

Treatment of acute ST-segment elevation myocardial infarction in West Pomerania province of Poland. Comparison between primary coronary intervention and thrombolytic therapy

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Abstract

Introduction: The majority of randomised studies on reperfusion in acute ST-segment elevation myocardial infarction (STEMI) show the advantage of primary percutaneous coronary intervention (PCI) over thrombolysis. However, the real world registers' data are not so unequivocal.

Aim: To evaluate the way acute STEMI is treated in West Pomerania province with emphasis on comparison of two reperfusion strategies, primary PCI vs thrombolytic therapy, in early and long-term perspective.

Methods: Medical records of 961 STEMI patients treated between 1 January 2003 and 31 December 2003 were analysed. Data were collected from 3 centres with emergency cath lab availability and 15 regional sites. Long-term mortality was assessed based on regional provincial office database data.

Results: 69.9% of the study group received reperfusion (44.6% primary PCI, 25.3% thrombolysis). Mean age of patients was 62 (21 to 91) years. Patients referred for PCI were younger compared to the thrombolysis group. The percentage of females was similar in both groups. The majority of patients treated with PCI or thrombolysis were admitted to the hospital between 2 and 6 hours after symptoms - 268 patients (46.4%). Seventy-nine patients (8.3%) died in the early (30-day) period. Mean age at time of death was 73 ±8 years, whereas survivors' age was 61.5 (±12) years ($p < 0.001$). Significantly higher mortality was observed in the conservative treatment group (12.7%) compared to patients treated with reperfusion. Forty-two out of 662 patients treated with PCI and thrombolysis died. The group of thrombolytic therapy tended to have higher mortality (7.9%) than PCI patients (5.5%); the difference however was not significant. Early mortality was influenced by older age (73.4 vs 59.5), female gender, low ejection fraction, and previous myocardial infarction. Current smoking has a positive effect on survival (mortality rate in smokers was 2.6%, in non-smokers 8.2%; $p=0.0001$). In long-term follow-up overall mortality in the entire group of 961 patients was 15.7% (12.1% in the reperfusion group). Long-term prognosis was worsened by older age, low ejection fraction, diabetes mellitus and non-smoking.

Conclusions: Treatment of STEMI in West Pomerania province is similar to that used in Europe and the USA. No significant difference in 30-day and long-term mortality between the two types of reperfusion were seen.

Key words: acute myocardial infarction, management, coronary angioplasty, thrombolysis

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Introduction

Recent randomised clinical trials on management of acute myocardial infarction (AMI) indicate the high effectiveness of percutaneous coronary interventions (PCI) and their advantage over thrombolytic treatment. However, a few European (German and French) and American registries as well as Silesian ones regarding so-called *real life* show a number of limitations resulting in the fact that clinical outcomes do not unequivocally support the benefits of PCI [1-5].

The aim of the study was to evaluate the way acute ST-segment elevation MI (STEMI) is treated in the West Pomerania province with emphasis on comparison of two reperfusion strategies: primary PCI vs thrombolytic therapy in early and long-term perspective.

Methods

At present, West Pomerania province is inhabited by 1,733,000 people, with a population density of 75 inhabitants per km². There are three centres performing PCI in this area. These include two sites in Szczecin and one in Koszalin.

The distance from these sites to most cities in the region does not exceed 100 km, which means a transfer time of up to two hours for the majority of AMI patients.

The analysis of medical records was performed in the three centres with emergency cath lab availability (invasive treatment of AMI) in the West Pomerania region and from 15 regional sites (cardiology and general medicine departments) offering thrombolytic therapy.

The patient inclusion criterion was hospitalisation due to the first or recurrent acute STEMI diagnosed according to European Society of Cardiology guidelines.

Patients were enrolled into the study group if meeting relevant criteria between 1 January 2003 and 31 December 2003. Patients were divided into subgroups of thrombolytic therapy, PCI and conservative treatment.

A unified template was used to put in order data obtained from patients' medical records.

This template included: risk factors (smoking, hyperlipidaemia), concomitant diseases (diabetes, arterial hypertension, gout, atrial fibrillation, past stroke/cerebral ischaemia), history of previous MI, duration of pain (onset of pain to hospital time), and complications of AMI.

Hyperlipidaemia was diagnosed if one of the following criteria was met: total cholesterol level greater or equal to 200 mg%, LDL-cholesterol above or equal to 130 mg%, HDL-cholesterol below or equal to

40 mg%, or triglyceride concentration above or equal to 200 mg%. Subsequently, these criteria were used to analyse the incidence of hyperlipidaemia in patients treated with reperfusion and to compare primary PCI and thrombolysis groups.

Moreover, periinfarction left ventricular ejection fraction (EF) assessment was carried out with echocardiography performed during STEMI hospitalisation, and data on primary PCI were evaluated as well. Finally, the analysis included data on pharmacological treatment in hospital and at discharge. Mortality in patients with STEMI was established based on hospital records and the regional provincial office database in Szczecin.

Statistical analysis was performed using Statistica, and the following tests were applied: Shapiro-Wilk, Student's t-test, Yates and Fisher, ANOVA and Kruskal-Wallis, Kaplan-Meier, and Mantel-Cox. A p value <0.05 was considered significant.

Results

Short-term results

Data for the early phase of all patients with STEMI treated with primary PCI in the area and from most regional hospitals were collected (from 15 of 18 hospitals, which enabled over 76% of the population of the region to be covered) between 1 January 2003 and 31 December 2003.

The study involved 961 patients. Patients were excluded from further analysis if treated during hospitalisation with both thrombolysis and PCI (8 subjects) and if no data were available regarding the therapy administered (6 subjects). Of 947 patients with STEMI in West Pomerania province in 2003, 422 individuals were treated with primary PCI and 240 with thrombolysis (98.7% using streptokinase; only three patients received tissue plasminogen activator); 285 patients received conservative treatment without any reperfusion therapy. Global patients' characteristics, including risk factors and concomitant diseases, are shown in Table I.

Patients referred for PCI were younger compared to the thrombolysis group. The percentage of females was similar in both groups. Females in the invasive treatment group were younger (mean age 62.8 years) compared to those treated with a thrombolytic agent (mean age 67 years).

Patients in the PCI group were significantly more frequently smokers, hypertensive and had a history of MI in comparison with patients treated with thrombolysis.

Table I. General characteristics, risk factors and concomitant diseases in patients with STEMI in West Pomerania province

Parametr	Entire group n=947		PCI group n=422		Thrombolysis group n=240		p*
	n	%	n	%	n	%	
Mean age (years)	62.2	–	58.3	–	63.7	–	0.00098
Females	303	31.5	118	28	83	34.6	NS
Smoking	334 (802)	41.6	179 (312)	57.4	93 (238)	38.9	0.00016
Diabetes mellitus	176 (827)	21.3	58 (300)	19.3	46 (239)	19.2	NS
Arterial hypertension (>140/90 mmHg)	485 (888)	54.6	226 (362)	62.6	115 (239)	48.1	0.00045
Past stroke/TIA	33 (802)	4.1	6 (276)	2.2	10 (238)	4.2	NS
Gout	7 (802)	0.9	2 (276)	0.7	1 (238)	0.4	NS
Renal failure	8 (804)	1	2 (276)	0.8	2 (239)	0.7	NS
Previous myocardial infarction	132 (826)	15.8	59 (300)	19.7	28 (239)	11.7	0.001
Hyperlipidaemia			144 (246)	58	67 (122)	54.9	NS

* – difference between PCI and thrombolysis groups. Numbers in brackets indicate the number of patients for whom data were collected

Table II. Number of patients in each pain-to-hospital time period treated with PCI and thrombolysis

	below 2 h		2-6 h		6-12 h		above 12 h	
	n	%	n	%	n	%	n	%
Total(n=578**)	164	28.4	268	46.4	92	15.9	54	9.3
Thrombolysis(n=201**)	77	38.3	75	37.3	42	21	7	6.4
PCI(n=377**)	87	23.1	193	51.2	50	13.3	47	12.4
p*	NS	0.00001	NS	0.00001				

* – difference between PCI and thrombolysis groups

** – may differ from total patient number - determination of duration of symptoms was impossible for all patients due to incomplete medical records

Table III. Mean ejection fraction (%) in selected pain-to-hospital time periods

	below 2 h	2-6 h	6-12 h	above 12 h
PCI and thrombolysis group	48.3	47.1	44.5	43.2
Thrombolysis	46.2	49.3	44.8	41.3
PCI	50.4	47.4	47.2	45.7
p*	NS	NS	NS	NS

* - difference between PCI and thrombolysis groups

In most cases in the PCI group the culprit artery was the occluded left anterior descending coronary artery (194 cases), followed by the right coronary artery (163 cases) and the left circumflex coronary artery (54 cases). In the majority of PCI procedures stents were implanted (in 94.8% of cases) and in 5.2% balloon angioplasty alone was performed. In 81 cases

glycoprotein IIb/IIIa receptor inhibitors were used during the coronary interventions (19.2%). The drugs were as follows: 46 patients - abciximab, 34 -eptifibatid, and 1 patient – tirofiban.

Analysis of the time from the onset of pain to hospitalisation shows that the majority of patients treated with PCI or thrombolysis were admitted

Table IV. Complications of myocardial infarction in patients undergoing reperfusion (PCI and thrombolysis). Number of patients for whom information about the specific complication was available in brackets - complete data were unavailable due to incomplete medical records

No.	Parameter	Thrombolysis		PCI		p
		N	%	N	%	
1.	VF/VT	21 (240)	8.8	18 (350)	5.1	NS
2.	AV III	11 (240)	4.6	8 (350)	1.1	0.0091
3.	Cardiogenic shock	30 (240)	12.5	34 (358)	9.5	NS

VT/VF - ventricular tachycardia/fibrillation

Table V. Pharmacologic treatment during hospitalisation. Number of patients for whom information about the specific pharmacological therapy was available in brackets - complete data were unavailable due to incomplete medical records

No.	Drug groups	Thrombolysis		PCI		p
		n	%	N	%	
1.	ASA	188 (206)	91.3	372 (389)	95.6	0.034
2.	β -blockers	188 (208)	90.4	225 (262)	86	NS
3.	ACE-I	116 (209)	55.5	187 (261)	71.4	0.0005
4.	Calcium channel blockers	5 (208)	2.4	8 (381)	2.1	NS
5.	Lipid lowering agents	197 (209)	94.3	228 (259)	88	0.013
6.	Diuretics	19 (211)	9	24 (264)	9.1	NS
7.	Nitrates	77 (209)	36.8	90 (263)	34.2	NS

Abbreviations: ASA - acetylsalicylic acid, ACE-I - inhibitors of angiotensin-converting enzyme

Table VI. Early mortality of STEMI patients treated with thrombolysis, PCI and conservatively

	N	%	p
PCI	23	5.5	p=0.002
Thrombolysis	19	7.9	
Conservative treatment	37	12.7	

p=0.32 (PCI vs Thrombolysis)
 p=0.0599 (Thrombolysis vs Conservative treatment)

Table VII. Long-term mortality of STEMI patients treated with thrombolysis, PCI and conservatively

	N	%	p
PCI	19	5.2	p=0.0001
Thrombolysis	14	6.6	
Conservative treatment	39	16	

p=0.375 (PCI vs Thrombolysis)
 p=0.0019 (Thrombolysis vs Conservative treatment)

between 2 and 6 hours after pain onset - 268 patients (46.4%, Table II).

Mean periinfarction EF in PCI and thrombolytic groups did not differ significantly. Analysis of pain-to-hospital times and periinfarction EF in the entire study group treated with reperfusion revealed a trend

toward a decrease of EF with delay of therapy initiation (Table III).

No significant differences were observed in the incidence of atrial fibrillation or atrial flutter and cardiogenic shock between patients from different groups. A significant difference was found in the

Table VIII. Risk factors of long-term mortality in patients treated with PCI and thrombolysis

Parameter	Survival in PCI and thrombolysis groups n = 546	Long-term mortality in PCI and thrombolysis groups n = 33	p
Females [n]	156	11	NS
Males [n]	390	22	
Age of patients in PCI and thrombolysis groups (mean)	59.2 (from 21 to 89)	70 (from 49 to 83)	0.00001
Females age (mean)	62.8 (from 35 to 89)	72 (from 50 to 82)	0.000028
Males age (mean)	57.8 (from 21 to 88)	69 (from 49 to 83)	0.0000001
Ejection fraction [%] (mean)	47.8	37.4	0.00001
Diabetes mellitus [n]	81 (476)	13 (29)	0.0005
Smoking [n]	240 (459)	4 (24)	0.001

brackets contain numbers of patients with available data on specific risk factor or concomitant disease - may be different from the total number of patients due to incomplete medical records

Table IX. Early mortality (in-hospital or 30-day*) in patients with ST-segment elevation myocardial infarction in American and European registries

Study/Country	Year	PCI (%)	Thrombolysis (%)	p
MITRA and MIR [12] Germany	1998	3.8	12.7	p < 0.001
NRM [17] USA	2002	4.4	4.3	no data
USIC [4] France	2000	5	7	NS
BLITZ [14] Italy	2001	6.5	6.4	no data
Silesia [6] Poland	2003 - 2004	4.1	no data	no data
Present study	2003	5.5	7.9	NS

* Some publications include only in-hospital mortality, some only 30-day mortality.

no data - no data regarding statistical significance between PCI and thrombolysis groups; Silesian registry contains comparison between PCI and conservative treatment

occurrence of third-degree atrioventricular block with less favourable results in the thrombolysis group (Table IV).

In-hospital pharmacological treatment of patients is presented in Table V. In the primary PCI group additional antiplatelet therapy was, in the majority of cases, ticlopidine: 78.9%. In 10% of patients clopidogrel was used and in 11.1% of subjects no second antiplatelet agent was administered. Aspirin was not given to 4.4% of patients from the PCI group. In this small group 82.4% of subjects received ticlopidine, 5.9% clopidogrel and 11.7% received no antiplatelet agent at all.

In the thrombolysis group aspirin was not given to 8.7% of patients. In this group 73.7% of subjects received ticlopidine, 5.3% clopidogrel and 21% (4 patients) received no antiplatelet agent at all. Twenty (10.6%) patients treated with aspirin

additionally received ticlopidine and one (0.5%) patient received clopidogrel.

During the short-term (30-day) follow-up 79 (3%) patients died. Mean age at time of death was 73±8 years, whereas mean age of survivors was 61.5±12 years (p < 0.001).

Considerably higher mortality was found in the conservative treatment group (12.7%) compared to PCI-treated patients. Forty-two out of 662 patients treated with PCI and thrombolysis died in the early phase of MI (i.e. 30 days). The group of thrombolytic treatment tended to have a higher mortality rate (7.9%) than PCI patients (5.5%, NS) (Table VI). A significant difference in the number of deaths between treatment groups was only observed in the subgroup of patients who were admitted to hospital between 6 and 12 hours from the onset of symptoms in favour of PCI (2% vs 11.9%; p=0.042).

Early mortality in the group treated with reperfusion (thrombolysis and PCI) was significantly influenced by the following factors: age (death vs survival: 73.4 vs 59.5 years, $p=0.000001$), periinfarction EF (death vs survival: 30.5 vs 47.7%, $p=0.001$), prior MI ($p=0.021$), non-smoking ($p=0.0001$), gender (mortality in females and males 11 and 4.3%, respectively; $p=0.0023$). Mortality rate in patients with prior MI was significantly higher in the PCI group than thrombolysis patients (16.9% vs 3.6%, $p=0.001$).

Complications of MI such as cardiogenic shock and third-degree atrioventricular block considerably influenced mortality. More than half of patients (54.7%) who died, had cardiogenic shock, and 26.7% of deaths were caused by complete heart block.

Long-term results

During long-term follow-up of the entire group of 961 patients with AMI another 72 deaths were observed, which together with the 79 deaths in the early 30-day period comprises an overall mortality rate of 15.7%.

In patients treated with PCI and thrombolysis an additional 33 deaths were observed during the long-term follow-up, which along with the 42 early deaths makes up 12.1%. Considerably higher long-term mortality was seen in the conservative treatment group compared to patients treated with reperfusion methods. No significant differences were found between thrombolysis and PCI groups (Table VII).

Long-term mortality in the PCI and thrombolysis groups was significantly affected by patients' age, periinfarction EF, diabetes mellitus and non-smoking. Hypertension, past MI, stroke and/or ischaemic episodes of the central nervous system as well as atrial fibrillation did not affect mortality (Table VIII).

Discussion

Data of all STEMI patients treated in 2003 with PCI as well as data from medical records of patients treated with thrombolysis or conservative therapy were collected from most of the regional hospitals in West Pomerania province. Information from only three small hospitals situated on the southern and south-eastern borders of the province were unavailable.

Mean age of patients was 62 years and was comparable to the age of patients with STEMI in the majority of European registries; slightly lower age was observed only in the French and American registers [1-5]. Patients from the STEMI Silesian registry were somewhat older - 63.1 years [6].

Mean age of our patients treated with PCI was, as in Silesia, significantly lower than in thrombolytic and conservative treatment groups. A similar difference was observed in many previous studies: younger patients were selected for PCI [7, 8].

Females made up about 30% of patients (similar percentage in PCI and thrombolysis groups). The same proportion of females was noted in European registries and 26.4% in the Silesian one [2-6]. Mean age of females was higher than males by about 5 years. Other investigators reported similar observations [9, 10].

One of the most important determinants of the effectiveness of reperfusion is time from the onset of symptoms of infarction. More than 70% of our patients were admitted to hospital within 6 hours, compared to 62.1% of patients in the Silesian registry. Unfortunately, patients presented to hospital mainly after between 2 and 6 hours of symptoms duration, which does not meet the golden hour criteria [11]. Significantly greater delay was found in the PCI group. It seems that two elements are of importance: transportation time and a decision-making system requiring a more precise diagnosis to be made by the admitting physician. Similar problems were addressed by investigators from France and the USA [1, 4, 12].

Pharmacological treatments used during hospitalisation in our region are consistent with current guidelines of cardiology societies, being even more beneficial than those in known European and American registers except for use of platelet glycoprotein IIb/IIIa inhibitors. West Pomerania Health Foundation does not fund drug programmes. It was noted that lipid-lowering therapy was widely used (in more than 85% of patients).

In 69.9% of our patients reperfusion therapy (PCI or thrombolysis) was implemented and in the Silesian registry this percentage was 69.7%. Subjects with STEMI in West Pomerania province were more often treated with PCI (44.6%) than with thrombolysis (25.3%). These rates were more beneficial with respect to invasive method in the Silesian registry (52.9% vs 16.8%). This rate is much higher than in European countries and in the USA: in France 25% of PCI and 28% of thrombolysis [4], in Germany 8.4% and 40.8%, respectively [13], in Italy 15% and 50%, respectively [14], and in the USA 24.4% and 59.1%, respectively [1].

Recently, a decrease in early (in-hospital and 30-day) mortality was observed in STEMI patients. In the 1960s the mortality rate was approximately 30%; later it decreased to 13-15% due to introduction of monitoring of patients (ER rooms) and thrombolytic therapy to finally reach about 6.5% in the USA (15) and 8.4% in Europe (16). In our series 30-day mortality was 8.3%.

Mean early mortality in the metaanalysis of Kelley et al. was 7% for invasive treatment and 9% for thrombolysis (the difference was statistically significant) [17].

Our observations remain consistent with these results, although the difference between PCI and thrombolysis groups was insignificant. Table IX presents a comparison with frequently cited registries. The main reason for the lack of statistical significance of influence of both reperfusion methods on 30-day mortality may be a history of past MI significantly more often seen in patients from the PCI group. Previous MI is a predictor of complications in 30-day and long-term follow-up [9].

Long-term mortality in our patients treated with PCI and thrombolysis was 12.1%. We proved that long-term prognosis is negatively influenced by patients' age, perinfarction EF, diabetes mellitus and non-smoking.

Similar findings were reported in other international registers, and patient age above 65 years is an independent risk factor that worsens prognosis in patients with STEMI [9, 18].

Values of perinfarction EF in fatal cases correlated with EF values available in the literature indicating with high probability the risk of death due to AMI. Decreased EF is recognised by cardiology societies as a predictor of serious AMI complications [19].

The unfavourable effect of diabetes mellitus on post infarction survival was previously known. In our population diabetic patients made up 21.3%, similar to the percentage found in other registers. Diabetes had no effect on early mortality, but it significantly influenced survival in the long-term follow-up.

Our study population consisted of 48.2% of smokers in PCI and thrombolysis groups. We found that smoking did not worsen prognosis. A comparable relationship was found in the French registry [4]. This phenomenon is explained by the better reaction of smokers to antiplatelet and thrombolytic therapy used [20].

Study limitations

As mentioned earlier, the source of data used in this analysis was mainly medical records from various clinical sites involved in AMI treatment. The lack of established standards of maintaining the records caused latitude in the recording of clinical facts (e.g. duration of clinical symptoms, which may have influenced the results) and inability to acquire some information on analysed patients.

Conclusions

1. Treatment of STEMI in West Pomerania province is similar to that used in Europe and the USA.
2. To take advantage of modern methods of treatment of acute myocardial infarction, education of people regarding the symptoms and threats of this disease should be improved, and logistic actions improving the time of patient's transportation to reference hospital should be undertaken.

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Leczenie ostrego zawału serca z uniesieniem odcinka ST w województwie zachodniopomorskim. Porównanie pierwotnej angioplastyki wieńcowej z leczeniem trombolitycznym

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w imieniu ordynatorów z 15 szpitali rejonowych województwa zachodniopomorskiego⁴

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Streszczenie

Wstęp: Większość raportów z badań z randomizacją dotyczących leczenia reperfuzyjnego w ostrym zawałe z uniesieniem odcinka ST (*ST-segment elevation myocardial infarction*, STEMI) wykazuje przewagę leczenia pierwotną przezskórną interwencją wieńcową (*percutaneous coronary intervention*, PCI) nad leczeniem trombolitycznym. Rejestry *real world* nie są już tak jednoznaczne w ocenie obu metod leczenia.

Cel: Ocena leczenia ostrego STEMI na terenie województwa zachodniopomorskiego, a szczególnie porównanie obu metod leczenia reperfuzyjnego: pierwotnej PCI i leczenia trombolitycznego w obserwacji wczesnej i odległej.

Metody: Przeanalizowano dane medyczne 961 chorych ze STEMI leczonych w od 1 stycznia do 31 grudnia 2003 r. Dane pochodziły z 3 ośrodków pełniących ostry dyżur angiograficzny i 15 ośrodków regionalnych. Odległą ocenę śmiertelności uzyskano na podstawie danych terenowego banku danych przy Urzędzie Wojewódzkim w Szczecinie.

Wyniki: Badana grupa w 69,9% była leczona metodami reperfuzyjnymi (44,6% pierwotną PCI, 25,3% trombolizą). Średni wiek chorych wynosił 62 lata (od 21 do 91 lat). Chorzy kierowani na PCI byli młodszy niż leczeni trombolitycznie. W obu grupach był podobny odsetek kobiet. Większość chorych leczonych PCI lub trombolitycznie trafiła do szpitala pomiędzy 2. a 6. godz. bólu – 268 chorych (46,4%).

W trakcie obserwacji wczesnej (30-dniowej) zmarło 79 chorych (8,3%). Średni wiek zmarłych wynosił 73 lata (± 8), natomiast w grupie żyjących 61,5 (± 12 lat), $p < 0,001$. W grupie leczonej zachowawczo (12,7%) stwierdzono istotnie wyższą śmiertelność w stosunku do grup leczonych metodami rekanalizacyjnymi. Wśród 662 osób leczonych PCI i trombolitycznie zmarły 42. Grupa leczona trombolitycznie miała wyższą śmiertelność (7,9%) niż grupa PCI (5,5%), ale różnica ta nie osiągnęła znamienności statystycznej. Na śmiertelność wczesną miały wpływ: starszy wiek (73,4 vs 59,5), płeć żeńska, niska frakcja wyrzutowa, uprzednio przebyty zawał serca. Aktualne palenie papierosów wpływało korzystnie na przeżycie (śmiertelność w grupie palących wyniosła 2,6%, a niepalących 8,2%, $p = 0,0001$).

W obserwacji odległej w całej grupie 961 chorych stwierdzono całkowitą śmiertelność 15,7% (w grupie leczonej reperfuzyjnie 12,1%). Odległe rokowanie pogarszały: starszy wiek, niska frakcja wyrzutowa, cukrzyca oraz niepalenie papierosów.

Wnioski: Leczenie STEMI w województwie zachodniopomorskim jest zbliżone do stosowanego w Europie i Stanach Zjednoczonych. Nie zaobserwowano istotnej różnicy w śmiertelności 30-dniowej i odległej w obu metodach leczenia reperfuzyjnego.

Słowa kluczowe: ostry zawał serca, leczenie, pierwotna angioplastyka wieńcowa, tromboliza

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