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Coronary Artery Disease

The Efficacy and Safety of Using Extension Catheters in Complex Coronary Interventions: A Single Center Experience

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Background: The extension catheter was originally developed to facilitate stent delivery to challenging lesions. We evaluated the efficacy and safety of using an extension catheter in patients undergoing percutaneous coronary interventions (PCI).

Methods: Two interventional cardiologists reviewed the records of all consecutive patients who, between November 2011 and October 2015, had undergone PCI with a GuideLiner or Heartrail ST-01 extension catheter. Clinical demographics, vessel characteristics, procedural details, and outcomes were recorded.

Results: We identified 136 (3.7%) eligible patients (male: 81.6%; mean age: 66.2 ± 11.2 years) in 3665 PCI procedures. Seventy-two (52.9%) cases required increased support to cross severely calcified lesions. The remainder were coronary tortuosity [47 (34.6%)], chronic total occlusions [35 (25.7%)], previously deployed proximal stents [16 (11.8%)], and anomalous origin of coronary artery [9 (6.6%)]. There were 43 type B and 91 type C lesions. The success rate was 86.8% (118) and the complication rate was 6.6% (7 coronary dissections, 1 thrombus formation, and 1 stent dislodgement). All complications were successfully managed using endovascular interventions. The failure rate significantly (25.5%) increased if more than 3 of 6 peri-procedural factors coexisted: 1) long lesions (> 30 mm), 2) tortuosity, 3) calcification, 4) chronic total occlusion, 5) previous intervention history, and 6) previously deployed proximal stents.

Conclusions: Using an extension catheter for challenging complex PCIs is safe and highly successful if the practitioner has adequate experience manipulating extension catheters.

Key Words: Child-in-mother catheter • Extension catheter • GuideLiner

INTRODUCTION

There is increasing interest in percutaneous coronary interventions (PCIs). In complex cases, extra support for wiring or delivering the devices to the target sites may be required. For example, in cases with calcified, tortuous vessels, chronic total occlusion (CTO) lesions, or anomalous orifices, there are many methods to increase support, including the distal (or side branch) anchor technique, a buddy wire (or balloon), a larger or extra-supportive guiding catheter, or a deep-seated guiding catheter. Each method, however, has its own limitations, and cannot overcome all complex lesions.

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The extension catheter (mother-and-child catheter system), which is an extra catheter that extends from the guiding catheter, facilitates coronary interventions,[1,2] and is sometimes used in bail-out conditions such as with trapped devices[3] or in anomalous origins of the coronary artery.[4] The two most frequently used commercial catheters are the Heartrail ST-01 (Terumo Corp., Tokyo, Japan) and the GuideLiner (Vascular Solutions, Inc., Minneapolis, MN, USA). The first-generation GuideLiner was FDA-approved in 2009, and subsequently proved to be particularly useful in interventions involving chronic total occlusions and extreme vessel tortuosity.[1-9] The GuideLiner ("child") is compatible with guiding catheters and can be advanced over a coronary wire through the "mother" catheter without disconnecting the hemostatic valve and without the assistance of an extension wire, which is different from the Heartrail ST-01 extension catheter.[1,2] However, potentially severe complications associated with the use of extension catheters have been reported, including coronary dissection,[2,9,10,11] stent damage,[6] and stent loss.[6] Nevertheless, the number of cases in these studies is relatively small, and they did not discuss possible reasons for procedure failure, even when using extension catheters.

In this study, we systematically review and describe our hospital experience using extension catheters in complex PCI. We examine our success and complication rates, and analyze the factors that could predict failure of the procedure.

METHODS

Ethical considerations

The protocol for this study was approved by the Institutional Review Board of National Cheng Kung University (NCKU) (IRB: A-ER-104-224).

Study population

We reviewed the records of a consecutive series of patients diagnosed with stable angina, unstable angina, or acute myocardial infarction and who underwent PCI that used an extension catheter at NCKU Hospital between November 2010 and October 2015.

Interventional procedures

Our PCI team included eight operators and performed 600 to 800 PCIs per year. All procedures were done using standard clinical protocols via the femoral artery with a 7-Fr guiding catheter, or via the radial artery with a guiding 6-Fr catheter. All patients were injected with a bolus of unfractionated heparin (5000 Units or 70-100 U/kg). The interventional approaches, devices, and techniques were decided upon by each operator based on guidelines and protocols. After the PCI, the patient was prescribed life-long aspirin, and clopidogrel or ticagrelor for 9-12 months, if not contraindicated.

Extension catheters

Two brands of extension catheters were used: the Heartrail ST-01 (Terumo Corp., Tokyo, Japan) and the GuideLiner (Vascular Solutions, Inc., Minneapolis, MN). The Heartrail ST-01 is a 5-Fr over-the-wire catheter (inner diameter: 1.50 mm; outer diameter: 1.73 mm; length: 120 cm), which can guide catheters bigger than 6-Fr. The GuideLiner is a coaxial monorail extension catheter comprised of a soft flexible yellow 20-25-cm straight "collar" stainless steel push rod, and based on a guiding catheter (Supplementary Figure 1). Three sizes are available in our hospital: 5.5-Fr, 6-Fr, and 7-Fr (length: 150 cm). The GuideLiner V3 has an additional 17-cm long half-pipe channel before the collar to allow for better stent accommodation and an inner diameter about 1-Fr smaller than the outer diameter; hence, it is unofficially called the "6-in-7 Fr" or "5-in-6 Fr" catheter. It can be inserted into the system from an existing Y-adapter and hemostatic valve for rapid exchange and delivery.

Both extension catheters permit deep-seated intubation of the target vessel, thus providing extra backup support for device delivery, and enabling the injection of contrast close to the target lesion, thereby improving target vessel visualization.

Data acquisition

We reviewed the charts of all patients and recorded data including age, sex, preexisting comorbidities, reasons for the intervention, laboratory examinations, and complications. We also reevaluated angiograms and procedure reports, and recorded all intervention details including access site, guiding catheter, lesion types, extension catheter type, the deepest position of the extension catheter, vessel characteristics, other devices or techniques to increase support, stent size and length, and intraprocedural complications. Vessel characteristics were defined as: (1) calcified: heavy density calcification visualized around a vessel wall and recorded on an angiogram; and (2) tortuous: ≥ 2 vessel bends before the target lesion. Procedural success was defined as delivery and placement of a stent to the target lesion, and < 10% residual stenosis.

Statistical analysis

Continuous variables are expressed as means and standard deviations, and categorical variables are expressed as counts and percentages, and separated into two groups based on the success or failure of the procedure. Two-tailed Student's *t* tests for continuous variables and χ^2 tests for categorical variables were used for univariate comparisons. Multivariate logistic regression was used to identify independent predictors of procedural failure. Statistical significance was defined as a 2-sided p value of < 0.05. SPSS 21 for Windows was used for all analyses (SPSS, Chicago, IL, USA).

RESULTS

From November 2010 to October 2015, we performed 3665 PCIs and used extension catheters for complex interventions in 136 patients (3.71%) (Table 1). The mean patient age was 65.5 ± 11.7 years, 111 (81.6%) were male, 64 (47.1%) had a history of PCI, and 12 (8.8%) had undergone coronary artery bypass grafting (CABG) surgery. The comorbidities included dyslipidemia [n = 78 (57.4%)], hypertension [n = 109 (80.1%)], diabetes [n = 76 (55.9%)], chronic kidney disease [n = 82 (60.3%)], and end stage renal disease [n = 33 (24.3%)].

We used an extension catheter most frequently (63.2%) in the right coronary artery (RCA), followed by the left anterior descending (LAD) artery 19.9%, and the left circumflex artery (LCX) 16.9% (Table 2). The complexity of the lesions was type-C in 66.9% of the patients including 35 cases of CTO (25.7%), type-B in 31.6%, and type-A in 1.5%. Most target vessels were 2.0-3.0 mm wide (40.4%) or 3.0-4.0 mm wide (55.9%). We more often used the GuideLiner as an extension ("child") catheter (89.7%) than the Heartrail ST-01 catheter (10.9%). The most frequently used type was the GuideLiner 6-Fr (60.3%). Because most cases were complex, we also chose femoral artery access (77.2%) more frequently than radial artery (22.8%) access. There were no statistically significant differences between the two groups.

The reasons for using an extension catheter to overcome a support problem are illustrated in Figure 1. In brief, the most compelling reason was a severely calcified lesion (52.9%), followed by coronary tortuosity (34.6%), CTO (25.7%), previously deployed proximal stent (11.8%), and ananomalous origin of the coronary artery (6.6%).

Our primary criterion for choosing a guiding catheter was adequate support. The most frequently used guiding catheter was an Amplatz left [AL (n = 38)], followed by a Shepherd's-Crook right [SCR (n = 31)], and an extra back-up [EBU (n = 27)] (Figure 2).

Eighteen of our cases (13.2%) were failures, and the success rate was 86.8%. The failed procedures included seven CTOs, nine severe calcifications, and seven tortuous vessels. Fourteen were device-delivery problems (10.3%), and four had complications (2.9%). Device delivery was performed via wiring, balloon delivery, or stent placement (Table 3). The major complications were seven catheter-related blood vessel dissections, one thrombosis, and one dislodged stent. Endovascular interventions were used to successfully solve all of the complications.

Table 1. Baseline demography – Groups according to procedure succeed or failed

Variable	Succeed (n = 118)	Failed (n = 18)	p
Mean age (years)	65.3 ± 12.2	66.8 ± 7.9	.613
Sex (male)	94 (79.7%)	17 (94.4%)	.034
Diabetes	69 (58.5%)	7 (38.9%)	.121
Hypertension	96 (81.4%)	13 (72.2%)	.369
Dyslipidemia	66 (55.9%)	12 (66.7%)	.393
Smoking	35 (29.7%)	7 (38.9%)	.434
Chronic kidney disease	71 (60.2%)	11 (61.1%)	.940
End stage renal disease	28 (23.7%)	5 (27.8%)	.711
PCI history	52 (44.1%)	12 (66.7%)	.080
CABG history	9 (7.6%)	3 (16.7%)	.346

CABG, coronary artery bypass grafting; PCI, percutaneous coronary intervention.

Table 2. Procedural details – Groups according to procedure succeed or failed

Character	Types	Succeed (n = 118)	Failed (n = 18)	p
Target vessel	LAD	23 (19.5%)	4 (22.2%)	.964
	LCX	20 (16.9%)	3 (16.7%)	
	RCA	75 (63.6%)	11 (61.1%)	
Extension catheter	GuideLiner 7-Fr	23 (19.5%)	5 (27.8%)	.796
	GuideLiner 6-Fr	73 (61.9%)	9 (50%)	
	GuideLiner 5.5-Fr	10 (8.5%)	2 (11.1%)	
	ST01	12 (10.2%)	2 (11.1%)	
Lesion types	A	2 (1.7%)	0 (0%)	.535
	B	39 (33.1%)	4 (22.2%)	
	C	77 (65.3%)	14 (77.8%)	
	CTO	27 (22.9%)	8 (44.4%)	.052
Vessel size	2.0-3.0	46 (39%)	9 (50%)	.507
	3.0-4.0	67 (56.8%)	9 (50%)	
	> 4.0	5 (4.2%)	0 (0%)	
Access site	Radial	28 (23.7%)	3 (16.7%)	.506
	Femoral	90 (76.3%)	15 (83.3%)	
Unfavorable lesion factors	Calcification	63 (53.4%)	9 (50.0%)	.790
	Tortuous	41 (34.7%)	6 (33.3%)	.907
	Long lesion (> 30 mm)	60 (50.8%)	11 (61.1%)	.427
	Proximal stent	11 (9.3%)	5 (27.8%)	.024
High support guiding catheter*		95 (80.5%)	15 (83.3%)	.778

CTO, chronic total obstruction; LAD, left anterior descending artery; LCX, left circumflex artery; RCA, right coronary artery.
* High support guiding catheter include Amplatz left (AL), Shepherd Crook right (SCR), extra back-up (EBU) catheter, VL, Voda left and XB, extra support.

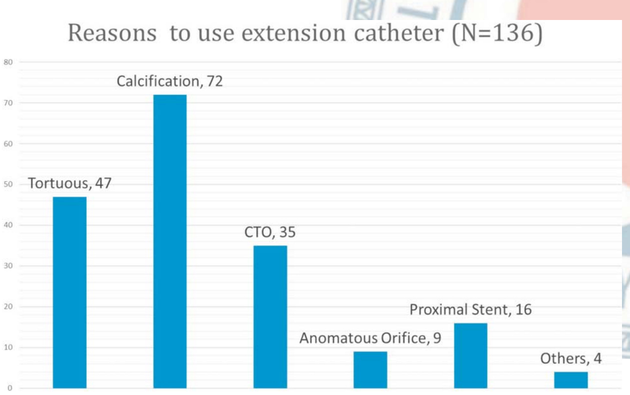

Figure 1. *Reasons to use a "child" catheter. The most common reason for using an extension catheter for support was calcification (dense calcium deposits around the vessel wall recorded by an angiogram). Other reasons included tortuous (≥ 2 vessel bends before the target lesion) vessels, CTO (chronic total obstruction), and a proximal stent.*

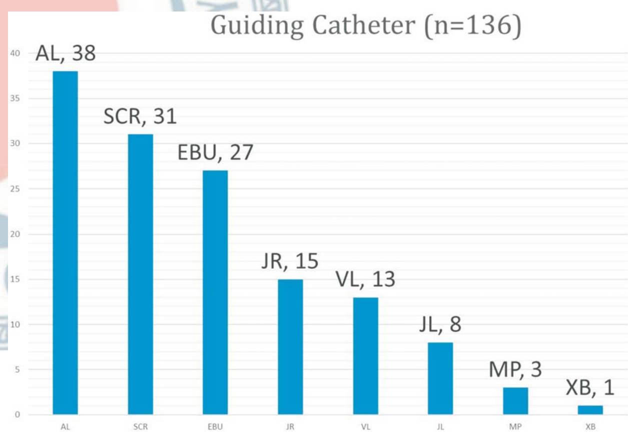

Figure 2. *Guiding catheter for the procedure. Most of our cases already started with high support guiding catheters, including Amplatz left (AL), Shepherd Crook right (SCR), VL, Voda left; XB, extra support; or extra back-up (EBU) catheter, rather than a MP: multipurpose, Judkin right (JR) or Judkin left (JL).*

DISCUSSION

The major findings of this study are the success rate of 86.8% and complication rate of 6.6%, which indicate the usefulness of extension catheters in complex PCIs. There is not, however, a standard protocol for extension catheter manipulation.

Predicting success and failure rates

Our success rate was lower than in previous studies,[1-3] which ranged between 93% and 98.3%. One possible explanation for this maybe that the complexity of our cases seemed to be higher; i.e., we had more cases of type-C (n = 91) and CTO (n = 35). Moreover, for most

Table 3. Failure cases: details

Case No.	Failure point	Vessel	Access	Guiding	Indications for extension catheter use
	Device delivery problem				
1	Wiring failed: inserted into false lumen	LCX	Femoral	EBU3.5	Calcification, tortuous
2	Wiring failed: could not pass CTO	RCA	Femoral	SAL1	CTO
3	Balloon passing	LCX	Femoral	EBU3.5	Calcification, tortuous
4	Balloon passing	LCX	Femoral	EBU3.5	Calcification
5	Balloon passing	RCA	Femoral	AL-1	CTO
6	Balloon passing	RCA	Femoral	SCR3.5	Proximal stent
7	Balloon passing	RCA	Radial	SAL1	CTO, tortuous
8	Balloon passing	RCA	Radial	SAL1	CTO
9	Balloon passing	RCA	Femoral	JR4	Calcification, CTO, proximal stent, tortuous
10	Stent delivery	LAD	Femoral	JL4	Calcification, CTO
11	Stent delivery	LAD	Femoral	EBU3.75	Proximal stent
12	Stent delivery	LAD	Femoral	EBU3.5	Calcification, proximal stent
13	Stent delivery	RCA	Femoral	JR4	Calcification
14	Stent delivery	RCA	Radial	AL.75	Tortuous, proximal stent
	Complication-related				
15	Stent could not pass transitional zone	LAD	Femoral	VL3.5	Calcification
16	Stent dislodged when passing transitional zone*	RCA	Femoral	SCR3.5	Tortuous
17	Proximal dissection	RCA	Femoral	JR4	Calcification
18	Proximal dissection	RCA	Femoral	SAL1	CTO

AL, Amplatz left; CTO, chronic total obstruction; EBU, extra backup; JL, Judkin left; JR, Judkin right; LAD, left anterior descending artery; LCX, left circumflex artery; RCA, right coronary artery; SAL, short-tip Amplatz left; SCR, Shepherd Crook right; VL, Voda left.
* Procedure succeeded using other technique later.

of our cases [110/136 (80.9%)], we initially used high-support guiding catheters (AL, SCR, EBU, XB, or VL), however we still required an extra extension catheter to increase support. In two previous reviews,[1,2] Judkin catheters were most often chosen as the guiding catheter (49% and 100%), however we used Judkin catheters in only 16% of our cases.

We analyzed all of the procedural details of our eighteen failures, and found that they may have been only partially related to an insufficient increase in support for device delivery (Table 3). Moreover, vessel preparation before device delivery and recognizing that an extension catheter was required early enough were equally important. With our experience of complex PCIs, we examined our failures and realized that in such difficult cases, it maybe more important to consider the mode of vessel preparation, such assize-tailored atherectomy or cutting balloon angioplasty, rather than continually increasing vessel support. Using an extension catheter before adequate vessel preparation may cause proximal- or target-vessel dissection, which will probably then preclude performing subsequent atherectomy.

Our univariate analysis showed that only "lesions with a proximal stent" significantly ($p = 0.024$) affected the procedure failure rate; however, that was not compatible with our experience. We believed that the coexistence of two or more factors was responsible rather than just a single factor, and this hypothesis was also closer to our clinical experience in complex cases. Therefore, we determined six factors that appeared to affect the success of using extension catheters from our experience: 1) long lesions (> 30 mm), 2) tortuosity, 3) calcification, 4) CTO, 5) a history of interventions, and 6) previously deployed proximal stents. The procedure failure rate was 5.88% when there were < 2 coexisting factors, but when there were ≥ 3 factors, the failure rate was significantly higher {> 25% [odds ratio (OR) 5.47, (95% confidence interval (CI) 1.82-16.47)]}. The discrepancy remained significant in a multivariate regression analysis adjusted for sex, comorbidities, and access site (Table 4).

Figure 3 shows an illustrated sequence of the steps required to manipulate a GuideLiner extension catheter,

Table 4. Multivariate regression analysis for failure prediction*

Variables	OR	95% CI	p	Variables	OR	95% CI	p
Gender (M)	3.257	0.38-28.24	.284	Gender (M)	4.763	0.55-41.07	.156
Hypertension	.528	0.14-2.04	.355	Hypertension	.527	0.14-1.95	.336
Diabetes mellitus	.402	0.12-1.31	.131	Diabetes mellitus	.364	0.11-1.17	.090
Hyperlipidemia	1.353	0.42-4.33	.611	Hyperlipidemia	1.403	0.43-4.56	.574
End stage renal disease	1.001	0.24-4.14	.998	End stage renal disease	1.344	0.34-5.25	.671
Radial access	.598	0.14-2.59	.492	Radial access	.669	0.16-2.89	.590
Calcification	1.533	0.46-5.15	.489				
Chronic total obstruction	3.520	0.90-13.79	.071				
Proximal stent	5.066	1.05-24.40	.043	More than 3 unfavorable factors#	7.079	2.14-23.42	.001
Previous intervention	1.912	0.58-6.30	.287				
Long lesion (> 30 mm)	1.614	0.50-5.26	.427				
Tortuous	2.205	0.57-8.61	.255				

* Dependent variable: procedure failure. # Out from six factors listed left side: calcification, chronic total occlusion, proximal stent, previous intervention, long lesion, and tortuous. CI, confidence interval; OR, odds ratio.

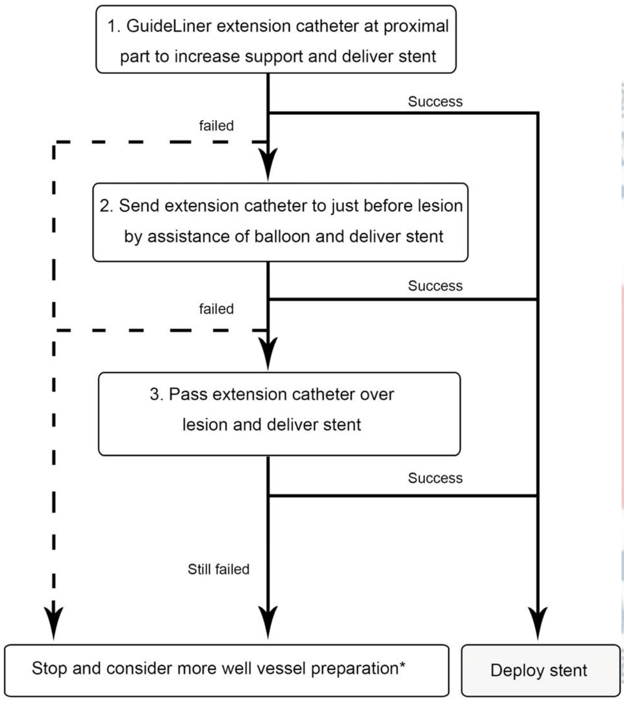

Figure 3. *Model for using the GuideLiner extension catheter in sequences:*
Step 1. *In a general case, short protrusion of the GuideLiner extension catheter and stent delivery. Advantage: Rapid manipulation, prevent proximal stent longitudinal deformation; Disadvantage: Offers least increased support.*
Step 2. *If Step 1 fails, a balloon can be used for a better coaxial, distal anchor to increase support, and then deliver the extension catheter to the spot just before the lesion. Advantages: Stronger support; Disadvantages: May cause jailed flow, proximal stent longitudinal deformation, or proximal vessel dissection, and may require extra time to change the device.*
Step 3. *In difficult cases, the extension catheter may have to be sent over the lesion using a balloon and bypassing the stent. Advantages: It is a direct passing device within the extension catheter with strongest support; Disadvantages: It poses a high risk of causing target lesion dissection or perforation, it requires more time for manipulation, and increases jailed flow time.*
** Such as size-tailored atherectomy or cutting balloon.*

and Figure 4 illustrates how we used this in two of our cases. We want to emphasize that it is not necessary to follow each step in-sequence, but rather to realize that each step which increases system support also increases the risk of dangerous complications.

Complications

The most concerning complication caused by using an extension catheter is proximal vessel dissection, which is induced by inserting the catheter too deeply. However, we found a low dissection rate of 5.1% (7/136), and many previous studies have reported a lower mean dissection rate [3/214, (1.4%)],[1,2,7-9] including one study in which the mean depth of GuideLiner catheter insertion was 30.3 mm.[2]

The second most concerning complication is a "transitional zone" problem. Stents can become deformed or dislodged when they are passed through the cylinder portion of the GuideLiner,[6,7] and one stent was dislodged in the transitional zone in the present study. The Heartrail ST-01 does not have this problem because of its over-the-wire design, and the newly designed transitional zone of the GuideLiner V3, with a tapering half-pipe channel, also helps prevent this problem.

In the present study, there were no cases of catheter insertion causing extension catheter-induced proximal longitudinal stent deformation (LSD). Arnous et al.[6] reported a significant odds ratio (22.09; p = 0.0001) of LSD when using a GuideLiner. Other rare complications include dislodgment of the GuideLiner catheter cylinder portion,[5,6] air embolism,[11] and forceful injection-in-

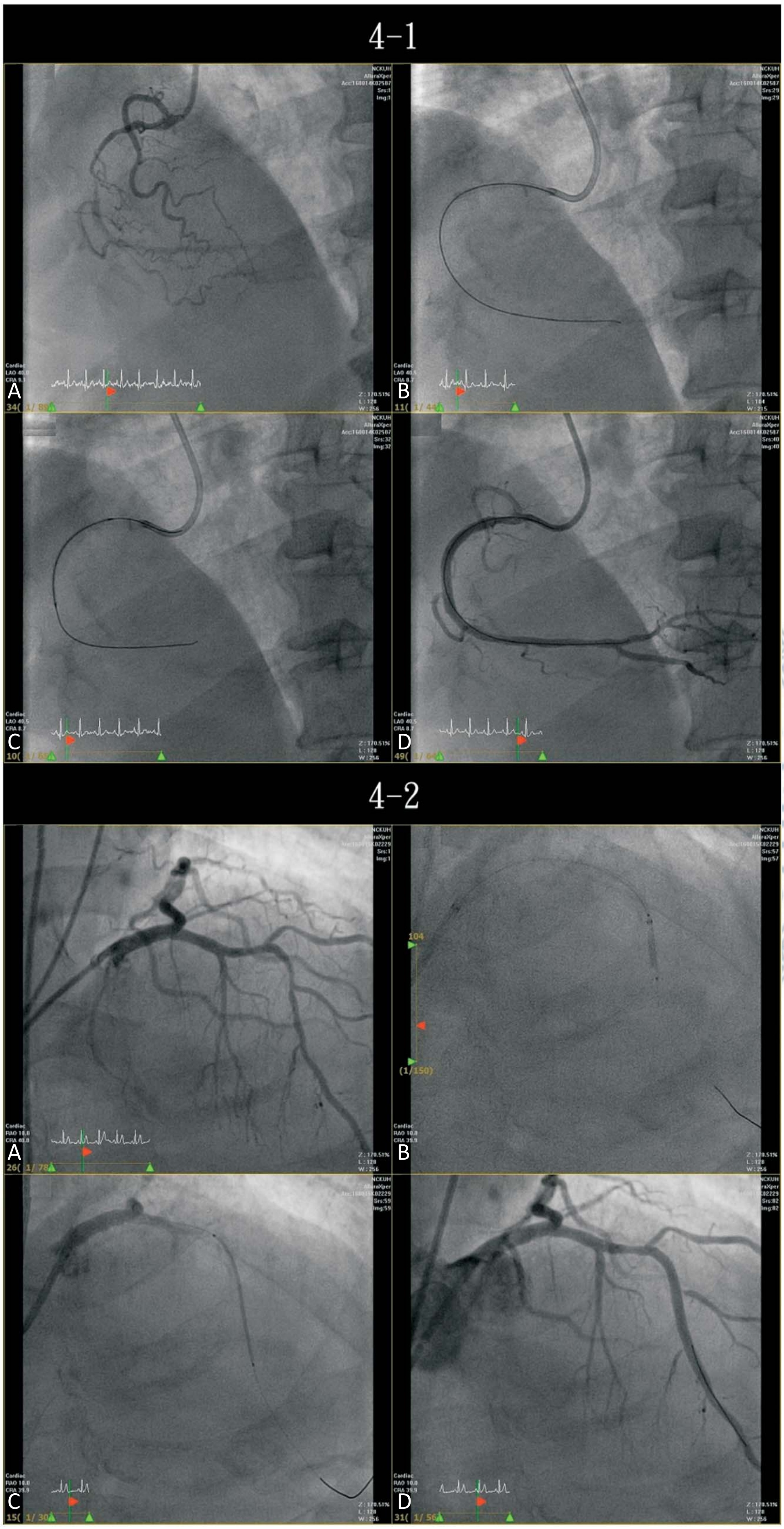

Figure 4. *Demonstration of intervention with the use of an extension catheter.*
4-1. *(A) Intervention for right coronary artery (RCA) chronic total occlusion (CTO), with a high support short-tip Amplatz (SAL) 0.75 guiding catheter. The stent could notreach the target site because of calcification and long lesion length; (B) AnST-01 extension catheter further advanced over the middle of the target lesion; (C) The stent was successfully delivered and deployed; (D) Final angiogram.*
4-2. *(A) Intervention for calcified left anterior artery (LAD) with a sharp angle before the long target lesion, hence the stent could not reach the target site; (B) The GuideLiner extension catheter was advanced over the major target lesion with the assistance of a balloon (advanced while deflating the balloon); (C) The stent was successfully delivered and deployed; (D) Final angiogram.*

duced GuideLiner ejection that caused left main dissection.[12]

Choosing between an extension catheter and a balloon anchor

A previous study[12] reported that, compared with conventional buddy-wire and balloon-anchoring techniques, the extension catheter can more effectively increase back-up support and facilitate the intervention.[13] This is consistent with out findings, in that sixty-nine cases that used a buddy-wire failed, but sixty-two of these cases were successful when an extension catheter was used. In addition, twenty-nine cases that used balloon-anchoring failed, but twenty-three of these cases succeeded when an extension catheter was used. Using an extension catheter therefore seems to be an effective bail-out technique for cases of anchor failure.

Choosing between a Heartrail ST-01 and different sizes of GuideLiner catheters

Before the development of the GuideLiner 5.5-Fr catheter, the Heartrail ST-01 catheter had the smallest diameter and was more favorable for deep-seated insertions. Furthermore, it was not associated with any transitional zone problems, as described in the complications subsection above. However, because of its over-the-wire design, catheter insertion took more manipulation time. Moreover, the catheter length needed careful consideration: the GuideLiner 5.5-Fr was 120 cm long, however a coronary guiding catheter is normally 90-100 cm long.

The 3rd-generation of the GuideLiner, the GuideLiner V3 catheter, introduced multiple size choices and a monorail design, and therefore it became more popular than the Heartrail ST-01 catheter, if price was not a consideration. In general, the larger GuideLiner catheter provides better support for delivering devices. Sometimes, however, when a more deep-seated insertion is required for better support, the 5.5-Fr size might be safer, especially for vessels with a proximal stent or with orifice lesions where severe dissection may occur. In the twelve cases in our study in which we used the 5.5-Fr GuideLiner, there were no complications. If a larger GuideLiner catheter is needed, the compatibility between one or two wires, balloons, or stents should be carefully considered (see Chan[1] for a detailed discussion).

Strengths of this study

Compared with previous studies, the advantages of this study are that it includes more cases and more complex interventions, that truly reflect daily practice.

Limitations

The main limitation of this study is its retrospective design, and many procedural details were collected by reviewing angiograms. Some of the information, e.g., the maximal depth of extension-catheter insertion, may have been lost because it was neither recorded nor stored during the procedures. The second limitation is that several different operators participated in this study. Different operators have different procedural habits such as catheter selection, timing of the use of a catheter, and familiarity with the available devices. However, this limitation may also be regarded as truly reflecting general practice.

CONCLUSIONS

Using an extension catheter to increase support and to facilitate challenging complex coronary interventions has a high success rate and a low complication rate. We successfully dealt with the complications using endovascular interventions.

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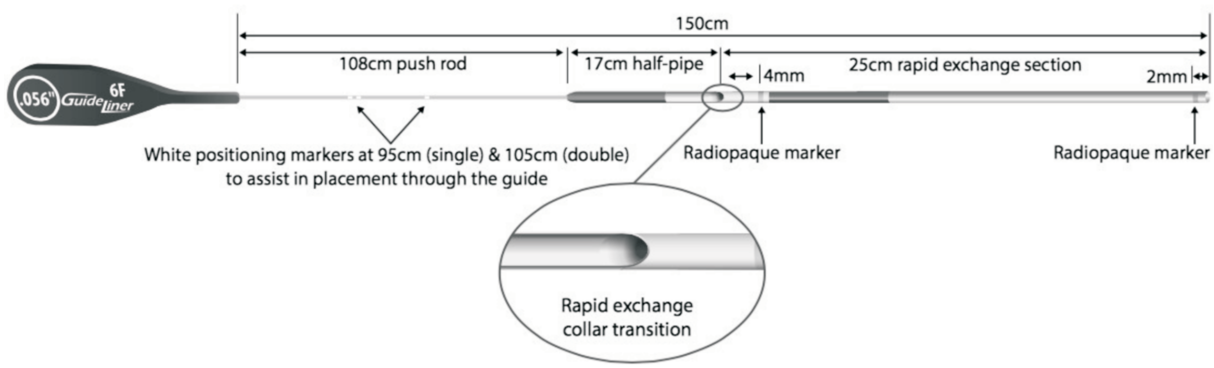
SUPPLEMENT

GuideLiner V3 Ordering Specifications*

Model	Size	Required Guide Catheter I .D.	GuideLiner I.D.	Rapid Exchange Length	Working Length
5570	5.5F	6F I.D. ≥0.066" (1.68mm)	0.051" (1.30mm)	25cm	150cm
5571	6F	6F I.D. ≥0.070" (1.78mm)	0.056" (1.42mm)	25cm	150cm
5572	7F	7F I.D. ≥0.078" (1.98mm)	0.062" (1.57mm)	25cm	150cm
5573	8F	8F I.D. ≥0.088" (2.24mm)	0.071" (1.80mm)	25cm	150cm

*Packaged in quantities of 1 unit per box.

GuideLiner V3 Dimensions



Supplementary Figure 1. *GuideLiner catheter design and profiles. The third generation increased the size of a 17-cm half-pipe design to facilitate device entering.*