Prostatic Artery Embolization: An Emerging Technique in Interventional Radiology

Sharon Lehmann, MS, APRN, CNS; Michael Rosenberg, MD; Prashant Shrestha, MD; Jafar Golzarian, MD; and Mary Schooley, BA, BAN, RN

ABSTRACT: This article will discuss benign prostatic hyperplasia and a new interventional radiology procedure, prostatic artery embolization. Information from diagnosis of benign prostatic hyperplasia to prostatic artery embolization procedure nursing care is included. A discussion of the U.S. Food and Drug Administration influence is given. (J Radiol Nurs 2015;34:209-221.)

KEY WORDS: Prostatic artery embolization; Benign prostatic hyperplasia; Interventional radiology; Nursing care.

INTRODUCTION

As a man ages, it is common that he will develop an enlarged prostate or benign prostatic hyperplasia (BPH). More than 50% of men aged 60-69 years and as many as 90% of men aged 70-89 years have clinical manifestations (Wei, Calhoun, & Jacobsen, 2005). BPH is a histologic diagnosis characterized by proliferation of the cellular elements of the prostate. BPH manifests itself in lower urinary tract symptoms (LUTS) which may include: weak urine stream or difficulty with urination, stopping and starting while urinating along with dribbling at the end of urination, straining while urinating, urinary frequency especially at night, urgent need to urinate and not being able to empty the bladder, blood in the urine, and urinary tract infections (Sarma, & Wei, 2012). The LUTS can be quantified with the International Prostate Symptom Score (I-PSS; McVary, et al., 2011). Age-related vasculopathy has been suggested as the cause for BPH. This theory...
creates a doughnut-shaped gland with multiple lobes, and it is located below the bladder about halfway between the rectum and the base of the penis. It encircles the urethra (the tube that carries urine from the bladder out through the penis), and in young men, it is normally about the size of a walnut. The prostate produces most of the fluid that makes up semen. The prostate is a doughnut-shaped gland with multiple lobes, and it is located below the bladder about halfway between the rectum and the base of the penis. It encircles the urethra (the tube that carries urine from the bladder out through the penis), and in young men, it is normally about the size of a walnut. The prostate produces most of the fluid that makes up semen. The prostate is a doughnut-shaped gland with multiple lobes, and it is located below the bladder about halfway between the rectum and the base of the penis. It encircles the urethra (the tube that carries urine from the bladder out through the penis), and in young men, it is normally about the size of a walnut. The prostate produces most of the fluid that makes up semen. The prostate is a doughnut-shaped gland with multiple lobes, and it is located below the bladder about halfway between the rectum and the base of the penis. It encircles the urethra (the tube that carries urine from the bladder out through the penis), and in young men, it is normally about the size of a walnut. The prostate produces most of the fluid that makes up semen. The prostate is a doughnut-shaped gland with multiple lobes, and it is located below the bladder about halfway between the rectum and the base of the penis. It encircles the urethra (the tube that carries urine from the bladder out through the penis), and in young men, it is normally about the size of a walnut. The prostate produces most of the fluid that makes up semen. The prostate is a doughnut-shaped gland with multiple lobes, and it is located below the bladder about halfway between the rectum and the base of the penis. It encircles the urethra (the tube that carries urine from the bladder out through the penis), and in young men, it is normally about the size of a walnut. The prostate produces most of the fluid that makes up semen. The prostate is a doughnut-shaped gland with multiple lobes, and it is located below the bladder about halfway between the rectum and the base of the penis. It encircles the urethra (the tube that carries urine from the bladder out through the penis), and in young men, it is normally about the size of a walnut. The prostate produces most of the fluid that makes up semen. The prostate is a doughnut-shaped gland with multiple lobes, and it is located below the bladder about halfway between the rectum and the base of the penis. It encircles the urethra (the tube that carries urine from the bladder out through the penis), and in young men, it is normally about the size of a walnut. The prostate produces most of the fluid that makes up semen. The prostate is a doughnut-shaped gland with multiple lobes, and it is located below the bladder about halfway between the rectum and the base of the penis. It encircles the urethra (the tube that carries urine from the bladder out through the penis), and in young men, it is normally about the size of a walnut. The prostate produces most of the fluid that makes up semen. The prostate is a doughnut-shaped gland with multiple lobes, and it is located below the bladder about halfway between the rectum and the base of the penis. It encircles the urethra (the tube that carries urine from the bladder out through the penis), and in young men, it is normally about the size of a walnut. The prostate produces most of the fluid that makes up semen. The prostate is a doughnut-shaped gland with multiple lobes, and it is located below the bladder about halfway between the rectum and the base of the penis. It encircles the urethra (the tube that carries urine from the bladder out through the penis), and in young men, it is normally about the size of a walnut. The prostate produces most of the fluid that makes up semen. The prostate is a dou

**Table 1. Age-specific reference ranges for serum prostate specific antigen**

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Dr. Carnevale and his group in Brazil, and Dr. Pisco and his group in Portugal have studied the PAE procedure extensively. Not only have they developed a technically successful procedure, they have followed the patients for an extended length of time noting successful reductions in I-PSS and quality of life scores, and significant reduction in PV. PAE offers a minimally invasive alternative treatment for patients with LUTS secondary to BPH. This procedure is performed with moderate conscious sedation on an outpatient basis (Carnevale, et al., 2010; Pisco, et al., 2011).

### PATHOPHYSIOLOGY

The prostate is a doughnut-shaped gland with multiple lobes, and it is located below the bladder about halfway between the rectum and the base of the penis. It encircles the urethra (the tube that carries urine from the bladder out through the penis), and in young men, it is normally about the size of a walnut. The prostate produces most of the fluid that makes up semen. The prostate can be felt easily during a rectal exam, as the prostate lies just in front of the rectum.

The prostate can be divided in two ways: by zone or by lobe (Figure 1 and Figure 2). It does not have a capsule; rather, an integral fibromuscular band surrounds it. It is sheathed in the muscles of the pelvic floor, which contract during the ejaculatory process.

The “zone” classification is more often used in pathology. The idea of “zones” was first proposed by McNeal in 1968 (Selman, 2011). McNeal found that the relatively homogeneous cut surface of an adult prostate in no way resembled “lobes” and thus led to the description of “zones.” The prostate gland has four distinct glandular regions; two of which arise from different segments of the prostatic urethra.

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The “lobe” classification is more often used in anatomy. The anterior lobe roughly corresponds to part of
the transitional zone. The posterior lobe roughly corresponds to the peripheral zone. The lateral lobes span all zones. The median lobe roughly corresponds to part of the central zone.

BPH refers to a noncancerous growth of the prostate gland (usually in the transition zone of the gland). The transition zone surrounds the proximal urethra and is the region of the prostate gland that grows throughout life and is responsible for BPH.

Bladder outflow obstruction due to BPH can result in structural changes in the bladder. The muscular walls of the bladder thicken and become stronger. These changes may lead to the development of LUTS such as the need to urinate more often nocturia and a reduced urine flow. The thickened walls of the bladder increase pressure within the bladder, which can cause pouches or diverticula to form and can lead to reverse pressure on the kidneys, causing kidney problems. The bladder becomes unable to empty efficiently, and infections and bladder stones can develop in the remaining urine (Sarma, & Wei, 2012).

DIAGNOSIS: A VISIT TO THE UROLOGIST

The diagnosis of BPH will be based on the patient’s medical history, physical examination including a digital rectal examination, blood tests including a PSA level, urinalysis, and other tests such as uroflowmetry (Qmax), postvoid residual urine test (PVR), ultrasound, and cystoscopy (McVary, et al., 2011). The patient will be asked to complete a couple of questionnaires.

About International Prostate Symptom Score

The International Prostate Symptom Score (I-PSS) is based on the answers to seven questions concerning urinary symptoms and one question concerning quality of life over the past month (McVary, et al., 2011; Table 2). Each question concerning urinary symptoms allows the patient to choose one of six answers indicating increasing severity of the particular symptom. The answers are assigned points from zero to five. The total score can therefore range from 0 to 35 (asymptomatic to very symptomatic).

The questions refer to the following urinary symptoms: (a) incomplete emptying, (b) frequency, (c) intermittency, (d) urgency, (e) weak stream, (f) straining, and (g) nocturia.

Question 8 refers to the patient’s perceived quality of life (QOL).

The first seven questions of the I-PSS are identical to the questions appearing on the American Urological Association symptom index which currently categorizes symptoms as follows: (a) mild (symptom score less than or equal to 7), (b) moderate (symptom score range 8-19), and (c) severe (symptom score range 20-35).

(Source: http://www.urospec.com/uro/Forms/ipss.pdf 2015.)

The International Scientific Committee, under the patronage of the World Health Organization and the Union for International Cancer Control, recommends the use of only a single question to assess the QOL. The answers to this question range from “delighted” to “terrible” or 0 to 6. Although this single question may or may not capture the global impact of BPH.
symptoms or QOL, it may serve as a valuable starting point for a doctor-patient conversation.

The International Scientific Committee has agreed to use the symptom index for BPH, which has been developed by the American Urological Association Measurement Committee, as the official worldwide symptoms assessment tool for patients suffering from BPH.

**International Index of Erectile Dysfunction Questionnaire**

There are five questions to be answered (Rosen, et al., 1997; Table 3). These questions ask about the effects that erection problems have had on man’s sex life over the past month. There is a scoring algorithm which divides the questions into five categories: (a) erectile function, (b) organic function, (c) sexual desire, (d) intercourse satisfaction, and (e) overall satisfaction.

The scores are rated from no dysfunction up to severe dysfunction.

**The Patient Will Undergo Testing**

Peak urinary flow rates are determined using uroflowmetry (Qmax). This test measures the volume of urine released from the body, the speed with which it is released, and how long the release takes. The test is performed by having the individual urinate in a special urinal or toilet with a machine that has a measuring device. The test must be performed when the individual has a full bladder. This test is useful in evaluating the function of the urinary tract.

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**Table 2. International Prostate Symptom Score (IPSS)**

<table>
<thead>
<tr>
<th>Patient name:</th>
<th>Date of birth:</th>
<th>Date:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Not at all</td>
<td>Less than 1 time in 5</td>
</tr>
<tr>
<td>Incomplete emptying: Over the past month, how often have you had a sensation of not emptying your bladder completely after you finish urinating?</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>Frequency: Over the past month, how often have you had to urinate again less than 2 hr after you finished urinating?</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>Intermittency: Over the past month, how often have you found you stopped and started again several times when you urinated?</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>Urgency: Over the last month, how difficult have you found it to postpone urination?</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>Weak stream: Over the past month, how often have you had a weak urinary stream?</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>Straining: Over the past month, how often have you had to push or strain to begin urination?</td>
<td>0</td>
<td>1</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Nocturia: Over the past month, many times did you most typically get up to urinate from the time you went to bed until the time you got up in the morning?</th>
<th>None</th>
<th>1 time</th>
<th>2 times</th>
<th>3 times</th>
<th>4 times</th>
<th>5 times or more</th>
<th>Your score</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Total IPSS score**

Quality of life due to urinary symptoms

<table>
<thead>
<tr>
<th>Delighted</th>
<th>Pleased</th>
<th>Mostly satisfied</th>
<th>Mixed—about equally satisfied and dissatisfied</th>
<th>Mostly dissatisfied</th>
<th>Unhappy</th>
<th>Terrible</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td>6</td>
</tr>
</tbody>
</table>

If you were to spend the rest of your life with your urinary condition the way it is now, how would you feel about that? Total score: 0-7 mildly symptomatic; 8-19 moderately symptomatic; 20-35 severely symptomatic.

Table 3. The International Index of Erectile Function (IIEF-5) Questionnaire

<table>
<thead>
<tr>
<th>Question</th>
<th>Response Options</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. How do you rate your confidence that you could get and keep an erection?</td>
<td>Very low 1, Low 2, Moderate 3, High 4, Very high 5</td>
</tr>
<tr>
<td>2. When you had erections with sexual stimulation, how often were your erections hard enough for penetration?</td>
<td>Almost never/never 1, A few times (much less than half the time) 2, Sometimes (about half the time) 3, Most times (much more than half the time) 4, Almost always/always 5</td>
</tr>
<tr>
<td>3. During sexual intercourse, how often were you able to maintain your erection after you had penetrated (entered) your partner?</td>
<td>Almost never/never 1, A few times (much less than half the time) 2, Sometimes (about half the time) 3, Most times (much more than half the time) 4, Almost always/always 5</td>
</tr>
<tr>
<td>4. During sexual intercourse, how difficult was it to maintain your erection to completion of intercourse?</td>
<td>Extremely difficult 1, Very difficult 2, Difficult 3, Slightly difficult 4, Not difficult 5</td>
</tr>
<tr>
<td>5. When you attempted sexual intercourse, how often was it satisfactory for you?</td>
<td>Almost never/never 1, A few times (much less than half the time) 2, Sometimes (about half the time) 3, Most times (much more than half the time) 4, Almost always/always 5</td>
</tr>
</tbody>
</table>


Usually, a patient having this test will report urination that is too slow. Normal values vary depending on age. A decrease in urine flow may suggest blockages in the urethra or weak bladder muscles. Alternatively, an increase in flow could signal weakness in the muscles that help control the flow of urine. An increase in urination could also be a sign of urinary incontinence (Nitti, 2012).

**Transrectal Ultrasound**

Transrectal ultrasound (TRUS) is used to measure and evaluate the prostate. A healthy adult PV is about 20-25 cc. With BPH, typically, there is an increase in volume of the prostate with a calculated volume exceeding 30 cc (Wasserman, 2006).

**PREINTERVENTIONAL RADIOLOGY CLINIC VISIT SCREENING**

Screening criteria have been established. Common considerations for eligibility of the PAE procedure are as follows (Pisco, et al., 2013a):

- When BPH is refractory to medical treatment for at least 6 months.
- The I-PSS score should be 13 or greater (early studies used the criteria of 18 or greater), and the QOL score 3 or greater.
- Prostate gland is greater than 40 cc.
- Peak urinary flow is abnormal, depending on the patient’s symptoms and age.

Patient must meet ONE of the following criteria:

- Baseline PSA ≥ 2.5 ng/mL and ≤ 10 ng/mL AND free PSA > 25% of total PSA (no prostate biopsy required).
- Baseline PSA ≥ 2.5 ng/mL and ≤ 10 ng/mL AND free PSA < 25% of total PSA AND a negative prostate biopsy result (minimum 12 core biopsy).
- Baseline PSA > 10 ng/mL AND a negative prostate biopsy (minimum 12 core biopsy).

Relative exclusions to the PAE procedure are: renal insufficiency.

Exclusions to the PAE procedure are overactive or hyperactive bladder, dysfunction or contraction of the bladder neck, sphincter dyssynergia, prostatitis, urethral strictures, prostate or bladder malignancy, interstitial cystitis, bladder diverticula with stones and advanced atherosclerosis, or tortuosity of the iliac arteries (on the basis of visual evaluation with computed topography [CT] angiograms or magnetic resonance [MR] angiograms obtained before PAE; Burnett, Wein, 2006; Pisco, et al., 2013a). Exclusion criteria for PAE have not been fully established, and further research is needed to establish contraindications (Pereira, et al. 2012).
THE INTERVENTIONAL RADIOLOGY CLINIC VISIT

The interventional radiologist will review the patient’s history, review test results, perform a physical examination, as appropriate, and most importantly explain the PAE procedure and its risks to the patient (Pereira, et al. 2012).

Potential Complications of Prostatic Artery Embolization

Minor side effects are common after PAE, including urinary frequency, dysuria, pelvic pain, hematuria, blood in the stool, hematospermia, and diarrhea. These are almost always self-limited but underscore the possibility that nontarget embolization may occur even if not detected during the procedure. Many patients came to the procedure with a bladder catheter in place and when screened had a urinary tract infection (Carnevale, et al., 2013; Pisco, et al., 2013b).

Urinary symptoms may worsen for the first few days after the procedure. This will improve over time. Less than 5% of the patients may experience acute urinary retention. If so, a temporary urinary catheter is placed and removed 2-3 hrs later (Pisco, et al., 2013a).

Mild suprapubic pain, referred to as a burning sensation, usually subsides after 24 hrs. For patients without urinary catheters, urethral burning during voiding is the most common symptoms after PAE. It usually lasts 3-7 days and has been treated with nonsteroidal anti-inflammatory drugs. In the studies performed by Pisco et al., the patients were queried as to their pain level during the procedure and after the procedure. On a scale of 1-10, the average pain rating was 1.7. One patient had a pain rating of 10, and this is the patient that developed a small area of bladder wall ischemia and was resected surgically (Pisco, et al., 2013b). Minimal amount of blood in the urine (from inflammation of the prostate and urethra) and in the stool (from rectal ulceration) has been reported and is self-limiting.

Complications were categorized as complications of angiography (related to puncture site, contrast material or radiation injury), pelvic infection, ischemic complications, sexual dysfunction, nonprostatic embolization, adverse drug reactions, and pulmonary embolization (Pisco, et al., 2013a). A case of radiation-induced dermitis has been reported (Laborda, et al., 2015). Nontarget embolization of the bladder and rectum causing ischemia or ulcers has been reported. This may or may not require a medical or surgical intervention (Moreira, et al., 2013; Pisco, et al., 2011).

Situations are considered to be minor complications/side effects if they can be easily be managed with ambulatory medical treatment and major if they led to prolonged hospitalization or readmission (Tinto, et al., 2012; Gao, et al., 2014). The PAE procedure is too new to fully establish the incidence and prevalence of the minor and major complications.

CT angiogram

The patient will be sent for a CT angiogram to evaluate pelvic and prostate anatomy. The radiologist needs to know the number of prostate arteries there are, their origin, trajectory, termination, and anastomoses with the surrounding arteries. There is typically more than one prostatic artery on each side. There is a lot of variation in the origin of the prostate arteries, and this can impact other origins. The CT angiogram is used for the radiologist to decide the best approach, the catheters to be used, and possible limitations or difficulties of the procedure. Some patients may need to be turned down for the procedure because of difficult vasculature (Bilhim, et al., 2012; Bagla, et al., 2013; Iyer, Shrestha, Konety, Snyder, & Golzarian, 2014).

Magnetic resonance imaging of the prostate

MR imaging (MRI) technology has provided an even greater resolution of both lobar and internal anatomy of the prostate. MRI imaging can be used to classify BPH into lobar distribution based on well-documented zonal anatomy. MR imaging not only allows for measurement of the prostate size before and after embolization but also can display prostatic artery anatomy and characteristics of the gland (Pisco, et al., 2011). MRI is found to be more accurate than TRUS for determining the prostate volume (Lee & Chung, 2007).

PATIENT CASE STUDY

This is a Caucasian gentleman in his early 60s who was referred by his urologist for further evaluation of the prostate for symptomatic BPH associated with LUTS. He notes significant nocturia every 2-3 hr that the patient attributes to his now bothersome insomnia. He denies hematuria and dysuria. He complains of a weak urine stream. He denies any blood in the stool. He denies chest pain, shortness of breath, and lower extremity swelling.

He has been taking finasteride (Proscar), tamsulosin (Flomax), and oxybutynin (Ditropan) without satisfactory improvement. His urologist also adjusted the dosage of his medications, with mild improvement in his symptoms. He remains very dissatisfied with his condition.

The I-PSS score is 20. His QOL is 5. His international index of erectile dysfunction score was 7 (severe
sexual dysfunction). His PSA level is .73 ng/mL. His creatinine level is .9 ng/dL.

TRUS demonstrated a 73.5-cc prostate.

- Uroflowmetry: Small bladder capacity of 397 mL. Good bladder compliance. Maximum voiding Pdet 59-cm H2O with a Qmax of 13.5 mL/s suggestive of bladder outlet obstruction. Incomplete bladder emptying, PVR 100 mL. Small right-sided bladder diverticulum without stones.
- Voiding diary: Voids every 2 hrs during the day, nocturia ×3. No episodes of incontinence.
- Total volume intake: 2950-3000 mL predominantly water and veg/fruit organic juice mixture.
- Total volume output: 1550-2520 mL; average voiding volume, 210 mL; largest voiding volume, 486 mL (to better understand Urodynamics see Nitti, 2012).

Initial MRI shows a PV of 49 cc.

The radiologist determined that the patient had failed medical therapy and is a good candidate for PAE. The procedure and its risks were discussed. The radiologist also discussed the fact that this is a new technique and that many of the outcome measures and complications are not yet known. The radiologist specifically discussed the risk of ischemia to other organs including the bladder and rectum. The patient agreed to proceed with the procedure. An MRI was performed, and the PV is 50 cc.

Preparing the patient for the procedure includes the following (Pisco, et al., 2011; Pisco, Pereira, Tinto, Fernandes, Bilhim, 2012):

1. The patient should be told to stop all prostate medications for 1 week before the procedure.
2. The patient should be told to start an acid suppressing drug such as omeprazole 20 mg daily.
3. The patient should be told to start an anti-inflammatory agent such as ibuprofen 800 mg twice daily, starting 2 days before the procedure and continuing for 7 days after the procedure. Because this medication is only taken for a short period, it should not increase the patient’s risk of bleeding. The purpose of this medication is to treat the inflammation that occurs with the PAE procedure.
4. On the day of the procedure, the patient should take the omeprazole and ibuprofen in the morning and the ibuprofen 8 hr after the procedure.
5. The patient should be told to start ciprofloxacin 750 mg twice a day for 2 days before and 7 days after the procedure. On the day of the procedure, the patient should take the morning dose with sips of water, and then the second dose should be taken orally 8 hr after the procedure for a total of 10 days. If the patient is allergic to ciprofloxacin, an alternative antibiotic would be in the sulfa family such as trimethoprim and sulfamethoxazole (Bactrim) or nitrofurantoin (Macrobid).
6. The patient should be premedicated with methylprednisolone according to American College of Radiology guidelines if they have a contrast allergy.
7. For patients that are taking warfarin (Coumadin), they will need to stop this medication 3-5 days before the procedure. It will be up to the patient’s physician who prescribed this medication, if the patient would need to be cross covered with another medication, such as Lovonox (enoxaparin). The International Normalized Ratio should be 1.8 or less at the time of the embolization procedure.
8. The patient will need to discontinue aspirin (acetylsalicylic acid) 5 days before the procedure.
9. The patient will need to discontinue antiplatelet inhibitors 5 days before the procedure with their physicians’ approval. This could include clopidogrel (Plavix), ticlopidine (Ticlid), dipyridamole (Persantine), aspirin/extended-release dipyridamole (Aggrenox), cilostazol (Pletal), ticagrelor (Brilinta), and prasugrel (Effient).
10. For patients that are taking metformin (Glucophage) and metformin containing medications, the patient should hold this medication at the time of the procedure and for 48 hr after the procedure.

**TABLE PREP AND EQUIPMENT FOR PAE**

Both main table and side table information is provided below.

**Main Table**

The tray should be set up for a basic angiogram.

- **Drugs**

  1% Lidocaine with 8.4% sodium bicarbonate.
  Heparin 1000 units/mL in saline (5 mL per 1000 mL saline) ×2.
  Contrast: Visipaque™ 320, if patient has a contrast allergy, check with radiologist (Distributed by GE Healthcare Inc. Princeton, NJ 08540 U.S.A.).

- **Tray**

  Diagnostic angiogram tray
  Towel pack
  Ultrasound probe cover (if ultrasound is needed)
  Mini stick set or thin wall needle (check with radiologist for access site)
.035 Bentson Guidewire (180 cm)
.035 Angled Guidewire (180 cm)
Neuro Angio Pack (closed system)
Vascular sheath (check with radiologist to see if power injector needed)
Catheter (this is dependent on the operator)
Check flow valve (flow switch) or stopcock.
43 “Injection line & HP e way— if using a power injector.
Check with radiologist for sizes and types.
Prep.
Need fluoro and possibly ultrasound (VF10-5 probe)
ChloroPrep® scrub ×2.
Drape with towels and femoral angiogram drape.
Load power injector with contrast.

Side Table
This is used for preparation of the PVA particles or Embospheres®.
Contrast is mixed 50/50 with saline.
Mixed in 20 mL and put on the three-way stopcock and then a 3-mL syringe is put on, and the mixture is drawn up into the 3-mL syringe and this is then used to slowly inject when the catheter is in the correct position.

Preprocedure Area
Informed consent is obtained by the radiologist. Sedation assessment (American Society of Anesthesiologists [ASA], Physical Status Classification System, Mallampati score, Modified Aldrete Sedation Scoring System, Ramsey Sedation Scale, and sedation plan) is also performed by the radiologist (McFadden & Glickman, 2014). The patient is prepared for the procedure as per a routine angiogram. The laboratory values are reviewed including kidney function, hemoglobin/hematocrit, platelet count, and coagulation studies. If the patient is diabetic, a blood glucose level is obtained and treated as appropriate. Other appropriate diagnostic tests, for example, cardiogram, are reviewed along with a current history and physical. The patient’s height and weight are noted. Fasting status is confirmed (Note: patients may take certain morning medications, for example, antihypertensives, with sips of water; Deichelbohrer, 2014).

An intravenous (IV) line is started, and IV fluids are initiated per physician order. A 20-22 gauge angiocath is preferred.

The nurse verifies that the patient took the medications omeprazole, ibuprofen, and antibiotic as instructed preprocedure.

Baseline vital signs are obtained. Baseline distal (pedal) pulses are palpated and marked.
Both groins are shaved per institutional routine.

Site marking is not required for this procedure. It is helpful to instruct the patient that they may be included in the team’s “Time Out” before the start of the procedure and given a little information about the sequence of events, procedure room, and so forth. This information should be tailored to each patient’s need and desire to know.

Intraprocedure Care
The patient is positioned on the procedure table. A “Time Out” is performed. If possible, the patient is included in the “Time Out.” The operator (radiologist) initiates the “Time Out” by saying the patients name, date of birth, and the procedure to be performed. The nurse reads the order and the consent and states the patients name and date or birth. The nurse also states any allergies the patient has. The technologist states the name and date of birth and what each tray is set up for. Then, the operator again states the name, date of birth, and procedure.

The PAE procedure time is measured starting with femoral puncture access and finishing with removal of the catheter after PAE. Fluoroscopy time is also recorded. This is typically the responsibility of the technologist.

The nurse’s responsibilities during the procedure are to monitor the patient’s vital signs, electrocardiogram recordings, and pain level, administer sedation as appropriate for this procedure based on the patient’s weight, administer other medications as needed during the procedure, and administer IV fluids as ordered. Ketorolac 30 mg (Toradol) IV is typically given at the midpoint of the procedure. Oxygen administration and monitoring are also the duty of the nurse. The nurse should provide a therapeutic environment for the patient. Special attention will need to be paid to any of the patient’s comorbid conditions. In the event of an emergency, the nurse takes charge to run the crash cart. A rapid response or code team may be called if the emergency cannot be handled easily. The patient may need to be transferred to a higher level of care after procedure, depending on the issue (McFadden et al., 2014).

Pain assessment is evaluated during the procedure and for 6-8 hrs after the procedure. During the procedure, most patients do not feel any pain. A small number of patients may experience a burning or heating sensation or slight pain in the urethra during embolization or contrast media administration (Pisco, et al., 2013b).

THE PAE PROCEDURE
The prostate receives its blood supply from the prostatic arteries, which arise singly or paired on each
side of the prostate. Superselection and embolization of the prostatic arteries lead to ischemic necrosis of a large proportion of the gland. Shrinkage of the gland follows with subsequent reduction of LUTS (Camara-Lopes, et al., 2013). The prostatic arterial supply is intimately related to that of the other pelvic organs, especially the bladder and rectum, and there is the potential for severe complications with nontarget embolization (Bilhim, et al., 2012).

Angiography is performed to evaluate the iliac and prostate arteries. Then, a catheter is threaded to reach the left hypogastric artery anterior division, then the inferior vesical artery, and finally the prostate artery. After angiography is performed to determine the correct position, the nonspherical PVA embolization particles are inserted. PVA particles 150-250 μm (Cook Medical, Bloomington, IN) are frequently used. Alternatively, the radiologist may use Embosphere® microspheres 300-500 μm (Merit Medical Systems Inc., South Jordan, UT). During embolization, the patients are asked to report any pain, and if so, the particles are upsized to avoid untargeted embolization. The end point chosen for embolization is slow flow or near stasis in the prostate artery with near disruption of the arterial flow and prostate gland opacification. Then, the same procedure is performed on the right side (Pisco, et al., 2012).

Many clinical trials are currently underway to determine the ideal size PVA particles or Embosphere® microspheres to use (Bilhim, et al., 2013; Brook, et al., 2013). A case report of coil embolization to redirect embolic flow and the potential value for using coils as an adjunct for this procedure has been published by Drs. Isaacson, Bhalakia & Burke, 2015.

In some cases, PAE cannot be technically achieved on at least one side, usually as a result of atherosclerosis, small artery size, tortuosity, or inability to obtain a safe position for embolization. Even when PAE is technically successful, not all patients experience significant clinical improvement. As many as 25% of patients may not show a significant reduction in I-PSS or improvement in PVR (Carnevale, et al., 2013).

**PATIENT CASE STUDY continued**

The procedure: fluoroscopy time 34 min. Sedation time: 3 hrs.

On the left side, embolization was performed with two injections of 100-300 μm of Embosphere® microspheres and the third injection with 300-500 μm of Embosphere® microspheres. There was complete stasis at the end (Figure 3).

On the right side, embolization was performed with two injections of 100-300 μm of Embosphere® microspheres and the third injection with 300-500 μm of Embosphere® microspheres. There was complete stasis at the end (Figure 4).

**Postprocedure Nursing Care**

The nurse should monitor the patient’s vital signs, distal pulses, and the groin puncture sites after...
hemostasis. The method of hemostasis will vary according to radiologist preference (Deichelhobrer, 2014).

The nurse should assess the patient as sedation wears off, note the patient’s pain level, and address the pain per protocol. IV fluids should be continued per physician order.

The patient will be started on clear liquids, advancing the diet as ordered.

When the patient has completed the ordered bed rest, the nurse will assist the patient with ambulation. The patient should be assisted to a sitting position slowly due to sedation and groin punctures and to avoid any vasovagal reaction. Groin puncture sites should be assessed after ambulation for any problems. If bleeding occurs during ambulation, the patient should immediately be returned to the stretcher/bed and direct manual pressure be applied until hemostasis is obtained. The radiologist or designee should be notified.

The nurse should assist the patient with their ability to urinate. Assess if the patient has voided a good amount. If the patient does not feel they are emptying their bladder, perform a bladder scan. It may be easier for the patient to empty their bladder if they are sitting on the toilet, rather than standing.

**PATIENT DISCHARGE**

The patient may be discharged when (Deichelhobrer, 2014):

- The vital signs are at baseline, and pulses are at baseline.
- The patient is off bed rest and is able to ambulate in the hall.
- The patient is tolerating a diet (usually clear liquids/saltines) without nausea.
- The patient is able to urinate, or if this is not feasible, a bladder catheter is placed.
- All postprocedure medications should be included in the medication reconciliation.
- The patient should be provided a procedure specific set of discharge instructions, and a copy should stay with the medical record.
- If the patient is discharged with a bladder catheter in place, appropriate teaching instructions for care should occur before discharge.
- The patient should be released with a responsible adult who is able to transport the patient home and stay with the patient due to sedation and possible puncture site bleeding as per usual angiogram instructions. Follow institutional protocols.
- The patient should understand the plan for restarting warfarin (Coumadin) and if needed cross cover with Lovenox (enoxaparin), if this applies to them. The patient should know when to have their INR redrawn.
- The patient should understand the plan for restarting their aspirin (acetylsalicylic acid) and antiplatelet inhibitors if this applies to them.
- The patient should check with the physician who ordered the metformin (Glucophage) or metformin-containing medications, to see if they need to have a GFR level drawn before restarting the medication.
- The patients rarely require a narcotic to be prescribed following this procedure. Acetaminophen (Tylenol) is suggested to be used if the patient experiences pain following the procedure. The patient should follow the directions on the bottle.

**FOLLOW-UP**

The following is included in the patient follow-up (Fernandes, et al., 2012):

1. An appointment is made for 1-2 weeks after the PAE procedure (The timing is more important if the patient has a bladder catheter in place).
2. A TRUS is performed at 3 months after procedure. This is used to measure the volume of the prostate.
3. A PSA level is performed at 3 months after procedure. The patient is asked to complete the following questionnaires: I-PSS and QOL, international index of erectile dysfunction. The patient is also asked to have a PVR and Qmax performed by the urology office.

**PATIENT CASE FOLLOW-UP**

The patient was followed up in clinic 3 months later. The patient was experiencing nocturia ×1. His difficulty with low urine flow had improved. Sexual function had improved. I-PSS score improved from 21 to 8. QOL improved from 5 to 1. PSA level was .57 ng/mL.

Uroflowmetry study: Large bladder capacity, 641 mL during today’s study, with a marked maximal voiding volume in voiding diary of 1005 mL. Excellent bladder compliance, Pdet was essentially zero throughout filling. Successful bladder emptying with peak voiding Pdet 36 cm H20. Qmax 18.5 mL/sec and study PVR of 127 mL; notably pretest PVR was low at 20 mL so the 7F Pves catheter was likely partially obstructing.

Voiding diary:

Voids every 3-4 hr during the day, nocturia ×1.
No incontinence; however, the patient notes some postvoid dribbling.
Total volume intake—3630 mL, mostly caffeinated tea, some juice, and water.  
Total volume output—2301-6174 mL; average voided volume, 510 mL; largest voided volume, 1006 mL.  
Follow-up MRI shows a PV of 40 cc (Figure 5).

DISCUSSION

PAE is a minimally invasive outpatient procedure performed with moderate conscious sedation. The PAE procedure is technically challenging, with a possibility of complications if it is not performed meticulously. Interventional radiologists, given their knowledge of arterial anatomy, experience with microcatheter techniques and expertise in other embolization procedures, are the specialists best suited for the performance of PAE. The Society of Interventional Radiology has written a Clinical Practice Guideline for PAE and supports the performance of high-quality research to expand the number of patient studies, to extend the duration of follow-up, and to compare the PAE procedure against existing surgical therapies (McWilliams, et al., 2014).

Interventional radiology physicians in the United States have encountered regulations that have slowed the entry of this procedure into their everyday practice. Dr. Golzarian et al. at the request of the Society of Interventional Radiology convened a multidisciplinary research consensus panel and published their findings as outlined below (Golzarian, et al., 2014).

The ease of adapting existing devices that have U.S. Food and Drug Administration (FDA) clearance for one use to a new intervention has been the catalyst that has driven advances in the field. The barrier to advance with the new procedures is the regulatory structure in place to ensure that new treatments are safe and effective. For interventional radiology, the most important regulatory authority is the Center for Devices and Radiologic Health within the FDA. The Center’s regulatory mandate includes insuring that new devices or a new application of previously cleared devices that potentially pose a significant risk are appropriately evaluated for effectiveness and safety.

Several regulatory mechanisms are in place, including premarket approval for devices with potential for significant harm and 510K for devices with less risk that have an identifiable predicate. The primary oversight mechanism used by the Center for Devices...
and Radiologic Health is the investigational device exemption (IDE), which allows an investigator, whether a company or an individual, to apply for an exemption to complete a study to test the effectiveness and safety of a device for medical treatment. An IDE is needed whenever the use of a device for a particular procedure might pose as significant risk to the patient. Under 21Code of Federal Regulations 812.3 (m), “a significant risk device is an investigational device that is intended as an implant and presents a potential for serious risk to the health, safety or welfare of the subject.”

The embolic material use for PAE is the same as the material used for other solid-organ embolization procedures and already has clearance for some of those procedures. However, the FDA mandate is to ensure the safety and effectiveness of a device for a specific indication. According to the FDA, the use of a device that is already approved for one indication must be evaluated for a new indication if that use represents a procedure associated with significant risk. The FDA considers PAE for BPH a “significant risk” procedure, given the potential for injury to other structures, such as the bladder and rectum. Therefore, an investigation of applying this technique to the prostate requires an IDE.

The multidisciplinary research consensus panel submitted an IDE application to the Center for Devices and Radiologic Health. The FDA has prepared guidelines for study proposals. The panel recommended a safety and effectiveness study in centers interested in pursuing PAE as a treatment for LUTS and bladder outlet obstruction associated with BPH. The first phase would provide the safety information to the FDA and would help interventional radiologists overcome the learning curve of the technique; both of which are necessary for a randomized study. The randomized study will compare PAE first with a sham procedure, using the I-PSS as the primary end point.

Bagla et al. performed a prospective clinical trial in the United States to evaluate the efficacy and safety of PAE for BPH. Embolization was performed using spherical embolic agents (Embozene microspheres, CeloNova BioSciences Peachtree City, GA). The primary outcome of this study was to measure the reduction in lower urinary tract symptoms. Early results from the clinical trial indicate that PAE offers a safe and effective treatment option. Continued follow-up of these patients continues for a period of 24 months (Bagla, et al., 2014).

There are some patients who still want this procedure, although the studies have not been completed in the United States. When the procedure is offered, the patient will have to sign a consent understanding that the radiologist is providing an “off label use” of the embolization technique for the PAE procedure.

References


