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Association Of Clinical And Radiological Factors With The Outcomes Of Central Venoplasty Among End-Stage Renal Disease Patients In Hospital Universiti Sains Malaysia

Abstract—Central venous stenosis is a common complication in end-stage renal disease patients receiving hemodialysis therapy with central venous catheters, and central venoplasty is the mainstay treatment. However, not all patients undergoing central venoplasty have a successful outcome. This study aims to determine the association between radiological factors and clinical factors determining the success rate of central venoplasty. A retrospective cross-sectional study conducted in Advanced Minimally Invasive Endovascular and Neurointervention (AMIEN) Unit, Hospital Universiti Sains Malaysia (HUSM) on 62 patients with central venous stenosis or occlusion and treated with central venoplasty in Hospital HUSM from 1st January 2016 until 31st August 2020. Radiological variables (location, grade, and length of stenosis) and clinical variables (gender, diabetes mellitus (DM), and hypertension) are assessed before central venoplasty. The association between the radiological and clinical factors with the outcome of central venoplasty was assessed using Chi-Square Test. A total of 62 patients were included in our study. There was no significant association between the location of veins, degree, and length of stenosis with the successful outcome. However, a single vein had a significantly higher success rate (92.6%) than multiple veins (7.4%). Apart from the radiological factors, the clinical factors (gender, DM, and hypertension) also show no significant association in determining successful outcomes with *p* values 0.159, 0.644, and 0.283 respectively (more than 0.05).

There is no association of clinical and radiological factors with the outcomes of central venoplasty among end-stage renal disease patients. A further study needs to be conducted with a larger sample size and other possible determining factors to help facilitate the procedure in the future.

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1 INTRODUCTION

Central venous stenosis (CVS) is defined as 50% or more narrowing of the superior vena cava, brachiocephalic or subclavian veins (1). The pathophysiology of CVS is the development of venous intimal hyperplasia that can be due to multiple causes. The most common one is central venous catheterization. Other causes of CVS include central venous port catheters, pacemakers, and defibrillator wires (2). CVS will cause outflow obstruction of the arteriovenous fistula among hemodialysis patients, leading to venous hypertension. Untreated CVS will cause upper limb edema and compromise the function of the arteriovenous fistula. The incidence of CVS in hemodialysis patients is 29% (3).

Central venoplasty is balloon angioplasty of the

brachiocephalic, subclavian, or superior vena cava (1). Central venoplasty is the first-line management of CVS rather than surgical treatment, given less morbidity and mortality associated with venoplasty (4). However, despite recognizing venoplasty as the mainstay of therapy, one-fifth of the total cases still needs to undergo re-plasty, and some are finally subjected to surgical repair (5,6). Factors associated with successful angioplasty, such as location, length, and grade of stenosis, are still debatable. Some study concludes that diabetes mellitus (DM) and stenosis length affected the primary cumulative patency of percutaneous transluminal angioplasty (PTA) in arteriovenous fistula (7). Another study found no significant associations between central venous stenosis and sex, ethnicity, comorbidity, or

type of primary kidney disease (8). Other factors, such as types of balloons with the successful outcome of angioplasty, especially fistuloplasty, have been well established (6,7,9). However, location, length, and degree of stenosis resulting from central venoplasty have yet to be investigated in detail. Therefore, this study aims to find the association between radiological factors such as location, grading, and length of stenosis and clinical factors such as gender, DM, and hypertension with the outcome of central venoplasty.

2 MATERIALS AND METHODS

Procedures approved by the Human Research Ethics Committee of Universiti Sains Malaysia (JEPeM code: USM/JEPeM/21030252), which complies with the Declaration of Helsinki.

2.1 Subjects and patients

A cross-sectional study was conducted in Advanced Minimally Invasive Endovascular and Neurointervention (AMIEN) Unit, Hospital Universiti Sains Malaysia (HUSM), Malaysia, using the retrospective data on the patients who had central venous stenosis or occlusion and were treated with central venoplasty in HUSM from 1st January 2016 until 31st August 2020.

A total of 62 cases were selected. All patients are ESRF patients older than 18 who underwent central venoplasty. 8 patients with other causes of central venous stenosis, such as complications of central venous port-patient with central venous port device subjected to the prolonged chemotherapy drug and parenteral nutrition, mechanical trauma due to clavicle fracture, Pancoast tumor and lung malignancy as well as clotting factor deficiency were excluded.

2.2 Venoplasty procedure

Angiographic images were obtained using a bi-plane angiography unit (SIEMEN-AXIOM ARTIS Zee, Series No: 154004,2012), with the image acquired at multiple planes as required. Intravenous non-ionic low osmolar contrast media; Visipaque 370mg/ml was used for angiography. AEC controlled the range of kV and mAs at 58-73kV and 102-276mAs. Central venoplasty are performed at the AMIEN suite by 2 Intervention Radiologists with more than five years of experience. Procedures are performed under local anesthesia with sedation as needed. Access is usually obtained via the venous limb of AVF or the

femoral vein. After an ultrasound-guided puncture and 7/8Fr sheath insertion, a 0.035" Glidewire (Terumo, Tokyo, Japan) with 4/5Fr Impress @ Cobra support catheter (Merit Medical) was used to cross the stenosis. On crossing the lesion, wire is exchanged to Amplatz Super Stiff (Boston Scientific, Marlborough, MA, USA), and central venoplasty is performed with either 10mm/12mm Mustang (Boston Scientific, Marlborough, MA, USA), 10mm/12mm Conquest (Bard, Covington, GA, USA) or 14mm Atlas (Bard, Covington, GA, USA) balloons.

2.3 Clinical data collection

The medical history of all patients was obtained from the patient's medical records and confirmed with a physician who treated the patients. Hypertension is taken when the persistent elevation of systolic blood pressure (BP) of 140 mmHg or greater and/or diastolic BP of 90 mmHg or greater, while DM is a chronic hyperglycemic state in conjunction with other metabolic derangements.

2.4 Radiological Data collection

By using the Picture Archive and Communication System (PACS) and Universal Viewer Zero Footprint, Digital Subtraction Angiography (DSA) images of central venoplasty were reviewed. Radiological variables assessed are location, grade, and length of stenosis before and after central venoplasty. The location of stenosis was identified as axillary, subclavian, brachiocephalic, or superior vena cava (10). The degree of stenosis was calculated from the initial DSA image. Lesion stenosis was measured against the diameter of the adjacent normal vein segment or graft. When stenosis was juxta-anastomotic, the vein segment preceding the stenosis, or the size of the anastomosis was used. Stenosis is divided into mild (<50%), moderate (50-75%), and severe (>75%) (11).

The stenosis length was measured using PACS or Universal Viewer Zero Footprint calipers. Length over 5 cm was considered long segment stenosis, whereas less than 5cm was short segment stenosis (12). Pre- and post-venoplasty venous stenosis was measured with electronic calipers from stored PACS images. Technical success is achieved when the residual stenosis is less than 30% compared to the preprocedural measurements following the Society of

International Radiology (SIR guideline (1,13). Failure of treatment is defined as the presence of more than 30% residual stenosis compared to the initial stenosis or lesion that cannot be crossed or passed through (14). All measurements were confirmed by two Interventional Radiologists with more than five years of experience.

2.5 Statistical analysis

Categorical data were presented in frequency and percentage. Comparisons between the radiological (location, degree, and length of stenosis) and clinical variables (age, DM, and hypertension) with a successful outcome of central venoplasty were made using the Chi-Square test or Fisher’s exact test appropriate. The P value of less than 0.05 was considered statistically significant. Statistical analysis was performed using version 26 of the SPSS software (SPSS Inc, Chicago, IL).

3 RESULTS

Within the study period, central venoplasty procedures were performed in 62 patients, out of which 59.7% were male. The comorbidities present included hypertension (67.7%) and diabetes mellitus (53.2 (Table 1). On review of PACS, 56.5% of the location of central venous stenosis were brachiocephalic, 21.0% were subclavian, 8.1% were superior vena cava, and 3.2% were axillary veins. A total of 7 patients (11.3%) had multiple veins involvement. The most common degree of stenosis was severe and moderate (58.1% and 35.5%, respectively). Long-segment stenosis was found in 20 of 62 patients, whereas short-segment stenosis was found in 42. The technical success rate was 43.5% (27 of 62 procedures). Residual stenosis of more than 30% was observed in 35 of 62 procedures (56.5%). (Table 1).

3.1 The outcome of central venoplasty

Brachiocephalic vein central venoplasty had the highest technical success rate at 74.1%, while the subclavian vein had a success rate of 11.1%. The superior vena cava and axillary vein showed similar success rates of 3.7%. Patients with single-vein involvement had a success rate of 92.6% after venoplasty. Stenosis grading showed an inverse relationship with the success score. Severe stenosis had the highest result at 59.3%, moderate stenosis at 40.7%, and mild stenosis at 0%. The technical success of central venoplasty was better

Table I: Patient clinical and radiological factors (n=62).

Variable		n	(%)
Gender	Female	25	40.3
	Male	37	59.7
DM	Non-diabetic	29	46.8
	Diabetic	33	53.2
Hypertension	Non-hypertensive	20	32.3
	Hypertensive	42	67.7
Location of CVS	Axillary	2	3.2
	BCV	35	56.5
	Subclavian	13	21.0
	SVC	5	8.1
Vein involvement (Single or multiple)	Single	55	88.7
	Multiple	7	11.3
Degree of CVS	Mild	2	3.2
	Moderate	22	35.5
	Severe	38	61.3
Length of CVS	Short	42	67.7
	Long	20	32.3
Success Outcome	No	34	54.8
	Yes	28	45.2

Abbreviations: CVS, Central venous stenosis; BCV, Brachiocephalic vein; SVC, Superior vena cava.

in the short stenosis group of 70.4%. The results are shown in Table 2.

The technical success rate for central venous stenosis was 51.9% in male patients and 48.1% in female patients. Regarding patient comorbidities, hypertensive patients show higher success rates than non-hypertensive patients, 63% and 37%, respectively. Successful outcomes for diabetic and non-diabetic patients were 51.9% and 48.1%, with no statistically significant difference. The details of the result are shown in Table 3.

Based on the Chi-Square Test, none of the demographics or radiological variables was significantly related to the technical success of central venoplasty.

Table 2: Association between the location of the stenosis, the degree of the stenosis, and the length of the stenosis with the outcome of central venoplasty (n=62)

Variable		Unsuccessful outcome		Successful Outcome		p-value*
		N	(%)	N	(%)	
Location of CVS	Axillary	1	2.9%	1	3.6%	NA
	BCV	15	44.1%	20	71.4%	
	Subclavian	10	29.4%	3	10.7%	
	SVC	4	11.8%	1	3.6%	
<u>Combined Veins</u>						
Axillary & Subclavian		11	36.7%	4	16.0%	0.087
BCV & SCV		19	63.3%	21	84.0%	
Type of Vein	Single	30	88.2%	25	89.3%	1.00^
	Multiple	4	11.8%	3	10.7%	
Degree of CVS	Mild	2	5.9%	0	0.0%	NA
	Moderate	11	32.4%	11	39.3%	
	Severe	21	61.8%	17	60.7%	
Degree of CVS	Mild-Moderate	13	38.2%	11	39.3%	0.933
	Severe	21	61.8%	17	60.7%	
Length of CVS	Short	22	64.7%	20	71.4%	0.573
	Long	12	35.3%	8	28.6%	

*Chi Square Test ^Fisher Exact Test
 Abbreviations: CVS, Central venous stenosis; BCV, Brachiocephalic vein; SVC, Superior vena cava.

Summarisation of the result in Table 4.

4 DISCUSSION

In this study, the technical failure of central venoplasty was higher at 56.5 % compared to the previous studies, which were 11% (1) and 18% (15). This was expected, as most patients referred to this center had chronic occlusion. These patients present with total occlusion and multiple prior catheterizations of the functioning arteriovenous fistula. Most other studies enrolled patients with a mean age of hemodialysis access of one to two years compared to our patients (8,16,17). We also found that fewer female ESRD patients underwent central venoplasty than men. This could be because females were less physically active or from a lower socioeconomic status. They also had higher BMI and waist circumference, higher FGF23 and serum phosphorus, and more elevated LDL cholesterol and lower HDL cholesterol. Females were also less likely to take cardioprotective medications. In contrast, proteinuria was lower, and the propensity to use tobacco was lower (18).

The successful outcome of central venoplasty was seen higher in hypertensive patients. However, in the Diabetes Mellitus and non-diabetes Mellitus groups, the result was almost similar even though some studies mentioned that metabolic alteration associated with diabetes could lead to a prothrombotic environment, endothelial dysfunction, and growth factor dysregulation, all of which predispose to stenosis. It is unclear whether this description applies to arterial and venous systems (19). We expected

Table 3: Association between clinical factors (gender, hypertension, and diabetes mellitus with the outcome of central venoplasty (n=62)

Variable		Unsuccessful outcome		Successful Outcome		p-value*
		N	(%)	N	(%)	
Gender	Female	11	32.4%	14	50.0%	0.159
	Male	23	67.6%	14	50.0%	
DM	Non-diabetic	15	44.1%	14	50.0%	0.644
	Diabetic	19	54.3%	14	50.0%	
Hypertension	Non-hypertensive	9	26.5%	11	39.3%	0.283
	Hypertensive	25	73.5%	17	60.7%	

*Chi-Square Test
 Abbreviations: DM, Diabetes Mellitus

Table 4: Associations between various variables and the success outcome, along with statistical significance and success rates

Variable	Association with Success Outcome	p-value	Success Rate (%)
Location of Veins	No significant association	0.455	
	Single vein vs. multiple veins		
	- Single vein: 92.6%		92.6
	- Multiple veins: 7.4%		7.4
BCV & SVC vs. Axillary & Subclavian		0.087	
	- BCV & SVC: 84.0%		84.0
	- Axillary & Subclavian: 10.7%		10.7
Degree of Stenosis	No significant association	0.867	
	Severe vs. Mild to Moderate		
	- Severe stenosis: 59.3%		59.3
	- Mild to moderate stenosis: 40.7%		40.7
Length of Stenosis	No significant association	0.697	
	Short vs. Long		
	- Short stenosis: 70.4%		70.4
	- Long stenosis: 29.6%		29.6
Gender	No significant association	0.270	
	Males vs. Females		
	- Males: 51.9%		51.9
	- Females: 48.1%		48.1
Diabetes Mellitus (DM)	No significant association	0.849	
	Diabetic vs. Non-diabetic		
	- Diabetic patients: 51.9%		51.9
	- Non-diabetic patients: 48.1%		48.1
Hypertension	No significant association	0.480	
	Hypertensive vs. Non-hypertensive		
	- Hypertensive patients: 63.0%		63.0
	- Non-hypertensive patients: 37.0%		37.0

Abbreviations: BCV, Brachiocephalic vein; SVC, Superior vena cava.

the lesions in patients with diabetes mellitus should be more stubborn and less amenable to treatment. However, our study found no association between this disease and technical success. Other confounding factors such as dyslipidemia were not included in this study as they have been studied in previous research.

Initially, we hypothesized that men had the more successful outcome of central venoplasty; however, based on this study, the percentage of success of central venoplasty among men and women was similar even though the numbers of male ESRD patients who underwent central venoplasty were higher. The higher number of male patients could have led to the apparent feeling of higher success among the males.

Our study saw a higher technical success rate for the brachiocephalic vein than other central veins, especially axillary veins and superior vena cava. The axillary vein and superior vena cava had the lowest success rate. The elastic recoil in the brachiocephalic vein was thought to be less than in the other central veins leading to better

maintenance of vessel diameter post-plasty and, therefore, a higher success rate. The brachiocephalic vein was also the most common vein stenosed in ESRD (1,17,20). This was also attributed mainly to vein trauma resulting from central venous catheterization for temporary access through the internal jugular and brachiocephalic veins. The thickening of the venous wall and the formation of platelet deposits brought on by the catheter's repeated friction with the venous wall and blood turbulence result in a loss of vascular tone in the veins (21). In addition, the brachiocephalic vein's longer, narrower, and more angular course appeared to offer more room for endothelial pathology (8).

Patients with single vein involvement also had more successful venoplasty than multiple locations. This could be due to multiple location occlusion resulting from chronic disease with more pronounced intimal hyperplasia than single vein occlusion. We hypothesize that single-vein involvement is more indicative of acute presentation than multiple-vein involvement.

However, this feature was not tested in this study but could be a precursor for future research.

Previous studies found that the degree of stenosis is linearly correlated to angioplasty success rate (7). However, we found that moderate and severe degrees of stenosis had a better percentage of a successful outcome post-central venoplasty. This was not in line with the theory of histopathological changes in central venous specimens with moderate or severe occlusion, which showed intimal hyperplasia, thrombus organization, endothelial cells, and increased collagen, possibly leading to the development of fibrin and the presence of fibrotic tissue. These changes are also commonly seen in patients with symptomatic stenosis (21). We postulated that such a finding could be due to the method of assessing the technical success used in this study. We compared pre- and post-plasty images and took the presence of residual stenosis of less than 30% compared to pre-plasty images as the marker of success. The percentage of recoil stenosis post-plasty will affect the minor stenosis more than the moderate and severe group due to the differences in diameter in pre-plasty images. The value is smaller in the minor group to start with.

Most of the short-segment stenosis in our study appeared to be a better outcome of central venoplasty than long-segment stenosis. This was because, in our center, we use a single direction and technique approach. The shorter segment should also represent an acute process compared to the longer stenosis due to the time to develop such a lengthy occlusion. It has shown that less than 6.5 cm is the critical length of the occluded segment for a unidirectional approach to be successful (4,22).

Despite some variables showing higher success rates, there was no significant correlation between radiological characteristics (location, grade, and length of stenosis) and clinical variables (age, gender, diabetes mellitus, and hypertension) and the outcome of central venoplasty in ESRD patients utilizing the angioplasty technique in this study. This could be because most patients have a chronic occlusion with the multifactorial cause of stenosed vessels. The longer the patient waits before getting the treatment, the individual characteristics of the occluders might affect other factors interchangeably, leading to no significant single confounding factor for stenosis.

The fact that this study was a retrospective

analysis at a single site was a drawback. A prospective design using a multicenter strategy, including a larger sample size, should be carried out to validate our findings.

5 CONCLUSION

There is no association of clinical and radiological factors with the outcomes of central venoplasty among end-stage renal disease patients. No statistically significant between radiological variables (location, grade, and length of stenosis) and clinical variables (gender, diabetes mellitus, and hypertension) are assessed before and after central venoplasty with the outcome of the central venoplasty.

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