

Operator Learning Curve for Prostatic Artery Embolization and Its Impact on Outcomes in 296 Patients

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Abstract

Purpose To define operator learning curve inflection points for prostatic artery embolization (PAE) and their impact on technical efficiency, clinical outcomes, and adverse events.

Materials and Methods Between May 2013 and May 2021, 296 consecutive patients with moderate-to-severe lower urinary tract symptoms, urinary retention, or gross hematuria from benign prostatic hyperplasia underwent PAE by an interventional radiologist without prior PAE-specific experience. Operator learning curves plotted procedure time, fluoroscopy time, contrast volume, and embolic endpoint data against sequential procedure number. Multiple regression analysis evaluated for improvements in these parameters, with segmented linear regression to detect learning curve inflection points. Linear and logistic regression evaluated for learning curve impacts on 6-month clinical outcomes and 90-day adverse events.

Results No baseline patient characteristic varied over the series apart from decreasing pre-procedural gland volume ($P < 0.01$). Multiple regression analysis demonstrated experience-dependent improvements in procedure time, fluoroscopy time, and contrast volume ($P < 0.01$), with corresponding learning curve inflection points at 76 ($P < 0.01$), 78 ($P < 0.01$), and 73 ($P = 0.10$) procedures. Embolic endpoints did not vary with experience ($P > 0.05$). Post-procedure reductions in International Prostate Symptom Score (21.5 ± 6.2 to 6.7 ± 4.7), Quality of Life score (4.5 ± 1.2 to 1.3 ± 1.2), post-void residual (190 ± 203 to 97 ± 148 mL), and gland volume (142 ± 97 to 76 ± 47 mL) were substantial ($P < 0.01$) but did not vary with experience ($P > 0.05$), nor did adverse event frequency/severity ($P > 0.05$).

Conclusion Operator technical efficiency plateaued after 73–78 PAE procedures. Clinical improvements were substantial and adverse event frequency/severity low, and neither varied with experience. Operators without prior PAE-specific experience may perform PAE safely and effectively from the outset.

Level of Evidence Level 2b, Cohort Study.

Keywords Prostatic artery embolization · Learning curve · Benign prostatic hyperplasia · Lower urinary tract symptoms · Urinary retention · Gross hematuria

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Abbreviations

| | |
|------|--------------------------------------|
| PAE | Prostatic artery embolization |
| LUTS | Lower urinary tract symptoms |
| BPH | Benign prostatic hyperplasia |
| CCI | Charlson comorbidity index |
| BMI | Body mass index |
| IPSS | International prostate symptom score |

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|-----|-----------------------|
| QoL | Quality of life score |
| PGV | Prostate gland volume |
| PVR | Post-void residual |

Introduction

Prostatic artery embolization (PAE) is a safe and effective treatment for lower urinary tract symptoms (LUTS), urinary retention, and gross hematuria caused by benign prostatic hyperplasia (BPH) [1, 2]. The United Kingdom's National Institute for Health and Care Excellence and the European Association of Urology have endorsed PAE as a treatment for symptomatic BPH; however, the American Urological Association has yet to accept PAE into its BPH management guidelines [3–5]. Although these guidelines reference the existing level of evidence for PAE as the primary limitation, they also cite PAE's technical challenge as an obstacle to its safe practice and wider acceptance.

PAE is indeed a technically demanding procedure due to complex and challenging pelvic arterial anatomy, and recognition of proper embolization endpoints is critical [2]. However, these challenges are common among standard embolization procedures that treat other conditions including gastrointestinal hemorrhage, hepatocellular carcinoma, and vascular malformations. Indeed, the number of high-volume PAE centers is steadily expanding worldwide, with no reports yet to support concern for prohibitive technical challenge with PAE.

Nevertheless, characterization of operator learning curves for PAE will be important to characterize how much experience is needed to develop adequate technique and obtain standard-of-care outcomes. Such operator learning curves are described in the surgical literature and have been reported for angiographic procedures including uterine artery embolization, adrenal venous sampling, and hepatic artery embolization, but not for PAE [6–10]. This study therefore seeks to quantify the PAE learning curve for a single operator from a high-volume center, and how it impacts technical efficiency, clinical outcomes, and adverse events for PAE.

Methods

Patients

Data were retrospectively reviewed under an institutional review board-approved protocol. Three hundred and seven consecutive patients (age = 74.6 ± 8.6 y, Charlson comorbidity index [CCI] = 4.0 ± 2.0 , body mass index [BMI] = 27.5 ± 4.6) treated with PAE at a single center from May 2013 through May 2021 were evaluated. All patients treated had LUTS (International Prostate Symptom Score [IPSS] > 12 and Quality of Life score [QoL] > 2), urinary retention, or gross hematuria of prostatic origin. Patients were excluded if no embolization was performed because of hazardous vascular shunts or lack of patent prostatic arteries ($n = 6$), or if prior embolization had been performed ($n = 5$). Hence, 296 patients had procedures analyzed for operator learning curves pertaining to procedural parameters. One hundred and eighty-seven out of two hundred and ninety-six (63%) patients were treated for LUTS (prostate gland volume [PGV] = 128 ± 77 mL, IPSS = 21.5 ± 6.2 , QoL = 4.5 ± 1.2) with 130/187 (70%) having 6-month follow-up data available. Eighty-five out of two hundred and ninety-six (29%) patients were treated for urinary retention (PGV = 139 ± 76 mL) with 78/85 (92%) having 6-month follow-up data available. Twenty-four out of two hundred and ninety-six (8%) patients were treated for severe gross hematuria (PGV = 310 ± 185 mL). Additionally, 92 patients from the LUTS and retention groups also had concurrent episodic gross prostatic hematuria, for a total of 116/296 (39%) patients who underwent PAE in the setting of gross prostatic hematuria. Of these, 90/116 (78%) patients had 6-month follow-up data available. Patients with bilateral prostatic arteries identified that received only unilateral or no embolization were considered technical failures.

Operator Skill Acquisition

This study's operator was a fellowship-trained interventional radiologist who completed all medical training at tertiary teaching hospitals in the USA, including 23 months of Interventional Radiology within a DIRECT Pathway training program, followed by board certification and a Certificate of Added Qualification from the American Board of Radiology. The operator performed over 100 microcatheter-

based non-PAE embolization procedures during training, and another 70 such procedures over 21 months as an attending interventional radiologist at a tertiary teaching hospital. Then in May 2013, the operator began performing PAE with no prior PAE-specific training or supervision. After performing 40 PAE procedures, the operator observed 2 PAE procedures performed by an interventional radiologist mentor who had accrued over 150 PAE procedures.

Procedure

All procedures were performed by a single senior operator with trainees assisting [11–14]. Femoral or radial arterial access was obtained using a 6F sheath. Radial access was selected per patient preference in under 10% of procedures, distributed randomly over the series. The bilateral internal iliac arteries were sequentially selected with a 5F catheter, and the prostatic arteries were sub-selected with a micro-catheter (2.4F Maestro or 2.4F SwiftNinja, Merit Medical, South Jordan, UT; 2.2F Sniper, Embolx, Sunnyvale, CA). Cone-beam computed tomography was performed as necessary to further delineate arterial anatomy. Any non-target vessels were either bypassed or protectively coil-embolized (Tornado, Cook Medical, Bloomington, IN or Concerto, Medtronic, Minneapolis, MN). Each vial of trisacryl gelatin spherical microspheres (Embosphere, Merit Medical, South Jordan, UT) contained 7 mL of saline and 2 mL of microspheres, which were combined with 11 mL of Omnipaque-300 (GE Healthcare, Marlborough, MA). After injecting 200 µg nitroglycerin into each prostatic artery to minimize vasospasm, embolization to stasis was achieved with 100–300 µm or 300–500 µm microspheres. Subsequently, more distal embolization was performed whenever possible [15]. 300–500 µm microspheres were used in under 10% of procedures, distributed randomly over the series, when shunting to non-target vessels was observed. Arterial access was subsequently removed, and hemostasis obtained with a 6F Angio-Seal device or a TR Band (Terumo Medical, Somerset, NJ). No substantial modifications in technique were made after the 2-procedure observation with the more experienced PAE provider. The balloon occlusion micro-catheter became available after 55 procedures and was used for almost all procedures thereafter.

Data Collection

To construct procedural operator learning curves, procedure time, fluoroscopy time, administered contrast volume, number of vessels protectively coiled, volume of embolic particle solution delivered, volume of embolic particle

solution delivered normalized to PGV, and technical success/failure were recorded for each procedure. Variations over the series in imaging equipment age and radiation dose reduction capabilities precluded evaluation of radiation dose data for learning curve purposes. To examine for effects of operator experience on clinical outcomes, follow-up data were collected at 6-months post-procedure to allow for complete clinical responses or failures, while avoiding longer-term confounding effects such as progressive bladder function deterioration [16–18]. Relative improvements in IPSS and QoL were tabulated for LUTS patients, as were relative trans-abdominal ultrasound post-void residual (PVR) improvements in LUTS patients with pre-procedural PVRs > 200 mL. Voiding trial results were tabulated for retention patients, and gross hematuria treatment response for hematuria patients. Relative changes in PGVs were measured with trans-abdominal ultrasound. 90-day adverse events were tabulated using Clavien–Dindo classification as previously adapted to PAE [19, 20].

Data Analysis

Linear regression (for age, CCI, BMI, IPSS, QoL, PGV, and PVR) and logistic regression (for presence of indwelling catheter or gross hematuria) were used to detect variations in baseline patient characteristics over the series. Operator learning curves were then constructed by plotting data for each procedural parameter (procedure time, fluoroscopy time, contrast volume, number of vessels coiled, embolic volume, and normalized embolic volume) against sequential procedure number. Multiple regression analysis evaluated for any improvements in these parameters, while accounting for any confounding variations in baseline patient characteristics over the series. Piecewise linear segmented regression was used to characterize procedural parameter learning curve inflection points. Regression was performed with optimal breakpoint selection, using a single breakpoint for each parameter as a function of sequential procedure number [21]. Linear regression (for relative improvements in IPSS, QoL, and PVR) and logistic regression (for voiding trial success or gross hematuria resolution) were used to analyze for variations in 6-month clinical outcomes over the series. Trends in technical failure incidence and adverse event frequency/severity were analyzed using ordinal logistic regression. All statistical analyses were performed using R (R Foundation for Statistical Computing, Version 4.0.0) with Stats (4.0.0), MASS (7.3–51.5), and Segmented (1.6-0) packages. *P* values < 0.05 were considered significant.

Results

Patient Cohort Characteristics

Over the case series, there were no variations in patient age at time of PAE, patient CCI, patient BMI, pre-procedure IPSS for LUTS patients, or the presence of an indwelling urinary catheter or gross hematuria ($P > 0.05$ for all). Baseline QoL increased slightly over the series ($P = 0.04$), but this was not deemed clinically meaningful and so was not factored into further analyses. Pre-procedural PGV decreased over the series ($P < 0.01$) (Fig. 1) and was therefore evaluated as a possible confounder in subsequent analyses.

Technical Outcomes

Multiple regression analysis showed that procedure time, fluoroscopy time, and contrast volume all decreased with increasing operator experience (Fig. 2), and independently of the decrease in PGV observed over the series ($P < 0.01$ for all). Learning curve analysis of these parameters demonstrated significant regression for procedure time with inflection point at 76 procedures (adjusted $R^2 = 0.346$, initial slope = -2.07 , final slope = 0.10 , $P < 0.01$) and for fluoroscopy time with inflection point at 78 procedures (adjusted $R^2 = 0.22$, initial slope = -0.55 , final slope = 0.02 , $P < 0.01$). Contrast volume showed a similar trend with inflection point at 73 procedures, but this was not significant (adjusted $R^2 = 0.07$, initial slope = -0.37 , final slope = -0.09 , $P = 0.10$) (Fig. 2). None of these curves demonstrated any significant variation beyond their inflection points. Multiple regression analysis did not show any variation in embolic volume or normalized embolic

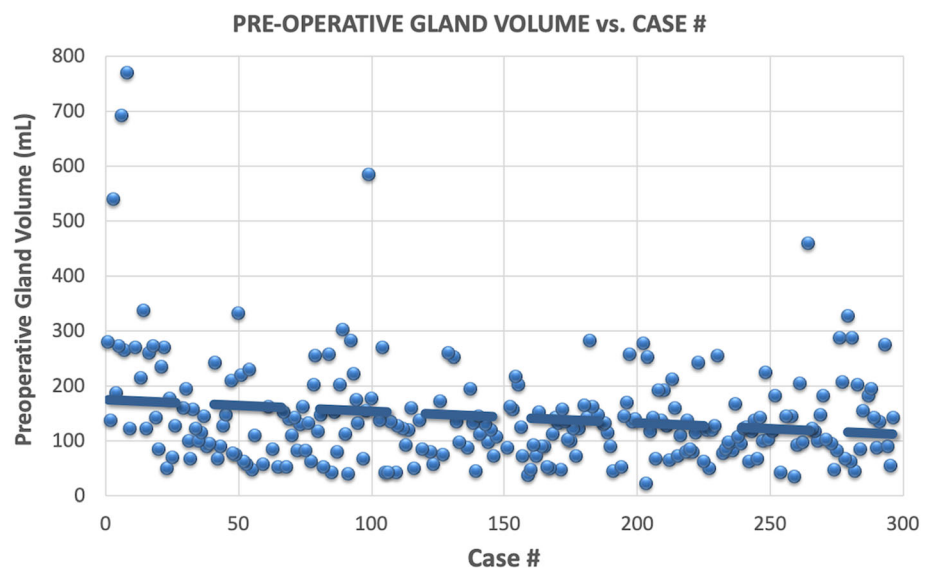
volume related to increasing operator experience (Fig. 3), nor was there any variation in number of vessels coiled. There were 10 (3%) technical failures, consisting of 5 unilateral and 5 bilateral embolization failures, with logistic regression showing no variation in incidence over the series.

Clinical Outcomes

At 6-month post-procedure, IPSS improved from 21.5 ± 6.2 to 6.7 ± 4.7 ($P < 0.01$) with mean decrease of $66\% \pm 24\%$. QoL improved from 4.5 ± 1.2 to 1.3 ± 1.2 ($P < 0.01$) with mean decrease of $69\% \pm 30\%$ (Fig. 4). PVR improved from 190 ± 203 to 97 ± 148 mL in all LUTS patients and from 438 ± 220 to 193 ± 233 mL in LUTS patients with pre-procedural PVR > 200 mL ($P < 0.01$ for both) (Fig. 5). Six-month PVR improvements trended to lower values later in the case series, but this was not significant ($P = 0.07$). 59/78 (76%) retention patients passed voiding trials by 6 months. Eighty-seven out of ninety (97%) gross hematuria patients remained free of gross hematuria at 6 months. There was no variation in distribution of voiding trial failures or gross hematuria recurrences over the case series ($P > 0.05$ for both). For all patients, PGV was smaller 6 months after embolization (142 ± 97 mL vs. 76 ± 47 mL, $P < 0.01$), with no relationship to operator experience observed ($P > 0.05$) (Fig. 5).

Regarding 90-day adverse events, 89/296 (30%) patients experienced a total of 112 adverse events, including 41 grade-I events, 63 grade-II events, 6 grade-III events (4 necrotic tissue sloughing episodes requiring cystoscopic removal, 1 arterial dissection requiring stenting, 1 groin hematoma), and 2 grade-V events (unrelated deaths from a

Fig. 1 Linear regression analysis demonstrated a significant decrease in baseline PGV over the course of the case series ($P < 0.01$), representing a possible confounding variable which was controlled for in subsequent analysis



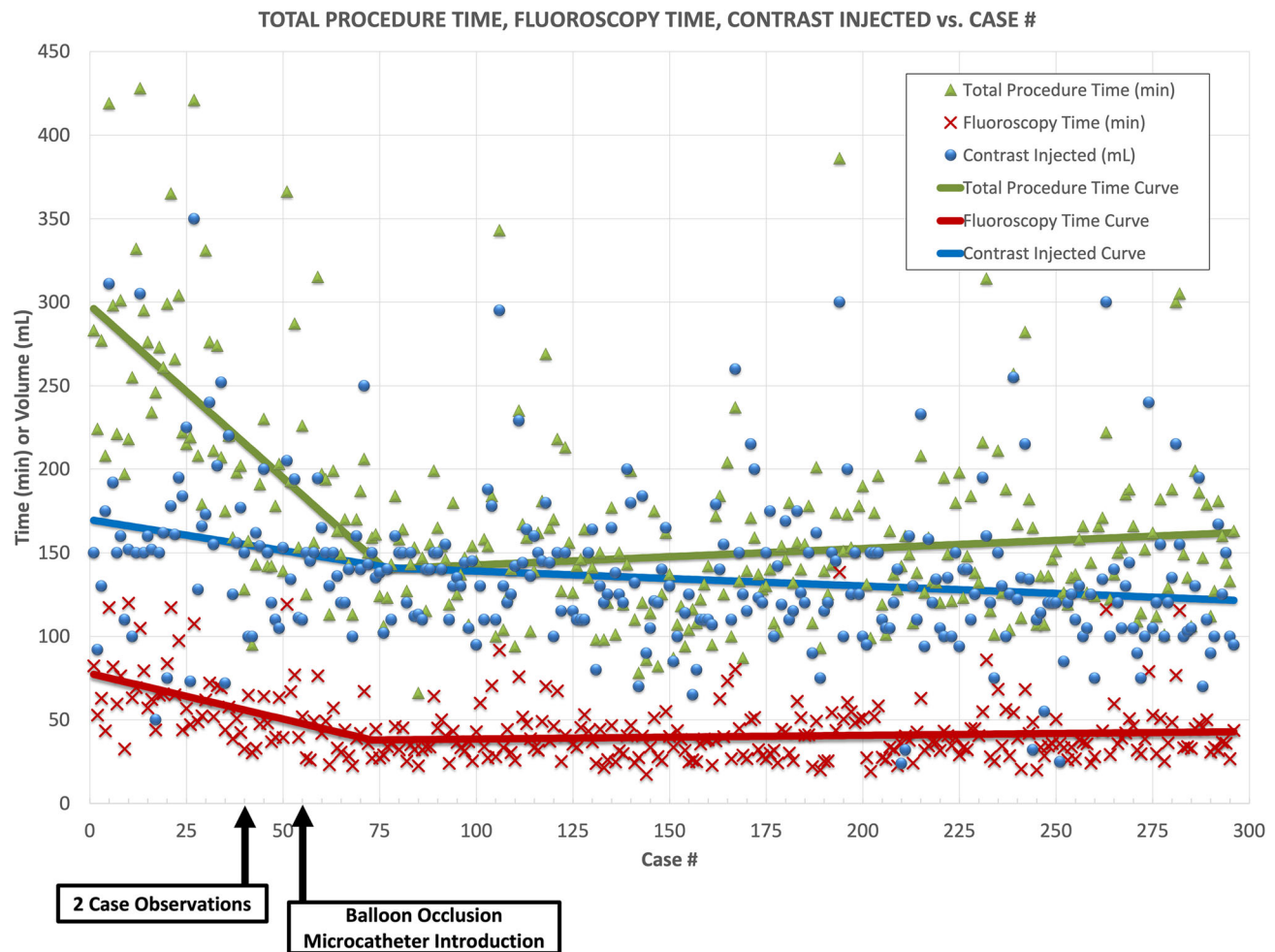


Fig. 2 Procedure time, fluoroscopy time, and volume of contrast injected all significantly decreased with increasing operator experience ($P < 0.01$ for all), and independently of the decreasing PGV also observed over the case series. The curves for these parameters demonstrated steady improvements until reaching inflection points at 76 procedures for procedure time ($P < 0.01$), at 78 procedures for

fluoroscopy time ($P < 0.01$), and at 73 procedures for contrast volume ($P = 0.10$). None of these curves demonstrated any significant variation beyond their inflection points. Case observations occurred after the 40th procedure, and balloon occlusion microcatheter introduction occurred after the 55th procedure

fall and fungemia in the setting of immunocompromise). Neither frequency nor severity of these events varied with operator experience or with the introduction of balloon-occlusion microcatheter utilization ($P > 0.05$ for all) (Fig. 6).

Discussion

Procedure time, fluoroscopy time, and administered contrast volume, which are procedural metrics related to operator technical efficiency, all steadily decreased over the operator's initial 73–78 PAE procedures, and then plateaued through remaining procedures. These learning curves were comparable to those reported in standard transurethral procedures [22–24]. There was no significant impact on these curves by the operator's observation of an

experienced provider's PAE procedures, as no corresponding inflection points were detected in the learning curves. However, improvements in technical efficiency may have developed earlier had such observations occurred earlier in the series. There were no confounding evolutions in procedural technique over those procedures apart from implementation of a balloon-occlusion microcatheter after 55 procedures. Use of a balloon-occlusion microcatheter in PAE has been previously reported to have no impact on technical outcomes or clinical improvements, apart from possible decreased fluoroscopy time and procedure time in one series [13], and possible decreased adverse events in another [25]. Although no discrete learning curve inflection points were detected at the implementation of the balloon-occlusion microcatheter, its introduction could still be a confounding factor in this analysis.

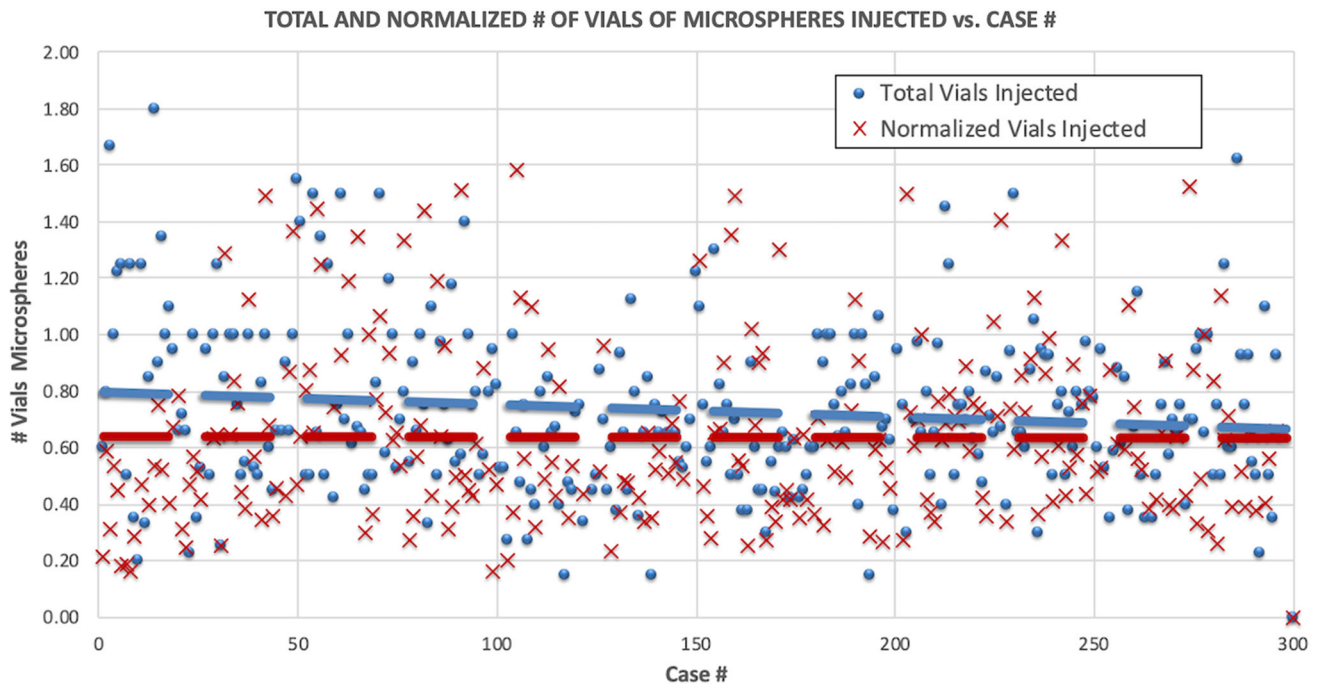


Fig. 3 Neither total volume of embolic particles injected, nor volume of embolic particles normalized to preoperative PGV demonstrated variation with operator experience ($P > 0.05$ for both)

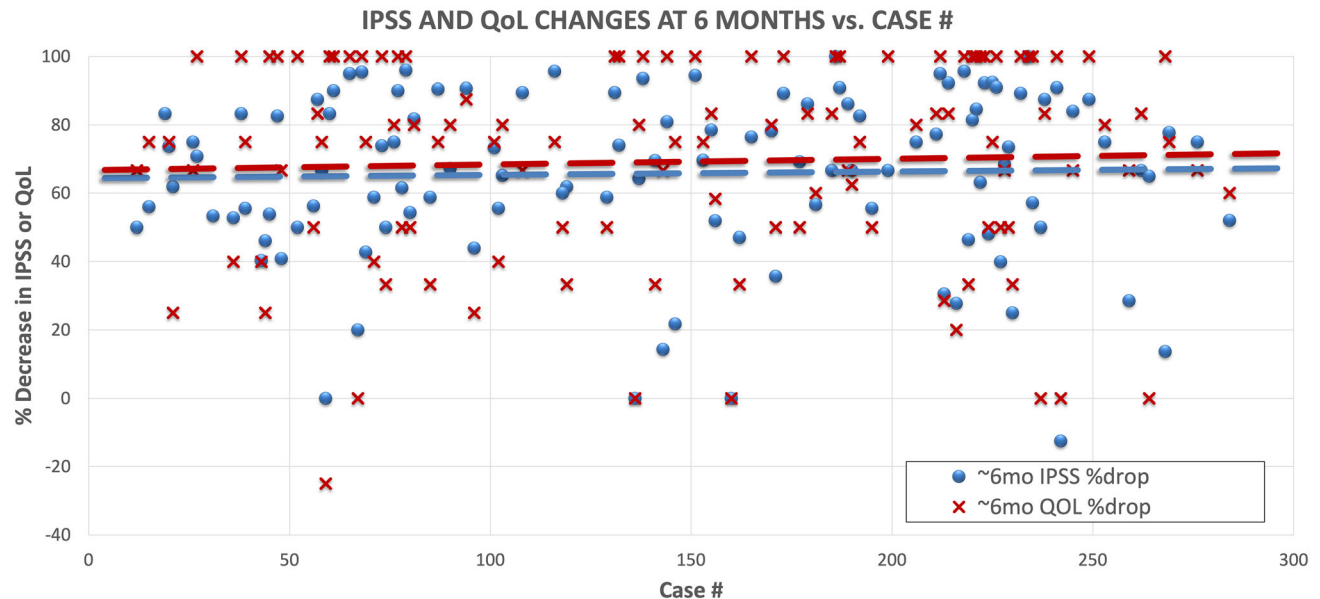


Fig. 4 Six-month postoperative IPSS and QoL both demonstrated substantial improvements when compared to preoperative values ($P < 0.01$). Improvements in IPSS and QoL were uniform over the

entire series without significant variation related to increasing operator experience ($P > 0.05$)

Procedural metrics that did not change with increasing operator experience included number of vessels coiled, total embolic volume injected, normalized embolic volume injected, and incidence of technical failure. Hence, there were no apparent improvements in achieving appropriate embolization endpoints over the series. Such procedural

metrics may be more dependent on patient anatomy rather than operator experience. Incidentally, the declining PGV over this series may have represented a shift toward increasing referrals of patients with less advanced BPH.

Importantly, increasing operator experience had no effect on clinical success at 6 months after PAE.

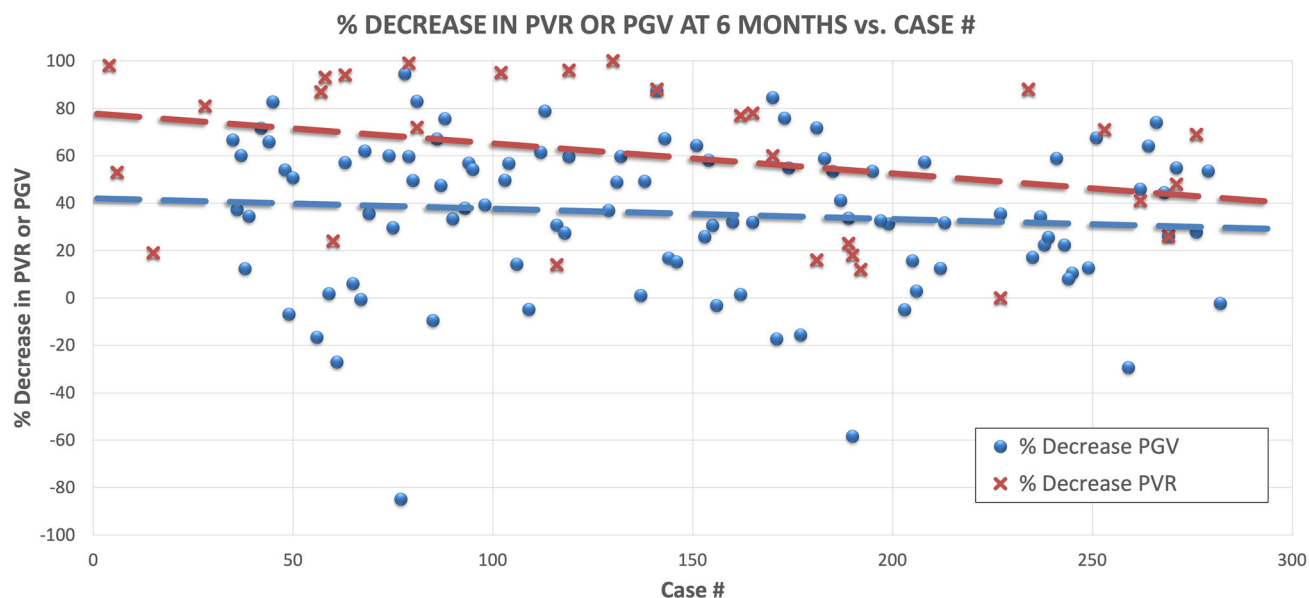
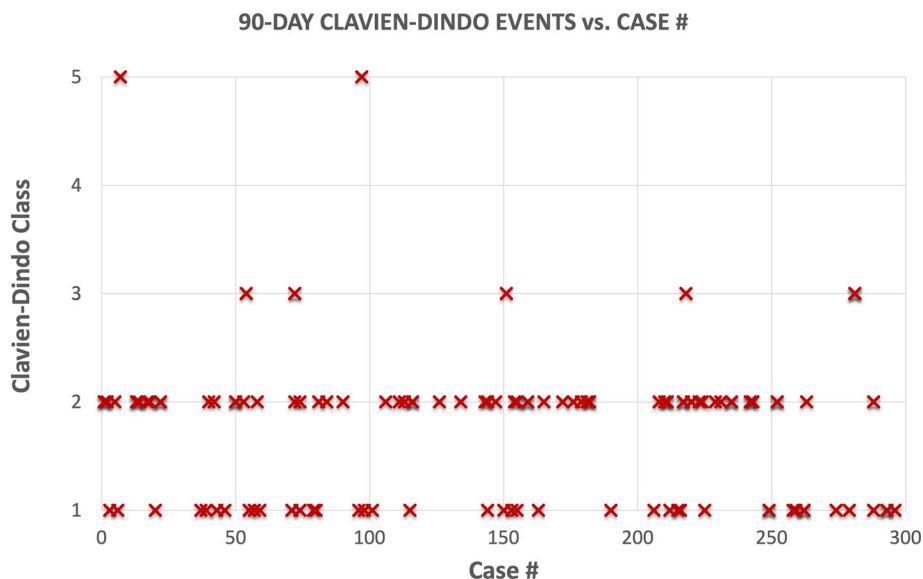


Fig. 5 Among patients who started with abnormally high PVRs > 200 mL, 6-month postoperative PVRs decreased substantially ($P < 0.01$). The trend of decreasing PVR improvement with increasing operator experience was not significant ($P = 0.07$) and of

unknown clinical importance. 6-month postoperative prostate gland volumes were substantially decreased compared to preoperative values ($P < 0.01$) with no variation observed with increasing operator experience ($P > 0.05$)

Fig. 6 Neither the frequency nor the severity of 90-day adverse events, as classified by the Clavien–Dindo system, showed any variation with increasing operator experience ($P > 0.05$ for both)



Reductions in IPSS, QoL, and PVR, voiding trial success, hematuria resolution, and PGV reduction were uniformly substantial over the entire series. Adverse event frequency and severity were also unaffected by operator experience. Taken together, these findings indicate that while increasing PAE experience improved an operator's technical efficiency, the rates of technical success, clinical success, and adverse events were steady throughout the operator's experience.

Technical learning curves have been reported for other angiographic procedures, with plateauing described after a

few dozen procedures [8–10]. In an adrenal venous sampling series, a satisfactory technical success rate was observed after 36 procedures [8]. In another report, procedural outcomes improved with experience in trans-radial liver tumor embolization, with the learning curve observed to flatten after 20 procedures [10]. That clinical outcomes do not vary with increasing operator experience has also been shown with other procedures. One report found that rates of survival, time to tumor progression, and post-procedure complications of hepatic arterial chemoembolization did not vary with years of experience among

operators at a tertiary referral center [9]. Nor were relationships found between years of experience and outcomes or complication rates in uterine artery embolization or trans-radial hepatic arterial tumor embolization [10]. In comparison, surgical procedures to treat large symptomatic prostate glands such as holmium laser enucleation of the prostate have been shown to have similar learning curves. One review found that approximately 50 such procedures were needed to attain proficiency, with structured mentorship helping to decrease that to 25 procedures [26].

This study's limitations include its single-center, single-arm, retrospective design which quantifies the experience of a single operator. Any ongoing angiographic skill acquisition from performing non-PAE embolization procedures during the learning curve period could not be controlled for, and generalizability of this single operator's learning curve to the general interventional radiologist population is limited. As mentioned, patient radiation dose data could not be used in this analysis. Involvement of trainees in procedures may have affected learning curve outcomes. Advancements in technology, technique, and available literature may have also the confounded results [27]. Incomplete follow-up among patients may have imparted responder bias. Finally, ultrasound measurements of PGV and PVR were subject to operator-related variation.

Conclusion

Overall, these findings suggest that an operator can perform PAE procedures safely and effectively from the beginning of their PAE experience. Although an operator's technical efficiency may improve with increasing experience, this study suggests that this learning curve may plateau after about 73–78 procedures and that this learning curve should not deter implementation of new PAE programs that can seemingly deliver safe and clinically meaningful outcomes from the outset.

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Declarations

Conflict of interests Dr. Bhatia receives grants and personal fees from Merit Medical Incorporated, personal fees from Terumo Incorporated, personal fees from Mentice, grants and personal fees from Siemens Medical, stock holdings with Embolx Incorporated, and personal fees from Medtronic, outside the submitted work. All other authors have no conflicts of interest.

Consent for Publication For this type of study consent for publication is not required.

Ethical Approval For this type of study formal consent is not required.

Informed Consent This study has obtained IRB approval from Yale University School of Medicine and the need for informed consent was waived.

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