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ORIGINAL ARTICLE

Fractional Flow Reserve: Cost-Effectiveness to Guide Coronary Interventions in Chronic Stable Angina.

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ABSTRACT

Background: In clinical practice management of patients with intermediate coronary artery disease efficiently without costing a lot of money has a value to this therapeutic dilemma, especially in patients presented to the catheterization laboratory without prior functional assessment.

Methods: A decision model to compare between the cost of FFR-guided coronary interventions and angiographically guided interventions was done. Intermediate coronary lesions in each patient were assessed twice by using the two methods leading to two decisions for each patient. A comparison between the costs of the two decisions was made.

Results: FFR-guided coronary intervention saved 63 stents in 122 lesions in 50 patients. The estimated cost of FFR-guided strategy per patient ranged from 25.000 Egyptian pound (EP) to 45.000 EP with mean value of 26.860±4.500 EP. Whereas the estimated cost of coronary angiography guided strategy per patient ranged from 15.000 EP to 61.000 EP with mean value of 31.740±12.960 EP.

Conclusions: Measuring FFR is cost-effective in chronic stable angina especially in diabetic patients with multi-vessel disease.

Keywords: Fractional Flow Reserve; guide to Coronary Interventions; Chronic Stable Angina

INTRODUCTION

Progression, prevention of future cardiac events such as myocardial infarction (MI) and heart failure, and finally improving survival. Percutaneous coronary intervention (PCI) should be reserved for patients who are not responding to medical treatment [1].

Coronary revascularization is generally accepted as of a good benefit in patients considered at higher risk, even in the setting of chronic stable angina, and is acknowledged to have revolutionized the management of coronary artery disease during the past 30 years [2].

Coronary angiography has always been the standard method to guide PCI [3]. The concept of myocardial fractional flow reserve (FFR) has been developed as an invasive maneuver to assess the functional severity of coronary stenosis. FFR is defined as the ratio between the maximal blood flow to the myocardium in the presence of a stenosis in the supplying coronary artery and the theoretical normal maximal flow in the same distribution derived from the aorta [4].

The aim of this study was to compare between the cost of angiographically guided PCI and FFR guided PCI in patients with chronic stable angina.

METHODS

Methods and study population: The study (Cross Sectional study) was carried out in Zagazig University hospital, Cardiology department and Kobry El Kobba Military hospital, Cardiology department in the period between February 2018 and August 2018 and included 50 patients presented by chronic stable angina; a clinical syndrome characterized by typical chest pain or discomfort which increases by physical exercise or emotional stress and relieved by rest and/or nitrates intake [5] and were indicated for invasive coronary angiography as they have subjective evidence of ischemia or patients who were not responding to medical treatment and ICA revealed 50-80% lesion(s).

A written informed consent was obtained from each participant and the study was approved by the research ethical committee of faculty of medicine, Zagazig university. The study was done according to the code of ethics of the world medical association (Declaration of Helsinki) for studies involving humans.

All patients were assessed by thorough history including age, sex, cardiac history and history of hypertension, diabetes mellitus and smoking. Clinical examination included BP, pulse, general and cardiac examination. Routine laboratory tests including complete blood count, serum creatinine, lipid profile and cardiac biomarkers. Non-invasive cardiac investigations included ECG to detect heart rate, rhythm and ischemic changes and Echocardiography to detect left ventricular systolic function. EF was measured by M-mode in PLAX view and Simpson's method.

Coronary angiography was performed and lesions with 50-80% stenosis were the lesions of our interest and are to be studied by both methods. The decision according to the coronary angiography was taken by a panel of interventional consultants and any lesion ≥ 70% stenosis at its maximum narrowing must be fixed. Lesions ≥ 50% stenosis at their maximum narrowing in the LM and/or proximal LAD must be fixed. Other lesions will not be intervened.

The 50-80% lesions were assessed again by using FFR. In order to measure FFR, a pressure sensitive coronary guidewire was advanced distal to the lesion to be assessed. FFR was measured by induction of intra-venous adenosine (140 mic/kg/min) or intra-coronary bolus starting from 60 mcg up to 120 mcg then FFR was monitored for significant changes. FFR was measured as the ratio between mean arterial pressure in the guidewire and the mean arterial pressure in the guiding catheter [6].

FFR <0.80 is an evidence-based physiological threshold that correlates with the presence of inducible ischemia on non-invasive testing and requires revascularization. FFR ≥ 0.80 indicates that the lesion is not physiologically effective and doesn't need any further intervention [1].

Two decisions were taken for each patient according to the measures mentioned above; angiographically guided and FFR-guided then a comparison was held between the costs of each group.

Exclusion criteria included chronic total occlusion, previous history of CABG, the patient is candidate for open heart surgery or acute renal failure or severe chronic non-dialysis-dependent kidney disease.

Statistical analysis:

Statistical Package of Social Science (SPSS) program for Windows (Standard version 21) were used to analyze the data. The normality of data was first tested with one-sample Kolmogorov-Smirnov test.

Qualitative data were described using number and percent. Association between categorical variables was tested using Chi-square test.

Continuous variables were presented as mean ± SD (standard deviation) for parametric data and median for non-parametric data. The two paired groups were compared with paired t- test for parametric data and Wilcoxon signed rank test t for non-parametric.

The Mann Whitney test was used to compare 2 medians while Kruskal Wallis test was used to compare more than 2 medians. Spearman correlation was used to correlate nonparametric data. A P value ≤0.05 was considered statistically significant.

RESULTS

The study included 49 males and one female with mean age 61.86 ± 6.96 years old who were referred to the Cath lab in Kobry El Kobba Military Hospital in the period between February 2018 and August 2018 (**Table 1).**

Twenty-Eight patients (56%) were hypertensive, 31 patients (62%) were diabetic, 30 patients (60%) were smokers and 12 patients (24%) had previous MI; seven of them had history of anterior MI while the other five had history of inferior MI. The Ejection Fraction of the patients ranged from 39% to 75% with a mean range of 59.96 ± 8.03 (**Table 2).**

We found that FFR is cost-effective in patients with chronic stable angina who are indicated for invasive coronary angiography.

In the coronary angiography decision only one patient needed five stents, nine patients needed four stents, 13 patients needed three stents, 15 patients needed two stents and 12 patients needed one stent. Two patients needed three balloons, 15 patients needed two balloons and one patient needed one balloon while in the FFR decision no patients needed four stents or more, one patient needed three stents, seven patients needed two stents and 42 patients needed only one stent. One patient only needed one balloon**.**

In the coronary angiography decision, the total of 122 stents and 37 balloons were needed. While in the FFR decision, a total of 59 stents and one balloon were needed.

FFR is cost-effective in reduction of the number of stents (p<0.001) and balloons (p=0.011) needed per patient **(Table 3, Figures 1 and 2).**

There was a positive correlation between the number of vessels and number of lesions and the

cost-effectiveness of the FFR (p<0.001) **(Table 4, Figures 3 and 4).**
The cost of FFR guided coronary intervention was less than coronary angiography guided intervention (p=0.002). The estimated cost of coronary angiography per patient ranged from 15.000 EP to 61.000 EP with mean value of 31.740±12.960 EP, while the estimated cost of FFR per patient ranged from 25.000 EP to 45.000 EP with mean value of 26.860±4.500 EP **(Table 5 and Figure 5).**
FFR guided coronary intervention was considered cost-effective in patients with DM (p=0.007), however it did not show cost-effectiveness in relation to hypertension, smoking or history of myocardial infarction **(Table 6).**
FFR guided coronary intervention was cost-effective as the number of vessels affected increased (p<0.001) and the number of lesions detected increased (p<0.001) **(Table 7).**
FFR guided coronary intervention was cost-effective in mid LAD lesions (p=0.05), lesions in the first diagonal branch (p=0.004), distal LCX lesions (p=0.025) and lesions in OM1 (p=0.05) **(Table 8)**.

Table 1: Demographic data of the studied group.

Demographic data		Study group (n=50)	
Sex	Male	49	98.0
	Female	1	2.0
Age/years			
Mean ± SD		61.86±6.96	
Range		47.00-72.00	

Table 2: Medical history and EF among the studied group.

Variables	Study group (n=50)	
	No	%
HTN		
Yes	28	56.0
No	22	44.0
DM		
Yes	31	62.0
No	19	38.0
Smoking		
Yes	30	60.0
No	20	40.0
History of MI		
No	38	76.0
Anterior	7	14.0
Inferior	5	10.0
EF		
Mean ± SD	59.96±8.03	
Range	39.00-75.00	

Table 3: Comparison as regards the number of stents and balloons.

Variables	Coronary angiography		FFR		Test of significance	P -value
	No	%	No	%		
Stents						
1	12	24.0	42	84.0	χ^2=39.8	<0.001*
2	15	30.0	7	14.0		
3	13	26.0	1	2.0		
4	9	18.0	0	0		
5	1	2.0	0	0		
Total no. of stents	122		59			
Median (Range)	2.00 (1.00- 5.00)		1.00 (1.00-3.00)		Z=5.51	<0.001*
Balloons						
1	1	2.0	1	2.0	χ^2=8.97	0.011*
2	15	30.0	0	0		
3	2	4.0	0	0		
Total no. of balloons	37		1			

Median (Range)	2.00 (1.00- 3.00)	1.00 (1.00-1.00)	-	-

χ^2: Chi square test, Z: Wilcoxon signed rank test, *significant p <0.05

Table 4: Correlation between no. of vessels and no. of lesions and cost effectiveness.

Items	Cost effectiveness	
	R	P - value
No. of vessels	0.681	<0.001*
No. of lesions	0.954	<0.001*

R: Spearman correlation

Table 5: Comparison between cost of coronary angiography and cost of FFR.

Cost	Cost coronary angiography	Cost FFR	Cost effectiveness
Mean ± SD	31.74±12.96	26.86±4.50	Median=6.0
Range	15.00-61.00	25.00-45.00	-10.00-26.00
Paired t-test	3.254		-
P – value	0.002*		

*: P value for comparison between cost of coronary angiography and cost of FFR

Table 6: Cost-effectiveness of FFR according to medical history.

Items	No	Cost effectiveness	Test of significance	P - value
		Median (Min-Max)		
HTN				
Yes	28	3.00 (-10.00-26.00)	Z=1.062	0.288
No	22	8.00 (-10.00-20.00)		
DM				
Yes	31	10.00 (-10.00-26.00)	Z=2.689	0.007*
No	19	0.00 (-10.00-19.00)		
Smoking				
Yes	30	6.00 (-10.00-20.00)	Z=0.241	0.809
No	20	6.00 (-10.00-26.00)		
History of MI				
No	38	6.00 (-10.00-26.00)	KW=0.476	0.788
Anterior	7	3.00 (-10.00-20.00)		
Inferior	5	10.00 (0.00-16.00)		

Z: Mann Whitney test, KW: Kruskil Wallis test

Table 7: Cost-effectiveness of FFR according to no. of vessels and no. of lesions.

Items	No. of patients	Cost effectiveness	Kruskil Wallis test	P – value
		Median (Min-Max)		
No of vessels				
1 vessel	23	-10 (-10-16)	24.02	<0.001*
2 vessels	21	16 (0-20)		
3 vessels	6	10 (10-26)		
No of lesions				
1 lesion	12	-10 (-10 - 0)	44.92	<0.001*
2 lesions	14	0.0 (0-6)		
3 lesions	14	10 (10-16)		
4 or more lesions	10	19 (10-26)		

Table 8: Cost-effectiveness of FFR according to the site of the lesion.

Items	No	Cost effectiveness		Mann Whitney test	P - value
		Yes	No		
LAD					
Proximal	16	10 (0-20)	6 (-10/26)	1.12	0.259
Mid	31	0.0 (-10/16)	10 (-10/26)	1.95	0.05*
Distal	2	18 (16-20)	6 (-10/26)	1.93	0.053
D1	11	16 (3-26)	0.0 (-10/20)	2.89	0.004*
D2	4	11 (6-19)	4.5 (-10/26)	1.36	0.173
LCX					
Proximal	7	10 (0-26)	6 (-10/20)	1.24	0.212
Mid	13	10 (-10/20)	6 (-10/26)	1.08	0.276
Distal	3	16 (16-20)	6 (-10/26)	2.24	0.025*
OM1	8	16 (0-19)	4.5 (-10/26)	1.96	0.05*
OM2	2	17.5 (16-19)	6 (-10/26)	1.83	0.066
RCA					
Proximal	8	10 (-10/26)	6 (-10/20)	0.82	0.412
Mid	12	10 (-10/20)	1.5 (-10/26)	1.26	0.205
Distal	2	13 (10-16)	6 (-10/26)	1.13	0.258
PDA	1	16 (16-16)	6 (-10/26)	1.09	0.275

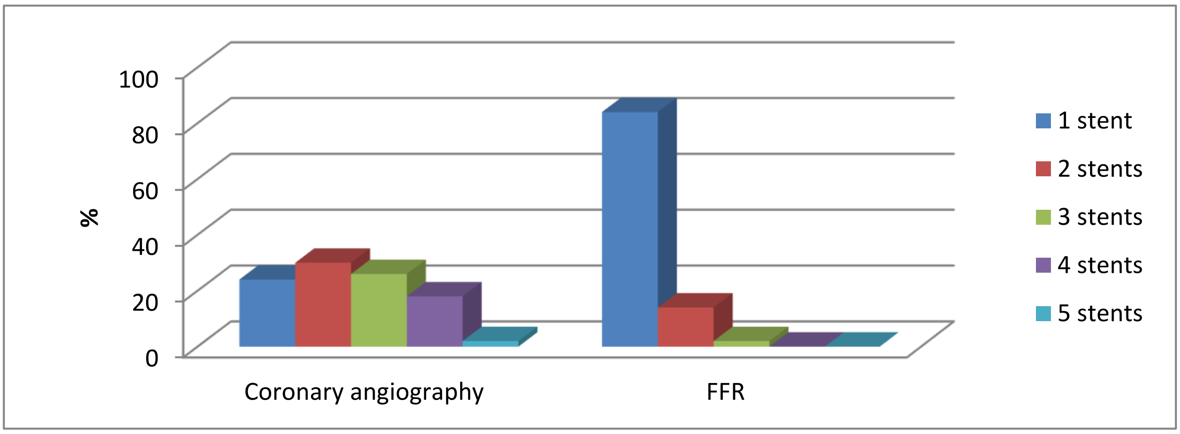

Figure 1: Number of stents by Coronary angiography and FFR.

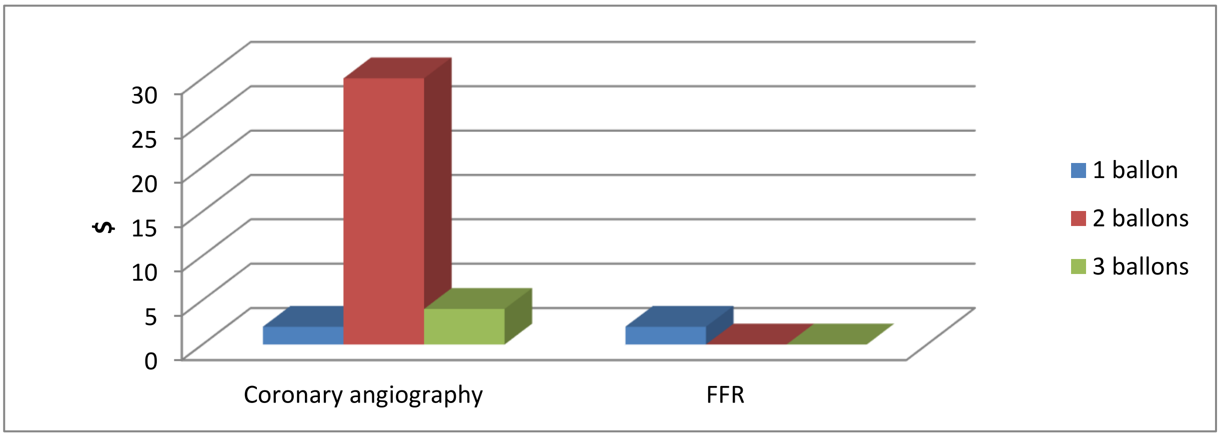

Figure 2: Number of balloons by Coronary angiography and FFR.

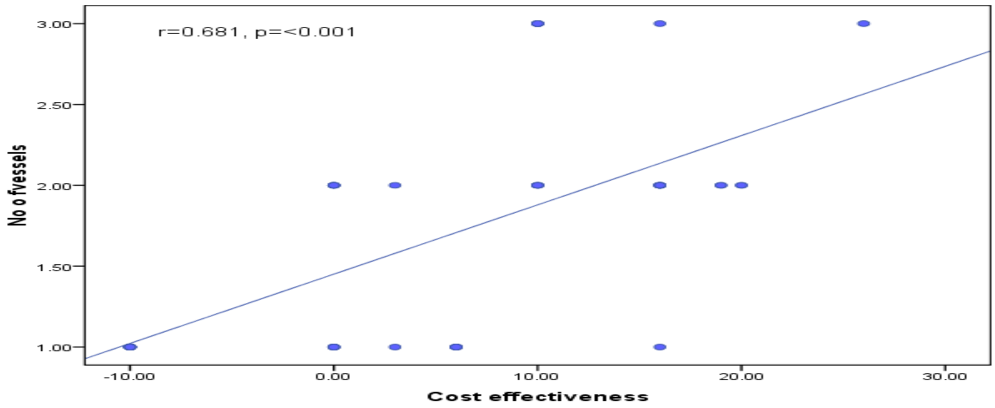

Figure 3: Scatter diagram for positive correlation between no. of vessels and cost effectiveness.

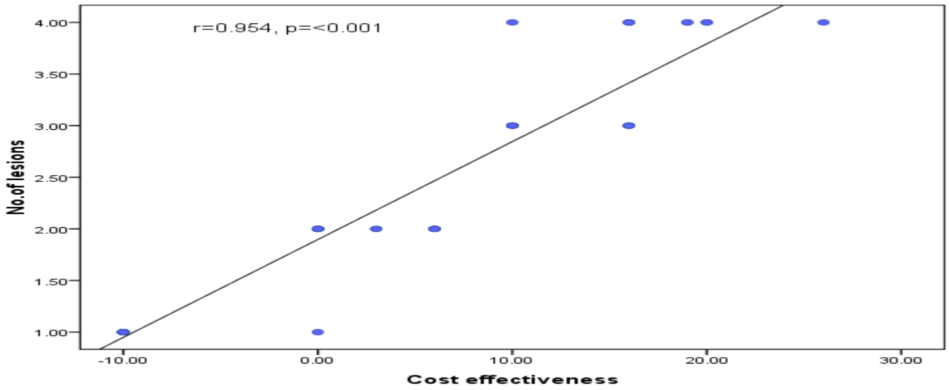

Figure 4: Scatter diagram for positive correlation between no. of lesions and cost effectiveness.

DISCUSSION

An angiographically intermediate but functionally non-significant stenosis revascularization has always been controversial. PCI of a functionally non-significant stenosis is associated with a good long-term follow-up. Addition of routine FFR to angiography improves outcomes of PCI at 1 year [3].

While analyzing the data obtained from the current study it is important to keep in mind the study population characteristics. All patients were presented by chronic stable angina and were indicated for invasive coronary angiography.

Our results stated that FFR-guided coronary intervention is more cost-effective than angiography-guided coronary intervention.

2018 ESC/EACTS Guidelines on myocardial revascularization declared that FFR is the current standard of care for functional assessment of intermediate coronary lesions without evidence of ischemia in non-invasive testing or in patients with multi-vessel disease.

With our results, ***Fearon et al.*** stated that using FFR to guide coronary interventions in patients with intermediate coronary lesions and no prior functional study lead to significant cost savings compared with simply stenting lesions in all patients [7].

Tonino et al. stated in the FAME study that the number of stents used per patient in the FFR group is less than the number of stents used per patient in the angiography group in patients with MVD [8].

In the 2-year follow-up of the FAME study, ***Pijls et al.*** found that significantly more stents per patient were deployed in the angiography-guided group compared with the FFR-guided group in patients with MVD [3].

In France and Belgium, ***Bornschein et al.*** reported that FFR-guided coronary interventions had significant lower costs. Cost saving reached approximately 900 EUR/patient for both countries. FFR was cost saving in >50% of all samples and cost effective in >90 % [9].

In Australia, ***Siebert et al.*** found that FFR-guided PCI in patients with multi-vessel coronary artery disease substantially improves QALYs and is cost-saving in the Australian health care system. The cost-effectiveness analysis showed that FFR was cost-saving and reduces costs by 1,776 AUD/patient for one year. Sensitivity analyses revealed that FFR was cost-saving over a wide range of assumptions [10].

Murphy et al. found in another study that FFR use saved money for both public and private sectors in Australia. Despite the cost of 1,200 AUD/FFR wire, FFR saved money. Mean savings in the public sector were 1,200 AUD/patient while in the private sector the savings were 5,000 AUD/patient [11].

Ihdayhid et al. assumed that FFR is a well validated, highly reproducible, cost effective technique that improves clinical outcomes and has become the reference standard for the assessment of lesion-specific ischemia [12].

In Japan, ***Tanaka et al.*** stated that the probability of deferral of PCI according to FFR in patients who were allocated to PCI based on coronary angiography is 90.1%. In the model analysis, the tests cost was increased by 185,660 JPY/patient by the addition of FFR measurement, but the cost of treatment with PCI only was reduced by 561,425 JPY/patient, and the entire cost of treatment was reduced by 322,675 JPY, leading to expected reduction in the total expected medical cost by 137,015 JPY/patient. Inappropriate application of PCI cost was reduced by FFR-guided PCI [13].

In UK, ***Nam et al.*** found that in patients with NSTEMI, FFR was cost-saving and reduced revascularization by either PCI or CABG [14].

This study included patients with NSTEMI and more information and additional long-term evidence on MACE are needed.

In German Federal Ministry of Health, ***Siebert et al.*** stated that using FFR to guide PCI in patients with coronary artery disease is cost-effective and FFR should be used routinely in decision making in patients with suspected CAD [15].

In India, ***Sengottuvelu et al.*** found that patients with CAD had benefit from FFR based management plan for intermediate lesions economically. Twenty-Six stents were avoided in 23 patients out of 65 [16].

Sandhu and Kaul found that FFR reduced the need for revascularization in the majority of cases. By assessment of 212 lesions, if PCI would have been considered for all the lesions, then 212 stents would have been used. Using FFR revealed that only 68 lesions were significant and needed to be fixed, thus saving 144 stents [6].

Murphy et al. saved $318,940 over 24-month period in their study on 144 vessels in 121 patients. They declared that FFR is a safe and cost-effective method in assessing intermediate coronary lesions [17].

In another study, ***Siebert et al.*** stated that using FFR to guide coronary interventions lead to significant cost-saving regardless the type of stents used (BMS or DES) [18].

Trivedi et al. agreed that although FFR wire added additional cost to the procedure, it's appropriate to use FFR to assess intermediate coronary lesions [19].

Fearon et al. also found that FFR guided PCI in patients with multi-vessel disease not only improves outcomes but also saves resources [20].

Quintella et al. stated that FFR reduced the number of lesions treated and stents, and the need for target-lesion revascularization, in patients with MVD [21].

Against our results ***Leone et al.*** suggested that hyperemia for FFR could be costly, time consuming and unpleasant to the patient [22].

This result could have been reached as a result of comparing FFR by hyperemia with contrast FFR not with angiographically guided PCI.

Although contrast FFR is considered a cheap and fast method for functional assessment of intermediate coronary artery lesions that also reduces the use of Adenosine, it hasn't been yet tested in randomized-controlled trials with clinical endpoints.

Hoole et al. found that using FFR in the assessment of intermediate coronary stenoses not only added the cost of the FFR wire but also lead to increase in the number of stents used [23].

This result is most probably due to under-estimation of the lesions by the interventionists. There was a wide difference between the three of them when assessing the severity of the lesions angiographically.

CONCLUSION

Measuring FFR is cost-effective in patients with chronic stable angina especially in diabetic patients with multi-vessel disease. In patients with single lesion in one vessel, measuring FFR is not cost-effective. Generally, measuring FFR in patients with chronic stable angina indicated for ICA reduced number of stents used.

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