Prospective randomised study to evaluate effectiveness of distal embolic protection compared to abciximab administration in reduction of microembolic complications of primary coronary angioplasty

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Abstract

Background: Myocardial reperfusion following primary percutaneous coronary intervention (pPCI) is limited due to, among other things, microembolic events. Abciximab and a mechanical system of distal protection both reduce their incidence during PCI.

Aim: Prospective, randomised study to compare effectiveness of abciximab and protection devices in reduction of microembolic complications during pPCI.

Methods: One hundred and twenty consecutive patients with ST elevation acute myocardial infarction referred for pPCI after coronary angiography were randomly assigned to the following groups: Group A (n=63), treated with abciximab; and Group B (n=57), treated using the distal protection system. Primary endpoint was blood flow through the infarct-related artery (IRA) using TIMI grading after pPCI; secondary endpoints included myocardial perfusion assessment using myocardial blush grade (MBG), ST resolution and improvement of echocardiographic left ventricular ejection fraction (LVEF) after pPCI.

Results: TIMI grade 3 flow after pPCI was obtained in 89% of patients in both groups, TIMI grade 2 flow in 5% (NS). Myocardial perfusion after pPCI assessed with MBG scored 3 in 66% of patients in group A and 62% of patients in group B (NS). ST resolution was present in 62% (26-84) in group A and 68% (41 – 86) in group B (NS). Logistic regression analysis showed no significant influence of selected variables on the primary endpoint. Analysis performed in the distal protection group revealed significant effects on the following factors on the final TIMI flow in IRA: presence of thrombus prior to pPCI (p=0.026), presence of residual thrombus after aspiration (p <0.001), and IRA diameter of ≥3.5 mm (p=0.01). Median LVEF in group A at sixth month of follow-up was 46% (44-50%), similar to group B – 46% (45-49%) (NS).

Conclusions: Use of the PercuSurge distal protection device during pPCI allows angiographic and electrocardiographic measures of reperfusion to be improved. It has a similar effect on left ventricular systolic function as administration of abciximab. The device seems to be useful in patients with culprit artery diameter of ≥3.0 mm, and optimally ≥3.5 mm and thrombus visible on angiography. Successful initial thrombectomy prior to deployment of stent seems particularly important when using the PercuSurge system.

Key words: primary coronary angioplasty, myocardial infarction, distal protection, microembolism

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Introduction

Early reperfusion in acute myocardial infarction (MI) has great prognostic impact. The high efficacy of primary percutaneous coronary interventions (pPCI) in restoring patency of the infarct-related artery makes it a method of choice for the treatment of acute MI [1]. However, the extent of post-infarction myocardial injury is determined not only by the duration of culprit artery occlusion, but also by adequate tissue reperfusion. Compromised microcirculation of the culprit artery

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leads to lack of normal flow (*no-reflow*) despite opening of the occlusion. In addition to endothelium dysfunction, no-reflow is caused by mechanical blockage of small vessels by debris of plaques and thrombi. The no-reflow phenomenon increases the risk of unfavourable remodelling of the left ventricle (LV), thus leading to development of heart failure and death [2]. Microembolisation visible on angiogram performed immediately after pPCI is also associated with increased risk of death in long-term follow-up [3].

The use of protection devices may be one method to reduce the extent of distal embolisation during pPCI. The randomised SAFER study showed their effectiveness in reducing the incidence of serious ischaemic events during percutaneous interventions in degenerated aorto--coronary grafts [4]. Other reports confirmed the safety of these devices during pPCI [5] as well as lower incidence of "no-reflow" phenomenon and greater regression of ST elevation with their use [6]. The multicentre, randomised EMERALD trial failed to show any influence of distal protection on coronary capillaries, infarct size or frequency of major adverse cardiac events [7].

Most commonly distal protection devices comprise modified angioplasty guidewires. They incorporate a filter at the end that captures debris distally to the angioplasty site, or a balloon that enables occlusion of the arterial lumen distally to the lesion and removal of embolic material from the dilated area using a specially designed catheter. Proximal protection devices act in a similar way – temporal occlusion of the artery with a balloon catheter placed in the proximal segment of the artery undergoing PCI [8].

Another method for improvement of tissue perfusion after pPCI is the use of platelet GP IIb/IIIa receptor blocker – abciximab. This agent improves both angiographic parameters and prognosis, most likely due to decrease of microembolisation which, for example, was confirmed by the following studies: EPISTENT [9], ADMIRAL [10], and CADILLAC [11].

The aim of this study was to evaluate the effectiveness of distal protection device vs. abciximab during pPCI in reduction of distal microembolisation and improvement of myocardial perfusion by means of a randomised, prospective trial. A PercuSurge protective device was chosen – an assembly comprising a guidewire, allowing for temporal occlusion of the lumen distally to the angioplasty site, and an aspiration catheter (i.e. export catheter).

Methods

Patients

The study enrolled consecutive patients with acute MI (<12 hours) referred for pPCI. Inclusion criteria were, in accordance with the guidelines of the European Society of Cardiology [12], presence of at least two of three signs and symptoms of acute MI: typical clinical symptoms, new ST-segment elevation in at least two adjacent ECG leads (≥0.2 mV in V_1-V_3 and ≥0.1 mV in the other leads) or elevation of troponin/creatine kinase MB isoenzyme blood levels above MI cut-off values. Other inclusion criteria were as follows: critical stenosis or total occlusion of infarct-related artery, and estimated reference diameter of infarct-related artery distally to the occlusion between 3.0 and 4.5 mm.

Exclusion criteria: lack of patient's informed consent, critical stenosis of the left main coronary artery (if intervention was performed in this artery), presence of complex occlusive lesion (defined as: lesion of >20 mm length or lesion in the segment bent at 90° or lesion incorporating ostium of a large side branch of >2 mm diameter). In addition, the following patients were not enrolled: those with cardiogenic shock, respiratory distress requiring intubation, if culprit artery was previously treated with PCI, after surgical myocardial revascularisation, if abciximab, aspirin, clopidogrel or heparin were contraindicated, with critical lesions in other segments of coronary arteries that may require revascularisation within the following six months, or with valvular disease requiring surgical intervention.

Study protocol

After confirming meeting of clinical inclusion and exclusion criteria, initial patient's consent to participate in the study was obtained immediately in the Admission Room and subsequently coronary angiography was performed. When the angiographic criteria were met the patients were randomly assigned to group A (abciximab) or group B (protection device). Prior to the procedure all patients received an oral dose of 300 mg of aspirin and 300 mg of clopidogrel. Before angioplasty, all patients in group A received an intravenous bolus infusion of heparin (70 IU/kg of body weight), adjusting the dose, if necessary, to obtain ACT >250 s. Next, a standard dose of abciximab was administered – intravenous bolus and infusion. Patients in group B received, prior to angioplasty, intravenous bolus of heparin (100 IU/kg of body weight) to target ACT >300 s, and abciximab use was subject to operator's judgment (in the case of a persistent large thrombus after PCI, presence of no-reflow or technical failure to use protection device).

Primary coronary angioplasty

In group A after passing the guidewire through the target artery occlusion site direct stenting was

recommended, and predilation was performed for vessels where direct stenting was impossible due to arterial anatomy. In group B the study protocol assumed insertion of the PercuSurge guidewire into the distal part of the artery as a first step. In case of technical problems (difficulties forcing the lesion, impossible assessment of segment beyond the occlusion), a standard angioplasty guidewire and then the PercuSurge wire were used. If difficulties were still present it was allowed to predilate the artery using a balloon catheter of smallest possible diameter. After successful inflation of the distal occlusion balloon an export catheter (provided with the PercuSurge device) was used to aspirate thrombotic debris from the occlusion site. This could be preceded by predilation performed also with the target artery temporarily occluded. After 2-3 passages of the export catheter the distal balloon was deflated and angiography was performed. Angiographic evidence of thrombus resulted in another occlusion of flow in the culprit artery and re-aspiration. After further angiographic assessment a stent was deployed at the stenosis/occlusion site. In both study groups bare metal stents were used and the ratio of their diameter to reference artery diameter was 0.9:1. Deployment of stents in group B was performed with occlusion balloon inflated, and after deployment of stents an export catheter was used to carry out another aspiration of material from the angioplasty site.

Endpoints

The study endpoint was blood flow through the infarct-related artery after coronary angioplasty as assessed using TIMI score [13]. Additionally, the following secondary endpoints were evaluated: myocardial contrast flow in the infarct area assessed with MBG (*myocardial blush grading*) [14], ST-segment resolution on ECG after pPCI, and increase of LV ejection fraction (LVEF) in 6-month follow-up.

Angiography was performed prior to and after coronary angioplasty in both groups in a way that enabled evaluation of epicardial artery blood flow using TIMI grading and myocardial perfusion using MBG. Electrocardiography (12-lead) was recorded on admission and 1 hour after opening of the infarct-related artery. ST-segment elevation was assessed in all leads in mV, and subsequently all ST elevations were summarised, resulting in baseline total elevation Σ_1 and total elevation after 60 minutes post pPCI – Σ_2. Values obtained 60 minutes after PCI were compared to the baseline trace and ST resolution was calculated using the following formula: $(\Sigma_1 - \Sigma_2) \times 100/\Sigma_1$. Echocardiography was performed on admission, immediately after coronary angiography and in the first and sixth month of follow-up. Left ventricular ejection fraction was assessed using apical four-chamber view directly after angioplasty and at month 6 – its change by 5% of an absolute value was found significant. All patients had necrosis biomarker levels routinely measured.

Long-term follow-up

Patients were followed for 6 months. Adverse events records were kept, with particular focus on deaths, including cardiac deaths, reinfarctions, revascularisation and unstable angina episodes.

Statistical analysis

Analysis of angiographic data was performed by an independent investigator using established criteria of TIMI grading and myocardial blush grading.

Statistical analysis (intention-to-treat) was performed using SPSS software with $p < 0.05$ being significant. Variables of normal distribution were presented as a mean and standard deviation, others as median and the first and third quartiles. Differences between groups were evaluated with Mann-Whitney test, χ^2 test, and influence of individual independent variables on the study endpoints with multiple logistic regression.

Ethics

The study was approved by the Bioethics Committee of the Silesian Medical Academy in Katowice and was conducted as part of the research of the KBN grant no. 3P05C 04625.

Results

The study enrolled 120 consecutive patients with acute MI. Group A in which abciximab was given routinely comprised 63 subjects, group B (angioplasty using the PercuSurge device) 57 subjects. There were no significant differences between study groups with respect to age, gender, prevalence of hypertension, hyperlipidaemia, smoking, diabetes or past MI. Demographic and clinical data of the study population are presented in Table I.

Median time from the onset of pain to first balloon inflation in the culprit artery was similar in both groups (6 hours); occlusions were most commonly located in the left anterior descending coronary artery. Distributions of these data as well as frequencies of angiographically confirmed thrombus, distribution of diameters of reference infarct-related arteries, length of deployed stent(s), and direct stenting rates in both groups are also included in Table I. These parameters showed no differences between the groups.

Table I. Demographic, clinical and angiografic data of studied patients

	Group A (n=63) abciximab	Group B (n=57) protection device	p
Demographic and clinical data			
Age [years]	58.71±7.41	57.75±6.78	NS
Females [%]	28.57	47.37	NS
Hypertension [%]	61.90	63.16	NS
LVEF on admission [%]	40 (38-44)	43 (39-45)	NS
Dyslipidaemia [%]	50.79	49.12	NS
Past myocardial infarction [%]	20.63	22.81	NS
Nicotinism [%]	49.21	49.12	NS
Diabetes mellitus [%]	30.16	26.32	NS
Pain-to-balloon inflation time (time, median, first-third quartile)	6 (5-12)	6 (4-9)	NS
Anterior wall myocardial infarction [%]	41.27	43.86	NS
Angiographic characteristics			
Infarct-related artery reference diameter [mm] (median, first-third quartile)	3.44 (3.16-3.69)	3.52 (3.28-3.70)	NS
Visible thrombus [%]	71.43%	57.89	NS
Length of deployed stent(s) [mm] (median, first-third quartile)	16 (16-18)	18 (16-18)	NS
Direct stenting [%]	65.70	70.48	NS

Baseline TIMI grade 0/1 flow was found in 78% of patients from group A and 84% from group B. Occlusion was successfully forced with the guidewire in both groups, although in group B 9 (16%) patients required the use of an additional standard angioplasty wire prior to placement of the protection device.

Direct stenting was performed in 68% of patients from group A, and in 70% of subjects from the other group (NS) – in the remaining cases it was necessary to predilate the artery using a balloon catheter to visualise the distal part of it and to enable insertion of a stent (group A) or adequate expansion of the distal protection balloon (group B). Angiographic evidence of a thrombus at the occlusion site was observed in 71% and 58% of patients, respectively (NS). After first aspiration of thrombotic debris in group B, a residual thrombus was found in 19 (33%) patients. Presence of a thrombus at the intervention site after aspiration and deployment of a stent was the indication for administration of abciximab (bail-out) in 5 (9%) patients from group B. All study patients underwent insertion of stent (s) at the occlusion site of the infarct-related artery, with mean residual stenosis of 5.2±3.3% in group A and 7.7±2.8% in group B (NS). Mean total occlusion duration of the culprit artery with the PercuSurge device was 8.21±2.13 min. Total procedure duration was 43 (25-87) minutes in group A and 58 (35-88) minutes in group B (NS). Fluoroscopy time of 17.1 (13.3-23.8) minutes in group B was significantly longer than in group A: 11.2 (6.9-16.2) minutes (p=0.023). Patients in group B received higher volume of contrast medium – 250 ml (150-300) compared to 230 ml (150-300) in group A – but the difference was not statistically significant (p=0.67).

In both groups TIMI grade 3 blood flow through the culprit artery was observed in about 89% of patients, and TIMI grade 2 flow in 5%. Detailed distributions of flow rates in selected ranges of TIMI grading are shown in Table II and there was no statistically significant difference.

Subsequent analysis of MBG of recorded angiograms, due to technical problems was performed in 58 patients from group A and 55 patients from group B (92.06 vs. 96.49%; NS). Taking into account their similar prognostic importance, grades 0 and 1 of MBG were combined into one class. Inter-observer reproducibility of MBG was 96%. In both groups myocardial perfusion evaluated angiographically with MBG grading showed no statistically significant difference, and more than half of patients failed to reach MBG grade 3. The distribution of this variable in the groups is also detailed in Table II.

Baseline LVEF was similar in the study groups and was 40% (38-44) in group A and 43% (39-45) in group B (NS). LVEF increased at month 6 in group A patients to

Table II. TIMI and MBG grading in the study groups

	Group A (n=63)	Group B (n=57)	p
Distribution of values of baseline flow in the culprit artery (%):			
TIMI 0/1	77.8	84.2	0.33
TIMI 2	12.7	7	
TIMI 3	9.5	8.8	
Distribution of flow rates in the culprit artery after PCI (%):			
TIMI 0/1	6.4	5.3	0.75
TIMI 2	4.8	5.3	
TIMI 3	88.9	89.5	
	Group A (n=58)	**Group B (n=55)**	
MBG distribution in the infarct area (%)			
MBG 0/1	15.5	16.4	0.68
MBG 2	19	21.8	
MBG 3	65.5	61.8	

Table III. ST-segment resolution in the study groups

Parameter	Group A	Group B	p
ST resolution <30% [% of patients]	30.2	21	0.39
ST resolution 30-70% [% of patients]	30.2	28.1	0.85
ST resolution >70% [% of patients]	39.7	50.9	0.23
Mean ST resolution [% of ST elevation] (median, first-third quartile)	62 (26-84)	68 (41-86)	0.42

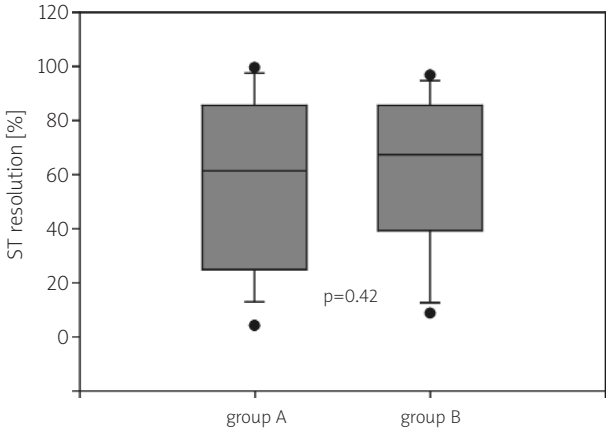

Figure 1. ST resolution after primary coronary angioplasty

46% (44-50%), and in group B *also* to 46% (45-49%) (NS). Secondary endpoint occurred in 32 subjects in group A, and in 28 patients in group B (NS). Changes of LVEF in 6-month follow-up did not show any significant differences between groups.

The difference between total ST elevation in baseline 12-lead electrocardiogram and recorded 60 minutes after restoration of blood flow in the culprit artery expressed as a percentage of the baseline value (ST resolution) was 62% (26-84) in group A and 68% (41-86) in group B (NS). The distribution of this variable is depicted in Figure 1.

Numbers of patients in individual groups who reached ST-segment resolution of <30%, 30-70%, and >70% were compared (Table III). There were no statistically significant differences in distributions between groups.

Analysis of influence of selected variables on TIMI grading of flow in the target artery was carried out. Multiple regression was applied to assess significance of variables independent of blood flow in the target artery. No statistical significance was confirmed for any single variable; however, variables close to reaching statistical significance were selected and analysed with logistic regression. These were: thrombus size on initial angiogram, diameter of post-infarction artery, infarct location, pain-to-balloon time, randomisation to distal protection device group and presence of diabetes. Logistic analysis was performed after dichotomisation of the dependent variable (TIMI 0/1 or 2/3 variable was set) using the following independent variables: large (>2 × artery diameter) thrombus on initial angiogram, diameter of post-infarction artery ≥3.5 mm, left anterior descending coronary artery as an infarct-related artery, pain to balloon time ≥6 hours, randomisation to distal protection device group and presence of diabetes. Logistic regression formula was obtained with Hosmer-Lemshow statistics of 2.05, in which the following variables were close to statistical significance: randomisation to group B (with distal protection device) (p=0.054), reference diameter of ≥3.5 mm (p=0.069) and visible large thrombus (p=0.054). Odds ratios and 95% confidence intervals (CI) for analysed data are shown in Figure 2.

Evaluation of significance of aspiration of embolic material for final TIMI flow in the culprit artery using the PercuSurge device involved logistic analysis of data pertaining to group B only. The dichotomic dependent variable was set as TIMI 0/1 or TIMI 2/3. The following independent variables were chosen: presence of large thrombus on the initial angiogram, presence of residual (angiographically visible)

thrombus following initial aspiration (effectiveness of aspiration), diameter of infarct-related artery of ≥3.5 mm, location of infarct-related artery (LAD vs. non-LAD), pain-to-intervention time (<6 hours vs. ≥6 hours) and diabetes (variables were selected based on stepwise regression analysis). The logistic regression model well approximated the value of the dependent variable (Hosmer-Lemshow statistic = 10.06). High statistical significance for the following variables was observed: presence of thrombus on the baseline angiogram (p=0.026), presence of thrombus after initial aspiration (p <0.001) and artery diameter of >3.5 mm (p=0.01). Figure 3 illustrates odds ratios and 95% CI.

Adverse events to be reported during the study included: death, cardiovascular death, reinfarction, unstable angina, re-PCI. No deaths occurred in the study groups. There were 2 STEMIs in group A and 3 in group B (3.2 vs. 3.5%; NS), episodes of unstable angina totalled 5 and 6, respectively (7.9 vs. 10.5%; NS), and re-PCIs were performed 8 times in both groups (12.7 vs. 14%; NS). Major bleeding was seen in three subjects – in each case it involved false aneurysms of the femoral arteries with bleeding requiring red blood cell concentrate transfusion and subsequent surgical intervention. The complication was observed in two patients in group A and one from group B, who also received abciximab (as *bail-out*) (NS).

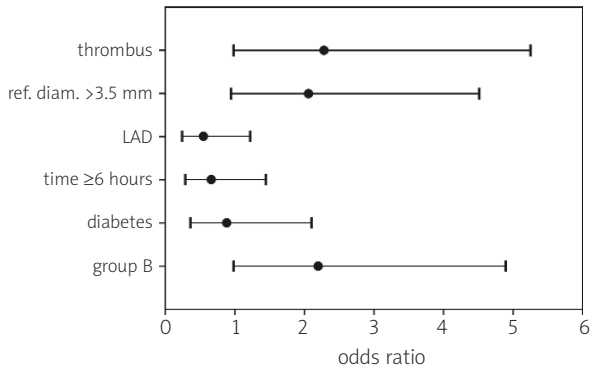

Figure 2. Logistic analysis – influence of selected variables on final TIMI grade

Discussion

During the period when our study was conducted, the results of two randomised trials on the use of protection devices with pPCI were published. In the EMERALD trial [7], in which a PercuSurge device was used, no additional benefits of its use were shown (assessed as ST-segment elevation resolution and infarct size in scintigraphy). Similar results were obtained in another randomised trial of Gick et al. [15]. These authors employed a filter-type protection device placed distally in the coronary artery. In both studies the majority of patients were receiving abciximab during pPCI regardless of the type of protection device used.

Administration of abciximab during pPCI both improves its early angiographic outcome and reduces the risk of serious adverse events in postprocedural course. In the ADMIRAL study TIMI grade 3 flow in the infarct-related artery after angioplasty was observed in 95.1% of patients who received abciximab, compared to 86.7% of subjects treated with placebo (p=0.04) [16]. In these groups the number of serious adverse events in 30-day follow-up was 6.0% and 14.6%, respectively (p=0.01), and a statistically significant difference persisted also in six-month and 3-year follow-up [10]. Abciximab administered during pPCI reduces periinfarction damage to the LV measured with ejection fraction [17].

In the presented clinical trial the use of abciximab remained the therapeutic alternative to distal protection. Effectiveness of abciximab in improving angiographic parameters and LVEF after pPCI makes comparison of the above-mentioned randomised clinical trials using distal protection devices with the results of our study difficult.

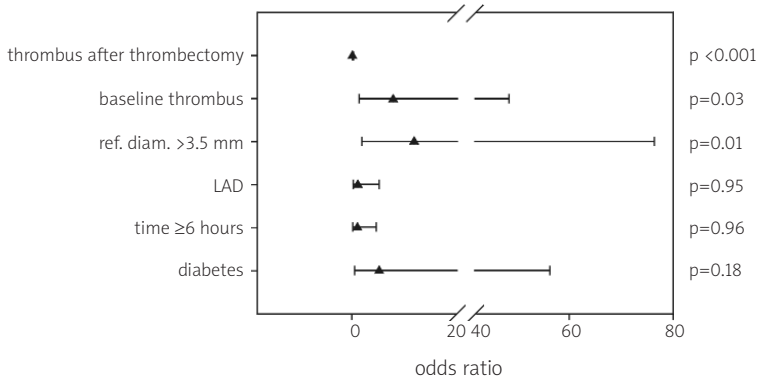

Figure 3. Logistic analysis – influence of selected variables on final TIMI grade in group B

Our study results showed comparable frequency of individual TIMI flow grades in infarction-related arteries after intervention, which may suggest similar effectiveness of abciximab and the PercuSurge system in reduction of postprocedural no-reflow.

The lack of differences between study groups with respect to echocardiographically assessed LVEF is consistent with the results of previously mentioned studies [7, 15]. However, taking into account the significant improvement of LVEF after administration of abciximab during pPCI and the fact that this drug was given in only 9% of patients from the distal protection group, it may be presumed that application of a distal protection device may also reduce postinfarction injury of the LV. This may be confirmed by the results of nonrandomised clinical trials. Kawaguchi et al. [18] showed that the mean LVEF on discharge in patients in whom a PercuSurge device was used was 55.5±8.5%, while in a matched population treated with standard pPCI the LVEF value was 45.7±11.1% ($p < 0.05$). Similar results were reported by Nakamura et al. [19] and in a selected group of patients by Mizote et al. [20].

No or a small influence of distal protection devices on angiographic and clinical effects of pPCI may also result from multifactorial reperfusion damage [21]. Effective capture of embolic debris by distal protection systems is well established [22, 23]; some embolic material may however move to the distal part of the coronary artery as early as during device placement. Other essential factors include the presence of numerous side branches in native coronary arteries and metabolic damage to the microcirculation during infarct, which may explain differences in effectiveness of distal protection systems used in acute coronary syndromes and elective repair procedures in the aorto-coronary grafts.

Another issue is the method of using the export catheter, provided as part of the PercuSurge device, during angioplasty. Stone et al. [7] mentioned aspiration of embolic material after predilation/insertion of a stent; in our study emphasis was put on an attempt to possibly complete aspiration of thrombus/embolic material from the occlusion site prior to continuation of standard angioplasty. Presence of residual thrombus in the infarct-related artery before deployment of a stent in the distal protection group significantly influences blood flow in this artery after the procedure, which was proven in multifactorial analysis.

Selection of a subgroup of patients in the EMERALD study [7] in whom angiographic signs of a large thrombus were found also failed to show either angiographic or clinical benefits of PercuSurge device use. It may be speculated that the presence of a thrombus in the arterial lumen is not so important as the occurrence of a large, ruptured plaque, as postulated by Mizote et al. [20]. The authors demonstrated significant improvement of angiographic signs of reperfusion and reduction of LV dysfunction after use of the distal protection system in patients with angiographically confirmed ruptured plaque.

Effective aspiration of embolic material using an export catheter seems to be particularly important in view of reports on benefits of thrombectomy followed by pPCI. The results of *ad hoc* manoeuvres performed when a large thrombus is confirmed at the occlusion site [24], as well as results of a randomised, multicentre clinical trial have been published recently [25].

The diameter of the vessel in which the distal protection devices are to be used is significant for their effectiveness. The PercuSurge system is intended for use in vessels of 2.5 to 5.0 mm diameter (and these values were inclusion criteria in the EMERALD trial). Patients were enrolled in our study with reference diameter of infarct-related artery distally to the occlusion site of at least 3.0 mm. Such a protocol was necessary to enable selection of patients with the culprit artery supplying a large area of myocardium and at the same time to reduce the likelihood of technical problems with the protection device. Median reference diameters in our study groups were 3.44 and 3.52 mm, and in the EMERALD trial – 3.05 and 2.99 mm.

The question regarding the importance of long-term effect of arterial wall injury caused by distal occlusion balloon remains unresolved. In case of presence of atherosclerotic lesions at the site, the probability of restenosis is increased [26].

Conclusions

1. Use of a PercuSurge distal protection device during primary coronary angioplasty allows improvement of angiographic and electrocardiographic signs of reperfusion. It has a similar effect on LV systolic function as administration of abciximab.
2. This device seems to be useful in patients with culprit artery diameter of ≥3.0 mm, and optimally ≥3.5 mm and with thrombus visible on angiography. Successful initial thrombectomy prior to deployment of a stent seems particularly important when using the PercuSurge system.
3. In the future (possibly after technological development) distal protection devices may become an alternative to GPIIb/IIIa receptor antagonists during primary coronary angioplasty, particularly in patients with contraindications to intensive antiplatelet therapy. Further investigations of this issue including the use of new types of devices for coronary protection and thrombectomy seem warranted.

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Prospektywna, randomizowana ocena skuteczności systemu dystalnej protekcji w porównaniu z abcyksymabem w zmniejszaniu powikłań mikrozatorowych podczas pierwotnej angioplastyki wieńcowej

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Streszczenie

Wstęp: Reperfuzja mięśnia sercowego po pierwotnej angioplastyce wieńcowej (pPCI) jest ograniczona między innymi mikrozatorowością. Zarówno użycie abcyksymabu, jak i mechanicznego systemu dystalnej protekcji podczas PCI zmniejsza jej prawdopodobieństwo.

Cel: Zaplanowano prospektywne badanie z randomizacją, którego celem było porównanie skuteczności abcyksymabu i urządzenia protekcyjnego w ograniczaniu powikłań mikrozatorowych podczas pPCI.

Metodyka: Kolejnych 120 pacjentów z ostrym zawałem mięśnia sercowego z uniesieniem odcinka ST zakwalifikowanych do pPCI po koronarografii przydzielano losowo do grup: A (n=64) – z użyciem abcyksymabu i B (n=57) – z użyciem systemu dystalnej protekcji. Pierwotnym punktem końcowym badania był przepływ w tętnicy dozawałowej (IRA) w skali TIMI po pPCI, drugorzędowymi punktami: perfuzja miokardium w skali MBG, rezolucja odcinka ST i poprawa ocenianej echokardiograficznie frakcji wyrzutowej (LVEF) po pPCI.

Wyniki: Przepływ TIMI 3 po pPCI uzyskano u 89% pacjentów z obu grup, natomiast TIMI 2 u 5% (NS). Perfuzję miokardium w skali MBG po pPCI oceniono jako 3 odpowiednio u 66% chorych w grupie A i 62% chorych w grupie B (NS). Rezolucja uniesienia odcinka ST wyniosła 62% (26–84) w grupie A i 68% (41–86) w grupie B (NS). Analiza logistyczna nie wykazała istotnego wpływu wybranych zmiennych na pierwotny punkt końcowy. Analiza logistyczna w grupie dystalnej protekcji wykazała istotny wpływ na finalny przepływ TIMI w IRA następujących czynników: obecność skrzepliny przed pPCI (p=0,026), obecność resztkowej skrzepliny po aspiracji (p <0,001), średnica IRA ≥3,5 mm (p=0,01). Mediana LVEF w grupie A w 6. mies. obserwacji wyniosła 46% (44–50%), podobnie jak w grupie B – 46% (45–49%) (NS).

Wnioski: Użycie systemu dystalnej protekcji PercuSurge podczas pPCI umożliwia poprawę angiograficznych i elektrokardiograficznych parametrów reperfuzji. Wywiera podobny wpływ na zachowanie się funkcji skurczowej lewej komory jak zastosowanie abcyksymabu. Wspomniany system może być przydatny u pacjentów z IRA o średnicy referencyjnej ≥3,0 mm, a optymalnie ≥3,5 mm i z widoczną angiograficznie skrzepliną. Szczególnie istotna przy stosowaniu systemu PercuSurge wydaje się skuteczna wstępna trombektomia przed implantacją stentu.

Słowa kluczowe: pierwotna angioplastyka wieńcowa, zawał mięśnia sercowego, dystalna protekcja, mikrozatorowość

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