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Hybrid Revascularization for Multivessel Coronary Artery Disease

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ABSTRACT

OBJECTIVES The aim of this study was to assess the feasibility of hybrid coronary revascularization (HCR) in patients with multivessel coronary artery disease (MVCAD) referred for standard coronary artery bypass grafting (CABG).

BACKGROUND Conventional CABG is still the treatment of choice in patients with MVCAD. However, the limitations of standard CABG and the unsatisfactory long-term patency of saphenous grafts are commonly known.

METHODS A total of 200 patients with MVCAD involving the left anterior descending artery (LAD) and a critical (>70%) lesion in at least 1 major epicardial vessel (except the LAD) amenable to both PCI and CABG and referred for conventional surgical revascularization were randomly assigned to undergo HCR or CABG (in a 1:1 ratio). The primary endpoint was the evaluation of the safety of HCR. The feasibility was defined by the percent of patients with a complete HCR procedure and the percent of patients with conversions to standard CABG. The occurrence of major adverse cardiac events such as death, myocardial infarction, stroke, repeated revascularization, and major bleeding within the 12-month period after randomization was also assessed.

RESULTS Most of the pre-procedural characteristics were similar in the 2 groups. Of the patients in the hybrid group, 93.9% had complete HCR and 6.1% patients were converted to standard CABG. At 12 months, the rates of death (2.0% vs. 2.9 %, p = NS), myocardial infarction (6.1% vs. 3.9%, p = NS), major bleeding (2% vs. 2%, p = NS), and repeat revascularization (2% vs. 0%, p = NS) were similar in the 2 groups. In both groups, no cerebrovascular incidents were observed.

CONCLUSIONS HCR is feasible in select patients with MVCAD referred for conventional CABG. (Safety and Efficacy Study of Hybrid Revascularization in Multivessel Coronary Artery Disease [POL-MIDES]; NCT01035567) (J Am Coll Cardiol Intv 2014;7:1277–83) © 2014 by the American College of Cardiology Foundation.

Conventional coronary artery bypass grafting (CABG) is still the current, evidence-based, gold standard treatment of patients with multivessel coronary artery disease (MVCAD) (1,2). The most advantageous part of CABG is the insertion of the left internal mammary artery (LIMA) graft in the left anterior descending artery (LAD) as it is associated with significantly reduced risk of death, myocardial infarction, and recurrent angina and has been proven to provide an excellent long-term patency rate (3–5). In contrast, the rate of saphenous vein graft (SVG) patency remains less than optimal with occlusion rates ranging from 6.2% to 30% at 12 months (6–8). In non-LAD coronary arteries, the 12-month rate of drug-eluting stent (DES) restenosis and thrombosis after percutaneous coronary intervention (PCI) is lower than the rate of SVG failure (9). Therefore, PCI with DES in non-LAD targets

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ABBREVIATIONS AND ACRONYMS

CABG = coronary artery bypass grafting

DES = drug-eluting stent(s)

HCR = hybrid coronary revascularization

HPS = HYBRID patency score

LAD = left anterior descending artery

LIMA = left internal mammary artery

MIDCAB = minimally invasive direct coronary artery bypass

MVCAD = multivessel coronary artery disease

MVD = multivessel disease

PCI = percutaneous coronary intervention

SVG = saphenous vein graft

provides a promising alternative to SVG. Thus, taking into account similar patency rates of DES and SVG and the superiority of the LIMA-LAD, the fundamental basis for the hybrid coronary revascularization (HCR) strategy was set, consisting of minimally invasive direct coronary artery bypass (MIDCAB) LIMA-LAD grafting using endoscopic LIMA harvesting (MIDCAB/endoscopic atraumatic coronary artery bypass) and catheter-based techniques with implantation of DESs in non-LAD vessels. Because of the lack of data from prospective, randomized trials comparing HCR with standard surgical revascularization in patients with MVCAD, the POL-MIDES (HYBRID) (Safety and Efficacy Study of Hybrid Revascularization in Multivessel Coronary Artery Disease) was designed as the first one to assess feasibility of such an approach.

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METHODS

STUDY DESIGN. The study design was described previously (10). Briefly, the POL-MIDES (HYBRID) is a prospective, single-center, randomized, open-label, parallel pilot study. The authors designed the study in collaboration with the Ministry of Science and Higher Education of Poland. A statistician performed the analyses of the data. The authors wrote the paper and confirm the completeness and accuracy of data gathering and analysis. The study protocol was approved by the local ethics committee and complies with the Declaration of Helsinki. Written informed consent was obtained from all study participants.

The Steering Committee of the POL-MIDES (HYBRID) comprising independent, university-based researchers (Medical University of Silesia, Katowice, Poland) with methodological and clinical experience was responsible for the assessment of all clinical events, data collection, monitoring, final analyses, as well as the preparation and publication of the manuscripts reporting the study results.

SELECTION AND RANDOMIZATION OF PATIENTS. All consecutive patients with angiographically confirmed MVD involving the LAD and critical (>70%) lesion in at least 1 (apart from the LAD) major epicardial vessel amenable to both PCI and CABG and referred for conventional surgical revascularization were screened by the local heart team (at least 1 interventional cardiologist with a cardiothoracic surgeon). The heart team checked all the inclusion/exclusion criteria and the eligibility to perform CABG and PCI in all study participants. It was determined that equivalent anatomic revascularization could be achieved in patients with either CABG or PCI using Xience everolimus-eluting stents (Abbott Vascular, Abbott Park, Illinois) were randomly assigned to undergo 1 of the 2 treatment options. Randomization was conducted in a 1:1 ratio. **Figure 1** shows the study flow chart.

PRIMARY ENDPOINT. The primary endpoint was the evaluation of the feasibility of HCR. The feasibility endpoint was defined by the percent of patients with a complete hybrid procedure according to study protocol and the percent of conversions to standard CABG. Occurrence of major adverse cardiac events such as death, myocardial infarction, stroke, repeat revascularization, major bleeding throughout the 12-month period after randomization was also assessed. An independent clinical events committee (including cardiologists, cardiac surgeons, and a neurologist) adjudicated all primary clinical endpoints, staged procedures, and cases of reopening of the sternal incision.

SECONDARY ENDPOINTS. The secondary endpoints were post-procedure and follow-up angiographic measurements (12 months after randomization) of the patency of the grafts and restenosis in revascularized segments, assessment of quality of life of study participants according to Short Form-36 Health Survey version 2 (1 and 6 months after the procedure), and cost-effectiveness defined as the cost of the revascularization procedure and of hospitalizations in both groups; the latter 2 points are the subject of a separate analysis and are not presented here.

REVASCULARIZATION AND PHARMACOLOGICAL TREATMENT. In both arms of the study, patients were treated with the intention of achieving complete revascularization of all vessels at least 2.0 mm in diameter with stenosis of ≥50%, as identified by the interventional cardiologist and cardiac surgeon. The surgical technique for CABG, the approaches used for HCR stages, and the post-procedure medication regimen were chosen according to local clinical practice and European Society of Cardiology guidelines. In patients in the HCR arm who underwent PCI, dual-antiplatelet therapy with aspirin and clopidogrel was recommended for at least 12 months after stent implantation. For CABG procedure, arterial revascularization was encouraged. Aspirin was prescribed indefinitely for all patients who underwent

randomization. The standard of post-intervention care was recommended.

Follow-up assessments were carried out at hospital discharge and at 3, 6, and 9 months after the revascularization procedure. After 12 months, patients were asked to undergo control angiography.

STATISTICAL ANALYSIS. The continuous variables are presented as the mean ± SD. The categorical variables are presented as percents. To test for differences between the CABG and HCR groups, the Student *t* and the chi-square tests were used. Major adverse cardiac events were analyzed using the Kaplan-Meier method, the log-rank test, and an observed difference with a 95% confidence interval was calculated. All analyses were on the basis of the intention-to-treat principle. A 2-sided p value <0.05 was considered statistically significant. Statistical tests were performed with STATISTICA 10PL software (StatSoft, Inc., Tulsa, Oklahoma).

RESULTS

From November 2009 to July 2012, 200 patients with confirmed MVD and referred for conventional CABG were randomized to HCR (n = 98) or CABG (n = 102) Demographic, clinical, angiographic, and procedural characteristics were well balanced and similar in both treatment groups (Table 1). Compared with the CABG group, patients in the HCR group had slightly lower body mass index (HCR, 28.2 vs. CABG, 29.1; p = 0.07). Overall, ~4 clinically significant coronary lesions were treated per patient (mean, 4.0 for HCR vs. 3.7 for CABG; p = 0.16). More than half of the study patients had 3-vessel disease (54.1% in HCR vs. 53.9% in CABG; p = 0.1). Despite the fact that significant left main artery disease and the presence of >1 chronic total occlusion were the exclusion criteria in the trial, a mean SYNTAX score was 23.4 in the HCR group and 22.8 in the CABG group (p = 0.48) (Table 1). Planned revascularization procedures were performed in 93.9% in the HCR group and in all patients in the CABG group and. In the HCR group, a mean of 2.3 stents per patient were placed, whereas in the CABG group, 85.0% of patients were operated on off-pump, using the off-pump CABG technique. Complete arterial revascularization was achieved in 24.5% of the patients, and an mean of 2.7 conduits were implanted.

As expected, the MIDCAB procedure was significantly shorter than CABG. The mean time from MIDCAB to PCI was 21 h. Together with DES implantation, the LIMA-LAD was assessed. In 2 patients, it was found to be suboptimal and resulted in subsequent PCI of the LAD in 1, and repeat MIDCAB in a second patient. The HCR group included 6 patients who were converted to sternotomy (intention-to-treat HCR). These patients did not undergo PCI, as all coronary lesions were addressed with CABG. There were 2 patients who had the first stage of the HRC performed (MIDCAB) but failed PCI (2%). These patients underwent PCI with rotational atherectomy as an auxiliary method at a later time (outside of time planned in the study protocol).

Clinical events occurring during hospitalization and the primary endpoint and its components are presented in Table 2. There were no significant differences in in-hospital outcome. In 1 patient in the HYBRID group, acute renal failure developed requiring dialysis. The incidence of perioperative myocardial infarction and length of hospitalization were similar.

The cumulative occurrence of major adverse cardiac events was 10.2% and 7.8% for HCR and

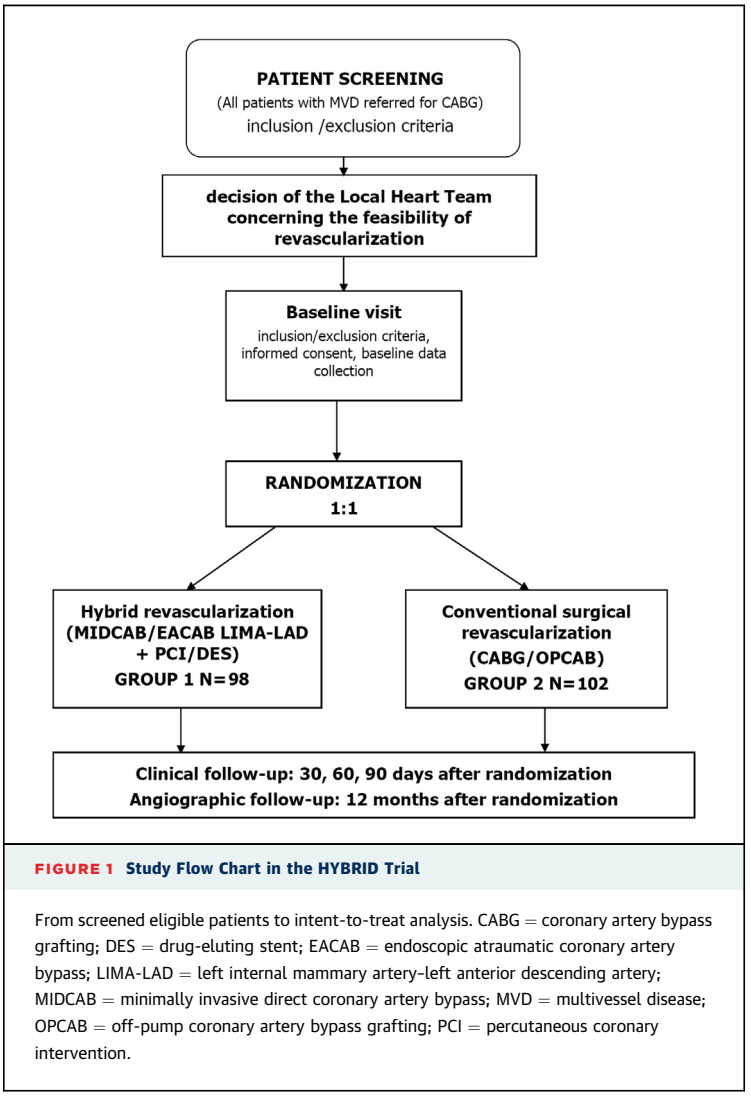

FIGURE 1 Study Flow Chart in the HYBRID Trial

From screened eligible patients to intent-to-treat analysis. CABG = coronary artery bypass grafting; DES = drug-eluting stent; EACAB = endoscopic atraumatic coronary artery bypass; LIMA-LAD = left internal mammary artery–left anterior descending artery; MIDCAB = minimally invasive direct coronary artery bypass; MVD = multivessel disease; OPCAB = off-pump coronary artery bypass grafting; PCI = percutaneous coronary intervention.

TABLE 1 Baseline Characteristics of the Patients, According to the Study Groups*

	CABG (n = 102)	HCR (n = 98)	p Value
Age at randomization, yrs	63.9 ± 8.4	63.1 ± 8.2	0.43
Male, %	71.6	79.6	0.19
Body mass index, kg/m^2	29.1 ± 4.2	28.2 ± 3.3	0.07
Medically treated diabetes, %†	30.4	25.5	0.44
Current smoker, %	35.3	30.6	0.48
Previous myocardial infarction, %	57.8	53.1	0.49
Previous stroke, %	4.9	4.1	0.95
Previous transient ischemic attack, %	2.9	1.0	0.64
Hypertension, %	82.4	88.8	0.20
Carotid artery disease, %	11.8	9.2	0.55
Hyperlipidemia, %	59.8	56.1	0.60
Angina, %			
Stable	83.2	85.7	0.64
Unstable	16.7	14.3	0.64
Ejection fraction, %	50.7 ± 7.0	49.8 ± 6.3	0.37
EuroSCORE value	3.4 ± 2.0	3.1 ± 2.1	0.23
SYNTAX score	22.8 ± 5.3	23.4 ± 6.3	0.48
No. of lesions	3.7 ± 1.2	4.0 ± 1.4	0.16
Total occlusion, %			
Left anterior descending artery	29.4	22.4	0.44
Right coronary artery	6.9	6.1	0.83
Ramus circumflex artery	10.8	8.2	0.28
No. of grafts	2.6 ± 0.7	1.2 ± 0.7	NA
No. of arterial grafts	1.6 ± 0.9	1.1 ± 0.1	NA
Complete arterial revascularization, %	24.5	–	NA
Post-procedural LIMA patency, %	–	97.8	NA
No. of stents used	–	2.3 ± 1.0	NA
Total drainage, ml	1,168 ± 486	1,018 ± 730	0.1
Time MIDCAB to PCI, h	–	21.0 ± 5.7	NA
In-hospital stay, days	8.9 ± 5.6	8.8 ± 4.3	0.88
Complete revascularization, %	78.4	78.6	0.84

Values are mean ± SD or %. *Values are given for the intention-to-treat population. †Medically treated diabetes was defined as diabetes for which the patient was receiving oral hypoglycemic agents or insulin at the time of enrollment.

CABG = coronary-artery bypass grafting; HCR = hybrid coronary revascularization; LIMA = left internal mammary artery; MIDCAB = minimally invasive coronary artery bypass; NA = not applicable; PCI = percutaneous coronary intervention.

CABG, respectively (p = 0.54 by the log-rank test) with an observed difference of 2.4% (95% confidence interval: −5.6% to 10.3%) (Figure 2). The secondary endpoint, 12-month follow-up angiographic measurements of the patency of grafts and restenosis in revascularized segments, is shown in Table 3. Angiographic follow-up was performed in 85% and 81% of patients in HCR and CABG groups, respectively (p = 0.41). The patency of arterial grafts to the LAD was substantial at 94% and 93% (HCR vs. CABG). Although 1 LIMA conduit was significantly narrowed in the HCR group, 5 grafts were found narrowed in the CABG group; 79% of the remaining conduits were free of occlusion and obstruction. In the HCR group, 5.1% stent occlusion rate and 7.5% significant in-stent restenosis was discovered. The HYBRID patency score (HPS) was created to compare the long-term effect of hybrid revascularization with long-term patency of the grafts after standard CABG defined as grafted or stented arteries free of stenosis and/or occlusions with the total number of grafted and stented arteries ratio, which was significantly higher in the HCR group (90% vs. 81%, p = 0.01).

DISCUSSION

The primary aim of the study was to evaluate the feasibility of an integrated, 2-stage HCR procedure in patients with MVD referred for standard, open-chest CABG. The POL-MIDES (HYBRID), the first randomized study for HCR is unique from various perspectives. First, it proved that HCR is feasible in a select population of patients with MVCAD. Second, MIDCAB with LIMA to LAD as a first-stage procedure in HCR patients was not associated with a significant increase in adverse events.

Our study has shown HCR to be safe in patients with MVCAD, with surgical treatment preceding endovascular. However, in 6 patients (6.1%), conversion to full sternotomy had to be performed. In 4 patients, the conversion was not emergent, but rather planned as the result of either the inability to perform single lung ventilation due to severe chronic obstructive pulmonary disease or the inability to visualize the LIMA due to pleural adhesions. In both cases, there were only port incisions on patients' chests, not thoracotomy incisions. In 2 other patients, endoscopic LIMA harvesting was successful, but the LAD could not be identified once thoracotomy was performed. In 1 patient, there was a significant muscular bridge covering the LAD, whereas in the second patient, there was a large amount of fatty tissue covering the entire myocardium. In both patients, full sternotomy provided better visualization, enabling complete surgical revascularization.

In the last 2 patients, emergent conversion was required. Hemodynamic instability that occurred shortly after LAD occlusion and preparation for intraluminar coronary shunt placement followed by ventricular fibrillation was the main reason for MIDCAB to CABG emergent conversion in the first patient. In the second patient, significant bleeding that was difficult to manage by endoscopic techniques led to prompt sternotomy. Similar reasons for emergent and planned sternotomy conversions were reported in patients with single-vessel diseases undergoing MIDCAB/endoscopic atraumatic coronary artery bypass (11). Most importantly, the above-mentioned events were easily managed with median sternotomy, which did not influence early or late outcome. It

TABLE 2 Clinical Endpoints Occurring in the Hospital or After Discharge According to Study Group*

	CABG	HCR	p Value
In-hospital outcomes, %			
Blood transfusion	26.5	19.4	0.23
Perioperative myocardial infarction	3.9	5.1	0.69
Renal failure	0	1.0	0.98
Stroke	0	0	NA
Death	0	0	NA
Primary endpoint			
Feasibility			
Patients with complete hybrid procedure, %	–	93.9	NA
Conversion to standard CABG, %†	–	6.1	NA
Safety			
Major adverse cardiac events at 12 mo after randomization			
Death, %	2.9	2.0	0.1
Myocardial infarction, %‡	3.9	6.1	NS
Stroke, %	0	0	NA
Target vessel revascularization, %	0	2.0	NS
Major bleeding, %	2.0	2.0	NS

*Values are given for the intention-to-treat population. †Reasons for converting: Left anterior descending artery not visible through mini-thoracotomy incision in 2 patients. Hemodynamically unstable when preparing left anterior descending artery for grafting, recurrent ventricular tachycardia, emergency conversion to full sternotomy in 1 patient. Left internal mammary artery damaged during endoscopic harvesting in 1 patient. Solid adhesions in the left thoracic cavity, endoscopic or direct left internal mammary artery harvesting impossible in 1 patient. Lack of tolerance of single lung ventilation in 1 patient. ‡Includes perioperative myocardial infarction.

Abbreviations as in Table 1.

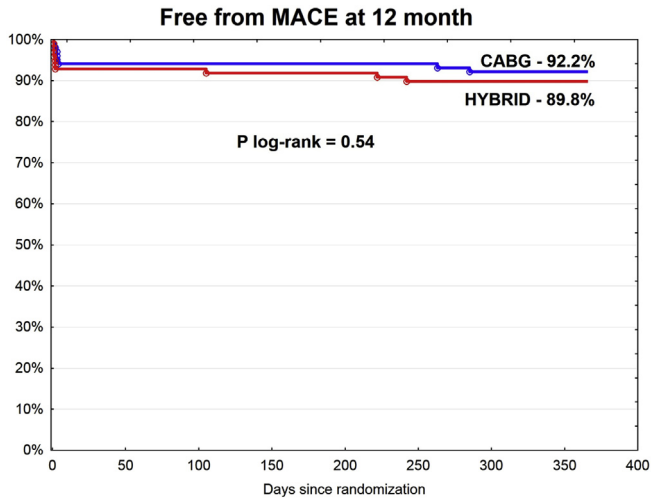

FIGURE 2 Kaplan-Meier Estimates of the Composite Primary Feasibility Endpoint

Percentage of patients free from MACE within a 12-month follow-up. CABG = coronary artery bypass grafting; MACE = major adverse cardiac event(s).

is noteworthy that the vast majority of patients in the surgical arm underwent off-pump CABG. Although the surgical technique was left to patients' preference, we did not observe significant differences between patients operated on using either method. There were no off-pump CABG to CABG intraoperative conversions.

As the population of the patients with MVD referred for CABG is growing older with greater comorbidities, less invasive and hazardous techniques should be explored. The intention of the coronary artery hybrid revascularization is to combine the most valuable asset of the standard CABG (i.e., excellent long-term durability of the LIMA-to-LAD graft) with the advantages of PCI (i.e., low rate of stent restenosis and durability of DES superior to SVG patency). Several small retrospective studies have demonstrated that a HCR strategy is safe with low mortality rates (0% to 2%) and event-free survival rates of 83% to 92% at 6 to 12 months of follow-up. The few series that compared the outcomes of HCR with the standard CABG reported similar outcomes at 30 days and 6 months (12–14). The results of these studies are consistent with our findings. To the best of our knowledge, to date, no randomized, controlled trial involving HCR has been published. Therefore, the current practice guidelines recommend HCR as reasonable only if CABG or PCI of the LAD are contraindicated due to severe clinical and/or anatomic reasons or recommend as worthy of consideration instead of CABG or multiple PCIs to improve the overall risk-benefit ratio of these procedures (2).

In the SYNTAX trial, more patients in the CABG group than in the PCI group declined to participate after providing consent, mostly due to the greater invasiveness of CABG (15). Despite this growing awareness of patients about the possibility of minimally invasive revascularization, the hybrid approach

TABLE 3 Secondary Endpoint: 12-Month Follow-Up Angiographic Measurements as Patency of Grafts and Restenosis in Revascularized Segments*

	CABG	HCR	p Value
Follow-up duration, months	12.6 ± 0.4	12.9 ± 0.4	
Angiographic follow-up, %	81	85	0.41
LAD arterial graft patency, %	93†	94‡	0.74
LAD arterial graft stenosis ≥70%, %	5	1	0.36
Other grafts patency, %§	79	–	NA
Other grafts stenosis, %	2	–	NA
In-stent occlusions, %	–	5.1	NA
In-stent restenosis ≥50%, %		7.5	NA
HYBRID patency score, %‖	81	90	0.01

*Values are given for the intention-to-treat population. †Seventy left internal mammary artery grafts and 13 right internal mammary artery grafts. ‡Aortic-LAD graft in 1 patient. §Saphenous vein grafts and non-LAD arterial grafts. ‖HYBRID patency score: free of stenosis/occlusions grafted or ratio of stented arteries to total number of grafted and stented arteries.

LAD = left anterior descending artery; other abbreviations as in Table 1.

has not been widely accepted. This may be explained by a number of practical concerns: the need for close cooperation of CABG and PCI operators, the logistic concerns of timing and sequencing of the procedure stages, use of aggressive antiplatelet/antithrombotic therapy during PCI that might complicate the surgical part of the HCR procedure with bleeding and a high risk of the surgical stage of the HCR, especially in unstable patients with MVD and critical stenoses in non-LAD segments. A small incision and difficult surgical (endoscopic) technique used to harvest LIMA remains a barrier for widespread acceptance. Therefore, we believe that this study provides unique and vital information to dispel doubts regarding HCR: first, the fact that mean enrollment time for 1 patient was 4.8 days proves that the heart team was well organized, effective, and bias free; second, a staged HCR procedure with PCI performed within first 24 h after the surgical portion is feasible. Moreover, verification of the LIMA-to-LAD conduit patency before PCI of other vessels adds to periprocedural safety despite the routine use of the transit time flow meter. The risk of perioperative bleeding that would occur if surgery were performed after PCI in a patient already started on dual-antiplatelet therapy is reduced. Third, we found that, despite the fact the patients received a full dose of clopidogrel after the surgical part of the HCR, blood loss and transfusion requirements were slightly reduced in the HCR group compared with the CABG group. These findings are corroborated by other reports (16), and in particular, the POL-MIDES (HYBRID) study results suggest that clopidogrel pretreatment is safe and potentially beneficial. Finally, the periprocedural myocardial infarction rate, although insignificantly higher in the HCR group, was low and without any severe consequences. The HPS was introduced to overcome limitations of classic head-to-head angiographic findings of the 2 different revascularization methods. The HPS consists of the ratio of the grafted or stented arteries free of stenosis/occlusion to all the grafted/stented arteries. In our analysis, we found that the HPS was significantly higher in the POLMIDES (HYBRID) group.

Easily calculated, comparable, and consistent, the HPS is a reliable tool to assess the angiographic effectiveness of HCR.

STUDY LIMITATIONS. Because of the pilot nature of the POL-MIDES (HYBRID) trial, although it was able to prove feasibility, it was not powered to detect difference in mortality. The second limitation is that the 12-month follow-up period may not be sufficient to reflect the true long-term effect of CABG compared with HCR when taking into consideration major adverse cardiac events. Investigators of the POL-MIDES (HYBRID) trial continue to monitor all study participants so that similar SYNTAX time points can be reported.

CONCLUSIONS

The results of our trial show that HCR is feasible in select patients with MVCAD referred for conventional CABG.

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KEY WORDS CABG, hybrid revascularization, multivessel coronary artery disease, PCI