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Comparison of Water Vapor Thermal Therapy and Prostate Artery Embolization for fragile patients with indwelling urinary catheters: preliminary results from a multi-institutional study

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Introduction

Acute urinary retention (AUR) is one of the most common urological emergencies in the aging male population. More than 10% of men in their 70's and a third of men in their 80's are expected to be affected by this condition [1-2]. In case of medically refractory and complete urinary retention, surgical treatment is considered to be the end point for AUR [3]. Catheter-dependent patients seek treatment to improve bladder function and quality of life, particularly to reduce long-term catheter complications [4]. However, the indication for conventional desobstructive surgery in older, frail-patients has to balance life expectancy, functional outcome, and surgical risk.

Transurethral resection of the prostate (TURP) has remained the cornerstone of benign prostatic obstruction (BPO) surgical treatment for more than nine decades. While endoscopic enucleation of the prostate whatever the energy used is gradually becoming the gold standard in BPO surgery, Minimally Invasive Surgical Therapy (MIST) is increasingly relevant as a large percentage of men who remain excluded from invasive surgery. Thermal water vapor therapy with the Rezūm™ system and prostate artery embolization (PAE) are MISTs that have demonstrated significant efficacy in controlled trials [5-9] for the treatment of lower urinary tract symptoms due to BPO. These MISTs could also be considered as an alternative to conventional surgical treatments for catheter-dependent patients with at high anesthesia risk due to comorbidities.

The aim of this multi-institutional study was to report our preliminary experience with water vapor thermal therapy and PAE for treatment of medically refractory, complete urinary retention to achieve successful cessation of catheter dependency in frail-patients.

Materials & Method

Study population

Ethical approval was obtained from the Ethics Committee of the French Association of Urology. Consecutive patients who underwent convective radiofrequency water vapor thermal therapy with the Rezūm™ System (Boston Scientific Corporation, Marlborough, MA) and PAE in three urology centers have been considered. Only one technique was available per center and patients could not choose between Rezūm™ and PAE. A radiologist and two surgeons with extensive previous experience in PAE and Rezūm™ performed all procedures. The included population focused on patients with medically refractory, complete urinary retention despite using at least one α -blocker and trial without catheter (TWOC). Patients known to have neurogenic bladder, prostate cancer, urethral stricture or who had previous BPO surgeries were not eligible for these minimally invasive surgical therapies. There were no restrictions regarding prostate volume for each treatment. Patients with water vapor thermal therapy were identified and matched (1:1) with patients who underwent PAE. The matching criteria were age, Charlson score, prostate volume and duration of follow-up.

Data collection

Retrospective data were collected from October 2017 to June 2020. Preoperative evaluations included digital rectal examination, urinary ultrasound, serum prostate-specific antigen (PSA), serum creatinine and urinary analysis including culture. Preoperative symptoms index score (international prostate symptoms score [IPSS]) as well as uroflowmetry (Qmax and post-voiding residual) parameters were not recorded in this catheter-dependent population. Urodynamic studies were not performed.

Water vapor thermal therapy

All the interventions were performed with the Rezūm™ system (Boston Scientific Corporation, Marlborough, MA), initially under short general anesthesia for comfort reasons and thereafter, under hypnosis or simple sedation. Briefly, the Rezūm™ system consists of a generator and a single-use device containing a retractable needle with a classical 4mm optic at 30 degrees fitted on it. The conformation of prostatic urethra was studied so as to map the prostate lobes. This mapping allowed the operator to plan the number and ideal location of the treatments to deliver. Treatment began with a first lateral puncture 1 cm downstream from the bladder neck and was completed by making the required number of punctures so that the overlapping of lesions creates a treatment area involving the whole prostate lobe. Treatment was conducted up to the end of the urethral prostate one centimeter before the verumontanum. The same procedure was performed on the contralateral lobe. If there was a median lobe or a lobe protruding into the bladder, the first treatment was made 1 cm downstream from the start of the protrusion or the median lobe to ensure that it is sufficiently far away from the meatuses.

Prostate artery embolization

All embolization procedures were performed under local anesthesia via femoral arterial access. Hypogastric arteriography was first performed using a 5F Cobra-type angiographic catheter (5-Cobra, Terumo, Tokyo, Japan). The arteries feeding the prostate were super-selectively catheterized with a 1.7F Echelon™ 10 Micro Catheter (Medtronic, Dublin, Ireland) and then embolized to stasis. The choice of embolic particle size was based on the operator's discretion with either 100–300 µm or 300–500 µm Embosphere Microspheres (Merit Medical Systems, South Jordan, Utah). Technical success was defined as bilateral

embolization. Vascular closure devices for femoral artery puncture sites used were 5F MynxGrip™ device (Cardinal Health, Dublin, Ohio) or 6F Exoseal™ device (Cordis Corporation, Milpitas, Calif).

Follow-up and study endpoints

Postoperative course was similar between both procedures. Patients were discharged home the same day or were observed overnight and discharged home within 24 hours. Alpha-blocker treatment was left for 7 days after Rezūm™ and PAE. In our clinical practice, postoperative management has evolved as experience was gained with the procedures. During the acute inflammatory period following each treatment, an indwelling catheter was left in place for several days to allow for reduction in edema associated with damaged tissues. At the beginning of our experience, whatever the technique, the first attempt to remove the catheter was earlier than currently, going from 3 to 15 days postoperatively. After catheter removal, the postvoid residual was tolerated up to 350 cc. If the patient fails the first TWOC, we repeated the TWOCs at 2 week intervals. Patients after MISTs were reviewed 1 month after urethral catheter removal to evaluate treatment response and adverse events. Further re-assessment at 6- and 12-months, and then once a year was scheduled.

The primary endpoint was urinary catheter free-survival which was defined as a spontaneous voiding without further intervention. Secondary outcomes included: safety of procedures which was evaluated according to the Clavien–Dindo classification of surgical complications [10], operative time and discontinuance of BPO medication.

Data analysis

Demographic data, preoperative clinical information, perioperative and follow-up variables were recorded from the patients' medical files. Descriptive statistics were delineated for the available variables. Quantitative variables were reported in median, interquartile range [IQR] and analyzed using Mann-Whitney test. Categorical variables were described as numbers and percentages and were analyzed by Fisher's exact test. Statistical analyses were performed using R Version 3.5.3 (The R Foundation for Statistical Computing). For all tests a p value of < 0.05 was considered statistically significant.

Results

A total of 23 and 11 consecutive frail-patients with complete urinary retention underwent respectively PAE and water vapor thermal therapy in our institutions between October 2017 and June 2020. Patients from the Rezūm™ group were matched to embolized patients in a 1:1 manner.

Patient baseline characteristics are summarized in Table 1. Both groups were comparable for each variable. Most patients were in poor health or unsuitable for conventional surgery. Respectively in the Rezūm™ and PAE groups, the median age was 75 (IQR 68-86) vs 77 (IQR 71-86) years and the median Charlson score was 6 (3-7) vs 6 (4-7). Cardiovascular diseases were the most common comorbidities, recorded in 18 cases (81.8%). All patients had refractory urinary retention despite the use of an α -blocker (n = 3) or dual therapy including one α -blocker and one 5- α -reductase inhibitor (n = 18) or including one phytotherapy and one 5- α -reductase inhibitor (n = 1). Catheter (n = 19) or clean intermittent self-catheterization (n = 3: two before PAE and one before Rezūm™) dependency before the procedures was a median of 2.3 (IQR 1.5-5.1) months in the Rezūm™ group and 3.7 (IQR 2-5.6) months in the PAE group. Information on number of previous failed TWOCs were available in 17 cases and the median number ranged from 2 (IQR 2-3) to 3 (IQR 2-3) respectively in the Rezūm™ and PAE groups.

Table 2 shows procedures outcomes. Bilateral artery embolization was successfully achieved in all cases. The median number of punctures during the Rezūm™ procedures was 7 (IQR 5-9) per treatment including 5 treatments of a median lobe. Procedures were significantly longer in the PAE group with a median operative time of 148 (IQR 123-161) min compared to the Rezūm™ procedures (8 [IQR 5-13] min, p < 0.001). The postoperative success of catheter removal was obtained in 100% of cases after the Rezūm™ procedure whereas only in 45.4%

(n = 5/11) of cases after PAE (p = 0.01). Thirty-day postoperative side-effect was observed in 2 cases after the Rezūm™ procedure (one gross hematuria in patient with preoperative antithrombotic intake and one urinary tract infection) while 3 cases of postembolization syndrome occurred after PAE. No serious adverse events occurred (> Clavien II). After a median follow-up of 12 months in both groups, spontaneous voiding was conserved in all cases after the Rezūm™ procedure and in 5 cases after PAE (p = 0.01). In catheter-free patients, the rate of benign prostatic hyperplasia (BPH) medication use after procedure was 40% for PAE and 18.2% for Rezūm™ patients (p = 0.54). The treatment used in these patients was dual therapy including one α -blocker and one 5- α -reductase inhibitor.

Discussion

Over the past 25 years, many MISTs for lower urinary tract symptoms associated with BPH have been developed using vastly different mechanisms of action, and resulting in very different efficacy and safety profiles [11, 12]. Currently, define potential target populations for these various new minimally invasive treatments is a major concern among urologists. One of the many advantages of these techniques would be to avoid prolonged general anesthesia for the increasing cohort of elderly, polymorbid patients unfit for conventional surgery. In this retrospective multi-institutional study, we report the first preliminary experience comparing water vapor thermal therapy and PAE for treatment of medically refractory, complete urinary retention in frail-patients. For elderly patients or patients in poor physical health considered to be at high risk of intraoperative complications and postoperative morbidity, this study shows the feasibility of PAE and Rezūm™ to restore spontaneous urination without being associated with the occurrence of major complications. Interestingly, our preliminary data suggests that Rezūm™ procedures may provide superior results in terms of cessation of catheter dependence.

Our efficacy rate to remove urinary catheter after water vapor thermal therapy compared favorably with the series of Mc Vary et al. which have included 38 patients with urinary retention due to BPO who underwent Rezūm™ procedure [13]. Approximately 70% of included patients could void spontaneously again at a median of 26 days, and 18/26 patients (69%) could discontinue using BPH drugs [13]. When comparing both study, each series included frail-patients with a similar age, prostate volume and preoperative catheterization time. The main difference between each series was the type of anesthesia: we performed all the interventions in the operating room in collaboration with the anesthesiologists while Mc Vary et al. performed several procedures in an office procedure room. Performing the

Rezūm™ procedure through a short general anesthesia allowed us to administer a higher median number of total water vapor injections per procedure (7 vs 5). However, the correlation between the number of injections and procedure outcomes remains unknown. PAE causes irreversible ischemic necrosis, resulting in shrinkage of adenomatous tissue. Bilateral embolization is routinely performed in prostate glands with volumes between 80mL and 250mL, on an outpatient basis under moderate sedation through an arterial puncture. Accordingly, PAE has potential to help urinary retention patients or patients deemed high risks for general anesthesia. In most of the available PAE studies, patients with preoperative urinary catheter were either not included [14-16] or represented a low sample size [17]. In the present series, only 45.4% of catheterized patients who underwent PAE were catheter-free after 12 months of follow-up. Similar to our results, Thulasidasan found that among 24 patients with indwelling urethral catheter who underwent PAE, 11 had unsuccessful trial without catheter after PAE and one required re-catheterisation 6 months post-PAE, resulting in a catheter-free survival rate of 50% at 12 month [18]. Conversely, our results compare unfavorably with previous data from Yu et al. [19], Rampoldi et al. [20], and Ayyagari et al. [21] who were able to achieve successful TWOC in 87.5%, 80.5%, and 87% of patients, respectively. However, the patients included in the previous series were younger and in better health than the frail patients included in our current series. Only Rampoldi et al. had included poor surgical candidates with demographic characteristics very similar to those of our patients [20]. However, in this series, despite a higher success of postoperative catheter removal (80.5%), the follow-up was shorter (6 months) and 46.5% of patients experienced urinary retention recurrence within 6 months after PAE. Taken together, data suggest that PAE remains an interesting option for treating frail patients with indwelling urinary catheter

but when possible, urodynamic testing should be included in the patient workup to exclude patients with detrusor muscle failure.

The present study confirms the feasibility of PAE and Rezūm™ in frail patients. Indeed, each procedure had a similar safety profile and no Clavien > 2 complications were recorded. However, there is some facts that could help clinicians refer each patient to the most appropriate technique. On the one hand, operative time and catheter-free survival were in favor of water vapor thermal therapy after a median follow-up of 12 months. On the other hand, a short general anesthesia is sometimes necessary to perform a Rezūm™. Indeed, we now perform all Rezūm™ procedures under simple sedation or hypnosis, but the possibility of a short general anesthesia is still possible. Thus, this possibility should be anticipated with the anesthesia team, which can be considered as a limit in frail patients, unlike PAE.

There are some limitations in this study. The main limitation is its retrospective design. Prospective randomized study is needed to confirm these results. Our study is limited by the low sample size included and short follow-up. Longer term follow-up to determine duration of catheter independence will be essential to evaluate merits of these procedures. The postvoid urine volume during initial retention, which may indicate poor response to treatment when greatly elevated, was not available in our database and could be considered as a drawback. Conversely, the main strength of this preliminary study was to report the early outcomes of the Rezūm® system and PAE in a real-life practice, which has never been reported in the literature. The design of our series was also well established, with a match ensuring the initial comparability between both groups.

Conclusion

In this multi-institutional study, we report our preliminary experience with water vapor thermal therapy and PAE for treatment of medically refractory, complete urinary retention to achieve successful cessation of catheter dependency in frail-patients. For patients in poor physical health considered to be at high risk of perioperative morbidity, this study shows the feasibility of PAE and Rezūm™ to restore spontaneous urination without being associated with the occurrence of major complications. Our early data suggests that Rezūm™ may provide superior results in terms of cessation of catheter dependence and operative time compared to PAE. Future studies are needed to definitively assess which treatment would be best suited for each patient.

The authors declare no conflicts of interest.

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Table 1 – Baseline characteristics

| | Rezūm™ (n = 11) | PAE (n = 11) | p |
|---|----------------------------|-------------------------|----------|
| Median (IQR) age, years | 75 (68-86) | 77 (71-86) | 0.84 |
| Median (IQR) age-adjusted Charlson comorbidity index | 6 (3-7) | 6 (4-7) | 0.74 |
| Antithrombotic, n (%) | 7 (63.6) | 10 (90.9) | 0.31 |
| Median (IQR) prostate volume, cc | 60 (60-75) | 74 (55-98) | 0.42 |
| Median (IQR) duration of catheter dependence, months | 2.3 (1.5-5.1) | 3.7 (2-5.6) | 0.68 |
| Median (IQR) number of previous failed TWOC | 2 (2-3) | 3 (2-3) | 0.44 |

Legend:

PAE: Prostate Artery Embolization; TWOC: Trial Without Catheter

Table 2 – Procedures outcomes

| | Rezūm™ (n = 11) | PAE (n = 11) | P |
|---|----------------------------|-------------------------|-------------------|
| Median (IQR) operative time, <i>min</i> | 8 (5-13) | 148 (123-161) | < 0.001 |
| Postoperative success of catheter removal, <i>n (%)</i> | 11 (100) | 5 (45.4) | 0.01 |
| Time to successful TWOC, <i>days</i> | 14 (5-28) | 15 (2-15) | 0.50 |
| 30-Days Postoperative Complication, <i>n (%)</i> | | | 1 |
| No | 9 (81.8) | 8 (72.7) | |
| Yes | 2 (18.2) | 3 (27.3) | |
| Catheter-free patients on the date of the latest news, <i>n (%)</i> | 11 (100) | 5 (45.4) | 0.01 |
| Median (IQR) duration of follow-up, <i>months</i> | 12 (6-15) | 12 (5-18) | 0.89 |
| Median (IQR) residual void volume in catheter-free patients, <i>mL</i> | 70 (54-157) | 50 (50-90) | 0.56 |
| Discontinued BPH medications in catheter-free patients, <i>n (%)</i> | | | 0.54 |
| No | 9 (81.8) | 3 (60) | |
| Yes | 2 (18.2) | 2 (40) | |

Legend:

PAE: Prostate Artery Embolization; TWOC: Trial Without Catheter; BPH: Benign Prostatic Obstruction