

EDITORIAL COMMENT

# COAST-ing Toward Covered Stents for Aortic Coarctation

## Not All Plain Sailing!\*

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It is fundamental to the human psyche to strive for the things we don't have. This need has driven innovation and technological advancement for millennia. Occasionally, however, this has come at a cost, especially when the pursuit to replicate technology available to others has led to impatience. The saga of large-diameter, balloon-expandable covered stent availability in the United States is no exception with the protracted process required to clinically test such a "low use" product, leading to somewhat circuitous ways to ensure technology available to others is available for our own patients (1). The most widely used such stent, the covered Cheatham-Platinum stent (CCPS) has been CE marked since 2003, and despite 13 years of data outside of the United States, there remains no U.S. approval for this stent. Arguably, this has led to unacceptable risk for U.S. patients and interventionalists, limiting their therapeutic options. However, thanks to the work of Taggart et al. (2), published in this issue of *JACC: Cardiovascular Interventions*, one can only hope that "looking over the garden wall" with envy at colleagues elsewhere in the world where covered stents are freely available will soon be a thing of the past.

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### The COAST II (Covered Cheatham Platinum Stents for the Prevention or Treatment of Aortic Wall Injury

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Associated With Coarctation of the Aorta) trial is a multicenter, single-arm trial using the CCPS for the treatment and/or prevention of aortic wall injury in patients with coarctation of the aorta (CoA). One-hundred and fifty-eight patients in 19 U.S. centers were either included as a treatment cohort (53%) or a prevention cohort (47%), and enrolled prospectively as part of this study, through emergency use of CCPS through the COAST trial, or through continued access following closure of the COAST II trial. There was 100% technical success, suggesting no issues with stent delivery and that perhaps pre-procedural imaging may have been available to optimize minimization of those with unsuitable anatomy. Excellent reduction in coarctation gradients were demonstrated, mirroring other large studies evaluating stenting as primary therapy for CoA (3-6). Indeed, most cardiologists would accept that stenting is the primary choice for coarctation and recoarctation therapy in older children and adults as a consequence of the excellent short- to medium-term outcome data. There remains some debate, however, as to which patients should receive a covered versus a bare-metal stent for CoA because there are ongoing concerns, highlighted again in this study, regarding added potential for complications associated with covered stents. When compared with femoral artery injury reported in the COAST trial (7), there was a more than 50% increase in serious and subclinical femoral artery injuries noted in the COAST II cohort. Indeed, the true incidence of femoral arterial complications encountered in this trial is not exactly known due to lack of systematic radiological evaluation after the treatment or at follow-up. There were also 2 patients with left-arm symptoms following covering of the left subclavian artery and 3 patients with major stent malposition, a consequence that holds far more

significance with covered stents. In patients with clear pre-existing aortic wall injury, the potential increased risks with covered stents are justified; however, determining which cohorts within the prevention group warrant a covered stent remains more challenging. A recently published randomized trial comparing the CP bare stent with the CP covered stent for severe native coarctation in adults demonstrated no difference in acute or follow-up aortic wall injury in the bare-metal stent group (8). Indeed, the cohort in this study had higher peak gradients and smaller mean minimum aortic diameters than those reported in the COAST II trial, suggesting more extreme CoA. The rationale for placing a covered stent to mitigate against longer-term aneurysm formation may be valid; however, reported rates of aneurysm formation, although varied, are generally low (0% to 4%) (7-10). Higher-risk groups have been identified, including those older than 40 years and those with an abdominal aortic coarctation (10) with probable increased risk with a pre-existing vasculopathy and a long, tortuous morphology. In general, the COAST II inclusion criteria reflected these higher-risk cohorts; however, the mean minimal diameters in the prevention group (5 mm) were 2 mm greater than the diameter outlined in the inclusion criteria for the study ( $\leq 3$  mm), suggesting operators were implanting for less severe CoA because it is hard to imagine the majority of the cohort were  $>60$  years or had a genetic syndrome with associated vasculopathy. This may reflect greater comfort with using a covered stent because it will protect against

catastrophic aortic wall injury; however, this may not be the case and indeed may lead to delayed recognition (11).

The other, slightly surprising, finding from this study was the 8% incidence of minor endoleak despite 7 patients receiving multiple CCPS for persistent leak. Although the anatomy in these cases is not identified, one has to question whether a self-expanding stent graft may be more suitable when there is a dominant aneurysm without significant residual coarctation (12). Endoleaks have still been reported with stent grafts; generally, however, these are type II endoleaks with residual flow to the aneurysm via retrograde flow through intercostal vessels.

It is beyond doubt that approval of a covered stent in the United States will have a significant impact on patient care, and the work carried out by Taggart et al. (2) will add greatly to this. A recent needs survey of pediatric interventional cardiologists identified availability of large-diameter covered stents as the device that would have the greatest impact on patient morbidity (13). That said, with new technology comes the responsibility to use it prudently and to continue to gather data. The range and functionality of covered stents extend well beyond the CCPS and to provide a complete therapy to our patients, we need to be versed in all available options and choose wisely.

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