VASCULAR AND ENDOVASCULAR TECHNIQUES

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Balloon-assisted over-the-wire technique for placement of the venous outflow component of the Hemodialysis Reliable Outflow (HeRO) device

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A modified technique for placement of the venous outflow component (VOC) of the Hemodialysis Reliable Outflow (HeRO) device (Hemosphere Inc, Minneapolis, Minn) is described. The purpose of the technique is to improve the system's trackability and facilitate device insertion in patients with central venous occlusion. Device preparation requires placement of a 6-mm × 4-cm angioplasty balloon within the leading end of the VOC. The leading 2 cm of the balloon are placed just distal to the radiopaque marker of the VOC. The balloon is inflated to profile and locked in this position within the leading end of the VOC. The VOC and balloon combination is advanced over the wire through the 20F peel-away sheath provided by the manufacturer. The described technique was used to successfully implant the HeRO device in 12 patients with central venous occlusion. This technique is recommended for placement of the VOC of the HeRO device in patients with central venous occlusions. (J Vasc Surg 2013;58:1117-9.)

Maintenance of reliable, functional long-term vascular access is critical for hemodialysis and remains a challenge in current practice.[1] Hemodialysis methods include tunneled central venous catheters, native arteriovenous fistulas, and synthetic arteriovenous grafts.[2] Patients who require chronic hemodialysis and who have experienced repeat access failures may require extreme procedures to preserve vascular access for dialysis such as the placement of translumbar catheters, tunneled transhepatic catheters,[3] and recanalization of occluded veins for dialysis catheter placement.[4] The long-term patency of these tunneled catheters is limited, and furthermore, the use of catheters for hemodialysis is associated with increased mortality.[5]

The Hemodialysis Reliable Outflow (HeRO) Vascular Access Device (Hemosphere Inc, Minneapolis, Minn) has emerged as an alternative for patients with limited vascular access who depend on dialysis catheters for treatment.[6-9] The device consists of two parts: an inflow component, comprising a 7-mm expanded polytetrafluoroethylene graft and a venous outflow component (VOC), a silicone-coated reinforced nitinol stent. The device is a direct arteriovenous hemodialysis system. The graft is anastomosed to the brachial or axillary artery, and the VOC is placed percutaneously through either internal jugular vein into the right atrium. These two parts are tunneled subcutaneously and connected at the deltopectoral groove using a titanium connector.[8] During dialysis sessions, needles are inserted into the synthetic graft segment of the system, and the reinforced nitinol stent provides direct venous outflow into the right atrium.[8]

The insertion kit for this device includes a 10F dilator, which is placed within the VOC to provide support during its insertion (Fig 1, *A*). As shown in the photograph, there is a diameter discrepancy between these two pieces. As pointed out by Glickman,[8] this diameter mismatch may lead to technical difficulties during insertion of the VOC, especially in patients with central venous stenoses or occlusions. The purpose of this report is to describe a modified, balloon-assisted technique for placement of the VOC of the HeRO device in patients with central venous occlusions.

METHODS

This is a retrospective study that was approved by the Rush University Medical Center Investigational Review Board. The HeRO device was placed in 14 patients. The modified technique was used in 11, and the standard technique in three. All included patients had history of previously failed dialysis accesses and central venous occlusions and were considered unsuitable candidates for hemodialysis access creation by the vascular access surgeons. Device

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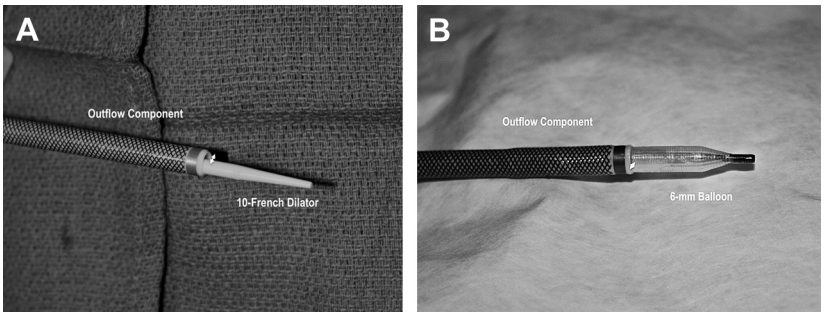

Fig 1. A, Frontal photograph of the 10F dilator within the venous outflow component (VOC) shows the diameter discrepancy between the two pieces (*double arrow*). **B,** Photograph shows venous outflow segment preparation. A 6-mm-diameter by 4-cm-long angioplasty balloon is placed within the VOC of the Hemodialysis Reliable Outflow (HeRO) device, and the balloon is inflated to profile.

placement was performed in two stages: (1) venous recanalization procedure and (2) HeRO device insertion.

Venous recanalization procedure. The venous recanalization procedure was performed under conscious sedation in the angiography suite. We decided to perform the procedure in two steps because we did not know if recanalization would be successful in any given patient. Some of these recanalization procedures were technically complex and could take 2 to 3 hours to complete successfully. Because the recanalization procedure could be performed under conscious sedation in the angiography suite, we decided not to spend operating room and anesthesia time in this part of the process. Once the recanalization was successfully completed in the interventional radiology suite, the patient was brought to the operating room the same day or ≤24 hours after a successful recanalization.

After ultrasound-guided puncture of either common femoral vein, a 10F Pinacle vascular sheath (Terumo, Tokyo, Japan) was inserted to secure vascular access. Then, a 5F, 90-cm Bernstein catheter (Cook Inc, Bloomington, Ind) and stiff glidewire (Terumo) combination was used to recanalize the occluded veins using previously described techniques.[10] A temporary Schon dialysis catheter (Angiodynamics, Latham, NY) was inserted through the recanalized vein with its tip placed within the right atrium. A femoral, tunneled Duraflow hemodialysis catheter (Angiodynamics) was placed through the accessed common femoral vein in all patients.

VOC implantation using the balloon-assisted modified technique. HeRO device placement was performed ≤24 hours of a successful venous recanalization. These procedures were performed in the operating room under general anesthesia. Once the patient was properly prepared and draped, the temporary dialysis catheter placed through the recanalized venous segment was removed over a Bentson angiographic wire (Cook Inc), followed by placement of a 10F vascular Pinnacle introduction sheath (Terumo). A 5F, 65-cm Bernstein catheter (Cook Inc) was used to gain access into the inferior vena cava. A 180-cm Amplatz superstiff guidewire (Boston Scientific, Natick, Mass) was then advanced into the inferior vena cava. A central venogram was performed though the 10F sheath to evaluate the extent of the venous occlusion. Angioplasty of the venous occlusion was performed in all patients using standard 8- to 12-mm-diameter angioplasty balloons.

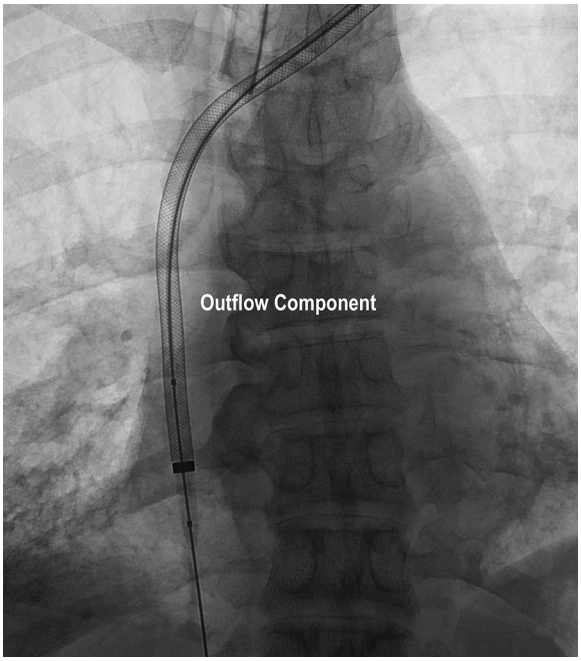

Fig 2. Spot film shows the process of advancing the balloon and venous outflow component (VOC) combination over a wire to its final position within the right atrium.

The VOC was then prepared for insertion by placing a 5F, 40-cm-shaft length, 6-mm-diameter by 4-cm-long angioplasty balloon within the leading end of the VOC in such a way that the leading 2 cm of the angioplasty balloon protruded distal to the tip of the VOC. The angioplasty balloon was then inflated to profile and locked with a flow switch (Fig 1, *B*). The insertion was then conducted by advancing the VOC and balloon combination over the wire through the 20F peel-away sheath provided in the device insertion kit. Fluoroscopic guidance was used to

advance the VOC and balloon combination over the wire to its final position within the midright atrium (Fig 2). HeRO device implantation was completed following the manufacturer's recommendations.[7]

RESULTS

A total of 14 patients (8 men, 6 women) underwent HeRO device placement between August 2009 and August 2011. The etiology for renal failure was hypertension in eight, hypertension and diabetes in three, and Goodpasture syndrome, systemic lupus erythematosus, and dysplastic kidney in one patient each. The mean time on dialysis was 7.5 years (range, 2-14 years).

Occluded veins included the superior vena cava (SVC) in seven patients, both subclavian veins and the SVC in three, both innominate veins in two, both subclavian veins in one, and occluded metallic stents in both subclavian veins in one. Veins used for the VOC insertion included small neck collateral in six, subclavian vein in three, external jugular vein in three, and internal jugular vein in two. A total of 11 patients underwent successful HeRO device VOC implants using the described balloon-assisted technique. Advancement of the VOC and balloon combination was always without technical difficulties. The standard implantation technique recommended by the manufacturer was attempted in three patients. The standard technique failed in one patient in whom the VOC could not be advanced across an occluded venous segment. This case was converted to a modified balloon-assisted technique, after which the device was successfully implanted.

One major complication occurred in the standard technique group. The patient developed severe hypotension and tachycardia shortly after HeRO device implantation. According to the operator, VOC implantation had been technically difficult. An emergency transesophageal echocardiogram showed a large pericardial effusion. The patient required a pericardial window to restore hemodynamic stability. The diagnosis was acute tamponade secondary to SVC damage by the leading edge of the VOC.

DISCUSSION

This report describes a modified, balloon-assisted technique for placement of the VOC of the HeRO device in patients with central venous occlusions. The technique is simple, and in our opinion, improves the trackability of the system.[8] Only three patients in this series underwent placement of the device using the standard technique recommended by the manufacturer. Placement of the VOC using the standard technique resulted in one major complication and one insertion failure.

CONCLUSIONS

Our results suggest that the described technique is useful for the implantation of the VOC of the HeRO device in patients with central venous occlusion.

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