

Prostatic artery embolization in patients with benign prostatic hyperplasia: perfusion cone-beam CT to evaluate planning and treatment response

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Summary. This proof of concept is to evaluate the utility of perfusion cone-beam computed tomography (CT) in patients undergoing prostatic artery (PA) embolization (PAE) for benign prostatic hyperplasia (BPH) with moderate or severe-grade lower urinary tract symptoms (LUTS). PAE is a novel minimally invasive therapy and is both safe and effective procedure with low risks and high technical successes, making this procedure as the best alternative to surgery. A lot of technical changes would compromise clinical outcomes after procedure, including a variable prostate vascular anatomy, thin PA, and extensive atherosclerotic disease. The purpose of our study is to exploit the advantages of Perfusion Cone Beam Computed Tomography (CBCT) that could impact treatment and help interventional radiologists for treatment planning, diagnosis and for assessing the technical feasibility during PAE, mitigating the risk of nontarget embolization and suggesting clinical outcomes. Qualitative and quantitative clinical pre- and post-treatment values will be compared, to reach the best possible results. (www.actabiomedica.it)

Introduction

Benign prostatic hyperplasia (BPH) is the most frequent benign tumor in men and is present in > 50% of men \geq 60 years old (1), associated with an increased incidence in advanced age: it is present in approximately 8% of men in the fourth decade of life but up to 90% of men in the ninth decade (2).

Proliferation of the glandular/stromal tissue in the transition zone of the prostate, located closest to the urethra, leads to a progressive bladder outlet obstruction and consequent lower urinary tract symptoms (LUTS) (3).

The International Prostate Symptom Score (IPSS), also known as the American Urologic Association Symptom Index (AUASI), is a validated instrument that quantifies patient's subjective urinary symptoms on a 35-point scale (4). The IPSS also incorporates urinary Quality Of Live score (QOL score), which assesses how the patient feels overall about his urinary symptoms (5). Scores characteristics are shown in Table 1.

In addition to diagnosis of BPH, the AUASI can aid in selecting initial therapy (Pharmacologic and Surgical Treatment) and monitoring the response.

Table 1. IPSS: International Prostate Symptom Score; QoL: Quality of Life

I-PSS: International Prostate Symptom Score							
In the past month:	Not at All	Less than 1 in 5 Times	Less than Half the Time	About Half the Time	More than Half the Time	Almost Always	Your score
1. Incomplete Emptying How often have you had the sensation of not emptying your bladder?	0	1	2	3	4	5	
2. Frequency How often have you had to urinate less than every two hours?	0	1	2	3	4	5	
3. Intermittency How often have you found you stopped and started again several times when you urinated?	0	1	2	3	4	5	
4. Urgency How often have you found it difficult to postpone urination?	0	1	2	3	4	5	
5. Weak Stream How often have you had a weak urinary stream?	0	1	2	3	4	5	
6. Straining How often have you had to strain to start urination?	0	1 Time	2 Times	3 Times	4 Times	5 Times	
7. Nocturia How many times did you typically get up at night to urinate?	0	1	2	3	4	5	

Total I-PSS Score ____

Score: 1-7: Mild; 8-19: Moderate; 20-35: Severe

Quality of Life (QoL)	Delighted	Pleased	Mostly Satisfied	Mixed	Mostly Dissatisfied	Unhappy	Terrible
Due to Urinary Symptoms If you were to spend the rest of your life with your urinary condition just the way it is now, how would you feel about that?	0	1	2	3	4	5	6

Medical and surgical therapies for BPH may be associated with major complications, including sexual dysfunction.

A number of surgical alternatives have been proposed in the past decades (6) to reduce the morbidity of surgical procedure for BPH. Minimally invasive surgical therapies (MIST) have been developed using mechanical and thermo-ablative strategies, but the role of minimally invasive surgical therapies in the treatment of BPH is still yet to be strongly defined (7).

Prostatic artery embolization (PAE) is emerging as a viable nonsurgical treatment for lower urinary tract symptoms caused by benign prostatic hyperplasia (BPH). Embolization of the prostatic arteries leads to ischemic shrinkage of the prostate gland and a substantial IPSS and QOL improvement with a low incidence of serious adverse events (AEs) (8).

The PAE procedure requires the use of radiation for procedural guidance and would be limited by its technical challenges, including a variable prostate vascular anatomy, thin prostatic arteries (9) and may not always be technically feasible, especially in patients with extensive atherosclerotic disease (3).

The purpose of our proof of concept is to exploit the advantages of Perfusion Cone Beam Computed Tomography (CBCT) to analyze the detailed anatomy of male pelvic arteries that could be extremely helpful to avoid complications of PAE, which include nontarget embolization of surrounding organs, reduction of procedure time/radiation exposure, and achievement of the best clinical outcomes possible.

Methods

Patients selection

This single-center study, approved by the institutional review board, will include eligible patients who will be informed regarding the procedure and written informed consent will be obtained from all patients.

Inclusion criteria for PAE will be age > 50years, a diagnosis of moderate-severe lower urinary tract symptoms (IPPS \geq 18 and QOL \leq 3), Q_{max} \leq 12 mL/s or Acute Urinary Retention (AUR) due to a

BPH, refractoriness to medical treatment for at least 6 months, unfit to surgery and PV > 40 mL.

Exclusion criteria included malignancy, large bladder diverticula or stones, chronic renal failure, neurogenic bladder and detrusor failure, active urinary tract infection and unregulated and uncontrollable parameters.

Pre-treatment evaluation

Before the procedure, all patient will be evaluated clinically by an interventional radiologist and urologist using qualitative clinical values (IPPS, QOL score and the International Index of Erectile Function IIEF questionnaire) and quantitative clinical values (prostate volume PV, prostate specific antigen PSA level, Q_{max} and postvoid residual PVR in patients who did not have AUR).

Post-treatment follow-up

In the immediate postoperative period, pain assessment will be evaluated using a Visual Analog Scale (VAS): patients will rate their pain severity from 0 (no pain) to 10 (the worst pain).

Our study aims to evaluate outcome of patient with serial clinical and instrumental follow-up using IPPS, QOL and IIEF scores but also measuring PSA level, Q_{max}, PVR and PV.

Procedural Approach

The most technically challenging part of PAE is the identification and catheterization of prostatic arteries due to the variable origin of the PA (10) that sometimes could be variable between the left and right side (11). PAs are small arteries that may be difficult to identify with digital subtraction angiography (DSA) that increase procedure time and the risk of nontarget embolization, related to misrecognition of the target vessel, reflux or collateral flow to nontarget sites (12).

Cone-Beam CT is an advanced imaging capability based on the rotation of C-arm equipped with a flat panel detector; 2D projections are acquired with a

circular path covering at least 180° rotation, volumetric images are obtained with a 3D cone-beam image reconstruction, like shown in the Figure 1 (13).

Unenhanced CBCT has been largely used like a guidance for percutaneous approach in lung (14), liver (15), vessels (16), alone or in combination with fusion imaging (FI) techniques (17, 18).

An intra-procedural three-dimensional (3D) perfusion angiography CBCT is needed during PAE, to localize the prostate, identify PAs and their anatomic variants: the role of CBCT with automatic

vessel detection (AVD) software (EmboGuide, Philips Healthcare) during PAE permits to assess the complex vascular anatomy after a single injection of contrast medium in the artery and may define vessels and perfused tissue territory, as an adjunctive technique to DSA (13).

CBCT must be performed with the catheter into the internal iliac artery (IIA) to evaluate the origin of the PAs. A new CBCT can be performed with the microcatheter in the PA, to avoid non-target embolization (19) (Figure 2).

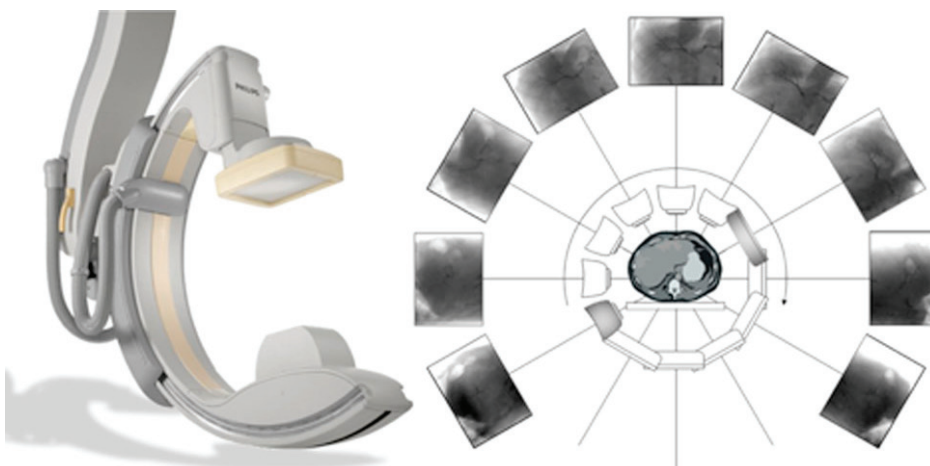


Figure 1. Cone-Beam CT imaging involves the rotation of a C-arm equipped with a flat panel detector around the patient (left image). Multiple 2D two-dimensional projections are acquired and reconstructed to generate a 3D three-dimensional volumetric data set (right image).

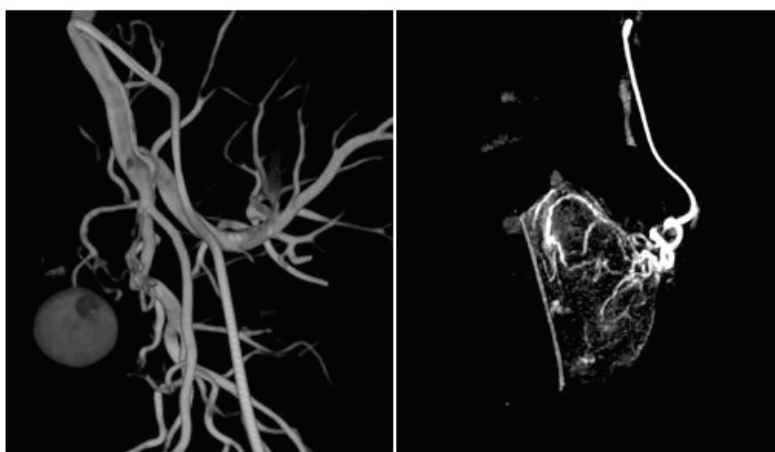


Figure 2. Non-selective cone-beam CT angiography was performed (left image): a Foley catheter is introduced into the bladder and filled with a mixture of iodinated contrast medium (20–30%) and saline solution. Selective catheterization (right image) permits parenchymal evaluation.

Software-assisted detection of prostatic vessels is feasible and collateral non-target vessels may also be successfully depicted on CBCT, to decrease risks and to increase operator confidence before embolization (13).

Acquired data could be enforced using a separate postprocessing workstation for volume rendering technique (VRT), multiple planar reformatted (MPR) and maximum intensity projection (MIP) reconstruction, resulting in a 3D layered images like CT scans during the procedure.

Those methods were already described in cerebral perfusion imaging and liver intraprocedural treatments (20–22) but also to detect vessels in endovascular treatments both for Endoleak (23) and in emergency transarterial embolization (24).

Postprocessing of acquired image data also permits to detect the presence of perfusion parenchymal blood volume (PBV) with contrast material in CBCT images, based on vascularization and enhancement, to generate color-coded perfusion maps. A recent study evaluates the utility of PBV before and after liver chemoembolization and suggests it like a surrogate biomarker to predict early success/failure of the procedure, helpful to optimize treatment following chemoembolization (25).

For these reasons we consider CBCT as an essential instrument for treatment planning, diagnosis and for assessing the technical feasibility during PAE: the direct visualization of prostatic parenchyma and his supplying arteries during prostatic angiography, can lead us to predict a technical success and clinical response.

Technical outcome

Technical success will be reached at least with one side prostatic arterial embolization. A pioneer study shows that unilateral embolization may lead to a technical success in a 50% of these patients, despite evidence suggesting a better clinical result after bilateral embolization (26).

Values for fluoroscopy time (in minutes), dose area product (DAP) totals, number of DSA series and cone-beam CTs will be recorder from the automated dose report.

Total contrast medium volume (in milliliters) will be calculated at the end of the procedure.

Possible complications

After treatment patients might suffer a postembolization syndrome, which can include pain, dysuria, frequency, and other irritative symptoms, that last less than 1 week and require only symptomatic management. AUR requiring temporary catheterization and urinary tract infection requiring oral antibiotic therapy (3). According to a recent meta-analysis study, major complications following PAE are rare and are potentially attributable to nontarget embolization (bladder, rectal or seminal vesicle injury), or to radiation-related skin injury (8).

Discussion

The prevalence of BPH increases with age; one fourth of men older than 70 years have moderate to severe LUTS (27).

Medical and surgical therapies for BPH may be associated with major complications.

Medical treatments are mostly alpha-1 blockers (AB), 5-alpha réductase inhibitors (5ARI) and phospho-diestérase inhibitors. Patients who cannot tolerate medical therapy or in case of failure, surgery can be indicated, after evaluation of the Bladder Outlet Obstruction (BOO) with urodynamic studies (28).

Prostatectomy via open surgery or transurethral resection of the prostate (TURP) is the standard treatment for benign prostatic hyperplasia (19) and is selected according to the size of the prostate, the expertise of the urologist and patient preference and is the standard treatment for benign prostatic hyperplasia (29).

TURP has been the Gold standard for treatment of prostate glands as large as 80-100 cm³ but can be associated with a lot of morbidity, including ejaculatory and erectile dysfunction, incontinence, urethral stricture, urinary retention and infection (30).

Surgical treatment is very efficient for prostates larger than 80-100 cm³ but carries frequent complications, more common than TURP, including

lymphocele, hematomas, major bleeding, incontinence, urethral stricture, urinary retention, sepsis, retrograde ejaculation which is very frequent and can compromise fertility and sexual pleasure (31, 32).

The scenery of BPH treatments is rapidly evolving, turning on minimally invasive therapies with mild side-effect profiles. PAE avoids transurethral access, anesthesia, and hospitalization, making it arguably the least invasive of the procedural therapies for LUTS (3).

A recent systematic review and meta-analysis investigate the efficacy and safety of PAE in the treatment of LUTS showing a significant outcome-improvements with a low risk of complications, especially in men with high risk of complications due to pre-existing medical conditions. Malling et al. also assert that rates of clinical and technical success were reported between 76.3 to 100% and 76.7 to 100%, respectively (33).

Pisco et al. evaluating 630 patients say that most clinical failures occurred during the short-term follow-up. As time increased after PAE, the incidence of clinical recurrence decreased. The cumulative clinical success rate at medium- and long-term follow-up were 81.9% and 76.3% (34).

Promising results are shown also by Unflackert et al. (8). After one year, PV decreased by 31.31cm³, PSA remained unchanged, PVR decreased by 85.54mL, Qmax increased by 5.39 mL/s, IPSS improved by 20.39points, QOL score improved by -2.49 points, and IIEF was unchanged. They record a low incidence of serious AEs (0,3%) although minor AEs were common (32,93%), with no adverse effect on erectile function.

Multiple randomized trial compared PAE versus transurethral resection of the prostate (35, 36), and show a similar reduction of LUTS in the PAE-group compared to that of TURP (36).

Both procedures resulted in significant clinical improvements in the treatment of BPH. However, the advantages of the PAE procedure must be weighed against the potential for technical and clinical failures in a minority of patients (35).

To limit these failures, it has become increasingly necessary to identify innovative therapeutic strategies and to adapt that to every single patient.

DSA based on 2-dimensional projection provides excellent visualization of pelvic vessels, but its low sensitivity for soft-tissue contrast and, sometimes, to identify the prostatic arterial supply. CBCT consists in an angiographic unit equipped with a flat-panel detector that can provide volumetric tomographic 3D images. Wang et al. discovered that CBCT provided more informations than DSA in 64.2% of cases (37).

Recent studies have shown how CBCT could impact treatment and help interventional radiologists for treatment planning, diagnosis and for assessing the technical feasibility during PAE, mitigating the risk of nontarget embolization, and suggesting clinical outcomes. Bagla et al. found that CBCT provided information that could probably save the patient from complications or recurrence in 46% of cases (38, 39).

New applications of CBCT have been extensively studied in the literature: the new software allow to measure not only the immediate therapeutic effects but also to define and manage the optimal endpoint of an embolization.

The presented analysis describes positive therapeutic results in PAE, but for continued prospective outcomes studies and clinical trials are needed to increase his technical success.

Conclusion

Literature data confirming that PAE is safe and effective treatment for BPH with good long-term results on almost all measured outcome parameters. The minimally invasive nature of the technique results in very low morbidity also in patients with other medical comorbidities.

The goal of our proof of concept is to evaluate the usefulness of perfusion imaging using CBCT, obtained during PAE in patients with BPH, for evaluating prostatic arterial anatomy that could be extremely helpful to avoid complications of PAE, reduction of procedure time/ radiation exposure and to reach the best possible outcomes. For this purpose, qualitative and quantitative clinical pre- and post-treatment values will be compared, to reach the best possible results.

Human and Animal Rights and Informed: All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Declaration of Helsinki and its later amendments or comparable ethical standards.

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