

The Utility of the Venous Clinical Severity Score in Limbs Treated by RF Saphenous Vein Ablation

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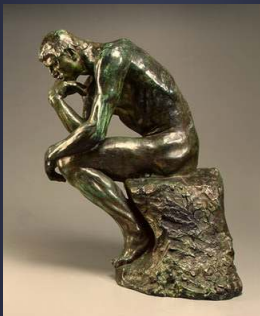
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像教行子孔師先



“A man who has committed a mistake and doesn't correct it, is committing another mistake.” Confucius



CEAP

- Clinical presentation: 1-6
- Etiologic basis: Primary, Secondary, Congenital
- Anatomic distribution: Superficial, Perforator, Deep veins divided into 18 anatomic segments
- Pathophysiologic basis: Reflux, Obstruction, Both

$C_{(1,6)(S \text{ or } A)}$ $E_{(P, S \text{ or } C)}$ $A_{(S, P \text{ and/or } D)}$ $P_{(R, O \text{ or both, with affected segments})}$



CEAP

- Excellent **descriptive** tool
- Relatively **static**
- Poor method to assess the usefulness of an intervention



Venous Clinical Severity Score (VCSS)



- Proposed by **American Venous Forum** Ad Hoc Committee on Venous Assessment March 2000
- Score from **0 – 30**
- Most **validated** and **reliable** method available for venous surgery outcome assessment
- **Evaluative** instrument designed to follow clinical condition over time
- **Easy** to use
- **Underutilized**

VCSS Components



| Attribute | Absent (0) | Mild (1) | Moderate (2) | Severe (3) |
|----------------------------|------------|-----------------|----------------------|---------------|
| Pain | None | Occasional | Daily | Daily w/ meds |
| Varicose veins | None | Few | Multiple | Extensive |
| Venous edema | None | Evening only | Afternoon | Morning |
| Skin Pigmentation | None | Limited, old | Diffuse, more recent | Wider, recent |
| Inflammation | None | Mild cellulitis | Mod cellulitis | Severe |
| Induration | None | Focal < 5cm | < 1/3 gaiter | > 1/3 gaiter |
| No. active ulcers | None | 1 | 2 | > 2 |
| Active ulcer size | None | < 2 cm | 2 – 6 cm | > 6 cm |
| Ulcer duration | None | <3 mo | 3 – 12 mo | > 1 yr |
| Compression Therapy | None | Intermittent | Most days | Fully comply |

The Objectives



Objectives

- Assess the **clinical outcome** of a large cohort of patients undergoing saphenous vein radiofrequency ablation (RFA) using the VCSS
- Identify **risk factors** associated with treatment failure

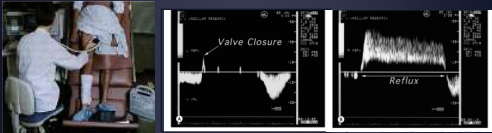


The Methods



Vascular Lab Evaluation

- Assess deep system for thrombus
- Rule out venous outflow obstruction
- Assess **valvular competency** in deep, superficial and perforator systems



Candidates for Surgical Intervention

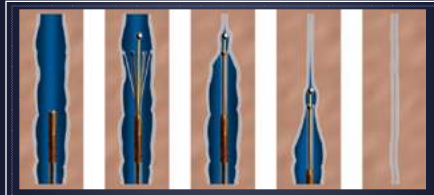
- **Symptomatic** varicosities w/ w/o swelling
- Recurrent superficial phlebitis
- Varicosity bleeding or erosion
- Chronic skin discoloration or induration
- Active or recurrent venous stasis ulcer

Exclusion criteria

- DVT, outflow obstruction
- PAD (ABI <0.8)
- Planned future pregnancy
- Non-compliance
- Severe obesity making US visualization of SFJ difficult



RFA Procedure (ClosurePlus)



Catheter inserted in refluxing vein Catheter Positioned, Electrodes deployed RF Energy heats and contracts vein wall Catheter slowly withdrawn, closing vein Treated vein is physically narrowed

SVRFA Procedure Method

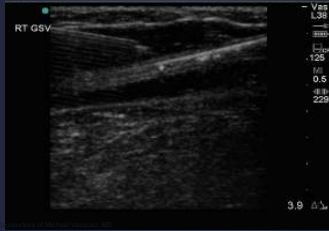
1. **Tumescent** +/- basal anesthesia
2. Access vein with IV cannula or sheath
 - Location typically **at knee**
3. Insert catheter into vein and advance catheter tip to SFJ using ultrasound guidance
4. Create a near-bloodless field
 - Heparinized -saline infusion at tip of catheter
 - Manual compression at groin
 - Trendelenburg
5. RF heating of vein lumen to 85°C +/- 3°C
6. Slow, **temperature-guided catheter pullback** at 2-3 cm/min
7. **Assess post-operative occlusion** with ultrasound

Tumescent Infiltration

- Dilution – 0.1% Lidocaine with epi
- Volume
 - Typically 220-320 cc for single vein segment (**10cc / cm**)
- Technique
 - Longitudinal infiltration initially **beyond SFJ**
 - Transverse infiltration also at SFJ
 - **Transverse assessment** of quality of infiltration

Case Study 1

Tumescent Infiltration: Longitudinal View



Note complete vein wall compression around catheter and tumescent above and below vein



Case Study 2

Pre-op Duplex Scan: GSV diameter: 2.14cm

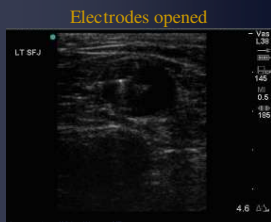


Case Study 2

Placement of the 8Fr Catheter



Distance to SFJ



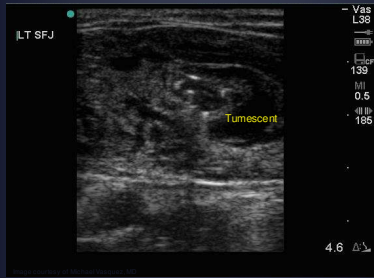
Electrodes opened

Note incomplete contact of electrodes against vein wall



Case Study 2

SFJ Post-Tumescent Infiltration



Tumescent fluid **circumferentially compresses** vein wall against electrodes

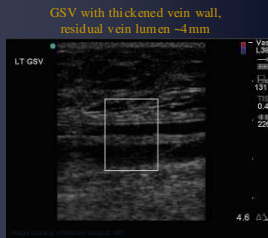


Case Study 2

SFJ and GSV Post Treatment



GSV at treatment starting point



GSV with thickened vein wall, residual vein lumen ~4mm



The Results



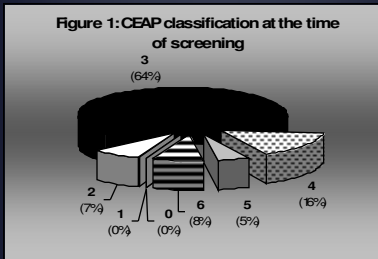
Our Data Summary

- Total 682 limbs in 499 patients over 18 months since September 2003
- Average Age = 53 ± 13 years

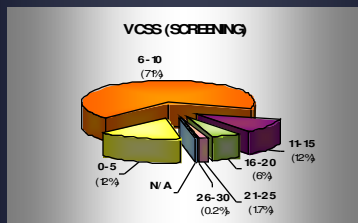
| | | | |
|------|-------|------|--------|
| Left | Right | Male | Female |
| 52% | 48% | 34% | 68% |

- Screening, and Follow-up at 4 days, 4 weeks, 4 months, and 1 year

Our Data Summary – CEAP Screening



Our Data Summary – VCSS Screening

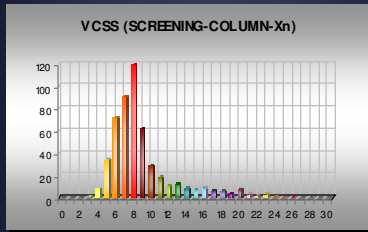


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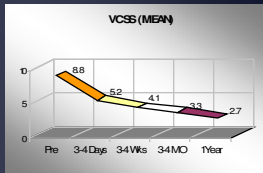


• Mean VCSS Screening = 8.8 ± 3.8

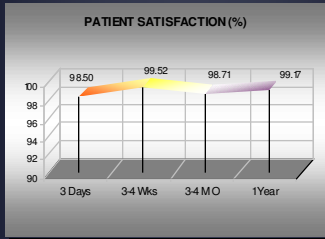
Our Data Summary – VCSS Overall



| Overall VCSS | | | | |
|---------------|--------------------|---------------------|----------------------|------------------|
| Pre-treatment | 3-4 Days Follow-up | 3-4 Weeks Follow-up | 3-4 Months Follow-up | 1 Year Follow-up |
| 8.8 | 5.2 | 4.1 | 3.3 | 2.7 |



Our Data Summary – Patient Satisfaction



- partly or very satisfied

Factors Associated with Successful Occlusion

| | RR | 95% CI | P value |
|-------------------|------|--------------|---------|
| Age (increasing) | 0.98 | (0.96, 1.00) | 0.06 |
| Female gender | 0.19 | (0.09, 0.41) | <0.0001 |
| Catheter (6/8 F) | 0.74 | (0.43, 1.28) | 0.28 |
| GSV side (R/L) | 1.03 | (0.98, 1.09) | 0.19 |
| Tumescent 250+ cc | 0.59 | (0.34, 1.02) | 0.06 |

The Visual Proof



Comparison Bilateral Disease

pre op right



Pain=2, VV=3, Edema=3, Pigmentation=1, Inflammation=0, Induration=1, Active ulcers, size, duration=0, Compression therapy=2
Total VCSS Score = 12 CEAP = 4

3 mo post op



Pain=0, VV=1, Edema=0, Pigmentation=1, Inflammation=0, Induration=0, Active ulcers, size, duration=0, Compression therapy=2
Total VCSS Score = 4 CEAP = 4

Closure and leg ulcers

pre



Pain=3, VV=2, Edema=2, Pigmentation=2, Inflammation=2, Induration=2, Active ulcers=1, Size=2, duration=1, Compression therapy=1
Total VCSS Score = 18 CEAP = 6


2 weeks post op



Pain=0, VV=1, Edema=1, Pigmentation=1, Inflammation=0, Induration=1, Active ulcers, size, duration=0, Compression therapy=3
Total VCSS Score = 7 CEAP = 5

Closure and leg ulcers

pre



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Closure and leg ulcers

pre



Pain=3, VV=3, Edema=3, Pigmentation=3, Inflammation=2, Induration=3, Active ulcers=1, size=2, duration=3, Compression therapy=3
VCSS = 26 CEAP 6

3 weeks post op



Pain=1, VV=1, Edema=1, Pigmentation=3, Inflammation=0, Induration=2, Active ulcers, size, duration=0, Compression therapy=3
VCSS = 11 CEAP 5

Closure and leg ulcers

pre



Pain=3, VV=3, Edema=2, Pigmentation=2, Inflammation=3, Induration=3, Active ulcers=1, size=3, duration=3, Compression therapy=3
VCSS = 26 CEAP = 6

1 week post



Pain=2, VV=2, Edema=1, Pigmentation=2, Inflammation=1, Induration=2, Active ulcers=1, size=3, duration=3, Compression therapy=3
VCSS = 20 CEAP = 6

3 months post op



Pain=0, VV=1, Edema=0, Pigmentation=2, Inflammation=0, Induration=1, Active ulcers, size, duration=0, Compression therapy=2
VCSS = 6 CEAP = 5

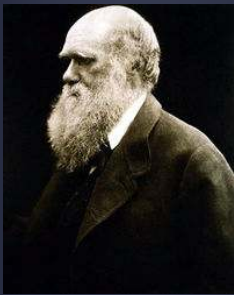
Article Conclusions

- RFA results in clinical improvement by VCSS.
- Elimination of superficial reflux encourages ulcer healing.
- Volume of tumescent, age, and female gender are all associated with high success rate of occlusion.
- Treatment to the knee is sufficient for the majority of patients with few adverse events.
- Waiting period of four months should be endured prior to the adjunctive treatment of residual varicosities.

Article Conclusions (cont.)

- Each of VCSS **components** useful, significant and easy to use
- VCSS is an excellent **stand alone tool** for assessing outcomes following RFA
- VCSS with CEAP should be used for outcome assessment in **any study** comparing different treatment modalities for SV ablation **so we all know what we are really talking about**





“It is not the strongest of the species that survives, nor the most intelligent, but the one most responsive to change.” **Charles Darwin**

