

Study on the Safety and Effectiveness of Drug-coated Balloons in Patients with Acute Myocardial Infarction

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Abstract

Background Drug-coated balloon (DCB) is a new technology that has emerged in recent years, and it has been proven to be effective and safe in the treatment of restenosis in the stent. The purpose of this article is to observe the safety and effectiveness of drug-coated balloons in patients with acute myocardial infarction. **Methods:** A total of 80 patients who were admitted to our department due to STEMI from January 2018 to December 2019 were selected. The subjects were randomly divided into drug-coated balloon treatment group (balloon group, n=38) and drug-eluting stent (DES) treatment group (stent group, n=42). The patients were followed up for 1 year to understand the incidence of major adverse cardiovascular events (MACEs) at 1 month, 6 months and 1 year after operation. Coronary angiography was reexamined at 1 year after operation to understand the late lumen loss (LLL) of the two groups.

Results: At the 1-year follow-up, the target lesion LLL in the balloon group was (-0.12 ± 0.46) mm, while the target lesion in the stent group was (0.14 ± 0.37) mm ($P < 0.05$). Within 1 year, the incidence of MACEs in the balloon group was 11%, and the incidence of MACEs in the stent group was 12%. There was no significant difference between the two groups.

Conclusion: DCB therapy alone is safe and effective when PCI is performed for STEMI, and it shows good clinical results during the 1-year follow-up period.

Introduction

Percutaneous coronary intervention (PCI) for acute ST-segment elevation myocardial infarction (STEMI) can reduce the size of myocardial infarction to the greatest extent and restore the blood flow perfusion of ischemic myocardial tissue. PCI generally includes coronary stent implantation and percutaneous transluminal coronary angioplasty (PTCA). Among them, stent implantation is the preferred treatment for patients with acute myocardial infarction. Because, compared with PTCA, stent implantation can significantly reduce the proportion of revascularization required. However, due to the existence of metal implants, the risk of coronary artery thrombosis will increase for a long time after stent implantation [2]. In-stent restenosis (ISR) has become a serious complication after stent implantation [3].

Drug-eluting stent (DES) has been used as a Class I recommendation for the treatment of restenosis in many countries [4]. However, clinical studies have shown that after DES implantation in STEMI patients, the risk of late and very late thrombosis is increasing year by year. Therefore, the security of DES is questioned [5]. Different from DES, drug-coated balloon (DCB) is a new technology that has emerged in recent years, and it has been proven to be effective and safe in the treatment of restenosis in the stent [6]. DCB is a semi-compliant balloon with anti-proliferative drugs on the outside. The drug is released into the blood vessel wall at a high concentration within a very short time (30-60s) in contact with the blood vessel wall [7]. The main advantage of DCB lies in the effect of local anti-proliferative drugs. At the same time, because there is no continuous stimulation of metal polymers, there is no sustained inflammatory response and delayed healing in the lesion area [8]. In addition, in preclinical studies, the positive

remodeling effect induced by DCB can be observed, which to some extent offsets the elastic retraction of blood vessels caused by traditional balloon dilation [9]. Theoretically, the application of DCB can also avoid other adverse reactions caused by long-term use of dual antiplatelet drugs.

At present, a small number of studies [10] believe that the use of DCB for interventional therapy in coronary De Novo lesions is safe and effective. These studies suggest that the application of DCB in patients with acute myocardial infarction should be an alternative. A small sample study found that in patients with acute myocardial infarction using DCB for dilation, if late lumen loss (LLL) and restenosis were used as the end points of the study, in the 6-month follow-up, DCB alone was better than DCB + bare stent, but inferior to drug-eluting stent [10].

Therefore, in this study, the patients who were treated with DCB were followed up. LLL, restenosis, target lesion revascularization (TLR) and major adverse cardiovascular events (MACEs) were used as the end points of clinical study, and the situation of patients after 12 months was observed.

1 Methods

1.1 Subjects:

STEMI patients who were hospitalized in cardiology department of our hospital and underwent emergency PCI from January 2018 to December 2019 were selected. Inclusion criteria: ☐ Age (18-80) years; ☐ Patients diagnosed with STEMI and planned to undergo emergency PCI; ☐ The duration from onset to vascular opening ≤ 12 h; ☐ New coronary artery disease (occlusion or severe stenosis). The reference vessel diameter was (2.5-4.0) mm, and there was no severe calcification. The diagnostic criteria refer to the "Guidelines for the Diagnosis and Treatment of Acute ST-segment Elevation Myocardial Infarction" issued by the Cardiovascular Branch of the Chinese Medical Association in 2015, including continuous chest pain for more than 30 minutes, ECG elevation of two consecutive limb leads exceeding 1mV, and the chest lead elevation exceeding 2mV, cardiac damage marker CK-MB increased more than 2 times, cardiac troponin I (cTnI) exceeding the upper limit of normal value. Exclusion criteria: ☐ history of active bleeding or recent (≤ 2 months) bleeding; ☐ history of intracranial diseases (bleeding, tumor, arteriovenous malformation, stroke, aneurysm); ☐ cardiogenic shock or cardiac arrest; ☐ in stent restenosis, ☐ history of stent implantation within 6 months; ☐ participating in another clinical trial; ☐ anti-platelet and anticoagulant therapy contraindications. Patients who met the selection criteria and agreed to participate in the study were randomly divided into the drug-coated balloon treatment group (balloon group, n=42) and the drug-eluting stent treatment group (stent group, n=42) using the random number table method. All selected patients signed an informed consent form, and the research protocol was approved by the ethics committee.

1.2 Methods:

1.2.1 Preoperative routine antiplatelet and lipid-lowering stable plaque treatment:

aspirin enteric-coated tablets 300mg+ clopidogrel 600mg, atorvastatin calcium 40mg, and treatments such as blood pressure reduction and blood sugar control for underlying diseases.

1.2.2 Treatment of the DCB group:

According to the standard operation of PCI, unfractionated heparin (100 U / kg) was given intravenously for anticoagulation, radial artery or femoral artery was selected as the path, finger guide tube and guide wire were placed, and thrombus was aspirated. In the DCB group, a semi-compliant balloon was used for dilation. If the dilation reached a residual diameter stenosis of $\leq 30\%$ and there was no C-F type dissection, it was considered that the dilation was up to the standard, indicating that the patients could be treated with DES; if C-F type dissection appeared after dilation, the patients would be treated with drug-eluting stent. In the balloon group, if the thrombus load is severe, if there is no more thrombus after thrombus aspiration and balloon dilation, DCB treatment should be performed immediately during the operation. If there is still a thrombus, the TIMI blood flow can be restored to level 3, and anticoagulation should be strengthened after the operation and DCB implantation should be performed again (3-5) days after the operation. The ratio of the diameter of the drug balloon to the diameter of the normal segment of the target vessel was 1.1:1, and the ratio of the implanted stent length to the diseased segment was 1.3:1. The dilation lasted for (50-60) s under standard pressure, and the balloon coated with paclitaxel and iopromide was used. In addition, for culprit vascular target lesions, a compliant balloon should be used for pre-dilation. In order to avoid severe dissection or tearing, it is required to use the spinous process balloon or cutting balloon to dilate once again to optimize the diameter of the blood vessel at the target lesion.

1.2.3 Treatment of the DES group:

According to PCI operation specifications, all patients in the stent group should be implanted with a stent immediately during the operation. The ratio of the diameter of the implanted stent to the diameter of the normal segment of the target vessel is 1.1:1, and the ratio of the length of the implanted stent to the diseased segment is 1.3:1.

1.2.4 Postoperative anticoagulation treatment and secondary prevention:

for balloon group after operation, aspirin enteric-coated tablets 100 mg/d + clopidogrel 75 mg/d was used continuously for 6 months, and for stent group, aspirin enteric-coated tablets 100 mg/d + clopidogrel 75mg/d was used continuously for 12 months. After the operation, both groups strengthened

anticoagulation, continued to take atorvastatin calcium 20mg once/d, and actively treated underlying diseases and did a good job in secondary prevention of coronary heart disease (such as quitting smoking, reducing blood pressure, controlling blood glucose, β -receptor blockers and angiotensin converting enzyme inhibitors or angiotensin II receptor antagonists).

1.3 Observation indexes:

The patients were routinely followed up at 1 month, 6 months and 1 year after operation. The CCS grading of patients with angina pectoris was observed according to the grading standard of fatigue angina established by the Canadian Cardiovascular Society (CCS), and the major adverse cardiovascular events (MACEs) of cardiovascular death, reinfarction and target lesion revascularization were observed. Coronary angiography was reexamined one year after operation. The lumen diameter of target lesion was compared immediately after operation and one year after operation by quantitative detection system of coronary angiography (QCA), and the late luminal loss (LLL) of target lesion was evaluated. The CCS grading standards for exertional angina are: Grade I: Daily activities do not cause angina, and strenuous, fast, and prolonged physical activities cause attacks; Grade II: Daily physical activity is slightly restricted, and the restriction is more obvious after a meal or when emotionally excited; Grade III: Daily physical activity is obviously restricted. Walking 1 km on flat ground or going up one floor under normal conditions at a normal speed can cause angina attacks; Grade IV: Light activity can cause angina attacks, even when resting.

1.4 Statistical processing:

SPSS16.0 software was used for statistics and analysis of data. Measurement data is expressed by $\bar{x} \pm s$ and analyzed by t test; count data is expressed by rate and analyzed by χ^2 test or corrected χ^2 test. $P \leq 0.05$ indicates that the difference is statistically significant.

2 Results

2.1 Number of participants:

In the drug-eluting stent group (n=42), 42 cases were enrolled. In the drug-coated balloon treatment group (n=42), 4 cases developed C-F type dissection after pre-dilation, and were converted to drug-eluting stent implantation. The 4 cases were counted as shedding and 38 cases were enrolled.

2.2 Balance test between two groups:

There were no significant differences in age, gender, body mass index (BMI), time from symptom onset to first balloon dilation, target vessels of left anterior descending artery (LAD), left circumflex artery (LCX)

and right coronary artery (RCA), basic complications, left ventricular end diastolic diameter (LVEDD) and left ventricular ejection fraction (LVEF) between the two groups, as shown in Table 1.

2.3 The CCS classification of angina pectoris in the two groups:

Followed up for 1 month, 5 cases of angina pectoris were classified as CCS grade I, 2 cases were CCS grade II, 2 cases were CCS grade III, and there were no patients with CCS grade IV in the balloon group. In the stent group, there were 8 cases of CCS grade I and 3 cases of CCS grade II. There were no patients with CCS grade III or IV. There was no significant difference between the two groups. Followed up for 6 months, 6 cases of angina in the balloon group were classified as CCS grade I, 3 cases were CCS grade II, and there were no patients with CCS grade III or IV. In the stent group, 10 cases of angina pectoris were classified as CCS grade I and 2 cases were classified as CCS grade II. There were no patients with CCS grade III or IV. The comparison between the two groups was not statistically significant. Followed up for 1 year, 5 cases of angina in the balloon group were classified as CCS grade I, 2 cases were CCS grade II, and there were no patients with CCS grade III or IV. In the stent group, 8 cases of angina pectoris were graded as CCS grade I and 2 cases were graded as CCS grade II. There were no patients with CCS grade III or IV. The comparison between the two groups was not statistically significant.

2.4 Comparison of LLL between the two groups in 1 year follow-up:

There were significant differences in the diameter of target vessels and LLL between the two groups immediately after operation ($P < 0.05$), as shown in Table 2.

2.5 Comparison of MACEs between two groups of patients:

MACEs events were defined as: cardiovascular death, reinfarction or target lesion revascularization during follow-up. One month after the operation, there were no MACEs in either group. Six months after the operation, in the balloon group, 1 patient died of severe heart failure after myocardial infarction, and 1 patient received coronary angiography due to repeated angina pectoris, indicating restenosis at the target lesion, and stent implantation was performed. In the stent group, 1 case suffered re-infarction due to thrombosis in the stent of the target lesion, and was treated with DCB again. One year after the operation, in the balloon group, 1 patient died of cardiovascular disease, and 1 patient received target vessel stent implantation due to severe angina pectoris again. In the stent group, 2 patients had re-infarction and died because they did not go to the doctor in time. The re-examination showed that there were 2 patients with restenosis, accompanied by angina pectoris. These 2 patients were treated with DCB. The total number of MACEs in the balloon group was 4 cases within 1 year and the event rate was 11%, and the total number

of MACEs in the stent group was 5 cases within 1 year, and the event rate was 12%. There was no significant difference between the two groups.

3 Discussion

In acute myocardial infarction, culprit stent placement is the first choice for coronary recanalization. However, due to the acute vascular occlusion, the vascular endothelial cells are hypoxic-ischemic and edematous, combined with the presence of vasospasm and other factors, resulting in changes in the area of the coronary lumen, which will have a certain impact on the selection of stents; On the other hand, under special conditions, such as patients who are allergic to metal stents, have a bleeding tendency and cannot take double-antibody drugs for a long time, or who refuse stent placement for any other reason, how to effectively protect the culprit's vascular reperfusion? Preventing restenosis of blood vessels is a problem.

At present, DCB is a Class I recommendation in the interventional treatment of restenosis and small vessel stenosis in metal stents. The mechanism of action of DCB includes [12]: ☒ Anti-cell proliferation drugs are delivered to the target diseased vessel through balloon dilation, thereby inhibiting the intimal proliferative inflammation;☒ The blood vessel wall has uniform absorption of the drug, and the tiny drug carrier covers the blood vessel wall to ensure the continuous release of the drug; ☒ The pre-dilation of the balloon can form a micro dissection, thereby promoting the transport of the drug through the intima and dissection. With the continuous deepening of the clinical application of DCB, it has been found that DCB treatment of primary coronary lesions in situ in non-STEMI patients also has a good effect [13–14]. However, STEMI lesions secondary to plaque rupture are accompanied by varying degrees of thrombus load [15]. The presence of thrombus may affect the rapid and effective entry of DCB antiproliferative drugs into the subintima of coronary artery lesions. Therefore, for the clinical application of DCB, STEMI is a special kind of in situ disease. Internationally, there are inconsistent conclusions about the effectiveness of DCB in treating STEMI [16].

More and more evidence supports the use of DCB in coronary De Novo lesions [17]. Even if it is used in large vessels with a diameter of > 2.8 mm, it can be as safe and effective as in small vessels, but there are only few reports at present. However, there are only a few reports on the use of DCB alone in patients with acute myocardial infarction. More than 60% of ISR patients present with acute coronary syndrome, and about 10% of them have clinical manifestations of acute myocardial infarction. Small vessel disease causes a relatively small area of myocardial infarction, which is also common clinically. The obstruction of the diagonal branch, obtuse marginal branch, middle branch or right coronary artery branch can be clinically manifested as acute ST-segment elevation myocardial infarction (STEMI), and can also be manifested as non-ST-elevation myocardial infarction (NSTEMI). The value of DCB in acute myocardial infarction caused by these two diseases is still affirmative. In 2018, Professor Wu Jiongren's team published a retrospective study of 117 patients with DES in stent restenosis manifested clinically as myocardial infarction (NSTEMI89%, STEMI11%) [17], 75 cases were treated with DCB, 42 cases were re-implanted with DES. There was no significant difference between the two groups in 1-year clinical

cardiovascular and cerebrovascular major adverse events and cardiovascular mortality. Does DCB therapy have its advantages in acute myocardial infarction lesions that are not caused by the above two conditions? In theory, late stent adhesion and delayed endothelial healing after STEMI emergency interventional stent placement are more common phenomena than elective stable disease. DCB can avoid the metal left behind, reduce the late stent thrombosis and the loss of vascular motor function. DCB therapy may be able to avoid the need for long-term dual antiplatelet therapy, and may benefit more patients with high-risk bleeding.

Limited results show that with LLL and TLR as the observation indicators, DCB and bare metal stent (BMS) or DCB + BMS have the same effect, but are inferior to paclitaxel drug-coated stent (PES) [18]. Unlike patients with stable coronary heart disease, patients with acute myocardial infarction often have a large number of thrombi in the occluded blood vessels, which will affect the penetration of drugs in DCB into the blood vessel wall. Therefore, in this study, in order to remove thrombus as much as possible, vascular aspiration and intracoronary injection of tirofiban were actively used. Compared with drug-eluting stent (DES) implantation, vascular pretreatment before DCB application is more important, because dissections above type C can affect coronary blood flow, so if DCB intervention is planned, the occurrence of dissection should be prevented as far as possible or at least controlled. In order to achieve this goal, cutting balloons or spinous process balloons are used more in this study, because the above two kinds of balloons can not only effectively increase the diameter of the lumen while reducing the occurrence of severe dissection, but also can improve the blood vessel wall, thereby promoting the absorption of drugs in the intima and media [10].

In this study, there was no statistically significant difference in the CCS classification of angina between the two groups of patients in the routine follow-up at 1 month, 6 months and 1 year after operation. Cardiac color Doppler ultrasound showed that the cardiac function of the two groups improved in the 6th month and 1 year after the operation compared with the hospitalization period. The difference was statistically significant, but there was no statistical difference between the two groups, which proves the effectiveness of DCB in the treatment of STEMI. The coronary angiography was followed up 1 year after the operation. The target lesion LLL in the balloon group was (-0.12 ± 0.46) mm, while the target lesion in the stent group was (0.14 ± 0.37) mm. The difference was statistically significant. It is suggested that positive remodeling occurred in the balloon group, which may be related to more and more uniform anti-proliferative drugs delivered by the drug balloon to the tube wall [19], avoiding the "blind zone" of drug release. In addition, the absence of metal beams reduces the impact on the original vascular anatomy, maintains the vasoconstrictor response and vascular geometry, thereby reducing abnormal blood flow. In addition, during the 1-year follow-up in this study, the incidence of MACEs in the balloon group was 11%, and the total number of MACEs in the stent group within 1 year was 5 cases and the incidence of events was 12%. There was no statistical difference between the two groups. This illustrated the safety and effectiveness of DCB in the treatment of STEMI, and showed good clinical results during the 1-year follow-up period. Coronary angiography supported the above results. In summary, the application of DCB alone in STEMI patients is safe and effective.

Compared with DES treatment strategy, DCB treatment has obvious advantages. First of all, according to the current consensus of experts, it only takes 1 to 3 months to perform dual antiplatelet therapy after DCB treatment, which greatly shortens the application time of dual antiplatelet drugs, thereby reducing bleeding complications. Therefore, it is more suitable for patients with high risk of bleeding. It is likely to be a more optimized interventional treatment option for STEMI patients, and it can reduce the treatment time of dual antiplatelet drugs. Secondly, the paclitaxel of DCB has an anti-proliferation effect of smooth muscle cells and can also promote cell apoptosis. Studies have found that after the use of DCB, the vascular lumen will be enlarged during follow-up, and even coronary aneurysm-like dilation will occur [20]. The more abundant the smooth muscle of the vessel wall, the stronger the elastic retraction effect, which is one of the reasons to exclude the use of DCB in left main artery disease and proximal anterior descending artery disease. The positive remodeling of blood vessels after DCB expansion is also related to the repair of endothelial injury and the inhibition of inflammation. In animal experiments, the blood vessels treated by DCB showed that inflammatory reaction and focal fibrin deposition were obviously inhibited, while apoptosis was increased for 6 months [9]. In addition, the regression of acute endothelial cell edema during follow-up and the reduction of atherosclerotic plaques also play a role in the positive remodeling of blood vessels. Finally, the DCB strategy has another obvious benefit, that is, delayed thrombosis after DCB use is extremely rare. It is speculated that this may be related to the shorter time for DCB to reach the target lesion through the guiding catheter, because the shorter the immersion time in the blood, the less the drug eluted, as a result, the drug reaching the target lesion vessel wall increased [21].

This study suggests that in clinical practice, if patients with acute myocardial infarction cannot accept metal stent implantation, the use of DCB for expansion is an alternative, safe and effective. The premise is to remove the thrombus as much as possible and control the dissection below the AB type.

First of all, as a single-center clinical study, the number of patients enrolled is relatively small; second, although the screening of lesions in this trial is strict, the selection is singular, basically simple lesions and non-bifurcated lesions. Therefore, the scope of application of the conclusions of this study is limited. It is only applicable to patients who meet the conditions for DCB use after lesion pretreatment. In the future, multi-center clinical trials are needed to expand the number of patients in order to further evaluate the efficacy of DCB in more suitable lesions.

Abbreviations

DCB: Drug-coated balloon

DES: drug-eluting stent

MACEs: major adverse cardiovascular events

LLL: late lumen loss

PCI: Percutaneous coronary intervention

STEMI: ST-segment elevation myocardial infarction

PTCA: percutaneous transluminal coronary angioplasty

ISR: In-stent restenosis

TLR: target lesion revascularization

cTnl: cardiac troponin I

CCS: Canadian Cardiovascular Society

QCA: quantitative detection system of coronary angiography

BMI: body mass index

LAD: left anterior descending artery

LCX: left circumflex artery

RCA: right coronary artery

LVEDD: left ventricular end diastolic diameter

LVEF: left ventricular ejection fraction

STEMI: ST-segment elevation myocardial infarction

NSTEMI: non-ST-elevation myocardial infarction

BMS: bare metal stent

PES: paclitaxel drug-coated stent

Declarations

Ethics approval and consent to participate

This study was conducted in accordance with the Declaration of Helsinki and approved by the ethics committee of Xinhua (Chongming) Hospital. All selected patients signed an informed consent form.

Consent for publication

Not applicable

Availability of data and materials

The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request.

Competing interests

The authors declare that they have no competing interests

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Not applicable

Authors' contributions

Hao XJ, Huang DM conceived of the study, and Wang ZX and Zhang JC participated in its design and coordination and LiuHQ, Lu YM helped to draft the manuscript. All authors read and approved the final manuscript.

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Tables

Table 1
Comparison of general baseline data between the balloon group and the stent group

| Item | Stent group (n= 42) | Balloon group (n= 38) |
|---|---------------------|-----------------------|
| Age(years) | 56±11 | 59±11 |
| Male | 35(82%) | 30(75%) |
| BMI(/m ²) | 25±12 | 26±5 |
| Time from symptom to balloon dilation (h) | 9±1 | 9±2 |
| Target lesion | | |
| LAD | 22(50%) | 19(52%) |
| LCX | 8(18%) | 7 (19%) |
| RCA | 12(26%) | 12(31%) |
| High blood pressure | 12(26%) | 8(22%) |
| Diabetes | 15(35%) | 10(28%) |
| Family history of coronary heart disease | 11(30%) | 11(25%) |
| Smoking | 28(31%) | 24(28%) |
| LVEDD (mm) | 55±10 | 52±13 |
| LVEF (%) | 45±8 | 48±11 |
| All count data are cases (%) | | |

Table 2
Comparison of LLL at 1 year after operation between the two groups (x̄ ± s)

| Group | Immediately after operation | 1 year after operation | |
|--|-----------------------------|-----------------------------|-------------------------|
| | Target lesion diameter (mm) | Target lesion diameter (mm) | LLL (mm) |
| Stent group (36 cases) | 3.17±0.36 | 3.01±0.43 | 0.13±0.3 |
| 6 balloon group (31 cases) | 2.85±0.28 ^a | 3.04±0.55 | -0.11±0.45 ^a |
| Compared with the stent group, ^a P < 0.05 | | | |

