Re-envisioning Fistula First in a Patient-Centered Culture

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Summary
The main options for vascular access in hemodialysis patients are arteriovenous fistulas (AVFs), arteriovenous grafts, and tunneled cuffed central venous catheters. AVFs have the lowest complication rate and require the fewest interventions and lowest cost to maintain. There has been a dramatic national increase in prevalent AVFs among patients with ESRD in the United States driven, in part, by the Fistula First Breakthrough Initiative. The Fistula First Breakthrough Initiative has engaged stakeholders in the dialysis community to disseminate best practices and quality improvement activities to increase AVF prevalence in suitable candidates. In the pursuit of maximizing AVF placement and prevalence, less emphasis has been placed on the individual patient context. An AVF may not be the best access choice in a subset of patients, particularly those with poor long-term prognoses or comorbid chronic diseases with a short life expectancy, those patients more likely to die than to have their CKD progress to ESRD requiring dialysis, and those with vascular anatomy not amenable to successful AVF placement. Placement of an AVF in these patients subjects them to uncomfortable and likely unnecessary and/or unsuccessful surgeries at an expense, while doing little to improve their clinical outcome or their individual experience of care. AVF prevalence as a pay-for-performance measure without the appropriate case-mix adjustment may penalize providers for accepting higher-risk patients. Although a functioning AVF that provides reliable hemodialysis remains the gold standard for vascular access for most patients, it may not be the most suitable option for every patient.

Introduction
Since Belding Scribner placed the first arteriovenous shunt for hemodialysis in 1960, vascular access creation and revision has become common surgery in the United States. The number of surgical vascular accesses placed each year is growing, with >500,000 procedures performed in 2007. Permanent vascular access to the bloodstream for dialysis can be achieved by an arteriovenous fistula (AVF), an arteriovenous graft (AVG), or a tunneled central venous catheter (CVC), the latter being the least optimal choice. In the 2 decades before the Fistula First Breakthrough Initiative (FFBI), AVG surgeries were performed more often than AVF surgeries in the United States. This trend was opposite of the European experience (1), although of late, it has reversed course (Figure 1).

The dramatic national increase in prevalent AVFs among patients with ESRD—the intended consequence of the FFBI—was surprising to some, expected by others, and perhaps unnoticed or ignored by a few. The FFBI, beginning initially as the National Vascular Access Improvement Initiative, a partnership between the Centers for Medicare and Medicaid Services (CMS), the ESRD Networks, and the entire renal community, was originally intended to increase the appropriate use of AVFs and to reach or exceed the prevalence goals for re-envisioning the concept of “Fistula First” as it fits with the current culture’s focus on improving the experience of care.

Individual Patient Context
In the vigorous pursuit to make surgically created vascular access universal, less emphasis has been placed on the individual patient context and on the recognition that an AVF may not be the best option for every patient with ESRD requiring dialysis. Population-based standards for CVC and AVF rates promoted by
FFBI perhaps have prompted some nephrologists, dialysis providers, and access surgeons to interpret “Fistula First” to mean “fistula only.” The NKF-KDOQI guidelines suggest that prevalent long-term or permanent CVC rates of <10% may be a realistic target. In conjunction with CMS’s national goal for an AVF prevalence of 66%; this implies that the remaining 20%–24% of patients will dialyze via AVGs. These numbers further suggest that although AVFs should be sought in most patients, there are patients in whom AVGs may be more suitable.

In its second edition, the Renal Physician Association’s (RPA) Clinical Practice Guideline, Shared Decision-Making in the Appropriate Initiation and Withdrawal from Dialysis emphasizes individualization of therapy when addressing risks versus benefits, and the choice of therapy likely to provide the most comfort to a patient when long-term survival may not be a realistic goal. This includes shared decision making about available dialysis modalities, conservative management in lieu of dialysis, or the consideration of a time-limited trial of dialysis to see how the patient responds and how dialysis complements (or detracts from) his or her lifestyle and goals of care (3). Furthermore, CMS, in its “Triple Aim,” emphasizes the importance of improving the patient’s experience of care, which acknowledges that the uniform application of evidence-based medicine must be tempered by the response of the patient, both physically and emotionally. A similar individualized treatment approach has been encouraged in the management of anemia with erythropoietin stimulating agents (ESA) in both CKD and dialysis patients (4). In the anemia arena it has been suggested that instead of focusing solely on hemoglobin values, focus should be placed on a patient’s anemia-related symptoms while being mindful of the risks and benefits of ESAs (5). Accordingly, the FFBI also embraces a patient-centered approach to vascular access choice, placement, and use. A functioning, complication-free vascular access is the ideal for all patients. Although the evidence clearly demonstrates that a functioning and reliable AVF is associated with the best outcomes in hemodialysis patients and remains the gold standard of vascular access, there are patients for whom an AVF may be a less appropriate choice.

Widespread education directed at nephrologists and surgeons, changes in reimbursement, and heightened awareness about the appropriate selection of access for dialysis patients by FFBI and CMS account for some of the changes in clinical practice responsible for the increased prevalence of AVFs in US dialysis patients over the past decade. There is, of course, more research required in this area to evaluate how these changes have affected patients’ experiences and outcomes. The mission and vision of FFBI (as articulated on its website www.fistulafirst.org) remain the improvement in survival and quality of life by promoting the “development and implementation of sustainable system changes that support AVF placement and use in suitable hemodialysis patients.” Optimizing vascular access selection by encouraging timely placement of a fistula first remains the goal for suitable patients, and particularly those for whom long-term dialysis is anticipated. Current reimbursement policies can create barriers to early placement of AVFs in patients without medical insurance who will ultimately be eligible for full Medicare coverage after the initiation of dialysis. This issue, as well as the necessity of CVC in urgent or acute dialysis starts, certainly contributes to the high prevalence of catheters in patients initiating dialysis (6). An AVF may not be the best choice for patients with poor prognoses or chronic diseases with a short life expectancy who are more likely to die than to progress to ESRD requiring dialysis and for those patients with vascular anatomy not amenable to successful AVF placement. Placement of an AVF in such patients subjects them to uncomfortable and likely unnecessary and/or
unsuccessful surgeries or radiologic interventions, at an expense, while doing little to improve their clinical outcome or their individual experience of care. This subset of patients may benefit more from an AVG that matures more quickly than an AVF resulting in a shorter time with or avoidance of a catheter. With the advent of AVGs that can be cannulated almost immediately postoperatively, this form of vascular access may become a more realistic option for some patients (7). The RPA, in partnership with the major dialysis organizations and other stakeholders in its vascular access initiative, emphasizes the critical role of the nephrologist in driving system change and engaging other stakeholders to change their practices to improve hemodialysis vascular access placement. The role of the nephrologist in this process is more than just ensuring that every patient has an AVF in place for hemodialysis but rather, critically evaluating which patients actually may not benefit from an AVF and identifying those who may have an improved experience of care with an alternate form of access (8,9). Shared decision making between patient, nephrologist and vascular surgeon should thoughtfully take into account the patient’s vascular anatomy, comfort, long-term prognosis, and likelihood of ever requiring dialysis. Patients undergoing surgical access creation need to understand the risks, benefits, and burdens of hemodialysis and vascular access placement, give informed consent, and realistically consider whether long-term dialysis can be expected to confer benefit in the form of improved quality or extended quantity of life.

**Elderly Patients and Multiple Comorbidities**

With an aging population in general, the demographics of ESRD patients are also changing; individuals aged ≥85 years comprise the fastest growing segment in the US population (10). The number of octogenarians and nonagenarians starting dialysis in the United States increased from 152.8 per million population in 1980 to 2926.2 per million population in 2010, representing a 19-fold increase. In comparison, the number of patients between the ages of 60 and 69 years has increased about 5-fold; thus, more elderly dialysis patients than ever before are under nephrologists’ care (11). In Canada, the number of patients aged ≥65 years has increased by 400% in the past decade (12), a trend occurring worldwide (13,14). Age-matched survival is poorer compared with people not on dialysis, which is similar to what is found in younger dialysis patients (7). Furthermore, elderly patients, particularly those with multiple comorbidities, may not live long enough to need dialysis, preempting the need for vascular access surgery at all. Accepted practice standards, guidelines, and quality measures are, for the most part, established from nongeneralizable studies in younger patients and applicability to this very elderly dialysis population, particularly with regard to vascular access has not been validated (15). Thus, it is important to be mindful of individual patient context when applying “standard” quality measures to this expanding population of very elderly patients (7), whose experience of care may be based on different criteria from those of a younger patient.
Life expectancy as well as quality of life are important considerations for health care providers and most patients considering dialysis. Studies have shown that dialysis may not confer a survival advantage in patients with two or more of the following: age 75 years and older, high comorbidity scores (e.g., modified Charlson Comorbidity Index score ≥8), marked functional impairment (e.g., Karnofsky Performance Status Scale score <40), or severe chronic malnutrition (e.g., serum albumin level <2.5 g/dl using the bromcresol green method). For patients with ESRD, the “surprise” question (“Would I be surprised if this patient died in the next year?”) is a strong indicator of 6- to 12-month mortality and can be used together with the above risk factors to estimate prognosis (3,16–26). Although the results of the above studies address whether patients should be initiated on dialysis at all, if the decision is made to proceed with a trial of dialysis, their poor prognosis should alter the way their nephrologist and vascular access surgeon approach their planning for a permanent access. These patients may be better suited for an AVG. A 2007 study showed a 1-year survival rate of 84% and 68% in dialysis patients aged >75 years in the dialysis group compared with the conservatively managed group, respectively; however, this survival benefit was not present in patients with multiple comorbidities (21). A 2009 study that examined primary assisted AVF patency in patients aged <70 years or >70 years found that patency was 35% in patients aged >70 years versus 67% in patients aged <70 years (27). Studies suggest that age itself is not a barrier to patient success on dialysis but rather age in conjunction with numerous comorbidities as described above (24), again highlighting the need for careful assessment of each individual patient’s situation, other comorbid conditions, expected life span, and resuscitation status when considering the most suitable access for a patient.

A functioning AVF has decreased thrombosis, fewer procedures to attain and retain patency, and less risk of infection than an AVG. However, for an AVF to confer these clinical benefits over an AVG, the patient must have a life expectancy long enough for these benefits to accrue. The benefits of an AVF over an AVG only become evident when the use or expected use of the AVF is >18 months (12). A 2005 study reported that although AVGs were more prone to thrombosis, this difference was not pronounced until 24 months. The authors of this study also noted that primary or assisted patency was similar at 12 and 24 months between their patients with AVGs and AVFs. It was only after 2 years that differences in patency became more pronounced and AVGs were more prone to late failure. In addition, this study and others did not find any differences in the rates of infectious complications (28). Thus, suitable patients for AVF placement should include those expected to have a reasonably good prognosis for survival as identified by age <75 years or ≥75 years with low comorbidity scores, limited functional impairment, and reasonable nutritional status.

### Unsuitable Vessels

An important prerequisite for achievement of a successful AVF is the presence of suitable vascular anatomy, the demonstration of which requires proactive evaluation and the availability of a reliable vascular laboratory. Patients considered to have favorable preoperative vascular mapping characteristics, the standard of care in surgically placed access planning, would include but not be limited to be those patients who have minimum vessel diameters of 2.5 mm for vein and 2 mm for artery and no evident stenosis or thrombosis (29). In addition to size, other important factors include vessel distensibility, peak systolic velocity, resistive index, and arterial stiffness.

Primary maturation failure of AVFs is reported to be as high as 60%, with the highest rates observed in older patients, female patients, African Americans and Hispanics, and those with cardiovascular disease (12). For the construction of simple AVFs, distal sites chosen first are recommended when possible; however, mid or upper arm AVFs may be more successful in older patients who are more likely to have thinning and fragile skin changes in the forearm, and poor forearm veins from multiple intravenous infusions and cannulation sites (10,14,15). In younger patients the practice of preserving more proximal veins for future access sites is certainly reasonable. In more elderly patients or those with a limited life expectancy, it may be in the patient’s best interest to place a more proximal fistula, especially if it means an improvement in patency and fewer surgical interventions.

A recent study found that artery diameter, not age, was the most important predictor for AVF patency. The authors noted that although age was not the primary predictor, indiscriminant placement of AVF in elderly patients poorly suited for an AVF would result in numerous AVF-salvaging procedures that may or may not be successful and may compromise quality of life (30). Quality of life can be

<table>
<thead>
<tr>
<th>Approach</th>
<th>Population Focused</th>
<th>Patient Centered</th>
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<tbody>
<tr>
<td>AVF</td>
<td>Presumed appropriate for 66%</td>
<td>Deemed appropriate based on suitability: clinical, prognostic, or vascular anatomy</td>
</tr>
<tr>
<td>AVG</td>
<td>Acceptable if AVF not possible</td>
<td>May be best choice in older patients with limited life expectancy and/or need of imminent dialysis or patients with anatomy not amenable to AVF</td>
</tr>
<tr>
<td>CVC</td>
<td>Acceptable for no more than 10%</td>
<td>Acceptable only for patients with vascular access failure or poor prognosis for long-term survival</td>
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AVF, arteriovenous fistula; AVG, arteriovenous graft; CVC, tunneled cuffed central venous catheter.
compromised not just with recurrent procedures but also potentially from the complications after sedation in an elderly population at higher risk of falls. A 2006 study produced a risk equation that found initial failure rates to be as low as 24% in patients identified as low risk by the predictor equation and as high as 69% in high-risk patients (31). Predictor equations like this may be helpful in saving patients from surgical procedures that are unlikely to be successful or beneficial and also helpful in identifying patients who would fare better with an AVG (32). In addition, surgical expertise in vascular access has been linked to lower rates of maturation failure, which highlights the importance of offering and promoting hemodialysis specific vascular access training in surgical residency programs to increase the pool of proficient and experienced access surgeons (33,34). Other practice changes can also help improve successful placement and survival of functioning fistulas such as early referral to nephrologists and access surgeons, closer postoperative monitoring of fistula maturation, and improved AVF cannulation techniques when the time comes.

AVFs have many benefits over AVGs, making AVFs the preferred internal access for most patients, but the rate of primary AVF failure and number of procedures required to achieve patency can be quite high, particularly in patients whose constitution and vascular anatomy may be poorly suited for an AVF. One study found that although the AVF is generally more cost-effective, the cost savings were not evident in patients with a high risk of primary AVF failure, thus further emphasizing that choice of access is not a one-size-fits-all decision and that there are some patients in whom AVG placement may be preferable (8). Annual costs for AVF access events (>3,000 per patient) include potential for cost savings that might be realized with enhanced patient selection for AVF placement at the outset (31,35–38).

Slowly Progressive CKD

Patients are often referred to vascular access surgeons based on the estimated GFR (eGFR), although because of the variable rates with which patients with CKD progress, timing a referral for vascular access placement may be less than straightforward and as difficult to predict as assuring a timely dialysis start. Reliably predicting each individual’s rate of decline of kidney function can be especially difficult. Older patients have a high prevalence of CKD, but lose renal function at slower rates than their younger counterparts, have a low incidence of progression to ESRD and shorter survival, and thus constitute a group for whom proactive AVF placement may result in the placement of AVFs that will never be used (39,40). An unfortunately high proportion of CKD patients inevitably require initiation of hemodialysis with the undesirable CVC in the setting of an acute illness or suboptimal preparation for renal replacement therapy. Once the acute issues have resolved, the appropriate planning should resume pursuing a suitable surgically placed access in these patients (41).

In a large cohort study of US veterans, those who were aged >75 years were far more likely to die than to develop ESRD even when their eGFR was as low as 15–29 ml/min per 1.73 m² (42). Placement of AVFs in all patients aged >75 years with a GFR <25 ml/min per 1.73 m² has been calculated to result in five unnecessary AVFs for every one AVF that was utilized within 1 year (39,42–46). Although many older patients with kidney disease do not progress, the need for vascular access assessment should be considered in patients with a GFR <20 ml/min per 1.73 m² who demonstrate progressive, irreversible deterioration in kidney function over a reasonable period of observation, are diabetic, or have proteinuria and have a reasonable life expectancy. Plans to incentivize AVF placement with pay-for-performance measures in these patients who have advanced CKD but are unlikely to progress to the point of requiring dialysis may prompt unnecessary surgeries and promote procedures that carry both risk and cost in patients who will not benefit from their placement.

Moving Forward

Type of vascular access is one of the clinical measures included in Medicare’s Quality Incentive Program for payment year 2014 and beyond. Data collection regarding the presence of an AVF or CVC as a pay-for-performance quality measure began in 2012. Catheter use for >3 months is already being used as a quality indicator in Brazil (47), where in 2008, 11.4% of patients had a catheter as their hemodialysis access. This is very close to the <10% target for CVCs used >90 days set by the NKF-KDOQI guidelines and certainly exceeds what has thus far been achieved in the United States, where in 2011, 65% of patients initiated hemodialysis with a catheter alone, only 15% of whom had maturing AVF (48). The Brazilian study found that age, presence of hypertension, and geographic location were the factors most associated with prolonged catheter use, demonstrating that even despite a prevalence that comes close to the NKF-KDOQI catheter target, subsets of patients exist for whom catheter elimination may be challenging. In a 2009 study from Taiwan that evaluated the presence of hemodialysis access in incident hemodialysis patients, an equally low prevalence of CVCs and a very high incidence of AVFs were observed. AVGs were most often found in women, elderly persons, and patients with diabetes (49). The European best practice guidelines report that, in general, Europe is doing much better in meeting the NKF-KDOQI guidelines for AVF use than is the United States. European patients who have AVGs are much more likely to be elderly individuals. Only 5% of patients aged <45 years use an AVG versus >8% in patients aged >75 years (2,50).

The FFBI and CMS have made tremendous progress in the United States, engaging stakeholders to disseminate best practices and quality improvement activities to increase AVF prevalence through education, heightened awareness, and intensified scrutiny. We strongly encourage a patient-centered approach by both the ESRD Networks and the individual dialysis centers to avoid placing AVFs in unsuitable patients to achieve pay-for-performance quality benchmarks. The Institute of Medicine recommends case-mix adjustment of quality measures used for public reporting and payment for performance to prevent providers from being penalized for accepting higher-risk patients and to provide safeguards against “cherry picking” lower-risk patients to ensure that quality benchmarks used for payment are met (51). Given the
importance of surgical experience and expertise, it would seem appropriate to include surgeons in the realm of accountabilily, assure that surgical outcome information is available to nephrologists, and encourage its use.

To conclude, placement of an AVF may be possible in many patients, but in patients with a poor prognosis for long-term survival or other reasons making them unsuitable for an AVF, the burdens of cost, pain, and other morbidities associated with surgical intervention may adversely affect an individual patient’s quality of life and experience of care. Second, proactive determination of surgical suitability, maturation potential, and cannulation readiness enhances and optimizes the chance that a functional AVF is achieved with minimal intervention, thus reducing vascular access costs and providing a smooth experience of care for more patients. Targeting only those patients most likely to reach ESRD for AVF placement rather than all of those with advanced CKD would likely reduce vascular access costs overall; further research in this area is required. Appropriate selection of patients would enhance the prevalence of successful AVFs and save some patients the burdens of surgical intervention that may be for naught.

These considerations highlight the complexities inherent in the decision making process and are intended to provoke additional discussion, thought, and research, both at the population level and at the individual patient level, about how to maximize quality of care and quantity of life, minimize risks, and provide optimal quality of life for every patient for whom hemodialysis is being contemplated or administered based on the best evidence available (Figure 2 and Table 1). The functioning AVF remains the gold standard for vascular access for most patients and the CVC should be reserved as a last resort in hemodialysis patients for whom a surgically created vascular access is not possible. Our obligation as nephrologists in the drive to improve ESRD vascular access practices is to ensure that our dialysis patients have the permanent access most suitable for them, remaining mindful that an AVF may not be the most suitable option for every patient.

Disclosures

R.S. is in a joint venture with Fresenius Medical Care. J.W. is a consultant for DaVita, Keryx Pharmaceuticals, and Sanoﬁ and is on the speaker’s bureau for AMAG, Takeda, and Sanoﬁ.
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