CARDIOVASCULAR

Intramyocardial Left Ventricle-to-Coronary Artery Stent: A Novel Approach for the Treatment of Coronary Artery Disease

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Background. **The direct intramyocardial left ventricle-to-coronary artery stent may provide an optional minimally invasive technique for coronary artery bypass graft surgery. We seek to test whether blood flow and regional myocardial function improve with this stent in totally ischemic myocardium.**

Methods. **The stent device was implanted in 8 anesthetized dogs using an open chest approach, arteriotomy of the proximal left anterior descending coronary artery, and connection of the vessel to the left ventricular chamber. Regional coronary blood flow and myocardial function were monitored under three conditions: normal coronary flow (baseline), coronary ligation, and stent flow.**

Results. **Left anterior descending coronary ligation markedly reduced coronary artery blood flow and regional myocardial function. With flow solely from the stent, the blood flow pattern changed to one with high peak forward flow during systole compared with baseline (94.8 ± 48.9 versus 56.8 ± 21.1 mL/min; $p < 0.05$) and one with significant negative backflow during diastole compared with baseline (−37.4 ± 23.1 versus 11.3 ± 17.2 mL/min; $p < 0.05$). However, the resultant mean forward flow increased to approximately 50% of baseline compared with less than 5% of baseline after coronary ligation. Regional myocardial function diminished entirely after coronary ligation, but recovered to approximately 60% of baseline with the stent. Normal systemic hemodynamics and global ventricular contractile function were maintained with the stent.**

Conclusions. **The left ventricle-to-coronary artery stent is a simple and readily deployable device that allows the perfusion of epicardial vessels directly from the left ventricle and can provide significant blood flow to improve the performance of ischemic myocardium. It may provide an effective, alternative means of treating coronary artery disease when standard coronary artery bypass graft surgery is not suitable.**

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More than 800,000 coronary artery bypass graft (CABG) procedures are performed each year to relieve symptoms and increase survival among patients with coronary artery disease [1]. Currently, CABG is still the most common surgical operation performed in the United States with half a million procedures performed annually [2]. Most of these cases are done with an open chest approach, use multiple native, biologic grafts, and include the use of cardiopulmonary bypass. Recent developments in total myocardial revascularization have enabled surgeons to perform this procedure without the use of the heart-lung machine in select patients through an operation termed off-pump CABG [3]. The benefits of off-pump CABG in select patient groups are clear and have paved the way toward novel approaches of revascularizing the myocardium. A more recent investigational strategy has been developed to facilitate total myocardial revascularization through the use of a device that establishes blood circulation between the left ventricle (LV) and a highly stenotic coronary artery—VSTENT (Percardia, Inc, Merrimack, NH) [4, 5]. This unique device is able to be deployed during off-pump CABG or traditional CABG using cardiopulmonary bypass.

To supply oxygenated blood to the coronary vasculature, the VSTENT establishes a direct channel from an epicardial coronary artery to the LV chamber. With the VSTENT in place, the normal blood flow relationship between the LV and the newly shunted epicardial coronary artery is altered because forward flow occurs primarily during systole, and, in the absence of any native or

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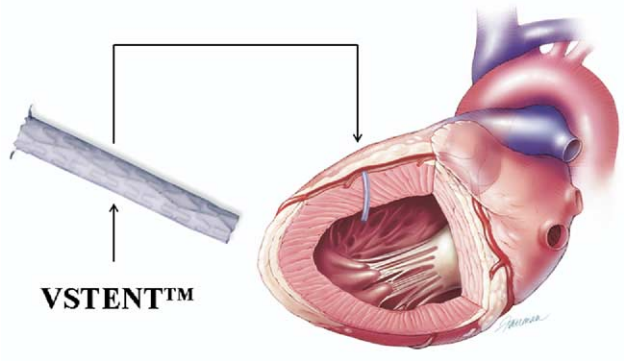

Fig 1. The VSTENT myocardial implant is placed through the myocardium to establish a connection between the coronary artery and the left ventricle.

stent valves, there is substantial backflow from the coronary artery to the LV.

The concept of using the LV as a source of oxygenated blood has been previously reported, although results suggested flow was insufficient to prevent ischemia [6–8]. In one particular study, high flow rates were reported, but these values were not correlated with improvements in regional function [9]. In a previous study by our group, we examined the concept of ventricular–coronary artery flow by the use of an extracorporeal off-artery device [4]. These results showed feasibility in such a way that enough net forward flow could be provided to prevent further myocardial ischemia and support regional myocardial function. In the present study, a VSTENT device amenable to minimally invasive delivery and deployment was assessed for its ability to preserve coronary blood flow and regional myocardial function in the face of varying levels of coronary occlusion.

Material and Methods

Studies were performed in compliance with the "Guide for the Care and Use of Laboratory Animals" by the Institute of Laboratory Animal Resources, National Research Council (Washington, DC), 1996. This study was approved by the Institutional Animal Care and Use Committee of Columbia University. The study was supported by the manufacturer of the VSTENT device, Percardia, Inc, which otherwise took no role in the design or control of the study, or the collection or interpretation of these data.

Device and Implantation Approach

The VSTENT device is a balloon-deployable, stainless steel, expanded polytetrafluoroethylene–covered stent, similar to traditional coronary stents (Fig 1). Its diameter is 2.5 mm, and it comes in five different lengths (14, 18, 21, 25, and 28 mm). For all animals in this study, the 25-mm length was sufficient to extend beyond the thickness of the myocardial wall. The device is implanted by means of a coronary arteriotomy between the first and second diagonal branches of the left anterior descending (LAD) coronary artery by using off-pump CABG surgery stabilization techniques. When implantation is complete, the VSTENT forms a 2.5-mm diameter direct channel between the LAD and the LV chamber through the intervening myocardium.

Surgical Procedure

Eight adult mongrel dogs of either sex weighing 26 to 32 kg were used in this study. Aspirin (325 mg oral) was administered daily for 3 days before surgery. Anesthesia induction was carried out with thiopental (5 to 7 mg/kg intravenously) and maintained with 1.5% to 2.0% inhaled isoflurane. Catheter-tip transducers (Millar Instruments, Inc, Houston, TX) were inserted into the LV and descending aorta through the right and left carotid arteries to measure LV pressure and aortic pressure, respectively. A 10- to 15-cm left thoracotomy was performed through the fifth intercostal space, and the pericardium was opened. A transit-time ultrasonic flow probe (Transonic Systems Inc, Ithaca, NY) was placed on a distal segment of the LAD to measure coronary artery blood flow. A pair of sonomicrometry crystals was placed mid-myocardium into the region supplied by the VSTENT (Sonometrics Corp, London, Ontario, Canada) to monitor segment shortening. All data were recorded by a digital sonomicrometry system (frequency approximately 200 Hz).

Before implantation of the VSTENT device, the dog was anticoagulated with 10,000 U of heparin intravenously. A 6-mm coronary arteriotomy was made and an intravascular shunt was placed for distal coronary artery protection. The VSTENT was then inserted into the underlying myocardium. This was accomplished with a delivery system by placing a needle through the arteriotomy and posterior wall of the artery, through the myocardium, and into the ventricle. A guide wire was inserted through the needle and into the LV, and the needle was removed. The VSTENT was premounted onto a balloon catheter and delivered until its upper edge was flush with the floor of the artery. This precise placement was achieved using a seating tool. The VSTENT was then

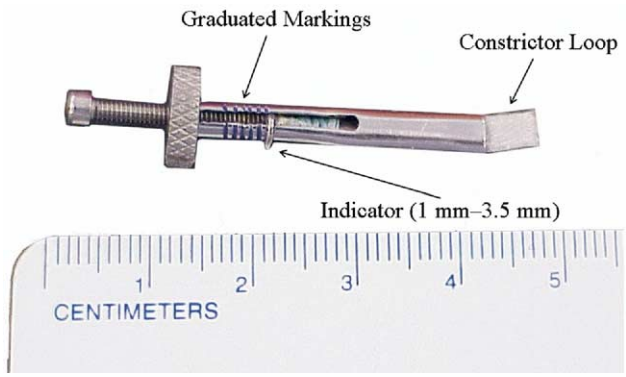

Fig 2. A microconstrictor device occludes the left anterior descending coronary artery proximal to the VSTENT in stepwise fashion to induce upstream coronary artery stenosis.