Percutaneous Creation of an Arteriovenous Fistula for Hemodialysis Access

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ABSTRACT

Purpose: Arteriovenous fistulae (AVFs) created by conventional surgical techniques are associated with suboptimal short- and long-term patency. This study investigated the feasibility of creating fistulae with a percutaneous system and evaluated the utility of percutaneous AVFs (pAVFs) in providing hemodialysis access.

Materials and Methods: From August 2012 to September 2013, a percutaneous system was used to attempt pAVF creation between the proximal ulnar artery and a closely associated ulnar vein in 33 patients. Technical success, adverse events, and time to pAVF maturity were recorded, as was clinical effectiveness at 6 months.

Results: A pAVF was successfully created in 32 of 33 patients (97%). Four patients died during the follow-up period from causes unrelated to the procedure; one patient was lost to follow-up. Of the remaining 27 patients, 24 were undergoing successful dialysis via their pAVF at 6 months. Two additional patients had usable access but did not initiate dialysis during the study. One spontaneous pAVF thrombosis occurred in a patient with preexisting central vein stenosis. Cumulative pAVF patency at 6 months was 96.2% (26 of 27; standard error, 3.8%). Mean time to pAVF maturation was 58 days (range, 37–168 d). There was one serious procedure-related adverse event and five minor procedure-related adverse events.

Conclusions: Although larger studies are required to validate efficacy in a wide range of patients, this study demonstrates hemodialysis access successfully created with an endovascular catheter-based system. Patency of pAVFs and time to maturation were superior to published results of surgical techniques.

ABBREVIATIONS

AVF = arteriovenous fistula, pAVF = percutaneous arteriovenous fistula, RF = radiofrequency

Two million people worldwide rely on hemodialysis to sustain life (1). Creating and maintaining a useable vascular access is essential in the care of patients undergoing hemodialysis. Traditionally, vascular access is created by one of three methods: (i) creation of an autogenous arteriovenous fistula (AVF), in which a surgical anastomosis is made between a superficial vein and a neighboring artery; (ii) implantation of an arteriovenous graft, in which a prosthetic graft tunneled just beneath the skin is surgically interposed between an artery and vein; or (iii) placement of an indwelling central venous dialysis catheter (2). There is consensus that the AVF is preferable because it avoids the high incidence of catheter-related infection and central vein complications associated with catheters and the need for frequent thrombectomies and surgical revisions associated with arteriovenous grafts (3,4).

In 1966, Brescia and colleagues (5) first described surgical creation of an AVF between the radial artery and the cephalic vein as a means to provide hemodialysis access after they noted ease of phlebotomy in patients with posttraumatic AVFs. Since then, numerous surgical fistulae have been described, created with the use of a variety of arteries and veins, including the brachial artery to cephalic vein, ulnar artery to basilic vein, and brachial artery to basilic vein (6,7). Despite significant

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advances during the past five decades, results of surgical AVFs are still suboptimal. Acute thrombosis occurs in 20% of cases, and 20%–60% of AVFs fail to mature (8–12). Successful fistulae require an average of two additional catheter-based procedures to facilitate maturation, resulting in delays of 7 months or more until usable access is available (13,14).

The present study was designed to assess the utility of a novel catheter-based system for the creation of AVFs between closely apposed arteries and veins and to compare acute patency, durability, and time to maturation of percutaneous AVFs (pAVFs) versus published surgical results.

MATERIALS AND METHODS

Study Design

This was a nonrandomized, prospective study intended to evaluate safety and efficacy of a percutaneous system (TVA Medical, Austin, Texas) for the creation of pAVFs in patients who required long-term hemodialysis. The three primary endpoints of the study were (i) successful creation of a patent pAVF between an upper-extremity artery and vein; (ii) dilation (ie, maturation) over time of a superficial vein of size and flow characteristics suitable for hemodialysis access assessed on a monthly basis with Doppler ultrasound (US); and (iii) occurrence of adverse events assessed with clinical examination and/or with US or angiography. The secondary endpoint was hemodialysis via the pAVF access for at least 75% of sessions over a 1-month period after AVF maturation (based on North American Vascular Access Consortium definition of fistula functionality as prescribed dialysis with two-needle cannulation for at least two thirds of dialysis sessions in 1 month [15]). Inclusion and exclusion criteria are listed in **Table 1**.

Patient Population

This study met Declaration of Helsinki guidelines related the conduct of research in human subjects. The protocol was approved by the institutional review board at Italian Hospital (Asuncion, Paraguay), and all patients provided written informed consent. From August 2012 to

Table 1. Inclusion and Exclusion Criteria

Inclusion criteria
Requiring vascular access procedure for long-term hemodialysis; candidacy for native surgical AVF
Advanced (stage 4/5) CKD; elective hemodialysis
$\leq$ 2 mm between target artery and vein
Target vein diameter $\geq$ 2.0 mm
Target artery diameter $\geq$ 2.0 mm
Not pregnant
Age $\geq$ 18 y
Estimated life expectancy > 1 y
Ability to consent to study
Exclusion criteria
Severe CHF (ie, history of decreased cardiac output, ejection fraction < 20%)
Age > 80 y
Immunosuppression, degenerative connective tissue disease (eg, Marfan, Ehlers–Danlos syndromes), lupus erythematosus if patient receiving immunosuppressants or high-dose prednisone (> 10 mg/d orally)
Central venous stenosis or upper-extremity venous occlusion ipsilateral to artery-to-vein connection
Excessive arm diameter preventing identification of superficial veins
Body mass index >40 kg/m^2
Documented history of drug abuse within previous 6 mo
"Planned" concomitant surgical procedure or major surgery within previous 30 d
Current treatment with another investigational device or drug
Known bleeding diathesis
Known or suspected concomitant bacterial, fungal, viral, or parasitic infection, including HIV in patients with CD4 counts < 200, but excluding hepatitis B/C
Severe underlying comorbidity or immediately life-threatening condition
Any condition that, in the investigator's opinion, could preclude evaluation of treatment response, prevent completion of follow-up, or affect patient safety
History or physical examination findings suggesting significant arterial insufficiency or occlusive disease that could affect patient safety or fistula performance in target extremity (eg, steal syndrome, hand ischemia, peripheral arterial/venous vascular disease)
Sclerotic/occluded cephalic and basilic veins within arm on preprocedural US

AVF = arteriovenous fistula, CHF = congestive heart failure, CKD = chronic kidney disease.

September 2013, 61 patients were screened for the study, and 33 (54%) were prospectively enrolled (Table 2). Screening included performance of an Allen's test on each patient. Previous access surgery was not an exclusion criterion, with four patients having undergone failed surgical arteriovenous accesses. Twenty patients were excluded because of absence or occlusion of the cephalic or basilic vein or because the veins were less than 2 mm in diameter. Each study patient was undergoing hemodialysis by indwelling catheter at the time of enrollment (n = 31) or was expected to require dialysis within the next 6 months (n = 2). Table 2 summarizes patient demographics.

Fistula Anatomy

A short segment of the proximal ulnar artery is flanked closely on either side by median and lateral ulnar veins. These originate as interosseous veins in the forearm and join the ulnar vein 4–5 cm from the brachial bifurcation. Proximally, they continue into the upper arm as the brachial veins. This short segment of ulnar artery between the brachial bifurcation and the origin of the interosseous branch is the desired location for creation of a pAVF: an ulnar artery–to–ulnar vein fistula. The ulnar veins at this anatomic location connect to the median antecubital, cephalic, and basilic veins by deep perforating branches (16). The location of the fistula created is somewhat similar to the surgically created Gracz fistula, which is described as a surgical anastomosis between the brachial artery and a deep venous perforator within the upper forearm (6). Consistency of this anatomic finding was confirmed in extensive human cadaveric dissections, methyl methacrylate vascular casts, and, ultimately, in our clinical study (Fig 1).

Percutaneous Arteriovenous Catheter System

The pAVF catheter system consists of a pair of over-the-wire 6-F catheters with small but powerful rare-earth magnets arranged to pull them into alignment and opposition. Integral to the venous catheter is a constrained, spring-loaded electrode. When the catheters are placed in their respective vessels and maneuvered into correct alignment, the electrode and a ceramic facet on the arterial catheter are brought into proximity. When the constrained electrode is released and subsequently energized with radiofrequency (RF) cutting current, tissue is vaporized, resulting in precisely aligned transmural incisions in both artery and vein walls.

Procedure

Patients received intravenous sedation and local anesthesia. The arm was immobilized with a dedicated padded arm board and Velcro straps, and heparin 1,000 U (an arbitrarily chosen dose) was administered intravenously. US-guided venipuncture of the brachial vein was performed in the mid-upper arm with a 21-gauge needle, and a 7-F vascular sheath was introduced. A guide wire was advanced into the ulnar vein with the aid of a selective catheter. The brachial artery was then accessed with a 21-gauge needle in an antegrade direction in the upper arm, and a 6-F vascular sheath was placed. The arterial and venous catheters were advanced under fluoroscopic guidance over 0.018-inch wires to the anatomic site previously described, after verification of position with angiography via a 4-F catheter. The pAVF catheters were rotated to bring the magnets into correct orientation, resulting in radiographic alignment and attraction of the catheters. The spring-loaded electrode was released from its housing, and correct alignment and orientation were reconfirmed fluoroscopically. RF cutting current was delivered for approximately 1 second, and electrode motion resulting from vaporization of tissue was confirmed by fluoroscopy. The spring-loaded electrode on the venous catheter was retracted, and both pAVF catheters were removed. No implant or other material was retained. An arteriogram was then obtained through the 6-F arterial sheath to verify pAVF creation and rule out extravasation (Fig 2). The cannulated brachial vein at the puncture site in the mid-upper arm was then occluded by coil embolization (Nester, 4–8 mm; Cook, Bloomington, Indiana) to decrease fistula flow into the deep venous system (to direct more flow to the superficial system via communicating perforators in the forearm), and the sheaths were removed. No antiplatelet medications were prescribed following the procedure.

Table 2. Patient Demographics

Characteristic	Group A (n = 7)	Group B (n = 9)	Group C (n = 8)	Group D (n = 9)	Total (N = 33)
Age (y)	48.6 ± 13.9	51.8 ± 9.4	49.8 ± 10.8	53.3 ± 12.9	51.0 ± 11.4
Male sex	5 (71)	4 (44)	4 (50)	7 (78)	20 (61)
BMI	24.9 ± 4.8	22.9 ± 2.4	25.4 ± 5.0	24.0 ± 3.2	24.3 ± 3.8
BMI ≥ 25 kg/m^2	3 (43)	2 (22)	3 (38)	2 (22)	10 (30)
Diabetes	2 (29)	4 (44)	7 (88)	6 (67)	19 (58)
PVD	0	0	2 (25)	0	2 (6.1)

Note–See *Evolution of Technique* for descriptions of the treatment groups. Values are presented as mean ± standard deviation where applicable.
BMI = body mass index, PVD = peripheral vascular disease.

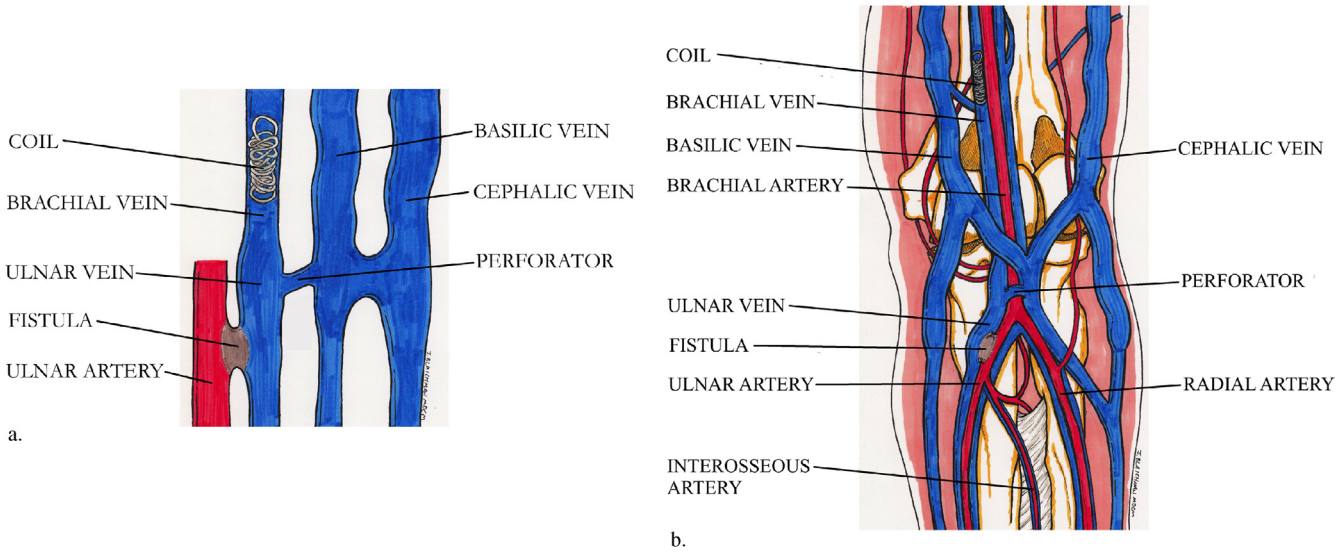

Figure 1. Vascular anatomy of the proximal forearm and site of pAVF creation. **(a)** Simplified diagram of the pAVF created. **(b)** Anatomic illustration of the pAVF created with coil embolization of upper-arm brachial vein and dilation of outflow veins that follows creation.

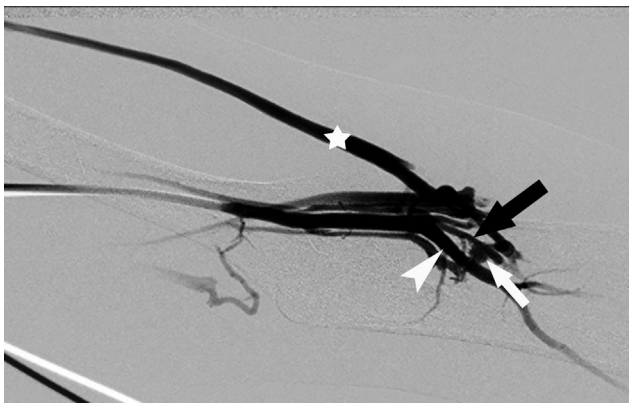

Figure 2. Angiogram after pAVF creation. Injection of contrast medium from the brachial artery sheath demonstrates rapid filling of the cephalic vein (white star). The pAVF (white arrow) is created between the ulnar artery (white arrowhead) and ulnar vein (black arrow).

Evolution of Technique

The 33 patients were enrolled into four separate treatment groups, designated groups A, B, C, and D according to when their procedure was performed. Patients in group A (n = 7) each received an axillary nerve block with 1% lidocaine as well as intravenous propofol titrated for sedative effect. Each patient subsequently underwent coil embolization of the dominant (ie, largest) brachial vein 1–2 months after AVF creation in a second catheter-based procedure. Patients in group B (n = 9) each underwent the same procedure as those in group A with the addition of a padded arm board and Velcro straps to decrease any arm movement that resulted from neuromuscular excitation at the moment of RF current delivery. Following a revision in protocol approved by the local institutional review board, patients in group C (n = 8) each underwent the same procedure as patients in group B, but with coil embolization of the brachial vein performed during the same procedure immediately after AVF creation. Patients in group D (n = 9) each underwent the same procedure as patients in group C, but with only mild intravenous sedation (with midazolam and fentanyl) and no intravenous propofol or axillary nerve block.

Definitions

Technical success was defined by creation of a patent connection between the proximal ulnar artery and the adjacent vein, with brisk flow demonstrated by angiography and absence of appreciable extravasation. The pAVF was considered mature when the treating nephrologist clinically assessed the fistula and considered the flow (brachial artery flow rate $\geq$ 500 mL/min) and vein diameter ($>$ 4 mm) to be adequate to support dialysis. Brachial artery flow has been recommended as an accurate method to evaluate AVF maturation (17,18). The intervention rate was the number of interventions following pAVF per patient over the duration of the study.

RESULTS

Technical success was achieved in 32 of 33 cases (97%). In the single case of technical failure, no fistula was created; however, there was no US or angiographic evidence of extravasation or vessel injury. Follow-up evaluation at 24 hours by Doppler US confirmed continued patency of 32 of 32 pAVFs.

Of the 32 patients with patent pAVFs, four died at various intervals from causes unrelated to the device or procedure. Causes of death included myocardial infarction, gangrenous intestine, diabetic foot infection with sepsis, and hyperkalemia-induced lethal dysrhythmia. In

three of the cases, death occurred in the first 2 months, before maturation of access (Fig 3).

The remaining 28 patients were deemed to have mature hemodialysis access at an average of 58 days (range, 37–168 d; standard deviation, 32 d). Average brachial artery flow rate 1 month after pAVF creation was 990 mL/min ± 580. In 24 of the 28 patients, the access was being used successfully to deliver hemodialysis at 6 months. Two patients with patent pAVFs and mature access did not require hemodialysis during the study period. One patient died after receiving dialysis for 1 month. One patient with documented central vein stenosis developed upper-extremity venous hypertension and arm swelling after pAVF creation that precluded successful access. Thrombosis of the pAVF was documented after 3.5 months. Cumulative patency of pAVFs was 96.2% at 6 months (standard error, 3.8%). Although the secondary outcome was pAVF hemodialysis use for 75% of sessions in the present study, only two patients did not have use of their pAVF for 100% of their dialysis sessions. Both had cannulation injuries that resulted in hematomas that prevented 100% use but resolved, allowing for greater than 75% use (Table 3).

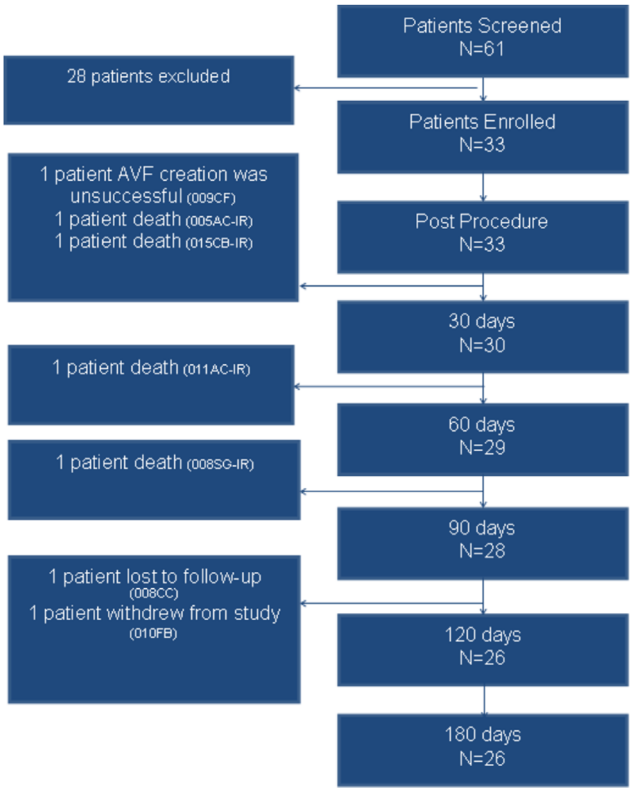

Figure 3. Patient outcomes. (Available in color online at *www.jvir.org*.)

The overall intervention rate was 0.6 per patient (1.1 in groups A and B and 0.1 in groups C and D). Patients in group A (n = 7) and group B (n = 9) required a subsequent catheter-based intervention 1–2 months after the index procedure, during which coil embolization of the dominant brachial vein was performed to decrease pAVF flow to the deep system. Additional interventions in groups A and B included one surgical AVF, two thrombin injections, and two balloon angioplasties of the cephalic vein. Patients in group C (n = 8) and group D (n = 9) underwent coil embolization of the brachial vein during the index procedure. In groups C and D, only one intervention was required (balloon angioplasty of central vein).

Six patients experienced device- or procedure-related adverse events, one serious and five minor. The serious event (in a patient in group A) was a pseudoaneurysm 3 cm in length noted at 1-month follow-up that was successfully treated with thrombin injection. A second small (<1 cm) pseudoaneurysm was noted in another patient in group A but required no treatment. Two additional patients developed small periarterial hematomas at the brachial artery access site that resolved spontaneously. The tip detached from the venous catheter during removal after successful pAVF creation in a fifth patient, necessitating a 3-cm incision for retrieval. One additional patient with preexisting central vein stenosis developed arm swelling and venous hypertension that precluded successful access. Thrombosis of the pAVF was noted after 3.5 months, as described earlier.

Table 3. Study Results

Outcome	Total	Group A	Group B	Group C	Group D
Primary endpoints (%)					
Technical fistula success at 24 h	97 (32/33)	86 (6/7)	100 (9/9)	100 (8/8)	100 (9/9)
Vein maturation at 3 mo	96 (27/28)	100 (6/6)	100 (9/9)	83 (5/6)	100 (7/7)
Serious device- or procedure-related adverse events	3 (1/33)	14 (1/7)	0 (0/9)	0 (0/8)	0 (0/9)
Additional analyses (%)					
Patency at 6 mo	96 (25/26)	100 (5/5)	100 (8/8)	83 (5/6)	100 (7/7)
Dialysis initiation/ready with AVF	96 (27/28)	100 (5/5)	100 (9/9)	86 (6/7)	100 (7/7)
Receiving dialysis with AVF > 1 mo	96 (25/26)	100 (4/4)	100 (8/8)	86 (6/7)	100 (7/7)
Mean time to fistula maturation (d)	58 (n = 27)	108 (n = 5)	62 (n = 9)	37 (n = 6)	37 (n = 7)

Note–See *Evolution of Technique* for descriptions of the treatment groups.
AVF = arteriovenous fistula.

No other patients experienced arm swelling or venous hypertension. In addition, there was no evidence of arterial steal or peripheral neuropathy in any patient. Patients did not report any significant pain during or after the procedure.

DISCUSSION

In the present study, hemodialysis access was successfully created with an endovascular catheter-based system. pAVF patency and time to maturation were superior to results reported in the surgical literature (13,19,20).

The feasibility of this approach was first suggested by findings in patients with penetrating injuries to the extremities resulting in posttraumatic AVFs (5). In many of these patients, angiography demonstrated a fistula without extravasation or hematoma. This suggested that arterial and venous injuries, if appropriately aligned in vessels that are in close proximity, resulted in blood flow from the high-pressure artery directly into the low-pressure vein. As a result, there is no appreciable extravasation even though the artery and vein are not sutured, coupled, or connected in any way.

Posttraumatic AVFs are often durable, requiring surgical or endovascular repair as they rarely close spontaneously (21). AVFs created surgically frequently close spontaneously, possibly because of the segment of vein that is deprived of its vascular supply during surgical mobilization in creating dialysis access, which develops intimal hyperplasia as a means of reducing wall tension and improving vein wall perfusion (22,23). Perhaps it is caused by inflammatory mediators released as a result of surgical trauma and soft-tissue dissection. For whatever reason, it is compelling to think that a technology that creates precisely aligned, clean, linear incisions in an artery and vein in close proximity without vein mobilization or surgical trauma might result in formation of an AVF with greater durability than traditionally reported for surgical AVF patency.

Although the lack of surgical connection between the vessels makes the nature of the fistula we describe unusual, the location is not. Several types of surgically created AVFs in the proximal forearm have been described, including the Gracz, Konner, and median cephalic vein–to–radial artery fistulae (6,7,24–26). AVFs constructed to a deep vein, resulting in arterialization of superficial veins by deep communicating perforators, are associated with excellent results (25). However, the proximal ulnar artery is difficult to expose surgically, so it is unlikely that this site will have been used in a previous surgical AVF attempt. Therefore, it is probable that this anatomic site will be available for pAVF creation in patients who have undergone numerous failed surgical attempts. In addition, the site of pAVF creation does not affect future common sites of surgical creation of fistulae and grafts in the proximal forearm and above the elbow.

Three of the technical problems reported in the present study occurred in the first seven patients treated. These include the two patients in whom pseudoaneurysms developed during the first month and the patient in whom no pAVF was created. In each case, elbow flexion was pronounced at the moment of energy delivery. Cine review demonstrated significant motion of the catheters relative to one another. In the unsuccessful pAVF attempt, the catheters completely separated during elbow flexion. In subsequent patients (groups B, C, and D), a dedicated padded arm board with integrated Velcro straps was used to immobilize the arm. After this change in technique was implemented, no pseudoaneurysms or technical failures occurred. In addition, patients in group A received heavy sedation with propofol and an axillary nerve block in an effort to decrease procedural discomfort. Despite our efforts, arm motion still occurred during energy delivery. We learned from patient interviews that the arm motion was a result of direct electrical neuromuscular stimulation and not discomfort. Adding the arm-board immobilization made it possible to dispense with the intravenous propofol and axillary nerve block.

The one late occlusion in the present series occurred in a patient in whom arm swelling and venous hypertension occurred 2 days after the pAVF was created. Although pAVF patency was verified by Doppler US at 2 months, the brachial artery flow rate, which had been measured at 615 mL/min at 1 month, decreased to 390 mL/min at 2 months. Venography revealed significant ipsilateral subclavian vein stenosis, but balloon venoplasty was unsuccessful. Subsequent Doppler US at 3.5 months demonstrated pAVF occlusion.

Although it is premature to make declarative statements about the relative merits of pAVF creation compared with the traditional surgical approach, there are some encouraging trends to observe in the present small series. The acute technical success rate of 97% (32 of 33 cases) compares favorably with the 93% rate reported for surgical AVFs (8,27,28). In addition, the late dialysis suitability failure rate of 3.5% (one of 28) with pAVF compares very favorably with reported surgical rates of 20%–60% (9). The present patient population was similar to that of the study of Dember et al (9) in regard to age, sex, diabetes, and peripheral vascular disease. The exception was that the present study population had a lower average body mass index (9). In addition, the need for an average of 0.6 subsequent interventions per patient compares favorably with the two additional procedures per patient reportedly required after surgical AVF creation (13). Time to maturation was considerably shorter with the percutaneous approach as well, requiring an average of 58 days, compared with 159 days (range, 77–285 d) for surgical AVF procedures (13,19,29–31). In group D, patients were ready for dialysis at 37 days $\pm$ 0.5 (n = 7).

The development of a percutaneous approach for the creation of durable hemodialysis access may also be

valuable from an economic standpoint. pAVFs created required fewer maturation interventions, which may translate into fewer subsequent interventions. In addition, if the technology enables a wider group of physicians to participate in access creation, perhaps a larger percentage of patients will avoid temporary placement of an indwelling central venous dialysis catheter, potentially positively impacting the associated increased risks and health care costs. These potential cost benefits will need to be assessed in future prospective studies.

The present study is limited by a patient population that had an average body mass index lower than the average seen in the United States. Our follow-up by study design was limited to 6 months. Longer follow-up may have allowed evaluation of the durability of the fistulae created. Finally, the study was not randomized to include a surgical treatment group for comparison.

In summary, we demonstrate successful creation of autogenous hemodialysis access with an endovascular system. In the present study, pAVF patency and time to maturation were superior to results reported in the surgical literature. Additional studies and longer follow-up in a wider range of patients will be required.

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