Improving Vascular Access Outcomes: A Systems Approach to Eliminating Structural Barriers

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Vascular access · AV fistula · PTFE graft · Hemodialysis · Cuffed catheter

Abstract
Maximizing AV fistula creation, regular access monitoring, prompt outpatient interventions and minimizing catheter use are well-accepted approaches for vascular access management. Systemic barriers impede the application of these strategies. A misaligned reimbursement system coupled with educational deficits and a lack of accountability has contributed to the institutionalization of substandard vascular access care. The hallmark of performance management is to create systems in which incentives are aligned to produce desired behaviors. Realigning reimbursement through a combination of pre-ESRD funding, enhancements to the composite rate to reward outcomes and cover vascular access monitoring and updated reimbursement for outpatient vascular access procedures would improve care and decrease unnecessary hospitalizations. This should be coupled with clearly defined outcome standards and accountability incorporated into hospital accreditation and credentialing. Capitation may provide alternative solutions. A two-phased approach including reimbursement reform while exploring capitation represents a prudent course with the best likelihood of success.

Introduction
Vascular access dysfunction remains a major source of morbidity and hospitalization for patients with end-stage renal disease (ESRD) resulting in annual expenditures in excess of USD 1 billion [1]. In the USA, the majority of patients continue to be dialyzed using prosthetic bridge grafts or dialysis catheters [2]. This continues despite overwhelming data that these accesses result in significantly higher patient morbidity and mortality [3, 4]. Over the past 10–15 years, numerous studies have addressed the clinical issues involved in the prevention and management vascular access failure. There is now an evolving consensus in the renal community of the accepted methods for managing dialysis access. This pattern of required care has been outlined and is widely endorsed.

Vascular access management begins with pre-ESRD education and nephrologic care to allow modality choice and timely surgical referral. This ensures that patients receive appropriate access placement prior to the onset of dialysis and avoid the need for dialysis catheters [5]. The use of preoperative imaging has been shown to increase successful AV fistula creation and to minimize the incidence of early access failure and development of a vascular steal syndrome [6]. Regular monitoring of vascular accesses to identify patients at high risk of subsequent access failure coupled with elective interventions to correct significant areas of stenosis result in significant decreases in access thrombosis rates, decrease total procedure rates and prolong access survival [7–10]. The evalua-
tion of all patients with failing accesses or catheters for secondary AV fistula creation can result in significant increases in AV fistula prevalence [11]. Restricting the use of dialysis catheters to situations where they are absolutely necessary decreases the risk of catheter-related bacteremia and the high morbidity and mortality associated with catheter use. Lastly, the availability of prompt outpatient intervention often in specially designed, dedicated ‘access centers’ prevents unnecessary hospitalizations, minimizes catheter use and prevents missed dialysis treatments. When taken together, these measures form the framework for vascular access care at the beginning of the 21st century. These practices have been codified in the widely accepted Kidney Disease Outcomes Quality Initiative (K/DOQI) clinical practice guidelines for vascular access [12]. Data from numerous centers throughout the USA indicate that following these guidelines results in marked improvements in patient care and clinical outcomes. Yet, despite an overall agreement in dialysis community, incorporation and use of these practices is sporadic. Although many programs utilize some of these strategies, few programs have been able to provide the consistent application of these strategies in a coordinated, comprehensive vascular access management program for all of their ESRD patients. The typical reaction has been to suggest that individual programs are not doing their job adequately. This however begs the question of why vascular access care remains fragmented and accepted care guidelines are not routinely practiced. A more fertile approach is to focus on the role of the healthcare delivery system in creating and perpetuating current national practice patterns and explore potential improvements viewed in the framework of a systems approach. The first step is to identify and understand the systemic barriers that perpetuate delivery of less optimal care and impede widespread adoption of preferred clinical practices. Once these specifics are defined, potential for structural solutions to improve vascular access outcomes can be explored. In the following sections, we will review the specific clinical strategies involved in optimal vascular access management and discuss the current barriers to their widespread adoption. These will be covered in four broad categories: (1) increasing AV fistula prevalence; (2) access monitoring; (3) providing prompt outpatient interventions, and (4) limiting catheter use.

Following this discussion, we will review the range of options that could potentially help alleviate this situation. Our hope is that this will help stimulate a broader dialogue about realistic approaches to improve vascular access care including the steps that would make this achievable.

Most hemodialysis patients in the USA rely on prosthetic bridge grafts or dialysis catheters for vascular access [2]. This is in contrast to the practice patterns in European centers. This difference was illustrated by the recent DOPPS study. At the start of hemodialysis, European DOPPS centers utilized fistulas in 67% of patients (permanent access rate 70%) and catheters in 30% of patients. In contrast, only 40% of patients in US centers had a permanent access (15% AV fistulas, 25% PTFE grafts) and 59% utilized dialysis catheters for their first dialysis. In European centers, 81% of prevalent patients utilized AV fistulas compared to 24% in the USA. Only 10% of the European prevalent patients used grafts (vs. 58% in the USA) and 8% used dialysis catheters (vs. 17% in the USA). These differences were not explained by clinical factors including age, sex or renal diagnosis [13]. These differences in practice patterns have a profound influence on overall patient outcomes. AV fistulae develop significantly fewer complications than PTFE grafts or cuffed catheters. The relative risk for prosthetic bridge grafts developing access thrombosis or requiring a revision was 7.02 and for requiring an access procedure was 8.09 when compared to AV fistulae [13]. Access selection also adversely impacts patient mortality. Patients with dialysis catheters have an increased relative risk of death when compared to patients with AV fistula (1.47 in diabetics and 1.34 in non-diabetics). This was true in both incident (relative risk 1.91) and prevalent (relative risk 1.54) patients. Prevalent patients with grafts also had an increase in the relative risk of death (1.41) when compared to AV fistulas [4]. Internal data from Fresenius Medical Care including >38,000 patients with adjustment for case mix (age, sex, diagnosis, diabetic status, etc.), body mass index, length of time on dialysis and laboratory factors including dialysis adequacy, Ca, PO₄, etc. revealed that the relative mortality risk of patients with catheters was 1.96 when compared to AV fistulas. The mortality risk was also increased in graft patients (1.32 vs. AVF) [E. Lowrie, pers. commun.].

**Increasing AV Fistula Prevalence**

There are several successful strategies for increasing AV fistula prevalence. The first is the use of pre-ESRD care. Pre-ESRD nephrology care including modality education and early elective referral for vascular access placement results in significantly higher levels of AV fistula use and less frequent use of catheters at the onset of dialysis. ESRD Network 1 reported that 65% of chronic renal dis-
ease patients with a predictable progression toward ESRD who were followed regularly by the nephrologist used a permanent access for their first dialysis (46% AVF, 19% PTFE grafts, 35% dialysis catheters). In comparison, patients followed by the nephrologist who presented a more rapid progression used a permanent access only 36% of the time (21% AVF, 15% PTFE graft, 62% catheters). Patients unknown to the nephrologist had only 12% permanent accesses in place for the first dialysis (2% AVF, 10% PTFE grafts) and utilized catheters 85% of the time [14]. Similar improvements in AV fistula creation have also been reported by disease management organizations involved in renal disease management [15]. Why is the coordinated pre-ESRD care unavailable to the majority of chronic renal disease patients in the USA? The issues involved are multifactorial. The first deficit is in education. Chronic kidney disease care is provided by a multitude of practitioners including family physicians and internists who are often unaware of the severity of the patients’ kidney disease (underrepresented by the serum creatinine) and of the impact early nephrologic referral and access placement has on the long-term patient outcomes. Patients are also unaware of the implications of their disease and often are reluctant to pursue further education and access placement. This results in nephrology referral often only when the need for dialysis is imminent. Another barrier to obtaining adequate preparation for the onset of dialysis treatment is financial. Delivery of chronic kidney disease services is not reimbursable under the Medicare system and frequently not reimbursed by commercial payers. Proper pre-ESRD care requires a multidisciplinary team including nephrologists, renal dieticians, social workers and nurse educators who can review a wide range of topics including modality choice, anemia management, diet, social work services, access placement, transplantation, etc. as part of a continuum of care. These programs require significant resources and are often beyond the scope of family physicians, internists, and even individual nephrology practices. Although dialysis providers have the personnel and expertise to provide these services, compliance issues and lack of funding limit their efforts.

There are several potential solutions on the horizon. Proposed legislation (HR 4729IH) sponsored by Stark, McDermit, Thurman, and Christianson was introduced in the US House of Representatives on May 14, 2002. This bill addresses the issue of pre-ESRD care by proposing inclusion of chronic kidney disease patients expected to need dialysis or transplantation within 2 years in the Medicare program thus insuring coverage for appropriate medical care. It also would expand Medicare coverage to pre-ESRD services including evaluation and education for vascular access placement and modality choices. A public education and awareness campaign combined with generalized use of the MDRD equation in laboratories to fully inform physicians of the glomerular filtration rate (GFR) implicated by serum creatinine results may help foster early referral. New funding in conjunction with new K/DOQI guidelines for chronic kidney disease may help alleviate some of the education and financial barriers that limit pre-ESRD referral for access placement [5].

Referral and education alone is not sufficient to increase the creation of AV fistulas. Historically, approximately one third of AV fistulas fail or never develop adequately for use in hemodialysis. This high incidence of early failure has contributed to the lack of fistula creation in the USA. In their seminal papers Silva et al. [6] demonstrated the ability to significantly increase successful fistula creation through the use of preoperative ultrasound imaging. Using criteria including an arterial diameter ≥ 2.5 mm, no dampening of the arterial wave form, a venous diameter ≥ 3 mm, continuity with deep venous system, absence of central vein stenosis and no significant difference in blood pressure between the two arms they were able to increase AV fistula creation in Newark, N.J. from 14 to 63%. Early failure decreased from 38 to 8.3% and catheter use decreased from 24 to 7%. They also described identification of appropriate sized veins in the forearm or upper arm and transposing them to more superficial locations for Anastomosis and use for dialysis access [16]. Subsequently, numerous groups have reported marked success with AV fistula creation using a similar approach. Ascher et al. [17] reported increasing fistula creation from 5 to 68% over a 3-year period with 6-week maturation rates ranging from 75 to 87%. In the last year of their program, 95% of new accesses procedures performed were AV fistula placements. Sedlacek et al. [18] extended this observation to diabetics. With use of preoperative imaging, 66% of diabetics underwent fistula placement with successful use reported in the range of 70%. Most recently, Huber et al. [19] reported that 83% of patients were candidates for fistulas using non-invasive imaging criteria similar to those used by Silva et al. [16]. Fistulas were subsequently placed in 90% of the cases with an 84% success rate on an intention-to-treat basis. AV fistulas adequately developed and were used for dialysis in 71% of the original 139 patients. These examples and others show that obtaining fistula creation rates in the range of 70% or greater is possible in the USA with the use of a coordinated programming including preoperative
imaging. Yet despite this, only 30% of incident patients and 28% of prevalent in the USA have AV fistulas [2]. Why does this lack of fistula creation persist despite ample evidence that this is not an optimum approach? Once again, systemic barriers appear to be involved. The first of these is an educational deficit on the part of patients, nephrologists and surgeons. A whole generation of vascular surgeons has grown up in a culture of PTFE grafts. Although AV fistula placement requires somewhat different training, it can easily performed by trained vascular surgeons who do more complicated in-situ bypass procedures on a regular basis.

Reimbursement limitations and the reimbursement structure play a significant role in this issue. Preoperative mapping for access placement is well within the capability of vascular laboratories in hospitals throughout the USA. Preoperative imaging by ultrasound is not generally reimbursed by most local intermediaries and therefore is only available on a limited basis. This is because there are no ICD-9 codes available for medical justification for preoperative imaging for vascular access placement. Surgeons are poorly paid for access placement in general and AV fistula creation in specific when compared to other surgical procedures. In addition, graft placement receives greater reimbursement than AV fistula placement. Although recently a code was enacted to reimburse transposed fistula creation at a higher rate, there is still an economic disincentive to AV fistula. Transposed fistula creation is extensive surgery that can last 2–3 h and is far more taxing than graft procedures which can be performed in less than an hour and have far fewer complications. Patients may also object to the extensive surgery required for such transpositions. This combination of late referral, high early failure rates, reimbursement barriers and lack of accountability present formidable barriers to routine AV fistula creation. AV fistulas take weeks to months to mature for use in dialysis. Surgeons must know they have the support of the nephrologic team behind their efforts. Development of regional referral centers with vascular surgeons with expertise and interest in AV fistula creation may help improve the current situation and provide alternatives for communities with few surgical options. Reimbursement levels need to be adjusted to provide increased incentives for AV fistula placement. Capitation and funding of pre-ESRD programs would also increase the incentives for AV fistula creation and help propel the development of regional programs. Ultimately, patients, nephrologists and payers should demand AV fistula placement and surgeons and hospitals should be held accountable for their results.

Access Monitoring and Elective Revisions

Access monitoring programs utilizing techniques including static pressure monitoring [20], access flow measurement [7–10] and ultrasound imaging [21] can identify subsets of patients at high risk of developing future access failure. Elective repair of identified stenosis by either surgery or percutaneous angioplasty decreases thrombosis rates, increases access survival and decreases the number of procedures patients require to maintain vascular access [7–10]. These programs also allow elective correction of lesions in an outpatient setting and decrease the need for the emergency treatment of thrombosis to allow ongoing dialysis. Smits et al. [8] reported that thrombosis in PTFE grafts was 0.52 per patient year in patients monitored with access flow or static venous pressure measurements compared to 1.24 per patient year in unmonitored graft patients. Other groups have reported even better results [7, 9, 10]. Schwab et al. [9] reported decreasing thrombosis rates to 0.156 per patient year in grafts and fistulae with the use of monthly access flow measurement coupled with elective arteriography and angioplasty of significant stenosis in patients with access flow ≤600 cm³/min or that decreased 25% from baseline and was <1,000 cm³/min. Procedure rates were <1 per patient year. Cost estimates (based on charges) have reported potential savings for access-related healthcare services of approximately 50% even after covering the additional costs incurred for access monitoring and elective interventions [10]. For these reasons, KDQOI recommends regular access monitoring for identifying significant stenosis.

Access monitoring however is not routinely practiced in most dialysis facilities in the USA. Why are these technologies neglected? This is predominantly a result of lack of reimbursement. Access monitoring including access flow measurement and ultrasound surveillance is considered to be part of the composite rate by the Center for Medicare and Medicaid services (CMS) (transmittal AB-00-55, June 2000, change request 1,117). This directive was issued despite the fact that these technologies were unknown at the time that the composite rate bundle of services was defined and that no increase in payment was provided to cover the costs of these additional services. Furthermore, none of the accrued savings from decreases in hospitalization or access procedures is available to dialysis facilities to cover the costs of access monitoring programs. The result is that access monitoring places a financial burden on dialysis facilities and dialysis staff. Legal and compliance issues restrict individual physicians from providing access monitoring without payment from the.

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Providing Prompt Outpatient Interventions

Access failure and thrombosis must be corrected promptly in order to allow ongoing dialysis. Even in programs that provide access monitoring, access thrombosis and access procedures are daily events. AV fistulas thrombosis rates are 0.1–0.25 per patient year and PTFE grafts have clotting rates averaging 0.15–0.4 per patient year [7–10, 12, 20, 21]. Total access procedure rates are rarely below 1 per patient year. In programs without access monitoring, AVF thrombosis rates average 0.2–0.4 per patient year and grafts thromboses average 0.8–1.2 per patient year. Total procedure rates generally run between 1.5 and 2.5 access procedures per patient year [7–10, 12, 20, 21]. Despite the frequency and emergent nature of access complications, patients usually have to wait extended periods of time for access procedures. Hospital surgery and radiology units routinely place patients with thrombosed accesses on the supplemental schedule. This results in extensive waits, unnecessary hospitalization, missed dialysis and catheter placement, and this further increases cost and may have a significant impact on mortality. Held et al. [22] reported that relative risk of death increased 14% in patients missing one dialysis per month.

Why does this dysfunctional care delivery persist? Several factors appear to be involved. Hospital surgery units and interventional radiology centers generally schedule most cases in advance. New cases are added to the supplemental schedule and performed after completion of the scheduled cases. Scheduled cases are only deferred (bumped) for emergencies (like ruptured aneurysm) that must be handled immediately. Because access procedures are semi-emergent, they are left to the supplemental schedule. Surgeons generally have regularly scheduled (blocked) OR time. Access procedures are often assigned to the next available slot for the particular surgeon of record. This avoids conflict with other surgeons and avoids performing cases at night with supplemental staff and after a full day of surgery. Similar issues exist in interventional radiology whose busy schedules are filled with hospitalized and scheduled patients. Low reimbursement rates exacerbate this situation. Most vascular access procedures can be performed on an outpatient basis in existing ambulatory surgical centers. Many of these procedures however (for example angioplasty and thrombectomy) are not reimbursed in ambulatory surgical centers. This was scheduled to be corrected 2 years ago. CMS however has still not updated the outpatient prospective payment program for non-hospital outpatient providers. In addition, outpatient centers remain at financial disadvantage because supply costs (catheters, etc.) are only reimbursed (passed through) in the hospital setting. These costs represent approximately one third of expenses.

Potential solutions to these impediments to care lie in the areas of accountability and reimbursement. Hospitals, surgeons and interventionalists must be held accountable for their clinical outcomes including the length of time required to obtain services. Reimbursement must be adjusted to allow less costly outpatient care in appropriate non-hospital settings. Another potential solution is the development of dedicated outpatient access intervention centers. These centers generally provide a range of percutaneous services including angioplasty and thrombectomy. These centers have successfully been able to meet the need for prompt efficient outpatient interventions. Although currently limited to 20–30 markets in the USA, their growth is expected to continue.
Limiting Catheter Use

Permanent catheter insertions and patients catheter days continue to increase. Catheter days per patient year of risk have increased from 17.5 days per year in 1996 to 30.7 days in 1999 with days per insertion increasing from 143.9 to 148.1 days [23]. This increased use of dialysis catheters is a major problem for dialysis patients and payers alike. Catheter patients have significantly higher morbidity and mortality resulting in increased costs and poor clinical outcomes [4, 24]. Most catheter patients actually have adequate vessels for alternative access creation [25]. Why does the extensive use of catheters persist? One reason is the need for immediate access. The contribution of lack of pre-ESRD care and easily available outpatient interventions has already been discussed. In addition, hospitals are under severe length-of-stay restrictions. This is exacerbated by DRG payments and payers who demand rapid turnover. Dialysis patients who present without a functioning access often receive catheters to allow for early discharge. Patients are expected to return at a later date for more permanent access placement. Frequently, these catheter patients choose not to go for further access, are not referred or wait weeks to see surgeons and be scheduled for access procedures. Vascular surgeons and hospitals are not held accountable for discharging patients with catheters or without permanent access. There is no requirement or significant incentives to limit catheters or place a minimum percentage of fistulas. Most hospitals and surgeons do not even collect and report data on the types of access placed. Decreasing catheter use will require financial incentives for placing permanent accesses and disincentives for continued catheter use. Standards for permanent access and catheter placement should be incorporated in credentialing and hospital accreditation.

Overall Solutions

Although the clinical guidelines for access management are well established and validated, routinely delivering these services is a daunting task, which requires extraordinary effort to be successful. This results in islands of excellence surrounded by widespread complacency. Reimbursement is at the heart of the structural impediments to improving vascular access outcomes. Realigned reimbursements must create financial incentives to reward and facilitate appropriate behaviors. Potential solutions must be practical, realistic and have the potential for implementation on a widespread basis. Necessary changes include Medicare coverage for pre-ESRD care, preoperative imaging, and access monitoring. Increased reimbursement for AV fistula creation, and outpatient intervention are also required. Enhancement of the composite rate is a potential avenue to fund access monitoring and catheter reduction programs only if structured in a fashion to prevent these funds from being diverted to cover increased pharmaceutical costs. Positive and negative adjustments to the composite rate could be established to reward AV fistula placement and provide disincentives for continued catheter use. These incentives can be tied to savings on inpatient and procedure costs to ensure that providers share some of the benefits of improved outcomes and that total reimbursement remains revenue neutral. Large-scale education programs need to be funded and the K/DOQI process must include educating the public, surgeons, hospitals and payers alike. Lastly, physicians, surgeons and hospitals must be held accountable for their clinical outcomes. This can be accomplished through incorporation of vascular access outcomes and minimum standards in hospital accreditation and credentialing.

Another potential option is capitation. If properly designed, capitation aligns incentives to provide care that reduces the need for hospitalization and procedures. This potentially could fit nicely with vascular access goals of increasing AV fistula prevalence, access monitoring, elective outpatient interventions and decreasing catheter use. Capitated systems however have other potential pitfalls. Widespread capitation of vascular access specifically or ESRD in general is untested. Unless broadly applied, dialysis facilities, providers and hospitals might have only a small number of capitated patients. This would be insufficient to ensure the structural changes necessary to improve care. Obtaining a general consensus for a switch to capitation will require further demonstration of successful implementation before any decision to utilize this strategy more broadly. With or without capitation, realigned reimbursement will offer opportunities to explore the impact of case management and disease management to improve patient outcomes.

Conclusions

The systemic barriers to improving vascular access outcomes discussed above are the result of a reimbursement system that is misaligned and out of touch with the needs of patients and payers alike. In addition, education-
al deficits and lack of accountability contribute to the institutionalization of substandard care. The hallmark of performance management is to create systems where the incentives are aligned to produce desired behaviors. This is coupled with continuous feedback of outcome data to reinforce appropriate behaviors and minimum standards to which providers and practitioners are held accountable. This is the approach necessary to guarantee improvements in vascular access care. Realigning reimbursement through a combination of pre-ESRD funding, enhancements to the composite rate cover vascular access monitoring and updated reimbursement for outpatient vascular access procedures coupled with clearly defined standards for vascular access outcomes with accountability incorporated in hospital accreditation and credentialing would be a major step to improving US vascular access outcomes. Capitation may provide alternative solutions. These capitated systems however have their own systemic barriers, which still seek solutions. At present a two-phased approach including reimbursement reform while exploring capitation represents a prudent course with the best likelihood of success.

References