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Cutting-balloon angioplasty before drug-eluting stent implantation for the treatment of severely calcified coronary lesions

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Abstract

Background Severely calcified coronary lesions respond poorly to balloon angioplasty, resulting in incomplete and asymmetrical stent expansion. Therefore, adequate plaque modification prior to drug-eluting stent (DES) implantation is the key for calcified lesion treatment. This study was to evaluate the safety and efficacy of cutting balloon angioplasty for severely calcified coronary lesions. **Methods** Ninety-two consecutive patients with severely calcified lesions (defined as calcium arc ≥ 180° calcium length ratio ≥ 0.5) treated with balloon dilatation before DES implantation were randomly divided into two groups based on the balloon type: 45 patients in the conventional balloon angioplasty (BA) group and 47 patients in the cutting balloon angioplasty (CB) group. Seven cases in BA group did not satisfactorily achieve dilatation and were transferred into the CB group. Intravascular ultrasound (IVUS) was performed before balloon dilatation and after stent implantation to obtain qualitative and quantitative lesion characteristics and evaluate the stent, including minimum lumen cross-sectional area (CSA), calcified arc and length, minimum stent CSA, stent apposition, stent symmetry, stent expansion, vessel dissection, and branch vessel jail. In-hospital, 1-month, and 6-month major adverse cardiac events (MACE) were reported. **Results** There were no statistical differences in clinical characteristics between the two groups, including calcium arc (222.2° ± 22.2° *vs.* 235.0° ± 22.1°, *P* = 0.570), calcium length ratio (0.67 ± 0.06 *vs.* 0.77 ± 0.05, *P* = 0.130), and minimum lumen CSA before PCI (2.59 ± 0.08 mm^2 *vs.* 2.52 ± 0.08 mm^2, *P* = 0.550). After stent implantation, the final minimum stent CSA (6.26 ± 0.40 mm^2 *vs.* 5.03 ± 0.33 mm^2; *P* = 0.031) and acute lumen gain (3.74 ± 0.38 mm^2 *vs.* 2.44 ± 0.29 mm^2, *P* = 0.015) were significantly larger in the CB group than that of the BA group. There were not statistically differences in stent expansion, stent symmetry, incomplete stent apposition, vessel dissection and branch vessel jail between two groups. The 30-day and 6-month MACE rates were also not different. **Conclusions** Cutting balloon angioplasty before DES implantation in severely calcified lesions appears to be more efficacies including significantly larger final stent CSA and larger acute lumen gain, without increasing complications during operations and the MACE rate in 6-month.

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Keywords: Cutting balloon angioplasty; Calcified lesion; Intravascular ultrasound; Percutaneous coronary intervention

1 Introduction

Significantly calcified lesions pose a particular challenge to the interventional cardiologist. Calcified coronary lesions are not a homogenous entity, and their response to percutaneous coronary intervention (PCI) varies according to severity of calcification. Severely calcified lesions respond poorly to balloon angioplasty,[1,2] and when stents are implanted in such lesions, an incomplete and asymmetrical stent expansion occurs in the majority of cases.[3,4] Drug-eluting stent (DES) underexpansion, minimal stent area, and long stent have been reported as the major factors for stent restenosis and thrombosis.[5,6] Therefore, adequate plaque modification prior to DES implantation is the key for calcified lesion treatment.[5]

A number of devices and techniques have been developed which attempt to overcome the difficulties posed by calcium. Several observational studies have confirmed that rotational atherectomy (RA) prior to stent deployment in severely calcified lesions is safe and does have potential utility.[7,8] The 2011 ACC/AHA guideline for PCI recom-

mends rotational atherectomy for heavily calcified lesions as Class IIa, evidence level is C.[9] However, the RA technology was not been widely utilized in the developing country, such as China, due to the high medical fee and relative complex procedure.

The usage of the cutting balloon for severely calcified lesions has been reported in a single case and achieved satisfied result.[10,11] Karvouni, *et al*.[12] firstly reported that the cutting balloon is feasible and safe for moderate and severe calcified lesions in a series of patients.

But there was no random study for evaluating the safety and efficacy of cutting balloon combined with DES for severely calcified lesions. The aim of this perspective study was therefore, to evaluate the safety and efficacy of cutting balloon angioplasty for severely calcified coronary lesions by intravascular ultrasound (IVUS).

2 Methods

2.1 Study patients

From March 2012 to March 2013, 92 consecutive patients with 92 severely calcified coronary lesions treated by cutting balloon angioplasty (CB) or conventional balloon angioplasty (BA) before DES implantation were evaluated in institution of Geriatric Cardiology in the Chinese People's Liberation Army (PLA) General Hospital, China. The enrolling criteria were as follows: (1) native coronary artery with a stenosis of $\geq 70\%$; and (2) target lesion calcified with severely calcification (the calcium arc $\geq 180°$, the calcium length ratio ≥ 0.5). The exclusion criterions were as following: (1) restenosis in-stent; (2) the extremely tortuous or angulated lesions; (3) lesions with dissection before balloon expansion; (4) lesions within vein graft; and (5) extremely narrow lesions in which IVUS could not get through the lesion even after pre-dilatation or rotational atherectomy.

The study protocol was approved by the ethics committee in Chinese PLA General Hospital. Informed consent was obtained in all patients before PCI. They were divided randomly into CB group and BA group. Randomization was performed after coronary angiography and IVUS examination. There were 45 patients in BA group and 47 patients in CB group. Seven cases in BA group were not entirely expanded after BA dilatation, and then were transferred into CB group. At last, there were 38 patients in BA group and 54 patients in CB group.

2.2 PCI procedure

All patients were pretreated with aspirin or either clopidogrel. A 300 mg loading dose of clopidogrel was adminis-

tered before the procedure if patients were not pretreated. Per-procedural glycoprotein IIb/IIIa inhibitors were used according to the operator's discretion. During interventions, patients received intravenous unfractionated heparin (100 IU/kg) to maintain activated clotting time ≥ 300 s. For angiography, we used digital cardiovascular system of Phillip Allura Xper FD20. The interventional strategy and size of sirolimus stent selection were left to the discretion to the same operator in all patients. Oral antiplatelet therapy followed current guidelines which recommend combination of aspirin and clopidogrel between 6 and 12 months for DES. Post-procedural medical therapy included aspirin, clopidogrel, statin, beta-blocker, angiotensin-converting enzyme-inhibitors (ACEI), and angiotensin-receptor blockers (ARB).

2.3 IVUS procedure

After regular coronary angiography, IVUS was performed at baseline (82 cases before pre-dilatation, 3 cases after rotational atherectomy and small balloon pre-dilatation, 7 cases after small balloon pre-dilatation) and repeated immediately after stent implantations in all cases. Studies were performed by using VOLCANO S5 imaging system (VOLCANO Corporation), with a single-element 30 MHz transducer of Eagle Eye® Gold. The IVUS catheter was carefully advanced distal to the culprit lesion under fluoroscopic guidance, and was then withdrawn automatically at 0.5 mm/s to perform the imaging sequence, which started 20 mm distal to the culprit lesion and ended at the aorto-ostial junction. In 6 severely narrow lesions in which IVUS could not arrive to the distal segment even after pre-dilatation, we used the lumen CSA of arrival section as the minimum lumen CSA.

2.4 Analysis of IVUS imaging

IVUS imaging was recorded on CD for offline analysis by a single experienced observer who was unaware of the clinical and angiographic information. IVUS measurements were assessed according to the American College of Cardiology Clinical Expert Consensus Document on Standards for Acquisition, Measurement, and Reporting of Intravascular Ultrasound Studies.[13]

The ischemia-related vessel was identified as narrow $\geq 70\%$ by angiography. The culprit lesion site selected for analysis was the image slice with the minimum lumen CSA. The proximal reference segment and the distal reference segment were defined as the most normal-looking cross-sections within the same arterial segment, typically ≤ 10 mm to the lesion, but before any large side branch.

At the minimum lumen area slice, we measured lumen

cross-sectional area (CSA), external elastic membrane (EEM), plaque and media CSA = EEM CSA − lumen CSA. Lumen CSA of every 1 mm of culprit lesion segment was measured and average lumen CSA was calculated. For calcium, we measured maximum calcium arc, calcium length, and calcium ratio (calcium length/lesion length). After stent implantation, we measured minimum stent CSA, minimum and maximum stent diameter, and the reference lumen CSA. Stent symmetry = minimum stent diameter/maximum stent diameter. Stent expansion = minimum stent CSA/reference lumen CSA.

Incomplete stent apposition was defined as insufficiently close contact between some struts and the underlying wall. Stent asymmetry was defined as stent symmetry of at least one section < 0.7. Stent underexpansion was defined as stent expansion rate < 0.8.

2.5 Clinical outcomes

In-hospital complications were recorded at time of discharge. Patients were follow-up in out-patient department at 30 days and 6 months after PCI. All cardiac events were documented including death, myocardial infarction (MI), target vessel revascularization (TVR), and composite major adverse cardiac events (MACE, consisting of death, MI and TVR). Death included all-cause mortality. MI was defined according to current guidelines.[14] TVR was a repeat revascularization in the follow-up period due to restenosis, either within the target lesion or within the same coronary artery.

2.6 Statistical analysis

Continuous variables were presented as mean ± SD and categorical variables as frequencies and percentages. Data were statistically analyzed with SPSS version 16. Continuous variables were compared using independent sample *t*-test. Categorical variables were compared with chi-square statistics, or Fisher's exact test. Fisher's exact test was used when any expected cell count was < 5 (not resulting from missing rows or columns in a larger table). All $P < 0.05$ were considered significant.

3 Results

3.1 Patient population and baseline lesion characteristics

Baseline demographics and clinical characteristics (Table 1) were similar between the two groups. Among the 92 patients, unstable angina took the most proportion as 54.3%. There were no significant differences in baseline lesion characteristics (Table 2). The maximum calcium arc and calcium length ratio were not different between two groups.

Before stent implantation, the minimum lumen CSA was $2.59 \pm 0.08 \text{ mm}^2$ in BA group and $2.52 \pm 0.08 \text{ mm}^2$ in CB group, without difference.

Table 1. Baseline patient characteristics.

	BA group (*n* = 38)	CB group (*n* = 54)	*P* Value
Age, yrs	63.5 ± 2.4	59.1 ± 2.1	0.197
Male, *n* (%)	22 (57.9%)	41 (77.8%)	0.199
BMI, kg/m²	25.76 ± 0.71	25.56 ± 0.64	0.832
Smoker, *n* (%)	14 (36.8%)	30 (55.6%)	0.245
BSP, mmHg	131.0 ± 3.9	126.8 ± 3.9	0.463
DSP, mmHg	70.0 ± 1.9	72.3 ± 2.0	0.421
Hypertension, *n* (%)	30 (78.9)	34 (63)	0.335
Diabetes mellitus, *n* (%)	4 (10.5)	12 (22.2)	0.440
Clinical presentation			0.612
SAP, *n* (%)	8 (21.1)	18 (33.3)	
UA, *n* (%)	24 (63.2)	26 (48.1)	
MI, *n* (%)	6 (15.8)	10 (18.5)	

BA: conventional balloon angioplasty; BMI: body mass index; CB: cutting balloon angioplasty; DBP: diastolic blood pressure; MI: myocardial infarction; SBP: systolic blood pressure; SAP: stable angina; UA: unstable angina.

Table 2. Angiography and IVUS characteristics before sent implantation.

	BA group (*n* = 38)	CB group (*n* = 54)	*P* Value
Vessel number			0.774
1, *n* (%)	12 (31.6)	12 (22.2)	
2, *n* (%)	14 (36.8)	22 (40.7)	
3, *n* (%)	12 (31.6)	20 (37.0)	
Target vessel			0.818
Left anterior, *n* (%)	30 (78.9)	48 (88.9)	
Left circumflex, *n* (%)	2 (5.3)	2 (3.7)	
Right coronary, *n* (%)	6 (15.8)	4 (7.4)	
The minimum lumen site			
Min lumen CSA, mm²	2.59 ± 0.08	2.52 ± 0.08	0.550
EEM CSA, mm²	13.73 ± 1.00	13.88 ± 0.76	0.904
Plaque and media CSA, mm²	11.14 ± 0.99	11.36 ± 0.74	0.856
Plaque burden, mm²	78.76 ± 1.73	80.71 ± 0.96	0.334
Lumen stenosis, mm²	57.36 ± 2.63	62.22 ± 1.73	0.153
Average lumen area, mm²	6.51 ± 0.48	7.00 ± 0.37	0.241
Maximum calcium arc	222.2° ± 22.8°	235.0° ± 22.1°	0.570
Calcium length ratio	0.67 ± 0.06	0.77 ± 0.05	0.130
Calcium location			
Superficial, *n* (%)	37 (97.4%)	54 (100%)	0.413
Deep, *n* (%)	15 (39.5%)	22 (40.7%)	0.790

BA: conventional balloon angioplasty; CB: cutting balloon angioplasty; CSA: cross-sectional area; EEM: external elastic membrane; IVUS: intra-vascular ultrasound.

3.2 Procedural characteristics

Procedural characteristics are presented in Table 3. The cutting balloon diameter was 2.56 ± 0.04 mm, and the inflation pressure was 11.6 ± 0.5 atm. There were thirty-eight patients in the CB group which used the conventional balloon after cutting balloon to have a further dilatation. There were no differences in conventional balloon diameter and dilatation pressure between the two groups. The number of post-balloons used in two groups was similar in the two groups (78.9% *vs.* 81.5%, *P* = 1.00). There was trend toward a larger post balloon diameter and a larger post dilatation pressure in CB group (3.48 ± 0.11 mm *vs.* 3.17 ± 0.06 mm, *P* = 0.073; 17.7 ± 0.5 atm *vs.* 16.0 ± 0.6 atm, *P* = 0.021).

3.3 IVUS results after stent implantation

As shown in Figure 1, although the minimum lumen CSA before stent implantation was similar, the final stent CSA and the acute lumen gain area were significantly greater in CB group than that in BA group after PCI. IVUS results after stent implantation are reported in Table 4.

Table 3. Procedural characteristics.

	BA group (*n* = 38)	CB group (*n* = 54)	*P* Value
Guide catheter			0.435
6-F, *n* (%)	34 (89.5)	40 (76.9)	
7-F, *n* (%)	4 (10.5)	12 (23.1)	
Cutting			
Balloon diameter, mm	0	2.56 ± 0.04	
Pressure, atm	0	11.6 ± 0.5	
Rotational atherectomy, *n* (%)	1 (2.6)	2 (3.7)	0.756
Pre-dilatation			
Pre-dilatation, *n* (%)	38 (100)	38 (70.4)	
Balloon diameter, mm	2.6 ± 0.0	2.6 ± 0.1	0.589
Pressure, atm	14.5 ± 0.4	15.4 ± 0.3	0.201
Balloon/artery ratio	1.25 ± 0.2	1.21± 0.1	0.769
DES type			
Sirolimus, *n* (%)	38 (100)	54 (100)	1.000
Stent			
Stent delivery failure, *n* (%)	0 (0)	0 (0)	1.000
Mean stent diameter, mm	2.99 ± 0.10	3.14 ± 0.08	0.254
Total stent length, mm	41.21 ± 4.62	41.22 ± 3.20	0.998
Stent release pressure, atm	12.7 ± 0.6	12.6 ± 0.3	0.669
Post-dilatation			
Post-dilatation, *n* (%)	30 (78.9)	44 (81.5)	1.000
Balloon diameter, mm	3.17 ± 0.06	3.48 ± 0.11	0.073
Pressure, atm	16.0 ± 0.6	17.7 ± 0.5	0.021

BA: conventional balloon angioplasty; CB: cutting balloon angioplasty.

The final minimum stent CSA, acute lumen area gain, and relative lumen gain of CB group were greater than that of BA group (6.24 ± 0.4 mm^2 *vs.* 5.03 ± 0.33 mm^2, *P* = 0.031; 3.74 ± 0.38 mm^2 *vs.* 2.44 ± 0.29 mm^2, *P* = 0.015; 150% *vs.* 93%, *P* = 0.004). The stent symmetry and stent expansion were not different between the two groups. The immediate complications of operation, including branch vessel jail and vessel dissection, were also not different.

3.4 Clinical outcomes

Procedural success rate was 100% in both groups. No stent thrombosis was recorded during hospitalization and all patients discharged in stable condition. Target vessel revascularization occurred in one patient in two groups separately at 1-month follow-up. The MACE rate was 2.6% in BA group and 1.9% in CB group. No other MACE was recorded at 6-month clinical follow-up in both groups.
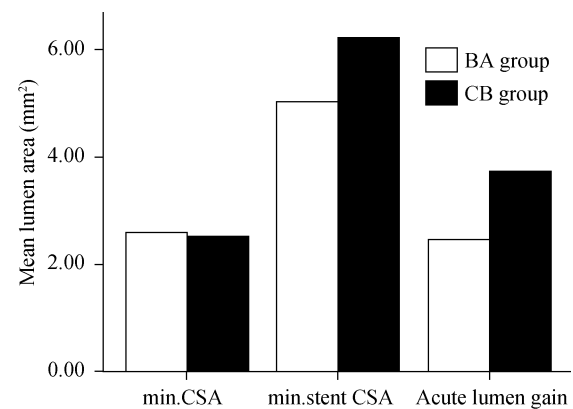

Figure 1. Lumen CSA before and after stent implantation. BA: conventional balloon angioplasty; CB: cutting balloon angioplasty; CSA: cross-sectional area.

Table 4. IVUS characteristics after stent implantation.

	BA group, *n* = 38	CB group, *n* = 54	*P* Value
Min stent CSA, mm^2	5.03 ± 0.33	6.26 ± 0.4	0.031
Reference lumen CSA, mm^2	7.33 ± 0.58	8.18 ± 0.38	0.067
Stent expansion, *n* (%)	70.86 ± 4.81	72.00 ± 2.95	0.587
Acute lumen gain, mm^2	2.44 ± 0.29	3.74 ± 0.38	0.015
Relative lumen gain, *n* (%)	93.1 ± 10.7	150.4 ± 15.2	0.004
Stent symmetry			0.171
≥ 0.7	28 (73.7)	46 (85.2)	
< 0.7	10 (26.3)	8 (14.8)	
Stent malposition, *n* (%)	8 (21.1)	10 (18.5)	0.763
Branch vessel jail, *n* (%)	4 (10.5)	4 (7.4)	0.883
Vessel dissection, *n* (%)	6 (15.8)	5 (9.3)	0.533

BA: conventional balloon angioplasty; CB: cutting balloon angioplasty; CSA: cross-sectional area; IVUS: intra-vascular ultrasound.

4   Discussion

Previous study on calcification considered calcium arc alone. Hsu, *et al*.[15] first brought calcium length ratio into the evaluation of the calcification in 2011, and proved that calcium length is the factor affecting PCI outcomes. Our study took both calcium arc and calcium length into consideration to define severely calcified lesions and randomly divided those into CB group and BA group. The average age of the patients was 61.3 years, belonging to the old, and is consistent with the previous study showing coronary calcification becoming more severe with age increase.[16] The age, sex, body mass index, diabetes mellitus, and other clinical base characteristics could match between the two groups.

In our study, the MACE rate was only 2.6% in BA group and 1.9% in CB group, which is significantly lower than the MACE rate (10.3% at 6-month follow-up) in the study conducted by Karvouni, *et al*.[12] We think that the usage of IVUS-guided is the reason why we had a lower MACE rate. The precise IVUS-guided procedure is quite important for raising the PCI success rate.[17] The low MACE rate proved the safety of cutting balloon for treatment of severely calcified lesions.

The minimum lumen CSA before stent implantation was similar. In fact, there were 7 cases firstly disposed by BA but didn't have a satisfied dilatation, and then they were changed into CB group. Therefore, we could see a more serious calcium degree in CB group. However, the final stent CSA and the acute lumen gain were significantly greater in CB group than that in BA group after PCI. This suggested that cutting balloon was efficacy for severely calcified lesions.

Song *et al*.[18] had shown that minimum stent CSA was a main predictor for in-stent restenosis. In sirolimus stent group, the minimum stent CSA predict restenosis in-stent was 5.5 mm^2, in zotaroliums eluting stent group was 5.3 mm^2, and in everolimus was 5.4 mm^2. In our study, the minimum stent CSA in BA group was 5.03 ± 0.33 mm^2, and that in CB group was 6.26 ± 0.24 mm^2. This may mean that the cutting balloon could reduce the rate of restenosis in stent, but it needs further follow-up to confirm.

Cutting balloon is a balloon catheter armed with 3–4 microsurgical blades mounted longitudinally on its outer surface. When the balloon is inflated, the blades initiate a score into the plaque. It could use lower balloon inflation pressure 11.6 ± 0.5 atm, and achieve a larger acute lumen gain. IVUS studies have shown that the mechanism of lumen gain obtained after BA consists of two major components, plaque rearrangement (fracture, compression, or redistribution) and

vessel stretching.[19] CB has been introduced as an alternative to BA to limit vessel injury and stretch by controlled cutting with the sharp metal blades, mainly splitting of the plaque, not severely squeezing plaque. The mechanism of acute lumen gain achieved by the CB is characterized by increased plaque reduction and a trend toward less vessel expansion compared to BA.[12] In calcified lesions, the acute lumen gain achieved by the CB was significantly larger with mechanisms similar to those of BA, which may be associated with the presence of gaps generated by the controlled cutting.[20]

As shown in Figure 2, it was a more than 180 degree calcification in IVUS imaging. Firstly, we used cutting balloon to split it, and 3 gaps could be seen after cutting. Then we used conventional balloon to squeeze the plaque for further pre-dilatation and implanted stent, getting a satisfied result.
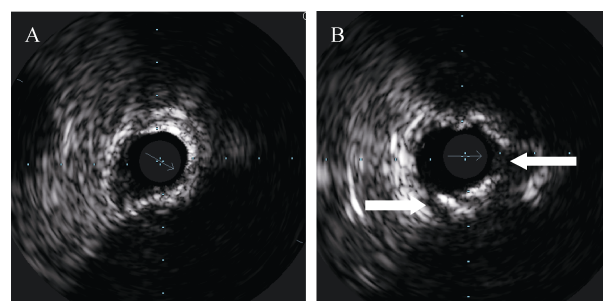

Figure 2.   The lumen before (A) and after (B) CB dilatation. The arrows showed the gap after dilatation. BA: conventional balloon angioplasty.

The success rate of conventional angioplasty in calcified lesions has been reported to be low. Calcified lesions are not only resistant to the high-pressure inflation of conventional balloon and non-compliant balloons, but the dilatation may also result in balloon rupture. In our study, 2 cases dealing with conventional balloon in which the cutting balloons were ruptured and were transferred into cutting group. In 2011 ACC/AHA guideline for PCI, for calcified lesions, the rotational atherectomy is recommended as the IIa, evidence level is C.[9] Cutting balloon is only recommended for in-stent restenosis and ostial lesions in side branches. Nowadays, DES has gradually replaced the bare metal stent, and restenosis in stent has a reducing trend. However, with population aging, the incidences of coronary calcification lesions are increasing. In our study, there were obvious advantages in using cutting balloon for increasing final stent CSA in severely calcified lesions. This study suggested that for calcified lesions, except conventional balloon, we could combine cutting balloon to obtain a better outcome. The cutting balloon may have an extended indication.

There are several limitations to be mentioned in our study. Firstly, this represented a single center study and the number of patients was relatively small. Secondly, for better evaluating for safety of cutting balloon, a longer follow-up study should be needed to confirm conclusions. Finally, conventional balloon was used after cutting balloon angioplasty to further optimize the angiographic result. The pure effect of cutting balloon is not known from this study.

In conclusion, for severely calcified lesions, we could get lager stent CSA and acute lumen gain by using cutting balloon angioplasty before DES implantation, without increasing complications during operations and the MACE rate in 6-month.

Acknowledgement

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