Outcomes of balloon angioplasty for failing upper extremity dialysis access

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Background
Percutaneous transluminal angioplasty (PTA) is the mainstay of treatment in stenosed hemodialysis access. Being less invasive and outpatient procedure, PTA is a safe and useful intervention to maintain access patency in patients with failing hemodialysis arteriovenous fistulas (AVFs). The aim of this study was to evaluate the efficacy of balloon angioplasty in treatment of patients with failing upper extremity hemodialysis access.

Methods
This is a prospective study of all adult patients who underwent balloon angioplasty for the treatment of patients with symptoms of a failing dialysis access due to presence of significant stenosis in dialysis access circuit. The study conducted at the Department of Vascular and Endovascular Surgery, Assiut University Hospital (a tertiary referral hospital), between January 2017 and December 2018. Both the primary and assisted primary patency rates were analyzed by the Kaplan-Meier plot method.

Results
149 patients underwent PTA for treatment of failing dialysis access symptoms. The most common site of stenosis in our study was the juxta-anastomotic site (49 %). The overall success rate was 96.6%. Balloon angioplasty was performed in all patients without stent placement. Sixteen (10.7%) complications were encountered in the study. At 1 year, the primary patency and the assisted primary patency rates was 60.5% and 80%, respectively. Age of the fistula (P=0.017), presence of multiple lesions (P=0.016), total lesion length >5cm (P=0.030), and diabetes mellitus (P=0.012) were significant independent predictors of loss of primary patency.

Conclusions
Balloon angioplasty is safe and effective treatment modality for treatment of stenosis in failing hemodialysis access patients with good technical success and acceptable short-term primary patency rates. Repeated interventions are required to maintain patency.

Keywords:
failing hemodialysis access, percutaneous transluminal angioplasty, stenosis

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Introduction

The presence of functioning vascular access with an adequate flow is the mainstay for patients undergoing chronic hemodialysis (HD) [1]. Vascular surgeon and nephrologist should carefully monitor these accesses for early recognition of complications to prolong as much as possible the patency of this access fistula [2]. Failure of the access occurs mostly owing to stenosis developing in the venous component [3]. This stenosis, if inadequately and timely treated, is associated with a high rate of morbidity, mortality, and loss of the vascular access [4,5]. Therefore, the Kidney Disease Outcomes Quality Initiative guidelines recommended early treatment of significant stenoses once detected in the arteriovenous fistula (AVFs) [6]. Both surgical correction and endovascular intervention are established techniques for treatment of HD patients with failing access. Currently, percutaneous transluminal angioplasty (PTA) has become the treatment of choice for stenosis in such patients [7,8]. Advantages of balloon angioplasty are being less invasive, providing better preservation of the vessels, and associated with high technical success rate [9]. The aim of the study was to assess the immediate and short-term outcomes of the application balloon angioplasty for salvage of failing AVFs.

Patients and methods

Patients

This prospective observational study was approved by our Institutional Review Board, and conducted

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between January 2017 and December 2018 in a high-volume, Tertiary Referral University Hospital. The study cohort included 149 consecutive patients with active HD who underwent endovascular interventions for treatment of failing upper extremity AVF.

Patients fulfilling at least one the following clinical and/or hemodynamic criteria of failing AVF were included [6]: first, difficulty with AVF cannulation; second, decreased thrill or bruit; third, prolonged bleeding from puncture site greater than 15 min after HD; fourth, elevated venous pressure greater than 150 mmHg; and fifth, decreased dialysis flow less than or equal to 200 ml/min.

Patients with inadequate fistula maturation, concomitant central venous stenosis, synthetic or composite grafts, thrombosed AVF, and known allergy to contrast agents were excluded from the study.

All patients underwent duplex ultrasound (DUS) scanning, using Philips HD5 (Philips Healthcare, Eindhoven, the Netherlands) fitted with 3–12 MHz linear array transducer, to confirm the diagnosis (≥50% reduction in luminal diameter of the feeding artery or outflow vein), identify its location and extent, assess the feeding artery, and plan for the puncture site for intervention.

All eligible patients were fully informed about the nature of the study, as well as the alternative treatment modalities available, and provided informed consent once agreed to participate in the study.

Procedure

All procedures were performed in a hybrid operative room, equipped with a mobile C-arm fluoroscopy device (Philips Pulsera; Philips Healthcare), by dedicated and experienced vascular surgeons, under local anesthesia (2% lidocaine), with optional monitored conscious sedation (midazolam and fentanyl).

Overall, 5000 IU of heparin was delivered intravenously at the beginning of the procedure to guard against thrombotic events. After gaining percutaneous access to the AVF, diagnostic fistulography of the entire access circuit to the level of the right atrium was performed, through a 6-Fr, 11-cm-long introducer sheath (Prelude; Merit Medical Systems Inc., South Jordan, Utah, USA), to confirm the diagnosis and identify the location and length of stenosis.

Stenotic lesions were negotiated using angled tip 0.035′ hydrophilic guide wires (Glidewire; Terumo Medical Corp., Somerset, New Jersey, USA), or 0.018′ guide wires (V-18 Control Wire; Boston Scientific, Marlborough, Massachusetts, USA).

Then angioplasty was performed using 3-mm to 12-mm-diameter, 4-cm to 8-cm-long high-pressure balloons (Dorado; Bard Peripheral Vascular Inc., Tempe, Arizona, USA and Mustang; Boston Scientific). The size of the balloon was selected according to the reference diameter of the most proximal nonaneurysmal vein segment. The balloon inflation time was 3–5 min and in cases of rupture or elastic recoil, inflation was extended for 5–10 min.

Postangioplasty completion angiography was obtained in two views as near to orthogonal as possible to assess the technical success of the procedure and exclude possible complications. The procedure was concluded with removal of the sheath, and hemostasis was achieved with the use of a purse-string suture [10]. Patients were prescribed lifelong aspirin 75 mg/day, and HD was resumed 1 day after the procedure.

Follow up

Monitoring and surveillance was subsequently performed using clinical and HD criteria, respectively, to detect a failing/failed access. Each patient's HD records were reviewed, and all access-related events were documented. Follow-up information for each patient was collected at 1, 3, 6, and 12 months after the treatment procedure.

Study outcome measures

Study outcome measures were defined according to the Society of Interventional Radiology reporting standards for percutaneous interventions in dialysis access, namely [11] first, technical success defined as patent access with less than 30% residual stenosis at the end of the procedure; second, primary patency defined as the interval following the first endovascular intervention until any intervention designed to maintain or to restore patency, access abandonment, or the time of measurement of patency; and third, assisted primary patency defined as the interval following the first endovascular intervention until access abandonment or the time of measurement of patency including intervening manipulations (surgical or endovascular) designed to maintain patency.

Statistical analysis

Statistical analysis was performed using SPSS 25.0 (SPSS Inc., Chicago, Illinois, USA) and MedCalc

Table 1 Patients demographics and access characteristics

Variables	Values (*n*=149) [*n* (%)]
Age (years)	
Mean±SD	46.2±10.6
Range	33–76
Median (IQR)	43 (17)
Sex	
Male	99 (66.4)
Female	50 (33.6)
Diabetes mellitus	81 (54.4)
Hypertension	48 (32.2)
Smoking	32 (21.5)
Access type	
Radiocephalic	11 (7.4)
Brachiocephalic	85 (57)
Brachiobasilic transposition	53 (35.6)
Access side	
Right	45 (30.2)
Left	104 (69.8)
Access age (months)	
Mean±SD	15.6±9.0
Range	6–40
Median (IQR)	13(12)

IQR, interquartile range.

16.8 (MedCalc Software, Ostend, Belgium). Continuous variables were expressed as mean±SD and/or median and interquartile range, and categorical variables as frequency and percentage. Patency rates were analyzed on an 'intention-to-treat' basis using Kaplan–Meier survival curve, reported as proportion±SE, and intergroup differences were compared using the log-rank test. Multivariate analysis using Cox proportional-hazards regression model with stepwise approach was generated to assess the influence of various demographic, access, and lesion characteristics on primary patency, with results presented as hazard ratio (HR) and 95% confidence interval (CI). A *P* value less than 0.05 was considered statistically significant.

Results

During the study period, 149 patients, including 99 (66.4%) males, with a mean age of 46.2±10.6 years, presenting with clinical and/or hemodynamic manifestations of failing upper extremity HD access underwent endovascular balloon angioplasty for significant stenotic lesion(s) along the access circuit.

A total of 104 AVFs (69.8%) were located on the left upper limb, and 85 AVFs (57%) were brachiocephalic. The mean interval between creation of the AVFs and endovascular intervention was 15.6±9.0 months. Patient demographics and access characteristics are summarized in Table 1.

Table 2 Procedural details

Variables	Values (*n*=149) [*n* (%)]
Indications for intervention	
Decrease dialysis flow rates	83 (55.7)
Inability/difficulty of cannulation	42 (28.2)
Decreased thrill	13 (8.7)
Prolonged bleeding from puncture site	11 (7.4)
Access for intervention	
Brachial artery	131 (87.9)
Venous limb of AVF	12 (8.1)
Radial artery	4 (2.7)
Femoral artery	2 (1.3)
Lesion number	
Single	108 (72.5)
Multiple	41 (27.5)
Lesion location	
Anastomotic	21 (14.1)
Juxta-anastomotic	73 (49)
Cephalic arch/proximal swing point	46 (30.8)
Mid-vein segment	51 (34.2)
Feeding artery	10 (6.7)
Total lesion length (cm)	
<2	18 (12.1)
2–5	97 (65.1)
>5	34 (22.8)

AVF, arteriovenous fistula.

The main indication for intervention was decreased dialysis flow rates (83/149, 55.7%), and stenotic lesions were most commonly juxta-anastomotic (73/149, 49%) (Fig. 1). A total of 41 accesses (27.5%) had multiple stenotic lesions, including 30 AVFs with two lesions and 11 AVFs with more than two lesions. Other lesion characteristics are illustrated in Table 2.

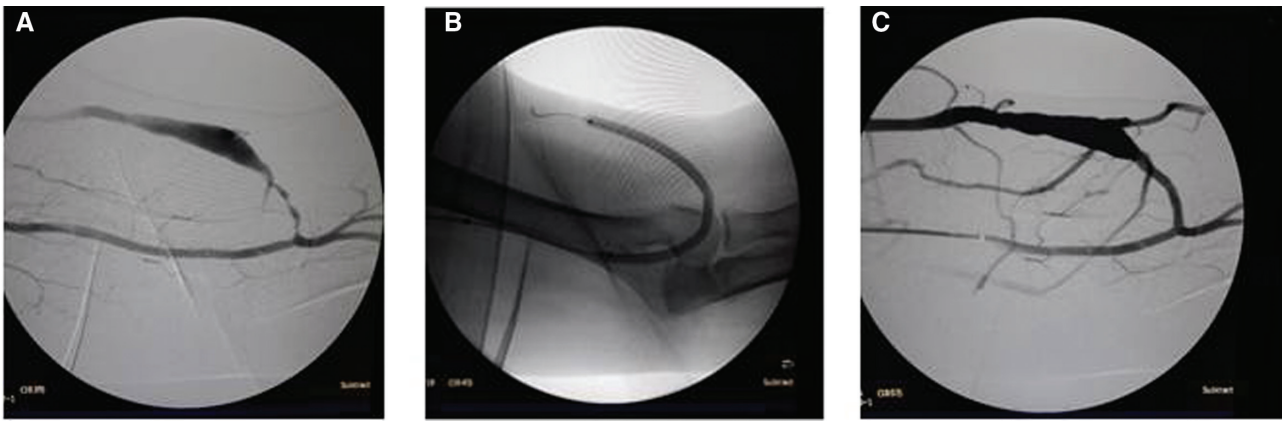
Technical success was achieved in 96.6% of cases (144/149). Failures were owing to residual stenosis greater than 30% in four patients and elastic recoil in one patient. These accesses underwent patch angioplasty (three patients) or abandonment (two patients) owing to presence of extensive lesion that was deemed beyond repair.

Complications developed in 16 (10.7%) accesses. Extravasation (due to vein rupture) occurred after balloon inflation in five patients, and hemostasis was successfully achieved by balloon tamponade combined with manually applying external compression. Persistent bleeding from the puncture site occurred in two patients and was managed with prolonged compression and additional purse-string suture when appropriate. Postoperative puncture site hematoma developed in six accesses and was treated conservatively. Moreover, three AVFs developed early thrombosis within the first postoperative day and were abandoned.

All patients were followed up for a mean period of 18.5 ±6.2 months. During the study period, 28 accesses were abandoned owing to either thrombosis (12 patients) or infection (16 patients). Twenty three were censored owing to loss of follow-up (nine patients), death (eight patients), and renal transplant (six patients). The post-intervention primary patency rate of the target lesions was 83.2±3.1, 74.0±3.6, and 60.5±4.2% at 3, 6, and 12 months, respectively (Fig. 2).

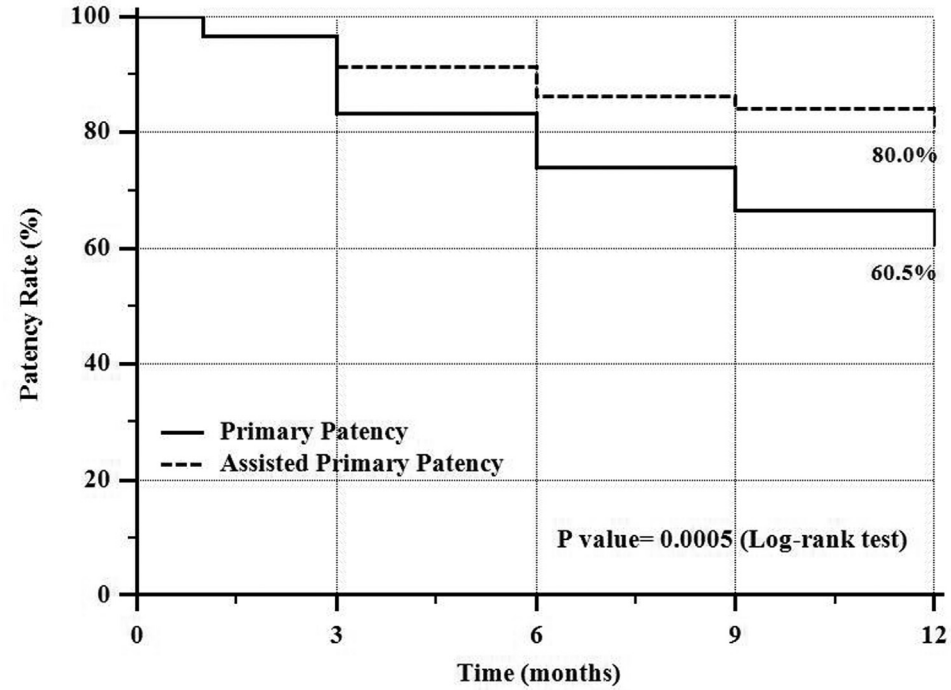
During follow-up, 27 (18.1%) patients showed greater than 50% target lesion recurrent stenosis and subsequently underwent preemptive high-pressure balloon angioplasty (i.e. primary patency ended). Re-interventions increased significantly the post-intervention assisted primary patency to 91.3 ±2.3, 86.3±2.9, and 80.0±3.4% at 3, 6, and 12 months, respectively (log-rank test, *P*=0.0005) (Fig. 2).

Figure 1



(a) Failing left brachiocephalic fistula with juxta-anastomotic stenoses; (b) balloon angioplasty of the lesion using 6×80 mm balloon; (c) final angiogram with resolution of the stenoses.

Figure 2



At Risk

Primary P.	149	117	98	78	71
Ass. Prim.	149	129	116	103	98

Kaplan–Meier.

Table 3 Univariate and multivariate analyses of demographics, access, and lesion characteristics for predictors of primary patency loss

Variables	Univariate analysis		Multivariate analysis	
	HR (95% CI)	*P* value	HR (95% CI)	*P* value
Age	1.01 (0.99–1.04)	0.359		
Male sex	0.76 (0.44–1.31)	0.325		
Diabetes	1.40 (0.82–2.40)	0.215	2.06 (1.18–3.60)	0.012
Hypertension	0.99 (0.56–1.75)	0.976		
Smoking	0.54 (0.26–1.14)	0.106		
Brachiocephalic AVF	1.61 (0.92–2.82)	0.098		
Left-sided access	0.90 (0.50–1.61)	0.726		
Access age	0.91 (0.88–0.95)	0.0001	0.95 (0.90–0.99)	0.017
Multiple lesions	5.57 (3.20–9.70)	<0.0001	2.74 (1.21–6.18)	0.016
Lesion length >5 cm	4.76 (2.80–8.10)	<0.0001	2.25 (1.09–4.67)	0.030

AVF, arteriovenous fistula; CI, confidence interval; HR, hazard ratio.

Univariate analysis for predictors of loss of primary patency is reported in Table 3. Multivariate analysis using Cox proportional-hazards regression model revealed that decreased access age (HR: 0.95; 95% CI: 0.90–0.99; *P*=0.017), presence of multiple lesions (HR: 2.74; 95% CI: 1.21–6.18; *P*=0.016), total lesion length greater than 5 cm (HR: 2.25; 95% CI: 1.09–4.67; *P*=0.030), and diabetes mellitus (HR: 2.06; 95% CI: 1.18–3.60; *P*=0.012) were the only significant independent predictors of loss of primary patency (Table 3).

Discussion

Maintenance of an appropriate function of the vascular access is the main target in HD patients. Thrombosis is the most fearsome complication and usually occurs owing to underlying stenosis in the access circuit. Thrombosis of the AVF requires multiple surgical procedures, which may lead to loss of the vascular access and creation of a new one [12]. Therefore, many studies supported the role of endovascular therapy in the treatment of symptomatic significant stenosis to reduce AVFs thrombosis rates [13,14].

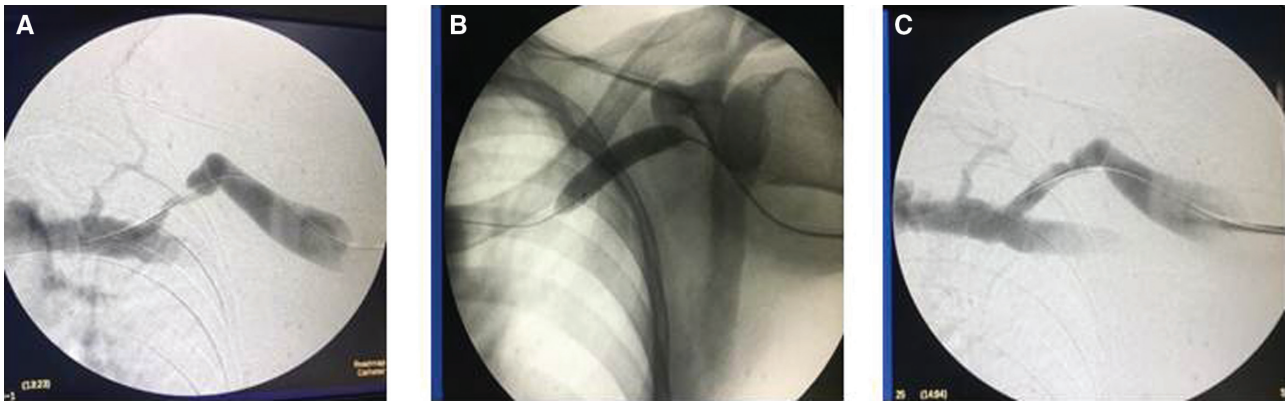
The main indication for angioplasty in a HD patient is the presence of luminal diameter stenosis greater than 50% detected by DUS, associated with clinical and/or hemodynamic abnormalities [15]. In the present study, decreased access flow rates (55.7%) were the main presenting symptom, suggesting that a patient's HD access was failing. This finding correlates with the results of Tan *et al.* [15], emphasizing the role of regular access monitoring. Routine clinical examination, DUS scanning, and dialysis flow parameters help in early detection and salvage of patients with failing dialysis access. However, other clinical trials revealed that the effect of regular surveillance program on patency is uncertain and exposes the patients to unnecessary interventions [16,17].

Stenosis is a common problem of AVFs and represents the main cause of dysfunction and thrombosis. Endovascular therapy has the advantage of being able to treat all types of stenosis in any location. Although, stenotic lesions can occur at any location in the dialysis access circuit, there are certain sites specific for each fistula type. For the radiocephalic fistulas, it is the juxta-anastomotic segment (located within the first 2–5 cm of the outflow vein). For the brachiocephalic fistula, it is the cephalic arch region (Fig. 3). Moreover, upper arm transposed brachiobasilic fistula is particularly vulnerable to the development of stenosis in the end of basilic vein transposition (proximal swing point) [18], owing to both anatomic location and hemodynamic factors [19].

The most common site of stenosis, in the current study, was the juxta-anastomotic site (49%) which is consistent with other reports [20,21]. The inflow artery was the least frequent location (6.7%), which also correlates with results of other series [22].

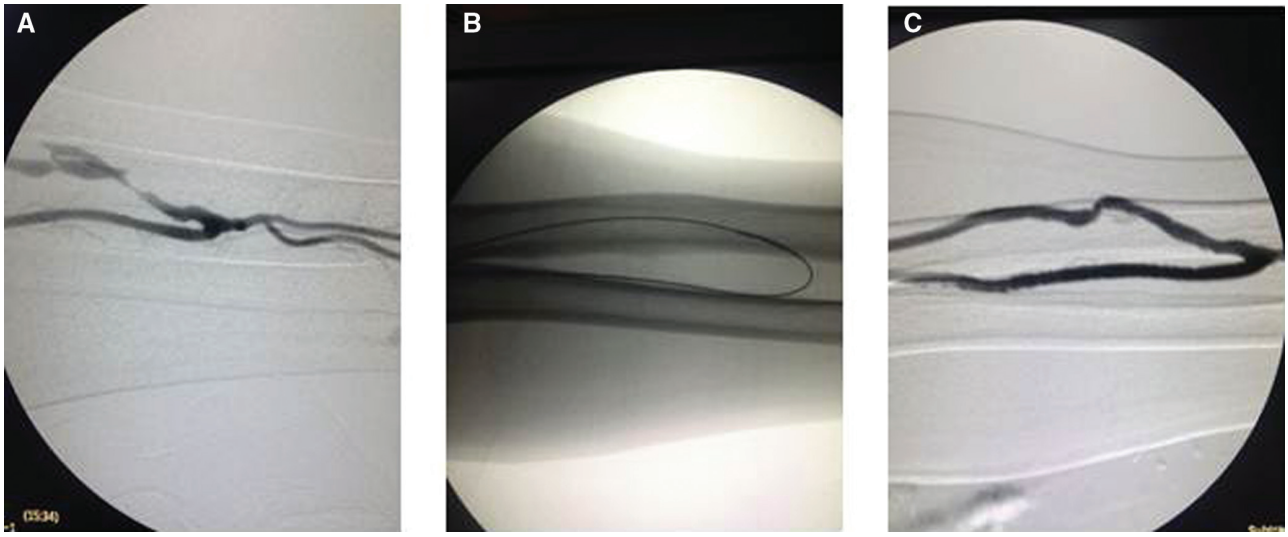
The optimal access site for intervention varies according to operator preference, suspected type and site of lesion, and the anatomic pattern of the fistula (Fig. 4). Currently, there is no consensus regarding the best approach for failing AVFs. The transbrachial approach was the most commonly used (87.9%) and preferred in the current study. The puncture of the brachial artery is usually technically straightforward and allows injection of contrast medium antegradely to the blood flow to provide good description of the arterial and venous vascular tree. Moreover, traversing the fistula in the direction of the blood flow is simple. However, compression of the brachial arterial after the procedure can damage the artery causing bleeding

Figure 3



(a) Failing left brachiocephalic fistula with cephalic arch stenosis; (b) balloon angioplasty of the lesion using 12×40 mm balloon; (c) final angiogram with absence of residual stenosis.

Figure 4



(a) Failing left radiocephalic fistula with juxta-anastomotic stenosis; (b) wire crossing of the lesion; (c) final angiogram after balloon angioplasty.

problems and may jeopardize the function of the fistula itself [5]. Vascular access through femoral artery offers the same advantages of transbrachial puncture in easy visualization of all the inflow and outflow vessels but necessitates the use of long wires, sheaths, and balloon catheter shafts. Although transvenous access by direct cannulation of the vein is usually relatively simple because the access vein is dilated in mature fistulas, the opacification of anastomotic, juxta-anastomotic area, and adjacent portion of the feeding artery is difficult, except by causing reflux of contrast material across the anastomosis by temporarily occluding the AVF using digital compression or inflation of a blood pressure cuff. However, this prohibits good image analysis [21].

The transradial approach to PTA for dysfunctional fistulas has rarely been reported. It allows visualization of the whole arterial and venous vascular tree of the AV fistula. Moreover, hemostasis at the radial artery puncture site can be achieved easily and safely by simple compression without obstructing the inflow and outflow of the AVF. On the contrary, the radial artery is small and may not accommodate the large sheath and balloon catheters needed for angioplasty. Puncture may be difficult because of the relatively weak radial arterial pulse owing to blood shunting through the AVF [23].

In recent years, many centers have considered balloon angioplasty as the first-line treatment modality for patients with failing AVF, whereas surgical method is suggested in case of angioplasty failure [24–26]. Angioplasty provides a quick intervention with low risk of infection. Moreover, there is no need for placement of a permanent

catheter, and HD is feasible during the same day after intervention.

In the current study, technical success was achieved in 144 (96.6%) patients. This is in accordance with results reported by other authors, who reported success rates of 75–100% [27,28]. High-pressure balloons were used for angioplasty. Stents were not used in this study because the stented venous segment cannot be used for placement of dialysis needle [21]. In addition, a stent placed across the cephalic arch protruding into the axillary vein will jeopardize the future use of the basilic and axillary vein for fistula creation or for drainage of an upper arm graft. Moreover, stents placed in this location are liable for kinking, crushing, and migration on movement of the shoulder [29].

During the past years, some researchers have investigated the use of cutting balloons and drug-coated balloons for treatment of dysfunctional AVFs [30]. However, the cost remains always a concerning problem with these techniques.

Complications were reported in 16 (10.7%) patients. Rupture of the vein is the most frequent complication of angioplasty, which can be treated conservatively, or in some cases, stent or covered stent placement may be needed [31]. In the present study, vein rupture associated with extravasation occurred after balloon inflation in five patients and was managed by balloon tamponade combined with manually applying external compression. However, other investigators reported vein rupture to be potentially more harmful, requiring transfusion and stent or stent graft placement [32].

Patency of AVFs can be maintained with both open and endovascular revisions. Although the durability of PTA seems to be shorter than surgery, the patency can be improved by repeated intervention. The target of endovascular intervention has to be 50% for primary patency during the first 6-month period [33].

During the study period, Kaplan–Meier analysis yielded a primary patency rate of 74.0±3.6 and 60.5 ±4.2% and assisted primary patency rate of 86.3±2.9 and 80.0±3.4% at 6 and 12 months, respectively. These results are comparable to those of other several reports [21,34–36].

According to the most recent guidelines of vascular access, the main benefit of treatment of hemodynamically significant stenoses is decreased thrombosis, avoidance of suboptimal HD, and decrease central venous catheters, and not necessarily prolonged life of the vascular access [37]. Our strategy of repeat PTAs with very restrictive use of open revision in failing AVFs resulted in an assisted primary patency rate of 80% at 12 months, which means that most of our patients had a functioning access at one year.

Various anatomic and clinical characteristics and their relation with primary patency were studied. It was found that the newer the AVF, the shorter the primary patency (P=0.017). Other series have concluded that AVFs less than 6 months old were associated with a shorter primary patency compared with fistulas more than 6 months old (P=0.007) [38–40]. On the contrary, Manninen *et al.* [13] did not find a significant relation between the age of fistula and the primary patency. This may be explained by that AVFs which develop stenosis early from time of creation are likely to have either preexisting diseased vein or healthy vein with accelerated neointimal hyperplasia in response to AVF itself.

Moreover, the multivariate analysis using Cox proportional-hazards regression model revealed that the presence of multiple lesions (P=0.016), total lesion length greater than 5 cm (P=0.030), and diabetes mellitus (P=0.012) were significant independent predictors of loss of primary patency. These findings were consistent with other results. One series suggested that lesions greater than 4 cm predicted primary patency loss (P=0.004) [38]. In another study [41], it is reported that only diabetes was a significant predictor of loss of patency (P=0.04). However, other studies showed no effect of presence of diabetes mellitus, lesion length, and number of stenoses on the long-term patency of AVFs [1,21].

Limitations of this study are being a single-center, single-arm study with relatively small number of patients and short follow-up period.

Conclusion

In conclusion, endovascular intervention, in the form of balloon angioplasty, is a safe and effective treatment modality for failing AVFs. Re-stenosis is common and often requires further intervention in the form of repeat angioplasty. The durability of re-PTA is satisfactory and achieves a good assisted primary patency rate at 1 year. Newer fistulas, presence of diabetes, and multiple and long lesions (>5 cm) are associated with reduced primary patency after angioplasty. Further multicenter studies, including

larger number of patients, with long-term follow-up are needed to confirm these findings.

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Conflicts of interest
There are no conflicts of interest.

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