

Endovascular management of central venous occlusive disease in hemodialysis patients with symptomatic venous hypertension

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Aim

The aim was to evaluate the feasibility and efficacy of balloon angioplasty in hemodialysis patients with venous hypertension.

Materials and methods

A prospective study was carried out from April 2017 to October 2019 at 6 October Insurance Hospital, Cairo, and Sohag University Hospitals on 32 patients with end-stage renal disease on hemodialysis complaining of venous hypertension owing to central vein occlusive disease treated with balloon angioplasty with or without stenting. Bailout stent was deployed in cases of significant residual stenosis more than 30% or venous recoil.

Results

The commonest site of central vein occlusion was the innominate vein in 21 (65.6%) patients. Technical success was achieved in 26 (81.3%) patients; 20 of them operated by balloon angioplasty and six achieved after stent deployment. Technical failure occurred in six (18.8%) patients. Overall primary patency rate was 76.9, 57.7, and 46.2% at 3, 6, and 12 months, respectively. Primary patency rate was 80, 65, and 55% at 3, 6, and 12 months, respectively, in those treated with balloon angioplasty, whereas it was 66.6, 33.3, and 33.3% at 3, 6, and 12 months, respectively, in those treated with stent deployment ($P=0.17$). Reocclusion was recorded in 14 (53.8%) of 26 patients; nine of them were previously managed by balloon dilatation, whereas the other five patients were previously managed by stent deployment. Of 14 cases, 7 were managed successfully by balloon dilatation, 2 of 14 patients were treated by stent deployment, whereas in 5 of 14 cases, revascularization failed. Analysis of data of failed cases denoted that 4/5 of them were in-stent occlusions and one case occluded after percutaneous angioplasty.

Conclusion

Balloon angioplasty for central vein occlusive disease in hemodialysis patients achieves comparable patency rates and clinical outcomes to venous stent. Although it achieves short-term durability, it should be applied firstly reserving the venous stent for significant residual stenosis.

Keywords:

central venous, hemodialysis, occlusive, venous hypertension

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Introduction

During the last decades, there has been an improvement in the quality of life of patients with end-stage renal disease (ESRD) [1]. Efficient hemodialysis depends mainly on maintaining vascular access capable of sustaining high blood flow rate [2].

Ideal vascular access for hemodialysis should be easy to access, effective, safe, and durable. Practically, there is no vascular access that can fulfill all these criteria all the time, and therefore, it usually requires multiple procedures to maintain its function. Arteriovenous fistula (AVF) is affected by many factors contributing to its failure, for example, arterial (inflow) or venous (outflow). These factors may be related to intraoperative technical errors or postoperative complications [3]. Consequently, it is

commonly confronted with exhausted AVF that had one or more of these difficulties either systemic, for example, high cardiac output or local, for example, thrombosis, venous hypertension, and vascular steal syndrome [4].

Central venous occlusive disease (CVOD) is one of the major dilemmas in those patients causing significant morbidity and leads to access dysfunction [5]. It is defined as more than 50% stenosis of internal jugular, subclavian, axillary, innominate, or superior vena cava [6]. It is mostly caused by either frequent venous punctures during temporary catheterization leading

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to intimal hyperplasia and fibrosis or hypercirculation state especially with proximal AVF [7].

Although ligation of AVF and creation of a new access will solve the problem and provide dramatic symptomatic relief, this will lead to loss of the dialysis access especially when other access options were exhausted or no longer be available [8].

Based on the concept of limited sites of available accesses for each patient beside the increasing life expectancy of patients with chronic renal failure, the guidelines recommended early detection and treatment of all significant fistula stenosis to extend the life span of each access and avoid the need to perform temporary catheters. Therefore, several salvageable procedures may be required to restore its function before going to create a new one [2].

Surgical and endovascular treatments are considered the treatment options for CVOD. Open surgical repair achieves high primary patency rates of approximately 80–90% at 1 year, but it carries significant morbidity and mortality. The Kidney Disease Outcomes Quality Initiative (KDOQI) guidelines recommended the endovascular option as the preferred method of treatment [4] as it is safe, achieves high technical success rate, and has shorter hospital stay, with less complications [9]. However, limited primary patency rate remains a limitation, and repeated angioplasty is required for secondary patency [10].

Several studies had used percutaneous angioplasty (PTA) with or without stenting. Many authors recommended PTA as the best modality that should be tried to maintain the fistula patency and reserve primary stenting in recurrent stenosis, whereas others preferred primary stenting [11].

Materials and methods

This prospective study was carried out from April 2017 to October 2019 at 6 October Insurance Hospital, Cairo and Sohag University Hospitals on 32 patients with ESRD on hemodialysis complaining of symptomatic venous hypertension manifested by edema of arm and face, painful hand, color changes, for example, cyanosis, ulceration, distended collateral veins over chest wall with impaired flow during dialysis, or prolonged bleeding from access puncture site at the end of dialysis sessions.

All patients were admitted and signed a written informed consent. This series was approved by the

Hospital Ethical Committee. Patients were evaluated clinically including type of hemodialysis access, site, its duration as well as limb edema, skin manifestations; cyanosis, and/or ulceration. Full laboratory investigations with special concern on the coagulation profile and renal function tests were performed.

Imaging studies included duplex ultrasound (US) to assess the blood flow in the fistula and detect presence or absence of normal respiratory variation in diameter of veins and polyphasic arterial waves. Computed tomography venography was performed to all cases.

Strategy of treatment was balloon angioplasty. Bailout stent might be deployed in cases of venous recoil or presence of significant residual stenosis more than 30%.

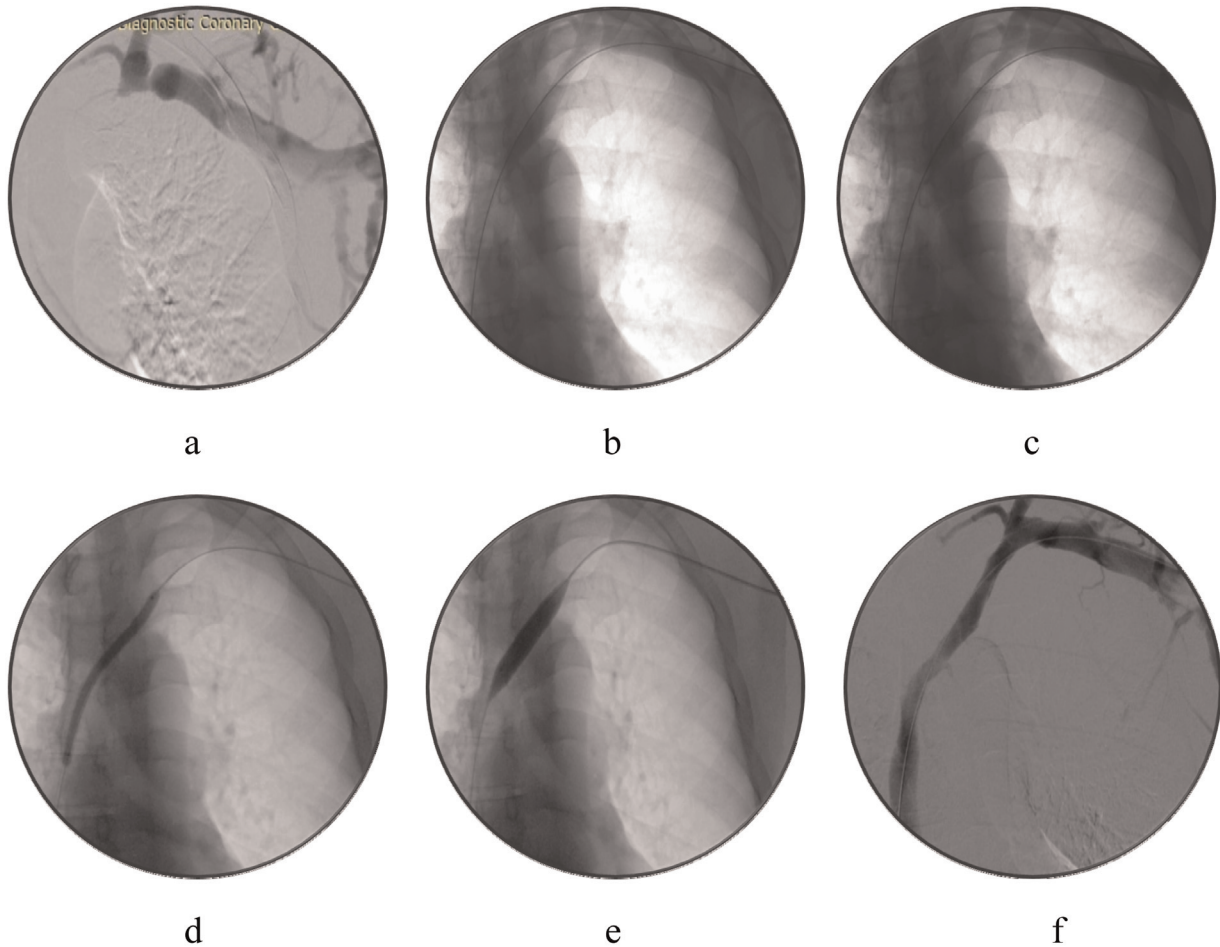
Puncture and vascular accesses were performed through the outflow vein of AVF or venous limb of graft AVF. Another retrograde femoral vein approach might be needed if the lesion could not be crossed through fistula access or in need for stent deployment.

All patients received a loading dose of 300-mg clopidogrel before the procedure and 70–100 U/kg of unfractionated heparin after sheath insertion.

Preprocedural venography was done to assess the lesion: its accurate site, extent, length, and stenosis/occlusion.

A 0.035 angled hydrophilic guidewire (Radifocus, Terumo, Japan) supported with 4-F vertebral catheter was used to navigate upward through the outflow vein until reaching distal to the lesion. Multiple attempts were tried to cross the lesion. If failed, a second puncture access through the femoral vein was performed. Another 0.035 guidewire supported with 4-F vertebral catheter was passed till the proximal end. Further venography was done simultaneously from both ends of the lesion to re-assess the lesion as well as the diameter of the adjacent normal vein. Bidirectional flossing wire technique was tried using the 'through-and-through wire technique.' Caution should be taken not to induce iatrogenic perforation. After crossing the lesion, balloon dilatation was performed using balloons diameters 10–16 mm and lengths 40–60 mm (XXL vascular large balloon; Boston Scientific, Massachusetts, USA) (Fig. 1). Deployment of stent was indicated in cases of residual stenosis greater than 30% or venous recoil after repeated dilatation. Stent diameter should be 1–2 mm larger than the

Figure 1



Left innominate vein occlusion. (a) Preprocedural venography; (b) crossing the lesion by guidewire; (c) wire within the contrast without extravasation or perforation; (d, e) gradual balloon dilatation; (f) completion venography.

adjacent normal vein. Type of used stent was Wall stent (Boston Scientific) of diameters 14–18 mm and lengths 60–90 mm. Completion venography was done to assess the technical success and procedure-related complications.

Fistula and upper limb manifestations were evaluated immediately postoperatively and then at 3-, 6-, and 12-month follow-up for assessment the feasibility for dialysis and detect any postoperative complications. Duplex US was performed to assess the improvement of blood flow through the fistula.

Statistical analysis

Data were analyzed by SPSS (SPSS Inc., Chicago, Illinois, USA). Categorical variables were reported as numbers and percentages. Continuous variables were reported as mean \pm SD. Paired *t*-test and analysis of variance test were used to compare parametric data. *P* value was considered significant if less than 0.05.

Definitions

Study outcome was improvement of clinical manifestation of venous hypertension and accessibility of AVF to carry out successful hemodialysis sessions.

Technical success was successful revascularization with less than 30% residual stenosis.

Technical failure was inability to cross or dilate the lesion.

Primary patency was uninterrupted patency after intervention until restenosis of more than 50% of the luminal diameter.

Results

A total of 32 patients with ESRD on hemodialysis complaining of symptomatic venous hypertension due to CVOD underwent endovascular intervention with balloon angioplasty with or without venous stenting. The commonest risk factors were hypertension and

Table 1 Demographic data

	n=32
Age	43 (38–52)
Males/females	22 (68.8%)/10 (31.2%)
Risk factors [n (%)]	
DM	17 (53.1)
Smoking	8 (25)
Hypertension	25 (78.1)
Ischemic heart disease	7 (21.9)

DM, diabetes mellitus.

diabetes. (Table 1) Mean age was 43 (38–52) years, and 22 (68.8%) patients were males. Type of AVF was brachiocephalic AVF in 19 (59.4%) patients, transposed brachiobasilic AVF in seven (21.9%) patients, axillobrachial graft AVF in four (12.5%) patients, and radiocephalic AVF in two (6.25%) patients. Baseline characteristics are shown in Table 2.

The commonest site of CVOD was innominate vein in 21 (65.6%) patients, subclavian vein in eight (25%) patients, and axillary vein in three (9.4%) patients. Stenosis was recorded in 25 (78.1%) patients and the remaining seven (21.9%) patients were occlusion (Table 2).

A total of 30 (93.8%) patients had past history of central venous catheter insertion: 21 patients in subclavian vein and nine patients in internal jugular vein.

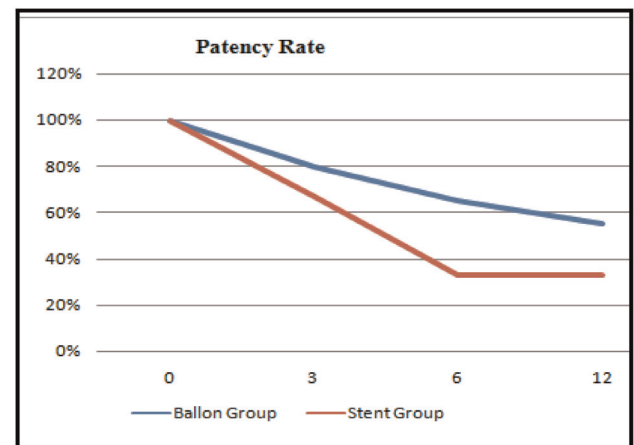
Technical success was achieved in 26 (81.3%) patients, where 20 of them operated by balloon angioplasty and six achieved after stent deployment. The indication of venous stenting was venous recoil in one patients and persistent residual stenosis in five patients. Failure to cross the lesion occurred in six (18.8%) patients. Overall, 1-year primary patency rate of study cohorts was 76.9, 57.7, and 46.2% at 3, 6, and 12 months, respectively. Primary patency rate was 80, 65, and 55% at 3, 6, and 12 months, respectively, in those treated with balloon angioplasty, whereas it was 66.6, 33.3, and 33.3% at 3, 6, and 12 months, respectively, in those treated with stent deployment, which was statistically insignificant ($P=0.17$) (Fig. 2).

Reocclusion was recorded in 14/26 patients (53.8%). Most of them occurred between the second and sixth months postoperatively. Nine of them were previously managed by balloon dilatation, whereas the other five patients were previously managed by stent deployment. Reintervention was needed in all of them to maintain the function of AVF; 7/14 cases were managed successfully by balloon dilatation, 2/14 patients treated by stent deployment, whereas in 5/14 cases, revascularization failed, and therefore, ligation of

Table 2 Patients and lesion criteria:

	n=32 [n (%)]
Type of AVF	
Brachiocephalic AVF	19 (59.4)
Brachiobasilic AVF	7 (21.9)
Graft AVF	4 (12.5)
Radiocephalic AVF	2 (6.25)
Duration of AVF (months)	3.2±1.8
Site of CVOD	
Innominate vein	21 (65.6)
Subclavian vein	8 (25)
Axillary vein	3 (9.4)
Type of lesion	
Stenosis	25 (78.1)
Occlusion	7 (21.9)
Lesion length (cm)	3.5±2.1
Vascular access	
fistula access	27 (84.4)
fistula access+femoral access	5 (15.6)

AVF, arteriovenous fistula; CVOD, central vein occlusive disease.

Figure 2

1-year primary patency rate showed insignificant difference ($P=0.17$).

fistula was needed to relieve the venous hypertension manifestation. Analysis of data of failed cases denoted that 4/5 of them were in-stent occlusions and one case occluded after PTA.

Regarding procedure-related complications, access site bleeding was noticed in five patients who were treated conservatively, thrombosed AVF in one patient, and significant stent shortening in another one patient who required additional stent. No cases of venous perforation were recorded. Death occurred in three patients after 1 year because of associated co-morbidities (Table 3).

Discussion

Central venous obstruction is one of the most common reasons for dialysis access dysfunction in hemodialysis

Table 3 Procedure-related complications

	<i>n</i> (%)
Access site hematoma	5/32 (15.6%)
Thrombosed AVF	1/26 (3.8%)
Stent shortening	1/6 (16.6%)
Central vein perforation	0

AVF, arteriovenous fistula.

patients. The incidence of subclavian vein obstruction owing to catheter insertion is 12–29%, whereas the internal jugular vein obstruction is 5% [12]. Maldonado *et al.* [13] attributed the reason of CVOD after venous catheterization by inflammatory response, fibrin sheath around the catheter, and subsequent intimal hyperplasia.

Without effective management, CVOD will result in decrease in the quality of life of such patients. Endovascular techniques have gained popularity for the initial treatment [5] because of less invasiveness, no surgical wound, shorter hospital stay, and the fistula can be used immediately for dialysis [2].

In this study, 59.4% of patients had brachiocephalic fistula, 21.9% had transposed brachio basilic fistula, 12.5% had axillobrachial graft AVF. This finding agreed with other series that the incidence of CVOD was higher with proximal AVF than those with distal ones [4].

Nearly all patients in this study had past history of insertion of temporary central venous line at the ipsilateral limb. This denotes the intimate relationship between the temporary dialysis catheters and occurrence of CVOD, especially with subclavian vein catheter rather than other types, as reported by others [4]. KDOQI guidelines advised prevention of subclavian vein catheterization in patients with chronic renal failure for temporary access [14]. Moreover, Kundu [15] has reported that the incidence of CVOD in USA has decreased significantly after the widespread transition from subclavian approach to jugular access.

Lesions were most commonly located in the innominate vein in 65.6% of patients followed by subclavian vein in 25% and axillary vein in 9.4% of patients. This was in agreement with Yadav *et al.* [16] who stated that most lesions were located at innominate vein. Overall, 78.1% of lesions were stenosis, and the remaining 21.9% were occlusive in nature, which is in agreement with Aytakin *et al.* [17] who found that most lesions were stenosis, representing 78.5%.

The main vascular access in this series was through the outflow of native vein or venous end of the graft AVF in all cases. When it was difficult to cross the lesion or in need to deploy venous stent, another femoral vein access was performed to complete the procedure. Huang *et al.* [18] had used three different accesses femoral vein access as a main recanalization approach, fistula access, and a new intervention access guided by ultrasound position about 7–10 cm distal from the occlusion lesion and called this access as ‘the third way.’

The optimal endovascular management remains vague with no clear advantage of primary stenting over angioplasty. The goal of treatment is to achieve symptomatic relief and maintaining AVF patency [19].

In this study, most of the cases (20 patients) were treated with balloon angioplasty, and only six venous stents were required owing to vessel recoil in one case and significant residual stenosis in five patients. This was matched with Sprouse *et al.* [20] in percentage of cases treated with stents in comparison with PTA group. Hongsakul *et al.* [21] had confirmed that the standard treatment is balloon angioplasty, whereas stenting is indicated in cases of elastic central vein recoil or recurrent stenosis within 3-month duration according to guidelines of KDOQI.

Many investigators confirmed that the durability of balloon angioplasty is limited, and therefore, patients may need repeated intervention to maintain the fistula function [22]. Panagiotis *et al.* [23] had reported that the use of high pressure balloons yields superior technical success and patency outcomes compared with conventional balloon.

Venous stents was first described in the last century by Haskal *et al.* [24], and since then, it was used largely after failed PTA or early recurrent stenosis. Although stent deployment has a well-known protocol in coronary and peripheral arterial disease, its role in dialysis access has been debated [25].

Bakken *et al.* [26] have shown that bare metal stent provided superior results for primary patency of 42–89% at 6 months and 14–73% at 12 months compared with plain balloon angioplasty. However, attempts of in-stent stenosis would decrease the patency duration owing to neointimal hyperplasia.

Stent deployment may be not preferable in certain situations: position of stenosis near bifurcation, for example, merging site of the right and left innominate veins and site of merging of subclavian

and internal jugular veins. Another drawback of venous stenting is early in-stent restenosis, which induces recurrent venous hypertension manifestations [21].

In this year 2020, Wu *et al.* [10] had performed a meta-analysis study including RCT and non-RCT studies, and they did not show a significant difference in primary patency rates between balloon angioplasty group and stent groups up to 24 months of follow-up ($P > 0.05$).

Stainless steel stent (e.g. Wall stent) is a first-generation self-expandable stent characterized by its flexibility, low profile, and radiopacity. Its disadvantages include unpredictable shortening during delivery, its capacity for changing position and concentric narrowing, as well as decreased radial strength. Shortening is observed in regions exposed to continuous pressure and movement, such as region of costoclavicular space and in tortuous vein, for example, left innominate vein [27]. Nitinol stents (e.g. Protégé, ev3 and Smart stent, Cordis) are second-generation self-expandable stents characterized by super elasticity [28]. Maya *et al.* [29] reported that no significant difference was found between patency rate of wall stents and nitinol stents. However, in another study [30] nitinol stents provided better patency rates.

Stent graft in central veins is another option for treating CVOD. Kundu *et al.* [31] reported primary patency at 9 months of 100%. Advantages of the covered stent are that they provide a relatively inert and stable intravascular matrix that therefore reduces intimal hyperplasia and, subsequently, the restenosis rates. However, stent stenosis can be found at the distal and proximal ends of the stent. Keerati *et al.* [21] had reported another disadvantage of covered stent, such as when it is thrombosed, the venous collaterals are blocked, which resulted in severe form of venous hypertension than those with bare metal stent, in addition to its higher cost. Therefore, Verstandig *et al.* [32] advised that it should be avoided whenever possible. No covered stent was used in this study.

Drug-coated balloon (DCB) provides better outcome by significant reduction of restenosis rate [33]. Keerati *et al.* [21], had reported that there is lack of data regarding DCBs because they are not available in large sizes in all countries. Massmann *et al.* [34] showed that DCB provided significantly greater freedom from target lesion revascularization than conventional balloon. No DCBs were used in this series as the largest available sizes are not available in Egypt.

In this series, technical success was achieved in 26 (81.3%) patients, which was nearly similar to results obtained by Yadav *et al.* [19]. Vogel *et al.* [35] reported higher technical success (96%). Bakken *et al.* [26] had confirmed that technical success of balloon angioplasties varied from 70 to 90%.

Huang *et al.* [18] had analyzed the aspects of technical success or failure and found two major factors: lesion crossing and revascularization. Crossing is the key for success. Revascularization is influenced by occlusion length, extent, and location. These were the main factors for resistance to passing the balloon through the occlusion. To facilitate this resistance, they used super stiff guidewire replacement, long sheath support, for example, 30-cm long Abrahams sheath (Cook, USA) with its tip close to the occlusion, or using the flossing wire technique, and they appreciated the latter, as it obtained 100% success rate. Kundu *et al.* [31] had found that lesion length more than 6.5 cm was a significant parameter of technical failure.

One-year primary patency rate was 80, 65, and 55% at 3, 6, and 12 months, respectively, in balloon group, whereas it was 66.6, 33.3, and 33.3% at 3, 6, and 12 months, respectively, in-stent group. Nearly similar results was reported in a series of Shi *et al.* [36] who found that primary patency rates were 88.9, 64.8, 48.6 at 3, 6, 12 months, respectively, in PTA group. Moreover, they reported in their series that they did not find any significant difference between PTA group and stent group. Higher results was achieved by Fotini *et al.* [37] who stated that 3-, 6-, 12-month primary patency rates of venous stenting were 88.3, 65.3, and 45.6%, respectively.

In this study, 14 cases were re-occluded (53.8%): nine from angioplasty group and five from stent group. Attempts of revascularization were performed to restore the fistula function. In PTA group, balloon dilatation was successful in 6/9 patients, deployment of stent in 2/9 patients, and failed revascularization in one patient. In occluded stent group, balloon dilatation was successful in only one patient and failed revascularization was observed in 4/5 patients, and therefore, ligation of fistula was performed. It was noticed that it was less difficult to deal with re-occluded CVOD after PTA angioplasty than those of in-stent occlusion. Wu1 *et al.* [10] had confirmed in their series that the long-term patency of CVOD was improved following balloon angioplasty than those achieved with venous stent with better assisted primary patency rates at 24-month follow-up. Falk *et al.* [38] presented the results of RESCUE trial

which was a multicenter, randomized trial of angioplasty versus covered stent for management of in-stent restenosis and showed superiority of stent graft compared with angioplasty in 6-month patency rate (66.4 vs 12.3%, $P < 0.001$).

No reported cases of central vein perforation were recorded. Yadav *et al.* [19] had recorded two cases of minimal perforation resulting in contrast extravasation, which stopped spontaneously. Perforation of central veins is a serious complication that is considered a life-threatening problem and may be fatal because of cardiac tamponade and hypovolemic shock. Diagnosis is challenging. When venography is negative, it does not imply absence of perforation owing to compression by a hematoma. Echocardiography is helpful for diagnosing hemopericardium. Immediate resuscitation, insertion of balloon for temporary tamponade at the rupture site, treatment of hemopericardium by pericardiocentesis, and urgent surgical management may be needed [39].

Conclusion

Balloon angioplasty for CVOD in hemodialysis patients achieves comparable patency rates and clinical outcomes to venous stent. Although it achieves short-term durability, it should be applied firstly reserving the venous stent for significant residual stenosis.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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