



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

FEBRUARY 7-9 2019

MARRIOTT RIVE GAUCHE & CONFERENCE CENTER
PARIS, FRANCE

WWW.CACVS.ORG



**Strengths and limitations
of EVRA**

Disclosure

Speaker name:

Marianne De Maeseneer

I have the following potential conflicts of interest to report:

Consulting

Employment in industry

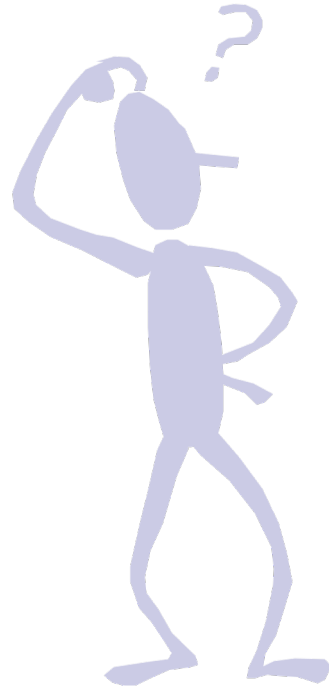
Shareholder in a healthcare company

Owner of a healthcare company

Other(s)

I do not have any potential conflict of interest

Strengths of E RA



Strengths – study hypothesis

- Clear clinical question:

What is the effect of early endovenous ablation of superficial venous reflux on ulcer healing?

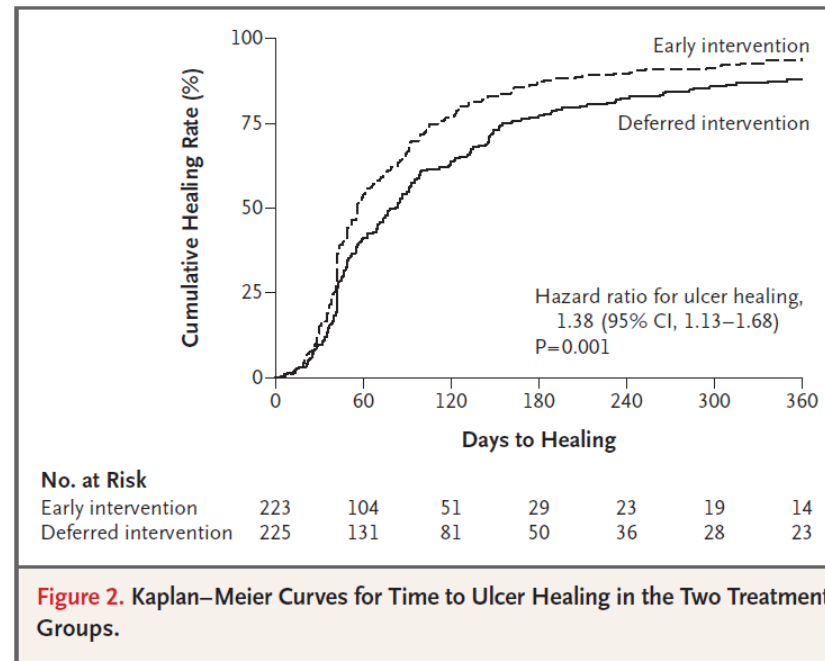
Strengths - methodology

- Randomized Trial – multicenter
- Calculation of the study sample – sufficiently powered
- Clear inclusion/exclusion criteria
- Proper randomization
- Standardized interventions
- Outcome criteria well defined: primary, secondary outcome

- ~ **PICO**

Strengths - results

- n = 450 inclusions were reached (3 yr)
- Baseline characteristics: no difference
- Timing and type of intervention clearly mentioned
- Kaplan-Meier analysis:



Strenghts – publication in NEJM

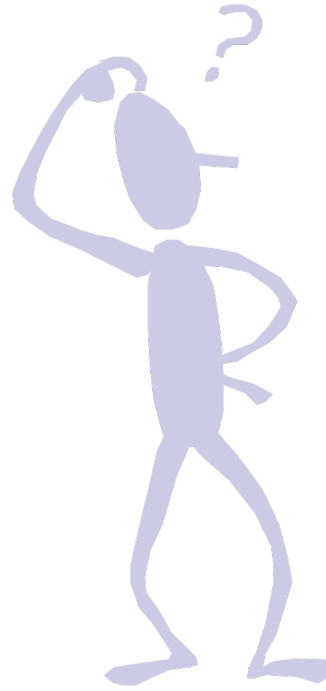
The NEW ENGLAND JOURNAL *of* MEDICINE

ORIGINAL ARTICLE

A Randomized Trial of Early Endovenous Ablation in Venous Ulceration

Manjit S. Gohel, M.D., Francine Heatley, B.Sc., Xinxue Liu, Ph.D.,
Andrew Bradbury, M.D., Richard Bulbulia, M.D., Nicky Cullum, Ph.D.,
David M. Epstein, Ph.D., Isaac Nyamekye, M.D., Keith R. Poskitt, M.D.,
Sophie Renton, M.S., Jane Warwick, Ph.D., and Alun H. Davies, D.Sc.,
for the EVRA Trial Investigators*

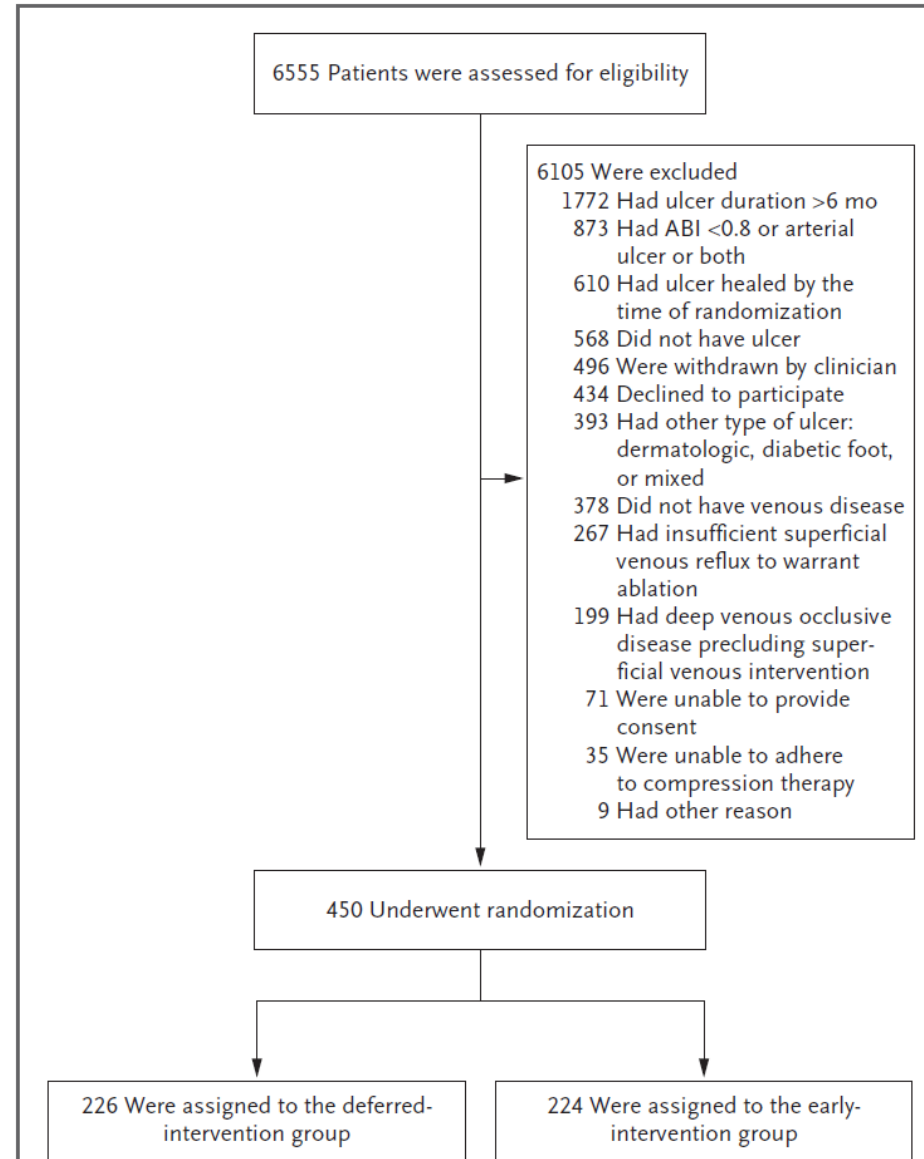
Limitations of E RA



Inclusions:

6555

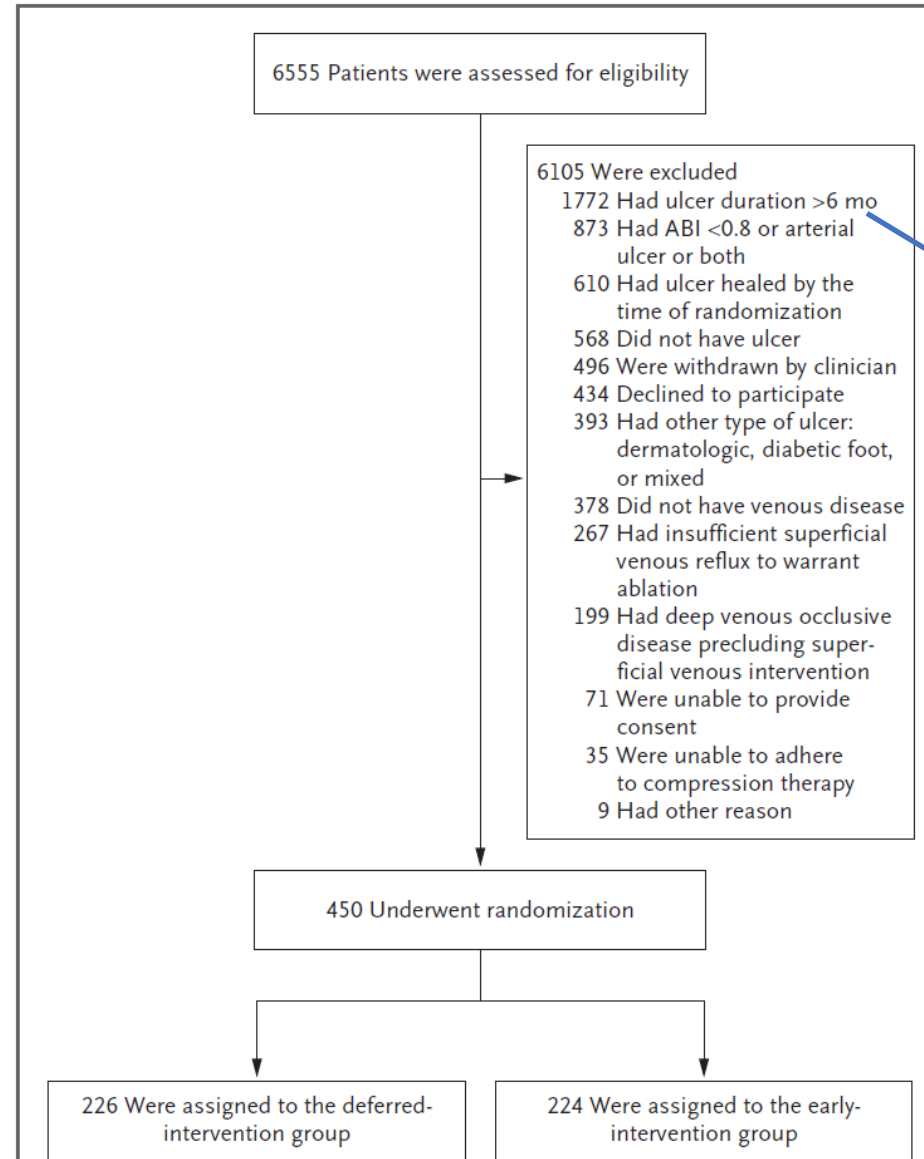
450
↓
= 7%



Inclusions:

6555

450
↓
= 7%



27% had ulcer for > 6 months!

Different ablation techniques:

Variable	Early Intervention (N = 224)	Deferred Intervention* (N = 226)
Type of endovenous intervention		
Endothermal ablation only§	71 (31.7)	54 (23.9)
Foam sclerotherapy only¶	111 (49.6)	100 (44.2)
Mechanochemical ablation only	5 (2.2)	1 (0.4)
Endothermal ablation and foam sclerotherapy§¶	27 (12.1)	16 (7.1)
Mechanochemical ablation and foam sclerotherapy¶	3 (1.3)	0
Abandoned treatment	1 (0.4)	0
No treatment	6 (2.7)	55 (24.3)

Small size of the ulcers:

Table 1. Baseline Characteristics of the Trial Participants.*		
Characteristic	Early Intervention (N=224)	Deferred Intervention (N=226)
Ulcer location		
Medial	116 (51.8)	118 (52.2)
Lateral	92 (41.1)	93 (41.2)
Circumferential	9 (4.0)	7 (3.1)
Not recorded	7 (3.1)	8 (3.5)
Median ulcer size (interquartile range) — cm ² **	2.4 (1.0–7.7)	2.9 (1.1–8.7)
Median score on Venous Clinical Severity Score assessment tool at baseline (interquartile range) ††	15 (14–18)	16 (14–18)
Presence of deep venous reflux ‡‡	74 (33.0)	69 (30.5%)

Summary - limitations

- Only 7% included:
 - ¼ chronic (more than 6 months)
 - chronic ulcers may have more deep vein disease
- Different ablation techniques used
- Small ulcer size (median 2-3 cm²)
- Varying extent of superficial and deep venous reflux
- DUS @ 6 weeks after intervention only required in 'early intervention' group
- Short FU (1 year) – recurrence?



10th *evf* HOW 2019

HANDS-ON WORKSHOP on VENOUS DISEASE

Lielupe Hotel, Jurmala (Riga), Latvia

17-19 Oct, 2019

www.evfvip.com