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The Efficacy and Safety of Drug-Coated Balloons in the Treatment of Acute Myocardial Infarction

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Abstract

The incidence of acute myocardial infarction (AMI) is increasing year by year, which seriously endangers human health around the world. The preferred treatment strategy for AMI patients is the use of drug-eluting stents (DES), as there is ample evidence to suggest that stent implantation can reduce major adverse cardiovascular events (MACEs). With the application of drug-coated balloons (DCBs) and the enhancement of the concept of interventional without implantation, the question is whether DCBs can be safely and effectively used in patients with AMI? The purpose of this study was to investigate the safety and effectiveness of DCBs in the treatment of AMI. A retrospective review of clinical data was conducted on 55 AMI patients who underwent primary percutaneous coronary intervention (PCI) from January 2020 to December 2021. Of these patients, 25 were treated with DCBs and 30 were treated with DESs. Optical coherence tomography (OCT) was used to measure the minimum lumen diameter, lumen stenosis, and coronary artery dissection before and after surgery, and angina pectoris attacks and various MACEs were recorded at 1, 6, and 12 months after surgery. The results showed that there were no significant differences in clinical baseline data between the two groups. However, the minimum lumen diameter of the DCB group immediately after the operation was smaller than that of the DES group, and the stenosis degree of the lumen in the DCB group was higher than that in the DES group. The incidence of coronary artery dissection in the DCB group was significantly higher than that in the DES group, but the majority of them were type B. At 1, 6, and 12 months after treatment, there was no significant difference in the occurrence of MACEs between the two groups. In conclusion, DCBs is a safe and effective treatment for AMI. However, the incidence of coronary artery dissection in DCB patients is higher than that in DES patients, but the majority of them are type B.

Keywords

Myocardial Infarction, Drug-Coated Balloon, Drug-Eluting Stents

1. Introduction

The preferred treatment strategy for AMI patients is the use of DES, as there is ample evidence to suggest that stent implantation can reduce major adverse cardiovascular events (MACEs). However, stent implantation has some drawbacks that need to be addressed, such as stent restenosis and early and late thrombosis in the stent. Additionally, the routine use of dual antiplatelet medication after stenting increases the risk of bleeding [1]. Late stent-associated MACEs occur between 1 and 5 years after stenting, and permanent stenting continuously impairs the diastolic function of the coronary endothelium and coronary arteries [2]. Since 2004, DCB has been in clinical use and has gained popularity. The European Society of Cardiology (ESC) guideline on myocardial revascularization recommended using DCB to treat in-stent restenosis in 2014 [3]. The primary benefit of DCB is its local antiproliferative effect. Moreover, using DCB can help avoid other side effects associated with long-term use of dual antiplatelet drugs because there is no continuous stimulation of metal polymers. Clinicians are gradually attempting to apply DCBs to AMI with skilled application and the expectation of "intervention without implantation." However, there are currently only a few related studies on the direct application of DCBs to AMI, and the majority of them are single-center studies with small sample sizes.

This study aims to compare the safety and efficacy of DCBs and DESs in acute myocardial infarction.

2. Data and Methods

The clinical data of 55 patients with acute myocardial infarction (AMI) who underwent emergency percutaneous coronary intervention (PCI) in Dalian Municipal Central Hospital from January 2020 to June 2021 were retrospectively analyzed. These patients included both ST segment elevation myocardial infarction (STEMI) and non-STEMI patients. The diagnostic criteria for AMI were based on the "Guidelines for Rapid Diagnosis and Treatment of Acute Coronary Syndrome".

The inclusion criteria were as follows: Age between 18 and 85 years old; AMI was diagnosed in the hospital, including STEMI with acute chest pain and sustained ST segment elevation, and NSTEMI with acute chest discomfort but no sustained ST segment elevation; and new lesions of the coronary artery.

The exclusion criteria were as follows: Age > 85 years or <18 years; previous history of PCI or coronary artery bypass grafting; known liver and kidney dysfunction, thrombocytopenia (platelet count $< 100 \times 10^9$/L), and other bleeding tendencies; cardiogenic shock; intracranial diseases such as space-occupying,

aneurysm, arteriovenous malformation, hemorrhagic cerebrovascular accident, ischemic cerebrovascular accident; gastrointestinal bleeding/urethral bleeding < 2 months; life expectancy < 12 months; and lesions near the left main trunk or anterior descending branch.

According to the treatment plan, the patients were divided into two groups: the DCB treatment group (DCB group, n = 25) and the DES treatment group (DES group, n = 30). Paclitaxel delivery balloons were used in the DCB treatment group, while rapamycin-coated balloons were used in the DES group. All selected patients signed an informed consent form, and the ethics committee approved the study protocol.

3. Data Gathering

General Data: Clinical data were collected from the patients using electronic medical records, including age, sex, blood pressure, blood lipids, blood sugar, hemoglobin, blood creatinine, left ventricular ejection fraction, drug use, coronary heart disease risk factors, and coronary angiography (CAG) results.

Perioperative Management: All patients diagnosed with AMI in the emergency room were given 300 mg aspirin + 180 mg tegrello or 300 mg aspirin + 300 mg clopidogrel orally. The procedure was carried out in accordance with the "China Expert Consensus on Clinical Application of DCB". Before interventional therapy, the patients in both groups completed the optical coherence tomography (OCT) examination to select the appropriate DCB and DES sizes and judge the residual stenosis, the type of interlayer, and the attachment of stents. Full prexpansion was performed before implantation of DCB. Common lesions were directly PR expanded with a cutting balloon or/and a spinous process balloon, while complex lesions were first expanded with a compliant balloon, and then gradually expanded with a Noncompliant Balloon, a cutting balloon or/and a spinous process balloon to reduce the residual stenosis. After predilation, if the blood vessel had no dissection or only type A and B dissection, the blood flow of the thrombus in myocardial infarction (TIMI) was graded as 3, and if the residual stenosis was ≤30%, a DCB was placed. A DCB with an appropriate size was released to the lesion for 60 s and then withdrawn, and the ratio of drug balloon/blood vessel diameter was 0.8 - 1.0. If severe dissection above grade C occurred during the operation, the diameter of the residual stenosis in the lumen was >30%, or if the TIMI blood flow grade was <3, DES was implanted as a remedy. In the DES group, after preexpansion, a drug-eluting stent with an appropriate size was selected according to the blood vessel condition. DES was delivered to the target lesion site and then released with appropriate pressure. The stent was then expanded with a high-pressure balloon to ensure that it was completely expanded and had adhered to the wall. Both groups of patients were treated with bivalirudin for anticoagulation during the operation (0.75 mg/kg before the operation, and then 1.75 mg/kg/h was continuously pumped until the end of the operation). Emergency PCI was only used to intervene in the respon-

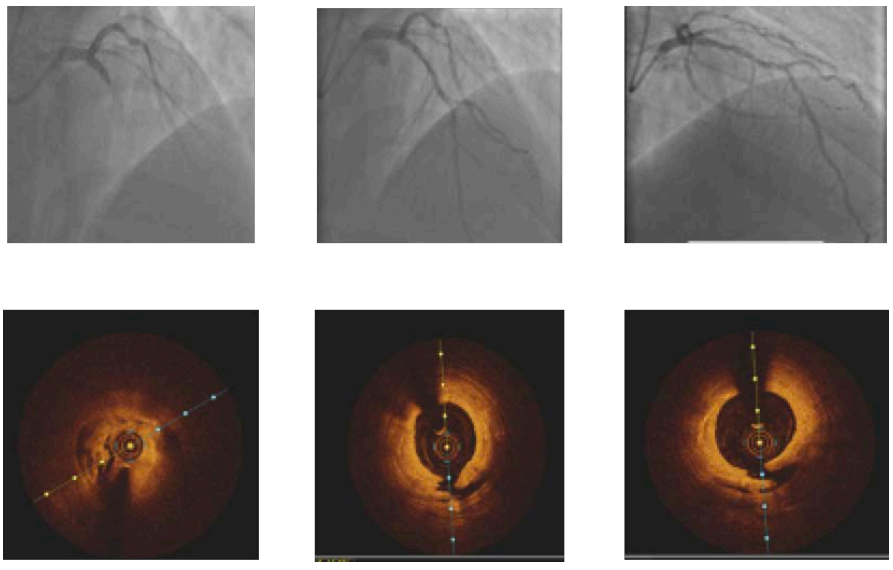
sible blood vessels, and after the operation, the patients continued to receive dual antiplatelet, statin, angiotensin converting enzyme inhibitor/angiotensin II receptor antagonist (ACEI/ARB), and beta blocker therapies and other secondary preventive drugs for coronary heart disease. Coronary angiography and OCT were reviewed 12 months later.

Follow-up and Observation: The study included the following observations: The minimum lumen diameter (MLD), stenosis degree, and coronary artery dissection were measured by OCT before and after DCB or DES. The incidence of angina pectoris and various MACEs(cardiac death, non-fatal myocardial infarction, target lesion revascularization) were recorded by telephone follow-up and outpatient records at 1, 6, and 12 months after operation, and drug treatment was provided. CAG and coronary OCT were reexamined in 8 patients in the DCB group 12 months after surgery (Figure 1). Statistical Processing: SPSS 25.0 software was used for statistical analysis. The measurement data conforming to the normal distribution were expressed as ± s. A t-test was used for comparison. The measurement data with a normal distribution are represented by the median and quartile [M (P25, P75)], and comparisons were made by the row rank sum test. The counting data were expressed as examples or percentages, and the χ^2 test was used for comparison. A P-value of less than 0.05 was considered statistically significant.

4. Results

The total number of patients was 55 (25 in the DCB group and 30 in the DES group).

General data. Clinical baseline data such as age, sex, blood pressure, blood



Note: 1A is before operation, 1B is immediately after DCB implantation, 1C is 12 after operation.

Figure 1. CAG and OCT examination data of a patient with proximal occlusion of the anterior descending branch at different times.

lipids, blood sugar, hemoglobin, serum creatinine, left ventricular ejection fraction, coronary heart disease risk factors, CAG results, intraoperative conditions, and postoperative drug use did not differ significantly between the two groups ($P > 0.05$). See Table 1.

Table 1. Comparison of baseline data of the two groups of patients.

article	Group DCB (n = 25)	Group DES (n = 30)	*P* value
AGE (age, $\bar{x} \pm s$)	65.1 ± 10.1	64.2 ± 11.7	0.76
Male [n (%)]	17 (68.0)	23 (76.7)	0.47
Hypertension [n (%)]	15 (60.0)	12 (40)	0.14
Diabetes mellitus [n (%)]	10 (40.0)	13 (43.3)	0.80
Family history of coronary heart disease [n (%)]	8 (32.0)	10 (33.3)	0.92
History of smoking [n (%)]	16 (64.0)	21 (70.0)	0.64
Systolic blood pressure (mmHg, $\bar{x} \pm s$)	124.3 ± 15.8	123.2 ± 16.5	0.80
Diastolic blood pressure (mmHg, $\bar{x} \pm s$)	78.2 ± 12.3	77.5 ± 12.0	0.83
Resting heart rate (times/min, $\bar{x} \pm s$)	75.4 ± 11.4	73.6 ± 10.8	0.55
Creatinine (μmol/L, $\bar{x} \pm s$)	74.1 ± 18.4	73.3 ± 16.7	0.87
Hemoglobin (G/L, $\bar{x} \pm s$)	136.2 ± 22.4	134.4 ± 34.8	0.78
LDL-C (mmol/L, $\bar{x} \pm s$)	3.51 ± 0.89	3.34 ± 1.08	0.53
LVEF (%, $\bar{x} \pm s$	55.7 ± 9.67	52.3 ± 10.4	0.22
STEMI [n (%)]	21 (84.0)	24 (80.0)	0.70
NSTEMI [n (%)]	4 (16.0)	6 (20.0)	0.70
Target blood vessel [example (%)]			
Left anterior descending branch	11 (44.0)	14 (46.7)	0.84
Left circumflex branch	6 (24.0)	5 (16.7)	0.50
Right coronary artery	8 (32.0)	11 (36.7)	0.80
Time from chest pain to balloon expansion (h, $\bar{x} \pm s$)	4.9 ± 3.2	5.6 ± 4.8	0.54
Number of DCB/DES ($\bar{x} \pm s$)	1.12 ± 0.96	1.43 ± 1.01	0.25
metoprolol [n (%)]	22 (88.0)	25 (83.3)	0.63
ACEI/ARB [n (%)]	23 (92.0)	28 (93.3)	0.85
Statins [n (%)]	23 (92.0)	26 (86.7)	0.53
Clopidogrel [n (%)]	11 (44.0)	9 (30)	0.28
Tirole [n (%)]	14 (56.0)	21 (70.0)	0.28

LDL-C, low-density lipoprotein cholesterol; LVEF, left ventricular ejection fraction; STEMI, ST segment elevation myocardial infarction; NSTEMI, non-ST-segment elevation myocardial infarction; DCB, drug-coated balloon; DES, drug-eluting stent; ACEI/ARB, angiotensin converting enzyme inhibitor/angiotensin II receptor antagonist.

OCT was used to measure the minimum lumen area, stenosis degree, and coronary artery dissection in both groups before and after surgery (11 patients in the DCB group had coronary artery dissection during operation, all of which were below B-type dissection, which did not affect the forward blood flow and did not require special treatment; coronary artery dissection occurred in 6 cases in the DES group, all of which were of type B or lower, with no blood flow effect and no special treatment.) Before the operation, there was no significant difference in MLD, stenosis degree, or coronary artery dissection between the two groups ($P > 0.05$). The MLD of the DCB group immediately after the operation was lower than that of the DES group ($P < 0.01$), the degree of lumen stenosis was higher than that of the DES group ($P < 0.01$), and the incidence of coronary artery dissection in the DCB group was significantly higher than that in the DES group ($P < 0.05$), as shown in Table 2.

At 1 month after treatment, the rates of cardiac death, nonfatal myocardial infarction, and target lesion revascularization were 0/25 (0), 2/25 (8%), and 1/25 (4%) in the DCB group and 1/30 (3.3%), 1/30 (3.3%), and 0/30 (0) in the DES group, respectively. At 6 month after treatment that were 1/25 (4%), 3/25 (12%), and 3/25 (12%) in the DCB group and 0/29 (0), 1/29 (3.4%), and 0/29 (0) in the DES group, respectively. At 12 month after treatment that were 1/24 (4.2%), 5/24 (20.8%), and 5/24 (20.8%) in the DCB group and 1/29 (3.4%), 3/29 (10.3%), and 2/29 (6.9%) in the DES group, respectively. There was no significant difference in the incidence of MACEs between the two groups at 1, 6 and 12 months after treatment ($P < 0.05$). See Table 3.

Table 2. Comparison of MLD, stenosis degree and coronary artery dissection between the two groups before and after the operation.

group	MLD/mm [M (P25, P75)]		Stenosis of lumen/%		Coronary artery dissection/ [n (%)]	
	Preoperative	postoperative	Preoperative	postoperative	Preoperative	postoperative
DCB group (n = 25)	0.12 (0,0.50)	2.17 ± 0.96	90.12 ± 11.22	19.86 ± 12.63	2 (8.0)	11 (44.0)
DES group (n = 30)	0.09 (0,0.79)	2.98 ± 0.55	88.45 ± 10.68	10.15 ± 4.27	3 (10.0)	5 (16.7)
P value	0.67	<0.01	0.57	<0.01	0.78	0.03

Table 3. Comparison of MACEs between DCB and DES patients at 1, 6 and 12 months after treatment [cases (%)].

group	One month after treatment			Six months after treatment			12 months after treatment		
	cardiac death	nonfatal myocardial infarction	target lesion revascularization	cardiac death	nonfatal myocardial infarction	target lesion revascularization	cardiac death	nonfatal myocardial infarction	target lesion revascularization
DCB group (n = 25)	0/25 (0)	2/25 (8.0)	1/25 (4.0)	1/25 (4.0)	3/25 (12.0)	3/25 (12.0)	1/24 (4.2)	5/24 (20.8)	5/24 (20.8)
DES group (n = 30)	1/30 (3.3)	1/30 (3.3)	0/30 (0)	0/29 (0)	1/29 (3.4)	0/29 (0)	1/29 (3.4)	3/29 (10.3)	2/29 (6.9)
P value	0.36	0.45	0.27	0.28	0.23	0.06	0.89	0.29	0.14

5. Discussion

Because stent implantation can significantly reduce ischemia, target vessel stenosis, and restenosis, it remains the preferred reperfusion strategy [4]. However, AMI patients often have factors such as endothelial cell edema, vascular spasm, and other factors that can cause changes in the actual lumen area of the coronary artery and affect stent selection [5]. In addition, stent implantation can cause damage to the endothelium and vascular wall, leading to an inflammatory response that increases inflammatory factors in the bloodstream. These increased inflammatory factors can stimulate smooth muscle cell proliferation and migration, leading to extracellular matrix formation and stent restenosis [6]. At the same time, after stent implantation, dual antiplatelet therapy must be taken regularly, which increases the risk of bleeding and the economic burden [7].

DCB is a new interventional therapy technique that, unlike traditional stent implantation, can rapidly deliver high concentrations of drugs to the coronary artery without the use of polymers and effectively addresses the various shortcomings of stent implantation and makes it a promising treatment strategy for AMI patients [8]. At the same time, compared with DES treatment, based on the active ingredients in the drug coating, it can bind to microtubule protein subunits, exerting an anti-proliferative effect by inhibiting the proliferation and migration of arterial smooth muscle cells, thereby preventing neointimal hyperplasia and restenosis. A randomized controlled study comparing the advantages and disadvantages of DCB and DES in emergency PCI, result showed that at 6 months, the incidence of major adverse cardiovascular events (MACEs) in the DCB and DES groups was 0% and 5.4% ($P = 0.29$), respectively, and that the late lumen loss of DCB was better than that of DES [(-0.09 ± 0.09) mm vs. (0.10 ± 0.19) mm [9]. The PEPCAD NSTEMI study was a randomized controlled clinical trial comparing DCBs and stents in NSTEMI patients. At 9 months, there was no significant difference in the incidence of target vessel failure and MACEs. However, 15% of the DCB group received remedial stent implantation, while 56% of the stent group received bare metal stents [10]. The REVELATION study, presented at the 2019 EuroPCR meeting, was a single-center randomized controlled trial involving 120 STEMI patients who underwent emergency PCI. The patients were randomly assigned to either the DCB or DES group, and the blood flow reserve fraction (FFR) was measured after 9 months. The results showed that at 9 months, the average FFR of the DCB group was 0.92 and that of the DES group was 0.91, achieving noninferiority ($P = 0.27$). Furthermore, there was no significant difference between the two groups in late lumen loss, reference vessel diameter, or minimum lumen diameter at 9 months [11].

The study found that DCBs are a safe and effective alternative to metal stent implantation for AMI patients undergoing emergency percutaneous coronary intervention (PCI), provided that thrombus is cleared as much as possible and coronary artery dissection is controlled below Type B without affecting blood flow. However, the study has some limitations, including a small sample size and

a short follow-up period. Additionally, it only focused on single, simple lesions and nonbifurcation lesions, limiting the scope of its application to patients who meet the DCB after lesion pretreatment requirements. Therefore, further multicenter clinical trials are necessary to evaluate the efficacy of DCBs in more appropriate lesions and increase the number of patients evaluated.

Under certain circumstances that DCBs are a safe and effective alternative to metal stent implantation for AMI patients undergoing emergency percutaneous coronary intervention (PCI).

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Conflicts of Interest

The authors declare no conflicts of interest regarding the publication of this paper.

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