



Management of concomitant central venous disease

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Abstract: Symptomatic central venous disease (CVD) is a significant common problem in patients with end-stage renal disease given its adverse impact on hemodialysis (HD) vascular access (VA). The current mainstay management is percutaneous transluminal angioplasty (PTA) with or without stenting which is typically reserved for unsatisfactory angioplasty or more challenging lesions. Despite factors such as target vein diameters and lengths and vessel tortuosity that may determine the choice of bare-metal versus covered stents (CS), current scientific literature is pointing out the superiority of the latter one. Alternative management options such as hemodialysis reliable outflow (HeRO) graft showed favorable results in terms of high patency rates and fewer infections, however, complications such as a steal syndrome and, to a lesser extent, graft migration and separation are major concerns. The surgical reconstruction approaches such as bypass, patch venoplasty, or chest wall arteriovenous graft with or without endovascular interventions as a hybrid procedure are still viable options and may be considered. However, further long-term investigations are needed to highlight the comparative outcomes of these approaches. Open surgery might be an alternative before proceeding to more unfavorable approaches such as lower extremity vascular access (LEVA). The appropriate therapy should be selected based upon a patient-centered interdisciplinary discussion utilizing the locally available expertise in the area of VA creation and maintenance.

Keywords: Central venous disease (CVD); end-stage renal disease (ESRD); vascular access (VA); hemodialysis reliable outflow (HeRO); hemodialysis (HD)

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Introduction

Background

The presence of central venous disease (CVD) has great clinical importance for chronic kidney disease and end-stage renal disease (ESRD) population. CVD may limit the options for the creation of new vascular access (VA) and for those patients in whom VA is undertaken, may compromise the quality of the hemodialysis (HD) experience by causing symptomatic arm swelling and interrupting the ability to consistently receive the prescribed HD. CVD, defined as more than 50% stenosis in the internal jugular, axillary,

subclavian, or innominate veins (1). The most common mechanism is turbulent flow and mechanical trauma caused by current and prior central venous catheters resulting in intimal hyperplasia. The high blood flow volume from a concurrent arteriovenous fistula/graft (AVF/AVG) VA accelerates this process (2). Fifty percent of patients with CVD who did not undergo HD were asymptomatic (3), however, the clinical symptoms often unmasked with the initial creation of VA or during subsequent HD. The high venous pressures associated with a functioning VA may exceed the capacity of the collaterals resulting in venous hypertension. Clinically, symptomatic CVD manifests as

Table 1 The current available covered stents used for the endovascular management of central vein stenosis or occlusion

Balloon expandable
iCAST (Atrium Medical Corporation, Hudson, NH, USA)
Gore Viabahn VBX (W. L. Gore & Associates, Inc., Flagstaff, AZ, USA)
Self-expanding
Gore Viabahn (W. L. Gore & Associates, Inc., Flagstaff, AZ, USA)
Covera Vascular (BD Interventional, Franklin Lakes, NJ, USA)
Fluency Plus Endovascular (BD Interventional, Franklin Lakes, NJ, USA)

ipsilateral upper extremity (UE) swelling, pain, decreased access flow, and inadequate dialysis (3-5). Rarely, CVD does lead to VA thromboses absent a lesion within the body or immediate outflow tract of the VA.

CVD is more prevalent among dialysis patients with rates reaching up to 50% (6,7) since the majority of end-stage renal disease patients initiate HD using a catheter (8). After 20 years from the National Kidney Foundation Kidney Disease Outcomes Quality Initiative (KDOQI), these statistics have improved only slightly, leading to the latest change from “fistula first” to “fistula first, catheter last” (9).

Rationale and knowledge gap

With progression of CVD, the options for conventional UE VA may prematurely become exhausted, leading to catheter-dependence or the need for lower extremity vascular access (LEVA). LEVA has favorable primary and secondary patency rates (10,11), however it is associated with high infection rates of 18–41% (12,13). Additionally, contraindications for LEVA may exist for the patient with diabetes, peripheral artery disease or morbid obesity. In particular, the diabetic patient may be vulnerable to the development of neuroischemic foot wounds due to their attendant micro- and macrovascular disease, especially if VA ischemia develops. Sixteen percent of patients with LEVA reported lower extremity (LE) ischemia, often leading to major amputation (10-12,14). Conversely, a long-term tunneled dialysis catheter as the definitive was also found to be associated with higher mortality rates (15) compared to AVF/AVG.

Objective

Endovascular interventions including percutaneous transluminal angioplasty (PTA) and percutaneous transluminal stenting (PTS) are the mainstay therapies for CVD. We provide an overview of current endovascular interventions, utilization of hemodialysis reliable outflow (HeRO) grafts, and hybrid surgical approaches in the treatment of CVD.

Discussion

Endovascular interventions

According to the latest 2019 KDOQI VA guidelines (16), HD patients with symptomatic CVD are using primary PTA with PTS reserved for lesions that demonstrate intraprocedural recoil following PTA, i.e., provisional stenting (17,18). Rates of immediate lesion recoil are high due to the morphology of CVD including factors like long length and fibro intimal lesion morphology. These findings raise the question of whether primary stenting is the preferred approach in era of covered stent (CS) grafts. The immediate technical success of PTA is high ranging from 70% to 90%, however, recurrence is high, and multiple repeat interventions are generally required to maintain vessel patency (19). A few retrospective studies reported data on patency rates. Gür *et al.* (20) reported a primary patency rate of 42.4% with primary-assisted patency of 68.4% at 12 months. Another study reported higher a 12-month primary patency rate of 57% (21). A recent meta-analysis (22) that included eight comparative studies has compared these two modalities. This study showed that PTA was associated with better primary assisted patency rates compared to the PTS group at the 24-month follow-up only while primary patency rates were insignificant at 3, 6, 12 and 24 months. However, this simple comparison between the both techniques without accounting for previous treatments may be biased, since all included studies compared PTA as first-line therapy with PTS that was used either provisionally (i.e., following unsatisfactory PTA) or following re-stenosis/recurrence in a different setting.

Currently, two endovascular stent platforms are commercially available: bare metal stents (BMS) and CS (Table 1). These groups can be further classified as self-expanding and balloon expandable. The relative clinical

Table 2 Studies reported data on the patency rates of covered stents

Study	Number of patients	Technical success	Primary patency	Primary assisted patency	Secondary patency	Stent used
Jones <i>et al.</i> 2011 (24)	30	100%	97%, 81%, 67%, and 45% at 3, 6, 12, and 24 months	100%, 100%, 80%, and 75% at 3, 6, 12, and 24 months	–	Viabahn ^a
Anaya-Ayala <i>et al.</i> 2011 (25)	25	100%	29% at 12 months	85% at 12 months	94% at 12 months	Viabahn ^a [24]; Fluency ^b [1]
Boutrous <i>et al.</i> 2019 (26)	29	100%	92.9%, 91.7% and 80% at 6, 12, and 24 months	–	96.4%, 95.8%, and 93.3% at 6, 12, and 24 months	Viabahn ^a

^a, W. L. Gore & Associates Inc., CA, USA; ^b, Bard Peripheral Vascular, Tempe, AZ, USA.

benefits and the choice between these options may be challenging and depends on clinical factors such as target vein diameters and lengths, vessel tortuosity, proximity to the thoracic inlet and the need to preserve the internal jugular vein or prevent jailing of the contralateral innominate vessel. While CS appears to have better results according to the current literature, limited supporting data are available without firm recommendations from KDOQI (16,23). *Table 2* lists a few studies that reported data on the safety and effectiveness of CS. Furthermore, a study by Chen *et al.* (27) reported that the use of CS (Viabahn[®], W. L. Gore & Associates Inc., Flagstaff, AZ, USA) was an independent predictor for better primary patency rates. The CS favorable outcomes can be attributed to the inherent mechanism of prohibiting in-stent intimal hyperplasia formation via the covered design, thus, reducing the need for additional patency maintaining interventions vis-à-vis the BMS. While intimal hyperplasia may grow within the interstices of the BMS, a CS prevents this pattern. However, intimal hyperplasia may still occur only from the peripheral stent edges- resulting in a “candy wrapper” pattern.

The type of CS chosen depends on factors such as the length and location of the lesion, the nominal vessel diameter, and the vessel tortuosity. Boutrous *et al.* (26) showed that a longer stent is associated with decreased patency rates (62.5 vs. 50 centimeters; P=0.002). In another study, larger vessel diameters (i.e., >12 mm) had higher primary patency rates as stents with larger diameters were used (27). Based on our previous experiences, for isolated innominate lesions, we would use either Bard Fluency Plus (BD Interventional, Franklin Lakes, NJ, USA) or Atrium iCAST (Hudson, NH, USA), both of which provide a benefit of accuracy for device deployment. For subclavian and axillary lesions to accommodate the dynamic forces that

exist in the thoracic inlet region of the venous circulation, we favor the BD Interventional Covera (Franklin Lakes, NJ, USA), Gore Viabahn (Flagstaff, AZ, USA) or Atrium iCAST (Hudson, NH, USA).

In the thoracic inlet, extrinsic compression is an underappreciated cause of central stenosis and we employ thoracic outlet syndrome (TOS) decompression surgery when the pathology is confirmed to be contributory. In our practice, we perform a surgical decompression using a transaxillary or supraclavicular approach for all confirmed cases. The patients first receive a venogram followed by intravascular ultrasound then undergo an angioplasty to relieve their symptoms (i.e., swelling), subsequently on a different setting, the decompression is performed. Lastly, the patients undergo a non-provisional stent deployment in another different setting. A study by Lim *et al.* (28) included 18 TOS patients who had undergone a decompression procedure for their subclavian vein stenosis for their existing ipsilateral UE HD access. The results were satisfactory procedures with 1-year primary, primary-assisted and secondary patency rates of 42%, 69%, and 93%, respectively, with zero 30-day mortality rate. Though the main goal of the procedure was to maintain HD access, the absence of a control group did not help in addressing the indications for such procedure to maintain an existing HD access.

Use of the HeRO graft

The HeRO graft (Merit Medical Systems, South Jordan, UT, USA) was approved by Food and Drug Administration in 2008 (29). This composite system consisting of a prosthetic graft combined with an intraluminal catheter can be used to endoluminally traverse the central venous stenosis/

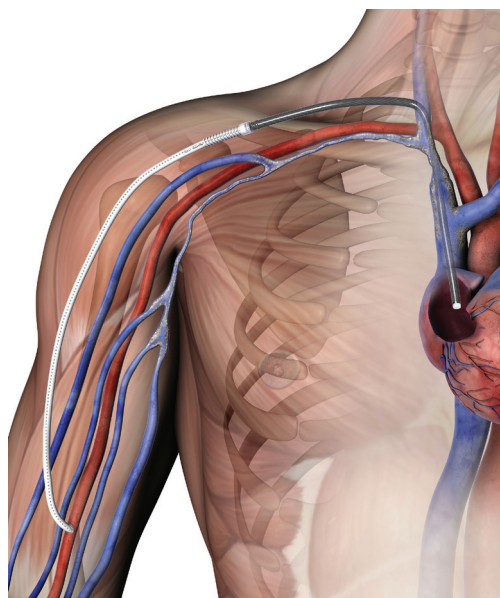


Figure 1 Hemodialysis Reliable Outflow (HeRO) graft; ©Merit Medical, Reprinted by Permission.

occlusion, thus, offering new VA for HD patients who would otherwise not be a candidate for UE traditional surgical VA options (16) (*Figure 1*). Promising results were published by a multi-center study (30) that included 164 patients who were treated with HeRO graft. The primary and secondary patency rates were (6 months: 60%; 12 months: 48.8%; 24 months: 42.9%) and (6 months: 90.8%; 12 months: 90.8%; 24 months: 86.7%), respectively. Over two-thirds of the patients required an additional intervention, and only 4.3% had access-related infections. Less favorable outcomes were reported by another study (31) that included 25 patients where primary patency rates were 47%, 37%, and 26%, and secondary patency rates were 80%, 70%, and 64% at 3, 6, and 12 months, respectively.

Nassar *et al.* (32) compared the patency rates of HeRO graft with conventional AVG for 143 patients who were randomized into two groups. The patency rates were comparable between the two groups, (primary patency: HeRO, 34.8%; AVG, 30.6%) and (secondary patency: HeRO, 67.6%; AVG, 58.4%). Another study by Proksch *et al.* (33) of 75 HD patients compared PTS (n=44) with HeRO graft (n=31). The 1- and 2-year access circuit primary access was similar between the two groups. Also, no significant differences were found in all-cause 1- and 2-year mortality rates between the two groups, (3.7% *vs.* 4.8%) and (11.8% *vs.* 23.5%), respectively, $P > 0.5$ in both.

A disadvantage of the HeRO graft is that it takes a few weeks to mature before it can be used. During this time, the patient is dependent on the central venous catheter (CVC), increasing their VA complications risk. Therefore, a group from Augusta University (29) decided to modify the HeRO graft with the use of an early-cannulation ACUSEAL vascular graft (W. L. Gore & Associates, Newark, Del) theoretically, obviating the need for a CVC. The group published their 6-month outcomes with primary and secondary rates of 70% and 90%, respectively.

HeRO graft complications have been reported in a number of studies, where one of these complications is steal syndrome. Despite a few studies reporting it in lower rates (1.4–2.6%) (30,34,35), a study by Wallace *et al.* (36) found that 22% of the included patients suffered from this complication. The authors attributed it mainly to the patient underlying comorbidities such as diabetes, smoking, and peripheral artery disease as well as the large diameter of arterial inflow component (6 mm polytetrafluoroethylene graft). Additionally, two separate case reports described complications of graft migration into the right ventricle of the heart (37) and graft separation during a percutaneous thrombectomy procedure (38). Fortunately, both patients were managed successfully.

Hybrid surgical approach

Although often overlooked, the anterior chest wall AVG can be a viable option before considering LEVA, given its similar patency to UE grafts. Patients with known CVD are usually not suitable for chest wall AVGs. However, in our previous study (39), we successfully performed a hybrid procedure through creating a chest wall AVG with concomitant central venous stenting in a patient central venous stenosis, without infraclavicular venous options.

In this hybrid case, the patient was suffering from a severe bilateral CVD (bilateral axillo/subclavian and innominate vein stenosis/occlusion) with multiple failed UE AVGs. Additionally, the femoral VA was not an option given the patient's severe peripheral artery disease, bilateral below-knee amputations, morbid obesity, and severe obstructive pulmonary disease. As a hybrid, same setting procedure a chest wall loop AVG was constructed with stenting of the patient's subclavian vein using a 10 mm × 40 mm self-expanding CS (Fluency Plus; Bard Peripheral Vascular, Tempe, AZ, USA) (*Figure 2*). The patient tolerated the procedure well and along with a maintenance procedure, the graft was found to be patent and functional at 1-year

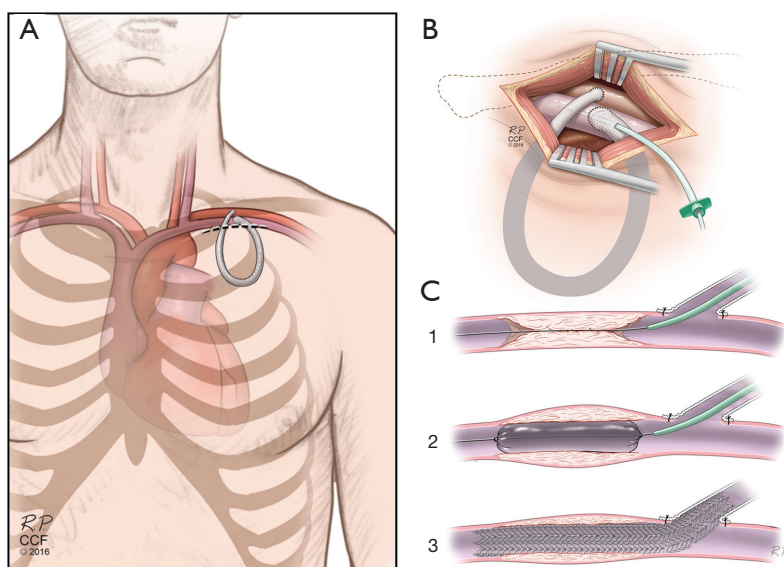


Figure 2 A hybrid case of a chest wall AVG creation with central venous stenting. (A) Typical infraclavicular incision for chest wall AVG. (B) Central vein oriented access through the venous limb of the Gore-Tex (W. L. Gore & Associates, Flagstaff, AZ) stretch vascular graft. (C) 1, crossing of the subclavian vein stenosis; 2, balloon angioplasty of subclavian vein stenosis; 3, covered self-expanding stent extending from within the graft to the central vein beyond the stenosis. AVG, arteriovenous graft. Reprinted with permission, Cleveland Clinic Foundation ©2023. All Rights Reserved.

follow-up (39). Despite the lack of studies investigating long-term patency rates of these hybrid chest wall AVG, we think that this case represents a new treatment option for patients with a concomitant CVD and could reduce the catheter dependence and the need for femoral access.

Additionally, this hybrid approach to permanent VA does raise the question of whether some currently available treatment options for CVD—like the aforementioned HeRO graft (Merit Medical Systems, South Jordan, UT, USA)—may be replaced by this technique. No comparative studies are available to answer this question. In addition, broad surgical application, acceptance, and experience with open chest wall AVGs would be necessary for such a claim to be valid.

Another case report by Ptohis *et al.* (40) described a hybrid approach where PTA was performed to the left brachiocephalic trunk followed by the insertion of a standard CVC as VA. The procedure went uneventful and the patient was doing well at the 6-month follow-up. Nevertheless, the reliance on CVC is problematic given its previously mentioned short- and long-term complications. Furthermore, it does not align with the ambitious Fistula first breakthrough initiative goal of reducing tunneled CVC

use to less than 10% for HD patients (41).

Surgical approach to CV occlusion

The surgical approach can be considered in symptomatic patients either in whom endovascular management has failed or as a primary intervention. Different surgical techniques were described in the literature. Babadjanov *et al.* (42) reported a successful axillary to innominate venous bypass via a median sternotomy incision. Zubair *et al.* (43) created a chest wall graft using a bovine carotid artery conduit from left axillary artery to the right atrium via a small thoracotomy incision. Axillary-femoral bypass using a long prosthetic graft is another surgical bypass option. On the other hand, a central vein patch can be another option, Gradman *et al.* (44) repaired occluded five subclavian veins with an autogenous and polytetrafluoroethylene (PTFE) patches, avoiding potential high infection and thrombosis rates of surgical bypasses. Despite no large studies were found in literature evaluating the outcomes of these open techniques, the favorable results as reported in aforementioned studies signify the reliability of open repair as an alternative to traditional endovascular interventions.

Conclusions

Central Venous Occlusive disease is common amongst the ESRD patient population and is associated with significantly worse immediate and long term clinical outcomes for the dialyzed patient. This disease pattern reduces the available options for current and future VA creation and impairs the reliability of existing VA. Efforts to reduce the prevalence of CVD should be directed at catheter avoidance strategies. From the most reductive perspective, the frequency of this occurrence represents an abject failure of our medical system to identify and manage patients prior to the need for renal replacement therapy.

The current first-line treatment option for CVD relies on endovascular options such as PTA with or without PTS. Emerging data suggests that CS platforms demonstrate mid and late term patency benefits by mitigating the pattern of in-stent restenosis. Higher quality evidence is necessary to definitively answer this comparative technology question. That said, in our opinion, the current 2019 KDOQI guidelines do not accurately reflect the current strength of evidence that appears to support the preferential treatment of CSs for the lesion morphology associated with CVD.

Other treatment options that can be considered include the HeRO graft as well as hybrid surgical and open surgical approaches, however, further long-term investigations are needed to elucidate and stratify the comparative outcomes for these therapeutic modalities.

The appropriate therapy should be selected based upon a patient centered interdisciplinary discussion utilizing the locally available expertise in the area of VA creation and maintenance.

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Footnote

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