Prognostic factors in patients with advanced multi-vessel coronary artery disease

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Abstract

Background: Multi-vessel coronary artery disease (CAD) not suitable for revascularisation remains a challenge for present cardiology. Due to high mortality and difficulties in pharmacological therapy patients with this particular disease constitute a group of great interest.

Aim: To define the main unfavourable prognostic factors in patients with clinically stable multi-vessel CAD who do not qualify for percutaneous or surgical revascularisation.

Methods: The analysed group consisted of 106 patients (79 men, 66±8 years) with multi-vessel CAD, confirmed in coronary angiography, who were primarily disqualified from interventional treatment. Thirty-eight (36%) of them had diabetes and 5 (5%) had a previous stroke. The left ventricular ejection fraction was 37±15%, and mean Gensini score – 72±34.

Results: During 7.4 \pm 4 years of follow-up, 19 (18%) patients died. Predicting factors of mortality included older age (p=0.014), higher heart rate (p=0.02), diabetes (0.003), renal failure (p=0.0003), heart failure (p=0.013), past stroke (p=0.006) and lower left ventricular ejection fraction (p=0.0012). In multivariate logistic analysis the only significant parameter related to prognosis was decreased level of haemoglobin (p=0.007) and elevated leucocytosis (p=0.002). The ROC curves analysis showed that decreased Hgb (<12.3 g/dl) and increased leucocytosis (>11.3 t/mm³) were significantly associated with higher mortality (HR 6.3).

Conclusions: In patients with multi-vessel CAD not amendable for revascularisation, the haemoglobin level and leucytosis seem to be at least as important as well known risk factors. More intensive complex pharmacotherapy and innovatory cell and gene therapeutic methods may improve the prognosis in this group of patients.

Key words: multi-vessel coronary artery disease, prognosis

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Introduction

Cardiovascular diseases are the leading cause of mortality in economically developed countries [1]. Regardless of the great progress that has taken place during past decades, the global number of deaths due to coronary artery disease (CAD) is still very high and in 2002 reached more than 7 million [1, 2]. Recently more advanced atherosclerotic lesions obstructing blood flow in all main coronary arteries have been frequently diagnosed [3]. This particular type of CAD was distinguished from other types into a separate nosologic unit – multi-vessel CAD. Multi-vessel CAD is

defined based on coronary angiography as the presence of subcritical or critical narrowing (luminal narrowing of more than 75%) in at least two main coronary vessels [1, 4]. In many studies it has been estimated that multivessel CAD may constitute up to 50% of all CAD cases [1, 2]. The severity of atherosclerosis and numerous clinical complications with concurrent lack of clear classification systems and diagnostic criteria lead to an exceptionally high mortality rate in this group of patients. It has reached 10-60% during five-year follow-up, depending on progression of atherosclerotic lesions and the presence of other risk factors [1-3, 5].

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Table I. Calculation rule of Gensini score

Gensini score=sum of (narrowing degree index multiplied by narrowing area index)						
Lesion localisation	Punctation value	Lesion localisation	Punctation value			
LM	5	d-LCx	1			
p-LAD	2.5	OM	1			
m-LAD	1.5	p-RCA	1			
d-LAD	1	m-RCA	1			
1 st Dx	1	d-RCA	1			
2 nd Dx	0.5	PD	1			
p-LCx	2.5	PL	1			
Narrowing degree	Punctation value	Narrowing degree	Punctation value			
25%	1	90%	8			
50%	2	99%	16			

LM – left main, LAD – left anterior descending, Dx – diagonal artery, LCx – left circumflex, OM – obtuse marginal artery, RCA – right coronary artery, PD – posterior descending, PL – posterolateral, p – proximal, m – medial, d – distal

100%

4

Thus, identification of unfavourable prognostic factors constitutes a fundamental part of complex management. It allows optimisation of therapeutic procedures (both medical and interventional) in the group of patients with particularly poor prognosis. The question arises are the generally accepted prognostic factors in CAD applicable also to this special, most advanced form of the disease? These factors include: diabetes, clinically overt peripheral arterial disease and significant left ventricular (LV) dysfunction (in the form of decreased LV ejection fraction). These parameters indicate a great risk of acute coronary episodes and thus call for more aggressive medical treatment [1, 3, 6, 7].

The aim of the study was to define the main unfavourable prognostic factors in patients with clinically stable multi-vessel CAD, who are not suitable candidates for percutaneous or surgical revascularisation.

Methods

75%

One hundred six patients hospitalised in the Second Department of Cardiology, Medical University of Łódź between 1994 and 2004 were enrolled in the study. The subjects fulfilled the following criteria:

- 1. Coronary artery disease confirmed in coronary angiography, involving at least two main arteries with narrowing of vessel lumen of 75% or more.
- 2. Luminal narrowing of left main coronary artery not greater than 50%.

- 3. Disqualification from surgical or percutaneous CAD treatment for clinical or technical reasons [1, 8, 9].
- 4. Absence of congenital heart defects.
- 5. Absence of serious comorbidities.

Apart from coronary angiography, in all patients a panel of additional tests to assess severity of CAD as well as the presence of other organ dysfunctions was performed. Apart from generally accepted prognostic factors [1, 3, 10, 11], many other, mainly biochemical indices were analysed, e. g. blood cell count, complete lipid profile, CKMB, urea, creatinine and hepatic aminotranspherases. The evaluation also included ECG recordings, echocardiographic parameters as well as exercise test and 24-hour ECG monitoring, and also basic data from the patient's history.

Based on coronary angiography, semi-quantitative assessment of coronary lesion severity was performed using so-called Gensini score [1, 9] (taking into consideration the division of coronary arteries into proximal segments, including LM, p-LAD, p-LCx, p-RCA – "proximal" Gensini score, and into distal for other segments – "distal" Gensini score) (Table I).

Since their first hospitalisation, all patients have been followed in the outpatient clinic and treated according to the current guidelines of the Polish Cardiac Society [12]. Special attention has been paid to the use of β -blockers and ACE inhibitors in adequate, high doses. Pharmacotherapy of 87 survivors included acetylsalicylic acid (n=84.96%), β -blockers (n=61.70%), ACE inhibitors (n=64.74%, statins (n=69.79) and clopidogrel or ticlopidine (n=6.7%) in those who had contraindications to acetylsalicylic acid. Disqualification from CABG was accomplished by an experienced cardiologist or cardiac surgeon during consultation with each patient enrolled in the study.

Statistical analysis

Distribution of variables was analysed using Kolomogorov-Smirnov test to confirm normal distribution. Differences in the incidence of analysed variables was assessed using variance analysis, Student t-test for paired and unpaired data or nonparametric Wilcoxon pair test. The results were considered statistically significant if the p value was <0.05. Uniand multivariate logistic analysis was performed using Medcalc 8.0 statistical software by establishing discrimination analysis with elimination of variables of statistical significance >0.05. Prognostic value of parameters was analysed by means of Kaplan-Meier method, using standard applications of Systat software. Prognostic power of individual factors was assessed using Mantel test.

Table II. Comparison of basic demographic parameters and cardiovascular risk factors between survivors (group I) and non-survivors (group II)

Parameter	Group I n=19	Group II n=87	р
Age (years)	66±8	61±9	0.014
Men	14 (74%)	65 (75%)	NS
Heart rate (/min)	76±11	70±10	0.02
Diabetes mellitus	12 (63%)	26 (30%)	0.003
Renal failure	11 (58%)	14 (16%)	0.0003
Obesity (BMI >25)	2 (10%)	10 (11%)	NS
Smokers	1 (5%)	20 (23%)	NS
Atrial fibrillation	1 (5%)	1 (1%)	NS
Cerebral stroke	3 (16%)	2 (2%)	0.006
Heart failure			
NYHA I	9 (47%)	66 (76%)	NS
NYHA II	4 (21%)	15 (17%)	NS
NYHA III	5 (26%)	7 (8%)	NS
NYHA IV	1 (5%)	1 (1%)	NS
NYHA II-IV	10 (53%)	23 (26%)	0.013
Systolic blood pressure (mmHg)	122±12	125±10	NS
Diastolic blood pressure (mmHg)	75±7	78±7	NS

Results

No patient was lost to follow-up. During mean follow-up of 7.4±4 years, 19 (18%) patients died due to cardiovascular causes. Eleven patients underwent CABG due to absolute indications; in 50 patients complications were noted, such as worsening of angina requiring hospitalisation (32 patients), nonfatal acute myocardial infarction (6 patients) or cerebral stroke (4 patients). Mean LV ejection fraction was 37%±15%, and Gensini score 72±34. The results are depicted in Tables II and III

In multivariate analysis, only low haemoglobin level (p=0.002) and high leukocytosis (p=0.005) were associated with poor prognosis. Although the presence of diabetes (p=0.003), low LV ejection fraction (p=0.0012), advanced age (p=0.014), history of stroke (p=0.006), and increased heart rate (p=0.02) were significant in univariate analysis, they were of inferior significance in multivariate analysis as compared to those mentioned above. Other factors analysed in the study, especially hypertension, overweight, functional class of heart failure and the severity of coronary lesions, did not reach statistical significance in the aspect of prognosis.

Table III. Comparison of results of basic additional tests between survivors (group I) and non-survivors (group II)

Parameter	Group I n=19	Group II n=87	р
Haemoglobin (g/dl)	13.3±2	14.4±1.6	0.002
Total cholesterol (mg/dl)	216±40	214±53	NS
HDL (mg/dl)	40±10	41±10	NS
TG (mg/dl)	169±79	195±110	NS
CKMB (U/l)	35	29.9	NS
Leukocytosis (1000/mm³)	10.7±5.7	8.2±2.2	0.005
Creatinine (mmol/l)	1.1±0.2	1.0±0.2	NS
Uricaemia (mg/dl)	45.4	39.7	NS
AspAT (U/I)	40±29	44±91	NS
Alat (U/l)	30.5	28.3	NS
EF (%)	37±15	46±11	0.0012
Left ventricular systolic diameter (mm)	41±9	38 ± 8	NS
Left ventricular diastolic diameter (mm) 50	50	NS
LBBB	3 (16%)	12 (14%)	NS
RBBB	3 (16%)	4 (5%)	NS
Gensini score	74±33	71±41	NS
Gensini score proximal	36±30	42±40	NS
Gensini score distal	38±27	28±24	NS

TG – triglycerides, CKMB – izoenzyme of creatine kinase, LBBB – left bundle branch block, RBBB – right bundle branch block, AlAt – Alanine aminotransferase, AspAt – Asparagine aminotransferase, EF – ejection fraction

The cut-off values of leukocytosis as well as haemoglobin level, which most precisely identified the groups of increased mortality risk, were established based on the ROC curves. Leucocytosis value of >11.3 \times 106 and haemoglobin level <12.3 g/dl were associated with higher risk of mortality – sensitivity and specificity were 35% and 91%, respectively. Area under ROC curve for leukocytosis and haemoglobin was 0.59 and 0.65, respectively.

Logistic regression analysis revealed that the risk of death in long-term follow-up was 6.3 times higher in patients with haemoglobin <12.3 g/dl (95% CI 1.4-29), and 6 times higher in patients with leukocytosis over 11.3 \times 106 (95% CI 1.4-25). The ROC curves and logistic regression analysis results are given in Figures 1-5.

Discussion

Identification of risk factors in patients with multivessel CAD primarily disqualified from interventional treatment allows therapeutic interventions to be intensified in order to reduce the incidence of cardiovascular complications, which are very frequent in

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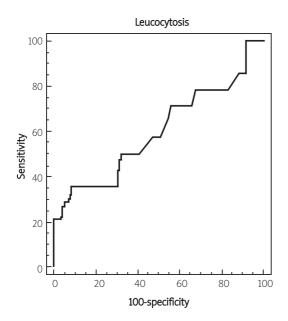


Figure 1. ROC curve presenting sensitivity and corresponding specificity for various cut-off values of leucocytosis. Values of leucocytosis higher than 11.3 t/mm³ are associated with 6 × higher risk of mortality-sensitivity 35%, specificity 91%, area under ROC curve 0.59

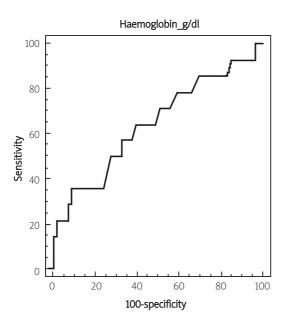


Figure 3. ROC curve presenting sensitivity and corresponding specificity for various cut-off values of haemoglobin. Values of level of haemoglobin under 12.3 g/dl are associated with 6.3 × higher risk of mortality-sensitivity 35%, specificity 91%, area under ROC curve 0.65

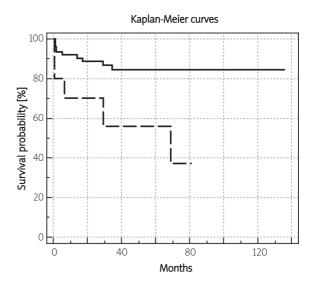


Figure 2. Survival of patients with leucocytosis lower (continuous line) and higher (dashed line) than 11.3 t/mm³

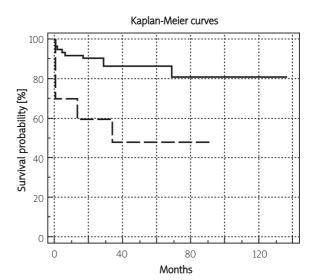


Figure 4. Survival of patients with values of haemoglobin level higher (continuous line) and lower (dashed line) than 12.3 g/dl

this group [1, 13]. The optimisation of pharmacotherapy seems to be a fundamental part of management. Invasive laser therapy as well as cellular and gene therapy and other methods hold some promise; their usefulness requires detailed studies [14-16].

In the present study, decreased LV ejection fraction, diabetes mellitus, advanced age, history of stroke and increased heart rate appear to be the risk factors of clinically stable multi-vessel CAD. Interestingly, the

highest statistical significance was reached by haemoglobin level and leucocytosis, the parameters assessed in the most frequently performed test, namely blood cell count. Usually they are not regarded as valuable predictors in this group of patients and often they are only a part of the routine diagnostic process. What is more, the above-mentioned factors appear to be stronger prognostic factors than those generally recognised, such as arterial hypertension, excess weight, overt peripheral artery disease or other parameters evaluated in the study [1, 3, 6, 7, 17].

Haemoglobin level as a significant prognostic factor in patients with CAD was evaluated in several studies [18, 19]. Many reports define anaemia as an unfavourable predictor in patients soon after acute coronary syndrome or in patients with heart failure. Low haemoglobin level increases myocardial energetic expenditure, leads to its overload and hypertrophy and thus increases the risk of cardiovascular events [18-20]. Comparing these results to our group of patients, many similarities can be noticed, justifying the validity of haemoglobin in the results of the present report. The study population was characterised by more or less advanced heart failure (mean EF=37%) due to the severity of atherosclerosis. In many patients coronary symptoms worsened and required hospitalisation during the follow-up.

Leucocytosis is also a demonstrated prognostic factor in CAD patients. Understanding the essence of atherogenesis, which for the pathologist is a form of inflammatory response to the factors adversely affecting the vessel wall, allows many markers of inflammatory reactions, essential for atherogenesis, to be identified. Apart from leucocytosis – the simplest diagnostic tool, but of the lowest sensitivity and specificity - available markers also include: pro- and anti-inflammatory cytokines, adhesion molecules, oxidated lipoproteins, C-reactive protein or type A amyloid [21]. Both in patients with acute coronary syndromes and with stable CAD high leucocytosis is associated with increased risk of subsequent cardiovascular events [22, 23]. As the results of the present study have shown, assessment of this obviously simple parameter can be helpful in specific clinical situations in patients with CAD, including multivessel disease. One should expect that other inflammatory markers mentioned but not analysed in the present study would also achieve statistically significant prognostic value in the study population, due to their considerably higher sensitivity.

It is noticeable that mortality in our patients with multi-vessel CAD was relatively low – total mortality was 18% which gives annual mortality of only 2.4%. We believe that the main reason for this improved

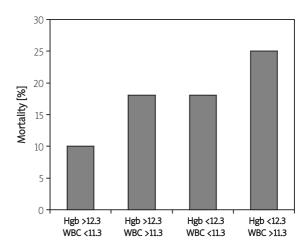


Figure 5. Mortality as a function of haemoglobin (Hgb) and leucocytosis (WBC) levels

prognosis are advances in pharmacological treatment of CAD. At the end of a 7-year follow-up period, all our patients were treated with anti-platelet agents and more than 70% received optimal four-drug anti-anginal protection. There are no recent data in literature on survival in patients with multi-vessel CAD who are not amenable to CABG. Our results documenting improved prognosis in this group of patients are important in view of data presented by Feit et al. [24] who in the meta-analysis of randomised studies comparing efficacy of CABG and coronary angioplasty in patients with multi-vessel CAD showed that the mortality rates in these two groups are comparable, being 13.9% and 14.2%, respectively.

In contrast in a study of Berton et al. [25] in 100 patients with 6 years of follow-up total mortality was as high as 42%. Female gender and functional class of heart failure appeared to be the most significant prognostic parameters. It should be emphasised that the spectrum of analysed factors was narrow, and haemoglobin level and leucocytosis were not taken into consideration. These data were presented in 1985, when the guidelines, and the pharmacotherapy in particular, differed from the present ones.

The above mentioned improvement in the prognosis of patients with a multi-vessel CAD, documented in our study, deserves further studies. It seems that nowadays this condition no longer belongs to illnesses with the most serious adverse prognosis.

Conclusions

Low haemoglobin level and high leucocytosis (multivariate analysis) and decreased LV ejection fraction, diabetes mellitus, advanced age, history of stroke and

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increased heart rate (univariate analysis) are risk factors in clinically stable multi-vessel CAD in patients who are not suitable candidates for interventional treatment. It implies the requirement of strict cardiologic monitoring of patients with poor prognosis. More intensive pharmacotherapy and the use of innovative methods of treatment in future, e.g. laser, cellular and gene therapy, may improve the prognosis.

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Czynniki prognostyczne u chorych z ciężką, wielonaczyniową chorobą wieńcową

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Streszczenie

Wprowadzenie: Wielonaczyniowa choroba wieńcowa bez możliwości przeprowadzenia zabiegów rewaskularyzacji stanowi wyzwanie dla współczesnej kardiologii. Bardzo wysoka śmiertelność, jak również trudności terapii farmakologicznej w tej grupie pacjentów decydują o wielkim zainteresowaniu tą jednostką chorobową.

Cel badania: Zdefiniowanie najistotniejszych czynników rokowniczych u chorych ze stabilną klinicznie wielonaczyniową chorobą niedokrwienną serca, u których nie jest możliwe przeprowadzenie zabiegu przezskórnej lub chirurgicznej rewaskularyzacji.

Metodyka: Grupę badaną stanowiło 106 pacjentów, w tym 79 mężczyzn, średni wiek 66±8 lat. W badaniu koronarograficznym rozpoznano wielonaczyniową chorobę serca, pierwotnie niekwalifikującą się do leczenia interwencyjnego – przezskórnej angioplastyki wieńcowej (PTCA) lub pomostowania aortalno-wieńcowego (CABG). Cukrzycę rozpoznano u 38 (36%) pacjentów, a u 5 (5%) – przebyty udar mózgu. Średnia wartość frakcji wyrzutowej lewej komory wynosiła 37±15%, średnie *Gensini score* naczyń wieńcowych 72±34.

Wyniki: W trakcie obserwacji, która trwała średnio 7,4 \pm 4 lata, zmarło 19 (18%) pacjentów, u 11 (10%) pacjentów wykonano ze wskazań życiowych CABG. Znaczenie rokownicze miały: starszy wiek (p=0,014), wyższa częstotliwość rytmu serca (p=0,02), współistnienie cukrzycy (p=0,003), niewydolność nerek (p=0,0003), niewydolność serca (p=0,013), przebyty udar mózgu (p=0,006), niższa frakcja wyrzutowa lewej komory (p=0,0012), jednak w analizie wieloczynnikowej parametrami najsilniej związanymi z rokowaniem były: obniżony poziom hemoglobiny (p=0,007) oraz podwyższona leukocytoza (p=0,002). Analiza krzywej ROC wykazała, iż pacjenci z hemoglobiną niższą niż 12,3 g/dl charakteryzowali się 6,3-krotnie wyższym ryzykiem zgonu w obserwacji odległej (95% CI 1,4–29), a z leukocytozą wyższą niż 11,3 × 10 6 – 6-krotnie wyższym ryzykiem zgonu (95% CI 1,4–25).

Wnioski: U pacjentów z wielonaczyniową chorobą wieńcową, niekwalifikujących się do zabiegu przezskórnej lub chirurgicznej rewaskularyzacji, wartość rokowniczą, poza współistnieniem cukrzycy, przebytym udarem mózgu, częstotliwością rytmu serca, wiekiem i frakcją wyrzutową lewej komory, mają także wysokie wartości leukocytozy oraz niskie wartości stężenia hemoglobiny. Intensywniejsza farmakoterapia oraz zastosowanie w przyszłości w tej grupie chorych nowatorskich form leczenia, m.in. laseroterapii, terapii komórkowej i genowej, może przynieść poprawę rokowania.

Słowa kluczowe: wielonaczyniowa choroba wieńcowa, rokowanie

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