From the Society for Clinical Vascular Surgery

A comparison of stenting versus hemodialysis reliable outflow graft for hemodialysis patients with recurrent central venous obstructions

Daisy M. Proksch, BS, Limael E. Rodriguez, MD, Animesh Rathore, MBBS, Samuel N. Steerman, MD, and Jean M. Panneton, MD, *Norfolk, Va*

ABSTRACT

Background: Central venous occlusive disease is a common cause of upper extremity arteriovenous access dysfunction in hemodialysis patients. When refractory to balloon angioplasty, the treatment options include central venous stenting and hemodialysis reliable outflow (HeRO; Merit Medical, South Jordan, Utah) graft. The purpose of the present study was to evaluate the outcomes of these options.

Methods: A retrospective review was performed of patients who had undergone central venous stenting or HeRO placement for central venous obstruction from December 2008 to March 2018. The primary outcomes were the reintervention rates, patency, and mortality.

Results: A total of 75 hemodialysis patients were identified after failed balloon angioplasty for central venous obstruction. Of the 75 patients, 44 underwent central venous stenting comprising coverage of the subclavian vein (n = 27), innominate vein (n = 18), and/or superior vena cava (n = 5). Six stent patients later underwent HeRO placement. The stents used were stent grafts in 65% (Viabahn, n = 9; Fluency/Flair, n = 19; iCast, n = 2; and other, n = 1) and bare metal stents in 35% (Wallstent, n = 6; Protégé, n = 1; Cobalt, n = 1; and other, n = 9). The remaining 31 patients underwent HeRO graft placement. The venous outflow component insertion sites were the internal jugular (n = 20), external jugular (n = 1), subclavian (n = 6), axillary (n = 2), and other (n = 2). The stent and HeRO groups were similar in the previous central venous intervention rates (median, 0.6 [interquartile range (IQR), 0-3.0]; vs median, 3.5 [IQR, 0-10.1] annually; P = .679). After the index procedure, no difference was found between the two groups in the frequency of dialysis circuit interventions annually (median, 2.0 [IQR, 0-6.0]; vs median, 2.0 [IQR, 0-7.0]; P = .291) nor central venous interventions (ie, angioplasty of the central veins or within the portion of the HeRO inside the central veins) annually (median, 2.0 [IQR, 0-4.1]; vs median, 0 [IQR, 0-2.4]; P = .419). The 1-year access circuit primary patency was 8.1% for stenting and 22.2% for HeRO (P = .109). The 2-year access circuit secondary patency was 40.0% for stenting and 52.4% for HeRO (P = .401). The all-cause mortality was similar at 1 year (3.7% vs 4.8%; P = .856) and 2 years (11.8% vs 23.5%; P = .368).

Conclusions: Central venous stenting and HeRO were shown to have similar rates of reintervention and patency. The results from the present study suggest that the multiple treatment options available for this problematic disease process can yield similar results when careful patient selection is applied. (J Vasc Surg: Venous and Lym Dis 2021;**E**:1-9.)

Keywords: Access salvage; Arteriovenous grafts; Hemodialysis access; Venous occlusive disease

Central venous obstruction (CVO) occurs in >50% of hemodialysis patients and can contribute to significant morbidity for this fragile population.¹ The central venous segment is composed of the axillary, subclavian, and

From the Division of Vascular Surgery, Eastern Virginia Medical School. Author conflict of interest: none.

2213-333X

Copyright © 2021 by the Society for Vascular Surgery. Published by Elsevier Inc. https://doi.org/10.1016/j.jvsv.2021.01.001 innominate veins and includes the superior vena cava. Patients with CVO can report arm edema, access dysfunction, and ipsilateral arm pain. These patients can also present with visible chest wall collaterals as the arm is decompressed through alterative pathways. CVOs can result from indwelling catheters or other intravenous devices: however, the incidence of stenosis at the subclavian vein has remained high, even with the decline in catheter insertion at this location. Central venous lesion occurrence has also been proportionally correlated with the time the patient has required hemodialysis.² Often, the first-line treatment of CVO is venous angioplasty; however, primary patency has tended to be poor.³ If the CVO is refractory to angioplasty, either from immediate elastic recoil or lesion recurrence within 3 months, the placement of a bare metal stent or stent-graft is the next step, as outlined in

Presented at the 2019 Meeting of the Society for Clinical Vascular Surgery, Boca Raton, Fla, March 16-20, 2019.

Correspondence: Samuel N. Steerman, MD, Division of Vascular Surgery, Eastern Virginia Medical School, 600 Gresham Dr, Ste 8620, Norfolk, VA 23507 (e-mail: snsteerm@sentara.com).

The editors and reviewers of this article have no relevant financial relationships to disclose per the Journal policy that requires reviewers to decline review of any manuscript for which they may have a conflict of interest.

2 Proksch et al

the Kidney Disease Outcomes Quality Initiative criteria.⁴ Central venous stenting has been shown to extend secondary patency in angioplasty-resistant lesions.^{5,6} Another access option, the hemodialysis reliable outflow (HeRO) graft (Merit Medical Inc, South Jordan, Utah), was designed to provide internal bypass through the CVO, which depressurizes the access and peripheral veins. Studies of this intervention have reported patency, reintervention, and infection rates comparable to those with conventional arteriovenous (AV) grafts (AVGs) and superior to those with tunneled dialysis catheters (TDCs). However, analysis of the HeRO graft has been limited because this device has only been commercially available since 2008. Most previous research compared HeRO grafts to other AVGs or TDCs, with stenting compared to angioplasty.^{1,7-} ¹¹ Very few studies have directly compared HeRO grafts and stenting.¹² The purpose of the present study was to compare the outcomes of central venous stenting and HeRO graft placement for upper extremity AV access salvage in patients with CVO refractory to balloon angioplasty.

METHODS

A retrospective medical record review was performed of patients in a single healthcare system with functional ipsilateral upper extremity AV access who had undergone central venous stenting or HeRO graft placement by a vascular surgeon in the hospital setting from December 2008 to March 2018 for treatment of symptomatic CVO. Patients aged <18 years or >89 years were excluded. The Eastern Virginia Medical School institutional review board approved the collection of data and waived the requirement for patient consent in accordance with the Health Insurance Portability and Accountability Act regulations.

The standard treatment of CVOs consisted of highpressure balloon angioplasty as first-line therapy. Failure of angioplasty was determined, at the operator's discretion, to have occurred either immediately owing to inadequate luminal gain or at recurrence of the lesion within a shorter than expected period. In the case of angioplasty failure, central venous stents or conversion to HeRO graft placement were used as a method to salvage the access.

Central venous stenting procedures were typically performed with the patient under moderate sedation after percutaneous balloon angioplasty of CVO. Multiple stents were placed if the lesion was especially long or if multiple lesions were present. Covered stents were used preferentially, if appropriate sizes were available and at the discretion of the operator. These stents were most often delivered percutaneously from the access site either through a sheath or without a sheath if the stent could be loaded on an appropriate delivery device.

HeRO conversions were performed with the patient under general anesthesia in either a hybrid or a standard Journal of Vascular Surgery: Venous and Lymphatic Disorders 2021

ARTICLE HIGHLIGHTS

- **Type of Research:** A single-center, retrospective cohort study
- **Key Findings:** Central venous stenting and hemodialysis reliable outflow (HeRO) graft (Merit Medical, South Jordan, Utah) placement for refractory central venous obstruction in hemodialysis patients demonstrated similar reintervention rates and patency at 1 and 2 years.
- **Take Home Message:** Both interventions yielded similar results with application of careful patient selection.

operating room. Venous outflow components (VOCs) were preferentially placed into the internal jugular vein; however, multiple venous options were used when the internal jugular vein was unavailable. The arterial inflow components were attached to the brachial, axillary, or subclavian artery. If the arterial and cannulation portions of the preexisting access were functional, the arterial inflow component was modified to accommodate the functional cannulation zone of the access.

Postoperative central venous interventions were defined as angioplasty of the central veins or the portion of the HeRO device within the central veins. The Society for Vascular Surgery reporting standards were used to define patency.¹³ The primary patency duration was defined as the interval between the index procedure and the first intervention to reestablish patency. Secondary patency was the interval between the index procedure ure and access circuit abandonment.

Categorical variables were summarized using percentages and compared using the χ^2 test. Continuous variables were summarized using the mean \pm standard deviation if normally distributed and the median and interquartile range (IQR) if not normally distributed. They were compared using the Student *t* test. A *P* value of <.05 was considered statistically significant. The patency and mortality data were additionally compared using Kaplan-Meier curves and the log-rank test. In accordance with the Society for Vascular Surgery reporting standards, the curves were truncated where the standard error had become >10%.¹³

RESULTS

A total of 75 patients were identified who had undergone central venous stenting (stent group) or HeRO graft placement (HeRO group) for symptomatic CVO during the study period. Of the 75 patients, 44 had received stents and 31 had undergone HeRO graft placement. The patient demographics (Table I) were similar for both groups in regard to age, sex, and race. The patients who had undergone HeRO graft placement had had a higher mean body mass index at 37.2 kg/m² vs 29.5 kg/

Journal of Vascular Surgery: Venous and Lymphatic Disorders Volume ■, Number ■

Table I. Patient demographics a	nd preoperative characteristics
---------------------------------	---------------------------------

Variable	Stent group (n = 44)	HeRO group (n = 31)	<i>P</i> value
Age, years	62.3 ± 14.5	56.5 ± 14.5	.054
Sex			
Male	40.9 (18)	51.6 (16)	.359
Female	50.1 (26)	48.4 (15)	.359
BMI, kg/m ²	29.5 ± 6.7	37.2 ± 16.2	.017
Race			
Other	13.6 (6)	3.2 (1)	.127
Black	72.7 (32)	87.1 (27)	.135
White	13.6 (6)	9.7 (3)	.603
Comorbidity			
Tobacco use	47.7 (21)	45.2 (14)	.826
Diabetes	72.7 (32)	67.7 (21)	.641
Depression	13.6 (6)	6.5 (2)	.321
Hypertension	100 (44)	93.5 (29)	.088
Hyperlipidemia	43.2 (19)	41.9 (13)	.914
CAD	25.0 (11)	29.0 (9)	.697
MI	6.8 (3)	16.1 (5)	.198
Stroke	18.2 (8)	16.1 (5)	.817
Heart failure	31.8 (14)	29.0 (9)	.797
PAD	15.9 (7)	16.1 (5)	.980
COPD	4.5 (2)	3.2 (1)	.774
Venous thromboembolism	15.9 (7)	32.3 (10)	.096
History of access infection	27.3 (12)	35.5 (11)	.428
Hemodialysis duration, years	4.8 (O-10.9)	3.8 (0.0-5.9)	.727
Age of existing access, years	2.0 (0.0-5)	0.5 (0.0-2.5)	.265
Total ipsilateral catheters	0.0 (0.0-1)	1.0 (0.0-4)	.024
Previous dialysis circuit interventions per year of access patency	1.1 (0.0-3.6)	3.5 (0.0-9.1)	.348
Previous central venous interventions per year of access patency	0.6 (0.0-3.0)	3.5 (0.0-10.1)	.679

BMI, Body mass index; *CAD*, coronary artery disease; *COPD*, chronic obstructive pulmonary disease; *HeRO*, hemodialysis reliable outflow; *MI*, myocardial infarction; *PAD*, peripheral arterial disease.

Data presented as mean ± standard deviation, percentage (number), or median (interquartile range).

 m^2 for the stent patients (P = .017). The groups had similar select comorbidities, including chronic obstructive pulmonary disease, coronary artery disease, depression, diabetes, heart failure, hypertension, hyperlipidemia, peripheral artery disease, previous myocardial infarction, previous stroke, previous venous thromboembolism, and tobacco use. Previous venous thromboembolism was defined as a history of deep vein thrombosis or pulmonary embolism not directly related to the dialysis catheter.

The dialysis access history was comparable between the two groups (Table I). The age of the existing access was also similar between the stenting and HeRO groups (median, 2.0 years [IQR, 0-5 years]; vs median, 0.5 [IQR, 0-2.5 years]; P = .265). The patients in both groups had required hemodialysis for multiple years (median, 4.8 years [IQR, 0-10.9 years]; vs median, 3.8 [IQR, 0-5.9 years]; P = .727). The stent patients had undergone a median of 1.1 angioplasties annually, 0.6 of which was central venous angioplasty. The HeRO group had previously received a median of 3.5 angioplasties annually, 3.5 of which were central venous angioplasties. The HeRO patients had had more ipsilateral dialysis catheters placed previously, with a median of 0 (IQR, 0-1) for stenting and 1 (IQR, 0-4) for HeRO (P = .024).

The procedure performed was determined by the operating surgeon. The presenting symptoms and indications for the procedure differed slightly between the two groups, with the stent group including more patients with arm edema compared with the HeRO group (59.1% vs 19.4%; P = .001; Table II). The two groups had a similar incidence of arm pain and high venous pressure Journal of Vascular Surgery: Venous and Lymphatic Disorders

Characteristic	Stent group (n $=$ 44)	HeRO group (n = 31)	P value
Index procedure indication			
Arm edema	59.1 (26)	19.4 (6)	.001
Arm pain	15.9 (7)	6.5 (2)	.215
High venous pressure	22.7 (10)	9.7 (3)	.142
Central venous occlusion	100 (44)	100 (31)	1.000
Type of vascular access			
Fistula	63.6 (28)	32.3 (10)	.005
Graft	36.4 (16)	67.7 (21)	.005
HeRO, Hemodialysis reliable outflow. Data presented as percentage (number).			

Table II. Perioperative characteristics

as an indication for the index procedure. The existing access was more often a fistula in the stent patients and a graft in the HeRO patients (fistula, 63.6% vs 32.3% [P = .005]; graft, 36.4% vs 67.7% [P = .005]).

A total of 48 central venous stents were placed in 44 patients to cover the subclavian vein (n = 27), innominate vein (n = 18), or superior vena cava (n = 5). Six stents traversed the thoracic inlet and four "jailed" the internal jugular vein. The stents used were stent grafts in 65%. These included 9 Viabahn stent-grafts (Gore Medical, Flagstaff, Ariz), 19 Fluency/Flair (Bard Peripheral Vascular Inc, Tempe, Ariz), 2 iCast (Atrium Medical Corp, Hudson, NH), and 1 other. Bare metal stents were used in 35%. These included 6 Wall stents (Boston Scientific, Marlborough, Mass), 1 Protégé (Medtronic, Fridley, Minn), 1 Cobalt (Medtronic), and 9 other.

The remaining 31 patients had had 37 HeRO grafts placed. The HeRO VOC insertion sites were the internal jugular in 20, external jugular in 1, subclavian in 6, axillary in 2, and other in 2. The HeRO arterial inflow component insertion sites were brachial in 23, axillary in 6, subclavian in 1, and other in 1.

The postoperative outcomes are presented in Table III. Primary patency of the access site was similar, with a median of 3.0 months for the stent patients and 1.5 months for the HeRO patients (P = .323). Secondary patency was a median of 8.0 months for the stent patients and 12.5 months for the HeRO patients (P = .698). At 1 year after the index procedure, 8.1% of the stent patients and 22.2% of the HeRO patients had maintained primary patency (P = .109). The secondary patency at 1 year was also similar (53.3% vs 73.9%; P = .126). At 2 years, 2.7% of the stent patients and 7.4% of the HeRO patients still had primary patency (Fig 1; P = .379). However, 40.0% of the stent patients and 52.4% of the HeRO patients had maintained secondary patency (Fig 2; P = .401).

To maintain secondary patency, the stent patients had undergone a median of 2.0 (IQR, 0.0-6) dialysis circuit interventions and a median of 1.0 (IQR, 0.0-4) central venous interventions during the remainder of their functional period. The median rate of circuit interventions and central venous interventions per year of access patency was 3.0 (IQR, 1.1-4.9) and 2.0 (IQR, 0.0-4.1), respectively. Similarly, the HeRO patients had undergone a median of 2.0 (IQR, 0-7) circuit interventions and a median of 0.0 (IQR, 0-3) central venous interventions. The median rate of circuit interventions and central venous interventions per year of patency was 5.4 (IQR, 0-15.2) and 0.0 (IQR, 0.0-2.4), respectively. One stent patient and eight HeRO patients had lost secondary patency because of infection (P = .002). All-cause mortality was similar at 1 year (3.7% vs 4.8%; P = .856) and 2 years (11.8% vs 23.5%; P = .368; Fig 3).

DISCUSSION

The present retrospective analysis of patients who had undergone central venous stenting or HeRO placement for recurrent CVOs consisted of well-matched patient groups with similar demographics, comorbidities, and hemodialysis access history. Both groups demonstrated similar primary and secondary patency lengths. Although the intervention frequencies of both groups had decreased after the index procedure, no intergroup differences were present in the dialysis circuit or central venous intervention frequencies required to maintain secondary patency.

A literature review identified one other study that had directly compared central venous stenting and HeRO graft placement. That study, which had included 14 central venous stent patients and 29 HeRO patients, also found no differences in patency and reintervention rates between the two groups. The study by Sur et al¹² found that the number of required reinterventions to maintain lesion patency for stenting vs HeRO was 2.3 and 1.4 annually, respectively. Similarly, our study found the mean number of central venous reintervention was 2.0 and 1.5 annually for stenting and HeRO, respectively. Although both studies had small sample sizes (43 vs 75), the similarity in the reintervention rates suggests some external validity for these results.

Journal of Vascular Surgery: Venous and Lymphatic Disorders Volume $\blacksquare,$ Number \blacksquare

Outcome	Stent group (n = 44)	HeRO group (n = 31)	<i>P</i> value	
Dialysis circuit interventions	2.0 (0.0-6)	2.0 (0.0-7.0)	.291	
Dialysis circuit interventions annually	3.0 (1.1-4.9)	5.4 (0.0-15.2)	.128	
Central venous interventions	1.0 (0.0-4.0)	0.0 (0.0-3)	.031	
Central venous interventions annually	2.0 (0.0-4.1)	0.0 (0.0-2.4)	.419	
Primary patency, months	3.0 (0.0-11.0)	1.5 (0.0-5.5)	.323	
Secondary patency, months	8 (0.0-27.0)	12.5 (0.0-39.5)	.698	
Secondary patency loss by infection	2.3 (1)	25.8 (8)	0.002	
HeRO, Hemodialysis reliable outflow. Data presented as median (interguartile range) or percentage (number).				

A clear algorithm had not been established for the management of these recalcitrant lesions. In the present study, different operators managed this problem using different approaches. Stents tended to be used for short lesions and HeRO grafts tended to be used to treat long or multiple lesions or within locations subject to extrinsic compressive forces. A common source of extrinsic compression is from the first rib on the subclavian vein. Although a stent's radial strength will normally be sufficient to prevent venous collapse, it will not be enough to counteract bony compression of the thoracic outlet. HeRO VOCs were used in many situations of thoracic outlet level compression owing to the greater radial strength of the VOC compared with that of intraluminal stents. No case of VOC compression was observed during the follow-up period, indicating that the VOC is

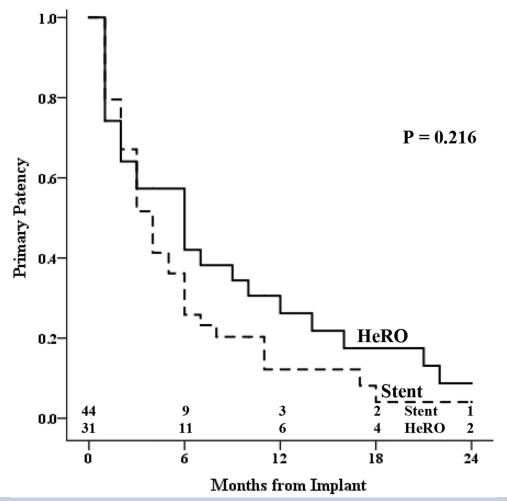
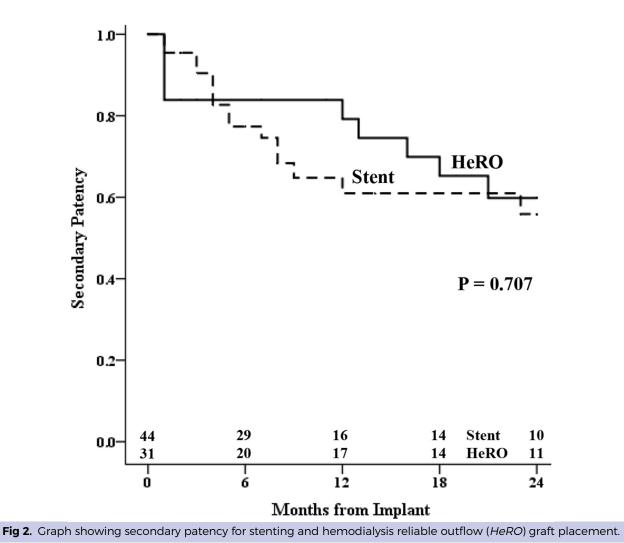


Fig 1. Graph showing primary patency for stenting and hemodialysis reliable outflow (HeRO) graft placement.

Journal of Vascular Surgery: Venous and Lymphatic Disorders



adequate to resist extraluminal compression at the thoracic outlet. First rib resection is a potential treatment option for this pathology; however, no patient in the present study had undergone that procedure and was beyond the scope of the present project. Another source of extrinsic compression is body habitus. In our study, HeRO patients had a significantly greater body mass index compared with the stent patients (class II obesity, 37.2 kg/m²; vs overweight, 29.5 kg/m²). Thoracic outlet level stenoses were more often seen in obese patients, which led to treatment of presumed extraluminal compression owing to the greater radial strength of the VOC over a minimally invasive, but less rigid, stent graft.

Fluency stent grafts that are sized large enough for central venous stenting (≤13.5 mm) were approved by the Food and Drug Administration in June 2014. More HeRO grafts were placed in the early and mid-periods of the present study with a lower rate after the introduction and wide adoption of the larger stent grafts. Although the HeRO graft is a good option for challenging access situations, it is not typically used as first-line access. Specifically, current data support usage only after failure of arteriovenous fistulas, AVGs, and some degree of endovascular treatment of outflow issues. The ultimate selection of the treatment modality was at the discretion of the operation surgeon, with multiple surgeons in the present study. Individual bias was also a factor in decision-making because some surgeons were more likely to perform stenting and others were more likely to place HeRO grafts. Broadly, stents were placed for shorter lesions, lesions that were less likely to cross the thoracic outlet, and in patients who were thought to be less suitable for open surgery. In contrast, HeRO grafts were more often placed for longer lesions, lesions that were less attractive to stenting owing to the involved venous confluences, and in patients with a patent access point for HeRO placement (ie, internal jugular, external jugular, subclavian, axillary). It is unclear why patients with arm edema were more likely to undergo stenting than HeRO graft placement. This was

Journal of Vascular Surgery: Venous and Lymphatic Disorders Volume ■, Number ■

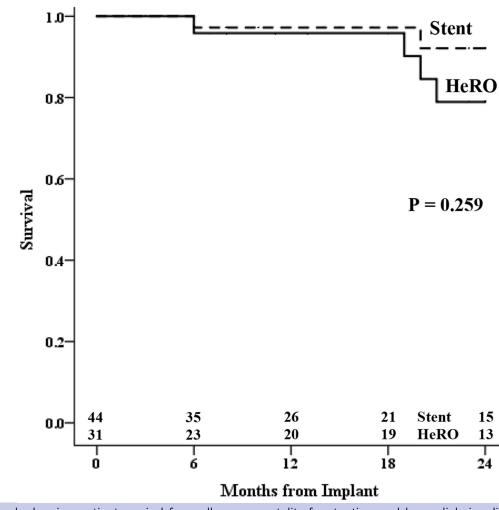


Fig 3. Graph showing patient survival from all-cause mortality for stenting and hemodialysis reliable outflow (*HeRO*) graft placement.

potentially because of a concern for healing with significant edema ipsilateral to the proposed surgical incisions for the HeRO graft.

Regarding access maintenance, HeRO thrombectomy is largely an easier procedure to perform than thrombectomy of an AV fistula or AVG, because, typically, a venous stenosis will not be present requiring navigation of the device. In contrast to most other access sites, the most common sources of thrombosis are in-graft stenosis of the cannulation zone or stenosis at the point of connection between the AVG and VOC. In addition, owing to the long segment of prosthetic through which the blood flows, hypotension and hypercoagulability can be sources of thrombosis that might affect the HeRO graft more often than a standard AVG. The stenosis between the AVG and VOC will typically receive standard endovascular therapy. The cannulation zone stenosis can be treated with endovascular techniques or might require surgical replacement. In most situations, the VOC was left in the patient after secondary patency loss. The

VOC was only removed for infection or insertion of a new device and the indwelling device was flow limiting.

The risk of infection was considered in selecting the treatment modality. Although the infection rates of stents have been negligible, graft-associated infections are not uncommon. In the present study, one stent patient and eight HeRO patients had lost secondary patency owing to removal of an infected AVG. The infected region in the stent patient was peripheral to and did not include the stent. If a patient has a strong history of access-related infection, a stent could be more appealing to minimize implantation of foreign material and, consequently, morbidity after access salvage.

Another consideration when deciding between stenting and HeRO placement is the monetary cost. The results from the present study suggest that when careful patient selection is applied, the outcomes can be similar, indicating that stenting might initially be the superior choice given the lower initial price and lower risk of implant infection. The average index device costs for a

bare metal stent, covered stent, and HeRO graft have been reported in previous studies as \$2236, \$3769, and \$17,697 USD, respectively.^{14,15} Additionally, research has been performed on the intermediate-term costs of some of these interventions. A U.K.-based 1-year cost of care analysis for HeRO vs TDC found that HeRO patients had experienced fewer device failures, access-related infections, and device thromboses compared with the TDC patients. The 1-year cost was slightly greater for the HeRO patients; however, the difference was attributed to the higher National Health Service reimbursement rate for hemodialysis via HeRO compared with that via TDC. If the hemodialysis reimbursement rates were assumed to be equal, HeRO was the more cost-effective option.¹⁵ A U.S.-based study found HeRO grafts had a lower 1year cost when the TDC infection rate was >16%.¹⁶ Another study found stent-grafts to be more cost effective at maintaining 24-month patency compared with angioplasty alone.¹⁷ Although none of these studies provided insight into the long-term costs of stenting compared with HeRO, they did establish that stenting and HeRO placement are more cost-effective than TDC dependence or frequent angioplasty.

Stent-grafts have been suggested to provide patency durations superior to those of bare metal stents, which is thought to result from protection from intimal hyperplasia.^{4,18} Previous studies have found the 6-month primary patency rate to be 55% to 100% for bare metal stents and 81% for stent grafts.¹⁸ In the present study, 35% of the stents used were bare metal stents. This was likely because of inadequate size availability of covered stents for central veins and, in some situations, provider preference. An interesting avenue for future research would be to compare covered and bare metal stents in the context of central venous stenosis. However, the stent group in the present study was too small for subset analysis.

The mortality rates were lower than the average annual mortality with dialysis of 10%, especially given that central stenosis is a marker for high comorbidity. However, this collection of patients had largely required hemodialysis for an average of 5 years, eliminating the patients from the mortality calculation who had started hemodialysis but failed rapidly. These patients have largely done well with hemodialysis.

An inherent flaw in retrospective medical record reviews of patients requiring dialysis is often related to the frequent need for urgent procedures. Although the healthcare network used in the present study encompassed many locations, several facilities were located in the study area where patients could have sought interventional care that was not captured by the medical record review, inaccurately extending the patency lengths. This is a confounding factor when analyzing patients located in an area where they receive care from multiple independent providers and cannot be accurately

Journal of Vascular Surgery: Venous and Lymphatic Disorders 2021

corrected for in a retrospective study. A prospective study of the treatment and management of central venous stenosis would be an excellent method to further expand knowledge about this problematic disease process without clear treatment algorithms.

Another limitation of the present study was the small sample size, which increased the risk of a type 2 statistical error because the HeRO outcomes were favorable compared with stenting but the differences were not statistically significant. The sample size was small for the study period owing to concerted efforts to reduce the risk factors for central venous stenosis. Patients with prolonged indwelling central venous catheters were contacted by the practice dialysis coordinator to ensure compliance with office visits and access procedures and to arrange for follow-up for catheter removal. In addition, patients with CVO were treated primarily by angioplasty, and the secondary procedures of stenting and HeRO placement were reserved for angioplasty failure. Finally, some patients with CVO had not exhibited symptoms of inadequate dialysis, arm edema, or extremity pain and had been treated conservatively.

A few data points were not collected but would have been of benefit in the present study, such as the incidence of superior vena cava syndrome as an index procedure indication, the presence of pacemaker or defibrillator wires, and the type of subsequent access after secondary patency loss. The precise lesion location, length, and degree of stenosis had not been consistently documented in the medical records and, consequently, could not be obtained. Additionally, functional patency duration could not be determined owing to an inability to obtain the date of the first successful access cannulation.

CONCLUSIONS

Central venous occlusive disease is a troublesome disease process affecting many hemodialysis patients. Effective treatment of the obstruction is crucial for access salvage. The present retrospective review comparing stenting and HeRO graft placement found these interventions to have similar reintervention and patency rates. The results from the present study suggest that the optimal treatment plan for these lesions can be determined by patient and anatomic factors rather than using one universally superior approach. Careful patient selection must continue to be applied to direct CVO management.

AUTHOR CONTRIBUTIONS

Conception and design: DP, AR, SS, JP Analysis and interpretation: DP, LR, AR, SS, JP Data collection: DP, LR, SS Writing the article: DP, LR, SS Critical revision of the article: DP, AR, SS, JP Final approval of the article: DP, LR, AR, SS, JP Journal of Vascular Surgery: Venous and Lymphatic Disorders Volume $\blacksquare,$ Number \blacksquare

Proksch et al 9

Statistical analysis: Not applicable Obtained funding: Not applicable Overall responsibility: DP

REFERENCES

- 1. Ratcliff C, Hansarani M. From ZeRO to HeRO: saving lives one HeRO at a time. Int J Surg Case Rep 2016;27:90-2.
- MacRae JM, Ahmed A, Johnson N, Levin A, Kiaii M. Central vein stenosis: a common problem in patients on hemodialysis. ASAIO J 2005;51:77-81.
- Agarwal AK. Endovascular interventions for central vein stenosis. Kidney Res Clin Pract 2015;34:228-32.
- Verstandig AG, Berelowitz D, Zaghal I, Goldin I, Olsha O, Shamieh B, et al. Stent grafts for central venous occlusive disease in patients with ipsilateral hemodialysis access. J Vasc Interv Radiol 2013;24:1280-7.
- Ozyer U, Harman A, Yildirim E, Aytekin C, Karakayali F, Boyvat F. Long-term results of angioplasty and stent placement for treatment of central venous obstruction in 126 hemodialysis patients: a 10-year single-center experience. AJR Am J Roentgenol 2009;193:1672-9.
- Kouvelos GN, Spanos K, Antoniou GA, Vassilopoulos I, Karathanos C, Matsagkas MI, et al. Balloon angioplasty versus stenting for the treatment of failing arteriovenous grafts: a meta-analysis. Eur J Vasc Endovasc Surg 2018;55: 249-56.
- 7. Al Shakarchi J, Houston JG, Jones RG, Inston N. A review on the hemodialysis reliable outflow (HeRO) graft for hemodialysis vascular access. Eur J Vasc Endovasc Surg 2015;50: 108-13.
- Glickman MH. HeRO vascular access device. Semin Vasc Surg 2011;24:108-12.
- 9. Nassar GM, Glickman MH, McLafferty RB, Croston JK, Zarge JI, Katzman HE, et al. A comparison between the HeRO graft and conventional arteriovenous grafts in hemodialysis patients. Semin Dial 2014;27:310-8.

- 10. Steerman SN, Wagner J, Higgins JA, Kim C, Mirza A, Pavela J, et al. Outcomes comparison of HeRO and lower extremity arteriovenous grafts in patients with long-standing renal failure. J Vasc Surg 2013;57:776-83.
- Maqsood MH, Rubab K. Quality of life of patients using the hemodialysis reliable outflow (HeRO) graft in hemodialysis. Cureus 2019;11:e3915.
- Sur B, Baran T, Foster T, Wilson I, Sasson T. Management of central venous stenosis in hemodialysis patients: comparison of outcomes with the hemodialysis reliable outflow (HeRO) graft versus stenting. J Vasc Interv Radiol 2017;28: S63.
- Sidawy AN, Gray R, Besarab A, Henry M, Ascher E, Silva M, et al. Recommended standards for reports dealing with arteriovenous hemodialysis accesses. J Vasc Surg 2002;35: 603-10.
- Dolmatch B, Hogan A, Ferko N. An economic analysis of stent grafts for treatment of vascular access stenosis: pointof-care and Medicare perspectives in the United States. J Vasc Interv Radiol 2018;29:765-73.
- 15. Shakarchi JA, Inston N, Jones RG, Maclaine G, Hollinworth D. Cost analysis of the hemodialysis reliable outflow (HeRO) graft compared to the tunneled dialysis catheter. J Vasc Surg 2016;63:1026-33.
- Dageforde LA, Bream PR, Moore DE. Hemodialysis reliable outflow (HeRO) device in end-stage dialysis access: a decision analysis model. J Surg Res 2012;177:165-71.
- Patel D, Ray CE Jr, Lokken RP, Bui JT, Lipnik AJ, Gaba RC. Advanced stent graft treatment of venous stenosis affecting hemodialysis vascular access: case illustrations. Semin Intervent Radiol 2016;33:39-45.
- Horikawa M, Quencer KB. Central venous interventions. J Vasc Interv Radiol 2017;20:48-57.

Submitted Sep 14, 2020; accepted Jan 1, 2021.