The Role of the Revived Directional Coronary Atherectomy (DCA)

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Directional coronary atherectomy (DCA) was developed in 1990 in the USA and expected to reduce the abrupt closure rate and the late restenosis of balloon angioplasty. However, the first large randomized clinical trial (CAVEAT study)¹⁾ failed to demonstrate the superiority of DCA compared to balloon angioplasty. Coronary stents became available in 1994 and were widely accepted, because stenting was simple, easy to perform, and effective. In addition, after the drug-eluting stent became available, DCA device users declined with the DCA catheter removed from the device market in 2008. On the other hand, there were some Japanese cardiologists, who strongly desire to revive the DCA device. They reported in 2007 that DCA was useful for limited patients, especially for bifurcated lesions including left main trunk (PERFECT Study)¹⁰⁾. A new DCA catheter has been developed by NIPRO Corporation (Osaka, Japan) and was approved by the Japan Ministry of Health, Labor and Welfare in December 2014. This article introduces the newly developed DCA catheter and considers the role of this device in the drug-eluting stent era.

KEY WORDS: directional coronary atherectomy, bifurcation lesion, intravascular ultrasound, stent, drug coated balloon

I. Background

The first successful coronary angioplasty was performed by Andrea Gruentzig in 1977. This procedure has become widely accepted around the world. However, there were 2 major limitations of this initial procedure ;

1. Abrupt closure immediately after the procedure (approximately 5%).
2. Restenosis at the chronic stage (approximately 40% to 50%).

Directional coronary atherectomy (DCA) was developed by Dr. John Simpson and first became available in 1990 in the USA. DCA was expected to reduce the abrupt closure rate and the late restenosis of balloon angioplasty. However, the first large randomized clinical trial (CAVEAT study)¹⁾ failed to demonstrate the superiority of DCA compared to balloon angioplasty. Even though the restenosis rate was similar in both groups, the incidence of early-phase composite endpoint was higher in the atherectomy group than the angioplasty group. Thereafter, intravascular ultrasound (IVUS)-guided DCA was recommended to debulk the coronary artery plaque effectively and safely as the previous studies reported that 70% of coronary artery plaque was eccentric^{2–4)}. In the late 1990's, several studies demonstrated the superiority of DCA compared to balloon angioplasty using the IVUS-guided technique^{5–7)}. However, coronary stenting became

available in 1994 ; and accordingly, the dual anti-platelet therapy was established in 1995. Many studies demonstrated that coronary stenting was effective to control abrupt closure and reduce restenosis compared to balloon angioplasty^{8, 9)}. Consequently, many user-friendly stents were developed and became widely accepted due to the fact that stenting was simple, easy to perform, and effective. In addition, the drug-eluting stent (DES) first became available in 2001 and the restenosis rate was reduced to less than 10%.

Under this environment, DCA device users declined, with the DCA catheter removed from the device market in 2008. On the other hand, there were some Japanese cardiologists who strongly desired to revive the DCA device. They reported in 2007 that DCA was useful for limited patients, especially for bifurcated lesions including left main trunk, the ostial left ascending coronary artery and the ostial left circumflex coronary artery¹⁰⁾ ; 2% of target vessel revascularization and no stent thrombosis (PERFECT study).

A new DCA catheter has been developed by NIPRO corporation (Osaka, Japan) and was approved by the Japan Ministry of Health, Labor and Welfare in December 2014. Nobuyuki Soeda (a medical engineer of our hospital) and I were actively involved in the device development process.

This article introduces the newly developed DCA catheter and considers the role of this device in the DES era.

II. Revived DCA catheter

Figure 1 shows the design of the revived DCA catheter.

The basic structure is similar to a previous DCA catheter (FILEXI-CUT ; Abbott. North Chicago, USA), which consists

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Fig. 1 The design of the new DCA catheter.

Fig. 2 Evaluation of machinability in experimental model.

of the nosecone, the metal housing, the shaft, connector and the motor drive unit. However, the functional performance of the revived DCA catheter is significantly improved compared to Flexi-cut. The rotation speed is 6,000 rpm and the cutter is made of a hard metal (SUS440 + diamond-like coating), which enables cutting of hard plaques. Figure 2 shows the machinability of the revived DCA catheter. The most significant structural change is “the guide wire support ring”, which is attached to the distal part of the housing for eliminating rotational distortion of the guide wire (Fig. 3). This ring prevents cutter prolapse from the window. A comparison between the newly developed device and FLEXI-CUT is shown in Table 1. Although the device is 7F guiding catheter compatible, some flow limitation to contrast media disbursement may occur and therefore use of an 8F guiding catheter is highly recommended.

III. Indications of DCA in the drug-eluting stent era

There are several difficulties associated with DCA compared to stenting. The procedures are more complex and time consum-

ing due to the need to confirm IVUS and coronary angiograms multiple times in order to retrieve the plaque from the coronary artery safely and effectively. Since an 8F guiding catheter is required, the access site is limited to a femoral approach.

Also, a large guiding catheter sometimes results in applying a relatively large amount of contrast medium ; accordingly it cannot be applied to the patients with chronic kidney disease. The most serious and specific complication associated with DCA is coronary perforation which is a critical limitation.

Consequently, the clinical indication of DCA is considered the most important point. From our experiences the best indication of DCA may be bifurcated lesions including the distal left main trunk (LMT), ostial left anterior descending (LAD) coronary artery and ostial left circumflex coronary artery (LCX). If a stent is implanted from the LMT to LAD, the ostium of the LCX will be compromised due to carina shift, which may lead to severe stenosis with ischemia. Figure 4 shows an examples of a bifurcated lesion. In this case, the lesions were located in the distal LMT to the ostial LAD, with two side branches located between the

Fig. 3 Detailed structure of the distal part of the DCA catheter.
The “guide wire support ring” prevents the cutter prolapse from the window.

Table 1 Specification of the revived device and FLEXI-CUT

	Development device	FLEXI-CUT
Material		
Cutter	Specialized coating (Vickers hardness: 900)	Titanium coating (Vickers hardness: 550)
Specification		
Maximum O.D.	$\phi 1.95\text{mm}$	$\phi 2.1\text{mm}$
Housing opening length	6mm, 9mm	9mm
Vessel diameter	3.0-4.4mm (3sizes)	2.5-4.0mm (3sizes)
Nose cone capacity	0.032mL	0.030mL
Guiding catheter	7Fr and/or more	8Fr and/or more
MDU Number of rotations	Approximately 6000 rpm	Approximately 3500 rpm

Fig. 4 A case of LMT bifurcated lesion, with two side branches located between the LAD and LCX.
If a stent is implanted from the LAD to LCX, side branches may potentially be compromised in this case. DCA was very effective.

LAD and LCX. If a stent is implanted from the LMT to LAD, the side branches may potentially be compromised. DCA was very effective without incurring restenosis. Figure 5 is another example of a good indication for DCA. The lesion was located at

the ostial LCX. If a stent is implanted from the LMT to LCX, the ostial LAD may be compromised.

In this case, DCA was performed in the ostial LCX lesion and then stenting was performed to the distal LCX. The LAD was

Fig. 5 Ostial LCX lesion is a good indication of DCA. DCA was performed in the ostial LCX lesion and then stenting was performed to the distal LCX. The LAD was not compromised by this strategy.

Fig. 6 DCA following by a drug coated balloon (DCB). DCA following DCB strategy may be promising in young patient (This patient was 40's years old male).

not compromised by this strategy. A drug coated balloon following by DCA may be an attractive strategy even in the DES era. Figure 6 illustrates a case of a 48-year-old male patient with effort angina pectoris with a lesion located in the LMT.

DCA was performed followed by drug coated balloon angioplasty (4.0×20mm). The final angiograms showed a smooth dilatation similar to a stented site. Further clinical trials are needed to evaluate the effectiveness of DCA and a drug coated balloon strategy.

IV. Carina shift in the stented bifurcation lesion

Bifurcated lesions still remain a challenge in percutaneous coronary intervention in the DES era. Previous studies have shown that the incidence of major adverse cardiac events includ-

ing stent thrombosis, myocardial infarction, and target vessel revascularization were higher in bifurcated lesions than non-bifurcated lesions. There are several factors that result in stented, bifurcated lesions resulting in poorer clinical outcomes: stent design, stenting methods and bifurcation angle.

A narrow bifurcated angle may cause carina shift and carina deformation which may impact on poorer clinical outcomes. Figure 7 highlights a case where the lesion was located in the distal LMT to ostial LAD.

Immediately after single crossover stenting, the ostial LCX became stenotic. The IVUS images showed severe carina shift and carina damage. If the plaque is retrieved from the LMT to LAD with DCA, the stent can easily be expanded to the opposite site of the carina, so that the carina shift and damage will be sup-

Fig. 7 Carina shift and deformation after single crossover stenting. Single crossover stenting caused carina shift, deformation and hematoma.

pressed. PERFECT study¹⁰⁾ showed that DCA prior to stenting remarkably decreased adverse cardiac events and resulted in good clinical outcomes.

V. DCA procedure in our daily practice

The following devices are used in the DCA procedure in our hospital.

1) Guiding catheter: 8F Hyperion Super Back-up ; 3.75 or 4.0 SH (ASAHI INTECC, Nagoya, Japan) / 8F Mach 1 ; JCL or FCL or Q curve (Boston Scientific, Marlborough, USA). 2) Guide wire: Grand Slam ; 300cm (ASAHI INTECC) / ABYSS Power Support 3 ; 300cm (NIPRO). 3) IVUS: OptiCross (Boston Scientific).

A soft wire with micro-catheter is introduced to the lesion and then the wire is exchanged to the stiff wire mentioned above. The IVUS catheter is introduced along the stiff wire to evaluate the plaque morphology, eccentricity and cutting direction prior to the DCA procedure. The right anterior oblique and caudal view or anterior-posterior and caudal view is recommended to perform DCA in a patient with proximal LAD or distal LMT disease. Thereafter, the DCA catheter is advanced to the lesion and is rotated to the cutting direction determined by IVUS findings. The first cut is performed with a low inflation pressure (1 or 2 atmosphere). The IVUS imaging is performed to confirm whether the cutting direction is correct or not. DCA is repeated until reaching the endpoint. The endpoint of the DCA procedure differs from patient to patient but is typically 50–60% plaque area.

VI. IVUS-guided DCA

There are many kinds of complications including death, coronary perforation, coronary aneurysm, abrupt closure, myocardial infarction and emergent bypass surgery^{1, 11)} reported from use of DCA. The worst complication is coronary perforation, which may be life threatening. IVUS guidance is the most crucial to overcome this complication.

The cutting direction should be correctly decided on the angiogram by using IVUS. There are two methods to determine the cutting direction by using IVUS. The first utilizes “diagonal branch origin” on the IVUS image¹²⁾; the other method uses “guide wire and IVUS bias” on the angiogram. Both methods are extremely important to effectively and safely retrieve the plaque and avoid coronary perforation. Figure 8 shows an example of the “guide wire and IVUS bias” method. In this RAO view, the IVUS catheter and a guide wire are completely separated on the angiogram. Therefore, this RAO view corresponds to the IVUS image looking from 3 o’clock. The plaque is predominantly located at 1 o’clock on the IVUS image. The correct cutting direction is determined to be 30 degree clockwise from the upper position on this RAO view.

VII. DCA in the future

The DCA device was removed from commercial use in 2008 due to not being user friendly, not easy to handle, and requiring IVUS-guidance. Therefore, there is a necessity to develop an IVUS equipped DCA catheter in the future. This would allow for

Fig. 8 Principle of “IVUS catheter and guide wire bias” method. In this RAO view, the IVUS catheter and a guide wire are completely separated. Therefore, this RAO view corresponds to the IVUS image looking from 3 o'clock. The plaque is mainly located at 1 o'clock on the IVUS image.

the DCA procedure to be performed much safer and effectively and allow usage for a greater number of cardiologists. We hope we can realize the development of a combined DCA with IVUS catheter in the near future.

VIII. Conclusions

DCA is now commercially available in Japan, but it must be kept in mind that it is potentially a high risk device due to vessel perforation. Upon approval of this DCA device, the Pharmaceuticals and Medical Devices Agency advised us that IVUS learning and proper lesion indications are essential due to some reports of serious complications such as vessel perforation associated with DCA in the past. However, DCA can support high quality coronary intervention in bifurcated lesions even in the DES era if it is performed safely and effectively with IVUS guidance.

Conflict of interest

I have received an advisory fee from NIPRO Corporation (Osaka, Japan).

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