

## Original Research Article

# Efficacy of balloon angioplasty and stent placement in the treatment of central venous stenosis in patients with chronic kidney disease on hemodialysis

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## ABSTRACT

**Background:** Central venous stenosis is a common complication in hemodialysis patients, often caused by multiple long-term catheter use. This retrospective observational study evaluated the efficacy of balloon angioplasty and stent placement in treating central venous stenosis secondary to hemodialysis catheter use.

**Methods:** A retrospective observational study was conducted at the Hospital General de México Dr. Eduardo Liceaga, analyzing clinical records of 16 chronic kidney disease patients diagnosed with central venous stenosis who underwent endovascular surgery between January 2022 and August 2024. The study evaluated demographic characteristics, comorbidities, stenosis location, and technical success. Statistical analysis included descriptive measures, Shapiro-Wilk test for normality, and paired Student's t-test ( $\alpha=0.05$ ) to compare pre- and post-angioplasty venous diameters.

**Results:** The mean age of patients was  $44.6\pm 13.5$  years, with a slight female predominance. The most common stenosis location was the right subclavian vein (31.2%), followed by the left brachiocephalic trunk (25%). Pre-procedure stenotic vessel diameter averaged  $3.86\pm 1.5$  mm, increasing to  $9.19\pm 2.03$  mm post-procedure. Statistical analysis showed a significant 138% increase in vessel diameter ( $p<0.001$ ). Of the 16 procedures, 11 patients underwent successful angioplasty, with 37.5% requiring stent placement due to recoil greater than 30%. In 5 cases, crossing the occlusive lesion was not possible.

**Conclusions:** The study demonstrated the effectiveness of balloon angioplasty and stent placement in treating central venous stenosis, with a statistically significant improvement in vascular diameter. However, further studies with long-term follow-up are needed to evaluate the durability of these results and optimize management of complex cases.

**Keywords:** Central venous stenosis, Hemodialysis, Angioplasty, Endovascular stent, Vascular access, Chronic kidney disease

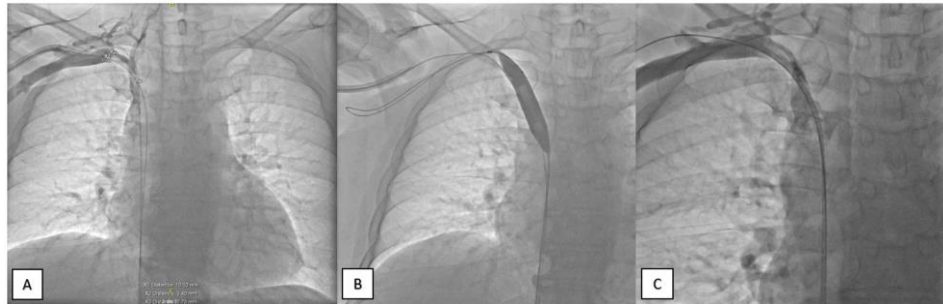
## INTRODUCTION

Central venous stenosis (Figure 1) is a common complication in patients receiving hemodialysis through an arteriovenous access, where the main causes are a history of multiple long-term catheters, especially in the subclavian and internal jugular veins.<sup>1</sup>

Symptoms of central venous stenosis arise from venous hypertension due to occlusion and may include ipsilateral arm edema (Figure 2), pain, facial edema, voice changes, severe venous dilatation, and development of collateral veins. The diagnosis is based on clinical history and physical examination, and is confirmed through imaging techniques, with conventional venography being the gold

standard.<sup>2</sup> Nearly 80% of patients in the United States initiate dialysis with a catheter, increasing the risk of central venous stenosis. In 2013, the prevalence was

estimated to be between 19-41%.<sup>1</sup> More recently, Echefu et al reported in their 2023 study a prevalence ranging from 4.3% to 41%, depending on the population studied.<sup>2</sup>



**Figure 1: Patient with central venous stenosis. (A) The lesion in the right subclavian vein is successfully crossed; (B) angioplasty is performed; (C) control phlebography shows adequate contrast medium flow towards the superior vena cava.**



**Figure 2: Central venous stenosis in a patient with chronic kidney disease and a history of subclavian vein catheterization.**

The pathophysiology of central venous stenosis involves three main mechanisms: venous wall thickening, endoluminal obstruction, and extrinsic compression.<sup>2</sup> Venous wall thickening is the most common mechanism and is caused by injuries from venous catheters or intravascular devices. This process begins with endothelial damage at the catheter insertion site, which is perpetuated by the presence of the non-biocompatible foreign body, this is followed by microlesions caused by the movement of the device.<sup>1</sup> This triggers an inflammatory response and the activation of the coagulation cascade, leading to platelet activation and aggregation. Over time, smooth muscle infiltration and formation of vascularized connective tissue occur. Endoluminal obstruction is due to the formation of thrombi associated with catheters. These thrombi can form inside the vessel or extraluminally, caused by endothelial injury, flow turbulence, and activation of coagulation. Extrinsic compression can be caused by tumors, surgical scars, musculoskeletal or vascular compression, and is common in the subclavian vein as it

crosses between the clavicle and the first rib. Additionally, factors contributing to central venous stenosis include high blood flow rates in hemodialysis access sites, which promote endothelial injury, and turbulent flow, which incites an inflammatory response and intimal hyperplasia. The continuous presence of the catheter as a foreign body perpetuates inflammation; these changes in the venous wall can occur within hours or days after catheter insertion and are usually progressive.<sup>2</sup> Angiography is the definitive method for diagnosing central venous stenosis. In some cases, duplex ultrasound can be used, but it is suboptimal for evaluating central veins. The main therapeutic approach is endovascular intervention, including angioplasty and stent placement. Angioplasty is estimated to have technical success rates of 70-90%, but long-term patency is variable. Stents are used for recurrent lesions, with variable results in patency. Avoiding catheter use is crucial for preventing central venous stenosis. Early referral for timely creation of arteriovenous fistulas is recommended.<sup>1</sup> The treatment of central venous stenosis

in hemodialysis patients remains a significant challenge in clinical practice. A recent meta-analysis comparing the efficacy of two endovascular interventions - angioplasty and stent placement - suggests that angioplasty may provide greater assisted primary patency compared to stent placement for the endovascular treatment of central venous stenosis or occlusion in patients undergoing hemodialysis.<sup>3</sup> This finding has potentially significant implications for the management of central venous stenosis, a frequent complication that can compromise the viability of vascular access and the efficacy of hemodialysis.<sup>4</sup>

## METHODS

A retrospective observational study was conducted through a review of clinical records from January 2022 to August 1, 2024, at the Angiology, Vascular and Endovascular Surgery Service of the Hospital General de México Dr. Eduardo Liceaga. The study included 16 patients with chronic kidney disease diagnosed with central venous stenosis who underwent endovascular surgery with phlebography plus angioplasty, and in some cases, endovascular stent placement. Patients with IMSS or ISSSTE medical insurance and those presenting for their second or third treatment were excluded. The variables studied included demographic characteristics such as age, sex, comorbidities, stenosis location, and technical success. A descriptive analysis of the variables was performed using measures of central tendency and dispersion for quantitative variables, and frequencies and percentages for qualitative variables. The Shapiro-Wilk statistical test was used to verify the normality assumption between pre- and post-angioplasty venous diameters. A paired Student's t-test was performed with a significance level ( $\alpha$ ) of 0.05. Patient data confidentiality was maintained throughout the study.

### Hypothesis

If balloon angioplasty and/or stent placement is effective in treating central venous stenosis secondary to the use of

hemodialysis catheters, then there will be a statistically significant difference between the pre- and post-intervention stenotic vascular diameter.

### General objective

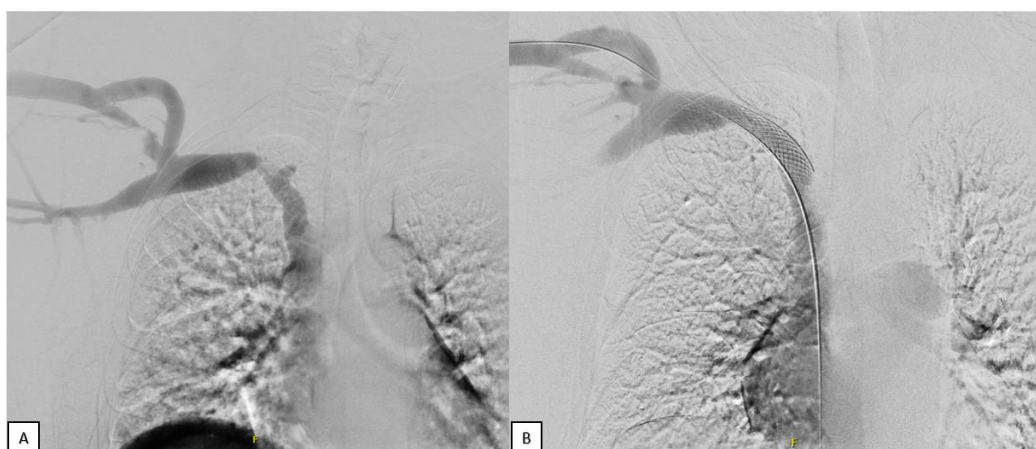
The objective was to evaluate the efficacy of balloon angioplasty and/or stent placement in the treatment of central venous stenosis secondary to hemodialysis catheter use, through statistical comparison of pre- and post-intervention vascular diameter.

### Secondary objectives

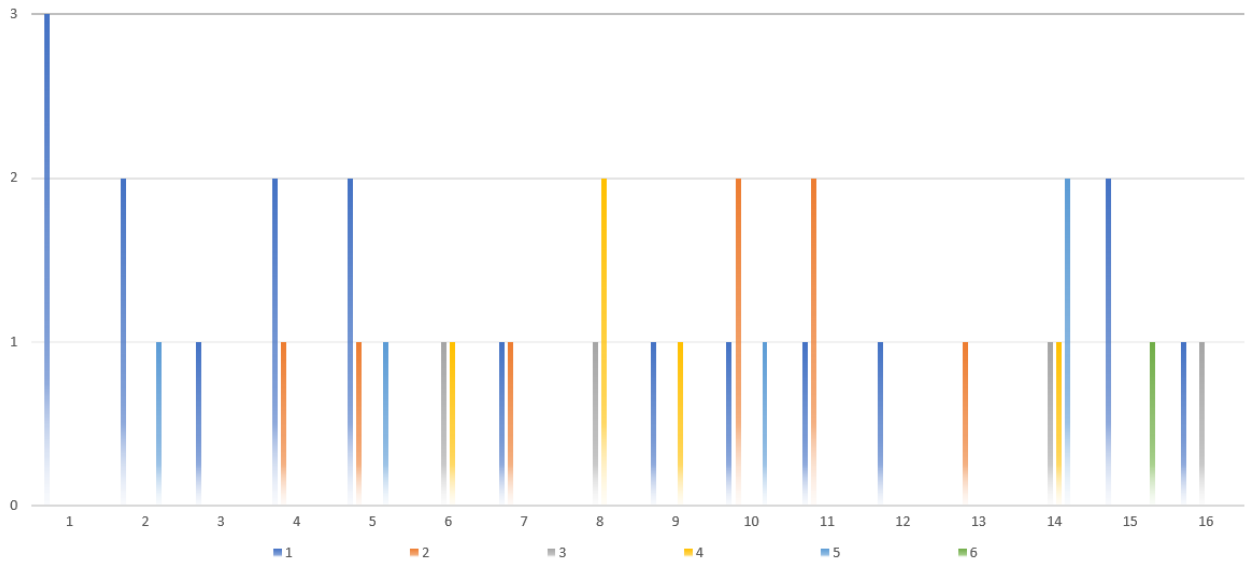
Secondary objectives were to determine if there is a statistically significant difference between the diameter of the stenosed central vessel compared to the diameter of the same vessel after treatment with angioplasty and/or stent placement; determine the demographic and clinical characteristics of patients with central venous stenosis secondary to the use of hemodialysis catheters; Identify the most frequent location of central venous stenosis in the studied population; quantify the distribution of technical success, defined as residual stenosis no greater than 30%, and quantify those patients in whom it was not possible to cross the stenotic lesion; determine the percentage of cases in which it was not possible to cross the stenotic lesion during the endovascular procedure, and analyze the anatomical and clinical characteristics associated with these failed cases.

## RESULTS

Between January 2022 and August 1, 2024, a total of 16 angioplasty procedures were performed, of which 6 included venous stent placement due to central vessel stenosis (Figure 3). The study population had a mean age of  $44.6 \pm 13.5$  years (range: 32-72 years), with a gender distribution of 9 female and 7 male patients. Regarding comorbidities, 3 patients had a history of type 2 diabetes mellitus and 11 of hypertension.



**Figure 3: Endovascular intervention for central venous stenosis. (A) Diagnostic phlebography revealing significant stenosis of the right subclavian vein; (B) post-intervention control phlebography, demonstrating restoration of venous lumen following balloon angioplasty and stent implantation.**



**Figure 4: Distribution of catheter placements by anatomical location: right internal jugular vein (18), left internal jugular vein (8), right subclavian vein (4), left subclavian vein (5), right femoral vein (5), and left femoral vein (1).** The data demonstrates a marked prevalence of the right internal jugular vein as the preferred site for vascular access, accounting for 43.9% of all catheter insertions in this cohort.

**Table 1: Comparison of vascular diameters pre- and post-angioplasty.**

		Statistic	Std. Error	
<b>Diameter pre</b>	Mean	3.864	0.4525	
	95% Confidence Interval for Mean	Lower bound	2.855	
		Upper bound	4.872	
	5% trimmed mean	3.804		
	Median	3.900		
	Variance	2.253		
	Std. Deviation	1.5008		
	Minimum	2.1		
	Maximum	6.7		
	Range	4.6		
	Interquartile range	2.4		
	Skewness	0.599	0.661	
	Kurtosis	-0.259	1.279	
<b>Diameter post</b>	Mean	9.191	0.6125	
	95% Confidence Interval for Mean	Lower bound	7.826	
		Upper bound	10.556	
	5% trimmed mean	9.190		
	Median	9.000		
	Variance	4.127		
	Std. Deviation	2.0315		
	Minimum	6.4		
	Maximum	12.0		
	Range	5.6		
	Interquartile range	4.1		
	Skewness	0.220	0.661	
	Kurtosis	-1.481	1.279	

Pre- and post-angioplasty vascular diameters in patients with central venous stenosis (n=11). A significant increase in mean post-intervention diameter (9.191 mm) is observed compared to pre-intervention (3.864 mm). The higher standard deviation in post-treatment measurements (2.0315 mm vs 1.5008 mm) suggests a wider variability in response to the procedure. The standard error of the mean also increased post-treatment, indicating greater uncertainty in the estimation of the population mean. These data demonstrate the efficacy of angioplasty in increasing vascular diameter, while revealing the variability in individual response to treatment.

**Table 2: Evaluation of normality of vascular diameters pre- and post-angioplasty.**

	Kolmogorov-Smirnov <sup>a</sup>			Shapiro-Wilk		
	Statistic	df	Sig.	Statistic	df	Sig.
<b>Diam.pre</b>	0.139	11	0.200*	0.933	11	0.443
<b>Diam.post</b>	0.174	11	0.200*	0.910	11	0.247

\*This is a lower bound of the true significance; a. Lilliefors Significance Correction. Kolmogorov-Smirnov and Shapiro-Wilk tests were performed to evaluate the normality of the distribution of vascular diameters pre- and post-angioplasty (n=11). Given the small sample size, the interpretation of the Shapiro-Wilk test was prioritized. For pre-angioplasty diameters, the Shapiro-Wilk statistic was 0.933 (p=0.443), while for post-angioplasty diameters it was 0.910 (p=0.247). In both cases, p>0.05 suggest that there is insufficient evidence to reject the null hypothesis of normality. These results support the use of parametric tests, such as the paired t-test, for subsequent data analysis.

**Table 3: Comparative analysis of vascular diameters pre- and post-angioplasty using paired t-test.**

Paired Samples Test		Paired Differences					t	df	Significance	
		Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference				One-sided P value	Two-sided p value
					Lower	Upper				
<b>Pair 1</b>	Diameter pre - Diameter post	-5.3273	1.7188	0.5182	-6.4820	-4.1726	-10.280	10	<0.001	<0.001

Results of the paired t-test comparing vascular diameters pre- and post-angioplasty. A mean difference of -5.3273 mm (95% CI: -6.4820 to -4.1726) is observed, indicating a significant increase in vascular diameter post-intervention. The t-value of -10.280 with 10 degrees of freedom resulted in a p<0.001, for both one-tailed and two-tailed tests. This suggests a statistically significant improvement in vascular diameter following angioplasty. The standard deviation of the differences (1.7188 mm) reflects the variability in individual response to treatment.

The distribution of hemodialysis catheter history in the studied sample was as follows: right internal jugular vein: 18 catheters; left internal jugular vein: 8 catheters; right subclavian vein: 4 catheters; left subclavian vein: 5 catheters; right femoral vein: 5 catheters; left femoral vein: 1 catheter (Figure 4).

The anatomical distribution of stenosis zones was observed as follows: right subclavian vein (31.2%), right brachiocephalic trunk (18.7%), left subclavian (18.7%), left brachiocephalic trunk (25%), and superior vena cava (6.2%).

The average diameter of the stenotic vessel prior to the procedure was 3.86±1.5 mm, while the diameter after the procedure reached 9.19±2.03 mm (Table 1). In 5 patients, it was not possible to cross the occlusive lesion (2 in the right subclavian vein, 2 in the right brachiocephalic trunk, and 1 in the left brachiocephalic trunk). Of the 11 patients who underwent angioplasty, 37.5% required stent placement due to recoil greater than 30%.

For statistical analysis, IBM SPSS Statistics V29.0.2.0 software was used. Given the small sample size, the Shapiro-Wilk test (Table 2) was used to verify the assumption of normality. The following hypotheses were proposed:

H<sub>0</sub>: The data come from a normal distribution

H<sub>1</sub>: The data do not follow a normal distribution

The results of the Shapiro-Wilk test for the pre- and post-treatment values were p=0.443 and p=0.247, respectively. These values, being higher than the established significance level (α=0.05), do not allow for the rejection of the null hypothesis, suggesting that the data fit a normal distribution. Subsequently, a paired t-test (Table 3) was performed with a 5% significance level to compare the values before and after angioplasty. The results revealed an average increase of 138% in vessel diameter (p<0.001), which indicates a statistically significant difference between the pre- and post-intervention values.

**DISCUSSION**

The use of tunneled hemodialysis catheters, the duration of central venous catheter dependence, the number of catheter placements, the presence of cardiac devices, and younger age at the initiation of dialysis are factors associated with central venous stenosis.<sup>2</sup> New coated stents and drug-eluting stents are being investigated to improve outcomes in the treatment of central venous stenosis.

Kitrou et al conducted a study comparing paclitaxel-coated balloons with conventional balloon angioplasty for the management of symptomatic central venous stenosis: 40 patients were included (20 in the paclitaxel group and 20 in the conventional angioplasty group). They observed that the median intervention-free period was significantly better in the paclitaxel balloon group (179 days vs. 124.5 days, p=0.026), subsequent investigations have reported similar results.<sup>5,6</sup>



Investigations have been conducted using PTFE and Dacron-coated stents, obtaining a primary patency of 32% at 360 days and a secondary patency of 29% at one year, respectively.<sup>7,8</sup> Jones et al conducted a long-term study on the effectiveness of covered stents in managing central venous stenosis refractory to angioplasty in hemodialysis patients with functioning arteriovenous fistulas. Their results indicated primary patency rates of 97%, 81%, 67%, and 45% at 3, 6, 12, and 24 months, respectively.<sup>9</sup>

Covered stents have shown promising results in the treatment of central venous stenosis in hemodialysis patients. Quaretti et al conducted a retrospective study comparing different endovascular treatments in 70 dialysis patients, where covered stents demonstrated superior primary patency rates compared to angioplasty alone and bare metal stents, reaching 100% at 3, 6, and 12 months, and 84% at 24 months.<sup>10</sup> The validation of these results through clinical trials could have significant implications for modifying guidelines and subsequent management of patients with central venous stenosis. Meanwhile, these findings provide a basis for informed clinical decision-making, suggesting that angioplasty could be a preferable option in certain clinical scenarios.<sup>11-16</sup>

### Limitations

The retrospective nature of the study is acknowledged, as well as the potential selection bias due to exclusion criteria related to the type of medical insurance and the lack of long-term follow-up.

### CONCLUSION

The present study demonstrated the efficacy of balloon angioplasty and/or stent placement in the treatment of central venous stenosis secondary to hemodialysis catheter use. A statistically significant difference was observed between pre- and post-intervention vascular diameter, with an average increase of 138% ( $p < 0.001$ ). The most frequent location of stenosis was the right subclavian vein (31.2%), followed by the left brachiocephalic trunk (25%). The studied population had a mean age of 44.6 years, with a female predominance and high prevalence of hypertension. These findings suggest that balloon angioplasty, complemented with stent placement when necessary, is an effective therapeutic option for managing central venous stenosis in hemodialysis patients. However, additional studies with long-term follow-up are needed to evaluate the durability of these results and optimize the management of complex cases where crossing the lesion is not possible.

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