2-year surveillance 2016 – Varicose veins in the legs (2013) NICE guideline CG168

Appendix A: decision matrix

Summary of new evidence from 2-year surveillance	Summary of new intelligence from 2-year surveillance	Impact
Information for people with varicose veins		
168 – 01 What are the perceptions and expectations of people with varicose veins (e.g. natural history, treatment) and how can they be addressed? (1.1.1, 1.1.2)		
No relevant evidence identified.	None identified relevant to this question.	No new evidence was identified that would affect recommendations.
Referral to a vascular service		
168 – 02 In people with leg varicose veins at CEAP class C2 which signs, symptoms and/or patient characteristics are associated with disease progression to i) C3, ii) C4, iii) C6? (1.2.2)		
No relevant evidence identified.	None identified relevant to this question.	No new evidence was identified that would affect recommendations.
168 – 03 In people with leg varicose veins at CEAP class C3 which signs, symptoms and/or patient characteristics are associated with disease progression to i) C4, ii) C6? (1.2.2)		
No relevant evidence identified.	None identified relevant to this question.	No new evidence was identified that would affect recommendations.
168 – 04 In people with leg varicose veins at CEAP class C4 which signs, symptoms and/or patient characteristics are associated with disease progression to C6? (1.2.2)		
No relevant evidence identified.	None identified relevant to this question.	No new evidence was identified that would affect recommendations.

Summary of new evidence from 2-year surveillance	Summary of new intelligence from 2-year surveillance	Impact
168 – 05 In people with leg varicose veins are there any factors (clinical signs and symptoms or patient reported outcomes) that would predict increased benefits or harms from varicose veins interventional treatments? (1.2.1-1.2.2)		
No relevant evidence identified.	None identified relevant to this question.	No new evidence was identified that would affect recommendations.
Assessment and treatment in a vascular service		
168 – 06 What is the diagnostic accuracy of hand held Doppler compared to duplex scanning when used in patients with varicose veins? (1.3.1)		
No relevant evidence identified.	None identified relevant to this question.	No new evidence was identified that would affect recommendations.
168 – 07 Does the use of duplex ultrasound during assessment improve outcome after interventional treatment compared to no duplex scanning in people with leg varicose veins? (1.3.1)		
No relevant evidence identified.	None identified relevant to this question.	No new evidence was identified that would affect recommendations.
168 – 08 What is the clinical and cost effectiveness of compression therapy compared with no treatment or lifestyle advice in people with leg varicose veins? (1.3.4)		
One double-blind RCT[1] of Kinesio taping to compress the calf and the ankle compared to placebo taping in post-menopausal women with mild-to-moderate chronic venous insufficiency was found (n=120). Results after 4 weeks of treatment showed improvements in heaviness, claudication, swelling, muscle cramps, venous refill time, venous pump function, extracellular water, severity, physical function and body pain in the intervention group compared to the control group. There was significant reduction in pain in both groups.	None identified relevant to this question.	New evidence is unlikely to impact on guideline recommendations. The guideline does not recommend compression hosiery to treat varicose veins unless interventional treatment is unsuitable (recommendation 1.3.4). One relatively small RCT, of a short duration, of Kinesio taping for compression of the leg compared to sham taping in post-menopausal women with mild-to-moderate chronic venous insufficiency[1] showed improvements in symptoms, peripheral venous flow and severity, in the intervention group compared to the control group, with significant reductions in pain

Summary of new evidence from 2-year surveillance	Summary of new intelligence from 2-year surveillance	Impact
		observed in both groups. This trial shows benefits for Kinesio taping in varicose veins but is limited by a relatively small sample size, made up of women only, and a short duration of follow-up. The trial considers a different intervention of Kinesio taping which is not included in the guideline recommendations. This is the only trial on this taping therefore it is pertinent to await further evidence before considering an update of this section of the guideline.
168 – 09 What is the clinical and cost effectiveness of compression therapy compared with foam sclerotherapy in people with leg varicose veins? (1.3.4)		
No relevant evidence identified.	None identified relevant to this question.	No new evidence was identified that would affect recommendations.
168 – 10 What is the clinical and cost effectiveness of compression therapy compared with stripping surgery in people with leg varicose veins? (1.3.4)		
One RCT[2] compared compression stockings with surgery in the treatment of patients with varicose veins with CEAP class C2-C3 and superficial venous reflux (n=153). After a 2- year follow up, there were significant improvements in the venous clinical severity score (VCSS), the venous segmental disease score (VSDS) and health-related quality of life (HRQoL) in the surgery group compared to the compression stocking group.	None identified relevant to this question.	New evidence is unlikely to impact on guideline recommendations. One study[2], a randomised trial of compression therapy versus surgery in patients with varicose veins found that surgery is an effective treatment when compared with compression stockings. This new evidence is unlikely to change the direction of the current recommendation which states: Do not offer compression hosiery to treat varicose veins unless interventional treatment is unsuitable (recommendation 1.3.4).
168 – 11 What is the clinical and cost effectiveness of compression therapy compared with endothermal ablation in people with leg varicose veins? (1.3.4)		
No relevant evidence identified.	None identified relevant to this question.	No new evidence was identified that would affect recommendations.

Summary of new evidence from 2-year surveillance	Summary of new intelligence from 2-year surveillance	Impact
168 – 12 What is the clinical and cost effectiveness of stripping surgery compared with foam sclerotherapy in people with truncal leg varicose veins? (1.3.2)		
A 3-year follow up of an RCT included in the guideline[3] comparing four treatments for varicose great saphenous veins - surgery, foam sclerotherapy, laser ablation and radiofrequency ablation (n=500, 580 legs) found significantly more treatment failures and reoperations following UGFS compared to the other treatments. There were no significant differences between groups for recurrence, with similar patterns of reflux and location of recurrent varicose veins between the groups. All four treatments improved VCSS and quality of life, with no significant differences between the groups.	None identified relevant to this question.	New evidence is unlikely to impact on guideline recommendations. The new evidence[3] is a longer term follow-up of an RCT that was included in the guideline. The findings of this 3-year report are that all four treatment modalities were effective and resulted in similar improvements in severity scores and quality of life. These results are similar to the results at 1 year that were included in the guideline. In addition, this review question (comparing stripping surgery with foam sclerotherapy) is linked to the other four review questions below on interventional treatment (one question comparing stripping surgery with endothermal ablation, one question comparing foam sclerotherapy with endothermal ablation; and two questions comparing treatment options for tributary veins), with the recommendation on interventional treatment in the guideline coming from an overall consideration of the evidence from these five review questions. Therefore, this new evidence is unlikely to change the direction of the current recommendation (1.3.2) which prescribes the following sequence for people with confirmed varicose veins and truncal reflux: • endothermal ablation • ultrasound-guided foam sclerotherapy, if endothermal ablation is unsuitable • surgery, if ultrasound-guided foam sclerotherapy is unsuitable.

Summary of new evidence from 2-year surveillance	Summary of new intelligence from 2-year surveillance	Impact
168 – 13 What is the clinical and cost effectiveness of stripping surgery compared with endothermal ablation in people with truncal leg varicose veins? (1.3.2)		
Two publications of one UK NIHR HTA-funded multicentre-RCT (the CLASS trial)[4,5] compared the clinical and cost-effectiveness of surgery, foam sclerotherapy and laser ablation (n=798). Results at 6 months revealed that the health gain achieved in the Aberdeen Varicose Vein Questionnaire (AVVQ) with foam sclerotherapy was significantly lower than with surgery, but was similar to that achieved with laser ablation. There were no significant differences between the three groups in generic QoL measures. Cost-effectiveness analysis suggested that, at 5 years, laser ablation would be most cost-effective at conventional thresholds, followed by foam sclerotherapy and surgery. There were significantly fewer procedural complications in the laser ablation group than after foam and surgery. There were no differences in VCSS between the three treatments. Truncal ablation rates were similar for surgery and laser ablation, with rates for both being significantly higher than for foam sclerotherapy. A cost-effectiveness study[6] of the CLASS trial found that at 6 months, foam sclerotherapy and laser ablation were cheaper than surgery on the average, and were even cheaper when costs associated with the use of the operation theatre were included. Foam sclerotherapy produced fewer quality-adjusted life years (QALYs), whereas laser ablation produced additional QALYs. Extrapolating to 5 years, laser ablation was associated with increased costs and QALYs compared with foam sclerotherapy, and generated cost savings and QALY	One GDG member commented that CLASS trial needs to be referenced but may not alter the recommendation.	New evidence is unlikely to impact on guideline recommendations. A number of RCTs[4-13] comparing surgery with endothermal ablation (and foam sclerotherapy in one study) were identified. Generally the studies showed that endothermal ablation was superior to the other options. Of particular note are the NIHR CLASS trial reports[4-6] that revealed endovenous laser ablation to be clinically and cost-effective compared to surgery and foam sclerotherapy. Therefore, this new evidence is unlikely to change the direction of the current recommendation (1.3.2) which prescribes the following sequence for people with confirmed varicose veins and truncal reflux: • endothermal ablation • ultrasound-guided foam sclerotherapy, if endothermal ablation is unsuitable • surgery, if ultrasound-guided foam sclerotherapy is unsuitable.

Summary of new evidence from 2-year surveillance	Summary of new intelligence from 2-year surveillance	Impact
gain compared with surgery. However, laser ablation was the most cost-effective treatment strategy when a threshold of £20 000 per QALY gained was used. A multi-centre RCT[7] comparing surgery and laser ablation with and without high ligation, for varicosity of the great saphenous vein (n=449) found significantly more refluxive side-branches in the laser ablation groups, but no significant differences for recurrences and sonographic reflux between groups. There was also significantly more matting and postoperative restrictions, lymphatic oedema and sensory disturbance of the saphenous nerve in the two laser groups compared with surgery. One RCT[8] of laser ablation of the great saphenous vein (GSV) compared to surgery (n=65) found similar occlusion rates in both groups at the 18-month follow-up. There were significant reductions in median CEAP scores in both groups after 1 week and for the rest of the study. The Aberdeen Varicose Vein Symptom Severity score was significantly lower in the laser ablation group at the 12- and 18-month follow-ups. There was no significant difference in patient satisfaction in both groups. One RCT[9] of conventional surgery versus laser ablation for small saphenous varicose veins (n=106) found no significant difference in clinical recurrence, sensory disturbance or any quality of life domain in the two groups, but laser ablation was significantly better than surgery in eliminating axial reflux. A 5-year follow-up data of an RCT[10] comparing high		

Summary of new evidence from 2-year surveillance	Summary of new intelligence from 2-year surveillance	Impact
ligation and stripping with high ligation and laser ablation of the great saphenous vein (n=100) found high patient satisfaction as well as significant improvements for both groups in CEAP-C class, VCSS, and the CIVIQ2 quality of life score. There was no difference in recurrence rates or rates of reopened or residual incompetent GSV between the two groups. A 5-year follow-up of an RCT included in the guideline[11] comparing laser ablation with open surgery in patients with great saphenous vein incompetence (n=121 patients, 137 legs) found no significant differences between the groups in the number of open refluxing segments of 5 cm or more, clinical recurrence, reoperations, VCSS, Aberdeen VVSS or SF-36 quality of life scores. One RCT[12] of laser ablation versus surgery in the treatment of small saphenous vein incompetence (n=175) found a much higher residual incompetence, higher rates of surgical site infection, longer operation time and significantly more neurological complications in the surgery group compared to laser ablation at 6 weeks. the laser ablation group experienced more pain after one week of treatment compared to surgery, however, both interventions resulted in less pain after 6 weeks. There was no significant difference between the groups for quality of life but there was quicker return to work and better appreciation of the scar after laser ablation. One RCT[13] of endovenous microwave ablation (EMA) with high ligation versus conventional surgery alone		

Summary of new evidence from 2-year surveillance	Summary of new intelligence from 2-year surveillance	Impact
(n=not reported in abstract) revealed complete occlusion of varicose veins, lower rate of recurrence, shorter operative time, less bleeding and smaller incisions with EMA than with surgery. There were no significant differences in AVVQ and VCSS scores between the groups although both groups had significant improvements in these scores following treatment. There were a few skin burns in the EMA group but there were fewer sensory changes and bruises.		
168 – 14 What is the clinical and cost effectiveness of foam sclerotherapy compared with endothermal ablation in people with truncal leg varicose veins? (1.3.2)		
A 3-year follow up of an RCT included in the guideline[3] comparing four treatments for varicose great saphenous veins - surgery, foam sclerotherapy, laser ablation and radiofrequency ablation (n=500, 580 legs) found significantly more treatment failures and reoperations following UGFS compared to the other treatments. There were no significant differences between groups for recurrence, with similar patterns of reflux and location of recurrent varicose veins between the groups. All four treatments improved VCSS and quality of life, with no significant differences between the groups. A 15-month follow up of an RCT included in the guideline[14] comparing laser ablation (accompanied by surgical removal of tributary veins) with foam sclerotherapy of the truncal vein only (n=100, 100 legs) found that occlusion of the great saphenous vein was more effective with laser ablation compared to foam sclerotherapy. However, both methods were equally effective at abolishing global venous reflux. Reductions	One GDG member commented that CLASS trial needs to be referenced but may not alter the recommendation.	New evidence is unlikely to impact on guideline recommendations. Five publications[3-6,14] comparing foam sclerotherapy with endothermal ablation (and surgery in one study) were identified. Overall the studies showed that endothermal ablation was superior to the other options. Of particular note are the NIHR CLASS trial reports[4-6] that revealed endovenous laser ablation to be clinically and cost-effective compared to surgery and foam sclerotherapy. Therefore, this new evidence is unlikely to change the direction of the current recommendation (1.3.2) which prescribes the following sequence for people with confirmed varicose veins and truncal reflux: • endothermal ablation • ultrasound-guided foam sclerotherapy, if endothermal ablation is unsuitable • surgery, if ultrasound-guided foam sclerotherapy is

Summary of new evidence from 2-year surveillance	Summary of new intelligence from 2-year surveillance	Impact
in VCSS, AVVQ and the saphenous treatment score were significant compared to baseline, but there were no significant differences between the groups. Two publications of one UK NIHR HTA-funded multicentre-RCT (the CLASS trial)[4,5] compared the clinical and cost-effectiveness of surgery, foam sclerotherapy and laser ablation (n=798). Results at 6 months revealed that the health gain achieved in the Aberdeen Varicose Vein Questionnaire (AVVQ) with foam sclerotherapy was significantly lower than with surgery, but was similar to that achieved with laser ablation. There were no significant differences between the three groups in generic QoL measures. Cost-effectiveness analysis suggested that, at 5 years, laser ablation would be most cost-effective at conventional thresholds, followed by foam sclerotherapy and surgery. There were significantly fewer procedural complications in the laser ablation group than after foam and surgery. There were no differences in VCSS between the three treatments. Truncal ablation rates were similar for surgery and laser ablation, with rates for both being significantly higher than for foam sclerotherapy. A cost-effectiveness study[6] of the CLASS trial found that at 6 months, foam sclerotherapy and laser ablation were cheaper than surgery on the average, and were even cheaper when costs associated with the use of the operation theatre were included. Foam sclerotherapy produced fewer quality-adjusted life years (QALYs), whereas laser ablation produced additional QALYs. Extrapolating to 5 years, laser ablation was associated with increased costs and QALYs compared with foam		unsuitable.

Summary of new evidence from 2-year surveillance	Summary of new intelligence from 2-year surveillance	Impact
sclerotherapy, and generated cost savings and QALY gain compared with surgery. However, laser ablation was the most cost-effective treatment strategy when a threshold of £20 000 per QALY gained was used.		
168 – 15 What is the clinical and cost effectiveness of avulsion surgery compared with foam sclerotherapy in people with tributary leg varicose veins? (1.3.2)		
No relevant evidence identified.	None identified relevant to this question.	No new evidence was identified that would affect recommendations.
168 – 16 What is the clinical and cost effectiveness of truncal vein treatment accompanied by tributary treatments compared with truncal vein treatment alone in people with leg varicose veins? (1.3.2)		
The ambulatory-varicosity-avulsion-later-or-synchronized (AVULS) trial[15] randomised patients undergoing endovenous thermal ablation to either simultaneous phlebectomy or delayed varicosity treatment (n=101). Participants were reviewed at 6 weeks, 6 months, and 1 year with clinical and quality of life scores completed, and were assessed at 6 weeks for need for further intervention for varicose veins. The authors found that participants in the simultaneous group showed a significantly improved VCSS at all time points, with significantly more people in the delayed group requiring further treatment compared to the simultaneous group. There was 1 superficial venous thrombosis in each group and no deep vein thromboses in either group.	None identified relevant to this question.	New evidence is unlikely to impact on guideline recommendations. One RCT[15] of simultaneous phlebectomy or delayed varicosity treatment for patients undergoing endovenous thermal ablation (the AVULS trial) was identified. Results indicated benefit for combining truncal vein treatment with tributary treatments compared to delaying tributary vein treatment in people with leg varicose veins undergoing endovenous thermal ablation. This is in line with the current recommendation (1.3.2) which states: “If incompetent varicose tributaries are to be treated, consider treating them at the same time”.
168 – 17 What is the clinical and cost effectiveness of interventional treatment followed by compression compared with interventional treatment alone in people with leg varicose veins, and, if so, what type of compression, pressure of compression and/or duration of compression is optimal? (1.3.3)		
One RCT[16] of compression stockings for 2 weeks versus no stockings 24 hours after laser ablation of the great	None identified relevant to this question.	New evidence is unlikely to impact on guideline recommendations.

Summary of new evidence from 2-year surveillance	Summary of new intelligence from 2-year surveillance	Impact
saphenous vein during which time all patients wore bandages (n=111) was found. Outcomes were assessed at 2 days, 2 weeks and 6 weeks after the procedure. Results showed significant differences in pain scores during the first week in favour of the stockings group, with higher rates of satisfaction at 2 days and 6 weeks. The group without stockings used significantly more analgesics. There were no significant differences between groups for leg circumference measurements, AVVQ scores, RAND 36-Item Health Survey scores, time to return to work or risk of complications. One RCT[17] of compression stocking for 48 hours or 7 days following laser ablation of the great saphenous vein (n=69) was found. Pain and quality of life were assessed at 48 hours, 1 week, and 6 weeks after treatment; ultrasound at 3 months to assess occlusion rates. Results showed significant differences in pain scores, physical function and vitality in favour of the 7-day group at 1 week but not at 6 weeks. There was complete GSV occlusion in all patients with no deep vein thromboses.		Two RCTs[16,17] of endovenous ablation of varicose veins in the leg followed by compression of various durations[17] or no compression[16] showed compression to be beneficial during the first week after treatment. This new evidence is unlikely to change the direction of the current recommendation (1.3.3) which states: "If offering compression bandaging or hosiery for use after interventional treatment, do not use for more than 7 days".
Management during pregnancy		
168 – 18 No specific clinical question (1.4.1-1.4.3)		
No relevant evidence identified.	None identified relevant to this question.	No new evidence was identified that would affect recommendations.

Summary of new evidence from 2-year surveillance	Summary of new intelligence from 2-year surveillance	Impact
Research recommendations		
RR – 01 Natural history of varicose veins - In people with varicose veins at CEAP (Clinical, etiological, anatomical and pathophysiological) stage C2 or C3, what are the factors that influence progression of the disease to CEAP stages C5 or C6?		
No relevant evidence identified.	None identified relevant to this question.	No new evidence was identified that would affect recommendations.
RR – 02 Natural history of varicose veins - Is pelvic venous incompetence related to recurrence and symptoms of varicose veins?		
No relevant evidence identified.	None identified relevant to this question.	No new evidence was identified that would affect recommendations.
RR – 03 Optimal interventional and conservative treatments at different stages of disease - What is the optimal treatment (compression, surgery, endothermal ablation or foam sclerotherapy) for varicose veins at each of the CEAP stages, that is CEAP stages 2-3, CEAP stage 4 and CEAP stages 5-6?		
No relevant evidence identified.	None identified relevant to this question.	No new evidence was identified that would affect recommendations.
RR – 04 Truncal treatment with or without concurrent tributary treatment - What is the clinical and cost effectiveness of concurrent phlebectomies or foam sclerotherapy for varicose tributaries during truncal endothermal ablation for varicose veins compared with: • **truncal endothermal ablation without concurrent phlebectomies or foam sclerotherapy?** • **truncal endothermal ablation with phlebectomies or foam sclerotherapy if needed, 6–12 weeks later?**		
The ambulatory-varicosity-avulsion-later-or-synchronized (AVULS) trial[15] randomised patients undergoing endovenous thermal ablation to either simultaneous phlebectomy or delayed varicosity treatment (n=101). Participants were reviewed at 6 weeks, 6 months, and 1 year with clinical and quality of life scores completed, and were assessed at 6 weeks for need for further intervention for varicose veins. The authors found that participants in the simultaneous group showed a significantly improved VCSS at all time points, with significantly more people in the delayed group requiring further treatment compared to the	None identified relevant to this question.	New evidence is unlikely to impact on guideline recommendations. One RCT[15] of simultaneous phlebectomy or delayed varicosity treatment for patients undergoing endovenous thermal ablation (the AVULS trial) was identified. Results indicated benefit for combining truncal vein treatment with tributary treatments compared to delaying truncal vein treatment in people with leg varicose veins undergoing endovenous thermal ablation. This is in line with the current recommendation (1.3.2) which states: “If incompetent varicose tributaries are to

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simultaneous group. There was 1 superficial venous thrombosis in each group and no deep vein thromboses in either group.		be treated, consider treating them at the same time".
RR – 05 Complete further evaluation on the systemic effect of foam sclerotherapy and endothermal ablation.		
No relevant evidence identified.	None identified relevant to this question.	No new evidence was identified that would affect recommendations.
RR – 06 Compression as a management option - What is the clinical and cost effectiveness of compression hosiery versus no compression for the management of symptomatic varicose veins?		
No relevant evidence identified.	None identified relevant to this question.	No new evidence was identified that would affect recommendations.
RR – 07 Compression after interventional treatment - What is the clinical and cost effectiveness of compression bandaging or hosiery after interventional treatment for varicose veins compared with no compression? If there is benefit, how long should compression bandaging or hosiery be worn for?		
One RCT[16] of compression stockings for 2 weeks versus no stockings 24 hours after laser ablation of the great saphenous vein during which time all patients wore bandages (n=111) was found. Outcomes were assessed at 2 days, 2 weeks and 6 weeks after the procedure. Results showed significant differences in pain scores during the first week in favour of the stockings group, with higher rates of satisfaction at 2 days and 6 weeks. The group without stockings used significantly more analgesics. There were no significant differences between groups for leg circumference measurements, AVVQ scores, RAND 36-Item Health Survey scores, time to return to work or risk of complications. One RCT[17] of compression stocking for 48 hours or 7 days following laser ablation of the great saphenous vein (n=69) was found. Pain and quality of life were	None identified relevant to this question.	New evidence is unlikely to impact on guideline recommendations. Two RCTs[16,17] of endovenous ablation of varicose veins in the leg followed by compression of various durations[17] or no compression[16] showed compression to be beneficial during the first week after treatment. This new evidence is unlikely to change the direction of the current recommendation (1.3.3) which states: "If offering compression bandaging or hosiery for use after interventional treatment, do not use for more than 7 days".

Summary of new evidence from 2-year surveillance	Summary of new intelligence from 2-year surveillance	Impact
assessed at 48 hours, 1 week, and 6 weeks after treatment; ultrasound at 3 months to assess occlusion rates. Results showed significant differences in pain scores, physical function and vitality in favour of the 7-day group at 1 week but not at 6 weeks. There was complete GSV occlusion in all patients with no deep vein thromboses.		
RR – 08 How long after giving birth should women wait before having interventional treatment for varicose veins?		
No relevant evidence identified.	None identified relevant to this question.	No new evidence was identified that would affect recommendations.
RR – 09 Should women have their varicose veins treated 'between' pregnancies or advised to wait until they do not plan to have any more children?		
No relevant evidence identified.	None identified relevant to this question.	No new evidence was identified that would affect recommendations.

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