



The Early Venous Reflux Ablation (EVRA) ulcer study



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on behalf of the EVRA trial investigators

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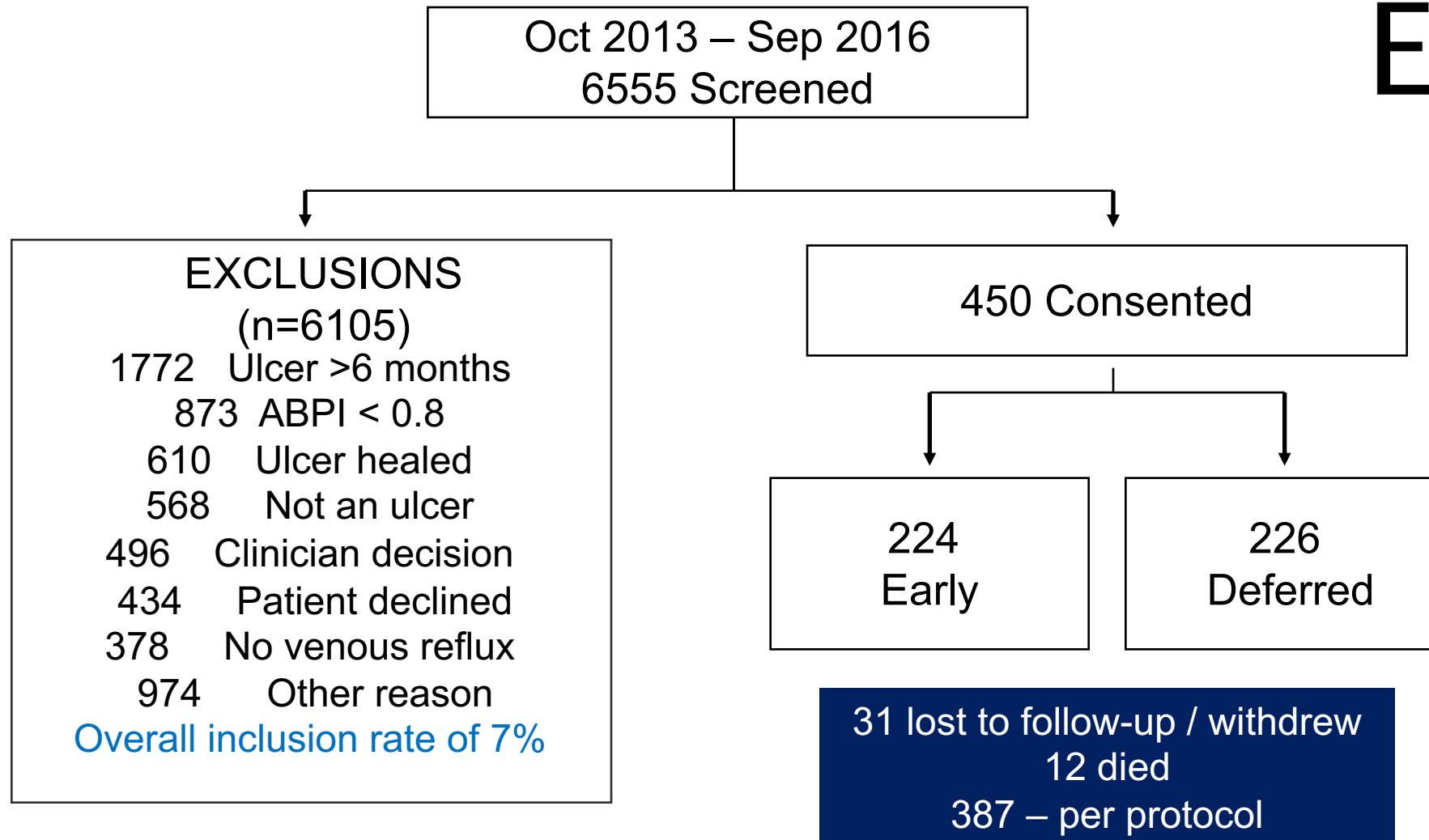
Disclosure

Speaker name: Manj Gohel

I have the following potential conflicts of interest to report:

- ✓ Consulting / Honoraria / Speaker fees
Medtronic, Cook Medical

- ✓ Other(s): Research grant Laboratoires Urgo





Baseline information



Baseline characteristics

	Early N=224	Deferred N=226
Age	67.0 (15.5) [n=224]	68.9 (14.0) [n=226]
BMI (kg/m²)	30.1 (7.8) [n=218]	30.4 (7.4) [n=219]
Gender		
Female	97 (43.3%)	106 (46.9%)
Male	127 (56.7%)	120 (53.1%)
Previous DVT in trial leg		
No	206 (93.3%)	203 (93.4%)
Yes	15 (6.7%)	15 (6.6%)

Mean (SD) presented for Age and BMI



Baseline information



Baseline characteristics

	Early N=224	Deferred
Age	67.0 (15.5) [n=224]	
BMI (kg/m ²)	30.1 (7.8) [n=224]	
Gender		
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Male	127 (56.7%)	
Previous DVT in trial leg		
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Mean (SD) presented for Age

Baseline reflux patterns

	Early N=224	Deferred N=226
Superficial venous reflux		
GSV reflux alone	123 (54.9%)	125 (55.4%)
SSV reflux alone	25 (11.2%)	30 (13.3%)
GSV and SSV reflux	65 (29.0%)	56 (24.8%)
Other pattern of reflux	11 (4.9%)	15 (6.6%)
Deep veins		
Normal	150 (67.0%)	157 (69.5%)
Abnormal	74 (33.0%)	69 (30.5%)
Reflux	74 (100%)	69 (100%)
Outflow obstruction	0 (0%)	0 (0%)



Baseline information



Baseline characteristics

	Early N=224	Deferred N=226
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Gender		
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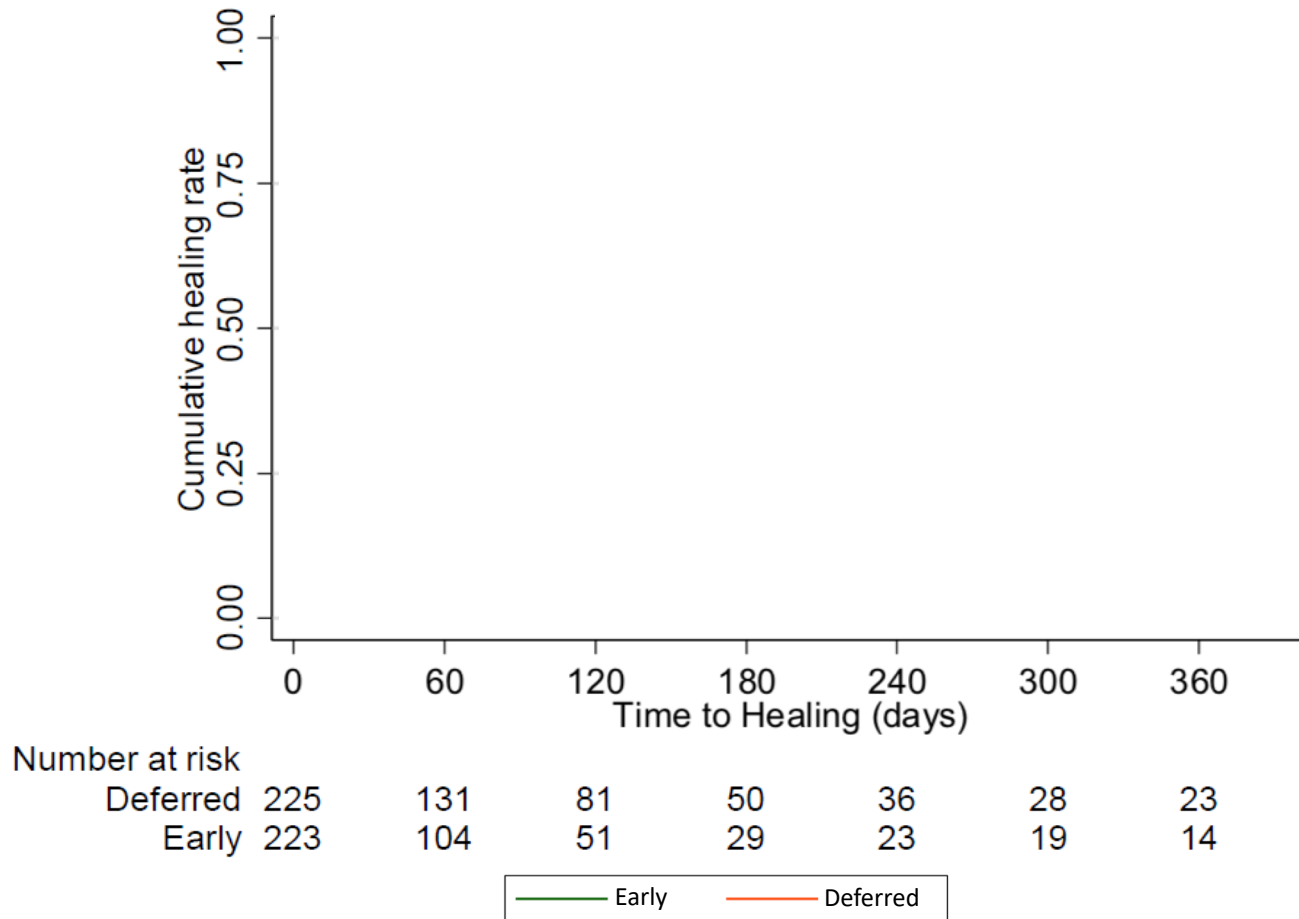
Ulcer characteristics

	Early N=224	Deferred N=226
Ulcer chronicity (months)	3.2 (2.3-4.2)	3.0 (1.7-4.2)
Ulcer size (cm²)	2.4 (1.0-7.1)	2.9 (1.1-8.2)
Previous ulcer (yes)		
No	106 (47.3%)	108 (48.0%)
Yes	118 (52.7%)	117 (52.0%)
Baseline Compression		
None	3 (1.3%)	7 (3.1%)
KTwo	32 (14.3%)	29 (12.8%)
Three-layer bandage	42 (18.8%)	41 (18.1%)
Four-layer bandage	59 (26.3%)	59 (26.1%)
European short stretch	43 (19.2%)	36 (15.9%)
Stocking	42 (18.8%)	53 (23.5%)
Other	2 (0.9%)	1 (0.4%)
Missing	1 (0.4%)	0 (0%)

**No significant differences
 between groups**



Ulcer healing

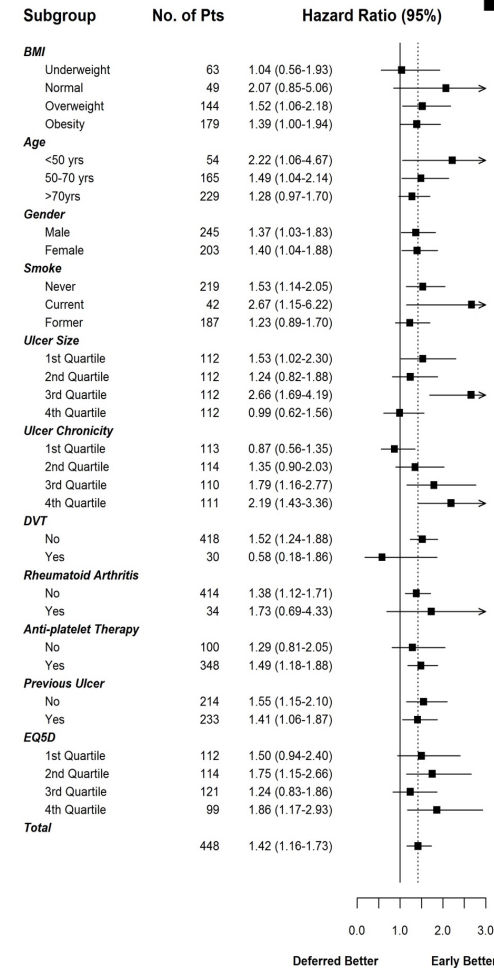
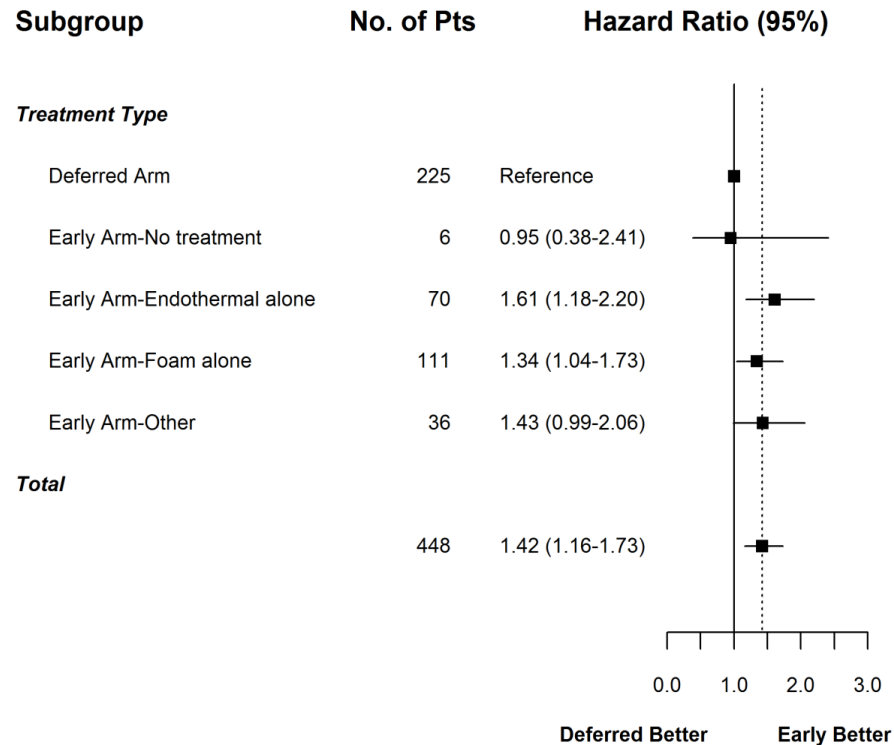


Unadjusted hazard ratio for ulcer healing in Early group:
1.38 (95% CI 1.13 – 1.68) p=0.001

	Early N=224	Deferred N=226
12-week ulcer healing rate	63.5%	51.6%
24-week ulcer healing rate	85.6%	76.3%



Ulcer healing





Ulcer free time



	Early N=224	Deferred N=226
No. patients with ulcer healed at 1 year	210 (93.8%)	194 (85.8%)
No. patients with recurrent ulcer	24 (11.4%)	32 (16.5%)
Ulcer free time (days)	306 (240-328) [n=204]	278 (175-324) [n=203]

Hazard ratio for ulcer free time in Early group:
1.54 (95% CI 1.07 – 2.21) p=0.02



Timing of interventions

	Early N=224	Deferred N=226
No treatment	6 (2.7%)	55 (24.3%)
Within 2-weeks	203 (90.6%)	1 (0.4%)
Before ulcer healing	200	1
After ulcer healing	3	0
Between 2-week and 4-week	9 (4.0%)	1 (0.4%)
Before ulcer healing	9	1
After ulcer healing	0	0
Between 4-week and 6-month	6 (2.7%)	103 (45.6%)
Before ulcer healing	4	4
After ulcer healing	2	99
After 6-month	0 (0%)	66 (29.2%)
Before ulcer healing	0	19
After ulcer healing	0	47





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Before ulcer healing	200	1
After ulcer healing	3	0
Between 2-week and 4-week	9 (4.0%)	1 (0.4%)
Before ulcer healing	9	1
After ulcer healing	0	0
Between 4-week and 6-month	6 (2.7%)	103 (45.6%)
Before ulcer healing	4	4
After ulcer healing	2	99
After 6-month	0 (0%)	66 (29.2%)
Before ulcer healing	0	19
After ulcer healing	0	47



Procedural complications

	Early N=28	Deferred N=24
Allergic reaction requiring local or no treatment	5	3
Bleeding requiring intervention	2	1
Cough / chest tightness	0	1
Deep vein thrombosis (DVT)	9	3
Infection	3	5
Edema	1	0
Pain	6	6
Patient reported paresthesia	1	1
Superficial thrombophlebitis	1	4



AVVQ

	Baseline	6 weeks	6 months	12 months
Deferred	44.3 (8.7) [n=192]	41.2 (9.3) [n=170]	39.5 (10.3) [n=140]	34.3 (10.4) [n=130]
Early	44.1 (9.0) [n=200]	39.4 (10.2) [n=176]	34.6 (9.4) [n=139]	32.4 (8.3) [n=127]
Difference	-0.2 (-2.0, 1.6) p=0.84	-2.1 (-4.0, -0.2) p=0.03	-4.8 (-6.9, -2.7) p<0.01	-1.8 (-4.0, 0.3) p=0.10



EQ-5D Index score

	Baseline	6 weeks	6 months	12 months
Deferred	0.73 (0.2) [n=226]	0.75 (0.2) [n=208]	0.76 (0.2) [n=192]	0.80 (0.2) [n=182]
Early	0.73 (0.2) [n=222]	0.79 (0.2) [n=211]	0.81 (0.2) [n=186]	0.83 (0.2) [n=184]
Difference	-0.01 (-0.04, 0.03) p=0.76	0.04 (0.00, 0.08) p=0.04	0.04 (0.00, 0.08) p=0.03	0.03 (-0.01, 0.07) p=0.19

SF-36 Body Pain

	Baseline	6 weeks	6 months	12 months
Deferred	41.6 (11.9) [n=224]	44.3 (12.3) [n=207]	45.9 (12.2) [n=193]	47.8 (11.2) [n=180]
Early	41.3 (11.1) [n=223]	46.6 (10.6) [n=212]	48.2 (11.0) [n=187]	49.3 (11.0) [n=182]
Difference [†]	-0.5 (-2.6, 1.6) p=0.67	2.2 (0.1, 4.4) p=0.04	2.1 (-0.2, 4.3) p=0.07	1.1 (-1.1, 3.3) p=0.34

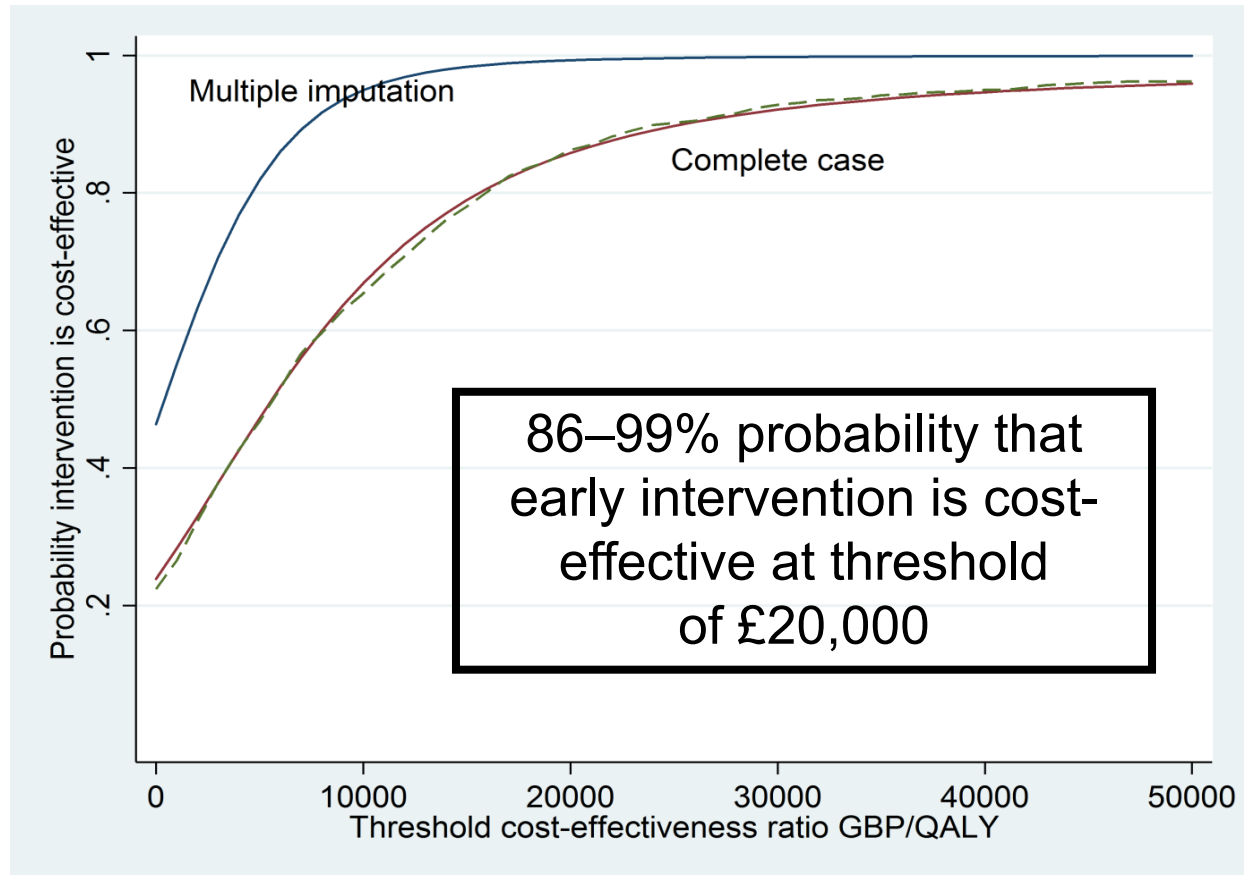
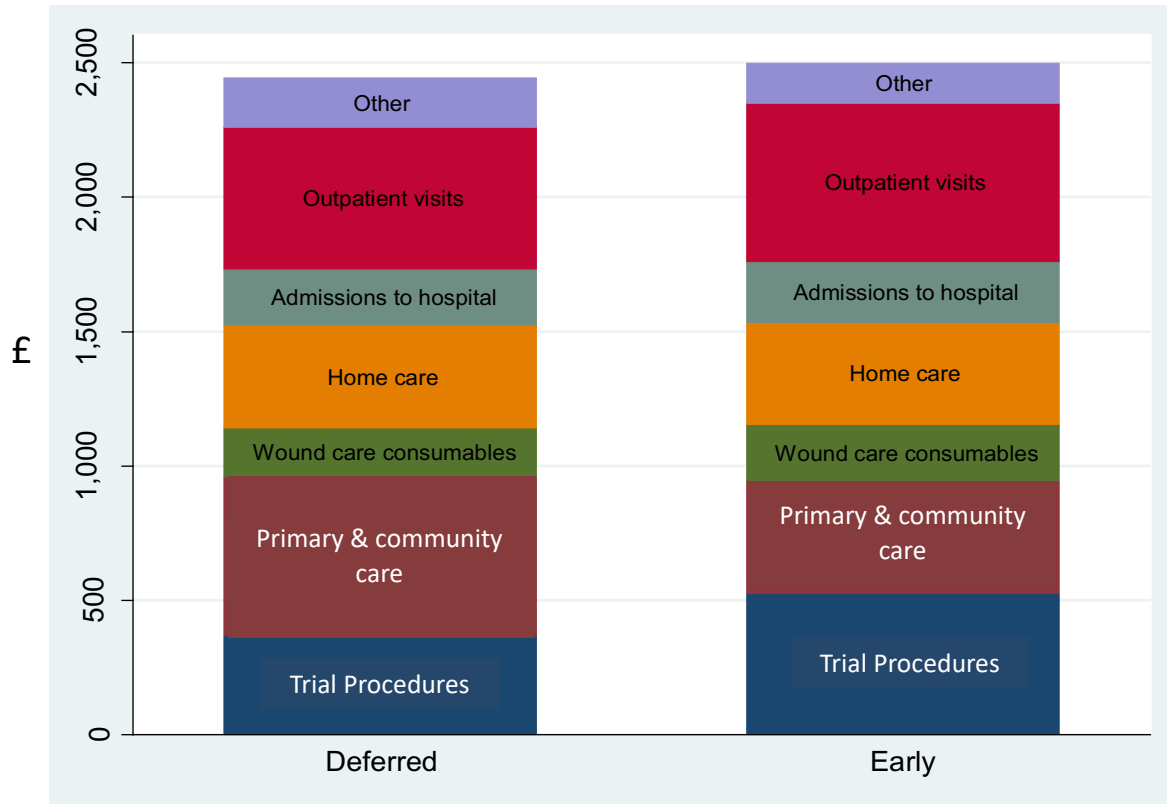


Cost effectiveness



£2442
 (SD 3216)

£2496
 (SD 2775)





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ORIGINAL ARTICLE

A Randomized Trial of Early Endovenous
Ablation in Venous Ulceration

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EVRA Trial Investigators*



EVRA is the first large randomised trial to
confirm that early endovenous ablation
accelerates ulcer healing

Early endovenous ablation also associated
with greater ulcer free time and is cost effective