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Predictive Factors for Cyanoacrylate Glue Migration during and after the treatment of Incompetent Truncal Saphenous Veins

INTRODUCTION

- Chronic venous insufficiency affects at least a third of the population and has a negative impact on quality of life 1,2 .
- When self-care is insufficient to control symptoms, non-surgical treatments such as endothermal ablation and sclerotherapy are usually offered.
- The VenaSeal[™] Closure System (VCS) is a novel non-thermal non-tumescent venous device that employs a cyanoacrylate glue (CAG) to occlude incompetent superficial truncal veins.
- VCS offers improved patient comfort and ease of use, and reduced risk of burns and nerve injury³.
- However, one of the concerns is the extent of CAG migration peri- and post-application, which may lead to thromboembolism if it enters the deep venous system⁴.

OBJECTIVES

The aim of this study was to investigate factors that may predict migration of the cyanoacrylate adhesive towards the deep vein junction in the peri-application period.

METHODS



Figure 1. VenaSeal[™] catheter in great saphenous vein (GSV) with glue application a distance from the SFJ The close-up on the right shows the stump distance (x), between the SFJ and the block of glue applied (shaded).

- Patients with symptomatic venous reflux disease who underwent VCS ablation were included. Patients were excluded from the study if there were pregnant, allergic or had previous hypersensitivity reaction to CAG, acute venous thromboembolism, sepsis or history of hypercoagulability and multiple drug allergies.
- All procedures were performed by TYT following a protocol⁵. The tip of the delivery catheter complex was advanced 5cm caudal to the saphenofemoral junction (SFJ) or sapheno-popliteal junction (SPJ) under ultrasound guidance (Figure 1).
- A duplex ultrasound scan was performed immediately and one week post-procedure.
- Stump distance was defined as the distance from the SFJ/SPJ to the start of the final position of the laid CAG in the proximal truncal vein (Figure 1).
- Descriptive statistics and association analysis with CAG movement were performed for (1) stump distance <30mm immediately post-procedure using logistic and (2) glue movement 1 week post-procedure using linear regression.

RESULTS and CONCLUSIONS

- 73 patients were enrolled and 15 of them had bilateral VCS ablation.
- Great saphenous vein (GSV) max upper thigh diameter was the sole predictor of SFJ stump distance <30mm immediately post-procedure (OR: 1.44 (95%CI: 1.05 – 1.97)).
- Factors predicting SFJ glue movement 1 week post-procedure include ischemic heart disease, max SFJ diameter, double treatment and stump distance <30mm immediately post-procedure (Table 4).
- The current safety instructions for use guidelines of starting 50mm caudal to the SFJ seem adequate but for patients with large SFJ or upper GSV diameters, starting further than 50mm from the SFJ is recommended.

Table 2. Pre-operative vein characteristics

Characteristic	
Right sided, n (%)	40 (46.0)
CEAP classification, n (%)	
2	7 (8.0)
3	18 (20.7)
4a	32 (36.8)
4b	12 (13.8)
5	13 (14.9)
6	5 (5.7)
Pre-operative vein parameters	
Common	
CFV reflux, n (%)	82 (94.3)
CFV reflux time (ms), median (range)	2001 (564 – 3800)
GSV (n = 85 limbs)	
GSV reflux time (ms), median (range)	1600 (525 - 4010)
SFJ incompetence, n (%)	72 (85.7)
SFJ peak reflux velocity (cm/s), median (range)	11.0 (3.0 – 55.0)
SFJ max diameter (mm), median (range)	8.0 (4.0 – 13.0)
GSV max diameter (mm), median (range)	
Upper thigh	5.0 (3.0 – 10.0)
Mid thigh	5.0 (2.0 – 9.0)
Lower thigh	4.0 (2.0 – 9.0)
SSV (n = 11 limbs)	
SSV max diameter (mm), median (range)	
Knee	6.0 (2.0 - 8.0)
Calf	3.0 (3.0 – 8.0)
Ankle	3.0 (2.0 - 4.0)

Table 3. Treatment characteristics

Characteristic				
Length treated (cm), median (range)				
GSV	48.0 (13.0 – 69.0)			
SSV	32.0 (19.0 – 40.0)			
Glue volume (ml), median (range)				
GSV	1.8 (0.6 – 6.1)			
SSV	1.1 (0.6 – 1.8)			
Double treatment of GSV at SFJ, n (%)	44 (51.8)			
Stump distance SFJ (mm), median (range)				
Immediately post-procedure	33.0 (0 – 58.0)			
One week post-procedure	25.0 (0 – 55.0)			
Glue movement immediately post-op	17.00 (-8.0 – 55.0)			
Glue movement after 1 week	8.3 (-15.0 – 38.0)			
Mean Stump distance SPJ (mm), median (range)				
Immediately post-procedure	27.0 (5.0 – 33.0)			
One week post-procedure	25.0 (5.0 – 30.0)			

Table 1. Baseline patient characteristics

Characteristic					
Age (years), median (range)	63.0 (26.0 – 85.0)				
Male gender, n (%)	35 (47.9)				
Ethnicity, n (%)					
Chinese	39 (53.4)				
Malay	23 (31.5)				
Indian	8 (11.0)				
Others	3 (4.1)				
Smoker, n (%)	27 (37.0)				
BMI, median (range)	27.2 (16.1 – 45.4)				
ASA physical status, n (%)					
1	19 (26.0)				
2	24 (32.9)				
3	30 (41.1)				
Comorbidities, n (%)					
Hypertension	50 (68.5)				
Diabetes Mellitus	17 (23.3)				
Hyperlipidemia	34 (46.6)				
Cardiac co-morbidities	11 (15.1)				
Osteoarthritis knees	24 (32.9)				
Anti-coagulation	15 (20.5)				

CFV: common femoral vein, GSV: great saphenous vein, SSV: short saphenous vein

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Glue movement after 1 week	0 (-5.0 – 13.0)

GSV: great saphenous vein, SSV: short saphenous vein, SFJ: sapheno-femoral junction, SPJ: sapheno-popliteal junction

Table 4. Multivariate analysis for SFJ glue movement 1 week post procedure

Characteristic	Estimate	Standard error	p-value
Ischemic heart disease	7.50	2.34	< 0.01
Maximum diameter SFJ	1.42	0.48	< 0.01
Double treatment	2.94	1.97	0.140
Stump distance <30mm	6.59	1.73	< 0.01
immediate post-procedure			

References

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ASA: American Society of Anesthesiologists, BMI: Body mass index