

## Clinical outcomes of hybrid coronary revascularization versus coronary artery bypass surgery in patients with diabetes mellitus

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**Background** Hybrid coronary revascularization (HCR) involves minimally invasive left internal mammary artery to left anterior descending coronary artery grafting combined with percutaneous coronary intervention (PCI) of non–left anterior descending vessels. The safety and efficacy of HCR among diabetic patients are unknown.

**Methods** Patients with diabetes were included who underwent HCR at a US academic center between October 2003 and September 2013. These patients were matched 1:5 to similar patients treated with coronary artery bypass grafting (CABG) using a propensity score (PS)-matching algorithm. Conditional logistic regression and Cox regression stratified on matched pairs were performed to evaluate the association between HCR and inhospital complications, a composite measure of 30-day mortality, myocardial infarction and stroke, and up to 3-year all-cause mortality.

**Results** Of 618 patients (HCR = 103; CABG = 515) in the PS-matched cohort, the 30-day composite of death, MI, or stroke after HCR and CABG was 4.9% and 3.9% (odds ratio: 1.25; 95% CI [0.47-3.33]; P = .66). Compared with CABG, HCR also had similar need for reoperation (7.6% versus 6.3%; P = .60) and renal failure (4.2% versus 4.9%; P = .76) but required less blood products (31.4% versus. 65.8%; P < .0001), lower chest tube drainage (655 mL [412-916] versus 898 mL [664-1240]; P < .0001), and shorter length of stay (<5 days: 48.3% versus 25.3%; P < .0001). Over a 3-year follow-up period, mortality was similar after HCR and CABG (12.3% versus 14.9%, hazard ratio: 0.94, 95% CI [0.47-1.88]; P = .86).

**Conclusion** Among diabetic patients, the use of HCR appears to be safe and has similar longitudinal outcomes but is associated with less blood product usage and faster recovery than conventional CABG surgery. (Am Heart J 2014;168:471-8.)

Coronary artery disease (CAD) is a major cause of morbidity and mortality among patients with diabetes mellitus. <sup>1</sup> Compared with nondiabetic patients, those with diabetes also have substantially worse outcomes. <sup>1,2</sup> Findings from recent studies demonstrate improved survival with coronary artery bypass grafting (CABG) surgery compared with percutaneous coronary intervention (PCI) with drugeluting stents (DES) in diabetic patients with multivessel CAD. <sup>3,4</sup> The

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observed survival benefit of CABG in these patients is presumed to be largely attributable to the left internal mammary artery (LIMA) to left anterior descending coronary artery (LAD) bypass, which provides excellent long-term durability.<sup>5</sup> However, CABG is also associated with significant inhospital morbidity, including stroke. In addition, the superiority of CABG over PCI in PCI amenable non-LAD lesions is questionable, given saphenous vein graft failure rates of approximately 10% to 20% within 1 year and  $\geq$ 50% at 10 years.<sup>6</sup> <sup>7</sup> Therefore, hybrid coronary revascularization (HCR) has been proposed as a combined surgical and percutaneous approach, which combines the benefits of a LIMA-LAD graft with the use of coronary stents for non-LAD lesions. In addition, when LIMA-to-LAD grafting is performed through limited incisions, HCR may also present a less invasive alternative to conventional CABG. A number of studies have been performed that suggest that HCR may result in faster recovery, fewer complications, and equivalent clinical outcomes compared

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with CABG in a general population of patients with multivessel CAD. <sup>8-11</sup> The purpose of this study was to compare clinical outcomes after HCR versus conventional CABG surgery in a matched high-risk population of patients with diabetes mellitus. We specifically sought to compare 30-day and longitudinal clinical outcomes, inhospital complications, and recovery.

### **Methods**

Study population and definitions

The starting population for the current analysis all eligible cases included in the Emory University institutional Society of Thoracic Surgeons (STS) Adult Cardiac Database (www.STS.org) between October 2003 and September 2013. At Emory, a custom data field was created within the STS database that defined hybrid patients on an intent-to-treat basis, in which HCR procedures involved a planned nonsternal LIMA-LAD bypass with PCI of  $\geq 1$  non-LAD lesion that were performed either in one setting or as 2-staged procedures. From this starting population of HCR "intention to treat" and other cardiac surgery procedures, we only selected patients with a history of diabetes (n = 4,032) (both insulin and noninsulin requiring) and applied a number of exclusion criteria, which are listed in Figure 1. From the remaining 3,427 patients, we then matched HCR cases ("as treated") to control patients who underwent elective or urgent conventional on- or off-pump CABG surgery. We also performed a sensitivity analysis in which diabetic patients were compared in whom HCR was considered (intention to treat) with a matched cohort of patients who underwent conventional CABG surgery. Diagnostic criteria for all characteristics other than HCR, including diabetes, were based on the STS registry definitions. This study was conducted in accordance with the Institutional Review Board approval of Emory University. The authors are solely responsible for the design and conduct of this study, all study analysis, the drafting and editing of the paper, and its final contents. No extramural funding was used to support this work.

## Indications, contraindications, and procedural information

At Emory, the consideration for HCR as well as the timing and sequence of the surgical and percutaneous components are carefully discussed with the heart team, but also with referring cardiologists as well as with the patient. The indications and contraindications for a hybrid approach as well as details on procedural information on HCR at Emory have been published previously. <sup>12,13</sup> In short, relative angiographic indications for HCR were presence of a significant stenosis in the proximal LAD disease that is amenable to LIMA-LAD bypass and non-LAD lesions that have an anatomy that is amenable to PCI. Relative contraindications for HCR included hemodynamic instability, prior cardiac or

#### Figure 1

#### Starting population Diabetic patients that underwent cardiac surgery at Emory between 2003-13 (n=4,032) Exclusions Clinical presentation of resuscitation or cardiogenic shock History of cancer (<5 years) or illicit drug use Prior cardiac surgery Concomittant non-coronary surgery Single vessel disease No internal mammary artery use (IMA) Intention to treat but not treated as HCR\* Diabetic population who underwent HCR or CABG N=3,410 (HCR n=103 , CABG n=3,307) Propensity score matched analysis Ratio: 1 to 5 (HCR:CABG) Study population N=618 (HCR n=103, CABG n=515)

Title: Flow diagram of the study population.Legend: Shown are the steps that led from the starting population to the PS-matched study population. \*These patients were included in a sensitivity analysis of intention to treat for HCR.

thoracic surgery, severe lung disease with the inability to tolerate single-lung ventilation, and morbid obesity. In most HCR cases, LIMA-to-LAD revascularization is performed first, with administration of clopidogrel (150 mg) approximately 4 hours after LIMA-LAD bypass and an additional loading dose of 300 mg at the time of PCI. This approach minimizes the risks of bleeding complications due to anticoagulation and dual-antiplatelet therapy use and allows assessment of patency of the LIMA-LAD graft at the time of PCI. However, patients with critical non-LAD anatomy PCI is usually performed first. In these cases, LIMA-LAD grafting was performed while continuing clopidogrel (75 mg/daily). For patients who underwent one-stage HCR procedures, 600 mg clopidogrel was administered through nasogastric tube after confirmation of LIMA patency but before coronary stenting. Most patients underwent both procedures during the index hospitalization to ensure complete revascularization. At Emory, the surgical component of HCR was performed with an endoscopic atraumatic coronary artery bypass approach up to 2009; thereafter, LIMA harvest was performed with the use of robotic assistance (Da Vinci Robotic surgical system; Intuitive Surgical, Sunnyvale, CA). After identification of the optimal target site on the LAD, the LIMA-to-LAD anastomosis is subsequently performed through a nonrib spreading, minithoracotomy, using a minimally invasive stabilizer (Nuvo; Medtronic, Minneapolis, MN). The whole procedure is performed without the use of cardiopulmonary bypass. The PCI component of HCR was performed using standardized methods and techniques. In most cases, coronary stent placement involved either first (sirolimus and placlitaxel) or newer (everolimus and zotarolimus) generation DES.

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