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Safety and efficacy of prostatic artery embolization in patients with hematuria due to benign prostate hyperplasia

Bilal Ahmad Hijazi[1,2], Hai-Bin Shi[1*], Sheng Liu[1], Tian Wei[1], Turki Atia Alqurashi[2], Zakir Jamal Sabri[2], Vinay Singh[1] and Hayam Hamdy[3]

Abstract

Background Benign prostate hyperplasia (BPH) commonly affects aging men that can result in hematuria. For patients who are not suitable candidates for surgery, prostatic artery embolization (PAE) has emerged as a minimally invasive alternative. This study aimed to assess the safety and efficacy of PAE specifically for treating hematuria in BPH patients who cannot undergo surgery.

Methods The study included $n = 110$ participants. PAE was performed, and outcomes of interest, including resolution of hematuria, improvement in lower urinary tract symptoms (LUTS), prostate volume (PV), and quality of life (QoL), were assessed. Adverse events were also analyzed.

Results The study demonstrated a 100% clinical success rate in resolving hematuria at 3 months, with no recurrence observed during the 6-month follow-up. Mean hemoglobin levels increased, indicating successful resolution of bleeding. PAE also led to a significant reduction in LUTS severity, as measured by the International Prostate Symptom Score (IPSS). Improvement in the mean maximum urinary flow rate (Qmax) indicated enhanced urinary flow. Additionally, MRI measurements showed a reduction in prostate volume following PAE. These improvements contributed to enhanced QoL for the patients.

Conclusions Prostatic artery embolization (PAE) was found to be a safe and effective treatment option for hematuria in BPH patients not suitable for surgery. PAE demonstrated a high success rate in resolving hematuria and resulted in significant improvements in LUTS, prostate volume, and QoL outcomes. These findings have important implications for clinical decision-making and improving patient care for BPH patients with hematuria. Further research and long-term follow-up studies are necessary to validate these findings and assess the durability of PAE outcomes in this patient population.

Keywords Prostate hyperplasia, Embolization, Hematuria, Lower urinary tract symptoms

*Correspondence:
Hai-Bin Shi
dr.shihb@hotmail.com
Full list of author information is available at the end of the article

1 Background

Benign prostatic hyperplasia (BPH) is the most common condition effecting elderly men, results in lower urinary symptoms (LUTS) sometimes associated with hematuria, which may have a significant effect on hemodynamic stability. Symptoms include urinary frequency, retention, dysuria, urinary tract infections (UTI), and incomplete emptying of the bladder [1]. These urinary symptoms can significantly impact the quality of life of individuals with BPH, affecting their daily activities, and overall well-being [2]. Currently, the treatment options for hematuria due to BPH are limited and often involve invasive procedures, such as open prostatectomy or transurethral resection of the prostate (TURP), transurethral microwave therapy (TUMT), and transurethral needle ablation (TUNA). Nevertheless, they can be associated with complications such as bleeding and impotence [3]. For hematuria caused by BPH, the prostatic artery embolization (PAE) has become a viable minimally invasive therapy option [4]. PAE involves the selective occlusion of the prostatic arteries, reducing blood flow to the prostate and potentially alleviating hematuria [5]. An interventional radiologist (IR) performs PAE, inserting embolizing agent entering the prostate's blood vessels, resulting in blocking the blood vessels and shrinking the prostate. Despite the growing interest in PAE as a treatment option for hematuria in BPH patients, the evidence supporting its effectiveness and safety is still limited, and the results from the previous studies are unclear. Some studies [6, 7] have reported conflicting results or highlighted potential safety concerns, such as complications related to embolization or post-procedural symptoms. Additionally, the follow-up duration and sample sizes in some studies had been relatively small, which may affect the generalizability of the results [8, 9]. To evaluate the efficacy of PAE, a well-designed research needed with larger sample sizes and more extended follow-up periods, safety in managing hematuria in BPH patients, and identify the optimal patient selection criteria and procedural techniques for achieving the best outcomes.

By assessing the safety and effectiveness of PAE as a therapeutic option for BPH-related hematuria. This study aims to evaluate the effects of PAE on the resolution of hematuria, improvement of LUTS, changes in prostate volume, and quality of life (QoL) outcomes. Additionally, the study analyzed the occurrence of any adverse events or complications associated with the PAE procedure. The findings of this study will provide valuable insights into the safety and efficacy of PAE as a treatment option for hematuria in BPH patients and contribute to the existing body of the literature on this topic. This research's result may influence clinical decision-making and improve patient care for BPH patients who experience hematuria and are refractory to medical treatment or unsuitable for surgery.

2 Methods

2.1 Study design

This study utilizes a single-arm design to investigate the safety and efficacy of prostatic artery embolization for the treatment of benign prostate hyperplasia. The design allows for assessing the outcomes of interest in patients undergoing the same treatment while excluding the chances of a placebo effect [10]. The rationale for using a single-arm design in this study is to evaluate the effectiveness of PAE as a stand-alone treatment for BPH in a real-world clinical setting.

One major limitation is the absence of a comparison group, which makes it difficult to determine whether the observed outcomes are solely attributable to the intervention or other factors. Factors such as the natural history of the disease and regression to the mean could impact the results [11–13]. In order to mitigate this limitation, the study conducted a sensitivity analysis where the data were analyzed to assess the stability and consistency of the results. Doing this allowed the researcher to confirm that indeed, the difference in HB levels, LUTS, MRI prostrate volume, IPSS, Qmax levels, PSA levels, and QoL scores across the baseline, 3-month, and 6-month follow-ups was solely due to PAE.

2.2 Participant characteristics

The hospital ethics committee approved this study as per the moral guidelines of the 1964 Declaration of Helsinki and its later amendments [14]. Patients who had undergone prostatic artery embolization to treat benign prostate hyperplasia at the hospital from June 2020 to July 2022 were recruited using convenience sampling method. The inclusion criteria were: patients having a diagnosis of gross hematuria attributable to BPH that has been resistant to medical treatment for at least 3 months, showing evidence of bleeding from prostatic tissue on cystoscopy, being ineligible for surgery or refusing surgery, and not using a bladder catheter continuously in the 3 months prior to hematuria. The patients with cancer, chronic renal failure, or uncontrolled coagulation parameters were excluded. After careful screening based on inclusion and exclusion criteria, $n=110$ participants were selected for the study, all returning for the 3-month and 6-month follow-up sessions (Fig. 1). When the researcher described the purpose and significance of the research, each participant voluntarily supplied written informed consent. The researcher also explained the research's aim and importance to the participants. This step ensured that the participants were aware of the nature of the

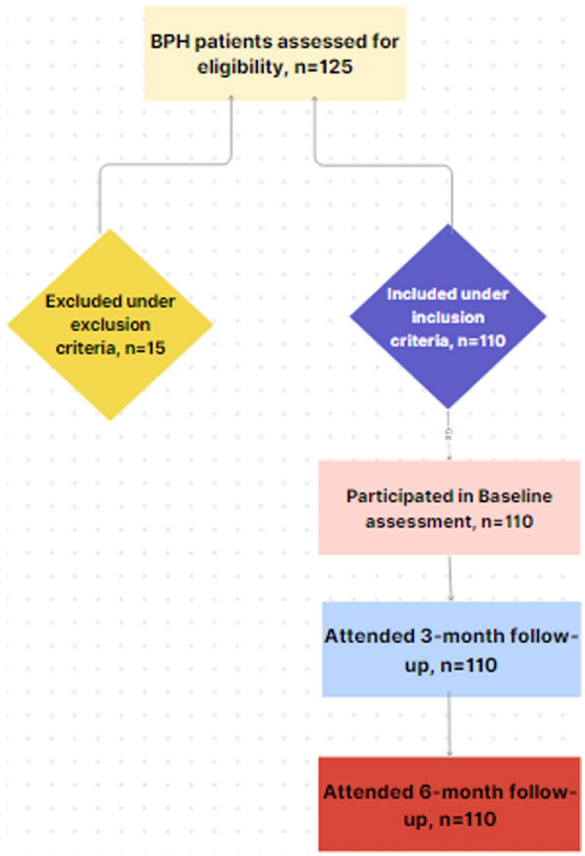

Fig. 1 Flowchart of study population**:** prostatic artery embolization for patients with BPH, patients assessed for study ($n=125$), excluded patients ($n=15$), baseline evaluation ($n=110$), follow-up after 3 months ($n=110$), and follow-up after 6 months ($n=110$)

study, its potential risks and benefits, and voluntarily agreed to participate.

2.3 Prostatic artery embolization

All patients stopped taking medicine for BPH 2 weeks prior to the procedure. The PAE procedure lasted between 1 and 4 h. It was performed using a standardized technique by an experienced interventional radiologist collaborating with a multidisciplinary team that included urologists in a sterile environment in the angiography suite (Philips, Best, The Netherlands) under local anesthesia (lidocaine) to minimize discomfort [15]. Using a typical Seldinger approach, the IR used the femoral artery to gain access to the arterial system [16]. The prostatic arteries were selectively catheterized using a microcatheter (Progreat; Terumo, Tokyo, Japan), with roadmap guidance (fluoroscopic imaging) to aid catheterization [17] and fluoroscopic imaging providing real-time visualization of the catheter tip [18]. The IR used a 5-French diagnostic catheter (Yashiro catheter; Terumo, Tokyo, Japan) to advance into the internal iliac artery. Once the microcatheter was in the prostatic arteries, digital subtraction angiography (DSA) was performed using a biplane system with anteroposterior (AP) and lateral angulations (30–45°) to visualize the prostatic arteries and assess the vascular supply to the prostate gland [19–21]. Angulation and views were adjusted as necessary to optimize the visualization of the prostatic arteries and their branches.

After visualizing the prostatic arteries, the IR selectively injected embolization material, polyvinyl alcohol (PVA) particles 100–500 µm (Contour; Boston Scientific, Natick, USA) mixed with contrast solution (2:1 ratio) were selectively injected into the prostatic arteries to occlude blood flow to the hyperplastic prostate tissue (Fig. 2) [22]. The study determined the technical success of PAE by successful catheterization of both prostatic arteries, visualization of the arteries on DSA, and successful embolization of the targeted arteries supplying the hyperplastic prostate tissue.

2.4 Post-procedure management

After embolization, the hospital monitored patients for immediate complications such as pain, infection, or vascular injury. Hemostasis was ensured at the puncture site, and patients were typically observed for a few hours in the recovery area before being discharged. Two to 3 days' follow-up appointments were scheduled to monitor the patient's progress and address any concerns or complications arising after the procedure.

2.5 Data collection

The following variables underwent baseline, 3-month, and 6-month follow-up data collection. Sample size ($n=110$), average age, prostate volume, hemoglobin level, International Prostate Symptom Score (IPSS), maximum urine flow rate (Qmax), and prostate-specific antigen (PSA) level were recorded. Data collection for the follow-up months was done through patient assessment of health records following the procedure.

2.6 Statistical analysis

Descriptive statistics and measures of central tendency were performed for the study population by Microsoft Excels, and statistical analysis was performed using R 4.2.2 software. ANOVA was used for inferential statistics to compare the baseline data with the 3-month and 6-month follow-up data. Statistical significance was defined as a p-value of 0.05.

The safety and efficacy outcomes of PAE were analyzed descriptively. Safety outcomes included immediate complications such as pain, infection, or vascular injury, reported as frequencies and percentages. Symptom changes (hematuria with lower urinary tract symptoms),

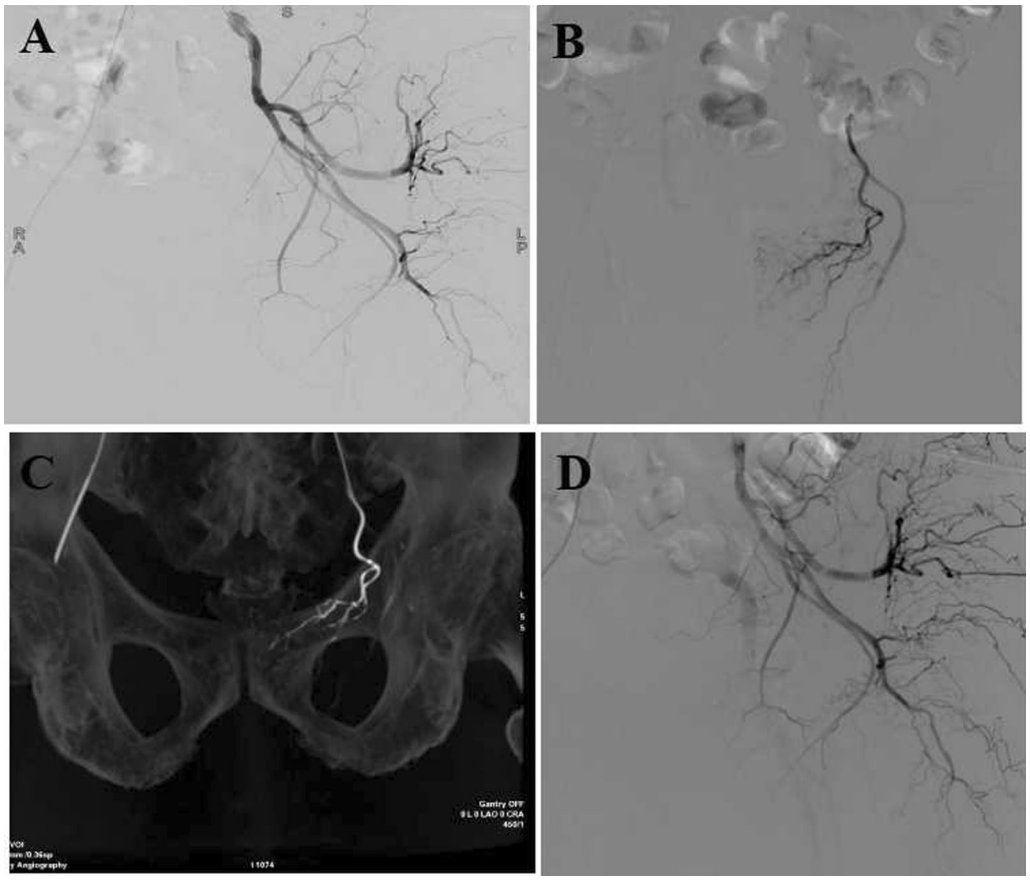

Fig. 2 Arteriographic images of a 77-year-old patient with lower urinary tract symptoms associated with benign prostatic hyperplasia who underwent bilateral prostatic artery embolization: **A** Angiography showing enhanced left internal iliac artery. **B** Super-selective angiography of the left prostatic artery. **C** C-CT during procedure showing left prostatic artery. **D** The left prostatic artery after embolization

prostate volume, HB level, IPSS, Qmax, PSA, score of the International Index of Erectile Function (IIEFS), and QoL at 3-month and 6-month follow-up compared to baseline were included as efficacy outcomes. The researcher reported these changes as mean and standard deviation.

3 Results

3.1 Procedural outcomes

There was a reported mean of 96 ± 2% (range: 92%–100%) technical success rate using PVA embolic alcohol in participants ($n=110$) who underwent bilateral PAE with both prostatic arteries catheterized, visualized on DSA. The average duration of the PAE procedure in the study population was 2 h (range: 1–4 h). There was also a 100% hemostasis success rate as 100% of patients ($n=110$) achieved successful hemostasis at the puncture site after the PAE procedure. Lastly, there was a reported 100% follow-up appointment completion rate as 100% of patients ($n=110$) attended the scheduled follow-up appointments after the PAE procedure.

3.2 Clinical outcomes

The mean age of participants in our study was 72.6 years (SD = 10.5, range: 54–90). The sample size through the three periods was the same at $n=110$. The mean IPSS was 25.33 ± 3.93. The residual hematuria was at 2.95 ± 0.85 (Table 1) shows these descriptive statistics at baseline.

All patients reported 100% clinical success in resolved hematuria by the first follow-up (3 months after PAE) with no recurrence on the 6-month follow-up. Hematuria resolved in all patients with an average of 5 days (Fig. 3). The mean residual hematuria was at 2.95 ± 0.85 at baseline, with no residual hematuria was observed in any participant after 3-month and 6-month follow-ups confirming that PAE is associated with a significant improvement in the resolution of hematuria compared to standard medical treatment or no treatment in BPH patients. These results (100%, 96 ± 2% technical success) and resolved mean residual hematuria from 2.95 ± 0.85 at baseline to after 3-month and 6-month follow-ups, with no recorded complications, confirm that PAE offers

Table 1 Baseline characteristics

Variable	Descriptive (mean ± SD)
Age, years	72.6 ± 10.5
MRI prostate volume, mL	68.16 ± 8.39
HB, g/L	116.89 ± 4.61
IPSS	25.33 ± 3.93
Qmax, mL/s	7.09 ± 1.75
PSA, ng/mL	6.95 ± 1.40
Residual hematuria, mL	2.95 ± 0.85
QoL score	4.43 ± 0.25
IIEFS	9.34 ± 1.41

MRI, magnetic resonance imaging; HB, hemoglobin; IPSS, International Prostatic Symptoms Score; Qmax, maximum urinary flow rate; PSA, prostate-specific antigen; QoL, quality of life; and IIEFS, International Index of Erectile Function Score

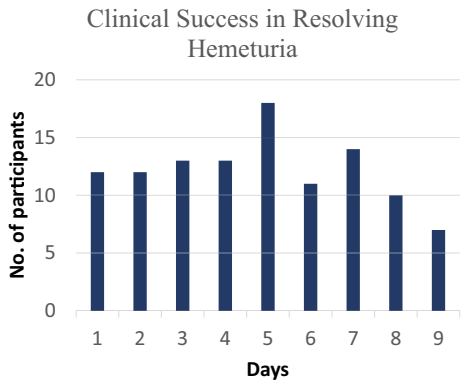

Fig. 3 The duration (days) to achieved clinical success in resolving hematuria due to benign prostate hyperplasia

safety and efficacy in patients with hematuria due to BPH.

The prostatic volume showed to be decreased after using embolizing PVA particles, and the results showed that the mean in the baseline was 68.2 ± 8.39, while after 3 months post-treatment, the volume was 52.9 ± 7.91, and after 6 months, it was 39.4 ± 5.78 (Fig. 4A). Additionally, mean hemoglobin (HB) levels increased steadily among all the participants post-PAE (Fig. 4B). Before the procedure, the mean HB levels were recorded at 117 ± 4.61 g/L but increased to 143 ± 2.86 g/L to a further 144 ± 2.91 g/L at the 3-month and 6-month follow-up, respectively, at $p < 0.001$. The results confirm that since there is no recorded hematuria in the 3-month and 6-month follow-ups, the participants' hemoglobin was able to improve.

All participants showed a reduced severity of LUTS based on their IPSS at observations (Fig. 4C). The mean of IPSS during baseline reduced from 25.33 ± 3.93 to 15.7 ± 2.37 at 3-month follow-up post-PAE and 7.23 ± 0.96 at 6-month follow-up. The significant difference was found as $p < 0.001$, indicating that the observed result is highly statistically significant level of significance in IPSS among the three groups, at baseline, 3 months, and 6 months' follow-up after PAE. These results support that PAE is associated with a significant improvement in LUTS compared to standard medical treatment or no treatment in BPH patients.

Additionally, participants recorded an increased mean maximum urinary flow rate (Qmax) (Fig. 4D) from 7.09 ± 1.75 during baseline to 8.58 ± 2.11 and 15.3 ± 2.34 at 3-month and 6-month follow-ups, respectively, at statistical significance $p < 0.001$. This rationale means that participants could quickly empty their third bladder after the PAE treatment. Increased ability to empty the bladder shows that the PAE effectively reduced prostate symptoms.

PSA results, however, show very minimal differences (Fig. 4E) between the means recorded at baseline, 3-month, and 6-months, and their means are 6.95 ± 1.40, 6.68 ± 0.78, and 6.24 ± 1.24, respectively. PSA shows statistical significance at $p < 0.001$, indicating that the PAE procedure successfully reduced PSA. Lastly, participants recorded an increased quality of life (QoL) indicated by the decreased QoL (Fig. 4F) scores from 4.43 ± 0.25 to 2.34 ± 0.38 and 1.57 ± 0.59 at the baseline, 3-month, and 6-month periods, respectively, with statistical significance of $p < 0.001$ confirming that PAE significantly improves QoL outcomes compared to standard medical treatment or no treatment in BPH patients.

Additionally, the analysis of IIEFS increased drastically. The means increased from 9.34 ± 2 to 14.62 ± 2 and 19.38 ± 2 at the baseline, 3-month, and 6-month follow-up, respectively, at $p < 0.001$(Fig. 4G). These results show that PAE successfully reduced participant discomfort, resulting in an increased quality of life and sexual confidence. All data between baseline, 3-, and 6-month post-PVA particles exposure were showed in mean ± S.D (Table 2).

4 Discussion

The study results show that all patients achieved 100% hemostasis at the puncture site after the PAE procedure, indicating the effectiveness of the hemostasis measures employed during the procedure. The clinical success was 100% and a 96 ± 2% technical success in resolving hematuria by the first follow-up (3 months after PAE), with no recurrence reported during the 6-month follow-up period, indicating high compliance and adherence of patients to the post-procedure management plan, and supporting the efficacy and safety of PAE in treating hematuria. One possible explanation for the rapid resolution of hematuria observed in the study, with most participants experiencing resolution within the first few days

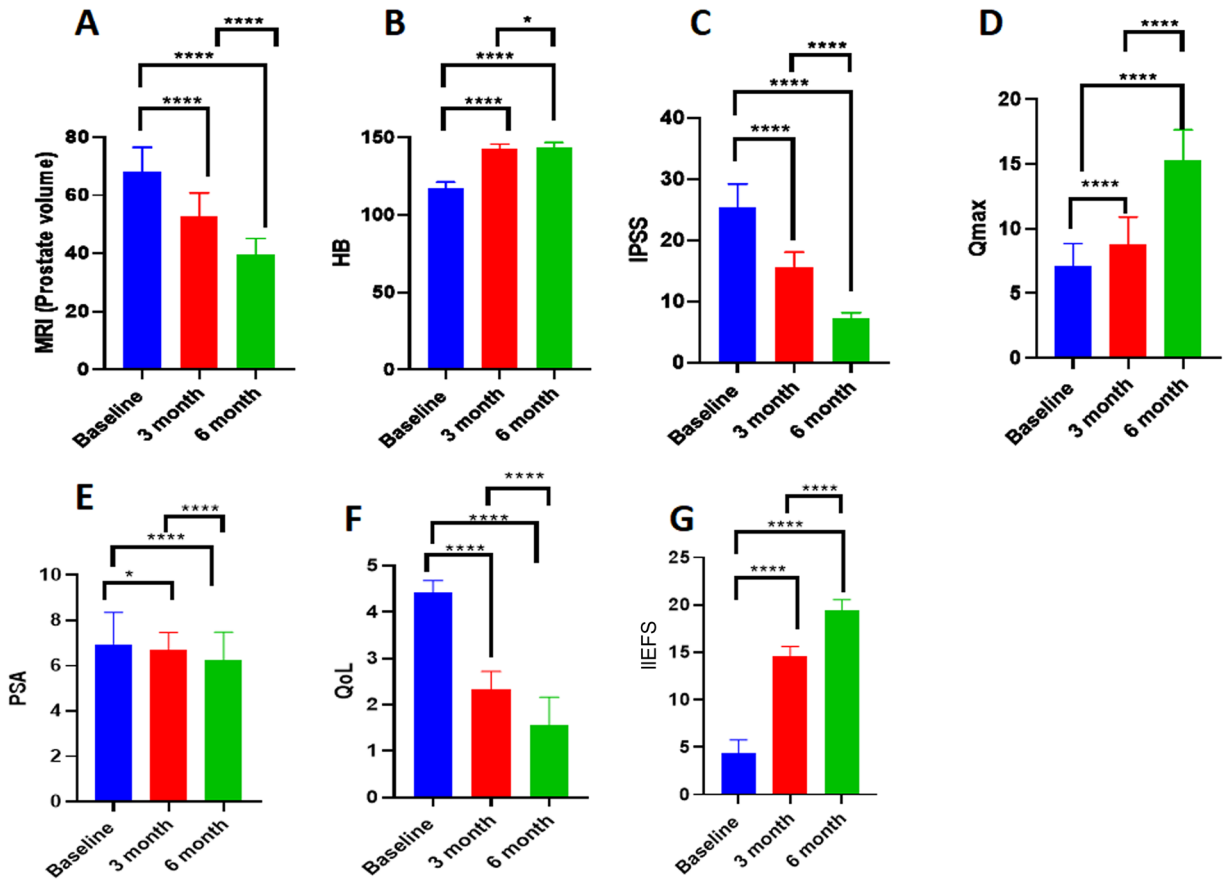

Fig. 4 Comparison between pre- and post-prostatic artery embolization treatment: **A** MRI prostate volume at baseline, 3, and 6 post-PAE, **B** HB values at baseline, 3, and 6 PAE, **C** IPSS at baseline, 3, and 6 post-PAE, **D** Qmax value at baseline, 3, and 6 post-PAE, **E** PSA value at baseline, 3, and 6 after PAE treatment, **F** QoL values at baseline, 3, and 6 after PAE, and **G** IIFFS values at baseline, 3, and 6 post-PAE treatment

Table 2 Comparison of clinical responses pre- and post-prostatic artery embolization

P. variable	Q. baseline	R. 3 months	S. 6 months	T. overall
MRI prostate volume, mL	68.2 ± 8.39	52.9 ± 7.91	39.4 ± 5.78	< 0.0001
HB, g/L	117 ± 4.61	143 ± 2.86	144 ± 2.91	< 0.0001
IPSS	25.3 ± 3.93	15.7 ± 2.37	7.23 ± 0.96	< 0.0001
Qmax, mL/s	7.09 ± 1.75	8.58 ± 2.11	15.3 ± 2.34	< 0.0001
PSA, ng/mL	6.95 ± 1.40	6.68 ± 0.78	6.24 ± 1.24	< 0.0001
QoL score	4.43 ± 0.25	2.34 ± 0.38	1.57 ± 0.59	< 0.0001
IIFFS	4.34 ± 1.41	14.6 ± 1.02	19.4 ± 1.16	< 0.0001

MRI, magnetic resonance imaging; HB, hemoglobin; IPSS, International Prostatic Symptoms Score; Qmax, maximum urinary flow rate; PSA, prostate-specific antigen; QoL, quality of life; and IIEFS, International Index of Erectile Function Score

after PAE, could be the reduction in prostate size and relief of pressure on the urinary tract. PAE is known to reduce the size of the prostate gland by selectively embolizing the prostatic arteries, leading to ischemic necrosis of the prostate tissue [17, 23]. According to Duan et al. [24], this reduction in prostate size may alleviate the compressive effects of the enlarged prostate on the blood vessels in the prostate, which could lead to the resolution of hematuria. The varying duration of hematuria resolution reported in the study could attribute to individual healing responses and the severity of hematuria, as reported by Carnevale et al. [25] and Rahman et al. [26]. Patients with mild hematuria or faster healing responses may experience quicker resolution, while those with

more severe hematuria or slower healing responses may take longer to achieve complete resolution [25, 26]. The study's results also showed that after performing PAE, there was a consistent increase in mean HB levels among all the participants, in line with Moreno et al.'s [27] study suggesting that PAE may positively affect hemoglobin levels due to reduced bleeding in the prostate gland or improved blood flow indirectly by alleviating the pressure of enlarged prostate gland on surrounding blood vessels.

The reduction in the severity of LUTS, as indicated by the IPSS, among all participants in this study after PAE aligns with relevant theories related to the pathophysiology of BPH. BPH is known to cause LUTS due to increased prostate size and compression of the urethra, leading to urinary symptoms such as frequency, urgency, and incomplete emptying [28]. PAE may relieve the compression of the urethra and improve urinary flow. The study supports this theory by participants revealing a significant reduction in prostate volume at both 3-month and 6-month follow-ups after PAE, as evidenced by the reduced means. Improved urinary flow and reduced pressure on the urethra lead to reduced severity of LUTS and increased Qmax, as observed in the study [29], which is also evidenced by the study's significant reduction in mean IPSS at 3 months and 6 months' follow-ups, as evidenced by the small p value ($p < 0.005$) in the single-factor ANOVA analysis.

Participants also recorded, although slight, a stable reduction in PSA levels post-PAE intervention. The previous research by Bilhim et al. [23] and Obinata et al. [30] has indicated that the size of the prostate gland has an impact on prostate-specific antigen [PSA] levels. Specifically, a larger prostate gland produces more PSA, while a minor prostate gland produces lower PSA levels [30]. This theory aligns with the study's findings that PAE resulted in reduced PSA levels recorded alongside reduced MRI prostate volume.

Reduced hematuria, LUTS, prostrate size, and ability to urinate freely may reduce the stress that BPH patients usually experience alongside the need for medication, such as 5-alpha-reductase inhibitors or alpha-blockers, to manage their urinary symptoms [31]. After successful PAE, patients may experience a reduced need for these medications, leading to improved IPSS, QoL, and Qmax. This process improves their overall well-being, leading to an even more improved quality. These results further support the study by Wei et al. [3], indicating that psychological elements, including tension, anxiety, and depression, can also affect sexual function, including erectile function. Successful treatment of BPH with PAE has relieved these psychological burdens, resulting in improved quality of life and, subsequently, improved erectile function, as reflected in increased IIEFS. The increased quality of life can also result from PAE being a less invasive procedure typically associated with less pain, shorter hospitalization, and quicker recovery than traditional surgical interventions for BPH, such as open prostatectomy or TURP [3]. The less invasive nature of PAE may contribute to decreased QoL scores, as patients may experience less post-procedural discomfort and a faster return to normal activities. Improving the quality of life following successful PAE may increase patient satisfaction. Increased satisfaction with overall well-being and reduced urinary symptoms may positively impact a patient's perception of their sexual function, leading to increased IIEFS [3, 32].

To date, few studies have been conducted with smaller sample size, and PAE has shown acceptable mid-term results on clinical safety and efficacy in resolving hematuria BPH. Similarly, our study had comparatively larger sample size, and clinical success was 100%. Statistically significant change in IPSS, QoL score, and resolving hematuria was obtained, with no severe complications. Individual moderate complications and postembolization syndrome resolved without the need for additional treatments. Consistent with other studies, this study confirmed the safety and efficacy of PAE to resolve hematuria due to BPH.

Our study has some limitations. First, it is a single-arm study without comparison with other treatments. Second, there may be a chance of bias because PAE was carried out by a senior interventional radiologist with his own extensive experience with PAE. Third, a short follow-up time of 3 and 6 months is a limitation by itself. However, our goal is to report the clinical data with relatively larger sample size of hematuria treated with PAE related to BPH. Further research and long-term follow-up studies are warranted to understand better PAEs long-term safety and efficacy in managing BPH and its impact on patient QoL. Additionally, evaluating the cost-effectiveness of PAE compared to other treatment options for BPH would provide valuable information for the physicians.

5 Conclusions

The study's findings imply that prostatic artery embolization can relieve hematuria, lower urinary tract symptoms, improve urinary flow, reduce prostate volume, and reduce the need for medication, may be an effective intervention for patients with BPH. These significant improvements may improve patients QoL, including psychological well-being and sexual function. PAE may also improve QoL by reducing post-procedural discomfort and allowing for a quicker recovery. The study's findings support using PAE as a safe and efficacious treatment option for BPH patients. Based on

these results, recommendations could include considering PAE as a viable treatment option for BPH patients experiencing hematuria and LUTS, when other treatment options may not be suitable.

Abbreviations

BPH	Benign prostate hyperplasia
PAE	Prostatic artery embolization
LUTS	Lower urinary tract symptoms
PV	Prostate volume
QoL	Quality of life
IPSS	International Prostate Symptom Score
Qmax	Maximum urinary flow rate
MRI	Magnetic resonance imaging
UTI	Urinary tract infections
TURP	Transurethral excision of the prostate
IR	Interventional radiologist
DSA	Digital subtraction angiography
PVA	Polyvinyl alcohol
HB	Hemoglobin
PSA	Prostate-specific antigen
IIEFS	International Index of Erectile Function Score

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Author contributions
BAH is the main surgeon who operated all patients in our study and participated in paper writing, research performance, and analysis. SL, ZS, VS, and TA participated in research design and patient workup, TW and HH performed statistical analysis, and SHB supervised paper writing. All authors read and approved the final manuscript.

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Availability of data and materials
The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

Declarations

Ethics approval and consent to participate
KAAH Institutional Ethical Committee approval was obtained from IEC-KAAH with IEC number C6A23995A56E. Informed written consent was obtained from all participants. A copy of ethical committee approval is available upon request.

Consent for publication
All the participants have consented for publication of their data.

Competing interests
All the authors hereby declare that no conflict of interest exists, and there are no financial or personal relationships or affiliations that could influence (or bias) the author's decisions, work, or manuscript.

Author details
[1]Department of Interventional Radiology, Jiangsu Province Hospital, The First Affiliated Hospital Nanjing Medical University, Nanjing, People's Republic of China. [2]Department of Imaging and Interventional Radiology, King Abdulaziz Hospital and Research Center, Riyadh, Saudi Arabia. [3]Department of Forensic Medicine and Toxicology, Faculty of Veterinary Medicine, New Valley University, New Valley, Egypt.

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