

# A Review of Adverse Events Related to Prostatic Artery Embolization for Treatment of Bladder Outlet Obstruction Due to BPH

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## Abstract

**Introduction** Minimally invasive procedures have gained great importance among the treatments for benign prostatic hyperplasia (BPH) due to their low morbidity. Prostatic artery embolization has emerged as a safe and effective alternative for patients with large volume BPH, not suited for surgery.

**Materials and Methods** Low adverse events rates have been reported following prostatic artery embolization and may include dysuria, urinary infection, hematuria, hematospermia, acute urinary retention and rectal bleeding.

Although most complaints are reported as side effects, complications can also be superimposed.

**Results** The prostate gland is the most common source of complaints following PAE, where the inflammatory process can create a large variety of localized symptoms. Periprostatic organs and structures such as bladder, rectum, penis, seminal vesicle, pelvis, bones and skin may be damaged by nontarget embolization, especially due to the misidentification of the normal vascular anatomy and variants or due to inadvertent embolic reflux. Radiodermatitis may also happen in case of small vessel size, atherosclerosis, the learning curve and long procedure or fluoroscopy times.

**Discussion** Regarding safety, it is pivotal to understand the pathophysiology of adverse events following PAE and their standardized reporting. The aim of this article is to discuss adverse events, their management and to review the current literature.

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## Introduction

The knowledge of side effects and complication rates is of pivotal importance to help patients choose a treatment for bladder outlet obstruction due to BPH. Minimally invasive procedures have gained great importance because of their lower morbidity. Monopolar transurethral resection of the prostate (TURP) is regarded as the gold-standard surgical treatment for BPH with overall complication rates greater than 10% [1].

Bipolar TURP and laser are surgical alternatives with lower complication rates [2].

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Prostate artery embolization (PAE) has emerged as a safe and effective alternative minimally invasive procedure that may improve lower urinary tract symptoms (LUTS), especially for patients with BPH, who are contraindicated for surgery [3–5].

Although the category of adverse events can include both side effects and complications, an understanding of the differences between them is fundamental. A side effect refers to any expected, but untoward response, while a “complication” refers to any unanticipated negative outcome related to the treatment [6, 7] (Fig. 1).

Standardizing descriptions of adverse events following PAE is an important element of quality reporting of outcomes and makes it possible to compare complications and their treatments in a systematic way. The Clavien–Dindo grading system (I–IV) for classification of surgical complications may be useful for reporting PAE adverse events. Regarding the intensity of the event, grades I and II are reported as minor and grades III and IV as major [5, 6]. The timing of events observed after PAE can be classified as immediate (within the first day), early (between the second and the 29th day) or late (30th day or after). Currently, only a few PAE trials have used standardized classifications for reporting adverse events [8, 10, 11].

Understanding the pathophysiologic source of symptoms following PAE will help to explain adverse events and differentiate side effects from complications. The aim of this article is to discuss post-PAE adverse events, their management and to review the current literature.

## Main Text

Prevention is of paramount importance when performing any controlled ischemic therapeutic treatment, including PAE. In this setting, infection is a great source of concern. Some authors recommend the use of antibiotic prophylaxis

for procedures involving the male genitourinary tract that result in a significant volume of necrotic tissue. Antibiotics are administered even without evidence of previous infection or positive cultures. In this situation, antibiotic choice should be based on local common organisms [12–14].

Advanced age, diabetes, chronic renal failure, compromised immune status, previous urethral instrumentation, bladder dysfunction, bacteriuria and stones are all considered risk factors for infectious complications, as well as urosepsis [15].

Pisco et al. [10] reported one case of urosepsis following PAE in a group of 255 patients of whom 32 patients had had indwelling catheters and 8 had undergone a previous TURP.

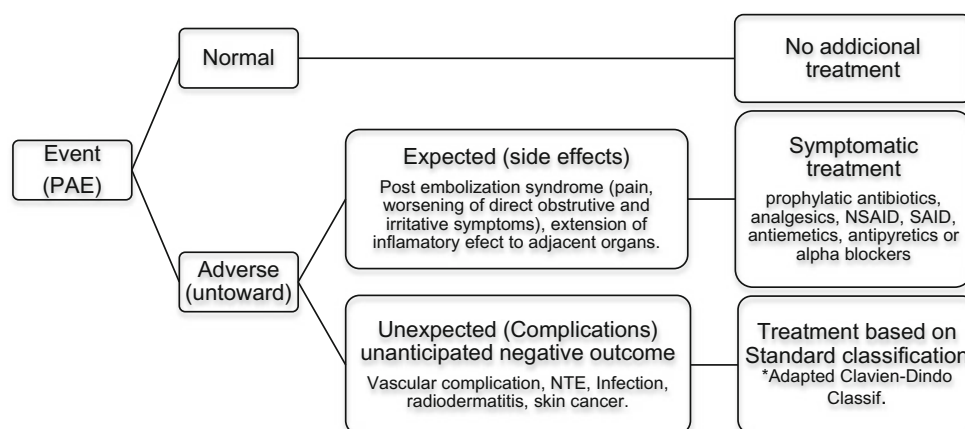
In a recent review, Jones et al. assessed seven trials of PAE for LUTS in which levofloxacin was prescribed 2 days before and 10 days after the procedure. Although there is no consensus, the use of antibiotic prophylaxis during PAE is justified considering risks [13, 14, 16–20].

The proper reporting of adverse events report following PAE is pivotal and may be done using standard classifications, including the Clavien–Dindo classification of surgical complications adapted to PAE procedure findings [8, 9].

Anticipated symptoms (side effects) are generally managed with prophylactic antibiotics, analgesics, NSAID, SAID, antiemetics and antipyretics and are not reported as complications (Fig. 1).

In Table 1, we suggest a modified Clavien classification adapted to the description of adverse events following PAE. In addition to reporting standardization, description and understanding of etiology will assist in choosing the best approach [21].

Adverse events can happen at all stages of the embolization procedure and should be classified into intraoperative and postoperative.



**Fig. 1** Therapeutic flowchart of events post-PAE

**Table 1** Clavien–Dindo classification of surgical complications adapted to PAE

Grade	Definition
I	Any unexpected deviation from the normal post-embolization course without the need for additional pharmacological, urologic surgical/endoscopic or radiological procedures*
II	The need for pharmacological treatment with drugs other than those allowed for grade I, as therapeutic use of antibiotics due to infection. Indwelling catheters are used in case of early acute urinary retention. Additional noninvasive tests
III	The need for pharmacological treatment with drugs used in grade II, as well as surgical/endoscopic or radiological procedures, under or without general anesthesia
IV	Any deviation from the normal post-embolization course with a life-threatening complication requiring ICU-management due to single or multi-organ dysfunction
V	Death
Suffix 'd'	If the patient suffers from a complication at the time of discharge, the suffix "d" (for 'disability') is added to the respective grade of complication. This label indicates the need for a follow-up to fully evaluate the complication

\*Remember that expected symptoms and signals observed post-PAE (side effects) are not considered to be classified as grade I. Accepted drugs to treat side effects include prophylactic antibiotics, analgesics, NSAID, SAID, antiemetics, antipyretics or alpha blockers

### Intraoperative Events

Vascular access, catheterization and embolization technique, device failure or incompatibility, manufacturing defects, or inappropriate use of materials, and drug or contrast reactions are all potential sources of intraoperative complications [22] (Fig. 2).

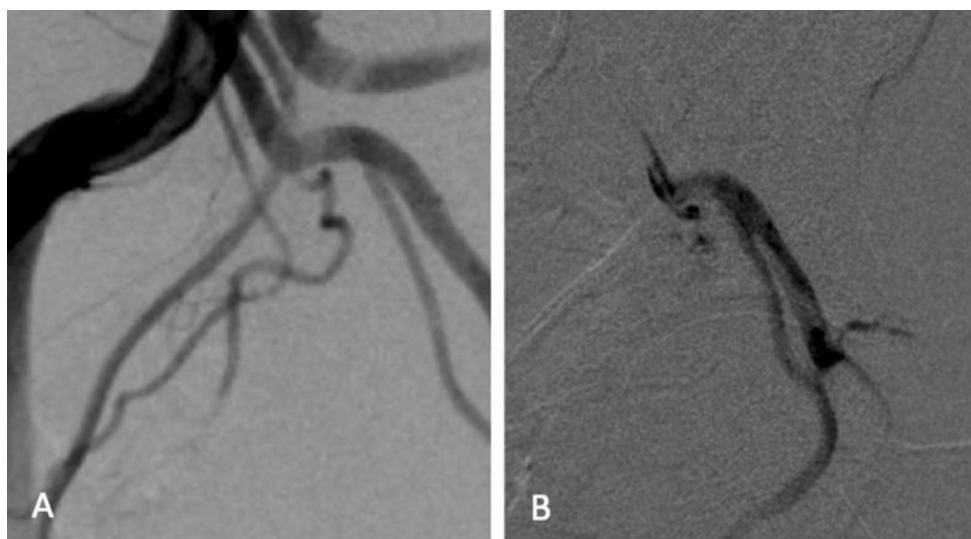
Although careful technique may avoid undesired events, vascular access, hematomas, pseudoaneurysms, vascular thrombosis, dissection, distal embolization and damage of the perivascular, neural and muscular structures may happen. These complications can lead to incomplete embolization or interruption of the procedure. Taking into account patient satisfaction and fewer local complications,

alternate vascular access techniques such as a transradial should be considered [23].

Furthermore, misinterpretation of vascular anatomy and inadequate suboptimal use of embolic agents may result in NTE [24].

Once the prostate arteries have been properly identified and catheterized, embolization can begin. More distal embolization, as reported with PErFecTED technique, appears to achieve the desired greater ischemic effect, but in some cases has been associated with more side effects including pain, urethral burning and urinary frequency [25].

It is not clear if the use of smaller particles is associated with increased NTE embolization, but a recent report



**Fig. 2** Selective Internal iliac artery angiography demonstrating a very tortuous inferior vesicle artery (A). After a failed catheterization attempt, new angiography demonstrates dissection, followed by occlusion (B)

suggests that the smaller the particle size, the more adverse events, like burning and dysuria, may be observed [26].

There are no reports regarding complications specifically due to reaction to angiographic contrast medium following PAE. Nevertheless, adverse events should be no different from any other embolisation or angiographic procedure, associated with a very low incidence rate, most of which are not life-threatening [27–29].

### Postoperative Events (PEv)

Adverse events following PAE generally include dysuria (9%), urinary infection (7.6%), macroscopic hematuria (5.6%), hematospermia (0.5%), AUR (2.5%) and rectal bleeding (2.5%) [3, 5, 9, 30–33] Tables 2 and 3.

We have grouped adverse events by pathophysiology and anatomical site of origin for easier discussion.

(a) *Prostate gland*: The prostatic and periprostatic inflammatory process generates the majority of anticipated symptoms following PAE.

Deep visceral structures are sensitive to distension, ischemia and inflammation. The prostatic pain following PAE may be correlated to the activation of visceral nociceptors and is usually reported as diffuse, difficult to localize, deep or superficial and perceived as a burning pain [34, 35].

After embolization, the urinary flow increases due to the block of the circulating androgens, destruction of the

innervation and decrease of smooth muscle tone and urethral resistance. Apoptosis, necrosis or infarction induces cytotoxic edema, leukocytic infiltration and ischemic inflammatory prostatitis which can produce a variety of symptoms, including pelvic pain or discomfort, perineal, suprapubic, coccygeal, rectal, urethral, testicular/scrotal pain and obstructive or urinary tract symptoms such as frequency, dysuria, incomplete voiding and ejaculatory pain [3, 30, 33].

In some patients there may also be nausea, vomiting and fever [29] as well as a temporary worsening of previous symptoms, especially the irritative voiding symptoms due to as increased post-embolic inflammatory process [36] (Fig. 3).

Collectively, these events comprise post-embolization syndrome (PES) and they should be considered expected side effects, not complications [34].

Although severity of PES cannot be predicted and it usually disappears within a week, its management is crucial to rapid recovery, patient satisfaction and a better quality of life.

Gao et al. [30] reported six cases of PES during the first 30 days following PAE in a group of 57 patients during a controlled trial comparing PAE versus TURP.

Acute urinary retention (AUR) can occur at an early or late stage following PAE. Early incidents may be caused by urethral compression due to edema and often disappear within 3 days [10].

**Table 2** Some of the post-PAE findings, with organ of origin, described by some authors, the year of description and the number of patients evaluated

Site of origin	Author Year	Antunes 2013 <i>n</i> = 11 (%)	Pisco 2013 <i>n</i> = 255 (%)	Bagla 2014 <i>n</i> = 72 (%)	Kurbatov 2014 <i>n</i> = 88 (%)	Gao 2014 <i>n</i> = 114 (%)	Assis 2015 <i>n</i> = 35 (%)	Wang 2015 <i>n</i> = 115 (%)
Prostate	Pelvic pain					1.9		
Prostate	Acute urinary retention		2.4			25.9		10.2–28.3
Urethra	Transient increase of urinary frequency			42				
Urethra	Burning urethral pain	82	9.2					10.2–16.7
Urethra	Urinary tract infection						2.9 M*	
Urethra	Urethral trauma						2.9	
Bladder	Hematuria	9	5.6					8.2–11.7
Bladder	Urinary tract infection		1.2		1.9			
Bladder	Bladder necrosis		0.4 M*					
Rectum	Diarrhea	18					2.9	
Rectum	Rectorrhagia	27	2.4				5.9	8.2–10
Penis	Ischemic balanitis	1.6					2.9	
Sem. vesicle	Hematospermia		4	16	1.09		5.9	8.2–11.7

M\* major complication

**Table 3** Potentially observed post-PAE adverse events

Adverse event and source	Symptom
Post-embolization syndrome	Perineal pain
	Retropubic pain
	Urethral pain
	Acute urinary retention
	Vomiting
	Nausea
	Hematuria
	Fever
Prostate site	Prostatic and periprostatic pain
	Retropubic pain
	Burning urethral pain
	Acute urinary retention
	Dysuria
	Urinary tract infection
Urethral site	Burning perineal pain
	Periprostatic pain
	Burning urethral pain
	Acute urinary retention
Bladder site	Dysuria
	Urinary tract infection
	Local or extensive necrosis
	Suprapubic pain
	Pelvic abscess
Rectum site	Hematuria
	Urinary tract infection
	Colic pain
	Anal spasms
	Diarrhea
	Anal fissures
	Rectal ulcers
	Pelvic abscess
	Blood in the stool
	Rectorrhagia
Penis site	Ischemic balanitis
	Sexual dysfunction
	Impotence
Seminal vesicle site	Hemospermia
	Reduction of the ejaculatory volume
	Gland atrophy
Pelvic, bone and skin site	Continuous or burning perineal pain
	Asymptomatic bone ischemia
	Skin Erythema
Radiodermatitis	Skin ulcers
	Cancer
	Skin erythema
	Skin ulcers

At a later stage, it may occur due to another inflammatory event or gland regrowth. Pisco et al. reported six cases of late AUR in 255 patients (10%) during 18 months of follow-up after PAE. Four cases (4/6) were managed with temporary indwelling catheters and repeated PAE, with good results [10].

Gao et al. reported 14 cases of early AUR (25.9%) during the 1st month post-PAE, but this incidence was not discussed in detail. Those patients required transient urinary catheterization and medical treatment [30].

(b) *Urethra*: The anatomical proximity of urethra and prostate may explain some of the complaints following PAE due to the inflammatory process. Another concern would be related to the diameter of the branches that supply the prostatic portion of the urethra (40–60 μm) which can be penetrated by small particles during embolization, producing ischemia. Although untargeted embolization and injury of the urethral wall should be a concern, Wang et al. [24] reported no strictures, after using particles with 50 and 100 μm in diameter in 117 patients with prostates >80 mL, during 24 months of follow-up after PAE.

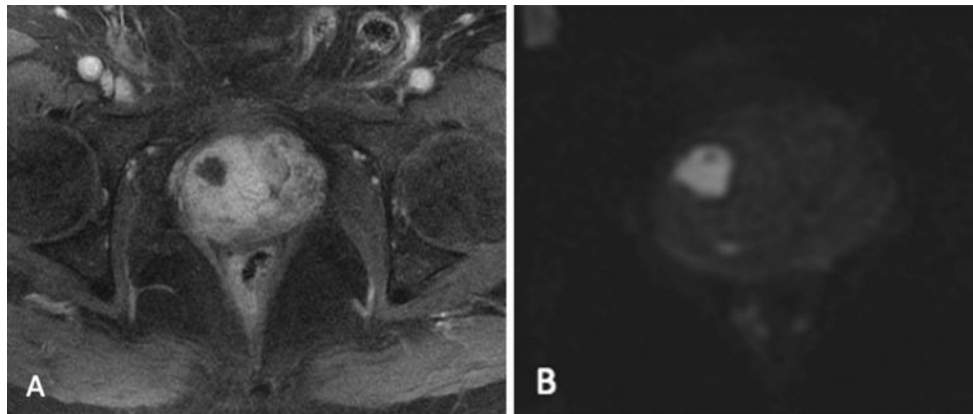
(c) *Periprostatic organs and structures*: The prostatic blood supply usually arises from the inferior vesical, as well as internal pudendal, middle rectal, umbilical, obturator or inferior gluteal arteries. The superior rectal artery has connections to prostatic branches in 32% of cases. While this wide regional, collateral arterial network may protect the patient against ischemic damages, it also increases the potential for NTE [37, 38].

NTE can occur due to misinterpretation of the blood supply to the prostate, vascular anatomical variations, high-flow vascular anastomoses, suboptimal catheter placement or inappropriate embolic agent [39].

Reflux to small vessels should always be avoided. Used carefully, vasodilators are useful for treating spasms, but they can inadvertently open peri or intraprostatic shunts. Selective angiograms and cone-beam computed tomography (CBCT) facilitate improved safety and efficacy during embolization, identifying potential sites of NTE and anatomical variations [40].

When larger anastomoses are identified during PAE, embolization is still possible with slow injection and/or protective occlusion, either temporary or permanent (micro coils), to avoid NTE [39, 41–45].

(c.1) *Bladder*: Minor areas of bladder ischemia following PAE are usually asymptomatic. Retrograde cystography, cystoscopy and bladder computed tomography (CT) or magnetic resonance imaging (MRI) can help to identify the number and size of ischemic areas, perforation to intraperitoneal or extraperitoneal zone or impairment of nearby areas [46, 47].



**Fig. 3** One year post-PAE pelvic MRI demonstrating a small well defined avascular area in the right prostate central zone (A). Diffusion-weighted imaging shows diffusion restriction in the same area, suggesting local abscess

Small, unperforated lesions can be treated with indwelling catheters and antibiotics. Surgery is indicated for extensive ischemic areas in the intraperitoneal zone and gross hematuria. Treatment of multiple ischemic areas in the extraperitoneal zone is still controversial [48, 49].

In 2013, Pisco et al. [10, 16] reported a case of bladder ischemia involving a small area (1.5 cm<sup>2</sup>) without impairment of the ureteral or urethral orifices. Surgical incision was required, but no bladder reconstruction was necessary.

Occasionally, ischemic tissue fragments and clots originating in the bladder or prostate gland may produce pain, AUR or urinary tract infection due to flow obstruction (Fig. 4) [49]. Cystoscopy may be used to evaluate these instances and clear the bladder [10, 16].

(c.2) *Rectum*: The arterial supply to the rectum and anus usually comes from the superior, middle and inferior rectal branches, and there is a rich vascular network connecting the inferior mesenteric, internal iliac, internal pudendal and marginal arteries. This explains the low incidence of ischemic proctitis [50].



**Fig. 4** Image of a small prostatic gland fragment eliminated during voiding attempt at 1 month following prostate artery embolization

Although, it is rare following PAE, it may occur due to NTE of the middle rectal artery or other variant branch [37] (Fig. 5).

Assis et al. described and categorized the prostatic origins found during PAE in 143 patients, proposing a I–V classification based on the inferior vesical artery origin to help identification of the most frequent vascular patterns. The most frequent was type IV, observed when the IVA arises from the internal pudendal artery, was associated with a high incidence of rectal branches, either adjacent or in a common trunk with the prostatic arteries. Protective embolization of rectal branches with coils may help to avoid NTE [51, 52].

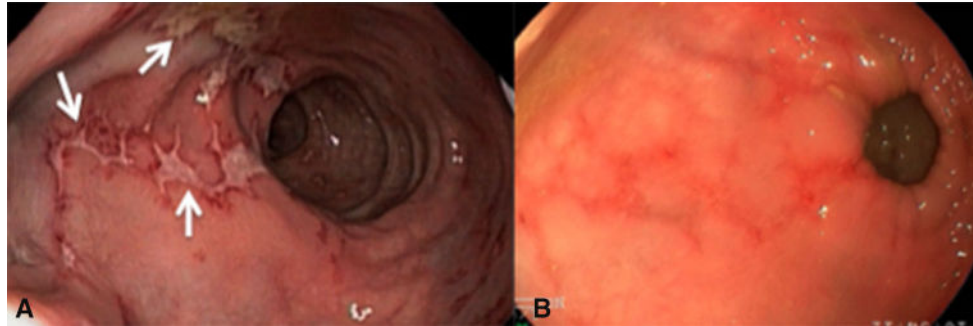
In the event of NTE of the rectum or anus, patients may complain of low abdominal pain, diarrhea that may include bloody discharge, proctalgia, erosions, fistula or abscess. Diarrhea and bleeding may be caused by inflammation or focal ischemia of the mucous membrane [53].

In 2013, Moreira et al. reported a case of a transient ischemic proctitis probably related to NTE. A small amount of blood mixed in the stool was observed during the first 3 days post-PAE. Colonoscopy at day 4 showed rectal ulcers, which had disappeared by day 16, without treatment [37].

In 2015, Jones et al. [16] in a review including different authors and number of patients reported the transient rectal bleeding incidence ranging between 2.4 and 27%.

Proctoscopy or colonoscopy should be reserved to severe cases or in context of trials to evaluate the mucosa and identify ischemic proctitis. The treatment depends on the severity of symptoms, but no cases requiring a surgical approach have been reported in the literature [54].

(c.3) *Penis*: Penile ischemia is commonly reported after trauma but may also be associated with misadministration of vasoconstrictors, diabetes mellitus, atherosclerosis, circumcision or vasculitis [55–57].



**Fig. 5** Colonoscopy (A) demonstrating small rectal ulcers due to ischemic proctitis. After 10 days, a new examination (B) found a local advanced healing process. (figure reprinted with permission of the author)

Because dorsal penile arteries are terminal vessels, the inadvertent reflux of embolic agents or misembolization during PAE may lead to ischemia [58].

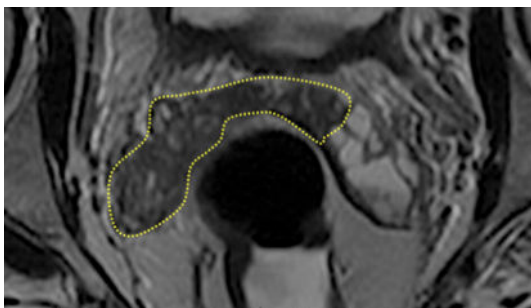
Such a complication may be reported as local pain, erythema, ulcers or sexual dysfunction. Although an erythematous appearance of the glans may suggest ischemia, it must be differentiated from balanitis or balanoposthitis [59].

Ultrasound Doppler exam and tissue culture may be useful for evaluation. Treatment includes NSAID, analgesics, steroids, vasodilators, antiplatelets, low molecular weight heparin, prostaglandin E1 and antibiotics. No irreversible lesions have been reported following PAE [58–60].

Possible scrotal skin necrosis may happen due to NTE of the external iliac artery or internal pudendal artery branches.

Another potential source of concern is erectile dysfunction, which may happen due to occlusion of the internal pudendal artery. Experimental studies report that after unilateral acute clamping of the internal pudendal, a compensatory contralateral flow is observed with a moderate impairment of intracavernous pressure. Bilateral occlusions resulted in a marked reduction in the intracavernous pressure and low response to neurostimulation [50].

No cases of erectile dysfunction following PAE have been reported so far [10, 33, 40].



**Fig. 6** T2-weighted MRI image in axial view demonstrates abnormal low-intensity signal of the right seminal vesicle and medial segment of the left seminal vesicle (dotted line), suggestive of infarction

(c.4) *Seminal vesicle*: Although usually asymptomatic, the post-ischemic inflammatory process of the seminal vesicle may result in back, low abdominal or perineal pain, painful ejaculation, hematospermia and irritative or obstructive voiding symptoms [61].

The true incidence of seminal vesicle ischemia following PAE is unknown.

Assis et al. reported two cases (5.9%), seen in a T2-weighted MRI as a bilateral low-intensity sign in the seminal vesical area. No treatment was necessary [4, 33] (Fig. 6).

Clinical seminal vesiculitis may happen due to inflammation observed following PAE. Patients may complain of hematospermia, discomfort and pain in lumbosacral or perineal region, irritative and obstructive urinary symptoms, decreased semen volume and/or azoospermia [62].

Patients with urethritis or epididymitis are likely to have seminal vesiculitis, suggesting a close relationship between them. Hematospermia usually is self-limiting, generally asymptomatic and resolves spontaneously within a few weeks or after approximately 10 ejaculations. Its correlation with seminal vesical ischemia remains unclear, since the bleeding can have its source in any portion of the genitourinary tract. A transrectal ultrasonography or pelvic MRI may help to diagnose these complications [10, 62–64].

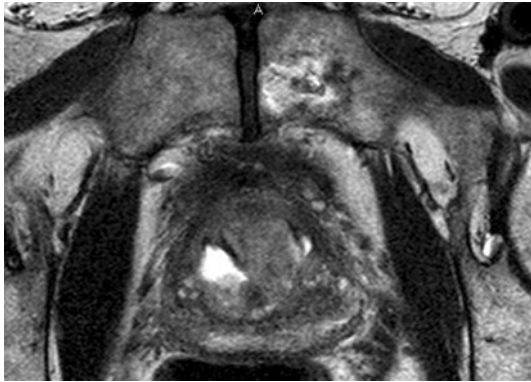
Pisco et al. [10] reported transient cases of hematospermia following PAE, with an incidence rate of 0.4% (10/250) but did not explain their causes.

To minimize complications in this setting, Bagla et al. suggested that more distal catheterization should be performed when it is seen during angiography to protect arterial supply to the vesicles [33, 40].

Treatment usually includes NSAID, analgesics and if necessary, steroids or antibiotics [10].

(c.5) *Other structures (pelvis, bones and skin)*: Pelvic embolization rarely results in unintended ischemia because of the rich vascular network. Complications such as sciatic neuropathy and pelvic osteonecrosis are rare [65].

The inadvertent embolization of the obturator artery may result in pubic or obturator ring bone ischemia. It is



**Fig. 7** One month post-PAE pelvic MRI T2 weighted imaging, in axial, coronal and sagittal view, showing a high signal lesion in the left pubic bone suggesting local infarction

usually asymptomatic and only found during CT or MRI [74]. MRI changes become apparent only after 6 h to 2 days [67–70] (Fig. 7).

Carnevale et al. reported one case of pubic ischemia observed on MRI at 3-month follow-up. The lesion disappeared without treatment [69].

Although few data have been published regarding radiation exposure following PAE, this is an important source of concern. Radiodermatitis is caused by changes in skin cells exposed to radiation, altering its ability to regenerate [66].

The SIR guideline for patient radiation dose management endorsed by CIRSE calls for specific follow-up for those receiving a significant dose of radiation and recommends threshold doses of 1–3 Gy per procedure [71].

PAE is a technically challenging procedure frequently with long fluoroscopy times by new operators and especially in cases of small vessels in atherosclerotic patients, anatomical variations or large pelvic anastomoses [71–74].

Laborda et al. [75] described a case in an obese patient following 72 min and 8,023,949 mGy/cm<sup>2</sup> of total radiation exposure during a PAE.

One study, including 34 patients with prostates exceeding 90 g, reported a mean procedure time of 158 min and a mean fluoroscopy time of 55.4 min [33], but no instances of radiodermatitis.

Pisco et al. reported a mean procedure time of 72 min and a mean fluoroscopy time of 18 min, which was lower than other published data. Such exposures can lead to stochastic effects [13, 34].

Fluoroscopy time can be used as an indicator of radiation dose, and times greater than 60 min should trigger a specific follow-up [67].

Reducing the number of DSA runs, pre-planning the procedure, using low-dose mode, pulsed fluoroscopy,

collimation and image hold capabilities help to avoid injuries [32].

PAE is a safe procedure with good functional outcomes. Complaints may be related to anticipated treatment side effects, as well as complications. Although most complications are described as minor (grades I and II), their recognition, understanding and standardized description are fundamental to minimization of risks, adequate management and to maximize the value of future trials.

## Summary

- Adverse events can include both side effects and complications. A side effect refers to any expected, but untoward response, while a “complication” refers to any unanticipated negative outcome related to the treatment.
- Standardizing descriptions of adverse events is an important element of quality reporting of outcomes and makes it possible to compare complications and their treatments in a systematic way.
- Prevention is of paramount importance when performing any controlled ischemic therapeutic treatment, including PAE.
- Adverse events can happen at all stages of the embolization procedure and should be classified into intraoperative and postoperative.
- Intraoperative events may include vascular access, catheterization and embolization technique, device failure or incompatibility, manufacturing defects, or inappropriate use of materials, and drug or contrast reactions, while post-PAE adverse events generally include dysuria, urinary infection, macroscopic hematuria, hematospermia, AUR and rectal bleeding. These findings may be correlated to the anatomical site of origin for easier discussion as prostate gland, urethra, periprostatic organs, bladder, rectum, penis, seminal vesicle and other structures as pelvis, bones and skin.
- NTE can occur due to misinterpretation of the blood supply to the prostate, vascular anatomical variations, high-flow vascular anastomoses, suboptimal catheter placement or inappropriate embolic agent as well as to reflux to small vessels should always be avoided.
- Although most complications are described as minor, their recognition, understanding and standardized description are fundamental to minimization of risks, adequate management and to maximize the value of future trials.



### Compliance with Ethical Standards

**Conflict of interest** On behalf of all authors, the corresponding author states that there is no conflict of interest.

**Ethical Approval** This article does not contain any studies with human participants or animals performed by any of the authors, and formal consent is not required.

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