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ORIGINAL ARTICLE

Impact of infarct related artery patency after early abciximab administration on one-year mortality in patients with ST-segment elevation myocardial infarction (data from the EUROTRANSFER Registry)

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Abstract

Background: Spontaneous early infarct related artery (IRA) recanalisation before primary percutaneous coronary intervention (pPCI) has a favourable impact on outcome. However, the role played by pharmacotherapy driven patency prior to pPCI is still a matter of debate.

Aim: To assess the role of early IRA patency (TIMI flow 2 or 3) after early abciximab administration in patients with ST-segment elevation myocardial infarction (STEMI) transferred for pPCI.

Methods: Data was gathered for 1,650 consecutive STEMI patients transferred for pPCI from hospital networks in seven countries in Europe between November 2005 and January 2007. We identified 691 patients who were pretreated with abciximab before transportation to a cathlab hospital and underwent PCI.

Results: Angiography showed early IRA patency (TIMI flow 2 or 3) in 233 (33.7%) patients, and occluded IRA (TIMI flow 0 or 1) in 458 (66.3%) patients. In patients with patent IRA, in baseline angiography the rate of TIMI 3 flow and ECG ST-segment resolution > 50% after PCI was higher compared to patients with occluded IRA. One year mortality was significantly lower in patients with patent IRA, 1.3% *vs* 7% (OR 0.17; CI 0.05–0.6; p = 0.001). In multivariable Cox regression analysis, IRA patency at baseline was identified as an independent predictor of one-year mortality.

Conclusions: Infarct related artery recanalisation after early pharmacological pretreatment in STEMI patients undergoing transportation for pPCI is associated with better post-procedural myocardial perfusion and lower one-year mortality.

Key words: myocardial infarction, angioplasty, abciximab, reperfusion, registries

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INTRODUCTION

It is now widely accepted that primary percutaneous coronary intervention (pPCI) improves survival in comparison with thrombolysis, and is the preferred method of treatment in patients with ST-segment elevation myocardial infarction (STEMI) [1, 2]. Spontaneous early patency of infarct related artery (IRA) upon arrival for pPCI favourably impacts upon the short and long-term outcome [3, 4]. However, attempts

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to increase the rates of early restoration of epicardial flow with pharmacotherapy prior to pPCI are still a matter of debate.

The aim of the present study was to assess the role of early IRA patency after early abciximab administration in patients with STEMI transferred for pPCI, based on data from the EUROTRANSFER (European Registry on Patients with ST-Elevation MI Transferred for Mechanical Reperfusion with a Special Focus on Upstream Use of Abciximab) Registry.

METHODS

Study population

The EUROTRANSFER Registry (ClinicalTrials.gov number NCT00378391) design and main results have been previously published [5–7]. The study protocol and execution complied with the Declaration of Helsinki, and was approved by the Jagiellonian University Bioethics Committee. This registry comprised data concerning 1,650 consecutive STEMI patients ≥ 18 years old who were scheduled for pPCI and who were transferred to the PCI hospital either from a referral hospital or who had been picked up by ambulance. For the purpose of the present analysis, data was retrieved concerning 691 (41.9%) registry patients who received abciximab before transfer to the cathlab hospital and who had undergone immediate PCI. Patients were analysed based on baseline IRA patency assessed according to the Thrombolysis In Myocardial Infarction (TIMI) flow.

Study outcomes

The primary outcome parameter of the present analysis was one-year all-cause mortality. Additionally, rates of all-cause death, nonfatal reinfarction, bleeding (intracranial haemorrhage, major bleeding requiring transfusion, and puncture site haematoma) were assessed at 30 days. The TIMI flow grade in IRA before and after PCI, ST-segment elevation resolution > 50% in electrocardiogram 60 min after PCI, and echocardiography left ventricular ejection fraction on the second to third day after PCI, were assessed at the investigators' discretion according to local practice. Data on the rates of complications during PCI (no-reflow, distal embolisation) was also collected.

Statistical analysis

Data was analysed according to established standards of descriptive statistics. Categorical variables were compared by a χ^2 test. Continuous variables were compared by the two-tailed Mann-Whitney U-test. Odds ratios and 95% confidence intervals were provided where appropriate. The difference in death rates between groups during a one-year follow-up period was assessed by the Kaplan-Meier method using log-rank test. Multivariable Cox regression analysis was performed to find independent predictors of one-year mortality. All tests were two-tailed and a p value of < 0.05 was considered statistically significant. STATISTICA v.8 was used for analysis (Statsoft, Poland).

RESULTS

A total of 691 patients who were pretreated with abciximab before transportation to the cathlab hospital and who underwent PCI entered the analysis. Angiography showed early IRA patency (TIMI flow 2 or 3) in 233 (33.7%) patients, and occluded IRA (TIMI flow 0 or 1) in 458 (66.3%) patients (Fig. 1). Baseline characteristics were similar in both groups (Table 1). Patients with occluded IRA were more frequently in cardiogenic shock (Killip class IV) upon arrival at the cathlab. Total ischaemic time from chest pain onset to first balloon inflation was similar, but time from abciximab administration to first balloon inflation was longer in the TIMI 2 or 3 group (Table 1).

Data concerning concomitant pharmacotherapy and interventional treatment is summarised in Table 2. Unfractionated heparin was more frequently administered before transportation in patients with patent IRA at baseline. The IRA distribution differed in the studied groups, with more frequent left anterior descending artery in the TIMI 0 or 1 group, and more frequent right coronary artery in the TIMI 2 or 3 group. Thrombectomy usage during PCI was similar in both groups. The stenting rate did not differ between groups. However,

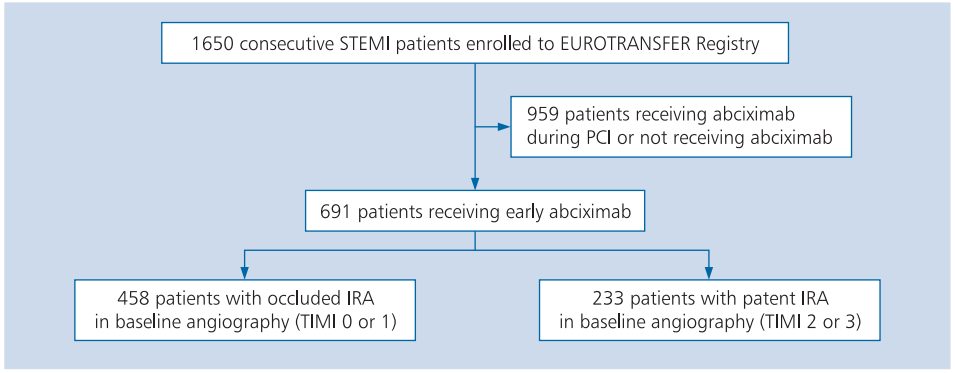

Figure 1. Registry group distribution according to infarct related artery patency in baseline angiography

Table 1. Baseline demographics and clinical status on admission to percutaneous coronary intervention centre. Timing information

	TIMI 0 or 1 (n = 458)	TIMI 2 or 3 (n = 233)	P
Age [years] (IQR)	64 (54–72)	66 (56–73)	0.18
Males	75.8%	72.5%	0.36
Systolic BP [mm Hg] (IQR)	130 (149–115)	130 (150–120)	0.10
Diastolic BP [mm Hg] (IQR)	80 (70–90)	80 (70–90)	0.98
Heart rate [bmp] (IQR)	75 (66–88)	74.5 (67–85)	0.58
Previous myocardial infarction	10.0%	11.2%	0.65
History of chronic renal failure	1.7%	1.3%	0.65
History of stroke	4.4%	3.0%	0.38
Previous PCI	8.7%	5.6%	0.14
Previous CABG	1.1%	0.9%	0.77
Peripheral artery disease	2.6%	2.6%	0.97
Current smoker	34.3%	36.9%	0.49
Diabetes mellitus	15.1%	16.3%	0.70
Killip IV (cathlab admission)	4.0%	0.4%	0.008*
Pain-to-abciximab time, median (IQR)	120 (75–210)	122 (76–225)	0.62
Abciximab-to-balloon time, median (IQR)	75 (60–95)	80 (66–106)	0.001*
Pain-to-balloon time, median (IQR)	205 (145–305)	216 (150–345)	0.15

*$p < 0.05$; BP — blood pressure; CABG — coronary artery bypass grafting; IQR — inter-quartile range; PCI — percutaneous coronary intervention

Table 2. Concomitant medications. Angiographic and interventional details

	TIMI 0 or 1 (n = 458)	TIMI 2 or 3 (n = 233)	P
Clopidogrel loading dose pre-cathlab	23.6%	18.0%	0.09
Unfractionated heparin pre-cathlab	67.3%	78.5%	0.002*
Unfractionated heparin dose, median (IQR) [U/kg]	55.5 (50–67)	52.6 (49–65)	0.1
IRA in baseline angiography:			
SVG	0.44%	0.0%	
LMCA	0.44%	0.9%	
LAD	53.0%	38.8%	
LCX	10.1%	16.8%	
RCA	36.1%	43.5%	0.003*
Multi-vessel disease	57.6%	52.8%	0.10
Thrombectomy usage	10.5%	8.6%	0.43
Stent (total)	91.9%	92.7%	0.72
Drug eluting stent	29.9%	27.0%	0.43
Direct stenting	12.7%	22.8%	< 0.001*
Intra-aortic balloon pumping	5.2%	1.3%	0.011*
No-reflow during PCI	3.1%	2.1%	0.50
Distal embolisation during PCI	2.0%	1.3%	0.52
TIMI 3 after PCI	92.1%	96.6%	0.024*

*$p < 0.05$; IRA — infarct related artery; LAD — left anterior descending artery; LCX — left circumflex artery; LMCA — left main coronary artery; PCI — percutaneous coronary intervention; RCA — right coronary artery; SVG — saphenous vein graft; TIMI — Thrombolysis in Myocardial Infarction

Table 3. Clinical outcome at 30-day and one-year follow-up

	TIMI 0 or 1 (n = 458)	TIMI 2 or 3 (n = 233)	P	OR; CI
Ischaemic complications at 30 days				
Death	4.4%	0.9%	0.01*	0.19; 0.04–0.8
Reinfarction	1.1%	0%	0.1	–
Death + reinfarction	5.5%	0.9%	< 0.001*	0.15; 0.04–0.64
Bleeding complications at 30 days				
Stroke, haemorrhagic	0%	0%	–	–
Major bleeding requiring transfusion	3.1%	0.9%	0.07	0.28; 0.06–1.22
All bleedings	9.4%	10.3%	0.7	1.1; 0.66–1.88
Ischaemic complications at one year				
Death	7%	1.3%	0.001*	0.17; 0.05–0.6

*p < 0.05; †major bleedings required transfusion or death or reinfarction; CI — confidence interval; OR — odds ratio

a direct stenting technique was more frequently used in patients with patent IRA. Intra-aortic balloon pumping was more often used in patients with occluded IRA. The rate of final TIMI grade 3 flow after PCI was higher in patients with TIMI 2 or 3 flow at baseline. ST-segment resolution > 50% 60 min after PCI was more frequent in the TIMI 2 or 3 group (79.9% *vs* 89.3%; p = 0.002). Additionally, left ventricular ejection fraction assessed on the second to third day after PCI was higher in patients with patent IRA at baseline (median [IQR] for TIMI 2 or 3 *vs* TIMI 0 or 1: 55 [45–60] *vs* 45 [35–55]; p < 0.0001).

Patients with patent IRA at baseline were at lower risk of ischaemic events during the 30-day follow-up. Moreover, one-year mortality was significantly lower in the TIMI 2 or 3 group (Table 3, Fig. 2). In multivariable Cox regression analysis, IRA patency in baseline angiography was identified as an independent predictor of death at one year (Table 4).

When we analysed the impact of early unfractionated heparin administration on IRA patency, a higher rate of TIMI 2 or 3 flow in baseline angiography was found in patients receiving abciximab with unfractionated heparin than abciximab alone (TIMI 2 or 3 flow: 37.3% *vs* 25%, p = 0.002). In multivariable analysis, early unfractionated heparin administration was also identified as an independent predictor of IRA patency in baseline angiography (OR 1.87; 95% CI 1.27–2.73; p = 0.001).

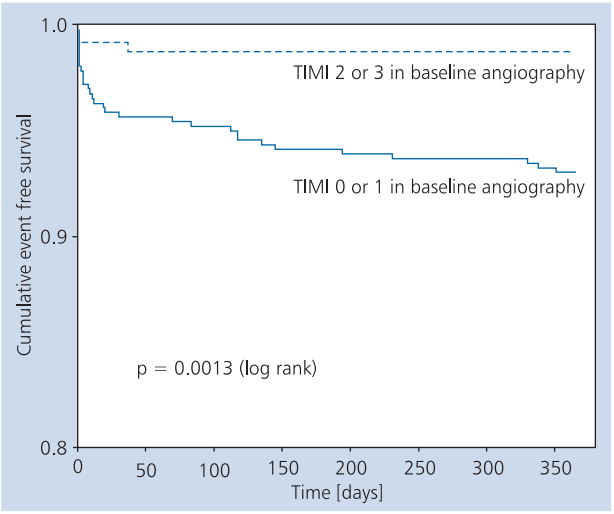

Figure 2. Kaplan-Meier survival curves for one-year follow-up

DISCUSSION

The presented analysis of the EUROTRANSFER Registry, based on a real-life consecutive patient population, showed that early IRA patency after early abciximab administration resulted in better myocardial perfusion after PCI and better one-year mortality.

Table 4. Multivariable Cox regression for death at one-year

	OR	95% CI	P
TIMI 2 or 3 in baseline angiography	0.19	0.058–0.624	0.006*
Age (per one year)	1.09	1.053–1.131	< 0.001*
Killip IV on cathlab admission	4.38	1.678–11.410	0.003*

*p < 0.05; CI — confidence interval; OR — odds ratio; TIMI — Thrombolysis in Myocardial Infarction

Spontaneous IRA patency before pPCI is associated with a favourable outcome [3, 4]. However, the role of pharmacologically driven patency is still under investigation. Previous studies with lytic based facilitated PCI showed higher rates of ischaemic and bleeding events after such therapy compared to pPCI [8]. It should be underlined that there were some important limitations in the analysed treatment, including usage of thrombolytic therapy alone (not with optimal antiplatelet treatment) or usage of obsolete thrombolytic agents. Lack of aggressive antiplatelet therapy may lead to an increased prothrombotic state after thrombolysis. This was one potential reason for the failure (i.e. increased mortality) of the facilitated PCI arm in the ASSENT-4 PCI study [9]. However, other research has suggested a beneficial effect of early IRA patency after pretreatment with half-dose lytics but with optimal antiplatelet inhibition with a full dose of abciximab [10].

Another strategy to increase early IRA patency is the concept of administering prehospital glycoprotein (GP) IIb/IIIa inhibitors. There is growing evidence suggesting the clinical benefit of such a strategy, including mortality reduction, with the greatest effect in high-risk patients [6, 11–13]. Despite no clinical benefit of early abciximab administration in the general FINESSE population in a short-term observation, further analysis showed a one-year mortality benefit in high-risk patients transferred to the cathlab with early STEMI presentation [14, 15]. Similarly to the main results of the FINESSE trial, a meta-analysis of randomised studies with early lytics and GP IIb/IIIa inhibitors has concluded that pharmacological facilitation of pPCI with GP IIb/IIIa inhibitors offers a higher rate of TIMI 3 flow before PCI without clinical benefit. Importantly, such a strategy does not translate into a higher rate of bleeding events [8]. Since this analysis, a great deal of new data has been published showing the benefit of early GP IIb/IIIa inhibitors administration [16, 17]. A direct analysis of the benefit of early IRA recanalisation after abciximab administration has not been published before. Such results are very important from the practical point of view. It is easier to perform successful PCI in STEMI when the IRA is open. The reasons for this include easier guidewire passage, lower risk of vessel wall dissection with the wire, more optimal stent selection, and the possibility of direct stenting. The direct stenting technique allows the risk of distal embolisation to be reduced [18]. Better stent selection in patent IRA may also result in a lower rate of stent thrombosis, but there is no clear evidence-based data regarding this issue.

Despite the similar pretreatment given to all patients, only some of them respond to such therapy, which results in early reperfusion. This problem has been previously discussed mainly based on studies with thrombolysis. Such individual responses may be caused by many clinical or anatomical factors, but also by biochemical haemostasis, thrombus composition (causing resistance of thrombus to dissolution), and heterogeneous response to aggressive antiplatelet or thrombolytic treatment [19–21]. The 'smoking paradox' has also been described based on thrombolysis studies, but the pathophysiological background has not been defined. It may be related to a larger proportion of thrombus burden to plaque burden in the occluded artery in smokers [22]. The smoking paradox was not observed in our group of patients. In our analysis, all patients had received early abciximab but not all had received early unfractionated heparin which influences the rate of IRA reopening. It is important not to forget about unfractionated heparin when administering abciximab, especially in an out-of-hospital rapidly changing scenario (e.g. ambulance). Also, early administered clopidogrel loading dose may influence the IRA patency [23]. This aspect was not assessed in our analysis due to the relatively low number of patients receiving clopidogrel before transportation. In the BRAVE 3 study in STEMI patients presenting up to 24 h from symptoms onset, abciximab administration on top of a clopidogrel loading dose was not more beneficial than a placebo [24]. However, in other recently published analyses, early clopidogrel administration did not blunt the positive effect of early GP IIb/IIIa inhibitors therapy [13, 25].

In our cohort of patients, PCI was performed immediately after coronary angiography, and we have not analysed the potential benefit of delayed PCI strategy which may be beneficial in patients with full reperfusion and a large thrombus burden [26]. When analysing the problem of IRA recanalisation, there will always be an issue as to what proportion of patients never really had an occluded artery, but presented with ST-segment elevation caused by a large thrombus and microcirculation injury with further good response to early pharmacotherapy and patent artery. This question still remains unanswered.

Limitations of the study

The main limitation of our study is the non-randomised nature and the potential for selection bias. However, for the purpose of this analysis, only patients pretreated with early abciximab were selected, so it is unlikely that these limitations could influence the study outcome. Another limitation is the lack of independent core laboratory analysis of angiography which was based on investigators' assessments. However, patients were divided based on IRA patency (patent *vs* occluded), but not based on detailed differences between all four grades on the TIMI scale. Also, electrocardiographic and echocardiographic data was based on a physician's assessment according to local practice. The one-year outcome data was limited to mortality. Not all patients received early heparin administration. This underlines the importance of heparin administration with abciximab.

CONCLUSIONS

Infarct related artery recanalisation after early pharmacological pretreatment in STEMI patients undergoing transportation for pPCI is associated with better post-procedural myocardial perfusion, and lower one-year mortality.

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Conflicts of interest: *Dariusz Dudek received a research grant (Principal Investigator of the EUROTRANSFER registry), travel grants and speaker fees from Eli Lilly and Company; Artur Dziewierz, Zbigniew Siudak, Tomasz Rakowski, Waldemar Mielecki, and Ralf Birkemeyer received travel grants and speaker fees from Eli Lilly and Company; Magnus Janzon received a consultancy fee (Swedish National Advisory Board) from Eli Lilly and Company; Krzysztof Zmudka and Jacek S. Dubiel have no conflict of interest in connection with the submitted article.*

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Wpływ drożności tętnicy odpowiedzialnej za zawał po wczesnym podaniu abciximabu na śmiertelność roczną pacjentów z zawałem serca z uniesieniem odcinka ST leczonych zabiegami przezskórnej interwencji wieńcowej. Dane z rejestru EUROTRANSFER

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Streszczenie

Wstęp: Wczesna, spontaniczna, rekanalizacja tętnicy odpowiedzialnej za zawał (IRA) przed zabiegiem pierwotnej przezskórnej interwencji wieńcowej (pPCI) wiąże się z korzystnym rokowaniem pacjentów z zawałem serca z uniesieniem odcinka ST (STEMI). Problem wczesnej drożności IRA po farmakoterapii pozostaje przedmiotem dyskusji.

Cel: Celem pracy była ocena roli wczesnej drożności IRA (napływ TIMI 2 lub 3) u pacjentów ze STEMI leczonych abciximabem przed transportem do pracowni hemodynamiki.

Metody: Do rejestru EUROTRANSFER w okresie od listopada 2005 do stycznia 2007 r. włączono w 7 krajach Europy łącznie 1650 pacjentów. Do prezentowanej analizy zakwalifikowano 691 osób, które otrzymały abciximab przed transportem do pracowni hemodynamiki, a następnie były poddane pPCI.

Wyniki: W wyjściowej angiografii u 233 (33,7%) pacjentów stwierdzono drożną IRA (TIMI 2 lub 3), natomiast u 458 chorych zamkniętą IRA (TIMI 0 lub 1). U osób z drożną IRA w wyjściowej angiografii zaobserwowano większą częstość TIMI 3 oraz rezolucji odcinka ST w EKG > 50% po zabiegu PCI w porównaniu z pacjentami z zamkniętą IRA. Śmiertelność w rocznej obserwacji była istotnie niższa u osób z drożną IRA: 1,3% *v.* 7% (OR 0,17, CI 0,05–0,6; p = 0,001). W analizie wieloczynnikowej (regresja Coxa) brak drożności IRA w wyjściowej angiografii był niezależnym czynnikiem ryzyka zgonu w okresie roku.

Wnioski: Wczesna rekanalizacja IRA po wstępnej farmakoterapii u pacjentów ze STEMI kierowanych do pPCI wiąże się z mniejszą śmiertelnością w rocznej obserwacji.

Słowa kluczowe: zawał serca, przezskórne interwencje wieńcowe, abciximab, reperfuzja, rejestr

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