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Transradial interventions with the GuideLiner catheter: Role of proximal vessel angulation

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ABSTRACT

Background: Transradial coronary intervention (TRI) is increasingly common, but anatomic variations and lack of guide catheter support may increase the complexity of TRI. The GuideLiner catheter (Vascular Solutions, Minneapolis,MN) is a guide catheter extension developed to provide increased guide catheter support. We hypothesized that TRI cases requiring GuideLiner support would have a greater proximal vessel angle and increased lesion angle tortuosity.
Methods: This was a retrospective study reviewing 146 TRI cases performed at a single institution between August 2010 and June 2012. 22 cases (15%) required use of the GuideLiner support catheter. Procedural and angiographic characteristics of all cases were analyzed. Multivariable analysis and receiver operator curves (ROC) were used to analyze predictors of GuideLiner use.
Results: The indications for TRI were similar between both groups. Subjects who required use of the GuideLiner support catheter at the time of TRI were significantly older (69 ± 12 years vs. 62 ± 13 years, $p = 0.03$). The proximal vessel angle was significantly greater in the cases requiring GuideLiner support (74° ± 35° vs. 37° ± 23°, $p < 0.001$). Lesion angle in the Guideliner group was also significantly greater (48° ± 32° vs. 28° ± 25°, $p < 0.001$). On multivariable analysis, proximal vessel angle independently predicted the need for GuideLiner support (AOR 1.4 per 10°, $p < 0.001$). A 45° proximal vessel angle predicted the need for GuideLiner use with a sensitivity of 73% and specificity of 74% (c-statistic 0.79). None of the Guideliner TRI cases required conversion to femoral access.
Conclusions: TRIs requiring GuideLiner catheter support had significantly increased lesion complexity and vessel tortuosity. Proximal vessel angulation is significantly associated with the need for GuideLiner use during transradial intervention. Use of the Guideliner facilitated successful completion of PCI despite the use of a wide variety of guiding catheters in this series.

1. Introduction

Transradial coronary intervention (TRI) is associated with significantly reduced rates of bleeding and access site related complications [1] compared to the transfemoral (TF) approach. Although TRI is increasingly common, it currently represents <10% of all PCIs in the USA. Barriers to TRI include a steep initial learning curve and time required to gain proficiency at TRI [2]. Additionally, anatomic variations and lack of guide catheter support increase the technical complexity of TRI [3,4].

During trans-radial cardiac catheterization, the anatomic and geometric characteristics of the ascending aorta relative to the catheter differ significantly from TF angiography. Specifically, guide catheters advanced from the right radial artery often approach the coronary ostia from a vertical downward approach, which excludes the aortic arch. As a result, less guide backup force is generated [5]. Since most guide catheters were also designed for a TF approach, they may provide less backup support and coaxial alignment for TRI. One technique to overcome lack of guide catheter support includes deep intubation of the guide catheter. However, most guide catheters are designed for support at the coronary ostia and such maneuvers can traumatize the target coronary artery [6]. More aggressive radial-specific guides can also be used, but these may also result in proximal vessel injury. With many new operators adopting radial catheterization and TRI, improved techniques to facilitate successful completion of the procedure could have significant advantages.

The GuideLiner catheter (Vascular Solutions, Minneapolis, MN) is a novel “mother and child” rapid exchange atraumatic guide catheter extension that allows deep vessel intubation with minimal trauma to the native coronary artery. Early reports demonstrated successful application of this catheter extension for complex TF coronary interventions including vein and LITA grafts [7–10]. However, no prior study has examined the utility and predictors of GuideLiner use as an adjunctive tool for TRI.

In this study, we characterized the procedural and angiographic characteristics of cases where GuideLiner use facilitated successful

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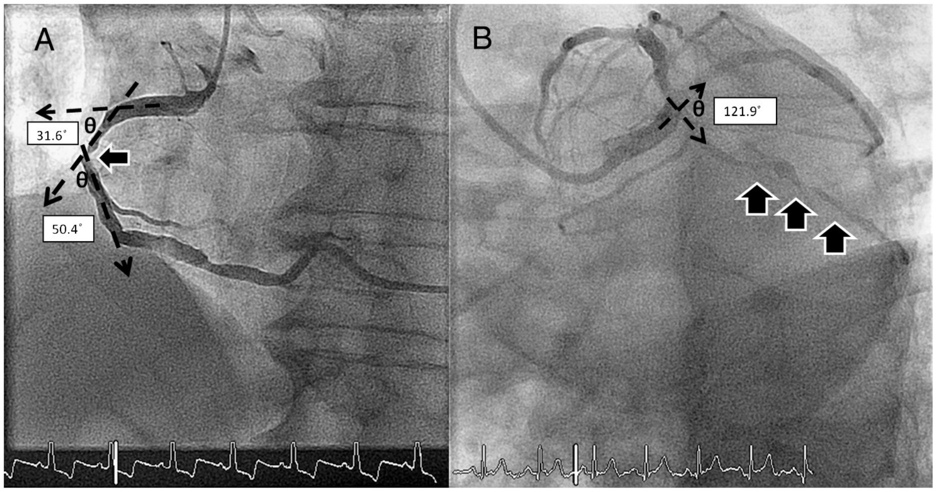

Fig. 1. Measurement of Proximal Vessel and Lesion Angulation. (A) Right Coronary Artery in LAO projection with overlaid measurements of proximal vessel and lesion angulation and (B) Left Circumflex Artery in LAO Caudal projection with overlaid measurement of proximal vessel angulation. Lesion(s) denoted by black arrows with white border.

TRI. We hypothesized that cases requiring the use of a GuideLiner catheter would have a higher prevalence of proximal angle and lesion angle tortuosity, and that GuideLiner use would be associated with high rates of procedural success and minimal need for crossover to a TF approach.

2. Methods

A total of 1292 PCIs were performed between August 2010 and June 2012 at the University of California, Davis Medical Center. During that timeframe, 146 of these cases were TRI, which comprise the study cohort. Among these 146 TRIs, 22 cases (15%) required use of the GuideLiner support catheter. The general approach to TR and TF intervention at our institution is to attempt PCI with conventional guide support, and to use a GuideLiner only in those cases where it became difficult or not feasible to deliver therapy to the target lesion. Thus, the use of the GuideLiner was at the operator's discretion. We analyzed patient characteristics, procedural characteristics, and angiographic variables of all TRIs. The following patient characteristics were determined: patient age, gender, demographic factors, and the indication for intervention. The following procedural characteristics were assessed: access site, target vessel, ACC/AHA lesion type (A, B1, B2, C) [11], size of the guide catheter, types of balloons/stents delivered, and procedural success. Procedural success was defined as final target lesion stenosis of <20% with TIMI 3 grade flow without major complications.

Angiographic variables quantified included: lesion length, vessel diameter proximal and distal to the target lesion, and lesion calcification. Proximal vessel and target lesion angulations (Fig. 1) were classified as minor (<45°), moderate (45°–90°), or excessive (>90°) [12]. Proximal vessel angulation was defined as the angle closest to the target lesion of interest. If the target vessel contained more than one angulation before the target stenosis, the angle immediately proximal to the lesion was taken. Vessel angulations were measured using QCA in the projection least likely to foreshorten the vessel of interest (Phillips Xcelera,The Netherlands). For example, the right coronary artery (RCA) was measured in the left anterior oblique (LAO) projection, left anterior descending (LAD) and left circumflex (LCx) takeoff was measured in LAO caudal projection, diagonal branches in the LAO cranial projection, and obtuse marginal (OM) branches were measured in the right anterior oblique (RAO) caudal projection. All vessel measurements were performed and verified independently by two cardiologists experienced in QCA analyses.

2.1. Statistical analysis

Mean values with standard deviation were used to describe continuous variables, and numerical counts (percentages) were used for categorical variables. Statistical analysis was performed by means of Pearson chi-square test for categorical variables. Student's t-test was used to test for differences in continuous variables. All values were expressed as mean ± SEM. Statistical significance was accepted with a p value of less than .05. A logistic model was developed to identify independent predictors of GuideLiner support catheter use by including all angiographic variables that were significant on univariate analysis using a cutoff of $p < 0.1$ for inclusion. Receiver operator curves of sensitivity vs. 1-specificity were constructed to identify the proximal vessel angle that maximized sensitivity and specificity for predicting GuideLiner use. All statistical analyses were performed using STATA version 11.2 (College Station, TX). All authors had full access to and take full responsibility for the integrity of the data. All authors have read and agree to the manuscript as written.

3. Results

Among 146 TRIs performed during the study period, 22 cases (15%) required use of the GuideLiner support catheter during TRI. Demographic data comparing baseline characteristics of subjects are

Table 1
Baseline demographics.

Variable	GuideLiner (N = 22)	No GuideLiner (N = 124)	P value
Male (%)	15 (68)	95 (77)	0.4
Age, years	69 ± 12	62 ± 13	0.03
Indication			0.6
Elective	10 (45)	49 (40)	
ACS	12 (55)	75 (60)	
Hypertension (%)	17 (77)	95 (77)	0.9
Hyperlipidemia (%)	16 (73)	66 (53)	0.09
Diabetes (%)	11 (50)	47 (38)	0.3
Active smoker (%)	2 (9)	28 (23)	0.1
Family history of CAD	1 (5)	7 (6)	0.8
Prior MI	2 (9)	12 (10)	0.9
Prior PCI	6 (27)	25 (20)	0.5
Prior CABG	6 (27)	21 (17)	0.3

Table 2
Angiographic and procedural characteristics.

Variable	Guideliner (N = 22)	No Guideliner (N = 124)	P value
Access Side			0.4
Right	13 (59)	89 (72)	
Left	8 (36)	33 (27)	
Both	1 (5)	2 (2)	
Femoral Conversion	0 (0)	2 (2)	0.6
Target Vessel			0.3
RCA	12 (55)	42 (34)	
LAD	5 (23)	46 (37)	
Circumflex	5 (23)	26 (21)	
Bypass Graft	0	1 (1)	
Left Main	0	9 (7)	
Lesion Category			0.01
A	1 (1)	18 (15)	
B1	1 (1)	36 (29)	
B2	6 (27)	30 (24)	
C	14 (64)	40 (32)	
Calcification			0.005
None	5 (23)	72 (58)	
Mild	6 (27)	29 (23)	
Moderate	7 (32)	16 (13)	
Severe	4 (18)	7 (6)	
Multiple Guide Catheters used(≥2)	4 (18)	18 (15)	0.7
Final Guide Catheter Used			
Right Coronary			
JR	9(75)	33(78)	
AL1	1(8)	4(10)	
AL 0.75	1(8)	4(10)	
AR1	1(8)	1(2)	
Left Coronary			
JL	3(30)	27(33)	
XB	2(20)	10(12)	
XBLAD	0	3(4)	
EBU	0	17(21)	
Q	4(40)	19(24)	
Ikari	0	1(1)	
AL	1(10)	4(5)	
Embolic Protection	1 (5)	5 (4)	0.9
Lesion Length	28 ± 22	19 ± 14	0.02
Proximal vessel, mm	2.4 ± 0.6	2.6 ± 0.7	0.3
Distal vessel, mm	2.3 ± 0.7	2.3 ± 0.6	0.9
Total stents delivered	1.9 ± 1.3	1.5 ± 1.1	0.2
Post Procedure TIMI flow <3	0	2 (2)	0.5
Vessel complications	0	6 (5)	0.3
Lesion angle	48 ± 32	28 ± 25	<0.001
Proximal vessel angle	74 ± 35	37 ± 23	<0.001

summarized in (Table 1). The indications for TRI were similar between both groups, with slightly over half of the procedures performed for acute coronary syndrome. Subjects who required use of the GuideLiner support catheter at the time of TRI were significantly older (69 ± 12 years vs. 62 ± 13 years, $p = 0.03$). The two groups had otherwise similar baseline demographic characteristics.

Procedural and angiographic details of the 146 TRI cases are reported in (Table 2). A wide variety of 6 French guiding catheters were used by the multiple operators who participated in this series highlighting the diversity of approaches seen in clinical practice. Cases requiring GuideLiner use were more likely to involve intervention to the RCA (55% vs. 34%). Several angiographic variables also differed between the two groups. The proximal vessel angle was significantly greater among cases that required GuideLiner support (74° ± 35° vs. 37° ± 23°, $p < 0.001$). Lesion angle was significantly greater among patients that required GuideLiner support (48° ± 32° vs. 28° ± 25°, $p < 0.001$). Vessel calcification, lesion complexity, and lesion length were significantly greater in the GuideLiner cases (28 ± 22 vs. 19 ± 14 mm, $p = 0.02$). Mean maximal GuideLiner intubation depth as measured from the coronary ostium was 23 ± 21 mm.

Table 3
Univariate predictors of Guideliner use.

Predictors	Unadjusted Odds Ratio	P value
Right Coronary Artery	2.3 [0.94–5.9]	0.07
Calcification	4.7 [1.6–13.6]	0.004
Lesion length, per 10 mm	1.3 [1.1–1.5]	0.02
Lesion Angle, per 10°	1.2 [1.1–1.4]	0.002
Proximal Vessel Angle, per 10°	1.4 [1.2–1.6]	<0.001
Age, per 10 years	1.4 [1.1–1.8]	0.03

Table 4
Patient outcomes.

Variable	Guideliner (N = 22)	No Guideliner (N = 124)	P value
Procedural Success	22 (100)	124 (100)	1.0
Angiographic Success	22 (100)	122 (98)	0.9
Major Bleeding	0	0	N/A
Femoral Conversion	0	2 (2)	0.6
Post Procedure TIMI flow <3	0	2 (2)	0.5
Vessel complications (Dissection or perforation)	0	6 (5)	0.3

On univariate analysis, predictors of GuideLiner use included proximal vessel angulation, lesion angle, lesion length, and lesion calcification (Table 3). On multivariable analysis, only proximal vessel angulation was remained a significant determinant of GuideLiner use (adjusted Odds Ratio 1.4 [95% CI 1.2–1.6] for each 10° of increased proximal vessel angulation, $p < 0.001$). Receiver operator curve analysis of proximal vessel angulation revealed that a proximal vessel angle of 45° had a sensitivity of 73% and specificity of 74% for predicting need for GuideLiner support during TRI (c-statistic 0.79).

The procedural success was 100%, the majority of cases were performed through the right radial artery access. No major complications were seen. None of the TRI cases in which the GuideLiner was used required conversion to femoral access (Table 4).

4. Discussion

Enthusiasm for transradial intervention (TRI) is often high during an operator's early experience with transradial catheterization due to reported benefits related to increased patient comfort and decreased bleeding complications. However, there are inherent challenges to the transradial technique, and inadequate guide support and difficulty in completing interventions that might be more easily accomplished from the more familiar femoral approach can dampen enthusiasm. Despite the availability of radial-specific guiding catheters, these guides tend to be more aggressive and many operators prefer femoral-type curves which are more familiar. It is therefore important

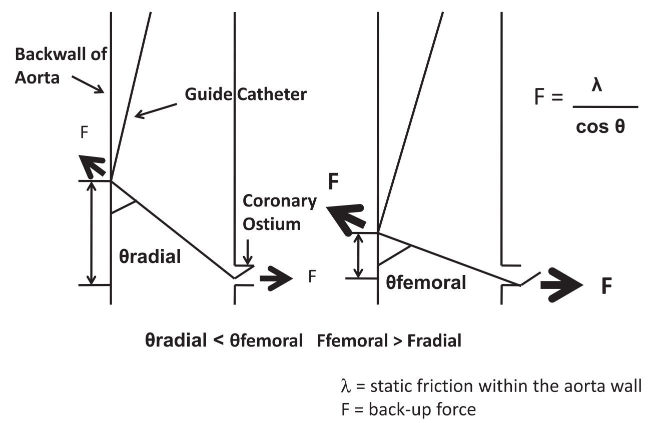

Fig. 2. Support Angulation During Coronary Intervention. Representation of the Ikari hypothesis and the role of support point angulation in generating back up force.

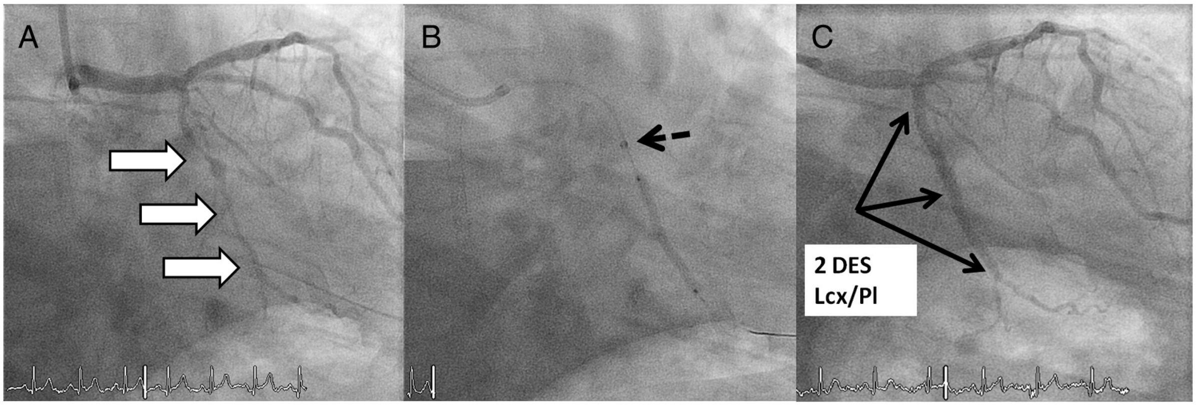

Fig. 3. Example of Deep Vessel Intubation with Guideliner. (A) Long mid-left circumflex lesion extending into a left posterolateral branch (White Arrow/Black Border) with tortuous proximal vessel (retroflexed circumflex origin). (B) Deep intubation with GuideLiner (Dashed Black Arrow) for stent delivery. (C) Left Circumflex artery after deployment of overlapping 2.5 × 28 mm 2.5 × 18 mm DES (Black Arrows).

to identify techniques that can facilitate TRI and ensure more consistent procedural success. In this study, we describe the angiographic characteristics of lesions that were more likely to necessitate GuideLiner support during TRI. The major finding of this study is that proximal vessel angulation is an important predictor of need for GuideLiner support, suggesting that this vessel characteristic could be used at the start of TRI to predict the need for more active guide support. With the use of this guide catheter extension technique, procedural success rates were very high (100%) and not different from transradial interventions that did not require Guide-Liner support.

Despite advances in guide catheter design and procedural techniques for coronary revascularization, adequate guide support continues to be a challenge, especially for complex coronary interventions through the transradial approach. Because of the angle between the innominate artery and ascending aorta, some of the principles of adequate backup support are lost when approaching TRI, particularly through the right radial artery. Those principles include an ideal supportive point directly opposite the coronary ostia. Ikari et al. have hypothesized that the backup force of that supportive point is directly proportional to two main factors: (1) Static friction (λ), as the length of guide catheter in contact with backwall of the aorta is increased, more friction is created and less chance of displacement; and (2) The angle made between guide catheter contact point along the contralateral aortic wall. The angle between the guide catheter and the backwall of the aorta is increased as the contact point of the guide catheter sits lower on the aorta, thereby increasing support forces in parallel with the coronary ostium (Fig. 2) [13–15]. Each of these support factors is potentially compromised during TRI, thereby decreasing guide catheter support and making the procedure more technically challenging.

Numerous approaches have been described to overcome the need for increased support during device delivery. These techniques include extra backup guides, dedicated radial support guides (which tend to be more aggressive), stiffer guidewires, buddy wires, and the anchor balloon technique [16,17]. The operator can also upsize to a larger guide for increased backup support; however, this option is more limited when performing a TRI due to the smaller caliber of the radial artery. Certain TRI cases can prove quite difficult despite these techniques, and in the past may have required conversion to femoral access for increased support [18]. However, the development of guide catheter extension systems such as the GuideLiner has provided an additional tool to help accomplish complex coronary interventions with a wide variety of guiding catheters. The use of the GuideLiner as a support catheter that can be placed into the target vessel helps facilitate equipment delivery in challenging coronary lesions and can assist with engagement of the coronary ostium. Takahashi et al. demonstrated that a guide catheter extension system can provide substantial improvement in back-up support for complex coronary interventions, including TRI [19]. Some of the cases required deep vessel intubation with the GuideLiner (Fig. 3). In most cases, the GuideLiner was simply advanced over the coronary guidewire or an

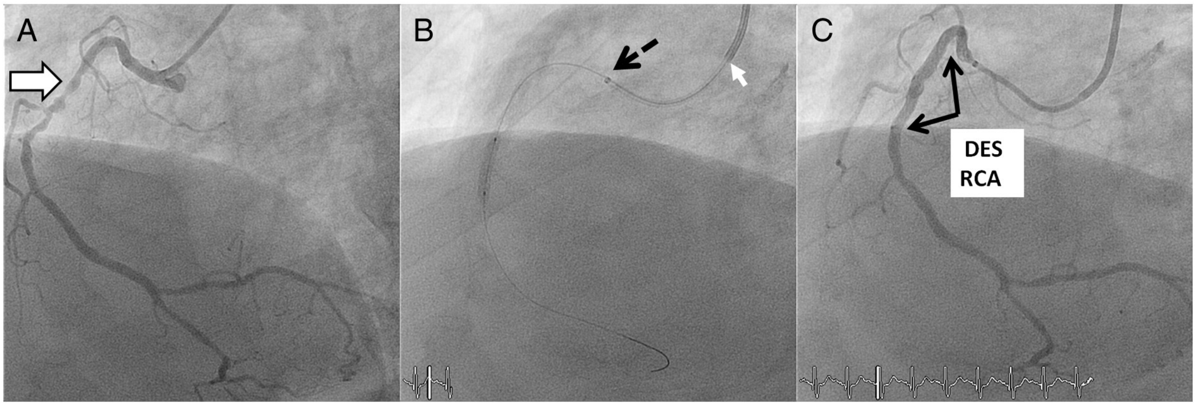

Fig. 4. Example of Guideliner Use for Proximal Lesion Tortuosity. (A) Long mid RCA lesion(White Arrow/Black Border) with proximal vessel "Shepherd's Crook" severe tortuosity. (B) GuideLiner distal tip (Dashed Black Arrow) can be seen at the ostium of the RCA with guide catheter (White Arrow) disengaged from coronary artery resting along the contralateral aortic wall. (C) RCA status post deployment of 3.0 × 30 mm DES (Black Arrows).

un-inflated balloon shaft. In some cases, deeper intubation was accomplished by inflating a balloon distally as an anchor, and advancing the GuideLiner over the inflated balloon shaft. In other cases, the GuideLiner provided increased support with minimal vessel intubation, because advancing the GuideLiner caused the guide to back out until it rested on contralateral aortic wall (so-called Swan-neck maneuver) (Fig. 4) [20]. In our study, the mean intubation depth of the GuideLiner catheter was fairly modest at 23 mm, highlighting the fact the many cases do not require deep intubation for procedural success.

This study reports the largest published number of transradial GuideLiner interventions and sought to identify the variables that were associated with the use of the GuideLiner support catheter. Demographics and clinical characteristics of the study population were similar in both groups. However, the lesions in the GuideLiner group were significantly more complex, more calcified, and tended to be longer. The most striking difference between groups was the angle of the proximal vessel and lesion angle. Severe proximal coronary angulations (e.g., shepherd's crook-shaped proximal RCA) (Fig. 4) pose an increased challenge for equipment delivery [21]. This study demonstrates the effectiveness of guide catheter extension in overcoming significant coronary vessel tortuosity as noted by a 100% success rate in TRI with use of the GuideLiner and no conversion to femoral access. This study also demonstrates the multiple methods in which the GuideLiner can be used for increase guide support. Despite the aggressive use of the GuideLiner in certain cases, there were no major complications as seen in previous studies [22–24]. In fact, there were a significant number of coronary vessel dissections in the no GuideLiner group. This higher than expected rate of coronary dissections may have been related to deep guide catheter intubation in an effort to achieve better guide support. These findings may support earlier use of a Guideliner cather in cases where device delivery may otherwise necessitate guide manipulation with an associated risk of vessel injury.

5. Conclusion

The purpose of this study was to describe the angiographic variables that predicted the use of the GuideLiner catheter during TRI at an institution with an emerging transradial program. The GuideLiner allowed successful completion of TRI with a wide spectrum of guiding catheters including a large number of JL and JR standard TF catheters. Radial specific guide catheters could have been used in many of these cases, thereby possibly reducing the need for GuideLiner use. However, this retrospective review represents the practice patterns of novice transradial operators, who may preferentially use familiar guide catheters. Thus, the GuideLiner support catheter can serve as a useful tool for difficult PCI as operators refine their skills at transradial intervention. TRIs facilitated by the GuideLiner catheter had significantly more lesion complexity including proximal vessel and lesion tortuosity, lesion calcification, and lesion length. After multivaraible analysis, only proximal vessel angulation was found to be a significant determinant of need for GuideLiner support. Such information could help the transradial interventionalist better recognize the features of a challenging case. By doing so, physician utilization of a Guideliner catheter "up front" for certain TRIs could reduce use of resources including contrast use, and total fluoroscopy time.

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