Prostate artery embolization has long term efficacy for treatment of severe lower urinary tract symptoms from giant prostatic hyperplasia

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Abstract

Background

Patients with severe lower urinary tract symptoms (LUTS) from giant prostatic hyperplasia (GPH): prostate volume larger than 200 mL that do not respond to medical therapy may not be eligible for surgical treatments due to morbidities, technical challenges, and patient preference. This retrospective study examined the safety and long-term efficacy of prostatic arterial embolization (PAE) as a treatment option for severe LUTS due to GPH in a large cohort of patients.

Methods

72 patients with GPH and severe LUTS who underwent PAE were retrospectively evaluated. PAE was performed bilaterally with two embolic agents in sequence: 100 µm to 250 µm embolic particles followed by 2 mm and 3 mm coils. Clinical assessment was performed by collecting international prostate symptoms score (IPSS), quality of life (QoL), and post-void residual volume (PVR) before PAE and 12 months and 24 months after PAE. Prostate volume (PV) was measured by multiparametric magnetic resonance (MR) imaging before PAE and 12 months and 24 months after PAE.

Results

Patients with severe LUTS from GPH experienced significant clinical improvements in IPSS, QoL, PVR, and PV at 12 months and 24 months after PAE. Mean IPSS decreased from 26.5 to 18.0 (P < .0.01) at 12 months and to 10.5 (P < .0.01) at 24 months. Mean QoL decreased from 6.0 to 4.0 (P < 0.01) at 12 months and to 2.0 (P < 0.01) at 24 months. Mean PVR decreased from 198.0 mL to 152.0 mL (P < 0.01) at 12 months and to 90 mL (P < 0.01) at 24 months. Mean PV decreased from 303.0 mL to 258.0 mL (P < 0.01) at 12 months and to 209.0 mL (P < 0.01) at 24 months. There were no major complications.

Conclusions

PAE is a safe treatment option with long term efficacy in patients with severe LUTS due to GPH. PAE may be a viable therapeutic option for patients with severe LUTS from GPH whom fail medical therapy and are not candidates for surgical treatments.

Background

Patients with severe lower urinary tract symptoms (LUTS) from prostatic hyperplasia that is refractory to medical therapy are offered surgical treatment options that range from minimally invasive procedures to transurethral resection of the prostate (TURP) to simple prostatectomy (1-4). The surgical treatment selection process is governed by prostate volume, presence of LUTS, comorbidities, risk-benefit profile, patient preference treatment availability and physician expertise (1-4). Prostate volume is a significant factor in surgical treatment selection (1-4). TURP and minimally invasive procedures, such as photoselective vaporization, laser enucleation, transurethral vapor and microwave ablation, transurethral incision, and prostate urethral lift, are best suited for patients with prostate volumes less than 80 mL (1-4). Large prostatic hyperplasia, which is defined as prostate volume larger than 100 mL, and giant prostatic hyperplasia (GPH), which is defined as prostate volume larger than 200 mL, may require simple prostatectomy however are at higher risk of morbidity from blood loss that requires blood transfusion (8-15%), urinary incontinence (10%), and urinary bladder neck stenosis and urethral strictures (5%) (1-9).

Prostate artery embolization (PAE) has emerged as a safe and efficacious treatment of patients with severe LUTS from prostatic hyperplasia with prostate volumes up to 100 mL, or large prostatic hyperplasia (5-13). Numerous retrospective and prospective studies of large cohorts of patients have shown that PAE safely provides long term reduction in symptoms and prostate volume by inducing ischemic necrosis, diminished hormonal response, and
Reduced prostate innervation with consequent reduced smooth muscle tone (5–13).

GPH, which is defined as prostate volume larger than 200 mL, has been described in several individual patients as case reports in a review of international scientific literature (14–19). Individual cases of patients with severe LUTS from GPH whom underwent treatment with surgery or minimally invasive ablative urological treatment have also been reported (20–26). However the safety and long-term efficacy of PAE for treatment of large cohorts of patients with severe LUTS from GPH has not been examined. One study retrospectively reviewed eight patients and one case report reviewed one patient whom underwent PAE for severe LUTS from GPH (27, 28). While these two studies reported short term efficacy: eight months and three months, respectively, for significant symptom relief, long term efficacy remains unknown (27, 28). A prostate volume limit that may render PAE ineffective, due to unsuccessful symptom and prostate volume reduction, has also not been established (1–4, 27, 28). This study evaluated the safety and long-term efficacy of PAE in the largest cohort of patients, to date, with severe LUTS due to GPH.

Methods

Institutional review board (IRB) approval was received for this retrospective study. A review of the electronic medical records (EMR) from a single center was conducted on all patients whom underwent PAE for severe LUTS between January 2016 and January 2020. Patients were considered for PAE if they had severe LUTS that did not respond to medical therapy and were not eligible for surgery or refused surgery. Written informed consent was obtained from the patients and any accompanying images. Patients gave consent for their personal or clinical details along with any identifying images to be published in this study. Prostate volumes were calculated with magnetic resonance (MR) imaging and recorded in 529 patients whom underwent bilateral PAE before the procedure. Only 72 patients with prostate volumes larger than 200 mL were reviewed for the study. International Prostate Symptom Score (IPSS), urinary quality of life (QoL), postvoid residual volume (PVR), and prostate volume (PV) were measured and collected before PAE and 12 months and 24 months after PAE.

Clinical Metrics

Clinical assessment was performed in all patients before PAE and 12 months and 24 months after PAE with history and physical examination, IPSS and QoL questionnaires, and PVR.

Prostate MR Imaging and Volume Measurement

Prostate volumes were calculated using multiparametric MR imaging obtained before PAE and 12 months and 24 months after PAE. At our institution, multiparametric prostate MR imaging is performed using 3.0 T magnet systems (Siemens Healthcare, Erlangen, Germany). Exams are performed with phased array torso coils using the following protocol (Table 1): axial, sagittal, and coronal T2-weighted turbo spin echo images; axial b50, b500, and b800 s/mm² diffusion-weighted images; synthetic extrapolated b1200, b1500, b2000, and b2500 diffusion-weighted images; apparent diffusion coefficient (ADC) map; axial T1 pre-contrast fat saturated volumetric interpolated breath-hold examination (VIBE) images; coronal T1-precontrast fat-saturated MR angiographic VIBE images of the pelvis; serial dynamic axial T1 pre-contrast fat saturated VIBE images obtained after intravenous gadolinium contrast injection (Gadavist 0.1 mmol/kg; Bayer Healthcare Pharmaceuticals, Wayne, New Jersey, U.S.A.); axial fat-saturated T1-weighted delayed postcontrast VIBE images.
Two diagnostic radiologists with twelve and six years of experience in interpreting multiparametric prostate MR imaging, respectively, independently reviewed the MR imaging exams before and after PAE. The radiologists used DynaCAD software (InVivo, Philips Healthcare, Amsterdam, Netherlands) on two separate workstations to perform semiautomated prostatic volumetric measurements of the prostate using the MR T2-weighted images. Prostatic volumes were manually confirmed by calculation of the ellipsoid volume formula \((L \times W \times H \times \pi/6)\). Discordant measurements were resolved by consensus agreement. The diagnostic radiologists also reviewed MR imaging before and after PAE for any prostate gland lesions suspicious for clinically significant cancer according to version 2.1 of Prostate Imaging-Reporting and Data System (PI-RADS) (29).

**Prostate Artery Embolization**

All PAE procedures were performed by a single operator with thirteen years of angiographic and embolization experience and four years of experience performing PAE. All patients received one dose of ciprofloxacin 400 mg administered intravenously for infection prophylaxis. All procedures were performed under moderate (conscious) sedation with local anesthesia in a therapeutic angiography unit. A unilateral left radial arterial approach was utilized in all patients. Real time ultrasound was used to visualize patency and access of the left radial artery,
which entered with a micropuncture set, 21-gauge needle, and a 5-French (-F) sheath. Patients underwent digital subtraction angiography (DSA) and PAE with a digital flat-panel detector system (Innova 4100 IQ; General Electric Healthcare, Chicago, Illinois, U.S.A.) with nonionic intravenous contrast (Omnipaque 350 mg/mL; General Electric Healthcare, Chicago, Illinois, U.S.A.). Internal iliac arterial angiography in the ipsilateral oblique projection was performed to identify the right and left prostatic arteries, accessory prostatic arteries, and variant anatomy. Pelvic and prostatic arteries were catheterized using a combination of wires and catheters: 5-F Cobra 2 catheter (Cook Medical, Bloomington, Indiana, U.S.A.), 4-F Berenstein catheter (Merit Medical Systems, Incorporated, South Jordan, Utah, U.S.A.), 2.4-F Progreat microcatheter (Terumo Interventional Systems, Tokyo, Japan) and 0.014-inch Transend microguide wire (Stryker Neurovascular, Fremont, California, U.S.A.). The prostatic arteries were identified with DSA. Advanced imaging was performed with localized intraoperative cone-beam computed tomography (CT) with intravenous contrast (100 mL Isovue 370, Bracco Diagnostics, Milan, Italy) prior to embolization. Cone-beam CT images were transmitted, reconstructed in three dimensions, and reviewed to confirm prostatic arterial vascular anatomy, prostate gland vascular supply, and ensure the absence of vascular supply to adjacent anatomical structures, such as the urinary bladder, penis, and rectum. Bilateral PAE was then performed to stasis with a primary embolic agent: 100 µm to 250 µm Embospheres (Merit Medical Systems, Incorporated, South Jordan, Utah, U.S.A.) and a secondary embolic agent: 2 mm and 3 mm CX coils (Boston Scientific, Marlborough, Massachusetts, U.S.A.). A band compression device was utilized to achieve radial arterial vascular access closure in all patients.

**Statistical Analysis**

The clinical metrics of IPSS, QoL, PVR, and PV were expressed as quantitative values with means and standard deviations (SD). These quantitative values were analyzed with a Wilcoxon signed rank test using SAS software, version 9.4 (SAS Institute Incorporated, Cary, North Carolina, U.S.A.). A probability value of P < 0.05 or lower was considered statistically significant. We had no missing information for the patients and data that were presented in this study.

**Results**

Bilateral PAE was technically successful with no major complications in all patients. 72 patients with GPH were included with a mean baseline prostate volume of 303 mL (range: 201–644 mL). Mean patient age was 71 years old (range: 53–89 years); 72 males; 34 patients identified as European descent, 21 patients identified as African descent, 12 patients identified as Asian descent, and 5 patients identified with various descents.

| Table 2. Clinical Metrics Summary |
|-----------------------------------|
| Clinical Metric                  | Before PAE | 12 months after PAE | 24 months after PAE |
| ---------------------------------|------------|---------------------|---------------------|
|                                  | Mean ± SD  | Mean ± SD           | Mean ± SD           |
| IPSS (points)                    | 26.5 ± 5.0 | 18.0 ± 4.5          | 10.5 ± 4.0          |
| QoL (points)                     | 6.0 ± 1.0  | 4.0 ± 1.0           | 2.0 ± 1.0           |
| PVR (mL)                         | 198 ± 20.0 | 152 ± 25.0          | 90 ± 15.0           |
| PV (mL)                          | 303 ± 20.0 | 258 ± 15.0          | 209 ± 15.0          |

IPSS International Prostate Symptom Score, mL milliliter, PAE prostate artery embolization, PV prostate volume, P1 QoL urinary quality of life, SD standard deviation
Certain patients may have contraindications to undergo MR imaging, such as medical devices, hardware, or contraindication to receiving procedural anesthetic moderate sedation, then a patient cannot undergo PAE. Available to all patients. Certain patients with LUTS from GPH may not be candidates for PAE. If a patient has a contraindication to receiving procedural anesthetic moderate sedation, then a patient cannot undergo PAE. Certain patients may have contraindications to undergo MR imaging, such as medical devices, hardware, or

Clinical metrics before PAE and 12 months and 24 months after PAE were collected (Table 2). Clinical metrics for each patient were retrieved from the EMR. Mean IPSS decreased from 26.5 ± 5.0 (SD) to 18.0 ± 4.5 (P < .001) 12 months after PAE and decreased from 18.0 ± 4.5 to 10.5 ± 4.0 (P < 0.01) 24 months after PAE. Mean QoL decreased from 6.0 ± 1.0 to 4.0 ± 1.0 (P < 0.01) 12 months after PAE and decreased from 4.0 ± 1.0 to 2.0 ± 1.0 (P < 0.01) 24 months after PAE. Mean PVR decreased from 198.0 mL ± 20.0 mL to 152.0 mL ± 25.0 mL (P < 0.01) at 12 months and decreased from 152.0 mL ± 25.0 mL to 90 mL ± 15.0 mL (P < 0.01) at 24 months. Mean PV decreased from 303.0 mL ± 20.0 mL to 258.0 mL ± 15.0 mL (P < 0.01) at 12 months and decreased from 258.0 mL ± 15.0 mL to 209.0 mL ± 15.0 mL (P < 0.01) at 24 months. No lesion suspicious for clinically significant cancer was detected on MR imaging exams obtained in patients before and after PAE.

**Discussion**

Patients with LUTS due to prostatic hyperplasia that do not respond to medical therapy may be candidates for surgical and minimally invasive treatments. However patients with GPH have limited treatment options due to risks associated with these therapies. Simple prostatectomy, which is the gold standard, and minimally invasive urological procedures may have complications such as blood loss that requires transfusion, urinary incontinence, urinary bladder neck stenosis, and urethral strictures (5–8). Moreover these surgical and minimally invasive treatments require general anesthesia, which has its own associated risks.

The current set of studies on the efficacy of PAE for treatment of LUTS from prostatic hyperplasia continues to grow. Our study can be added to the contemporary data. This investigation demonstrated the safety and long term efficacy of PAE for treatment of severe LUTS from GPH: prostate volumes larger than 200 mL, in a large patient cohort. These results are similar to prior studies that illustrated the efficacy of PAE for treatment of LUTS due to large prostate hyperplasia: prostate volumes 80 to 100 mL [5–13]. These studies demonstrated significant decreased severity of symptoms, improved quality of life, and reduction in post void residual and prostate volumes (5–13). Multiple prior investigators have shown the safety and efficacy of PAE in patients with LUTS from large prostatic hyperplasia: prostate volume larger than 100 mL however clinical outcomes specifically in patients with GPH, prostate volumes larger than 200 mL, were not reported [5–13]. Bhatia et al. reported a single patient whom underwent PAE for treatment of severe LUTS from GPH had significant symptomatic relief at three months: IPSS decreased from 26.0 to 4.0, QoL decreased from 6.0 to 1.0, and PV decreased from 571 mL to 270 mL; PVR was not measured before PAE due to inability to void and was 50 mL after PAE. [27]. Mathevosian et al. showed similar success and short term efficacy in eight patients whom underwent PAE for severe LUTS from GPH and had sustained symptomatic relief at eight months: IPSS decreased from 20.5 to 3.8, QoL decreased from 4.4 to 1.4, and PV decreased from 318 mL to 212 mL [28]. However the limitations of these studies are small patient cohorts, one and eight, and short follow-up times, three months and eight months [27, 28]. Larger cohorts of patients and long term efficacy have not been examined. Moreover an upper limit prostate volume for the efficacy of PAE has not been established. We confirmed that PAE is not only an effective treatment but also a safe therapy for severe LUTS in patients with prostate volumes larger than 200 mL because no major complications occurred. This upper limit volume number can be used to match patients to the appropriate therapy.

Our study has objective strengths with limitations. While we examined the largest number of patients whom underwent treatment of LUTS from GPH with PAE to date, results may be improved with larger cohorts. The length of follow-up time was longer than any other prior study: 24 months, which establishes sustainability, nevertheless longer-term follow-up studies may verify sustained patient outcomes. Our patients were referred from urologists and therefore subject to intrinsic referral bias. This bias was abated by blinding the interpreting radiologists to the indication for the multiparametric MR imaging exams. There were additional limitations to this investigation. This study was a single-institution, retrospective experience at a tertiary care academic medical center with urology, PAE, and MR availability and experience. Therefore our results may not be transferrable to all patient populations due to accessibility and contraindications. PAE is a procedure that may not be widely available to all patients. Certain patients with LUTS from GPH may not be candidates for PAE. If a patient has a contraindication to receiving procedural anesthetic moderate sedation, then a patient cannot undergo PAE. Certain patients may have contraindications to undergo MR imaging, such as medical devices, hardware, or
claustrophobia, for prostate volume measurement. In these patients, CT may be used for follow-up imaging for prostate volume measurement. Future research may be directed to prospective, multivariate comparisons of the efficacy of minimally invasive urological procedures and PAE in large patient cohorts for long follow-up times.

**Conclusions**

PAE is a safe and efficacious treatment that provides significant and sustained relief of severe LUTS in patients with GPH. PAE may play an important role in the treatment patients with severe LUTS from GPH in whom medical therapy has failed, are not candidates for surgical and minimally invasive treatments, or refuse surgical treatment. We hope that these results, along with future investigations directed to prospective, multivariate, comparative and randomized studies, may provide patients with the best treatment to optimize symptom relief, minimize morbidity, and achieve safe and successful outcomes.

**Abbreviations**

Giant prostatic hyperplasia (GPH), benign prostatic hyperplasia (BPH), prostatic artery embolization (PAE), lower urinary tract symptoms (LUTS), International Prostate Symptom Score (IPSS), milliliter (mL), prostate volume (PV), postvoid residual volume (PVR), QoL urinary quality of life (QoL), magnetic resonance imaging (MRI), apparent diffusion coefficient (ADC), diffusion weighted imaging (DWI), field of view (FOV), fat saturated (FS), magnetic resonance angiography (MRA), echo time (TE), repetition time (TR), turbo spin echo (TSE), volumetric interpolated breath-hold examination (VIBE), French (F), digital subtraction angiography (DSA), institutional review board (IRB), electronic medical records (EMR), Health Information Portability and Accountability Act (HIPAA)

**Declarations**

**ETHICS APPROVAL AND CONSENT TO PARTICIPATE**

This study was performed in compliance with the 1996 Health Information Portability and Accountability Act (HIPAA). The investigation location and source of the participants in this investigation was Mount Sinai Hospital in New York, New York where Institutional Review Board and Ethics Committee approved the study (IRB-19-02489), granted ethical approval, and all patients provided written informed consent to allow their medical records to be examined and used in this retrospective study. A standardized research protocol for the data collection was utilized.

**CONSENT FOR PUBLICATION**

Written informed consent was obtained from the patients and any accompanying images. Patients gave consent for their personal or clinical details along with any identifying images to be published in this study. A copy of the written consent is available for review by the Editor-in-Chief of this journal.

**AVAILABILITY OF DATA AND MATERIAL**

The data sets used and analyzed during the current study are available from the corresponding author on reasonable request.

**COMPETING INTERESTS**

None.

**FUNDING**
AUTHORS' CONTRIBUTIONS-APPROVAL

A.S.S. developed the concept and design, performed critical revision of the manuscript for intellectual content, performed imaging interpretations, acquired data, which was analyzed and interpreted, completed statistical analysis, supervised the investigation, and performed final approval.

S.M. performed critical revision of the manuscript, performed imaging interpretations, and acquired data, which was analyzed and interpreted.

L.M.F. performed critical revision of the manuscript, performed imaging interpretations, and acquired data, which was analyzed and interpreted.

V.S.K. performed critical revision of the manuscript, performed imaging interpretations, and acquired data, which was analyzed and interpreted.

All authors, A.S.S., S.M., L.M.F., and V.S.K., have read and approved the manuscript in its current state.

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   Weinreb JC, Barentsz JO, Choyke PL, et al. PI-RADS Prostate Imaging – Reporting and Data System: 2015, Version 2. European Urology 2016 (69), 16–40.
A 71 year-old patient with severe lower urinary tract symptoms (LUTS) from giant prostatic hyperplasia (GPH) underwent prostate artery embolization (PAE). a. Axial T2-weighted turbo spin echo (TSE) image, b. coronal T2-weighted TSE image, and c. sagittal T2-weighted image from multiparametric magnetic resonance (MR) imaging show giant hyperplasia of the prostate gland (arrow) that measures 312 mL in volume. d. Digital subtraction
angiography (DSA) of selective catheterization of the right internal iliac artery anterior division shows a common origin of the right prostatic artery (straight arrow), which is hypertrophied, and the right superior vesical artery (open arrowhead). The anterior/lateral prostatic artery (single arrowhead) and the posterior/lateral prostatic artery (double arrowheads) are hypertrophied with a corkscrew pattern of the intraprostatic arterioles. e. Cone-beam computed tomography (CT) with intravenous contrast in the coronal plane after selective catheterization of the internal iliac artery anterior division shows the anatomy of the right prostatic artery: a common origin of the right prostatic artery (straight arrow) and the right superior vesical artery (open arrowhead), hypertrophy of the anterior/lateral prostatic artery (single arrowhead) and the posterior/lateral prostatic artery (double arrowheads), and no vascular supply to the adjacent anatomical structures, to include the urinary bladder, penis, and rectum.