



Hybrid Coronary Revascularization for the Treatment of Multivessel Coronary Artery Disease

A Multicenter Observational Study

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ABSTRACT

BACKGROUND Hybrid coronary revascularization (HCR) combines minimally invasive surgical coronary artery bypass grafting of the left anterior descending artery with percutaneous coronary intervention (PCI) of non-left anterior descending vessels. HCR is increasingly used to treat multivessel coronary artery disease that includes stenoses in the proximal left anterior descending artery and at least 1 other vessel, but its effectiveness has not been rigorously evaluated.

OBJECTIVES This National Institutes of Health-funded, multicenter, observational study was conducted to explore the characteristics and outcomes of patients undergoing clinically indicated HCR and multivessel PCI for hybrid-eligible coronary artery disease, to inform the design of a confirmatory comparative effectiveness trial.

METHODS Over 18 months, 200 HCR and 98 multivessel PCI patients were enrolled at 11 sites. The primary outcome was major adverse cardiac and cerebrovascular events (MACCE) (i.e., death, stroke, myocardial infarction, repeat revascularization) within 12 months post-intervention. Cox proportional hazards models were used to model time to first MACCE event. Propensity scores were used to balance the groups.

RESULTS Mean age was 64.2 ± 11.5 years, 25.5% of patients were female, 38.6% were diabetic, and 4.7% had previous stroke. Thirty-eight percent had 3-vessel coronary artery disease, and the mean SYNTAX (Synergy Between PCI With Taxus and Cardiac Surgery) score was 19.7 ± 9.6 . Adjusted for baseline risk, MACCE rates were similar between groups within 12 months post-intervention (hazard ratio [HR]: 1.063; $p = 0.80$) and during a median 17.6 months of follow-up (HR: 0.868; $p = 0.53$).

CONCLUSIONS These observational data from this first multicenter study of HCR suggest that there is no significant difference in MACCE rates over 12 months between patients treated with multivessel PCI or HCR, an emerging modality. A randomized trial with long-term outcomes is needed to definitively compare the effectiveness of these 2 revascularization strategies. (Hybrid Revascularization Observational Study; [NCT01121263](https://clinicaltrials.gov/ct2/show/study/NCT01121263)) (J Am Coll Cardiol 2016;68:356–65)
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The tradeoffs in the benefits and risks associated with surgical and percutaneous coronary revascularization strategies pose challenges to physicians and patients alike when selecting the preferred intervention. The durability of surgical arterial grafts, weighed against the decreased invasiveness of percutaneous coronary revascularization, and the risks associated with both procedures have been the focus of important comparative effectiveness trials over the past 2 decades. More recent trials have sought optimal approaches for subgroups of patients on the basis of coronary anatomy or comorbidities. The recently reported 5-year outcomes from the SYNTAX (Synergy Between PCI With Taxus and Cardiac Surgery) trial, for example, demonstrated that coronary artery bypass graft (CABG) was superior to percutaneous coronary intervention (PCI) in patients with complex left main coronary artery (LMCA) or 3-vessel coronary artery disease (CAD) (1). Moreover, the FREEDOM (Comparison of Two Treatments for Multivessel Coronary Artery Disease in Individuals With Diabetes) trial showed that patients with diabetes mellitus treated with CABG had longer survival and fewer major adverse cardiac and cerebrovascular events (MACCE) than those treated with multivessel PCI, particularly patients with left anterior descending (LAD) artery disease, of whom more than 90% received a surgical left internal mammary artery (LIMA) graft (2). The benefits of CABG over PCI in these subpopulations have also been supported by the results of large registry studies (3). However, a trend toward a higher incidence of stroke was observed in the CABG arm of the SYNTAX trial, and a statistically significant increase in the incidence of stroke was observed in the CABG arm of the FREEDOM trial. The long-term patency of saphenous vein grafts has been questioned, with 1-year failure rates up to 46%, whereas later-generation everolimus and zotarolimus drug-eluting stents (DES) have 1-year restenosis rates <5% (4). The optimal revascularization strategy would combine a minimally invasive procedure that reduces perioperative risk, while maximizing durability and survival.

Hybrid coronary revascularization (HCR), combining minimally invasive CABG to the LAD coronary

artery and percutaneous intervention (PCI with DES) of non-LAD vessels, offers potential advantages beyond CABG or PCI alone, and, as such, could have a major impact on health outcomes and the health care system. The ability to deliver a new therapy for CAD that provides durability, without the trauma and prolonged recovery time associated with conventional CABG, would be a major advance in cardiovascular medicine. The interdisciplinary HCR approach has been steadily growing in cardiac centers across the United States and has the potential to disseminate widely to become the third major coronary artery revascularization alternative for patients with multivessel CAD. However, the known efficacy and safety of this novel approach rests upon data obtained through predominantly small, single-center observational studies (5-9).

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The overall objectives of this observational study were to explore the characteristics and outcomes of a contemporary patient population undergoing clinically indicated HCR in order to inform the design and feasibility of a subsequent comparative effectiveness trial. MACCE rates in patients undergoing clinically indicated HCR or multivessel PCI were therefore assessed, as were management practices for both revascularization procedures among participating institutions.

METHODS

This prospective cohort study was conducted at 11 clinical centers in the United States and was funded by the National Heart, Lung, and Blood Institute of the National Institutes of Health. In-person assessments were conducted at an initial visit, and patient follow-up was collected by telephone at 6, 12, 18, and 21 months after the initial revascularization or until August 31, 2012, whichever came first. Study data were transmitted from the clinical sites to a secure server at the Data Coordinating Center using a web-based, Health Insurance Portability and

ABBREVIATIONS AND ACRONYMS

CABG	= coronary artery bypass graft
CAD	= coronary artery disease
CI	= confidence interval
DES	= drug-eluting stent(s)
HCR	= hybrid coronary revascularization
HR	= hazard ratio
LAD	= left anterior descending
LIMA	= left internal mammary artery
LITA	= left internal thoracic artery
LMCA	= left main coronary artery
MACCE	= major adverse cardiac and cerebrovascular event(s)
MI	= myocardial infarction
PCI	= percutaneous coronary intervention
RCA	= right coronary artery

New York; and ⁹Medtronic, Inc., Fridley, Minnesota. National Institutes of Health and National Heart, Lung, and Blood Institutes grant 1-RC1-HL100951 to Drs. Puskas and Ascheim funded this study. Dr. Halkos has served as a consultant to Intuitive Surgical and Medtronic. Dr. Sutter serves on the Speakers Bureau of Intuitive Surgical. Dr. Shapiro serves on the Speakers' Bureau of Astra Zeneca; and serves as a consultant to Intuitive Surgical. Dr. Hoff serves as a peer trainer and consultant for Medtronic. Dr. Vassiliades is a full-time employee of Medtronic. All other authors have reported that they no relationships relevant to the contents of this paper to disclose. Friedrich-Wilhelm Mohr, MD, PhD, served as Guest Editor for this paper.

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