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AVF4

Outcomes of Inferior Vena Cava Filter Placement in Patients With Perceived Contraindications to Anticoagulation

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Objective: Patients with prolonged periods of immobilization including those who have undergone recent surgery, spinal trauma, and stroke are at particularly high risk for the development of deep venous thrombosis (DVT) and subsequently pulmonary embolism (PE). Current PE prevention strategies include prophylactic anticoagulation and inferior vena cava (IVC) filter placement. Those patients at highest risk for DVT-induced PE frequently have contraindications to chemical prophylaxis and therefore meet an accepted indication for IVC filter placement. The aim of this study was to evaluate incidence of PE in patients with DVT who were treated with anticoagulation alone vs those treated with IVC filter placement or delayed anticoagulation after resolution of perceived contraindication to anticoagulation.

Methods: A matched case-control study was completed including hospitalized patients who were diagnosed with venous thromboembolism either before or during their hospital stay who also were found to have high risk for PE (Geneva score > 8). The study group included 33 patients who received IVC filters with a control group of 165 patients who did not receive IVC filters. Participants were matched by age, sex, body mass index, revised Geneva score, and D-dimer level at presentation. Patients were observed during hospitalization and for 90 days after discharge from the hospital. PE diagnosis was defined as a symptomatic episode that was confirmed with imaging study.

Results: The initial DVT was diagnosed before hospitalization in 15% of the study group ($n = 5$) and in 16% of the control group ($n = 27$; $P = .6$). Active cancer was present in 6% of the study group ($n = 2$) and in 13% of the control group ($n = 22$; $P = .2$). Despite initially perceived contraindications, 80% of the study group IVC filter patients ($n = 27$) were started on anticoagulation within 3 days of IVC filter placement. The remaining 20% of the study group IVC filter patients ($n = 6$) did not receive anticoagulation during their hospital stay because of noted recent active bleeding ($n = 4$) and heparin-induced thrombocytopenia ($n = 2$). The incidence of PE during hospital stay and within 90 days after discharge was 33% in the IVC filter group ($n = 11$) and 25% in the control group ($n = 41$; $P = .2$).

Conclusions: The 90-day incidence of symptomatic PE was not different between patients with and without an IVC filter. The majority of patients with initially stated contraindication to anticoagulation received anticoagulation within 3 days from IVC filter placement.

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AVF5

Prosthetic Valve for Post-phlebitic Syndrome

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Objective: There are 2.4 million people are affected with chronic venous insufficiency in the United States. Nearly 1 million people a year are treated for venous stasis ulcers determined by the Medicare database. There are few options for those patients who develop post-thrombotic disease secondary to deep venous reflux. These options include compression, elevation, and wound care.

Methods: A new venous prosthetic valve, the VenoValve (Hancock Jaffe Laboratories, Irvine, Calif), has been developed to be surgically implanted into the deep venous system of patients with C5 to C6 disease. This device is a combination of a stainless steel frame and porcine aortic monocusp leaflet. In Bogotá, Colombia, 15 patients have undergone implantation of this device into the femoral vein in a first-in-human study in patients with C5- C6 disease. All operations were performed in an ambulatory surgery center.

Results: Results of 9-month data demonstrate a dramatic decrease in reflux time in five of six patients who have reached 9 months of follow-up. There was 68% improvement in reflux time compared with preoperative values. Significant improvement in Venous Clinical Severity Scores, visual analog scale scores, and Venous Insufficiency Epidemiological and Economic Study on Quality of Life/Symptoms scores was also noted. The remaining patients with a mean follow-up of 6 months continue to demonstrate similar improvements. All patients were maintained on long-term anticoagulation. Two patients who had venous stasis ulcers for >2.5 years demonstrated near healing within 90 days of implantation. Surgical implantation technique has also been perfected during the course of this study.

Conclusions: Results of a first-in-human study using a venous prosthetic valve appear promising with improvement in clinical outcomes as well as quality of life evaluation and marked reduction in pain in these complex and difficult to treat patients.

Author Disclosure: J. Ulloa: Hancock Jaffe Laboratories; **M. Glickman**: Hancock Jaffe Laboratories.

AVF6

Contralateral Limb Improvement in Patients Undergoing Iliofemoral Venous Stenting

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Objective: Symptoms of chronic venous insufficiency secondary to obstructive iliofemoral disease are often bilateral. The impact of iliofemoral stenting of the more symptomatic lower extremity on clinical outcomes in the less affected contralateral extremity is not clear. Such benefit, secondary to offloading of collaterals, may potentially be of the magnitude that the contralateral extremity does not require intervention.

Methods: A retrospective review of contemporaneously entered electronic medical record data of 369 patients/limbs with initial unilateral iliocaval stents (241 left, 128 right) placed during a 3-year period from 2015 to 2017 was performed. Patients who underwent simultaneously bilateral stenting or had occlusive disease were excluded. Of the remainder, the impact of stenting on contralateral leg symptoms was evaluated by analyzing visual analog scale (VAS) pain score (1-10), grade of swelling (1-3), and Venous Clinical Severity Score (VCSS). The duration of any improvement and need for intervention on the contralateral side were also appraised. Kaplan-Meier analysis was used to assess stent patency after intervention; paired *t*-tests were used to examine clinical outcomes.

Results: Of the 369 limbs that underwent stenting (Wallstent [Boston Scientific, Marlborough, Mass]-Z stent [Cook Medical, Bloomington, Ind] combination) for stenotic lesions, 307 had contralateral symptoms (202 left, 105 right) including 91 men and 216 women. The cause was post-thrombotic syndrome in 232 limbs and May-Thurner syndrome/non-thrombotic iliac vein lesion in 75 limbs. In this contralateral group, at 12 months, the VAS pain score improved from 5 to 0 ($P < .0001$), the grade of swelling went from 3 to 1 ($P < .0001$), and VCSS went from 5 to 3 ($P < .0001$) after stenting of the ipsilateral side. During the median follow-up of 20 months, 17 contralateral limbs underwent stenting. Median time to stenting of the contralateral limb after ipsilateral stenting was 11 months. The median VAS pain score, grade of swelling, and VCSS score in this group before stenting were 6.5, 2, and 5 compared with 0 ($P < .0001$), 1 ($P = .27$), and 3 ($P = .0021$) in those members of the contralateral group who did not require stenting. Primary and primary assisted patencies at 12 months after contralateral stenting were 75% and 100%, respectively. There were no stent occlusions after contralateral stenting.

Conclusions: Patients with bilateral obstructive iliofemoral venous lesions often experience improvement of the contralateral limb symptoms (94%) after stenting of the worse ipsilateral limb. Only 17 of 307 (6%) symptomatic contralateral limbs had to undergo stenting during the follow-up period because of a worsening clinical picture. This represents

an improvement (from 20%) compared with use of Wallstents alone. Based on this, a staged approach to iliofemoral stenting in patients with bilateral symptoms focusing initially on the more symptomatic limb is suggested.

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AVF7

Deep Vein Stenting Is the Only Therapy to Improve Healing of Venous Leg Ulcerations in Patients With Deep Venous Stenosis

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Objective: Venous leg ulceration (VLU) can arise from deep, superficial, or perforator vein disease or some combination thereof. Our objective was to determine whether the presence of deep venous stenosis (DVS) affects wound healing prognosis in patients with VLU and to identify treatment strategies that affect ulcer healing in patients with DVS.

Methods: A multicenter retrospective study was conducted, enrolling patients presenting with VLU between 2013 and 2017. Attention was focused on the cohort with DVS (involving the femoral or iliac veins or inferior vena cava, diagnosed by computed tomography, magnetic resonance, or conventional venography). Baseline characteristics, anatomy of venous disease and wounds, treatments performed, and wound healing trajectories were studied. The primary outcome was successful healing of the largest index ulcer.

Results: We identified 832 patients across 11 centers. Among these, 134 (16.1%) had stenosis in the deep venous system. Patients with DVS were more likely to have a history of deep venous thrombosis (47.0% vs 23.6%; $P < .001$), to have a hypercoagulable state (27.6% vs 10.7%; $P < .001$), and to be receiving anticoagulation (71.6% vs 25.5%; $P < .001$). On average, DVS patients were more likely to have multiple ulcers (20.2% vs 9.9%; $P = .002$) that were of similar size (5.85 vs 5.47 cm^2; $P = .57$) compared with those without DVS. All DVS patients had concomitant superficial vein reflux and 35 (26.1%) had refluxing perforator veins. Stenting was performed in 95 (70.9%), truncal ablation in 60 (44.8%), and perforator ablation in 28 (20.9%). When both stenting and truncal ablation were performed, stenting was performed first in 53.5% of cases. Patients who underwent deep vein stenting healed wounds faster than those with untreated DVS (hazard ratio [HR], 2.46; 95% confidence interval, 1.49-4.06; $P < .001$; higher HR indicates faster healing). In a multivariate model, deep vein stenting was the only treatment modality that improved wound healing (HR, 2.48, 95% confidence interval, 1.46-4.24; $P = .001$), with no benefit derived from truncal or perforator ablation (Table).

Conclusions: VLU secondary to DVS represents a distinct class of patients who require a unique treatment paradigm. Stenting improved wound healing rates, but ablation of pathologic superficial or perforator veins did not. Routine imaging of the iliocaval segment may help the clinician to pursue early deep vein stenting to maximize ulcer healing and to avoid unhelpful truncal and perforator interventions.

Table. Multivariate predictors of ulcer healing

Predictor	Multivariate HR	95% CI	*P* value
DVS	2.48	1.46-4.24	.001
Truncal ablation	1.14	0.72-1.81	.59
Perforator ablation	0.81	0.47-1.39	.44
Anticoagulation	1.89	1.08-3.32	.03
History of DVT	0.41	0.26-0.65	<.001

CI, Confidence interval; *DVS*, deep venous stenting; *DVT*, deep venous thrombosis; *HR*, hazard ratio.

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AVF8

Comparison of Two Clinical Scales to Assess the Post-thrombotic Syndrome: Secondary Analysis of a Multicenter Randomized Trial of Pharmacomechanical Catheter-Directed Thrombolysis for Deep Venous Thrombosis

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Objective: Post-thrombotic syndrome (PTS) occurs in 20% to 50% of patients after proximal deep venous thrombosis (DVT) despite anticoagulation treatment. The International Society on Thrombosis and Haemostasis recommends using the Villalta scale to standardize the diagnosis of PTS and to quantify its severity. However, many investigators use the Venous Clinical Severity Score (VCSS) to assess PTS. Different from the Villalta score, the VCSS was developed as a measure of chronic venous disease and not PTS specifically. The aim of the study was to determine whether the Villalta score or VCSS best captures clinically important PTS and PTS severity by analyzing the relationship of each to quality of life

Table. Correlation between Villalta score, Venous Clinical Severity Score (*VCSS*), and quality of life (*QoL*) score

		Pearson correlation coefficient (*r*)			
		Villalta score		VCSS[a]	
QoL scale	Visit, month	Estimate	95% CI	Estimate	95% CI
VEINES-QoL	Baseline	−0.51	−0.56, −0.45		
	1	−0.61	−0.65, −0.56		
	6	−0.68	−0.72, −0.63	−0.37	−0.44, −0.30
	12	−0.73	−0.77, −0.69	−0.39	−0.46, −0.31
	18	−0.68	−0.73, −0.63	−0.39	−0.46, −0.31
	24	−0.70	−0.75, −0.66	−0.39	−0.46, −0.31
VEINES-Sym	Baseline	−0.50	−0.55, −0.44		
	1	−0.66	−0.70, −0.61		
	6	−0.70	−0.74, −0.66	−0.36	−0.43, −0.29
	12	−0.76	−0.79, −0.72	−0.41	−0.48, −0.33
	18	−0.71	−0.76, −0.67	−0.40	−0.47, −0.32
	24	−0.74	−0.78, −0.70	−0.41	−0.49, −0.33
SF-36 PCS	Baseline	−0.35	−0.41, −0.28		
	1	−0.46	−0.52, −0.40		
	6	−0.49	−0.55, −0.42	−0.31	−0.38, −0.23
	12	−0.54	−0.60, −0.48	−0.32	−0.39, −0.24
	18	−0.54	−0.60, −0.48	−0.32	−0.40, −0.23
	24	−0.52	−0.58, −0.45	−0.31	−0.40, −0.23
SF-36 MCS	Baseline	−0.21	−0.28, −0.14		
	1	−0.27	−0.34, −0.20		
	6	−0.31	−0.38, −0.24	−0.14	−0.22, −0.06
	12	−0.38	−0.45, −0.30	−0.15	−0.23, −0.06
	18	−0.31	−0.39, −0.23	−0.12	−0.21, −0.03
	24	−0.32	−0.40, −0.24	−0.12	−0.21, −0.02

CI, Confidence interval; *MCS*, mental component score; *PCS*, physical component score; *SF-36*, 36-Item Short Form Health Survey *VEINES-QOL/Sym*, Venous Insufficiency Epidemiological and Economic Study on Quality of Life/Symptoms.
[a]VCSS not measured at baseline or 1 month.