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Original article ■

Routine Coronary Angiography and Revascularization after Thrombolysis- Impact on One - Year Prognosis

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SUMMARY

The most often used reperfusion strategy for patients with STEMI is still thrombolysis, but it is not the end of treatment. The aim of this paper was to show whether routine in-hospital coronary angiography and subsequent revascularization (percutaneous or surgery) after thrombolysis improve an one-year prognosis in patients with STEMI. The study involved 155 patients, 29-79 years old, with first STEMI. They were treated with fibrinolytic, aspirin, and enoxaparin. Group I (102 patients) underwent coronary angiography on approximately the 5th day of hospitalization, then percutaneously or surgically revascularized if considered appropriate. In group II (53 patients), in-hospital angiography was not done. Mortality, reinfarction, angina and left ventricular systolic function were analyzed during one-year period. Patients in group II were older, they received clopidogrel and statin less frequently and ACE inhibitors more frequently. The groups were significantly different regarding the in-hospital (3% vs. 15%, p=0.008) and one-year mortality (2% vs. 11.1%, p=0.03). There was a numeric trend for higher frequency of reinfarction in group II (3% vs. 11.1%, p=0.06). After one year, more patients in group II had angina (2.9% vs. 13.2%, p=0.03). In hospital, the groups had similar EF (54% vs. 51.2%, ns), but after one year EF in group I was higher (55.2% vs. 47.6%, p=0.02). Multivariable analysis adjusted for age and differences in drug therapy showed that the lack of routine elective coronary angiography and revascularization is an independent predictor of one-year mortality (RR 4.7, p=0.019) and independent predictor of combined mortality, reinfarction and angina (RR 3.2, p=0.028). Routine coronary angiography and revascularization after thrombolysis improve in-hospital and one-year survival, decrease the frequency of reinfarction and angina, and improve the left ventricular function.

Key words: **myocardial infarction, thrombolysis, coronary angiography, revascularization, prognosis**

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INTRODUCTION

In most cases the cause of acute myocardial infarction with ST-segment elevation (STEMI) is sudden reduction in coronary blood flow caused by thrombotic occlusion of a proximal, larger branch of the coronary circulation (1). The primary aim of acute coronary occlusion treatment is early, complete and sustained reperfusion (2). Even though the most efficient way to deal with it is primary percutaneous coronary intervention (PCI) (3), it is not quite available yet. The most commonly used reperfusion strategy for patients with STEMI is still thrombolysis (4,5), but it is not the end of treatment. Rescue PCI must be performed if thrombolysis has failed. Blood flow restoration through an infarct vessel with successful thrombolysis causes more often residual ischemia, reinfarction, haemorrhagic complications and is less stable than primary PCI. That is the main reason for additional PCI if needed, to restore the circulation through infarct-related artery and prevent reocclusion. When there is no possibility to do a primary PCI, optimal reperfusion strategy for patients with STEMI is possible (6,7).

In patients in whom reperfusion is achieved with thrombolysis, there is no consensus as to whether they should subsequently be submitted to angiography and / or revascularization, and if so, when (8).

According to current guidelines of the European Society of Cardiology for percutaneous coronary intervention, after successful thrombolysis, routinely coronary angiography and percutaneous intervention should be done within 24h from thrombolysis even in asymptomatic patients without inducible ischemia. If PCI center is not available within 24h, ischemia-inducible coronary angiography and revascularization need to be done (9). There is no certain use of coronary angiography and PCI done more than 24h after thrombolysis (1).

The aim of this research was to show whether routine in-hospital coronary angiography and revascularization if considered appropriate (percutaneous or surgery) after thrombolysis improve one-year prognosis in patients with STEMI.

EXAMINEES AND METHODS

We prospectively enrolled 155 patients (116 male, 39 female) hospitalized in the coronary care unit of the Cardiology Clinic in Niš, between November 2005 and December 2006, who were admitted within six hours after the onset of chest pain with the diagnosis of the first acute STEMI. Patients with previously performed myocardial revascularization, contraindicated for thrombolytic therapy, while those who died within the first six hours post-admission were excluded. They were all treated with fibrinolytic therapy (streptokinase 1500000 IU in 30-60 minutes or alteplase 100 mg according to accelerated protocol), aspirin (immediately 150 mg if taken before, or 300 mg if not, then 100-150 mg/day), anticoagulant therapy with low-molecular-weight heparin-enoxaparin administered 30 mg i.v. bolus on admission, and then subcutaneously on a weight-adjusted basis 1mg/kg every 12h up to seven days. One group of randomly chosen patients was administered a loading dose of clopidogrel 300-600 mg on a weight-adjusted basis, followed by a maintenance dose 75 mg/day. The treating physician decided about the prescription of clopidogrel; owing to the time when the study was conducted, the use of this medication was not in the current guidelines for treating patients with STEMI (10), but it was given according to the first results obtained from the large randomized trials in this indication (11, 12). All patients were evaluated by means of clinical, laboratory and echocardiographic examination. Systolic function of the left ventricle was measured by the estimation of ejection fraction (EF) referred to Simpson rule between the 2^{nd} and 4^{th} day of hospitalization. All patients gave their informed consent.

In group I, involving 102 patients, coronary angiography was performed between the first day and the end of hospitalization (5^{th} day on average). That was the way to evaluate the patency of the infarct-related artery and other coronary arteries. If indicated (occluded infarct-related artery, insufficient flow-TIMI flow less than 3, or high residual stenosis), at the same time PCI was performed with the stent implantation on culprit lesion. Rescue PCI was performed immediately to clinically unstable patients with recurrent chest pain and persistent or recurrent ST elevation inadequate to response to medical therapy. In cases of the left main stenosis or multivessel coronary artery disease which cannot be solved with percutaneous intervention, patients were subjected to surgical revascularization. In group II, encompassing 53 patients, in-hospital coronary angiography was not performed because patients refused to undergo the procedure.

The patients were called for clinical and echocardiographic follow-up one year after discharge.

They were evaluated for in-hospital and one-year mortality, hemorrhagic complications, reinfarction and angina pectoris, surgical revascularization and left ventricle systolic function during one-year period.

For the evaluation, standard descriptive statistical methods were used (average value, standard deviation) and appropriate statistical tests applied (Student T test, χ^2 test). Multivariate analyses were done using logistic regression model. Using computer statistical software (SPSS version 15 for Windows) we processed data and showed the results in tables. $P<0.05$ was taken as signifficant.

RESULTS

Baseline demographic and clinical characteristics of examined groups of patients are shown in Table 1.

Two groups were similar regarding gender, localization of infarction, Killip class on admission, time from the onset of a chest pain to admission to coronary care unit and presence of cardiovascular risk factors. Patients in group II were older (54.8 vs. 62.6 years, $p<0.001$), they received clopidogrel and statin less frequent and ACE inhibitors more frequent on discharge. No significant differences were shown in the use of beta blockers and choice of fibrinolytic.

Table 1. *Baseline demographic and clinical characteristics of the examined groups*

	Group I (n=102)	**Group II (n=53)**	**P**
Age	54.8±10	62.6±11.1	<0.001
Gender			
Male	80 (78%)	35 (66%)	NS
Female	22	18	
Infarction localization			
Anterior	37 (36%)	22 (41%)	NS
Inferior	65	31	
Approximate pain lasting (min)	184.6±185.8	204.1±178.7	NS
Killip class			
1	89	43	NS
≥2	13 (12.7%)	10 (18.9%)	
Diabetes mellitus	13 (12.7%)	11 (20.7%)	NS
Hypertension	49 (48%)	25 (47.2%)	NS
Hyperlipidemia	50 (49%)	22 (41.5%)	NS
Smoking	73 (71.6%)	30 (56.6%)	NS
Family history of CAD	48 (47%)	18 (34%)	NS
Thrombolytic therapy			
Streptokinase	89 (87.2%)	50 (94.3%)	NS
Alteplase	13	3	
Therapy on discharge	n=99	n=45	
Aspirin	96 (97%)	40 (89%)	NS
Clopidogrel	83 (83.8%)	7 (15.5%)	<0.0000001
Beta blocker	90 (90.1%)	37 (82.2%)	NS
ACE inhibitor	55 (55.5%)	34 (75.5%)	0.02
Statin	88 (88.9%)	25 (55.5%)	<0.0001

Group I consisted of 102 thrombolysed patients in whom in-hospital coronary angiography and revascularization were performed if considered appropriate. In six patients rescue PCI was performed, in 50 delayed PCI with stent implantation within first 10 days of hospitalization (approximately 5th), and in 23 patients there was an indication for surgical revascularization due to multivessel coronary artery disease or left main stem disease. Two of 23 patients died before surgical revascularization.

Four patients had normal coronary angiogram. After coronary angiography, 23 (22.5%) patients were not revascularized due to the following reasons: thrombolysis achieved TIMI 3 flow, insignificant residual stenosis, low caliber blood vessel with distal lesion, unsuitable lesion for percutaneous intervention in one vessel disease and no significant lesion on the left anterior descending artery, therefore no indications for surgical revascularization (Table 2).

Table 2. *Angiographic characteristics in group I of patients*

TIMI flow in infarct-related artery	
0	15 (14.7%)
1	3 (2.9%)
2	38 (37.2%)
3	46 (45%)
Clinically significant coronary artery disease	
Single vessel	45
Two vessels	25
Three vessels	26
Left main stem	2
Normal coronary angiogram	4
Rescue PCI	6 (5.9%)
Postponed in-hospital PCI with stent implantation	50 (49%)
Surgical revascularization	23 (22.5%)

The two groups were significantly different regarding the in-hospital mortality. During hospitalization, three (2.9%) patients died in group I and 8 (15%) in group II, p=0.008 (Table 3).

A total number of bleeding complications was nine (5.8%): five (4.9%) in group I, four (7.5%) in group II, NS. We found no difference between groups regarding the frequency of minor or major bleeding complications. The total major bleeding rate was 1.9% (1% in group I, 3.8% in group II, NS). According to TIMI bleeding definition, minimal and minor bleedings were considered as minor, and their total rate was 3.9% (3.9% in group I, 3.8% in group II) (Table 3).

Table 3. *In-hospital mortality and hemorrhagic complications in examined groups*

	Group I (n=102)	**Group II (n=53)**	**P**
In-hospital mortality	3	8	0.008
Hemorrhagic complications	5	4	
Major bleeding	1	2	NS
Minor bleeding	4	2	

One-year prognosis of the patients who survived in-hospital period is shown in Table 4. The groups were significantly different regarding the one-year mortality. After one year, mortality in group I was 2% (2 patients), in group II 11.1% (5 patients), p=0.03. More reinfarctions occurred in group II (3% vs. 11.1%) but without statistical significance (p=0.06). After one year, more patients in group II had angina pectoris (3% vs. 15.5%, p=0.01).

Coronary angiography and revascularization after thrombolysis had the influence on the left ventricle systolic function. The groups were similar regarding the average EF during their first echocardiographic examination (54% vs. 51.2%, ns), but after 12 months the average EF in group I was significantly higher (55.2% vs. 47.6%, p=0.02).

Table 4. *One-year prognosis and left ventricle function in examined groups*

	Group I (n=99)	Group II (n=45)	P
Sudden death	2 (2%)	5 (11.1%)	0.03
Reinfarction	3 (3%)	5 (11.1%)	NS
Angina pectoris	3 (3%)	7 (15.5%)	0.01
EF %			
In-hospital	54.1±10.4	51.2±11.9	NS
After 1 year	55.2±8	47.6±10.6	0.02

Multivariable analysis adjusted for age and differences in drug therapy, using logistic regression model showed that routinely elective coronary angiography and following myocardial revascularization is an independent predictor of one-year survival (RR 3.41, 95% CI 1.37-9.96, p=0.019), (Table 5). Therapy with clopidogrel on discharge was excluded from regression analysis model due to tight connection with percutaneous intervention and invasive approach after thrombolysis.

Table 5. *Multivariable analysis of parameters that examined groups differ (influence on one-year mortality)*

	Risk ratio	95% CI	P
Age	0.99	0.92-1.06	0.76
ACE inhibitor on discharge	-	-	0.997
Statin on discharge	0.24	0.02-2.40	0.223
In-hospital angiography	3.41	1.37-9.96	0.019

After one year, mortality, reinfarction and angina pectoris combined were less frequent in group I of patients, moreover multivariable analysis adjusted for age and drug therapy with statin and ACE inhibitor on discharge showed also that coronary angiography and revascularization influenced a combined outcome (RR 3.28, 95% CI 1.14-9.49, p=0.028), as shown in Table 6.

Table 6. *Multivariable analysis of parameters that examined groups differ - influence on combined outcome (one-year mortality, reinfarction and angina pectoris)*

	Risk ratio	95% CI	P
Age	1.05	0.99-1.10	0.078
ACE inhibitor on discharge	0.81	0.30-2.20	0.686
Statin on discharge	1.03	0.34-3.11	0.952
In-hospital angiography	3.28	1.14-9.49	0.028

DISCUSSION

Results of this research show that thrombolytic therapy opened the infarct-related artery in high percentage of patients, even though 77.4% of our patients were in need of the subsequent percutaneous or surgical revascularization. That fact justifies the use of routine in-hospital coronary angiography. Coronary angiography was performed on the 5th day of hospitalization on average, therefore, threre was no increasing in the hemorrhagic complications and their consequences. The total rate of bleeding in our patients was 4.9%-7.5% and major bleeding 1%-3.8%, that is similar to greater studies (13, 14).

The patients included in this research, whose infarct-related arteries were completely reperfused after thrombolysis, had better in-hospital and one-year survival and less ischemic attacks during 12 months of evaluation compared to the patients treated conservatively after thrombolysis. Many studies have proved the beneficial effects of early post-thrombolysis PCI regarding recovery and maintaining patency of infarct-related artery. GRACIA-1 trial showed that coronary angiography, performed approximately 19.6 hours after thrombolysis with alteplase (in 80% of these patients percutaneous revascularization with stent implantation was performed) resulted in reduction of: mortality, reinfarction, rehospitalization, ischemia - induced revascularization related to patients in whom in-hospital coronary angiography was not performed or it was ischemia-induced. In this way of treating, hemorrhagic complications and duration of hospitalization were reduced (14). GRACIA-2 trial compared patients in whom PCI was performed within 3-12 hours after thrombolysis with tenecteplase with the patients treated with primary PCI and abciximab. Apart from higher frequency of epicardial and myocardial reperfusion in the group with PCI done after thrombolysis, the groups were similar regarding infarction size, left ventricle function, bleeding rate and six-month prognosis (15). SIAM III trial showed that early angiography and revascularization after thrombolysis gave better prognosis compared to angiography done after two weeks (16). WEST trial showed no difference in 30-day prognosis between patients treated with primary PCI, and those treated with tenecteplase and invasive approach within 24 hours (17).

Is PCI really necessary to be performed within 24 hours after thrombolysis? Do patients have benefit from later PCI?

Irish authors` research showed that in-hospital PCI done in patients with STEMI on average 2nd day of hospitalization, after thrombolytic therapy, resulted in significant reduction of one-year mortality. According to multiple logistic regression model, independent predictors of mortality were: age, initial systolic blood pressure $\leq$80 mmHg, initial Killip class $\geq$3 and lack of in-hospital PCI (18).

ALKK trial did the research on low-risk patients with single vessel disease after STEMI. In one group PCI was performed on average on the 23rd day after infarction, and the other one was treated with medical therapy. One-year prognosis was better in the first group, but not significant (p=0.06). Approximately 56 months of long-term follow-up resulted in significantly better survival of the first group of patients. It is important to say that this research included only low-risk patients, and that most percutaneous intervention meant only balloon dilatation, while stent was implanted in 17% of patients (19). Furthermore, modern anti-thrombotic drugs were not used.

The results of OAT trial reported that elective PCI done on occluded infarct-related artery, 3-28 days after infarction, in stable patients, had no overall advantage of preserving left ventricle function and preventing cardiovascular events during a 4-year period, compared to optimal medical therapy. Similar conclusions were shown in DECOPI trial as well (20, 21). However, only stable patients were included in these trials and with occluded infarct-related artery (TIMI flow 0 or 1), compared to our study which had a small number of such patients.

Meta-analysis of 15 randomized studies which included over five thousand patients supports the rescue PCI and early systemic PCI within 24 hours after thrombolysis compared to delayed and/or ischemia inducible PCI (22).

In spite of the recommendation of the European Society of Cardiology for PCI that systemic angiography and PCI after thrombolysis should be done within 24h (9), the studies pointed out that even later-on performed angiography and PCI are beneficial to long-term prognosis of patients after STEMI (18,19). The results of our research are in accordance with this, too. In the latest update of ACC/AHA guidelines for treating patients with STEMI, PCI performed on a hemodinamically significant stenosis of a patent's infarct-related artery more than 24 hours after infarction is considered to be a part of invasive strategy (23).

The results of this research, also, showed that complete revascularization after STEMI preserved and improved the left ventricle function, while in the group of patients conservatively treated after thrombolysis, the contractile function deteriorated during one-year follow-up.

PACT trial was designed to prove whether thrombolytic therapy before angiography resulted in higher degree of saving myocardium. Left ventricle function was assessed 5-7 days after STEMI. The results proved that the left ventricle function was deteriorating with every 30-minute delay of reperfusion, which was important for the long-term prognosis. Time from the onset of symptoms to patency of infarct-related artery determines the left ventricle systolic function after adjusting for other factors. The conclusion is that pharmacological reperfusion should be done, followed by coronary angiography and possible dilatation, if delaying time of primary PCI was more then 60 minutes (24).

In our patients, early revascularization, which could contribute to significant saving of myocardium in acute phase of STEMI, was not performed. PCI done after thrombolysis is more efficient in preserving myocardial perfusion and function than thrombolysis itself and it is good alternative if primary PCI is unavailable. The efficiency of thrombolysis increases with later-on mechanical intervention. This combined strategy is as efficient as primary PCI in establishing tissue perfusion and improvement of the left ventricle function after STEMI. Italian authors` research showed that patients treated with primary PCI and those treated with tenecteplase and postponed PCI approximately 20±2 hours after thrombolysis had similar myocardial perfusion and function, estimated by contrast echocardiography on discharge and after three months. During the follow-up period there was an improvement in the left ventricular function in these two groups of patients compared to patients treated with thrombolysis alone, which had worse in-hospital myocardial perfusion and left ventricle function, showing no improvement (25).

Late PCI can restrict the process of left ventricle remodeling, therefore providing long-term benefit. Post-infarction period is characterized by dynamic processes, including the apoptotic death of cardiomyocites and regeneration that lasts several weeks after the initial attack. Better survival of cells in that period can be one of the potential mechanisms, so the hypothesis of open and late open infarct-related artery is still actual (1,26).

Besides positive effect on the infarct - related artery, adequate revascularization of lesions on other arteries is also important. It probably prevents new ischemic attacks in infarct and in remote (non-infarct) myocardial regions which were under the risk caused with severe lesions.[14] All the facts mentioned above can explain the benefit of late revascularization that our patients experienced concerning better long-term prognosis after STEMI.

Limitation of this study

This is the prospective, observational analysis of the treatment of patients with STEMI in the "real life" rather than a randomized study. Therefore, the patients who did not undergo coronary angiography are older than those who did. The elderly are more likely not to give the consent for an invasive procedures and interventions which may be needed later on.

The differences in therapy at the hospital discharge between the observed groups are due to the individual physician's decision. We could overcome this by having the protocols for the treatment which would be mandatory and in accordance with the proposed guidelines. However, we should keep in mind that the guidelines are changing, too. At the time of this observation was taken, clopidogrel was not in the guidelines for treatment of all the patients with STEMI. This could explain the fact that the clopidogrel was underused in the patients who have received only thrombolythic therapy.

CONCLUSION

Routine in - hospital coronary angiography and following revascularization if considered appropriate, in patients with STEMI treated with thrombolysis, improve in - hospital and one-year survival, decrease the frequency of reinfarction and angina and improve the left ventricle function, without increasing the risk of hemorrhagic complications, even if performed more than 24 hours after admittance.

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RUTINSKA KORONARNA ANGIOGRAFIJA I REVASKULARIZACIJA MIOKARDA NAKON TROMBOLIZE - UTICAJ NA JEDNOGODIŠNJU PROGNOZU

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Sažetak

Najčešće korišćena reperfuziona strategija za bolesnike sa STEMI je i dalje tromboliza, ali ona ne predstavlja završeno lečenje. Cilj istraživanja bio je da pokaže da li intrahospitalna koronarna angiografija i eventualna perkutana/hirurška revaskularizacija nakon trombolize, popravlja jednogodišnju prognozu bolesnika sa STEMI. Prospektivnim ispitivanjem obuhvaćeno je 155 bolesnika sa prvim STEMI, starosti 29-79 godina, koji su lečeni trombolitičkom terapijom. Prvu grupu činila su 102 bolesnika kojima je tokom hospitalizacije (prosečno petog dana) urađena koronarna angiografija i perkutana ili hirurška revaskularizacija ukoliko je bilo indikovano. Druga grupa se sastojala od 53 bolesnika kojima intrahospitalno koronarna angiografija nije urađena. Praćen je intrahospitalni i jednogodišnji mortalitet, pojava reinfarkta i angine pektoris i sistolna funkcija leve komore tokom jednogodišnjeg perioda. Bolesnici u II grupi bili su značajno stariji, ređe su dobijali klopidogrel i statin, a češće ACE inhibitor. Grupe su se značajno razlikovale po intrahospitalnom (3% vs. 15%, p=0.008) i jednogodišnjem mortalitetu (2% vs. 11.1%, p=0.03). Nađeno je više reinfarkta u II grupi (11.1% vs 3%, p=0.06, NS). Nakon godinu dana značajno više bolesnika u II grupi imalo je anginu pektoris (15.5% vs 3%, p=0.01). Intrahospitalno grupe se nisu razlikovale po prosečnoj EF (54% vs 51.2%, NS), ali nakon 12 meseci, prosečna EF u I grupi bila je veća (55%, vs 47.5%, p=0.02). Multivarijantnom regresionom analizom pokazano je da intrahospitalna koronarna angiografija sa sledstvenom revaskularizacijom značajano utiče na jednogodišnje preživljavanje (RR 3.41, 95% CI 1.37-9.96, p=0.019), nakon korekcije za starost i terapiju po kojoj su se grupe razlikovale, kao i na mortalitet, reinfarkt i pojavu angine pektoris kombinovano (RR 3.28, 95% CI 1.14-9.49, p=0.028). Rutinska koronarna angiografija kod bolesnika nakon STEMI koji su lečeni trombolitičkom terapijom i sledstvena revaskularizacija, ukoliko je indikovana, popravlja i intrahospitalno i jednogodišnje preživljavanje, smanjuje učestalost angine pectoris nakon godinu dana i popravlja funkciju leve komore.

Ključne reči: **infarkt miokarda, tromboliza, koronarna angiografija, revaskularizacija, prognoza**