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Venous Care Partnership

Evidence Supporting Intervention for Venous Reflux across the Spectrum of Venous Disease

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Venous Care Partnership

Disclosures

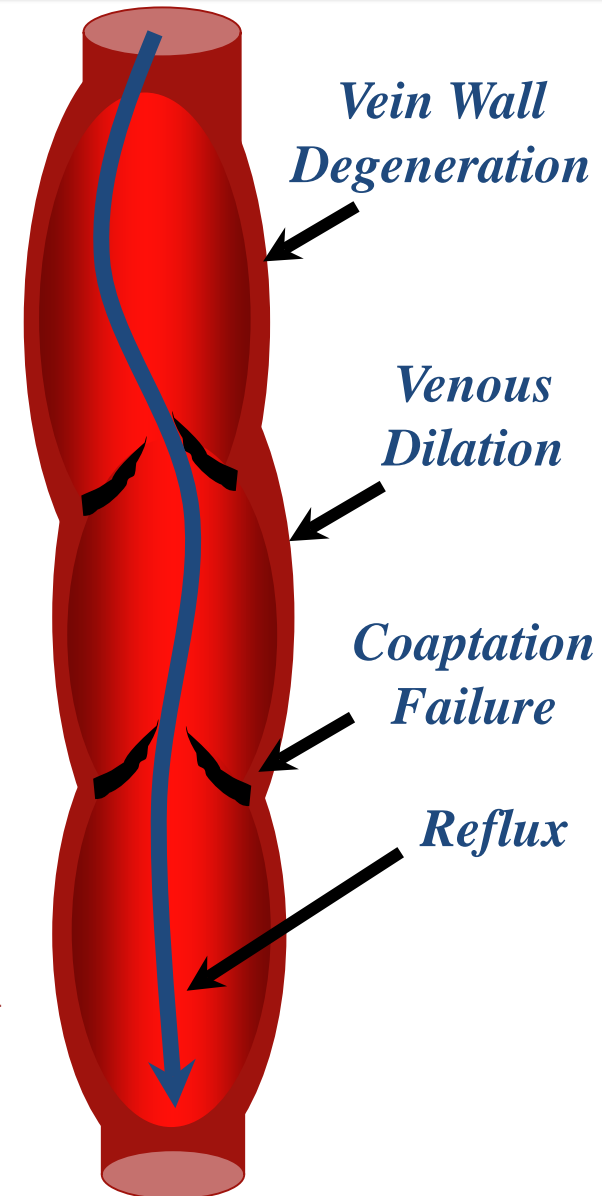
Mark H. Meissner, MD

*I Have No Disclosures Relevant To This
Presentation*

Venous Care Partnership

What is Venous Reflux?

- **Definition – Retrograde venous flow**
- **Etiology**
 - **1° - Vein wall degeneration**
 - Smooth muscle fragmentation
 - Increased collagen
 - Decrease elastin
 - Loss of vascular reactivity
 - **2° - Post – thrombotic**
 - Valvular damage
 - Often concurrent with obstruction
- **Ambulatory venous hypertension**
 - **Resultant microcirculatory inflammation**
 - **C2 to C4 - Pain, edema, skin changes**
 - **C5, 6 – Venous ulceration**



Treatment of *Symptomatic* Venous Reflux



C2

Varicose Veins



C3

Swollen Leg



C4

Skin Changes



C5-6

Skin Ulcer

- **Conservative measures (“Standard of Care”)**
 - **Graduated compression stockings**
 - **Leg elevation**
 - **Exercise**
- **Superficial venous intervention**
 - **Saphenous stripping**
 - **Endovenous thermal ablation (laser / radiofrequency)**
 - **Non-thermal ablation (Foam sclerotherapy, MOCA, cyanoacrylate glue)**

Is Compression Effective (C2 – C4)?

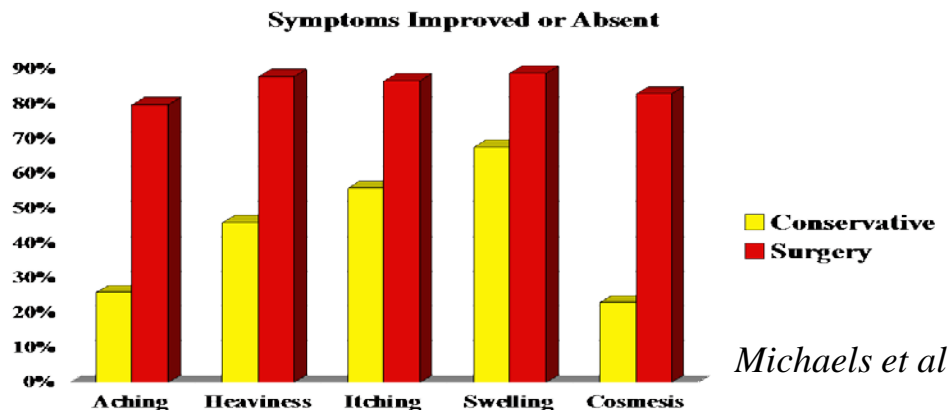
Systematic Reviews of GCS for Varicose Veins

- *Palfreyman SJ, Phlebology 2009*
 - **Systematic review of 3 RCTs, 11 comparative studies**
 - **Outcome measures inadequate in all trials**
 - Subjective improvement in symptoms (Visual analog scale)
 - Hemodynamic improvement (Air plethysmography, foot volumetry)
 - **No quantitative quality of life data**
 - *“Published literature is contradictory with methodologic flaws”*
- *Shingler S, Cochrane Database of Systematic Reviews 2013*
 - **GCS versus placebo / no treatment (7 RCTs, 356 patients)**
 - **Poor compliance (30% drop out rate)**
 - **Subjective symptom improvement, but no quantitative comparison**
 - **No quality of life outcomes**
 - *“Insufficient high quality data...to determine effectiveness”*

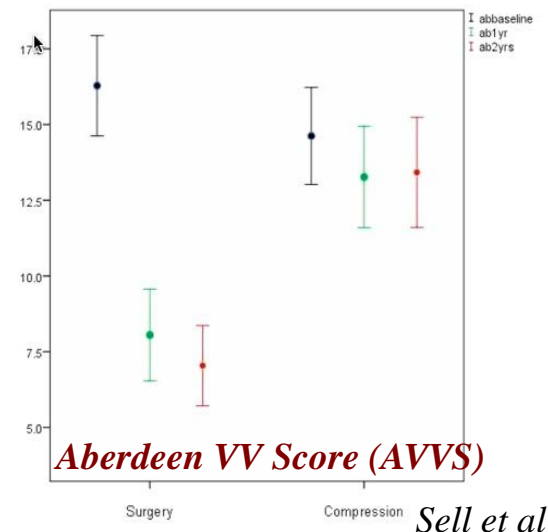
Superficial Venous Intervention *IS* Effective

Randomized trials of stripping / phlebectomy vs compression

- *Michaels JA et al, Heath Technol Assess 2006*
 - 246 patients with extensive varicose veins
 - Fewer symptoms at 1 year with surgery
 - HRQoL (SF-6D) at 2 yr significantly better with surgery
0.083 (.005 - .16) increased QALY
Incremental cost effectiveness - £ 4682 (2039 – 20830) per QALY
- *Sell H, Eur J Vasc Endovasc Surg 2014*
 - 153 patients with C2 – C3 disease
 - Improved VCSS and QoL (AVVS) at 2 years with surgery



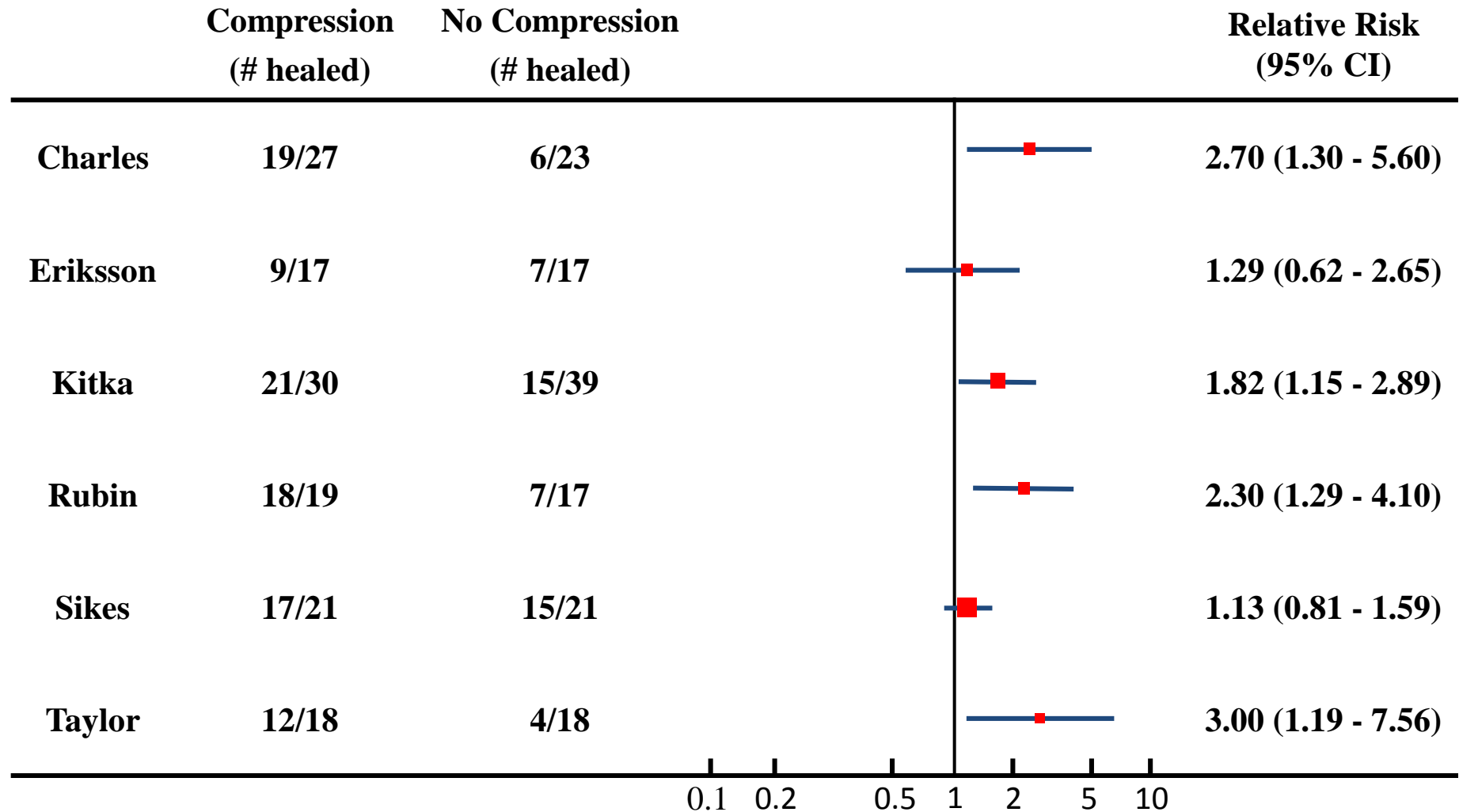
Michaels et al



Sell et al

Compression for Ulceration (C₆)

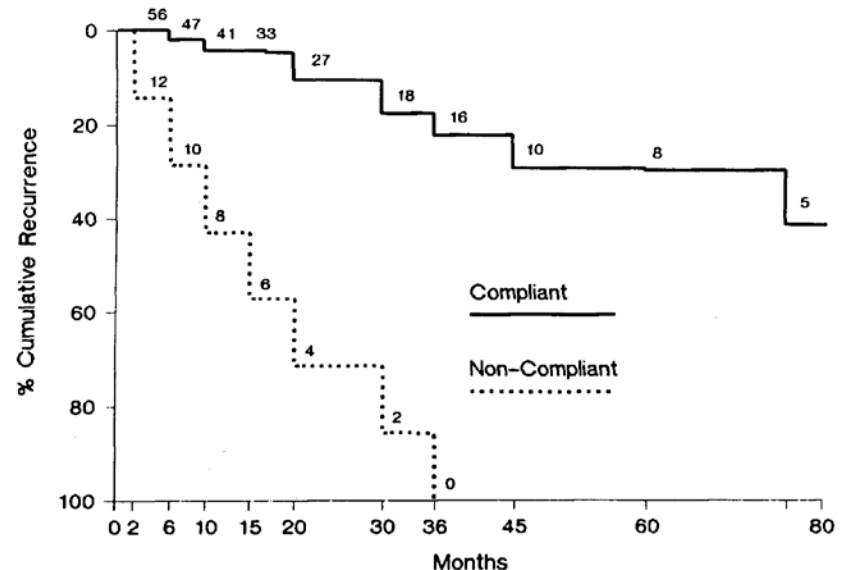
Cullum et al, Cochrane Reviews 2001



Compression for Venous Leg Ulcers

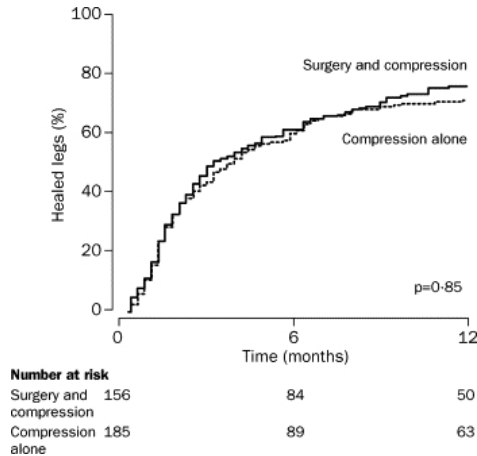
Mayberry, Surgery 1991

- **Observational study of 119 patients**
 - **34% bed rest followed by ECS**
 - **66% ambulatory treatment with ECS**
- **Complete Healing**
 - **Compliant 97%**
 - **Noncompliant 55%**
- ***Recurrence (5 yr life table)***
 - ***Compliant - 29%***
 - ***Noncompliant - 100%***

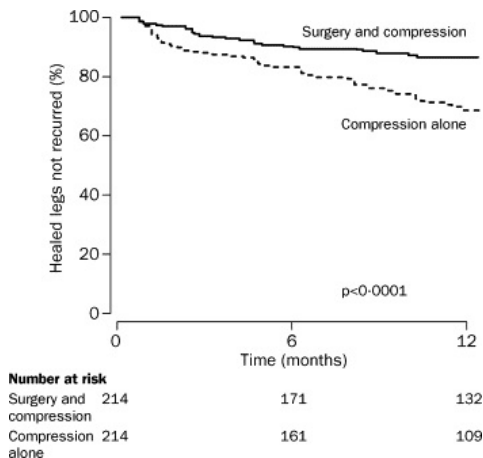


Surgery for C5-6 Disease

The ESCHAR Trial - Barwell JR, Lancet 2004



Ulcer healing



Freedom from recurrence

- **Prospective randomized trial**
 - **High ligation, stripping, phlebectomy**
 - **Multilayer compression bandaging**
- **500 patients with CEAP 5 and 6 disease**
- **Endpoints**
 - **24 week ulcer healing (NS)**
 - Compression - 65%
 - Surgery + Compression - 65%
 - **12 month ulcer recurrence ($p < .0001$)**
 - Compression - 28%
 - Surgery + Compression - 12%

C2 – C4 disease

Guideline	Description	Strength / Grade
SVS / AVF	We recommend <i>against</i> compression therapy as the primary treatment of symptomatic varicose veins in patients who are <i>candidates for saphenous vein ablation</i> .	1B
ACP	We <i>recommend against compression therapy</i> as a prerequisite therapy for symptomatic venous reflux disease when other definitive treatments such as endovenous ablation are appropriate	1A
ESVS	For non-complicated varicose veins (C2, C3), <i>surgical treatment is recommended instead of conservative management</i>	1B

C5 – 6 disease

Guideline	Description	Strength / Grade
SVS / AVF	We recommend compression as an adjuvant to superficial vein ablation to prevent <i>ulcer recurrence</i>	1A
ESVS	Compression with bandages is recommended as the initial treatment for venous ulcer; however, <i>the possibility of active intervention should be offered to maintain healing</i>	1B

Conclusions

For adults with varicose veins and/or other clinical symptoms or signs of chronic venous insufficiency, how confident are you that there is sufficient evidence for an intervention that improves immediate & long-term health outcomes?

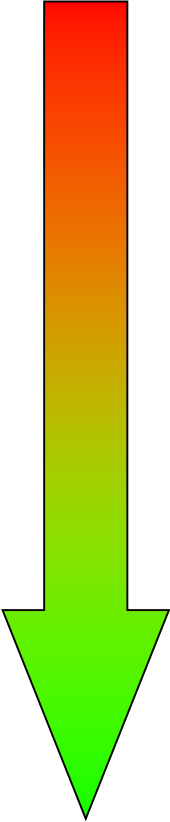
- **Compression as first line treatment**
 - **C2 – C4 disease**
 - Low quality data
 - Methodological flaws
 - Complete absence of quality of life (QoL) data
 - Inadequate to support effectiveness
 - **C5 – C6 disease**
 - Very suggestive data showing effectiveness in compliant pts, but...
 - 30% recurrent ulceration at 1 to 5 years
- **Superficial venous intervention**
 - **C2 – C4 disease**
 - Robust data showing improved symptoms and QoL
 - Cost effective at usual willingness to pay thresholds
 - **C5 – C6 disease - > 50% reduction in recurrent ulceration at 12 mo**

References

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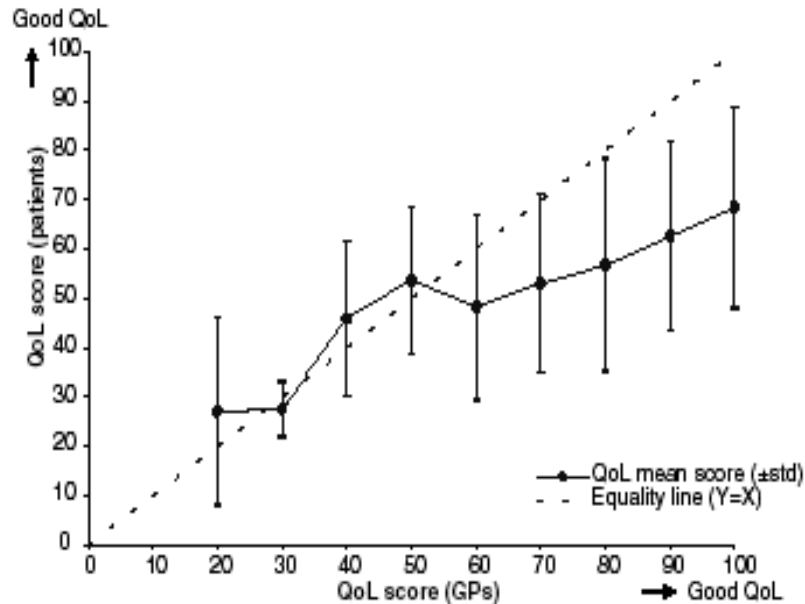
Supplemental Slides

Outcome Measures In Chronic Venous Disease

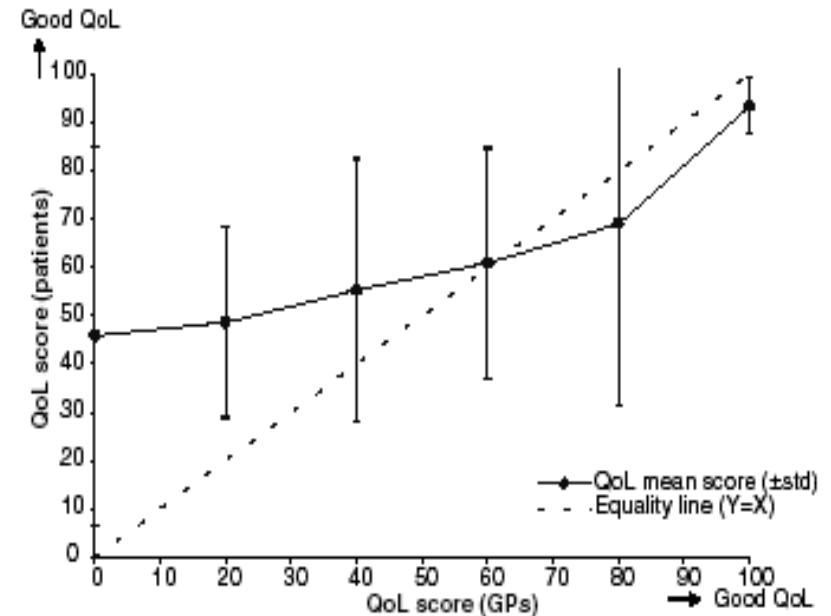
Validity	Outcome Type		Outcome Measure
	<i>Surrogate</i>	Technical	Reflux Closure Rates
	<i>Clinically Relevant</i>	Clinical	VV Recurrence Ulcer Recurrence VCSS
		Functional (QoL)	CIVIQ AVVS SCOR-V VEINES-Sym/QoL

QoL: Physician vs Patient Perceptions

Chassany et al; Value Health 2006



Chronic Venous Disease
(CIVIQ)



Claudication
(CLAU-S)

- Patient vs physician reported QoL
 - Disease impact underestimated in CVD
 - Disease impact overestimated in claudication

Treatment of Varicose Veins: A Meta-Analysis

Murad et al; J Vasc Surg 2012

- **Systematic review/meta-analysis commissioned by SVS/AVF**
 - **Surgery, radiofrequency & laser ablation, sclerotherapy**
 - **39 comparative trials**
 - **8285 patients**
- **Conclusions**
 - **Sclero vs surgery – Increased recurrence (RR 0.45, 0.22-0.93)**
 - **Laser vs surgery**
 - Early benefit, no late difference**
 - Meta-analysis of recurrence not feasible**
 - **Radiofrequency versus surgery**
 - Early benefit, no late difference**
 - No difference in recurrence (RR 0.94, 0.25 – 3.46)**
- **No direct comparisons of laser vs RF at time of review**



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