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Unmet Clinical Needs in AV Access

By Andrew Holden, MBChB, FRANZCR, EBIR

End-stage chronic kidney disease is a major health problem, increasing in prevalence in both developed and developing countries.[1] Renal replacement therapy comes at a significant cost, both in terms of health providers as well as time and morbidity for patients.[1] The most common method of renal replacement therapy for patients with end-stage kidney failure is hemodialysis. Long-term hemodialysis is commonly secured through the creation of arteriovenous (AV) access, a high-flow communication between an artery and vein in an accessible location for percutaneous access. Traditionally, AV access has been secured through an AV graft or autologous AV fistula. In recent years, there has been a clear preference for autologous AV fistula due to superior longer-term patency and functionality.[1] The most common sites for autologous AV access are between the radial artery and cephalic vein in the forearm (radiocephalic) or brachial artery and adjacent superficial veins in the upper arm (brachiocephalic or brachiobasilic). Unfortunately, AV access circuits are characterized by high failures rates, with the major cause of dialysis dysfunction being stenosis, typically located in the access circuit (extending from the AV anastomosis to the cephalosubclavian venous junction) or central veins. The major unmet clinical need in AV access maintenance is a method to provide effective and durable treatment of AV access stenoses.

Stenosis involving the AV access and central veins are usually due to trauma to the venous endothelium—most commonly barotrauma in the arterialized vein but also trauma related to repeated percutaneous access or central venous catheters. AV access stenosis is fibrotic and often resistant to angioplasty with conventional balloons, even when dilated to high pressures.[2-4] Other technologies have demonstrated excellent acute results including high-pressure, cutting, and scoring balloons.[5,6] There is no clear evidence regarding which technology is most effective, but high-pressure balloons are the most widely used. As long as one of these technologies is used, successful angioplasty with minimal acute residual stenosis should now be achieved in most cases. However, none of these technologies have been specifically developed for AV access intervention, and industry could consider shorter catheter lengths, larger balloon diameters, and more uniform guidewire compatibility for these devices. Guidelines on appropriate balloon sizing where there is a marked change in vessel caliber, such as the AV anastomosis or a lesion associated with poststenotic dilatation, should also be developed.

Restenosis after successful initial angioplasty is a major challenge to AV access maintenance, and a number of strategies have been evaluated to address this. The incidence of postangioplasty dissection in fibrotic AV stenosis is low, so bailout stenting is rare, but self-expanding stents have been used in restenosis with variable reported results. There are geographic variations in stent use in AV access, but generally, these are not widely used due to significant restenosis. Covered stents have a clear role in patients with true or false aneurysms of the AV circuit and some studies have reported superior patency to angioplasty or bare-metal stents.[7,8] However, covered stents are not in routine use, with one limitation being excessive cost.

Given the impact of drug-coated balloons (DCBs) in femoropopliteal arterial intervention, there has been considerable interest worldwide in evaluating this technology in the management of AV access stenosis. Currently, this approach is under investigation in large, multicenter, randomized controlled clinical trials and

practitioners are eagerly awaiting long-term results, including clinical efficacy and cost-benefit analysis. To date, the Lutonix™* DCB (BD Interventional) is the sole DCB approved for use in the United States, and interventionalists look forward to additional data from their investigational device exemption trial as well as others of all levels of evidence to help develop algorithms for treatment of AV access restenosis.

There are significant geographic differences in the approach to AV access intervention, influenced by evidence, device approvals, and remuneration. In New Zealand, AV access stenosis is initially managed with plain balloon angioplasty with refractory stenosis treated with cutting or high-pressure balloon angioplasty. DCB angioplasty is reserved for restenotic lesions and is only considered where the stenosis can be adequately dilated. Stents and covered stents are rarely used.

Although optimum management of AV access circuit stenosis provides the biggest current challenge, there are other unmet needs in AV access intervention. The optimum management of central venous stenosis remains unclear, as is the AV access with failed maturation. Techniques for the percutaneous creation of AV access are currently under evaluation as are devices to provide access when no superficial veins are available or can be created, such as the HeRO™* Graft (Merit Medical Systems, Inc.). Although AV access maintenance remains challenging, it is encouraging that new and potentially effective treatment strategies are on the horizon. ■

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Andrew Holden, MBChB, FRANZCR, EBIR
Director of Interventional Radiology
Auckland Hospital
Auckland, New Zealand
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