Transurethral water vapour thermal therapy for benign prostatic hyperplasia under local anaesthesia alone: initial experience in Chinese patients

KL Lo, Alex Mok, Ivan CH Ko, Steffi KK Yuen, Peter KF Chiu, CF Ng *

ABSTRACT

Introduction: This study evaluated the perioperative and early postoperative outcomes of transurethral water vapour thermal therapy (WVTT) under local anaesthesia alone for benign prostatic enlargement in Chinese patients.

Methods: This retrospective review of transurethral WVTT for benign prostatic enlargement focused on 50 Chinese patients who exhibited clinical indications (acute retention of urine or symptomatic lower urinary tract symptoms due to benign prostatic enlargement) for surgical treatment between June 2020 and December 2021 in Hong Kong. Exclusion criteria included active urinary tract problems and urological malignancies. Follow-up was conducted at 3 months postoperatively.

Results: The median patient age was 71.5 years. The mean preoperative prostatic volume was 56.7 mL. The mean operation time was 25.1 minutes. All procedures were performed under local anaesthesia alone. The mean pain scores for transrectal ultrasound probe insertion, transperineal local anaesthesia injection, and transurethral WVTT were 2, 5, and 4, respectively. Forty-nine patients (98%) were discharged on the same day with a urethral catheter. Forty-eight patients (96%) successfully completed a trial without catheter within 3 weeks postoperatively. Five patients (10%) had unplanned hospital admission within 30 days postoperatively due to surgical complications (Clavien–Dindo grade 1).

Conclusion: Transurethral WVTT, an advanced surgical treatment for benign prostatic enlargement, is a safe procedure that relieves lower urinary tract symptoms with minimal hospital stay. It can be performed in an office-based setting under local anaesthesia, maximising utilisation of the surgical theatre.

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New knowledge added by this study

- This is the first study concerning the efficacy and safety profile of water vapour thermal therapy (WVTT) in Asian patients. It can relieve lower urinary tract symptoms with minimal hospital stay.
- This is the first study of WVTT in an office-based setting under local anaesthesia, maximising utilisation of the surgical theatre.

Implications for clinical practice or policy

- Water vapour thermal therapy is an effective and safe alternative for patients who have high surgical risk of benign prostatic enlargement under general or spinal anaesthesia.

Introduction

Benign prostatic hyperplasia (BPH) is characterised by a non-malignant growth in the prostate gland that can cause a wide range of lower urinary tract symptoms (LUTS). These symptoms can greatly reduce a patient's quality of life (QoL) and may eventually lead to acute retention of urine (AROU).

Current standard treatments for BPH include conservative, pharmacological, and surgical approaches. For patients who fail to successfully complete a trial without catheter (TWOC) after AROU secondary to BPH, surgical intervention remains the main therapeutic approach. Surgical treatment options for BPH have evolved from electrosurgical resection to enucleation, ablation of the prostate, and other techniques.[1] Transurethral

局部麻醉下使用經尿道水蒸氣熱力治療良性前列腺增生：中國患者的初步經驗

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引言：本研究評估了在局部麻醉下使用經尿道水蒸氣熱力治療良性前列腺增生的中國患者的圍手術期及術後早期結果。

方法：這項經尿道水蒸氣熱力治療良性前列腺增生的回顧性研究，記錄了香港於2020年6月至2021年12月期間50名中國患者的臨床數據。這些患者的臨床指徵包括因良性前列腺增生導致的急性尿潴留或下尿路症狀，他們需在該段期間接受手術。排除標準包括活躍泌尿道問題及泌尿系統惡性腫瘤。患者在術後3個月進行隨訪。

結果：患者年齡中位數為71.5歲，術前前列腺平均總體積為56.7毫升，平均手術時間為25.1分鐘。所有手術均在局部麻醉下進行。超聲波探頭插入直腸、經會陰局部麻醉注射及經尿道水蒸氣熱力治療的平均疼痛評分分別為2、5和4。49名患者（98%）術後當天出院，帶有導尿管。術後3週內，48名患者（96%）術後3星期內在試行拔除導尿管的情況下成功自行排尿。五名患者（10%）在術後30天內因手術併發症（Clavien–Dindo第1級）計劃外入院。

結論：經尿道水蒸氣熱力治療良性前列腺增生是安全的先進手術方法，術後可緩解患者的下尿路症狀，而且住院時間短。它可以在辦公室佈局下以局部麻醉方式進行，能騰出手術室空間。

resection of the prostate (TURP), first performed over 90 years ago, continues to be regarded as the gold standard for the treatment of BPH with prostatic volumes of 30 to 80 mL.[2] Although TURP results in statistically significant improvements in symptom scores and maximum urinary flow rate (Q_{max}), it has some limitations. Perioperative morbidities and complications of TURP include infection, bleeding, urinary retention, incontinence, urethral stricture, erectile dysfunction, and ejaculatory dysfunction. Additionally, TURP requires general or spinal anaesthesia and postoperative hospitalisation. Through technological advancements, several minimally invasive procedures (eg, UroLift and prostatic artery embolisation) have been developed for specific groups of patients with BPH to minimise the aforementioned limitations.[3-5] Among these new-generation BPH surgical approaches, transurethral water vapour thermal therapy (WVTT) provides some of the best surgical outcomes.

Transurethral WVTT uses the thermodynamic principle of convective energy transfer, whereas other techniques (eg, transurethral microwave thermotherapy or transurethral needle ablation of the prostate) involve conductive heat transfer.[6] The thermal therapy system consists of a generator with a radiofrequency power supply that creates water vapour from sterile water, as well as a disposable transurethral delivery device. The tip of the delivery device contains an 18-gauge needle with 12 small emitter holes circumferentially arranged for water vapour dispersion into the targeted prostatic tissue. The release of thermal energy causes tissue necrosis. The most important characteristic of this technique is that, during treatment of the transitional zone, energy is only deposited within this specific region of the prostate. Reviews of histological evidence and magnetic resonance images have revealed that thermal lesions are limited to the transitional zone without affecting the peripheral zone, bladder, rectum, or striated urinary sphincter.[7,8] At 6 months after treatment, the total prostatic volume is reduced by 28.9% and the resolution of thermal lesions, as determined by gadolinium-enhanced magnetic resonance imaging, is almost complete.[8]

A pilot study showed that transurethral WVTT can serve as a safe and effective treatment in men with LUTS due to BPH.[8] In the first multicentre, randomised controlled study, 197 men were enrolled and randomised in a 2:1 ratio to treatment with the transurethral WVTT or a sham procedure.[9] The sham procedure consisted of rigid cystoscopy with sound effects that mimicked the thermal treatment. The primary efficacy endpoint was met at 3 months: relief of symptoms, measured as a change in International Prostate Symptom Score (IPSS), was detected in 50% of patients in the thermal treatment group compared with 20% of patients in the sham procedure group ($P<0.0001$). In the thermal treatment group, the Q_{max} increased by 63%—from 9.9 mL/s to 16.1 mL/s ($P<0.0001$)—after 3 months. This clinical benefit was sustained throughout the study period, with a 54% improvement at the 12-month follow-up. In the most recent update regarding 5-year outcomes, the improvement in voiding (as measured by IPSS and uroflowmetry) had persisted for 5 years, with a surgical retreatment rate of 4.4%.[10]

Thus far, studies of transurethral WVTT for BPH have mainly focused on Caucasian populations. To provide information regarding its tolerability and effectiveness in the Chinese population, this study investigated the safety profile and efficacy of transurethral WVTT under local anaesthesia alone for BPH among Chinese patients in Hong Kong.

Methods

Study protocol

This retrospective study investigated transurethral WVTT for benign prostatic enlargement. The inclusion criteria included Chinese ethnicity and clinical indications for surgical treatment, including AROU or symptomatic LUTS due to benign prostatic enlargement. Exclusion criteria included active urinary tract problems such as infection, bleeding disorder, bladder pathologies (eg, bladder stones and neurogenic bladder), and urethral stricture, as well as urological malignancies including bladder and prostate cancer.

Intervention

The procedure was performed with perioperative antibiotic prophylaxis. Patients were placed in the dorsal lithotomy position. After local anaesthesia, cystoscopy was performed to assess the anatomy of the bladder and prostate. A specialised handpiece with an optical lens was inserted under direct visual guidance into the prostate channel. Treatment began with the needle tip visually positioned and inserted approximately 1 cm distal to the bladder neck. Each treatment lasted for 9 seconds. After 9 seconds, an audible signal was produced by the system and the treatment needle was retracted. The handpiece was then repositioned 1 cm distal to the previous treatment site; repositioning was repeated until reaching a treatment site immediately proximal to the verumontanum. During each water vapour injection, the majority of the targeted tissue was treated. All treatment cycles involving one lateral lobe were completed as a group to utilise residual heat from prior treatments involving that lobe. Subsequently, the contralateral lateral lobe was treated in a similar manner. An enlarged median lobe could be treated by positioning the needle at a 45-degree angle towards the targeted lobe using the same technique. After the procedure, a 14-Fr Foley catheter was inserted. A 1-week course of antibiotic treatment was administered after surgery.[10] Patients were discharged with the urethral catheter and readmitted for a TWOC at approximately 1 to 2 weeks after surgery. Upon satisfactory completion of the TWOC, patients were scheduled for follow-up at 3 months postoperatively.

Statistical analysis

Preoperative parameters and perioperative outcomes were collected and tabulated using SPSS software (Windows version 28.0; IBM Corp, Armonk [NY], United States). Descriptive statistics were used to summarise the demographic data and perioperative patient characteristics. Paired sample *t* tests were used to compare continuous variables with normal distributions; the Mann-Whitney *U* test was used to compare continuous variables with skewed distributions, and the Chi squared test was used to compare categorical variables. Two-sided P values of <0.05 were considered statistically significant.

Results

Demographics

Between June 2020 and December 2021, 50 eligible patients were included in this study. The median age was 71.5 years (interquartile range [IQR]=64-75.25). In terms of indications, 27 patients (54%) had symptomatic BPH, 13 patients (26%) had AROU with a urethral catheter, and 10 patients (20%) had AROU without a urethral catheter. Of the 50 patients, 39 (78%) were categorised as American Society of Anesthesiologists class 2, whereas the remaining 11 were categorised as class 3. Most patients (68%) did not use any antiplatelet or anticoagulant therapy. The numbers of patients using aspirin, clopidogrel, dual antiplatelet therapy, and apixaban were 11 (22%), three (6%), one (2%), and one (2%), respectively. All antiplatelet and anticoagulant agents were temporarily discontinued before the operation (Table 1).

Operation

The mean preoperative prostatic volume was 56.7 mL (standard deviation [SD]=24.6; range, 29.2-119.0). The mean operation time was 25.1 minutes (SD=8.4). All procedures were conducted under local anaesthesia alone. Lignocaine 1% with adrenaline was injected into the periprostatic space using a transperineal approach. The mean pain scores for transrectal ultrasound probe insertion, transperineal local anaesthesia injection, and transurethral WVTT were 2, 5, and 4, respectively.

Postoperative course

Only one patient (2%) required bladder irrigation for 5 days postoperatively; that patient had been taking apixaban before surgery. All other patients were discharged on the same day with a urethral catheter. A TWOC was planned at around 1 week (for the AROU without urethral catheter or symptomatic BPH group) to 2 weeks (for the AROU with urethral catheter group) after surgery. Forty-eight patients (96%) in our study successfully completed a TWOC within 3 weeks postoperatively; the median time was 7 days (IQR=7-14). The median successful TWOC times were 14 days (IQR=8-21) for the AROU with urethral catheter group and 7 days (IQR=7-12) for the AROU without urethral catheter or symptomatic BPH group. Two patients (4%) with an initially unsuccessful TWOC began temporary clean intermittent self-catheterisation; they were subsequently weaned from this management approach on postoperative days 40 and 45, respectively.

Five patients (10%) had unplanned hospital admission within 30 days postoperatively due to surgical complications (Clavien–Dindo grade 1). The

TABLE 1. Use of antiplatelet or anticoagulant therapy (n=50)

	No. (%)
Aspirin 80 mg daily	11 (22%)
Clopidogrel 75 mg daily	3 (6%)
Aspirin 80 mg daily plus clopidogrel 75 mg daily	1 (2%)
Apixaban 5 mg twice daily	1 (2%)
No antiplatelet or anticoagulant therapy	34 (68%)

TABLE 2. Reasons for readmission (n=50)

	No. (%)	Remarks
Haematuria	1 (2%)	Light haematuria, discharged on day 2 of readmission
Post-obstructive diuresis	1 (2%)	No deterioration of renal function, discharged on day 2 of readmission
Recurrent AROU	2 (4%)	Successful TWOC, discharged on day 2 of readmission
UTI with AROU	1 (2%)	Successful TWOC, discharged on day 8 of readmission

Abbreviations: AROU = acute retention of urine; TWOC = trial without catheter; UTI = urinary tract infection

TABLE 3. Descriptive statistics of preoperative and postoperative parameters*

	Preoperative	Postoperative 3 months
PSA, ng/mL	5.1 (n=34, IQR: 2.9-9.2)	3.2 (n=34, IQR: 1.7-7.4)
PVRU, mL	134 (n=25, IQR: 57-243)	83 (n=40, IQR: 42-128)
Q_{max}, mL/s	9.0 (n=25, IQR: 7.0-10.4)	13.9 (n=40, IQR: 10.9-17.1)
IPSS	23.5 (n=50, IQR: 20.0-27.0)	12.0 (n=50, IQR: 7.0-15.0)
QoL score	4.0 (n=50, IQR: 4.0-5.0)	2.0 (n=50, IQR 2.0-3.0)

Abbreviations: IPSS = International Prostate Symptom Score; IQR = interquartile range; PSA = prostate-specific antigen; PVRU = post-void residual urine; Q_{max} = maximal urinary flow rate; QoL = quality of life

* Data are shown as median

TABLE 4. Mean differences of parameters 3 months after the procedure

	PVRU, mL (n=22)	Q_{max}, mL/s (n=22)	IPSS (n=50)	QoL score (n=50)
Preoperative*	150	8.3	22.9	4.4
Postoperative*	109	14.9	12.0	2.2
Mean difference	-41	+6.6	-10.9	-2.2
Standard deviation	107	5.4	5.8	1.5
P value	0.04	<0.001	<0.001	<0.001

Abbreviations: IPSS = International Prostate Symptom Score; PVRU = post-void residual urine; Q_{max} = maximal urinary flow rate; QoL = quality of life

* Mean values

reasons for readmission are listed in Table 2.

There were significant differences in preoperative and 3-month postoperative parameters, including prostate-specific antigen level, post-void residual urine (PVRU) level, Q_{max}, IPSS, and QoL assessment. Table 3 shows the medians and IQRs of these data. As indicated in Table 4, the mean differences in PVRU, Q_{max}, IPSS, and QoL score were -41 mL (SD=107), +6.6 mL/s (SD=5.4), -10.9 points (SD=5.8), and -2.2 points (SD=1.5), respectively.

No patients in this study exhibited *de novo* retrograde ejaculation or stress urinary incontinence at 3 months postoperatively. However, there were three reported cases (6%) of new-onset erectile dysfunction postoperatively. All three patients had temporary erectile dysfunction that resolved within 6 months postoperatively without requiring medication.

Discussion

Our study is the first to focus on the application of transurethral WVTT (Rezūm therapy) under local anaesthesia alone among Chinese men with BPH. Our results demonstrated clinically significant outcomes comparable to other treatments for BPH. Transurethral WVTT provided effective symptomatic improvement, as illustrated by a decrease in PVRU of 41 mL, an increase in Q_{max} of 6.6 mL/s, and a substantial decrease in IPSS of 10.9 at the 3-month follow-up (Table 4). These results were also comparable to outcomes in a recent international study of this therapy.[10] The postoperative outcome was favourable, with a successful TWOC rate of 96% within 3 weeks postoperatively. Moreover, all patients with urethral catheters before surgery successfully completed a TWOC after transurethral WVTT. The median successful TWOC time was 7 days postoperatively. However, compared with data from other studies (4.1 to 5 days),[11,12] our centre had a longer duration of catheterisation, which could be explained by our centre's policy of scheduling a TWOC on postoperative days 7 and 14 for patients without and with a urethral catheter before surgery, respectively. Five patients were readmitted within 30 days after surgery due to haematuria, post-obstructive diuresis, recurrent AROU, and urinary tract infection with AROU (Table 2). All were uneventfully discharged without further readmission; none of them developed postoperative urinary incontinence. Three patients reported *de novo* erectile dysfunction, higher than the rate observed in the recent international study.[10] However, the rate remained significantly lower than that associated with TURP.[13] Considering the minimally invasive nature of this procedure, it could revolutionise future management of BPH.

The current management algorithm for BPH does not include transurethral WVTT as a first-line treatment due to the relative lack of evidence regarding its mid- to long-term efficacy and safety.[2] However, it has considerable potential in the management of BPH because of unique advantages

compared with TURP. Transurethral WVTT can be an office-based procedure with a short learning curve. If a surgeon completes 10 cases of transurethral WVTT under supervision, he/she will become independent from a surgical trainer. Because BPH is a particularly common urological disease and often requires surgical management,[14] the minimally invasive nature of transurethral WVTT can help reduce the number of patients waiting for operations in overcrowded hospital facilities. The results of our study provide initial evidence that transurethral WVTT is well-tolerated among patients under local anaesthesia alone. We did not administer any sedation to the patients because they might move during the operation, resulting in a high risk of water vapour leakage. Such leakage would lead to inadequate treatment.

In Hong Kong, total health costs represent about 19% of the total government budget,[15] and public in-patient health costs in 2021/2022 constituted 32% of total health costs.[16] Operation time is one of the most important factors affecting in-patient costs. According to a meta-analysis by Mamoulakis et al[17] in 2009, the mean operation time for TURP ranged from 39 to 79 minutes. In the present study, the mean operation time was 25.1 minutes. Thus far, no studies have directly assessed the cost-effectiveness of transurethral WVTT in the Chinese population. In the United States, a cost-effectiveness analysis of six therapies for BPH, published in 2018,[18] showed that transurethral WVTT was more cost-effective than other minimally invasive therapies, such as combination medical treatment and UroLift. Moreover, McVary et al[10] reported that the 5-year retreatment rate after transurethral WVTT was 4.4%, which was significantly lower than that after UroLift therapy (13.6%) reported by Roehrborn et al.[5]

Notably, transurethral WVTT leads to lower incidences of bleeding, urgency, urge incontinence, and ejaculatory dysfunction compared with TURP.[19] The more favourable side-effect profile has resulted in considerable interest concerning its potential to replace TURP as the first-line surgical treatment in the future. No head-to-head trials have compared other surgical modalities with transurethral WVTT. Indirect comparison through a meta-analysis revealed that TURP outperformed transurethral WVTT by providing greater relief of LUTS,[19] although it carried a greater cost and higher complication rate.[18] Although pharmacological treatment is currently the first-line treatment for moderate to severe LUTS, it is associated with complications such as dizziness, postural hypotension, reduced libido, and erectile dysfunction. Gupta et al[20] compared standard medical therapy with transurethral WVTT using cohort data from the MTOPS trial (Medical Therapy of Prostatic Symptoms); they showed that transurethral WVTT had superior outcomes in terms of QoL, IPSS, and prostatic volume reduction. Considering these advantages, transurethral WVTT can be regarded as a first-line treatment option for patients with symptomatic LUTS who prefer a short operation, rather than lifelong pharmacological treatment.

Limitations

There were some limitations in this study. First, a substantial proportion of our patients had been catheterised preoperatively (74%) and thus could not undergo uroflowmetry studies before the operation. Due to the coronavirus disease 2019 pandemic and the associated community isolation policy, some other patients did not complete uroflowmetry studies. However, all IPSS data were able to be collected via telemedicine, ensuring the inclusion of those data in the analysis. Second, our study did not have a sufficient number of patients to allow subgroup analysis of patients with different indications for transurethral WVTT; future studies should explore treatment outcomes among patients with different indications for transurethral WVTT. Third, our inclusion period was prolonged, partly due to the coronavirus disease 2019 pandemic and partly because transurethral WVTT mainly was regarded as a self-financed item in our centre; these aspects led to some difficulty in accumulating a sufficient number of patients for analysis. Finally, this study used a single-arm design with a relatively short follow-up period; additional studies are needed to assess long-term treatment outcomes and retreatment rates after transurethral WVTT under local anaesthesia alone.

Conclusion

Transurethral WVTT is a safe and effective treatment for benign prostatic hyperplasia in the Chinese population. It can also be conducted in an office setting under local anaesthesia alone, avoiding use of the surgical theatre and its associated costs.

Author contributions

Concept or design: KL Lo, CF Ng.
Acquisition of data: KL Lo.
Analysis or interpretation of data: A Mok, ICH Ko.
Drafting of the manuscript: KL Lo, A Mok, ICH Ko.
Critical revision of the manuscript for important intellectual content: All authors.

All authors had full access to the data, contributed to the study, approved the final version for publication, and take responsibility for its accuracy and integrity.

Conflicts of interest

As an editor of the journal, CF Ng was not involved in the peer review process. Other authors have disclosed no conflicts of interest.

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Ethics approval

This research was approved by the Joint Chinese University of Hong Kong–New Territories East Cluster Clinical Research Ethics Committee, Hong Kong (Ref No.: 2019.662). The patients were treated in accordance with the tenets of the Declaration of Helsinki and have provided written informed consent for all treatments and procedures and consent for publication.

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