Society of Interventional Radiology Multisociety Consensus Position Statement on Prostatic Artery Embolization for Treatment of Lower Urinary Tract Symptoms Attributed to Benign Prostatic Hyperplasia: From the Society of Interventional Radiology, the Cardiovascular and Interventional Radiological Society of Europe, Société Française de Radiologie, and the British Society of Interventional Radiology

Endorsed by the Asia Pacific Society of Cardiovascular and Interventional Radiology, Canadian Association for Interventional Radiology, Chinese College of Interventionalists, Interventional Radiology Society of Australasia, Japanese Society of Interventional Radiology, and Korean Society of Interventional Radiology

Justin P. McWilliams, MD, Tiago A. Bilhim, MD, PhD, EBIR, Francisco C. Carnevale, MD, PhD, Shivank Bhatia, MD, Ari J. Isaacson, MD, Sandeep Bagla, MD, Marc R. Sapoval, MD, PhD, Jafar Golzarian, MD, Riad Salem, MD, MBA, Timothy D. McClure, MD, Bruce R. Kava, MD, James B. Spies, MD, MPH, Tarun Sabharwal, MBBCh, FRCSI, FRCR, EBIR, Ian McCafferty, MD, MBBS, BSc, MRCP, and Alda L. Tam, MD, MBA

From the Department of Radiology, Division of Interventional Radiology (J.P.M.), David Geffen School of Medicine at UCLA, Los Angeles, California; Interventional Radiology Department (T.A.B.), St. Louis Hospital, Lisbon, Portugal; Department of Interventional Radiology (F.C.C.), University of Sao Paulo Medical School, Sao Paulo, Brazil; Department of Radiology and Division of Vascular Interventional Radiology (S.Bh.) and Department of Urology (B.R.K.), University of Miami Miller School of Medicine, Miami, Florida; Department of Radiology (A.J.I.), University of North Carolina, Chapel Hill, North Carolina; Vascular Institute of Virginia (S.Ba.), Woodbridge, Virginia; Department of Vascular and Oncologic Interventional Radiology (M.R.S.), Hôpital Européen Georges Pompidou, Paris, France; Department of Radiology, Division of Interventional Radiology and Vascular Imaging (J.G.), University of Minnesota, Minneapolis, Minnesota; Department of Radiology (R.S.), Northwestern University, Chicago, Illinois; Department of Urology (T.D.M.), Weill Cornell Medicine, Lefrak Center for Robotic Surgery, New York, New York; Department of Radiology (J.B.S.), Georgetown University Medical Center, Washington, DC; Department of Radiology (T.S.), Guys and St Thomas' Hospital, London, United Kingdom; Department of Clinical Radiology (I.M.), Queen Elizabeth Hospital Birmingham, Birmingham, United Kingdom; and Department of Interventional Radiology (A.L.T.), MD Anderson Cancer Center, Houston, Texas. Final revision received and accepted February 13, 2019. **Address correspondence to** J.P.M., c/o Elizabeth Himes, SIR, 3975 Fair Ridge Dr., Suite 400 N., Fairfax, VA 22033; E-mail: jumcwilliams@mednet.ucla.edu

T.A.B., M.R.S., and T.S. are from the Cardiovascular and Interventional Radiology Society of Europe.

M.R.S. is from Société Française de Radiologie.

I.M. is from the British Society of Interventional Radiology.

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Appendix A and Tables E1 and E2 can be found by accessing the online version of this article on *www.jvir.org* and clicking on the Supplemental Material tab.

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ABBREVIATIONS

BPH = benign prostatic hyperplasia, IIEF = International Index of Erectile Function, IPSS = International Prostate Symptom Score, LUTS = lower urinary tract symptoms, MIST = minimally invasive surgical therapies, OP = open prostatectomy, PAE = prostatic artery embolization, PVR = postvoid residual, QOL = quality of life, RCT = randomized controlled trial, TURP = transurethral resection of the prostate, UK-ROPE = United Kingdom Register of Prostate Embolization

BACKGROUND

Benign prostatic hyperplasia (BPH) describes the proliferation of the glandular and stromal tissue in the transition zone of the prostate, which may result in bladder outlet obstruction and consequent lower urinary tract symptoms (LUTS). The prevalence of BPH increases with age, affecting more than 70% of men older than 70 years (1), and one fourth of men older than 70 years have moderate to severe LUTS that impair their quality of life (QOL) (2,3). Thus, BPH and ensuing LUTS represent a significant health issue affecting millions of men.

The International Prostate Symptom Score (IPSS; also known as the American Urologic Association Symptom Index) is a validated instrument that quantifies a patient's subjective urinary symptoms on a 35-point scale (4). The IPSS also incorporates a urinary QOL score, which assesses how the patient feels overall about his urinary symptoms. Nearly all studies assessing BPH treatments for LUTS use the IPSS and QOL scores to assess patients before and after treatment. A 3-point change in IPSS is noticeable by a man with LUTS (5), and a 30% reduction in IPSS is considered clinically acceptable for a treatment to be considered effective (6,7).

Medical therapies, including α-1 blockers and 5-α reductase inhibitors, are the mainstay of treatment for mild to moderate LUTS. The symptomatic relief is relatively modest, with IPSS improvement in the range of 3–7 points (8). Although generally considered safe, medical therapy may cause several adverse effects. α-Blockers commonly cause retrograde ejaculation, and the earlier nonspecific agents can elicit orthostatic hypotension. 5-α reductase inhibitors may cause sexual side effects such as loss of libido or erectile dysfunction.

Patients who cannot tolerate medical therapy or in whom medical therapy fails are considered for more invasive treatments. Historically, transurethral resection of the prostate (TURP) has been the gold standard for treatment of prostate glands as large as 80–100 cm^3. TURP produces significant IPSS improvement of 15–16 points (7,9) and marked improvement in urinary flow rate. However, the associated morbidity can be considerable, including ejaculatory dysfunction, erectile dysfunction, urethral stricture, urinary retention, urinary tract infection, transfusion requirement, and incontinence (7,10). For prostates larger than 80–100 cm^3, open prostatectomy (OP) has been the historical gold standard. OP results in IPSS improvement of 13–18 points (11,12) and excellent objective improvement, but requires a longer convalescence (13). Morbidities are more common with OP than with TURP, and include major bleeding, sepsis, urinary retention, incontinence, and urethral stricture (14,15).

The morbidity associated with traditional BPH treatments has prompted the development of a variety of minimally invasive surgical therapies (MIST). Contemporary MIST include transurethral microwave therapy, prostatic urethral lift, water vapor thermal therapy, and a variety of laser therapies. All function by destruction or displacement of the obstructing prostatic tissue. MIST result in less morbidity than TURP and OP but are generally associated with less IPSS improvement and higher rates of repeat treatment (7,16,17). Several of the MIST, such as prostatic urethral lift and water vapor thermal therapy, are office-based procedures that may not require anesthesia or indwelling bladder catheterization; IPSS improvement for these therapies averages 10–12 points (7,17). With the exception of some laser therapies, MIST are not typically recommended for patients with very large prostates, and they are variably effective in patients with a prominent median lobe (18).

Prostatic artery embolization (PAE) is a novel minimally invasive treatment for LUTS attributed to BPH. Embolization of the prostatic arteries leads to ischemic shrinkage of the prostate gland and subsequent reduction of LUTS. This effect may be potentiated by a reduction of the α-1 adrenergic receptor density in the embolized prostate, causing relaxation of smooth muscle (19). The therapeutic effect of PAE was first described in a case report in 2000 (20), and animal studies in the next decade substantiated the effect (21,22). The first intentional treatment of BPH in humans was reported in 2010 (23), and early cohort studies from around the world soon followed (24–26).

The Society of Interventional Radiology (SIR) published an initial position statement on PAE for BPH in 2014 (27), which concluded that PAE was a safe and effective treatment for BPH and recommended further clinical investigation, including expansion of the number of patients treated, increase in the duration of follow-up, and inclusion of more prospective comparisons with surgical therapies. Since that time, substantial research has accumulated, and clinical practice patterns are evolving. Under the direction of the SIR Standards Division, a multidisciplinary group was convened, including leading clinical and research experts on PAE from North America, South America, and Europe. Here we review the updated global experience with PAE and state the joint position and recommendations of SIR, the Cardiovascular and Interventional Radiological Society of Europe, Société Française de Radiologie, and the British Society of Interventional Radiology with regard to the use of PAE for LUTS secondary to BPH.

LITERATURE REVIEW

A comprehensive literature review was undertaken using PubMed search terms "(prostate or prostatic) and (embolization or embolisation)." The literature search yielded 280 articles published between the first PAE case series in April 2010 and the date of the literature review in September 2018; 230 of these studies were published in the past 4 years. After excluding duplicative cohorts, case reports, technical papers, letters or comments, and unrelated articles, a total of 67 publications relevant to clinical outcomes following PAE for BPH were identified and reviewed. The total number of patients studied had expanded from 400 at the time of the initial 2014 position statement to more than 2,200, and the longest duration of follow-up increased from 3 years to 6.5 years. Three randomized controlled trials comparing PAE with TURP had been published. Three nonrandomized comparative studies had been performed, 2 comparing PAE with TURP and 1 comparing PAE with OP. Seventeen unique cohort studies were identified from 11 different countries. Six meta-analyses and 19 review articles had been published summarizing the efficacy and safety of PAE. The Executive Summary (**Appendix A** [available online on the article's Supplemental Material page at *www.jvir.org*]) summarizes the updated clinical recommendations and qualifying statements.

Comparative Trials

Outcomes of the randomized controlled trials and comparative studies are summarized in **Table 1** and **Table E1** (available online on the article's Supplemental Material page at *www.jvir.org*) (28–33). The first randomized controlled trial comparing PAE with TURP was previously reported (28). In that trial, a total of 114 patients with moderate to severe LUTS, peak flow rate < 15 mL/s, and prostate volume < 100 cm^3 were randomized to undergo PAE or TURP and followed for 24 months. TURP was associated with better functional outcomes at 1 and 3 months after the procedure, but all outcomes, including IPSS, QOL, peak flow, and postvoid residual volume (PVR), were equivalent between the 2 groups at 12 and 24 months. Patients who underwent TURP were more likely to require bladder catheterization and inpatient hospitalization, and duration of hospitalization

was longer in the TURP group. Major complications were encountered only in the TURP group.

A second randomized controlled trial (29) prospectively randomized 30 patients to undergo PAE or TURP. These patients were also compared with a nonrandomized cohort of 15 patients who underwent PAE with a specialized technique with both proximal and distal embolization. Patients had severe LUTS and prostate volumes of 30–90 cm^3. All 3 groups experienced significant improvement at 1-year follow-up, with IPSS improving by 21.5 points in the TURP group, 12.5 points in the PAE group, and 21.0 points in the PAE with proximal and distal embolization group. Urinary QOL and peak flow rates were superior in the TURP group, but significant improvement was seen in all groups. No major complications were observed in the PAE groups.

A third randomized controlled trial (30) compared 48 patients who underwent PAE versus 51 patients who underwent TURP. Recruited patients had a prostate volume of 25–80 cm^3, IPSS of at least 8, urinary QOL of 3 or higher, and urinary flow rate of less than 12 mL/s or urinary retention. At 12 weeks after the procedure, the mean improvement in IPSS was not significantly different between the 2 groups (9.2 points for PAE and 10.8 points for TURP). All other patient-reported symptoms were also similar, including urinary QOL, frequency of urination, and nocturia. Urinary peak flow and PVR were improved in both groups, but the degree of improvement was greater with TURP (+5.2 mL/s vs +15.3 mL/s and −86.4 mL vs −200.0 mL, respectively). TURP was associated with twice as many adverse events as PAE, including more than 3 times as many severe adverse events. Blood loss, duration of hospitalization, and bladder catheterization time were higher for TURP than for PAE.

A 1:1 matched-pair analysis comparing PAE with OP (31) was undertaken in 160 patients with moderate to severe LUTS, peak flow rate < 15 mL/s, and prostate volume > 80 cm^3. Both groups showed significant improvement in IPSS, peak flow, and PVR, but the degree of improvement of urinary function was higher in the OP group. IPSS improved by 20.0 points in the OP group versus 13.6 points in the PAE group, and peak flow increased by 16.0 mL/s in the OP group versus 9.6 mL/s in the PAE group. Erectile function was significantly better in the PAE group, which showed a 0.7-point increase in the International Index of Erectile Function (IIEF) from baseline, compared with a 4.2-point decrease from baseline in the OP group. Patients in the OP group required a 7-day-longer hospital stay and 6 days of bladder catheterization, which was rarely needed in the PAE group. The OP group had a higher overall complication rate of 31.2%, compared with 8.8% for PAE, and the major complication rate was 3.8% for OP, compared with 0% for PAE.

In 2018, the results of the United Kingdom Register of Prostate Embolization (UK-ROPE) study were published (32). This registry-based observational study recruited 305 patients from 17 centers across the United Kingdom, 216 of whom underwent PAE and 89 of whom underwent TURP. Patients treated with PAE were younger (66 y vs 70 y) and had larger prostates (101.2 cm^3 vs 65.6 cm^3). At 1 year after intervention, both groups showed significant improvement, but the TURP group exhibited greater improvements in IPSS (15.2 points vs 10.9 points), urinary QOL (3.4 points vs 2.6 points), and peak flow rate (8.6 points vs 4.4 points). Length of stay was shorter for PAE (median, 0 d vs 2 d), and the complication profile of PAE was milder, including lower rates of hematuria and retrograde ejaculation. Median return to normal activities was 5 days for PAE and 14 days for TURP.

Cohort Studies

Twelve prospective (34–45) and 5 retrospective (46–50) unique cohort studies of PAE for BPH were published in the past 4 years. The largest cohort of PAE recipients, and the one with the longest follow-up, remains that of a Portuguese group (50) that expanded their cohort to 630 patients in 2016. Technical success, defined as bilateral PAE, was achieved in 92.6% of patients, and cumulative clinical success rates were 81.9% at 1–3 years and 76.3% at 3–6.5 years. There was significant improvement in all clinical parameters, including IPSS, urinary QOL, prostate volume, peak flow rate, PVR, and IIEF score. The other 16 unique cohort studies at different institutions all reported similar positive outcomes in terms of efficacy and safety. Considering the 7 cohort studies of PAE with 25 or more patients and 1 year or longer follow-up (35,40,41,43,44,48,50), mean IPSS improvement ranged from 11.2 to 18.0 points and QOL improvement ranged from 1.9 to 4.7 points. Technical success rates were 93.2%–100% for unilateral embolization and 86.3%–97.4% for bilateral embolization. Peak flow rates increased by 3.1–10.0 mL/s, PVR decreased by 30.6%–75.5%, prostate volumes decreased by 21.1%–44.9%, and erectile function was stable to slightly improved (**Table 2** and **Table E2** [available online on the article's Supplemental Material page at *www.jvir.org*)] (34–50).

Meta-Analyses

Six meta-analyses of PAE for BPH have been published (51–56). The largest and most recent (51) was a systematic review of trials studying the efficacy of PAE to treat LUTS, performed according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses guidelines, with a meta-analysis done using the random-effects model. Their review extracted data from 13 studies of PAE between 2014 and 2017, totaling 1,254 patients. Baseline LUTS were severe, with a mean IPSS of 23.5 and a QOL score of 4.7. Summative results at 1 year showed a mean reduction of 16.2 points in IPSS (a 67% improvement) and improved QOL by 3.0 points, along with prostate volume reduction averaging 26%. IPSS, QOL, PV, PVR, and IIEF score remained statistically significantly improved after 3 years. Five smaller meta-analyses published in the 3 years preceding the present literature review (52–56) analyzed overlapping data and produced similar results.

SAFETY OF PAE

A postembolization syndrome, which can include pain, dysuria, frequency, and other irritative symptoms, is anticipated following PAE. These effects typically last less than 1 week and require only symptomatic management (57). Minor complications requiring therapy include acute urinary retention requiring temporary catheterization in 2.5%–4.6% of patients and urinary tract infection requiring oral antibiotic therapy in 2.6%–7.6% of patients (51).

Major complications following PAE are rare. In review of more than 2,000 patients in the 17 unique cohort studies and 6 comparative trials, a total of 6 major complications were encountered (**Table 3**) (30,50,57,58). Two cases required surgical intervention; both were cases of bladder ischemia requiring partial resection (30,50). No major complications related to vascular access were reported. Occurrences of technical or clinical failure have been reported as complications of PAE by some authors; this is a nonstandard reporting method, as "failure to cure" should not be considered a complication of a procedure (59). Overall, the major complication rate of PAE is estimated to be less than 0.5% (51,55).

Sexual function affects QOL in patients with BPH and frequently motivates choice of therapy (60). Regarding erectile function, PAE studies have routinely included pre- and postprocedural assessment of the IIEF. None of the reviewed studies showed a decrease in IIEF score after PAE. Three meta-analyses of PAE (51,54,56) showed slight improvement of IIEF score after PAE, whereas 2 meta-analyses (52,55) showed no change. The 3 RCTs of PAE (28–30) showed no change in IIEF score following PAE. The effect of PAE on ejaculatory function was reported by 11 of the reviewed studies. There were no instances of retrograde ejaculation in 5 cohort studies totaling 340 patients (39,41,43,44,46,48), 1 cohort (34) reported 5 of 51 cases with dry or reduced ejaculation after PAE, and another cohort (35) showed reduced ejaculation in 14 of 97 patients. In the prospective UK-ROPE registry (32), 24.1% of patients reported retrograde ejaculation following PAE; however, the data were confounded by many patients having preexisting retrograde ejaculation related to medical therapy. One randomized controlled trial (29) reported that 3 of 30 patients experienced reduced ejaculation following PAE, and a second RCT (30) reported that 14 of 25 patients had reduced or dry ejaculation following PAE. Both RCTs demonstrated a significantly lower incidence of retrograde ejaculation for PAE compared with TURP. One prospective trial (43) used a validated scoring tool to objectively measure ejaculatory function before and after PAE; there was no change in ejaculatory function during the 1-year study duration. Meta-analyses have estimated the risk of retrograde ejaculation following PAE as 0%–2.3% (51,54,56).

Table 1. Comparative Studies (28–33)

Study, Year	Country	Study Type	Pts. in Each Treatment Group	Mean Age (y)	Mean CCI	Unilateral/Bilateral Technical Success (%)
Gao et al (28), 2014	China	RCT	57 PAE	67.7	NR	94.7/84.2
			57 TURP	66.4	NR	100
Russo et al (31), 2015	Russia	Prospective comparative	80 PAE	67	2.1	NR
			80 OP	68.4	1.9	NR
Carnevale et al (29), 2016	Brazil	RCT	15 original PAE	63.5	NR	100/86.7
			15 PErFecTED PAE	60.4	NR	100/100
			15 TURP	66.4	NR	100
Qiu et al (33), 2017	China	Retrospective comparative	17 PAE	75.5	NR	100/100
			40 TURP	73.4	NR	100
Ray et al (32), 2018	UK	Prospective comparative registry	216 PAE	66†	NR	NR
			89 TURP	70†	NR	NR
Abt et al (30), 2018	Switzerland	RCT	48 PAE	65.7	3.6	100/75
			51 TURP	66.1	4.3	100

Baseline						Change at 3 mo					
IPSS	QOL	IIEF-5	Peak Flow (mL/s)	PVR (mL)	PV (mL)	IPSS	QOL	IIEF-5	Peak Flow (mL/s)	PVR (mL)	PV (mL)
24.3	4.8	NR	7.8	126.9	64.7	−8.7†	−1.9†	NR	9.5†	−70.1†	−21.3†
23.1	4.6	NR	7.3	115.4	63.5	−13.7†	−2.3†	NR	14.1†	−82.2†	−36.2†
24	4.4	14.4	7.3	64.2	112.8	NR	NR	NR	NR	NR	NR
23.4	4.1	15.1	7.8	65	109.7	NR	NR	NR	NR	NR	NR
25.3	4.7	14.3†	7†	127	63	NR	NR	NR	NR	NR	NR
24.6	4.7	17.3†	5.1†	74.2	66.2	NR	NR	NR	NR	NR	NR
27.6	4.6	12.5†	9.7†	78.3	56.6	NR	NR	NR	NR	NR	NR
23.9	4.1	NR	9.5	NR	64.6	−8.4†	−1.3†	NR	3.7†	NR	−12.3†
24.5	4.1	NR	9.4	NR	68.7	−12.2†	−2†	NR	11†	NR	−38.8†
21.3	4.6	14.4	8.8	161.6†	101.2†	−11.7	−2.7	1.8	4.8	−35.4	−29.1
21.6	4.9	14.4	10.4	263.6†	65.6†	−11.8	−3	1.2	10.4	−174.8	−6.9
19.4	4	15.2	7.5	168.5	52.8	−9.2	−2.3	−1	5.2	−86.4	−12.2
17.6	4.2	13.1	7.2	230.7	56.5	−10.8	−2.7	−1.8	15.3	−200	−30.3

continued

Table 1. Comparative Studies (28–33) *(continued)*

Change at 12 mo						Change at 24 mo					
IPSS	QOL	IIEF-5	Peak Flow (mL/s)	PVR (mL)	PV (mL)	IPSS	QOL	IIEF-5	Peak Flow (mL/s)	PVR (mL)	PV (mL)
−13.4	−2.9	NR	14.3	−99.6	−29.1†	−15.6	−3.2	NR	13.7	−107.5	−29.8†
−14.5	−2.8	NR	15.8	−93.1	−37.1†	−16.3	−3.2	NR	14.8	−100.2	−36.9†
−13.6†	−1.6†	0.7†	9.6†	−43.8†	NR	NR	NR	NR	NR	NR	NR
−19†	−3.4†	−4.2†	16†	−58.8†	NR	NR	NR	NR	NR	NR	NR
−12.5†	−2.5†	−1.7	3.1†	−64.7†	−12.1†	NR	NR	NR	NR	NR	NR
−21†	−3.1†	1.4	11.6†	−25.6†	−16.2†	NR	NR	NR	NR	NR	NR
−21.5†	−3.7†	3.6	17.4†	−70†	−24.6†	NR	NR	NR	NR	NR	NR
−10.8†	−2†	NR	12.3†	NR	−22.6†	NR	NR	NR	NR	NR	NR
−14.3†	−2.4†	NR	14.9†	NR	−35.8†	NR	NR	NR	NR	NR	NR
−10.9	−2.6	1	4.4	−40.4	−28.6	NR	NR	NR	NR	NR	NR
−15.2	−3.4	−0.2	8.6	−78.1	NR	NR	NR	NR	NR	NR	NR
NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR
NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR

Ejaculatory Dysfunction (%)*	Mean Hospital Stay (d)	Mean Bladder Catheter Indwell (d)	Mean Postprocedure Hemoglobin Change (g/dL)	Repeat Operation (%)	Complications (%)	
					Minor Requiring Treatment (Clavien–Dindo 2)	Major (Clavien–Dindo ≥ 3) (%)
NR	2.9†	NR	−0.3†	NR	28.1†	0‡
NR	4.8†	NR	−2.1†	NR	8.8†	3.5‡
NR	2.5†	0†	0†	0	1.2†	0†
NR	9.2†	6.1†	−2.9†	0	12.5†	3.8†
13.3	0.2†	NR	NR	13.3	0	0
6.7	0.2†	NR	NR	0	0	0
100	2.1†	NR	NR	0	26.7	13.3
NR	NR	NR	NR	NR	0	0
NR	NR	NR	NR	NR	NR	0
24.1	0§	0	NR	19.9†	0.9	0
47.5	2§	NR	NR	5.6†	2.2	0
56	2.2†	1.3†	−0.4†	NR	22.9†	4.2†
84	4.2†	3.3†	−1.4†	NR	43.1†	13.7†

Note–**Table E1** (available online on the article's Supplemental Material page at *www.jvir.org*) is the full version of **Table 1**.

CCI = Charlson comorbidity index; IIEF = International Index of Erectile Function; IPSS = International Prostate Symptom Score; NR = not reported; OP = open prostatectomy; PAE = prostatic artery embolization; PErFecTED = proximal embolization first; then embolize distal; PV = prostate volume; PVR = postvoid residual; QOL = quality of life; RCT = randomized controlled trial; TURP = transurethral resection of the prostate.

*Inclusive of patients with reduced ejaculate volume or retrograde/dry ejaculation. Some cases may have been preexisting.

†Significant difference between groups.

‡Excludes technical and clinical failures.

§Median reported instead of mean.

Table 2. Study Cohorts (34–50)

Study, Year	Country	Study Type	Pts. Receiving PAE	Pts. with Indwelling Bladder Catheter	Mean Age (y)	Mean CCI	Unilateral/Bilateral Technical Success (%)
Kurbatov et al (40), 2014	Italy	Prospective cohort	88	0	66.4	3	NR
Bagla et al (47), 2015	USA	Retrospective cohort	16 Small	0	62.7	NR	99/96
			26 Medium	0	65.5	NR	
			36 Large	0	66.1	NR	
Wang et al (44), 2015	China	Prospective cohort	117	0	71.5	NR	93.2/86.3
Grosso et al (38), 2015	Italy	Retrospective cohort	13	7	75.9	NR	92/69.2
Pisco et al (50), 2016	Portugal	Retrospective cohort	630	67	65.1	NR	98.1/92.6
Gabr et al (37), 2016	Saudi Arabia	Prospective cohort	22	NR	72.5	NR	100/100
Isaacson et al (39), 2016	USA	Prospective cohort	12	0	69	NR	100/100
Amouyal et al (46), 2016	France	Retrospective cohort	32	0	65	NR	100/97
Bhatia et al (49), 2017	USA	Retrospective cohort	30	24	73.1	4.5	100/93.3
Carnevale et al (35), 2017	Brazil	Prospective cohort	59 original PAE	12	64.6	NR	100/91.5
			38 PErFecTED PAE	1	62.3	NR	100/97.4
Rampoldi et al (42), 2017	Italy	Prospective cohort	43	43	77.9	5.7	95.3/76.7
Yu et al (45), 2017	Hong Kong (China)	Prospective cohort	16 with AUR	16	66	NR	100/100
			15 without AUR	0	66	NR	100/100
Maclean et al (41), 2018	UK	Prospective cohort	86	0	64.9	NR	100/96.5
Salem et al (43), 2018	USA	Prospective cohort	45	4	67	2.6	100/93
Bhatia et al (48), 2018	USA	Retrospective cohort	93	0	68.5	3.2	100/97
Franiel et al (36), 2018	Germany	Prospective cohort	30	1	66*	NR	90/80
Brown et al (34), 2018	Australia	Prospective cohort	51	10	67.8	NR	100/92.1

Baseline			Change at 1 mo			Change at 3 mo			Change at 6 mo		
IPSS	QOL	IIEF-5	IPSS	QOL	IIEF-5	IPSS	QOL	IIEF-5	IPSS	QOL	IIEF-5
24	5.1	14.4	NR	NR	NR	−11.8	−2.3	1.1	−12.6	−2.3	1.1
27.2	4.6	15	−13.2	−1.8	−0.2	−15.3	−1.9	2.4	−11.3	−1.9	2.6
25.6	4.9	14.8	−8.5	−1.8	−0.4	−9.3	−1.9	2.5	−12.1	−2.8	2.1
26.5	5	12.7	−11.3	−2.7	0.5	−14.1	−2.9	4.3	−12.9	−3	3.7
26	5	11	−16.5	−2.5	0	−17.5	−2	−1	−18.5	−2	1
29.2	4.3	8.8	NR	NR	NR	NR	NR	NR	NR	NR	−15.8
23.1	4.2	18.5	NR	NR	NR	NR	NR	NR	NR	NR	NR
22.4	4.2	15.8	−9.5	−1.4	0.7	−10.8	−1.3	0.8	NR	NR	NR
23.9	4.8	13	−12.6	−3.1	4	−18.2	−3.5	2	NR	NR	NR
16.3	5.4	NR	NR	NR	NR	−11	−2.9	NR	−7.4	−2.3	NR
NA	5.3	NR	NR	NR	NR	NA	−4.1	NA	NA	−4.6	NA
22.4	5.1	NR	NR	NR	NR	−19.8	−4.1	NR	NR	NR	NR

continued

Table 2. Study Cohorts (34–50) *(continued)*

Baseline			Change at 1 mo			Change at 3 mo			Change at 6 mo		
IPSS	QOL	IIEF-5	IPSS	QOL	IIEF-5	IPSS	QOL	IIEF-5	IPSS	QOL	IIEF-5
20.8	4.5	NR	NR	NR	NR	−16.7	−2.9	NR	NR	NR	NR
16.9	4.8	NR	NR	NR	NR	NR	NR	NR	−7.1	−3.6	NR
21	6	7.5	−15.5	−4	−3	NR	NR	NR	NR	NR	NR
19	4	9	−12	−3	0	NR	NR	NR	NR	NR	NR
23.3	5.2	15.1	NR	NR	NR	NR	NR	NR	NR	NR	NR
23.6	4.8	NR	−11.6	−2.2	NR	−13.4	−2.4	NR	−12.6	−2.5	NR
22.3	4.4	15.1	−14	−2.7	−0.1	−15.2	−3.2	1.8	−15.9	−3.4	1.2
23[†]	5[†]	10.5[†]	−12[†]	−2[†]	4[†]	−12[†]	−2[†]	1.5[†]	−13.5[†]	−3[†]	0[†]
23.1	4.7	NR	−18.4	−3.4	NR	−18.8	−3.8	NR	NR	NR	NR

Change at 12 mo			Change at 24 mo			Bladder Catheter Removed (%)	Ejaculatory Dysfunction (%)*	Complications (%)	
IPSS	QOL	IIEF-5	IPSS	QOL	IIEF-5			Minor Requiring Treatment (Clavien–Dindo 2)	Major (Clavien–Dindo ≥ 3)
−13.6	−2.9	0.7	NR	NR	NR	NA	NR	0	0
NR	NR	NR	NR	NR	NR	NA	NR	2.8	0
NR	NR	NR	NR	NR	NR	NA			
NR	NR	NR	NR	NR	NR	NA			
−18	−2.5	2	−17	−2	−1	NA	0	26.5	0
−17.1	−2.6	2.6	NR	NR	NR	100	NR	0	0
−13.7	−1.9	1.7	−14.5	−2	1.6	89.6	NR	6	0.4
NR	NR	NR	NR	NR	NR	NR	NR	68.2	0
NR	NR	NR	NR	NR	NR	NA	0	16.7	0
NR	NR	NR	NR	NR	NR	NA	0	3.1	0
NA	−4.7	NA	NR	NR	NR	86.7	NR	6.7	0
−16.4	−3.7	NR	NR	NR	NR	83.3	17	0	0
−17.5	−3.1	NR	NR	NR	NR	100	10.5	0	0
NR	NR	NR	NR	NR	NR	80.5	NR	20.9	0
NR	NR	NR	NR	NR	NR	87.5	NR	0	0
NR	NR	NR	NR	NR	NR	NA	NR	0	0
−11.2	−2.1	2.7	NR	NR	NR	NA	0	0	0
−11.2	−2.2	NR	NR	NR	NR	100	0	4.4	0
−15	−3.1	2	NR	NR	NR	NA	0	1.1	0
NR	NR	NR	NR	NR	NR	100	NR	0	0
NR	NR	NR	NR	NR	NR	70	9.8	0	0

Note–**Table E2** (available online on the article's Supplemental Material page at *www.jvir.org*) is the full version of **Table 2**.
AUR = acute urinary retention; CCI = Charlson comorbidity index; IIEF = International Index of Erectile Function; IPSS = International Prostate Symptom Score; NA = not applicable; NR = not reported; PAE = prostatic artery embolization; PV = prostate volume; PVR = postvoid residual; QOL = quality of life.
*Inclusive of patients with reduced ejaculate volume or retrograde/dry ejaculation. Some cases may have been preexisting.
†Median reported instead of mean.

Table 3. Major Complications in Published Studies (30,50,57,58)

Study, Year	Study Type	Major Complication	Management	Outcome
de Assis et al (58), 2015	Prospective cohort	Severe urinary tract infection	Admission with IV antibiotics	Resolved
Pisco et al (50), 2016	Retrospective cohort	Bladder wall ischemia	Partial bladder resection	Resolved
		Severe perineal pain	Analgesia	Resolved
Moreira et al (57), 2017	Review	Rectal ulcers	Colonoscopy	Resolved
Abt et al (30), 2018	RCT	Bladder wall ischemia	Partial bladder resection	Resolved
		De novo erectile dysfunction	Not reported	Not reported

IV = intravenous; RCT = randomized controlled trial.

PAE requires the use of radiation for procedural guidance. A recent study (61) prospectively analyzed radiation parameters in 25 consecutive PAE procedures and found a mean fluoroscopy time of 30.9 minutes and a mean peak skin dose of 2,420 mGy. This is comparable to other abdominal embolization procedures such as hepatic chemoembolization, embolization of pelvic arteriovenous malformations, and embolization for gastrointestinal hemorrhage (62). One case of radiodermatitis following PAE has been reported (63). Stochastic effects, such as cancer induction, have not been assessed specifically for PAE. These effects are not considered substantial for other pelvic embolization procedures (64,65), and the male sex and more advanced age of the PAE recipient would further reduce this effect (66).

SPECIFIC CLINICAL SCENARIOS

Very Large Prostates

A number of recent studies have focused on PAE for LUTS in patients with prostate volumes exceeding 80–100 cm^3. A Russian cohort of 88 patients with prostate volume > 80 cm^3 (40) reported IPSS improvement of 13.6 points and urinary QOL improvement of 2.9 points following PAE. A prospective cohort study of 35 Brazilian patients with prostate volumes of 90–252 cm^3 (58) demonstrated IPSS reduction of 15.6 points and QOL improvement of 3.9 points. A prospective cohort of 12 American patients with prostate volumes of 80–150 cm^3 (39) reported IPSS improvement of 18 points and QOL improvement of 3.6 points. A second American cohort of 93 patients with prostate volumes of 80–424 cm^3 (48) revealed a 15.0-point improvement in IPSS and 3.1-point improvement in QOL after PAE, along with mean volume reduction from 141.7 cm^3 to 82.2 cm^3. A retrospective review of 152 Portuguese patients with prostate volumes of 101–383 cm^3 (67) reported clinical success rates of 81.1% at 1 year and 72.4% at 5 years. There was 1 major complication among the 380 patients in these 5 studies.

Three studies made direct comparisons between PAE in different prostate sizes (41,47,56). An American study (41) analyzed outcomes of PAE performed in patients with prostate volumes < 50 cm^3, 50–80 cm^3, and > 80 cm^3. IPSS improvements at 6 months were 11.3 in the small prostate group, 12.1 in the medium group, and 12.9 in the large prostate group, without a significant difference. A Chinese study of 115 patients (56) compared a cohort of patients with markedly enlarged prostates (mean volume, 129 cm^3) against a cohort with moderately enlarged prostates (mean volume, 64 cm^3). Both groups showed significant improvements, but the group with larger prostates showed significantly more improvement in IPSS (14 points vs 10.5 points), peak flow (6.0 mL/s vs 4.5), PVR (−89 mL vs −60 mL), and urinary QOL (−3.0 vs −2.0). A more recent British study of 86 patients treated with PAE (41) compared multiple baseline factors and found that larger initial prostate size was significantly predictive of good symptomatic outcome at 12 months. No maximum prostate size for PAE has been reported.

Patients with Indwelling Foley Catheters

A minority of patients treated with BPH have exhausted their urologic options and are relegated to an indwelling bladder catheter. This results in significant morbidity, including urethral erosion, recurrent urinary tract infections, and decreased QOL (68). PAE has been studied as a treatment alternative in this patient group, with success being defined as the ability to remove the indwelling catheter and void spontaneously without the need for repeat catheterization. In the largest PAE cohort of 630 patients (50), 67 patients had an indwelling bladder catheter at baseline. Sixty of these patients (89.6%) achieved catheter independence between 2 days and 3 months after the procedure. In a Brazilian cohort of 24 patients with indwelling bladder catheters (69), 62.5% achieved catheter independence between 7 and 40 days after PAE. A study in Hong Kong (45) recruited 18 consecutive patients with acute urinary retention caused by BPH and achieved catheter independence in 87.5% of patients within 14 days after PAE. A prospective Italian study (42) enrolled 43 patients who had indwelling bladder catheters and were ineligible for surgical intervention; of the 41 patients who underwent PAE, catheter independence was achieved in 33 (80.5%). In an American cohort of 30 patients classified as "highly comorbid" with urinary retention (48), PAE allowed urinary catheter removal in 86.7% of patients at a mean of 18 days after the procedure. No major complications were encountered in these studies.

Hematuria of Prostatic Origin

Prostatic bleeding occurs in approximately 2.5% of cases of BPH (70). Hematuria can also occur secondary to iatrogenic trauma related to BPH such as TURP or traumatic bladder catheter removal. The mechanism of action of PAE is well suited to stopping prostatic bleeding, and pelvic embolization has been used for this purpose for more than 40 years (71). Superselective PAE for hematuria of prostatic origin has been a more recent advance, but data are emerging. Eight patients with hematuria of prostatic origin were reported in a case series in 2008 (72). PAE resulted in immediate cessation of gross hematuria in all patients, without complication. Three patients with prostatic hematuria related to TURP or traumatic bladder catheter removal were reported in a second case series (73); PAE resolved the hematuria within 24 hours and caused no complications. In a prospective cohort study of 12 patients with BPH-related hematuria (70), cessation of bleeding was achieved by PAE in all patients, with no adverse events.

COST ANALYSIS

Annual health care costs of BPH exceed $3 billion in the United States, and these costs are set to increase as the population ages, making cost considerations important (74). A recent study (75) compared direct costs for 86 patients who underwent TURP versus 70 patients who underwent PAE. Although disposable equipment costs for PAE were higher, TURP was associated with higher costs for anesthesia staffing and supplies. PAE was performed on an outpatient basis, whereas TURP required inpatient admission. Overall, the in-hospital cost for TURP was more than 3 times higher than that of PAE ($5,338 vs $1,678). Additional studies including direct and indirect costs were recommended.

CURRENT GUIDELINES

The United Kingdom National Institute for Health and Care Excellence initially reviewed PAE in 2013 (76), and concluded that more research was needed to establish its efficacy and safety. Informed by additional data including the UK-ROPE registry, updated guidelines were released in 2018 (77). Their recommendations now state that current evidence on the safety and efficacy of PAE for BPH is adequate to support the use of this procedure. PAE is now reimbursed by the UK National Health Service as part of routine care of BPH with LUTS.

In the United States, the Food and Drug Administration reviewed the published clinical studies of PAE for BPH in 2016 and concluded that the data support that the probable benefits outweigh the probable risks for this indication (78). Based on their review, the Food and Drug Administration granted 513(f)(2) classification to expand the indication for Embosphere microspheres (Merit Medical, South Jordan, Utah) to include PAE for BPH. A second embolic agent, Embozene microspheres (Boston Scientific, Marlborough, Massachusetts), was later approved via the 510k pathway for the same indication.

The American Urological Association guidelines on surgical management of BPH with LUTS (18) do not recommend PAE outside the context of a clinical trial, based on expert opinion of the urology panel. Two studies of PAE were referenced (28,29). Their explanation cited "heterogeneity in the sparsely available literature in addition to safety concerns regarding radiation exposure, post-embolization syndrome, vascular access, technical feasibility and adverse events" (18).

DISCUSSION

The landscape of BPH treatments is rapidly evolving, with increasing patient interest in minimally invasive therapies with mild side-effect profiles. PAE avoids transurethral access, anesthesia, and hospitalization, making it arguably the least invasive of the procedural therapies for LUTS. At the same time, it is a powerful therapy with reproducible outcomes spanning 23 studies from 11 countries. Based on published data for more than 2,000 patients with BPH and LUTS, PAE has proven to be effective, with mean IPSS improvement ranging from 10.8 to 18.0 points, and safe, with fewer than 0.5% of patients experiencing major complications. PAE is durable at midterm follow-up, and, in cases of clinical failure after PAE, patients still have the option of any urologic treatment or repeat PAE (50).

PAE, therefore, is a valuable minimally invasive option for patients who cannot tolerate medical therapy, in whom medical therapy has failed, or who are poor surgical candidates or refuse invasive surgery. It also provides a definitive treatment option for multiple underserved patient groups who may not have satisfactory urologic treatment options. Examples of underserved groups include older patients with multiple comorbidities, patients with very large prostates ($>$ 80–100 cm^3), patients with hematuria of prostatic origin, patients with indwelling bladder catheters, patients with coagulopathy or who cannot stop anticoagulation therapy, and patients who desire to preserve sexual function. These patients are often poor candidates for surgery, but can be excellent candidates for PAE.

PAE does have some disadvantages compared with traditional urologic surgeries. Objective measures of urinary obstruction, such as peak flow rate and PVR, may improve less following PAE compared with TURP and OP. The long-term durability and criteria for repeating PAE have not been clearly established, but data are emerging. The PAE procedure can be challenging as a result of the anatomy involved and may not always be technically feasible, especially in patients with extensive atherosclerotic disease.

As a minimally invasive technique, it is appropriate to compare PAE with urologic MIST. PAE shares many of the advantages of MIST, including outpatient procedure, short recovery time, and low bleeding risk. PAE has several advantages over MIST, however. PAE is effective in large prostates, with no maximum prostate size. PAE avoids transurethral access, eliminating the risk of urethral stricture, bladder neck stenosis, and urinary incontinence; in addition, bladder catheterization is rarely needed. PAE appears effective in patients with a prominent median lobe, which is a contraindication for several MISTs (79). As with MIST, sexual function is better preserved with PAE than with traditional surgery. Erectile function is unchanged or slightly improved following PAE. Ejaculatory dysfunction occurs occasionally following PAE, but markedly less often than with OP and TURP.

Evaluation and preoperative testing to determine candidacy for PAE should follow established guidelines for other BPH interventions, including complete medical and urologic history, physical examination, laboratory testing and urinalysis, and baseline prostate imaging; uroflowmetry and urodynamic studies should be considered on a case-by-case basis (18). Because LUTS can have myriad etiologies besides BPH, including detrusor overactivity, neurogenic bladder dysfunction, urinary tract infection, and malignancy, it is important that men considered for PAE undergo a thorough evaluation of their LUTS. Collaboration with urology personnel for patient workup and longitudinal follow-up is encouraged.

There is a need for continued prospective outcomes studies and clinical trials of PAE for BPH, including comparison of PAE against best medical therapy, comparison of PAE versus urologic MIST, and long-term follow-up with subsequent reporting. These are recommended by the professional societies issuing the present statement to further improve the evidence supporting PAE as well as to delineate the circumstances in which PAE should be preferred compared with other urologic treatments.

CONCLUSIONS

The data supporting PAE for BPH have advanced since the SIR Position Statement was published in 2014 (27), confirming that PAE is a safe and effective treatment for BPH with good short- and midterm durability. Symptomatic and QOL improvement approach that seen with TURP and OP, and subjective and objective measures compare favorably to urologic MIST. The minimally invasive nature of the technique results in very low morbidity and expands the pool of patients who are eligible for therapy. Based on comprehensive review, SIR, the Cardiovascular and Interventional Radiological Society of Europe, Société Française de Radiologie, and the British Society of Interventional Radiology jointly conclude that current evidence is adequate to support the use of PAE for BPH in appropriately selected patients. Based on the updated SIR methodology for evidence grading (80), the societies make the following recommendations.

RECOMMENDATIONS

1. PAE is an acceptable minimally invasive treatment option for appropriately selected men with BPH and moderate to severe LUTS. (Level of evidence: B; strength of recommendation: strong.)
2. PAE can be considered as a treatment option in patients with BPH and moderate to severe LUTS who have very large prostate glands ($>$ 80 cm^3), without an upper limit of prostate size. (Level of evidence: C; strength of recommendation: moderate.)
3. PAE can be considered as a treatment option in patients with BPH and acute or chronic urinary retention in the setting of preserved bladder function as a method of achieving catheter independence. (Level of evidence: C; strength of recommendation: moderate.)
4. PAE can be considered as a treatment option in patients with BPH and moderate to severe LUTS who wish to preserve erectile and/or ejaculatory function. (Level of evidence: C; strength of recommendation: weak.)
5. PAE can be considered in patients with hematuria of prostatic origin as a method of achieving cessation of bleeding. (Level of evidence: D; strength of recommendation: strong.)
6. PAE can be considered as a treatment option in patients with BPH and moderate to severe LUTS who are deemed not to be surgical candidates for any of the following reasons: advanced age, multiple comorbidities, coagulopathy, or inability to stop anticoagulation or antiplatelet therapy. (Level of evidence: E; strength of recommendation: moderate.)
7. PAE should be included in the individualized patient-centered discussion regarding treatment options for BPH with LUTS. (Level of evidence: E; strength of recommendation: strong.)
8. Interventional radiologists, given their knowledge of arterial anatomy, advanced microcatheter techniques, and expertise in embolization procedures, are the specialists best suited for the performance of PAE. (Level of evidence: E; strength of recommendation: strong.)

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APPENDIX A. EXECUTIVE SUMMARY

Executive Summary: Society of Interventional Radiology Multisociety Consensus Position Statement on Prostatic Artery Embolization for Treatment of Lower Urinary Tract Symptoms Attributed to Benign Prostatic Hyperplasia: From the Society of Interventional Radiology, the Cardiovascular and Interventional Radiology Society of Europe, Société Française de Radiologie, and the British Society of Interventional Radiology

Endorsed by the Asia Pacific Society of Cardiovascular and Interventional Radiology, Canadian Association for Interventional Radiology, Chinese College of Interventionalists, Interventional Radiology Society of Australasia, Japanese Society of Interventional Radiology, and Korean Society of Interventional Radiology

Clinical Question

What is the current role for the use of prostate artery embolization (PAE) to address lower urinary tract symptoms (LUTS) secondary to benign prostatic hyperplasia (BPH)?

Target Population

Patients with LUTS secondary to BPH.

Target Audience

Interventional radiologists and other clinicians who provide care for patients defined by the target population.

Methods

A multidisciplinary expert panel was assembled to update the 2014 SIR Position Statement on PAE (1). A comprehensive review of the literature was performed, and relevant evidence was evaluated for inclusion into this updated document. Evidence was rated according to the updated SIR evidence grading system (2). The recommendations represent consensus among the expert writing panel.

New Recommendations

1. PAE is an acceptable minimally invasive treatment option for appropriately selected men with BPH and moderate to severe LUTS. (Level of evidence: B; strength of recommendation: strong.)
2. PAE can be considered as a treatment option in patients with BPH and moderate to severe LUTS who have very large prostate glands (> 80 cm^3), without an upper limit of prostate size. (Level of evidence: C; strength of recommendation: moderate.)
3. PAE can be considered as a treatment option in patients with BPH and acute or chronic urinary retention in the setting of preserved bladder function as a method of achieving catheter independence. (Level of evidence: C; strength of recommendation: moderate.)
4. PAE can be considered as a treatment option in patients with BPH and moderate to severe LUTS who wish to preserve erectile and/or ejaculatory function. (Level of evidence: C; strength of recommendation: weak.)
5. PAE can be considered in patients with hematuria of prostatic origin as a method of achieving cessation of bleeding. (Level of evidence: D; strength of recommendation: strong.)
6. PAE can be considered as a treatment option in patients with BPH and moderate to severe LUTS who are deemed not to be surgical candidates for any of the following reasons: advanced age, multiple comorbidities, coagulopathy, or inability to stop anticoagulation or antiplatelet therapy. (Level of evidence: E; strength of recommendation: moderate.)
7. PAE should be included in the individualized patient-centered discussion regarding treatment options for BPH with LUTS. (Level of evidence: E; strength of recommendation: strong.)
8. Interventional radiologists, given their knowledge of arterial anatomy, advanced microcatheter techniques, and expertise in embolization procedures, are the specialists best suited for the performance of PAE. (Level of evidence: E; strength of recommendation: strong.)

Qualifying Statements

The SIR develops Clinical Practice Guidelines (CPGs) to provide educational resources to practicing clinicians to promote high-quality outcomes and patient safety in in vascular and interventional radiology. CPGs are not fixed rules, nor are they the sole determinant of treatment choice, and are not intended to establish a legal standard of care. Use of the CPGs is voluntary, and a deviation from the recommendations should not automatically be interpreted as the delivery of care that is substandard. CPGs are not intended to supplant professional judgment, and a physician may deviate from these guidelines as necessitated by the individual patient, practice setting, or available resources. Other sources of information may be used in conjunction with these principles to produce a process leading to high-quality medical care. The ultimate judgment regarding the conduct of any specific procedure or course of management must be made by the physician, who should consider all circumstances relevant to the individual clinical situation. These guidelines are provided "as is," and SIR does not warrant the accuracy, reliability, completeness, or timeliness of the guidelines. SIR is not responsible for any actions taken in reliance on these guidelines, including but not limited to any treatment decisions made by any health care provider reading these guidelines, and SIR assumes no responsible for any injury or damage to persons or property arising out of or related to any use of these guidelines or for any errors or omissions.

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