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Predictors of Excess Patient Radiation Exposure During Chronic Total Occlusion Coronary Intervention: Insights from a Contemporary Multicenter Registry

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Abstract

Background—High patient radiation dose during chronic total occlusion (CTO) percutaneous coronary intervention (PCI) may lead to procedural failure and radiation skin injury.

Methods—We examined the association between several clinical and angiographic variables on patient air kerma (AK) radiation dose among 748 consecutive CTO PCIs performed at 9 experienced US centers between May 2012 and May 2015.

Results—Mean age was 65 ± 10 years, 87% of patients were men, and 35% had prior coronary artery bypass graft surgery (CABG). Technical and procedural success was 92% and 90%, respectively. The median patient AK dose was 3.40 (2.00, 5.40) Gray and 34% of the patients received >4.8 Gray (high radiation exposure). On univariable analysis male gender ($p=0.016$), high body mass index ($p<0.001$), history of hyperlipidemia ($p=0.023$), prior CABG ($p<0.001$), moderate or severe calcification ($p<0.001$), tortuosity ($p<0.001$), proximal cap ambiguity ($p=0.001$), distal cap at a bifurcation ($p=0.006$), longer CTO occlusion length ($p<0.001$), blunt/no blunt stump ($p<0.001$), and center ($p<0.001$) were associated with higher patient AK dose. On multivariable analysis high body mass index ($p<0.001$), prior CABG ($p=0.005$), moderate or severe calcification ($p=0.005$), longer CTO occlusion length ($p<0.001$), and center ($p<0.001$) were independently associated with higher patient AK dose.

Conclusions—Approximately 1 in 3 patients undergoing CTO PCI receives high AK radiation dose (>4.8 Gray). Several baseline clinical and angiographic characteristics can help predict the likelihood of high radiation dose and assist with intensifying efforts to reduce radiation exposure for the patient and the operator.

Keywords

Percutaneous coronary intervention; chronic total occlusion; radiation; complications; fluoroscopy; air kerma

Introduction

Use of radiation is necessary for fluoroscopically-guided procedures, yet there is increasing recognition of the potentially adverse effects of radiation exposure during cardiac

catheterization and percutaneous coronary intervention (PCI) on both the patient and the operator.¹⁻³ Every effort needs to be made to reduce radiation exposure, following the principle of “as low as reasonably achievable” (ALARA).

Radiation exposure is of particular concern during chronic total occlusion (CTO) PCI, as these procedures can be complex requiring longer use of fluoroscopy and cineangiography.⁴ Understanding parameters associated with higher radiation exposure during CTO PCI could facilitate procedural planning and even assist with selection of revascularization strategy. We examined a large contemporary multicenter CTO PCI registry to identify parameters associated with high patient radiation dose.

Methods

We examined demographic, clinical and procedural data of 748 consecutive patients who underwent CTO PCI between May 2012 and May 2015 at 9 high volume US centers: Appleton Cardiology, Appleton, WI; Columbia University Hospital, New York, New York; Henry Ford Health System, Detroit, MI; Loveland Medical Center of the Rockies, Rockville, CO; Massachusetts General Hospital, Boston, MA; St. Luke's Health System's Mid-America Heart Institute Kansas City, MO, Kansas City; PeaceHealth St Joseph Medical Center, Bellingham, WA; Piedmont Heart Institute, Atlanta, GA; and VA North Texas Healthcare System, Dallas, TX. For patients who underwent >1 CTO PCIs during the study period, only the first procedure was included in the present analysis. All procedures were performed by operators with expertise in CTO PCI using a hybrid approach. Data collection was performed both prospectively and retrospectively and recorded in a dedicated CTO database (PROGRESS CTO, [Clinicaltrials.gov](https://clinicaltrials.gov/ct2/show/study/NCT02061436) Identifier: NCT02061436). The study was approved by the institutional review board of each site.

Coronary CTOs were defined as coronary lesions with thrombolysis in myocardial infarction (TIMI) grade 0 flow of at least 3-month duration. Estimation of the occlusion duration was based on first onset of anginal symptoms, prior history of myocardial infarction in the target vessel territory, or comparison with a prior angiogram.

Calcification was assessed by angiography as mild (spots), moderate (involving 50% of the reference lesion diameter) and severe (involving >50% of the reference lesion diameter). Moderate proximal vessel tortuosity was defined as the presence of at least 2 bends >70 degrees or 1 bend >90 degrees and severe tortuosity as 2 bends >90 degrees or 1 bend >120 degrees in the CTO vessel. The Japanese Chronic Total Occlusion (*J-CTO*) score was calculated as described by Morino et al.⁵ Technical success of CTO PCI was defined as successful CTO revascularization with achievement of <30% residual diameter stenosis within the treated segment and restoration of TIMI grade 3 antegrade flow. Procedural success was defined as achievement of technical success with no in-hospital major adverse cardiac events (MACE). In-hospital MACE included any of the following adverse events prior to hospital discharge: death, acute myocardial infarction, urgent repeat target vessel revascularization with PCI or coronary artery bypass graft surgery (CABG), tamponade requiring either pericardiocentesis or surgery, and stroke.

Clinical characteristics, angiographic measures and in-hospital outcomes were reported using descriptive statistics. Continuous variables were presented as mean $\pm$ standard deviation or median (interquartile range) and compared using analysis of variance or Kruskal Wallis test, as appropriate. Categorical data were reported as frequencies or percentages and compared using the chi-square test. The primary endpoint of the study was patient air kerma (AK) radiation dose. We used linear regression (univariable and multivariable analysis) to examine the association of several clinical and angiographic variables with AK radiation dose during CTO PCI (the association was quantified using beta coefficients). Only variables with $p < 0.10$ on univariable analysis were included in the multivariable model. All analyses were performed with JMP 11.0 (SAS Institute, Cary, North Carolina). Two-sided p -values < 0.05 were considered statistically significant.

Results

During the study period, 748 patients underwent CTO PCI at the study sites and had data on AK patient radiation dose. The baseline demographic, clinical and angiographic characteristics of the study population are summarized in Table 1. Overall, 87% of the patients were men with mean age of 65 ± 10 years. Forty-four percent had diabetes, more than one-third (35%) had prior CABG, 40% had prior myocardial infarction and 64% had prior PCI. The most common target vessel was the right coronary artery (62%), followed by left anterior descending artery (21%), and the left circumflex (17%). The final successful crossing approach was antegrade wiring (36%), antegrade dissection/re-entry in 26% and the retrograde approach in 29%. The overall technical and procedural success rates were 92% and 90%, respectively.

The median and mean patient AK dose was 3.40 (2.00, 5.40) and 4.00 ± 2.58 Gray, respectively. The mean fluoroscopy time was 52 ± 33 minutes and the mean contrast volume were 293 ± 147 mL respectively. Patients were divided in tertiles, based on AK radiation dose: those who received > 4.8 Gray (67th percentile), were categorized as high radiation exposure whereas those who received < 2.4 Gray (33rd percentile) were categorized as low radiation exposure.

As shown in Table 2, compared with CTO PCIs with low patient radiation dose, procedures with high patient radiation dose had longer duration, longer fluoroscopy time, and higher contrast volume. Baseline variables associated with high patient AK dose on univariable and multivariable analyses are summarized on Table 3. On univariable analysis male gender ($p = 0.016$), high body mass index (< 0.001), history of hyperlipidemia ($p = 0.023$), prior CABG ($p < 0.001$), moderate or severe calcification ($p < 0.001$), tortuosity ($p < 0.001$), proximal cap ambiguity ($p = 0.001$), distal cap at a bifurcation ($p = 0.006$), longer CTO occlusion length ($p < 0.001$), blunt/no blunt stump ($p < 0.001$), and center (< 0.001) were associated with higher patient AK dose. On multivariable analysis high body mass index ($p < 0.001$), prior CABG ($p = 0.005$), moderate or severe calcification ($p = 0.005$), longer CTO occlusion length ($p < 0.001$), and center ($p < 0.001$) were independently associated with higher patient AK dose. The X-ray systems used at each cardiac catheterization laboratory are shown in Table 4. As compared with successful cases, failed cases had higher median patient AK dose: 3.30 (1.98, 5.30) vs. 5.30 (2.83, 7.58) Gray, $p < 0.001$.

Discussion

The main findings of our study are that among patients undergoing CTO PCI at experienced centers using contemporary techniques: (a) approximately one third received high AK radiation dose, and (b) patient radiation dose was associated with several clinical (such as high BMI and prior CABG), angiographic (such as moderate/severe calcification, blunt stump, and high J-CTO score), and logistical (center/operator performing the procedure) characteristics. These variables can help identify patients at increased risk for receiving high radiation dose, that would be excellent candidates for implementing enhanced radiation reducing actions.

Radiation-associated complications can be categorized as deterministic (which have a threshold above which injury occurs, e.g. skin injury) and stochastic (that have no threshold for injury to occur, e.g. cancer, infertility and pregnancy-related side effects).^{6,7} Godino et al demonstrated that the lung has the highest radiation absorption during PCI and that patients who undergo CTO PCI had on average double risk for both lung and red bone marrow cancer.⁸ Reducing radiation exposure of both the patient and medical staff is of paramount importance, and could potentially be achieved by better understanding of the parameters associated with higher radiation exposure and by taking preventive actions.

The side effects of radiation on the skin include erythema, dermal atrophy and ulcers.³⁵⁻³⁸ The generally accepted threshold for radiation-induced skin injury is 5 Gray, although skin injury could occur with radiation doses as low as 2 Gray.^{9,10} Depending on dose, some side effects (e.g. erythema) can occur immediately following the procedure (within 24h) whereas some others may be delayed for several years. In our study approximately one third of patients received >5 Gray AK dose, suggesting that the potential for skin injury remains even with contemporary CTO PCI techniques at experienced centers. Patients who receive >5 Gray AK dose after CTO PCI (or any fluoroscopically-guided procedure) should be counseled about the potential of skin injury and followed-up clinically to detect any potential injury.

Our study showed that patient radiation dose during CTO PCI was associated with multiple modifiable and non-modifiable factors, such as prior CABG and high BMI. Patients with high BMI have higher tissue thickness for the X-rays to penetrate, resulting in higher X-ray beam intensity created by the X-ray tube.¹¹ CTO PCI in prior CABG patients can be more complex, in part due to greater calcification and longer duration of occlusion.¹² Application of multiple crossing techniques during the same procedure can also lead to higher procedure time and radiation dose.¹³ Several angiographic characteristics, such as longer occlusion length and moderate/severe calcification were associated with higher radiation dose. These characteristics are commonly encountered in more complex lesions, which usually require longer procedural time and subsequently more fluoroscopy and radiation. Moreover, when diagnostic catheterization is done in the same setting as CTO PCI overall radiation dose increases, hence ad-hoc CTO PCI should be avoided with rare exceptions (such as patients with acute saphenous vein graft occlusions that cannot be recanalized).³⁴

Our study demonstrated also that there is a significant variability in regards to radiation used during CTO PCI among different operators and centers. Operator experience can significantly enhance radiation safety,¹⁴ because it directly affects fluoroscopy time and patient dose, as shown in an analysis of the National Cardiovascular Data Registry.¹⁵ The RadiCure trial¹ also showed remarkable variation of first operator radiation exposure among the 18 different operators that participated in the study. Our study suggests that addressing site-specific factors (e.g. additional radio-protective measures, newer versions X-Ray systems) could improve radioprotection.

Although both the patient and the operator are exposed to radiation, the operator may be at higher long-term risk due to repeated exposure, often during many years. Both the American College of Cardiology and the American Heart Association have published guidelines on clinical competence and training of people involved with radiation, to ensure radiation exposure is kept to a minimum.¹⁶ Similarly, there are guidelines for reducing radiation exposure in the cardiac catheterization laboratory.¹⁷ In our opinion, best practices for reducing operator radiation dose include: (a) low frame per second fluoroscopy (7.5 frames per sec or lower);²⁴ (b) using the fluoro-store function of the X-ray equipment instead of cine-angiography whenever possible; (c) optimizing patient and equipment positioning, by maximizing the distance between the patient and the X-ray tube, minimizing the distance between image intensifier and the patient^{18-20,32} and avoiding extreme angulations^{22,23}; (d) collimation;¹⁸⁻²⁰ (e) shielding, both fixed and disposable (such as the Radpad, Worldwide Innovations & Technologies, Inc),³³ thyroid collar, leaded glasses for eye protection as well as radiation protective hats;²⁵⁻²⁸ (f) using radiation monitors that provide real time feedback;¹ and (g) using newer X-ray systems that reduce patient (and operator) radiation dose.³¹

Our study has important limitations. Operator radiation exposure was not available from most centers and angiographic and procedural characteristics of patients in this study were reported by the participating centers. Use of disposable radiation shields was not collected; although such shields decrease operator radiation exposure, they do not reduce patient radiation dose and in fact increase it.³⁰ Newer X-ray systems can significantly reduce radiation exposure,³¹ but were used in few the participating cardiac catheterization laboratories during the study period. Most patients were men, limiting extrapolation of the results to women, but this is typical of populations undergoing CTO PCI. All procedures were performed by experienced operators at high-volume institutions that have invested significant resources to develop expertise in CTO PCIs, and may not apply to less experienced centers, although an even more pronounced impact of CTO PCI on patient radiation exposure might be observed in such sites.

Conclusions

In summary, our study demonstrated that several baseline clinical and angiographic characteristics (such as prior CABG, higher BMI, long occlusion length and severe calcification) can help predict the likelihood of high patient radiation dose, and assist with intensifying efforts to reduce radiation exposure of both the patient and the operator.

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Study data were collected and managed using REDCap electronic data capture tools hosted at University of Texas Southwestern Medical Center.³ REDCap (Research Electronic Data Capture) is a secure, web-based application designed to support data capture for research studies, providing 1) an intuitive interface for validated data entry; 2) audit trails for tracking data manipulation and export procedures; 3) automated export procedures for seamless data downloads to common statistical packages; and 4) procedures for importing data from external sources.

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Brief summary

We sought to identify variables independently affecting patient radiation exposure during chronic total occlusion percutaneous coronary intervention. Several parameters, such as prior coronary bypass graft surgery, moderate or severe calcification, longer occlusion length, high body mass index, and center at which the procedure was performed were associated with higher patient radiation dose, identifying potential targets for enhancing radioprotection.

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Figure 1.
Boxplots of patient air kerma radiation dose at each participating center.

Table 1

Baseline patient and angiographic characteristics, classified according to patient air kerma radiation dose.

Variable	Overall N=249	Air kerma dose <2.4 Gray N=249	Air kerma dose 2.40 and <4.80 Gray N=250	Air kerma dose 4.80 Gray N=249	p
Age (years) *	65 ± 10	64 ± 11	65 ± 10	65 ± 10	0.46
Men, %	87	82	87	92	0.005
Body mass index (kg/m ²) *	31 ± 7	29 ± 6	31 ± 6	33 ± 7	<0.001
Ejection Fraction (%) *	50 ± 14	50 ± 16	51 ± 13	50 ± 12	0.441
Diabetes Mellitus, %	44	41	46	46	0.413
Hypertension †, %	91	89	94	91	0.075
Dyslipidemia ‡, %	96	93	97	97	0.031
Smoking (current), %	35	30	35	39	0.266
Prior Chronic Heart Failure, %	28	25	24	34	0.029
Prior Myocardial Infarction, %	40	38	40	43	0.469
Prior Coronary bypass surgery, %	35	26	34	46	<0.001
Prior PCI, %	64	60	65	67	0.344
Cerebrovascular disease, %	11	11	14	9	0.195
Peripheral vascular disease, %	18	17	18	20	0.722
Baseline creatinine *	1.18 ± 0.76	1.16 ± 0.72	1.19 ± 0.70	1.19 ± 0.85	0.896
CTO Target Vessel (%)					
Right coronary	62	61	58	67	0.164
Left anterior descending	21	24	21	18	
Left circumflex	17	15	21	15	
Prior attempt to re-canalize CTO (%)	16	14	16	18	0.516
J-CTO score *	2.53 ± 1.20	2.06 ± 1.19	2.59 ± 1.16	2.94 ± 1.07	<0.001
Calcification (moderate/severe), %	54	39	53	69	<0.001
Tortuosity (moderate/severe), %	34	23	40	40	<0.001
Proximal cap ambiguity, %	30	23	29	39	0.01
In-stent restenosis, %	13	15	12	11	0.473
Blunt/no stump, %	68	61	66	76	0.001

Variable	Overall	Air kerma dose <2.4 Gray N=249	Air kerma dose 2.40 and <4.80 Gray N=250	Air kerma dose 4.80 Gray N=249	p
Side branch at the proximal cap, %	44	42	40	52	0.077
Vessel diameter, mm [*]	2.75 (2.5, 3)	2.875 (2.5, 3.0)	2.5 (2.5, 3.0)	2.75 (2.5, 3.0)	0.881
Occlusion length, mm [*]	30 (20, 50)	28 (16, 38)	30 (20, 50)	40 (29.75, 62)	<0.001
Successful Crossing Strategy (%)					
Antegrade wiring	37	55	37	18	<0.001
Retrograde	29	18	29	40	
Antegrade dissection and re-entry	26	22	28	29	
Technical Success, %	92	95	94	87	0.001
Procedural Success, %	90	95	92	83	<0.001

CTO, chronic total occlusion; PCI, percutaneous coronary intervention.

^{*} mean ± standard deviation or median (interquartile range)

[†] Defined as blood pressure of >140/90 mmHg or >130/80 mmHg in patients with diabetes mellitus

[‡] Based on the recommendations of the National Cholesterol Education Program Adult Treatment Panel (III)

Table 2

Procedural outcomes, classified according to patient air kerma radiation dose.

Variable	Overall	Air kerma dose <2.4 Gray N=249	Air kerma dose 2.40 and <4.80 Gray N=250	Air kerma dose 4.80 Gray N=249	P
Procedural time (min) *	133 ± 76	90 ± 49	127 ± 61	191 ± 81	<0.001
Fluoroscopy time (min) *	52 ± 33	33 ± 24	49 ± 28	74 ± 33	<0.001
Contrast volume (mL) *	293 ± 147	210 ± 98	288 ± 112	383 ± 166	<0.001

* mean ± standard deviation

Table 3

Univariable and multivariable linear regression analysis of patient air kerma radiation dose. Values represent beta coefficients (standard error).

Variable	Univariable	Multivariable	Univariable p-value	Multivariable p-value
Age (years)	0.006 (0.010)	-	0.539	-
Men	0.332 (0.137)	0.092 (0.149)	0.016*	0.537
Body mass index (kg/m ²)	0.104 (0.015)	0.077 (0.014)	<0.001	<0.001
Ejection fraction (%)	0.007 (0.008)	-	0.347	-
Center				
-Center 1	0.889 (0.263)	1.133 (0.227)	<0.001	<0.001
-Center 2	-0.47 (0.260)	-		
-Center 3	-0.867 (0.471)	-0.189 (0.383)		
-Center 4	-1.221 (0.273)	-0.867 (0.246)		
-Center 5	0.41 (0.452)	-0.581 (0.375)		
-Center 6	-0.139 (0.249)	0.299 (0.215)		
-Center 7	-0.605 (0.42)	-0.446 (0.380)		
-Center 8	1.699 (0.208)	-		
(Ref. Center: center 9)				
Diabetes	0.052 (0.095)	-	0.582	-
Dyslipidemia †	0.519 (0.228)	0.152 (0.213)	0.023	0.474
Hypertension †	0.144 (0.168)	-	0.393	-
Prior myocardial infarction	0.038 (0.097)	-	0.697	-
Prior congestive heart failure	0.105 (0.105)	-	0.319	-
Prior PCI	0.16 (0.098)	-	0.104	-
Prior coronary bypass graft surgery	0.537 (0.096)	0.278 (0.098)	<0.001	0.005
Cerebrovascular disease	-0.198 (0.149)	-	0.186	-
Peripheral vascular disease	0.144 (0.122)	-	0.238	-
Prior attempt to recanalize CTO	0.094 (0.13)	-	0.467	-
Moderate/severe calcification	0.71 (0.092)	0.268 (0.096)	<0.001	0.005
Moderate/severe tortuosity	0.457 (0.099)	0.093 (0.101)	<0.001	0.357
Vessel diameter (mm)	0.217 (0.189)	-	0.252	-
CTO occlusion length (mm)	0.028 (0.003)	0.018 (0.004)	<0.001	<0.001

Variable	Univariable	Multivariable	Univariable p-value	Multivariable p-value
Proximal cap ambiguity	0.368 (0.111)	0.172 (0.120)	0.001	0.152
Side branch at proximal cap	0.192 (0.101)	0.084 (0.100)	0.059	0.40
Distal cap at bifurcation	0.305 (0.111)	0.144 (0.100)	0.006	0.151
Interventional collaterals	-0.072 (0.106)	-	0.497	-
In-stent restenosis	-0.206 (0.142)	-	0.147	-
Blunt stump/No stump	0.467 (0.099)	0.128 (0.106)	<0.001	0.227

BMI: body mass index; EF: ejection fraction; CHF: congestive heart failure; PCI: percutaneous coronary intervention; CVD: cerebrovascular disease; PVD: peripheral vascular disease; CTO: chronic total occlusion.

[†] Defined as blood pressure of >140/90 mmHg or >130/80 mmHg in patients with diabetes mellitus

[‡] Based on the recommendations of the National Cholesterol Education Program Adult Treatment Panel (III)

Table 4

X-Ray equipment used at each participant center.

Center	X-Ray Equipment	Year	Frames per sec	Radpad used	Annual Procedural Volume	Fluoro Store Used
Center 1	Philips Allura	2008	7.5	No	62/year	Yes
Center 2	Siemens Artis Q(a), Philips Allura Clarity (b)	(a) 2015 (b) 2012	7.5 (both)	No (both)	140/year	Yes (both)
Center 3	Siemens Artz Zee VC 20	2009	10	Yes	56/year	Yes
Center 4	GE Innova XRT	2010	15	No	77/year	Yes
Center 5	Philips Allura	2008	7.5	No	103/year	Yes
Center 6	Philips Allura	2003	15	No	73/year	Yes
Center 7	Philips Allura FD10	2007	15	No	34/year	Yes
Center 8	Toshiba CAT-850B	2009	7.5	No	164/year	No
Center 9	GE Innova (a), Philips Allura (b)	(a) 2012 (b) 2005	7.5 (both)	Yes (both)	58/year	Yes (both)