Letter to the Editor

First Experiences with Vascular Closure Devices in the Endovascular Treatment of Aortic Coarctation

Endovascular therapy is now considered an effective and safe therapeutic solution for patients with coarctation of the aorta (CoA); nonetheless, vascular access complications are still deemed a significant etiology of procedural failure, mainly due to the application of large-bore devices in small-caliber access sites.[1] While aortic pathology was indicated as the principal etiology of inadequately developed post-CoA vasculature, some investigators have suggested a more generalized vasculopathy in patients with CoA, predisposing to higher vascular access complications.[2] Traditionally, surgical cut-down and manual compression were applied as the main strategies for access site hemostasis.[3] Recently, given the acceptable safety of vascular closure devices (VCDs) in abdominal and thoracic aortic repair, VCD application has been advocated as an alternative. Still, the previously mentioned small-caliber vascular access sites and the presumably generalized vasculopathy of the aorta prohibit VCD use in patients with CoA.[4] Additionally, a retrospective study revealed a high complication rate for VCD compared with surgical cut-down or manual compression.[3] No prospective study has, however, specifically evaluated VCD safety in this group of patients.

The present all-comers cohort recruited consecutive adult patients with de novo native CoA, no history of surgical or endovascular aortic repair, and common femoral and external iliac arteries larger than 6 mm in diameter. Preprocedural aortic computed tomography angiography (CTA) was mandatory for all potentially eligible patients for the accurate evaluation of access-site appropriateness, aortic analysis, and subsequent stent sizing. All access punctures were performed under ultrasound guidance through the common femoral artery, and 2 ProGlide VCDs (Abbott Vascular, Redwood City, CA, USA) were deployed routinely for each patient before the introduction of the larger sheet. (Long sheets [12 Fr] were ultimately placed for all the study participants.) The endovascular procedure has been explained in detail previously.[1] All the access punctures were ultrasound-guided through the middle of the anterior wall of the common femoral artery and above the profunda artery. The study physician followed up on the studied patients throughout their hospitalization, and the latter underwent 48-hour and 6-month postprocedural Doppler ultrasound examinations. The study protocol was approved by the Ethics committee of Rajaie Cardiovascular Medical and Research Center, and written informed consent was obtained from the participating patients.

Between September 2021 and June 2022, 32 patients were considered candidates for endovascular coarctoplasty. Seven patients were excluded for their history of coarctoplasty, and 25 patients at a median age of 30.0 years (27.0-37.0) (11 [44%] females) were included in the study. Table 1 summarizes the baseline clinical, imaging, and procedural characteristics of the study population. The procedure was successful in all the patients, with the right common femoral artery (the mean diameter = 8.8±1.4 mm by CTA) being almost the dominant vascular access site. Balloon-expandable stents were used for 17 patients (68%), and temporary cardiac pacemakers were deployed via the contralateral femoral vein for 5 patients with no complications. Three patients suffered vascular access complications: 2 hematomas (< 5 cm and 5-10 cm) and one 1.2×0.8 cm femoral artery pseudoaneurysm confirmed via the 48-hour ultrasound examination. Both hematomas were resolved, and the pseudoaneurysm was successfully treated with ultrasound-guided compression. Otherwise, no pathology was recorded in 48-hour and 6-month ultrasound examinations, nor was any sign of obstruction or diminished arterial flow reported in the 6-month ultrasound examination.

While controversies persist regarding the superiority of percutaneous access over cut-down access for endovascular aortic aneurysm repair vis-à-vis major vascular access complications, VCDs have a considerably low rate of periprocedural complications with improved procedural time and patient ease.

Our study is the first prospective report to show the safety of VCDs in terms of acute major vascular access complications in patients undergoing the endovascular treatment of CoA, with no vascular sequelae on 6-month follow-up imaging. As our study protocol shows, the concern surrounding small-caliber access sites in patients with CoA could be resolved by meticulous preprocedural imaging, ensuring vascular access size adequacy and safety. Moreover, the previously described generalized vasculopathy, albeit not yet proven, predominantly involves the pre-stenotic vasculature,[5] sparing the lower limb access site.

The considerable limitations of the current study are its observational nature and small sample size. Undoubtedly, the low incidence of de novo native CoA renders the design and conduct of comparative studies challenging. However, considering the safety concerns regarding VCD use in patients with CoA based on the available evidence, we conclude that a small proof-of-concept study before any large-scale investigation might be more ethical. Furthermore, the present study recruited only adult patients with a mean

diameter of 8 mm in the femoral access. Thus, VCD application in younger populations with smaller vascular access sites needs elucidation.

Table 1. Demographic, Clinical, Imaging, and Procedural Characteristics of the Study Population*

Characteristic	Value
Age (y) (IQR)	30.0 (27.0-37.0)
Sex	
Female (%)	11 (44.0)
Hypertension (%)	24 (96.0)
Cigarette smoking (%)	1 (4.0)
Coronary artery disease (%)	1 (4.0)
Diabetes mellitus (%)	1 (4.0)
Hyperlipidemia (%)	2 (8.0)
Number of antihypertensive medications	2.5 (1.2-3.0)
Hemoglobin (mg/dL)	13.0±1.51
Creatinine (mg/dL)	0.9 (0.8-1.1)
INR	1.1 (1.0-1.1)
CTA Parameters	
Diameter of the coarctation (mm)	3.52±2.55
Proximal portion of the descending aorta (mm)	13.83±4.19
Diameter of the aorta at the diaphragmatic level (mm)	16.72±3.67
Right femoral artery diameter (mm)	8.81±1.46
Left femoral artery diameter (mm)	8.32±1.65
Aortic Arch type (%)	
Type I	18 (72.0)
Type II	6 (24.0)
Type III	1 (4.0)
Femoral bifurcation above the inguinal ligament (%)	0
Anterior or near circumferential calcific disease (%)	0
Transthoracic Echocardiography Parameters	
Left ventricular ejection fraction (%)	55 (50-55)
Bicuspid aortic valve (%)	16 (64.0)
Moderate-to-severe aortic regurgitation (%)	7 (28.0)
Procedural Characteristics	
Pre-stenting pressure gradient (mm Hg)	40.0 (40.0-50.0)
Post-stenting pressure gradient (mm Hg)	0.0 (0.0-5.0)
Intraprocedural temporary pacemaker (%)	5 (20.0)
Access Site for Stent Delivery (%)	
Right femoral artery	23 (92.0)
Left femoral artery	2 (8.0)
Stent Type (%)	
Self-expandable	8 (32.0)
Balloon-expandable	17 (68.0)
Stent diameter (mm)	20.0 (18.0-22.0)

*Data are presented as mean±SD, $IQR_{25\%-75\%}$ or n (%).
INR, International normalized ratio; CTA, Computed tomography angiography; IQR, Interquartile range; SD, Standard deviation

We confirm that the approval of the Ethics Committee of Rajaie Cardiovascular Medical and Research Center was obtained, where necessary, as acknowledged within the text of the submitted manuscript. We also confirm that guidelines on patient consent have been met, and any details of informed consent obtained are indicated within the text of the submitted manuscript.

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