

CONTROVERSES ET ACTUALITÉS EN CHIRURGIE VASCULAIRE
**CONTROVERSIES & UPDATES
IN VASCULAR SURGERY**

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**MARRIOTT RIVE GAUCHE & CONFERENCE CENTER
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**PRESENTATION AND CRITICAL ANALYSIS OF EVRA STUDY
– Justification and methodology for EVRA**

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On behalf of MS Gohel, F Heatley, X Liu, A Bradbury, R Bulbulia, N Cullum, DM Epstein, I Nyamekye, KR Poskitt, S Renton MS, J Warwick, AH Davies and the EVRA trial investigators

Chief investigator : AH Davies, Trial Manager: F Heatley

NIHR HTA 11/129/197; ISRCTN023



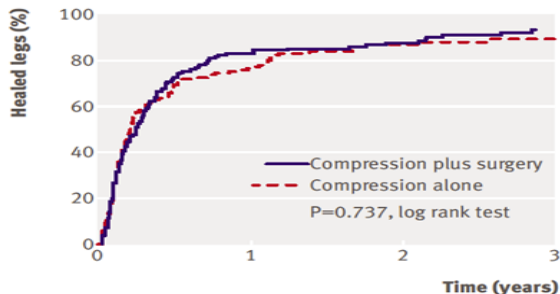
Disclosure

Speaker name:

.....**Isaac Nyamekye**

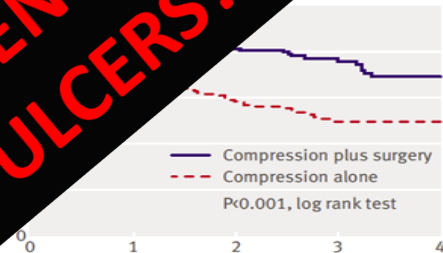
- ☐ I have the following potential conflicts of interest to report:
 - ☐ Consulting
 - ☐ Employment in industry
 - ☐ Shareholder in a healthcare company
 - ☐ Owner of a healthcare company
 - ☐ Other(s)
- ☒ I do not have any potential conflict of interest

ESCHAR STUDY



“Patients with open ulcers do not benefit from surgery in the treatment of superficial venous reflux”

6



“Superficial venous surgery reduces risk of ulcer recurrence”

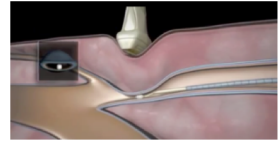
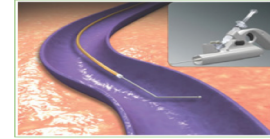
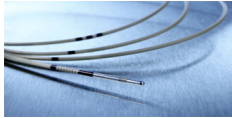
Not statistically powered to detect difference in healed -C5 & unhealed -C6 patients recruited)

Mean time to surgery was 12 weeks (delayed additional benefit of surgery on healing)

25% had limited reflux (junctional ligation alone under LA)

High treatment cross-over (20% of surgery arm refused surgical treatment)

2017: DOES SUPERFICIAL VENOUS REFLUX ABLATION HEAL ULCERS?



Effects of Endovenous Reflux Ablations on Ulcer Healing in Cohort Studies

- Superior healing rates with intervention (non-randomised)
- No 'level 1 or 2 evidence' to support intervention



EVRA study could help define the role of early reflux ablation in pathways of care for venous leg ulcers

Study design

- Multicentre
- Parallel-group
- Randomized controlled trial

INCLUSION CRITERIA

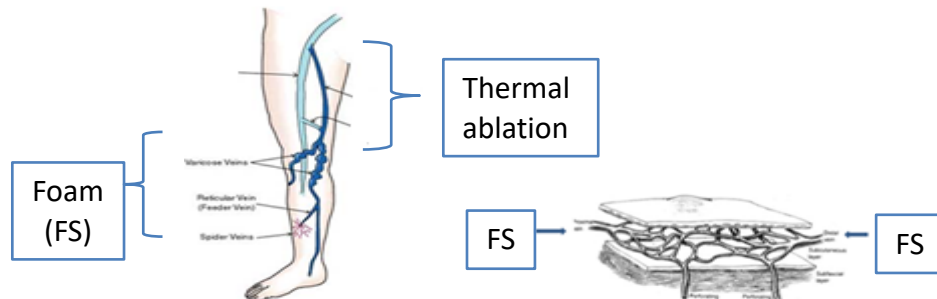
Patient age > 18 years
 ABPI > 0.8
 Primary or recurrent superficial reflux
Leg ulceration of duration: 6wks- 6mts

EXCLUSION CRITERIA

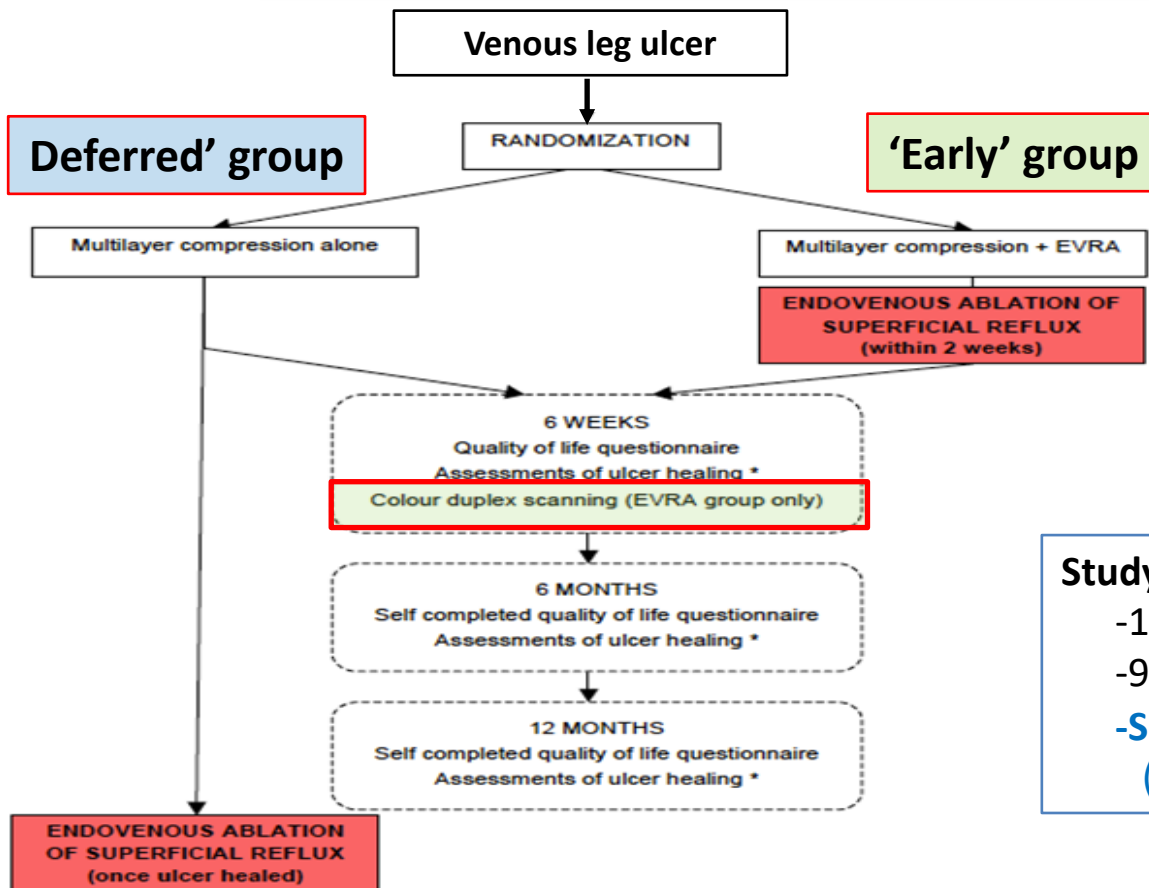
Unable to tolerate compression
 Deep venous occlusive disease
 Ulcer of non-venous aetiology
 Patient requiring skin grafting
 Pregnancy

Local treatment strategies

Any Endovenous ablation
 Ablate incompetent truncal vein(s)
 Treat to lowest point of reflux if possible
 Continue compression after intervention



Evaluate whether early endovenous ablation can improve venous ulcer healing in **addition to compression therapy**



Study power

- 15% (60% vs 75%) healing @24/52
- 90% power, 5% significance
- Sample size 450 patients**
(254 healing events)

Ulcer Healing

PRIMARY OUTCOME

Time to ulcer healing



ulcer healed?

Core lab
Verification

EVRA EVRA Trial ID ☐ ☐ ☐

ULCER HEALED

Date patient informed site ulcer was healed (Also date of visit)	-- / -- / 20 -- (DD / MMM / YYYY)
WEEK 1	
Date of verification visit	-- / -- / 20 -- (DD / MMM / YYYY)
Photographic evidence has been sent to the trials unit:	☐ Yes ☐ No (SEND NOW!)
Date of the photo	-- / -- / 20 -- (DD / MMM / YYYY)
WEEK 2	
Photographic evidence has been sent to the trials unit:	☐ Yes ☐ No (SEND NOW!)
Date of the photo	-- / -- / 20 -- (DD / MMM / YYYY)
WEEK 3	
Photographic evidence has been sent to the trials unit:	☐ Yes ☐ No (SEND NOW!)
Date of the photo	-- / -- / 20 -- (DD / MMM / YYYY)
WEEK 4	
Photographic evidence has been sent to the trials unit:	☐ Yes ☐ No (SEND NOW!)
Date of the photo	-- / -- / 20 -- (DD / MMM / YYYY)

Outcome measures

SECONDARY

Ulcer healing rate (24 weeks)

Rate of ulcer recurrence to 12 months

Ulcer free time (after f/u to 1 year)

Venous Clinical Severity Score (VCSS)

Quality of life (AVVQ, EQ-5D-5L, SF36)

Cost effectiveness

Statistical analysis

ULCER HEALING

Unadjusted Cox regression model with recruiting centre as a random effect (prespecified analysis)

ULCER FREE TIME

Ordered logistic regression

Statistical significance: a two-sided alpha level of 5%.

Trial centres



- London (Prof A Davies)
- Cheltenham (Mr K Poskitt)
- Worcester (Mr I Nyamekye)
- Harrow (Miss S Renton)
- Cambridge (Mr M Gohel)
- HEFT (Prof A Bradbury)
- UHB (Mr Rajiv Vohra)
- Dudley/Wolverhampton (Mr A Garnham)
- York (Mr Andrew Thompson)
- Hull (Mr Daniel Carradice)
- Bournemouth (Mr Dynesh Rittoo)
- Plymouth (Mr Jamie Barwell)
- Frimley Park (Mr Patrick Chong)
- Carlisle (Mr Thomas Joseph)
- Leeds (Prof Julian Scott)
- Salisbury (Miss Sarah Hulin)
- Bradford (Mr Kevin Mercer)
- Sheffield (Mr Dominic Dodd)
- Taunton (Mr James Coulston)

- Prof N Cullum, Mr R Bulbulia, Dr D Epstein, Dr J Warwick



ORIGINAL

A Randomized Trial of Endovenous Ablation for Venous Ulceration

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 Andrew Bradbury, M.D., Nicky Cullum, Ph.D.,
 David M. Fennell, M.D., Keith R. Poskitt, M.D.,
 Sophie Renwick, Ph.D., and Alun H. Davies, D.Sc., for the
 Trial Investigators*

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