

Primary angioplasty – the standard of treatment for acute ST segment elevation myocardial infarction?

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Summary

Although a large multicenter randomised controlled trial (RCT) is missing, there is accumulating evidence from smaller RCT's that primary angioplasty for acute myocardial ST segment elevation infarction (AMI) is superior to intravenous thrombolysis in reducing hospital events, such as mortality, reinfarction and stroke. However, this is only true if primary angioplasty is performed by physicians experienced in primary angioplasty at high volume angioplasty centres and door-to-balloon times within 90 minutes. These results were confirmed by the current analyses of the German MITRA / MIR databases, which could show for the first time that primary angioplasty even performed in a clinical routine setting is superior to thrombolysis for AMI patients.

However, angioplasty facilities are available only at a minority (<20%) of hospitals in the industrial countries. Therefore recommendations on the use of angioplasty in the setting of AMI have taken this into account and differentiate between hospitals with and without angioplasty facilities.

Introduction

Treatment of acute ST segment elevation myocardial infarction (AMI) with intravenous thrombolysis, as shown by the GISSI (1) and the ISIS (2) trials, established the value of early reperfusion therapy by reducing mortality and morbidity for AMI patients compared to no reperfusion therapy.

Percutaneous transluminal coronary intervention (PCI) is an alternative to thrombolysis to achieve reperfusion. Since the introduction of mechanical reperfusion therapy for the treatment of AMI by Hartzler et al. (3) and Meyer et al. (4) in 1983, it took

its use in the scenario of AMI treatment (5-8).

However, there are still controversies on angioplasty in the setting of AMI, which are mainly concerning its availability in clinical practice as well as the possibility to reproduce the results from randomised controlled clinical trials (RCT's) performed at specialized centres in clinical practice (9).

The scope of this review article is to

- 1) show indications and types of use of angioplasty in the treatment of AMI
- 2) review the evidence of treatment with primary angioplasty compared to thrombolysis for AMI
- 3) suggest a feasible and rational approach for the current use of angioplasty for AMI

Definitions

In the setting of an AMI percutaneous coronary intervention (PCI), that is percutaneous transluminal coronary angioplasty (PTCA) ± stent implantation, can be

used in quite different circumstances:

- *Primary (direct or immediate) angioplasty*: PCI without preceding thrombolysis within the first 12 hours after symptom onset or different
- *combinations of PCI with thrombolysis*:
 - *facilitated - PCI*: thrombolysis followed immediately by PCI
 - *early - PCI*: PCI within 1 or 2 days after thrombolysis
 - *late - PCI*: PCI >2 days after thrombolysis
 - *„rescue“ - PCI*: PCI for „ineffective“ thrombolysis

Sometimes the term “*facilitated*” PCI is also used when glycoprotein IIb/IIIa antagonists are used in combination with PCI. In our opinion this term should however be restricted for the combination of thrombolysis (±glycoprotein IIb/IIIa antagonists) with PCI.

Primary angioplasty as the accepted standard of reperfusion therapy for acute myocardial infarction

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nearly 20 years of investigation to establish clear recommendations on

1. Patients with contraindications for thrombolysis

AMI patients with contraindications for thrombolysis should be the ideal candidates for primary angioplasty. Absolute contraindications for thrombolysis, such as stroke within the last 3 months, active bleeding or trauma or surgery within the last 14 days, are present in about 6% of AMI patients presenting within 12 hours after symptom onset (10). The MATE trial (11) as well as an analysis of the MITRA trial (10) could show, that an early invasive strategy using primary angioplasty is superior to no reperfusion therapy for these patients. However, less than 20% of AMI patients with contraindications were treated with primary angioplasty in the MITRA database(10) and only about 6% of patients with

transferred for primary angioplasty (12).

2. Patients with cardiogenic shock

The presence of cardiogenic shock in an AMI patient is the single most important predictor of death. Data of the NMRI-2 randomised SHOCK study Multicenter Trial showed a survival advantage for primary angioplasty compared to the SHOCK strategy. In a retrospective analysis, patients with cardiogenic shock were transferred to hospitals with angioplasty facilities. The

3. Patients with ineffective thrombolysis

Fast and persistent reperfusion of the infarct related artery can be achieved by thrombolysis in only about 60% of patients within 90 minutes after

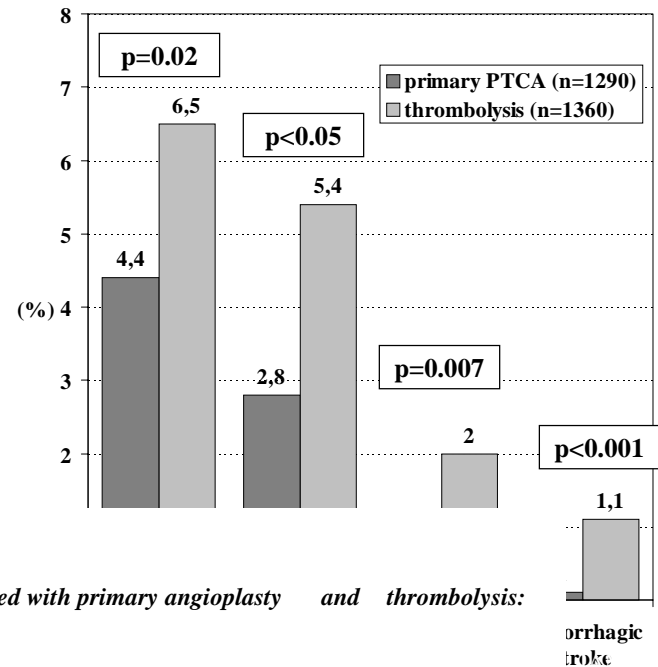


Table 1: Comparison of hospital mortality of AMI patients treated with primary angioplasty and thrombolysis: Data from randomised controlled trials (RCT's) versus registries.

Studies	Primary angioplasty	Thrombolysis	relative risk	p - value
<i>(selected) RCT's</i>				
PAMI(26) (PD = 195; TL = 200)	2.6%	6.5%	0.40	p=0.06
GUSTO IIb(31) (PA = 565; TL = 573)				
meta-analysis of RCT's(32) (PA = 1290; TL = 1316)				
<i>Registries</i>				
MITI (retrospective)(36) (PA = 1050; TL = 2095)				
NRMI-2 (prospective)(13) (PA = 4939; TL = 24705)				
French registry (prospective)(37) (PA = 152; TL = 569)				
MITRA/MIR (prospective)(39) (PA = 1327; TL = 8579)				
MITRA/MIR (prospective)(39) cardiogenic shock excluded (PA = 1214; TL = 7672)				

PA = primary angioplasty ; TL = thrombolysis

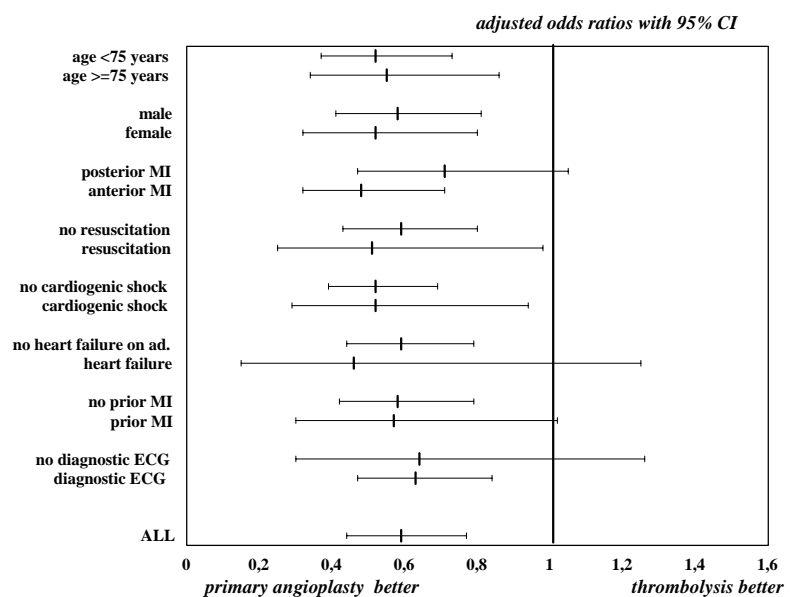


Fig. 2: Multivariate analysis of hospital mortality for primary angioplasty and thrombolysis performed in different subgroups of patients (from ref. 39, with permission)

thrombolysis are not daily practice in most hospitals, neither are clear strategies to submit such patients for subsequent coronary interventions.

Primary angioplasty versus intravenous thrombolysis:

Data from randomised controlled trials

With the publication of 3 RCT's in 1993 (26-28) the controversial discussion on the superiority of primary angioplasty over thrombolysis began. Up to 1 series of predominantly prospective RCT's comparing primary angioplasty with intravenous thrombolysis is available

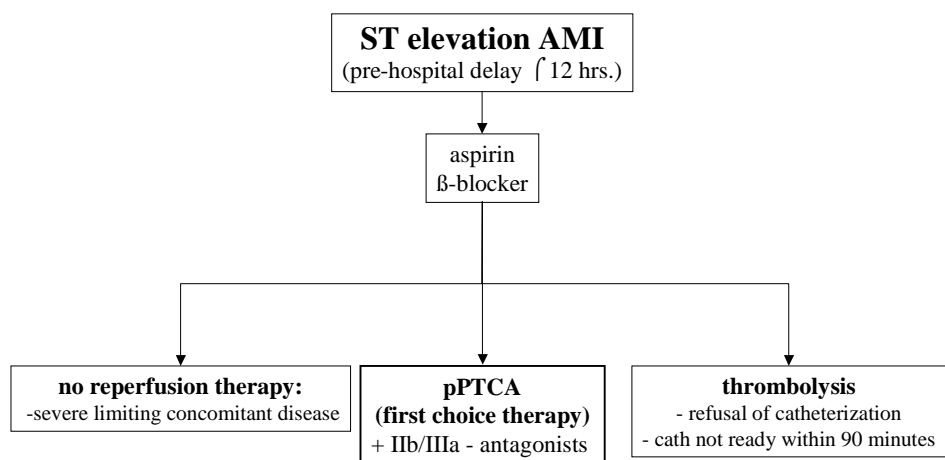
angioplasty technique, that is high use of stents and glycoprotein IIb/IIIa antagonists at a high volume centre, with the gold standard thrombolysis showed a higher absolute benefit in favour of primary angioplasty than those previous RCT's(35).

Data from registries

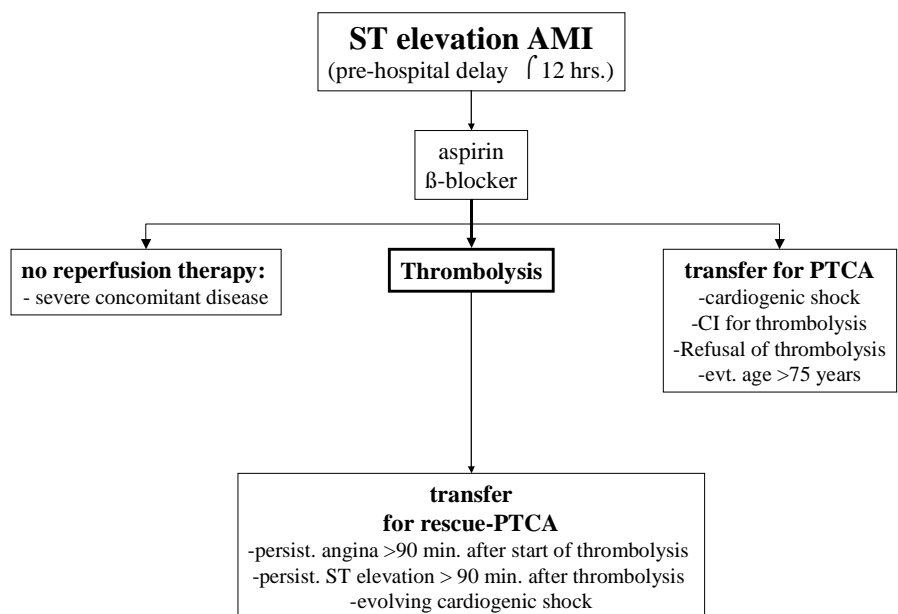
There was concern if these beneficial results from highly specialized

versus 11.3%, OR = 0.54, 95% CI: 0.43-0.67 and the combined endpoint of death, reinfarction or stroke: 9.1% versus 15.8%; OR = 0.54, 95% CI: 0.44-0.65). This was confirmed after adjusting for other identified confounding parameters: multivariate OR for hospital mortality = 0.58, 95%CI: 0.44-0.77, p<0.001 in favour for primary angioplasty. Subgroup analysis showed that the benefit of primary

Hospitals with qualified pPTCA facilities



Hospitals without qualified pPTCA facilities



31). Neither of them was powerful enough to detect a significant survival benefit in favour of primary angioplasty.

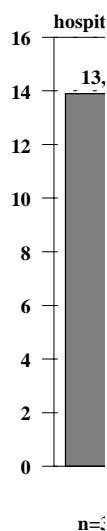


Fig. 4a + 4b: Reperfusion strategies at hospitals with and without angioplasty facilities

Fig. 3 - Hospital mortality (38, with permission)

To our opinion, the growing experience with primary angioplasty is the most important factor to explain these findings. Grassman et al(47) as well as an analysis of the ALKK study group from Germany(48) could show that a higher hospital volume in performing primary angioplasty was associated with better clinical results compared to low volume hospitals. These findings were confirmed by recent data(49-51), which also could show that continuous quality measurement could shorten in-hospital time delay(52). Beside the hospital volume, the individual volume of each physician performing primary angioplasty is important as well(53). The importance of both factors is not surprisingly, for primary angioplasty is not a trivial technique. It will only result in good outcome, if performed by experienced physicians with a well trained team and optimised hospital logistics to keep time from admission until reperfusion as short as possible.

Practical considerations

Taking these data into account, it is obvious that primary angioplasty performed at high volume interventional hospitals from experienced physicians 24 hours/7 days a week is superior to thrombolysis. However, angioplasty facilities are available only at a minority (<20%) of hospitals in the industrial countries(54;55). Currently even at hospitals with angioplasty facilities thrombolysis is still more often used than primary angioplasty as method of first choice for the treatment of AMI in Germany(56). Transportation of AMI patients for primary angioplasty will result in a time loss to achieve reperfusion. With a time delay of more than 2 hours the benefit of primary angioplasty will be lost.

Primary angioplasty at hospitals with facilities to perform coronary angioplasties

We suggest, that such hospitals should (*Figure 4a*):

- choose primary angioplasty as the treatment of first choice for patients with AMI. This would enable doctors to become more experienced with the procedure, and thus better results can be achieved.
- establishing a 24 hour, 7 days a week service. This would enable these hospitals to achieve the goal of treating 90% of AMI patients with a reperfusion therapy, especially patients contraindicated for thrombolysis.
- introduce a round the clock service with experienced personnel. Then the angioplasty service could be offered to the surrounding hospitals where the facilities are lacking to perform primary angioplasty. Patients with contraindications to thrombolysis, with ineffective thrombolysis or high risk patients could be transferred to these centres to be treated using primary angioplasty within an acceptable time limit.

With such efforts, the goal of treating up to 90% of AMI patients with a pre-hospital delay ≤ 12 hours after the onset of symptoms with some kind of reperfusion therapy, would no longer be restricted to some enthusiastic hospitals, but would be achievable for whole regions.

Primary angioplasty at hospitals without angioplasty facilities

We currently suggest thrombolysis to be the treatment of first choice (*Figure 4b*). However, patients should be carefully observed for signs of failed thrombolysis or development of cardiogenic shock. Then a rapid transportation to an angioplasty centre should be initiated.

If such a transportation is possible within 60 minutes after admission of the patient at the non-invasive hospital, the PRAGUE study could show a superiority of immediate transfer of such patients for primary angioplasty compared to thrombolysis at the initial

hospital(57). However, before we would suggest such a strategy for general use, these data has to be confirmed by ongoing trials, such as the FINESSE and CARESS trials. These trials will also determine if the combination of thrombolysis (\pm glycoprotein IIb/IIIa antagonists) with angioplasty (facilitated PCI) is superior to primary angioplasty (\pm glycoprotein IIb/IIIa antagonists) alone, which was suggested by the PACT study(58), although a prior study did not find an advantage of such a combination therapy(59). Older studies on immediate angioplasty after thrombolysis found only an increase in complication rates but no reduction in events compared to thrombolysis and a more conservative approach concerning invasive therapy(60-62).

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Ci vediamo a Verona