

# The management of venous leg ulceration post the EVRA (early venous reflux ablation) ulcer trial: Management of venous ulceration post EVRA

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## Abstract

**Objectives:** This survey study evaluates current management strategies for venous ulceration and the impacts of the EVRA trial results.

**Methods:** An online survey was disseminated to approximately 15000 clinicians, through 12 vascular societies in 2018. Survey themes included: referral times, treatment times and strategies, knowledge of the EVRA trial and service barriers to managing venous ulceration. Data analysis was performed using Microsoft Excel and SPSS.

**Results:** 664 responses were received from 78 countries. Respondents were predominantly European (55%) and North American (23%) vascular surgeons (74%). Responses varied between different countries. The median vascular clinic referral time was 6 weeks and time to be seen in clinic was 2 weeks. This was significantly higher in the UK ( $p \leq 0.02$ ). 77% of respondents performed surgical/endovenous interventions prior to ulcer healing, the median time to intervention was 4 weeks. 31% of participants changed their practice following EVRA. Frequently encountered barriers to implementing change were a lack of operating space/time (18%).

**Conclusion:** Venous ulcers are not managed as quickly as they should be. An evaluation of local resource requirements should be performed to improve service provision for venous ulceration. When interpreting the results of this survey consideration should be given to the response rate.

## Keywords

Venous ulceration, EVRA, endovenous ablation, surgical ablation

## Background

Venous leg ulceration (VLU) affects an estimated 1%<sup>1</sup> of the population internationally. It costs approximately 2% of healthcare budgets in western societies<sup>2</sup> and has a significant impact on patient morbidity.<sup>3,4</sup> There are no national guidelines for the treatment of VLU in England, however, the National Institute for Health and Care Excellence (NICE) guidance for varicose veins<sup>5</sup> suggest that patients with ulceration that persists for more than two weeks should be referred to a specialist vascular unit. Patients referred to vascular units often receive a duplex scan and, if indicated, surgical/endovenous ablation of superficial veins. The ESCHAR<sup>6</sup> study suggested that there was reduced ulcer recurrence in patients who received compression with surgery as opposed to compression alone. Consequently, surgery was frequently performed once ulcers had healed to prevent recurrence. This is further

reflected in European and American guidelines.<sup>7–9</sup> The Early Venous Reflux Ablation (EVRA) ulcer trial<sup>10</sup> identified that patients who underwent early endovenous ablation had improved ulcer healing rates and ulcer free time. The implementation of both the NICE guidelines on referrals and the EVRA study results are likely to be challenging; indeed it has been shown that patients with ulcers are not referred to specialist care within the 2 week limit in the UK.<sup>11,12</sup>

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This survey study aims to determine the standards of the global management of patients with VLU, four to six months after the release of the EVRA trial results.

## Methods

This descriptive, cross-sectional study utilised an online survey to collate VLU practices and perspectives. The initial survey was designed using the Qualtrics management platform (Qualtrics, Utah, USA) following discussion of important themes in a focus group with three vascular clinicians. Themes included: time from VLU development to secondary care referral and clinic visit, understanding of the NICE guidelines, knowledge of the EVRA study trial results and the impact these have had on practice. Additional information on clinician demographics was collected. The survey underwent five rounds of revision following review and feedback by a panel of vascular surgeons. The final online survey (Appendix, Supplementary material), consisting of 11 questions, was piloted on an additional five vascular surgeons prior to dissemination. The survey was circulated to approximately 15,000 participants through 12 national and international vascular societies. Responses were collected over a four-month period between September 2018 and December 2018.

Outcomes of interest included referral time, time to vascular clinic review, aimed and actual time to surgical/endovenous intervention, whether interventions were performed before or after ulcer healing, whether EVRA trial results had changed practice, what the anticipated and actual barriers to implementing change were and views on the clinical and cost effectiveness of the EVRA trial findings.

Referral time was defined as the time between a patient's first presentation to primary care for a venous ulcer to the date that they were referred to a vascular service. Time to vascular clinic review was defined as the time between the vascular clinic referral and first being seen in vascular clinic. Surgical/endovenous interventions encompassed all methods of superficial venous ablation. Time to intervention was defined as the time from the clinical decision to proceed with intervention to the patient undergoing this.

Descriptive statistics and normality were calculated using Microsoft Excel to analyse the results. All evaluated outcomes were not normally distributed and summarised using medians and interquartile ranges (IQRs). Categorical variables were summarised using frequencies and percentages. Free text in survey responses were categorised by common themes for the ease of interpretation. A Mann-Whitney U test in SPSS was used to compare differences between the UK and global responses.

## Results

664 responses were received from 78 countries giving an approximate response rate of 4.4%. Respondent characteristics are summarised in Table 1. Respondents were predominantly vascular surgeons (74.2%). Most clinicians worked in Europe (54.5%) or North America (23%). Of 659 respondents, 454 (69%) had heard of the EVRA trial and 415 (63%) were familiar with the results. Of 627 respondents, 82% believed early surgical/endovenous intervention would reduce recurrence rates, 0.3% thought it would increase them, 13% thought there would be no effect, 3.7% thought it would depend on other factors such as the age of the ulcer, or extent of deep disease.

### Current intervention

Globally, the median referral time from primary care to a vascular service was six weeks (IQR 2-12 weeks); this was longer in the UK where the median time was 8 weeks (IQR 4-14 weeks),  $p=0.02$ . The median time to outpatient clinic appointment once referred was 2 weeks (IQR 1-4 weeks); increasing to 4 weeks in the UK (IQR 2 - 6),  $p < 0.01$ .

Of 656 global respondents, 507 (77%) reportedly performed surgical/endovenous intervention prior to ulcer healing, 129 (20%) after ulcer healing and 20 (3%) did not perform surgical/endovenous intervention for ulceration. Of the 507 global respondents who treated prior to ulcer healing, 227 (45%) aimed to perform the intervention immediately, of these, 142 (63%) were able to do this. 280 (55%) of global respondents did not aim to immediately perform intervention and instead aimed-to-treat at a median time of 3 weeks (IQR 2 to 4). The median time to actually treating patients was 4 weeks (IQR 2 to 5).

Of the 129 global respondents who treated after ulcer healing, 50 (39%) of participants would aim to perform the intervention immediately after healing, 28 (56%) of these participants were able to. For those who did not aim-to-treat immediately, the median aim-to-treat time was 4 weeks (IQR 2 to 4) after ulcer healing. The median time from healing to actual intervention was 4 weeks (IQR 4 to 8).

Of 107 UK respondents, 70 (65%) usually performed surgical/endovenous intervention prior to ulcer healing, 32 (30%) after and 5 (5%) did not perform intervention. Of the 70 respondents who treated prior to ulcer healing, 23 (33%) would aim to perform intervention immediately. However, only 9 (39%) of these were able to do so. For those who did not aim to treat immediately, the median aim-to-treat-time was 4 weeks (IQR 2 to 6). The median time to treatment was 6 weeks (IQR 4 to 8).

**Table 1.** Baseline characteristics of respondents.

Clinician type (n = 662)	
Vascular surgeon	491 (74.2%)
Phlebologist	68 (10.3%)
General surgeon	38 (5.7%)
Interventional radiologist	16 (2.4%)
Vascular nurse specialist	12 (1.8%)
Dermatologist	5 (0.8%)
Interventional cardiologist	4 (0.6%)
Consultant vascular nurse	3 (0.5%)
Family medical practitioner	1 (0.2%)
Plastic surgeon	0 (0%)
Aesthetic practitioner	0 (0%)
Tissue viability nurse	0 (0%)
Other	24 (3.6%)
Region of practice* (n = 660)	
Europe (excluding UK)	252 (38.2%)
North America	152 (23.0%)
Central America	4 (0.6%)
United Kingdom	108 (16.4%)
South America	62 (9.4%)
Asia	39 (5.9%)
Australasia	24 (3.6%)
Africa	16 (2.4%)
Middle East	3 (0.5%)
Area of care (n = 657)	
Academic/teaching	369 (56.2%)
Secondary/district general/county hospital	127 (19.3%)
Primary/Community	94 (14.3%)
Other	67 (10.2%)

\*Algeria (n = 1), Albania (n = 2), Argentina (n = 10), Australia (n = 19), Austria (n = 7), Bahrain (n = 1), Bangladesh (n = 1), Belarus (n = 1), Belgium (n = 12), Bolivia (n = 1), Bosnia (n = 1), Brazil (n = 40), Bulgaria (n = 7), Canada (n = 6), Chile (n = 1), China (n = 1), Colombia (n = 4), Costa Rica (n = 1), Croatia (n = 3), Cuba (n = 1), Czech Republic (n = 4), Denmark (n = 2), Ecuador (n = 2), Egypt (n = 5), El Salvador (n = 1), Finland (n = 4), France (n = 5), Georgia (n = 1), Germany (n = 22), Greece (n = 12), Honduras (n = 1), Hong Kong (n = 1), Hungary (n = 3), India (n = 11), Indonesia (n = 2), Iraq (n = 1), Ireland (n = 6), Israel (n = 4), Italy (n = 37), Japan (n = 2), Kenya (n = 1), Kosovo (n = 1), Kuwait (n = 1), Latvia (n = 2), Lithuania (n = 3), Malaysia (n = 1), Mexico (n = 19), Monaco (n = 1), Montenegro (n = 1), Netherlands (n = 8), New Zealand (n = 5), Norway (n = 4), Pakistan (n = 2), Palestine (n = 1), Paraguay (n = 1), Peru (n = 1), Poland (n = 8), Portugal (n = 23), Romania (n = 3), Russia (n = 9), Serbia (n = 3), Slovakia (n = 5), Slovenia (n = 6), South Africa (n = 8), South Korea (n = 1), Spain (n = 20), Sri Lanka (n = 2), Sweden (n = 10), Switzerland (n = 5), Taiwan (n = 1), Thailand (n = 9), Turkey (n = 6), Ukraine (n = 3), United Kingdom (n = 108), USA (n = 127), Uruguay (n = 1), Missing (n = 3)

Of the 32 UK respondents who treated after ulcer healing, only 5 (16%) would aim to treat immediately after ulcer healing. Only one respondent was able perform the intervention immediately. For those who did not aim-to-treat immediately, the median recorded aim-to-treat time was 4 weeks (IQR 3 to 5.25) after ulcer healing. The median time from healing to treatment was 8 weeks (IQR 4 to 10).

### Changing practice

Clinical practice before and after EVRA are described in Table 2. 195 (30%) of global respondents (n = 637) reported they had changed practice with respect to the timing of intervention based on the results of the EVRA study, 418 (66%) did not change practice and 24 (4%) did not answer the question. Of the 418 global

participants who did not change practice, 192 (46%) stated that they would like to, 206 (49%) stated that they already treat prior to ulcer healing and 20 (5%) participants did not wish to change.

In the UK, of 100 respondents, 48% stated that they changed their practice with respect to the timing of intervention based on the EVRA results, 50% did not and 2% did not answer. Of the 50 respondents who did not change following EVRA, 22 (44%) indicated that they would like to, 26 (52%) stated they already treat prior to ulcer healing and 2 (4%) participants did not wish to change.

### Barriers to changing practice

195 (31%) global respondents stated they had changed practice with respect to the timing of intervention

**Table 2.** Current practices for surgical/endovenous interventions for venous ulcers.

Current interventions	Global participants	UK participants
Median referral time from primary care to a vascular service	6 weeks (IQR 2-12)	8 weeks (IQR 4-14)
Median time to outpatient clinic appointment once referred	2 weeks (IQR 1-4)	4 weeks (IQR 2-6)
Surgical/endovenous intervention <b>prior</b> to ulcer healing	507/656 (77%)	70/107 (65%)
<ul style="list-style-type: none"> <li>• Aimed to perform immediately</li> <li>• Number of participants who planned to perform procedure immediately and were able to</li> </ul>	227/507 (45%)	23/70 (33%)
<ul style="list-style-type: none"> <li>• If not immediate, median number of weeks clinicians aimed to perform procedure</li> </ul>	142/227 (63%)	9/23 (39%)
<ul style="list-style-type: none"> <li>• Time actually taken to perform procedure</li> </ul>	3 weeks (IQR 2-4)	4 weeks (IQR 2-6)
Surgical/ endovenous intervention <b>after</b> ulcer healing	4 weeks (IQR 2-5)	6 weeks (IQR 4-8)
<ul style="list-style-type: none"> <li>• Aimed to perform immediately</li> <li>• Number of participants who planned to perform procedure immediately and were able to</li> </ul>	129/656 (20%)	32/107 (30%)
<ul style="list-style-type: none"> <li>• If not immediate, median number of weeks clinicians aimed to perform procedure</li> </ul>	50/129 (39%)	5/32 (16%)
Time actually taken to perform procedure	28/50 (56%)	1/5 (20%)
Practice change based on EVRA	4 weeks (IQR 2-4)	4 weeks (IQR 3- 5.25)
Number of participants who changed practice based on EVRA	4 weeks (IQR 4-8)	8 weeks (IQR 4-10)
Reasons why participants had not changed practice	Global participants	UK participants
<ul style="list-style-type: none"> <li>• Would like to change practice</li> <li>• Already treat patients according to EVRA</li> <li>• Did not wish to change practice</li> </ul>	195/637 (30%)	48/100 (48%)
	192/418 (46%)	22/50 (44%)
	206/418 (49%)	26/50 (52%)
	20/418 (5%)	2/50 (4%)

Changes to practice based on EVRA.

based on the results of EVRA study. The barriers faced by the respondents in changing practice are summarised in Table 3. Respondents could select more than one barrier and therefore 347 barriers were recorded in total. The most frequently anticipated and encountered barriers to implementing EVRA were a lack of operating space/time (18%) and a lack of theatre space (15%). A fifth of participants felt there were no barriers to changing practice.

192 (43%) global respondents stated they had not changed practice with respect to the timing of intervention based on the results of the EVRA study but would like to. These respondents listed their anticipated barriers (Table 3).

62% of respondents stated that the cost effectiveness results would alter how they made clinical decisions and 30% said they would not have any impact. 4% stated that this would depend and 4% said the decisions are made by someone else such as Clinical Commissioning Groups (CCGs) in the UK.

## Discussion

The survey responses generated from this study provide helpful insights into the global management of venous leg ulceration post the EVRA trial.<sup>10</sup>

Globally, the median time to referral was 6 weeks, increasing to 8 weeks in the UK. This is longer than the

recommendations issued by NICE.<sup>5</sup> Reasons for this could include education in primary care,<sup>13</sup> ease of referral, access to secondary care services and patient preference. Recent evidence suggests that most CCGs commission this service in the UK<sup>14</sup> and measures are being taken to improve referral access from primary to secondary care.<sup>15</sup>

This survey has additionally shown that there are some perceived constraints in secondary care with approximately only 60% of participants feeling they are able to perform intervention in the time frame in which they hope to. This is reflected when evaluating perceived barriers to implementing EVRA as many respondents cited a lack of theatre space or time as barriers to care.

A minority of clinicians chose to perform surgical/endovenous intervention after ulcer healing. Although evidence from randomised control trials indicates that surgical/endovenous intervention can help promote venous ulcer healing,<sup>10</sup> this is not reflected in the UK,<sup>5</sup> European<sup>9</sup> or American guidelines.<sup>8</sup> The results of this survey suggest that most clinicians would align their practice with the EVRA trial results. The EVRA trial results should be reflected in national and international guidelines to better guide clinical practice.

This survey suggests that the UK comparatively has significantly longer referral times, longer waiting times to secondary care and longer times to intervention.

**Table 3.** Clinician perspectives on the barriers of implementing EVRA in normal practice.

Barriers to changing practice	Actual (n = 347)	Anticipated (n = 347)
I had no barriers changing practice	70 (20.2%)	66 (19.0%)
Lack of operating space or time	63 (18.2%)	59 (17.0%)
Theatre capacity	52 (15.0%)	49 (14.1%)
Primary/secondary care integration/referral	26 (7.5%)	28 (8.1%)
Duplex scanning capacity	26 (7.5%)	21 (6.1%)
Reimbursement by health service or insurance companies	21 (6.1%)	38 (11.0%)
Resistance from colleagues	20 (5.8%)	18 (5.2%)
Cost of changing the service model	19 (5.5%)	18 (5.2%)
Other	15 (4.3%)	11 (3.2%)
Local/Clinical Commissioning Group Guidelines	12 (3.5%)	8 (2.3%)
Lack of trained staff	9 (2.6%)	10 (2.9%)
National guidelines	8 (2.3%)	9 (2.6%)
The decision to change practice was made by somebody else	5 (1.4%)	8 (2.3%)
Other costs	1 (0.3%)	4 (1.2%)

Clinicians who have already implemented EVRA listed the actual barriers they experienced doing this. Clinicians who have not yet implemented EVRA listed the barriers that they anticipated would arise.

This is supported elsewhere where it is suggested that the UK is possibly undertreating patients with chronic venous disease.<sup>16</sup> This may relate to relative constraints of the National Health Service compared to other privatised health care systems globally.

The survey was predominantly completed by vascular surgeons working in academic units in Europe; this selection bias could lead to inadequate representation of the care administered in other types of units. Although the number of respondents was high, there was a low overall response rate; this again could contribute to a selection bias. The survey was only performed 6 months after the EVRA trial results were published; the impact of the EVRA trial may become more pronounced with time. It is also important to note that this survey evaluates subjective clinician perspectives on how venous ulceration is currently managed; further work evaluating additional objective measures should be performed.

## Conclusion

Evaluating clinician perspectives has provided helpful insights into the current management of venous ulceration and what impacts EVRA may have had on this. This survey has identified that although many clinicians are aware of EVRA, there may be a number of barriers in implementing its findings to clinical practice. The healthcare structures in each geographical region may vary significantly. Given the low response rate, a more in-depth evaluation of the barriers to achieving and delivering best practice care should be performed in each local region to advance service provision.

## Declaration of Conflicting Interests

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## Ethical approval

No ethical approval or patient consent was required for this article.

## Guarantor

AHD.

## Contributorship





FH and AHD conceived the research idea. FH and AK designed the questionnaire. FH performed the data collection and data analysis via Excel. SS performed the data analysis via SPSS. SS wrote the manuscript, supported by FH, SO and AHD. All authors commented on the manuscript.

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### Supplemental material

Supplemental material for this article is available online.

### References

1. Rabe E, Guex JJ, Puskas A, et al. Epidemiology of chronic venous disorders in geographically diverse populations: results from the vein consult program. *Int Angiol* 2012 ; 31: 105–115.
2. Rabe E and Pannier F. Societal costs of chronic venous disease in CEAP C4, C5, C6 disease. *Phlebology* 2010; 25: 64–67.
3. Sritharan K, Lane TRA and Davies AH. The burden of depression in patients with symptomatic varicose veins. *Eur J Vasc Endovasc Surg* 2012; 43: 480–484.
4. Souza Nogueira G, Rodrigues Zanin C, Miyazaki MCOS, et al. Venous leg ulcers and emotional consequences. *Int J Low Extrem Wounds* 2009; 8: 194–196.
5. National Institute for Health and Care Excellence. Varicose veins: diagnosis and management. Clinical guideline [CG168], <https://www.nice.org.uk/Guidance/CG168> (accessed 7 October 2020).
6. Barwell JR, Davies CE, Deacon J, et al. Comparison of surgery and compression with compression alone in chronic venous ulceration (ESCHAR study): randomised controlled trial. *Lancet* 2004; 363: 1854–1859.
7. Glociczki P, Comerota AJ, Dalsing MC, et al. The care of patients with varicose veins and associated chronic venous diseases: clinical practice guidelines of the society for vascular surgery and the American Venous Forum. *J Vasc Surg* 2011 May; 53: 2S–48S.
8. O'Donnell TF, Jr, Passman MA, Marston WA, et al. Management of venous leg ulcers: clinical practice guidelines of the society for vascular surgery® and the American Venous Forum. *J Vasc Surg* 2014; 60: 3S–59S.
9. Wittens C, Davies AH, Baekgaard N, et al. Editor's choice – management of chronic venous disease: clinical practice guidelines of the European Society for Vascular Surgery (ESVS). *Eur J Vasc Endovasc Surg* 2015; 49: 678–737.
10. Gohel MS, Heatley F, Liu X, et al. A randomized trial of early endovenous ablation in venous ulceration. *N Engl J Med* 2018; 378: 2105–2114.
11. Davies HOB, Popplewell M, Bate G, et al. Impact of UK NICE clinical guidelines 168 on referrals to a specialist academic leg ulcer service. *Phlebology* 2018; 33: 84–88.
12. Guest JF, Ayoub N, McIlwraith T, et al. Health economic burden that different wound types impose on the UK's National Health Service. *Int Wound J* 2017; 14: 322–330.
13. Lane TRA, Sritharan K, Herbert JR, et al. Management of chronic venous disease by primary care. *Phlebology* 2013; 28: 299–304.
14. Carradice D, Forsyth J, Mohammed A, et al. Compliance with NICE guidelines when commissioning varicose vein procedures. *BJS Open* 2018; 2: 419–425.
15. NHS England and NHS Improvement. CCG indicator specifications for 2020-2021, <https://www.england.nhs.uk/wp-content/uploads/2020/01/cquin-20-21-indicator-specifications.pdf> (accessed 7 October 2010).
16. Moore HM, Lane TRA, Thapar A, et al. The European burden of primary varicose veins. *Phlebology* 2013; 28: 141–147.