

Functionally driven complete vs incomplete revascularisation in multivessel coronary artery disease — long-term results from a large cohort

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Abstract

Background: Complete revascularisation (CR) by means of percutaneous coronary intervention (PCI) has been associated with better long-term prognosis than incomplete revascularisation (IR) in several clinical trials. However, in the published studies, the completeness of myocardial revascularisation has been judged mainly on an anatomical basis, while including criteria directed at functionally driven IR might lead to different results.

Aim: To examine the potential value of functionally driven IR in a large cohort of patients with multivessel coronary artery disease (MVD) undergoing PCI.

Methods: The study population consisted of 908 patients with MVD undergoing PCI without stenting between 1988 and 1997. Functionally driven IR was defined as dilation of all segments with > 70% stenosis, with the exception of arteries supplying an area of previous transmural myocardial infarction (MI) or a small amount of myocardium. Complete revascularisation was defined as successful PCI of all coronary artery lesions with significant narrowing not fulfilling the above criteria. Patients were followed for a mean 11 years (range 8–16 years). End-points included: death, MI, re-PCI or coronary artery bypass grafting (CABG).

Results: Complete revascularisation was performed in 284 (31.3%) patients. Follow-up was obtained from 873 (96.1%) patients. There was no significant difference in the frequency of all-cause mortality, cardiovascular deaths or MI between patients who underwent CR and IR. Patients who underwent IR were more likely to require re-PCI and had a trend toward more frequent CABG.

Conclusions: In comparison to CR, a strategy of functionally driven IR by means of PCI without stenting does not increase the rate of major cardiovascular outcomes, but is related to higher frequency of repeat procedures during a long-term follow-up.

Key words: coronary artery disease, percutaneous coronary intervention, revascularisation, outcomes

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INTRODUCTION

Complete revascularisation (CR) by means of percutaneous coronary intervention (PCI) has been associated in several clinical trials with better long-term prognosis than incomplete revascularisation (IR) [1–7]. However, in the published

studies the completeness of myocardial revascularisation has been judged mainly on an anatomical basis, while including criteria directed at functionally driven IR might lead to different results [8]. Such a strategy is based on the definition of IR as revascularisation limited to stenotic segments sup-

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plying large amounts of myocardium without evidence of previous myocardial infarction (MI). Single reports on relatively small samples, and with a follow-up not exceeding three years, indicated that IR could be an attractive alternative to CR [9, 10].

In order to further analyse the potential value of functionally driven IR, we sought to compare long-term outcomes in a large cohort of patients with multivessel coronary artery disease (MVD) undergoing PCI without stenting. Additionally, we attempted to find the independent risk factors of long-term outcomes in the studied group.

METHODS

Patients and PCI procedures

There were 3,252 PCI procedures (all without stenting) performed in our institution between 1988 and 1997. Of those, 908 patients with angiographically confirmed MVD who underwent PCI of at least one coronary artery without serious in-hospital complication (death, MI) were included in the further analysis. The mean age of patients was 53 years (range 30–83) and 83% of them were male.

Indications for CR were: the presence of significant stenosis (> 70%) in the first two segments of the left anterior descending (LAD) or circumflex (Cx) artery; or in the first three segments of the right coronary artery (RCA); or in the secondary arteries (diagonal, marginal) if they supplied a large amount of myocardium (the decision was left to the interventional cardiologist and the treating physician) without evidence of previous Q-wave MI.

Incomplete revascularisation followed the same rules for the localisation of stenosis as CR, but excluded arteries supplying areas with the evidence of previous Q-wave MI or a small amount of myocardium. The diagnosis of Q-wave MI had to be confirmed by echocardiography showing akinesis or dyskinesis of the left ventricular (LV) wall corresponding with ECG changes. Complete revascularisation was defined as successful PCI of all coronary artery lesions with > 70% stenosis with residual stenosis of less than 50%. Patients not meeting the definition of CR were defined as having IR.

Baseline patient characteristics included: cigarette smoking (defined as current smoking or smoking cessation less than six months before PCI); hyperlipidaemia (defined as total cholesterol concentration in plasma > 200 mg/dL, LDL-cholesterol concentration in plasma > 130 mg/dL or treatment with lipid-lowering agents); diabetes (defined as fasting plasma glucose concentration above 125 mg/dL or current treatment with oral hypoglycaemic drugs or insulin); glucose intolerance (defined as fasting plasma glucose concentration between 110–125 mg/dL, glucose concentration in plasma after standard oral glucose tolerance test between 140–199 mg/dL or current hypoglycaemic treatment); LV systolic dysfunction (defined as LV ejection fraction [LVEF] on echocardiography or ventriculography below 40%); hypertension

(defined as an arithmetic mean of blood pressure from three consecutive registrations after ten minutes of supine rest exceeding ≥ 140 mm Hg for systolic blood pressure or ≥ 90 mm Hg for diastolic blood pressure or as a current antihypertensive treatment).

Follow-up

All patients were seen three, six and nine months after the percutaneous revascularisation and once a year thereafter for the next five years. Each visit included a clinical examination, exercise ECG testing and optimisation of drug treatment. Patients with recurrent angina or with a positive exercise ECG test were referred for coronary angiography. Long-term follow-up was performed after a mean of 11 years of observation (range 8–16 years). End of follow-up was defined as death or 31 December 2004. All data regarding new cardiovascular (CV) events during follow-up was collected via a questionnaire. Date and causes of death were obtained from family members, with a subsequent verification of medical records (including autopsy) or by checking data from the General Electronic Population Death Registry System of the Ministry of Internal Affairs and Administration of Poland. Information on other CV events was analysed from available medical records or by contacting the general practitioner.

Study end-points

Primary end-points were defined as: death from any cause, CV death or MI. Secondary end-points included the need for repeat PCI (re-PCI) or coronary artery bypass grafting (CABG).

Statistical analysis

All categorical variables are expressed as numbers and percentages and continuous variables as means and standard deviations or by medians and interquartile ranges in the presence or absence of normal distribution. Categorical variables were compared by χ^2 test and continuous variables by student t-test or Wilcoxon test, when appropriate. A Kaplan-Meier plot was used to show the association of CR and IR with study end-points. Subsequently, a multivariable Cox proportional hazards model was developed to evaluate the relationship between the type of revascularisation and the occurrence of the study end-points. Variables that entered the multivariable stage, except the type of revascularisation, were age, sex, unstable coronary artery disease (CAD), previous MI, hypertension, hyperlipidaemia, glucose intolerance, LV systolic dysfunction, three-vessel CAD, RCA disease and chronic total coronary occlusion. Multivariable stepwise logistic regression analysis, including all of the baseline characteristics parameters and the type of revascularisation, was performed to find independent predictors of pre-defined CV outcomes. All tests were two-tailed and p value < 0.05 was considered statistically significant. All statistical analyses were

Table 1. Baseline characteristics of the two studied groups

Parameters	Complete revascularisation (n = 284)	Incomplete revascularisation (n = 624)	P
Median age [years]	52.9 ± 10.0	52.9 ± 10.1	0.52
Male sex	237 (83.4%)	514 (82.4%)	0.30
Obesity	122 (43.0%)	236 (37.8%)	0.12
Body mass index [kg/m ²]	26.2 ± 1.3	26.5 ± 1.5	0.65
Unstable CAD	87 (30.6%)	225 (36.1%)	0.01
Previous myocardial infarction	166 (58.4%)	409 (65.5%)	0.04
Q-wave	83 (29.2%)	240 (38.5%)	0.003
Cigarette smoking	175 (61.6%)	372 (59.6%)	0.59
Hypertension	143 (50.3%)	266 (42.6%)	0.04
Hyperlipidaemia	106 (37.3%)	293/474 (61.8%)	< 0.0001
Diabetes	17 (6.0%)	45 (7.2%)	0.58
Glucose intolerance	81 (28.5%)	53 (8.5%)	< 0.0001
Left ventricular systolic dysfunction	28 (9.9%)	331 (53.0%)	< 0.0001
Multivessel CAD:			< 0.0001
Two-vessel	269 (94.7%)	512 (82.1%)	
Three-vessel	15 (5.3%)	112 (17.9%)	
Coronary artery stenosis (including main branches):			
LM	1 (0.4%)	2 (0.4%)	1.0
LAD	196 (69.0%)	448 (71.8%)	0.44
Cx	160 (56.3%)	350 (56.1%)	0.99
RCA	191 (67.3%)	345 (55.3%)	< 0.001
Chronic total coronary occlusion	71 (25.0%)	296 (47.4%)	< 0.0001

CAD — coronary artery disease; Cx — circumflex; LAD — left anterior descending; LM — left main; RCA — right coronary artery

performed using SAS software version 8e (SAS Institute, Cary, NC, USA).

RESULTS

Baseline characteristics

Complete revascularisation was successfully performed in 284 (31.3%) patients. Patients with IR were more likely to have unstable CAD, previous MI (especially Q-wave), hyperlipidaemia, LV systolic dysfunction, three-vessel CAD and chronic total coronary occlusion, but less likely to have hypertension, glucose intolerance or RCA stenosis compared to patients who underwent CR (Table 1). Medications prescribed during follow-up are shown in Table 2. Patients with CR received statins, beta-blockers, calcium-channel blockers, angiotensin converting enzyme (ACE) inhibitors and insulin more often than those with IR.

Long-term outcomes in CR and IR groups

Follow-up was obtained from 873 (96.1%) patients. The remaining 35 patients were lost to follow-up, but their baseline characteristics did not significantly differ from those of the

patients who remained in observation (data not shown). Long-term CV events in the two studied groups are presented in Table 3. There was no significant difference in the frequency of all-cause mortality, CV deaths or MI between patients with CR and IR assessed by means of the log-rank test (Fig. 1A–C) and with Cox proportional hazards model with and without adjustment for confounding factors (Table 3). However, patients who underwent IR were more likely to require re-PCI or had a trend toward higher frequency of CABG (Fig. 1D–E, Table 3).

Independent predictors of long-term outcomes

Multivariable logistic regression analysis demonstrated that the type of revascularisation (CR or IR) was not an independent predictor of all-cause death, CV death or MI. The only independent predictors of all-cause mortality were age (OR = 1.23 for every ten year increase, 95% CI 1.03–1.44, $p < 0.05$) and LV systolic dysfunction (OR = 2.0, 95% CI 1.35–2.95, $p < 0.001$). The only independent predictor of CV death was female gender (OR = 1.82, 95% CI 1.1–3.0, $p = 0.02$) and the independent predictors of MI were age (OR = 1.2 for

Table 2. Medications during follow-up in the two studied groups

Medication	Complete revascularisation (n = 284)	Incomplete revascularisation (n = 624)	P
Acetyl salicylic acid	212/233 (91.0%)	433/473 (91.5%)	0.92
Statin	194/233 (83.4%)	363/475 (76.4%)	0.04
Beta-blocker	213/233 (91.5%)	397/475 (83.6%)	0.006
Calcium-channel blocker	109/233 (46.6%)	176/475 (37.1%)	0.02
Angiotensin converting enzyme inhibitor	185/233 (79.1%)	334/474 (70.3%)	0.01
Long-acting nitrate	101/233 (43.2%)	188/468 (40.2%)	0.47
Diuretic agent	38/233 (16.2%)	73/470 (15.7%)	0.76
Warfarin	12/233 (5.1%)	16/468 (3.4%)	0.37
Oral hypoglycaemic agent	25/233 (10.7%)	41/470 (8.7%)	0.47
Insulin	18/233 (7.7%)	17/470 (3.6%)	0.03

Table 3. Long-term cardiovascular events in the two studied groups

Outcome	Complete revascularisation (n = 274)	Incomplete revascularisation (n = 599)	Unadjusted HR (95% CI)	P	Adjusted HR (95% CI)	P
All-cause mortality	46 (16.8%)	107 (17.9%)	1.04 (0.74–1.45)	0.84	1.04 (0.68–1.59)	0.86
Cardiovascular mortality	35 (12.8%)	75 (12.5%)	0.97 (0.65–1.45)	0.87	0.88 (0.53–1.47)	0.63
Myocardial infarction	62 (22.6%)	141 (23.5%)	1.01 (0.74–1.37)	0.97	1.28 (0.85–1.92)	0.23
re-PCI	34 (12.4%)	166 (27.7%)	2.33 (1.59–3.45)	< 0.0001	3.03 (1.85–4.76)	< 0.0001
CABG	44 (16.1%)	145 (24.2%)	1.56 (1.09–2.22)	0.02	1.54 (0.98–2.44)	0.06

Adjusted for: age, sex, unstable coronary artery disease, previous myocardial infarction, hypertension, hyperlipidaemia, glucose intolerance, left ventricular systolic dysfunction, three-vessel disease, right coronary artery disease and chronic total coronary occlusion; HR — hazard ratio; CI — confidence interval; re-PCI — repeat percutaneous coronary intervention; CABG — coronary artery bypass grafting

every ten year increase, 95% CI 1.1–1.31, $p = 0.03$) and previous MI (OR = 1.49, 95% CI 1.02–2.15, $p = 0.04$). Incomplete revascularisation and unstable CAD were independent predictors of a repeat PCI during follow-up (OR = 2.5, 95% CI 1.64–4.0, $p < 0.0001$ and OR = 1.2, 95% CI 1.02–1.49, $p = 0.03$, respectively). Incomplete revascularisation was also the only independent predictor of CABG (OR = 1.59, 95% CI 1.06–2.38, $p = 0.03$).

DISCUSSION

In the presented large cohort single-centre prospective registry of patients undergoing functionally driven CR or IR by means of PCI without stenting, there was no difference in terms of mortality or the frequency of MI between the two strategies at long-term follow-up. However, IR was related to higher frequency of repeat PCI and a trend toward higher frequency of CABG in comparison to CR.

As defined, IR was limited to stenotic arteries supplying large areas of uninfarcted myocardium. Therefore, patients undergoing IR were more likely to have a history of previous MI, the presence of chronically occluded coronary artery, and

lower LVEF. Despite a higher baseline risk and a lower likelihood of treatment with medications known to improve prognosis in patients with CAD (such as statins, beta-blockers and ACE-inhibitors) patients subjected to IR did not have an increased risk of major CV end-points in comparison to those undergoing CR [11]. Similar observations were made by Bourassa et al. [12] who analysed the results of percutaneous treatment in the BARI trial. In a group of approximately 900 patients, the type of revascularisation did not influence the frequency of deaths or MI at five-year follow-up, despite the poorer clinical profile of patients undergoing IR (i.e. higher frequency of prior MI, diabetes and multivessel disease, lower LVEF) in comparison to patients subjected to CR.

Our group is similar to the one reported by the National Heart, Lung and Blood Institute which included 757 consecutive patients, of whom 132 underwent CR (17.4%) [13]. After nine years of follow-up, there was no difference in mortality or MI between patients with IR and CR. However, patients after IR were more likely to report angina and require CABG. However, contrary to our results, patients with CR were more likely to be referred for repeat PCI. This may be

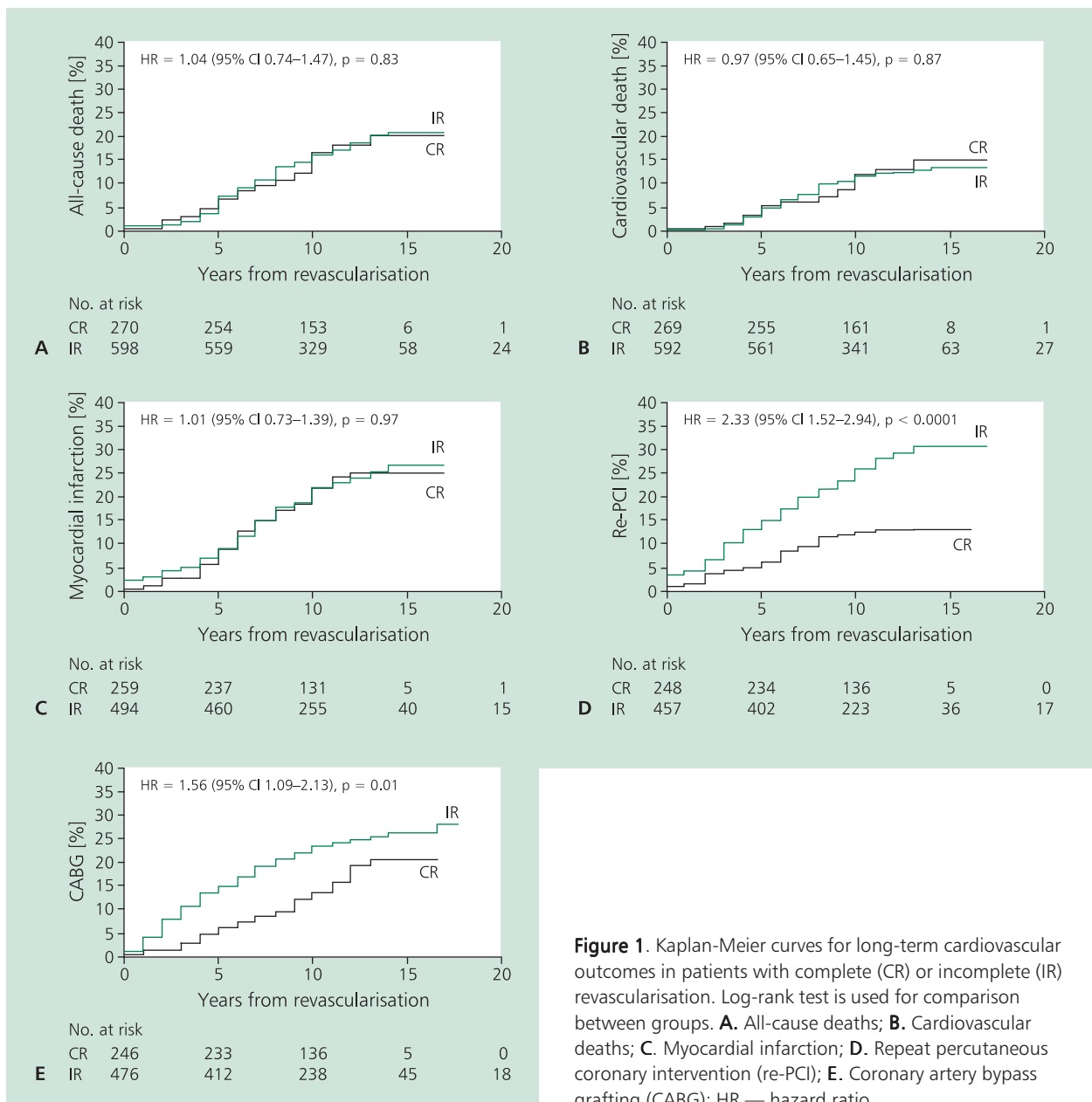


Figure 1. Kaplan-Meier curves for long-term cardiovascular outcomes in patients with complete (CR) or incomplete (IR) revascularisation. Log-rank test is used for comparison between groups. **A.** All-cause deaths; **B.** Cardiovascular deaths; **C.** Myocardial infarction; **D.** Repeat percutaneous coronary intervention (re-PCI); **E.** Coronary artery bypass grafting (CABG); HR — hazard ratio

influenced by the fact that the study methods we used to assess infarct transmuralty and, therefore, lack of myocardial viability, are no longer used. Those criteria most probably underestimated the area of viable myocardium, because even akinetic or dyskinetic regions with the evidence of Q waves in the corresponding ECG leads may have a substantially preserved viability with myocardial hibernation. This has been demonstrated using newer and much more sensitive techniques such as stress echocardiography, magnetic resonance imaging or nuclear studies [14, 15]. Therefore it is possible that in the current study some patients with preserved myocardial viability were incorrectly classified as having non-viable myocardium via ECG or basic

echocardiographic criteria, and more frequently required a repeat procedure. Application of modern viability criteria could have lessened the difference in the frequency of re-PCI between the CR and IR groups.

Our study supports the hypotheses presented in two relatively small reports comprising similar patient populations which demonstrated that, anatomically, IR may lead to results comparable to CR. In a group of 139 consecutive patients, Faxon et al. [9] demonstrated that the successful dilation of all bypassable vessels supporting viable myocardium defined as functionally adequate was similar to CR at one year follow-up in terms of the frequency of death, MI or CABG. Cowley et al. [10] showed in a group of 370 patients that

coronary arteries serving modest amounts of myocardium did not seem to need revascularisation to achieve a good long-term outcome with coronary angioplasty during a follow-up lasting more than two years. Our results are based on the analysis of the largest group of patients undergoing functionally driven IR to date, and with the longest follow-up period (mean 11 years).

All the PCI procedures in our study were performed between 1988 and 1997 and did not include stenting of the stenotic arteries, which most certainly influenced the results. Stenting has now become a routine procedure during PCI, significantly reducing the frequency of restenosis and the need for repeat procedures [16, 17]. Recent studies have shown that, anatomically, CR with either bare metal [2–5] or drug eluting stents [6, 7] is related to better outcomes, including fewer major CV events. However, none of these studies used the adequate criterion of IR and therefore the value of this strategy in the stent era is still a matter of debate.

Our study has some other limitations. It is not a randomised, controlled trial evaluating different revascularisation types in patients with MVD. This could result in a bias, which cannot be fully eliminated by a multivariable analysis. Another limitation was the lack of contemporary antiplatelet treatment including clopidogrel and glycoprotein IIb/IIIa use, as well as the use of cardioverter-defibrillators.

CONCLUSIONS

In comparison to CR, a strategy of functionally driven IR by means of PCI without stenting does not increase the rate of major cardiovascular outcomes, but is related to higher frequency of repeat procedures during a long-term follow-up. The LVEF and age were the only independent predictors of long-term all-cause mortality in this large group of patients.

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Czynnościowo ukierunkowana pełna v. niepełna rewaskularyzacja w wielonaczyniowej chorobie wieńcowej — wyniki odległe dużej grupy pacjentów

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Streszczenie

Wstęp i cel: Celem pracy była ocena potencjalnych korzyści z ukierunkowanej czynnościowo niepełnej rewaskularyzacji (IR) w dużej grupie pacjentów z wielonaczyniową chorobą wieńcową (MVD) poddawanych przezskórnej interwencji wieńcowej (PCI).

Metody: Do badania włączono 908 pacjentów z MVD poddawanych PCI bez implantacji stentu w latach 1988–1997. Czynnościowo ukierunkowana IR była definiowana jako poszerzenie wszystkich segmentów tętnic wieńcowych zwężonych > 70%, z wyłączeniem tętnic zaopatrujących obszar mięśnia sercowego po przebyłym pełnościennym zawale lub obszar mięśnia nieistotny czynnościowo. Pełna rewaskularyzacja (CR) była definiowana jako skuteczna PCI wszystkich istotnych zmian w tętnicach wieńcowych niespełniających powyższych kryteriów. Pacjenci byli obserwowani przez średnio 11 (8–16) lat. Punkty końcowe obejmowały: zgon, zawał serca, potrzebę ponownej PCI (re-PCI) lub pomostowania aortalno-wieńcowego (CABG).

Wyniki: Pełną rewaskularyzację osiągnięto u 284 (31,3%) pacjentów. Dane na temat zdarzeń w obserwacji odległej uzyskano dla 873 (96,1%) chorych. Nie stwierdzono istotnej różnicy w częstości śmiertelności całkowitej, śmiertelności sercowo-naczyniowej lub zawałów serca w zależności od obranej metody leczenia (IR v. CR). Pacjenci poddani IR częściej wymagali zabiegów re-PCI. W tej grupie chorych obserwowano także tendencję do częstszego wykonywania CABG.

Wnioski. W porównaniu z pełną rewaskularyzacją strategia czynnościowo ukierunkowanej niepełnej rewaskularyzacji za pomocą PCI bez implantacji stentu nie zwiększa częstości głównych zdarzeń końcowych, ale wiąże się z większą częstością ponownych zabiegów na tętnicach wieńcowych w obserwacji odległej.

Słowa kluczowe: stabilna choroba wieńcowa, przezskórna interwencja wieńcowa, rewaskularyzacja, zdarzenia końcowe

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