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## **Four-year impact on voiding and storage symptoms in BPH patients treated with prostatic artery embolization**

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All authors: Conflict of interest: none.

# **Four-year impact on voiding and storage symptoms in BPH patients treated with prostatic artery embolization**

## **Abstract**

### **Purpose**

To study the subscore improvement in the International Prostate Symptom Score (IPSS) after prostatic artery embolization (PAE)

### **Materials and Methods**

A single-center retrospective study was carried out with prospective follow-up from December 2013 to July 2019 in 37 consecutive patients ( $66.0 \pm 8.8$  years) who underwent PAE with both pre-PAE and post-PAE results. IPSS was divided into storage subscore (IPSS-s) and voiding subscore (IPSS-v). The changes of IPSS-s and IPSS-v at 1, 3, 6 and 12-months follow-up, as well as the last follow-up, were compared with baseline. The percentage changes of IPSS-s and IPSS-v and the changes of average ratios of IPSS-s to total IPSS (IPSS-s/IPSS-t) and IPSS-v to IPSS-t (IPSS-v/IPSS-t) were also analyzed.

### **Results**

In the study population consisting of 37 patients, IPSS-t significantly decreased from  $16.5 \pm 7.2$  at baseline to  $8.3 \pm 5.7$  at the last follow-up (4 years) ( $p < 0.0001$ ).

In addition, the changes in voiding symptoms (IPSS-v) were greater than the changes in storage symptoms (IPSS-s) at 1, 3, 6 and 12-months follow-up reaching a statistical

significance at 6 months with a decrease of  $72.9\% \pm 42.4\%$  for IPSS-v and a decrease of  $50.1\% \pm 52.2\%$  for IPSS-s ( $p=.009$ ).

## **Conclusion**

PAE can successfully reduce both IPSS-s and IPSS-v with predominant IPSS-v reduction. The improvement of both subscores is sustained up to 4 years of follow-up.

## Introduction

Prostatic artery embolization (PAE) is a new technique to treat bothersome lower urinary tract symptoms (LUTS) related to benign prostatic hyperplasia (BPH). Its safety and efficacy have been shown in several meta-analysis, in 4 randomized control trials against trans urethral resection of the prostate (TURP) and in a large comparative cohort trial that led to the adoption of PAE for symptomatic BPH by the National Health Service in the United Kingdom [1–9]. It has recently been adopted by the Society of Interventional Radiology (SIR) and several other interventional radiology societies worldwide [10]. For example, a recent large meta-analysis of 1254 patients found an IPSS reduction of 11.6, 12.2, 12.3 and 16.2 points at 1, 3, 6 and 12-months follow-up respectively [9].

The International Prostate Symptom Score (IPSS), is a validated reference method to evaluate the results of medical and surgical treatment for BPH [11], as well as the outcomes of PAE. Consisting of 7 questions, it encompasses all BPH related symptoms, including both voiding (4 questions on incomplete emptying, intermittency, weak stream and straining) and storage symptoms (3 questions on frequency, urgency and nocturia) as detailed in Table 1 [11].

Despite a large quantity of published evidence and the fact that PAE is now practiced worldwide, the mechanism of action for PAE is still incompletely understood, and it is of interest to assess whether it can reduce both the obstructive and bladder overactivity related symptoms. Various medical and surgical management techniques have been shown to reduce the voiding and storage symptoms of bothersome LUTS related to BPH [12–14]. If PAE could also improve both aspects of the disease, it would add evidence to support that PAE could be proposed as an attractive treatment option in selected patients. We undertook this prospective data

collection study based on a retrospective patient cohort to address this question.

## **Materials and Methods**

### Patient population

This retrospective study with prospective follow-up was carried out as a single-center study. From December 2013 to June 2015, 49 consecutive patients underwent PAE for symptomatic BPH, either because they refused surgery or because they had a contraindication for surgery. Patients were referred for PAE following consultations with both the attending urologist and interventional radiologists, and received a full explanation of the results and limitations of PAE including complications. All patients gave written informed consent for the procedure.

This study was approved by the Institutional Review Board of Comité de Protection des Personnes Ile de France II. The primary endpoints were the changes in IPSS and other clinical results after PAE. The secondary points were the correlations between IPSS changes and uroflowmetry results after PAE.

### PAE technique

The PAE procedures were performed by 3 interventional radiologists with experience of 5, 15 and 25 years in interventional radiology. All procedures were performed under local anesthesia via a right trans-femoral approach as previously described [15].

Using appropriate projection and image analysis, a 5Fr vertebral catheter was used to catheterize the left internal iliac artery and the left prostatic artery was further catheterized with a microcatheter (mostly 2.0Fr Progreate<sup>®</sup> microcatheter (Terumo, Tokyo, Japan)) and a 0.014In. Fathom<sup>®</sup> micro guidewire (Boston Scientifics, Natick,

Massachusetts, USA). Cone beam CT was performed to ensure that there was no unwanted collateral embolization.

Embolization was performed with 300–500  $\mu\text{m}$  trisacryl microspheres (Embosphere®, Merit Medical, Salt Lake City, USA), with total occlusion as the endpoint. We advanced the microcatheter into the central gland for distal embolization [4; 15]. We aimed at embolizing both the left and right prostatic artery. If it was impossible to catheterize one of the prostatic arteries, unilateral PAE was performed. The details of the PAE procedure has been well described in previous publications [15], and a summary of the PAE procedure for this cohort is listed in Table 2.

#### International Prostate Symptom Score (IPSS)

The French validated version of IPSS was used [16; 17]. The IPSS score was obtained before and after PAE procedures at 1, 3 and 6-months follow-up. During each consultation, the patient received the IPSS questionnaire in hand and completed it before entering the room for the consultation. In a few cases, the IPSS was obtained by mail or email. The changes in each single question of the IPSS were analyzed and the changes of voiding symptoms (IPSS-v) and storage symptoms (IPSS-s) were evaluated as well.

IPSS included 4 questions related to voiding symptoms (defined as IPSS-v) and 3 questions related to storage symptoms (defined as IPSS-s). The total IPSS was the sum of IPSS-v and IPSS-s and was defined as IPSS-t. The following percentages were calculated to evaluate their changes after PAE:  $((\text{Post-PAE IPSS-s} - \text{pre-PAE IPSS-s})/\text{pre-PAE IPSS-s})$  and  $((\text{post-PAE IPSS-v} - \text{pre-PAE IPSS-v})/\text{pre-PAE IPSS-v})$ .

The ratios of the storage subscore to IPSS-t and voiding subscore to IPSS-t before and after PAE were also calculated as previously used in studies evaluating the

medical treatment [14]. The ratio names were abbreviated as (IPSS-s/IPSS-t) and (IPSS-v/IPSS-t).

#### Additional clinical evaluation

The questionnaire for Quality of Life (QoL) before PAE and at 1, 3, 6 and 12-months follow-up were obtained and the prostate volume (PV) by either US or MRI was recorded. Uroflowmetry (maximum urinary flow rate (Q<sub>max</sub>) and post-void residual urine volume (PVR)) were recorded before the procedure and at 3-months follow-up.

This retrospective study followed the STROBE guidelines (Figure 1). Among the 49 patients who underwent PAE for bothersome LUTS between December 2013 and June 2015, 1 patient was excluded because there was no IPSS questionnaire before undergoing PAE and 11 patients were excluded because they underwent surgery between 9 and 36 months after PAE.

Our study population therefore, comprised of 37 patients ( $66.0 \pm 8.8$  years) having more than 3-months follow-up after PAE and available IPSS questionnaires, in the absence of surgery. The baseline demographic descriptions of these 37 patients are summarized at Table 2. There were 30 patients who had more than 12-months follow-up (mean:  $52.1 \pm 10.2$  months). This cohort had overlap with patient groups in 3 previous publications (in 2015 and 2016) [15; 18; 19].

#### Statistical analysis

A paired-sample Wilcoxon signed-rank test was used to compare the results of the changes in IPSS-t, IPSS-v, IPSS-s, QoL, Q<sub>max</sub>, PVR and PV between the baseline and 1, 3, 6 and 12 months, as well as the last available follow-up after PAE (the relative changes were also computed). Correlations between the changes in IPSS at 3



months and uroflowmetry results were tested using Spearman correlation coefficient (*r*). For all the endpoints, no replacement of missing data was performed.

Data are expressed as mean  $\pm$  standard deviation (SD). All the statistical tests were carried out with SAS software (version 9.4; SAS Institute, Cary, North Carolina). The significance of the statistical tests was assessed at the  $p < 0.05$  level.

## Results

We found a significant reduction in the average IPSS (IPSS-t) score in our 37 patient group up to the last follow-up. It significantly decreased from  $16.5 \pm 7.2$  at baseline to  $6.4 \pm 6.4$  at 3-months ( $p < 0.0001$ );  $5.5 \pm 4.4$  at 6-months ( $p < 0.0001$ );  $3.9 \pm 4.1$  at 12-months ( $p = 0.001$ ) and  $8.3 \pm 5.7$  at the last follow-up (48 months) ( $p < 0.0001$ ).

In addition, both the IPSS-s and the IPSS-v decreased significantly when compared to baseline, with the greatest reduction occurring at the 12-month follow-up (Table 3). The changes in voiding symptoms (IPSS-v) were greater than the changes in storage symptoms (IPSS-s) at 1, 3, 6 and 12-months follow-up (Figure 3). It reached statistical significance at 6-months with a decrease of  $72.9\% \pm 42.4\%$  for IPSS-v and a decrease of  $50.1\% \pm 52.2\%$  for IPSS-s ( $p = 0.009$ ). Moreover, the IPSS-v changes correlated with IPSS-t changes at 3, 6 and 12-months follow-up and the last follow-up ( $r = 0.842, 0.833, 0.675$  and  $0.915$ , respectively;  $p < 0.0001, p < 0.0001, p = 0.008$  and  $p < 0.0001$ ).

The average ratio of IPSS-v/IPSS-t (0.6) was initially higher than the ratio of IPSS-s/IPSS-t (0.4), similar to the results of the nature contributions in storage and voiding symptoms of the total IPSS score. The ratios of IPSS- IPSS-v/IPSS-t decreased significantly at 3-months follow-up ( $0.50 \pm 0.25$ ,  $p=0.005$ ), 6-months follow-up ( $0.39 \pm 0.31$ ,  $p=0.002$ ) and 12-months follow-up ( $0.33 \pm 0.26$ ,  $p=0.022$ ) as compared with baseline ( $0.57 \pm 0.16$ ). On the contrary, the ratios of IPSS-s/IPSS-t increased at 3, 6 and 12-months (Figure 4). There was statistical significance between the changes of IPSS-v/IPSS-t and IPSS-s/IPSS-t at 3-months follow-up ( $-0.17 \pm 0.29$  vs.  $0.17 \pm 0.29$ ;  $p=0.002$ ), 6-months follow-up ( $-0.21 \pm 0.19$  vs.  $0.22 \pm 0.19$ ;  $p=0.008$ ) and 12-months follow-up ( $-0.22 \pm 0.24$  vs.  $0.23 \pm 0.24$ ;  $p=0.025$ ). Therefore, the above results revealed that improvements in voiding symptoms were higher than storage symptoms from 3 to 12-months follow-up. However, at the last follow-up, the advantages of the voiding subscore reduction was no longer seen.

The QoL also revealed significant reduction from baseline ( $4.8 \pm 1.2$ ) at 1-month ( $3.7 \pm 1.9$ ;  $p=0.02$ ), 3-months ( $2.8 \pm 1.7$ ;  $p<0.0001$ ) and 6-months ( $2.6 \pm 1.5$ ;  $p=0.0003$ ) follow-up. The PV and uroflowmetry results at 3-months follow-up showed a significant reduction of PV from  $91.6 \pm 37.0$  ml to  $67.8 \pm 29.6$  ml ( $p<0.0001$ ), a significant increase of Qmax from  $8.8 \pm 3.6$  ml/s to  $17.7 \pm 13.3$  ml/s ( $p=0.0002$ ) and a significant reduction of PVR from  $86.5 \pm 102.6$  ml to  $51.9 \pm 94.1$  ml ( $p=0.0035$ ).

There was significant improvement in uroflowmetry results at 3-months follow-up. Furthermore, there was a tendency toward a significant correlation between IPSS-t and IPSS-v changes and an increase in Qmax was found (Table 4).

## Discussion

### International Prostate Symptom Score (IPSS)

The development of the International Prostate Symptom Score (IPSS) followed the need for outcome evaluation and a robust method for allowing the comparison of treatment effectiveness among different treatment choices. In 1992, the American Urologic Association designed and validated an index (American Urological Association Symptom Index) for symptom measurements, and the index is now accepted worldwide as IPSS [11]. The IPSS consists of 7 questions and has been used to evaluate the outcome of basically all treatments for BPH, including drugs and surgery. It is reproducible, reliable and validated. The IPSS is internally consistent (Cronbach's  $\alpha=0.86$ ) and the 1-week test-retest reliability is high ( $r=0.92$ ) [11].

It is accepted that the 7 questions of IPSS can be divided into 3 questions related to storage symptoms (frequency, urgency and nocturia) and 4 questions related to voiding symptoms (incomplete emptying, intermittency, weak stream and straining). In prevalence studies, both storage and voiding symptoms increase with age and the prevalence of storage symptoms is higher than voiding symptoms among men aged  $\geq 40$  years [20].

### IPSS subscores in evaluating medication and surgery

In the effectiveness study of Tadalafil, medications were shown to significantly reduce both storage and voiding symptoms and the ratio of storage symptoms to total IPSS (IPSS-s/IPSS-t) remained constant between baseline and 12 weeks [14]. On the other hand, surgical treatment of BPH, such as suprapubic prostatectomy and transurethral resection of the prostate (TURP), mainly reduced voiding symptoms while the storage symptoms were reduced to a lesser degree [12].

Clinical success after TURP may be due to reducing the bladder outlet obstruction, as well as reducing detrusor/bladder overactivity [21–23]. The conversion from unstable detrusor to stable detrusor after surgery was found in 62% of cases [22].

#### IPSS subscores in this study and comparison with surgery

In this cohort, a 4-year follow-up of PAE was carried out in 37 patients and the results revealed that symptom improvement was seen at 12-months follow-up and for a longer duration of more than 12-months. It was confirmed that IPSS-t, IPSS-v and IPSS-s were reduced after PAE in the long-term follow-up. In previous publish, few conducted the long-term follow-up for more than 2 years [24; 25]. In a series of 630 patients, 328 subjects had complete 36-months follow-up. It was found a mean IPSS changes of  $12.1 \pm 8.6$  points [24]. Our study provided clinical evidence of LUTS improvement for more than 4 years after PAE.

The mean of IPSS-v in this study was higher than IPSS-s at baseline, reflecting symptoms resulting from an enlarged prostate gland. After PAE, both subscores were reduced with a predominant reduction in voiding symptoms (IPSS-v). An almost 80% reduction of voiding subscore was observed at 12-months follow-up. The improvement of voiding symptoms is related to the improvement of the bladder outlet obstruction from a decreased prostate volume and a release of the pressure on the prostatic urethra. A previous study by Antunes et al. confirmed that bladder outlet obstruction (BOO) was reduced by PAE [26]. They evaluated uroflowmetry parameter changes before and after PAE in patients with acute urinary retention, and they also utilized the bladder outlet obstruction index (BOOI) to evaluate. All the patients had an obstructed condition (BOOI >40) before PAE and 30% of them became totally unobstructed (BOOI <20) after PAE. Apart from voiding symptoms, our results also

confirmed the improvement of storage symptoms, although the improvement was at lesser degree. This suggests that the mechanism of symptomatic improvement after PAE is similar to that following TURP, reducing both voiding and storage symptoms. In a previous study of TURP, the IPSS-s decreased from  $6.7 \pm 3.6$  to  $3.1 \pm 2.5$  and the IPSS-v decreased from  $9.7 \pm 5.0$  to  $3.4 \pm 3.0$  at 6-months follow-up [12]. The results were similar to our study in that IPSS-s decreased from  $6.8 \pm 3.4$  to  $3.2 \pm 2.4$  and the IPSS-v decreased from  $9.7 \pm 5.0$  to  $2.3 \pm 2.6$  at 6-months follow-up.

High-power photo laser photoselective vaporization prostatectomy (PVP) is an alternative to TURP with a reduced risk of perioperative hemorrhage. For patients with intravesical prostate protrusion, IPSS-s decreased from  $8.0 \pm 3.6$  to  $6.2 \pm 2.8$  and IPSS-v decreased from  $14.8 \pm 4.1$  to  $8.6 \pm 3.3$  at 6-months follow-up after PVP [13]. The reduction was also similar to TURP. From the experience of TURP and PVP, it is suggested that the improvement of IPSS-s and IPSS-v is similar between surgery and PAE.

Considering each question of the IPSS, point reductions were found in both voiding and storage questions after PAE, with a greater reduction in voiding questions. Among the 7 questions, straining (Q6, a typical voiding symptom) showed the best response to PAE at 6-months follow-up. On the contrary, frequency (Q2, a typical storage symptom) showed the worst response to PAE at 6-months follow-up (Figure 2). A previous study showed that patients with unstable bladder had significantly higher scores in frequency, urgency and nocturia than those with a stable bladder [27]. The author also suggested that high contractility may result in a lower score of week stream (Q5) but a higher score of urgency (Q4). Therefore, it is suggested that although PAE can reduce both voiding and storage symptoms, the symptoms of unstable bladder with high contractility had the poorest response.

### Uroflowmetry results after PAE

In this cohort, a significant improvement in maximum urine flow rate at 3-months follow-up was found, confirming a good response in PAE to bladder outlet obstruction in both subjective and objective measurements. Using Spearman's correlation, the subjective and objective results were not significantly correlated to each other. This reflects that the subjective symptom improvement that satisfied the patients may have been greater than the objective improvement.

There are several limitations to this study. First, the patient number was small and the study had no control arm. Second, limited data for follow-up uroflowmetry study was obtained.

In conclusion, our study confirms that PAE is able to improve both voiding and storage symptoms for up to 4 years in patients suffering from bothersome LUTS related to BPH.

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## **Tables legends**

Table 1. The questionnaires of IPSS and the storage and voiding subscores

Table 2. Baseline characteristics

Table 3. Average IPSS-s and IPSS-v at baseline, 1, 3, 6, 12-months follow-up and at last follow-up.

Table 4. Correlations between uroflowmetry results and IPSS changes at 3-months follow-up

## Figure legends

Figure 1. The flow chart of study enrollment according to STROBE guideline.

Figure 2. The score changes of each question at, 1, 3, 6, 12-months follow-up and at last follow-up. The changes of each question were compared with baseline.

Figure 3. The percentage changes of IPSS-v and IPSS-s comparing with baseline.

Figure 4. Average ratio of IPSS-v/IPSS-t and IPSS-s/IPSS-t from baseline to last follow-up.

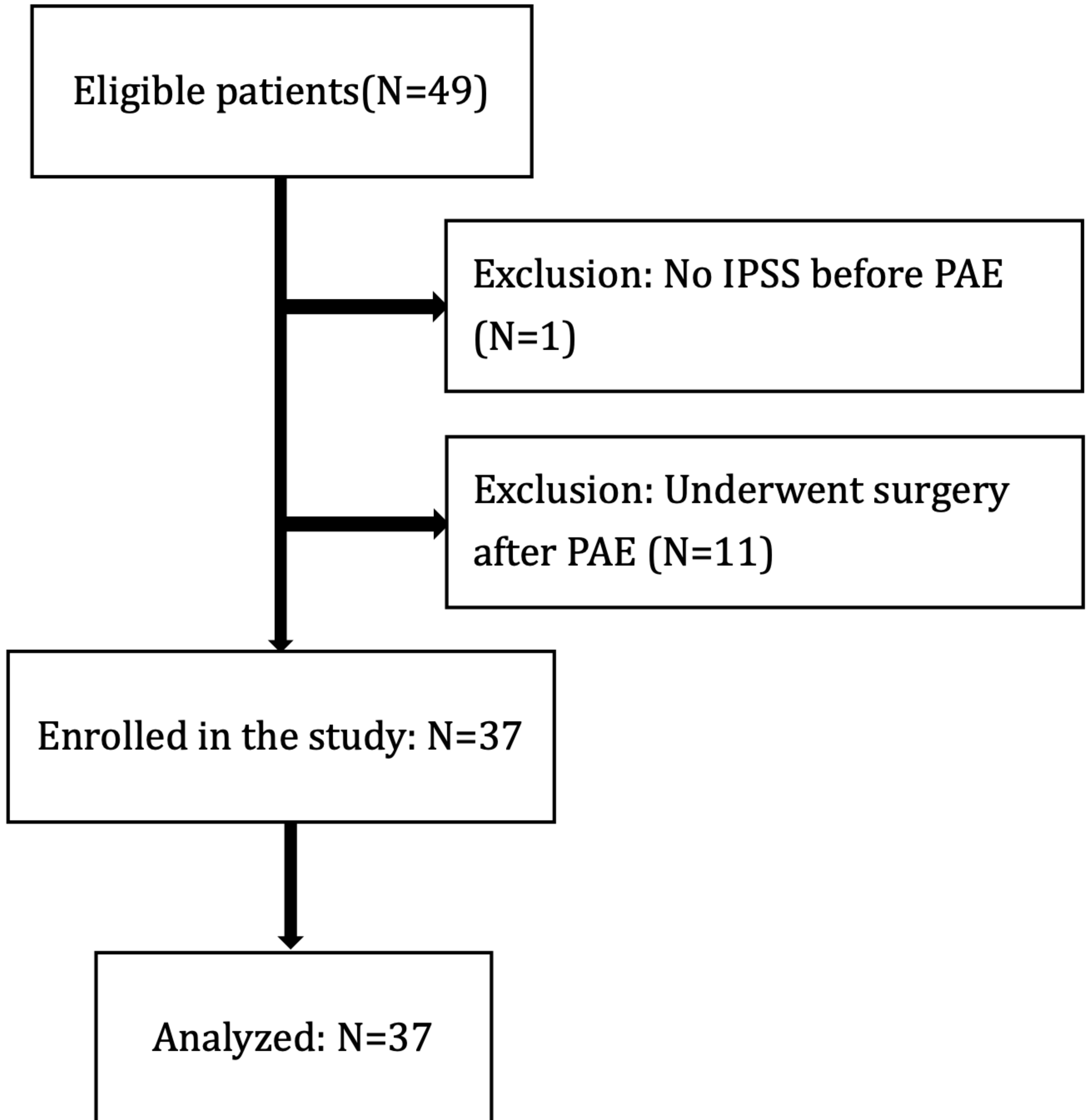
Eligible patients(N=49)

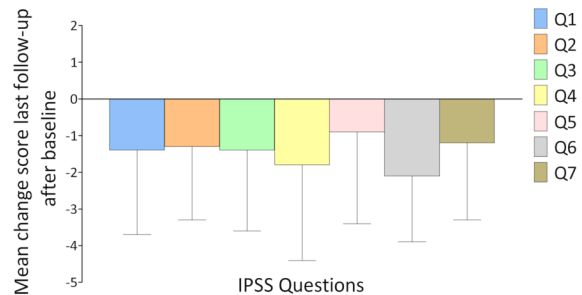
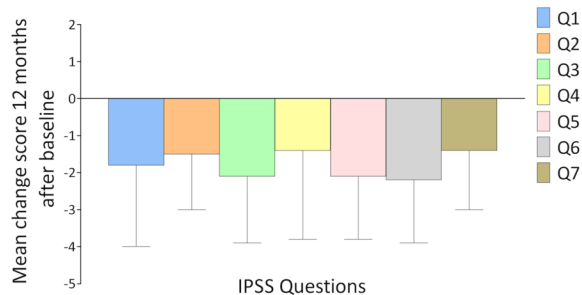
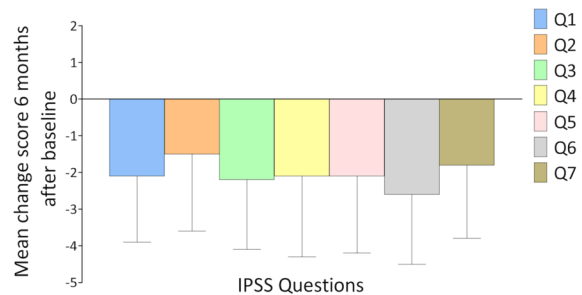
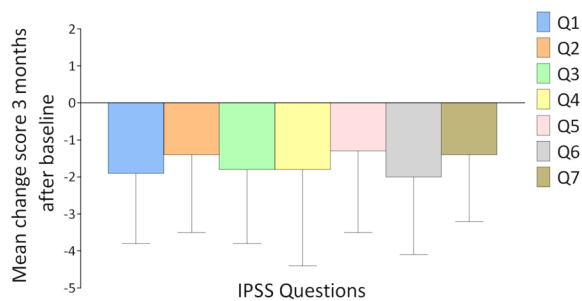
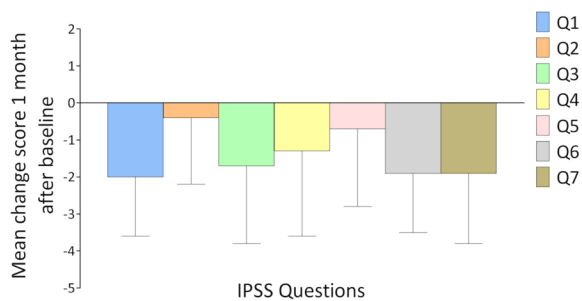
Exclusion: No IPSS before PAE  
(N=1)

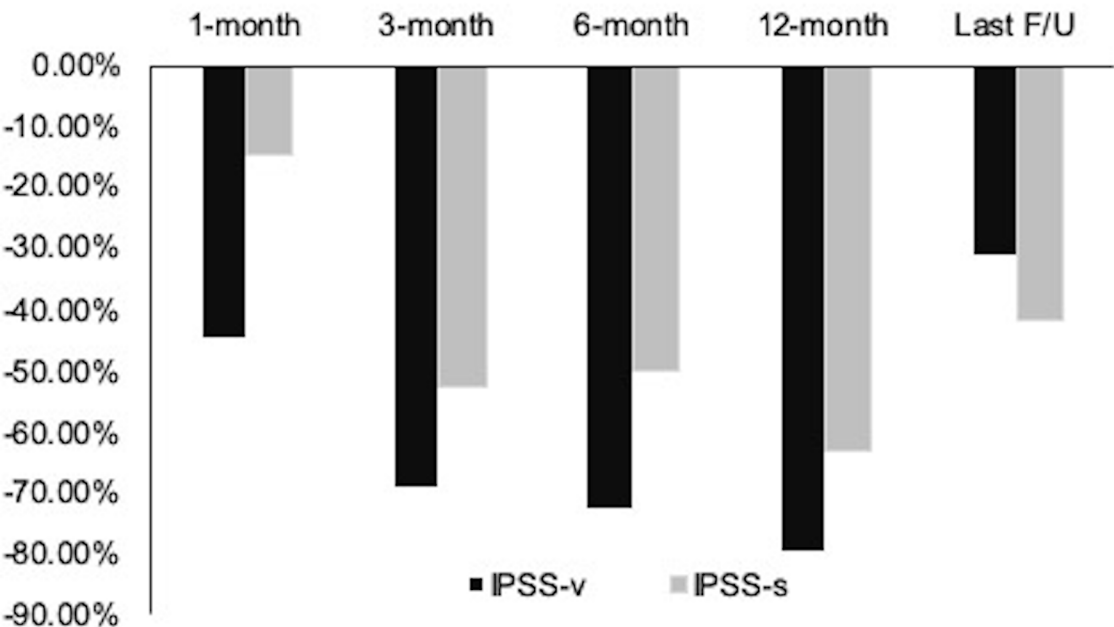
Exclusion: Underwent surgery  
after PAE (N=11)

Enrolled in the study: N=37

Analyzed: N=37









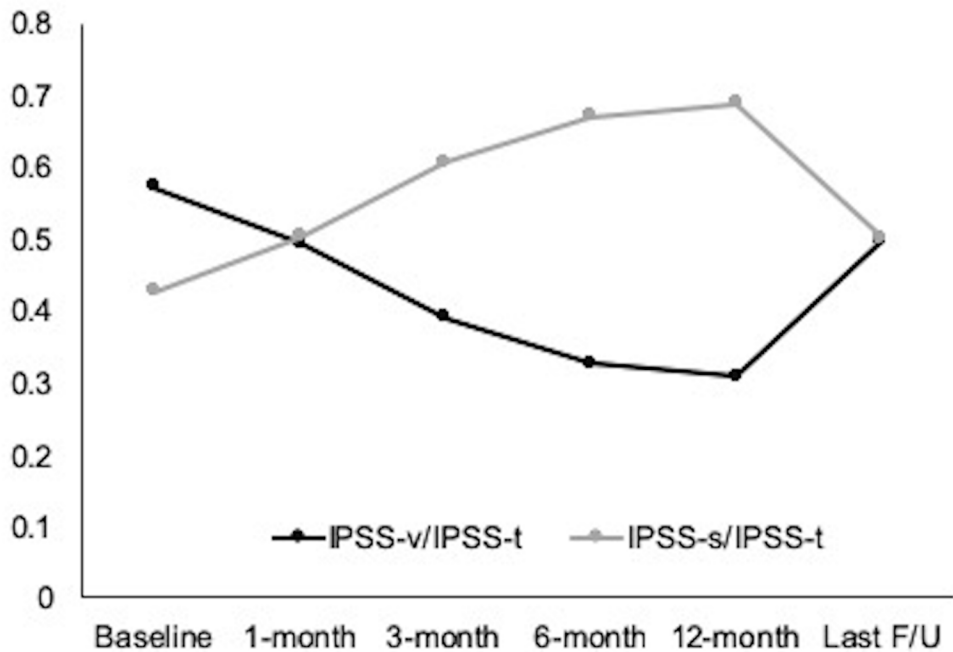


Table 1. The questionnaires of IPSS and the storage and voiding subscores

Questions	Descriptions	Storage/Voiding subscores
Q1. How often have you had the sensation of not emptying your bladder?	Incomplete emptying	Voiding
Q2. How often have you had to urinate less than every two hours?	Frequency	Storage
Q3. How often have you found you stopped and started again several times when you urinated?	Intermittency	Voiding
Q4. How often have you found it difficult to postpone urination?	Urgency	Storage
Q5. How often have you had a weak urinary stream?	Weak stream	Voiding
Q6. How often have you had to strain to start urination	Straining	Voiding
Q7. How many times did you typically get up at night to urinate?	Nocturia	Storage

P.S. All the questions are scored according to the fillings in the past month subjectively. The scores of Q1–Q6 are based on severity: Not at all (0), less than 1 in 5 times (1), less than half the time (2), about half the time (3), more than half the time (4) and almost always (5). Q7 is scored in frequency: None (0), 1 time (1), 2 times (2), 3 times (3), 4 times (4) and 5 times (5).

Table 2. Baseline characteristics

Descriptions	Number or Mean $\pm$ SD
Patient (N=37)	
Age	66.0 $\pm$ 8.8
PV (cm <sup>3</sup> )	91.6 $\pm$ 36.9
Qmax (ml/s)	8.8 $\pm$ 3.6
PVR (ml)	86.5 $\pm$ 102.6
IPSS-t	16.5 $\pm$ 7.2
IPSS-s	6.8 $\pm$ 3.4
IPSS-v	9.7 $\pm$ 5.0
QoL	5.8 $\pm$ 1.2
PAE procedure	
Unilateral/Bilateral PAE	2/35
Procedural time (min)	175.5 $\pm$ 38.4
Fluoroscopic time (min)	51.1 $\pm$ 13.7
Dose-area product ( $\mu$ Gy.m <sup>2</sup> )	32764.7 $\pm$ 14899.3

Table 3. Average IPSS-s and IPSS-v at baseline, 1, 3, 6, 12-months follow-up and at last follow-up.

Descriptions	N=	Mean $\pm$ SD	<i>p</i> value <sup>&amp;</sup>
IPSS-s			
Baseline	37	6.8 $\pm$ 3.4	
1-month	7	5.4 $\pm$ 4.1	0.406
3-months	33	3.1 $\pm$ 3.0	< 0.0001
6-months	17	3.2 $\pm$ 2.4	0.0009
12-months	14	2.6 $\pm$ 2.9	0.001
Last follow-up	30	3.5 $\pm$ 2.7	< 0.0001
IPSS-v			
Baseline	37	9.7 $\pm$ 5.0	
1-month	7	5.7 $\pm$ 6.1	0.141
3-months	33	3.3 $\pm$ 4.0	< 0.0001
6-months	17	2.3 $\pm$ 2.6	< 0.0001
12-months	14	1.3 $\pm$ 1.9	0.0004
Last follow-up	30	4.7 $\pm$ 4.3	< 0.0001

<sup>&</sup> The results were compared with baseline.



Table 4. Correlations between uroflowmetry results and IPSS changes at 3-months follow-up

Parameters	N=	r=	<i>p</i> value
IPSS-t change vs. Qmax change	21	r = -0.39	0.0792
IPSS-s change vs. Qmax change	21	r = -0.29	0.2035
IPSS-v change vs. Qmax change	21	r = -0.40	0.0703
IPSS-t change vs. PVR change	15	r = 0.14	0.6235
IPSS-s change vs. PVR change	15	r = -0.01	0.9746
IPSS-v change vs. PVR change	15	r = 0.22	0.4277