



Multicentre Randomised Controlled Trial Comparing Mechanochemical Ablation to Radiofrequency Ablation: The Venefit[™] versus Clarivein® for Varicose Veins (VVCVV) trial

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Varicose Veins

- Varicose veins are common
- Prevalence:
 - Men: 10-40%
 - Women: 20-51%
- Causes physical symptoms and can lead to complications (e.g., ulcers)
- Affects quality of life of patients





Radiofrequency Ablation (RFA)

- NICE guidelines recommends endothermal ablation
- Minimally invasive
- Efficacy: >90%
- Improves QoL
- Earlier return to normal activities (compared to surgery)
- Tumescent anaesthesia used can be painful





Mechanochemical Ablation (MOCA)

- Hybrid system:
 - Mechanical: rotating wire within venous lumen causes intimal injury (at 3500rpm)



- Chemical: sclerosant act on injured wall to produce fibrosis
- Efficacy: >90%
- Non-thermal, non-tumescent technique (NTNT)



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Venefit versus Clarivein for Varicose Veins (VVCVV) Trial

• Primary Outcome:

- Pain experienced during ablative procedure (but before tributary treatment)
- Methods:
 - Power calculations: 47 patients per group needed to show difference
 - Intended recruitment of 85 per group because of expected nonattendance at follow-up clinics
 - Patients with primary GSV or SSV reflux randomised to either MOCA or RFA
 - All procedures as day case
 - 2 sites: Charing Cross and Northwick Park





Baseline Characteristics and Veins Treated

	ΜΟϹΑ	RFA	p-value
Females (%)	57	60	0.669
Age (years) [SD]	55.1 [±18]	50.6 [±17]	0.091
Left leg treated (%)	41	55	0.068
GSV (%)	88	84	0.429
Length of vein treated (cm) [SD]	34 [±13]	35 [±14]	0.788
Vein diameter (mm) [SD]	7.0 [±2]	7.4 [±3]	0.325
Avulsions carried out (%)	68	75	0.258

CEAP Classification

CEAP	MOCA (%)	RFA (%)
1	0	0
2	18.5	25.0
3	27.5	22.4
4	45.0	44.7
5	6.3	6.6
6	2.5	1.3
		p=0.544

CONSORT Diagram





Maximum Pain Score - Median



p=0.028



Average Pain Score - Median



Secondary Outcomes

	<u>Baseline</u>			<u>1 month F/U</u>		
	MOCA (n=87)	RFA (n=83)	p-value	MOCA (n=66)	RFA (n=59)	p-value
Clinical Scores						
VCSS [SD]	6.4 [±3]	5.6 [±2]	0.097	2.7 [±3]	3.3 [±3]	0.279
VDS [SD]	1.4 [±0.5]	1.3 [±0.5]	0.166	0.52 [±0.7]	0.65 [±0.8]	0.365
QoL Scores						
AVVQ [SD]	23 [±12]	22 [±14]	0.805	14 [±9]	16 [±13]	0.381
EQ-VAS [SD]	80 [±16]	80 [±16]	0.947	84 [±11]	77 [±20]	0.041
EQ-5D [SD]	0.70 [±0.19]	0.75 [±0.22]	0.239	0.79 [±0.19]	0.77 [±0.24]	0.670

Time to Return to Normal Activities



p=0.721



Time to Return to Work



Secondary Outcomes

- Complete/proximal occlusion rate at 1 month:
 - MOCA: 91%
 - RFA: 92%





Complications

- Minor incidences of phlebitis in both groups
 - 3 in MOCA and 2 in RFA
- 2 DVTs
 - -1 in MOCA:
 - Left GSV treated
 - Tongue of thrombus extending into CFV (<50%) [ECIT 2]
 - -1 in RFA:
 - Right GSV treated
 - Calf vein DVT extension into gastrocnemius vein into popliteal vein



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Conclusion



- Maximum pain significantly less in MOCA compared to RFA
- Similar improvements in clinical and QoL scores in MOCA and RFA at 1 month



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Thank You!

