Recanalization of chronic total occlusion using a new device: the real-time intravascular ultrasound double-lumen microcatheter

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To the Editor: Revascularization after chronic coronary total occlusion (CTO) can relieve symptoms of angina and improve both cardiac function and clinical prognosis.[1,2] However, percutaneous coronary intervention (PCI) for revascularization of CTO lesions is challenging because of a high incidence of complications and long X-ray exposure time. While the success rate for PCI in CTO has significantly increased in recent years due to the emergence of new technologies, devices and anticoagulation strategies,[3,4] these new devices have also led to complications such as coronary artery perforation and cardiac tamponade, which limit their application. As routine PCI procedures for CTO intuitively require operationally safe devices, we have developed a new device called the real-time intravascular ultrasound (IVUS) double-lumen microcatheter (RLS catheter). Here, we briefly describe the RLS catheter, report our experience with this device, and provide data on its efficacy and safety in CTO revascularization.

This study was approved by the Ethics Committee of our hospital (No. 201215). All enrolled patients provided prior written informed consent for the use of the RLS catheter in their treatment. Statistical analysis was performed using SPSS19.0 statistical software (SPSS Inc, Chicago, IL, USA). Normally distributed continuous variables were expressed as mean ± standard deviation (SD), while non-normally distributed variables were expressed as median. Categorical variables were expressed as *n* (%).

Patients with CTO who underwent PCI between February 2018 and May 2019 at the Department of Cardiology in our hospital were selected for participation in this study. PCI was performed using the RLS catheter by a cardiologist in patients with an ambiguous proximal cap or in those where the guidewire situated in the false lumen could not easily re-enter the true lumen. We enrolled 12 CTO patients with a median age of 54.0 years and a median left ventricular ejection fraction of 62.0%. This cohort included nine males. Further, nine patients suffered from unstable angina, seven (58.3%) had hypertension, seven had diabetes, five had hyperlipidemia, five were smokers, four had a history of myocardial infarction, and three had previously PCI.

The RLS catheter is composed of an IVUS catheter and a microcatheter.[5] The IVUS catheter serves as a monorail lumen, and the probe at the tip of the IVUS catheter acquires real-time cross-sectional images of the vascular wall. The microcatheter serves as an over-the-wire (OTW) lumen such that the penetrating guidewire is advanced through the microcatheter into the lesion through an aperture in the side [Supplementary Figures 1A, B, http://links.lww.com/CM9/A367]. The length of the device is 1350 mm, the aperture on the side is situated 20 mm from the distal tip of the microcatheter, and the exit port is at a distance of 240 mm from the distal tip of the IVUS catheter. The widest part of the device is 3.6 Fr and there are three radiopaque marks on the device [Supplementary Figure 1B, http://links.lww.com/CM9/A367]. The RLS catheter can support a guidewire through the occlusion stump or upon re-entry into the true lumen. According to our experience, when it was difficult to find an entry point at the cap of a CTO, the RLS catheter was advanced using the guidewire in the side branch [Supplementary Figure 1C, http://links.lww.com/CM9/A367]. Next, under the guidance of realtime IVUS images, the CTO-dedicated guidewire was advanced through the aperture on the side to penetrate the occluded lesion [Supplementary Figure 1D, http://links.lww.com/CM9/A367]. When the guidewire had entered the false lumen, the RLS catheter was advanced over the guidewire into the false lumen [Supplementary Figure 1E, http://links.lww.com/CM9/A367]. Finally, a CTO-dedicated guidewire was selected and introduced to the true lumen under the guidance of realtime IVUS images [Supplementary Figure 1F, http://links.lww.com/CM9/A367].

The most frequently affected vessels were the left anterior descending (9/12) and the right coronary artery (6/12), and

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3/12 of the patients had multivessel CTO lesions. The morphology of the lesions included severely tortuous (3/12), stumpless CTO (5/12), length of the CTO lesion >20 cm (10/12), and in-stent occlusions (1/12). We used a 6 Fr guiding catheter in 3 patients and a 7 Fr guiding catheter in the rest. Eight cases required the use of the RLS catheter to facilitate guidewire entry into the occlusion, while in five cases it was for guidewire re-entry into the true lumen. The technical success rate and the procedural success rate were both calculated to be 11/12. Technical failure was seen in one patient with an in-stent occlusion wherein the RLS catheter was damaged during guidewire re-entry into the in-stent space. Revascularization using the RLS catheter was successful in all the other 11 patients with a median procedure time of 70.5 min. The median time for guidewire passage through the CTO lesion was 32.0 min, and after the RLS catheter was advanced, the median time taken for guidewire penetration through the target lesion was 3.0 min, and the median time for guidewire passage through the CTO lesion was 9.5 min.

Importantly, angina was relieved in all patients, and no complications such as coronary artery perforation, pericardial tamponade, or acute myocardial infarction occurred in any of the patients, either during or after the procedure. The median follow-up time was 18.0 months. Only one patient reported recurrence of angina pectoris at 17 months after the procedure, and the others did not experience any main adverse cardiovascular events.

The unique design of our RLS catheter overcomes the disadvantages associated with exchanging the IVUS and the double-lumen microcatheter while maintaining the advantages of both. Further, its double-lumen structure provides better support and facilitates placement of the guidewire. As the relative positions of the guidewire and the IVUS probe are fixed in this device, the directional accuracy of the guidewire during lesion penetration is significantly improved. Importantly, the IVUS of the RLS catheter can identify the entry point, distinguish between true and false lumens, define the relative position of the guidewire and target lesion, and provide real-time guidance during lesion entry. These characteristics of the RLS catheter improve its accuracy and thereby, reduce both procedure time and the incidence of complications. Lastly, as the external diameter of the RLS catheter is 3.6 Fr, it can be inserted through a routinely-used 6 Fr or 7 Fr guiding catheter.

This retrospective study provides evidence that the RLS catheter is effective and safe for use in complex CTO revascularization procedures as it supports the guidewire in two ways, namely, its entry into the lesion and its re-entry into the true lumen. Both device and procedure success rates were higher than 90%. The time taken between the guidewire entry into the lesion and its re-entry into the true lumen was only several minutes after the RLS catheter was advanced, attesting to the efficiency of the RLS catheter. Notably, successful CTO revascularization was achieved in four patients using the RLS catheter after conventional ante grade and/or retrograde intervention had failed, demonstrating that our RLS catheter could increase the success rate of CTO revascularization. No complications occurred during the perioperative period, and only one patient developed angina pectoris after the procedure, attesting to the safety of the RLS catheter in the treatment of CTO lesions. As the sample size is relatively small, the results need to be confirmed by larger multicenter studies.

In summary, these results indicate that the RLS catheter is useful in CTO revascularization and that it can potentially be used in routine clinical practice.

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Conflicts of interest

None.

References

1. Li KHC, Wong KHG, Gong M, Liu T, Li G, Xia Y, *et al*. Percutaneous coronary intervention versus medical therapy for chronic total occlusion of coronary arteries: a systematic review and meta-analysis. Curr Atheroscler Rep 2019;21:42. doi: 10.1007/s11883-019-0804-8.
2. Zivelonghi C, van Andel M, Venturi G, Amoroso G, Teeuwen K, Tijssen JGP, *et al*. Angiographic and clinical outcomes of antegrade versus retrograde techniques for chronic total occlusion revascularizations: insights from the PRISON IV trial. Catheter Cardiovasc Interv 2019;93:E1–E9. doi: 10.1002/ccd.27795.
3. Kanno D, Tsuchikane E, Nasu K, Katoh O, Kashima Y, Kaneko U, *et al*. Initial results of a first-in-human study on the PlasmaWire System, a new radiofrequency wire for recanalization of chronic total occlusions. Catheter Cardiovasc Interv 2018;91:1045–1051. doi: 10.1002/ccd.27333.
4. Li ZZ, Tao Y, Wang S, Yin CQ, Gao YL, Cheng YT, *et al*. Unfractionated heparin with sequential enoxaparin in patients with complex coronary artery lesions during percutaneous coronary intervention. Chin Med J 2018;131:2417–2423. doi: 10.4103/0366-6999.243559.
5. Ma Y, Peng Y, Wang G, Ru L. A novel real-time intravascular ultrasound double-lumen microcatheter for recanalization of chronic total occlusion: a case report. J Med Case Rep 2019;13:315. doi: 10.1186/s13256-019-2230-5.

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