Journal of Invasive Cardiology

Published on *Journal of Invasive Cardiology* (http://www.invasivecardiology.com)

GuideLiner Catheter Facilitated PCI – A Novel Device with Multiple Applications

By *hmpeditor*
Created *10/26/2011 - 11:37*
November 2011 [1]

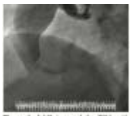
GuideLiner Catheter Facilitated PCI – A Novel Device with Multiple Applications

- Wed, 10/26/11 - 11:37am
- 0 Comments
-

Section:
Online Exclusive
Issue Number: Volume 23 - Issue 11 - November 2011 [2]
Author(s):

Ashish Pershad, MD, Victor Sein, MD, Nathan Laufer, MD

[3]**ABSTRACT: Objective.** The GuideLiner catheter (*Vascular Solutions, Inc.*) is a monorail guiding catheter extension that serves to facilitate stent delivery and is approved for providing extra support and coaxial guide engagement. The objective of this manuscript is to familiarize interventionalists with this new device, describe its versatile uses, and its limitations with case-based examples. **Background.** Failure of stent delivery is responsible for 5% of procedural failures in coronary interventions in the current era. Different techniques to enhance guiding catheter support and facilitate device delivery have been described. These include use of buddy wires, anchoring balloons at different locations for extra support for device delivery, and even rotational atherectomy in the most calcified lesions. **Methods.** The database of coronary interventions at Banner Good Samaritan Medical Center was queried for use of the GuideLiner catheter and stents. The angiograms of all those cases were reviewed and selections of cases highlighting different uses of the catheter were chosen for inclusion in this manuscript. **Results.** All potential uses of the GuideLiner catheter are described in this manuscript. Nuances about use and tips and tricks related to the device are also discussed in the case examples. **Conclusions.** The manuscript provides a complete summary of the different uses and limitations of the catheter and its contemporary role in modern day coronary intervention.

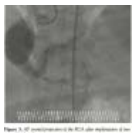


J INVASIVE CARDIOL 2011;23(11):E254-E259

---

[4]PCI has been simplified greatly over the last decade. Lower profile balloons and versatile guidewires have made coronary device delivery and interventions relatively simple as compared to a few decades ago. However in about 5% of cases, stent delivery is unsuccessful and is one of the main causes of procedural failure.[1] Drug-eluting stents have a higher profile as compared to bare metal stents and are more difficult to deliver, but they provide a remarkable benefit with respect to reduction in target lesion revascularization. Use of multiple shorter drug-eluting stents is not economical. Longer drug-eluting stents are not easy to deliver to the lesion site especially in tortuous and calcified coronary vessels. This poses new dilemmas to operators and presents a new challenge in coronary stenting. This may have added significance when more and more interventional procedures are being done using smaller guiding catheters via the radial approach.

DOCKET ALARM
Find authenticated court documents without watermarks at docketalarm.com.

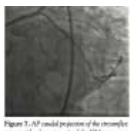


[5]The GuideLiner catheter (*Vascular Solutions, Inc.*) is a novel device that is FDA approved and CE marked for assistance with device delivery during coronary interventional procedures. It is an extension of the mother-and-child guide concept, but the advantage over the Heartrail mother-and-child guiding catheter is that the entire procedure can be completed using the same guide catheter with the convenience of a rapid exchange format.[2] In this article, all the different applications of the GuideLiner catheter will be presented with case examples. A brief discussion of the limitations as well as some tips related to its use will be highlighted.

[6]**Case 1.** *A 63-year-old African American female presented with chest pain, bradycardia, and ECG evidence of a STEMI. The culprit vessel was the right coronary artery (RCA). The RCA was noted to have a complete occlusion at the bifurcation of the posterior descending artery (PDA) and posterolateral branches (Figure 1). The proximal RCA had a huge aneurysm measuring 1.0–1.2 cm with swirling of contrast in the aneurysmal segment and no visualization of the distal vessel even with injections of 20cc of contrast through an automated injection [7] system (ACIST CVi). PCI of the RCA was planned urgently. A 7 Fr JR4 (Medtronic) guiding catheter was used to engage the RCA. A 2 mm over the wire Sprinter balloon (Medtronic) was advanced into the distal RCA over a Prowater Flex 0.014 coronary guidewire (Abbott Vascular). The wire was unable to cross the occlusion and attempts to visualize the distal vessel were futile because of the proximal aneurysm and the swirling of contrast in the proximal RCA. At this point it was decided to place a GuideLiner catheter beyond the aneurysm in the distal RCA to facilitate subselective injection into the distal RCA. This was effectively achieved over the same wire (Figure 2). Once it was possible to see the distal vessel better, a hydrophilic 0.014-inch guidewire was advanced into the posterolateral and then the PDA respectively; PCI of both vessels was performed successfully using 24 mm Vision (Abbott Vascular) bare metal stents (Figure 3).*

[8]*This case highlights another niche role of the GuideLiner catheter. In addition to providing support for facilitating stent delivery and enhanced backup for coronary interventions, this device allows safe subselective injections for better visualization of the distal vessel and decreasing contrast load. This particular application of the GuideLiner catheter has not been described in the literature thus far.*

Case 2. *A 50-year-old male with known occlusion of his RCA and inferior wall ischemia was referred for angiography. Bilateral femoral access with 8 Fr sheaths was obtained and simultaneous injections of the RCA and left coronary were performed (Figure 4) with a JR4 guiding catheter in the RCA. The CTO was successfully crossed using the antegrade approach and the GuideLiner catheter was then used to deliver long DES successfully (Figure 5). The final angiogram demonstrated the RCA successfully recanalized and a diffuse negatively modeled distal vessel (Figure 6).*



[9]**Case 3.** *A 65-year-old male presented with unstable angina. Diagnostic angiography demonstrated triple vessel coronary disease and normal ventricular function (Figure 7). After intervention on the RCA was performed, attention was turned to the circumflex artery (Figure 8). A 7 Fr EBU (Medtronic Vascular) guiding catheter was used for the intervention on the circumflex artery. A BMW (Abbott Vascular) guidewire was used to cross the lesion in the circumflex artery and angioplasty performed with a 3mm Voyager (Abbott Vascular) balloon. After [10]predilatation, there was difficulty advancing the stents through the calcified proximal vessel (Figure 8). A GuideLiner catheter was then advanced into the circumflex artery and this facilitated delivery of long drug-eluting stents to treat the stenosis successfully without need for a different wire or a different guiding catheter (Figure 9).*

The GuideLiner catheter allowed a second vessel (circumflex) to be treated ad hoc by greatly simplifying a complex procedure and minimizing contrast load and radiation exposure to the patient. The patient was then brought back for treatment of the LAD chronic total occlusion. This enabled complete revascularization for this patient.

[11]**Case 4.** *In this case, another potential advantage of the GuideLiner is highlighted. A 66-year-old male presented with stable angina and a history of prior CABG and inferior ischemia on noninvasive perfusion imaging. The culprit lesion was identified in the PDA. The proximal and mid RCA were previously stented, the ostium of the RCA was anterior, and the vessel was very tortuous proximally (Figures 10 and 11). A 7 Fr AL 0.75 guiding catheter engaged the RCA ostium coaxially. After a BMW wire was used to cross the lesion, [12]predilatation of the lesion was performed with a 2.75 mm balloon and then the GuideLiner catheter was advanced past the previously placed stents (Figure 12). This permitted placement of a 2.75 mm x 23 mm Promus (Boston Scientific) DES with relative ease (Figure 13). The GuideLiner allows delivery of stents distally past previously placed stents,*

DOCKET ALARM Find authenticated court documents without watermarks at docketalarm.com.

which is an advantage in cases like this when there is a new de novo lesion beyond previously placed stents or even in difficult cases in stenting a distal dissection after placement of freshly placed stents. This challenges the well-established dictum of stenting from distally in the vessel to proximally in the vessel because the atraumatic soft tip of the GuideLiner catheter can easily be placed past freshly placed stents for extra support to deliver a stent distally in the vessel.

[13]**Case 5.** *A distal lesion in a small posterolateral vessel was successfully treated after very deep engagement of the GuideLiner catheter (Figures 14–16). In the past, this lesion would either be treated medically or with balloon angioplasty, but with the availability of drug-eluting stents in smaller diameters (2.25 mm) and low late loss of 0.1 mm, these patients can be offered relief of their angina as was demonstrated in this case. Caution needs to be exercised with such maneuvers with the catheter.*

[14]**Case 6.** *This case demonstrates the utility of the GuideLiner catheter in coaxial alignment for delivering stents even in very proximal coronary segments because of difficulties related to extreme proximal vessel tortuosity. An extremely angulated take off of the left circumflex artery off the left main coronary artery was dealt with by placing a GuideLiner catheter into the distal left main. Even though the GuideLiner did not actually enter the circumflex artery, it provided enough support for the delivery of a drug-eluting stent to treat the entire proximal stenosis successfully with one stent (Figures 17–19).*

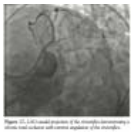
[15]**Discussion.** The GuideLiner catheter is a coaxial guiding catheter extension delivered through a standard guiding catheter on a monorail. It is comprised of a 20 cm yellow straight extension whose inner diameter is 1 Fr size smaller than the guiding catheter.[3] This extension is tri-layered. The inner most layer is PTFE; the second layer is a stainless steel coil, which imparts flexibility and strength; and the outer lining is that of pebax polymer with silicone coating. The silicone coating imparts lubricity. This is connected to a stainless steel push tube and a metal collar that can be deployed through the "Y" adapter. There is a radiopaque marker 2.6 mm from the tip of the extension and 2 white positioning markers at 95 cm and 105 cm on the push tube. This construction and design does not lengthen the guiding catheter. By not adding length to the guiding catheter it does not reduce working length of balloons and stents. This may confer an advantage when treating distal lesions. Also, this does not require a separate hemostatic valve. These are significant advantages over the Heartrail mother-and-child catheter.

[16]After guide catheter and wire placement, the GuideLiner catheter can be advanced over the wire through the hemostatic valve as an extension to the guide catheter for extra back up and deep guide engagement. The rest of the interventional procedure is completed as usual through the same hemostatic valve and guide catheter without need for disconnection and reattachment. The interventional equipment tracks over the wire and through the GuideLiner collar with exit at the distal tip of the catheter at the desired vascular location. On completion of the case, the GuideLiner catheter can be removed in a similar fashion to removal of a monorail balloon. In the first case, the use of the GuideLiner catheter as a tool for distal vessel visualization and subselective injection of contrast is showcased. This has never been described previously in the literature. Without the GuideLiner catheter, due to the presence of a coronary aneurysm the distal vessel was unable to be opacified. This was in spite of injecting 20 cc of contrast (10 cc/sec for 2 sec) via the ACIST CVi automatic injection system. Once advanced past the aneurysm, the GuideLiner allowed for subselective injection, providing complete distal vessel opacification utilizing <8 cc of contrast. This can be used to our advantage in coronary intervention on patients with compromised renal function minimizing contrast load and thereby potentially reducing the incidence of contrast associated nephropathy. This is especially important given the knowledge about adverse outcomes in patients with CIN following PCI.[4] In this particular case, an unusual problem was elegantly solved with the assistance of the GuideLiner catheter.

[17]Chronic total occlusions represent a unique challenge with respect to the diffuse nature of the disease even proximal to the occluded segment of the vessel and the small negatively remodeled distal target vessel. The GuideLiner catheter lends itself to use in this lesion subset because of the ability for deep engagement of the guiding catheter atraumatically and providing the support necessary for delivery of long drug-eluting stents for definitive treatment. The safety of the GuideLiner when used for deep intubation relies on the absence of a primary curve for the extension. It provides a safer alternative to using aggressive guiding catheters like the Amplatz left curves for the RCA. This is amply demonstrated in the second case in which the RCA chronic total occlusion was successfully treated with deep atraumatic engagement of the RCA ostium and subsequent delivery of long relatively inflexible first generation drug-eluting stents. The device allows for robust support for secure delivery of equipment to distal segments of the coronary tree. During *in vitro* testing, when extended 15 cm into the vessel, the 6 Fr GuideLiner catheter provides greater back up support than even an 8 Fr guiding catheter.

DOCKET ALARM Find authenticated court documents without watermarks at docketalarm.com.

[18]In the third, fourth, and fifth cases, the reason for the development of this device, facilitating distal stent delivery, is demonstrated. Commonly used methods to overcome difficulty with stent delivery include straightening of the vessel with a buddy wire, use of an anchor balloon, and using large diameter guiding catheters with more supportive curves. The GuideLiner facilitates delivery of stents to distal segments of the coronary vessel (Figures 4 and 5) by allowing safe deep vessel intubation. This provides the necessary extra back-up support needed for stent delivery. In an era when radial artery intervention is making a comeback into the mainstream, this may have added significance because the vast majority of cases via the radial artery are performed with 6 Fr guiding catheters. Also because of the angle of entry from the radial approach into the aortic sinus, coaxial guide placement is difficult. The GuideLiner catheter may allow for maintaining coaxial guide orientation. In case 3, a long circumflex artery stenosis was treated with deep engagement of the GuideLiner catheter to deliver 2 long DES as opposed to several shorter length drug-eluting stents. This may have incremental value in an era of cost containment by treating long lesions with fewer drug-eluting stents, thus lowering the cost per case.



[19]With this technique, use an inflated low profile balloon or a microcatheter on the wire while the catheter is advanced into the coronary artery. This reduces the dead space between the GuideLiner catheter and guidewire, providing a tapered, atraumatic leading edge. It also stiffens the rail over which the device can be advanced. This decreases the incidence of coronary dissections in the proximal vessel. An extension of this concept involves using the GuideLiner catheter even with aggressive guiding catheters, especially when there is a need for delivery of long stents to distal portions of the vessel. This is amply illustrated in cases 4 and 5 of this series. When delivering stents to distal parts of the vessel, caution needs to be exercised when the metal collar of the GuideLiner extends past the secondary curve of the guiding catheter. This is the basis for the recommended deep seating distance of 10 cm from the tip of the guide. If necessary, deeper engagement (>10 cm) can be performed without risk to the vessel or the patient.

[20]Another situation where the GuideLiner finds utility in coronary intervention is in the setting of proximal vessel tortuosity illustrated in case 6. In this case, the extreme angulation of the origin of the circumflex artery from the left main artery made it impossible to advance the stent past the proximal vessel even after straightening out the proximal vessel with stiff coronary guidewires and with deep engagement of the guiding catheter. The soft atraumatic tip of the GuideLiner catheter allowed delivery of stents relatively easily after negotiating the proximal bend of the vessel. This can greatly shorten the case and fluoroscopy times and minimize contrast load to the patient.

[21]**Limitations.** Every time a catheter is used for deep intubation of a coronary vessel, regardless of how soft the tip is, there remains a risk of dissection of the ostium and/or the proximal aspect of the vessel. It is no different with the GuideLiner catheter with reported dissection rates of 0.5%–1%. One of the techniques described in this manuscript involves using a low-profile balloon to eliminate the dead space between the catheter tip and wire, which greatly reduces the risk of dissection. Particular caution needs to be exercised in the setting of an anomalous origin of a vessel and in the setting of a diffusely diseased proximal segment. The GuideLiner is less likely to dissect the coronary ostia than a guiding catheter because of the lack of a primary curve in the GuideLiner catheter and the inner coating of the GuideLiner tip provides atraumatic support. Another drawback of this device is the potential for stents especially larger profile stents to get caught on the metal collar of the device. This can damage the stent and may even cause it to shear off, if this is not readily recognized. The cause of this complication is wire wrap around the metal collar. If any resistance is encountered during advancement of the stent through the GuideLiner catheter, the stent should not be pushed but instead withdrawn and inspected for damage to its integrity.

Wire wrap is another important consideration while using this device. When two wires are used in a coronary intervention, the GuideLiner catheter should be advanced only over the primary wire as the secondary wires may wrap around the GuideLiner catheter and prevent advancement of devices. When inserting the GuideLiner into the guiding catheter, the flat push tube should be oriented laterally and be advanced without rotation to avoid wrapping of even the primary guidewire.

Conclusion. The GuideLiner catheter has greatly simplified coronary intervention and broadened the lesion subsets that can be safely treated with 6 Fr guiding catheters and via the radial approach. The catheter could be used upfront or if difficulty is encountered delivering stents or devices as a bailout option. Like all new devices there are certain precautions and limitations that operators need to be aware of prior to using this device.

Future iterations of the device may aim to provide modifications at the steel collar to minimize risk of damage to larger profile stents and find ways to avoid wire wrap.

DOCKET ALARM Find authenticated court documents without watermarks at docketalarm.com.

References

1. Nikolsky E, Gruberg L, Pechersky L, et al. Stent deployment failure: Reasons, implications and short- and long-term outcomes. Catheter Cardiovasc Interv. 2003;59(3):324-328.
2. Mamas MA, Eichhöfer J, Hendry C, et al. Use of the HeartRail II catheter as a distal stent delivery device: An extended case series. EuroIntervention. 2009;5(2):265-271.
3. Kumar S, Gorog DA, Secco GG, Di Mario C, Kukreja N. The GuideLiner "child" catheter for percutaneous coronary intervention-early clinical experience. J Invasive Cardiol. 2010;22(10):495-498.
4. McCullough P. Outcomes of contrast-induced nephropathy: Experience in patients undergoing cardiovascular intervention. Catheter Cardiovasc Interv. 2006;67(3):335-343.
5. Takahashi S, Saito S, Tanaka S, et al. New method to increase a backup support of a 6 French guiding coronary catheter. Catheter Cardiovasc Interv. 2004;63(4):452–456.
6. Nakamura M, Shiba M, Wada M. A novel method for deploying a stent into a highly angulated position through use of a stent strut: Application of a five-in-seven system. J Invasive Cardiol. 2006;18(3):E105-107.

From Banner Good Samaritan Medical Center Interventional CV Program, Phoenix, Arizona.
Disclosure: The authors have completed and returned the ICMJE Form for Disclosure of Potential Conflicts of Interest. The authors report no conflicts of interest regarding the content herein.
Manuscript submitted March 14, 2011, provisional acceptance given April 11, 2011, final version accepted April 28, 2011.
Address for correspondence: Ashish Pershad MD, Heart and Vascular Center of AZ, 1331 N. 7th Street; #375 Phoenix, AZ 85006. Email: asper1971@cox.net [22]

[23] [24]

Online Exclusive

Source URL: http://www.invasivecardiology.com/articles/guideliner-catheter-facilitated-pci-%E2%80%93-novel-device-multiple-applications

Links:
[1] http://www.invasivecardiology.com/issue/3006
[2] http://www.invasivecardiology.com/content/volume-23-issue-11-november-2011
[3] http://www.invasivecardiology.com/files/9%20OE_E249_Fig%201.png
[4] http://www.invasivecardiology.com/files/9%20OE_E249_Fig%202.png
[5] http://www.invasivecardiology.com/files/9%20OE_E249_Fig%203.png
[6] http://www.invasivecardiology.com/files/9%20OE_E249_Fig%204.png
[7] http://www.invasivecardiology.com/files/9%20OE_E249_Fig%205.png
[8] http://www.invasivecardiology.com/files/9%20OE_E249_Fig%206.png
[9] http://www.invasivecardiology.com/files/9%20OE_E249_Fig%207.png
[10] http://www.invasivecardiology.com/files/9%20OE_E249_Fig%208.png
[11] http://www.invasivecardiology.com/files/9%20OE_E249_Fig%209.png
[12] http://www.invasivecardiology.com/files/9%20OE_E249_Fig%2010.png
[13] http://www.invasivecardiology.com/files/9%20OE_E249_Fig%2011.png
[14] http://www.invasivecardiology.com/files/9%20OE_E249_Fig%2012.png
[15] http://www.invasivecardiology.com/files/9%20OE_E249_Fig%2013.png
[16] http://www.invasivecardiology.com/files/9%20OE_E249_Fig%2014.png
[17] http://www.invasivecardiology.com/files/9%20OE_E249_Fig%2015.png
[18] http://www.invasivecardiology.com/files/9%20OE_E249_Fig%2016.png
[19] http://www.invasivecardiology.com/files/9%20OE_E249_Fig%2017.png
[20] http://www.invasivecardiology.com/files/9%20OE_E249_Fig%2018.png
[21] http://www.invasivecardiology.com/files/9%20OE_E249_Fig%2019.png
[22] mailto:asper1971@cox.net
[23] http://www.invasivecardiology.com/printmail/3022
[24] http://www.invasivecardiology.com/print/3022

DOCKET ALARM
Find authenticated court documents without watermarks at docketalarm.com.