

REVIEW

Five Year Results of Great Saphenous Vein Treatment: A Meta-analysis

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WHAT THIS PAPER ADDS

This meta-analysis reports the long-term outcomes after the different treatments for great saphenous vein (GSV) incompetence, with anatomical success (including absence of reflux) as the primary outcome. This is the first meta-analysis focusing specifically on long-term outcomes after treatment of GSV incompetence. It consists of only RCTs or follow-up studies of RCTs. The most important duplex ultrasound findings were evaluated such as anatomical success and rates of recurrent reflux at the saphenofemoral junction, as well as effects on clinical scores and quality of life. This study provides additional information on the long-term efficacy of the different treatment options for GSV incompetence.

Objectives: The most frequently used treatment options for great saphenous vein incompetence are high ligation with stripping (HL+S), endovenous thermal ablation (EVTA), mainly consisting of endovenous laser ablation (EVLA) or radiofrequency ablation, and ultrasound guided foam sclerotherapy (UGFS). The objective of this systematic review and meta-analysis was to compare the long-term efficacy of these different treatment modalities.

Methods: A systematic literature search was performed. Randomised controlled trials (RCTs) with follow-up ≥ 5 years were included. Pooled proportions of anatomical success, which was the primary outcome, rate of recurrent reflux at the saphenofemoral junction (SFJ), and mean difference in venous clinical severity score (VCSS) were compared using a z test or Student t test. Quality of life data were assessed and described.

Results: Three RCTs and 10 follow-up studies of RCTs were included of which 12 were pooled in the meta-analysis. In total, 611 legs were treated with EVLA, 549 with HL+S, 121 with UGFS, and 114 with HL+EVLA. UGFS had significantly lower pooled anatomical success rates than HL+S, EVLA, and EVLA with high ligation: 34% (95% CI 26–44) versus 83% (95% CI 72–90), 88% (95% CI 82–92), and 88% (95% CI 17–100) respectively; $p \leq .001$. The pooled recurrent reflux rate at the SFJ was significantly lower for HL+S than UGFS (12%, 95% CI 7–20, vs. 29%, 95% CI 21–38; $p \leq .001$) and EVLA (12%, 95% CI 7–20, vs. 22%, 95% CI 14–32; $p = .038$). VCSS scores were pooled for EVLA and HL+S, which showed similar improvements.

Conclusion: EVLA and HL+S show higher success rates than UGFS 5 years after GSV treatment. Recurrent reflux rates at the SFJ were significantly lower in HL+S than UGFS and EVLA. VCSS scores were similar between EVLA and HL+S.

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INTRODUCTION

Varicose veins are a common medical condition with a prevalence of around 25–40% in the adult population.^{1–3} In the past, saphenous varicose veins were mainly treated

surgically by means of high ligation with or without stripping. Ultrasound guided foam sclerotherapy (UGFS) has been used since 1997 and was the first minimally invasive treatment option. However, since 2000, endovenous thermal ablation (EVTA) using laser, radiofrequency, or steam has become more popular. Recently, interest in less invasive and less painful procedures with non-thermal non-tumescent techniques, such as mechano-chemical ablation and cyanoacrylate, has been growing.

Several guidelines recommend EVTA as the treatment of choice for saphenous varicose veins, followed by UGFS, and

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lastly surgical intervention.^{4–6} This recommendation is based on a number of studies showing that EVTA is as effective as surgery but is associated with fewer complications, less pain, and shorter recovery time.^{7–11} Most of the available meta-analyses, however, consisted mainly of studies with short to medium-term follow-up^{8–10} (average between 1 and 2 years). Moreover, as until recently evidence from randomised controlled trials (RCTs) was lacking, they were predominantly based on observational studies.^{12,13} In the Cochrane review by Nesbitt et al.¹⁰ only one study with 5 year follow-up was included, so the data were merely described, as they could not specifically be pooled for long-term results.

In the past few years more RCTs with long-term results have been published, which finally make it possible to perform a higher quality meta-analysis. Therefore, the objective was to perform a systematic review and meta-analysis on RCTs or follow-up studies of RCTs with a minimum follow-up of 5 years to compare long-term outcomes, such as technical success, recurrent reflux at the groin, venous clinical severity score (VCSS), and quality of life of the different treatments for incompetent great saphenous veins (GSVs).

MATERIALS AND METHODS

Types of studies

Only RCTs or follow-up studies of RCTs evaluating the treatment of GSVs with a follow-up of at least 5 years were included in this systematic review. There were no restrictions regarding publication date or language.

Types of participants

Participants of all ages and all clinical classes of CEAP who received treatment for GSV incompetence and were followed up for at least 5 years after treatment were considered.

Types of interventions

Trials comparing one of the following interventions, endovenous laser ablation (EVLA), radiofrequency ablation (RFA), UGFS, or high ligation combined with truncal treatment, such as stripping (HL+S), EVTA, or UGFS, were included in this study.

Types of outcome measures

The primary outcome measure, the anatomical success rate, was defined as absence of reflux in the treated vein after 5 years on duplex ultrasound (DUS). This definition was chosen instead of the occlusion rate because not all studies described occlusion of the vein as an outcome. The secondary outcome measure was the recurrent reflux rate at the saphenofemoral junction (SFJ) or in the groin. Other outcomes of interest were the Venous Clinical Severity Score (VCSS) to evaluate clinical outcome, and the Aberdeen Varicose Vein Questionnaire (AVVQ) and Chronic Venous Insufficiency Quality of Life Questionnaire (CIVIQ) to study the effects on quality of life (QoL). The VCSS evaluates pain and clinical symptoms such as oedema, skin changes,

inflammation, and ulcers. The scale of severity ranges from 0 (absent) to 3 (severe) per item with a total maximum score of 30 points.¹⁴ The AVVQ and CIVIQ are both disease specific QoL questionnaires. The AVVQ consists of 13 questions and evaluates physical symptoms (i.e., pain, ankle oedema, ulcers), social issues, use of compression therapy, and effect on daily activities and is scored from 0 (no effect) to 100 (severe effect).¹⁴ The CIVIQ evaluates four categories (physical, psychological, social, and pain) in 20 questions resulting in a score between 0 and 100. The scoring system is reversible, which means a score of 100 can either represent the lowest or highest effect on QoL.^{14,15} Unfortunately the minimal clinically important difference (MCID) is unknown for all three outcomes.

Although most studies used the DUS result as an outcome measure, there was a lot of diversity in the definitions of anatomical success and recurrent reflux at the SFJ or in the groin. Therefore the following definitions were accepted as anatomical success of the treated GSV trunk: total/complete obliteration, obliterated, occlusion, partial obliteration with antegrade flow, competent, abolition of reflux, and no recanalisation.⁷ If a study reported both “obliteration” and “competent” as an outcome measure, the number of patients in both groups was added as both these definitions mean there is absence of reflux. If an article only described the number of patients with treatment failure, these numbers were deducted from the total number of patients to calculate the percentage of patients with treatment success. One study described the number of open or partially open GSVs without defining if there was absence of reflux. Therefore only the number of patients/legs with completely closed or absent GSVs was used, as it was not known if the (partially) open veins were competent. The definitions accepted as recurrent reflux at the SFJ/groin were reflux at the SFJ, reflux at the groin, reflux at least 2 cm from the SFJ, reflux in the groin detected in vessels > 2 mm connected to the common femoral vein, retrograde flow of > 1 s at the SFJ, and recurrence at the groin defined by Stonebridge type 1.¹⁶

Literature search

An electronic literature search was conducted in Embase, Medline (Ovid-SP), PubMed, Web of Science, Google Scholar and The Cochrane Central Register of Controlled Trials (CENTRAL) up to December 22, 2015. This search was updated on December 30, 2016, after which no new articles were included in this study. The search terms can be found in [Table S1](#).

Study selection and data extraction

The title and abstract of all the retrieved articles were screened for relevance and selected based on the pre-defined inclusion and exclusion criteria. The risk of bias of each study was assessed using The Cochrane Collaboration tool for assessing risk of bias in randomised trials.¹⁷ As blinding was not possible in almost all studies due to the difference in treatment procedures, this domain was not included in the overall risk assessment. The studies were

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