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Role of Prosthetic Hemodialysis Access Following Introduction of the Dialysis Outcome Quality and Fistula First Breakthrough Initiatives

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The emphasis on increasing the use of autogenous hemodialysis access in the United States has clearly changed the practice pattern of vascular surgeons during the past decade. However, this change has also been associated with an increased use of cuffed dialysis catheter and a decrease in the autogenous access maturation rate. Future efforts to increase autogenous access use will be hampered, in part, by the characteristics and comorbidities of the aging hemodialysis population and system-wide health care delivery issues, such as late referral for vascular access. As a result, prosthetic access will continue to play an important role in providing vascular access for the US hemodialysis population. This article reviews contemporary trends and evidence-based literature related to autogenous and prosthetic access procedures, as well as factors that influence access choice.
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IN 1966, BRESCIA AND colleagues described the surgical creation of radial-cephalic autogenous access.[1] Their innovation allowed patients with end-stage renal disease (ESRD) to be maintained on hemodialysis for prolonged periods. The initial criteria used by nephrologists to select patients for treatment with chronic hemodialysis were quite different than today and, therefore, the cohort of patients on dialysis was dramatically different. Most patients were young men with little comorbidity. Diabetic nephropathy was initially generally considered a contraindication to dialysis support. The favorable anatomy of this primary dialysis population almost guaranteed the success of a functional autogenous access in the majority of patients. The reported long-term patency rates for the radial-cephalic autogenous access during this period were excellent and the nonmaturation rate was only 8% to 12%.[2] By virtue of these early results, the radial-cephalic autogenous access quickly earned the reputation as the "gold standard" for vascular access, a label that persists even today. However, in the decades following this "golden era" of vascular access, significant changes in dialysis technique and the demographics of patients undergoing treatment for ESRD rendered these initial access outcomes obsolete. As a result of a greater emphasis on dialysis adequacy, flow rates were increased from 250 to 400 mL per minute, thereby placing a greater burden on smaller autogenous accesses that may not be able to sustain such flows. Furthermore, the ESRD population has changed, and now includes more elderly patients, women, diabetics, and patients with peripheral vascular disease, all of which have been shown to adversely affect autogenous access maturation, short-term and long-term patency rates, and ease of cannulation. Ultimately, these changes in demographics and comorbidities have led to an increased number of interventions to manage access-related complications.

Difficulties creating and maintaining a functional autogenous access in this challenging ESRD patient population have become more evident with the implementation of the national initiatives designed to increase their use. Although such programs have significantly expanded the use of autogenous access, they also have led to greater cuffed dialysis catheter use as well as a higher nonmaturation rate.[3,4]

This article will review trends related to vascular access following the national initiatives and examine recent evidence-based literature comparing outcomes for prosthetic and autogenous accesses. It will also use general principles of vascular access, consensus opinions related to access type/site selection, and the author's opinion in an attempt to answer the seemingly simple question that every vascular access surgeon must address. Specifically, which risk factor or combination of factors adversely influences autogenous access

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Table 1 Results of Prosthetic Arteriovenous Hemodialysis Access Using Polytetrafluoroethylene

First Author	Location	Study Design	n	Primary Patency (%)		Secondary Patency (%)		Infection (%)	Steal
				1 year	2 years	1 year	2 years		
Lenz[7]	FA-L	Prospective	56	49	38	92	59	2	?
Rizzuti[8]	FA-L	Retrospective	111	—	—	80	70	10	
Rizzuti[8]	FA-S	Retrospective	68	—	—	70	47	—	
Bosman[9]	FA	Retrospective	67	40	—	63	—	13	
Steed[10]	UA	Retrospective	20	84	67	—	—	10	
Staramos[11]	UA	Retrospective	64	—	—	80	64	—	
Coburn[12]	UA	Retrospective	47	70	49	87	64	16	8
Matsuura[13]	UA	Retrospective	68	68	46	78	51	10	
Cull[14]	T	Retrospective	116	34	19	68	54	41	
Khadra[15]	T	Retrospective	74	—	—	74	63	16	3
Bhandari[16]	T	Retrospective	49	—	—	85	82	35	
Vega[17]	BJ	Retrospective	51	57	43	74	63	2	
McCann[18]	AA, AJ	Retrospective	40	63	43	85	68	3	

Abbreviations: AA, axillary-axillary; AJ, axillary-internal jugular; BJ, brachial-jugular; FA-L, forearm loop; FA-S, forearm straight; T, thigh UA; upper arm.

maturation to such a degree that a prosthetic access may be preferable?

Evidence-Based Literature: Autogenous Versus Prosthetic Access

In order to determine the role of prosthetic accesses in the decade following the initial publication of the National Kidney Foundation's Kidney Disease Outcome Quality Initiative (KDOQI), two questions must be considered: Is the autogenous access superior to a prosthetic access? If so, what is the relative benefit of an autogenous access compared to a prosthetic one? The latter question is particularly important and has not been adequately addressed by documents such as KDOQI Clinical Practice Guidelines for Vascular Access and the Society for Vascular Surgery Clinical Practice Guidelines for the Surgical Placement and Maintenance of Arteriovenous Hemodialysis Access.[5,6] Indeed, supposed consensus about the superiority of autogenous access has been misconstrued that autogenous access should be placed in every conceivable case and that autogenous access utilization is an absolute measure of quality. The vascular access surgeon is often confronted with a patient who has anatomic or medical factors than make him or her a less than an ideal candidate for autogenous access creation. When deciding how aggressive one should be in creating an autogenous access in such patients, it is important to differentiate the relative benefits of an autogenous access as compared to a prosthetic one. If that advantage is great, an aggressive approach that emphasizes autogenous access creation in nearly every case is warranted, even if the access is less likely to mature. However, if the benefit is less significant, it might be more prudent to place a prosthetic access in situations where an autogenous access is not likely to mature.

Because the body of literature reporting outcomes for prosthetic and autogenous accesses is so extensive, it would seem that the relative benefits of autogenous and prosthetic accesses would be well-documented. However, outcomes for the various prosthetic access procedures vary widely and, thus, make any comparison of the procedures difficult (Table 1).[7-18] This variability is largely due to differences in patient selection and the methods of reporting outcomes.

Two systematic reviews provide insight into the relative benefits of autogenous access. A recent meta-analysis by Murad and associates[19] offers the best evidence yet that autogenous accesses are superior to prosthetic ones. It also highlights the profound limitations of objectively determining the extent of any benefit. This review, comprising nearly 83 studies and 70,000 patients, showed that autogenous accesses were associated with a significant decreased risk of death and access-related infection, as well as a nonstatistically significant decreased risk of complications (hematoma, bleeding, pseudoaneurysm, and access-related ischemia) and length of hospitalization when compared to prosthetic accesses. Autogenous accesses also had better primary and secondary patency at 12 and 36 months. These authors emphasize that 80 of the 83 reports included in their review were nonrandomized and that the choice of access type in these studies was based on surgeon preference, patient factors, and other potential confounders. For example, the cohorts that received prosthetic access included more elderly patients, diabetics, and those with peripheral vascular disease. They concluded that low-quality evidence appeared to show that autogenous accesses were superior to prosthetic ones. However, they admitted that their results likely overestimated the actual benefit associated with autogenous access due to selection bias.

A second meta-analysis compared the patency rates of autogenous and prosthetic accesses and only included studies that used accepted standards for reporting outcomes.[20] Thirty-four reports met criteria for inclusion in this meta-analysis. The primary patency rates for the autogenous and prosthetic accesses at 18 months were 51% and 33%, respectively, while

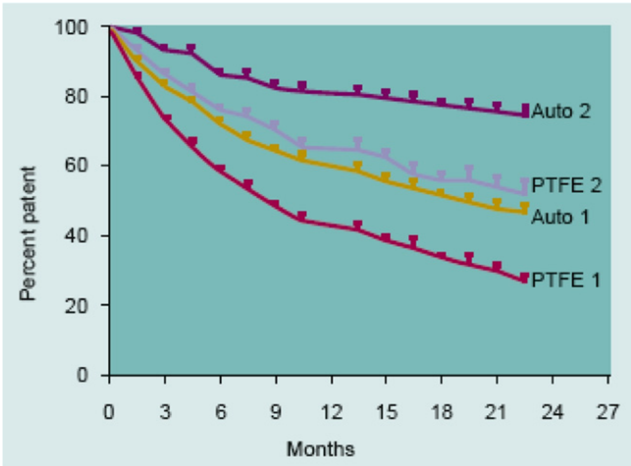

Figure 1 The patency rates (percent patent) for the autogenous (Auto) and polytetrafluoroethylene (PTFE) upper extremity hemodialysis accesses are plotted against time (months) with the positive standard error bars. Both the primary (Auto 1, PTFE 1) and secondary (Auto 2, PTFE 2) patency rates for the two access types are shown. The patency rates for the autogenous accesses were better than their corresponding PTFE counterparts, with the one exception of the initial (1.5 months) time point for the primary patency comparison. (Reprinted from Huber TS, Carter JW, Carter RL, Seeger JM: Patency of autogenous and PTFE upper extremity arteriovenous hemodialysis accesses: a systematic review. J Vasc Surg 38:1005-1011, 2003, with permission.[20])

the corresponding secondary patency rates were 77% and 55% at 18 months (Fig 1). This analysis was unable to compare the other, nonthrombotic complication rates because these events were either not described or the reporting methods were inconsistent.

The majority of studies included in these meta-analyses were published in the period before KDOQI. It is certainly possible that the demographics and comorbidities of patients receiving prosthetic access have changed since these publications and that this has adversely affected longer-term outcomes. The National Institutes of Health recently sponsored two studies that offered more contemporary patency results for prosthetic and autogenous accesses.[21,22] Both were multicenter prospective randomized trials examining the influence of antiplatelet therapy on prosthetic and autogenous access patency rates. Neither study showed that antiplatelet therapy improved access outcomes. However, these trials reported several interesting finds, independent of the antiplatelet effect. Notably, the primary access patency in for the prosthetic accesses (n = 328) was only 23% at 1 year, while 61% of the autogenous accesses (n = 877) failed to mature, both rates dramatically worse than historically reported (Table 1).[21,22] These trials were performed by a consortium of academic medical centers carefully selected by the National Institutes of Health. These results, therefore, provide an estimate of patency rates for prosthetic access and expected autogenous access maturation for dialysis populations that followed the publication of KDOQI and implementation of programs directed at increasing autogenous access use. These trials also suggest that contemporary patency outcomes for prosthetic accesses and autogenous access maturation are distressingly poor and may get even worse as further attempts to increase autogenous access use are implemented.

In summary, substantial evidence suggests that there is a real functional patency advantage for the autogenous access although precise quantification of this benefit cannot be derived from published reports. Patient selection bias (ie, healthier patients generally receive an autogenous access, while sicker patients with disadvantaged anatomy generally get a prosthetic one) likely accounts for part of the observed advantages of autogenous accesses. This benefit may well be negated if the early failure and nonmaturation rates for the autogenous access are excessive. Accordingly, careful patient selection in terms of both access type and site are crucial to realize the advantages of an autogenous access.

Vascular Access Trends Post−Fistula First Initiative

There are several purported advantages of prosthetic access (Table 2). Not surprisingly, these advantages were used to justify their widespread use and were partly responsible for the fact that prosthetic arteriovenous accesses were the most common type across the United States before the initiatives. However, a number of epidemiologic and clinical studies suggest that patients with prosthetic accesses experience an increased risk of death and infection as well as decreased primary and secondary patencies when compared to patients who dialyze via autogenous access.[4,19,23,24]

In response to recommendations from the KDOQI Guidelines, initially published in 1997, the Fistula First Breakthrough Initiative (FFBI) was launched by a cross-section coalition of the ESRD community and the Centers for Medicare and Medicaid Services. Its primary focus was to improve vascular access outcomes by increasing the incident and prevalent rates of autogenous accesses in the US. Benchmarks for autogenous access were established and these have become de facto surrogate markers for the quality of a dialysis access program. This has dramatically changed the practice pattern of US access surgeons during the past decade. The initial FFBI targets were identical to those for the DOQI (incidence, 50%; prevalence, 40%), but these were revised in 2006 with a target autogenous access prevalence rate of 66% by 2009. It appears that the FFBI has fallen well short of this goal. According to statistics from the 2010 United States Renal Data System, only 31% of incident hemodialysis patients

Table 2 Advantages of Prosthetic Hemodialysis Access

Provides a large surface area for needle cannulation
Technically easier to cannulate
Variety of prosthetic lengths and configurations provide a number of options for access placement in patients with disadvantaged vascular anatomy
Short maturation period
More amenable to surgical or interventional thrombectomy

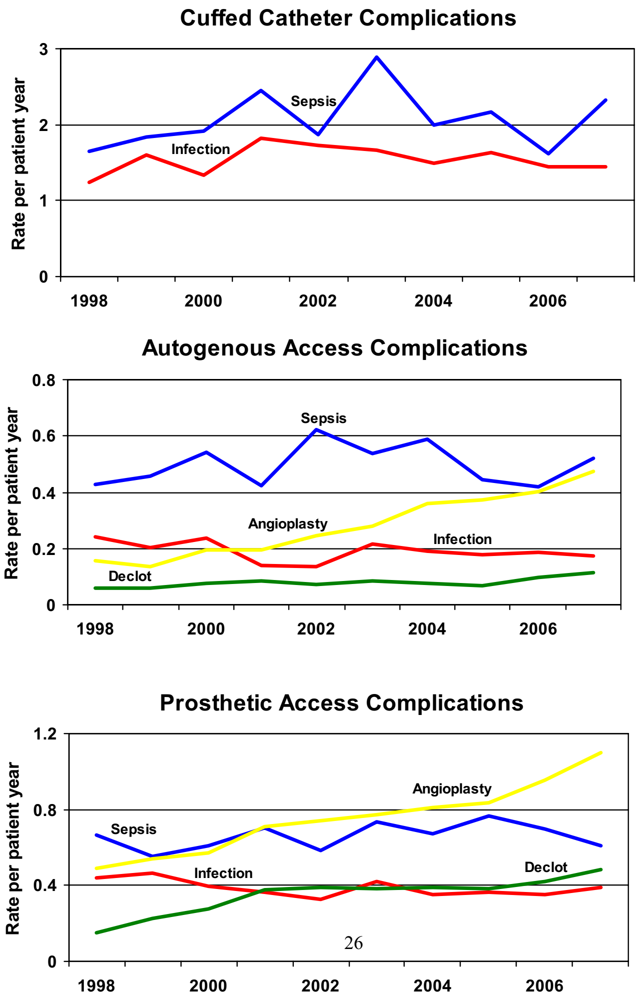

Figure 2 The access-related complications since the publication of the original Kidney Disease Outcomes Quality Initiative Guidelines are shown for cuffed catheters, autogenous accesses, and prosthetic accesses as reported from the US Renal Data System 2010 Annual Data.[4] There does not appear to be a decrease in the rates per patient-year for sepsis or infection for any of the three access types. Notably, there does appear to be an increase in the rate of angioplasty procedures for autogenous and prosthetic accesses.

use an autogenous access on their first dialysis run, while only 41% have a functioning autogenous access during their first year of dialysis. The use of autogenous access in prevalent hemodialysis patients is currently 55%. These efforts to maximize autogenous access use may have been associated with several unintended adverse consequences. Recent studies suggest that the percentage of autogenous accesses failing to mature has risen dramatically.[3,22] The increased use of cuffed dialysis catheters may also be a consequence of prolonged attempts to obtain a functional autogenous access. Unfortunately, no significant drop has been noted in the occurrence of access-related septic complications during this same period (Fig 2).[4]

It is likely that the success of KDOQI and FFBI to reduce morbidity and cost associated with vascular access have already been achieved by "picking the low hanging fruit" or the easy targets. Further efforts to increase use of autogenous access may prove to be more difficult and may even be detrimental. There are several problems outside the access surgeon's control in the United States (eg, late referral to the surgeon for vascular access, reliance on inexperienced dialysis technicians to cannulate the access) that are partly responsible for lower prevalence rate of autogenous access rate relative to other countries. Until these multiple problems are corrected, prosthetic access will continue to be a necessity in a significant proportion of the dialysis population. Surgeons who blindly attempt to create an autogenous access in every patient without first considering the likelihood of maturation and the consequences of failure will not reach the ultimate goal of providing a functional, durable vascular access for many of their patients, and it is important to emphasize that this functional, durable access is the goal, not specifically an autogenous access.

Role of the Prosthetic Vascular Access in 2011

The Society for Vascular Surgery assembled a panel of expert vascular surgeons and nephrologists in order to develop Clinical Practice Guidelines for the Surgical Placement and Maintenance of Arteriovenous Hemodialysis Access. Their recommendations were recently published in the *Journal of Vascular Surgery*.[6] Three basic principles for vascular access site selection were proposed:

1. The distal extremity access options should be considered before proximal extremity options;
2. Upper extremity access options should be expended before considering lower extremity or body wall access options;
3. Autogenous accesses are preferable to prosthetic accesses. The panel also formulated an "order of preference" for vascular access site/type selection (Table 3). This order of preference list gives a practical starting point for selecting the most appropriate vascular access for each patient.

Table 3 Society for Vascular Surgery Clinical Practice Guidelines: Vascular Access Order of Preference

Autogenous posterior radial branch-cephalic access (snuffbox fistula)
Autogenous radial-cephalic access (Cimino-Brescia fistula)
Autogenous radial-cephalic forearm transposition
Autogenous brachial-cephalic forearm looped transposition
Autogenous radial (ulnar)-basilic forearm transposition
Prosthetic forearm looped access versus autogenous upper arm access
Autogenous brachial-cephalic access
Autogenous brachial-basilic transposition
Prosthetic upper arm access
Autogenous femoral-great saphenous transposition
Autogenous femoral-femoral vein transposition
Prosthetic lower extremity access
Prosthetic chest wall access

Table 4 Factors Influencing Vascular Access Selection and Success

Clinical Scenarios Favoring Autogenous Success	Clinical Scenarios Favoring Prosthetic Access	Factors That Adversely Influence Autogenous Access Maturation
Young patient age	Imminent need for or currently on hemodialysis	Diabetes mellitus (radial and ulnar-based accesses)
Favorable vascular anatomy (artery >2.0 mm: vein >3.0 mm)	Short life expectancy	Arterial diameter <2.0 mm
Chronic skin diseases	Morbid obesity	Calcified radial artery
History of multiple previous access infections	Unfavorable vascular anatomy	Vein diameter <3.0 mm
Immunosuppression/HIV		Congestive heart failure
Hypercoagulability		Advanced patient age
Multiple prior prosthetic access failures		Female gender

Abbreviation: HIV, human immunodeficiency virus.

This order of preference list contains seven autogenous access procedure options for the upper extremity, five in the forearm and two in the upper arm. The vascular access surgeon must have these procedures in his or her surgical armamentarium. Although every patient referred for permanent hemodialysis access should be considered a potential candidate for an autogenous access as outlined on this list, an autogenous access is not superior to a prosthetic one in every clinical scenario. The presence of certain clinical or anatomic factors may justify skipping down the order of preference list to a prosthetic rather than an autogenous access. A list of clinical scenarios and factors that influence autogenous access success and may thereby favor one access over another are provided in Table 4. Although the presence or absence of one of these factors should not necessarily preclude an access option, they still should be considered when weighing the benefit of an autogenous access against the risk of its nonmaturation. Two case scenarios serve to illustrate this point.

Case 1

A 34-year-old male with ESRD due to diabetic nephropathy is referred for vascular access. The patient is not expected to require hemodialysis for at least 6 months. Radial and ulnar pulses are normal. The radial artery diameter is 1.6 mm. No suitable vein for autogenous access creation is evident on tourniquet examination in the forearm. By vein mapping, the cephalic vein diameter measures 2.0 to 2.5 mm throughout the length of the upper extremity, while the basilic vein is <2.0 mm in the forearm and 2.0 to 3.0 mm in the upper arm.

There are three factors that could adversely affect radial-cephalic autogenous access maturation in this case:

1. Radial artery diameter is small (<2.0 mm);
2. Vein diameter is small (<3.0 mm);
3. Diabetes mellitus is the underlying etiology for the renal failure.

Although it is less likely that a radial-cephalic autogenous access would mature in this case, an attempted radial-cephalic autogenous access seems reasonable because the patient is young and referred for access at least 6 months before anticipated initiation of dialysis. If the access fails to mature, there is still adequate time to create a new access without the need for a cuffed dialysis catheter. Furthermore, the placement of a radial-cephalic autogenous access does not compromise future access procedures. In short, the potential long-term benefits of a radial-cephalic access in this patient appear to justify the high risk of access failure or nonmaturation given the acceptable consequences of a failed access.

Case 2

A 78-year-old female with ESRD due to diabetic nephropathy is referred for vascular access. The patient has symptomatic, uncorrectable coronary artery disease and chronic obstructive pulmonary disease. She is on hemodialysis via a cuffed dialysis catheter. Radial and ulnar pulses are normal. The radial artery diameter is 1.6 mm. No suitable vein for autogenous access creation is evident on tourniquet examination in the forearm. By vein mapping, the cephalic vein diameter measures 2.0 to 2.5 mm throughout the length of the upper extremity, while the basilic vein is <2.0 mm in the forearm and 2.0 to 3.0 mm in the upper arm.

This patient has the same arterial and venous anatomy as the first patient. However, given the combination of her clinical factors (ie, advanced age, poor arterial and venous anatomy, multiple comorbidities), and the fact that she is already on dialysis, the consequences of an access that fails to mature are clearly increased. The relative benefit of an autogenous access as compared to a prosthetic one is not sufficient in this case to justify the risk of prolonged catheter-based dialysis and a subsequent access procedure after failure of the radial-cephalic attempt. This patient would be best served by either a looped prosthetic access in the forearm or an autogenous access in the upper arm if her anatomy was suitable.

Tertiary Access Procedures

Once the traditional access options in the upper extremity are exhausted, patients should be considered for more complex or tertiary procedures including:

1. Prosthetic thigh access;
2. Autogenous thigh access;
3. Prosthetic chest wall access; and

4. Hemodialysis Reliable Outflow (HeRO) Vascular Access Device.

The published experience with the prosthetic thigh access far exceeds that of the other three options. Indeed, the entirety of the literature documenting outcomes for the other three options comprises only a handful of small case series. Accordingly, the Society for Vascular Surgery Clinical Practice Guidelines recommendation that autogenous thigh access options are preferred to prosthetic ones is based purely on the concern that a prosthetic access is associated with a higher infection rate rather than on any direct or indirect comparison of outcomes between these procedures. In fact, during the past 40 years, only four small case reports/series comprising a total of 17 patients have reported outcomes for the autogenous femoral artery-greater saphenous vein transposition.[25-28] These reports document that early functional failure and wound complications for this procedure are common and that patency rates are poor. The thick-walled greater saphenous vein, as compared to the thin-walled cephalic and basilic veins, does not usually dilate in response to the hemodynamic changes associated with an arteriovenous fistula. Accordingly, it can be difficult to cannulate for dialysis because its diameter rarely exceeds the 6-mm target suggested for a mature autogenous access. In the author's opinion, the Society for Vascular Surgery Clinical Practice Guidelines recommendation that the autogenous femoral artery-greater saphenous vein access is preferable to a prosthetic thigh access places too much emphasis on the risk of prosthetic access infection rather than considering the overall functionality and durability of the two procedures. This is one situation where the "fistula first" dictum does not hold true.

The largest collective experience with autogenous femoral artery-femoral vein transposition was documented in two separate reports by Gradman et al.[29,30] In the initial series of 25 patients, significant access-related limb ischemia and major wound complications occurred in 32% and 28% of cases, respectively.[29] By excluding patients with ankle brachial indices of <0.85 or absent pedal pulses, modifying the surgical technique, and performing prophylactic fasciotomy for patients with diminished pulses postoperatively, no access-related steal occurred in their subsequent series of 22 patients.[30] Almost 20% of the patients in both series were children. A common problem encountered with this access configuration is that the femoral-popliteal vein complex may be too short to transpose more superficially in obese patients. However, the autogenous femoral artery-femoral vein transposition is an excellent option for young, nonobese patients with normal lower extremity arterial circulation. Unfortunately, the majority of patients who require a lower extremity access procedure do not meet these strict selection criteria.

Given the poor outcomes for autogenous femoral artery-greater saphenous vein transposition and the strict selection criteria required for the autogenous femoral artery-femoral vein transposition, the prosthetic thigh and body wall accesses play an important role in maintaining patients on long-term hemodialysis once the traditional upper extremity accesses options have been exhausted. Current experience with the HeRO Vascular Access Device (Hemosphere, Inc., Minneapolis, MN) is too limited to fully establish its role as a tertiary vascular access. The advantages of the prosthetic thigh access over other tertiary access procedures include the following: prosthetic thigh access placement is relatively simple to perform because of the accessibility and size of femoral vessels; patency rates for these accesses are comparable, if not superior, to upper extremity access procedures; surgical management of complications such as graft infection and anastomotic stenosis is easier than for accesses of the chest wall; and both of the patient's hands are free to self-cannulate the access or to perform activities during dialysis. Our group has reported one of the largest series of prosthetic thigh accesses, comprising 116 patients.[14] Although the infection rate was 41%, many of these were localized infections at the cannulation sites, permitting access salvage in the majority of cases with segmental graft resection and bypass. Most importantly, the secondary patency rate for prosthetic access in our series was a respectable 54% at 2 years, which is particularly notable given the limited access option for this subgroup of patients. Several authors have suggested that limb loss attendant to prosthetic thigh access is common, occurring in up to 8% of cases.[12] However, all of those studies were retrospective case series that failed to differentiate limb loss due to access-related limb ischemia from that resulting from progression of peripheral arterial disease. In our experience, access-related limb ischemia requiring limb amputation is uncommon.

Conclusions

A number of barriers have hampered efforts to increase autogenous access use in the United States relative to the other developed countries. Chief among these is the lack of high-quality evidence incorporating patient-specific factors that would allow development of algorithms to determine the most appropriate access procedure. Until these necessary algorithms are developed, approaches to vascular access will continue to be based largely on opinion, the outcomes will often be unsatisfactory, and prosthetic accesses will continue to play an important role in providing vascular access. It is likely that this much needed, high-quality evidence will demonstrate that mature autogenous access are superior to prosthetic ones and, accordingly, every patient should be evaluated for an autogenous configuration. However, this evaluation process should also include an assessment of the probability and consequences of nonmaturation. In cases where maturation of an autogenous access is unlikely, prosthetic access placement is justified to avoid futile procedures and prolonged catheter-based dialysis.

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