



Clinical outcomes of prostate artery embolization for management of benign prostate hyperplasia (prostate larger than 100 mL) with or without hematuria

Soodong Kim

Department of Urology, Dong-A University Hospital, Busan, Korea

Background: In this study, we report 1-year follow-up clinical results of prostate artery embolization (PAE) in patients with glandular hematuria or acute urinary retention caused by a large prostate (over 100 mL).

Methods: Twenty-one consecutive patients undergoing PAE from March 2018 to July 2020 were included in this retrospective study. Clinical follow-up was conducted for all patients 1, 3, 6, and 12 months after the procedure. The outcome measures included the International Prostate Symptom Score (IPSS), quality of life (QoL), peak urinary flow rate (Q_{max}), post-void residual (PVR), prostate volume, prostate-specific antigen, and complications. A *p*-value <0.05 was considered statistically significant.

Results: Twenty-one patients with severe benign prostatic hyperplasia (BPH) with acute urinary retention or prostatic hematuria were enrolled in this study. Technical success rate was 90.5% (19/21), and unilateral PAE was done in 2/21 (9.5%) patients by pelvic vascular obliteration. In all patients, the mean IPSS, QoL score, Q_{max}, and PVR were significantly improved at 12 months post-PAE. The mean IPSS decreased from 26.1 to 12.1 points (*p*<0.05), mean QoL score decreased from 4.6 to 2.9 points (*p*<0.05), mean Q_{max} increased from 2.1 to 9.4 mL/s (*p*<0.05), and mean PVR decreased from 300.0 to 70.7 mL (*p*<0.05). The catheter was successfully removed from 19/21 patients and clinical success rate was 90.5%.

Conclusions: PAE was an effective and safe treatment option for patients with BPH and very large prostates (>100 mL) and urinary retention or gross hematuria associated with BPH in men unfit for surgery.

Keywords: Embolization; Hematuria; Prostatic hyperplasia

Introduction

Benign prostatic hyperplasia (BPH) is a benign enlargement of prostate gland and is a major cause of lower urinary tract symptoms (LUTS) in men. Usually, BPH is not life-threatening condition, but it adversely affects quality of life (QoL). Among patients with BPH, LUTS were induced in approximately one in three men, and the clinical pro-

gression in 10% despite medication.

Histologically at autopsy, the prevalence of BPH increased to 50%–60% in men in their 60s and gradually increased with age. As the aging society gradually enters, the prevalence of BPH is increasing [1]. So, the better treatment is necessary for growing number of elderly men [2]. Basically, BPH is treated with medical treatment (α -adrenoreceptor antagonists or 5 α -reductase inhibitors). If medical treat-

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Corresponding Author: Soodong Kim, MD, PhD

Department of Urology, Dong-A University Hospital, 26 Daesingongwon-ro, Seo-gu, Busan 49201, Korea

Tel: +82-51-240-2673 Fax: +82-51-253-0591 E-mail: urotan@dau.ac.kr

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ment is ineffective, surgical treatment could be considered [3]. Although transurethral resection of the prostate (TURP) is the standard treatment for patient who do not respond to medical treatment, but some patients cannot tolerate TURP for medical (e.g., comorbidity) or technical (e.g., large prostate) reasons [4]. In response to this, interest in minimal invasive surgery with less morbidity is increasing [5-7].

As the number of elderly patients increases and the number of comorbidities they have, the number of patients taking anticoagulants is increasing. Along with this phenomenon, the proportion of patients with enlarged prostate and hematuria is increasing. Prostatic origin gross hematuria usually resolved conservative measures but, in refractory hematuria cases especially in large prostate hyperplasia, prostate artery embolization (PAE) could be a good option [8].

As a form of minimal invasive treatment, PAE treatment was introduced in 2010 [9]. PAE is an interventional radiological technique that directly occludes the prostate artery and causes prostate infarction. The effectiveness and safety of this technique have already been demonstrated following its initial clinical implementation. However, there are not much data on the clinical effect of PAE in cases of very large prostate (>100 mL). In this study, we report 1-year follow-up clinical results of PAE in patients with glandular hematuria or acute urinary retention (AUR) by large prostate (over 100 mL).

Methods

Ethical statements: This study was approved by the Institutional Review Board of Dong-A University Hospital (IRB No. DAUHIRB-19-026) and was conducted in accordance with the recent Declaration of Helsinki. Informed consent was waived.

From January 2018 to December 2020, at a single-center, 21 consecutive patients who received PAE were retrospectively reviewed under an institutional review board approved protocol and ethical issues were considered [10].

Included patients were who had gross hematuria or AUR due to larger than 100 mL prostate. All patients underwent evaluations of medical and surgical history, International Prostate Symptom Score (IPSS), QoL index questionnaire and Charlson Comorbidity Index. Peak urinary flow rate (Qmax) and post-voiding residual urine volume were recorded. Also, pre-procedure prostate-specific antigen (PSA)

and prostate volume (PV; transrectal or transabdominal ultrasound) were obtained. The prostate biopsy was performed for distinguishing prostate cancer when PSA level was above 4.0 ng/dL. In patients with gross hematuria, urine cytology, ultrasound of the kidneys, ureters & Bladder, and cystoscopy were performed to discriminate urinary tract malignancy, also. Exclusion criteria for PAE included biopsy proven prostatic cancer, active prostatitis or urinary tract infection, previous surgical procedure or other invasive treatment for benign prostate hyperplasia, large bladder diverticula or bladder stones, and chronic renal failure.

1. Follow-up and outcome evaluation

Clinical follow-up was done in all patients 1, 3, 6, and 12 months after the procedure. Outcome measures included IPSS, QoL, Qmax, post-void residual urine volume (PVR), PV, PSA, and complications. A *p*-value <0.05 was considered statistically significant. The technical success was defined as bilateral successful PAE. Clinical success was defined as improvement of LUTS. The LUTS was assessed by using IPSS and QoL questionnaires or self-voiding was possible in men with urinary retention prior to PAE. Clinical failure was considered a case where self-voiding was impossible after indwelling catheter removal.

2. Procedure

Angiography and PAE were performed by one interventional radiologist on an inpatient basis at the interventional radiology suite (Allura Clarity FD 20; Philips Healthcare) equipped with the cone-beam computed tomography (CBCT) option (XperCT; Philips Healthcare) after patients have signed informed consent. The procedure was performed via the right femoral arterial access under local anesthesia. Initial pelvic angiography was performed using a power injector to evaluate iliac vessels and the prostate arteries during arterial and late phases. Then, selective bilateral internal iliac arteriograms were obtained using a 5-French Robert's uterine artery catheter (RUC catheter; Cook) in the anterior-posterior view. CBCT was performed with the 5-French RUC catheter located in the main trunk of internal iliac artery in the same tip of the catheter as was used with digital subtraction angiography to evaluate the origin of the prostate arteries. Prostate arteries for each side were identified by using vessel-tracking software (EmboGuide; Philips Healthcare) applied to the CBCT datasets. The

software allowed the automated extraction of candidate vessels between a user-selected starting point (the catheter tip) and a segmented target (the prostate). Super-selection of each prostate artery was performed by using microcatheter (Veloute 1.7; Asahi) and microguidewire (Meister 0.016; Asahi) in the best aspect (ipsilateral oblique perspective, 25°–55°) to identify the prostate artery under the road-map technique. Then, prostatic arterial digital subtraction angiography was performed by manual injection in the anterior-posterior and same ipsilateral oblique view. Embolization was performed using 250 to 355 non-spherical polyvinyl alcohol particles (Contour; Boston Scientific) in all patients. Contour was diluted in 20 mL of normal saline and 30 mL of contrast medium in a 2:3 solution. The mixture was slowly injected through 1-mL syringe under fluoroscopic guidance until we reached an end point of near stasis of contrast agent without reflux of embolic agent.

3. Statistical analysis

The categorical variables were presented as numbers and frequencies and continuous variables were presented as

mean±standard deviation or median and interquartile range. For trend analysis, repeated measure analysis of variance was used for IPSS, QoL, Qmax, PVR, PSA, and PV. All tests were two-sided, and *p*-values <0.05 were considered statistically significant. Analyses were performed using SPSS statistics v 18.0 for Window (IBM Corp.).

Results

Twenty-one patients with severe BPH with AUR or prostatic hematuria were enrolled in this study. Patients' basic demographic data are presented in [Table 1](#). Bilateral PAE was technically successful in 19 out of 21 patients (90.5%), and unilateral PAE was done in two out of 21 patients (9.5%) by pelvic vascular obliteration.

Patients were followed for at least 12 months. Patient data before and after PAE are presented in [Table 2](#). In all patients, the mean IPSS, QoL score, Qmax, and PVR were significantly improved at 12 months postoperatively ([Table 2](#)). The mean IPSS decreased from 26.1 to 12.1 points (*p*<0.05), mean QoL score decreased from 4.6 to 2.9 points (*p*<0.05),

Table 1. Baseline clinical characteristics of participants prior to PAE

Characteristic		Value (n=21)
Age (yr)	Mean±SD	72.6±4.7
	Median (IQR)	72 (65–75)
Charlson Comorbidity Index	Mean±SD	6.1±1.2
	Median (IQR)	6 (5–7)
IPSS	Mean±SD	26.1±4.3
	Median (IQR)	26 (24–28)
IPSS-QoL	Mean±SD	4.6±0.5
	Median (IQR)	4 (4–5)
Post-void residual urine volume (mL)	Mean±SD	300.0±112.8
	Median (IQR)	280 (230–350)
PSA (ng/mL)	Mean±SD	7.4±3.8
	Median (IQR)	6.2 (4.1–9)
Prostate volume (mL)	Mean±SD	118.1±15.1
	Median (IQR)	119 (107–130)
Comorbidity, No. (%)		
Cerebrovascular accident		6 (28.6)
Diabetes mellitus		10 (47.6)
Coronary heart disease		3 (14.3)
Gross hematuria, No. (%)		8 (38.1)
Pre-PAE catheterization due to AUR, No. (%)		17 (81.0)

PAE, prostate artery embolization; IPSS, International Prostate Symptom Score; QoL, quality of life; PSA, prostate-specific antigen; AUR, acute urinary retention; SD, standard deviation; IQR, interquartile range.

Table 2. Summary of the mean changes from baseline at 1, 3, 6, and 12 months

Variable	Pre-PAE	1 mo	3 mo	6 mo	12 mo	<i>p</i> for RM
IPSS						<0.05
Mean±SD	26.1±4.3	14.1±3.0	13.1±3.2	12.8±3.4	12.1±3.1	
Median (IQR)	26.0 (23.5–29.0)	13.0 (13.0–15.5)	12.0 (11.0–14.0)	11.0 (10.5–15.0)	12.0 (10.0–13.5)	
QoL						<0.05
Mean±SD	4.6±0.5	2.7±0.9	2.8±0.9	2.8±0.9	2.9±0.8	
Median (IQR)	5.0 (4.0–5.0)	3.0 (2.0–3.0)	3.0 (2.0–3.0)	3.0 (2.0–3.0)	3.0 (2.0–3.0)	
Qmax (mL/s)						0.004
Mean±SD	2.1±1.9	12.1±17.2	8.9±1.9	9.1±1.7	9.4±1.9	
	2.7 (0.0–3.5)	8.5 (7.3–10.0)	9.3 (7.9–10.2)	9.0 (8.5–10.4)	9.0 (8.9–10.5)	
PVR (mL)						<0.05
Mean±SD	300.0±112.8	85.0±40.6	74.3±37.4	73.4±31.8	70.7±29.5	
Median (IQR)	280.0 (225.0–375.0)	75.0 (56.0–95.0)	75.0 (45.0–88.0)	65.0 (52.5–85.0)	64.0 (57.0–76.5)	
PSA (ng/dL)						<0.05
Mean±SD	7.4±3.8	6.0±1.7	5.2±1.9	3.4±0.7	3.3±0.6	
Median (IQR)	6.2 (4.0–10.0)	6.0 (4.5–7.0)	5.0 (3.9–6.5)	3.5 (2.8–3.8)	3.2 (3.0–3.7)	
Prostate volume (mL)						<0.05
Mean±SD	118.1±15.1	-	94.5±12.0	87.1±12.1	79.5±15.1	
Median (IQR)	119.0 (105.0–130.0)	-	95.0 (84.0–104.0)	87.0 (77.0–95.0)	78.0 (70.0–83.0)	

PAE, prostate artery embolization; RM, repeated measure; IPSS, International Prostate Symptom Score; QoL, quality of life; Qmax, peak urinary flow rate; PVR, post-voiding residual urine volume; PSA, prostate-specific antigen; SD, standard deviation; IQR, interquartile range.

mean Qmax increased from 2.1 to 9.4 mL/s ($p<0.05$), and mean PVR decreased from 300.0 to 70.7 mL ($p<0.05$). Furthermore, the mean prostatic volume and mean PSA level decreased from 118.1 to 79.5 mL (mean reduction of 32.7%, $p<0.05$) and 7.4 ng/dL to 3.3 ng/dL ($p<0.05$), significantly (Fig. 1).

The catheter was successfully removed from 19 of 21 patients and clinical success rate was 90.5%. Seventeen patients were able to remove the catheter after 1 week of the procedure. However, two patients needed additional 2 weeks of catheter placement. Median hospital stay was 2 days. Two patients could not void after PAE, they diagnosed as a detrusor underactivity by urodynamic study. Eight patients with hematuria had controlled of bleeding following the embolization in all patients.

Adverse events were summarized in Table 3. There were no major complications (>3 Clavian complications) and nontarget embolization. Nine patients had minor complications. Four patients (19%) had a urinary tract infection, and they were controlled by 2 weeks of antibiotics. Two patients (9.5%) felt a burning sense of the perineum and they were controlled by nonsteroidal anti-inflammatory drug (NSAID) only. Three patients developed urge incontinence

after removed catheter. They needed 2 to 3 diapers per day immediately after removed catheter for managing urge incontinence, but this symptom was resolved by conservative care with anticholinergics.

Discussion

The patients with a prostate larger than 100 mL had limited treatment options. Traditionally, surgery (simple prostatectomy) has been considered as treatment of choice. But these have a relatively high risk of adverse events like that bleeding and postoperative incontinence [1,2]. In addition, endoscopic approach using Holium or Thulium laser (Holium laser enucleation of prostate and Thulium laser enucleation of prostate) has been widely used as the development of minimal invasive treatment. However, endoscopic laser enucleation also has many difficulties that necessity of anesthesia, bleeding, incontinence, urethral stricture, or retrograde ejaculation etc. in applying to all large BPH patients, and steep learning curve [11–14]. Nowadays PAE has been considered as another minimal invasive treatment of option for who could not be suited to surgery.

Patients included in this study had difficulties in surgery

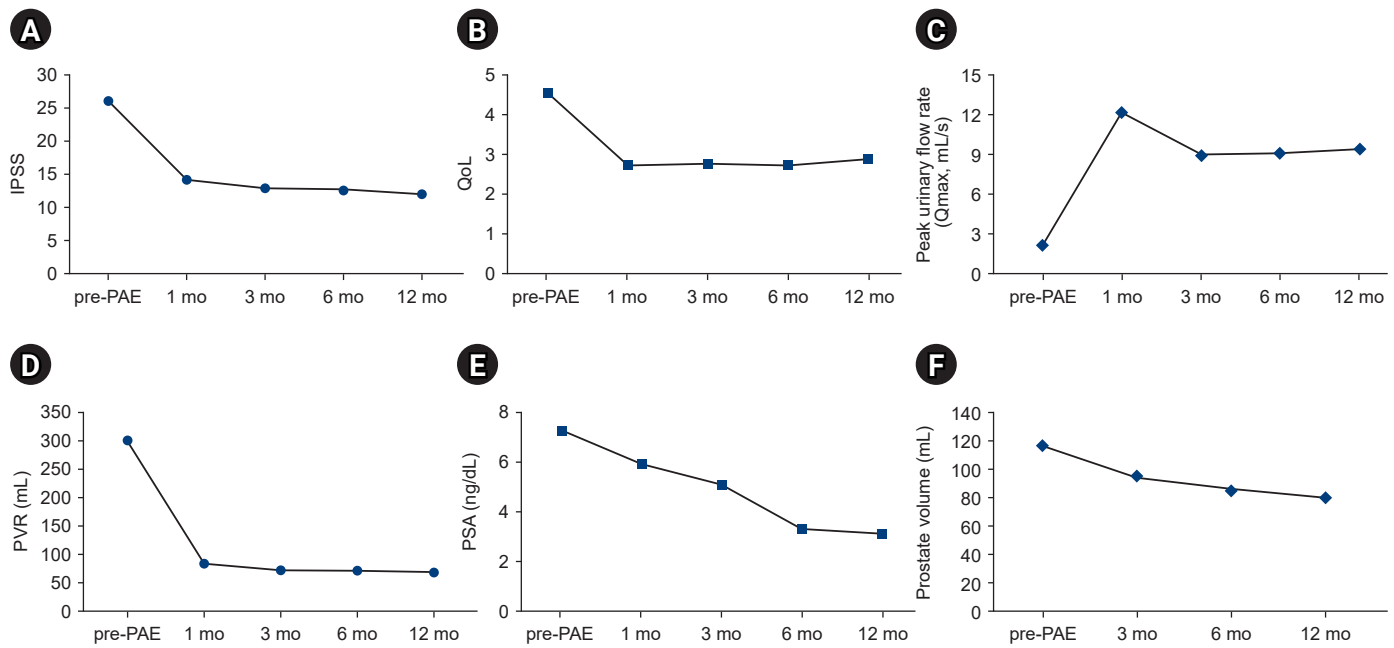


Fig. 1. Comparisons of the following parameters from the preoperative assessment through 1, 3, 6, and 12 months postoperatively: (A) mean International Prostate Symptom Score (IPSS); (B) mean quality of life (QoL) score; (C) mean peak urine flow rate (Qmax); (D) mean post-void residual (PVR) urine volume; (E) mean prostate-specific antigen (PSA) level; and (F) mean prostate volume. PAE, prostate artery embolization.

Table 3. Adverse events (n=21)

Minor complication	No. (%)	Managements
Urinary tract infection	4 (19.0)	2 wk antibiotics
Urge incontinence	3 (14.2)	Anti-cholinergic medication
Pelvic pain	2 (9.5)	NSAID with conservative care

NSAID, nonsteroidal anti-inflammatory drug.

or anesthesia due to comorbidity, 13 out of 21 (61.9%) patients taking anticoagulant due to previous coronal heart disease or cerebrovascular accident. And seven patients (33%) had gross hematuria, also.

Recent papers have shown good results for the treatment of large prostates with PAEs, with prostate size reductions of 32% to 45% over 12 months, and 57% to 68% of the IPSS and QoL improved [15-19]. Feng et al. [20] performed a meta-analysis that reported the efficiency and safety of PAE and indicated that the IPSS and QoL scores showed great improvement after PAE ($p < 0.05$). In present study, the PV reduction rate was 32.7% (from 118.1 to 79.5 mL) and IPSS decreased from 26 points to 12 points (-53.6%) after 12 months of observation. Besides these, other monitored

functional results (QoL, PSA, post-voiding residual urine volume, and urine flow rate) were significantly improved at 12 months post-PAE, like the results reported by Gao et al. [21]. Furthermore, Lebdaï et al. [22] reported mean IPSS reduction was 11.9 points at post-PAE 1 month, which was maintained post-PAE 6 months.

In this study, IPSS and QoL at 1 month were improved and which was persisted for 12 months, also. PV showed a significant reduction at 3 months post-PAE, and it was maintained continuously for 12 months (Fig. 1). Pisco et al. [23] reported that the post-PAE PV reduction was related to clinical efficiency. These clinical results are presumed to be related to the histopathologic degeneration of the prostate by occluding the prostate vasculature [24].

Additionally, a study investigating PAE specifically in catheter-dependent patients with large BPH showed 86% success in catheter removal in mean of 18.2 days after procedure [11]. In this study, mean catheterization date was 7.7 days and 90.4% (19/21) catheter free rate, also. Catheter were removed after 1 week of PAE procedure in outpatient clinic. After removal of the catheter, four patients could not void and maintained an additional catheterization for 2

weeks. After 2 weeks of additional catheterization, two patients were able to void, but two patients were still unable to void, and they needed intermittent catheterization. These patients were checked urodynamic study and diagnosed as detrusor underactivity.

In our study, PAE was performed by a single radiologist who had enough experience, and 21 cases were performed successfully. Most studies used computed tomography angiography or magnetic resonance angiography prior to the intervention to identify the prostatic artery [23,25-31], and CBCT was usually performed only to rule out nontarget embolization. We checked CBCT before embolization in all patients [31,32]. For achieving optimal outcome bilateral PAE is important [33]. CBCT can help reduce the risk of embolization by visualizing the prostate arteries to help identify collateral supply vessels. We defined technical success as accomplished bilateral PAE, can be achieved at 90.5%. Two patients had pelvic vascular obliteration by atherosclerosis, so we did unilateral PAE.

PAE is a relatively safe method except for possible mis-embolization, there is no expected major complication. In recent meta-analysis found that major complication rate was 0.3% due to nontarget embolization, and the most common minor complications were dysuria (17.0%) and transient increased urinary frequency (11.6%) [34]. In this study, adverse events were summarized in Table 3. There were no major complications (>3 Clavian complications) and nontarget embolization. Nine patients had minor complications. Four patients (19%) had a urinary tract infection, and they were controlled by 2 weeks of antibiotics. Two patients (9.5%) felt burning sense of the perineum and they were controlled by NSAID only. Three patients developed urge incontinence after removed catheter. They needed 2 to 3 diapers per day immediate after removed catheter for managing urge incontinence, but this symptom was resolved by conservative care with anticholinergics.

Limitations of this study include the single-center, retrospective fashion, which may decrease the quality of evidence. Second, the sample size of patients was small and there was a selection of bias. This small sample size probably influenced the results of this study to obtain relatively better results compared to other studies. Additionally, we reported the results of 1-year follow-up, but the follow-up period was not sufficient. Despite the small sample size and insufficient follow-up period, reduction in prostate size and

improvement of LUTS were confirmed in patients with an enlarged prostate greater than 100 mL at risk of surgery, and the clinical usefulness of PAE was confirmed. In the future, additional studies are needed on the efficacy of PAE in the enlarged prostatic hyperplasia of the median lobe and small benign prostate hyperplasia patients.

In conclusion, PAE could be a secondary option for treating large BPH (over 100 mL) and urinary retention or gross hematuria associated with BPH in men unfit for surgery. Proper patient selection through evaluation is especially important to ensure clinical success.

Article information

Conflicts of interest

No potential conflict of interest relevant to this article was reported.

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Author contributions

All the work was done by SK.

ORCID

Soodong Kim, <https://orcid.org/0000-0002-3818-5149>

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