Target vessel only revascularization versus complet revascularization in non culprit lesions in acute myocardial infarction treated by primary PCI

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Abstract

Background: Several randomized trials performed in the era of total revascularization showed reduction in myocardial complication when compared with target vessel revascularization only in cardiogenic shock and heart failure only. **Methods:** This prospective study included 100 consecutive patients with acute ST segment elevation myocardial infarction and multivessel and suitable for stenting, all underwent primary PCI and were divided into two groups; Group I who target vessel revascularized only and group II who totally revascularized. Safety and efficacy was evaluated. **Results:** incidence of stent thrombosis in TR group (10%) while no stent thrombosis occurred in COR group (0%), also there was higher incidence of contrast induced nephropathy in TR group (25%) compared to 10% of COR group, p = 0.4 . **Conclusion:** Despite higher incidence of stent thrombosis and contrast induced nephropathy in patients who had total revascularization but this did not reach statistical significant differences, other adverse events were equivalent between both stratigies.

Key words: STEMI, coronary revascularization, stenting

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Introduction

Coronary intervention (PPCI).We aimed to compare between culprit only revascularization versus total revascularization in primary percutaneous coronary intervention in patients with multi vessel disease present with ST-segment elevation myocardial infarction. All patients signed an informed consent and the study was approved by the local ethics committee. Key inclusion

criteria were: Subject must be at least 18 years of age, Subject is able to verbally confirm understandings of risks, benefits and treatment of culprit or complete revascularization and legally authorized representative provides written informed consent prior to any study related procedure, Subject must have significant more than two target lesions and requiring primary PCI for acute ST elevation myocardial infarction (STEMI), Target lesion(s) must be located in a native coronary artery and Target lesion(s) must be amenable for percutaneous coronary intervention. Key exclusion criteria were: The patient has a known hypersensitivity or contraindication to heparin, Aspirin or Both, history of bleeding diathesis or known coagulopathy (including heparin-induced thrombocytopenia), or will refuse blood transfusions. An elective surgical procedure is planned that would necessitate interruption of thienopyridines during the first 6 months post enrollment, non-cardiac comorbid conditions are present with life expectancy over 1 year or that may result in protocol non-compliance, Patients with LVEF less than 25% or those with cardiogenic shock and creatinine level more than 3mg per dL or dependence.

Methods

Baseline evaluation

All patients had review of medical history on admission to emergency department including analysis of demographic data (age, sex), presence of risk factors of coronary atherosclerosis, associated co morbidities, 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. Trans femoral approach was done in all patients using 6 Fr sheaths. Diagnostic coronary angiography was done to explore non-infarct related artery. XB or Judkin left and right judkin guides catheters used during PPCI. Aspiration catheters and glycoproteins inhibitors (GPI) were used in lesions with heavy thrombus burden and or impaired TIMI flow after PPCI. Bare metal or drug eluting stent were used, its size and length was detected by the operator.

Study protocol

After PPCI, patients were subsequently divided into 2 group; Group (I) which included 50 patients in whom culprit lesion revascularization only (II) which included 50 patients in whom total revascularization.

Study end points

a) Primary end point target vessel related major adverse cardiac events Cardiac death, ST elevation myocardial infarction (STEMI), Ischemic driven target lesion revascularization (TLR).

b) Secondary end point was, All cause of death including cardiac and non-cardiac death, composite cause of death, recurrent MI, any revascularizations (TLR or TVR), dye nephropathy, Procedure time, Complication (puncture site hematoma, bleeding).

Statistical analysis

Data are presented as mean+ SD for continuous data and as number (%) for categorical data. Between groups analysis was done using student t-test for continuous data and by Chi-square test for qualitative data. Level of evidence was detected to be significant at P value <0.05. Data were collected and analyzed by SPSS (version 17, USA, IL).

Results

Study population

The mean age was 57 ± 11.4 years (58.1± 11.5 y versus 56.7 + 11.0 y in group I and II respectively, P = 0.55), 67% were males (62% versus 72% in group I,II respectively P = 0.28), 33%had diabetes (28% versus 38% in group I,II respectively P = 0.28), 38% had hypertension (38 % in each group P = 1.0), 29 % had dyslipidemia (30% versus 28% in group I,II respectively P = 0.82), 47 % were smokers (50% versus 44% in group I,II respectively P = 0.54), 20% had positive family history of CAD (18% versus 22% in group I,II respectively P = 0.40). Between groups analysis showed no statistical significant differences in baseline characteristics.

Time from symptom onset to admission

The mean time was 7.07 ± 2.7 hours (6.45 ± 2.39 hours in group I versus 7.7 ± 2.97 hours in group II, P = 0.16), 10 % of patients were presented less than 3 hours (4 % versus 6 % in group I, II respectively, P = 0.5), 21 %were admitted between 3-6 hours from onset of symptoms (11 % in group I versus 9% in group II, P = 0.5). 69% were admitted after 6 hours from onset of symptoms (68% versus 70% in group I, II respectively, p= 0.5).

Door to balloon time

The mean time was 80.2 ± 38.5 minutes in all patients (73.5 ± 31.1 minutes in group I, versus 87 ± 44.49 minutes in group II, P =0.3).

Target infarction detected by ECG

79 % had extensive anterior STEMI (80% versus 78% in group I, II respectively, P = 1.000), 15% had anteroseptal STEMI (14 % versus 16% in group I, II respectively, P =1.000), 6% of patients had anterolateral STEMI (6% versus 6% in group I, II respectively, P = 1.000).

Coronary angiography before PPCI

Number of diseased vessel were two vessele disease in 65% of patients and three vessel disease in 35% of patients of both group. Culprit artery was LAD in 55% of all patients (45% versus 65 % in group A, B respectively, P =0.3), RCA was the culprit artery in 35% in both groups (45% versus 25% in group A, B respectively, P =0.39), while LCX was the culprit artery in 10 % of both groups (10% in each group). Table (15), figure (7). Non infarct related artery was LAD in 15% of patients of both groups (15% versus 15% in group A, B respectively), while RCA in 27.5% of all patients (30% versus 25% in group A, B respectively, P =0.8), LCX was in 22.5% of patients of all groups (20% versus 25% in group A,B respectively, P =0.81), while LAD and LCX were presented in 10% of all patients (15%versus 5% in group A, B respectively),while LCX and RCA were presented in 25% of all patients (20% versus 30% in group A, B respectively, P =0.8). Table (1). Timi flow pre PCI was zero in 70% of all patients (65%versus 75% in group A, B respectively P =0.4), while TIMI flow 1 was present in 30% of all patients (35%versus 25% in group A, B respectively P =0.4) Table (1).

Procedural data

All patients received 10000 units of UFH pre PCI, femoral approach was done in all patients using 6 fr sheath, XB guiding catheter was used in 37.5% of all patients while JR was used in 22.5% of all patients,while in 40% of patients of both groups XB and JR were used, floppy wire was used in 90% of all patients, while coated wire in 10 % of patients, predilatation was done in 55% of all patients, aspiration devices were used in 12.5% of all patients, glycoprotein inhibitors were used in 50% of all patients (40% versus 60% in group A, B respectively, P =0.2). The stent number was one in 42.5% of all patients (85% versus 0% in group A,B respectively, P =0.001), while two stents in 35% of all patients (15% versus 55%in group A,B respectively), three stents were inserted in 20 % of all patients (0 % versus 40% in group A, B respectively), while four stents were inserted in 2.5% of patients (0% versus 5% in group A, B respectively), the mean stent length was 21.8±5.63 mm (23.95±5.11 mm versus 20.72± 5.62 mm in group A and group B respectively, P = 0.03), the mean stent diameter was 2.87±0.28 mm (3.0±0.3 mm versus 2.8± 0.28 mm in group A, B respectively, P=0.01). Table (2) TIMI flow in culprit artery after PPCI was III in 97.5% of all patients (95% versus 100%in group A,B respectively),while TIMI flow II

was 2.5% of all patients (5% versus 0% in group A,B respectively), the mean procedural time was 47.75±13.49 minutes in all patients (41.5±8.5 min versus 54±14.7 min in group A,B respectively, P =0.003), the mean contrast volume was215±78.6 ml (172.5±73.4 ml versus 257.5±59.1 ml in group A,B respectively, P =0.001). Table (2), figure (2).

Table (1): Coronary angiography

		All patients N = 100	Group A No = 50	Group B No = 50	P value
TIMI flow	0	(70%)	(65%)	(75%)	0.49
Pre PCI	I	(30%)	(35%)	(25%)	
Culprit artery					
LAD		(55%)	(45%)	(65%)	0.39
RCA		(35%)	(45%)	(25%)	
LCX		(10%)	(10%)	(10%)	
Other non infarct related artery					
LAD		(15%)	(15%)	(15%)	0.81
RCA		(27.5%)	(30%)	(25%)	
LCX		(22.5%)	(20%)	(25%)	
LAD - LCX		(10%)	(15%)	(5%)	
LCX – RCA		(25%)	(20%)	(30%)	

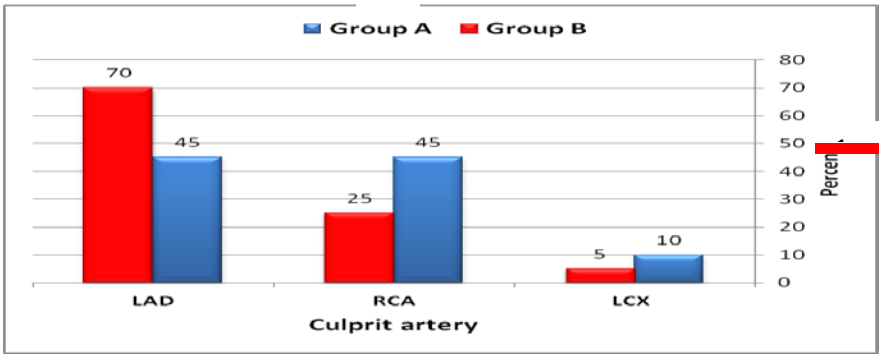

Figure (1): Culprit artery.

In hospital outcome

No reported cases of cardiogenic shock, reinfarction, stroke and major bleeding in either groups. Recurrence of chest pain was reported in7.5% of all patients (10% versus 5% of group A,B respectively, P =1.0), minor bleeding occurred in 17.5% of all patients (10% versus 25% in group A, B respectively, P =0.4), contrast induced nephropathy was evident in 47.5% in all patients (10% versus 35% of group A,B respectively, P =0.4), stent thrombosis occurred in 5% of all patients (10% of group B but not in group A, P=0.4), in the two patients stent thrombosis occurred in LAD which was the culprit artery and was treated by re-intervention, one patient in group B (5%) had sudden cardiac death but not in group A, heart failure occurred equally in both groups (10%), also arrhythmia was reported equally in both groups (15%).

30 days outcome

Combined end point of adverse cardiovascular events was reported in 37.5% of all patients (40% versus 35% in group A, B respectively, P=0.5). All cause mortality occurred in one patient from group B (5%). No reported cases of sub acute stent thrombosis in either group, no re-infarction. Recurrence of ischemic symptoms was reported in 15% of patients (25% versus 5% in group A, B respectively, P =0.2). Heart failure was evident in 15% of all patients (15% in each group), the need for re-intervention was reported in 10% of all patients from group B but not in group A, no reported cases of cerebrovascular stroke.

Table (2): Procedural data

	All patients N = 100	Group A No = 50	Group B No = 50	P value
PCI time /min				
Mean ± SD	47.75±13.49	41.50 ± 8.59	54.0 ± 14.74	0.003
Range	30 – 90	30 – 60	40 – 90	
PCI contrast /ml				
Mean ± SD	215.0±78.6	172.50 ± 73.40	257.50 ± 59.10	0.001
Range	100 – 400	100 – 300	200 – 400	
Guiding catheter				
XB	(37.5%)	(55%)	(20%)	<0.001
JR	(22.5%)	(45%)	(0%)	
XB – JR	(40 %)	(0%)	(80%)	
Guiding wire				
Floppy	(77.5%)	(85%)	(70%)	0.04
Coated	4 (10%)	(15%)	(5%)	
Floppy – coated	(12.5%)	(0%)	(25%)	
Aspiration device	(12.5%)	(15%)	(10%)	1.0
Glycoprotein inhibitors	(50%)	8 (40%)	(60%)	0.2
Pre-dilatation	(55%)	9 (45%)	(65%)	0.2
TIMI flow post PCI II	(2.5%)	(5%)	(0%)	1.0
III	(97.5%)	(95%)	(100%)	
Number of stent				
1	17 (42.5%)	17 (85%)	0 (0%)	<0.001
2	14 (35%)	3 (15%)	11 (55%)	
3	8 (20%)	0 (0%)	8 (40%)	
4	1 (2.5%)	0 (0%)	1 (5%)	
Stent diameter				
Mean ±SD	2.87±0.28	3.0 ± 0.30	2.80 ± 0.26	0.01
Range	2.5 – 3.5	2.5 – 3.5	2.5 – 3.5	
Stent length				
Mean ±SD	21.80±5.63	23.95 ± 5.11	20.72 ± 5.62	0.03
Range	2 – 33	15 – 30	2 – 33	
Type of stent				
BMS	36 (90%)	17 (85%)	19 (95%)	0. 6
BMS – DES	4 (10%)	3 (15%)	1 (5%)	

BMS: Ber metal stent. **DES:** Drug eluting stent.

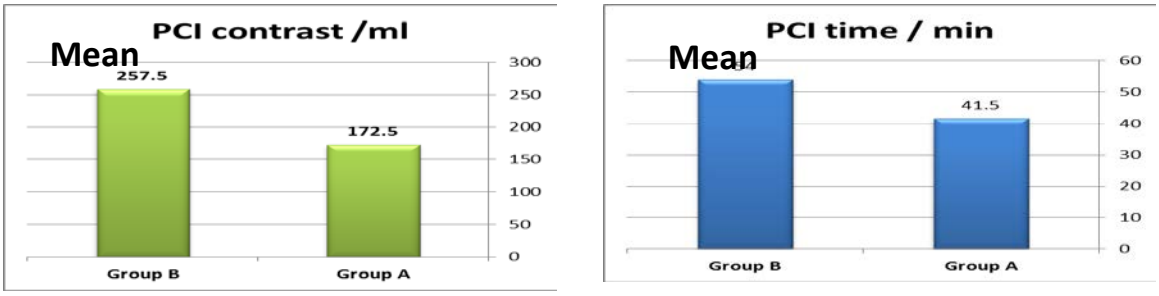

Figure (2): PCI duration and contrast volume.

	All patients N = 100	Group A No = 50	Group B No = 50	P value
Re-infarction	(0%)	(0%)	(0%)	----
Stent thrombosis	(5%)	(0%)	(10%)	0.49
Chest pain	(7.5%)	(10%)	(5%)	1.0
Arrhythmia	(15%)	(15%)	(15%)	1.0
Heart failure	(10%)	(10%)	(10%)	1.0
Cardiogenic shock	(0%)	(0%)	(0%)	----
Major bleeding	(0%)	(0%)	(0%)	----
Minor bleeding	(17.5%)	(10%)	(25%)	0.41
Renal impairment	(47.5%)	(10%)	(35%)	0.41
Further revascularization PCI to LAD	(5%)	(0%)	(10%)	0.48
Stroke	(0%)	(0%)	(0%)	----

Table (3): 30 day outcomes

	All patients N = 100	Group A No = 50	Group B No = 50	P value
Adverse events (yes %)	(37.5%)	(40%)	(35%)	0.5
All cause mortality	(2.5%)	(0%)	(5%)	1.0
Re-infarction	(0%)	(0%)	(0%)	----
Chest pain	(15%)	(25%)	(5%)	0.18
Heart failure	(15%)	(15%)	(15%)	1.0
Further revascularization				
PCI to LAD	(5%)	(0%)	(10%)	0.48
Stroke	(0%)	(0%)	(0%)	----

Discussion

This study evaluated the short term outcome of culprit only revascularization compared to total revascularization in the setting of STEMI with MVD. We reported higher incidence of stent thrombosis and contrast induced nephropathy in patients assigned to total revascularization. However this was not of significant differences. More over no reported differences in other major adverse events between both treatment strategies. In the present study we reported higher incidence of stent thrombosis in TR group (10%) while no stent thrombosis occurred in COR group (0%), also there was higher incidence of contrast induced nephropathy in TR group (25%) compared to 10% of COR group. This is explained by larger amount of contrast used in the TR patients. However, we did not report any significant difference between both groups in other adverse events during the in- hospital stay period**.** Prior trials as Mohamed et al., 2010[1] and Cavender et al., 2009[2] both suggested that multivessel intervention in patients not in cardiogenic shock undergoing primary PCI does not improve the in-hospital outcomes. However, Qarawani

et al., 2007[3] reported that patients who underwent COR were found to be at risk for increased in-hospital complications including acute heart failure, longer hospitalization, but also reported that TR strategy was also associated with a longer, more complex procedure, increased radiation exposure and increased incidence of acute renal failure secondary to increased contrast dye load. Also Politi et al., 2010[4] and Ijsselmuiden et al., 2004[5] and Di mario et al., 2004[6] revealed that complete revascularization by PCI was associated with a lower strategy success rate, higher procedural costs, and similar in-hospital out comes. Other trials like Kong et al., 2006[7] revealed that multi-vessel angioplasty remained a significant predictor of lower in-hospital death and no difference was noted in the end points of acute occlusion or stent thrombosis, stroke, renal failure, or length of hospital stay. We did not report differences between both treatment strategies considering the 30 days outcome except that more patients in COR group had recurrent chest pain. Corpus et al., 2004[8] revealed that 30 days follow up of patients who underwent TR had more fatal re-infarction and more MACEs than patients who underwent COR strategies. Also the data observed in Roe et al., 2001[9] showed that multivessel PCI may be associated with an increased risk of adverse outcomes, also Moreno et al., 1998[10] found that patients with MVD who underwent TR during primary angioplasty for STEMI, had higher rate of in hospital &30 days mortality than those undergoing COR strategy. Also Hannan et al., 2010[11] 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. However other trials, like Ijsselmuiden et al., 2004[5] found that multivessel approach had better outcome by decreasing the need for further revascularization. Qarawani et al., 2007[3] observed that patients who underwent total revascularization during PPCI had lower incidence of further revascularization. Also Politi et al., 2010[4] 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 Di mario et al., 2004[6] 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. The differences in both in-hospital and 30 days outcome between previously mentioned studies may be explained by the differences in study populations, sample size, associated co morbidities, left ventricular functions, lesions complexity, and skills of the operators, and finally the post PCI care.

Summary

We reported higher incidence of stent thrombosis and contrast induced nephropathy in patients who were assigned to total revascularization but this was not of significant difference. More over no reported differences in 30 days outcome between both group were detected.

Conclusion

Despite higher incidence of stent thrombosis and contrast induced nephropathy in patients who had total revascularization but this did not reach statistical significant differences, other adverse events were equivalent between both stratigies.

Recommendation

Further studies with larger sample size are required to asses safety and efficacy of infarct–related artery only PCI compared to total revascularization in the setting of STEMI patients with MVD.

Study limitation

- Small sample size.
- Short follow up period.
- Single centre study.

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