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Traditional versus Endoscopic Saphenous Vein Stripping: A Prospective Randomized Pilot Trial

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Abstract *Introduction:* The aim of this pilot study was to compare two methods of removing the great saphenous vein (GSV) from the groin to the limit of distal venous incompetence. Pur aim was to compare endoscopically assisted GSV stripping to conventional stripping.
Design: Randomised pilot study.
Patients and methods: 60 patients presenting with primary GSV incompetence and symptomatic varicose veins were randomly assigned to sapheno-ligation and either conventional GSV stripping or endoscopically assisted GSV stripping. The primary endpoint was the number of adverse events including haematoma in the thigh, ecchymosis, seroma, wound healing complications and wound infections. The SF-36 health survey was completed before treatment and one and four weeks postoperatively. The study was approved by the local ethics committee (EK 07-041-VK).
Results: 60 patients were enrolled in the study and randomized to endoscopic ($n = 30$) and to traditional ($n = 30$) stripping. The patients age ranged from 30 to 75 years (mean 53 years), 18 patients were male, 42 female. The combined rate of postoperative morbidity at week 1 was 32 events (53%), 13 (42%) events in the endoscopic and 19 (63%) in the conventional group (not significant). The SF-36 assessment one week postoperatively showed that patients in the endoscopic group reported significantly less pain ($P = 0.03$, Mann-Whitney). At four weeks, patients in the endoscopic group had significantly less pain ($P < 0.005$) and better physical function ($P < 0.005$) and physical role ($P = 0.01$). For all other parameters no significant difference noted.
Conclusion: The results of this study suggest that endoscopic GSV excision showed no difference in adverse events between treatments, although our pilot study may have been under-powered to demonstrate this. The SF-36 assessment suggests more rapid return to normal activities post-operatively in the endoscopic group.

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Introduction

Varicose veins are among the most common medical condition in western countries necessitating surgical intervention.[1] Many different methods for treating varices arising from the great saphenous vein (GSV) have been described. The main principle of treatment is to remove or obliterate saphenous veins combined with all incompetent tributaries and varices.

Ligation of the sapheno-femoral junction and stripping of the saphenous vein remains a common method of treatment. However, endovenous methods of vein ablation now challenge this technique as the ''gold standard''.[2] Post-operative compression treatment is usually required to achieve a good outcome.[1] Damage to cutaneous nerves is a frequent complication with reported rates ranging from 4 to 50%.[3–7] Thigh length compression stockings cause discomfort and poor patient compliance.[8]

Minimally invasive treatments such as endovenous laser treatment (EVLT) or endovenous radiofrequency obliteration (RFO) of the GSV have different complications such as thermal damage to the skin or the saphenous nerve[9] and thrombus extending into the deep venous system,[10] potentially risking pulmonary embolism. These methods may not be suitable for large tortuous vessels,[9] and recanalisation rates may reach 24% at one year.[11] Finally, results from a large RFO registry demonstrated that patients with a BMI above 25 kg/m^2 – representing a relevant proportion of patients with varicose veins - have higher early failure rates.[12]

The aim of this pilot study was to compare two methods of removing the GSV from the groin to the distal region of venous incompetence. The main emphasis was to assess whether endoscopically assisted GSV stripping is comparable or superior both surgically and regarding patient quality of life with the standard surgical technique of sapheno-femoral ligation and stripping.

Patients and Methods

We considered patients attending our institute for management of symptomatic varicose veins for inclusion in our study. Inclusion criteria for the study were primary varicosities of the great saphenous vein of all clinical stages in patients aged 18 or older who were able to give informed consent. Eligible subjects had an American Society of Anesthesiologists (ASA) risk assessment score of I or II and were scheduled to undergo unilateral intervention. Patients with post-thrombotic or other secondary venous insufficiency, pregnant patients, patients with thrombophilia or coagulopathy as well as patients taking aspirin and/or plavix or not able to give informed consent were excluded from participating in the study.

103 patients with varicose veins presenting to our institution during a 5 month period were screened for inclusion in the study. 21 patients had undergone previous surgery for varicose veins, 7 patients had incompetence of the small saphenous vein leaving 75 patients with primary GSV incompetence. Of these, 15 refused to participate in a clinical study. 60 patients complying with the study inclusion criteria were randomly assigned to sapheno-femoral ligation and either conventional stripping or endoscopically assisted saphenous vein stripping. All patients gave written informed consent for their inclusion and the study was approved by the local ethics committee (EK 07-041-VK).

The venous system was investigated in all patients by preoperative colour duplex ultrasonography (39% of patients) or phlebography (61% of patients) according to standard practice in our hospital. The aim was to evaluate all deep and superficial veins of the lower limb. A baseline assessment of the quality of life with the SF-36 questionnaire was done (Hofgrefe -Verlag für Psychologie). The primary endpoint was the number of adverse events including haematoma in the thigh, ecchymosis (excluding sites of phlebectomy for varices in the thigh and calf), seroma, wound healing complications and wound infections. The SF-36 health survey was completed before treatment and one and four weeks postoperatively.

Surgical technique

Patients in the conventional group had a 3 to 4 cm incision in the groin and a standard sapheno-femoral ligation. The GSV was ligated at the level of the femoral vein, and all tributaries were ligated with a 3–0 resorbable suture (Safil, Braun-Melsungen, Germany). The GSV was located at the distal limit of venous incompetence and a stripper (Vastrip,Astra Tech, Mölndal, Sweden) was inserted along the vein permitting the vein to be stripped from the distal insufficiency to the groin. Varices were removed by phlebectomy through small incisions without suturing. Larger incisions were closed with 4–0 interrupted sutures (Premilene, Braun Melsungen, Germany).

Patients in the endoscopic group had both, sapheno-femoral ligation and a cut down at the distal point of incompetence of the GSV. Additionally, a 2 cm cutdown to the GSV was performed above or below the knee or in the mid thigh region, depending on anatomical situation. Then, the Clear Glide endoscopic vein harvesting device (Datascope Cardiac Assist, Fairfield, New Jersey, USA) was inserted and under endoscopic visualization, all tributaries were interrupted with ultracision harmonic scalpel curved shears (Ethicon Endosurgery, Norderstedt, Germany) up to the saphenofemoral junction and down to the knee (Figure 1A–C). Then the GSV was stripped from the distal limit of incompetence to the groin (Vastrip, Astra Tech, Mölndal, Sweden). Finally, varices were removed by phlebectomy. All incisions other than those for phlebectomies were closed with 4–0 interrupted sutures (Premilene, Braun Melsungen, Germany).

Compression therapy

Immediately after surgery, legs were wrapped in sterile gauze dressing and covered with a compression bandage (Raucodur, Lohmann Rauscher, Austria). After 24 hours, bandages were removed and class 2 compression stockings up to the groin were applied until the first follow up visit (7 to 9 days postoperatively). Patients in the conventional group continued with class II thigh length compression until the second follow up (4 weeks postoperatively), patients in