A randomized multicenter study of the outcome of brachial-basilic arteriovenous fistula and prosthetic brachial-antecubital forearm loop as vascular access for hemodialysis

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Background: **Vascular access is a necessity for patients with end-stage renal disease who need chronic intermittent hemodialysis. According to Kidney Disease Outcomes Quality Initiative (KDOQI) guidelines, radial-cephalic (RC) and brachial-cephalic (BC) arteriovenous fistulas (AVF) are the first and second choice for vascular access, respectively. If these options are not possible, an autogenous brachial-basilic fistula in the upper arm (BBAVF) or a prosthetic brachial-antecubital forearm loop (PTFE loop) may be considered. Until now, it was not clear which access type was preferable. We have performed a randomized study comparing BBAVF and prosthetic implantation in patients without the possibility for RCAVF or BCAVF.**
Methods: **Patients with failed primary/secondary access or inadequate arterial and/or venous vessels were randomized for either BBAVF or PTFE loop creation. The numbers of complications and interventions were recorded. Kaplan-Meier method was used to calculate primary, assisted-primary and secondary patency rates. The patency rates were compared with the log-rank test. Complication and intervention rates were compared with the Mann-Whitney test.**
Results: **A total of 105 patients were randomized for a BBAVF or PTFE loop (52 vs 53, respectively). Primary and assisted-primary 1-year patency rates were significantly higher in the BBAVF group: 46% ± 7.4% vs 22% ± 6.1% (*P* = .005) and 87% ± 5.0% vs 71% ± 6.7% (*P* = .045) for the BBAVF and PTFE group, respectively. Secondary patencies were comparable for both groups; 89% ± 4.6% vs 85% ± 5.2% for the BBAVF and PTFE group, respectively. The incidence rate of complications was 1.6 per patient-year in the BBAVF group vs 2.7 per patient-year in the PTFE group. Patients in the BBAVF group needed a total of 1.7 interventions per patient-year vs 2.7 per patient-year for the PTFE group.**
Conclusion: **These data show a significantly better primary and assisted-primary patency in the BBAVF group compared with the PTFE group. Furthermore, in the BBAVF group, fewer interventions were needed. Therefore, we conclude that BBAVF is the preferred choice for vascular access if RCAVF or BCAVF creation is impossible, or when these types of access have already failed. (J Vasc Surg 2008;47:395-401.)**

As the dialysis population gets older and has more comorbidities, the creation of an autogenous forearm fistula (radial-cephalic arteriovenous fistula [RCAVF] or brachial-cephalic arteriovenous fistula [BCAVF]) becomes more difficult. Forearm vessels are not suitable for vascular access creation if the diameter is too small, or the vessels are thrombosed or diseased.[1-5] Whenever forearm vessels are not suitable for RCAVF/BCAVF creation or when these AVFs have failed, the options for vascular access are either brachial-basilic arteriovenous fistula (BBAVF) or the use of a prosthetic implant as recommended by the KDOQI and European guidelines.[6,7] Autogenous arteriovenous fistulas are known for their better long-term patencies and lower thrombotic complication rates compared with prosthetic implants.[8-10] The advantages of prosthetic implants are the low primary failure rate, no need for maturation, and ease of cannulation.[9] On the other hand, the infection and thrombosis rates are reported higher in the literature compared with the BBAVF.[9,11,12] Because there is no consensus on which of these types of vascular accesses is to be preferred, we performed a randomized clinical trial between the BBAVF and prosthetic brachial-antecubital forearm loop (PTFE loop) graft to elucidate this problem. The purpose of our study was to compare primary and secondary patency rates, complications and interventions in the BBAVF, and prosthetic forearm loop vascular access.

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Competition of interest: none.

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METHODS

In this multicenter study, all patients in which previous RCAVF/BCAVF had failed or in which creation of a forearm fistula was impossible were included in one university and two regional hospitals between October 1, 2003 and May 1, 2006. Patients were randomized between BBAVF creation and creation of a brachial-antecubital forearm loop graft. Informed consent was obtained from all patients. The study was approved by the ethical committee of the university as well as the regional hospitals.

Preoperative assessment. All patients in need of vascular access in the three participating hospitals underwent clinical examination and duplex scanning of the upper extremity as a standard investigation before operation. Clinical examination consisted of inspection and palpation of the vessels of the arm, and measurement of blood pressure on both sides. Duplex scanning of the arteries and superficial veins 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. A radial artery and/or cephalic vein diameter of less then 2 mm at the wrist and less then 3 mm at the elbow were defined as unsuitable for the creation of a RCAVF or BCAVF.[7] Although, for the creation of a BBAVF, a diameter of the basilic vein at the elbow of 3 mm was preferred, the quality of the vein (nonstenotic and nondiseased) was considered more important for the decision whether the basilic vein was suitable for BBAVF creation. Patients with small diameter or thrombosed vessels, or failed RCAVF/BCAVF were asked to participate in the study. Patients with an active local or general infection and/or peripheral ischemia of the upper extremity were excluded. After informed consent, the patients were randomized by a computer system for either a brachial-basilic arteriovenous fistula or a brachial-antecubital forearm loop graft.

Surgical procedure. All procedures were performed under local/regional or general anesthesia. All patients received prophylactic antibiotic therapy according to the local hospital standard.

Brachial-basilic arteriovenous fistulas were constructed by making a continuous or interrupted longitudinal incision at the medial side of the upper arm to dissect the basilic vein. A transverse incision 2 cm proximal to the elbow was made to explore the brachial artery. The basilic vein was mobilized proximally to the confluence with the deep venous system. Side branches were ligated and, subsequently, the vein was transected as distal as possible. While mobilizing the basilic vein, the medial brachial cutaneous nerve was carefully spared to avoid nervous disturbances. At the proximal end of the basilic vein, a bulldog clamp was placed and, subsequently, the vein was gently dilated with a saline injection. After local heparinization, the vein was marked to prevent twisting. An anterolateral subdermal tunnel was created with the use of a tunneling device at the upper arm, with a diameter of at least 10 mm. Subsequently, the basilic vein was pulled through the tunnel and an end-to-side vein-to-artery anastomosis was performed with a running 7-0 polypropylene (Prolene) suture with a limited arteriotomy of 7 mm.

For creation of a PTFE loop, 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 tunneling device in the forearm between the brachial artery and a suitable elbow vein. Arterial and venous anastomoses were created with running 7-0 polypropylene (Prolene) sutures.

Access patency was confirmed peroperatively either by palpation, Doppler examination, or angiography. All patients received 100 mg of aspirin per day unless already on oral anticoagulation. Cannulation of the fistula was allowed after wound healing and maturation (BBAVF), approximately 4 to 6 weeks for the BBAVF and 2 weeks after surgery for the PTFE fistula.

Follow-up. All patients were followed for 12 months after operation. Complications and interventions were recorded for this period. Monitoring (once a month) and indications for interventions of the vascular access were standardized. Interventions were done according to the local hospitals standards. Nonmaturation (for BBAVF) was defined as inability to cannulate the AVF. Clinical criteria were used to detect thrombosis. Percutaneous transluminal angioplasty (PTA) was done whenever a flow decrease of more than 25% or <600 ml/min was measured during dialysis (Transonic), or if patients had significantly longer bleeding time or an increased venous pressure. A significantly longer bleeding time is defined as a bleeding time of 150% of the patients' usual bleeding time (which usually varies from 5 to 15 minutes).

End points. End points were primary, assisted-primary, and secondary patency for both types of fistula.

Statistical analysis. A power calculation was performed before the start of the study to determine the number of patients needed to demonstrate a difference in patency between the two groups after 1 year follow-up of 25% with a power of 80% and an α of .05. In each group, 51 patients were needed. For the definition of incidence rate, we used number of complications or interventions per patient-year (py), the cumulative follow-up time of all patients, and analyzed with the Mann-Whitney test. The different patency rates were defined as described by Sidawy et al.[13] Primary patency was defined as the interval from the time of access placement until any intervention designed to maintain or reestablish patency, access thrombosis, or the time of measurement of patency. Assisted-primary patency is defined as the interval from the time of access placement until access thrombosis or the time of measurement of patency, including intervening manipulations designed to maintain the functionality of a patent access. Secondary patency was defined as the interval from the time of access placement until access abandonment, thrombosis, or the time of patency measurement including intervening manipulations designed to reestablish functionality in thrombosed access. Patency rates were calculated with the Kaplan-Meier life-table analysis. The log-rank test was used

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

	BBAVF (*n = 52*)	*Prosthetic AVF* (*n = 53*)
Male	26 (50%)	30 (57%)
Mean age (y)	60	66
Diabetes	20 (38%)	25 (47%)
Hypertension	21 (40%)	27 (51%)
Ischemic cardiac disease	21 (40%)	12 (23%)
Peripheral arterial obstructive disease	12 (23%)	14 (26%)
Cerebrovascular disease	3 (6%)	9 (16%)
Previously on hemodialysis	33 (63%)	29 (55%)
Previous vascular access	27 (52%)	8 (15%)

BBAVF, Brachial-basilic arteriovenous fistula; *AVF,* arteriovenous fistula.

to compare the patencies for the two groups. Differences were considered statistically significant when the *P* value was less than .05. Patients with a patent fistula who died, had successful kidney transplantation, or were withdrawn from hemodialysis alive were censored.

RESULTS

One hundred seventeen patients were included in this study, 12 of which were withdrawn before the surgical procedure because of possibility to create a RCAVF after all (n = 7), death of the patient (n = 2), improvement of kidney function (n = 2), and patient withdrawal (n = 1). Therefore, 105 patients were randomized, 53 of which for a PTFE forearm loop graft. In all patients, peroperative evaluation showed that it was possible to create either a BBAVF or a PTFE forearm loop graft. Equal distributions were seen regarding the peroperative patient characteristics and the local risk factors (Table I). In spite of peroperative evaluation, peroperatively basilic vein caliber appeared unsuitable for creation of a basilic vein transposition in two patients, and therefore, another type of vascular access was created. In the PTFE group, it was decided not to create a prosthetic forearm loop in two patients because of low blood pressures. Therefore, 101 patients were eligible for analysis of survival curves (PTFE forearm loop graft = 51). Mean follow-up time (±SE) was 340 (±11) vs 325 (±15) days for the BBAVF and PTFE group, respectively. Total follow-up time was 39.3 py for the PTFE group and 41.0 py for the BBAVF group. Mean time to cannulation was 51 (±9.9) days vs 60 (±8.5) days in the PTFE and BBAVF group, respectively.

Patency rates. A significant lower 1 year primary and assisted-primary patency rate (±SE) was seen in the PTFE group compared with the BBAVF group, 22% ± 6.1% vs 46% ± 7.4% (P = .005; Fig 1) and 71% ± 6.7% vs 87% ± 5.0% (P = .045; Fig 2), respectively. The secondary patency rate after 1 year was comparable for the two groups, 85% ± 5.2% vs 89% ± 4.6% (P = .532; Fig 3) for the PTFE and BBAVF group, respectively.

Twenty patients in the PTFE (12) and BBAVF (8) group died of complications of their kidney failure with a patent fistula during the follow-up period, three of which died within 1 week after operation (2 PTFE; 1 BBAVF). Four patients underwent successful kidney transplantation during the follow-up period, three of which in the BBAVF group.

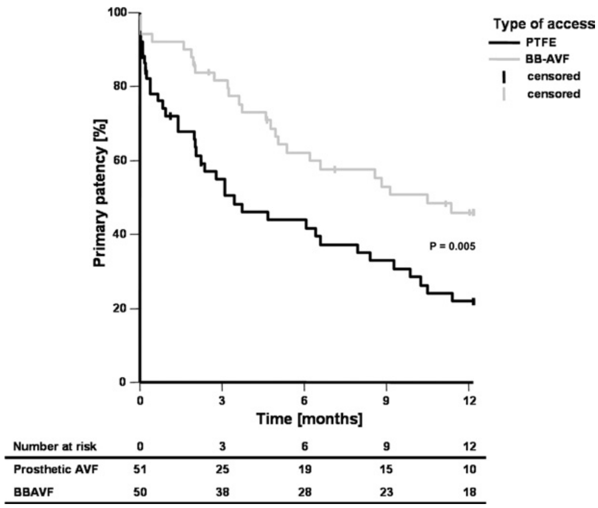


Fig 1. Primary patency rates of the brachial-basilic arteriovenous fistula (BBAVF) and prosthetic arteriovenous fistula (AVF).

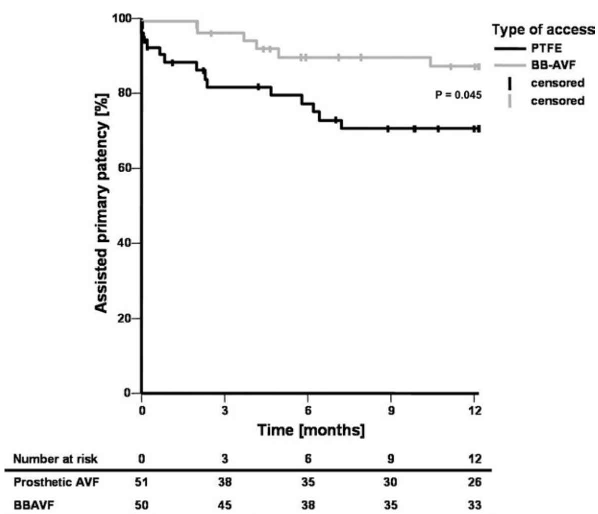
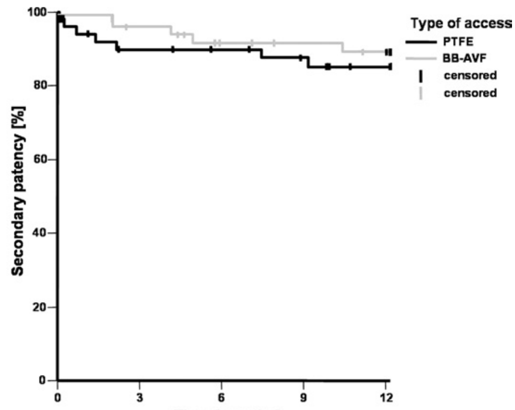


Fig 2. Assisted-primary patency rates of the brachial-basilic arteriovenous fistula (BBAVF) and prosthetic arteriovenous fistula (AVF).

Complications. Twenty-two early complications (<30 days of operation) occurred in 18 patients. They consisted of hematoma (PTFE 1; BBAVF 2), thrombosis (PTFE 8; BBAVF 2), ischemia (PTFE 2), and infection (PTFE 6; BBAVF; 1). In two patients (PTFE 1; BBAVF 1), early thrombosis led to definitive failure of the access.

Nonmaturation occurred in two patients. These fistulas could be saved by multiple PTAs and a surgical revision of the anastomosis. Significantly, more infections (P = .031) and thrombotic events ($P < .001$) were seen in the PTFE



Number at risk	0	3	6	9	12
Prosthetic AVF	51	42	40	37	31
BBAVF	50	45	39	37	34

Fig 3. Secondary patency rates of the brachial-basilic arteriovenous fistula (BBAVF) and prosthetic arteriovenous fistula (AVF).

group (Table II). The incidence rate of total complications was significantly higher in the PTFE group with 2.7 complications/py (n = 104) compared with the BBAVF group with 1.6 complications/py (n = 65) ($P < .001$). High output cardiac failure was not seen in these patient groups.

Interventions. The incidence rates for interventions was 2.7 interventions/py (n = 104) for the PTFE group vs 1.7 interventions/py (n = 70) for the BBAVF group ($P = .018$). In Table III, the different types of interventions are outlined. Significantly more surgical thrombectomies were needed in the PTFE group ($P < .001$). Two PTAs (subclavian artery) and two banding procedures with flow reduction were needed for ischemic complications in the PTFE group. In the BBAVF group, three PTAs (subclavian and brachial artery), one stent placement (subclavian artery), two proximalizations of the arteriovenous anastomosis[14] and two banding procedures were performed. Eventually, one fistula in the BBAVF group was ligated due to persistent ischemia after proximalization of the arteriovenous anastomosis.

DISCUSSION

These data show that a BBAVF needs fewer interventions to prevent failure compared with prosthetic (PTFE) forearm grafts. In addition, incidence rates for thrombosis and infection are significantly better.

As the dialysis population becomes older (with various comorbidity), the need for secondary and tertiary access, including BBAVFs and prosthetic implants, will grow. There is still no consensus which type of access is to be preferred as randomized trials on this subject are lacking.

Although the surgical procedure for BBAVF creation may be more difficult compared with prosthetic graft implantation, only in two patients (3.9%) in this study it was not possible to perform a BBAVF because of small brachial artery diameter. Similarly, in the PTFE group, it was also impossible to create a forearm loop graft in two patients (3.8%). The cause for this was low blood pressure in both patients.

One of the main disadvantages of BBAVFs is maturation failure. The incidence of nonmaturation has been reported within the range of 0% to 38%, although many reports lack information on this issue.[15] Hakaim reported adequate maturation in a population with predominantly diabetics.[16] In our study, the nonmaturation rate was low, which is in line with the lowest figures from the literature. Nonmaturation of a BBAVF also has a lower incidence as compared with the RCAVF,[15,17] which can be explained by the pristine condition of the basilic vein, which is protected from iatrogenic damage due to its deep location in the upper arm compared with the cephalic vein which has a more superficial localization. Another advantage of the BBAVF may be the proximal location; therefore, the basilic vein more often has a sufficient diameter (>3 mm) for creation of an AVF. When the diameter is smaller than 3 mm, a two-stage procedure may be advocated, with enhancement of diameters in first instance and superficialization in a second stage. In our study, all patients underwent a one-stage procedure with good early and late results. In this study population, infection occurred almost exclusively in the PTFE grafts. Most infections presented within 30 days after operation, indicating peroperative contamination. Cannulation-related infection, as described in the literature, has not been found.[18] In a recent review, infection rate is reported as 3.6%.[15] We found similar percentages as seen by Coburn et al who described a higher infection rate in the PTFE group in their retrospective study of BBAVF and PTFE grafts.[8]

Surveillance with access flow monitoring has been advocated by recent American and European guidelines. A significant flow decrease (25%) or low flow (<600 ml/min) was the main reason for pre-emptive PTA. More PTAs were needed in the PTFE group, indicating a high incidence of stenosis formation. With this intensive surveillance and treatment protocol assisted-primary patencies were well acceptable for both BBAVF and prosthetic grafts.

Ischemic complications and intervention rates for ischemia were similar for both groups. These figures are comparable with the rates found in the literature,[15,18,19] although incidence rates might be underestimated, as has recently been shown, when using specific questionnaires for patients, focusing on ischemic complaints.[20]

High-output cardiac failure is one of the feared complications of upper arm fistulas in this predisposed patient population. Up to 75% of the end-staged renal disease patients already has left ventricular hypertrophy even before hemodialysis.[21] Due to the high access flows the cardiac load increases and may induce cardiac failure eventually.[22-24] High-output cardiac failure may occur in high-flow AVFs, but was not observed in our patients.[15]

The primary patency rates of both groups were lower compared with the literature.[9,11,12,16,18,19,25-30] These low primary patency rates can be explained by before-mentioned

Table II. Number of complications per patient-year in BBAVF vs prosthetic AVF group

	BBAVF (n = 50)	*IR*	*Prosthetic AVF (n = 51)*	*IR*	P
Hematoma	3	.073	1	.026	.200
Infection	1	.024	6	.154	.031*
Thrombosis	6	.146	33	.846	<.001*
Aneurysm	2	.049	0	0	.131
Ischemia	4	.098	3	.077	.387
Stenosis	16	.390	16	.410	.444
Nonmaturation	2	.049	—	—	—
Flow decrease	29	.707	41	1.051	.051
Venous hypertension	2	.049	4	.103	.209
Total complications	65	1.585	104	2.667	<.001*

BBAVF, Brachial-basilic arteriovenous fistula; *AVF,* arteriovenous fistula; *IR,* incidence rate.
*Indicates statistical significance.

Table III. Number of interventions per patient-year in BBAVF vs prosthetic AVF group

	BBAVF (n = 50)	*IR*	*Prosthetic AVF (n = 51)*	*IR*	P
PTA	50	1.220	61	1.564	.096
Surgical thrombectomy	3	.073	23	.590	<.001*
Surgical revision	9	.220	10	.256	.371
Surgical intervention for ischemia	4	.098	2	.051	.245
Ligation	2	.049	0	0	.131
Thrombosuction	0	0	2	.051	.119
Other interventions	2	.049	6	.154	.079
Total interventions	70	1.707	104	2.667	.018*

BBAVF, Brachial-basilic arteriovenous fistula; *AVF,* arteriovenous fistula; *IR,* incidence rate; *PTA,* percutaneous transluminal angioplasty.
*Indicates statistical significance.

pre-emptive interventions, which were performed in an early stage due to close monitoring of the arteriovenous fistulas. It is known that interventions with PTA or surgical revision to correct stenosis reduces the rate of AVF thrombosis.[31-34] These interventions have also the supplementary economic impact of reducing emergency admissions due to access thrombosis, reducing the need for central venous catheters with their attendant complications, and preventing underdialysis with its associated morbidity and mortality rates.[35] Therefore, pre-emptive interventions in fistulas at risk for thrombosis at the current time is more a standard than an acceptance, which results in lower primary but higher assisted-primary and secondary patency rates.

More interventions were needed in the PTFE group compared with the BBAVF group. This could be partly explained by the pre-emptive interventions, as a result of surveillance and close monitoring. The total number of interventions was done in a smaller group of patients in the BB-AVF group compared with the PTFE group (24 patients vs 36 patients, respectively). Some patients needed more interventions than others, but this number of patients was limited. For example two patients needed several PTAs in the BBAVF group, one patient needed seven and the other patient needed thirteen. These patients may confound the data. Nevertheless, overall fewer interventions were needed in the BBAVF group. The median time to intervention is significantly longer in the BBAVF, with similar secondary patency rates after 1 year of follow-up, but with significantly less interventions needed in the BBAVF group. Similar results were seen from a randomized study in which prosthetic implants were compared to RCAVFs.[12]

It remains disputable whether an autogenous AVF with the risk for nonmaturation should always be preferred in an elderly population with various comorbidities like diabetes and PAOD, of which 50% dies within 2 years.[36] One could argue to implant PTFE grafts in these patients with accessibility for cannulation within weeks.[6] However, as patients are referred in an early stage, and surgical experience with BBAVF creation is sufficient, our preference would be the BBAVF because of low intervention rates and long thrombosis-free interval with high secondary patency rates after 1 year of follow-up. In addition, the total costs of access-related hospital admissions and revisions may be lower in patients with BBAVFs, due to the fewer interventions needed. Whenever BBAVFs fail, it is still possible to create a prosthetic graft fistula in most patients.[37]

Limitations of the study were the relatively short follow-up time, although a significantly better primary and assisted-primary patency was already shown after 1 year. It is not known if longer follow-up periods might influence the secondary patency. However, graft deterioration due to repetitive cannulation, might result in significant differences in secondary patency also after a longer follow-up period.

CONCLUSION

In this prospective, randomized study, we found that after BBAVF creation, the need for intervention to prevent failure of the access occurs later and the number of interventions needed is less compared with prosthetic graft implantation, which corresponds to a significantly better primary as well as assisted-primary patency for the BBAVF. Secondary patencies are comparable between both access types. Therefore, we conclude that BBAVF creation is the preferred option for a tertiary vascular access in hemodialysis patients.

AUTHOR CONTRIBUTIONS

Conception and design: XK, AK, FS, JT
Analysis and interpretation: XK, AK, JT
Data collection: XK, AS, FS, RW, JT
Writing the article: XK
Critical revision of the article: XK, AS, AK, FS, RW, JT
Final approval of the article: XK, AS, AK, FS, RW, JT
Statistical analysis: XK, AK
Obtained funding: FS, JT
Overall responsibility: XK

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