ORIGINIAL ARTICLE

Comparison of clinical results and life quality after myocardial infarction therapy with primary percutaneous coronary intervention and fibrinolytic angents

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KEY WORDS

fibrynolytic drugs (FD), primary percutaneous coronary intervention (PPCI), professional activity, quality of life, ST-segment elevation acute coronary syndrome, thrombolysis

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ABSTRACT

INTRODUCTION   A correct and early diagnosis of ST-segment elevation myocardial infarction (STEMI) and implementation of treatment with the aim to regain patency of the infarct-related artery is crucial for prognosis and the ability to return to normal activities.

OBJECTIVES   The aim of the current analysis was to compare two strategies of STEMI therapy in terms of decreasing the impairment level in patients undergoing treatment, expressed as the time to the return to normal social and professional life.

PATIENTS AND METHODS   Two 100-patient groups of patients with STEMI were enrolled into the study. In the first group a fibrinolytic drug was used, while in the other primary percutaneous coronary intervention (PPCI) was performed. The material for the study was collected in the unique transitional period (2001–2002), when the 24-hour call schedule in the catheterization laboratories was introduced in the Ludwik Perzyna Complex Hospital in Kalisz.

RESULTS   During the 6-month follow-up mortality in the fibrinolysis group was 18%, and in the PPCI group 1 death (1%). In both groups, there were recurrent chest pain (63% vs. 38.5%, p <0.0001), the need for nitroglycerin use (73% vs. 37.4%, p <0.0001), recurrent STEMI (7% vs. 0%, p = 0.02), and recurrent hospitalizations (35% vs. 15.2%, p = 0.003). Marked limitations of activity in family and social life were more commonly observed in the thrombolytic drugs-treated group (p <0.0001). A small percentage of patients who returned to work was observed, however in favor of the PPCI group (20% vs. 38%, p = 0.009). Differences between groups concerning professional status 6 months after STEMI were significant (p = 0.046; χ^2).

CONCLUSIONS   Treatment of STEMI with PPCI was associated with an earlier return of respondents to health and a significantly smaller limitation of their activity during the 6-month follow-up.

INTRODUCTION   Myocardial infarction (MI) is the most dramatic manifestation of ischemic heart disease associated with high mortality. It often leads to development of heart failure and other dangerous cardiac complications. Based on the extrapolation of data from the pilot PL-ACS registry, the number of acute coronary syndromes (ACS) in Poland was estimated at 175,000, with 50,000 ST-segment elevation myocardial infarction (STEMI) cases.[1] A correct and early MI diagnosis and initiation of treatment that aims at regaining patency of the infarct-related artery (IRA) in a specialized center is crucial for prognosis. For this reason a significant improvement in MI therapy has been observed over recent decades as a result of better organization of out-of-hospital (R teams) and hospital medical care (intensive cardiac care units),

TABLE Characteristics of the analyzed groups

	PPCI n = 100 (%)	Fibrinolysis n = 100 (%)	p
age (years)	50 ±10	55 ±10	0.0005[b]
male	63	67	NS[b]
hypertension	47	45	NS[a]
hypercholesterolemia	60	45	0.047[a]
diabetes	45	35	NS[a]
BMI >30 kg/m^2	30	25	NS[a]
smoking	51	40	NS[a]
past myocardial infarction	8	25	0.0002[a]
anterior infarction	60	75	NS[a]
pain-to-reperfusion time (h)	3.7 ±1.53	3.4 ±1.54	<0.0001[a]
result in Antman scale	3.6 ±1.2	4.8 ±1.7	<0.0001[a]
duration of hospitalization (days)	7.7 ±3.7	16.0 ±4.9	<0.0001[a]
6-month mortality	1%	18%	0.0001[a]

a χ^2 test
b t-Student's

BMI – body mass index, NS – not significant, PPCI – primary percutaneous coronary intervention

and also modern modes of reperfusion therapy such as fibrinolytic agents and primary percutaneous coronary intervention (PPCI). The 24-hour call schedule in the cathaterization laboratory, currently available in the whole Poland, is being developed.

Physicians diagnosing MI can administer fibrynolytic drugs (FD) or perform PPCI. The FTT meta-analysis (Fibrynolytic Therapy Trialists) that encompassed large randomized trials on FD effectiveness in over 45,000 patients, showed benefits from this therapy, independently of sex, age, and concomitant diseases, including diabetes mellitus (DM).[2] A relatively low cost of the therapy and its easy application, possible even in out-of-hospital conditions are also of significance by making it possible to reduce a delay in IRA opening. However, the disadvantages of fibrinolytic therapy are numerous contraindications to its use, which limit the number of patients in whom the drugs can be used. It should also be emphasized that there is a variability in effectiveness of fibrinolysis, ranging from 30 to 80%. According to the current guidelines, fibrinolysis is a mode of treatment having the same effectiveness as PPCI when used within 3 hours from pain onset.[3]

As shown in the meta-analysis of 23 randomized trials that compared the 2 discussed types of reperfusion therapy, mechanical gain of IRA patency results in a decrease in short-term mortality (7.0 vs. 9.3%, p = 0.0002), recurrent MI (2.5 vs. 6.8%, p <0.0001), stroke (1.0 vs. 2.0. p = 0.0004) and long-term mortality (9.6 vs. 12.8%).[4,5] For this reason, PPCI is at present the preferred therapy, if it can be performed in less than 90 minutes from the first medical contact.[3] Anatomy of coronary lesions in over 90% of cases allows effective PPCI performance with a low risk of related complications.[6,7]

Implementation of the expensive system providing 24-hour call schedule in hemodynamic laboratories in all regions, and costs of coronary angiographs and medical devices for the PPCI purpose should be justified from a point of view of national health policy. For this reason the subject of the current analysis was to compare 2 strategies of STEMI treatment effectiveness with respect to reducing disability in patients undergoing the treatment, expressed as the time to return to work and the extent of this work compared to the pre-infarction level.

The aims of the study were:

1 comparative analysis of direct and long-term effectiveness of pharmacological and invasive treatment of STEMI in the initial phase of the 24-hour on-call hemodynamic schedule implementation in a district hospital,

2 questionnaire-based analysis of professional activity taken up by patients treated with both methods because of STEMI.

Patients and methods **Patients** 200 patients with STEMI hospitalized in the Cardiologic Ward of the Ludwik Perzyna Complex Hospital in Kalisz were qualified for the study between 01.01.2002 to 30.06.2002. Half of the patients were given FD. In the remaining 100 patients the PPCI procedure was performed after the introduction of regular hemodynamic in this unit on 01.07.2002. The follow-up was 6 months from the first day of hospital stay for MI. Distribution of demographic characteristics of patients in each group is shown in TABLE. Patients in the PPCI group were younger (50 vs. 55 years, p = 0.0005) and had more often hypercholesterolemia (p = 0.047). Delayed treatment implementation was also observed in this group (p <0.0001). However, in the FD group the number of patients with past MI was greater (8 vs. 25, p = 0.0002). The mean score in the Antman scale (p <0.0001) was higher, and duration of hospitalization (p <0.0001) was longer in patients treated with FD.

The analyzed groups did not differ with regard to the educational status and the proportion of patients living in rural areas.

Diagnosis of myocardial infarction The diagnosis of STEMI was made on the basis of the American Heart Association and American College of Cardiology criteria.[8] In respect to the localization of ST segment elevation on the electrocardiogram, which qualifies to STEMI treatment, it was categorized into anterior MI (elevations in leads V1–V$_6$, I, aVL) and posterior MI (elevations in leads II, III, aVF). Significant increases in levels of myocardial necrosis markers (creatine kinase isoenzyme, troponin I) and their typical evolution were observed in all patients.

Thrombolysis Streptokinase was used in 50% of patients from the FD group. Tissue-type plasminogen activator was administered to the remaining patients.
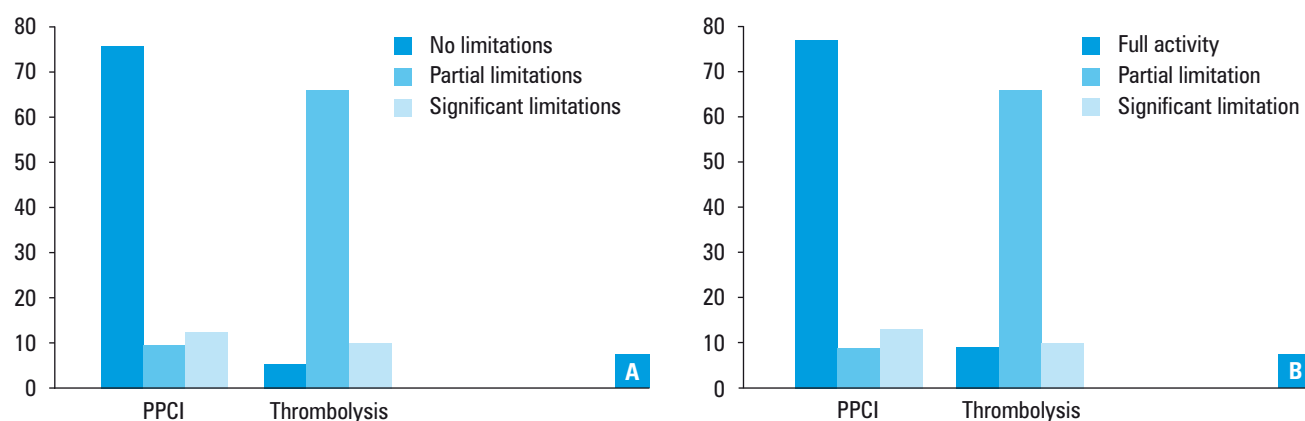
FIGURE 1 Influence of the treatment on activity in social (A) and family (B) life in patients after myocardial infarction Abbreviations: PPCI – primary percutaneous coronary intervention

Primary percutaneous coronary intervention Coronary angiography performed in the PPCI group revealed single-vessel disease in 80%, two-vessel disease in 11%, and significant narrowings in 3 vessels in 9% of patients. Complete occlusion (TIMI 0) was observed in 80% of patients. Baloon dilatation of stenosis was performed after IRA identification. Classic balloon angioplasty (plain old balloon angioplasty – POBA) was used in only 79% of procedures. Coronary stent implantation was performed during 21% of procedures. In 40% of the stent procedures stents were implanted electively, whereas 60% of them were due to unsatisfactory POBA effects. All patients obtained clopidogrel, however GP IIb/IIIa receptor antagonist (abciximab) was administered to 30 patients only (30%). Good outcome of primary procedure, expressed in TIMI 3 reflow, was obtained in 87% of cases; in 9% the reflow was not obtained (TIMI 0).

Questionnaire methodology After collection of data concerning cardiovascular risk factors in both groups, and 6 months from the time of hospitalization all patients completed a standardized questionnaire consisting of 11 questions, developed by us. Respondents were asked to specify the information on recurrences of chest pain, recurrent hospitalizations, functioning in the family, social life and work. Patients' activity and functioning in the family and social life was assessed only on the basis of his/her subjective self-esteem of usefulness in family life, ability to perform everyday house duties and satisfaction with sexual activity. Similarly, social activity was defined as a subjective feeling of the ability to handle official business, take part in local social life and the will to maintain acquaintances.

Analyzed outcomes Clinical variables, that is in-hospital and long-term mortality, frequency of recurrent pain, recurrent hospitalizations and MI were assessed. Among social prameters the percentages of patients who returned to normal work, took up part-time jobs or continued to remain on medical leave were analyzed.

Statistical analysis Analysis of statistical parameters was performed with the Windows XP, using licensed software:

1 Excel 97 calculation sheet (Microsoft Corporation, 1985–1997)
2 statistical program MedCalc 8.0 for Windows (Frank Schoonjans, 1993–2005).

Analyses of compliance distribution of particular variables with normal distribution were made with the Kolmogorov-Smirnov test. In case of non-normal distribution, the median was used as a measure of minimal and maximal result distribution of the variable: Me [min–max]. Mann-Whitney's test was used in the analysis of difference significance between the medians. Variables with the distribution different from the normal one, were presented as arithmetical means ± standard deviation. Mean values in subgroups were compared with t-Student's test for subgroup with the normal distribution of variables. Differences in the distribution of qualitative variables between the study groups were analyzed with the χ^2 test. The value of probability corresponding to statistical significance was $p < 0.05$.

RESULTS During hospitalization 12 deaths in the pharmacologically treated group were noted, while in the PPCI group no patients died. After the 6-month observation mortality in the thrombolysis group was 18%, and in the PPCI group 1 death (1%) occurred. In the 6-month observation recurrent anginal pain (63% vs. 38.5% after PPCI, $p < 0.0001$), a need for the use of nitroglycerine preparations (73% vs. 37.4% after PPCI, $p < 0.0001$), recurrent MI (7% vs. 0% after PPCI, $p = 0.02$), recurrent hospitalizations because of exacerbation of anginal pain (35% vs. 15.2% after PPCI, $p = 0.003$) were observed more commonly in respondents treated pharmacologically in the course of MI.

Part of the questionnaire concerning the patient's evaluation of his/her everyday activity indicated the advantage of PPCI compared with the group treated with FD, which significantly influenced the subjective improvement in the health of respondents, where considerable limitations in family and social life were more commonly noted ($p < 0.0001$). Detailed data is presented in FIGURE 1.

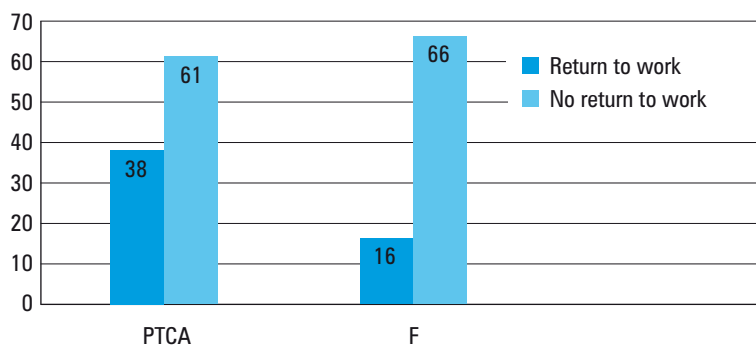In both groups of respondents treated pharmacologically and with the PPCI method

a small percentage of the return to work was observed, however with the distinct superiority of invasive treatment (20% vs. 38% for PPCI, p = 0.009 [**FIGURE 2**]).

A significant number of patients returned to full-time jobs (8% vs. 23.2% for PPCI). However, differences in the case of the return to part-time jobs after MI (11% vs. 7% for PPCI) and the frequency of remaining on medical leave were not observed (19% vs. 21% for PPCI). The percentage of respondents receiving Social Insurance Institution benefits – disability pensions or pensions after MI – was 62% vs. 48.5% for PPCI, respectively (**FIGURE 3**). The discussed differences between the analyzed groups in professional status 6 months after MI were statistically significant (p = 0.046; χ^2).

DISCUSSION The present study assesses long-term results of MI treatment performed in the unique time of implementation of 24-hour interventional duties. The original finding of the study is the fact that it was performed in everyday practice in the multi-specialized regional hospital, in which the authors referred to the results of large multi-center clinical trials reporting on the effectiveness and superiority of mechanical reperfusion over fibrinolytic treatment.

Clinical results of the 6-month observation expressed in differences in mortality, frequency of recurrences of anginal pain, MI and hospitalizations because of cardiovascular causes confirm the superiority of PPCI over fibrinolytic therapy[4] described in the available literature. It should be highlighted that patients were enrolled into the study, when the invasive treatment team had been just increasing experience in the routine 24-hour treatment of patients with MI, whereas thrombolytic treatment protocols had been used in this unit for many years. The so-called 'learning curve phenomenon' probably had some influence on higher than cited in available data percentages of failures in restoring IRA patency during percutaneous intervention (about 9%).

The difference between groups in respect to mortality is also larger than in available data.[9] It is difficult to indicate unanimously the causes of such clear differences in prognosis; however, it can be assumed that patients treated with fibrinolytic agents were initially associated with

worse prognosis. A higher percentage of previous MI and their anterior localization in this group support this concept. These prerequisites may indicate a higher frequency of post-infarction heart failure (PIHF) occurrence, significantly worsening long-term prognosis. The difference in the Morrow-Antman index based on 8 parameters calculated during hospitalization for all patients confirms a higher initial heart failure risk in the fibrinolysis group.

A more durable effect of mechanical restoration of IRA patency and, in consequence, a smaller number of serious coronary events during the first 6 months after MI support the superiority of PPCI. All componens – recurrent MI, recurrent hospitalizations because of angina exacerbation and frequent direct use of nitroglycerin preparations – were significantly more commonly observed in the group initially treated with fibrinolytic agents. To prevent this phenomenon, the current guidelines recommend (level IB)[10] coronary angiography in patients after effective thrombolysis, in which during non-invasive tests cardiac ischemia could be induced.

The second part of the study was a questionnaire-based analysis of subjective feelings of patients on their return to social, family and professional life. Activity of patients before the MI episode was determined as a reference level. It is well known that acute coronary events cause rapid disturbances and often prevent the return to a normal everyday life style.[11] Patients after PPCI more commonly reported the return to normal activity in all mentioned areas. Unfortunately, the precise causes of these differences and their nature were not analyzed. Probably the main causes of withdrawal from professional life and worse self-esteem, causing problems in family and social life, were both PIHF and post-infarction depression.

A decreased psychomotor drive or lack of activity caused by a self-esteem decrease or a conviction about the necessity of leading a protective lifestyle which result from fear of "disease recurrence" are basic depression symptoms in patients after MI. Depression is a well documented independent risk factor of worse prognosis after MI.[12-14] Its development in patients with symptomatic post-infarction heart dysfunction appears to be an especially unfavorable combination.[15] It has been shown that heart failure increases depression frequency,[16] the occurrence of which significantly worsens quality of life and increases the number of reported non-cardiac somatic symptoms.[17] The role of educating family members by nursing staff on how to support patients during post-infarction recuperation is stressed in available data.[18-20]

From an economical point of view the ability to use therapy, which can increase the chances of returning to work, is crucial. In the current analysis PPCI seems to be the therapy. As shown in published studies, the PPCI procedure is a more effective method of MI treatment from an economical point of view despite its greater direct
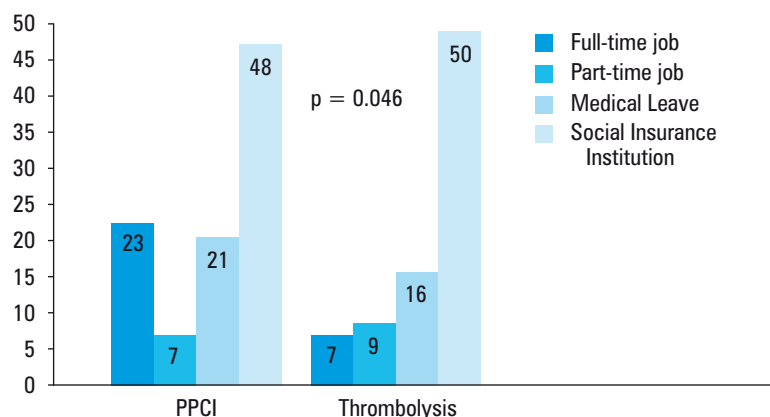
FIGURE 3 Professional activity status 6 months after myocardial infarction (a number of patients in each group is presented)

Legend: Full-time job, Part-time job, Medical Leave, Social Insurance Institution; p = 0.046

costs.[21-22] A smaller frequency of re-interventions compared with patients treated initially with FD was the main factor testifying to PPCI benefits. According to authors of the meta-analysis oriented on the cost effectiveness of both strategies of reperfusion therapy, PPCI decreases mortality after 6 months of about 30% on average (7.6% vs. 4.9%), reduces the frequency of repeated MI occurrence of 50% (7.6% vs. 3.1%) and risk of central nervous system stroke in 2/3 of cases (2.3% vs. 0.7%), mainly due to the decreased number of hemorrhagic strokes; a number of procedures of aortic-coronary bypass grafting was also smaller of about 30% (13.2% vs. 8.4%), if PPCI was the method of choice.[23] Undoubtedly, PPCI requires higher device expenditure and maintenance of a larger number of employees for the 24-hour service purpose. For this reason cost effectiveness of this therapy is dependent on the proper planning of the hospital network, so that at least 200 PPCI can be performed annually in each center.[24] So far, the benefits resulting from the combination of both modes of MI therapy, determined as the so-called facilitated PCI, have not been unambiguously confirmed.[25,26] The goal of facilitation is to increase the probability of early initial IRA patency restoration with FD and subsequent PCI IRA performance.

The small percentage of coronary stents used in the analyzed group of patients (typical of the period of the test performance) is worth noting. It is well known that use of metal stents in PPCI offers additional benefits to POBA[27,28] and takes an acknowledged position in the present guidelines of cardiac societies.[29] Due to lower prices of available metal stents, their costs in cases of interventional treatment compared with previous years are much more lower.[30]

An insufficient number of patients for the questionnaire study and the short 6-month follow-up represent additional limitations of the study. Echocardiographic parameters, describing the degree of post-infarction cardiac dysfunction and data on percentages of cardiac catheterization and invasive revascularization procedures during the in- and out-of-hospital observation in both groups were not analyzed. Standardization of the questionnaire used for patient status evaluation is also a limitation. However, this method reflects the main components and

aspects of patients' activity after MI in Polish conditions and for this reason, we believe that it is a valuable tool.

In summary, MI therapy with PPCI was associated with an earlier return to health and a significantly less limited activity of the patients during the 6-month follow-up.

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