Improving Cone-Beam CT Angiography for Prostatic Artery Embolization: Is a Low-Dose Protocol Equivalent to the Standard?

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ABSTRACT

Purpose: To compare the utility of low-dose versus standard cone-beam computed tomography (CT) angiography protocols in identifying nontarget embolization (NTE) during prostatic artery embolization (PAE).

Materials and Methods: A prospective, single-center, Phase-1 study (NCT02592473) was conducted for lower urinary tract symptoms in benign prostatic hyperplasia. Prostate volume, international prostate symptom score (IPSS), quality of life score (QoL), International Index of Erectile Function (IIEF), peak flow rate, UCLA Prostate Cancer Index (UCLA-PCI), and postvoid residual were recorded at baseline and 1, 3, 6, 12, and 24-months after PAE. Six-second (standard protocol, n = 29) or 5-second (low-dose protocol n = 45) rotations were made. Images were selected and matched in pairs by areas of NTE and compared by readers using a binomial generalized estimating equation model. Procedural outcomes were analyzed using a linear mixed model.

Results: Seventy-four cone-beam CT angiographies were performed in 21 patients. IPSS and QoL scores significantly improved ($P < .05$). There was no change in UCLA-PCI or IIEF scores. Dose area product of the low- and standard-dose protocol were 37,340.82 mGy·cm^2 ± 104.66 and 62,645.66 mGy·cm^2 ± 12,711.48, respectively, representing a dose reduction of 40.4%. A total of 120 comparisons showed no preference between the 2 protocols ($P = .24$). Observers identified 76 and 69 instances of NTE in the standard- and low-dose protocols, respectively ($P = .125$).

Conclusions: Low-dose cone-beam CT angiography achieved equivalent clinical utility in identifying NTE during PAE, with the advantage of a lower radiation dose.

ABBREVIATIONS

BPH = benign prostatic hyperplasia, IIEF = International Index of Erectile Function, IPSS = International Prostate Symptom Score, LUTS = lower urinary tract symptoms, NTE = nontarget embolization, PAE = prostatic artery embolization

Prostatic artery embolization (PAE) has become a useful alternative in the management of lower urinary tract symptoms (LUTS) due to benign prostatic hyperplasia (BPH), particularly in men seeking an alternative to surgical therapies (1). Although the incidence of major complications with PAE is low according to multiple meta-analyses, the risks of nontarget embolization (NTE) remain a concern for operators performing the procedure (2–7). In addition, the angiographic anatomy of the prostatic artery is complex, with numerous intrapelvic anastomoses and variants. To mitigate these risks, the use of cone-beam computed tomography (CT) angiography has been advocated as an adjunctive technique to assist in excluding areas of NTE prior to embolization (8–12). One of the criticisms of PAE is the high radiation dose during the procedure, and cone-beam CT angiography typically adds a considerable amount of exposure to the patient (13). While cone-beam CT angiography can be performed with minimal exposure to staff, patients are exposed to deterministic effects of radiation, and prior cases of radiation dermatitis during PAE have been

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Table 1. Demographics

Demographic Table		Mean	SD	Range
Mean Age (n = 21)		69.62	6.03	55–80
Previous Medical Therapy				
α1-ARA monotherapy	8			
5-ARI monotherapy	1			
Combination therapy	6			
Refused medical therapy	6			
Catheter dependent	1			
Baseline Evaluation				
IPSS		23.15	7.64	0–33
QoL		4.8	0.93	2–6
IIEF		17.73684	4.18	11–25
Qmax (mL/s)		6.405	2.54	1.2–11
PVR (mL)		155.45	193.76	0–897
UCLA-PCI		80.52381	5.26	71–90

IIEF = International Index of Erectile Function; IPSS = International Prostate Symptom Score; QoL = quality of life; PCI = prostate cancer index; PVR = postvoid residual; SD = standard deviation; α1-ARA = alpha 1 adrenergic receptor antagonist; 5-ARI = 5 alpha reductase inhibitor.

reported (14). Thus, dose mitigation during PAE remains a focus of clinical improvement, and a reduction in the spin time and frame rate during cone-beam CT angiography may achieve lower doses, despite a similar dose per frame and kVp. The drawback to reducing these parameters includes increased motion artifacts, decreased signal-to-noise ratio, and potentially compromising diagnostic image quality (11). The aim of this study is to compare the clinical utility of a 5-second low-dose cone-beam CT angiography protocol versus a 6-second standard-dose protocol during PAE with respect to the ability to identify areas of NTE.

MATERIALS AND METHODS

Study Design

A prospective, single-center, analytic/experimental non-randomized Phase 1 study (NCT02592473) was conducted for LUTS due to BPH in 21 patients from February 2016 to July 2019. The study was performed under a Food and Drug Administration Investigational Device Exemption (IDE#G150021). The Food and Drug Administration dictated the study size. Forty-five patients were recruited, 21 of whom met the inclusion and no exclusion criteria and underwent the procedure, with a total of 74 cone-beam CT angiographies. Baseline demographic information can be found in Table 1. Prostate volume, International Prostate Symptom Score (IPSS), quality of life score, International Index of Erectile Function (IIEF), peak flow rate (Qmax), UCLA prostate cancer index (UCLA-PCI), and postvoid residual were recorded at baseline and at 1, 3, 6, 12, and 24 months after PAE. Prostate volume was estimated using the ellipsoid formula ($H \times W \times L \times 0.524$) from measurements acquired with pelvic CT angiography at baseline, and with transrectal ultrasound at 6 and 24 months. Patients discontinued medications for 30 days prior to the PAE procedure if tolerated. Inclusion criteria were age 45–80 years, diagnosis of LUTS due to BPH with IPSS score >7 and Qmax <12 mL/s, prostate volume >50 g, and failure or refusal to undergo medical therapy. Exclusion criteria for PAE included biopsy-proven prostate or urethral cancer, urinary tract infections (>2/year), prostatitis, or interstitial cystitis, cancer of the lower urinary tract, LUTS due to bladder atonia, neurogenic bladder, bladder sphincter abnormalities, prior surgical management for BPH, uncorrectable coagulopathy, and history of prior pelvic irradiation.

Procedure

All procedures occurred in a Siemens Artis Q ceiling-mounted angiography suite (Siemens Healthineers, Forchheim, Germany). Procedures were performed by 2 interventional radiologists (Z.J.H. and A.U.) via right or left femoral access using a 5-F sheath (Boston Scientific, Marlborough, Massachusetts) and 5-F angiographic catheters (Angiodynamics, Latham, New York) with coaxial 0.017 Echelon microcatheters (Boston Scientific) for prostatic artery selection over a 200-cm Synchro Soft microwire (Stryker Neurovascular, Kalamazoo, Michigan). Six-second (standard protocol, n = 29) or 5-second (low-dose protocol, n = 45) C-arm rotations were made during low-volume, low-flow power injections, which ranged from 0.1 to 2 mL/s using Omnipaque 350 (Iohexol, GE Healthcare, Chicago, Illinois) prior to embolization. The 6-second standard protocol had a frame rate of 66 frames/sec, kVp of 102 keV, and a dose per frame of 360 mGy/frame with a total of 396 images per acquisition. The 5-second standard protocol had a frame rate of 49.4 frames/sec, kVp of 113 keV, and a dose per frame of 360 mGy/frame with a total of 247 images per acquisition. Injections were performed with an X-ray delay ranging from 3 to 16 seconds at 600 psi. Indications for each cone-beam CT angiography, contrast dose and flow rate, radiation dose, and catheter position were recorded. The cone-beam CT angiographies were reviewed, and once the operator was satisfied with the catheter position within the target prostatic artery, an embolization was made with either 100 μm or 250 μm Embozene particles (Varian, Palo Alto, CA) until stasis, which was defined as complete occlusion of the prostatic artery with contrast reflux into more proximal vessels on completion hand-injection angiography.

Data Analysis

All cone-beam CT angiography image series were reviewed by the operators who performed the PAE procedures. The operators reached a consensus on the interpretation of the studies with regards to the distribution of the contrast enhancement, laterality, and the presence of NTE. Contrast enhancement during super-selective angiography during cone-beam CT angiography acquisitions in the seminal vesicles, rectum, bladder, pelvic wall, and bulbus penis were

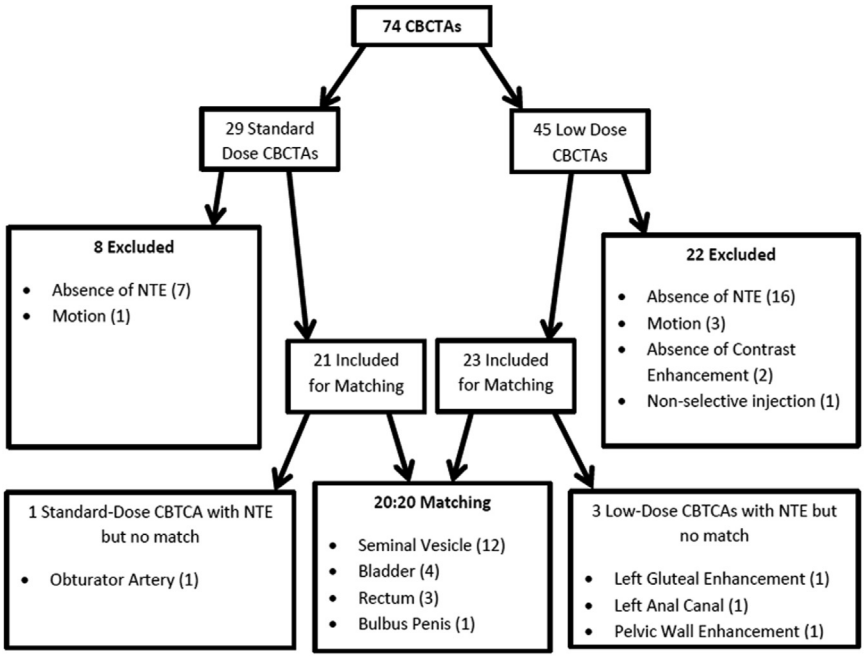

Figure 1. Flow chart showing the breakdown and distribution of the 74 cone-beam CT angiograms obtained in the study.

defined as sites of NTE. Selection criteria for cone-beam CT angiography images to be included in the data analysis were the presence of contrast enhancement in one or more pelvic structures during super-selective angiography during PAE, presence of nontarget embolization on cone-beam CT angiography, and consensus among the 2 operators who performed the PAE procedures on findings. Exclusion criteria were patient motion during cone-beam CT angiography acquisition, nonselective injection during acquisition, absence of contrast enhancement during acquisition, and absence of NTE on image interpretation. Cone-beam CT angiography image series were then segregated into standard- and low-dose groups according to the diagram in Figure 1, matched based on laterality, and enhanced in an area of NTE in the same anatomical location. Cone-beam CT angiography image series which did not have a match were not included in the analysis.

Six fellowship-trained interventional radiologists with experience ranging from 1 to 7 years compared 20 low-dose and 20 standard-dose cone-beam CT angiography acquisitions for the presence of nontarget embolization. Observers were also asked to assess image quality based on a subjective assessment of spatial resolution, noise, and artifact, and to indicate if an image series was superior or equivalent to its match. Observers were blinded to whether a cone-beam CT angiography was acquired with the standard-dose or low-dose protocols. Observers also were blinded to the fact that all studies had sites of NTE. Images were displayed on a high-resolution picture-archiving and communication system monitor used for diagnostic radiological interpretation. Image sets could be viewed in their entirety and simultaneously to allow direct comparisons, and observers could scroll through image series freely. A generalized estimating equation approach was used to test if the preference for the standard-dose protocol was equal to the low-dose protocol.

Statistical Methods

Analyses of image dose preference. Among those matched image pairs in which readers reported an imaging dose preference (low-dose vs standard-dose), a binomial generalized estimating equation model was used to test the null hypothesis that the probability (P) of the low-dose protocol is preferred over the standard-dose protocol is the same as the probability that the standard-dose protocol is preferred over the low-dose protocol (ie, $P = .5$). The binomial generalized estimating equation model was used to test the null hypothesis because the intrareader case to case image preferences cannot be assumed to be uncorrelated, and the generalized estimating equation model takes this aspect of the sampling design into account in the estimation of the image dose preference standard error. A significance level of 0.05 was used for the 2-side type I error rate of the null hypothesis test.

Postprocedure outcome variable change analyses. Longitudinal changes in IPSS, quality of life, UCLA-PCI, IIEF, Qmax, and postvoid residual at 1, 3, 6, 12, and 24 months were evaluated via measures linear mixed models. A linear mixed model also was used to evaluate the longitudinal changes in prostrated volume at 1, 12, and 24 months. At each assessment time point, the null hypothesis that the mean change in the outcome variable is equal to zero was tested. A Bonferroni corrected family-wise significance level of 0.05 was set so that the

Table 2. Outcomes

Parameters	Baseline		1 Month				3 Months				6 Months				12 Months				24 Months			
	n = 21	SD	n = 20	SD	Change	*P*-Value*	n = 18	SD	Change	P-Value*	n = 16	SD	Change	*P*-Value*	n = 16	SD	Change	*P*-Value*	n = 10	SD	Change	*P*-Value*
IPSS	23.2	7.8	14.3	6.6	−8.8	<.001	11.9	6.4	−11.3	.002	10.3	7.1	−13.6	<.001	8.1	5.4	−15.8	<0.001	8.1	5.2	−18.0	<.001
QoL	4.8	1.0	3.2	1.5	−1.6	.002	2.2	1.1	−2.7	<.001	1.9	1.3	−2.9	<.001	1.4	1.5	−3.4	<0.001	1.3	1.3	−3.7	<.001
UCLA-PCI	80.5	5.3	81.2	6.3	0.7	1.000	82.6	6.2	1.6	.98	84.4	8.1	3.4	.288	81.4	5.8	0.4	1.00	81.1	7.6	0.7	1.0
IIEF	17.7	4.3	18.3	4.4	0.7	1.000	19.9	3.4	1.8	.45	19.9	4.0	1.5	.260	20.1	3.9	1.6	0.25	19.9	3.2	2.0	.59
Qmax (mL/s)	6.4	2.5	9.8	6.5	3.6	.046	12.3	6.5	5.7	.006	13.9	8.2	7.2	.013	11.2	5.9	4.4	0.082	13.3	5.8	6.7	.029
PVR (mL)	155.5	198.8	96.4	83.0	−20.1	1.000	62.6	50.6	−54.3	.251	104.6	101.2	−13.7	1.000	67.9	69.7	−50.3	0.4	105.8	87.4	−24.3	1.000
Prostate Volume (g)	82.8	30.4									54.5	25.4	−25.8	<.001					56.4	23.7	−31.8	.017

IIEF = International Index of Erectile Function; IPSS = International Prostate Symptom Score; QoL = quality of life; PCI = prostate cancer index; PVR = postvoid residual; Qmax = peak flow rate; SD = standard deviation.
*All *P*-values are Bonferroni-corrected.

Table 3. Cone-Beam CT Angiography and Procedural Details

Procedure Data		
Cone-beam CT angiography, n =	74	
Standard/low-dose cone-beam CT angiographies	29/45	
Procedures, n =	21	**SD**
Mean Fluoroscopy time (s)	45.84	17.61
Skin entry dose (mGy)	4275.71	1774.78
DAP (mGy·cm^2)	50,5352.24	20,8448.17
Mean flow rate for cone-beam CT angiography (mL/s)	0.41	0.79
Mean X-ray delay (s)	12.62	3.31
Contrast volume per cone-beam CT angiography	3.97	2.70
Protocol Details		
Parameters	**Standard**	**Low Dose**
Spin time (seconds)	6.00	5.00
Frame rate (fps)	66	49.4
kVp (keV)	102	113
Dose per frame (mGy)	360	360
Field of View (cm)	18.5 × 24	18.5 × 24
Number of images	396	247
Dose Comparison		
Standard Cone-Beam CT Angiography		**SD**
Skin entry dose (mGy)	202.10	40.99
DAP (mGy·cm^2)	62,645.66	12,711.48
Low-Dose Cone-Beam CT Angiography		
Skin entry dose (mGy)	120.32 (*P* <.01)*	33.73
Low-Dose cone-beam CT angiography	37,340.82 (*P* <.01)*	10,466.85

DAP = dose area product; fps = frames per second; keV = kilo electron Volt.
*P-values indicate a comparison between the standard and low-dose protocols.

overall type I error rate for the each outcome variable was no greater than 0.05.

RESULTS

Results for the PAE procedure are provided in Table 2. Cone-beam CT angiography data can be found in Table 3. Mean fluoroscopy time was 45.84 minutes ± 17.61, mean contrast injection volume per acquisition was 3.97 mL (± 2.7; range, 1–16 mL), the mean flow rate was 0.41 mL/s (± 0.79; range, 0.1–6 mL/s), and mean X-ray delay was 12.62 seconds (± 3.31) in the low-dose and standard protocols. Skin entry dose and dose area product were 120.33 mGy ± 33.73 vs 202.10 mGy ± 40.99, and 37,340.82 mGy·cm^2 ± 104.66 vs 62,645.66 mGy·cm^2 ± 12,711.48 in the low-dose vs the standard protocol, respectively, representing a dose reduction of 40.4%.

A total of 120 comparisons were made (20 per protocol between 6 observers) between the low-dose and standard

Table 4. Data Analysis of Dose Preference

Protocol Preference Overall				Instances of Identification of NTE		
Standard Dose		**Low Dose**		**Standard Dose**	**Low Dose**	***P*-value**
18 (60.0)		12 (40.0)		76	69	.125
Reader Preferences						
Reader 1 Dose Preference		Reader 4 Dose Preference		Dose		% [95% CI]
Standard Dose	Low Dose	Standard Dose	Low Dose	Standard		61.5 [42.3, 77.8]
5 (62.5)	3 (37.5)	8 (57.1)	6 (42.9)	Low Dose		38.5 [32.2, 57.7]
Reader 2 Dose Preference		Reader 5 Dose Preference		Test for Preference Equality		
Standard Dose	Low Dose	Standard Dose	Low Dose	Hypothesis:		
2 (66.6)	1 (33.3)	10 (58.8)	7 (41.2)	Standard Dose		
Reader 3 Dose Preference		Reader 6 Dose Preference		Preference = Low Dose Preference = 50.0%		*P*-value
Standard Dose	Low Dose	Standard Dose	Low Dose			.239
3 (60.0)	2 (40.0)	4 (80.0)	1 (20.0)			

Note–Values in parentheses represent percentages (%).
NTE = nontarget embolization.

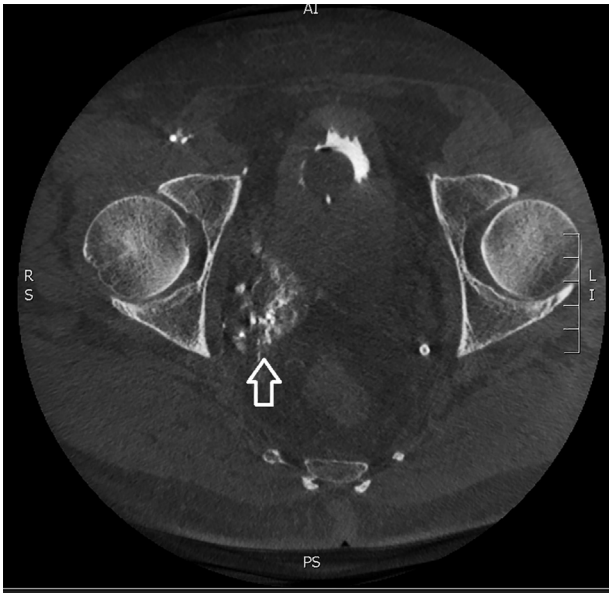

Figure 2. Single axial slice of a cone-beam CT angiogram with a microcatheter positioned in the right prostatic artery showing nontarget enhancement in the right seminal vesicles (arrow). This example is from an acquisition made with the standard-dose, 6-second protocol.

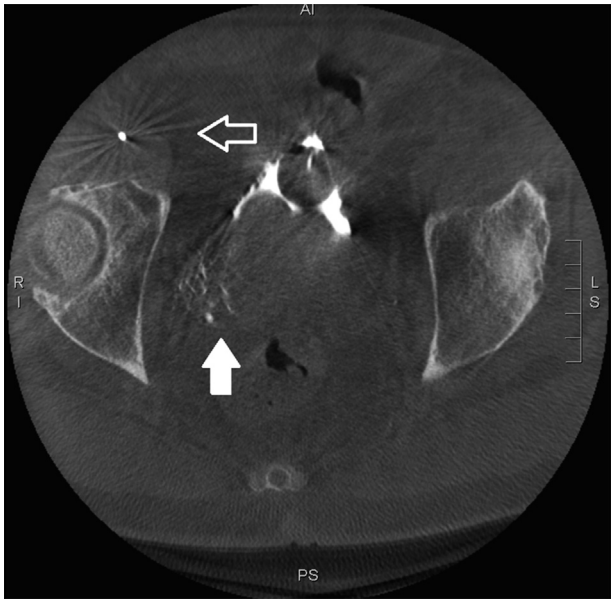

Figure 3. Single axial slice of a cone-beam CT angiogram with a microcatheter positioned in the right prostatic artery showing nontarget enhancement in the right seminal vesicles during an acquisition made with the low-dose, 5-second protocol. There is an increased beam hardening artifact (hollow arrow) and noise in the image, but enhancement in the seminal vesicles can be identified (solid arrow).

cone-beam CT angiography protocols. No preference was found for the standard-dose protocol compared with the low-dose protocol (P =.24) in terms of image quality. The ability to visualize sites of NTE also was not different among all observers (P =.12). Observers identified 145 sites of NTE, for an NTE rate of 60.4% (n = 145/240). Details of the comparisons can be found in Table 4.

There were 14 minor adverse events (n = 14/21, 66.7%) and one major adverse event (n = 1/21, 4.7%), which was a case of hydronephrosis treated with ureteral stents, which resolved within 3 months of placement. This major adverse event was determined to be likely related to the procedure, but no obvious source of NTE could be identified in this case. One minor adverse event included a previously reported case of tissue passage.

DISCUSSION

Given that the prostatic arterial bed is highly variable with numerous anastomoses to adjacent pelvic structures, NTE remains a top concern to practitioners performing PAE (15,16). Cone-beam CT angiography can help detect areas of NTE prior to administration of embolics, thereby potentially helping reduce the risk of serious adverse events

(8,10,11,17). Unfortunately, cone-beam CT angiography adds a considerable amount of radiation dose to the procedure, and mitigating high exposure during PAE remains a challenge (13).

The data presented herein demonstrates that a significant reduction in dose can be achieved with a 5-second cone-beam CT angiography protocol without the loss of image quality or diagnostic efficacy. The mean dose area product for the standard 6-second cone-beam CT angiography performed in this study was 62,645.66 mGy·cm^2 ± 12,711.48, whereas the low-dose 5-second cone-beam CT angiography had an mean dose area product of 37,340.82 mGy·cm^2 ± 104.66, representing a dose savings of 25,304.84 mGy·cm^2. Although the appearance of the cone-beam CT angiography acquisitions could vary substantially (**Figs 2**, **3**), the dose savings was achieved without sacrificing diagnostic efficacy, as demonstrated by 120 direct comparisons between the 2 protocols. Furthermore, there was no change in the rate of identification of NTE sites among observers.

The utility of cone-beam CT angiography during PAE remains a subject of debate among practitioners performing PAE. The theoretical advantage that proponents of the use of cone-beam CT angiography mention is the potential identification and mitigation of serious potential adverse events related to NTE prior to embolotherapy. To date, the incidence of adverse events has not been directly compared with a randomized trial of patients undergoing PAE with and without cone-beam CT angiography. However, proponents of cone-beam CT angiography during PAE argue that the ability to detect the prostatic artery and potential sites of NTE make adjunctive use of the technique desirable, especially to those with less experience in the procedure. Since gland infarction and volume decreases have been associated with clinical improvements after PAE, cone-beam CT angiography also may assist in gauging the extent of the coverage of embolization and clue the operator to areas supplied by accessory or anastomotic branches not supplied by the target artery (18).

This study had several limitations, which included a relatively small sample size and the subjective nature of comparisons by the observers. Because the procedures were performed by 2 operators, image selection and interpretation were limited to these 2 observers, which can introduce bias into image selection. However, image comparison and assessment were performed by blinded observers who did not participate in the image selection process in order to mitigate this risk of bias. Initial injections made during the study generally had a higher contrast flow rate than in the later procedures, which may have caused reflux, and thus false positive instances of NTE detection. A direct comparison of adverse events related to NTE between the 2 protocols was not possible due to the low rate of serious adverse events in the study, which is in line with current literature. It would be useful to compare the rate of adverse events related to NTE, including skin necrosis, bladder or rectal injury, and pelvic pain, between PAE procedures performed with and without cone-beam CT angiography, and with a low-dose cone-beam CT angiography protocol, to further clarify the role of cone-beam CT angiography in this procedure. Technical and clinical success rates also were not comparable between protocols because some patients underwent PAE with cone-beam CT angiographies using a standard-dose and a low-dose protocol in the same procedure.

The present study demonstrates that a significant dose reduction (40%) can be achieved without compromising the diagnostic quality of cone-beam CT angiography during PAE. No difference in the detection of NTE was observed, suggesting that a 5-second spin time can be used to reduce radiation exposure without compromising the potential safety of PAE.

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