


ORIGINAL STUDIES

A retrospective study of radiation dose measurements comparing different cath lab X-ray systems in a sample population of patients undergoing percutaneous coronary intervention for chronic total occlusions

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Abstract

Objectives: A retrospective study was performed to investigate if the generation of X-ray system used was an independent factor for radiation dose in chronic total occlusion (CTO) percutaneous coronary intervention (PCI).

Background: PCI procedures for CTOs are known to be associated with higher doses of radiation. The authors suspected progressive reductions in radiation doses for CTO PCI as newer X-ray systems were introduced into clinical practice.

Methods: Procedures performed over a five-year period by three interventional cardiologists were retrospectively reviewed. Five different X-ray systems were used across three hospital sites. These included: Axiom Artis and Coroskop HIP (both Siemens), Innova (GE), Allura Xper FD 10, and Allura Clarity FD 10 (both Philips). Procedural and demographic data including body mass index (BMI; kg/m²), fluoroscopy time (min), and dose area product (DAP; cGycm²) were collated for each procedure. Statistical analysis was performed to compare the influence each X-ray system would have on DAP values after BMI and fluoroscopy time were controlled for.

Results: In total, 860 procedures were analyzed. Mean fluoroscopy time was 40.00 ± 19.99 min, mean BMI was 29.90 ± 5.13 kg/m², mean DAP 11,980 ± 7,947 cGycm². Log values of DAP were used to normalize results in a general linear model. A significant statistical difference in DAP between X-ray systems was demonstrated after fluoroscopy time and BMI were controlled for ($P \leq 0.001$).

Conclusion: There is a significant impact on DAP values resulting from the generation of X-ray system used, measured during PCI for CTOs, with the most modern systems producing the lowest radiation doses.

KEYWORDS

angiographic systems, 3-D/digital subtraction/radiation (ANGS), coronary artery disease (CAD), chronic total occlusion (CTO), percutaneous coronary intervention (PCI), radiation physics/dosimetry (RADI), stent, drug eluting (DES)

Abbreviations: ADR, antegrade dissection and re-entry; AK, Air Kerma; ALARA, as low as reasonably achievable; AWE, antegrade wire escalation; BMI, body mass index; CTO, chronic total occlusion; DAP, dose area product; DRL, dose reference levels; PCI, percutaneous coronary intervention; RDR, retrograde dissection and re-entry; RWE, retrograde wire escalation; SD, standard deviation; TAVI, trans-catheter aortic valve implantation.

There was no involvement of industry in this retrospective study

1 | INTRODUCTION

While ionizing radiation is essential in a number of medical and surgical specialties, it remains a hazard for both patients and individuals working in these areas. This is particularly relevant for cardiac interventions due to a large volume of cases per day and the potential for long periods of fluoroscopy and cinematic acquisition. Chronic total occlusion (CTO) percutaneous coronary intervention (PCI) is a complex procedure that is known to be associated with both longer fluoroscopy times and increased radiation dose [1–4].

A variety of consensus documents recommend that quality assurance and quality improvement systems and processes should be standard for all cardiac catheter laboratory equipped facilities [5–7]. Components of these programs include: clinical proficiency, equipment management/maintenance, peer review/data submission for benchmarking and optimization of radiation safety for patients as well as staff [5,6]. It is important to effectively measure radiation doses acquired by patients and cath lab personnel in order to minimize potentially harmful stochastic or deterministic effects. Furthermore, steps should be taken to continually audit clinical practice with the aim of minimizing radiation doses as a continuous process. In common with any diagnostic or interventional procedure that uses ionizing radiation, CTO PCI should also be performed according to the ALARA (as low as reasonably achievable) principle [5,8,9].

Different measurements can be used to assess radiation dose. These include Air Kerma (AK) and dose area product (DAP). Kerma is a term derived from “kinetic energy released in material” [8]. AK refers to the sum of the kinetic energy of all of the charged particles liberated per unit mass of air. This is a measurement of energy that reflects ionization in air and not tissue. Therefore, this does not directly quantify the effect of radiation in humans. DAP is calculated as the product of the dose in air in a given plane and the area of the irradiating beam. DAP is less dependent on the distance from the X-ray source and is generally viewed as a better assessment of patient exposure. Indeed, this is the gold standard for benchmarking and data returns in the United Kingdom.

In addition to standard recommended procedures, we have adopted a number of routine maneuvers in CTO PCI in an effort to reduce radiation exposure to both patients and staff. In routine PCI, fluoroscopy usually comprises the majority of the total X-ray procedure time but only 40% of the total radiation exposure to staff and patients. Cine angiography, although representing a minority of the total procedure time, accounts for approximately 60% of the total radiation exposure to staff and patients [10]. In view of this, recurrent fluoroscopic stores are preferred to acquisition runs throughout CTO PCI in our centers. Furthermore, lower frame rates (7.5 frames per second) are also routinely selected for both fluoroscopy and acquisition where practicable. Single plane, shallow angulations are preferred with the image intensifier (e.g. right or left anterior oblique 30° for work within the right coronary artery) [11]. In our experience, the access site does not adversely affect radiation exposure [12]. The RADPAD protective drape is used routinely to reduce staff exposure [13].

As X-ray systems have evolved, in general, radiation exposure has reduced over time. Christopoulos et al. showed using an anthropomorphic phantom, significant differences were identified between different manufacturers in terms of radiation doses in comparable views [14]. Our impression from clinical practice over several years was that more modern X-ray systems were associated with lower doses per procedure. These newer machines allow for a variety of different algorithms to decrease X-ray dose, while maintaining image quality. The purpose of this retrospective study was to assess if this was the case in a real world population of patients undergoing PCI for CTOs.

2 | METHODS

A sample of 860 CTO PCI procedures was performed in 802 patients between 17/03/2011 and 15/06/2016 across three sites (Belfast City Hospital, Belfast, Northern Ireland; Royal Edinburgh Infirmary, Edinburgh, Scotland; Royal Victoria Hospital, Belfast, Northern Ireland). A total of five different fluoroscopy X-ray machines were used with the following protocols:

Lab 1 Coroskop HIP (Siemens) year of manufacture 1996 cine frame rate: 7.5 frames per second/fluoroscopy: 7.5 pulses per second. This lab was decommissioned in 2014.

Lab 2 Axiom Artis (Siemens) year of manufacture 2005, cine frame rate: 7.5 frames per second/fluoroscopy: 6 pulses per second.

Lab 3 Innova (GE) year of manufacture 2005, cine frame rate: 7.5 frames per second/fluoroscopy: 7.5 pulses per second.

Lab 4 Allura Xper FD 10 (Philips) year of manufacture 2012, cine frame rate: 7.5 frames per second/fluoroscopy: 15 pulses per second at 50% standard radiation dose.

Lab 5 Allura Clarity FD 10 (Philips) year of manufacture 2015, cine frame rate: 15 frames per second at 25% standard radiation dose/fluoroscopy: 15 pulses per second at 25% standard radiation dose.

Procedural and demographic data were collected from an anonymized online audit tool that is used to collate outcome data for consecutive CTO PCIs. Data fields for analysis included: date of procedure; hospital site; fluoroscopy X-ray system used in each case; total fluoroscopy time (minutes); frame rate per second of each X-ray system; patient body mass index (BMI, kg/m²); DAP (cGycm²); J-CTO score. The J-CTO score (Multi-Centre CTO Registry of Japan) is a validated and widely used assessment of CTO lesion complexity. This five-point system scores lesions according to angiographic and clinical factors. These include the presence or absence of a blunt stump (present = 1 point), CTO lesion length (>20 mm = 1 point), within CTO tortuosity (present = 1 point), visible calcification within the CTO segment on angiography (present = 1 point) and whether or not there was a previous attempt to cross the lesion (yes = 1 point). Lesion complexity can be grouped as easy (J-CTO 0), 1 intermediate (J-CTO 1), difficult (J-CTO 2), and very difficult (J-CTO ≥3) [15].

CTO PCIs were all performed by expert operators with a lifetime experience of >1,000 CTO PCIs each, inclusive of the cases from this audit. The procedural approaches were at the discretion of the operating cardiologist, but were performed in line with the hybrid algorithm

TABLE 1 Summary of demographic and radiation data for each X-ray system

X-ray system	Procedure number	Mean fluoroscopy time \pm SD (min)	Mean DAP \pm SD (cGycm ²)	Mean BMI \pm SD (kg/m ²)	Mean JCTO score \pm SD
Coroskop HIP (Siemens, 1996)	77 (9%)	39.19 \pm 21.09	14,608 \pm 9,132 Range (1,766-53,815)	29.26 \pm 4.47	2.86 \pm 1.44
Axiom Artis (Siemens, 2005)	284 (33%)	38.52 \pm 19.39	11,774 \pm 7,039 Range (1,000-43,685)	29.78 \pm 5.30	2.73 \pm 1.38
Innova (GE, 2005)	294 (34%)	42.15 \pm 20.97	13,429 \pm 8,932 Range (1,200-53,980)	30.02 \pm 5.19	3.14 \pm 1.32
Allura Xper FD 10 (Philips, 2012)	88 (10%)	40.02 \pm 18.18	9,736 \pm 6,131 Range (1,272-36,837)	29.55 \pm 4.53	2.72 \pm 1.46
Allura Clarity FD 10 (Philips, 2015)	117 (14%)	38.70 \pm 18.32	8,772 \pm 6,180 Range (1,178-51,990)	30.30 \pm 5.49	2.70 \pm 1.27

BMI, body mass index; DAP, dose area product; JCTO score, multi-centre CTO Registry of Japan scoring system used to assess CTO lesion complexity; SD, standard deviation.

[16]. Strategies to cross lesions included antegrade wire escalation (AWE), antegrade dissection and re-entry (ADR), retrograde wire escalation (RWE), and retrograde dissection and re-entry (RDR) with CTO anatomy used to determine the initial approach to the lesion, but early switches in strategy carried out if a procedure stalled. Our local practice and its outcomes are described in detail elsewhere [17].

Statistical analysis was performed to show if the type of X-ray system used produced a significant difference in total radiation dose, measured as the DAP, when the confounding variables of BMI and fluoroscopy time were controlled for using a general linear regression analysis. The following parameters were entered into the model: X-ray system, BMI, fluoroscopy time, and the log values of the DAP. The five different X-ray systems were used as the nominal independent variable along with BMI and fluoroscopy time as continuous independent variables and log values of DAP as the continuous dependent variable (log values of DAP were used to obtain a normal distribution). Correlation calculations were performed to show the relationships between lesion

complexity (JCTO score) and DAP; BMI and DAP. Mean values \pm SD of DAP, fluoroscopy time, BMI, and mean JCTO score were also calculated for each X-ray system.

A *P* value of <0.05 was considered statistically significant. All analyses were carried out using statistics software (IBM-SPSS Statistics Version 21), applying correlation and general linear regression models.

3 | RESULTS

Complete data were available for all 860 procedures. The overall percentage success for CTO PCI per lesion in this cohort was 92% with a final approach to the lesion being AWE in 39%, antegrade dissection re-entry in 24%, RWE in 5%, and retrograde dissection re-entry in 32%. The mean fluoroscopy time was 39.65 \pm 19.99 min; range 5.00–108.00 min. The mean BMI was 29.90 \pm 5.13 kg/m²; range 17.43–62.80 kg/m². The mean DAP was 11,980 \pm 7,947 cGycm²; range 1,000–53,980 cGycm². Demographic and radiographic details are presented in Table 1.

There was no statistical difference of the recorded BMIs (*P* = 0.58) or fluoroscopy times (*P* = 0.23) between X-ray system patient groups (Figure 1).

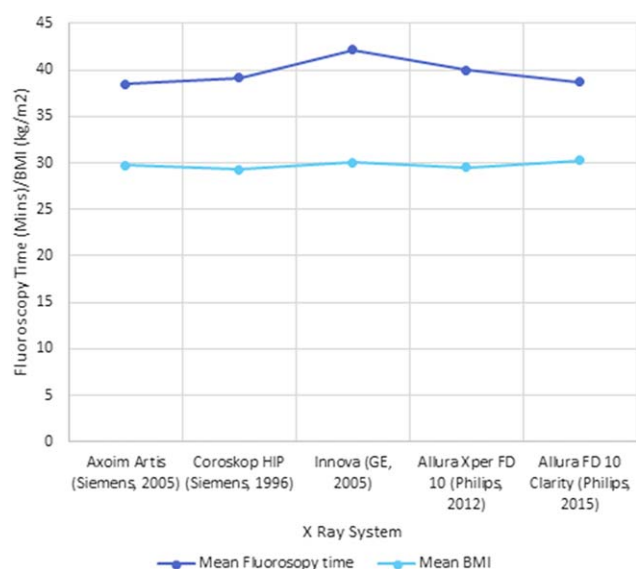


FIGURE 1 Graph showing relationship of mean fluoroscopy and BMI between X-ray systems. BMI, body mass index (kg/m²) [Color figure can be viewed at wileyonlinelibrary.com]

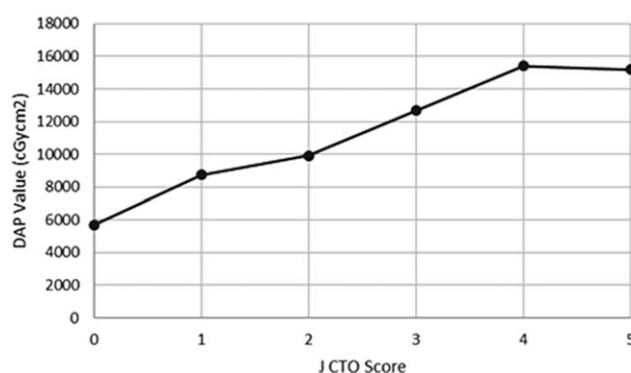


FIGURE 2 Graph of mean DAP values against JCTO Score for all X-ray systems. DAP, dose area product; JCTO Score, Multi-Centre CTO Registry of Japan scoring system used to assess CTO lesion complexity

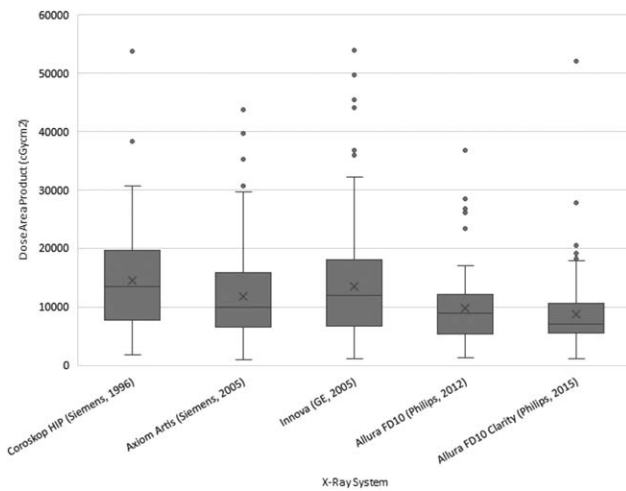


FIGURE 3 Graph of unadjusted dose area product data for each X-ray system

As expected, lesion complexity as defined by the JCTO score, showed a strong correlation with an increase in DAP (Figure 2). Variations in DAP were mainly driven by fluoroscopy time and BMI.

The unadjusted DAP data for each X-ray system is shown in Figure 3. There is a decreasing trend of recorded DAP values as more modern X-ray systems are used, despite no significant intersystem difference in fluoroscopy times. There is also less variability in the range of DAP values recorded with the more modern X-ray systems.

To analyze the impact of the X-ray system on DAP values, log values of DAP were used to obtain a normal distribution (Figure 4). There was a significant statistical difference in DAP values, accounted for by the X-ray system type, when fluoroscopy time and BMI were controlled for, using a general linear regression model ($P \leq 0.001$) (Table 2).

The five systems could be divided into three groups with respect to statistical differences (Figures 4 and 5).

- Lab 1, Coroskop HIP (Siemens, 1996).
- Labs 2, Axiom Artis (Siemens 2005) and 3, Innova (GE, 2005).
- Labs 4, Allura Xper FD10 (Philips, 2012) and 5, Allura Clarity FD 10 (Philips, 2015).

4 | DISCUSSION

This study demonstrates a statistically significant difference in DAP values between different X-ray systems in a cohort of patients undergoing CTO PCI with the most modern systems producing the lowest radiation doses and the older systems producing the highest doses in our patient cohort.

Fetterly et al. showed a 40% decrease in the radiation dose administered to patients over a three-year period following the uniform implementation of a number of practice and technical changes. The main driver was a reduction in fluoroscopy time and cine angiography [18]. As mentioned previously, our practice has already been continuously

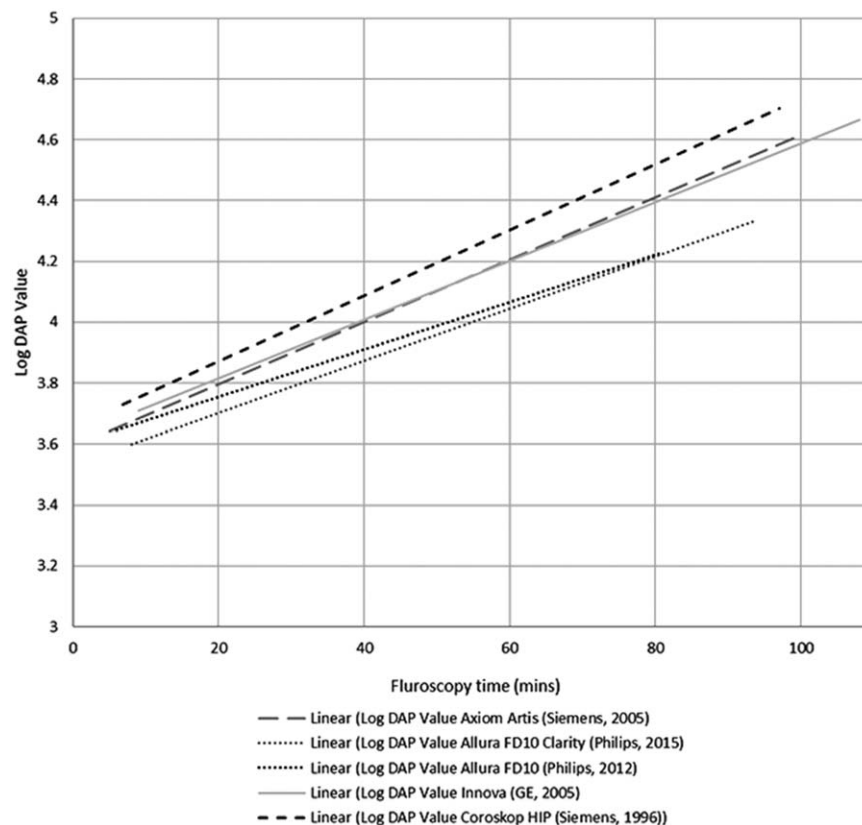


FIGURE 4 Graph showing linear trendline of logarithmic dose area product (DAP) values against fluoroscopy time highlighting the five different X-ray groups. Log DAP, logarithmic value of dose area product

TABLE 2 Pairwise comparisons of X-ray systems using log values of the dose area product (DAP) as the dependent variable

X-ray machine	X-ray machine	Mean difference of DAP log values	Std. error	Sig. ^a	95% confidence interval for difference ^a	
					Lower bound	Upper bound
Axiom Artis (Siemens, 2005)	Coroskop HIP	-0.080 ^b	0.025	0.002	-0.130	-0.030
	Innova	0.014	0.017	0.407	-0.019	0.047
	Allura Xper FD 10	0.091 ^b	0.025	0.0002	0.042	0.139
	AlluraClarity FD10	0.146 ^b	0.023	<0.0001	0.101	0.191
Coroskop HIP (Siemens, 1996)	Axiom Artis	0.080 ^b	0.025	0.002	0.030	0.130
	Innova	0.094 ^b	0.025	0.0002	0.045	0.143
	Allura Xper FD 10	0.171 ^b	0.031	<0.0001	0.110	0.231
	AlluraClarity FD10	0.225 ^b	0.029	<0.0001	0.168	0.283
Innova (GE, 2005)	Axiom Artis	-0.014	0.017	0.407	-0.047	0.019
	Coroskop HIP	-0.094 ^b	0.025	0.0002	-0.143	-0.045
	Allura Xper FD 10	0.077 ^b	0.024	0.002	0.029	0.124
	AlluraClarity FD10	0.132 ^b	0.022	<0.0001	0.088	0.176
Allura Xper FD 10 (Philips, 2012)	Axiom Artis	-0.091 ^b	0.025	0.0002	-0.139	-0.042
	Coroskop HIP	-0.171 ^b	0.031	<0.0001	-0.231	-0.110
	Innova	-0.077 ^b	0.024	0.002	-0.124	-0.029
	Allura Xper Clarity FD10	0.055	0.029	0.056	-0.001	0.111
Allura Clarity FD10 (Philips, 2015)	Axiom Artis	-0.146 ^b	0.023	<0.0001	-0.191	-0.101
	Coroskop HIP	-0.225 ^b	0.029	<0.0001	-0.283	-0.168
	Innova	-0.132 ^b	0.022	<0.0001	-0.176	-0.088
	Allura Xper FD 10	-0.055	0.029	0.056	-0.111	0.001

Based on estimated marginal means.

Sig., significance; Std. Error, standard error.

^aAdjustment for multiple comparisons: Least Significant Difference (equivalent to no adjustments).

^bThe mean difference is significant at the 0.05 level.

refined in order to minimize radiation exposure. In our cohort, all three consultants adhered to very similar practice including management of fluoroscopy time and using fluoroscopic stores rather than cinematic acquisition as a regular part of every procedure.

The protocols for each X-ray system were similar, excluding the Allura Clarity system (Philips) that allows for an algorithm-based delivery of lower doses. Frame rates for cine angiography were kept to the recommended 7.5 frames per second for every case that this was feasible. The Philips Clarity technology uses powerful image processing to improve image quality but at a lower radiation dose. The system has a facility, unlike the other systems in the study, to manually adjust the radiation dose for a given frame rate. For example, radiation exposure of the Allura Xper system at 7.5 frames per second is comparable to the Allura Clarity at 15 frames per second at 50% standard radiation dose. The protocol in this study for cinematic acquisition with Clarity was 15 frames per second at 25% standard radiation dose.

In addition, the Philips systems have the potential to produce less radiation during fluoroscopy, which is particularly important in CTO cases. This is mainly due to copper filtration in the X-ray tube absorbing low energy radiation in the beam thus reducing patient dose and scattered radiation. The Allura Xper has a 0.1 mm copper filter, whereas the Allura Clarity uses up to a 0.4 mm copper filter depending on the fluoroscopy setting. Keeping tube current (mA), tube potential

(kV), and pulse duration (ms) constant, increasing copper from 0.1 to 0.4 mm reduces radiation dose by approximately 50%. Philips has also reduced the pulse durations at the lowest fluoroscopy setting from 4 to 2 ms resulting in further dose reduction.

There have been studies showing a significant reduction in DAP comparing the Allura Clarity with other X-ray systems in neuroradiology and trans-catheter aortic valve implantation (TAVI) [19].

In this study, whilst the Allura Clarity mean DAP value was less than the Allura Xper mean DAP value, the difference did not reach statistical significance. This could be explained by two reasons. This was a retrospective study and the protocols were not designed to compare radiation doses for similar image quality between X-ray systems. For cinematic acquisition, the Allura Xper frame rate was set at 7.5 frames per second and the Allura Clarity frame rate was set at 15 frames per second but at 25% standard radiation dose. In this case, one would expect to achieve improved image quality with a similar radiation dose. Secondly, although the lowest settings are selected as standard they may need to be altered at the time of the procedure by the operator and radiographer depending on image quality.

The more modern Philips systems had significantly lower DAP values than the other X-ray systems in the study. The system with the highest DAP values, Coroskop HIP (Siemens) was the oldest, manufactured in 1996.

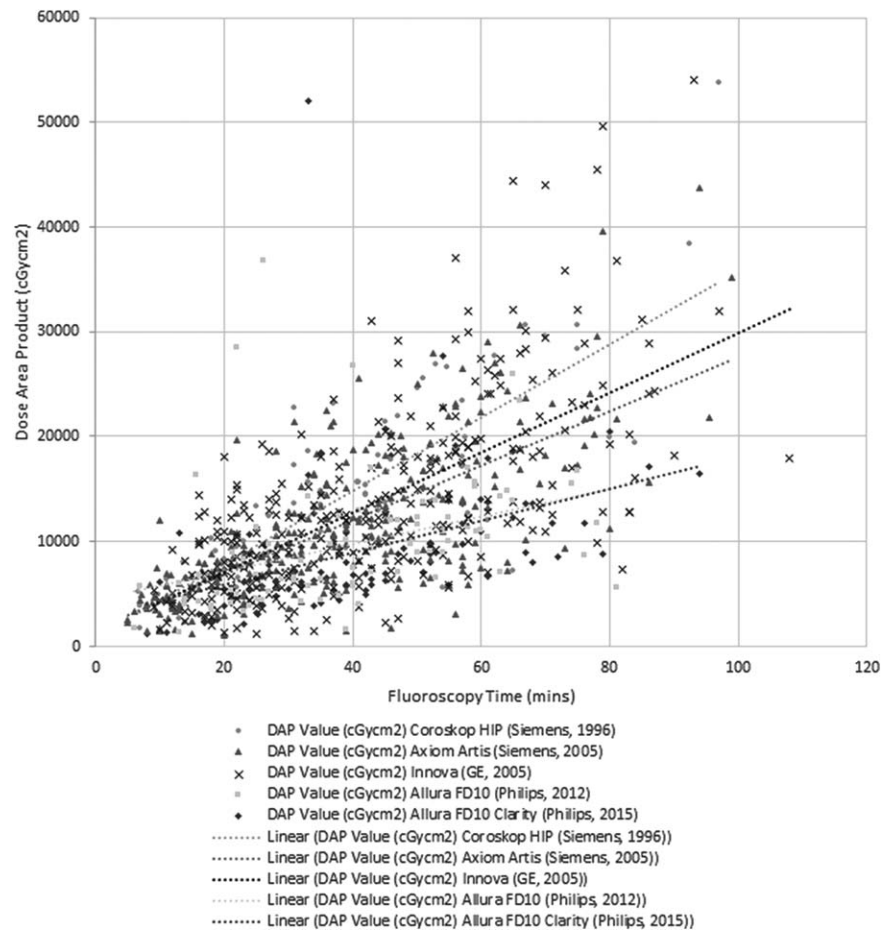


FIGURE 5 Graph showing plot of dose area product (DAP) values against fluoroscopy time for the different X-ray systems

Currently there are no universal diagnostic reference levels (DRL) for recanalization of CTOs. Maccia et al. determined local DRL for CTO PCI in their large volume center. Irrespective of procedural approach, mean DAP was 25,200 cGycm²; 75th percentile DAP was 35,000 cGycm² [20]. Therefore, despite the relatively high DAP values of the older systems in our study, they are still lower than what is considered to be an acceptable radiation dose. Our study results (mean fluoroscopy time 40.0 min and mean DAP 11,980 cGycm²) also compare favorably to large registry data, suggesting optimal practice. Multi-center CTO registry data from Japan (2013), the United States (2012–2015) and Europe reported mean fluoroscopy times of 70.6, 44.0, and 66.7 min, respectively. DAP values were not reported [21–23].

Comparing the three operators in this study is challenging as operators 1 and 2 used multiple systems (Siemens and Philips excluding GE system), whereas operator 3 used the GE system exclusively. However, no significant intersystem difference in fluoroscopy times would suggest similar practice.

We have previously described four anatomical features of a CTO lesion that help decide initial strategy, in order to optimize procedural efficiency [24]. In addition, the hybrid algorithm strongly encourages switches in strategy when procedural barriers are encountered. Using this approach, would be our interpretation of the plateauing of fluoroscopy time and DAP values for lesions defined as JCTO 4 and 5. In our

experience, this degree of lesion complexity almost always requires an up-front dissection re-entry strategy. Identifying the need to adopt these approaches early saves radiation that would otherwise potentially be wasted on futile wire-based strategies.

There is a learning curve to applying this approach and this will be a contributing factor to the reduction in the variability of DAP values observed using the more modern X-ray systems (Figure 3) which were used later during the study period. Other factors are improved image quality and the observation of the study that more modern systems use less radiation when confounding variables are controlled for.

Therefore, a procedural approach using the hybrid CTO algorithm, vigilant radiation awareness, and modern X-ray equipment are all important factors in reducing radiation exposure during PCI for CTOs.

5 | CONCLUSION

X-ray systems have a significant impact on DAP values, measured during PCI for CTOs. We propose that centers performing complex PCI and in particular specialist CTO centers, should be using the most up-to-date X-ray system as a default in order to adhere to the ALARA principle.

These data reinforce the need for institutions to continue to modernize medical equipment as a key aspect of patient and staff safety. For centers with multiple cardiac catheter laboratories of varying ages, local protocols should be considered to facilitate complex interventions including CTO PCI, being performed in the room that has the most modern X-ray equipment available. However, our findings will only have significant implications if the basics of radiation safety are consistently performed well.

CONFLICT OF INTEREST

The authors declare that there is no conflicts of interest.

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