Effect of a low-dose interventional x-ray system on radiation exposure in the higher body surface area patient population

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ABSTRACT

Low-dose interventional x-ray systems have been shown to substantially reduce radiation dose in the pediatric and adult structural and interventional realm. We evaluated our single-center experience with Philips AlluraClarity software for all cardiovascular procedures; we also compared performance relative to patient body size. A total of 1155 patients were included. Data on dose area product (DAP) for radiation exposure, along with body surface area (BSA) and fluoroscopy time, were retrospectively collected for 467 patients before implementation of the Clarity system and for 688 patients after system implementation. DAP was then compared to BSA and fluoroscopy time. BSA was categorized into four quartiles to assess the relationship between radiation dose across small to large patient size populations. The mean BSA between two groups was similar (2.03 vs 2.02 m², $P=0.48$), with a 44.7% reduction in radiation dose with DAP indexed to BSA. A significant reduction in radiation dose was seen across all quartiles, with the highest reduction in the post-Clarity sample population with the largest BSA. Fluoroscopy time in the pre-Clarity period was lower than in the post-Clarity period (mean of 7.6 vs 10.2 min; $P\leq 0.001$), with a total 57.7% radiation dose reduction with DAP indexed to fluoroscopy time ($P\leq 0.001$). There was a 45.2% overall decrease in radiation dose with AlluraClarity ($P\leq 0.001$). In conclusion, AlluraClarity significantly reduced overall radiation dose, irrespective of BSA. The largest reduction in radiation was seen in patients with the highest BSA, suggesting that obese patients derive the most benefit. To our knowledge, this is the first study to describe this relationship with BSA and AlluraClarity. The Clarity system also substantially reduced radiation dose despite longer fluoroscopy time.

KEYWORDS Body surface area; cardiac catheterization; interventional cardiology; interventional procedures; low-dose x-ray; obesity; radiation safety

The field of interventional cardiology has seen tremendous growth in the past decade, with the expansion of minimally invasive percutaneous procedures for complex coronary and structural interventions. These advances have increased patient access to beneficial procedures, particularly for patients at prohibitively high surgical risk.^{1,2} Minimizing radiation exposure and procedure time is an important quality and safety measure that affects both the patient and laboratory staff. Philips introduced the AlluraClarity live image guidance system in 2013, which offers a lower radiation dose without

compromising image quality, irrespective of patient size.^{3,4} More than 500 elements are fine-tuned and dependent upon the individual field's needs. For cardiology procedures, the motion compensation feature enhances image quality and reduces temporal noise, and the Xper C-arm acquires angiographic views in a curved trajectory rather than multiple acquisitions. For vascular procedures where digital subtraction is commonly used, advanced spatial filtering highlights structures and reduces background noise, and filtering is enhanced with high-speed parallel processing compared with the conventional sequential manner. Real-time pixel shift is

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Table 1. Radiation dose (indexed to BSA and fluoroscopy time), patient size, and procedure time before and after installation of AlluraClarity

	Pre-AlluraClarity (N = 467)	Post-AlluraClarity (N = 688)	P value
DAP (mGy cm ²)	104,163.52	57,094.27	<0.001
BSA (m ²)	2.03	2.02	0.48
DAP (mGy cm ²)/BSA (m ²)	50,659.17	28,029.83	<0.001
Fluoroscopy time (min)	7.59	10.19	<0.001
DAP (mGy cm ²)/fluoroscopy time (min)	18,371.22	77,67.98	<0.001

BSA indicates body surface area; DAP, dose area product.

applied in neuroradiology procedures to visualize small vessels. Less scatter radiation has been reported, reducing radiation to physicians and staff. All these features make the ClarityIQ system more efficient and allow it to acquire images of better quality with less radiation dose.⁵ Thus far, studies of the Clarity system have shown promising results, with up to 75% dose reduction for coronary angiography, 40% for electrophysiology interventions, 83% for digital artery subtraction, and 43% for transcatheter aortic valve implantation.^{6–8} We sought to define our single-center experience with respect to dose area product (DAP), a product of total radiation dose absorbed multiplied by area of tissue irradiated. We analyzed DAP indexed to body surface area (BSA) and its relationship across patient sizes ranging from small to large. In addition, we compared mean fluoroscopy time and its relationship to DAP. To our knowledge, this is the first study to look at BSA and its relationship to the low-dose interventional x-ray system.

METHODS

This retrospective, observational study was conducted at the Salem Veterans Affairs Medical Center in Salem, Virginia. One year of patient data was compared between two systems: the FD 20 fluoroscopy system with the pre-Clarity reference technology AlluraXper, March 31, 2013, to February 28, 2014, and Philips AlluraClarity, from July 1, 2015, to June 30, 2016. Included in the study were all procedures involving diagnostic or interventional cardiac catheterization or a peripheral artery procedure, right heart catheterization, intra-aortic balloon pump insertion, pericardiocentesis, or transvenous pacemaker insertion. Procedures with missing data on BSA, fluoroscopy time, or DAP were excluded.

Data were gathered from the cardiac catheterization clinical application, Clinical Assessment, Reporting, and Tracking System for Cardiac Catheterization Laboratories (CART-CL). The study was reviewed and approved by the institutional review board at Salem Veterans Affairs Medical Center.

Table 2. Absolute difference and percentage change before and after installation of AlluraClarity

	Absolute difference	% Change
DAP (mGy cm ²)	47,069.25	45.19%
BSA (m ²)	0.01	0.51%
DAP (mGy cm ²)/BSA (m ²)	22,629.35	44.67%
Fluoroscopy time (min)	–2.60	–34.27%
DAP (mGy cm ²)/fluoroscopy time (min)	10,603.24	57.72%

BSA indicates body surface area; DAP, dose area product.

A two-tailed Student *t* test was used to compare DAP, DAP indexed to BSA, DAP by BSA divided into evenly populated quartiles, and DAP indexed to fluoroscopy time in minutes. Absolute difference and percentage change between the two periods were also analyzed. A *P* value <0.05 was considered significant.

RESULTS

Data for 1155 patients were included in the final analysis, with 467 in the pre-Clarity period and 688 in the post-Clarity period. Five patients with missing data were excluded from the study, one from the pre-Clarity group and four from the post-Clarity group. There was no difference in mean BSA in the two study groups (*Table 1*). Mean fluoroscopy time was significantly lower in the pre-Clarity group (7.6 vs 10.2 min; *P* ≤ 0.001, *Table 1*). A 45.2% decrease in DAP was achieved with AlluraClarity in our study population: the mean DAP was 104,163 mGy cm² in the pre-Clarity group versus 57,094.3 mGy cm² in the post-Clarity group, an absolute difference of 47,069 mGy cm² (*P* ≤ 0.001, *Tables 1 and 2*, *Figure 1*).

A 44.7% overall reduction in radiation dose was seen when DAP was indexed to BSA in the post-Clarity group (absolute difference 22,629 mGy cm²/m²; *P* ≤ 0.001; *Table 2*). Patients were divided into quartiles of BSA (*Table 3*). The mean DAP was higher in all four quartiles pre-Clarity compared with post-

Figure 1. Histogram depicting the distribution of total dose area product values before and after installation of AlluraClarity.

Table 3. BSA divided into four quartiles with evaluation of mean dose area product before and after installation of AlluraClarity

Quartiles	BSA (m ²)	Mean DAP (mGy cm ²)		Absolute difference	P value
		Pre-Clarity	Post-Clarity		
1	0–1.9	81,603	41,989	39,614	<0.001
2	1.9–2	90,735	58,426	32,309	<0.001
3	2–2.2	104,381	64,050	40,332	<0.001
4	>2.2	159,224	69,386	89,838	<0.001

BSA indicates body surface area; DAP, dose area product.

Clarity ($P < 0.001$ for all). The largest dose reduction was seen in the largest patients in the fourth quartile (Figure 2).

A 57.7% reduction in radiation dose was seen when DAP was indexed to fluoroscopy time. The mean DAP was 18,371 mGy cm²/min pre-Clarity versus 7768 mGy cm²/min post-Clarity ($P \leq 0.001$, Table 2). There was a linear correlation between DAP and fluoroscopy time both pre- and post-Clarity (Figure 3).

DISCUSSION

The harmful effects of ionizing radiation are well recognized and include both acute (deterministic) effects and cumulative (stochastic) effects. These are universally recognized as important for both patients and providers. The gold standard for current radiology laboratories worldwide is to follow the ALARA (as low as reasonably achievable) method to minimize radiation dose by practicing three key safety principles: minimizing time of exposure, doubling distance from exposure, and using lead or Plexiglas shielding.⁹ Despite adherence to these models, a significant risk remains.

Radiation with interventional procedures may cause skin erythema, ulcers, cataracts, and malignancies.^{10,11} A concerning predominance of left-sided brain tumors in interventional cardiologists and radiologists, who stand with their left side adjacent to the radiation source, has been reported.¹² AlluraClarity has been shown to significantly reduce radiation exposure in neurointerventional, cardiac structural/interventional, and interventional radiology procedures.^{3–8} Our single-center experience adds further support and, particularly, shows a greater reduction in patients with larger BSA. The AlluraClarity system reduced radiation exposure even with longer fluoroscopy time, with a mean reduction in radiation dose from 104,163.52 mGy cm² to 57,094.27 mGy cm² ($P < 0.001$).

To our knowledge, this is the first study to evaluate the performance of AlluraClarity with respect to BSA. We opted to use BSA instead of weight or body mass index for clinical significance, since it has been shown to be a better indicator of metabolic mass.¹³ Obese patients have been shown to

Figure 2. Body surface area divided into evenly populated quartiles related to dose area product. A significantly lower radiation dose was seen across all four quartiles of body surface area ($P \leq 0.001$), with the largest absolute difference in patients with the largest body surface area.

receive more than twice the radiation dose of normal-weight patients.¹⁴ We divided our sample population into four quartiles from smallest to largest BSA. A statistically significant reduction in patient radiation dose was seen across all four quartiles, but the largest reduction was seen in the fourth quartile group with the highest BSA. This signifies that more obese patients may derive the most net clinical benefit. A 44.7% overall radiation dose reduction was seen with DAP indexed to BSA (Tables 1–3, Figure 2).

Mean fluoroscopy time was higher in the post-Clarity group likely due to an increase in the number of peripheral and complex coronary procedures performed in that period. These procedures typically take longer and subsequently have an increased fluoroscopy time. Second, we experienced an increase in the proportion of coronary interventions in the post-Clarity period, which also likely increased procedure and fluoroscopy time. Despite the increased fluoroscopy time, we still observed a reduction in mean radiation dose. A 57.7% reduction in radiation dose was seen with DAP over fluoroscopy time. If this trend toward more complex peripheral and coronary interventions continues, then the radiation reduction benefits of AlluraClarity will be even more impactful.

This study had several limitations. First, it was an observational retrospective study and not conducted in a randomized manner. It did not account for day-to-day variances related to staff, operator, or procedure, which can be better controlled with randomization. We also looked at all cardiac catheterization laboratory procedures. Correlating similar procedures may affect results, as peripheral and complex, higher-risk procedures require longer procedure time and higher radiation doses.

In conclusion, AlluraClarity reduced patient radiation dose by 45.2%. This reduction was significant despite longer procedure times. Importantly, the x-ray system reduced radiation exposure irrespective of BSA, with the largest reduction in those with the highest BSA. As the field of interventional cardiology continues to see landmark growth with structural and complex procedures among high-risk patients requiring increased fluoroscopy times, adopting practices to reduce radiation dose becomes increasingly important.

Figure 3. Dose area product for all procedures related to fluoroscopy time before AlluraClarity (blue, $n=467$) and after AlluraClarity (orange, $n=688$). There was a linear correlation between dose area product and fluoroscopy time. The trend line for the pre-AlluraClarity period indicated a higher dose area product compared to the post-AlluraClarity period for (a) all fluoroscopy times and (b) shorter fluoroscopy times (magnifying the black box from part a).

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