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Percutaneous management of perianastomotic stenosis in arteriovenous fistulae: Results of a prospective study

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Surgical creation of new anastomosis has been proposed as the preferred treatment for perianastomotic stenoses of fistulae. However, disadvantages of surgical approach have included (1) frequent conversion of fistula to a graft by using synthetic graft material to create a new anastomosis, (2) shortening the length of the cannulation segment by proximal autologous arteriovenous neoanastomosis, and (3) abandoning the fistula altogether in favor of a synthetic graft. We report the results of a prospective study using percutaneous balloon angioplasty (PTA) to treat fistulae with perianastomotic lesions. Seventy-three consecutive patients undergoing 112 PTA procedures for the treatment of perianastomotic lesions were studied. Primary and secondary patency rates were calculated. Procedure success, procedure-related complications, and conversion of fistulae to grafts were recorded. The initial success rate was 97%. The degree of stenosis before and after PTA was 81±9 and 11±11%, respectively. Primary patency rates at 6, 12, and 18 months were 75, 51, and 41%, respectively. Secondary patency rates at 6, 12, and 18 months were 94, 90, and 90%, respectively. Grade I hematoma occurred in three and vein rupture in two cases. No grafts were inserted. These outcomes are superior to those that have been reported for surgery. The outpatient PTA is safe and effective for the management of perianastomotic stenosis. Because of its advantage of fistula preservation, the percutaneous approach should be considered as the preferred first-line therapy for the management of perianastomotic fistula lesions.

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Surgery has been proposed as the preferred treatment over the percutaneous approach for the management of perianastomotic lesions associated with arteriovenous fistulae (AVF) created for hemodialysis. However, this approach is supported by only a small number of studies.[1–5] In addition, the presence of multiple confounders in these reports such as the inclusion of small number of patients with stenosis in the anastomotic region, a retrospective study design, limited availability of demographic characteristics of study patients, and variable definitions of patency rates does not allow a firm conclusion in favor of surgery.[1–5] An issue of particular concern in these studies is the frequent surgical insertion of synthetic material to repair the fistula with consequent conversion of a fistula to an arteriovenous graft and thereby introducing all of the complications (stenosis, thrombosis, and infection) commonly associated with this type of device. In addition, the surgical approach can result in limitation of the fistula segment available for cannulation and abandonment of fistulae with early failure in favor of graft insertion.[1,5]

This is a report of a prospective analysis of the percutaneous approach to the treatment of perianastomotic stenosis in AVF cases.

RESULTS

Demographic characteristics of the study patients revealed that 72% of patients were males with a mean age of 52.6±9.3 years (range 23–70) (Table 1). African Americans and Hispanics comprised 85% of the study population and hypertension was the cause of end-stage renal disease in over half of the patients.

One hundred and twelve consecutive procedures were performed in 73 patients. The location of stenotic lesions in all procedures is shown in Table 2. Juxta-anastomotic stenosis was the most common lesion observed, occurring in 98 cases, as the only stenosis in 76 cases, and in combination with anastomotic and/or arterial stenosis in 22 cases. Arterial anastomosis stenosis was documented in 32 cases, in combination with juxta-anastomotic and/or arterial lesions in 22 cases. In addition, 39 cases demonstrated stenosis above the juxta-anastomotic region (proximal venous only = 30, central venous only = 5, and both proximal and central = 4). Overall, 49 cases (44%) with stenosis in the perianastomotic

Table 1 | Demographic characteristics of the study patients

Number of patients	73
Age (years)	52.6 ± 9.3
Gender	
Men (%)	72%
Race/ethnicity	
African American	39 (53%)
Hispanic	23 (32%)
Haitian	6 (8%)
Caucasian	5 (7%)
Cause of ESRD	
Hypertension	41 (56%)
Diabetic nephropathy	23 (32%)
Glomerulonephritis	2 (3%)
Polycystic kidney disease	2 (3%)
Lupus nephritis	2 (3%)
HIV-associated nephropathy	1 (1%)
Obstructive uropathy	1 (1%)
Chemotherapy	1 (1%)
Type of fistula	
Forearm	41 (56%)
Upper arm	32 (44%)

ESRD, end-stage renal disease.
Data are mean ± s.d.

Table 2 | Location of stenoses in all 112 procedures

Type of stenosis	Number
Juxta-anastomotic stenosis	98
JAS only	76
JAS+arterial anastomosis	16
JAS+arterial anastomosis+arterial stenosis*	2
JAS+arterial stenosis*	4
Arterial anastomotic stenosis	32
Arterial anastomosis only	10
Arterial anastomosis+arterial stenosis*	4
Coexisting stenosis on the venous side	39
Proximal stenosis only	30
Central stenosis only	5
Proximal+central stenosis	4

JAS, juxta-anastomotic stenosis.
In 10 cases of perianastomotic lesions (*2+4+4), a coexisting stenosis was found in the artery upstream from the anastomosis. Likewise, in 39, cases a coexisting lesion was seen on the venous side in patients with perianastomotic stenosis.

area demonstrated coexisting lesions elsewhere in the access circuit (feeding artery proximal to the anastomosis = 10 and stenosis on the venous side = 39).

Percutaneous balloon angioplasty was attempted in all 112 cases, with an initial success rate of 97%. This procedure was not successful in three cases. The degree of stenosis before angioplasty was 81 ± 9%. After angioplasty, the residual stenosis was found to be 11 ± 11%. Primary patency rates at 6, 12, and 18 months were 75, 51, and 41%, respectively (Figure 1). Secondary patency rates at 6, 12, and 18 months were 94, 90, and 90%, respectively.

There were 41 patients with forearm (radiocephalic = 38 and radiobasilic = 4) and 32 with upper arm fistulae who

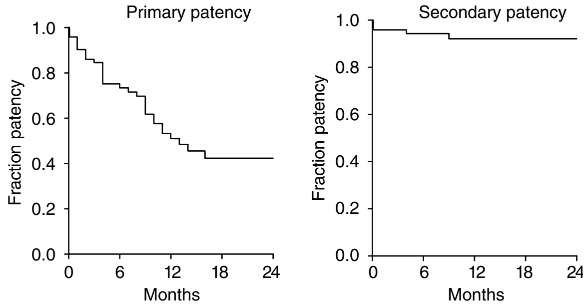

Figure 1 | Primary and secondary patency following percutaneous balloon angioplasty of perianastomotic AVF stenosis.

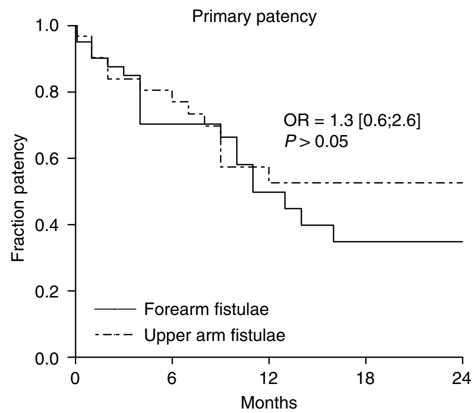

Figure 2 | Comparison of primary patency between forearm and upper arm fistulae.

underwent 63 and 49 procedures, respectively. There was no statistical difference in the number of procedures in each category. Comparison of primary patency rates between these two groups suggested a trend to higher patency rates in upper arm fistulae ($P > 0.05$). Compared to forearm fistulae, primary patency rates in upper arm fistulae were 77 vs 70% at 6 months, 52 vs 47% at 12 months, and 52 vs 35% at 18 months (Figure 2).

Patency analysis based on the status of the AVF revealed that there were 41 patients with early AVF failure (forearm = 23 and upper arm = 18) and 32 patients with mature fistula dysfunction (forearm = 18 and upper arm = 14). Fistulae with early failure underwent 69 procedures,whereas mature fistulae had 43 procedures. Overall, patients with early failure received 1.7 ± 0.1 procedures, whereas mature fistulae had 1.4 ± 0.1 procedures ($P = 0.04$). Compared to mature fistulae, primary patency rates were significantly lower in fistulae with early failure ($P = 0.027$): 59 vs 89% at 6 months, 46 vs 59% at 12 months, and 25 vs 56% at 18 months (Figure 3). Secondary patency rates revealed no significant differences for fistulae with early failure vs mature fistulae: 94 vs 95% at 6 months and 94 vs 93% at 12 and 18 months. Median primary patency was 24 months for mature fistulae; for fistulae with early failure, median primary patency was 11 months ($P = 0.018$).

There were 29 patients who underwent repeat procedures and were included in the life table analysis. A total of 68 procedures were performed in this cohort. The demographic characteristics of this group demonstrated that 69% (20/29) of the patients who required repeat intervention had early AVF failure (Table 3). In contrast, there were only nine patients with mature fistulae that needed a repeat intervention. The demographic characteristics also revealed that there were no significant differences regarding age, race, gender, and the cause of end-stage renal disease between patients with early failure requiring repeat procedures and those with mature AVF needing repeat procedures.

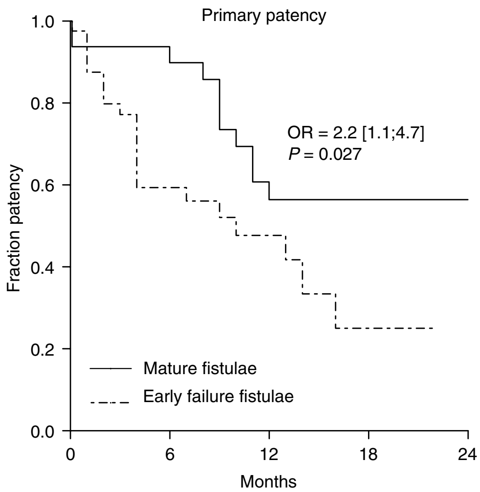

Figure 3 | Comparison of primary patency between mature and fistulae with early failure. Secondary patency rates revealed no significant differences for fistulae with early failure vs mature fistulae: 94 vs 95% at 6 months and 94 vs 93% at 12 and 18 months.

Table 3 | Demographic characteristics of patients undergoing repeat interventions

Number of patients	29
Age (years)	54±8
Gender	
Men (%)	66%
Race/ethnicity	
African American	14 (48%)
Hispanic	10 (35%)
Haitian	3 (10%)
Caucasian	2 (7%)
Cause of ESRD	
Hypertension	16 (55%)
Diabetic nephropathy	11 (38%)
Glomerulonephritis	1 (3.5%)
Lupus nephritis	1 (3.5%)
Type of fistula	
Forearm	17 (59%)
Upper arm	12 (41%)
Status of fistula	
Early failure	20 (69%)
Mature fistula	9 (31%)

ESRD, end-stage renal disease.
Data are mean±s.d.

Both pre- and postangioplasty flow studies were available in 60 of the 68 cases of mature fistulae. In these patients, postangioplasty flow showed a mean of 1009±347 ml/min compared to a pretreatment value of 524±189 ml/min. Blood flow failed to increase by more than 20% in seven cases (preangioplasty=632±179 ml/min and postangioplasty=679±181 ml/min). Five were forearm and two were upper arm fistulae. Access flow was available in 38/41 patients with early AVF failure. In this group, postangioplasty access flow was 969±394 ml/min. Preprocedure flow was not available in these cases because none of the patients in this cohort had started dialysis.

In this study, there were five complications (4.4%): three minor (2.6%) and two major (1.7%). Minor complications included one minor extravasation of radiocontrast and two patients with a grade I hematoma that did not need any specific intervention. The two major complications were both vein rupture that required prolonged inflation of the angioplasty balloon to stop an expanding hematoma. These two patients developed fistula thrombosis. In one patient, this occurred during the first procedure when vein rupture occurred and the access thrombosed. In the other, it resulted during a repeat procedure at 4 months owing to vein rupture. Both these patients lost their access. The three initial failures were owing to the inability to navigate the guidewire across the arterial anastomosis and into the proximal radial artery. These patients, all having a radiocephalic fistula, were referred to vascular surgery for the creation of a loop fistula using the same cephalic vein. Two received a loop fistula successfully, whereas the third patient refused further access surgery, and became catheter consigned.

Of note, none of the patients in this study were converted to an arteriovenous graft and 68/73 (93%) are functional with a mean follow-up of 12±7.4 months.

DISCUSSION

The autologous AVF is the preferred form of hemodialysis access because of its superior longevity as well as lower complication rates. However, even this type of access does experience complication such as venous stenosis. Recent data have emphasized that the lesions in the perianastomotic region are more common (~40%) than previously reported.[6,7] In fact, these are the predominant stenoses in fistulae with early failure.[7] Previously, surgical creation of a new anastomosis has been highlighted to be the preferred approach for the management of these lesions.[1–5] However, the findings of the current study suggest that these stenoses can be safely and successfully managed percutaneously, an approach that offers advantages over surgery.

The surgical approach for the management of stenosis in the arterial anastomotic region has been supported by only a few reports.[1–5] Importantly, not all of the patients in these studies demonstrated perianastomotic lesions. Additionally, these studies have clearly used synthetic material to treat anastomotic stenosis, thereby converting AVF to grafts. Only one study was both prospective and controlled (Tessitore N, Lipari G, Poli A *et al. J Am Soc Nephrol* 2004; **15**: 202A). The others were all retrospective and a majority limited by a small sample size ranging from 14 to 29 patients.

In contrast to the surgical reports, all 112 cases treated with PTA in the current study had stenosis in the arterial anastomotic region. Of note, none of the patients received an arteriovenous graft, whereas the surgical approach has documented placement of synthetic material in as many as 39–54% of the patients[5] (Tessitore N, Lipari G, Poli A *et al. J Am Soc Nephrol* 2004; **15**: 202A). The cannulation area was preserved in all of the patients treated in the present study, whereas reduction in this segment has been a concern with the surgical approach.[1,4,5] Because surgical reports also included patients with stenoses in locations other than the perianastomotic area, used a variable definition of patency rates, or excluded patients with early fistula failure, the comparison of patency rates of these studies with the percutaneous management must be performed with caution[1,2,4,5] (Tessitore N, Lipari G, Poli A *et al. J Am Soc Nephrol* 2004; **15**: 202A). Nevertheless, the cumulative patency rates of 79 and 64% and 67 and 50% reported by two surgical reports[1,5] at 6 and 12 months are comparable to the primary patency of 76 and 51% at 6 and 12 months, respectively, for the present study. In contrast, excellent secondary patency (94 and 90% at 6 and 12 months, respectively) was documented by the current report.

In a prospective controlled trial, Tessitore *et al.* (Tessitore N, Lipari G, Poli A *et al. J Am Soc Nephrol* 2004; **15**: 202A) evaluated the role of percutaneous vs surgical management of the venous perianastomotic stenosis of dysfunctional mature forearm fistulae. The surgical modality was employed in 22 patients and included the creation of a new anastomosis by either proximal neoanastomosis ($n=10$) or a short 4–7 cm synthetic graft interposition ($n=12$), whereas percutaneous intervention consisted of balloon angioplasty ($n=40$).[8] Although primary patency was better in the surgical group (surgery vs percutaneous: 100 vs 85 ± 6%, 86 ± 7 vs 68 ± 8%, 69 ± 11 vs 36 ± 10%, 60 ± 12 vs 36 ± 10%, and 50 ± 14 vs. 18 ± 10% months at 6, 12, 24, 36, and 48 months, respectively, $P=0.02$), there were no statistical differences in either the overall success rate (surgery 100% vs percutaneous 96%) or the assisted primary patency rates for the two modalities (surgery vs percutaneous: 100 vs 98 ± 2%, 86 ± 7 vs 94 ± 4%, 69 ± 11 vs 90 ± 5%, 60 ± 12 vs 79 ± 9%, and 50 ± 14 vs 64 ± 12% months at 6, 12, 24, 36, and 48 months, respectively, $P=0.22$). However, the immediate surgical success observed in this study required the insertion of a 4–7 cm segment of synthetic graft to repair the stenosis in the venous perianastomotic region in over one-half (54%) of the cases. This, in effect, converted what had been a fistula into an arteriovenous graft. It should also be noted that this study included only mature fistulae. The current study includes data on fistulae with early failure. Although primary patency as determined by these data was lower than that reported by Tessitore, secondary patency rates were similar (94 and 90% at 6 and 12 months, respectively) and the result was achieved without the conversion of any fistulae to arteriovenous grafts by the insertion of synthetic material.

The use of a short piece (4–7 cm)[9] of graft material to repair a fistula can markedly confound the understanding of the differences between an arteriovenous graft and an AVF. Because only a small piece of prosthetic material is used instead of insertion of the usual 20–30 cm graft, one may erroneously conclude that it is still a fistula. The question is, does a small piece of synthetic graft material not induce neointimal hyperplasia (NH)? Although it would be difficult to design a study in dialysis patients to reveal the histologic changes induced by a short vs a long segment of graft material, the answer can be derived from existing data based upon multiple well-conducted animal studies that have used graft length ranging from 2.5 to 7 cm.[10–14] These studies have clearly demonstrated that NH develops regardless of the length of the graft material inserted. In an elegant study, Kelly *et al.*[10] used a 7 cm loop graft inserted between the femoral artery and vein of the domestic pigs to study the development of NH. These investigators demonstrated significant NH and venous stenosis by 28 days at the graft–vein anastomosis. In addition, minimal NH was also found at the graft–artery anastomosis. Of particular importance, at the cellular level, this study revealed that NH was characterized by the presence of smooth muscle cells, angiogenesis within both the neointima and adventitia, and the presence of an active macrophage cell layer lining the graft material. These changes are virtually identical to those reported in the NH lesion associated with grafts in dialysis patients.[14] Although most of the animal studies utilized 7 cm polytetrafluoroethylene material, graft lengths as small as 2.5–5 cm have been found to produce the same lesion.[12] These studies also illustrate that puncture and cannulation of the graft is not necessary to induce NH.[10–13]

Graft insertion to repair a perianastomotic lesion in a patient with a fistula subjects the patient to two vessel–graft anastomotic sites, thereby introducing the risk of NH associated with polytetrafluoroethylene material. Short or long, insertion of graft material to repair a fistula essentially converts it into an arteriovenous graft.

Many interventions have been highlighted to maximize fistulae in chronic dialysis patients.[7,15–21] Salvage of fistulae with early failure also works toward improving fistula prevalence.[7,21] In the current report, fistulae with early failure were not abandoned. The majority, 38/41 (95%), of these fistulae were salvaged and successfully used for dialysis, although primary patency rates (59 and 46%, at 6 and 12 months, respectively) were lower than those obtained for mature fistulae (88 and 56% at 6 and 12 months, respectively) ($P=0.02$) (Figure 3). In addition to the present study, Beathard *et al.*[7] previously demonstrated successful treatment and excellent primary patency in a study that included early failure fistula patients with perianastomotic lesions. Our patency rates of fistulae with early failure were inferior to those reported by this study (primary patency of 72 and 68% at 6 and 12 months, respectively). It should be noted, however, that the current study involved consecutive cases, without exclusions, the previous study[7] was based upon cases derived from multiple centers, and the criteria for patient referral from the dialysis facility to the interventional center are not known.

Previous investigators have considered patients with multiple or critical (>90%) perianastomotic (artery or vein) stenoses as not amenable to angioplasty.[9] There is no unique relationship between the perianastomotic site of stenotic lesions and the degree to which either stenosis or flow improves after angioplasty. This was shown by reduction of degree of stenosis by nearly 70% (81 ± 9 to 11 ± 11%) and increment of access flow by at least 20% (524 ± 189 to 1009 ± 347%) after angioplasty in the current study. In only seven cases, postangioplasty flow did not increase by more than 20%.

Multiple procedures were performed in 26 of our patients. The demographic characteristics of these subjects did not reveal an overabundance of diabetes (38%) or advanced age (54 ± 8 years) (Table 3). However, a majority (69%) of these fistulae had early failure.

Of note, 49 cases (44%) with stenosis in the arterial anastomotic area demonstrated coexisting lesions elsewhere in the access system. Ten cases revealed a stenosis in the feeding artery proximal to the anastomosis, whereas 39 cases harbored lesions on the venous side. This emphasizes the need for a more thorough evaluation of the access system before subjecting the patient to a specific treatment. In addition to complete imaging of the venous side of the access circuit, evaluation must undertake investigation of the feeding artery in order to avoid overlooking lesions upstream from the arterial anastomosis, a specific scenario possibly overlooked in surgical series where an undetected arterial stenosis in the feeding artery could result in subsequent fistula failure, as reported previously.[4] It has been highlighted in the surgical literature that angiography may occasionally be helpful in these cases.[22] On the contrary, complete radiocontrast imaging of patients with perianastomotic lesions (feeding artery and venous outflow) is critical to optimally identify the coexisting stenoses and formulate a treatment strategy.

Before the availability of interventional nephrology at our medical center, it was common for fistula patients with perianastomotic stenoses to be referred to the vascular surgeon for access revision. The surgical approach to fistula revision most commonly employed was the insertion of an interposition graft to revise the anastomosis *per se* or replacement of the fistula with a graft either in the same arm or contralaterally. Early-failure fistulae were typically abandoned in favor of conversion to a synthetic graft. Vascular reconstruction by means of creating a more proximal native arteriovenous anastomosis was rarely undertaken. Comparing our percutaneous results to those reported for the surgical approach demonstrates that there is no need to refer such fistula patients for surgery unless the interventional approach fails in an individual patient.

Conclusion

The outpatient interventional approach of diagnostic angiography and therapeutic angioplasty is safe and effective for the management of fistula patients with perianastomotic stenosis. Because of its ability to diagnose and treat coexisting stenoses in the entire access system and its consequent advantage of fistula preservation, the interventional percutaneous approach should be considered as the preferred first-line therapy for management of perianastomotic fistula lesions.

MATERIALS AND METHODS

Settings and study design

During the 27 months from March 2003 to July 2005, 108 hemodialysis patients were referred to the University of Miami Interventional Nephrology Vascular Laboratory for outpatient angiographic evaluation of either early AVF failure or mature fistula dysfunction (access flow (Qa) less than 600 ml/min or Qa less than 1000 ml/min that had decreased by more than 25% over 4 months[23]). Reported in this study are 73 consecutive patients found to have perianastomotic stenosis. Stenotic lesions were treated with PTA. All patients were followed prospectively to determine the fate of the fistulae.

Local institutional review board approval was obtained for this study. All study procedures were carried out in accordance with the Declaration of Helsinki Principles regarding research involving human subjects.

Definitions

Stenosis was defined as $\geqslant$50% narrowing in luminal diameter based upon comparison with the adjacent normal vessel.[23] Juxta-anastomotic stenosis was defined as narrowing of the AVF immediately downstream from the arterial anastomosis.[7] Combined, arterial anastomosis and juxta-anastomotic areas were referred to as the perianastomotic region. None of the patients in this report had previously treated perianastomotic lesions. Based on a previous study addressing stenosis at the arterial anastomotic site,[24] the same rule of $\geqslant$50% was applied to the arterial anastomosis where the comparison was made with the adjacent normal artery. Proximal venous stenosis was defined as a stenotic lesion anywhere in the vein from the juxta-anastomotic portion to the central veins, whereas central stenosis was defined as the narrowing in the subclavian or brachiocephalic veins or in the superior vena cava.[7] The degree of stenosis was measured using calibrated computer software within the digital imaging system (C-Arm 9800 Vascular Package) (General Electric, Milwaukee, WI, USA).

Early AVF failure was defined as an AVF that never developed to the point that it could be used or that failed within the first 3 months of usage.[7]

Primary patency was defined as the time period during which no procedure or intervention was required to maintain patency. Secondary patency after intervention was defined as patency until the access was surgically revised, declotted, abandoned, or lost to follow-up.[25] Thrombolysis and percutaneous thrombectomy were considered compatible with secondary patency, as was multiple repetitive treatments.[25] A functional fistula was defined as one that could successfully support dialysis with access flow of 350–400 cm^3/min without recirculation.

Complications encountered within 30 days of the procedure were considered to be procedure-related. Grading of hematoma was based on recent published definitions.[26]

Description of angiography and angioplasty

Both antegrade and retrograde angiography were employed to thoroughly evaluate the AVF. Retrograde angiography was performed either by manually occluding the outflow tract of the AVF or by advancing a diagnostic catheter into the arterial system in order to visualize the juxta-anastomotic venous portion of the access, the arterial anastomosis as well as the feeding artery.[24] Application of a blood pressure cuff or any other device to the outflow tract to perform retrograde angiography was not required and never performed. Images were recorded using digital subtraction angiography in multiple planes including the orthogonal views.

Angioplasty was performed using a standard technique.[7,27] Low (Classique; Ultrathin diamond; Boston Scientific), medium-to-high (Workhorse; Angiodynamics: Queensburry, NY, USA: BlueMax; Bostons Scientific: Natick, MA, USA), and ultra-high-pressure balloons (Conquest; Bard Peripheral: Tempe, AZ, USA) were all used for angioplasty depending upon the situation. In general, low-pressure balloons were used for arterial lesions, whereas high- and ultra-high-pressure balloons were used for the venous side.

Parameters recorded

Demographic characteristics of the 73 study patients were analyzed. The number and location of stenoses were recorded. Coexisting stenoses were also investigated. The degree of stenosis before and after angioplasty was assessed. Procedure success, primary and secondary patency, repeat interventions, and procedure-related complications were recorded. Patency variations were compared for forearm vs upper arm and mature vs early-failure fistulae. AVF conversion to a graft was also investigated.

The success of angioplasty was defined as per the Kidney Disease Outcomes Quality Initiative (K-DOQI) vascular access guidelines ($\leqslant$30% residual stenosis).[23] The pre- and postangioplasty access flows (measured by ultrasound dilution technique within 2 weeks after angioplasty) were recorded for cases with mature fistulae in all instances in which these studies could be accomplished. Postangioplasty flows were recorded in early AVF failure cases.

Statistical analysis

The summary statistics of continuous variables were reported as mean $\pm$ s.d. Means of two independent groups were compared by *t*-test. Proportions were compared using χ^2 analysis. Kaplan–Meier survival curves and Cox regression analysis using the log-rank test were used to compare patency rates. Life table analysis was used to calculate median times of unassisted patency. The level of significance was set as $P<0.05$.

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