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EDITORIAL COMMENT

Covered Stents for Coarctation of the Aorta

Treating the Interventionalist or the Patient?*

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Interventionalists treating congenital heart lesions are constantly faced with challenging therapeutic decisions, often without randomized trials to support one approach over the other. Indeed, detailed outcome data, particularly outside of the United States, may lag behind the availability of a particular device or stent, and therefore, application of a procedure may be based on rational thought and evolving clinical experience rather than on published trials. This is certainly the case with the use of covered stents for endovascular treatment of coarctation of the aorta (CoA). Therapeutic options for native CoA in adults have evolved from surgical correction through balloon angioplasty in the early 1980s to stent implantation in the 1990s. Concerns regarding the potential for aortic wall trauma with endovascular arterioplasty evolved following reports describing high aneurysm rates (7% to 20%) (1,2). Although reported rates of aortic wall injury with stenting are significantly lower (0% to 4%) (3–5), scattered reports of aortic wall rupture following stenting (6,7) have led to the perception that covered stents mitigate against this, despite the fact that aortic wall disruption following covered stent implantation has also been reported (8,9). Therefore, outside of the United States and due to easy availability, there is a move toward elective use of covered stents for most aortic coarctation because of the perception that this is safer for the patient. However, large studies assessing the outcomes with bare-metal stents have demonstrated excellent safety profiles. The largest of these studies demonstrated aortic dissection in 9 of 565 procedures (1.6%) (5). In general, acute aortic wall injury (3.9%) was significantly more common in those who underwent pre-stent balloon angioplasty (odds ratio [OR]: 4.2) and patients over 40 years of age (OR: 2.95). A follow-up study from the same group evaluating aneurysm formation with post-procedural imaging (albeit in only 27% of the cohort) confirmed the deleterious impact of pre-stent angioplasty (10). Age at stent implantation in this study was not found to be significantly associated with aortic wall injury; however, abnormalities increased with a balloon/CoA ratio ≥3.5 (OR: 1.5). More contemporary studies with complete follow-up imaging have reported lower indexes of aortic wall injury (0% to 1%) (3,4). Recently, the COAST (Coarctation of the Aorta Stent Trial) (11) reported on 105 patients with a median age of 16 years who underwent implantation of a bare-metal Cheatham-Platinum stent (NuMed Inc., Hopkinton, New York) for native or recurrent coarctation through 19 centers in the United States. Of 167 patients screened, 122 participants had a stent implanted, 17 (14%) of whom had a covered stent (available under emergency use protocol) due to pre-existing aortic wall injury, near atresia of the aorta, or physician preference. Indeed, 4 patients were found to have a small aortic aneurysm after compliance testing with subsequent implantation of a covered stent, which raises further questions about the risk/benefit ratio of compliance testing in this setting. Of the 105 bare-metal implants, 1 patient (1%) developed a localized dissection after stenting that was not seen with computed tomography the following day, suggesting that the injury had healed. These studies support the use of bare-metal stenting for the majority of patients with CoA, with covered stents reserved for those deemed to be high risk or with pre-existing aneurysm formation. The definition of high risk is somewhat empiric but has evolved from previous reports (5,8,10) and included older patients (age >40 years), patients with Turner syndrome, and those with near atresia of the aorta. Hence, variance of opinion still exists with regard to the place for covered stents in the setting of endovascular treatment of CoA with the spectrum ranging from elective use in all patients to bailout use with aortic wall injury following bare-metal stenting.

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In this issue of *JACC: Cardiovascular Interventions,* Sohrabi et al. (12) contribute significantly to the debate regarding choice of appropriate stent type in adult patients with native CoA. This is the first randomized trial addressing the use of bare and covered stents for the treatment of CoA. They report acute and medium-term results from 120 patients with a median age of 23.6 years, randomized to receive either bare-metal or covered Cheatham-Platinum stents. The majority of patients had severe CoA with mean coarctation diameters of 3.3 mm in both cohorts (similar measurements in COAST were 7.9 mm). The protocol outlined an aggressive single-step dilation strategy with no limitation placed in relation to balloon/CoA ratio and a goal to achieve dilation up to the diameter of the

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proximal isthmus at the level of the takeoff of the left subclavian artery and not exceeding the aortic diameter at the level of the diaphragm. Excellent procedural outcomes were achieved in both groups with no major acute complications including aortic wall compromise. Over a follow-up period of 31 months, including high-resolution computed tomographic angiography assessment at 6 months in all patients, pseudoaneurysm formation was noted in 2 patients, both in the covered stent cohort. Both patients had elective successful occlusion of these aneurysms with placement of further covered stents. Recoarctation was noted in 4 patients; all were in the bare-metal stent cohort and all were treated with further elective covered stent implantation, although the reason for choosing a covered stent in this setting is unclear and presumably related to concerns regarding intimal ingrowth. These data support the preexisting literature demonstrating excellent therapeutic outcomes with stenting for CoA. However, what conclusions can be drawn regarding the need for covered stent implantation? Elective covered stent implantation offered no particular advantage in patients with severe native CoA, and this is supported by numerous contemporary, albeit nonrandomized, studies reaffirming excellent outcomes with minimal complication rates with bare-metal stents. One may argue that covered stents may provide an "insurance policy" against aortic dissection and rupture; however, this is not supported by the albeit sparse literature, with 1 report describing rupture following covered stent implantation for a large aortic aneurysm (8). The investigators in this report concluded that a self-expanding stent graft may have been more appropriate, and this highlights the need for a sensible application of available stent types to the varied anatomy seen in CoA patients. Covered stents are an essential part of the story, and the lack of wide availability in the United States has limited choices for physicians and patients alike; however, this should not translate into using them universally just because they are available. As many cases of stent embolization have been reported as cases of severe aortic wall trauma, and covered stent migration may be equally catastrophic in this setting. Therefore, as interventionalists, we should trust the data, and those who are fortunate enough to have access to covered stents should use them appropriately when potential benefit is expected. To summarize, we still believe that availability of covered stents is important in the armamentarium of the interventional cardiologist. We also believe, based on this study, that not every case of CoA should have a covered stent implanted. Perhaps future studies should focus on identifying high-risk groups that may truly benefit from implantation of a covered stent.

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Key Words: aneurysm ■ aorta ■ coarctation ■ covered stent.