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Palliative Prostate Artery Embolization for Prostate Cancer: A Case Series

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Abstract

Introduction Prostate artery embolization (PAE) is recognized as a treatment for lower urinary tract symptoms (LUTS) in men with benign prostatic hyperplasia. LUTS and urinary retention are common in men with prostate cancer (PCa). The purpose of this study was to estimate the efficacy and safety of palliative PAE on LUTS or urinary retention in men with advanced PCa.

Materials and methods This prospective, single-center trial was conducted from March 2017 to November 2018. The trial protocol was registered online (ClinicalTrials.gov Identifier: NCT03104907). Only men with advanced PCa suffering from LUTS or urinary retention were included. The primary outcome was the ability to void without a catheter and International Prostate Symptom Score (IPSS) in non-catheter-dependent patients. The paired t test was used to analyze changes from baseline with 95% confidence intervals (CI). A p value < 0.05 was considered statistically significant.

Results Seventeen patients were assessed for eligibility, and 15 patients with a mean age of 73.8 years were enrolled. Four men did not complete follow-up: cancer-related death ($n = 2$), lost to follow-up ($n = 1$), and unsuccessful embolization due to severe atherosclerosis ($n = 1$). Bilateral embolization was achieved in ten cases, and urinary retention resolved in one of six patients. LUTS improved in the remaining ($n = 5$) patients by a mean 12.2-point reduction in IPSS (95% CI − 23.53; − 0.87). According to the CIRSE classification, two grade 1 and two grade 3 complications occurred.

Conclusion In this study, palliative PAE was safe and efficient for treatment for LUTS associated with PCa.

Level of Evidence Level 4, Case Series.

Trial registration ClinicalTrials.gov Identifier: NCT03104907.

Keywords Lower urinary tract symptoms · Prostatic neoplasms · Embolization · Therapeutic · Clinical trial · Urinary retention · Palliative care

Introduction

Prostate cancer (PCa) is a worldwide health problem due to the high incidence, prevalence, and many associated symptoms including gross hematuria, impaired bowel function, urinary retention, incontinence, pelvic pain, and lower urinary tract symptoms (LUTS) [1–5]. It is estimated that one in three men with localized PCa managed on watchful waiting experience distress from voiding problems [6]. The incidence is even higher in metastatic PCa where half of the patients develop LUTS [7]. The proportion of men presenting with metastatic disease at the time of diagnosis varies from a few percents in countries with intense screening to about 10–20% in countries without intense screening [8, 9]. Metastatic PCa is associated with significant morbidity and rapid deterioration of the quality

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of life [8, 10]. More than three in ten patients with metastatic PCa will require lower urinary tract surgery, and the need for palliation continues in the later stage of disease where one in four patients requires catheterization, suprapubic tube insertion, or palliative transurethral resection of the prostate (TURP) in the last 3 years of life [7, 11, 12].

Palliative TURP remains the mainstay treatment of bladder outlet obstruction (BOO) when hormone therapy is not tolerated or has failed [13–16]. However, palliative TURP is associated with a higher risk of complications, including prolonged catheterization, incontinence, lower symptomatic relief, and re-operation rates up to 30% compared to men treated for benign prostatic hyperplasia (BPH) [3, 13]. These facts warrant a continuous need for new treatments to improve patient care [17].

Prostate artery embolization (PAE) was recently introduced as a minimally invasive treatment for LUTS associated with BPH [18]. Ischemia is induced by occluding the blood supply to the prostate with embolic particles, which subsequently leads to necrosis and shrinkage. The transitional zone which predominates in BPH is particularly susceptible to embolization, but ischemia of the peripheral zone has been reported suggesting a potential clinical implication in the treatment of PCa [19, 20]. The procedure is performed under local anesthetics qualifying men with cardiopulmonary comorbidity who would not tolerate general or spinal anesthesia associated with conventional lower urinary tract surgery [21]. Studies have shown that the results on patient-reported outcomes of PAE are comparable to TURP but with $< 0.5\%$ major complications occurring [22]. Additionally, the treatment is well tolerated by elderly men as well as poor surgical candidates suffering from comorbidities which are relevant since $> 70\%$ of all cases of PCa are diagnosed in men ≥ 65 years [23].

The purpose of this study was to estimate the efficacy and safety of palliative PAE on LUTS or urinary retention in men with advanced PCa.

Materials and Methods

This prospective, single-center trial was conducted from March 2017 to November 2018 by the departments of Urology and Diagnostic Radiology at Rigshospitalet, Copenhagen University Hospital. The trial was carried out in accordance with the 1964 Declaration of Helsinki, and the study protocol was approved by the IRB (ID: H-17000714). A protocol with pre-specified outcome measures was registered online at ClinicalTrials.gov with the identifier NCT03104907. Written informed consent was obtained from all patients.

Study Population

An experienced urologist identified and evaluated all patients in the clinical setting. Men with a biopsy-proven diagnosis of PCa who had either moderate to severe LUTS (International Prostate Symptom Score, IPSS ≥ 8) or were dependent on urinary catheterization were included. Only men who refused or not eligible for TURP due to competing comorbidities were included. The exclusion criteria were known bladder dysfunction, urethral strictures, bladder neck contractures, sphincter anomalies, large bladder diverticulum or stones, renal insufficiency (eGFR < 45 mL/min), other active urogenital cancer than PCa, coagulation disturbances, severe atherosclerosis, or tortuosity on computed tomography angiography (CTA) that could prevent selective catheterization of the internal iliac artery or prostate artery, allergies to iodine contrast medium, or contraindication to magnetic resonance imaging (MRI).

Embolization

A pre-procedural CTA was performed to evaluate vascular anatomy and plan the procedure. All CTA scans were performed on a 320-detector row computed tomography (CT) scanner (Aquilion One, Toshiba Medical Systems) approximately 1 month before treatment.

PAE was performed by two interventional radiologists familiar with the procedure and with more than 20 years of experience in interventional radiology. A 5F sheath (Fortress, Biotronik) was placed in the right common femoral artery under local anesthesia. The prostatic arteries were localized on each hemipelvis and super-selectively catheterized with 2.0 F microcatheters (Progreat, Terumo Interventional Systems). During microcatheter maneuvering, intra-arterial nitroglycerine was injected to prevent vessel spasm. Cone beam CT (Allura, Philips) was used to confirm catheter placement in the prostate artery and exclude aberrant collaterals before manually injecting 300–500 µm tris-acryl gelatine microspheres particles (Embosphere microspheres, Merit Medical) under fluoroscopic guidance until the angiographic endpoint with stasis of flow in the prostate (Fig. 1a–c). The PErFecTED—proximal embolization first, then embolize distal—technique was applied [24]. PAE was considered technically successful when stasis was achieved on both sides due to the greater clinical response demonstrated after bilateral embolization [25].

The duration, fluoroscopy time, radiation exposure to the patient, technical outcome (unilateral, bilateral, or no embolization), iodine contrast medium, and the volume of particles administered were registered.

Patients were admitted on the day of the procedure and stayed overnight to allow for observation and 24-h post-

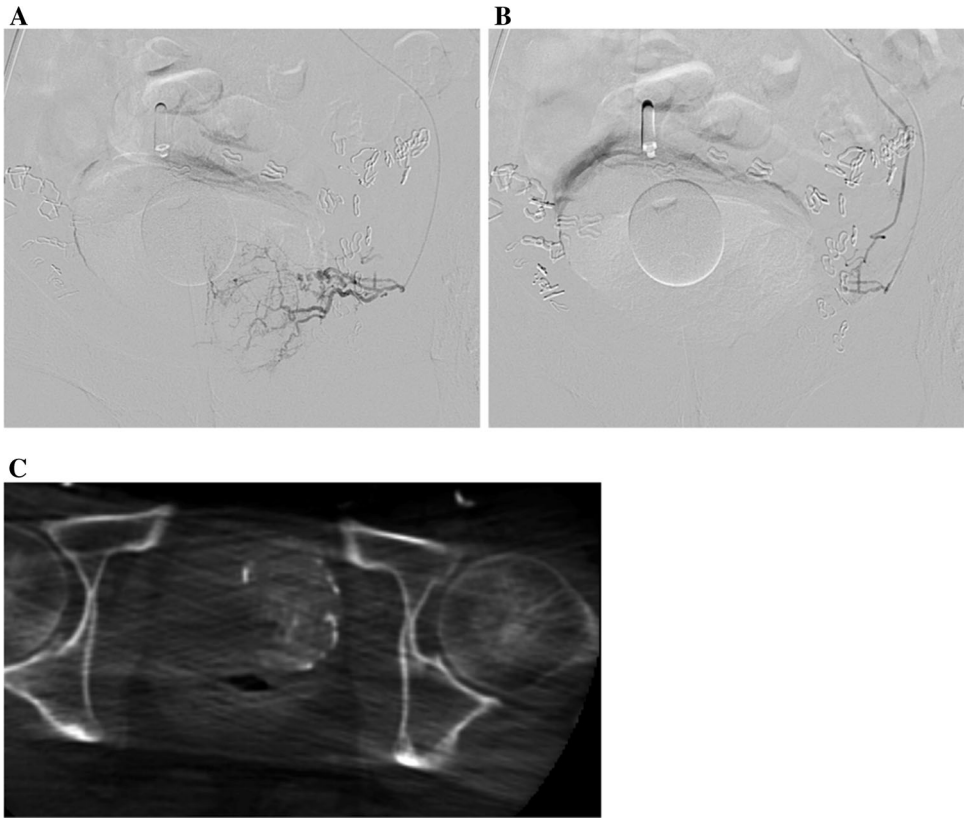

Fig. 1 **a** Digital subtraction angiography (DSA) before embolization with injection on the microcatheter in the left prostate artery. **b** DSA demonstrating the angiographic endpoint after embolization with the microcatheter in the same position. There is a small reflux in a proximal branch to the prostate artery. **c** Coronal cone beam computed tomography with contrast enhancement in the left lobe confirming correct catheter placement

treatment blood sampling. A 14-F Foley balloon catheter was inserted and filled with a 10 mL mixed solution of 30% contrast medium and 70% saline. Catheter-dependent patients at baseline had their catheter changed before treatment. All patients received antibiotic prophylaxis consisting of a single intravenous injection of 1.5 g cefuroxime before embolization and orally 200 mg trimethoprim twice daily for 3 days.

Post-embolization syndrome, i.e., dysuria, frequency, pelvic discomfort, and transient (< 5 days) worsening of LUTS, was treated with orally administered paracetamol and a nonsteroid anti-inflammatory drug.

Outcome Measures

Baseline medical interview and age, weight, height, duration of catheter treatment, prostate-specific antigen (PSA), Gleason score, and clinical tumor, node, metastasis (TNM) classification of PCa at the time of diagnosis, time from diagnosis to PAE, disease and treatment status before PAE were recorded.

The primary outcome was the ability to void after removing the urinary catheter in catheter-dependent men at 6-month follow-up and IPSS with a quality of life (IPSS-QoL) scale from 0 (delighted) to 6 (terrible) answering the question "If you were to spend the rest of your life with your urinary condition just the way it is now, how would you feel about that?" in patients suffering from LUTS. Secondary outcome measures included the 5-item International Index of Erectile Function (IIEF-5), prostate volume (PV), post-void residual (PVR), peak void flow rate (Qmax), and PSA at 6-month follow-up. PV was measured on MRI using the FDA-certified edition of OsiriX medical imaging viewer. All scans were performed on a 3-Tesla scanner (Verio, Siemens) using a phased-array 32-channel body coil. The protocol consisted of a T2-weighted turbo spin echo sequence in the transversal and sagittal plane.

Outcome measurements were collected at baseline, 1, and 6 months after embolization. Prostate-specific antigen (PSA) was also sampled 24 h after treatment. IPSS, IPSS-QoL, PVR, and flow studies were not used to evaluate catheter-dependent patients.

The ability to pass urine after removing the catheter was considered clinical success. In patients without urinary retention, clinical success was defined as IPSS $\leq$ 19, and $\geq$ 3-point improvement in IPSS, which is the estimated minimum clinical difference in symptom score needed to be perceived as an improvement.

Complications were reported according to the CIRSE classification system for complications from grade 1 (complication during the procedure which could be solved within the same session; no additional therapy, no post-procedure sequelae, no deviation from the normal post-therapeutic course) to grade 6 (death) [26]. Post-

embolization syndrome was considered an expected side effect [27].

Statistical Analysis

Data management was performed in research electronic data capture (REDCap) software. The statistical analysis was performed using R statistical software version 3.5.2 for Windows. Absolute frequencies with percentages and mean with standard deviations (SD±) were used to report on categorical and continuous variables, respectively. The paired t test for repeated measurements was used to analyze changes from baseline, and 95% confidence intervals (CI) were reported. A p value < 0.05 was considered statistically significant.

Results

A total of 17 patients were assessed for eligibility, two patients were excluded due to severe atherosclerosis and 15 patients with a mean age of 73.8 years (SD ± 9.5) were included. Four patients suffering from urinary retention did not complete the 6 months of follow-up; one man was lost to follow-up, two died of cancer-related causes, and the remaining could not be embolized due to severe atherosclerosis. The trial flow is illustrated in Fig. 2, and baseline characteristics are given in Table 1.

PCa status at the time of enrollment was metastatic castration-resistant prostate cancer (n = 7), watchful waiting (n = 4), bicalutamide monotherapy for locally advanced non-metastatic PCa (n = 2), non-metastatic castration-resistant prostate cancer (n = 1), and newly diagnosed metastatic disease (n = 1). The mean time from PCa diagnosis to PAE was 4.9 years (range 0.6–12.4). At the time of cancer diagnosis and before PAE, mean PSA was 107.5 µg/L (range 6.1–644) and 20.3 µg/L (range 0.2–65), respectively. Three patients had previously undergone TURP (all of whom did not complete follow-up), one had received radiation therapy, and one both radiation therapy and TURP.

At baseline, ten men suffered from urinary retention for a mean of 20.4 months (range 1–87). The remaining patients experienced severe LUTS with a mean IPSS and IPSS-QoL of 23.6 and 4.6 (SD ± 5.3 and 1.1), respectively. The mean PV was 66.7 cm^3 (SD ± 42). Qmax and PVR were pragmatically reported. However, only a minority of patients could perform uroflowmetry, but it was not possible to obtain adequate volumes of urine (> 150 mL) to allow for accurate measures. IIEF-5 was unchanged in the one patient reporting sexual activity in the past 6 months.

Technical success (i.e., bilateral embolization) was achieved in 10 cases (67%), and one patient could not be embolized due to severe atherosclerosis. The remaining four men underwent unilateral embolization because no contralateral prostate artery was identified (n = 1), stenosis of the internal iliac artery (n = 1), or severe atherosclerosis (n = 2). Two men unilaterally embolized did not complete the follow-up. The mean procedure time was 150 min (SD ± 50.4) with a fluoroscopy time of 48 min (SD ± 13.3). Patients were exposed to a dose area product of 1017.5 Gy cm^2 (SD ± 382.7) and received 5.1 mL (SD ± 3.3) and 124.3 mL (SD ± 32.3) embolic particle suspension and contrast medium, respectively.

Clinical success with a significant mean IPSS improvement of 12.2 points (95% CI − 23.53; − 0.87) was achieved in all five patients suffering from LUTS, including one unilaterally embolized. IPSS-QoL improved by 2.4 points 1 month after treatment, but the change was not significant at 6-month follow-up. None of the remaining outcome measures changed significantly (Table 2).

One of the six patients (17%) with urinary retention for 10 months had a successful trial without a catheter, despite biochemical progression, and reported an IPSS as well as IPSS-QoL of 2 at 6-month follow-up. Two men who had previously received radiation therapy and one man unilaterally embolized did not respond.

Post-embolization syndrome was reported by four patients (27%) and resolved within 5 days of treatment. Grade 1 complications occurred in two patients and included groin hematoma and self-limiting balanitis in a catheter-dependent patient who had phimosis before treatment. Urinary tract infection managed with oral antibiotics for 7 days, and prolonged (> 5 days) pelvic pain treated with paracetamol made up the two grade 3 complications observed.

Discussion

Urinary retention and LUTS are the most common indications for palliative TURP in men with PCa [14, 15, 28]. In this study, all five patients suffering from LUTS achieved clinical success and a 12.2 points (95% CI − 23.53; − 0.87) reduction in IPSS at 6-month follow-up. IPSS-QoL did not significantly improve which may be a result of the distress caused by the malignant nature of the disease. A successful trial without catheter was achieved in one case which is considerably less than the 90% chance of success reported in men with urinary retention secondary to BPH [29]. Recent evidence shows that men catheterized for more than 3 months are less likely to have a successful trial without catheter [30]. This could explain the results in our cohort where patients completing follow-up had urinary

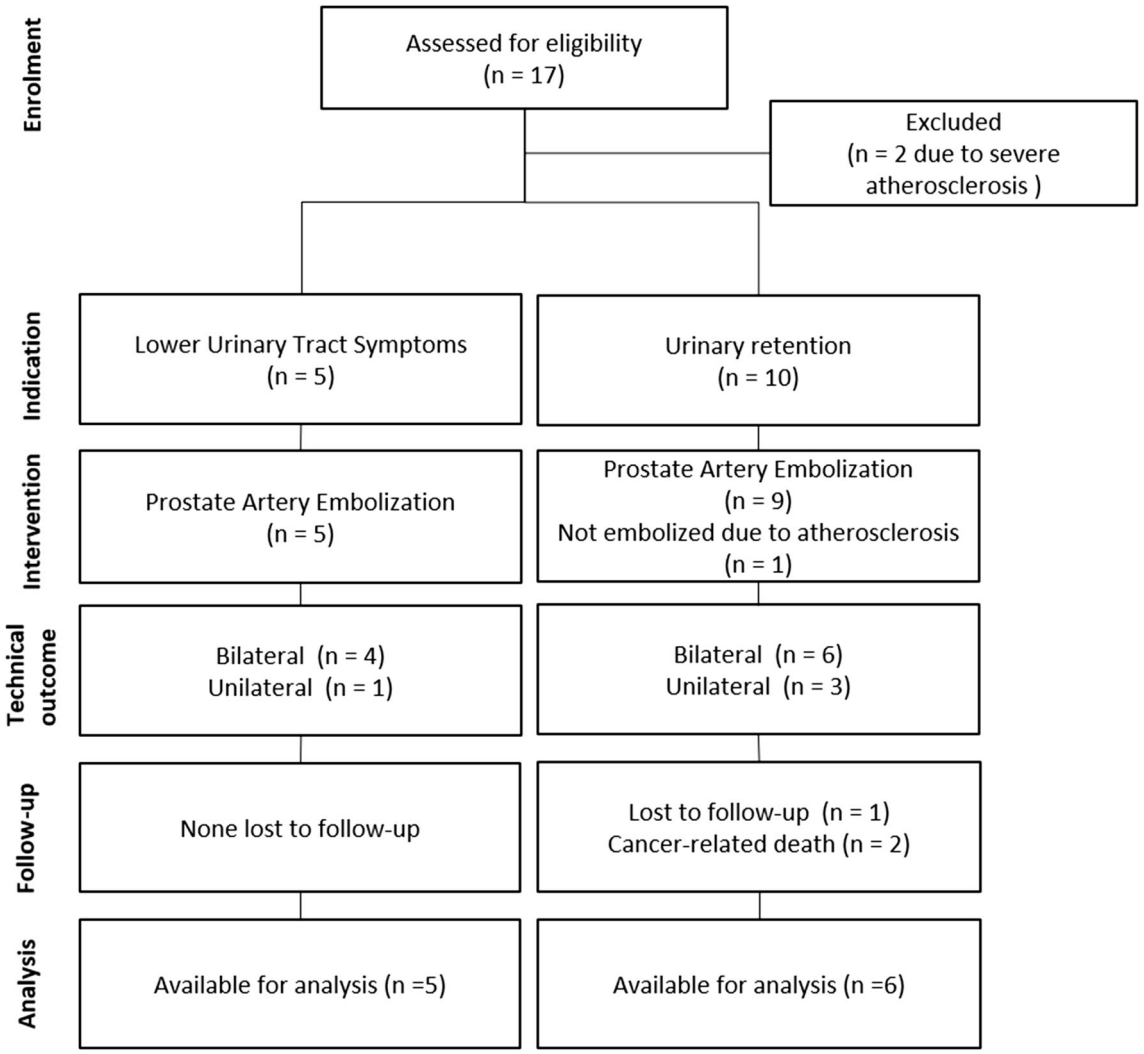

Fig. 2 Trial flow diagram

retention for 7 months or more (range 7–56). However, it may not be feasible to directly compare palliative treatment in advanced PCa to symptoms associated with BPH. Men suffering from advanced PCa tend to be older, have a higher prevalence of detrusor underactivity due to long-standing pre-procedural catheter dependency often precluded by chronic urinary retention as well as detrusor overactivity for reasons that are yet to be explained [3]. Urodynamics was not performed in this study where the participants were enrolled explicitly because no other treatment was available to them. Applying urodynamics could have clarified any underlying bladder dysfunction. However, no good-quality evidence supports the use before prostate surgery and results from the "Urodynamics for Prostate Surgery Trial; Randomised Evaluation of Assessment Methods (UPSTREAM)" designed to address this issue are pending [31].

The safety demonstrated in men with BPH was confirmed by our findings where no patient needed invasive therapy or experienced postprocedural sequelae. In contrast, the minimal invasiveness of PAE in men with PCa was questioned based on previous reports where a relatively high incidence of bladder wall ischemia occurred [32–34]. However, the authors had deliberately applied a very aggressive embolization technique using small embolic particles (100 μm) in one study and chemoembolization in the other to achieve maximal prostatic and tumor ischemia. On the contrary, no complications were observed by Chen et al. [35] who demonstrated that gross hematuria in men with T4 disease resolved in two-thirds after PAE within the 3-month follow-up. Gross hematuria is a frequent and debilitating complication secondary to PCa as well as BPH, and a common indication for TURP [28, 36]. However, the effect is poorly documented, and hematuria is common even after palliative TURP [37].

Table 1 Baseline characteristics

	n	Mean	SD	min	max
Age, years	15	73.8	9.5	59.4	91.7
BMI	15	26.3	3.4	21.2	33.5
IPSS	5	23.6	5.3	18.0	31.0
IPSS-QoL	5	4.6	1.1	3.0	6.0
IIEF-5	1	5.0	–	5.0	5.0
Qmax, mL/s	4	11.0	7.1	5.7	21.3
PVR, mL	2	171.6	128.1	81.0	262.1
PV, cm^3	15	66.7	42.0	20.6	150.0
PSA, µg/L	15	20.3	20.1	0.2	65.0
PSA at diagnosis, µg/L	15	107.5	178.6	6.1	644.0
Catheter treatment duration, months	10	20.4	28.4	1.0	87.0
Time from diagnosis to PAE, years	15	4.9	3.4	0.6	12.4

TNM classification	At diagnosis		Before PAE	
	n	%	*n*	%
T1	4	27	2	13
T2	2	13	3	20
T3	7	47	5	33
T4	2	13	5	33
Metastatic disease	3	20	8	53
Gleason score				
6	1	7	–	–
7	6	40	–	–
8–10	8	53	–	–

BMI body mass index, *IIEF-5* International Index of Erectile Function, *IPSS* International Prostate Symptom Score, *IPSS-QoL* quality of life, *PSA* prostate-specific antigen, *PV* prostate volume, *Qmax* peak urinary flow rate, *SD* standard deviation, – not available

The potential of PAE in primary PCa treatment was elucidated by two studies evaluating biochemical response and necrosis of the index lesion, respectively. Mordasini et al. [33] performed a histological examination in men with localized PCa undergoing PAE 6 weeks before radical prostatectomy. They found complete necrosis of the index lesion in 12.5%, but viable cancer cells were still present in all patients. Pisco et al. [34] evaluated 16 men with T2 disease who received chemoembolization to reduce PSA to < 2 ng/mL (from a mean of 5.88 ng/mL) within 18 months of follow-up. Biochemical success was achieved in 62.5%. Tumor response was not investigated in our study. However, PSA elevation was observed in six men (four with the urinary retention and two with LUTS) and a doubling of PV in two men, which explains the (insignificantly) elevated PSA and PV reported at 6-month follow-up. Based on current evidence, PAE is inadequate as the primary treatment of PCa but can, however, successfully treat complications associated with PCa such as LUTS, urinary retention, and hematuria with a low risk of serious adverse events.

Significant pain relief was observed in one patient with a 334 cm^3 prostate who suffered from metastatic castrate-resistant prostate cancer (T4) and required monthly hospital admissions due to intolerable pelvic pain. Despite clinical progression, a 2-point improvement in IPSS-QoL was reported suggesting a new indication for treatment. More importantly, the monthly admissions were avoided for 4 months improving patient care while reducing in-hospital cost significantly.

The limitations of this study are related to the small sample size and heterogeneity of the included patients regarding urinary condition (LUTS or retention) and PCa status. No conclusions could be made on uroflowmetry since only a minority of patients could participate, and none delivered adequate volumes of urine. The non-controlled design carries an inherent risk of bias regardless of the pre-specified protocol and outcome measures. No urodynamic investigations were available to address any underlying bladder dysfunction. Larger-scale, controlled studies are needed to establish the potential of PAE in palliative care.

Table 2 Change from baseline

Variable	*n*	Change	95% CI	*p* value
IPSS				
1 month	5	− 9.6	[− 18.32; − 0.88]	0.038
6 months	5	− 12.2	[− 23.53; − 0.87]	0.04
IPSS-QoL				
1 month	5	− 2.4	[− 4.48; − 0.32]	0.033
6 months	5	− 2.4	[− 5.39; 0.59]	0.09
IIEF-5				
1 month	1	–	–	–
6 months	1	–	–	–
Qmax, mL/s				
1 month	3	2.73	[− 3.89; 9.35]	0.22
6 months	2	0.2	[− 30.29; 30.69]	0.95
PVR, mL				
1 month	1	–	–	–
6 months	1	–	–	–
PV, cm^3				
1 month	13	1.01	[− 14.73; 16.76]	0.89
6 months	11	9.86	[− 32.30; 52.03]	0.61
PSA, μg/L				
24 hours	13	63.56	[− 38.36; 165.48]	0.2
1 month	13	0.78	[− 3.30; 4.87]	0.68
6 months	11	16.42	[− 9.89; 42.73]	0.19

CI confidence interval, *IIEF-5* International Index of Erectile Function, *IPSS* International Prostate Symptom Score, *IPSS-QoL* quality of life, *PSA* prostate-specific antigen, *PV* prostate volume, *Qmax* peak urinary flow rate, – not available

In conclusion, palliative PAE was a safe and efficient treatment for LUTS associated with PCa.

Compliance with Ethical Standards

Conflict of interest Lars Lönn is medical director at Mentice who specializes in the development of endovascular education. None of the other authors report a potential conflict of interest associated with this work and there is no grant support associated with this work.

Ethical Approval All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Declaration of Helsinki and its later amendments or comparable ethical standards. This study was approved by Institutional Review Board (IRB) approval no. (H-17000714).

Informed Consent Informed consent was obtained from all individual participants included in the study.

Consent for Publication Consent for publication was obtained for every individual person's data included in the study.

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