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EUROPEAN SOCIETY OF CARDIOLOGY

SINDROMI CORONARICHE ACUTE STE

INDICAZIONI ALLA PTCA

Linee Guida ESC 2004

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Linee guida delle SCA
Crotone 1 Ottobre 2004

Primary angioplasty versus intravenous thrombolytic therapy for acute myocardial infarction: a quantitative review of 23 randomized trials

Ellen C. Keeley, Joudith A Boura, Cindy L. Grines
Lancet 2003; 361:13-20

Primary PTCA is more effective than thrombolytic therapy for the treatment of ST-segment elevation AMI!

Why thrombolytic therapy is still used far more often in daily practice ?

This is caused by issues such as logistical difficulties, reimbursement, variability of angioplasty results, and safety and feasibity of interhospital trasportation.

As the large majority of patients with acute ST elevation myocardial infarction are presented in hospital without the capability to perform primary angioplasty, interhospital network play a central role.

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revised version as of July 30th 2004

European Guidelines for Percutaneous Coronary Interventions (PCI)

GUIDELINES CLASSES

Classe I Condition for wicth is general accord or evidence that *procedur/therapy is useful or efficacy*

Class II Condition for wicth are *conflicting evidences or opinion* divergences that procedur/therapy is useful or efficacy

Class II a The weight of the evidence or the opinions is *to favor of the usefullness or effectiveness* of procedur/therapy.

Class II b The usefullness and the effectiveness of the procedure/therapy has not been demonstrated and *they are not thought probable*

Class III Conditions for which there are evidences or exists a general agreement based on which the therapy is *not thought useful* and effective and in some cases *it can also be harmful*.

Levels of Evidence

LEVELS OF EVIDENCE	A	Multiple clinical randomized study
LEVELS OF EVIDENCE	B	One clinical randomized study or non randomized studies
LEVELS OF EVIDENCE	C	Expert opinions

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Primary PCI

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Primary PCI is defined as intervention *within 12 hours after the onset of chest pain*, without prior (full or concomitant) thrombolytic therapy.

Many randomised controlled trials have documented that primary PCI is superior to intravenous thrombolysis for the immediate treatment of STEMI (more effective restoration of patency, less reocclusion, improved residual left ventricular function and better clinical outcome including strokes).

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Primary PCI

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PCI for STEMI requires an experienced team of interventional cardiologists working together with a skilled support staff. This means that

only hospitals with an established interventional program should use PCI for STEMI

instead of intravenous thrombolysis. Most of the trials comparing thrombolysis versus primary PCI were carried out in high volume centres, by experienced operators, with short response times.

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Transfer of patients for primary PCI fibrinolytic-ineligible patients

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There is no doubt that patients presenting within 12 hours after onset of chest pain in hospitals without PCI facilitites and having contraindications to thrombolysis *should be immediately transferred* for coronary angiography and, if applicable, primary PCI. PCI might be their only chance for quickly opening the coronary artery.

Recommendation for primary PCI in patients with contraindications to thrombolysis: I C

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Routine stenting in STEMI ?

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One trial has suggested that direct stenting (without prior balloon dilatation) is associated with a more complete ST-segment resolution.

Three studies have documented the usefulness of routine stenting in patients with STEMI: *Zwolle, Stent-PAMI and CADILLAC.*

Recommendation for routine stenting in STEMI: I A.

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Rescue PCI after failed thrombolysis

Rescue PCI was defined as PCI (*within 8 hours*) in a coronary artery that remains occluded despite thrombolytic therapy. Failed thrombolysis is generally suspected when

persistent chest pain and non-resolution of ST-segment elevation are evident (after 90' of lytic).

It is then confirmed angiographically (significant epicardial coronary lesion together with impaired flow <TIMI 3).

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Rescue PCI after failed thrombolysis

A meta-analysis from the RESCUE I, RESCUE II and other clinical experiences suggested a *probable benefit of rescue PCI*. In the MERLIN trial, *rescue PCI did not improve survival by 30 days*, but improved event-free survival almost completely due to a *reduction in subsequent rivascularisation*. The most serious limitation of MERLIN, however, was that it was considerably underpowered

Recommendation for rescue PCI in patients with failed thrombolysis: I C

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COMBINATION THERAPY GP IIB/IIIA INHIBITORS

ACC/AHA Guidelines 2004

CLASS IIb

- Combination therapy with abciximab and half-dose reteplase or TNK may be considered for prevention of reinfarction (Level of Evidence: A) and other complications of STEMI in selected patients: anterior location of MI, age less than 75 years, and no risk factors for bleeding. In two clinical trials of combination reperfusion, the prevention of reinfarction did not translate into a survival benefit at either 30 days or 1 year. (Level of Evidence: B)
- Combination pharmacological reperfusion with abciximab and half-dose reteplase or tenecteplase may be considered for prevention of reinfarction and other complications of STEMI in selected pts: anterior location of MI, age less than 75 years, and no risk factors for bleeding in whom an early referral for angiography and PCI (facilitated PCI) is planned. (Level of Evidence: C)

CLASS III

- Combination pharmacological reperfusion with abciximab and half-dose reteplase or TNK should not be given to pts aged greater than 75 years because of an increased risk of ICH. (Level of Evidence: B)

PROCEDURE	INDICATION	RECOMMENDATION	STUDIES for Level A-B
PRIMARY PCI	pts presenting <12 h after onset of chest pain and up to 90 min after first qualified medical contact	I A	PAMI GUSTO-IIb C-PORT PRAGUE 1–2 DANAMI-2
PRIMARY PCI	when lysis is contraindicated	I C	--
PRIMARY PCI	preferred more than lysis for pts presenting within >3 and <12 h after pain onset	I C	--
STENTING routine use during PCI	primary PCI	I A	Zwolle Stent-PAMI CADILLAC

PROCEDURE	INDICATION	RECOMMENDATION	STUDIES for levels A-B
RESCUE PCI	within 8 h after failed lysis in patients with large (anterior) MI	I C	--
EMERGENCY PCI (MULTIVESSEL)	cardiogenic shock, in association with IABP even >12 <36 hours	I C	--
POST-LYSIS ANGIOGRAPHY and PCI (if applicable)	(immediately after or up to 12-24 hours after lysis), independent of angina and/or ischaemia	II a	SIAM III GRACIA-1
ISCHAEMIA-DRIVEN PCI after successful lysis	predischarge angina and/or ischaemia after (first) STEMI treated with lysis	I B	DANAMI-1

FIBRINOLYSIS IS PREFERRED

EARLY PRESENTATION

(less than 3 hours from sympton onset and delay to invasive strategy)

INVASIVE STRATEGIES NON AN OPTION

Catheterization lab occupied/not available

Vascular access difficulties

Lack of access to a skilled PCI lab

DELAY TO INVASIVE STRATEGY

Prolonged transport

Medical Contact or Door to Balloon are greater than 90 mimutes

INVASIVE STRATEGY IS PREFERRED

SKILLED PCI LAB AVAILABLE WITH SURGICAL BACKUP

MEDICAL CONTACT DOOR TO BALLOON IS LESS THAN 90‘

HIGH RISK STEMI
Cardiogenic Shock
Killip class is greater than or equal to 3

CONTRAINDICATIONS TO FIBRINOLYSIS
including increased risk of bleeding and ICH

LATE PRESENTATION
The synptom onset was greater than 3 hours ago

DIAGNOSIS OF STEMI IS IN DOUBT

AMI NETWORK

CARDIOLOGY DEPARTMENT

CCU

EMERGENCY DEPARTMENT

MOBILE CARE UNIT

ACS CENTER

MEDICINE DEPARTMENT

PREHOSPITAL THROMBOLYSIS

Indications for Drug-Eluting-Stents

ESC PCI guidelines 2004

Class I
(Level of Evidence: B)

CYPHER

De novo lesions in native vessels, according to the inclusion criteria (SIRIUS)

TAXUS

De novo lesions in native vessels, according to the inclusion criteria (TAXUS IV)

TAXUS

de novo long and complex lesions in native vessels, according to inclusion criteria (TAXUS VI)

ACC/AHA PCI guidelines 2001

No Indications

Routine angiography early post thrombolysis?

Two studies have contributed to recommend routine coronary angiography and -if applicable- PCI early post thrombolysis: SIAM III and GRACIA-1.

In GRACIA-1, *routine PCI <24 hours* -independent of the thrombolysis result- significantly improved the primary endpoint (combination of death, reinfarction, need for revascularisation) after 1 year. This was predominantly driven by the lower need for revascularisation. Thus, SIAM III and GRACIA-1 contributed to the solution of an old but still pivotal problem: the incidence of reinfarction, the "Achilles heel" of thrombolysis.

Recommendation of routine (<24h) angiography and PCI, if applicable, in pts after successful thrombolysis: II A

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Ischaemia-driven PCI after lysis

The DANAMI-1 trial was the first and only prospective, randomised study comparing an invasive strategy of PCI/CABG-surgery with a conservative strategy in patients with pre-discharge inducible myocardial ischaemia after thrombolytic treatment for a first STEMI.

Thus, patients who have received treatment with thrombolytics for their first STEMI with inducible ischaemia before discharge should be referred to coronary angiography and revascularised accordingly independent of "maximal" medical therapy.

Recommendation for ischaemia-driven PCI after successful thrombolysis: I B

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REPERFUSION IN STEMI

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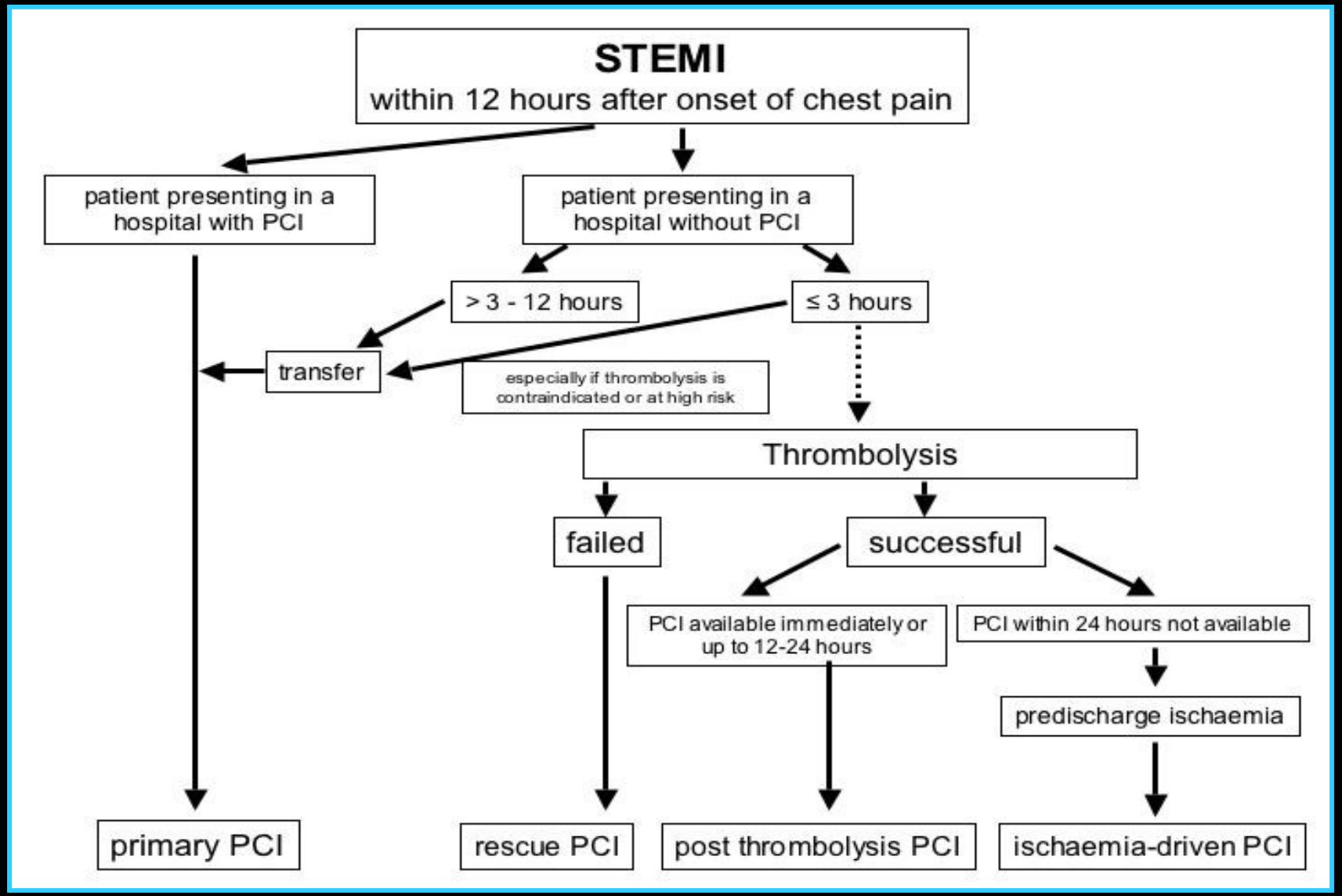

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REPERFUSION IN STEMI

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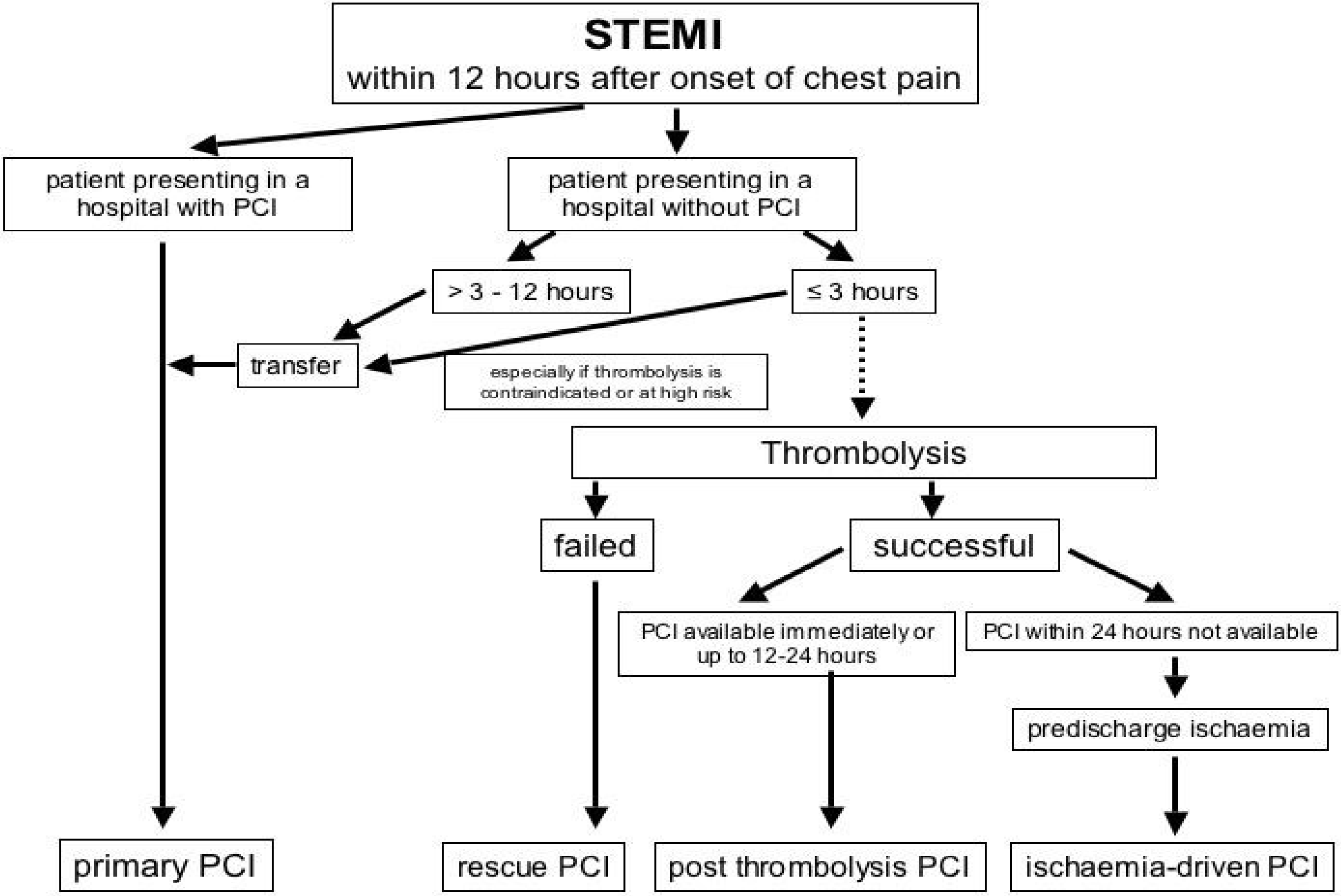
The goal is to keep total ischemic time

within 120 min !


STEMI
within 12 hours after onset of chest pain
patient presenting in a hospital with PCI
patient presenting in a hospital without PCI
> 3 - 12 hours
≤ 3 hours
transfer
especially if thrombolysis is contraindicated or at high risk
Thrombolysis
failed
successful
PCI available immediately or up to 12-24 hours
PCI within 24 hours not available
predischarge ischaemia
primary PCI
rescue PCI
post thrombolysis PCI
ischaemia-driven PCI

Ischaemia-driven PCI after lysis

The DANAMI-1 trial was the first and only prospective, randomised study comparing an invasive strategy of PCI/CABG-surgery with a conservative strategy in patients with pre-discharge inducible myocardial ischaemia after lytic treatment for a first STEMI.

The ocurrences of the primary endpoint (mortality, reinfarction and admission with unstable angina) were significantly reduced with 15.4% vs. 29.5% at 1 year, 23.5% vs. 36.6% at 2 years, and 31.7% versus 44.0% at 4 years.

Thus, patients who have received treatment with thrombolytics for their first STEMI with inducible ischaemia before discharge should be referred to coronary angiography and revascularised accordingly – independent of "maximal" medical therapy.

Recommendation for ischaemia-driven PCI after successful thrombolysis: I B

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PCI for patients not having received thrombolysis within the

Late reperfusion therapy is defined as thrombolysis or PCI starting > 12 hours after onset of chest pain (for late PCI in cardiogenic shock please see above). Thrombolytic therapy for the late treatment of patients with STEMI did not reduce the infarct size or preserve left ventricular function, probably because it was ineffective in establishing coronary patency.

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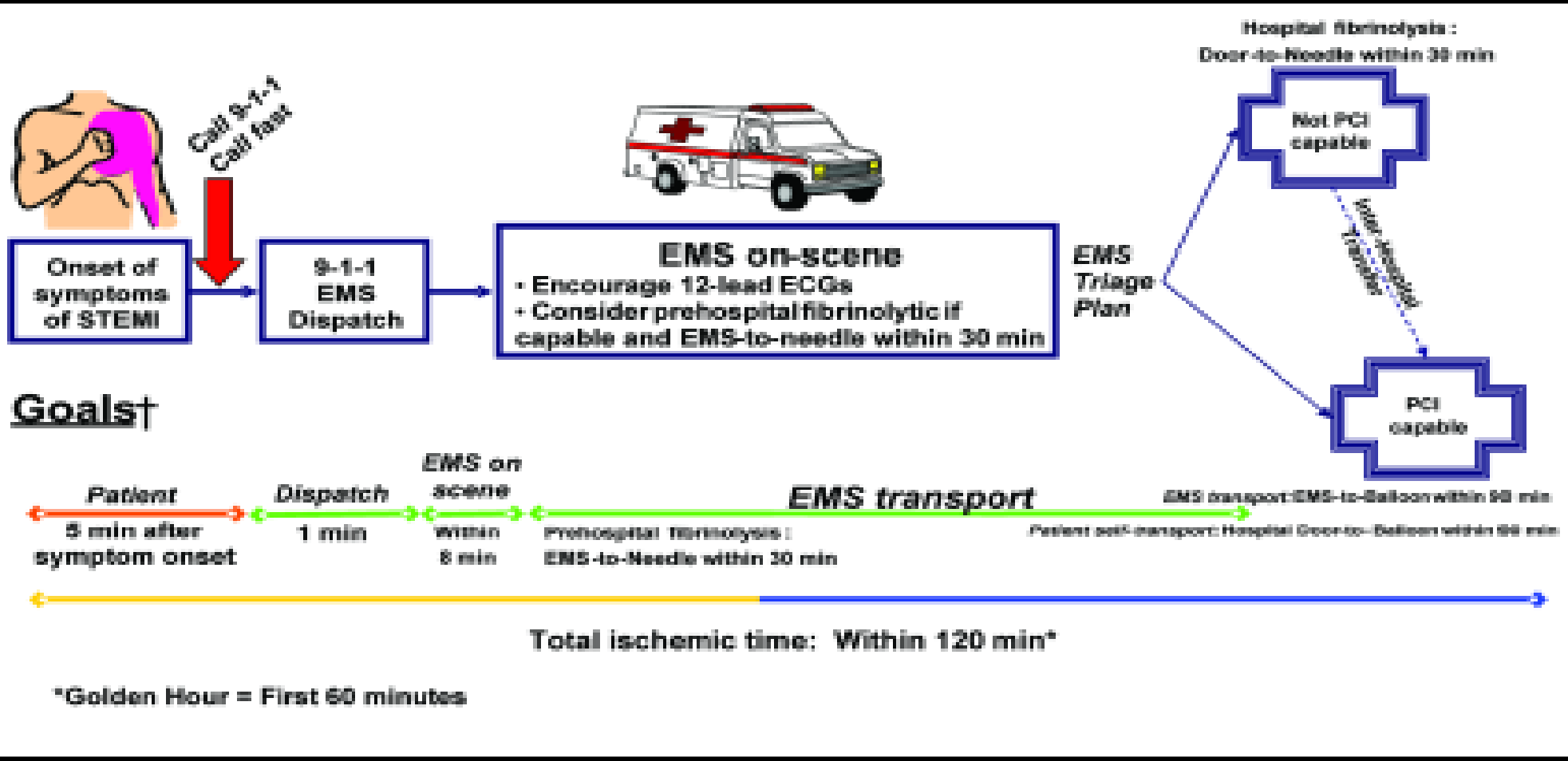
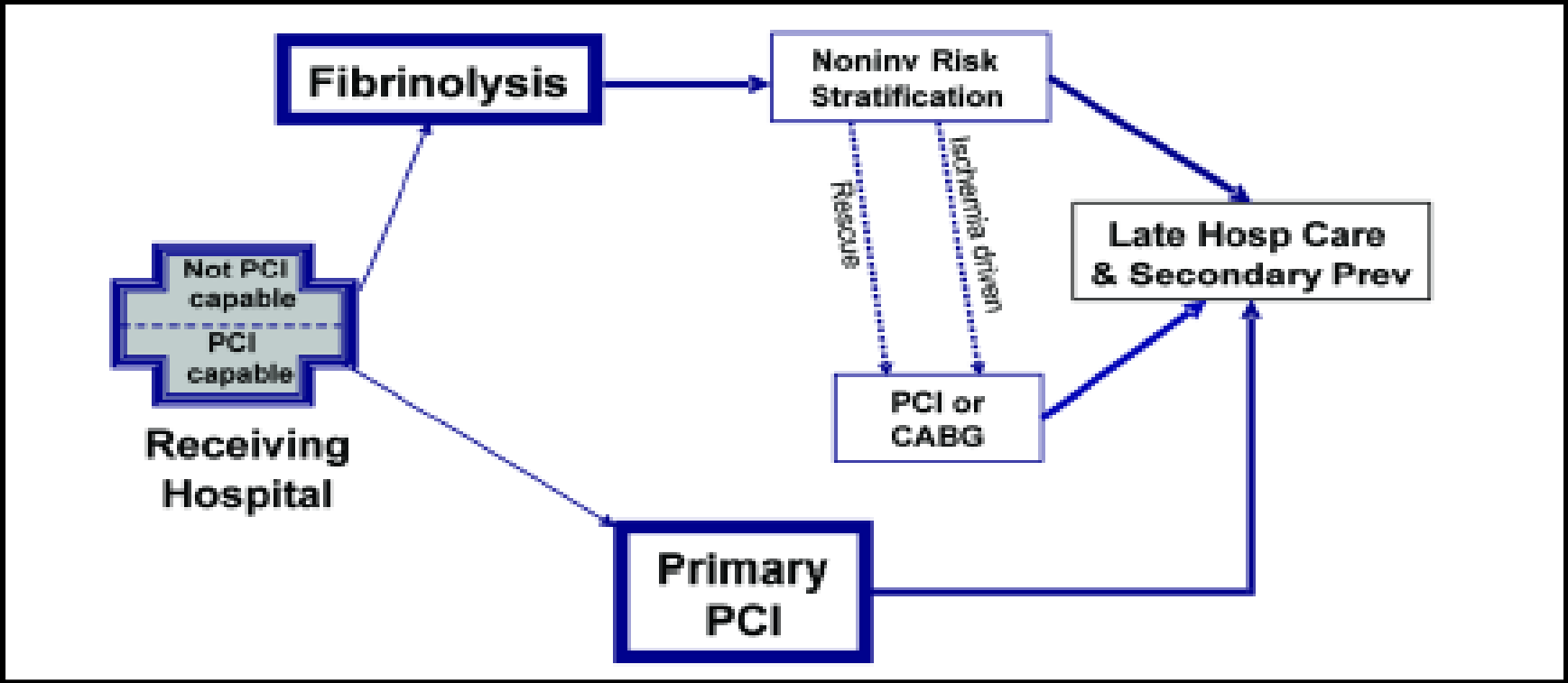
GP IIb/IIIa inhibitors for PCI in STE-ACS (STEMI)

Compared with patients with NSTE-ACS, Tirofiban and Eptifibatide are less well investigated in patients with STEMI. Abciximab has been evaluated in 5 randomised, controlled trials in association with primary PCI: RAPPORT, ISAR-2, CADILLAC, ADMIRAL and ACE.

(Recommendation for Abciximab in primary PCI with stenting: IIa A).



Transport time to the hospital is variable from case to case, but the goal is to keep total ischemic time within 120 min. There are 3 possibilities: 1) If EMS has fibrinolytic capability and the patient qualifies for therapy, prehospital fibrinolysis should be started within 30 min of EMS arrival on scene; 2) If EMS is not capable of administering prehospital fibrinolysis and the patient is transported to a non PCI-capable hospital, the hospital door-needle time should within 30 minutes for patients in whom fibrinolysis is indicated; 3) If EMS is not capable of administering prehospital fibrinolysis and the patient is transported to a PCI-capable hospital, the hospital door-to-balloon time should be within 90 min.



For patients who receive fibrinolysis, noninvasive risk stratification is recommended to identify the need for rescue PCI (failed fibrinolysis) or ischemia driven PCI. The medical system goal is to facilitate rapid recognition and treat-ment of patients with STEMI such that door-to-needle (or medical contact–to-needle) for initiation of fibrinolytic therapy can be achieved within 30 minutes or that door-to-balloon (or medical contact–to-balloon) for PCI can be achieved within 90 minutes. These goals should not be understood as 'ideal‘ times, but rather the longest times that should be considered acceptable for a given system.