FOLIA MEDICA CRACOVIENSIA
Vol. LVIII, 3, 2018: 23–34
PL ISSN 0015-5616
DOI: 10.24425/fmc.2018.125069

Evaluation of the effectiveness of laser photoselective vaporization of the prostate in the treatment of patients with benign prostatic hyperplasia

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Abstract: Introduction: The prolongation of the life of men results in the growing number of people suffering from benign prostatic hyperplasia (BPH). In 2010, BPH concerned more than 200 million men in the whole world, which at that time made up 6% of the population of men at large. Currently, the population of men in the world amounts about three billion six hundred million. The modern surgical treatment of BPH consists of minimally invasive techniques, including laser systems.
Aim: Evaluation of the effectiveness of photoselective vaporization of the prostate (PVP) on the basis of subjective parameters assessed by patients using IPSS and QoL questionnaires as well as objective parameters obtained from results of urodynamic tests.
Material and Methods: Between 2012 and 2015, 120 patients with benign prostatic hyperplasia were included in the study and underwent PVP. Finally, 77 patients were included in the study. In all patients, IPSS and QoL sheets were carried out 1, 6 and 12 months, and urodynamic tests 12 months after the surgical treatment.
Results: The statistically significant change in the value of each parameter assessed: decrease in the IPSS, QoL, PVR, Pmax, Pop, the degree of obstruction according to Schäfer and ICS nomogram, and an increase in the values of Qmax and Qave.
Conclusions: Photoselective vaporization of the prostate is an effective method of therapy in patients with benign prostatic hyperplasia.

Key words: minimal invasive surgery, benign prostatic hyperplasia, photovaporisation.

Introduction

The prolongation of the life of men in the world leads to the from-year-to-year growing number of people suffering from urination disorders resulting from benign prostatic hyperplasia. In analyzing epidemiological studies carried out, Berry *et al.* have demonstrated that 50% of men in the age group of 50–60 are found to have pathological changes typical of a benign prostatic hyperplasia [1]. This percentage increases with age. Autopsies have demonstrated that 80% of men over 80 years old have characteristic histological changes typical of BPH [2].

In 2010, BPH concerned more than 200 million men in the whole world, which at that time made up 6% of the population of men [3]. Currently, the population of men in the world amounts to about three billion six hundred million.

The surgical treatment of BPH currently includes a removal of prostatic adenoma using open surgical techniques with a transvesical or prevesical approach and several endoscopic methods, also minimally invasive ones, using various forms of energy, above all laser systems.

The natural trend of every surgery domain is to reduce the degree of invasiveness and extent of operative procedures necessary for the achievement of a good therapeutic effect.

The use of endoscopic methods based on laser systems enables a reduction of the number and severity of undesirable effects and a qualification of a broader group of patients for operative treatment, including those with conditions constituting contraindications to the use of conventional procedures.

A KTP laser was first used in the treatment of BPH patients in 1997 (Malek, Mayo-Clinic, USA) [4]. A KTP laser uses a potassium-titanyl-phosphate crystal as an active medium through which a Nd-YAG laser light wave of the length of 1064 nm passes and continuously works. As a result a light wave of the length 532 nm in the range of green visible light is achieved. A certain light property of this wave features a genuine quality: it is absorbed by haemoglobin and fully transmitted by water, including aqueous irrigation fluids, and reaches the cell without losses of energy. This allows for an effective vaporization of the tissue with an additional effect of coagulation that ensures a hemostasis and thus a good visualization of the operated field. Thus the name of the operative procedure derives from using a KTP laser: photoselective vaporisation of the prostate (PVP).

The risk of bleeding in the case of PVP is low in comparison to the transurethral resection of the prostate (TURP), which is still treated a gold standard. This makes possible a safe completion of procedures also in patients with cardiovascular disorders, including those under chronic anticoagulantion [5]. The duration of bladder catheterization and the hospitalization period are also shorter in the case of a PVP compared to a TURP. The problem of the postresection syndrome is also absent [6].

Aim of study

Evaluation of the effectiveness of PVP on the basis of subjective parameters assessed by patients using IPSS and QoL questionnaires as well as objective parameters obtained from results of urodynamic tests including an analysis of the following parameters: maximum urinary flow rate (Qmax), average urinary flow rate (Qave), postvoid residual (PVR) urine volume, maximum detrusor pressure (Pmax), urethral opening pressure (Pop), maximum cystometric capacity of the bladder (MCC) and the degree of obstruction according to Schäfer and ICS nomograms before and after the treatment.

Materials and Methods

During the period between 2012 and 2015, 120 patients with benign prostatic hyperplasia at the age of 50–87 were included in the study at the Department of General, Functional and Oncological Urology at the Military Institute of Medicine in Warsaw. During the period from 1 January 2012 to 31 December 2015, each of the patients included in the study underwent operative procedures. Ultimately, 77 patients who later underwent a PVP were included in the study. The limitation of the ultimate number of patients qualified for the study was caused among other things by a failure of patients to come for follow-up examinations (a large number of the patients were from distant locations), absence of a solid cooperation by the patients, incompleteness of the results of examinations used in the analysis due to their partial absence, illegibility or loss.

A presence of a bladder outlet obstruction of varying degrees has been confirmed by preoperative urodynamic tests in almost all the patients qualified for a surgical treatment. All the patients were found to have a prostate enlargement with a volume of 30–110 cm^3, 61.9 cm^3 on average, in ultrasonography. The age of the patients ranged between 50 and 87, and it was 67.9 on average.

During the physical examination, all the patients have reported lower urinary tract symptoms (LUTS) characteristic of BPH, despite the earlier pharmacological therapy. This has been confirmed in the preoperative scores obtained from IPSS questionaires. The score ranged from 11 to 31 and the mean was 19.9. On the basis of the IPSS questionnaires, it has been determined that complaints of moderate or severe intensity occurred in all the patients, whereas the percentage proportion was 58%/42% and the number ratio was 45/32, respectively.

During the preoperative period, examinations of all the patients in accordance with the recommendations of the European Association of Urology (EAU) enabling an appropriate qualification for surgical treatment for a BPH were performed. These examinations included collection of medical history, physical examinations,

laboratory tests and imaging. In accordance with the EAU guidelines, a completion of the IPSS and QoL questionnaires by each patient was an integral part of collecting their medical history. Furthermore, each patient underwent a urodynamic test before the surgery in order to make a precise assessment of the function of lower urinary tract, in particular of the degree of bladder outlet obstruction.

Urodynamic parameters in patients before PVP were as follows: a Qmax of 8.3 ml/s, Qave of 4.1 ml/s, PVR of 199.6 cm^3, Pmax of 109.6 cm H_2O, Pop of 89.7 cm H_2O and MCC of 355.2 cm^3. The results obtained from the questionnaires were as follows: IPSS — 19.9 and QoL — 4.8. These values indicate clearly clinically relevant urinary outflow disturbances related to bladder outlet obstructions in the course of BPH. This is reflected in the averaged value of the degree of obstruction by Schäfer and ICS nomograms. The averaged degree of obstruction according to Schäfer nomogram was 4.3, whereas 93.4% patients were found to have significant urinary outflow obstruction by the ICS nomogram.

The laser vaporization of the prostate was carried out using an AMS LaserScope Greenlight HPS system (Serial No 2021) produced in the US. This 50–60 Hz and 20 A device generates a laser beam with the wavelength of 532 nm characteristic of the green spectrum. The range of power is 20–120 W and it allows an adjustment in steps of 10 W. The energy flows through a LASEROSCOPE GreenLight HPS optical fibre. This device uses a working fibre with the diameter of 600 microns and 366 cm long that enables a sideward projection of laser beam. The device is also equipped with a visual tracking with a light source, camera, monitor and continuous flow rigid cystoscope with a diameter of 24F.

In line with the aim of the study, 12 months after the surgical treatment, all the patients included in the final study were subjected to an assessment of complaints in the form of LUTS based on the IPSS and QoL questionaires, follow-up examinations with an analysis of urinary flow, cystometry/micturition and urethral profilometry with an additional assessment of the degree of bladder outlet obstruction according to Schäfer nomogram and classification of ICS.

The analysis of operative treatment effectiveness formulated in such a way is in line with the recommendations on IC and BPH of the Clinical Research Criteria Committee [7]. The determination of the period of one year as the time of the follow-up examination enabled, firstly, a determination of the long-term outcome of operative treatment, while, on the other hand, it made possible an avoidance of effects of irritation symptoms occurring after operative treatment on urodynamic parameters in accordance with the elaborations of the Authors prepared so far [8–10].

The research was approved by the Bioethics Commission of the Military Medical Institute No. 92/WIM/2018 dated. 21/02/2018.

Statistical analysis

The aim of the statistical analysis is to determine whether the chosen method of treatment of benign prostatic hyperplasia significantly differentiates the results of subjective and objective parameters of the treated patient.

A one-way ANOVA along with tetrachoric correlation coefficients for binary variables were used as a research tool.

Analysis of variance — ANOVA, allows to assess the impact of the classifying factor x_j o to the distribution of a dependent variable measured on interval scale. The homogeneity of the variance of parameters was confirmed by the Levane test.

The level of significance was 0.01 ($p = 0.01$).

Tetrachoric correlation coefficients are a measure of the dependence between the features measured on the dichotomous (binary) scale. Binary variables are then treated as hidden continuous variables with a normal distribution. This approach allows to estimate what the correlation between the given features would be if it were possible to observe unsettled values on the binary scale.

The normality of distribution of dependent variable in each of the groups determined by the categories of classifying variables was checked using the Kolmogorov-Smirnov test [11].

Results

The results of the analysis carried out indicate that a classifying variable (time of measurement — before and after the treatment) for most of the analyses of variance models (apart from the analysis of variance model for the MCC variable) differentiates significantly mean values of parameters. Consequently, there are statistically significant differences in the average values of parameters before the treatment of patients using the method of PVP and after a treatment using this method ($p < 0.01$). This is confirmed by the benefits of the performance of PVP in respect of both subjective and objective symptoms related to benign prostatic hyperplasia.

The maximum cystometric capacity (MCC) ($p = 0.648$) is the only parameter for which there is no significant difference in the results before and after the treatment. However, it is not a parameter of high relevance in comparison with the other parameters assessed regarding the issue of assessment of bladder outlet obstruction. This parameter is also not used to determine bladder outlet obstruction using Schäfer and ICS nomograms.

Mean values, standard deviations and results of statistical analysis of parameters before and after the use of treatment method of PVP are shown in Table 1, whereas the proportions of patients having respective grades of obstruction according to Schäfer nomogram are shown in Table 2.

Table 1. Mean values, standard deviations and results of statistical analysis of parameters of the method of PVP before and after the treatment.

Variable	Mean value and standard deviation before the treatment	Mean value and standard deviation after the treatment	Test statistics	*p*-value
IPSS (point)	19.9 ± 4,8	1 month: 10.6 ± 3.0	198.8	<0.01 ($<2e^{-16}$)
		6 months: 6.9 ± 2.0	464.0	<0.01 ($<2e^{-16}$)
		12 months: 6.3 ± 2.3	488.6	<0.01 ($<2e^{-16}$)
QoL (point)	4.8 ± 0.9	1 month: 2.2 ± 0.8	312.9	<0.01 ($<2e^{-16}$)
		6 months: 1.6 ± 0.9	454.7	<0.01 ($<2e^{-16}$)
		12 months: 1.6 ± 0.8	468.3	<0.01 ($<2e^{-16}$)
Qmax (ml/s)	8.3 ± 4.3	23.9 ± 9.3	171.6	<0.01 ($<2e^{-16}$)
Qave (ml/s)	4.1 ± 2.2	12.3 ± 5.7	136.3	<0.01 ($<2e^{-16}$)
PVR (ml)	199.6 ± 172.8	18.9 ± 80.0	67.57	<0.01 ($9.45e^{-14}$)
Pmax (cm H_2O)	109.6 ± 39.1	65.4 ± 24.9	67.82	<0.01 ($8.96e^{-14}$)
Pop (cm H_2O)	89.7 ± 34.7	50.6 ± 24.7	62.73	<0.01 ($5.37e^{-13}$)
MCC (ml)	355.2 ± 133.1	363.8 ± 94.3	0.209	0.648
Obstruction acc. to Schäfer's classification (grade)	4.4 ± 1.2	1.5 ± 1.0	229.100	<0.01 ($<2e^{-16}$)

Table 2. Proportions as a percentage of patients having respective Schäfer's obstruction grades before and after the treatment using the method of PVP.

Grade of obstruction	Before PVP (%)	After PVP (%)
0	1.4	17.4
1	0	36
2	2.7	29.3
3	19	12
4	31	5.3
5	27	0
6	18.9	0

The results of the IPSS questionnaire in 1st, 6th and 12th month after the treatment decreased from a baseline value of 19.9 to 10.6, 6.9 and 6.3, respectively, which was an improvement in respect of LUTS reported by the patients. Similar results were obtained in the case of answers to questions concerning the quality of life. Before the treatment, the average result of QoL was 4.8, whereas in 1st, 6th and 12th months after the treatment it improved up to the average level of 2.2, 1.6 and 1.6, respectively.

Before the treatment, 93.3% of patients were found to give answers that are considered to be negative, i.e. within the score of 4–6 (rather bad, bad and very bad state of being). In 1th, 6th and 12th months after PVP, no values higher than 4 were found using the QoL. After 1 month 2.9% of patients, and after 6 months 2.8% of patients, were found to have a value of 4; and after 12 months none of the patients had a value of 4. The answers considered to be positive, i.e. having a score of 0, 1 and 2 (an excellent, very good and rather good general feeling) were recorder for 61.7%, 90.3% and 90.8% of patients after 1, 6 and 12 months, respectively.

The values obtained during the uroflowmetry, including the values of Qmax, Qave and PVR, improved and were 8.3 ml/s, 4.1 ml/s and 199.6 ml against 23.9 ml/s, 12.3 ml/s and 18.9 ml, respectively.

The values obtained during the cystometry and the results of the flow and pressure measurements including determinations of Pmax, Pop and MCC improved and were 109.6 cm H_2O, 89.7 cm H_2O and 355.2 ml against 65.4 cm H_2O, 50.6 cm H_2O and 363.8 ml, respectively.

The median grade of bladder outlet obstruction in patients before the surgical procedure was 4.4 according to Schäfer nomogram. It decreased to 1.5 ($p < 0.01$) after the treatment. The statistically significant improvement in this respect indicated a clinically relevant diminishment of the grade of bladder outlet obstruction or in some cases a complete disappearance of the obstruction. Before the treatment, 96% of patients were qualified to be within a medium and high Schäfer's obstruction grade (III–VI), of which 76.9% of patients had a large (grade IV, V, VI) obstruction. 2.6% of patients have remained in the equivocal grade. 1 patient (1.3%) was found not to have any obstruction, despite a BPE and more intense LUTS were found. After the laser photovaporization, 53.3% of patients who underwent surgery were found to have no obstruction or only a small (grade 0–I) obstruction. 29.3% of patients have remained in the equivocal (grade II) zone. 12% and 5.3% of patients were qualified as grade III and IV, respectively. Based on urodynamic test, none of the patients who underwent PVP was found to have a grade V or VI obstruction according to Schäfer nomogram. 5% and 12% of patients were still found to have an obstruction of grade IV and III. In 53.3% of patients who underwent PVP complete disappearance of obstruction was recorded.

The change in the value of each parameter assessed, i.e. a decrease in the IPSS, QoL, PVR, Pmax, Pop, and the degree of obstruction according to Schäfer nomogram and an increase in the values of Qmax and Qave demonstrate a beneficial effect of the operative method on the conditions of micturition and symptoms related to this process.

A graphical representation of the treatment outcomes in relations to the degree of bladder outlet obstruction assessed using Schäfer nomogram is shown in Fig. 1.

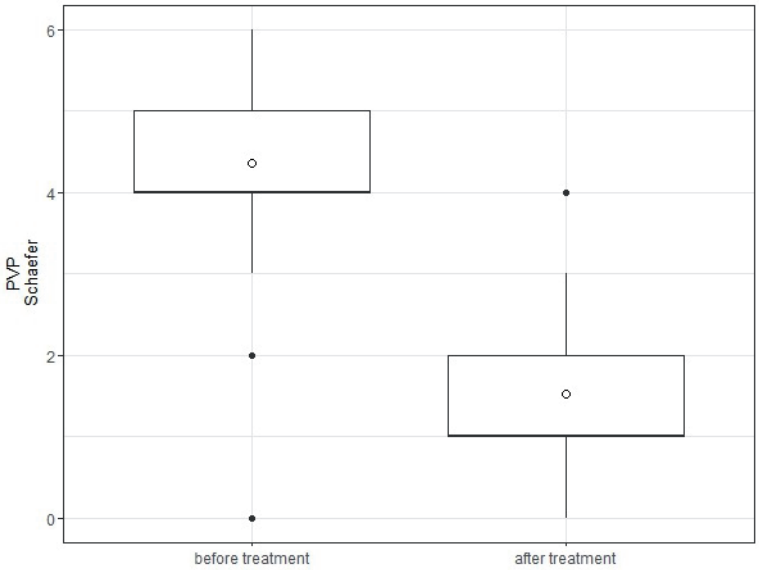

Fig. 1. A diagram of the mean values, median, first and third quartile of the Schäfer classification of the treatment method of PVP by the time of measurement (before and after the treatment).

Due to the binary character of the variable value that features a presence of an obstruction according to the ICS nomogram, the tetrachoric correlation coefficient for this parameter was calculated in order to evaluate the effectiveness of PVP.

The value of the tetrachoric correlation coefficient for the ICS parameter in patients treated using the PVP method was –0.9705914. The outcomes of the PVP treatment in relation to the ICS parameter are shown in Table 3.

The obtained results of statistical analyses indicate that in the case of the binary variable of the ICS a bladder outlet obstruction was found in the patients before the treatment, whereas the use of the method PVP resulted in a disappearance of such an obstruction. Before the PVP, 93.5% of patients were found to have an obstruction according to the ICS nomogram and the result values of 4.9% of patients remained in the equivocal zone. After the treatment, 72.1% of patients were found to have a disappearance of obstruction, the result values of 4.4% of patients remained in the equivocal zone and 23.5% of patients were still found to have an obstruction.

Table 3. Percentage of patients without an obstruction, with their result values in the equivocal zone and with a bladder outlet obstruction according to the ICS nomogram before and after the PVP treatment, respectively.

Obstruction acc. to the classification of ICS	Before the treatment (%)	After the treatment (%)
No	1.6	72.1
Equivocal zone	4.9	4.4
Yes	93.5	23.5

A significant difference in the values of these variables before and after the PVP treatment was demonstrated in the study carried out (confirmed by a statistical analysis) using subjective (IPSS, QoL) and objective (Qmax, Qave, PVR, Pmax, MCC, Pop) parameters that were later used in the assessment of bladder outlet obstruction using Schäfer and ICS nomograms. The differences from the analysis in parameter values assessed before and after the treatment demonstrate the effectiveness of the method in the potential to eliminate bladder outlet obstruction, reduce postvoid residual urine volume, increase urinary flow rate, decrease the value of detrusor pressure and of urethral opening pressure.

Discussion

More than 80 years have now passed since the introduction of the McCarthy electroresector into urological practice. The subsequently modified transurethral electroresection of the prostate has become the gold standard in the treatment of patients with benign prostatic hyperplasia by the present day [12–15].

High risk of complications associated with TURP, gave rise to development laser methods including: potassium-titanyl-phosphate laser photoselective vaporization prostatectomy (PVP), holmium laser enucleation of the prostate (HoLEP), 2-μm (thulium) laser resection of the prostate-tangerine technique (TmLRP-TT) [16].

The photoselective vaporization of the prostate constitutes a method which may fullfil all the above requirements. First reports about the use of green light laser systems, then of KTP lasers, in urological practice date back to 1986. The technique of the use of 60-W KTP lasers for vaporizations of the prostate was elaborated by Malek *et al.* at the Mayo Clinic in 1997 [4]. The results presented by the authors indicated that the new method is safe and effective. A generator using a lithium triborate (LBO) crystal through which a Nd-YAG laser light wave with a power level of up to 120 W is transmitted has been introduced into urological practice in 2006. Furthermore, new generation fibres improving the collimation of laser beam and also increasing the procedure effectiveness were introduced [17]. A laser system with such a power level brings about a more effective vaporization, consequently, enabling a shortening of the

procedure duration [18]. It also makes possible effective vaporizations of large volume glands [13]. An increase in the frequency of complications and undesirable effects resulting from the procedure were not observed with an increase in power level [19].

Since then, many reports on the use of 120-W LBO lasers in the treatment of patients with benign prostatic hyperplasia have been mentioned in the medical literature.

Sixty men who underwent PVP in 1th, 3rd, 6th, 12th, 24th and 36th month after the treatment were evaluated in the study performed by Al-Ansari *et al.* in 2010. 54 men participated in the whole follow-up of 36 months. The analyzed parameters were: IPSS, Qmax and PVR. A significant improvement in respect of the baseline values of parameters was achieved. An improvement of IPSS from 27 to 10 and of Qmax from 6.9 to 17 ml/s has been recorded in the group of patients treated by a PVP after 36 months and the PVR decreased from 53 to 11 ml. Severe intraoperative complications in patients after a PVP were not recorded, none of the patients required a transfusion of blood products and — in accordance with the technique of the method — no postresection syndrome has occurred in the patients [20].

The study carried out by the Capitan's team in 2011 included a group of 50 men who underwent PVP. The evaluation of patients after 24 months showed an improvement in respect of both subjective (IPSS: –15.7) and objective (Qmax: +14.5) parameters [21]. In 2013, Xue *et al.* has analyzed data of 100 patients who underwent PVP. The IPSS and QoL sheets as well as the results of uroflowmetries including an assessment of maximum urinary flow rates and of postvoid residual urine volumes were also the parameters analyzed in this study. Like in the results of the other authors, a significant improvement in respect of both subjective and objective parameters has been achieved compared with the preoperative values [22].

Pereira-Correia *et al.* have urodynamically assessed patients who underwent a procedure of PVP. The observation period was 24 months. Like in the previous elaborations, the analysis was based on results of the IPSS and QoL questionnaires. However, in addition to that a urodynamic test of the subjects was carried out during the observation period after 6, 12 and 24 months, respectively. Based on the values obtained from the study, the bladder outlet obstruction index (BOOI) was calculated using the following formula: BOOI = PdetQmax – 2Qmax. BOOI values <20 indicated an absence of obstruction, whereas a result of ≥20 indicated a presence of obstruction or corresponded to the equivocal zone. The mean baseline values of urodynamic parameters including Qmax, PVR and PdetQmax were 10 ml/s, 150 ml and 73.1, respectively. Analogous results were obtained in both groups after 6, 12 and 24 months: a Qmax of 16.7, 22.2 and 20.5 ml/s, a PVR of 3 ml, 2 ml and 4 ml, a PdetQmax of 29.3, 24.2 and 27.7, respectively. The averaged baseline values BOOI were 60. During the observation period, the BOOI was 8.7, 12 and 4.5 in the 6th, 12th and 24th month, respectively. The obtained results confirmed the high effectiveness of

PVP in respect of both LUTS and the improvement in lower urinary tract function. The authors believe that the high-power PVP can lead to results comparable with a TURP in respect to effectiveness [23, 24].

The above mentioned figures allow for the conclusion to be drawn that photoselective vaporization of the prostate is an effective method of therapy in patients with benign prostatic hyperplasia and is an alternative to transurethral electroresection of the prostate.

Conclusions

The differences in the values of the evaluated parameters before and after the treatment showed high effectiveness of PVP.

PVP leads to diminishing the severity of lower urinary tract symptoms, reducing postvoid residual volume, detrusor pressure and increasing the flow rate.

Acknowledgments and disclosures

Acknowledgments — none.

Conflict of interest

None declared.

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