CLINICAL STUDY

Role of Ultrasound Elastography in Patient Selection for Prostatic Artery Embolization

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ABSTRACT

Purpose: To determine the effects of prostatic artery embolization (PAE) on prostate elasticity as assessed using ultrasound elastography (US-E) and to describe baseline US-E's potential role in patient selection.

Materials and Methods: This was a prospective investigation that included 20 patients undergoing PAE to treat lower urinary tract symptoms attributed to benign prostatic hyperplasia (BPH). US-E with measurement of the prostatic elastic modulus (EM) and shear wave velocity (SWV) was performed before PAE and at 1-month follow-up. Baseline, 3-month, and 1-year follow-up evaluations included prostate-specific antigen, uroflowmetry, pelvic magnetic resonance imaging, and clinical assessment using the International Prostate Symptom Score (IPSS) and quality of life (QoL) metrics.

Results: Seventeen patients entered statistical analysis. US-E showed a significant reduction in mean prostatic EM (34.4 kPa vs 46.3 kPa, −24.7%, $P < .0001$) and SWV (3.55 m/s vs 4.46 m/s, −20.0%, $P < .0001$) after PAE. There were moderate positive correlations between baseline EM and 1-year IPSS ($R = 0.62$, $P = .007$) and between baseline SWV and 1-year IPSS ($R = 0.68$, $P = .002$). Baseline SWV $\geq$ 5.59 m/s and baseline EM $\geq$ 50.14 kPa were associated with suboptimal IPSS and QoL outcomes after PAE with high degrees of sensitivity (100%) and specificity (69-100%).

Conclusions: PAE led to a positive effect on the BPH dynamic component related to prostatic elasticity. There was a moderate positive correlation between baseline prostatic elastographic parameters and 12-month IPSS. Measurement of baseline elastographic characteristics may become useful for the evaluation and selection of patients for PAE.

ABBREVIATIONS

BOO = bladder outlet obstruction, BPH = benign prostatic hyperplasia, EM = elastic modulus, IPSS = International Prostate Symptom Score, LUTS = lower urinary tract symptoms, MR = magnetic resonance, PAE = prostatic artery embolization, Qmax = peak urinary flow rate, QoL = quality of life, ROC = receiver operating characteristic, SWE = shear wave elastography, SWV = shear wave velocity, US-E = ultrasound elastography

Recently, ultrasound elastography (US-E) was described as a novel tool to address the effects of prostatic artery embolization (PAE) in prostate's elasticity, helping comprehend the procedure's mechanisms of action and serving as a noninvasive tool capable of providing both anatomical and functional assessments in patients with benign prostatic hyperplasia (BPH) (1–3).

In 2019, the pilot series of the present investigation demonstrated, on the basis of US-E data of 8 patients, that PAE not only causes prostate volume reduction but also leads to a positive effect on the α-adrenergic–mediated muscular tonus of the gland, relieving the dynamic component of the bladder outlet obstruction (BOO). Based on the measurement of direct elastographic parameters using

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RESEARCH HIGHLIGHTS

- Prostatic artery embolization (PAE) resulted in significant reductions of prostatic elastic modulus (EM) (−24.7%, $P < .0001$) and shear wave velocity (SWV) (−20.0%, $P < .0001$), as assessed using ultrasound elastography.
- Baseline elastographic parameters moderately correlated with PAE clinical results (R = 0.62 for EM and R = 0.68 for SWV; $P < .01$ for both).
- Baseline EM ≥ 50.14 kPa and SWV ≥ 5.59 m/s predicted suboptimal International Prostate Symptom Score (IPSS) and Quality of Life (QoL) outcomes with 100% sensitivity and 69-100% specificity.
- Ultrasound elastography may become a useful prognostic tool in the evaluation of potential PAE candidates.

shear wave elastography (SWE), a significant reduction of both transitional zone elastic modulus (EM) and shear wave velocity (SWV) was observed after PAE (−29.8% and −19.0%, respectively; $P < .01$ for both) (1).

Subsequently, another study evaluating the prostate's elastographic modification after PAE was published. Moschouris et al (2) presented the preliminary results obtained from a cohort of 11 patients undergoing PAE to treat symptomatic BPH using strain elastography. Although strain elastography does not provide objective parameters such as EM and SWV, the authors were able to produce reliable elastographic maps in 5 patients and reported a similar increase in elasticity after PAE of 15.9% considering the entire prostate and 32.6% considering only the transitional zone ($P < .05$).

Although both investigations provided some interesting insights about PAE's mechanisms of action, nothing could be inferred about US-E prognostic role. Therefore, this study aimed to confirm the effects of PAE on prostate elasticity using US-E in a larger cohort and describe its role as a novel imaging tool for prognostic assessment and patient selection for the procedure.

MATERIALS AND METHODS

This prospective, observational, single-center cohort study included 20 consecutive patients with lower urinary tract symptoms (LUTS) attributed to BPH treated with PAE. 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. All participants signed written informed consent to participate in the investigation, and this study was approved by the institutional ethics committee University of Sao Paulo Medical School Ethics Committee (protocol number: 96732718.9.0000.0068). This manuscript has been written on the basis of the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) checklist for cohort studies (4).

STUDY DETAILS

Study type: Prospective, observational, descriptive study

The sample size was calculated on the basis of the primary endpoint (change in elastographic parameters after PAE), and the expected results and standard deviations were obtained in the pilot series of this study (1). Considering a type I error of 0.05 and statistical power of 80%, the number of patients calculated was 16, thus 20 patients were included to account for possible data loss. The first 8 patients' elastographic results included in this cohort have already been published elsewhere (1).

Inclusion Criteria

1. LUTS attributed to BPH for at least 6 months, refractory to standard medical treatment (α-1-adrenergic receptor antagonist ± 5-α-reductase inhibitor)
2. International Prostate Symptom Score (IPSS) of ≥8
3. Prostatic volume of ≥40 cm^3 and ≤200 cm^3

Exclusion Criteria

1. Biopsy-confirmed prostatic cancer
2. Active urinary infection
3. Patients with urinary retention, using Foley urinary catheter
4. Serum creatinine of ≥2.0 mg/dL
5. Previous pelvic surgery or radiotherapy

From February 2018 to October 2019, 20 patients who met the inclusion criteria underwent PAE and US-E evaluation. Two of them did not return for clinical follow-up, and the other refused to repeat US-E after PAE, being excluded from the study. Therefore, 17 patients entered statistical analysis, and their baseline characteristics have been summarized in **Table 1**.

PAE was performed according to the previously described methods, aiming to embolize every feeding branch to the prostate bilaterally (5), using 300–500-μm trisacryl gelatin microspheres until complete stasis (Embosphere; Biosphere Medical, Roissy, France). Cone-beam computed tomography was used to confirm the anatomical findings in all patients. All PAEs were performed using a unilateral right femoral arterial approach, and patients were discharged from the hospital 2–6 hours after the procedure.

Endpoints and Follow-up Protocol

The primary endpoints consisted of prostatic EM (in kilopascal) and SWV (in meter per second), assessed using US-E before and 30 days ± 7 after PAE. All patients who were previously using α-1-adrenergic receptor antagonists

Table 1. Baseline Characteristics

Baseline variables	Mean ± SD	Q1	Q3	N
Age (y)	66.4 ± 5.8	61.0	70.0	17
IPSS	20.1 ± 6.1	15.0	25.0	17
QoL	4.1 ± 0.9	3.0	5.0	17
Qmax (mL/s)	8.0 ± 3.7	6.2	9.2	17
PV (cm^3)	89.2 ± 38.8	64.8	105.1	17
PSA (ng/ml)	4.8 ± 5.6	1.4	6.3	17
EM (kPa)	46.3 ± 17.6	33.0	61.5	17
SWV (m/s)	4.46 ± 0.95	3.7	5.4	17

EM = elastic modulus; IPSS = International Prostate Symptom Score; PSA = prostate-specific antigen; PV = prostatic volume; Qmax = peak urinary flow rate; QoL = quality of life; SD = standard deviation; SWV = shear wave velocity; Q1 and Q3 = interquartile intervals.

during the first US-E evaluation maintained the medication, in the same posology, until the 1-month US-E reevaluation, as those medications actively interfere in prostatic elasticity (6). Subsequently, the use of α-1-adrenergic receptor antagonist was permanently withdrawn.

The secondary endpoints included IPSS, quality of life (QoL), peak urinary flow rate (Qmax; assessed using uroflowmetry), prostatic volume (assessed using magnetic resonance [MR] imaging), and prostate-specific antigen. Patients' clinical symptoms were assessed using the IPSS questionnaire and the IPSS-QoL item, for which responses range from "6, terrible" to "0, delighted." *Clinical failure* was defined as QoL of ≥3 during follow-up. All efficacy endpoints were obtained before PAE and at 3- and 12-month follow-up.

A modified Clavien–Dindo grading system (I–V) to classify surgical complications was used to report adverse events. Regarding the event's intensity, Grades I and II were reported as minor and Grades III, IV, and V as major (7). Adverse events were actively surveyed during follow-up.

The detailed follow-up protocol has been demonstrated in **Figure 1**.

US-E Technical Protocol

US-E examinations were performed up to 30 days before PAE and repeated 30 days ± 7 after the procedure. All examinations were performed in a Toshiba Aplio i800 (Toshiba Medical Systems Corporation, Otawara, Japan), using a transrectal approach, with a dedicated endocavity probe (11C3; Toshiba Medical Systems Corporation). The elastography technology is based on a 2-dimensional SWE (acoustic structure quantification), with dynamic energy generation by the device (acoustic radiation force impulse), not depending on tissue compression by the operator during the examinations. In 2-dimensional SWE, the dynamic stress generated by acoustic radiation force impulse is multifocal, making it possible to measure EM and SWV by building colored elastographic maps. Moreover, it is possible to obtain elastographic and B-mode imaging simultaneously, in real-time (**Fig 2**).

The mean EM and SWV values were obtained from a large elastographic map including the transitional zone of both lobes of the prostate simultaneously, in at least 2 axial slices at the level of the middle third of the gland. The map containing the most representative elastographic map (ie, fewer artifacts such as calcifications and fewer areas of elastographic loss of signal) was chosen to extract the EM and SWV values (**Fig 3**). All examinations were performed by the same radiologist (A.S.Z.M.), with 23 years of experience in abdominal and pelvic ultrasound and specific training in US-E.

Statistical Analysis

Statistical analyses were performed using GraphPad Prism 3.0 (San Diego, California). Categorical variables were expressed as percentages, and numeric variables were described as means accompanied by standard deviations and interquartile intervals. After verifying the distributions' normality, comparisons over time were performed using paired Student *t* test or repeated measures analysis of variance test.

The association between baseline elastographic parameters (EM and SWV) and 1-year IPSS was assessed using the Pearson product-moment correlation test. Finally, to investigate US-E's prognostic performance, receiver operating characteristic (ROC) curves were produced to determine predictive cutoff values of baseline EM and SWV. For that, PAE efficacy variables at 1 year (IPSS, QoL, and Qmax) were categorized as optimal or suboptimal as follows:

1. IPSS < 8, optimal; IPSS ≥ 8, suboptimal
2. QoL < 2, optimal; QoL ≥ 2, suboptimal
3. Qmax ≥ 12 mL/s, optimal; Qmax < 12 mL/s, suboptimal

The respective area under the curve, accompanied by a 95% confidence interval, was obtained for each ROC curve.

Statistical significance was defined as a bicaudal type I error (*P* value) of $<.05$ in all analyses.

RESULTS

Of the 17 patients, 16 (94.1%) underwent bilateral embolization. In 1 patient (5.9%), catheterization was technically unsuccessful due to atherosclerosis.

Regarding the elastographic results, a significant reduction in the transitional zone EM (−24.7%, $P < .0001$) and SWV (−20.0%, $P < .0001$) after PAE was observed. Individually, all patients presented with a reduction in both EM and SWV. The detailed results of the elastographic findings have been described in **Table 2**.

After PAE, a significant improvement in all efficacy endpoints was observed ($P = .04$ for prostate-specific antigen and $P < .001$ for IPSS, QoL, prostatic volume, and Qmax; **Table 3**). One patient (5.9%) presented with clinical failure at the 12-month follow-up (QoL = 4, IPSS = 16) and

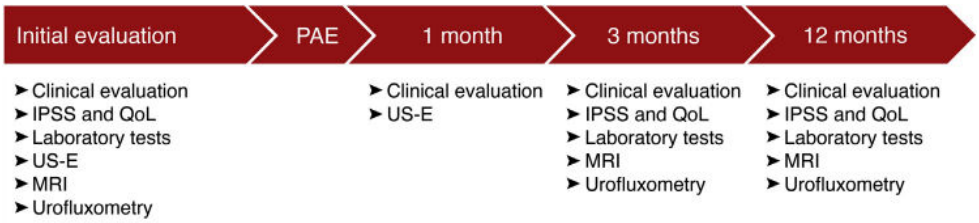

Figure 1. Initial evaluation and follow-up protocol. IPSS = International Prostate Symptom Score, MRI = magnetic resonance imaging, PAE = prostatic artery embolization, QoL = quality of life, US-E = ultrasound elastography.

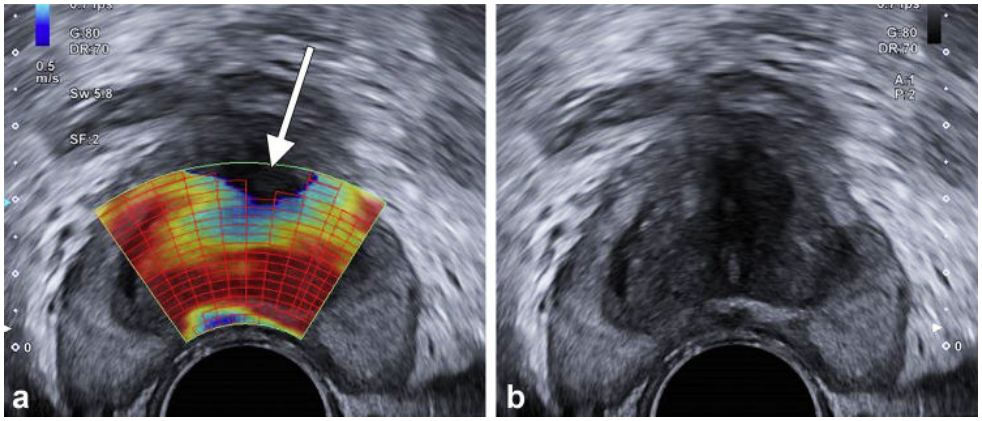

Figure 2. Simultaneous evaluation of the elastographic map **(a)** and the B mode **(b)** aspects during shear wave elastography. Note the small area of signal loss in the anterior third of the transitional zone (arrow).

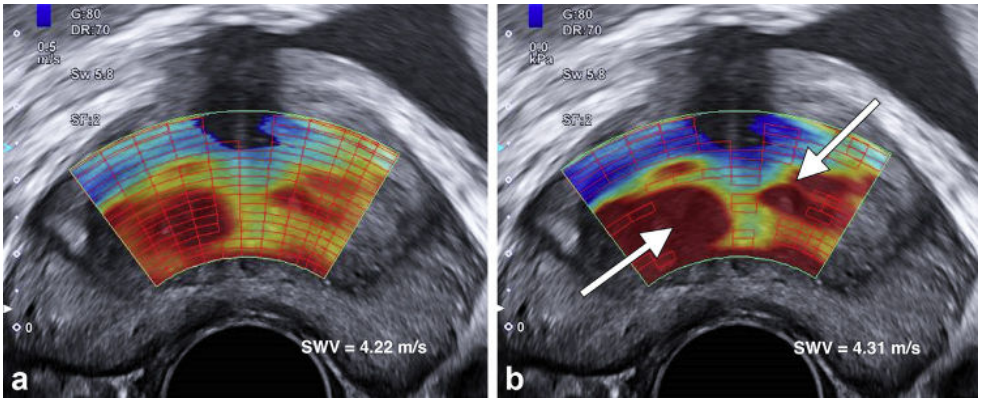

Figure 3. Baseline ultrasound elastography imaging from the same patient, in slightly different axial slice across the middle third of the gland. Observe the placement of a large elastographic map, including the transitional zone of both prostatic lobes simultaneously in **(a)** and **(b)**. In **(b)**, multiple areas of loss of elastographic measurement are observed (noncheckered areas, arrows). SWV data were, therefore, obtained from the map shown in **(a)**. SWV = shear wave velocity.

was treated with repeat PAE and reintroducing the adrenergic receptor antagonist with LUTS improvement.

All 17 patients (100%) had symptoms consistent with a post-PAE syndrome, including dysuria, increased urinary frequency, and mild pelvic pain, which lasted from 1 to 10 days. Those were considered side effects rather than complications (7). All patients showed improvement of post-PAE syndrome with usual medication, without the need for specific treatment. One patient (5.9%) presented with a

Table 2. Changes in Prostatic Elastographic Parameters after Prostatic Artery Embolization

Elastographic parameters	Baseline	1-Month follow-up	Change	% Change	*P* value
EM (kPa)	46.3 ± 17.6	34.4 ± 12.5	−11.9	−24.7%	<.0001
SWV (m/s)	4.46 ± 0.95	3.55 ± 0.76	−0.91	−20.0%	<.0001

Note–Variables are expressed as means ± standard deviation. EM = elastic modulus; SWV = shear wave velocity.

Table 3. Prostatic Artery Embolization Efficacy Outcomes After 3 and 12 Months

Efficacy endpoints	Baseline	3 months	Change (%)	12 months	Change (%)	*P* value
PSA (ng/ml)	4.8 ± 5.6	2.0 ± 1.4	−2.8 (−58.3%)	2.6 ± 2.3	−2.2 (−45.8%)	.04
IPSS	20.1 ± 6.1	4.6 ± 3.4	−15.5 (−77.1%)	6.1 ± 4.4	−14.0 (−69.5%)	<.0001
QoL	4.1 ± 0.9	0.9 ± 0.9	−3.2 (−78.0%)	1.5 ± 0.9	−2.6 (−63.4%)	<.0001
PV (cm^3)	89.2 ± 38.8	58.7 ± 21.6	−30.5 (−34.2%)	61.1 ± 23.5	−28.1 (−31.5%)	.0003
Qmax (mL/s)	8.0 ± 3.7	13.7 ± 4.7	+5.7 (+71.3%)	15.3 ± 6.4	+7.7 (+91.3%)	<.0001

Note–Parametric variables are expressed as means ± standard deviations.
IPSS = International Prostate Symptom Score; PSA = prostate-specific antigen; PV = prostatic volume; Qmax = peak urinary flow rate; QoL = quality of life.

self-limited macroscopic hematuria, in a small amount, during the third week of follow-up and was considered a minor Grade I complication. There were no major complications in this cohort.

Correlation tests were performed to verify the association between baseline elastographic parameters (EM and SWV) and the PAE efficacy endpoints at the 12-month follow-up (IPSS, QoL, and Qmax). A moderate positive correlation between baseline EM and 12-month IPSS (R = 0.62, $P = .007$) and between baseline SWV and 12-month IPSS (R = 0.68, $P = .002$) was observed. There was also a tendency of positive association between baseline SWV and 12-month QoL (R = 0.41, $P = .09$). The results of the correlation tests have been summarized in Table 4 and Figure 4.

ROC analyses were performed to assess the prognostic performance of US-E based on baseline EM and SWV values. Considering the suboptimal values of IPSS (≥8), QoL (≥2), and Qmax (<12 mL/s), the cutoff values of EM and SWV of clinical interest were determined. The sensitivity and specificity of such cutoff values have been described in Table 5.

Table 4. Correlation Coefficients between Baseline Elastographic Variables and 12-month IPSS, QoL, and Qmax

Elastographic parameters	Efficacy variable	R	*P* value
EM (kPa)	IPSS	0.62	.007
	QoL	0.01	.22
	Qmax (mL/s)	−0.20	.21
SWV (m/s)	IPSS	0.68	.002
	QoL	0.41	.09
	Qmax (mL/s)	−0.27	.29

EM = elastic modulus; IPSS = International Prostate Symptom Score; Qmax = peak urinary flow rate; QoL = quality of life; SWV = shear wave velocity.

DISCUSSION

In the last decade, PAE has emerged as a safe and effective therapeutic alternative for the treatment of symptomatic BPH (8–14). Some aspects related to PAE's mechanisms and the selection of patients for the procedure are unclear and remain topics of current debate. The findings described in this study may help to understand such aspects and to improve patient selection, and consequently, to improve PAE's clinical results.

PAE leads to occlusion of the distal arterial microvascular bed of the prostate at the level of internodal intraprostatic branches (15). As a result, tissue ischemia and coagulative necrosis of BPH nodules are observed, leading to volume reduction and improvement of the extrinsic obstruction of the prostatic urethra (16,17). Besides that, the findings described in this cohort demonstrated that the tissue damage caused by embolization also plays a relevant role in modifying the elasticity of the prostate, with a significant improvement in the elastographic parameters in the US-E after the procedure (−20.0% for SWV and −24.7% for EM; $P < .05$ for both).

The 2 baseline elastographic parameters studied (EM and SWV) showed a moderate, statistically significant positive correlation with 1-year IPSS (R = 0.62 for EM, R = 0.68 for SWV; $P < .05$ for both), consistently demonstrating inferior PAE results for patients with very low initial prostate elasticity (Table 4). The correlation results based on QoL and Qmax did not reach statistical significance, which may be due to the small sample size, although a moderate positive correlation trend between the initial SWV and the QoL after PAE has been demonstrated (R = 0.41, $P = .09$). Similarly, the findings determined by the ROC analyses demonstrated that patients with very low initial elasticity as assessed using US-E showed suboptimal symptomatic improvement, based on IPSS (specificity = 84.6% for EM ≥ 50.14 kPa and specificity = 100% for SWV ≥ 5.59 m/s), QoL (68.8% for baseline EM ≥ 50.14 kPa and 81.3% for baseline SWV ≥ 5.59 m/s), and Qmax (80.0% for baseline EM ≥ 50.14 kPa and 90.0% for baseline SWV ≥ 5.59 m/s) (Table 5).

Although the individuals included have not been assessed using invasive urodynamic testing, patients with baseline EM of ≥50.14 kPa may have severe BOO, according to a previous study investigating the association between prostate EM and the urodynamic degree of BOO (18). In this study including 55 patients, a positive correlation was demonstrated between the baseline prostatic EM and the severity of BOO (R = 0.666, $P < .001$), and patients with

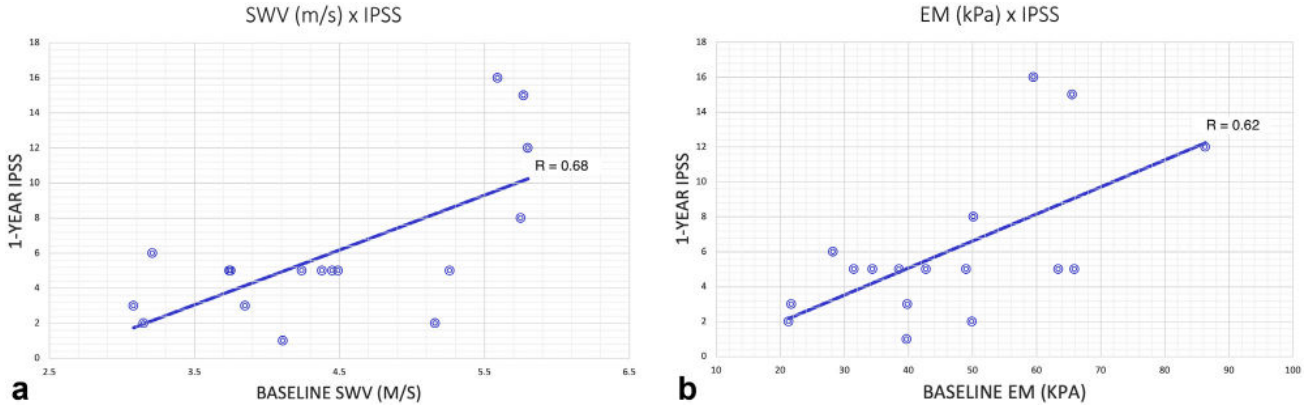

Figure 4. Scatter plots showing a moderate positive correlation between baseline SWV and 12-month IPSS (R = 0.68, $P = .002$) **(a)** and EM and 12-month IPSS (R = 0.62, $P = .007$) **(b)**. EM = elastic modulus, IPSS = International Prostate Symptom Score, SWV = shear wave velocity.

Table 5. Cutoff Values and Prognostic Performance for Baseline Elastic Modulus and Shear Wave Velocity

Elastographic parameters	Efficacy variable	Cutoff value	AUC (95% CI)	Sensitivity	Specificity
EM (kPa)	IPSS	50.14	0.90 (0.76, 1.00)	100.0%	84.6%
	QoL	50.14	0.75 (0.52, 1.00)	100.0%	68.8%
	Qmax (mL/s)	50.14	0.77 (0.53, 1.00)	57.1%	80.0%
SWV (m/s)	IPSS	5.59	1.00 (0.82, 1.00)	100.0%	100.0%
	QoL	5.59	0.81 (0.56, 1.00)	100.0%	81.3%
	Qmax (mL/s)	5.59	0.77 (0.54, 1.00)	42.9%	90.0%

AUC = area under the curve; CI = confidence interval; EM = elastic modulus; IPSS = International Prostate Symptom Score; Qmax = peak urinary flow rate; QoL = quality of life; SWV = shear wave velocity.

severe BOO had a higher average EM than those with moderate and mild BOO (36.3 kPa vs 30.6 kPa vs 27.7 kPa, respectively; $P < .001$). Based on these findings, the severity of BOO in patients with baseline prostatic EM of ≥50.14 kPa possibly explains the suboptimal outcomes seen in that specific subgroup. Thus, those patients may have a greater benefit if they undergo surgical procedures that improve urodynamic BOO more reliably, such as transurethral resection of the prostate (19).

The limitations of this study include the short time of follow-up and its small sample size. Despite that, the sample size was calculated on the basis of the assumptions obtained in the pilot study of this project, making it possible to demonstrate statistical significance for the primary and most of the secondary outcomes. Even so, the 95% confidence interval of the parameters with high variance was relatively wide (**Table 5**). In addition, the paired performance of US-E by the same professional, with specific training, was designed to reduce variability; however, external validation of the findings will require larger sample sizes and multiple operators.

Technically, the main limitation of US-E referred to the prostate's elastographic heterogeneity, which makes the evaluation using small samples less reliable, and was mitigated by the construction of multiple large elastographic maps for every patient (**Fig 3**). Nevertheless, the selection of the most representative map to extract data could also generate bias. Finally, there were small areas of signal loss in the anterior transitional zone in a few patients (**Fig 2**), which can pose a problem for the individual assessment of elasticity in patients with larger prostates.

Overall, US-E was demonstrated as a useful diagnostic and prognostic tool in the assessments before and after PAE. In addition to the possibility of anatomical and volumetric evaluation of the prostate in B mode (**Fig 5**), US-E provides functional data regarding prostatic elasticity, which correlates with the urodynamic degree of BOO (18). Moreover, there is no use of ionizing radiation or contrast media in US-E. US-E may replace MR imaging in places where the latter is not available or for patients with contraindications, such as those with a cardiac pacemaker or renal failure. Furthermore, it can be used as an additional investigation in patients with less nodular transitional zone, who usually present lesser volumetric reduction after PAE (20).

In conclusion, PAE caused a significant improvement of prostatic elasticity according to US-E, leading to a positive effect on the dynamic component of BPH. There was a positive correlation between the initial elastographic parameters and the clinical outcomes of PAE. High baseline values of EM (≥50.11 kPa) and SWV (≥5.59 m/s) predicted

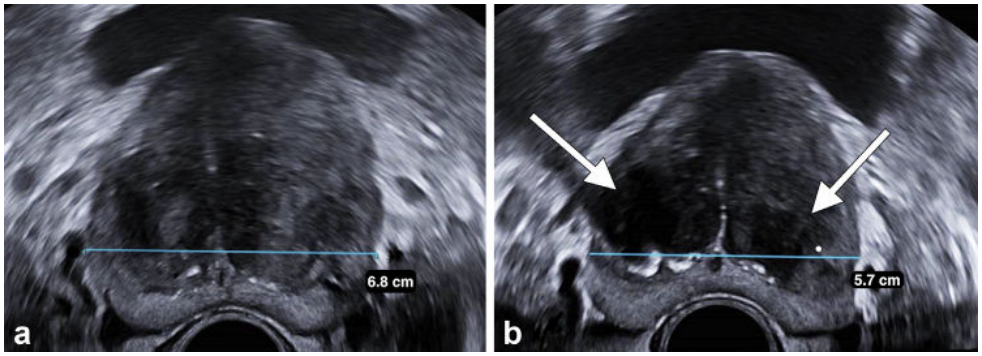

Figure 5. Ultrasound in B mode before **(a)** and after prostatic artery embolization **(b)**, showing prostatic volumetric reduction (blue rule measuring maximum transverse diameter) and hypoechogenicity of the transitional zone (arrows).

inferior results after PAE with high degrees of sensitivity and specificity. Validation of elastographic threshold values may prove to be useful in the optimization of patient selection for PAE.

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