

# Angiography Offers Hope for Patients Suffering from Prostate-Related Urinary Disorders

By Chris Kraul

**A minimally invasive catheterization technique known as prostatic artery embolization shows promise as an outpatient treatment for patients suffering from increasingly prevalent prostate hyperplasia. Pioneered by a Brazilian radiologist, the procedure began U.S. Food and Drug Administration approved trials this fall in twelve medical centers in the USA and Europe.**



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Francisco Cesar Carnevale, MD, PhD, known as the pioneer of the prostatic artery embolization (PAE) procedure, has been Chief of Interventional Radiology at University of Sao Paulo Medical School since 2002.

A native of Sao Paulo, he studied medicine at the city's University of Mogi das Cruzes, and subsequently undertook fellowships and research stays at several U.S. institutions including the MD Anderson Cancer Center, the University of California-San Diego, and Beth Israel Deaconess Medical Center – Harvard Medical School, Boston, MA. He returned to the University of Sao Paulo in 1997 to complete a PhD in interventional radiology. He is a co-founder of the Brazilian Society of Interventional Radiology and Endovascular Surgery (SoBRICE). He has published over 50 peer-reviewed articles, as well as 25 book chapters on IR. The second edition of his vital reference book guide, *Radiologia Intervencionista e Cirurgia Endovascular*, originally published in 2006, is pending publication.

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# *“By lessening pressure on the urethra and easing the mechanical obstruction of the bladder, PAE enhances quality of life.”*

**Professor Francisco Cesar Carnevale, MD, PhD**

Department of Radiology, Interventional Radiology Section, University of Sao Paulo, Brazil

Uses of interventional catheterization have evolved far beyond the angioplasties that were its original focus. Increasingly versatile catheters, guided with the aid of angiography are competing with surgery to treat cases ranging from liver cancer and brain aneurysms, to uterine fibroids and faulty heart valves. This can save recovery time and costs for patients, while reducing the risk of post-operative complications and after-effects.

A procedure known as Prostatic Artery Embolization (PAE) has now joined angiography's therapeutic array as an option for men who suffer from benign prostatic hyperplasia (BPH), the principle cause of lower urinary tract symptoms experienced to some degree by around half the male population over 60. Symptoms include an increased frequency and urgency of urination, painful burning sensations, and intermittence of urinary stream due to mechanical compression of the urethra.

In simple terms, PAE involves the insertion of a catheter with a diameter of 2 mm at the femoral artery, which is then guided to the two main arteries feeding blood to the prostate gland. Safe catheter navigation is performed

under image guidance using Siemens angiographic equipment. When the catheter is in the correct position, microspheres are injected into the feeding arteries of the prostate in order to block blood flow. This creates an obstruction that can reduce the volume of the prostate by as much as 30–40 percent over the ensuing three months.

The shrinkage of the prostate in turn eases pressure on the urethra, allowing for better urine flow and a reduction in BPH symptoms.

Pioneered by Brazilian interventional radiologist Francisco Cesar Carnevale, a radiology professor at the University of Sao Paulo Medical School, the procedure is performed using Siemens imaging equipment and syngo DynaCT guidance and mapping software as an outpatient alternative for those who might otherwise have to resort to prostatectomies or a resection technique called TURP and laser, all of which require hospitalization.

### **Improved Quality of Life**

PAE is still a comparatively novel technique – approximately 1,000 patients have so far been treated

mainly in Brazil, Portugal, the USA and France. Other centers performing PAE are Italy, Spain, Russia and China. However, urologists and interventional radiologists are enthused by early results that show prostate shrinkage and positive outcomes for quality of life.

“By lessening pressure on the urethra and easing the mechanical obstruction of the bladder, PAE enhances quality of life. And if you have extreme BPH symptoms, life can be miserable. In extreme cases, patients may require permanent catheterization or have to self-catheterize every time they have to urinate,” Carnevale explains. “A common symptom among BPH sufferers is nocturia – waking up several times a night to urinate, which causes loss of sleep and makes you tired at work the next day.”

The bonus for PAE recipients is that they go home the same day and suffer none of the possible TURP-associated side effects such as retrograde ejaculation and temporary incontinence.

The new treatment is entering a critical stage this fall with the launching

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of the first large-scale clinical trial under the auspices of the U.S. Food and Drug Administration (FDA). Carnevale will act as principal investigator in the trial. The four-year test will track 186 patients in twelve USA and European hospitals to compare the experience of patients that undergo PAE with those treated with TURP.

#### **The Cost of BPH**

Success in FDA trials could significantly impact BPH protocols. Data from a study in 2005 show that treatment of the condition costs an estimated 3.9 billion U.S. dollars annually and accounts for up to 38 million lost hours of worker productivity. Authors said BPH patients also make 4.4 million medical office appointments and more than 117,000 emergency room visits. More than 105,000 patients are hospitalized in the U.S. each year.

Incidences of highly prevalent BPH is likely to rise in the foreseeable future as the global male population lives longer. Environmental factors including rising obesity, diabetes, and sedentary lifestyles are also fueling increased reporting of enlarged prostates – which is not

necessarily an indicator or precursor of prostate cancer.

#### **Advantages of PAE**

While TURP has been recognized with excellent efficacy in prostate size reduction and symptoms relief, it can also carry the risk of retrograde ejaculation, which means sperm and seminal liquid are ejaculated into the bladder, instead of out through the penis. TURP also requires general, intradural or peridural anesthesia, whereas PAE patients receive only local anesthesia.

#### **Disadvantages of PAE?**

Carnevale explains that the use of angiography means doctors, patients, and medical technicians are exposed to radiation for 30–40 minutes during the two-hour procedure, although Siemens engineers are working to reduce fluoroscopy time and dose based on proprietary Artis low-dose software. Another risk is that some patients' kidneys react poorly to contrast agents used in angiography, which can cause renal failure in rare instances.

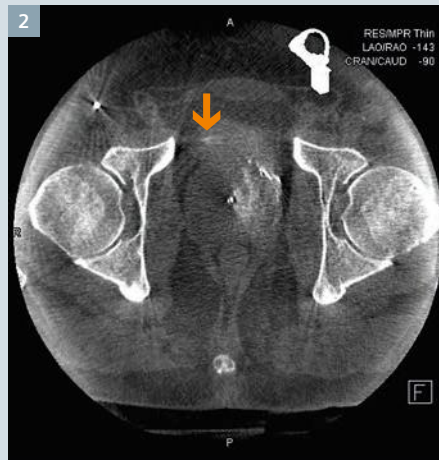
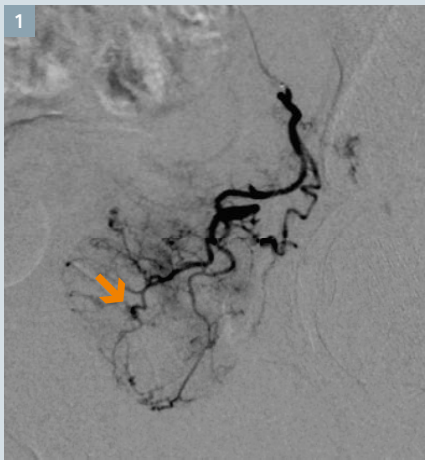
It is crucial to occlude both left and right prostatic artery since unilateral embolization can lead to recurrence.

In Sao Paulo, 92% of the patients are embolized bilaterally. “This is how we define technical success of a PAE procedure.” However bilateral embolization goes along with longer procedure and fluoroscopy times and a higher amount of contrast medium used. “Therefore we need to make use of all available measures to reduce dose for patient and staff. We all use protective goggles and clothing and Siemens CARE+CLEAR to lower the dose. In some interventions we even have performed the procedure with as little as 20–30 minutes fluoroscopy time,” Carnevale said.

#### **Avoiding Non-Targeted Embolization with syngo DynaCT**

Low-dose imaging is one of the many advantages that derive from working with Siemens, according to Carnevale. Others include after-sales consultation and engineering, image clarity, and user friendly syngo DynaCT software.

“syngo DynaCT is the most important software for the embolization procedure because it identifies the arteries feeding the prostate. It can guide you to where you have to go with the microcatheter. While I'm working, it also gives me an idea of the percent-



- 1 Digital subtraction arteriogram (DSA) with the microcatheter positioned into the left inferior vesical artery (left ipsilateral oblique perspective) previously to the left lobe prostate embolization. Note the opacification of the left intraprostatic branches. Procedure performed using the Artis zeego.
- 2 syngo DynaCT with reduced dose acquired before embolization of left prostatic lobe shows risk of non-target embolization of bladder wall (arrow). In addition, only partial left prostate enhancement is observed indicating either additional prostatic feeder or catheter position being too distal.

age of the prostate I am treating,” Carnevale said. “Even more importantly, it helps me avoid non-targeted embolization – the areas I don’t want to affect – because with syngo DynaCT, we can identify the arteries feeding the non-targeted organs.”

The idea for PAE came to Carnevale in 2006 after he had read an article in a medical journal about doctors who used embolization to stop a patient’s persistent BPH-related prostate bleeding. In a one-year follow-up of this case, the doctors noticed that in addition to a stop to the bleeding, the embolization caused a reduction in prostate size and an improvement in his quality of life by easing urinary tract symptoms.

“It was just an observation, but we thought, why not look at prostate embolization as a therapy for BPH,” Carnevale said. Fortunately, he was invited and moved to Harvard University in 2007 on a research grant and was able to test the theory by embolizing animals with that group. They injected resin microspheres into the prostate arteries of six dogs and one month later, saw that the dogs’ prostate glands had shrunk by 40 percent. He then knew he was on to something.

#### FDA study launched

Since Carnevale administered the first PAE procedure in 2008 at the University of Sao Paulo Medical School, the use of the technique has slowly grown. In recent years, he helped set up training centers in Paris, Zaragoza and Milan. He has trained close to 30 interventional radiologists in the procedure. Recently, he went to Mount Sinai and Johns Hopkins, both in the USA, where he launched the FDA trial by treating the first of 186 patients in the test population.

“The fact that we have developed this technique and are pioneers in training doctors on several continents in its use is adding to Brazil’s medical prestige,” Carnevale said, who is aware of the economic condition in health care in his country. And he finalizes “this is very important for our department, our university and our country.”

A former foreign correspondent for the Los Angeles Times, **Chris Kraul** is a Bogota-based freelance writer who specializes in economics, healthcare, and the environment.

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