

The First Clinical Experience With a Novel Catheter for Collateral Channel Tracking in Retrograde Approach for Chronic Coronary Total Occlusions

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Objectives The aim of this study was to report the initial experience with a novel catheter in the retrograde approach for chronic total occlusion (CTO).

Background Although the use of the retrograde approach in percutaneous coronary intervention for CTO has been established, some procedural difficulties remain.

Methods A novel over-the-wire catheter (channel dilator) specifically designed for the retrograde approach has been developed for the treatment of CTO. The channel dilator was used in 93 CTO lesions after successful wiring of collateral channels using the retrograde approach.

Results Successful channel crossing of the catheter was achieved in 90 of the lesions (96.8%), and the channel dilator successfully advanced into the occlusion reversely during retrograde wiring in 85 lesions (94.4%). Of the 75 lesions with successful advancement of the retrograde wire into the proximal true lumen, the entire occlusion was crossed retrograde with the channel dilator in 63 lesions (84.0%). To evaluate the feasibility of the catheter, 93 CTO lesions in the preceding period were compared. Procedure and fluoroscopy time tended to be lower in the study group than in the control group. The success of the retrograde procedure was significantly higher in the study group than in the control group (98.9% vs. 92.5%, $p = 0.030$).

Conclusions The channel dilator may facilitate the conventional retrograde approach with a high level of success. (J Am Coll Cardiol Intv 2010;3:165–71) © 2010 by the American College of Cardiology Foundation

Recanalization of chronic total occlusion (CTO) by percutaneous coronary intervention (PCI) has been widely attempted since the mid-1990s as the result of technical improvements and introduction of available devices (1–5). One of the most recent advancements related to the CTO-PCI was the introduction of the retrograde approach. The first report of PCI using the retrograde approach was described in 1990 (6). However, the investigators used only saphenous vein grafts for the treatment of nonoccluded lesions in native coronary arteries in that study. Since then, the retrograde approach has been considered an alternative method for treating CTO, especially among Japanese interventional cardiologists, despite its indication being limited to lesions with large epicardial collateral where saphenous vein grafts can be used. In 2005, the septal channel dilation technique (7) and controlled antegrade and retrograde subintimal tracking (CART) technique (8) were developed to enhance advantages of the retrograde approach. The former contributed to expand its indications whereas the latter enhanced its credibility. The CART technique was developed to create subintimal dissection with limited extension only at the site of CTO (9). These 2 techniques

Abbreviations and Acronyms

CART = controlled antegrade and retrograde subintimal tracking

CTO = chronic total occlusion

PCI = percutaneous coronary intervention

have improved procedural success rates and eventually established the basis of the current technique used of the retrograde approach. However, some procedural difficulties still remain. For example, the septal dilation technique always carries the risk of septal injury. The CART technique requires retrograde balloon access into the occlusion; however, complexities of the anatomy often prevent the device from crossing even after dilation of the septal channel. In addition, long procedural times always carry the risk of donor artery trouble, such as thrombus formation. To overcome these difficulties and facilitate the procedure, we developed a novel catheter for collateral channel tracking during the retrograde approach. The aim of this study was to report the initial experience with the novel catheter in treating CTO.

Materials and Methods

The Corsair microcatheter (Asahi Intecc Co. Ltd, Aichi, Japan) was originally developed as a collateral channel dilator to facilitate retrograde approaches for CTO-PCI. This is an over-the-wire hybrid catheter that has features of a microcatheter and a support catheter. Figures 1 and 2 show a picture and the design of the Corsair. The shaft consists of 8 thin wires wound with 2 larger wires. This spiral structure allows the bidirectional rotation to be transmitted to the distal shaft for crossing small tortuous collateral channels. The working shaft length is 150 cm and

the distal part of the catheter within 60-cm length is coated with hydrophilic polymer to provide lubricity. The braided portion of the catheter is covered with polyamide elastomer, and the inner lumen of the shaft (excluding the connector portion) is lined with a fluoropolymer layer to enable tip injections and facilitate movement of the guidewire. The tip contains tungsten powder and a marker that enhances the visibility of the catheter. The maximum outside diameter is 0.93 mm (2.8-F), and the inner diameter is 0.45 mm, which is suitable for a 0.014-inch guidewire.

The Corsair microcatheter was applied to patients in whom successful collateral channel tracking was achieved during the retrograde approach in CTO-PCI, without case selection and when it was available. The standard procedure was as follows. First, an attempt was made to advance the Corsair microcatheter through the channel without balloon dilation. If this was unsuccessful, the dilation technique was applied in septal channels. Second, the retrograde wiring into the occlusion was done using the Corsair microcatheter and the catheter was also advanced into the occlusion if necessary. Third, after a successful retrograde wire crossing or reverse CART procedure, the Corsair microcatheter was advanced through the entire occlusion if possible. Retrograde wire crossing implies crossing the entire occlusion using retrograde wire only (9–12). The reverse CART technique is a modification of the CART technique, in which antegrade balloon dilation creates a space that leads the retrograde wire toward the proximal true lumen (8,9). The kissing wire and knuckle wire techniques without balloon dilation are defined as bilateral wiring techniques (9,12).

Data were collected from 2 experienced CTO-PCI operators in whom the Corsair microcatheter was initially supplied for examination. The baseline and procedural-related characteristics, procedural success rate, and complications were compared with those of the control group. To eliminate the bias in other procedural techniques and devices, the control group included the same number of patients in whom successful collateral channel tracking was achieved by each operator just before introduction of the Corsair.

Q-wave myocardial infarction was diagnosed with the documentation of new pathological Q waves in 2 or more contiguous leads in an electrocardiogram associated with any elevation of creatine kinase-myocardial band. Non-Q-wave myocardial infarction was defined as the elevation of creatine kinase to more than twice the upper limit associated with any elevation of creatine kinase-myocardial band without the appearance of Q-waves. Written informed consent to the protocol approved by each institutional review board was obtained from all eligible patients.

Statistical methods. Continuous variables were expressed as the mean \pm SD. Variable categories were expressed as frequencies. Student *t* test or a nonparametric analysis using the Mann-Whitney *U* test was used for numerical comparisons between groups. The chi-square test or Fisher exact

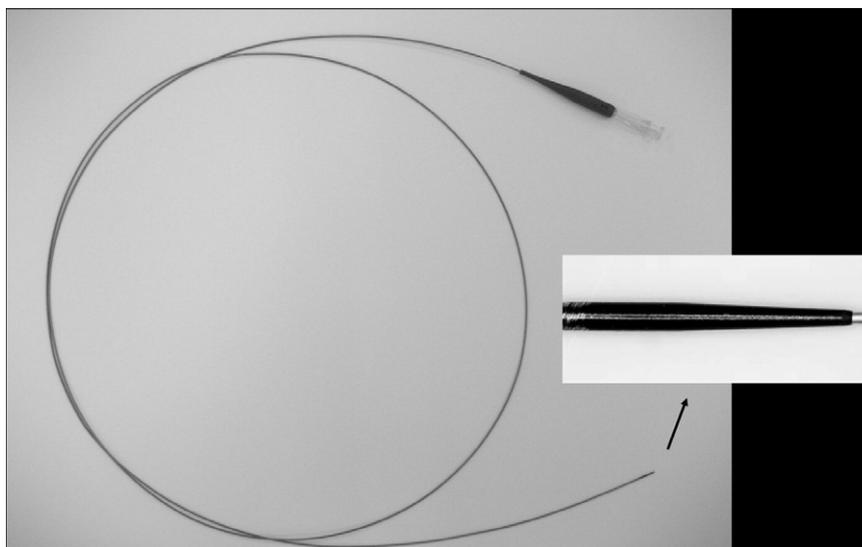


Figure 1. Whole Picture of the Corsair Catheter and Image of the Catheter Tip

A unique over-the-wire hybrid catheter has the features of a microcatheter and a support catheter.

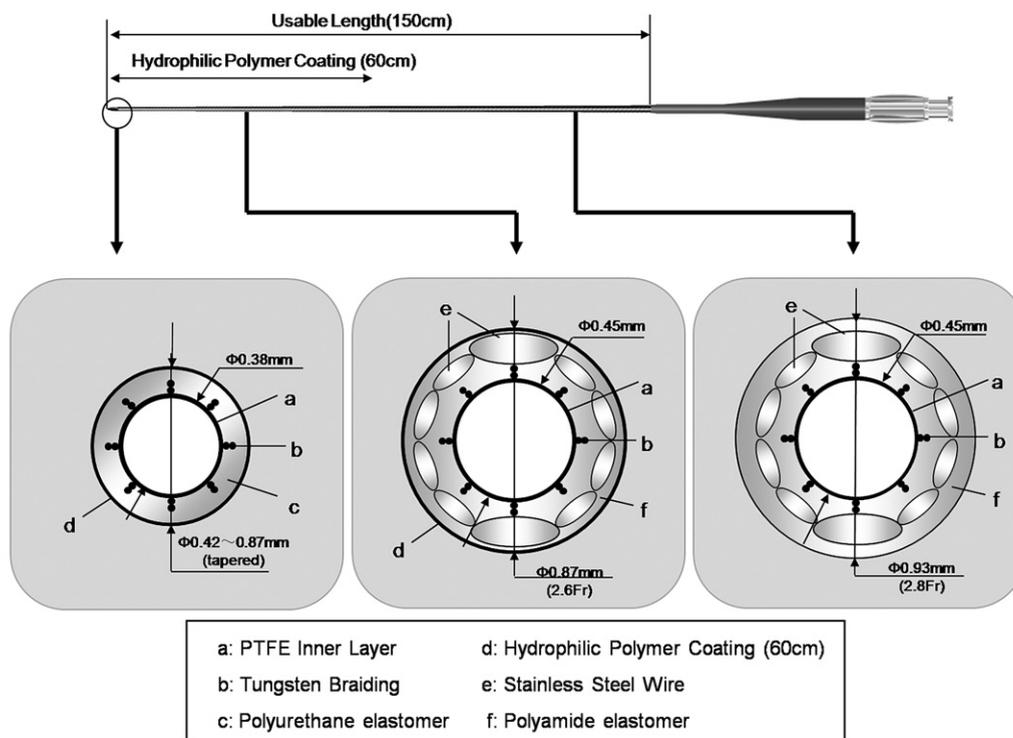


Figure 2. Structural Illustration of the Corsair Catheter

The shaft consists of 8 thinner wires wound with 2 larger ones. This unique spiral structure allows rotation to be transmitted to the distal shaft. PTFE = polytetrafluoroethylene.

test was used to compare variable categories expressed as frequencies. StatView version 4.11 (Abacus Concepts, Berkeley, California) was used for data analysis. Statistical significance was established at a p value of <0.05.

Results

The evaluation of the catheter began in September 2007 by 1 of the operators. The other operator started the evaluation in May 2008. Until September 2008, 180 CTO-PCIs were performed by these 2 operators, and the overall success rate during this period was in 176 of 180 CTO-PCIs (97.8%). The retrograde approach was attempted in 124 lesions (68.9%). Of these lesions, 80 lesions were reattempted cases and the remaining was initially considered to be difficult with the conventional antegrade approach only because of complex anatomy. In these attempted lesions, successful guidewire crossing of collateral channels was achieved in 114 lesions (91.9%). The Corsair microcatheter was used in 93 CTO lesions, depending on the availability of the catheter, and these lesions were included in this study. Ninety-three consecutive CTO lesions in which successful collateral channel crossing was achieved by the same operators, just before the Corsair microcatheter was introduced, were used as the control cohort.

In the Corsair group, successful channel crossing of the catheter was achieved in 90 lesions (96.8%). The Corsair microcatheter could not be advanced through 3 septal channels, and a conventional balloon dilation technique was successfully performed for them. The Corsair microcatheter was successfully advanced into the occlusion reversely during the retrograde wiring procedure in 85 of these 90 lesions (94.4%). In addition, the entire occlusion was crossed retrograde with the Corsair microcatheter in 63 of 75 lesions (84.0%) in which the retrograde wire crossing or reverse CART procedure was successful.

The baseline clinical and lesioned characteristics were similar between the 2 groups, as shown in Tables 1 and 2. Although no significant differences between groups were

Table 2. Baseline Lesion Characteristics

Variable	Corsair (n = 93)	Control (n = 93)	p Value
Target vessel			0.69
Right coronary artery	79.6% (74)	76.3% (71)	
Left anterior descending artery	16.1% (15)	19.4% (18)	
Left circumflex artery	3.2% (3)	4.3% (4)	
Left main trunk	1.1% (1)	0	
Reattempted	65.6% (61)	62.4% (58)	0.65
Calcified	60.2% (56)	55.9% (52)	0.55
Proximal tortuosity	32.3% (30)	31.2% (29)	0.87
Bending (≥45°)	29.0% (27)	25.8% (24)	0.62
Occlusion length, mm	32.4 ± 19.8	30.9 ± 18.1	0.64
Reference diameter, mm	3.00 ± 0.63	3.02 ± 0.59	0.87
Occlusive duration			0.62
Within 1 yr	8.6% (8)	10.8% (10)	
>1 yr or unknown	91.4% (85)	89.2% (83)	

observed, the epicardial collateral channel was more commonly used in the Corsair group (Table 3). As shown in Table 3, the selection of the guidewires for the occlusions has been changed between the 2 groups since the use of stiff wires was decreased in the Corsair group. Moreover, reverse CART technique was more frequently performed in the Corsair group because retrograde balloon access was not required. The fluoroscopic time and procedural time were shorter in the Corsair group than in the control group, but the difference was not statistically significant. However, the rate of retrograde procedural success was significantly higher in the Corsair group than in the control group (98.9% vs. 92.5%, p = 0.030). In 1 lesion from the Corsair group, the retrograde wire could not be advanced into the severely calcified occlusion. In 4 lesions from the control group, all catheters that were used failed to advance through the channel. Wire access into the occlusion was unsuccessful in 3 lesions from the control group.

In terms of procedural complications, no deaths, emergent bypass procedures, or Q-wave myocardial infarction were observed. Non-Q-wave myocardial infarction was observed in 4 (4.3%) patients in the Corsair group and in 5 (5.4%) patients in the control group. No major damage (such as channel rupture requiring implantation of a hemostatic coil or channel rupture untreated during the procedure causing a clinical event such as a tamponade) in the collateral channel requiring additional treatment was observed in either group. In 2 patients in the Corsair group, the tip of a catheter became trapped inside severely calcified occlusions, but it was successfully retrieved percutaneously without any complications. The first case occurred after the externalization of a 300-cm retrograde guidewire. A 1.5-mm balloon was antegrade advanced through the wire and dilated the trapped lesion. The tip was then released and retrieved by pushing with an antegrade microcatheter.

Table 1. Baseline Demographics of Patients

Variable	Corsair (n = 93)	Control (n = 93)	p Value
Men	86.0% (80)	84.9% (79)	0.76
Age, yrs	63 ± 9	62 ± 9	0.76
Previous MI	59.1% (55)	57.0% (53)	0.77
Previous CABG	10.8% (10)	9.7% (9)	0.81
Multivessel	69.9% (65)	67.7% (63)	0.75
Hypertension	59.1% (55)	60.2% (56)	0.88
Diabetes mellitus	37.6% (35)	38.7% (36)	0.88
Hyperlipidemia	57.0% (53)	54.8% (51)	0.77
Previous smoker	47.3% (44)	44.1% (41)	0.66

CABG = coronary arterial bypass grafting; MI = myocardial infarction.

Table 3. Procedural Results in Both Groups

Variable	Corsair	Control	p Value
Collateral channel used			0.18
Saphenous vein graft	2.2% (2)	7.5% (7)	
Epicardial channel	15.1% (14)	10.8% (10)	
Septal channel	82.8% (77)	81.7% (76)	
Wires used in collateral channel tracking			0.53
Fielder FC	80.6% (75)	79.6% (74)	
Fielder XT	16.1% (15)	19.4% (18)	
Whisper MS	3.2% (3)	1.1% (1)	
Stiff wires used for occlusion antegrade or retrograde*			0.0003
Fielder FC	14.0% (13)	4.3% (4)	
Fielder XT	6.5% (6)	1.1% (1)	
Pilot 200	10.8% (10)	4.3% (4)	
Miracle 3	17.2% (16)	16.1% (15)	
Miracle 6	1.1% (1)	3.2% (3)	
Miracle 12	26.9% (25)	57.0% (53)	
Confianza Pro 9	16.1% (15)	5.4% (5)	
Confianza Pro 12	7.5% (7)	8.6% (8)	
Retrograde wiring technique			<0.0001
Retrograde wire crossing	20.6% (19/92)	24.4% (21/86)	
Bilateral wiring alone	7.6% (7/92)	8.1% (7/86)	
CART	10.9% (10/92)	64.0% (55/86)	
Reverse CART	60.9% (56/92)	3.5% (3/86)	
Contrast dose, ml	258.8 ± 168.6	283.6 ± 158.0	0.38
Fluoroscopy time, min	60.1 ± 26.3	67.8 ± 29.1	0.087
Procedural time, min	135.6 ± 57.4	155.5 ± 65.0	0.078
Retrograde procedure success	98.9% (92/93)	92.5% (86/93)	0.030

*Confianza Pro 9, Confianza Pro 12, Fielder FC, Fielder XT, Miracle 3, Miracle 6, Miracle 12 (Asahi Intecc Co. Ltd, Aichi Japan). Pilot 200, Whisper MS (Abbott Vascular, Santa Clara, California).
 CART = controlled antegrade and retrograde subintimal tracking.

In the second case, the fractured tip was tangled around the retrograde guidewire, and thereby it could be retrieved together with the wire. A typical example of the successful recanalization of a complex CTO lesion with a Corsair microcatheter is shown in Figure 3.

Discussion

Introduction of the septal dilation and CART techniques have increased the chances of using a retrograde approach in CTO-PCIs (7,8), but some difficulties remain. Septal channel dilation carries the risk of septal channel damage, and the conventional CART technique requires retrograde balloon access, which is sometimes difficult because of the complex CTO anatomy. Additionally, long procedural time always carries the risk of donor artery complications such as thrombus formation. To improve the current retrograde approach technique, a novel catheter named Corsair was introduced. The present study demonstrated the safety and effectiveness of the Corsair microcatheter. Overall, 92 of 93 CTO lesions in the Corsair group were successfully recana-

lized using a retrograde procedure without any major adverse events. A higher success rate was attributable to enhanced crossability in the collateral channel and improvements in backup guidewire support, which are prominent advantages of the Corsair microcatheter. Therefore, our initial experience with this catheter satisfied our primary objective of offering treatment options and modifying the current retrograde approach.

Alternative channels. We previously reported 2 septal collateral perforations in 21 lesions of septal dilation (7). In a European study, collateral perforation/hematoma occurred in 12 of 175 (6.9%) lesions using the retrograde approach (10). Furthermore, the latest study from our center, conducted in 157 consecutive patients who underwent retrograde CTO recanalization, found septal perforation in 6 of 157 (3.8%) patients (11). Therefore, septal perforation and hematoma are possible complications associated with septal dilation. However, channel dilation is not mandatory with the use of the Corsair microcatheter, thereby reducing the risk of channel injury. In our initial experience, no collateral channel damage was observed during the procedure. The avoidance of channel dilation offers the use of another alternative channel, which was less common in the pre-Corsair era. In the present study, the epicardial channel was used in 10.8% of the control group and in 15.1% of the Corsair group. Because the Corsair microcatheter eliminates the need for channel dilation, the epicardial channel more frequently becomes the candidate for collateral channel tracking in the retrograde approach.

Reverse CART technique and externalization of a 300-cm guidewire. Of the several available retrograde wiring techniques (12), the reverse CART technique has become the most commonly used technique in the Corsair era because retrograde balloon access is not required. Also the guidewire selection for CTO lesions has been significantly changed. In the Corsair era, use of a stiff guidewire is dispensable due to the improvement of retrograde wiring support. Furthermore, floppy guidewires are sometimes good enough to connect the antegrade and retrograde channels under the implementation of the reverse CART technique, which might allow the use of a larger balloon catheter to dilate proximal vessels. After successful use of the reverse CART technique, the retrograde wire can be exchanged to a 300-cm guidewire to facilitate the subsequent procedure, similar to the retrograde wire crossing technique. In the present study, the Corsair microcatheter frequently reached into the proximal true lumen after the successful application of these 2 techniques (84%). In this situation, the 300-cm guidewire can be advanced through the Corsair microcatheter to the antegrade guiding catheter, and the wire tip can then be grasped outside the patient's body. An antegrade balloon can

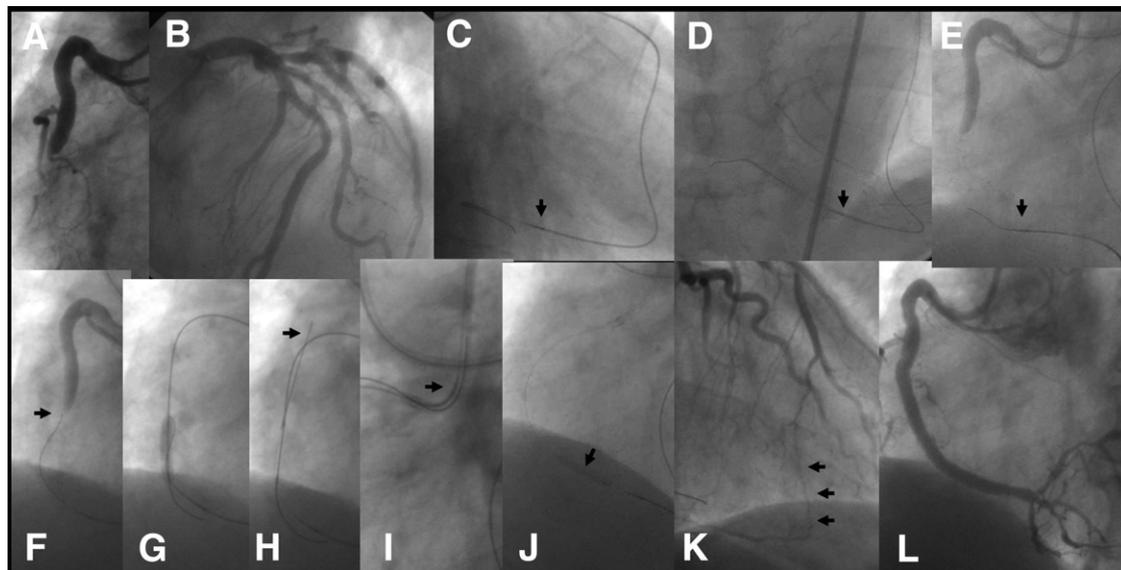


Figure 3. An Example of the Successful Recanalization of a Complex CTO Lesion With a Corsair Microcatheter

The patient was a 65-year-old man. He was suffering from angina because of chronic total occlusion (CTO) in the mid right coronary artery with previous percutaneous coronary intervention failure (A). There was no significant stenosis in the left coronary artery sending good collateral up to the distal right coronary artery bifurcation (B). After successful wire crossing through a septal channel, the Corsair was easily advanced into posterior descending artery without any dilation (C, arrow). The Corsair supported the manipulation of a retrograde wire (Miracle 3, Asahi Intecc) into the occlusion (D, arrow). During the retrograde wiring, the Corsair could be also advanced into the occlusion (E, arrow). After the retrograde wire reached the proximal end of CTO (F, arrow), the antegrade balloon (3.0-mm) dilation was conducted (G). Then the retrograde wire could be advanced into the proximal true lumen (H, arrow), which was the reverse controlled antegrade and retrograde subintimal tracking technique. After trapping the wire inside the antegrade guiding catheter using 3.0-mm balloon, the Corsair could also be advanced into the guiding catheter (I, arrow). Through the Corsair, the wire was successfully switched to a 300-cm wire (Fielder FC, Asahi Intecc) up to the proximal end of the antegrade guiding catheter (externalization), so that subsequent antegrade ballooning (2.5-mm) was conducted through this reversed 300-cm wire (J, arrow). Then the wire was changed to a conventional wire in the antegrade manner. There was no injury in the septal channel after removal of Corsair (K, arrows). Final angiogram after stenting showed an optimal result (L).

be advanced through the distal end of the 300-cm wire for the subsequent procedure in the antegrade manner. The advent of the Corsair microcatheter, therefore, has led to the new era of retrograde CTO-PCI.

Benefits of the novel approach. Besides the improvement in the success rate of retrograde procedures, we observed other advantages using the Corsair microcatheter to facilitate the retrograde procedure in the present study. Although there were no significant differences in contrast dose, fluoroscopy time, and procedural time between the groups in the present study, the outcomes were better in the Corsair group, even though the same operators performed the procedures. Elimination of the need for channel dilation and improvements in both the crossability of the collateral channel and in backup support for retrograde wiring may help decrease the time required for the procedure. Because antegrade dye injection should be avoided during the reverse CART technique to prevent enlargement of the dissection created by the antegrade balloon catheter, the change in retrograde wiring techniques because of the introduction of the Corsair microcatheter may help to reduce the amount of contrast dose needed.

Precautions for Corsair microcatheter usage. Despite the advantages of the Corsair microcatheter described earlier, this catheter has some limitations. First, the Corsair microcatheter needs to be carefully manipulated when it is inserted and removed. The accumulation of too much torque in 1 direction may destroy the catheter itself. Thus, if the catheter becomes stuck, particularly in severely calcified occlusions, the operator should stop turning the catheter in the same direction and use an alternative strategy without the Corsair microcatheter. Second, as previously mentioned, antegrade injection of contrast medium during the reverse CART technique should be avoided. Instead, the use of intravascular ultrasound is recommended when it is necessary to check the position of the wire and/or the vessel size for balloon dilation and to determine the position for stent implantation. Hence, no single device is perfectly suited to performing CTO-PCIs.

Despite the potential advantages of the Corsair usage, retrograde approach should be performed only when the initial attempt of antegrade approach is failed or antegrade approach seems to be difficult due to severe or complex lesion morphology.

Conclusions

The new Corsair microcatheter facilitates the current retrograde approach with a high level of success. Further study is warranted to confirm the effectiveness of this novel approach.

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Key Words: percutaneous coronary intervention ■ chronic total occlusion ■ retrograde approach ■ collateral channel tracking.