, with a mean age of 69.5 years. In group 2 (PVP), the age range was 53 to 78 years, with a mean age of 67.4 years. Preoperative IPSS values in the SP group ranged from 20 to 33, with an average of 26.5, and in the PVP group from 12 to 35, with an average of 22.5. Before treatment, quality of life was scored by SP-treated patients at 4 to 6 points, with an average of 5 points, and by PVP-treated patients at 3 to 6 points, with an average of 5 points.

In the group of patients before PVP treatment, the averaged uroflowmetric parameters were as follows: Qmax: 7.14 ml/s; Qave: 5.11 ml/s; and PVR: 184.34 cm^3, definitively indicating clinically important urinary outflow abnormalities associated with the existence of a subvesical obstruction in the course of BPH. The objective findings obtained confirm the subjective IPSS and QoL results. In patients who qualified for SP, preoperative results also indicated significant urinary outflow obstruction: Qmax: 9.17 ml/s; Qave: 4.43 ml/s; and PVR: 130.52 cm^3. These data are presented pictorially in Figures 3A, B, C.

In the ultrasound examinations performed, Pvol in the SP group ranged from 84 cm^3 to 200 cm^3, mean:

Table 1. *Parameter values before and after treatment of patients with simple prostatectomy and photoselective vaporization of the prostate methods*

Variable	Simple prostatectomy				PVP			
	Before treatment		After treatment		Before treatment		After treatment	
	average	dev. std.	average	dev. std.	average	dev. std.	average	dev. std.
IPSS (points)	26.47	2.72	6.22	1.89	22.51	4.99	7.41	5.47
QoL (points)	4.95	0.58	1.30	0.61	4.76	0.86	1.63	0.97
Qmax (ml/s)	9.17[1]	1.86[1]	27.86	10.27	7.14[2]	2.88[2]	23.28	9.17
Qave (ml/s)	4.43[1]	1.39[1]	16.13	5.80	5.11[2]	1,76[2]	12,05	4.69
PVR (ml)	130.52[1]	99.26[1]	13.42	20.04	184.34[2]	115.47[2]	21.98	22.70
Volume of the prostate (cm^3)	113.85	21.24	43.24	4.09	86.49	7.71	41.73	4.25
Creatinine concentration (mg%)	0.99	0.28	0.97	0.35	1.05	0.21	1.03	0.20
PSA level (ng/ml)	4.38	2.95	1.33	1.00	2.75	1.39	1.79	2.70

[1] n = 52, [2] n = 37
IPSS – International Prostate Symptom Score; Qave – average rate of urethral flow; Qmax – maximal urethral flow; QoL – quality of life; PSA – prostate-specific antigen; PVP – photoselective vaporization of the prostate; PVR – post-void residual volume

Table 2. *Mean and standard deviation values of parameters (variables) for the early postoperative period for simple prostatectomy and photoselective vaporization of the prostate methods*

Variable	SP		PVP	
	average	dev. std.	average	dev. std.
Duration of hospitalisation (days)	9.49	0.90	2.27	0.63
Catheterisation time (days)	8.90	0.71	1.80	0.64
Creatinine concentration (mg%)	0.97	0.35	1.03	0.20
Haemoglobin concentration (g/dl)	12.98	1.29	14.34	0.81

PVP – photoselective vaporization of the prostate; SP – simple prostatectomy

Table 3. *Results of one-way analysis of variance for simple prostatectomy method (before and after treatment)*

Variable	Average value before treatment	Average value after treatment	p-value
Qmax (ml/s)	9.17[1]	27.86	<0.01
Qave (ml/s)	4.43[1]	16.13	<0.01
PVR (ml)	130.52[1]	13.42	<0.01
Pvol	113.85	43.24	<0.01
Concentration creatinine (mg%)	0.99	0.97	0.658
PSA level (ng/ml)	4.38	1.33	<0.01

[1] n = 52
Qave – average rate of urethral flow; Qmax – maximal urethral flow; PSA – prostate-specific antigen; PVR – post-void residual volume; Pvol – prostate volume

113.85 cm^3 (range, 80–112 cm^3), while the average volume in the PVP group was 86.49 cm^3 (Fig 3E).

Table 1 shows the mean values of the parameters observed before and after treatment, which were analysed for the SP and PVP methods, respectively. Testing of objective parameters including Qmax, Qave, and PVR was not performed before treatment in patients with urinary retention (AUR).

The distribution of the values of the analysed parameters is shown in Figure 3.

The average duration of hospitalisation of patients treated with SP was 9.5 days (8–11 days), while patients who underwent PVP stayed in the hospital for an average of 2.3 days (1–4 days). In the SP group, catheterisation time ranged from 8 to 10 days (average, 8.9 days), while in the PVP group, it ranged from 1 to 3 days (average, 2.3 days) (Table 2). In the postoperative period, creatinine and haemoglobin levels in SP-treated patients were 0.54–2.8 mg% (mean 0.97) and 9.1–15.2 g/dL (mean 13.0 g/dL), respectively, while in the PVP group they were 0.7–1.4 mg% (mean 1) and 11.8–15.8 g/dL (mean 14.3 g/dL), respectively.

Objective parameters were not studied in the early post-operative period because individual patients may have had an increase in the severity of lower urinary tract symptoms during this time, and they do not reflect the actual condition for comparing the 2 methods. Moreover, dysuric symptoms resolved at an average of 2 weeks after the PVP procedure. The section on the incidence of late complications includes information on the occurrence of recurrent urinary tract infections and the presence of long-lasting dysuric symptoms.

Table 4. *Polychoric correlation results for subjective parameters in patients treated with simple prostatectomy (before and after treatment)*

Variable	The value of the correlation coefficient
IPSS	-0.998
QoL	-0.998

IPSS – International Prostate Symptom Score; QoL – quality of life

Table 5. *Results of one-way analysis of variance for the photoselective vaporization of the prostate method (before and after treatment)*

Variable	Average value before treatment	Average value after treatment	p-value
Qmax	7.14[2]	23.28	<0.01
Qave	5.11[2]	12.05	<0.01
PVR	184.34[2]	21.98	<0.01
Pvol	86.49	41.73	<0.01
Creatinine concentration (mg%)	1.05	1.03	0.676
PSA (ng/ml) level	2.75	1.79	<0.05

[2] n = 37
Qave – average rate of urethral flow; Qmax – maximal urethral flow; PSA – prostate-specific antigen; PVR – post-void residual volume; Pvol – prostate volume

Table 6. *Polychoric correlation results for subjective parameters in photoselective vaporization of the prostate treated patients (before and after treatment)*

Variable	The value of the correlation coefficient
IPSS	-0.911
QoL	-0.994

IPSS – International Prostate Symptom Score; QoL – quality of life

The first stage of the analysis evaluated the effectiveness of treatment methods.

Simple prostatectomy: assessment of the effectiveness of the treatment

The results of the analysis, which are indicated in Table 3, suggest that there were significant differences ($p < 0.05$) in the mean values of the parameters before and after the application of SP treatment to patients. The exception is the result of creatinine, for which no significant differences were noted before and after the treatment (Fig. 3F).
Regarding qualitative traits, the relationship between pre-treatment and post-treatment SP parameter scores was assessed using the value of the polychoric correlation coefficient. Initially, the scores of the IPSS questionnaire were 26.5; however, this decreased to 6.2 at a later observation time after the implementation of treatment, which indicates a significant improvement, in terms of subjective symptom entrainment. Before treatment, the average QoL score was 4.9, while at the distant follow-up visit after the implementation of treatment, it improved significantly to an average of 1.3. Following the SP procedure, the observed change in the value of each evaluated parameter led to the conclusion of the beneficial effect of this surgical method on the patients' urination conditions.
The results shown in Table 4 indicate a negative correlation between the values of subjective parameters (IPSS and QoL) and the time of their measurement (before and after treatment). Among SP-treated patients, IPSS and QoL questionnaire scores were significantly lower after treatment compared to before treatment.

Table 7. *Results of one-way analysis of variance for selected objective parameters in patients treated with simple prostatectomy or photoselective vaporization of the prostate*

Variable	Average value after SP treatment	Mean value after PVP treatment	p-value
Qmax (mL/s)	27.86	23.28	<0.05
Qave (mL/s)	16.13	12.05	<0.01
PVR (mL)	13.42	21.98	<0.05
PSA (ng/mL) level	4.38	1.79	0.178

Qave – average rate of urethral flow; Qmax – maximal urethral flow; PSA – prostate-specific antigen; PVP – photoselective vaporization of the prostate; PVR – post-void residual volume; SP – simple prostatectomy;

Table 8. *Polychoric correlation results for subjective parameters in patients treated with simple prostatectomy and photoselective vaporization of the prostate (after treatment)*

Variable	Value of the correlation coefficient
IPSS	0.026
QoL	0.221

IPSS – International Prostate Symptom Score; QoL – quality of life

Photoselective vaporization of the prostate: evaluation of the effectiveness of the treatment

As with the application of SP treatment, the results of the analysis show that there were significant differences in the mean values of parameters before and after PVP treatment. The exception is the creatinine results, for which there were no significant differences before and after treatment. IPSS questionnaire scores also decreased significantly from a baseline of 22.5 to 7.4 in the late period. This indicates a sig-

nificant improvement with regard to the symptoms of LUTS that were reported by patients.
Before treatment the average QoL score was 4.8, while in the post-treatment period this score improved to an average of 1.6. The change in the value of each evaluated parameter, i.e. a decrease in IPSS, QoL, and PVR, and an increase in Qmax and Qave, confirm the beneficial effect of the treatment method on urination. These results indicate that the presence of a sub-bladder obstruction was confirmed in patients before applying the treatment; hence, the application of the PVP method influenced its resolution.
The results shown in Table 6 indicate a negative correlation between the values of subjective parameters (IPSS and QoL) and the time they were measured (before and after treatment). Furthermore, among PVP-treated patients, the IPSS and QoL questionnaire scores were significantly lower after treatment than prior to treatment.
The change in the value of each evaluated parameter, i.e. a decrease in IPSS, QoL, and PVR, and an increase in the values of Qmax and Qave, suggest the beneficial effect of the treatment method on urinary conditions and on any symptoms related to this process. The results, which were obtained through statistical analyses, clearly indicate that the presence of a sub-bladder obstruction in patients prior to the application of treatment; furthermore, the introduction of the PVP method influenced its resolution.

Comparative evaluation of the effectiveness of simple prostatectomy and photoselective vaporization of the prostate

It is extremely important to evaluate the comparative effectiveness of the 2 treatment methods analysed. The evaluation was made on the basis of qualitative parameters, including IPSS and QoL, as well as quantitative parameters, namely, Qmax, Qave, PVR, and PSA.
Additionally, after both forms of treatment, there was a significant improvement in urethral flow, as well as a decrease in the PVR. Considering the average values of quantitative parameters, such as Qmax, Qave, and PVR, after treatment, the SP method proved to be the better method. The results shown in Table 7 and Fig. 3 indicate some differences in objective parameters (Qmax, Qave, and PVR) depending on the treatment method used. The Qmax and Qave parameters were lower and the PVR parameter was higher for patients treated with PVP compared to those of patients treated with SP. However, there were no significant differences in PSA concentrations between the 2 treatment methods (Table 7 and Figure 3D). Regarding qualitative characteristics, the correlation between parameter scores after SP and PVP treatment indicated that there were no clear differences in IPSS and QoL scores among patients treated with SP and PVP.
Regarding qualitative traits, the relationship between parameter scores after SP and PVP treatment was assessed based on the value of the polychoric correlation coefficient. The relationship was tested between a given subjective parameter (IPSS, QoL) and the treatment method (SP, PVP).
The results shown in Table 8 indicate a low positive correlation between the values of subjective parameters, IPSS and QoL, and the method of treatment used. Hence, there were no clear differences in IPSS and QoL questionnaire scores among patients treated with SP and PVP.
The above results demonstrate several conclusions. First, regarding baseline parameters after both forms of treatment, there was a significant improvement in urethral flow, as well as a decrease in the volume of urine that lingered after micturition (PVR). Second, due to quantitative parameters, such as Qmax, Qave, and PVR, better average results were obtained after SP treatment.

Comparative evaluation of photoselective vaporization of the prostate and simple prostatectomy in relation to adverse effects

An important issue representing another objective of the analysis was the comparison of the 2 surgical methods in the context of certain side effects. After each procedure, we analysed the decrease in haemoglobin (Hb) concentration in the patients' blood, which was associated with intra- and postoperative bleeding, and consequently we also determined the frequency of red blood cell concentrate (RBC) transfusions.
For comparative evaluation of PVP and SP values obtained before surgery, haemoglobin levels in patients treated with SP and PVP were 13.9 g/dL and 14.6 g/dL, respectively. After surgery, the above values were 13.0 g/dL and 14.3 g/dL, respectively.
The rate of postoperative complications treated with the SP method according to C-D was 24%. Complications in this area included, in particular, infections, haematuria and anaemia. Complications of grade II C-D occurred in 14 (18%) patients, and 9 (10%) in grade I. All the above-mentioned complications were managed conservatively with medication and blood transfusion. No C-D complications were observed in higher grades.
The rate of postoperative complications treated with PVP according to C-D was 17.5%. Complications in this area included, in particular, increase in body

temperature, transient haematuria, and anaemia. Complications of grade II C-D were not observed, while 4 (10%) had grade I complications. All the above-mentioned complications were managed conservatively with the administration of medications. No C-D complications were observed in higher grades. No patients required a re-intervention because of bleeding (Clavien-Dindo >IIIa) in the PVP group.
The results of comparative statistical analysis proved that the average haemoglobin concentration was significantly lower in patients who were treated with the SP method than in those treated with the PVP method; therefore, blood loss was statistically higher in patients who underwent SP ($p < 0.01$). In addition, 14 SP-treated patients (18% of the study group) were accompanied by the need for blood clot transfusion. In contrast, PVP treatment did not require the transfusion of the CRC to any patient after the procedure.

DISCUSSION

In the last century, SP has become the primary treatment for BPH. It was considered the gold standard for the treatment of this condition. Although, at the turn of the century, significant progress was made in the development and introduction of minimally invasive techniques for the treatment of BPH, open access approaches are still widely used, especially for large adenomas [6, 7, 8]. Although until recently it was recognized that the limit of eligibility for con-fluence between transurethral surgery and open prostatectomy remained a matter of debate, including in the AUA and EAU guidelines for the treatment of lower urinary tract symptoms in men, the open method is still recommended for adenomas with volumes >80–100 ml [9, 10]. More recently, this limit for transurethral access has been questioned in several studies, due to the increasing use of laser treatments [11].
Despite the wide spread use of "gold standard" treatments including transurethral electroresection (TURP) with bipolar (BiTURP) and laser procedures, such as PVP and holmium laser enucleation (HoLEP), or thulium laser (TuLEP), which are considered by some to be the best treatment option for BPH regardless of prostate size [12 ,13], SP remains the procedure of choice for patients with glands that are too large for safe endoscopic resection [9, 10].
SP is undoubtedly a treatment option that significantly reduces LUTS symptoms [14–18]. In a comparative randomized trial, Meyhoff et al. showed that SP was well accepted by patients, as only 9% of those who underwent this procedure were dissatisfied with the treatment outcomes compared to 15% of those who underwent TURP, which is considered the "gold standard" for treating BPH [19, 20, 21]. Tubaro et al. examined patients who underwent urodynamic evaluation 12 months after SP [16]. The study showed a significant reduction in symptoms in terms of assessed IPSS parameters, QoL, Qmax, and PVR. Approximately 84% of patients reported subjective improvement in QoL. None of the patients had a value greater than 3, with a mean value of 0.2. In this study, 60% of patients reported no LUTS after treatment, and 96.9% of patients had a flow rate greater than 15 ml/s one year postoperatively [16]. Varkarakis et al. confirmed these data in another study [17]. Additionally, another study retrospectively evaluated 151 patients who underwent SP for BPH (adenoma mass greater than 70 g) 5 years postoperatively [16]. The study showed significant improvement after 8 to 12 months of follow-up, as shown by an increase in Qmax, a significant re-duction in PVR a decrease in LUTS symptoms, as well as improvements in QoL, which were statistically significant 12 months after surgery and did not change significantly after longer follow-up (mean 41.8 months). Unfortunately, open surgery is associated with a higher rate of complications compared to endoscopic procedures. Complications related to wound healing or the occurrence of bladder-skin fistula occur in 0.4–4% of patients in the immediate postoperative period [17, 22]. The duration of hospitalisation after the procedures performed was not significantly different; the duration of hospital stay is also usually longer with open procedures. According to Tubaro and Varkarakis, the average duration of hospitalisation was 6–10 days, and this is related to the period of catheterization (a median of 5 days) [16, 17, 22].
PVP is a technique that is increasingly used in urology. Studies have shown the effectiveness of this treatment method in BPH. Published studies indicate a reduction in bladder catheterization time and hospitalisation time, as well as the possibility of using this method in patients treated with antiaggregants and/or anticoagulants. Considering the parameters mentioned, IPSS and Qmax improved significantly and were compared in a prospective study with the group treated with SP. The result of treatment, in terms of subjective evaluation, was satisfactory in both groups, and as emphasized, PVP is an alternative method of treating BPH in patients with large adenomas. Rajbabu et al. noted that there were no major complications or the need for blood transfusions, confirming the safety and efficacy of laser vaporization of large volume prostates [13]. A study by Raimbault et al. [23] compared data collected retro-

spectively for the SP-treated group with data from a prospective analysis for the PVP group with adenomas weighing more than 80 g. The patients were followed for one year. Although the guiding purpose of the study was to compare the economic aspects of the 2 methods, it also presented data showing their efficacy. Forty-one patients in the SP group and 53 in the PVP group treated with a GreenLight laser (LBO) were evaluated. The mean length of stay was significantly shorter in the PVP group than in the SP group (3.0 ±1.0 days vs 10.4 ±4.0 days; p <0.001). Reoperations after one year were less frequent in the PVP group than in the SP group (1.9% vs 19.5% p <0.001). Furthermore, patients in the SP group had a higher mean prostate weight (129 vs 110 g) and higher mean PSA values (11.4 vs 8.7 ng/ml). The treatment duration was comparable for both methods (100.4 ±29.5 min for the group that underwent SP vs 104.9 ±47.8 min for the PVP group). The study also considered the number of patients treated with antiaggregants and/or anticoagulants. In the open procedure group, 21.9% of patients (9/41) were administered antiplatelet drugs, and 4.9% (2/41) of patients received anticoagulants. All patients in this group discontinued these drugs preoperatively. In the PVP group, 40.4% of patients (21/52) used antiplatelet drugs, and 3 of the patients continued treatment during surgery. The reoperation rate (immediate and late) was 19.5% in the suprapubic adenomectomy group and 1.9% in the PVP group (p <0.001) [23]. On the other hand, in a comparative analysis of BPH treatments using PVP and SP in patients with prostate adenomas of over 80 g, Raimbault and Watt observed that the average length of stay was significantly shorter in the group of patients treated with PVP, and this significantly reduced treatment costs [23]. The comparison also examined the costs associated with the procedure, including hospitalisation costs. The PVP-treated patient group had a significant reduction in hospitalisation and bladder catheterization time maintained for approximately 24 hours; moreover, the procedure could be used in patients treated with antiaggregants and/or anticoagulants [23]. Although the cost of purchasing a generator and fibre is significant, given the short hospitalisation time, the PVP procedure is more economical. According to Rajbabu and Chandrasekar, the duration of the procedure was similar in both. Patients treated with the open procedure experienced more bleeding than those in the PVP group, which was confirmed by the changes in haemoglobin levels before and after the procedure. This resulted in the need for blood transfusions in 15 patients who were treated with open surgery, while patients who underwent PVP did not require transfusions. Furthermore, another advantage of PVP was the rate of total reoperation (immediate and late), which was 19.5% in the SP-treated group versus 1.9% in the PVP group (p <0.001). PVP is the dominant management strategy because it reduces the number of reoperations while reducing the immediate cost of surgery compared to open surgery. Moreover, PVP is a technique that is increasingly used in urology, and conducted analysis has shown its effectiveness in reducing symptoms of BPH when compared to that of TURP [23, 24, 25]. This study confirms the safety and efficacy of the laser in large-volume sterile vaporization. No major complication or the need for transfusion was found during or after the procedure [13].

There are few reports on the comparative evaluation of the effectiveness of the treatment of prostate adenomas with a volume of more than 80–100 ml using the PVP method with the XPS 180 W laser and the SP surgical method, which is still in use. The large size of the compared patient groups and the study design used for the analysis made it possible to obtain reliable results. Undoubtedly, the advantage of this study is the relatively long follow-up period, at an average of 38 months. The validated questionnaires for assessing LUTS (IPSS – International Prostate Symptom Score, ICIQ-MLUTS – International Consultation on Incontinence Ques-tionnaire, and DAN-PSS – Danish Prostate Symptom Score) meet the recommendations for diagnostic tools in benign prostatic hyperplasia. Based on the above questionnaires, it is possible to estimate the severity of complaints and determine the predominant ones, which makes them valuable tools in monitoring patient outcomes [17, 18].

Analysis of the objective parameters, which were obtained using uroflowmetry examination in the period before the treatment and an average of 38 months after the treatment, including maximum urethral flow, average urethral flow, and PVR, shows that both in the case of SP and PVP there was a significant improvement in their values, with particular emphasis on the improvement of urinary conditions after treatment and the abolition of symptoms of urinary out-flow obstruction.

Regarding IPSS and QoL, as well as Qmax, Qave, and PVR, the study conducted indicates that significant improvements were obtained regardless of the treatment method used. This study also conducted a comparative evaluation of the described treatment methods, using the same subjective and objective parameters. Considering their mean values after treatment, more favourable, results

were obtained after SP. The Qmax and Qave parameters were lower, and the PVR parameter was better, for patients treated with SP compared to those treated with PVP. In contrast, there were no clear differences in IPSS and QoL questionnaire scores among SP- and PVP-treated patients.

The study clearly indicates that the new treatment method of PVP has measurable results and is as effective as SP (which has been used for many years) in the treatment of BPH.

It is worth noting that an additional element of the above study was the evaluation and comparison of side effects and complications that occurred in patients treated with both methods. Accordingly, factors that occur immediately after performance of the procedure and at a later time were evaluated. Factors that were analysed and occurred immediately after the procedure focused on post-operative bleeding, haemoglobin levels, the need for transfusions of blood products (CRP) after the procedure, and the occurrence of infectious symptoms.

It has been shown that there are important differences regarding the frequency of intraoperative and postoperative bleeding, and in the reduction in haemoglobin concentration in patients who require blood transfusion in exceptional situations. The comparative results obtained prove that the average haemoglobin concentration was significantly lower in patients who were treated with SP than in those treated with PVP, while blood loss was statistically higher in patients who underwent SP. In addition, after treatment with SP, approximately 18% of the study group required transfusion of blood cells. In contrast, treatment with the PVP method did not create a need for transfusion of the CRC for any patient after the procedure.

The results obtained in the study on postoperative assessment of prostate adenoma using both methods according to the Clavien-Dindo classification are similar to the results obtained in other urological trials [26, 27, 28].

In our study the postoperative complications treated with the SP method according to C-D were observed in grade I and II. Immediate complications (18%) were mainly represented by perioperative bleeding with the need for blood transfusion (complication grade II)

Postoperative complications treated with PVP according to C-D were observed in grade I. Complications of grade II C-D were not observed, while 7 (17.5%) had grade I complications. All the above-mentioned complications were managed conservatively with the administration of medications. No C-D complications were observed in higher grades, and no patients required a re-intervention because of bleeding (Clavien-Dindo >IIIa) in the SP and PVP group.

Fever requiring antipyretic drugs was the main cause of grade I complications. This value was influenced by perioperative antibiotic therapy and the identification of urinary tract infections before surgery.

The results obtained are comparable to data presented by other authors [29, 30, 31]. Considering postoperative bleeding, which significantly affects the clinically relevant decrease in haemoglobin concentration and creates the need to supplement blood products, the present analysis confirms previous reports in the literature emphasizing the superiority of PVP over SP in this regard ($p < 0.01$) and showing the greater safety of PVP laser vaporization over SP. The number of patients who are administered anticoagulants for cardiovascular conditions increases every year, and their use is a contraindication to performing SP because they are associated with the risk of serious bleeding complications. The purpose of the above analysis was not to assess the feasibility of performing PVP and the risk of postoperative bleeding in patients receiving anticoagulants and antiaggregants. However, data from the literature on the superiority of PVP over other methods in this regard, including SP, confirms the safety of this method [27, 32, 33].

In a study performed at the Department of Urology, Oncological, and Functional Urology at the WIM in Warsaw, the efficacy of PVP treatment in patients with BPH using the GreenLight XPS, LBO 180W laser was evaluated. A definite improvement in maximum urinary flow rate (Qmax) was observed from 8.9 before treatment to 20.8, 21.4, and 21.2 ml/s after 1, 3, and 6 months, respectively. The IPSS decreased from 23.8 to 8.3, 7.7, and 7.1 points at 1, 3, and 6 months, respectively, while the QoL score decreased from 4.2 to 1.8, 1.7, and 1.5 points at 1, 3, and 6 months, respectively. The authors of the study observed no significant complications or changes in blood parameters (haemoglobin and sodium) during PVP. The most common post-operative complications included transient dysuria and haematuria [34]. Favourable clinical effects of SP in the treatment of patients with BPH were observed, and this study attempts to answer the question of whether the new treatment method, which is based on PVP, is equally effective and whether it can be used as the gold standard in the treatment of BPH on its own.

An undeniable benefit flowing from the use of PVP is the shorter hospitalisation period for patients. The average length of hospitalisation for patients undergoing SP was 9.49 days, while patients who underwent PVP stayed in the hospital for an average of only 2.27 days. This supports the notion that pa-

tients treated with PVP are likely to quickly return to full social and professional activity.
The study's results completely confirm the previously formulated assumptions, recognizing the effectiveness of PVP at almost the same level as SP and identifying its superiority in some respects. Based on these data and premises, it should be concluded that PVP can be used extensively in the treatment of BPH. Additional analysis of side effects associated with both methods confirmed the superiority of PVP over SP in this regard, as already recognized in previous literature reports.

CONCLUSIONS

This study demonstrated the comparable and high efficacy of SP and PVP with the GreenLight XPS 180W in the treatment of patients with BPH. The evaluation of subjective parameters, which were obtained based on the IPSS and QoL questionnaires, also showed high therapeutic efficacy for both methods studied, and there were no statistically significant differences between them.
The results of the statistical analysis showed that patients treated with the SP method had better results in terms of objective parameters, such as the Qmax, Qave, and PVR. However, in terms of the abolition of the symptoms of LUTS and the fact that an improvement in micturition was obtained lastly, both methods should be considered effective in the treatment of BPH. Moreover, this was confirmed in the evaluation of treatment efficacy for each method in terms of objective and subjective results. Furthermore, PVP with the GreenLight XPS 180W had a more favourable safety profile than SP in terms of intraoperative bleeding, urinary tract infection risk, catheterization duration, and hospital stay. This makes it an effective and safe method for treating BPH in high-risk patients who cannot undergo previous treatments.
These results make PVP with the GreenLight XPS 180W an effective and safe method for treating BPH, allowing for the safe expansion of indications and coverage of treatment for patients in risk groups. The low number of complications and side effects, low invasiveness of the method, and short hospital stay enable a faster return to the daily life activities of patients and provide tangible socioeconomic benefits.
The study evaluated the efficacy parameters at an average of 38 months after surgery, which effectively assessed the distant results of the treatment. However, a longer period of observation (e.g. 5–10 years after the procedure) would provide unequivocal confirmation of the long-term persistence of treatment effects. While a comparative analysis may provide further verification, the parameters used in this study based on objective and subjective criteria are sufficient. The literature on the subject indicates that many papers comparing other therapeutic methods for BPH use identical research instruments. Therefore, the results of this study provide an opportunity to confirm the favourable changes occurring in the improvement of objective test results after surgical treatment.

CONFLICTS OF INTEREST

The authors declare no conflicts of interest.

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