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GuideLiner Mother-and-Child Guide Catheter Extension: A Simple Adjunctive Tool in PCI for Balloon Uncrossable Chronic Total Occlusions

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Objectives: *To investigate the use of the GuideLiner "mother-and-child" guide catheter extension system as a simple solution to facilitate initial device delivery in balloon uncrossable chronic total occlusions (CTOs) undergoing percutaneous coronary intervention (PCI).*
Background: *During PCIs for CTO lesions, an important reason for procedural failure is the inability to deliver a balloon or microcatheter across the lesion.*
Methods: *We retrospectively accessed our interventional registry for 07/01/2010 to 03/21/2012 and extracted data on all CTO lesions involving GuideLiner catheter use. Cine review was performed to identify cases where a guidewire had crossed the CTO and the use of a GuideLiner catheter facilitated initial device delivery.*
Results: *We identified 28 patients that underwent PCI for CTO with a GuideLiner catheter used to assist initial balloon or microcatheter advancement across the culprit lesion. Mean overall CTO length was 26.3 ± 18.1 mm. The GuideLiner catheter was successful in delivering a small balloon to the CTO lesion in 85.7% of cases (24/28). A single CTO PCI resulted in a distal guidewire perforation, but there was no hemodynamic compromise or pericardial effusion and the patient was discharged the next day. Overall procedural success in these selected cases (where a guidewire had already crossed the CTO) was 89.3% (25/28).*
Conclusions: *The GuideLiner mother-and-child catheter is a simple, safe and efficacious adjunctive device for difficult CTO PCIs where despite standard measures it is not possible to deliver an initial balloon or microcatheter across the occluded segment.* (J Interven Cardiol 2013;26:343–350)

Introduction

There is growing interest in percutaneous coronary intervention (PCI) for chronic total occlusions (CTOs), particularly in patients with myocardial ischemia of the CTO territory despite optimal medical therapy. CTO lesions present numerous challenges that may reduce procedural success. However, several important technical and device advances have recently been made that appear to have positively impacted the likelihood of procedural success, including newer generation and novel guidewires, retrograde techniques, novel catheters, and smaller profile balloons and stents.[1,2] Nevertheless, perhaps due to increasingly challenging patient and lesion selection, in contemporary series the overall procedural success rate for CTOs has remained stable at only 65–70%.[3] Continued advancement in relevant techniques and equipment will be required if the success rate of PCI for CTO is to improve.

Importantly, once a CTO lesion has been successfully wired, a key reason for procedural failure is the inability to deliver a balloon, microcatheter and/or stents to the target lesion. Interventionalists often colloquially refer to this situation as "the wire has crossed but nothing will go." Several options are available in this scenario of a balloon uncrossable CTO lesion during PCI. Standard initial maneuvers in this situation include deep

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inspiration by the patient, use of a second (buddy) wire, using a lower profile balloon, deep seating or changing the guide catheter to a more supportive configuration or attempting to rewire the lesion with a stiffer guidewire.[1] If these actions fail, some of the more technically complex options include anchor balloon techniques, changing to a retrograde approach, or attempting to rewire the lesion with a rotawire and performing rotational atherectomy with a small burr (Rotablator®; Boston Scientific, Natick, MA, USA).[1] However, not all operators are familiar with these latter techniques, and the unsuccessful termination of a failed CTO PCI is a not uncommon outcome if standard maneuvers have failed to deliver an initial device to the target lesion. Recently, "mother-and-child" guide catheter extension systems have been introduced into the interventional armamentarium. These catheters may be extended beyond the angioplasty guide catheter, and enable deep culprit vessel intubation to achieve extra support and improve alignment.[4,5] Currently available mother-and-child catheters include the Heartrail® (Terumo, Somerset, NJ, USA) and GuideLiner® (Vascular Solutions, Minneapolis, MN, USA).[4,5] Here, we report our initial experience using the GuideLiner catheter as an adjunct device in CTO cases where despite standard measures it was not possible to deliver an initial balloon or microcatheter to the target lesion and to perform a first balloon dilation.

Methods

The purpose of this study was to describe the procedural and clinical outcomes in CTO PCI patients where a guidewire had been successfully navigated into the distal vessel, but neither microcatheter nor balloon could be advanced across the lesion. The study was performed using our single center interventional registry. Details of this registry have been published previously.[6] In brief, all PCI procedures are entered into a prospectively collected, institutional review board approved registry. Data collected includes baseline clinical characteristics, procedural details (including CTO vs. non-CTO PCI, equipment use, and procedural success), details of events occurring immediately post-procedure, in-hospital clinical course, laboratory data, and other test results associated with the procedure. After discharge, subjects are routinely contacted and undergo 30-day and 12-month follow-up. We retrospectively accessed our interventional registry for the period of July 1, 2010 to March 31, 2012 (inclusive) and extracted data on every PCI performed (n = 8,306) that included the use of the GuideLiner catheter (204 GuideLiner cases; 2.4% overall GuideLiner use). All unstable patients including those with myocardial infarction (ST-segment elevation or non-ST-segment elevation) were then excluded. There were 372 CTOs that underwent PCI during this period (successful and unsuccessful), indicating a CTO PCI rate of 4.5% (372/8306). Initially, 66 patients were identified that fulfilled our screening criteria of having CTO PCI with GuideLiner use. Next, because the GuideLiner catheter may also be used to deliver stents through tortuous or calcified vessels, or for other reasons unrelated to initial device delivery, cineangiographic review was performed to identify CTO cases with documented GuideLiner use (GuideLiner advanced beyond vessel ostium) to deliver an initial balloon or microcatheter, or at first balloon inflation (28 cases identified). Cineangiographic review was performed by 2 experienced interventional cardiologists, blinded to the procedural and clinical outcomes. Cases were discarded from this analysis if the GuideLiner was not visible in the first angiographic image showing a balloon inflation or microcatheter delivery across the culprit lesion. Cineangiographic review also included angiographic quantitative coronary analysis (QCA) to determine: (1) Shepherd's Crook right coronary artery (RCA) morphology (as defined by Gossman et al.[7]) in all cases; (2) CTO length (all cases), and; (3) estimated distance of GuideLiner intubation into the target vessel (performed in 26/28 cases—in two cases technical difficulties prevented QCA assessment of intubation distance). QCA was performed using the Cardiovascular Angiographic Analysis System (CAAS) Version 5.7 (Pie Medical Imaging B.V., Maastricht, The Netherlands). Additional lesion and procedural details were obtained from the PCI registry, but were also verified during cineangiographic review. For in-hospital and long-term clinical outcomes, the following definitions were used: myocardial infarction was defined according to the Universal definitions of Thygesen et al.[8]; bleeding was defined using BARC criteria[9]; vascular access complications were defined according to ACUITY criteria.[10]

Revascularization Procedure. All patients presenting to the catheterization laboratory routinely received 325 mg aspirin > 90 minutes prior to angiography and were reloaded with clopidogrel (300 mg) (n = 21) or prasugrel (30 mg) (n = 4) "on-table"

immediately prior to CTO PCI. Patients naïve to these latter medications received a 600 mg "on-table" loading dose of clopidogrel (n = 3). No patient reported here received ticagrelor. As an institutional protocol we use a 45 cm long sheath for improved guide catheter support in all CTOs attempted via a transfemoral approach. All patients were anticoagulated using bivalirudin with loading bolus followed by a weight-adjusted infusion to maintain an activated clotting time of ≥300 seconds. Although the GuideLiner V2 catheter was approved for use in the US in December 2011, all cases in this study were performed with the GuideLiner V1 device. Other technical decisions regarding the PCI and CTO procedure were at the operator's discretion.

Statistical Analysis. This was not a comparative study as the number of patients was too small to permit meaningful statistical analyses. Data are presented as mean ± SD, or as % (n).

Results

During the study period there were 372 CTOs that underwent PCI, with the GuideLiner catheter used in 17.8% (66/372) of these cases. After exclusion of PCIs in which the GuideLiner was used for other reasons (e.g., advancement of a stent), we identified 28 patients that underwent PCI for CTO with a GuideLiner catheter used to assist advancement of an initial balloon or microcatheter to the culprit CTO lesion. In 22/28 (78.6%) of these cases the GuideLiner was first used for the specific purpose of initial balloon or microcatheter advancement to the culprit lesion after successful wiring of the vessel. Alternatively, in 6/28 (21.4%) cases the GuideLiner was first used during wiring of the lesion and then further utilized to assist balloon or microcatheter advancement. Baseline patient characteristics are presented in Table 1. The majority of patients had undergone prior PCI (85.7%), 50% had suffered a prior myocardial infarction, and 42.9% were diabetic. Among the 24 patients (85.7%) that had not previously undergone coronary artery bypass graft surgery, the mean SYNTAX score at the time of CTO PCI was 18.2 ± 11.6. CTO lesion characteristics are presented according to SYNTAX criteria in Table 2. The RCA was the most common culprit vessel (75%), and mean overall CTO length was 26.3 ± 18.1 mm. In four cases (14.3%) the CTO lesion was due to occlusive in-stent restenosis. Heavy calcification was judged to be present in only 4 CTO lesions (14.3%). All CTOs except 1 were performed using an antegrade approach, with a single CTO initially attempted via retrograde approach that was then converted to antegrade. In this case, the GuideLiner was used only during the antegrade attempt. Contralateral injection was performed in 13 cases (46.4%). A mean of 5.1 ± 2.1 guidewires were used per CTO (Table 3). By entry criteria, a GuideLiner catheter was used in every case. In 27 cases (96.4%) this was a 6 Fr-compatible GuideLiner within a 6 Fr guide catheter, while in 1 case (3.6%) a 7 Fr-compatible GuideLiner was used in a 7 Fr guide catheter. The mean estimated distance of GuideLiner intubation into the culprit vessel was 26.0 ± 20.0 mm, while intubation distance was >10 cm in only a single case (3.6%). The mean diameter of the smallest dilation balloon used in association with the GuideLiner was 1.39 ± 0.21 mm, with a 1.25 mm diameter balloon being the most frequent (used in 15 cases). Although technically possible, in no case was the GuideLiner successfully used to facilitate delivery

Table 1. Baseline Patient Characteristics

Variable	% (n) or Mean ± SD
Male/female	82/18% (23/5)
Age (years)	64.1 ± 10.0
Hypertension	100% (28)
Hyperlipidemia	100% (28)
Diabetes mellitus	42.9% (12)
Current smoking	25% (7)
Peripheral vascular disease	3.6% (1)
Prior myocardial infarction	50% (14)
Prior CABG	14.2% (4)
Prior PCI	85.7% (24)
Baseline serum creatinine (mg/dl)	0.97 ± 0.19
CKD	14.2% (4)
LVEF	45.5 ± 17.4
Medication use	
Aspirin	93% (26)
Clopidogrel	75% (21)
Prasugrel	14% (4)
Beta blocker	86% (24)
ACE inhibitor/ARB	54% (15)
Calcium channel blocker	57% (16)
Statin	82% (23)
Diuretic	29% (8)
Nitrates	32% (9)
Ranolazine	14% (4)

ACE, angiotensin converting enzyme; ARB, angiotensin II receptor blocker; CABG, coronary artery bypass graft surgery; CKD, chronic kidney disease (eGFR < 60 ml/min/1.73 m^2); LVEF, left ventricular ejection fraction.

Table 2. Baseline CTO Lesion Characteristics

CTO and Vessel Characteristics	% (n) or Mean ± SD
Vessel	
Right coronary artery	75% (21)
Shepherd's Crook right coronary morphology	52.4% (11/21)
Left circumflex artery	17.9% (5)
Left anterior descending artery	7.1% (2)
Most proximal occluded segment	
Proximal vessel	35.7% (10)
Mid vessel	35.7% (10)
Distal vessel	10.7% (3)
Branch (marginal, postero-lateral, and posterior-descending, diagonal)	17.9% (5)
Number of occluded segments	
1	57.1% (16)
2	39.3% (11)
3	3.6% (1)
Blunt stump	25% (7)
Side branch involvement	
None	7.1% (2)
<1.5 mm diameter side branch only	67.9% (19)
>1.5 mm diameter side branch only	0% (0)
Both <1.5 and >1.5 mm side branches	25% (7)
Age of CTO	
Unknown	7.1% (2)
<3 months	0 (0%)
>3 months	92.9% (26)
Antegrade bridging collateral vessels	67.9% (19)
Length of CTO (mm)	26.3 ± 18.1
Heavy calcification (angiographic assessment)	14.3% (4)
In-stent restenosis of CTO lesion	14.3% (4)

Table 3. Procedural Details

Procedural/Technical Details	% (n) or Mean ± SD
Approach	
Femoral access site for primary guide catheter	92.9% (26)
Radial access for primary guide catheter	7.1% (2)
Contralateral injection	46.4% (13)
Antegrade CTO approach	96.4% (27)
Retrograde CTO approach*	3.5% (1)
Supporting equipment and maneuvers	
Long sheath (45 cm)§	92.9% (26)
Number of guidewires	5.1 ± 2.1
Parallel or buddy wire technique	28.6% (8/28)
Number of balloons	3.1 ± 1.4
Mean smallest diameter balloon (mm)	1.39 ± 0.21
Anchor balloon technique	7.1% (2)
Finecross micro-catheter†	100% (28)
Corsair micro-catheter‡	32.1% (9)
Tornus micro-catheter‡	0% (0)
Rotational atherectomy¶	7.1% (2)
Stent use in CTO segment (excluding non-CTO lesions in culprit vessel)	
Number of stents deployed in CTO	1.2 ± 0.7
Total stent length in CTO (mm)	40.4 ± 13.4
Maximum stent diameter in CTO (mm)	3.0 ± 0.36
Total stent use per culprit vessel (including CTO segment and other lesions)	
Number of stents deployed in culprit vessel	2.0 ± 1.0
Total stent length in culprit vessel (mm)	62.7 ± 22.9
Maximum stent diameter in culprit vessel (mm)	3.15 ± 0.35
Fluoroscopy time/contrast use	
Total fluoroscopy time (minute)	45.4 ± 22.0
Contrast use (ml)	206.9 ± 84.4

*Later converted to antegrade—the GuideLiner was used during the antegrade attempt; †Terumo Interventional Systems, Somerset, NJ, USA; ‡Asahi Intecc Co., Ltd., Aichi, Japan; §100% use for transfemoral cases (not used in 2 radial cases); ¶Both cases were failed use of GuideLiner to deliver balloon/microcatheter.

of a microcatheter or any other device (other than a balloon) across the CTO lesion. Example images (Fig. 1) are provided showing a case where it was initially not possible to deliver any device, but then a small balloon was able to be passed using a GuideLiner catheter.

Overall procedural success in these selected cases (where a guidewire had already crossed the CTO lesion) was 89.3% (25 CTO PCIs). The GuideLiner catheter was successful in delivering a small balloon to the CTO lesion in 85.7% of cases (24 CTO PCIs) (Fig. 2). Of the failed cases, in 2 CTO PCIs the operators were entirely unsuccessful at delivering any device to the lesion (despite GuideLiner use) and the PCI was abandoned. In 2 cases the GuideLiner failed to permit balloon or other device delivery, but the operators were able to rewire the CTO with a rotafloppy wire (Boston Scientific) and perform rotational atherectomy with a 1.25 mm burr. A final CTO PCI resulted in a distal guidewire perforation. In this case, the GuideLiner was successfully used to deliver a balloon across the CTO and although balloon dilation was performed, a stent was not placed to avoid opening flow to the perforation. However, it was unclear if the perforation was related to GuideLiner use, or if this occurred during earlier attempts to deliver a balloon and/or microcatheter. There was no hemodynamic compromise and transthoracic echocardiography did not demonstrate any pericardial effusion. The patient was discharged home the next day. Apart from this wire perforation there were no other in-hospital complications including periprocedural myocardial infarction,

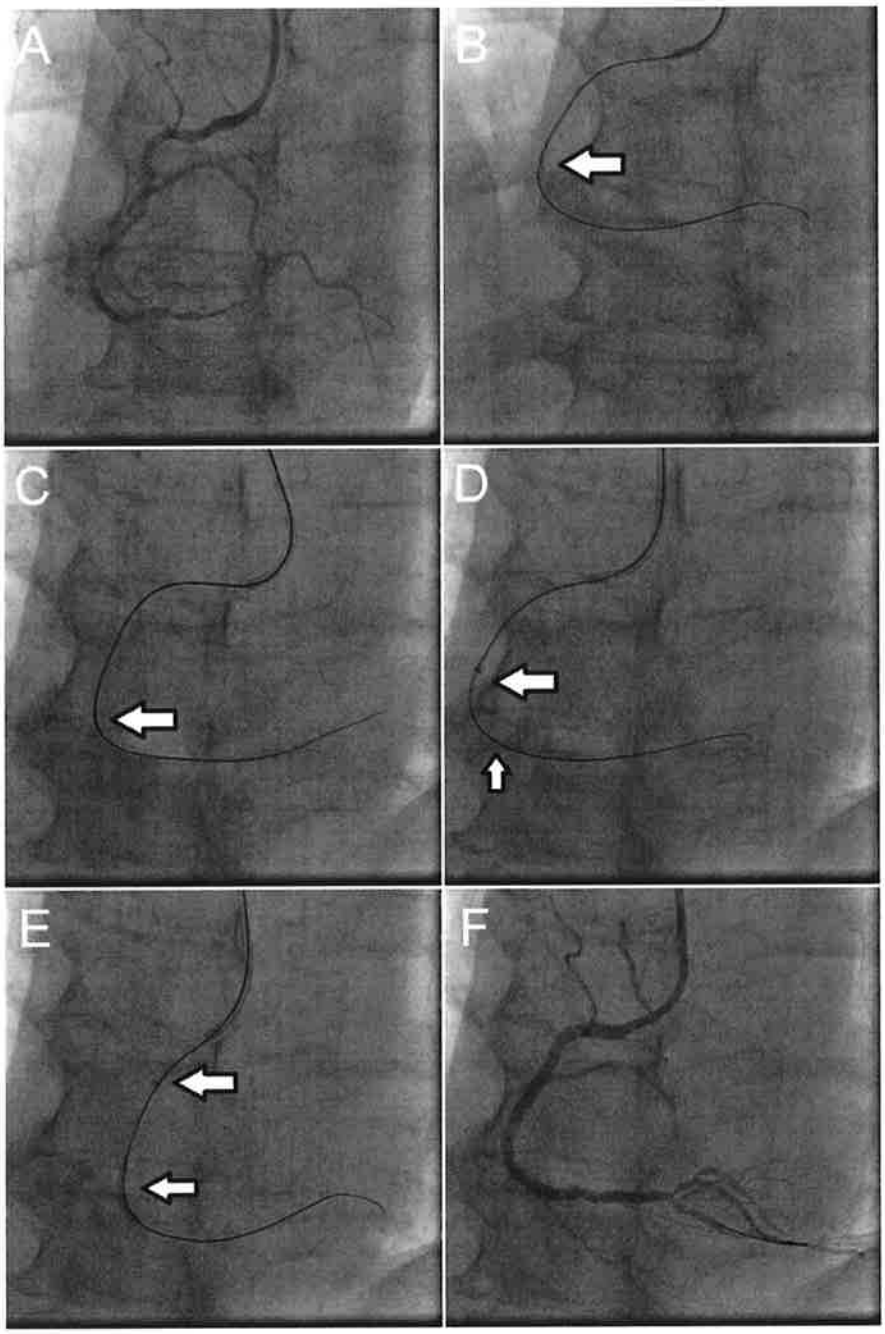

Figure 1. A: Right coronary artery CTO prior to revascularization. B: Guidewire successfully placed distal to the lesion using a FineCross microcatheter (Terumo). A second guidewire is seen to be coiled up at the site of the occlusion (arrow). Even after removing the second (redundant) wire, the FineCross catheter was not able to be advanced across the lesion. C: The operators then attempted to pass several different balloons and devices across the lesion, including a 1.25 mm × 6.0 mm balloon and a Corsair microcatheter (Asahi Intecc Co., Ltd.). Here the guide catheter is seen to be "kicking out" in an attempt to pass a device (arrow) across the CTO lesion. D: A 6 Fr GuideLiner catheter is advanced to the lesion (upper arrow), and a Rapid Exchange Apex 2.0 mm × 20 mm balloon (Boston Scientific) was able to be passed across the occluded segment (lower arrow marks distal edge of balloon). E: The Apex 2.0 mm × 20 mm balloon was inflated to 16 atm. F: Final angiographic result after deployment of a 3.5 mm × 38 mm (proximal), 3.0 mm × 28 mm (mid) and 2.5 mm × 23 mm (distal) Xience V stents (Abbott, Abbott Park, IL, USA) with TIMI III final flow.

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