Steam *vs* **laser** the results of a RCT

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Disclosure

Speaker name: Renate van den Bos

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x I do not have any potential conflict of interest

First RCT on Endovenous Steam Ablation

Randomized clinical trial

Randomized clinical trial of endovenous laser ablation *versus* steam ablation (LAST trial) for great saphenous varicose veins

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Background: The aim was to compare endovenous laser ablation (EVLA) and endovenous steam ablation (EVSA) for great saphenous varicose veins in a non-inferiority study.

Methods: Patients with primary great saphenous vein reflux were randomized to EVLA (940 nm) or EVSA (SVS™). Primary outcomes were treatment success (vein obliteration) at 52 weeks, and Venous Clinical Severity Score (VCSS) at 12 weeks. Secondary outcomes were pain, satisfaction with treatment, duration of analgesia use and days lost from daily activities, changes in Aberdeen Varicose Vein Questionnaire (AVVQ) and EQ-5D™ scores after 12 weeks, and complications at 2 and 12 weeks.

Results: A total of 227 legs were treated (EVSA, 117; EVLA, 110); 36 legs treated with EVSA received a low dose and the remaining 81 a higher dose. At 1 year, the treatment success rate after high-dose EVSA was not inferior to that of EVLA: 92 (95 per cent confidence interval (c.i.) 86 to 98) *versus* 96 (92 to 100) per cent respectively. Changes in VCSS after 12 weeks were similar: −2·69 (95 per cent c.i. −2·34 to −3·04) and −2·51 (−2·10 to −2·93). AVVQ, EQ-5D™ and EQ VAS scores improved equally 12 weeks after both treatments. Patients treated with EVSA reported less postprocedural pain, fewer days of analgesia use, were more satisfied with therapy, and had a shorter convalescence. Complication rates were comparable.

Conclusion: The 1-year treatment success of high-dose EVSA was not inferior to that of EVLA. Several secondary outcomes were in favour of EVSA. Registration number NCT02046967 (http://www.clinicaltrials.gov).

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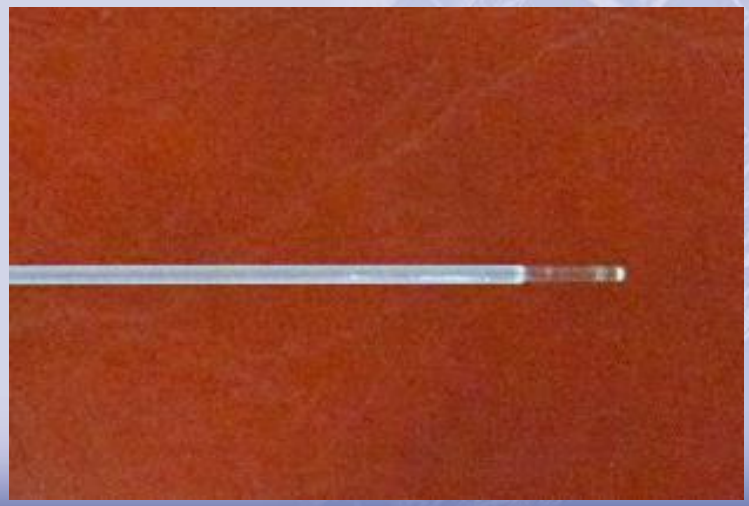
Methods

- Multicentre trial
- Non-inferiority design
- Primary insufficient GSVs



Methods - Treatments

EVSA

- First 36 legs:
  - 1 puls/cm <7 mm
  - 2 pulses/cm 7-10 mm
  - 3 pulses/cm >10 mm
- Following 81 legs:
  - 2 pulses/cm <7 mm
  - 3 pulses/cm 7-10 mm
  - 4 pulses/cm >10 mm

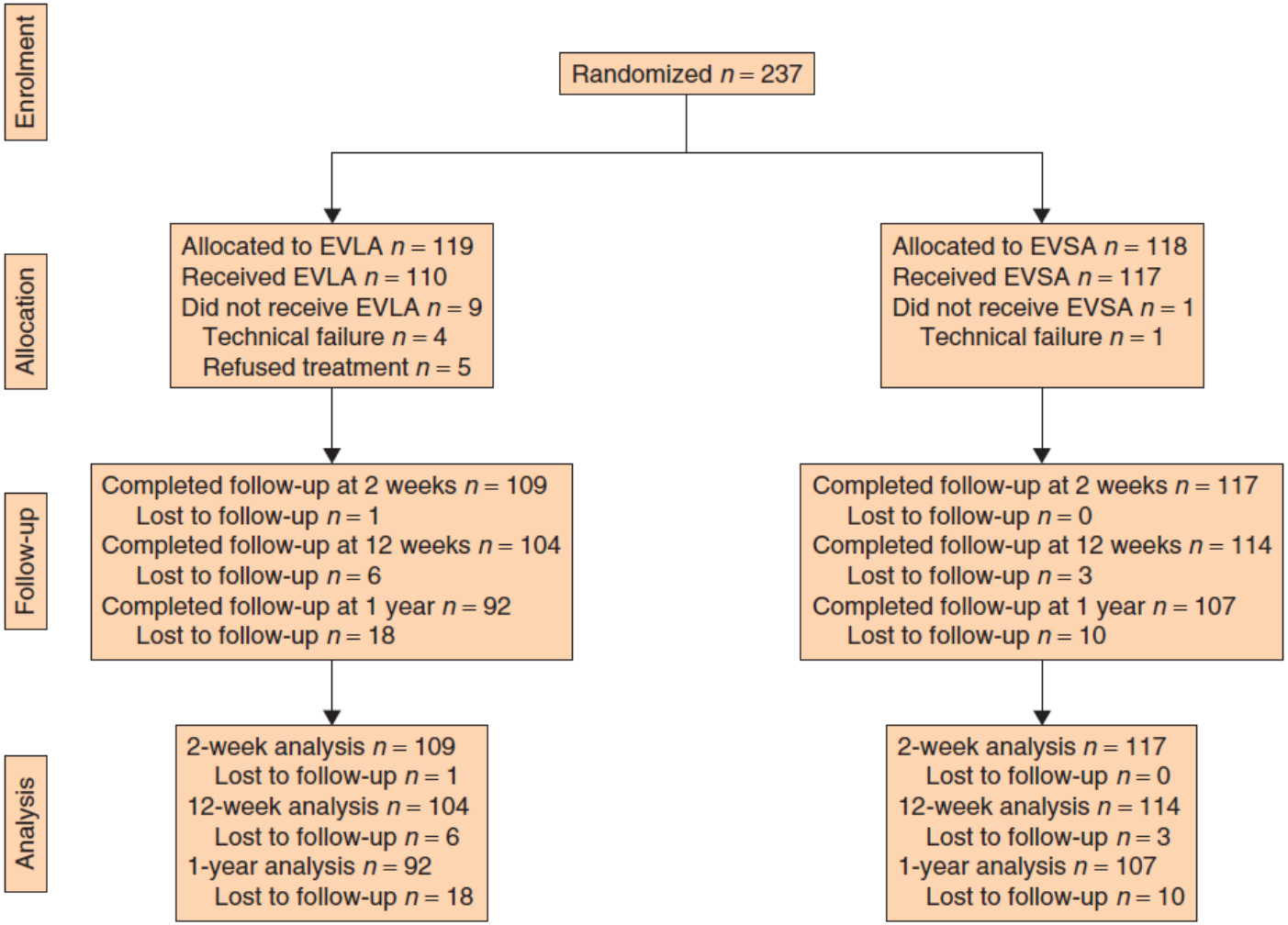
EVLA

- 940 nm
- Bare fiber
- 12 W
- 60 J/cm

Methods - Outcomes

- **Outcomes**
  - Primary
    - Succes of treatment
    - VCSS
  - Secondary (PROs)
    - Pain, painkiller use, satisfaction, number of days off
    - QoL (AVVQ and EQ-5D questionnaires)

- **Follow-up**
  - 2, 12 en 52 weeks


Enrolment
Randomized n = 237
Allocation
Allocated to EVLA n = 119
Received EVLA n = 110
Did not receive EVLA n = 9
Technical failure n = 4
Refused treatment n = 5
Allocated to EVSA n = 118
Received EVSA n = 117
Did not receive EVSA n = 1
Technical failure n = 1
Follow-up
Completed follow-up at 2 weeks n = 109
Lost to follow-up n = 1
Completed follow-up at 12 weeks n = 104
Lost to follow-up n = 6
Completed follow-up at 1 year n = 92
Lost to follow-up n = 18
Completed follow-up at 2 weeks n = 117
Lost to follow-up n = 0
Completed follow-up at 12 weeks n = 114
Lost to follow-up n = 3
Completed follow-up at 1 year n = 107
Lost to follow-up n = 10
Analysis
2-week analysis n = 109
Lost to follow-up n = 1
12-week analysis n = 104
Lost to follow-up n = 6
1-year analysis n = 92
Lost to follow-up n = 18
2-week analysis n = 117
Lost to follow-up n = 0
12-week analysis n = 114
Lost to follow-up n = 3
1-year analysis n = 107
Lost to follow-up n = 10

Results – Primary outcomes

	Treatment success T=12	Treatment success T=52	Change in VCSS T=12
EVLA	97.1% (93.8, 100)	95.6% (92.0, 100)	-2.51 (-2.10, -2.93)
EVSA (all)	93.9% (89.5, 98.3)	86.9% (80.5, 93.3)	-2.90 (-2.42, -3.58)
P	0.251	**0.032**	0.242
EVSA (high dose)	97.4% (93.9, 100)	91.9% (85.8, 98.1)	-2.69 (-2.34, -3.04)
P	0.896	**0.311**	0.279

Results - PROs

	EVLA	EVSA (all)	P	EVSA (high dose)	P
T=2 weeks	n=109	n=116		n=81	
Pain (VAS)	5.1 (4.7, 5.6)	2.6 (2.1, 3.1)	<0.001	2.7 (2.1, 3.3)	<0.001
Satisfaction (VAS)	7.7 (7.3, 8.1)	8.6 (8.3, 9.0)	0.001	8.5 (8.1, 8.9)	0.007
Painkiller use (days)	3.3 (2.6, 4.1)	0.9 (0.5, 1.4)	<0.001	1.5 (0.5, 1.8)	<0.001
Days off	4.2 (3.4, 5.0)	1.6 (1.0, 2.1)	<0.001	1.6 (0.9, 2.3)	<0.001

Results - QoL

	EVLA	EVSA (all)	EVSA (high dose)
T=12 weeks	n=104	n=114	n=78
AVVQ delta	-5.47 (-3.93, -7.01)	-5.17 (-3.63, -6.70)	-5.10 (-3.14, -7.06)
EQ-5D delta	0.039 (0.010, 0.067)	0.05 (0.011, 0.059)	0.033 (0.003, 0.062)
EQ VAS delta	1.9 (0.4, 3.4)	0.8 (-0.9, 2.4)	0.0 (-2.1, 2.1)

Results - Complications

	EVLA	EVSA (all)
T=2 weeks	n=109	n=117
DVT	1 (0.9%)	0 (0%)
SVT	10 (9.2%)	10 (8.5%)
Nerve injury	0 (0%)	1 (0.9%)
Skin infection	0 (0%)	1 (0.9%)
Ecchymosis (cm^2)	4.5 (13.1)	1 (3.1)
Hyperpigmentation (cm^2)	0.9 (3.9)	0.9 (4.6)
T=12 weeks	n=98	n=107
SVT	0 (0)	3 (2.8)
Nerve injury	0 (0)	2 (1.9)
Hyperpigmentation (cm^2)	0.1 (0.5)	(0.3 (1.8)

Limitations of this study

- Change in dose EVSA during study
- EVLA with 940 nm and bare fiber
- Blinding impossible

Conclusions of this RCT

1. Success of treatment 1 year FU: EVSA is not inferior to EVLA

2. Efficacy of EVSA is better with higher dose (more pulses/cm)

3. PROs seem to be better for EVSA