

The global management of leg ulceration: Pre early venous reflux ablation trial

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Abstract

Background: Various guidelines exist worldwide for the diagnosis and management of venous leg ulcers; however, these are difficult to implement resulting in disparate treatment of patients globally.

Method: An online, 26-question survey was designed to evaluate the current global management of venous leg ulceration and was emailed globally to approximately 15,000 participants (November 2017–February 2018).

Results: Overall, 799 responses were received from 86 countries, with a 5% response rate. The respondent physicians saw a median of 10 (interquartile range 5–20) patients per month, with a median time to referral from primary to secondary care of six weeks. Of the respondents, 61% arranged an ankle brachial pressure index on first visit and 84% performed a venous duplex, with 95% prescribing compression for those in whom it was not contraindicated. Fifty-nine percent performed endovenous intervention or surgery prior to ulcer healing.

Conclusions: The survey showed a diversity of treatment pathways. The need to develop a robust, clear pathway for patients with leg ulceration is clearly required.

Keywords

Venous ulceration, leg ulcers, compression bandaging, chronic venous insufficiency, endovenous treatment

Introduction

Venous leg ulcers (VLUs) are common, accounting for an estimated 70% of all leg ulcers and affecting up to 2% of the adult population. The estimated annual UK health service cost burden is between £400 million and £1 billion,^{1–5} with the USA estimating costs to be as high as \$15 billion.^{6,7} The condition can be extremely distressing for patients, greatly affecting their quality of life.^{8,9} There is currently no standalone National Institute for Health and Care Excellence (NICE) guideline for the treatment and management of leg ulceration in the UK, and there is evidence of considerable variation between National Health Service trusts as to which patients qualify for referral or treatment of varicose veins and leg ulcers. A substantial proportion of patients are still managed in the community, without referral to a specialist service, with widespread acceptance that the modern management of patients with VLUs is suboptimal.^{10–12}

The 2013 NICE clinical guideline (CG) 168 for the diagnosis and management of varicose veins¹³ recommends that patients with current ulceration should be

referred to a vascular service for assessment and treatment within two weeks and that a venous duplex is performed to confirm the presence of superficial or deep venous reflux. The guidelines state that the first line of treatment should be interventional, and compression therapy alone should only be used if this is not indicated. Endothermal ablation (including radiofrequency ablation and endovenous laser ablation) should be considered, followed by ultrasound-guided foam sclerotherapy if endothermal ablation is deemed unsuitable, and finally surgery if both the former are not deemed suitable options. Intervention in the UK is usually performed once an ulcer is healed to prevent recurrence based on the results of the ESCHAR

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study,¹⁴ with the use of compression bandaging if interventional treatment is not suitable or post intervention.

Guidelines in the USA and Europe do not make recommendations regarding referral from the community to specialist centres, but recommend ablation of the incompetent superficial veins in addition to compression therapy to help ulcer healing and prevent recurrence.^{6,15,16} Unfortunately, as guidelines can be difficult to implement¹⁷ and embed in healthcare systems, patients in both the UK and USA often suffer from delays in referral resulting in disparate care and harder to heal ulcers. A recent UK study looked at the number of leg ulcer referrals before and after implementation of the NICE CG 168 and found that, despite noting an increase in overall referrals since implementation, this did not impact on early referral, and it is likely that many patients are not referred at all.^{4,18}

A National Institute of Health Research funded randomised controlled trial, Early Venous Reflux Ablation (EVRA), investigated the clinical and cost effectiveness of treating patients with early superficial venous ablation. Published in April 2018,¹⁹ this study has the potential to influence chronic venous disease guidelines worldwide. The aim of this study was to determine the standards of global management of VLUs prior to publication of the 12-month outcome results of the EVRA study.

Methods

An online, 26-question survey, with an introduction detailing the EVRA trial, was designed using the Qualtrics management platform (Qualtrics, UT, USA) to assess various aspects of the global management of venous leg ulceration. A focus group of clinicians was asked to identify important and appropriate questions to include. The survey aimed to collect the number of patients with leg ulceration seen and referral times from primary to secondary care, whether ankle brachial pressure index (ABPI) and duplex ultrasound (DUS) assessments were performed, whether compression therapy was utilized, whether endovenous interventions or surgery were performed and, if so, the methods and timing of these. Clinicians were also asked their opinion on whether intervention affects healing and recurrence and whether the results of the EVRA study would influence their practice. The survey is detailed in supplementary Appendix 1 and was classed as a service evaluation exercise according to the Health Research Assessment (HRA) decision tool and therefore did not require ethical approval.²⁰ The survey underwent internal and external testing and was piloted externally to confirm appropriate content and face validity.²¹

An invitation email to complete the survey was circulated by various societies to approximately 15,000 participants using local, national and international mailing lists.

Responses were collected within Qualtrics over a four-month period (November 2017–February 2018) prior to the publication of the EVRA trial. Continuous variables that follow a normal distribution were summarised using means and standard deviations. Skewed continuous variables were summarised using medians and interquartile ranges (IQRs). Categorical variables were summarised using frequencies and percentages.

Results

There were 799 responses received from 86 countries, with a 5% response rate; Table 1 details the baseline characteristics of the respondents and global responses by country. As some respondents did not answer all questions, the total number of responses is stated in each section.

Number of patients seen each month with open leg ulceration

The median number of patients seen with open leg ulceration each month globally (and also in the UK) was 10 (IQR 5–20), as described by 797 respondents.

Average referral time from primary care

Of 797 respondents, the overall median referral time from primary care to a specialised vascular service was six weeks (IQR 2–12), whereas the median referral time in the UK was eight weeks (IQR 6–12).

ABPI performed or arranged

Of the respondents ($n=786$), 61% performed or arranged an ABPI at the first visit. Those who did not, reported that they relied on a physical exam (palpable pulses), review of symptoms or results of a DUS.

Venous duplex performed or arranged

A venous DUS was performed on or arranged for patients presenting with a leg ulcer by 84% of the respondents ($n=793$). Those who did not, stated that they mostly relied on a clinical arterial assessment or physical exam.

Compression prescribed

With respect to compression, 95% of the 793 respondents prescribed compression if not contraindicated, with 51% prescribing compression bandages, 31%

Table 1. Respondent baseline characteristics.

Characteristic	Respondents (n = 799)
Age (years)	n = 798
Under 30	10 (1.3%)
30–39	113 (14.2%)
40–49	222 (27.8%)
50–59	280 (35.1%)
Over 60	173 (21.7%)
Clinician type	n = 799
Vascular surgeon	552 (69.1%)
Phlebologist	115 (14.4%)
General surgeon	51 (6.4%)
Dermatologist	10 (1.3%)
Family medical practitioner	3 (0.4%)
Vascular nurse specialist	15 (1.9%)
Other	53 (6.6%)
Gender	n = 798
Female	112 (14.0%)
Male	681 (85.3%)
Prefer not to say	5 (0.7%)
Region of practice ^a	n = 799
United Kingdom	128 (16.0%)
Europe (excluding UK)	331 (41.4%)
North America	172 (21.5%)
Central America	16 (2.0%)
South America	48 (6.0%)
Australasia	19 (2.4%)
Africa	12 (1.5%)
Asia	59 (7.4%)
Middle East	14 (1.8%)
Area of care	n = 798
Primary/community	147 (18.4%)
Secondary/district general/county hospital	232 (29.1%)
Academic/teaching	316 (39.7%)
Other	102 (12.8%)

^aAlbania (n = 3), Argentina (n = 11), Australia (n = 15), Austria (n = 6), Bangladesh (n = 1), Belarus (n = 4), Belgium (n = 9), Bosnia (n = 1), Brazil (n = 26), Bulgaria (n = 5), Canada (n = 5), Caribbean (n = 3), Central America (n = 6), Chile (n = 3), Colombia (n = 3), Costa Rica (n = 1), Croatia (n = 1), Cyprus (n = 1), Czech Republic (n = 4), Denmark (n = 5), Ecuador (n = 2), Egypt (n = 3), El Salvador (n = 1), Estonia (n = 1), Finland (n = 1), France (n = 11), Georgia (n = 2), Germany (n = 21), Greece (n = 12), Honduras (n = 2), Hong Kong (n = 1), Hungary (n = 1), Iceland (n = 1), India (n = 27), Indonesia (n = 1), Iran (n = 1), Ireland (n = 8), Israel (n = 4), Italy (n = 49), Japan (n = 5), Jordan (n = 2), Kenya (n = 1), Kosovo (n = 1), Kuwait (n = 1), Latvia (n = 7), Lebanon (n = 3), Lithuania (n = 10), Luxembourg (n = 1), Mexico (n = 14), Moldova (n = 2), Morocco (n = 1), Nepal (n = 1), Netherlands (n = 15), New Zealand (n = 4), Nicaragua (n = 2), Norway (n = 7), Pakistan (n = 2), Panama (n = 1), Paraguay (n = 1), Peru (n = 2), Poland (n = 15), Portugal (n = 18), Romania (n = 2), Russia (n = 22), Saudi Arabia (n = 1), Senegal (n = 1), Serbia (n = 4), Slovakia (n = 4), Slovenia (n = 4), South Africa (n = 3), South Korea (n = 11), Spain (n = 23), Sri Lanka (n = 1), Sweden (n = 20), Switzerland (n = 6), Taiwan (n = 3), Thailand (n = 4), Tunisia (n = 1), Turkey (n = 9), United Arab Emirates (n = 2), Uganda (n = 1), Ukraine (n = 9), United Kingdom (n = 128), USA (n = 153), and Missing (n = 19).

prescribing stockings and 18% cited using other types of compression (n = 776).

Does treatment of superficial truncal venous reflux by endovenous intervention or surgery improve ulcer healing/reduce ulcer recurrence in patients with chronic venous ulceration?

Of the respondents (n = 787), 78% thought that the treatment of superficial truncal venous reflux by endovenous intervention or surgery improves ulcer healing in patients with chronic venous ulceration. Similarly, 80% of the respondents thought that the treatment of superficial truncal venous reflux by endovenous intervention or surgery reduces recurrence rates in patients with chronic venous ulceration.

Timing of intervention

Figure 1 shows the timing of endovenous intervention or surgery; 59% of respondents usually performed endovenous intervention or surgery prior to ulcer healing, with 19% after and 19% depending on the individual circumstances.

Intervention strategy preferences

Endothermal ablation alone was the most utilized method, followed by a combination of foam and endothermal, followed by foam alone and open surgery. Mechanochemical ablation, glue and combinations of those were the least utilized (Table 2).

Cost appeared to be the driver to use foam alone and open surgery, whereas guidelines were the driver for utilizing endothermal ablation alone, foam alone or a combination of the two. Clinician preference drove those using endothermal ablation alone and endothermal ablation and foam combination, whereas patient

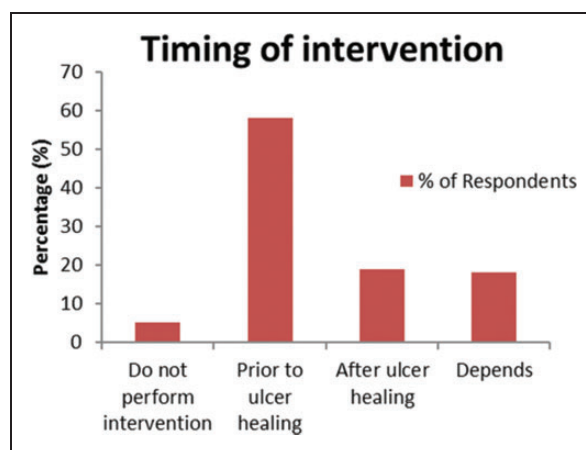


Figure 1. Timing of endovenous or surgical interventions (n = 785).

Table 2 Interventional strategies employed to treat truncal superficial venous reflux in patients with active leg ulceration.

Interventional strategy	Always (%)	Mostly (%)	Sometimes (%)	Never (%)	Total (n)
Endothermal ablation alone	14.6	38.3	34.7	12.5	583
Foam and endothermal ablation combination	9.7	22.3	40.6	27.4	547
Open surgery alone	4.2	17.0	43.4	35.4	553
Foam alone	3.5	8.4	51.2	36.9	549
Open surgery and foam	1.5	6.7	33.5	58.3	537
Mechanochemical endovenous ablation alone	1.2	5.0	22.2	71.6	514
Foam and mechanochemical endovenous ablation combination	0.9	2.6	16.9	79.5	508
Glue alone	0.2	1.2	15.9	82.7	504
Foam and Glue combination	0.00	1.2	10.9	87.9	506
Other method not stated	2.1	3.2	5.8	88.9	380

preference drove those using endothermal ablation alone and foam alone.

Assessing technical success

Of 647 respondents, 73% stated that they always perform a DUS post intervention to assess technical success. Those who did not usually cited lack of resources or that they had confidence in the effectiveness of their treatment. Some reported that performing a post interventional duplex was dependent on whether symptoms had resolved, whether the ulcer had healed or not, or if any complications were apparent.

Of those who perform a post interventional duplex ($n = 473$), 48% usually perform one, 16% perform two, 9% three and 3% four. Six percent of respondents perform more than four and 18% did not state the number. With respect to timings ($n = 473$), 42% performed the first post intervention duplex at one-week, 32% between one and six weeks and 9% post six weeks.

Healthcare perceptions of important outcome measures

Outcome measures of endovenous or surgical intervention were ranked in importance (1 most important; 6 least important) to the clinician. Ulcer healing was reported as being the most important outcome measure to the respondents (66.5%), followed by quality of life (22.2%) and ulcer recurrence (8.9%), whereas cost (1%) and number of reinterventions (0.7%) were considered much less important.

Changing practice

Of 681 global respondents, 46% stated that they would amend their practice to treat prior to ulcer healing if the EVRA study were to show that early intervention improves ulcer healing; 37% stated that they would not change practice but already treated prior to ulcer

healing, 6% would not change practice and currently treat after ulcer healing and 11% said it would depend on other factors not collected. If the EVRA trial were to show that early endovenous ablation did not improve ulcer healing, 46% of respondents ($n = 676$) stated that they would not change their practice. Reasons cited were that they were confident early ablation did improve ulcer healing, and it was already proven to reduce recurrence. A change in practice would be considered by 28% of respondents; reasons stated included insurance companies no longer covering early intervention or clinicians adopting less aggressive strategies.

Discussion

The survey results show that the referral and management of venous ulceration is disparate globally despite Level 1 evidence that surgical correction of truncal superficial venous reflux can reduce the risk of ulcer recurrence and Level 2 evidence that endovenous ablation may improve ulcer healing.¹⁴ The results echo the findings of van der Velden et al.²² who also demonstrated global variation in the management of patients with superficial venous disease and is likely a result of the difficulty of implementing guidelines, coupled with variation in the uptake of guidelines.^{23,24}

If we look at the UK data as an example, the median number of patients seen by specialist vascular centres per month was reported to be 10 (IQR 5–20), which would indicate that only a small proportion of patients with leg ulceration (currently estimated at 278,000⁴) are actually referred to secondary care, assuming that each vascular surgeon in the UK sees 120 patients each year, which in itself may be an overestimation by the respondents.⁴ It should be noted that there was no discrimination between new and recurrent ulcers in the survey responses.

The reported referral times were longer than the two weeks recommended by NICE.¹³ These appear to

be unjustified treatment delays which may impact on ulcer healing times²⁵ and, indirectly, on the important clinical, quality of life and financial burden of venous leg ulceration. It is likely that the reasons for this are multifactorial; economic constraints, training and education of primary care providers, lack of patient awareness of available treatments and the absence of an evidence base underpinning the guidelines to encourage early diagnosis, referral and intervention at the time of survey completion.²⁶

Investigations

The survey revealed that there was poor compliance with the recommendations for ABPI and venous duplex despite USA and UK guidelines advocating these.^{6,16,27} Perhaps surprisingly, 73% of the respondents reported performing a DUS post intervention to assess technical success. Although not examined in detail by this survey, it is likely that this practice is related to the availability of funding to perform these assessments in different healthcare systems (e.g. nationalised versus private).

Interventions

The interventional strategies varied greatly, with the most utilized method reported as endothermal alone, which highlights potential under treatment by not targeting the incompetent tributaries or the veins in the sub-ulcer plexus. The UK recommends endothermal ablation as the first-line treatment, but kit availability varies amongst Trusts, with foam widely utilized due to its low cost. Globally, health systems have different methods and rules of reimbursement which may affect intervention timing and modality. Indeed, cost appears to be the driver to use foam alone, whereas guidelines were the driver for utilising endothermal ablation alone, foam alone or a combination of the two.

It is possible that the proportion of patients treated prior to ulcer healing will increase with Level 1 evidence now available from the EVRA trial that early intervention improves ulcer healing.¹⁹ Indeed, nearly half of the respondents stated that they would change practice with respect to intervention timing if the EVRA study results show that early intervention improves ulcer healing, with surprisingly only a small number of clinicians reporting barriers to changing practice. There is no doubt that issues still exist with respect to referrals from primary to secondary care, resulting in a number of patients not receiving interventional treatment despite the evidence that this can prevent ulcer recurrence.^{14,18,24,28} It will be interesting to see if the results of the EVRA trial influence practice in reality, and it would be helpful to resurvey the

participants to gain an understanding of the impact of the publication and gain a better insight into the challenges of changing leg ulcer pathways globally.

Limitations

The study is limited by the response rate which was estimated to be at least 5%, although it was impossible to determine the exact rate as some surgeons were listed multiple times, so it is likely the rate was higher than this; overall, 799 responses were received from 86 countries. In UK, 128 vascular surgeons responded to the survey; as there are approximately 450 consultant vascular surgeons registered with the Vascular Society of Great Britain and Ireland, nearly a third of the total vascular surgeons responded. As not all the surgeons will treat patients with venous ulceration, it is likely the representation is higher than anticipated.²⁹ It is also possible that the respondents may have overestimated the number of patients seen or treated, and therefore, the real-world scenario may be worse than demonstrated by these results.

Other potential limitations include selection bias for only targeting society members, although it would be almost impossible to contact clinicians who were not members of these societies for data protection reasons. The reimbursement mechanism (private versus state funded) of the targeted healthcare system was not collected which would have influenced some of the responses.

Conclusion

This survey highlights that global leg ulcer care is inconsistent, with a clear need to develop a robust pathway for patients with leg ulceration. The reasons for the variation are multifactorial, including local funding availability, access to healthcare, differences in training and education and inconsistent referral pathways coupled with a lack of Level 1 evidence that early intervention improves ulcer healing.

What does this study/review add to the existing literature and how will it influence future clinical practice?

This study highlights the disparity between current global venous leg ulceration practices with respect to the referral, assessment and management; it is likely that the recent randomised controlled EVRA trial will impact the management of these patients.

Declaration of Conflicting Interests

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Ethical approval

The survey was classed as a service evaluation exercise according to the HRA decision tool and therefore did not require ethical approval

Guarantor

AHD.

Contributorship

FH and SO researched literature and conceived the survey, which was reviewed by AHD. FH was involved in survey distribution, data collection and data analysis. FH wrote the first draft of the manuscript. All authors reviewed and edited the manuscript and approved the final version of the manuscript.

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Supplemental material

Supplemental material for this article is available online.

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