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Central venous occlusion in hemodialysis access: Comparison between percutaneous transluminal angioplasty alone and nitinol or stainless-steel stent placement

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Central vein occlusion;
Angioplasty;
Hemodialysis;
Central venous occlusion;
Stenting

Abstract

Purpose: The purpose of this study was to compare the primary and secondary patency rates of percutaneous transluminal angioplasty (PTA) alone with those of metallic stent placement in patients with hemodialysis access and central venous occlusion (CVO) and to compare the respective effects of nitinol and stainless-steel stents on patency.

Materials and methods: A total of 150 consecutive patients with hemodialysis access who underwent endovascular treatment for symptomatic CVO with ipsilateral functioning hemodialysis access were evaluated. There were 67 men and 83 women with a mean age of 56.2 ± 15.2 (SD) years (range: 15–86 years). The primary endovascular treatment of CVO was PTA alone. Stent placement either with nitinol or stainless-steel stents was performed as a bailout procedure. The results were analyzed on a per patient basis.

Results: Technical success was achieved in 141/150 patients (94%). Of the 141 patients, 109 (77%) underwent PTA alone and 32 (23%) underwent stent placement. The mean number of interventions in the stent group [4.3 ± 2.5 (SD)] was significantly higher than that in the PTA alone group [2.6 ± 2.8 (SD)] ($P=0.002$). The primary patency rates at 12, 24, and 60 months for the stent group (58.7%, 41.9%, and 27.9%, respectively) were significantly higher than those in the PTA alone group (42.4%, 36.3%, and 20.2%, respectively) ($P=0.036$). Secondary patency rates at 12, 24, and 60 months for the stent group (87.6%, 80.7%, and 50.3%, respectively) were

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significantly greater than those in the PTA alone group (68.4%, 56%, and 38.6%, respectively) ($P=0.046$). Furthermore, the primary patency rates at 6 and 12 months in the nitinol stent group (89% and 80.9%, respectively) were significantly greater than those in the stainless-steel stent group (78.8% and 38.4%, respectively) ($P=0.007$). The secondary patency rates at 6, 12 and 24 months for the nitinol stent group (92.8%, 87.7% and 65.8%, respectively) were significantly greater than those in the stainless-steel stent group (85.7%, 76.2% and 65.3%, respectively) ($P=0.011$).

Conclusion: Although PTA alone is an effective interventional treatment strategy of CVO in short term, stent placement yields greater primary and secondary patency rates in the long-term. But the mean number of interventions per vein after stenting is significantly higher. Close follow-up and multiple re-interventions are necessary to ensure long-term patency.

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Central venous occlusion (CVO) is a common and serious complication of hemodialysis access. The incidence of CVO ranges between 25% and 40% [1,2]. Previous history of venous catheterization is the most common cause of CVO in hemodialysis access [3]. Central venous injury and subsequent inflammatory response trigger intimal hyperplasia and lead to CVO [4]. Fibrin sheath formation after chronic central venous catheterization is common and leads to catheter dysfunction and CVO [5]. Furthermore, angioplasty can aggravate the venous intimal response and thus accelerate stenotic process [4]. The primary standard treatment for CVO in hemodialysis access is percutaneous transluminal angioplasty (PTA) [6]. However, additional stent placement may be needed in patients who have insufficient blood flow during intervention or early postoperative period [7]. Nitinol stents and stainless steel stents have been used for stenting [8–10]. Primary patency rates of stents and PTA are poor and secondary patency can be maintained with repeated interventions. Treatment with conventional PTA and stenting paradoxically triggers the development of venous neointimal hyperplasia in long-term. Therefore, efforts to prevent obstruction caused by neointimal hyperplasia triggered by interventional treatment are increasing. Studies have focused on covered stents and paclitaxel-coated balloons (PCBs) to improve long-term patency of recurrent hemodialysis access vascular stenosis and CVO caused by neointimal hyperplasia [11–15].

In the present study, it was hypothesized that stenting may have better primary and secondary patency rates than PTA alone and the patency of nitinol stents may be longer than that of stainless-steel stents in the treatment of CVO in hemodialysis access.

The purpose of this study was to compare the primary and secondary patency rates of PTA alone with those of metallic stent placement in patients with hemodialysis access and CVO and to compare the respective effects of nitinol and stainless-steel stents on patency.

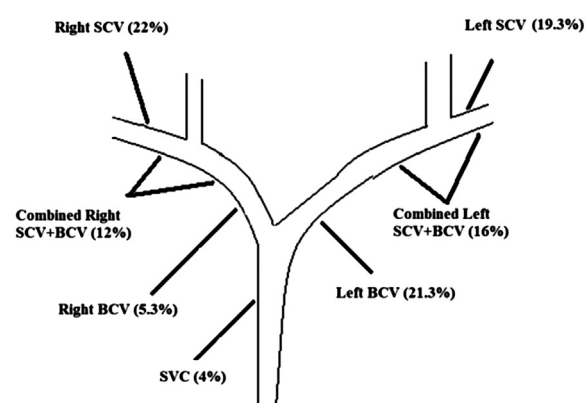


Figure 1. Diagram shows all central vein lesion sites in 150 patients with corresponding prevalence in percentage. SCV indicates subclavian vein, BCV indicates brachiocephalic vein, SVC indicates superior vena cava.

Materials and methods

Patients

This study was approved by the institutional review board of our local ethics committee. The records of 150 consecutive hemodialysis patients who underwent endovascular treatment of symptomatic CVO ipsilateral hemodialysis access between 2000 and 2014 were retrospectively reviewed. There were 67 men and 83 women with a mean age of 56.2 ± 15.2 (SD) years (range: 15–86 years). CVO was located in the right subclavian vein (SCV) in 33/150 patients (22%), left brachiocephalic vein (BCV) in 32/150 patients (21.3%), left SCV in 29/150 patients (19.3%), left SCV and BCV in 24/150 patients (16%), right SCV and BCV in 18/150 patients (12%), right BCV in 8/150 patients (5.3%) and superior vena cava (SVC) in 6/150 patients (4%) (Fig. 1).

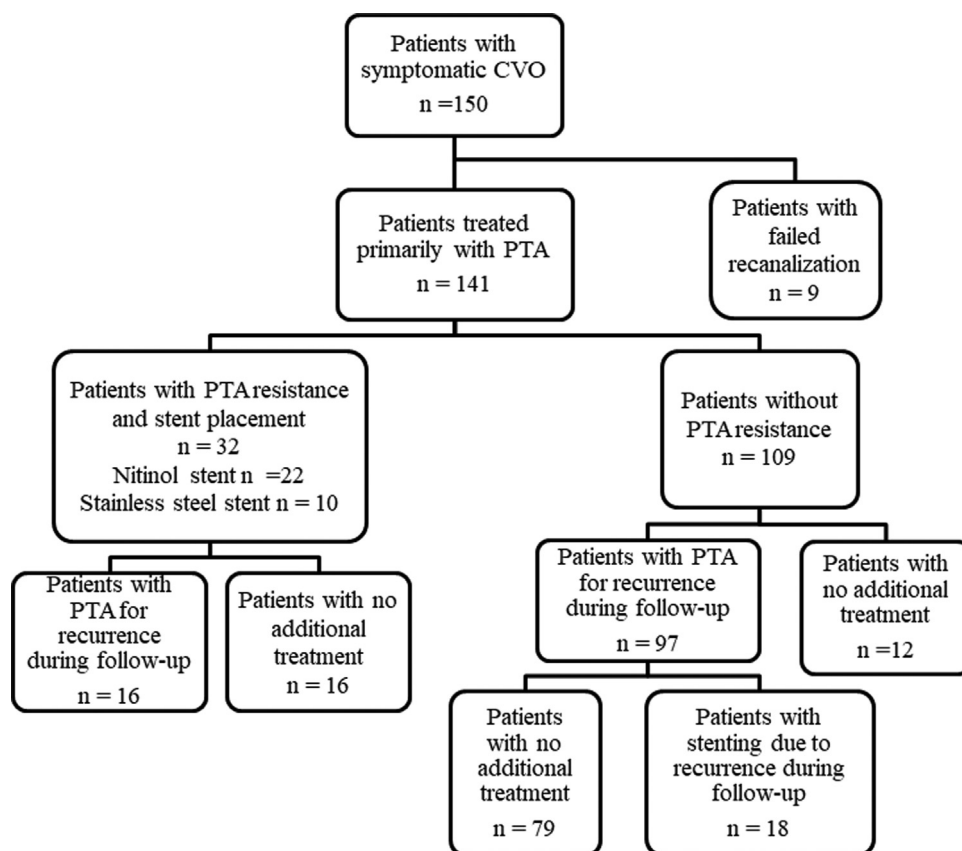


Figure 2. Flow chart of the study. CVO indicates central venous occlusion. PTA indicates percutaneous transluminal angioplasty.

A total of 141 patients who underwent successful endovascular treatment were included in the study. Nine patients in whom the CVO could not be traversed during the primary intervention were excluded from the study group. Additionally, patients with prior episode of severe allergy to iodinated contrast material and clinically unstable patients were not treated and also excluded from the study. Patients were referred to our interventional radiology clinic with prolonged bleeding following hemodialysis, elevation of static venous pressure, and ipsilateral arm or neck swelling.

Demographic data of patients and medical records were obtained from the hospital information system. Details were obtained from interventional radiology reports and venography images stored in digital media.

Procedure details

A diagnosis of CVO was confirmed based on venography. All procedures were performed by 3 interventional radiologists with at least 5 years of experience and with national board certification approved by the Cardiovascular and Interventional Radiological Society of Europa (S.G., 10 years; L.O., 25 years; M.G., 5 years). All venograms and endovascular interventions were performed using a digital subtraction angiography unit (Innova[®] 3100, General Electric Healthcare, or Multistar[®], Siemens Healthineers). All endovascular interventions were outpatient procedures performed

during the same session with diagnostic venography. The lesions treated with PTA or stent placement were the same lesions and the results were considered on a per patient basis.

Access to the vein was achieved with a single-wall puncture under ultrasound guidance. We initially placed a 5-F vascular sheath into the access vein. The basilic or the brachial veins were favored for the diagnostic venogram and endovascular intervention; however, the cephalic vein was also used if these vessels were not suitable. When CVO was confirmed by venography, the 5-F vascular sheath was replaced by an 8-F to 10-F vascular sheath and 5000 IU of heparin was administered intravenously. The stenotic vessel segment was passed by a guidewire and PTA was performed. When occlusion was present, then it was traversed with an angled or a straight hydrophilic guidewire (Glidewire, Terumo, or Roadrunner, Cook) with the help of an angled catheter (Kumpe, Cook,). High pressure balloons (Atlas/Conquest, Bard) were used for PTA-resistant lesions. The diameters of the balloon catheters ranged from 10- to 18-mm (mean, 12.8 ± 1.5 mm [SD]). Stent diameters ranged from 10–18 mm [mean, 11.2 ± 4.7 mm (SD)] and stent length ranged from 40–90 mm. Stents were only used as a bailout procedure and all the stents used were self-expanding and either stainless-steel (Wallstent[®], Boston Scientific) or nitinol (Protégé[®], ev3, or Smart[®], Cordis,). The flow chart of the study is given in Fig. 2.

Table 1 Demographics of 141 patients with hemodialysis access with technically successful percutaneous transluminal angioplasty for central venous occlusion.

Variable	PTA group (n = 109)	Stent group (n = 32)	Initially included patients (n = 150)
Sex			
Male	50	12	67
Female	59	20	83
Age (year) $\pm$ SD	54.7 $\pm$ 15.9 [15–78]	60.7 $\pm$ 12.6 [30–86]	56.2 $\pm$ 15.3 [15–86]

PTA: percutaneous transluminal angioplasty; SD: standard deviation. Numbers in brackets are range.

Follow-up

Repeated venography was performed in patients with recurrent symptoms. Follow-up was finished when loss of follow-up, patient death, abandoning of the ipsilateral hemodialysis access, or renal transplantation occurred.

Outcome definitions

CVO was defined as a stenosis greater than 50% or occlusion of the central venous system that included SCV, BCV and SVC. Technical failure was defined as the impossibility to cross vascular lesions. Technical success was defined as restoration of flow without significant residual stenosis < 30%. A significant decrease in the pressure gradient in patients with persistent collateral vein filling was also accepted as success. Post-intervention primary patency was defined as the interval of uninterrupted patency after endovascular intervention within a dialysis circuit to thrombosis or repeated endovascular intervention in the PTA alone group and stent groups. Post-intervention secondary patency of PTA was defined as the interval from the initial procedure until permanent occlusion or intervention necessitating stent placement. Post-intervention secondary patency of stent group was defined as the interval from the placement of first stent until permanent occlusion of the lesion, surgical ligation, renal transplant, and/or loss to follow-up or death [16].

Statistical analysis

A statistics software package (SPSS, version 19.0, SPSS) was used for statistical analysis. Quantitative variables were expressed as mean $\pm$ standard deviation (SD) and range, or median, first (Q1) and third quartiles (Q3). Qualitative variables were expressed as raw numbers, proportions and percentages. Survival curves for the primary and secondary vein patency of the different intervention types and different stent types were generated using Kaplan-Meier survival analysis, and the log-rank test was used to compare luminal patency. Differences between means for continuous variables were evaluated using the Student *t*-test. The Mann-Whitney U test was used to compare the outcome of patients treated with stainless steel with that of patients treated with nitinol stent. Pearson's correlation test was used to investigate the relationship between lesion length and secondary patency results. Significance was set at *P*-value < 0.05.

Results

The most common patient complaints were ipsilateral arm swelling (145/150 patients; 97%), additional face or neck swelling (57/150 patients; 38%), breast swelling (5/150 patients; 3.3%), and inability to puncture the vascular access (19/150 patients; 12.6%). There was no significant difference between the PTA and stent groups in terms of age and sex (Table 1). Twenty-five patients (25/150; 17%) had radiocephalic arteriovenous fistula (AVF), and 125 patients (125/150; 83%) had brachiocephalic AVF. One hundred and thirty-five patients (135/150; 90%) had a previous ipsilateral central venous catheter placement. Eighty-five patients (85/150; 57%) had a history of a single catheter placement, and the remaining 50 patients (50/150; 33.3%) had a history of more than one catheter placement. Eighty-four patients (84/150; 56%) had an internal jugular vein (IJV) catheter, and 51 patients (51/150; 34%) had a SCV catheter. All of SCV catheters were implanted in outside institutions.

Ninety-one patients (91/150; 61%) had stenosis greater than 50%, and 59 patients (59/150; 39%) had occlusion. Forty-two patients (42/150; 28%) had multiple stenoses and twenty-four of them (24/150; 18%) were on the left side. All of SCV-BCV combined lesions in 42 patients (42/150; 28%) accepted as a single lesion and the results were considered on a per patient basis. The locations and types of lesions are presented in Table 2. Technical success was achieved in 141 patients (141/150; 94%). The CVO could not be re-canalized in nine patients (9/150; 6%). Of the 141 patients, 14 (14/141; 10%) had additional acute central venous thrombosis that was found initially. Catheter-directed thrombolysis in 4 patients (4/141; 2.8%) and manual aspiration thrombectomy in 10 (10/141; 7%) patients was performed. All patients with acute or subacute central venous thrombosis had an underlying chronic stenosis or occlusion, and were treated with PTA alone in 12 patients (12/141; 10.6%) or with PTA and bailout stenting in 2 patients (2/141; 1.4%).

Stents were placed in 32 patients (22 nitinol stents and 10 stainless steel stents) with PTA-resistant lesions. However, PTA was again the primary treatment for in-stent occlusive lesions, and repeat stenting was performed in PTA-resistant lesions. In 6/141 patients (4%), four stenosis (4/141; 2.8%) and two occlusions (2/141; 1.4%) were present in the SVC.

The mean follow-up interval for all patients was 36.5 $\pm$ 21.9 (SD) months (range: 1–93 months). The mean follow-up interval was 36.6 $\pm$ 21 (SD) months (range: 1–93 months) for the PTA group and 37.6 $\pm$ 27.3 (SD) months (range: 6–93 months) for the stent group. According to

Table 2 Locations and types of lesions in 141 treated patients.

Lesion sites	PTA group (n = 109)		Stent group (n = 32)		Total (n = 141)
	Type of lesions		Type of lesions		
	Stenosis	Occlusion	Stenosis	Occlusion	
SCV	31 (31/141; 21.9)	19 (19/141; 13.4)	2 (2/141; 1.4)	3 (3/141; 2.1)	55 (55/141; 39)
BCV	19 (19/141; 13.4)	5 (5/141; 3.5)	9 (9/141; 6.3)	4 (4/141; 2.8)	37 (37/141; 26.2)
SCV + BCV	19 (19/141; 13.4)	11 (11/141; 7.8)	3 (3/141; 2.1)	10 (10/141; 7)	43 (43/141; 30.4)
SVC	4 (4/141; 2.8)	1 (1/141; 0.7)	0 (0/141; 0)	1 (1/141; 0.7)	6 (6/141; 4.2)
Total	73 (73/141; 51.7)	36 (36/141; 25.5)	14 (14/141; 10)	18 (18/141; 12.7)	141 (141/141;100)
SCV indicates subclavian vein; BCV indicates brachiocephalic vein; SVC indicates superior vena cava. Numbers in parentheses are proportions followed by percentages.					

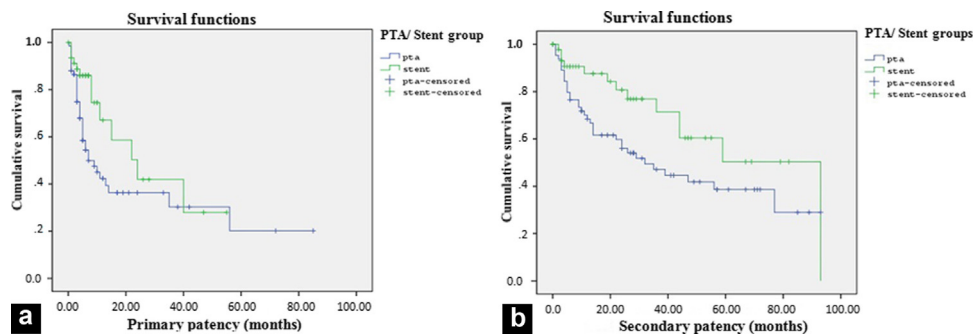


Figure 3. Graphs show patency of central vein after primary percutaneous transluminal angioplasty (PTA) in 109 patients and after stenting in 32 patients. Graphs show primary patency (a) and secondary patency (b) of central veins. There is significant difference in primary or secondary patency rates between the PTA and stent group ($P = 0.036$ and $P = 0.046$, respectively) by Kaplan-Meier analysis. PTA = percutaneous transluminal angioplasty.

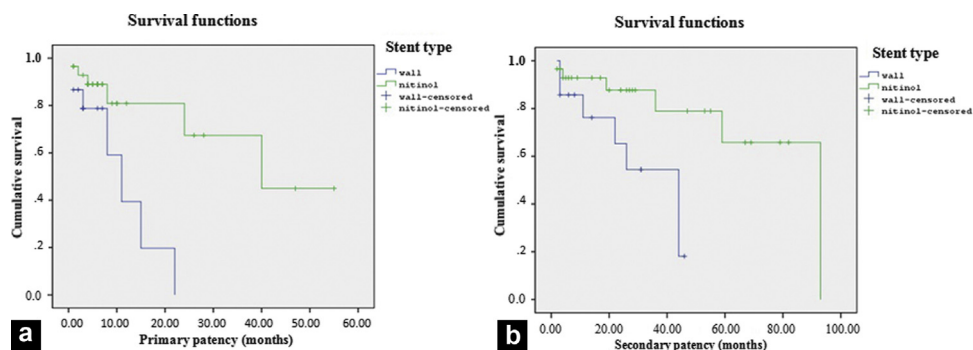


Figure 4. Graphs show patency of central vein after placement of 22 nitinol stents and placement of 10 stainless-steel stents. Graphs show primary patency (a) and secondary patency (b) of central vein. Primary and secondary patency rates in the nitinol stent group are significantly greater compared to the stainless-steel stent group ($P = 0.024$ and 0.011 , respectively) by Kaplan-Meier analysis.

Kaplan-Meier analysis, the primary patency rates at 12, 24, and 60 months were significantly greater in the stent group (58.7%, 41.9%, and 27.9%, respectively) than in the PTA alone group (42.4%, 36.3%, and 20.2%, respectively) ($P = 0.036$) (Fig. 3). Secondary patency rates at 12, 24, and 60 months were significantly greater in the stent group (87.6%, 80.7%, and 50.3%, respectively) than in the PTA alone group (68.4%, 56%, and 38.6%, respectively) ($P = 0.046$) (Fig. 3). Furthermore, the primary patency rates at 6 and 12 months were significantly greater in the nitinol stent group (89% and 80.9%, respectively) than in the stainless-steel stent

group (78.8% and 38.4%, respectively) ($P = 0.007$) (Fig. 4). The secondary patency rates at 6, 12 and 24 months were significantly greater in the nitinol stent group (92.8%, 87.7% and 65.8%, respectively) than in the stainless-steel stent group (85.7%, 76.2% and 65.3%, respectively) ($P = 0.011$) (Fig. 4).

The mean number of interventions per vein was 2.9 ± 2.8 (SD) for all patients (range, 1–17). For the PTA group, the mean number was 2.6 ± 2.8 (SD) (range, 1–10), and the mean number was 4.3 ± 2.5 (SD) (range, 1–17) for the stent group. The mean number of interventions per vein following stenting (4.3 ± 2.5 [SD]) was significantly greater than

Table 3 Median (Q1–Q3 percentile values) of primary and secondary patency for different obstruction sites and lesions.

	Median (Q1–Q3) primary patency (month)			Median (Q1–Q3) secondary patency (month)		
	PTA group (n = 109)	Stent group (n = 32)	total (n = 141)	PTA group (n = 109)	Stent group (n = 32)	total (n = 141)
<i>Lesion Sites</i>						
SCV	4 (1–8)	8 (6.2–22.2)	9 (1–8)	24 (6–51)	22 (11–55)	29.5 (6–51)
BCV	8 (5–13.5)	4 (2–6.5)	6 (5–13.5)	24.5 (12.5–51.7)	24 (3.5–46.5)	28 (12.5–51.7)
SCV-BCV	5 (3–8.5)	5 (3–9.5)	6 (3–8.5)	19 (5.7–39.7)	24 (6–37.5)	27 (5.7–39.7)
<i>Lesion Types</i>						
Stenosis	5 (3–12)	6 (3.7–10.2)	6 (3–11)	25 (10–41.2)	28 (8.5–50.5)	31 (10–42)
Occlusion	4 (3–9)	4 (2.5–9.5)	6 (3–9)	11.5 (4.7–56.2)	17 (3.5–44)	24 (4–47)

PTA: percutaneous transluminal angioplasty; PTS: percutaneous transluminal stenting; SCV: subclavian vein; BCV: brachiocephalic vein.

that after management with PTA alone ($P=0.002$). In all patients with stenting, neointimal hyperplasia developed in the stent walls during the follow-up period. Ninety-seven patients (97/109; 89%) in the PTA group underwent 176 repeat PTA procedures. In 16 patients (16/32; 50%) of the stent group, 150 re-interventions were performed for recurrent lesions. Seventy-nine of the recurrent lesions in seventy-nine patients (79/109; 72.4%) responded well to PTA alone, but additional stents were needed in 18 patients (18/109; 16.5%).

There was no significant difference in primary and secondary patency rates of PTA and stenting for occlusion versus stenosis ($P=0.6$, $P=0.3$, $P=0.2$, $P=0.1$). Median primary and secondary patency for the PTA group, the stent group, and the whole study group are reported according to obstruction site (BCV, SCV, or combined) and lesion type (stenosis or occlusion) in Table 3. A poor negative correlation was found between lesion length and secondary patency after PTA ($r=-0.35$; $P=0.004$).

Four patients (4/141; 2.8%) had extravasation following PTA. After temporal balloon tamponade, the extravasation was resolved in all patients. Two patients required placement of additional stents due to shortening of the stainless-steel stents in both SCVs. Complications were minimal and did not require hospitalization according to Society of Interventional Radiology Standards of Practice Committee [16]. During follow-up, two nitinol stents that were placed in the SCV were fractured and one nitinol stent in the left BCV collapsed because of extrinsic compression. These three patients were treated with stent-in-stent placement. There was no fracture with the stainless-steel stents. There were no periprocedural mortalities.

Discussion

In this study, we have compared the patency rates of PTA alone to those of bailout stenting in patients with CVO and hemodialysis access. We found that stenting yielded longer primary and secondary patency rates than PTA. In the stent group, the frequency of re-interventions was greater than that in the PTA alone group. The complication rates in both PTA alone and stent groups were very low. Additionally,

nitinol stents yield significantly longer primary and secondary patency rates compared to stainless-steel stents.

One-year primary patency after PTA have been reported between 20% and 50% in the literature and the maximum one-year primary patency was 77% in the study that was conducted by Ozyer et al. [10,17–20]. The results of present study are consistent with those of prior studies. One-year primary and secondary patency after primary stenting or stenting after a failed PTA have been reported between 14% and 76% as well as 33% and 100%, respectively [9,21–23]. In recent literature, it was reported that PCBs seem to improve patency rates of central veins [24]. However, further randomized controlled trials are needed to fully determine the efficacy of this treatment.

This present study showed that bailout stenting had higher primary and secondary patency results compared to PTA alone. This result is different from those of previous studies [10,17,20]. Although our study showed that patency results of stenting were better than PTA, stenting has been recommended as a salvation procedure by the Society of Interventional Radiology and in the K/DOQI guidelines [7,16]. While stenting may have superior patency, there are drawbacks such as jailing other veins and potentially increasing neointimal hyperplasia. Probably due to the development of neointimal hyperplasia, the mean number of re-interventions following stenting was significantly higher than that after PTA [20].

Neointimal hyperplasia is the most important factor that decreases long-term patency in the subsequent period of endovascular treatment of CVO. Over the last ten years, clinical investigations have focused on overcoming neointimal hyperplasia [25]. Covered stents and PCBs have been used to improve long-term patency of central veins and hemodialysis access stenosis [5,11–15,26]. The advantage of covered stents include providing relative inert stable intravascular matrix for endothelialization and a barrier for the development of neointimal hyperplasia [27]. Verstandig et al. reported that central venous covered stent placement is associated with prolonged access patency; but coverage of major venous confluences is disadvantage [12]. It should be avoided if it is possible. Although there are many studies that emphasize the effect of PCBs on long-term patency in the hemodialysis access stenosis, the usage of these balloons in CVO is not clear. A study showed that PCBs yield

longer patency compared to standard balloon angioplasty in the endovascular treatment of central vein restenosis [28]. The most common cause of CVO in hemodialysis patients is previous history of venous catheterization [3]. SCV catheterization is an important risk factor of CVO and if it causes CVO, it inhibits subsequent AVF creation. Thus, the use of SCV catheter has been not recommended in patients with kidney disease, according to K/DOQI guidelines [7]. In our study, 44% of patients had a SCV catheterization. However, none of them were placed in our clinic.

In the present study, it was found that nitinol stents had significantly longer primary and secondary patency results compared to the stainless-steel stents. This finding may be interested with stent structure and composition. To date, this association has not been clearly demonstrated in the literature. According to the literature, in addition to stent type and composition, recanalization type and other factors can be effective on the outcomes [29,30]. Self-expanding stents have generally been used for CVO. The stainless-steel stent is a first-generation, self-expandable stent and the advantages of this stent include a low profile, flexibility, and radiopacity. The disadvantages of stainless-steel stent include an unpredictable amount of shortening during delivery. In addition, its capacity for changing position and concentric narrowing as a result of eccentric loading and decreased radial strength [31]. Shortening is especially observed in regions exposed to continuous pressure and movement, such as the costoclavicular space and the tortuous vein that occurs in the left BCV. Nitinol stents are second generation, self-expandable stents. In addition to super elasticity, nitinol stents have several physical characteristics that may confer longer patency compared to stainless-steel stents [32]. Some previous studies have reported higher patency rates for nitinol stents compared to stainless-steel stents, while others found no significant difference between the patency rates of the two stent types [10,20,23,24,33,34].

There are some limitations in the study. First, it is a retrospective study. Randomized controlled studies may be more informative to evaluate the most effective treatment of CVO in hemodialysis patients. Currently there are no such trials. Secondly, the number of patients in the stent group was smaller than that in the PTA group. In addition, stenting was not a primary treatment and was selectively performed in PTA-resistant lesions. Finally, there was no uniformity for choosing between bare metal stent types as this depended on operator's preference.

In conclusion, the endovascular approach is an effective treatment in CVO of hemodialysis access. However, systematic follow-up and re-interventions are necessary to maintain access patency in the long-term. Stenting offers higher primary and secondary patency rates than PTA alone. Stent placement should not be performed as the primary treatment for CVO; stents should be recommended in only bailout treatment. Although we found that nitinol stents have longer primary and secondary patency results than stainless-steel stents and bailout stenting than PTA alone, more prospective, randomized controlled trials should be performed to evaluate the effectiveness of different endovascular treatment modalities.

Human and animal rights

The authors declare that the work described has been carried out in accordance with the Declaration of Helsinki of the World Medical Association revised in 2013 for experiments involving humans.

Informed consent and patient details

The authors declare that this report does not contain any personal information that could lead to the identification of the patient(s).

The authors declare that they obtained a written informed consent from the patients and/or volunteers included in the article. The authors also confirm that the personal details of the patients and/or volunteers have been removed.

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Author contributions

All authors attest that they meet the current International Committee of Medical Journal Editors (ICMJE) criteria for Authorship.

Credit author statement

Serkan Gür, M.D.: Formal analysis; Investigation; Methodology; Project administration; Resources; Software; Supervision; Validation; Visualization; Writing - original draft; Writing - review & editing.

Levent Oguzkurt, M.D.: Methodology; Project administration, Supervision; Validation, Writing - original draft; Writing - review & editing.

Murat Gedikoglu, M. D.: Investigation, Resources; Software.

Disclosure of interest

The authors declare that they have no competing interest.

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