Original Investigation

Investigation of Radiation Dose Estimates and Image Quality Between Commercially Available Interventional Fluoroscopy Systems for Fluoroscopically Guided Interventional Procedures

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Rationale and Objectives: To investigate differences in radiation dose and image quality for single-plane flat-panel-detector based interventional fluoroscopy systems from two vendors using phantom study and clinical procedures.

Materials and Methods: AlluraClarityIQ (Philips) and Artis Q (Siemens-Healthineers) interventional fluoroscopy systems were evaluated. Phantom study included comparison of system-reported air-kerma rates (AKR) for clinical protocols with simulated patient thicknesses (20–40 cm). Differences in system-reported radiation dose estimates, cumulative-air-kerma (CAK) and kerma-area-product (KAP), for different clinical procedures were investigated. Subset analysis investigated differences in CAK, KAP and other factors affecting radiation dose when the same patients underwent repeat embolization procedures performed by the same physician on the two different fluoroscopy systems. Two blinded interventional radiologists reviewed image-quality for these procedures using a five-point scale (1–5; 5-best) for five parameters.

Results: Phantom study revealed that air-kerma rates was significantly higher for Artis Q system for 30-40cm of simulated patient thicknesses (p < 0.05). Overall data analysis from 4381 clinical cases revealed significant differences in CAK and KAP for certain procedures (p < 0.05); with significantly lower values for AlluraClarityIQ systems (median CAK lower by: 29%-58%). Subset analysis with 40 patients undergoing repeat embolization procedures on both systems revealed that median CAK and KAP were significantly lower for AlluraClarityIQ systems (p < 0.02) by 45% and 31%, respectively. Image quality scores for AlluraClarityIQ systems were significantly greater (mean difference range for five parameters: 1.3-1.6; p < 0.005).

Conclusion: Radiation dose and image quality differences were observed between AlluraClarityIQ and Artis Q systems. AlluraClarityIQ systems showed lower radiation utilization and an increase in subjective perception of image quality.

Key Words: Radiation dose; Image quality, Fluoroscopically guided interventional procedures; Embolization; Angiography.

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Abbreviations: AKR air kerma rate, CAK cumulative air kerma, DSA digital subtraction angiography, FPS frames per second, KAP kermaarea product

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INTRODUCTION

luoroscopy accounts for about 18% of the medical exposure related radiation, but it has the potential to impart some of the largest tissue doses to individual patients (1,2). The estimated range of doses from complex interventional fluoroscopy procedures is at least an order of magnitude higher relative to other diagnostic x-ray based examinations (1,2). Further, the number of fluoroscopically

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guided interventional procedures are increasing with approximately 9 million procedures performed annually in the United States (2). There have been several investigations into tissue reactions following interventional fluoroscopy procedures and into occupational exposure effects (3-7). Consequently, there have been many guidelines and regulations established to control radiation exposure during fluoroscopic procedures, both to the patient and to the staff members (2,7-12). These guidelines/regulations require the manufacturers of the interventional fluoroscopy system to indicate radiation dose estimates i.e., air kerma rate (AKR) and cumulative air kerma (CAK) at an interventional reference point and kerma-area product (KAP) (2,7). These dose indicators provide an indirect estimate of the incident skin dose to the patient. Threshold levels have been suggested for CAK and KAP such that values in excess of the threshold levels may elicit tissue reactions and thus, patient follow-up and counseling is considered prudent in such cases (2). There have been recent reports tracking these dose estimates for typical interventional fluoroscopy procedures (13,14).

In addition to the recommended guidelines and regulations to reduce radiation exposure to patients undergoing fluoroscopically guided interventional procedures and to members of staff, there have been technological advancements that have shown potential to reduce radiation utilization during these procedures. These advancements include adoption of flatpanel based image receptors, dynamic beam filtration, protocol-specific automatic dose rate regulation, and signal and image processing applications in real-time (15-19). Vendorspecific approaches for optimizing radiation dose during fluoroscopy procedures aim to maintain clinical task based image quality at acceptable noise levels (quantum mottle) with optimized radiation dose rates. There have been some investigations into comparing such vendor-specific dose optimization approaches, but these studies are limited to either in vitro evaluations (using phantoms) or comparisons between features and upgrades for a specific vendor (15,18,20). Radiation dose and image quality comparisons between interventional fluoroscopy systems from different vendors are rare. Such inter-vendor comparisons may highlight differences and provide a pathway for standardization in terms of radiation dose utilization and acceptable image quality for similar procedures (21).

Therefore, the purpose of this study was multifold: to compare system-reported AKR between interventional fluoroscopy systems from two vendors using phantoms, to compare radiation dose estimates from clinical procedures performed using these systems — including a subset analysis comparing radiation utilization for the same patients undergoing the same procedures performed by the same physician using these systems, and to investigate image quality in clinical cases performed using these systems.

MATERIAL AND METHODS

Data for this study were acquired from four commercially available single-plane flat-panel-detector based interventional

fluoroscopy systems manufactured by two manufacturers: Allura Xper FD20 with ClarityIQ and AlluraClarityIQ systems from Philips Healthcare (together referred to as Allura-ClarityIQ systems in this manuscript), and Artis Q system with Pure and Clear from Siemens Healthineers. One Philips Allura Xper FD20 system was manufactured in October-2009, installed in December-2009 and upgraded to ClarityIQ in December-2014. Other Philips Allura Xper FD20 system was manufactured in January-2011, installed in April-2011 and upgraded to ClarityIQ in December-2013. Philips AlluraClarityIQ system was manufactured in July-2014 and installed in September-2014. Siemens Artis Q system was manufactured in September-2015 and installed in November-2015. The software versions for Allura Xper FD20 systems upgraded to ClarityIQ were 8.1.17.2 and 8.2.17, for AlluraClarityIQ system was 8.2.25 and for Artis Q system was VD11C 161025. Note, ClarityIQ (from Philips) and Pure and Clear (from Siemens Healthineers) are a portfolio of image processing/dose optimization vendor-specific features provided with interventional fluoroscopy systems. Additional details about these vendor-specific features and systems are provided elsewhere (15, 18, 20) – specifically the details with respect to technology available on these fluoroscopy systems and how the kVp and mA modulation along with copper filtration changes work as per the systems' automatic exposure rate control logic for radiation dose optimization. In the respective sub-sections of this manuscript we have provided information about protocol selection and respective parameter settings.

Phantom Study

The purpose of this phantom study was to compare the radiation dose output of fluoroscopy systems under standardized conditions before comparing radiation dose estimates from clinical procedures. Two clinically used protocols were used for the phantom study – for the Artis Q system the protocol used was 'DSA Abdomen: 3 FPS' (FPS: frames per second) whereas for AlluraClarityIQ systems the protocol used was 'Abdomen 3 FPS'; both these protocols were configured to operate at 15 pulses per second (for the phantom study), by selecting this option from the available options for different pulse rates. We selected these specific protocols because in a subset analysis of the clinical study we compare radiation utilization in clinical cases performed using these protocols.

First, accuracy of the system-reported AKR at the interventional reference point (in mGy/min) was evaluated using a solid-state detector (AGMS-D detector with AGDM digitizer, Radcal Corporation, Monrovia, CA) for each interventional fluoroscopy system using standardized method (22). Then, acrylic sheets (30 cm x 30 cm x 0.5 cm) were used to simulate three levels of patient thicknesses: 20 cm, 30 cm and 40 cm. Acrylic sheets were placed on the patient table along with the table pad mimicking a clinical setup. Initially, source-to-image distance was set to a standard value of 100 cm (with 30 cm of acrylic thickness) and then adjusted

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with varying phantom thickness. For each level of simulated thickness, system-reported AKR was noted in the vendorconfigured 'Low-Dose' and 'Normal-Dose' modes. These measurements were performed for similar magnification modes for both types of systems (AlluraClarityIQ: 48 cm, 43 cm, 33 cm, 20 cm and 15 cm; Artis Q: 48 cm, 42 cm, 32 cm, 22 cm and 16 cm). For comparisons between systems, the system-reported AKR values for the Artis Q system were adjusted using an inverse square law correction factor to account for differences in the interventional reference point and in the floor-to-focal spot distance between the systems (20). AlluraClarityIQ system utilizes static beam filtering and the filter combinations used in 'Low-Dose' and 'Normal-Dose' modes are '0.4 mm Copper with 1.0 mm Aluminum' and '0.1 mm Copper and 1.0 mm Aluminum', respectively. Artis Q system utilizes dynamic filtering approach and the filtration changes depending on attenuation in the x-ray beam's path even for the same protocol. For reference, we also measured the half-value layer (indicating an x-ray beam's penetrability; in units of mm of Aluminum) for the 'Normal Dose Mode'. These measurements were performed for all the magnification modes considered in this study, using the AGMS-D solid-state detector along with the table and the table-pad in the x-ray beam's path.

Clinical Study

Institutional Review Board approved this retrospective review of radiation dose data from clinical cases with waived informed consent requirement. The clinical study was divided into three parts: an overall comparison of radiation utilization across different types of procedures, a controlled comparison of radiation utilization using the same patients treated using both systems, and an image quality comparison. For all three parts of the clinical study, clinical cases performed over a 16-month period were reviewed (December 2015 till March 2017). No changes were made to the protocols configured on the fluoroscopy systems during this study period.

Clinical Study – Overall Radiation Utilization Comparison: All interventional cases performed using the AlluraClarityIQ and Artis Q systems were extracted from Centricity RIS (GE Heathcare) and Dosemetrix (Primordial Design). All cases performed outside the interventional radiology suites at our academic medical center (e.g., an affiliated community hospital, vascular surgery operating room, etc.) were excluded. These cases were grouped by procedure codes. All procedure codes with greater than 30 cases (for statistical comparisons) performed on each type of system were included in the analysis. For the included cases, system-reported CAK (in units of mGy) at the interventional reference point, KAP (in units of mGy.cm²), and total fluoroscopy time were extracted. These values were reviewed and any typographical deletions/errors were corrected before comparison (these values were verified explicitly with the values displayed on the dose-capture screen report after completion of a procedure). Similar to the correction for the phantom study, CAK values reported by the Artis Q systems were adjusted using an inverse square law correction factor to account for inter-system differences.

Clinical Study – Radiation Utilization Comparison in a Controlled Subset: A subset analysis was performed for a controlled comparison of clinical radiation dose utilization. Patients with metastatic uveal melanoma receiving repeat chemo/ immuno-embolization of the same liver lobe performed in the same manner by the same physician (DJE, CFG, RDA) on AlluraClarityIQ and Artis Q systems were identified. These patients generally undergo repeated monthly treatment and on the day of treatment get randomly assigned to an interventional suite depending on clinical workflow. This was a source of randomization, such that in some cases the first treatment was performed on an Artis Q system and in other cases the first treatment was performed on an Allura-ClarityIQ system. Embolization procedures are potentially high-radiation dose procedures (2) and therefore identifying radiation dose differences for such a procedure may have radiation safety implications. In this subset, along with CAK, KAP and fluoroscopy time, factors that may account for differences in radiation dose utilization were also extracted from radiation dose structured reports using DoseMetrix (Primordial) and CareAnalytics (Siemens Healthineers). These factors were source to detector distance, tube kilo-voltage, number of digital acquisition sequences, total number of images in the digital acquisition sequences, tube angulations (primary and secondary angles) and longitudinal table positions. Additionally, two interventional radiologists (DJE and RDA) also reviewed the acquisition series and any 3D rotational acquisitions or additional acquisition sequences (attributable to contrast injection failure, etc.) were excluded (i.e., corresponding radiation dose values were subtracted from CAK and KAP) to reflect similar workflow on repeat procedures. This was done because radiation dose rates and dose contribution toward CAK is relatively high during digital acquisition sequences (as compared to routine fluoroscopy) and any additional sequences (either on AlluraClarityIQ or Artis Q system) would have biased the dose values. This ensured a controlled identical workflow on both the systems available for comparison on a case-by-case basis.

Clinical Study - Image Quality Review: Two experienced interventional radiologists (DJE and CFG; with 26 and 20 years of experience) performed a blinded image quality review (i.e., no identifying information of the system producing these images). The arteriogram sequences from Allura-ClarityIQ and Artis Q systems covering the same anatomy with the same projection were presented to the interventional radiologists for scoring of the following features on a five-point scale ranging from 1 (very poor) to 5 (excellent): visualization of blood vessels, distinction of blood vessels, visualization of tumor vasculature, noise texture (affecting image interpretation), and overall image quality. These five features were selected based on previous studies (15,18). Each interventional radiologist reviewed all the cases that were included in the controlled subset analysis for radiation utilization comparison for image quality, independently.

Statistical Analysis

For the phantom study, accuracy of system-reported AKR values was evaluated with reference to the acceptable tolerance level of $\pm 35\%$ (7). Pairwise comparisons of AKR between AlluraClarityIQ and Artis Q systems were performed for different dose modes and acrylic phantom thicknesses, with Bonferroni corrections for multiple comparisons. To compare overall radiation dose utilization in clinical cases, tests of normality were performed for CAK, KAP and total fluoroscopy time parameters. If there was no statistically significant difference from normality then Unpaired T-tests were used or else Mann-Whitney U tests were used to compare these three parameters between different interventional systems for each type of procedure code (with Bonferroni corrections for multiple comparisons). Even for the comparison of all parameters in the subset study, similar statistical methodology and tests were used with the exception that all parameters (e.g., source to detector distance, kV, etc.) were compared. For the image quality review, an interclass correlation coefficient (ICC) was computed to assess reliability between measurements performed by the two readers. Image quality review scores averaged over two readers were compared by using pairwise comparisons for each image quality parameter. IBM's SPSS statistics (version 24) was used for analysis. Results with *p-values* less than 0.05 were considered statistically significant.

RESULTS

Phantom Study

The magnitude of the maximum difference between systemreported and measured AKR for AlluraClarityIQ and Artis Q systems was 11% and 13%, respectively; for all of the systems, the reported AKR was more than the measured AKR. Table 1 shows the range of AKR values across the different magnification modes for the two types of systems. Note that the AKR values are reported at a fixed point in the center of the primary x-ray beam and were adjusted for the Artis Q system so that the fixed point represents the same distance from the x-ray tube focal spot and floor as for the AlluraClarityIQ systems. Differences between AlluraClarityIQ and Artis Q systems with simulated patient thickness of 20 cm were not significant (p value for 'Low-Dose' mode 0.13 and for 'Normal-Dose' mode 0.17). However, statistically significant differences were seen between the AlluraClarityIQ and Artis Q systems with simulated patient thicknesses of 30 cm and 40 cm for both of the dose modes ($p \le 0.05$; Fig 1). In the 'Low-Dose' mode, the mean difference (\pm standard deviation of the differences) in AKR between AlluraClarityIQ and Artis Q systems was 30.4 ± 0.7 mGy/min and 40.5 ± 0.8 for 30 cm and 40 cm of simulated patient thicknesses with AKR for AlluraClarityIQ systems being lower than for Artis Q systems. In the 'Normal-Dose' mode, the mean difference (\pm standard deviation) in AKR between AlluraClarityIQ and Artis Q systems was 18.7 ± 8.8 mGy/min and 19.9 ± 2.0 for 30 cm and 40 cm of simulated patient thicknesses with AKR for AlluraClarityIQ systems being lower than for Artis Q systems. For the Artis Q and AlluraClarityIQ systems the halfvalue layer measurements across the different magnification modes ranged from 5.8 to 6.5 mm of Aluminum and from 3.9 to 7.4 mm of Aluminum, respectively.

Clinical Study

Overall, data were obtained from 7950 cases during the 16month study period.

Clinical Study – Overall Radiation Utilization Comparison: After data exclusion criteria, there were 13 different types of procedures (Table 2) with greater than 30 cases performed on each type of system (AlluraClarityIQ and Artis Q). The total number of cases corresponding to these 13 different types of procedures were 4381. The number of cases per procedure ranged from 150 to 758. Tests of normality for CAK, KAP and fluoroscopy time revealed a statistically significant difference from normality for these three parameters ($p \le 0.05$) and therefore, nonparametric tests were performed for comparison between types of interventional fluoroscopy systems. Figure 2 shows the ratio for these three parameters as a function of procedure type expressed as the value obtained from Artis Q system divided by the value obtained from the AlluraClarityIQ system. The ratios for median and mean values are

TABLE 1. Range of AKR Values Across Different Magnification Modes Shown for Different Dose Modes and Acrylic Thicknesses for the Two Types of Systems/Protocols

Dose Mode	Acrylic	AKR Range (mGy/min)		
	Thickness (cm)	AlluraClarityIQ System Protocol: Abdomen 3 FPS	Artis Q System Protocol: DSA Abdomen: 3 FPS	
'Low'	20	4–11	7–23	
	30	12–13	42–44	
	40	15–16	56–57	
'Normal'	20	14–37	10–37	
	30	51-73	81-83	
	40	90-94	111–115	

AKR, air kerma rate; DSA, digital subtraction angiography; FPS, frames per second.



Simulated patient thicknesses with acrylic (cm)

Figure 1. Mean differences (with standard deviation) in system-reported air-kerma rates (AKR) between the AlluraClarityIQ and Artis Q systems after correcting for variations in the interventional reference point location [mean differences are expressed as AKR (Artis Q) – AKR (AlluraClarityIQ)] i.e., positive differences indicating that AKR for Artis Q was greater. Statistically significant differences ($p \le 0.05$) between the two types of systems are marked with an asterisk (*).

parison Along with Nu	mber of Cases Belonging to Each Procedure Code		
Procedure Code	Description	Number of Cases on AlluraClarityIQ Systems	Number of Cases on Artis Q System
IRARTCHEMO	Arteriogram chemo-/immuno- embolization	542	216

TABLE 2. Procedure Codes, with the Procedure Description, Included in the Clinical Study for Overall Radiation Utilization Com-
parison Along with Number of Cases Belonging to Each Procedure Code

		AlluraClarityIQ Systems	Artis Q System
IRARTCHEMO	Arteriogram chemo-/immuno- embolization	542	216
IRARTEMBO	Arteriogram embolization	166	38
IRCHKABSC	Drainage catheter check – abscess	530	200
IRCHKBILI	Drainage catheter check – biliary/Gl	198	52
IRCHNGABSC	Drainage catheter change – abscess	157	53
IRCHNGBILI	Drainage catheter change biliary/GI	181	58
IRCHNGGU	Drainage catheter change - GU	241	75
IRPLDRABSC	Drainage catheter placement – abscess	268	49
IRVACXPRT1	Venous access – chest port, single lumen	305	125
IRVAPHCN	Venous access – dialysis/catheter, non-tunneled	196	61
IRVAPHCT	Venous access – dialysis/catheter, tunneled	181	60
IRVAPICC1	Venous access – PICC, single lumen	118	32
IRVAPICC2	Venous access – PICC, double lumen	234	45

GI, gastrointestinal; GU, genitourinary; PICC, peripherally inserted central catheter.

shown (Fig 2) with a value greater than 1 indicating that the corresponding value for Artis Q system was greater than the value for the AlluraClarityIQ system. The Mann-Whitney U test revealed that CAK for eight (out of 13) procedure types, KAP for two (out of 13) procedure types and fluoroscopy time for one (out of 13) procedure type were statistically significantly greater ($p \leq$ 0.05) with the Artis Q system relative to the AlluraClarityIQ system. For those procedures in which CAK was statistically significantly different between these two types of systems, the range of differences in median CAK values was 29% to 58% with values for Artis Q system being



Figure 2. Ratio (Artis Q/AlluraClarityIQ) of cumulative air kerma (CAK; **a**), kerma-area product (KAP; **b**) and time (**c**) for different procedure codes. Both the ratios for median and mean values are shown along with a reference line at 1.0 indicating hypothetical equality in measured values from the two systems. Values greater than 1.0 indicate that the corresponding values for Artis Q system were relatively higher (procedure codes showing statistically significant differences in parameters between Artis Q and AlluraClarityIQ systems are marked with *).

significantly greater ($p \le 0.05$). Similarly, for two procedure types showing statistically significant differences in KAP, the value for Artis Q system was greater by 37% and 44%; for a single procedure type showing a significant difference in fluoroscopy time, the value for Artis Q system was greater by 27%.

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TABLE 3. Parameters Compared in the Subset Study When the Same Patients (n = 40) Underwent the Same Procedure Performed
by the Same Physician using Two Different Types of Systems (Note, Parameters Showing Statistically Significant Differences with
$ ho \leq$ 0.05 are Marked with *)

Parameter	AlluraClarityIQ System		Artis Q System	
	Mean \pm Standard Deviation	Median	Mean \pm Standard Deviation	Median
Cumulative air kerma (CAK; mGy) *	152 ± 150	126	$\textbf{308} \pm \textbf{275}$	231
CAK: fluoroscopy (mGy) *	75 ± 67	55	139 ± 108	126
CAK: angiography sequences (mGy) *	77 ± 85	64	169 ± 175	100
Kerma-area product (KAP; mGy.cm ²) *	49656 ± 42858	44150	89610 ± 83217	63754
KAP: fluoroscopy (mGy.cm ²)	$\textbf{14309} \pm \textbf{14334}$	9617	17832 ± 14857	14319
KAP: angiography sequences (mGy.cm ²) *	$\textbf{35347} \pm \textbf{31605}$	31201	$\textbf{71778} \pm \textbf{70183}$	46394
Total x-ray beam on time (minutes)	10 ± 4	10	11 ± 6	9
Source to detector distance (cm) *	98 ± 5	99	94 ± 3	93
Kilo-voltage (kV) *	91 ± 11	88	72 ± 3	72
Number of angiography sequences	5 ± 2	4	5 ± 2	4
Total images in angiography sequences	$\textbf{183} \pm \textbf{87}$	154	210 ± 127	170
Primary tube angle (°)	-0.1 \pm 0.8	0.0	-0.1 ± 1.3	0.0
Secondary tube angle (°)	0.0 ± 0.7	0.0	$\textbf{0.3}\pm\textbf{1.0}$	0.2
Table longitudinal position (cm)	23 ± 27	22	$\textbf{16} \pm \textbf{28}$	16

Clinical Study - Radiation Utilization Comparison in a Controlled Subset: This subset included 40 patients that underwent repeat chemo/immuno-embolization of the same lobe of the liver performed by the same physician on both AlluraClarityIQ and Artis Q systems at different time points. The interval between the repeat procedures ranged from 26 days to 337 days (mean: 95 days). Table 3 shows the statistical descriptors (mean, standard deviation and median) for parameters extracted for comparison between the systems; parameters between the AlluraClarityIQ and Artis Q systems showing a statistically significant difference are marked. Figure 3 shows the CAK and KAP values for the embolization procedures performed on the AlluraClarityIQ and Artis Q systems. For CAK, statistically significant differences were seen in total values (median CAK for Artis Q system greater by 45%) as well as CAK attributed to fluoroscopy (median CAK for Artis Q system greater by 56%) and acquisition sequences (median CAK for Artis Q system greater by 36%) ($p \leq$ 0.02). For KAP, statistically significant differences were seen in total values (median KAP for Artis Q system greater by 31%) and KAP attributed to acquisition sequences (median KAP for Artis Q system greater by 33%; $p \leq 0.02$), however the difference in KAP due to fluoroscopy was not significant (p = 0.11).

Clinical Study – Image Quality Review: Figure 4 shows representative images included in the image review. The average ICC were ≥ 0.75 and therefore, for all parameters, a good inter-reader reliability was noted. Given a good inter-reader reliability, average scores from both readers were used to compare images between different vendor systems. Table 4 shows the mean scores from the image quality review. Pairwise comparisons revealed a statistically significant difference (p < 0.005) with scores from the AlluraClarityIQ system

significantly greater compared to the scores from the Artis Q system across all parameters.

DISCUSSION

This study investigated differences between AlluraClarityIQ and Artis Q fluoroscopy systems in radiation dose utilization and image quality from a phantom study and based on data from 4381 clinical cases. Differences in radiation dose rates between AlluraClarity IQ and Artis Q systems were observed utilizing phantoms simulating different patient thicknesses, with statistically significant differences for relatively higher simulated patient thicknesses. This indicates that radiation dose rates and consequently radiation utilization between the two types of systems will be different for patients based on attenuation differences. Smaller patient thicknesses (i.e., patient thicknesses in the anterior-posterior dimension < 20cm) were not simulated in this study, however the differences with 20 cm simulated thickness were not significant implying that the results for even smaller thicknesses (< 20 cm) would not be different. Radiation dose differences observed in the phantom study were also reflected in the clinical study for different types of procedures (Table 2, Fig 2).

A controlled subset analysis further revealed that even for the same patients undergoing repeat embolization procedures of the same lobe of the liver performed by the same physician, the radiation dose differences were present between Allura-ClarityIQ and Artis Q systems. Interestingly, for this controlled subset, there were no statistically significant differences in fluoroscopy time, number of acquisition sequences, total number of images in the acquisition sequences, tube angulations or longitudinal table positions (Table 3). This indicates that the cases in the controlled subset were comparable in complexity and performed utilizing



Figure 3. Cumulative air kerma (CAK; **a**) and kerma-area product (KAP; **b**) for patients with metastatic uveal melanoma undergoing repeat chemo/immuno-embolization of the same liver lobe by the same physician on both types of systems (error bars indicate standard deviation). Differences between the AlluraClarityIQ and Artis Q systems in CAK and in KAP were statistically significant (p < 0.02), with lower radiation dose utilization for AlluraClarityIQ systems.

standardized workflow (including contrast administration and utilization). There was a statistically significant difference in kilo-voltage stemming from the type of automatic exposure rate control logic utilized by these interventional systems. The functioning of this automatic exposure rate control logic is detailed elsewhere (20). Briefly, the Artis Q system uses dynamic beam filtering during data acquisition whereas the AlluraClarityIQ system uses static beam filtering based on the selected clinical protocol and dose mode. In dynamic beam filtering approach, the filtration changes (even for a given protocol) as per the attenuation in the x-ray beam's path and other parameters (e.g., kilo-voltage, tube current, etc.). Whereas in static beam filtering approach, the filtration is dependent on the selected protocol and then other

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Figure 4. Representative celiac artery digital subtraction angiography (DSA) images obtained for the same patient on an AlluraClarityIQ system (a) and Artis Q system (b) performed by the same physician. Images are at the same window level/width settings.

TABLE 4. Mean Scores (From Two Interventional radiologists Across Reviewed Images) From Image Quality Review (Mean Difference was Statistically Significant Across all Parameters; p < 0.005)

Parameter	AlluraClarityIQ System	Artis Q System	Mean Difference
Visualization of blood vessels	$\textbf{4.7} \pm \textbf{0.3}$	$\textbf{3.4} \pm \textbf{0.5}$	1.3
Distinction of blood vessels	$\textbf{4.7} \pm \textbf{0.3}$	$\textbf{3.3} \pm \textbf{0.5}$	1.4
Visualization of tumor vessels	$\textbf{4.4} \pm \textbf{0.4}$	$\textbf{2.9} \pm \textbf{0.6}$	1.5
Noise texture	$\textbf{4.4} \pm \textbf{0.3}$	$\textbf{2.8} \pm \textbf{0.5}$	1.6
Overall image quality	$\textbf{4.6} \pm \textbf{0.3}$	$\textbf{3.1}\pm\textbf{0.5}$	1.5

impact of differences in source to detector distances (a factor

of 1.1) was less than the observed differences in median CAK

parameters (e.g., kilo-voltage, tube current, etc.) change as per the automatic exposure rate control logic. There was also a statistically significant difference in the source to detector distance with the median distance for all cases being 99 cm for AlluraClarityIQ system and 93 for Artis Q system. While this indicates a slightly different setup on each type of system, the difference in the median values may only account for a factor of 1.1 in radiation dose differences (based on inverse square law). Overall, median CAK and KAP were 45% and 31% greater for Artis Q relative to AlluraClarityIQ systems. Subjective perception of image quality (by two interventional radiologists) revealed significantly better scores for images obtained with AlluraClarityIQ systems.

There are several studies published regarding radiation doses for interventional fluoroscopy systems (2,3,13–15,18,20). Some of these studies have looked at patient monitoring and followup after potentially-high radiation dose procedures (3,14), while some studies have looked at cumulative radiation dose utilization based on all interventional fluoroscopy systems at a particular site (2,13). There are other studies that have looked at the impact of vendor-specific product upgrades on radiation dose and image quality (15,18); however these studies are limited to comparisons of radiation dose and image quality for fluoroscopy systems from the same vendor (before and after upgrades). Another study comparing radiation dose utilization between fluoroscopy systems from different vendors was performed, but it was limited to investigations utilizing phantoms only (20). The present study is different from the above-mentioned studies because it incorporates multi-vendor fluoroscopy systems for several common interventional procedures, including the same patients who were treated for the same clinical condition by the same physician on systems from different vendors. Such single-site multivendor comparisons are needed to identify differences between fluoroscopy systems from different vendors. Identification of these differences may pave a path for standardization between different fluoroscopy systems in terms of radiation dose utilization and acceptable image quality for similar procedures. With the growing trend of mergers and acquisitions in the healthcare industry (23), multi-vendor sites are not uncommon and thus, standardization of protocols, procedures and workflows are desired. Overall, investigation of radiation dose utilization for fluoroscopically guided interventional procedures between systems from different vendors performed in this study revealed differences in radiation dose (and image quality) levels, that may have implications for radiation dose management.

Limitations of this study include comparison of multi-vendor systems at a single site, no calculation of peak skin dose to the patient, subjective image quality assessment, retrospective study design, and lack of proprietary information about the dose modulation and image processing features on Allura-ClarityIQ and Artis Q systems (that contributed to the reported differences in radiation dose and image quality). Peak skin dose calculation is based on CAK values reported by the system taking into account other factors like source to detector distance (24), but these methods have been shown to have uncertainty as high as 50% (25). In the present study, values (45%) for the subset study. Thus, the calculated peak skin doses (based on CAK) would still be higher for Artis Q systems relative to AlluraClarityIQ systems for these cases. The retrospective design prevented any potential bias by performing physician towards any type of interventional fluoroscopy system. Additionally, for the subset study, some of the patients underwent the embolization procedure for the first time on the Artis Q system while other patients underwent the embolization procedure for the first time on the Allura-ClarityIQ system. Therefore, there was randomization in terms of the type of system used during the first embolization procedure which mitigates any bias originating from a physician's prior knowledge of patient anatomy. Variability in the overall comparison of 4381 clinical cases (segregated by procedure type) may be substantial and attributed to confounders including but not limited to operator ability, anatomy, patient body habitus, equipment setting, study type, etc. But, the controlled subset analysis of 40 patients that underwent repeat chemo/immuno-embolization of the same lobe of the liver performed by the same physician on different systems substantiates the inference from the overall comparison of 4381 cases in reference to radiation utilization between the two types of fluoroscopy systems. While interventional fluoroscopy systems from limited vendors (all vendors at the current site) were compared in this study, such an analysis including systems from other vendors and different sites may highlight implications for radiation dose management. Given there were more AlluraClarityIQ systems, the relative time spent by an interventional radiologist in an interventional radiology suite with ClarityIQ system is more than it is with the Artis Q system, and that this may have contributed to the subjective evaluation of image quality. Lastly, subjective evaluation of image quality was performed in this study for comparing different systems; objective evaluations using test phantoms would have been useful for image quality comparisons except that quantitative metrics derived from standard fluoroscopy phantoms have been shown to lack the discriminatory ability to assess vendor-specific advancements in interventional fluoroscopy systems¹.

CONCLUSIONS

In conclusion, radiation dose and image quality differences were observed between AlluraClarityIQ and Artis Q systems in phantom and clinical studies even for same patients treated on both types of systems. When the differences were significant, AlluraClarityIQ systems showed lower radiation utilization and an increase in subjective perception of image quality.

¹ Forsberg MA, Talreja P, Eschelman DJ and Dave JK. Do quantitative metrics derived from standard fluoroscopy phantoms used for quality control assess vendor-specific advancements in interventional fluoroscopy systems? Proc. SPIE 10136, Medical Imaging 2017: Image Perception, Observer Performance, and Technology Assessment, 1013619; (DOI: http://dx.doi.org/ 10.1117/12.2254561).

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