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Pure Bipolar Plasma Vaporization of the Prostate: The Zürich Experience

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Introduction and Objectives: Bipolar plasma vaporization (BPV) has been introduced as an alternative to transurethral resection of the prostate (TURP). Promising short-term results, but inferior mid-term results compared to TURP have been reported following first-generation bipolar electrovaporization. Outcome data following second-generation BPV are still scarce. The aim of this investigation was to evaluate the intra- and postoperative outcomes of contemporary BPV in a center with long-standing expertise on laser vaporization of the prostate.

Methods: A consecutive series of 83 patients undergoing BPV in a tertiary referral center was prospectively evaluated. The investigated outcome parameters included the maximum flow rate (Qmax), postvoid residual volume, International Prostate Symptom Score (IPSS)/quality of life (Qol), and prostate-specific antigen (PSA) tests. Follow-up investigations took place after 6 weeks, 6 months, and 12 months. The Wilcoxon signed-rank test was used to compare pre- and post-treatment parameters.

Results: The median (range) preoperative prostate volume was 41 mL (17–111 mL). The preoperative IPSS, Qol, Qmax, and residual volume were 16 (2–35), 4 (0–6), 10.1 mL/s (3–29.3 mL/s), and 87 mL (0–1000 mL), respectively. One third of the patients were undergoing platelet aggregation inhibition (PAI). No intraoperative complications occurred. Postoperatively, 13 patients (15.7%) had to be recatheterized. Three patients (3.6%) had clot retention and 28 patients (34%) reported any grade of dysuria. After 6 weeks, all outcome parameters improved significantly and remained improved over the 12-month observation period [IPSS: 3 (0–2); Qol: 1 (0–4); Qmax: 17.2 mL/s (3.2–56 mL/s); residual volume 11 mL (0–190 mL)]. The PSA reduction was 60% at study conclusion. Three patients (3.6%) developed a urethral stricture and four patients (4.8%) bladder neck sclerosis. Re-resections were not necessary.

Conclusions: Contemporary BPV is a safe and efficacious treatment option even for patients undergoing PAI. Early urinary retention and temporary dysuria seem to be specific side effects of the treatment. Bleeding complications are rare. Long-term follow-up is needed to confirm these promising short-term results.

Introduction

MONOPOLAR TRANSURETHRAL RESECTION of the prostate (TURP) has been shown to be an efficacious and durable treatment option for patients with lower urinary tract symptoms caused by prostatic enlargement.^{1–3} It is considered the surgical reference standard for patients with a prostate volume of less than 80 mL.⁴ However, despite many technical refinements over the last decades, it is still associated with a relevant rate of complications mainly caused by bleeding and the so-called TUR syndrome.^{2,5,6} The morbidity of TURP and the growing number of patients with significant cardiovascular comorbidities or with an imperative indication for platelet aggregation inhibition (PAI) or anticoagulation

prompted the development of novel, minimally invasive alternatives.

Bipolar TURP and 532 nm laser vaporization are two safe and efficacious minimally invasive treatment options. They both are characterized by improved hemostatic properties and the possibility to perform intraoperative irrigation with isotonic saline. A lower rate of bleeding complications compared to conventional TURP and excellent clinical outcomes have been reported for these procedures.^{7–9} Prostate vaporization using the 532 nm laser is even safe in patients undergoing PAI or anticoagulation.¹⁰

Bipolar plasma vaporization (BPV) of the prostate has been introduced to further improve the hemostatic properties of bipolar TURP. Contemporary BPV using a hemispherical

vaporization electrode combines the advantages of the bipolar technique (affordable equipment, saline irrigation) with the benefits of the 532 nm laser technique (tissue vaporization, reduced bleeding, excellent overview, and short learning curve). However, outcome data following contemporary BPV of the prostate are still scarce. Initial reports are very promising with low intra- and perioperative morbidity and functional short-term results comparable or even superior to TURP.¹¹⁻¹³ The aim of the present investigation was to evaluate the intra-, peri-, and postoperative outcomes of the initial BPV series of our center, which has a long-standing expertise on prostate vaporization using the 532 nm laser.

Patients and Methods

A consecutive series of patients undergoing BPV for prostatic bladder outlet obstruction in a tertiary referral center between August 2009 and November 2011 were prospectively evaluated. Approval for this observational study was obtained from the local ethics committee and all enrolled patients provided written informed consent.

The attending urologist generally made the indication for BPV after unsuccessful medical treatment or if the patient had refused medical therapy for his symptomatic prostatic bladder outlet obstruction. BPV was offered to all patients without PAI or anticoagulation, but also to those undergoing PAI.

Preoperatively, patients were asked to complete the International Prostate Symptom Score (IPSS) and quality of life (QoL) questionnaire. Transrectal ultrasound of the prostate, uroflowmetry, and postvoid residual volume measurement were performed. The preoperative blood work included a prostate-specific antigen (PSA) test. Patients with a PSA value >4 ng/mL or a suspicious digital rectal examination underwent BPV only if a preoperative prostate biopsy showed no malignant results. Urinalysis and a urine culture were also routinely performed.

All patients with a normal preoperative urine status received intravenous single-shot antibiotic prophylaxis with Trimethoprim-Sulfamethoxazole 160/80 mg 30-60 minutes before the operation. In patients with significant leukocyturia, antibiotic treatment was initiated preoperatively and continued for at least 5 days after catheter removal.

The procedure was carried out under either general or spinal anesthesia. A SurgMaster UES-40 generator and the hemispherical bipolar HF-vaporization electrode were used in combination with a 24F OES continuous-flow Iglesias resectoscope (all Olympus Winter & Ibe GmbH, Hamburg, Germany). The power output used for tissue vaporization and tissue coagulation was 290-320W and 150-170W, respectively. The operation was performed using the vaporization mode and coagulation was only used selectively for localized bleeding. All procedures were carried out under continuous low-pressure irrigation using an automated irrigation suction pump (Endo Fluid Management System Urology, Future Medical System SA, Genève, Switzerland) and prewarmed isotonic saline (37°C).

The operation was carried out analogous to a conventional TURP. After insertion of the cystoscope and careful inspection of the prostate and bladder, the ureteral orifices were identified. Vaporization was initiated at the bladder neck to ablate the median lobe of the prostate. The procedure was continued at the lateral lobes. Finally, the anterior part of the prostate

and the apical/paracollicular region were vaporized until the appearance of a TURP-like cavity. Extensive coagulation of the cavity at the end of the operation was generally avoided. In patients with a prostate volume of less than 30 mL, an additional bladder neck incision was regularly performed. At the end of the procedures, a 20F three-way irrigation catheter was inserted and continuous irrigation with isotonic saline was initiated. The operative time (from insertion of the cystoscope to insertion of the catheter), the total amount of irrigation fluid, and all intraoperative complications were recorded.

Generally, the catheter was removed after 3 days. In the case of persisting hematuria, catheter removal was postponed. After removal of the catheter, uroflowmetry and postvoid residual volume measurements were done. Perioperative complications, the duration of catheterization, and recatheterizations were recorded.

The patients were regularly seen in follow-up after 6 weeks, 6 months, and 12 months in the outpatient clinic. At each follow-up visit, uroflowmetry, residual volume measurements, and a PSA test were performed. Additionally, the IPSS and QoL questionnaire were completed. Furthermore, the patients were asked to report symptoms of dysuria.

All data are presented as median and range. Statistical analysis was done using IBM SPSS Statistics software 20.0 (IBM, Armonk, NY). The preoperative variables were compared to postoperative variables using the Wilcoxon signed-rank test. All *p*-values <0.05 were considered statistically significant.

Results

A total of 83 patients were included in this study. The preoperative patient characteristics are displayed in Table 1. Twenty-six patients (31.3%) were operated under ongoing

TABLE 1. BASELINE PATIENT CHARACTERISTICS

Number of patients	83
Age (y)	67 (48-89)
Prostate volume (mL)	41 (17-111)
PSA (ng/mL)	2.69 (0.26-22.5)
IPSS	16 (2-35)
QoL	4 (0-6)
Qmax (mL/s)	10.1 (3-29.3)
Residual volume (mL)	87 (0-1000)
Indwelling catheter (<i>n</i>)	20 (24.1%)
ASA score	2 (1-3)
1	8 (9.6%)
2	50 (60.2%)
3	25 (30.1%)
Coagulation modifiers (<i>n</i>)	26 (31.3%)
Acetylsalicylic acid (<i>n</i>)	26 (31.3%)
Clopidrogel (<i>n</i>)	1 (1.2%)
Coumarin (<i>n</i>)	0 (0%)
Dual therapy (<i>n</i>)	1 (1.2%)
Positive urine culture (<i>n</i>)	32 (38.5%)
Indwelling catheter (<i>n</i>)	18 (21.6%)
No catheter (<i>n</i>)	14 (16.8%)

Data presented as median (range) or number (percent).

PSA = prostate-specific antigen; IPSS = International Prostate Symptom score; QoL = quality of life; Qmax = maximum flow rate; ASA score = American Society of Anesthesiology score.

TABLE 2. INTRA- AND PERIOPERATIVE RESULTS

Operative time (min)	80 (34–145)
Irrigation volume (l)	22.5 (12–39)
General anesthesia (<i>n</i>)	60 (72.2%)
Spinal anesthesia (<i>n</i>)	23 (27.8%)
Blood transfusion (<i>n</i>)	0 (0%)
Duration of catheterization (d)	3 (2–13)
Duration of hospitalization (d)	4 (2–11)
Recatheterization (<i>n</i>)	13 (15.6%)
Urinary retention (<i>n</i>)	10 (12%)
High residual volume + UTI (<i>n</i>)	2 (2.4%)
Clot retention (<i>n</i>)	1 (1.2%)

Data presented as median (range) or number (percent).
UTI=urinary tract infection.

PAI with acetylsalicylic acid. One patient had dual PAI with additional clopidrogel medication. In all six patients with oral anticoagulation, the coumarin medication was perioperatively replaced by low molecular weight heparin at therapeutic doses. Heparin was stopped 24 hours before the operation and reinitiated with subtherapeutic doses after the procedure. It was then gradually increased and replaced by coumarin if no macrohematuria occurred.

All patients underwent the preoperative, initial postoperative, and 6-week assessment. A total of 75 (90%) and 71 (86%) patients were available for the evaluation after 6 and 12 months, respectively.

The intra- and perioperative results are shown in Table 2. BPV was performed by a total of five surgeons. Three senior surgeons did 67 procedures (81%) and two senior residents did 16 supervised procedures (19%) in the form of a teaching operation. Pure BPV was successfully completed in 82 patients (98.8%). Conversion to conventional bipolar TURP was necessary in one patient with a prostate volume of 110 mL due to intraoperative diffuse hemorrhage, which resulted in poor visibility. The patient was not undergoing PAI, but was under antibiotic therapy for an asymptomatic urinary tract infection. Major intraoperative complications did not occur and intra- or perioperative blood transfusions were not necessary in any of the patients.

A total of 32 patients (36%) had a positive preoperative urine culture. Nine of these patients had an unsuspecting urine status. Postoperatively, a positive urine culture was found in nine patients who subsequently were treated with antibiotics. Only one of these patients had an indwelling catheter preoperatively. None of the patients developed symptoms of a systemic urinary tract infection or an urosepsis.

Four of the 13 patients who needed postoperative re-catheterization had an indwelling catheter preoperatively. Three patients were discharged with a catheter of which, two were successfully removed after 13 days. In one patient with persistent urinary retention, a suprapubic cystostomy was performed for a permanent solution. Perioperatively, one patient developed gross hematuria with clot retention. Following cystoscopic clot evacuation, transurethral coagulation of the ablation cavity was undertaken. One patient developed a small bowel volvulus associated with an adhesive strangulation 3 days after the operation. After laparotomy, a segment resection and enteroenterostomy were performed. Seven days later an anastomotic leak was detected and a revision of the enteroenterostomy was necessary. The patient was discharged 36 days after BPV.

Table 3 summarizes the postoperative outcome parameters. The maximum flow rate (Qmax) and the residual volume were already investigated after catheter removal. The Qmax increased nonsignificantly to 14 mL/s ($p=0.06$), whereas the reduction of the residual volume was already statistically significant at this early postoperative assessment ($p<0.001$). After 6 weeks, all functional outcome parameters improved significantly compared to the baseline values (Wilcoxon $p<0.001$ (IPSS, QoL, residual volume) and Wilcoxon $p=0.006$ (Qmax)). A further significant improvement was detectable after 6 months for the IPSS and QoL and after 12 months for the IPSS. All parameters remained significantly improved over the entire 12-month observation period (Table 3). The PSA value was already significantly reduced after 6 weeks ($p<0.001$). After 12 months, a 60% reduction of the initial PSA value was detectable (Table 3).

Table 4 illustrates further postoperative results. Of the 15 patients who were found to have a positive urine culture 6 weeks after surgery, six had an indwelling catheter and ten a positive urine culture preoperatively. All patients were treated with oral antibiotics. One patient was diagnosed with a pyelonephritis 1 month after the operation. The urine was found to be positive for mycobacterium tuberculosis. An initial four-drug regimen was followed by a three-drug treatment for 9 months. Subsequently, mycobacteria were not detectable anymore. Four patients were diagnosed with a urinary tract infection between the 6-week and 6-month follow-up. Afterward, urinary tract infections were not diagnosed anymore.

Two patients (2.4%) presented with delayed hematuria and clot retention after 4 and 6 weeks, respectively. Both patients were hospitalized for cystoscopic clot evacuation and subsequent coagulation. One of these patients was undergoing dual

TABLE 3. BASELINE AND POSTOPERATIVE OUTCOME PARAMETERS

Parameter	Baseline	Postoperative	6 weeks	6 months	12 months
IPSS	16 (2–35)	N/A	8 ^a (0–29)	3 ^{a,b} (0–24)	3 ^{a,b} (0–20)
QoL	4 (0–6)	N/A	2 ^a (0–6)	1 ^{a,b} (0–4)	1 ^a (0–4)
Qmax (mL/s)	10.1 (3–29.3)	14.0 (3.8–47)	16.7 ^a (2.3–52)	16.7 ^a (5–53.8)	17.2 ^a (3.3–56)
Residual volume (mL)	87 (0–1000)	20 ^a (0–900)	10 ^a (0–437)	6.5 ^a (0–500)	11 ^a (0–190)
PSA (ng/mL)	2.69 (0.26–22.5)	N/A	1.36 ^a (0.04–9.56)	1.27 ^a (0.15–6.98)	1.11 ^a (0.08–7.18)

Data presented as median (range).

^aIndicates a statistically significant improvement compared to the baseline value (Wilcoxon signed-rank test).

^bIndicates a statistically significant improvement compared to the preceding assessment (Wilcoxon signed-rank test).

N/A=not applicable.

TABLE 4. POSTOPERATIVE RESULTS

Urinary tract infection	
≤6 weeks (<i>n</i>)	15 (18%)
6 weeks–6 months (<i>n</i>)	4 (4.8%)
6 months–12 months (<i>n</i>)	0 (0%)
Delayed clot retention (≤6 weeks; <i>n</i>)	2 (2.4%)
Dysuria	
6 weeks (<i>n</i>)	28 (34%)
6 months (<i>n</i>)	2 (2.4%)
12 months (<i>n</i>)	3 (3.6%)
Urethral stricture (<i>n</i>)	3 (3.6%)
Bladder neck sclerosis (<i>n</i>)	4 (4.8%)
Re-resection (<i>n</i>)	0 (0%)

Data presented as median (range) or number (percent).

PAI medication, and therefore laser coagulation of the ablation cavity was performed. In three symptomatic patients (4%), a *de novo* urethral stricture was diagnosed and treated by visual internal urethrotomy after 6 and 8 months and by a simple dilatation procedure after 11 months, respectively. All of the four patients who developed a symptomatic bladder neck sclerosis were treated by transurethral bladder neck incision after 2 months (*n*=1) 4 months (*n*=2) and 7 months (*n*=1), respectively. Only one of the patients had an initial prostate volume of less than 30 mL and none of the patients had a urinary tract infection pre- or postoperatively.

Discussion

This prospective investigation of intra-, peri-, and postoperative outcomes following pure contemporary BPV of the prostate revealed that the procedure is safe, has a low morbidity, and results in significant improvements of all investigated outcome parameters. No major intraoperative complications occurred and conversion to conventional bipolar transurethral resection was necessary in only one patient with a large prostate. Postoperative bleeding complications, which required reinterventions but no transfusions, occurred in three patients of whom one was undergoing dual PAI. Interestingly, two of these complications occurred with a delay of 4 to 6 weeks after the operation. Urinary tract infections were relatively frequent preoperatively, but also in the early postoperative period. One third of the patients reported dysuria after 6 weeks. After 6 months, urinary symptoms were generally rare. Reoperations due to persistent obstructive tissue were not necessary, but seven patients (8%) were treated for symptomatic urethral strictures (*n*=3) or bladder neck sclerosis (*n*=4).

Kaplan and Te introduced electrovaporization of the prostate using a rollerball electrode in 1995.¹⁴ Despite promising functional results, this monopolar technique was soon abandoned due to higher rates of irritative voiding symptoms and stress urinary incontinence compared to conventional TURP.^{11,15} In 2001, Botto and colleagues reported their initial results of a bipolar vaporization technique using a special bar electrode.¹⁶ Subsequently, several studies revealed a lower intra- and perioperative morbidity and functional short-term results comparable to conventional TURP.^{17–20} However, midterm results have been reported to be inferior compared to TURP.^{7,21}

In 2008, a novel bipolar device using an ergonomic, hemispherical electrode and a different energy setting was laun-

ched.²² To date, only limited data are available for this contemporary BPV technique. In 2010, Reich and colleagues reported their initial clinical experience of a very small series of 30 patients with a follow-up of 6 months.¹¹ Four different surgeons from two centers did the operations. Their short-term functional results were comparable to the results of the present study. Bleeding complications did not occur and one patient with a large initial prostate volume required reoperation 4 weeks after the initial procedure.

Robert and colleagues reported a French multicenter observational study of 106 consecutive patients with a short-term follow-up of 3 months.¹³ Patients were recruited from eight different centers. A maximum of three surgeons per center performed the operations resulting in an average of only seven operations per surgeon. Improvements of the IPSS and bother score were comparable to the improvements observed in the present study. However, a high failure rate of eight percent after 3 months indicates that tissue ablation might have been insufficient in a relevant proportion of patients in this study. Additionally, three major complications (urethral necrosis with urinary fistulas (*n*=2) and significant bladder necrosis (*n*=1)) occurred in three consecutive patients from one center. These complications were considered to be associated with material failure. The case of a small bowel volvulus requiring a segment resection represents a serious complication in our series. It is likely that the development of the volvulus is somehow related to the initial surgery. However, we do not believe that this complication is specifically related to the BPV procedure.

The same group from France reported a *post hoc* retrospective comparison of 54 patients under oral anticoagulation from their initial study and 57 patients undergoing TURP under oral anticoagulation.²³ Comparable functional results after 3 months, but significantly less bleeding complications after BPV were seen. It is noteworthy that most of the patients were not under oral anticoagulation but under PAI. Furthermore, PAI was stopped in the majority of the patients and oral anticoagulation was replaced by heparin in all patients before surgery. In the present investigation, 30% of the patients were under ongoing PAI. Intraoperative bleeding complications did not occur in these patients. However, dual PAI and urinary tract infections might increase the risk of intra- and perioperative bleeding complications.

Two randomized trials comparing BPV with monopolar and bipolar TURP were conducted by Geavlete and colleagues.^{12,24} In their first study, they reported the 6-month results of 155 patients undergoing either BPV (*n*=75) or monopolar TURP (*n*=80) done by a single surgeon.²⁴ The operative time, catheterization period, and hospital stay were significantly shorter in the BPV arm. Furthermore, all relevant outcome parameters were in favor of BPV and the complication rate was significantly lower following BPV compared to TURP. The mean operative time was 35.1 minutes and the mean prostate volume decreased from 56.2 to 16.8 mL after 6 months. Compared to the present investigation, the Qmax in their study was slightly higher and the recatheterization rate and dysuria rate lower. Urethral strictures and reoperations were not reported.

The second trial by the same group indicated to evaluate long-term results of a randomized trial of 510 patients who underwent BPV (*n*=170), monopolar TURP (*n*=170), and bipolar TURP (*n*=170).¹² However, with a follow-up of only 18

months, we think that the results of this trial represent rather short-term than long-term results. This large-scale single center trial revealed a clear benefit for BPV in terms of complications and clinical outcome. The intraoperative complication rate was significantly lower in the BPV arm compared to both, the monopolar and the bipolar TURP arm. Postoperative irritative voiding symptoms and urethral strictures were comparable between the three groups. However, a significantly lower recatheterization rate, a lower rate of bladder neck sclerosis, and fewer retreatments were detectable following BPV. Furthermore, improvements of IPSS, QoL, and Qmax were significantly better in the BPV arm. It remains unclear why the bipolar TURP arm and the additional 95 and 90 patients in the BPV and monopolar TURP arm, respectively, were not reported in the initial series that was published only 12 months earlier. Long-term follow-up will show if these excellent results are durable.

In the present study the duration of catheterization was significantly longer compared to the other studies.^{11,13,24} This difference is not related to a higher rate of bleeding complications, but is mainly due to local reimbursement policies in Switzerland. The present investigation also revealed a lower Qmax compared to the studies by Geavlete and colleagues.^{12,24} The improvement of the Qmax in the present investigation is comparable to what has been reported in the studies by Reich and Robert, respectively.^{11,13} However, it seems also to be significantly lower than the improvement reported following monopolar TURP.^{7,24} All other investigated functional outcome parameters are comparable to the results reported after BPV and monopolar TURP. The studies of Geavlete and colleagues also showed a lower complication rate compared to the present investigation. We found more urinary tract infections, recatheterizations, and higher rates of dysuria and bladder neck sclerosis. Dysuria, early postoperative urinary retention, and urinary tract infections have been reported to be frequent after 532 nm laser vaporization of the prostate.⁷ The higher rate of these complications in the present study might indicate that these complications are associated with prostate vaporization in general. Given the wide range of the reported rate of bladder neck sclerosis following BPV among different studies (0.6% to 7.2%), the rate in the present study appears to be rather average.^{12,25} Furthermore, it seems to be comparable to what has been reported for monopolar and bipolar TURP.^{26,27} In our collective, retreatments were not necessary during the 12-month observation period. This is lower compared to published BPV and TURP data. A longer follow-up has to confirm this promising result.

The generally excellent coagulation properties of the bipolar vaporization device result in an excellent overview during the procedure and, in our opinion, make this treatment modality particularly appealing for teaching operations. However, we also realized that the procedure has to be performed in a speedy manner to achieve sufficient tissue ablation in a reasonable time. The experience of the surgeon is likely to influence the speed and efficiency of tissue vaporization during BPV. In the study by Geavlete, a single surgeon did all the procedures. This might explain the excellent ablation rate of approximately 40 mL in 35 minutes and the above average clinical outcome.²⁴ The high retreatment rate in the French study might reflect the insufficient tissue ablation of surgeons, who were rather inexperienced using this technique.¹³ All senior surgeons in the present study were experienced

in prostate vaporizations using the 532 nm laser. This experience might improve the vaporization efficiency particularly in the learning phase of the BPV procedure. The PSA reduction of 60% and the lack of necessity for reoperations substantiate this assumption.

A drawback of the present investigation is the lack of a control group, which limits the ability to compare the results with those of other techniques. However, given the sparsely available data of contemporary BPV, our study adds important information to the published evidence. Furthermore, we did not design and power this study for subgroup analyses, which might allow identifying predictors of clinical outcome following BPV. A larger prospective investigation would be required to formally identify these predictors and our results can be helpful in designing such a study. The long-standing experience with prostate vaporization techniques in our center, the longer follow-up period, the larger number of patients, and the lower number of surgeons who performed the procedure compared to most of the other BPV studies are specific advantages of our investigation.

Conclusion

Contemporary BPV is a safe and efficacious treatment option even for patients undergoing PAI. BPV results in significant improvements of all relevant outcome parameters over a 12-month period. Bleeding complications are rare. Early urinary retention and temporary dysuria seem to be specific side effects of the treatment. A multi-institutional study with long-term follow-up is needed to confirm the promising short-term results and to further evaluate the durability of the procedure.

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Author Disclosure Statement

The authors declare that no competing financial interests exist.

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Abbreviations Used

BPV = bipolar plasma vaporization
 IPSS = International Prostate Symptom Score
 PAI = platelet aggregation inhibition
 PSA = prostate-specific antigen
 Qmax = maximum urinary flow rate
 Qol = quality of life
 TURP = transurethral resection of the prostate