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Review Article

Review of Prostate Artery Embolization for Benign Prostatic Hypertrophy

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Abstract

Lower urinary tract symptoms from benign prostatic hyperplasia are a very prevalent disease process which affects more than 40% of men over age 60. When LUTS from BPH become medically refractory, transurethral resection of the prostate and prostatectomy have been the gold standards for treatment. While the efficacy of these procedures has been clearly delineated, they are also associated with significant peri-operative morbidity. Prostatic artery embolization is a new treatment for medically refractory benign prostatic hyperplasia. The data for this treatment is still limited but multiple studies have been published. This article reviews the available literature on this subject.

ABBREVIATIONS

AUA-American Urological Association; BPH-Benign Prostatic Hyperplasia; IIEF-International Index of Erectile Function; IPSS-International Prostate Symptom Score; LUTS-Lower Urinary Tract Symptoms; PAE-Prostate Artery Embolization; PSA-Prostate Specific Antigen; PVR-Post Void Residual; TURP-Transuretheral Resection of the Prostate; UTI-Urinary Tract Infection; QoL-Quality of Life; Qmax-Peak Urinary Flow Rate

INTRODUCTION

Lower urinary tract symptoms (LUTS) are an extremely common issue for men, especially as they age. The most common cause for LUTS in middle age and older men is benign prostatic hyperplasia (BPH) [1]. The prevalence of symptomatic BPH has been reported to be as high as 430 per 1000 men aged 60-69 [1] with the overall prevalence in men aged 40 to 80 estimated at 33% in the USA [2]. BPH leads to both a decline in urinary associated and overall quality of life [3,4]. Moreover, this condition results in significant economic burden with eight million visits made to physicians with a primary or secondary diagnostic code of BPH in the USA during 2000 [5].The estimated cost was 1.1 billion dollars without factoring in the cost of pharmaceuticals, with up to 38 million hours in lost productivity [5]. Initial therapy for symptomatic BPH is medical, typically 5-alpha-reductase inhibitors or alpha blockers. However, for many patients, this is not sufficient and intervention is needed. Transurethral resection of the prostate (TURP) has been considered for many years to be the gold standard therapy for medically refractory patients. Unfortunately, TURP has significant associated morbidity with reported rates of transfusions (8.6%), impotence (3.4%-32%), incontinence (1.8%-5%), bladder neck or urethral stricture (3.8%), and retrograde ejaculation (53%-75%) being higher than desired [6,7]. The high level of morbidity has led to great interest in developing a new, less invasive, way of treating this very common disease. Multiple new techniques are being developed including different types of laser therapy and prostatic urethral lift.

One of the minimally invasive techniques for treating BPH that has been studied over the last several years is prostate artery embolization (PAE). This article reviews the published data on PAE.

The medical subject headings (MeSH) terms “prostate artery embolization” and “benign prostate hyperplasia” were searched for in the pub med, Ovid, and Embase data bases. The date range of 1/1/2000-3/15/2016 was used. This resulted in 40 abstracts which were reviewed using the following inclusion and exclusion criteria. Inclusion criteria include studies in which patients were treated for BPH by PAE, reporting of international prostate symptom score (IPSS) before and after therapy, complication rates, as well as technical and clinical success rates. Studies were excluded if they comprised less than ten patients or were treating patients for reasons other than BPH. When a patient cohort was published several times the largest/most inclusive published patient cohort was included in the review to avoid over reporting.

Only published papers were considered, abstract presentations were not included.

A flow chart of article selection is presented in figure (1). Of the 40 articles, eight met the previously stated inclusion/exclusion criteria. The bibliographies of the papers were reviewed and two additional articles were identified. In total 10 articles meeting the inclusion/exclusion criteria are reviewed here. No meta-analysis or post publication statistical analysis was performed in this review.

RESULTS

Table (1) lists all articles reviewed by study design and reports the primary aim of the study and number of patients. Table (2) reviews the IPSS, quality of life (QoL), and erectile function as measured by the international index of erectile function (IIEF)questionnaire in each study while table 3 lists the peak urinary flow rate (Qmax), post void residual (PVR), and prostate volume. They are divided below into retrospective or single arm prospective studies and randomized controlled trials.

Retrospective and single arm prospective studies

In their largest published patient group, Pisco et al reported short and medium-term results from a prospectively collected group of 255 patients in 2013 [8]. The mean age of this cohort was 65.5; the patients had LUTS refractory to medical therapy for at least 6 months. They demonstrated a technical success rate, defined as ability to perform embolization of at least one prostatic artery, of 98% (250 of 255) patients. Eighty-eight percent of patients (220/250) were discharged the same day and the remaining 18% (30/250) were discharged the following

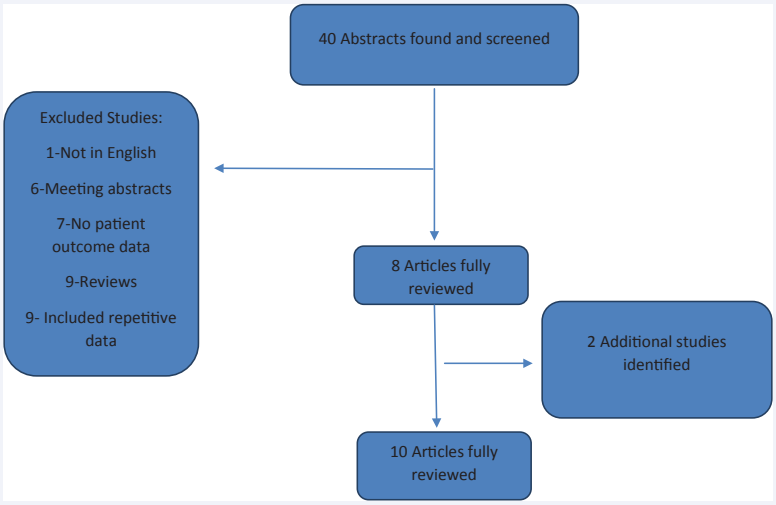

Figure 1 Flow chart of article selection.

Table 1: All studies by study design.

Study	Study purpose	Number of patients
Randomized Controlled Trials		
Gao et al [26]	To compare efficacy of TURP and PAE	107
Carnavale et al [28]	To compare efficacy of TURP and PAE	45
Prospective Single Arm Studies		
Pisco et al [11]	Determine efficacy and safety of PAE	255
Antunes et al [16]	Determine effectiveness of PAE in patients with urinary retention due to BPH	11
Bagla et al [17]	Determine efficacy and safety of PAE	20
Groso et al	Determine efficacy and safety of PAE	13
Kurbatov et al	Determine efficacy and safety of PAE in patients with prostates >80 cm^3	88
Wang et al	Determine efficacy and safety of PAE in patients ≥75 years old	157
de Assis et al	Determine efficacy and safety of PAE in patients with prostates >90 g	35
Retrospective review		
Amouyal et al	Determine efficacy and safety of PAE	32

TURP: Transurethral Resection of the Prostate, PAE: Prostate Artery Embolization

day. Clinical success, defined as IPSS reduction of at least 25% or total score lower than 18 points, and QoL improvement of 1 point or QoL score≤ 3 points, was seen in 81.9% (195/250) patients at 1 month. The Kaplan-Meier estimates of cumulative rates of clinical success at 3, 6, 12, 18, 24, and 30 months were 80.7%, 75.2%, 72%, 72%, 72%, and 72% respectively. The IPSS, QoL, Qmax, PVR, prostate specific antigen (PSA), and IIEF had all significantly improved at follow up as compared to baseline (p<0.0001 in all cases). They experienced one major complication, necrosis of inferior bladder wall requiring surgical repair. Minor complications consisted of burning sensation in the urethra and/or in the anus during the procedure (9.2%, 23/250), urinary tract infection (UTI) (7.6%, 19/250 though 14/19 had UTI prior to procedure), transient haematuria (5.6%, 14/250), transient hematospermia (4%, 10/250), small rectorrhagia (2.4%, 6/250), and balanitis (1.6%, 4/250).

Antues et al reported a group of 11 patients treated for urinary retention secondary to BPH with PAE [13]. No technical failures were described. Clinical success, defined as ability to void after Foley catheter removal, was demonstrated in 91% (10/11) of patients. The IPSS, which could not be evaluated at baseline, had decreased significantly at one year as compared to 30 days (p = 0.04). The QoL (p<0.001) and PSA (p=0.004) had improved significantly from baseline. They reported no major complications. Several minor complications were seen including mild transient pain in 82% (9/11), minimal rectal bleeding in 27% (3/11), 24 hours of diarrhea in 18% (2/11), and transient hematuria in 9% (1/11).

Bagla et al reported early findings from a prospective trial conducted in the United States to evaluate the efficacy and safety of PAE for BPH [14]. Seventy-two patients were screened and 20 patients underwent treatment in this single arm prospective study. Embolization was technically successful, defined as bilateral PAE, in 18 of 20 patients (90%). Unsuccessful embolizations were secondary to atherosclerotic occlusion of prostatic arteries. Clinical success, which was not defined, was seen in 95% of patients (19 of 20) at 1 month, with average American Urological Association (AUA) symptom score improvement of 10.8 points at 1 month (p=0.0001), 12.1 points at 3 months (p=0.0003), and 9.8 points at 6 months (p=0.06). QoL scores improved at 1 month (1.9 points; p=0.0002), 3 months (1.9 points; p=0.003), and 6 months (2.6 points; p=0.007). Sexual function improved by 34% at 1 month (p=0.11), 5% at 3 months (p=0.72), and 16% at 6 months (p=0.19). Prostate volume at 6 months had decreased 18% (n = 5; p=0.05). No minor or major complications were reported.

Grosso et al reported on 13 patients treated with PAE for medically refractory BPH [15]. The procedure was technically successful, defined as ability to embolize at least one prostatic artery, in 92% (12/13) of patients. They demonstrated an improvement in IPSS (mean 17.1 point improvement), QoL (mean 2.6 point improvement), and IIEF (2.6 mean point improvement).

Table 2: Results by questionnaire.

Study	Number of patients	month follow up/mean IPSS score (p† score)	QoL score mean (p† value)	IIEF (p value)
Pisco et al [11]	238 236 224 167 101 58 25 14 9	Baseline 24.1 1 months 12.2(<0.0001†) 3 months 11.0 6 months 11.5 12 months 10.4 18 months 10.1 24 months 9.0 30 months 8.1 36 months 9.1	Baseline 4.40 1 month 2.48(<0.0001†) 3 months 2.23 6 months 2.27 12 months 1.96 18 months 1.83 24 months 1.76 30 months 1.85 36 months 1.67	Baseline 18.9 1 month 20.6(0.002†) 3 months 20.9 6 months 20.5 12 months 20.1 18 months 20.4 24 months 18.7 30 months 20.0
Antunes et al[16]	11	Baseline N/A¥ 1 month 7.8 12 months 2.8 (0.04)	No numbers (0.001)	N/A
Bagla et al [17]	20 19 13 5	AUA Baseline 34.9 1 month 24.1(<0.0001) 3 months 24.1(0.0003) 6 months 21.8(0.06)	Baseline 7.69 1 month 5.79(0.0002) 3 months 5.61(0.003) 6 months 5.80(0.007)	Baseline 10.9 1 month 13.4(0.02) 3 months 13.0 6 months 11.2
Groso et al	13	Baseline 29.25 Mean 244 days 12.25	Baseline 4.33 Mean 244 days 1.75	Baseline 8.83 Mean 244 days 11.42
Kurbatov et al	88	Baseline 23.98 12 months 10.40(<0.05)	N/A	N/A
Wang et al	147	Baseline 26.5 Mean 20 months 8.5(0.017)	Baseline 5.0 Mean 20 months 1.5(0.024)	No numbers but p=0.656
Amouyal et al	32	Baseline 16.3 3 months 5.3(<0.0001) 6 months 8.9(0.006)	Baseline 5.4 3 months 2.5(<0.0001) 6 months 3.1(0.002)	Baseline 48.4 3 months 51.0(0.933) 6 months 49.1(0.893)
de Assis et al	33	Baseline 18.3 3 months 2.7(<0.0001)	Baseline 4.8 3 months 0.9(<0.0001)	N/A

† Random effects Gls regression. A significant p value is evidence that the mean value of an outcome variable changes over time. N/A: Not Available.
¥- not available because all patients had indwelling Foley catheters at baseline.

Table 3: Objective measurements.

Study	Number of pts	Qmax mL/s	PVR (mL)	PV (mL
Pisco et al [11]	238 236 224 167 101 58 25 14	Baseline 9.2 1 months 11.9(<0.0001†) 3 months 12.4 6 months 12.0 12 months 12.8 18 months 13.0 24 months 13.9 30 months 10.8	Baseline 102.9 1 month 65.6(<0.0001†) 3 months 59.2 6 months 62.8 12 months 51.7 18 months 75.4 24 months 91.9 30 months 95.3	Baseline 83.5 1 month 66.8(<0.0001†) 3 months 68.3 6 months 66.6 12 months 69.9 18 months 72.0 24 months 90.9 30 months 72.0
Antunes et al [16]	11	Baseline 0 Follow up 11.9 (0.001)	N/A	3 months mean reduction of 34.3%
Bagla et al [17]	20 19 13 5	Baseline N/A 1 month 8.64 3 months 9.26 6 months 7.40	N/A	Baseline N/A 1 month 82.7 3 months 66.4 6 months 56.7
Groso et al	10 5 2	N/A	N/A	3 months -32.8% 6 months -15.8% 12 months -33.9%
Kurbatov et al	88	Baseline 7.28 12 months 18.38(<0.05)	Baseline 75.25 12 months 18.38(<0.05)	Baseline 129.31 12 months 71.20(<0.05)
Wang et al	147	Baseline 7.5 Mean 20 months 15.5(0.015)	Baseline 140 Mean 20 months 20(0.012)	Baseline 79.5 Mean 20 months 50.5(0.033)
Amouyal et al	32	Baseline 9.2 3 months 16.7(0.007) 6 months 19.2(0.250)	Baseline 83.8 3 months 40.9(0.047) 6 months 122.7(0.625)	Baseline 90.7 3 months 65.7((<0.0001) 6 months 62.2(0.009)
de Assis et al	33	Baseline 7.1 3 months 15.2(<0.0001)	N/A	Baseline 135.1 3 months 91.9(<0.0001)

† Random effects Gls regression. A significant *p* value is evidence that the mean value of an outcome variable changes over time. N/A, not available.
Abbreviations: AUA: American Urological Association; IIEF: International Index of Erectile Function; IPSS-International Prostate Symptom Score; PVR: Post Void Residual; QoL: Quality of Life; Qmax: Peak Urinary Flow Rate

All 12 patients who were treated were considered to achieve clinical success, which was defined as improvement in symptoms. This group reported no minor or major complications.

Kubatov et al [16] reported similarly good mid-term outcomes of 88 patients treated in Italy. They did not report any technical failures. They too showed a significant improvement in mean IPSS ($p < 0.05$), mean Qmax ($p < 0.05$), PVR ($p < 0.05$), prostate volume ($p < 0.05$), and QoL score ($p < 0.05$) at 12 months. They experienced no minor or major complications as defined by the Society of Interventional Radiology reporting standards.

In 2015 and early 2016 a Chinese group reported on their experience with PAE in three different papers [17-19]. The third paper with the largest cohort is reviewed here. They reported a cohort of 157 patients with an average age of 69.5 years. They reported a technical successrate, defined as the ability to embolize both prostatic arteries, of 93.6% (147/157). No major complications were reported. Minor complications included urethral burning (15%, 22/147), hematuria (9.5%, 14/147), hematospermia (8.2%, 12/147), rectal bleeding (7.5%, 11/147), acute urinary retention (15.6%, 23/147), and inguinal hematoma (4.1%, 6/147). They demonstrated significant improvement in the IPSS (p=0.017), QoL (p=0.024), Qmax (p=0.015), and PVR (p=0.012).

In 2016 a French group published their experience with 32 consecutive patients, which were retrospectively reviewed [20]. They reported a 100% technical success, defined as ability to embolize at least one prostatic artery. Clinical success, defined as a decrease of 25% or 8 points of initial IPSS and/or Qmax > 8mL/sec or an increase of 25% of initial Qmax value, was noted in 84% (21/32) of patients. They showed significant improvement in IPSS (p=0.006), QoL (p=0.002), and PV (p=0.009) at 6 months. They reported the following complications: Transient hematospermia (9%, 3/32), transient rectorrhagia (9%, 3/32), and acute urinary retention (3%, 1/32).

Finally, Carnevale et al have published several studies [21,25]. The largest cohort thus far was a prospectively collected group of 35 patients who had very large prostates (>90 g), which ranged in size from 90-252 g [24]. This is a subset of patients that would typically require total prostatectomy. They achieved technical success, defined as bilateral prostatic artery embolization, in 94% (33/35) of patients. In their report of 3 month follow up, the mean prostate size decreased significantly ($p< 0.001$), QoL scores improved significantly ($p< 0.001$), Qmax increased significantly ($p< 0.001$), and IPSS improved significantly ($p< 0.001$). They also demonstrated a significant decrease in PSA ($p= 0.002$). They did have minor complications in a few patients which included two cases of rectal bleeding (6%), two cases of hematospermia (6%), one case of diarrhea (1%), and one case of urethral trauma secondary to Foley insertion (1%). No major complications were reported.

Prospective randomized controlled trials

In early 2014, Gao et al conducted and published a prospective

trial comparing TURP to PAE [26]. This demonstrated that while initially the TURP cohort showed significantly better improvement in IPSS, QoL scores, Qmax, and PVR at 1 and 3 months, these differences disappear and the treatments become equivalent at 6 months and remained equivalent at 12 and 24 months. The study reported minor complications in 40.7% (22/54) of PAE patients and 24.1% (13/53) TURP patients. The group also reported that 14.8% (8/54) of PAE and 7.5% (4/53) of TURP patients had major complications. These results were surprising in the number of complications experienced in the PAE group. These authors choose to label technical and clinical failures as major complications, which has been criticized by other authors [27]. The authors also choose to not consider hemorrhage requiring blood transfusion as a complication in the TURP cohort. The lack of any retrograde ejaculation, impotence, or incontinence in the TURPgroup has also raised questions regarding this study's adverse event reporting [27].

In 2016, Carnevale et al published a randomized controlled trial of 30 patients who were randomized to TURP or Pae [28]. They also compared a group of 15 prospectively collected patients who were treated with a modified PAE technique. They showed significantly improved IPSS in the TURP and modified PAE group as compared to the original PAE group. The QoL and Qmax scores were significantly better in the TURP group compared to the PAE and modified PAE groups. They noted complications of transient minimal rectal bleeding (6.7%, 2/30), hematospermia (6.7%, 2/30), reduction in ejaculate volume (10%, 3/30 PAE patients), transient pubic bone ischemia (3.3%, 1/30), and hematuria (6.7%, 2/30) in the PAE patients. They noted pollakiuria, dysuria, and hematuria in all patients in the TURP cohort for 2 weeks. They had a single serious adverse event in the TURP cohort, from venous sinus rupture of the prostatic capsule. One TURP patient was readmitted for hematuria requiring irrigation (7%), four suffered early urinary incontinence (27%), and all had retrograde ejaculation (100%). They concluded that TURP demonstrated better urine flow rates at the expense of higher complication rates.

DISCUSSION

PAE is a new therapy for BPH that has limited long term outcome data at this time. The early studies outlined above demonstrate some promising results. It will require more investigation to determine what role, if any, PAE should play in the treatment of these patients.

One issue with the current literature is the lack of consistent definition of even basic outcomes such as clinical and technical success. The majority of studies is retrospective, or single arm prospective trials with varied outcomes reporting, an issue discussed in a systematic review by Schreuder et al [29]. Unfortunately, the two randomized controlled trials that have been performed were not only small in scope but have been criticized for their design choices and adverse event reporting. Until, further larger randomized controlled trials can be performed, PAE therapy should be pursued with caution.

At the current state of knowledge it appears there are a few patient populations that may benefit from consideration of PAE after failing medical management for their BPH symptoms. The first are those patients who are deemed to be high risk from a surgical or anesthesia standpoint. This group would include American Society of Anesthesiologists (ASA) class III and IV patients. The ability to perform PAE under conscious sedation would allow these patients, who would not be good TURP or prostatectomy candidates, another treatment option. Other groups to consider for PAE would be those with refractory hematuria, an advanced age, and morbid obesity. Those patients who wish to maintain fertility may be considered for PAE instead of TURP given the high rates of retrograde ejaculation seen with TURP. These patients should be cautioned that while infertility has never been reported with PAE, it is a theoretical risk. Lastly, patients who are resistant to undergo surgical treatment, but poorly controlled on medications may benefit from referral for PAE evaluation. As PAE does not preclude future surgical intervention, these patients maintain all future treatment options.

Moving forward, it will be important to conduct further studies that investigate many aspects of PAE. The two small, randomized controlled trials [26,28] have shown similar IPSS outcomes at mid-term follow up with significantly higher improvement in uro flow parameters in patients undergoing TURP patients as compared to PAE. The durability of PAE will be important to determine and helpful in patient selection. The basic technique of PAE will also require further investigation and refinement. As demonstrated by the technique variation in one of the two randomized controlled trials [28]. Many basic questions need to be answered in this area to maximize efficacy.

In conclusion, while available data are limited, PAE appears to hold promise for the treatment of medically refractory BPH. The efficacy, and in particular the durability of symptomatic improvement after PAE in comparison to TURP, needs to be further evaluated. For these reasons it seems logical to consider PAE in patients who are poor candidates for prostatectomy or TURP.

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