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 ± SD age 68.0 ± 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 ± 0.05) was significantly higher than that of DSA (4.00 ± 0.05, 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.

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

Acad Radiol 2022; 1-9
INTRODUCTION
Benign 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 lack of general anesthesia, 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 hyperplastic 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 intravascular 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 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 stagnation of blood flow. Bilateral embolization was performed in all treatments using 100–300 μm embolizing spheres. PAE was planned on an outpatient basis so that all patients were discharged on the same day. No severe complications were observed.
**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 mGy/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 mGy cm² (± 8293.2, [1028-59234]). Mean entrance dose (RP) was reported with 272.29 mGy (± 328.19, [110-1006]) and an average of n = 14 (± 9, [6-40]) images series was acquired. Mean fluoroscopy time was 21.43 minutes (± 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

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**Table 1. Demographic Table. Patient Demographics:**

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

**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.

\[
\text{CNR} = \frac{|\text{Mean}_v - \text{Mean}_b|}{\text{Std}_b}
\]

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 5-grade 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.

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

| 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 p | Interrater Agreement (image number) | Fleiss Kappa | Kappa p |
|-------------------|---------|-----------|-----------|------------------|--------------------------|----------------------------------|----------------|------------------------------------|--------------|---------|
| Large vessel      | 12      | 28        | 68        | -                | 108                      | 63% (68/108)                     | < 0.005         | 58% (373/648)                      | 0.02         | 0.61    |
|                   | (n = 108)|           |           |                  |                          |                                  |                | (n = 108)                          |              |         |
| Small vessel      | 6       | 17        | 85        | -                | 108                      | 79% (85/108)                     | < 0.001         | 70% (452/648)                      | 0.13         | 0.001   |
|                   | (n = 108)|           |           |                  |                          |                                  |                | (n = 108)                          |              |         |
| Tissue blush      | 4       | 4         | 62        | 38               | 108                      | 89% (62/70)                      | < 0.001         | 79% (332/420)                      | 0.18         | < 0.001 |
|                   | (n = 70)           |           |           |                  |                          |                                  |                | (n = 70)                          |              |         |
| Feeding artery    | 5       | 12        | 62        | 29               | 108                      | 79% (62/79)                      | < 0.001         | 65% (306/474)                      | 0.07         | < 0.001 |
|                   | (n = 79)           |           |           |                  |                          |                                  |                | (n = 79)                          |              |         |
results

Our retrospective observational study included 30 male patients undergoing PAE (mean ± SD age 68.0 ± 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 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
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 sub-
jective 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 particu-
larly improves the visualization of tissue blush (DVA prefer-
ence 89%) small vessels (DVA preference 79%), 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

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 Vispaeque 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.
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, 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 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.

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.

FUNDING

The study was supported by the European Commission EIC Accelerator Pilot grant (968430 KMIT-ACC), the National Research, Development and Innovation Office of Hungary (NKFI; NVKP-16-1-2016–0017 National Heart Program, and 2020-1.1.5-GYORSfTÓSÁV-2021-00018) and by the Thematic Excellence Program (2020-4.1.1-TKP2020) of the Ministry of Innovation and Technology of Hungary, within the framework of the BIOImaging Excellence program at Semmelweis University.

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