

# Endovascular TODAY

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## VALUE-BASED DECISIONS FOR DIALYSIS ACCESS

How practitioners of dialysis access creation and intervention are improving patient outcomes while reducing system costs.

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# Vascular Access Innovation in a Changing Health Care Environment

An opinion piece describing how global payment systems could potentially incentivize vascular access innovation.

**BY PRABIR ROY-CHAUDHURY, MD, PhD**

**H**emodialysis vascular access is the lifeline for more than 400,000 patients on hemodialysis in the United States. Unfortunately, due to the high incidence of dialysis vascular access dysfunction, it is also the “Achilles’ heel” of hemodialysis.<sup>1-3</sup> There are currently three main forms of permanent dialysis vascular access, all of which have their benefits and disadvantages.<sup>4</sup>

Arteriovenous fistulas (AVFs) are the preferred form of permanent dialysis vascular access because of good long-term survival and low rates of infection. Unfortunately, they have a very high failure-to-mature rate (ie, the inability of the AVF to increase blood flow and diameter adequately to support hemodialysis),<sup>5,6</sup> likely a result of a combination of neointimal hyperplasia and a lack of outward or positive remodeling.<sup>7</sup> Arteriovenous grafts (AVGs) do not have these early “failure to mature” problems; in fact, over 90% can be used for hemodialysis within the first 6 weeks.<sup>1</sup> However, AVGs have a dismal 1-year unassisted patency rate of only 23% due to a predictable and aggressive stenosis at the graft-vein anastomosis as a result of neointimal hyperplasia.<sup>8</sup> The least desirable form of permanent dialysis vascular access is the tunneled dialysis catheter (TDC), which carries a high morbidity and mortality burden as a result of catheter-related bloodstream infections; fibrin sheath formation, which leads to inadequate blood flow; and central vein stenosis.<sup>9</sup> Despite the problems associated with TDC dysfunction, almost 80% of new (incident) patients start hemodialysis with a TDC.<sup>10</sup>

The complications result in a significant morbidity and mortality burden for hemodialysis patients, substantially degrading their quality of life and imposing a heavy financial burden on our health care system. The total cost of dialysis vascular access is thought to be over \$1 billion per year with each additional interventional procedure costing between \$5,000 (angioplasty alone) and \$15,000 (thrombectomy and stent placement). In addition, each

episode of a catheter-related bloodstream infection is estimated to cost between \$15,000 and \$20,000.

This article describes the clinical problem of dialysis vascular access dysfunction, identifies possible reasons for the current lack of effective therapies for this important clinical problem, provides an overview of the current sweeping changes in the health care environment with a particular emphasis on added value, and speculates on how these changes could incentivize the development of innovative therapies for vascular access dysfunction.

## LACK OF EFFECTIVE THERAPIES FOR DIALYSIS VASCULAR ACCESS DYSFUNCTION

Despite the magnitude of the clinical problem and the fact that there have been significant advances in our understanding of the pathogenesis of AVF and AVG stenosis (neointimal hyperplasia and inadequate vascular remodeling) as well as TDC-related infections (biofilm formation), effective therapies for this critically important problem are lacking. There are a number of reasons for this paradox.

First, although an important strength of vascular access is its multidisciplinary nature, this has also been a weakness. The clinical leadership for vascular access care is fragmented and disorganized, which has resulted both in a lack of clearly defined research initiatives and clinical protocols in this area.<sup>11</sup> Second, at the level of health care economics, the presence of a fee-for-service model has not incentivized the development of preemptive therapies that would prevent downstream interventions and complications (eg, hospitalizations, readmissions, emergency department and interventional suite visits).

## CHANGES IN THE HEALTH CARE ENVIRONMENT: VALUE VERSUS VOLUME

We are currently in the midst of profound changes in health care. At the core of these changes is the focus



Figure 1. Continuum of United States health care payment systems. Note the gradual progression from fee-for-service, episodic care systems on the left to more global, population-focused, preventive, and holistic payment systems on the right.

on increasing value in health care, with “value” defined as improved outcomes at the same or lower cost.<sup>12,13</sup> In order to improve outcomes, we are rapidly moving from a volume-based system to a value-based system—from caring for an individual to caring for populations and from reactive care to preemptive care. Simultaneously, the payment systems are being realigned to pay for quality rather than quantity, by transitioning from a fee-for-service system to payment for performance to bundled payments to global payment systems (Figure 1).

Nowhere are these changes more apparent than within nephrology, particularly with regard to hemodialysis patients. The reason for this is in some ways self-apparent. Hemodialysis patients have extremely poor outcomes (35% mortality at 5 years<sup>14</sup>), but at the same time, these patients cost a lot of money to manage (poor value by any standard). For example, the total cost of hemodialysis for a single patient in the United States is \$85,000 per year, and the total cost of managing end-stage renal disease (ESRD), including hemodialysis, peritoneal dialysis, and transplantation, is \$49.3 billion.<sup>14</sup>

### THE ESRD SEAMLESS CARE ORGANIZATION MODEL

The combination of poor outcomes and extremely high costs is one of the reasons why the Centers for Medicare & Medicaid Services Innovation Center decided to develop the first disease-specific accountable care organization, known as the ESRD Seamless Care Organization (ESCO), for hemodialysis patients.<sup>15</sup> To date, there are 13 test ESCOs, most of which are partnerships between a nephrology physician group, a large dialysis organization, and a health care organization. For example, in Phoenix, Arizona, there is an ESCO that includes the Southwest Kidney Institute (a large, forward-thinking, community nephrology practice), Davita (a large dialysis organization), and Banner Health (a large health care organization that is also one of the nation’s most successful pioneer accountable care organizations).

In brief, in the ESCO model, the ESCO agrees to take on the entire cost of health care for at least 300 dialysis patients for a fixed sum of money. If the ESCO is able to manage these patients for less than the allotted amount (while meeting certain quality indicators), the ESCO

shares in the profit. On the other hand, if the ESCO spends more money than what was agreed upon, it shares in the loss. It is likely that the physician groups, large dialysis organizations, and health care organizations with the best and most streamlined process of care pathways will be successful in this global payments system model. However, in all cases, the likely winner will be the patient, as the ESCO model will move the needle toward a more preventive and holistic model of care as compared to the current episodic and interventional process of care.

Although the jury is still out on the clinical quality, process of care feasibility, and economic viability and success of the ESCOs, an additional benefit that has not been emphasized enough to date is that the ESCO model could also incentivize innovation within the world of kidney disease, especially in the context of vascular access. In particular, the ESCO model would favor interventions (eg, drugs, devices, and biologics) that reduce downstream costs due to hospitalizations or interventions. One could argue that the real benefit of the GORE® VIABAHN® Endoprosthesis in the setting of polytetrafluoroethylene graft stenosis was not necessarily the significant improvement in 6-month postinterventional unassisted primary patency (which diminishes), but rather the 27% reduction in costly downstream interventions over a 2-year period.<sup>16,17</sup>

### INCENTIVIZING NOVEL THERAPIES FOR VASCULAR ACCESS DYSFUNCTION

In the current fee-for-service, episode-of-care payment system, there is little incentive to develop interventions that reduce the number of downstream interventions and complications. In fact, the additional procedures could be important revenue generators. For example, consider a device that, when applied to an AVF at the time of surgery, ensures AVF maturation in 4 weeks, with no downstream episodes of TDC-related infection or endovascular/surgical procedures to help with AVF maturation. In the current fee-for-service system where payment is episodic, a \$2,000 price tag for such a therapy might be unsustainable because the benefit of this quicker and more successful maturation (less TDC-related infection and fewer endovascular maturation procedures) is not part of the same payment pie. In fact, in previous years (prior to the institution of quality metrics), the additional

downstream patient morbidity and cost generated by AVF maturation failure, such as TDC-related bacteremia and endovascular procedures, were actually important revenue generators.

In a global payment system such as the ESCO, an intervention that enhances AVF maturation priced at \$2,000 and that results in a shorter TDC contact time (due to rapid AVF maturation) and fewer maturation procedures would be a huge money saver. It has been estimated that each episode of TDC-related infection costs \$15,000 to \$20,000, and each angioplasty/stent placement costs between \$5,000 and \$15,000. Decreasing the number of TDC-related infections by only one episode and the number of endovascular maturation procedures by two for each unique patient would result in a per-person savings of \$40,000, which would pay for the \$2,000 cost of the device many times over. This would be separate from the huge, yet intangible, benefits that would accrue as a result of a reduction in morbidity and an improvement in the quality of life.<sup>18</sup>

## SUMMARY

Although there is uncertainty with regard to the introduction of global payment systems such as the ESCOs, one benefit that has been underplayed is the fact that these global payments could actually incentivize the development and use of innovative devices that would reduce downstream costs as a result of fewer hospital admissions and procedures—a true example of added value (eg, improved outcomes at a lower overall cost) due to innovative therapies. ■

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# How Value-Based Health Care Is Redefining ESRD Management and the Impact to Vascular Specialists

A discussion of how value in dialysis access might be achieved, the potential role of the ESRD Seamless Care Organization, and the impact of new care models on future decision making.

**BY SCOTT S. BERMAN, MD, MHA, FACS**

One in 10 adults in the United States has some level of chronic kidney disease,<sup>1</sup> and approximately 449,000 patients with end-stage renal disease (ESRD) initiated some form of dialysis by the end of 2012.<sup>2</sup> The Centers for Medicare & Medicaid Services (CMS) has reported that although ESRD patients represent a small percentage of the Medicare population (1.3%), they represent 7.5% of overall Medicare spending.<sup>3</sup> Because of the expenditures on this complex patient population, it is no surprise that CMS is undertaking measures to streamline care to reduce costs, shifting the focus away from a fee-for-service model and instead initiating value-based payment programs. The Comprehensive ESRD Care Initiative, the first disease-specific accountable care organization (ACO) model, was introduced in 2013 by the CMS Innovation Center in an effort to test a new system of payment and care delivery, with the goal of improving care for ESRD and lowering costs associated with care. The premise is that this model will result in comprehensive and coordinated delivery of care, enhanced patient-centered care, improved physician-physician and physician-patient communication, and improved access to service. This article describes how value in dialysis access might be achieved through ACOs, the potential role of the ESRD Seamless Care Organization (ESCO) to vascular specialists, and how value-based health care could impact future decision making for the ESRD population.

## ACHIEVING VALUE IN DIALYSIS ACCESS THROUGH ALTERNATIVE CARE MODELS

The current fee-for-service model is complex and can lead to fragmentation of care, potentially resulting in unnecessary, repeated tests and interventions due to the lack of communication between treating physicians and misdirected objectives by providers inherent in the payment model (Figure 1). Although the ESCO model is in its experimental stage, it is designed to be a population management model for ESRD, wherein all members of the model are responsible for the care of a defined cohort of ESRD patients (Figure 2). Currently, there are 13 ESCOs participating in the pilot program across the United States. The goal is to affect two parameters in the value equation: quality and cost. Dialysis access centers, dialysis providers, and nephrologists will jointly manage the population. The costs and expenses will be analyzed over time, and preliminary results will serve as benchmarks for improvement. This is a challenging initiative given that the ESRD population is a formidable patient population to manage. In addition to kidney disease, it is a population with other significant chronic health conditions, such as diabetes, hypertension, coronary disease, and vascular disease. Essential to any comprehensive care process is participation and accountability on the part of the patient, although this critical component is characteristically lacking in most health reform initiatives.

The ultimate goal is to have a healthier ESRD population that uses fewer resources. Specifically in dialysis access,

there is some controversy as to whether dialysis access surveillance is cost-effective. Some studies have shown that dialysis access surveillance can prevent patients from missing dialysis days, subsequently providing more cost-effective care.<sup>4</sup> However, other studies have shown that surveillance results in more procedures performed, but not necessarily improvements in quality of life or longer time to graft or fistula failure.<sup>5</sup> In the current fee-for-service model, a provider is reimbursed per procedure. In proposed ACO models, the provider receives a fixed payment for a fixed amount of time for providing all the necessary care for that patient, which includes the resources required every time that patient is treated (eg, facility, staff, catheters, wires, balloons, stents, and other devices). In the ESRD population, surveillance is challenging because there is a lack of well-defined algorithms to optimize patient care and minimize the utilization of resources.

### THE NEW FRONTIER OF ESCOS

By 2018, it is projected that approximately 90% of Medicare payments will be value based.<sup>6</sup> With only 13 ESCOs in the pilot program, vascular surgeons are watching from the sidelines to see how the model might affect future patient care. In my practice, we try to be thoughtful with our approach to dialysis access. For instance, we perform intraoperative flow measurements during access intervention in an attempt to optimize outcomes. In a future ESCO setting, a nephrologist running the program will look to send patients where there is the highest likelihood of success with the fewest number of procedures. Provision of these data by surgeons will be essential for ESCOs to make these distinctions.

In order to be prepared for recruitment into value-based programs, vascular specialists should collect data on value-based outcomes, such as the number of fistulas versus grafts for new dialysis patients, primary patency for arteriovenous access at 12 months, incidence of complications (eg, infection), as well as any associated costs. We are already seeing this change take effect, with information systems being redesigned to produce costs related to procedures.<sup>7</sup>

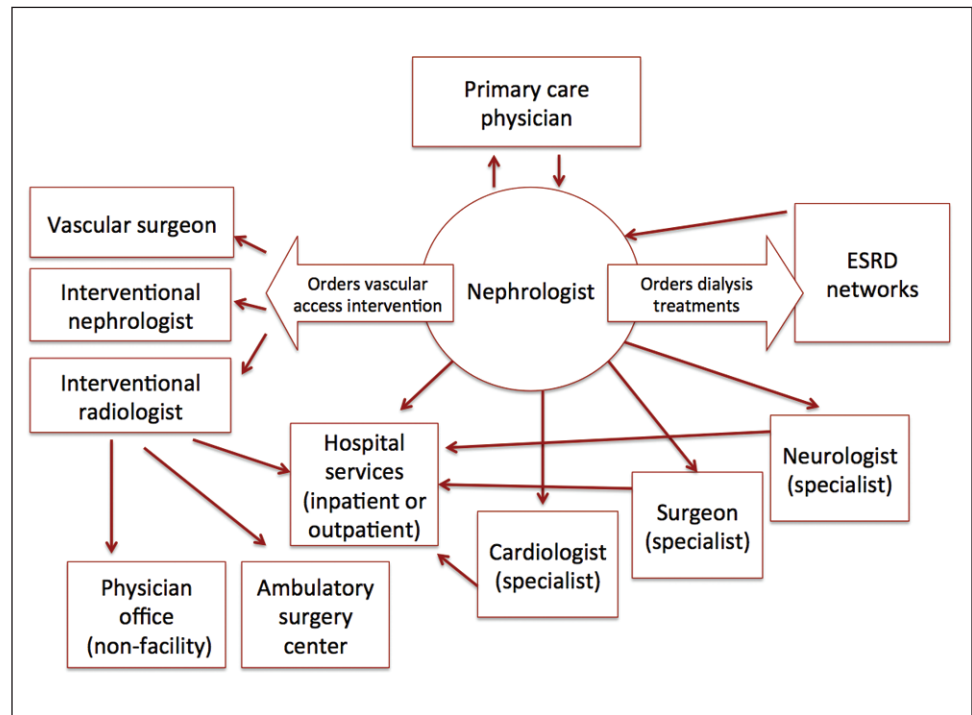


Figure 1. The fee-for-service model for ESRD care.

### THE IMPACT OF VALUE-BASED HEALTH CARE ON DECISION MAKING

The ideal role of the vascular specialist in an ESCO model may be participation in early referral of patients for dialysis access creation, promoting fistulas whenever possible, and making decisions with other members of the ESCO on an algorithm for managing a failing or failed access, including for the patients' future access. If the patient is dialyzing well, the algorithm would include periodic evaluation of that patient for their next access option should the current one fail. In general, all members of the ESCO will need to be committed to the patient population and the unique challenges they present, as well as be intimately involved in decision-making as soon as a patient is identified as stage 4 chronic kidney disease with a glomerular filtration rate  $\leq 20$  mL/min/1.73 m<sup>2</sup>.

A critically important part of decision-making in a new value-based health care model is integration of electronic health record systems, so that providers do not duplicate efforts. Patient education is also valuable, providing knowledge of the disease process and what to expect in the future, with the thought that a knowledgeable consumer will seek treatment earlier and potentially reduce costs of care.

In terms of device selection, the ESCO will absorb all of the costs associated with the care of the dialysis patient, including creation and maintenance of dialysis access. As a result, it may be beneficial to pay a higher upfront cost for a dialysis device if it translates into fewer downstream

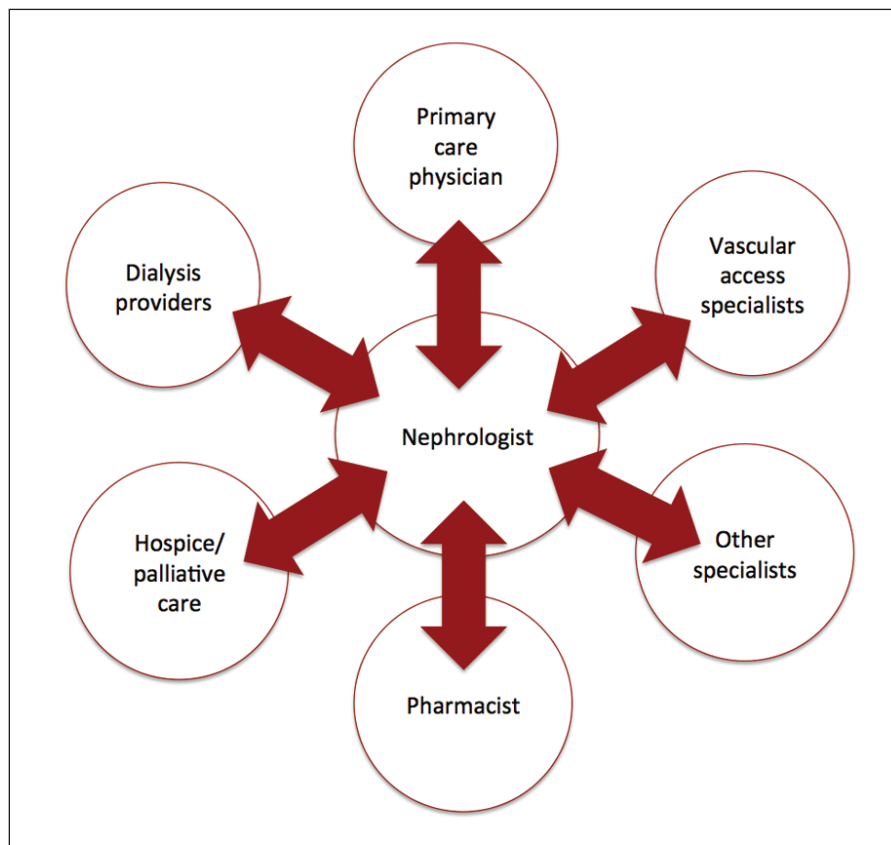


Figure 2. The new ESCO model for ESRD care.

interventions and revisions. In order to be competitive in the dialysis market, it will likely be essential for manufacturers to show value over time with a cost-benefit analysis for any new device they propose for dialysis access interventions.

### WHAT TO AVOID IN THE NEW WORLD OF VALUE-BASED HEALTH CARE

Although the concept of value-based health care attempts to put a “one size fits all” formula to care delivery, the complexity of ESRD and the individual patient should still be taken into consideration, and the treatment algorithm for these patients should allow for some differences in care. For instance, segregating the outcomes for the population of patients who are offered catheters because they have no other options away from the outcomes of patients who do have options other than catheters. Moreover, population health management principles inherently imply redistribution of resources that may force a reassessment of the appropriateness of even offering hemodialysis to patients whose comorbid conditions preclude the creation of an arteriovenous fistula or graft.

Failing to benchmark and standardize clinical practices can affect patient outcomes and costs.<sup>8</sup> In the future world of value-based health care, the risk is shifting to

the providers, and measures must be in place to assess costs related to treatment protocols and initiate process improvements in order to improve outcomes and reduce costs.

The shift from a supply-driven health care system to a patient-centered system is on the horizon, and vascular specialists should not disengage from new models and partnerships for health care delivery. Any outcomes collected should also consider the total value, so that they are easily incorporated into and analyzed as part of any value-based payment program.

### SUMMARY

The shift from fee-for-service to value-based health care is underway. It will be interesting to see how the ESCO model affects the care of the ESRD population and how the transition to value-based care will impact vascular specialists. Collection of outcomes data with consideration of value will be increasingly important as the new

health care system models strive for high-quality care at the lowest costs. ■

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# Value-Based Dialysis Access Realized Via Early Cannulation

Dr. David Kingsmore discusses the methods for achieving dialysis access and the challenges in obtaining better outcomes.



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## What is currently the most prevalent method of renal access for patients with end-stage renal disease undergoing dialysis?

Currently, most units around the world aspire to use native arteriovenous fistulas (AVFs) for both long-term and incident patients requiring vascular access. However, the success of this strategy varies by unit and country, with some units achieving up to 90% prevalence rates of AVFs. Worryingly, the most recent data for the United States suggest that 83% of patients initiate hemodialysis through a catheter despite 25% to 35% better survival if catheters are avoided.<sup>1</sup>

## Do you favor this method? If not, what method do you prefer, and what experience led you to this?

Without doubt, a native AVF that is established has the best longevity and lowest complication rate. However, in order to achieve this, an average of two procedures or interventions are required with a primary failure rate of around 30% in most studies. Clearly, crude incidence rates do not really show how clinical decisions affect the incorporation of available options (including peritoneal dialysis), the urgency for immediate access, and the long-term need (including survival and likelihood of transplantation).

It is my belief that blindly striving to achieve an AVF in every patient can be to the detriment of many patients who end up with a prolonged period of dialysis through a catheter. Ultimately, the aim for every patient should be to achieve a method of vascular access that is sufficient to meet their individual need: a personal access solution. Avoiding peripheral prosthetic grafts at all costs guarantees central venous catheters and a slower attainment of a personal access solution. Currently, we struggle with two cohorts: (1) legacy patients with numerous failed access procedures, a long exposure to catheters, and subsequent central vein stenosis; and (2) older patients who are increasingly frail with diabetes, obesity, and a long history of venesection that leaves little venous capital from which to construct native AVFs. Both of these could be avoided with a more rational approach to a personal access solution that includes all options.

## What is the current perception of arteriovenous grafts (AVGs) versus AVFs in terms of patency, infection, and costs for intervention? Which study results guide this thinking?

In general, vascular surgeons' experience of bypass surgery in patients with peripheral vascular disease and intermittent claudication has led to a healthy skepticism of prosthetic grafts. However, the evidence of three randomized trials and many observational studies of large databases like the United States Renal Data System has shown that prosthetic grafts for arteriovenous access have a useful role. These trials consistently showed that grafts are comparable to fistulas but require more interventions. However, AVGs and AVFs are not equally considered in the literature. For example, the patency of AVGs is far superior to AVFs by intention-to-treat analysis for the first few years, and based on a cost model, the increased use of tunneled central venous catheters (TCVCs) in patients in whom AVFs are pursued have significantly higher costs

due to the cost of treating line infection. Perhaps most importantly, the personal cost to patients of repeated admissions and failed procedures far outweighs the increased number of interventions required to maintain graft patency.

### **What is the current role of TCVCs?**

Currently, TCVCs are used as the primary immediate solution for patients requiring hemodialysis in whom there is no native access. For most patients with no native access at initiation of renal replacement therapy, TCVCs will remain in use for the first year, with only 40% of patients graduating to an AVF at 6 months. The saying “start with a line, keep the line” remains true.

### **Do you believe that arteriovenous access using TCVCs can be improved? If so, how?**

Many trials have looked at improving catheter patency rates and reducing line infections—as evidenced by the 30-odd meta-analyses and reviews! That in itself says something. Perhaps the most important data come from knowing your own unit’s outcomes, not data from a trial. Many units struggle to obtain accurate data on outcomes related to catheters (eg, delays, rates of replacement, complications, bacteremia), but it is only in knowing these data that the true cost to patients and the service can be rationalized and balanced against the alternatives.

### **How would you summarize the design and results of the randomized controlled trial evaluating immediate-access AVGs versus TCVCs?**

Our trial was relatively straightforward and sought to be inclusive and not select out the most problem-

atic patients nor choose only those initiating dialysis. We wanted to look at whether the strategy of TCVC replacement with early cannulation AVG was feasible and worthwhile. We randomized 121 patients referred for a catheter to either standard care (TCVC) or an early cannulation AVG. The results were very clear—over a 6-month follow-up period, the early cannulation AVG group had a significantly reduced initial hospital stay, half the number of readmissions, half the number of hospital days, and one-fifth the number of culture-positive bacteremic events, at a nonsignificantly lower cost and significantly higher quality of life. The downside to the improved patient outcomes was a shift in work to interventions to maintain graft patency.

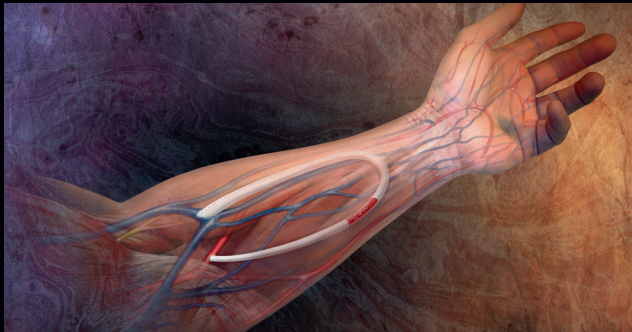
### **In what ways might this trial represent a change in current practice patterns, and what guidance would you offer those who may be considering this change in strategy?**

The entire practice of vascular access really needs to reconsider the patient pathway. There are effective alternatives to TCVCs that are cheaper or cost-neutral and have better and lower overall maintenance costs than TCVCs. In addition to these direct benefits, there is the indirect benefit of initiating non-TCVC dialysis. To do this requires a significant shift in the nature of work from medically treating line infections to maintaining graft patency rather than an escalation in work itself, which is a significant benefit to patients with prophylactic treatment rather than therapeutic. ■

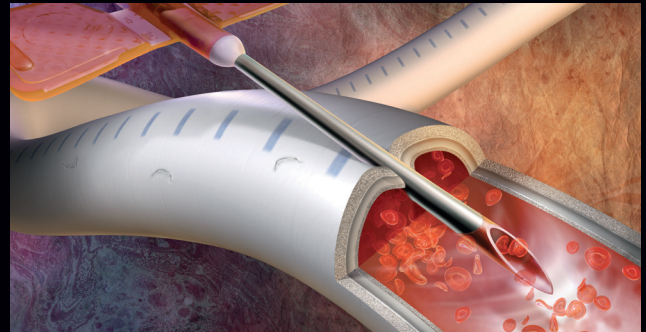
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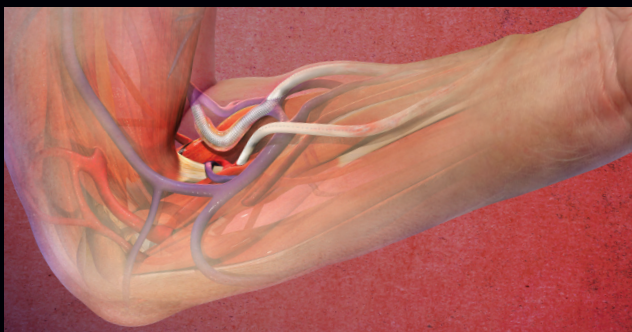
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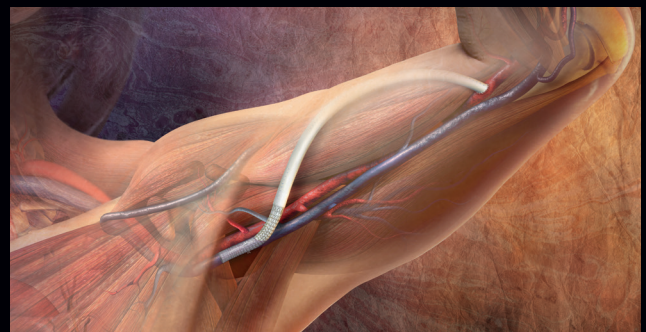
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# Improving Cost-Effectiveness: How Stent-Grafts Change the Natural History of the Dialysis Access Circuit

Advancing the paradigm for the treatment options of hemodialysis access grafts.

BY JOHN E. ARUNY, MD, AND BELINDA A. MOHR, PhD

After its initial clinical success as graft material for femoropopliteal artery bypass, expanded polytetrafluoroethylene (ePTFE) was proposed as a vascular access conduit for chronic hemodialysis.<sup>1</sup> ePTFE was believed to have similar complication rates when compared to widely used bovine heterografts with improved availability, ease of handling, and decreased cost. After slightly more than a year, complications leading to graft failure were identified. Venous anastomotic stenoses were found to be a leading cause of the majority of these graft failures.<sup>2</sup>

Longitudinal reporting of ePTFE patency revealed a primary patency rate of 41% and a secondary patency rate of 59% at 1 year.<sup>3</sup> Cumulative patency was maintained by surgical revisions that often included jump grafts that shortened the length of available vein for future access placement. Importantly, the interval patency after each revision was shorter than previously reported rates, with 1-year patency rates of 23%, 16%, and 17% after the first, second, and third revisions, respectively. The number of surgical revisions needed to maintain 1-year cumulative patency was not disclosed, making the costs difficult to determine.

Thus, the natural history of ePTFE access grafts, from their earliest days of hemodialysis access use, was defined by poor primary patency, followed by a need to maintain secondary patency through subsequent interventions that were less effective, eventually culminating in graft abandonment.

## BALLOON ANGIOPLASTY

In 1982, the application of balloon angioplasty expanded the treatment options with emphasis on the nonsurgical preservation of dialysis access.<sup>4</sup> Today, despite the development of high-pressure balloons and smaller delivery systems,

the patency results remain disappointing. Reports from the percutaneous transluminal angioplasty (PTA) arm of several comparative trials, including the FLAIR trial, the GORE REVISE clinical study, and a peripheral cutting balloon study showed a 6-month primary patency rate between 23% and 36% at the treatment site.<sup>5-7</sup> The 6-month primary patency at the dialysis access circuit was between 20% and 36% (weighted average, 30%). Elastic recoil of the treatment site, development of intimal hyperplasia, and occasional rupture of the native vein are the limiting factors of PTA alone. Thus, PTA alone failed to meaningfully alter the natural history of failing synthetic grafts.

## BARE-METAL STENTS

After gaining experience in the treatment of these difficult lesions, it became apparent that PTA alone would not solve the recurrent problems of venous outflow stenoses from ePTFE dialysis conduits. The feasibility and safety of using self-expanding metal stents was demonstrated in 1989 with the clinical use of the WALLSTENT™ Endoprosthesis (Boston Scientific Corporation) to treat lesions that responded poorly to PTA alone.<sup>8</sup> Bare-metal stents (BMS) solved the problem of technically failed PTA secondary to elastic recoil, but were disappointing in significantly prolonging patency. Ingrowth of intimal hyperplasia remained unchecked. No multicenter, prospective, randomized trial comparing BMS to PTA has ever been conducted. Retrospective analysis of access circuit 6-month primary patency in studies reported between 2004 and 2013 using a variety of BMS varied between 19% and 67% (weighted average, 33%).<sup>9-16</sup> Disappointingly, the results are not significantly different from PTA alone,



**TABLE 1. PATENCY RESULTS OF THE GORE REVISE CLINICAL STUDY FOR THE TARGET LESIONS AND THE ENTIRE DIALYSIS ACCESS CIRCUIT<sup>7</sup>**

Outcomes Effectiveness-per-protocol group	GORE® VIABAHN® Endoprosthesis (N = 131)	Angioplasty (N = 138)	P Value
Target lesion primary patency (TLPP)			.008
Month 6	52.9%	35.5%	—
Month 12	30.2%	18.2%	—
Month 24	15.7%	9.9%	—
Median days to loss of TLPP	203	108	—
Vascular access circuit primary patency (CPP)			.035
Month 6	43.4%	29.4%	—
Month 12	21.4%	15.2%	—
Month 24	9.6%	6.8%	—
Median days to loss of CPP	126	91	—

suggesting an inability of BMS to reliably alter the natural history of a failing synthetic graft.

## STENT-GRAFTS

Like BMS, ePTFE-covered stents address elastic recoil—one of the major failings of PTA. However, unlike BMS and PTA, the ePTFE covering can also more effectively address a second failure mode of restenotic lesions at the graft venous anastomosis—exuberant tissue hyperplasia. The ePTFE covering adds a physical barrier through which tissue cannot penetrate. Covered stents alter the natural history of a failing graft with this dual effect of limiting tissue ingrowth and resisting elastic recoil.

Two large, multicenter, randomized trials comparing the results of PTA alone with PTA plus stent-grafts have been conducted to investigate this line of thinking. The first study, the FLAIR trial, randomized 190 patients at 13 sites with dialysis access graft venous anastomotic stenosis to PTA alone or PTA with placement of a self-expanding nitinol stent covered in carbon-impregnated ePTFE (FLAIR® Endovascular Stent-Graft, Bard Peripheral Vascular, Inc.).<sup>5</sup> The results showed statistically better primary patency of both the site target lesion (51% vs 23%;  $P < .001$ ) and the access circuit at 6 months (38% vs 20%;  $P = .008$ ). In addition, freedom from subsequent

interventions at 6 months was lower in the stent-graft group (78% vs 28%;  $P < .001$ ).

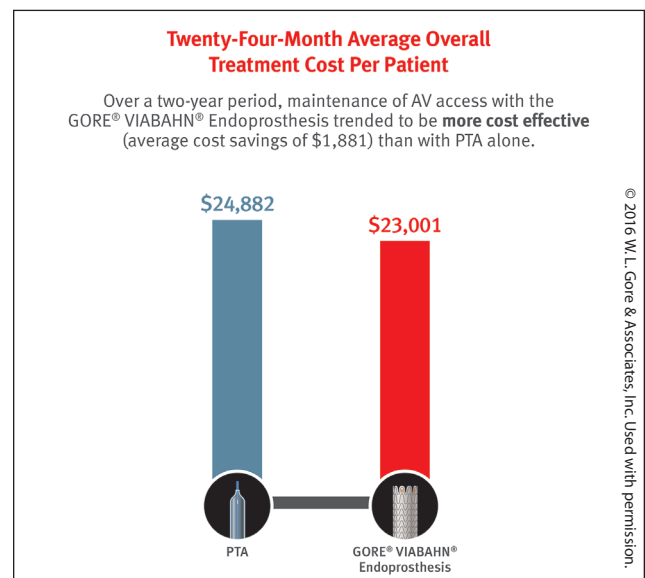
The GORE REVISE clinical study is a multicenter trial that randomized 293 patients with significant stenosis at the venous anastomosis of an ePTFE graft to PTA alone or PTA plus placement of the GORE® VIABAHN® Endoprosthesis with Heparin Bioactive Surface.<sup>7</sup> The GORE REVISE clinical study allowed the inclusion of thrombosed grafts as well as those that were failing. Patients were followed for 2 years, and the primary patency results are presented in Table 1.

Because of differences in follow-up methods and inclusion/exclusion criteria, it is difficult to directly compare the results of the two trials. However, it is clear that both trials showed superiority of stent-grafts in prolonging primary patency, thereby altering the natural history of the access in some way.

The 24-month results of the GORE REVISE clinical study further support that stent-grafts alter the natural history of a failing synthetic graft. Indeed, the clinical superiority of prolonged primary patency translated into fewer interventions to maintain secondary patency of the circuit (3.7 vs 5.1 over 24 months) and pointed to a potential economic benefit of this treatment modality.

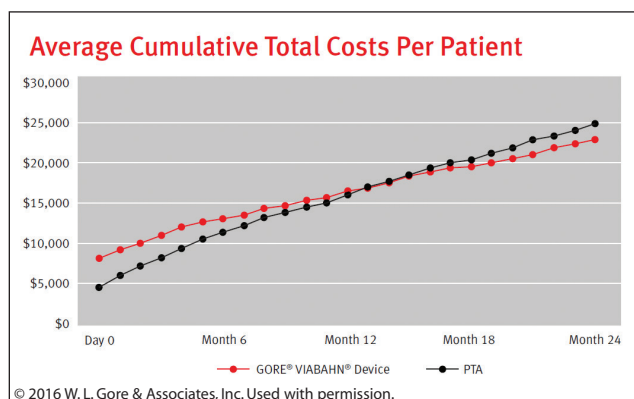
Figure 1 demonstrates cost-effective results of improved primary patency and fewer interventions to maintain secondary patency realized when patients were treated with PTA plus the GORE VIABAHN Endoprosthesis. The average total cost at 24 months for the PTA plus GORE VIABAHN Endoprosthesis group was \$23,001 compared to \$24,882 for the PTA alone group, representing a cost savings of \$1,881.<sup>17</sup>

Figure 2 shows the crossing point at 13 months of the cost curves. At this point, the initial increased cost of implanting a covered stent is exceeded by the more



**Figure 1. Average total costs at 24 months for PTA versus the GORE® VIABAHN® Device in the GORE REVISE clinical study.**





**Figure 2.** Cost curves for the GORE REVISE clinical study showing average total cumulative costs per patient. Note the curves cross at 13 months, where the increased costs of maintaining the grafts treated with PTA alone surpass the costs of the cohort treated initially with the stent-graft.

frequent, costly procedures in the PTA alone cohort to maintain secondary patency at 2 years. In the entire PTA alone group, repeat interventions cost \$20,632. Although repeat interventions were \$14,939 in the PTA plus the GORE VIABAHN Endoprosthesis group, there was a savings of \$5,693 over 2 years ( $P < .001$ ).<sup>17</sup>

In the GORE REVISE clinical study, when grafts presented thrombosed, the cost-effectiveness was amplified as compared to the entire group. The average total cost at 24 months in the PTA alone cohort was \$31,717. This included an initial index procedure cost of \$5,202 and subsequent cost of \$26,514 for repeat interventions over 2 years. In the covered stent cohort, the larger initial index procedure cost of \$9,074 was neutralized over 2 years by significantly decreased repeat intervention costs of \$15,989 ( $P < .001$ ).<sup>17</sup>

## STENT-GRAFTS AS PRIMARY THERAPY?

Given the complexities and uniqueness of each patient's access, many physicians find it difficult to believe that every stenosis at the venous anastomosis of a synthetic graft should receive a stent-graft at first pass. Thus, although there is level 1 evidence that clearly demonstrates the clinical and economic advantages of stent-grafts over PTA alone, it remains to be seen if this is the right choice for treating de novo lesions for every patient. More studies are needed to better clarify which patients should be treated with a stent-graft as a first-line therapy.

## SUMMARY

Clinical superiority of stent-grafts over PTA alone to treat lesions at the venous anastomosis has been demon-

strated by two large, multicenter, randomized trials that demonstrated how to change the natural history of failing synthetic grafts in ways that alternative therapies have not. The GORE REVISE clinical study showed that altering the natural history of the dialysis graft with stent-grafts has economic benefits. Integrating patency data with cost data from the GORE REVISE clinical study shows economic value of stent-grafts as a primary treatment for dysfunctional and especially thrombosed grafts. Further research efforts should focus on clarifying when and for what patients a stent-graft is the optimal choice. ■

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# The Need for Value-Based Outcomes in Future Dialysis Access Device Trials

Defining clinically and economically meaningful outcomes in the new environment of value-based health care.

BY CHARLES E. RAY, MD, PhD

**T**he value of medical devices is becoming increasingly important in the practice of interventional medicine. This is especially evident in patient care related to end-stage renal disease (ESRD), where the emergence of the ESCO (ESRD Seamless Care Organization)—an effort to control costs and improve outcomes for the 1.3% of the Medicare patient population that consumes 7.5% of Medicare spending<sup>1</sup>—could rapidly and radically change how physicians deliver care. Indeed, many physicians are increasingly being asked to justify device use to decision makers in their institutions, which fundamentally requires an understanding of the value of a given device. Yet, have device manufacturers armed physicians with the data they need to justify device use when talking to a diverse set of stakeholders, which often includes nonclinical procurement staff? In this author's opinion, physicians and medical device manufacturers must work together to better define, collect, and communicate device value. This will ultimately result in clinical study endpoints that are more clinically and economically meaningful to the provider, payer, physician, and, most importantly, the patient.

## HOW VALUE IS DETERMINED

At its core, value means that the physician's selection and use of a device balances the outcomes they expect to achieve against costs of care—both upfront and ongoing costs—over a period of time. Historically, value has been defined by the equation:

$$\text{Value} = \text{Outcome}/\text{Cost}$$

Accountable care organizations/accountable care entities are altering this equation by tying payments to specific quality initiatives. Therefore, quality will figure into the value proposition by becoming a part of the outcome

measure; outcomes will include a quality component. The new paradigm for value will then change the equation to:

$$\text{Value} = (\text{Outcome} \times \text{Quality})/\text{Cost}$$

Are interventionists armed with the correct information to make value arguments, specifically information focused on outcomes and quality? What data are needed, and how do these data differ from those produced in the past? How can device manufacturers provide the data needed to promote interventional techniques?

## OUTCOME MEASURES AND THE DIALYSIS ACCESS POPULATION

The outcome for any medical diagnostic modality or treatment is variably defined—survival, quality-adjusted life-years, and time to progression are some common measures. In the future, outcome measures will increasingly have to consider cost and value. The following are this author's views on how outcome measures will be affected by value-based health care, with specific examples focused on the dialysis access population.

### Clinical Trials Comparing Single Outcomes Will No Longer Be Adequate

Traditionally, clinical trials, including randomized controlled trials, have had one primary endpoint. In the dialysis access population, this endpoint has traditionally been 6-month primary patency of the anatomic region intervened upon or patency of the circuit. This endpoint will continue to be important, but other measures will likely take precedence. This shift to new outcome measures will be driven by the need for interventional devices to drive down the total cost of care—estimated by the US Renal Data System to be approximately \$85,000 per hemodialysis patient per year<sup>2</sup>—and not just the primary patency of the first intervention.

### Endpoints Focusing on Repeat Interventions Will Be Most Important

Not only are repeat interventions costly and resource intensive (and raise questions about the quality of the first intervention), but they also lead to patient dissatisfaction that subsequently can lead to migration of patients from one ESCO to another. In the ESCO model, these combined factors will lead both to significantly increased expenses and decreased revenues for a health care organization. For example, consider a device that could alert a physician to a condition that requires an intervention and thus avoid hospitalization for care. This could significantly reduce the total cost of care for that patient, even though in both instances, the procedure would be reported clinically in terms of a single intervention.

### A Cost Component Must Be Included in Future Clinical Studies

Costs of procedures have historically been ignored in clinical trials, particularly with regard to imaging and endovascular intervention publications. As value will be tied into costs and quality, these variables must be quantified and reported in future clinical trials. As for the dialysis access population and the use of stent-grafts, it is likely that the increased upfront cost of the device will be negated when the patient undergoes fewer future reinterventions compared to angioplasty alone. This argument is particularly important to health system administrators, who will not only be interested in charges to third-party payers, which have been focused on in the past, but also in overall costs of performing these procedures to the health care system. This includes direct costs as well as indirect costs, the former of which significantly increases with reinterventions.

### Evolving Payment Structures Will Likely Affect the Provider Decision-Making Process

With physician payments and technical fees all coming from the same limited funds within the accountable care organization/accountable care entity structure, the incentive to perform one procedure instead of two will

become greater by an order of magnitude. The financial incentive to perform multiple procedures will disappear as the interventional suite converts from one of the largest revenue producers in a health care system to one of the largest cost centers; this will not go unnoticed by health care administrators. Future clinical trials must take into account not just the costs of such repeat procedures, but the quality measures that should be tied into the outcomes. Outcomes related to the health care system, outcomes based on provider specialty, and outcomes based on specific devices will become increasingly important in future clinical trials.

### SUMMARY

The changes in health care delivery are intimidating to those in the medical field. However, such changes are overdue and already occurring, and practitioners and device manufacturers need to adjust accordingly. By remaining patient focused, with an eye to outcomes, cost, and quality, clinical trials will be the key to producing value-based medical care for all patients. Medical device manufacturers and physicians have the opportunity to work together to define clinically and economically relevant outcomes for medical devices. Examining the value of a device over a relevant period will enable physicians to justify their selection and use to decision makers. ■

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# Treating Disadvantaged Venous Anatomy With the GORE® Hybrid Vascular Graft

How the stent-driven venous anastomosis can be used to create and maintain vascular access in challenging dialysis patients.

BY SOO YI, MD; PATRICIA ROSENBERRY, MS, BSN; AND DAVID B. LEESER, MD, MBA

**T**he GORE® Hybrid Vascular Graft (GHVG) was cleared for use in the United States in 2010.<sup>1</sup> Over the last 5 years, the GHVG has allowed for percutaneous and sutureless\* venous anastomosis and has provided many novel ways to maintain vascular access in some of the most challenging patients.<sup>2,3</sup> The specific types of patients in which the GHVG can be used is invaluable. In this article, we use a series of short case vignettes to highlight how the stent-driven venous anastomosis can be used to treat disadvantaged venous anatomy. Case examples include the morbidly obese patient, the patient with stented outflow from a graft that needs to be replaced, a patient with axillary veins that are too small to create a standard sutured anastomosis, and a patient with a previous upper arm arteriovenous graft that has failed but with a patent axillary vein above the old graft's anastomosis.

## CASE VIGNETTE 1: PLACING A STENT-GRAFT IN A MORBIDLY OBESE PATIENT

Creating vascular access in a morbidly obese patient can be extremely challenging. We have had several patients with a body mass index greater than 50 kg/m<sup>2</sup>. Technically, suturing the venous anastomosis is difficult because the vein can be located more than 8 to 10 cm below the skin and large amounts of subcutaneous adipose tissue. In these cases, the incision required to expose the axillary vein is very large. Comorbid conditions, such as diabetes mellitus, combined with the large amount of subcutaneous adipose tissue create a significant risk for postoperative wound infections and seroma formation. The GHVG allows for the creation of a technically less difficult venous anastomosis through a 1- to 2-cm incision in the axilla, which is far less susceptible to complications. Consideration should be given to placing a GHVG as the first choice in all patients

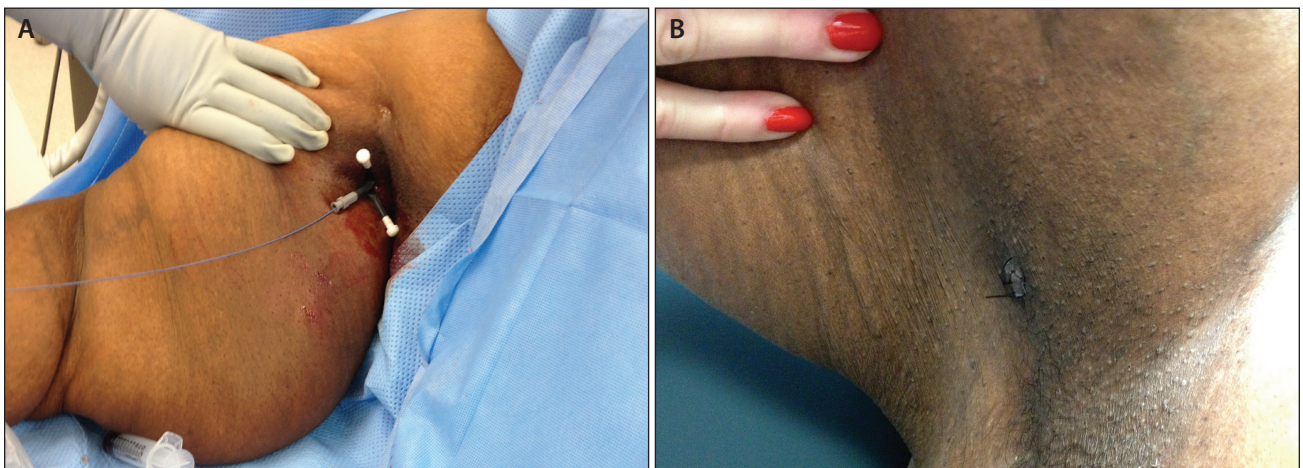
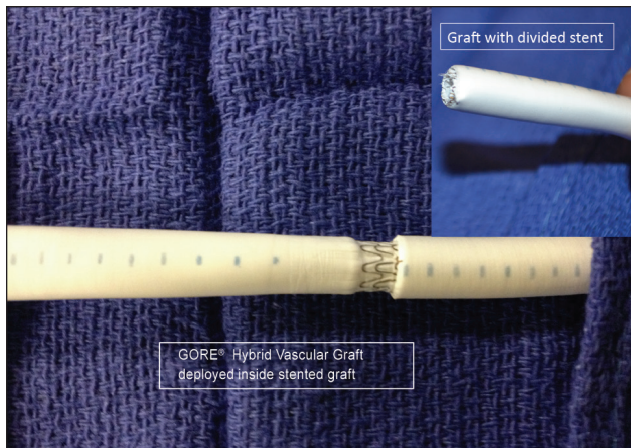


Figure 1. A morbidly obese patient with a percutaneous sheath in place (A) and a healed venous anastomosis incision in the axilla (B).

\*Two stay sutures located through the nitinol reinforced section and the vessel wall are required per the Instructions for Use.





**Figure 2.** Graft with stent divided and with the GORE® Hybrid Vascular Graft deployed inside the stented graft.

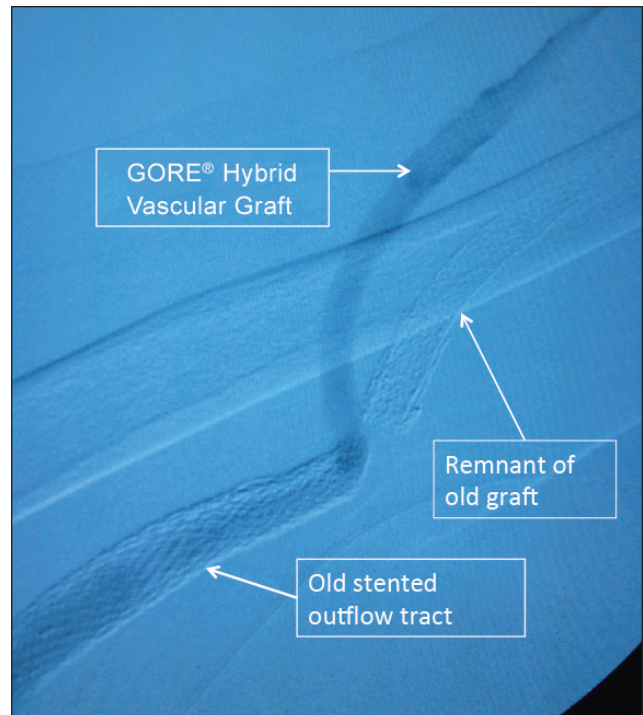
with body mass index  $\geq 35 \text{ kg/m}^2$ . The minimally invasive nature of the GHVG allows for the avoidance of significant morbidity in these patients and is technically easier for the well-trained vascular access surgeon (Figures 1A and B).

### CASE VIGNETTE 2: A PATIENT WITH STENTED OUTFLOW AND INFECTION REQUIRING GRAFT REPLACEMENT

In a second case example, a patient presented with an infected needle stick site in a graft that had been in place for several years.<sup>2</sup> Stents had previously been placed from the distal aspect of the graft through the venous anastomosis and into the subclavian vein. A new graft could not be sutured in because there was no area that could be transected without transecting the wires belonging to the stents. We decided to replace the old graft by dividing the old graft through the stented portion and deploying the stent portion of the GHVG inside the lumen of the divided stent, thus excluding the divided ends of the wires from the stent from the circulation within the graft (Figures 2 and 3). The patient was able to continue dialysis access in her upper extremity.

### CASE VIGNETTE 3: A PATIENT WITH SMALL-CALIBER AXILLARY VEINS

The GHVG can create a viable access in a small or friable axillary vein, where a standard graft may fail. In these cases, either via an open or percutaneous approach, the covered stent portion of the GHVG can be placed through a smaller vein in which a standard sutured anastomosis would stenose the outflow. With the GHVG, the landing zone is more centrally located in a larger vein so that the flow through the graft is not compromised by the small caliber of the axillary vein. The instructions for use for the GHVG recommend sizing the stent section 5% to 20% larger than the healthy vessel diameter. In cases in which there is a



**Figure 3.** Graftogram of the GORE® Hybrid Vascular Graft deployed into the stented outflow.

long segment of vein that is compromised, a GHVG with a 10-cm stent section can be used to extend the graft vein interface more proximally. If the stent portion of the GHVG terminates in an area of the vein that is not ideal, then a covered stent of the same size as the outflow stent portion of the GHVG can be used to extend the graft to a suitable site within the vein. The adequacy of the outflow should be confirmed by performing a graftogram with visualization of the outflow before tunneling after deployment within the venous system to confirm adequate outflow. In addition, a graftogram should be completed after tunneling of the graft to ensure that there is no kinking at the junction of the stented and nonstented portion of the graft.

### CASE VIGNETTE 4: MAINTAINING ACCESS IN A PATIENT WITH A FAILED ARTERIOVENOUS GRAFT IN THE UPPER ARM

The GHVG can be used to maintain access in a patient with a failed upper arm polytetrafluoroethylene graft that was placed using a standard open technique. In these cases, a preoperative ultrasound should be performed to visualize the axillary vein to confirm patency as well as determine that the vein can be cannulated to allow for percutaneous access to the axillary vein above the failed graft. Once these conditions are confirmed, the patient is scheduled for the operating room. The axillary vein can be cannulated with a micropuncture set, and a venogram



is performed through the microsheath to confirm that the vein is of adequate caliber and quality for placement of the GHVG. In addition, the outflow through the central circulation to the right atrium should be confirmed. After confirmation of the outflow, the GHVG is placed in the standard percutaneous fashion. In these cases, the venous outflow of the graft can be at or just beyond the chest wall. This technique can allow a patient to maintain access in their upper extremity and delay or avoid placement of an arteriovenous graft in the lower extremity.

## SUMMARY

The GHVG is an important tool for all vascular access specialists to have in their access toolbox. As our case vignettes show, the GHVG can allow for the preservation of upper arm access in patients with failing or failed upper arm grafts. The GHVG can avoid morbidity in obese patients who present difficult access challenges, with a secondary patency of over 60% at 1 year.<sup>4</sup> The GHVG allows for the creation of a sutureless\* anastomosis in cases in which a standard graft could not be successfully deployed. Surgeons who develop the required skills to create access options using the GHVG will become essential members of the access team and provide life-preserving care for patients with end-stage renal disease. As we know, the first access placed is not the most important—it's the fourth, fifth, sixth, seventh, and beyond that maintain a patient's life line. The GHVG has an important role in the ongoing efforts to achieve and maintain dialysis access in this challenging patient population. ■

\*Two stay sutures located through the nitinol reinforced section and the vessel wall are required per the Instructions for Use.

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# The High-Cost, Low-Quality Impact of Central Venous Catheters in Dialysis Access

Rethinking the approach to managing ESRD patients with emergent dialysis needs using early cannulation grafts.

BY KARL A. ILLIG, MD

Approximately 662,000 Americans have prevalent end-stage renal disease (ESRD), and there were 117,162 newly reported cases in 2013.<sup>1</sup> Approximately 80% of patients with ESRD began hemodialysis via central venous catheter (CVC) in 2015, with only 17% initiated with an arteriovenous fistula (AVF) and 3% with an arteriovenous graft (AVG).<sup>2</sup> At 90 days after initiation of dialysis, 68.3% of hemodialysis patients were still using a CVC. The high use of CVCs persists despite the Fistula First Breakthrough Initiative, which when launched in 2005, stressed the importance of placing AVFs as primary access in at least 50% of newly diagnosed ESRD patients and in 40% of prevalent patients undergoing hemodialysis, as recommended by national guidelines.<sup>3</sup> In 2013, the Centers for Medicare & Medicaid Services increased the goal to 68% of prevalent patients.<sup>4</sup>

## REASONS FOR THE HIGH PREVALENCE OF CVC USE

Despite the goals of the Fistula First Breakthrough Initiative, there are several reasons for the prevalence of CVCs, including delays in referrals for AVF creation and AVFs placed well in advance that were still unusable.

Although autologous AVFs remain the most effective means of providing dialysis access, they often require a period of 10 to 12 weeks to fully mature before they can be used for access, thereby necessitating alternative means of access in an emergent ESRD patient. CVCs are also used when an AVF is no longer usable and a replacement has not been created or fully matured.

Far too often, patients and their referring nephrologists do not seek vascular access in a timely manner. As recommended by the National Kidney Foundation's Kidney Disease Outcomes Quality Initiative clinical practice guidelines, patients should be referred for an AVF "at least 6 months prior to the anticipated start of hemodialysis

treatments. This timing allows for access evaluation and additional time for revision to ensure a working fistula is available at initiation of dialysis therapy."<sup>5</sup> The guidelines further note that, "a graft should, in most cases, be placed at least 3 to 6 weeks before the anticipated start of [hemodialysis] therapy. Some newer graft materials may be cannulated immediately after placement."<sup>5</sup>

In addition to the delay in referral for AVF creation, only 50% to 80% of fistulas mature. Thus, physicians resort to a CVC because of the relative ease of insertion and the quick access. However, the convenience of CVCs comes at a cost in terms of infection and mortality. In addition, patients with CVCs have a reduced quality of life, as the CVC limits their ability to shower or swim. It is time to consider a new paradigm for the treatment of ESRD patients.

## INFECTION RATES

In general, infection remains the primary concern with dialysis access. In the chronic uremic patient on hemodialysis, infection is a leading cause of morbidity, second only to cardiovascular disease as a cause of death.<sup>2</sup> According to the United States Renal Data System, the total mortality rate due to infection is 76 per 1,000 person-years at risk, and sepsis is responsible for three-quarters of these deaths.<sup>2</sup> Compared with the general population, the incidence of sepsis in patients with ESRD can be up to 100 times as high. Infection is a major cause for hospitalization in this population, estimated to be responsible for as many as 20% of inpatient admissions.<sup>2</sup> These infections confer a higher risk of mortality in the ESRD patient than in the general population, with a diagnosis of septicemia carrying a cumulative mortality rate of 43% at 1 year versus 20% for the general population.<sup>6</sup>

As compared with other forms of dialysis access, AVFs have the lowest rate of thrombosis,<sup>7</sup> require the fewest

interventions,<sup>7,8</sup> and provide longer survival of the access.<sup>7-10</sup> AVFs have lower rates of infection than AVGs, which in turn, are less prone to infection than CVCs. The infection rates of CVCs are stubbornly high. Patients receiving CVCs for dialysis access had relative risk of infection of 2.3 as compared with 1.47 for AVGs.<sup>5</sup>

### USE OF EARLY CANNULATION GRAFTS

Early cannulation grafts, such as the GORE® ACUSEAL Vascular Graft, can provide emergent dialysis patients with a better alternative to CVCs. The GORE ACUSEAL Vascular Graft is a low-bleed, trilayer vascular graft that includes an elastomeric middle membrane between inner and outer layers of expanded polytetrafluoroethylene. The graft is designed to hinder suture line and cannulation needle bleeding. The dialysis unit nurses and technicians should hold pressure for 10 to 15 minutes to achieve hemostasis after needle removal. The GORE ACUSEAL Vascular Graft can be cannulated within 24 hours of implantation. Glickman et al conducted a study of 138 patients receiving the GORE ACUSEAL Vascular Graft and found that the graft can be cannulated within 72 hours of implantation with patency and complication rates similar to those observed with standard cannulation of expanded polytetrafluoroethylene grafts.<sup>11</sup> As a result, these new early cannulation grafts may allow early removal of CVCs or avoid their use entirely.

### New Treatment Algorithm

The advent of early cannulation grafts has resulted in changing my personal algorithm for treating emergent dialysis patients (Figure 1). If the patient is healthy enough for surgery, instead of inserting a CVC, I begin by inserting a GORE ACUSEAL Vascular Graft. The patient is then able to begin dialysis in a matter of hours. If the patient is unable to undergo surgery, I first place a temporary jugular or femoral catheter and dialyze the patient once or twice. Once the patient has stabilized, I would insert a GORE ACUSEAL Vascular Graft and remove the catheter. Both of these strategies essentially eliminate the longer-term morbidity and mortality associated with catheter use and allow for quicker dialysis access.

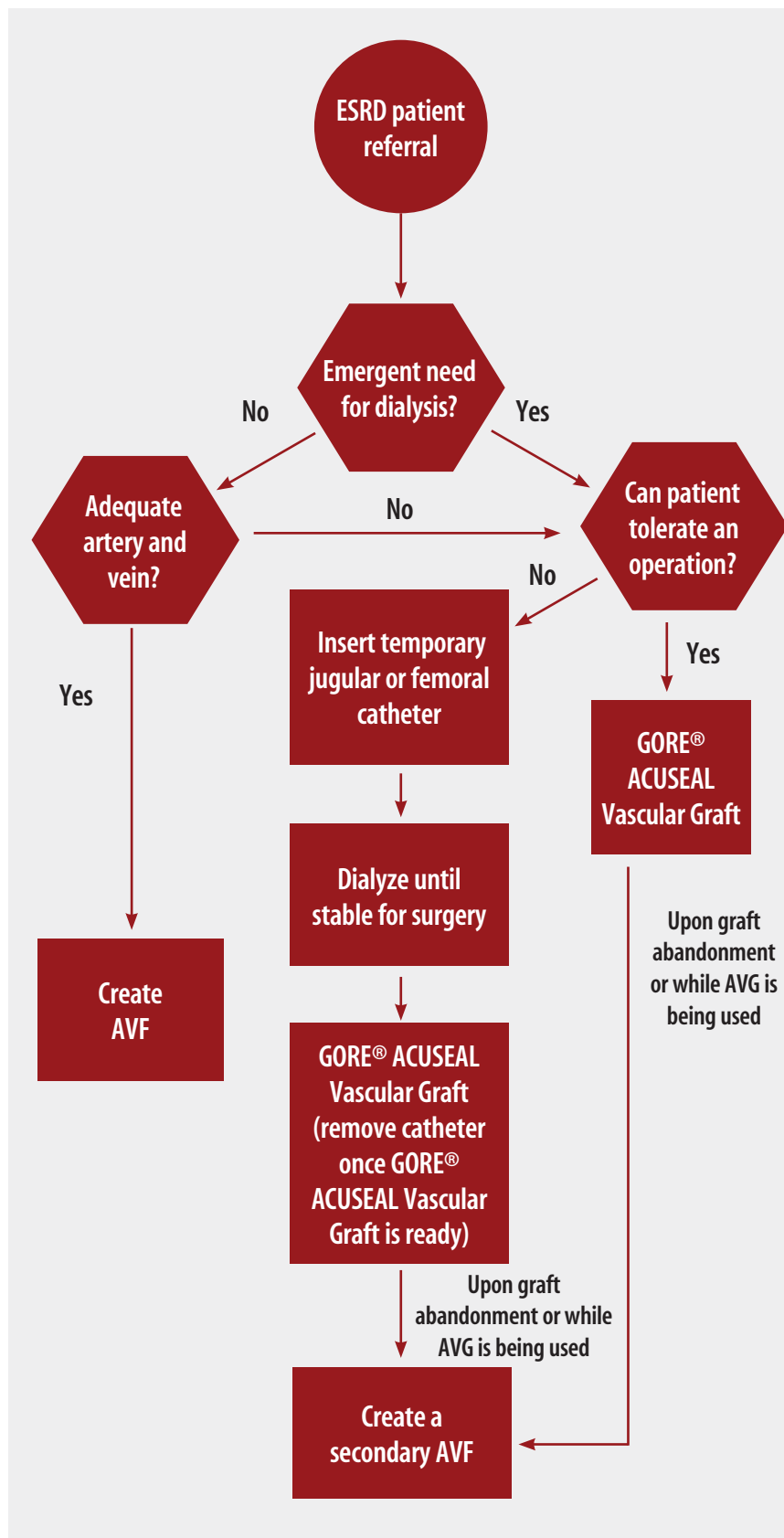


Figure 1. Algorithm for treating emergent dialysis patients.

## Economic Benefits

A recent study analyzed the cost of the comparative treatments for patients with ESRD on dialysis and concluded that the GORE ACUSEAL Vascular Graft has the lowest cost. The United States study compared patients treated with the GORE ACUSEAL Vascular Graft, CVCs, AVGs, and AVFs. Patients were followed over 6 months. Infection, reintervention, and comparison with national cohorts were determined with actual costs projected to 1 year using a propensity score-matched cohort.<sup>12</sup>

The rate of sepsis requiring hospitalization per 1,000 dialysis days was 1.4 for CVC, 0.3 for AVF, and 0.5 for AVG and the GORE ACUSEAL Vascular Graft ( $P < .001$ ). The total cost of care at 1 year was \$10,056 for CVCs, \$6,442 for AVFs, \$8,325 for AVGs, and \$5,422 for GORE ACUSEAL Vascular Graft ( $P < .05$ ).<sup>12</sup> Primary-assisted patency was 100% for all dialysis access at 6 months with no deaths. The study demonstrated that the GORE ACUSEAL Vascular Graft had the lowest cost of care and a significantly lower rate of infection compared with CVCs.<sup>12</sup>

## SUMMARY

The ability to implant a graft that allows almost immediate cannulation is changing the way we approach ESRD patients with emergent dialysis needs. The comparative lower infection and morbidity rates associated with the GORE ACUSEAL Vascular Graft over CVCs point the way to a better solution to managing patients who are in emergent need of dialysis. ■

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# Achieving Durable Outcomes in Dialysis Access With the GORE® VIABAHN® Endoprosthesis

Leading physicians share best practices and discuss how the GORE VIABAHN Endoprosthesis has contributed to their practices.



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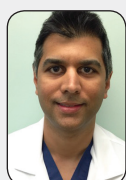
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### Please share the impact that the GORE® VIABAHN® Endoprosthesis has on outcomes for your most challenging patients with end-stage renal disease (ESRD) on hemodialysis.

**Dr. Alvarez:** A stent-graft with the flexibility, durability, and proven clinical performance of the GORE VIABAHN Endoprosthesis allows me to treat a broader and more complex patient population. Primary treatment of the venous anastomosis stenosis with the GORE VIABAHN Endoprosthesis leads to better primary patency and fewer repeat interventions for maintenance of secondary patency when compared to traditional percutaneous transluminal angioplasty (PTA). Because of the device's flexibility and durability under mechanical stress, I can treat the most chal-

lenging venous anastomosis locations, in particular, lesions across the elbow, as the device conforms to the changes of the vascular anatomy of the moving arm without the risk of fracture or kinking. The GORE REVISE clinical study showed 53% target lesion primary patency at 6 months. The reduced number of interventions to maintain secondary patency leads to better patient satisfaction because they have to spend less time receiving medical care on the days they are not on dialysis.

**Dr. Ross:** In terms of patient outcomes, running blood can be established peripherally with the GORE VIABAHN Endoprosthesis, which is different because of the flexibility limitations of other stent-grafts. In my experience, the GORE



VIABAHN Endoprosthesis is much easier and is cost-effective for maintenance. It is simple to perform thrombectomy. The GORE VIABAHN Endoprosthesis is an endovascular bypass graft that can be used across all joints. From a provider perspective, there are fewer interventions and thus greater patient satisfaction.

**Dr. Wayne:** The GORE VIABAHN Endoprosthesis is the most versatile of the available stent-grafts that we use in the field of vascular access, and I use it often in my practice. It is flexible, easy to deploy, and has been tested in a real-world population. In the GORE REVISE clinical study, we saw impressive results with the GORE VIABAHN Endoprosthesis in terms of effectiveness at the venous anastomosis, with a target lesion primary patency rate at 2 years of 53% compared to 36% for PTA alone. It was also found to be quite effective across all joints, and in December of 2013, the US Food and Drug Administration approved its use for those specific pathological sites. Additional studies are needed to answer specific questions about the effectiveness of the GORE VIABAHN Endoprosthesis in areas outside of graft outflow.

**Dr. Patel:** For us, the GORE VIABAHN Endoprosthesis has been a real game changer. I think one of the main benefits is that it has a long-lasting effect. In dialysis access, we frequently see recurrence of stenosis after treatment with balloon angioplasty. Neointimal hyperplasia can be quite aggressive, and recurrent stenosis may ultimately lead to access failure and thrombosis. Bare-metal stents were a poor option for us—they resulted in a high number of recurrent lesions with thrombosis. The neointimal hyperplasia associated with dialysis access lesions tends to aggressively grow through the struts of bare-metal stents, limiting long-term efficacy. The design of the GORE VIABAHN Endoprosthesis really has made a huge difference in patency as well as long-term outcomes for dialysis access, and the key seems to be the ability to create a barrier for neointimal hyperplasia growth. This has translated into our ability to provide a long-lasting treatment for dialysis access stenosis—in comparison to shorter-term efficacy with primary balloon angioplasty or bare-metal stent placement. We can now “cure” recurrent lesions—and this has led to significant improvement in our access care.

In thrombotic patients, if we cannot restore flow with a conventional angioplasty or thrombectomy, we frequently have been able to turn an unsuccessful procedure into a successful one by identifying the culprit lesion and utilizing the GORE VIABAHN Endoprosthesis. The benefits here are significant: where we've prolonged the life of an access, avoided any catheter placement, minimized any missed dialysis treatments, and reduced the need for any further surgical access creation. The use of the GORE VIABAHN Endoprosthesis in these settings has helped to salvage

accesses that others have been unsuccessful at restoring, and this has resulted in better outcomes and greater satisfaction from the patients, dialysis units, and referring physicians.

As far as the ability to place the GORE VIABAHN Endoprosthesis in different locations, there has really been nothing like it. The ability of the GORE VIABAHN Endoprosthesis to conform with the natural anatomy of the vessel is unique as a fully covered, flexible stent-graft. At the same time, the durability and long-term patency of keeping open lesions at these sites has translated into prolonged access patency. Having the ability to place the GORE VIABAHN Endoprosthesis in areas of flexion or areas of turns has been fundamental to our success.

From a provider perspective, it really goes back to taking the best care of your patients. For those patients with recurrent lesions or recurrent thrombosis, the entire management of dialysis access can be quite frustrating. Dialysis patients really live challenging lives, and dialysis access issues can disrupt their overall health. The need to go through multiple procedures and revisions can add to the overall burdens these patients often face. A well-placed stent-graft can oftentimes break the cycle of frequent access dysfunction—and patients and referring providers can immediately appreciate the benefits here. It's not always the case with dialysis access work, but the GORE VIABAHN Endoprosthesis has really helped us to provide long-term success in treating recurrent lesions. As a provider, it's immensely satisfying to “fix” this type of issue and to really help our patients live the best lives they can.

## How has clinical data from the GORE REVISE clinical study helped you decide when to use the GORE VIABAHN Endoprosthesis?

**Dr. Ross:** The results of the GORE REVISE clinical study say it all. You can expect 69% of accesses to still be patent at 2 years by placing the GORE VIABAHN Endoprosthesis. Additionally, this can be achieved with an average of fewer than three interventions.

**Dr. Patel:** The study shows benefits for treatment of venous anastomosis lesions and goes even further in demonstrating these benefits in thrombotic patients. These results have helped guide us toward the earlier use of stent-grafts at the venous anastomosis. Previously, we only resorted to stent-grafts when angioplasty procedures consistently failed at the venous anastomosis. However, we often found ourselves treating the same lesions over and over, with recurrent thrombosis. By placing the GORE VIABAHN Endoprosthesis in the appropriate locations, it has translated into longer-lasting, better outcomes in our patients.

This has reduced the frequency of access thrombosis in our practice and has extended the lifespan of failing grafts. We have had numerous patients who have gone from

experiencing a high frequency of graft thrombosis to now going “thrombosis-free” for many months or years after GORE VIABAHN Endoprosthesis placement. This experience has helped to guide us more toward GORE VIABAHN Endoprosthesis placement during initial thrombectomy procedures, as we’ve noted high rates of recurrent stenosis when we’ve previously approached these lesions with primary angioplasty instead of stent-graft placement. Through this approach, we’ve been able to maintain graft patency for an extended amount of time, and we have numerous grafts in our practice that are well over 5 to 10 years old. This is quite remarkable for a graft and a huge leap forward from the initial days of treatment without stent-grafts.

**Dr. Wayne:** Many useful conclusions were obtained from the GORE REVISE clinical study data. It is the only study that I am aware of that included both thrombosed and nonthrombosed patients, which increased the credibility of the trial. Use of the GORE VIABAHN Endoprosthesis at the venous anastomotic stenoses showed a statistically significant superiority over PTA at 6 months (53% vs 36%). In addition, there was improvement in 6-month outcomes for both the thrombosed and nonthrombosed groups. The number of interventions over a 2-year period decreased following placement of GORE VIABAHN Endoprosthesis when compared to PTA only. The GORE REVISE clinical study also revealed that when addressing a patient with venous anastomotic stenosis and no prior interventions, there was less of a gain in patency between PTA (44%) and stent-graft placement (51%); however, in patients with one or more prior interventions, the value of the GORE VIABAHN Endoprosthesis versus PTA was dramatic, with a patency of 54% versus 29% at 6 months, respectively. Given the results of the GORE REVISE clinical study, placing the GORE VIABAHN Endoprosthesis may not be necessary in patients with no prior intervention and if PTA alone reveals satisfactory postangioplasty dilatation. However, for patients with prior interventions, the GORE VIABAHN Endoprosthesis should be placed without hesitation in my opinion.

Since December 2013, in our outpatient facility, we have placed 32 GORE VIABAHN Endoprosthesis across significant venous anastomotic stenoses, and our unpublished data is at least equal to the results shown by the GORE REVISE clinical study. As a result, I am further convinced that the use of the GORE VIABAHN Endoprosthesis performs its function admirably.

**Dr. Alvarez:** The results of the GORE REVISE clinical study clearly showed a clinical benefit when using the GORE VIABAHN Endoprosthesis as primary treatment of the target lesion versus PTA alone. The study found greater target lesion primary patency in both thrombotic and non-thrombotic patients over a 2-year period, and of particular

interest to me, the study found a reduction in the cumulative number of interventions for maintaining circuit patency. These results have led me to use the GORE VIABAHN Endoprosthesis as primary treatment of target lesions with very few exceptions. Because of the demonstrated safety of the device (ie, no fractures reported over a 2-year period including when used across the elbow), I use the GORE VIABAHN Endoprosthesis in more challenging locations of the target lesions and have confidence in obtaining the clinical benefit.

### **How has the flexibility and durability of the GORE VIABAHN Endoprosthesis changed your approach to treating lesions that span the elbow?**

**Dr. Wayne:** When addressing stenotic lesions at the elbow joint, our prior treatment choices were quite limited. The GORE VIABAHN Endoprosthesis has allowed us to achieve long-term patency because of its flexibility and durability. Other stent-grafts have a tendency to kink, and bare-metal stents, although more flexible, have a tendency to fracture and become disrupted with motion of the elbow joint, creating a new problem in an already compromised patient. As a result, I have used the GORE VIABAHN Endoprosthesis at venous anastomotic stenoses at the elbow joint and have seen significant long-term patency.

**Dr. Alvarez:** The flexibility and durability of the device, which allows it to conform to the vascular anatomy of the moving arm without the risk of fracture, has allowed me to treat venous anastomosis stenosis in the most challenging locations (eg, points of flexion such as the elbow), while still obtaining the superior clinical benefit as compared to PTA alone.

**Dr. Ross:** The simplicity of the endovascular approach of the GORE VIABAHN Endoprosthesis and proven performance in points of flexion makes traditional jump graft use rare in lesions that span the elbow.

**Dr. Patel:** The traditional approach (ie, simple balloon angioplasty) does not yield long-term success at the venous anastomosis of a forearm graft. Many of our patients presented with recurrent stenosis and thrombosis due to lesions at this site. There was really no other effective device to use across the elbow. The GORE VIABAHN Endoprosthesis is unique in its ability to bend across the elbow, and it has been a durable treatment for us. We were skeptical at first about its ability to handle the stresses of flexion across the joint, but it has proven to be quite effective. The GORE REVISE clinical study did not demonstrate any GORE VIABAHN Endoprosthesis fractures across the antecubital fossa, and our clinical experience has supported this. I think the caveat for practitioners is to always keep in mind where

your target is going to be for the stent-graft placement at the antecubital fossa. You want to avoid losing upper arm arteriovenous access options through stent-graft placement. However, when appropriately placed, stent-grafts can be effective for maintaining a forearm access and preserving future upper arm access options. We utilize Doppler ultrasound in our practice to identify the vessels around the elbow joint to better plan for the target landing areas for stent-grafts.

At the venous anastomosis of an upper arm graft, we've also found good success through sites of flexion at the axilla. It is important to appreciate the mobility of vessels across the axilla, which may be overlooked as a patient is lying still on the procedure table. The ability of the GORE VIABAHN Endoprosthesis to bend in these areas, while maintaining vessel patency, has been revolutionary in the care of these often-recurrent lesions.

**How do you foresee the ESRD Seamless Care Organization model and other Medicare innovations related to quality and outcomes impacting how you evaluate and choose devices such as the GORE VIABAHN Endoprosthesis in the future?**


**Dr. Alvarez:** Briefly, in the ESCO model, the role of the physician (nephrologist) is to organize and coordinate care and drive better outcomes with providers working as a team while at the same time being responsible for the cost of care. In an ESCO setting, I would evaluate and choose devices that would help me improve outcomes in a cost-effective way. A device like the GORE VIABAHN Endoprosthesis would fit such a profile. Despite a higher initial procedure cost, the reduced number of interventions when using the GORE VIABAHN Endoprosthesis trends toward reduced costs over a 2-year period when compared to PTA alone.

**Dr. Ross:** It is a simple formula of functional time economic ratio where the ratio equals time (patency of functional graft) over cost (costs of the procedure or device). You always want the functional time economic ratio to be a large number to show long-term outcomes validate the initial expense.

**Dr. Patel:** I think it is challenging to predict where this model will go in the future, and there is a lot of uncertainty as to where we will end up. There seems to be a movement toward a more global payment system, where there is an interest to reduce the number of procedures for patients. I think minimizing the number of procedures per patient should be an underlying goal for improved patient care, regardless of whatever the favored payment systems are. In our practice, the GORE VIABAHN Endoprosthesis has helped to reduce necessary repeated angioplasty pro-

cedures at recurrent lesions. There is also a significant financial value to maintaining a dialysis access. There is a huge cost advantage to avoiding catheters and catheter-associated infections and hospitalizations. The maintenance of existing accesses has helped us avoid these costs, and by avoiding catheters, I believe we have also been able to extend the lifespans of our patients. I think that it is best practice to try to give our patients the longest-lasting results with any procedure we do. Given the high costs with dialysis and the multiple comorbidities associated with ESRD, the ESRD population is already a target for cost-cutting measures. Additionally, we are seeing continued significant growth in this patient population. Anything we can do to increase the longevity of an access will translate into an overall savings to the system. The goal ultimately is to provide the highest quality of care to the patient, and the GORE VIABAHN Endoprosthesis has helped us to achieve success in dialysis access care.

**Dr. Wayne:** The GORE VIABAHN Endoprosthesis has a proven track record for long-term value, and its use in this selected ESRD patient population is not only beneficial to the patient, but also beneficial to the interventionist. In the past and likely more so in the future, favorable outcomes are going to play a significant role in reimbursement. We have learned, from the GORE REVISE clinical study that after placing the GORE VIABAHN Endoprosthesis at the venous anastomosis, the number of interventions decreased over the following 2 years when comparing PTA alone to GORE VIABAHN Endoprosthesis placement (3.7 vs 2.7 for target lesion patency and from 5.1 vs 3.7 for access circuit patency). Although the upfront costs of the GORE VIABAHN Endoprosthesis may be more, over a 2-year period, maintenance of arteriovenous access with the GORE VIABAHN Endoprosthesis trended to be more cost-effective than with PTA alone due to the reduced number of interventions. Over the past 10 years, interventionists and vascular surgeons have developed improved techniques in the care of the ESRD patient population, and the medical device companies have answered our needs with better medical devices, which in turn have improved patient outcomes. In order for the ESCO model to function properly, interventionists and vascular surgeons will need to continue to improve the technical care of the ESRD patient population. Further, even though medical device companies continue to enhance our procedures with new and innovative equipment, the ESRD patient population will need to become more aware of their disease, its complications, and become more compliant with follow-up appointments and postprocedure orders for maximum results to be obtained. In combination, this trio of players will be well positioned to lower the overall costs of care to this increasing population of patients with ESRD. ■

**INTENDED USE / INDICATIONS:** The GORE® VIABAHN® Endoprosthesis is indicated for improving blood flow in patients with symptomatic peripheral arterial disease in superficial femoral artery de novo and restenotic lesions up to 270 mm in length with reference vessel diameters ranging from 4.0 – 7.5 mm, in superficial femoral artery in-stent restenotic lesions up to 270 mm in length with reference vessel diameters ranging from 4.0 – 6.5 mm, and in iliac artery lesions up to 80 mm in length with reference vessel diameters ranging from 4.0 – 12 mm. The GORE® VIABAHN® Endoprosthesis is also indicated for the treatment of stenosis or thrombotic occlusion at the venous anastomosis of synthetic arteriovenous (AV) access grafts. Refer to Instructions for Use at [goremedical.com](http://goremedical.com) for a complete description of all contraindications, warnings, precautions and adverse events. 

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