洛和会病院医学雑誌　Vol.30：86－91, 2019

原　著

Incidence of Filter Slow flow in Patient with Acute Coronary Syndrome Using Distal Protection Device

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【Abstract】

Aim: Effectiveness of distal protection device in primary PCI has been controversial. Actually, in daily practice we sometimes experience filter slow-flow after stenting and sometimes not. So we assumed that those cases which filter slow flow occurred should be the subsets which would receive the benefits by using distal protection devices for avoiding no-flow/slow-flow in ACS circumstances.

Method: The subjects consisted of 273 consecutive ACS patients who underwent primary PCI using distal protection device (Filtrap, NIPRO) between May 2009 and January 2018.

They were divided into 2 groups depending on the occurrence of filter slow-flow after stenting; the filter slow-flow (FS) group (n=129) and no filter slow-flow (nFS) group (n=144). Patient's characteristics, lesion and procedural characteristics were analyzed between the two groups.

Results: There were no significant differences in patient characteristics regarding cardiovascular risk factors (Hypertension, Diabetes, Hemodialysis and Smoking), except dyslipidemia (65.9% vs 42.3%, $p < 0.01$). The total occlusion lesion on control CAG was significantly common in FS group than nFS group (69.8% vs 57.6%, $p < 0.05$). Moreover, the large amount of thrombus burden just after wiring were more likely found in FS group than nFS group (44.1% vs 2.1%, $p < 0.01$). The existence of calcification and tortuosity of lesion were fewer in FS group than nFS group (67.4% vs 85.3%, $p < 0.01$), which showed the lesions in FS group have more fragile atherosclerosis or thrombus. As a result, aspiration thrombectomy just after wiring (64.3% vs 27.1%, $p < 0.01$) and predilatation procedures (61.2% vs 21.3%, $p < 0.01$) were higher in FS group.

Conclusion: These results demonstrate that the selective use of distal protection device in the fragile and high thrombus burden lesion which are more likely found in FS group is the key to avoid slow flow/no reflow phenomenon and serious adverse cardiac events after revascularization.

【Introduction】

It is evident that the occurrence of distal embolization and associated slow-flow/no-reflow phenomenon after percutaneous coronary intervention (PCI) for acute coronary syndrome (ACS) result in poor prognosis. However, the effectiveness of distal protection device in primary PCI has been controversial. Actually, in daily practice we sometimes experience filter slow-flow after stenting and sometimes not. So we assumed that those cases which filter slow flow occurred should be the subsets which will receive the benefits for avoiding no-flow/slow-flow in ACS recanalization treatment.

【Methods】

Study Population

Between May 2009 and January 2018, 273 consecutive ACS patients who underwent primary PCI using distal protection device (Filtrap, NIPRO) were enrolled in this study. They were divided into 2 groups depending on the occurrence of filter slow-flow after stenting: the filter slow-flow (FS) group (n=129) and no filter slow-flow (nFS) group (n=144).

Procedures

We retrospectively analyzed the patient's clinical data, procedures and angiographic findings by two different observers. All patients were pre-medicated 200mg of aspirin and bolus injection of 5000IU heparin at ER and 5000IU of heparin intracoronary of the culprit vessel at control CAG. In addition, all patients were prescribed a loading dose of Clopidogrel or Prasugrel at ER. PCI was performed according to the standard clinical techniques with radial or femoral artery approaches. Culprit lesions were classified according to the AHA/ACC classification. Severity of lesion stenosis was divided into three categories according to percentage of stenosis on control CAG: (1) Mild; stenosis <75% (2) Moderate; Stenosis between 75 and 99% (3) Severe; stenosis >99% or Total occlusion lesion. Thrombus burden was defined as: (1) Small; Only intra luminal staining (2) Moderate; Other filling defects not associated with calcification, lesion haziness, irregularity with ill-defined borders (3) Large; Intraluminal, round filling defect, visible in two views, largely separated from vessel wall. Severity of calcification was categorized as: (1) Mild; Arterial wall calcification seen as thin line (2) Moderate; filling defect in lesion not associated with thrombus seen even before and after contrast injection (3) Severe; heavy easily seen calcification. Target lesion tortuosity was defined as (1) Mild; straight segment or only one bend of 60 degree or more (2) Moderate; two bends of 60 degree or more (3) Severe; three or more bends of 60 degree or more. Intra-arterial flow was graded as 0-3 according to the Thrombolysis in Myocardial Infarction trial (TIMI) classification. Collateral flow was graded according to Rentrop's score. After the control angiogram, 7Fr guiding catheter was used for all of the patients, and the lesion was crossed with 0.014 inch floppy guidewire. Usage of thrombus aspiration procedure was depended on each operator's choice. Then we evaluated IVUS findings in most cases except from hemodynamically unstable patients. In severe organic stenotic or calcified lesions dilatation by balloon (< 3 mm) was added. According to the IVUS finding and angiographic information, the operator deployed Filtrap. Then we implanted a drug-eluting stent.

The Basic Principle of Filtrap

Details of Filtrap (NIPRO, Japan) have already been described elsewhere. In brief, the filter is attached to the distal end of a 0.014-inch guidewire. The filter membrane is attached to half of the filter basket. The filter membrane is made of polyurethane and has approximately 1800 holes. Each hole size is approximately 100 μm, and the membrane is 40 μm thick.

Statistical Analysis

SPSS version 21.0 (SPSS Inc., Chicago, IL) was used for all analyses. Categorical data was expressed as absolute frequencies and percentage. The date was compared using a Chi Square test or Fisher's exact test, as appropriate. Continuous variables, which are expressed as the mean ± standard deviation (SD), were compared using either an unpaired Student's t-test or the Mann-Whitney U test. A p value of < 0.05 was considered statically significant.

【Results】

Baseline Demographic

Filter slow-flow occurred in 129 patients (Table 1). Although there were no significant differences in other basic background of patient's characteristic between two groups, patients in the FS group showed significantly higher LDL cholesterol level at admission than those in the n-FS group.

Lesion Characteristics

The morphological characteristics of the lesions in two groups are shown in Table 2 and Table 3. As for pre-procedural angiographic finding, target lesions were more common in RCA and LAD than LCX and target segment were detected in proximal and mid segments more than distal segments, which were no significant differences in both groups. Regarding the lesion characteristics, total occlusion lesion on control CAG was common in FS group than nFS group (69.8% vs 57.6%, $p < 0.05$). In addition, the FS group had significantly larger amount of thrombus burden just after wiring compared with nFS group (44.1% vs 2.1%, $p < 0.01$). In FS group, mild calcified lesions were significantly higher than nFS group (85.3% vs 67.4%, $p < 0.001$). On the other hand, the lesions with moderate calcification in FS group were less than nFS group (9.3% vs 22.9%, $p < 0.01$)

Table 1. Baseline patient characteristics

Variable	Total (n = 273)	FS group (n= 129)	n-FS group (n= 144)	P value
Age (years)	70.2 ±12.1	70.1±11.9	70.3±12.3	0.89
Males	213(78.1%)	105(81.3%)	108(75.2%)	0.24
Hypertension	175(64.1%)	78(60.1%)	97(67.2%)	0.25
Diabetes Mellitus	101(37.0%)	51(40.3%)	50(35.1%)	0.45
Smoking	132(48.4%)	62(48.1%)	70(49.3%)	1.00
Hemodialysis	10(3.7%)	3(2.1%)	7(5.3%)	0.34
Dyslipidemia	80(29.3%)	51(65.9%)	29(42.3%)	<0.01*
Systolic Blood ressure (mmHg)	146.7±29.3	144.1±29.7	149.1±28.8	0.53
LVEF (%)	53.8±12.2	51.7±11.6	55.7±12.6	0.12

Continuous data is presented as mean ± standard deviation; categorical data is presented as a number (%)
LVEF left ventricular ejection fraction

Table 2. Pre-procedural morphological characteristics of target vessels

Variable	Total (n = 273)	FS group (n= 129)	n-FS group (n= 144)	P value
Lesion Location				
LAD	120(43.1%)	58(45.1%)	62(43.4%)	1.00
LCX	14(5.1%)	6(4.8%)	8(5.2%)	0.41
RCA	139(51.2%)	65(50.1%)	74(51.4%)	0.76
Target Lesion Segment				
Proximal (Seg.1, 5, 6, 11)	147(53.8%)	71(55.0%)	76(52.8%)	1.20
Mid (Seg.2, 7, 9, 12, 13)	115(41.1%)	52(40.4%)	63(43.8%)	1.21
Distal (Seg.3, 4, 8)	11(4.1%)	6(4.6%)	5(3.4%)	1.00

Categorical data is presented as a number (%)

Table 3. Lesion characteristic on CAG

Variable	Total (n = 273)	FS group (n= 129)	n-FS group (n= 144)	P value
% Stenosis Control CAG				
<75%	46(17.0%)	16(12.4%)	30(20.1%)	0.17
75-99%	54(19.7%)	23(17.8%)	31(22.2%)	0.33
100%	173(63.3%)	90(69.8%)	83(57.6%)	<0.05
Thrombus Burden just after wiring				
Small	150(55.0%)	45(34.9%)	105(72.9%)	<0.01
Moderate	63 (23.1%)	27(21.0%)	36(25.0%)	0.42
Large	60 (21.9%)	57(44.1%)	3(2.1%)	<0.01
Calcification				
Mild	207(75.8%)	110(85.3%)	97(67.4%)	<0.001
Moderate	45(16.5%)	12(9.3%)	33(22.9%)	<0.01
Severe	21(7.7%)	7(5.4%)	14(9.7%)	0.33
Target Lesion Tortuosity				
Mild	178(65.2%)	75(58.1%)	103(71.5%)	<0.05
Moderate	60(21.9%)	39(30.2%)	21(14.6%)	<0.05
Severe	35(12.8%)	15(11.6%)	20(13.9%)	1.00

Continuous data is presented as mean ± standard deviation; categorical data is presented as a number (%)

Procedural Characteristics

Regarding procedural characteristics, there were no significant differences in predilatation balloon size (2.8 ± 0.6 mm vs 2.9 ± 0.5 mm, p=0.54), stent diameter (3.4 ± 0.4 mm vs 3.4 ± 0.3 mm, p=1.0) and stent length (25.1 ± 7.0 mm vs 24.4 ± 6.4 mm, p=0.23) between both groups. (Table 4) Moreover, there was also no significant difference in single stent procedure (75.9% vs 82.7%, p=0.24) and multiple stent procedure (24.1% vs 17.3%, p=0.45) between both groups (Table 4). The rate of thrombus aspiration just after wiring were significantly higher in FS group than nFS group (64.3% vs 27.1%, p <0.01). In addition, the rate of predilatation with balloon (POBA) was significantly higher in FS group than nFS group (61.2% vs 24.3%, p <0.01).

【Discussion】

In comparison with lesions found in stable coronary artery diseases, coronary lesions responsible for acute coronary syndromes (ACS) consists of disrupted plaques with superimposed thrombus, and disrupted plaques which tend to have larger necrotic cores and greater plaque inflammation (1). Distal embolization of thrombus or atheromatous gruel from epicardial culprit lesion is common in ACS and might be further triggered by percutaneous coronary interventions (PCIs) (2, 3). Factors that increase the risk of distal embolization which in turn manifest as slow/no reflow phenomenon include PCI to lesions containing large amounts of friable atheroma, PCI to culprit lesions containing thrombus responsible for ACS, and use of atherectomy. (4-6). According to this study, the patients with dyslipidemia were higher in FS group. So these patients had more chance of slow/ no flow after procedure for ACS. In the lesion characteristics, total occlusion lesion on control CAG and lesion with

Table 4.Procedural Characteristics

Variable	Total (n = 273)	FS group (n= 129)	n-FS group (n= 144)	P value
Predilatation balloon size(mm)	2.9±0.5	2.8±0.6	2.9±0.5	0.54
Stent diameter (mm)	3.4±0.4	3.4±0.4	3.4±0.4	1.00
Stent Length(mm)	24.8±19.4	25.1±7.0	24.4±6.4	0.23
Number of Stent				
One stent	217(79.4%)	98(75.9%)	119(82.7%)	0.24
Two or More Stents	56(20.6%)	31(24.1%)	25(17.3%)	0.45
Aspiration Thrombectomy Just after wiring	122(44.6%)	83(64.3%)	39(27.1%)	<0.01
Predilatation (POBA)	114(41.7%)	79(61.2%)	35(24.3%)	<0.01

Continuous data is presented as mean ± standard deviation; categorical data is presented as a number (%)

large thrombus burden just after wiring were higher in FS group than nFS group. In addition, the existence of calcification and tortuosity of lesions were fewer in FS group than nFS group. These results indicate the lesions in FS group have fragile massive atherosclerosis and thrombus. As result, aspiration thrombectomy just after wiring and predilatation procedures by POBA were used frequently in FS group.

The effectiveness of distal protection device in primary PCI has been controversial so far. That is because those population have wide variations in both patient background and lesion character background. So, we need to select the patients who would get more benefit of distal protection device. Our study was retrospective study from single center experience, however it could be a milestone for the beneficial use of distal protection devices in primary PCI.

【Limitations】

This study has several potential limitations. First this study was a retrospective single-center experience in a limited number of patients. Second, we cannot analyze lesions morphologies in all patients by IVUS study because of hemodynamic instability in some patients. However, even under these conditions, we can exhibit that the fragile atherosclerosis, totally occluded lesions and large thrombus burden lesions in dyslipidemia patients were associated with high frequency of filter slow flow during the procedure.

【Conclusion】

This study demonstrated the patients, lesions and procedural characteristics that increase the risk of distal embolization by mean of filter slow flow. So, selected use of distal protection device in these patients and lesion categories are important during revascularization procedure in primary PCI.

【Acknowledgments】

A part of this work was presented at the 27th Annual Meeting of the Japanese Association of Cardiovascular Intervention and Therapeutics.

【Conflicts of Interest】

The authors report no financial relationships or conflicts of interest regarding the content herein.

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