

Facilitated Percutaneous Coronary Intervention in Acute Myocardial Infarction

Is it beneficial to patients?

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Suwon, Korea**

Facilitated PCI .. background

- Degree of coronary flow at the time of primary PCI associated with
 - Procedural feasibility and success rate
 - Prognosis (LV function, MACE) after PCI
- Improving coronary flow before primary PCI may increase the time window to PCI and salvage more myocardium

Facilitated PCI .. the term to describe

- Early planned PCI after a pharmacologic regimen intended to open the infarct-related artery (reperfusion therapy).
- Facilitated PCI by a combination of abciximab and reduced-dose reteplase was safe and effective in AMI.
 - Improves infarct-related artery patency.
 - Higher success rate and lower mortality than previous studies in similar clinical setting.

Herrmann et al. SPEED(GUSTO-4 Pilot) Trial, J Am Coll Cardiol 2000:1489-96

Facilitated PCI .. must be differentiated from

- Direct or primary PCI without thrombolysis
- Immediate, early, or delayed PCI after full-dose thrombolysis
- Rescue PCI after failed thrombolysis with or without glycoprotein IIb/IIIa inhibitor
- Primary PCI with glycoprotein IIb/IIIa inhibitor alone, either before or during PCI .. Is it not facilitated PCI?

Herrmann et al. SPEED(GUSTO-4 Pilot) Trial, J Am Coll Cardiol 2000:1489-96

Facilitated PCI .. should be considered as

- The pharmacologically advancing the opening of the epicardial artery in AMI patients who undergo immediate PCI may be associated with restoration of epicardial flow and/or tissue-level reperfusion.
- Therefore, facilitated PCI should be considered in a broader and appropriate context as PCI performed after pretreatment with antithrombotic drugs to reduce infarct size and mortality.

Facilitated PCI

ACC/AHA Practice Guideline 2004

- Facilitated PCI refers to a strategy of planned immediate PCI after an initial pharmacological regimen such as full dose fibrinolysis, half-dose fibrinolysis, a GP IIb/IIIa inhibitor, or a combination of reduced-dose fibrinolytic therapy and a platelet GP IIb/IIIa inhibitor.
- Facilitated PCI should be differentiated from primary PCI without fibrinolysis or GP IIb/IIIa inhibitor therapy, from primary PCI with a GP IIb/IIIa inhibitor started at the time of PCI, and from rescue PCI after unsuccessful fibrinolysis..

Facilitated PCI .. when and why in a broader context ?

- **To increase the time window to PCI and salvage myocardium in planned but delayed primary PCI.**
- **To improve the result of planned immediate primary PCI in any clinical setting.**

Facilitated PCI .. should be confirmed by..

- Pharmacologic facilitation increase the time window to PCI and salvage myocardium in planned delayed primary PCI?
 - vs. Thrombolysis alone
 - vs. Planned delayed PCI without facilitation
- Pharmacologic facilitation improve the result of planned immediate primary PCI in any clinical setting?
 - vs. Primary PCI without facilitation

Primary PCI .. vs. thrombolysis, 23 RCTs

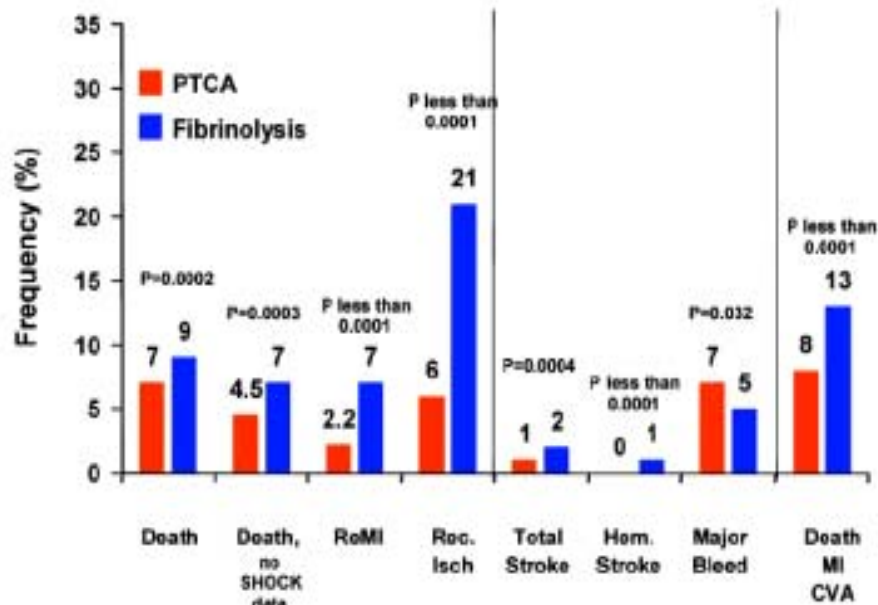
- Primary PCI is better than thrombolytic therapy at reducing overall short-term death, nonfatal reinfarction, stroke, and the results remained better during long-term follow up.
- Independent of
 - the type of thrombolytic agent used
 - whether or not the patient was transferred for primary PCI
 - time of presentation *

Keeley EC, et al. Lancet 2003:13-20

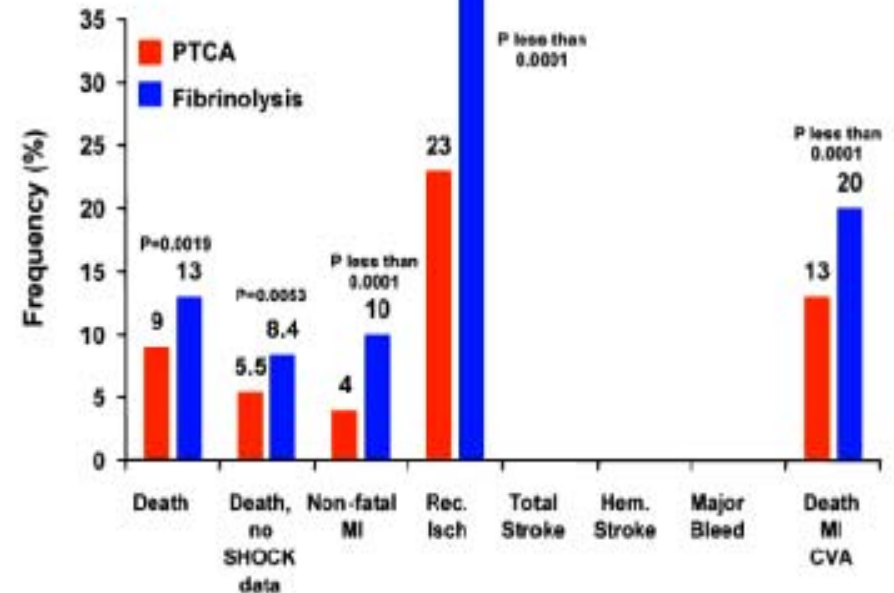
** Zijlstra F, et al. Eur Heart J 2002:550-57*

Primary PCI vs. Fibrinolysis .. 23 RCTs

**PCI vs Fibrinolysis:
Short-Term Clinical Outcomes**



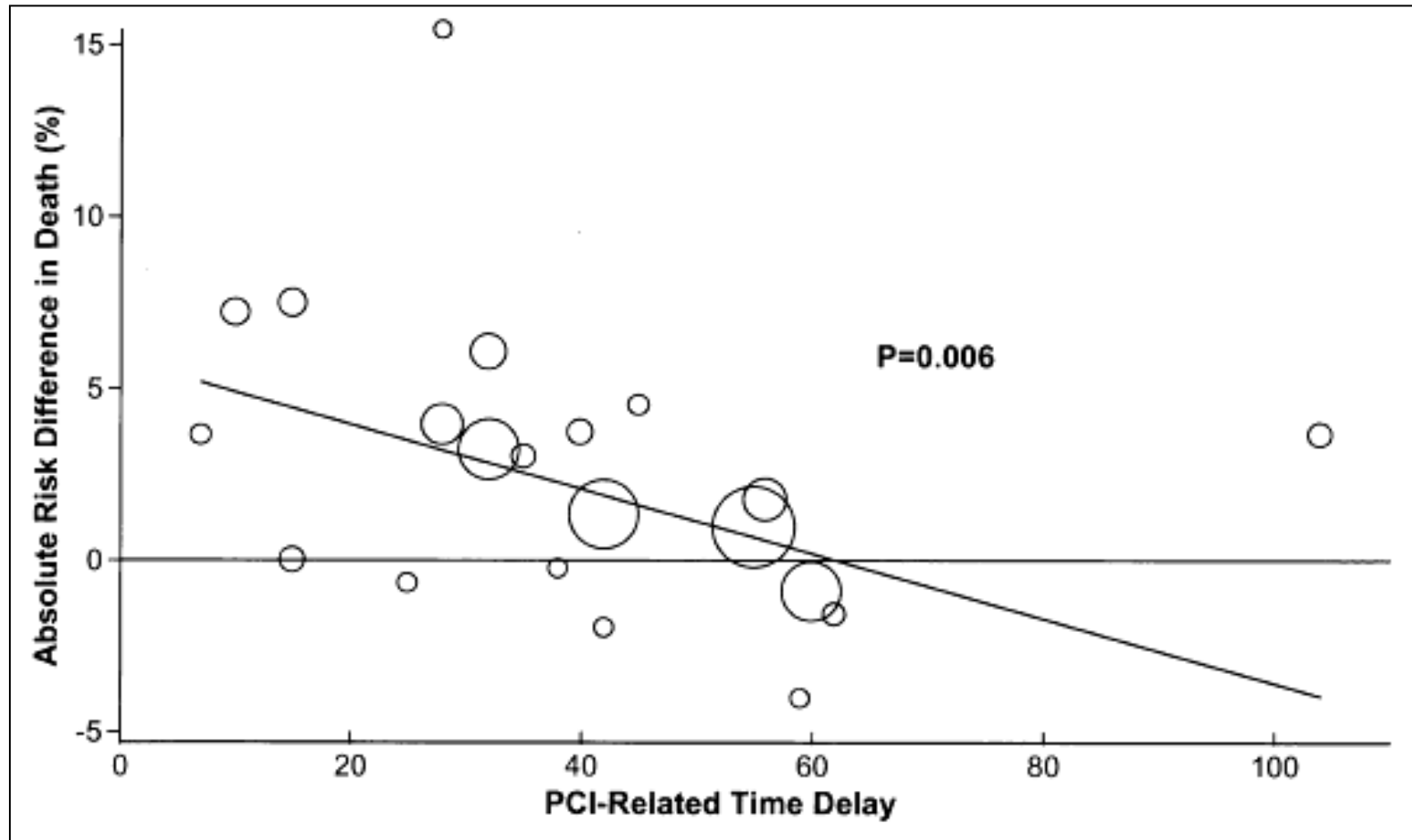
**PCI vs Fibrinolysis:
Long-Term Clinical Outcomes**



Primary PCI .. substantial time delays may restrict its benefit

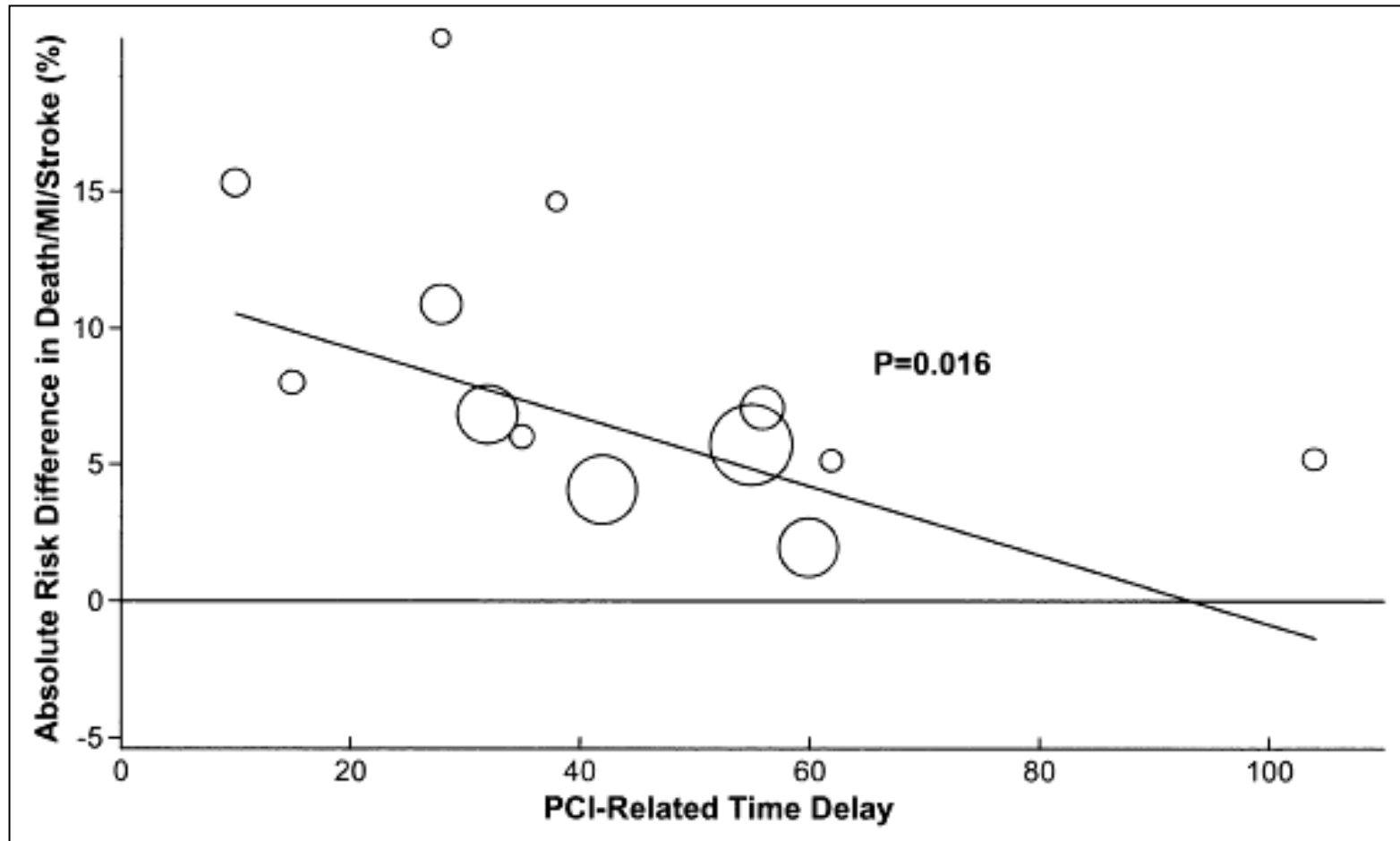
- Outcome differences between primary PCI and fibrinolytic therapy is associated with PCI-related time delay.
- The mortality benefit associated with primary PCI in STEMI may be lost if door-to-balloon time is delayed by >1 hour as compared with fibrinolytic therapy door-to-needle time.
- To achieve the benefits of primary PCI, we should not delay door-to-balloon time by >60 minutes.

Primary PCI .. mortality reduction vs. thrombolysis



Nallamothu BK, et al. Am J Cardiol 2003;824-826

Primary PCI .. MACE reduction vs. thrombolysis



Nallamothu BK, et al. Am J Cardiol 2003;824-826

Door-to-balloon time .. NRMI-4

1st Door to Data:
9 min. (4-16 min.)

Data (Transport) to
Cath Lab Arrival:
132 min. (88-219 min.)

Cath Lab to
Balloon:
37 min. (28-50 min.)



Total Door 1 to Balloon Time: 185 minutes (137-276 minutes)

Percent of Patients with Door-to-Balloon Time Less Than 90 Minutes: 3.0%

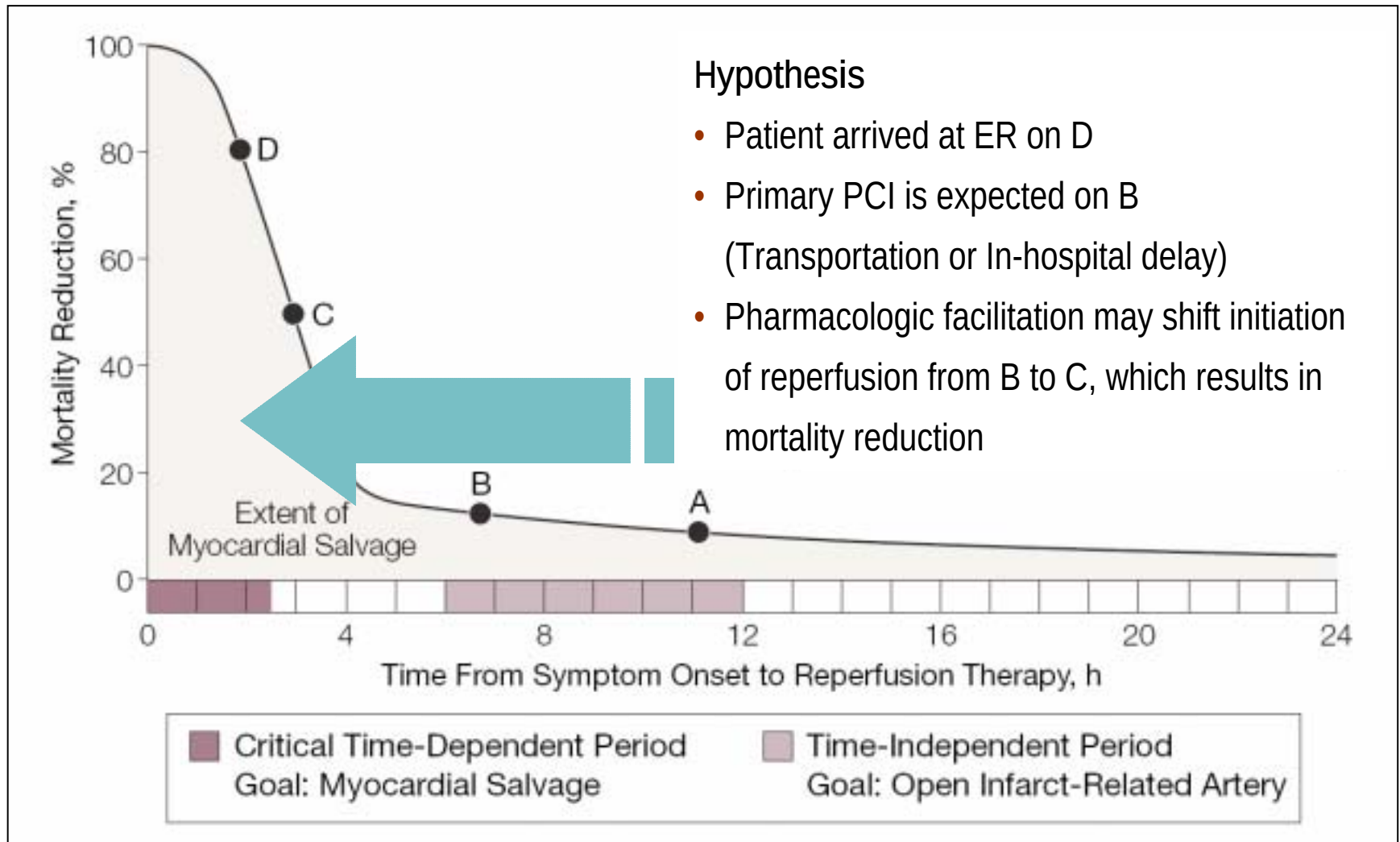
Sample Size: 1346; Time Period: January 2002 – December 2002

Modified from NRMI-4 Investigators: The National Registry of Myocardial Infarction-4 Quarterly Report. 2003;2 (458).

Transport of Patients With STEMI for Primary PCI

Study (Reference)	No.Transported	Distance, km	Time Between Randomization and First Balloon Inflation, min
Vermeer et al. (419)	75	25-50	85*
PRAGUE-1 (408)	101	5-74	80*
AIR-PAMI (421)	71	51 plus or minus 58*	155†
PRAGUE-2 (177)	429	5-120	97*
DANAMI-2 (306)	559	3-150	90†
Total	1235	3-150	
*Mean. †Median.			

Mortality reduction as a benefit of reperfusion therapy



Modified from Gersh BJ, et al. JAMA 2003;824-826

Facilitated PCI

- To increase the time window to PCI and salvage myocardium in planned delayed primary PCI
- To improve the result of planned immediate primary PCI in any clinical setting.

Facilitated PCI .. results of small RCTs

Study	No	Methods	Results
LeMay et al, 2004 CAPITAL - AMI	170	Randomized(<6h from onset) Tenecteplase in all patients (A) Immediate angiography(facilitated) (B) Standard care(Tenecteplase alone)	In facilitated PCI(A), decreased incidence of new-onset angina and trend toward decrease in recurrent MI No difference in bleeding
Kastrati et al, 2004 BRAVE	253	Randomized (A) half dose tPA + Abciximab(facilitated) (B) Abciximab alone followed by immediate angiography	No difference in infarct size Increased rate of TIMI 3 flow in combined group(A)
Aviles et al, 2003 GARCIA-2	205	Randomized(3-12h from onset) (A) Tenecteplase+immediate PCI(facilitated) (B) Primary PCI alone	Increased TIMI 3 flow in facilitated arm(A) Comparable composite end points and major bleeding rates Thrombolytics may be able to prolong the window to PCI
Scheller et al, 2003 SIAM III	163	Randomized(<12h from onset) (A) Reteplase+immediate(<6h) stenting (facilitated) (B) Reteplase+delayed stenting	Significant reduction in combined end points and improved LVEF in immediate stent group(A)
Van't Hof et al, 2003 * ON TIME	507	Randomized (A) Tirofiban before transport(facilitated) (B) Tirofiban on arrival in laboratory followed by primary PCI in all	No difference in clinical events Lower rate of thrombus on initial angiography in tirofiban pretreated group(A)
Widimsky et al, 2000 PRAGUE	300	Randomized(<6h from onset) (A) Streptokinase alone (B) Streptokinase during transport(facilitated) (C) Transport to primary PCI alone	Death/Reinfarction/Stroke was less frequent in primary PCI alone A(23%);B(15%);C(8%), p<0.02
Ross et al, 1999 PACT	606	Randomized (A) 50mg tPA(facilitated) (B) Placebo followed by immediate planned rescue angioplasty	Increased patency on initial angiography in tPA arm(A) Patent IRA associated with increased discharge LVEF No difference in bleeding
Vermeer et al, 1999 LIMI	224	Randomized (A) tPA alone (B) tPA for transfer (facilitated) (C) Primary PCI alone	Trend toward better outcomes in primary PCI alone
O'Neill et al, 1992	122	Randomized (A) Streptokinase(facilitated) (B) Placebo followed by angiography/PCI in all	No difference in mortality and LVEF In streptokinase(A), increased costs, duration of hospital stay, emergency CABG

 Improved clinical outcome

 Improved angiographic outcome

 No benefit or PCI alone better

Facilitated PCI .. results of small RCTs

- Pharmacologic facilitation before primary PCI improve coronary flow at the time of intervention and may increase the time window to PCI.
- Fibrin-specific agents or combination of fibrinolytic and glycoprotein IIb/IIIa inhibitor are preferred.
- Facilitated PCI is more effective and safe than thrombolytic therapy alone. However, it showed limited benefit compared with primary PCI alone.
- The role of facilitated PCI needs to be established in large multicenter randomized clinical trials.

Facilitated PCI .. when and why?

- To increase the time window to PCI and salvage myocardium in delayed primary PCI
- To improve the result of planned immediate primary PCI in any clinical setting

Facilitated PCI? .. RCTS with abciximab

Study	No	Methods
Brener et al, 1998 RAPPORT	483	Abciximab: 250µg/kg bolus, 0.125 µg/kg/min 12h infusion, maximum 10µg/min Abciximab Tx: Pre-angiography Heparin: bolus to ACT>300s, 48h infusion Onset-to-PCI time<12h Stent: No (balloon angioplasty, DCA) Thienopyridine: No Treatment blinded: Yes
Neumann et al, 2000 ISAR-2	401	Abciximab: 250µg/kg bolus, 0.125 µg/kg/min 12h infusion, maximum 10µg/min Abciximab Tx: Post-angiography Heparin: (+) Abciximab: bolus 7500U, (-) Abciximab: bolus 15000U, 12h infusion Onset-to-PCI time<48h Stent: Yes Thienopyridine: Yes Treatment blinded: No
Montalescot et al, 2002 ADMIRAL	300	Abciximab: 250µg/kg bolus, 0.125 µg/kg/min 12h infusion, maximum 10µg/min Abciximab Tx: Pre-angiography Heparin: bolus to ACT>200s, 24h infusion Onset-to-PCI time<12h Stent: Yes Thienopyridine: Yes Treatment blinded: Yes
Stone et al, 2002 CADILLAC	2082	Abciximab: 250µg/kg bolus, 0.125 µg/kg/min 12h infusion, maximum 10µg/min Abciximab Tx: Post-angiography Heparin: (+) Abciximab: bolus to ACT 200-300s, (-) Abciximab: bolus to ACT>350s Onset-to-PCI time<12h Stent: Yes (Randomized to stent or balloon) Thienopyridine: Yes Treatment blinded: No

Facilitated PCI? .. RCTS with abciximab

Study	No	Clinical Results			
		Clinical Events	Placebo/Control(%)	Abciximab(%)	p value
Brener et al, 1998 RAPPORT	483	6-mo composite end points	31.9	28.0	0.31
		Death	4.7	3.2	0.43
		Reinfarction	8.4	5.5	0.23
		Urgent TVR	10.5	3.7	0.006
		Any TVR	26.2	22.5	0.32
		Death/Reinfarction/Urgent TVR	19.9	10.6	0.004
		Major bleeding	9.5	16.6	0.02
Neumann et al, 2000 ISAR-2	401	30-days composite end points	10.5	5.0	0.038
		Death	4.5	2.0	0.16
		Nonfatal reinfarction	1.5	0.5	0.62
		TLR	5.0	3.0	0.30
		Transfusion	4.5	3.5	0.79
Montalescot et al, 2002 ADMIRAL	300	6-mo composite end points	33.8	22.8	0.03
		Death	7.3	3.4	0.13
		Reinfarction	4.0	2.0	0.32
		Urgent TVR	6.6	2.0	0.049
		Any TVR	23.8	17.4	0.17
		Death/Reinfarction/Urgent TVR	15.9	7.48	0.02
		Major bleeding	0	0.7	0.31
Stone et al, 2002 CADILLAC	2082	6-m composite end points(PTCA)	20.0	16.5	ns
		Death	4.5	2.5	ns
		Reinfarction	1.8	2.7	ns
		Urgent TVR	15.7	13.8	ns
		Any TVR	16.9	14.8	ns
		Major bleeding	0.6	0.4	ns
		6-mo composite end points (Stent)	11.5 *	10.2 *	ns
		Death	3.0	4.2	ns
		Reinfarction	1.6	2.2	ns
		Urgent TVR	8.3 *	5.2 *	ns
		Any TVR	8.9 *	5.7 *	ns
		Major bleeding	0.2	0.8	ns

Composite end point: death, reinfarction, any (urgent or elective) target vessel revascularization. * p<0.05 for two-way comparison with PTCA and PTCA plus abciximab (CADILLAC trial).

Facilitated PCI? .. RCTS with abciximab

- Meta analysis of interventional RCTs evaluating adjuvant abciximab therapy in AMI has found a 46% significant reduction in the combination of death, reinfarction, and ischemic TVR, and a trend toward reduction in combination of death and reinfarction.

盲人摸象?



Kandzari DE, et al. Am Heart J 2004:457-462

- In the setting of primary PCI, four clinical trials involving over 3,000 pts demonstrated that GP IIb/IIIa inhibition results in a significant decrease in the need for urgent TVR, but not in reductions of death or recurrent MI. Therefore, GP IIb/IIIa inhibition may provide only limited benefits in acute STEMI.

Eisenberg MJ, et al. J Am Coll Cardiol 2003:1-6

Pharmacological Reperfusion

ACC/AHA Practice Guideline 2004

6.3.1.6.3.8. Combination Therapy With GP IIb/IIIa Inhibitors

Class IIb

- 1. Combination pharmacological reperfusion with abciximab and half-dose reteplase or tenecteplase 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 (394a) (*Level of Evidence: B*).
- 2. 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 patients: anterior location of MI, age less than 75 years, and no risk factors for bleeding in whom an early referral for angiography and PCI (i.e., facilitated PCI) is planned. (*Level of Evidence: C*)

Class II: Conditions for which there is conflicting evidence and/or a divergence of opinion about the usefulness/efficacy of a procedure or treatment.

Class IIa: Weight of evidence/opinion is in favor of usefulness/efficacy.

Class IIb: Usefulness/efficacy is less well established by evidence/opinion.

Level of Evidence C: Only consensus opinion of experts, case studies, or standard-of-care.

Primary PCI .. Facilitated PCI

ACC/AHA Practice Guideline 2004

6.3.1.6.4.4. Facilitated PCI

Class IIb

- Facilitated PCI might be performed as a reperfusion strategy in higher-risk patients when PCI is not immediately available and bleeding risk is low. (**Level of Evidence: B**)
- Facilitated PCI refers to a strategy of planned immediate PCI after an initial pharmacological regimen such as full dose fibrinolysis, half-dose fibrinolysis, a GP IIb/IIIa inhibitor, or a combination of reduced-dose fibrinolytic therapy and a platelet GP IIb/IIIa inhibitor.
- Facilitated PCI should be differentiated from primary PCI without fibrinolysis or GP IIb/IIIa inhibitor therapy, from primary PCI with a GP IIb/IIIa inhibitor started at the time of PCI, and from rescue PCI after unsuccessful fibrinolysis.
- Potential advantages include earlier time to reperfusion, improved patient stability, greater procedural success rates, higher TIMI flow rates, and improved survival rates (36,346,428,469,470). However, preliminary studies have not demonstrated any benefit in reducing infarct size or improving outcomes (471-473).
- It is unlikely that this strategy would be beneficial in low-risk patients.
- A strategy of facilitated PCI holds promise in higher-risk patients when PCI is not immediately available. Potential risks include increased bleeding complications, especially in those 75 years of age or older (see Section 6.3.1.6.3.8), and potential limitations include added cost. Several randomized trials of facilitated PCI with a variety of pharmacological regimens are in progress (473a).

Class II: Conditions for which there is conflicting evidence and/or a divergence of opinion about the usefulness/efficacy of a procedure or treatment.

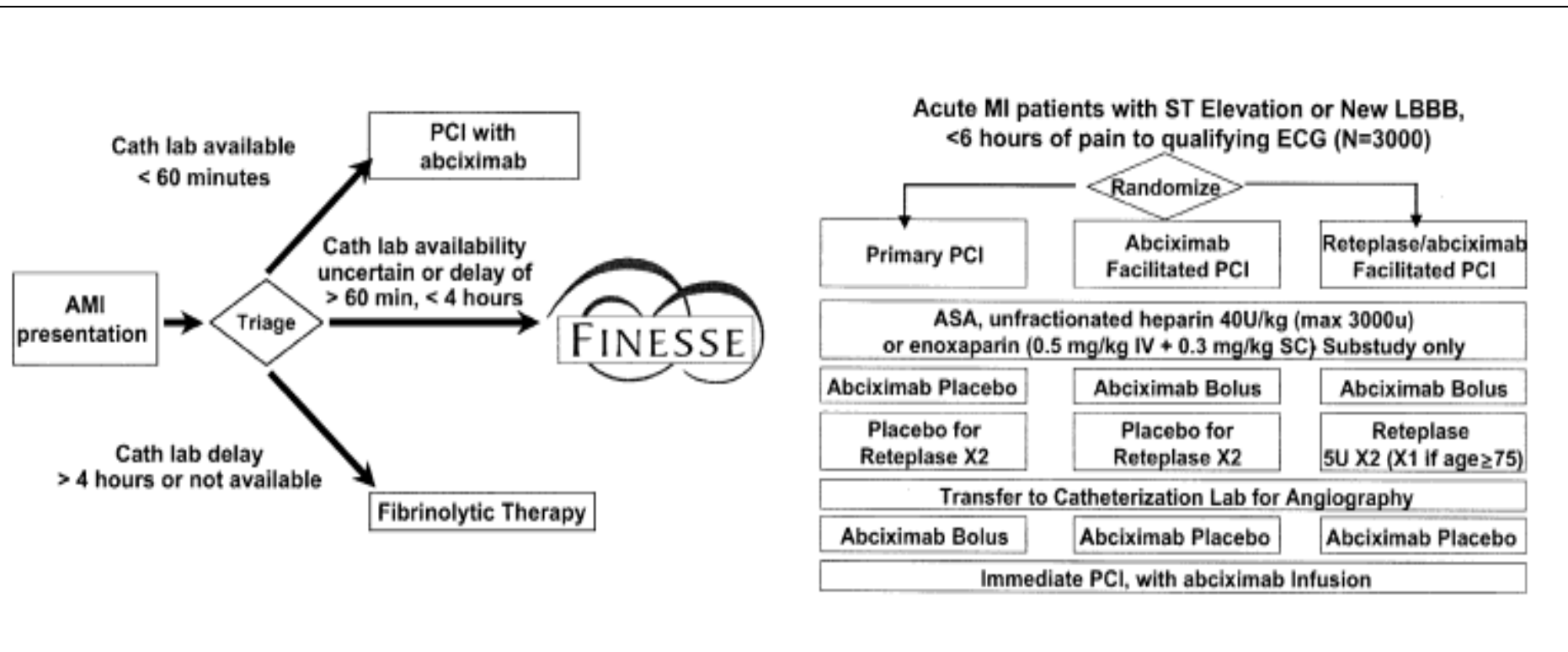
Class IIa: Weight of evidence/opinion is in favor of usefulness/efficacy.

Class IIb: Usefulness/efficacy is less well established by evidence/opinion.

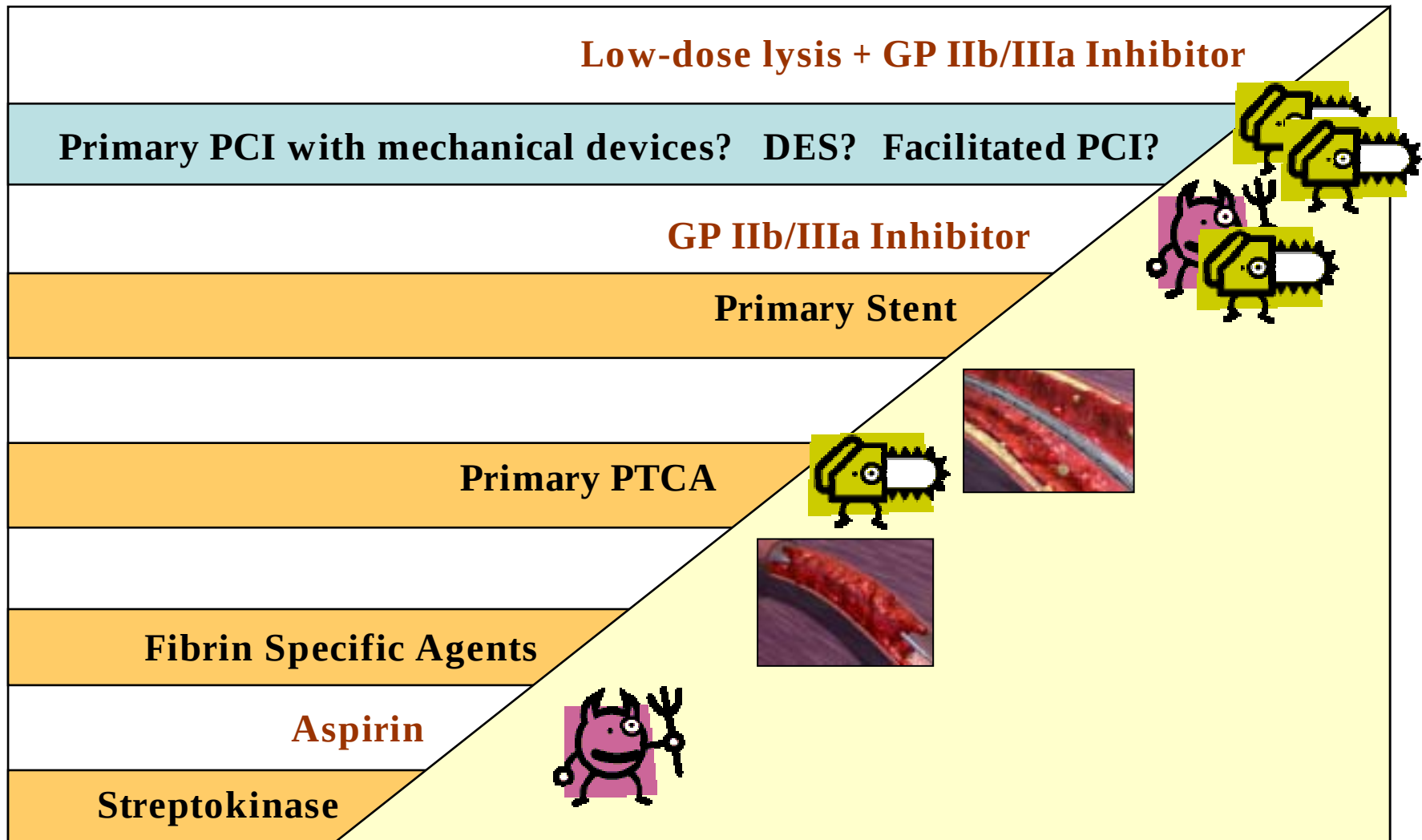
Level of Evidence B: Data derived from a single randomized trial, or nonrandomized studies.

FINESSE .. target population and study design

- The efficacy and safety of facilitated PCI in AMI with various pharmacologic regimens should be confirmed in large randomized multicenter clinical trials.

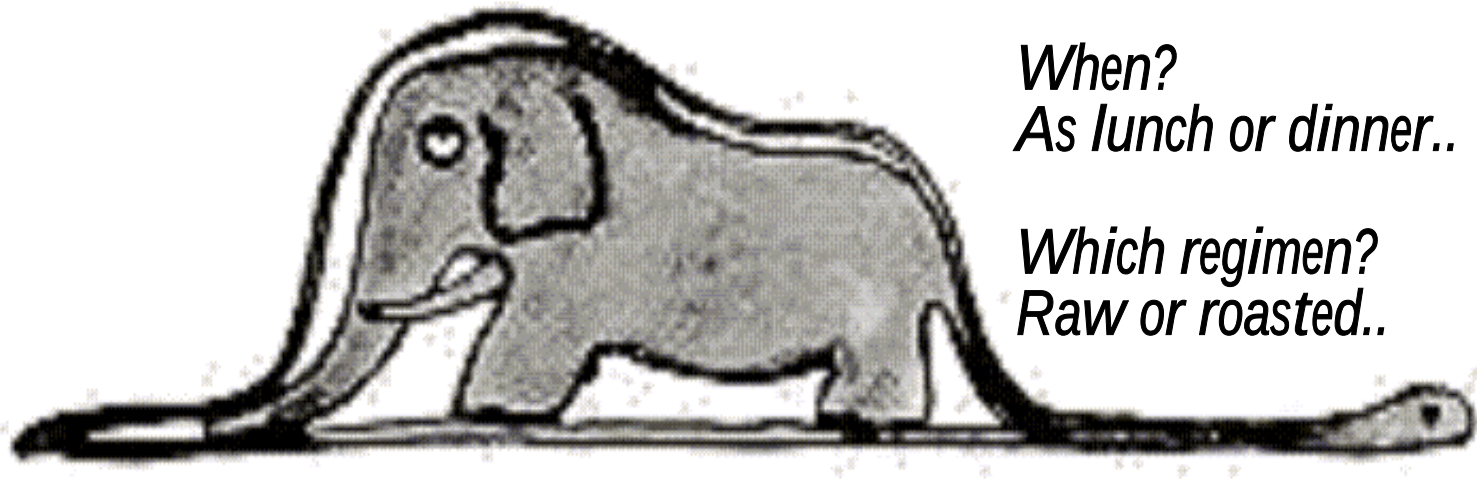


Facilitated PCI .. steps in reperfusion reading to ..



Modified from Kelly BV, et al. Am Heart H J 2004:211-222

Facilitated PCI .. things not yet determined..



*When?
As lunch or dinner..*

*Which regimen?
Raw or roasted..*

End of Presentation

Assessment of Reperfusion Option in STEMI

ACC/AHA Practice Guideline 2004

- Assess Time and Risk
 - Time since onset of symptom
 - Risk of STEMI
 - Risk of fibrinolysis
 - Time required for transport to a skilled PCI lab
- Determine if fibrinolysis or invasive strategy is preferred
 - Presentation <3h and no delay to invasive strategy: no preference for either strategy

Fibrinolysis is preferred

- Early presentation ≤3h and delay to invasive strategy
- Invasive strategy is not an option
 - Cath lab. Occupied/not available
 - Vascular access difficulties
 - Lack of access to a skilled PCI lab
- Delay to invasive strategy
 - Prolonged transport
 - (Door-to-Balloon)-(Door-to-Needle) >1h
 - Medical contact-to-balloon or door-to-balloon >90min

Invasive strategy is preferred

- Skilled PCI lab available with surgical BU
 - (Door-to-Balloon)-(Door-to-Needle) <1h
 - Medical contact-to-balloon or door-to-balloon <90min
- High risk STEMI
 - Cardiogenic shock
 - Killip class ≥3
- Contraindication to fibrinolysis
- Late presentation >3h
- Diagnosis of STEMI is in doubt

Primary PCI .. GP IIb/IIIa inhibitors

ACC/AHA Practice Guideline 2004

6.3.1.6.8.2.3. Glycoprotein IIb/IIIa inhibitors.

Class IIa

- It is reasonable to start treatment with abciximab as early as possible before primary PCI (with or without stenting) in patients with STEMI. (*Level of Evidence: B*)

Class IIb

- Treatment with tirofiban or eptifibatide may be considered before primary PCI (with or without stenting) in patients with STEMI. (*Level of Evidence: C*)
- Five randomized trials compared abciximab to placebo control in a collective total of 3666 patients undergoing primary PCI for STEMI (34-36,38,582). A total of 1843 patients received abciximab, a relatively small data set on which to base recommendations for treatment. In addition, in the setting of primary PCI, periprocedural recurrent MI is not easily measured, so the benefit of antiplatelet therapy with GP IIb/IIIa inhibitors is harder to determine.
- The Writing Committee believes that it is reasonable to start treatment with abciximab as early as possible in patients undergoing primary PCI (with or without stenting), but given the size and limitations of the available data set, assigned a Class IIa recommendation.

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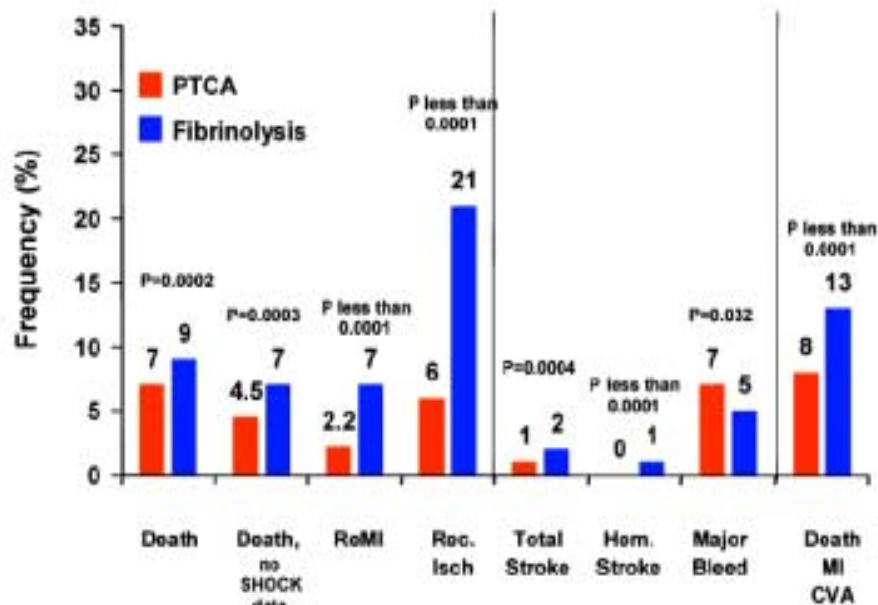
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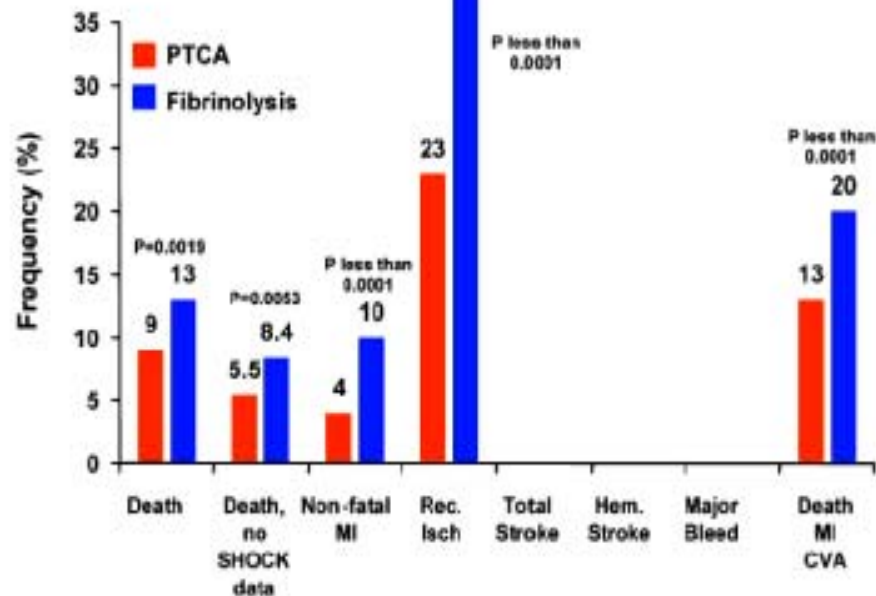
Primary PCI vs. Fibrinolysis .. 23 RCTs

ACC/AHA Practice Guideline 2004

**PCI vs Fibrinolysis:
Short-Term Clinical Outcomes**

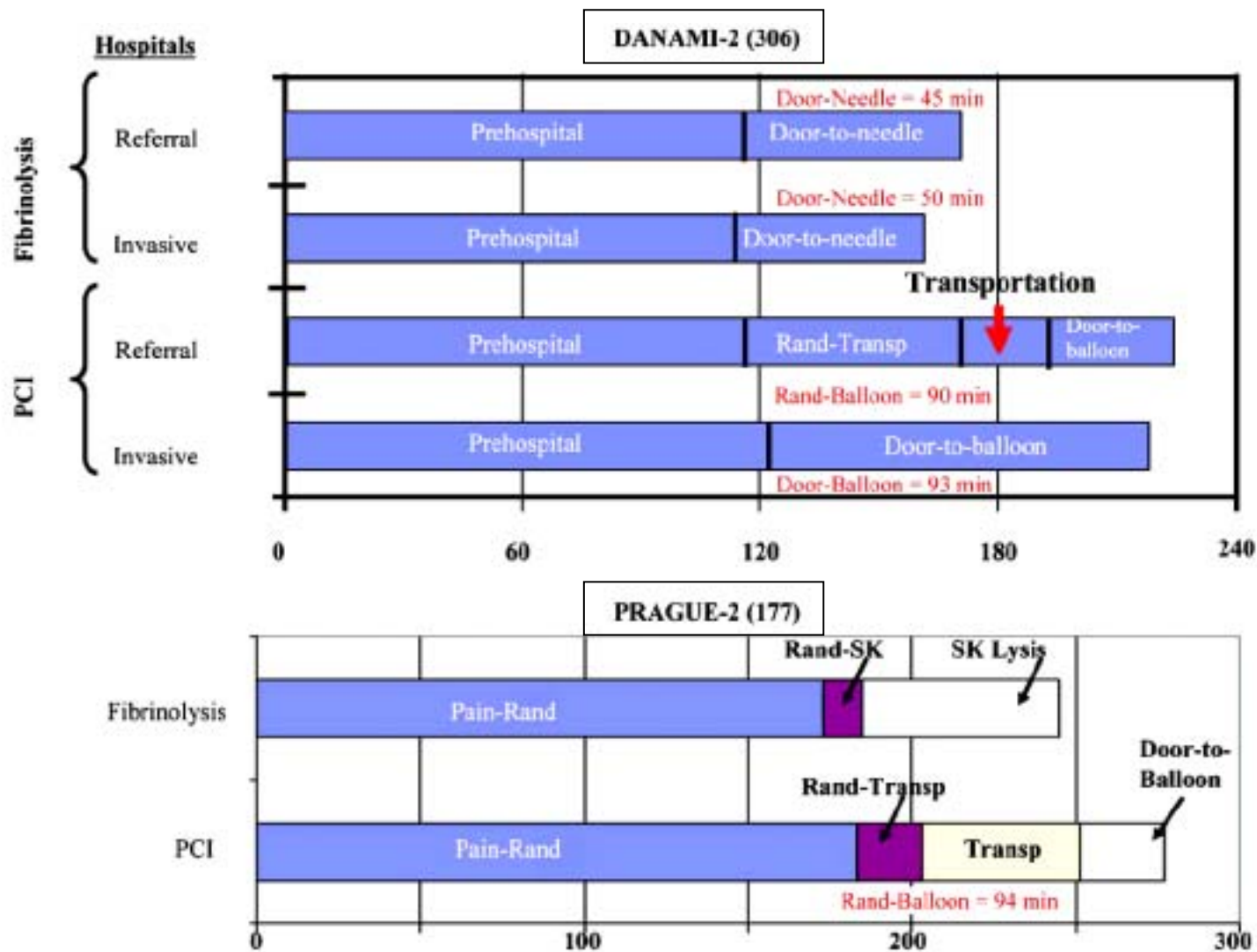


**PCI vs Fibrinolysis:
Long-Term Clinical Outcomes**



Comparison of elapsed time to fibrinolysis vs. primary PCI

ACC/AHA Practice Guideline 2004



Door-to-balloon time

ACC/AHA Practice Guideline 2004

1st Door to Data:
9 min. (4-16 min.)

Data (Transport) to
Cath Lab Arrival:
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Percent of Patients with Door-to-Balloon Time Less Than 90 Minutes: 3.0%

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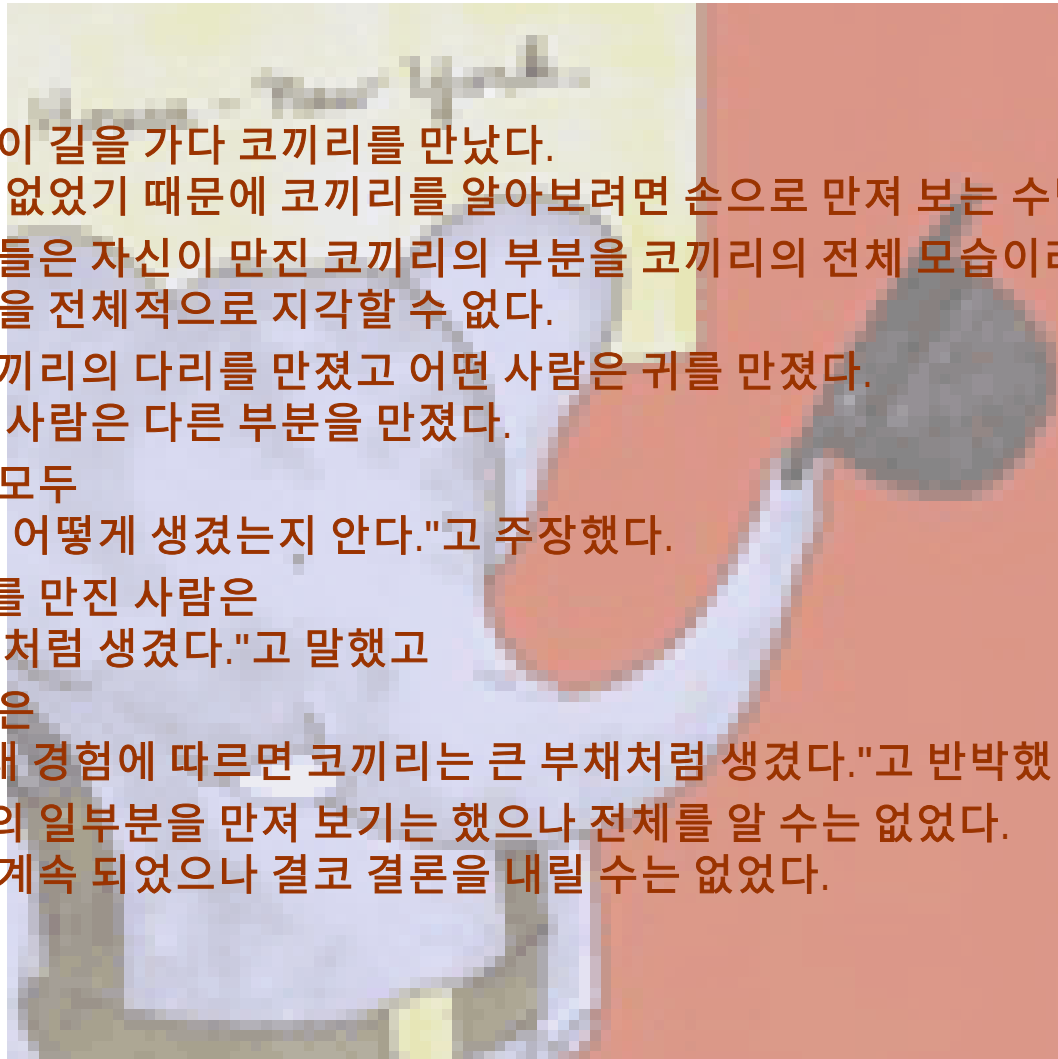
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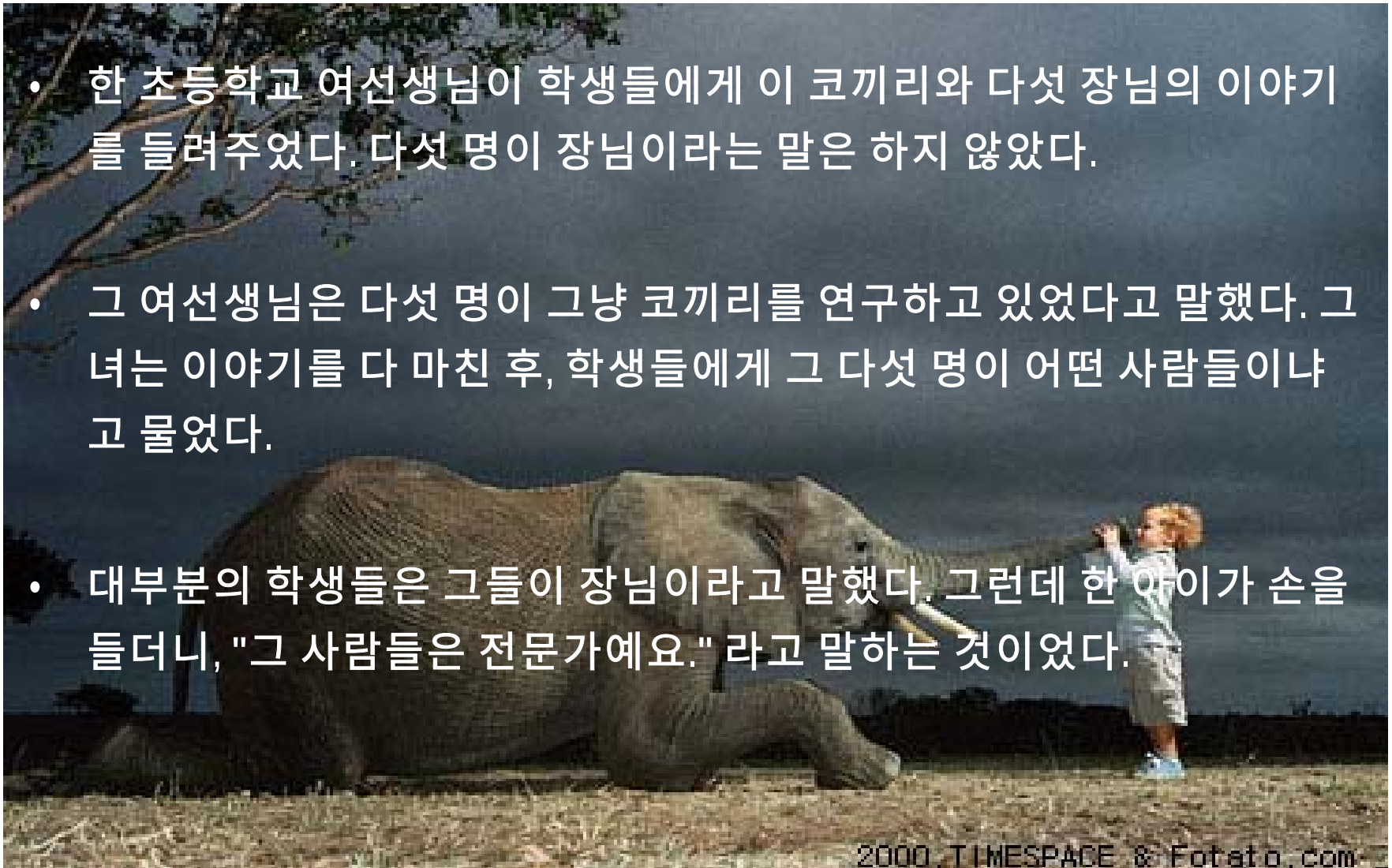
涅槃經 - 盲人摸象, 群盲評象, 象徵操作

- 다섯 명의 장님이 길을 가다 코끼리를 만났다.
그들은 볼 수가 없었기 때문에 코끼리를 알아보려면 손으로 만져 보는 수밖에 없었다.
- 그리고 이 장님들은 자신이 만진 코끼리의 부분을 코끼리의 전체 모습이라고 생각했다.
눈이 멀면 사물을 전체적으로 지각할 수 없다.
- 어떤 사람은 코끼리의 다리를 만졌고 어떤 사람은 귀를 만졌다.
그리고 또 어떤 사람은 다른 부분을 만졌다.
- 그리고 그들은 모두
"나는 코끼리가 어떻게 생겼는지 안다."고 주장했다.
- 코끼리의 다리를 만진 사람은
"코끼리는 기둥처럼 생겼다."고 말했고
- 귀를 만진 사람은
"너는 바보다. 내 경험에 따르면 코끼리는 큰 부채처럼 생겼다."고 반박했다.
- 그들은 코끼리의 일부분을 만져 보기는 했으나 전체를 알 수는 없었다.
그들의 토론은 계속 되었으나 결코 결론을 내릴 수는 없었다.



涅槃經 - 盲人摸象, 群盲評象, 象徵操作

- 한 초등학교 여선생님이 학생들에게 이 코끼리와 다섯 장님의 이야기를 들려주었다. 다섯 명이 장님이라는 말은 하지 않았다.
- 그 여선생님은 다섯 명이 그냥 코끼리를 연구하고 있었다고 말했다. 그녀는 이야기를 다 마친 후, 학생들에게 그 다섯 명이 어떤 사람들이냐고 물었다.
- 대부분의 학생들은 그들이 장님이라고 말했다. 그런데 한 아이가 손을 들더니, "그 사람들은 전문가예요." 라고 말하는 것이었다.



2000, TIMESPACE & Fotato.com

涅槃經 - 盲人摸象, 群盲評象, 象徵操作

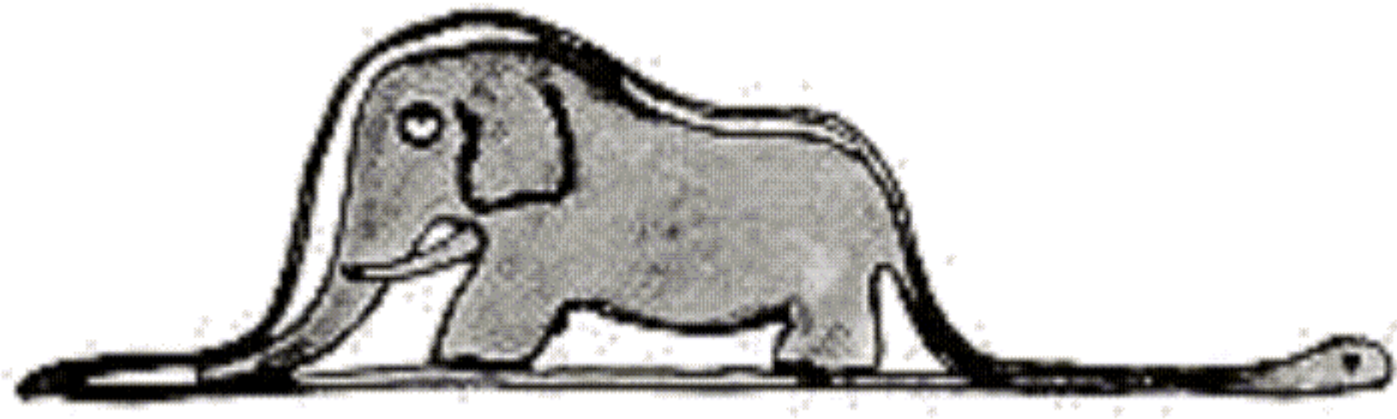
- 다섯 명의 장님이 길을 가다 코끼리를 만났다.
그들은 볼 수가 없었기 때문에 코끼리를 알아보려면 손으로 만져 보는 수밖에 없었다.
- 그리고 이 장님들은 자신이 만진 코끼리의 부분을 코끼리의 전체 모습이라고 생각했다.
눈이 멀면 사물을 전체적으로 지각할 수 없다.
- 어떤 사람은 코끼리의 다리를 만졌고 어떤 사람은 귀를 만졌다.
그리고 또 어떤 사람은 다른 부분을 만졌다.



- 그리고 그들은 모두
"나는 코끼리가 어떻게 생겼는지 안다."고 주장했다.
- 코끼리의 다리를 만진 사람은
"코끼리는 기둥처럼 생겼다."고 말했고
- 귀를 만진 사람은
"너는 바보다. 내 경험에 따르면 코끼리는 큰 부채처럼 생겼다."고 반박했다.
- 그들은 코끼리의 일부분을 만져 보기는 했으나 전체를 알 수는 없었다.
그들의 토론은 계속 되었으나 결코 결론을 내릴 수는 없었다.

涅槃經 - 盲人摸象, 群盲評象, 象徵操作

- 한 초등학교 여선생님이 학생들에게 이 코끼리와 다섯 장님의 이야기를 들려주었다. 다섯 명이 장님이라는 말은 하지 않았다. 그 여선생님은 다섯 명이 그냥 코끼리를 연구하고 있었다고 말했다.



- 그녀는 이야기를 다 마친 후, 학생들에게 그 다섯 명이 어떤 사람들이냐고 물었다. 대부분의 학생들은 그들이 장님이라고 말했다. 그런데 한 아이가 손을 들더니, "그 사람들은 전문가예요." 라고 말하는 것이었다.