Fractional Flow Reserve Guided Coronary Revascularization in Drug-Eluting Era in Thai Patients with Borderline Multi-Vessel Coronary Stenoses

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Background: *Previous studies have shown the cost benefit of fractional flow reserve (FFR) - guided coronary revascularization in the patient with multivessel borderline coronary artery stenoses. However, they have been performed in the Bare-metal stent era. It is a challenge to demonstrate the benefit of the FFR-guided coronary revascularization in the patient with multivessel coronary disease (MVD) in the drug-eluting era in Thai patients.*

Material and Method: *Forty-nine patients with MVD (71 stenotic vessels) underwent FFR-guided revascularization (FFR group) compared with forty-nine patients with MVD (79 stenotic vessels) underwent traditional PCI (Traditional group) on the basis of visual estimation of the stenotic lesion. PCI has been performed in the FFR group patient with FFR value $\leq$ 0.75, whereas those with FFR value $\geq$ 0.75 continued on medical treatment. The event rates of chest pain, repeat revascularization, hospitalization, myocardial infarction and death were compared between both groups. Total costs incurred in the catheterization laboratory, including the cost of stent, balloon, pressure guide wire, contrast media and other supplies, were computed between both groups.*

Results: *In FFR group: in 46 vessels, FFR was 0.87 $\pm$ 0.06 and PCI was avoided, the other 25 vessels, baseline FFR was 0.65 $\pm$ 0.09 and were underwent PCI. Two patients proceed CABG. In the traditional PCI group: 79 vessels were underwent PCI. In comparison of event free survival between the FFR and the traditional PCI groups during follow-up (mean follow-up 8.27 $\pm$ 5.45 vs. 9.49 $\pm$ 5.39 months), they were not different in MACE, chest pain, repeat revascularization, hospitalization, myocardial infarction and death (8.2% vs. 13.3%, p = 0.33). The average total cost saving per patient was 63,290 Baht (p < 0.001).*

Conclusion: *For patients with borderline MVD, FFR-guided coronary revascularization with drug eluting stent placement could save a total cost per patient at 63,290 Bath without compromising safety.*

Keywords: *Fractional flow reserve (FFR), Intermediate, Borderline coronary stenosis, Drug-eluting, Multivessel*

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Coronary revascularization is being performed based on visual estimation of coronary stenosis. However, angiographic estimation using quantitative coronary angiogram has shown to be a poor predictor of functional significance of a stenosis especially in an borderline coronary stenosis (stenosis 50-70%)[1,2,7-10,12-14]. Fractional flow reserve (FFR) measurement is a useful index for determining the functional severity of a borderline coronary stensosis. Bech et al has demonstrated that in a patient with chest pain referred for PTCA of intermediate coronary stenosis, deferral of the intervention on the basis of a FFR > 0.75 is safe. In this study, only four target vessels related coronary events occur out of one-hundred patients at 18 months follow-up[3,5,6,11]. In the patients with multivessel coronary artery disease, the use of fractional flow reserve guided selective coronary revascularization has a greater event free survival rate of 89% at 30 months as compare to traditional multivessel coronary artery stenting of 59% at 30 months[4]. Significant adverse events in the traditional multivessel coronary artery stenting group contributed to repeat revascularization. This may be because many patients for whom coronary revascularization was based on angiographic assessment may not have truly had functionally significant stenosis. Receiving unnecessary coronary

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stenting leads to in-stent restenosis and repeat coronary revascularization. However, the prior study has been performed in the bare metal stent era. It is a challenge to evaluate the benefit of the FFR-guided coronary revascularization when compared with angiographic guided coronary revascularization in drug-eluting era in Thai patients.

Objective

Primary Objective

To compare the outcome of major adverse cardiac events (MACE), death, myocardial infarction and revascularization, between the group receiving of FFR-guided coronary revascularization and traditional coronary revascularization with drug-eluting stent in treatment of borderline coronary stenosis.

Secondary Objective

To evaluate the cost-effectiveness between these two groups.

Material and Method

This is a retrospective cohort review of patients with coronary artery diseases who underwent coronary revascularization at Faculty of Medicine Siriraj Hospital between November 2005 and November 2007. Patients were included in this study if their coronary angiography showed multivessels coronary disease (MVD) with at least one vessel had borderline (50-70%) stenosis. The severity of coronary stenosis was based on operator's visual estimation and assisted by Quantitative Coronary Angiography (QCA). The patients were excluded if there had been coronary revascularization by bare metal stent, angiographic involvement of left main disease, history of prior coronary bypass graft or myocardial infarction within 6 weeks. This study was not a randomized trial. The patients will be enrolled if they have met inclusion and exclusion criteria. The decision to do FFR measurement before stenting or not was depend on operator's discretion.

The patients with MVD with at least one vessel which had borderline (50-70%) stenosis will then divided into two groups: the first group as the FFR-guided revascularization group (the decision to performed coronary revascularization with drug eluting stent placement based on physiologic assessment by FFR of those borderline coronary stenoses with FFR ≤ 0.75 who will undergo coronary intervention (PCI) with drug-eluting stent, whereas those with FFR ≥ 0.75 will have deferred revascularization and continue medical therapy) and the second group as the traditional PCI group (the decision to performed coronary revascularization with drug eluting stent placement of that borderline stenosis is based on angiographic assessment either by visual estimation or quantitative coronary angiogram). Institutional Review Board approved the study.

Fractional Flow Reserve (FFR)

FFR was calculated during hyperemia by intracoronary administration of adenosine (13-14) (36 to 42 mg in the left coronary artery and 18 to 24 mg in the right coronary artery) as FFR = Pd (the distal coronary pressure)/Pa (the aortic pressure), as described previously (1,5).

Quantitative Coronary Angiography (QCA)

Quantitative coronary angiography performed by using the contrast-filled distal guiding catheter for calibration. The angiographic projection with the most severe diameter narrowing without foreshortening was used for analysis of stenosis severity. Minimal lumen diameter (MLD), reference lumen diameter, and percent diameter stenosis (%DS) were determined using a validated, edge detection software (QCA-CMS, version 5.2, CMS-MEDIS).

Follow-up and Clinical Events

The patients' data were collected and reviewed from OPD card and cardiac catheterization reports. The investigators contacted patients within their admission period and routine follow-up at PCI clinic (or contacted them by telephone) at 1,3,6,12,18, 36 month after PCI. Also the medical records of those suffering events was examined. Major Adverse Cardiac Events (MACE) are defined as death, myocardial infarction, revascularization by CABG or PCI and readmission because of unstable angina and recurrent angina. Myocardial infarction diagnosed when two of these three criteria are met: prolonged (> 30 min) chest pain, CK-MB and Troponin-T elevation above the normal limit, or development of new Q waves.

Maximum duration of the follow-up of these clinical events was at 36 months before data analysis. Total costs incurred in the catheterization laboratory including the cost of stent, balloon, pressure guide wire, contrast media and other supplies in both groups will be calculated and compared.

Statistical Analysis

For continuous variables: age, LVEF, number

of diseased vessel, minimal lumen diameter, length of lesion, percent vessel stenosis (by QCA), number of vessels angioplasty, number of stents, number of balloon angioplasty, total duration, duration of fluoroscopy, duration of procedure, amount of contrast media; unpaired t-test were used to compare two means from independent groups. The correlation between FFR value and % vessel stenosis by QCA was investigated using Pearson coefficients (Pearson's r). For categorical variable: sex, hypertension, diabetes, hypercholesterolemia, history of family history of CAD, smoking status; the differences between groups were examined using Chi-square test.

For survival analysis: Event-free survival curve for MACE was estimated using the Kaplan-Meier method, and statistical differences between curves were assessed by the log-rank test.

P-value < 0.05 was considered significant. Data analysis performed by using the SPSS version 11 for Windows (SPSS Inc., an IBM, Chicago, Illinois, USA).

Results

Ninety-eight patients were enrolled according to strictly inclusion and exclusion criteria as described above. Forty-nine patients who had coronary revascularization with drug eluting stent placement based on physiologic assessment by FFR were assigned as FFR-PCI group. The other 49 patients had coronary revascularization with drug eluting stent placement based on coronary angiogram, either QCA or visual estimation and were assigned to the Traditional-PCI group. The baseline clinical and angiographic characteristics were similar in both groups (Table 1).

Procedural data

In FFR-PCI group (71 vessels were evaluated for significant functional stenosis with FFR); baseline FFR was 0.87 ± 0.06 in 46 vessels and PCI was avoided. The other 25 vessels, baseline FFR was 0.65 ± 0.09 and were underwent PCI. Two patients underwent

Table 1. Baseline Characteristics of the patients

Characteristic Clinical	FFR-PCI (n = 49)	Traditional-PCI (n = 49)	p-value
Age-yr	67.79 ± 8.8	66.10 ± 10.2	0.38
Male sex-no. (%)	31 (63.3)	27 (55.1)	0.54
History-no./total no. (%)			
Family H/O CAD n (%)	7/49 (14.3)	3/49 (6.1)	0.32
Hypertension n (%)	42/49 (85.7)	40/49 (81.6)	0.79
Diabetes n (%)	28/49 (57.1)	19/49 (38.8)	0.11
Hypercholesterolemia n (%)	42/49 (85.7)	44/49 (89.8)	0.76
Current smoking-no./total no. (%)	7/49 (14.3)	8/49 (16.3)	0.78
LVEF (%)	62.15 ± 13.58	63.42 ± 13.21	0.69
Angiographic			
No.of diseased vessels-no./total no.(%)			0.80
2	31/120 (63.3)	34/116 (69.4)	
3	14/120 (28.6)	12/116 (24.5)	
4	4/120 (8.2)	3/116 (6.1)	
Minimal Lumen Diameter (mm)	1.35 ± 0.5	1.33 ± 0.3	0.79
Reference Lumen Diameter (mm)	2.52 ± 0.6	2.63 ± 0.5	0.22
Length of lesion (mm)	11.76 ± 5.8	10.97 ± 5.8	0.42
% vessel stenosis (by QCA)	48.4 ± 14.3	49.1 ± 8.8	0.73
Procedural			
No.of vessels angioplasty	0.65 ± 0.7	1.59 ± 0.6	< 0.001
No.of stents	0.63 ± 0.7	1.84 ± 0.9	< 0.001
No.of ballon angioplasty	0.8 ± 0.3	0.10 ± 0.3	0.73
Total duration (min)	78.0 ± 24.9	78.1 ± 20.3	0.98
Duration of fluoroscopy (min)	18.3 ± 8.6	19 ± 9.2	0.69
Duration of procedure (min)	59.6 ± 19.3	59.1 ± 16.7	0.88
Amount of contrast media (ml)	128.3 ± 43.2	154.2 ± 48.3	0.006

CABG. In the traditional PCI group: 79 vessels were all underwent PCI. Comparing FFR-PCI and traditional-PCI group, FFR guided revascularization resulted in less number of coronary vessels that needed to be revascularized (Table 1). The rate of balloon angioplasty (0.65 ± 0.66 vs. 1.59 ± 0.61, p < 0.001), and number of drug eluting stent used (0.63 ± 0.73 vs. 1.84 ± 0.85, p < 0.001) were less in FFR-PCI group. The amount of dye used was lower in FFR-PCI as compared to a traditional PCI (128.27 ± 43.16 vs. 154.18 ± 48.28, p = 0.006). There were similar in number of total time, duration of fluoroscopy and duration of procedure between both groups. The correlation between FFR value and % vessel stenosis by QCA was also analyzed and exhibited, indicated a moderately inverse correlation as shown in Fig. 4 (r = -0.6, p < 0.001).

Clinical Outcome

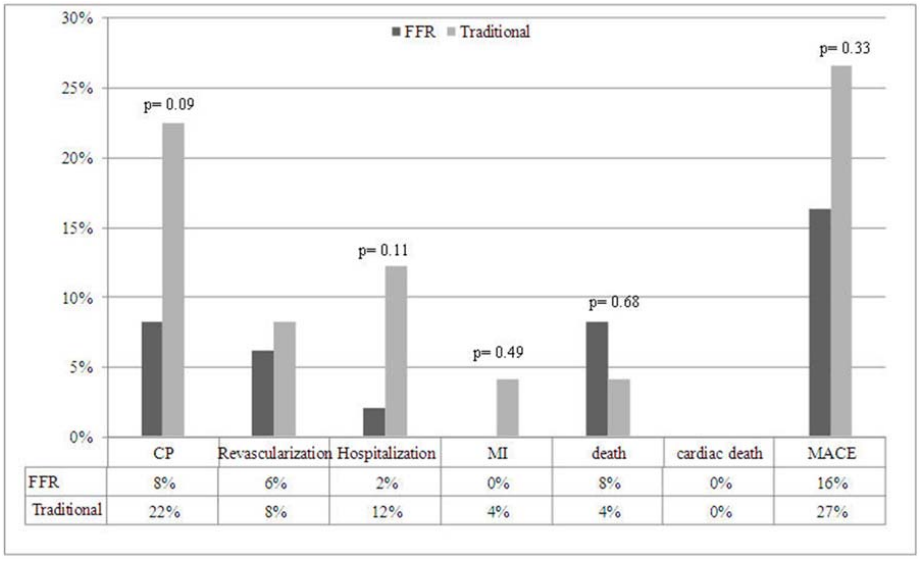
In comparison of event free survival rate between the FFR and the traditional PCI groups during follow up (mean follow-up 8.27 ± 5.45 vs. 9.49 ± 5.39 months respectively, p = 0.27), there were no in-hospital MACE and no difference in long-term MACE (16.3% vs. 26.5%, p = 0.33), recurrent chest pain (8.2% vs. 22.4%, p = 0.09), repeat revascularization (6.1% vs. 8.2%, p = 1.00), hospitalization (2% vs. 12.2%, p = 0.11), myocardial infarction (0% vs. 4.1%, p = 0.49) and death (8.2% vs. 13.3%, p = 0.68) (Fig. 1). Causes of all deaths were non-cardiac (Sepsis 2, Acute renal failure 2, acute stroke 2). And as shown in Fig. 2, the events free survival rate in both groups was also no different (p = 0.37).

Furthermore, when comparing the total cost between both groups, the total cost per patient in FFR-PCI group is about 63,290 baht cheaper than the Traditional PCI group (p < 0.001) (Fig. 3).

Discussion

A preceding study[4] in the bare-metal stent era, in patients with borderline multi-vessels coronary artery disease, indicated that the use of fractional flow reserve guided selective coronary revascularization has a greater events free survival rate when compare to traditional multivessel coronary artery stenting. The launching of the drug eluting stent has significantly lowered the restenosis rate from 20-30% in bare metal stent to less than 10% in the drug eluting stent. Moses et al has recently reported a pooled analysis from four randomized trials using drug-eluting stent in a borderline lesion, which showed markedly lower rate of target vessel revascularization from 20.3% with baremetal stent to 3.4% with drug-eluting stent[15].

This study compared the clinical outcome for the patients with MVD and borderline coronary stenosis between those using FFR-guided revascularization and those receiving traditional coronary revascularization in the drug-eluting era in Thai populations. The study demonstrated FFR guided revascularization resulted in fewer coronary vessels



	CP	Revascularization	Hospitalization	MI	death	cardiac death	MACE
FFR	8%	6%	2%	0%	8%	0%	16%
Traditional	22%	8%	12%	4%	4%	0%	27%

Fig. 1 Events rate compared between the patients with MVD underwent FFR-PCI vs. Traditional PCI during mean follow-up 8.27 ± 5.45 vs. 9.49 ± 5.39 months (p = 0.27)

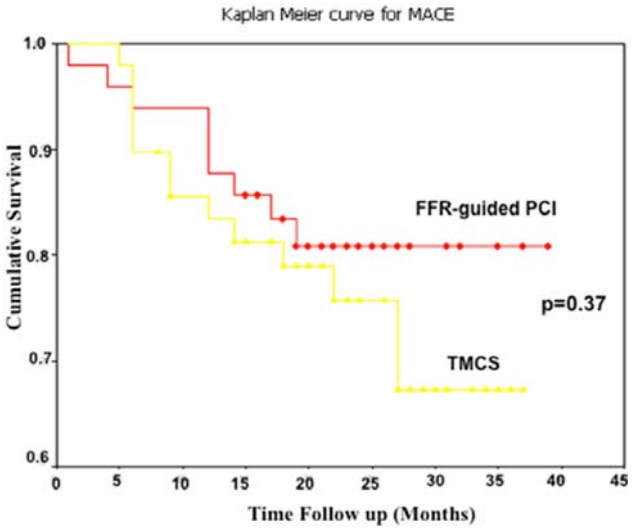


Fig. 2 Kaplan-Meier survival curve for Major Adverse Cardiac Event rate between FFR-PCI versus Traditional-PCI

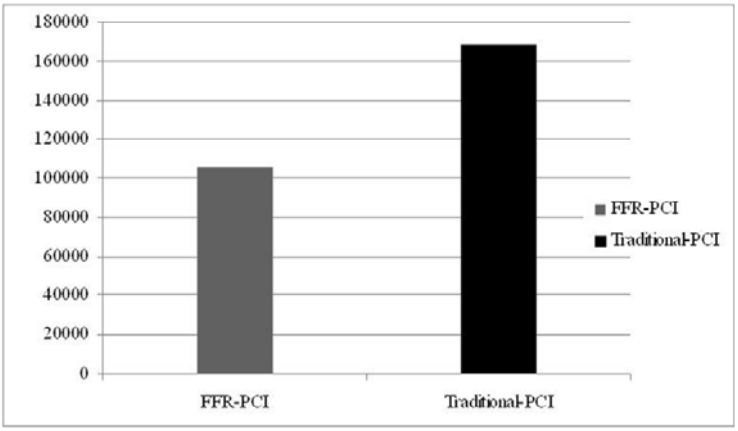


Fig. 3 Compared total cost analysis between FFR-PCI group and Traditional-PCI group, which showed lower total cost in FFR-PCI group significantly ($p < 0.001$)

requiring to revascularization, fewer numbers of drug eluting stent being used and an expense which is 63,290 Bath cheaper in the total cost per patient, all without compromising safety in either of the two groups. As in Fig. 1, we also found that episode of chest pain in the traditional coronary revascularization group was more frequent than in the FFR-guided revascularization group, but was not significant ($p = 0.09$). From our previous study, traditional coronary stenting in borderline stenoses will lead to unnecessary stenting in the lesion that does not cause ischemia. It wills eventually increased restenosis[4].

Since the study was conducted and internationally presented before the FAME study, we were still using the cut off of FFR of 0.75 as previously described in the literature. In contrast to the FAME study[16], which recruited those with stenosis of more than 50% (40% of vessels had 50-70% stenosis and the other 60% of vessels had stenosis 70-99%), this study is mainly focused on the group which had borderline 50-70% stenosis. For borderline angiographic stenosis (50-70%), visual estimation for physiologic significance is more likely to be wrong. As later demonstration in a FAME sub-study[17], in the category of 50% to 70% stenosis, only 35% were physiologically significant. In category of 70% to 90% stenosis, 80% were physiologic significant. In category of 90% to 99% stenosis, almost all (96%) were of physiologic significance. For the cost

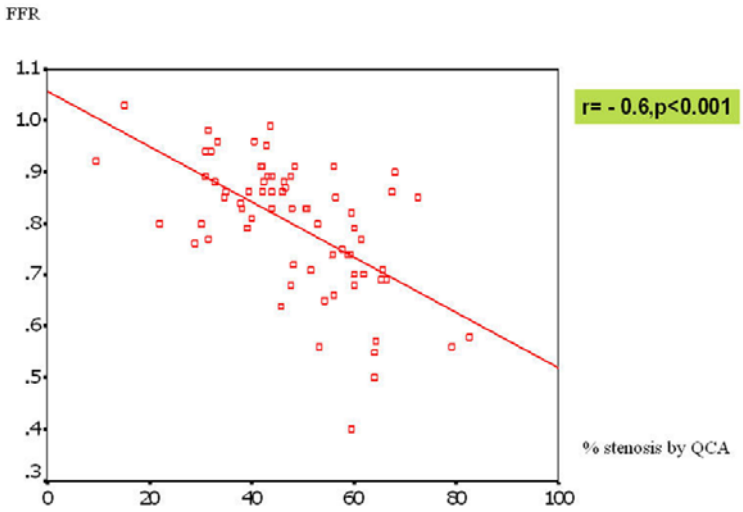


Fig. 4 Bivariate correlation between FFR value and % vessel stenosis by QCA

effectiveness, the value of FFR guided revascularization is the greatest in borderline 50% to 70% stenosis. We did not find a difference in MACE between the two groups which could be due to a smaller number of patients and a short duration of follow-up.

Nevertheless, FFR-guided coronary revascularization clearly demonstrated the superior benefit of total cost saving per patient when the clinical outcome did not differ from the traditional coronary revascularization. Therefore, FFR-guided coronary revascularization in borderline coronary stenosis still useful in the drug-eluting era in Thai patients. These findings should motivate the interventionists to determine the physiologic assessment of borderline coronary stenosis in the patients with multivessel disease by FFR-guided method before making a decision about placement of drug-eluting stent(s).

Study limitations

This study is a retrospective, non-randomized control trial. The number of patients recruited in the study was small.

Potential conflicts of nterest

None.

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การตรวจวัด fractional flow reserve เพื่อช่วยในการตัดสินใจในการใส่ขดลวดเคลือบยาในผู้ป่วยคนไทยที่มีหลอดเลือดหัวใจตีบหลายเส้นแบบก้ำกึ่ง

ธีรานันท์ อังคณานาฏ, ณัฐวุฒิ วงษ์ประภารัตน์, ดำรัส ตรีสุโกศล, ประดิษฐ์ ปัญจวีณิน

ภูมิหลัง: *การตรวจวัดการขาดเลือดของหัวใจโดยเฉพาะการทำ fractional flow reserve (FFR) เพื่อช่วยในการตัดสินใจว่าต้องทำการรักษาโดยการใส่ขดลวด พบว่ามีประโยชน์ในการลดค่าใช้จ่ายและลดอัตราการเกิด CV events ในผู้ป่วยที่มีหลอดเลือดหัวใจตีบแบบก้ำกึ่ง (50-70%) ของหลอดเลือดหัวใจหลายเส้น ปัจจุบันไม่มีการศึกษาการใช้ FFR ในคนไทยที่มีหลอดเลือดหัวใจตีบแบบก้ำกึ่งของหลอดเลือดหัวใจหลายเส้น*

วัสดุและวิธีการ: *เป็นการศึกษาแบบย้อนหลังในผู้ป่วย 98 คน ที่มีหลอดเลือดหัวใจตีบแบบก้ำกึ่งในหลอดเลือดหัวใจอย่างน้อย 2 เส้น ผู้ป่วยกลุ่มแรกการตัดสินใจว่าจะต้องใส่ขดลวดเคลือบยากี่ตำแหน่ง จากการวัดโดยการตรวจ FFR ผู้ป่วย กลุ่มที่สองการตัดสินใจรักษาโดยการใส่ขดลวดเคลือบยา โดยทำตามวิธีปกติโดยการประมาณจากสายตาหรือวัด quantitative coronary angiogram (QCA)*

ผลการศึกษา: *ในผู้ป่วยกลุ่มแรกหลอดเลือดหัวใจที่ตีบแบบก้ำกึ่ง (50-70%) จำนวน 46 เส้น ไม่มีการขาดเลือดจากการวัด FFR (FFR = 0.87 $\pm$ 0.06) จึงไม่ต้องทำการรักษาโดยใส่ขดลวด หลอดเลือดที่ตีบแบบก้ำกึ่ง (50-70%) จำนวนที่เหลืออีก 25 เส้น การตรวจ FFR พบมีการขาดเลือดจริงและได้ทำการใส่ขดลวดเคลือบยา ในผู้ป่วยกลุ่มที่ 2 ที่ทำการรักษาตามปกติหลอดเลือดหัวใจทั้ง 79 เส้น ได้รับทำการใส่ขดลวดเคลือบยา เมื่อติดตามการรักษาที่ 9 เดือน ไม่พบความแตกต่างของการเกิดภาวะหัวใจขาดเลือดเฉียบพลันหรืออัตราการตาย เมื่อคำนวณค่าใช้จ่ายเนื่องจากผู้ป่วยกลุ่มแรกลดจำนวนขดลวดเคลือบยาจาก 1.84 $\pm$ 0.85 ลงเหลือ 0.63 $\pm$ 0.78 ($p < 0.01$) จึงสามารถประหยัดค่าใช้จ่ายลงประมาณ 63,290 บาทต่อคน*

สรุป: *การตรวจวัดการขาดเลือดของหัวใจโดยใช้ FFR ในผู้ป่วยคนไทยที่มีหลอดเลือดหัวใจตีบแบบก้ำกึ่ง (50-70%) ในหลอดเลือดหัวใจตีบหลายเส้น เพื่อช่วยในการตัดสินใจในการทำการรักษาโดยการใส่ขดลวดเคลือบยาสามารถประหยัดค่าใช้จ่ายประมาณ 63,290 บาทต่อคน โดยไม่ได้เพิ่มความเสี่ยงต่อการเกิดหลอดเลือดหัวใจขาดเลือดเฉียบพลัน หรืออัตราการตายที่ 9 เดือน*