A Prospective, Randomized Clinical Trial Comparing Plasmakinetic Resection of the Prostate with Holmium Laser Enucleation of the Prostate Based on a 2-Year Followup

Yan-Bo Chen,* Qi Chen,* Zhong Wang,† Yu-Bing Peng,† Li-Ming Ma, Da-Chao Zheng, Zhi-Kang Cai, Wen-Ji Li and Liang-Hong Ma

From the Department of Urology and Andrology, Ninth People's Hospital, School of Medicine, Shanghai Jiaotong University, Shanghai, and Department of Urology, General Hospital of Ningxia Medical University, Yinchuan (LMM), China

Purpose: We compared plasmakinetic resection with holmium laser enucleation of the prostate for the treatment of benign prostatic hyperplasia by analyzing 2-year followup data from a prospective randomized clinical trial.

Materials and Methods: A total of 280 patients were randomly treated with plasmakinetic resection or holmium laser enucleation of the prostate. Perioperative and postoperative outcome data were obtained during a 2-year followup.

Results: No significant differences between the 2 surgical groups were observed in the preoperative data. Both groups displayed significant improvements after surgery. However, we identified no significant differences between the 2 groups in the 2-year followup data for I-PSS (International Prostate Symptom Score), quality of life scores or maximum flow rate values. Patients in the holmium laser enucleation group displayed a lower risk of hemorrhage, shorter bladder irrigation and catheter times, and shorter hospital stays. A larger amount of prostate tissue was retrieved in the holmium laser enucleation group, but the operation time was longer for this group than for the plasmakinetic resection group.

Conclusions: Plasmakinetic resection and holmium laser enucleation of the prostate are effective and safe treatments for benign prostatic hyperplasia. Holmium laser enucleation of the prostate can be applied to prostates of all sizes, and involves less risk of hemorrhage, decreased bladder irrigation and catheter times, as well as reduced hospital stay. Thus, we believe holmium laser enucleation of the prostate should be proposed as a potential new gold standard surgical therapy instead of transurethral resection of the prostate for patients with benign prostatic hyperplasia.

Key Words: prostatic hyperplasia; transurethral resection of prostate; lasers, solid-state

Abbreviations and Acronyms

BPH = benign prostatic hyperplasia

HoLEP = holmium laser enucleation of the prostate

PKRP = plasmakinetic resection of the prostate

PSA = prostate specific antigen

PVR = post-void residual

Qmax = maximum flow rate

QoL = quality of life

TRUS = transrectal ultrasound

TURP = transurethral resection of the prostate

UI = urinary incontinence

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* Equal study contribution.

† Correspondence: Department of Urology, Ninth People's Hospital, School of Medicine, Shanghai Jiaotong University, 639 Zhi Zaoju Rd., Shanghai, China (ZW telephone: 86-[0]13301980998; FAX: [86-21]63136856; e-mail: zhongwang2001@yahoo.com; YP e-mail: pybkzt@yahoo.com.cn).

FOR many years transurethral resection of the prostate has been considered the gold standard for the surgical treatment of BPH.[1] However, significant morbidity after TURP has led to a continuous decrease in the number of TURP procedures performed[2,3] and an increase in the use of other new techniques for the treatment of lower urinary tract symptoms resulting from BPH, including plasmakinetic resection and holmium laser enucleation of the prostate. Recently PKRP (a type of bipolar TURP) has demonstrated fewer complications and comparable results to the standard TURP in early

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and short-term followup.[4–6] HoLEP has been shown to be as effective as TURP in the management of bladder outlet obstruction and results in less perioperative morbidity than TURP.[7–9] Both of these new techniques appear to be likely candidates to replace traditional TURP as the gold standard for the surgical treatment of BPH. However, few studies have compared PKRP with HoLEP. Fayad et al reported that HoLEP and bipolar TURP were effective in treating patients with lower urinary tract symptoms due to BPH.[10] However, the report criticized HoLEP for its long operative time, steep learning curve and higher cost, ultimately reporting in favor of bipolar TURP. Therefore, we conducted a prospective randomized study with a 2-year followup to compare PKRP with HoLEP in terms of efficacy and safety.

PATIENTS AND METHODS

The study was performed at our institution and included patients undergoing surgical therapy for lower urinary tract symptoms and obstruction due to benign prostatic hyperplasia at our hospital from August 2008 to February 2010. In total, 280 patients were randomized to PKRP (140) or HoLEP (140) after ethical approval and the written informed consent of the patients were obtained. In addition, all patients were previously treated with conservative medical therapy using α-blockers and 5α-reductase inhibitors, which did not result in significant improvement in I-PSS and Qmax or PVR. The study inclusion criteria were indications for the surgical treatment of BPH. Patients with severe pulmonary disease or heart disease, bladder calculus, neurogenic bladder dysfunction, bladder cancer, previous prostate surgery, prostate cancer, urethral stricture or coagulopathy were excluded from study.

Allocation concealment was done using sequentially numbered and sealed envelopes. Each patient was assigned with an envelope through the computerized random number generator. The study was a single blinded trial in which only the patients were blinded to the treatments while the surgeons and supervisors were not.

Before surgery we collated the baseline characteristics of the patients, which consisted of urological history, presence of concurrent diseases, previous drug therapy, prostate volume (TRUS measurement), PVR volume, I-PSS, QoL score, Qmax and the 5-item version of the IIEF (International Index of Erectile Function). Blood tests (PSA, serum sodium and hemoglobin measurement) were also performed and recorded preoperatively. Serum sodium and hemoglobin levels were measured immediately after surgery, and operation time, resected prostatic weight, serum sodium decrease, hemoglobin decrease and early complications were recorded. Bladder irrigation and catheterization time as well as hospitalization duration were noted. Followup was assessed at 1, 6, 12 and 24 months after surgery. Assessments consisted of I-PSS, QoL score and Qmax as primary outcomes, and PVR volume, TRUS and late complications as secondary outcomes of the study. Furthermore, we recorded the IIEF-5 to evaluate patient sexual function.

HoLEP was performed using a 550 μm end firing laser fiber and a 100 W continuous flow VersaPulse® holmium laser, and a 27Fr resectoscope with a modified bridge to hold the laser fiber (Storz, Tuttlingen, Germany). Power settings were 80–100 W at 2–1.5 J per second and 50–40 Hz. Transurethral morcellation was performed through a 26Fr nephroscope using a mechanical morcellator (VersaCut™).

PKRP was performed using the PlasmaKinetic™ SuperPulse system, consisting of a PK® generator, a PK resectoscope and a Plasma-Sect® electrode. The generator for PKRP was set at 160 W for cutting and 100 W for coagulation. A 27Fr continuous flow resectoscope (Storz) was used for PKRP.

All HoLEP procedures were performed by a single surgeon, whereas all PKRP procedures were performed by surgeons with considerable experience in the method. A week before surgery all patients stopped therapy with α-blockers, 5α-reductase inhibitors, anticholinergics and anticoagulants. The patients received epidural anesthesia and all were in the lithotomy position during surgery. The irrigation fluid used was 3 l normal saline (0.9%) and all irrigation bags were hung 60 cm above the operating table. In addition, all patients were covered perioperatively with appropriate antibiotics. An irrigating catheter was inserted after surgery. Bladder irrigation was used as necessary until hematuria resolved, and the standard for catheter removal was clear urine without gross hematuria.

On the basis of our previous work on bipolar TURP we expected that the operation time of the HoLEP group would be 25% longer than that of the bipolar group.[11] The sample size was calculated to be at least 30 patients in each group with $\alpha = 0.05$, $\beta = 0.10$ and a desired statistical power level of 90%. Considering our research expenses and study period, 140 patients were set in each arm. All measurement data were statistically analyzed with a 2-tailed Student's t test and presented as mean $\pm$ SD. The results were analyzed using descriptive statistics with a paired t test and a chi-square test to calculate continuous variables and categorical data. Differences were considered statistically significant at $p < 0.05$.

RESULTS

The baseline characteristics of the PKRP vs HoLEP groups were not significantly different in any aspect. There was no difference in patient age between the groups (73.48 $\pm$ 8.8 vs 72.11 $\pm$ 7.8 years, $p = 0.17$). The perioperative parameters measured for both groups are listed in table 1. As shown, HoLEP was superior to PKRP with respect to bladder irrigation, catheter time and hospital stay, but the procedure required more time to perform. Whereas serum so-