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# Randomized Clinical Trial of Hybrid vs. Surgical vs. Percutaneous Multivessel Coronary Revascularization: 5-year Follow-up of HREVS Trial

*Aim* To evaluate 5-year results of the HREVS (Hybrid REvascularization Versus Standarts) study.

*Material and methods* The study included 155 consecutive patients with multivessel coronary artery disease who were randomized into 3 groups: coronary artery bypass grafting (CABG) (n=50), hybrid coronary revascularization (HCR) (n=52) and percutaneous coronary intervention (PCI) (n=53) according to the consensus of the cardiology team on the technical and clinical feasibility of each of the three coronary revascularization strategies. The primary endpoint of the study was residual ischemia 12 months after revascularization according to data of single-photon emission computed tomography (SPECT). Secondary endpoints were major adverse cardiac and cerebrovascular events (MACCE) over 5 years of follow-up, which included all-cause death, myocardial infarction, stroke, and clinically determined repeat myocardial revascularization.

*Results* Baseline characteristics of patients did not differ between study groups. Median residual ischemia determined by SPECT data after 12 months was not statistically significantly different in the CABG, HCR and PCI groups: 6.7 [4.6; 8.8] %, 6.4 [4.3; 8.5] % and 7.9 [5.9; 9.8] %, respectively (p=0.45). Mean follow-up period was 76.5 months (at least 60 months). There were no statistically significant differences in all-cause mortality between the CABG, HCR and PCI groups, 10.6, 12.8 and 8.2%, respectively (p=0.23). Statistically significant differences between the groups of CABG, HCR and PCI in the incidence of myocardial infarction (12.8; 8.5 and 16.3%; p=0.12), stroke (4.2; 6.4 and 10.2%; p=0.13), repeat revascularization for clinical indications (23.4; 23.4 and 34.7%; p=0.11) were not observed either. However, the cumulative 5-year MACCE value was similar in the HCR group and the CABG group but significantly lower than in the PCI group (51.1, 51.1 and 69.4%, respectively; p=0.03).

*Conclusion* HCR that combines advantages of PCI and CABG is a promising strategy for coronary revascularization in multivessel coronary artery disease. HCR demonstrates satisfactory long-term results comparable to those of CABG but superior to PCI. To confirm the safety and efficacy of HCR, a large multicenter study is required that would have a sufficient power to evaluate clinical endpoints.

*Keywords* Ischemic heart disease; multivessel coronary artery disease; coronary artery bypass grafting; percutaneous coronary intervention; hybrid coronary revascularization

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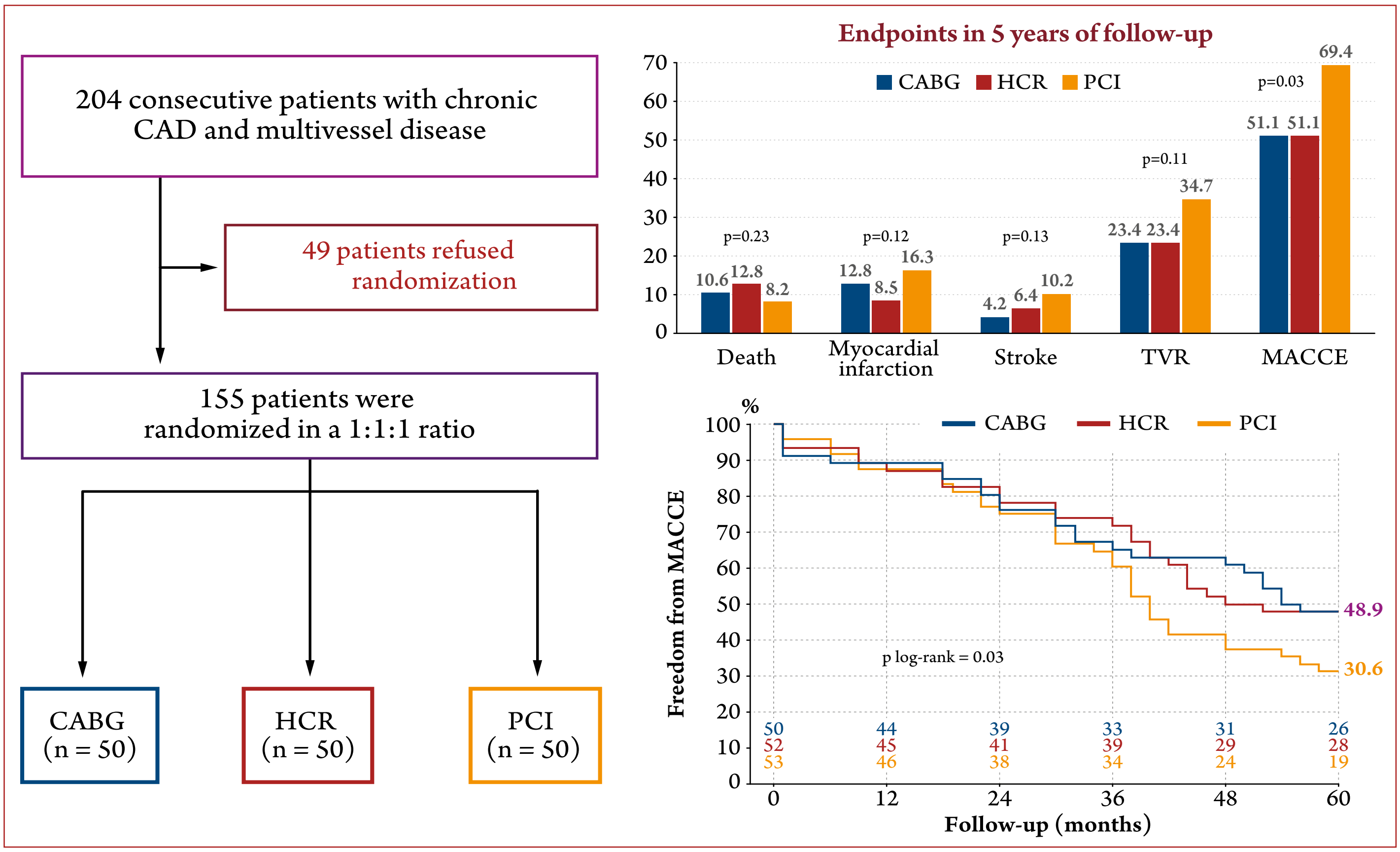
## Introduction

There is still no consensus on the choice of the best possible revascularization strategy for multivessel coronary artery disease [1]. Coronary artery bypass grafting (CABG) and percutaneous coronary intervention (PCI) are the main methods of myocardial revascularization. The distal potency of the anastomosis between the left internal mammary artery (LIMA) and the left anterior descending artery (LAD) is the proven advantage of CABG, which determines the survival of patients after revascularization [2]. However, CABG is associated with surgical trauma, which increases the risk of perioperative complications. It is possible to escape the disadvantages of conventional CABG by giving preference to minimally invasive techniques and avoiding cardiopulmonary bypass [3].

The main advantage of multivessel PCI is its less invasive nature and lower risk of perioperative complications compared to those in CABG [4]. When modern drug-

Central illustration. Randomized Clinical Trial of Hybrid vs. Surgical vs. Percutaneous Multivessel Coronary Revascularization: 5-year Follow-up of HREVS Trial




eluting stents are used, the incidence of restenosis and thrombosis is lower than that of vein graft failure [5, 6]. These data were the basis for considering a hybrid strategy as the third modern approach to myocardial revascularization in patients with chronic multivessel coronary artery disease (CAD) [7–11]. Hybrid coronary revascularization (HCR) combines the advantages of CABG and PCI and outweighs their disadvantages.

We have already presented encouraging three-year outcomes of HCR in selected patients with multivessel disease [12]. Based on this study, we extended the follow-up period to compare the long-term outcomes of the three revascularization methods.

## Objective

Evaluate the 5 year clinical outcomes of the Hybrid REvascularization Versus Standards (HREVS; NCT 01699048) study.

## Material and Methods

### *Study design and patient selection*

The HREVS study is a prospective, randomized, open-label, parallel study of safety and efficacy. The study design has been already described [13]. Of the 204 consecutive patients with chronic multivessel CAD selected by the Heart team, 155 patients were randomized to one of 3 treatment groups: conventional CABG (LIMA-LAD anastomosis, vein bypass grafting of other coronary arteries), HCR (Minimally invasive direct coronary artery bypass MIDCAB – LAD, stenting of other coronary arteries), or multivessel PCI using second-generation drug-eluting stents.

Inclusion criteria: age ≥18 years; angina pectoris class II–IV (Canadian Cardiovascular Society); angiographically confirmed multivessel coronary artery disease with LAD involvement, stenosis of ≥ 70% of the diameter according to quantitative assessment (QCA); 50–70% stenosis with functional confirmation of significance using single-photon emission computed tomography (SPECT) or fractional flow reserve (≤ 0.80); consensus of the Heart team on the possibility of performing complete myocardial revascularization by any of the 3 methods of interest (CABG, HCR, PCI); written informed consent.

Exclusion criteria: acute coronary syndrome; history of any type of myocardial revascularization; pregnancy; involvement of the left main coronary artery; severe coronary artery calcification and/or chronic total occlusions; left ventricular aneurysm or valvular heart disease requiring surgical correction; severe concomitant pathology limiting life expectancy by ≤ 5 years; contraindications to dual antiplatelet therapy; participation in other clinical studies.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The protocol of this study was approved by the local ethics committee. All subjects signed the informed consent.

### *Drug treatment and revascularization*

Acetylsalicylic acid (ASA) (100 mg/day) was prescribed lifelong to all study patients before revascularization. In the PCI and HCR groups, antiplatelet therapy also included clopidogrel (a loading dose of 300 mg in naive patients followed by 75 mg/day for 12 months). Postoperative drug therapy had to include statins, angiotensin-converting enzyme inhibitors or angiotensin II receptor blockers, and follow the current clinical guidelines.

In this study, we tried to achieve complete myocardial revascularization (target vessels with a diameter of at least 2.5 mm and stenosis of 70% or more) in all patients in accordance with the consensus of the Heart team. Venous revascularization of the right coronary and circumflex artery in CABG was performed following the local clinical practice. In the HCR group, MIDCAB LIMA-LAD was performed as the first step followed by PCI within 3 days.

### *Study endpoints*

The primary study endpoint was residual ischemia 12 months after revascularization by SPECT. The secondary endpoints included major adverse cardiac and cerebrovascular events (MACCE) within 5 years of follow-up, including all-cause death, myocardial infarction (MI), stroke, and repeat myocardial revascularization. The composite endpoint including all of the above was also evaluated. The definitions of MI and stroke coincided were in line with international guidelines [14, 15].

Five-year endpoint analysis was performed in 94%, 90.4%, and 92.4% of the subjects in the CABG, PCI, and HCR groups, respectively. Decisions on clinically significant adverse events were made by an external clinical event committee that had access to the patients' baseline data.

### *Statistical analysis of study results*

The data obtained were analyzed in Statistica v.10.0 (StatSoft, Inc., USA).

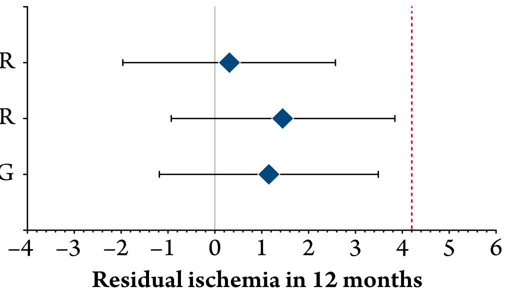
Normally distributed parametric characteristics are presented as the means and standard deviations (M ± SD) and non-normally distributed parametric characteristics are expressed as the medians and interquartile ranges (Me [Q1; Q3]). The Kolmogorov–Smirnov test was used to determine the normality of distribution. Non-parametric indicators are presented as percentages. Normally distributed variables of the baseline characteristics were compared using the ANOVA test, non-normally distributed variables were compared using the Kruskal-Wallis test, and Pearson's chi-squared test was used for categorical variables. MACCE was analyzed using the Kaplan-Meier method, a log-rank test, and a 95% confidence interval. Two-tailed values were statistically significant at $p < 0.05$.

**Table 1.** Baseline and procedural characteristic of the patient groups

| Parameter | CABG (n = 50) | HCR (n = 52) | PCI (n = 53) | p |
|---|---|---|---|---|
| Age, years | 61.3 ± 6.8 | 62.0 ± 7.4 | 61.7 ± 7.7 | 0.802 |
| Male | 70.0 (35) | 75.0 (39) | 69.8 (37) | 0.901 |
| Smoking | 50.0 (25) | 46.1 (24) | 47.2 (25) | 0.922 |
| Arterial hypertension | 66.0 (33) | 65.4 (34) | 67.9 (36) | 0.963 |
| Diabetes mellitus | 22.0 (11) | 17.3 (9) | 20.7 (11) | 0.832 |
| Chronic kidney disease | 0 | 1.9 (1) | 5.7 (3) | 0.323 |
| COPD/asthma | 4.0 (2) | 7.7 (4) | 11.3 (6) | 0.430 |
| History of myocardial infarction | 56.0 (28) | 51.9 (27) | 58.5 (31) | 0.790 |
| History of stroke | 6.0 (3) | 7.7 (4) | 5.7 (3) | 0.924 |
| Peripheral vascular disease | 24.0 (12) | 30.8 (16) | 30.2 (16) | 0.700 |
| Left ventricular ejection fraction, % | 54.0 ± 7.4 | 56.2 ± 6.3 | 53.3 ± 9.9 | 0.159 |
| EuroSCORE II score | 1.70 ± 0.76 | 1.71 ± 0.72 | 1.70 ± 0.79 | 1.000 |
| **Number of index lesions** | 2.7 ± 0.7 | 2.9 ± 0.8 | 2.7 ± 0.9 | |
| 2 | 42.0 (21) | 36.5 (19) | 50.9 (27) | — |
| 3 | 44.0 (22) | 42.3 (22) | 30.2 (16) | 0.350 |
| > 3 | 14.0 (7) | 21.2 (11) | 18.9 (10) | 0.831 |
| SYNTAX score | 19.3 ± 3.0 | 19.4 ± 3.0 | 19.5 ± 2.7 | 0.913 |
| Arterial grafts | 37.8 (50) | 77.6 (52) | — | NA |
| Venous grafts | 62.2 (82) | 22.4 (15) | — | NA |
| Number of stents | — | 1.5 ± 0.9 | 2.7 ± 0.9 | NA |
| Incomplete revascularization | 8.0 (4) | 7.7 (4) | 5.7 (3) | 0.862 |

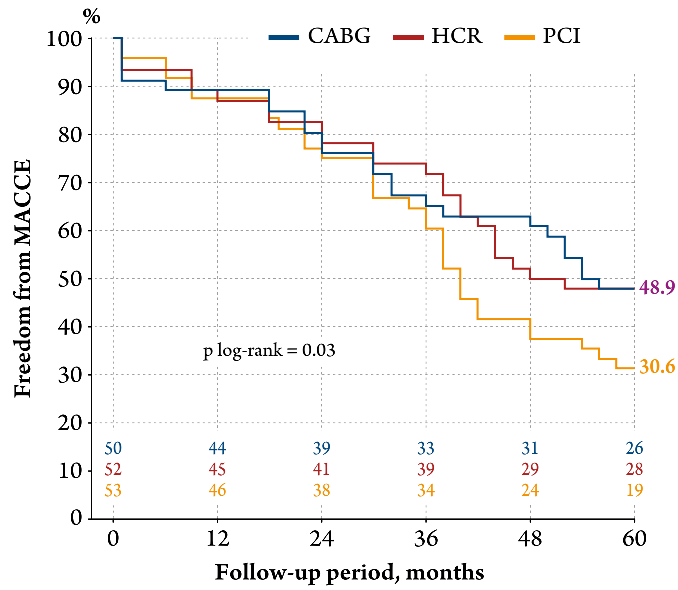
The data are expressed as M ± SD or % (n). CABG, coronary artery bypass grafting; HCR, hybrid coronary revascularization; P CI, percutaneous coronary intervention; COPD, chronic obstructive pulmonary disease. NA, not applicable.

**Figure 1.** Differences between median residual myocardial ischemia (SPECT) between the study groups in 12 months of follow-up




SPECT, single-photon emission computed tomography; CABG, coronary artery bypass grafting; HCR, hybrid coronary revascularization; PCI, percutaneous coronary intervention.

**Figure 2.** Kaplan-Meier curves of the 5 year absence of MACCE. Number of patients at risk is shown above the horizontal axis




CABG, coronary artery bypass grafting; HCR, hybrid coronary revascularization; PCI, percutaneous coronary intervention; MACCE, major adverse cardiac and cerebrovascular events (death / stroke /myocardial infarction / clinically indicated repeat revascularization).

## Results

Demographic, clinical, and angiographic characteristics were comparable in the three study groups (Table 1).

The mean age of patients was 62 ± 7 years, 71.6% of patients were male. Mean left ventricular ejection fraction (LVEF) was 54.5 ± 8.0%. Mean SYNTAX score was 19.4 ± 2.9, and mean EuroScore II score was 1.71 ± 0.76.

Patients subjected to HCR, except for 5 (9.8%) patients who were converted to CABG, underwent PCI under the protocol within 3 days (24 hours in most cases) after MIDCAB LIMA-LAD. Complete revascularization was performed in the CABG, HCR, and PCI groups in 92.0%, 92.3%, and 94.3% of cases, respectively (p = 0.862). MACCE did not differ statistically significantly in the CABG, HCR, and PCI groups (8.0%, 5.8%, and 3.8%, respectively; p = 0.371) within 30 days; perioperative MI prevailed in the structure of adverse events. One death was registered in the HCR group during hospital stay (the patient had perioperative MI and fatal stroke).

The medians of residual ischemia did not differ statistically significantly in the CABG, HCR, and PCI groups according to SPECT in 12 months: 6.7 [4.6; 8.8] %, 6.4 [4.3; 8.5] %, и 7.9 [5.9; 9.8] %, respectively; p = 0.450). The intergroup differences in median residual ischemia were significantly lower than the predetermined non-inferiority threshold of 4.2% (Figure 1). There were no statistically significant differences in the endpoints during the 12 month follow-up period (Table 2).

The mean follow-up period was 76.5 months (minimum 60 months). During the 5 year period, 12 patients (n = 3 in the CABG group, n = 5 in the HCR group, and n = 4 in the PCI group) was lost for follow-up. A total of 143 patients (n = 47 in the CABG group, n = 47 in the HCR group, and n = 49 in the PCI group) composed the main sample at this stage of the study. There were no statistically significant

**Table 2.** Study outcomes at 12 months of follow-up

| Endpoint | CABG (n = 50) | HCR (n = 52) | PCI (n = 53) | p |
|---|---|---|---|---|
| **Primary endpoint in 12 months** | | | | |
| Residual ischemia according to SPECT, % | 6.7 [4.6; 8.8] | 6.4 [4.3; 8.5] | 7.9 [5.9; 9.8] | 0.450 |
| **Secondary endpoints in 12 months** | | | | |
| All-cause death | 2.0 (1) | 5.8 (3) | 3.8 (2) | 0.781 |
| Stroke | 0 | 3.8 (2) | 0 | 0.213 |
| Myocardial infarction | 8 (4) | 5.8 (3) | 7.5 (4) | 0.664 |
| Clinically indicated repeat revascularization | 2.0 (1) | 1.9 (1) | 5.7 (3) | 0.540 |
| MACCE | 12.0 (6) | 13.4 (7) | 13.2 (7) | 0.831 |

The data is presented as Me [Q1; Q3] or % (n). HCR, hybrid coronary revascularization; SPECT, single photon emission computed tomography; MACCE, major adverse cardiac and cerebrovascular events (death / stroke /myocardial infarction / clinically indicated repeat revascularization).


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**Table 3.** Study outcomes based on 5 year follow-up

| Secondary endpoints | CABG, n = 47 (94.0 %) | HCR, n = 47 (90.4 %) | PCI, n = 49 (92.4 %) | p |
|---|---|---|---|---|
| All-cause death | 10.6 (5) | 12.8 (6) | 8.2 (4) | 0.231 |
| Myocardial infarction | 12.8 (6) | 8.5 (4) | 16.3 (8) | 0.124 |
| Stroke | 4.2 (2) | 6.4 (3) | 10.2 (5) | 0.129 |
| Clinically indicated repeat revascularization | 23.4 (11) | 23.4 (11) | 34.7 (17) | 0.112 |
| MACCE | 51.1 (24) | 51.1 (24) | 69.4 (34) | 0.033 |

The data is expressed as % (n). CABG, coronary artery bypass grafting; HCR, hybrid coronary revascularization; MACCE, major adverse cardiac and cerebrovascular events (death / stroke /myocardial infarction / clinically indicated repeat revascularization).

differences in all-cause mortality between the CABG, HCR, and PCI groups (10.6%; 12.8%, and 8.2%, respectively; p = 0.231). There were also no statistically significant differences between the CABG, HCR, and PCI groups in the incidence of MI (12.8%; 8.5%, and 16.3%, respectively; p = 0.124), stroke (4.2%; 6.4%, and 10.2%, respectively; p = 0.129), clinically indicated repeat revascularization (23.4%; 23.4%, and 34.7%, respectively; p = 0.112) (Table 3). However, the 5 year composite endpoint of MACCE was similar in patients subjected to HCR to that in those after CABG, but statistically significantly lower than in the PCI group (51.1%; 51.1%, and 69.4%, respectively; p = 0.033) (Figure 2).

## Discussion

HREVS is the first randomized controlled study comparing the outcomes of the three myocardial revascularization strategies in patients with multivessel coronary artery disease. We showed in this study that all three strategies had no difference in residual ischemia according to SPECT 12 months later, which is a generally accepted indicator of the coronary revascularization efficacy and a predictor of favorable long-term prognosis [13]. Despite insufficient power for clinical events, we found no statistically significant differences in all-cause mortality, the incidence of MI and stroke, repeat coronary revascularization during the 5 year follow-up period (see Table 2). In our study, the frequency of revascularization was higher in the PCI group than in the CABG and HCR group, but the difference was statistically insignificant, probably due to the small sample size. However, this led to the fact that the 5 year MACCE was comparable in the HCR and CABG groups but statistically significantly lower than in the PCI group (see Figure 2). This fact should be confirmed in a larger multicenter study.

Our study has the following advantages:

- Quantifiable primary endpoint of 12-month residual ischemia according to SPECT, which is an independent prognostic factor for cardiac death or MI, with necessary power to compare the non-inferiority of 3 treatment methods;
- No clinical or angiographic differences between patients who agreed to be randomized and were included in the study;
- The HREVS findings serve as an important addition to existing knowledge in the context of increasing frequency of PCI and the assumption that HCR is a promising treatment method that is not inferior to CABG;
- Instead of comparing established control versus conventional CABG, HREVS is a randomized, parallel comparison study.

Each of the standard methods of myocardial revascularization has disadvantages, such as the invasive nature of CABG and increased risk of repeat revascularization in PCI [2]. Thus, the best possible revascularization approach should combine the less invasive nature, a low risk of perioperative complications, and a favorable long-term prognosis. MIDCAB causes less surgical trauma, a reduced risk of bleeding and infections, and a shorter hospital stay [1, 16]. The combination of MIDCAB with PCI on non-LAD vessels excludes aortic manipulation and cardiopulmonary bypass, which reduces the risk of perioperative complications [10, 15]. Thus, HCR may have potential advantages over PCI and CABG [15]. Moreover, HCR has a lower risk of neurological complications [8, 17]. In this study, there were no statistically significant differences in the incidence of neurological complications in the CABG and HCR groups (see Table 2).

The outcomes of HCR have been compared so far mainly with conventional CABG [1, 3, 10, 14], including only one randomized trial, which, however, did not have an endovascular treatment group [18]. In the only randomized study comparing HCR and CABG, the 5-years incidence of MACCE after hybrid myocardial revascularization was comparable to that for CABG [18]. This study reported relatively low MACCE rates (45.2%) for HCR in 5 years of follow-up. In the HREVS study, MACCE for HCR was 51.1% in 5 years of follow-up (see Table 2). Tajstra et al. [18] showed a relatively high rate of repeat revascularization in patients subjected to HCR (37.2%). In contrast, the rate of clinically indicated repeat revascularization in the HCR group was 23.4% in our study. Our 5 year finding show that the frequency of repeat revascularization did not differ in the HCR and CABG groups (see Table 2).

There are no sufficient clinical data collected during the long-term follow-up period, thus, a larger multicenter study comparing HCR with CABG and PCI is required to determine the best possible strategy for myocardial revascularization in multivessel coronary artery disease. It should be noted that the National Heart, Lung, and Blood Institute (NHLBI) study of HCR (NCT03089398) was completed early due to slow patient enrollment in North America and a delay in the inclusion of clinical sites outside of North America [19].

The current guidelines on myocardial revascularization confirmed the lack of consensus on HCR, because the hybrid strategy is a class IIb recommendation with the level of evidence class C [2]. Thus, the potential of HCR among the conventional methods of revascularization in patients with multivessel coronary artery disease is not completely clear.

### *Limitations*

One of the main limitations of the HREVS study is that it does not have sufficient statistical power to compare clinical endpoints between the CABG, HCR, and PCI groups. Large randomized controlled trials with sufficient power to confirm the efficacy and safety of HCR should be conducted. Moreover, this study is single-center – it is not quite correct to extrapolate its results to the general population. The moderate risk in the study sample according to the SYNTAX score should also be taken into account, which is due to the technical feasibility of all revascularization strategies. Thus, patients with LMCA stenosis, severe calcification and chronic total occlusions of coronary arteries were excluded from the study.

## Conclusion

Thus, hybrid coronary revascularization combining the benefits of percutaneous coronary intervention and coronary artery bypass grafting is a promising strategy for coronary revascularization in selected patients with multivessel coronary artery disease. Hybrid coronary revascularization had satisfactory long-term outcomes comparable to those of coronary artery bypass grafting but superior to percutaneous coronary intervention. A large multicenter study with the sufficient power for clinical endpoints is necessary to confirm the safety and efficacy of hybrid coronary revascularization.

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*No conflict of interest is reported.*

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