Anchoring Improved: Introduction of a New Over-the-Wire Support Balloon

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ABSTRACT: Coronary chronic total occlusion (CTO) interventions continue to be technically challenging for interventional cardiologists despite the advent of multiple devices and techniques. Successful CTO percutaneous coronary intervention (PCI) has proven to improve symptoms, long-term mortality, and ejection fraction. We present a case of a patient with symptomatic right coronary artery (RCA) CTO who failed maximal medical therapy as well as multiple antegrade PCI attempts. Successful RCA CTO intervention was finally achieved using a novel over-the-wire balloon catheter (Prodigy; Radius Medical) in an antegrade fashion.

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KEY WORDS: chronic total occlusion, PCI, RCA

Chronic total occlusions (CTOs) are associated with severe lifestyle impairment, reduced cardiac performance, and worsened longevity.[1,2] The weight of current evidence suggests successful revascularization of CTOs is associated with improved long-term survival and left ventricular systolic function, as well as reducing angina.[3-5] Percutaneous coronary intervention (PCI) of CTO continues to be a technical challenge for interventional cardiologists. In an attempt to improve the success rates, multiple novel PCI techniques have been developed, including CTO wiring strategies (wire shaping, selection, characteristics, parallel wire technique, and handling), antegrade dissection reentry technique (the Stingray System; BridgePoint Medical), and retrograde techniques, including the controlled antegrade retrograde tracking (CART) and reverse CART methods,[6-18] the use of intravascular ultrasound (IVUS) and optical coherence tomography (OCT), penetration catheters (Asahi Tornus; Abbott Vascular), and limited antegrade subintimal tracking (LAST). All of these techniques, even in experienced hands, often require prolonged fluoroscopy time and greater contrast volume.

In addition to visualization of the distal vessel from simultaneous contralateral angiography, guiding catheter support is imperative. Even with Amplatz guide catheters (Medtronic), guiding catheter support might not be adequate. Over-the-wire (OTW) balloons, microcatheters (Finecross; Terumo Corporation), or extension support catheters (GuideLiner; Vascular Solutions) are often utilized for more support. Furthermore, OTW balloons are commonly used to improve guide support using the anchoring technique. Limitations of this technique are the length of patent segment proximal to the CTO, small size of the side branches, as well as the propensity for barotrauma from the anchoring balloon. We present a case report in a patient with CTO of the right coronary artery (RCA) that was successfully recanalized by utilizing Prodigy (Radius Medical), a novel OTW balloon support catheter.

Case Report. *The patient was a 72-year-old male, with a past medical history of hypertension, diabetes mellitus (DM), coronary artery disease (CAD), and PCI of the left anterior descending (LAD) artery with drug-eluting stent in 2008. The patient had ischemic cardiomyopathy (ICM) with an ejection fraction (EF) of 30% and has an implantable cardioverter defibrillator (ICD). Over the past 5 years, the patient had New York Heart Association (NYHA) class 1 functional status. Gradually, over the past 6 months his functional status declined; he developed NYHA class 3 symptoms of exertional dyspnea and angina pectoris. He received maximal anti-anginal and heart failure medical therapy. He underwent an exercise nuclear stress test that was significant for severe inferior ischemia. Consequently, he underwent a coronary angiogram, which revealed normal left main, patent mid-LAD stent with left to right septal collaterals, and normal left circumflex (LCX) artery. The RCA was mild to moderately calcified and was 100% occluded proximally; the CTO was about 30 mm in length with minimal bridging collaterals, and a side branch at the proximal cap. Although the patient had good left to right septal collaterals, they were highly tortuous with less likelihood for successful retrograde approach. Left ventriculography revealed EF 30%-35% with mid-distal anterior hypokinesis.*

Two prior attempts by other experienced operators to open the CTO through antegrade approach were unsuccessful. The prior attempts were through femoral approach; they utilized Amplatz (AL) catheters, anchoring balloon in the side branch, wire escalation techniques, and the use of specialty wires like Asahi MiracleBros 3 and 12 (Abbott Vascular), Asahi Confienza (Abbott Vascular), and Asahi Fielder XT (Abbott Vascular). On this third attempt, a 6 Fr sheath was placed in the right radial artery and was utilized for the CTO intervention using an AL-2 guide catheter. A 5 Fr sheath was placed in the right common femoral artery and Judkins Left (JL-4) diagnostic catheter was used for simultaneous contralateral angiography aimed for better visualization of the distal RCA and the CTO.

The Prodigy, a novel OTW supporting balloon, was introduced into the proximal RCA and placed 5-10 mm proximal to the CTO (Figure 1) over a MiracleBros 3 wire. The balloon was inflated to 1 atm. With the anchoring support of the balloon, and close proximity to the cap, we were able to penetrate the proximal cap of the CTO into the distal RCA while remaining intraluminal. At this point, the Prodigy balloon was removed and a Finecross catheter

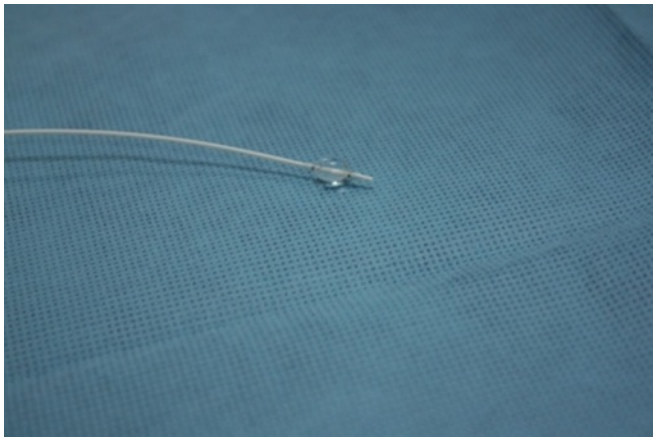

FIGURE 1. The Prodigy support balloon catheter.

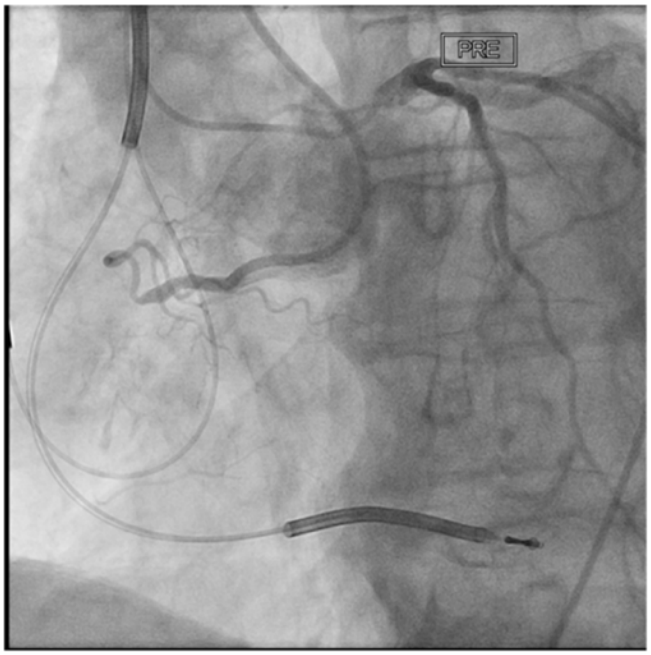

FIGURE 2. The LAO angiogram is performed with the radial catheter in the right coronary artery and the left Judkins catheter in the left coronary artery. This simultaneous injection delineates the chronic total occlusion.

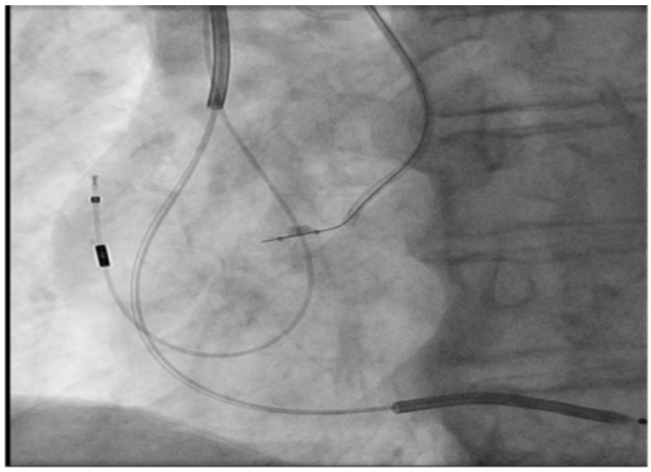

FIGURE 3. The Prodigy support balloon catheter is at the origin of the right coronary artery.

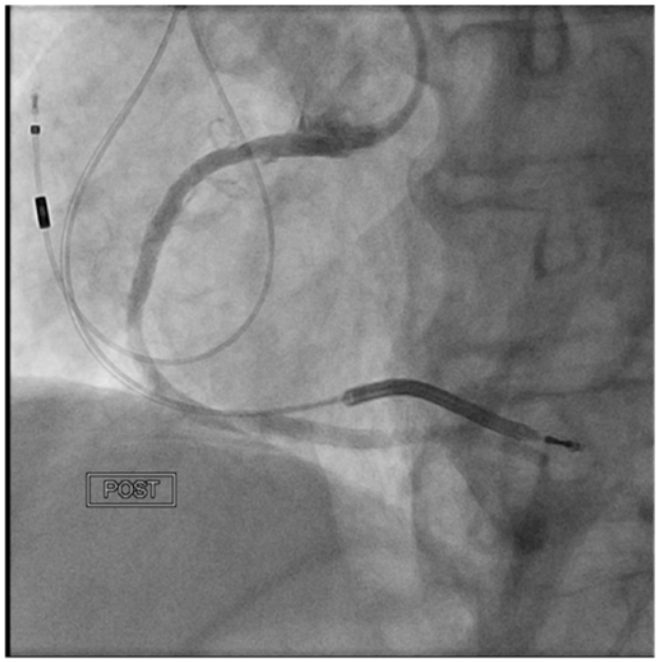

FIGURE 4. This LAO angiogram was performed after successful recanalization and stenting of the right coronary chronic total occlusion.

(Terumo Corporation) was advanced distally in the RCA. The MiracleBros 3 wire was exchanged for a Whisper wire (Abbott Vascular), which we commonly use in our laboratory. The Finecross catheter was removed and a 2.5 x 30 mm Trek OTW balloon (Abbott Vascular) was advanced distally into the RCA. Sequential distal to proximal dilatations were completed using the 2.5 x 20 mm balloon as well as a Sprinter 3.0 x 30 mm balloon (Medtronic). Four Xience drug-eluting stents (Abbott Vascular; 3.0 x 38 mm, 3.0 x 28 mm, 3.25 x 38 mm, and 3.5 x 33 mm) were deployed into the distal RCA, mid-RCA and proximal RCA, respectively. The final result is shown in Figure 2.

From the time the Prodigy balloon was placed in the proximal RCA, it took 7.5 minutes of fluoroscopy to penetrate the proximal cap and 10.7 minutes of fluoroscopy to completely cross the chronic total occlusion, with total fluoroscopy time of 24.2 minutes. We utilized 98 mL of intravenous contrast to cross the CTO, with total contrast use of 146 mL. After the successful revascularization, the patient's symptoms improved dramatically. Four weeks post procedure, his functional status improved to NYHA class 2. Six months post procedure, and with cardiac rehabilitation, the functional status returned to baseline of NYHA class 1.

Discussion. Contemporary techniques and technologies can achieve high success rates with a reasonable safety profile for percutaneous revascularization of coronary CTO. The Prodigy support catheter is a novel Food and Drug Administration (FDA)-approved device to be used in conjunction with steerable wires in order to access CTO lesions. It is a one-size 6 mm OTW elastomeric (very compliant) balloon, with rated burst pressure (RBP) of 1.2 atm, which allows utility in various vessel diameter sizes, and strong anchoring with minimal barotrauma to the artery. The inflation lumen includes a pressure relief valve that will limit the inflation pressure to 1 mm Hg. It has a very short tip (<2 mm in length), which allows close proximity to the CTO lesion with more accurate placement of the wire in the proximal cap, and more support while avoiding side branches and bridging collaterals. The actual balloon length is 5 mm, which allows placement in short patent segments of the CTO vessel. It is well visualized through two radiopaque markers at either end of the balloon. We speculate that the above unique features of the Prodigy provided us with better anchoring and support, with less barotrauma to the vessel wall, while using less traumatic wires than commonly used in CTO lesions, such as Shanobi (Cordis Corporation), Asahi Conquest, or Asahi Confienza. Furthermore, the relatively rapid penetration of the CTO reduced the amount of contrast as well as radiation exposure. The improved support provided by this balloon could potentially increase CTO revascularization procedure success through radial access which, historically, has been limited in CTO-PCI due to submaximal catheter support, which is mainly caused by smaller guiding catheter sizes that could be used in radial access.

The Prodigy balloon support catheter is potentially an effective tool for the antegrade approach in CTO intervention. It provides exceptional anchor support with less barotrauma to the artery, and allows proximity to the CTO cap aiding in avoiding side branches. These features certainly could reduce contrast utilization and radiation exposure. Furthermore, the improved support provided by this balloon could potentially increase CTO revascularization success through radial access.

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Disclosure: The authors have completed and returned the ICMJE Form for Disclosure of Potential Conflicts of Interest. Dr Heuser is the co-developer of the Prodigy catheter (Radius Medical), and holds patents related therein. The remaining authors report no conflicts of interest regarding the content herein.

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