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[Intervention Review]

Endovenous ablation (radiofrequency and laser) and foam sclerotherapy versus open surgery for great saphenous vein varices

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ABSTRACT

Background

Minimally invasive techniques to treat great saphenous varicose veins include ultrasound-guided foam sclerotherapy (UGFS), radiofrequency ablation (RFA) and endovenous laser therapy (EVLT). Compared with flush saphenofemoral ligation with stripping, also referred to as open surgery or high ligation and stripping (HL/S), proposed benefits include fewer complications, quicker return to work, improved quality of life (QoL) scores, reduced need for general anaesthesia and equivalent recurrence rates. This is an update of a review first published in 2011.

Objectives

To determine whether endovenous ablation (radiofrequency and laser) and foam sclerotherapy have any advantages or disadvantages in comparison with open surgical saphenofemoral ligation and stripping of great saphenous vein varices.

Search methods

For this update the Cochrane Peripheral Vascular Diseases Group Trials Search Co-ordinator searched the Specialised Register (last searched January 2014) and CENTRAL (2013, Issue 12). Clinical trials databases were also searched for details of ongoing or unpublished studies.

Selection criteria

All randomised controlled trials (RCTs) of UGFS, EVLT, RFA and HL/S were considered for inclusion. Primary outcomes were recurrent varicosities, recanalisation, neovascularisation, technical procedure failure, patient QoL scores and associated complications.

Data collection and analysis

CN and RB independently reviewed, assessed and selected trials which met the inclusion criteria. CN and RB extracted data and used the Cochrane Collaboration's tool for assessing risk of bias. CN and RB contacted trial authors to clarify details as needed.

Main results

For this update, eight additional studies were included making a total of 13 included studies with a combined total of 3081 randomised patients. Three studies compared UGFS with surgery, eight compared EVLT with surgery and five compared RFA with surgery (two studies had two or more comparisons with surgery). Study quality, evaluated through the six domains of risk of bias, was generally moderate for all included studies, however no study blinded participants, researchers and clinicians or outcome assessors. Also, nearly all included studies had other sources of bias. The overall quality of the evidence was moderate due to the variations in the reporting of results, which limited meaningful meta-analyses for the majority of proposed outcome measures. For the comparison UGFS versus surgery, the findings may have indicated no difference in the rate of recurrences in the surgical group when measured by clinicians, and no difference between the groups for symptomatic recurrence (odds ratio (OR) 1.74, 95% confidence interval (CI) 0.97 to 3.12; $P = 0.06$ and OR 1.28, 95% CI 0.66 to 2.49, respectively). Recanalisation and neovascularisation were only evaluated in a single study. Recanalisation at < 4 months had an OR of 0.66 (95% CI 0.20 to 2.12), recanalisation > 4 months an OR of 5.05 (95% CI 1.67 to 15.28) and for neovascularisation an OR of 0.05 (95% CI 0.00 to 0.94). There was no difference in the rate of technical failure between the two groups (OR 0.44, 95% CI 0.12 to 1.57). For EVLT versus surgery, there were no differences between the treatment groups for either clinician noted or symptomatic recurrence (OR 0.72, 95% CI 0.43 to 1.22; $P = 0.22$ and OR 0.87, 95% CI 0.47 to 1.62; $P = 0.67$, respectively). Both early and late recanalisation were no different between the two treatment groups (OR 1.05, 95% CI 0.09 to 12.77; $P = 0.97$ and OR 4.14, 95% CI 0.76 to 22.65; $P = 0.10$). Neovascularisation and technical failure were both statistically reduced in the laser treatment group (OR 0.05, 95% CI 0.01 to 0.22; $P < 0.0001$ and OR 0.29, 95% CI 0.14 to 0.60; $P = 0.0009$, respectively). Long-term (five-year) outcomes were evaluated in one study so no association could be derived, but it appeared that EVLT and surgery maintained similar findings. Comparing RFA versus surgery, there were no differences in clinician noted recurrence (OR 0.82, 95% CI 0.49 to 1.39; $P = 0.47$); symptomatic noted recurrence was only evaluated in a single study. There were also no differences between the treatment groups for recanalisation (early or late) (OR 0.68, 95% CI 0.01 to 81.18; $P = 0.87$ and OR 1.09, 95% CI 0.39 to 3.04; $P = 0.87$, respectively), neovascularisation (OR 0.31, 95% CI 0.06 to 1.65; $P = 0.17$) or technical failure (OR 0.82, 95% CI 0.07 to 10.10; $P = 0.88$).

QoL scores, operative complications and pain were not amenable to meta-analysis, however quality of life generally increased similarly in all treatment groups and complications were generally low, especially major complications. Pain reporting varied greatly between the studies but in general pain was similar between the treatment groups.

Authors' conclusions

Currently available clinical trial evidence suggests that UGFS, EVLT and RFA are at least as effective as surgery in the treatment of great saphenous varicose veins. Due to large incompatibilities between trials and different time point measurements for outcomes, the evidence is lacking in robustness. Further randomised trials are needed, which should aim to report and analyse results in a congruent manner to facilitate future meta-analysis.

PLAIN LANGUAGE SUMMARY

Endovenous ablation (radiofrequency and laser) and foam sclerotherapy versus open surgery for varicose veins

Varicose veins are dilated, tortuous superficial veins. When they are in the legs they can be painful, itchy or unsightly, especially when patients are standing and walking. Varicose veins are conventionally treated with surgery to remove the veins, by stripping them to the level of the knee (so-called high ligation and stripping). New less invasive treatments seal the main leaking vein in the thigh using foam sclerotherapy, laser (endovenous laser therapy) or radiofrequency ablation. These techniques may result in less pain after the procedure, fewer complications, and a quicker return to work and normal activities with improved patient quality of life, as well as avoiding the need for a general anaesthetic.

Our review brought together all available randomised controlled trials that compared the new techniques to surgery in the treatment of varicosities in the great saphenous vein. We found 13 trials, with a combined total of 3081 randomised patients, which met our inclusion criteria. Three trials compared foam sclerotherapy with surgery, eight trials compared endovenous laser therapy with surgery and five compared radiofrequency ablation with surgery (two studies had two or more comparisons with surgery). Overall the quality of the studies was acceptable, however none of the studies tried to conceal the treatment type from the participants, researchers and clinicians, or those who measured the outcomes. Most of the studies also had other biases.

For foam compared with surgery, there was no difference between the treatment groups in the rate of recurrence as measured by a clinician and the rate of recurrence that was noted by patient symptoms. There was also no difference between the treatment groups

for technical failure. Comparing laser therapy and surgery, there was no difference between the recurrence rates (either clinician noted or by symptoms) or for reopening of the treated vein (recanalisation). New vein growth (neovascularisation) and technical failure were both higher in the surgery group than in the laser group. For the comparison between radiofrequency ablation and surgery there were no differences between the treatment groups for recurrence, recanalisation, neovascularisation or technical failure. Outcomes that measure changes in patients' quality of life, operative complications and pain were not able to be compared directly, however quality of life generally increased similarly in all treatment groups and complications were generally low, especially major complications. Pain reporting varied greatly between the studies but in general pain was similar between the treatment groups.

The limited evidence that is available supports that foam sclerotherapy, endovenous laser therapy and radiofrequency ablation are no worse than open surgery. However, it should be noted that there were large differences between the way the studies reported their outcomes, which included definitions and collection time points. These differences limited the findings of our review. We need more data from randomised controlled trials comparing these novel therapies to surgery before we really know their true potential.