

Characteristics, management and five-year outcomes of patients with high risk, stable multivessel coronary heart disease

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Abstract

Background: Multivessel coronary artery disease (MCAD) is a common manifestation of advanced coronary atherosclerosis.

Aim: To determine the clinical characteristics and long term follow up prognostic factors in patients with high risk, stable MCAD from a single institution.

Methods: We included in the final analysis 270 patients with stable MCAD. Patients were followed for the occurrence of death, stroke and myocardial infarction (MI). We defined a cumulative major adverse cardiac and cerebrovascular event (MACCE) as a composite of death, stroke, MI and urgent revascularisation. Median follow up was 5 years (4–5.5 years). 176 (65%) patients were treated surgically (coronary artery bypass grafting, CABG), 19 (7%) patients were treated percutaneously, while 75 (28%) patients were treated medically; this meant that 94 (35%) patients were treated non-surgically.

Results: Predictors of MACCE in the study group of patients revealed by univariate logistic regression analysis were: diabetes mellitus ($p = 0.04$), kidney failure ($p = 0.05$), total cholesterol ($p = 0.05$), LDL-cholesterol ($p = 0.02$), chest pain symptoms in CCS III class ($p = 0.05$), heart rate ($p = 0.02$), NT-proBNP ($p = 0.01$), left ventricular diastolic ($p = 0.003$) and systolic diameter ($p = 0.003$), left ventricular ejection fraction ($p = 0.001$), Gensini score ($p = 0.05$) and CABG treatment strategy ($p = 0.001$). In Cox logistic regression analysis, non CABG treatment strategy ($b = 0.06$), heart rate ($b = 0.02$), and LDL cholesterol level ($b = 0.006$) were independent predictors of MACCE ($p = 0.01$).

Conclusions: Our study showed that patients with advanced MCAD who are qualified for complete surgical revascularisation benefitted more with regard to several primary end points at five-year follow-up than those who were not qualified for surgery and who were treated with medical therapy supplemented in selected cases with incomplete percutaneous revascularisation.

Key words: multivessel coronary artery disease, stable, prognosis, treatment

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INTRODUCTION

Coronary artery disease (CAD) is the main cause of death in developed countries [1]. Despite the progress in cardiology, global cardiovascular mortality is still very high, exceeding 7 million in 2002 [2]. Multivessel coronary artery disease (MCAD), defined as subcritical or critical stenosis (cross-section area decreased by $\geq 75\%$) of at least two of the three main coronary arteries supplying the myocardium, is a common manifestation of advanced coronary atherosclerosis [2]. It has been estimated that it could make up as much as

50% of all cases of CAD. The severity of atherosclerosis and numerous complications, with a concomitant lack of clear classification systems and diagnostic criteria, bring about an exceptionally high mortality rate in this population, which in five-year follow-ups ranges from 10% to as much as 60%, depending on the advancement of atherosclerotic lesions as well as other risk factors [3].

Coronary artery bypass grafting (CABG) is the treatment of choice for patients with MCAD, and its effectiveness has been confirmed by many randomised trials [4–6]. However,

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the introduction of drug-eluting stents (DES) has improved the results of percutaneous coronary interventions (PCI) in terms of restenosis, thus increasing the percentage of multivessel disease patients treated with the catheter-based approach.

Nonetheless, due to many reasons (e.g. the presence of serious medical conditions, one or more chronic total occlusions, left ventricular dysfunction, or simply because the physician's opinion the treatment of selected lesions and vessels is considered adequate for the relief of symptoms) PCI patients cannot always be offered complete revascularisation, making this strategy less attractive for most MCAD patients [7].

The aim of this study was to determine the clinical characteristics and long term follow up prognostic factors in patients with high risk, stable MCAD.

METHODS

The study involved a group of 302 patients hospitalised at the Department of Cardiology, Medical University in Lodz, Poland, from July 2007 to May 2009 who met the following criteria: (1) CAD with $\geq 75\%$ diameter stenosis in three main coronary branches (right coronary artery, circumflex branch and left anterior descending branch of left coronary artery) as confirmed on coronary angiography. Diameter stenosis of the left main coronary artery exceeding 70% represented an exclusion criterion due to the need for urgent revascularisation; (2) stable coronary heart disease (Canadian Cardiovascular Society; CCS I–III); (3) heart failure symptoms New York Heart Association (NYHA) class I–III; and (4) absence of significant acquired valve disease resulting in predicted survival below one year.

Following discharge from the Department, all patients remained under the care of the Cardiology Outpatient Clinic and were treated according to the guidelines of the European Society of Cardiology. The choice of treatment strategy (CABG, PCI or medical strategy) was made during joint consultations between cardiologists and cardiac surgeons (the Heart Team). The main factors determining treatment strategy were the clinical severity of the disease, angiographic presentation, as well as patient preference. All the patients qualified for CABG were treated in the 1st Department of Cardiosurgery, Medical University in Lodz, receiving left internal mammary artery grafting of the left descending branch (LIMA to LAD) and at least two saphenous vein grafts to other coronary vessels (and complete revascularisation). There were no cases with complete arterial revascularisation. All the patients qualified for PCI were treated for selected lesions. This was considered adequate for the relief of the patient's symptoms (incomplete revascularisation). Patients included in the study signed informed consent to participate; the study was also approved by the Bioethics Committee at the Medical University in Lodz (Poland).

All the patients had additional laboratory tests including: complete blood count, complete lipid profile, fasting

blood glucose (and in non-diabetic patients an oral glucose tolerance test with blood glucose measurement after 2 h), creatinine kinase-MB, urea, creatinine, glomerular filtration rate (GFR; measured with the Cockcroft-Gault formula), hepatic transferases, C-reactive protein and N-terminal pro B-type natriuretic peptide (NT-proBNP) levels. Transthoracic echocardiography, resting electrocardiography, and electrocardiographic exercise test, were performed at baseline in all patients. Based on coronary angiographic results, the severity of atherosclerotic changes was semiquantitated with Gensini score. Lesions formed (involving lesion severity and location) in left main and proximal segments of left descending artery, circumflex and right coronary artery were grouped to calculate the proximal Gensini score; distal lesions located in the remaining coronary segments yielded the distal Gensini score.

Patients were followed for the occurrence of death (all-cause and cardiac), stroke and myocardial infarction (MI). We defined a cumulative major adverse cardiac and cerebrovascular event (MACCE) as a composite of death, stroke, MI and urgent revascularisation. The necessary medical information was obtained from phone calls to patients or their family (from October to December 2012). MI during follow-up was defined according to the recent universal definition. Death was classified as cardiac if the predominant and immediate cause was related to ischaemia, arrhythmia, refractory heart failure or if death was sudden and unexpected in nature. Kidney failure was defined as a GFR below 30 mL/min. Information regarding death was obtained by review of the death certificate and conversation with the family.

Statistical analysis

Statistical analysis was performed using the MedCalc 11.4.4.0. The Shapiro-Wilk test was used for determining the normality of distribution of the analysed variables. Constant variables showing normal distribution are presented as means \pm standard deviations, whereas constant variables of distribution different from normal and ordinal variables are expressed as medians (25th–75th percentile). Variance analysis and the Wilcoxon non-parametric test were applied to compare the differences in the presence of particular features in patient groups. The results were considered statistically significant if the p value was < 0.05 . In univariate analysis, due to lack of normality of distribution of the majority of the analysed variables, the Mann-Whitney U test was used to compare continuous variables in the study group, and the χ^2 test for independence was applied to compare constant variables. For selected parameters, receiver operating characteristic curves (ROC) were plotted. Cox logistic regression analysis was used regarding variables that significantly influenced MACCE in univariate analysis (diabetes mellitus, kidney failure, total cholesterol, low density lipoprotein [LDL]-cholesterol, chest pain symptoms in CCS III class, heart rate, left ventricular diastolic and systolic diameter, left ventricular ejection fraction [LVEF],

Gensini score and non CABG treatment strategy). Results were presented as regression coefficient (b) and standard error (SE). Kaplan-Meier analysis was used to compare the survival in groups defined by treatment strategy.

RESULTS

Baseline characteristics

302 patients were enrolled in the study. As some were lost to follow up, we included in the final analysis 270 patients. Median follow up was 5 years (4–5.5 years). Of the 270 patients, 208 (77%) were male, and mean age was 66 years. All the patients complained of chest pain, 108 (40%) patients had CCS III class chest pain, 46 (17%) patients had NYHA III class heart failure symptoms. The mean Gensini score in the study group was 85 (56–116), with the proximal Gensini score being 44.5 (19–80) and the distal one 32 (10–34). The baseline demographic, clinical, laboratory, angiographic characteristics, as well as medical treatment during follow up stratified by the treatment strategy are shown in Tables 1–3. 176 (65%) patients were treated surgically (CABG), 19 (7%) patients were treated percutaneously, while 75 (28%) patients were treated medically; this meant that 94 (35%) patients were treated non-surgically.

Patients qualified for medical therapy were older and had significantly more severe heart failure symptoms, lower LVEF, and higher distal Gensini score.

Clinical endpoints

During median 5 years (4–5.5 years) follow up from 270, there were 62 deaths (23%, 59 from cardiovascular reasons), including 28 (16%) in the CABG group and 34 (36%) in the non CABG group. There were 20 (7%) strokes (12 vs. 8), 19 (7%) MIs, and 12 (4%) urgent PCI revascularisations. A cumulative MACCE occurred in 88 (33%) patients (42 [24%] in the CABG group and 46 [48%] in the non CABG group). All events during follow-up are summarised in Table 4.

Survival analysis

Predictors of MACCE in the study group of patients, revealed by univariate logistic regression analysis were: diabetes mellitus ($p = 0.04$), kidney failure ($p = 0.05$), total cholesterol ($p = 0.05$), LDL-cholesterol ($p = 0.02$), chest pain symptoms in CCS III class ($p = 0.05$), heart rate ($p = 0.02$), NT-proBNP ($p = 0.01$), left ventricular diastolic ($p = 0.003$) and systolic diameter ($p = 0.003$), LVEF ($p = 0.001$), Gensini score ($p = 0.05$) and non CABG treatment strategy ($p = 0.001$). LVEF $\leq 35\%$ was associated with a 3.65-fold increase in MACCE risk (OR 3.65; 95% CI 1.6–8.4); LDL ≥ 80 mg/dL with a 2.98-fold increase in MACCE risk (OR 2.98; 95% CI 0.8–8.2); and NT-proBNP ≥ 299 pg/mL with a 3.1-fold increase in MACCE risk (OR 3.1; 95% CI 1.2–11.3) (Figs. 1–3).

In Cox logistic regression analysis, non CABG treatment strategy ($b = 0.06$; SE = 0.01; $p = 0.01$), heart rate ($b = 0.02$;

Table 1. Selected demographic and clinical data of patients with multivessel coronary disease stratified by treatment strategy (CABG vs. non-CABG)

	CABG (n = 176)	Non CABG (n = 94)	P
Male	135 (77%)	73 (77%)	NS
Age [years]	65 (63.4–66.5)	68 (66.4–70.4)	0.002
Diabetes mellitus	67 (38%)	36 (38%)	NS
Kidney failure	4 (2%)	5 (5%)	NS
Arterial hypertension	149 (85%)	83 (88%)	NS
Smoking	37 (21%)	18 (19%)	NS
Obesity	89 (51%)	39 (41%)	NS
Atrial fibrillation	9 (5%)	7 (7%)	NS
Past stroke	12 (7%)	4 (4%)	NS
MI history	110 (62%)	64 (68%)	NS
CCS III	73 (41%)	35 (37%)	NS
NYHA III	20 (11%)	26 (28%)	0.006
LVEF < 40%	30 (17%)	29 (31%)	0.01
Heart rate [bpm]	70 (62–75)	70 (60–75)	NS
METS during ET	5.8 (5.4–6.2)	5.6 (4.9–6.3)	NS
LVEF [%]	50 (43–55)	47 (37–52)	0.005
LV diastole [mm]	50 (45–52)	48 (46–55)	0.04
LV systole [mm]	34 (31–39)	36 (33–44)	0.03
Gensini score	83 (56–113)	90 (60–116)	NS
Proximal Gensini score	46 (19–83)	42 (19–80)	NS
Distal Gensini score	30 (6–48)	36 (16–60)	0.007

CABG — coronary artery bypass grafting; CCS — Canadian Cardiovascular Society; ET — exercise test; LVEF — left ventricular ejection fraction; LV — left ventricle; METS — metabolic equivalents; MI — myocardial infarction; NS — not significant; NYHA — New York Heart Association

Table 2. Medical treatment during five-year follow-up in multivessel coronary heart disease patients according to treatment strategy (CABG vs. non CABG)

	CABG (n = 176)	Non CABG (n = 94)	P
Acetylsalicylic acid	172 (98%)	94 (100%)	NS
Clopidogrel	5 (3%)	8 (8%)	NS
ACEI/ARB	158 (90%)	90 (96%)	NS
Beta-blockers	170 (97%)	91 (94%)	NS
Statins	173 (98%)	90 (97%)	NS
Nitrates	96 (55%)	48 (51%)	NS
Digoxin	16 (9%)	18 (19%)	NS
Diuretics	26 (15%)	20 (21%)	NS

ACEI — angiotensin converting enzyme inhibitors; ARB — angiotensin receptor blockers

Table 3. Selected laboratory test results in multivessel coronary heart disease patients according to treatment strategy (CABG vs. non CABG)

	CABG (n = 176)	Non CABG (n = 94)	P
Total cholesterol [mg/dL]	176 (150–210)	172 (149–201)	NS
LDL cholesterol [mg/dL]	99 (76.5–126.5)	103.5 (80–123)	NS
HDL cholesterol [mg/dL]	45 (39–53)	45 (38–52)	NS
Triglycerides [mg/dL]	128 (94–182)	126 (92–173)	NS
Creatinine [mg/dL]	0.96 (0.84–1.1)	0.975 (0.85–1.1)	NS
C-reactive protein [g/dL]	2.1 (1.3–5.3)	3 (1.9–5.7)	NS
Glucose [mg/dL]	103 (92–126)	100 (88–134)	NS
Haemoglobin [mg/dL]	14.45 (13.5–15.4)	14.2 (13.3–15.4)	NS
NT-proBNP [pg/mL]	288 (155–829)	540 (174–1,200)	0.05

CABG — coronary artery bypass grafting; NT-proBNP — N-terminal pro B-type natriuretic peptide

Table 4. MACCE during follow up in study groups

	CABG (n = 176)	Non CABG (n = 94)	P
Death	28 (16%)	34 (36%)	0.001
Stroke	12 (7%)	8 (8%)	NS
Myocardial infarction	6 (3%)	13 (14%)	0.001
Urgent PCI	9 (5%)	3 (3%)	NS
Hospitalisation	44 (25%)	38 (40%)	NS
MACCE	42 (24%)	46 (49%)	0.001

CABG — coronary artery bypass grafting; MACCE — major cardiac and cerebrovascular adverse events; PCI — percutaneous coronary intervention

SE = 0.005; p = 0.03) and LDL-cholesterol level (b = 0.006; SE = 0.002; p = 0.04) were independent predictors of MACCE (p = 0.01).

DISCUSSION

Our study presents long-term outcome data from a single institution to report on five-year outcomes of patients with stable MCAD treated with one of the three current therapeutic strategies: CABG, medical therapy alone, or PCI.

Because of the small number of PCI patients who had received incomplete revascularisation (treatment of selected

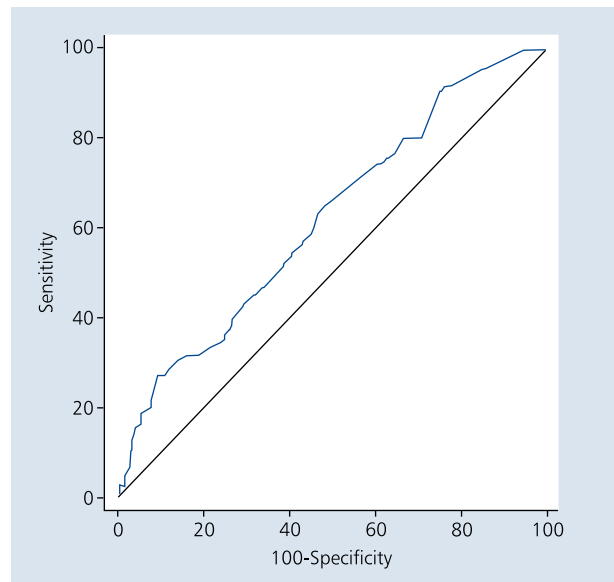


Figure 1. Receiver operating characteristic (ROC) curve presenting sensitivity and corresponding specificity for various cut-off values of ejection fraction (EF) values. Values of EF below 35% are associated with a 3.65 × higher risk of major cardiac and cerebrovascular adverse events (MACCE); area under ROC curve 0.62 (p < 0.001)

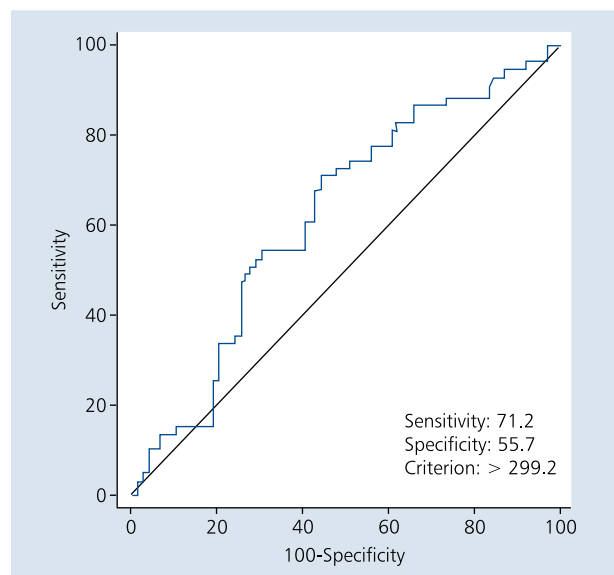


Figure 2. Receiver operating characteristic (ROC) curve presenting sensitivity and corresponding specificity for various cut-off values of N-terminal pro B-type natriuretic peptide (NT-proBNP) values. Values of NT-proBNP higher than 299 pg/mL are associated with a 3.1 × higher risk of major cardiac and cerebrovascular adverse events; area under ROC curve 0.62 (p = 0.01)

lesions was considered adequate for the relief of symptoms) and the small value of the potential statistic, we decided to

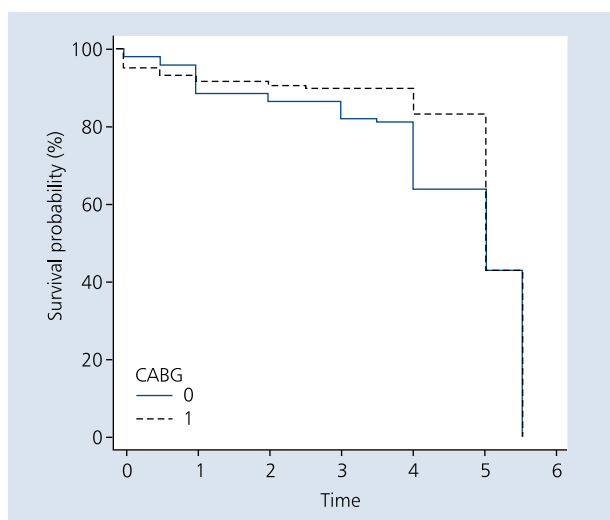


Figure 3. Kaplan-Meier curves for major cardiac and cerebrovascular adverse events (MACCE) according to coronary artery bypass grafting (CABG) qualifications (log-rank $p = 0.0004$)

combine these patients into the medical therapy group and create a non CABG treated group. The present data from the five-year outcomes shows that compared to CABG, non CABG strategy was associated with a significantly higher incidence of combined events, cardiac death and subsequent MI. Additionally, lack of qualification to CABG surgery was in multivariate logistic regression analysis, after LDL level and heart rate ratio, an independent predictor of MACCE.

Our findings are similar to those of large trials and meta-analyses of previous randomised trials comparing PCI vs. CABG and medical therapy alone vs. CABG, conducted in patients with multivessel disease, which showed a significantly higher mortality rate with percutaneous or medical treatment during long term follow up (SoS, MASS II, SYNTAX) [8–13]. On the other hand, in other big trials there were no significant differences in mortality rates at five-year follow-up (BARI: 10.7% for CABG compared to 13.7% for angioplasty; ARTS: 8.0% vs. 7.6%, respectively) and CABG strategy was superior only due to the reduced further need for revascularisation [14, 15]. In our study, overall mortality rates were much higher than in the aforementioned trials (16% in the CABG group and 36% in the non CABG group at five years). These differences are the consequences of the much more serious clinical characteristics of our population, with a higher incidence of risk factors, older age of patients, more severe heart failure symptoms, and a higher incidence of very diffuse atherosclerotic process in coronary vessels (very high Gensini score, especially distal Gensini score).

The role of CABG surgery in contrast to medical therapy has been assessed in meta-analyses as well as in some smaller trials that have shown a significant survival benefit for patients with MCAD [16–19]. Moreover, CABG surgery compared

to medical therapy improves quality of life [20]. On the other hand, new medical treatment methods (with angiotensin converting enzyme inhibitors and beta-blockers) have evolved to offer patients a survival rate that is much higher than the natural history of their disease [21–23]. Moreover, no evidence exists that PCI in stable patients prolongs life [24]. Unfortunately, very little information is currently available from randomised controlled trials that have included the medical strategy alone. In the MASS II and ARTS trials, CABG was superior to medical therapy for the relief of angina and less objective ischaemia. Moreover, CABG reached an independent significant reduction of major adverse cardiac events compared to medical treatment alone.

The results of a meta-analysis based on existing reports showed that patients receiving complete revascularisation experience better clinical outcomes than those receiving incomplete revascularisation [25].

In our study, all CABG patients achieved complete anatomic revascularisation compared to PCI patients where procedures were limited only to lesions, which was considered adequate for the relief of symptoms. That is one of the reasons behind the reduced number of angina-free patients at five-year follow-up in the CABG group. Additionally, these results might be related because of the unexpected very little further revascularisation procedures in the non CABG group, lower than in the CABG group (3 vs. 9 in CABG group). This could be because of the more serious clinical characteristics of the non CABG population, with a higher incidence of very diffuse atherosclerotic process in coronary vessels proceeding to advanced heart failure symptoms.

CONCLUSIONS

Our study strongly showed the benefit of complete surgical revascularisation over medical therapy connected with percutaneous interventions in selected patients with advanced MCAD with regard to several primary end points at five-year follow-up. Additionally, CABG surgery was an independent predictor of higher rates of event-free survival.

Conflict of interest: none declared

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Charakterystyka, leczenie i rokowanie pacjentów ze stabilną, wielonaczyniową chorobą wieńcową: pięcioletnia obserwacja

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Streszczenie

Wstęp: Wielonaczyniowa choroba wieńcowa (MCAD) jest częstą manifestacją zaawansowanego stadium miażdżycy.

Cel: Celem pracy były jednośrodkowa charakterystyka oraz identyfikacja czynników rokowniczych u pacjentów wysokiego ryzyka ze stabilną MCAD w trakcie 5-letniej obserwacji.

Metody: Do ostatecznej analizy włączono 270 pacjentów ze stabilną MCAD. Pierwszorzędowy złożony punkt końcowy (MACCE) zdefiniowano jako zgon, udar mózgu, zawał serca i konieczność pilnej rewaskularyzacji. Mediana czasu obserwacji wyniosła 5 lat (4–5,5 roku). Kardiochirurgicznie leczono 176 (65%) pacjentów, u 19 (7%) osób wykonano zabieg przezskórny jednej z tętnic wieńcowych, 75 (28%) chorych leczono zachowawczo; co stanowi 94 (35%) pacjentów leczonych niechirurgicznie.

Wyniki: W analizie jednoczynnikowej parametrami istotnie powiązanymi z wystąpieniem MACCE były: cukrzyca typu 2 ($p = 0,04$), niewydolność nerek ($p = 0,05$), stężenie cholesterolu całkowitego ($p = 0,05$), stężenie cholesterolu frakcji LDL ($p = 0,02$), nasilenie dławicy do III klasy CCS ($p = 0,05$), częstość rytmu serca ($p = 0,02$), stężeniami N-końcowego fragmentu propeptydu natriuretycznego typu B (NT-proBNP, $p = 0,01$), wymiar rozkurczowy ($p = 0,003$) i skurczowy lewej komory ($p = 0,003$), frakcja wyrzutowa lewej komory ($p = 0,001$), Gensini score ($p = 0,05$) oraz niechirurgiczna strategia terapeutyczna ($p = 0,001$). W analizie regresji logistycznej metodą Coxa czynnikami niezależnie powiązanymi z rokowaniem były: niechirurgiczna metoda leczenia ($b = 0,06$), częstość rytmu serca ($b = 0,02$) i stężenie cholesterolu frakcji LDL ($b = 0,006$); $p = 0,01$ dla modelu.

Wnioski: Pacjenci z grupy wysokiego ryzyka ze stabilną MCAD poddawani pełnej chirurgicznej rewaskularyzacji, w porównaniu z chorymi leczonymi zachowawczo, w wybranych przypadkach wraz z zabiegiem przezskórnej, niepełnej rewaskularyzacji, odnoszą większą korzyść wyrażoną redukcją wybranych punktów końcowych w trakcie 5-letniej obserwacji.

Słowa kluczowe: leczenie, rokowanie, stabilna, wielonaczyniowa choroba wieńcowa

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