The GuideLiner catheter: A supportive tool in percutaneous coronary intervention of chronic total occlusion

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Background: **Failure of delivering a stent or a balloon across the target lesion during percutaneous coronary intervention (PCI) of chronic total occlusion (CTO), especially in arteries with calcified tortuous anatomy, is often due to insufficient backup support from the guiding catheter. The purpose of this study was to assess the feasibility of the GuideLiner (GL) catheter use.**

Methods: **We examined 18 patients and used the GL catheter to overcome poor support and excessive friction in standardized antegrade and retrograde CTO procedures. The GL is a coaxial, monorail guiding catheter extension delivered through a standard guiding catheter and is available in different sizes.**

Results: **Almost all lesions were classified as severely calcified (94.4 þ 0.24%). The Japanese CTO score reflecting lesion complexity was 3.56 þ 0.78. All procedures were performed femorally; the retrograde approach was used in 27.8 þ 0.46% of cases. The overall success rate was 88.9 þ 0.32%; there were no relevant complications.**

Conclusions: **The GL catheter is an adjunctive interventional device which enhances and amplifies CTO-PCI. Its use is indicated in cases in which back-up force needs to be strengthened to pass a CTO despite advanced calcification. It can be recommended as an important additional tool in advanced interventional cardiology such as antegrade and retrograde CTO-PCI if other techniques like anchor balloon or anchor wire are not possible.**

Keywords: Chronic total occlusion, GuideLiner catheter, Percutaneous coronary intervention, Severe calcification

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Introduction

Recanalization of chronic total occlusions (CTO) remains a challenge in interventional cardiology. A CTO of a coronary artery can be identified in up to 30% among patients with a clinical indication for coronary angiography [1,2]. Due to new interventional techniques and the use of further advanced sophisticated materials, success rates of CTO recanalization increased steadily in recent years. In experienced hands, reopening rates exceed 85% [3,4].

If significant myocardial ischemia exists combined with clinical symptoms due to ischemia, recanalization is indicated; left ventricular function can be improved, more invasive therapies like coronary artery graft surgery can be avoided at lower complication rates, and even the prognosis of the disease can be improved in suitable cases with both a short-term and long-term survival benefit [5,6].

A strong and stable backup of the guide catheter is essential to advance guidewires, balloons, and stents over the lesion in highly calcified and tortuous vessels. Regardless of the clinical setting, an enhanced backup provides one of the most important preconditions to ensure guide wire and balloon advancement and stent delivery, thereby enabling a successful percutaneous coronary intervention (PCI) [7]. Additionally, the use of stiffer wires, the anchoring balloon technique, and deep intubation of the guiding catheter may be applied to improve the backup support [8–10]. Various companies have implemented guiding catheter extensions in their portfolio to overcome the problem of a poor backup support. IMDS produces the Guidion (IMDS, Roden, Netherlands) catheter which has a more flexible atraumatic distal end. The Guidezilla (Boston Scientific, Natick, MA, USA) has a hydrophilic coating with a polymer-coated metal collar to facilitate device insertion and is only available in a 6-Fr size. The Heartrail system (Terumo, Tokyo, Japan) is available in 5-Fr, 6-Fr, and, 7-Fr sizes [8,11].

The purpose of this study was to assess the feasibility and safety of the usage of the GuideLiner (GL) catheter (Vascular Solutions Inc., Minneapolis, MN, USA) extension system in complex PCI of CTO.

Abbreviations

CABG	coronary artery bypass graft
CAD	coronary artery disease
CART	controlled antegrade and retrograde tracking
CTO	chronic total occlusion
DES	drug-eluting stents
EF	ejection fraction
GL	GuideLiner
J-CTO	japanese CTO score
MI	myocardial infarction
MRI	magnetic resonance imaging
PCI	percutaneous coronary intervention
RCA	right coronary artery
TIMI	Thrombolysis in Myocardial Infarction

Materials and methods

A total of 130 CTO-PCI were performed in our center between 2015 and 2016. In this retrospective study, we analyzed the data of 18 patients (14%) in whom the GL was applied to facilitate CTO-PCI if an alternative technique such as an anchor balloon or a buddy wire was not possible. The procedures were performed by two high-volume operators. Indications for inclusion were angina pectoris and/or a positive functional ischemia test by magnetic resonance imaging or transthoracic echocardiography in the territory of the occluded artery of more than 10%. Antegrade and retrograde CTO techniques were considered, and the procedures were performed in a standardized manner.

PCI procedures were performed via the femoral route. Heparin was given during the interventions guided by the activated clotting time (>300 seconds). In all cases, contralateral injection of contrast fluid was performed to determine the length of the lesion and the quality of intercoronary collaterals. In this study, guiding catheter extensions of only 7-Fr and 8-Fr sizes were used.

The antegrade approach was used as the first step. Coronary wiring started with tapered polymer soft tip guide wires and stepwise accelerated up to super-stiff guidewires (12-gauge wires) if necessary. Complex lesions with an ambiguous proximal cap and poor distal target were attempted by retrograde approach. Only drug-eluting stents (DES) were implanted.

After PCI a standard antiplatelet regime was conducted. Procedural success was defined as recanalization of the CTO with a residual stenosis of <30% and restoration of thrombolysis in myocardial infarction grade-3 flow.

A composite safety endpoint summarizing severe complications, such as cardiovascular mortality, vessel perforation, cardiac tamponade, myocardial infarction, and stroke, was evaluated for each patient.

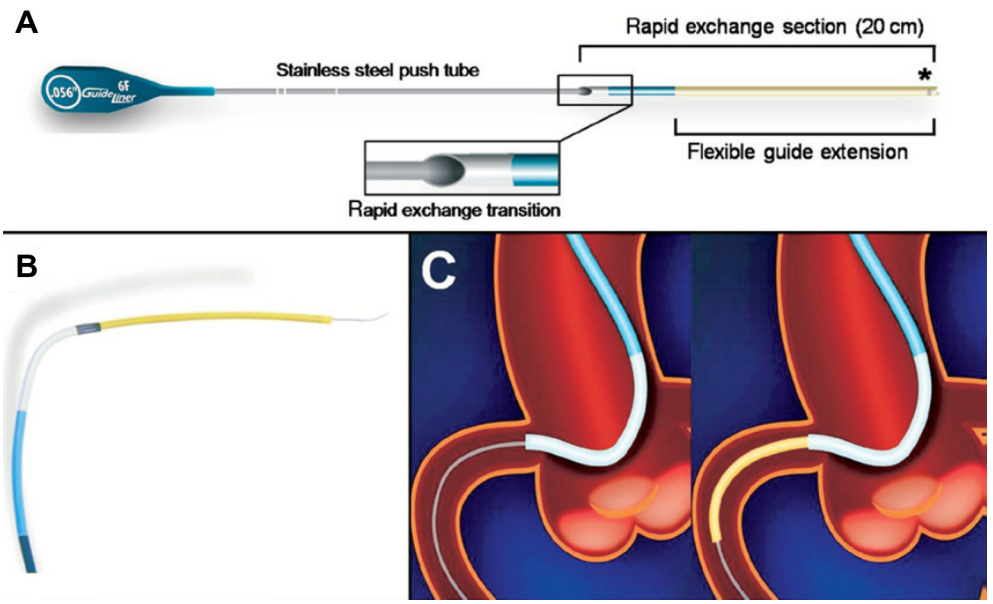

Figure 1. Schematic presentation of the GuideLiner catheter. Note. From ''Use of a second buddy wire during percutaneous coronary interventions: a simple solution for some challenging situations,'' by Burzotta et al, 2005, J Invasive Cardiol, 17, p. Copyright 20xx, Name of the copyright holder. Reprinted with permission. (A) and (B) show that wire crossing and Guideliner catheter introducing was achieved in the mid RCA. (C) A ballon could be put forward and inflated.

The GL catheter is a simple, adjunctive coaxial monorail guiding catheter extension delivered through a standard guiding catheter. The indication for using the guiding catheter extension was the inability to advance the balloon or stent across the lesion because of poor backup or failed stent delivery due to eccentric plaque or pronounced tortuosity. The GL provides active guide support and may bypass friction and tortuosity by its 20-cm-long flexible tubular end, which can be deeply advanced into a vessel.

The extension comprises an inner polytetrafluoroethylene (Teflon) lining, surrounded by a stainless-steel coil, and an outer layer of Pebax polymer. The GL is available in different sizes: 5-in-6 Fr (internal diameter 1.4 mm), 6-in-7 Fr (1.7 mm), an in 7-in-8 Fr (1.8 mm). The soft distal tip prevents dissections unlike deep-seating of regular guiding catheters (Fig. 1). In summary, the GL catheter allows deep intubation of the target vessel and provides a strong backup support to facilitate stent delivery across heavily calcified lesions in tortuous vessels [12].

To advance and position the guiding catheter extension properly, we always applied and inflated a balloon in the target lesion and used it as an anchor, thereby improving the support of the guide catheter while advancing the GL through complex anatomy.

We did not request for an ethical approval and patient consent in this study because it was an anonymous registration, and we evaluated the data retrospectively.

Table 1. Baseline characteristics.

Variable	Mean	Standard deviation
Age (y)	60.94	10.36
Male sex	77.8	0.43
BMI score	29.44	3.50
Hypertension	94.4	0.24
Hypercholesterolaemia	72.2	0.46
Diabetes mellitus	38.9	0.50
Current smoker	27.8	0.46
Family history of CAD	16.7	0.38
Prior MI	27.8	0.46
Prior PCI	50.0	0.51
Prior CABG	0	0
Coronary 1-vessel disease	27.8	0.46
Coronary 2-vessel disease	33.3	0.49
Coronary 3-vessel disease	38.9	0.50
Ejection fraction	58.8	6.96

Data presented as *n* (%), mean ± standard deviation.
BMI = body mass index; CABG = coronary artery bypass graft; CAD = coronary artery disease; MI = myocardial infarction; PCI = percutaneous coronary intervention.

Statistical analysis

Values are expressed as mean ± standard deviation. Comparison of continuous variables was performed with the one-sample *t* test. Categorical variables are presented as numbers or percentages and were tested with the binomial test. A *p*

Table 2. Target vessels and lesion characteristics.

Variable	Mean	Standard deviation
LAD CTO	11.1	0.32
RCA CTO	88.9	0.32
LCX CTO	0	0
Length of occlusion, mm	38.06	17.67
Severe calcification	94.4	0.24
Vessel tortuosity	72.2	0.35
Blunt stump	77.8	0.43
In-Stent occlusion	11.1	0.32
Ostial occlusion	5.6	0.24
J-CTO score	3.56	0.78

Data presented as *n* (%), mean ± standard deviation.
CTO = chronic total occlusion; J-CTO = Japanese chronic total occlusion; LAD = left anterior descending artery; LCX: left circumflex artery; RCA = right coronary artery.

Table 3. Procedural characteristics.

Variable	Mean	Standard deviation
Fluoroscopy time, min	48.61	22.03
Examination time, min	128.89	34.28
Amount of contrast medium, mL	210.56	86.40
DES, %	100	0
Retrograde approach, %	27.8	0.46
Length of stents, mm	38.06	17.67
Number of stents, *n*	2.39	1.24
Procedural success, %	88.9	0.32
Complications, %	0	0

Data presented as *n* (%), mean ± standard deviation.
DES = drug eluting stent.

value <0.05 was considered to be statistically significant.

Results

Table 1 shows the demographic and baseline characteristics. The mean age was 60.94 ± 10.36 years, and the majority of the 18 patients were male (77.8 ± 0.43%). The average body mass index was 29.44 ± 3.50; 38.9 ± 0.5% had diabetes and 94.4 ± 0.24% had an arterial hypertension. Furthermore, 27.8 ± 0.46% of the patients were smokers and 16.7 ± 0.78% had a familiar liability for a coronary artery disease (CAD).

Seven patients suffered from a multivessel CAD, and the mean ejection fraction was 58.8 ± 6.96% with the right coronary artery as the main target lesion (Table 2). The lesion characteristics confirm the complexity of the coronary anatomy. Almost all lesions were classified as severely calcified (94.4 ± 0.24%). The mean occlusion length was 38.06 ± 17.07 mm, and a blunt stump could be identified in 14 cases. The Japanese CTO score reflecting lesion complexity was 3.56 ± 0.78.

In three antegrade cases (17%), we used the parallel wire technique with a Confienza Pro 12 wire (Asahi Intecc, Japan), a tapered tip guide wire with 12 g tip load, for a successful recanalization. In one case with an excessive calcification and a high torsion of the vessel, only the use of the GL catheter proved effective to place the balloon and the stent (Fig. 2).

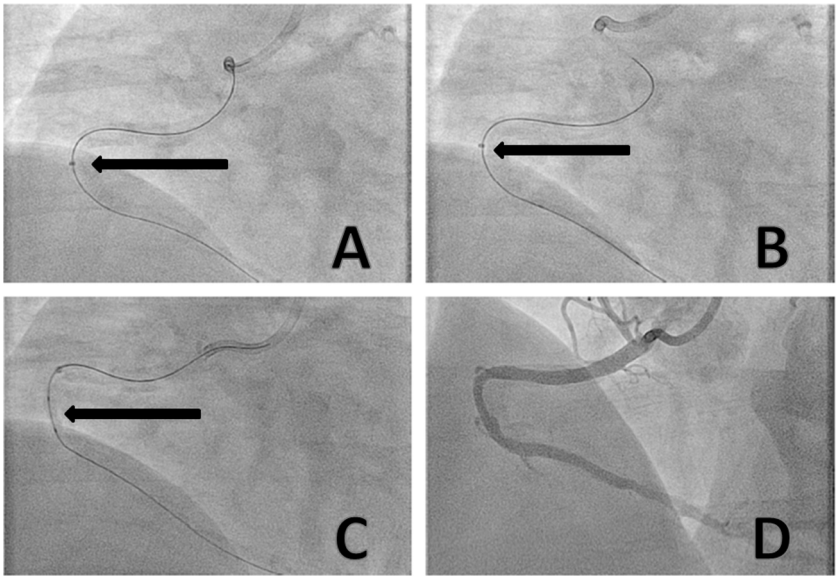

Figure 2. Angiography of a chronically occluded right coronary artery. (A) and (B) Wire crossing was achieved and the Guideliner catheter is introduced. (C) A balloon could be inflated. (D) The vessel after the successful procedure.

In two cases, the GL catheter was used for applying the ''capture technique'' (Guideliner Reverse CART) [13]. Both the retrograde wire and the microcatheter failed to reach the antegrade guide catheter because of a long collateral channel. The retrograde microcatheter only reached the mid segment of the right coronary artery. The GL catheter was introduced to capture the retrograde microcatheter. Subsequently, the externalization could be completed for a successful recanalization. This is an elegant modification of classical reverse CART shortening the distance between the site of re-entry of the retrograde guidewire and the antegrade guiding catheter [11].

All procedures were performed femorally; the retrograde approach was used in 27.8 ± 0.46% of cases (Table 3). The overall success rate was 88. ± 0.32%; 2.39 ± 1.24 DES were implanted. In two cases, it was impossible to perform a successful recanalization. There were no severe complications.

Discussion

Due to the demographic development with an increasing age of the population undergoing PCI and advances in interventional cardiology, coronary interventional procedures, particularly in CTO, are becoming increasingly complex [14–17]. In CTO recanalization, it is essential for successful wiring and equipment delivery to establish a stable backup. The use of a buddy wire, deep intubation of the guide catheter into the target vessel, and anchor ballooning are standard means in this setting [10,18].

The ''mother and child'' technique was introduced to improve the backup support. A small catheter for intracoronary insertion was applied through a guiding catheter. Unfortunately, this system was a complex and time-consuming process and required removal of the hemostatic valve followed by advancement over the coronary wire into and through the guide catheter, with subsequent reconnection of the hemostatic valve to the proximal end of the catheter [11]. The new guiding catheter extensions overcame most of these limitations.

The use of a long 5-Fr guide catheter inserted into a 6-Fr catheter enhances backup support, and the so called ''rail-roading'' maneuver with a catheter extension system for deeper intubation of the guide catheter is a further helpful adjunctive technique [12,19]. During CTO-PCI, procedural failure can be caused by an inability to deliver a balloon or micro-catheter across the lesion [20]. The guiding catheter extension was invented to overcome these obstacles and enables a successful CTO-PCI even in highly calcified and tortuous vessels.

In the Twente Registry, 70 coronary lesions were treated using a ''5-in-6'' GL catheter with a success rate of 93% without any relevant complications [12]. Kovacic et al. [20] obtained a success rate of 89% in 28 patients. Compared with our data, there were fewer retrograde cases and the lesion length was shorter.

Tunuguntla et al. [21] reported that using the GL catheter reduces the amount of contrast medium by performing more selective contrast injections. This is particularly helpful in patients with chronic kidney disease. However, it should be noted that forceful injections may cause spiral dissections because of a strong jet between guide and guiding catheter extension.

In 2013, Mozid et al. [13] successfully showed that a catheter-assisted reverse CART technique can be performed easily. We demonstrated this technique as well, and it provides a direct path to the guide catheter and a subsequent externalization. In case of a proximal left anterior descending artery CTO, the use of this tool avoids subinitimal crossing within the left main and protects the left circumflex artery.

Farooq et al. [19] showed that the GL catheter is also a valuable tool if implemented as an aspiration device, and Benezet et al. [22] demonstrated that the transradial approach is also feasible [22].

Until now, only few complications have been reported. Seto and Kern [23] described stent destructions while moving the stent through the proximal GL collar, and Man and Birgelen [12] reported regarding a case with air embolism. To prevent this, Boukhris et al. [8] suggested venting the guiding catheter extension system regularly. Chang et al. [24] described a dissection of the left main coronary artery following the use of the GL catheter; they recommend a final control angiogram after the completion of PCI [24]. In 2012, Murphy et al. [25] presented a case of balloon damage at the site of metallic collar. The recently implemented generation of GL catheter (V3) has a 25-cm cylinder at the distal tip and a half-pipe design facilitating smooth device entry and delivery to prevent these kind of complications in future [8].

Study limitations

There are several limitations to our study. This was a retrospective study, and all data were collected from one single center. The results of

this study could be influenced by selection criteria, operator experience, and varying techniques used by the operators. Furthermore, there was no follow-up beyond the in-hospital phase, and some information regarding the cardiovascular risk, such as cholesterol levels or incidence of prior stroke, was not available.

Conclusion

Nowadays, different types of guiding catheter extension are available and are substituting the older ''mother in child'' concept. The GL catheter is a safe and additional device for complex CTO recanalization. It allows delivery of balloons and stents across the occluded segment, advancement of devices in very tortuous vessels, and successful externalization maneuvers using the retrograde approach. It can be recommended as an important additional tool in advanced interventional cardiology such as antegrade and retrograde CTO-PCI.

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