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Successful primary coronary angioplasty improves early and long-term outcomes in ST segment elevation acute coronary syndromes in patients above 80 years of age

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Abstract

Background: ST segment elevation myocardial infarction (STEMI) in patients above 80 years of age continues to be a therapeutic challenge. Patients in this age group are rarely included in randomised clinical trials.

Aim: Comparison of the effectiveness and safety of STEMI management in octogenarians in hospitals with a 24-hour percutaneous coronary intervention (PCI) capability and hospitals without PCI access.

Methods: A retrospective analysis of medical records of 50 octogenarians who were treated with PCI (group 1) in one center and 50 patients treated noninvasively in the other 3 hospitals (group 2). We evaluated mortality and major adverse cardiac events after 10 days, 30 days and 1 year.

Results: There were no significant differences in the demographic characteristics of the study groups. The duration of coronary pain was similar in both groups: 318 min in group 1 *vs* 383 min in group 2 (NS). Mortality in group 2 was significantly higher than in group 1: 40% *vs* 14%, respectively, after 10 days ($p = 0.0034$); 48 *vs* 18% after 30 days ($p = 0.0014$); and 54% *vs* 24% after 1 year ($p = 0.0021$). Thrombolytic treatment was used in only 40% of the patients in group 2. In group 2, acute heart failure (HF) (Killip class III and IV) was diagnosed more frequently than in group 1 (28% *vs* 12%, $p = 0.034$). In patients with Killip class I/II HF, mortality in patients in group 2 and group 1 was 22% *vs* 9%, at 10 days; 31% *vs* 14% at 30 days; and 39% *vs* 20% at 1 year. In patients with Killip class III/IV HF, mortality was 86% *vs* 50%, at 10 days; 93% *vs* 50% at 30 days; and 93% *vs* 50% at 1 year, respectively (all differences NS). In multivariate analysis adjusted for the differences between groups, HF (a negative effect) and a successful PCI (a positive effect) were independent predictors of 1-year survival.

Conclusions: Successful primary PCI in STEMI patients above 80 years of age resulted in a reduction of early and long-term mortality compared to the medically treated patients. The benefits of PCI treatment accrued during the follow-up. In patients treated in the tertiary reference centre in whom PCI was not successful or was not deemed feasible, prognosis was similar to that in the medically treated patients. The latter patients rarely received thrombolytic treatment.

Key words: STEMI, primary percutaneous coronary intervention, prognosis, octogenarians

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INTRODUCTION

In the developed countries, coronary artery disease is the most common cause of mortality in patients aged more than 65 years [1]. This is most evident in Europe where aging of the population results in an increased number of patients treated due to ischaemic heart disease [2]. This trend is expected to continue with further steady increase in life expectancy.

The ST-segment elevation myocardial infarction (STEMI) management guidelines recommended primary percutaneous coronary intervention (PCI) as the treatment of choice, provided that this treatment may be initiated within 90 min from the initial contact with the patient [3–6]. Although no age limits for this treatment were given in the guidelines, everyday clinical practice shows that elderly patients with an acute coronary syndrome are much less likely to undergo invasive treatment. According to the Polish Registry of Acute Coronary Syndromes (PL-ACS), coronary angiography was performed in about 65% of STEMI patients aged 50–59 years compared to about 25% of STEMI patients aged 80–90 years. The percentage of patients in these age groups referred for invasive treatment from hospitals without 24-hour PCI capability was about 30% *vs* 10%, respectively [7]. Thus, it seems reasonable to determine whether these elderly patients, as a high risk group, actually benefit from PCI compared to patients treated medically.

The aim of this study was to compare the effectiveness and safety of STEMI management in octogenarians in hospitals with a 24-hour PCI capability and hospitals without PCI capability.

METHODS

We performed an observational, retrospective study based on the analysis of data form medical records of consecutive STEMI patients. Patients were included in the study using the following criteria: age 80–90 years on admission, the diagnosis of STEMI or a new left bundle branch block, and chest pain onset within 24 hours.

Exclusion criteria included chest pain lasting more than 24 hours, the diagnosis of STEMI secondary to other conditions, and concomitant disease with a significant effect on future prognosis.

We analysed patient medical records retrieved from the hospital archives in three centers that had no 24-hour coronary angiography and PCI service in 2004–2007. These patients were treated medically according to the established myocardial infarction (MI) guidelines, including with the use of fibrinolytic treatment when indicated. Patients aged more than 80 years constituted approximately 20% of all treated patients. From these 3 centres we obtained medical records of 56 consecutive patients treated in 2004–2007 who fulfilled the entry criteria, particularly in regard to the timing of infarction. In 15 cases, MI was older than 24 hours or the precise timing could not be established based on the available data. From the further analysis, we excluded 6 patients (11%) who had other serious diseases effecting outcome.

Patients treated medically were compared with a group of patients fulfilling the entry criteria who were treated during the same period of time in two catheterisation laboratories, providing 24-hour coronary angiography and PCI service. During the study period, 65 patients with STEMI aged > 80 years and fulfilling the entry criteria were treated in the cathlabs. We did not consider patients who were transferred from other hospitals beyond 24 hours from the onset of chest pain. In all patients in whom PCI treatment of MI was deemed feasible, coronary angiography was performed. Ten patients in the study group were found to be unsuitable candidates for coronary intervention due to technical inability of such treatment, i.e. the presence of diffuse coronary lesions. The PCI was unsuccessful in further 5 patients. Optimal effect of PCI was achieved in 50 patients. Statistical analysis included 50 patients treated in centers without PCI capability (medically treated patients) and 50 patients who underwent successful coronary angioplasty of the culprit vessel (the PCI group). We also evaluated mortality in 15 patients who could not be treated with PCI due to technical reasons or underwent unsuccessful PCI. The study protocol was approved by the local ethics committee.

We evaluated mortality at 10 days, 30 days and 1 year. One-year mortality data were obtained from the Polish national population registration system. We also evaluated the rate of major complications including recurrent MI, stroke, and major bleeding depending on the treatment modality. We analysed the frequency of use, success rate and complications of fibrinolytic treatment in medically treated patients.

Statistical analysis

Statistical analysis was performed using the SAS 8.2 package. Results are expressed as mean values and SD or median values and interquartile ranges for quantitative variables and rates and percentages for qualitative and categorical variables.

The Shapiro-Wilk test was used to evaluate normal distribution of the evaluated continuous variables. To compare differences between normally distributed continuous variables, the Student t-test or the Welch test was used, depending on the criterion of homogenic variance as evaluated using the Levene test. Differences between non-normally distributed variables (e.g. troponin and CK-MB level) were tested using the nonparametric Mann-Whitney test. To test qualitative and ordinal variables, contigency tables were used, and distributions were tested using Pearson χ^2 test or the exact Fisher test if the expected number of observations was less than 5. The Kaplan-Meier curves were plotted for the study groups and compared using the log rank test. All study hypotheses were verified using two-tailed tests at the alpha level of ≤ 0.05. We performed multivariate analysis using the Cox proportional hazards model to evaluate predictors of mortality. We

Table 1. Baseline characteristics of the patients (n = 100)

	Medically treated group	PCI group	P
No. of patients	50	50	
Age [years]	83.9 ± 2.65	83.0 ± 2.3	NS
Men	14 (28%)	21 (37%)	NS
Duration of pain [min]	382 ± 311	318 ± 250	NS
SBP [mm Hg]	128 ± 38	125 ± 22	NS
DBP [mm Hg]	77 ± 17	78 ± 11	NS
Heart rate [bpm]	90 ± 28	79 ± 19	0.02
Tn 0 [mg/mL]	0.81*	1.47*	NS
Tn max. [mg/mL]	20.7*	32.5*	NS
CK-MB 0 [mg/mL]	36*	9.35*	0.01
CK-MB max. [mg/mL]	84*	70.5*	0.04
Unconscious patients	0 (0%)	3 (6%)	NS
Decreased level of consciousness	15 (30%)	12 (24.5%)	NS
Killip class III or IV	14 (28%)	6 (12%)	0.034
Anterior wall MI	25 (50%)	26 (52%)	NS
History of CAD	26 (52%)	23 (46%)	NS
Previous MI	8 (16%)	13 (26%)	NS
Previous PCI	2 (4%)	3 (6%)	NS
Previous CABG	1 (2%)	1 (2%)	NS
Hypertension	28 (56%)	32 (64%)	NS
Diabetes	9 (18%)	10 (28%)	NS
Peripheral arterial disease	2 (4%)	2 (4%)	NS

*Median values are given as the distribution was not normal; PCI — percutaneous coronary angioplasty; SBP — systolic blood pressure; DBP — diastolic blood pressure; Tn — troponin; CK-MB — creatinine kinase isoenzyme MB; MI — myocardial infarction; CAD — coronary artery disease; CABG — coronary artery bypass grafting

calculated the hazard ratios and 95% confidence intervals for variables showing a significant predictive value in the mortality analysis.

RESULTS

The demographic characteristics of the study groups were similar. The mean age was about 83 years in both groups. The two groups did not differ in regard to the duration of chest pain from its onset to hospital admission nor the localisation of infarction, with anterior wall infarction comprising about 50% of all cases in both study groups. The medically treated patients more often presented with severe heart failure (HF) (Killip class III or IV) and higher heart rate. Baseline and peak creatinine kinase isoenzyme MB (CK-MB) levels were higher in medically treated patients and the troponin levels were similar in both groups. Level of consciousness on admission did not differ between the two groups. The prevalence of coronary disease risk factors was similar in both groups (Table 1).

In all evaluated time periods, mortality was lower in the PCI group. No differences in mortality were found between women and men (Fig. 1). Analysis of the survival curves showed significantly larger treatment benefits in patients who

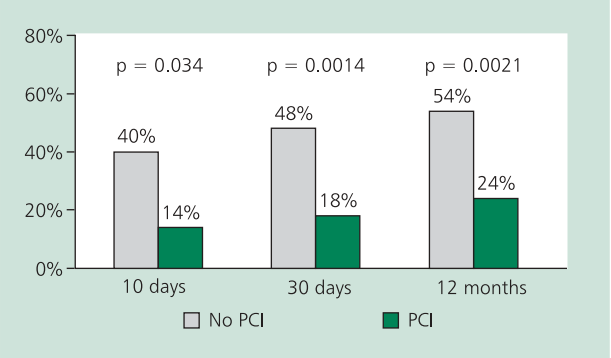

Figure 1. Mortality at 10 days, 30 days, and 1 year depending on the use of percutaneous coronary angioplasty (PCI) treatment

underwent successful PCI. The probability of 3-year survival in this group was 69% compared to 31% in the medically treated patients (p = 0.0007) (Fig. 2).

We also showed large differences in mortality (by 50%) in favour of the PCI group in different HF class subsets and other evaluated subgroups but these differences did not re-

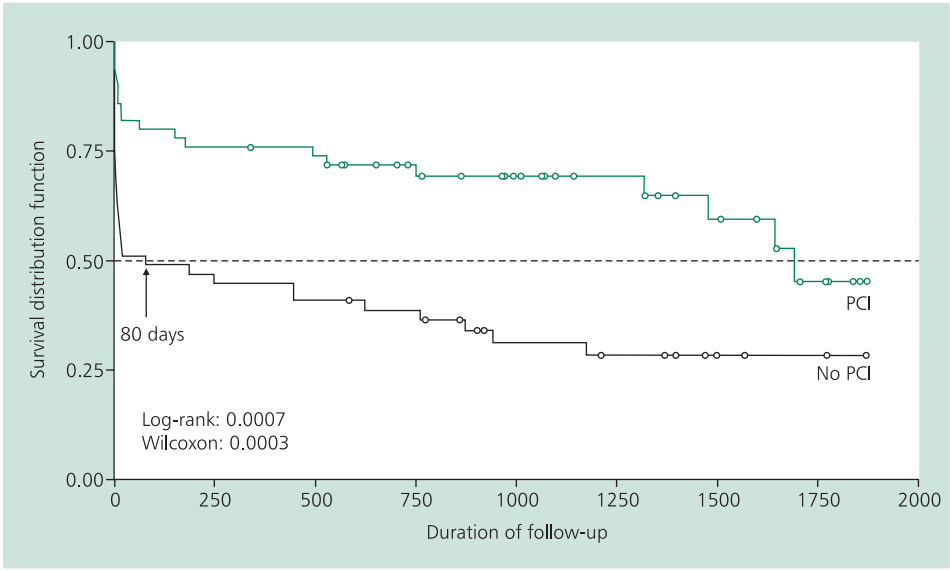

Figure 2. Probability of 3-year survival in patients treated with percutaneous coronary angioplasty (PCI) compared to the medically treated patients

Table 2. Mortality depending on the severity of heart failure as assessed by the Killip class

	Killip class I–II		Killip class III–IV	
	Medically treated group n = 36	PCI group n = 44	Medically treated group n = 14	PCI group n = 6
10-day mortality	8 (22%)	4 (9%)	12 (86%)	3 (50%)
30-day mortality	11 (31%)	6 (14%)	13 (93%)	3 (50%)
1-year mortality	14 (39%)	9 (20%)	13 (93%)	3 (50%)

PCI — percutaneous coronary angioplasty; all differences NS

Table 3. Predictors of one-year mortality

Variable	Relative risk	95% confidence interval	P
Test likelihood ratio: $p < 0.0001$, Wald: $p < 0.0001$, Score: $p < 0.0001$			
Killip class II	1.059	0.456–2.459	0.8932
Killip class III	3.232	1.017–10.265	0.0467
Killip class IV	7.123	3.006–16.876	< 0.001
Percutaneous coronary angioplasty	0.397	0.193–0.815	0.0118

ach statistical significance. Of note, among medically treated patients with Killip class III or IV HF on admission, only two of 14 patients survived until discharge, and only one patient survived 30 days. On the other hand, all patients with Killip class III or IV HF on admission who survived 30 days, regardless of the treament used (PCI or no PCI), were still alive at 1 year (Table 2).

Independent predictors of one-year survival in the multivariate analysis included HF on admission (a negative predictive factor) and successful PCI (a positive predictive factor) (Table 3). In contrast, differences in CK-MB level did not reach statistical significance.

The presence of Killip class III HF was associated with worse 1-year outcomes only. In these patients, mortality at 1 year was increased 3.3 times compared to Killip class I ($p < 0.05$), while 3-year survival was not affected: the relative risk of death was 2 but this difference was not significant. Relative mortality risk in patients with Killip class IV HF was higher at 1 year

(7.1; $p < 0.0001$) than at 3 years (6.1; $p < 0.0001$). In contrast, benefits from PCI increased slightly with longer follow-up, with the relative mortality risk of 0.40 ($p < 0.05$) at 1 year and 0.24 ($p < 0.01$) at 3 years.

We did not find any differences between the study groups in regard to the incidence of other in-hospital complications such as recurrent MI, stroke, major bleeding, recurrent angina, acute HF, arrhythmia, and conduction disturbances. Mechanical complications of MI (free wall or interventricular septum rupture) were similarly common in both study groups, as was respiratory failure requiring ventilation (Table 4). A statistically significant fall in haemoglobin level and haematocrit was noted in patients treated with PCI. This did not result, however, in more frequent need for packed erythrocyte transfusion.

All patients treated with PCI received acetylsalicylic acid (ASA), as did 92% of the medically treated patients ($p = 0.056$), and 6% of the patients in the latter group received oral anticoagulant. Medically treated patients were less likely to receive statin during hospitalisation ($p = 0.003$). The use of ASA and statins tended to increase during the follow-up. By 2006–2007, statins and ASA were used with the same frequency in both study groups.

On discharge, patients received medications as recommended in the guidelines. The only difference we noted was less frequent use of statins in the medically treated patients.

Survival curves for patients treated in the tertiary reference centre in whom coronary intervention was not feasible or nor successful ($n = 15$) and patients treated medically in hospitals without 24-hour PCI capability were similar (Fig. 3).

Table 4. In-hospital complications

Complication	Medically treated group	PCI group	P
Recurrent MI	1 (2%)	4 (8%)	NS
Ischaemic stroke	1 (2%)	3 (6%)	NS
Haemorrhagic stroke	0 (0%)	0 (0%)	
Major bleeding	0 (0%)	1 (2%)	NS
Recurrent angina	7 (14%)	8 (16%)	NS
Early ventricular fibrillation	4 (8%)	2 (4%)	NS
Late ventricular fibrillation	1 (2%)	1 (2%)	NS
Paroxysmal atrial fibrillation	6 (12%)	3 (6%)	NS
II/III degree AV block	6 (12%)	9 (18%)	NS
Left ventricular wall rupture	2 (4%)	3 (6%)	NS
Peripheral embolism	1 (2%)	0 (0%)	NS

PCI — percutaneous coronary angioplasty; MI — myocardial infarction; AV — atrioventricular

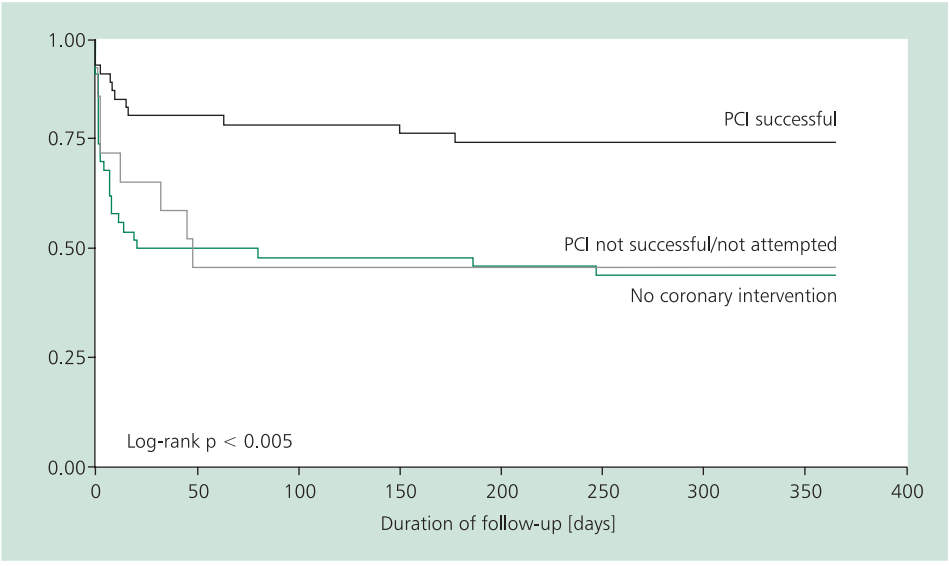

Figure 3. One-year survival curves depending on the use and the success of percutaneous coronary angioplasty (PCI)

Table 5. Patient characteristics in medically treated group (no percutaneous coronary angioplasty) depending on the use of fibrinolytic treatment

	Fibrinolysis (n = 20)	No fibrinolysis (n = 30)	P
Mean age [years]	83.7	83.9	NS
Previous myocardial infarction	3 (15%)	5 (17%)	NS
Hypertension	9 (45%)	19 (63%)	NS
Stroke	1 (5%)	3 (10%)	NS
Duration of pain [min]	275	475	0.034

Table 6. Mortality in medically treated group (no percutaneous coronary angioplasty) depending on the use of fibrinolytic treatment

Mortality	Fibrinolysis	No fibrinolysis	P
10-day	8 (40%)	12 (40%)	NS
30-day	10 (50%)	14 (47%)	NS
1-year	10 (50%)	17 (57%)	NS

Analysis of the treatment used in the medically treated patients showed that only 40% of the patients received fibrinolytic therapy and these patients had shorted duration of chest pain. Apart from that, the subgroup of patients who received fibrinolytic therapy did not differ in regard to age and the prevalence of the history of hypertension, MI and stroke (Table 5). Mortality at 10 days, 30 days and 1 year in patients who did not receive fibrinolytic therapy was similar to that in patients who received fibrinolytic therapy (Table 6).

DISCUSSION

Guidelines for the management of STEMI were developed based on the analysis of 20 randomised studies evaluating the effectiveness of primary PCI compared to fibrinolytic treatment in overall 7388 patients [8–27]. Assuming normal distribution of age of these patients, it can be estimated using the reported standard deviations that the evidence base for ESC and ACC/AHA guidelines included data obtained in approximately 791 patients aged more than 75 years, or 12% of all patients in these studies.

In large U.S. registries of MI such as GRACE and NMRI, 28% of all patients were above 75 years of age [28]. Thus, there is significant discrepancy between the patient population evaluated in the clinical trials, with 12% of patients above 75 years of age, and the proportion of such patients (28%) in routine clinical practice.

Review of the literature shows that three small randomised studies comparing PCI and fibrinolysis in the treatment of STEMI in the elderly have been published in the last 10 years [13, 29, 30]. The first of these studies included patients aged more than 75 years and showed superiority of primary PCI compared to intravenous streptokinase treatment. The combined primary endpoint of all-cause mortality, recurrent MI and stroke occurred in 9% *vs* 29% of patients, respectively ($p = 0.01$) [13]. In the second study, patients with STEMI aged more than 70 years were referred to two nearby centres. In one of these centres, tissue plasminogen activator was used, while primary PCI was performed in the other centre. Outcomes at 6 months did not show lower mortality in the primary PCI group but these patients less often required repeated revascularisation (9% *vs* 61%; $p = 0.001$) [29]. In 2009, results of a randomised TRIANA study were reported. At 30 days, no statistically significant difference in the occurrence of the combined endpoint was observed between STEMI patients aged more than 75 years treated with tenecteplase (25.4%) or treated with PCI (18.9%; $p = 0.21$). However, the need for repeat revascularisation with PCI was significantly less frequent in the intervention group (0.8% *vs* 9.7%; $p < 0.001$) and this effect was maintained at 12 months [30].

In another study, results of primary PCI in the treatment of STEMI in patients aged more or less than 75 years were compared, showing smaller reduction of both in-hospital and 1-year mortality in the older patients compared to the younger group. Of note, in-hospital complications were similarly frequent in both age groups [31].

Our study was not randomised, reflecting everyday clinical practice. Despite lack of randomisation, both study groups were similar in regard to age, duration of chest pain, localisation of MI, level of consciousness on admission, and the prevalence of coronary artery disease risk factors. Of note, 70% of our patients were women, while women in this age group usually contribute less than 50% of subjects enrolled in clinical trials, which may be related to a longer average life span of women in many populations.

Severe HF (Killip class III or IV) was more commonly present on admission in the medically treated patients. This is a limitation of our study but also suggests that severe clinical condition at the time MI was diagnosed might have led to

a physician decision not to refer the patient for invasive treatment. This resulted in 93% 30-day mortality among patients with Killip class III or IV HF (only one of 14 patients survived) compared to 50% mortality in patients treated with successful PCI. When we analysed all these very elderly patients with HF, regardless of the Killip class, we showed a significant superiority of the invasive treatment over the medical treatment of MI.

It should be stressed that the survival curve for patients treated in the tertiary reference centre in whom coronary intervention was not feasible or nor successful, virtually overlapped with the survival curve for patients treated medically in hospitals without 24-hour PCI capability. In this regard, it is of note that cardiological centres selected for our study were very experienced ones. Our study also showed that PCI in patients aged more that 80 years is safe. The incidence of major bleeding was not increased, and the significant reduction of haematocrit observed at the time of hospital discharge in patients treated with PCI did not result in more frequent need for packed erythrocyte transfusion.

Drug therapy used in our patients was similar and consistent with the guidelines in the two study groups both during the in-hospital treatment and at discharge. However, fibrinolytic treatment was used in only 40% of the medically treated patients. Due to small size of subgroups, we could not evaluate the effect of fibrinolytic treatment on mortality risk in our studies. Outcomes of fibrinolytic treatment have been reported in numerous studies [32, 33]. Relatively infrequent use of fibrinolytic treatment in the elderly patients in our study likely resulted from the concerns regarding possible complications and is consistent with current clinical practice.

Another particularly interesting finding is only a small difference between 30-day and 1-year mortality in both groups, especially in the context of the elderly age of the studied patients. In agreement with current efforts to reduce age-related disparities in access to healthcare services, our study confirmed that invasive treatment of MI in octogenarians is reasonable. It also showed, however, that successful PCI is often not possible in these patients.

Limitations of the study

Limitations of our study included its retrospective nature and lack of randomisation. The small size of the study groups was an additional limitation. However, our study was designed as to reflect daily clinical practice.

CONCLUSIONS

Successful primary PCI in STEMI patients above 80 years of age resulted in a reduction of early and long-term mortality compared to the medically treated patients. The benefits of PCI treatment accrued during the follow-up. In those patients in whom PCI was not successful or was not deemed feasible, prognosis was similar to that in the medically treated patients. Elderly patients treated in hospitals without PCI capability are relatively rarely considered for thrombolytic treatment.

Conflict of interest: *none declared*

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Skuteczna pierwotna angioplastyka wieńcowa poprawia rokowanie wczesne i odległe w ostrym zespole wieńcowym z uniesieniem odcinka ST u osób powyżej 80. roku życia

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Streszczenie

Wstęp: W dostępnym piśmiennictwie jest mało danych oceniających skuteczność i bezpieczeństwo leczenia ostrego zawału serca z uniesieniem odcinka ST (STEMI) u chorych powyżej 80. rż., gdyż osoby w tej grupie wiekowej rzadko są włączane do dużych, randomizowanych badań klinicznych.

Cel: Celem pracy było porównanie skuteczności i bezpieczeństwa leczenia STEMI u pacjentów powyżej 80. rż. w ośrodku pełniącym 24-godzinny dyżur hemodynamiczny w odniesieniu do szpitali, w których nie było możliwości wykonania interwencji na naczyniach wieńcowych w warunkach dyżurowych.

Metody: Analizie poddano historie chorób 50 pacjentów w wieku 80–90 lat ze STEMI leczonych inwazyjnie za pomocą angioplastyki wieńcowej (PCI) w ośrodku pełniącym 24-godzinny dyżur hemodynamiczny i porównano z wynikami leczenia w tym samym okresie w 3 ośrodkach kardiologicznych niedysponujących pracownią hemodynamiczną. Oceniono śmiertelność 10-dniową, 30-dniową i roczną oraz wystąpienie istotnych powikłań klinicznych.

Wyniki: Porównywane grupy nie różniły się między sobą pod względem demograficznym. W obydwu grupach czas trwania bólu dławicowego, od momentu wystąpienia do przyjęcia do szpitala, nie różnił się znamiennie: grupa I bez PCI — 383 min, grupa II z PCI — 318 min, p = 0,35. W grupie I bez PCI częściej stwierdzano objawy zaawansowanej niewydolności serca (klasa Killipa III lub IV), odpowiednio 28% *v*. 12%, p = 0,034. We wszystkich przedziałach czasowych śmiertelność w grupie I bez PCI w porównaniu z grupą II z PCI była zdecydowanie wyższa i wynosiła odpowiednio: 10-dniowa — 40% *v*. 14% (p = 0,0034), 30-dniowa — 48% *v*. 18% (p = 0,0014), roczna — 54% *v*. 24% (p = 0,0021). Analiza śmiertelności w podgrupach I lub II wg Killipa i III lub IV wg Killipa wykazała również wyższą śmiertelność w poszczególnych podgrupach bez PCI. W klasie I lub II wg Killipa śmiertelność wynosiła odpowiednio: 10-dniowa 22% *v*. 9%, 30-dniowa 31% *v*. 14%, roczna 39% *v*. 20%. W klasie III lub IV wg Killipa natomiast wyniosła odpowiednio: 10-dniowa 86% *v*. 50%, 30-dniowa 93% *v*. 50%, roczna 93% *v*. 50% (p = NS ze względu na liczebność). W analizie wieloczynnikowej uwzględniającej różnice międzygrupowe stwierdzono, że niezależnym predyktorem rocznej przeżywalności są niewydolność serca w momencie hospitalizacji (wpływ negatywny) oraz zastosowanie skutecznego PCI (wpływ pozytywny).

Wnioski: 1. Skuteczna pierwotna PCI u osób z STEMI w wieku > 80 lat prowadzi do zmniejszenia śmiertelności wczesnej i rocznej w porównaniu z chorymi nieleczonymi interwencyjnie. Korzyści z terapii pierwotną PCI wzrastają w dalszej obserwacji. 2. Chorzy, u których PCI nie była wykonana lub była nieskuteczna w ośrodku referencyjnym, mają rokowanie zbliżone do leczonych niezabiegowo w rejonowych oddziałach kardiologicznych. 3. Chorzy w podeszłym wieku leczeni na oddziałach kardiologicznych bez pracowni hemodynamicznych są rzadko (40%) kwalifikowani do terapii fibrynolitycznej.

Słowa kluczowe: STEMI, pierwotna angioplastyka wieńcowa, rokowanie, osoby w podeszłym wieku

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