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

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KEYWORDS
GSV; Varicose vein; Stripping; Endoscopy; SF-36

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. Purpos 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 postoperatively in the endoscopic group.

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Introduction

Varicose veins are among the most common medical condition in western countries necessitating surgical intervention. 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". Post-operative compression treatment is usually required to achieve a good outcome. Damage to cutaneous nerves is a frequent complication with reported rates ranging from 4 to 50%. Thigh length compression stockings cause discomfort and poor patient compliance.

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 and thrombus extending into the deep venous system, potentially risking pulmonary embolism. These methods may not be suitable for large tortuous vessels, and recanalisation rates may reach 24% at one year. Finally, results from a large RFO registry demonstrated that patients with a BMI above 25 kg/m² — representing a relevant proportion of patients with varicose veins — have higher early failure rates.

The aim of this pilot study was to compare two methods of removing the GSV from the groin to the distal region of the 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
the endoscopic group were asked to wear knee length class II compression stockings until the second follow up. Post-operative analgesic therapy consisted of 500 mg Paracetamol six hourly and 200 mg Ibuprofen on demand (maximum three times a day) until postoperative week 4.

Follow Up

Follow up was 7 ± 2 days postoperatively (at time of removal of sutures) and 4 weeks ± 5 days postoperatively. During follow up, the operated limb was inspected. Haematoma (in the groin and course of the GSV in the thigh) and seroma were assessed clinically. If clinically present, ultrasound of the thigh was performed and haematoma and seroma drained with a needle and syringe. Ecchymosis was defined as being present if larger than 1.5 cm surrounding phlebectomies and incisions in the thigh. Wound healing complications (including dehiscence of phlebectomy incisions), seroma, phlebitis and infections were noted. Post operative complications were assessed only during the first post-operative week. Both groups wore thigh length class II medical compression stockings during this week.

There was no formal assessment for pain score, patients were asked about the adequacy of pain medication and need for ibuprofen as break through medication (0–5 tablets, 5–10 tablets and 10–15 tablets).

Patients completed the Medical Outcomes Study Short Form 36 (SF-36) at both visits, a quality of life assessment tool consisting of eight domains: physical function, physical role, pain, general health, vitality, social function, emotional role and mental health.

Statistical analysis

Results were analysed using Epi-Info 2002 (Epi-Info 2002 software package, Centers for Disease Control and Prevention, GA, Atlanta). Significance testing between groups was assessed using a Mann-Whitney U Test. Descriptors used for normally distributed variables are the mean and range. For non-normally distributed data the median and inter-quartile range have been used. Discrete variables were expressed as numbers (percentages) and contingency tables analysed by chi-squared test or by Fischers exact test, respectively. All tests of significance were 2-tailed; \( P \) values of ≤ 0.05 were considered significant.

Results

During a 5 month period 60 consecutive patients were enrolled in the study and randomized to the two treatment groups (30 to endoscopic and 30 to traditional stripping); all patients attended 1 and 4 week follow up appointments. The patients age ranged from 30 to 75 years (mean 53 years), 18 patients were male, 42 female.

Clinical presentation according to the CEAP classification was for the combined endoscopic and traditional group C2 5 (17%) and 7 (23%) patients, C3 9 (30%) and 8 (27%) patients, C4 11 (37%) and 12 (40%) patients and C5 5 (16%) and 3 (10%) patients, respectively. The BMI ranged from 19.8 kg/m\(^2\) to 33 kg/m\(^2\) (mean 25.9 kg/m\(^2\)), 17 (57%) patients in the endoscopic and 18 (60%) in the conventional group had a BMI greater 25 kg/m\(^2\). There was no significant difference between groups for the SF-36 questionnaire at baseline.
The combined rate of postoperative morbidity at 1 week (patients had comparable compression therapy during the first week) was 32 events (53%), 13 (42%) events in the endoscopic and 19 (63%) in the conventional group (no significant difference) (Table 1). The SF-36 assessment between groups one week postoperatively showed that patients in the endoscopic group had significantly less pain ($P < 0.03$). For the summary measures of physical health and mental health, there was no significant difference at week 1 between groups.

At four weeks, patients in the endoscopic group had significantly less pain ($P < 0.005$) and better physical function ($P < 0.005$) and better physical role ($P = 0.01$) compared to patients in the conventional group. For all other parameters, no significant difference noted (Tables 2 and 3).

**Discussion**

To our knowledge, this is the first study assessing endoscopically assisted GSV removal for varicose veins. In the current paper, standard sapheno-femoral ligation and stripping was compared to a modified method in which all side tributaries and perforators of the GSV in the thigh were interrupted endoscopically with ultracision harmonic scalps. For this manoeuvre, only one additional 2 cm incision was necessary. The suggested benefit of this therapy is that bleeding from tributaries into the residual canal of the GSV does not occur and hence the duration of postoperative thigh length compression treatment may be reduced. We hoped to show that the incidence of postoperative haematoma and adverse event in the thigh may be reduced.

Patients in the endoscopic group had numerically fewer postoperative complications than in the conventional group (42% versus 63%), however, this does not reach statistical significance. A possible explanation is that the study was underpowered to demonstrate these effects. Nevertheless, patients in the endoscopic group had significantly less pain at one week postoperatively according to the SF-36 questionnaire; at 4 weeks, patients in the endoscopic group had less pain, better physical function and role, suggesting more rapid recovery in this group. Compression therapy was changed to knee high class II compression stockings in the endoscopic group. A possible explanation of the improved physical function and role parameters is that this was due to the change in compression regime. The endoscopic method of treatment resulted in less postoperative pain control and allowed patients to pursue normal physical activities. We decided to apply thigh high compression in the conventional stripping group for at least 4 weeks after surgery which has been standard practice at our institution for many years. Additionally, a recent randomized study demonstrated that thigh high compression after surgery for 3 weeks reduced the consumption of analgesic medication compared to 1 week compression yielding similar cosmetic results. Reducing analgesic medication consumption is worthwhile since these drugs may cause significant morbidity.

**Table 1** Postoperative morbidity

<table>
<thead>
<tr>
<th></th>
<th>conventional % ($n = 30$)</th>
<th>endoscopic % ($n = 30$)</th>
<th>$P$</th>
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</thead>
<tbody>
<tr>
<td>haematoma</td>
<td>20% (6)</td>
<td>10% (3)</td>
<td>ns</td>
</tr>
<tr>
<td>ecchymosis</td>
<td>10% (3)</td>
<td>14% (4)</td>
<td>ns</td>
</tr>
<tr>
<td>seroma</td>
<td>16% (5)</td>
<td>6% (2)</td>
<td>ns</td>
</tr>
<tr>
<td>wound healing complication</td>
<td>7% (2)</td>
<td>3% (1)</td>
<td>ns</td>
</tr>
<tr>
<td>phlebitis</td>
<td>10% (3)</td>
<td>6% (2)</td>
<td>ns</td>
</tr>
<tr>
<td>wound infection</td>
<td>0% (0)</td>
<td>3% (1)</td>
<td>ns</td>
</tr>
<tr>
<td>total operative morbidity</td>
<td>63% ($n = 19$)</td>
<td>42% ($n = 13$)</td>
<td>ns</td>
</tr>
</tbody>
</table>

Statistics: Chi-square; ns: not significant.

**Table 2** SF-36 assessment of patients at first follow up 10 days after surgery; score in means (range); Conventional: conventional crossectomy and stripping group; endoscopic: endoscopically assisted crossectomy and stripping group

<table>
<thead>
<tr>
<th>SF-36 domain</th>
<th>SF-36 Question</th>
<th>SF-36 Score Conventional ($n = 30$)</th>
<th>SF-36 Score Endoscopic ($n = 30$)</th>
<th>$P$</th>
</tr>
</thead>
<tbody>
<tr>
<td>physical function</td>
<td>Q1</td>
<td>2 (1/2)</td>
<td>2 (2/3)</td>
<td>0.22</td>
</tr>
<tr>
<td>physical function</td>
<td>Q2</td>
<td>2 (3/3.5)</td>
<td>2 (2/3)</td>
<td>0.53</td>
</tr>
<tr>
<td>physical function</td>
<td>Q3</td>
<td>25 (21/26)</td>
<td>26 (24/27)</td>
<td>0.12</td>
</tr>
<tr>
<td>physical role</td>
<td>Q4</td>
<td>6 (5/7)</td>
<td>6 (5/7)</td>
<td>0.93</td>
</tr>
<tr>
<td>mental health</td>
<td>Q5</td>
<td>4.5 (3/5.5)</td>
<td>4 (4/5)</td>
<td>0.83</td>
</tr>
<tr>
<td>emotional role</td>
<td>Q6</td>
<td>2 (1/3)</td>
<td>2 (1/2)</td>
<td>0.40</td>
</tr>
<tr>
<td>pain</td>
<td>Q7</td>
<td>3 (1/5/4)</td>
<td>2 (2/3)</td>
<td>0.19</td>
</tr>
<tr>
<td>pain</td>
<td>Q8</td>
<td>2.5 (2/3)</td>
<td>2 (1/2)</td>
<td>0.03*</td>
</tr>
<tr>
<td>vitality</td>
<td>Q9</td>
<td>34 (33/36)</td>
<td>35 (34/37)</td>
<td>0.19</td>
</tr>
<tr>
<td>social function</td>
<td>Q10</td>
<td>4.5 (4/5)</td>
<td>4 (4/5)</td>
<td>0.20</td>
</tr>
<tr>
<td>general health</td>
<td>Q11</td>
<td>12 (11/13)</td>
<td>13 (12/14)</td>
<td>0.14</td>
</tr>
</tbody>
</table>

* indicating statistically significant differences with $P < 0.05$; statistics: Mann Whitney U test; data are presented as median (inter-quartile range).
Table 3  SF-36 assessment of patients at first follow up 4 weeks postoperatively; score in means (range); Conventional: conventional crossectomy and stripping group; endoscopic: endoscopically assisted crossectomy and stripping group

<table>
<thead>
<tr>
<th>SF-36 domain</th>
<th>SF-36 Question</th>
<th>SF-36 Score Conventional (n = 22)</th>
<th>SF-36 Score Endoscopic (n = 21)</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>physical function</td>
<td>Q1</td>
<td>2 (1/2)</td>
<td>2 (2/3)</td>
<td>0.22</td>
</tr>
<tr>
<td>physical function</td>
<td>Q2</td>
<td>2 (2/3)</td>
<td>2 (2/3)</td>
<td>0.55</td>
</tr>
<tr>
<td>physical function</td>
<td>Q3</td>
<td>25 (23/27.5)</td>
<td>28 (27/30)</td>
<td>&lt;0.005*</td>
</tr>
<tr>
<td>physical role</td>
<td>Q4</td>
<td>6 (6/7)</td>
<td>7 (6/8)</td>
<td>0.01*</td>
</tr>
<tr>
<td>mental health</td>
<td>Q5</td>
<td>5 (4/6)</td>
<td>5 (5/6)</td>
<td>0.38</td>
</tr>
<tr>
<td>emotional role</td>
<td>Q6</td>
<td>2 (1/2)</td>
<td>1 (1/2)</td>
<td>0.23</td>
</tr>
<tr>
<td>pain</td>
<td>Q7</td>
<td>2 (1/3)</td>
<td>2 (1/2)</td>
<td>0.14</td>
</tr>
<tr>
<td>pain</td>
<td>Q8</td>
<td>2 (2/2)</td>
<td>1 (1/1)</td>
<td>&lt;0.005*</td>
</tr>
<tr>
<td>vitality</td>
<td>Q9</td>
<td>34 (33/36)</td>
<td>35 (34/37)</td>
<td>0.19</td>
</tr>
<tr>
<td>social function</td>
<td>Q10</td>
<td>5 (4/5)</td>
<td>5 (4/5)</td>
<td>0.42</td>
</tr>
<tr>
<td>general health</td>
<td>Q11</td>
<td>12 (11/13)</td>
<td>13 (12/14)</td>
<td>0.20</td>
</tr>
</tbody>
</table>

* indicating statistically significant differences with P ≤ 0.05; statistics: Mann Whitney U test; data are presented as median (inter-quartile range).

The new endoscopic method applies well known techniques of vein harvesting for varicose vein surgery. Perception of technical complexity of the method is very much dependent on training of the surgeon. If proficient in endoscopic surgery of the gallbladder and hernia, 3–5 interventions are sufficient to acquire the skills required. The disadvantages of the procedure are cost and time. Disposable devices accounted in our hospital for 437 Euros per intervention and an additional 10 to 15 minutes for surgery. However, all patients had sapheno-femoral ligation in this study for comparability between groups. This is not necessary if the proximal GSV is competent. Thus a groin incision can be omitted in some cases and the GSV removed endoscopically from a more peripheral incision, reducing over all intervention time.

Sapheno-femoral ligation does not prevent recurrence, since in the majority of cases this is due to neovascularisation. Recurrent at the SFJ may be avoided by not intervening in the groin. In one study, 77% of patients treated by high sapheno-femoral ligation had at least one incompetent superficial vein in the thigh on duplex follow up. The authors speculate that patients must have had a bifid venous system or — much more likely — dilatation and thus incompetence of other thigh tributaries.

In 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 with less pain at 1 week and 4 weeks and improved physical function at 4 weeks.

References