Basic Science Review

New Method to Increase a Backup Support of a 6 French Guiding Coronary Catheter

Saeko Takahashi,^{1*} MD, Shigeru Saito,¹ MD, Shinji Tanaka,¹ MD, Yusuke Miyashita,¹ MD, Takaaki Shiono,¹ MD, Fumio Arai,¹ MD, Hiroshi Domae,¹ MD, Shutaro Satake,¹ MD, and Takenari Itoh,² PhD

A 6 Fr guiding catheter is commonly used in the percutaneous coronary intervention (PCI). However, one of the limitations of the 6 Fr guiding catheter is its weak backup support compared to a 7 or an 8 Fr guiding catheter. In this article, we present a new system for PCI called the five-in-six system. Between March 2003 and September 2003, this system was tried on eight chronic total occlusion cases. The advantage of the five-in-six system is that it increases backup support of a 6 Fr guiding catheter. *Catheter Cardiovasc Interv 2004;63:452–456.* © 2004 Wiley-Liss, Inc.

Key words: five-in-six system; backup support; 6 Fr guiding catheter; chronic total occlusion

INTRODUCTION

Currently, a 6 Fr guiding catheter is commonly used in percutaneous coronary intervention (PCI), since its use can decrease access site complication, enable early ambulation, and reduce the consumption of the contrast dye [1–4]. Major limitations of a 6 Fr guiding catheter are the inner lumen is not big enough to accommodate bulky atherectomy devices, and its backup support is not strong compared to a 7 or an 8 Fr catheter. In this report, we demonstrate a new technique for PCI called the fivein-six system, which increases a backup support of a 6 Fr guiding catheter.

MATERIALS AND METHODS

The Five-in-Six System

The five-in-six system is a method of inserting a 5 Fr guiding catheter (Heartrail, Terumo, Japan) into a 6 Fr guiding catheter to increase backup support. As we insert the 5 Fr inner guiding catheter into the target artery through the outer 6 Fr guiding catheter, stronger backup support can be generated (Fig. 1A).

This 5 Fr Heartrail straight guiding catheter is 120 cm in length, whereas the 6 Fr guiding catheter is 100 cm. The 5 Fr Heartrail catheter has a very soft 13 cm end portion. This soft end portion can easily negotiate the tortuous coronary artery with the minimal damage and then it can be inserted more deeply into the artery. The input luman of the 5 Fr Heartrail catheter is 0.050' in

diameter; it can accept normal balloons or stent delivery systems less than 4.0 mm in diameter. The inner lumen of the outer 6 Fr catheter needs to be more than 0.071' in diameter to accommodate the 5 Fr Heartrail catheter; Launcher (Medtronic), Heartrail, and Radiguide (Terumo) guiding catheters can meet this inner lumen diameter.

In Vitro Experiments

We measured the backup support of this five-in-six system in vitro using an experimental system. The artery model had three curves simulating tortuous coronary arteries. It was filled with water that was kept at 37° C (Fig. 1B). A guiding catheter was engaged into the ostium of the artery model. Then a rapid-exchange balloon catheter (Ryujin 2.5 × 20 mm; Terumo) was pushed into

¹Division of Cardiology and Catheterization Laboratories, Heart Center of ShonanKamakura General Hospital, Kamakura City, Japan ²Research and Development Section of Ashitaka Factory, Terumo Corporation, Fujinomiya City, Japan

*Correspondence to: Dr. Saeko Takahashi, Division of Cardiology and Catheterization Laboratories, Heart Center of ShonanKamakura General Hospital, 1202-1 Yamazaki, Kamakura City, 247-8533, Japan. E-mail: saekot@wa2.so-net.ne.jp

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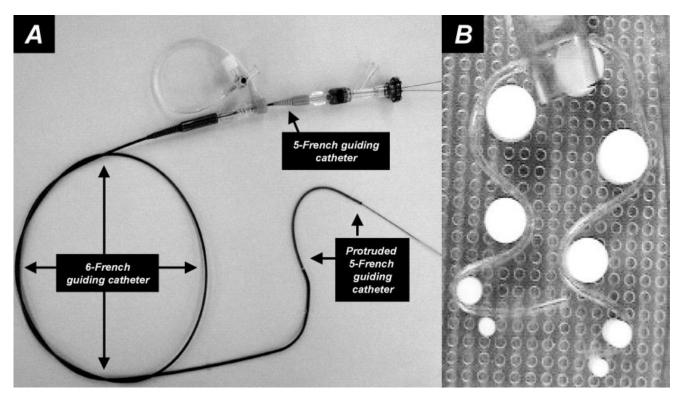


Fig. 1. A: The whole five-in-six system. B: A coronary artery model.

the artery model along a regular PCI guidewire (BMW, Guidant) at a constant speed of 5 mm/sec by a pushable gauge machine (Fig. 2A). The pushable gauge machine can measure a resistance of a balloon catheter. The maximal backup support of this experimental system was defined as the resistance of a balloon catheter when the guiding catheter could not keep a coaxial engagement to the artery model and the catheter was pushed away. If the guiding catheter has a stronger backup support, it can stand up to the higher resistance of a balloon catheter.

In the five-in-six system, the backup support was measured while protruding the 5 Fr catheter into the artery model out of the outer 6 Fr catheter by 0, 5, 10, and 15 mm (Fig. 2B). Then the maximal backup support was measured in the 6, 7, and 8 Fr guiding catheters (Heartrail) alone as well as in the five-in-six system. Each measurement was repeated 10 times. Data were expressed as mean \pm standard deviations. Comparison of continuous variables between equivalent groups was calculated by ANOVA. *P* value ≥ 0.05 was considered statistically insignificant.

Switching to Five-in-Six System During PCI

When we could not cross a lesion by a balloon catheter or a stent delivery system in the regular 6 Fr system, we switched to the five-in-six system. First, the balloon catheter or the stent delivery system was removed from the 6 Fr guiding catheter, while the PCI guidewire and the 6 Fr guiding catheter remained in situ. Second, the Y-connector that was connected to the 6 Fr guiding catheter was also removed (Fig. 3A). Third, a 5 Fr guiding catheter was inserted along the PCI guidewire to the 6 Fr guiding catheter (Fig. 3B). At this point, the 5 Fr guiding catheter should not protrude out of the tip of the 6 Fr guiding catheter (Fig. 3C). Finally, we connected the Y-connector with the 5 Fr guiding catheter and devices were delivered through it. The side tube of the Y-connector of the 5 Fr guiding catheter was connected with the pressure and contrast dye lines (Fig. 3D). Before we advanced the 5 Fr catheter into the target artery, we first put a balloon catheter near the target lesion in the artery (Fig. 3E). Keeping a slight tension on the balloon catheter, we pushed the 5 Fr guiding catheter out slowly in order to avoid the possible injury to the coronary artery by the tip of the 5 Fr catheter (Fig. 3F).

RESULTS

In Vitro Results

Figure 4 shows in vitro results of the backup support. Only inserting the 5 Fr guiding catheter into the 6 Fr catheter increased the backup support from 63.1 ± 2.1 of a 6 Fr guiding catheter alone to 72.0 ± 3.7 gram force (af: P < 0.01). When the inner catheter was protruded by

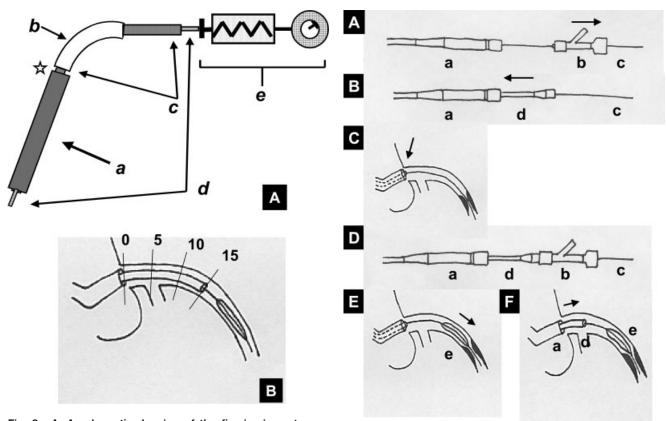


Fig. 2. A: A schematic drawing of the five-in-six system. a denotes a model coronary artery; b, a 6 Fr outer guiding catheter; c, a 5 Fr inner guiding catheter; d, a balloon catheter; e, a pushable gauge machine. Star symbol: the maximal backup support of this experimental system was defined as the resistance of a balloon catheter when a 6 Fr guiding catheter could not keep a coaxial engagement to the artery model. B: The backup support was measured while protruding a 5 Fr catheter into the artery model out of a 6 Fr catheter by 0, 5, 10, and 15 mm.

5 mm into the artery, its backup support was 106.5 ± 3.9 gf, which was stronger than 96.7 ± 2.6 gf generated by a 7 Fr guiding catheter alone (P < 0.01). The five-in-six system can generate a stronger backup support by a longer insertion of the 5 Fr catheter into the artery model.

CASE REPORT

Between March 2003 and September 2003, the fivein-six system was tried on eight chronic total occlusion (CTO) cases (Table I). In seven out of these eight cases, the balloon catheter could cross the CTO lesions with the use of the five-in-six system. The following case is one of the successful five-in-six system procedures.

A 73-year-old male with a previous history of a stenting of the mid right coronary artery (RCA) was referred for a coronary angiography because of shortness of breath for the past several months. His coronary angiography showed the chronic total occlusion at the distal

Fig. 3. A: A Y-connector is removed from the 6 Fr guiding catheter. B: A 5 Fr guiding catheter is inserted along the PCI guidewire to the 6 Fr guiding catheter. C: The 5 Fr guiding catheter should not protrude out of the tip of the 6 Fr guiding catheter. D: The Y-connector is connected with the 5 Fr guiding catheter. E: A balloon catheter is put near the target lesion. F: The 5 Fr guiding catheter; b, a Y-connector; c, a PCI guidewire; d, a 5 Fr guiding catheter; e, a balloon catheter.

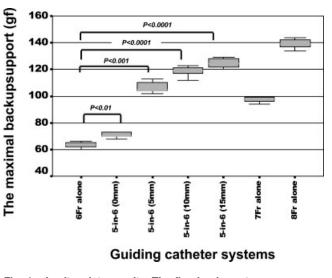


Fig. 4. In vitro data results. The five-in-six system can generate a stronger backup support by a longer insertion of the 5 Fr

Case			Target	Uncrossed			Puncture				Duration	
no.	Age	Sex	vessel	balloon size	6 Fr guiding catheter	PCI guidewire	site	DM	HL	ΗT	of CTO	Result
1	73	М	RCA	2.5×20	Amplatz 1.0	Cross-It 100	Radial artery	+	+	+	< 10 months	Success
2	55	Μ	LAD	1.5×20	Short tip left Judkins 4.0	Conquest Pro	Radial artery	+	+	+	3 years	Success
3	56	F	RCA	1.5×20	Amplatz 1.0	Conquest Pro	Radial artery	_	+	+	4 years	Success
4	64	Μ	RCA	1.5×20	Amplatz 1.0	Whisper LS	Radial artery	_	_	+	1 year	Success
5	75	F	LAD	$1.2.5 \times 15$	Short tip left Judkins 3.5	Cross-It 100	Radial artery	_	+	+	4 months	Success
6	65	Μ	LAD	1.5×20	Extra backup	Magic FA	Brachial artery	+	$^+$	+	3 months	Success
7	77	Μ	LCx	1.5 imes 15	Amplatz 1.0	Miracle 12	Radial artery	+	_	+	3 months	Failed
8	70	Μ	RCA	1.5×15	Short tip Amplatz 1.0	Conquest Pro	Radial artery	+	+	+	Unknown	Success

TABLE I. Patient Characteristics

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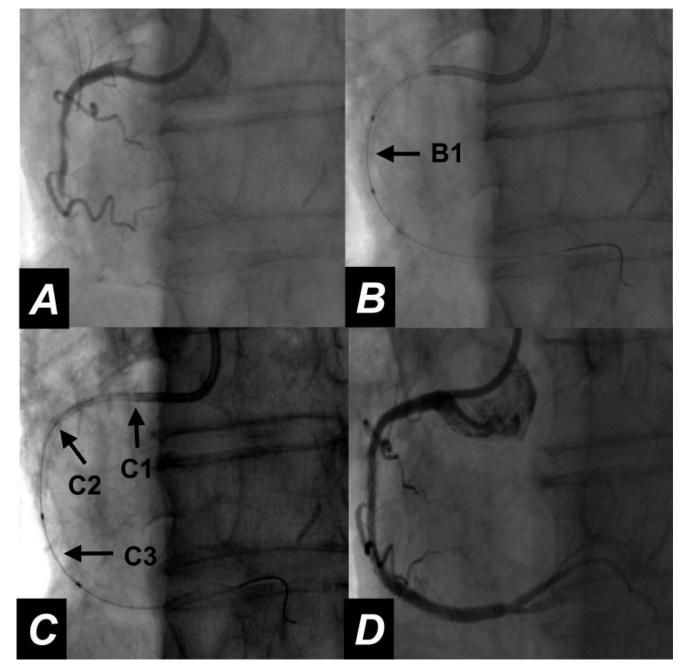


Fig. 5. A: The distal edge of the stent in RCA was totally occluded with bridging collaterals. B: A balloon catheter could not pass the CTO lesion. B1 denotes a balloon catheter. C: A balloon catheter could cross the lesion by using five-in-six system. C1 denotes the tip of the 6 Fr guiding catheter; C2, the tip of the 5 Fr guiding catheter; C3, the balloon catheter, which could cross the lesion.

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edge of the previous stent with bridging collaterals (Fig. 5A). We inserted a 6 Fr AL-1 guiding catheter (Heartrail) into RCA via the right radial artery. A PCI guidewire (Cross-It 100; Guidant) successfully crossed the lesion. However, a 2.5×20 mm balloon (Ryujin; Terumo) could not pass the lesion (Fig. 5B). The guiding catheter showed a good coaxial engagement into the coronary artery, but its backup support was inadequate. Then we switched to the five-in-six system. While inserting the 5 Fr catheter into RCA by about 15 mm, the same balloon could successfully pass and dilate the total occlusion (Fig. 5C). Finally, a 3.0×28 mm stent (Penta; Guidant) was successfully placed in the lesion (Fig. 5D).

DISCUSSION

DOCKET

In this article, we demonstrate a new approach for the coronary interventions to increase the backup support of a 6 Fr guiding catheter. A strong backup support of a guiding catheter is essential in achieving a successful result in PCI [3,4]. In vitro experimental model showed that the five-in-six system could generate a better backup support compared to a 6 or even a 7 Fr guiding catheter alone. In seven of our eight clinical cases, the use of this technique created a stronger backup support, then we could cross the lesions by balloon catheters successfully. It clearly shows that this system is effective at increasing the backup support of a 6 Fr guiding catheter.

Due to an improvement of a guidewire technology, the success rate of PCI for CTO lesions is improving [5]. However, it is still a big problem that a balloon catheter sometimes cannot pass through the CTO lesion after a PCI guidewire has successfully passed through. Several techniques have been proposed to create a better backup support. A deep engagement of the guiding catheter into the coronary artery and a buddy wire technique are already well known for increasing the backup support [6–8]. Recently, a new technique, the Anchor balloon technique, was reported by Fujita et al. [9]. In our cases, we could not use these techniques because of their complicated CTO lesions.

Changing a guiding catheter is another option to get better backup support. If we start PCI with a 6 Fr guiding catheter, we can change to a 7 or an 8 Fr guiding catheter, which can generate better backup support [3,4]. Amplatz or Voda guiding catheters are very well known because their designs give strong backup support [10–12]. However, when we try to exchange the guiding catheters, there is a significant risk of losing the position of the PCI guidewire, which has already crossed the lesion. In one patient who had a severely calcified CTO lesion, this system could not produce enough backup support to cross the lesion by a balloon catheter. However, we can conclude that this five-in-six system will work in many clinical situations when we need a stronger backup support of a 6 Fr guiding catheter.

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