



Review

Guide extension, unmissable tool in the armamentarium of modern interventional cardiology. A comprehensive review



Enrico Fabris MD^{a,c}, Mark W. Kennedy MB, BCh, BAO^a, Carlo Di Mario MD, PhD^b, Gianfranco Sinagra MD^c, Vincent Roolvink MD^a, Jan Paul Ottervanger MD, PhD^a, Arnoud W.J. van't Hof MD, PhD^a, Elvin Kedhi MD, PhD^{a,*}

^a ISALA Hartcentrum, Zwolle, The Netherlands

^b Royal Brompton Hospital & NHLI Imperial College, London, United Kingdom

^c Cardiovascular Department, Ospedali Riuniti and University of Trieste, Trieste, Italy

ARTICLE INFO

Article history:

Received 15 June 2016

Accepted 27 July 2016

Available online 29 July 2016

Keywords:

Complex PCI

Guide extension catheter

GuideLiner

ABSTRACT

Due to the aging population undergoing percutaneous coronary intervention (PCI), interventional cardiologists are confronted daily with treatment of lesions with complex anatomy. Despite improvements in stent devices and PCI techniques, these lesions remain a challenge in terms of procedural success. Guide-extensions (GE) are coaxial “mother and child” catheters employed to facilitate device delivery but they can be used in many different complex scenarios. A comprehensive review of the possible applications of GE and of the GuideLiner™ (GL), the most widely used GE device, is missing. We therefore aim to provide a comprehensive review of all the potential applications of the GL and other GE devices, describe its limitations as well as tips and tricks for successful usage of this GE catheter.

© 2016 Elsevier Ireland Ltd. All rights reserved.

1. Introduction

With the increasing age of the population undergoing percutaneous coronary intervention (PCI) and advances in interventional cardiology, increasingly complex procedures are being faced on a regular basis. In coronary lesions with extreme tortuosity and/or calcifications, stent delivery to the target lesion may be challenging despite adequate lesion preparation and improved deliverability of novel stent devices. Adequate back-up support remains the cornerstone for successful PCI. Extra back-up support guiding catheters and active support techniques, such as deep intubation in combination with either buddy wires and/or an anchor balloon, are commonly used to improve support. The “mother and child” concept of having a smaller catheter for intracoronary insertion through the conventional guiding catheter was introduced by skilful Japanese colleagues advising Terumo on the design of the first dedicated device, the Heartrail™ system (Terumo, Japan). Unfortunately this system was cumbersome and required removal of the haemostatic valve followed by advancement over the coronary wire into and through the mother guide, with subsequent reconnection of the haemostatic valve to the proximal end of the Heartrail catheter. The GuideLiner™ (GL) catheter (Vascular Solutions, Minneapolis, MN), connecting a distal flexible 20 cm catheter to steel rod, and allowing

for rapid exchange, being a monorail system, overcame most of these limitations and became the prototype of other similar guide-extension (GE) systems (Guidion™ Flexible Guide Extension, IMDS, the Netherlands and Guidezilla™ Guide Extension Catheter, Boston Scientific, Boston). Since the first-in-man report of the successful use of GL for distal stent delivery following failure of conventional techniques [1], this device has gained popularity and has been used for many other applications. The aim of this manuscript is to offer a complete overview of the current possible applications of the GL and other GE devices, to describe its limitations and to report results obtained in prior studies.

2. The GuideLiner and other guide extension devices

The GL is a coaxial “mother and child” GE system, which has been developed for deep vessel engagement and device delivery; providing active guide support by its long flexible tubular end, which can be deeply advanced into the target vessel. Unlike deep intubation of a guiding catheter, the GL has no primary curve and its soft distal tip promises a low dissection risk compared to deep seating of regular guides. The first generation GL received FDA approval and CE marking in 2009 and was designed as a single lumen rapid exchange catheter with a flexible 20-cm tip connected by a metal collar to a 115-cm stainless steel shaft. The second-generation V2 system has a 5 cm longer flexible tubular end and an all polymer collar for increased flexibility; in the more recent V3 the 25 cm rapid exchange section is maintained but with an additional

* Corresponding author at: Isala Hartcentrum, Docter van Heesweg 2, Zwolle, The Netherlands.

E-mail address: e.kedhi@isala.nl (E. Kedhi).

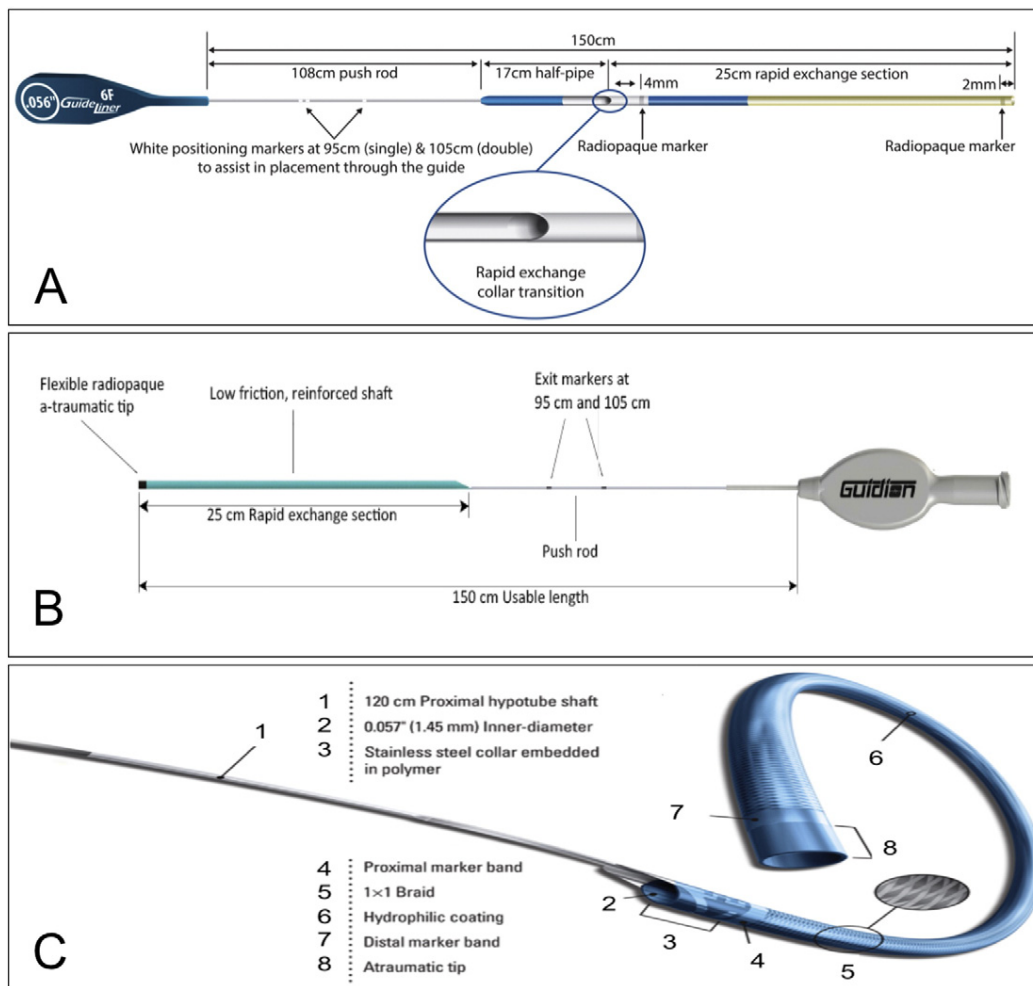


Fig. 1. Guide-extension catheters A) The GuideLiner™-V3 extension catheter. B) Guidion™ Flexible Guide Extension and C) Guidezilla™ Guide-Extension Catheter.

“half-pipe” to assist device alignment when passing through the collar transition (Fig. 1) and to limit the incidence of stent collar interactions. The GL reduces the inner guide diameter by approximately 1Fr and is currently available in 4 sizes: 5.5, 6, 7, and 8 Fr. Once the guide catheter and guide wire are placed, the GL catheter can be advanced over the guide wire through the haemostatic valve as an extension to the guide catheter. Subsequently, the procedure can be continued as usual, without need for disconnection and reattachment. The Guidezilla™ is available only in a 6 Fr compatible version, with an inner lumen minimally larger than the corresponding GL (0.057" instead of 0.056"), with a hypotube rather than a steel ribbon to improve pushability, a proprietary coating rather than silicone and with a polymer coated metal collar to facilitate device insertion at the transition point. The Guidion™ has a more flexible atraumatic distal end; the most recent version promises to have better pushability and is available also in a 5 Fr compatible version. Besides being usable with smaller 5 Fr guiding catheters, the 5 Fr option allows insertion alongside a balloon catheter (for instance during anchoring) and its use in combination with a 6 Fr guide extension to create a telescopic system able to reach more distal locations and offer greater support.

3. Principal indication for device utilization

Current published data shows that GL is primarily used in patients who are significantly older, more frequently have multi-vessel disease [2] and present lesions which are significantly more complex [2], more calcified, and have longer lesion length [3] compared to patients

in which PCI can be performed without using the device. The main GL case series/registries, which have described target lesions using the AHA/ACC lesion characteristics, report a percentage of B2/C ranging between 91 and 97% [3–5], and in the largest series [2] the percentage of Type-C lesions was 78% (Fig. 2). In the context of such complex anatomy, reported procedural success using the GL, in series with at least ten patients, ranges from 80% to 100% (Table 1).

3.1. Presence of vessel angulation and tortuosity

Despite improvements in second-generation stent design, including improved stent trackability, pushability and overall deliverability, severe vessel angulation and tortuosity remain the most frequent cause of procedural failure. The GL provides an elegant method to overcome this challenge, and represents one of the most common indications for its use. Eddin et al. [2] have shown that proximal vessel angulation and lesion angle were the main predictors of GL use. A 45° proximal vessel angle predicted the need for GL use with a sensitivity of 73% and specificity of 74%. Chan et al. [6] have also reported that an angulated take-off of the target vessel and tortuosity represented the 31% and 7%, respectively, of the indication for GL usage. Furthermore, coronary artery tortuosity, defined as ≥ 3 bends of $\geq 45^\circ$ or ≥ 1 bend of $\geq 90^\circ$ change in vessel direction, was identified in 43% of cases in a series of PCI with GL support [7]. Finally, proximal tortuosity was found in 21.9% of cases by Dursun et al. [5] and severe tortuosity was reported in 35% of case in one of the largest series published [8].

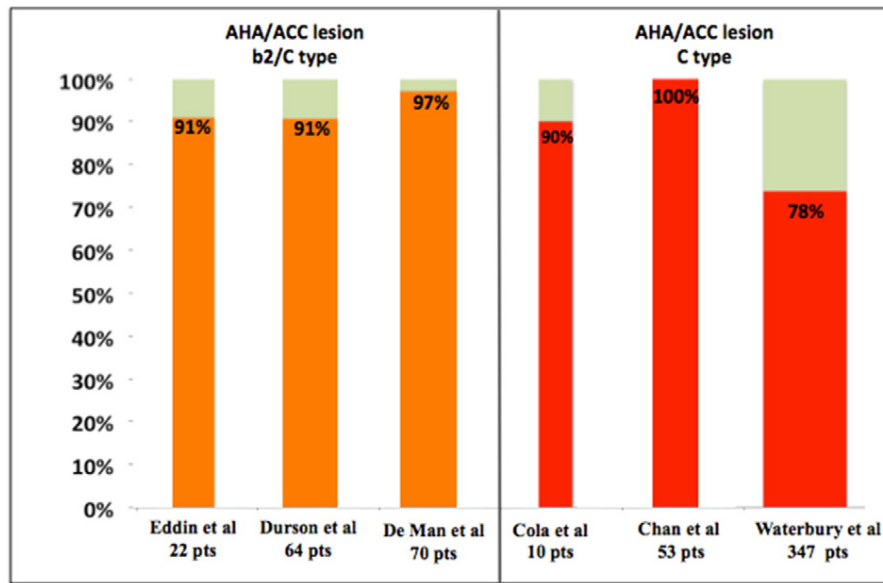


Fig. 2. Percentage of AHA/ACC type lesions characteristics reported in published case series/registries. Left side: percentage of b2/C type lesions; right side: percentage of C type lesion. The width of the columns is representative of the sample size. Pts = patients.

3.2. Presence of severe calcification

In vessels with heavy proximal calcification, advancement of a stent to a distal target lesion can remain challenging, owing to significant friction between stent struts and the calcified vessel wall. GL utilization in this particular situation has a dual benefit: it provides robust back-up and therefore improves stent trackability and when advanced until just proximal to the target lesion; it avoids friction between the stent and calcified vessel wall. In the main case series, the presence of heavy calcification in PCI performed using the device ranges from one-third to two-third of cases [1,5,7–9]. While use of rotational atherectomy may be necessary to provide full deployment of the stent in calcified lesions [10], burr delivery to distal lesion sites can remain difficult, particularly in tortuous anatomy, and in such situations is associated with an increased risk of vessel perforation. Anecdotal case reports have described the passage of the GL beyond the proximal tortuous segment facilitating burr delivery to distal calcified lesions [11,12].

1.25–1.5 mm burrs can be accommodated through a 7Fr GL [11,12]. However the insertion of the burr through the collar can be challenging [11]. A way to overcome the problem is to manually load the burr inside the distal end of the GE outside the body advancing both together up to the ostium and then sliding the GE.

3.3. Chronic total occlusion

Chronic total occlusion (CTO) intervention represents one of the most challenging subsets of PCI. During CTO PCI, procedural failure is often due to an inability to deliver a balloon or micro-catheter across the lesion [13]. GL use achieves better support and deeper intubation of target vessels and its value has been demonstrated in numerous series [6,13,14]. A single centre experience has reported use of GL in 17.8% (66/372) of CTO procedures [13]. In 28 of these cases, GL assisted initial balloon or micro-catheter advancement to the culprit CTO lesion and in 6 of these cases was used to support the initial wiring of the

Table 1

Registries/case series including at least 10 patients.

Studies	Date of publication	Number of pts	Age (years)	By pass n(%)	Procedural success (%)	Stent deformation or dislodgment (%)	Coronary dissection (%)	Other complications
Mamas et al. [1]	2010	13	67 ± 13	1(7.6%)	97%	6.2%	–	–
Cola et al. [9]	2011	10	71 ± 10	–	90%	20%	30%	–
Dardas et al. [7]	2012	16	68 ± 8	3(18.7%)	100%	–	12.5%	–
Luna et al. [32]	2012	21	65 ± 13	2(9.5%)	90%	–	–	1 acute vessel closure; pressure damping in 57%
De Man et al. [4]	2012	70	67 ± 13	10(14.2%)	93%	1.4%	–	1 air embolism
Eddin et al. [3]	2013	22	69 ± 12	–	100%	–	–	–
Kovavic et al. [13]	2013	28 ^a	64 ± 10	–	82%	–	–	1 wire perforation
Garcia-Blas et al. [34]	2014	15 ^b	72 ± 8	–	87.5%	–	6.25%	–
Chan et al. [6]	2015	55 ^c	69 ± 13	12(21.8%)	98%	–	–	–
Dursun et al. [5]	2015	64	70 ± 10	3(4.6%)	95%	–	–	–
Waterbury et al. [2]	2015	347 ^d	71.5 ± 11	28(8.5%)	80%	2.3%	3.3%	1 ventricular arrhythmia
Alkhalil et al. [8]	2016	188 ^e	70.5 ± 10	2(1%)	86%	11.1%	0.5%	–
Alkhalil et al. [8]	2016	124 ^f	69 ± 10	2(1.6%)	93%	2.4%	–	–

^a 1 patient had successful renal denervation.

^b 16 consecutive procedures in 15 patients.

^c All CTO procedures.

^d 363 procedures in 347 patients.

^e All procedures in which GuideLiner-V2 were used.

^f All procedures in which GuideLiner-V3 were used. n = number, Pts = patients.

lesion. The GL successfully facilitated micro-balloon crossing of the CTO lesion in 85.7% of cases (24/28), when a guidewire had already crossed the CTO. Similar procedure success (97%) was also reported from Chan et al. [6] in 33 CTO GL-facilitated PCI. Furthermore, during reverse controlled antegrade and retrograde subintimal tracking (CART) the advancement of the GL from the antegrade guide catheter can offer a visible and accessible target for the retrograde wire. “Guideline reverse CART” is an elegant modification of reverse CART shortening the distance between the site of re-entry of the retrograde guidewire and the antegrade guiding catheter [15–17] (Fig. 3).

3.4. Anomalous origin of coronary arteries or grafts

Extreme take-off angulation, particularly in case of anomalous origin of coronary arteries represents a challenge to adequate catheter engagement, and may result in dissection or insufficient support during PCI. GL utilization may improve both guide catheter coaxial orientation and support (Fig. 4). Ramanathan et al. [18] described an anomalous origin of a right coronary artery (RCA) arising from the left coronary cusp, where GL facilitated coaxial engagement and stent delivery after failure of conventional guides to achieve selective cannulation. Similarly, in a case with critical left circumflex artery (LCX) stenosis, which arose from an anomalous LM coronary artery originating from the right sinus of Valsalva, GL was placed in the distal LM for additional support and avoided guide disengagement [19]. In a recent case, GL was successfully used to enhance backup and increase pushing strength allowing stent deployment in distal LCX arising from a single left coronary artery [20].

Similarly, one of the main difficulties in graft PCI, may be the near impossibility of coaxial engagement of the ostia. GE often provides the only solution to properly engage with adequate support both vein grafts in the ascending aorta or the mammary artery, especially in the presence of an extremely tortuous subclavian. Farooq et al. [21] have highlighted the feasibility of GE devices, including GL, to overcome many of these problems and facilitate trans-radial graft interventions in a series of selected complex cases. Park et al. [22] reported a challenging PCI in which GL allowed stent deployment in left anterior descending (LAD) artery through a tortuous left internal mammary artery (LIMA). Additional backup support for equipment delivery can be achieved by deep intubation of GL in the graft or indeed deep insertion of guide catheter over GL system (“Rail-Road”). Finally, when

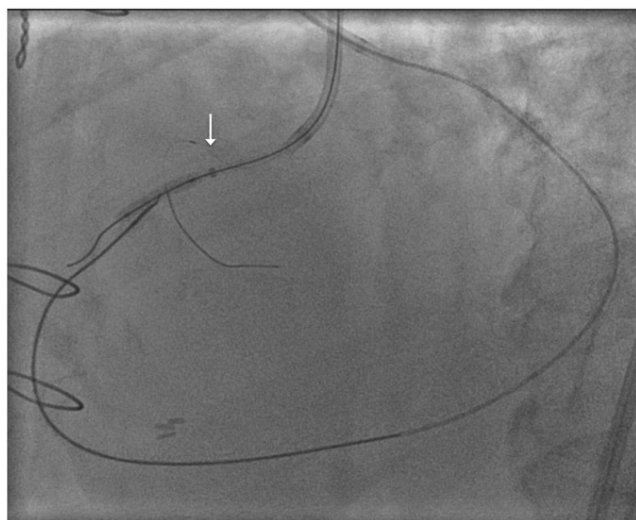


Fig. 3. “Guideline reverse CART”. GuideLiner is advanced antegradely (arrows) to reduce the distance between the site of re-entry of the retrograde guidewire and the antegrade guiding catheter.

faced with a proximal graft lesion, which may prevent deep guide intubation, further backup may be achieved with a ‘Swan-Neck’ maneuver [21] with the guide catheter positioned in the aortic sinus and tip of the GL extended to the vein graft ostium.

4. Other possible applications

Although GL was primarily designed to access discrete regions of the coronary vasculature, and to facilitate placement of interventional devices, other versatile applications of this device have been reported.

4.1. Selective injection of target coronary segments to reduce contrast usage

As the GL catheter is based upon a monorail rapid-exchange platform, contrast injections through the guiding catheter enter the proximal portion of the GL and exit it distally (selectively in the target segment). Since there is no loss of contrast into proximal side branches, the volume of contrast necessary for target vessel opacification is typically lower than if injected through the guiding catheter alone [23]. Serajian et al. [24] using the above-mentioned property, have shown that in situations with competitive LIMA flow, GL may be used for selective LAD angiography. Using such a technique provided visualization of an LAD lesion, which otherwise was not well appreciated.

Pershad et al. [25] after failed attempts to visualize a distal vessel because of the presence of proximal aneurysm with swirling of contrast in the proximal segment, successfully used a GL catheter placed beyond the aneurysm to facilitate sub-selective injection into the distal vessel.

4.2. Optical coherence tomography assessment of a vessel through the GuideLiner

Optical coherence tomography (OCT) assessment through the GL may be another potential application. Mitomo et al. [26] reported a case in which a GL was used to facilitate OCT catheter delivery and minimize the contrast dose used in a challenging complex lesion.

4.3. GuideLiner for thrombectomy

Stys et al. [27] and Farooq et al. [28] presented successful use of the GL for thrombus aspiration after failure of dedicated manual aspiration thrombectomy devices. The GL should be removed with the guide catheter fully intubated in the coronary ostium to prevent any potential embolization of thrombus to the systemic vasculature [28]. Further blood should be then aspirated from the guide catheter to ensure no thrombus remains within the guide catheter.

An overview of potential indications for GE use is represented in Table 2.

5. Potential complications

As described, GL may significantly facilitate PCI; nonetheless it also carries some device-specific complications; these include stent damage, stent loss, stent catheter deformation, dissection, air embolism and pressure dampening (see Tables 1 and 3). Awareness of the system limitations can simplify and render safer use of the device.

5.1. Stent and balloon disruption

The stainless steel collar present in the first generation GL has been implicated in several instances of stent and balloon disruption [1,13,29]; and in fact the main limitation encountered at the beginning experience of the device [1] was stent damage which occurred in two of the 32 stents delivered (6.2%) as the stents were advanced through the catheter portion of the device. Similarly, Seto et al. [30] witnessed damage of stent struts in two cases upon attempted advancement through

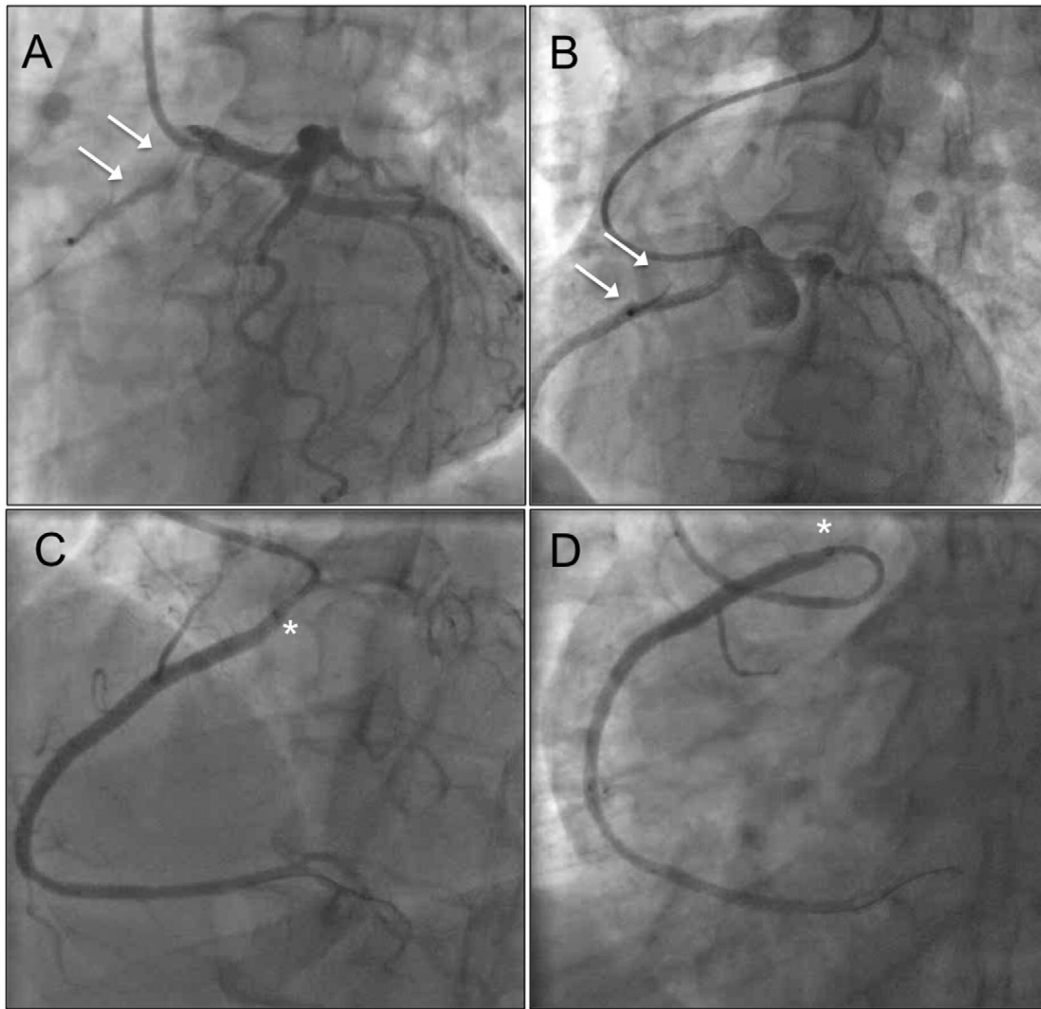


Fig. 4. GuideLiner use for anomalous coronary origin. Anomalous origin of the right coronary artery from the left sinus (arrows). With only guiding catheters, it was very difficult to visualize angiographically the vessel (A–B). The use of GuideLiner (*) is useful to properly engage the vessel and for a better diagnostic evaluation (C–D).

Table 2

Potential indications for guide-extension use.

Potential indications
<i>Common indications</i>
Devices delivery in presence of vessel angulation and tortuosity [2,5–7]
Devices delivery in presence of diffuse coronary calcifications [1,3–5,7–9]
Facilitation of catheter engagement and intervention in anomalous coronary arteries [18–20] and grafts [21,22]
Supporting the initial wiring or to assist advancement of balloon or micro-catheter during chronic total occlusion interventions as well as to facilitate re-entry of the retrograde guidewire.
<i>Other possible indications</i>
Selective injection of target coronary segments to reduce contrast usage [23]
Focused injection to selective opacification of distal vessels in presence of proximal aneurisms [25] or presence of graft competitive flow [24]
Thrombectomy in bail-out situations dealing with very large thrombus burden [27,28]
Optical coherence tomography assessment of a tortuous vessel through the GuideLiner [26]
Delivery of the burr and enabling safe rotational atherectomy in tortuous calcific lesion [11,12]
<i>Anecdotal cases</i>
Retrieval of entrapped rotablator burr using counter-traction with a GuideLiner [35]
Maintenance of coronary guidewire position during exchange of the guide catheter [36]
Renal denervation with the aid of a GuideLiner catheter [6]

the proximal GL collar, such resistance to stent advancement through the device, may be due to the lifting up (flowering) of stent struts against the collar of the GL [31].

Table 3

Lists of possible complications associate with GuideLiner use.

Complications	Notes
Stent deformation on advancement or withdraw [1,2,4,8,30,31]	It is more likely to occur when using guide catheters with a secondary bend Newer GL-V3 should prevent deformation and/or damage on advancement
Disruption of the stent catheter [8,29]	The proximal collar cut the stent delivery balloon shaft while GL was withdrawn backwards to ‘unsheath’ a delivered stent. Occurred using a sharply angled Kimmy guide catheter.
Coronary Dissection [2,6,8,32]	Also observed with a 6-Fr GL catheter in 7-Fr Kimmy guiding catheter during forceful dye injection with GL catheter ejection forward creating the dissection.
Pressure dampening [32] Air embolism [4]	Mainly observed during “6-in-7” Fr GL As a result of insufficient venting of the wedged GL
Dislodgement of the distal marker [31]	Occurred after extensive manipulations. Dislodgement of the distal marker was possibly due to damage of the GL inner lining from a deformed stent.

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts



Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research



With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips



Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS

Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS

Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS

Sync your system to PACER to automate legal marketing.