

# Clarivein: the answer to avoid heat treatments?

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# COI

- Grants:
  - Vascular Insights
  - Urgo Laboratoire
  - Firstkind
  - Acergy
  - NIHR
  - BHF
  - Circulation Foundation
  - Royal College of Surgeons
  - European Venous Forum
  - Graham Dixon Charitable Trust
  - Masons Charitable Trust
  - Sapheon Inc
- Chair of NICE guidelines group
- Member of NICE Q&A group





# **Sclerotherapy and foam sclerotherapy for varicose veins.**

- RCTs limited
- Foam better than liquid
- 3% polidocanol foam is no more effective than 1%
- optimum ratio of gas to liquid is 4:1
- carbon dioxide foam reduces the systemic complications
- The relative advantages or disadvantages of this treatment in the longer term have yet to be published.

Coleridge Smith 2009



# Ultrasound-guided foam sclerotherapy is a safe and clinically effective treatment for superficial venous reflux

Andrew W. Bradbury, BSc, MB, ChB, MBA, MD, FRCSEd, Gareth Bate, RGN, Karl Pang, MB, ChB, Katy A. Darvall, MB, ChB, MRCS, and Donald J. Adam, MB, ChB, MD, FRCSEd, *Birmingham, United Kingdom*

**Objective:** To test the hypothesis that ultrasound-guided foam sclerotherapy (UGFS) is a safe and durable treatment for superficial venous reflux (SVR) associated with CEAP clinical grade 2-6 disease.

**Methods:** This was an interrogation of a prospectively gathered computerized database.

**Results:** Between March 23, 2004 and December 31, 2009, 977 patients (1252 legs) underwent UGFS for unilateral (702 legs) or bilateral (550 legs) SVR in association with CEAP clinical grade 2-3 (n = 868), 4 (n = 232), or 5/6 (n = 152) disease. The following reflux in 1417 venous segments was treated: primary great saphenous vein (GSV) (n = 745); recurrent GSV (n = 286), primary small saphenous vein (SSV) (n = 189), recurrent SSV (n = 50); primary anterior accessory saphenous vein (AASV) (n = 93); recurrent AASV (n = 46); vein of the popliteal fossa (VOPE) (n = 5), and Giacomini vein (GV) (n = 3). Three hundred forty-eight legs (27.8%) had undergone previous surgery. Three patients suffered post-UGFS deep vein thrombosis (DVT) and one a pulmonary embolus (PE), all within the first month (0.4% venous thrombo-embolic complication rate). Five patients (0.5%) had transient visual disturbance at the time of, or shortly after, treatment. No other neurologic or serious complications were reported. During a mean (range) follow-up of 28 (<1 to 68) months, 161 (12.9%) legs underwent a further session of UGFS for truncal VV at a mean (range) of 17 (<1 to 63) months following the first treatment. In 52 legs, retreatment was due to the development of new SVR and in 109 legs was for true recurrence (8.7% complete or partial recanalization rate leading to treatment). There was no significant difference in retreatment rates between UGFS for GSV and SSV reflux or between UGFS for primary or recurrent disease.

**Conclusion:** UGFS for CEAP 2-6 SVR is associated with a low complication and retreatment rate. However, as patients are at risk of developing recurrent and new SVR they should be kept under review. Further UGFS for new or recurrent disease is simple, safe, and effective. (J Vasc Surg 2010;52:939-45.)

# Cather directed foam sclerotherapy



## Original article

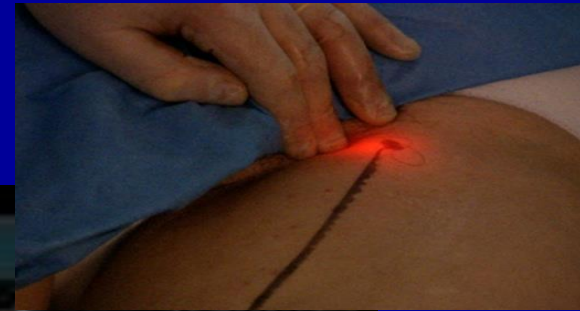
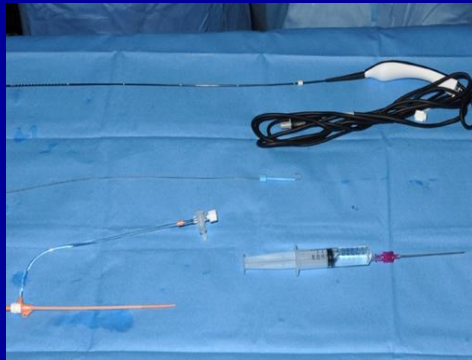
### **Triple-lumen double-balloon catheter for foam sclerotherapy of the great saphenous vein: critical review on preliminary results**

**S Reich-Schupke, P Altmeyer and M Stücker**

Department of Dermatology and Allergology, Ruhr University Bochum, Bochum, Germany







# Tumescent Anesthesia

Klein Pump

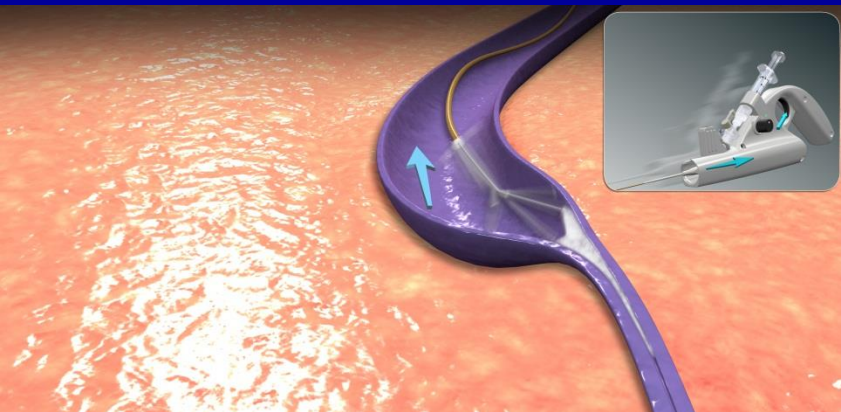
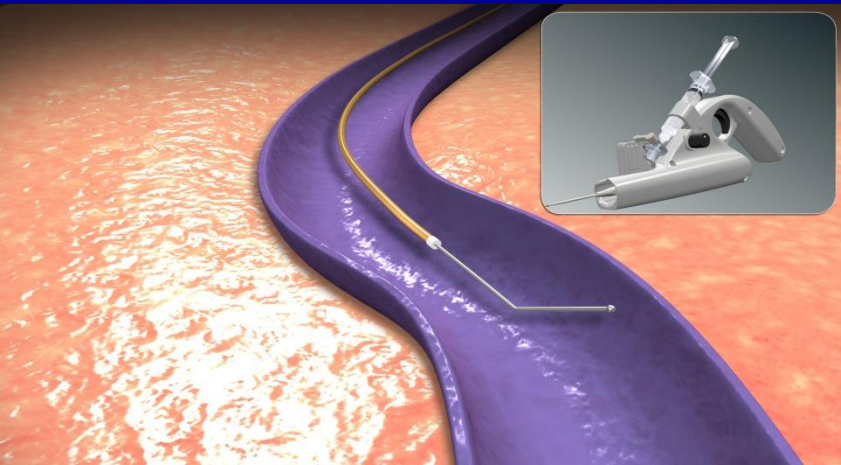
15L/hr-5 50Hz  
EKG/ECG 40mm  
Supert. Ven  
General IV  
70dB TI/1/2/4  
Calen 9dB a+3  
EKG/ECG  
EKG/ECG

RT GSV





# ClariVein

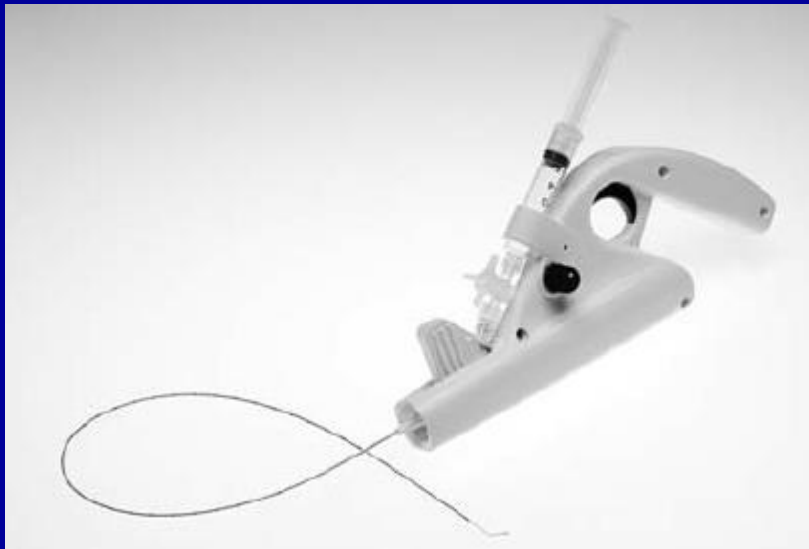


- Mechanical agitator & precision drug deliver ensures excellent results
- Rotating tip agitates & sensitises the endothelium
- Simultaneously, a sclerosant drug is sprayed from the tip of the catheter ensuring precision longitudinal and radial drug delivery.
- The vein is occluded through this mechanism

# **Mechanochemical tumescentless endovenous ablation: final results of the initial clinical trial**

**S Elias\* and J K Raines†**

\*Columbia Vein Programmes, Columbia University, New York, NY; †University of Miami, Homestead, FL, USA



# MOCA: FIM 30 GSV

- GSV size – 8.1 mm.
- GSV length treated – 36 cm.
- GSV treatment time – 5 min.
- Overall treatment time - 14 min
- No tumescence or sedation



# MOCA Results \*

- 6 month – 29/30 (96%)
- 12 month – 29/30 (96%)
- 24 month – 27/28 (96%)

\*Elias S, Raines JK. Mechanochemical tumescentless endovenous ablation: final results of the initial clinical trial. Phlebology;27:67-72.

# MOCA: Dutch Series

- 224 GSV's
- GSV diameter 7 mm (3 – 11)
- GSV length 41 cm (24 – 55)
- treatment time 16 min (13 – 22)
- 96% occlusion - 6 months (1 yr. pending)

Ramon RJP, van Eekeren MD, Elias S et al. Endovenous mechanochemical ablation of great saphenous vein incompetence using the ClariVein device: a safety study. J Endovasc Ther 2011; 18:328-334.

# Mechanochemical Endovenous Ablation of Small Saphenous Vein Insufficiency Using the ClariVein<sup>®</sup> Device: One-year Results of a Prospective Series

D. Boersma <sup>a,\*</sup>, R.R.J.P. van Eekeren <sup>b</sup>, D.A.B. Werson <sup>a</sup>, R.I.F. van der Waal <sup>c</sup>, M.M.J.P. Reijnen <sup>b</sup>, J.-P.P.M. de Vries <sup>a</sup>

<sup>a</sup> Department of Vascular Surgery, St. Antonius Hospital, Koekoekslaan 1, 3540CM Nieuwegein, The Netherlands

<sup>b</sup> Department of Surgery, Rijnstate Hospital, Arnhem, The Netherlands

<sup>c</sup> Department of Dermatology, St. Antonius Hospital, Nieuwegein, The Netherlands



**Conclusions:** MOCA<sup>™</sup> is a safe, feasible and efficacious technique for treatment of SSV insufficiency. One-year follow-up shows a 94% anatomic success rate and no major complications.

## WHAT THIS PAPER ADDS?

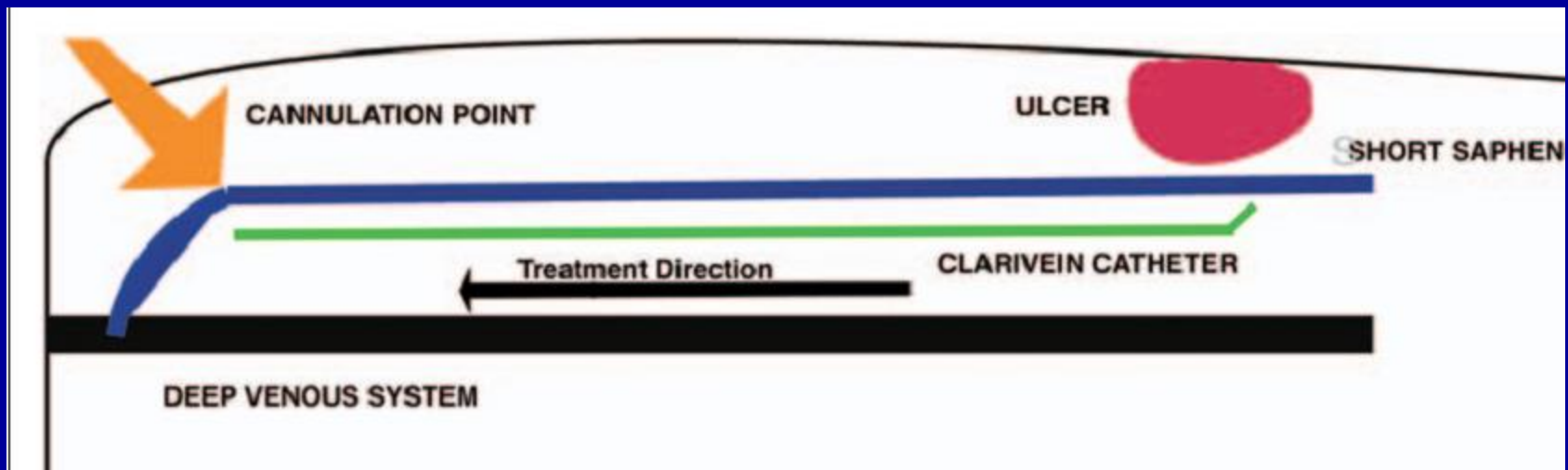
This study is the first study showing feasibility, safety and efficaciousness of mechanochemical endovenous ablation (MOCA<sup>™</sup>) of small saphenous vein (SSV) insufficiency.



# Retrograde mechanochemical ablation of the small saphenous vein for the treatment of a venous ulcer

Hayley M Moore, Tristan RA Lane, Ian J Franklin and Alun H Davies

2013

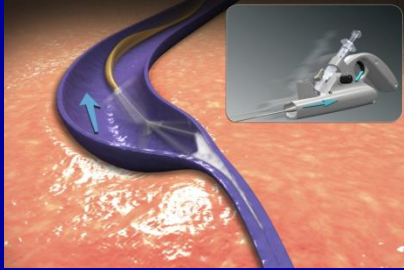


	Laser/Rf	ClariVein/Venaseal
Risk of thermal damage to nerves, skin, surrounding tissue-paresthesia	Yes	No
Requires tumescent anaesthesia	Yes-multiple injections	No
Percutaneous access	6Fr or larger	4-6 Fr
Generator purchase (capital equipment)	Yes	No
Equipment maintenance costs	Yes	No—totally disposable
Anatomical treatment suitability	GSV & SSV (not ideal for SSV-nerve thermal damage)	GSV & SSV and small veins down to ankle
Positioning & pull back speed	2 cms from SFJ/6-8cms per min	0.5cm to 1cm Clarivein 5cm Venaseal
Patient pain & bruising	More	None / little

# Occlusion Rates @ 1 year

Technique	Occlusion rate greater than 90%
RFA	√√
Laser	√√
Foam	XX
Steam	X
MOCA	√√
Glue	√

# RCT



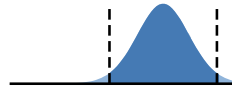
VS



VAS.Max.mm  
by Treatment.1.Clarivein.2.VNUS

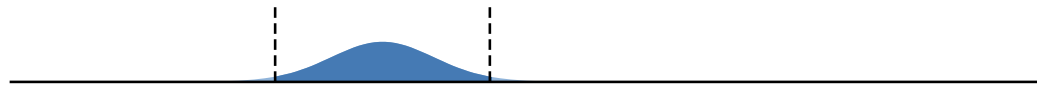
1

$13.871 \pm 4.852$



2

$33.69 \pm 9.694$





# Cost-effectiveness of traditional and endovenous treatments for varicose veins

M. S. Gohel<sup>1</sup>, D. M. Epstein<sup>2</sup> and A. H. Davies<sup>1</sup>

<sup>1</sup>Imperial Vascular Unit, Charing Cross Hospital, London, and <sup>2</sup>Centre for Health Economics, University of York, York, UK

Correspondence to: Professor A. H. Davies, Imperial Vascular Unit, Charing Cross Hospital, Fulham Palace Road, London W6 8RF, UK  
(e-mail: a.h.davies@imperial.ac.uk)

*British Journal of Surgery* 2010; **97**: 1815–1823

## Aim

To evaluate the cost effectiveness of traditional and endovenous treatments for varicose veins



# Cost-effectiveness of traditional and endovenous treatments for varicose veins

M. S. Gohel<sup>1</sup>, D. M. Epstein<sup>2</sup> and A. H. Davies<sup>1</sup>

Treatment	Cost of initial surgery (£)	Reinterventions for residual varicosity at 3 months (£)	Reinterventions for GSV reflux over 5 years (£)	Total cost over 5 years (£)	QALYs over 5 years	Incremental cost (£)	Incremental QALY	ICER per QALY	Probability that treatment is cost-effective at threshold of £20 000 per QALY
Conservative	0	0	0	0	3.522	—	—	—	< 0.01
UGFS (LA)	202	101	125	429	3.836	429	0.314	1366	0.10
EVLA (LA)	698	161	173	1031	3.940	602	0.104	5799	0.35
RFA (LA)	776	166	168	1110	3.944	78	0.005	17 350	0.24
Surgery (DC)	980	12	251	1242	3.951	133	0.007	19 012	0.29
EVLA (GA)	1524	12	380	1915	3.954	—	—	ED	0.01
RFA (GA)	1602	12	351	1964	3.958	722	0.007	100 451	< 0.01
Surgery (IP)	1583	12	405	2000	3.951	—	—	D	0.00

This study suggested that either RFA or EVLA, performed under local/tumescent anaesthesia in an outpatient or office-based setting, or day-case traditional GSV surgery were likely to be cost-effective strategies for the treatment of primary GSV reflux at a conventional threshold for a cost per QALY in the UK. Interestingly, despite the perceived

# Cost-effectiveness of traditional and endovenous treatments for varicose veins

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# Comparative Costs

	<b>VNUS</b>	<b>Laser</b>	<b>Clarivein</b>
Catheter	£290	£250	£350
Tumescence / Drugs	£30	£30	£5
Generator	£50	£50	£0
Packs	£50	£50	£50
Total	£420	£380	£405

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Clarivein cost very similar, hence if QALY similar should be cost effective

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# Varicose veins in the legs

The diagnosis and management of varicose veins

*Clinical guideline*

*Methods, evidence and recommendations*

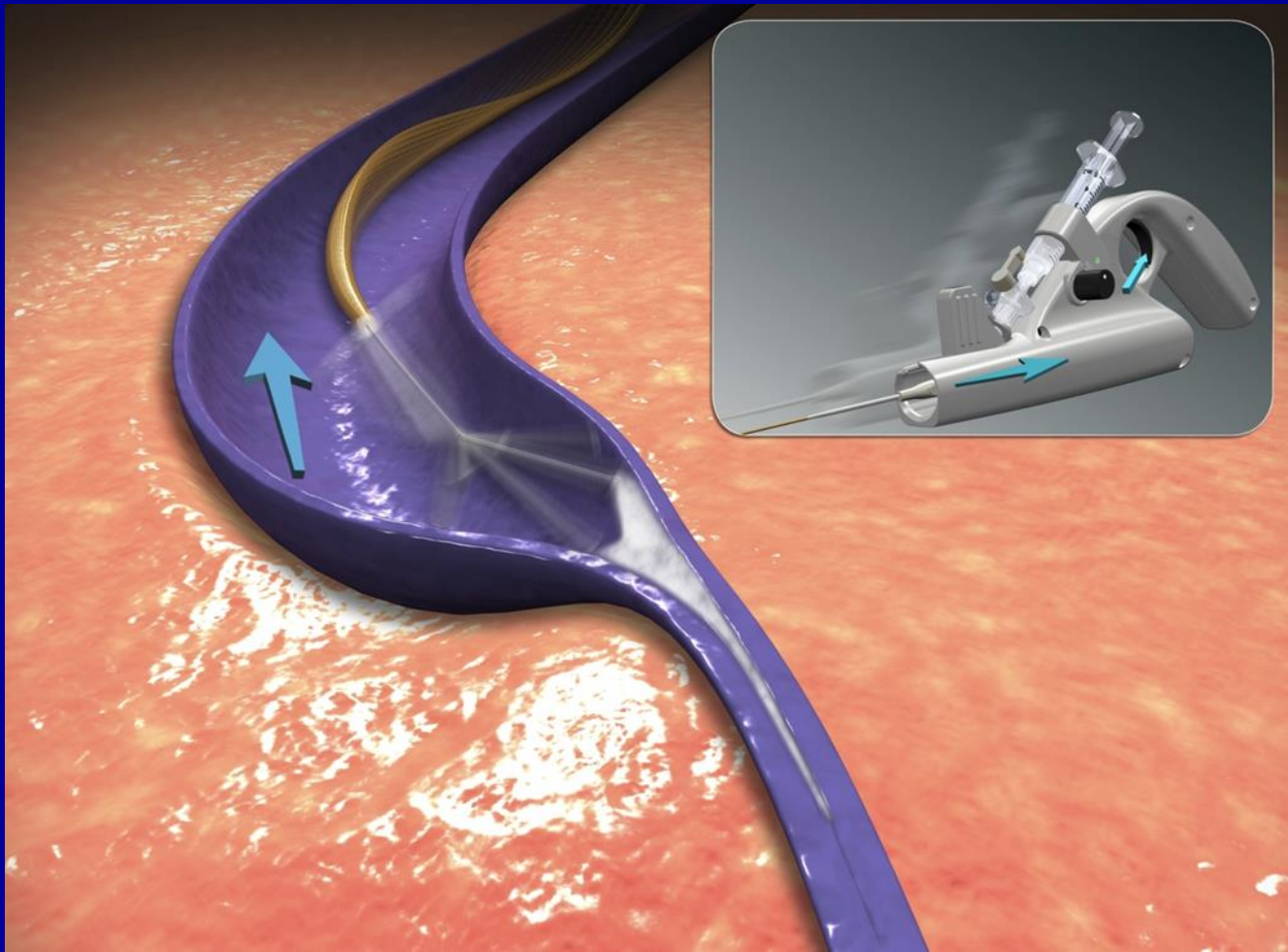
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Health and Clinical Excellence

*Final Version*

*Commissioned by the National Institute for  
Health and Care Excellence*







*"That's all Folks!"*