Prostate Artery Embolization: A Novel Approach for treating Benign Prostate Enlargement

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Abstract

Prostate Artery Embolization (PAE) has emerged as a novel treatment option for Benign ProstaticHypertrophy (BPH) with clinical efficacy comparable to the current surgical gold standard, transurethral resection of the prostate (TURP). In a multicentric study, 5 patients with high-risk BPH selected from June 2021 to March 2022 underwent PAE to evaluate efficacy, safety and postoperative quality of life after treatment with PAE. Different variables like changes of international prostate symptom score (IPSS), post void residual volume (PVR), maximum urine flow rate (Qmax) and Prostate Volume (PV) were compared before and after operation. PAE was successful in all 4 patients. 1 patient was lost to follow up after 1 month despite of improvement in Qmax. No severe complications were noted in the postoperative patients. The IPSS, PV and PVR levels of the patient at follow up were lower than those before surgery, while the Qmax level was higher than that before procedure. For high-risk BPH patients, PAE is an effective and safe method with good application prospects and fewer complications eliminating need of general anesthesia or hospitalization. However, due to the small sample size in this study, further observation and study is needed to determine its long-term efficacy and safety.

Keywords: Prostate artery embolization, Benign prostatic hypertrophy, transurethral resection of the prostate, clinical efficacy, quality of life

INTRODUCTION

According to American Urological Association (AUA), benign prostatic hyperplasia (BPH) refers to the hyperplasia of prostatic interstitial and glandular components within the prostatic transition zone surrounding the proximal urethra, which makes up about 5% of the prostate[(1)].It causes compression ofurethraleading to Bladder Outflow Obstruction or BOO resulting inlower urinary tract symptoms (LUTS), such as, urgency, nocturia, dysuria, increased frequency, problems in bladder emptying or in initiating micturition,and weak or intermittent stream[(2)].It is agreed that BPH increase in prevalence with age. At the age of 60 approximately 60% of men are affected with some degrees of clinical BPH [(3,4)]. In long term, this disease can lead to serious damage to the bladderand kidney function, and negative impact on patients' quality of life. Hence the main objective of treatment of BPHis to alter disease progression and to prevent BPH related complications, e.g., urine retention[(5)].

Variety of medicines have been employed to alleviate symptoms of BPH, like, alpha adrenergic blockers, beta adrenergic agonist, 5 alpha reductase inhibitors(5-ARIs), Anticholinergics, vasopressin analogues, PDE inhibitors,Phytotherapeutics, which can be prescribed alone or in combination[5,6].However, sometimes conservative management with life style modification and pharmacological treatment may not help the patients, warranting need for invasive procedures available for the treatment of LUTS attributed to BPH. The treatment options available including transurethral resection of the prostate (TURP), transurethral vaporization of the prostate (TUVP), prostatic urethral lift (PUL), Holmium Laser Enucleation of the Prostate (HoLEP), etc. But, transurethral resection of the prostate (TURP) has been accepted as the gold standard to alleviate obstructive voiding dysfunction in men with BPH surgically. [7,8]

Development of advanced surgical equipment, such as plasma and laser, has greatly improved the safety of prostate surgery, but still, clinical complications can happen, such as, retrograde ejaculation, urinary incontinence, hematuria, urethral strictures and bladder neck sclerosis. Especially in elderly and high risk patients with high surgical mortality risk, either indwelling catheter or cyctostomy for a long time can be accepted only. On one hand, improvement in quality of life cannot be guaranteed in such patients, and on other hand, the risk of infection is increased[9]. Hence, finding a surgical method having ideal therapeutic effect but with higher safety is the focus of research in the treatment of BPH.

Prostate artery embolization (PAE) has emerged as a novel treatment option in recent years for this common problem with clinical efficacy comparable to the current surgical gold standard, transurethral resection of the prostate (TURP) [10]. It has the advantages of less bleeding, low incidence of complications during and after procedure and outstanding therapeutic effect [10,11,12].

PAE is an interventional radiological technique involving the injection of small particles directly into the prostatic arteries bilaterally, leading to devascularization of hypervascular nodules.

PAE has been further developed using the 'PErFecTED' technique, in which standard proximal embolization is followed by deep microcatheter placement within the prostate gland and further embolization.

In this study, high-risk BPH patients were treated with prostatic artery embolization, with aim of observing the efficacy of this surgical method and the impact on related laboratory indicators.

MATERIALS AND METHODS

A mutli-centric single-arm study, including 5 patients, in a 'all comers' design, conducted in Department of Urology, Jinnah Postgraduate Medical Center and Angiography Suite, Ziauddin University Hospital North Nazimabad Branch in Karachi,treated with PAE from July 2021 to March 2022. Patients were evaluated through medical history and physical examination. Patients were explained about the procedure and only those who were willing for prostate artery embolization instead of conventional transurethral resection of prostate were enrolled and informed consent was taken. Average age of the patients was 68.1 ± 9.2 years and the average prostate volume was 44.40 ± 8.26 cm^3. CT angiography was done before Prostate Artery

Embolization to rule out atherosclerosis or any vascular malformations. Preoperative examination algorithm included determining the volume of the prostate by performing a transurethral ultrasound (PV), determining the volume of residual urine using ultrasound (PVR), a blood test for prostate-specific antigen (PSA), uroflowmetry to determine Qmax, and determining the LUTS using the IPSS questionnaires.

Angiography and embolization:

Technique:

Procedures were performed on an outpatient basis. After skin preparation of the right inguinal region, 10 ml of 2% lidocaineHCl was injected locally. The right femoral artery was punctured with an 18G angiocatheter needle and a 6 Fr arterial access sheath was then placed. Bilateral internal iliac arteries and their anterior division were selected using a 5 Fr Cobra type catheter (Cordis) & a 0.035-inch Terumo wire (Terumo), pelvic angiography was performed. 5 Fr SIM 1 catheter was used in one patient in which there was tortuous arteries. Digital subtraction angiography (DSA) of the anterior division of the internal iliac arteries was performed. For super-selective catheterization of the prostatic arteries, a Progreat 2.1 or 2.7Fr microcatheter (Terumo) and a 0.016-inch hydrophilic guide wire (Glidewire GT; Terumo) were used which is inserted coaxially through the macrocatheter. After catheterization of the prostatic artery, embolization was performed using 150 -250 mm polyvinyl alcohol particles (Boston Scientific or CooK)

The embolization endpoint selected was occlusion of the arterial branches supplying the prostate gland with exclusion of prostatic blush, and reflux toward the origin of the prostatic artery or the anterior division of the internal iliac artery.

To provide good orientation to the prostate site and related structures in the pelvis, a foley balloon is introduced into the bladder in every patient. It is used just during the procedure and gives both a better image and understanding of the prostate, the internal iliac artery branches and related structures to avoid nontarget embolization complications. It is an excellent landmark during the procedure.

We believe that using high dilution and very slow injection is essential to avoid early proximal occlusion and to achieve the goal of diffuse gland parenchymal ischemia. The mixture is injected slowly under fluoroscopic guidance. After achieving a good endpoint, the microcatheter should be pulled back to the origin of the inferior vesical arteries and a manual injection run performed for final control and to look for additional prostatic branches. If any accessory prostatic branch is not embolized, poor long-term clinical results may occur, including reduced prostate shrinkage and return of LUTS symptoms. Bilateral inferior vesical arteries and any other prostatic branches should be embolized to achieve optimal prostate ischemia, resulting in volume reduction for better long-term results.

Postprocedure Management:

Post-procedure, manual compression was maintained at puncture site with the patient lying in supine position for hemostasis.

After the procedure, patients remain 6 h without moving the punctured leg to avoid bleeding complications from disrupting the vascular site. During this resting time after PAE, the use of the Foley balloon is very important, because patients can void normally without straining, which reduces the risk of puncture site complications.

Technical and Clinical Success:

We consider it a technical success when main bilateral prostatic arteries are embolized. The purpose of PAE is to produce as much gland ischemia as possible, because we have observed that better long-term clinical and urodynamic results are correlated with prostate ischemia.

Clinical success is defined by multiple criteria: removal of the Foley catheter in patients with AUR, LUTS symptom improvement according to the IPSS& improvement in Qmax, and no sexual disorders or serious adverse events from the treatment.

The follow-up period was 12 months with control examinations in outdoor patient department wit same parameters at 3, 6 and 12 months after PAE.

Indications for PAE included; prostate volume greater than **60 cm3**, no effect of conservative therapy after 6 months,Qmax< 13 ml/s,IPSS scale >18 points, anamnesis of acute or chronic urinary retention.However, main indication was inability to perform surgical procedure.Contraindications for PAE were Catheter dependant individuals, drug intolerance of contrast drug used in x-ray contrast drug, vascular malformations in area of aortic bifurcation and external or internal iliac arteries and severe atherosclerosis.

PAE was performed until arterial stasis using the PErFecTEDtechnique. Most of the patients were treated as a day-care procedure.

For statistical processing of the results, IBM SPSS Statistics v28 software was used.

RESULTS

BetweenJuly, 2021 to March, 2022, a total of 5 patients underwent PAE for symptomatic BPH at our institution.

4 (80%) patients underwent bilateral PAE and 1 (20%) underwent unilateral PAE(One patient had variant anatomy of unilateral prostatic artery, so single vessel embolization was done).

Embolization of the prostatic arteries was successfully performed in all of the cases using PErFecTED technique. The most common complications of PAE in the early postoperative period were postembolization syndrome (hyperthermia, dysuria, perineal pain) observed in 4 (80%) patients and urinary tract infection was observed in 2 (40%) patients.However, no patient

reported acute retention of urine. None of the complications identified during the observation period required active surgical intervention and were completely resolved with conservative therapy. In 1 (20%) case with LUTS due to BPH, satisfactory clinical improvement in symptoms and Qmax score was noted at 1 month follow-up; but patient was lost to follow-up and underwent TURP.

The clinical efficacy (success) of super selective embolization of the prostatic arteries in the treatment of BPH was 94.8%.

Embolization was technically possible in all of the patients; hence 100% technical success was achieved.

No patient had major post procedure complication. None of patients had repeat procedure.

During the 12-month control, the observed patients showed positive dynamics in comparison with the initial results in terms of PSA (2.29 ± 0.43 vs 3.88 ± 1.64), prostate volume (44.00 ± 19.59 vs 53.40 ± 20.65), IPSS (6.50 ± 0.57 vs 20.70 ± 8.58), maximum urination rate or Qmax (18.92 ± 2.32 vs 7.82 ± 2.50), and post void residual volume (98.80 ± 25.93 vs 43.75 ± 18.40); (Table 1)

Table 1: comparison of PSA levels, Prostate Volume (PV), IPSS scores, Maximum flow rate (Qmax) and Post Residual Volume (PVR) in patients at presentation, at 3 months, 6 months and 12 months

TIME	PSA	PV	IPSS	Qmax	PVR
Baseline	3.88 ± 1.64	53.40 ± 20.65	20.80 ± 8.58	7.82 ± 2.50	98.80 ± 25.93
3 months	2.29 ± 0.61	51.00 ± 27.86	12.50 ± 2.38	12.85 ± 4.72	72.00 ± 20.31
6 months	2.15 ± 0.69	54.75 ± 29.40	8.00 ± 0.816	16.05 ± 2.10	53.00 ± 12.72
12 months	2.29 ± 0.43	44.00 ± 19.59	6.50 ± 0.57	18.92 ± 2.32	43.75 ± 18.40

Table 2: comparison of PSA levels in patients at presentation, at 3 months, 6 months and 12 months

Column1	BASELINE	3 MONTHS	6 MONTHS	12 MONTHS
PATIENT 1	3.11	2.71	2.6	2.4
PATIENT 2	4.74	2.9	2.88	2.22
PATIENT 3	4.02	1.99	1.7	1.8
PATIENT 4	5.95			
PATIENT 5	1.61	1.59	1.44	1.43

	BASELINE	3 MONTHS	6 MONTHS	12 MONTHS

N	Valid	5	4	4	4
	Missing	1	2	2	2
Mean		3.8860	2.2975	2.1550	1.9625
Median		4.0200	2.3500	2.1500	2.0100
Std. Deviation		1.64239	.61326	.69328	.43500

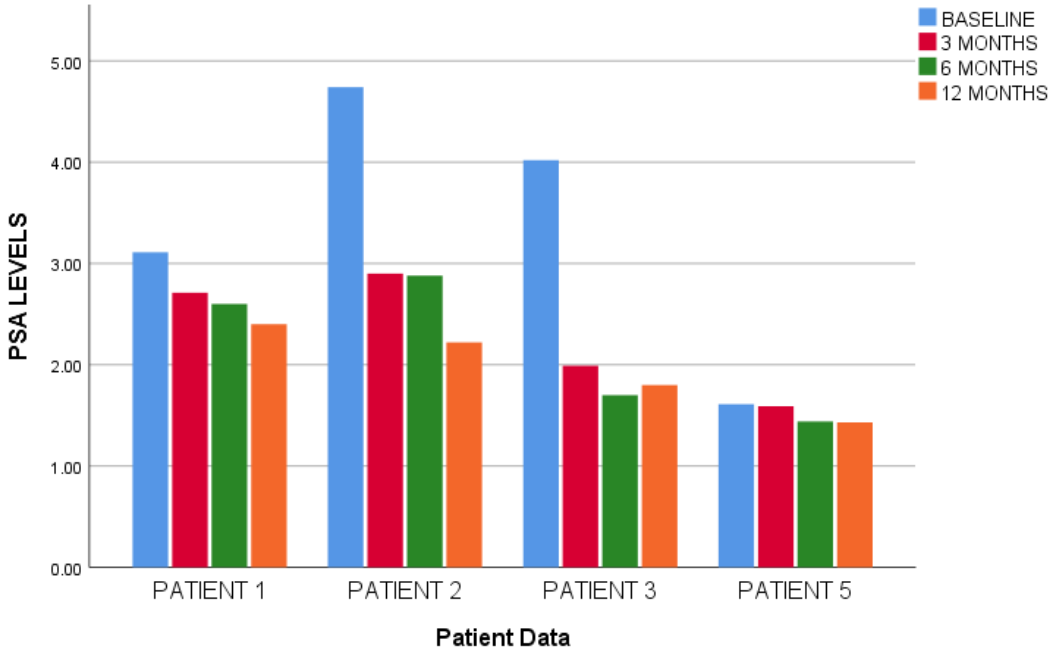


Table 3: comparison of PROSTATE VOLUME (PV) in patients at presentation, at 3 months, 6 months and 12 months

	BASELINE	3 MONTHS	6 MONTHS	12 MONTHS
PATIENT 1	44	48	79	60
PATIENT 2	47	17	18	20
PATIENT 3	46	54	44	36
PATIENT 4	40			
PATIENT 5	90	85	78	60

		BASELINE	3 MONTHS	6 MONTHS	12 MONTHS
N	Valid	5	4	4	4
	Missing	1	2	2	2
Mean		53.40	51.00	54.75	44.00
Median		46.00	51.00	61.00	48.00
Std. Deviation		20.635	27.869	29.409	19.596

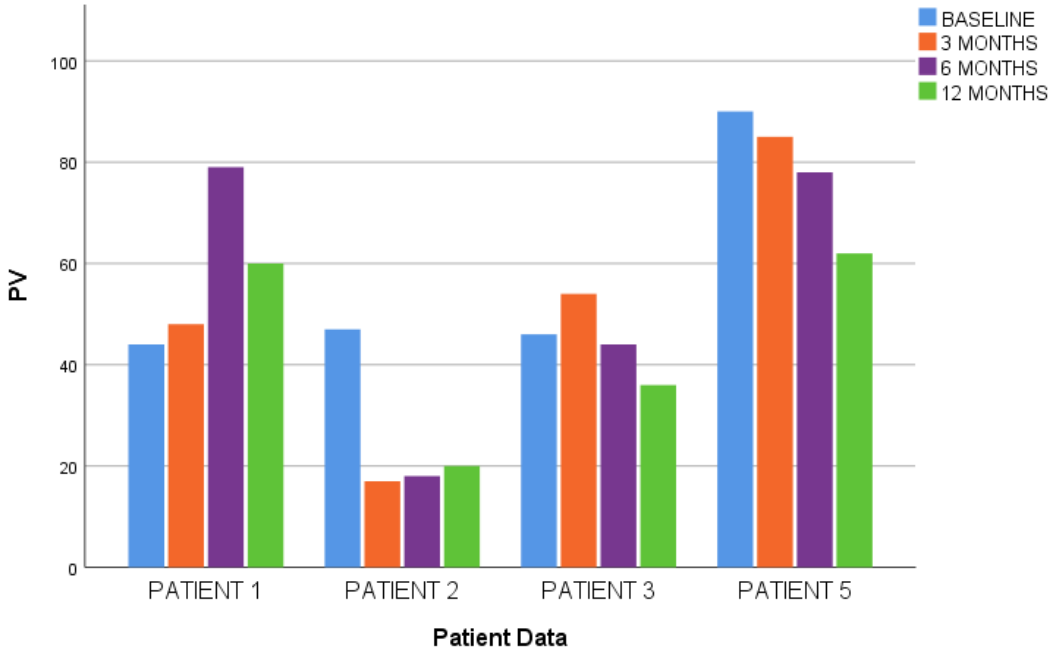


Table 4: comparison of IPSS SCORE in patients at presentation, at 3 months, 6 months and 12 months

Column1	BASELINE	3 MONTHS	6 MONTHS	12 MONTHS
PATIENT 1	22	11	7	7
PATIENT 2	30	10	8	7
PATIENT 3	7	14	8	6
PATIENT 4	20			
PATIENT 5	25	15	9	6

		BASELINE	3 MONTHS	6 MONTHS	12 MONTHS
N	Valid	5	4	4	4
	Missing	1	2	2	2
Mean		20.80	12.50	8.00	6.50
Median		22.00	12.50	8.00	6.50
Std. Deviation		8.585	2.380	.816	.577

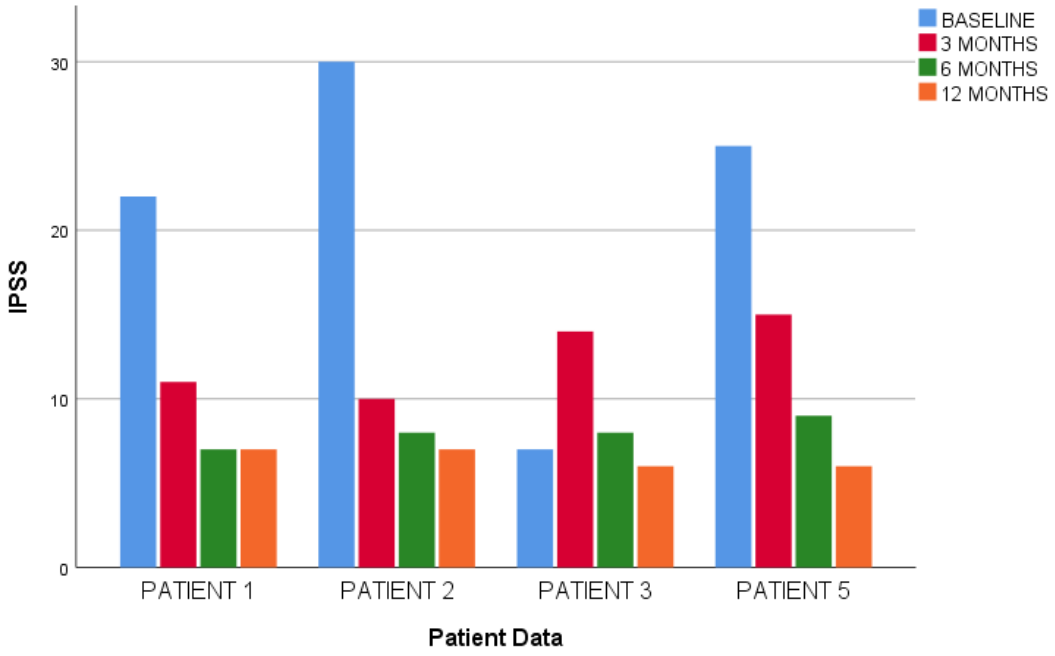


Table 5: comparison of Maximum flow rate (Qmax) as determined by uroflowmetry in patients at presentation, at 3 months, 6 months and 12 months

Column1	BASELINE	3 MONTHS	6 MONTHS	12 MONTHS
PATIENT 1	7.1	14	15.6	18
PATIENT 2	5.5	18.4	19	22
PATIENT 3	6.5	7	14	16.5
PATIENT 4	12			
PATIENT 5	8	12	15.6	19.2

		BASELINE	3 MONTHS	6 MONTHS	12 MONTHS
N	Valid	5	4	4	4
	Missing	1	2	2	2
Mean		7.820	12.850	16.050	18.925
Median		7.100	13.000	15.600	18.600
Std. Deviation		2.5074	4.7283	2.1063	2.3286

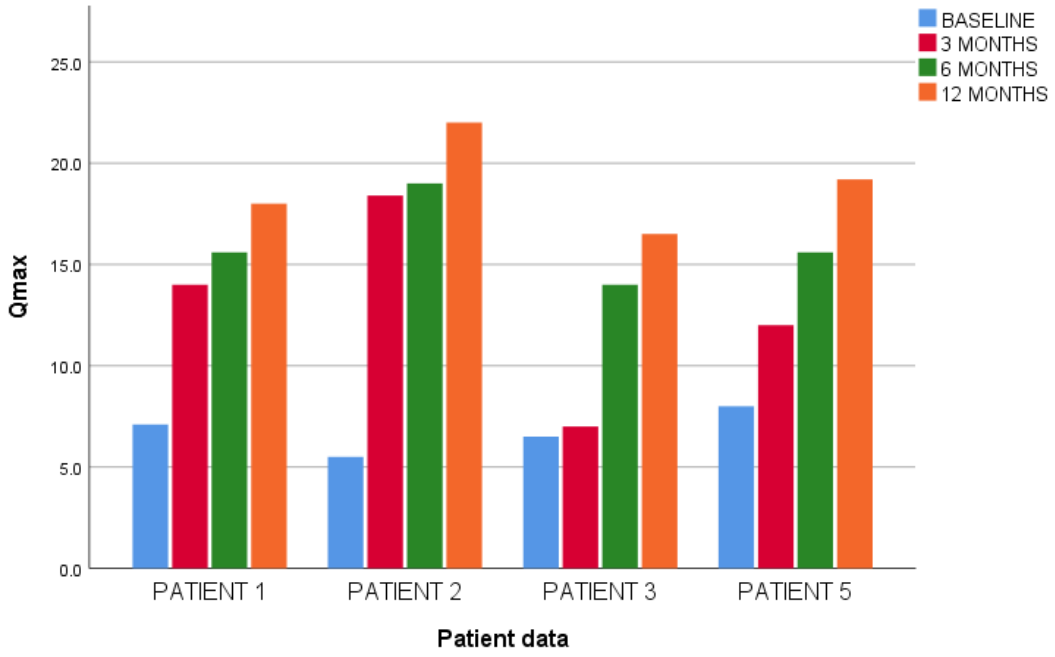
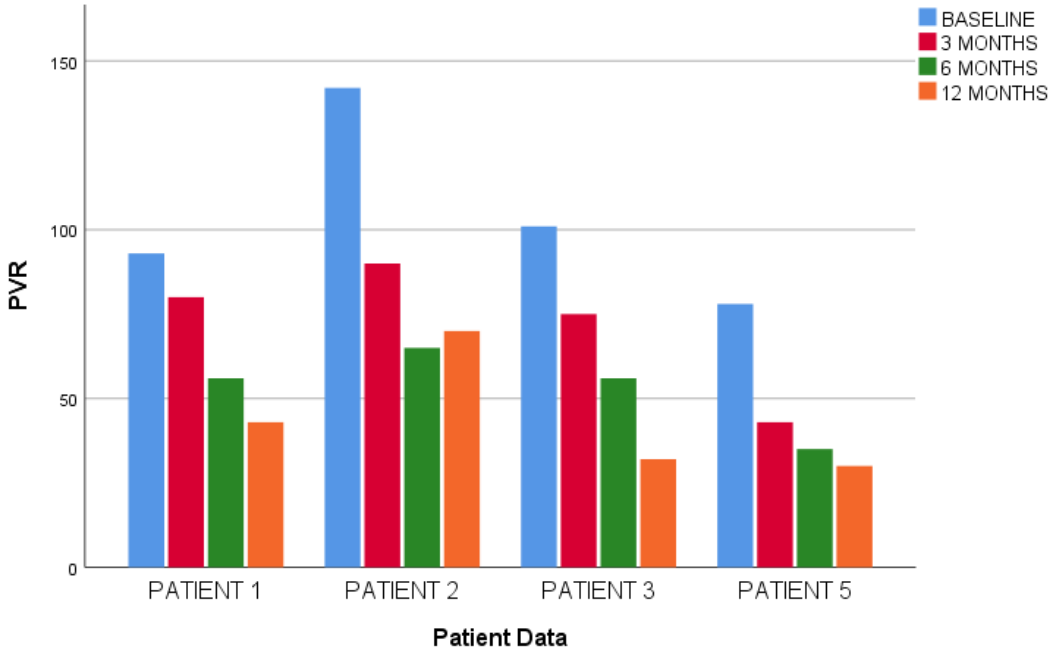


Table 6: comparison of Post residual volume (PVR) as determined by ultrasound in patients at presentation, at 3 months, 6 months and 12 months

Column1	BASELINE	3 MONTHS	6 MONTHS	12 MONTHS
PATIENT 1	93	80	56	43
PATIENT 2	142	90	65	70
PATIENT 3	101	75	56	32
PATIENT 4	80			
PATIENT 5	78	43	35	30

		BASELINE	3 MONTHS	6 MONTHS	12 MONTHS
N	Valid	5	4	4	4
	Missing	1	2	2	2
Mean		98.80	72.00	53.00	43.75
Median		93.00	77.50	56.00	37.50
Std. Deviation		25.936	20.314	12.728	18.410



DISCUSSION

The results of the present study demonstrate that PAE presents a safe and effective minimally invasive alternative for treatment of BPH.

LUTS is a common complaint resulting from BPH and is one of the most common urological diseases in aging men. Over past three decades, treatment of BPH has been changed significantly. Now, most of the patients are offered medical therapy with good result and those who require surgical intervention havetypically been offered TURP, and laser prostatectomy, such as HoLEP, most recently. In this scenario, the development of prostate artery embolization which can lead to reduced volume without surgical removal of tissue is promising. It can be implemented on other areas as well, such as, in treatment of symptomatic uterine fibroids,

embolization is now a well-established alternative to more invasive surgical procedures with favorable results [12].

PAE includes selective cannulation of bilateral prostatic arteries and injection of microspheres into both sides to induce diffuse ischemia in prostate parenchyma. Prostate artery embolization can be performed from a femoral or radial approach [13]. Mostly, the primary source of prostate blood supply is the left and right prostatic arteries forming a characteristic rhomboid plexus by bending around the gland and terminating into numerous branches going to the center of the prostate gland. Preoperative or intraoperative examination showed a single artery that supplies the prostate can be found in 96.4% of cases. In 1.1% two unilateral prostatic arteries that supply the gland are detected, and in 2.5% of cases even three prostatic arteries are identified [13, 14]. The prostatic arteries branch from the anterior portion of the internal iliac artery or from the main arterial trunk. Mostly, the prostate gland has blood supply from vesico-prostatic trunk (truncusvesico-prostatic) which is formed by the fusion of the lower cystic artery and the PA. Sometimes, middle rectal artery can supply blood supply additionally. [15]

On selective angiograms, three groups of vessels can be clearly seen: The first group or the stromal branches supplies the gland tissue itself; the second group or the capsular branches supply the surface of the gland; and the third group of vessels or periurethral vessels supply the length of the prostate part of the urethra. Main effect of intervention is achieved by selective embolization of the cranial branch with PAE, although embolization of the caudal branch is also necessary for achieving good clinical result.

The most common anastomosis is a direct communication of the PA with the cystic arteries. However incidental embolization of the lower cystic artery is usually not accompanied by any clinical symptoms because patency of the contralateral artery is maintained [14]. Secondly, ingress of embolus particles into anastomoses of PA with superior, middle and lower rectal arteries can cause ischemic damage to the intestine, paresis and even necrosis of the sphincter of the rectum. The most noticeable clinical manifestations occur due to temporary disturbance of soft tissue trophism and erectile dysfunction in case of nontargeted embolization of PA anastomoseswith peripheral branches of the dorsal artery of the penis. Similar manifestations occur in the case of embolization of anastomosis of PA with terminal branches of the internal genital and obturator artery. [13]

In this paper we have described the results of a prospective, multi-center, single-arm study the results of which showed that PAE is an effective method for treating BPH, with a good safety profile. Our results are consistent with evidence from randomized trials from the last 5–8 years.

DeMeritt et al. performed the embolization of the right lower cystic artery in 2000 on a 76-year-old man with incurable macrohematuria caused by BPH. It was noted that the International Prostate Symptom Score (IPSS) improved from 24 to 13 points and prostate volume decreased by 40% from 305 to 190 ml in 12-month follow-up. [16]Whereas, our results showed

improvement in IPSS score of about 19 points and decrease in PV of about 50cc in 12 month follow-up.

In a study conducted in Russia by Yakovets et al. (2010) in 2010, 38 patients with BPH underwent PAE. Qmax improved in all patients, prostate volume decreased, and 4 patients had cystostomy drainage removed. [17]. Improvement in Qmax is consistent with our study however significant decrease in PV was not noted.

In 2011, Pisco et al. (2011) published the results of a study describing effectiveness of PAE in patients with lower urinary tract symptoms (LUTS) because of BPH. 14 out of 15 patients reported significant decrease in IPSS with a mean of 6.5 point, peak urination rate increased by 3.85 mL/sec, and prostate volume decreased of 26.5 mL.[18]vs decrease in IPSS of mean 19.3 points, increase in Qmax of 10.1 ml/sec and decrease in prostate volume by 0.9 ml as evident in our study.

Kurbatov, Sitkin, et al, were the first from Russia to present a report on joint work with A.I. Neymarkin 2011 at the congress of American Urological Association (AUA). published data on PAE treatment of 106 patients with a prostate volume of more than 80 cm^3. Patients treated with TURP showed greater degrees of improvement in the IPSS, peak urinary flow, and postvoiding residual urine volume at 1 and 3 months, as well as greater reductions in the PSA level and prostate volume at all follow-up time points, when compared with the PAE group ($P < .05$).[14]Whereas, when compared with the results of a randomized controlled study in 114 patients with BPH divided in 2 equal groups in 2014 by Gao et al. showed similar values of maximum urination flow rate (Qmax) and postvoid residual as well as similar improvement in IPSS and QoL scales were noted In patients of both groups, 24 months after the operation.[19]

PAE is not inferior to TURP as evident by the drop in IPSS score observed at 6 months post procedure. We observed a mean drop of 19.3, which is similar to that reported for patients in the randomized study by Carnevale 2015[20]and recent systematic review by Pyo and Cho [21], across seven randomized studies. Talking about other quantifiable urological findings, the Q_{max} and PVR findings also showed improvements similar to those reported by Pyo and Cho. In our study we observed about 20% reduction in prostate volume. This was comparable to 29% reported by Pyo and Cho, and the 19% reported for original PAE by Carnevale et al.

Our approach was similar to UK-ROPE study, where each clinical team was expected to make a clinical judgment on the suitability of a patient for PAE without any inclusion and exclusion criteria, in an 'all-comers' design as if PAE were a freely-available procedure in a real-world setting.[22]

The PAE technique has a low complication rate. In our embolization cohort, we had one patient with fever, which was settled with conservative treatment. In one patient initially worsening of symptoms was observed in first 3 months but then symptoms were improved with good improvement in IPSS noted.

To avoid the risk of non-target embolization, our interventional radiologist underwent formal training. Digital subtraction angiography was used to analyze the anastomosis carefully on each

side in every patient. No cases of rectal or bladder necrosis were recorded. Unlike traditional prostate surgery there is minimal blood loss after PAE [23], therefore, anemia, clotting disorders and anticoagulant therapy are not contraindications for PAE.None of the more serious complications that are often associated with TURP, such as TUR syndrome or blood transfusion, were observed. These complications carry a 1.4% and 4.1% risk in TURP, respectively, making them very unlikely in our study.

Patient-reported complications were favorable for PAE, particularly compared with the surgical alternatives. Throughout follow-up, patients in the PAE group reported lower pain on average and no haematuria was observed.

PAE may also be compared with the UroLift implant, as this is another emerging, less invasive alternative to transurethral surgical options. [25] Our findings are comparable to those presented in a recent meta-analysis, which reported the following improvements at 12-months post-Urolift treatment: an IPSS improvement of −10.5 points, a +3.5-mL/s improvement in Q_{max}, and a small improvement in PVR of −5.7 mL. That study also presented economic data in which day-case Urolift treatment was cost-saving compared with inpatient TURP and HoLEP.[26]Mean length of postoperative stay after Urolift was of 0.25 days. Whereas, our findings in the study show that 100% of PAE cases were either performed as outpatient or day case procedures, with a similar mean length of stay of 0.33 days (median 0.0 days), and therefore has the potential for cost savings once implemented. A full economic study would need to be performed to explore this potential fully.

We faced some challenges in this study, including specific difficulties in arranging finances for PAE for recruited patients. A limitation of the study was limited finances so the procedure could be arranged for only 5 patients as our targeted population belongs to lower to lower middle socio-economic class. We used face-to-face questionnaire system to collect IPSS data from our patients in out-patient departments. For evaluation of prostate volume and post void residual, we got ultrasound scans.

In conclusion, this study adds to the growing evidence that indicates that PAE is a safe and efficacious procedure, providing clinically significant improvements in IPSS score over a 6-month follow-up period. Comparative analysis showed that, while PAE not only has similar efficacy as TURP in IPSS improvement, but also offer other benefits to patients such as shorter hospital stay, faster return to normal activities, and reduction in some adverse effects. In the right type of patient, there is little to be lost by trying PAE, as it is safe, with minimal complications and a modest failure rate. Our findings are largely in agreement with those in recently available RCTs and we recommend that cost-effectiveness studies are now needed in order to evaluate the economic benefits of PAE in standard practice.

CONCLUSION

Prostatic artery embolization has emerged as an alternative to surgical treatments for BPH. Patient selection and refined technique are essential for good results. Technical limitations to this technique are related to elderly patients with tortuous and atherosclerotic vessels, anatomical

variations, difficulty visualizing and catheterizing small diameter arteries feeding the prostate, and the potential risk of bladder and rectum ischemia.

The data of our study indicate that the selective embolization of the prostatic arteries is an effective and safe method for minimally invasive treatment of BPH. PErFecTED embolization is a more effective method than classical PAE. Significant improvement IPSS and Qmax were observed in individuals who underwent PAE and the results are comparable to current gold standard i.e., TURP.

DECLARATION OF CONFLICTING INTERESTS

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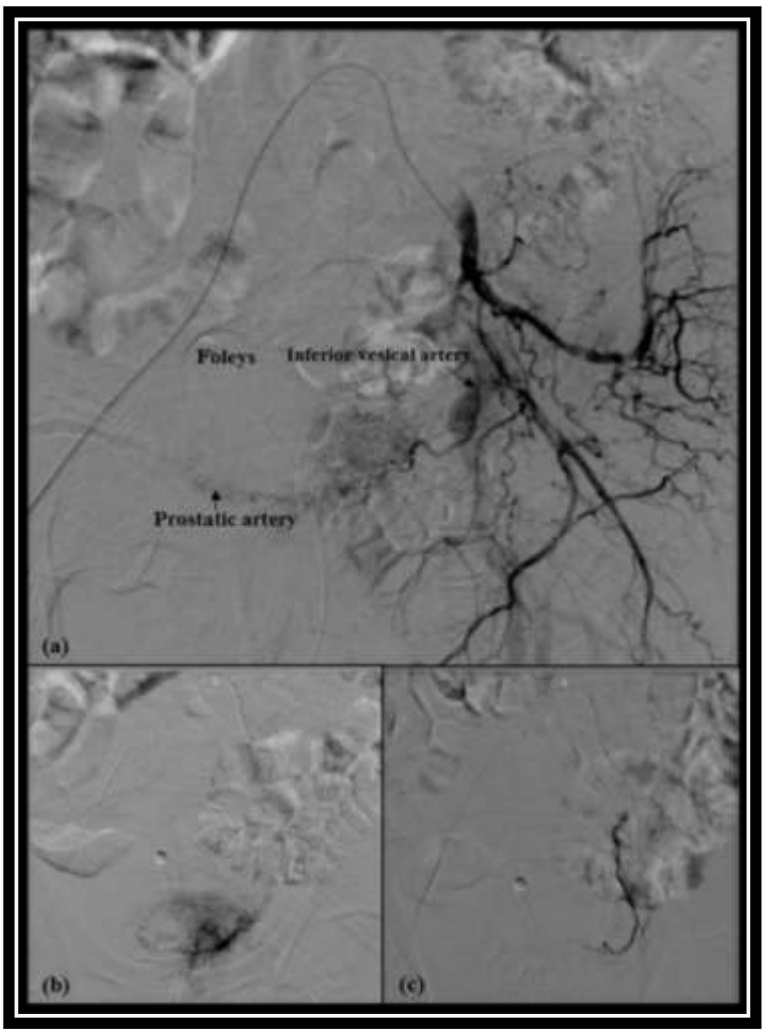

Figure 1: (a) Pre-embolization angiogram performed with C2 catheter, demonstrates left inferior vesical and prostatic arteries. Urinary bladder catheterized with Foley's catheter

(b) Super-selective angiogram of left prostatic artery shows prostatic blush.

(c) Post embolization super-selective angiogram shows exclusion of prostatic blush/ hypervascularity.

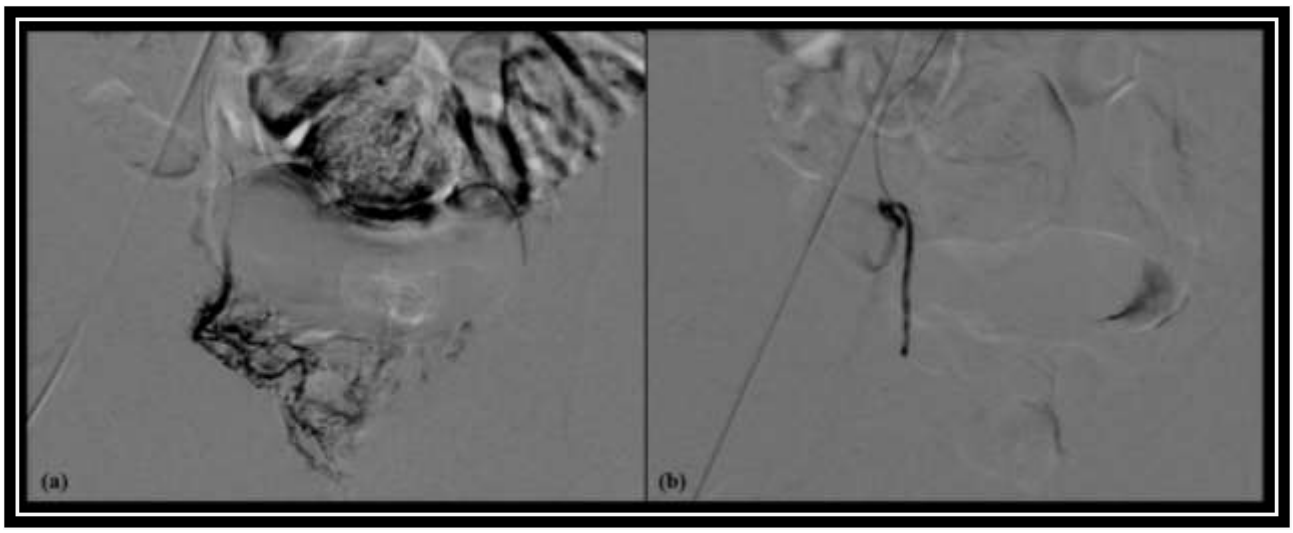

Figure 2: (a) Super-selective angiogram of right prostatic artery shows prostatic blush.

(c) Post embolization super-selective angiogram shows exclusion of prostatic blush/ hypervascularity.

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