

Prospective randomised piLOt study evaluating the safety and efficacy of hybrid revascularisation in MultI-vessel coronary artery DisEaSe (POLMIDES) — study design

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Abstract

Background: Hybrid coronary artery revascularisation (HCR) is a combination of minimally invasive left internal mammary artery bypass grafting to the left anterior descending artery (LAD) and percutaneous coronary interventions (PCI) with drug eluting stent implantation to other coronary arteries. Due to the paucity of data from large, prospective randomised trials comparing HCR to standard surgical revascularisation, the POLMIDES study has been designed to assess the safety and efficacy of HCR in patients with multivessel coronary artery disease (CAD) referred for standard coronary artery bypass grafting (CABG).

Aim: The primary objective is evaluating the feasibility and safety of HCR.

Methods: Feasibility has been defined by means of the percentage of patients with a complete hybrid procedure according to the study protocol and a percentage of conversion to standard CABG. Safety has been defined as the occurrence of major adverse cardiac events such as death, myocardial infarction, stroke, repeat revascularisation and major bleeding within the 12 month period after randomisation. All consecutive patients with angiographically confirmed multivessel CAD involving LAD and a critical (> 70%) lesion in at least one major epicardial vessel (except LAD) amenable to both PCI and CABG referred for conventional surgical revascularisation, will be randomised in a 1:1 fashion for HCR or standard surgical revascularisation.

Conclusions: The POLMIDES is a prospective, randomised pilot trial designed to determine whether HCR in patients with multivessel CAD referred for conventional CABG is safe, feasible and efficacious (ClinicalTrials.gov number, NCT01035567).

Key words: multivessel coronary artery disease, hybrid revascularisation, clinical pilot trial, study design

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INTRODUCTION

Currently there are two revascularisation options for patients with coronary artery disease (CAD): coronary artery bypass grafting (CABG) and percutaneous coronary interventions (PCI).

Both of them are routinely performed in everyday clinical practice. According to current guidelines, CABG remains the treatment of choice for patients with multivessel coronary disease [1]. However, the drawbacks associated with stan-

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dard, open-chest techniques and possible adverse reactions often caused by extracorporeal circulation (ECC) limit positive outcomes [2–5]. Hence, in order to remove the need for ECC and median sternotomy, minimally invasive, off-pump surgical techniques have evolved. Minimally Invasive Direct Coronary Artery Bypass/Endoscopic Atraumatic Coronary Artery Bypass/Totally Endoscopic Coronary Artery Bypass (MIDCAB/EACAB/TECAB) are well-established methods of coronary revascularisation with excellent long-term outcomes. However, their use is restricted to very limited groups of patients.

The most important feature of CABG in long-term survival and an advantage over PCI is arterial revascularisation. Left internal mammary artery (LIMA) graft sewn to the left anterior descending artery (LAD) is associated with a significantly reduced risk of death, myocardial infarction (MI) and recurrent angina [6, 7]. Moreover, during 10-year follow-up, 90% of patients were free from coronary reinterventions [8].

Although total arterial surgical revascularisation is recommended, saphenous vein grafts (SVG) still remain the most commonly employed conduits for non-LAD vessels during CABG despite the high occlusion rate, reaching 15–20% at six to 12 months after surgery [9, 10]. The introduction of drug eluting stents (DES) has resulted in a significant reduction in the rate of repeated interventions, with similar rates of death and MI compared to bare metal stents [11].

Taking into account the short-term patency of DES and SVG, PCI with DES in vessels other than LAD provides a promising alternative to SVG. Together with LIMA-LAD bypass advantages, it constitutes the fundamental basis for the hybrid coronary revascularisation (HCR) strategy which consists of endovascular minimally invasive surgery with LIMA to LAD and catheter-based techniques with the implantation of DES in non-LAD vessels.

Due to the paucity of data from large, prospective randomised trials comparing HCR to standard surgical revascularisation, the POLMIDES pilot study has been designed to assess the safety and efficacy of hybrid revascularisation in patients with multivessel CAD referred for standard CABG.

The authors' guiding principle

Conventional CABG is an evidence-based gold standard in the treatment of patients with multivessel CAD. However, the limitations of standard CABG, with sternal incision, aortic manipulation and cardiopulmonary bypass-related complications, are well documented [2–5]. Conventional CABG disadvantages may be avoided when minimally invasive techniques are used. It is indisputable that LIMA to LAD conduit is the best route of surgical coronary revascularisation. These findings, combined with the advancement in PCI with DES, formed the rationale for the HCR. The optimal order and timing of the successive stages of revascularisation in HCR is still unknown. Therefore, the POLMIDES trial has been designed to evaluate the safety, feasibility, efficacy and clinical

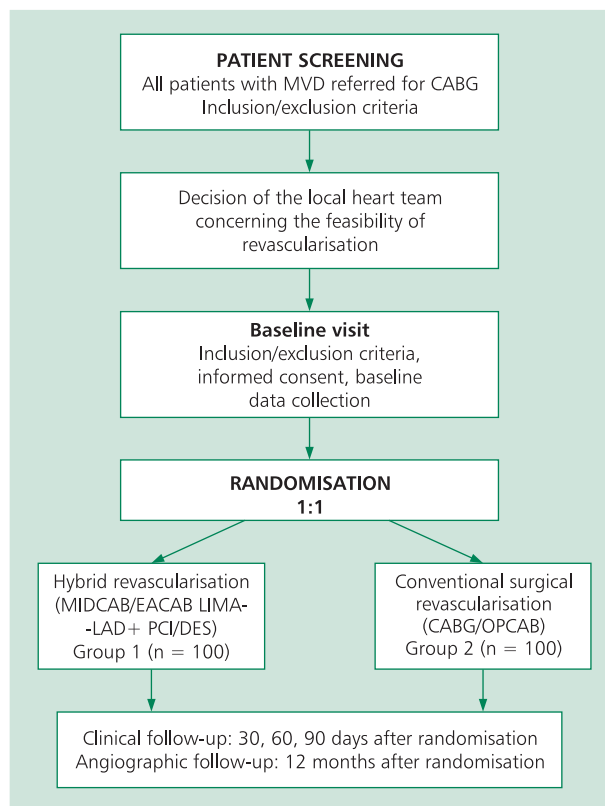


Figure 1. Study flow chart in the POLMIDES trial; CABG — coronary artery bypass grafting; DES — drug eluting stent; EACAB — endoscopic atraumatic coronary artery bypass; LIMA — left internal mammary artery; LAD — left artery descending; MIDCAB — minimally invasive direct coronary artery bypass; MVD — multi-vessel coronary disease; OPCAB — off-pump coronary artery bypass; PCI — percutaneous coronary intervention

outcomes of the integrated, two-staged HCR procedure in a prospective and randomised fashion.

Study objectives

Study design. The POLMIDES trial is a prospective, single-centre, randomised, open label, parallel, safety/efficacy pilot study. All consecutive patients with angiographically confirmed multi-vessel CAD involving LAD and a critical (> 70%) lesion in at least one major epicardial vessel (except LAD) amenable to both PCI and CABG referred for conventional surgical revascularisation, are screened by a local heart team (at least one interventional cardiologist and a cardiothoracic surgeon). The heart team will check all the inclusion/exclusion criteria and the eligibility to perform CABG and PCI. Patients who qualify for the study will be randomised in a 1:1 fashion for HCR or standard surgical revascularisation. The study flow chart is shown in Figure 1. The study protocol has been approved by the local ethics committee and complies with the Declaration of Helsinki. Written informed consent will be obtained from all study participants.

Primary endpoint. The primary endpoint is the evaluation of the feasibility and safety of HCR. The feasibility has been defined by means of the percentage of patients with a complete hybrid procedure according to the study protocol and a percentage of conversion to standard CABG. The safety has been defined as the occurrence of major adverse cardiac events (MACE) such as death, MI, stroke, repeat revascularisation, or major bleeding during the 12-month period after randomisation.

Death. In comparing the two treatment strategies, death for any reason will be examined. All deaths are considered cardiac, unless an unequivocal non-cardiac cause can be established.

Stroke (cerebrovascular event). Cerebrovascular event (CVA) is any acute event related to the impairment of the cerebral circulation that lasts more than 24 hours and results in irreversible brain damage or permanent body impairment. Strokes may be further classified as ischaemic or haemorrhagic, based on imaging studies. The definitive evaluation of CVA will be conducted and confirmed by a local neurologist.

Myocardial infarction. Will be considered an event whether it occurred spontaneously or in association with PCI or CABG procedures. A definite diagnosis of MI will be made based on the following: within the first seven days post-intervention (HCR or CABG) — either new, abnormal Q waves and 1 ratio of peak creatine kinase-MB (CK-MB)/peak total CK > 10%, or new, abnormal Q-waves and 1 plasma level of CK-MB $5 \times$ the upper limit for normal; seven days after any intervention procedure (HCR or CABG) — either new, abnormal Q waves or enzyme changes defined as more than 10% of the ratio of peak CK-MB/peak total CK on one or more than one sample (if no ratio is available — one or more than 1 plasma level of CK-MB $5 \times$ the upper limit for normal) [12].

Repeat revascularisation. Every subsequent revascularisation procedure and its indication will be reported and documented.

Major bleeding. Major bleeding episodes have been defined as substantially disabling bleeding, intraocular bleeding leading to the loss of vision, or bleeding necessitating the transfusion of at least two units of blood. Major bleeding is classified as life-threatening if the bleeding episode was fatal or led to a reduction in the haemoglobin level of at least 5 g/dL, or to substantial hypotension requiring the use of intravenous inotropic agents, if it necessitated a surgical intervention, if it was a symptomatic intracranial haemorrhage, or if it necessitated the transfusion of four or more units of blood. Minor bleeding episodes include other haemorrhages that led to the interruption of the study medication [13].

Secondary endpoints. The secondary endpoints are:

- postprocedure and follow-up angiographic measurements (12 months after randomisation) as patency of grafts and restenosis in revascularised segments;

- assessment of quality of life of living study participants according to SF-36 Health Survey version 2 (one and six months after procedure);
- cost-effectiveness defined as the cost of the revascularisation procedure and costs of hospitalisation in both groups.

METHODS

Study population

Two hundred consecutive patients referred for conventional CABG will be randomised into the HCR (Group 1) vs standard surgical revascularisation (Group 2) at the study centre. The inclusion and exclusion criteria are shown in Table 1. All patients will receive acetylsalicylic acid in a dose of 75 mg per day, and other medication according to the guidelines of the European Society of Cardiology.

Risk profiles

EuroSCORE. The EuroSCORE is a prognostic scoring system calculating the predicted operative mortality for patients undergoing cardiac surgery [14]. For every patient, the EuroSCORE will be calculated to estimate predictive operative mortality and to balance baseline patient characteristics.

Syntax SCORE. The SYNTAX score is being developed to characterise prospectively disease complexity of the coronary vasculature with respect to lesion frequency, location, and angiographic complexities [12]. The SYNTAX score will be assessed on the basis of preprocedure diagnostic angiography.

Procedural techniques

Group 1 — hybrid revascularisation. The surgical procedure is the first stage of the above-mentioned HCR strategy. The implantation of LIMA into LAD will be performed during MIDCAB/EACAB (at the surgeon's discretion). In the second stage, within 36 hours of the surgery, PCI with DES in non-LAD arteries qualified for revascularisation will be carried out. The precise time of PCI will be assessed based predominantly on the clinical status and chest drainage (less or equal to 25 mL/h for two consecutive hours with haematocrit level $\geq 25\%$ and platelets level $\geq 80,000/\text{mm}^3$). Clopidogrel with a loading dose of 300 mg or 600 mg will be administered orally six or two hours before the planned PCI respectively, followed by 75 mg daily thereafter.

The first stage — MIDCAB technique. Intubation with a double-lumen endotracheal tube will be performed in order to achieve one lung ventilation. Minimally invasive direct coronary artery bypass will be carried out via small (6–8 cm), antero-lateral thoracotomy. First, LIMA harvesting will be executed using totally endoscopic or partially endoscopic techniques facilitating harmonic scalpel (Ethicon). An incision in the fourth or fifth intercostal space will be performed, then the pericardium will be opened longitudinally, and subsequently the anterior wall of the heart will be exposed. The anastomosis will be made on the beating heart with the aid of

Table 1. Inclusion and exclusion criteria

Inclusion criteria	Exclusion criteria
<ul style="list-style-type: none"> • Age 18 or over • Angiographically confirmed multi-vessel CAD involving LAD and a critical (> 70%) lesion in at least one major epicardial vessel (except LAD) amenable to both PCI and CABG • Indication for revascularisation based on symptoms of angina and/or objective evidence of myocardial ischaemia • Patient willing to comply with follow-up visits • Patient signed informed consent 	<ul style="list-style-type: none"> • Severe congestive heart failure (class III or IV according to NYHA, or pulmonary oedema, cardiogenic shock) at the time of enrolment • Prior surgery with the opening of pericardium or pleura • Prior stroke (within six months) or more than six months if there are substantial neurological defects • Prior history of significant bleeding (within the previous six months) that might be expected to occur during PCI/CABG related anticoagulation • One or more chronic total occlusions in major coronary territories • Left main stenosis (at least 50% diameter stenosis) • Acute ST-elevation MI within 72 hours prior to enrolment requiring revascularisation • Planned simultaneous surgical procedure unrelated to coronary revascularisation (e.g. valve repair/replacement, aneurysmectomy, carotid endarterectomy or carotid stenting) • Contraindication to either CABG, MIDCAB or PCI/DES because of a coexisting clinical condition • Significant leukopenia, neutropenia, thrombocytopenia, anaemia, or known bleeding diathesis • Intolerance or contraindication to aspirin or both clopidogrel and ticlopidine • Extra-cardiac illness that is expected to limit survival to less than five years e.g. oxygen-dependent chronic obstructive pulmonary disease, active hepatitis or significant hepatic failure, severe renal disease • Suspected pregnancy. A pregnancy test will be administered pre-randomisation to all women of child-bearing age • Concurrent enrolment in another clinical trial • Patient inaccessible for follow-up visits required by protocol

CAD — coronary artery disease; LAD — left anterior descending; PCI — percutaneous coronary intervention; CABG — coronary artery bypass grafting; NYHA — New York Heart Association; MI — myocardial infarction; MIDCAB — minimally invasive direct coronary artery bypass; DES — drug eluting stent

a stabilising device (Medtronic), using the Prolene (7–0 or 8–0) monofilaments suture (Ethicon). The patency of the anastomosis and LIMA will be assessed intraoperatively, using transit time ultrasound (MediStim). Blood flow < 10 mL/min and pulsatility index > 5 will indicate poor outcome and distal anastomosis will be revised.

The second stage — PCI technique. Coronary angiography and PCI will be performed in the cath lab in the study centre via a femoral or radial artery approach. Based on angiography, after intracoronary nitroglycerine administration, the severity of the lesion (by the QCA) qualified for PCI, reference diameter of the vessel and TIMI flow will be assessed. Before PCI, angiography of LIMA to LAD conduit will be routinely performed. The choice of the guiding catheters, guidewires, pre- and post-dilatation strategy, and the use of vessel occluders will be left to the operator. Before the start of PCI, unfractionated heparin in a dose of 100 units per kilogram will be given. An additional dose will be administered according to

the active clotting time measurements during the procedure. The Xience (Abbot) everolimus eluting stents should be attempted for each lesion in a vessel \geq 2 mm (by visual assessment) that supplies viable myocardium, as evaluated on diagnostic angiogram. Every lesion should be completely covered by the stent with an overlap at both edges of at least 3 mm. Concomitant medications are detailed in Table 2.

Group 2 — conventional surgical revascularisation. The CABG will be performed at the surgeon's discretion and according to local clinical practice. The off-pump coronary artery bypass (OPCAB) technique as well as arterial revascularisation (LIMA as gold standard, right internal mammary artery as a second choice, radial artery as the third option) is preferred and will be attempted in all patients. A final decision regarding the surgical technique will be made on the table after intraoperative assessment of the haemodynamic and electrical status of the patient. Patients can be operated upon with or without ECC. Patients undergoing CABG/OPCAB

Table 2. Periprocedural medication

Group 1. Hybrid revascularisation	
First stage: MIDCAB/EACAB LIMA-LAD	
Pre-procedure:	aspirin 75 mg/d starting at least 12 h before procedure
Post-procedure:	aspirin 75 mg/d indefinitely
Second stage: PCI with DES	
Pre-procedure:	clopidogrel after obtaining a permissible amount of chest drainage, a loading dose of at least 300 mg 6 h before PCI, or 600 mg 2 h before PCI
Procedural:	heparin initial bolus <i>i.v.</i> with additional boluses to maintain an ACT > 250 s
Post-procedure:	aspirin 75 mg/d indefinitely, clopidogrel 75 mg/d for 12 months
Group 2. Surgical revascularisation	
Pre-procedure:	aspirin 75 mg/d starting at least 12 h before the procedure
Post-procedure:	aspirin 75 mg/d indefinitely

MIDCAB — minimally invasive direct coronary artery bypass; EACAB — endoscopic atraumatic coronary artery bypass; DES — drug eluting stent; PCI — percutaneous coronary intervention; ACT — activated clotting time

will be operated upon with the intention of complete revascularisation. All vessels with a significant stenosis of at least 50% in a vessel with a diameter of ≥ 2.0 mm (as previously estimated on the diagnostic angiogram during the local heart team's conference) should be considered for bypass surgery. The patency of the newly constructed conduits will be asses-

sed intraoperatively using transit time ultrasound (MediStim). Blood flow < 10 mL/min and pulsatility index > 5 will indicate a poor outcome, and distal anastomosis will be revised. Concomitant medications are detailed in Table 2.

Follow up

The follow-up assessment will be carried out at hospital discharge, and again three, six and nine months after the procedure. After 12 months, all patients will be hospitalised and control angiography will be performed. The follow-up schedule is shown in Table 3.

Statistical considerations

Statistical methods. All statistical analyses will be performed using Statistica software, version 7.1 or newer (Statsoft Inc, OK, USA). Continuous variables will be presented using mean, SD, median, 25th and 75th percentile, minimum and maximum values, as appropriate. Discrete variables will be presented in frequencies and percentages. Data collected during the follow-up period will be analysed using appropriate univariate and multivariate techniques. Kaplan-Meier plots of time-to-event variables will be constructed. The Cox proportional hazards regression model may be used to assess the effects of risk factors on the time-to-event variables. Loglinear models or logistic regression models may be used similarly for discrete outcomes. If baseline differences are observed between the hybrid patients and the CABG patients, a secondary analysis will be performed in which comparisons between treatment groups for principal safety and efficacy end-points will be adjusted for those baseline covariates that are found to be different.

Table 3. Follow-up schedule

	In hospital		Discharge	3 months	6 months	9 months	12 months
	Before procedure	After procedure					
Informed written consent	X						
Inclusion/exclusion criteria	X						
Randomisation	X						
Electrocardiogram	X ¹	X ²					X
Echocardiogram	X		X				X
Blood tests	X	X	X				X
Stress test		X ³					
Adverse events assessment	X	X	X	X	X	X	X
Study end-points assessment		X	X	X	X	X	X
QoL evaluation	X		X				X
Pregnancy test	X						X
Control angiography							X

¹after admission; ²within 30 minutes after the procedure; ³performed if indicated; QoL — quality of life

Power calculation. Post-hoc power analysis for the primary end-point will be performed after completion of the study.

Study organisation and interim analysis. University-based researchers (Medical University of Silesia, Katowice, Poland) with methodological experience will form the steering committee of the study, which will be responsible for the study design, implementation, data collection, monitoring, and final analyses. The steering committee is also responsible for the preparation and publication of the manuscripts reporting the study results. No formal interim analysis of the primary end-point of this study will be performed.

CONCLUSIONS

The POLMIDES is a prospective, randomised pilot study designed to determine whether HCR is safe, feasible and efficacious in patients with multi-vessel CAD referred for conventional CABG.

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Conflict of interest: none declared

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Prospektywne, randomizowane pilotażowe badanie oceniające skuteczność i bezpieczeństwo hybrydowej rewaskularyzacji w wielonaczyniowej chorobie wieńcowej (POLMIDES) — plan badania

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Streszczenie

Wstęp: Hybrydowa rewaskularyzacja wieńcowa (HCR) to połączenie małoinwazyjnych technik pomostowania przedniej gałęzi zstępującej lewej tętnicy wieńcowej (LAD) i przezskórnych interwencji wieńcowych (PCI) z implantacją stentów uwalniających leki antymitotyczne (DES) do pozostałych tętnic wieńcowych. Ze względu na brak danych z dużych, prospektywnych, randomizowanych badań klinicznych porównujących HCR ze standardową rewaskularyzacją chirurgiczną badanie POLMIDES zaprojektowano w celu oceny bezpieczeństwa i skuteczności HCR u osób z wielonaczyniową chorobą wieńcową, zakwalifikowanych do chirurgicznego pomostowania wieńcowego (CABG).

Cel: Głównym celem pracy jest ocena możliwości i bezpieczeństwa wykonania HCR.

Metody: Możliwość wykonania zdefiniowano jako odsetek pacjentów z pełną rewaskularyzacją hybrydową wykonaną zgodnie z protokołem badania oraz odsetek konwersji do standardowego CABG. Bezpieczeństwo zdefiniowano jako występowanie poważnych niekorzystnych incydentów sercowych, takich jak zgon, zawał serca, udar mózgu, powtórna rewaskularyzacja i poważne krwawienie w ciągu 12-miesięcznego okresu po randomizacji. Kolejni pacjenci z angiograficznie potwierdzoną wielonaczyniową chorobą wieńcową obejmującą LAD i krytyczne (> 70%) zmiany w co najmniej jednej z głównych tętnic nasierdziowych (poza LAD), kwalifikującą się zarówno do PCI, jak i CABG, zakwalifikowani do konwencjonalnej rewaskularyzacji chirurgicznej, zostaną poddani randomizacji 1:1 do HCR lub standardowej chirurgicznej rewaskularyzacji.

Wnioski: POLMIDES to prospektywne, randomizowane badanie pilotażowe mające na celu ustalenie, czy HCR u osób z wielonaczyniową chorobą wieńcową, zakwalifikowanych do konwencjonalnego CABG jest bezpieczne, możliwe i skuteczne (ClinicalTrials.gov, numer NCT01035567).

Słowa kluczowe: wielonaczyniowa choroba wieńcowa, rewaskularyzacja hybrydowa, kliniczne badanie pilotażowe, projekt badania

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