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ORIGINAL ARTICLE

Is water vapor thermal therapy safe and feasible in elderly and frail men? The Italian experience

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Abstract

Purpose In recent years, water vapor thermal therapy (WVTT) has spread as minimally invasive technique in lower urinary tract symptoms due to benign prostatic hyperplasia treatment. Even if its safety and feasibility have been largely proved in young men, nobody has proved the same feasibility and safety in the elderly (men older than 75 years old). Our aim is to compare WVTT safety outcomes in men older than 75 with younger men.

Methods We prospectively collected data on men who underwent water vapor thermal therapy from 2019. We compared data on operative time, number of injections, intra-operative and post-operative complications, reinterventions rate.

Results We enrolled 426 patients; among these, 60 were older than 75 years old, 366 were younger. Our cohorts of patients had similar results in terms of intra-operative and post-operative complications. Operative time accounts about 11 min for both groups ($p = 0.535$), total number of injections was seven for young men and eight for elderly ($p = 0.314$). We found no intra-operative complications in elderly men group and only one in the younger group ($p = 0.678$), while five younger men underwent clot retention, and two elderly men experienced this complication ($p = 0.239$). Only one transfusion occurred in the elderly group. No differences between groups occurred in terms of length of stay, post-operative urinary retention and reintervention rate, while catheterization time was longer in the elderly men.

Conclusion WVTT is a safe procedure in elderly patients with comparable intra-operative and post-operative complication rate in comparison with younger patients.

Keywords Benign prostatic hyperplasia · Aging · Frailty · Water vapor thermal therapy

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Introduction

Benign prostatic hyperplasia (BPH) is the most common diagnosed urological condition in patients older than 50 years old. Undeniably, its prevalence increases proportionally to the increase of age with the vast majority of the octogenarians affected by it [1]. Most of the patients affected by BPH may refer a variety of lower urinary tract symptoms (LUTS) including voiding and storage symptoms and recurrent urinary tract infections.

Moreover, the raise of mean age of the general population, together with the raise of prevalence of metabolic syndrome is leading to a simultaneous raise of BPH incidence and prevalence with a consequent economical burden on healthcare [2].

To relieve patients affected by BPH from its bothering symptoms, they could beneficiate from pharmacological therapy that mainly consists of alpha-blocker drugs and five alpha reductase inhibitors. Unfortunately these are associated with a not negligible rate of discontinuation and adverse events [3]

In alternative, surgery is an option that must be proposed in case of LUTS refractory to medical therapy, particularly in cases of high post-voiding residual volumes and inability to void, sometimes leading to severe clinical complications such as renal insufficiency or recurrent urinary tract infections [4].

Nevertheless, surgical and technological evolution leads to the possibility to manage minimally invasive surgical BPH also in patients affected by mild to moderate LUTS who do not tolerate any medical treatment, but truly are still not candidates to standard surgical treatments.

In fact, recently many minimally invasive surgical techniques (MIST) are gaining relevance in BPH treatment, thus giving the possibility to a more patient-tailored treatment choice, based mostly on his needs and expectations [5–7].

Among MIST, one of the most recent and promising is the water vapor thermal therapy (WVTT) which was specifically developed as a platform technology for transurethral energy transfer using the convective properties of water, releasing large amounts of stored thermal energy (540 cal/mL H_2O) as the vapor contacts prostate tissue and condenses back to water. This technology has been considered the most versatile between MIST, as it can be efficiently performed in a wide variety of cases, with prostate volumes ranging between 30 and 80 cc (and more) and with any shape of median lobe ensuring excellent midtime results with very limited impact on sexual functions [8–10].

As BPH grows with aging, a similar trend is associated to frailty, which is a state of reduced physiologic reserve beyond that which would be expected with normal aging, and is thought to result from the cumulative effect of multiple physiologic changes over time. Frailty, which accounts for factors beyond age-related physiologic changes alone, is increasingly appreciated as a predictor of adverse post-operative outcomes [11].

Indeed, frailty severely affects BPH treatment choices and minimally invasive techniques are highly demanded in such patients [12].

To our knowledge, nothing is reported in literature about the safety and feasibility of WVTT in elderly patients and there are still no comparisons between elderly and younger patients.

Aim of our study is to answer to such question, and thus compare WVTT results in terms of feasibility and safety between elderly and younger patients in our Italian multicentric cohort.

Materials and methods

Pre-operative assessment

We conducted a retrospective cohort study of patients affected by LUTS/BPH and treated with WVTT, in a multi-institutional, prospectively collected database, in eight Italian institutions between June 2019 and September 2021. The study is still ongoing.

A comprehensive recording of medical history, digital rectal examination (DRE), and a prostate specific antigen (PSA) was conducted. In case of suspect prostate cancer, patients underwent a multiparametric magnetic resonance imaging and/or a prostatic biopsy to rule it out. To quantify LUTS and to assess continence and erectile function, patients were evaluated with the International Prostatic Symptom Score (IPSS), the Overactive Bladder Questionnaire (OAB-q SF), the International Consultation on Incontinence (ICIQ-SF), and the International Index of Erectile Function (IIEF-5). All patients underwent also an ultrasonographic assessment of the prostate volume, plus a uroflowmetry with post-voiding residual volume (PVR) measurement. Each patient was adequately informed about the difference in outcomes reported in literature regarding WVTT and standard therapy (TURP/enucleation of the prostate/Greenlight) with their subsequent consequences on the micturition and on the sexual function and chose WVTT. Of course, for bigger prostates, each institution proposed surgical alternatives, including open, laparoscopic and endoscopic laser enucleation of the prostate. Every candidate had an anesthesiologic pre-operative assessment and had the American Society of Anesthesiology (ASA) score and the Charlson Comorbidity Index (CCI).

Eligibility criteria

Patients whose prostate volume was smaller than 30 cc or bigger than 150 cc were excluded. Middle lobe was not an exclusion criterion.

Antiplatelet or anticoagulant therapies in patients who took those for cardiocirculatory reasons, as any kind of antidiabetic or antihypertensive drug, were not interrupted and considered no exclusion criterion.

Signed informed consent, age > 18 years and a full data set were mandatory for inclusion in this study.

Surgical procedure

A pre-operative negative urine culture needed to be achieved before treatment. After positioning the patient on a lithotomic position, we reached the transitional zone of the prostate through the endoscopic device and performed one injection per 9 g of prostate making a symmetric treatment between the two lobes, treating also the median lobe when present and maintaining a distance of 1 cm from the bladder neck. At the end of the procedure, a Foley catheter was placed and a first attempt of remotion of it was prescribed 7 days after the surgery, as previously described [13]. Alpha blockers were prescribed for 1 month after the surgical procedure while all of the other medical treatments were discontinued immediately after surgery.

Intra- and post-operative assessment

We assessed all data regarding the surgical procedure, including operation time, number of total injections, incidental bladder cancer findings, length of stay in hospital (days), bladder catheter in site (days).

As safety was mandatory for the purpose of this study, a particular attention was dedicated to post-operative complications that were classified according to the Clavien–Dindo classification.

Statistical analysis

Patients were divided according to age into elderly, with age > 75 years and not-elderly, age < 75 years to conduct comparisons.

All data were reported appropriately: continuous variables as median and interquartile range (IQR) and categorical variables as absolute number and percentage. The statistical comparisons between elderly and not-elderly patients were conducted for the selected outcomes through Mann–Whitney test and Chi-squared test as appropriate. Statistical significance was set with $p < 0.05$. Data were analyzed using IBM SPSS 28.0.1.0 (IBM Corp., Armonk, N.Y., USA).

Ethics

To proceed with the study, ethical appraisal was obtained for the current study (Ref AOC-0020489-2022). Data sharing between centers was conducted according to EU privacy regulations, with anonymized data to safeguard patients' privacy.

Results

After careful revision of inclusion and exclusion criteria, patients with adequate follow-up and eligible for enrollment were 426 men, 366 were younger than 75 years old (Group 1), non-elderly, while 60 were above this age (Group 2), elderly. Group 1 had a median age of 63 (IQR 57–67), while Group 2 had 78 years (IQR 76–82), $p < 0.001$. Regarding frailty, Group 2 differed for a higher CCI, 2 (1–3) vs 1 (0–2), and ASA score, 2 (2–2) vs 2 (1–2), with $p = 0.015$ and $p < 0.001$, respectively. Accordingly, antiplatelets and anticoagulants use was higher for Group 2, $p < 0.001$. Groups were indeed similar for PSA, prostate volume, continence (ICIQ-SF), and LUTS (OAB-q SF; IPSS), but they had a statistically significant difference for erectile function (IIEF-5) and ejaculatory dysfunction regarding sexual function, which was higher in Group 2 ($p < 0.001$ and $p = 0.018$, respectively), and for acute urinary retention rate, which was significantly higher in Group 2 ($p < 0.001$). All these data are reassumed in Table 1.

Regarding operative and perioperative data for feasibility and safety, operation time accounts about to 11 min for both groups ($p = 0.535$). Total number of injection was similar between groups, with 8 injections IQR (5–9) in Group 2 vs 7 injections IQR (6–11) in Group 1, $p = 0.314$, as the number of median lobe injections ($p = 0.946$). We found no differences for intra-operative complications between the two groups, with only one which occurred in the non-elderly group ($p = 0.678$). Clot retention occurred two times in Group 2 and five times in Group 1 ($p = 0.239$). Blood transfusion was reported only once in Group 2. The length of hospital stay was 1 day in Group 2 (IQR 0–1) and 0 days in Group 1 (IQR 0–1 days), $p = 0.073$. We found a statistically but not clinically significant difference in terms of number of days of catheter in site accounting for 7 days (IQR 7–7) for Group 1, and 7 (IQR 7–14) in the Group 2, $p = 0.002$. No differences were found in terms of post-operative complications in general with 30 events in Group 2 (33.3%) and 108 events in Group 1 (29.5%), $p = 0.226$ and similarly for reintervention rate. Data are reassumed in Table 2.

Table 1 Comparison of baseline patients' characteristics in non-elderly (Group 1) and elderly (Group 2)

	Group 1 ($n=366$)	Group 2 ($n=60$)	p
Age, years	63 (57–67)	78 (76–82)	< 0.001
BMI, Kg/m^2	24.1 (23.2–26.3)	25.3 (23.0–27.4)	0.380
ASA	2 (1–2)	2 (2–2)	< 0.001
CCI	1 (0–2)	2 (1–3)	0.015
Maximum flow, ml/s	8.0 (6.1–10.0)	8.1 (7.7–9.8)	0.945
Post-void residual volume, ml	90 (60–132)	100 (75–150)	0.185
IPSS	23 (19–26)	23 (18–26)	0.655
IPSS-storage	10 (8–12)	10 (7–12)	0.920
IPSS-QoL	4 (4–5)	4 (4–5)	0.932
OAB-q SF	39 (26–60)	43 (28–60)	0.344
ICIQ-SF	0 (0–1)	0 (0–1)	0.835
IIEF-5	20 (16–22)	10 (5–19)	< 0.001
PSA, ng/ml	2.5 (1.4–3.9)	2.8 (1.8–4.0)	0.668
Prostate volume, ml	60 (45–80)	64 (48–88)	0.074
Anterograde ejaculatory absence	255 (69.7%)	33 (55%)	0.018
BPH treatment			
None	40 (10.9%)	1 (1.7%)	0.06
Alpha-blocker	245 (66.9%)	36 (60.0%)	
5-ARI	7 (1.9%)	5 (8.3%)	
Phytotherapy	13 (3.6%)	5 (8.3%)	
Antimuscarinic	1 (0.3%)	1 (1.7%)	
PDE5-I	2 (0.6%)	0	
Combination therapy	58 (15.8%)	12 (20.0%)	
Antiplatelets or anticoagulants			
None	331 (90.4%)	33 (55%)	< 0.001
Single antiplatelet	30 (8.2%)	21 (35%)	
Double antiplatelet	3 (0.8%)	2 (3.3%)	
Anticoagulant	1 (0.3%)	4 (6.7%)	
Both	1 (0.3%)	0	
Acute urinary retention			
Never	304 (83.1%)	40 (66.7%)	< 0.001
Past episode	23 (5.2%)	5 (8.3%)	
Bladder catheter in place	39 (10.7%)	15 (25%)	
Median prostate lobe	196 (53.6%)	35 (58.3%)	0.953
Median prostate lobe length, mm	1.0 (0.2–1.8)	1.2 (0.5–2.2)	0.731
Bladder stones	7 (1.9%)	0	0.273
Bladder diverticulum	20 (5.5%)	2 (3.3%)	0.469
Previous urethrotomy	1 (0.3%)	0	0.680

Discussion

Nowadays the number of patients that could beneficiate from a surgical treatment for BPH is increasing together with the aging of population [14, 15]; indeed, as previously reported, many surgical treatments have been recently approved for the management of BPH, which differs from the more common transurethral resection of the prostate (TURP) and endoscopic or surgical enucleation of the prostate for their less surgical invasiveness and for the lower anesthesiological impact.

These surgical techniques differ from each other for the kind of energy delivered and for the mechanical approach used to gain a functional recovery in BOO affected patients but for almost all of them, a large consensus on the safety profile and on the feasibility in the elderly and frail population has been reached [16].

In this contest, WVTT is spreading through other novel mini-invasive surgical techniques because of its great versatility and recognized effectiveness. Being first proposed as an ejaculation sparing solution for patients affected by LUTS/BPH, WVTT showed to be a better option than

Table 2 Comparison of intra- and post-operative characteristics between non-elderly (Group 1) and elderly (Group 2) patients

	Group 1 ($n=366$)	Group 2 ($n=60$)	p
Time, minutes	11 (9–15)	11 (9–14)	0.535
Injection total number	7 (5–9)	8 (6–11)	0.314
Median lobe injections	1 (0–2)	1 (0–2)	0.946
Incidental bladder cancer	3 (0.8%)	0	0.473
Intra-operative complications	1 (0.3%)	0	0.678
Clot retention	5 (1.4%)	2 (3.3%)	0.239
Blood transfusion	0	1 (1.7%)	0.014
Length of stay, days	0 (0–1)	1 (0–2)	0.073
Bladder catheter in site, days	7 (7–7)	7 (7–14)	0.002
Post-operative complications			
AUR	36 (9.8%)	6 (10.0%)	0.226
Hematuria	6 (1.6%)	2 (3.3%)	
Mild LUTS	58 (15.8%)	6 (10.0%)	
Severe LUTS	6 (1.6%)	6 (10.0%)	
Groin pain	2 (0.5%)	0	
Reinterventions	13 (3.6%)	1 (1.7%)	0.654

pharmacotherapy in preserving sexual function [17, 18], adapt for prostate volumes initially ranged between 30 and 80 mL, but later also for patients with prostate volumes > 80 mL [19].

In this study, we proved that WVTT perioperative outcomes are similar when compared between two different cohorts in terms of age and frailty domains as CCI, ASA score, and anticoagulant/antiplatelet assumption, but scarce sample size did not allow further comparisons.

Even if the mean prostate volume was similar between the groups, a lower number of injections (even if not statistical different) was found in the Group 1 probably reflecting the intention of the surgeons to be as conservative as possible in sexually active patients not impairing their ejaculatory function and limiting all side effects. Moreover, even if we found a statistical difference between the number of days of catheterization (with elderly that maintained it up to 14 days), there is not a clinical significant difference between the groups (median catheterization time 7 days) (Table 2).

The only discomfort for patients who undergo WVTT stands in the necessity to maintain the catheter after the procedure for a short time. However, it has to be considered that there is an high rate of elderly patients who refer to urologist for being catheter dependent due to acute or chronic urinary retention and that accept too easily to undergo a less invasive procedure that provides an earlier discharge.

Although lots of different percentage of success after catheter removal are reported in literature with some authors describing low urinary retention rates [20], in our experience, the mean catheterization time for both the elderly and the not-elderly group of patients was of 7 days with 10% of AUR episodes after the first attempt of catheter removal supporting the current knowledge that pre-operative PVR is the only independent predictor of post-operative AUR after WVTT [21]. Moreover, supporting the feasibility of WVTT in a frail population, Tadrist et al. proved the efficiency of this technique in voiding recovery in multimorbid and frail patients with indwelling catheter and a median age of 77 years old; however, in their finding, the post-operative indwelling catheter time seems to be longer than in our results with a median post-operative catheterization time of 21 days [22].

Even if the hospital stay could be influenced by the private or public healthcare system with some of these requiring one or more night of hospitalization, one of our most interesting findings stands in the length of hospital stay that accounts for 0 days for the young group and 1 day median permanence for the elderly group (IC 0–2 days) that is shorter than the mean length of stay in hospital for patients who undergo conventional surgery [23]. Although the difference in hospital stay has to be attributed primarily to the different invasiveness of the procedures, with WVTT being less invasive, some authors in other fields proved that general anesthesia may lengthen the hospital stay [24]. In our experience, the majority of the procedures has been performed under sedation, but it has to be pointed that it has been yet described the feasibility of WVTT performing a local intraprostatic anesthesia delivered transurethrally (TUIA) using a particular device, the so called "Schelin catheter" and that other authors described the safety and efficacy of low-dose methoxyflurane disposable inhaler (Penthrox) for pain control during WVTT [25, 26].

WVTT may guarantee durable improvements in terms of symptoms relief in patients affected by moderate–severe LUTS (IPSS > 13) with a 4-year reduction of IPSS accounting for 46.7%; moreover, in the pilot study, a reintervention

was needed only in 4.4% of cases (6 on 135 patients), with 4 out of these 6 patients who had a non-treated middle lobe at first surgical procedure [5]. Treating all kind of prostate, including the glands with an obstructing median lobe, we limited the post-operative reintervention rate at the 1.7% in the elderly group within the first year.

Similarly, Campobasso proved WVTT safety and effectiveness, not registering Clavien–Dindo III or IV events but minor early complications in 39.3% of cases, with 4 cases of clot retention and 1 case of blood transfusion in a 262 patients cohort, that have post-operative complication rates similar to that we found in our cohorts [10].

The biggest limitation of this study stands in the scares sample size of group 2 that did not give us the possibility to define a predictor of success of the technique in both of our groups. Other limitations are the retrospective nature, the big discrepancy in number of included patients between the two groups, and the multi-center experience. However, the conspicuous study population and the comparison between two different populations undergoing the same surgical procedure are the major strengths of our work to better define the real safety and feasibility of WVTT in older patients.

Conclusion

WVTT is a safe and feasible procedure in men older than 75 years old as for younger patients. We did not find any difference in terms of intra-operative and post-operative complications between two groups. This technique should be proposed particularly to people having multiple comorbidities and subsequent augmented anesthesiologic risks, thanks to the possibility to be performed under sedation or local anesthesia.

Author contributions AM: data collection, manuscript writing. SM: data analysis, manuscript writing. FF: data collection. DM: data collection. FV: data collection. ST: data collection. GF: project development. GS: project development, data collection. EC: data collection. RP: project development. FU: project development. Balsamo R: project development, data collection. RMS: project development, manuscript supervision. LC: project development, data analysis, manuscript supervision.

Data availability The raw data are available upon reasonable and motivated request.

Declarations

Conflict of interest The authors declare no competing financial interests and no other conflict of interests to disclose.

Research involving human and animal participants The research involves human participants but not animals.

Ethical approval To proceed with the study, ethical appraisal was obtained for the current study (Ref AOC-0020489-2022). Data sharing between centers was conducted according to EU privacy regulations, with anonymized data to safeguard patients' privacy.

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