

PRIMARY CORONARY ANGIOPLASTY IN ACUTE MYOCARDIAL INFARCTION

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No field in medicine has undergone as much transformation as management of acute myocardial infarction. Gone are the days when patients were confined to beds for thirty days and masterly inactivity was the order of the day. Earlier emphasis was on controlling of arrhythmias with the introduction of monitoring, CCU and antiarrhythmics. Reduction in myocardial infarct size was the focus of attention for the next decade. Now the emphasis is on the restoration of blood supply following the occlusion of infarct related artery. Blood supply can be restored both by thrombolytics and primary angioplasty, The aim is that the reperfusion should be restored at the earliest, it should be complete and sustained. An attempt has been made in this review to consider the merits, demerits of both strategies and compare the two protocols in the light of present evidence.

Thrombolytics-merits

The biggest point in favor of thrombolytics is that it is readily available, can be quickly administered and can be given by any trained personnel. To save time prehospital administration is possible and seems an attractive offer. The effects are time dependent. The therapy can be administered

equally effective by in small as well as in tertiary centers. The protocol is fairly simple and it does not require a lot of equipment. Different thrombolytics are available at different prices with different regimens but all of them have been shown to be nearly equally effective.¹ (Table-1)

THROMBOLYTICS-MERITS

❖ Readily available
❖ Quickly administered
❖ Given by any trained personnel
❖ Pre hospital administration
❖ Time Dependent effect
❖ Equally effective in small vs tertiary centers
❖ All are effective

TABLE-1

The therapy has been shown to be effective and has a time dependent effect. The lives saved per 1000 patients are 35 when administered within 1st hour, 30 when administered 2nd - 3rd hour, 27 when administered 4th - 6th hour and 21 when administered 7th - 12th hour. So 1.6 lives are saved per hour. Time is muscle and the earlier its administered the better are the results.¹ (Table-2)

THROMBOLYTICS IN AMI

Lives saved per 1000 patients	
35	within 1st hour
30	2nd - 3rd hour
27	4th - 6th hour
21	7th - 12th hour
1.6 lives per hour	

TABLE-2

Thrombolytic are effective in all sites of infarction but it has more to offer in patients at high risk. Lives saved per 1000 patients with LBBB are 49, Anterior MI are 37 as compared to 8 in Inferior MI, in ages 65-74 years are 27 as compared to 11 in ages less than 50 yrs, with low blood pressure (BP < 100mmHg) 62, with tachycardia (HR > 100 bpm) 33 as compared to 13 with heart rate less than 80 bpm, with diabetes 37 in contrast to 15 with no diabetes.²

Thrombolytic demerits:

Thrombolytics like other therapeutic agents have their own limitations. The drug cannot be administered to a significant portion of population due to various factors. Some patients have contraindications to thrombolytics and cannot receive the therapy. Some patients cannot be given thrombolytics due to late presentation and due to non-diagnostic ECG changes. 10-15 % patients

THROMBOLYTICS LIMITATIONS

❖ Contraindications to thrombolytics
❖ Late presentations
❖ Non diagnostic ECG changes
❖ 10-15% persistent occlusion or reocclusion
❖ Lack of effect and fear of side effect - <i>Thrombolytic plateau</i>
❖ High rate of recurrent ischaemia
❖ Reocclusion
❖ Reduced rate of IRA patency
❖ Intracranial bleeding

TABLE -3

will have persistent occlusion or re-occlusion of infarct related artery. A majority of patients are found to have a significant residual stenosis.³ The therapy is not being widely applied due to thrombolytic plateau - lack of effect and fear of side effect. Thrombolytic therapy has been associated with high rate of recurrent ischaemia, reocclusion, reduced rate of infarct related artery patency and intracranial bleeding. Early occlusion has been reported as 5-10 % where as late reocclusion as 30%, failed thrombolysis has been shown to be 20-50 %. Long term patency of infarct related artery following thrombolytics is around 50%.⁴ (Table-3)

Primary Coronary Angioplasty (PCA)

Primary coronary angioplasty had always been an attractive strategy offering an opportunity of not only opening the infarct-related artery by lysing of clot but also taking care of the underlying basic lesion. It is now established that reperfusion can be effectively achieved by primary coronary angioplasty (PCA).^{5,6} Using a guidewire and balloon catheter, it is technically easier to cross a total occlusion consisting of a fresh thrombus than to cross a long standing occlusion of a coronary artery.

Angioplasty can be useful to achieve reperfusion in three quite different circumstances.⁷ (1) Primary coronary angioplasty as a primary procedure instead of thrombolytic therapy. This is referred to as direct or primary angioplasty (2) Secondary angioplasty as adjunctive therapy with thrombolysis or as a management strategy in sub acute phase of AMI (days 2-7) in-patients who do not receive thrombolysis. (3) Rescue angioplasty where thrombolytics administered have not been effective and patient continues to show evidence of continued ischaemia.⁸ Here the discussion

MORTALITY IN PCA

	AGE	(%)	
❖	< 50	(22%)	3.0
❖	50-59	(23%)	2.82
❖	60-69	(27%)	5.07
❖	70-79	(22%)	10.28
❖	80-89	(5.1%)	15.65
❖	> 90	(0.4%)	12.5

TABLE 4

will be confined to the first category i.e Primary Coronary Angioplasty.

Primary Coronary Angioplasty is as effective as and is actually shown to be superior to thrombolytic therapy. PCA is recommended in thrombolytic ineligible patients or if the patient is at relatively high risk of intracerebral hemorrhage consequent to thrombolytic therapy, or if the anticipated time to placement of angioplasty catheters is less than 1 hour from the patients presentation to the emergency departments.^{9,10,11} In the special circumstances of cardiogenic shock the observational data to date is more favourable for primary coronary angioplasty than thrombolysis.¹²

Factors determining outcome

Important predictors of increase mortality in PCA are previous PCA and CABG, carotid artery disease, ventricular arrhythmia, hemodynamics instability and diabetes mellitus. Although PCA appears to have a particular advantage over thrombolysis for the management of high-risk AMI patients. Mortality linearly increases as age advances. Mortality as 3% in patient under 50 years of age and 15.65% in patient 80-90 years of age. (Table-4) The outcome of PCA also depends on the type of lesion to be tackled. Mortality in type A, B, C lesion is 4.76%, 5.22% and 7.08% respectively. Mortality in PCA is more in multivessel disease. The highest mortality in-patient going for

PCA recorded is 40% in left main stem disease. Ejection fraction EF is an important predictor for mortality in PCA. EF > 30% showed 26.05% mortality, EF 30- 39%, showed 7.96% and EF > 40 showed 2.56% mortality.¹³ (Table-5)

PCA-Better than thrombolytic therapy!

The advantages of PCA over thrombolytic therapy are many. PCA has superior short term and long term results over thrombolytic therapy. Mortality reported with primary angioplasty is 2.6% to 7.8% between 6 to 12 hours.⁵ Thirty days mortality is 4.2% as compared to 6.9% in the thrombolytic group. ($p<0.005$).¹⁴ At 6 months mortality is 6.1% as compared to 8.1% in the thrombolytic group ($p<0.001$). Pooled data from 10 randomized trails revealed significant reduction in mortality in patients treated with primary coronary angioplasty.¹⁵

In the co-operative cardiovascular project data base, primary coronary angioplasty was associated with improved 30 days survival (hazard ratio 0.74, 95% confidence interval 0.63-0.88 and one year survival (hazard ratio 0.88, 95% confidence interval (0.73-0.94).¹⁶ Immediate results have shown lesser mortality (2.6%) as compared to (6.5%) thrombolytic therapy ($p<0.6$), lower rate of reinfarction and death (5.1%) to (12%) ($p<0.02$) and no intracranial hemorrhage as compared to (2%) with thrombolytics ($p<0.05$).¹⁷ The long term results of PCA showed that recurrent ischemia was less 36.4% as compared to thrombolytic therapy (48%) ($p< 0.02$), reintervention was much

MORTALITY IN PCA
EJECTION FRACTION

❖	<30	(5.2%)	26.05
❖	30-39	(8.8%)	7.96
❖	≥40	(54.7%)	2.56

TABLE - 5

MORTALITY IN P C A IN SHOCK
32-45 %

❖ II NRMI	(4.2% of 4939)	32%
❖ OKeefe	(7.9% of 1000)	44%
❖ Hannon	(7.6% of 2291)	45.1%

TABLE - 6

less required (27.2%) as compared to thrombolytics (46.5%) ($p < .0001$), rehospitalization was also less in PCA group (58.9%) as compared to thrombolytic (69%) ($p < .035$), death and reinfarction was similarly less in PCA group (14.9%) as compared to thrombolytics (23% $p < .034$)¹⁸

In a randomized trial of PCA versus intravenous streptokinase for AMI in patients presenting on average of 3 hours after symptoms of onset. Le Boer et al found that infarct size measured by enzymes release was reduced by 23% and global and regional left ventricular function was improved in group undergoing PCA.¹⁹ Systematic reviews of seven trials of primary coronary angioplasty versus thrombolysis collectively enrolling just under 1200 patients revealed a 40% reduction in the composite end point of death by 6 weeks.²⁰

Different available thrombolytic have been shown to be superior to PCA in the setting of acute myocardial infarction. In ALKK study group 14980 patients were evaluated, 31 months mortality was low in PCA group 4.3% as compared to 10.3% in streptokinase group ($p < .001$).²¹ Similarly PCA was superior to tPa in elderly with

anterior MI in terms of mortality (2.8% Vs 10.8%, $p = 0.2$). Angina and positive ETT (11.9% Vs 25.2% $p = .01$), revascularization procedure done (22% vs 47%, $p < .001$), deaths at 6 months (4.6% vs 11.7%, $p < .05$) and less revascularization at 6 months (31.2% Vs 55.9%, $p < .001$).^{22,23}

Meta analysis of seven trials of PCA versus thrombolytics enrolling about 1200 patients revealed a 40% reduction in short term mortality in patients treated with PCA with a similar reduction in the composite end point of death or non fatal AMI by 6 weeks. A non-significant trend favoring PCA was present at one year.²⁰

Cardiogenic shock – thrombolytic vs PCA

Patients in cardiogenic shock form a different group. Mortality is high in patients with cardiogenic shock. Thrombolytics have been able to reduce mortality but it still has a limited role to play. Treated with PCA mortality has been reduced much more than in-patient with cardiogenic shock than treated with thrombolytics. Mortality in patients with cardiogenic treated with primary angioplasty is 45% reported by Lee et al and 46% in SHOCK Trial Registry.^{12,24} The impact of PCA on cardiogenic shock is remarkable. Those patients who had successful PCA (62%) had 71% survival rate as compared to those with unsuccessful PCA (38%) who had only 29% survival rate. 80%

SECOND NATIONAL REGISTRY OF MYOCARDIAL INFARCTION (NRMI-2)

❖ 24,705 alteplase and 4,939 PCA
❖ stroke rate 1.6% vs. 0.7% $p < 0.0001$
❖ death and nonfatal stroke not different
❖ Reinfarction (2.9% rt-PA & 2.5% PTCA)
❖ median time rt-PA was 42 min; balloon inflation 111 min ($p < 0.0001$).
❖ In-hospital mortality in shock after rt-PA 52% vs. PCA 32%, $p < 0.0001$
❖ In-hospital mortality 5.4% after rt-PA and 5.2% after PTCA.

TABLE -7

of patients who had successful PCA were followed for 2.3 years with 36% rehospitalization, 8% had reinfarction, 8% had CABG and 24% were having angina.²⁵

PCA is it really that good?

There had been widespread criticism on the trials reported above. Main argument had been that these 'wonderful results' were achieved in research centres with maximal resources and staff. Can similar results be achieved in other community based hospitals? These important and pertinent questions were addressed in these trials and registry. In the 'Real World' survey which was prospective, observational survey designed to assess the results achieved in terms of early and late (1-year) mortality. The patient managed by PCA had 85.5% as compared to 89.5% survival in thrombolytic therapy ($p=0.18$) at 1 year. The results of this large registry of real world practice indicated no survival benefit for patients with primary angioplasty as compared with those who received thrombolytic therapy. Old age, female gender, anterior MI, history of CCF were significant factors effecting mortality at 1 year.²⁶

Second National Registry of MI (NRM1-2) studied patient with acute myocardial infarction who were lytic eligible. This registry showed in lytic eligible patients, not in shock, PCA and tPa are comparable alternative methods of reperfusion when analyzed in term of hospital mortality, mortality plus non fatal stroke and reinfarction.²⁷ (Table-4)

Myocardial infarction Triage and intervention (MITI) registry failed to demonstrate any significant advantage for primary coronary angioplasty in a population of patients admitted to the participating Seattle hospitals from 1988 to 1994. According to MITI registry there was 30% less angiography 15% less intervention and 13% less costs in thrombolytic therapy then PCA group.²⁸

PCA PROBLEMS

❖	No reflow	5-10%
❖	Acute thrombosis	5-10%
❖	Subacute thrombosis	5-10%
❖	Failure	5-25%
❖	Restenosis	30-50%

TABLE - 8

Problems with PCA — any solutions?

Primary Coronary Angioplasty has an advantage over thrombolysis in AMI patients. But there are some inherent problems with PCA like no re flow phenomenon in 5-10%, acute thrombosis in 5-10%, sub acute thrombosis in 5-10%, failure to achieve adequate luminal diameter in 5-25 and restenosis rate of 30-50%, 28 Different strategies have been advised and tried to overcome these problems of PCA. Three strategies have been successful primary stenting and use of IIb/IIIa blockers and antiplatelet agents like ticlopidine. A high procedure success rate was reported and the sub acute thrombosis rate was low (<3%), largely due to aggressive use of antiplatelet therapy with aspirin and ticlopidine.

Stenting:

PAMI-STENT, a slightly lower rate of TIMI grade 3 flow was seen with stenting compared with PCA, raising the possibility of embolization of platelet aggregates at the time of stent deployment. Mortality rates were generally low, with slight non significant trends favouring stenting. The major benefit of stenting was seen in a significant reduction in incidence of the subsequent target vessel revascularization ²⁹ Table 1 summarize major randomized trials of primary stenting Vs PCA in AMI.

The long term follow up results of STENTIM-2 revealed event free survival in stent group at 6 months and 12 months was

RANDOMIZED TRIALS OF PRIMARY STENT PLACEMENT VS PCA IN ACUTE MYOCARDIAL INFARCTION

	ESCOBAR	FRESCO	GRAMI	PASTA	PRISM	PAMI-STENT
No of Patients						
• Stent	112	75	52	67	39	452
• PTCA	115	75	52	69	49	448
Enrolment Criteria	≥ 6 hrs after symptoms onset; 6-24 hrs of persistent symptoms	≥ 6 hrs after symptoms onset; 6-24 hrs of persistent symptoms ST elevation	< 30mm after symptoms, ST elevation; < 24 hrs after symptoms onset; < 75 yrs old	≤ 12 hrs onset	≤ 24 hrs after symptoms onset	< 12 hrs after symptoms onset
Randomization Criteria	Lesion suitable for stenting	Optimal PCA results	Lesion suitable for stenting	Lesion suitable for stenting	Lesion suitable for stenting	Lesion suitable for stenting
Length of follow up	6 months	6 months	1 year	< 1 year	6 months	30 days
Crossover No (%)	15 (13)	0 (0)	13 (25)	--	--	68 (15.1)
TIMI -- 3 % stent	--	100	98 P = < 0.03	--	--	88.9
PTCA Mortality %	--	99	83	--	--	92.7
Stent	2	1	3.8	4.8	0	3.5
PTCA	3	0	7.6	9.1	0	1.8
Target Vessel Revascularization %	4 P=0.0016	7 P=0.002	14 P=NS	186 P=0.009	11 P=0.01	0.9 P=0.006
Stent	17	25	21	37.6	36	3.5
PTCA						

TABLE 9

81.2 % and 80.2 % as compared to control group 72.7% and 71.8% ($p<0.14$ and $p<0.16$) respectively. Repeat revascularization rate was low in stent group at 6 month and 12 month of 16.8% and 17.8% as compared to control group 26.4% and 28.4 ($p<0.1$ and $p<0.1$) respectively.³⁰

Several randomized trials have compared primary stenting with PCA in patients with AMI (Table 1). Based on the meta analysis of these 6 trials in AMI, Stent and PCA were found to have similar mortality from 6 months to 1 year, although stent patients had a significant lower risk of developing adverse events related to recurrent ischemia. The difference in mortality between these two treatment strategies has not yet been sufficiently studied and need to be better defined in future trails of larger size and longer follow up.

IIb/IIIa blockers:

The use of Iib/IIIa before direct angioplasty and stenting in AMI has shown encouraging results. The ADMIRAL study shows that TIMI-3 flow was 86% as compared to 78% in control group, ejection fraction increased from 55% Vs 51% at 24 hours to 63% Vs 55% at 1 month follow up period. Major adverse cardiac events was 10.7% who receive abciximab Versus 20% in control group.³¹

A meta-analysis of 1369 patients from five randomized clinical trials (EPIC, RAPPORT, ISAR-2, ADMIRAL and STOPAMI)

of abciximab in percutaneous intervention for acute myocardial infarction in 684 patients who received abciximab with 685 patients who did not receive abciximab. The benefit was apparent at 30 day follow up and was more pronounced at 6 month follow up (Table 2).³²

Tirofiban (Aggrastat) given in the emergency room before primary angioplasty initiated in a study at Standford hospital. The compared to a control group receiving tirofiban in the cath lab. The end point for this study included, bleeding complication and thrombocytopenia and 30 days major adverse cardiovascular events. Enrollment is currently underway; interim results revealed a higher TIMI Grade flow at angioplasty with early administration of tirofiban when compared to initiating the drug in cath lab.

Acute and long term follow up based upon preliminary data from these trials, the GP IIb/ IIIa inhibitors appear to hold promise in the treatment of acute MI.

Friends or foes? (Both strategies are effective for reperfusion but are these friends or foes)

Only 33% of the subject with acute MI receive thrombolytic therapy. There are several contraindication to thrombolytic therapy. The risk of intracerebral bleeding is more with thrombolytic therapy. Early occlusions are more and long term patency is around 50%. Many patients report late and some present with non-diagnostic ECG

AGGREGATE DATA FROM 5 RANDOMIZED TRIALS

	Abciximab	No Abciximab	Odds ratio	95% CI	P Value
30 days Death	2.8%	4.2%	0.65	0.30 - 1.16	0.141
30 days Death / MI	4.2%	7.2%	0.57	0.36 - 0.92	0.02
6 months Death	4.2%	6.7%	0.61	0.38 - 0.98	0.043
6 months Death / MI	7.0%	11.7%	0.57	0.39 - 0.83	0.003

TABLE 10

PCA VS THROMBOLYTICS

❖ Both are effective
❖ Both time dependent
❖ Both have inherent problems
❖ Both need improvements
❖ None is ideal
❖ ? complimentary

TABLE - 11

changes. Such patients do not receive thrombolytic therapy. In such condition PCA can be helpful. But can PCA be widely rapidly and expertly applied? Less than 20% in USA and less than 10% in Europe hospitals have facility for cardiac catheterization. The majority of acute AMI patients are not reperfused with PCA within the recommended ACC/AHA time constraints. In expert centres the door to needle time for thrombolytic therapy is 30-60 minutes where as door to balloon time is 60-90 minutes in expert centers but in community hospital it is 102 minutes and in low volume centre it is 138 minutes where PCA is performed on less than 40% in acute MI patients. Both of the strategies should be employed as complimentary.

CONCLUSION

PCA and thrombolytics both are effective and time dependent. None is ideal having inherent problems, and perhaps their best utility lies in being complimentary to each other. PCA is perhaps preferable in high risk patients in an expert center with expert (willing operators)/staff when it can be performed in requisite time.

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