Received: 25 November 2022 | Revised: 2 February 2023 | Accepted: 16 February 2023

DOI: 10.1002/ccd.30605

ORIGINAL ARTICLE - CLINICAL SCIENCE

WILEY

Safety and efficacy of an ultra low dose fluoroscopic protocol for chronic total occlusion recanalization

Elodi Bacci MD[1,2] | Mauro Chiarito MD[2,3] | Jorge Sanz-Sanchez MD[2] | Pier Pasquale Leone MD[2] | Aisha Gohar MD[2] | Laura Novelli MD[2,3] | Mihajlo Kovacic MD[4] | Damiano Regazzoli MD[2] | Bernhard Reimers MD[2] | Francesco Contorni MD[1] | Nicolò Ghionzoli MD[1] | Matteo Cameli MD[1] | Gabriele L. Gasparini MD[2]

[1]Department of Medical Biotechnologies, Division of Cardiology, University of Siena, Siena, Toscana, Italy

[2]Humanitas Research Hospital IRCCS, Milan, Rozzano, Italy

[3]Department of Biomedical Sciences, Humanitas University, Pieve Emanuele-Milan, Italy

[4]Županijska bolnica Čakovec, Čakovec, Croatia

Correspondence

Gabriele L. Gasparini, MD, IRCCS Istituto Clinico Humanitas, Via Manzoni 56, 20089, Rozzano-Milan Italy.

Email: Gabriele.gasparini@gmail.com

Abstract

Background: Chronic total occlusion (CTO) revascularization is a major source of radiation for both patients and physicians. Therefore, efforts to minimize radiation during CTO percutaneous coronary intervention (PCI) are highly encouraged.

Aims: To evaluate the impact of an Ultra Low fluoroscopic Dose Protocol (ULDP), based on 3.75 frames per second for the fluoroscopy and 7.5 frames per second for the cine acquisition, during CTO PCI.

Methods: One hundred fifty consecutive patients who underwent CTO PCI were retrospectively enrolled. Eighty-five underwent standard dose protocol (SDP) and 65 ULDP. Radiation exposure and acute clinical outcomes were compared between groups. Results were stratified according to lesion complexity.

Results: Patients undergoing ULDP, as compared to those undergoing SDP, showed a significant reduction of kerma area product, both for simple lesions (6861.0 vs. 13236.0 $mGy \times cm^2$; $p = 0.014$) and complex lesions (CL) (8865.0 vs. 16618.0 $mGy \times cm^2$; $p < 0.001$). Similarly, Air Kerma (AK) was lower when ULDP was used (1222.5 vs. 2015.0 cGy in SL, $p = 0.134$; 1499.0 vs. 2794.0 cGy in CL, $p < 0.001$). No significant differences were reported regarding procedural success and in-hospital major adverse cardiovascular events between groups. Notably, there was not any crossover from ULDO to SDP due to poor quality images. Interestingly, fluoroscopy time, procedural time and contrast volume was significantly lower in patients undergoing ULDP only for CLs.

Conclusions: ULDP significantly reduces radiation exposure in the setting of high complexity procedures such as CTO PCI. This reduction seemed to be greater with increased procedural complexity and did not impact acute success or adverse clinical events.

KEYWORDS

chronic total occlusion, coronary artery disease, fluoroscopy, percutaneous coronary intervention, radiation exposure, X-ray

1 | INTRODUCTION

The cardiac catheterization laboratory is a major source of medical radiation for both patients and physicians. Radiation injuries may manifest as tissue reactions (deterministic effects, such as skin burns) or develop stochastically (when the risk of an outcome is proportional to the dose received as seen with cancer).[1] Compared to clinical cardiologists, interventional cardiologists are at greater risk of developing somatic DNA damage and chromosomal abnormalities when measured using micronucleus assay in peripheral lymphocytes[2]; furthermore, a higher incidence of brain tumors among these physicians has been shown.[3] As both the frequency and complexity of percutaneous coronary intervention (PCI) are increasing, a more meticulous use of angiography whilst maximizing currently available protective equipment is required without compromising results. For this purpose, we evaluated the impact of an Ultra Low fluoroscopic Dose Protocol (ULDP), when compared with a standard dose protocol (SDP), in patients receiving percutaneous revascularization of coronary chronic total occlusion (CTO).

2 | METHODS

In this retrospective study, 150 patients with CTO who underwent PCI were enrolled in a single high-volume Center, between January 2019 and August 2021.

All participants signed an informed consent form at the hospital admission for research purpose, then our local Ethics Committee approved the use of these data and the study design. All patients underwent percutaneous recanalization of one or more CTO, defined as the presence of a TIMI (Thrombolysis In Myocardial Infarction) 0 flow within an occluded arterial segment of >3 month standing. PCIs were performed by the same primary operator, a certified member of EuroCTO. Procedures were performed using single or double access (single femoral, double femoral, single radial, double radial, double access radial/femoral) according to the operator's preference. The procedures were divided by the degree of complexity using the JCTO (Multicenter CTO Registry in Japan) score system into simple lesions (SL) (JCTO < 2) and complex lesions (CL) (JCTO ≥ 2). Data regarding angiographic success rate (defined as a TIMI 3 flow at the end of procedure) and in hospital major adverse cardiovascular events (MACE) (death from any cause, stroke, target vessel coronary perforation, donor vessel dissection/thrombosis, redo-PCI, emergency cardiac surgery) were collected to have a performance parameter.

2.1 | Dose protocols

All procedures were performed in the same catheterization laboratory using a Philips AlluraClarity single plane C-arm with Flat Panel Detector technology (Philips Medical, Netherlands). Data on radiation exposure were collected through an integrated dosimeter on the X-ray tube collimator.

Two different protocols were used: SDP used 7.5 frames per second for the cine acquisition and 7.5 frames per second for the fluoroscopy; ULDP, used 7.5 frames per second for the cine acquisition and 3.75 frames per second for the fluoroscopy. SDP was used from January 2019 to July 2020 in 85 patients. To reduce radiation dose an ULDP was introduced in August 2020. From August 2020 to August 2021 ULDP was used as the upfront protocol in 65 consecutive patients. In both protocols, the last fluoroscopy hold tool was used, which enables dynamic storage of the last fluoroscopy sequence for documentation (recorded fluoro runs). The interventional fluoroscope was equipped with integrated dosimetric instrumentation. The performance of this instrumentation is verified twice a year, as part of the Hospital's Quality Assurance program run by the local Medical Physics Department. The radiation dose during each procedure was recorded using:

1. The air kinetic energy released per unit mass (kerma) area product (KAP), is also known as the dose area product. KAP, measured in Gray-square centimeters ($Gycm^2$), is the product of absorbed dose to air and beam cross-sectional area and is a quantity independent of the distance to the X-ray tube focal spot and is considered a surrogate measure of the patient's risk of stochastic radiation effects.[4]
2. Air Kerma at the interventional reference point (AK), which represents the ionizing energy released in air at 15 centimeters from the isocenter toward the X-ray tube. AK is used for tracking the dose of ionizing radiation to the patient and relates to the patient's risk of deterministic radiation effects.

Continuous data are presented as median and interquartile range (25th to 75th percentile) or mean and 95% CI, as appropriate and have been compared using the Mann–Whitney *U* or Student *t* tests, based on the normality (Kolmogorov–Smirnov goodness-of-fit test) of the data. Categorical data are presented as counts or percentages and have been compared with the Pearson's χ^2 test. $p < 0.05$ has been considered statistically significant. Data were analyzed with IBM SPSS Statistics for Windows, version 21.0 (IBM Corp.).

3 | RESULTS

A total of 150 consecutive patients undergoing PCI for CTO from January 2019 to August 2021 have been evaluated. Of these, 53 had a SL and 97 had a CL as per the JCTO score. A total of 65 patients were treated with the LDP (28 within the SL group and 37 within the CL group) while a total of 85 patients were treated with the SDP (25 within the SL group and 60 within the CL group) (see the flow chart in Figure 1). Baseline clinical and procedural characteristics stratified by the degree of complexity and by the two radiological protocols are presented in Tables 1–3. The only significant differences found were a higher proportion of right coronary artery procedures were

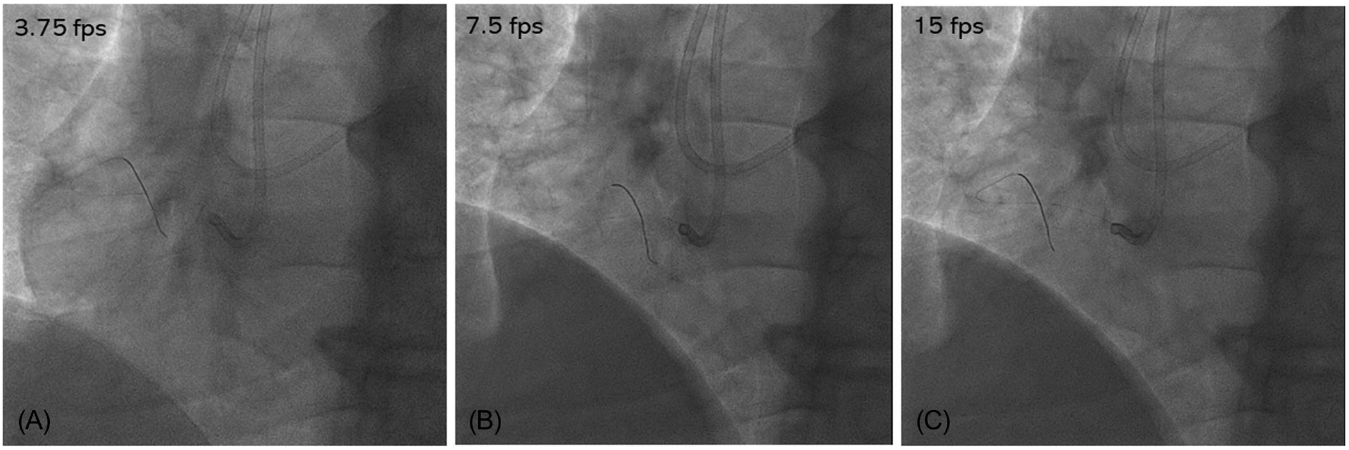

FIGURE 1 The figure represents the comparison of angiography acquired using different protocols 3.5 fps (A), 7.5 fps (B) and 15 fps (C). Fps, frames per second.

TABLE 1 The table summarizes baseline clinical stratified by the degree of complexity and by the two radiological protocols.

	CTO SL (*n* = 53)			CTO CL (*n* = 97)		
	ULDP (28)	SDP (25)	*p*	ULDP (37)	SDP (60)	*p*
Age	68 (60.25–73.25)	65 (61.50–74.50)	0.894	68.00 (63.50–72.00)	69.00 (62.50–74.75)	0.685
Male	26 (92.9%)	23 (92%)	0.906	35 (94.6%)	56 (93.3%)	0.802
BMI	28.4 (25.28–29.38)	30.45 (27.14–33.22)	0.053	26.6 (24.45–29.31)	27.70 (24.85–30.77)	0.285
Diabete mellitus	8 (28.6%)	8 (32%)	0.786	9 (24.3%)	18 (30%)	0.545
Smoker	16 (57.1%)	18 (72%)	0.260	23 (62.2%)	39 (65%)	0.777
Typical angina	16 (57.1%)	14 (56%)	0.933	25 (67.6%)	35 (58.3%)	0.363
Creatinine clearance	82.4 (66.40– 91.42)	78.08 (57.47–101.17)	0.845	85.55 (69.14–94.18)	82.25 (65.36–99.88)	0.988

Abbreviations: BMI, body mass index; CL, complex lesion; CTO, chronic total occlusion; SDP, standard dose protocol; SL, simple lesion; ULDP, ultra-low dose protocol.

TABLE 2 The table highlights the angiographic characteristics of the CTOs.

	CTO SL (*n*=53)			CTO CL (*n*=97)		
	ULDP (28)	SDP (25)	*p*	ULDP (37)	SDP (60)	*p*
CTO on RCA	17 (60.7%)	7 (28%)	0.017	21 (56.8%)	29 (48.3%)	0.420
CTO on LAD	5 (17.9%)	10 (40%)	0.074	10 (27%)	18 (30%)	0.754
CTO on Cx	6 (21.4%)	5 (20%)	0.898	6 (16.2%)	11 (18.3%)	0.790
CTO on side branch	0 (0%)	3 (12%)	0.059	0 (0%)	2 (3.3%)	0.262
CTO ostial tract	3 (10.7%)	4 (16%)	0.570	5 (13.5%)	11 (18.3%)	0.534
CTO proximal tract	15 (53.6%)	10 (40%)	0.323	8 (21.6%)	24 (40%)	0.061
CTO intermediate tract	7 (25%)	11 (44%)	0.145	22 (59.5%)	24 (40%)	0.062
CTO distal tract	3 (10.7%)	0 (0%)	0.092	2 (5.4%)	1 (1.7%)	0.302
CTO instent	5 (17.9%)	4 (16%)	0.857	3 (8.1%)	4 (6.7%)	0.790
Multiple lesions	1 (3.6%)	0 (0%)	0.340	1 (2.7%)	14 (23.3%)	0.006
Bifurcation involved	12 (42.9%)	8 (32%)	0.416	9 (24.3%)	16 (26.7%)	0.798

Abbreviations: CL, complex lesion; CTO, chronic total occlusion; Cx, circumflex artery; LAD, left anterior descending artery; RCA, right coronary artery; SDP, standard dose protocol; SL, simple lesion; ULDP, low dose protocol.

performed using the ULDP and more multiple lesions were treated in the SDP groups. While no significant difference was observed between the ULDP and SDP in terms of fluoroscopy time, procedural time and contrast volume when considering only SLs, all of these variables significantly decreased with the ULDP used for CLs (Table 4). In the ULDP group, a significant reduction of both kerma area product was observed as compared with SDP, both when SLs (6861.0 vs. 13236.0 mGy × cm^2; $p = 0.014$) and CLs (8865.0 vs. 16618.0 mGy × cm^2; $p < 0.001$) were analyzed. Similarly, AK was lower when ULDP was used (1222.5 vs. 2015.0 cGy in SL, $p = 0.134$; 1499.0 vs. 2794.0 cGy in CL, $p < 0.001$), as shown in Figure 2. Interestingly, no significant difference was reported regarding procedural success and in-hospital MACE between groups (Figure 3; Table 5).

4 | DISCUSSION

This study reports a single-center cohort study of consecutive patients evaluated for two different radiation protocols during CTO-PCI. The main findings are:

1. The use of a ULDP significantly reduces the PCI radiation exposure regardless of procedural complexity.

TABLE 3 The table focus the access used for CTO procedures dividing patients into complex and simple lesion and stratifing for ULDP or SDP.

	CTO SL (*n* = 53)		CTO CL (*n* = 97)	
	ULDP (28)	SDP (25)	ULDP (37)	SDP (60)
Radial access (TV)	22 (78.6%)	11 (44%)	28 (75.7%)	8 (13.3%)
Femoral access (TV)	6 (21.4%)	14 (56%)	9 (24.3%)	52 (86.7%)
Radial access (DV)	20 (71.4%)	6 (24%)	25 (67.6%)	15 (25%)
Femoral access (DV)	4 (14.3%)	9 (36%)	7 (18.9%)	28 (46.7%)
Double access	22 (78.6%)	15 (60%)	28 (75.7%)	43 (71.7%)

Abbreviations: CL, complex lesion; CTO, chronic total occlusion; DV, donor vessel; SDP, standard dose protocol; SL, simple lesion; TV, target vessel; ULDP, ultra-low dose protocol.

2. The use of a ULDP does not appear to significantly impact on acute outcomes in terms of procedural successes and periprocedural complications.

It is well known that CTO-PCI is associated with higher radiological exposure for both patients and operators as compared with non-CTO interventions, possibly with a higher risk of radiation associated damage.[5] Concerns about the need to reduce this X-ray exposure within the catheterization laboratory has led to the pursuit of appropriate strategies to minimize such risk. It is important to stress that this tool should not be considered as a solution by itself but instead as part of a wider multi step strategy, in addition to a broad range of protection devices and procedural techniques. The optimization of fluoroscopic protocols could be considered a new fundamental step to provide a greater reduction in radiation dose without hampering outcomes. In the last few years several studies have been published comparing the effectiveness and safety of low dose fluoroscopic protocols: whilst there is firm evidence for the 7.5 fps fluoroscopic protocols,[6,7] data on 3.75 fps protocols are lacking. Despite the retrospective nature of the study, no difference in the baseline characteristics of the population were found. Interestingly, no significant differences emerged also in terms of body mass index (BMI). Indeed, BMI is an important factor to consider as patients with high BMI require an increase in the radiological parameters in the X-ray tube to generate images of acceptable quality, thus resulting in greater radiation exposure. Patents were well matched between groups also when lesion complexity was considered. The difference found in fluoroscopic time, procedural time and contrast volume in the CL group can therefore not be accounted for by the complexity of the procedure but may possibly be due to the higher number of multiple lesions treated in the same procedure in the SDP group (Figure 4).

5 | LIMITATIONS

This is a retrospective single-center observational analysis and thus is subject to many limitations of such types of analyses. Although baseline variables are similar between groups, unmeasured confounders may still have played a role. In addition, operator radiation doses were not evaluated. Finally, whether these results can be achieved in different X-ray machines is unknown and deserves further investigation.

TABLE 4 The table shows the procedural characteristics regarding both procedural and fluoroscopic time, contrast volume.

	CTO SL (*n* = 53)			CTO CL (*n* = 97)		
	ULDP (28)	SDP (25)	*p*	ULDP (37)	SDP (60)	*p*
Procedulral time	87.50 (64.00–118.75)	90.00 (65.50–161.50)	0.359	107.00 (80.50–135.00)	136.00 (115.75–194.75)	0.001
Fluoroscopic time	38.50 (26.50–52.50)	40.00 (27.50–69.50)	0.309	52.00 (37.50–75.00)	66.50 (47.00–93.75)	0.014
Contrast volume	150.00 (100.00–200.00)	180.00 (105.00–200.00)	0.405	170.00 (120.00–225.00)	230.00 (180.00–300.00)	0.003

Abbreviations: CL, complex lesion; CTO, chronic total occlusion; SDP, standard dose protocol; SL, simple lesion; ULDP, ultra-low dose protocol.

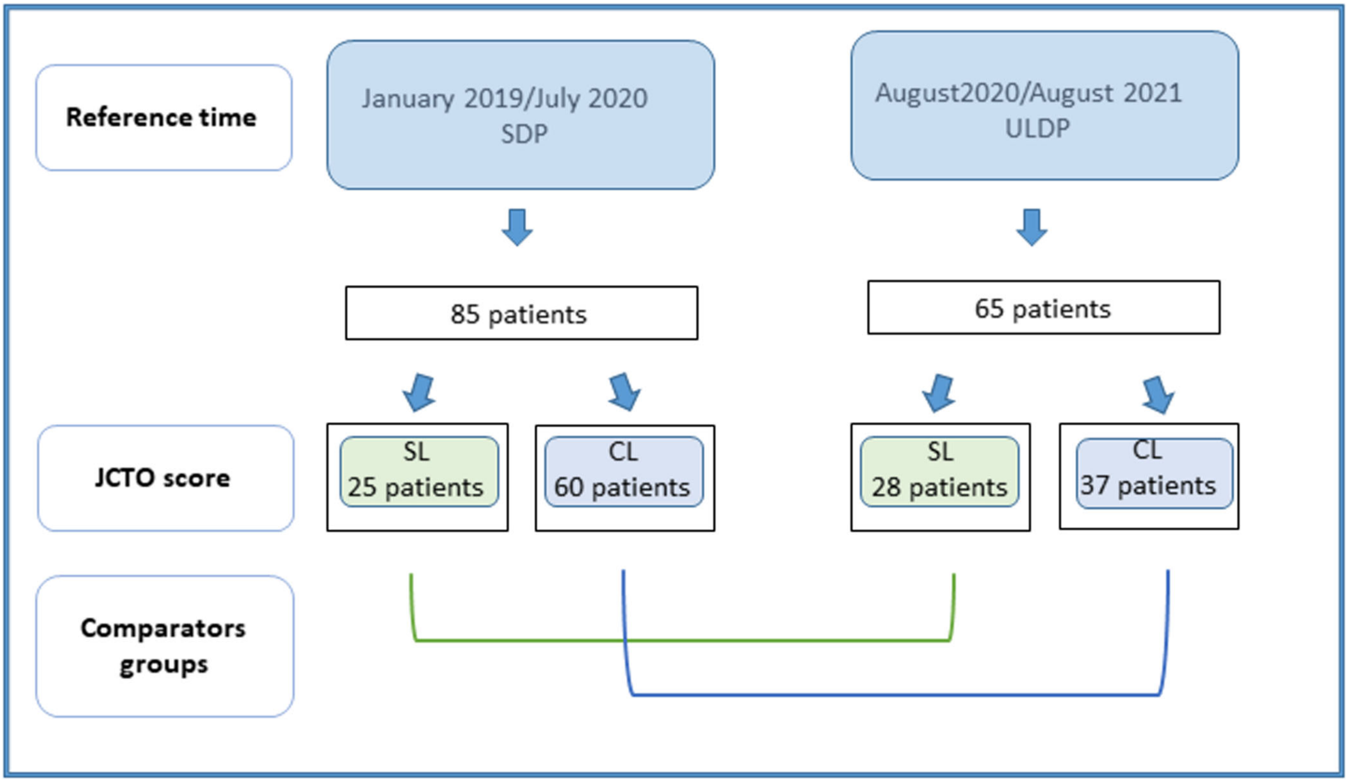

FIGURE 2 The figure shows flow chart patients' enrollment. CL, complex lesion; SDP, standard dose protocol; SL, simple lesion; ULDP, ultra-low dose protocol. [Color figure can be viewed at wileyonlinelibrary.com]

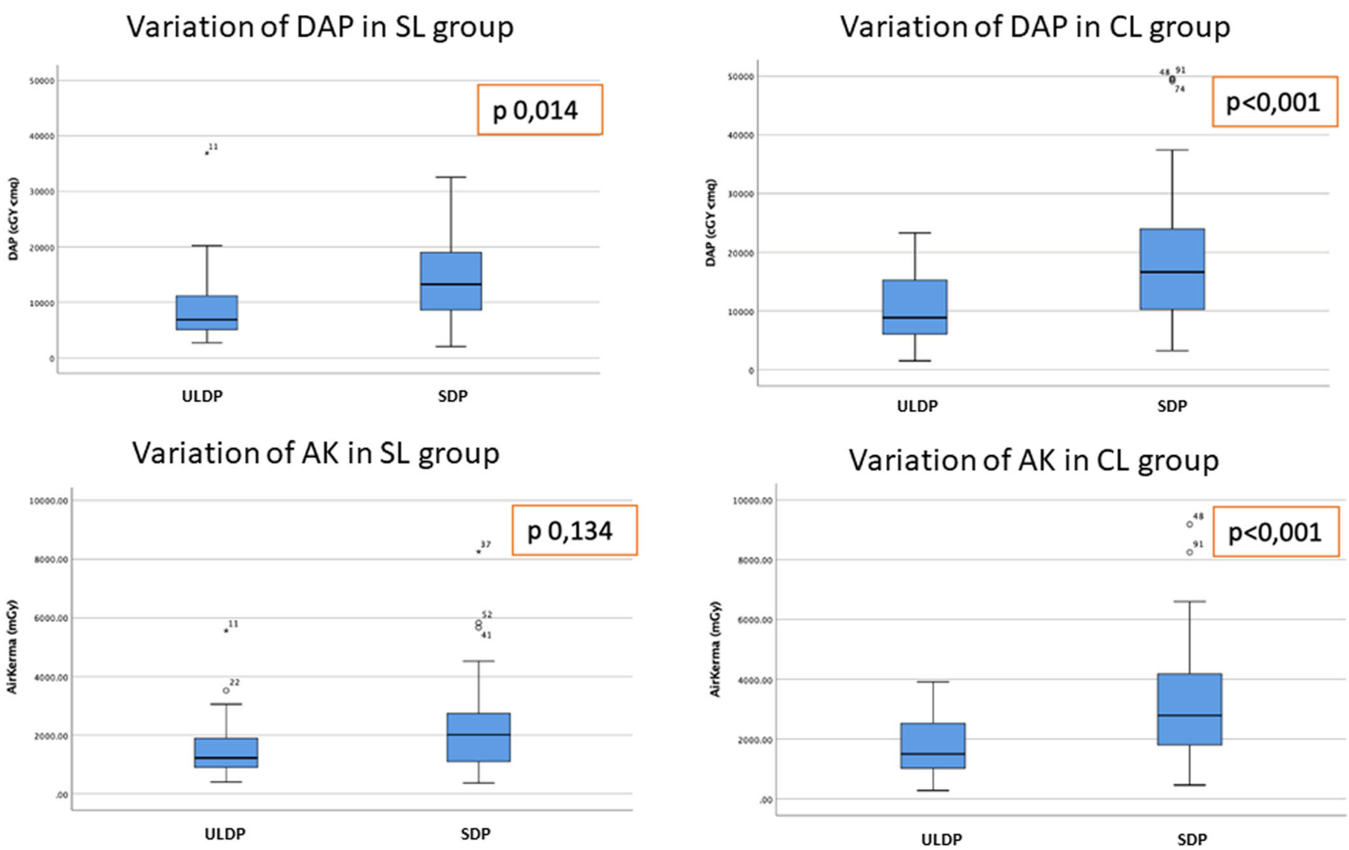

FIGURE 3 The figure represents the different variations of DAP and AK in SL group and CL group using ULDP or SDP. AK, AirKerma; CL, complex lesion; DAP, dose area product; SDP, standard dose protocol; SL, simple lesion; ULDP, ultra-low dose protocol. [Color figure can be viewed at wileyonlinelibrary.com]

TABLE 5 The table illustrates in-hospital MACE between groups.

	CTO SL (*n* = 53)			CTO CL (*n* = 97)		
	ULDP (28)	SDP (25)	*p*	ULDP (37)	SDP (60)	*p*
Death for any cause	0 (0%)	0 (0%)	/	0 (0%)	0 (0%)	/
Stroke	0 (0%)	0 (0%)	/	0 (0%)	3 (5%)	0.167
Target vessel perforation	0 (0%)	4 (8%)	0.312	1 (2.7%)	6 (10%)	0.523
Donor vessel dissection/thrombosis	0 (0%)	0 (0%)	/	0 (0%)	1 (1.7%)	0.430
Emergency Re-PCI	0 (0%)	0 (0%)	/	0 (0%)	1 (1.7%)	0.430
Emergency surgery	0 (0%)	0 ((0%)	/	0 (0%)	0 (0%)	/

Abbreviations: CL, complex lesion; CTO, chronic total occlusion; MACE, major adverse cardiovascular events; SDP, standard dose protocol; SL, simple lesion; ULDP, ultra-low dose protocol.

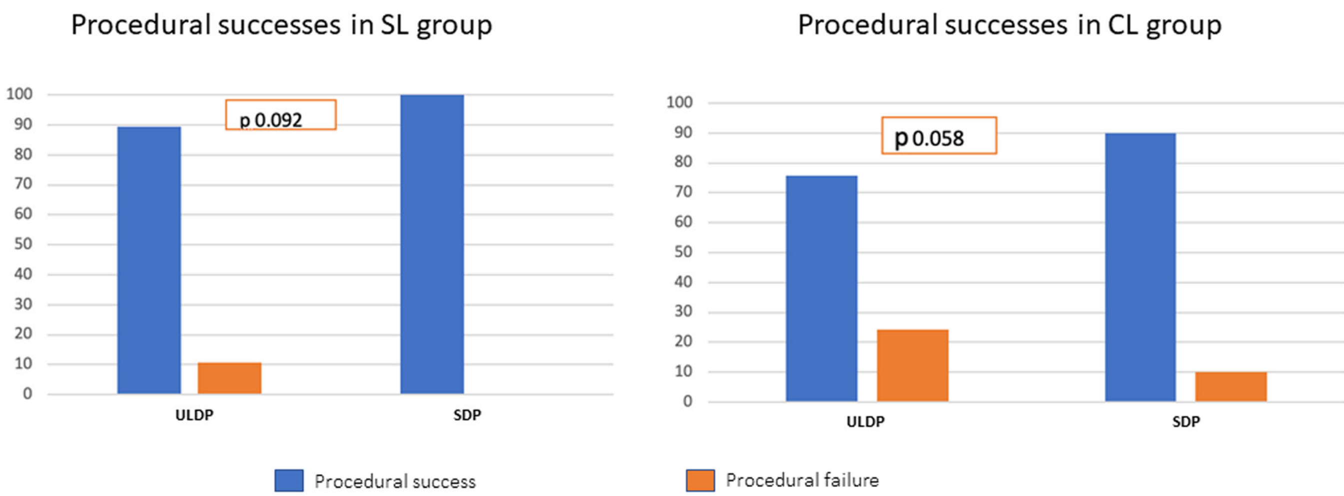

FIGURE 4 The figure reports the difference regarding procedural success and in-hospital MACE between groups. CL, complex lesion; MACE, major adverse cardiovascular events; SDP, standard dose protocol; SL, simple lesion; ULDP, ultra-low dose protocol. [Color figure can be viewed at wileyonlinelibrary.com]

6 | CONCLUSIONS

Data from this retrospective registry show that an Ultra-Low Dose Fluoroscopic Protocol significantly reduces radiation exposure in the setting of high complexity procedures such as CTO PCIs. This reduction seemed to be greater with increased procedural complexity and did not impact acute success or adverse events. The demonstrated feasibility and safety of this new strategy in complex scenarios, such as CTO PCI, should encourage operators to use this protocol during interventional procedures, regardless of complexity.

ACKNOWLEDGEMENTS

Open access funding provided by BIBLIOSAN.

CONFLICT OF INTEREST STATEMENT

The authors declare no conflict of interest.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the corresponding author upon reasonable request.

ORCID

Mauro Chiarito http://orcid.org/0000-0002-9333-2658
Jorge Sanz-Sanchez http://orcid.org/0000-0003-4991-6549
Laura Novelli http://orcid.org/0000-0002-1547-3252
Mihajlo Kovacic http://orcid.org/0000-0002-2577-9474
Francesco Contorni http://orcid.org/0000-0003-1257-5197

REFERENCES

1. Mettler FA, Huda Jr W, Yoshizumi TT, et al. Effective doses in radiology and diagnostic nuclear medicine: a catalog. *Radiology*. 2008;248(1):254-263.
2. Andreassi MG, Cioppa A, Botto N, et al. Somatic DNA damage in interventional cardiologists: a case-control study. *FASEB J*. 2005;19:998-999.
3. Roguin A, Goldstein J, Bar O. Brain tumours among interventional cardiologists: a cause for alarm? Report of four new cases from two cities and a review of the literature. *EuroIntervention*. 2012;7(9):1081-1086.
4. Wambersie A, DeLuca PM, Zoetelief J, ICRU. Preface. *J ICRU*. 2005;5:1-2.
5. Suzuki S, Furui S, Kohtake H, et al. Radiation exposure to patient's skin during percutaneous coronary intervention for

various lesions, including chronic total occlusion. *Circ J*. 2006;70: 44-48.
6. Maccagni D, Godino C, Latib A, et al. Analysis of a low dose protocol to reduce patient radiation exposure during percutaneous coronary interventions. *Am J Cardiol*. 2017;119(2):203-209.
7. Fu MH, Pan YY, Tao XF, Du J, Cheng B. Safety and efficacy of a low frame rate protocol for percutaneous coronary intervention for chronic total occlusions. *Chin Med J*. 2021;134(10):1215-1217.

How to cite this article: Bacci E, Chiarito M, Sanz-Sanchez J, et al. Safety and efficacy of an ultra low dose fluoroscopic protocol for chronic total occlusion recanalization. *Catheter Cardiovasc Interv*. 2023;101: 911-917. doi:10.1002/ccd.30605

Visit IAC at SCAI 2023 . Booth 224

Explore IAC Accreditation

IAC offers a **unique approach to accreditation** and is leading the field with **innovative, customized solutions** for your facility.

IAC is a nonprofit, nationally recognized accrediting organization, founded by medical professionals to advance appropriate utilization, standardization and quality of diagnostic imaging and intervention-based procedures.

- **Customer Service:** Facilities are busy caring for their patients and accreditation should not interfere with that. IAC clinical staff are available to guide applicant facilities through the accreditation process via phone, live chat or e-mail quickly and efficiently.
- **Quality & Safety Focused:** Offering a meaningful clinical peer review of case studies (with pathology) to evaluate diagnostic quality, report accuracy and report completeness, IAC is a partner in quality. IAC provides quality improvement-focused solutions such as the IAC QI Self-Assessment Tool, to help facilities optimize processes and improve patient safety and outcomes.
- **Continuous Improvement:** Accreditation must be thorough to truly affect the quality of care provided; however, IAC continues to explore ways to enhance the application process to make it simpler, more efficient and cost-effective to applicants including a base application fee reduction for facilities applying in 2023 and discounts on multiple site applications.

Join the more than 14,000 IAC-accredited facilities who consistently express the highest levels of satisfaction with IAC's customer service and resources. IAC offers accreditation for:

Vascular Testing
Echocardiography
Nuclear/PET
MRI · CT / Dental CT
Carotid Stenting
Cardiac Electrophysiology
Cardiovascular Catheterization
Vascular Interventional

IAC
Improving health care through accreditation®
intersocietal.org | 800.838.2110

IAC Offering 20% Reduction on Base Application Fees for 2023

To learn more or access our Online Fee Estimator, scan the QR code to the left or visit our website at ***intersocietal.org/iac/2023fees***.