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# Safety and efficacy of a low frame rate protocol for percutaneous coronary intervention for chronic total occlusions

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Chronic total occlusion (CTO) is the complete obstruction of a coronary artery for >3 months, combined with thrombolysis in myocardial infarction (TIMI) flow grade 0. Percutaneous coronary intervention (PCI) is widely used to treat CTO but is less used than coronary artery bypass graft surgery (CABG).[1] However, PCI for CTO may increase the exposure of patients and operating physicians to radiation compared with non-CTO PCIs,[2] and higher radiation exposure is linked to long-term adverse outcomes.[3] PCI operators are exposed to significantly less radiation than patients during each procedure; however, repeated exposure during a lifetime may cause health problems. Therefore, reducing the exposure of PCI cardiologists to radiation without compromising the surgical success rate and clinical outcomes of patients is crucial. A low frame rate (LFR) protocol and/or selective fluoroscopy image storage decreases the exposure of PCI operators and patients to radiation during PCIs. The objective of this study is to evaluate the safety and efficacy of an LFR protocol for managing CTO patients.

The study protocol was approved by the Ethics Committee of the Sichuan Provincial People's Hospital, University of Electronic Science and Technology of China (No. 2018-127). All participants signed informed consent forms. A total of 110 consecutive patients with CTO who underwent PCI in our hospital between January 2017 and June 2019 were retrospectively analyzed. In this cohort, 53 patients received PCI with an LFR protocol (intervention group, IG) and 57 received PCI with a standard protocol (SP) (control group, CG). CTO was defined as a TIMI flow grade 0 with coronary occlusion for ≥3 months. The inclusion criterion was CTO patients aged >18 years who underwent PCI, and the exclusion criterion was patients with hemodynamic instability. Demographic and baseline clinical characteristics were obtained from the database of our hospitals. All CTO cases were diagnosed by CTO expert and Fellow of the American College of Cardiology—Biao Chen. Each procedure was performed according to current guidelines and algorithms.

The SP and LFR protocols are detailed in Supplementary Table 1, http://links.lww.com/CM9/A468. In brief, the main differences were that the LFR protocol had (1) an extra 0.9 mm copper (Cu) spectral filter for fluoroscopic mode; (2) lower cineradiography (from 15.0 to 7.5 frames per second [FPS]); and (3) an extra 0.1 mm/1.0 mm Cu/aluminum (Al) filter for cineangiography mode. The air kerma radiation exposure was registered as indicated by the X-ray system.

The measured angiographic indices included the location of the CTO, stump morphology, calcification at the occlusion site (presence of radiopacity before contrast injection), vessel tortuosity (presence of at least one bend >45° proximal to the occlusion) and grades of collateral circulation. The Multicenter CTO Registry of Japan (J-CTO) score was calculated according to Yoshihiro *et al*.[4] All acquired images were reviewed by at least two qualified PCI operators. Technical success was defined as a restoration of TIMI flow grade 3 in the target vessel and residual stenosis <30% estimated visually. Procedural success was defined as achievement of technical success without in-hospital major adverse cardiac events (MACEs). In-hospital outcome evaluations included in-hospital MACEs, periprocedural myocardial injury (PMI), and procedural complications. In-hospital MACEs included any of the following adverse events before hospital discharge: all-cause death, stent thrombosis (ST)/Q-wave myocardial infarction (MI), ischemia-driven revascularization, and emergency cardiac surgery. ST was defined according to the Academic Research Consortium criteria.[5] PMI was defined according to the Third Universal Definition of MI.[6] Procedural complications included

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donor vessel dissection, vessel perforation, collateral perforation, and cardiac tamponade. Coronary perforation was defined as having any contrast pool or evidence of contrast leak into cardiac chambers or pericardial space. Perforations were divided into two categories according to location: (1) target vessel perforation, and (2) collateral perforation.

All data were analyzed using SPSS software version 13.0 (SPSS, Chicago, IL, USA). Continuous variables with normal distribution were expressed as means ± standard deviations (SD) and analyzed by using Student's *t* test. Categorical variables were presented as numbers and percentages and analyzed by using Chi-squared test or Fisher's exact test. A two-tailed *P* value of less than 0.05 was considered statistically significant.

The demographic and baseline clinical characteristics of patients are shown in Supplementary Table 2, http://links.lww.com/CM9/A468. Male patients accounted for 83.0% and 80.7% of the IG and CG group, respectively. There were no significant differences in demographic parameters, including gender and age, and no significant differences in baseline clinical characteristics, including BMI, stable and unstable angina, non-ST-segment elevation myocardial infarction, hypertension, diabetes, dyslipidemia on medications, prior MI, prior CABG, smoking, left ventricular ejection fraction, and J-CTO scores between the two groups (all $P > 0.05$). However, the proportion of asymptomatic patients was significantly higher in the CG than in the IG group (3.5% *vs.* 1.9%, $P = 0.041$).

There were no significant intergroup differences in procedure-related parameters, including contrast volume (327.1 ± 101.2 mL *vs.* 308.4 ± 98.5 mL, $t = 0.906$, $P = 0.343$), procedure duration (142.3 ± 52.1 min *vs.* 137.8 ± 51.5 min, $t = 0.741$, $P = 0.500$), and fluoroscopy duration (56.8 ± 9.7 min *vs.* 52.4 ± 10.7 min, $t = 0.876$, $P = 0.351$). However, the procedural success rate was significantly higher in the IG group (7.5% *vs.* 5.3%, $P = 0.072$) [Supplementary Table 3, http://links.lww.com/CM9/A468]. There was no significant difference in electromagnetic radiation exposure between the two groups (0.23 ± 0.03 V/m *vs.* 0.25 ± 0.07 V/m, $t = 0.875$, $P = 0.383$), whereas air kerma radiation exposure (4.3 ± 1.4 Gy *vs.* 6.9 ± 2.1 Gy, $t = 3.251$, $P = 0.010$) and air kerma radiation exposure per min (75.8 ± 11.4 mGy *vs.* 131.7 ± 21.8 mGy, $t = 3.169$, $P = 0.011$) were significantly lower in the IG group [Supplementary Table 3, http://links.lww.com/CM9/A468]. These results suggest that the LFR protocol significantly reduced the radiation dose during the PCI procedure.

In-hospital MACEs, including death, ST/Q-wave, ischemia-driven revascularization, emergency cardiac surgery, PMI, and procedural complications such as donor vessel dissection, target vessel perforation, collateral perforation, and cardiac tamponade were used as endpoints to compare the safety of the two protocols. ST/Q-wave MI, a major adverse event, occurred in two patients (3.8%) in the IG and three patients (5.3%) in the CG group ($P = 0.074$) [Supplementary Table 4, http://links.lww.com/CM9/A468]. There were no significant differences in the other MACEs between the two groups. In addition, there were no significant intergroup differences ($P > 0.05$) in target vessel perforation, collateral perforation, and cardiac tamponade; however, the donor vessel dissection rate was significantly lower in the IG than in the CG group (9.4% *vs.* 10.5%, $\chi^2 = 9.873$, $P = 0.020$). These findings support the hypothesis that the LFR protocol is safer than the SP regarding the occurrence of donor vessel dissection.

It is well known that CTO-PCI emits more radiation to patients and operators compared with non-CTO interventions, and high radiation exposure is linked to long-term adverse outcomes.[3] Therefore, the radiation dose should be reduced during PCIs by adopting appropriate protocols. However, lower radiation doses are associated with deterioration of image quality, which could impair the effectiveness of the procedure. For this reason, a good balance between these two factors is critical. We employed an LFR protocol with an extra 0.9 mm Cu filter for fluoroscopic mode, lower cineangiography (from 15.0 to 7.5 FPS), and an extra 0.1 mm/1.0 mm Cu/Al filter for cineangiography mode to compare the safety and efficacy of this protocol with an SP. The LFR protocol had a significantly higher technical success rate. In turn, there were no significant intergroup differences in other procedural parameters such as contrast volume, procedure duration, and fluoroscopic duration. Moreover, with regard to clinical endpoints, the rate of adverse outcomes after PCI was similar between the two protocols. Nonetheless, the LFR protocol reduced the rate of occurrence of donor vessel dissection. These findings support the premise that the LFR protocol is safer than the SP for PCI-treated CTO patients.

LFR protocols are used to reduce radiation doses. In the present study, the following three parameters were used to assess whether these protocols could reduce the radiation dose to CTO patients: electromagnetic radiation exposure, air kerma radiation exposure, and air kerma radiation exposure per min. There was no significant difference in electromagnetic radiation exposure between the two groups. However, the LFR protocol significantly decreased air kerma radiation exposure and air kerma radiation exposure per min compared with the SP. In the LFR protocol, the standard frame rate was maintained but other parameters such as cineradiography (FPS), fluoroscopy (Cu+Al) and cineradiography (Cu+Al) were changed. We believe that the LFR protocol should be used in CTO patients during PCI because this protocol significantly reduced the radiation dose during the procedure and caused fewer severe complications compared with the SP.

This study has some limitations. First, the retrospective nature of the study, the small sample size, and the absence of randomization might lead to sampling bias. Second, only one LFR protocol was used; for this reason, the safety and efficacy of other LFR protocols for PCI-treated CTO patients need to be examined and compared.

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### *Conflicts of interest*

None.

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