

# Similar outcome of ST-elevation myocardial infarction patients treated with primary percutaneous coronary intervention regardless of presence of cardiac surgery on-site

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## Abstract

**Background:** The growing penetration of mechanical reperfusion in ST-elevation myocardial infarction (STEMI) has been achieved by the creation of new percutaneous coronary intervention (PCI) centres which have helped to shorten delays but have compromised PCI volumes.

**Aim:** To compare the outcomes in STEMI patients treated in PCI centres with or without surgical back-up.

**Methods:** Data concerning 1,650 registry patients was analysed. The analysis was based on cathlab classification with cardiac surgery on site (n = 996) and without (n = 654).

**Results:** There was a 0.3% rate of transfer (two patients out of 654) for urgent coronary artery bypass grafting from PCI centres without cardiac surgery on site. There were no differences in in-hospital and long-term mortality in patients in both studied groups.

**Conclusions:** No differences in short and long-term outcomes were noticed for STEMI patients treated in centres with or without cardiac surgery on-site.

**Key words:** angioplasty, cardiac surgery, myocardial infarction

Kardiol Pol 2014; 72, 10: 949–953

## INTRODUCTION

The introduction of primary percutaneous coronary intervention (PCI) by the European Society of Cardiology (ESC) guidelines as the treatment of choice for ST-elevation myocardial infarction (STEMI) eligible patients (class IA) has led to the dynamic evolution of PCI centres in most European countries [1]. The growing penetration of mechanical reperfusion in STEMI, reaching over 80–90% in some regions in Europe, has been achieved by the creation of new PCI centres, including in rural areas far from large academic teaching hospitals. This has helped shorten delays, but at

the same time it has compromised PCI volumes performed at such centres [2]. Doubts have been raised, supported by clinical data, that an uncontrolled spread of PCI capable hospitals may adversely impact not only the quality of care, but also survival [3–5]. Additional voices have also spoken against the separation of PCI in acute myocardial infarction from surgical on-site back-up [5, 6].

Our aim was to analyse the real life registry data from the EUROTRANSFER database in order to compare outcomes in STEMI patients treated in PCI centres with or without surgical back-up.

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Received: 20.12.2013

Accepted: 24.03.2013

Available as AoP: 11.06.2014

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## METHODS

The current patient and invasive cardiology centre (cathlab) analysis was based on the EUROTRANSFER Registry data (ClinicalTrials.gov NCT00378391), the main results of which have already been published [7, 8]. The registry database of 1,650 patients enrolled between 2005 and 2007 in 15 catheterisation laboratories in seven European countries (Poland, Sweden, Germany, Italy, Spain, Finland, and Slovenia) was researched. The study protocol complied with the Declaration of Helsinki and was approved by the Jagiellonian University Bioethics Committee in Krakow, Poland.

The primary analysis in this paper was based on the presence or absence of on-site (within one hospital area) cardiac surgery affiliated to the cathlab.

The primary end-points of this analysis were in-hospital, 30-day and one-year all-cause mortality. Additional end-points included all-cause death and non-fatal re-infarction and additional urgent revascularisation (PCI or coronary artery bypass graft [CABG]) during the 30-day observation period. PCI general complications and bleeding events such as puncture site haematomas and major bleedings requiring blood transfusion (at least one pack of blood cells) were also assessed.

### Statistical methods

Data was analysed according to the established statistical protocols. Results were presented as percentages of patients or means ( $\pm$  standard deviation) where applicable. Differences between groups were tested using  $\chi^2$  test and Mann-Whitney U test for continuous variables. Kaplan-Meier survival curve was plotted for one-year survival and compared using log-rank test. All tests were two tailed and a p value of less than 0.05 was considered to be statistically significant. Statistical analyses were performed using SPSS 20 (SPSS Inc., Chicago, IL, USA).

## RESULTS

There were 996 (60%) patients who were admitted to PCI centres with cardiac surgery on-site and 654 (40%) patients admitted to cathlabs with no cardiac surgery on-site. Baseline characteristics and clinical status on admission, as well as procedural details of angiography and PCI, were similar in both groups (Table 1). There was a 0.3% rate of transfer (two patients of 654) for urgent CABG from a PCI centre without cardiac surgery on site. There were no differences in in-hospital and long-term mortality in patients in both studied groups. Comparable one-year mortality in those patients who required immediate bypass surgery (CABG) was found in hospitals with and without cardiac surgery on-site (Table 2, Fig. 1). Of 15 participating centres, seven (47%) were high primary PCI centres ( $> 300$  PPCI per year), and eight (53%) were moderately low primary PCI centres ( $< 300$  PPCI per year). On-site cardiac surgery was available for four (57%) high volume PPCI centres and for four (50%) low volume PPCI centres ( $p > 0.05$ ). The in-hospital and one year mortality of STEMI patients did not differ in low vs. high PPCI volume centres in our study (7.6% vs. 8.9%,  $p = 0.417$ ).

## DISCUSSION

The rapid expansion of PCI procedures for acute myocardial infarction in Europe over the past decade has led to an enormously high penetration of PPCI services in countries like Germany, Switzerland, Poland, Sweden and the Czech Republic [2]. The launching of more and more catheterisation labs, not only in academic centres and not always with on-site surgical back-up, has resulted in reasonable doubts as to whether the safety of patients in terms of clinical and periprocedural outcomes will remain secure in a low volume setting and in those without on-site surgery [3]. Historical data from Wennberg et al. [5] showed a significant mortality benefit if PCI was

**Table 1.** Demographics and angiography divided by on-site cardiac surgery

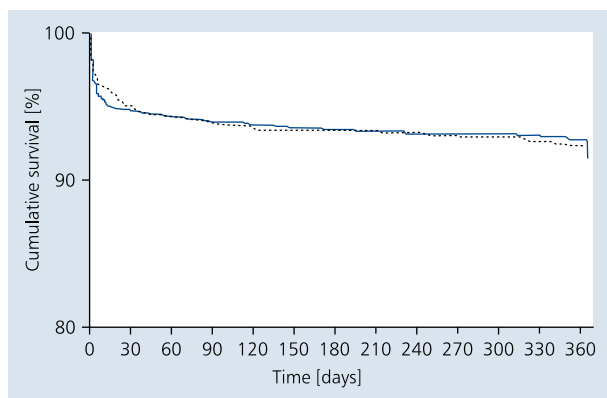
	On-site (n = 996)	None (n = 654)	P
Age	63.7 $\pm$ 12.5	64.5 $\pm$ 11.9	0.184
Sex [males]	73% (727)	71% (464)	0.481
Previous myocardial infarction	11.5% (114)	14% (92)	0.079
Smoking habit	36.5% (363)	35.5% (232)	0.735
Diabetes mellitus	15% (149)	18% (118)	0.125
Previous PCI	7% (70)	8% (52)	0.435
Killip 3+4 on admission	5.9% (59)	4.6% (30)	0.277
Radial access	20% (199)	3.5% (23)	0.001
TIMI 3 in baseline angiography	14% (139)	13% (85)	0.701
TIMI 3 post PCI	96% (956)	95% (621)	0.319

PCI — percutaneous coronary intervention; TIMI — Thrombolysis in Myocardial Infarction

**Table 2.** Primary percutaneous coronary intervention (PCI) outcome and complications divided by on-site cardiac surgery

	On-site (n = 996)	None (n = 654)	P
<b>Ischaemic complications</b>			
Death in-hospital	3.8% (38)	4.1% (27)	0.796
Death at 30 days	5.3% (53)	5.4% (35)	0.979
Death+reMI+rev at 30 days	8.4% (84)	6.6% (43)	0.186
Death at one year	8.4% (84)	8.3% (54)	0.899
Urgent CABG in-hospital	1.3% (13)	0.3% (2)	0.059
One-year death	30.8% (4)	50% (1)	0.931
Urgent PCI in-hospital	1.7% (17)	0.9% (6)	0.204
<b>Bleeding in-hospital</b>			
Intracranial haemorrhage	0% (0)	0% (0)	–
Puncture site haematoma	7.5% (75)	4.0% (26)	0.003
Blood transfusion	2.0% (20)	1.1% (7)	0.167
<b>Time delays</b>			
Admission to balloon [min]	36 ± 24	34 ± 24	0.690
<b>PCI complications</b>			
No-reflow	3.2% (32)	2.8% (18)	0.661
Distal embolisation	1.6% (16)	2.4% (16)	0.274
Perforation	0.2% (2)	0% (0)	0.521
Tamponade	0.2% (2)	0% (0)	0.373
Side branch occlusion	1% (10)	0% (0)	0.008

reMI — repeat myocardial infarction; rev — revascularisation; CABG — coronary artery bypass grafting



**Figure 1.** Kaplan-Meier survival curves for patients treated in invasive cardiology centres without cardiac surgery on-site (fine line) and with cardiac surgery on-site (dotted line). Statistically non-significant  $p = 0.799$  (log-rank test)

performed in hospital with surgical back up. In 2001, the American College of Cardiology/American Heart Association issued a class III recommendation for performing angioplasty in centres with no surgery on-site [6]. Real life has verified these recommendations and alarmist voices have turned out to be at least exaggerated in terms of the high demand for life

and quality of life saving procedures like PCIs. Current ESC guidelines recommend that minimal minimum of 0.3 million inhabitants should comprise one PCI centre [1].

Some more recent papers have indicated that it is a well-organised high volume system that influences the outcome most, not factors concerning the operators, and the experience of the whole team plays a major role [9, 10]. A study by Wharton et al. [11] goes further, concluding that the transfer of high risk acute myocardial infarction patients to hospitals with surgical back-up postpones reperfusion by more than 60 min, provides similar safety, and a 30-day death rate of 8.5% compared to 3.4% ( $p = 0.054$ ) in patients treated in PCI centres without surgery on-site.

The most striking finding in the EUROTRANSFER Registry data, however, is the scarce need for urgent CABG in patients treated in hospitals with no on-site cardiac surgery (ca. 0.3%). This translates to one patient a year who needs to be dispatched for surgery in a centre with 300 PPCI per year. Does this justify the need for on-site surgery if the outcome is the same? It also seems that the presence of surgeons on-site makes invasive cardiologists more inclined to send their patients to their colleagues (0.3% vs. 1.3%,  $p = 0.059$ ), while the outcome of patients treated by cardiac surgeons is fairly low in both situations (mainly due to poorer baseline clinical

characteristic of patients). High volume PPCI centres with cardiac surgery on-site are becoming a rarer commodity as more cathlabs are launched every year. We believe that our results support the role and safety of PCI centres who work on a daily basis without surgical back up on-site. In our study, we observed more frequent access site bleeding complications in a group of patients treated in cathlabs with on-site surgery. These have not, however, triggered major bleeding complications requiring transfusions which were equally distributed between the groups. The outcome may result from factors the influence of which was not recorded in this study.

The EUROTRANSFER registry was performed in 15 invasive cardiology centres in Europe and may thus reflect only the situation in these centres and regions of Europe.

### CONCLUSIONS

No differences in short and long-term outcome were noticed for STEMI patients treated in centres with or without cardiac surgery on-site.

**Conflict of interest:** none declared

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# Podobne rokowanie pacjentów z zawałem serca z uniesieniem odcinka ST poddawanych pierwotnej angioplastyce wieńcowej niezależnie od obecności oddziału kardiologii na miejscu

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## Streszczenie

**Wstęp:** Coraz większy odsetek chorych z zawałem serca z uniesieniem odcinka ST (STEMI) leczonych metodami przezskórnej angioplastyki wieńcowej (PCI) został osiągnięty poprzez tworzenie nowych pracowni kardiologii inwazyjnej, co pozwoliło skrócić czas do uzyskania docelowej terapii.

**Cel:** Celem pracy było porównanie rokowania pacjentów z STEMI leczonych PCI w ośrodkach z bezpośrednim zabezpieczeniem kardiologicznym i bez niego.

**Metody:** Zebrano dane dotyczące 1650 pacjentów. Spośród nich 996 było leczonych w pracowniach kardiologii inwazyjnej z zabezpieczeniem kardiologicznym na miejscu, a 654 bez bezpośredniego zabezpieczenia kardiologicznego.

**Wyniki:** W grupie pacjentów z pracowni bez oddziału kardiologii na miejscu tylko 0,3% osób z STEMI (2 chorych z 654) zostało przekazanych do pilnej operacji pomostowania aortalno-wieńcowego. Nie zaobserwowano różnic w śmiertelności odległej w obu porównywanych grupach w 12. miesiącu po PCI.

**Wnioski:** Obecność oddziału kardiologii na miejscu nie jest wymogiem koniecznym do prowadzenia interwencyjnego leczenia zawału serca w pracowniach kardiologii inwazyjnej i nie wiąże się z lepszymi odległymi wynikami klinicznymi.

**Słowa kluczowe:** angioplastyka, kardiologia, zawał serca

Kardiologia 2014; 72, 10: 949–953

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Praca wpłynęła: 20.12.2013 r.

Zaakceptowana do druku: 24.03.2013 r.

Data publikacji AoP: 11.06.2014 r.