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PERIPHERAL

Immediate Outcomes of Covered Stent Placement for Treatment or Prevention of Aortic Wall Injury Associated With Coarctation of the Aorta (COAST II)

Nathaniel W. Taggart, MD,[a] Matthew Minahan, BS,[b] Allison K. Cabalka, MD,[a] Frank Cetta, MD,[a] Kudret Usmani, BA, BSc,[b] Richard E. Ringel, MD,[c] on behalf of the COAST II Investigators

ABSTRACT

OBJECTIVES This study aimed to describe the safety and short-term efficacy of the Covered Cheatham-Platinum stent (CCPS) in treating or preventing aortic wall injury (AWI) in patients with coarctation of the aorta (CoA).

BACKGROUND The COAST II trial (Covered Cheatham-Platinum Stents for Prevention or Treatment of Aortic Wall Injury Associated with Coarctation of the Aorta Trial) is a multicenter, single-arm trial using the CCPS for the treatment and/or prevention of AWI in patients with CoA and pre-existing AWI or increased risk of AWI.

METHODS Patients were enrolled if they had a history of CoA with pre-existing AWI (Treatment group) or with increased risk of AWI (Prevention group). Pre/post-implant hemodynamics and angiography were reported. A core laboratory performed standardized review of all angiograms. One-month follow-up was reported.

RESULTS A total of 158 patients (male = 65%; median age 19 years) underwent placement of CCPS. Eighty-three patients had pre-existing AWI. The average ascending-to-descending aorta systolic gradient improved from 27 ± 20 mm Hg to 4 ± 6 mm Hg. Complete coverage of pre-existing AWI was achieved in 66 of 71 patients (93%) with AWI who received a single CCPS. Ultimately, complete coverage of AWI was achieved in 76 of 83 patients (92%); 7 patients had minor endoleaks that did not require repeat intervention. Four patients experienced important access site vascular injury. There were no acute AWI, repeat interventions, or deaths.

CONCLUSIONS The CCPS can effectively treat and potentially prevent AWI associated with CoA. Access site arterial injury is the most common important complication. Longer-term follow-up is necessary to define mid- and late-term outcomes. (J Am Coll Cardiol Intv 2016;9:484–93) © 2016 by the American College of Cardiology Foundation.

Coarctation of the aorta (CoA) occurs in approximately 4 of 10,000 live births and comprises 5% to 8% of congenital heart disease (1). When present without additional defects, CoA may not be detected until late childhood or adulthood (2). Infants and young children with native CoA are typically treated surgically, but remain at risk for recurrent obstruction (3). Older children and

From the [a]Division of Pediatric Cardiology, Department of Pediatric and Adolescent Medicine, Mayo Clinic, Rochester, Minnesota; [b]Department of Cardiology, Boston Children's Hospital, Boston, Massachusetts; and the [c]Division of Pediatric Cardiology, Department of Pediatrics, Johns Hopkins University School of Medicine, Baltimore, Maryland. Support for the COAST II study is provided by a grant from the FDA Office of Orphan Product Development, grant number: 1R01FD003898-01. The NuMED Corp., maker of the Covered CP stent and Balloon-in-Balloon catheters, provided funding for this trial, including salary and administrative support for Mr. Minahan, Ms. Usmani, and Dr. Ringel. All other authors have reported that they have no relationships relevant to the contents of this paper to disclose.

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adults may be managed either surgically or percutaneously. Although surgical repair in this age group may be definitive, up to 10% of older children or adults require further intervention (4,5).

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Balloon angioplasty of native CoA, carries a relatively higher risk of aortic wall injury (AWI) and recurrent obstruction (6–8). This has led to the "off-label" use of bare-metal stents in older patients (9–14). Although such interventions are generally safe, aortic dissection, aneurysm, and rupture have been reported, particularly in the context of severe or complex lesions (15–17). To prevent AWI during the primary stent implantation procedure, covered stents, currently unavailable for use within the United States, have been used in Europe and elsewhere with reports of safety and efficacy (11,18–23).

The balloon-expandable Covered Cheatham-Platinum (CP) stent (CCPS) (NuMED, Hopkinton, New York) was developed for the transcatheter treatment of native and recurrent CoA. It received the European Union C.E. mark in 2003 and is widely available outside of the United States. The Covered CP stent is composed of a bare-metal CP stent, covered its entire length with an expandable sleeve of ePTFE. Dilation of the CP stent to 22-mm diameter results in stent shortening of approximately 20%. The ePTFE sleeve has a wall thickness of 0.005-inch with an internodal distance of 35 to 55 μm. The tubing is attached to each end of the CP stent with a cyanoacrylate adhesive on a physically etched section of the sleeve.

The COAST (Coarctation of the Aorta Stent Trial) multicenter study began in 2007, demonstrating the safety and efficacy of bare-metal CP stents for treatment of CoA (24,25). As part of the investigational device exemption protocol and the COAST trial, CCPS was available at participating sites for compassionate use and emergency implantation in case of AWI during the procedure. Informed consent included trial information. Although such implants preceded the start of the COAST II (Covered Cheatham-Platinum Stents for Prevention or Treatment of Aortic Wall Injury Associated With Coarctation of the Aorta) study, patients were prospectively followed using COAST protocol. Once the COAST II study opened, these patients were included and identified as "legacy patients." The prospective arm of the COAST II study began in 2010 and continued through December 14, 2011. Subsequent to closure of enrollment, ongoing use of the CCPS was made available under a Continued Access protocol. We report technical results, short-term efficacy, and safety of the CCPS for prevention and treatment of AWI associated with CoA through September 2014.

METHODS

SCREENING/INTAKE EVALUATION. The COAST II trial is a multicenter, single-arm clinical study of the safety and efficacy of CCPS for treating AWI in patients with a history of CoA (Treatment group) or preventing AWI in patients with CoA and presumed risk factors for developing AWI with bare-metal stent placement (Prevention group). **Table 1** summarizes inclusion and exclusion criteria. **Figures 1 and 2** demonstrate representative baseline and post-implant angiography of patients in the Treatment and Prevention groups. Nineteen pediatric cardiac centers in the United States participated in the COAST II trial. The study received approval by the Johns Hopkins Institutional Review Board and by institutional review boards of all participating centers.

Participants described in this report were enrolled in the COAST II study and are referred to as: 1) prospectively enrolled patients, if enrolled directly into the COAST II study; 2) legacy patients, if a CCPS was implanted during the original COAST trial via Food and Drug Administration (FDA) Emergency Use or FDA Compassionate Use guidelines; or 3) continued access patients, if treated after pivotal trial enrollment closed, under FDA-approved continued access,

TABLE 1 Patient Selection

Inclusion criteria
• Native or recurrent aortic coarctation* associated with 1 or more of the following:
• Acute or chronic aortic wall injury†
• Nearly atretic descending aorta to 3 mm or less in diameter
• Genetic syndromes associated with aortic wall weakening (e.g., Marfan syndrome, Turner syndrome, familial bicuspid aortic valve with ascending aortic aneurysm)
• Advanced age (60 yrs or older)
Exclusion criteria
• Patient size too small for safe delivery of the device (absolute exclusion of patients <20 kg), possible exclusion of patients 20 to 30 kg after discussion of risk with parents/guardians
• Planned deployment diameter of stent <10 mm or >22 mm
• Location of coarctation would require placement across a carotid artery‡
• Adults lacking capacity to consent
• Pregnancy

*The significance of aortic obstruction was left to the judgment of the participating investigator. Indications might include mild resting aortic obstruction associated with: exercise related upper extremity hypertension; severe coarctation with multiple and/or large arterial collaterals; single-ventricle physiology; left ventricular dysfunction; ascending aortic aneurysm. †Aortic wall injury might include descending aortic aneurysm; descending aortic pseudoaneurysm; contained aortic wall rupture; noncontained rupture of the aortic wall. ‡Crossing or covering of a subclavian artery was permissible in certain situations, but only after alternative treatments had been considered.

ABBREVIATIONS AND ACRONYMS

AE = adverse event(s)
AWI = aortic wall injury
CP = Cheatham-Platinum (stent)
CCPS = Covered Cheatham-Platinum stent
CoA = coarctation of the aorta
CT = computed tomography
FDA = Food and Drug Administration
SBP = systolic blood pressure

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