

Medium term follow up of culprit only revascularization versus total revascularization in primary percutaneous coronary intervention in patients with multi vessel disease

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Abstract

Background: Several randomized trials performed in the era of Total revascularization in the patients presented with STEMI & multivessel coronary disease showed a reduction in major adverse cardiac events when compared with culprit only revascularization.

Methods: This prospective study included 100 consecutive patients with acute ST segment elevation myocardial infarction & multivessel disease. All patients underwent primary PCI and were divided into two groups; Group 1 undergo Complete revascularization and group 2 undergo culprit only revascularization in the setting of PPCI. In-hospital & 30 days followup mortality, reinfarction, bleeding and stroke were reported in all patients.

Results: Primary end point showed that there was no significant difference between both groups regarding Non fatal MI (0% in both groups), Target vessel revascularization (4% vs 2%), Mortality (2% vs 2% with P 1,000) or Stroke (0% in both groups) and total MACE (6% vs 4%).

Conclusion: The results of the current study suggest that Multivessel revascularization didn't show extra benefit regarding Total MACE however it may improve the clinical status by decreasing the frequency of ischemic chest pain.

Key words: STEMI, Coronary intervention, PCI

{**Citation:** Mohamed Magdy, Osama Sanad, Aly Attia, Ahmed Magdy, Saeed Fawzy.
Medium term follow up of culprit only revascularization versus total revascularization in primary percutaneous coronary intervention in patients with multi vessel disease. American

Journal of Research Communication, 2016, 4(1): 49-59} www.usa-journals.com, ISSN: 2325-4076.

Introduction

Cardiovascular disease is the leading global cause of death, accounting for 17.3 million deaths per year, a number that is expected to grow to more than 23.6 million by 2030 (1)

Coronary artery disease (CAD) is a major cause of mortality and morbidity in developed countries(2). Before developing the technique of percutaneous coronary intervention (PCI), coronary artery bypass graft (CABG) had been the standard for revascularization procedure. Besides, CABG is proved to be effective in improving anginal symptoms for at least 1 year after the operation(3). Fortunately, there is an alternative treatment for CAD, the PCI which is effective, safe, less disabling and less expensive revascularization procedure compared with CABG(4).

Primary percutaneous coronary intervention (PPCI) is the most effective available method to reestablish coronary perfusion in patients presenting with ST-elevation myocardial infarction (STEMI).

Primary percutaneous coronary intervention in acute myocardial infarction result in greater patency of infarct related artery and lower rates of death, reinfarction and stroke when compared with fibrinolysis done (5).

The prevalence of multi vessel disease in patients present with STEMI approaches 40% (6). The conventional strategy of primary percutaneous Coronary intervention (PPCI) in setting of STEMI usually involve selective intervention of infarct related artery (IRA), (Culprit only revascularization) with treatment for Significant non IRA in patients with multi vessel disease (M.V.D), to be performed later as staged PCI procedure (staged revascularization) (7).

Early revascularization of infarct related artery (IRA) by PPCI is recommended according to recent guidelines. But strategy for treatment of non infarct related artery (non IRA) lesions in this setting remain unclear(8).

In this study we compared medium term effects between PPCI to infarct related artery (culprit only revascularization) and that for both infarct related artery and non infarct related artery (total revascularization) in STEMI patients with MVD.

Patients & Methods

Study Design

This prospective, controlled, non-randomized study enrolled 100 consecutive patients with acute STEMI. The study was done at the National Heart Institute, Cairo, Egypt in the period from January 2013 to June 2014. 50 patients have done Complete revascularization & the other 50 patients have done culprit only revascularization. All patients signed an informed consent and the study was approved by the local ethics committee. Key inclusion criteria were: Patients who were presented within 12 hours from the onset of symptoms with a new, or presumed new ST segment elevation in 2 or more contiguous leads of at least 2mm in leads V2-V3 or 1mm in other leads or those with new LBBB & has multi vessel coronary artery disease on angiography suitable for percutaneous coronary intervention. Key exclusion criteria were Left main coronary artery disease, Severe renal impairment (S. creatinine >3.0 mg/dl), Patient in whom non IRA is <2.5 mm, or is totally occluded or showing extensive calcification.

Methods

Baseline evaluation: All patients had review of their medical history on admission to emergency department including analysis of demographic data (age, sex), presence of risk factors of coronary atherosclerosis, associated comorbidities, general and cardiac examination, 12 leads ECG which was performed immediately on admission and every 6 h during the first 24 h, and once daily until discharge, routine laboratory investigations including cardiac biomarkers (Troponin I & CK-MB). Coronary angiography and PPCI Aspirin (300 mg loading, then 75 mg maintenance) and clopidogrel (600 mg loading, then 150 mg/day maintenance for one week, then 75 mg/day for one year) were given on admission and after PPCI. Un-fractionated heparin (UFH) of 10000 units bolus

dose was given after sheath insertion. The procedure was done according to the standard technique for coronary angiography and PCI. Transfemoral approach was done in all patients by using 6 Fr sheaths. Diagnostic coronary angiography was done to explore non-infarct related artery. XB or Judkin left guide catheters were used during PPCI in left system, while Judkin right catheter in RCA. Aspiration catheters were used in lesions with heavy thrombus burden and or impaired TIMI flow after PPCI. Bare metal stents were used in all patients. The operator determined the size, length of the stent. Sheaths were removed 4-6 hours after the procedure or 4 hours after stop of GPI infusion.

Study end points

- a) Primary end point: Composite end point of in-hospital mortality, reinfarction, bleeding (according to TIMI classification) and stroke.
- b) Secondary end point: 30 days all cause mortality and reinfarction.

Statistical analysis

Data were analyzed using IBM® SPSS® Statistics version 22 (IBM® Corp., Armonk, NY, USA) and MedCalc® version 14 (MedCalc® Software bvba, Ostend, Belgium).

Continuous numerical data were presented as mean (SD) and inter-group differences were compared using the unpaired *t* test. The Welch test was used in place of the *t* test whenever equality of variance could not be assumed. Discrete data were presented as median (interquartile range) and differences were compared using the Mann-Whitney test. Categorical data were presented as number (%) and between-group differences were compared using the chi-squared test with Yates' continuity correction or Fisher's exact test, when appropriate. Ordinal variables were compared using the chi-squared test for trend.

Results

Study Population

77% of the general population (n=154) were males, 43% were diabetics(n=86), hypertensives were 62 % of the population (n=124),69% were smokers(n=138),35% had history of prior CAD (n=70), 3% percent with history of previous PCI (n=6), no patients with history of

previous CABG , 14% had family history of CAD (n=28)and 62% of the females were in the postmenopausal periode(n=124).

Table1. Patients' characteristics in both study groups

Variable	Group A(Culprit revascularization) (n=50)	Group B (Total revascularization) (n=50)	p-value
Age (years)Mean(+_SD) Range	56(+_10) (41-75)	57 (+_8) (38-73)	0.391
Male genderMean %	33 (66.0%)	44 (88.0%)	0.017
DM %	19 (38.0%)	24 (48.0%)	0.419
Hypertension %	34 (68.0%)	28 (56.0%)	0.303
Dyslipidemia %	25 (50.0%)	21 (42.0%)	0.547
Smoking %	32 (64.0%)	37 (74.0%)	0.387
Postmenopausal %	9 (52.9%)	6 (100.0%)	0.058
Prior CAD %	19 (38.0%)	16 (32.0%)	0.675
Prior PCI %	0 (0.0%)	3 (6.0%)	0.242
Prior CABG %	0 (0.0%)	0 (0.0%)	-
Family history of CAD %	8 (16.0%)	6 (12.0%)	0.773
Number of risk factors (standard deviation)	4 (3 – 5)	4 (3 – 4)	0.526

Clinical presentation

There was no stastical significant difference between both groups A vs B regarding Mean ABP (98 vs 102 ,P value 0,111) , Life threatening arrhythmia (8% vs 12% ,P 1,00) , Kilip Class II (10%vs10% ,P 1,00) or Type of MI Anterior (56 % vs 60 %,) , Inferior (44%vs38% ,P 0,387) , anterior & inferior (0%vs2%) with P value 0,685). However there was statistical significance regarding Heart Rate which was higher in group B with mean (97 vs 84) P value 0,007) .

Angiographic data

There was no significant difference regarding the TIMI flow between the both groups : TIMI 0 (86% vs 74%) , TIMI I (14% vs 26%) ,(p 0,211), or between the number of vessels : 2 vessels (62% vs 88%) , 3 vessels (38% vs 12%) and the Table shows the distribution of the vessels culprit & non infarct related artery with no statistical significant difference .

Procedure Data

There was a statistical significant difference between both groups regarding Door to balloon time which was more in group B with mean (98min vs 71 min) P value < 0,0001 , duration of PCI which was more in group B with mean (52min vs 44min) P 0,0004, volume of contrast which was more in group B (283ml vs 199ml) p value < 0,0001 & number of stents which was normally more in group B with P value 0,001 however there was no statistical significance between group A &B regarding the use of aspiration device (44% vs 48%) or use of GpIIb/IIIa (84% vs 88%) .

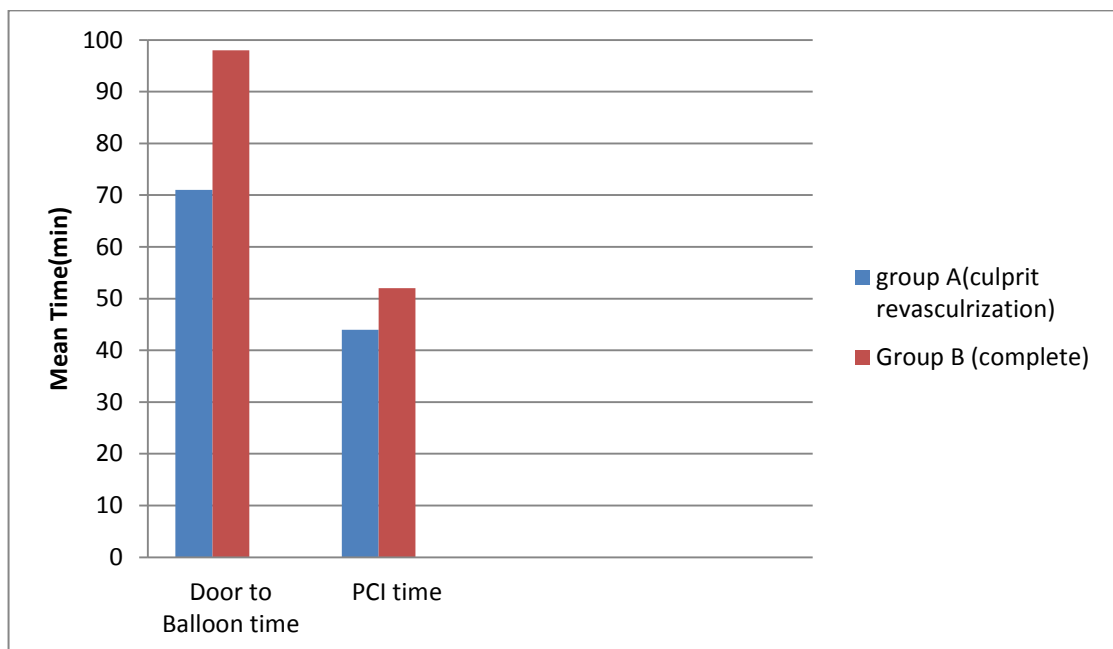


Figure 1. Door-to-balloon and PCI time in both study groups

30 days outcome

There was no significant difference between both groups regarding Non fatal MI (0% in both groups), Target vessel revascularization(4% vs 2%) , , Mortality (2% vs 2 % with P 1,000) or Stroke (0 % in both groups) and total MACE (6% vs 4%).

There was significant difference between both groups regarding Reccurent chest pain which was more in group A (34% vs 12 %, P 0,017) but there was no statistical significance regarding Congestive Heart Failure (14% vs 8% , p 0,523).

Discussion

Recent studies suggest that acute coronary syndromes, including AMI, may result from a systemic inflammatory process, causing multiple unstable lesions. Thus, a strategy of multivessel PCI in the peri-infarct period may be important in improving the outcomes of primary PCI.

Such an attempt of complete revascularization may prevent recurrent ischemia from 'non-infarct-related' lesions, obviating the need for repeat intervention, and also possibly improves the late outcome by reducing the ischemic burden following myocardial damage.

Contemporary guidelines recommend PCI only to the InfarctRelated Artery during the urgent procedure, leaving the other stenosed vessels untreated (culprit-only revascularization) or to dilate during a second elective procedure (staged revascularization). Simultaneous treatment of IRA and non-IRA is recommended only in patients with cardiogenic shock .

The current study evaluated the 1 month outcome of culprit only revascularization compared to total revascularization in the setting of STEMI with MVD.

The principle findings of the present study are

1. There was significant increase in the duration of Primary procedure & volume of contrast in the Total revascularization group.

2. There was no significant reduction in (Mortality , Non Fatal MI , TVR, Stroke or MACE between both groups
3. There was significant reduction in recurrent chest pain in in the Total revascularization group.

In the present study the mean total duration of the procedure was significantly higher in the total revascularization group than in the culprit group. This was concordant with *Di mario et al., 2004* who reported that in TR group the mean PCI time was significantly higher in the Total revascularization group .

In the present study the mean volume of contrast was significantly more in the Total group in the culprit group, this was agreed by the cvLPRIT study where the mean volume of contrast was significantly higher in the total group than in the culprit group (*Gershlick et al., 2015*).

This was logic, because some extra time and contrast was needed to treat the non culprit artery lesions.

In the present study there was no significant statistical difference regarding Non fatal MI, Target vessel revascularization) , total Mortality or Stroke or total MACE in both groups.

However there was a significant decrease in recurrent chest pain in the total revascularization group.

This data was concordant with *Di mario et al., 2004* who showed that there was no excess in-hospital or 1-year MACE (defined as death, repeat MI, urgent PTCA, or CABG) associated with complete revascularization

Also *Politi et al., 2010* suggested that the multivessel approach was safe and possibly less expensive than an incomplete approach by reducing the probability of further unplanned procedures and without affecting the length of hospitalization.

Also, regarding TVR This study was discordant with *Corpus et al., 2004* revealed that 30 days follow up of patients who underwent TR .

Also the data observed in *Roe et al., 2001* showed that multivessel PCI may be associated with an increased risk of adverse outcomes, also *Moreno et al., 1998* found that patients with MVD who underwent TR during primary angioplasty for STEMI.

Unlike other trials, like *Ijsselmuiden et al., 2004* who found that multivessel approach had better outcome by decreasing the need for further revascularization.

Also *Qarawani et al., 2007* observed that patients who underwent total revascularization during PPCI had lower incidence of further revascularization.

Regarding Non Fatal MI there was increase in Non fatal MI shown by *Corpus et al., 2004*.

Mortality was found more by *Moreno et al., 1998* & Also *Hannan et al., 2010* who found that patients with multivessel disease STEMI who underwent multivessel primary PCI had mortality rates that were higher than rates for patients with culprit vessel PCI alone.

Other founds that Multivessel PCI had improved the Total MACE like with the PRAMI study there was significant reduction in the number of death from cardiac causes, number of Non fatal MI & number need to repeat revascularization in the Total group in the long term follow up of the patients (*Wald DS et al., 2013*) & in the cvLPRIT study there was also significant reduction in MACE the total group.

Study Limitation

- The short term follow up of the patient .
- the small sample size .
- we didn't use DES so we can not judge its effect on our result .
- It was a non randomized study .

Conclusion

Multivessel revascularization didn't show extra benefit regarding Total MACE however it may improve the clinical status by decreasing the frequency of ischemic chest pain.

Recommendation

Decisions about PCI of the non-infarct vessel(s) should be individualized. Further large randomized trials with more longer follow up will help us solve this dilemma.

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