JOURNAL OF THE AMERICAN COLLEGE OF CARDIOLOGY
VOL. 70, NO. 6, 2017

ISSN 0735-1097/$36.00
http://dx.doi.org/10.1016/j.jacc.2017.06.020

First-in-Human Closed-Chest Transcatheter Superior Cavopulmonary Anastomosis

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ABSTRACT

BACKGROUND In the care of patients with congenital heart disease, percutaneous interventional treatments have supplanted many surgical approaches for simple lesions, such as atrial septal defect. By contrast, complex congenital heart defects continue to require open-heart surgery. In single-ventricle patients, a staged approach is employed, which requires multiple open-heart surgeries and significant attendant morbidity and mortality. A nonsurgical transcatheter alternative would be attractive.

OBJECTIVES The authors sought to show the feasibility of catheter-only, closed-chest, large-vessel anastomosis (superior vena cava and pulmonary artery [PA] or bidirectional Glenn operation equivalent) in a patient.

METHODS In preclinical testing over a decade, the authors developed the techniques and technology needed for nonsurgical crossing from a donor (superior vena cava) to a recipient (PA) vessel and endovascular stent-based anastomosis of those blood vessels. The authors undertook this transcatheter approach for an adult with untreated congenital heart disease with severe cyanosis and significant surgical risk. They rehearsed the procedure step by step using contrast-enhanced cardiac computed tomography and a patient-specific 3-dimensional printed heart model.

RESULTS The authors describe a first-in-human, fully percutaneous superior cavopulmonary anastomosis (bidirectional Glenn operation equivalent). The patient, a 35-year-old woman, was homebound due to dyspnea and worsening cyanosis. She was diagnosed with functional single ventricle and very limited pulmonary blood flow. The heart team believed surgical palliation conferred high operative risk due to the patient's complete condition. With the percutaneous procedure, the patient recovered uneventfully and remained improved clinically after 6 months.

CONCLUSIONS This procedure may provide a viable alternative to one of the foundational open-heart surgeries currently performed to treat single-ventricle congenital heart disease. (J Am Coll Cardiol 2017;70:745–52) © 2017 by the American College of Cardiology Foundation. Published by Elsevier. All rights reserved.

Many patients with congenital heart disease are born with 1 main pumping chamber or a functional single ventricle rather than the normal 2-ventricle circulation. Infants born with a single ventricle number about 5 per 10,000 live births (1). Without multiple palliative open-heart surgeries, their prognosis is poor and mortality is high. Occasionally, patients with a single ventricle present in adulthood (1).

In single-ventricle patients, surgery is often required in infancy to establish a temporizing source of pulmonary blood flow (2,3). Thereafter, improved and stable pulmonary blood flow is established by the bidirectional Glenn shunt (superior cavopulmonary

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Manuscript received March 28, 2017; revised manuscript received June 6, 2017, accepted June 7, 2017.

ABBREVIATIONS AND ACRONYMS

3D = 3-dimensional
BMS = bare-metal stent(s)
CT = computed tomography
PA = pulmonary artery
SVC = superior vena cava

anastomosis) surgery, which diverts superior vena cava (SVC) blood flow into the pulmonary arteries (PAs) (4,5). Months or years later, a passive pulmonary blood flow circuit is completed with the modified Fontan surgery, which consists of an inferior cavopulmonary anastomosis (6). This allows the single ventricle to exclusively support the systemic circulation.

Multiple open-heart surgeries, each requiring median sternotomy and cardiopulmonary bypass, come at the expense of cumulative morbidity and mortality. The superior cavopulmonary anastomosis has a morbidity rate close to 20% and mortality approximately 5% (7). Some post-surgical patients eventually require heart transplantation (8). Pre-operative atrioventricular valve regurgitation is an independent risk factor for death or heart transplantation (7,8). Post-operative morbidity can affect many organ systems, ranging from chylothorax and diaphragm paralysis to extracorporeal membrane oxygenation and cardiac arrest (7,9). Surgery in adults with single-ventricle congenital heart disease confers additional risk (10).

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For more than 2 decades, our group and others have been working to develop minimally invasive, nonsurgical therapy for patients with single-ventricle physiology (11–13). We describe a novel entirely transcatheter, nonsurgical, closed-chest procedure, which is the anatomic equivalent of the contemporary surgical superior cavopulmonary anastomosis. Our approach uses transcatheter electro-wire perforation to cross unoperated or naive intact blood vessel walls and transcatheter anastomosis using stents to connect adjacent large blood vessels.

METHODS

Previously, we investigated a percutaneous approach to cavopulmonary anastomosis using modified magnet catheters. Ultimately, we were successful in using transseptal needle puncture aimed at balloon targets, followed by covered stent placement in animals to create a "classic Glenn" or unidirectional cavopulmonary anastomosis (SVC connected exclusively to the right PA and excluding the left PA) (12). More recently, we accomplished transcatheter bidirectional cavopulmonary anastomosis (SVC blood flow distributed to both the right and left PA) using real-time cardiac magnetic resonance imaging guidance in animals (13).

We have tested an x-ray fluoroscopy-guided technique to cross between nearby blood vessels (inferior vena cava/abdominal aorta) using an off-the-shelf guidewire electrified by connecting to an electrosurgery pencil or "Bovie" in animals (14). To prepare for the procedure, we tested this identical vessel-crossing technique from the SVC into the PA in 6 animals. For the cavopulmonary anastomosis application, we positioned a coaxial crossing system (**Figure 1**) from the SVC, consisting of a 0.014-inch Astato XS20 guidewire (Asahi Intecc, Santa Ana, California), 0.035-inch PiggyBack wire converter (Teleflex Vascular Solutions, Minneapolis, Minnesota), NAVICROSS microcatheter (Terumo Interventional Systems, Somerset, New Jersey), and JR4 guiding catheter (Cordis, Milpitas, California). We aimed the crossing system toward an Amplatz Gooseneck target snare (Medtronic, Minneapolis, Minneapolis) in the PA. The 0.014-inch guidewire was electrified by attaching the back end to the electrosurgery pencil (**Figure 1**) set to pure cutting mode at 50 W before advancing the wire across donor and recipient vessel walls. Once across, the guidewire was exchanged for a stent delivery system. Vessel-to-vessel crossing was successful in all. In 3 of those animals, we attempted transcatheter covered-stent implantation to achieve cavopulmonary anastomosis. All were successful. Animal procedures were approved by the institutional animal care and use committee, and followed contemporary National Institutes of Health guidelines.

PRELIMINARY PREPARATION AND PROCEDURE. We trained in the electro-wire crossing technique with experienced operators during clinical transcaval access for transcatheter aortic valve replacement (15). We planned the procedure step by step using pre-procedure contrast-enhanced computed tomography (CT) (**Figure 2**) (16). For vessel-to-vessel crossing, we paid particular attention to an optimal SVC exit point and PA entry point, fluoroscopic visible landmarks and projection angles, and avoiding interposed vital structures. For covered- and bare-metal stent (BMS) anastomosis, target dimensions and distances were planned. We simulated the procedure beforehand on a patient-specific 3-dimensional (3D) printed heart model (**Figure 3**) based on the contrast-enhanced cardiac CT.

The procedure has 3 key steps: 1) the walls of 2 nearby blood vessels to be connected (SVC and right PA) were traversed by electrifying a small, insulated commercial 0.014-inch guidewire as described (14,15); 2) after the wire connected the 2 large blood vessels, we implanted a covered stent ("endograft") to bridge the 2 vessels; and 3) BMS anchoring was used as an SVC end-to-end anastomosis landing zone and to secure the right PA end-to-side anastomosis. In