RAISING THE STANDARDS for Dialysis Access Care
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Continuous Quality Improvement in ESRD Care

Discussion on the treatment algorithm, clinical outcomes, and value analysis related to the use of the GORE® ACUSEAL Vascular Graft in dialysis care.

BY SAPAN S. DESAI, MD, PhD, MBA, FACS

According to the United States Renal Data System (USRDS), a National Institute of Diabetes and Digestive and Kidney Diseases data system, 80% of patients initiate hemodialysis via a central venous catheter (CVC). Complications associated with CVCs remain a leading cause of death in this vulnerable population and are a major contributor to the $90,971 average annual per person cost of care. GORE® ACUSEAL Vascular Grafts decrease the use of CVCs and thus reduce the complication rate associated with end-stage renal disease (ESRD) patients who require urgent-start dialysis.

TREATMENT ALGORITHM

Placement of an arteriovenous fistula (AVF) remains the standard of care for patients with chronic kidney disease (CKD). The ideal patient has stage 3 or 4 CKD and sufficient time (4–8 weeks) to permit maturation of an AVF. However, as noted by the USRDS data, most patients present to the hospital with ESRD and require urgent-start dialysis. As we have recently shown, we believe that the proper management of these patients is placement of a GORE ACUSEAL Vascular Graft. GORE ACUSEAL Vascular Grafts are associated with fewer complications compared with CVCs, a low rate of surgical site infections, better clinical outcomes at 1 year compared with CVCs, and a dramatically lower cost of care at 1 year compared with CVC and AVF combinations.

Patients who present with ESRD and require urgent-start dialysis should undergo an appropriate history and physical examination. Basic lab work should be completed, and any significant medical issues should be promptly addressed. Barring symptomatic hyperkalemia or uremia, most patients will be candidates for timely placement of a GORE ACUSEAL Vascular Graft, which permits cannulation for dialysis within 24 hours after placement. Most patients with ESRD who require urgent-start dialysis can be medically stabilized while they await timely placement of arteriovenous access.

CLINICAL OUTCOMES

We have been able to achieve CVC rates as low as 5.4% in our patient population using this strategy. By opting for a GORE ACUSEAL Vascular Graft instead of a CVC and AVF, we have decreased the cost of care from $17,523 per year to $5,894 (P < .01) at our institution. This approach is also associated with a survival advantage for GORE ACUSEAL Vascular Graft patients (85% for GORE ACUSEAL Vascular Grafts vs 78.6% for AVFs at 1 year; P < .05). Approximately 92% of patients were dialyzed within 24 hours after placement of a GORE ACUSEAL Vascular Graft.

DIALYSIS ACCESS PROGRAM

Central to the success of our program is our effort to improve care coordination among all key stakeholders. Recognition of the value of a GORE ACUSEAL Vascular Graft in the overall strategy to improve clinical outcomes and decrease the cost of care for dialysis patients is important for nephrologists, surgeons, interventionalists, access centers, hospitals, and the patient. Good communication between the nephrologist and surgeon helps ensure that patients who require urgent-start dialysis are appropriately prioritized. Few patients will require urgent GORE ACUSEAL Vascular Graft placement overnight, but these patients should be prioritized during the day to ensure safe, timely, cost-effective, efficient, and patient-centered care.

Key to this strategy is a robust surveillance program to monitor these patients every 3 months. At each visit, flow velocities are collected along with completion of a duplex ultrasound. Our program has also sought to achieve more transparent information exchange between access centers, interventionalists, and surgeons. Patients who have poor flow velocities or difficulty with cannulation at an access center are promptly referred to the surgeon for further evaluation. The surgeon then helps coordinate care, leveraging interventional resources and early intervention.
to avoid graft thrombosis. Preferential placement of a GORE® VIABAHN® Endoprosthesis in the venous outflow, even across the elbow joint, is indicated when there is significant outflow stenosis. This strategy has helped us to reduce the number of secondary interventions for GORE ACUSEAL Vascular Grafts to just 17% of cases compared with 52.5% for the CVC and AVF combination (P < .001). CLOSING THE COMMUNICATION LOOP
Closing the communication loop is also important. At every episode of care, we update the access center with a drawing of the GORE ACUSEAL Vascular Graft that clearly shows the location of the inflow, conduit, and outflow. Information about depth and other potential pitfalls are also highlighted. This drawing is distributed with the patient and also directly faxed to the access center.

VALUE ANALYSIS
We recently completed a study of 397 patients who required urgent-start dialysis for ESRD. We measured patient demographics, comorbidities, interventions, complications, and the cost of care. ESRD patients who initiate dialysis via a GORE ACUSEAL Vascular Graft were significantly more likely to have permanent access for hemodialysis at 1 year compared with patients who initiated dialysis via a CVC and AVF (P < .01). This translated into a significantly lower rate of CVC days (17.6% for AVF patients vs 3.4% for GORE ACUSEAL Vascular Graft patients; P < .01).

A lower rate of CVC usage, lower rate of complications, lower mortality, and fewer secondary interventions translated into a significantly lower cost of care for patients with GORE ACUSEAL Vascular Grafts compared with CVC and AVF patients, with a lower cost evident just 1 month after the index procedure. When combined with a robust monitoring program and the use of aspirin and clopidogrel in GORE ACUSEAL Vascular Graft patients, we were able to achieve an 80.8% primary-assisted patency rate and 84% secondary patency rate for GORE ACUSEAL Vascular Graft patients.

CONCLUSION
GORE ACUSEAL Vascular Grafts are associated with significantly improved clinical outcomes and a lower cost of care compared with CVCs and AVFs when used for ESRD patients who require urgent-start dialysis. Fewer CVC-related complications and secondary interventions result in a greater quality of life for dialysis patients.

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Management of Venous Outflow Stenosis in Dialysis Patients

BY SAPAN S. DESAI, MD, PhD, MBA, FACS

The management of venous outflow stenosis in patients undergoing dialysis remains a challenge for practitioners. Flow-limiting disease that is uncorrected can lead to graft failure. Inappropriate management can lead to multiple secondary interventions, which in turn can lead to complications and graft thrombosis. We have refined the management of patients with arteriovenous grafts who develop flow-limiting venous outflow stenoses and have developed a surveillance program and protocol for management to reduce secondary interventions, improve overall graft patency, and reduce the cost of care.

PATIENT PRESENTATION

A 67-year-old man developed end-stage renal disease (ESRD) secondary to uncontrolled hypertension and diabetes. He required urgent-start dialysis and initiated hemodialysis via placement of a GORE® ACUSEAL Vascular Graft. We exclusively use the GORE ACUSEAL Vascular Graft in our practice due to its unique construction, ability to cannulate for dialysis within 24 hours of placement, and its favorable 1-year outcomes.1-5

The patient received a 4–7-mm tapered GORE ACUSEAL Vascular Graft placed in a forearm loop configuration. The brachial artery and vein were used as the inflow and outflow, respectively. We created a generous C-shaped loop when constructing the dialysis access to avoid kinking and subsequent graft stenosis (Figure 1). The patient was able to use this GORE ACUSEAL Vascular Graft within 1 hour of placement and subsequently had no issues with dialysis. He was discharged to home on postoperative day 1 and was seen in the clinic as part of our dialysis access surveillance program.5,6

The patient was followed in clinic at 1 month, then subsequently at 3-month intervals from the index procedure. At the time of the clinic visit, the patient had a review of his most current flow velocities during dialysis and a duplex ultrasound to identify any flow-related issues. At 1-year follow-up, duplex ultrasound revealed significantly elevated flow velocities and concern for a venous outflow stenosis located at the elbow joint.

TREATMENT OPTIONS

There are numerous options for treating a clinically significant venous outflow stenosis at the elbow joint. Options include:

• Continued monitoring and follow-up in 30 to 90 days with repeat imaging
• Perform either plain old balloon angioplasty or drug-coated balloon angioplasty
• Complete angioplasty with placement of a stent or stent graft
• Convert to a fistula or place a new graft

The first two options are commonly done, leading to a greater than expected rate of access failure in patients undergoing dialysis.1,5,7,8 The last option is unnecessary at this point, as minimally invasive interventional options have been shown to be more effective.5,7 We have recently shown that early, definitive intervention for venous outflow stenosis leads to improved long-term outcomes when treating these lesions with a GORE® VIABAHN® Endoprosthesis.5

The patient in this case was taken to the catheterization lab and underwent percutaneous access of the stent graft near the C-shaped loop; subsequent angiography revealed a high-grade venous outflow stenosis across the elbow.

Figure 1. Placement of a forearm loop 4–7-mm tapered GORE® ACUSEAL Vascular Graft (white arrowheads).
COURSE OF TREATMENT
We placed an 8-mm x 10-cm GORE VIABAHN Endoprosthesis across the elbow joint (Figure 2). The flow-limiting venous outflow stenosis is clearly seen in Figure 2. After dilating the stent graft, we completed additional angiography that revealed no further flow-limiting lesions and brisk flow into the central venous circulation. To confirm the highly flexible nature of the GORE VIABAHN Endoprosthesis, we completed additional imaging with the elbow joint flexed (Figure 3), revealing no kinking of the stent graft.

RESULTS
The patient had no postprocedural issues or complications. He was discharged shortly after his procedure and had routine follow-up with us in the clinic, resuming his normal postoperative surveillance program. We recommended follow-up at 1 month postprocedure, then regularly every 3 months. At each visit, a duplex ultrasound is performed and flow rates are reviewed. This patient’s flow velocities returned to normal, and he continued to use his GORE ACUSEAL Vascular Graft without any further interventions or issues at 2-year follow-up.

DISCUSSION
In our practice, patients who present with ESRD and require urgent-start dialysis are preferentially treated with placement of a GORE ACUSEAL Vascular Graft due to its lower rate of complications, secondary interventions, and cost of care compared with a central venous catheter (CVC) and arteriovenous fistula (AVF) combination. Routine follow-up should be initiated as part of an integrated surveillance program geared toward early identification of additional pathology.

Patients who develop venous outflow stenosis should be treated as soon as the stenosis is identified to avoid the development of further pathology along the circuit and potential thrombosis of the graft. We prefer to treat patients with placement of a GORE VIABAHN Endoprosthesis, thus reducing the number of additional secondary interventions and greatly improving overall patency of the GORE ACUSEAL Vascular Graft.

We have recently published our results with GORE ACUSEAL Vascular Grafts and this treatment paradigm. We found a survival advantage associated with GORE ACUSEAL Vascular Grafts compared with AVFs and CVCs when used for immediate dialysis access for ESRD patients (15% mortality vs 21.4% mortality at 1 year; P < .05). Fewer interventions and fewer hospitalizations were needed for patients who had GORE ACUSEAL Vascular Grafts compared with AVFs. This lower rate of complications leads to a significantly lower cost of care for GORE ACUSEAL Vascular Graft patients, contributing to $11,630 in cost savings associated with GORE ACUSEAL Vascular Grafts at 1 year ($5,894 vs $17,523; P < .01).


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The Value of the GORE® ACUSEAL Vascular Graft

Assessing the clinical and economic value of the GORE® ACUSEAL Vascular Graft for AV access in the office-based lab setting.

BY SATYAKI BANERJEE, MD

In managing patients with end-stage renal disease (ESRD), it is common that the first treatment to prepare for dialysis begins with a tunneled dialysis catheter (TDC). This is mostly because a sustained surgical intervention is involved for the creation of an arteriovenous fistula (AVF) or arteriovenous graft (AVG). However, an AVF takes time to mature before it can be effectively used for hemodialysis, which often leads to dependence on TDCs. The incidence of TDC placement ranges from 75% to 80% and becomes pertinent in cases of delays in referral, noncompliance, or inability to ascertain timely intervention.

Reliance on TDCs in patients with ESRD for dialysis is often associated with complications due to infections with high rates of morbidity and mortality. It has been reported that patients who use a TDC for dialysis have a sevenfold risk of infection, emphasizing the need for an AVG that can be cannulated earlier to reduce or avoid dependence on a TDC for dialysis. The FDA-cleared GORE® ACUSEAL Vascular Graft is designed to be cannulated within 24 hours of surgical implantation and represents a promising option to overcome the TDC challenges.

Our center is a nephrology practice with an office-based laboratory that serves the dialysis access needs of patients with renal disease in the Albuquerque metropolitan area as well as adjoining areas of New Mexico. We are focused on providing our ESRD patients with the best possible outcomes by using fluoroscopic- and angiography-guided techniques for dialysis access creation and maintenance. This article discusses the value of early cannulation vascular grafts and the nonsurgical perspective on such a vascular graft.

EARLY CANNULATION VASCULAR GRAFTS

In the past 15 years, the field of dialysis access has seen an emergence of early cannulation graft implantation to circumvent the problems associated with the use of TDCs. Frequent infections, occlusions, chronic venous stenosis, and exhaustion of the conventional access routes have led to adoption of the immediate-access AVGs.

Randomized clinical trial, Aitken et al found that the rate of infectious complications was 13% less with the use of immediate-access AVGs when compared with the AVF plus/minus TDC group.

The GORE ACUSEAL Vascular Graft is designed to be cannulated within 24 hours of surgical implantation. The three-layer design incorporates an elastomer membrane between two layers of expanded polytetrafluoroethylene (ePTFE), where the inner luminal layer is bonded with the CBAS* Heparin Surface (Gore & Associates) (Figure 1). It is the elastomeric middle layer that imparts the capability of early cannulation by providing low bleed, removing the need for tissue incorporation before cannulation. Although thicker than conventional grafts, the GORE ACUSEAL Vascular Graft remains very flexible and resists kinking and compression.

Glickman et al reported that the GORE ACUSEAL Vascular Graft had overall patency rates comparable with those of historical control ePTFE grafts. More importantly, GORE ACUSEAL Vascular Grafts cannulated in the early phase (< 72 hours after implantation) had no statistically significantly different patency rates compared with those grafts that were cannulated after 21 days. Desai et al reviewed the health economic impact of the
GORE ACUSEAL Vascular Graft and showed a significant cost savings associated with the device as compared with TDCs.6

RECOGNIZED CLINICAL VALUE

In our practice, patients who have the GORE ACUSEAL Vascular Graft benefit from early cannulation of the access, thereby bypassing the use of TDCs. The clinical value of early cannulation to the patient is realized by the completely subdermal access, which lessens infection risk, and the graft can be effectively used for dialysis with 17-gauge needles as early as postoperative day 1. Postoperative edema and healing time are drastically reduced and allow for early cannulation.

The GORE ACUSEAL Vascular Graft also allows for arterialization of upper arm veins when placed in the forearm loop or straight configuration, which fosters the maturation process for a future AV access. The dialysis unit staff have been successful in cannulating the GORE ACUSEAL Vascular Graft very effectively with proper guidance. It is very helpful if the implanting surgeon outlines the graft location and marks the direction of blood flow for the dialysis unit cannulator to further optimize dialysis treatments.

Our continued use of the GORE ACUSEAL Vascular Graft has repeatedly shown a reduction in both the placement and the duration of TDC use. The TDC is used as a bridge access to allow healing from the implantation procedure up to 2 months postsurgery prior to use of the GORE ACUSEAL Vascular Graft. Additionally, we have noticed the rates of catheter use continue to drop, which is reflected by better long-term central vein preservation, consequently improving dialysis and patient quality of life.

ECONOMIC BENEFITS

By lowering the prevalence and duration of TDCs, the GORE ACUSEAL Vascular Graft has had an economic impact on both our practice and the health care system by decreasing hospitalization rates from catheter-related bacteremia, sepsis, and need for long-term antibiotics for the treatment of these catheter-related events. The benefits are also felt at the dialysis units with lower catheter rates and decreased use of antibiotics. Reimbursement rates are positively impacted by decreased TDC prevalence at outpatient dialysis units and home dialysis programs. Furthermore, reimbursement rates are potentially increased if patients have fewer days with a TDC.

ENDOVASCULAR INTERVENTION

In our practice, the GORE ACUSEAL Vascular Graft has rarely required thrombectomy as compared with other grafts. The clot burden of the GORE ACUSEAL Vascular Graft is minimal and relatively easy to remove with the help of commonly available endovascular tools (Figures 2 and 3). Graft vein anastomosis is usually not stenosed and does not require stent graft placement as often as other grafts. However, I have stented the graft vein anastomosis as with any other graft that is clotted with an appropriately sized covered stent after angioplasty. Intragraft stenosis has been even rarer, but should it arise, a 6- to 7-mm medium- or low-profile balloon is recommended. A low inflow, either from a patient’s low blood pressure or stenosis at the graft arterial anastomosis, can be a reason for early thrombosis of the GORE ACUSEAL Vascular Graft; in these rare instances, addressing them is paramount.
When gaining access for an intervention with the GORE ACUSEAL Vascular Graft, I recommend the standard micropuncture Seldinger technique under ultrasound guidance, which allows visualization through the thick three-layer wall while introducing and advancing sheaths. Once the needle and wire are in, larger devices including balloons, catheters, stents, and stent grafts easily slide through the wall layers, which tolerate the interventions very well. The triple layer of the graft allows fewer chances of pseudoaneurysm formation or wall damage. I have not seen a single case of pseudoaneurysm thus far. The thick layer also allows for quicker hemostasis after needle or interventional apparatus withdrawal. I typically hold manual pressure or apply a temporary purse-string suture to achieve hemostasis.

At the dialysis access unit, initial cannulation into the graft is easy with small 17-gauge needles. As with any AVG, avoid the anastomoses (arterial and venous) by a three-finger breadth distance. In my opinion, it is better to rotate from a bevel-up needle position at skin entry to a bevel-down position while going through the GORE ACUSEAL Vascular Graft wall. Once there is blood return, move the needle again to the bevel-up position by going through a rotating action. When good blood flow is obtained, connect the lines to the dialysis machine.

CONCLUSION
The GORE ACUSEAL Vascular Graft is clinically proven to be cannulated in the early postoperative period, which allows for earlier TDC removal or outright avoidance of TDCs. In our practice, the GORE ACUSEAL Vascular Graft has effectively proven to be a viable early cannulation access graft with undoubted long-term reliable use. In the future, I see increased prevalence of the GORE ACUSEAL Vascular Graft in renal failure patients requiring hemodialysis.


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Dialysis Community Collaboration: A Multidisciplinary Approach to Patient Care

Discussing the need for collaboration and communication across nephrology, vascular surgery, and interventional radiology to benefit patient care.

BY DAVID B. KINGSMORE, MD, FRCS, AND PETER C. THOMSON, MD, FRCP

There are currently 63,162 patients requiring renal replacement therapy (RRT) in the United Kingdom, of whom 22,261 (41%) are treated with hemodialysis. These figures are representative of worldwide data. For example, according to a recent report from the United States Renal Data System, there were 124,675 new patients registered with end-stage renal disease (ESRD) on hemodialysis during 2016, bringing the total to 726,331 patients with ESRD on hemodialysis; this carried an expenditure of $114 billion for 1 year. These figures are projected to rise as they have for the past 15 years. The patient population currently being treated has not only increased in number but has also increased in medical comorbidity. Transplantation has been very successful, but this has altered the dialysis population with an increasing proportion who are elderly, comorbid, and frail, alongside those who are actively waiting for a transplant (average time on the waiting list is 3 years) and those who are returning to regular dialysis following a failed transplant (average lifespan of a transplant is 10 years).

A key variable in the cost of hemodialysis is its method of delivery—vascular access. From a superficial viewpoint, provision of good vascular access should be straightforward; when hemodialysis is required, an arteriovenous fistula (AVF) should be created because it has a lower cost and requires fewer maintenance interventions than the alternatives such as tunneled central venous catheters (TCVCs) or arteriovenous grafts (AVGs). However, despite significant pressure from organizations, health care providers, professional societies, and guidelines, there remains wide variation in the proportion of patients who start and are maintained on hemodialysis through arteriovenous access. This may be because obtaining vascular access is not a simple process, as each step of the pathway has nuances, influences, preconceptions, and subtle drivers. Simply focusing on one component separate from the overall process is unlikely to lead to significant changes because competing interests and unforeseen opposing needs may minimize and negate improvements. This can be seen in the stalling of the Fistula First Breakthrough Initiative, which led to a large increase in the number of AVFs being created, but the rates of successful AVFs for regular hemodialysis remain largely unchanged.

Vascular access is a key issue in hemodialysis, as it is the main modifiable factor in determining morbidity, mortality, and costs to patients and the service. The three main methods by which vascular access is achieved have been thoroughly studied in isolation, but rarely as part of a comprehensive overall access strategy. For instance, (1) an AVF may have significant delays and failures, necessitating catheters and leading to catheter-related morbidity; (2) a TCVC may avoid unnecessary and futile surgery but carries a reasonable burden of short- and long-term morbidity; and (3) a prosthetic AVG, despite having more effective utilization, may require an enhanced surveillance program to optimize outcomes. Therefore, patients may endure myriad imaging techniques and procedures with variable rates of success. Preemptively creating a vascular access is futile in many ways: 8% of patients will die in the first year and a similar number will undergo renal transplantation, 5% will convert to peritoneal dialysis, 30% will remain in predialysis, and there is a significant proportion of patients in whom AVF creation is thwarted by primary failure to achieve a functional AVF. However, simply waiting until hemodialysis is established before creating an AVF defaults to catheter use, which can be prolonged and carry higher bacteremia rates, involve replacement
procedures for poor central venous catheter patency, and confers poorer longer-term outcomes. There is an increasing understanding that early cannulation grafts may have a larger role in providing reliable vascular access for patients in whom the alternatives have greater costs, both personally to the patient and to the wider expenses involved in providing RRT. Furthermore, as the strategic landscape behind a vascular access provision is changing, there are other factors increasingly blurring the traditional separation of surgery, radiology, and nephrology, with interventional nephrologists performing surgery and the development of endovascular techniques that allow radiologists to perform AVF creation.

THE PATIENT JOURNEY

The transition of patients from chronic kidney disease (CKD) to RRT begins with their identification and referral to nephrology services. For many patients, their CKD will have been treated, supported, and tracked through outpatient nephrology clinics for a reasonable period of time, such that when RRT is likely required in the long term, they may receive timely education on their RRT options, determine whether transplantation can be pursued, and if a period of hemodialysis is likely, the role of vascular access in facilitating the effective delivery of hemodialysis can also be explored. Some patients, however, may only be identified at the point of advanced CKD, whereby a considerable amount of clinical activity may be concentrated into a short period of time and may impact the vascular access options available for hemodialysis in the immediate term.

The progression of patients to hemodialysis is highly variable, which makes education and decision-making about the various interventions and their wide range of success and outcomes difficult. In addition, these decisions, which are difficult even for those intrinsically involved in vascular access, are often being made by sick patients who may have limited understanding of the major imminent changes, deep concerns about their immediate future, and uncertainty about their longer-term health. Helping patients with these decisions are low-clearance clinic specialist nurses, nephrologists, and—only after many clinical decisions—surgeons.

Many parts of nephrology seem opaque to those outside the field. It is not often recognized that the bulk of a nephrologist’s workload relates to the prevention and avoidance of ESRD, with hemodialysis often being a smaller part. To nonnephrologists, measures of renal function such as eGFR are often used to gauge the progression of renal failure, but the timing of hemodialysis initiation may be influenced by many more factors, including a patient’s capacity to tolerate the symptoms of uremia, as well as societal or organizational factors. When ESRD progresses toward the need for RRT, the patient pathway is unpredictable. International comparisons show not only wide variation in the eGFR at which RRT is provided between countries but also in the modality of how it is provided. For example, an AVF is the modality of use for the initiation of hemodialysis in only 20% in the United States, compared with up to 80% in some European countries. Population-derived scoring systems may help predict the need for RRT, but simply applying these to an individual patient is unlikely to make a significant impact on the overall efficacy of a vascular access provision. This variation in practice remains despite scoring systems, meetings, trials, evidence, and guidelines that all portray vascular access as a simple process. The surgical options are highly varied with technical considerations on the location and methodology of anastomosis and anesthetic techniques to facilitate it, balanced against the spectrum of advantages and disadvantages for each surgical procedure for both the short- and long-term goals of the individual patient. For example, the decision to pursue a wrist AVF rather than an elbow AVF may balance the imminent lower likelihood of success against the better longer-term patency that patients may require in the future.

APPROACHES IN DIALYSIS CARE

The Current Approach

Until recently, the basis to improve provision of vascular access has been to break down the overall aims into its component parts and fix each in isolation—a reductionist approach. This approach is best exemplified by the use of a randomized controlled trial in which one discrete intervention is isolated and improved. Although trials are an essential part of improving contemporary practice, this approach is not well suited for situations that involve many varying participants with complex interactions and interdependency that evolve over time. It is understandable that overall progress toward a unified approach and improved outcomes for vascular access seems as far away as ever with large differences between units, centers, regions, and countries; it cannot simply be that the referral patterns differ.

A Multidisciplinary Approach

A novel approach toward improving health care has been proposed based on complex-systems theory. A complex-systems approach differs from a reductionist approach in that it is dynamic rather than fixed; has many factors necessary to achieve realistic improvements; recognizes that individuals have erratic and varying progression pathways; and is able to be adaptive,
utilize opportunities, and minimize unforeseen events. Vascular access is a typical complex system because it involves multiple disciplines, including nursing, surgery, nephrology, and interventional radiology (IR), each competing for ownership of the required resources (increasing surgical input and costs may reduce nephrology bed use while reducing catheter use). It also relies on interdependency (nephrology recognizes and prescribes a treatment that is provided through surgical success), which is ongoing and requires each service to be dependent on another (losses of AV access through poor cannulation or IR intervention to maintain patency). It acknowledges that decisions often have longer-term unforeseen effects (e.g., central vein stenosis that presents years later to plague efforts at achieving AV access) that are often self-organized rather than centralized. Furthermore, the patient’s progression to requiring RRT is not easily predictable. Complex decisions about the multitude of options for vascular access are influenced and informed as much from intrinsic philosophy as robust evidence, and complex health needs often supervene planned interventions.

It is vital that an approach is taken that utilizes these separate disciplines to optimize care and focus efforts on the central key person—the patient. It is only through considering the interaction between all of the involved medical specialties, nursing teams, and the patient that significant progress will be made.

This multidisciplinary approach demands clear lines of communication between all specialties and the ability to reference all relevant elements of the patient's access history and ongoing RRT strategy. Issues must be dealt with promptly and their workup has to fit around regular dialysis schedules, as well as intercurrent illnesses and other health problems. As such, a multidisciplinary approach requires speed, efficiency, flexibility, reliability, and reproducibility.

REAL-WORLD PROGRESS

A recent national appraisal of vascular access services in Scotland highlighted the importance of clearly structured pathways for creating and maintaining access in delivering safe, effective, patient-centered care.6 The initial identification of patients predominately occurs within nephrology services. Clarification of each individual’s RRT goals, relating these to their circumstances, and initiating education and dialogue with patients and their families are required to determine their optimal vascular access solution. Thereafter, imaging specialists are often involved in the practical aspects of catheter placement or assessing the vasculature for placement of AVGs or AVFs by surgical or interventional specialists. Once established, all functioning accesses must be routinely assessed for the development of complications. This is often achieved through educating and involving patients in assessing their own access, regular appraisal of the access during dialysis treatments by nursing staff within the dialysis center, and proactive and/or reactive assessment of access problems by vascular access specialist nurses who may seek onward referral for consideration of intervention for problematic accesses by interventional radiologists or surgical specialists.

Services that established structured patient pathways found that they facilitated the successful configuration of the various health care professionals involved in the patient’s journey. This, in turn, was associated with the most successful outcomes and reported patient experiences.6

CONCLUSION

Fundamentally, improvements in the provision of efficient vascular access care in an economically challenged climate requires a shared vision, simple patient-centered principles, and flexible local care environments.


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The Value of the GORE® VIABAHN® Endoprosthesis

Reviewing the clinical, practice, and economic benefits of the GORE® VIABAHN® Endoprosthesis in treating dysfunctional arteriovenous grafts in the outpatient setting.

BY DANIEL V. PATEL, MD

Use of the GORE® VIABAHN® Endoprosthesis in our outpatient dialysis access center has transformed management of our patients with end-stage renal disease (ESRD). The performance and reliability of the device have improved the overall management of venous anastomosis lesions, and the ability to place a reliable stent graft at the venous anastomosis has enabled us to salvage arteriovenous (AV) grafts that have been abandoned. Furthermore, the ability to use the GORE VIABAHN Endoprosthesis in the outpatient setting has translated into fewer patient hospitalizations and reduced frequency of interventions in our practice. This has extended AV graft longevity and diminished catheter dependence in our patient population, which has reduced the overall cost of care to the health care system, providing both clinical and economic value in our management of vascular access in the ESRD population.

CLINICAL VALUE

Although AV fistulas are the ideal form of vascular access for ESRD patients, AV grafts continue to play a vital role in patients with anatomy unfavorable for fistula creation. In this patient cohort, the venous anastomosis remains the Achilles’ heel of graft patency, where graft failure is often attributed to aggressive stenosis and neointimal hyperplasia at the graft–vein junction.

With venous anastomosis management utilizing the GORE VIABAHN Endoprosthesis, we have seen a considerable clinical improvement in the management of these lesions. Although balloon angioplasty was once the standard of care in treating these lesions, multiple studies have shown improvement in outcomes with treatment using stent grafts at these sites.1–3

The GORE VIABAHN Endoprosthesis is a highly flexible stent graft available for dialysis access, and the Gore REVISE Clinical Study further supports superior outcomes using the GORE VIABAHN Endoprosthesis to treat stenotic and thrombosed grafts compared with balloon angioplasty.3 Additionally, the device has shown success in treating lesions across the antecubital fossa in dysfunctional forearm grafts.3 This showcases the durability of the GORE VIABAHN Endoprosthesis to maintain patency in areas of anatomic flexion and extension. These characteristics make the GORE VIABAHN Endoprosthesis a unique tool in AV access management.3

In the era of angioplasty-only management, we often encountered recurrent stenosis at the venous anastomosis. Clinically, patients experienced prolonged bleeding after cannulation needle withdrawal, decreased clearances during dialysis, limitations in blood flow through the graft, and recurrent thrombosis within the graft. This led to a high frequency of recurrent angioplasty at the venous anastomosis and manifested over time with recurrent graft thrombosis.

The failure of angioplasty alone to support prolonged venous anastomosis patency was frustrating for all those involved in the patient’s care. With the inherent nature of venous anastomosis neointimal hyperplasia and stenosis, grafts often failed despite initial surgical technical success. For interventionalists managing these patients, there was frustration with apparent recoil of angioplasty that often had a limited durability and manifested with a short-term recurrence of symptoms. Particularly frustrating were cases with successful thrombectomies that experienced rapid recoil, sometimes with rethrombosis of the graft between the time the patient left the angiography suite and when they arrived in recovery.

Nephrologists and dialysis staff face further issues in patients with thrombosed grafts. The first logistical challenge is to find an available physician to reestablish vascular access as promptly as possible. The next issue concerns the need to dialyze the patient within a reasonable amount of time. Prior to development of
dedicated outpatient centers focused on dialysis access management, delays in care and catheter placements were common.

Patients also developed frustration with recurrent graft issues, which required frequent procedures and surgical revisions. Many grafts were abandoned, leading to prolonged periods of catheter dependence. Some patients exhausted all reasonable access options, with recurrent graft failures through the extremities that led to catheter dependence and infections. With frequent procedures and recurrent failures, treatment of venous anastomosis lesions with balloon angioplasty alone was inefficient, unreliable, and costly to the health care system.

Reflecting the clinical and economic benefits of the Gore REVISE Clinical Study data, our usage of the GORE VIABAHN Endoprosthesis has reduced our frequency of recurrent venous anastomosis stenosis and thrombosis. Clinically, this has translated into a significant increase in secondary graft patency and reduced our incidence of graft failure and thrombosis. With the usage of stent grafts at the venous anastomosis, we now have a barrier to recoil and neointimal hyperplasia that allows for a more durable treatment. We have seen a significant reduction in the number of necessary surgical revisions and repeat graft placements in our ESRD patients. In extending the longevity of existing AV grafts in this complex patient population, we have reduced our dependence on catheters, femoral grafts, and MERIT® HeRO® Grafts.

For interventionalists and surgeons, this has reduced the frustrations of short-term recoil and thrombosis of AV grafts. A flexible, reliable physical barrier now exists to support patency at the venous anastomosis after angioplasty. For our patients and dialysis staff, there has been a significant reduction in missed dialysis treatments and urgent procedures to manage recurrent graft thrombosis. Overall, this has led to a significant improvement in patient and physician satisfaction.

PRACTICE VALUE

The ability to treat the venous anastomosis with the GORE VIABAHN Endoprosthesis has brought value to centers with dedicated experience in managing vascular access. In a patient population with a high morbidity and a high prevalence of vascular disease, establishing and maintaining vascular access can be challenging. For dialysis patients and their providers, the prompt and expert care of this vascular access is essential.

There has been a movement in treating these patients in specialized outpatient centers. In these settings, interventional nephrologists, interventional radiologists, and surgeons focus on vascular access management in free-standing centers. Having dedicated centers to treat dialysis access allows for rapid and focused care, reducing the burden on the traditional hospital systems. These outpatient settings further reduce the overall ESRD Medicare expenditures on vascular access, with lower costs in comparison with hospital settings. The convenience of outpatient management has helped to decrease missed outpatient dialysis treatments, where often same-day or next-day access care is available.

Expert focus on dialysis access is necessary to achieve the best patient care. The establishment and ongoing success of outpatient centers with a focus on dialysis access requires superior outcomes. Given the history of frustrations in dialysis access management, dialysis patients and referring providers tend to identify centers of excellence, where optimal outcomes and reliable care are ideal for vascular access management. These centers of excellence distinguish themselves in their attention to patient care and attract patients from a variety of dialysis units and referring providers. Reimbursement changes have continued to be a challenge in the shifting payment models in office-based labs and ambulatory surgical centers. However, as the ESRD population continues to grow, an ongoing demand for high-quality vascular access care persists.

In our practice, the evidence-based usage of the GORE VIABAHN Endoprosthesis has reduced our overall volume of graft thrombectomy cases. We prioritize thrombectomy cases over other procedures in order to return these patients back to dialysis as soon as possible. However, this disrupts scheduling and workflow within access centers. Now, with a reduced incidence of unplanned thrombectomy cases, we can better provide streamlined services in the outpatient setting. This reinforces our mission to continue to offer timely access care, while also giving us stronger results from our venous anastomosis management.

Our value to the nephrologists and dialysis units further extends into helping to reduce the rates of catheter-dependent dialysis patients. Dialysis clinics face potential financial penalties for having higher rates of catheter-dependent patients, and the clinical benefits of continued graft patency further leads a reduction in catheter volume, which reduces infection risks in the ESRD population.

CASE PRESENTATION

At times, we have been able to salvage grafts otherwise abandoned after a failure of angioplasty to restore access function. In these instances, we use the GORE VIABAHN Endoprosthesis as an endovascular bypass graft to provide
We present a 54-year-old man who has had ESRD for the past 8 years. The patient presented for vascular mapping to create a new AV access. Access options on his right arm were exhausted, with a previously failed brachiobasilic AV fistula and a failed right brachial-axillary AV graft. He recently had a left brachial-axillary 6-mm polytetrafluoroethylene (PTFE) AV graft placed, which was thrombosed at his outpatient surgical appointment 1 month after initial creation. Given the failure of the graft, vascular mapping was requested. The patient had a right internal jugular tunneled catheter in place.

Given inadequate veins and limited other access options, a potential femoral access or MERIT HeRO Graft were considered. A Doppler ultrasound evaluation of the recently thrombosed left arm AV graft revealed a venous anastomosis stenosis with thrombus through the graft. The graft was otherwise intact. An endovascular thrombectomy was attempted with the rationale that treatment of the venous anastomosis could restore the graft function.

We identified a venous anastomosis stenosis with a pullback angiogram (Figure 1). Angioplasty was performed on the venous anastomosis and to further macerate the graft thrombus using a 7-mm X 8-cm BD® VACCESS® Balloon Catheter (Figure 2). Subsequently, a 4-F EDWARDS LIFESCIENCES FOGARTY® Balloon Catheter was used to clear the arterial plug, which restored access flow. Despite flow restoration, only a weak thrill was present, secondary to ongoing chronic adherent thrombus at the venous anastomosis (Figure 3).

Given the data from the Gore REVISE Clinical Study, the decision was made to place an 8-mm X 5-cm GORE VIABAHN Endoprosthesis at the venous anastomosis stenosis to exclude the chronic thrombus from the lumen and provide a durable treatment for the thrombosed graft (Figure 4). This restored brisk flow and a strong thrill through the access. The graft was allowed to further endothelialize for 2 weeks, and then the patient underwent successful cannulation. Three weeks after thrombectomy, the dialysis catheter was removed. The patient maintained access function with no further intervention at 9 months. The GORE VIABAHN Endoprosthesis served as an endovascular PTFE bypass graft, extending the PTFE coverage from the graft and beyond the site of venous anastomosis stenosis to the patent outflow vein (Figures 5 and 6).

Of note, a venous valve was identified at the draining outflow vein. These valves may develop stenosis over time; however, to date, the graft has remained patent without access dysfunction.
In the case described, outpatient salvage of the abandoned graft resulted in significant savings to the health care system. No further surgical revision or new access surgery was required. The patient avoided associated inpatient admissions for surgery, medical consultations, and inpatient dialysis treatments. With rapid removal of the dialysis catheter, there was a reduced risk of costly catheter infections or hospitalizations.

The recently released long-term analysis of the Gore REVISE Clinical Study data further supports the economic value of the usage of the GORE VIABAHN Endoprosthesis at the venous Anastomosis of a dysfunctional and thrombosed AV graft. Although there is a higher initial upfront cost in the use of a stent graft versus a balloon angioplasty catheter, the analysis shows a reduced cost of care over 2 years given a reduction in repeat interventions when using the GORE VIABAHN Endoprosthesis. This demonstrates the durability of stent graft management. The economic value is considerable, given the size and growth of the ESRD population. For practices that take part in ESRD Seamless Care Organizations or other shared-savings models, this has significant financial ramifications.

In the case illustrated, we directly applied evidence-based data and innovative techniques to impact the care of the patient. Beyond the economic ramifications, the use of the GORE VIABAHN Endoprosthesis gave the patient the best possible outcome, resulting in provider and patient satisfaction. This approach to the management of complex patients is invaluable and can be life changing for the vulnerable ESRD population. This is the true value in patient care—achieving optimal results and reducing the frequency of interventions with the best treatment available.


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