Photoselective vaporization combined with bipolar transurethral resection for the treatment of large prostate adenoma in high-risk patients

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ABSTRACT

الأهداف: تقييم مدى سلامة وفعالية الجمع بين عمليتي استئصال تضخم البروستات باستخدام الليزر وبتوجيه الموجات فوق الصوتية عبر الإحليل (PVP) وعملية استئصال تضخم البروستات عن طريق المنظار الضوئي وباستخدام محلول الإرواء الملحي (TURP) وذلك في المرضى الذين يعانون من مشاكل صحية شديدة وتضخم البروستات.

الطريقة: أُجريت هذه الدراسة الاستطلاعية في مستشفى جامعة شاندونغ، جينان، مقاطعة شاندونغ، الصين وذلك خلال الفترة من يناير 2007م إلى يناير 2010م. شملت هذه الدراسة 101 مريضاً يعاني من أمراض مجموعية، حيث كانوا ضمن التصنيف ASA 3 أو أكثر وذلك وفقاً لجمعية أطباء التخدير الأمريكية. لقد خضع هؤلاء المرضى للعملية التي تجمع بين استئصال تضخم البروستات باستخدام الليزر وبتوجيه الموجات فوق الصوتية عبر الإحليل وعملية استئصال تضخم البروستات عن طريق المنظار الضوئي وباستخدام محلول الإرواء الملحي وكان ذلك بسبب معاناتهم من مشاكل في المسالك البولية السفلى نتيجةً لتضخم البروستات الحميد، وقد وصل تضخم غدة البروستات إلى أكثر من 80 مل. وبعد ذلك تم عمل الاختبارات التالية: الاختبار العالمي لتقييم أعراض مرض تضخم البروستات الحميد واستبيان تقييم مدى تأثير المرض على الحياة (IPPS-Qol)، ومعدل التدفق الأقصى (Qmax)، واختبار تحديد بقايا البول في المثانة (PVR)، وتصوير حجم البروستات بالرنين المغناطيسي. وقمنا بمقارنة البيانات الطبية وتقييم التحسن الوظيفي والمشاكل التي طرأت قبل وبعد العملية الجراحية، وتمت متابعة المرضى وتقييم حالتهم بعد العملية الجراحية بحوالي 3، و6، و12 شهراً.

النتائج: أشارت الدراسة إلى أن متوسط الوقت الذي استغرقته العملية الجراحية قد كان 68.5±23.9 دقيقة. وكان متوسط حجم غدة البروستات قبل العملية الجراحية 102.2±33.1 مل، ومن ثم أصبح متوسط حجم الغدة بعد العملية 40.4±15.6 مل. لم يتم ملاحظة أي تعقيدات أو مشاكل خلال العملية أو بعدها، وتم تسجيل الاختلافات الواضحة في كل من: الاختبار العالمي لتقييم أعراض مرض تضخم البروستات الحميد واستبيان تقييم مدى تأثير المرض على الحياة، ومعدل التدفق الأقصى، واختبار تحديد بقايا البول في المثانة وذلك خلال متابعة المرضى بعد العملية الجراحية.

خاتمة: أظهرت الدراسة مدى فعالية وقلة سلبيات الجمع بين عمليتي استئصال تضخم البروستات باستخدام الليزر وبتوجيه الموجات فوق الصوتية عبر الإحليل وعملية استئصال تضخم البروستات عن طريق المنظار الضوئي وباستخدام محلول الإرواء الملحي وذلك في المرضى الذين يعانون من مشاكل صحية شديدة بالإضافة إلى تضخم البروستات.

Objectives: To evaluate the safety and effectiveness of the combined photoselective vaporization of the prostate (PVP) and bipolar transurethral resection of the prostate (TURP) in high-risk symptomatic patients with large prostates.

Methods: Between January 2007 and January 2010, a prospective study was performed in Shandong Provincial Hospital, Shandong University, Jinan, Shandong Province, China. One hundred and one patients presenting with various kinds of systematic diseases, and with an American Society of Anesthesiologists score of 3 or greater underwent PVP plus bipolar TURP for severe lower urinary tract symptoms due to benign prostatic hyperplasia with prostatic volume greater than 80 ml. The International Prostate Symptom Score (IPSS) and quality-of-life questionnaire (IPPS-QoL), maximum flow rates (Qmax), postvoid urine residues (PVR), and MRI prostatic volumes were recorded. Perioperative data, functional outcome, and complications were evaluated. Patients were reassessed at 3, 6, and 12 months.

Results: The mean operation time was 68.5±23.9 minutes. The mean pre- and post- operative prostate volumes were 102.2±33.1 ml and 40.4±15.6 ml. No severe complications were observed. Significant differences in IPSS, Qmax, and PVR values were recorded within the follow-up period.

Conclusions: The results of our study show that PVP plus bipolar TURP have an excellent efficiency and low morbidity in high-risk patients with large prostates.

Saudi Med J 2010; Vol. 31 (12): 1320-1325

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Received 21st August 2010. Accepted 18th October 2010.

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Benign prostatic hyperplasia (BPH) is one of the most frequent diseases in men, and a major cause of lower urinary tract symptoms (LUTS). The aim of endoscopic treatment for BPH is to remove as much of the prostatic tissue as possible with low complications and short hospitalization and catheterization time.[1] Transurethral resection of the prostate (TURP) has been the gold standard of treatment for symptomatic BPH for many decades. However, despite its effective results, TURP is of limited use due to morbidities such as bleeding and TUR syndrome, especially in the treatment of patients presenting with grave concomitant diseases.[2] Therefore, several minimally invasive alternative treatment modalities are developed. One such therapeutic alternative is transurethral photoselective vaporization of the prostate (PVP), which is performed with the Greenlight laser at 532 nm. Since the introduction of the 80-W high-power generator in 2001, encouraging results of PVP have been published.[1] The PVP has gained broad acceptance because of its excellent intraoperative safety.[3] At the same time, several studies showed that parameters such as reduction of prostate volume and operating time were in favor of TURP.[4] In our prospective study, we studied the efficacy, and safety of PVP plus bipolar TURP in high-risk patients accompanied with prostate volumes greater than 80 ml.

Methods. Between January 2007 and January 2010, a prospective study was performed in Shandong Provincial Hospital, Shandong University, Jinan, Shandong Province, China. One hundred and one patients with high surgical risk underwent PVP in combination with bipolar TURP for lower urinary tract symptoms due to BPH. Prostate size was measured by MRI, and only the patients with an overall prostatic volume larger than 80 ml were accepted. The preoperative evaluation also included medical history, physical examination, including digital rectal examination, routine urine and blood analyses, including determination of serum prostate-specific antigen (PSA) level. The maximal urinary flow rate (Qmax), and average urinary flow rate, and postvoid residual urine (PVR) volumes were measured. Patients were also asked to complete the International Prostate Symptom Score and quality-of-life questionnaire (IPPS-QoL). The postoperative prostate volume was measured by MRI at the day before discharge. All patients were reevaluated at discharge and 3, 6, and 12 moths postoperatively. At each point International Prostate Symptom Score (IPSS), Qmax, PVR, and adverse events were assessed. Serum PSA levels were measured at 3, 6, and 12 months postoperatively.

Inclusion criteria for surgery comprised Qmax less than 15 ml/s or transvesically measured PVR more than 100 ml in conjunction with an IPSS greater than 7. Criteria for patient exclusion from the study were patients with documented or suspected prostate cancer, neurogenic bladder disorder, urethral strictures, PVR greater than 400 ml, any previous prostatic, bladder neck, or urethral surgery.[5] The American Society of Anesthesiologists (ASA) grading system was applied by the same anesthetist for each patient to estimate the health status and to assess the risk of anesthesia. In the present study, high risk was defined as patients presenting with various kinds of systematic body diseases and with ASA score of 3 or greater. The patient population data is listed in **Table 1**. All patients signed an informed consent and the protocol was approved by the ethics committee of our hospital.

Technique. The operation was performed under spinal anesthesia. All surgical procedures were completed by 2 experienced surgeons, both of whom had performed >600 TURPs and >300 PVPs before starting the study. Endoscopic examination of the bladder and prostatic urethra was carried out before the procedure. Bipolar TURP was performed by the Olympus transurethral resection in saline (TURIS) system. The Surgmaster™ (Olympus, Tokyo, Japan) generates a high frequency current that passes through the active electrode (resection loop) and returns via the return electrode (sheath of resectoscope). The generator setting for cutting and coagulation were 180-W and 100-W. The PVP was performed with an 80-W KTP side-firing laser (GreenLight PVTM, Laserscope®, San Jose, CA, USA) system. The KTP/532 laser energy was delivered by a 6F side-deflection fiber with a 23F continuous-flow cystoscope. Saline solution was used for irrigation during surgery. The surgical technique can be divided into 2 steps: Firstly, bipolar TURP is used to eliminate most of the adenoma. The bladder neck, median lobe, and lateral lobes of the prostate are removed consecutively. Afterward, remnant tissue, including the apical prostatic portion is vaporized very precisely by the KTP-laser. Special care is taken in order to protect the verumontanum as well as the external sphincter. Finally, the KTP-laser is used to ensure optimum coagulation and create a bloodless surgical field. At the end of the procedure, the capsular fibers are visible and a large cavity is obtained. In cases where there was perceivable angiectasis on the surface of the prostate, PVP was first applied to stop bleeding before bipolar TURP was performed. Postoperatively, a 20F triple-lumen catheter

Disclosure. This study was funded by the Shandong Science and Technology Project of China (BS2009YY028).

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was inserted into the bladder. Antibiotic prophylaxis was administered both preoperatively and for 7 days postoperatively. Perioperative parameters including operation time, postoperative changes of hemoglobin and serum sodium, hospital stay, catheter removal time, and intra- and early postoperative complications were evaluated.

Statistical analysis. Data were presented as mean±SD. Statistical analysis was performed with the use of the Statistical Package for Social Sciences version 12.0 (SPSS Inc., Chicago, IL, USA). Related variables were compared using the Wilcoxon test. A p-value of less than 0.05 was considered to be statistically significant.

Results. The procedure was performed successfully in all 101 patients. All patients were followed for 12 months. The patient is population and their preoperative data are listed in **Tables 1 & 2**. **Figure 1** shows the result obtained in one case with large adenoma and an accentuated middle lobe. During the operation, there was no perforation of the bladder wall or prostatic capsule. None of the patients required blood transfusion, and no serum electrolyte abnormalities due to intraoperative fluid absorption were observed. The catheter was usually removed the next morning. Seven patients received postoperative bladder irrigation for 24 hours because of slight hematuria, and the catheterization time in this group was longer than usual. Most of these 7 patients were under ongoing oral anticoagulation. The baseline values and postoperative measurements of IPSS, QOL, Qmax, and PVR at different points during the 12 months follow-up period are summarized in **Table 3**. Significant

Table 1 - Patient's population (N=101).

Cases	Frequency
Hypertension	57
Ischemic heart disease	24
Cerebrovascular accident	14
Arrhythmia	9
Renal insufficiency	7
Diabetes mellitus	39
Chronic obstructive pulmonary disease	25
Patients with more than one diseases	30
Patients on anticoagulant therapy	26

Table 2 - Perioperative data.

Data	Mean ± SD
Preoperative	
Age	77.5 ± 9.5
PSA (ng/ml)	4.8 ± 3.7
Prostate volume (ml)	102.2 ± 33.1
Serum sodium (mmol/l)	140.6 ± 2.9
Hemoglobin (g/dl)	14.5 ± 2.1
Intraoperative	
Operating time (min)	68.5 ± 23.9
Applied energy (kJ)	72.1 ± 18.8
Resected prostate tissue (g)	59.0 ± 13.2
Postoperative	
Prostate volume (ml)	40.4 ± 15.6
Serum sodium (mmol/l)	137.6 ± 3.2*
Hemoglobin (g/dl)	13.1 ± 1.9*
Catheterization time (d)	2.1 ± 1.2
Hospitalization time (d)	4.5 ± 3.7

Statistical comparison of serum sodium and hemoglobin between pre- and post- operative value performed using Wilcoxon test (SPSS 11.5) *p>0.05. PSA - prostate-specific antigen

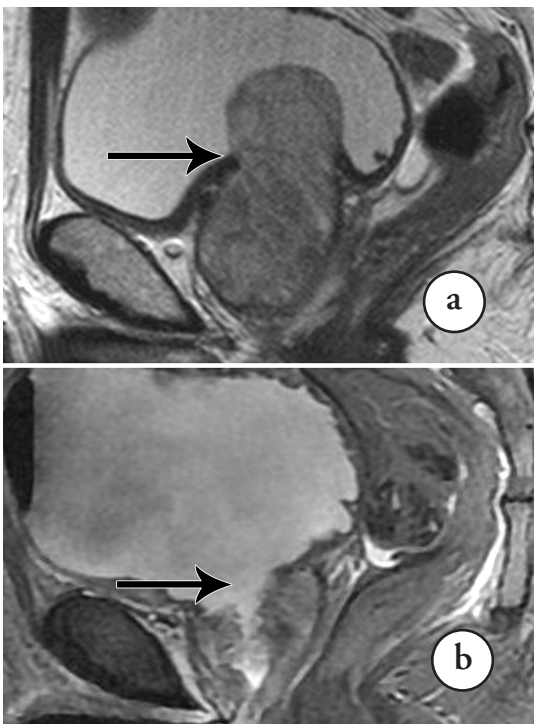

Figure 1 - Magnetic resonance imaging showing **a**) before and **b**) after the procedure. Prostate volume as determined by MRI varied from approximately 103.1 ml before the operation to 39.9 ml after the treatment and 61.6 g adenoma were resected. The applied laser energy was 69.8 kJ and the surgical time was 61.5 minutes. (Arrows denote the resection of large prostate adenoma)

Table 3 - Follow-up of subjective and objective voiding parameters.

Parameters	Baseline	Discharge	3 months	6 months	12 months
IPSS	29.3±6.7	10.3±6.1*	8.1±5.1†	6.9±4.7‡	7.1±4.3‡
QOL score	3.3±1.8	1.9±1.2*	1.1±1.0*	0.9±0.9‡	0.9±0.7‡
Qmax (ml/s)	7.1±3.1	13.9±8.6*	18.1±9.6*	17.9±8.9‡	17.7±10.1‡
PVR (ml)	237±250	21±28*	25±31‡	27±34‡	23±35‡
PSA(ng/ml)	4.8±3.7	-	2.3±3.3*	2.1±2.9‡	2.1±2.6‡

*p<0.0001, †p=0.005, ‡p>0.05.
Data presented as mean±SD. Statistical comparison to the previous value performed using Wilcoxon test (SPSS Version 11.5).
IPSS - International Prostate Symptom Score, QOL - quality-of-life, Omax - maximal urinary flow rate, PVR - postvoid residual urine, PSA - prostate-specific antigen

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clinical improvement of all parameters evaluated were achieved and maintained throughout the 12-month follow-up period. Transient mild to moderate dysuria was seen in 8 patients postoperatively. Three patients went into transient retention and had to be recatheterized temporarily. After an additional 4-7 days, the catheter was successfully removed in all these patients. Urinary tract infection was reported by 10 patients. A self-limiting urinary incontinence occurred in 3 cases. These patients were usually treated successfully by pelvic floor muscle training. Urethral strictures developed in 3 cases and were effectively managed with urethral dilatations.

Discussion. Transurethral resection of the prostate is currently considered to be the reference-standard minimally invasive surgical treatment for BPH; however, it can cause immediate and postoperative morbidity, such as a hemorrhage requiring blood transfusion, and the risk of dilutional hyponatremia.[6] In an attempt to minimize the morbidity of TURP, various alternative procedures have been developed, which might be more appropriate for the aged, and patients at high risk.[7] Among these, holmium laser enucleation of the prostate (HoLEP) and PVP have demonstrated similar efficacy to TURP.[1] As a prostate-size independent technique, the advantages of HoLEP compared with conventional surgery include reduced blood loss, lack of TUR syndrome, and shorter convalescence time. Yet, HoLEP is associated with a steeper learning curve, longer operation time, and difficulty in tissue removal.[8] Despite the excellent intra- and postoperative safety, HoLEP is primarily restricted to a few centers of excellence with high expertise.[1] A positive correlation between experience of the surgeon and rate of complications was reported.[4] In a recent study by Martin et al,[9] of the 130 patients who underwent HoLEP, 8 (6.7%) were found to require transfusion postoperatively.[9] While the holmium laser is used as an incisional and dissecting tool mimicking the action of the index finger in open prostatectomy, PVP is a TURP-like technique relatively easy to learn.

Since the 80-W high-power generator is available, encouraging results with excellent efficacy and safety of PVP with relatively long-term follow-up have been published.[10,11] In the first study comparing PVP and TURP by Bachmann,[5] these 2 techniques were similar in improving symptoms and urinary flows in treating small and moderately sized prostates.[5] The PVP was reported superior to TURP in terms of intraoperative and perioperative parameters, such as blood loss, catheterization time, and hospital stay.[12-14] As there were no blood transfusion requirements and no fluid absorption, this technique can be applied to high-risk patients relatively safely. Several studies were performed on patients with ongoing oral anticoagulation, and no severe perioperative complications were observed. Anticoagulant therapy was not a contraindication for the use of the 80W KTP laser procedure.[15-17]

However, PVP has some inherent disadvantages. The efficacy of PVP in treatment of large prostate remains controversial.[8] Vaporization procedures will achieve less tissue ablation compared with resection techniques. Compared with PVP, the percentage of the reduction in prostate volume was significantly higher in the TURP group.[18] In a study by Te et al,[19] an observable association was noted between the preoperatively measured prostate volume and the outcome after PVP.[19] Horasansli et al[14] compared the short-term outcomes of PVP and TURP for glands >70 ml.[14] They reported that TURP is more effective than PVP in terms of the prostatic volume reduction and early functional results of TURP in terms of symptom scoring, and objective parameters were superior to PVP. Furthermore, the reoperation rate was significantly higher in the PVP group. However, according to another study by Ruszat et al,[17] no significant differences were observed in functional outcome parameters between patients with small and large prostates undergoing PVP, except higher retreatment rates.[17] In addition, access to tissue can be challenging and time-consuming in complex gland geometries with large lobes in PVP. Thus, the operation time of PVP is rather longer than TURP, which means increased surgical risk especially in high-risk patients. An early reoperation rate was also in favor of TURP.[18] Moreover, vaporization efficiency is impaired after applying energy of approximately 150 kJ, owing to a functional deterioration of the fiber.[20] Usually, more than one fiber is needed for large prostates, and the costs for surgical equipment increase.Meanwhile, the use of TURP in treating large prostates in high-risk patients is limited mainly due to intraoperative and postoperative morbidities such as bleeding with the need for transfusion, and transurethral resection syndrome.[21] Bipolar TURP, the most significant modification of TURP, is clinically comparable to monopolar TURP with an improved safety profile.[22] Several studies have proven that no clinically relevant differences in short-term efficacy exist between these 2 techniques.[23-25] As saline solution is used for irrigation during surgery, bipolar TURP has an advantage of reducing the decline in postoperative serum sodium levels and the risk of TUR syndrome. As a solution for the patients with large adenomas and serious systemic medical problems, the combination of the 2 techniques, PVP and TURP, has been introduced. Application of laser

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coagulation decreases the morbidity of TURP because less bleeding occurs. No patient in our study required any blood transfusion. Also, the catheterization time decrease markedly to only 2.1±1.2 days. On the other hand, with the help of bipolar TURP, more tissue can be resected and the disadvantages of PVP, relative long operating time and the inability to sample tissue for histologic evaluation, are avoided. Our data shows that the portion of ablated tissue is estimated to reach 60.5% by combining vaporization and resection, and a favorable perioperative outcome after combined therapy is achieved. In addition, the procedure has the potential to reduce health care expenses for the treatment of BPH. Usually, a second fiber was needed to attain a sufficient de obstruction of the prostatic cavity in vaporization of large prostate by PVP.[17] Combined with the bipolar TURP, the energy required in PVP is obviously reduced. In our study, the mean energy applied in the procedure was 72.1 kJ and one laser fiber was sufficient for the procedure. Compared with traditional TURP, although the disposable laser fiber cost is significant, cost saving may become evident because of shorter hospital stay and lower incidences and less severity of peri- and postoperative complications, especially in high-risk patients.

Finally, although the technique provides a satisfactory outcome in our series, it must be stressed that further reliable long-term data and large-scale randomized trials are needed to draw definitive conclusions regarding the safety and efficacy of the procedure.

In conclusion, the results of our study demonstrate that PVP plus bipolar TURP have excellent efficiency and low morbidity in men with large prostates. The procedure could be applied in a safe manner for the treatment of large prostate adenoma in high-risk patients. However, further evaluation is necessary, with randomized clinical trials and longer follow-up period, to reinforce the present findings and to reveal its durability and limitations.

Acknowledgment: *Dr. Yong Zhao and Dr. Ji Chen, contributed equally to the work.*

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