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A comparison of the outcome in diabetic and non-diabetic patients with prolonged ST-segment elevation myocardial infarction subjected to primary coronary angioplasty on the basis of the Western Pomerania Database for the year 2003

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Abstract

Background: *Of all patients with acute coronary syndrome with prolonged ST-segment elevation (STEMI) 13–25% suffer from diabetes mellitus. Despite the introduction of fibrinolytic therapy, patients with STEMI and diabetes have worse prognosis than those without diabetes. The introduction of primary angioplasty as the preferred method of treatment in this group of patients has improved the prognosis somewhat. However, the problem has not been totally solved and diabetic patients still show worse prognosis when compared to non-diabetics, especially in long-term follow-up. The aim of our study was to compare short-term and long-term outcomes in diabetic and non-diabetic patients treated with primary angioplasty for STEMI in the Western Pomeranian Region of Poland between January and December 2003.*

Methods: *The medical files of patients treated for acute coronary syndromes in centres in the Western Pomeranian Region of Poland were analysed. The inclusion criteria were hospitalisation between January 1st and December 31st of 2003 as a result of a first or subsequent STEMI recognised according to European Cardiological Society guidelines. The study enrolled 329 patients including 60 diabetics (18.2%). The data obtained were categorised according to the unified scheme including risk factors, coexisting diseases and a previous history of myocardial infarction. The following parameters were analysed: complications of the acute phase of myocardial infarction, 30-day mortality and one-year mortality.*

Results: *Significantly higher 30-day mortality was noted in diabetic patients who underwent percutaneous revascularisation. Similar results were seen in one-year mortality, with values almost four times as high as those for the non-diabetic group ($p = 0.00023$).*

Conclusions: *An analysis of the medical files of STEMI patients revealed a higher 30-day mortality and a higher one-year mortality in those patients with coexisting diabetes. These results cannot be attributed to delayed reperfusion therapy, TIMI flow in the related artery or*

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adjuvant pharmacological therapy. The data obtained confirm the observation that diabetes is an important factor in a poor prognosis in patients with acute coronary syndrome with prolonged ST-segment elevation. (Folia Cardiol. 2006; 13: 486–493)

Key words: myocardial infarction, diabetes mellitus, primary angioplasty, mortality

Introduction

Diabetic patients make up 13–25% of patients suffering from ST-segment elevation myocardial infarction (STEMI) [1–7]. Despite the introduction of fibrinolytic therapy, the outcomes in STEMI patients with diabetes remain unsatisfactory [8–11]. The introduction of primary coronary angioplasty as the preferred method of treatment in this group of patients has improved the prognosis. Diabetic patients still have a worse prognosis when compared to non-diabetics, especially in long-term follow-up [12, 13]. The introduction of platelet glycoprotein IIb/IIIa receptor blockers and stents has reduced mortality to the rates seen in non-diabetic patients [14].

The aim of our study was to compare the short--term and long-term outcomes in diabetic and non--diabetic patients subjected to percutaneous intervention in the Western Pomeranian Region of Poland between January and December 2003.

Methods

The medical files of patients from centres treating acute coronary syndromes in the Western Pomeranian Region were subjected to retrospective analysis. The centres providing invasive procedures in the treatment of acute myocardial infarction included two from Szczecin and one from Koszalin. The inclusion criterion was hospitalisation as a result of first or consecutive acute myocardial infarction with STEMI in accordance with the criteria accepted by the European Cardiological Society [15].

The study group enrolled all consecutive patients with STEMI hospitalised in the centres referred to above and scheduled for primary coronary angioplasty between January 1st 2003 and December 31st, 2003. The data obtained from the medical files were recorded uniformly in a protocol. Included were risk factors such as smoking, high total cholesterol and LDL cholesterol levels, coexisting disease (arterial hypertension, gouty diathesis, atrial fibrillation, a previous history of stroke/TIA) and a positive history of previous myocardial infarctions.

The duration of chest pain from onset to admission to hospital was analysed as were the following complications of the acute phase of myocardial infarction: ventricular fibrillation/flutter, third degree heart block and cardiogenic shock, recognised on the basis of clinical symptoms and a systemic systolic blood pressure below 90 mm Hg or a sudden drop in initial systolic blood pressure of 30 mm Hg lasting at least 30 minutes without administration of inotropic agents and intra-aortic balloon counterpulsation.

The data on percutaneous coronary intervention (stent, platelet glycoprotein IIb/IIIa receptor blocker and pre-procedure and post-procedure TIMI) were analysed. Hyperlipidaemia was evaluated using widely applied criteria: total cholesterol level $\geq$ 200 mg/dl, LDL-cholesterol level $\geq$ 130 mg/dl, HDL-cholesterol level $\leq$ 40 mg/dl, triglyceride level $\geq$ 200 mg/dl. The use of oral hypoglycaemic agents or insulin on admission day was recognised as evidence of the presence of diabetes mellitus (Table 1).

Evaluation of late mortality was performed on the basis of a questionnaire sent to all patients. These data were recorded between June 2004 and December 2004. The cases without response were verified on the basis of telephone contact and data from the Regional Registry, Regional Office, Szczecin.

Statistical analysis

The patient's age was the only continuous variable (data are shown as means and minimal and maximal values). Normal distribution of the continuous variables was tested with the Shapiro-Wilk test and the homogeneity of variance in the groups compared was tested with the Snedecor and Brown-Forsythe tests. Since the majority of variables were not normally distributed, non-parametric methods, namely the Kruskal-Wallis and Mann-Whitney U tests, were applied in the comparisons of means so that uniform calculations could be performed.

Qualitative variables were tested with Pearson's χ^2 test of independence. Fisher's exact test was applied for the 2×2 contingency tables at expected frequencies ≤ 40, and Yates' correction was applied for the 2×2 contingency tables at expected frequencies ≤ 10.

Owing to the retrospective nature of the study and the paucity of documentation we failed to

Table 1. Baseline characteristics of patients with STEMI.

Parameters	Whole group (n = 329)	Diabetes mellitus group (n = 60)	Non-diabetes mellitus group (n = 269)	p
Age of patients: middle (min and max)	60 (32–85)	62.6 (43–85)	57.4 (32–83)	0.002222**
Hypertension (> 140/90mm Hg)	204 (61.3%)	48 (84.2%)	156 (56.5%)	0.00017
Smoking	190 (59.4%)	17 (38.6%)	173 (62.7%)	0.00436
Stroke/TIA	6 (2.1%)	1 (2.7%)	5 (2.0%)	NS
Gout	2 (0.7%)	0 (0%)	2 (0.7%)	NS
Renal insufficiency	2 (0.7%)	1 (2.7%)	1 (0.4%)	NS
Former infarct	47 (16%)	14 (33.3%)	33 (13.2%)	0.00213
High level LDL-cholesterol	113 from 238* (47.5%)	9 from 33 (27.3%)	104 from 205* (50.7%)	0.02052
Low level HDL-cholesterol	38 from 238* (13.9%)	10 from 33 (30.3%)	28 from 205* (13.7%)	0.01541
High level total cholesterol	145 from 255* (56.9%)	12 from 33 (36.4%)	133 from 222* (59.9%)	0.01828
Left ventricular ejection fraction	47.4%	45.6%	47.6%	NS

*Information for these patients only; **Mann-Whitney U-test

Table 2. Time from onset of symptoms to admission to hospital.

	Diabetes mellitus group (n = 58*)	Non-diabetes mellitus group (n = 237)	p
Time to 6 h	39 (67.24%)	182 (76.79%)	NS**
Time > 6 h	19 (32.76%)	55 (23.21%)	NS**
Time > 12 h	9 (15.52%)	28 (11.81%)	NS**

*Information for these patients only; **Pearson's χ^2 test

collect complete data for all diabetic patients. Thus we intentionally abandoned multivariate analysis.

For all calculations the accepted level of significance was $p = 0.05$.

Early outcomes

Between January 1st 2003 and December 31st 2003 primary coronary angioplasty was performed in 329 patients, including 60 diabetic patients (18.2%). The mean patient age was 60 years, 62.6 years for the diabetic group and 57.46 years for the non-diabetic group ($p = 0.0022$).

A statistically significantly higher incidence of coexisting arterial hypertension ($p = 0.00017$) and previous myocardial infarctions ($p = 0.00213$) were found in the diabetic group. Significantly lower total cholesterol ($p = 0.01828$) and LDL-cholesterol ($p = 0.02052$) levels and significantly higher HDL-cholesterol ($p = 0.01541$) levels were found in the diabetic group.

Analysis of the time between the onset of myocardial infarction symptoms and initiation of the revascularisation procedure revealed that the majority of patients had received definite care within 6 hours of the onset (75%). No significant correlation was found between the groups studied in the categorised time from the onset of chest pain to coronary intervention. Detailed data on the time from the onset of myocardial infarction symptoms to coronary intervention are shown in Table 2.

In the diabetic patients the most frequently affected vessels turned out to be the right coronary artery and the left anterior descending coronary artery. The difference was non-significant. The detailed distribution is shown in Table 3.

In both groups of patients a high rate of stent implantation was noted, 83.3% in the diabetic group and 79.9% in the non-diabetic group (NS). The use of platelet glycoprotein IIb/IIIa receptor blockers was at unacceptably low rates, 15.0% and 17.4%

Table 3. Infarct-related artery.

	Diabetes mellitus group (n = 60)	Non-diabetes mellitus group (n = 269)	p
Left anterior descending	26 (43.3%)	127 (46.9%)	NS*
Right coronary artery	7 (11.7%)	39 (14.7%)	NS*
Left circumflex artery	27 (45%)	103 (38.5%)	NS*

*Pearson's χ^2 test

Table 4. Use of stents and IIb/IIIa blockers.

	Diabetes mellitus group (n = 60)	Non-diabetes mellitus group (n = 269)	p
Stent	50 (83.3%)	215 (79.9%)	NS
IIb/IIIa blockers	9 (15%)	47 (17.4%)	NS

Table 5. TIMI flow after percutaneous transluminal intervention.

	Diabetes mellitus group (n = 60)	Non-diabetes mellitus group (n = 269)	p
2 and 3 TIMI flow	89.36%	94.97%	NS

Table 6. In-hospital pharmacological treatment.

	Diabetes mellitus group	Non-diabetes mellitus group
Acetylosalicylic acid	32 (94.1%)	220 (93.2%)
Beta-blocker	31 (91.2%)	202 (85.6%)
Angiotensin-converting enzyme inhibitors	26 (76.5%)	167 (70.8%)
Calcium-channels blocker	1 (2.9%)	11 (4.7%)
Hypolipidaemic agents	30 (88.2%)	205 (87.2%)
Diuretics	4 (11.8%)	19 (8.1%)
Nitrates	9 (26.5%)	85 (36%)
Tienopirydynes	31 (91.2%)	209 (87.1%)

p = NS

respectively. The difference was non-significant (Table 4).

The angiographic analysis did not reveal any significant differences between the groups in the TIMI flow grades achieved within the infarct-related artery. These data are shown in Table 5.

Statistically insignificantly lower left ventricle ejection fraction values were found in the diabetic group.

Pharmacotherapy

When analysing in-hospital therapy we found that large numbers of patients received adjunctive treatment, including beta-blockers, hypolipidaemic agents and ACE inhibitors. No significant differences in drug administration were found between the groups studied. A similar pre-surgery protocol of percutaneous revascularisation was followed in both groups. The majority of patients received 300 mg acetylsalicylic acid, tienopiridine and intravenous unfractionated heparin administered directly before the surgery.

Similar results were obtained in the long-term analysis of pharmacotherapy. Again it was found that a large number of patients were receiving beta-blockers and hypolipidaemic agents. However, ACE inhibitors were statistically significantly more frequently administered in the diabetic group. The details are shown in Tables 6 and 7.

Table 7. Pharmacological treatment in patients with STEMI during follow-up.

	Diabetes mellitus group	Non-diabetes mellitus group	p
Acetylosalicylic acid	20 (90.9%)	132 (91.7%)	NS
Beta-blocker	20 (90.9%)	119 (83.8%)	NS
Angiotensin-converting enzyme inhibitors	20 (90.9%)	93 (66.9%)	0.0471
Calcium-channels blocker	1 (4.55%)	8 (5.7%)	NS
Hypolipidaemic agents	20 (90.9%)	127 (89.4%)	NS
Nitrates	8 (36.4%)	50 (35.7%)	NS

Table 8. Infarct complications.

	All group	Diabetes mellitus group	Non-diabetes mellitus group	p
Ventricular fibrillation/flutter and ventricular tachycardia	17	2 (4%)	15 (5.6%)	NS
Complete block	4	0 (0%)	4 (1.5%)	NS
Cardiogenic shock	21	7 (13.2%)	14 (5.3%)	0.0332

Table 9. 30-day and one-year mortality.

	Diabetes mellitus group	Non-diabetes mellitus group	p
30-day mortality	7 (11.5%)	11 (4%)	0.01855
One-year mortality	13 (22.8%)	17 (6.3%)	0.00023

In-hospital complications

No significant differences were found between the groups studied in the rates of severe complications in the acute phase of myocardial infarction (ventricular fibrillation and flutter and third degree heart block). However, a significant difference was found with respect to cardiogenic shock, which occurred more frequently in the diabetic patients (13.2%) than in the non-diabetic group (5.3%) ($p = 0.0332$). Details are shown in Table 8.

30-day and one-year mortality

A significantly higher 30-day mortality was noted in diabetic patients subjected to a percutaneous revascularisation procedure. Similarly, one-year mortality was almost four times higher than in the non-diabetic group ($p = 0.00023$). The details are shown in Table 9.

The analysis revealed that 30-day mortality among the patients as a whole was significantly affected by previous myocardial infarction. Moreover, one-year mortality was additionally influenced by previous stroke. In this group non-smokers showed a higher probability of 30-day and one-year mortality. However, in the diabetic group no correlation between 30-day mortality and other risk factors was found. The only correlation found was between previous myocardial infarction and one-year mortality (Tables 10 and 11).

Discussion

In the population with acute STEMI from the Western Pomeranian Region of Poland the prevalence of diabetic patients was 18.2%, a result comparable to registries elsewhere in Europe and worldwide [1, 3–5, 16].

The mean age of patients treated with coronary interventions was 60 years, a result comparable to the age of patients from the majority of European registries and the Silesian Myocardial Infarction Registry [3–7]. STEMI patients with coexisting diabetes were significantly older and more frequently had a history of myocardial infarction and arterial hypertension. Similar data have been reported by other researchers [16–19].

Table 10. Risk factors and mortality in whole group.

	30-days follow-up			Year follow-up		
	Current	**Absent**	**p**	**Current**	**Absent**	**p**
Hypertension	6.51 (17/261)	4.65 (6/129)	0.61281	10.97 (26/237)	8.59 (11/128)	0.59183
Stroke	16.67 (1/6)	4.64 (13/80)	0.69322	33.33 (2/6)	7.35 (20/272)	0.01971
Smoking	1.58 (3/190)	8.46 (11/130)	0.00741	2.69 (5/186)	13.49 (17/126)	0.00060
Atrial fibrillation	0 (0/11)	5.09 (14/275)	0.95629	18.18 (2/12)	7.49 (20/262)	0.47311
Gout	0 (0/2)	4.93 (14/84)	0.18604	0.00 (0/2)	7.97 (22/276)	0.36900
Former infarct	17.19 (11/64)	3.25 (8/246)	0.00012	26.23 (16/61)	5.04 (12/238)	0.00001

In brackets — number of deaths/number of patients with or without a particular risk factor.

Table 11. Risk factors and mortality in subgroup with diabetes mellitus.

	30-days follow-up			Year follow-up		
	Current	**Absent**	**p**	**Current**	**Absent**	**p**
Hypertension	14.58 (7/48)	0 (0/9)	0.50295	27.27 (12/44)	11.11 (1/9)	0.54743
Stroke	0 (0/1)	8.33 (3/36)	0.91892	100.00 (1/1)	12.12 (4/33)	0.14706
Smoking	0 (0/17)	11.11 (3/36)	0.41818	0 (0/16)	20.00 (5/25)	0.15565
Atrial fibrillation	0 (0/2)	8.57 (3/35)	0.84234	50.00 (1/2)	12.50 (4/32)	0.27629
Former infarct	21.43 (3/14)	7.14 (2/28)	0.39963	42.86 (6/14)	8.00 (2/25)	0.01609

In brackets — number of deaths/number of patients with or without a particular risk factor.

Diabetic neuropathy is a very important factor influencing the clinical course of myocardial infarction in patients with diabetes mellitus. Damage to the autonomous nervous system results in persistent tachycardia and a painless or atypical course of acute coronary syndromes is frequently observed. Moreover, hypoglycaemic agents influence the electrocardiogram and may result in a delay in the introduction of reperfusion therapy among diabetic patients [20]. A similar delay in the application of percutaneous reperfusion therapy was observed in diabetic patients with cardiogenic shock [21].

In our analysis the time that elapsed from the onset of coronary symptoms to the initiation of invasive management was comparable in both groups and we did not observe any additional delay in the initiation of therapy resulting from coexisting diabetes mellitus. Similar observations have been noted by authors reporting from the Cracow Region of Poland [17].

The effectiveness of coronary angioplasty based on TIMI flow was similar in diabetic and non-diabetic patients, an observation in agreement with results reported by other authors [22]. However, it should be underlined that previous analyses had already indicated that TIMI epicardial flow grade was not the only indicator of normal myocardial tissue perfusion [23]. The nature of our study prevented us from performing a detailed analysis of this problem based on, for example, the myocardial blush grade.

A comparison of adjunctive pharmacotherapy revealed no differences between the groups of patients studied in the administration of each drug group. This observation differs from those reported in the literature. Other authors have reported lower rates of administration of beta-blockers and acetylsalicylic acid in diabetic patients [5, 6].

Platelets and thrombogenesis contribute significantly to the pathophysiology of cardiovascular diseases. The increased risk of vascular incidents in diabetes results from platelet hyperactivity, fibrinolytic disequilibrium, endothelial dysfunction and impaired blood flow [24]. The recently underlined poor platelet response to acetylsalicylic acid in diabetic patients should result in administration of platelet glycoprotein IIb/IIIa receptor blockers [25].

Recent age-adjusted studies have revealed decreased mortality in patients with cardiovascular system diseases. This is not, however, noticeable among diabetic patients, although widely applied stents and platelet glycoprotein IIb/IIIa receptor blockers have resulted in significant progress in mortality limitation in this group of patients [12, 26].

In our research we noted that stenting procedures were performed at a significant rate in both groups of patients (diabetic patients: 83.3%, non-diabetic patients: 79.9%, the difference being non-significant).

The National Health Fund in Western Pomerania failed to reimburse the therapeutic programmes for interventional cardiology; thus the unsatisfactory use of platelet glycoprotein IIb/IIIa receptor blockers in the STEMI patients came as no surprise (15.0% and 17.4%, respectively, the difference being non-significant). This observation was a likely cause of higher in-hospital mortality rates in diabetic patients.

Analysis of in-hospital complications revealed a significant difference between the groups studied in the occurrence of cardiogenic shock: the diabetic patients showed higher rates of cardiogenic shock than non-diabetic patients (13.2% *vs.* 5.3%; $p = 0.0332$). Similar observations have been reported by other authors [19, 27].

The adverse influence of diabetes mellitus on short-term and long-term survival in patients with acute myocardial infarction was confirmed by the results of our study. The 30-day mortality in diabetic patients subjected to percutaneous revascularisation was significantly higher at 11.5% as compared with 4% in the non-diabetic group of patients. Moreover, one-year mortality was almost four times as high in the diabetic group as in the non-diabetic patients ($p = 0.00023$). This is consistent with the results achieved by other authors [5, 6, 16, 19, 28–32].

Limitations of the study

The medical files from the three centres in Western Pomerania providing invasive treatment for acute myocardial infarction were the source of data used in the present study. Shortcomings in the standards of documentation and latitude in the interpretation of clinical facts were the likely causes of data being inconsistent or missing. Analysis of long-term outcomes was based on questionnaires received from the patients and these files were also inconsistent, which might have influenced the conclusions.

Conclusions

The present analysis, performed in a population with ST-segment elevation myocardial infarction revealed higher 30-day mortality and one-year mortality in diabetic patients. These results cannot be attributed to delayed reperfusion therapy, TIMI flow in the related artery or adjuvant pharmacological therapy. The data obtained confirm the observation that diabetes is an important factor of poor prognosis in patients with acute coronary syndrome with prolonged ST-segment elevation.

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