Prostatic Artery Embolization for Treatment of Symptomatic Benign Prostatic Hyperplasia Patients: Short- and Intermediate- term Outcome

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Abstract:

Background: Benign prostatic hyperplasia (BPH) is one of the most common diseases in ageing men and is the most common cause of lower urinary tract symptoms (LUTS). There are several treatment options for benign prostatic hyperplasia. **Aim:** This study aims to evaluate the effectiveness, safety, morbidity and short- and intermediate-term results of prostatic artery embolization (PAE) for symptomatic BPH patients with moderate to severe LUTS. **Methods**: A prospective cohort study was carried out on 33 BPH patients, with moderate to severe LUTS. PAE was performed for patients and they were followed up at 3, 6 and 12 months post-procedural. **Results and conclusion:** Post-embolization follow-up results revealed significant reduction in the mean prostatic volume, post-voiding residual urine volume, severity of symptoms , total prostate specific antigen (PSA) level as well as significant improvement in patients' quality of life (QoL). Meanwhile, no statistically significant changes were found in the erectile function post-procedural. Future researchers are recommended to replicate this study with longer follow-up periods, especially multi-center randomized controlled trials, using different types of embolic agents.

Key words: Prostatic Artery Embolization; Prostatic; Hyperplasia

Introduction

Benign prostatic hyperplasia (BPH) is a non-cancerous increase in the size of the prostate [1] which may be complicated by urinary tract infections, bladder stones and chronic kidney problems [2]. Its symptoms may include frequent urination, trouble starting to urinate, weak stream, urinary retention or urinary incontinence [1].

Benign prostatic hyperplasia is one of the most common diseases in ageing men and is the most common cause of lower urinary tract symptoms (LUTS). The prevalence of BPH increases after the age of 40 years, with a prevalence of 8%–60% at the age of 90 years [3]**.**

There are several treatment options for BPH and the treatment choice depends upon age of the patient and his overall health, the size of the prostate and the severity of symptoms. Treatment options include: medications (alpha blockers, 5-alpha reductase inhibitors, combination drug therapy and tadalafil), transurethral resection of the prostate (TURP), transurethral incision of the prostate (TUIP), transurethral microwave thermotherapy (TUMT), transurethral needle ablation (TUNA), laser therapy, prostatic urethral lift (PUL), embolization and open prostatectomy [4].

Although the TURP is still considered the gold standard for BPH surgical treatment, yet it has some complications including morbidity of about 20% and other complications as ejaculatory dysfunction, erectile dysfunction, urethral strictures, urinary tract infection and post-operative bleeding [5]. Moreover, some patients are unfit for surgery based on their comorbidities [6].

New minimally invasive procedures have been developed for patients unfit for or refusing surgery, with a safer profile that is fundamental for QoL after treatment and equally effective to surgical techniques as well as sparing costs with a durable relief of symptoms [7].

Among the available minimally invasive procedures, the prostatic artery embolization (PAE) can be considered an emerging technique which is performed by interventional radiologists under radiological guidance through selective prostatic arteries embolization [8] which causes the prostate to decrease in size [4] and hence clinical improvement and this is the rationale for PAE [9].

This study aims to evaluate the effectiveness, safety, morbidity and short- and intermediate-term results of PAE for

symptomatic BPH patients with moderate to severe LUTS. For this purpose , pre- and post- embolization results were compared as regards : MRI estimated mean prostatic volume , US estimated post voiding residual urine volume , IPSS score , QoL , IIEF-5 score and total PSA level .

Materials and Methods Study

design and time frame

This study was a prospective cohort study carried out on BPH patients with moderate-to-severe LUTS at Nasser Institute for research and treatment during the period July 2016 – October 2019.

Study population

The target population for this study were BPH patients with moderate-to-severe LUTS who arrived to hospital and were fulfilling inclusion and exclusion criteria.

Inclusion criteria: BPH patients with moderate to severe LUTS subsequent to BPH and were resistant to medical treatment for 6 months (International prostate symptom score "IPSS" not improving or flow rate less than 15ml/sec).

Exclusion criteria: BPH patients who have active urinary tract infection, allergy to iodinated contrast, positive prostatic biopsy for malignancy or history of prostate malignancy, history of neurogenic bladder or un-regulated coagulation parameters.

The study included 33 BPH patients.

Study tools

1) Pre-procedural assessment:

Patients' clinical symptoms of the lower urinary tract were evaluated using self-administered questionnaires: International Prostatic Symptoms Score (IPSS), the Quality of Life (QoL) and International Index Erectile Function (IIEF-5) [2]. Urine analysis and culture were performed.

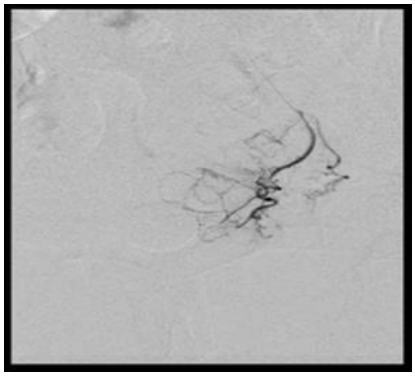
A. Magnetic resonance imaging (MRI), 1.5 Tesla MR Scanner were performed to assess the prostate and related structures with post intravenous (IV) contrast dynamic imaging. Computed tomography (CT) pelvis without and with IV contrast administration and CT angiography for pelvic arteries were performed for one patient.
B. Prostate diameters, shape, volume, and post-void residual volume were assessedbytransabdominal ultrasonography and Transrectal ultrasound (TRUS). TRUS was performed for four patients and TRUS biopsy was performed for one patient with normal PSA and a suspicious lesion on TRUS and the biopsy result came negative.

C. Serum total prostate specific antigen (PSA) levels were measured in all cases.

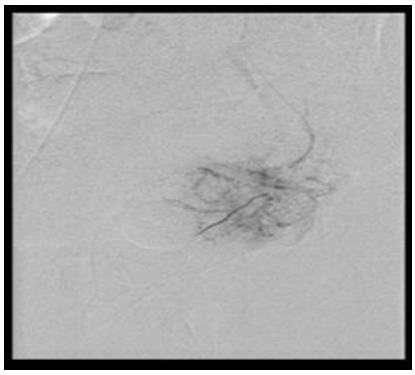
Patients were given ciprofloxacin, 500 mg twice daily 2 days before the procedure and continued for seven days following PAE. In addition, Omeprazole 20 mg once daily and Naproxen 1,000 mg, were prescribed twice daily. Patients were admitted one day before the procedure. Urinary 14 F Folly's catheter was inserted; the balloon was inflated with 6 ml saline and 4 ml contrast mixture on the table.

2) Procedure:

Prostate embolization was performed in the therapeutic angiography suite (Innova 9100, GE Medical Systems). Unilateral puncture approach through the right femoral artery was used. The left internal iliac artery and its anterior division were catheterized using 5-F RUC. Digital subtraction angiography (DSA) was obtained in 35° and 45° with 10° craniocaudal angulations in the right oblique. The prostatic vessels were selectively catheterized with a coaxial microcatheter using micro-wire. Another angiogram was performed to confirm the position of the catheter in the prostatic artery followed by injection of 200µ of nitroglycerine. The microcatheter was then advanced distally into the prostatic artery before embolization, and an angiogram was obtained, confirming the position of the microcatheter distally in the artery and embolization was performed (fig. 1).



(A)



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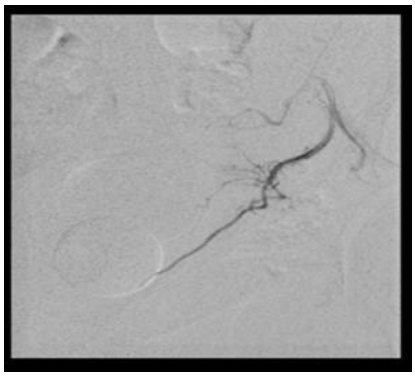


(C)

Figure 1: Digital subtraction angiography, (A) Right internal iliac angiogram showing prostatic arteries (B) Superselective catheterization of right prostatic artery. (C) Post successful embolization of right prostatic artery.

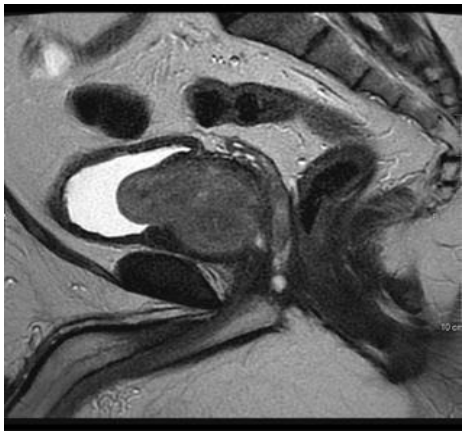
Embolization was performed using diluted tri-acryl gelatin microspheres 300-500 µm under fluoroscopy. One ml of the embolizing material was injected followed by washing the catheter with one ml saline, then two ml saline, it continued until complete stasis of flow at prostatic artery was achieved.

After completion of the embolization of the left prostatic arteries, the microcatheter was removed, and the Waltman loop was formed on the RCU; the right prostatic arteries were cannulated and embolized in the same manner. Post-embolization pelvic angiogram was performed confirming proper embolization without acute complication; the sheath was removed and hemostasis was secured by manual compression.

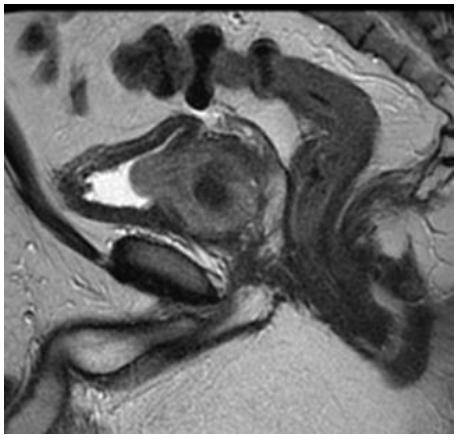
Bilateral embolization was performed for 29 patients and was technically successful. The procedure was repeated for one patient with unsuccessful first one. The second procedure was done after 6 months' interval with unilateral approach [left sided] embolization due to difficulty in demonstration of prostatic arteries. Unilateral approach [embolization] was adopted in four patients. No major complications reported, most of patients were discharged from hospital the next post- operative day.

3) Post-procedural assessment :

Prostatic specific antigen (PSA) was assessed at 24 hours after the procedure and then at 12 months post-procedural. MRI pelvis (fig. 2), Pelvic US and residual volume calculation were performed at 3, 6 and 12 months post-procedural. IPSS and QoL were assessed at 3, 6 and 12 months post-procedural. IIEF-5 was assessed at 6 and 12 months post-procedural.



2(a)



2 (b)

Figure 2 : (A) Pre-procedure MRI study Sagittal T2 WI, showing enlarged prostate, elevating UB base with estimated prostate Volume 140 c.c. (B) Post procedure follow up MRI after 6 months: Sagittal T2 image, showing decreased prostatic volume measuring 85 c.c.

Statistical analysis

Data were collected, revised, coded, tabulated and analyzed using the statistical package for social science (IBM SPSS) version 20. Quantitative data were presented as means and standard deviations and one way ANOVA test was used for comparison between more than two groups in this case. Meanwhile, qualitative variables were presented as numbers and percentages, Chi-square test was used for comparison between groups of qualitative variables and Fisher exact test was used when the expected count in any cell was found to be less than 5. The confidence interval was set to 95% and the margin of error accepted was set to 5%. So, the p-value was considered significant at the level of < 0.05.

Results

The mean prostatic volume was significantly reduced (p=0.001) in post-embolization MRI studies [after 3 months, 6 months and 12 months] when compared to pre-embolization MRI studies (table 1 and fig. 3).

A significant (p=0.001) reduction in the estimated mean residual volume in post-embolization US studies [after 3 months, 6 months and 12 months] occurred in comparison to pre-embolization US studies (fig. 3) .

As regards the severity of prostatic symptoms , a significant reduction (p=0.001) in the mean IPSS score in post-embolization follow-up visits [after 3 months, 6 months and 12 months] was detected in comparison to pre-embolization mean score.

Together with significant changes (p=0.001) in the quality of life in post- embolization follow-up visits [after 3 months, 6 months and 12 months] in comparison to pre-embolization visits with increase in the percentages of mixed and mostly satisfied patients and decrease in the percentages of mostly dis-satisfied, unhappy and terrible patients (fig. 4).

Meanwhile, no statistically significant changes were found in the mean IIEF-5 score in post-embolization follow-up visits [after 6 months and 12 months] when compared to pre- embolization mean score. And as for the PSA level, it increased significantly at 24 hours after the procedure, with a mean 23 times relative to its baseline value and was dropped back after 12 months.

Table (1): Comparison between pre-embolization and post-embolization MRI estimated mean prostatic volume:

	Pre embolization (No.=33)		After 3 months (No.=27)		After 6 months (No.=29)		After 12 months (No.=24)		One way ANOVA	
	Mean	SD	Mean	SD	Mean	SD	Mean	SD	f	p value
MRI Prostate Volume (mg)	96.94	43.41	66.96	24.43	54.35	23.59	62.00	23.43	12.110	<0.001

	Post hoc test		
	Pre vs after 3 months	Pre vs after 6 months	Pre vs after 12 months
MRI Prostate Volume (mg)	0.001	0.001	0.001

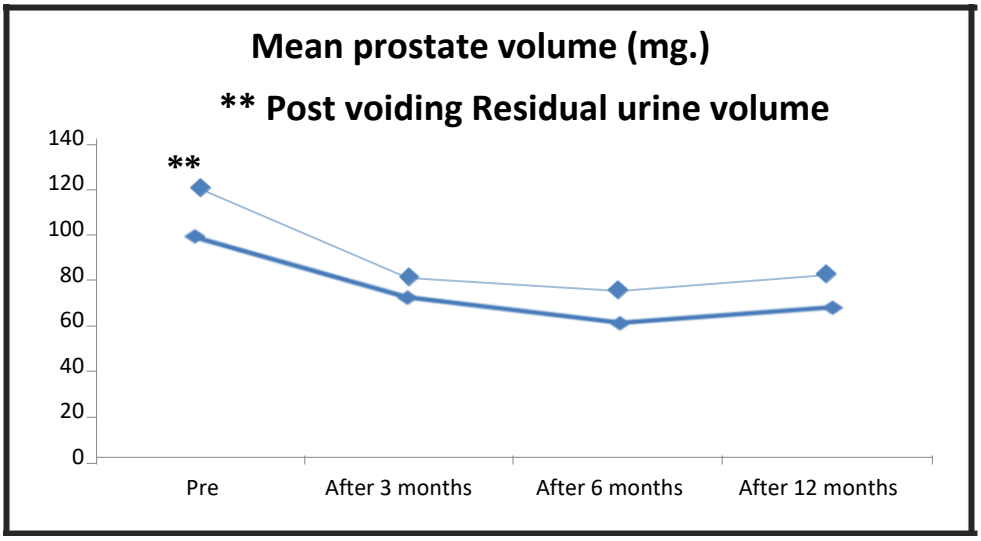


Figure (3) : Graph of mean MRI prostate volume and mean US estimated post voiding residual urine (**) pre- and post- embolization.

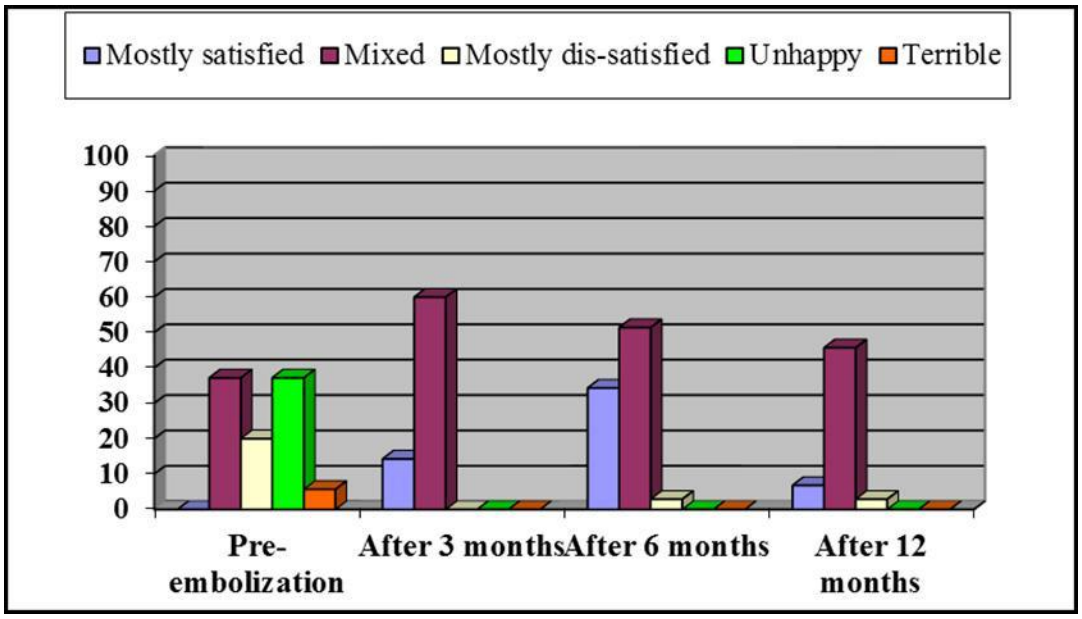


Figure (4) : QoL pre- and post-embolization

Discussion

The current study revealed that there was a significant reduction in the mean prostatic volume in post-embolization MRI studies [after 3 months, 6 months and 12 months] in comparison to pre-embolization MRI and this decrease in the prostatic volume following PAE is explained by the fact that prostate ischemia leads to prostatic volume reduction [9] .

Concurrently, there was significant reduction in the estimated mean residual volume in post-embolization US studies in comparison to pre-embolization. Similar findings of significant prostatic volume and corresponding mean residual volume reduction were reported in a number of studies [10, 11, 12].

As regards the severity of prostatic symptoms, the present study revealed that there was a significant reduction in the mean IPSS score in post-embolization follow-up visits [after 3 months, 6 months and 12 months] in comparison to pre-embolization mean score. Similar findings of reduced severity of symptoms with significant reduction of IPSS following PAE in BPH patients from baseline in a number of studies [10, 11, 12, 13], so that, it was concluded that BPH patients with failed medical treatment who are at high risk for surgery

and/or anesthesia could be treated safely and effectively through PAE.

Concerning the QoL following PAE, the present study revealed that there were significant changes in the quality of life in post-embolization follow-up visits [after 3 months, 6 months and 12 months] in comparison to pre-embolization visits with increase in the percentages of mixed and mostly satisfied patients and decrease in the percentages of mostly dis-satisfied, unhappy and terrible patients. Similarly, significant improvement in QoL following PAE in BPH patients was reported in previous studies [11, 13].

On the other hand, the current study revealed that there were no statistically significant changes in the mean IIEF-5 score in post-embolization follow-up visits [after 6 months and 12 months] compared to pre-embolization mean score. This finding comes in line with other studies [10,11] .

For the PSA level, the present study revealed that the mean total PSA increased significantly at 24 hours after the procedure , with a mean 23 times relative to its baseline value and was dropped back after 12 months and this increase in the PSA level might be explained by prostate ischemia following PAE [10]. This comes in line with what was reported in a previous study [10].

Conclusion

PAE is an effective treatment method for BPH patients with moderate-to-severe LUTS , in whom medical therapy has failed and are not candidates for surgical treatment and those refusing surgery. Careful embolization of bilateral prostatic arteries is associated with good clinical outcomes. PAE would soon prove effective primary alternative to the available surgical treatment.

Recommendations

Future researchers are recommended to replicate this study with longer follow-up periods to bring additional information and demonstrate the recurrence rate of symptomatology. More studies are also needed, especially multi-center randomized controlled trials, using different types of embolic agents.

Limitations

One of the limitations of this study is the relatively small sample size which did not provide much statistical power for the results**.** Another limitation is the relatively limited follow-up period. A third limitation is that only PVA particles were used for our procedures and further investigation using different types of embolic agents is recommended .

Ethical approval

The study protocol received approval from Institutional Review Board (IRB) – Benha Faculty of Medicine. Administrative approval and official permissions were obtained at Nasser Institute for research and treatment prior to data collection. Verbal consent was obtained from patients included in the study following guarantee of data confidentiality to them.

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