

# A Roundtable on Chronic Dialysis

What are your options for patients with limited access availability?  
A multispecialty panel weighs in.

## PANEL



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## How do today's chronic dialysis interventionists handle the dilemma posed by the fact that some of the devices used in this population are not intended for long-term use?

**Dr. Dolmatch:** When considering long-term use, it is important to appreciate that unlike most other vascular reconstructions, the primary patency of arteriovenous (AV) access is measured in months, and the cumulative patency is rarely more than several years. Additionally, it is the sad reality that hemodialysis patients have compromised life expectancies compared to patients with normal renal function. Therefore, the concept of *long-term* is much shorter for end-stage renal disease (ESRD) patients with AV access than for patients who are treated with AAA endografts or SFA stents.

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—Dr. Davidson

As for device usage, remember that we still primarily use angioplasty, which leaves nothing behind. Stents, although not approved for peripheral AV access indications, are used for bailout of suboptimal angioplasty or angioplasty-related rupture, and are therefore viewed in terms of dealing with an acute problem. Nevertheless, stents seem to remain intact on follow-up studies, although they develop in-stent stenosis. I believe that the particular issue we will face regarding long-term device use concerns covered stents.

Results from the FLAIR covered stent trial demonstrated durability to 6 months, and the ongoing RENO-VA and REVISE trials of the Flair (Bard Peripheral Vascular, Inc., Tempe, AZ) and Viabahn (W. L. Gore & Associates, Flagstaff, AZ) covered stents, respectively, will hopefully provide data regarding long-term use, or at least use to 1 year following device placement, because it seems that covered stents do provide long-term benefit in AV access.

**Dr. Work:** The KDOQI Vascular Access Guidelines that were published in 2006 emphasize the need for clinical research in this area because the outcomes are dismal. Hopefully, this emphasis will lead to new approaches, such as access stratification algorithms, more effective utilization of pre-emptive transplantation, and peritoneal dialysis, which will result in better outcomes for our patients.

**Dr. Davidson:** We seem to spend much time and efforts on sophisticated, high-tech, and expensive devices in patients who have exhausted their access from lack of planning, “vein abuse,” and poor dialysis needle puncture techniques. To decrease the need for these short-term solutions, the dialysis access caretakers and stakeholders must develop algorithms aimed at utilizing the best dialysis choices for patients at all times. This includes proper patient selection over a patient’s lifetime. For example, the first dialysis access should be peritoneal dialysis, while a native AV fistula can be planned, or ideally a kidney transplant. We are far from this futuristic goal. Until then, we are forced to use short-term solutions to solve long-term problems. The two most important factors in obtaining long-term effective renal replacement therapy are early patient referral and prevention of “vein abuse” by health care workers.

## In what ways does infection prevention and management affect clinical decision making in this population? Does CMS’s recent decision to stop paying hospitals for treating catheter-associated infections compound this issue?

**Dr. Work:** CMS will stop paying hospitals for catheter-associated infections. The rationale is that CMS should not pay a hospital for the higher costs of treating a condition that was acquired during the hospital stay and that was determined to be reasonably preventable through compliance with widely accepted, evidence-based guidelines. These guidelines include using maximum barrier precautions during central venous catheter (CVC) insertion, using appropriate skin antiseptic preparation, avoiding routine replacement of CVCs, and using antiseptic/antibiotic short-term CVCs.

On the one hand, this initiative may reduce the unnecessary use of catheters that occurs too often, such as is the case with the use of peripherally inserted central catheter (PICC) lines. This is particularly important in the chronic kidney disease population because the use of PICC lines frequently results in the loss of a potential vascular access site. However, this initiative may also have the unintended consequence of increasing costs. If in an effort to identify infections that are present before patients are admitted, hospitals begin obtaining unnecessary urine cultures or other tests for patients upon admission, these additional tests may actually drive up health care costs. Time will tell.

**Dr. Davidson:** One effect of this CMS decision is that high-risk patients will be directed to large academic institutions associated with county and state hospitals. I

agree with Dr. Work's statement that PICC lines must never be used in patients likely needing future dialysis.

### Have antibacterial and antimicrobial catheter coatings helped in this regard?

**Dr. Work:** Although there is evidence that short-term coated CVC use for IV access may be efficacious in preventing infections, unfortunately, there are no data to support the usefulness of these coatings in the prevention of infection associated with CVCs used for hemodialysis access. Several coated dialysis catheters are now available, but there are no randomized controlled trials demonstrating their effectiveness in preventing infections.

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—Dr. Dolmatch

**Dr. Dolmatch:** I have seen no compelling data to demonstrate any benefit of catheter coatings. This does not mean that they don't help, but there haven't been prospective comparative clinical trials of significant quality or number—no level I data. Given that about a quarter of all hemodialysis patients at any given time use a catheter for their dialysis access, and that the cost of these catheters and their associated morbidity is enormous, it is surprising that we do not have useful data yet.

**Dr. Davidson:** Physical properties and surface coatings of current and future devices is a subject that interests me. I agree with Drs. Work and Dolmatch that we do not really know if device coatings with antibiotics work. On a related subject, heparin-coated PTFE grafts appear to have a 20% clot-free and graft survival benefit over standard PTFE grafts.

### What progression of access options do you use? Is this decision unique to each physician and practice, or is there a more or less agreed upon progression?

**Dr. Work:** The recent article by Drs. Davidson, Gallieni, Saxena, and Dolmatch in the *Journal of Vascular Access* addresses this issue in detail.<sup>1</sup> Basically, access options are "patient-centric" and as such should be individualized for each patient. Indeed, each patient should have an *ESRD life plan*, a term coined by Dr. John Burkhart. This approach optimizes the patient's out-

come, which includes quality of life and individual lifestyle choices. Thus, there is no one-modality-fits-all approach, nor an agreed upon progression, and a given patient may utilize all modalities multiple times as part of his ESRD life plan. The nephrology community must ensure that all modalities are used effectively including pre-emptive transplantation, which offers the best patient outcome when appropriately used, as well as peritoneal dialysis.

### When do you know it is time to abandon an access? At what point do you stop attempting endovascular interventions or surgical repairs and move on to another access?

**Dr. Dolmatch:** This question recurs daily and we don't have a good answer. Some patients have few options for new access creation, so preservation of an existing access with repeated interventions or surgery, while inconvenient and costly, may be the best solution. In fact, it may be less costly than trying to place and maintain a new access or using a catheter for long-term dialysis access. Other patients may have excellent options for a new access, and therefore, repeated efforts to maintain their failing accesses should be limited. But without large studies that provide data about what to do and when to do it, we are unfortunately working in the realm of opinion and perception. There are great opportunities here for clinical research.

**Dr. Work:** Each intervention on a dysfunctional access, even if the intervention is successful, should evoke the question: What is the next access for this patient? Early planning for the next access is important so that when the current access is abandoned, there is a plan in place that will minimize total catheter contact time or avoid a catheter altogether. For example, if during an intervention a patient is noted to have an excellent upper arm outflow vein for a secondary fistula, the interventionist should include this information to the referring physicians as well as the patient so that an opportunity for a secondary fistula is not missed.

There are no data that speak directly to this issue. However, the rule of thumb that if an access fails more than three times within 2 months, it is time to actively pursue a new access plan, seems to empirically work. This is clearly an area that requires good clinical research.

**Dr. Davidson:** Access planning and interventions are similar to the treatment of malignancies. Each procedure is aimed at prolonging life and improving the quality of life. Access failure can often be predicted by the

experienced caretaker. New access modalities and sites can usually be placed before failing accesses are abandoned, thus avoiding temporary CVC use. These decisions are plagued by the difficulties in performing randomized studies, with multiple confounding factors in these heterogeneous and rapidly changing dialysis population demographics. Additionally, the rapidly developing and competing technologies, wide spectrum of professional experience, bias, and various socioeconomic forces all make dialysis access issues quite multivariate and complex.

### To what degree is the patient a decision maker in this process?

**Dr. Dolmatch:** Patients rarely seem to understand the complexities of access maintenance. It's really not their fault, though. I am convinced that from the very earliest considerations of dialysis, most patients are not informed of their options and do not actively participate in the decisions regarding the type of dialysis (peritoneal vs hemodialysis), the type of access (AV fistula vs AV graft), or the selection of procedures that are used to maintain their access (percutaneous vs surgical).

**Dr. Work:** The nephrology community has not done a good job in including the patient in this process. We need to ensure that all patients with advanced chronic kidney disease and their families are educated about and offered a choice in modality selection.

**Dr. Davidson:** It really can vary. I have had patients bring articles on dialysis access requesting a specific device or procedure when I was in private practice. The other more common extreme, as alluded to by Drs. Dolmatch and Work, is best characterized by the phrase, "Doctor, you know best. I trust you." We can do a better job of informing patients by changing our vocabulary. As a surgeon, I always draw lines on the patient in the clinic during the ultrasound vascular mapping session. This visual message seems to sink into their memory, and the patient now comes back for surgery knowing the extent of the incision.

### One of the most rapidly growing patient segments includes individuals who have no more access options. First, how can this scenario be avoided as long as possible?

**Dr. Work:** In part, this is a result of a health care system barrier. Because the US health care system often does not provide for pre-ESRD planning, most patients initiate dialysis using a catheter for their first vascular access. Furthermore, this "catheter-first" approach is

compounded in that Medicare coverage does not begin until day 91 for eligible patients who begin in-center dialysis. This prolonged catheter contact time often leads to central vein stenosis and, therefore, the limitation on vascular access choices that central vein stenosis creates.

We need to first develop stratification criteria that match the best access to the individualized needs of a given patient. These criteria must include peritoneal dialysis as a first-choice modality for appropriate patients. Second, we must change the systemic barriers that lead to the current "catheter-first" approach.

**Dr. Dolmatch:** Trauma to a patient's arm veins and central veins from IV catheters and lines may compromise options for AV access at a later time. Although IV access is often necessary, there are a number of ways to spare those veins that are typically used in AV access. Specifically, placement of an IV in the cephalic or median cubital vein should be avoided, and PICC lines should be tunneled to the internal jugular vein rather than being placed in an arm vein. Subclavian catheters should be avoided if there is any possibility that the arm will be used for future AV access. If a CVC is needed, the internal jugular vein should be used. These issues are not only important for physicians and nurses, but it is essential that we educate patients about where they should allow IVs, PICC lines, and central lines to be placed.

**Dr. Davidson:** It is all in your short- and long-term planning. Hospital policies against PICC lines and other "vein abuse" in ESRD patients must be developed and enforced, along with patient education. It must start at the top. For example, Medicare must change the 91-day rule to even begin thinking about decreasing the 80% catheter-initiation rate.

### What are the treatment options once all conventional accesses have been exhausted?

**Dr. Work:** Many patients who are labeled as having exhausted all vascular access options frequently benefit from taking a fresh look—anything from repeat detailed vessel mapping, another set of eyes, referring the patient to a vascular surgeon for another look, etc. This approach may reveal options that have been overlooked, for example, a dialysis modality change, or a necklace access.

**Dr. Davidson:** Most patients with seemingly exhausted access still have viable options. First, think *peritoneal dialysis*. Many patients have not even heard about

“belly” dialysis. Second, I am present and perform all vascular mapping myself. Uniformly, there is an outflow vein somewhere. But you have to make an effort. It may take 30 to 45 minutes to explore all options in depth, but it saves and prolongs lives. Also, now we have a new option in the HeRO device (Hemosphere, Inc., Eden Prairie, MN).

### What is your last resort? For instance, would you place a leg graft before a subcutaneous implant like the HeRO device?

**Dr. Work:** The initial experience with the HeRO device for the patient with central vein occlusion has been very promising. Rather than view this device and the leg graft as accesses of last resort, they each provide an additional treatment option for the challenging patient.

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—Dr. Work

**Dr. Davidson:** The HeRO is a very promising device and may prove to be the most effective way to get the “permanent” catheter rate down.

### To what degree does reimbursement affect decision making? How does reimbursement vary between access options?

**Dr. Work:** Unfortunately, the reimbursement system may influence decision making in a perverse way. The degree of this influence is unknown. Cynics once labeled the vascular graft as “the gift that keeps on giving” because the reimbursement for a graft was higher than for a fistula, and the graft required frequent interventions in order to maintain patency. However, the success of the Fistula First Initiative without a change in reimbursement essentially belies this claim. On the other hand, the increase in the endovascular use of stents in dialysis access parallels the marked increase in reimbursement for stent placement that took place in 2008. However, the accepted criteria for stent placement in dialysis access have not changed.

**Dr. Dolmatch:** I treat patients in our academic hospital setting, and management of hemodialysis access is one of the many services we provide. There is no link between physician reimbursement and procedural pay-

ments, nor have we gotten any pushback from the hospitals on how we treat patients regarding reimbursement of procedures or supplies. Therefore, I am fortunate that I can decide on appropriate therapy based on data and experience—not reimbursement. But I think the landscape is different in free-standing centers where the case mix is predominately AV access, and the balance between cost and reimbursement determines physician payment as well as survival of the center. I worry that in this scenario, reimbursement may indeed impact the decision-making process.

**Dr. Davidson:** In my opinion, economics, physician training, and bias favor hemodialysis over the better choice of peritoneal dialysis, perhaps more subliminally in the US and many Western societies.

### Similarly, how do infection rates vary between access sites and options?

**Dr. Work:** A working fistula clearly has the lowest infection rate of any access option. The key word is *working* because, unfortunately, a fistula also has the highest primary failure rate. The graft has a higher infection rate compared to a working fistula, but is far better than the vascular catheter, which has the highest infection rate. Do not overlook the peritoneal dialysis catheter, which has the lowest per-person, per-year access cost compared to vascular catheters, grafts, or AV fistulae.

**Dr. Davidson:** Again, because of confounding factors, you cannot compare grafts with native vein fistulae, because these represent two very different ESRD patient populations. And we are not about to have a randomized study of PTFE grafts versus AV fistulae. With the increasing number of placed fistulae (driven by the Fistula First Initiative) the failure-to-mature rate is an astonishing 60%.<sup>2</sup> Using the common sense algorithm we outlined in the *Journal of Vascular Access*,<sup>1</sup> my institution’s graft survival rate has exceeded that of native vein AV fistulae in the last 25 years. I do not favor a specific access site, device, or mode of dialysis. Over a lifetime, optimally treated patients are likely to have experienced several types of renal replacement therapies. These include peritoneal dialysis, a native vein fistula or PTFE graft, and a transplant. The decision is made each time based on a number of factors that we summarized in our previously mentioned article.

1. Davidson I, Gallieni M, Saxena R, Dolmatch B. A patient centered decision making dialysis access algorithm. *J Vasc Access*. 2007;8:59-68.

2. Dember LM, Beck GJ, Allon M, et al. Effect of clopidogrel on early failure of arteriovenous fistulas for hemodialysis: a randomized controlled trial. *JAMA*. 2008;299:2164-2171.