



Clinical Review of Efficacy and safety of balloon- assisted microdissection with MeCross CTO Balloon Dilatation Catheter 1.0 mm in balloon-uncrossable chronic total occlusion lesions

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Abstract

Objective: Earlier studies have shown that the balloon-assisted microdissection (BAM) technique is feasible using a 1 mm to 1.5 mm small balloon in balloon-uncrossable chronic total occlusion (CTO) lesions. This study was performed to assess the efficacy and safety of the BAM technique with a MeCross CTO Balloon Dilatation Catheter manufactured by Shenzhen Medoo Medical Tech. Co., Ltd. The catheter is indicated for balloon dilatation of the stenotic portion of a coronary artery or bypass graft stenosis for the purpose of improving myocardial perfusion.

Methods: In this retrospective study, patients undergoing percutaneous coronary intervention for CTO were consecutively screened for balloon-uncrossable CTO lesions using BAM with the MeCross CTO 1.0 mm balloon. The patients' clinical and angiographic characteristics and procedural outcomes were collected for analyses.

Results: Twenty-four balloon-uncrossable CTO lesions were identified. Most of the CTO lesions were located in the right coronary artery, followed by the left anterior descending artery and left circumflex artery. The mean Japanese Multicenter CTO Registry (J-CTO) and Prospective Global Registry for the Study of Chronic Total Occlusion Intervention (PROGRESS CTO) scores were 1.96 and 1.38, respectively. The total technical success rates were 91.6% (22/24) and 75.00% (18/ 24) for the lesions that were successfully treated with BAM. No patients developed major complications with the exception of one patient who developed a femoral hematoma. Conclusion: BAM with the MeCross CTO 1.0 mm balloon may be an effective and safe technique for balloon-uncrossable CTO lesions.

Keywords: BAM, CTO, Prospective Global Registry, retrospective study

Introduction

Several new techniques and equipment have recently been developed for treatment of chronic total occlusion (CTO). This has led to improvements in the effectiveness and feasibility of percutaneous coronary intervention (PCI) for CTO. Furthermore, such developments have improved the success rate of PCI for CTO, which has reached 85% to 90% in experienced centers. The inability to pass through the CTO lesion with a balloon after successful guide wire

crossing is one of the most common reasons for failure of PCI. This often occurs because of severe calcification and/or tortuosity at the occlusion site. Data from the Prospective Global Registry for the Study of Chronic Total Occlusion Intervention (PROGRESS CTO) showed that balloon-uncrossable lesions accounted for 9% of all CTOs and were associated with significantly lower technical and procedural success compared with balloon-crossable lesions³.

Balloon-uncrossable lesions are primarily treated by increasing guiding catheter support and implementing plaque modification. Balloon-assisted microdissection (BAM), also known as intentional balloon rupture or grenadoplasty, is a plaque modification technique. A 1 mm to 1.5 mm balloon is pushed deep into the CTO lesion and intentionally inflated using an increasing level of high pressure until the balloon ruptures. However, this can lead to vessel perforation or dissection and resultant problematic removal of the ruptured balloon. The mechanism of the BAM technique involves modification of the plaque by rupture of the balloon; thus, the BAM balloon should be pushed against the CTO lesion as deeply as possible. The McCross CTO 1.0 mm balloon is the smallest balloon for PCI and might be more easily inserted into a CTO lesion. In the current study, we aimed to determine the efficacy and safety of BAM using it.

Methods

This retrospective study involved patients who underwent PCI for CTO from January 2018 to January 2020 at Beijing Anzhen Hospital and Tongliao Hospital. These patients were reviewed consecutively for balloon-uncrossable CTO lesions, which were defined as CTO lesions unable to be crossed by balloons despite an increase in guiding catheter support and appropriate balloon manipulation. The study was approved by the Institutional Review Board of Beijing Anzhen Hospital in Beijing (No. 2020027X; date of approval: 3 March 2020). All patients provided con- sent for treatment, and all patients' details have been de-identified.

As part of our routine practice, once the guidewire had successfully crossed the CTO lesion, an attempt was made to advance the antegrade microcatheter by replacing the CTO wire with the workhorse wire whenever possible. When the small semi-compliant predilation balloon and/or microcatheter failed to cross the CTO lesion, small balloons (starting with a balloon diameter of 1.5 mm and ending with the McCross CTO 1.0 mm balloon) were pushed against the CTO lesions with alternating forward and backward movements with inflation up to nominal pressure. Meanwhile, augmentation of guide catheter support with guide manipulation, an anchor balloon, and/or guide catheter extension was implemented whenever possible. The BAM technique with the McCross CTO 1.0 mm balloon was applied when the above-mentioned attempts failed, before performing

other crossing techniques such as excimer laser coronary atherectomy (ELCA) or rotational atherectomy (RA). As described previously⁴, a rapid exchange McCross CTO 1.0 mm balloon was replaced and pushed deep against the CTO lesion. The balloon was inflated to high pressure at 2 atm per second until it ruptured. To prevent blood from entering the balloon catheter, negative pressure was immediately applied, followed by neutral placement. BAM using other small balloons was not attempted.

CTOs were defined as occluded coronary lesions with at least 3 months of Thrombolysis in Myocardial Infarction (TIMI) grade 0 flow. Major adverse cardiac events (MACE) were defined as a composite of all-cause death, myocardial infarction, stroke, ischemia-driven revascularization, or cardiac tamponade requiring pericardiocentesis. Moderate calcification was defined as radiopaque densities observed only during the cardiac cycle (usually involving only one side of the vessel wall). Severe calcification was defined as radiopaque densities observed without cardiac motion prior to contrast injection (usually involving both sides of the vessel wall).⁵ Intravascular ultrasound (IVUS) revealed the largest arcs of calcium in the CTO segments, measured in degrees using a protractor centered on the lumen.

Further, calcification was classified as 0 to 90°, 91 to 180°, 181 to 270°, or >270°.⁶

BAM technical success was defined as successful delivery of the balloon into the CTO immediately after BAM and <30% residual angiographic stenosis with TIMI grade 3 flow after PCI. BAM procedural success was defined as achievement of <30% residual angiographic stenosis and restoration of TIMI grade 3 flow without MACE. The Japanese Multicenter CTO Registry (J-CTO) score and PROGRESS CTO score were calculated as described previously.^{7,8} Vascular complications were defined as femoral hematomas of 5 cm, retroperitoneal bleeding confirmed by computed tomography, any access-site surgical intervention, and femoral artery pseudoaneurysm confirmed by Doppler ultrasound.⁹

Categorical variables are presented as a percentage, and continuous variables are presented as mean standardized deviation. Successful and unsuccessful BAM groups were compared using Fisher's exact test for categorical variables and the *t* test for continuous variables. The statistical tests were two-sided, and statistical significance was defined as $P < 0.05$. The

statistical analyses were performed using SPSS Version 20.0 (IBM Corp., Armonk, NY, USA).

Results

In total, 263 cases of PCI for CTO were screened, and 24 patients with 24 balloon- uncrossable CTO lesions were included in the study. The patients' clinical and angiographic characteristics are listed in Table 1. The mean age of the patients was 61.3 years, and 66.7% of

the study population was male. Conventional cardiovascular risk factors, including hypertension, diabetes, and smoking, were common among the patients, with a prevalence of 70.8%, 45.8%, and 50.0%, respectively. Most of the CTO lesions were located in the right coronary artery, followed by the left anterior descending artery and left circumflex artery. The mean J-CTO score was moderate because of the low proportion of reattempted cases.

Table 1. Patients' clinical and angiographic characteristics.

Variables	Overall (n /%)
Age, years	61.3(10.1)
Male	16(66.7)
Smoking	12 (50.0)
Hypertension	17 (70.8)
Diabetes	11 (45.8)
Prior MI	6 (25.0)
Prior PCI	5 (20.8)
CTO target Vessel	
LAD	7 (29.2)
LCX	5 (20.8)
RCA	12 (50.0)
J-C TO Score	1.9(60.96)
Blunt stump	8 (33.33)
Calcification	16 (66.7)
>45 bend	10 (41.7)
>20-mm length	10 (41.7)
Re-attempt	3 (12.5)
PROGRESSCTO Score	1.3(80.92)
Proximal Capambiguity	9 (37.5)
Tortuosity	5 (20.8)
LCXCTO	5 (20.8)
Absence of Interventional collaterals	14 (58.3)

Data are presented as mean standard deviation or n(%). MI, myocardial infarction; PCI, percutaneous coronary intervention; CABG, coronary artery bypass grafting; CTO, chronic total occlusion; LAD, left anterior descending artery; LCX, left circum flex artery; RCA, right coronary artery; J-CTO score, Japanese Multicenter CTO Registry score; PROGRESSCTO score, Prospective Global Registry for the Study of Chronic Total Occlusion Intervention score.

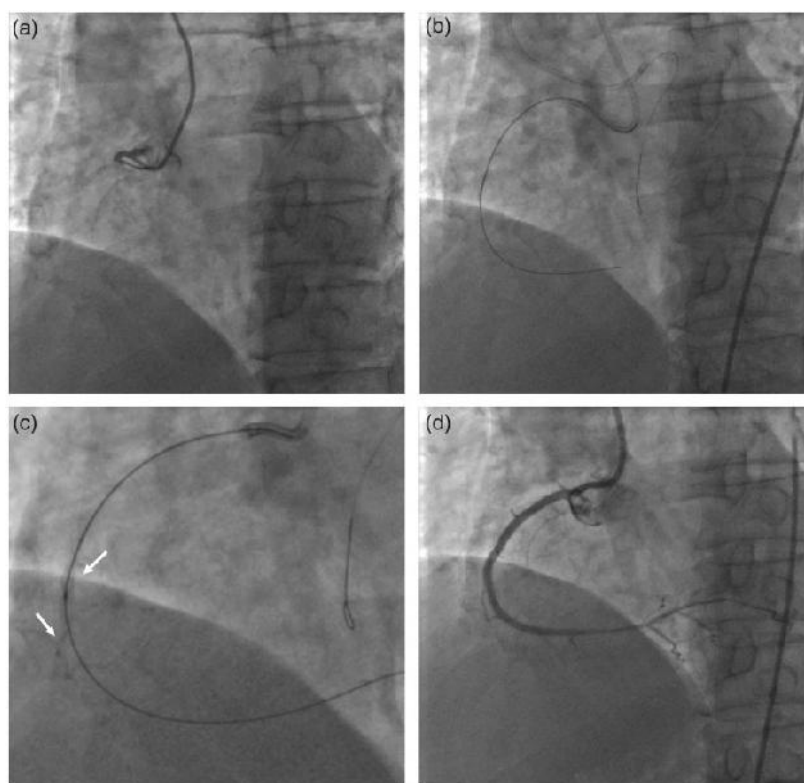


Figure 1. Uncrossable chronic total occlusion (CTO) lesion in the right coronary artery successfully treated with MeCross CTO 1.0 mm balloon using the balloon-assisted micro dissection (BAM) technique.

An angiogram indicated the CTO. (b) A small balloon still failed to cross the CTO lesion after balloon maneuvering and inflation. (c) BAM technique: rupture of MeCross CTO 1.0 mm balloon with contrast leakage (white arrows). (d) Final angiogram after recanalization.

Data are presented as mean standard deviation or n (%). BAM, balloon-assisted micro dissection; ELCA, excimer laser coronary atherectomy; RA, rotational atherectomy; MACE, major adverse cardiac event.

The patients' procedural and clinical outcomes are listed in Table 2.

Table 2. Patients' procedural and clinical outcomes.

Variables	Overall (n/424)
Approach	
Antegrade	22(91.7)
Retrograde	2 (8.3)
Fluoroscopy time, minutes	37.017.5
Radiation dose, mGy	1585920
Intravascular Ultrasound	8 (33.3)
Overall technical success	22 (19.6)
BAM technical success	18 (75.0)
Successful additional techniques	4 (16.6)
ELCA	2 (8.3)
RA	2 (8.3)
Overall Procedural success	22 (91.6)
Vascular complication	1 (4.1)
In- Hospital MACE	0 (0.0)
Coronary perforation	0 (0.0)
Cononary dissection	0 (0.0)

Successful CTO wire crossing was achieved in all patients, mostly using the ante grade approach (91.7%). The BAM technique was applied in all patients, and the technical success rate was 75% (18 of 24 cases). Wire entrapment with balloon rupture occurred in one case; the ruptured balloon and wire were simultaneously removed, and re-crossing the CTO was successful with the help of a new wire and balloon. A typical balloon-uncrossable CTO lesion in the right coronary artery is shown in Figure 1. This lesion was successfully treated using the BAM technique with MeCross CTO 1.0 mm balloon.

The other advanced techniques that were applied to the lesions failed with use of the BAM technique. Four patients underwent successful recanalization with ECLA (n 2) or RA (n 2). Despite attempting all available techniques, treatment

failure occurred in one patient. Another patient developed an uncontrolled femoral hematoma during the procedure. Neither coronary dissection nor perforation was identified using the procedure in any patients. No patients developed MACE during hospitalization.

The pressure at which the balloon ruptured was 12 atm in most cases, with the highest pressure being 20 atm (Figure 2(a)). The patients in the unsuccessful BAM group were older and most had moderate or severe calcification compared with patients in the successful BAM group (Table 3). IV US data were available for only eight patients (five in the successful BAM group and three in the unsuccessful BAM group). In the unsuccessful BAM group, the arc of calcification in IVUS was >270 (Figure 2(b)).

Table 3. Comparisons between successful and unsuccessful BAM groups

Variables	Successful BAM (n¼ 18)	Unsuccessful BAM (n¼ 6)	P Value
Age, years	59.1.9.8	68.2.7.99	0.045
Male	14 (77.8)	2(33.3)	0.129
Smoking	12 (66.7)	2(33.3)	0.192
Hypertension	13(72.2)	4(66.7)	1.000
Diabetes	7 (38.9)	4(66.7)	0.357
Prior MI	4 (22.2)	2 (33.3)	0.480
Prior PCI	3 (16.7)	2 (33.3)	0.568
Prior CABG	1 (5.6)	1 (16.7)	0.446
CTO target Vessel			
LAD	4 (22.2)	3 (50.0)	0.240
LCX	5 (27.8)	0(0.0)	/
RCA	9 (50.0)	3 (50.0)	/
J-C TO Score	1.941.06	2.000.63	/
Calcification			
None/Mild	9 (50.0)	0(0.0)	0.971
Moderate	7 (29.2)	3 (50.0)	0.041
Severe	2 (20.8)	3 (50.0)	/
Intravascular Ultrasound	5 (27.8)	3 (50.0)	/
Size of guiding catheter			
7 French	18 (100)	6(100)	/
6 French Antegrade access	0(0.0)	0 (0.0)	0.302
Radial arteries	11 (61.1)	4(67.0)	1.000
Femoral arteries	7 (38.9)	2 (33.0)	1.000
Fluoroscopy time, minutes	36.617.1	38.020.4	0.883
Radiation, mGy	1518 941	1763932	0.507

Data are presented as mean standard deviation or n(%).

BAM, balloon-assisted microdissection; MI, myocardial infarction; PCI, percutaneous coronary intervention; CABG, coronary artery bypass grafting; CTO, chronic total occlusion, LAD, left anterior descending artery; LCX, left circumflex artery; RCA, right coronary artery; J-CTO score, Japanese Multicenter CTO Registry score; PROGRESS CTO score, Prospective Global Registry for the Study of Chronic Total Occlusion Intervention score.

Table 4. Comparisons of plaque modification techniques for balloon-uncrossable CTOs.

Techniques	Number of cases	Technical success rate	Coronary perforation	Additional wiring	Additional equipment	Approximate cost (RMB)*
BAM	17	47	0	None	None	2600
Seesaw ballon- Wire cutting	17	81	0	Yes	None	3000
ELCA	58	91	3.4	None	Yes	35,000
Rotational atherectomy	45	95	0	Yes	Yes	13,00

CTO, chronic total occlusion; BAM, balloon-assisted microdis section; ELCA, excimer laser coronary atherectomy.

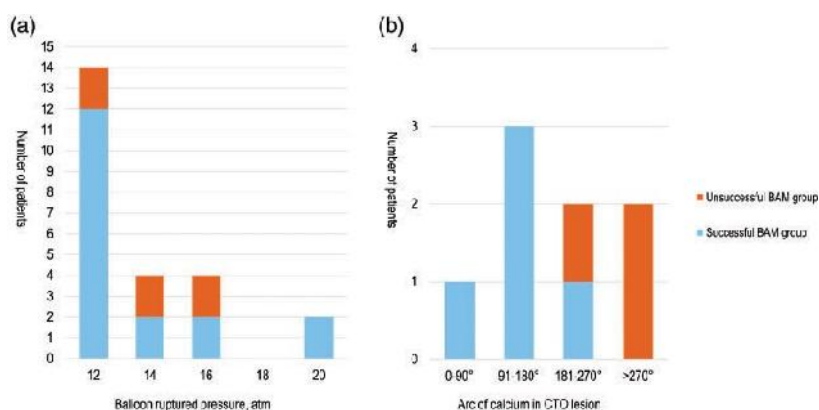


Figure 2. (a) Balloon rupture pressure in balloon-assisted micro dissection (BAM) technique. (b) Largest calcium arc in the chronic total occlusion (CTO) segment assessed by intravascular ultrasound.

Discussion

In the current study, the technical success rate of BAM with the MeCross CTO 1.0 mm balloon reached 75% without coronary dissection or perforation. Therefore, this technique is suggested to be effective and safe for patients with balloon-uncrossable CTO lesions. Patients who underwent failed treatment with the BAM technique had more complex calcified lesions than those who underwent successful treatment with BAM. The two main ways to manage balloon-uncrossable CTO lesions are augmentation of guide support and plaque modification.

Several factors are associated with guide support, including vascular access (femoral artery) and the size and shape of the guiding catheter. For most cases, however, changes in the vascular access and/or guiding catheter are not allowed once wire crossing has been successfully performed in PCI for CTO lesions. In such circumstances, application of a guide extension or anchor balloon technique serves as an efficient means to enhance guide support. Kovacic et al.¹⁰ reported that guide extension, with a procedural success rate of 89.3%, is a simple, safe, and efficacious adjunctive device for balloon-uncrossable CTO. Thus, when appropriate, the guide extension and anchor balloon technique was used for all patients prior to BAM application in the present study.

Another approach to manage balloon-uncrossable CTO is plaque modification. BAM is one of the simplest and most widely used techniques and has a high technical success rate.^{3,4} However, if BAM fails, advanced techniques such as ELCA and RA are considered for atherectomy. In the LEONARDO Study, 80 patients with 100 complex coronary lesions, including CTO lesions, were treated using ECLA.¹¹ Technical success was achieved in 90 lesions (93.7%) and procedural success was achieved in 88 lesions (91.7%), and no severe complications occurred.¹¹ Fernandez et al.¹² reported 58 cases of balloon failure in patients treated with ELCA, with or without RA. Further, the procedural success rate was 91%, with four procedure-related complications (including two coronary perforations).¹² The noteworthy advantage is the ability of ELCA to be performed over the CTO guide wires. However, ELCA may not be effective in patients with severely calcified long lesions, which is an indication for RA. Pagnotta et al.¹³ reported that in resistant CTO lesions, RA can achieve a success rate of up to 95% without increasing the risk of coronary perforation. However, although RA is highly effective in terms of crossing different types of resistant lesions, recrossing the CTO with the RA guide wire can become extremely challenging because of the need to exchange the RA guidewire.^{14,15} The seesaw balloon-wire cutting technique is another option for treating balloon-uncrossable lesions and has demonstrated favorable technical success.¹⁶ Apart from efficacy and safety, cost-effectiveness is another factor that needs to be considered when evaluating a new technique. As listed in Table 4, although the BAM technique does not provide the highest technical success rate, it is convenient, safe, and economic in treating balloon-uncrossable lesions. Thus, it should be considered as the first-line option when augmentation of guide support fails to facilitate balloon crossing.

The conventional BAM technique uses a balloon ranging in size from 1 to 1.5 mm. Although no specific data regarding the required burst pressure for rupturing the balloon have been reported, it is understood that high pressure is required to induce intentional balloon rupture. Voetal.⁴ considered the BAM technique to be safe because no complications were noted in 17 balloon-uncrossable CTO lesions. However, unintentional balloon rupture can reportedly lead to coronary dissection, perforation, balloon entrapment, and distal embolization during PCI.^{17,18} We used small balloons in the present study, and most of the balloons ruptured at a relatively low pressure (12–14 atm), providing a safe option for treating balloon-uncrossable lesions.

Our study has several limitations. First, because of the small sample size, it is difficult to identify the predictors of technical success. Second, the MeCross CTO 1.0 mm balloon was not compared with other traditional BAM balloons. Third, IVUS data were available for only one-third of the patients. Finally, this was a retrospective study with small sample size; the conclusion of the study requires confirmation in a large prospective study.

This clinical review and survey were done according to MDD 93/42/EEC and relevant guidelines MEDDEV 2.4/1 where the collected and revised clinical data and clinical review were adequate to demonstrate clinical safety and performance of MeCross CTO Balloon Dilatation Catheter manufactured by Shenzhen Medoo Medical Tech. Co., Ltd; where the review done provide sufficient clinical performance and safety based on equivalent devices with the same clinical performance and clinical safety.

Conclusion

In conclusion, BAM with the MeCross CTO 1.0 mm balloon may be considered effective and safe for patients with balloon-uncrossable CTO lesions. However, further study is required to verify this technique.

Declaration of conflicting interest

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