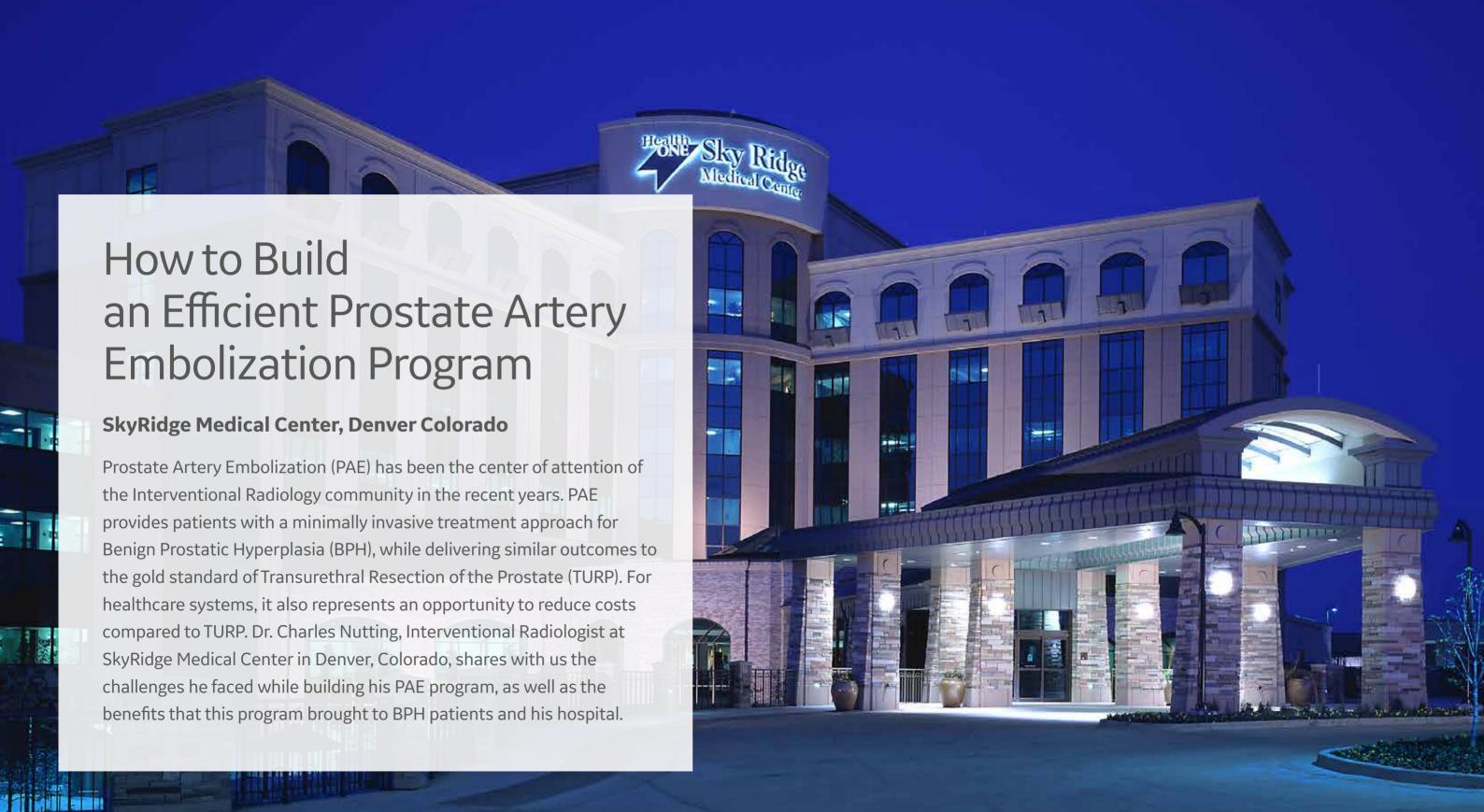
Reduce costs of delivering care

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enign Prostate hyperplasia (BPH) is a common condition as men get older. Benign prostatic hyperplasia affects about 50 percent of men between the ages of 51 and 60 and up to 90 percent of men older than 801.

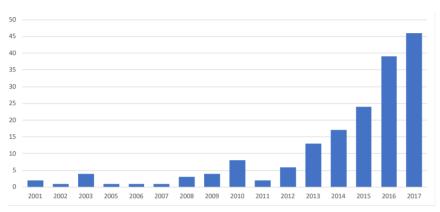
An enlarged prostate gland can cause bladder, urinary tract or kidney problems. The quality of life of people suffering from this condition is compromized as common symptoms include increased urinary frequency, urgency, incontinence, and voiding at night.

Over the past years, urologists have developed several effective treatments to manage BPH including medications, minimally invasive therapies and surgery. Nevertheless, all those approaches are correlated to non-negligible side effects such as incontinence, erectile dysfunction and retrograde ejaculation amongst other side effects. Because of these

associated side effects, as many as half of all men affected do not seek treatment.

At the dawn of the 21st century, a new minimally invasive procedure arose, called Prostate Artery Embolization (PAE), with promising initial results both on treatment efficacy and minimal side effects.

The principle of this technique consists in embolizing the arteries that feed the prostate gland, leading to a progressive shrinking of the gland. Since 2001, the number of publications assessing this procedure has increased exponentially.



Number of publications related to PAE since 2001 (extract from Pubmed with keyword "Prostate Artery Embolization")

https://www.niddk.nih.gov/health-information/urologic-diseases/prostate-problems/prostate-enlargement-benign-prostatic-hyperplasia

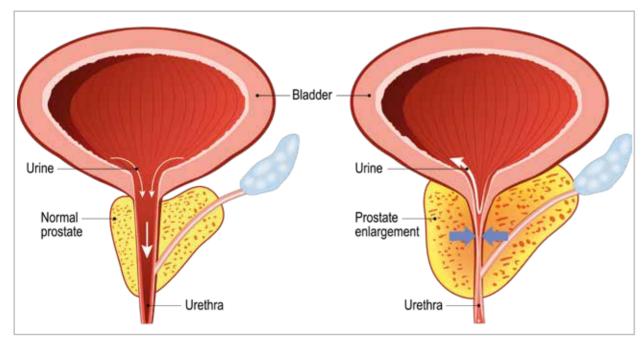


Fig. 1 Illustration of benign prostate hyperpalsia (BPH), left side showing a normal prostate, and right side showing a prostate enlargement



One of the early adopters in performing the PAE procedure in the United States

Dr. Charles Nutting Interventional Radiologist at SkyRidge Medical Center in Denver, Colorado

Dr. Charles Nutting, Interventional Radiologist at SkyRidge Medical Center in Denver, Colorado tells us about about his experience of PAE.

What is your clinical background?

Dr. Nutting: "I did my training in Chicago, started with an internship in Radiology Residency, and then one year fellowship in Interventional Radiology in Presbyterian Medical Center. I then moved to Phoenix to a large trauma center where I worked for about five years and fell in love with the field of Interventional Oncology."

What drove you to work in the IO field?

Dr. Nutting: "It is a field that allows us to help patients that might otherwise have no other options to treat their

cancer. I performed the first SIR-sphere (Selective Internal Radiotherapy) radioactive embolization in the liver in 2001, I helped build an Interventional Oncology program in that facility, then moved to Denver."

Then, how did you move to PAE?

Dr. Nutting: "I joined a large radiology group in Denver, and over the last 10 years I have become very interested in treating BPH using embolization. I' have been fortunate enough to travel the world and learn from some of the pioneers and started up a prostate program in SkyRidge Medical Center. I performed my first PAE about 10 years ago, but it has really taken off over the last 2 years with the FDA approval of the embospheres for the treatment of the BPH."

What is your current interventional equipment at Skyridge?

Dr. Nutting: "We currently use two GE rooms for our Interventional Oncology practice and to perform our PAE procedures. One of them is a Discovery IGS 740, the other one is an Innova IGS 630 biplane shared with cardiologists. The image quality of those two rooms is superb, we have Vessel ASSIST available on both systems, which helps me perform my embolizations. If it is a



larger patient, the wide bore of the Discovery IGS 740 is definitely an advantage to be able to perform the CBCT on all patients."

How do you split your activity in the cathlab?

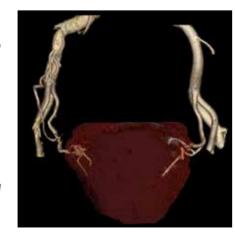
Dr. Nutting: "At this point in my career, I spend half of my time with PAE, the other half with Interventional Oncology. I do two to five PAE a week and about the same amount of Interventional Oncology procedures. So far I have performed more than 1400 liver related procedures and more than 140 PAE."

How long does it take to perform a PAE today?

Dr. Nutting: "I would say a very quick case for us is 45min, a long case would be around 3h30min. Our typical fluoro times are approximately 30min with

less than 1 Gy. Obviously, it all depends on case complexity, vessel tortuosity and number of prostate arteries to be embolized."

A sticking point in PAE can be patient recruitment, as they usually come from urologists who offer a surgical treatment for BPH.



3D rendering of the bilateral prostate arteries

How do you work with urologists?

Dr. Nutting: "We now work collaboratively with urologists locally and around the country. We work closely with a urologist who sends us a lot of patients. She is always looking at the spectrum of therapies wich are available to treat her patients. She feels PAE is a reasonable alternative to surgical interventions. A large majority of patients could indeed benefit from PAE. For those who are not eligible to PAE, they can go for TURP, green light laser, or robotic prostatectomy.

Today, the majority of patients we get are those who are not eligible for surgery. Indeed, a lot of patients are not eligible for TURP, because of very large prostates, anticoagulation treatments, or multiple comorbidities making these patients difficult surgical candidates. These patients are now getting PAE instead of surgical intervention. It reminds me of the time when we started with Y-90. We treated patients who were surgical failures, patients who were chemo-refractory, for whom everybody had tried everything but nothing worked.

However, not all urologists are favorable to PAE. Now that literature is bringing more and more outcomes, they start to look at it as a potential treatment option. Now that NICE (National Institute for Health and Care Excellence, United Kingdom) has approved it, each additional study or approval from a country gives more credibility. In our institution, urologists and IR's are not working in competition, but in collaboration to provide the best patient care."

What are the clinical challenges to perform a PAE?

Dr. Nutting: "One of the main challenges is the difficult anatomy. The arterial blood supply to the prostate is variable with different blood supplies from each side of the prostate itself. There can be collateral vessels that go to unintended areas like the rectum, the penis and the bladder so it is very important to understand the normal arterial anatomy and collateral blood supply.

Planning is also a crucial part of PAE. Before performing a PAE procedure, I want to make sure thai I will be able to identify the blood vessels that supply the prostate, catheterize these vessels and deliver the embolic agent safely."

How does the imaging technology available in your cathlab help you

perform your procedure with more confidence?

Dr. Nutting: "From an imaging standpoint, we need to see very tiny vessels. Indeed, the average size of a prostate artery is 1.4mm which makes it critical to see on a regular CT. That is why we always perform a Cone-Beam CT at the beginning of the procedure to understand the prostatic anatomy and know whether there is a single or double blood supply to the prostate. We then use Vessel ASSIST to extract the prostatic arteries. We can then use this data and superimpose the CBCT on top of the fluoroscopy to have a roadmap of the prostatic artery, thus allowing a real time visualization of these vessels during the angiography and catheterization. 3D roadmap also...



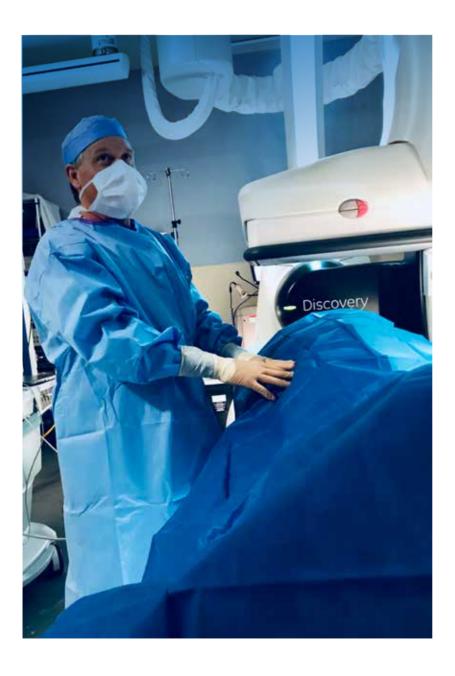
2D angiography of the pelvis showing the complex vascular anatomy

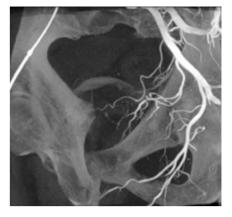


allows us to perform less DSA, thereby reducing the radiation dose to operator and patient.

While before we used magnification to switch to a bigger field of view, we now use the digital zoom to have a better understanding of the anatomy without increasing radiation dose to the

operator and patient." \sqcap





CBCT provides the required spatial resolution to accurately assess the complex vasculature of the pelvis area

"Most of what we do in 10 is complex microcatheter work with 3D visualization. either in our mind or using Cone Beam CT. People who do different cancer work are very well suited to perform Prostate Artery Embolization"