

Predictors of Recanalization of the Great Saphenous Vein in Randomized Controlled Trials 1 Year After Endovenous Thermal Ablation

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WHAT THIS PAPER ADDS

This is the first study to analyse candidate predictors of recanalization after endovenous thermal ablation by using individual patient and limb level data of previously published randomized controlled trials. Several important predictors of recanalization and health related quality of life were found that may be valuable in clinical practice in the future.

Objective/Background: The objective was to identify predictors to develop and validate a prognostic model of recanalization of the great saphenous vein (GSV) in patients treated with endovenous thermal ablation (EVTA).

Methods: The search strategy of Siribumrungwong was updated between August 2011 and August 2014 using MEDLINE, Embase, and the Cochrane register to identify randomized controlled trials (RCTs), in which patients presenting with GSV reflux were treated with radiofrequency or endovenous laser ablation. Leg level data ($n = 1226$) of 15/23 selected RCTs were pooled. The primary outcome was recanalization of the GSV; the secondary outcome was change in health related quality of life (HRQoL) measured by the Chronic Venous Insufficiency quality of life Questionnaire or Aberdeen Varicose Vein Questionnaire 1 year post-procedure. Candidate predictors were age, sex, body mass index, clinical class, GSV diameter, saphenofemoral junction reflux, type of device, energy, and length of treated vein.

Results: At 1 year, 130 GSVs were recanalized (11%). Clinical class (odds ratio [OR] 2.1, 95% confidence interval [CI] 1.4–3.3) and diameter (OR 1.8, 95% CI 1.2–2.7) of the GSV were the strongest predictors of recanalization. Other predictors included in the final model were sex, type of device, and length of treated vein. The performance of the recanalization model was moderate, with an area under the curve above 0.717. GSV diameter, type of device, and amount of energy delivered were the only predictors of the change of HRQoL. None of the candidate predictors were included in the final HRQoL model ($R^2 = .027$).

Conclusion: There are several important prognostic factors for GSV recanalization and change of HRQoL after EVTA. However, the performance of each model was unsatisfactory to allow use in clinical practice yet.

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INTRODUCTION

In the Western world, endovenous thermal ablation (EVTA) is the most commonly used technique to treat patients with saphenous vein reflux. The therapeutic goal of this technique is to obliterate the treated vein segment by thermal injury to the venous wall.

Although EVTA is highly effective, recanalization of the great saphenous vein (GSV) is reported in up to 10% of patients after 1 year.^{1–3} In these patients, recanalization may

be the result of the technique used (e.g., laser or radio-frequency [RF]), device settings (e.g., energy delivered, number of RF cycles), and/or experience of the physician.^{4–6} Other factors may also play a role, such as patient characteristics, and clinical and duplex ultrasound (DUS) findings.^{7,8}

If patient characteristics and DUS findings are indeed associated with the risk of recanalization, physicians might be able to predict which patients are likely to develop recanalization prior to treatment. Identification of patient specific predictors may result in a more personalized approach in phlebologic practice. If patient tailored treatments are offered from the start, the need for extensive secondary procedures could be reduced and healthcare expenses kept as low as possible.⁹

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The objective of this study was to identify patient, DUS, and device related characteristics associated with recanalization of the GSV after treatment with EVTA using 1 year follow up data from multiple randomized controlled trials (RCTs). The secondary objective was to assess factors associated with change of health related quality of life (HRQoL) after treatment with EVTA.

METHODS

Data selection

From August 2011 to August 2014, two independent investigators (SKvdV and RRvdB) searched in MEDLINE (OvidSP), Embase, and the Cochrane Central Register of Controlled Trials to identify studies. Search terms were “varicose veins”, “chronic venous disease”, “chronic venous insufficiency”, “great saphenous vein”, “RF ablation (RFA)”, “RFA”, “endovenous ablation”, “EVTA”, “EVLA (endovenous laser ablation)”, and “randomized controlled trial”. The identified RCTs were screened for eligibility and combined with the selected RCTs of one recent systematic review of RCTs comparing EVTA and surgical interventions in patients with varicose veins (Supplementary Table S1).¹⁰ Only those RCTs in which patients presented with GSV reflux were randomized to RFA or EVLA were eligible. In addition outcomes regarding GSV patency and/or HRQoL were documented for at least 1 year of follow up. If multiple publications of the same study were present, the study closest to the 1 year follow up was selected.

Data collection

The investigators contacted the corresponding authors of the 23 eligible RCTs by email between August 2013 and January 2015. For non-responders, a second and third attempt was made a few months later. Five authors were also contacted by phone because of a non-responding after the third email. If available, authors were asked to collaborate and share their patient level data about age, sex, unilateral or bilateral inclusion, body mass index (BMI) in kg/m², clinical class at baseline (C of the CEAP classification), Venous Clinical Severity Score (VCSS), and HRQoL outcomes at baseline and after a follow up of at least 1 year.¹¹ DUS data gathered were diameter of the GSV at baseline (mm), presence of saphenofemoral junction (SFJ) reflux at baseline and anatomical outcomes of the treated segment of the GSV (e.g., obliteration, recanalization, absence or presence of GSV reflux). The authors were also asked to share their procedure -related data such as device type and characteristics (wavelength, fiber type, energy delivered [J/cm], number of RF cycles), length of treated segment, and additional treatment of tributaries. The earliest year of inclusion was reported and divided into two groups: 2000–06 or 2007–13. This cut off was chosen to obtain an equal distribution of devices in each group and to analyse subsequently the influence of physicians' experience.

Outcomes

The primary outcome measure was recanalization of the GSV after follow up of at least 1 year. Recanalization was defined as an open section of the treated vein >5 cm in length. Secondary outcome was changed HRQoL at 1 year follow up compared with baseline (Δ HRQoL). HRQoL questionnaires were defined as instruments that measure objective functioning, subjective well being, or both. Disease specific HRQoL questionnaires were preferred because they often show more sensitivity to change than generic HRQoL questionnaires.¹²

Two disease specific questionnaires were included to assess QoL: the Aberdeen Varicose Vein Questionnaire (AVVQ) and the Chronic Venous Insufficiency Questionnaire (CIVIQ). Total scores of both questionnaires ranked between 0 and 100, with 0 representing the most favorable HRQoL. Therefore, AAVQ and CIVIQ outcomes were pooled and analyzed together.

Candidate predictors

Candidate predictors were selected based on the available data. Patient characteristics at baseline (e.g., age, clinical class, and BMI), DUS features (diameter of the GSV and presence of SFJ reflux), and technical aspects of treatment (e.g., device, length of treated segment, energy delivered, and number of RF cycles) were considered as important predictors of recanalization and Δ HRQoL. VCSS and additional treatment of tributaries were recorded for <50% of the limbs and therefore not considered as candidate predictors.

Study population

Corresponding authors from 15 (response rate 65%) different EVTA RCTs in Europe,^{1,3,13–21} the USA,¹⁶ Asia,²² and Africa²³ agreed to collaborate (Supplementary Table S2). Of the excluded RCTs, five authors refused to participate, two authors were non-contactable, and one author had lost the study data. The included RCTs were conducted in secondary care populations between 2000 and 2013. If outcome measures were missing, leg level data were excluded ($n = 142$ in the anatomical cohort and $n = 798$ in the HRQoL cohort) (Fig. 1). In the HRQoL cohort, for each patient only one leg was included. Finally, 1226 legs (1174 patients) were included in the anatomical cohort and 537 legs (537 patients) in the HRQoL cohort.

Statistical analysis

Multivariable regression modeling techniques were used to predict recanalization and HRQoL. The initial study design was to split the complete dataset into a development dataset and an external validation dataset. Owing to the low number of events (i.e., development dataset $n = 93$, external validation dataset $n = 37$), it was decided to develop the model using the complete dataset. Therefore, the model could be validated internally but not externally.

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