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Prosthetic thigh arteriovenous access: Outcome with SVS/AAVS reporting standards

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Purpose: **Differences in the reporting methods of results for arteriovenous (AV) access can dramatically affect apparent outcome. To enable meaningful comparisons in the literature, the Society for Vascular Surgery and the American Association for Vascular Surgery (SVS/AAVS) recently published reporting standards for dialysis access. The purpose of the present study was to determine infection rates, patency rates, and possible predictive factors for prosthetic thigh AV access outcomes with the reporting standards of the SVS/AAVS.**

Methods: **A retrospective analysis was performed of all patients who underwent placement of thigh AV access by the Surgical Teaching Service at Greenville Memorial Hospital between 1989 and 2001. Outcomes were determined based on SVS/AAVS Standards for Reports Dealing with AV Accesses. The rate of revision per year of access patency was also determined; this end point more accurately reflects the true cost and morbidity associated with AV access than do patency or infection rates alone.**

Results: **One hundred twenty-five polytetrafluoroethylene thigh AV accesses were placed in 100 patients. Nine accesses were excluded from the study, six because there was no patient follow-up and 3 as a result of deaths unrelated to the access procedure and which occurred less than 30 days after access placement. There were six (4%) late access-related deaths. There were 18 (15%) early access failures, related to infection in 14 cases (12%), thrombosis in three cases (2%), and steal in one case (1%). Early failure was more common in patients with diabetes mellitus (*$P = .036$*). The primary and secondary functional patency rates were 19% and 54%, respectively, at 2 years. Infection occurred in 48 (41%) accesses. The patency and infection rates were not influenced by patient age, gender, body mass index, or diabetes mellitus. The median number of interventions per year of access patency was 1.68, and this outcome was positively correlated with body mass index (*$P < .001$*).**

Conclusions: **Prosthetic AV access in the thigh is associated with higher morbidity compared with that reported for the upper extremity, and should be considered only if no upper extremity AV access option is available. Early access failure and the requirement for an increased number of interventions to reestablish and maintain access patency are more common in patients with diabetes mellitus and obesity. The number of interventions per year of access patency is a valuable end point when assessing the outcome of AV access procedures. (J Vasc Surg 2004;39:381-6.)**

Surgeons are often tasked to provide dialysis access for patients with no sites available for access in the upper extremity, because of venous thrombosis, axillosubclavian arterial occlusive disease, or ischemic complications. An alternative procedure for arteriovenous (AV) access after upper extremity options have been expended is the prosthetic thigh AV access.

The literature reporting outcomes for prosthetic thigh AV access is conflicting. Although some studies report a high rate of infection and limb amputation associated with prosthetic thigh AV access, others report favorable results, with patency and infection rates comparable to those achieved for prosthetic AV access in the upper extremity. These conflicting conclusions regarding prosthetic thigh AV access are the result of differences in the methods of reporting outcomes, which can dramatically alter the apparent patency rates. In an effort to enable meaningful comparisons between studies in the dialysis access literature, the Society for Vascular Surgery and the American Association for Vascular Surgery (SVS/AAVS) recently published recommended standards for reports dealing with AV access.[1]

We report our experience with prosthetic thigh AV access using the reporting standards for outcome developed by the SVS/AAVS to assess the durability, infection rate, and patient factors that influence outcome. We also determined the rate of revision per year of access patency, and factors that influence this rate. This approach for determining outcome more accurately reflects the true cost and morbidity associated with AV access than do patency rates alone.

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METHODS

Office, hospital, dialysis clinic, and operative reports were retrospectively reviewed for all patients who underwent placement of a prosthetic thigh AV access at the Surgical Teaching Service at Greenville Memorial Hospital between August 1989 and December 2001. All grafts were polytetrafluoroethylene (W. L. Gore Co, Flagstaff, Ariz)

Table I. Patient demographic data

	n	%
Number of patients*	100	
Age (y)		
Median	58	
Range	19–85	
Gender		
Male	37	37
Female	63	63
Race		
White	35	35
Black	64	64
Other	1	1
Diabetes mellitus	44	44
Body mass index		
Underweight	15	15
Ideal weight	35	35
Overweight	17	17
Obese	27	27
Unknown	6	6

*Includes patients lost to follow-up (n = 6) and patient death unrelated to the access <30 days after access placement (n = 3).

Table II. Ipsilateral limb ischemic complications after thigh arteriovenous access placement

Patient	*Ischemic complication*	*Months after access placement*	*Access status*
1	Foot ulcer	2	Patent
2	Revision, BKA to AKA	4	Patent
3	AKA	2	Patent
4	Revision, BKA to AKA	1	Patent
5	BKA	4	Patent
6	AKA	10	Patent
7	Rest pain	1	Ligated
8	Revision, BKA to AKA	4	Ligated
9	AKA	16	Patent
10	AKA	65	Patent
11	AKA	8	Thrombosed
12	Rest pain	18	Ligated
13	AKA	28	Patent

BKA, Below-knee amputation; *AKA,* above-knee amputation.

and ranged in diameter from 6 to 8 mm. The graft size was selected at the surgeon's discretion. All grafts were placed in a loop configuration. The grafts were sewn end-to-side to either the superficial femoral artery or the common femoral artery. The venous anastomosis was end-to-side to the proximal superficial femoral vein, greater saphenous vein, or common femoral vein.

Primary and secondary functional graft patency rates were determined with the reporting standards set by the Committee of Reporting Standards for AV Accesses of the SVS/AAVS. In accordance with those standards, the following criteria were used to define access patency and failure. An access was considered patent if it delivered a flow rate of 350 to 400 mL/min without access recirculation. An access that was removed, ligated, abandoned, or could not deliver an adequate flow rate was considered failed, and patency was calculated up to the time of permanent cessation of dialysis with that access. Primary patency was defined as the interval from the time of access placement until any intervention designed to maintain or reestablish access function. Assisted primary patency was defined as the interval from the time of access placement until access thrombosis, including intervening manipulations designed to maintain functioning of a patent access. Secondary patency was defined as the interval from the time of access placement until access abandonment. Survival curves were estimated with the Kaplan-Meier product limit method. The log-rank test was used to compare survival curves. Censored end points were death, transfer of care to another institution, transplantation, loss to follow-up, and access survival to the end of the study. A patient was considered lost to follow-up if dialysis records ended and transplantation or death could not be confirmed. The influence of age, gender, race, body mass index (BMI), and diabetes mellitus on patency and infection rates was examined first, with the Fisher exact test for proportions and the Wilcoxon rank sum test for medians. BMI was subdivided into four categories for analysis: underweight (BMI <18.5), ideal weight (BMI 18.5-24.9), overweight (BMI 25-29.9), or obese (BMI ≥30). Multiple linear regression and Cox proportional hazards modeling were used to assess the combined influence of risk factors on the frequency of access interventions and patency, respectively. The relationship of BMI to the frequency of access interventions was assessed with the Pearson correlation coefficient and linear regression. To calculate the number of revisions per year of access patency the following formula was used: number of surgical or percutaneous interventions performed on the access to reestablish or maintain function, divided by the number of months of access patency, divided by 12.

RESULTS

From August 1989 to December 2001, 145 thigh AV accesses were performed in 111 patients. Twenty-nine thigh AV accesses were excluded from the study, because of inadequate follow-up (n = 6), use of bovine heterograft (n = 6), and patient death unrelated to the access procedure less than 30 days after access placement (n = 3). The outcomes of 14 cryopreserved femoral vein thigh AV accesses were published in a previous report and were also excluded from the present study.[2] The study cohort was thus comprised of 116 prosthetic thigh AV accesses performed in 91 patients.

Demographic data are shown in Table I. Patients in this cohort were predominantly female (63%) and African American (64%); their median age was 58 years. Forty-four percent of patients had diabetes, and 47% were either overweight or obese. Mean patient follow-up was 20 months (range, 1-111 months).

The arterial inflow was the common femoral artery in 46 patients and the superficial femoral artery in 35 patients.

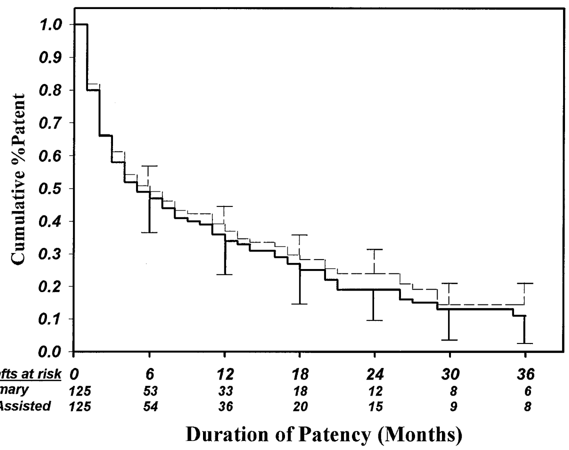

Fig 1. Kaplan-Meier survival curve for primary *(solid line)* and assisted primary *(dashed line)* functional patency. *Bars* represent 95% confidence interval.

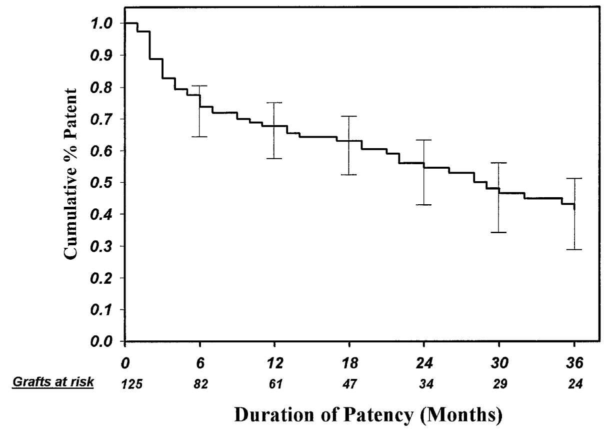

Fig 2. Kaplan-Meier survival curve for secondary functional patency. *Bars* represent 95% confidence interval.

The venous outflow was the greater saphenous vein in 46 patients, the common femoral vein in 26 patients, and the superficial femoral vein in 14 patients. The operative report did not delineate the site of the arterial anastomosis in 35 patients or the venous anastomosis in 30 patients. The site of the arterial or venous anastomosis did not influence the primary patency rate (both, $P > .2$). However, use of the common femoral artery significantly improved survival time in comparison with the superficial femoral artery: median access survival, 30 months vs 11 months, respectively ($P = .03$). Venous anastomosis was not significantly related to secondary patency ($P = .50$).

Early access failure, defined as access abandonment less than 30 days after placement, occurred in 18 (15%) patients, and was caused by infection in 14 patients and thrombosis in 3 patients. One early failure occurred in a patient whose access was ligated for treatment of arterial steal. At bivariate analysis, early access failure was significantly more common in patients who had diabetes mellitus (24%) than in those without diabetes (9%; $P = .036$). Age, gender, race, and BMI were not significantly associated with early access failure (all, $P > .1$).

The primary functional patency rate was 34% at 1 year and 19% at 2 years. The assisted primary patency rate was 37% at 1 year and 24% at 2 years (Fig 1). The secondary functional patency rate was 68% at 1 year and 54% at 2 years (Fig 2). The median access survival time was 28 months (interquartile [IQ] range 6, 79 months). Age, gender, race, diabetes mellitus, and BMI did not significantly influence secondary patency (all, $P > .1$).

Infection requiring surgical intervention (grade 2 infection, SVS reporting standards) or resulting in patient death occurred in 48 (41%) accesses. There were 14 early access infections. Twelve of the early access infections were treated with graft removal. Two patients died of sepsis before graft removal. There were 34 late access infections, which occurred between 1 and 64 months (mean, 19 months) after graft implantation. Nineteen of the late infections were localized, and were treated with the technique of segmental graft resection and bypass described by our group.[3] Fifteen of the late access infections could not be treated with segmental resection and bypass, and required complete or partial excision of the graft and abandonment of the access. The overall infection rate was not influenced by age, gender, race, diabetes mellitus, or BMI; however, early graft failure, which was most often caused by infection (14 of 18), was more common in patients with diabetes mellitus.

There were six (4%) access-related deaths due to infection. Four patients died within 30 days of removing an infected access. Two patients with access infection did not undergo graft excision, and died of sepsis.

Ipsilateral limb ischemia after thigh AV access placement occurred in 13 (11%) patients. Ten (9%) major limb amputations ipsilateral to the thigh access were performed between 1 and 65 months (mean, 14 months) after access placement. In 1 patient a foot ulcer developed 2 months after access placement. Two accesses were ligated, 1 month and 18 months, respectively, after placement for treatment of ischemic rest pain (Table II).

The median number of interventions per year of access patency was 1.68 (IQ range 0.5, 3.0). The median number of interventions per year of access patency was 0 (IQ range 0, 1.7) for patients who were underweight, 1.68 (IQ range 0.6, 3.0) for patients who were at ideal weight or overweight, and 2.28 (IQ range 1.1, 3.4) for patients who were obese. The relationship of BMI to the number of interventions per year of access patency is shown in Fig 3. There was a positive correlation between BMI and the number of interventions required to reestablish or maintain access patency ($r = 0.40$; $P < .001$).

The median patient survival from the time of the first thigh AV access placement was 24 months (IQ range 12, 62; Fig 4). Patient age and BMI were significantly associated with patient survival at multivariate analysis. The median survival for patients younger than 45 years was 41 months (IQ range 15, 75), for those 46 to 65 years was 24

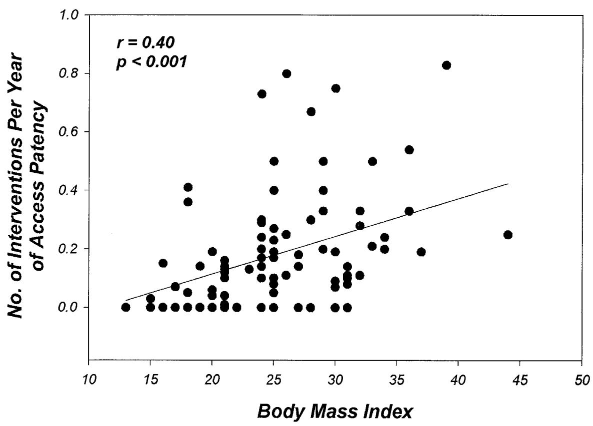

Fig 3. Scatterplot of body mass index and median number of interventions required per year of access patency. *Line* represents linear regression. Pearson correlation coefficient, 0.40; $P < .001$.

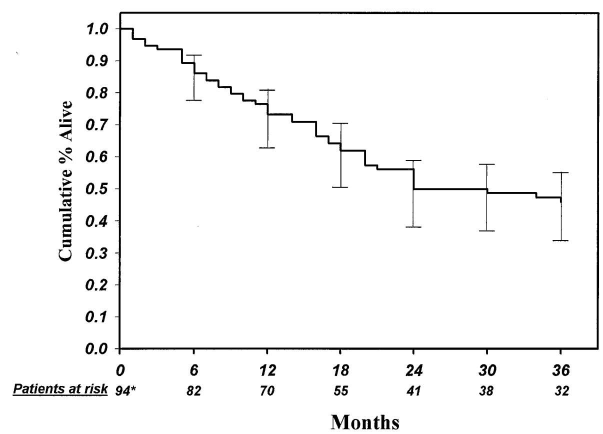

Fig 4. Kaplan-Meier survival curve for patient survival after access placement. *Bars* represent 95% confidence interval. *Excludes six patients with no follow-up.

months (IQ range 11, 62), and for those older than 65 years was 17 months (IQ range 6, 42) (P = .049). The median survival of patients who were underweight was 15 months (IQ range 12, 23), for those with ideal weight or overweight was 37 months (IQ range 17, 75), and for those who were obese was 41 months (IQ range 9, 84; $P = .029$). The median survival of patients with diabetes mellitus was 19 months (IQ range 9, 46 months), compared with survival of 38 months (IQ range 21, 45) for patients without diabetes; this difference did not reach statistical significance ($P = .095$).

DISCUSSION

Several recently published studies report the outcome of prosthetic thigh AV access.[4-7] The conclusions of these studies differ dramatically. Some suggest that thigh AV access is safe, with excellent long-term patency; others consider it a procedure of last resort, because of the high rate of complications, such as infection and arterial steal.

Tashjian et al[4] recently reported primary and secondary patency rates for prosthetic thigh AV access of 71% and 83%, respectively, at 1 year. The incidence of infection in their series was 22%. They concluded that the incidence of infection and thrombosis is comparable to that of prosthetic upper extremity AV access.[4] Khadra et al,[5] in a series of 74 polytetrafluoroethylene thigh AV accesses, reported a patency rate of 50% at 1 year and an infection rate of 16%. Bhandari et al[6] reported an 85% 1-year total access survival rate and a 35% infection rate in their series of 49 thigh accesses. In a previous series from our institution, Taylor et al[7] reported primary access patency of 52% at 1 year, and 47% at 2 years, for thigh AV access. Taylor et al[7] reported a 38% incidence of major graft complications, including an 18% incidence of infection and a 16% incidence of distal limb ischemia. Differing methods of reporting outcomes is, in large part, responsible for the disparate conclusions derived from these studies. For example, Tashjian et al[4] excluded accesses lost to infection from patency curves; whereas Taylor et al[7] defined failure as a loss of access function regardless of the cause, and included accesses lost to infection in the calculation of patency. Khadra et al[5] reported patency as mean access survival time. Patency results using mean survival time are disproportionately affected by a few accesses with prolonged patency. Bhandari et al[6] did not define patency in their series, and used a cumulative survival curve to report patency. The studies by both Taylor et al[7] and Khadra et al[5] excluded early access failures from patency calculations. The effect of different reporting methods on outcome results for AV access was demonstrated in a recent study by Hodges et al.[8]

To enable meaningful comparisons of outcomes from the AV access literature, the Committee on Reporting Standards for AV Access of the SVS/AAVS recently published reporting standards for AV access studies. Using these standards we obtained a secondary functional patency rate for thigh AV access of 68% at 1 year and 54% at 2 years. Our patency results would be similar to those achieved by Tashjian et al,[4] had they included accesses lost to infection rather than considering those accesses separately. Our patency results cannot be compared with the results of Khadra et al,[5] Bhandari et al,[6] or Taylor et al,[7] because of differences in reporting methods. However, the median patency of 24 months reported by Taylor and colleagues is similar to the 28 months obtained in the current study.

The infection rate for thigh AV access in our series was 41%. This rate included only those infections that resulted in the patient's death or required access revisions or graft excision (grade 2 infections) for treatment. We did not include those infections treated with antibiotic agents alone (grade 1 infections) in the calculation of the infection rate, because confirmation of minor infections is unreliable in a retrospective study. The infection rate in our series is similar to the infection rate of 35% reported by Bhandari et al,[6] but is higher than the

16% to 22% reported by other authors. These differences may be due to differences in patient population, completeness and duration of patient follow-up, and period of patient accrual. Both the study by Bhandari et al[6] and the present study included patients with accesses placed over 12 years, a period that is substantially longer than the other studies.

The reporting standards for AV access developed by the SVS/AAVS uses primary, assisted primary, and secondary patency as measures of success. The cost and morbidity associated with hemoaccess, however, is also significantly influenced by the number of interventions required to reestablish and maintain access patency. Consequently, we believe that the number of interventions per year of access patency should be included as an end point for AV access outcome. We show that the median number of interventions per year of access patency for thigh grafts is 1.68 and is significantly influenced by BMI.

A review of local complications such as prolonged puncture site bleeding, pseudoaneurysm, or seroma or lymphocele, and remote complications such as venous hypertension, neuropathy, and congestive heart failure was not included in our study unless these complications directly affected access function. Although these complications can result in considerable morbidity, the documentation and grading of severity of these complications is incomplete and subjective, and cannot be accurately accomplished in a retrospective study.

The reported incidence of ischemic limb complications related to thigh AV access ranges from 1% to 16%.[4-7] Ipsilateral ischemic limb complications after thigh AV access placement occurred in 11% of patients in our series, which is higher than the 4.6% to 8% incidence of limb ischemia reported for upper extremity AV access.[9,10] Several of the ischemic complications in our series, however, occurred many months after access placement or after the access had thrombosed. In these cases it could not be determined from the medical record whether limb loss was related to the AV access or to progression of arterial occlusive disease.

The literature reports a 47% to 70% secondary patency rate at 2 years and a 2% to 16% infection rate for prosthetic AV accesses of the upper extremity.[9,11,12] Results of our study indicate that the secondary patency rate for prosthetic AV accesses of the thigh is equivalent to that for the upper extremity, but the infection rate is higher. Therefore placement of prosthetic AV access in the thigh should be considered if no alternative in the upper extremity is possible.

The thigh AV access can provide prolonged, reliable dialysis access for patients who have few alternative sites for access placement. However, patient survival for those who require a thigh graft is limited, and the morbidity and mortality associated with the procedure and its complications are significant. Patients with diabetes mellitus are at increased risk for early access failure, most often caused by infection, and there is a direct correlation between BMI and the number of interventions required to reestablish and maintain access patency. It may be appropriate for patients with these risk factors, in whom life expectancy is limited, that an alternative means of dialysis, such as a tunneled cuff dialysis catheter, be considered.

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DISCUSSION

Dr Sachinder S. Hans (Warren, Mich). I have one question. What about size of the graft? Did you use any 4 by 6, or were they all 6-mm grafts?

Dr David L. Cull. Nine of the accesses were constructed with 8-mm grafts. Six-millimeter grafts were used for the remaining accesses in this series.

Dr Hans. And do you have any data on pre-op arterial status; do you have any segmental pressures or ankle-brachial indices prior to placing the grafts and then for the progression down the road?

Dr Cull. This was a retrospective study that covered a 12-year period. Although the medical record for many of these patients indicated that they had peripheral arterial disease, there was often little objective data, such as an ankle-brachial index, to establish the diagnosis.

Dr Harry Schanzer (New York, NY). I agree with the presenters that this is an access that produces a significant number of steal syndromes. In my experience, about 10% of them, at least, will develop, in 2 to 3 years, steal. I have done in the past 4 years three DRIL procedures in order to save these limbs and save the access. What have you done in this setting for your patients?

Dr Cull. We have performed DRIL procedures in the upper extremity. In this particular series of patients the DRIL procedure was not performed.

Although we had 13 ischemic complications, from this retrospective review it is extremely difficult to determine whether this was due to progression of arterial occlusive disease or related to the steal. So we really can't comment on the specific incidence of steal. Like you, I believe it is significant.

Dr G. Patrick Clagett (Dallas, Tex). I have a question. I'm very curious to know how you get so many of these patients. We have a huge access population between our VA Hospital and Parkland Hospital, and this is an extraordinarily rare access.

Dr Cull. Greenville has a drawing area of about 350,000 people. Essentially all of the vascular access is done by our group. Consequently, we have 12 dialysis units in our region, and we're responsible for taking care of all of those.

Dr Clagett. Do you not do basilic vein transposition, necklace-type accesses, axillary-axillary type of bypasses, things like those that are alternatives?

Dr Cull. We do basilic vein transpositions and forearm vein transpositions. We have a series of 20 chest wall AV accesses. We prefer the thigh AV access to the chest wall access. Although the complication rate was slightly less for the chest wall access, the management of those complications associated with the chest wall access is extremely difficult.

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