

Effect of transurethral split of the prostate using a double-columnar balloon catheter for benign prostatic hyperplasia

A single-center experience of 565 consecutive patients

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Abstract

We aimed to evaluate the long-term therapeutic effect of transurethral split of the prostate (TUSP) with a newly improved double-columnar balloon catheter on patients with benign prostatic hyperplasia (BPH).

Total 565 BPH patients (mean age 73.6 years, range 46–94 years) who underwent TUSP surgery between January 2006 and January 2015 were included. Patient's baseline characteristics, prostate size, PSA, preoperative and postoperative maximum urinary flow rate (Q_{max}), postvoid residual (PVR), international prostate symptoms score (IPSS) and quality of life (QOL) score, perioperative data and postoperative complications were recorded.

The mean preoperative prostates size was 48.6 ± 8.2 mL (range 33–230 mL), and the PSA level was 0.8 to 18.6 ng/mL. The mean duration of TUSP procedure from the catheter localization to the split of capsula prostatica was ~10 minutes. After surgery, the mean Q_{max} increased from 5.2 ± 1.4 to 12.8 ± 2.2 mL/s ($P < 0.001$). Patients had improved mean PVR, QOL score, and IPSS after TUSP (76 ± 8 vs 20 ± 8.5 mL, 4.6 ± 0.2 vs 1.4 ± 0.3 , and 20.2 ± 4.4 vs 6.6 ± 1.1 , respectively, all $P < 0.001$). Until September 2014, 328 patients were successfully followed up for a long-term period of 38 to 99 months. There was no other case of recurrence with dysuria despite 2 recurrent cases.

The TUSP with a double-columnar balloons catheter was a safe and long-term efficient treatment for BPH, with minimal invasion, short operative time, few postoperative complications, and low recurrence rate.

Abbreviations: BPH = benign prostatic hyperplasia, IPSS = international prostate symptoms score, PVR = postvoid residual, Q_{max} = maximum urinary flow rate, QOL = quality of life, SD = standard deviation, TUDP = transurethral dilation of the prostate, TURP = Transurethral resection of the prostate, TUSP = transurethral split of the prostate.

Keywords: benign prostatic hyperplasia, columnar balloon, transurethral split of the prostate, urethral patency

1. Introduction

Benign prostatic hyperplasia (BPH), a common problem in ageing male,^[1] is a histologic diagnosis that refers to abnormal proliferation of stromal and epithelial cells within the prostatic transition zone.^[2] It has been the most responsible reason for urinary outflow obstruction^[3] as the enlarged gland could directly result in bladder outlet obstruction (BOO, static

component) or enhance smooth muscle tone and resistance (dynamic component).^[4] Although the lower urinary tract obstruction secondary to BPH is not usually life-threatening, it is more often associated with poor quality of life.^[4]

Transurethral resection of the prostate (TURP) has been considered as the gold standard to treat BPH for decades.^[5] However, TURP is rather invasive as evidenced by that significant complications were witnessed in about 20% patients within 10 years.^[6,7] Accordingly, more interests are focused on other minimally invasive therapy as an alternative choice of the treatment for this disease. Thereafter, laser ablation or variants of direct therapeutic injection into the gland were reported to achieve at least a relief effect on the stenotic prostatic urethra and symptoms.^[8–11]

However, since Castaneda et al^[12] first reported the application of transurethral dilation of the prostate (TUDP) on patients with BPH, it faded out the treatment of BPH because of uncertain therapeutic effect of balloon dilation method,^[13] although it has ever been prevalently performed worldwide owing to simple operation and less invasion.^[14]

Fortunately, our department has been committed to improve the balloon catheter and we previously reported that the transurethral split of the prostate (TUSP) with a double-deck columnar balloons (internal and external balloons) catheter was associated with good therapeutic effect and few complications in 113 BPH patients.^[15] Recently, we further developed a double-columnar balloon (proximal and distal balloons) catheter based on the previous research. In the present case series of 565 patients

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Table 1**Baseline characteristics of patients with benign prostatic hyperplasia.**

Parameter	BPH patients (n=565)
Age, range, y	73.6 (46–94)
Concurrent diseases, n (%)	
Hypertension, coronary heart disease, and cardiac insufficiency	159 (28.1)
Pulmonary incompetence	81 (14.3)
Diabetes mellitus (DM)	63 (11.2)
Cerebrovascular function sequelae	9 (1.6)
Chronic cerebral infarction	12 (2.1)
Acute retention of urine	28 (5.0)
Chronic urine retention with repeated cannula or suprapubic cystostomy (SPC), accompanied with mid-moderate renal function lesion	198 (35.0)

BPH=benign prostatic hyperplasia.

with BPH, the therapeutic effect of TUSP with the newly designed catheter was evaluated for a long term.

2. Methods

2.1. Patients

This retrospective study reviewed 565 patients (mean age 73.6 years, range 46–94 years) with BPH who underwent TUSP surgery between January 2007 and January 2015 in our hospital. All patients had a 2 to 15 years' history of BPH-induced lower urinary tract obstructions, such as urination waiting, thin or weak urinary stream, or repeated urine retention. Patients with acute urethritis, acute prostatitis, chronic urethritis with much purulent secretions, urethral injury, neurogenic bladder, or who had previous history of pelvic surgery, as well as who was suspected with urethral neoplasms, have been excluded. Baseline characteristics of patients were shown in Table 1. Informed consents were obtained from all patients before participation.

All patients preoperatively received routine examination, B-ultrasonography, digital rectal examination, and laboratory examination. Among the 565 patients with BPH, a diagnosis of prostate cancer was eliminated in 40 patients by prostatic puncture biopsy despite a suspected diagnosis by using digital rectal examination and ultrasonography, including 25 cases of recurrence after TURP and 1 case of recurrence after open operation. Patients' baseline characteristics, prostate size, PSA, preoperative and postoperative maximum urinary flow rate (Q_{max}), postvoid residual (PVR), international prostate symptoms score (IPSS)^[16] and quality of life (QOL) score, perioperative data, and postoperative complications were all recorded.

2.2. Double-columnar balloon catheter

The double-columnar balloon catheter used in this study was made of thermoplastic polyurethane. It was designed with a proximal (pars prostatica) balloon and a distal (pars membranacea) columnar balloon (Fig. 1), which would expand the bladder neck and prostatic urethra, and membranous urethra under the same pressure of 0.3 Mpa during the TUSP surgery, respectively. There were various sizes of columnar balloon catheters, with the maximum proximal and distal balloon lengths of 8 and 5 cm, and the internal diameter of 3.5 cm. The adequate columnar balloon catheter was selected based on the patients' prostates size and the posterior urethra length. This double-columnar balloon (proximal and distal balloons) catheter has

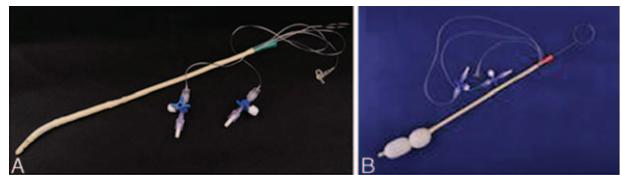


Figure 1. The structure of the double-columnar balloon catheter. (A) Various sizes of columnar balloon catheters before the injection of sterile water. (B) An inflated columnar balloon catheter after the injection of sterile water during the procedure of transurethral split of the prostate (TUSP).

been approved by Jiangsu Food and Drug Administration as disposable medical equipment for using in the surgical treatment of BPH-induced urinary tract obstructions.

2.3. Operative procedure

After the preoperative routine examination for the diagnosis of chronic diseases, active treatments were performed in senile patients at high risk to control their internal complications. The anticoagulant agent was forbidden for at least 5 days. Under low-set epidural anesthesia and lumbar anesthesia, patients were placed in lithotomy position. A metal expander was lubricated and inserted to expand the urethra to F24–26. Then, the columnar catheter was advanced into the bladder and pulled out gradually until the appearance of a breakthrough feeling, at which time the positioning protrusion just passed through the external sphincter of pars membranacea. The distal balloon was then confirmed at the anatomical location of membranous urethra and the proximal balloon was at bladder neck and prostatic urethra if locating protrusion could be touched at the skin margin of perineal bulb of urethra. Thereafter, the distal balloon as well as the proximal balloon was slowly inflated to 0.3 MPa with sterile water. Finally after the proper irrigation, the balloon catheter was plugged and banded with gauze in case of catheter retraction. Besides, gradual decompression was conducted by water drain (1/4 of injection rate every 0.5 hours) at postoperative 3 days, and the gauze was removed within 24 hours after TUSP. The balloon catheter was left in situ for 6 to 7 days. The patient was discharged from the hospital with unobstructed urination after 1 week supply of oral α -receptor blocking pharmacology. Each patient was followed up once a month for the measurement of Q_{max} , PVR, QOL score, and IPSS.

2.4. Statistical analyses

Data were shown as mean \pm standard deviation (SD) and analyzed using Biostatistics ver.3 software (San Diego, CA). Comparisons between preoperative and postoperative data were analyzed by *t* test. A *P*-value of <0.05 was considered statistically significant difference.

3. Results

3.1. Preoperative symptoms of patients, intraoperative and postoperative treatment

Among the 565 patients undergoing TUSP, 452 (80%) cases were senile patients and at high risk who could not tolerate TURP due to the poor body constitution. Table 2 lists the lower urinary tract symptoms of the patients before and after TUSP procedure. The mean preoperative prostates size was 48.6 ± 8.2 mL with a range from 33 to 230 mL, and the PSA level was 0.8 to 18.6 ng/mL. All patients received successful transurethral dilation with the

Table 2

Lower urinary tract symptoms of patients with benign prostatic hyperplasia before and after transurethral split of the prostate.

Indicators	Before TUSP	Post-TUSP	P
Q_{\max} , mL/s	5.2 ± 1.4	12.8 ± 2.2	<0.001
PVR, mL	76 ± 8	20 ± 8.5	<0.001
QOL	4.6 ± 0.2	1.4 ± 0.3	<0.001
IPSS	20.2 ± 4.4	6.6 ± 1.1	<0.001

Data presented as mean \pm standard deviation (SD). $P < 0.05$ was considered statistically significant. IPSS = international prostate symptom score, PVR = postvoid residual, Q_{\max} = maximum urinary flow rate, QOL = quality of life, TUSP = transurethral split of the prostate.

double-columnar balloon catheter, and the mean duration of TUSP procedure from the catheter localization to the split of capsula prostatica by water-filled balloons was about 10 minutes. Figure 2 presented the expansion of posterior urethra by water-filled balloon under CT scan during the TUSP procedure. The mean total operative time from the successful anesthesia to the finish of the catheter fixation was about 15 minutes. In this study, there were 186 patients with a long history of oral anticoagulant despite a 5 to 10 days of withdrawal time, and 65 cases had hemorrhage after surgery, ~ 10 to 20 mL. After symptomatic treatments, all these patients had no bleeding anymore. Another 2 patients had severe hemorrhage (50–100 mL) 2 hours after the surgery and received suprapubic vesicostomy by puncture. Then, their urine turned clear the next day. There was no patient converted to open surgery or received transurethral electric coagulation for hemostasis. Besides, 56 patients developed urgent micturition and incomplete urinary incontinence after TUSP, but these symptoms disappeared within 2 to 10 days postoperatively.

3.2. Postoperative symptoms

During the follow up of 3 to 24 months after TUSP, patients were examined for Q_{\max} , PVR, QOL score, and IPSS at each return visit. As shown in Table 2, the mean Q_{\max} increased from 5.2 ± 1.4 mL/s to 12.8 ± 2.2 mL/s ($P < 0.001$) after surgery, whereas a significant reduction was witnessed in mean PVR (76 ± 8 mL vs 20 ± 8.5 mL, $P < 0.001$). Besides, patients had improved mean QOL score and IPSS after operation compared with that before TUSP (4.6 ± 0.2 vs 1.4 ± 0.3 and 20.2 ± 4.4 vs 6.6 ± 1.1 , respectively, both $P < 0.001$).

3.3. Complications

At postoperative 2 years, 48 patients developed dysuria and urine dripping, among whom 45 patients recovered to normal urination after the urethral catheterization and the oral administration of α -receptor blocking pharmac, but other 3 cases still suffered from repeated urine retention. Thereafter, 2 of the 3 recurrent cases received the TUSP procedure again, and the other one underwent TURP. Until September 2014, 328 patients were successfully followed up for a long-term of 38 to 99 months. The aforementioned 2 recurrent cases were improved after the second TUSP procedure. Apart from this, there was no other case of recurrence with dysuria until the date of the last follow-up.

4. Discussion

Our previous study had reported the successful accomplishment of TUSP using a double-deck columnar balloons (internal and external balloons) catheter, with significantly good therapeutic

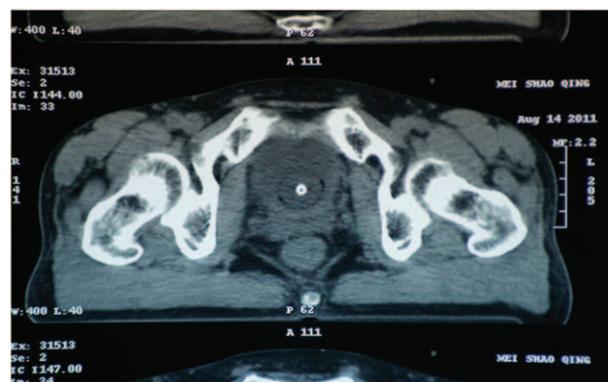


Figure 2. Intraoperative CT scan showed the expansion of posterior urethra (prostatic urethra and membranous urethra) by water-filled columnar balloon during the TUSP procedure. TUSP = transurethral split of the prostate.

effect and few complications.^[15] Considering that the internal balloon might be influenced by the external balloon with regard to the location, in this study, we currently improved the double-columnar balloons (proximal and distal balloons) catheter on the basis of our previously designed catheter, and evaluated the long-term therapeutic effect of TUSP with this newly designed catheter on patients with BPH-induced lower urinary tract obstructions. The results showed that all patients had the urethral patency after TUSP, with the mean Q_{\max} , PVR, QOL score, and IPSS recovering to normal levels.

Unlike the traditional TUDP procedure, during which the spherical balloon only expanded the urethra at the transitional and central prostatic zones, almost within the proximal 1/2 of the prostatic urethra,^[3] we developed the TUSP with the new improved double-columnar balloons catheter, which would not only expand the bladder neck and prostatic urethra with a proximal balloon, but also expand the membranous urethra with a distal balloon. The re-expansion of urethra by hyperbaric water sac coincided with the split of the prostate capsule at the 12 o'clock position (the ventromedian circumference of the prostate capsule).^[17] That's also why we had named this procedure as "transurethral split of the prostate" (TUSP).

As shown in the CT images of our present and previous studies,^[15] the fibromuscular stroma and prostate capsule were split to both sides at the 12 o'clock position. However, they were not reduced after patients recovered as evidenced by a craterlike hole witnessed at where the urethra was reconstructed. That was because that peripheral tissues, such as the retropubic adipose and fascia tissues, filled the dehiscence of the capsule, and urethral tissue bulged, resulting in the displacement of prostate gland.

Previous researches had suspected the therapeutic effect of the balloon dilation method on the treatment of BPH due to the high recurrence rate of urethral obstruction and various complications.^[13] However in our study, only 2 cases of recurrence with dysuria were recorded among the 328 patients who were followed up for a long-time of 38 to 99 months, supporting our previous view that revealing an excellent long-term therapeutic effect of TUSP.^[15] It could be explained by several reasons: first, the double-columnar balloon catheter used in this study, expanded the membranous urethra with a distal balloon, and the external sphincter made the apex of prostate displaced. Second, the displacement of prostate gland at the 12 o'clock position was also responsible for the long-term patency of

urethra. Furthermore, the content of collagen protein substances played an important role in the development of BPH, as Bianchi-Frias et al^[18] and Huang et al^[15] previously demonstrated the abundant content of collagen protein substances in the aging prostate but less in the bladder neck, prostatic urethra, and urethral stroma after TUSP, respectively. Hence, it also might be the decline of the collagen protein substances that weakened the contractility of prostatic tissues and prevented it from retraction. Besides, the delicate shape and lithesome texture of the double-columnar balloons catheter also lightened the stimulation to urethra inner wall, facilitating the decreased complication rate.

Conventional TURP surgery has many disadvantages: hypovolemia and dilution hyponatremia at an incidence rate of ~2% due to the excessive absorption of rinse solution, the risk factors included much intraoperative bleeding, long operation time, and large prostate size. During the TURP procedure, blood transfusion was needed in 2% to 5% of patients. The prolonged TURP surgery significantly increased the risk of TURP syndrome, and the postoperative complication such as urinary incontinence, retrograde ejaculation, bladder neck contracture, and urethral stricture, occurred at the incidence rates of 1% to 2.2%, 65% to 70%, 4%, and 3.8%, respectively. However, we almost found no defects or complications following TUSP in our patients. Besides, TUSP was successfully performed in senile patients at high risk who were unwell or intolerant for TURP. Nevertheless, because the comparison between TUSP and TURP was not virtually performed in the present study, further study was needed to compare the therapeutic effects of TUSP and TURP.

We further summarized our key techniques including: (1) the accurate localization of the water-filled columnar balloons, with the proximal balloon at the bladder neck and prostatic urethra and the distal balloon at the membranous urethra; (2) the optimal choice of columnar balloon catheters at a certain size according to the patient's prostates size and posterior urethra length; (3) the successful combined anesthesia with low-set epidural anesthesia and lumbar anesthesia. However, TUSP was performed only for the patency of the urinary tract, but it had no effect on the abnormal urination induced by other metabolic diseases such as diabetes. One disadvantage of this double-columnar balloon catheter is its unavailability for viewable operation. Hence, we are concentrating on the research and development of viewable and automated instrument.

Several limitations in our study must be addressed. First, as the study was not prospective and randomized, neither the comparisons between TUSP and TURP nor between TUSP and TUDP were included. Second, prostatic tissue was not collected for histologic examination because this TUSP surgery was performed with the preservation of prostate function. Third, the cases with long term of follow-up were insufficient as many patients were lost to follow-up. The high lost-to-follow-up rate was attributed to the fact that most cases (80%) in this study were senile patients at high risk, and many patients had been dead. The alteration of patients' address due to the urbanization transformation of the city was the other reason for the high lost-to-follow-up rate.

Not with standing its limitation, this study did suggest that TUSP with a double-columnar balloons (proximal and distal balloons) catheter was a safe and long-term efficient treatment for BPH, with minimal invasion, short operative time, few postoperative complications, and low recurrence rate. It would be an ideal choice for BPH patients who were unwell or intolerant for TURP, especially in senile patients.

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