From the Society for Vascular Surgery

Primary balloon angioplasty of small (≤2 mm) cephalic veins improves primary patency of arteriovenous fistulae and decreases reintervention rates

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Purpose: **The purpose of this study was to evaluate the effect of primary balloon angioplasty (PBA) of cephalic veins with diameter ≤2 mm on patency and maturation time of autogenous radiocephalic arteriovenous fistulae (AVF) for hemodialysis.**

Methods: **Forty patients, all candidates for distal AVF, with a cephalic vein ≤2 mm, were randomized to two different surgical procedures: (1) PBA of a long segment of the cephalic vein from the wrist up to the elbow (n = 19); and (2) hydrostatic dilatation (HD) of a short venous segment (5 cm) at the level of the anastomosis (n = 21). PBA was performed using a standard balloon 4 × 150 mm. Primary end points were primary patency and reintervention rates. Secondary end points were maturation time and the rate of working AVF. Follow-up included physical and duplex ultrasound (DUS) examinations at 1,4, and 8 weeks, and every 3 months thereafter.**

Results: **Risk factors were homogeneously distributed between the two groups. Mean vein diameter was 1.8 ± 0.2 mm for the PBA group and 1.7 ± 0.2 mm for HD. Immediate success rate was 100% for PBA and 67% for HD groups ($P = .04$). Causes of failure in the HD group included early vein thrombosis in seven patients (33%). Mean fistula maturation time was 32 days in the PBA group and 55 days in the HD group ($P = .04$). During the mean follow-up of 7 months, three patients underwent drug-eluting balloon angioplasty for failure of AVF to mature due to stenosis (1 in the PBA group and 2 in the HD group). Six-month reintervention rate was significantly lower in the PBA group (5%) compared with the HD group (43%) ($P = .02$). At 6 months, primary patency rates were 95% in the PBA group and 57% in the HD group ($P = .01$). Working AVF rate was 100% in the PBA vs 90% in the HD group.**

Conclusions: **PBA of very small cephalic veins during the creation of a distal AVF for hemodialysis is a safe and feasible procedure. This technique assures excellent primary patency, maturation time, and dramatically decreases reintervention rate. (J Vasc Surg 2013;57:131-6.)**

In the past 10 years, the number of dialysis-dependent patients has increased an estimated 3.2% each year. Autogenous arteriovenous fistula (AVF) has been shown to be superior to prosthetic graft or catheter access in terms of patient morbidity and mortality, and less expensive in terms of maintenance.[1-6] Although the National Kidney Foundation-Kidney Disease Outcomes Quality Initiative Clinical Practice Guidelines for Vascular Access[1] stated that the vascular access should be performed in all patients with endstage renal disease (ESRD) 4 to 6 months before starting chronic hemodialysis, to reduce the risk of sepsis and death related to the use of hemodialysis catheters, only a minority of patients have a well functioning AVF at the time of starting hemodialysis.[7] The most important factor limiting the AVF growth and patency is the availability of a venous segment with adequate diameter: cephalic veins smaller than 2.5 mm in diameter have been reported to increase immediate failure rate and to decrease primary patency rate.[8,9]

The purpose of this study was to evaluate if primary balloon angioplasty (PBA) of cephalic veins with a preoperative diameter of ≤2 mm could improve the primary patency rate and maturation of autogenous distal AVFs.

METHODS

This study was approved by the institutional review board of our institution. Clinical, anatomic, and procedural data of all consecutive patients with ESRD who underwent AVF creation between 2009 and 2011 were entered into an institutional database. Inclusion criteria were radial artery with normal duplex ultrasound (DUS) parameters and cephalic vein ≤2 mm in diameter. Exclusion criteria in-

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cluded segmental cephalic vein occlusions, and brachial and radial artery extensive disease that precluded the creation of a distal autogenous AVF.

Patients were randomized on a 1:1 basis into two groups according to the technique used to increase the vein caliber (see Techniques). All patients signed a written informed consent before their surgical procedure. One patient scheduled for PBA of the cephalic vein refused the procedure and underwent a standard hydrostatic dilation of the vein.

Preoperative work-up included physical examination (including upper arm inspection with and without the tourniquet and Allen test to evaluate the quality of the collateral flow to the hand) and DUS. Parameters evaluated by DUS were patency, diameter, and peak systolic velocity (PSV) of the brachial and radial arteries and diameter, patency, and depth of the cephalic vein. In particular, vein diameter was measured by DUS with a tourniquet, inner wall to inner wall. The nondominant upper limb was usually preferred, when feasible. Demographics, clinical characteristics, and operative data were obtained from the medical records. Medical therapy included acetylsalicylic acid started at least 1 week before the procedure and continued for 4 weeks after the procedure. Early postprocedure period was defined as occurring within the first 30 days or within hospital stay. Technical immediate success was defined as a presence of a thrill during palpation and a bruit at auscultation, associated with a PSV <200 cm/s by intraoperative DUS at the site of anastomosis. Follow-up period was defined as after 30 days or dismissal, and consisted of clinical examination and DUS at 1, 4, and 8 weeks after the procedure, and every 3 months thereafter. Diminished or absent thrill and decreased flow rate (<250 mL/min) were considered an indication for early evaluation beyond the established protocol of surveillance. A significant stenosis was defined as a PSV >400 cm/s by DUS or a luminal diameter reduction of 50% on angiography.[10] Stenosis was considered in the peri-anastomotic site and at venous outflow levels. Primary patency (intervention-free access survival) was defined as the interval from time of access placement to any intervention designed to maintain or re-establish patency or to access thrombosis or the time of measurement of patency.[11] Fistula failure was defined as any event that required an intervention to maintain or re-establish patency, including stenosis, thrombosis, hemorrhage, and ischemia of the hand, leading to a new access. Maturation time was defined as the interval from the AVF creation to first successful hemodialysis use. Working AVF was defined as the AVF useful for hemodialysis access.

Primary end points were 6-month primary patency of AVF and reintervention rates. Secondary end points included maturation time and the rate of working AVFs.

Surgical techniques. All surgical procedures have been performed by the same surgeon (P.V.). All patients received a systemic anticoagulation using 2500 IU of heparin 3 minutes before clamping the cephalic vein and the radial artery.

No intravenous or local vasodilators were used. Patients were randomized into two groups:

a. Hydrostatic dilatation (HD): after isolation of about 5 cm of cephalic vein at the wrist with ligation of collateral veins, the vein was dilated by injection of high-pressure sterile solution through a syringe 20 mL and 16-gauge plastic cannula to achieve the final diameter of 4 mm. The anastomosis was performed end-to-side with the radial artery, with 7/0 polypropylene running sutures.
b. PBA: after isolation of 3 to 4 centimeters of cephalic vein, a guidewire 0.018 inches (V-18; Boston-Scientific, Natick, Mass) was introduced through the cephalic vein and advanced up to the elbow under direct palpation, or DUS guidance in cases of deep cephalic vein. A noncompliant balloon, 4 mm × 150 mm (Pacific Extreme; Medtronic-Invatec, Frauenfeld, Switzerland), was introduced and gently inflated to 12 atmospheres of pressure for a period of 60 seconds, from the elbow to the level of the anastomosis (Fig 1, *A*), to achieve the final diameter of 4 mm. The anastomosis was performed end-to-side with 7/0 polypropylene running sutures (Fig 1, *B*). After declamping, the cephalic vein was evaluated by intraoperative DUS to assure that the required vein diameter was achieved. In case of incomplete segmental vein dilatation, a second angioplasty, using the same balloon, was performed through a collateral branch of the cephalic vein.

Statistical analysis. Patency was analyzed using Kaplan-Meier estimator. The Pearson χ^2 or Fisher exact test was used for analysis of categorical variables. Differences between means were tested with two-sided *t*-test, the Wilcoxon rank-sum test, or the Mann-Whitney *U* test. A value of $P < .05$ was used to determine statistical significance.

RESULTS

During the study period, 130 patients with ESRD underwent AVF creation. Among these, 40 patients met the criteria of this study. Patients' characteristics were similar between the two groups and are summarized in the Table. There were no differences in terms of cardiovascular risk factors, including hypertension, hyperlipidemia, tobacco use, coronary artery disease, and chronic obstructive pulmonary disease between the two groups. Of the 40 procedures, 19 (47%) were performed using a PBA of the cephalic vein, whereas in 21 cases (53%), a hydrostatic dilatation was performed to increase the vein caliber.

Immediate success rate was 100% for PBA and 67% for HD groups. Causes of failure included early AVF thrombosis in seven patients (33%). Immediate surgical revision was performed in all cases, including thrombectomy of the anastomosis and the cephalic vein, combined with plain old balloon angioplasty (POBA) of the cephalic vein for the entire length of the forearm. Finally, a new anastomosis was performed in all patients.

During the mean follow-up of 7 months (range, 1-15 months), three patients underwent reintervention for stenosis (one in the PBA group and two in the HD group).

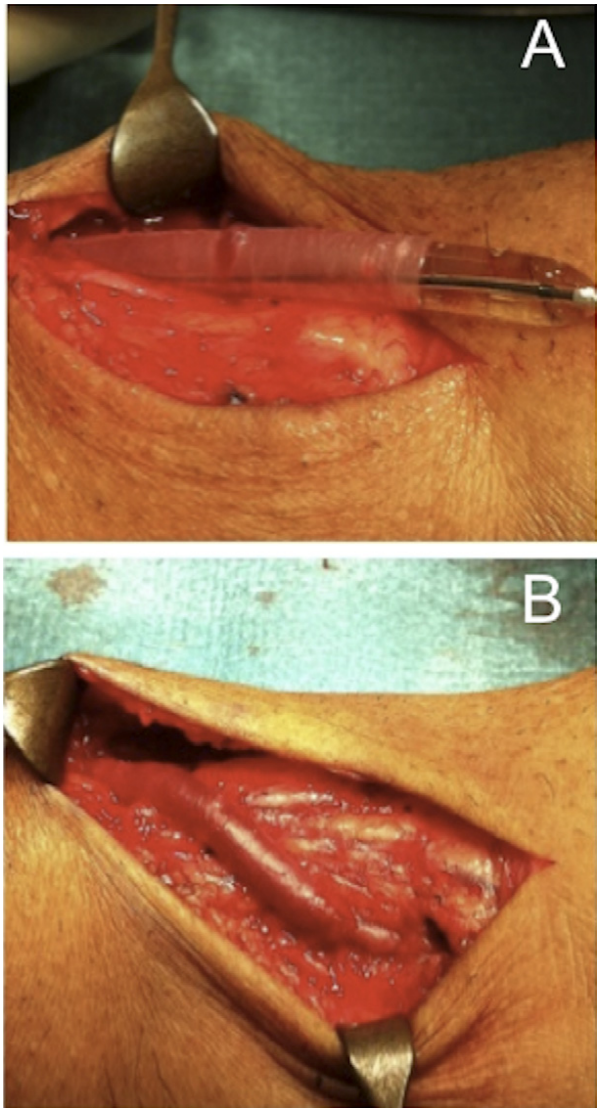

Fig 1. A, Balloon dilatation of a long segment of the cephalic vein. **B,** Final overview of the working arteriovenous fistula (AVF).

Stenosis was found at the anastomotic level in two cases and close to the anastomosis in one.

All patients underwent angiographic evaluation of the vascular access, followed by percutaneous transluminal angioplasty (PTA). The PTA was performed by proximal catheterization of the AVF with the introduction of 4 Fr sheaths. The vessel was dilated using a 0.018-inch guidewire (V-18 Boston-Scientific) and a drug-eluting balloon (DEB) (In Pact Amphirion; Medtronic/Invatec, Frauenfeld, Switzerland). The DEB was maintained insufflated for 120 seconds using a pressure ranging from 8 to 12 atm. DEB-PTA was successful in two patients. In one patient (HD group), a surgical approach with redoing the anastomosis to a more proximal level of the cephalic vein was performed. Six-month primary patency rate was 95% and 57% for the PBA group and the HD group, respectively

Table. Characteristics of 40 patients undergoing primary balloon angioplasty (*PBA*) or hydrostatic dilatation (*HD*) for autogenous arteriovenous fistula (AVF) creation

Patient characteristics	*PBA* *n = 19 (%)*	*HD* *n = 21 (%)*	P *value*
Male	13 (68)	16 (76)	.80[a]
Female	6 (32)	5 (24)	
Mean age (mean ± SD)	55 ± 8	54 ± 8	.30[b]
Hypertension	19 (100)	21 (100)	1.0[a]
Hyperlipidemia	15 (79)	13 (62)	.50[a]
Tobacco use	11 (58)	11 (52)	.70[a]
Coronary artery disease	8 (42)	7 (33)	.60[c]
Peripheral artery disease	8 (42)	6 (29)	.50[c]
Chronic pulmonary disease	5 (26)	5 (24)	1.0[c]
Diabetes	6 (32)	4 (19)	.30[c]
Dialysis	13 (68)	4 (19)	.20[c]
No dialysis	6 (32)	4 (19)	.30[c]
Arterial diameter (mean ± SD)	1.8 ± 0.4	1.9 ± 0.3	.80[b]
Vein diameter (mean ± SD)	1.8 ± 0.2	1.7 ± 0.2	.78[b]

SD, Standard deviation.
[a]Chi-square test used.
[b]*t*-test used.
[c]Fisher exact test used.

(Fig 2). The reintervention rate was 5% in the PBA group vs 43% in the HD group ($P = .02$). Mean fistula maturation time was 32 days (range, 21-38 days) in the PBA group and 55 days (range, 34-60 days) in the HD group ($P = .04$). A working AVF was obtained in 19 patients (100%) in the PBA group and 19 (90%) in the HD group ($P = .5$).

DISCUSSION

This study demonstrated that PBA of cephalic veins ≤2 mm may improve the medium-term patency rate of autogenous distal AVF compared with standard hydrostatic technique.

The goals of the National Kidney Foundation-Kidney Disease Outcomes Quality Initiative Clinical Practice Guidelines for Vascular Access were to increase the prevalence of autogenous arteriovenous access placement to 66% by 2009 and to prolong the use of existing accesses by early dysfunction detection.[12] Ideally, every patient should initiate dialysis with a mature fistula suitable for cannulation. This requires a number of intermediate steps, including pre-ESRD care by a nephrologist, pre-ESRD access surgery, adequate fistula maturation, and successful fistula cannulation by the dialysis staff. Omission of any of these steps results in a patient who initiates dialysis with a central venous catheter. Although autologous AVF is considered the gold standard, the reported 1-year patency rates vary from 36% to 62.5%, with the vein diameter being the most important factor affecting patency[8]: using smaller veins has resulted in an increased number of reinterventions and failed fistulae.[5] On the other hand, native fistulae fail to mature at higher rates than do grafts[13-16] and this may counterbalance the above-mentioned advantages.

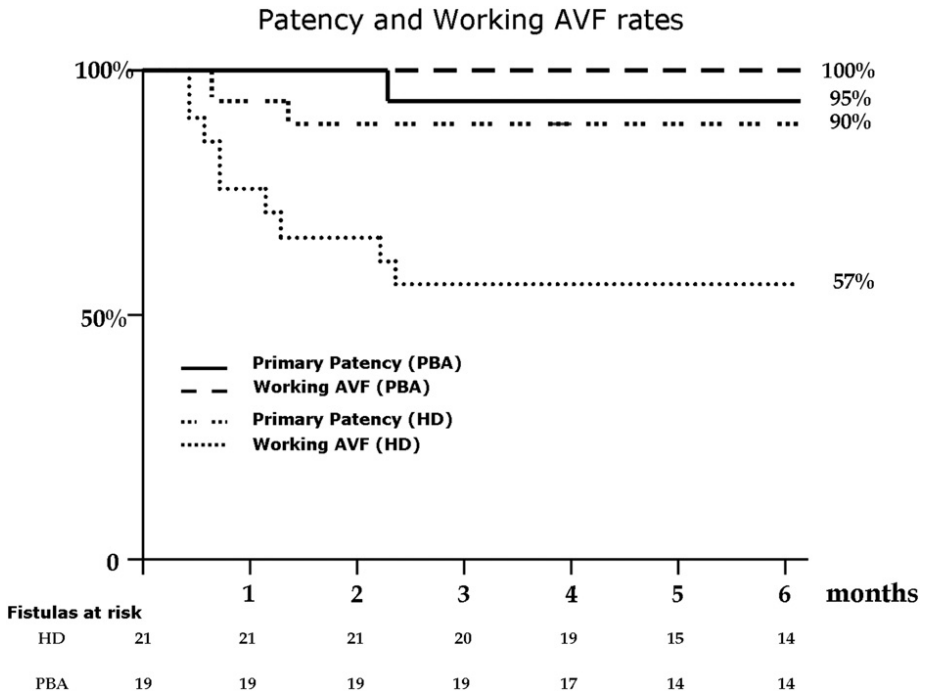

Fig 2. Patency and working fistula rates at 6 months of 40 patients undergoing primary balloon angioplasty (*PBA*; n = 19) or hydrostatic dilatation (*HD*; n = 21) for autogenous arteriovenous fistula (*AVF*) creation.

De Marco Garcia et al[17] described an interesting technique of ballooning of a short segment of cephalic vein (from midforearm to the wrist, length from 4 to 12 cm) at the time of fistula creation, in a subgroup of patients with a cephalic vein diameter <3 mm. However, 53 of 62 patients needed repeated POBA under fluoroscopy at 2, 4, and 6 weeks after AVF creation: failure in AVF maturation was probably related to the high resistances of the distal nondilated small cephalic vein (from the midforearm to the elbow).

In contrast, in our study, we have performed a ballooning of a longer segment of cephalic vein from the wrist to the elbow, before the AVF creation: this resulted in a well-functioning AVF even in patients with very small cephalic vein (≤2 mm). Moreover, this technique allowed us to achieve a low resistance venous outflow that was associated with an excellent 6-month primary patency and working AVF rate (95% and 100%, respectively).

Although the concept of multiple ballooning during the maturation time can be appealing, patients are exposed to the risks of multiple angiograms, renal function deterioration, and embolism. Repeated ballooning may also cause intimal injury, which increases the risk of restenosis and thrombosis. Finally, this technique is highly costly and not comfortable for the patients.

The strength of our technique is in that it is easily reproducible, not expensive, and avoids the need for multiple angiograms. In our study, the achieved cephalic vein diameter of 4 mm for the entire length of the forearm was easily maintained over the time by the arterial blood pressure, creating favorable conditions for a working AVF. Moreover, the very low reintervention rate (5%) in our PBA group showed that dilatation of a longer segment of the cephalic vein at the time of AVF creation is highly effective, avoiding the need for multiple late PTAs, as reported in the study by De Marco Garcia et al.[17]

In our series, 6-month primary patency in the HD group was significantly lower than in the PBA group (57% vs 100%; $P = .04$). In these patients, the key factor affecting the patency of AVF was the high resistance venous outflow, because there were no reported technical defects at the level of the anastomosis. Surgical thrombectomy combined with a dilatation of the upper part of the cephalic vein with a noncompliant balloon resulted in an excellent working AVF rate of 90%.

Several studies[18-20] have provided evidence that active surveillance and pre-emptive repair of a subclinical stenosis reduces the thrombosis rate and prolongs the functional life of mature forearm AVFs.

In the recent literature, endovascular therapy has been increasingly considered as a first choice of treatment for AVF late stenosis. Although the technical success has been reported to be very high, patency rates have been moderate at best.[21] In a series of 536 POBAs performed for treatment of vascular access stenosis, the technical success rate was 94%. However, the patency rate had dropped to 38% after 1 year.[22] In another series, 61% of patients (48 of 79) underwent a second PTA during follow-up due to the failure of the first POBA.[23] In a recent nonrandomized study, surgical and endovascular treatment of anastomotic and juxta-

anastomotic stenoses were compared. Angioplasty and surgery showed similar results, but repeat procedures were more frequent with angioplasty.[23] Additional stent placement might also be beneficial in patients with autologous AVF stenosis, but data are lacking.

Due to the high rate of restenosis associated with POBA of AVF,[23] we used DEB to treat re-stenosis of vascular access, with promising results.

Medical therapy may play an important role in preventing early AVF thrombosis and optimizing fistula maturation. Several small placebo-controlled trials showed lower rates of early fistula thrombosis with short-term use of antiplatelet agents in the postoperative period.[24-30]

Recently, Dember et al[31] reported on the use of clopidogrel in the perioperative period to reduce AVF thrombosis without increasing bleeding events. However, the beneficial effect on thrombosis was not accompanied by an increase in the proportion of fistulae that were suitable for dialysis.[31]

Early patency is necessary but not sufficient for fistula maturation, suggesting that thrombosis may be a manifestation rather than a cause of maturation failure. We used acetyl salicylic acid 1 week before and at least 4 weeks after the procedure. In our experience, antiplatelet drugs did not reduce thrombotic events in the HD group, emphasizing that hemodynamic and anatomic defects play a more significant role in determining fistula thrombosis rather than the type of prophylactic medical therapy.

Our technique has the great potential to improve the pool of candidates for autologous vascular access for hemodialysis by including those patients who have been previously discarded for distal autogenous AVF due to small distal cephalic veins. However, there are several shortcomings that need to be discussed. First of all, the small sample size and the short follow-up did not allow us to reach definitive conclusions, because future stenosis could potentially be encountered during a long-term surveillance. Second, the strict selection criterion of this study prevents the use of this technique on a large number of patients.

In conclusion, PBA of very small cephalic veins performed before the creation of a distal AVF for hemodialysis is a safe and feasible procedure. This technique is associated with excellent patency and maturation, dramatically decreases the need for reintervention, and is superior to the standard hydrostatic dilatation technique.

AUTHOR CONTRIBUTIONS

Conception and design: PV
Analysis and interpretation: PV, TT
Data collection: AG, DZ, NS, CV
Writing the article: TT, PV, MV
Critical revision of the article: PV, MV, PG
Final approval of the article: PV, MV
Statistical analysis: TT
Obtained funding: Not applicable
Overall responsibility: MV

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