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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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 challenging 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, its 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 nonthrombotic 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 is 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 procedures 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. ■