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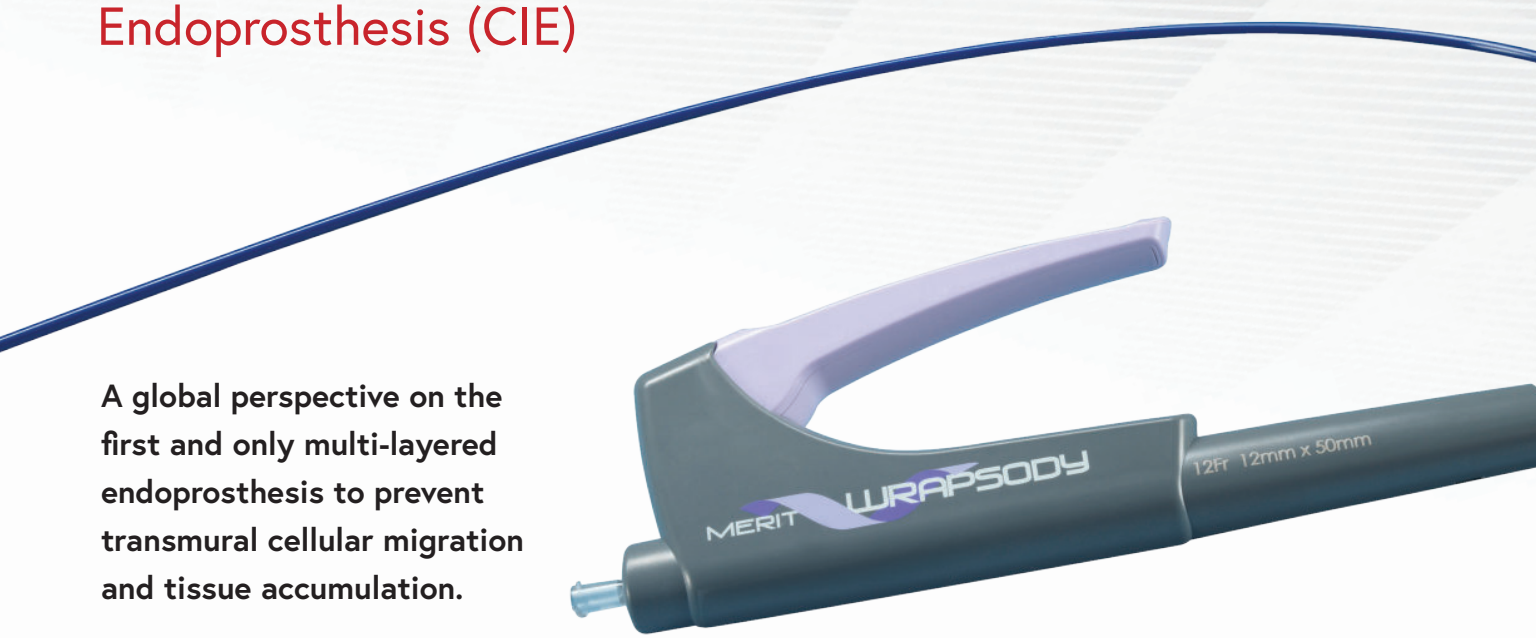
INTRODUCING THE MERIT WRAPSODY®

Cell-Impermeable Endoprosthesis (CIE)



A global perspective on the first and only multi-layered endoprosthesis to prevent transmural cellular migration and tissue accumulation.

The Evolution of Covered Stents for Hemodialysis Access

The WRAPSODY® Cell-Impermeable Endoprosthesis (CIE) addresses the shortcomings of previous covered stents, offering a durable, optimized option for treating stenosis in AVFs and AVGs.

By Bart Dolmatch, MD, FSIR

Covered stents (also called stent grafts) have become one of the mainstays for treatment of hemodialysis access stenosis, with extensive data to support their use. Since the concept of a small-vessel covered stent was published 30 years ago,[1] there have been many important covered-stent innovations that have improved outcomes for patients who rely upon hemodialysis for their survival. This is a brief review of the evolution of covered stents, from the earliest experience to advanced design concepts that are pivotal for maintaining well-functioning hemodialysis access circuits for patients with end-stage renal disease.

ORIGINS OF COVERED STENT TECHNOLOGY

The underlying problem for many hemodialysis arteriovenous (AV) circuits is development of obstruction, which is the dominant failure mode in both hemodialysis AV grafts (AVGs) and AV fistulas (AVFs). Although most of these stenoses responded well when treated with percutaneous transluminal angioplasty (PTA), restenosis is common. The use of self-expanding bare-metal stents (BMS), such as the WallStent™* Endoprosthesis (Boston Scientific Corporation) and later various nitinol stents, seemed to be an attractive adjunct to PTA, as the angiographic result after stent placement was often better than what was achieved using only PTA. However, BMS did little to improve patency due to development of in-stent restenosis (ISR) caused by ingrowth of neointimal tissue through the interstices of the bare stent (Figure 1). The concept of applying a polymeric covering on the stent to prevent ingrowth of tissue made sense, hence the early development of covered stents for the purpose of preventing ISR.

Different covering materials were considered for stents: polyethylene terephthalate (PET), often referred to as polyethylene or by the trade name Dacron®* [DuPont]); and expanded polytetrafluoroethylene (ePTFE), often referred to as Teflon®* (the Chemours Company). One of the first reports of a covered stent in hemodialysis access circuits used the PET-covered Cragg Endopro™* System I (Boston Scientific Corporation), which was available in sizes appropriate for this application. The WallGraft™* Covered Stent (Boston Scientific Corporation) was another self-expanding, PET-covered stent used in AV access. Unfortunately, these PET-covered stents developed restenosis within the body of the implants. In vivo investigations showed that stenosis within PET-covered stents was caused by an inflammatory giant cell reaction,[2-4] sometimes with clinical manifestation of inflammation. In one case, surgical removal of a Cragg Endopro System I device was required due to inflammation.[3] PET was clearly not suitable for use in AV access covered stents.

The shortcomings of PET devices led to investigations of ePTFE, which proved to be much less inflammatory than PET. The first ePTFE-covered stent designed for AV access was the Flair™* Endovascular Stent Graft (BD Interventional), specifically intended for use in AVGs at the venous anastomosis. Because of this specific application, it was only available in short lengths and limited diameters. It was also fairly inflexible due to its relatively rigid self-expanding stent. Although it was safe and significantly improved both the target lesion primary patency (TLPP) and access circuit primary patency (ACPP) compared to PTA,[5,6] it was not suitable nor tested for use in AVFs. The Fluency™* Plus Endovascular Stent Graft (BD Interventional) was studied in AVGs and central thoracic veins where a previously placed BMS developed ISR. In a randomized prospective comparison to PTA, the Fluency stent proved to be superior to PTA for treating ISR.[7] The Gore Viabahn®* Endoprosthesis (Gore &

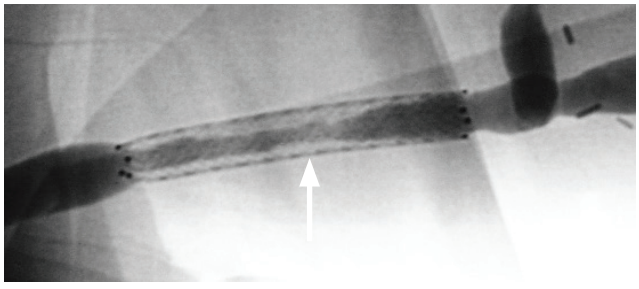


Figure 1. Diffuse ISR (white arrow) in a bare self-expanding stent placed at the venous anastomosis of an AVG.

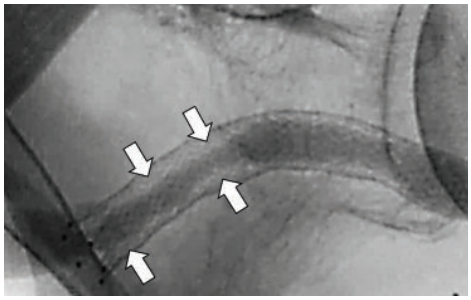


Figure 2. Diffuse ISR within an ePTFE-covered stent (white arrows) placed in the cephalic vein arch of an AVF at 8 months.

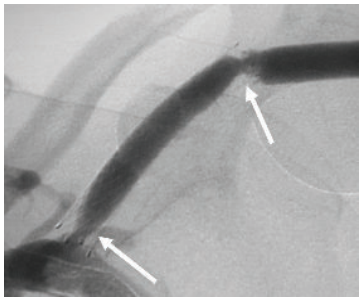


Figure 3. Classic edge stenoses (white arrows) in a covered stent placed in the cephalic vein arch of an AVF.

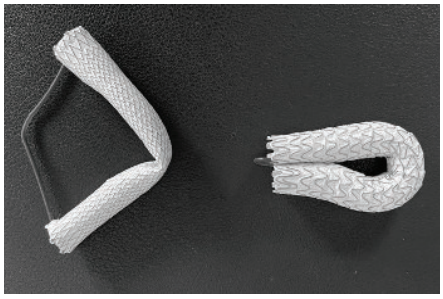


Figure 4. Benchtop demonstration showing a kinked, laser-etched, ePTFE-covered stent that kinked at 90° (left) and the wire-wound WRAPSODY CIE at 180° remaining free from kinking (right).

Associates) proved superior to PTA for treatment of AVG stenosis in both stenotic and thrombosed AVGs but has not been adequately studied in AVFs.[8]

More recently, the Covera™* Vascular Covered Stent (a newer generation of the Flair stent) used ePTFE on a flexible, laser-cut LifeStent™* (BD Interventional). Covera was studied in both AVGs and AVFs and has demonstrated superior TLPP compared to PTA.[9,10] However, ACPP for patients with AVF was not statistically better with the Covera, perhaps due to the inclusion of other stenoses in the circuit that could only be treated with PTA.[10]

Although in vivo and human clinic studies showed that ePTFE-covered stents performed well and were not inducing inflammation, the porous nature of ePTFE allowed cells to penetrate into and through the ePTFE covering. This cellular proliferation could extend into the flow lumen of the various covered stents and in some cases led to significant ISR (Figure 2). Furthermore, ePTFE-covered stents were built on self-expanding stents with the greatest degree of outward expansile force at the ends, not in the middle. This outward edge expansile force has been theorized to explain why edge stenosis is the leading cause of covered stent restenosis and failure (Figure 3).

WRAPSODY CIE: THE NEXT INNOVATION

To overcome the various limitations of ePTFE-covered stents, the WRAPSODY CIE (Merit Medical Systems, Inc.) was developed. The base stent is a wire-wound nitinol stent designed to reduce the degree of radial force at the ends of the device, with the intent of reducing edge stenosis. Greater outward expansile force was achieved throughout the body of the device to hold the treatment site open. The wire-wound stent design also afforded a greater degree of flexibility that can prevent the kink formation often seen with laser-cut, nitinol covered stents in small-radius angulations (Figure 4).

Beyond stent design, the covering of the WRAPSODY CIE has a novel structure with three bonded layers.[11] The inner-most layer, which is exposed to blood flow, is not ePTFE but rather a novel-spun PTFE (Figure 5). Compared to ePTFE, spun PTFE reduces fibrin deposition and thrombus formation without coatings or drugs.[12] The cell-impermeable middle layer prevents cells from migrating through the covering to the luminal surface, thereby preventing ISR (Figure 6). In vivo histology demonstrated that the cell-impermeable layer prevented ingrowth of tissue into the covering and inhibited formation of luminal neointima (Figure 7).[11] The outermost third layer of the covering is "typical" ePTFE, which has been shown to allow adequate healing and incorporation of the abluminal surface of the device when placed within a blood vessel.

How does the WRAPSODY CIE compare to other AV access covered stents in human clinical trials? In AVGs, it has the best patency compared to other covered stents.[13,14] In AVFs, it has demonstrated not only the highest TLPP when compared to PTA but also has shown statistically superior ACPP.[15] Circuit patency is important because prolonged circuit patency is beneficial for both the patient and the payor.

On a more technical note, the WRAPSODY CIE has a very broad range of diameters and lengths, including diameters

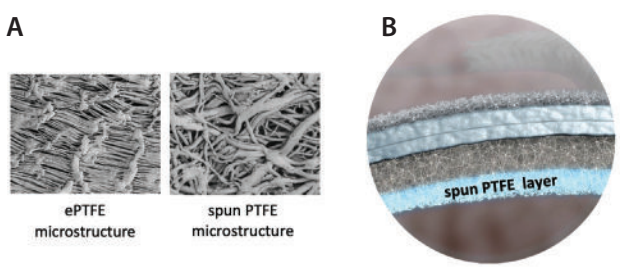


Figure 5. Micrographs of the surface of ePTFE and spun PTFE demonstrate the different microstructures (A). A graphic illustration shows the location of this inner-most spun PTFE layer in a WRAPSODY CIE (B).

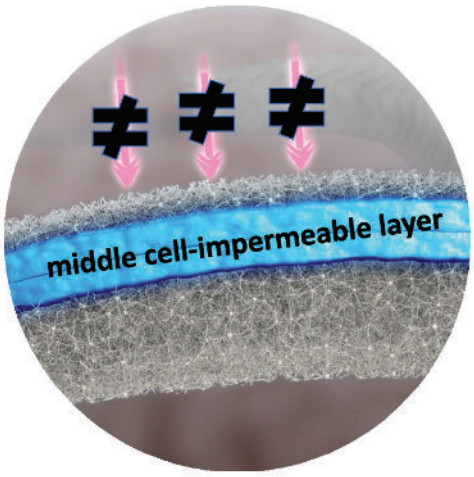


Figure 6. Graphic illustration of the middle cell-impermeable layer in the WRAPSODY CIE polymeric covering. Hatched arrows indicate that cells cannot penetrate from the adventitia through the graft covering.

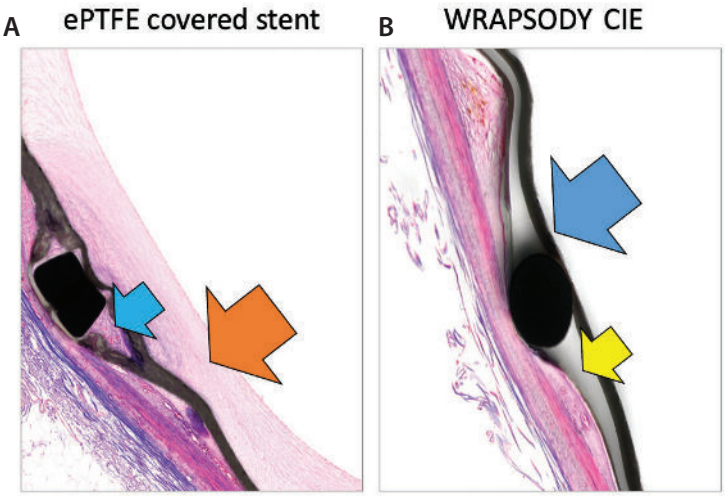


Figure 7. Healing of the WRAPSODY CIE in an ovine arterial model.[11] Histologic cross-sections of the ePTFE-covered stent demonstrate ingrowth of tissue through the graft, around the stent strut (blue arrow), and into the lumen (orange arrow) (A). The WRAPSODY CIE has a middle cell-impermeable layer (yellow arrow) that prevents luminal neointimal formation (blue arrow) (B).

from 6 mm to 16 mm. For the larger diameters (12, 14, and 16 mm), the size matrix provides lengths in 10-mm increments—for example, the 14-mm WRAPSODY CIE comes in lengths of 14 X 30, 40, 50, 60, 70, and 80 mm. It is no longer necessary to accept the sizing limitations of ePTFE-covered stents. Given the broad size matrix available, selection of an on-label covered stent for treating AV access stenosis can be based on clinical data showing superior performance in an AV access circuit, rather than on the basis of available device sizes. In this regard, the WRAPSODY CIE is well suited for treatment of nearly all AV access stenoses.

Finally, the WRAPSODY CIE delivery system allows extremely accurate placement, employing a one-handed delivery handle, a hydrophilic surface coating that facilitates ease of placement of the delivery catheter system, and easily visualized markers on the device and delivery catheter system.

CONCLUSION

Since the 1990s, a great deal has been learned about optimizing the design of covered stents for treating stenosis in AVGs and AVFs. The shortcomings of prior covered stents have been recognized. The latest device—the WRAPSODY CIE—addresses the many limitations of previous covered stents and will further improve the durability of AV access circuits for patients who require hemodialysis. ■

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Bart Dolmatch, MD, FSIR
The Palo Alto Medical Foundation
El Camino Hospital
Mountain View, California
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The Early Days of the WRAPSODY® Cell-Impermeable Endoprosthesis (CIE)

A case highlighting the efficacy and durability of the WRAPSODY CIE and an overview of how my practice utilizes it.

By Andrew Wigham, BSc(Hons), MBBS, MRCS, FRCR

The majority of our hemodialysis patient cohort consists of patients with native arteriovenous fistulas (AVFs) and arteriovenous grafts (AVGs). Access circuit stenoses are a common problem and have a significant impact on the speed and efficiency of dialysis sessions and patient quality of life. Pathophysiology is a multifactorial process, involving turbulent flow, inflammation, neointimal hyperplasia, and thrombus formation. The aims of fistula intervention should be to optimize fistula function, prevent circuit thrombosis, and minimize the number of reinterventions. We are fortunate to have an excellent surveillance program combining clinical and transonic assessment to enable early identification and intervention of access circuit stenosis, thus preventing complications.

The WRAPSODY CIE (Merit Medical Systems, Inc.) has been designed from its inception to meet the challenges of access circuit stenotic disease. It features optimized radial force and crush resistance, reduced radial force at each end of the CIE to minimize stent edge neointimal hyperplasia, a cell-impermeable middle layer to reduce cellular in-growth, and a novel-spun, inner polytetrafluoroethylene microstructure to reduce thrombosis without the addition of drugs or coatings.

We were honored to be selected as one of the centers for the WRAPSODY first-in-human (FIH) study[1] and placed the first device in the study—a proud moment for us, a momentous day for the Merit WRAPSODY team, and the culmination of many years of hard work. The FIH results were exceptional and are paving the way for significant disruption of the status quo of access circuit stenosis treatment.

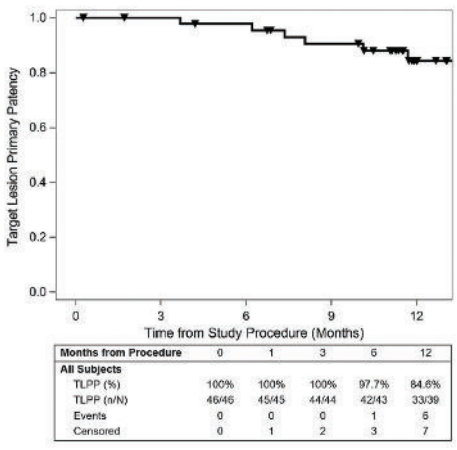


Figure 1. Kaplan-Meier curve of TLPP for all patients through 12 months. Reprinted from Gilbert J, Rai J, Kingsmore D, et al. First clinical results of the Merit WRAPSODY™ cell-impermeable endoprosthesis for treatment of access circuit stenosis in haemodialysis patients. Cardiovasc Intervent Radiol. 2021;44:1903-1913. doi: 10.1007/s00270-021-02953-8

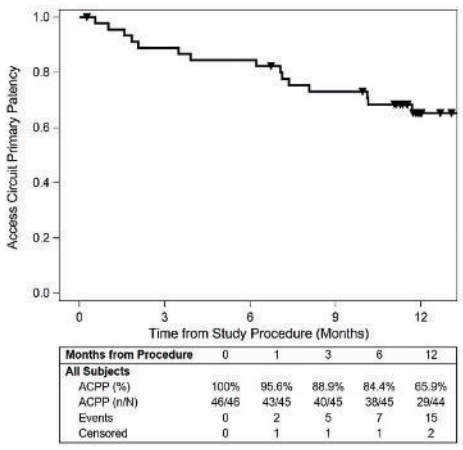
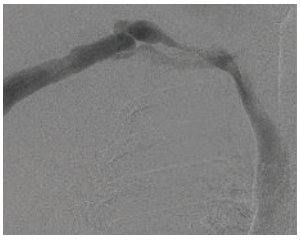


Figure 2. Kaplan-Meier curve of ACPP for all patients through 12 months. Reprinted from Gilbert J, Rai J, Kingsmore D, et al. First clinical results of the Merit WRAPSODY™ cell-impermeable endoprosthesis for treatment of access circuit stenosis in haemodialysis patients. Cardiovasc Intervent Radiol. 2021;44:1903-1913. doi: 10.1007/s00270-021-02953-8

The FIH study was performed across three centers in Europe. Forty-six patients met the eligibility criteria and were enrolled. The study cohort consisted of patients with both native AVFs and AVGs and included stenotic lesions in the cephalic arch, graft-vein anastomosis, and central veins.[1*]

All procedures were technically successful, and all but one patient were free from safety events at 30 days (97.8% [45/46]). Target lesion primary patency (TLPP) rates at 6 and 12 months were 97.7% (42/43) and 84.6% (33/39), respectively, and 6- and 12-month access

*The WRAPSODY CIE is not approved for use in central veins in the United States.



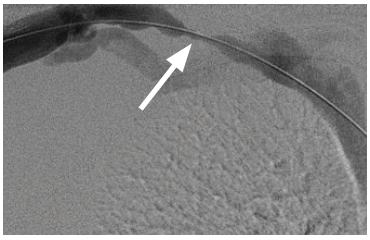


Figure 3. Repeat fistulograms showing severe residual cephalic arch stenosis (white arrow).

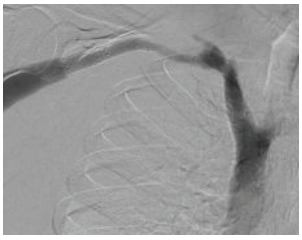


Figure 4. WRAPSODY CIE deployed.

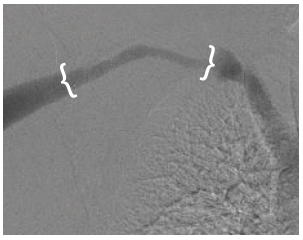


Figure 5. Fistulogram showing widely patent cephalic arch WRAPSODY CIEs 6 years after initial placement (bracket arrows).

circuit primary patency (ACPP) rates were 84.4% (38/45) and 65.9% (29/44), respectively (Figures 1 and 2).[1]

This article highlights the efficacy and durability of the WRAPSODY CIE in one of our earliest cases and describes how we incorporate it into our treatment algorithm.

CASE STUDY

The patient presented with a brachiocephalic fistula created 1 year prior and increasing venous pressures and aneurysmal fistula dilatation. A significant stenosis was identified in the cephalic arch, and the patient underwent angioplasty, which provided no benefit.

The patient was subsequently referred for repeat fistulography, which showed severe residual cephalic arch stenosis (Figure 3). This was treated with angioplasty and stenting with 8-, 10-, and 12-mm WRAPSODY CIE devices, which were deployed in a telescoped fashion to overcome inflow/outflow vessel-size discrepancy (Figure 4).

The patient has since undergone a renal transplant, which unfortunately failed, followed by replacement of native vein segments in the arm with graft material due to vein degradation. Throughout this time (6 years after initial placement), the cephalic arch venous stents have remained widely patent with no target lesion reintervention required (Figure 5).

DISCUSSION

The positive results of the WRAPSODY FIH study have been further reinforced with the recently published data from the WRAPSODY Arteriovenous Access Efficacy (WAVE) trial.[2] In the AVF cohort, patients were randomized 1:1 to treatment with the WRAPSODY CIE or percutaneous transluminal angioplasty (PTA). The 12-month TLPP and ACPP rates reported from WRAPSODY CIE were 70.1% and 58.1%, respectively, as compared with 41.6% and 34.4%, respectively, in the PTA arm.[3] These results appear to further confirm that the novel design features of the WRAPSODY CIE are translating into improved clinical performance.

In my practice, stenting with the WRAPSODY CIE has been successfully used across a range of lesion types. All AVF intervention begins with adequate lesion preparation, often in the form of high-pressure or cutting balloons to ensure the waist of the stenosis is overcome prior to stenting. AVG venous anastomoses are treated with venoplasty and primary stenting. There is good level 1 evidence that stenting in this location is appropriate.[4] In the cephalic arch, we would certainly use a stent if a suboptimal result is obtained after venoplasty or in the case of early recurrence after treatment, and we are increasingly performing primary stenting in this region.

CONCLUSION

The evidence supporting the use of the WRAPSODY CIE to treat access circuit dysfunction continues to grow, based on the early highly promising FIH study and results of the WAVE trial. Moreover, the unique features of the device appear to be translating into improved TLPP and ACPP. Real-world evidence from the WRAP Global Registry (NCT05062291) and WRAP North America Registry (NCT06807099) will continue to address the need for ongoing evidence related to the performance of the WRAPSODY CIE. ■

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Andrew Wigham, BSc(Hons), MBBS, MRCS, FRCR
Consultant Interventional Radiologist
Oxford University Hospitals NHS Foundation Trust
Oxford, Oxfordshire, United Kingdom
Disclosures: Speaking/consulting fees from Merit Medical Systems, Inc., Penumbra, Inari Medical, BD, Medtronic, and Philips Volcano.

WRAPSODY® Clinical Trial Program

A discussion of the WAVE trial's methods and insights gained, impactful results from the 6-month AVF cohort, and the unique features of the WRAPSODY Cell-Impermeable Endoprosthesis (CIE).

With moderator Dr. Dheeraj Rajan and panelists Drs. Mahmood Razavi and Robert Jones

MODERATOR
Dheeraj K. Rajan, MD, FRCPC, FSIR, FACR
Professor
Division Head, Vascular/Interventional Radiology
University of Toronto
Toronto, Ontario, Canada

Mahmood Razavi, MD
Interventional Radiologist
Vascular & Interventional Specialists of Orange County
Orange, California

Robert G. Jones, MBChB, FRCR
Consultant Interventional Radiologist
Queen Elizabeth Hospital
Birmingham, United Kingdom

Long-term vascular access remains a major determinant of morbidity and mortality for hemodialysis-dependent patients. Although percutaneous transluminal angioplasty (PTA) remains the gold standard for treating vascular stenosis—the most common cause of dysfunction—recent studies have shown that stent grafts and drug-coated balloons offer improved outcomes over PTA. However, most, if not all, of these available devices were originally designed for arterial use.

The WRAPSODY CIE (Merit Medical Systems, Inc.) is the first purpose-built device for the treatment of obstructions in the venous outflow circuit of patients with an arteriovenous fistula/graft (AVF/AVG) on hemodialysis. Key characteristics unique to the device include a cell-impermeable middle layer and a novel-spun, inner polytetrafluoroethylene (PTFE) layer. Additionally, the device has been designed with softened end rows, and higher outward radial force in the central region of the device. Although these design features are innovative, a key question is whether these characteristics translate into improved outcomes over PTA and other devices.

Results from the investigational device exemption trial provide key evidence in support of improved outcomes following use of WRAPSODY CIE. Published outcomes from the investigational device exemption, randomized controlled arm involving 245 AVF patients demonstrated superiority of the WRAPSODY CIE over PTA for both target lesion primary patency (TLPP) and access circuit primary patency (ACPP) at 6 months (89.8% vs 62.8% and 72.6% vs 57.9%, respectively).[1] At 12 months, this superiority was maintained for TLPP and ACPP (70.1% vs 41.6% and 58.1% vs 34.4%, respectively).[2] For the nonrandomized single cohort of patients with AVG obstruction, 6-month TLPP was significantly greater than the effectiveness performance goal based on benchmark stent graft outcomes (81.4% vs 60%), with publication of results forthcoming.[3] The primary safety outcomes favored the WRAPSODY CIE in the AVG cohort compared to the safety performance goal (95.4% vs 89%). In the AVF cohort, no significant differences were observed for patients treated with the WRAPSODY CIE versus PTA (96.6% vs 95%).[1]

In addition, the global postmarket approval WRAP Registry study has enrolled 450 of 500 patients to date, and the North American registry study with an enrollment population of up to 250 patients will be initiated this year. Overall, more than 1,000 patients will have had the WRAPSODY CIE device implanted within these studies, with favorable results that have been published and presented.

In this roundtable discussion, I ask Co-Global Principal Investigators Drs. Mahmood Razavi and Robert Jones to comment on the study design, endpoints, and insights gained from the WRAPSODY Arteriovenous Access Efficacy (WAVE) trial; the most impactful 6-month results observed for the AVF cohort; and the unique features of the WRAPSODY CIE.

Dr. Rajan: Dr. Razavi, as one of the Principal Investigators for the WAVE trial, tell us a little bit about the study design and key primary/secondary endpoints.

Dr. Razavi: The WAVE trial was a two-arm pivotal trial designed to assess the safety and efficacy of the WRAPSODY CIE device to treat malfunctioning

arteriovenous (AV) access in patients on hemodialysis. The first arm of WAVE was an international, prospective, multicenter, randomized trial of WRAPSODY CIE versus PTA alone to treat patients with malfunctioning AVFs due to venous outflow stenosis or occlusion. The second arm was a multicenter, single-arm cohort treating obstructions of the venous anastomosis in patients with AVGs. The safety and efficacy of the AVG cohort were compared to performance goals from prior published studies using covered stents.

The primary efficacy endpoint of the trial was TLPP at 6 months, defined as freedom from clinically driven target lesion revascularization or thrombosis. The primary safety endpoint was the proportion of patients without a local or systemic safety event affecting the access or venous outflow circuit and resulting in reintervention, hospitalization, or death within 30 days of the index procedure.

As is usual with these types of pivotal studies, a number of secondary endpoints were examined, which provided a better understanding of both the technical and clinical performance of the device. Key among these secondary endpoints was an analysis of the ACPP.

Dr. Rajan: Dr. Razavi, what did you find most impactful about the 6-month AVF study results recently published in *Kidney International*?[1]

Dr. Razavi: Management of malfunctioning AV access due to venous outflow disease in this patient population has been a challenging task. Traditional balloon angioplasty, which remains the most common intervention in such patients, has had poor outcomes, leading to multiple repeat interventions and eventual abandonment of the access site. The socioeconomic impact of this is significant and has been well documented in the literature.

Advances in interventional techniques and devices in recent years have had a meaningful impact on outcomes of all endovascular interventions, and it appears the same can be said about failing AVF.

The WAVE trial confirmed the promising results of the previously published first-in-human (FIH) study of the WRAPSODY CIE device,[4] in which use of the device was associated with a TLPP of 89.8% as compared with 62.8% observed in the PTA group with no significant difference in safety. Similarly, the 6-month ACPP was also superior to that of PTA (72.6% vs 57.9%, respectively). The positive results of the FIH and WAVE clinical studies led to the FDA approval of the WRAPSODY CIE, which is one of only two covered stents with randomized data and an FDA indication in AVF. The other FDA-approved covered stent, Covera™* Vascular Covered Stent (BD Interventional), had a 6-month TLPP of 78.7% and ACPP of 50.7% in the AVeNEW trial (Figure 1).[5]

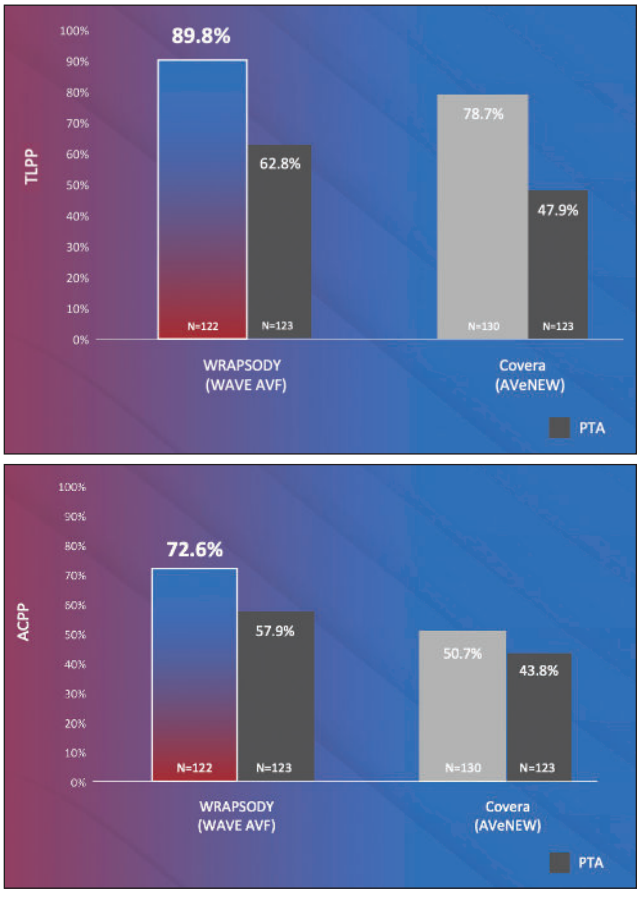

Figure 1. TLPP and ACPP rates at 6 months for WRAPSODY CIE and Covera. Note: Patency rates are defined differently; results are from different studies and may vary in head-to-head comparison, graphics are for illustrative purposes only.

Dr. Rajan: Dr. Razavi, why is ACPP so important for the dialysis access patient population?

Dr. Razavi: In the setting of clinical trials testing the outcome of medical devices, it is important to carefully control the inclusion/exclusion criteria and choose focused primary outcomes to gain a clearer understanding of performance of a new device. This is especially true in disease states where there are multiple confounding variables affecting outcome, such as malfunctioning dialysis access sites in patients on hemodialysis, which is why TLPP is the usually selected as the primary efficacy endpoint.

Beyond the arguments regarding focused primary endpoints, what is important to this patient population and the physicians caring for them is the proper functioning of the entire access circuit, not just the target lesion. Although the access circuit will likely not be usable in the absence of target lesion patency, the patency of a target lesion in absence of a functioning access circuit is

also of little relevance to these patients. Hence, one could argue that ACPP is a more clinically relevant measure than TLPP.

Dr. Rajan: Dr. Jones, as the Co-Principal Investigator for the WAVE trial, is there any interesting insight specific to the safety data collected between the WRAPSODY CIE arm and the PTA arm of the study?

Dr. Jones: First, it's important to remind ourselves that 30-day safety was a primary endpoint for the WAVE study. The data analysis demonstrated no significant difference in safety events to 30 days between the two groups (WRAPSODY CIE and PTA) in the randomized, native AVF cohort of the study. It's also important to point out that the introducer sheath size for the WRAPSODY CIE is typically 1 to 2 F size larger than is necessary for comparator devices and even more so for comparable PTA balloon catheter sizes. This is particularly true of the 14-mm and 16-mm diameter devices, which are not available from competitors. Therefore, these safety data are reassuring when considering these sheath size differences.

Dr. Rajan: Dr. Jones, what are your thoughts on the correlation between ACPP and reintervention rates from the 12-month WAVE study results? What might this mean for these patients who already spend 10+ hours in the dialysis center each week?

Dr. Jones: ACPP is arguably the more important parameter to the patient, as it reflects the number of reinterventions they require in the whole access circuit, and this in turn determines the amount of disruption to them in terms of returning to the hospital for additional procedures. The 12-month AVF outcome data demonstrated ongoing statistically superior ACPP compared to the PTA group (58.1% vs 34.4%), and 44.6% fewer reinterventions were required in the WRAPSODY CIE arm overall at 12 months (compared to PTA), which was also statistically significant.[2] No other randomized study comparing similar devices and PTA in native fistulas has shown this significant difference in ACPP at 12 months.

This finding is really of some magnitude when you consider that dialysis patients can already spend ≥ 10 hours per week on dialysis, before factoring in time for additional maintenance procedures.

Dr. Rajan: Dr. Jones, tell us more about the unique features of the WRAPSODY CIE and the correlation to excellent patency results.

Dr. Jones: The WRAPSODY CIE was designed and engineered specifically with vascular access circuit stenosis in mind. There are several unique features in the design that have undoubtedly contributed to the performance of the device in this study. Let's remind ourselves that PTFE is to some extent porous, but the WRAPSODY CIE device has a unique triple-layer design with an impermeable middle layer, which prevents cellular migration from the vessel wall into the lumen, thereby preventing in-stent restenosis. Furthermore, the novel-spun PTFE inner layer is designed to be less thrombogenic without the need for drugs or coatings.

One of the most important and impressive design features of the WRAPSODY CIE is the softened end rows at the extremities of the device. We know that edge stenosis is a common mode of failure for covered stents. These end rows were engineered to reduce vessel trauma at the interface with the normal adjacent vein wall to reduce the development of edge stenosis. With that, there is no compromise in the radial force of the main body of the device, which has optimized compression resistance. The device is also enclosed with the delivery catheter and has excellent trackability through the vessels when advancing the device to the target lesion. ■

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Disclosures

Dr. Rajan: Paid consultant to Becton Dickinson, WL Gore, and Merit Medical Systems, Inc.

Dr. Razavi: Receives consulting fee from Merit Medical Systems, Inc.; institution receives research grants from Merit Medical Systems, Inc.

Dr. Jones: Receives honorarium from Merit Medical Systems, Inc. for educational events.

WRAPSODY® WAVE Study Core Lab Findings and Health Economics

A summary of my center's experience in the WAVE pivotal trial, what makes the WRAPSODY Cell-Impermeable Endoprosthesis (CIE) unique, and the importance of access circuit primary patency in payment models and costs of arteriovenous access management.

By Saravanan Balamuthusamy, MD, FASN, FASDIN

Patency maintenance in arteriovenous (AV) access is critical for sustaining optimal dialysis to achieve adequate clearance of nitrogenous waste products and electrolytes. Although there are several implantable devices available on the market intended to sustain access patency, none of them have demonstrated benefit in improving access circuit primary patency (ACPP) compared to percutaneous transluminal angioplasty (PTA). The WRAPSODY CIE (Merit Medical Systems, Inc.) is manufactured for deployment in dysfunctional AV fistulas (AVFs) and AV grafts (AVGs) due to an obstruction in the venous outflow. Unlike stent grafts (SGs), the endoprosthesis has a middle cell-impermeable layer designed to prevent in-stent restenosis (ISR). The luminal-spun polytetrafluoroethylene (PTFE) microstructure is also unique in the WRAPSODY CIE compared to commercially available SGs.

WRAPSODY ARTERIOVENOUS ACCESS EFFICACY (WAVE) PIVOTAL TRIAL: OUR EXPERIENCE

The WAVE study is a prospective, international, multicenter trial designed to evaluate the safety and performance of the WRAPSODY CIE. Tarrant Vascular (Texas Research Institute) was one of the 43 sites that enrolled patients with AVFs and AVGs into the study. The study included two patient cohorts: those with dysfunctional AVFs and AVGs. Patients in the AVF cohort were randomized (1:1) to treatment with the WRAPSODY CIE or standard PTA.[1] All patients with dysfunctional AVGs were treated with the WRAPSODY CIE, and primary safety and efficacy endpoints were compared to performance goals based on data from prior trials at the time the study was designed. The eligibility criteria and endpoints of the WAVE trial were similar to prior published SG trials. The primary efficacy outcome was 6-month target lesion primary patency (TLPP). The primary safety endpoint was freedom from localized or systemic events through 30 days following treatment that affected the access or venous outflow circuit and resulted in reintervention, hospitalization, or death. Clinically driven target lesion revascularization or reintervention for target lesion thrombosis were attributed to the primary efficacy endpoint rather than safety. A key secondary endpoint was ACPP, which is the time to occurrence of any venous outflow reintervention, access thrombosis, or access abandonment following the index procedure. Core laboratory analysis was performed on stenotic, restenotic, and thrombotic lesions that required intervention. The CIE devices were available in diameters ranging from 6 mm to 16 mm; this enabled investigators to size the device according to the reference vessel diameter as specified in the trial protocol. Enrollment in the study was based on symptomatic AV access dysfunction that required an intervention to improve access function. Our vascular laboratory services a large population in North Texas for AV access creation and maintenance, and therefore, recruiting to the trial was accomplished

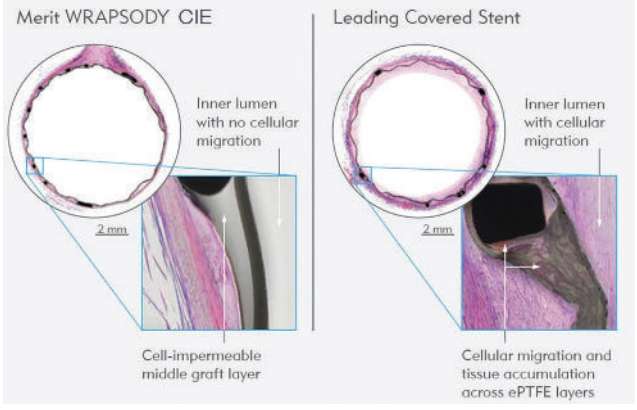

Figure 1. Histopathologic difference in endothelialization with WRAPSODY CIE and SG.

within a relatively brief period due to the unmet need for managing AV access outflow stenosis.

WHAT MAKES THE WRAPSODY CIE UNIQUE

There are four SGs available in the dialysis access market. Each is supported by robust data through randomized controlled trials, so one might question the need for additional trials. The best TLPP rate at 12 months was approximately 70%; however, no statistically significant improvements in ACPP were observed relative to PTA. As a result, the ability to reduce reinterventions and extend functionality of the AV access remains an unmet need in this patient population.[2-4] The improved technology associated with the WRAPSODY CIE was developed to help address these unmet needs. In addition to the cell-impermeable middle graft layer, the WRAPSODY CIE was designed with softer stent edges (ie, end rows), maintains high radial force in the body of the device, and offers a novel-spun PTFE luminal surface (Figure 1). The device is loaded on a coaxial delivery system with a ratchet handle that facilitates precise deployment at the target site (Figure 2).

PIVOTAL TRIAL RESULTS AND ANALYSIS

Results from the WAVE trial demonstrated statistically significant improvement associated with the WRAPSODY CIE versus PTA at 6 months for TLPP (89.8% vs 62.8%) and ACPP (72.6% vs 57.9%). These improved patency rates in the AVF cohort were maintained at 12 months, with

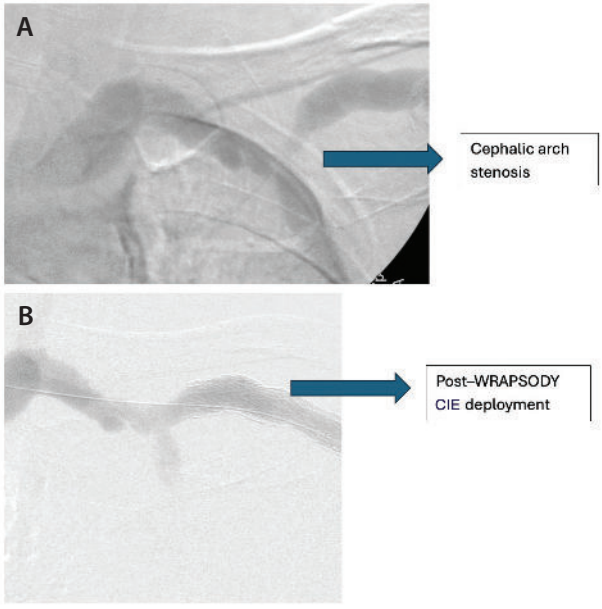

Figure 2. Cephalic arch stenosis (A) and WRAPSODY CIE deployed across a high-grade cephalic arch stenosis (B).

> "For the first time in AV access maintenance, significant improvements in ACPP are reported with an implantable device compared to PTA."

statistically significant improvement with WRAPSODY CIE versus PTA for TLPP (70.1% vs 41.6%) and ACPP (58.1% vs 34.4%).[1] For the first time in AV access maintenance, significant improvements in ACPP are reported with an implantable device compared to PTA.

Although a direct comparison was not performed between the CIE and SGs, hypotheses could be formulated based on observations from the core laboratory analysis of patients who developed target lesion or access circuit restenosis or thrombosis and required a clinically indicated reintervention. Restenosis that occurred with the CIE was different from what we have observed in SGs. Unlike prior devices, in our experience stenoses that developed following treatment with the CIE were observed outside the body of the device (Figure 3).

PAYMENT MODELS IN CHRONIC KIDNEY DISEASE AND END-STAGE RENAL DISEASE (ESRD)

Optimal dialysis vascular access care has a significant bearing not only on patient outcomes and satisfaction but also on clinical metrics and cost benchmarks needed to demonstrate success in value-based care programs. The Centers for Medicare & Medicaid Services has initiated quality initiative programs in chronic kidney disease and ESRD over the last 7 years. The recently concluded ESRD treatment choices program and the ongoing Comprehensive Kidney Care Contracting program (part of the Kidney Care Choices model) have been adopted by several nephrology practices across the country that provide care to fee-for-service Medicare beneficiaries.[5] Physician performance is measured with metrics, such as starting patients on an optimal access, initiating a home modality of renal replacement therapy, tunneled dialysis catheter avoidance, increasing transplants, and decreasing hospitalizations. Physician practices could be responsible for the cost of care if they exceed the approved benchmarks and do not meet the aforementioned quality metrics. Therefore, for practice viability, it is imperative to preserve patency of AV access as long as possible with the least number of interventions.

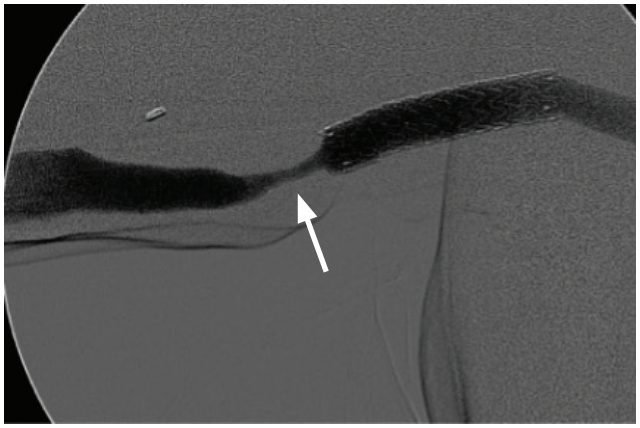

Figure 3. Core laboratory image of ISR seen with the WRAPSODY CIE. Stenosis is seen outside the CIE in the adjoining vessel (white arrow) as opposed to within the CIE body.

ECONOMIC IMPLICATIONS IN AV ACCESS

Using a hypothetical model of reinterventions based on SG trials by Dolmatch et al to analyze the total cost of AV access care in patients on dialysis,[6] with each PTA reintervention costing anywhere between $1,200 to $6,500 based on site of service, a 0.5 mean reintervention with CIE compared to 1.08 with PTA would mean a > 50% reduction in procedures. However, it should be noted that assumptions in the Dolmatch et al study were based only on TLPP, as no available data at that time demonstrated a significant result in ACPP with implantable devices.

It would be difficult to directly estimate the impact of reinterventions between the CIE and SGs, because there are no data comparing the two approaches. However, there could be an incremental cost reduction over a 12-month period on reinterventions with CIEs compared to SGs given the significant patency in the access circuit seen in 56% of patients. In our experience, AVFs have a median survival of 5 to 9 years (depending on their location), with 0.5 to 2 interventions required each year to maintain patency in most of these fistulas. Hence, reducing reinterventions over the life of an access could help reduce not only the direct procedural cost but also indirect costs associated with hospitalization due to access dysfunction. Actuarial analysis of long-term, real-world data would be needed to assess the cumulative cost impact of the WRAPSODY CIE on reintervention reductions in dysfunctional AV access compared to PTA and other SGs.

CONCLUSION

There has been a need for advancing stent technology to achieve ACPP and decrease the need for reinterventions in AV access. Reducing the number of cumulative interventions would improve patient-reported outcomes and help patients adhere to renal replacement therapy without interruption. With improvements in cardiovascular care, the overall survival of our patients has increased; thus, it is important to preserve their vascular access as long as possible with the fewest number of interventions. ■

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Saravanan Balamuthusamy, MD, FASN, FASDIN
Professor of Medicine and Nephrology
Executive Vice President, PPG Health PA
Chairman, Division of Internal Medicine
Medical City Fort Worth
Fort Worth, Texas
Disclosures: Consultant to Merit Medical Systems, Inc.

Real-World Experience With the WRAPSODY® Cell-Impermeable Endoprosthesis (CIE): Results From a Multicenter Registry in Brazil

A summary of clinical outcomes from the Vascular and Endovascular Access Society (SAVE)* patient registry in Brazil, implications for practice, and notable features of the WRAPSODY CIE that are changing the reality of dialysis management.

By Leonardo Harduin, MD, MSc, PhD

It is estimated that 10% of the global population has some degree of kidney failure.[1] In Brazil, the incidence of dialysis patients is approximately 214 per million population, and the prevalence is 758 per million population, totaling approximately 160,000 people requiring dialysis therapy.[2] According to the Brazilian Society of Nephrology, the main modality of dialysis in Brazil is hemodialysis (95%), and health care is divided into public (70%–80%) and private (20%–30%) assistance, bringing significant disparities between these systems.[2] In public health care, there are challenges in access creation and management, culminating in an elevated number of patients who depend on temporary catheters, mainly in poor regions. On the other hand, in private health care, patients usually have better management and access to new technologies. Nevertheless, over 90% of patients have hemodialysis initiated through a catheter in an emergency. These realities bring significant challenges to the physicians involved in the management of vascular access.[3]

In contrast with the United States and Europe, vascular access care is a recent development in Brazil. Until a few years ago, most patients on hemodialysis just underwent catheter implantations and arteriovenous fistula (AVF) or arteriovenous graft (AVG) creations, as there were few to no dedicated vascular surgeons or vascular centers focused on dialysis patients to perform open and endovascular procedures.[4]

SAVE GROUP

SAVE is a Portuguese acronym that stands for Vascular Access and Endovascular Symposium.* The main objective of SAVE is to create, preserve, and save dialysis access to prolong the life of patients with chronic kidney disease in Latin America.

Currently, the SAVE group is a reference for vascular access care, research, and professional training in Latin America. Over the last few years, the group has performed hands-on training, created courses, contributed to the Brazilian vascular access guidelines,[4] and planned six international symposia. This year, the 6th annual SAVE Symposium took place in São Paulo City, Brazil, with more than 600 attendees, including 15 international speakers.

SAVE REGISTRY

Contributing to best practices in vascular access care, the SAVE group has been involved with the development of new technologies, the Brazilian vascular access guidelines, and research programs, such as the WRAPSODY Arteriovenous Access Efficacy (WAVE) trial and the global WRAPSODY (WRAP) Registry.[4-6]

Recently, the SAVE group published clinical outcomes from its SAVE Registry, which is evaluating real-world outcomes following use of the WRAPSODY CIE (Merit Medical Systems, Inc.) in the treatment of vascular access outflow stenosis.[7] Stenosis in the outflow of the access circuit is an important cause of AVF/AVG dysfunction, thrombosis, and abandonment of the vascular access, mainly in upper-arm AVFs and AVGs, that negatively impacts the quality of life for patients on hemodialysis. The first-in-human clinical trial on the WRAPSODY CIE provided evidence regarding various benefits associated with the use of the device in outflow lesions, chiefly high target lesion primary patency (TLPP) rates and access circuit primary patency (ACPP) rates.[8] However, understanding how the WRAPSODY CIE performs outside of the clinical trial setting is key. Results from the SAVE Registry address this knowledge gap by describing the device's safety and effectiveness in real-world practice.

Outcome Measures and Results

The SAVE Registry was a retrospective, multicenter, single-arm analysis of 113 hemodialysis patients with clinically dysfunctional

*The SAVE Group was created by Drs. Leonardo Harduin, Thiago Barroso, Leonardo Cortizo, and Márcio Filippo.

TABLE 1. CHARACTERISTICS OF PATIENT DIALYSIS ACCESS CIRCUITS AND STENOSIS (N = 113)

Variable		n	%
Arteriovenous access	Brachiocephalic	41	36.3
	Basilic transposition	25	22.1
	Arteriovenous graft	38	33.6
	Radiocephalic	5	4.4
	Other	4	3.6
Stenosis type	Cephalic arch	20	17.7
	Swing point	15	13.3
	Venous anastomosis	25	22.1
	Central venous stenosis	33	29.2
	Outflow	20	17.7

Reprinted from Harduin LO, Barroso TA, Guerra JB, et al. Safety and performance of a cell-impermeable endoprosthesis for hemodialysis vascular access outflow stenosis: a Brazilian multicenter retrospective study. Cardiovasc Intervent Radiol. 2024;47:1057-1065. doi: 10.1007/s00270-024-03790-1

AVFs and AVGs due to significant outflow obstruction or occlusion, treated with the WRAPSODY CIE. The primary study outcome measure was the TLPP rate at 12 months and 30-day safety performance. Additional endpoints evaluated were ACPP, target lesion secondary patency, technical success (ie, successful device deployment), and procedural success (< 30% restenosis following the procedures and resolution of clinical indicators of dysfunction). Among the patients analyzed, 34% presented with recurrent lesions, and 35% had thrombosis at the initial presentation. The types of stenoses treated were 33 central venous lesions,† 25 venous graft anastomosis stenoses, 20 cephalic arch obstructions, 20 stenoses in the venous outflow, and 15 basilic swing point lesions (Table 1).[7] During the follow-up period, all patients were evaluated at 1, 3, 6, and 12 months. All patients experienced technical and procedural success. TLPP and ACPP at 6 and 12 months were 86% and 70% and 71% and 56%, respectively (Figure 1).[7] Considering that this study included real-world patients with thrombosis and challenging lesions, these results are encouraging. Although results cannot be directly compared, the patency rates reported were higher than studies evaluating prior-generation stent grafts (SGs).[9-11]

IMPLICATIONS FOR CLINICAL PRACTICE

Stenosis along the vascular access circuit can be caused by different pathophysiologies, and response to treatment may differ. In general, vascular access stenosis can occur due to multiple factors, including intimal hyperplasia, fibrosis, ischemia, torsions, valves, external compression, and turbulence/high flow. These factors can present in combination as a cause of vascular access obstruction, making the choice for treatment challenging. This fact provides a better understanding as to why stenoses in the vascular access circuit, such as cephalic arch stenosis, basilic swing point lesions, and venous graft anastomosis stenosis, demonstrate variable results after endovascular treatment.

The SAVE Registry evaluated TLPP rates according to the location of stenosis. Across the segments, TLPP rates at 12 months in the outflow segment, basilic swing point lesions, cephalic arch stenosis, and venous graft anastomosis stenosis were 89%, 75%, 63%, and 45%, respectively. Notably,

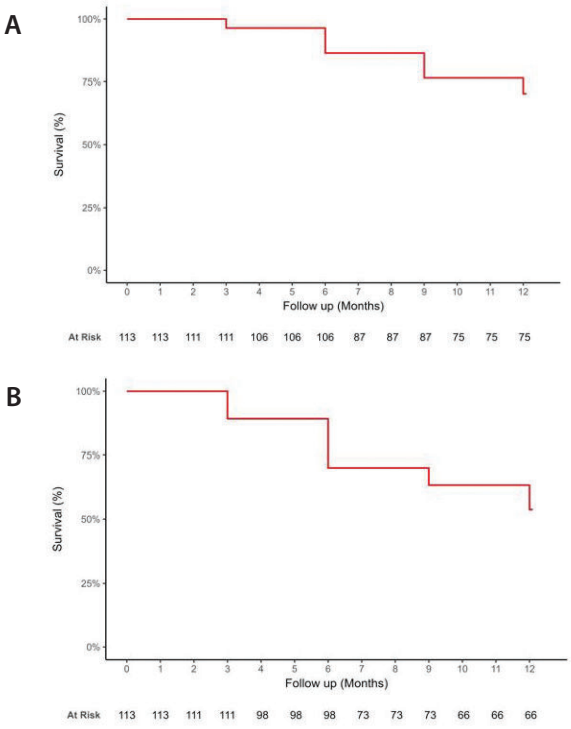

Figure 1. TLPP rate at 12 months (A). ACPP rate at 12 months (B). Reprinted from Harduin LO, Barroso TA, Guerra JB, et al. Safety and performance of a cell-impermeable endoprosthesis for hemodialysis vascular access outflow stenosis: a Brazilian multicenter retrospective study. Cardiovasc Intervent Radiol. 2024;47:1057-1065. doi: 10.1007/s00270-024-03790-1

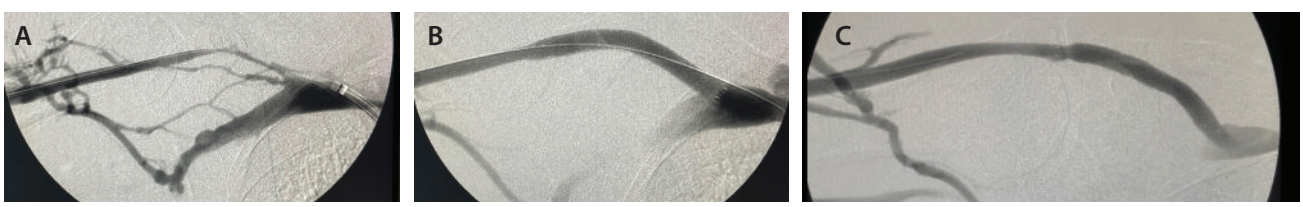

Figure 2. Cephalic arch stenosis (A). After deployment of an 8-mm X 75-mm WRAPSODY CIE (B). Angiography 24 months later showing minimal intimal hyperplasia (C).

†The WRAPSODY CIE is not approved for use in central veins in the United States.

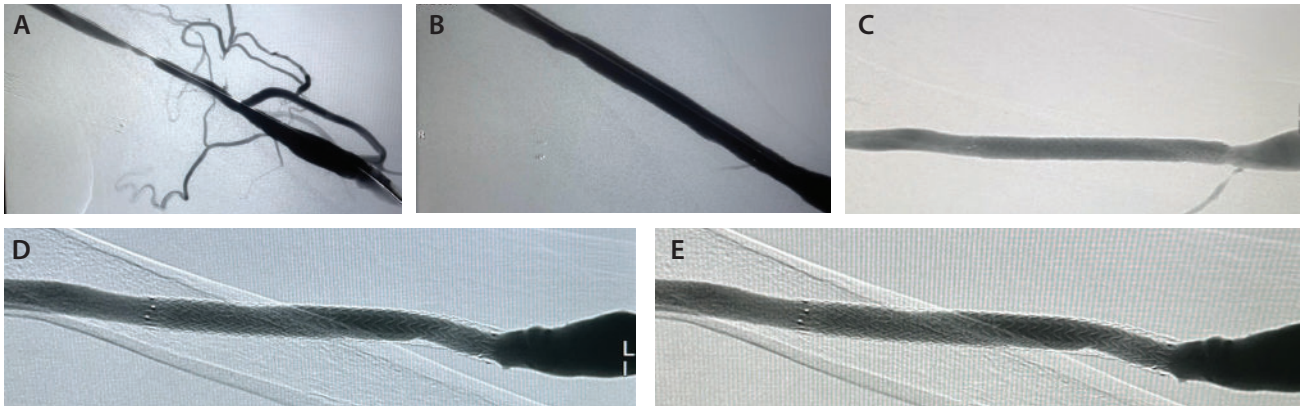

Figure 3. Stenosis in the cephalic vein after the cannulation zone (A). After deployment of a 9-mm X 100-mm WRAPSODY CIE (B). Angiography 12 months later without restenosis (C). Angiography at 30-month follow-up (D, E).

the 12-month TLPP rate at the basilic swing point segment after treatment with the WRAPSODY CIE was considerably higher than patencies following other endovascular treatment options (eg, SGs, drug-coated balloons).[12,13] Performance at the cephalic arch also demonstrated interesting results, with at least 25% improvement in the 6-month TLPP rate compared to rates reported with other SGs.[14,15]

ACPP is considered an important indicator of effectiveness of an endovascular intervention in vascular access. Improvements in ACPP are associated with a lower number of interventions to maintain patency of the access circuit and thus more cost-effective in dialysis care. Previous studies of covered stents noted ACPP rates ranging from 28% to 42%.[10,11,15] These results were lower than the 56% ACPP rates described in the SAVE Registry at 12 months. Recently, Razavi et al published the 6-month results from the WAVE trial and described a very similar performance compared to the data published by the SAVE group, supporting the improvement in vascular access survival with use of the WRAPSODY CIE.[5,7] The clinical benefits of the WRAPSODY CIE in all the segments, considering both TLPP and ACPP rates, suggest that the WRAPSODY CIE may be considered a safe and durable option in the treatment of outflow disorders (Figures 2 and 3).

NOTABLE FEATURES OF THE WRAPSODY CIE

The WRAPSODY CIE prolongs functionality of vascular access because of two notable design features. First, the device produces a reduced radial force on both edges, resulting in less trauma on the vessel wall and thereby reducing the intimal hyperplasia and restenosis in this segment. Another important feature is the middle cell-impermeable graft layer designed to prevent transmural cellular migration and avoid stenosis within the lumen of the device.[16]

CONCLUSION

Based on these encouraging data and new design features, an increasing number of physicians have been adopting the WRAPSODY CIE as their first choice in the treatment of vascular access outflow stenosis since 2021, when the device was launched in Brazil. This trend is improving the reality for hemodialysis patients in our country—reinterventions, thrombosis, and catheter dependence are decreasing, bringing a better quality of life for this population. ■

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Leonardo Harduin, MD, MSc, PhD
Vascular Surgeon, LIVCARE Access Center
Rio de Janeiro, Brazil
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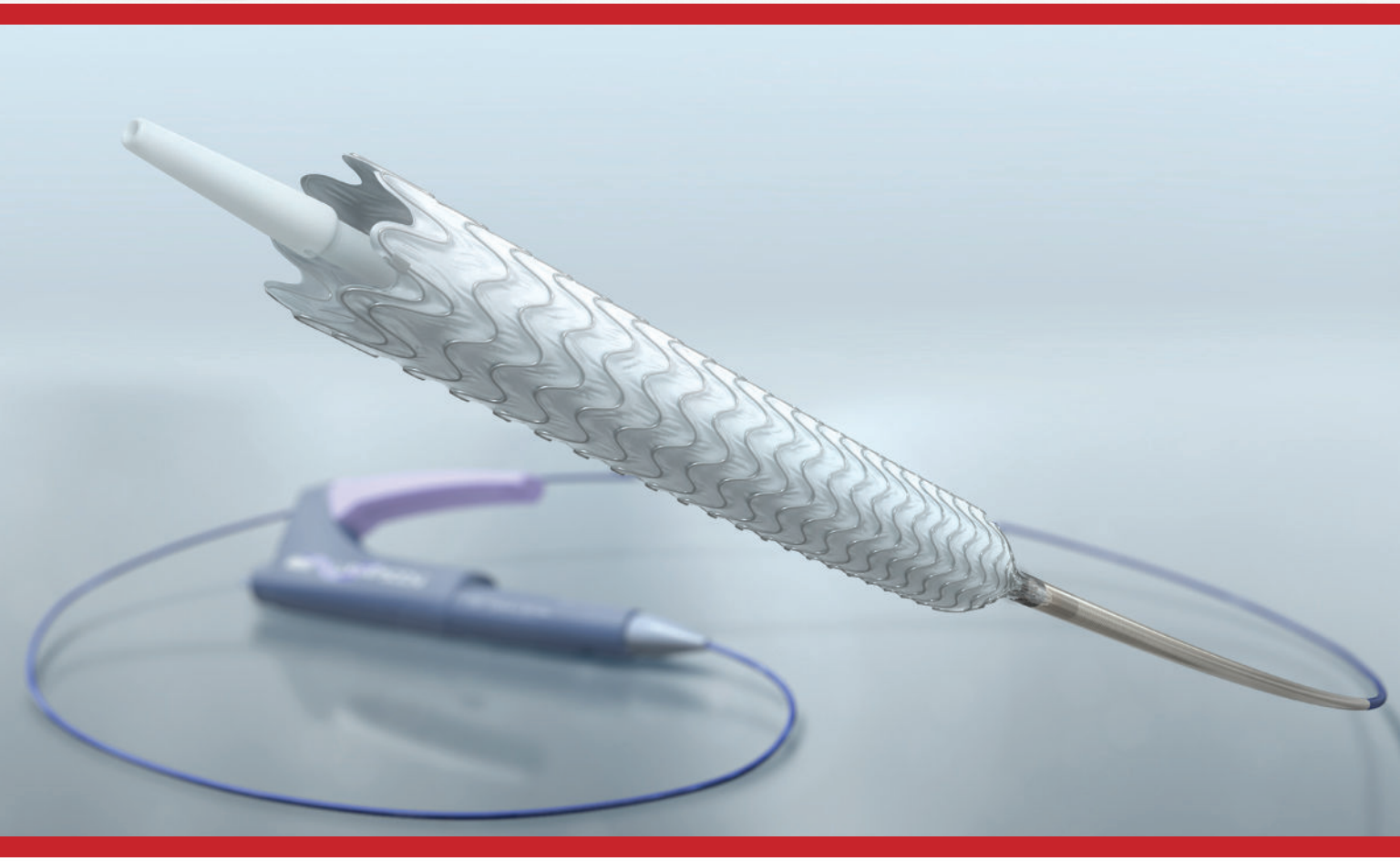

Before using refer to Instructions for Use for indications, contraindications, warnings, precautions, and directions for use.

The Merit WRAPSODY® Cell-Impermeable Endoprosthesis (CIE) is a flexible, self-expanding endoprosthesis indicated for use in hemodialysis patients for the treatment of stenosis or occlusion within the dialysis access outflow circuit, including stenosis or occlusion:

- in the peripheral veins of individuals with an arteriovenous fistula (AVF),
- and/or at the venous anastomosis of a synthetic arteriovenous graft (AVG).