

Imperial College
London

Updates on the cost effectiveness of glue and MOCA techniques vs thermal ablation



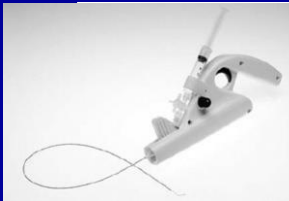
Professor Alun H Davies
Section of Vascular Surgery,
Imperial College,
Charing Cross & St Mary's Hospital,
London

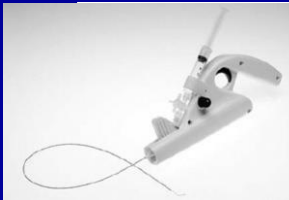


Disclosures

- Grants:- NIHR, RCS, EVF, Circulation foundation, Stroke association.
- Commercial support:- Biolas, Vascular Insights, Urgo Laboratoire, Acergy, Medtronic, Firstkind, Veniti.



		SAMPLE SIZE	DURATION	OCCCLUSION	VENOUS CLINICAL SEVERITY SCORE (VCSS)	PATIENT PAIN SCORES (VAS 100MM OR 10 POINT)	RETURN TO NORMAL ACTIVITIES/ WORK	MAJOR ADVERSE EVENTS
	ELIAS ET AL, 2013 ¹¹	29 patients 30 limbs	2 years	Immediate- 100% 6 months- 96.7% 2 years – 96%	N/A	No complaints of pain	N/A	None
	OZEN ET AL, 2014 ¹⁵	63 patients 73 limbs	2 years	Immediate- 98% 6 months- 94% 1 year- 95% 2 years- 95%	6 Months: -3.2 1 year: -1.2 2 years: -1.1	N/A	N/A	None
	BOERSMA ET AL, 2012 ¹²	50 patients	1 year	Immediate- 100% 6 Week- 100% 1 Year- 94%	Baseline- 3.0 6 weeks- 1.0 1 year 1.0	2	N/A	None
	BOOTUN ET AL, 2014 ⁶	117 patients 119 limbs (59 ClariVein limbs)	1 month	92%	N/A	19.3 mm	3.5 days/ 5.3 days *patients in Great Britain historically take more time for recovery	None
	VAN EEKEREN ET AL, 2014 ⁹	92 patients 106 limbs	6 months	Immediate- 100% 6 months- 93.2% 1 year- 88.2%	Baseline- 4.0 6 months- 1.0 1 year- 1.0	20 mm 14 days- 7.5mm	1 day/ 1 day	None
	BISHAWI ET AL, 2013 ¹⁰	126 patients	6 months	Immediate- 100% 6 months- 94%	Baseline- 9.0 1 week- 6.5 3 months- 4.0 6 months- 3.0	2 1 week- >1	N/A	None
	VAN EEKEREN ET AL, 2013 ⁸	68 patients (34 ClariVein)	6 weeks	N/A	Baseline- 3.0 6 weeks- 1.0	22 3 days- 6.2 14 days- 4.8	1 day/ 1 day	None
	VAN EEKEREN ET AL, 2011 ¹³	25 patients 30 limbs	6 weeks	Immediate- 100%	Baseline 3.0 6 weeks 1.0	4 7 days- 2 mm	N/A	None
	VUN ET AL, 2014 ⁷	127 patients 147 limbs (57 ClariVein limbs)	Immediate	91%	N/A	1	N/A	None



	SAMPLE SIZE	DURATION	OCCCLUSION	VENOUS CLINICAL SEVERITY SCORE (VCSS)	PATIENT PAIN SCORES (VAS 100MM OR 10 POINT)	RETURN TO NORMAL ACTIVITIES/ WORK	MAJOR ADVERSE EVENTS
ELIAS ET AL, 2013 ¹¹	29 patients 30 limbs	2 years	Immediate- 100% 6 months- 96.7% 2 years – 96%	N/A	No complaints of pain	N/A	None
Overall	1000 + cases overall 95% + closure rate Marked improvement in VCSS Safe Rapid recovery						
BOER							
BOER							
VAN EKEREN ET AL, 2013 ⁸	33 patients (34 ClariVein)	6 weeks	N/A	Baseline- 3.0 6 weeks- 1.0	3 days- 6.2 14 days- 4.8	1 day/ 1 day	None
VAN EKEREN ET AL, 2011 ¹³	25 patients 30 limbs	6 weeks	Immediate- 100%	Baseline 3.0 6 weeks 1.0	4 7 days- 2 mm	N/A	None
VUN ET AL, 2014 ⁷	127 patients 147 limbs (57 ClariVein limbs)	Immediate	91%	N/A	1	N/A	None



Clinical Studies with VenaSeal™ System

Feasibility Study

- 38 Patients, enrollment completed Aug. 2011
- 1, 3, 6, 12, 24 and 36 month follow-ups
- Primary endpoint: Safety: rate of serious adverse events, Efficacy: vein closure during follow-up

eSCOPE

(European multicenter study)

- 70 patients, enrollment completed Sept. 2012
- 2 day, 1, 3, 6, 12, 24 and 36 month follow-ups
- Primary endpoint: closure w/o use of sedation, tumescent anesthesia or compression stockings

VeClose

(U.S. pivotal trial)

- 242 patients, enrollment completed Sept. 2013
- 3 day, 1, 3, 6, 12 months & 2, 3 year follow-ups
- Primary endpoint: non-inferior to RFA in GSV closure
- Secondary endpoint: superiority in reduction of post procedural pain and bruising



Clinical Studies with VenaSeal™ System

Feasibility Study

- 38 Patients, enrollment completed Aug. 2011
- 1, 3, 6, 12, 24 and 36 month follow-ups
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COOPER

- 70 patients, enrollment completed Sept. 2012

Venaseal equivalent initial clinical results to Venefit

VeClose (U.S. pivotal trial)

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- 3 day, 1, 3, 6, 12 months & 2, 3 year follow-ups
- Primary endpoint: non-inferior to RFA in GSV closure
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PROS

CONS



Quality of life & occlusion rates @ 1 year

Technique	Quality of life improvement	Occlusion rate greater than 90%
RFA	+++	√√
Laser	+++	√√
Foam	++ (+)	XX
Steam	??	X
MOCA	+++	√√
Glue	+++	√ √

Endovenous mechanochemical ablation for varicose veins

Interventional procedure guidance

Published: 25 May 2016

nice.org.uk/guidance/ipg557



1 Recommendations

- 1.1 Current evidence on the safety and efficacy of endovenous mechanochemical ablation for varicose veins appears adequate to support the use of this procedure provided that standard arrangements are in place for consent, audit and clinical governance. Clinicians are encouraged to collect longer-term follow-up data.

Cost-effectiveness of traditional and endovenous treatments for varicose veins

M. S. Gohel¹, D. M. Epstein² and A. H. Davies¹

¹Imperial Vascular Unit, Charing Cross Hospital, London, and ²Centre 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)

Eur J Vasc Endovasc Surg (2015) 50, 794–801

A Cost-effectiveness Analysis of Surgery, Endothermal Ablation, Ultrasound-guided Foam Sclerotherapy and Compression Stockings for Symptomatic Varicose Veins

G. Marsden ^{a,f,*}, M. Perry ^a, A. Bradbury ^b, N. Hickey ^c, K. Kelley ^a, H. Trender ^d, D. Wonderling ^a, A.H. Davies ^e

^a National Clinical Guideline Centre, Royal College of Physicians, London, UK

^b University Department of Vascular Surgery, University of Birmingham, Solihull, UK

^c Worcestershire Royal Hospital, Worcester, UK

^d Sheffield Vascular Institute, Sheffield Teaching Hospital Foundation Trust, Sheffield, UK

^e Department of Surgery & Cancer, Imperial College & Imperial College NHS Trust, Charing Cross Hospital, London, UK

COST-EFFECTIVENESS OF RADIOFREQUENCY ABLATION VERSUS LASER FOR VARICOSE VEINS

Amanda C. Shepherd

Academic Section of Vascular Surgery, Imperial College School of Medicine, Charing Cross Hospital

Marta Ortega-Ortega

Department of Applied Economics, University of Granada

mortega2@ugr.es

Manj S. Gohel

Academic Section of Vascular Surgery, Imperial College School of Medicine, Charing Cross Hospital;
and Department of Vascular Surgery, Addenbrooke's Hospital Cambridge

David Epstein

Department of Applied Economics, University of Granada

Louise C. Brown

Medical Research Council, Clinical Trials Unit, University College London

Alun H. Davies

Academic Section of Vascular Surgery, Imperial College School of Medicine, Charing Cross Hospital

Cost-effectiveness of ultrasound-guided foam sclerotherapy, endovenous laser ablation or surgery as treatment for primary varicose veins from the randomized CLASS trial

E. Tassie¹, G. Scotland^{1,2}, J. Brittenden³, S. C. Cotton², A. Elders², M. K. Campbell², B. Campbell⁴, M. Gough⁵, J. M. Burr⁶ and C. R. Ramsay² on behalf of the CLASS study team

¹Health Economics Research Unit, ²Health Services Research Unit and ³Division of Applied Medicine, University of Aberdeen, Aberdeen, ⁴Royal Devon and Exeter Hospital and University of Exeter Medical School, Exeter, ⁵Vascular Surgery, Vascular Laboratory, St James's University Hospital, Leeds, and ⁶School of Medicine, Medical and Biological Sciences, University of St Andrews, St Andrews, UK

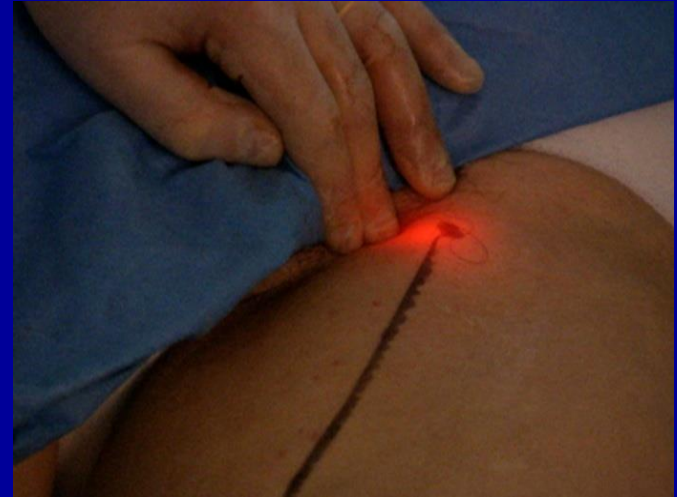
Correspondence to: Ms E. Tassie, Health Economics Research Unit, University of Aberdeen, Foresterhill, Aberdeen AB25 2ZD, UK

(e-mail: e.tassie@abdn.ac.uk)

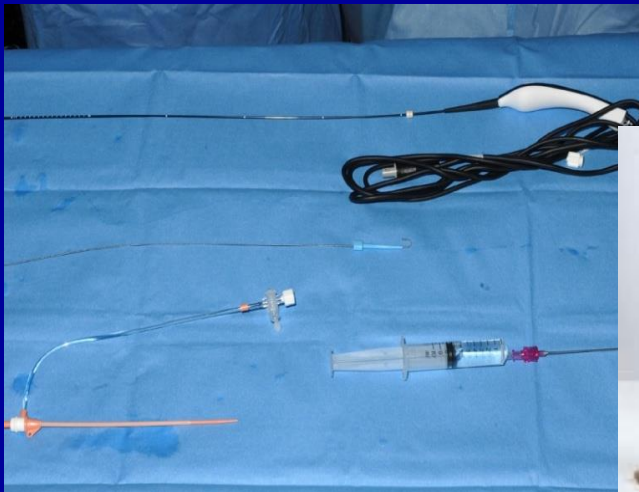
Treatment options



Surgery



Laser

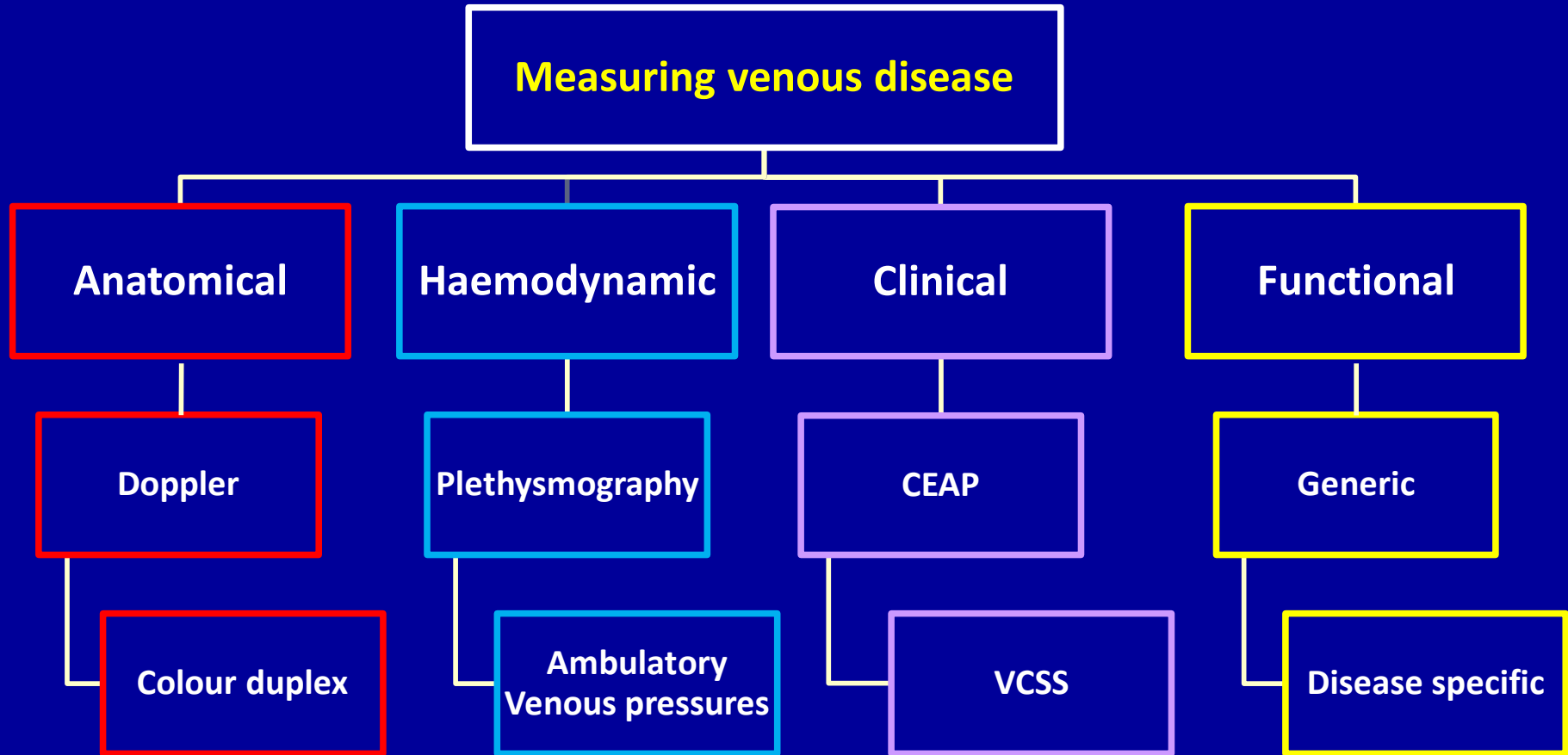


Radiofrequency

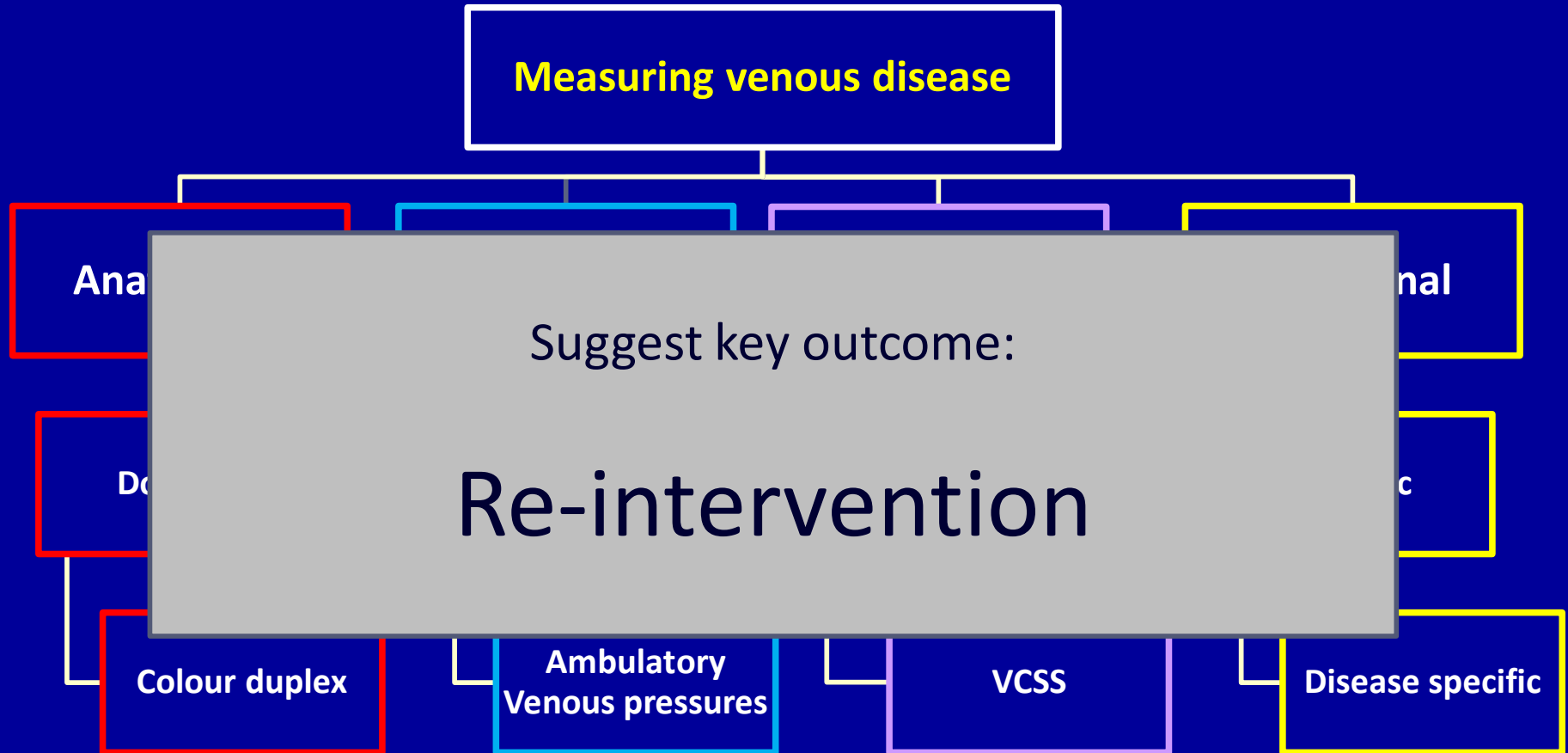


Sclerotherapy

How to measure outcomes in venous disease?



How to measure outcomes in venous disease?



Aims

1. Systematic review of the literature with particular emphasis on MOCA and cyanoacrylate
2. Determine the cost-effectiveness of the newer non-thermal interventions

Methods

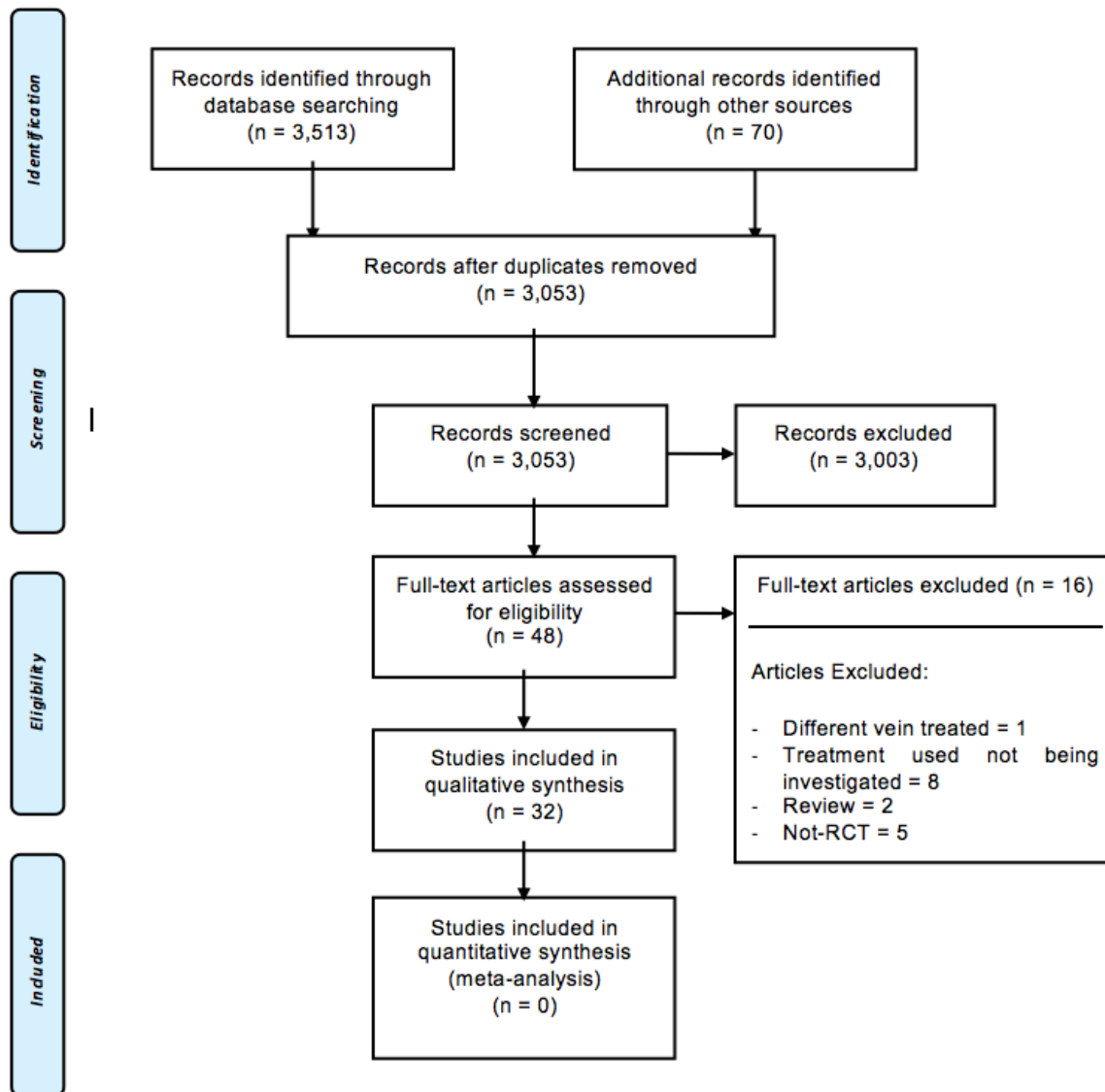
- Systematic review of the literature to determine the relative effectiveness of each intervention (RFA, EVLA, Surgery, MOCA, CAE and Conservative care)
 - Protocol on PROSPERO: CRD42015029618
- Cost-effectiveness of each intervention



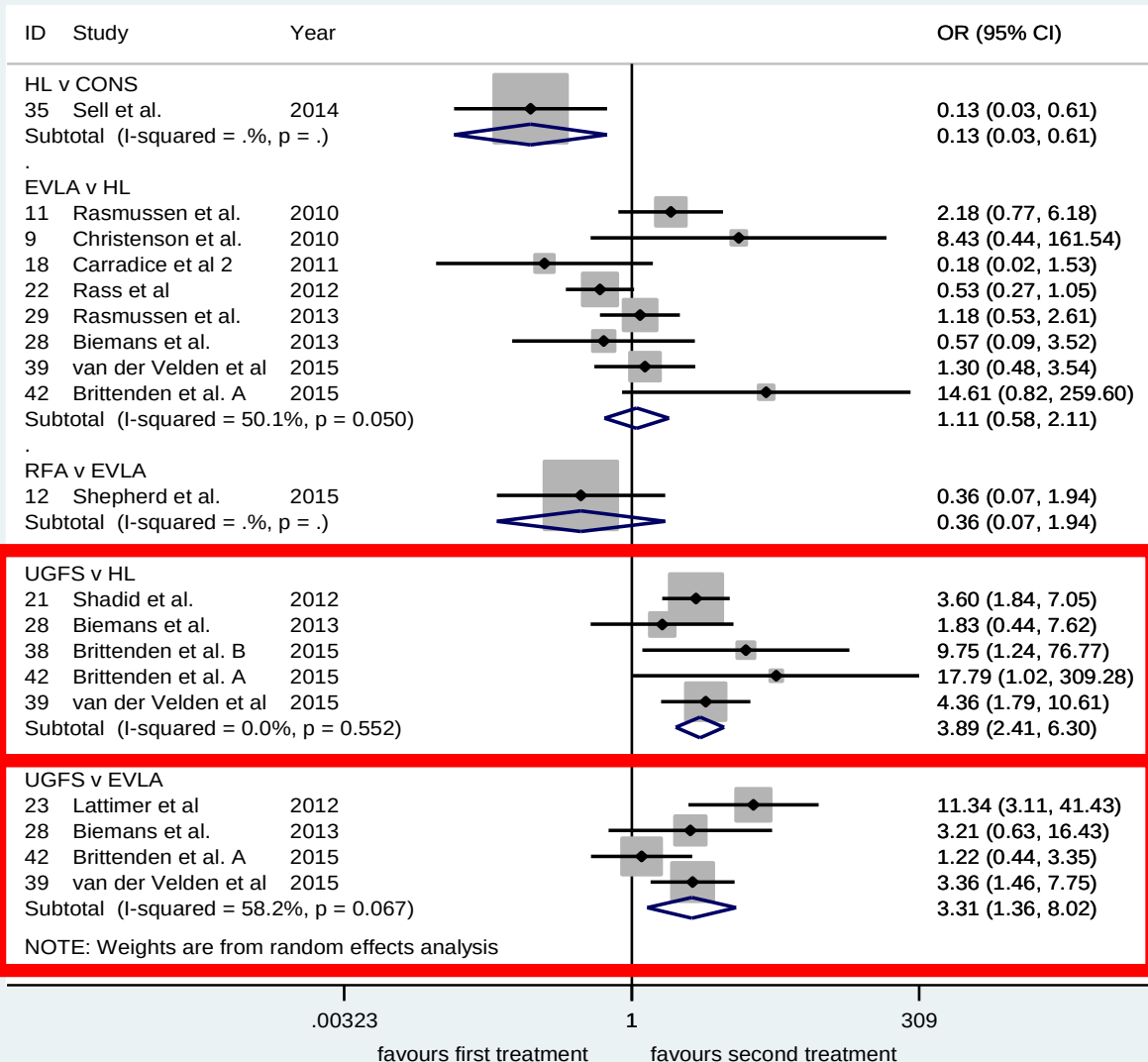
Results

- 33 RCTs included
- Further 10 non-RCTs evaluating MOCA and CAE
- Intervention on truncal vein re-intervention available from 16 studies (13 RCTs and 3 non-RCTs)
- 1 non-RCT of re-intervention post-MOCA and no studies on re-intervention post-CAE

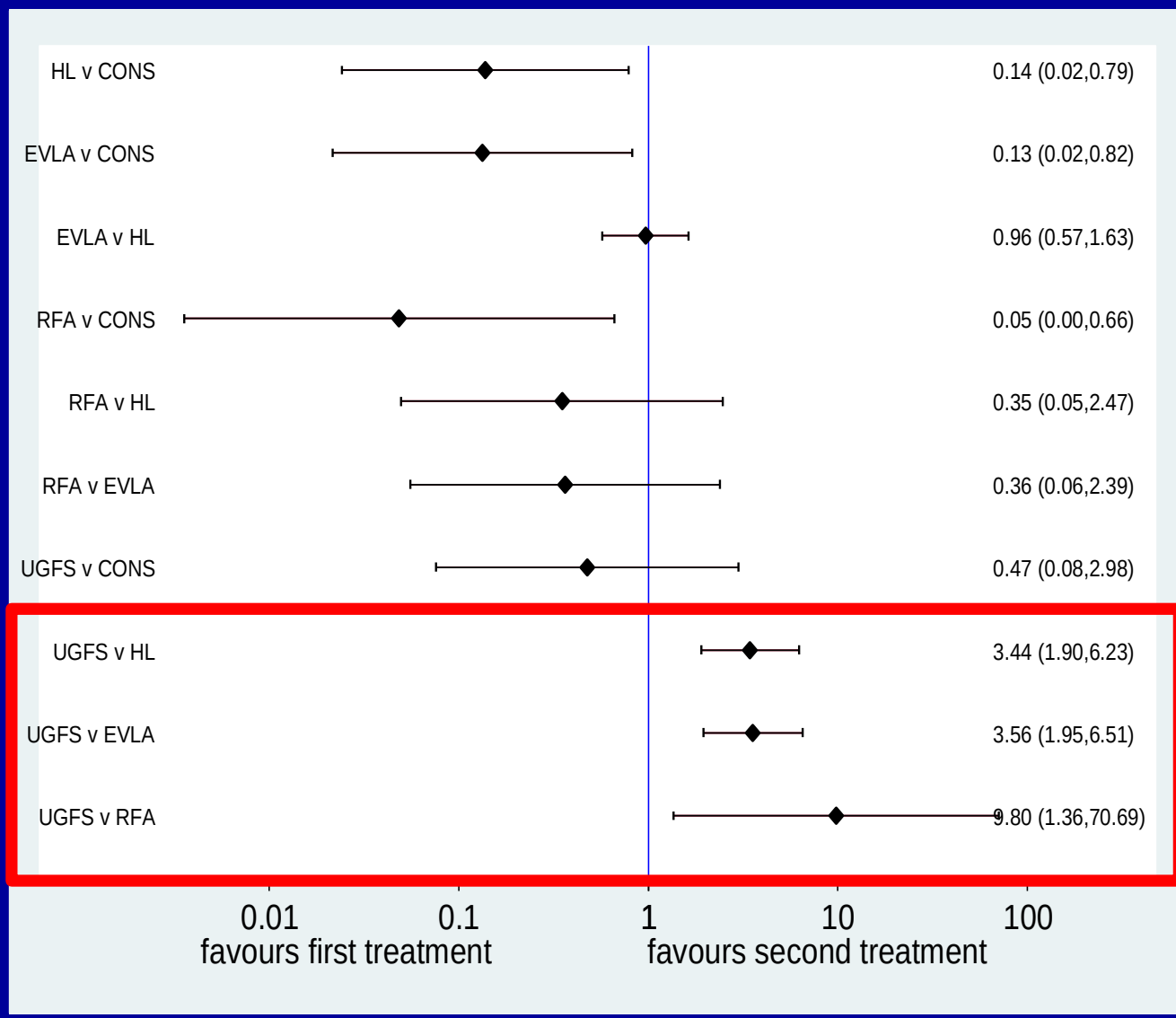
Prisma Diagram



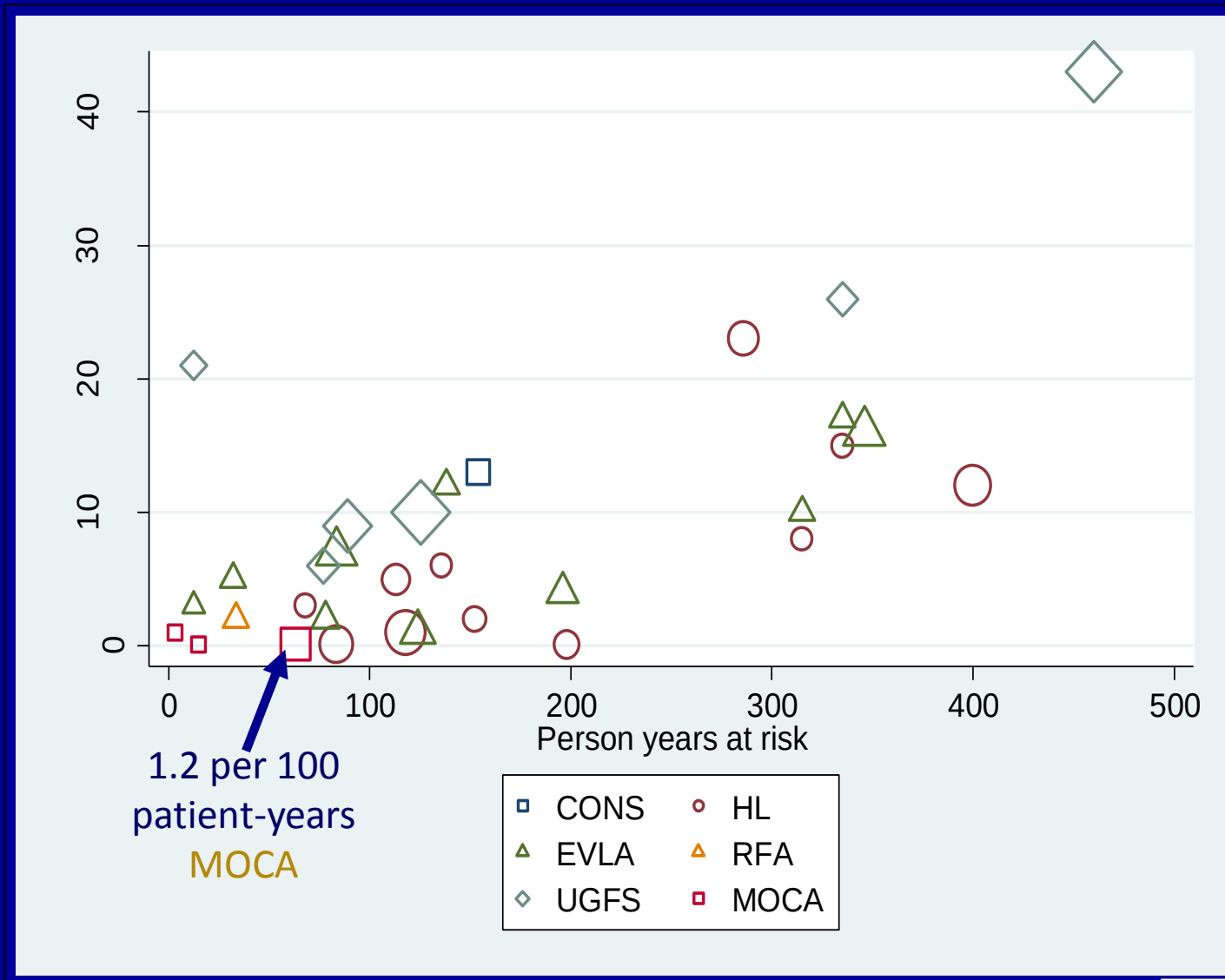
Truncal Vein Re-intervention



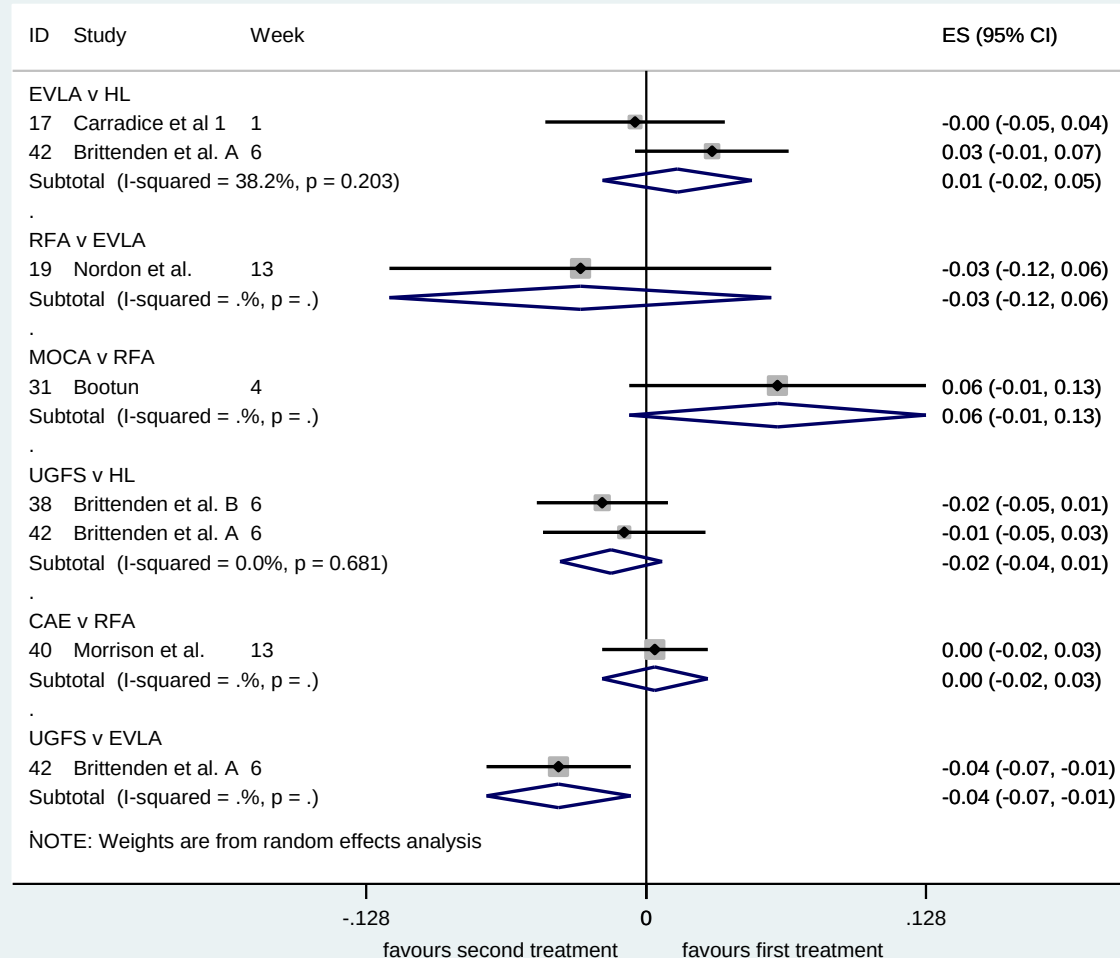
Network Meta-Analysis



Re-intervention

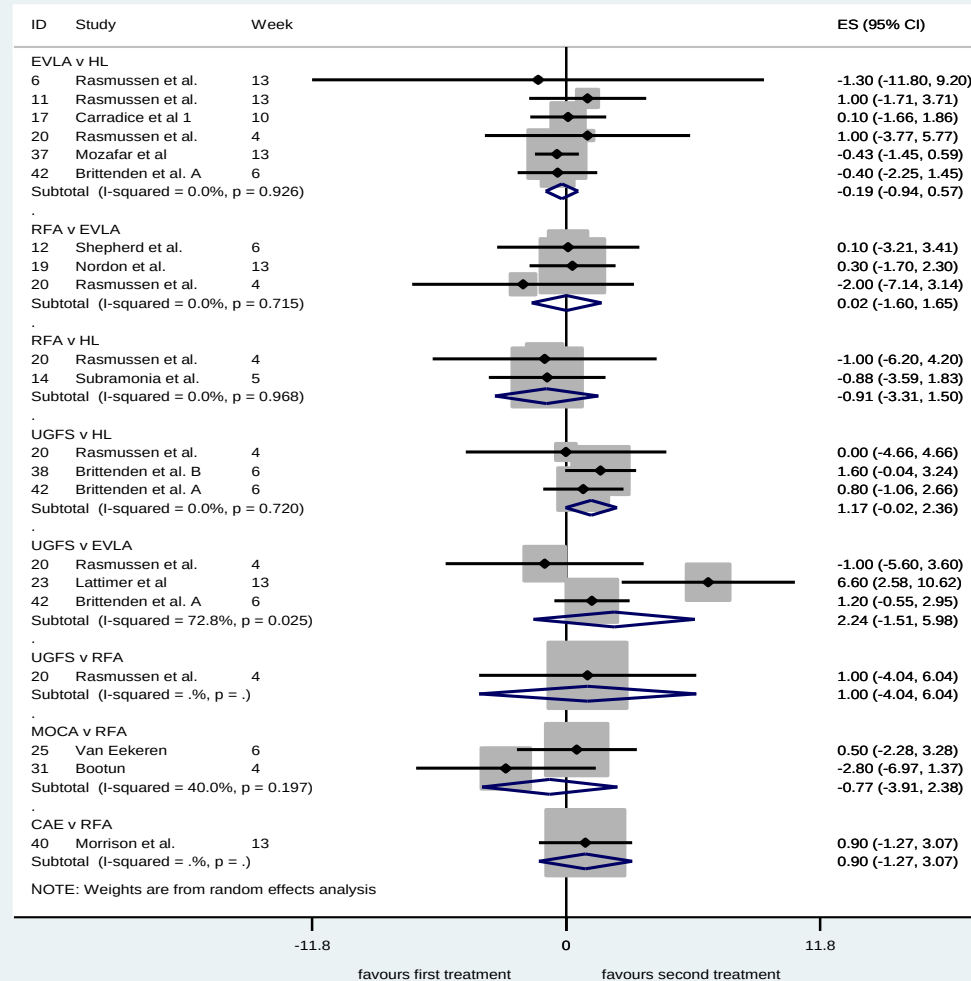


Generic Quality of Life – EQ-5D



EQ-5D-3L index

Disease-Specific QoL - AVVQ

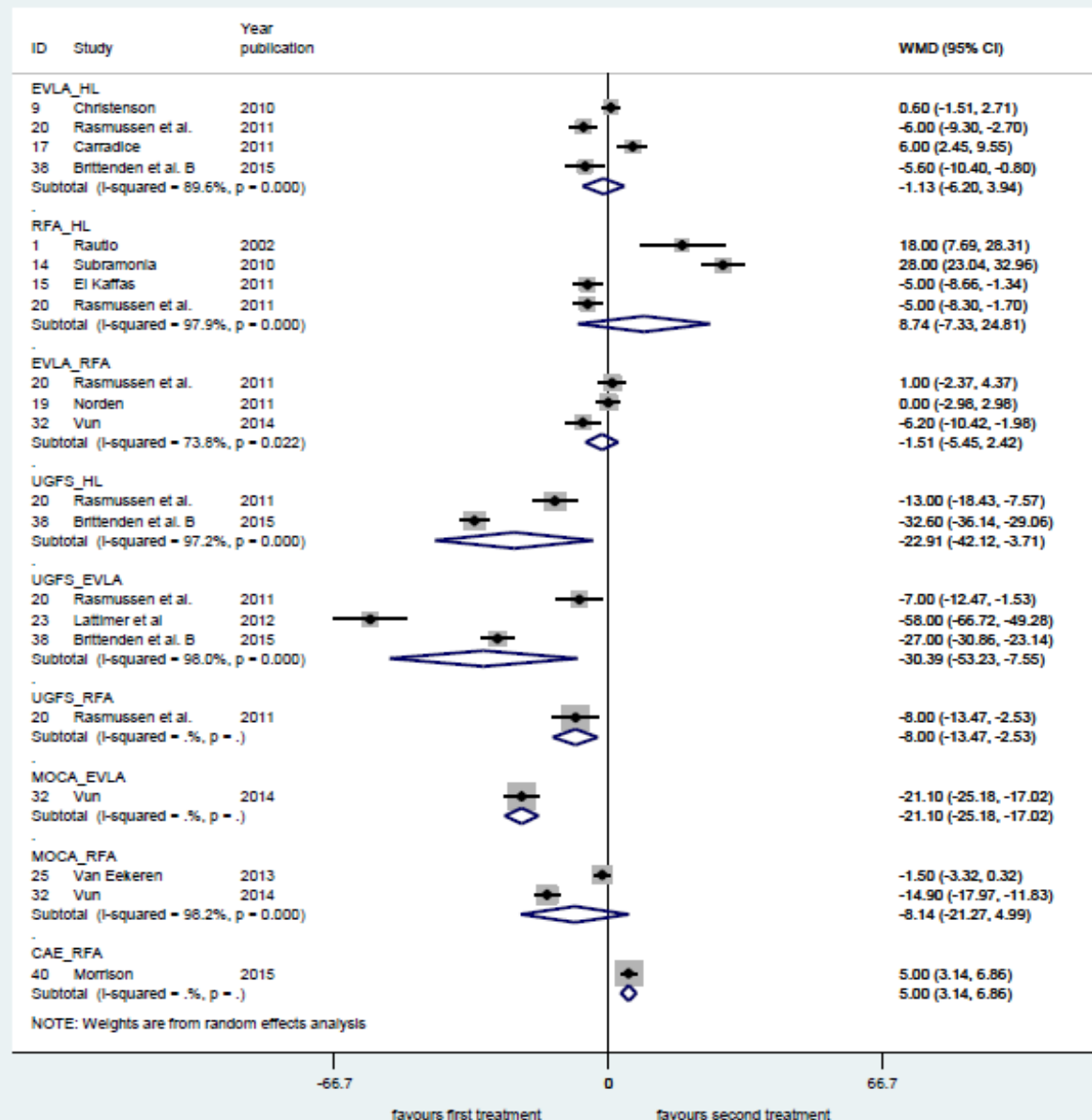


Aberdeen Venous Vein Score

Duration of Procedure

	Difference in operative time (minutes)	SE	z	P value	Confidence Interval	
EVLA	6.0	6.4	0.9	0.346	-6.5	18.6
RFA	5.2	6.5	0.8	0.428	-7.6	18.0
UGFS	-24.8	8.7	-2.9	0.004	-41.9	-7.7
MOCA	-5.5	11.3	-0.5	0.628	-27.6	16.6
CAE	10.2	16.2	0.6	0.531	-21.6	41.9

Procedure Times



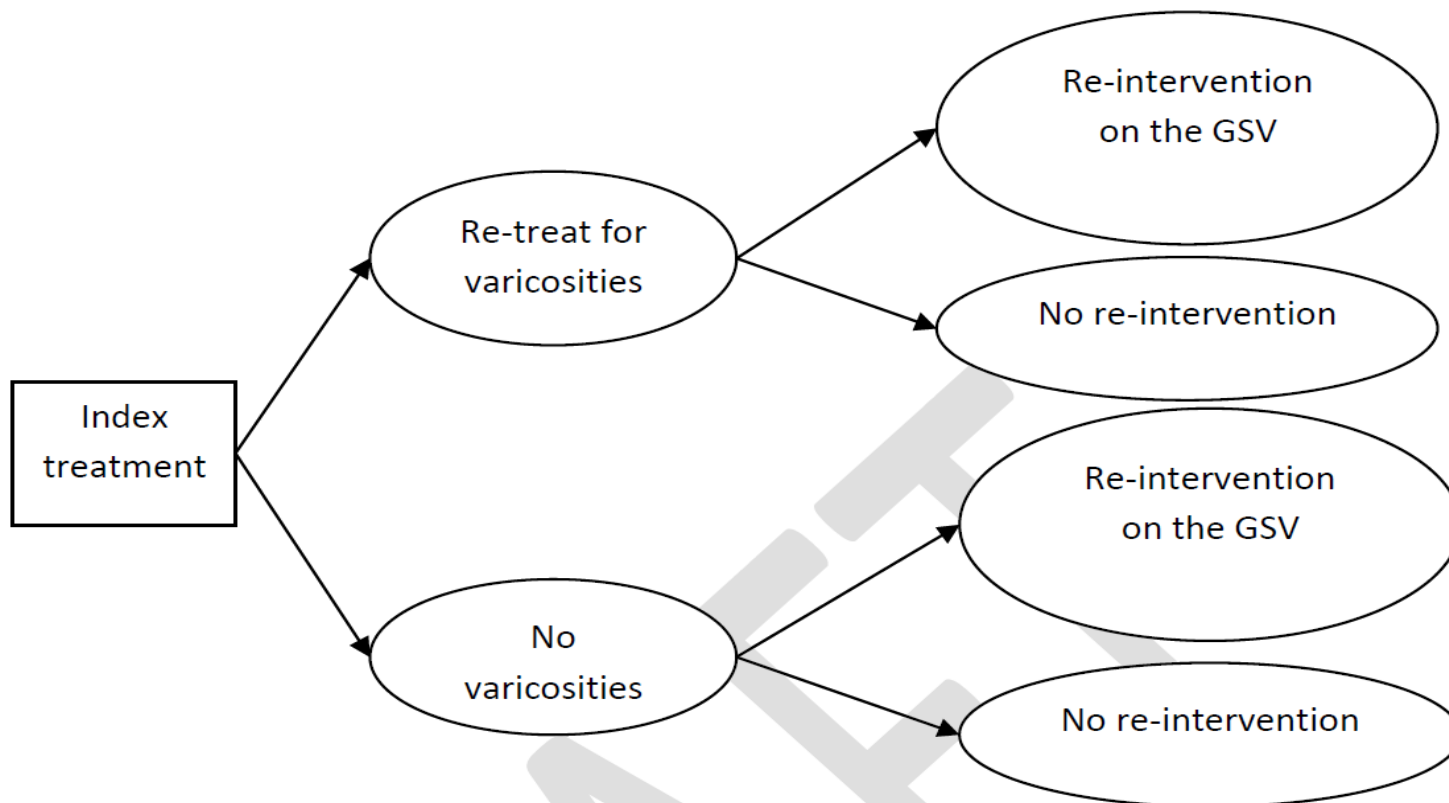
Procedure Cost

	<u>Source</u>	<u>HL/S</u>	<u>EVLA</u>	<u>RFA</u>	<u>UGFS</u>	<u>MOCA</u>	<u>CAE</u>
Cost theatre (£)		529	338	333	143	270	362
Theatre time (min)	a	52	58	57	27	46	62
Cost per min, theatre (£)	b	10.27	5.87	5.87	5.35	5.87	5.87
Kit and equipment (£)		150	322	346	50	441	866
Kit (£)	c		256	280		375	800
Consumables & anaesthetic (£)	b	150	66	66	50	66	66
Other Costs (£)		257	72	72	42	72	72
Preparation (£)	b	29	29	29	28	29	29
Recovery (£)	b	74	32	32	4	32	32
Equipment (£)	b	4	11	11	10	11	11
Total Cost (£)		786	732	751	235	783	1300

a. Network Meta-analysis; b. From Brittenden et al. (2015); c. Manufacturer's list price and Rautio et al. (2002)

Model used for comparrison

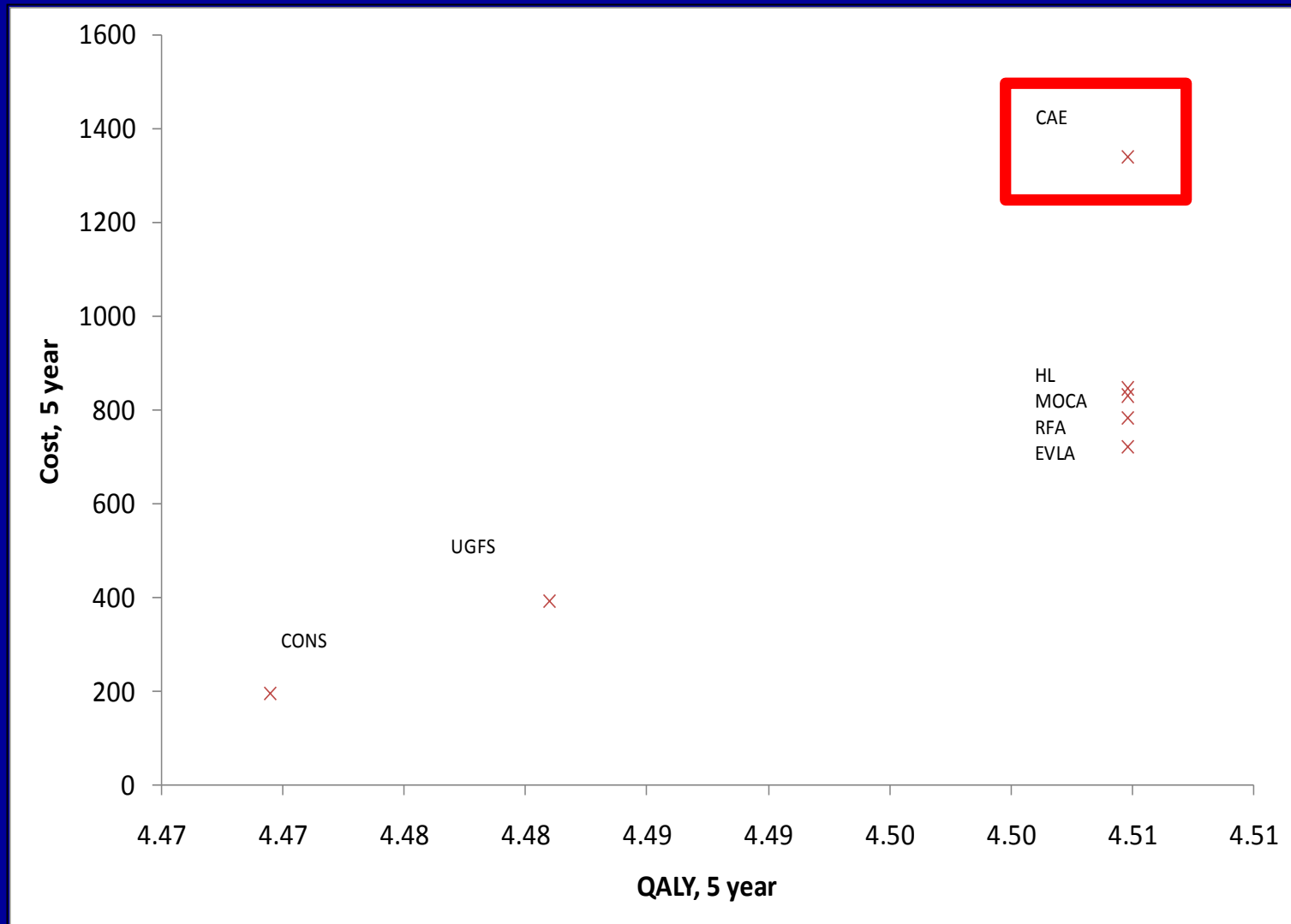
Figure 1. Structure of model. Residual varicosities are re-treated at 6 weeks and re-interventions can occur up to 5 years after index procedure



Probability of Re-intervention

Strategy	Probability of re-treatment for varicosity (6 weeks)	Probability of truncal vein re-intervention during 5 years	Discounted QALY (5 years)	Discounted Total Mean Cost (5 years)
CONS	0.36	0.72	4.47	197
UGFS	0.36	0.56	4.48	394
RFA	0.04	0.26	4.50	745
MOCA	0.04	0.26	4.50	822
EVLA	0.04	0.26	4.50	824
HL	0.04	0.27	4.50	828
CAE	0.04	0.26	4.50	1392

QALY at 5 year time horizon



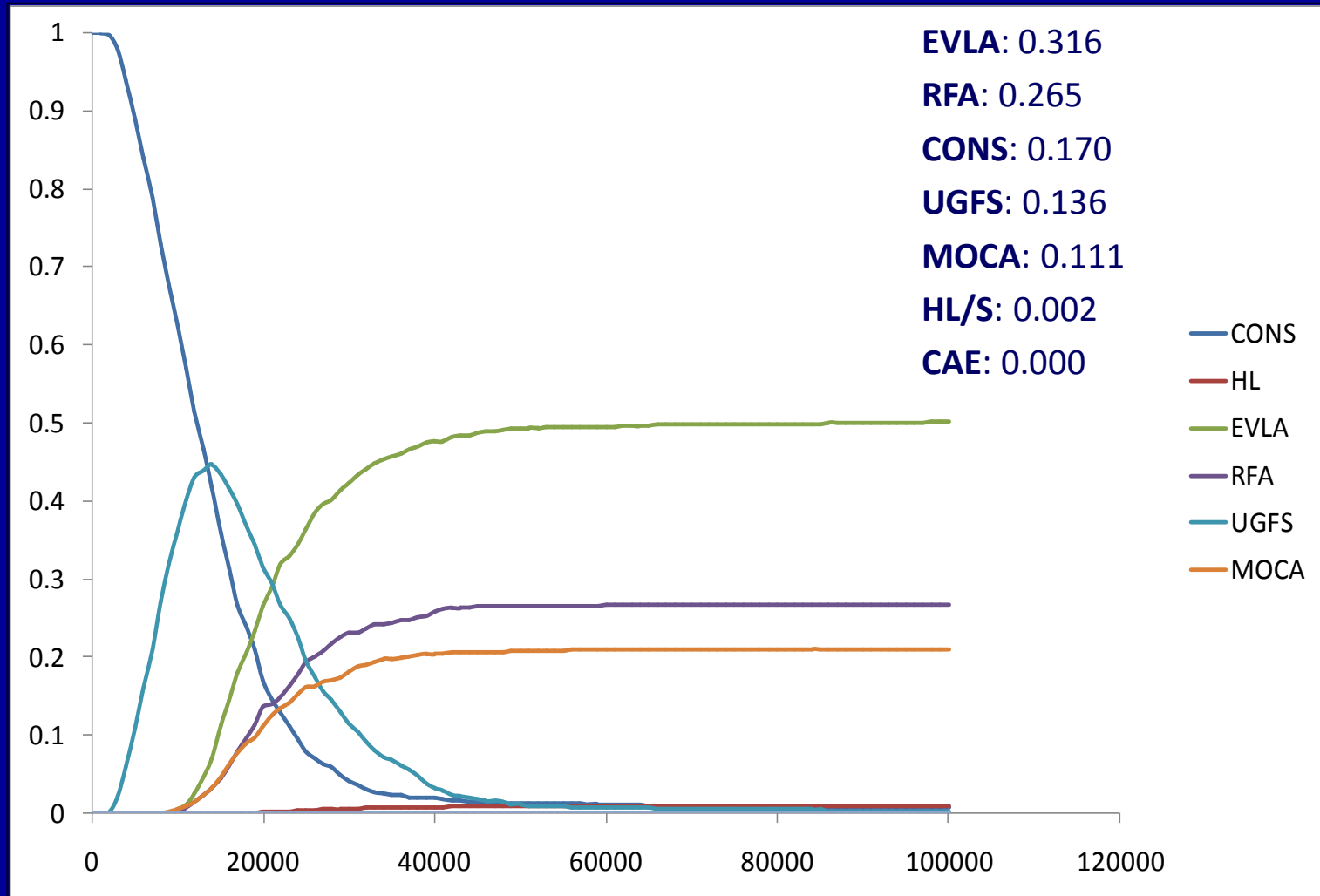
Conclusion

- Surgery, EVLA and RFA have lower re-intervention rates compared to UGFS and conservative care
- Re-intervention rate for MOCA appear similar to the endothermal methods and surgery
- No re-intervention data available for CAE
- Insufficient evidence for CAE at present to properly evaluate their cost-effectiveness

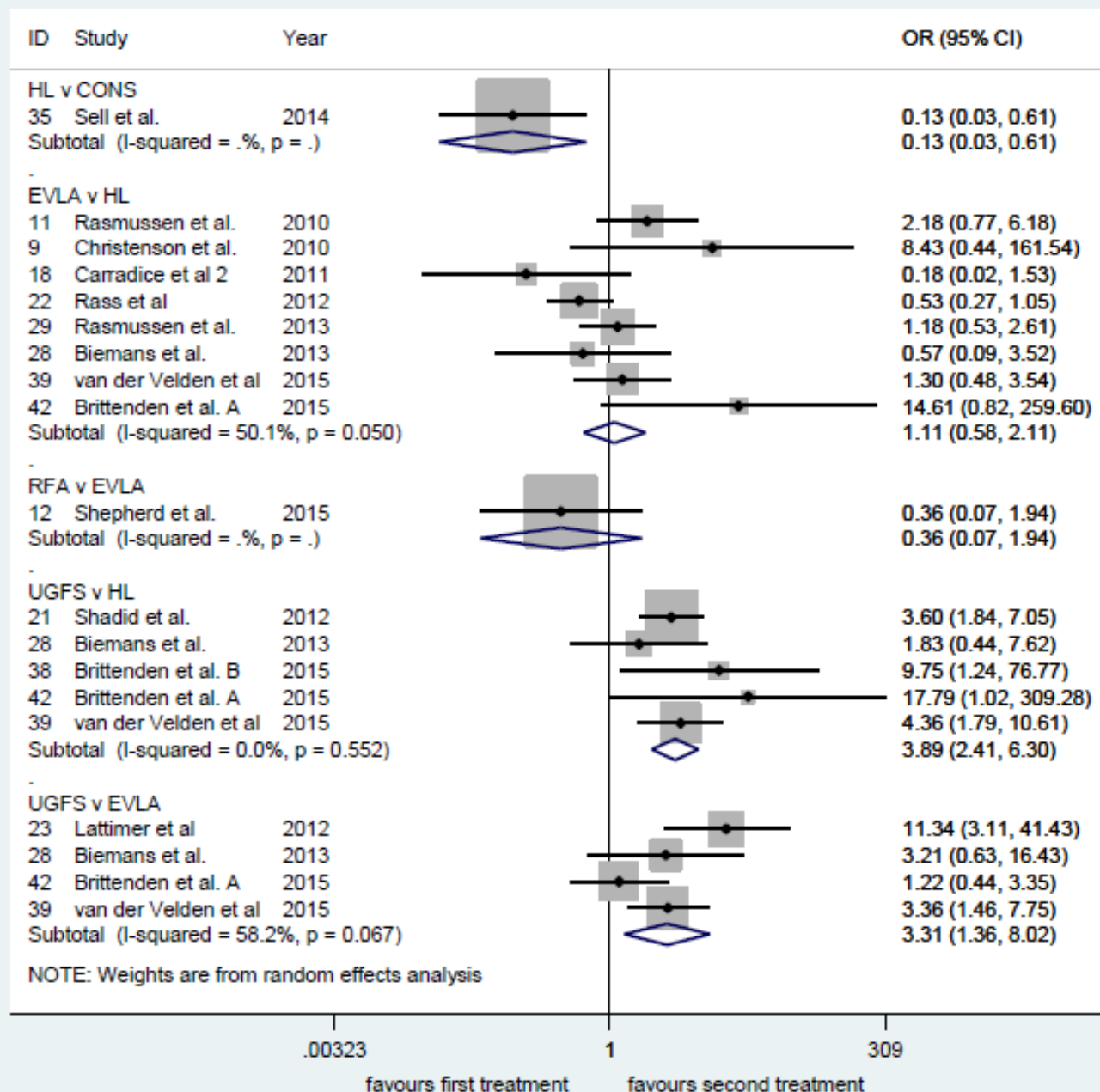
Thank You!



Cost-effectiveness



Re-intervention Comparison



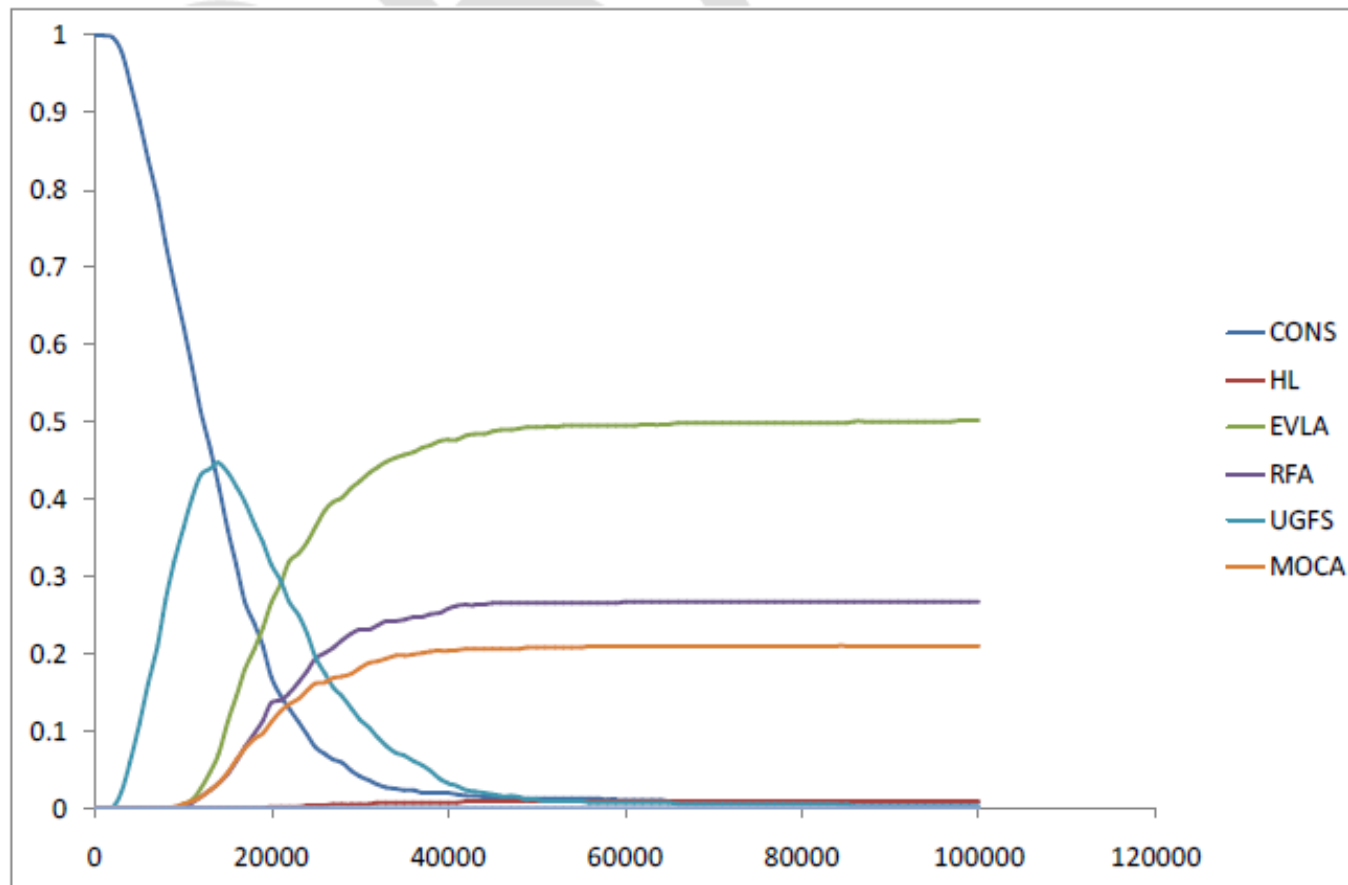
Cost of index procedure

Table 1. Cost of index procedure

	Source	HL	EVLA	RFA	UGFS	MOCA	CAE
Theatre time, min	a	52	58	57	27	46	62
Cost per min, theatre, £	b	10.27	5.87	5.87	5.35	5.87	5.87
<i>Cost theatre, £</i>		<i>529</i>	<i>338</i>	<i>333</i>	<i>143</i>	<i>270</i>	<i>362</i>
Kit, £	c		256	280		375	800
Consumables and anaesthetic, £	b	150	66	66	50	66	66
<i>Kit and equipment, £</i>		<i>150</i>	<i>322</i>	<i>346</i>	<i>50</i>	<i>441</i>	<i>866</i>
Preparation, £	b	29	29	29	28	29	29
Recovery, £	b	74	32	32	4	32	32
Equipment, £	b	4	11	11	10	11	11
<i>Cost, other, £</i>		<i>257</i>	<i>72</i>	<i>72</i>	<i>42</i>	<i>72</i>	<i>72</i>
<i>Total cost, £</i>		<i>786</i>	<i>732</i>	<i>751</i>	<i>235</i>	<i>783</i>	<i>1300</i>

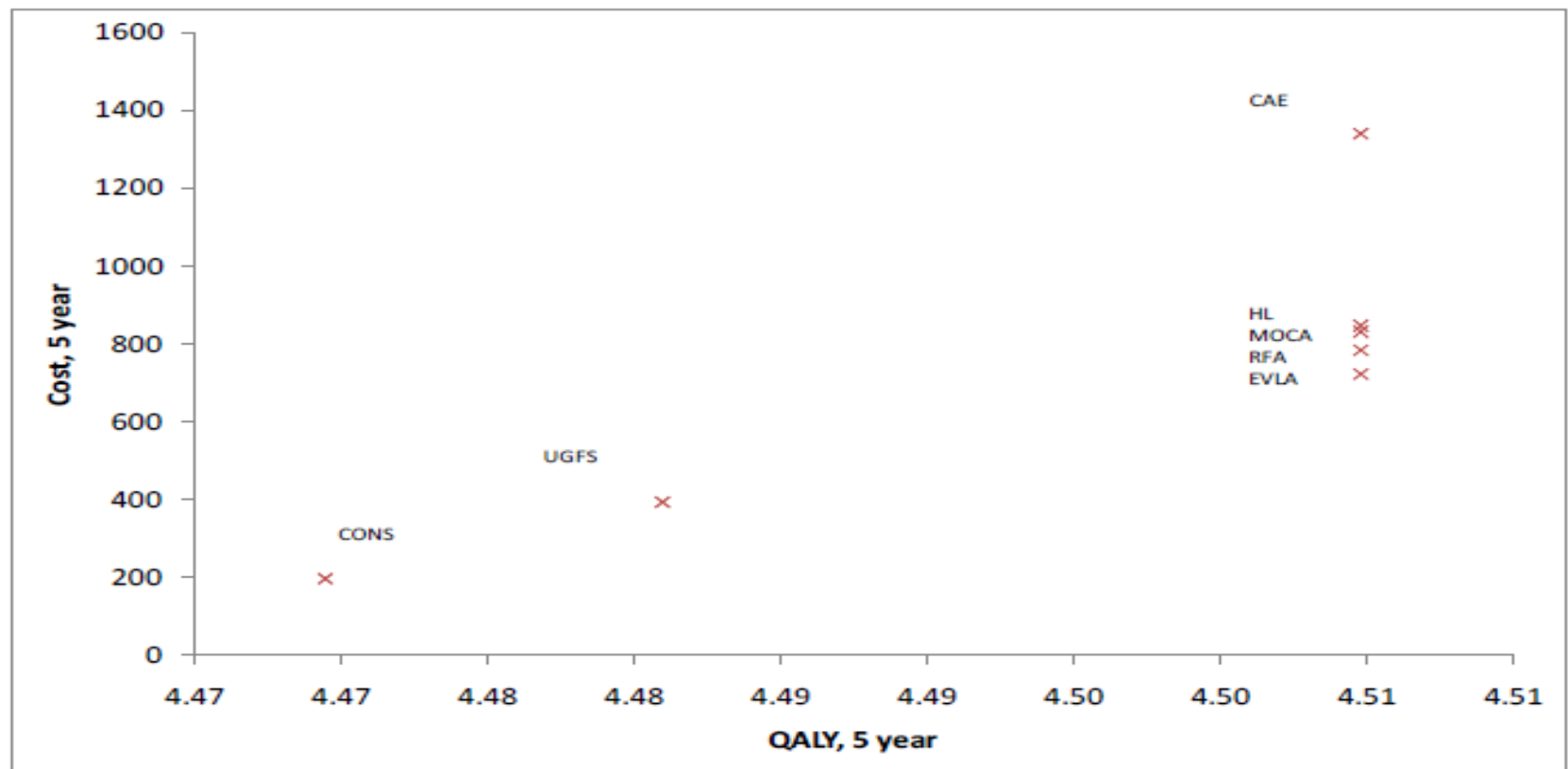
Cost effectiveness

Figure 4. Cost-effectiveness acceptability curves for each treatment option. The curve shows the probability that a given treatment obtains the highest net benefit at different thresholds for cost-effectiveness.



Mean cost and QALY 5 year horizon

Figure 3. Total mean cost and mean QALY per person over 5 years for each strategy.





"That's all Folks!"