Is transport with platelet GP IIb/IIIa inhibition for primary percutaneous coronary intervention more efficient than on-site thrombolysis in patients with STEMI admitted to community hospitals? Randomised study. Early results

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Abstract

Introduction: The advantage of primary percutaneous coronary intervention (pPCI) in the management of ST-elevation myocardial infarction (STEMI) over thrombolytic therapy has been demonstrated. However, an optimal medical treatment of STEMI patients admitted to regional hospitals without catheterisation facilities has not yet been established. Delay in initiation of pPCI resulting from transportation to the catheterisation laboratory may diminish the benefits of such therapy in comparison with thrombolysis administered in a regional hospital. Early initiation of therapy with platelet glycoprotein IIb/IIIa receptor inhibitor, which provides protection for the transportation, may be a reasonable solution to maintain the advantage of pPCI over thrombolysis alone in STEMI patients.

Methods: The studied group comprised patients with STEMI (infarct duration time <12 hours, typical clinical and electrocardiographic criteria of MI) who were randomly assigned in 13 regional hospitals located 20 to 150 km from invasive centre to one of two subgroups, either to thrombolysis in the community hospital or to transport after thrombolysis initiation with platelet GP IIb/IIIa receptor inhibitor (tirofiban; 10 μg/kg in intravenous bolus in the emergency room of the community hospital followed by continuous intravenous infusion of 0.1 μg/kg/min during transport as well as coronary procedure) in order to receive pPCI. All patients with cardiogenic shock on admission were routinely treated with PCI and were excluded from the study.

Results: 341 patients were included in the study (169 were randomised to receive thrombolytic therapy and 172 - transport with intention to perform PCI). Mean time between onset of MI and randomisation was similar in the transport and thrombolysis groups, (139±133 min. *vs* 143±117 min., respectively, p=0.94). Mean infusion time of tirofiban to the beginning of PCI in the transport group was 121±36 min. Anterior MI was present in 42.6% of patients in the PCI group and in 41.5% in the thrombolytic group (p=0.085). Mean time from randomisation to pPCI was 158±60 min., and to thrombolysis initiation in 44±43 min. (p <0.0001). None of the patients died during transfer. In a 30-day follow-up we noted (pPCI vs thrombolytic group, respectively): mortality 3.49% *vs* 8.88% (p=0.04); reinfarction 1.16% *vs* 5.92% (p=0.02), stroke 0.58% *vs* 1.18% (p=0.55). In-hospital stay was significantly shorter in the transport group (9±3 days *vs* 14±7 days, p <0.0001). During hospitalisation, 17 (10.05%) patients initially assigned to thrombolysis alone had to be transferred to the catheterisation laboratory to undergo PCI (rescue PCI or PCI for postinfarction angina). Combined end-point (death/reinfarction/stroke) was reached more frequently in the thrombolytic group (15.98% *vs* 5.23%, p=0.001).

Conclusions: A strategy of invasive therapy involving transport with GP IIb/IIIa receptor inhibitor and pPCI in STEMI patients admitted to hospital without catheterisation facilities was found to be more effective than thrombolytic therapy alone employed in the regional hospitals.

Key words: primary coronary angioplasty, thrombolysis, tirofiban

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Introduction

Currently in clinical practice most patients with ST-elevation myocardial infarction (STEMI) are admitted to hospitals without catheterisation facilities and usually receive fibrinolytic therapy. Alternatively, they can be transferred to invasive cardiology centres for primary percutaneous coronary intervention (pPCI). Up to now, results of published investigations have proved the advantage of such a strategy over fibrinolysis in regional hospitals [1]. This benefit is even more pronounced in patients admitted to hospital later than 3 hours after onset of clinical symptoms of MI [2]. However, it has not been established how to optimise management of patient transport in order to improve clinical outcome.

An undisputable factor affecting the efficacy of invasive management is the time between onset of MI and the initiation of invasive treatment, with the important contribution of transport time. Medical treatment that would favourably influence infarct-related artery (IRA) patency seems reasonable to reduce the unfavourable impact of transport-related delay on the invasive therapy outcome. A promising group of agents is the glycoprotein platelet (GP) IIb/IIIa receptor inhibitors [3, 4].

The purpose of this project was to compare the efficacy of two reperfusion strategies in STEMI patients admitted to regional hospitals without catheterisation laboratory availability in the Podlasie region: group 1 – transported for pharmacologically facilitated pPCI with the use of GP IIb/IIIa receptor inhibitor tirofiban, vs group 2 – fibrinolytic therapy alone in the regional hospital.

Methods

Randomisation principles

STEMI patients in the Podlasie region were randomly assigned in 13 regional centres either to n-site fibrinolysis or to transfer to the catheterisation laboratory (cathlab) in order to undergo pPCI. The regional hospitals were located 20 to 150 km away from the cathlab. Each patient was randomised in the emergency department of the regional hospital by telephone contact with a physician on duty in the cathlab. Randomisation was done by means of computer software on the basis of MI localisation, patient age and gender. As soon as a patient was randomised, all information regarding important clinical events (with attention paid to the time of their occurrence) were systematically recorded in the study questionnaire. Patients were referred to the cathlab by ambulance or by air trnsport.

Examined group

Inclusion criteria were as follows: age 18 to 80 years, infarction pain lasting >30 minutes but <12 hours, abnormalities in ECG – ST segment elevation >0.1 mV in at least two adjacent limb leads or 0.2 mV in two adjacent precordial leads. Patients were excluded from the study if the pain lasted longer than 12 hours, there were contrain- dications to thrombolysis, or in the presence of severe neoplastic disease or any organ dysfunction, left bundle branch block, recent surgical revascularisation, drug addiction, alcohol addiction or pregnancy. All patients signed informed consent to participate in this study. All patients presenting symptoms of cardiogenic shock on admission were routinely treated with the use of PCI, and were not included in the present analysis. The study protocol is presented in Figure 1. It was approved by the Local Ethics Committee of the Medical University, Białystok

Thrombolytic therapy

Patients randomly assigned to thrombolysis received a 300 mg oral dose of acetylsalicycic acid (ASA) and fibrinolytic agent. The study protocol did not specify which fibrinolytic drugs had to be administered. The choice of drug was left to the discretion of the treating physician and depended on the availability of agents in individual regional hospitals. In the case of streptokinase, subcutaneous injection of low molecular weight heparin in a dose of 0.6 ml immediately prior to thrombolysis and every 12 hours afterwards for at least 3 days was recommended. If tPA was used, an intravenous bolus of unfractionated heparin (UFH) in a dose of 5000 IU followed by infusion of 1000 IU/hour corrected according to APTT was recommended. In the case of a lack of clinical symptoms or electrocardiographic signs of reperfusion, physicians in the regional hospitals were encouraged to refer such patients to the cathlab in order to perform rescue percutaneous coronary intervention (rescue PCI).

Invasive strategy

Individuals randomised to the transport group, received in the regional hospitals orally 300 mg of ASA, intravenous bolus of UFH in a dose of 5000 IU and tirofi- ban, GP IIb/IIIa inhibitor, initially as an intravenous bolus in a dose of 10 μg/kg followed by infusion of 0.1 μg/kg/min. during transport and the periprocedural period. Prior to the coronary intervention, the dose of UFH was adjusted according to ACT. After the coronary procedure, intravenous UFH in a dose of 1000 IU/hr with APTT adjustment until the end of tirofiban infusion was administered. The arterial sheath was removed following APTT normalisation.

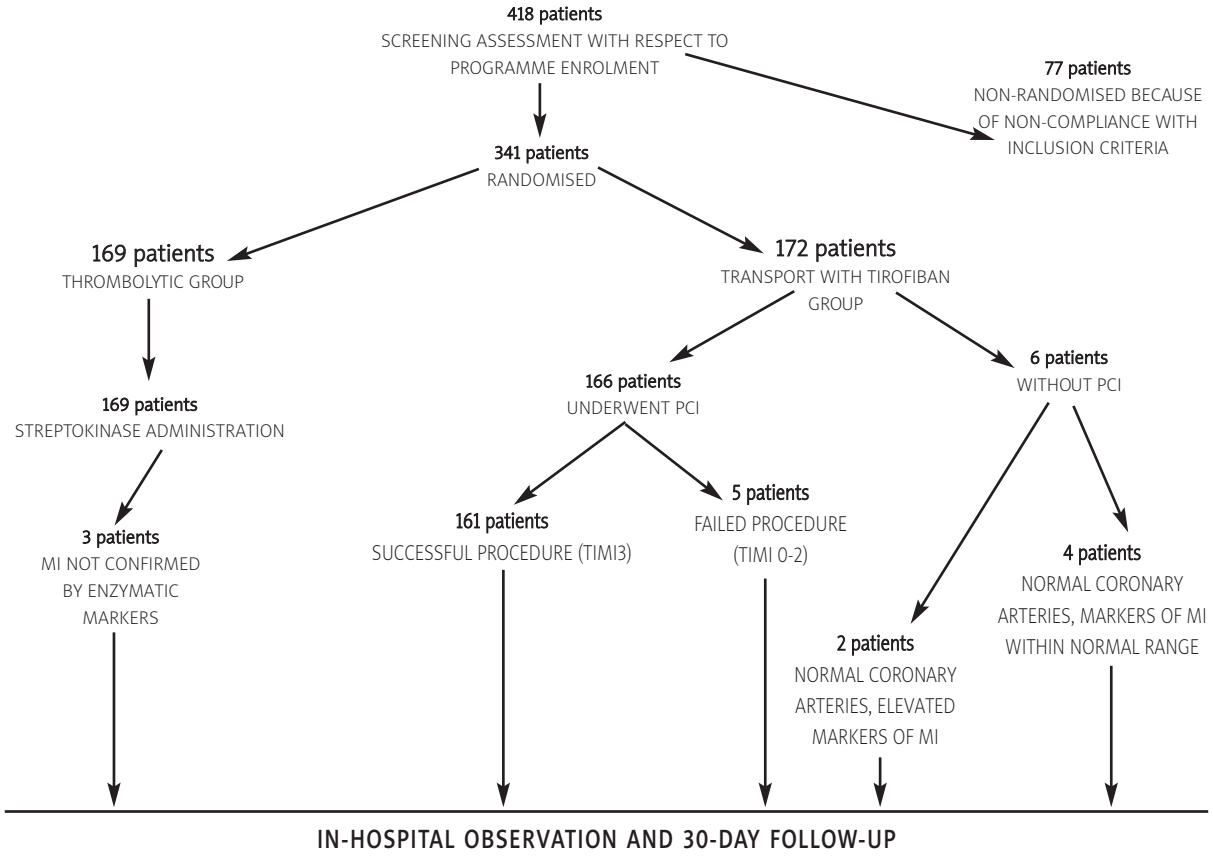

Figure 1. Study protocol

After the patient was referred to the cathlab and examined by the physician, coronary angiography followed by angioplasty of IRA was performed. Stent implantation was recommended. The decision regarding possible angioplasty of other stenotic lesions in IRA artery or non-related one was operator-dependent. The procedure was considered successful when complete flow restoration in IRA (TIMI 3) accompanied by residual stenosis ≥30% was achieved.

Statistical analysis

Data are presented as mean ± standard deviation or numbers and percentages. Statistical differences were analysed with the use of student t-test (continuous variables) or χ^2 test (categorical data) A p value <0.05 was considered statistically significant.

Results

From February 2002 to September 2003, 341 patients were enrolled in this study, including 169 patients who received fibrinolytic therapy alone in a regional hospital (thrombolytic group) and 172 referred to the cathlab to undergo pPCI (transport group). Baseline patient characteristics in both groups are outlined in Table I.

The mean interval between onset of MI and randomisation was similar in both subgroups 139±133 min. in the transport and 143±117 min. in the pPCI group (NS). Average time from randomisation to the initiation of definite treatment was 158±760 min. in the primary PCI, and only 44±43 min. in the fibrinolysis group (p <0.0001). Mean time of tirofiban infusion prior to pPCI in the transport group was 121±36 min. All patients randomly selected for thrombolysis received streptokinase. None of the patients transported to the catheterisation laboratory in order to receive pPCI died during transport. Angiographic flow assessment in IRA prior to pPCI according to TIMI classification is presented in Table II. Successful procedure was performed in 161 (93.6%) patients. Stent implantation in the infarct-related lesion was possible in 127 (78.9%) patients.

In-hospital complications and complications occurring during 30-day follow-up are shown in Table III. Patients with reinfarction were treated invasively in both subgroups. Additionally, during the in-hospital period,

Table I. Demographic and clinical characteristics of patients

	Transport group (n=172)	Fibrinolytic group (n=169)	P
Age (years)	63±12	64±11	0.94
Male gender	133 (77.3%)	119 (70.4%)	0.15
History of IHD	80 (46.5%)	59 (34.9%)	0.03
Arterial hypertension	89 (51.7%)	89 (52.7%)	0.87
Diabetes	25 (14.5%)	32 (18.9%)	0.28
Hypercholesterolaemia	62 (36%)	53 (31.4%)	0.36
Smoking (current)	72 (41.9%)	81 (47.9%)	0.26
Familial IHD	36 (20.9%)	35 (20.7%)	0.96
Previous MI	22 (12.8%)	7 (4.1%)	0.004
Anterior MI	73 (42.4%)	70 (41.4%)	0.85
Killip-Kimball class			
1	104 (60.5%)	116 (68.6%)	0.12
2	65 (37.8%)	53 (31.4%)	0.21
3	3 (1.7%)	0	0.09

Abbreviations: IHD – ischaemic heart disease; MI – myocardial infarction

Table II. Angiographic assessment of the blood flow in the infarct-related artery prior to pPCI procedure

TIMI	n (%)
0	93 (54.1)
1	9 (5.2)
2	32 (18.6)
3	38 (22.1)

17 (10.05%) patients treated initially with thrombolysis were referred to the central cathlab and underwent PCI due to postinfarction angina (11 patients) whereas in 6 (3.55%) cases rescue PCI was necessary. One patient in the fibrinolytic group died of stroke.

In one (0.6%) patient in the transport group and another one (0.5%) in the fibrinolysis group, bleeding requiring blood transfusion was noted. In both cases the gastrointestinal bleeding was treated medically. Patients treated with thrombolysis received significantly less β-blockers and ACE inhibitors. In-hospital pharmacotherapy of patients in both subgroups is outlined in Table IV.

Mean hospitalisation time differed significantly between the groups and was 9±3 days in the transport and 14±7 days in the fibrinolytic group (p <0.0001).

Discussion

Randomised studies evaluating the treatment of patients with STEMI demonstrated the advantage of interventional strategy over fibrinolytic therapy, both in early and long-term follow-up [5, 6]. Analysis of results in patients admitted to medical centres without catheterisation facilities showed that pPCI was still a more effective option than thrombolytic therapy alone, even when the delay of pPCI initiation related to patient transport was taken into account [1]. Moreover, patient transport to the cathlab was found to be safe.

Analysis of our results revealed that the most significant delay was due to time wasting in regional hospitals. It was mainly the result of lacking algorithms of management of cardiac patients.

In the strategy of patient transfer to the invasive centre, the major problem is related to transport delay prior to pPCI. Recently published guidelines recommend that the time between the first medical contact and pPCI should not exceed 90 minutes [7]. In a meta-analysis performed by Dalby et al. (the largest six relevant studies) average time to the initiation of invasive therapy was approximately 90 minutes [1]. Among studies included in this meta- analysis, only in the AIR PAMI trial, involving high risk patients, was intervention time delay longer i.e., 122 minutes [8]. In the DANAMI-2 study most patients were transported within two hours of randomisation [9]. There are also reports indicating longer time to initiation of pPCI and presenting good clinical outcomes. Thus, it seems that time delay to pPCI may be regarded as acceptable, particularly if therapy favourably affecting IRA patency during transport is employed. It is known that higher

Table III. In-hospital and 30-day follow-up results

	Transport group n=172	Fibrinolytic group n=169	p
In-hospital events			
Deaths	5 (2.9%)	14 (8.28%)	0.03
Repeat MI	2 (1.16%)	6 (3.55%)	0.15
Stroke	0	2 (1.18%)	0.15
Combined end-point (death/repeat MI/stroke)	7 (4.07%)	22 (13.02%)	0.003
30-day follow-up			
Deaths	6 (3.49%)	15 (8.88%)	0.04
Repeat MI	2 (1.16%)	10 (5.92%)	0.02
Stroke	1 (0.58%)	2 (1.18%)	0.55
Combined end-point (death/repeat MI/stroke)	9 (5.23%)	27 (15.98%)	0.001

Abbreviations: as in Table I

Table IV. In-hospital medications

	Transport group n=172	Fibrinolytic group n=169	p
Aspirin	172 (100%)	169 (100%)	1.0
β-blockers	160 (93%)	138 (82%)	0.0016
ACE inhibitors	155 (90%)	127 (75%)	0.0003
Statins	143 (83%)	134 (79%)	0.36
Low molecular weight heparin	164 (95%)	156 (92%)	0.24

baseline flow in IRA prior to pPCI provides better results of the treatment. It was stressed for the first time in the ADMIRAL trial that patients pretreated with abciximab, platelet GP IIb/IIIa receptor inhibitor, had better clinical outcome [3]. In our previous study we observed a higher ratio of baseline TIMI 3 flow in patients with tirofiban combined with heparin during transport in comparison to patients receiving intravenous heparin alone [10]. Results of the TIGER-PA and On-TIME trials with tirofiban used in acute MI patients showed that early antiplatelet treatment increased the number of patent arteries and was associated with better myocardial tissue perfusion prior to pPCI [4, 11]. Meta- analysis of studies assessing earlier infusion of GP IIb/IIIa inhibitor indicates that better baseline flow in IRA correlates with a trend towards lower mortality in such patients [12]. However, this meta-analysis still involves too small number of patients to establish definitely the role of pharmacologically facilitated pPCI. Currently, we are awaiting the results of large clinical trials, e.g. FINESSE and ASSENT 4.

Recently, attention has been paid mainly to the time of initiation of reperfusion therapy in relation to the onset of MI. Experience of the centre in Zwolle showed that mortality among patients randomised to pPCI was lower and was kept at this level, regardless of the time of assignment to the therapy, when compared to thrombolysis, with the rate of cardiac events increasing along with therapy initiation delay [13]. Brodi et al. emphasised that time to reperfusion was much more important for thrombolysis than for primary PCI [14]. In the PRAGUE-2 study, 30-day mortality among patients receiving thrombolysis was 7.4% if the definitive treatment was used within 3 hours after the onset of MI and two times higher (15.3%) if the time from the first symptoms to therapy exceeded 3 hours [2]. Similar findings were reported by Zijlstra in his meta-analysis [15]. These results are reflected in the latest guidelines regarding medical management in STEMI patients [7].

In our study relatively low mortality in the fibrinolysis group may be a result of early initiation of the therapy – mean time between symptoms onset and treatment initiation was slightly over 3 hours. We must be aware that patients after failed thrombolysis and with persistent coronary instability were referred to the central cathlab and underwent successful intervention. These patients were analysed as belonging to the thrombolysis group.

The next important issue is the place of pPCI procedure. Data adopted from the National Registry of Myocardial Infarction (NRMI) show that in hospitals

with volume ≤16 PCI procedures/year, time from admission to the beginning of therapy is longer and in-hospital mortality of patients who underwent PCI significantly higher than in hospitals with moderate (17-48 PCI/year) or high (≤49 PCI/year) number of performed procedures (mortality of 6.2% *vs* 4.5% *vs* 3.4% respectively, p <0.01) [16]. Thus, PCI procedures should be performed by experienced operators in centres that have developed an algorithm of management of acute MI patients. It enables maximum reduction of the time to the beginning of intervention and the procedure itself. So far in our centre we have performed approximately 800 PCI procedures in STEMI patients, including as many as 50% referred from regional hospitals.

The current study differs slightly from those published earlier. We used wide inclusion criteria. Additionally, management in the emergency room of regional hospitals, except for randomisation, depended only on the preferences of the admitting physician and was not defined in the investigation hypotheses. Our results reflect conditions of daily medical care in Poland. In all thrombolytic patients, streptokinase was used, confirming its position as the basic fibrinolytic agent in local clinical practice. Moreover, analysis of in-hospital pharmacological therapy, showing marked differences in the use of β-blockers and ACE inhibitors in the early period of MI reflects the wide range of experience or non-compliance with recommended standards.

Conclusions

Both results of in-hospital and 30-day follow-up in STEMI patients admitted to hospital without catheterisation facilities showed the advantage of a strategy including transport to the catheterisation centre in order to perform pPCI accompanied by therapy with platelet GP IIb/IIIa receptor inhibitor over fibrinolysis alone employed in the regional hospital. Additionally, STEMI patient transfer was found to be safe and hospitalisation period significantly shorter when compared to the fibrinolysis group.

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Czy transport chorych z ostrym zawałem serca zabezpieczonych blokerem IIb/IIIa i następnie pierwotna przezskórna interwencja wieńcowa są skuteczniejsze niż leczenie trombolityczne na miejscu w szpitalu rejonowym? Badanie z randomizacją. Wyniki wczesne

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Streszczenie

Wstęp: W leczeniu ostrego zawału serca z uniesieniem odcinka ST (STEMI) przewaga pierwotnej interwencji wieńcowej (*primary* PCI, pPCI) nad trombolizą została udowodniona. Jednak najlepszy sposób leczenia STEMI u chorego przyjętego do szpitala bez pracowni hemodynamicznej nie został ostatecznie ustalony. Opóźnienie rozpoczęcia zabiegu pPCI wynikające z czasu transportu może niwelować korzyści płynące z tej strategii leczenia w stosunku do trombolizy podanej na miejscu w szpitalu. Wczesne rozpoczęcie leczenia blokerem GP IIb/IIIa na okres transportu do ośrodka kardiologii inwazyjnej może być rozwiązaniem pozwalającym na utrzymanie przewagi pPCI w leczeniu STEMI.

Metoda: Grupę badaną stanowili chorzy ze STEMI (czas trwania zawału <12 godz., typowe kliniczne i EKG kryteria zawału) randomizowani w 13 szpitalach rejonowych położonych w odległości 20–150 km od ośrodka kardiologii inwazyjnej do trombolizy na miejscu w szpitalu przyjęcia lub do transportu z towarzyszącą terapią blokerem GP IIb/IIIa (tirofiban w dawce 10 µg/kg bolus i.v. w izbie przyjęć szpitala rejonowego i wlew *i.v.* 0.1 µg/kg/min podczas transportu i w czasie zabiegu) celem pPCI. Wszyscy pacjenci we wstrząsie kardiogennym byli obligatoryjnie leczeni za pomocą PCI, ale zostali wyłączeni z prezentowanej analizy.

Wyniki: Do badania włączono 341 chorych (169 do trombolizy i 172 do transportu w celu wykonania PCI). Średni czas od początku zawału do randomizacji był podobny w grupie transportowanej i w grupie trombolitycznej – odpowiednio 139±133min i *vs* 143±117 min, p=0,94. Średni czas podawania tirofibanu do rozpoczęcia PCI w grupie transportowanej wyniósł 121±36 min. Przedni zawał rozpoznano u 42,6% chorych w grupie PCI i 41,5% w grupie trombolitycznej, (p=0,85). Średni czas od randomizacji do rozpoczęcia pPCI wyniósł 158±60 min, a od randomizacji do rozpoczęcia trobmolizy 44±43 min, (p <0,0001). Żaden pacjent nie zmarł podczas transportu. W trakcie 30-dniowej obserwacji stwierdzono: (grupa pPCI *vs* grupa leczona trombolitycznie) śmiertelność 3,49% *vs* 8,88%, p=0,04; ponowny zawał 1,16% *vs* 5,92%, p=0,02, udar 0,58% *vs* 1,18%, p=0,55. Czas pobytu w szpitalu był krótszy w grupie transportowanej: 9±3 dni *vs* 14±7 dni, p <0,0001; w okresie szpitalnym 17 (10,05%) pacjentów z grupy trombolitycznej przewieziono w celu wykonania PCI (*rescue* PCI lub PCI z powodu dławicy pozawałowej). Złożony punkt końcowy (zgon/ponowny zawał/udar) wystąpił istotnie częściej w grupie leczonej trombolitycznie w porównaniu z grupą transportowaną i wyniósł odpowiednio 15,98% *vs* 5,23% (p=0,001).

Wnioski: U chorych ze STEMI przyjętych do szpitali bez pracowni kardiologii inwazyjnej strategia leczenia inwazyjnego obejmująca transport w celu pPCI z towarzyszącą terapią blokerem GP IIb/IIIa okazała się skuteczniejsza niż leczenie trombolityczne w szpitalu rejonowym.

Słowa kluczowe: pierwotna angioplastyka wieńcowa, tromboliza, tirofiban

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