Initial experience and outcome of a new hemodialysis access device for catheter-dependent patients

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Objective: **The effects of a new long-term subcutaneous vascular access device were studied in access-challenged patients who were poor candidates for fistulas or grafts due to venous obstruction. Bacteremia rates, patency, and function of the Hemodialysis Reliable Outflow (HeRO) Vascular Access Device (Hemosphere Inc, Minneapolis, Minn) were evaluated.**
Methods: **The HeRO device consists of a 6-mm expanded polytetrafluoroethylene graft attached to a 5-mm nitinol-reinforced silicone outflow component designed to bypass venous stenoses and enter the internal jugular vein directly, providing continuous arterial blood flow into the right atrium. The HeRO device was studied in a multicenter clinical trial to test the hypothesis that access-challenged patients would experience a statistically significant reduction in bacteremia rates compared with a tunneled dialysis catheter (TDC) literature control of 2.3/1000 days. HeRO-related bacteremia rates, adequacy of dialysis, patency, and adverse events were analyzed.**
Results: **The HeRO device was implanted in 36 access-challenged patients who were followed for a mean 8.6 months (9931 HeRO days). The HeRO-related bacteremia rate was 0.70/1000 days. All HeRO-related bacteremias occurred during the bridging period when a TDC was still implanted before HeRO graft incorporation. HeRO adequacy of dialysis (mean Kt/V) was 1.7. HeRO primary patency was 38.9%, and secondary patency was 72.2%.**
Conclusions: **In access-challenged patients, a statistically significant reduction in HeRO-related bacteremia was noted compared with TDC literature. The device had similar function and patency compared with conventional arteriovenous graft literature. (J Vasc Surg 2009;50:600-7.)**

Tunneled dialysis catheters (TDCs) are considered the vascular access of last resort when all other options for arteriovenous fistulas (AVFs) and grafts (AVGs) have been exhausted. TDCs are associated with an increased incidence of bacteremia, thereby leading to higher morbidity and mortality that results in significantly increased hospital costs.[1] TDCs are also associated with less effective dialysis due to reduced blood flow rates, frequent malfunctions, and the development of central venous stenosis.

Despite these disadvantages, and considering the relative success of the National Kidney Foundation Kidney Dialysis Outcome Quality Initiative (KDOQI)[2] and the Fistula First movement,[3] the number of patients undergoing dialysis with TDCs continues to increase. The 2007 End-Stage Renal Disease Clinical Performance Measures Project (ESRD CPM Project) reported a 58% growth in catheter usage between 2002 and 2006 in the access-challenged population.[4] Many of these patients likely require catheters for dialysis because venous obstruction makes them ineligible for the benefits of a long-term subcutaneous AV access option.

A new long-term subcutaneous AV access, the Hemodialysis Reliable Outflow (HeRO) Vascular Access Device (Hemosphere Inc, Minneapolis, Minn), was approved by the United States Food and Drug Administration (FDA) as a graft for use in ESRD patients in whom peripheral venous access sites suitable for traditional fistulas or grafts have been exhausted. This study evaluated bacteremia rates, patency, and function of the HeRO device in the access-challenged patient population.

METHODS

Device description. The HeRO device is a standard 6-mm inner diameter expanded polytetrafluoroethylene (ePTFE) graft attached to a 5-mm inner diameter nitinol-reinforced silicone outflow component. The device is designed such that the ePTFE is placed in the upper arm over the biceps muscle. The silicone outflow component is placed similar to a TDC, and by way of a counter incision at the deltopectoral groove, the two components are brought together entirely subcutaneously with a titanium connec-

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This study was sponsored by Hemosphere Inc, to collect safety and efficacy data in support of a 510(k) submission to the Food and Drug Administration seeking market clearance for the HeRO Vascular Access Device. All of the authors' institutions were compensated by Hemosphere for conducting the study.

Competition of interest: Marc H. Glickman, MD, and John R. Ross, were paid consulting fees during the product development period, which have since ceased as of 2007.

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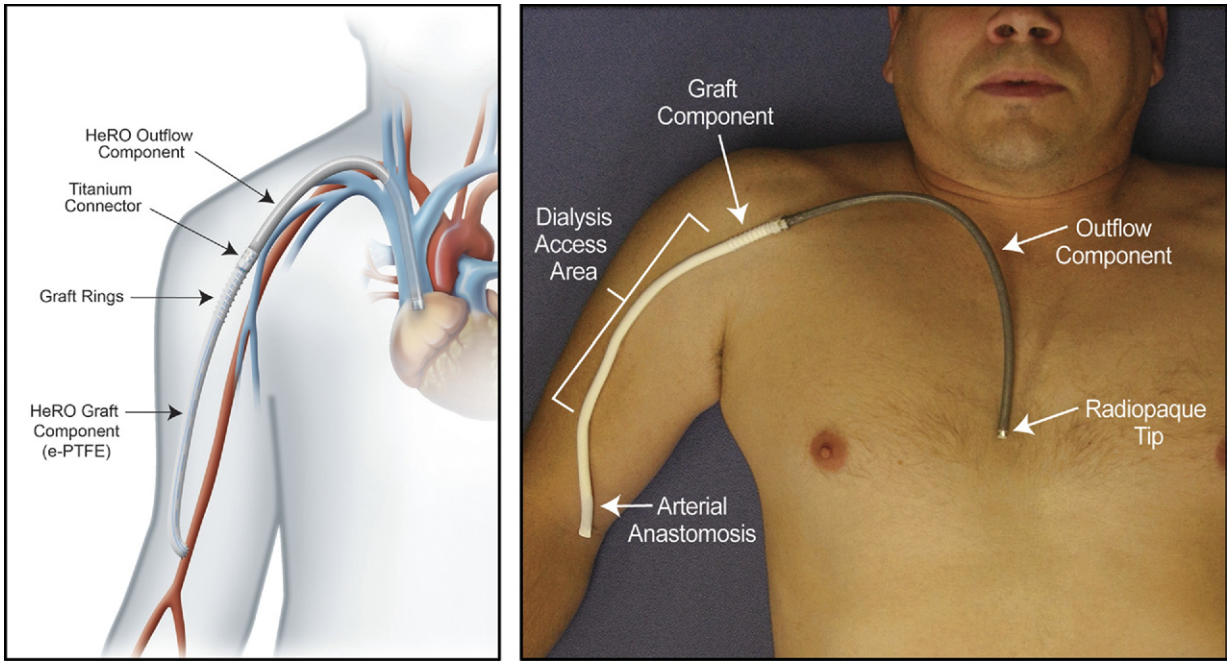

Fig 1. Hemodialysis Reliable Outflow (*HeRO*) right-sided implant. *e-PTFE,* Expanded polytetrafluoroethylene.

tor. The distal end of the silicone outflow component is placed in the right atrium (Figs 1 and 2). Therefore, the device provides continuous arterial blood flow into the central venous system, forming a subcutaneous AV access that bypasses central venous stenosis and the need for a graft-to-vein anastomosis. The device can be placed in the right or left upper extremity, depending on the venous anatomy and presence of outflow obstruction.

Study design and end points. Enrollment in this prospective, United States, multicenter, nonrandomized study of access-challenged patients commenced in March 2006. The primary end point was bacteremia related to the HeRO device and the implant procedure. Secondary end points included serious adverse events related to the device and the implant procedure, need for subsequent interventions and adequacy of dialysis including urea reduction ratio (URR) and Kt/V, where K is dialyzer clearance of urea, t is dialysis time, and V is patient's total body water. Follow-up was conducted at 3, 6, 9 and 12 months. The clinical protocol and informed consent were approved by the Institutional Review Board at each participating site, and all patients provided informed consent.

Bacteremia literature control. To determine a reasonable expected rate of bacteremia from TDCs, an internal meta-analysis was performed from previous publications. This meta-analysis of internal jugular TDC-related bacteremia rates was based on data published in 15 articles that met the following criteria: prospective studies, including prospective cohort and randomized controlled trials of tunneled, cuffed catheters with at least 20 patients.[5-19] Studies of the LifeSite Hemodialysis Access System (Vasca Inc, Tewksbury, Mass) and Dialock Access System (Biolink Inc, Norwell, Mass) were excluded. The final normalized cumulative TDC bacteremia control rate was 2.3/1000 catheter days.

Fig 2. Hemodialysis Reliable Outflow (HeRO) graft to outflow component connection.

Patency and intervention literature control. The catheter patency literature control was based on data published in six articles that met the following criteria: retrospective and prospective studies of chronic hemodialysis catheters for primary patency (data reported on 475 catheters at 6 months[14,20-24] and 362 catheters at 12 months[20-22,24]), primary-assisted patency (data reported on 67 catheters[13]), and secondary patency (data reported on 738 catheters at 6 months[14,20-24] and 591 catheters at 12 months[20-22,24]). The catheter patency literature control values were normalized.

The catheter intervention literature control was based on the same set of articles as the catheter patency literature control. The control value was based on the assumption that thrombolytic treatments and secondary patency required a catheter intervention. From these articles, the incidence of thrombolytic treatments was calculated to be 3.1 per year, and replacements were calculated to be 2.7 per year, resulting in a catheter intervention literature control rate of 5.8 per year.

The AVG patency literature control for primary and secondary patency was based on a published meta-analysis of 34 AVG studies.[25] The AVG patency literature control for primary-assisted patency was based on data published in two articles that were randomized controlled trials of 6-mm ePTFE grafts with ≥20 patients in which primary-assisted patency data were reported.[26,27] The data were normalized for the number of participants.

The AVG intervention literature control was based on data published in two articles that were prospective studies, including prospective cohort and randomized controlled trials of 6-mm ePTFE grafts with ≥20 patients for whom an intervention rate was reported. The data were not normalized; rather, a range of reported intervention rates was used, resulting in an AVG intervention literature control range of 1.6 to 2.4 per year.[26,28]

Adequacy of dialysis literature control. The adequacy of dialysis literature control was based on a review of retrospective and prospective articles of hemodialysis catheters and grafts. This review resulted in a catheter Kt/V control range of 1.18 to 1.46 (4399 patients)[4,29-32] and URR of 67.3% (901 patients),[13,30,33,34] and an AVG Kt/V control range of 1.37 to 1.62 (7250 patients)[4,29-32] and URR of 70.6% (4893 patients).[30,34]

Defining bacteremia. A HeRO device-related bacteremia was defined as at least one positive blood culture (preferentially obtained from a peripheral vein), one or more clinical manifestations of infection (ie, fever, witnessed rigors, hypotension), and no other apparent source for the bacteremia, requiring systemic treatment. This definition, with the exception of the need for systemic treatment, is based upon the Centers for Disease Control and Prevention definition of catheter-related bacteremia.[35]

Bacteremia related to the HeRO implant procedure was defined as any bacteremia seeded by the patient's previous TDC (cultured at the time of HeRO implant), any bacteremia that might have been seeded by a pre-existing infection elsewhere in the patient's body (possibly making the patient more susceptible to bacteremia in the perioperative period), or any other bacteremia that occurred in the perioperative period for which the source could not be identified.

Bacteremia data were analyzed as a rate per 1000 days for three cohorts:

1. The HeRO overall period, which included days from HeRO implant to HeRO explant, ligation, or patient death;
2. The HeRO bridging period, which included HeRO days from implant to bridging TDC removal; and
3. The HeRO alone period, which included days from bridging TDC removal to HeRO explant, ligation, or patient death.

Bacteremias were adjudicated by an independent Clinical Event Committee (CEC), consisting of two vascular surgeons, a nephrologist, and an interventional radiologist. Those termed as "probably" or "definitely" related to the HeRO device or implant procedure were considered "HeRO-related" for analytic purposes. Bacteremias adjudicated as "possibly," "unlikely," or "not related" were considered unrelated for analytic purposes.

Defining patency. The *Journal of Vascular Surgery* reporting standards for primary, primary-assisted, and secondary patency definitions were followed.[36] Primary patency was the interval from the time of access placement until any intervention designed to maintain or re-establish patency, access thrombosis, or the time of measurement of patency. Assisted primary patency was the interval from the time of access placement until access thrombosis or the time of measurement of patency, including intervening surgical or endovascular interventions designed to maintain the functionality of a patent access. Secondary patency was the interval from the time of access placement until access abandonment, thrombosis, or the time of patency measurements including intervening surgical or endovascular interventions designed to re-establish functionality in a thrombosed access.

Defining HeRO days. HeRO days were defined as accumulated days from HeRO implant to explant, ligation or death. For purposes of measuring the primary end point bacteremia rate, this is comparable to the term "catheter days," meaning days with an indwelling catheter as commonly referred to in the catheter literature.

Adverse events. Serious adverse events were defined as events requiring hospitalization ≥24 hours or requiring prolongation of an existing hospitalization, events resulting in persistent or significant disability or incapacity, events considered life-threatening, or events resulting in death.

All adverse events were collected. Events classified by the investigator as serious or potentially related to the HeRO device or implant procedure, or both, were reviewed by the CEC. Adverse events adjudicated by the CEC as "probably" or "definitely" related to the HeRO device or implant procedure were considered "HeRO-related" for analytic purposes. Adverse events adjudicated as "possibly," "unlikely," or "not-related" were considered unrelated for analytic purposes.

Eligibility criteria. Eligible patients were those aged >21 years in ESRD requiring hemodialysis with no remaining upper extremity AVF or AVG options, as identified by vein mapping, venography, or upper extremity arterial evaluation, with brachial arteries >3 mm by duplex examination. Exclusion criteria were significant arterial insufficiency, ejection fraction <20%, systolic blood pressure <100 mm Hg, known or suspected active infection, degen-

erative connective tissue disease, known bleeding diathesis or hypercoagulable state, ipsilateral implantable cardioverter defibrillator or pacemaker, superior vena cava syndrome, documented drug abuse ≤6 months of scheduled implant, planned concomitant surgical procedure or previous major surgery ≤30 days of scheduled implant, or scheduled renal transplant ≤12 months.

Surgical procedure. Implantation of the HeRO device begins with introduction of the silicone outflow component into the internal jugular vein using standard Seldinger technique, ultrasound guidance, and fluoroscopy. The radiopaque-enhanced distal tip of the outflow component is positioned in the mid to upper right atrium so that the distal outflow component tip resides at or just beyond the superior vena cava-atrial junction when the patient is upright. The graft component is tunneled in a gentle C-curve along the anterolateral aspect of the upper arm, from the brachial artery just proximal to the antecubital fossa to the deltopectoral groove. The outflow component is then attached to the titanium connector. To complete the procedure, a graft-to-brachial artery anastomosis is created in the same manner as a conventional upper arm ePTFE AVG.

As with all standard ePTFE grafts, the HeRO device requires tissue incorporation before cannulation; during this period, a bridging TDC is generally required. Once the HeRO device is ready for cannulation, it is cannulated in the same manner as a conventional AVG.

Statistical analysis. The study sample size, based on the number of accumulated HeRO days, was calculated using a one-sided, one-sample, super-superiority test on the number of bacteremia events per 1000 HeRO days, with an overall $\alpha = 0.025$ and 80% power. The hypothesized null literature TDC bacteremia control rate was 2.3/1000 days (derived from the internal meta-analysis). Assuming a HeRO-related bacteremia rate of 0.92/1000 days, an estimated minimum 6912 HeRO days of follow-up were required to show superiority to the TDC bacteremia control rate.

RESULTS

A total of 38 patients were enrolled at seven sites, and the HeRO device was successfully implanted in 36 (94.7%). Two implant procedures were unsuccessful due to poor brachial artery inflow or tortuous and stenotic veins that could not be sufficiently dilated by angioplasty to accommodate the HeRO device. In 32 patients (89%), a bridging TDC was required until HeRO graft incorporation. The four patients without a bridging TDC underwent dialysis on a failing fistula, failing graft, or received peritoneal dialysis until successful HeRO cannulation. Of the 32 patients who required a bridging device, a femoral TDC was used in 59%. The mean TDC bridging time, managed according to site standard practice, was 38 ± 21 days. The study accumulated 9931 HeRO days (mean 276 days/patient), with a mean follow-up of 8.6 months. No patients were lost to follow-up.

Table I. Demographics and access history

Variable	*Value*
Patients, No.[a]	38
Years on dialysis, mean ± SD (range)	5.1 ± 4.0 (1-17)
Previous bacteremias, mean ± SD (range)	1.8 ± 0.97 (1-4)
Age, mean y	62.7
Male, %	50.0
White, %	50.0
African American, %	36.8
Hispanic, %	13.2
Diabetes mellitus, %	68.4
Coronary artery disease, %	57.9
Hypertension, %	100.0
BMI, mean ± SD (range), kg/m^2	29.0 ± 7.5
Previous accesses, mean ± SD (range), No.	5.4 ± 4.3 (1-22)
Previous AVF, % (range)	65.8 (1-2)
Previous AVG, % (range)	78.9 (1-5)
Previous TDC, % (range)	100.0 (1-16)

BMI, Body mass index; *SD,* standard deviation.
[a]Includes two enrolled patients who did not receive the Hemodialysis Reliable Outflow (HeRO) device.

Demographics and access history. Enrolled patients had a history of significant access challenges, including multiple years on dialysis, multiple accesses, and a history of bacteremia. All patients had hypertension and most were diabetic (Table I).

Bacteremia results. Seventeen bacteremia events were reported while a HeRO device was implanted during a mean 8.6 months, providing an overall bacteremia rate of 1.71/1000 days. Of these 17 bacteremia events, 7 (41.2%) were adjudicated as HeRO-related. Four of these 7 events required HeRO device explant due to the infection. The HeRO-related bacteremia rate was 0.70/1000 days in the HeRO overall period (upper confidence bound rate <2.3/1000 days) which was statistically significantly lower than the literature control (Table II). The HeRO-related bacteremia rate was 1.52/1000 days when the HeRO device was placed ipsilaterally to the previous TDC and 0.30/1000 days when placed contralaterally to the previous TDC. No HeRO-related bacteremia events occurred in the HeRO-alone period after all bridging TDCs were removed.

The CEC adjudicated 10 of the 17 bacteremia events (58.8%) as being related to a source other than the HeRO device or implant procedure. In all cases, the HeRO device showed no signs of infection, including no pus, redness, or warmth (Table III, online only).

Patency and intervention data. HeRO device patency at a mean follow-up of 8.6 months was 38.9% primary, 86.1% assisted primary, and 72.2% secondary. The rate of intervention for the HeRO device was 2.5 per year. One patient was excluded from this calculation due to a suspected hypercoagulable state, noncompliance with warfarin, and >20 thrombectomy procedures. Refer to Table IV for a comparison of HeRO patency and intervention data with AVG and TDC literature.

Adequacy of dialysis. HeRO mean Kt/V was 1.7 ± 0.3 (range, 1.2-2.4) and mean URR was 74.3 ± 3.8 (range,

65.3-83.0). The observed HeRO mean blood flow rate was 1302 mL/min.

Adverse events. Serious HeRO-related adverse events are presented in Table V. One patient experienced a nonbacteremic arm infection; the HeRO device was never cannulated and the event was possibly related to calciphylaxis. The CEC believed the wound would not have occurred without the device being present. One patient experienced right atrial clot and probable pulmonary embolism. This hypercoagulable individual, in whom multiple previous accesses had failed, had a history of stroke and congestive heart failure. Warfarin was held for a period of time due to the HeRO implant procedure, and a pulmonary embolism was suspected approximately 2 weeks later. No ventilation scan was conducted to confirm the diagnosis; however, there was no other obvious explanation for noted perfusion defects given a normal chest radiograph. The HeRO device was explanted after the diagnosis of pulmonary embolism and right atrial clot. Even after the HeRO device was removed, subsequent TDCs caused the same coagulation process in this individual. All other adverse events are presented in Table VI.

DISCUSSION

The HeRO device was studied in high-risk, access-challenged patients with limited access options and complicated access histories. Patients had advanced progression of their diseases, as demonstrated by a mean time on dialysis of 5.1 years (range, 1-17 years) and having undergone a mean of 5.4 previous access procedures (range, 1-22). In addition, peripheral or central venous stenosis, or both, was clearly evident in these patients, and 59% required a bridging femoral TDC until HeRO cannulation because no other access sites were available. Vessel mapping, with attention to central vein patency, confirmed the limited access sites.

A statistically significant reduction in HeRO-related bacteremia rates was observed in this study compared with an internal meta-analysis of bacteremia rates from the TDC literature. Although the device is susceptible to colonization like other synthetic devices, its completely subcutaneous position decreases its infection potential. Placement of the HeRO device in the same tract as a potentially infected TDC can also predispose it to infection.

A higher HeRO-related bacteremia rate occurred during the HeRO bridging period (5.10/1000 days). The observed bacteremia rate in the bridging period likely resulted because (1) a large number of patients underwent dialysis via femoral TDCs (59%), (2) a long mean bridging period (38, ±21 days) extended the increased bacteremia risk, and (3) the calculated rate of bacteremia was exacerbated due to the small sample size in this cohort (only 1373 HeRO days).

Although relatively high compared with the HeRO-overall and HeRO-alone periods, the bacteremia rate during the bridging period was within the range of 1.6 to 5.5 per 1000 days reported in catheter literature for internal jugular and femoral TDCs.[37]

Given the findings in this study, we recommend the following measures to reduce the risk of bacteremia during the HeRO bridging period:

- Draw blood cultures before HeRO implantation to identify nonsymptomatic infections.
- Culture the TDC tip when removed and treat accordingly based on bacteremia determination and colony counts.
- Avoid placement of the HeRO device in previously infected.
- Initiate prophylactic treatment during the perioperative period with antibiotics based on the patient's bacteremia history.
- Consider prescribing prophylactic antibiotic or antimicrobial TDC lock.
- Consider applying antibiotic ointment to the TDC exit site.
- Cannulate the HeRO device as soon as possible and remove the bridging TDC.

Clinicians should anticipate a higher rate of bacteremia when the HeRO device is placed in access-challenged patients due to their inherent increased infection risk compared to graft-eligible patients. These include presence of previous TDC fibrin sheaths and comorbidities such as diabetes.[37]

The HeRO device also demonstrated improved adequacy of dialysis compared with TDC literature, which could have a significant effect on mortality rates in this population. Each 0.1 decrease in Kt/V is associated with a 7% increase in annual mortality.[38] The mean Kt/V observed in this study for the HeRO device of 1.7 was improved vs the range of 1.18 to 1.46 in the TDC literature,[4,29-32] comparable to the 1.37 to 1.62 range in the AVG literature,[4,29-32] and well above the 1.4 target of the KDOQI Adequacy of Hemodialysis Guidelines.[37] Improved adequacy of dialysis with the HeRO device compared with TDCs was likely a result of improved blood flow rates through the device. Observed HeRO mean blood flow rates (1302 mL/min) were comparable to conventional AVGs (1169 mL/min).[39]

The HeRO device secondary patency of 72.2% at 8.6 mean follow-up months and intervention rates of 2.5 per year were comparable with the rate of 65% at 12 months and range of 1.6 to 2.4 per year reported for conventional AVGs. The lack of venous anastomosis and associated neointimal hyperplasia makes it conceivable that the HeRO device could show improved secondary patency compared with conventional grafts in a study with longer follow-up, where venous hyperplasia develops in a significant portion of grafts.

The HeRO device secondary patency rates and intervention rates are an improvement over those reported in the literature for TDCs (37% at 12 months; 5.8 per year). With continuous arterial flow and high blood flow rates through the HeRO device compared with a TDC, fibrin sheaths are less likely to develop at the HeRO outflow

Table II. HeRO-related bacteremia results

Analyzed HeRO cohorts	*No.*	*Total days*	*Related bacteremia events*	*Bacteremia rate/1000 days*	*UCB (97.5%)*	*Control rate/ 1000 days*
Overall	36	9931	7	0.70	1.45	2.3[5-19]
Bridging period	32[a]	1373	7	5.10	10.50	1.6-5.5[37]
Alone	29[b]	8525	0	0.0	0.43	2.3

HeRO, Hemodialysis Reliable Outflow; *UCB,* upper confidence bound.
[a]Four patients did not require a bridging tunneled dialysis catheters and received dialysis through a failing arteriovenous fistula or graft, or underwent peritoneal dialysis until the HeRO device could be cannulated.
[b]Seven patients did not make it to the HeRO-alone period because of explant, ligation, or death.

Table IV. HeRO patency and intervention rates vs literature

	HeRO	*AVG literature*[36]		*TDC literature*	
Variable	*At 8.6 mean mon*	*At 6 mon*	*At 12 mon*	*At 6 mon*	*At 12 mon*
Patency					
Primary, %	38.9	58	42	50[14,20-24]	36[20-22,24]
Assisted-primary, %	86.1	68	52	92%[13]	NR
Secondary, %	72.2	76	65	55[14,20-24]	37[20-22,24]
Intervention rates, y	2.5	1.6-2.4[26,28]		5.8[14,20-24]	

AVG, Arteriovenous graft; *HeRO,* Hemodialysis Reliable Outflow; *TDC,* tunneled dialysis catheter.

Table V. Serious HeRO-related adverse events

Adverse event	*No. (%) (N = 38)*
Bleeding, hemorrhage or hematoma	2 (5.3)
Cardiac arrhythmia	1 (2.6)
Death	0 (0.0)
Edema (includes edema and swelling)	1 (2.6)
Infection (not bacteremia)	1 (2.6)
Pulmonary embolism	1 (2.6)
Right atrial clot	1 (2.6)
Steal[a]	1 (2.6)
Stroke	0 (0.0)
Trauma to major veins, arteries, nerves	0 (0.0)
Wound problems (includes dehiscence)	1 (2.6)

HeRO, Hemodialysis Reliable Outflow.
[a]Defined as a persistent hypoperfusion requiring surgical intervention supported by clinical and objective evidence of ischemia. Any transient, temporary hypoperfusion that is reversible and does not require surgical intervention was not considered a steal.

Table VI. All other reported adverse events

	N = 38	
Event	*Total events*	*Patients with ≥1 event (%)*
Abnormal healing/skin erosion	0	0 (0.0)
Allergic reaction	0	0 (0.0)
Bleeding	6	5 (13.2)
Cardiac arrhythmia	4	3 (7.9)
Death	13	13 (34.2)
Edema	4	4 (10.5)
Embolism[a]	2	2 (5.3)
Heart failure	4	3 (7.9)
Hematoma	6	5 (13.2)
Hypertension	1	1 (2.6)
Hypotension	3	3 (7.9)
Infection (not bacteremia)	24	18 (47.4)
Kinking or compression	5	5 (13.2)
Myocardial infarction	0	0 (0.0)
Other	64	30 (78.9)
Partial or full occlusion of nonstudy device	2	1 (2.6)
Partial or full occlusion of vein or artery	1	1 (2.6)
Prosthesis technical failure	1	1 (2.6)
Pseudoaneurysm, aneurysm in graft	2	2 (5.3)
Respiratory/cardiac arrest	1	1 (2.6)
Seroma	0	0 (0.0)
Site pain	2	2 (5.3)
Trauma to major veins, arteries, nerves	0	0 (0.0)
Vascular insufficiency due to steal syndrome	1	1 (2.6)
Wound dehiscence	2	2 (5.3)

[a]Includes stroke and pulmonary embolism.

component tip, resulting in improved secondary patency and intervention rates.

In our experience, the HeRO device provided a significant reduction (69%) in device- and procedure-related bacteremia compared with a TDC and offered the flow, patency, and function of a conventional AVG. Although the HeRO device requires a surgical procedure for implant and more involved maintenance than a TDC, the advantage of device longevity, improved adequacy of dialysis, and significantly reduced bacteremia rates outweigh these considerations for access-challenged patients. Patients with venous obstruction who have failed previous fistulas or grafts stand to derive the most benefit from this technology. Thorough vessel mapping should be conducted to confirm HeRO eligibility.

CONCLUSION

The HeRO device offers a valuable access option for access-challenged patients due to central venous obstruction, with reduced bacteremia episodes and im-

proved dialysis adequacy compared with historical catheter literature controls. Given the growth in the TDC-dependent patient population and the morbidity and mortality associated with catheters, this new dialysis access device can potentially have a great impact on this fragile patient population.

AUTHOR CONTRIBUTIONS

Conception and design: JR
Analysis and interpretation: HK, RM, JR, MG, LT
Data collection: Hemosphere, Inc
Writing the article: HK, RM
Critical revision of the article: HK, RM, JR, MG, EP, JL, LT
Final approval of the article: HK
Statistical analysis: LT
Obtained funding: HK, RM, JR, MG, EP, JL, LT
Overall responsibility: HK

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APPENDIX

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Table III (online only). Clinical Event Committee determination of bacteremia events not related to the HeRO device or implant procedure

Event	*CEC determination*
1	Bacteremia was due to a urinary tract infection with white blood cells in urine indicating pyuria. The HeRO device showed no signs of infection.
1	Bacteremia was due to community-acquired pneumonia as evidenced by radiograph. During hospitalization, patient developed bacteremia of gastrointestinal origin (*Enerococcus faecalis*).
1	Likely cause was sepsis related to infarcted bowel after endovascular repair of thoracic aortic aneurysm.
1	Bacteremia was believed related to an abscess on the left upper extremity. Adjudicated as "unlikely" related to the HeRO device and implant procedure because the graft component was healed, the patient scratched and an abscess developed independent, presumably, of the device; fungemia developed from the abscess, and the patient continued scratching. There was no apparent communication with the abscess and the HeRO device before the fungemia was reported. The HeRO device was never cannulated for dialysis, therefore, the CEC determined that the HeRO device was adjacent to but did not contribute to the abscess.
1	Bacteremia was believed related to a groin abscess, a complication due to a femoral TDC placed 1 year after HeRO implant.
1	The origin of the bacteremia could not be definitely determined. This event developed during a hospitalization in a patient who had negative cultures upon admission. The patient had elevated WBC, evidence for disseminated intervascular coagulation, and may have aspirated. The HeRO device showed no severe local reaction to indicate graft infection.
1	Bacteremia was related to femoral TDC placed after occluded HeRO device. Sputum, blood, and TDC tip cultured positive MRSA. There was no evidence of infection in the HeRO device. This event was adjudicated as "not-related" to the HeRO device or implant procedure.
1	The CEC believed the most likely source of the infection was an existing femoral TDC placed 9 days prior to HeRO implant, or possibly the hand (knuckle wound culture positive mixed aerobic organisms); the blood cultured coagulase negative Staphylococcus. The HeRO device showed no signs of infection and had never been cannulated. Adjudicated as "unlikely" related to the HeRO device and "not related" to the implant procedure.
1	The CEC believed the most likely source of the bacteremia was a femoral TDC or possibly previous HeRO thrombectomy procedure. Was adjudicated as "possibly" related to HeRO device and "not related" to the implant procedure. The HeRO device showed no signs of infection. The patient underwent dialysis using the HeRO device for 12 months with no infection.
1	Catheter infection associated with nontunneled central catheter that was not used for dialysis. The central catheter cultured positive for same organism as blood. The HeRO device showed no signs of infection.

CEC, Clinical Event Committee; *HeRO,* Hemodialysis Reliable Outflow; *MRSA,* methicillin-resistant *Staphylococcus aureus*; *STDC,* tunneled dialysis catheter; *WBC,* white blood cell.