One Year Results of Fractional Flow Reserve Guided Percutaneous Coronary Revascularization in Central Chest Institute of Thailand

Krittaporn Pumchand, MD[1], Thamarath Chantadansuwan, MD[1], Kriengkrai Hengrassamee, MD[1]

[1]Division of Cardiology, Central Chest Institute of Thailand.

Abstract

Background: The angiographic visual estimation may under or overestimate the degree of lesion stenosis. This can lead to a wrong treatment such as unnecessary revascularization. Fractional Flow Reserve (FFR) is used to assess angiographic intermediate coronary lesions and could be useful for guiding revascularization decisions.

Objective: To identify the outcomes of FFR guided percutaneous coronary revascularization in Central Chest Institute of Thailand (CCIT).

Methods: A single-centered prospective cohort study enrolled patients with coronary arterial disease who undergone a FFR measurement between August 31, 2011 and April 30, 2013. The patients were divided into three groups, FFR less than 0.75, FFR 0.75 to 0.80, and FFR greater than 0.80. All patients with FFR less than 0.75 underwent percutaneous coronary intervention (PCI). All the patients with FFR greater than 0.80 were deferred PCI. The interventionist decided to perform or defer PCI on the patients with FFR 0.75 to 0.80. The primary end point were the rate of major adverse cardiac events (MACE), which was considered a composite of death recurrent myocardial infarction, any repeat revascularization, stroke, or congestive heart failure within a follow-up of at least six months.

Results: One hundred thirty three patients were eligible. The median follow-up time was 11.7 months (Range 6.05-24.03 months). Ninety-four percent of the patients were in the Canadian Cardiovascular Society (CCS) Angina class I or II . The most common clinical presentation was chronic stable angina (87.2%). Forty-five patients underwent PCI, of which 38 patients underwent PCI with drug-eluting stents (DES). There were no significant difference in the rate of MACE between groups of FFR smaller than 0.75, FFR 0.75 to 0.80 with PCI, FFR 0.75 to 0.80 with deferred PCI, and FFR greater than 0.80. (7.4 vs. 11.1 vs. 16.7 vs. 2.4, p=0.094). The cost of materials in PCI group were higher than deferred PCI group (140,000 vs. 45,000 Baht, p<0.001). The Kaplan-Meier event-free survival show the worst outcome in the group of FFR 0.75 to 0.80 who deferred PCI (one-year event free=78.8%, p=0.257).

Conclusion: There was no significant difference between the three groups of FFR (FFR smaller than 0.75, FFR0.75 to 0.80, and FFR greater than 0.80) in term of MACE. There was no significant difference in the subgroup of FFR 0.75 to 0.80 PCI or deferred PCI either. However, the patients in the group of FFR 0.75 to 0.80 with deferred PCI had a trend to have the worst one-year event-free survival. In summary, the use of FFR measurement to assess the intermediate lesion will decrease the unnecessary PCI.

Keywords: Fractional flow reserve, PCI, Intermediate coronary lesion

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Introduction

The limitations of coronary angiography for determination of lesion severity have been well described, especially in an intermediate lesion. Angiographic visual estimation may under- or over-estimate the degree of lesion

stenosis. This can lead to a wrong treatment such as unnecessary revascularization. As we know, performing percutaneous coronary intervention (PCI) on non-ischemic stenosis is not beneficial and is probably harmful[1,2].

In the past decades, many devices, such as Fractional Flow Reserve (FFR), Intravascular ultrasonography (IVUS), and Optical coherence tomography (OCT) were developed to assess the true picture of anatomical or functional stenosis in this type of lesion.

Fractional Flow Reserve (FFR), a pressure-derived index that was developed in 1990s, has been used during coronary angiography to assess the potential of a coronary stenosis. According to the 2011 ACCF/AHA/SCAI Guideline for Percutaneous Coronary Intervention, FFR is used to assess angiographic intermediate coronary lesions (50% to 70% diameter stenosis) and can be useful for guiding revascularization decisions [3].

The correlation of ischemic stress testing with FFR values of less than 0.75 has been established in numerous comparative studies with high sensitivity (88%), specificity (100%), positive predictive value (100%), and overall accuracy (93%)[4]. The data from DEFER study has shown that the 5-year outcome for patients with medical therapy based on an FFR greater than 0.75 were superior as compared with PCI[5]. Therefore, FFR may reduce the need for revascularization. Conversely, FFR-guided PCI, as compared with the best medical therapy alone, decreased major cardiac adverse event (MACE) in patients with FFR equal or less than 0.80[6]. In case where the value of FFR measurement is between 0.75 and 0.80, it is still a grey zone for decision [7]. We still do not know what is the best cut-point value between 0.75 and 0.80 for FFR guided PCI. Thus, this group of patients is one of target group in our study.

Central Chest Institute of Thailand (CCIT) has been performing FFR during Coronary angiography since August 31, 2011. However, the data of the results in these groups of patients have never been evaluated. Therefore, we conducted this study to identify the outcome of FFR guided percutaneous coronary revascularization in CCIT, including the group of FFR value between 0.75 and 0.80.

Methods

The study design was prospective, single-centered cohort study that was conducted in Central Chest Institute of Thailand. The study protocol was approved by ethics committee of the hospital.

Study protocol

We enrolled the patients with stable coronary arterial disease, unstable angina, and Non-ST Elevation Myocardial Infarction (NSTEMI) who underwent an FFR measurement procedure during coronary catheterization between August 31, 2011 and April 30, 2013. The indication to perform an FFR measurement depended on the interventionist to consider which one was an intermediate lesion. Patients who had undergone previous PCI or CABG could be included in the study. FFR was measured with a coronary pressure guidewire (VOLCANO PrimeWire Guide Wire) at maximal coronary hyperemia induced by intracoronary adenosine. FFR is calculated as the mean distal coronary pressure (measured with the pressure wire) divided by the mean aortic pressure (measured simultaneously with the guiding catheter) during maximal coronary hyperemia.

The patients were divided into three groups according to FFR smaller than 0.75, FFR 0.75 to 0.80, and FFR greater than 0.80. All patients with FFR smaller than 0.75 underwent percutaneous coronary intervention (PCI). All patients with FFR greater than 0.80 were deferred PCI. The treatment of the patients with FFR 0.75 to 0.80 was decided by the interventionist, to perform or defer PCI.

End points and follow-up

The primary end point was the rate of major adverse cardiac events (MACE) within the period of follow-up of at least six months. MACE was defined as a composite of death, recurrent myocardial infarction (MI), any repeat revascularization, stroke, or congestive heart failure (CHF). The secondary end point included functional class as assessed with the use of the Canadian Cardiovascular Society classification system and the cost of materials in catheterization laboratory.

After discharge, a follow-up assessment was performed approximately one month. Then the further follow-up schedule was judged by the doctor at the out-patient department (OPD). If the patient discontinues the follow up at the OPD, the investigator will make a contact by phone.

Statistical analysis

The categorical data (i.e. sex, underlying diseases) were presented as the frequency and percentage. The numerical data (i.e. age and LVEF) were presented as mean±S.D. (if normal distribution) or median minimum and maximum (if skewed distribution)

The One-Way ANOVA was used to compare mean values for quantitative variables and Chi-square test or Fisher's exact test was used to compare qualitative variables. The rates of freedom from MACE were constructed according to Kaplan and Meier and compared with the Breslow's test. Differences were considered statistically significant at a level of $P < 0.05$. All statistical analyses were done with SPSS for Windows, version 17.0.

Results

One hundred thirty seven patients who performed FFR between August 31, 2011 and April 30, 2013 were enrolled. Four patients were excluded because the data record form of FFR was lost for one patient, unsuccessful FFR measurement caused by the side effect of bradycardia after adenosine injection for two patients, and the FFR measurement was not performed before PCI, but performed after PCI for one patient. Finally, there were 133 patients in this study. The median follow-up time was 11.7 months (Range 6.05-24.03 months).

All baseline characteristics between the three groups of patients were not different (Table 1). The mean ages of patients were 62.7±9.7 years. Most patients were male (72.9%). Ninety-four percent of the patients were in the Canadian Cardiovascular Society (CCS) Angina class I and II. Forty-four percent of the patients had diabetes. The most common clinical presentation was chronic stable angina (87.2%). Nevertheless, 15 patients (11.3%) presented with NSTEMI. The mean of LVEF was 59.6±12.8% and 90 patients (67.7%) had LVEF greater than 55 %. The mean of creatinine was 1.0±0.2 mg/dl. Almost all patients had taken Aspirin (95.5%) and Statin (98.5%).

Forty-five patients underwent PCI, of which 38 patients underwent PCI with drug-eluting stents (DES), four patients with Bare-metal stents (BMS), and three patients with Plain old balloon angioplasty (POBA). The numbers of stents used per patient were 1.38±0.54. The mean of total stent length was 27.88±0.42mm. The mean of stent diameter was 3.00 ±0.42mm. (Table 2.)

By visual estimation, eight (6%) and nine patients (6.8%) had less than 50 % and more than 70% lesion stenosis, were, respectively. The interventionist considered to perform the FFR in this group of patients.

Eleven patients had Left main (LM) disease. Nine of them received FFR at the LM lesion. Everyone had FFR value of greater than 0.75.

The most common lesion that had FFR performed was proximal Left anterior descending artery (LAD) (33.8%) and the second most common was mid LAD (31.6%). Most patients were induced maximum coronary hyperemia during FFR measurement by intracoronary adenosine. Only one patient used intravenous infusion adenosine technique.

In the group of FFR 0.75 to 0.80, 18 patients underwent PCI and six patients were deferred PCI. These decisions were made by an interventionist. Only one patient had CV death. This patient was in the group of FFR 0.75 to 0.80 who was deferred PCI. (Table 3.)

There were no significant difference of the rate of MACE between groups of FFR smaller than 0.75, FFR 0.75 to 0.80 with PCI, FFR 0.75 to 0.80 with deferred PCI, and FFR greater than 0.80. (7.4 vs. 11.1 vs. 16.7 vs. 2.4, p=0.094). In addition, there was no significant difference in CCS improvement (22.2 vs. 50.0 vs. 33.3 vs. 37.8, p=0.27), respectively.

All patients with FFR 0.80 had an event-free from all cause of death, recurrent MI, and repeat revascularization. However, one patient had CHF and the other one had an ischemic stroke in this group.

Table 1. Baseline characteristics

	Total (n=133)	FFR			p-value
		<0.75 (n=27)	0.75-0.8 (n=24)	>0.8 (n=82)	
Demographic data					
Age-yr	62.7±9.7	62.9±10.9	61.5±9.3	63.0±9.4	0.788
Gender-no. (%)					0.282
Male	97 (72.9)	21 (77.8)	20 (83.3)	56 (68.3)	
Female	36 (27.1)	6 (22.2)	4 (16.7)	26 (31.7)	
Angina classification -no. (%)					0.117*
class I-II	125 (94.0)	23 (85.2)	23 (95.8)	79 (96.3)	
class III-IV	8 (6.0)	4 (14.8)	1 (4.2)	3 (3.7)	
Diabetes-no. (%)	59 (44.4)	13 (48.1)	13 (54.2)	33 (40.2)	0.437
Hypertension-no. (%)	112 (84.2)	25 (92.6)	21 (87.5)	66 (80.5)	0.325*
Dyslipidemia-no. (%)	126 (94.7)	27 (100.0)	23 (95.8)	76 (92.7)	0.413*
Smoking-no. (%)					0.368*
Current	13 (9.8)	1 (3.7)	3 (12.5)	9 (11.0)	
Quit	55 (41.4)	14 (51.9)	12 (50.0)	29 (35.4)	
Previous PCI-no. (%)	77 (57.9)	18 (66.7)	14 (58.3)	45 (54.9)	0.560
LVH-no. (%)	44 (33.1)	7 (25.9)	8 (33.3)	29 (35.4)	0.664
Clinical Manifestation-no. (%)					0.491*
Stable angina	116 (87.2)	22 (81.5)	23 (95.8)	71 (86.6)	
Unstable angina	2 (1.5)	0 (.0)	0 (.0)	2 (2.4)	
NSTEMI	15 (11.3)	5 (18.5)	1 (4.2)	9 (11.0)	
LVEF-%	59.6±12.8	61.0±12.7	59.5±12.1	59.1±13.2	0.592
<30%-no. (%)	4 (3.0)	1 (3.7)	0 (.0)	3 (3.7)	
30-45%-no. (%)	16 (12.0)	2 (7.4)	5 (20.8)	9 (11.0)	
45-55%-no. (%)	23 (17.3)	7 (25.9)	3 (12.5)	13 (15.9)	
>55%-no. (%)	90 (67.7)	17 (63.0)	16 (66.7)	57 (69.5)	
Laboratory					
Creatinine (mg/dl)	1.0±0.2	1.0±0.2	1.1±0.3	1.0±0.2	0.173
LDL (mg/dl)	99.0±28.3	102.1±22.5	107.2±32.5	95.6±28.4	0.725
Hematocrit (%)	39.0±4.0	39.5±4.3	38.7±4.2	38.9±4.0	0.795
Medication-no.(%)					
Aspirin	127 (95.5)	27 (100.0)	22 (91.7)	78 (95.1)	0.337*
Clopidogrel	93 (69.9)	22 (81.5)	17 (70.8)	54 (65.9)	0.306
Beta-blocker	94 (70.7)	19 (70.4)	18 (75.0)	57 (69.5)	0.873
Nitrate	94 (70.7)	18 (66.7)	14 (58.3)	62 (75.6)	0.230
Statins	131 (98.5)	27 (100.0)	24 (100.0)	80 (97.6)	1.000*
ACEI/ARB	88 (66.2)	15 (55.6)	17 (70.8)	56 (68.3)	0.415
Spironolactone	9 (6.8)	3 (11.1)	2 (8.3)	4 (4.9)	0.483*
Trimethazidine	5 (3.8)	2 (7.4)	0 (.0)	3 (3.7)	0.544*

*Fisher's exact test

Table 2. Results of coronary angiography

	Total (n=133)	FFR		
		<0.75 (n=27)	0.75-0.8 (n=24)	>0.8 (n=82)
Stenosis- no(%)				
<50%	8 (6.0)	0 (0)	2 (8.3)	6 (7.3)
50 - 70%	116 (87.2)	20 (74.1)	21 (87.5)	75 (91.5)
>70%	9 (6.8)	7 (25.9)	1 (4.2)	1 (1.2)
Number of diseased vessel-no.(%)				
SVD	34 (25.6)	3 (11.1)	5 (20.8)	26
(31.7)				
DVD	43 (32.3)	13 (48.2)	6 (25.0)	24 (29.2)
TVD	45 (33.8)	9 (33.3)	10 (41.7)	26 (31.7)
LM+DVD	6 (4.5)	0 (0)	3 (12.5)	3 (3.7)
LM+TVD	5 (3.8)	2 (7.4)	0 (0)	3 (3.7)
Lesion Location				
Proximal RCA	8 (6.0)	2 (7.4)	2 (8.3)	4 (4.9)
Mid RCA	14 (10.5)	2 (7.4)	3 (12.5)	9 (11.0)
Left main	9 (6.8)	0 (.0)	2 (8.3)	7 (8.5)
Proximal LAD	45 (33.8)	14 (51.9)	7 (29.2)	24 (29.3)
Mid LAD	42 (31.6)	6 (22.2)	8 (33.3)	28 (34.1)
Distal LAD	2 (1.5)	1 (3.7)	1 (4.2)	0 (0)
Proximal LCX	8 (6.0)	2 (7.4)	1 (4.2)	5 (6.1)
Mid LCX	5 (3.8)	0 (0)	0 (0)	5 (6.1)
Maximum dose of adenosine-no.(%)				
IC <200 µg	34 (25.5)	18 (66.6)	12 (50.0)	4 (4.9)
IC 200 µg	78 (58.6)	7 (25.9)	7 (29.2)	64 (78.0)
IC > 200 µg	20 (15.0)	2 (7.4)	4 (16.7)	14 (17.1)
IV 140 µg/kg/min	1 (0.8)	0 (0)	1 (4.2)	0 (0)

Table 3. Results of clinical outcome

	PCI		Defer PCI		p-value
	<0.75 (n=27)	0.75-0.8 (n=18)	0.75-0.8 (n=6)	>0.8 (n=82)	
MACE	2 (7.4)	2 11.1)	1 (16.7)	2 (2.4)	0.094*
CV death	0	0	1	0	
Recurrent MI	0	1	0	0	
Any revascularization	2	0	0	0	
CHF	0	0	0	1	
Ischemic stroke	0	1	0	1	
CCS improvement**	6 (22.2)	9 (50.0)	2 (33.3)	31 (37.8)	0.272*

*Fisher's exact test

**CCS improvement compared between CCS at the day that performed FFR and at the day that last follow-up.

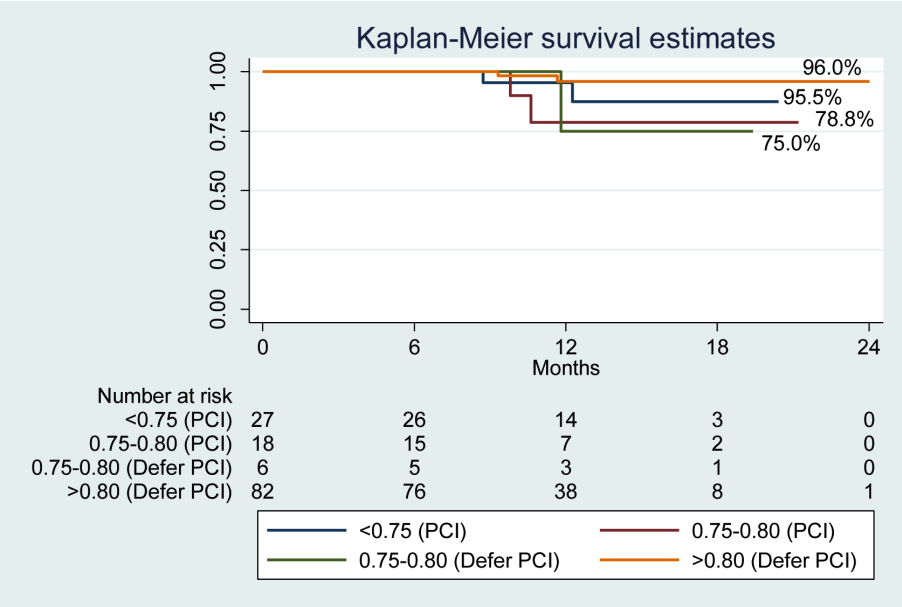
The figure 1 shows no significant difference of event free survival between all groups of FFR, even if they underwent PCI or deferred PCI.

However, the patients in the group of FFR 0.75 to 0.80 who deferred PCI had a trend to have the worst one-year event-free survival.

Discussion

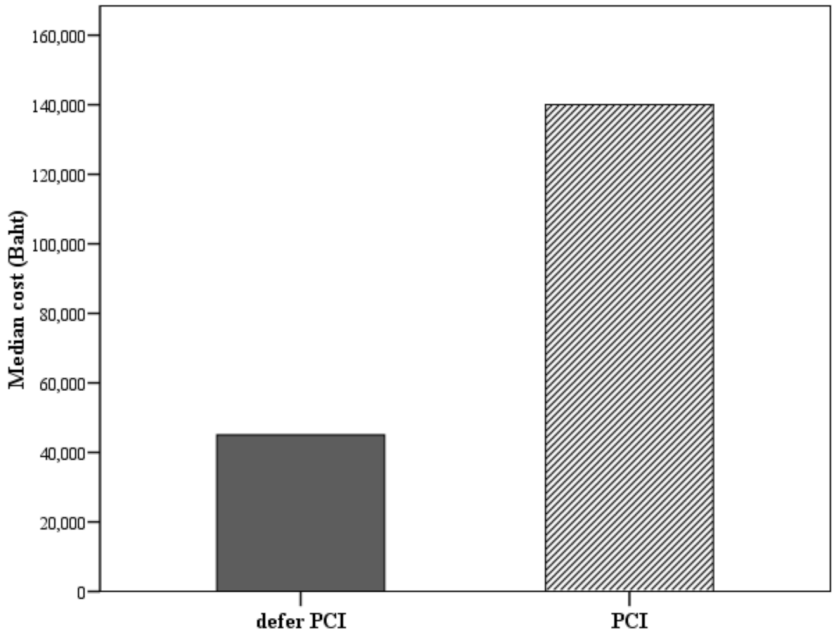
The results of this study showed no significant difference of event-free survival between all groups of FFR, even if they underwent PCI or deferred PCI. However, the patients in the group of FFR 0.75 to0.80 who deferred PCI

Figure 1.: The Kaplan-Meier percentage event-free survival



p-value=0.257 (Breslow's test)

Figure 2.: The cost of materials between PCI and deferred PCI



The cost of materials in PCI group were higher than deferred PCI group (140,000 vs. 45,000 Baht, p<0.001).

had a trend to have the worst one-year event-free survival. If there were enough sample size in this study, it may have shown a statistical significance. When we focused especially on the patients with a grey zone of FFR (FFR 0.75 to 0.80), this result can imply that we probably prefer to perform PCI over deferred PCI. Just like the results from the previous study[8] that compare between PCI and deferred PCI in the group of FFR 0.75 to 0.80, the PCI group had a lower rate of MACE. Therefore, the cut-point of FFR to perform PCI should be 0.80, not 0.75. However, there were some contradicting results of the other study that showed the better outcome in the patients who deferred PCI in FFR 0.75 to 0.80 than performed PCI[9]. Therefore, a large randomized control trial should be conducted in these groups of patients to find out the real cut-point of FFR.

There were MACE events in this study as compared with the previous study[2]. The reason maybe 1) the short follow-up time, which was only six to 24 months, And 2) the patients in this study had lower risk features than the other study, for example, most of patients had normal LVEF and serum creatinine.

The results of our study showed that no significant difference in the anginal class (CCS) among all groups of FFR, regardless of PCI or deferred PCI. It may be because most patients in this study had little symptom (CCS I or II 94%) before performing FFR. Therefore, after performing FFR, the symptom may not show a significant improvement. The cost of materials in PCI group is so much higher than deferred PCI group, and it helps confirm the concept that FFR guided deferred PCI is very useful in terms of saving.

Limitations

This study had some limitation. First, the study design was a cohort study, thus there are many confounding factor and some missing data. Second, some patients discontinued follow-up at the OPD or the doctor referred them to another hospital. We contacted them by phone to follow-up, which could have missed some information. There was no MACE in 20 patients who lost to follow-up. Third, our study involved too small sample size to demonstrate the different outcome between each group. Forth, we mainly induced the maximum coronary hyperemia during FFR measurement by the intracoronary adenosine, which is not a standard recommendation. Furthermore, many patients in our study had DM and LVH. Therefore, it could affect the results of FFR by inadequate maximum coronary hyperemia. Fifth, the period of follow-up was too short. Hence, MACE occurred very rarely. Nevertheless, this study can provide preliminary data of the results of FFR in CCIT.

Conclusion

There were no significant differences between the three groups of FFR (FFR smaller than 0.75, FFR0.75 to 0.80, and FFR greater than 0.80) in term of major cardiac adverse event (MACE). In the subgroup of FFR 0.75 to 0.80, there was no significant difference between PCI and deferred PCI either. However, in deferred PCI group, it tends to have the worst one-year event-free survival. This information can imply that this group may have a better outcome if they are performed with PCI. Nevertheless, the large, randomized control trials should be conducted in these groups of patients to find out the real cut-point of FFR.

FFR guided deferred PCI can save the cost of procedure in catheterization laboratory. In addition, we still can use FFR measurement as the standard guideline recommendation for guided PCI in routine practice.

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การศึกษาผลลัพท์การใช้ Fractional flow reserve ในการชี้นำการสวนขยายหลอดเลือดหัวใจในสถาบันโรคทรวงอก

กฤตพร พุ่มจันทน์, พบ.[1], ธรรมรัฐ ฉันทแดนสุวรรณ, พบ.[1], เกรียงไกร เฮงรัศมี, พบ.[1]

[1]กลุ่มงานอายุรศาสตร์หัวใจ สถาบันโรคทรวงอก

บทคัดย่อ

ที่มาการศึกษา: การประเมินการตีบของหลอดเลือดหัวใจด้วยสายตา อาจมีความคลาดเคลื่อนได้ ซึ่งจะนำมาสู่การรักษาที่ผิดพลาดตามมา ในปัจจุบันมีการนำเครื่องมือ Fractional flow reserve (FFR) มาใช้เพื่อช่วยประเมินและตัดสินใจในการพิจารณาสวนขยายหลอดเลือดหัวใจ โดยเฉพาะในรอยโรคที่มีการตีบระดับปานกลาง

วัตถุประสงค์: เพื่อศึกษาผลลัพท์การใช้ Fractional flow reserve ในการชี้นำการสวนขยายหลอดเลือดหัวใจในสถาบันโรคทรวงอก

วิธีการวิจัย: เป็นการศึกษาแบบ Prospective cohort study โดยเก็บข้อมูลจากผู้ป่วยโรคหลอดเลือดหัวใจ ที่มารับการทำ FFR ทุกคนในสถาบันโรคทรวงอก ตั้งแต่วันที่ 31 สิงหาคม พ.ศ. 2554 ถึง 30 เมษายน พ.ศ. 2556 ทำการแบ่งผู้ป่วยออกเป็น 3 กลุ่มตามค่า FFR ได้แก่ FFR<0.75, FFR0.75-0.80 และ FFR>0.80 โดยกลุ่มที่มีค่า FFR<0.75 จะได้รับการสวนขยายหลอดเลือดหัวใจทั้งหมด ในกลุ่มที่มีค่า FFR>0.80 จะไม่ได้รับการสวนขยายหลอดเลือดหัวใจ ส่วนในกลุ่มที่มีค่า FFR0.75-0.80 ซึ่งเป็นกลุ่มที่ค่าอยู่ในช่วง Borderline การพิจารณาสวนขยายหลอดเลือดหัวใจจะขึ้นอยู่กับดุลยพินิจของแพทย์ ที่ทำ FFR ครั้งนั้น โดยผลลัพท์การศึกษาจะดูอัตราการเกิด major adverse cardiac events (MACE) ซึ่งเป็นผลรวมของ death, recurrent myocardial infarction, repeat revascularization, stroke และ congestive heart failure และจะทำการติดตามผู้ป่วยเป็นระยะเวลาอย่างน้อย 6 เดือน

ผลการวิจัย: มีจำนวนผู้ป่วยในการศึกษาทั้งหมด 133 คน ค่ามัธยฐานของระยะเวลาการติดตามผู้ป่วยอยู่ที่ 11.7 เดือน ผู้ป่วยส่วนใหญ่เป็นผู้ป่วย Chronic stable angina ร้อยละ 87.2 โดยไม่มีความแตกต่างกันในอัตราการเกิด MACE ระหว่างกลุ่มที่ FFR<0.75, FFR 0.75-0.80 ที่ได้รับการสวนขยายหลอดเลือดหัวใจ, กลุ่มที่ FFR 0.75-0.80 ที่ไม่ได้รับการสวนขยายหลอดเลือดหัวใจ และ กลุ่มที่ FFR>0.80 (7.4 vs. 11.1 vs. 16.7 vs. 2.4, p=0.094) กราฟ Kaplan-Meier event-free survival แสดงให้เห็นถึงกลุ่มที่ FFR 0.75-0.80 ที่ไม่ได้รับการสวนขยายหลอดเลือดหัวใจ มีแนวโน้มที่แย่ที่สุด อยู่ที่ร้อยละ 78.8% (p-=0.257) และค่าใช้จ่ายในกลุ่มที่ได้รับการสวนขยายหลอดเลือดหัวใจ สูงกว่ากลุ่มที่ไม่ได้รับการสวนขยายหลอดเลือดหัวใจอย่างชัดเจน (140,000 vs. 45,000 บาท, p<0.001)

สรุป: ไม่มีความแตกต่างกันของกลุ่ม FFR ทั้ง 3 กลุ่ม (FFR<0.75, FFR0.75-0.80 และ FFR>0.80)ในแง่อัตราการเกิด MACE แต่ในกลุ่มย่อยที่มีค่า FFR0.75-0.80 ที่ไม่ได้รับการสวนขยายหลอดเลือดหัวใจมีแนวโน้มที่จะมีผลลัพท์ไม่น่าพึงพอใจ ดังนั้นการใช้ FFR มาเพื่อช่วยประเมินรอยโรคที่มีการตีบระดับปานกลาง จะช่วยลดการสวนขยายหลอดเลือดหัวใจโดยไม่จำเป็นลงได้

คำสำคัญ: Fractional flow reserve, PCI, Intermediate coronary lesion