Editorial Commentary

The Optilume BPH Catheter System for the treatment of lower urinary tract symptoms secondary to benign prostatic hyperplasia

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Benign prostatic hyperplasia (BPH), a histological increase in prostate volume, is a common disease in men worldwide. Clinical BPH is defined as prostate adenoma, which can lead to severe bladder outlet obstruction (BOO) associated with lower urinary tract symptoms (LUTSs). LUTS is mainly divided into storage and voiding symptoms of the urinary tract. Storage symptoms include urinary urgency, increased urination frequency, urination at night, and urinary incontinence. etc., while voiding symptoms consist of a feeling of partial bladder emptying, urge to strain urine, delayed and diminished urinary stream, and postvoid residual urine volume (PVR). Clinical BPH is often diagnosed with ultrasound and can then be graded according to the shape and size of the prostate. The severity of the disease and BOO is defined according to the staging system classification, which is the basis for further treatment planning. The staging system classification of a patient includes the International Prostate Symptom Score (IPSS) questionnaire, International Consultation on Incontinence Questionnaire (ICIQ), Quality of Life (QoL) score, and uroflowmetry (measurement of urinary flow) to examine maximum urinary flow rate (Qmax, pathologic: <10 mL/s). Initial treatment starts with careful watching and waiting with the help of lifestyle and nutritional changes for patients with mild discomfort. Medical drug therapy, including α-adrenergic antagonists (α-blockers), 5-α reductase inhibitors (5-ARIs), or a combination of the two, could be the next option if this primary approach of monitoring doesn't lead to satisfactory recovery from the symptoms. If the patient denies drug therapy or symptoms persist after taking medicines along with the appearance of new adverse side effects related to diminished sexual activity, patients move to invasive or surgical procedures. With the demand and envision that BPH can be treated in a single procedure of an office-based setting with minimal side effects and recovery time, novel minimally invasive surgical treatments (MISTs), which fall in between drug therapy and surgical procedures, have been discovered to treat BPH safely and efficiently (1,2). Most prevalent types of MISTs comprise water vapor thermal therapy, transurethral microwave thermotherapy, prostatic arterial embolization, prostatic urethral lift, and temporary implantable nitinol device (3); however, newer energy-based MISTs include transperineal laser ablation, transurethral ultrasound ablation, and high-intensity focused ultrasound. Transurethral resection of the prostate (TURP) has been used as a gold standard method for prostate volumes from 75 to 125 g or mL. During the emergence of balloon dilation treatments, transurethral columnar balloon dilation and the Optilume BPH Catheter System procedures have been gaining primary attention (4).

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In the recently published article, Kaplan *et al.* (5) performed the 'Pinnacle Study' implicating MIST to observe the effect of the 'Optilume BPH Catheter System', a paclitaxel-coated minimally invasive device with a dual mechanical and pharmacological mechanism of action for the treatment of LUTS in BPH patients at 18 centers in the US and Canada. This study involved a randomized, double-blind, sham-controlled clinical trial where 148 subjects received randomized treatment in a 2:1 fashion with Optilume BPH and a sham surgical procedure to compare the adequacy and safety of Optilume BPH. The eligible subjects involved were men between 50 and 80 years old with a symptomatic BPH (NCT04131907). The other eligible criteria were the prostate volume of 20–80 g, Qmax between 5 and 12 mL/s, a prostatic urethral length of 32–55 mm, and IPSS of ≥13. Patients with urinary tract infection, PVR >300 mL, and prostate-specific antigen value (PSA) >10 ng/mL without negative biopsy or patients with a possibility of prostate or bladder cancer were excluded from the present study. Other exclusions were patients who had prior surgery or had other bladder or urinary tract conditions that could affect urinary function.

The Optilume BPH Catheter System is composed of two dilation balloon catheters: one uncoated pre-dilation catheter and one drug-coated balloon (DCB) catheter. The drug used is known as paclitaxel, which is an antiproliferative agent required to maintain luminal patency of the prostatic urethra after dilation. Therefore, the objective of the Optilume BPH procedure is to generate an anterior commissurotomy and deliver paclitaxel simultaneously to the prostatic adenoma to hamper its further growth and the refusion of the lateral lobes. The uncoated pre-dilation catheter is first inserted and positioned at the distal end of the external sphincter during the Optilume BPH procedure, which is monitored through cystoscopy during the whole procedure. The pre-dilation balloon is then inflated and held for approximately 1 minute to commence an anterior commissurotomy. The resulting anterior commissurotomy was further propagated by inserting and positioning DCB in a similar pattern, also delivering paclitaxel to the prostatic urothelium. However, the DCB is inflated for 5 minutes as compared to the 1-minute inflation of the pre-dilation balloon. In the sham procedure, sheathed (21-F) Optilume BPH pre-dilation catheter was used that was not inflated. The sham device was held for 5 minutes to mimic the Optilume BPH Catheter System treatment. After the whole procedure, a Foley catheter is placed for 2 days in Optilume BPH Catheter System and sham-treated BPH patients. The procedures involved in the studies, like treatment location, anesthesia, and catheter insertion protocols, remained the same to fulfill the blind-study requirements in the subjects of both arms. All the subjects receiving treatment in the categories of Optilume BPH and sham procedure, as well as evaluating persons, were blinded for 1 year of post-procedure follow-ups. Subjects in both arms were monitored at 14 days, 30 days, 3 months, 6 months, and 1 year after the treatment for IPSS, BPH impact index, PVR, uroflowmetry, QoL, and sexual function assessments.

Based on the assessments after 1 year of post-treatment, Optilume BPH treatment was quite convincing as the treatment immediately improved the urinary obstructive symptoms and flow rate (Qmax) from 8.9 mL/s at average baseline to 17.6 mL/s after 1 month of the procedure.

Improvements in Qmax and PVR were preserved throughout the 12-month post-procedure follow-up while sustaining the sexual functions in BPH patients with minimal treatment-related adverse side effects. Optilume BPH-treated patients observed an IPSS decrement of 11.5±7.8 points as compared to an abatement of 8.0±8.3 points after 3 months in the sham-treated patients. Other measures of urinary health-related QoL, such as IPSS-QoL and BPH-II, were also improved substantially after Optilume BPH treatment.

Although the Optilume BPH treatment was significantly beneficial, the results may not be hypothesized toward all men experiencing LUTS associated with BPH since subjects only with prostate volume below or equal to 80 g were considered and enrolled. In addition, the large size of balloons used in the procedure was associated with urinary incontinence and higher rates of post-procedural bleeding. The paclitaxel was still detectable in the semen even after 6 months of the treatment, although the amount was very low (0.1±0.2 ng/mL). Since the information about the potentially harmful effects mediated by paclitaxel present in semen is unknown, individuals reluctant to abstain totally from sexual activity or use highly effective contraceptive methods and protective measures for 6 months were excluded from the studies. The efficacy of the Optilume BPH study could be strengthened by extending the trial further to more patients and by gathering long-term evidence for patient counseling (4,5). A similar DCB treatment device approved by the Food and Drug Administration (FDA) previously for urethral strictures also exhibits a similar paclitaxel concentration pattern (4,6,7). Thus, MISTs that do not involve the removal of prostate tissue and have reduced adverse side

effects during treatment have been proposed as alternatives to invasive surgeries. MISTs have convincingly relieved urinary tract symptoms; however, these therapies could not replace Qmaxs. However, the prime benefit of the Optilume BPH treatment discussed in this article is that it is very convenient, comfortably tolerated, and can be performed smoothly and efficiently in an office or ambulatory setting. Further research and data collection are needed to assess its durability and any potential complications over an extended period. Considering the large-scale incidences of BPH and associated LUTS, the Optilume Study and similar studies are steps towards improving the clinical management of this disease.

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Footnote

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