Outcomes of salvage of hemodialysis arteriovenous access with variable thrombus load

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Introduction
Arteriovenous fistulas (AVFs) are the preferred choice for long-term hemodialysis because of their low rates of complications and associated costs compared with other forms of accesses. One of these complications is the susceptibility to stenoses and subsequent thrombotic occlusion. The aim of this study is to establish a valid classification for thrombosed AVFs based on their thrombus load and to describe different procedures for AVF salvage based on this classification.

Patients and methods
In this prospective study, 90 patients with failed AV access were enrolled in this study and divided into three groups based on the thrombus load within the vein of the AV access based on clinical and ultrasonographic assessment. The diameter of the thrombosed vein was measured and accordingly the three groups were divided into: Group A: minimal thrombus load (diameter less than 6 mm). Group B: moderate thrombus load (diameter more than 6 mm and less than 12 mm or the presence of one aneurysm within the vein with a diameter less than 2 cm). Group C: high thrombus load (diameter: more than 12 mm or the presence of more than one aneurysm within the vein or the presence of any aneurysm >2 cm in diameter). Patients were subjected to angioplasty with or without thrombectomy according to their classification and were monitored for functional outcome and patency rates.

Results
The success rate was 95.1% in group A, 90.9% in group B, and 87.5% in group C. Over a period of 1, 3, and 6 months postoperatively, the primary patency rates were 94.8%, 91.5%, and 89.2% in group A, 89.3%, 87.0%, and 84.2 in group B, and 85.7%, 81.9%, and 75% in group C, respectively.

Conclusion
Thrombosed AVFs are amenable for salvage whatever their thrombus load. There is no statistical difference in the patency of salvaged AVFs with variable thrombus load among the three groups.

Keywords:
angioplasty, arteriovenous fistula (AVF), end-stage renal disease (ESRD), thrombectomy, thrombus load

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Introduction

Arteriovenous fistulas (AVFs) are the preferred choice for long-term hemodialysis because of their low rates of complications and associated costs compared with other forms of accesses. One of these complications is the susceptibility to stenoses and subsequent thrombotic occlusion, which can threaten both their short- and long-term patency. As the patency of dialysis vascular access is of utmost importance for dialysis patients, the clinical signs of dysfunction should be immediately investigated. Stenoses can occur at different levels of the arteriovenous circuit and hence are categorized based on the anatomic location into:

(1) Arterial, proximal, or juxta-anastomotic
(2) Anastomotic
(3) Venous: juxta-anastomotic, needling sites, junctional or central

The most common site for development of a stenosis in arteriovenous graft is at the venous anastomosis. Neointimal hyperplasia is eventually the cause of all stenoses, wherever the site is. Several studies have shown that neointimal hyperplasia is strongly influenced by the turbulent flow [1]. Fundamentally, there are multiple techniques for re-establishing flow in an occluded access, including mechanical thrombectomy, thrombolysis, or percutaneous endovascular intervention. Some of these techniques can be used together to optimize the results of intervention.

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According to Clinical Practice Guidelines of the European Society for Vascular Surgery [2], although percutaneous endovascular approach is an established treatment option for dysfunctional dialysis-access treatment, with outcomes enhanced using new devices such as stent grafts, paclitaxel-coated balloons, and high-pressure and cutting balloons, the consensus regarding dysfunctional fistula with variable thrombus load is not established so far. There is no clear classification available of thrombosed AV accesses based on their thrombus load. The aim of the current study is to establish a classification for thrombosed AVFs based on their thrombus load, to describe a simple plan for management according to the above-mentioned classification, and to evaluate the duration of postprocedural patency.

Patients and methods

This is a prospective study that was conducted on 90 end-stage renal disease (ESRD) patients in Kasr-Al-Ainy, Cairo University Hospitals, over a period of 8 months from July 2018 to February 2019. Patients enrolled in the study were on regular hemodialysis with thrombosed AVF or AV graft. We included patients with thrombosed AV access within 2 weeks from the onset of thrombosis. We excluded patients with AVF thrombosis extending to central veins, central venous occlusion, persistent hypotension, infected access, or patients with known allergy to contrast material. 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.

We classified them during the initial period of the study based on clinical grounds and ultrasonographic assessment of the thrombosed vein/graft diameter into:

Group A: minimal thrombus load (diameter less than 6 mm).

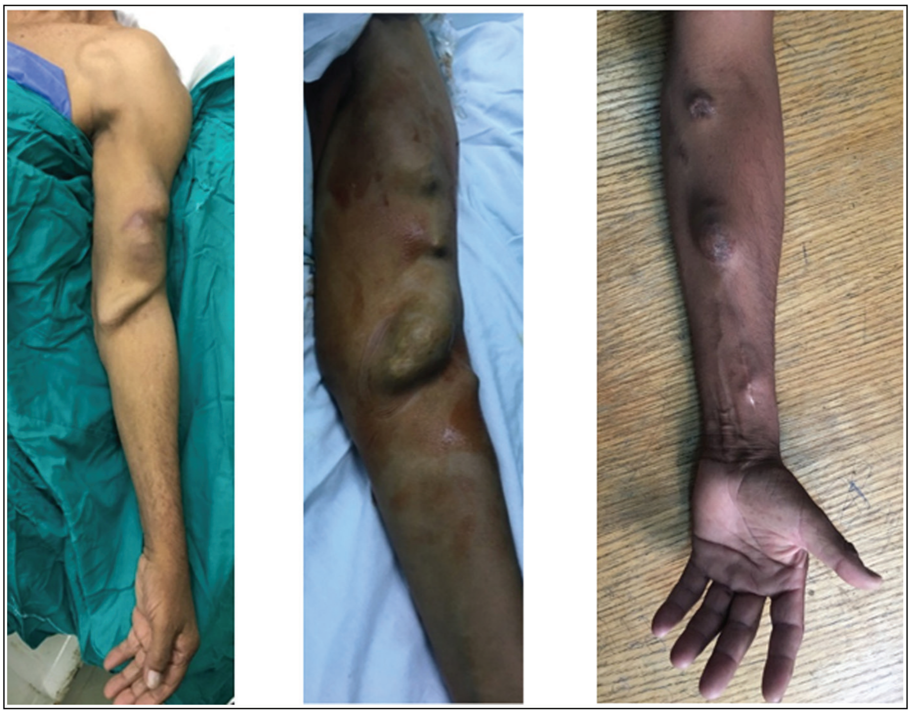
Group B: moderate thrombus load (diameter more than 6 mm and less than 12 mm or the presence of one aneurysm within the vein with a diameter less than 2 cm).

Group C: high thrombus load (diameter more than 12 mm or the presence of more than one aneurysm within the vein or the presence of any aneurysm >2 cm in diameter).

Intervention

The planned intervention was endovascular (balloon angioplasty), which may be combined with open thrombectomy. The use of open thrombectomy was preplanned according to the group in which the patient was enrolled:

Figure 1



Three patients with thrombosed arteriovenous fistulas with high thrombus load (group C).

(1) Group A (minimal thrombus load): endovascular intervention (balloon angioplasty).
(2) Group B (moderate thrombus load): endovascular intervention with or without open thrombectomy.
(3) Group C (high thrombus load): endovascular intervention combined with open thrombectomy (Fig. 1).

Conventional balloon angioplasty

All cases were operated upon in the hybrid angiosuite. The field was sterilized using Povidone/Iodine Prep solution 10%. Patients were monitored for pulse, blood pressure, and oxygen saturation. All procedures were performed under a local anesthetic (Lidocaine HC1 1%) infiltrated at puncture and incision sites.

Access

A puncture needle (20 gauge) was used to access the corresponding artery, vein, or graft. A sheath (usually 6F) was then advanced over the wire. The sheath was then tested for free blood flow and 5000 IU of heparin was injected and flushed with saline, to prevent thrombosis.

Diagnostic fistulogram

An angiogram was done by injecting contrast directly through the sheath. The angiographic findings were then interpreted to put a plan for proper management.

Passing the guidewire

In case of radial artery access, Terumo Guidewire 0.035' guidewire was then passed through the sheath and advanced up through the arteriovenous anastomosis to the level of the central veins over which a Boston Scientific ImagerTM II Angiographic Catheter Bern Selective 4F or 5F was inserted. If a stenotic lesion or an occlusion was present juxta-anastomotic or intravenous, the wire, and catheter were torqued and rotated to pass the lesion. The angiogram was repeated in the central veins to evaluate the condition and exclude the presence of central venous stenoses or occlusions.

Balloon introduction

An angioplasty was done using balloons with different sizes that ranged from 4 to 8 mm in diameter and different lengths that ranged from 4 to 15 cm. The balloon was then inflated for 1 min and then deflated. The procedure was repeated as the balloon was withdrawn distally (Figs. 2 and 3). An angiogram was repeated to assess the outcome of the balloon dilatation. In case of tight lesions resistant to dilatation, the following was attempted:

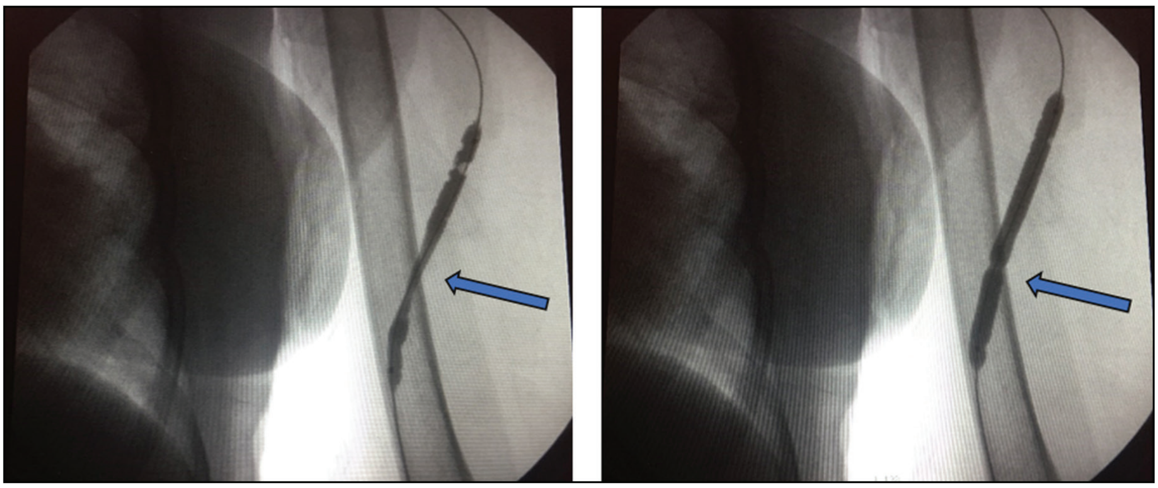
(1) Redilatation.
(2) Increasing the dilatation time.
(3) Switching to a high-pressure balloon.
(4) Using a balloon with larger diameter.

After balloon dilatation was completed, the balloon was deflated and withdrawn, with the guidewire left in situ and a final angiogram was done to assess the vein patency and exclude any residual stenoses or flow-limiting and floating thrombi (Figs. 4–7). After completion of the procedure, the sheath was removed, and the puncture site was manually compressed carefully, until proper hemostasis was secured. If the endovascular access was done using an arterial cutdown, the artery was repaired using prolene 6/0 sutures.

Thrombectomy (for all cases with high thrombus load and some with moderate thrombus load)

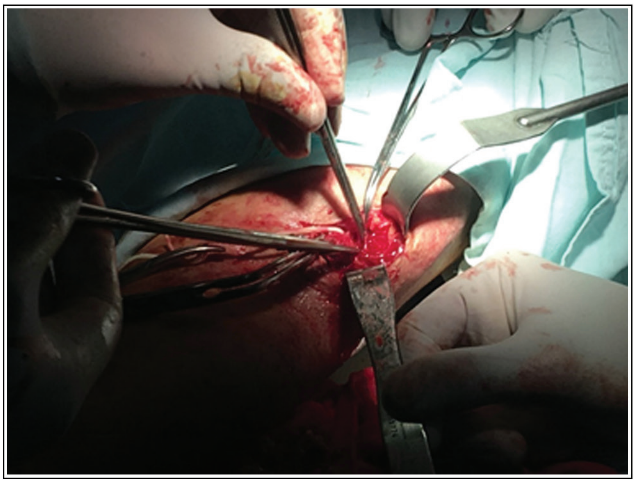
Under local anesthesia, a ~3-cm transverse skin incision was made over the juxta-anastomotic segment. The vein/graft was dissected from the surrounding tissue

Figure 2



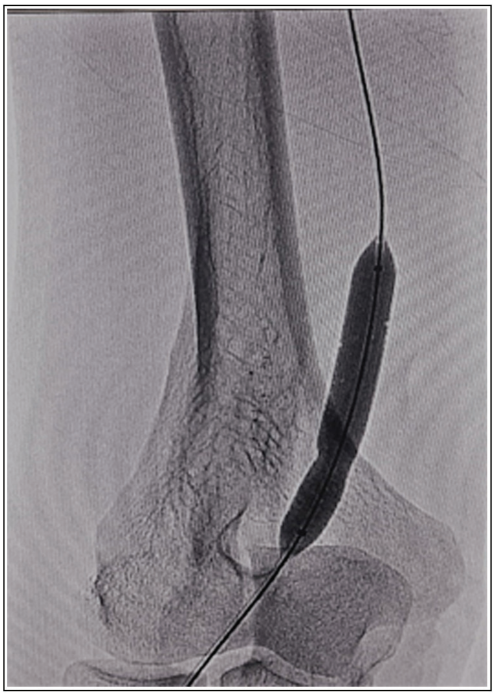
Balloon dilatation of an occluded basilic vein (notice the waist in the balloon being dilated).

Figure 3



Venotomy and manual extraction of the thrombi.

Figure 4



Successful balloon dilatation (disappearance of the balloon waist).

and controlled with a vessel loop proximally and distally. In some cases, the vein was externally clamped as an attempt to be less invasive and injurious to the vein. A transverse venotomy/graftotomy was made and the distal thrombi were removed using milking squeezing technique and occasionally a LeMaitreTM Fogarty Catheter 5F or 6F in size (Fig. 3). If remnant thrombi were found after a fistulogram, manual squeezing was attempted and the thrombectomy procedure was repeated. After completion of thrombectomy, any residual stenoses were managed by conventional balloon angioplasty. Venotomy/graftotomy was closed with 5/0 or 6/0 polypropylene sutures and the skin was

Figure 5

Successful balloon dilatation (disappearance of the balloon waist).

closed using prolene 3/0 sutures. When the aneurysm is more than 2 cm, aneurysmorrhaphy was done.

Important definitions

Angiographic success

This was defined as restoration of luminal diameter with less than 30% residual-diameter venous stenosis.

Clinical success

This was defined as restoration of thrill and bruit over the vein and the ability to carry out a successful hemodialysis session using a pump of 300 ml/min or more.

Primary patency

It is uninterrupted patency after intervention, until the next access thrombosis or reintervention. Primary patency ends with treatment of a lesion anywhere within the access circuit, from the arterial inflow to the superior venacava right atrial junction.

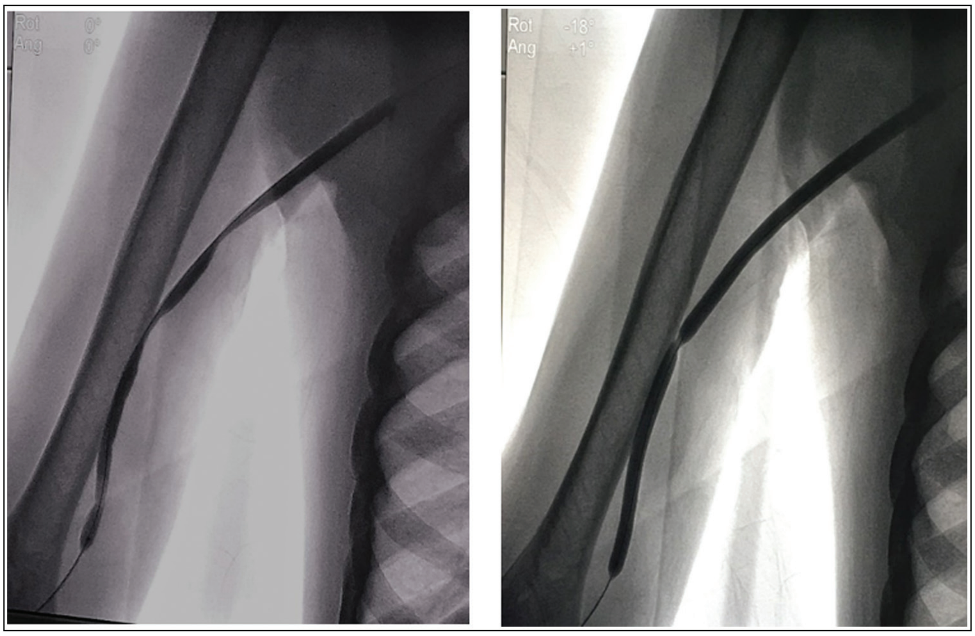
Secondary patency

It is patency after the access is revised by whatever method.

Follow-up

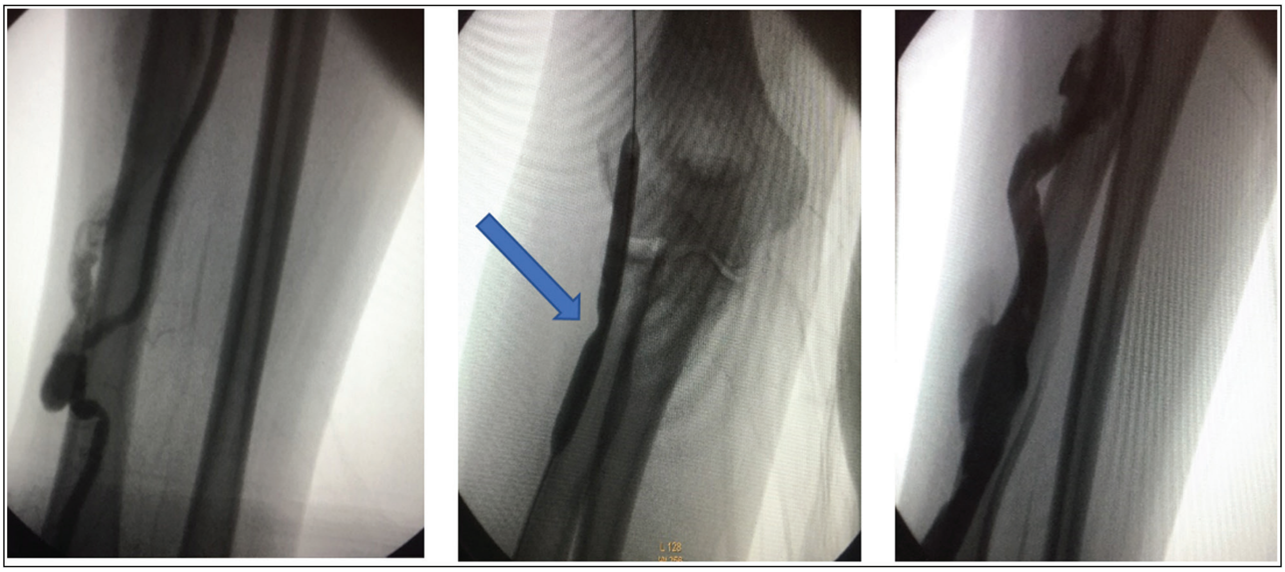
Patients were advised to come for follow-up visits, including physical examination and duplex scan if required to evaluate the anatomy and hemodynamic status of the fistula in the outpatient clinic within a month after the procedure and every 3 months thereafter.

Figure 6



Successful balloon dilatation of the basilic vein.

Figure 7



Successful thrombectomy combined with angioplasty for heavily thrombosed right R–C arteriovenous fistula.

Statistical methods

Data were coded and entered using the statistical package SPSS (Statistical Package for the Social Sciences) version 25. Data were summarized using mean, SD, median, and minimum and maximum in quantitative data and using frequency (count) and relative frequency (percentage) for categorical data. Comparisons between quantitative variables were done using the nonparametric Kruskal–Wallis and Mann–Whitney tests (Chan, 2003a). For comparing categorical data, χ^2 test was performed. Exact test was used instead when the expected frequency is less than 5 (Chan, 2003b). *P* values less than 0.05 were considered as statistically significant.

Results

A total of 90 patients with ESRD on regular hemodialysis (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 July 2018 and February 2019. Because of recent dysfunction of their AV access with the inability to obtain a good dialysis dose, they were enrolled in our study. The patients comprised 47 males and 43 females, with mean age of 52.9 ± 15.3 years. Patients' clinical characteristics are shown in Table 1 and the type and site of AVF and the number of patients in each group (Tables 2 and 3). In Table 4, we compare the type and site of AVF and type of intervention done.

Table 1 Demographic and clinical characteristics of the study

Male	47 (52.2%)
Female	43 (47.8%)
DM	17 (18.9%)
HTN	60 (66.7%)

DM, diabetes mellitus; HTN, hypertension.

Table 2 Desacribing the site, anatomy, and type of the AV accesses

	Number (%)
Site of AV access (upper limb)	
Right	42 (46.7)
Left	48 (53.3)
Anatomical structure of the fistula	
Radiocephalic	27 (30)
Brachiocephalic	34 (37.8)
Brachiobasilic (superficialization)	25 (27.8)
Brachioaxillary	4 (4.4)
Type of AV access	
Native	86 (95.6)
Graft	4 (4.4)

AV, arteriovenous.

Table 3 Describing the number of cases in each classification of thrombus load

		Number (%)
Classification of thrombus load	A (minimal)	41 (45.6)
	B (moderate)	33 (36.7)
	C (high)	16 (17.8)

Table 4 Comparing the age and duration of successful hemodialysis from the failed access between the three groups

	Classification of thrombus load			*P* value
	A number (%)	B number (%)	C number (%)	
Site of AV access				
Right	15 (36.6)	17 (51.5)	10 (62.5)	0.166
Left	26 (63.4)	16 (48.5)	6 (37.5)	
Anatomical structure of the fistula				
Radiocephalic	24 (58.5)	2 (6.1)	1 (6.2)	<0.001
Brachiocephalic	12 (29.3)	18 (54.5)	5 (31.3)	
Brachiobasilic (superficialization)	5 (12.2)	9 (27.3)	11 (68.8)	
Brachioaxillary	0 (0.0)	4 (12.1)	0 (0.0)	
Type of AV access				
Native	41 (100.0)	29 (87.9)	16 (100.0)	0.033
Graft	0 (0.0)	4 (12.1)	0 (0.0)	
Intervention: angioplasty				
Yes	41 (100.0)	33 (100.0)	16 (100.0)	–
Intervention: thrombectomy				
Yes	0 (0.0)	16 (48.5)	16 (100.0)	<0.001

AV, arteriovenous.

Classification of the AV access based on the thrombus load

Technical success was achieved in 39 of 41 (95.1%) patients with group A, and in 30 of 33 (90.9%) patients in group B, whereas technical success was achieved in 14 out of 16 (87.5%) patients in group C. 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 5 shows the technical and clinical success rates.

Comparison between groups

Regarding intraprocedural and postprocedural complications (Table 6), they were all the common encountered problems after conventional angioplasty procedures, complications are more common in group A (three patients had hematoma over the course of the vein at the puncture sites and were managed conservatively, and two patients had contrast allergy). In group B, two patients had hematoma over the course of the vein, whereas perforation and ligation of the vein were done in two patients in group C.

During the follow-up after 1 month, patent-functioning access was achieved in 37 (94.8%), 25 (89.3%), and 12 (85.7%) patients in groups A, B, and C, respectively.

During the follow-up after 6 months, patent-functioning access was achieved in 25 (89.2%), 16 (84.2%), and 6 (75%) patients in groups A, B, and C, respectively (Table 7).

Discussion

AV-access failure is a serious complication that results in increased central venous catheter use and higher infection rates and mortality. Some important

Table 5 Comparing the outcome and complications of the three groups

	Classification of thrombus load			*P* value
	A number (%)	B number (%)	C number (%)	
Successful outcome	39 (95.1)	30 (90.9)	14 (87.5)	0.597
Complications	5 (12.2)	2 (6.1)	2 (12.5)	0.645

Table 6 Describing the complications and their count in each group

	Classification of thrombus load (count)		
Complications	A	B	C
Hematoma over the course of the vein managed conservatively	3	2	0
Perforation and ligation	0	0	2
Radiocontrast allergy	2	0	0

Table 7 Comparing the follow-up of the three groups regarding the patency rates

	Classification of thrombus load			*P* value
	A number (%)	B number (%)	C number (%)	
Follow-up 1 month	37 (94.8)	25 (89.3)	12 (85.7)	0.521
Follow-up 3 months	32 (91.5)	20 (87.0)	9 (81.9)	0.683
Follow-up 6 months	25 (89.2)	16 (84.2)	6 (75.0)	0.517

questions were raised in the initial period of the study, regarding the failed AVFs and needed answers:

(1) Does the mere presence of a thrombus in an occluded AVF preclude intervention?
(2) Do we have an established classification for this thrombus load and if the answer is no, can we establish a classification and on what basis would that be?
(3) Would the thrombus load affect our management? How and what would the outcome be?
(4) If the thrombus is to be debulked, are we going to adopt the same techniques adopted elsewhere?

Regarding the first question of whether the presence of a thrombus in an occluded AVF precludes intervention, in the near past, when a vascular surgeon was confronted with a failed AV access for dialysis, the usual decision was to abandon the fistula completely and plan for the creation of a new access elsewhere. The causes of avoiding intervention included the fear of dislodgement of thrombi into central veins and consequently the increased risk of pulmonary embolism or occlusion of the artery through the arteriovenous anastomosis. However, studies such as the one conducted by Achkar and Nassar [3] proved that these risks, despite being present, had a very low incidence. The cost-effectiveness of the procedure in relation to the success and patency rate was also put into question, but since the most expensive material used in the procedure was the balloon and as it was not unpacked, unless the lesion was passable by the guidewire, the procedure seemed to be cost-effective after all. To avoid the rapid consumption of potential sites of future accesses, the decision to give an occluded AV access its best chance before its exclusion came into light.

To answer the second question, it must be acknowledged that the association between the degree of thrombus load in an occluded AVF and the best-possible intervention would have important implications for service delivery, healthcare costs, and patient outcomes. Despite proper search through websites of medical journals such as PubMed, no study was found classifying patients with thrombosed A–V accesses according to their thrombus load. Therefore, the aim of this study was to establish a classification for thrombosed AVFs based on their thrombus load.

The basis of producing this classification came from the fact that Kasr-Al-Ainy Medical School, Cairo University Hospital is a tertiary healthcare center, with thousands of cases being admitted and managed for ESRD annually. Consequentially, the number of patients suffering from occluded AVFs drastically increased in the past 10 years and so did the expertise in managing these cases in Kasr-Al-Ainy. In this single-center study, we describe AV-access failures, interventions, outcomes, and primary-patency follow-up in 90 patients on hemodialysis. The study population is demographically representative of the contemporary Egyptian hemodialysis population. About 52.2% of the patients in the study were males and 47.8% were females. Regarding the comorbidities present along with ESRD, 66.7% of the patients were hypertensive and 18.9% of them were diabetic. Eighty-six patients presented with failed AVFs and only four presented with failed AV grafts. Patients with thrombosed AV accesses were classified into three groups A, B, and C according to their thrombus loads and the outcome of intervention between the three groups was observed and compared. Patients in group A were defined as having accesses with minimal thrombus load when vein diameter was less than 6 mm. Group B was defined as having moderate thrombus load when vein diameter was more than 6 mm and less than 12 mm or the presence of one aneurysm within the vein with a diameter less than 2 cm. Group C was defined as having high thrombus load when vein diameter was more than 12 mm or the presence of more than one aneurysm within the vein or the presence of any aneurysm >2 cm in diameter. At the end of the study, there were 41 patients in group A, 33 in group B, and 16 in group C.

The mean duration of successful hemodialysis from the access before its thrombosis was statistically significant between the three groups with a *P* value of 0.004, signifying that people with heavier thrombus load dialyzed for longer periods from their accesses before its failure. There was also a statistical significance regarding the anatomical structure of the AV access and the thrombus load as 11 out of the 16 patients in group C had a brachiobasilic AVF. As for the third question "Would the thrombus load affect our management? How and what would the outcome be?" the answer to this is that the presence of a higher thrombus load will not dissuade us to intervene in the thrombosed access, but the higher the thrombus load, the more likely an additional procedure, thrombectomy, will be needed. All patients with minimal thrombus load (group A) underwent angioplasty only, with a success rate of 95.1%. All patients with moderate thrombus load (group B) had a trial of angioplasty done first and accordingly the decision whether to perform a thrombectomy or not was determined, with a success rate of 90.9%. The decision of whether to perform a thrombectomy or not in group B depended on the initial technical success after angioplasty to be as less invasive as possible, because a channel can be created through an adherent organized thrombus, resulting in a rapid technical success. The presence of filling defects or floating thrombi necessitated the addition of thrombectomy to prevent early occlusion and decrease the risk of embolization to pulmonary vessels or to a nearby artery involved in the anastomosis causing acute ischemia. Cases in group A had their thrombus easily squashed to the vein wall after balloon dilation. Out of 33 patients in group B, 16 needed thrombectomy. In patients with high thrombus load (group C), thrombectomy was combined with and done before angioplasty in all cases to optimize the outcome and decrease the incidence of complications with a success rate of 87.5%. There was no statistical significance between the success rates of the three groups with a *P* value of 0.597, indicating that the thrombus load does not significantly affect the success rate. However, the presence of heavier thrombus load necessitates the addition of thrombectomy to maintain this success rate in comparison with minimal thrombus load in which angioplasty only was enough. In comparison with the study conducted by Quencer and Friedman [4], in which the technical success was 71%, the results in the current study were significantly higher owing this possibly to the classification of cases into variable thrombus loads. The total number of patients in the study who had complications related to intervention was nine (10% of all cases). In total, five patients developed hematoma over the course of the vein, two suffered from vein perforation that necessitated ligation, and two developed radiocontrast allergy that leads to abortion of the procedure. Regarding the complication rate, no statistical significance was present between the three groups, being 12.2% in group A, 6.1% in group B, and 12.5% in group C. The implication of this result was important as it was long feared that patients with high thrombus load were at great risk of developing serious complications such as pulmonary embolism. Fortunately, and surprisingly, in this study, no case was documented to suffer from pulmonary embolism in all groups. In the current study, the rate of complications was less than the study conducted by Miquelin *et al.* [5], which was up to 20% of the cases. As for follow-up, no statistical significance was present between the three groups. Over a period of 1, 3, and 6 months postoperatively, the primary patency rates were 94.8%, 91.5%, and 89.2% in group A, 89.3%, 87.0%, and 84.2% in group B, and 85.7%, 81.9%, and 75.0% in group C, respectively. However, some patients were "lost to follow up" in the 1-, 3-, and 6-month assessment periods. In comparison with the study conducted by Miquelin *et al.* [5], the primary outcomes were almost equal in both studies. However, the patency rate in the current study was higher by about 30%. Moreover, the 6-month follow-up of the primary patency rate in our current study was much higher than the one conducted by Quencer and Friedman [4], in which the rate was 25%–30%. Finally, regarding the fourth question of whether we are going to adopt the same techniques implemented elsewhere, the answer is that not all techniques used in other centers, such as pulse-spray-aided pharmacomechanical thrombolysis and thromboaspiration used in other studies such as the one conducted by Quencer and Friedman [4], were effective regarding the cost-effectiveness and the applicability to all patients. The main reason was that techniques including thrombolysis limited the number of patients eligible for intervention as most patients presented within days after occlusion of their access, making this inefficient and expensive in contrast to percutaneous transluminal angioplasty and thrombectomy in which the tools used were less expensive and more effective. Thus, another point to be stressed in the current study is that the timing since occlusion of the access and the presentation of the patients ranged from 2 days to 2 weeks increasing the window and consequently the chance of patient's fistula to be salvaged.

Conclusion

There is no clear classification available for thrombosed AV accesses based on their thrombus load. Angioplasty is usually enough for patients with minimal thrombus load; however, patients with high thrombus load should undergo a thrombectomy followed by angioplasty of stenotic lesion. We suggest that this new classification of thrombosed AVFs based on vein diameter (minimal, moderate, and high thrombus load) should be considered when managed by failed AVF. Thrombosed AVFs are amenable for salvage whatever their thrombus load. There is no statistical difference in the patency of salvaged AVFs with variable thrombus load.

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Conflics of interest

No conflicts of interest.

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