Routine upfront abciximab vs. standard peri-procedural therapy in pts. undergoing primary PCI for cardiogenic shock: The PRAGUE-7 Study

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Background

- Outcome of AMI complicated with cardiogenic shock is poor.
- The aim was to analyze, whether upfront abciximab (when compared to routine therapy) improves the outcomes of cardiogenic shock.

Patients

- Multicenter open randomized trial
- 80 cardiogenic shock (AMI) pts. expected to undergo primary PCI (mean age 66 years)
- 25% after cardiopulmonary resuscitation, 46% on mechanical ventilation

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Treatment arms

Group A

- **Routine upfront – preprocedural - abciximab bolus followed by 12-hours abciximab infusion**

Group B

- **Standard therapy with optional abciximab administration according to the interventional cardiologist.**

Entry criteria

Inclusion criteria:

- Evolving AMI (ST ↑, ST↓, BBB) AND
- Indication for urgent CAG (± primary PCI) AND
- Signs of cardiogenic shock (incl. incompletely developed shock)

Exclusion criteria:

- Contraindications for abciximab
- Severe valvular disease
- Mechanical complication of AMI
- Non-cardiac cause of shock
- Pre-admission administration of > 10,000 IU of heparin

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Study endpoints

Primary:

- 30-day combined outcome (death / reinfarction / stroke / new renal failure).

Secondary:

- LV EF day 30
- major bleeding complications
- myocardial blush grade (MBG) after PCI
- TIMI-flow after PCI

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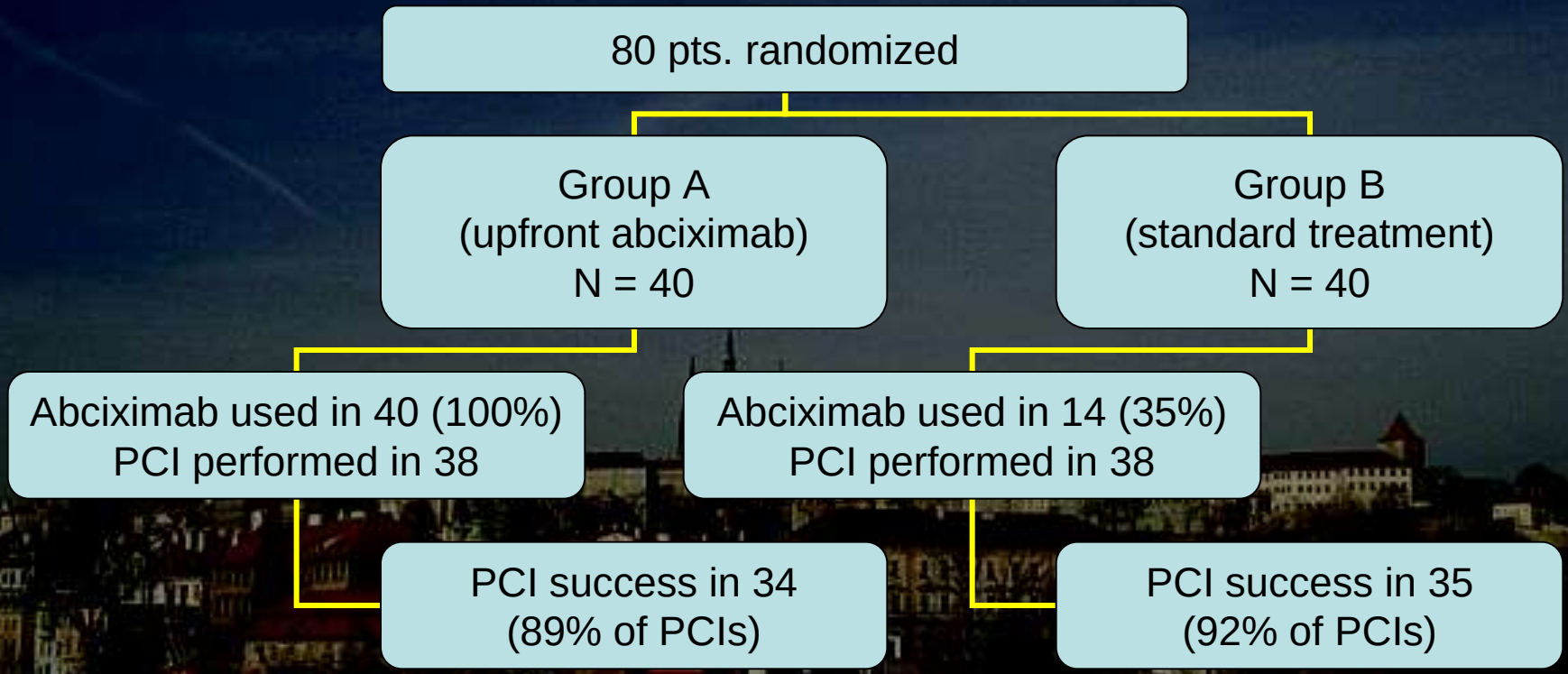
Patients flow chart



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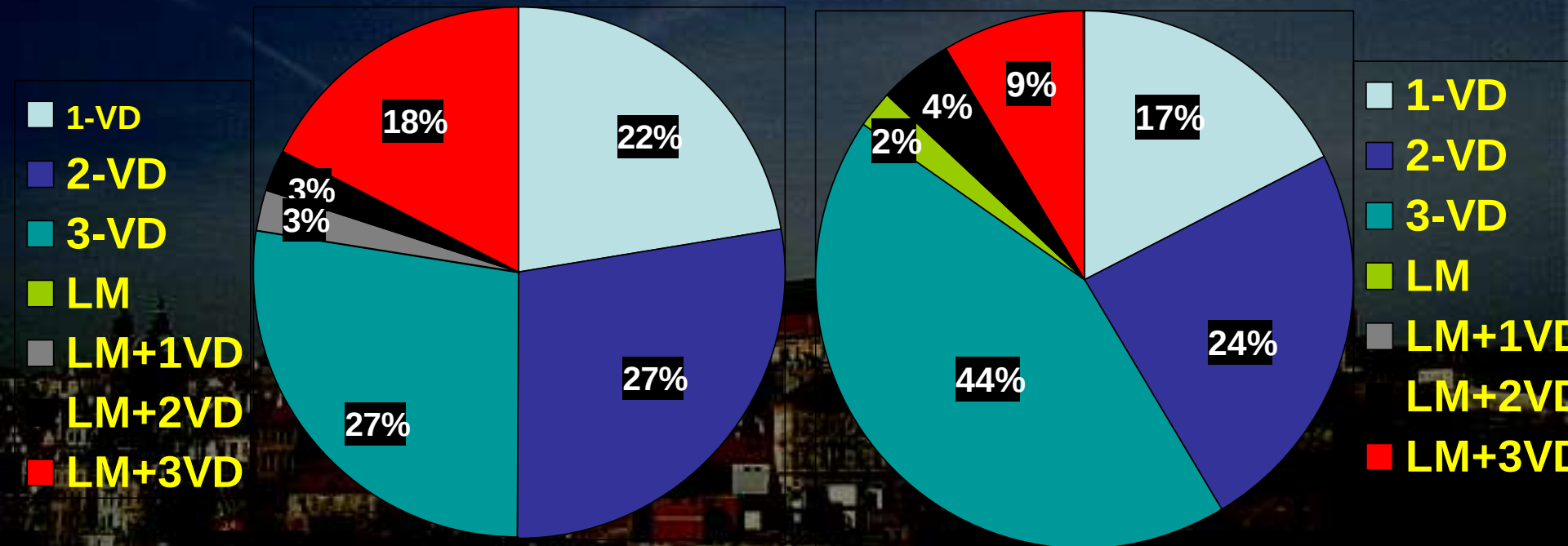
CAG findings

Group A vs. Group B



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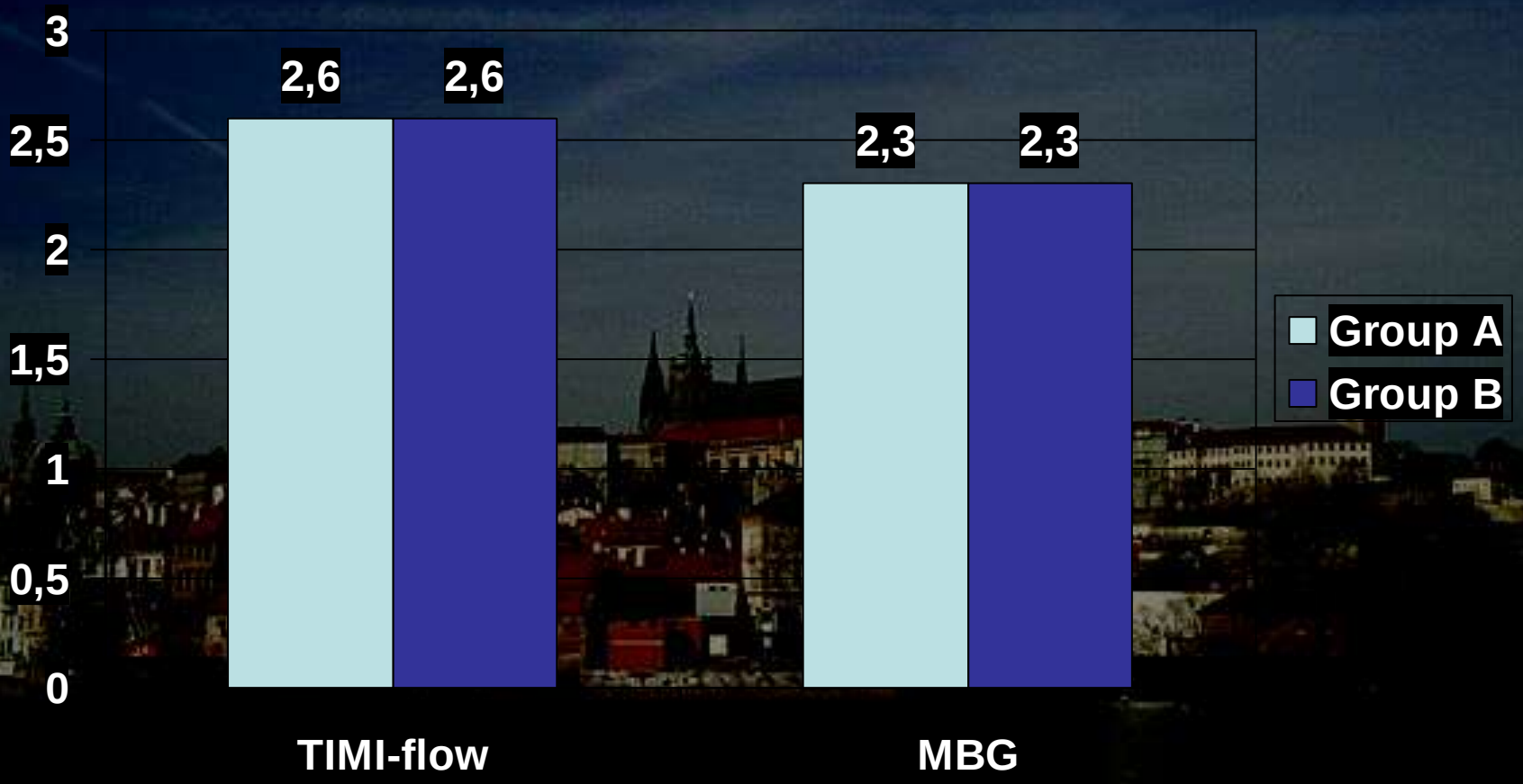
Coronary / myocardial flow after PCI



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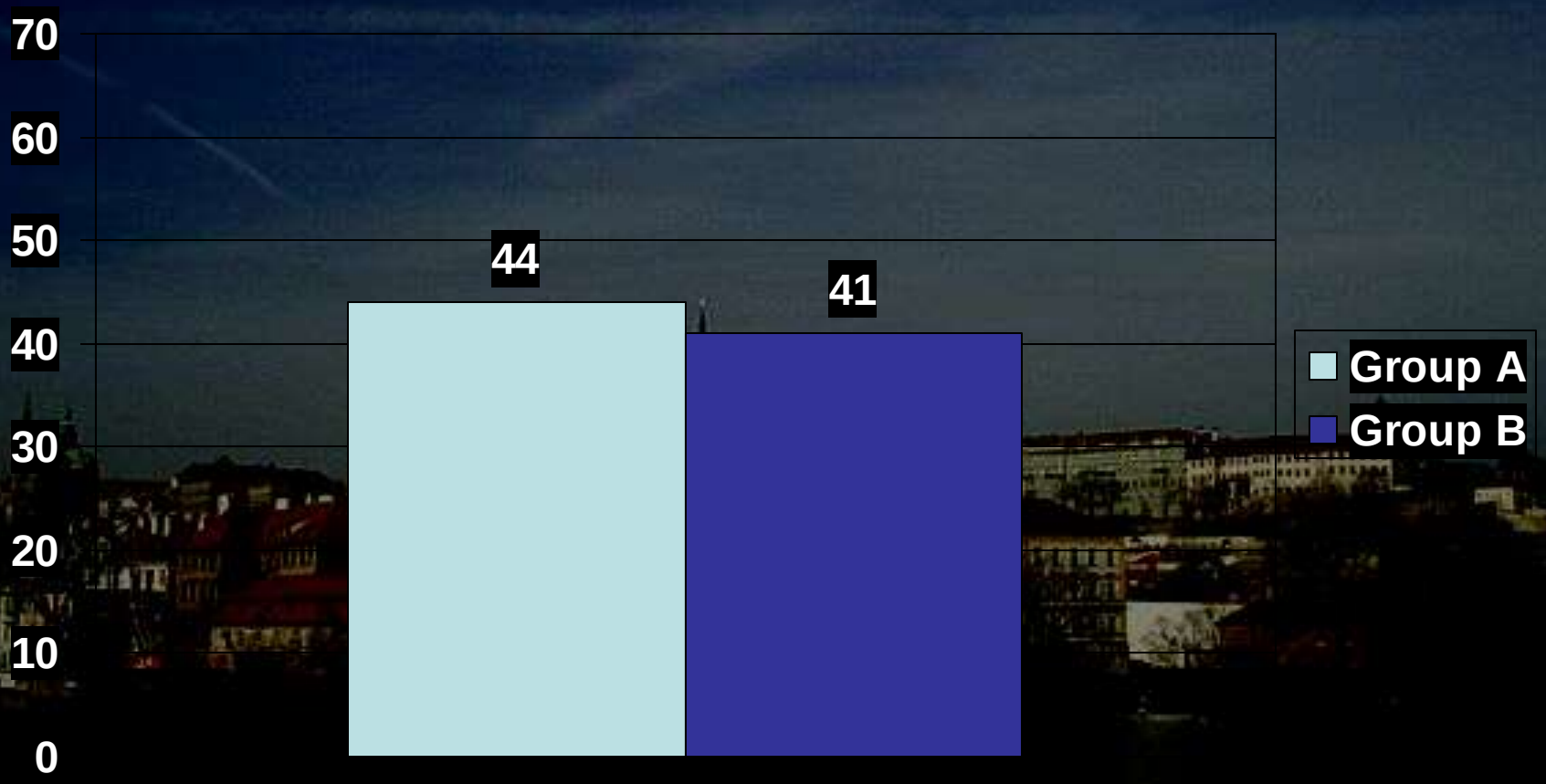
Ejection fraction at 30 days (survivors only)



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Clinical outcomes

(all differences n.s.)

	Group A (upfront abciximab)	Group B (routine treatment)
Primary end-point	17 (42%)	11 (27%)
In-hospital mortality	15 (37%)	13 (32%)
TIMI major bleeding	4 (10%)	2 (5%)
Stroke	1 (2,5%)	2 (5%)

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Conclusions

- This small study failed to show benefit from routine pre-procedural abciximab when compared to a selective abciximab use during the PCI procedure.
- In-hospital mortality of pts. with cardiogenic shock treated early by primary PCI was 35%.

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At least one of the following shock criteria had to be present:

1) Shock index > 1 (hypotension ≤ 90 mmHg + tachycardia > 90/min) OR
2) Tachycardia (> 90/min) + organ hypoperfusion (cold, wet, sweating skin) OR
3) Need for catecholamine support to maintain BP > 90/min OR
4) Acute heart failure + low blood pressure (Killip II–III + systolic BP < 120 mmHg)

Study definitions

- **Reinfarction:** recurrent ischaemic symptoms with a new increase in CK-MB or troponin
- **Stroke:** any new neurological deficit lasting > 24 h
- **Acute renal failure:** absolute change in serum creatinine level > 90 µmol/L
- **Major extracranial bleed:** retroperitoneal or intraocular bleeds, bleeds requiring blood transfusion, or haemoglobin decreases of 50 g/L or more.
- **TIMI major bleeding** (intracranial or any overt bleeding with a decrease in haemoglobin > 50 g/L, or decrease in haematocrit > 15%)
- **TIMI minor bleeding** (decrease in haemoglobin > 30 g/L, but with a < 15% decrease in haematocrit)

Statistical analysis

- Categorical data were presented as absolute and relative frequencies.
- The differences in proportions between groups were analysed using Fisher's exact test and the corresponding 95% confidence intervals (95% CI).
- Arithmetic means and medians were used as measures of continuous variables. Standard deviations (SD) and interquartile ranges (IQR) served as measures of variability.
- Between-group comparisons were made using the two-sample *t*-test and the Mann–Whitney *U*-test.
- All statistical tests were evaluated at a significance level of 0.05. Statistical analysis was carried out using the statistical software package Stata, release 9.2 (Stata Corp Lp, College Station, TX).