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Early Outcome of Percutaneous Transluminal Angioplasty for Central Venous Disease in Hemodialysis Patient

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ABSTRACT

Introduction: Central venous stenosis and obstruction (CVSO) are frequent issues that result in access, morbidity and dysfunction for cases undergoing regular dialysis. Although multiple treatment options exist, such as endovascular and surgical procedures, the best treatment approach for CVSO is still unclear.

Objective: This study aimed to identify immediate and early outcomes after percutaneous transluminal angioplasty (PTA) for central venous disease in hemodialysis individuals.

Methodology: This is a prospective interventional study conducted on thirty-four end-stage renal disease individuals receiving regular dialysis with upper limb venous hypertension. It was conducted at a tertiary university-based hospital. A comprehensive history and examination were done. Everyone underwent PTA of CVSO lesions with balloon insertion. Following the intervention, they were evaluated at one week, one month, and three months. The primary patency rates and short-term results were calculated.

Results: The 34 patients were 15 males and 19 females. The mean age was 47.9±10.37 years. Initial success was accomplished in 29 (85.29%) cases. Two cases required a stent, representing 5.88%. Recurrence at 6 months occurred in 13 patients (38.24%), including six re-occlusions and seven restenosis, with a mean time to recurrence of 2.88±0.133 months. The patency rate after the intervention was significantly higher for patients with stenosis (73.07%) compared to those with occlusion (25%) (P=0.033) and was also higher for lesions ≤3 cm (P=0.025).

Conclusion: For patients receiving regular hemodialysis, endovascular treatment of central venous stenosis and occlusion is a safe and efficient procedure with acceptable primary patency rates.

Keywords: Central venous disease, Angioplasty, Hemodialysis, Venous hypertension.

INTRODUCTION

Common problems that cause severe morbidity and access dysfunction in hemodialysis (HD) patients include central vein stenosis and occlusion (CVSO) [1]. CVSO is noticed in 25–40% of these patients. Although this illness has numerous causes, the most frequent one is the extended usage of central veins as a temporary access point for ipsilateral arteriovenous fistula (AVF) and hemodialysis [2]. The hemodialysis patient's life expectancy decreases with the development of more lesions over time, making access preservation more difficult [1]. Venous hypertension is a condition experienced by CVSO patients. This disorder causes severe edema in the upper extremities, which impairs limb function and causes pain and ulcers. This could lead to the vascular access being sacrificed or perhaps severed, which would be an extreme solution [3].

Despite various treatments, including endovascular and surgical interventions, the optimal course of treatment for CVSO remains unknown [4].

High primary patency rates are a benefit of surgical management alternatives. Still, they are also linked with severe morbidity due to deep vein exposure, especially in light of the poor health of the majority of hemodialysis patients [5].

Endovascular therapy techniques are a preferred choice despite the relatively rapid recurrence of the condition [6].

Although numerous studies have published their findings, there is still a debate about whether primary percutaneous transluminal stenting (PTS) or percutaneous transluminal angioplasty (PTA) is the best option for treating central venous obstruction [7].

Angioplasty for stenosis of AVFs was initially noted in 1981. Since then, significant progress has been made in PTA for AVFs and arteriovenous grafts (AVG). Recent research has focused on drug-eluting balloons (DEBs), highlighting the need for methods or materials that maximize patency while minimizing side effects on the vascular wall of AVF/AVG [8].

AVF or AVG angioplasty has been used on multiple occasions in HD patients. These include stenosis > 50% with prior thrombosis, elevated venous pressure during HD, worsening lab results (e.g., hyperkalemia, uremia), reduced murmur upon auscultation, and decreased blood flow on color Doppler [9].

Thus, this study aimed to identify the immediate and early outcomes after PTA for central venous disease in hemodialysis cases.

PATIENTS AND METHODS

This prospective interventional study was performed on 34 end-stage renal disease (ESRD) cases on regular hemodialysis. They were admitted to the Department of

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Vascular Surgery of a tertiary university-based hospital from April 2022 to April 2023. The study included patients of both genders diagnosed with CVSO, including only innominate and subclavian vein lesions. All types of upper limb (UL) AVF and AVG, radiocephalic (RC), brachiocephalic (BC), and brachiobasilic, were included.

We excluded patients with ipsilateral peripheral vein stenosis or occlusions, those who needed concomitant arterial angioplasty, those with superior vena cava (SVC) stenosis or occlusion, and those with previous surgical intervention for the fistula to correct stenosis or repair aneurysms.

Sample size: The clincalc sample size calculator for analytic studies was employed, with 0.05 alpha error and power of the study 0.8, Cl of 90%. Based on this, 34 patients, including a 10% increase, were needed to cover the follow-up period.

Preoperative preparation:

A full history, including medical and surgical history, was taken. A thorough clinical examination was done. Routine preoperative laboratory investigations involved a complete blood count and coagulation profile. Imaging techniques were performed, including a duplex ultrasound machine with a linear probe (6–13MHz) to examine each patient in order to identify the access site and evaluate the patency of the neck and limb veins. The dysfunction of hemodialysis was verified via Doppler analysis prior to angioplasty in the form of significant stenosis (>50%), reduced flow volume in the draining vein (< 250 mL/minute), and/or a peak systolic velocity (PSV) ratio of ≥ 3 (PSV at stenotic site/ PSV in distal draining vein). Prophylactic antibiotic (Cefotaxime, 2 g IV) was administered to the patients.

Operative procedures:

Meperidine or fentanyl was used as preoperative intravenous analgesics to help with the local anesthetic (2% lidocaine) utilized for the procedure. Cases who were uncooperative needed to be put under general anesthesia. Patients were monitored utilizing a pulse oximeter and an electrocardiogram (ECG).

Retrograde, anterograde, or dual access locations might be utilized during the treatment, depending on the anatomy and location of the stenosis. Venography of the central veins was performed after the vein was punctured, and the 6F to 10F sheaths were inserted. A 4F or 5F Angle-shaped catheter and a hydrophilic guide wire (0.035 Terumo, Tokyo, Japan) were then used to probe the steno-obstruction.

During angioplasty, a 10–16 mm balloon was used, and a sturdy wire was used in place of the guide wire if the lesion was easily traversed. If the lesion was tight and couldn't be crossed using this method, the right internal jugular vein was attempted as an alternative access location.

Under ultrasound guidance, the retrograde technique (left or right femoral vein) was carried out in case the antegrade approach failed. In situations where both antegrade and retrograde access were required, a femoral approach was also required. A 5F catheter was deployed to cross the CVSO using an 8F trans-femoral vein introducer sheath. Under high pressure (10–15 atmosphere), the utilized angioplasty balloons (6–16 mm) were inflated over the stenotic or obstructed segments after being inserted via the puncture site.

Following PTA, a completion angiogram was conducted promptly. If there was less than 30% residual stenosis, the procedure was deemed successful. In cases of venous rupture, immediate recoil, collateral vascular persistence during angioplasty, or ≥30% residual stenosis, a stent was placed. The stents used were 12x40 mm and 14x60 mm stents (Vici, Boston Scientific Corporation, USA).

The stent length was determined to be 20 mm longer than the lesion and to be dilated 10-20% larger than the diameter of the non-affected adjacent vein.

Once the outcome was satisfactory, the sheath was taken off, polypropylene 5\0 suture was used to close the puncture site, and the patients were discharged following a short monitoring period.

Post-procedure assessment and follow-up:

In the case of stenting, patients were given antiplatelet drugs (100mg/day). They received low molecular weight heparin (Clexane 40 mg/day) for one week postoperatively.

Follow-up was conducted at 1 week, 1 month, and 3 months. Each patient was assessed for complications such as hematoma, infection, bleeding, fistula flow, evaluation of UL edema, chest wall collaterals, and face edema. It also included vascular ultrasound assessment at 1 month and 3 months postoperatively.

Symptom evaluation was used to gauge clinical success. When a patient reported better symptoms, it was a sign that the surgery was clinically successful.

As seen by a venogram or duplex scan, primary patency was defined as uninterrupted patency in a patent central vein without recurrent stenosis or occlusion, without the need for additional central vein intervention, and no stenosis or stenosis of less than 30% in the central vein.

A luminal diameter improvement of less than 50% was considered a technical failure. An occlusion or 50% or more restenosis within 30 days following the initial procedure or the inability to bridge the lesion at the time of the primary procedure were considered early failures. When compared to nearby healthy veins, residual stenosis

was defined as more than 30% of the stenosis after intervention.

Ethical consideration:

The study was approved by the institutional Ethics Committee of Cairo University (Code: MS-574-2023). An informed written consent was obtained from each patient. The patients were allowed to not participate in the study if they did not want to. Any unexpected risks during the research were cleared to participants and the ethical committee on time. According to the Declaration of Helsinki, there were adequate provisions to maintain the privacy of participants and the confidentiality of the data. All patient's data were confidential. All data given were used for the current medical research only.

Statistical analysis: Statistical Package for the Social Sciences (SPSS) version 26 was used for statistical analysis (IBM Inc., Chicago, IL, USA). The data distribution's normality was assessed using the Shapiro-Wilks test. The paired T-test was used to compare quantitative parametric data, which were displayed as mean and standard deviation (SD). Chi^2 test or Fisher's exact test was used to compare the qualitative variables, which were displayed as frequency and percentage (%). The mean time to recurrence was displayed using the Kaplan-Meier curve. A two-tailed P-value < 0.05 was considered statistically significant.

RESULTS

This study was performed on 34 ESRD regular HD patients. Their mean age (± Standard deviation, SD) was 47.91 (±10.37) years. More than half of the study participants (19; 55.88%) were females. The most commonly associated comorbidities of the study cohort were hypertension (55.88%) and diabetes (41.18%) (**Table 1**).

Table (1): Demographic data and co-morbidities of the studied patients (N=34).

Age (years)	
Mean ± SD	47.9 ± 10.37
Range	32 – 65
Sex	
Male	15 (44.12%)
Female	19 (55.88%)
Co-morbidities	
Diabetes Mellitus	14 (41.18%)
Hypertension	19 (55.88%)
Coronary artery disease	4 (11.76%)
Smoking	7 (20.59%)

The type of AVF was native in 31 patients. About two-thirds (23) of the patients had left-sided AVF. The AVF was in the UL brachiocephalic in 22 patients, UL radiocephalic in 3 patients, and UL brachiobasilic in 9 patients. The duration of AVF was 21.7 ± 14.04 months, ranging from 2 to 66 months **(Table 2)**.

The lesion was stenotic in 26 patients and occlusion in 8 patients. The affected site was axillary in 5 patients, subclavian in 13 patients, and innominate vein in 16 patients. Length of lesions was ≤ 3 cm in 22 of patients **(Table 2)**.

Table (2): AVF and lesion characteristics of the studied patients.

		N (%) (n=34)
Type of AVF	**Native**	31 (91.18%)
	AV graft	3 (8.82%)
Side of AVF	**Right**	11 (32.35%)
	Left	23 (67.65%)
Site of AVF	**UL brachiocephalic**	22 (64.71%)
	UL radiocephalic	3 (8.82%)
	UL brachiobasilic	9 (26.47%)
Duration of AVF (Months)	**Mean ± SD**	21.7 ± 14.04
Type of lesion	**Stenosis**	26 (76.47%)
	Occlusion	8 (23.53%)
Site of lesion	**Axillary**	5 (14.71%)
	Subclavian	13 (38.24%)
	Innominate vein	16 (47.06%)
Length of lesions	**≤ 3 cm**	22 (64.71%)
	> 3 cm	12 (35.29%)

UL: Upper limb, AVF: arteriovenous fistula.

A previous ipsilateral central catheter was placed in 28 (82.35%) patients, in the subclavian vessels in 22/28 (78.57%) patients, and in the Jugular in 6 /28 (21.43%) patients.

In the analysis of presenting symptoms, arm and face swelling was reported in 29 patients. Additionally, dilated chest wall veins were noted in 14 patients. Prolonged bleeding after dialysis was documented in 7 patients **(Figure 1).**

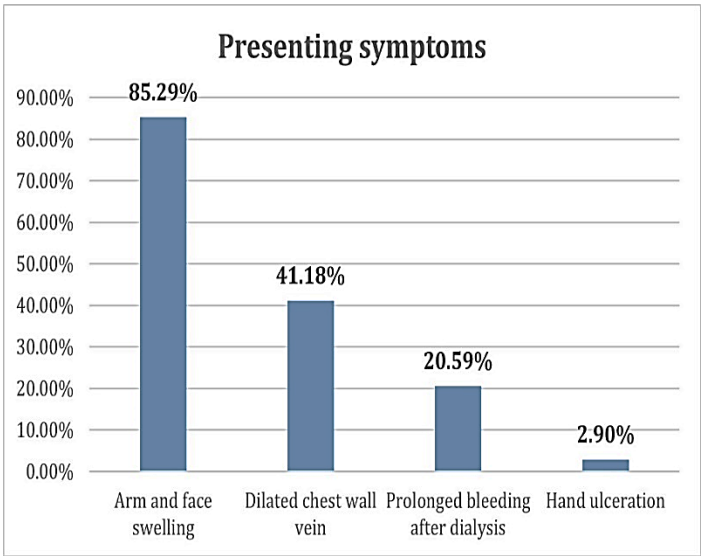

Figure (1): Presenting symptoms of the studied patients.

Regarding the patients' outcome, the initial success rate occurred in 29 patients. The patency rate was 73.5% at 1 month and 55.9% at 3 months (P-value =0.128). Two patients required a stent, representing. Recurrence occurred in 13 patients (6 re-occlusion and seven restenosis) **(Table 3).** Recurrence occurred after a mean time of 2.88±0.133 months (SE 0.067, and 95% CI 2.747 - 3.013) **(Figure 2)**.

Table (3): Outcome of the studied patients.

	N (%) (n=34)
Initial success rate	29 (85.29%)
Patency at 1 month	25 (73.5%)
Patency at 3 months	19 (55.9%)
Required stent	2 (5.88%)
Recurrence rate	13 (38.24%)

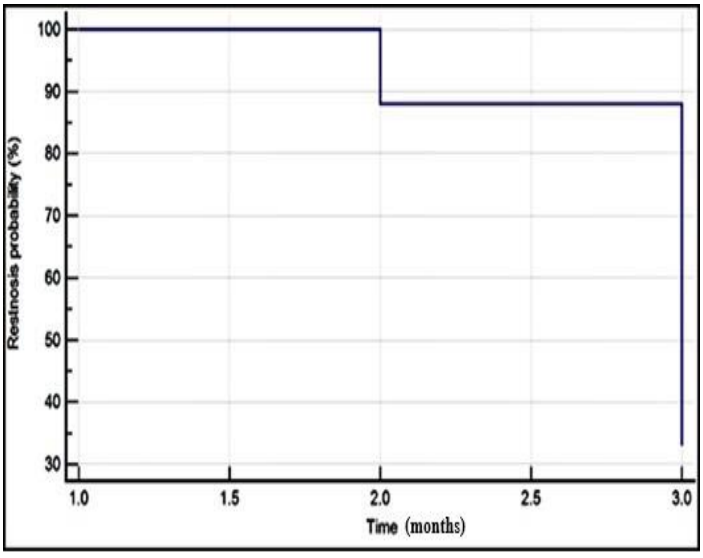

Figure (2): Kaplan-Meier recurrence analysis of the studied patients.

The patency rate after intervention was significantly greater in the cases presented with stenosis (73.07%) than in the cases presented with occlusion (25%). The patency rate was significantly greater in patients when the lesion was less than 3 cm **(Table 4).**

Table (4): The relationship between patency rate at one month, type of lesion, and length of lesions among studied patients.

		Patent (n=21)	Recurrence (n=13)	P value
Type of lesion, N (%)	**Stenosis (n=26)**	19 (73.07%)	7 (26.9%)	**0.033***
	Occlusion (n=8)	2 (25%)	6 (75%)	
Length of lesions, N (%)	**≤ 3 cm (n=22)**	17 (77.3%)	5 (22.7%)	**0.025***
	> 3 cm (n=12)	4 (33.3%)	8 (66.7%)	

*: Significant as P value<0.05.

DISCUSSION

Hemodialysis is essential for ESRD cases, but maintaining vascular access is still one of the most intriguing aspects of patient management [1]. Of the primary issues is CVSO, which leads to various complications [3]. Although several treatment options are available, choosing these methods remains controversial. Endovascular approaches such as PTA are commonly used due to their minimally invasive nature, but recurrence rates and long-term outcomes remain a concern [4,5].

This prospective study aimed to estimate the effectiveness of PTA using standard balloon dilatation techniques in 34 hemodialysis patients with central venous stenosis or occlusion, specifically its immediate and early-term outcomes at 1 week, 1 month, and 3 months

The present study found that the mean age of patients undergoing PTA was 47.9 years, with a slight female predominance (55.88%). This demographic distribution aligns with the general hemodialysis population, where middle-aged to older adults are most commonly affected by vascular complications. Furthermore, previous studies have reported similar trends in gender distribution, though slight variations in male-to-female ratios exist across different populations. The predominance of females in our study could be linked to the longer life expectancy of women, leading to a higher prevalence of age-related complications in vascular access [5].

The present study found that hypertension (55.88%) and diabetes mellitus (41.18%) were the most common comorbidities among the study population. The prevalence of coronary artery disease (11.76%) and smoking (20.59%) in our cohort also highlights the role

of cardiovascular risk factors in exacerbating vascular access issues. These findings are consistent with the well-established association between these comorbidities and vascular complications in HD patients [10].

The current study demonstrated that the majority of patients undergoing PTA for CVSO had native arteriovenous fistulas (91.18%), with the brachiocephalic fistula being the most common type (64.71%). This aligns with current clinical guidelines that emphasize the preference for native AVFs over synthetic grafts owing to their superior long-term patency rates and lower risk of infection [11].

In the current study, stenosis was the most frequent lesion type (76.47%), with the innominate vein accounting for 44.12% of cases and the subclavian vein accounting for 32.35% of cases. In concordance, a previous study reported frequent involvement of the subclavian vein in CVSO, with severe obstructions frequently occurring at this location [12].

CVSO often results from prolonged catheter use, leading to significant complications. In 2023, **Echefu and his group** noted that innominate vein stenosis poses a technical challenge and requires early intervention to prevent access loss [13]. Established guidelines suggest that early detection and aggressive management with angioplasty can improve outcomes, although restenosis remains a concern [14].

The present study showed an initial patency rate of 73.5% at one month in all patients (with short and long lesions) after PTA. These results are less than the typical outcomes reported in the literature, where PTA has been demonstrated to offer a great short-term success rate, reaching 85%, in restoring blood flow through stenosed vessels, especially in patients with short or less complex lesions [15]. However, the patency rate declined to 55.9% at 3 months, consistent with the well-documented issue of restenosis over time. While PTA offers excellent short-term results, restenosis frequently occurs within six to twelve months, particularly in patients with more severe CVOS, necessitating repeated procedures or additional interventions such as stenting [16].

As expected, shorter lesions are generally easier to manage with PTA, resulting in higher patency rates [17]. Currently, this study demonstrated that the majority of patients presented with lesions of 3 cm or less (64.71%), while a smaller group (35.29%) had longer lesions. Those presented with short lesions (≤3cm) resulted in a patency rate of 77.3% at 1 month after PTA. This was similar to previous literature, which showed that when treated promptly, shorter lesions led to a better patency rate with fewer complications, and lesions under 3 cm had higher success rates without the need for adjunct procedures like stenting [18].

On the other hand, patients with lesions longer than 3 cm (35.29%) in the present study had a patency rate of 33.33%. The variation in lesion length observed in the present study underlines the importance of individualized treatment plans. While shorter lesions are typically easier to treat with single PTA interventions, longer lesions demand more complex management strategies, including repeated PTA or stenting. A study in 2020 demonstrated that stent placement, especially in longer lesions, resulted in a high patency rate [19]. These rates are higher than those in the present study, as stent placement was limited to 2 patients (5.88%).

The current study's findings demonstrated that primary patency at 1 month was 73.5% and 55.9% at 3 months. A restenosis rate of 38.24%, with a mean restenosis time of 2.88 months post-PTA, was observed. The long-term patency rate after PTA declines steadily, and secondary interventions like stent placement are often required to maintain vascular access [20]. In the present study, secondary interventions were not included.

As previously noted, research indicates that the restenosis rate is significantly influenced by factors such as lesion length and location. In 2015, **Rajan and his team** [21] observed comparable recurrence rates in patients with more complex lesions, highlighting the necessity for repeat interventions or alternative treatment approaches, such as stent placement and the usage of covered stents, which significantly reduces recurrence rates compared to PSA alone as well as providing a more durable solution for maintaining vascular access in patients with recurrent stenosis [15,19,22,23]. This finding aligns with the current study and emphasizes the importance of ongoing follow-up and repeat interventions [20]. Finally, previous research reported that hemodialysis patients with CVSO often experience complications due to the compromised blood flow in their veins. These complications can include insufficient dialysis, access dysfunction, and increased risk for thrombosis, which highlights the importance of proper management of CVSO to ensure long-term patency and utilization of AVFs [24,25].

LIMITATIONS

The study had a relatively small sample size at a single center, combined with a limited follow-up time, making it difficult to assess the durability of PTA interventions.

CONCLUSION

This study highlighted the efficacy of PTA in restoring vascular access for hemodialysis patients with CVSO. While PTA showed an acceptable initial patency rate, it declined over time, indicating the need for monitoring and possible reintervention. Stenting is essential in cases of probable restenosis. Comorbidities, including hypertension and diabetes, were linked to poorer outcomes, emphasizing the need for tailored management. Additionally, shorter lesions showed better success rates with PTA alone.

RECOMMENDATIONS

While this study focused on short-term success rates, long-term outcomes, including quality of life and psychological impacts of frequent interventions, are crucial for assessing PTA effectiveness. Future research should incorporate advanced parameters like biomarkers and imaging techniques to predict stenosis recurrence and include patient-reported outcomes to understand treatment success comprehensively. Given the decline in patency rates, future strategies might explore drug-coated balloons or stents to prolong the intervals between interventions.

Conflict of interest: Authors declare no conflict of interest is present.

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