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.²

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.² 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 due to the extremties 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...
a durable treatment for grafts abandoned for recurrent or early venous anastomosis stenosis and thrombosis.

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.
ECONOMIC VALUE

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 patent 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.