


CIRSE Standards of Practice on Prostatic Artery Embolisation

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Abbreviations

BPH	Benign prostatic hyperplasia
CBCT	Cone-beam CT
IIEF	International Index of Erectile Function
IPSS	International Prostate Symptom Score
LUTS	Lower urinary tract symptoms
PAE	Prostatic artery embolisation
PERFecTED	Proximal Embolization First, Then Embolize Distal
PSA	Prostate-Specific Antigen
PVR	Post-void residual volume

QOL	Quality of life
TURP	Transurethral resection of the prostate

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Rationale of PAE

Epidemiology Including Clinical Features

Benign prostatic hyperplasia (BPH) is a benign proliferation of stromal and epithelial cells combined with decreased programmed cell death [1], leading to both fibroadenomatous hyperplasia and an increase in the glandular part of the prostate, and thus eventually an enlarged overall prostate volume [2]. BPH produces lower urinary tract symptoms (LUTS), which include an irritative micturition syndrome in the storage phase: increased nycturia, frequent urination of small amounts, involuntary urge to urinate and dysuria, but also bladder outlet obstruction during the emptying phase: delayed start of micturition, prolonged micturition time, weakening of the urinary stream and a feeling of incomplete emptying of the bladder. Prostate size and symptoms are not necessarily correlated. BPH is highly prevalent, affecting up to 50% of males at the age of 50 years and 90% of males over 80 years. It is estimated that symptomatic BPH needing treatment is present in 50% of men with an enlarged prostate [3].

Eligibility and Results of Surgical Approaches

Indications for treatment are based on the symptoms and their impacts on quality of life or the presence of complications [1, 4, 5]. Important diagnostic predictors are age (≥ 60 years), urodynamic examinations including peak urinary flow rate (Q_{\max} , uroflowmetry), post-void residual volume (PVR) and the determination of the prostate volume via ultrasound (transrectal or abdominal) or MRI [2]. The severity of symptoms should be estimated quantitatively using the International Prostate Symptom Score (IPSS) questionnaire. The therapeutic strategy is incremental from lifestyle modification, to medical treatment ($\alpha 1$ -adrenoreceptor antagonists which relax the smooth muscles of the bladder neck, the prostate, and the urethra and/or 5α -reductase inhibitors to reduce the glandular volume), to invasive options [1, 3]. If the patient is refractory to medical treatment, invasive methods are generally considered. The gold standard is the transurethral resection of the prostate (TURP) for prostates up to 80 mL, but laser methods (holmium laser enucleation) or vaporisation of the prostate can also be performed [6]. Open prostate adenoma enucleation is still performed for larger volumes (over 80 mL), even though laser enucleation allows treating larger sized prostates [3]. Open prostatectomy usually requires longer hospitalisation time.

Strategy of Interventional Techniques

Prostatic artery embolisation (PAE) can be performed as an alternative to surgical options in patients with a prostate > 30 – 50 mL without an upper size limit [7]. Some patients may have comorbidities (for instance, patients undergoing continuous anticoagulation or antiplatelet therapy), and surgical methods may be associated with an increased risk of postoperative bleeding, in particular in patients with a prostate volume > 65 mL [8]. Moreover, PAE may be suited to younger, sexually active patients who have concerns about retrograde ejaculation (a frequent consequence of TURP in over 75% of patients), erectile dysfunction or urinary incontinence [7]. The rationale of PAE is supported by the prostate volume and tissue stiffness reductions observed after treatment [9], although the mechanism of action in reducing LUTS is likely multifactorial.

Methods

The PAE working group operated under the purview of the CIRSE Standards of Practice Committee. A systematic MEDLINE/PubMed literature search was performed with different combinations of terms, such as “prostate

embolisation”, “prostate”, “embolisation”. The defined time period included articles published between January 2010 and August 2019. Original articles were selected by the Writing Group based on their clinical relevance. Cited references from selected articles were analysed to find and include significant papers previously excluded from the search or that did not come to initial attention.

Definitions

Symptom Scores and Specific Measures of Assessment

The severity of symptoms of BPH can be estimated quantitatively using the following scores (Level 1a):

- The International Prostate Symptom Score (IPSS) questionnaire includes seven questions on symptoms and one question regarding quality of life (QoL) [4, 5]. Based on this self-evaluation by the patient on a scale of 35, a total point value < 8 corresponds to minimal symptoms, 8–19 to moderate symptoms, and 20–35 to severe symptoms.
- The International Index of Erectile Function (IIEF-5) provides a broad measure of erectile function and detects treatment-related responses in patients with erectile dysfunction.
- Urodynamic testing or urodynamics is a study that assesses how well the bladder and urethra store and release urine [4, 10–12]. It represents two possible methods: a simplified Flow max measurement and full urodynamic study which requires simultaneous urinary and rectal catheter placement.
- The PSA (prostate-specific antigen) value evaluates the risk of prostate cancer, although BPH and age result in normal increase in the PSA value.
- The Charlson score predicts 10-year survival in patients with multiple comorbidities.

Complications (Minor/Major)

The description of adverse events following PAE can follow the modified Clavien classification [13] (Level 1a).

Pre-treatment Imaging

- Ultrasound easily assesses prostate volume and PVR (Level 1a)
- CT angiography (CTA) can be proposed to assess vessel patency/course and collaterals (Level 2b) [14, 15].

- MRI is performed to assess prostate volume and anatomy to serve as the baseline for follow-up (Level 2b) [4].

Indications for Treatment and Contraindications

Indications

Indications for PAE [16–19] are:

- Patients with moderate-to-severe LUTS (Level 1a): IPSS ≥ 8 ; QoL ≥ 3 ; prostate volume > 30 – 50 mL; a urine peak flow less than 5 mL/s at micturition volume of minimum 150 mL; postvoid residual volume (only monitoring, no upper or lower limit); and prostate volume of less than 50 mL are possible candidate for PAE, but the results of PAE are less favourable and the technique is more complex;
- Patients with symptomatic BPH who have already undergone failed medical (Level 1a);
- Patients suffering from urinary retention due to BPH without an upper limit of prostate size (Level 1b);
- Patients with BPH and acute or chronic urinary retention but with preserved bladder function as a method of achieving catheter independence (Level 2b);
- Patients with BPH and moderate-to-severe LUTS who wish to preserve erectile and/or ejaculatory function (Level 2b);
- Patients with haematuria of prostatic origin, as a method of achieving cessation of bleeding (Level 2b);
- Patients with BPH and moderate-to-severe LUTS who are deemed not to be surgical candidates for any reason, including patients presenting with advanced age, multiple comorbidities, coagulopathy, or inability to stop anticoagulation or antiplatelet therapy (Level 2b); and
- Patients refusing surgery.

Relative Contraindications (Level 1a)

- Patients with severe atherosclerosis and/or tortuosity of the vessels depicted with CTA may be excluded. Pre-operative imaging with a pelvic MRI and/or CTA or MRA assessing pelvic vasculature is recommended in severe atherosclerotic patients [14, 15].
- Other exclusion criteria are bladder diverticuli size > 2 cm, bladder stone, detrusor hyperactivity or hypocontractility, neurogenic bladder and renal insufficiency.
- In case of PSA level above 4 ng/mL, prostate biopsies have to be discussed before the procedure in a multidisciplinary disease management team meeting

(MDT). Only in rare cases, PAE can be performed in elderly patients with positive biopsies to reduce LUTS, after curative cancer options have been ruled out in MDT [20], or in advanced cancer [21].

Patient Preparation

Pre-procedural Laboratory and Clinical Assessment (Scores), and Urodynamic Work-up

Q_{\max} is measured at the baseline (patients without indwelling catheter) and after the intervention, as well as IPSS, patient's QoL, reduction in prostate volume, sexual function by IIEF, PSA and PVR, satisfaction of the patient with the operation and adverse events related to study procedure [4, 5].

Standard preparation for angiographic procedures

PAE can be performed on an outpatient basis. PAE is performed under local anaesthesia at the femoral or radial puncture site. In some situations (5%) a bilateral puncture is needed. Pain is infrequently reported and is controlled with oral medication only (Level 2a). Antibiotics (ciprofloxacin or cefazoline) are recommended due to the risk of urinary tract infections, as in any prostate intervention (Level 5). A urinary catheter partially filled by contrast media (10–20%) may be inserted and used for orientation during PAE. It may also make the intervention more tolerable for the patient, by allowing unobstructed urine flow (Level 2b). The balloon can be removed soon after PAE. Many centres do not, however, insert a urinary catheter and instead use a cone-beam CT (CBCT) to confirm prostate artery localisation (Level 2a) [22].

Equipment Specifications: DSA Equipment and CBCT

To identify the anatomical vascular conditions, one can use CBCT angiography scan with the catheter tip in the distal abdominal aorta to visualise both sides with a single injection, or with the diagnostic catheter at the internal iliac artery (Level 2a) [22, 23]. The rotation CBCT angiography scan of the pelvic arteries is typically acquired with a total of 30–40 mL of a contrast agent, an injection rate of 2–6 mL/s (800–900 psi), and an X-ray delay of 2–4 s using contrast agent with an iodine concentration of at least 250–320 mg/mL. Using and comparing the 3D reconstruction as maximum intensity projections (MIP) of CBCT, the origin of the prostate artery is identified.

Once the prostatic artery is identified on manual overview angiography with ipsilateral alignment of the detector of 30°–40° ipsilateral anterior oblique and caudocranial angulation of 10°–15°, super-selective catheterisation is then performed using a microcatheter of 1.7–2.4 F, and full digital subtraction angiography work-up allows visualisation of the characteristic blush of the hemi-prostate (Level 2a). Alternatively, CBCT may be used for this purpose. In the prostatic arteries, a flow rate of 0.3–1 mL/s in a total of 3 mL and 600 psi with a 1–2-s delay is recommended. Having similar performance in terms of detection of prostate arteries, the use of CBCT during the procedure in comparison to pre-PAE pelvic conventional CTA results in improved signal-to-noise and contrast-to-noise ratio, using less radiation and less contrast volume [24].

Procedural Features and Variations of the Technique(s)

Different Access Routes (Femoral, Radial)

Bilateral embolisation of the prostate arteries is ideally performed through a single femoral or radial artery puncture. If the crossover manoeuvre is not successful, a second access can be alternatively created on the contralateral side to again attempt to probe the ipsilateral internal iliac artery.

Femoral approach is more often performed. Transradial arterial access also represents a safe and feasible method for performing PAE (Level 2a) [25, 26]. However, a potential challenge is the small diameter of the radial artery relative to the diameter of the femoral artery, rendering the procedure more challenging and requiring further training for practitioners. Longer catheters and microcatheters are necessary for this approach.

Diagnostic Arteriography Including Common Vascular Variants

Once the prostate artery has been catheterised, 100–200 µg of nitroglycerin may be injected to prevent vasospasm and to increase the diameter of the artery to facilitate distal catheterisation. Isosorbide mononitrate (10 mg on each side) may be used as an alternative drug. The prostate artery has an average diameter of 0.9 mm (range: 0.5–1.5 mm) and usually originates from the internal pudendal artery or from a common origin with the superior vesical artery, obturator, middle rectal and gluteopudendal trunk (medial branches of the internal iliac artery) (Fig. 1) [27]. Super-selective CBCT may be used when the catheter is located in the prostate artery to confirm the adequate position and avoid non-targeted embolisation. There are typically branches to the seminal vesicles and also to the

base of the bladder, especially when a common origin of the superior and inferior vesical artery and the prostate artery is present. The central gland of the prostate is typically supplied by only 1 main branch of the prostate artery. Before reaching the prostate, the prostatic artery divides into a cranial branch for supplying the central gland part and a lateral branch for supplying the peripheral zone. These two branches feeding the prostate may also arise independently.

Collateral and Anatomical Variation Management

Anatomical variations are often observed [28]. The most common origin of the prostate artery, in 34% of cases, was reported in the middle third of the internal pudendal artery (Fig. 1). A common origin of the prostate artery and the superior vesical artery was observed in only 20% of cases. Independent prostate arteries were observed on each pelvic side in 43% of patients, with an average 2.9 ± 0.9 prostate arteries per patient. Moreover, small anastomoses or collateral vessels from the prostate artery to the middle rectal artery, internal pudendal artery, or inferior vesical artery can be observed in approximately a third of patients. Anastomoses to the opposite side of the prostate are also observed in 20% of patients. Meticulous evaluation of arterial anatomy before embolisation is therefore required [29].

Pelvic arterial supply is markedly interconnected by anastomoses, most of which are characterised by low flow, and are identifiable only on angiogram with pressured injection of contrast media [30, 31]. Some anastomoses, however, provide communication between the prostate territory and structures of clinical interest including the bladder, rectum and penis [30–32]. These anastomoses can be selectively protected with microcoils or gelatin sponge to reduce the risk of non-target embolisation, especially in the case of high-flow anastomoses (Level 2a) [33, 34]. Another possibility in such cases is to navigate the microcatheter deeper into the prostate and distal to the anastomotic origin and perform prostate embolisation avoiding reflux of embolic material. On the other hand, migration of small amounts of embolic agent through anastomoses involving the obturator territory or other pelvic parietal structures may not lead to clinically relevant complications; therefore, there is usually no need for occluding those connections. Likewise, particle reflux or migration to seminal vesicle branches does not seem to cause major complications, although it can lead to self-limited haematospermia [29]. It is also common to identify intraprostatic connections, both ipsilateral-anastomoses between anteromedial and posterolateral prostatic branches of the same side and contralateral anastomoses. Due to the presence of contralateral anastomoses, it can be possible to

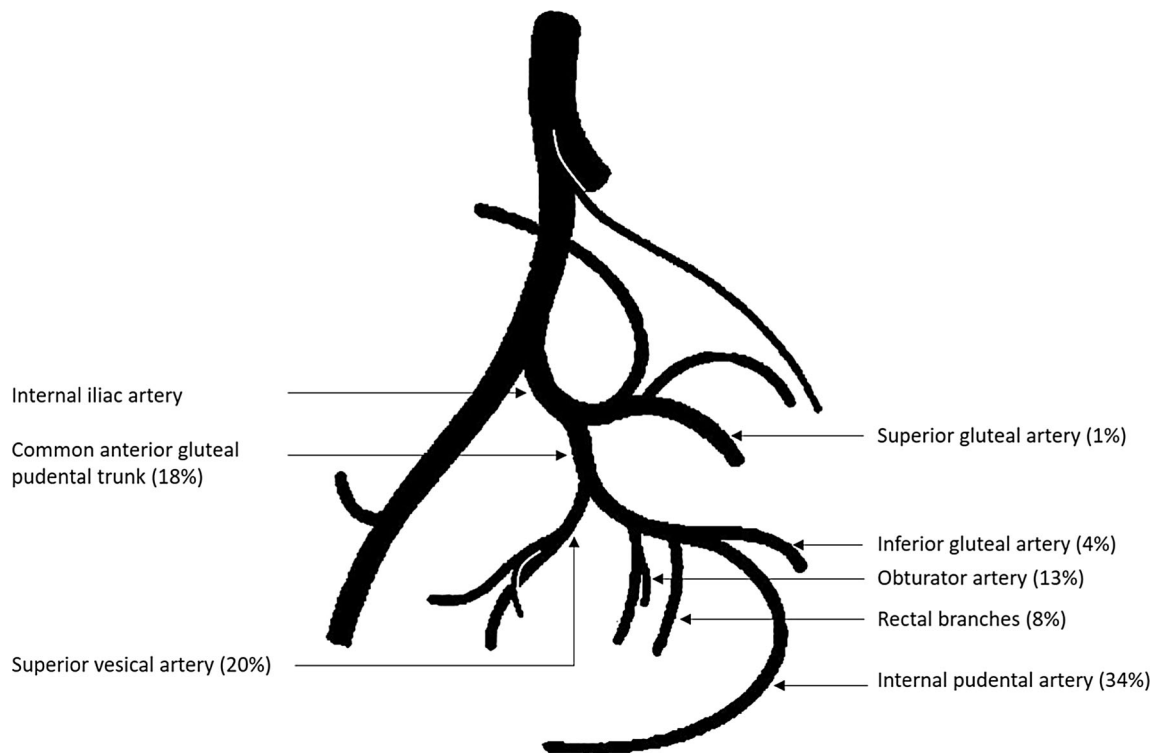


Fig. 1 Collaterals of internal iliac artery and variation of origin of prostate arteries (left hemipelvis angiogram of the internal iliac artery under ipsilateral oblique projection)

achieve embolisation of both prostate lobes through catheterisation of the prostatic artery on only one side [35]. For the same reason, embolisation of the first hemilobe of the prostate may require a larger number of particles than the second lobe, because the contralateral side is already partially embolised by intraprostatic contralateral communications, especially when using the PErFecTED (Proximal Embolization First, Then Embolize Distal) technique.

Methods of Embolisation: Conventional, PErFecTED, Balloon Occlusion

Once the embolisation position is confirmed, slow-flow injection of microspheres (300–500 μm) or polyvinyl alcohol particles (100–300 μm), highly diluted with contrast medium (20–40 mL of embolisation solution), is performed with a complete occlusion as end-point (Level 2a) [36–39]. The procedure is performed bilaterally and unilaterally only in the case of a failure to catheterise 1 side. The use of small microspheres (100–300 μm) may increase the risk of adverse events [13]. Embolisation of the prostatic arteries is completed when slow flow or stasis is observed, with disruption of arterial flow and opacification of the prostate gland [40]. For complete unilateral embolisation of the prostate artery, less than 0.5 mL of microspheres are generally required, but the volume often

depends on the intraprostatic vascularisation and size of the prostate. If the microcatheter position within the main prostatic artery trunk is proximal, premature complete stasis is frequently seen with reflux, not allowing delivery of more embolic volume. To overcome this limitation and although further evaluation is needed, the PErFecTED technique or balloon occlusion may be used as options to allow for the use of greater embolic volumes while limiting non-target embolisation and rupture of the small intraprostatic branches (Level 3b) [41–43].

Medication and Peri-procedural CARE

Patient Monitoring and Analgesia

The procedure is performed under local anaesthesia (Level 1a) [8]. In general, patients do not experience pain during or after PAE. If pain occurs, it can be controlled with oral medication. The use of smaller microspheres (100–300 μm) has shown higher pain levels, mainly urethral burning when urinating [23]. In most cases, the procedure is performed in an ambulatory setting, or with 1 night of hospitalisation. Patients usually receive hydration, 500 mg ciprofloxacin, phenazopyridine, a non-opioid analgesic and nonsteroidal anti-inflammatory drugs. If

necessary, corticosteroids and/or opioids can be used for pain management. Patients are usually discharged 3–6 h post-procedure (Level 2a). Those taking oral medications for LUTS can continue them for 1–2 weeks post-PAE.

Indwelling Urinary Catheter

Patients with indwelling catheters due to urinary retention at baseline usually return at 2 weeks for catheter removal and, in most situations (80–90%), spontaneous urination is restored. In case of failure, additional attempts to remove the Foley catheter are made every week for an additional 2–3 weeks for patients whose first attempt failed.

Post-procedural Follow-up Care (Including Imaging)

Clinical follow-up is performed at 3, 6 and 12 months, including IPSS, IIEF and patient-reported complication domains (Level 1a) [5]. At 3 and 12 months, additional clinical follow-up is performed with flow studies such as Q_{max} , and a prostate volume study. MRI and ultrasound may be performed at 3 and 6 months.

Outcomes

Effectiveness

Primary/Secondary

The procedure is considered successful if at least one hemi-prostate is embolised, but in the vast majority of cases both sides are embolised (Level 1a) [44]. The success rate defined by the embolisation of at least one hemi-prostate ranged from 90 to 98% [45]. Major atherosclerosis, small diameter of the prostatic arteries and severe artery tortuosity are reasons for failed catheterisation.

Comparison with Conservative Treatment and Surgery

No significant differences are observed in terms of rates of clinical failure for TURP and PAE [46–48]. Mean reduction in IPSS from baseline to 3 months is similar [49, 50]. However, at 3 months, PAE is less effective than TURP regarding changes in Q_{max} , PVR, prostate volume and desobstructive effectiveness according to pressure flow studies. Fewer adverse events occurred after PAE than after TURP. Hospital stay after PAE is significantly shorter than TURP (3 days vs 5 days) [7]. There was no significant difference regarding mean operative time between both groups (80–90 min).

Clinical Efficacy, Scores and Flowmetry (Short-/Mid-/Long-Term Results)

Criteria of symptomatic improvement are defined by an IPSS < 18 with a decrease of at least 25% and a QoL score ≤ 3 , with at least a one-point decrease compared to baseline (Level 2b) [4, 5].

Clinical failure of the procedure is defined as the persistence of severe symptoms (IPSS decrease $\leq 25\%$, IPSS score ≥ 18 , QoL score decrease ≤ 1 , and a QoL score ≥ 4) (Level 2b).

The success rates at 6 and 12 months are 78% and 75%, respectively [45]. At 6 months, mean improvement of the IPSS, the IIEF-score, the QoL score and the urinary flow was up to 12.9 points, 1.6 point, 2.8 points and 2.8 mL/s, respectively (Level 1a). At 6 months, PSA level and prostate volume mean reductions were of 1.38 ng/mL (24%) and 16.9 mL (20%). There is no statistical association between symptomatic improvement and prostate volume reduction. However, in patients with prostate volumes > 80 mL and Charlson score ≥ 2 , the mean IPSS and peak flow were significantly improved at 3 months and 1 year, compared to baseline as well as mean QoL score and post-void residual volume [32, 51, 52]. A significant decrease in prostate volume (up to 30%) and PSA level was also reported.

Complications and Their Management

Adverse events related to PAE are mostly mild and are similar to other endovascular embolisation intervention [53]. A minor post-embolisation syndrome is frequently observed during the first 3 days following the procedure. This syndrome may include nausea, vomiting, slight hyperthermia, painful urination, pelvic pain, rectal bleeding and haematuria. Additionally, a few patients report a feeling of slight pressure or minimal pain in the pelvic region radiating into the perineal region in the first 2 days after PAE. These issues can be well managed with oral analgesics. Dysuria (9%) is part of the post-embolisation syndrome and is not a complication. Other reported complications are urinary infections (7.6%), self-contained macroscopic haematuria (5.6%), acute urinary retention (2.5%) and rectal bleeding (2.5%) [45]. This is usually an embolisation effect due to the initial stages of necrosis. However, it may also be the result of non-target embolisation, but this is rare [54]. Hematospermia (0.5%) should be considered as an adverse event and not a complication. Urinary retentions are treated with transient urinary catheterisation, but other complications do not require any specific treatment. Major complications include severe urinary sepsis that may require readmission for intravenous antibiotic treatment; bladder ischaemia that could, although

rare, require a surgical excision of the necrotic area; and ischaemia of the glans [55].

Conclusion

PAE is an effective method for treating symptoms related to BPH and is a new minimally invasive alternative to classic urological surgical procedures in patients presenting with a large prostate. However, due to the small diameter of the prostate artery and anatomical variations as well as anastomoses, PAE needs meticulous work-up and should be performed by a trained IR.

A summary of key recommendations can be found in Table 1.

Supplementary Material

A table with Levels of Evidence is available in the online supplementary material of the article.

Compliance with ethical standards

Conflict of interest T. Bilhim is on the Advisory Board of Merit Medical, is a consultant for Terumo, a stock holder in the company “Embolx” and has a speaker agreement with Philips. M. Sapoval is a consultant for Merit Medical and has received research grants from BTG and Merit Medical. All other authors declare that they have no conflict of interest.

Table 1 Summary of recommendations

	Recommendation	Level of evidence
Indications	Patients with moderate-to-severe lower urinary tract symptoms (LUTS) related to BPH may benefit from prostatic artery embolisation (PAE)	Level 1a
	PAE can be performed in patients with symptomatic benign prostatic hyperplasia (BPH), in case of failure of medical treatment	Level 1a
	PAE can be performed in patients suffering from urinary retention due to BPH without an upper limit of prostate size	Level 1b
	PAE can be performed in patients who have comorbidities (for instance, patients using anticoagulation or antiplatelet therapy)	Level 2b
	PAE is suited to younger, sexually active patients who have concerns about retrograde ejaculation, erectile dysfunction or urinary incontinence	Level 2b
	PAE may be performed 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 2b
	PAE may achieve cessation of bleeding in patients with haematuria of prostatic origin	Level 2b,
Pre-operative scores and testing	International Prostate Symptom Score (IPSS) and urodynamic testing provide a broad measure of the severity of symptoms of BPH. Inclusion criteria for PAE are: IPSS ≥ 8 and/or quality of life score (QoL) ≥ 3 ; prostate volume > 30 – 50 mL; a urine peak flow less than 15 mL/s; post-void residual volume < 200 mL	Level 1a
Contraindications	Relative contraindications to PAE are patients with bladder diverticuli size > 2 cm, bladder stone, detrusor hyperactivity or hypocontractility, neurogenic bladder and severe renal insufficiency	Level 1a
	In case of) PSA (prostate-specific antigen level above 4 ng/ml, prostate biopsies must be discussed before the procedure with the referring urologist	Level 1a
Imaging	Imaging by ultrasound, CT angiography (CTA) and MRI can be used in combination to assess: prostate volume and post-void residual (PVR); vessel patency/course and collaterals; and serve as the baseline for follow-up, respectively	Level 1a
	Pre-operative imaging with a pelvic MRI and/or CTA or MR angiography scan may assess pelvic vasculature	Level 2b
Patient preparation, procedural features and variations of the technique of PAE	Antibiotics (ciprofloxacin or cefazoline) can be used due to the risk of urinary tract infection, as in any prostate intervention	Level 5
	Although femoral approach is more often performed, transradial arterial access represents a safe and feasible method for performing PAE	Level 2a
	Cone-beam CT (CBCT) angiography may be used to identify the anatomical vascular anatomy of the prostate	Level 2a

Table 1 continued

	Recommendation	Level of evidence
	Digital subtraction angiography work-up allows visualisation of the prostate arteries and the characteristic blush of the prostate	Level 2a
	If anastomoses with pelvic arteries occur, proximal closure of the anastomoses can be performed using coils to avoid non-target embolisation	Level 2a
	Slow-flow injection of highly diluted (20–40 mL solution) calibrated microspheres (300–500 µm) or polyvinyl alcohol particles (100–300 µm) is performed with a complete occlusion as end-point	Level 2a
	The procedure is considered successful if at least 1 hemi-prostate is embolised, but in the vast majority of cases both sides are embolised	Level 1a
	PERFECTED (Proximal Embolization First, Then Embolize Distal) technique and balloon occlusion PAE may be used as options to secure prostate arterial occlusion	Level 3b
Medication and Peri-procedural Care	PAE is usually performed under local anaesthesia as an outpatient intervention	Level 1a
	Pain is infrequently reported and is controlled with oral medication	Level 2a
	Patients are usually discharged 3–6 h post-procedure.	Level 2a
Outcomes	Clinical follow-up is performed at 3, 6 and 12 months, including IPSS, international index of erectile function (IIEF) and patient-reported complication domains	Level 1a
	Criteria of symptomatic improvement are defined by an IPSS < 18 with a decrease of at least 25% and a QoL score ≤ 3 with at least 1 point decrease, compared to baseline	Level 2b
	Clinical failure of the procedure is defined as the persistence of severe symptoms (IPSS decrease ≤ 25%, IPSS score ≥ 18, QoL score decrease ≤ 1, and a QoL score ≥ 4), or a decrease in the peak urinary flow	Level 2b
	In reporting adverse events following PAE, it is recommended to use the modified Clavien classification	Level 1

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