Current Overview of Rotational Atherectomy. Does Rotablator Make Sense?

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Introduction

Over the last two decades after Andreas Gruentzig performed the first percutaneous transluminal coronary angioplasty (PTCA) using a plain balloon catheter in Zurich in 1977, percutaneous revascularization for obstructive coronary artery disease has evolved significantly. Initially, the indication of the PTCA was limited purely for the patients with short, discrete, concentric, non-calcified lesions in proximal coronary arterial segments (1). Nowadays, with advanced equipment and skilled hands, PTCA is safely applied to more complicated lesions, and is regarded as an alternative to medical or surgical treatment in wide range of the patients.

However, in significant subsets of lesions, the result of plain old balloon angioplasty (POBA) is not satisfactory due to low initial success rate or high occurrence of late restenosis. To conquer these problems in POBA, new interventional devices have been developed. These include two types of devices. One is the endovascular scaffolding device such as stents and others is the debulking device.

The Rotablator (SCIMED, Boston Scientific Corporation, Boston, MA) is the one of latter devices which was invented by David Auth (2) and has been used investigationally in human coronary arteries in 1988 (3). In this article, we summarize the principle, the system, the technique, and the currently available clinical data concerning this device and present our experience.

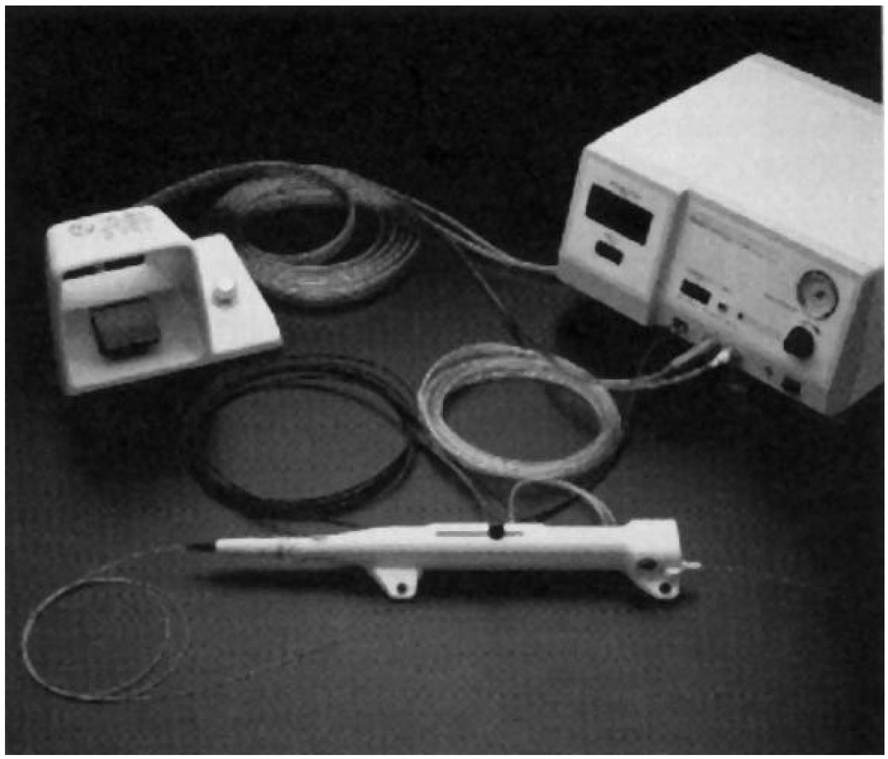

Figure 1 *Current system of rotational atherectomy: RotaLink and its control system.*

Principle of Rotablator

High-speed rotational atherectomy with the Rotablator system has an unique characteristic compared with other atherectomy devices. It removes plaque by abrading the atherosclerotic material, producing millions of microparticles which are smaller than red blood cell. These microparticles are dispersed into the distal coronary circulation and are cleared by reticulo-endothelial system in liver, lung, and spleen.

The two major principles that govern the ability of the Rotablator system to treat the atherosclerotic lesions are "differential cutting" and "orthogonal displacement of friction".

Differential cutting means the ability to remove hard (inelastic) tissue while sparing soft (elastic) tissue which can deflect away from the advancing rotating abrasive burr. According to this principle, the burr preferentially abrades hard and

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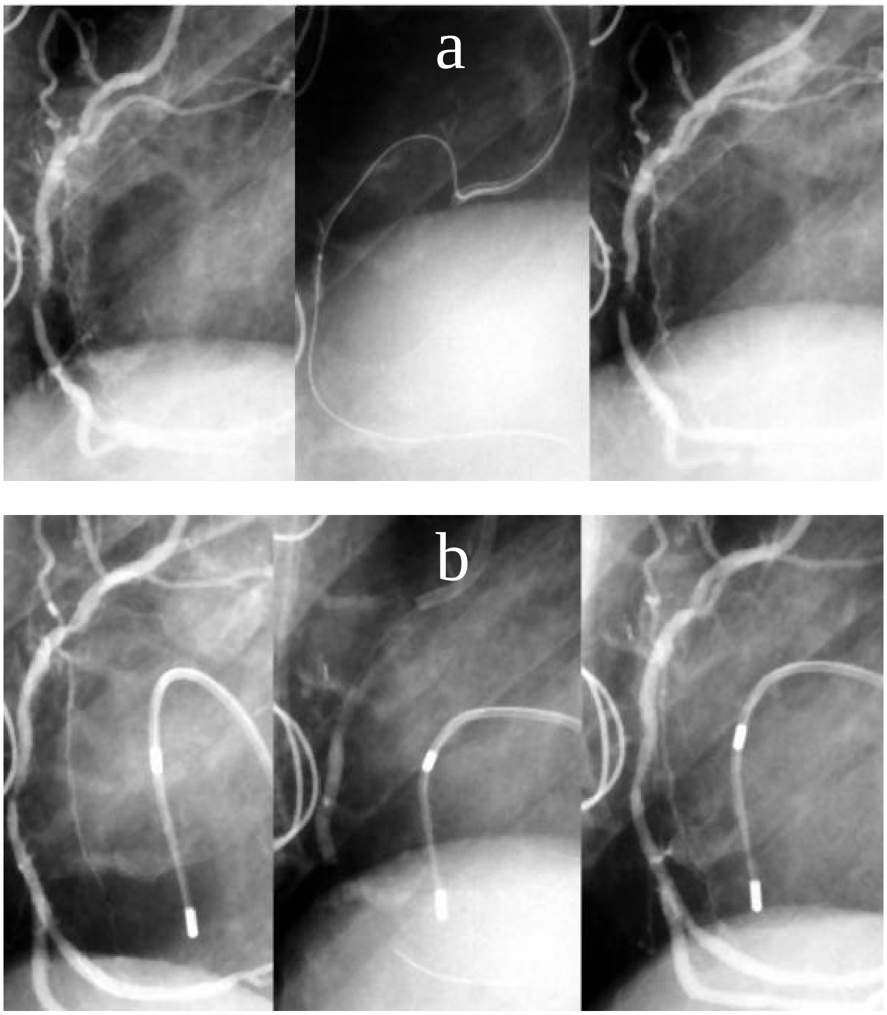

Figure 2. *Uncrossable lesion.*
In this eccentric lesion with heavy calcification in mid portion of right coronary artery, the balloon was uncrossable (in panel A). After the use of Rotablator (1.25 mm burr), this lesion was easily crossable and was dilated by balloon (with 4 atm) (in panel B).

even calcified atherosclerotic plaque while deflecting the normal tissue, which is soft and elastic.

The second principle, orthogonal displacement of friction, provides easy passage of the burr through tortuous and diseased segments of the coronary tree. This principle involves change in the effective friction in one direction between two adjacent sliding surfaces that results from relative motion between the two surfaces in a plane perpendicular to that direction. In addition to facilitating movement through coronary arteries, this principle is useful in the exchange procedure over the guidewire.

Description of Rotablator

The Rotablator system includes an advancer that houses the air turbine, drive shaft, and burr and a console to monitor and control the rotation by regulating air supply to the advancer and the Dynaglide foot pedal. The abrasive tip is welded to a long flexible drive shaft tracking along a central flexible stainless steel guidewire. The drive shaft is housed in a 4.3-Fr Teflon sheath which prevents tissue injury caused by the spinning shaft and also acts as a conduit for a flush solution. Original guidewires (Type C and Type A wire) were not easy to handle and could not go through the conventional balloon catheter. However, the introduction of new guidewires (RotaWire Floppy and RotaWire Extra Support) enabled operators to select the guidewire best suited for the lesion site and vessel tortuousity. These new guidewires have a safety core through the distal spring tip, providing improved flexibility, trackability, and steerability. The abrasive tip is an elliptically shaped burr, available in various sizes for coronary use (1.25, 1.50, 1.75, 2.00, 2.15, 2.25, 2.38 and 2.50 mm in diameter). The distal half is coated with diamond chips 20 to 30 μm in diameter. Rotational energy is transmitted by a compressed air motor that drives the flexible helical shaft at speeds up to 200,000 rpm. The number of rpm is measured by a fiber optic light probe and displayed on a console. The console indicates the time period of a treatment. The speeds of rotation and of advancement of the burr are controlled by the operator. During rotation, saline-based flush solution irrigates the catheter sheath to lubricate and cool the rotating parts. The burr and the drive shaft move freely over a central coaxial guidewire (0.009 inch in diameter, 300 cm in length), with a flexible radiopaque platinum distal tip (0.014 inch in diameter, 20 mm long), which is locked and does not rotate with the burr abrasion. The wire and the abrasive tip can be advanced independently, which allows the wire to be placed in a safe distal location before the burr is advanced into the diseased artery. Currently, the second generation of the system, the Rotalink system (Fig. 1), which was modified in the tube layout and was refined on handling, is widely used. Also in guidewire, GoldWire, which was improved in visibility, is also available.

Indications

Basically, the impetus to select an alternative device to the POBA is to improve an initial success rate or to reduce the restenosis rate. However, the sufficient luminal gain, which is closely related to the occurrence of restenosis, cannot be attained in many cases by the Rotablator alone because the size of burr is limited by the size of guide catheter and the currently available data does not show the improvement of restenosis rate after the use of Rotablator (4-5). Therefore, the Rotablator is mainly used to improve procedural outcome and to expand the indications of percutaneous coronary intervention in the following lesions; 1) balloon undilatable or uncrossable lesions

(Fig. 2), especially with superficial calcification, 2) ostial lesions, particularly aorto-ostial stenosis, 3) bifurcation lesions (Fig. 3), and 4) long lesions less than 25 mm, especially with calcification.

In contrast, the Rotablator is contraindicated for the following lesions because of the higher occurrence of complication; 1) thrombus-containing lesions, 2) degenerated saphenous vein grafts and 3) long lesions more than 25 mm.

According to the National Cardiovascular Network's Coronary Interventional Database at 12 US hospitals between 1994 and 1997, the Rotablator was used in 8% of cases (6).

Procedure

To prevent the vasospasm during the procedure, all the patients have to be pretreated with oral calcium antagonist and the vasodilators such as nitroglycerin and/or verapamil should be added to flush solution (Rotaflush). Other procedural management is similar to POBA. Administration of platelet glycoprotein IIb/IIIa inhibitors is reported to reduce the incidence of slow flow or no reflow during the procedure (7).

Guide catheter selection

In the Rotablator, the selection and the positioning of the guide catheter are important for the ease of advancement of the burr and the trajectory of the guidewire which orients the burr and affects the direction of ablation plane. Coaxial alignment of the guide catheter and guidewire has to be verified before ablation.

The inner diameter of the guide catheter has to be 0.004 inch larger than the final burr. Most 8 Fr, 9 Fr and 10 Fr guide catheters permit passage of up to a 2.15 mm, 2.38 mm and 2.50 mm burr, respectively. A 1.75 mm burr is available in 6 Fr guide catheter.

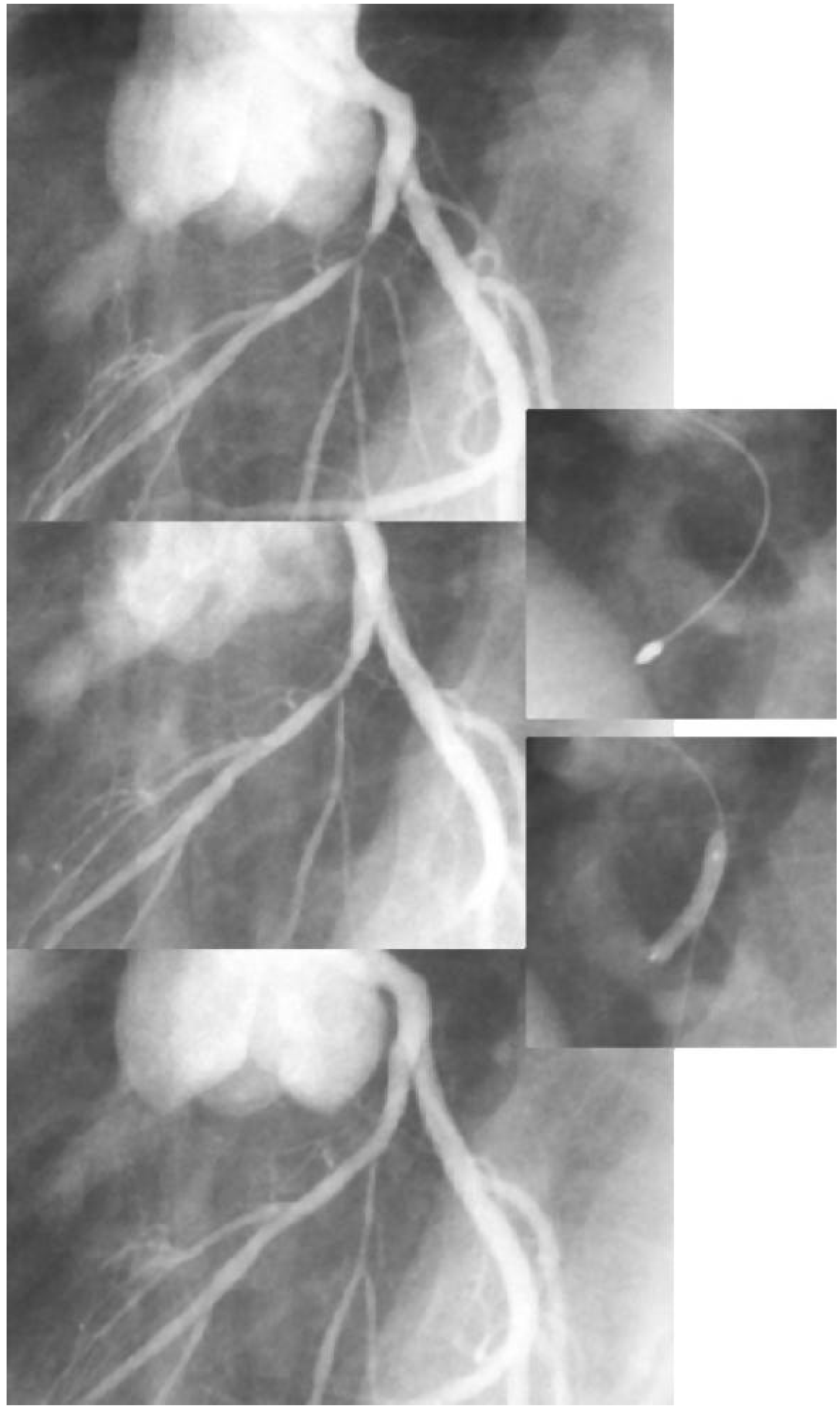

Figure 3. *Bifurcation lesion.*
Highly stenotic lesion in both left anterior descending artery (LAD) and its diagonal branch with small reference vessel diameter. After the ablation of LAD, adjunctive balloon angioplasty was done in LAD. Diagonal branch was not occluded.

Burr selection and treatment strategies

Burr selection is dependent on the treatment strategies with Rotablator, which are also dependent on the lesion morphologies and the clinical backgrounds. There are three strategies concerning the use of this device; Rotablator-alone, burr-balloon and Rota-Stent strategy.

Rotablator-alone strategy (primary therapy) is to achieve a satisfactory result with the use of a single large burr or, alternatively, with the use of several burrs by stepwise increments until a satisfactory angiographic results has been obtained. In this strategy, the noncompliant oversized balloon (less than 1 atm) was

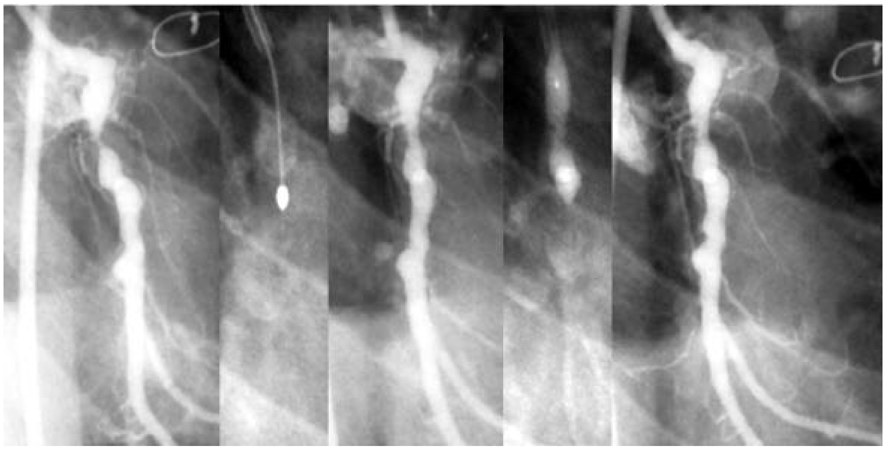

Figure 4. *Primary therapy.*
Heavily calcified lesion with aneurysm formation in mucocutaneous lymph-adenopathic syndrome (MCLS). After the ablation using 2.15 mm burr, no additional luminal gain could be attained with adjunctive balloon angioplasty.

applied for the bailout from an angiographic complication or for the relief of vasospasm. The burr-to-artery ratio in these cases is in the range of 0.7-0.9. Therefore, the lesion morphologies that are applicable to this strategy are limited to those without severe angulation and with good distal runoff. Heavily calcified stenotic lesion with aneurysm formation in mucocutaneous lymph-adenopathic syndrome (MCLS) is the representative lesion which is suitable for this strategy (Fig. 4).

Burr-balloon strategy is commonly used approach. In this strategy, the Rotablator is used to improve the lesion characteristics (lesion modification) in order to apply the conventional balloon. This proposes the use of an undersized burr (burr-to-artery ratio 0.6-0.75) with minimal risk, followed by adjunctive balloon angioplasty. In the recent literatures, it is recommended to use the noncompliant oversize balloon with minimal pressure (1 atm) (8). Therefore, this strategy is safer than Rotablator-alone strategy and applicable much wide spectrum of the lesions.

Rota-stent strategy is to put the stents after the pretreatment by the Rotablator and adjunctive balloon angioplasty (Fig. 5). In the heavily calcified lesion, it is sometimes difficult to put the stent even after the preballoon dilation. In that case, the passage of the stent can be easy by the

Table I. *Initial results after Rotablator*

Author	No	Type of lesion	Procedural success	Adjunctive balloon	Residual stenosis	Restenosis	TLR
Kiesz et al.	111	B;18.5%, C;81.5%	98%	All	18%	28%	23%
Kini et al.	574	A;10%, B1;12%, B2;54%, C;26%	98%	All	14%		
	254	A;12%, B1;13%, B2;44%, C;31%	95%	All	21%		
	172	A;13%, B1;8%, B2;42%, C;37%	94%	All	24%		
Braden et al.	100	B2, C;75%	99%	All	26%	28%	
Levin et al.	178	A;3%, B1;26%, B2;46%, C;25%	94%	93%	19%		14%
Brown et al.	525	A;6%, B1;24%, B2;57%, C;14%	88%	88%	26%		26%
DART	222	A or B1	99%				
ERBAC	231	A;1%, B1;20%, B2;65%, C;14%	89%	93%	33%	57%	42%
Reisman et al.	200	A;8%, B;75%, C;17%	96%				
	2953	A;17%, B;66%, C;17%	95%				
MacIsaac et al.	2,161	Calcified;50%, Non-calcified;50%	94.50%	74%	22%		
Sterzer et al.	656	A;11%, B1;14%, B2;29%, C;46%	96.50%	65%			
Ellis et al.	316	A;24%, B;70%, C;6%	89.80%	82%	27%		
Warth et al.	709	A;27%, B;59%,C;14%	94.70%	44%		38%	
Borrione et al.	166	Complex; 63%	95%	All	18%		
Guerin et al.	61	B2;100%	93.40%	All		39%	
Gilmore et al.	108		91.70%				
Stertzer et al.	242	A;7.5%, B/C;92.5%	94%	77%			38%
Safian et al.	104	A;20%, B;76%,C;4%	95.20%	77%	30%	51%	36%

pretreatment using the Rotablator. Also stent expansion and apposition are supposed to be improved after the use of Rotablator (9).

Guidewire selection

The guidewire in the Rotablator is not simply a device for burr delivery but has an integral role in ablation. Therefore, the position, tension, and stiffness of guidewire are important to do safe and effective ablation.

The divergence from the central axis of the vessel is referred to as guidewire bias. Usually, guidewire bias is unfavorable because it resulted in preferential cutting along one wall of the vessel and if the force exceeds the elastic threshold of the vessel, normal tissue will be ablated. However, guidewire bias can be favorable when it orients the burr toward the lesion and may result in larger luminal achievement than the size of burr.

Burr speed and burr advancement

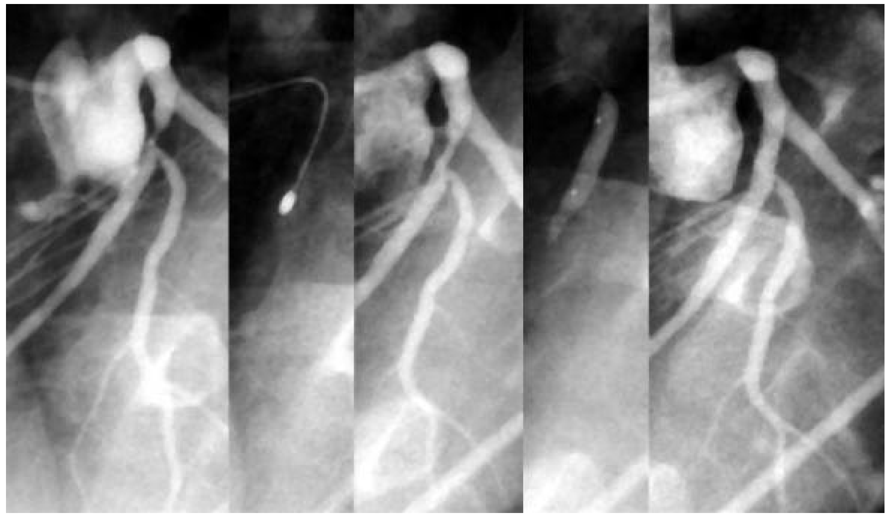

Figure 5. *Rota-Stent strategy*
Bifurcation lesion with highly stenotic lesion only in left anterior descending artery (LAD) with large reference vessel diameter. After the ablation of LAD, stent implantation was done in LAD. Diagonal branch was not occluded.

The burr speed is adjusted according to burr size and the recommended speed for smaller burr (less than 2.0 mm) is 180,000 rpm and that for larger burr (more than 2.15 mm) is 170,000 rpm. However, the recent experimental study revealed that the reduction of burr speed to the minimal approved level (140,000 rpm) much reduced the platelet aggregation due to heat generation (10). This low

Table II. *In-hospital major complications after Rotablator*

Author	No.	Death	CABG	Q MI	Non-Q MI
Kiesz et al.	111	None	None	None	4.5%
Kini et al.	574	0.2%	0.2%	0.7%	
	254	0.8%	0.8%	1.2%	
	172	1.7%	1.7%	2.3%	
Levin et al.	178	1.1%	2.2%	2.8%	0.6%
Brown et al.	525	0.8%	0.4%	1.1%	5.2%
ERBAC	231	0.9%	0.9%	1.3%	2.2%
MacIsaac et al.	2,161	0.8%	2.0%	0.7%	8.8%
Sterzer et al.	656	0.5%	1.4%	3.4%	
Ellis et al.	316	0.3%	0.9%	2.9%	5.7%
Reisman et al.	200	3.0%	2.5%	0.5%	6.0%
	2953	1.0%	2.5%	1.2%	6.1%
Warth et al.	743	0.8%	1.7%	0.9%	3.8%
Borrione et al.	166	1.8%	None	0.6%	8.4%
Guerin et al.	61	None	1.6%	1.6%	6.6%
Gilmore et al.	108	0.9%	2.8%	0.9%	2.8%
Safian et al.	104	1%	1.9%	4.8%	2.9%
Stertzer et al.	302	None	1.0%	2.6%	

Table III. *Angiographic complications after Rotablator*

Author	No.	Abrupt closure	Slow flow or No reflow	Perforation	Dissection	Side branch occlusion	Spasm
Kini et al.	574	1.1%	2%	1.0%	4%	5%	5%
	254	2.3%	4%	0.7%	4%	5%	5%
	172	4.0%	9%	0.6%	5%	4%	7%
Levin et al.	178			1.7%			
Brown et al.	525	1%	1%	1%	15%	1%	2%
MacIsaac et al.	2,161	3.6%		0.7%	13%		
Sterzer et al.	656	2.7%	1.8%	0.6%	10.4%	1.7%	5.3%
Ellis et al.	316	5..5%	7.6%	1.5%			
Reisman et al.	200	3.4%		0.4%	11.6%		
	2953	4.1%		0.6%	11%		
Warth et al.	743	3.1%	1.2%	0.5%	10.5%	0.1%	1.6%
Borrione et al.	166	1.8%		0.6%			
Safian et al.	104	11.2%	6.1%	None		1.8%	

speed treatment may be beneficial for the reduction of slow flow or no reflow which is often complicated with the treatment in the lesion with highly complex morphologiy, especially in the long lesion. On the other hand, it takes longer ablation time and needs more refined hands.

During the ablation, excessive deceleration (more than 5,000 rpm) must be avoided because it results in improper ablation and increases the risk of vessel injury, the formation of large particles,

Table IV. *Randomized study concerning Rotablator*

	AIM AND NO. OF CASE	PRIMARY ENDPOINT	RESULT
ERBAC	Comparison between device Rotablator (n=231) POBA (n=222) ELCA (n=232)	Procedure success	Procedural success 89% vs. 80% vs. 77% TLR 42% vs. 32% vs. 46%
STRATAS	Comparison between strategy (B/A: Burr/artery ratio) Aggressive (B/A=0.7-0.9, n=250) Conservative (B/A=0.6-0.8, n=250)	MACE at 6 months MLD at 6 months	Death 2.5% vs. 5.1% MI 2.5% vs. 1.0% TLR 35% vs. 27%
DART	Comparison between device Rotablator (n=222) POBA (n=220)	Composite precedural success without major complications	MACE 1.3% vs. 0% Slow flow/No reflow 8.0% vs. 0.5% Major dissection 8.0% vs. 16% Bailout stenting 6.0% vs. 14%
CARAT	Comparison between strategy Aggressive (B/A >0.7, n=104) Conservative (B/A <0.7, n=118)	Procedural success and TLR at 6 months Final diameter stenosis	Angiographic complication 16% vs. 8% TLR 21% vs. 22%

and ischemic complications related to excessive heat generation (11).

Clinical results

Table I, Table II, and Table III show that the initial results and the follow up results concerning the restenosis, in-hospital major complications, and angiographic complications in different series reported in the literature, respectively (4,7-8,12-25). Despite the type of treated lesion is different, over all success rate is ranged from 88% to 99%. Mortality is ranged from 0% to 3.0%. This success rate and the complication rate (in-hospital and angiographic) remain unchanged despite the lesions treated in the recent literatures have more complex morphologies which are unsuitable for POBA.

Four randomized trail (4,15,26) (Table IV) were completed concerning the use of Rotablator.

As for the complex lesions which are suitable both for POBA and Rotablator, the ERBAC trial was conducted and concluded that the initial success rate was higher in the Rotablator, but the subsequent revascularization at the target vessel was more frequent in the Rotablator. In contrast to the ERBAC trial, the Rotablator was compared with POBA in the noncomplex lesions in the DART and initial outcome was evaluated. Although the rate of slow flow/no reflow was higher in the Rotablator, the rate of major dissection and the need for bailout stenting were lower in the Rotablator. The STRATAS trial was planned to compare the outcome of an aggressive strategy (burr-to-artery ratio of 0.7-0.9) with no-or low-pressure (< 1 atm) POBA versus that of a conventional strategy (burr-to-artery ratio of 0.6-0.8) with conventional pressure (> 4 atm) POBA. At 6 months follow up, the restenosis rate is not different between the groups. Similar to the STRATAS trial, the aggressive versus conservative strategy were compared in the small reference artery (2.7 mm average) in the CARAT. With the Rotablator, a conservative strategy achieved similar immediate lumen enlargement and late target lesion revascularization compared to aggressive strategy, but with fewer angiographic complications.

In contrast to higher procedural success rate in the complex lesions, the restenosis rate after the Rotablator is still not satisfactory. Although the reason for high occurrence of restenosis after the Rotablator is supposed to be multi-factorial, several modification in the technique was introduced to reduce the vessel trauma and to achieve the effective debulking. After these modification, very low restenosis rate (28%) is reported in recent two literatures (8,12).

Summary

Despite many years of widespread application of this device, technique of Rotablator is still very subjective and changing. Moreover, the efficacy of this device is highly operator dependent compared with other devices. Although the Rotablator could not be the mainstay of percutaneous coronary intervention, the Rotablator is indispensable device for specific lesion unsuitable for POBA and stent.

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