Original Investigation

Initial Experience Using Digital Variance Angiography in Context of Prostatic Artery Embolization in Comparison with Digital Subtraction Angiography

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Rationale and Objectives: In previous clinical studies digital variance angiography (DVA) provided higher contrast-to-noise ratio (CNR) and better image quality in lower extremity angiography than digital subtraction angiography (DSA). Our aim was to investigate whether DVA has similar quality reserve in prostatic artery embolization (PAE). The secondary aim was to explore the potential advantages of the color-coded DVA (ccDVA) technology in PAE.

Material and Methods: This retrospective study evaluated 108 angiographic acquisitions from 30 patients (mean \pm SD age 68.0 \pm 8.9, range 41-87) undergoing PAE between May and October 2020. DSA and DVA images were generated from the same unsubtracted acquisition, and their CNR was calculated. Visual evaluation of DVA and DSA image quality was performed by four experienced interventional radiologists in a randomized, blinded manner. The diagnostic value of DSA and ccDVA images was also evaluated using clinically relevant criteria (visibility of small [< 2.5 mm] and large arteries [> 2.5 mm], feeding arteries and tissue blush) in a paired comparison. Data were analysed by the Wilcoxon signed rank test or the binomial test, the interrater agreement was determined by the Kendall W or Fleiss Kappa analysis.

Results: DVA provided 4.11 times higher median CNR than DSA (IQR: 1.72). The visual score of DVA images (4.40 \pm 0.05) was significantly higher than that of DSA (3.39 \pm 0.07, p < 0.001). The Kendall W analysis showed moderate but significant agreement ($W_{DVA} = 0.38$, $W_{DSA} = 0.53$). The preference of ccDVA images was significantly higher in all criteria (63-89%) with an interrater agreement of 58-79%. The Fleiss Kappa range was 0.02-0.18, significant in all criteria except large vessels.

Conclusion: Our data show that DVA provides higher CNR and better image quality in PAE. This quality reserve might be used for dose management (reduction of radiation dose and contrast agent volume), and ccDVA technology has also a high potential to assist PAE interventions in the future.

Key Words: Angiography, Digital Subtraction, Diagnostic Imaging, Image Enhancement, Subtraction Technique.

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Abbreviations: (BPH) Benign Prostatic Hyperplasia, (ccDVA) Color-Coded Digital Variance Angiography, (CNR) Contrast-to-Noise Ratio, (DSA) Digital Subtraction Angiography, (DVA) Digital Variance Angiography, (ICM) Iodinated Contrast Media, (LUTS) Lower Urinary Tract Symptoms, (NICE) National Institute for Health and Care Excellence, (PAE) Prostatic Artery Embolization, (ROI) Region Of Interest, (SEM) standard error of mean, (TURP) Transurethral Resection of the Prostate

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INTRODUCTION

B enign Prostatic Hyperplasia (BPH) is one of the most common and frequently treated diseases in elderly men. Prostatic artery embolization (PAE) is a new therapeutic approach for lower urinary tract symptoms (LUTS) associated with BPH (1). The positive effect of PAE on BPH-associated symptoms was first observed by Demerritt et al. in 2000 (2). Since then, PAE has been described as an effective and safe method (3,4) and since 2018 been recommended by the British guideline of the National Institute for Health and Care Excellence (NICE) (5). Increasing patient numbers indicate that PAE is gradually accepted as a treatment alternative to traditional transurethral resection of the prostate (TURP), mainly due to the minimally invasive oneday surgery approach, the lack of general anaesthesia, and a low complication rate (5,6).

PAE is usually performed in an angiography room under sterile conditions with C-arm image guidance using digital subtraction angiography (DSA) and fluoroscopy. The interventional radiologist has to identify the dominant feeding artery of the hyperplasic prostate region, then this artery has to be embolized in order to reduce blood supply of the target region without embolizing other important arteries (like pudendal arteries). Pre-existing conditions of elderly patients, such as atherosclerosis, arterial hypertension, or complex vascular anatomy complicate intravasal navigation of catheters and anatomical orientation and sometimes bilateral puncture or a two-stage procedure is required (3,5). During these steps a large number of DSA acquisitions are prepared, which can be accounted for the majority (80%-90%) of the total procedural radiation load. Due to this complexity of PAE interventions, high radiation exposures and amounts of contrast agent are needed (7). increasing the risk of radiation injury, nephropathy and loss of renal function (7-9).

A recently developed new image processing technology, digital variance angiography (DVA) might provide dose management solutions in PAE. DVA is based on the principles of kinetic imaging (10). While DSA records a native image before the injection of contrast media, and subtracts this mask from every subsequent contrasted image frame, DVA does not use a mask, but calculates the standard deviation of pixel intensities in an unsubtracted image series for each pixel. This mathematical algorithm extracts more information from the raw data than DSA, because it enhances the signal generated by contrast agents, but suppresses image noise. These features result in higher image quality, which has been verified in multiple clinical studies on lower limb angiography using either iodinated contrast media (ICM) (11-13) or carbon dioxide (14,15). This quality reserve might provide opportunity for the reduction of radiation exposure (16) or contrast media (17). Our primary aim was to compare the performance of DVA and DSA in terms of CNR and image quality, in order to investigate whether the precondition of dose management, the quality reserve of DVA can be observed

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also in PAE. An additional aim was to investigate the potential advantages of color-coded DVA (ccDVA) – a recently developed DVA image modality suitable for the visualization of certain hemodynamic information-in the visibility of small [< 2.5 mm] and large arteries [> 2.5 mm], feeding arteries and tissue blush, as the recognition of these structures is critically important in PAE.

MATERIALS AND METHODS

In our observational study image series were retrospectively collected from patients undergoing PAE at *******BLINDED*******. Ethical approval was obtained from the Institutional Review Board (IRB no. 467-17) with a waiver for informed consent.

Patients

Between May and October 2020, a total of 32 patients were screened for study inclusion. After exclusion of two patients due to incomplete PAE intervention (the patients could not collaborate to follow instructions, therefore the intervention could not be completed), 30 male patients were included consecutively. The number of patients was determined on the basis of an FDA Guideline developed for the concurrence testing of X-ray imaging devices (18). None of the patients underwent previous TURP, and 72% of patients received alpha-1-inhibitors (Prazosin, Tamsulosin) prior to the PAE treatment, but they were classified as therapy refractory or showed progredient LUTS under medication. Table 1 shows the detailed demographic data.

Study Design

Each patient received a regular PAE-intervention with commonly used fluoroscopy and DSA image-guidance. DSA, DVA and ccDVA images were retrospectively generated from the stored unsubtracted acquisitions. As primary outcomes, the contrast-to-noise ratio (CNR) and the visual evaluation scores of DSA and DVA images were compared. An additional paired comparison was performed between DSA and ccDVA images. Fig. 1 shows the flow chart of the study.

PAE Procedure

PErFecTED PAE technique (19) was applied, using unilateral puncture of the right femoral artery in Seldinger technique. To avoid false embolization and to avoid collaterals, the prostatic artery (PA) was reached superselectively with 2.4F microcatheters (Progreat; Terumo, Tokyo, Japan). The PA was embolized as distally as possible aiming for complete stasis. Bilateral embolization was performed in all treatments using 100-300 μ m embolizing spheres. PAE was planned on an outpatient basis so that all patients were discharged on the same day. No severe complications were observed.

TABLE 1. Demographic Table. Patient Demographics: *n* Number of Patients. Values are Mean \pm Standard Deviation (range); *p* < 0.05Indicates a Significant Difference Between Pre- and Post-PAE Values. IPSS, International Prostate Symptom Score; QoL, Quality of Life; IIEF, International Index of Erectile Function; PAE, Prostate Artery Embolization; PV Prostate Volume

	Patient Demographicn = 30
Age, y	68.0 ± 8.9 (41-87)
PSA [ng / ml]	1.80 \pm 0.09 (0.01-2.10)
	IPSS score (possible range 0-35)
pre-PAE	20.74 \pm 7.00 (17-34)
post-PAE	11.33 \pm 6.03 (5-18)
p-value	< 0.001
	QoL score (possible range 0-5)
pre-PAE	4.06 ± 1.29 (3-5)
post-PAE	2.13 ± 1.32 (1-4)
p-value	< 0.001
	IEEF (possible range 1-30)
pre-PAE	21.50 \pm 10.15 (9-28)
post-PAE)	24.00 ± 10.38 (9-28)
p-value	0.216
	PV, [ml]
pre-PAE	75.4 \pm 49.1 (35.3-107.2)
post-PAE	55.5 \pm 13.2 (28.9-87.3)
p-value	0.032

Image Acquisition

PAE was performed on a latest generation angiography suite (ARTIS pheno[®]; Siemens Healthineers, Forchheim,

Germany) using fluoroscopy and DSA image-guidance. Standard, pre-installed image acquisition protocols protocols (CARE aorta, CARE pelvis) were used for DSA image acquisition (1.17 μ Gy/frame, 2 fps). A Medrad Mark 7 Arterion (Bayer AG, Leverkusen, Germany) automatized injector was used for injecting 15-30 ml/injection ICM (Ultravist 370, Bayer) at 3-10 ml/s flowrate. Cumulative radiation dose measurements for the procedures resulted in a mean dose are product (DAP) of 19203.24 μ Gy·m2 (\pm 8293.2, [1028-59234]). Mean entrance dose (RP) was reported with 272.29 mGy (\pm 328.19,[110-1006]) and an average of n = 14 (\pm 9,[6-40]) image series was acquired. Mean fluoroscopy time was 21.43 minutes (\pm 11.21,[5.3-47.0]).

All images were retrieved from the angiography suite as unsubtracted raw-data (DICOM-files). DSA images (common cumulative OPAC files) were exported without compression. Mask images were manually chosen by the discretion of an experienced interventional radiologist with over 20 years of experience. DVA and ccDVA images were retrospectively generated on a dedicated local workstation (Kinepict Medical Imaging Tool, v4.0) using the same raw DICOM file as for DSA images.

CNR Calculation

As described earlier (11), regions of interest (ROI) were defined on vessels and background regions by using Image J (v.2.0.0-rc-68/1.52e, Creative Common License, NIH). The vascular and adjacent background ROI were placed in pairs. ROI positions



Figure 1. Flow chart of the study. Elective patients with benign prostatic hyperplasia (BPH), referred to our institute for prostatic artery embolization (PAE) between May and October 2020, were screened for inclusion. Patients with completed PAE were added in a consecutive manner. All patients received standard treatment, and the observational study was performed retrospectively (dashed rectangle). Digital subtraction angiography (DSA) images were prepared during the intervention by the Siemens Syngo workstation, whereas digital variance angiography (DVA) images (both normal and color-coded [ccDVA]) were generated later by the Kinepict Medical Imaging Tool from the same unsubtracted series as DSA images. Contrast-to-noise ratio (CNR) and single image visual score was determined for DSA and DVA images, whereas ccDVA images were compared to DSA images in another blinded and randomised survey.

were adjusted when patient positioning or pixel shifting caused slight geometric differences. CNR values were calculated for all ROI pairs individually according to the following formula (20), wherein *Mean_v* and *Mean_b* referred to mean pixel intensity values of the vascular and background ROI respectively and *Std_b* being the background standard deviation

$$CNR = \frac{|Mean_v - Mean_b|}{Std_b}$$

 CNR_{DVA}/CNR_{DSA} ratios (R) for each corresponding DVA and DSA ROIs were calculated (Table 2).

Visual Evaluation

A blinded evaluation of images was done by four interventional radiologists (the number after the initials represent the relevant experience in years: AA 5, BB 7, CC 25, DD 6). DVA and DSA images were evaluated using the following 5grade rating scale:

- (1)Non-diagnostic
- (2)Low
- (3)Medium
- (4)Good
- (5)Outstanding

For further details see Fig. 3. The rating scale was implemented in a blinded and randomized web-based survey and data were collected automatically in a data base for later processing.

DSA and ccDVA images were evaluated in a paired comparison, where the experts had to choose between the DSA



Figure 2. Contrast-to-noise ratio (CNR) results. The box and whisker plots show the mean (x), median (line), interquartile range (box) and internal fences (whiskers) of CNR values in each group. The paired data were analysed by the Wilcoxon signed rank test (*** p < 0.001). Abbreviations: DVA: digital variance angiography; DSA digital subtraction angiography.

and corresponding ccDVA image in terms of visibility of small

[< 2.5 mm] and large arteries [> 2.5 mm], feeding artery and tissue blush. There were four options: DVA is better, DSA is better, no difference, and in case of tissue blush and feeding artery an additional option (not relevant) was available, for indicating that the structure was not visible on the image. Only those images were included in the statistical analysis, where all four readers recognized the given structure. In the

TABLE 2. Comparison of Digital Subtraction Angiography (DSA) and Color-coded Digital Variance Angiography (ccDVA) Images. Readers Evaluated four Subcategories (visibility of large and small vessels, tissue blush, feeding artery), Where They Had Three Options DSA Is Better, ccDVA Is Better, or No Difference. As Tissue Blush and Feeding Arteries Were Not Present in All Images, in These Categories There Was a Fourth Option (not relevant). Only Those Images Were Included in the Final Analysis, Where All four Readers Recognized and Rated the Given Structure (see Eq). The Image Was Rated as 'ccDVA', if at least three readers selected ccDVA, 'equal' if Exactly Two Readers Selected ccDVA, and 'DSA' if Maximum One Reader Voted for ccDVA. For Further Details, See the Materials and Methods Section. The Significance of Preference Values Was Evaluated by the Binomial Test. Interrater Agreement Was Analysed by the Fleiss Kappa Test, and Included Only Those Images Where All Readers Recognized the Given Structure

Category	DSA (a)	Equal (b)	ccDVA (c)	Not Relevant (d)	Total Images (e = a+b+c+d)	DVA Preference (f = 100*c/[e-d])	Binomial Test <i>p</i>	Interrater Agreement (image number)	Fleiss Kappa	Kappa <i>p</i>
Large vessel	12	28	68	-	108	63 % (68/108)	< 0.005	58 % (373/648) (n = 108)	0.02	0.61
Small vessel	6	17	85	-	108	79 % (85/108)	< 0.001	70 % (452/648) (n = 108)	0.13	0.001
Tissue blush	4	4	62	38	108	89 % (62/70)	< 0.001	79 % (332/420) (n = 70)	0.18	< 0.001
Feeding artery	5	12	62	29	108	79 % (62/79)	< 0.001	65 % (306/474) (n = 79)	0.07	< 0.001



Figure 3. Visual evaluation of digital subtraction angiography (DSA) and digital variance angiography (DVA) images. The box and whisker plots show the mean (*x*), median (line), interquartile range (box) and internal fences (whiskers) of the 5-grade Likert scale scores in each group. (1) Non-diagnostic: unsuitable for diagnosis (2) Low: main vessels are distinguishable but not examinable. (3) Medium: sufficient for diagnosis in the main arteries, but smaller vessels and collateralization are not examinable. (4) Good: both smaller and the main vessels are examinable, suitable for everyday use (5) Outstanding: much richer in details compared to the everyday routine, makes decision-making easier. The paired data were analysed by the Wilcoxon signed rank test (*** p < 0.001).

final analysis the 'DSA is better' and 'equal' judgments were cumulated and compared to the 'DVA is better' option. For any image, 'DVA is better' was the final judgement if at least three readers selected the DVA image, and 'equal' if exactly two readers voted for DVA. In any other cases the outcome was 'DSA is better'. For further details see Fig. 5 and Table 2.

Statistical Analysis

Calculations of CNR and R medians and interquartile ranges were performed using Excel 2016 (Microsoft, Redmond, WA). CNR values were compared by the Wilcoxon signed rank test (Prism 8.4.2., GraphPad).

For visual evaluation scores, the mean and standard error of mean (SEM), and because of the non-Gaussian distribution of data, the median and interquartile range (IQR) were also calculated. The visual scores of the corresponding DSA and DVA images, generated from the same unsubtracted image series, were compared by the Wilcoxon signed rank test, The level of significance was set at p < 0.05 in all tests. The interrater agreement was analyzed by the Kendall's W test.

For the DSA-ccDVA comparison the binomial test was used. Interrater agreement was analysed by the Fleiss kappa test. In the tissue blush and feeding artery categories only those images were included in the analysis, where all readers recognized the evaluated structure.

RESULTS

Our retrospective observational study included 30 male patients undergoing PAE (mean \pm SD age 68.0 \pm 8.9, range 41-87) at our institute. Table 1 shows the detailed demographic data. Patients were enrolled in a consecutive manner. The exclusion criteria and the flow chart are shown on Fig. 1.

CNR Calculations

CNR data were calculated on 108 DSA and DVA image pairs using 1418 ROI pairs. The median CNR for DSA images was 7.33 (IQR: 6.40), whereas for DVA it was 29.99 (IQR: 25.93), thus DVA provided a significantly higher (Wilcoxon signed rank p < 0.001), more than 4-fold CNR than DSA (Fig 2), the median R value was 4.11 (IQR: 1.72).

Visual Evaluation I: Single-image Evaluation of DSA and DVA Images

The visual evaluation of 108 DSA and 108 DVA images was performed in a blinded and randomized manner by four readers using a 5-grade Likert scale. DVA images received a significantly higher visual score (Mean \pm SEM was 4.40 \pm 0.05, Wilcoxon signed rank p < 0.001) than DSA images (3.39 \pm 0.07). Score values showed a highly asymmetric distribution (Fig 3), therefore the median and IQR values were also calculated, yielding a similar difference between DVA (4.50, IQR: 0.75) and DSA (3.50, IQR: 1.00) images. The interrater agreement was 87% and 92% in the DSA and DVA groups, respectively. The Kendall W analysis showed a moderate but significant agreement in both groups (DVA W = 0.38, DSA W = 0.53). Fig. 4 shows representative DSA and DVA images for comparison.

Visual Evaluation II: Paired Comparison of DSA and ccDVA Images

For the paired evaluation, the readers had to compare DSA and corresponding ccDVA images regarding different clinically important aspects, such as the visibility of large vessels, small vessels, feeding artery and tissue blush. The preference of ccDVA images was significantly higher in all evaluated categories (binomial test p < 0.01). The best performance was observed in the visibility of tissue blush (89%), the preference was slightly lower in the small vessels (preference 79%) and in the feeding artery category (79%), whereas the least advantage was observed regarding the visualisation of large vessels (63%) (Fig 5). As feeding arteries and tissue blush were not visible in all image pairs, only those answers were included in the statistical analysis, where all readers recognized and judged these structures (70 and 79 images in the tissue blush and feeding artery categories, respectively). The interrater agreement ranged between 58% and 79%, the Fleiss Kappa analysis showed slight agreement in all categories ranging from 0.02 (large vessels) to 0.18 (tissue blush), which was significant in



Figure 4. Representative digital subtraction angiography (DSA, left side) and digital variance angiography (DVA, right side) images of the common iliac artery after manual application of 8ml contrast agent bolus (4 ml Vispaque 320 and 4 ml NaCl 0.9% solution) through a pigtail catheter in a 78 year-old patient receiving PAE. Little difference can be observed at the level of large vessels, but small arteries have sharper contour and the overall background noise is lower in DVA images. The lower panels show the magnification of the marked segments of upper images.

small vessels, tissue blush and feeding artery visibility. The detailed results with statistical evaluation are shown in Table 2. Fig. 6 shows a representative DSA-ccDVA image pair.

DISCUSSION

Our aim was to compare the image quality of DVA to that of DSA in context of PAE. The primary question was whether the previously observed quality advantage of DVA, described in endovascular lower limb procedures (11-14,16), also exists in prostatic interventions. Our data show that DVA provides more than four-times higher CNR than the traditionally used DSA and this objective advantage is reflected also in subjective visual evaluation, as the Likert score of DVA images was one unit higher than that of DSA images. These data clearly verify the quality reserve of DVA in PAE. A secondary aim was to compare the performance of ccDVA with DSA. The visual comparison data show that ccDVA provides a

better insight in the clinically relevant domains, as it particularly improves the visualization of tissue blush (DVA preference 89%) small vessels (DVA preference79%), and feeding arteries (DVA preference 79%). These structures are critically important in PAE procedure, therefore ccDVA might be a very useful tool to avoid complications (such as non-target embolization of important collaterals), judge the efficacy of embolization during intervention, shorten intervention time and, thereby of all, improve clinical outcome. These potential benefits, however, have to be verified in carefully designed prospective studies.

Our data might have major clinical implications. Previous studies have shown that the quality reserve of DVA can be effectively used for dose management. DVA allowed 50% reduction of contrast media without compromising the image quality in carotid angiography (17). A recent report has shown that 70% reduction of the dose/frame value in lower limb angiography yielded 68% reduction of the DSA-related

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dose-area-product, and DVA with reduced radiation dose provided non-inferior image quality in the abdominal and femoral regions, and superior image quality in the crural region compared to full dose DSA images (16). As PAE has been reported as effective as TURP in improving subjective symptom scores, with fewer complications and shorter hospitalization times (6), the procedure will play an increasing role in the treatment of BPH. The associated radiation burden,

Figure 5. Comparison of digital subtraction angiography (DSA) and color-coded digital variance angiography (ccDVA) images. Readers performed a paired comparison, and evaluated the visibility of large and small vessels, tissue blush and feeding arteries. In these categories there was also a 'no difference' option, and for the tissue blush and feeding artery an additional 'not relevant' option, to exclude those images where the structures were not visible. For further details, see the Materials and Methods section and Table 2. The ccDVA preference over the cumulated 'DSA' or 'no difference' options was significantly higher in all categories using the binomial test.

however, might be a risk for the patients (7-9) and also for the medical staff (8,21,22), and the contrast agents used might increase the risk of renal impairments (17,23,24). Thus, the dose management efforts might be crucial in PAE, and DVA has the potential to address these problems. The dose management capabilities of DVA in PAE have to be validated in further clinical studies.



Figure 6. Representative example of digital subtraction angiography (DSA) and color-coded digital variance angiography (ccDVA) images in a 63 year-old patient. Left: Application of 6 ml contrast agent (3 ml Vispaque 320 and 3 ml NaCl 0.9% solution) in the left pudendal artery (PuA) at the origin from the distal internal iliac artery (black arrow). The prostatic artery (short white arrow) is visible as a direct branch from the PuA. Proximal of the origin of the PuA the inferior vesical artery (IVA) is visible (long white arrow), with a proximal smaller lumen, suspicious for a stenosis. Right: The colors represent the time elapsed until the appearance of the contrast media in a specific blood vessel segment. In the IVA, color progression from orange to blue is visible, indicating a slower flow. Smaller vessels, like the characteristic corkscrew pattern (*) or the collateralization of dominant prostatic artery to the pudendal areas (**) have a higher visibility, and parenchymal blush is visible as greenish diffuse attenuation.

The comparison of DSA and ccDVA images clearly show, that the color-coded technology provides more information on small arteries, tissue blush and feeding arteries. The idea of color-coded imaging is not new. Major manufacturers have already developed their own solutions (25,26) to visualize the temporal appearance of contrast media in blood vessels in a single composite image, where the different colors represent the time elapsed until the contrast media reaches a specific vessel segment. This parametric imaging can help the understanding of hemodynamic conditions. Nevertheless, it requires a high frame rate (4-7.5 fps) to obtain good time resolution and a relatively long acquisition time (8-10 s) to also visualize the venous phase, therefore the method is not widespread because of the required high radiation dose. As ccDVA is based on the DVA technology, it might substantially reduce the radiation burden because of its dose management capabilities, thereby it might help the use of parametric imaging by reducing the associated risks.

Our study has several limitations. First, as it was designed as a small-cohort proof-of-concept retrospective study, the number of patients is relatively low, nevertheless, the number of analysed images allows to reach statistically valid conclusions. Second, all DVA and ccDVA images were generated in a retrospective manner from the unsubtracted acquisitions, therefore they could not serve any help for the medical staff during the interventions. As the DVA workstation has already been installed in the operating room, our future clinical investigations will use real-time data processing (14). Third, the color-coded imaging is a parametric technology, which requires a quantitative analysis, but in our case we have used only a qualitative evaluation. In further studies we will use the parametric ccDVA tool, which provides quantitative information on the hemodynamic conditions.

CONCLUSION

In conclusion, our study demonstrated that DVA can provide higher CNR and better visual image quality in PAE than DSA. This quality reserve might be used for dose management of radiation and contrast media amount. The qualitative evaluation of ccDVA suggests that the technology might help the decision-making process during PAE interventions. The verified quality reserve of DVA and the advantages of ccDVA provide a basis for further prospective clinical studies in the field of PAE and possibly other embolization settings.

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