CLINICAL STUDY

Intravesical Prostatic Protrusion Does Not Influence the Efficacy of Prostatic Artery Embolization

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ABSTRACT

Purpose: To compare the outcomes of prostatic artery embolization (PAE) in patients with different intravesical prostatic protrusion (IPP) grades.

Materials and Methods: This retrospective single-center study included 128 patients (aged 50–86 years) who underwent PAE from 2013 to 2017. IPP grades were classified as follows: grade I (<10 mm), grade II (10–19 mm), and grade III (≥20 mm). Nineteen patients (14.8%) had grade I [mean IPP 7.8 mm, prostatic volume (PV) 64.1 cm^3], 77 (60.2%) had grade II (mean IPP 14.9 mm, PV 87.0 cm^3), and 32 (25%) had grade III (mean IPP 26.2 mm, PV 132.6 cm^3), $P < .01$. The outcomes, including PV, international prostate symptom score (IPSS), and quality of life (QoL), were compared between the IPP grades at the 12-month follow-up. Clinical failure was defined as IPSS >7 or QoL >2.

Results: IPP decreased (I: −8.2%, II: −27.3%, and III: −38.7%, $P = .01$), and all other endpoints improved ($P < .01$). Adjusted covariance analysis, considering baseline PV as a confounding factor, showed no correlation between the 12-month outcomes and baseline IPP. Clinical failure was observed in 17/128 patients (13.3%) and was similar in prevalence among the IPP groups ($P = .20$). Minor complications occurred in 43 patients (33.6%) and major in 3 (2.3%). There were statistical differences in the complications between IPP grades II and III ($P < .01$).

Conclusions: PAE was similarly effective in all the IPP grades at the 12-month follow-up, and there was no difference in the clinical failure between the groups. Complications in IPP grade III were more frequent than those in IPP grade II.

ABBREVIATIONS

BPH = benign prostatic hyperplasia, IPP = intravesical prostatic protrusion, IPSS = international prostate symptom score, LUTS = lower urinary tract symptoms, PAE = prostatic artery embolization, PSA = prostate-specific antigen, PV = prostatic volume, PVR = postvoid residual volume, Q_{max} = peak urinary flow rate, QoL = quality of life, TURP = transurethral prostate resection

Prostatic artery embolization (PAE) is a minimally invasive technique for the treatment of symptomatic benign prostatic hyperplasia (BPH) and an emerging alternative to surgical approaches. For the treatment of BPH using PAE, clinical and technical experience has been accrued (1–4). Nevertheless, the clinical aspects of baseline anatomical features of the prostate and their influence on PAE outcomes are not completely understood. One such parameter is the intravesical prostatic protrusion (IPP) index, obtained by measuring the vertical distance from the tip of the protruding prostate gland to the base of the bladder in a sagittal plane.

It is known that the IPP index may be correlated to the outcomes of several BPH treatment alternatives. Studies have shown that men with bladder outlet obstruction and higher IPP values are poor responders to medical treatment (5,6). The influence of IPP on transurethral prostate resection (TURP) outcomes has also been investigated, with conflicting results. In a retrospective series of 177 patients, Lee et al (7) compared the results of TURP at 6 months for

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IPP <5 mm versus that for IPP ≥5 mm and observed that the international prostate symptom score (IPSS) was further improved when IPP was ≥5 mm ($P = .04$). However, another study (8) showed that patients with a prostate protruding into the bladder had a smaller decrease in their IPSS scores compared with patients who did not have prostate protrusion (9.87 vs 13.18, $P = .02$). The author concluded that patients with prostate protrusion experienced less symptomatic relief after TURP.

Regarding the most recent urological therapies, the impact of IPP is not well understood. Transurethral incision of the prostate is suitable for prostate glands with <30-mL volume without a median lobe (9), and a prostatic urethral lift might not be suitable for a prostate with an obstructing median lobe as the procedure involves anterolateral retraction of the lateral lobes (10). Conductive heat transfer technology, utilized in transurethral needle ablation of the prostate and transurethral microwave thermotherapy, also produces unsatisfactory results in the treatment of the median lobe (11). However, it is suggested that convective water vapor thermal therapy using the Rezum system (NxTHera, Inc., Maple Grove, Minnesota) can be used to treat all critical prostatic sites, including the median lobe (12). The most recent study demonstrates the therapy's safety and efficacy up to 48 months after the intervention. Therefore, further studies on these new therapies are required to assess the influence of IPP and its outcome following the therapy, including prolonged symptom relief and retreatment rates.

A previous study has shown that in a small series, PAE is efficient in reducing IPP (13) and that early results do not appear to be influenced by the degree of the IPP (14). However, evaluating IPP without the influence of prostate volume and determining whether the previous IPP value can be considered as a detrimental response predictor of a larger cohort over longer follow-up periods require further investigation. Therefore, the aim of the present study was to compare the outcomes of PAE for the treatment of lower urinary tract symptoms (LUTS) related to BPH in patients with different IPP grades during a 12-month follow-up.

MATERIALS AND METHODS

Study Design

This is a retrospective single-center study, including 128 consecutive patients with LUTS due to BPH, who underwent PAE between March 2013 and March 2017 and met the inclusion criteria. All the patients gave their informed consent for the procedure and were followed up for 12 months. During the study period, 182 patients underwent PAE, of which 128, with an average age of 65 years (ranging from 50–86 years), met the inclusion criteria (**Fig 1**). The baseline characteristics for the IPP groups are shown in **Table 1**. This study was approved by the Institutional Review Board and carried out in accordance with the ethical standards of the 1964 Helsinki Declaration and its later amendments. Research subject review board exemption was obtained under the category of secondary use of pre-existing data.

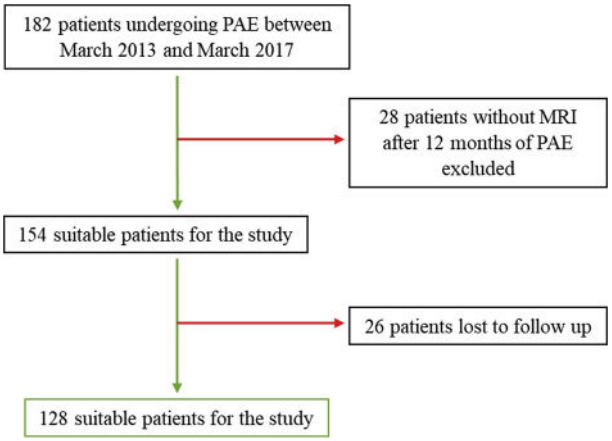

Figure 1. Patient disposition according to the inclusion criteria.

The inclusion criteria were as follows: clustered patients who were aged ≥45 years with LUTS secondary to BPH and were intolerant or refractory to medical treatment for at least 6 months (alpha-1-adrenergic receptor antagonist and/or 5-alpha reductase inhibitor). A histological diagnosis of prostate cancer, hypocontractive bladder, or other neurogenic bladder disorders was contraindicative for PAE. All patients with a serum prostate-specific antigen (PSA) level >4.0 ng/mL or those who underwent an abnormal rectal examination underwent transrectal ultrasound-guided prostate biopsy to exclude the presence of a prostate malignancy. Additionally, PAE was not performed when surgery was indicated for reasons other than BPH, such as bladder diverticulum or urolithiasis. Patients who were lost to follow-up before the 12-month period or did not undergo a 12-month magnetic resonance (MR) imaging examination were excluded from the study. Thus, there was no loss of data during the follow-up as only patients with complete data were included in the study.

The initial evaluation included MR imaging for prostatic volume (PV) and IPP assessment, uroflowmetry, serum PSA levels, IPSS, and quality of life (QoL) questionnaires as well as transabdominal ultrasound for postvoid residual volume (PVR).

Based on a routine follow-up for patients undergoing PAE, all the patients included in the analysis were followed up using MR imaging, uroflowmetry, serum PSA level assessment, and IPSS and QoL questionnaires 12 months after undergoing PAE.

Technical success was defined as bilateral embolization. Clinical failure was defined as IPSS >7 and/or QoL >2 at any time during the 12-month follow-up. Complications were recorded based on the Clavien–Dindo classification employed for PAE (grades I–IV). Regarding the intensity of the event, grades I and II are considered minor and grades III and IV as major (4). Of note, in the reported cohort, all patients have been previously described with a focus on

Table 1. Baseline Characteristics for Each IPP Grade Group

Parameters	Baseline IPP grade			*P* value
	I n = 19 (14.8%)	II n = 77 (60.2%)	III n = 32 (25.0%)	
IPP (mm)	7.8 ± 1.6	14.9 ± 2.8	26.2 ± 6.1	<.01
PV (cm^3)	64.1 ± 24.3	87.0 ± 36.7	132.6 ± 52.1	<.01
PSA (ng/mL)	3.0 ± 1.5	4.7 ± 4.3	7.0 ± 6.9	.07
IPSS	15.6 ± 5.1	19.9 ± 6.2	19.4 ± 5.8	.02
QoL	4.4 ± 0.6	4.8 ± 0.8	4.7 ± 0.9	.07
Q_{max} (mL/s)	7.6 ± 3.2	6.4 ± 3.5	7.4 ± 4.9	.22
PVR (mL)	42.9 ± 49.0	113.5 ± 140.1	144.5 ± 120.6	<.01

IPP = intravesical prostatic protrusion; IPSS = international prostate symptom score; PSA = prostate-specific antigen; PV = prostatic volume; PVR = postvoid residual volume; Q_{max} = maximum urinary flow rate; QoL = quality of life.

improving the mean IPSS, QoL score, embolic agents, prostate size, and techniques used (1).

Imaging

A prostate 1.5- or 3.0-tesla MR imaging scan was performed before and after PAE using a phased pelvic array coil. A gadolinium-based contrast medium with a power injector, at a dose of 0.1 mL/kg (or 0.2 mL/kg) followed by 20 mL of saline flush, was used. Prostate measurements (cephalocaudal, transverse, and anteroposterior) were obtained, and the volume was calculated using the ellipse equation. IPP represents the growth of the prostatic median lobe with consequent intravesical protrusion. The bladder base was defined as a straight line drawn through the 2 points where the prostate met the mucosa of the urinary bladder (**Fig 2**). Each MR image was analyzed by 2 different reviewers (with 5 and 12 years of experience each), and disparate measurements were resolved by consensus.

The IPP grading was performed using a modified version of the ultrasound classification proposed by Chia et al (15) since currently, there are no specific MR imaging classifications. IPPs were categorized as grade I (<10 mm), grade II (10–19 mm), and grade III (≥20 mm). The same measurement system was used in all MR imaging examinations, both before and after the PAE procedure (**Fig 3**).

PAE Procedure

The PAE procedures were performed using the same technique as previously described (1), aiming to achieve bilateral embolization of the prostatic arteries. All the procedures were performed in an interventional radiology suite (Innova 4100, GE Healthcare; Chalfont St. Giles, Buckinghamshire, United Kingdom) using a nonionic contrast medium (320 mg I/mL of iodixanol [Visipaque; GE Healthcare, Cork, Ireland]). The procedures were performed under local anesthesia using a unilateral femoral artery approach.

Selective catheterization of the right and left prostatic arterial arteries was performed using ≤2.4-Fr microcatheters (Progreat; Terumo, Japan) and a cone-beam CT (0.3 mL/s; 3–5 mL using power injection with a 5-second spin and 10-second delay) when necessary, followed by embolization with trisacryl gelatin microspheres of size 300–500 μm or a combination of 100–300 and 300–500 μm (Embospheres, Merit Medical Systems Inc., South Jordan, Utah) until complete stasis was achieved. When required, the patients were administered steroidal or nonsteroidal antiinflammatory medications and/or nonopioid analgesics during and after the procedures, along with ciprofloxacin. The use of the alpha blocker was continued from 2–4 weeks after PAE to control post-PAE syndrome. All the patients were discharged from the hospital on the same day of the procedure.

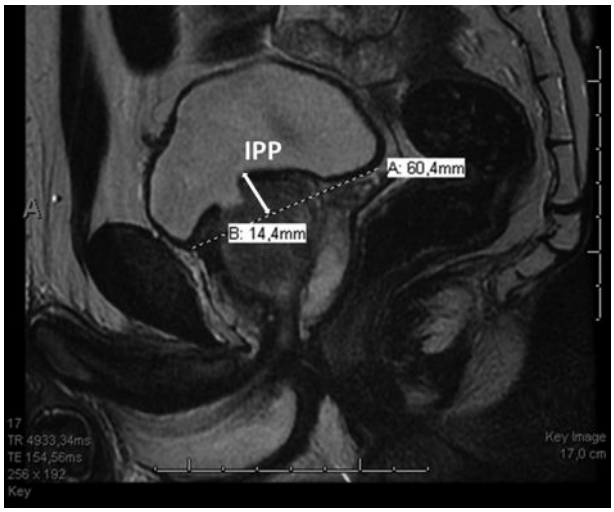

Figure 2. T2-weighted image in the sagittal plane. The topography of the midline of the prostate gland shows enlargement of the middle lobe and glandular protrusion into the urinary bladder. The calculated intravesical prostatic protrusion (IPP) is 14 mm.

Statistical Analysis

Wilcoxon signed-rank test was used to compare the IPP, IPSS, QoL, peak urinary flow rate (Q_{max}), PSA, PV, and

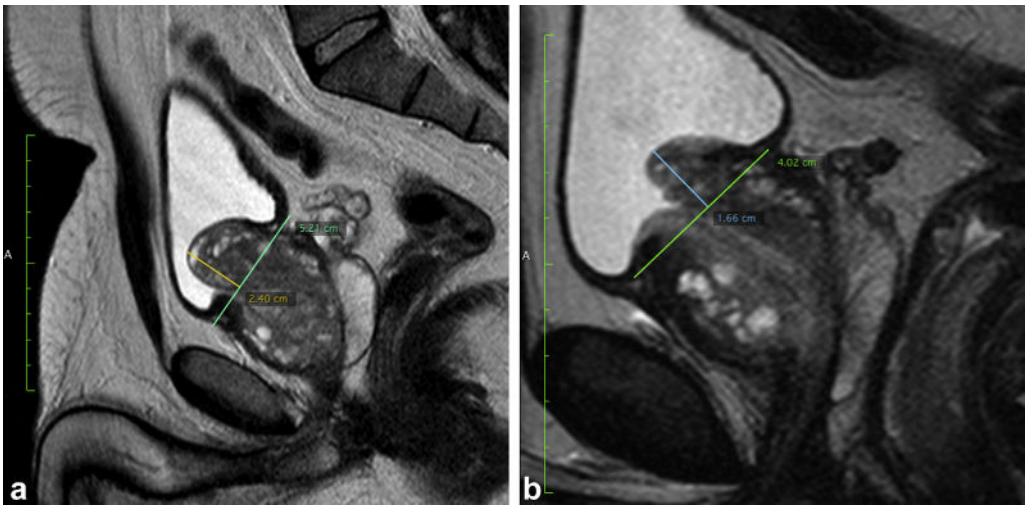

Figure 3. T2-weighted image in the sagittal plane. **(a)** Patient presenting with an intravesical prostatic protrusion (IPP) measured as 24 mm before embolization (grade III). **(b)** Reduction of IPP to 16 mm 12 months after PAE (grade II).

Table 2. Absolute and Relative Changes in PAE Outcomes at 12 Months Classified according to Baseline IPP Grade

Endpoints	Baseline IPP grade			*P* value
	I n = 19 (14.8%)	II n = 77 (60.2%)	III n = 32 (25.0%)	
IPP (mm)	−0.3 ± 1.5 (−3.0% ± 20.1)	−1.9 ± 2.5 (−12.8% ± 16.5)	−4.9 ± 3.0 (−18.7% ± 11.0)	.01
PV (cm^3)	−12.1 ± 11.5 (−18.0% ± 16.4)	−20.9 ± 19.8 (−22.7% ± 19.4)	−43.0 ± 35.1 (−29.6% ± 18.0)	.10
PSA (ng/mL)	0.0 ± 1.3 (−8.2% ± 38.6)	−2.2 ± 3.3 (−27.3% ± 57.8)	−4.5 ± 7.3 (−38.7% ± 53.0)	.01
IPSS	−10.6 ± 6.6 (−65.8% ± 32.5)	−15.9 ± 7.1 (−79.3% ± 21.4)	−14.8 ± 5.6 (−79.9% ± 18.9)	.11
QoL	−2.6 ± 1.1 (−57.8% ± 20.7)	−3.4 ± 1.3 (−68.8% ± 22.3)	−3.1 ± 1.4 (−66.0% ± 23.8)	.14
Q_{max} (mL/s)	+7.6 ± 6.0 (+112.4% ± 76.1)	+7.4 ± 6.3 (+177.4% ± 201.1)	+6.5 ± 7.5 (+150.4% ± 185.3)	.70
PVR (mL)	−6.5 ± 53.5 (−41.3% ± 109.2)	−64.1 ± 142.7 (−27.0% ± 85.1)	−52.9 ± 108.3(−17.8% ± 96.0)	.08

IPP = intravesical prostatic protrusion; IPSS = international prostate symptom score; PAE = prostatic artery embolization; PSA = prostate-specific antigen; PV = prostatic volume; PVR = postvoid residual volume; Q_{max} = maximum urinary flow rate; QoL = quality of life.

PVR results obtained before and after PAE. The McNemar–Bowker test was used to assess the correlation between the changes in IPP scores, and the nonparametric Kruskal–Wallis test was used to evaluate whether there was a significant difference between the groups. When there were differences, multiple comparisons using the Steel–Dwass method were performed. The Fisher's Exact test was used to study the complications and clinical failure rates. All the statistical tests were performed using SAS software (version 9.4; SAS Institute, Cary, North Carolina). $P < .05$ was considered as statistically significant.

RESULTS

Bilateral PAE was performed in 118 patients (92.2%); trisacryl gelatin microspheres of size 300–500 μm were used in 105 patients (82%), whereas a combination of microspheres of size 100–300 and 300–500 μm were used in 23 patients (18%).

The patients were classified according to their IPP grades: 19 (14.8%) had grade I (mean IPP 7.8 mm, PV 64.1 cm^3, PSA 3.0 ng/mL, IPSS 15.6, QoL 4.4, Q_{max} 7.6 mL/s, and PVR 42.9 mL), 77 (60.2%) had grade II (mean IPP 14.9 mm, PV 87.0 cm^3, PSA 4.7 ng/mL, IPSS 19.9, QoL 4.8, Q_{max} 6.4 mL/s, and PVR 113.5 mL), and 32 (25%) had grade III (mean IPP 26.2 mm, PV 132.6 cm^3, PSA 7.0 ng/mL, IPSS 19.4, QoL 4.7, Q_{max} 7.4 mL/s, and PVR 144.5 mL).

Table 2 shows a standard comparison between baseline IPP grades, suggesting a correlation between a higher IPP reduction and better PSA outcomes after PAE (grade I: −8.2% ± 38.6, grade II: −27.3% ± 57.8, grade III: −38.7% ± 53.0; $P = .01$) at the 12-month follow-up.

A covariance analysis considering the basal PV as a confounding factor showed no significant difference between the groups ($P > .05$ for all endpoints, except IPP, Table 3).

Clinical failure occurred in 17 patients (17/128, 13.3%), with 5 patients with grade I IPP (5/17, 29.4%), 7 with grade

Table 3. Comparison of PAE Outcomes Relative to Changes in IPP Grades (Adjusted by Baseline Prostatic Volume)

Endpoint changes	Unadjusted *P*-values	*P*-values Adjusted for baseline PV	Tukey test		
			I vs II	I vs III	II vs III
IPP	.01	.02	0.07	0.02	0.38
PV	.10	.86			
PSA	.01	.36			
IPSS	.11	.14			
QoL	.14	.11			
Q_{max}	.70	.37			
PVR	.08	.08			

IPP = intravesical prostatic protrusion; IPSS = international prostate symptom score; PAE = prostatic artery embolization; PSA = prostate-specific antigen; PV = prostatic volume; PVR = postvoid residual volume; Q_{max} = maximum urinary flow rate; QoL = quality of life.

II (7/17, 41.2%), and 5 with grade III (5/17, 29.4%). There was no statistical significance between the baseline IPP grade and clinical failure ($P = .20$).

The PAE-related complications are presented in Table 4. Unanticipated negative outcomes were found in 46 patients (35.9%). The complications were considered minor in 43 patients (93.5% of cases) and major in 3 (6.5%). The most frequent minor complications were self-limiting hematuria (n = 12, 26.1% of patients) and self-limiting hematospermia (n = 9, 19.6% of patients). The major complications included a collapsed asymmetric median lobe, collapsed asymmetric median lobe, and persistent urinary tract infection. The complications observed were statistically different between the groups ($P < .01$), and both minor and major complications were more frequent in patients with grade III IPPs. When comparing the groups two by two, a significant difference was found between grades II and III ($P < .01$), as shown in Table 5.

DISCUSSION

In this retrospective study, several baseline characteristics were significantly different between the IPP grades ($P < .05$ for PV, IPSS, and PVR) and significantly lower in the grade I group. As has been previously reported, the higher the baseline PV, the better the outcomes following PAE (16). Therefore, an adjusted statistical analysis, controlling the effects of baseline PV, was performed; in addition to the IPP reduction, all other variables improved, including IPSS, QoL, PSA, Q_{max}, PV, and PVR ($P > .05$ for all). Clinical failure (IPSS > 7 or QoL > 2) was also comparable between the IPP grades ($P = .20$).

The IPP grade and its influence on the treatment of bladder outlet obstruction due to BPH has been the subject of previous studies (5–8,13,14). Inadequate responses to medication may be correlated with an enlarged prostate morphology (5). Even in small prostates, IPP due to the median lobe enlargement can act as an obstacle that cannot be medically managed despite its local action on smooth muscle cells (17). PAE may have the advantage of directly acting on the glandular arterial flow rather than exclusively on microscopic cellular receptors.

Within the scope of minimally invasive procedures, Lin et al (13) conducted the first study investigating the effects of IPP grades on PAE outcomes. In this retrospective single-arm study of 18 patients, the authors showed that the patients had a significant decrease in IPP (−2.7 mm, $P < .01$)

Table 4. Complications that Occurred during the 12-Month Follow-up after PAE and Correlation with the IPP Grade prior to the Procedure

Complication type	Baseline IPP grade			*P* value*
	I	II	III	
	n = 19	n = 77	n = 32	
Minor	**8 (42.1%)**	**18 (23.4%)**	**17 (53.1%)**	<.01
Self-limiting hematuria	3	4	5	
Self-limiting hematospermia	3	4	2	
Low fever	1	3	1	
Penile/Scrotal ulcer	0	3	1	
Ejaculatory volume reduction	0	0	3	
Prostatic tissue elimination	0	0	3	
Self-limiting hematochezia	1	1	0	
Diarrhea	0	1	1	
Pubic bone infarct	0	2	0	
Urethral trauma (Foley placement)	0	0	1	
Major	**0 (0.0%)**	**0 (0.0%)**	**3 (9.4%)**	
Collapsed asymmetric median lobe	0	0	1	
Cystoscopy for clot removal	0	0	1	
Persistent urinary tract infection	0	0	1	
Total complications	**8 (42.1%)**	**18 (23.4%)**	**20 (62.5%)**	

IPP = intravesical prostatic protrusion; PAE = prostatic artery embolization.
*Comparison among levels of complication (Major/Minor/Total) and IPP grade.

Table 5. Comparison of Total Complications between the IPP Grades

IPP grades	*P* value
I vs II	.15
I vs III	.23
II vs III	<.01

IPP = intravesical prostatic protrusion.

as well as a significant symptomatic improvement at 3 months following PAE, with a reported mean IPSS decrease from 14.7 to 4.9 after embolization (72.3%, $P < .01$) and a mean QoL score decrease from 5.4 to 2.4 (54.3%, $P < .01$). Similarly, the findings described in the present case demonstrated a significant decrease in IPP (mean change of −2.4 mm, −12.8%, $P < .01$).

Moreover, this study suggests that patients with different baseline IPP grades would be equally suitable to undergo PAE as they presented with comparable results at the 12-month follow-up. These results are in line with those of Maron et al (14), who classified patients into severe (>10 mm) and nonsevere (<10 mm) IPP grades and demonstrated that there were no significant differences. Despite the short follow-up time (38 days vs 12 months) and the small cohort of patients (54 vs 128), these results strengthen the findings of the present study.

More recently, Yu et al (18) reported advancements in this investigation and shed light on the possible repercussions owing to different IPP morphologies. Their results suggested that patients with tall and pedunculated protrusions into the bladder neck might be poor candidates for PAE. IPPs with a thickness-to-height ratio of ≤1.3 correlated with reductions in suboptimal IPSS and QoL at 12 months ($P = .02$ and $P < .01$, respectively). A thickness-to-height ratio of ≤1.3 was also correlated with the occurrence of more complications after the procedure (34.3% vs 4.5%, $P < .01$), suggesting that this association was not due to inferior prostatic infarction but rather a specific morphology of the median lobe.

In the present study, complications were found in 46 patients (35.9% of cases). They were mostly considered minor (43/46, 93.5% of cases) and more frequent in patients with grade III IPP ($P < .01$). However, this type of complication did not require additional pharmacological, urological surgery or endoscopy, or radiological procedures. These results are in line with those of a study on other urological treatments for BPH, which showed greater complications in patients with prostatic median lobes (19). However, major complications were found in 3 patients (3/46, 6.5% of patients). Unanticipated negative outcomes in this group were as follows: 1 patient with self-limited hematuria that required cystoscopy for clot removal; 1 patient with a persistent urinary tract infection that required hospitalization for treatment with intravenous antibiotics, with a satisfactory outcome; and 1 patient with a "ball-valve" effect after undergoing PAE, who underwent TURP 3 months later. The "ball-valve" effect represents a critical morphologic condition that is prone to causing a bladder outlet obstruction when coupled with prostate tissue flaccidity after embolization, with the highly mobile and deformable tissue collapsing toward the lumen of the prostatic urethra (18). Interventional radiologists and urologists should consider advising patients with higher IPP grades about this possible complication before performing PAE. Although major complications were infrequent, they occurred in patients with grade III IPPs ($P < .01$). The Fisher Exact test was performed to compare the proportions of complications between the 3 IPP grades. A difference was found between grades II and III ($P < .01$). This result may represent a spurious statistical significance since it is not in agreement with the study by Maron et al (14), who found no statistical difference between the proportion of patients experiencing adverse events in the severe and nonsevere IPP cohorts ($P = .99$). Larger cohort studies are needed to establish whether there is a relationship between complications and a higher IPP grade.

The present study has some limitations regarding its retrospective nature, which comprises intrinsic flaws, notably selection bias. The baseline characteristics, such as PV, PSA, IPSS, and PVR, varied significantly between the groups; however, this was mitigated by the adjusted statistical analyses, controlling their effects. An additional limitation that should be highlighted concerns the morphology of the IPP. It has been shown that an IPP thickness-to-height ratio of 1.3 predicts the occurrence of complications occurring after the procedure for urinary obstruction (18).

Indeed, the more severe baseline LUTS observed in the grade II and III groups strengthens the hypothesis of a nondetrimental effect of large medium lobes since the overall results were comparable between the 3 groups. Finally, the number of patients included was relatively small, especially in the grade I group (n = 19), and the follow-up time was short.

In conclusion, PAE was clinically effective in all 3 IPP groups. Different IPP grades did not influence the PAE efficacy during the 12-month follow-up period, nor were they related to a higher clinical failure rate. Although most complications were considered minor, they were more frequent in patients with higher IPP grades. A significant IPP reduction was observed in patients with higher IPP grades (grades II and III) compared those with grade I IPP. Therefore, PAE can be effectively performed in patients with BPH-related LUTS irrespective of their IPP grades.

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