

Physiological evaluation of the provisional Side-branch intervention strategy for bifurcation lesions using pressure wires .



BY

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Introduction



Bifurcation lesions remain as one of the most challenging lesion subsets in the field of coronary intervention. Even in the era of drug eluting stents.



Colombo A , et al 2004

No previous study has shown the benefit of systematic two stenting over provisional side branch intervention strategy .



(Steigen TK, et al 2006).

Doppler wire use for functional assessment of coronary lesions severity and to guide coronary intervention has a very well established validity.

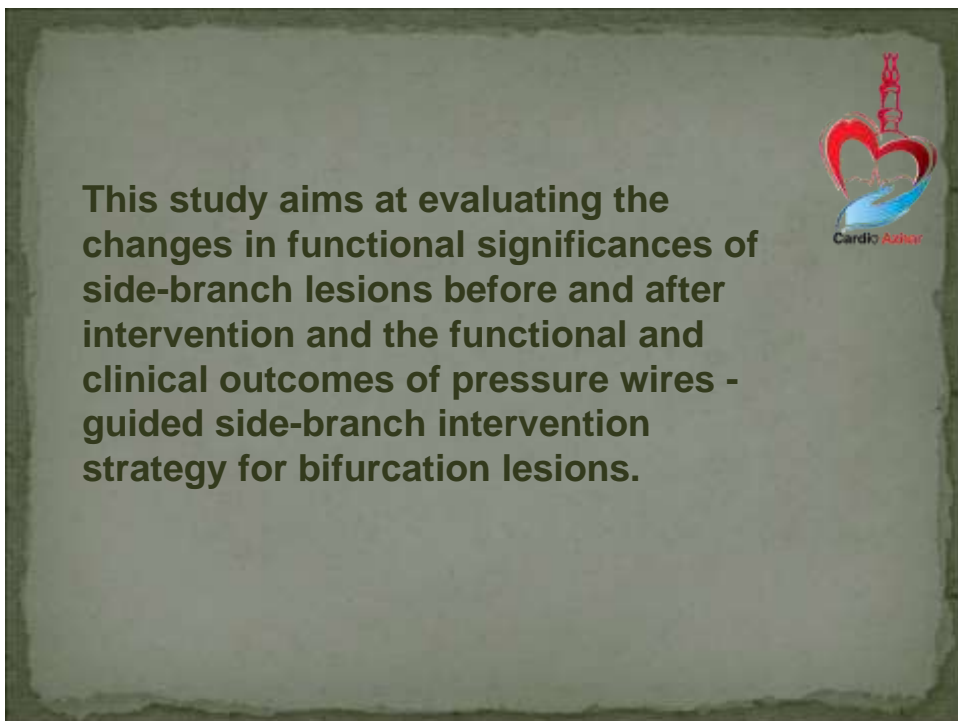
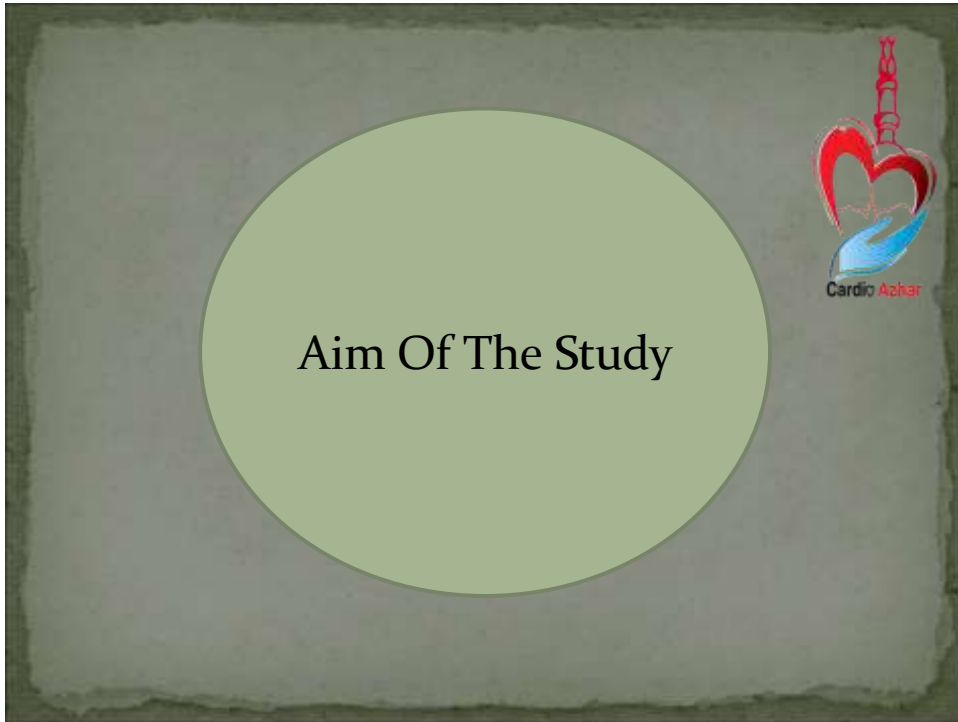


Bruce A. Samuels, et al 2014.

Functional assessment using instantaneous fractional reserve (iFR) has proven to have a similar predictive accuracy to fractional flow reserve (FFR) in the determination of a lesion's physiological significance.



Berry C., et al 2012).





Patient & Methods

This prospective case control study included 50 patients with acute coronary syndrome (ACS) who had a culprit lesion with bifurcational anatomy, as 25 consecutive patients in each group, whom were admitted to the coronary care units (CCU).



1st group (iFR group): 25 consecutive ACS patients having bifurcation lesions, with iFR-guided side-branch intervention, done in Aseer central hospital.



2nd group (conventional group): 25 consecutive ACS patients with bifurcation lesions done in Saudi German Hospital (SGH) Asser. The interventional strategy is left to the operator discretion and is not iFR guided.

Inclusion criteria:-

- The culprit lesion is a bifurcation lesion according to Medina classification,
- The side branch vessel size ≥ 2 mm,
- The side branch vessel length ≥ 40 mm,
- Lesion length < 10 mm by visual estimation.

Exclusion criteria:-

- Left main stenosis,
- Totally occluded lesion,
- Significant lesion within the main branch proximal to the stented segment
- Primary myocardial disease.
- Serum creatinine ≥ 2 mg/dL.



METHODS

All the patients were subjected to the following:

- Informed consent
- Complete history including; age, gender, risk factors, previous MI, previous angina, previous PTCA,
- Full physical examination,
- Resting 12 leads ECG before and after PCI,
- Cardiac enzymes biomarkers before and after PCI including troponin I & CKMB.
- Transthoracic echocardiography before and after PCI.
- Recording of the details of coronary angiography and PCI procedures.



Coronary angiography and intervention procedures:

All coronary angiography and PCI procedures in the 2 study groups were done by the same operators.

The procedures were performed by the percutaneous femoral approach. In both groups culprit lesion severity was judged by multiple views, including orthogonal projections.

The cut-off value of coronary intervention was lesion stenosis of $\geq 70\%$.

Van Werkhoven JM,



Coronary stenting of the main branch was performed with standard interventional techniques using new generations of drug-eluting stents, guide wires were re-crossed followed by high pressure balloon inflation and proximal optimization technique, whenever needed.



Side branch pre-dilatation was essentially avoided. After successful stenting, a reference image was obtained.

In the iFR group, pressure measurement was performed using pressure guide wire.

Following the zeroing process, pressure wire was passed through the stent struts of the main branch to side branch and iFR was measured at 5 mm distal to the side-branch ostium to assess the severity of stenosis.



Lesions with an iFR ≤ 0.89 were considered to have functionally significant stenosis and side-branch balloon dilatation was allowed only for these lesions.

A smaller drug-eluting balloon (DEB) than the side-branch vessel diameter was routinely used, if suitable size was available, otherwise plain balloon was used, followed by kissing balloon inflation according to the general recommendations.



After DEB balloon inflation, iFR was measured again at the same site and further intervention was only recommended when iFR was ≤ 0.89 after side branch dilatation.

In the conventional group, the decision to treat the side branch lesion and the method of intervention were all up to the operators' discretion, and iFR use was not allowed.



At the end of PCI procedure orthogonal angiographic views of the culprit lesion were taken.

In-hospital outcome of creatinine clearance amount of dye, fluro time, MACCE , instent thrombosis all this followed within days of admission & predischarge.



Clinical follow-up was performed after PCI, every 6 months by adverse cardiac events were defined as cardiac death, myocardial infarction, and stroke or target vessel revascularization during the follow-up period.

Study End Points:

Primary end point:

In-hospital adverse cardiac events were defined as cardiac death, myocardial infarction, or target vessel revascularization.

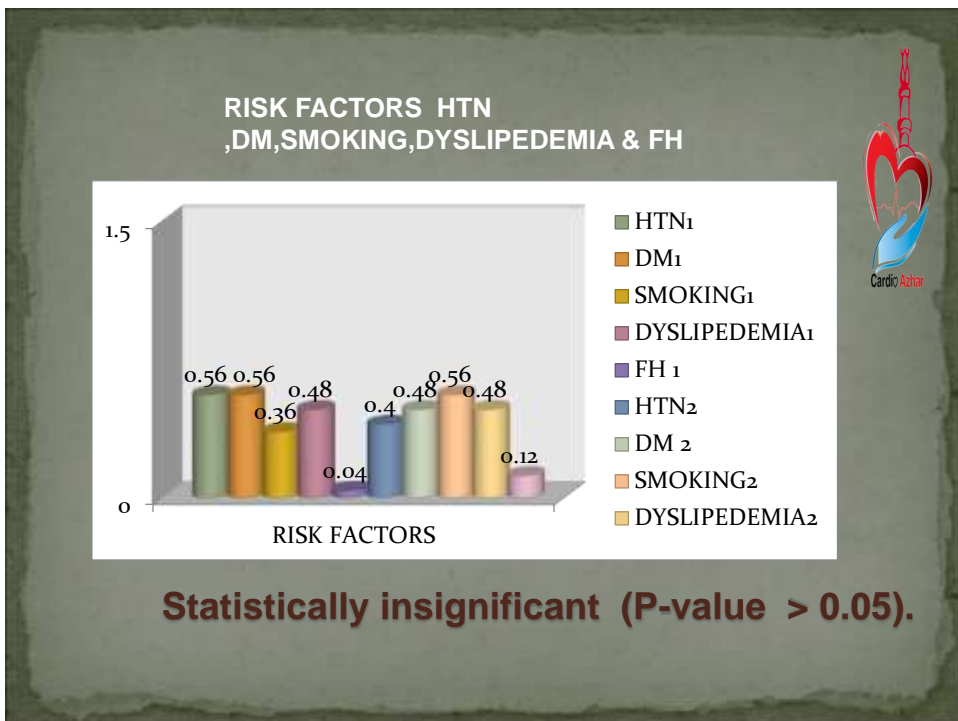
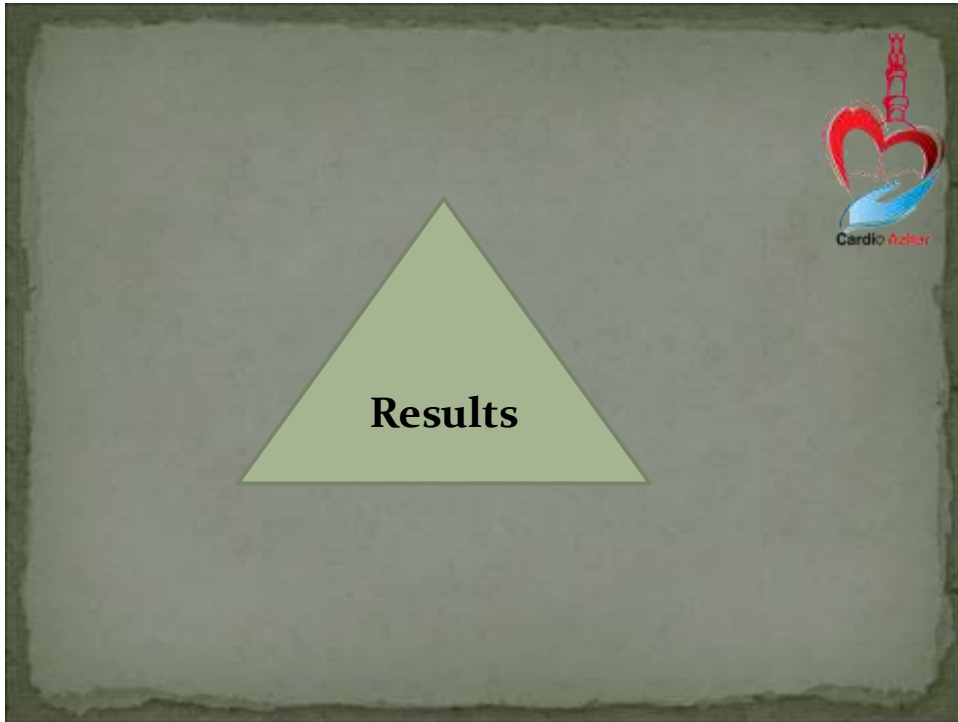
Stent thrombosis ,Procedure time, fluoroscopy time and contrast volume.

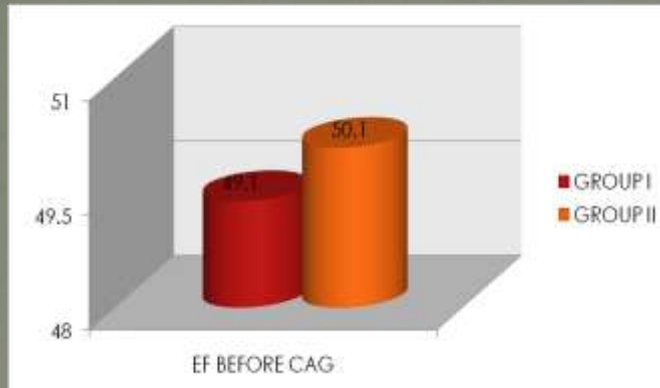
Creatinine clearance.

Secondary end points:

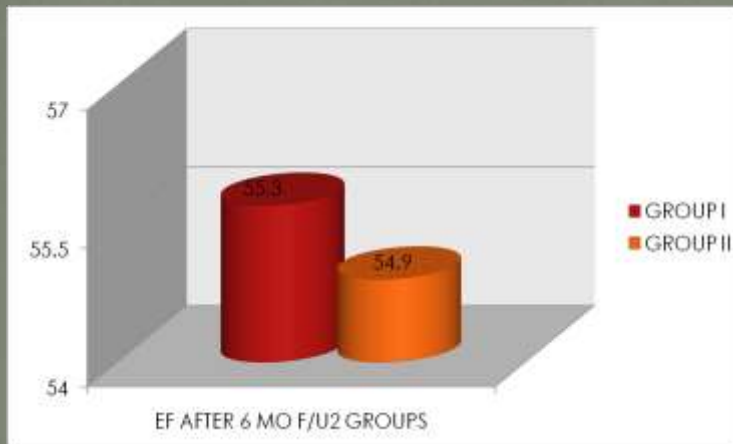
Adverse cardiac events were defined as cardiac death, myocardial infarction, or target vessel revascularization during the follow-up period , late Stent thrombosis (6 months.) & EF after 6 months f/u.



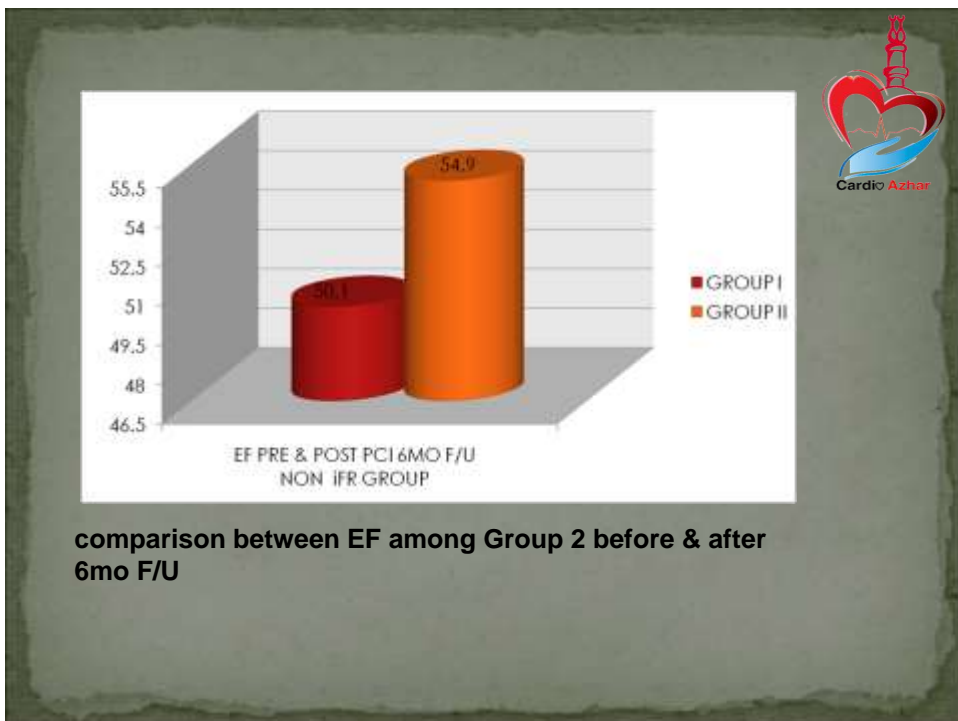


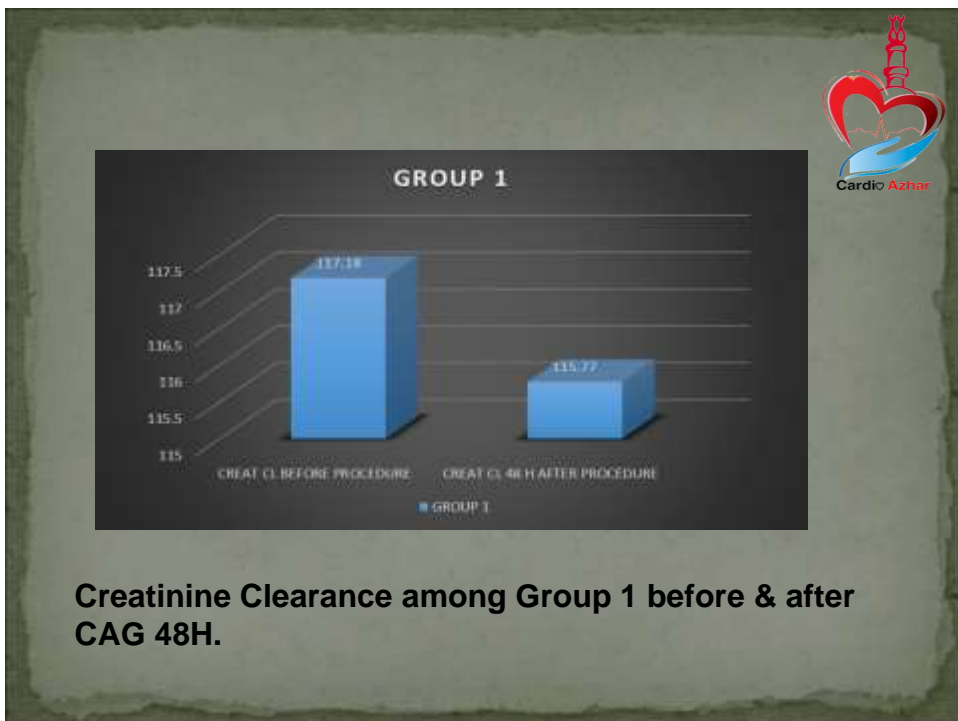
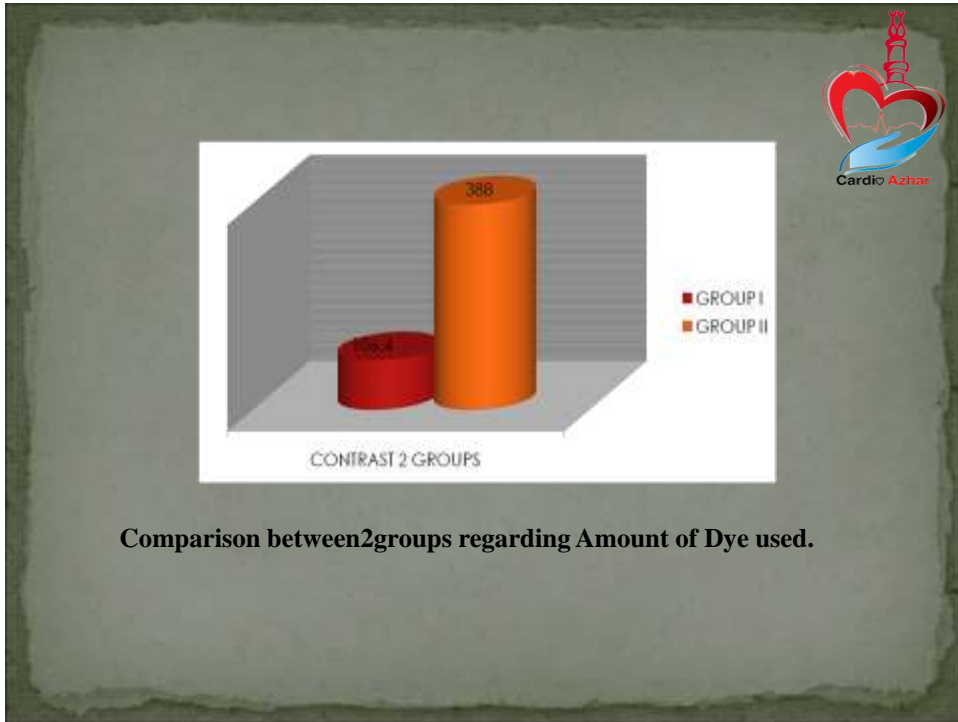


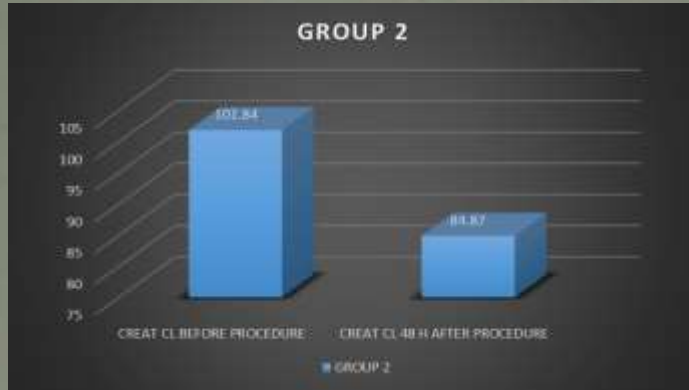
Comparison between 2group before CAG regarding EF.



comparison between 2G regarding EF before PCI.







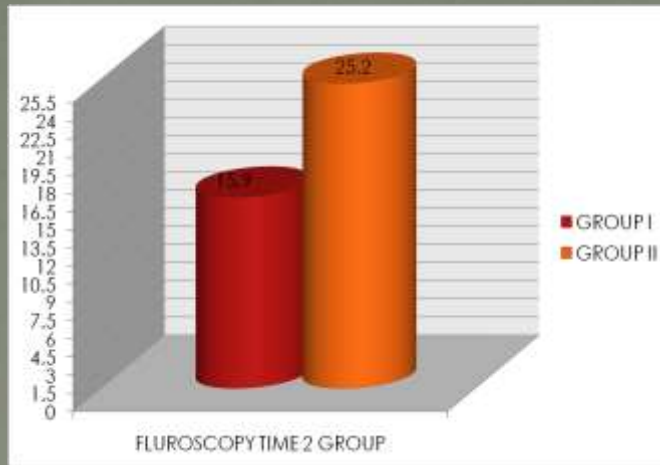
Creatinine Clearance among Group 2 before & after CAG 48H.



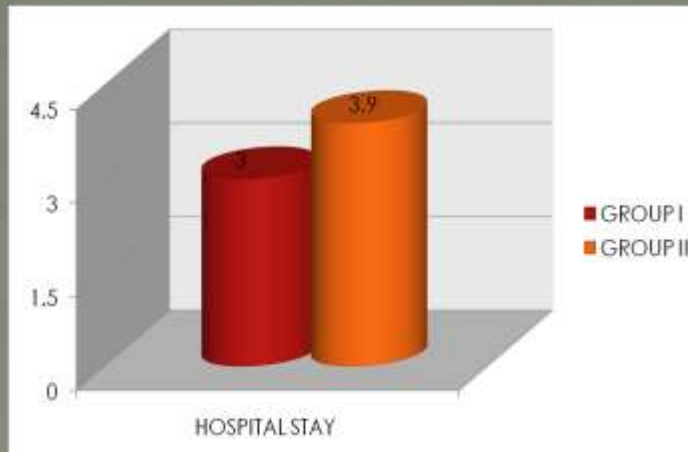
Creatinine Clearance among 2Group before CAG.



Creatinine Clearance among 2Group post CAG 48H.



Fluoroscopy Time among 2 Group.



comparison between Hospital stay among 2Group.

As regard iFR use in bifurcation lesion & side branch assessment during bifurcation intervention till now and at the time of publication to our study no study about that topic , only study support the use of pressure wires was used (FFR) for physiological assessment of jailed side branch .

the most famous study was Bon-Kwon Kool et al (2008) which concluded that :-
FFR-guided side-branch intervention strategy resulted in good functional outcomes. Measurement of FFR seems to be helpful in determining the functional significance of lesions at each step of the provisional side-branch intervention strategy



Bon-Kwon Kooi, et al ,2008 .

Limitations





1-Relatively small number of patient were studied.

2-Bifurcation Procedure dependent mainly on operator's professionalism & his skills of intervention.



**Conclussions
&
Recommendations**

Coronary angiography overestimates the functional severity of jailed side-branch lesions.

Measurement of fractional flow reserve seems to be helpful in determining the functional significance of lesions at each step of the provisional side-branch intervention strategy.



The iFR procedure is simple and its use can reduce unnecessary complex interventions and improve the functional outcomes of patients with bifurcation lesions.

More trials are needed for further assessment of the effect of pressure wires on decision making during bifurcation intervention





Thanks



The sample size will be calculated using the following formula:

$$n = 2 \left[\frac{(Z_{\alpha/2} + Z_{\beta}) * \sigma}{\mu_1 - \mu_2} \right]^2 \quad (347).$$

Where:

n = sample size

$Z_{\alpha/2} = 1.96$ (The critical value that divides the central 95% of the Z distribution from the 5% in the tail)

$Z_{\beta} = 0.84$ (The critical value that separates the lower 20% of the Z distribution from the upper 80%)

σ = the estimate of the standard deviation of the percentage of side-branch residual stenosis = 15.5% (333)

μ_1 = mean in the study group = 75% (333)

μ_2 = mean in the control group = 60% (333)

So, by calculation, the sample size will be equal to 25 cases per group.

For 2 groups, this gives a total sample size of 50 cases.