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Clinical Efficacy of Drug-coated Balloons Applied during Percutaneous Coronary Intervention in Patients with Unstable Angina Pectoris

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Abstract: *Objective:* To evaluate the therapeutic effect of using drug-coated balloon (DCB) during percutaneous coronary intervention (PCI) for unstable angina (UA). *Methods:* 97 patients with UA treated in the Twelfth People's Hospital of Guangzhou between August 2019 and June 2023 were selected, all of whom underwent PCI. Random number table grouping, 49 cases in the experimental group were treated with DCB during the operation; 48 cases in the reference group were treated with drug-coated stent (DSE) implantation during the operation, comparing the cardiac function indexes, prognostic indexes, quality of life scores, and adverse cardiovascular events (MACE) in the 2 groups. *Results:* There was no difference in the cardiac function indexes between the two groups when comparing preoperative and 6 months postoperative ($P > 0.05$). In the immediate postoperative period and 1 year postoperatively, there was no difference in the comparison of reference vessel diameter (RVD) and minimum lumen diameter (MLD) between the two groups ($P > 0.05$); the level of late lumen loss in the experimental group was lower than that in the reference group ($P < 0.05$). Preoperatively, there was no difference in the comparison of quality of life scores between the two groups ($P > 0.05$). At 1 year postoperatively, the quality of life score of the experimental group was higher than that of the reference group ($P < 0.05$). The incidence of MACE in the experimental group was lower than that in the reference group ($P < 0.05$). *Conclusion:* The use of DCB therapy and DSE implantation in PCI can enhance the cardiac function of patients with UA, improve the levels of RVD and MLD, and prevent luminal restenosis, improve the postoperative quality of life, and have a high therapeutic safety.

Keywords: Percutaneous coronary intervention; Drug-coated balloon; Unstable angina; Clinical efficacy

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1. Introduction

The etiology of UA is the occurrence of atherosclerotic plaques in the coronary arteries, in which unstable plaque rupture is accompanied by varying degrees of surface thrombus and vasospasm, which significantly reduces the coronary blood supply and then induces angina pectoris. The conventional treatment is PCI, which can unblock the coronary artery and reduce the risk of UA [1]. PCI mostly adopts the stent implantation method,

which is a simple operation procedure, but it will reduce the elasticity of blood vessels, affect the repair ability of blood vessels, change the haemodynamics, and increase the incidence of thrombus. Balloon dilatation is a new therapeutic method in PCI, which can fully dilate coronary arteries in a short time and protect vascular function. DCB is a drug-coated on the surface of the balloon, which can reduce the rate of cell proliferation and give full play to the effect of the drug in the endothelial part of the diseased vessel, thus preventing adverse events such as restenosis, etc. DCB does not contain a metal structure, which can inhibit endothelial proliferation and delay the growth of the smooth muscle, and has a guaranteed effect on the long-term efficacy of PCI [2]. In this study, 97 patients with UA were selected to evaluate the effect of DCB treatment during PCI.

2. Information and methods

2.1. General information

Ninety-seven patients with UA admitted to the Twelfth People's Hospital of Guangzhou between August 2019 and June 2023 were selected, and the surgical method was PCI. Random number table grouping, 49 cases in the experimental group, 27 men, 22 women; age in the range of 40–75 years old, the average (53.29 ± 5.34) years old; duration of the disease in the range of 1–5 years, the average (2.75 ± 0.36) years; comorbidities: 17 cases of hypertension and 25 cases of hyperlipidaemia. In the reference group, there were 48 cases, 29 males and 19 females; age ranged from 41 to 78 years, mean (53.72 ± 5.68) years; duration of the disease ranged from 1 to 4 years, mean (2.61 ± 0.38) years; comorbidities: 15 cases of hypertension and 23 cases of hyperlipidaemia. $P > 0.05$ when comparing the general information of the two groups.

Inclusion criteria: age < 80 years; normal liver and kidney function; vessel diameter ≤ 3 mm; normal coagulation function; relatively complete clinical data; informed and consent to the study.

Exclusion criteria: history of PCI surgery; malignant tumor; acute infection; haematological disease; mental disorder.

2.2. Methods

Prior to PCI, patients were treated with antiplatelet drugs, the specific regimen was: oral aspirin enteric-coated tablets at a dose of 300 mg, oral clopidogrel at a dose of 300 mg or Tegretol at a dose of 180 mg. Coronary angiography was performed using an angiographic machine, and multiple projection positions were used to assess the location and severity of the lesion. After the PCI surgical operation was started, the arterial sheath was accurately placed and 100 U/kg of normal heparin was injected into the arterial sheath.

In the experimental group, DCB was performed during PCI: firstly, the lesion was pretreated, and then a drug balloon was delivered to dilate the lesion, and the balloon coating drug was paclitaxel. The specifications of the drug balloon were reasonably selected according to the diameter of the blood vessel so that the direct ratio was 0.8–1.0, the dilatation pressure was 7–8 atm, and the dilatation was continued for 30–60 s. After the dilatation was completed, the drug was released within 2 min, and the coverage of the balloon was guaranteed to exceed the edge of the lesion by 2–3 mm.

In the reference group, stent implantation was carried out during PCI: the access route was radial artery access or femoral artery access; after disinfection and toweling, local infiltration anaesthesia was applied, an arterial sheath was inserted, and coronary artery angiography was carried out to clarify the location of the lesion. A microguidewire is taken and placed slowly along the catheter to reach the lesion. The diameter of the vessel was assessed and a balloon was implanted, which was withdrawn and a balloon stent was implanted after obtaining a more favorable dilatation. The diameter of the stent is 1.1:1, so that the stent arrives at the lesion and is released, and then the stent is dilated with a high-pressure balloon, with a pressure value of 12–14

mm Hg. Coronary angiography is reviewed in multiple projection positions to assess the satisfaction of stent implantation.

2.3. Observation indexes

(1) Cardiac function indexes: ejection fraction (EF), cardiac index (CI) and cardiac output (CO) were evaluated by cardiac ultrasound before and 6 months after the operation.

(2) Prognostic indicators: Immediately after the operation and 1 year after the operation, coronary angiography was carried out to measure RVD and MLD and to record late lumen loss.

(3) Quality of life scores: preoperatively and 1 year postoperatively, quality of life was evaluated using a brief health questionnaire containing 8 items including somatic pain, physiological functions, etc., all of which were scored positively out of 100.

(4) MACE: 1 year follow-up, observe the incidence of reinfarction, cardiovascular death, recurrent angina, and target lesion revascularization.

2.4. Statistical analysis

The data were processed using SPSS 28.0 software, and the measurement data were expressed as mean ± standard deviation (SD), compared and tested by *t*-value, and the count data were expressed as [*n*/%], compared and tested by χ^2-value, and if statistically significant, then $P < 0.05$.

3. Results

3.1. Comparison of cardiac function indexes between the two groups

There was no difference in the cardiac function indexes of the two groups before and 6 months after the operation ($P > 0.05$). See **Table 1**.

Table 1. Comparison of cardiac function indexes between the two groups (mean ± SD)

Subgroups	*n*	EF (%)		CI (L/min)		CO [L/(min·m^2)]	
		Preoperative	6 months after surgery	Preoperative	6 months after surgery	Preoperative	6 months after surgery
Experimental group	49	74.59 ± 5.94	87.18 ± 8.82	3.38 ± 0.45	4.16 ± 0.63	2.58 ± 0.48	4.55 ± 0.71
Reference group	48	74.51 ± 5.86	86.12 ± 8.77	3.41 ± 0.49	4.11 ± 0.58	2.61 ± 0.51	4.51 ± 0.69
t	-	0.067	0.593	0.314	0.406	0.298	0.281
P	-	0.947	0.554	0.754	0.685	0.766	0.779

3.2. Comparison of prognostic indicators between the two groups

In the immediate postoperative period and 1 year postoperative period, there was no difference in the comparison of RVD as well as MLD levels between the two groups ($P > 0.05$), see **Table 2**. The level of late lumen loss in the experimental group was (0.12 ± 0.04) mm, and that in the reference group was (0.31 ± 0.10) mm, and the comparison of the two groups was $t = 12.332$, $P = 0.000$.

Table 2. Comparison of prognostic indicators between the two groups (mean ± SD/mm)

Subgroups	*n*	RVD		MLD	
		Immediately after surgery	1 year after surgery	Immediately after surgery	1 year after surgery
Experimental Group	49	2.55 ± 0.26	2.72 ± 0.31	0.60 ± 0.12	1.99 ± 0.37
Reference Group	48	2.54 ± 0.28	2.69 ± 0.30	0.62 ± 0.14	2.04 ± 0.39
t	-	0.182	0.484	0.756	0.648
P	-	0.856	0.629	0.452	0.519

3.3. Comparison of quality of life scores between the two groups

Preoperatively, there was no difference between the quality of life scores of the two groups ($P > 0.05$). One year after surgery, the quality of life score of the experimental group was higher than that of the reference group ($P < 0.05$). See **Table 3**.

Table 3. Comparison of quality of life scores between the two groups (mean ± SD/points)

Subgroups	*n*	Physical pain		Physiological functions		General health		Physiological functions	
		Preoperative	1 year after surgery	Preoperative	1 year after surgery	Preoperative	1 year after surgery	Preoperative	1 year after surgery
Experimental group	49	51.95 ± 6.27	75.29 ± 5.87	49.82 ± 4.36	70.26 ± 4.98	55.19 ± 4.48	67.98 ± 4.76	57.33 ± 5.91	72.03 ± 6.49
Reference group	48	52.86 ± 6.33	68.11 ± 5.78	49.77 ± 4.41	65.06 ± 4.91	55.23 ± 4.50	63.12 ± 4.80	57.28 ± 5.89	68.02 ± 6.44
t	-	0.711	6.069	0.056	5.178	0.044	5.007	0.042	3.054
P	-	0.479	0.000	0.955	0.000	0.965	0.000	0.967	0.003
Subgroups	***n***	**Vitality**		**Social Functions**		**Emotional function**		**Mental health**	
		Preoperative	**1 year after surgery**	**Preoperative**	**1 year after surgery**	**Preoperative**	**1 year after surgery**	**Preoperative**	**1 year after surgery**
Experimental group	49	62.36 ± 4.99	69.75 ± 5.86	60.94 ± 5.11	73.27 ± 5.97	60.38 ± 4.81	72.11 ± 5.08	65.18 ± 4.79	79.39 ± 5.78
Reference group	48	62.27 ± 4.89	65.02 ± 5.81	60.91 ± 5.15	68.05 ± 5.91	60.27 ± 4.94	68.02 ± 5.04	65.11 ± 4.68	74.15 ± 5.16
t	-	0.090	3.991	0.029	4.327	0.111	3.980	0.073	4.707
P	-	0.929	0.000	0.977	0.000	0.912	0.000	0.942	0.000

3.4. Comparison of the incidence rate of MACE between the two groups

The incidence rate of MACE in the experimental group was lower than that in the reference group ($P < 0.05$). See **Table 4**.

Table 4. Comparison of the incidence rate of MACE in the two groups (*n*/%)

Subgroups	n	Re-infarction	Cardiovascular death	Recurrent angina	Target lesion revascularization	Incidence
Experimental group	49	0	0	1 (2.04)	1 (2.04)	4.08 (2/49)
Reference group	48	1 (2.08)	0	4 (8.33)	3 (6.25)	16.67 (8/48)
χ^2	-	-	-	-	-	4.153
P	-	-	-	-	-	0.042

4. Discussion

UA is a myocardial ischaemic disease caused by thrombosis, atherosclerotic plaque rupture or coronary artery stenosis, the pathogenesis of which is based on atherosclerotic plaques, and once the plaque fibrous cap rupture occurs, coagulation factors are released, which activate the coagulation system as well as platelets. The ruptured plaque will aggregate platelets in large quantities, releasing a variety of procoagulant factors continuously, and then forming thrombi [3]. In addition, platelet aggregation has an obstructive effect on coronary blood flow, which can induce or aggravate myocardial ischaemia. In addition, decreased vascular smooth muscle function and abnormal neural regulation can induce coronary artery spasm, increase the degree of coronary artery stenosis, and cause sudden interruption of coronary artery blood flow, leading to angina symptoms.

Stent implantation can restore coronary blood flow and correct myocardial ischaemia by mechanically expanding the narrowed blood vessels with stents, which has a better therapeutic effect. However, stent implantation is highly irritating, which can easily lead to various adverse events after the procedure [4]. DCB treatment during PCI is a new therapy for UA, which can rapidly release anti-cell proliferation drugs in the endothelium, and after dilating the stenotic area, it can make the coated drugs such as paclitaxel penetrate into the inner blood vessel through the endothelium, thus reducing inflammatory reaction and improving the PCI treatment effect. Effectiveness.

Both DCB and stent implantation can improve the cardiac function of patients with UA, which can fully dilate the coronary arteries and improve the rate of coronary artery recanalization, thereby increasing myocardial perfusion, restoring the blood flow status of myocardial tissues, and effectively enhancing cardiac function [5]. In the results, there was no difference in the cardiac function indexes of the two groups of patients when comparing the preoperative period and 6 months after the operation ($P > 0.05$). The above results are basically consistent with the findings of He Xinrong et al (2022) [8].

DCB can directly release paclitaxel drug components in the vessel wall during balloon dilatation, thereby inhibiting the excessive proliferation of vascular smooth muscle cells and preventing vascular restenosis [6]. Moreover, this therapy can increase the flow rate of coronary blood flow and maintain its patency, so it can improve the postoperative RVD and MLD levels. Stent implantation can provide a supportive structure at the stenosis, effectively expanding the stenotic artery, thereby enlarging the internal diameter of the vessel and keeping the vessel open for a long period of time, which is also conducive to the enhancement of RVD and MLD levels [7,8]. Based on this, in this study, there was no difference in the comparison of RVD as well as MLD levels between the two groups in the immediate postoperative period and 1 year postoperative period ($P > 0.05$). However, the level of late lumen loss in the experimental group was lower than that in the reference group ($P < 0.05$). This indicates that DCB can significantly reduce the chance of lumen restenosis and has high long-term efficacy.

Compared with stent implantation, DCB can significantly prevent restenosis, reduce inflammation, improve vascular elasticity, and maintain vascular patency, so patients' angina symptoms are significantly relieved and their quality of life is higher [9]. Based on this, the quality of life score of the experimental group was higher than that of the reference group 1 year after the operation in this study ($P < 0.05$). In addition, DCB using paclitaxel for drug coating, during balloon dilatation can make the drug components bound to microtubule proteins, thus blocking the process of microtubule polymerization, improving microtubule stability, and avoiding excessive migration or division of proliferating cells, which can improve the function of vascular endothelial cells and smooth muscle cells, and thus prevent MACE [10,11].

5. Conclusion

In conclusion, DCB treatment during PCI can improve cardiac function and RVD and MLD levels in patients with UA, and its therapeutic effect is not significantly different from that of stent implantation. However, DCB can reduce the risk of luminal restenosis, significantly improve patients' postoperative quality of life and is safe.

Disclosure statement

The authors declare no conflict of interest.

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