Autogenous radial-cephalic or prosthetic brachial-antecubital forearm loop AVF in patients with compromised vessels? A randomized, multicenter study of the patency of primary hemodialysis access

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Objective: **The construction of an autogenous radial-cephalic direct wrist arteriovenous fistula (RCAVF) is the primary and best option for vascular access for hemodialysis. However, 10%-24% of RCAVFs thrombose directly after operation or do not function adequately due to failure of maturation. In case of poor arterial and/or poor venous vessels for anastomosis, the outcome of RCAVFs may be worse and an alternative vascular access is probably indicated. A prosthetic graft implant may be a second best option. Therefore, a randomized multicenter study comparing RCAVF with prosthetic (polytetrafluoroethylene [PTFE]) graft implantation in patients with poor vessels was performed.**

Methods: **A total of 383 consecutive new patients needing primary vascular access were screened for enrollment in a prospective randomized study. According to defined vessel criteria from the preoperative duplex scanning, 140 patients were allocated to primary placement of an RCAVF and 61 patients to primary prosthetic graft implantation. The remaining 182 patients were randomized to receive either an RCAVF (n = 92) or prosthetic graft implant (n = 90). Patency rate was defined as the percentage of AVFs that functioned well after implantation.**

Results: **Primary and assisted primary 1-year patencies were 33% ± 5.3% vs 44% ± 6.2% (*P* = .03) and 48% ± 5.5% vs 63% ± 5.9% (*P* = .035) for the RCAVF and prosthetic AVF, respectively. Secondary patencies were 52% ± 5.5% vs 79% ± 5.1% (*P* = .0001) for the RCAVF and prosthetic AVF, respectively. Patients with RCAVFs developed a total of 102 (1.19/patient-year [py]) vs 122 (1.45/py; *P* = .739) complications in the prosthetic AVFs. A total of 43 (0.50/py) interventions in the RCAVF group and 79 (0.94/py) in the prosthetic graft group were needed for access salvage (*P* = .077).**

Conclusions: **Although there were more interventions needed for access salvage in the patients with prosthetic graft implants, we may conclude that patients with poor forearm vessels do benefit from implantation of a prosthetic graft for vascular access. (J Vasc Surg 2005;42:481-7.)**

A well-functioning vascular access remains the lifeline of end-stage renal disease patients needing chronic intermittent hemodialysis. The Kidney Dialysis Outcomes Quality Initiative (K/DOQI) and European guidelines for vascular access propose the construction of an autogenous radial-cephalic direct wrist arteriovenous fistula (RCAVF) as the primary and best option.[1,2] The usefulness of an RCAVF depends on an efficient dilatation and arterialization of the forearm veins used for the creation of arteriovenous anastomosis, which makes repeated successful cannulations possible. RCAVFs that mature without any early complications may function for many years. However, 10%-24% of RCAVFs thrombose directly after operation or do not function adequately due to failure of maturation.[3-7] This results in delay of initiation of dialysis treatment with the need for placement of central venous catheters with their related morbidity and mortality. Usually, arteriovenous fistula (AVF) nonmaturation depends on the quality and size of the vessels used for the arteriovenous anastomosis and the ability of vessel adaptation induced by the augmented blood flow volumes. To predict successful maturation, duplex-derived criteria have shown beneficial effects of using well-sized radial arteries and cephalic veins.[8-10]

In cases of very small or diseased arteries and/or veins, the risk of access failure is probably higher and an alternative vascular access may be considered. However, there are only few data on the outcome of RCAVFs in patients with poor or questionable vessels, and no information on the

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performance of alternative access in these patients is available. An upper arm direct AVF, anastomosing the brachial artery with the cephalic or basilic vein may be a good second best option after failure of an RCAVF, but in K/DOQI guidelines, no consensus for either this option or the implantation of a prosthetic graft implant has been outlined. In addition, upper arm access has a considerably higher incidence of peripheral ischemia and cardiac failure due to high access flow. Therefore, to address this subject, we performed a randomized multicenter study comparing RCAVF vs forearm prosthetic graft (polytetrafluoroethylene [PTFE]) implantation in patients with poor (questionable) vessels.

METHODS

Between January 1999 and April 2003, 383 consecutive new patients from six dialysis facilities with end-stage renal failure were screened for enrollment in the study. This study was approved by the Medical Ethics Committee of all participating hospitals. According to the defined vessel criteria from the preoperative duplex scanning, 140 patients were allocated to primary placement of an RCAVF and 61 patients to primary prosthetic graft implantation. The remaining 182 patients (97 men, 85 women; mean age, 59 years) were randomized to receive either an RCAVF (n = 92) or prosthetic graft implant (n = 90) (Fig 1). Patient characteristics of both groups are shown in Table I. Preoperative assessment included a standard physical examination and blood pressure measurement on both arms according to the Riva-Rocci method with a proximal pressure cuff and auscultation of the brachial artery. All patients underwent preoperative duplex ultrasonography of the arteries and superficial veins of the upper extremity. Duplex scanning was performed according to a standard protocol by experienced vascular technicians. The angle of the emitted Doppler ultrasound wave from the probe was adjusted to 60 degrees to achieve the Doppler signal of the strongest intensity. The anteroposterior internal diameter of the vessel was measured using B-mode technique with a proximal tourniquet to engorge the veins. Vessels were diagnosed as obstructed when no Doppler signal could be obtained. From the literature, we defined certain vessel diameters as cutoff values for randomization. When the radial artery had a diameter <1 mm with or without an absent cephalic vein, patients were allocated to implantation of a prosthetic brachial-antecubital forearm loop access. When the radial artery was >2 mm and the cephalic vein was 1.6 mm, an RCAVF was created. Patients with a radial artery between 1 and 2 mm and/or a cephalic vein ≤1.6 mm were randomized for the creation of either an RCAVF or prosthetic brachial-antecubital forearm loop.

The number of complications and interventions were registered and primary, assisted primary, and secondary patencies were calculated by life table methods.

Surgical procedure. All procedures were performed under local/regional or general anesthesia with the use of antibiotic prophylaxis. RCAVFs were constructed by exposing the radial artery and cephalic vein through a longitudinal or transverse incision 4-5 cm proximal of the radial styloid process. After sufficient vein mobilization an end-to-side vein-to-artery anastomosis was performed with a running 7-0 polypropylene monofilament suture (Prolene; Ethicon, Johnson & Johnson, Amersfoort, The Netherlands). The length of the arteriotomy was 10-15 mm and internal vessel diameters were measured with coronary probes. Thin-walled stretch PTFE grafts (Gore-Tex, WL Gore & Associates, Flagstaff, Ariz) with a wall thickness of 0.5 mm and an internal diameter of 6 mm, were positioned in a subcutaneous loop with the use of a tunneler device in the forearm between the brachial artery and a suitable elbow vein. Arterial and venous anastomoses were created with running 7-0 polypropylene sutures. AVF patency was confirmed perioperatively by palpation and Doppler examination. Coumarin (Sintrom [acenocoumarol]; Novartis Pharma GmbH, Nürnberg, Germany) was given after surgery to all patients in a dose that was sufficient for an adequate anticoagulation (international normalized ratio >2.5) for a period of 3 months. Postoperative evaluation was done by palpation and auscultation. Patients were regularly seen by the nephrologist, and the decision to start dialysis treatment was made based on the severity of deterioration of renal function. The first cannulation of the RCAVF was performed when the vessels had matured adequately, usually after 4-6 weeks. When cannulation was not possible due to nonmaturation, dialysis was started by means of a central vein catheter.

Follow-up. Clinical follow-up was performed during a 12-month period. Early and late complications and radiographic and surgical interventions were registered. Complications were treated according to the standard clinical practice of the hospital where the patient was being dialyzed. Patency was defined as functional patency with adequate dialysis. Clinical criteria were used for detection of AVF thrombosis and nonmaturation. Inability to cannulate the AVF or to obtain sufficient dialysis blood flow (≥250 mL/min) within 6 weeks after fistula creation were indicators of a poorly functioning AVF. All patients with nonmaturing RCAVFs underwent angiography, visualizing the proximal arterial inflow by retrograde contrast filling initiated through a proximal occluding cuff. Venous outflow vessels were imaged by contrast injection after the release of the proximal cuff.

End points. End points were defined as AVF failure, death, successful kidney transplantation, or transfer to continuous ambulatory peritoneal dialysis (CAPD) treatment.

Statistical analysis. For statistical analysis, the statistical package of SPSS 11.0 for Windows (SPSS, Inc., Chicago, Ill) was used. Before the start of the study, a power calculation had been performed to determine the number of patients needed per group to demonstrate an improvement in 1-year primary patency rate of 18%. For a power of 80%, at $\alpha = 0.05$, the resulting group size was 90 patients per study group. The incidence rate was defined as the number of complications or interventions per patient-year (py), the cumulative follow-up time of all patients and analyzed with the Mann-Whitney test. Patency rates were

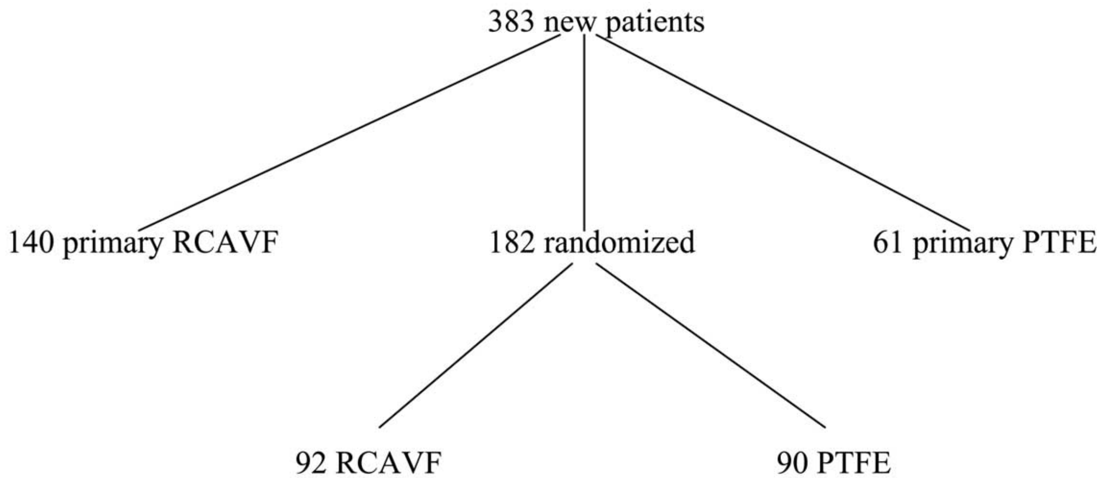

Fig 1. Algorithm for the creation of vascular access in new patients.

Table I. Patient characteristics in patients with RCAVF and prosthetic AVF

	RCAVF	*Prosthetic AVF*
No.	86	84
Male	44 (51%)	45 (54%)
Mean age (y)	57.6	62.5
Diabetes	27 (31%)	26 (31%)
Hypertension	69 (80%)	56 (67%)
Ischemic cardiac disease	11 (13%)	17 (20%)
Peripheral arterial obstructive disease	13 (15%)	18 (21%)
Cerebrovascular disease	9 (10%)	12 (14%)

RCVAF, radial-cephalic direct wrist arteriovenous fistula; *AVF,* arteriovenous fistula.

obtained by Kaplan-Meier life table analysis and compared with the log-rank test. Primary patency rate was defined as the percentage of AVFs that functioned well without any intervention after implantation. Assisted primary patency rate was defined as the percentage of failing but still patent AVFs undergoing elective intervention, and secondary patency was defined as the proportion of patent AVFs still in use for hemodialysis after successful intervention for thrombosis.[11] Patients with a patent AVF who died, received a kidney transplant, or were withdrawn from hemodialysis alive were censored. Differences were considered statistically significant when $P < 0.05$.

RESULTS

Of the patients randomized for an RCAVF, one patient was still waiting for an operation, one patient underwent a successful kidney transplantation while waiting for an operation, three patients died before undergoing the operation, and one patient was lost to follow-up. A total of 86 patients randomized for an RCAVF were subjected to further analysis. Six patients exhibited insufficient wrist vessels noticed during the operation and received PTFE graft AVFs. These six cases were considered primary failures. Fifty-nine percent of the RCAVFs were functional for dialysis treatment after 6 weeks, resulting in a primary failure rate of 41% due to early thrombosis (n = 8), failure to mature (n = 21), or insufficient vessels noticed during operation (n = 6). After 6 weeks, one patient developed steal (1.2%) with the need for fistula ligation, one patient was lost to follow-up, one patient stopped dialysis treatment, and eight patients died in the first year after creation of the RCAVF. Of the patients randomized for a prosthetic AVF, two patients were still on the list for operation, and four patients died before undergoing the operation. A total of 84 patients randomized for prosthetic graft implant were subject for further analysis. In one patient, it was not possible to implant a prosthetic graft due to abnormal vascular anatomy at the elbow; this patient received an RCAVF. The mean brachial artery diameter in the prosthetic group was 3.8 mm (range, 2.0-6.0 mm) and the mean cephalic vein diameter at the elbow was 3.1 mm (range, 0.8-7.2 mm). In only one patient, thrombotic occlusion occurred within the first 6 weeks after operation. No attempt at revision was made, and this patient received a new vascular access. Thus, 98% of prosthetic graft AVFs were functional for dialysis treatment. One patient developed a steal syndrome (0.01/py), five patients were lost to follow-up, one patient stopped cooperating with the study, 17 patients died of complications of their renal failure with a patent graft, three patients underwent successful kidney transplantation, two patients switched to peritoneal dialysis, and in two patients, the graft was explanted because of infection (0.02/py).

Patients with RCAVFs developed a total of 102 (1.19/py) vs 122 (1.45/py; P = .739) complications in the prosthetic AVFs (Table II). The incidence of thrombosis was significantly higher in the prosthetic graft group (0.54/py vs 0.19/py; P = .049). Also infection was seen significantly more often in patients with prosthetic grafts (0.13/py vs 0.03/py; P = .009). Pseudoaneurysm formation was only seen in the prosthetic AVF group. A total of

Table II. Number of complications per patient-year in RCAVF group and prosthetic AVF group

	RCAVF	*Prosthetic AVF*	P
No.	86	84	—
Hematoma	0.20	0.13	NS
Seroma	0	0.02	NS
Infection	0.03	0.13	.009
Thrombosis	0.19	0.54	.049
Pseudoaneurysm	0	0.10	.006
Steal syndrome	0.01	0.01	NS
Stenosis	0.29	0.30	NS
Nonmaturation	0.24	—	—
Inability to cannulate	0.14	0.05	NS
Bleeding	0.02	0.04	NS
Others	0.06	0.14	NS
Total no. of complications	1.19	1.45	NS

RCAVF, radial-cephalic direct wrist arteriovenous fistula; *AVF,* arteriovenous fistula; *NS*, not significant.

Table III. Number of interventions per patient-year in RCAVF group and prosthetic AVF group

	RCAVF	*Prosthetic AVF*	P
No.	86	84	—
PTA	0.26	0.30	NS
Surgical thrombectomy	0.10	0.45	.008
Surgical revision	0.10	0.05	NS
Other interventions	0.03	0.14	.028
Total no. of interventions	0.50	0.94	NS

RCAVF, radial-cephalic direct wrist arteriovenous fistula; *AVF,* arteriovenous fistula; *NS*, not significant.

43 (0.50/py) interventions in the RCAVF group and 79 (0.94/py) in the prosthetic graft group were needed for access salvage (P = .077) (Table III). Significantly more surgical thrombectomies were done in the prosthetic graft group (0.45/py vs 0.10/py; P = .008). However, percutaneous transluminal angioplasty (PTA) was almost equally performed in both groups (0.26/py in the RCAVF group vs 0.30/py in the prosthetic graft group; P = .437). In addition, surgical revisions (0.10/py in the RCAVF group vs 0.05/py in the prosthetic graft group; P = .086) were executed for access salvage.

Of the 43 interventions in the RCAVF group, 13 interventions were performed in nine patients to improve maturation. Anastomotic stenosis in two patients was successfully treated by PTA. In two other patients, PTA failed, and in these two subjects, a prosthetic graft was implanted. One subject underwent repeated PTA for cephalic vein stenosis, without success. Therefore, a surgical revision was performed, also without success. Finally, after a last unsuccessful PTA, the patient received a new AVF in the contralateral arm. Another three patients underwent unsuccessful surgical revisions, including basilic vein transposition, venous interposition, and ligation of tributary veins. Last, one patient underwent two surgical interventions, with ligation of tributary veins, followed by a new proximal radiocephalic anastomosis. However, in these patients, surgical revisions failed and prosthetic grafts were implanted. At the end, two of nine patients with nonmatured RCAVFs received successful interventions.

Primary and assisted primary 1-year patencies were 33% ± 5.3% vs 44% ± 6.2% (P = .03; Fig 2) and 48% ± 5.5% vs 63% ± 5.9% (P = .035; Fig 3) for RCAVF and prosthetic AVF, respectively. Secondary patencies were 52% ± 5.5%) vs 79% (± 5.1%) (P = .0001; Fig 4) for RCAVF and prosthetic AVF, respectively.

DISCUSSION

For the past decades, the autogenous RCAVF has been accepted as the vascular access of first choice. Therefore, it

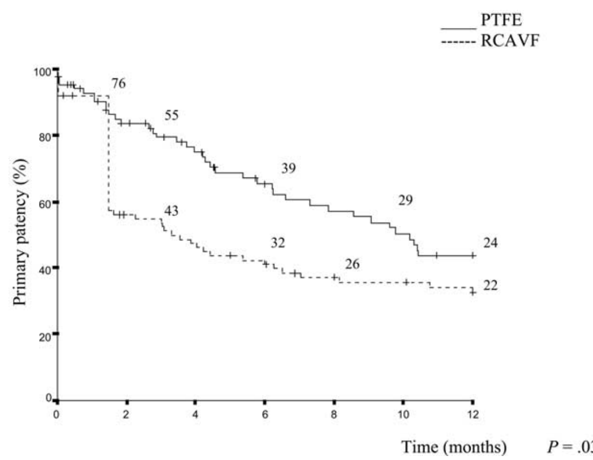

Fig 2. Primary patency rates. Patency rate is shown in percentages and time in months. Number of patients is presented in the graph. *P* values calculated with the log-rank test.

seems logical to obtain autogenous fistulas in all new dialysis patients. However, data from a recent meta-analysis show a high primary failure rate and moderate patency rates at 1 year of follow-up.[12] Similar outcomes could be confirmed by the current study in which a high primary failure rate of 41% and moderate 1-year patencies of 33% and 52% (primary and secondary, respectively) were found in the patients with RCAVFs. This is mainly due to early postoperative thrombosis and failure to mature. Nonfunctioning vascular access results in delay of initiation of dialysis treatment with additional morbidity. Access abandonment leads to the need for temporary central vein catheter placement with the risk of catheter thrombosis (24%-40%),[13-15] infection and sepsis (2%-18%),[14-16] and central vein obstruction (30%).[17] Usually, primary failure of RCAVFs depends on the quality and size of the vessels used for the arteriovenous anastomosis and the ability of vessel adaptation (remodeling) induced by the increased blood flow volumes. An adequate preoperative vessel assessment with noninvasive Doppler ultrasonography can select well-sized arteries and veins for RCAVF creation with subsequent improvement in the outcome of the vascular access.[8-10] Certain duplex-derived parameters may predict the risk of failure or dysmaturation. The internal radial artery diameter has been

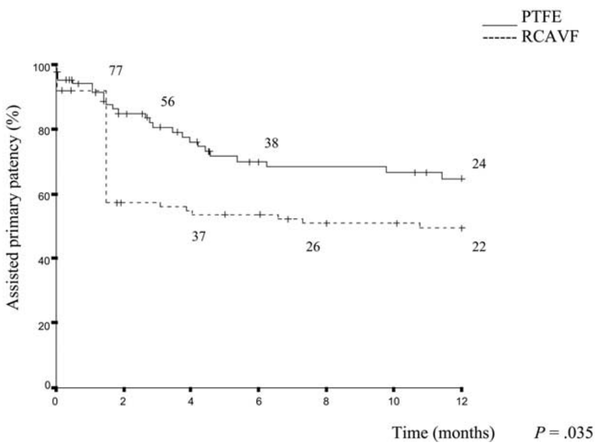

Fig 3. Assisted primary patency rates. Patency rate is shown in percentages and time in months. Number of patients is presented in the graph. *P* values calculated with the log-rank test.

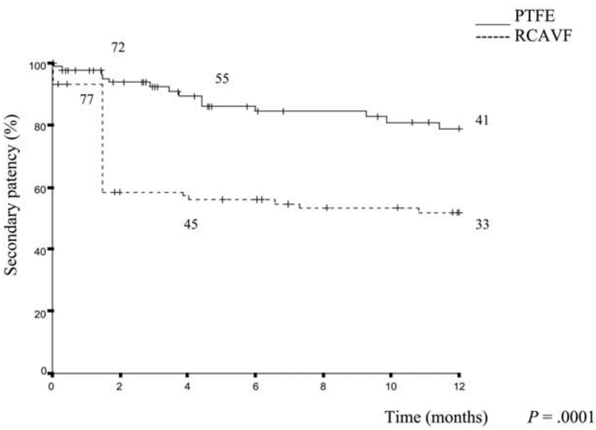

Fig 4. Secondary patency rates. Patency rate is shown in percentages and time in months. Number of patients is presented in the graph. *P* values calculated with the log-rank test.

used in several studies to predict the outcome of RCAVFs or to plan strategies for vascular access. Wong et al[18] observed primary failure of RCAVFs in patients with a radial artery and/or cephalic vein diameter <1.6 mm. Strategies for vascular access creation can be based on preoperative duplex scanning. Patients with a radial artery diameter of ≥2 mm and a cephalic vein diameter of ≥2.5 mm received RCAVFs, with, as result, a low primary failure rate of 8%.[9] However, there is still debate whether RCAVFs should be performed in patients with very small and/or diseased poor vessels. An "all autogenous" vascular access policy, including creation of fistulas with small vessels, probably results in high primary failure rates and the need for multiple interventions. Until today, no studies are available that elucidate this subject and that was the reason for performing the present study and investigating which method for hemodialysis vascular access in patients with poor forearm vessels may be the best option. In this study, we found a dismal 1-year primary patency of 33% in the RCAVF group compared to 44% in the prosthetic AVF group. Also, a secondary patency of 52% at 1 year in the RCAVF group was significantly lower compared to 79% in the PTFE graft group. We conclude from these results that patients with poor forearm vessels may possibly benefit from implantation of a prosthetic graft, and this may a better option than a primary autogenous radial-cephalic direct wrist access. In addition, the primary selection of a PTFE AVF in elderly patients may be worthwhile, given the reduced life expectancy of these patients (50% mortality at 2 years)[19] and the risk of long periods of indwelling central vein catheters with their related morbidity, when attempts to make nonmatured fistulas functioning fail.

One limitation of this study is the relatively short follow-up period of 1 year, because it is conceivable that there may be patency advantage for the RCAVF beyond 1 year. Another limitation is the fact that the duplex measurements of the vessel diameters were performed only once. There may be some variation in vessel diameter measured at different times and different days. Also, there may be influence of regional anesthesia on vessel diameters due to a vasodilatation mechanism.

One might argue for trying to create autogenous fistulas in patients with poor vessels, and indeed still 52% of patients who received an RCAVF in this study did develop functioning access with ultimately fewer interventions for access salvage (0.94/py vs 0.50/py interventions). Also, when an RCAVF does fail, it is still possible to implant a forearm prosthetic AVF. The total number of complications in RCAVFs is similar to those of prosthetic AVFs (1.19/py vs 1.45/py). The number of thrombotic occlusions was significantly higher in grafts, whereas nonmaturation and cannulation difficulties occurred in RCAVFs in particular.

Of the 43 interventions in the RCAVF group, 13 interventions were performed in nine patients to improve maturation. Interventional treatment by means of PTA and surgical revision resulted in maturation in only two patients (22%). The impact of reintervention on fistula maturation and maintenance was recently reported by two studies.[20,21] In these studies, not only concerning radial-cephalic but also brachial-cephalic and basilic AVFs, a 10% improvement was seen in accomplishing a functional AVF, achieved by either PTA or surgical intervention. In the current study, only PTA was successful in accomplishing a functional access in a minority of patients. In the other patients with nonmatured accesses, beyond the 6-week period, no further improvement was observed and these accesses were replaced by alternative fistulas. An aggressive approach to evaluate and intervene in immature fistulas may improve the maturation rate. Beathard et al[22] reported on their experience with 71 patients referred because of inadequate maturation of their fistulas. Eight were not evaluated further because they were believed to have an inadequate arterial inflow. The remaining 63 patients underwent angioplasty of a stenotic lesion in the draining vein, ligation of one or more tributary veins, or a combination of both procedures. As a result of these salvage attempts, 82.5% of the fistulas matured adequately to be used for dialysis. Turmel-Rodriques et al[23] reported in their study that interventional radiology can treat the majority of cases and achieve a 97% success rate. However, they also found out that early recurrence of stenoses can occur.

Early detection and correction of hemodynamically significant stenosis in both autogenous and prosthetic AVFs reduce the thrombosis rates. In addition, intervention with PTA or surgical revision to correct stenosis reduces the rate of AVF thrombosis.[24-28] This preemptive correction of AVF at risk of thrombosis should have the additional economic impact of reducing emergency admissions due to access thrombosis, reducing the need for temporary access catheters with their attendant complications and preventing underdialysis with its associated morbidity and mortality rates. All patients in our study were on anticoagulants for 3 months. In Europe, anticoagulant treatment of a prosthetic graft, in particular, is quite common.

In the current study, a low infection incidence of 0.03/py in the RCAVF group and 0.13/py in the prosthetic AVF group was seen. Early postoperative wound infection after RCAVF and prosthetic AVF construction poses a high risk of wound dehiscence and secondary hemorrhage. These patients require treatment with intravenous antibiotics and drainage of pus collections. Late-onset infections of prosthetic AVFs often occur at cannulation sites and may resolve with simple antibiotic therapy, eventually combined with segmental graft replacement through a new subcutaneous route.[29,30] In cases of severe infection and risk of sepsis, graft explantation is required.

The incidence of steal syndrome, in which a sufficient proportion of the arterial flow is shunted away from the distal upper extremity, resulting in peripheral ischemia, is usually low in distal AVFs. Only two patients (one with an RCAVF and one with a prosthetic graft) in our study developed steal syndrome, necessitating access ligation.

In summary, we performed a prospective, randomized study comparing primary RCAVF and prosthetic (PTFE) implantation in patients with poor vessels. Although there were more interventions needed for access salvage in the PTFE group, we conclude that patients with poor forearm vessels may benefit from implantation of a prosthetic graft.

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INVITED COMMENTARY

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The authors report a randomized, controlled trial comparing autogenous radiocephalic and prosthetic forearm accesses in patients with compromised vessels for the autogenous choice. They should be commended for their efforts and study design given the limited evidence in the literature to justify the choice of the various access configurations. Indeed, the paucity of level 1 evidence is staggering given the overwhelming number of patients on hemodialysis in the United States and abroad. The authors found that the primary (33% vs 44%) and secondary (52% vs 79%) annual patency rates were higher for the prosthetic accesses, although the associated complication (1.19 patients per year) and intervention (0.94 patients per year) rates were also greater. These results are not particularly surprising given the study inclusion criteria for the autogenous access (radial artery diameter between 1 and 2 mm and/or cephalic vein ≤1.6 mm) and the mean diameters for the brachial artery (3.8 mm) and the cephalic vein (3.1 mm) in the prosthetic group.

It is not particularly clear how the results of the study should affect our clinical practices. Extending the indications for the autogenous radiocephalic access to patients with compromised vessels affords another access option that does not preclude a subsequent prosthetic forearm access. However, there is a significant downside to accesses that never mature sufficiently for cannulation, including the prolonged use of temporary catheters among the patients already on hemodialysis and the associated economic/psychologic effects. Indeed, the increased emphasis on autogenous accesses in the United States has resulted in the unintended consequence of increasing their primary failure rates (nonmaturation).

The more pivotal question that merits a randomized, controlled trial is the choice between a prosthetic forearm loop or an autogenous brachiobasilic access given the K/DOQI that recommend the autogenous radiocephalic and brachiocephalic routes as their first and second access choices, respectively. The results of the current study can be used to reach the opposite conclusion and seem to justify extending the indications for autogenous radiocephalic access to these compromised patients. Indeed, the patency rates for the autogenous and prosthetic accesses seem to parallel each other after the initial failures are excluded, and it is conceivable that the longer-term patency rates (>1 year) for the autogenous accesses may be superior. Furthermore, the results underscore the importance of pre–end-stage renal disease care and the importance of early referral to an access surgeon before initiating dialysis to allow adequate time to achieve an effective access. It is imperative to realize that maintaining an effective hemodialysis access is a difficult problem that usually requires multiple procedures and interventions and lifelong planning.