TITLE PAGE

Prostate Artery Embolization for Benign Prostate Syndrome

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I, the corresponding author, hereby confirm that all listed authors agree to the publication

Introduction

The prostate artery embolization is a radiological intervention treating symptoms of the Benign Prostate Syndrome (BPS). Those Lower Urinary Tract Symptoms (LUTS) include voiding and storage symptoms [1]. As other therapies require general anesthesia and often go along with high risk of incontinence, bleeding or erectile dysfunction [2], new minimal invasive procedure are under current investigation. Avoiding these risks PAE has gained increasing interest over the past few years. In 2000 DeMerritt et al. [3] described positive effects on LUTS of a PAE performed in order to stop prostate hemorrhage. In the following years, evidence of an effective and safe treatment with PAE was gained. In 2018 the UK National Institute for Health and Care Excellence (NICE) included PAE as recommended treatment for BPS and 2020 the German Society for Interventional Radiology (DeGIR) positioned itself positive towards the PAE [4, 5].

Technique

Most treatments for BPS are performed via a transurethral access whereas the PAE is performed using a vascular approach through femoral arteries. This angiographic mode provides low bleeding risks and spares the urogenital organs. Until today, there is no standardized protocol for the procedure. Thus, there are differences in the performance of the PAE e.g. particle size and material used as well as patient selection and procedure planning. In the following, the approach followed at the Institute of Diagnostic and Interventional Radiology in Frankfurt/Main is described.

In our institute, we perform the PAE as outpatient treatment if no complications occur. PAE is performed in a sterile work area by experienced interventional radiologists. After injecting local anesthesia, unilateral transfemoral approach is achieved and a 5F sheath is inserted via the Seldinger technique. Subsequently 5F Sidewinder or 4F Cobra catheter are used to catheterize the pelvic arteries, whereas the PA mostly needs further selection with a 2F microcatheter. MRA guidance prior to the procedure (Fig. 1) as well as angiographic guidance are used to visualize the pelvic arteries and identify target vessel. If there is a risk of nontarget embolization, further selective catheterization is attempted or protective coil embolization of the affected vessel is conducted. In rare cases cone beam CT (CBCT) is performed if anastomoses cannot be ruled out. Selective embolization of PA is performed with microspheres of 300-500 µm (Embosphere® Microspheres; ©2018 Merit Medical Systems, South Jordan, Utah, USA) as distally as possible until almost complete blood flow stasis in all branches is achieved (Fig. 2). Due to the presence of anastomoses to the PA of the other prostate side, bilateral embolization

should be attempted in all cases. Following the removal of catheters and sheath, the approach is occluded using a vascular closure device.

Currently different particles are in use for PAE: spherical and non-spherical particles, gelatin and polyvinyl materials and different sizes such as 100-300 µm or 300-500µm [6]. The smaller particles are likely to cause more ischemia as they occlude smaller vessels, whereas the larger particles tend to be less painful and result in fewer adverse events [7]. The superiority of one specific particle is under current investigation [6, 8]. Additionally, there are differences in planning PAE as well. Some centers use only intraprocedural imaging such as DSA or CBCT, whereas others use CTA or MRA to plan the procedure and display their reconstructions in the angio room during PAE. Technical improvement is promised by the *Proximal embolization first then embolize distal method of PAE* (PErFecTED-method) introduced by Carnevale et al. [9]. They recommend embolizing the proximal branches first to increase blood flow towards the prostate and then superselectively embolizing the distal branches of the central gland.

The blood supply of the central gland of the prostate is reduced [10] by embolization. This mechanism results in different effects of the PAE. In addition to necrosis and apoptosis induced by hypoxia, the lower blood supply reduces the transformation of blood testosterone into dihydrotestosterone (DHT) [11]. The immediate effect is said to be achieved by the reduced DHT levels as well as relaxation of smooth muscle tissue [8]. This relaxation might be a result of elevated NO levels and reduced alpha-1-receptor density [8]. Volume decrease is said to be a result of hypoxic ischemia and edema and develops over the following months as the necrotic tissue is resorbed [8, 10].

Technical challenges

As pelvic vessel anatomy is highly variable detailed knowledge of the possible PA origins as well as the individual anatomy of the patient is crucial whilst identification of the PA during the procedure can be challenging [12]. Due to these anatomical challenges preprocedural imaging or periinterventional CBCT is important.

The prostate artery itself is often described as an independent and highly variable vessel [13]. Additionally, the PA shows anastomoses to other organs such as urinary bladder or rectum in up to 60% [12]. These anastomoses can be identified in the preprocedural imaging. In most cases the PA approaches the prostate in four quadrants, i.e. two anteromedial and two posterolateral branches [14]. The anteromedial branches supply the blood for the central gland

whereas the posterolateral branch provides blood for the peripheral gland. In up to 40% of the cases these branches can arise from different origins as two PAs per pelvic side [14]. Due to intraprostatic anastomoses, embolization of all branches is necessary to reduce the risk of revascularization and achieve a good clinical result [15].

Patient selection and diagnosis prior to PAE

Due to the variety of methods of BPH therapy, patient selection and informed consent on all available options are mandatory and important for the success of the therapy. First, the diagnostic findings, including the leading symptoms, as well as objective parameters such as flow rate or prostate volume should be analyzed in detail. Further considerations should focus on the patient's general condition and thus on the eligibility for surgery. Subsequently, the patient's expectations, goals and fears must be carefully determined and weighed up, and the side effect profile and financial aspects must be considered.

It is crucial to evaluate clinical symptoms before and after PAE via the *International Prostate Symptom Score*- (IPSS-) and *Quality of Life*- (QoL-) questionnaires [16]. The effect of the PAE on the erectile function should be assessed using the *International Index of Erectile Function* (IIEF). Digital-rectal examination, transrectal ultrasound, the determination of urodynamic parameters such as urinary flow rate and residual urine volume and, if necessary, contrast-enhanced ultrasound of the prostate should be performed prior to PAE to determine the objective parameters of benign prostatic syndrome [17]. MRI may be useful for detailed volumetry of the prostate and analysis of morphological aspects such as intravesical prostate protrusion (IPP) and prostate urethra angle (PUA) as well as adenomatous nodules [18, 19]. If malignancy is suspected by PSA values or imaging, it should be confirmed by a biopsy [20]. As described above, an analysis of the pelvic vessel anatomy prior to PAE is crucial, as this knowledge may not only reduce radiation exposure but also the risk of non-target embolization. However, this information can also be obtained by CBCT during the intervention, which further increases the amount of radiation. At 3- to 6-month intervals after PAE, clinical, imaging and urological control examination are indicated.

Typically, the indications for PAE comprise symptomatic BPH with a volume of ≥30-40ml, moderate to severe LUTS symptoms (IPSS 7-19) and a QoL score of ≥3 [21, 22]. In different studies, however, these criteria sometimes differ considerably. As contraindications, we determine severe atherosclerosis, known neurogenic bladder outlet disorder, prostatitis or prostate cancer [21, 23]. Furthermore, there are specific contraindication for angiographic

interventions such as severe bleeding tendency, hypersensitivity to contrast media, renal insufficiency or severe comorbidity. Therefore, prior to PAE, prostate-specific antigen (PSA) and creatinine level should be evaluated.

If urodynamic problems predominate, if there are recurrent urinary tract infections or if a neurogenic cause of LUTS can be assumed, PAE may not be the method of choice [24]. However, if general anesthesia is a significant risk to the patient, if the patient is anticoagulated or if there are concerns about maintaining erectile function, PAE should be considered [23, 25]. Furthermore, PAE is a suitable treatment method for prostates with a volume >80 ml as an alternative to prostate enucleation [26]. Some authors also describe PAE as an effective therapy for BPH-associated acute urinary retention [23, 24].

Clinical results and predicting factors

Early results showed success rates of 76% after 12 months [27]. In the literature clinical success rates between 72.1% and 100% are documented [28, 29]. However, the criteria for clinical success are inhomogeneous. In most cases, a reduction of the IPSS value by -25 % and a post-interventional value of <15 points as well as an improvement of the quality of life by -1 point and a post-PAE-QoL of <3 points are considered as a clinical success [29, 30]. The meta-analysis by Malling et al. summarized 13 studies with a total of 1,254 patients [31]. They described a mean improvement of the IPSS by -16.2 points (-67 %), of the QoL score by -3.0 points, of the prostate volume by -20.3 ml, and of the IIEF by +1.3 points after 12 months. These values showed a significant improvement even after three years. Other long-term studies showed a IPSS reduction of -16.94 points after 6.5 years of follow-up [11]. However, the IPSS improvement is highly variable as results between -9.1 and -21 points are reported [28, 30]. A case with significant reduction of prostate volume and IPSS is shown in Fig. 3.

Therefore, there must be other factors influencing the clinical outcome. Young age and higher prostate volume appear to be associated with higher IPSS improvement from PAE [6, 32]. Little et al. [18] found that adenoma-dominated hyperplasia responds better to PAE, whereas Assis et al. [33] documented better clinical results with larger central glands. A high degree of atherosclerosis and vascular convolutions are considered to be negative predicting factors [34, 35]. However, the influence of technical parameters such as the size of the particles and the end point of therapy are controversial and have not yet been uniformly defined [8].

Radiation

Due to its technically challenging nature, PAE often requires high radiation doses. Atherosclerosis and complicated vessel anatomy might have an influence on the radiation dose needed [36]. Currently dose area products between 11,305 and 45,070 μGym^2 per procedure are documented [30, 37]. Mean entry doses are described between 339 and 2,420 mGy [22, 37]. In their systematic review Zumstein et al. [38] documented mean DAPs of 19,514 μGym^2, no entry doses were analyzed. If CTA or CBCT are used for visualizing the PA, additional radiation occurs. For CTA a mean dose of up to 808.4 mGycm and for CBCT dose area products between 1,900 and 3,652 μGym^2 are documented [24, 39].

Reducing the radiation exposure is an important goal in further developing the PAE method. One way to achieve this might be using MRA for preprocedural planning, as it offers detailed information about the origin of the prostate artery without applying any radiation.

Adverse events

PAE seems to be a safe method to treat BPS without major adverse events [25, 31, 40]. Most common complications are transient dysuria, hematuria, dysesthesia, or the occurrence of urinary tract infection [21, 31]. Further complications as hematoma or postembolization syndrome are related to the interventional nature of the procedure. However, in 0.1% of the cases major adverse events like non-target embolization of rectum, bladder or penile structures are documented [25, 31]. These can usually be prevented by precise knowledge of the individual vessel anatomy, superselective embolization and protection of anastomoses.

Comparison to other BPS therapies

In several randomized controlled trials and meta-analyses [21, 28, 30] PAE has been compared to transurethral resection of the prostate (TURP), the gold standard of BPH therapy, in recent years. Although PAE has shown benefits in terms of risks and adverse events, it has usually failed to achieve the clinical and urodynamic improvements of TURP [21, 41]. Carnevale et al. [28] in their randomized study and Gao et al. [30] in their meta-analysis, however, reported similarly good results for PAE compared to TURP. Both achieved IPSS improvements of 21 and 16 points, respectively. However, urodynamic improvements of transurethral prostate resection (TURP) were superior to PAE in both studies.

Although the PAE seems to be functionally inferior, it is becoming more attractive with regard to its side effect profile. In a randomized controlled trial, Abt et al. [21] registered only about half as many adverse events (Clavien I-III) in PAE as in TURP. A major advantage over transurethral procedures is the significantly lower incidence of postinterventional erectile dysfunction and retrograde ejaculation [21, 28]. Serious bleeding is also less frequent than with standard therapies [24].

To our knowledge, a comparison with other minimally invasive methods such as holmium laser enucleation of the protaste (HoLEP) or thermo-ablative procedures or with drug therapy within a randomized study has not yet taken place. However, these findings would be of great interest in classifiying PAE between these different therapy options for BPS. In contrast to many other minimally invasive procedures, PAE is not limited to any maximum volume of the prostate and does not use a transurethral approach, which means that post-interventional strictures and incontinence can be avoided [31].

Conclusion

Summarizing the current study situation, PAE is no replacement for established surgical procedures for severe obstructions due to urodynamic inferiority. It is as a treatment option with low complication profile for moderate to severe symptoms, and as a possibility for younger, sexually active patients or those with contraindications against surgery. Previous studies have already demonstrated the effectiveness and safety of PAE in a suitable patient population.

In conclusion, PAE is an effective method with a low complication rate for treating at least moderate LUTS with growing evidence. Patient selection is crucial for the clinical success of this method. Preprocedural planning is important and reduces radiation exposure.

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Figures

Figure 1 – Freely rotatable 3-dimensional MRA reconstruction.

A: View from the left pelvic side and origin analysis of the left prostatic artery (arrow).

B: View from the right pelvic side and origin analysis of the right prostatic artery (arrowhead).

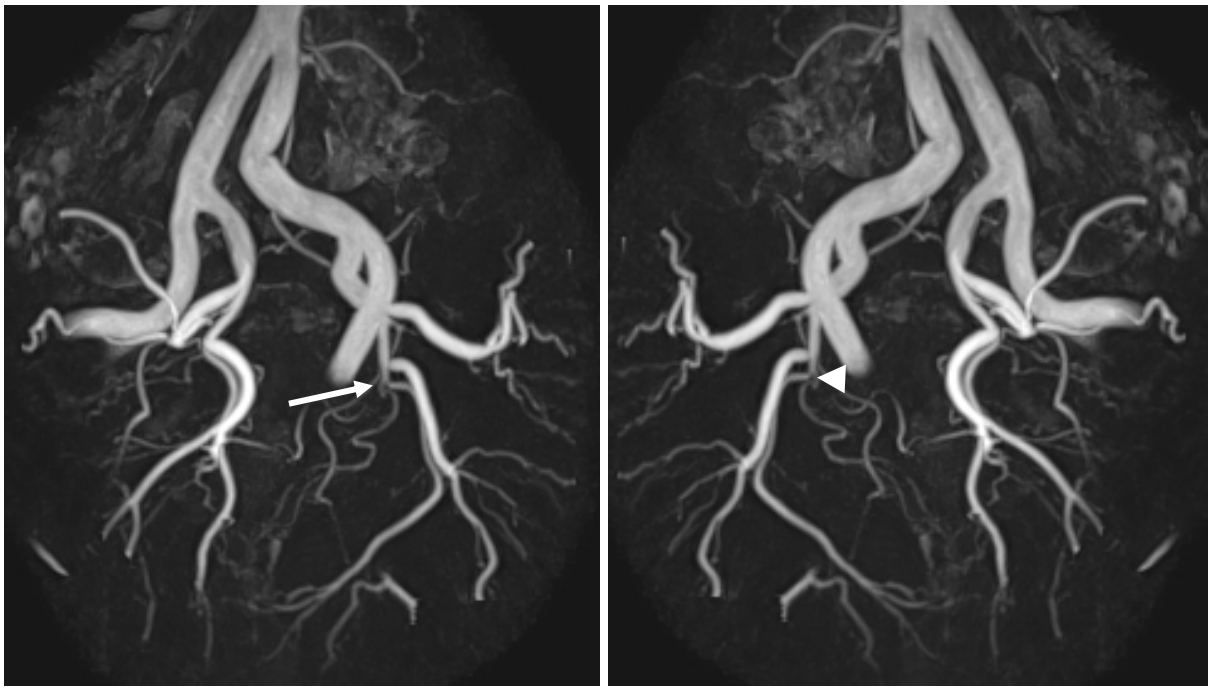

Figure 1A Figure 1B

Figure 2 – DSA and embolization of the left and right prostatic artery of a 59-year-old patient.

A: DSA of the left prostatic artery before prostatic artery embolization (PAE). The presence of anastomoses to the contralateral prostate vessels is visible.

B: DSA after performing the PAE with complete blood stasis in the left parts of the prostate.

C: DSA of the right prostate artery before PAE. In comparison to the left side, there is a sharper line between the sides as a result of contralateral embolization.

D: DSA of the right prostate artery after the embolization. After embolizing both sides, no contrasted vessels or anastomoses were seen.

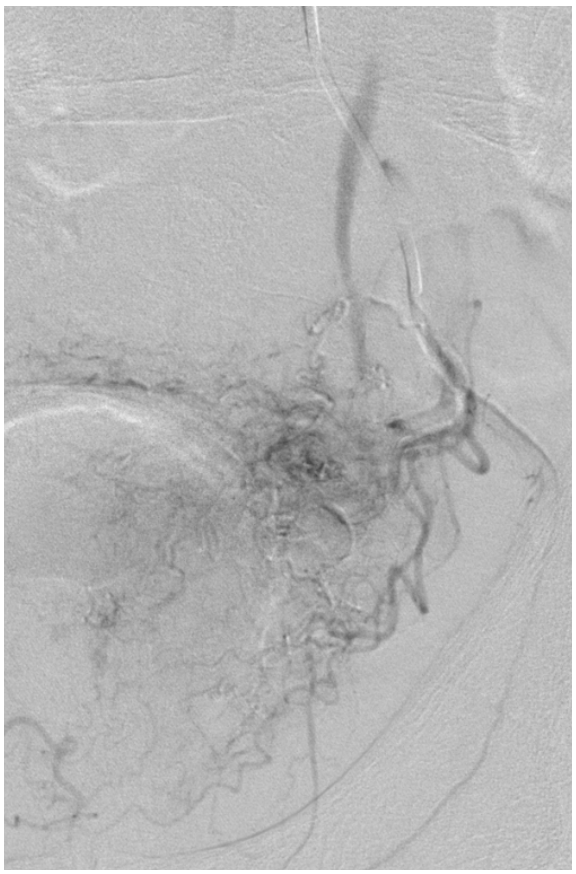

Figure 2A

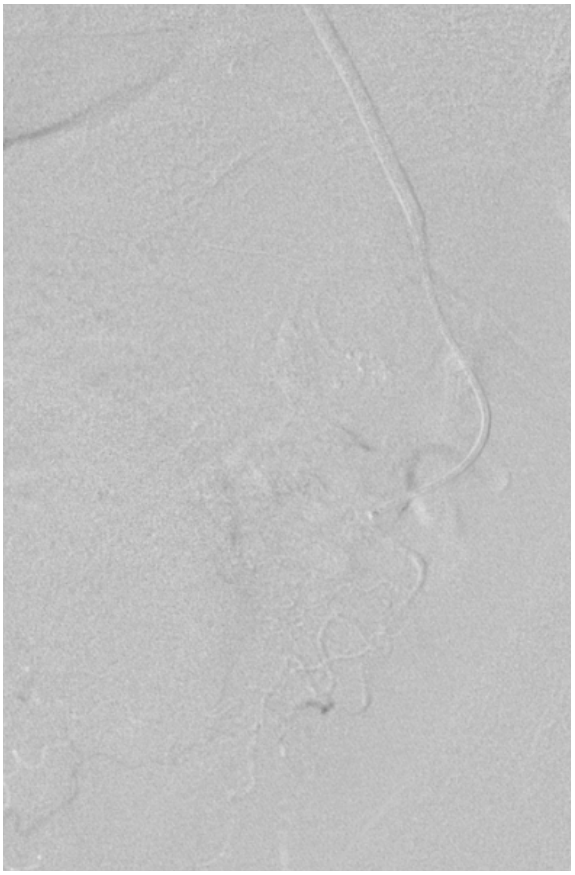

Figure 2B

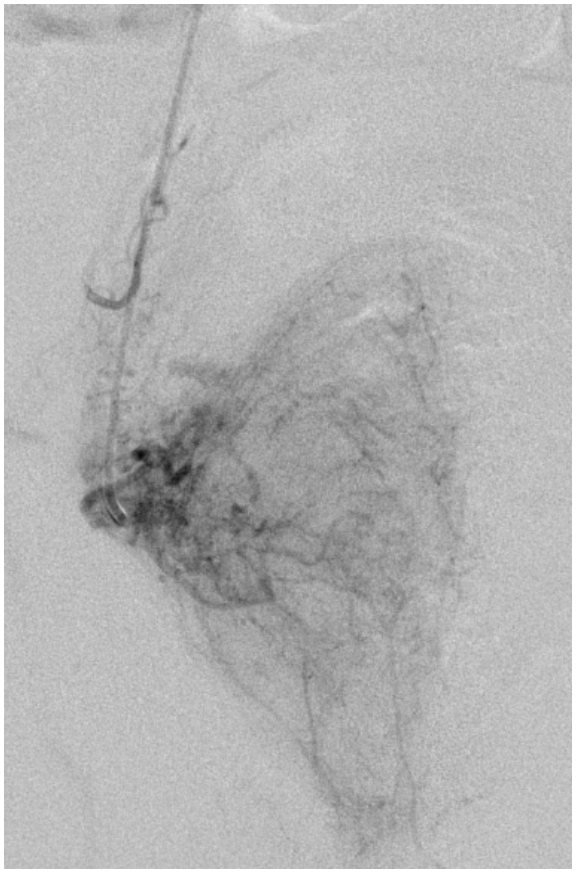

Figure 2C

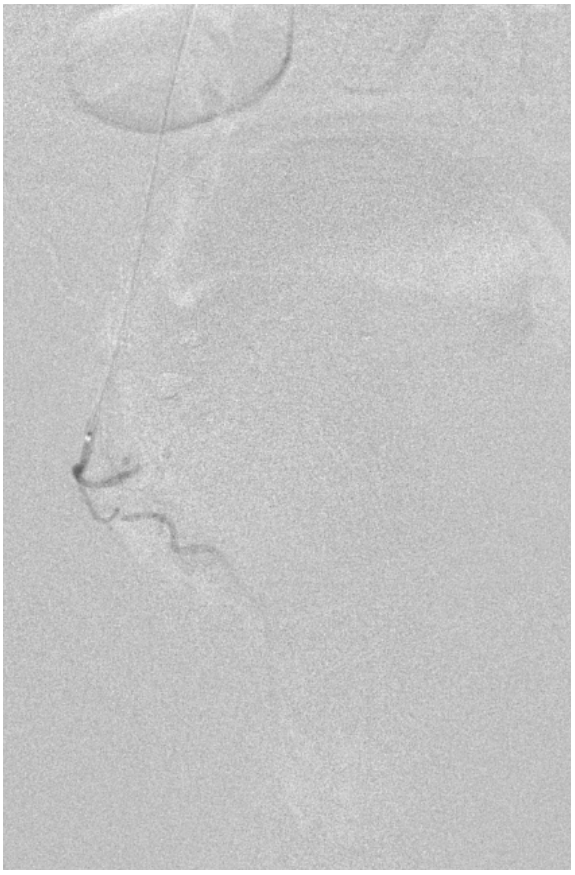

Figure 2D

Figure 3 – Axial and sagittal MRI of a 59-year-old patient before (A) and after (B) PAE with an initial prostate volume of 99.2 ml, an IPSS of 31 points and a QoL score of 5 points. In the follow-up four months after PAE, a significant reduction of the prostate size to a volume of 77.5 ml (-21,9%) and a decrease in the IPSS to 10 points (-68%) as well as a reduction of the QoL-score to 2 points (-60%) was documented.

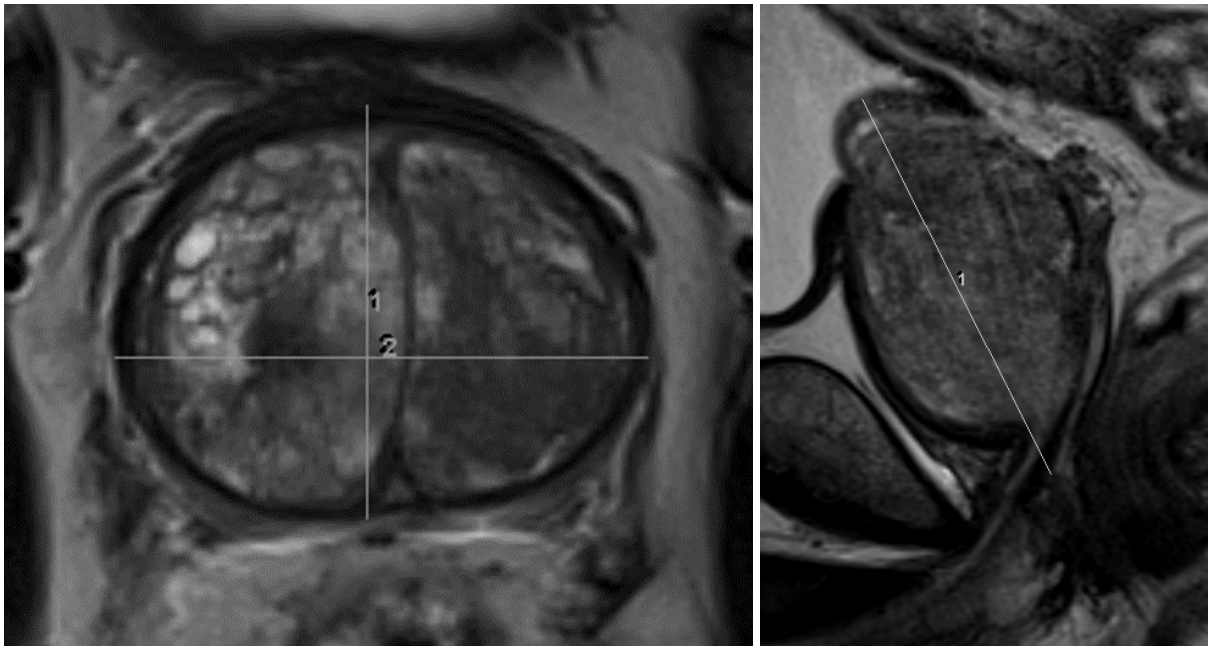

Figure 3A – Axial and sagittal MRI before PAE

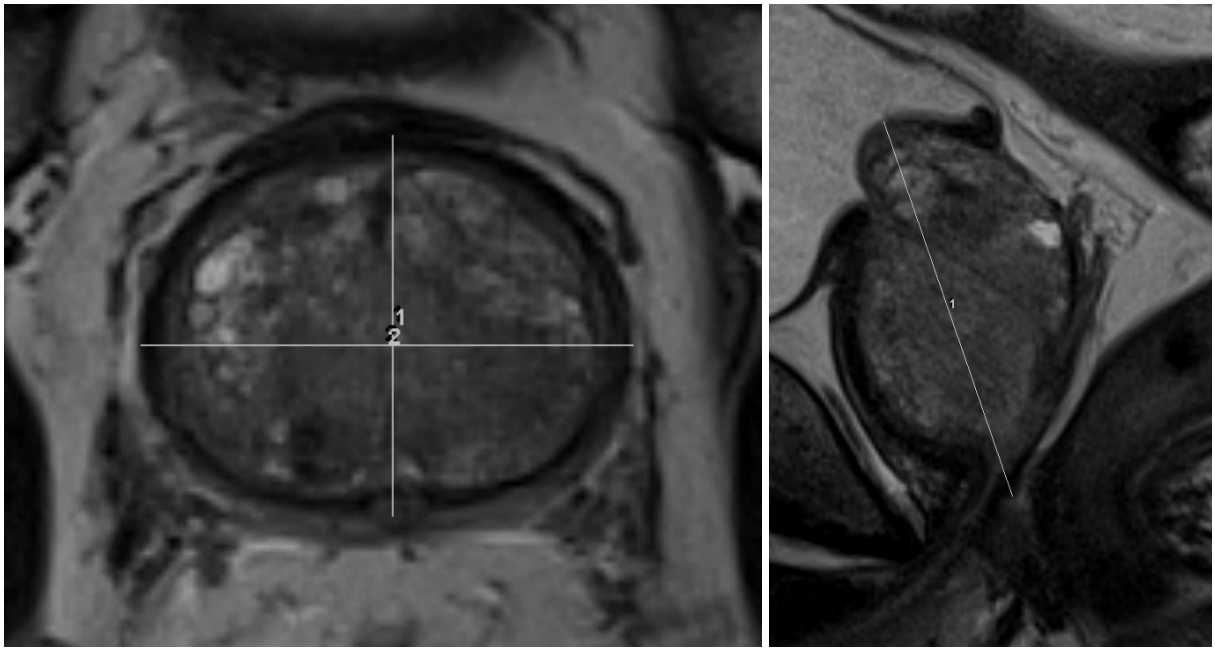

Figure 3B – Axial and sagittal MRI after PAE