Drug-coated balloon angioplasty for failing arteriovenous fistulae: feasibility and short-term outcomes

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Aim
To evaluate the feasibility, efficacy, and short-term and mid-term outcomes of drug-coated balloons (DCBs) in salvage of failing dialysis access owing to significant access vein stenosis.
Patients and methods
DCB angioplasty was used for salvage of failing arteriovenous fistulae in patients with clinical and radiological evidences of recently (within 14 days) failing hemodialysis access between March 2019 and September 2019.
Results
A total of 23 patients were enrolled, comprising 15 males and eight females, with mean age of 52.9±15.3 years. All lesions were successfully crossed and predilated with plain old balloons sized to the available normal vein diameter before DCB angioplasty, except in one patient with central vein tight stenosis. Technical success was achieved in 21 of 23 patients. At 1 month after angioplasty, among 21 successful angioplasty patients, one patient had died of cause not related to the procedure. For the remaining 20 patients, 17 patients still had a patent access, representing 80.9% success rate; two patients could not show any clinical improvement for their access although remaining patent; and one patient showed early access thrombosis about 1 weak after angioplasty. In the 6-month follow-up, of the remaining 17 patients with successful angioplasty, one patient had died owing to causes not related to the procedure. In the remaining 16 patients, 15 patients still had a patent vascular access with one patient lost to follow-up, thus representing an overall success rate of 71.4%.
Conclusion
DCB angioplasty is a safe and effective method for salvage of the failing arteriovenous fistulae and could successfully delay recurrence of stenosis.

Keywords:
angioplasty, arteriovenous fistulae, drug-coated balloon

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Introduction

End-stage renal disease (ESRD) is a huge public health problem with significant morbidity, mortality, and cost [1]. Hemodialysis (HD) is still considered the most common therapy for patients with ESRD worldwide [2]. Constant attention to the vascular access patency and function is an integral part of the care for HD patients [3]. One of the most common referrals that vascular surgeons encounter is HD patients with failing of their arteriovenous fistulas (AVFs). Early intervention on AVFs with recently diagnosed access dysfunction increases the chance that the same access can still be used to provide future dialyses [4]. Because of the poor patient outcomes owing to vascular access stenosis, several treatment methods have been developed to deal with this problem [5]. For years, the golden standard for significant AVF stenoses with risk of access thrombosis has been percutaneous transluminal angioplasty, generally with conventional high-pressure plain balloons accompanied by bare metal stents as a bail-out method [6]. However, restenosis and reintervention rates remain high. According to recently published articles, up to 60 and 70% of patients develop access restenosis after percutaneous transluminal angioplasty at 6 and 12 months, respectively [6]. Drug-coated balloons (DCBs) delivering antiproliferative drugs such as paclitaxel at the angioplasty site have proved their efficacy in the treatment of coronary and peripheral arterial stenotic lesions. Therefore, it represents a novel attractive option for AVF stenoses [7]. Because still the current data regarding this new modality are scarce, the aim of this paper was to examine the efficacy of DCBs in AVF stenosis management [7].

Aim

The aim was to evaluate the feasibility, efficacy, and short-term and mid-term outcomes of DCBs in salvage

of failing dialysis access owing to significant access vein stenosis.

Patients and methods

We prospectively included in this study all patients with clinical and radiological evidences of recently (within 14 days) failing HD access of either autogenous AVF or synthetic AV grafts who were referred by their nephrology physicians to our Vascular Department at Kasr-Alaini Hospital between March 2019 and September 2019. According to Kidney Disease Outcome Quality Improvement (KDOQI) guidelines, a failing HD access was defined as an access that has been used to establish good dialysis dose but encountered some changes as reduced thrill and documented decrease in dialysis flow rate [4]. The parameters of failing access include flow less than 600 ml/min or less than 1000 ml/min with a more than 25% decrease over a 4-month period and documented increased venous pressure during dialysis of more than 150 mmHg, with significant (≥50%) access vein stenosis detected by duplex ultrasound [4]. We excluded patients with thrombosed dialysis access, failed access maturation, and stenosed or thrombosed arterial inflow. Ethical approval was obtained from the surgery department research committee, and an informed written consent was obtained from patients themselves or their first degree relatives after full explanation of the procedure.

Preoperative assessment

Preoperative assessment including clinical, routine laboratory investigations, and radiological assessment were done to confirm diagnosis of recently failing access and to detect site of stenosis. Efficacy of arterial inflow was checked by duplex ultrasound. Patients were admitted 1 day before the procedure where a temporary double-lumen central catheter was inserted in the contralateral internal jugular or subclavian veins and a preoperative HD session was given the night of the procedure to optimize the fluid and electrolyte balance.

Procedure

All procedures were carried out in our angiography suite with blood pressure and cardiac monitoring and under local anesthesia using 10 ml of lidocaine 2%. The patients were operated upon while in the supine position with the target upper extremity cleaned with an appropriate antiseptic solution and draped on a nearby arm board. In most cases, the venous part of the AVF access was punctured and an antegrade access was performed with insertion of an 11-cm 5- or 6-F sheath. The sheath was inserted in the ipsilateral radial artery or retrograde insertion in the access vein in cases with anastomotic or juxta-anastomotic lesions as appeared in the preoperative duplex scanning. An initial diagnostic angiography of the upper extremity access and the central veins was done using a small dose of nonionic contrast agents to localize the site and length of the stenotic lesion. After systemic heparin administration (80 IU/kg; 3000–5000 IU), the navigation of the lesion to be treated was conducted via the roadmap technique, and after determining the location of the stenotic lesions, crossing the lesion was done using an angled soft tip hydrophilic-coated 0.035-inch guide wire (TERUMOGLIDEWIRE; Terumo Medical Co-Operation, Tokyo, Japan) supported by a suitable curved catheter (4 F Bernstein or Vertebral catheter; Cordis, Warren, New Jersey, USA) or low-profile plain balloon. After crossing the lesion, balloon angioplasty with a 6–8-mm paclitaxel-coated balloon (IN.PACT Admiral DCB; Medtronic Vascular, Santa Rosa, California, USA) was performed for 3 min. If the first attempt is not successful, balloon angioplasty is repeated using the same balloon with a longer inflation time (for 5 min). Then completion angiography was done to confirm the procedure success. The sheath was removed and puncture site was manually compressed for 15 min. Unless contraindicated, patients were given anticoagulation therapy with low-molecular-weight heparins adjusted to the renal dose for 5 days. Patients were discharged the next day if no complications (hematoma, active bleeding, or access thrombosis) were encountered and was started on HD from the access after 1 week from the procedure. Technical success was defined as the restoration of flow combined with no stenosis or a residual stenosis of less than 30%, as compared with the initial angiography, whereas clinical success was defined as the successful restoration of AVF flow with satisfactory dialysis using the restored access after the procedure. Primary patency was calculated from the date of the initial procedure to the next subsequent access failure or thrombosis.

Follow- up protocol

Patients were followed up at outpatient department and examined for AV access function at each outpatient visit every 1, 3, and 6 months after discharge. Surveillance of complications was done and includes general complications such as death, myocardial infarction, pulmonary embolism and dye allergic reactions, together with local complications, such as access failure, hematoma, infection, bleeding, rupture, and acute ischemic embolism. Duplex

scanning was done before discharge and at 1, 3, and 6 months thereafter by an independent experienced operator to measure the access flow rate.

Results

A total of 23 patients with ESRD on regular HD from an upper extremity AV access were referred by their nephrology physicians to our vascular surgery department at Cairo University Hospitals from the period between March 2019 till September 2019 because of recent dysfunction of their AV access with inability to obtain a good dialysis dose with an identified access vein stenosis by duplex ultrasound and were enrolled in our study. The patients comprised 15 males and eight females, with mean age of 52.9±15.3 years. Patients' clinical characteristics are shown in Table 1.

All patients were previously diagnosed of having a recently failing upper extremity AV access within 14 days based on a previously performed venous duplex scanning that was done before referral by the nephrology physicians. A total of five patients had radial artery to cephalic vein AV shunts, whereas the rest of patients were all having brachial artery–based AV accesses (11 cases to cephalic vein, four cases to basilic vein, and three patients with bridge synthetic graft to the axillary vein). In most cases, we obtained antegrade vein access (16 patients), retrograde vein access was done in two cases for isolated anastomotic and juxta-anastomotic lesions, whereas radial artery access was done in five cases using micropuncture set that was replaced for 4-F sheath (Fig. 1). Types of treated AV access, sites of the stenotic lesions, and types of utilized endovascular access are all shown in Table 2. All lesions were successfully crossed and predilated with plain old balloons sized to the available normal vein diameter before DCB angioplasty except in one patient with central vein tight stenosis that we failed to cross even with the support of suitable curved catheters.

Table 1 Demographic and clinical characteristics of the study group

	n (%) (*N*=23)
Male	15 (65.3)
Female	8 (34.7)
DM	8 (34.7)
HTN	6 (26)
DM and HTN	6 (26)
No DM or HTN	3 (13)
Known cardiac problems	3 (13)
Known pulmonary problems	1 (4.34)

DM, diabetes mellitus; HTN, hypertension.

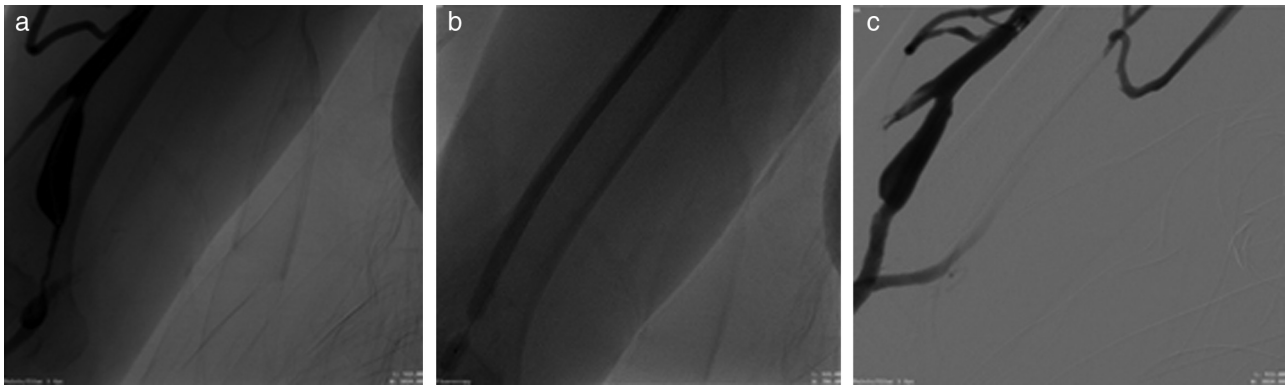
In another patient, rupture of the vein at the needling segment in the upper arm during the angioplasty procedure and rapid development of an expanding hematoma led to abortion of the procedure and ligation of the access.

Technical success was achieved in 21 of 23 patients. There were four cases of clinical failure: two of them technically failed and were excluded from subsequent analysis, one owing to failure of passing guide wire through the near totally occluded central vein and the other owing to rupture of the vein during procedure with access ligation, and the remaining two cases were technically successful, but the access function after the procedure was not sufficient for subsequent dialysis, and they were eventually rethrombosed. All cases of clinical or technical failure were scheduled for surgical operations of new access placement within 2–3 weeks after the endovascular procedure at our department. Table 3 shows the technical and clinical success rates.

Regarding intraprocedural and postprocedural complications, they were all the common encountered problems after conventional angioplasty procedures, with new uncommon problems, such as one patient had nonsignificant bleeding along the access vein course that was caused by vessel tearing during balloon angioplasty and was successfully controlled by external compression after the procedure with no effect on access function, two patients had superficial infection at the puncture sites and was managed conservatively by broad spectrum antibiotic for average of 10 days, and five patients showed postoperative access site hematoma probably owing to inadequate manual compression after removing the sheath, and all hematomas resolved soon by conservative measures. Few patients (four cases) subjectively complained of a feeling of discomfort along the access vein course that disappeared gradually during the subsequent follow-ups.

At 1 month after angioplasty, among 21 successful angioplasty patients, one patient had died of cause not related to the procedure. For the remaining 20 patients, 17 patients still had a patent access after 1 month from the angioplasty procedure, representing 80.9% success rate; two patients could not show any clinical improvement for their access although remaining patent; and one patient showed early access thrombosis about 1 weak after angioplasty. For all the three patients with failure, a new access was made to resume HD. In the 6-month follow-up, of the remaining 17 patients with successful angioplasty, one patient had died owing to causes not related to the procedure. In the remaining 16 patients, 15 patients

Figure 1



Juxta-anastomotic stenosis of a brachial to cephalic AVF. (a) Significant stenosis of the juxta-anastomotic segment of the cephalic vein. (b) DCB angioplasty of the lesion. (c) Status after angioplasty. AVF, arteriovenous fistulae; DCB, drug-coated balloon.

Table 2 Lesions characteristics and types of endovascular access approaches

	n (%) (*N*=23)
Type of AV access	
Radial to cephalic	5 (21.7)
Brachial to cephalic	11 (47.8)
Brachial to basilic	4 (17.3)
Brachial to axillary bridge graft	3 (13)
Site of access stenosis	
Anastomotic/juxta-anastomotic	2 (8.7)
Junctional (between conduit and deep system)	10 (43.4)
Anastomotic/juxta-anastomotic and needling segment	1 (4.3)
Anastomotic/juxta-anastomotic and junctional	3 (13)
Needling segment and junctional	5 (21.7)
Anastomotic/juxta-anastomotic and central veins	1 (43.7)
Needling segment and central veins	1 (43.7)
Site of endovascular access	
Antegrade access vein	16 (69.5)
Retrograde access vein	2 (8.6)
Antegrade radial artery	5 (21.7)

Table 3 Technical and clinical success rates

Technical success		
Successful	21/23	91.3%
Failed	2/23	8.7%
Clinical success		
Successful	19/21	90.5%
Failed	2/21	9.5%

Table 4 Procedural success rate during follow-up periods

	N	Success rate (%)
At 1 month	17/21	80.9
At 3 months	17/21	80.9
At 6 months	15/21	71.4

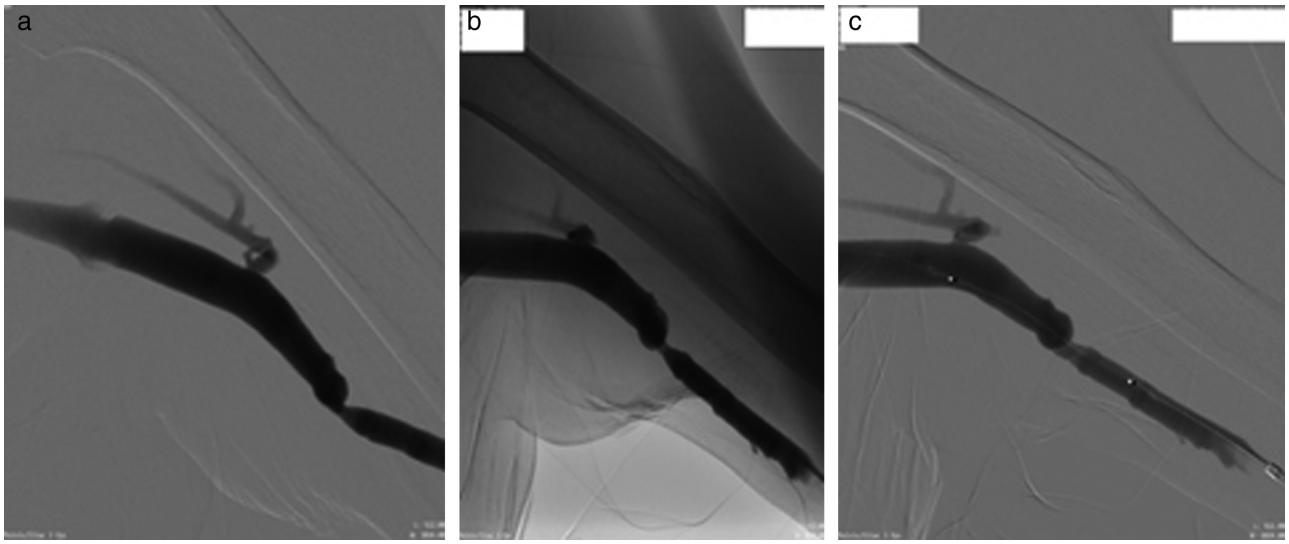
still had a patent vascular access with one patient lost to follow-up, thus representing an overall success rate of 71.4%, as shown in Table 4.

Discussion

HD vascular access in patients with ESRD is considered their lifeline. The best type of vascular access are the AVFs when fully matured after construction, because they have a lower infection rate with longer durability as compared with bridge grafts and tunneled permanent central venous dialysis catheters. One of the commonest lesions of AVFs that affect their efficiency in dialysis is access vein stenosis. Stenosis may develop shortly after AVF creation and cause nonmaturation, or it may develop late after access maturation and use, causing dysfunction with resultant inadequate dialysis, and a shortened lifespan [8]. Although the pathologic lesions causing stenosis have been well addressed, their management remains controversial [8]. Once AVFs stenosis is recognized by the nephrology physicians, patients are referred to our

Vascular Surgery Department for early management before access failure and thrombosis. The conventional management usually starts by minimally invasive interventions like balloon angioplasty in view for the associated morbidities in most patients with ESRD. In most cases, plain balloon angioplasty dilates the stenosis and restores AVF function successfully, but unfortunately like most endovascular interventions, the trauma of the procedure results in recurrence, and a vicious cycle sets in. The primary patency of AVFs after angioplasty has been low, with less than 25% of angioplasted lesions remaining patent after 1 year [9]. The site of access vein stenosis was found to be an important factor affecting the rate of stenosis recurrence with high rate of recurrence at the segment of cephalic arch as compared with the juxta-anastomotic segment [10]. The use of antiproliferative drugs after angioplasty via DCBs has been successfully used in coronary arteries and peripheral arteries in lower limbs to delay the postprocedure recurrence, which suggests similar results could be achieved in the access vein of AVFs if the same approach is used [11]. Because data are few, the aim of this research was to review the concepts and examine the results of DCBs in AVF stenosis management. In this prospective study for patients with recent HD access failure, patients were referred from dialysis centers soon after diagnosis of failing of their regular AVF access. Careful clinical and radiological assessment of acutely failed HD access was done to evaluate technical aspect of angioplasty which is of utmost importance to judge suitability of the procedure. Conventional balloon angioplasty (CBA) was performed first to fix the underlying lesion which was then followed by DCB angioplasty to prevent lesion recurrence (Fig. 2). The procedural technical success rate was 91.3%, whereas the clinical success at 1 and 6 m after intervention was 80.9 and 71.4%, respectively. There were four cases of clinical failure: two of them technically failed, one owing to failure of passing guide wire through totally occluded central vein and the other owing to rupture of the vein during procedure and expanding hematoma led to abortion of procedure and ligation of access, whereas the other two cases were technically successful, but the access function during HD was not sufficient, and the access eventually thrombosed due to recoil after DCB. No major complications occurred, and all complications were managed intraoperatively during the procedure. In one case, the access vein ruptured during the angioplasty procedure with formation of a rapidly expanding hematoma that was managed by abortion of procedure and ligation of the vein. During the follow-up period, two cases died from causes not related to the angioplasty intervention. In our study, 11 (47.8%) patients had brachial cephalic fistula, five (21.7%) patients had radial cephalic, four (17.3%) patients had brachial basilic, and three (13%) patients had brachioaxillary graft. The mean time interval between diagnosis of access failure and angioplasty procedure was 8.6±3.4 days, and mean age of access was 23.9±21.1 months. It was found that there is no statistically significant difference in clinical success outcome regarding the type of access and access age ($P>0.05$); which indicated no effect of these variables on clinical success rate. Although HD

Figure 2



Drug-coated balloon (DCB) angioplasty of significant stenosis of the mid segment of cephalic-brachial AVF. (a) Stenosis of cephalic vein at AP projection. (b) Stenosis of cephalic vein at lateral projection. (c) Status after angioplasty using DCB. AVF, arteriovenous fistulae.

access salvage is considered an emergency procedure, late referral of patient with failing access could occur, owing to lack of adequate timely diagnosis and/or patient's poor general condition. If late presentation occurred, salvage procedure should be tried, as it was found that interval between access failure and salvage procedure has no effect on clinical success rate. The results of our study were similar to other studies regarding clinical success rate and the 6-month primary patency. In a study by Massmann *et al.* [12], technical and clinical success rates were 100%, with no documented minor or major complications. Mean follow-up period was 18.4±17.5 months. Analysis for freedom from target lesion revascularization (TLR) found paclitaxel-coated balloon angioplasty (PCBA) superior to CBA (P=0.029). Median freedom from TLR after PCBA was 5 months, with more than 50% of patients being event free during the observation period [12]. In another recent Turkish study by Çildağ *et al.* [13], the type of AVFs enrolled was 41 (78.8%) radiocephalic and 11 (21.2%) brachiocephalic. Primary patency rates between the PCBA and CBA group showed no statistically significant difference at the 6-month follow-up period (P=0.449), whereas at 12 months, a significant difference in favor for PCBA was evident (P<0.05). Further analysis showed no statistically significant difference based on either the patient age, patient sex, or fistula type between the two groups (P>0.05) [13].

On the contrary, in the study by Björkman *et al.* [14], 88.9% (16/18) of cases in the DCB group were revascularized or occluded within 1 year, compared with 22.2% (4/18) of the stenoses in the balloon angioplasty group. Mean time to TLR was 110 and 193 days after the DCB and balloon angioplasty, respectively. These worse results by the DCB angioplasty was explained by differences in the biological response to the antiproliferative effect of paclitaxel in the venous wall compared with its effect in the arterial wall after DCB treatment of atherosclerotic occlusive lesions. The National Kidney Foundation Dialysis Outcomes Quality Initiative suggests that selecting the method of salvage procedure should depend largely on the ability of each institution [4]. In this context, many endovascular treatment options have been used to delay recurrences of AVFs stenosis after balloon angioplasty, like cutting balloons and bare metal stent placement, but with no evidence of clear benefits over CBA [15,16]. The use of stent grafts in AV bridge grafts stenosis has shown superior results over CBA in terms of rate of recurrence of stenosis and patency rates [17,18], but similar studies about the use of covered stents in autogenous AVFs have not been conducted which stands against the liberal use of this devices for all cases of falling AVFs [19]. Perhaps because of some technical problems, deployment of stent grafts in AVFs is a challenging procedure owing to concerns of proximal or distal device migration, pain, and even stent graft infection that possibly may occur whenever located in the needling zone. Also, recurrent in-stent and end-stent stenosis, which is seen commonly in the commercially available stent graft devices [15]. Considering the aforementioned problems in the use of covered stents, the idea of delaying recurrence of stenosis of the access vein during salvage of failing AVFs by inflating a DCB at the site of stenosis after conventional angioplasty seems a very simple and efficient approach [19]. On the basis of trial by Sachdeva and Abreo, the Food and Drug Administration has approved the use of paclitaxel DCB angioplasty for treatment of recurrent stenosis in mature AVFs after access dysfunction [20]. The preliminary findings of this study are encouraging and hopefully will help us to further add this technique at our arsenal as a new weapon to counteract the problem of access stenosis recurrence. We hope that with the findings of this study DCB angioplasty will delay recurrence of stenosis in AVFs and thereby decrease morbidity and cost for patients on HD.

Conclusion

DCB angioplasty is a safe and effective method for salvage of the failing AVFs and could successfully delay recurrence of stenosis. However, further studies with randomized controlled fashion on larger patient's population are required before advocating the wide adoption of this technique.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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