Long-Term Outcomes of Endovascular Intervention for May-Thurner Syndrome

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Background: Endovascular interventions for May Thurner Syndrome (MTS) have become first line therapy, often performed in a young patient population despite the lack of robust supportive data. This paper reports on long term outcomes from a large series of patients treated for de-novo or posthrombotic presentation.

Methods: A retrospective review of MTS patients stented between 2006 and 2010 at two institutions. Patients who presented with acute iliofemoral DVT were treated with either catheter directed thrombolysis (CDT) and/or pharmacomechanical thrombolysis (PMT) and identified as having a venous stenosis by venogram. Patients who presented with leg pain or swelling but no DVT and evidence of MTS on duplex were evaluated by venography. IVUS was selectively utilized. Stenting of the iliocaval junction was performed in all patients with a >50% diameter stenosis on venogram, or a >70% area stenosis on IVUS.

Table. Patient characteristics and procedure analysis

	Stenting after PMT/CDT (postthrombotic) N=38(%)	*Stenting alone (de novo presentation) N=15(%)*	P *value*
Females	23 (61%)	11 (73%)	.38
Average age	52 (range, 16-80 years)	55 (range, 25-67 years)	.60
Hypercoagulable state	9 (24%)	0	.04
Coronary artery disease	6 (16%)	1 (7%)	.38
Diabetes	4 (11%)	4 (27%)	.14
Hyperlipidemia	13 (34%)	3 (20%)	.31
Hypertension	17 (45%)	7 (47%)	.90
Left side	34 (89%)	11 (73%)	.14
Average preoperative CEAP score	2.7	3.8	.05
Number of patients wearing compression stockings pre-operatively	16 (42%)	15 (100%)	<.01
Average stent size (mm)	14 mm (range, 10-22)	17 mm (range, 12-22)	<.01
IVUS use	19 (51%)	12 (80%)	.04
Stent type			.01
-Balloon expandable	7 (18%)	8 (53%)	
-Self expanding	31 (82%)	7 (47%)	
○Protégé (EV3)	28 (90%)	4 (57%)	
○Wallstent (Boston Sci)	3 (10%)	3 (43%)	
Bleeding complications	0	0	N/A
Mean length of follow-up	15 months	11 months	
Complete or partial symptom relief	31 (89%)	15 (100%)	.17
Change in CEAP score at follow-up	−0.16 (*P*=.81)	−0.27 (*P*=.04)	

Results: 51 patients with MTS underwent 53 lower extremity interventions. They were divided into two groups: postthrombotic (Group 1) and de-novo presentation of swelling/pain but no DVT (group 2). There were 38 extremities in group 1 and 15 extremities in group 2 (Table). Both groups were comparable in terms of gender distribution and comorbidities, but hypercoagulable state was more common in group 1 (*P*=.04), and average CEAP score on presentation was higher in group 2 (*P*=.05).There were left sided symptoms in 34 (89%) patients in group 1 and 10 (77%) of group 2 (*P*=.26). Males represent 75% of patients with right sided symptoms, but only 30% of patients with left sided symptoms (*P*=.019). The average stent size was significantly different among the groups, (*P*<.001), with different types used in each group. (Table). There were no procedural complications in either group. Mean follow-up was 15 months in group 1 (range, 1-42 months) and 11 months in group 2 (1-24 months). Complete or partial symptom relief was reported for 31 (89%) extremities in group 1 and 15 (100%) extremities in group 2 (*P*=.17). A normal Valsalva response was seen in all patients with a patent stent on the most recent follow up duplex, with an overall primary patency at 3 years by lifetable analysis of 96% (94% in group1, 100% in group 2) and secondary patency of 98%.

Conclusion: Stenting of MTS has proven to be safe, efficacious and durable for up to 36 months in both the post thrombotic patient as well as those treated for edema alone.

Outcomes and Predictors of Secondary Intervention for Chronic Venous Insufficiency Following Endovenous Radiofrequency Ablation

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Background: Endovenous ablation for the treatment of chronic venous insufficiency (CVI) affords patients a minimally invasive treatment alternative to traditional surgical procedures. Endovenous ablation is highly technically and clinically successful such that only a minority of patients may require subsequent treatment for either extensive varicosities or for veins in which ablation was unsuccessful. The purpose of this study was to develop a predictive model to forecast this requirement for secondary procedures despite successful primary endovenous radiofrequency ablation (RFA) for CVI.

Methods: Subjects were identified from a University Vein Center database and assigned to one of two groups: (1) Control: patients whose RFA was successful as a primary standalone procedure in alleviating symptoms and decompressing varicosities, or (2) Reintervention: patients who required additional treatment to correct their disease after initial RFA did not provide a complete clinical response. For patients who had bilateral RFA, each limb was identified independently for both the primary and secondary procedures. Secondary procedures were defined as phlebectomy, vein stripping, sapheno-femoral junction (SFJ) ligation, or radiofrequency ablation of the same vein or additional accessory veins. Patients who were treated exclusively with sclerotherapy as a secondary intervention were excluded. Data was analyzed using sequential univariate and multivariate regressions along with Chi-square goodness of fit.

Results: Of the 185 patients included in this study, 32 patients required a secondary intervention (17.3%). Secondary procedures included phlebectomy 53%, secondary RFA 28%, combined RFA and phlebectomy 6%, SFJ ligation 6%, and vein stripping 3%. The mean Venous Clinical Severity Scores (VCSS) for the control and reintervention groups were 4.8 and 6.7, respectively (*P*=.001). The overall median VCSS was 5 (range, 2 - 17). For subjects with a VCSS > 5, the requirement for secondary procedures was 10-fold greater. Univariate regression suggested that BMI, diabetes, pain, varicosities, edema, pigmentation, induration, compression, and total VCSS contributed to the need for secondary intervention at the p<.1 level. Multivariate regression modeling these covariates showed independent predictive association between increasing total VCSS and secondary intervention (*P*=.0001), and an inverse association between increasing BMI and a decreased risk of reintervention following RFA (*P*=.008).

Conclusions: Secondary procedures were required only in 17% of patients following RFA, so for most, a staged approach to any secondary procedures may be appropriate. With the knowledge gained from this study, clinicians may be able to better individualize patient treatment by identifying those at up front greater risk of requiring a secondary procedure. For this subset, providing comprehensive treatment, such as a combination of RFA with SFJ ligation or phlebectomy, could mitigate the risks of additional surgical procedures.

Soluble P-Selectin for the Diagnosis of Lower Extremity Deep Venous Thrombosis

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Background: Although duplex ultrasound is the gold standard for the diagnosis of lower extremity deep venous thrombosis(LE-DVT), imaging is not always available. The use of D-dimer can exclude(high sensitivity), but not rule in(low specificity) LE-DVT. In a derivation cohort, we previously demonstrated that soluble P-selectin(sPsel) with Wells score, establishes the diagnosis of LE-DVT with specificity of 96% and positive predictive value(PPV) of 100%. In order to validate our previous results, we applied the model from our derivation cohort to a separate but similar validation cohort, differing by allowing inclusion of patients on immunosuppression or prophylactic anticoagulation.

Methods: Demographics, clinical data, D-dimer, sPsel, C-reactive protein(CRP), ADAMTS-13, and von Willebrand factor(vWF) levels were prospectively collected in 160 patients presenting to our ultrasound lab with an anticipated diagnosis of LE-DVT. Continuous (Students t-test) and categorical (Chi squared test) variables among patients with ultrasound confirmed LE-DVT were compared to patients without LE-DVT. The diagnostic sensitivity, specificity, PPV and negative predictive value(NPV) was then calculated using cut points from our derivation cohort to rule in LE-DVT (sPsel≥ 90ng/mL or D-dimer≥ 500ng/mL and Wells score ≥2) as well as exclude LE-DVT(sPsel<60ng/mL or D-dimer<500ng/mL and Wells score <2).

Results: 80/160 patients had a confirmed LE-DVT. There was a significant difference in all biomarkers among those patients with LE-DVT. (Table I) When Wells score ≥2, sPsel could rule LE-DVT with a specificity of 96% and a PPV of 89%, which was more accurate than Wells score ≥2 and D-dimer (specificity 65% and PPV 71%). (Table II) When Well's score was <2, D-dimer was superior to sPsel for excluding the diagnosis of LE-DVT (sensitivity 100%, NPV 100% vs. sensitivity 90%, NPV 77%). The use of additional biomarkers did not increase the specificity/sensitivity for diagnosing LE-DVT. Using a combination of Wells score, D-dimer, and sPsel we could correctly diagnose LE-DVT in 27% (43/160) of patients without the use of imaging.

Conclusions: In validating our previous study, we have demonstrated, in the setting of Wells score ≥2, sPsel is an excellent biomarker rule in LE-DVT. Different from our derivation cohort, D-dimer and a Wells score <2 was more sensitive at excluding a diagnosis of LEDVT than sPsel and a Wells score <2. Together, Wells score, sPsel, and D-dimer can both rule in and exclude LE-DVT.

Table I. Demographics and biomarkers

Variable	*Negative LEDVT (95% confidence intervals)*	*Positive LEDVT (95% confidence intervals)*	P *value*
Female gender n (%)	53 (66%)	34 (43%)	.002
Age	53.2 years (50.2-56.1)	57.6 years (54.4-60.7)	.046
Wells score	1.6 (1.4-1.8)	3.0 (2.6-3.3)	<.001
D-Dimer (ng/mL)	986.4 ng/mL (756.5-1216.3)	6268.4 ng/mL (5356.1-7180.7)	<.001
sPsel (ng/mL)	57.2 ng/mL (50.8-63.6)	78.4 ng/mL (70.8-85.9)	<.001
CRP (μg/mL)	1.34 μg/mL (0.65-2.03)	5.74 μg/mL (4.22-7.25)	<.001
vWF (% activity)	113.3% (95.3-131.3)	151.7% (134.6-168.8)	.002
ADAMTS-13 (% activity)	102% (97-106)	91% (86-95)	<.001

Table II. Specificity, sensitivity, positive predictive value, negative predictive value

Biomarker	*Specificity (95% confidence interval)*	*Sensitivity (95% confidence interval)*	*Positive predictive value*	*Negative predictive value*
sPsel (≥ 90ng/mL) + Wells score (≥ 2)	96% (88.7-99%)	31% (21.6-42.7%)	89%	58%
D-dimer (≥ 500ng/mL) + Wells score (≥ 2)	65% (53.4-75.1%)	84% (73.4-90.7%)	71%	80%
sPsel (<60ng/mL) + Wells score (<2)	34% (23.8-45.3%)	90% (80.7-95.3)	58%	77%
D-dimer (<500ng/mL) + Wells score (<2)	32% (22.7-44%)	100% (94.3-100%)	60%	100%

Deep Venous Thrombosis After Abdominal Aneurysm Repair

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Objective: Thromboprophylaxis guidelines after abdominal aortic aneurysm repair are scarce. The objective of this study was to examine venous thromboembolism (VTE) rates, timing and risk factors after nonruptured open or endoluminal (ELG) Abdominal Aortic Aneurysm repair.

Methods: A systematic study of patients undergoing AAA repair was performed. We queried the ACS NSQIP dataset from 2005-2009 for AAA repairs using [CPT] and [ICD-9] codes. We excluded emergent/ruptured AAA operations. Forward stepwise multivariable logistic regression of all 30-day VTE was performed.

Results: Our query yielded 12,469 patients. The mean age was 73.2 ± 8.7 (s.d.) years and 2466 (19.8%) were female. The DVT rate within 30 days of operation was 0.9% (n=106) and the PE rate was 0.3% (n=36). Diagnosis of both was rare (n=7) and the combined DVT or PE rate (VTE) was 1.1% (n=135). Thirty-day mortality was 1.9% (238/12,469) and VTE was associated with increased 30-day mortality from 1.9% (232/12,102) in patients without VTE to 4.4% (6/135) in patients with VTE (Chi-square p = .035). Thirty-percent (40/135) of treated VTEs were diagnosed after surgical discharge. The median postoperative days to VTE diagnosis was 8 (interquartile range, 4 to 15 days). Multivariable forward stepwise logistic regression yielded only four independent ACS NSQIP preoperative predictors of VTE. They are shown in Table I by their order of entry into the model (and therefore importance). This is after consideration of over fifty clinical risk variables. Intraoperative risk factors are shown in Table II. After adjustment, open repair had higher risk for VTE (OR, 1.46; 95% CI, 0.93-2.30) but this was no longer statistically significant, p = .104.

Risk factors identified were ASA class 4-5(odds ratio[OR] 1.77, *P*=.002), operative duration>4hrs(OR 2.33, *P*=.14) and intraoperative blood transfusion. Operative duration and transfusion were both risk factors and increased with increasing "dose".

Discussion: Although VTE after AAA repair was infrequent, it was associated with higher mortality. Open AAA repair increases risk for postoperative VTE as compared to ELG. It was surprising to find that 1/3 of VTE's were diagnosed after discharge. Patients with the aforementioned risk factors may benefit from pharmacologic thromboprophylaxis after AAA repair. Pharmacologic thromboprophylaxis may not be necessary after ELG.

Table I.

Step	*Variable*	*Incidence*	*%*	*Odds ratio (95% CI)*	P *value*
1	ASA class 4-5 vs 1-3	2480	19.9	1.77 (1.22-2.55)	.002
2	Dyspnea	3049	24.5	1.68 (1.17-2.39)	.005
3	Race vs white	10696	85.8	Reference	
	Black	467	3.7	2.21 (1.18-4.15)	.013
	Other/unknown	1306	10.5	0.93 (0.51-1.70)	.820
4	Recent weight loss > 10%	2318	18.6	2.31 (1.00-5.32)	.050

Table II.

Variable	*Incidence*	*%*	*Odds ratio for VTE (95% C.I.)*	P *value*
Open vs endovascular repair	3967	31.8	1.46 (0.93-2.30)	.104
Intraoperative transfusion PRBCs vs none	8551	68.6	Reference	
1-2 U	2200	17.6	1.23 (0.73-2.08)	.430
3-4 U	978	7.8	1.48 (0.79-2.79)	.221
5+ U	740	5.9	2.39 (1.27-4.48)	.007
Operative duration vs ≤ 2 hrs	3133	25.1	Reference	
2.01-3 hrs	4350	34.9	1.78 (0.95-3.28)	.070
3.01-4 hrs	2586	20.7	1.70 (0.87-3.35)	.123
> 4 hrs	2400	19.2	2.33 (1.18-4.59)	.014
Wound class not clean	320	2.6	2.01 (1.03-3.94)	.041

Thrombolytic Therapy For Significant Pulmonary Emboli

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Background: This study is a retrospective review of the treatment of patients with significant pulmonary emboli (PE) with thrombolytic therapy in a rural setting hospital. Significant PE is defined as a patient with hypoxemia ± right ventricular strain ± hemodynamic compromise. Long-term studies with emphasis on recurrent deep vein thrombosis was assessed as well. Patients studied were in the interval of 2000-2010. Records prior to 2000 were not available.

Methods: To review initial thrombolytic therapy, operative reports were interpreted and evaluated to determine therapy implemented, and if complete or partial lysis of emboli was achieved. For long-term studies annual venous duplexes were assessed.

Results: Records from 2000-2010 showed that 51 patients were treated with thrombolytic therapy. Of those patients, 7 received Urokinase (drip ranges between 100,000 - 200,000 units/hour), 44 received TPA (drip ranges between 0.5 - 2 mg/hour). The majority of patients were dripped via the Unifuse catheter; recently the EKOS catheter has been implemented upon which 9 out of 51 patients received. Thirty-five out of 51 patients received vena cava filters. Three patients received mechanical lysis with the Angiojet Device. All patients were on a heparin drip protocol systematically while on lytic therapy. The average drip duration for treatment ranged between 12 hours and 24 hours. The average drip duration for TPA was 24.23 hours for bilateral treatment with a standard deviation of ± 21.68 hours. The average for Urokinase was 16.57 hours with a standard deviation of ± 4.47 hours. Patients who received TPA and EKOS adjunct averaged 14.44 hours. The study showed no procedural mortalities and no deaths at 30 days prior to therapy. Fifty-three percent of patients had complete lysis, 47% had substantial partial lysis with freedom from supplemental oxygen. All patients improved hemodynamically. Twelve out of 51 patients required a blood product during their hospitalization. Nine patients required PRBC, 2 FFP, and 1 with CryoPPT. There were no GI bleeds or retroperitoneal hematomas. Long-term follow-up to 4 years showed 70% venous reflux in the common femoral vein. Less than 20% of patients experienced a low incidence of recurrent deep vein thrombosis while on anti-coagulants.

Conclusions: In conclusion, aggressive thrombolysis in significant PE is safe with substantial results within 24 hours of therapy and rapid improvement in symptoms over a short duration of therapy.