PERCUTANEOUS VASCULAR ACTIVE BALLOON PROTECTION FOR PERCUTANEOUS CORONARY INTERVENTION IN PATIENTS WITH CORONARY ARTERY BIFURCATION

Qifeng Zhang, Bin Li, Xuebo He, Hao Wang, Wenhao Chen, Junping Huang, Zhixiog Zhong*
Department of Cardiology, Meizhou People's Hospital (Meizhou HospitalAffiliated to Zhongshan University), Meizhou, China

ABSTRACT

Objective: *This paper analyses patients with coronary artery bifurcation lesions undergoing percutaneous coronary intervention (PCI) with active vascular graft protection to explore the efficacy of this technique in patients with coronary artery bifurcation lesions.*

Methods*: The surgical data of the two groups were collected and compared. The SF-36 health status questionnaire was used to evaluate the quality of life of patients before and after 6 months of follow-up. The incidence of vascular occlusion, restenosis and MACE were followed up 6 months after the operation.*

Results*: The operation time of the experimental group was 57.4±18.8 s, the amount of contrast agent was 91.6±23.7 ml, the ratio of no-reflow in the intraoperative branch was 2.00% and the number of sacral extensions in the branch was 4.00%; all these values were significantly lower than in the control group. In the control group, the corresponding values were 76.3±25.4 s, 121.5±30.9 ml, 13.04% and 23.91%, respectively (P<0.05). The quality-of-life scores of the postoperative group were significantly higher than those of the control group (P<0.05). Additionally, 6 months after the operation, the rate of restenosis of the side branch vessels was 6.00% and the incidence of MACE major events was 4.00% in the postoperative group, significantly lower than the corresponding values of 19.57% and 17.39%, respectively, in the control group (P<0.05).*

Conclusion*: The active balloon protection technique of the side branch vessels can reduce the incidence of postoperative bilateral haemorrhagic restenosis and MACE events in patients with coronary artery bifurcation lesions treated with PCI and effectively improve the quality of life and prognosis of patients, making it worthy of clinical application.*

Keywords: *Active vasculature, Protective technique, Vascular occlusion, PCI, Coronary bifurcation.*

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Introduction

Coronary bifurcation lesions may involve either a single vessel or the main branch or branch vessel. In recent years, many scholars have chosen single or double stent surgery to treat bifurcation lesions, but research on the selection criteria is lacking[1-2]. Clinically, for side branch vessels with a diameter <2.5 mm, the main branch vessel single stent technique is generally used. If necessary, the stent is implanted into the side branch. However, if the side branch vessel has lesions, placement of the stent may cause occlusion of the lateral branch vessel[3]. The side bracket balloon protection technology is a kind of side branch protection technology based on single stent technology. It can change the plaque traits and protect the side branches through the side-supporting balloon, thus reducing complications and the risk of occlusion[4]. Therefore, we selected 96 patients with coronary artery bifurcation lesions who underwent PCI in our hospital as our research subjects and assessed the treatment effect of the side-arm balloon protection technology. The results are reported below.

Materials and methods

Study Population

A retrospective analysis of 96 patients with coronary artery bifurcation lesions who underwent PCI in our hospital between May 2017 and March 2020 was performed. The patients included 62 men and 34 women aged 42-76 years (mean age 57.76±12.94 years) and were divided into a control group (n=46) and experimental group (n=50) according to the PCI operation.

The inclusion criteria were as follows:

• bifurcation lesions with vascular diameter stenosis >70% confirmed by coronary angiography and patients with collateral vessel diameter <2.5 mm[5]

• no surgical contraindications.

The exclusion criteria were as follows:

• presence of malignant tumours or life expectancy of not more than 1 year;

• patients diagnosed with coronary bifurcation lesions who needed to receive double stent treatment;

• patients with severe liver and kidney dysfunction;

• patients who could not tolerate long-term antiplatelet therapy. The study was approved by the hospital ethics committee and the patients or their family members signed informed consent forms for participation.

Treatment Method

All patients were given 300 mg of aspirin + 300 mg clopidogrel tablets 1 day before surgery. Patients routinely take 100 mg/d aspirin and 75 mg/d clopidogrel for at least 1 year after PCI surgery[5]. The patients were also given an IV bolus of 100 U/kg of heparin before surgery. The conventional radial artery requires a 6F guide catheter (0.07 in) with a lumen diameter. If necessary, the femoral artery was used. After the guide tube reached the target vessel, two run-through guide wires (0.014 in) were delivered to the main branch and branch vessels[1]. For the control group, only the guide wire was used to protect the side branch vessels and the balloon of the primary branch diseased vessel was pre-expanded; then, the stent was placed into the main branch vessel. After coronary angiography, no residual stenosis was observed in the main branch stent, no thrombus was formed, and an endometrial tear was formed. There was no residual stenosis in the branch vessel opening. There was no thrombus or intimal tear in the branch opening during expansion. Coronary artery therapy (TIMI) blood flow level 3, can meet the above conditions to end the surgery[6]. In the experimental group, the main vessel vascular balloon was pre-expanded (specification 2.5 mm × 20 mm) based on the condition of the side branch vessel disease. The balloon size is 2.0 mm × 20 mm). The capsule was pre-set in the branch vascular lesion area, and a reasonable drug-eluting stent (DES) was selected according to the size of the main branch vessel. The 4-6 atm branch balloon was slowly expanded, then the main branch stent was released and the expansion pressure was appropriately selected and expanded. After completion, the vascular balloon was withdrawn from the side and the main branch was expanded in the stent[7]. The standard of successful surgery was referenced to the control group.

Observation Index

The operation time of the two groups of patients, the amount of contrast agent, the ratio of no-reflow in the intraoperative branch, the expansion of the side branch, and the number of brackets placed in the side were assessed. The SF-36 (8) health status questionnaire was used to evaluate the quality of life before and 6 months after surgery. It consisted of eight dimensions (somatic function, physical role, overall health, vitality, body pain, social function, emotional role and mental health) with a total of 36 items. According to the scoring criteria, the initial score of each dimension was converted into a percentage system and higher scores indicated better quality of life. The incidence of vascular occlusion, branch vascular restenosis and MACE major events (including angina pectoris, myocardial infarction and cardiac death) were followed up for 6 months after the operation.

Statistical Processing

The data were processed using the statistical software SPSS v22.0. Counts are expressed as n (%) and the X^2 test was performed. The measurement data are represented as ($\bar{x}$±s) and the line test was performed to evaluate differences between groups. A P value <0.05 indicated that the difference was statistically significant.

Results

Comparison of Basic Data between the Two Groups

There were no significant differences between

the two groups in terms of age, hypertension, hyperlipidaemia, gender and coronary bifurcation lesions (P>0.05). See Table 1 for details.

Parameter		Test group (n=50)	Control group (n=46)	t/X^2 value	P value
Age (years)		56.6±13.1	58.2±12.9	0.602	0.548
Male/female		32/18	29/17	0.009	0.923
Basic illness	Hypertension	35 (70.00%)	28 (60.87%)	0.885	0.347
Diabetes		20 (40.00%)	18 (39.13%)	0.008	0.931
Hyperlipidaemia		15 (30.00%)	15 (32.61%)	0.076	0.783
Previous myocardial infarction		8 (16.00%)	5 (10.87%)	0.539	0.463
History of smoking		29 (58.00%)	23 (50.00%)	0.618	0.432
Family history		6 (12.00%)	5 (10.87%)	0.03	0.862
LVEF (%)			55.4±7.3	54.6±8.5	0.496	0.621
LDC-C (mmol/L)			3.1±0.9	3.2±0.8	0.573	0.568
Bifurcation lesion	Anterior descending branch - diagonal branch		32 (64.00%)	32 (69.56%)	0.334	0.563
	Convoluted branch		11 (22.00%)	8 (17.39%)	0.321	0.571
	Right coronary bifurcation		6 (12.00%)	7 (15.22%)	0.212	0.645

Table 1: Comparison of baseline data between the two groups (n (%) and $\bar{x}$±s)
LVEF: left ventricular ejection fraction; LDC-C: low-density lipoprotein cholesterol.

Comparison of Surgical Conditions between the Two Groups

The operation time, amount of contrast agent, ratio of no-reflow of the intraoperative branch and the number of branches and side support brackets of the experimental group were significantly lower than those of the control group (P<0.05). See Table 2 for details.

Group	Surgery time (s)	Contrast dosage (ml)	Intraoperative side branch no-reflow	Side branch	Number of side support brackets
Test group (n=50)	57.4±18.8	91.6±23.7	1 (2.00)	2 (4.00)	3 (6.00)
Control group (n=46)	76.3±25.4	121.5±30.9	6 (13.04)	8 (23.91)	8 (17.39)
t/X^2 value	4.166	5.344	4.322	8.114	3.064
P value	<0.001	<0.001	0.038	0.004	0.08

Table 2: Comparison of surgical conditions between the two groups (n (%) and $\bar{x}$±s).

Comparison of Preoperative and Postoperative Quality-of-Life Scores between Patients in Both Groups

The quality-of-life scores regarding the eight dimensions of the SF-36 questionnaire were significantly higher in the experimental group than in the control group and before treatment (P<0.05). The physical function, vitality and mental health scores of the control group were significantly higher than those before treatment (P <0.05). See Table 3 for details.

Group	Time point	Physical function	Physical role	Overall health	Vitality	Somatic pain	Social function	Emotional role	Mental health
Test group (n=50)	Preoperative	67.4±10.5	65.4±11.3	47.6±7.2	66.8±21.4	70.3±13.9	72.6±14.5	69.4±13.6	57.3±10.5
	6 months after surgery	89.5±13.8	76.4±23.1	58.3±18.2	80.6±16.2	87.6±27.3	87.5±25.7	79.9±17.1	74.8±24.3
	t value	9.012	3.025	3.866	3.636	3.993	3.57	3.398	4.675
	P value	<0.001	0.003	<0.001	<0.001	<0.001	0.001	0.001	<0.001
Control group (n=46)	Preoperative	68.1±10.3	64.9±10.4	48.2±7.9	66.7±21.5	70.6±14.5	72.1±14.8	68.7±13.3	57.1±11.2
	6 months after surgery	75.3±13.8	67.2±20.5	50.4±16.1	74.2±11.7	76.0±19.2	77.1±23.4	72.5±16.4	64.5±21.7
	t value	2.836	0.679	0.832	2.078	1.522	1.225	0.984	2.055
	P value	0.006	0.499	0.408	0.041	0.131	0.224	0.328	0.043
Comparison of t values between preoperative groups		0.329	0.225	0.389	0.023	0.103	0.167	0.255	0.09
P value		0.743	0.822	0.698	0.982	0.918	0.868	0.8	0.928
Comparison of t values between groups		5.037	2.057	2.245	2.202	2.389	2.067	2.16	2.183
P value		<0.001	0.042	0.027	0.03	0.019	0.041	0.033	0.032

Table 3: Comparison of postoperative quality-of-life scores between the two groups ($\bar{x}$±s).

Comparison of follow-up results 6 months after operation in both groups

The rates of restenosis and MACE events in the experimental group were significantly lower than those in the control group (P<0.05). See Table 4 for details.

	Vascular occlusion	Side branch vessel restenosis >50%	MACE incidence
Test group (n=50)	1 (2.00)	3 (6.00)	2 (4.00)
Control group (n=46)	5 (10.87)	9 (19.57)	8 (17.39)
X^2 value	3.217	4.031	4.604
P value	0.073	0.045	0.032

Table 4: Comparison of follow-up results 6 months after surgery in both groups (n (%)).

Discussion

Coronary bifurcation lesions refer to coronary artery stenosis involving vascular lesions of the main branch and side branch vessels[9]. Long-term clinical follow-up shows that the main manifestations of bifurcation lesions after PCI are significantly increased restenosis and revascularization rate. The technique of double stent placement is complicated, the operation and radiation exposure times are long and the cost is high. The rate of restenosis and the incidence of MACE are higher[10-11]. Therefore, the current clinical use of single stent surgery to complete coronary bifurcation lesion PCI surgery, in the treatment of coronary bifurcation lesions, often due to the main branch of the stent caused by the plaque displacement to the side branch vessels, so the side branch. If the blood vessels are not properly protected in advance, restenosis or occlusion of the side branch vessels and even slow blood flow without reflow may occur, which will cause angina, heart failure and other dangerous conditions[12-13].

The side-supporting balloon protection technique can be seriously involved in the blood flow of the side branch. When the balloon is expanded or placed into the side support, a sufficient main branch-side branch channel can be established, and the guide wire can easily enter the side branch vessel. This is useful to reduce the difficulty of treatment, shorten the operation time, improve the success rate of intervention and reduce the probability of occlusion of the side branch[14-15]. The results of this study showed that the operation time, contrast agent dosage, and no-reflow of the test group were significantly lower than those of the control group. Other studies have also pointed out that compared with the guide wire technology, the side balloon protection can shorten the operation time[16]. It is suggested that the therapeutic effect of the balloon-expanding technique is superior to that of the guide wire. The reason may be that the blood vessel wall is more elastic. If there is no reflow in the side branch after surgery, the balloon is expanded and the space expands correspondingly to establish a sufficient space for the operation to proceed smoothly.

The results of this study also showed that compared with the control group, the probability of the occurrence of MACE events and side vascular stenosis >50% in the experimental group was smaller than in the control group, which was basically consistent with the results of Meng Xiaoxue[17]. An international study also showed[18] that long-term inflation could be performed using a non-compliant balloon with a diameter within the expansion range of the device, which resolved all patient complications. All patients had a good clinical course, with no in-hospital death or myocardial infarction. It is suggested that the use of active balloon protection technology rather than wire protection technology can effectively reduce restenosis after PCI surgery[19]. The reason may be that the active balloon protection technology pre-expands the small balloon to occupy the position before the plaque is displaced. After the stent is placed, the lesion at the bifurcation opening cannot move toward the branch opening due to the plaque, ensuring that the side branch vessel blood flow is unblocked; in addition, after the main stent is implanted, if the blood flow of the side branch is not damaged, the side branch balloon can be directly withdrawn, and the probability of occurrence of the side branch vessel and the thrombus can be reduced. At the same time, the quality-of-life score of the experimental group was significantly higher than that of the control group in this study, suggesting that the PCI procedure using active balloon protection can significantly improve the quality of life after surgery.

Conclusion

In summary, the active balloon protection technique of the side branch vessels can reduce the probability of occlusion of the lateral branch vessels after PCI-treated coronary artery bifurcation lesions, improve the quality of life of patients after surgery, reduce the mortality rate of patients, and improve patient prognosis; thus it is worthy of clinical application.

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Corresponding Author:
Zhixiog Zhong
Email: k95jnk@163.com
(China)