

How Do Emerging Technologies in AV Access Fit Within the Current Economic Climate of Your Practice?

A discussion of the economic benefit of drug-coated balloons and covered stents and the current economic challenges of treating AV access patients.

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Vascular access in hemodialysis patients is regarded as a critical determinant of morbidity and mortality. Studies have shown that native arteriovenous fistulas (AVFs) are associated with better survival, fewer occurrences of mechanical and infectious complications, longer patency, and reduced health care costs compared with AV grafts (AVGs).¹⁻⁴ Both options are better than central venous catheters.

The main cause of AVF or AVG dysfunction is the development of stenoses that lead to reduced blood flow, which may reduce the quality/efficacy of hemodialysis.⁵⁻⁷ If untreated, stenoses could progress and lead to thrombosis and possible access circuit abandonment, with high associated economic burden. The basic management of vascular access stenoses is percutaneous transluminal angioplasty (PTA) with or without stenting. For the last few decades, the standard of care for stenoses has been considered to be PTA alone^{8,9}; however, keep in mind that long-term patency is limited, and reinterventions to maintain patency are common.

A randomized controlled trial evaluated the safety and efficacy of the LUTONIX® 035 Drug Coated Balloon (DCB) PTA Catheter (BD) versus PTA alone in treating stenotic lesions of AVFs. The LUTONIX® 035 DCB showed

a prolonged reintervention-free interval of 114 more days at 24 months than standard PTA,¹⁰ resulting in a relevant benefit for patients with end-stage renal disease who receive hemodialysis. This is strongly supported by the Lutonix Global AV registry with 73.5% target lesion primary patency and 70.9% access circuit primary patency at 6 months.¹¹ In addition, an economic model (developed from a United States payer perspective based on 12-month reintervention rates from the Lutonix AV trial) predicted that the LUTONIX® 035 DCB would be cost-effective in the first year, with a reasonable incremental cost savings of \$661 per patient compared with PTA.¹²

In my practice (in the German health care system), DCB devices are still reimbursed, which makes sense because it benefits the patients; but there is an ongoing discussion with health insurance companies/payers because general reimbursement of DCBs in AV access would lead to widespread use in hemodialysis patients.

Due to the obvious benefits of DCB in AVF stenoses, de novo lesions in hemodialysis patients at our vascular center are primarily treated with DCBs, because PTA alone is known as a strong risk factor for restenosis.^{13,14} The potential lack of reimbursement in different national health care systems could be a hindrance for DCBs, depending on the structure of their specific reimbursement models.

Situations with elastic recoil in AVF/AVG stenoses cannot be addressed by a DCB. Therefore, the approach of a “nothing left behind” strategy must be modified in those patients. Although not indicated for use, bare-metal stents (BMSs) have been used to treat AVF/AVG stenoses despite the inconsistent results in observational studies and absence of randomized controlled trials.¹⁵⁻¹⁷ In-stent restenosis with BMSs will limit long-term patency as well.^{18,19} To overcome limitations associated

with PTA and BMSs, stent grafts are a strong option to inhibit restenosis and reestablish a functional AVF. The COVERA™ Vascular Covered Stent (BD) showed superior primary patency when compared with standard PTA at 6 months in AVeNEW, the first level 1 clinical trial on the use of a covered stent in AVFs.²⁰ In the covered stent group, primary patency was 78.7% versus 47.9% in the angioplasty group. This is a difference of > 30% at 6 months, with a highly significant *P* value at < .001 according to Kaplan-Meier analysis. This is consistent with our clinical experience using the COVERA™ Vascular Covered Stent in our daily routine since 2016. Fortunately, the German diagnosis-related group systems have covered the additional expenses until now, allowing a patient-optimized therapy strategy. An economic model published by Dolmatch et al in 2018 predicted that an increased use of stent grafts for treatment of AVG anastomotic stenosis and AVF/AVG in-stent restenosis can be economically favorable, while providing improved patient care through reduced reinterventions.²¹

I believe that incorporating DCB and stent graft technology, with their proven extension of intervention-free intervals, will change the way we care for patients with AV access dysfunction.

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Despite significant enthusiasm for payment reform over the last 5 years, there has been little practical change to the way most providers of AV access care receive reimbursement (ie, fee for service [FFS]). Few private payers have adopted alternative payment methods (APMs) for care that impact vascular access for hemodialysis. However, cuts have been made to providers based on the site of service, with significant reductions to reimbursement for vascular access maintenance procedures performed in an office-based setting but increases in reimbursement for those same procedures performed in ambulatory surgery centers over the last 2 years.¹ This "shell game" of reimbursement precipitated by the Centers for Medicare &

Medicaid Services makes it incredibly difficult for practices to manage their AV access business. The recent trend of either closing office-based facilities or converting them to ambulatory surgery centers will likely continue until the next round of fee adjustments comes from the Centers for Medicare & Medicaid Services, which will then prompt the appropriate compensatory response from access providers in order to remain profitable.

If a provider performs all of their vascular access procedures at a hospital, then these regular adjustments to reimbursement in the ambulatory setting will likely have less impact on your practice. This has been my situation, and because none of my payer contracts involve APMs, my incentive to reduce interventions and maximize longevity of treatments has been motivated only by my commitment to quality care and not mandated through economic pressure. It is important to point out, however, that a FFS payment model rewards volume of care, not value—providers are compensated every time the patient requires an intervention, controlled only by global billing policies and not by clinical outcomes, as would be the case with APMs and other value-based payment models.

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A different way for providers to think about the business side of FFS is that, ultimately, we are consuming a limited resource, and despite economic pressure to the contrary, each provider needs to conserve the resources for the future, including care that they themselves may need.

Given those provisos, any treatment for AV access maintenance that reasonably prolongs uninterrupted use of the access and is not prohibitively expensive has a role in my practice. The LUTONIX® 035 DCB PTA Catheter is one device that fills these criteria. Not only did the balloon provide a 31% improvement in primary patency at 12 months compared with plain old balloon angioplasty, but the improvement in time to first intervention of nearly 2 months translates into a savings per patient of around \$600.² This savings does not include the cost of missed dialysis occurring with failure after plain old balloon angioplasty.

In the ambulatory care environment, particularly settings owned and managed by physicians, incremental device-related cost increases directly and negatively affect profit margin.³ The answer to these economic challenges in AV access maintenance may ultimately

be found in the outcomes of end-stage renal disease seamless care organizations (ESCOs). ESCOs currently provide coordinated care for patients in renal failure and are a form of APM whereby the integrated network is at risk for the cost of the care it provides.³ Cost savings appreciated by the ESCO realized over time will be shared with the provider network as will economic losses. More successful treatment decisions will translate into lower resource utilization and, therefore, cost savings. ESCOs are an example of a payment model that requires providers to consider long-term effects of treatment and device costs in their treatment algorithms, because they are financially at risk for treatment failures and subsequent resource utilization associated with reinterventions.³ This is in stark contrast to FFS whereby providers have little to no financial risk associated with treatment outcomes.

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Historically, the standard of care for hemodialysis vascular access stenosis has been PTA, but long-term vessel patency has been limited by elastic recoil and the formation of neointimal hyperplasia.¹⁻⁴ Post-PTA use of BMSs lacks FDA approval and has limited effectiveness due to development of in-stent restenosis (ISR).⁴⁻⁷ To overcome limitations of PTA and BMSs, recent treatment options have grown to DCBs and covered stents (also known as stent grafts). Now with a wide body of clinical evidence, covered stents are an attractive, FDA-approved adjunct to PTA that improve clinical outcomes. The nitinol scaffold in a covered stent prevents elastic recoil, and the expanded polytetrafluoroethylene (ePTFE) coating limits neointimal hyperplasia and ISR.^{4,8-10} Although clinical and biologic benefits are paramount to the patient, the current health care landscape requires providers and payers to carefully balance benefits with costs when treating hemodialysis

vascular access circuits, especially with advanced technologies such as covered stents.

To effectively manage outcomes and costs, the right product must be used. BD offers a range of covered stents for use in dysfunctional hemodialysis circuits. The FLAIR® Endovascular Stent Graft was the first ePTFE-covered stent to receive FDA approval for the treatment of vascular access stenosis in AVGs.⁵ The FLAIR® Endovascular Stent Graft is being replaced by the COVERA™ Vascular Covered Stent, which builds on a more flexible stent architecture suitable for use within tortuous vessel segments of the venous outflow. The COVERA™ Vascular Covered Stent is the first ePTFE-covered stent to receive FDA approval for the treatment of stenosis in nonstented AVFs.¹¹ The FLUENCY® PLUS Endovascular Stent Graft is available for treatment of ISR occurring in AVFs, AVGs, and central veins and has an additional indication to treat nonstented venous outflow stenosis in AVGs.¹²

The efficacy and safety of the FLAIR® Endovascular Stent Graft, the COVERA™ Vascular Covered Stent, and the FLUENCY® PLUS Endovascular Stent Graft are well supported by several clinical trials. The FLAIR® Endovascular Stent Graft was evaluated in the PIVOTAL Study and the RENOVA trial for treatment of AVG stenosis. It demonstrated significantly higher primary patency* compared with PTA through 24 months.¹³⁻¹⁵ The COVERA™ Vascular Covered

Stent was also studied in AVG stenosis in the AVEVA trial and demonstrated a primary patency[†] of 71% at 6 months.¹¹ In patients with AVF stenosis, the COVERA™ Vascular Covered Stent showed a significantly higher primary patency[‡] compared with PTA at 6 and 12 months in the AVEVEW trial.¹¹ For treatment of ISR within AVGs, AVFs, or central veins, the FLUENCY® PLUS Endovascular Stent Graft was evaluated in the RESCUE trial and exhibited significantly higher primary patency[§] compared with PTA at 6 months.^{12,16}

In addition to providing improved clinical outcomes compared with PTA, the use of covered stents may have important economic benefits to both payers (eg, Medicare) and points of care (POC) (eg, hospitals and freestanding outpatient centers) due to reduced resource use over 2 years.¹⁷ To highlight this, we recently conducted an economic analysis evaluating the impact of increasing the adoption of covered stents in clinical practice for treatment of AVG stenosis and AVF/AVG ISR from two different United States stakeholder perspectives. Our results highlighted the change in costs between the real-world mix of treatments for vascular access stenosis (88.9% PTA, 5.5% BMS, and 5.5% covered stents, as measured in 2016) to two different projected future treatment mixes where use of covered stents was increased for a hypothetical cohort of 1,000 patients. In the first projected scenario, the amount of PTA remained fixed, with the increased adoption of covered stents resulting from decreased BMS use (88.9% PTA, 2.8% BMS, 8.3% covered stents). In the second projected scenario, the use of covered stents and PTA were assumed to increase, resulting in further decreases in BMS use (90.3% PTA, 1.4% BMS, 8.3% covered stents). This assumption was supported by clinical trial data that found that use of covered stents resulted in reduced stenting relative to PTA reinterventions.¹⁷

The primary outcomes of our analyses were the costs associated with the index procedure and reinterventions over 2 years. These costs varied by stakeholder perspective (ie, POC or payers). The POC analyses considered the device costs for the index procedure and reinterventions. For the payer analyses, costs for the index procedure and reinterventions were based on 2017 Medicare reimbursement payments for procedures performed in physician office-based labs, ambulatory surgery centers, and hospital outpatient centers.¹⁷

To inform our reintervention outcomes, we used data from the RENOVA and RESCUE trials for AVG stenosis and AVF/AVG ISR, respectively. These outcomes included reintervention rates at 2 years and the breakdown of reintervention treatments after covered stent and PTA index procedures. Due to a lack of randomized evidence for currently used BMSs in hemodialysis vascular access and no definitive observational evidence supporting the use of BMSs over PTA for the treatment of AVG stenosis at 6 to 12 months, the clinical outcomes for BMSs were assumed to be equivalent to PTA.¹⁷

From a POC perspective, results of the AVG stenosis population predicted cost savings, with reduced overall spending on devices over 2 years ranging from \$4,106 to \$34,420 per 1,000 patients. In the AVF/AVG ISR population, the incremental results over 2 years ranged from an additional cost of \$17,187 to potential cost savings of \$13,159 per 1,000 patients, depending on the breakdown of interventions in the two projected scenarios. From Medicare's perspective, the two projected scenarios anticipated costs savings for the AVG stenosis and AVF/AVG ISR populations over 2 years. The predicted reduction in total Medicare payments per 1,000 patients ranged from \$57,401 in the AVG/AVF ISR population to \$169,544 in the AVG stenosis population, depending on the projected treatment mix.¹⁷

The projected economic advantages of covered stents demonstrated in our analyses are primarily driven by two factors. First, covered stents have been shown to reduce reinterventions over 2 years compared with PTA. In the RENOVA trial, use of the FLAIR® Endovascular Stent Graft resulted in less frequent reinterventions over 24 months compared with PTA (3.4 vs 4.3, respectively).¹⁵ In the RESCUE trial, use of the FLUENCY® PLUS Endovascular Stent Graft also led to less frequent reinterventions over 24 months compared with PTA (5 vs 5.5, respectively).^{12,16} In the AVEVEW trial, use of the COVERA™ Vascular Covered Stent in AVF stenosis reduced the risk of clinically driven reintervention at the target lesion by 68%[¶] and decreased the average number of reinterventions at the target lesion and AV access circuit at 12 months compared with PTA.^{||}¹¹

The second benefit with covered stents is the anticipated reduced cost of reinterventions due to less postprocedural stenting. In the RENOVA and RESCUE clinical trials, a larger proportion of reinterventions after

*Primary patency in the FLAIR pivotal study (n = 190) was defined as treatment area primary patency and was significantly greater for the FLAIR® Endovascular Stent Graft compared with PTA (51% vs 23%, respectively; *P* < .001).

†Primary patency in the AVEVA trial (n = 110) was defined as 6-month target lesion primary patency.

‡Primary patency in the AVEVEW trial (n = 280) was defined as 6-month target lesion primary patency and was significantly greater for the COVERA™ Vascular Covered Stent compared with PTA at 6 months (78.7% vs 47.9%, respectively; *P* < .001) and 12 months (57.5% vs 21.2%, respectively; *P* < .001).

§Primary patency in the RESCUE trial (n = 275) was defined as 6-month access circuit primary patency and was significantly greater for the FLUENCY® PLUS Endovascular Stent Graft compared with PTA (18.6% vs 4.5%, respectively; *P* < .001).

¶Reduction in risk of clinically driven reintervention at the target lesion with the COVERA™ Vascular Covered Stent measured as a hazard ratio (0.322; 95% confidence interval, 0.207–0.503; one-sided *P* < .001).

||Mean number of AV access circuit reinterventions at 12 months with the COVERA™ Vascular Covered Stent and PTA were 1.74 and 2.10, respectively. Mean number of target lesion reinterventions at 12 months with the COVERA™ Vascular Covered Stent and PTA were 0.76 and 1.71, respectively.

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covered stent treatment were PTA, whereas patients with an index PTA treatment had a greater proportion of reinterventions using stents (both BMSs and covered stents).^{12-14,16} The difference in distribution of reintervention treatments compounds the economic benefits of covered stents, as the lower rate and reduced costs can offset the increased device costs of index procedure.

With recent shifts in the health care landscape, clinical and economic outcomes for the treatment of vascular access stenosis are becoming increasingly important to both payers and hospitals, making the use of covered stents an attractive option. From a payer perspective, the push to reduce costs and maintain clinical outcomes makes the use of covered stents an attractive treatment option compared with historical methods. From a hospital perspective, when moving beyond a traditional FFS model into more value-based global payment systems, the total costs of care—rather than just device/consumable costs—become very relevant because every patient reintervention does not necessarily translate into a separate reimbursement payment by payers. With the increasing shift away from volume-based FFS systems, evidence about strategies that provide the greatest clinical and economic benefit is critical to allow hospitals to remain competitive.¹⁷ In these situations, cost analyses such as ours can be effective tools in helping physicians and other health care stakeholders make decisions that involve trade-offs between benefits and costs. ■

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