Reduction of Neoreflux After Correctly Performed Ligation of the Saphenofemoral Junction. A Randomized Trial

N. Frings,1* A. Nelle,1 Ph. Tran,1 R. Fischer2 and W. Krug3

1Mosel-Eifel-Klinik, Varicose Veins Clinic, Bad Bertrich, Germany; 2Centre for Vascular Diseases, St Gallen, Switzerland; and 3Department of Statistics, University of Trier, Trier, Germany

Background. Neoreflux at the sapheno-femoral junction (SFJ) is an important cause of recurrent great saphenous varicose veins. This study compares four surgical methods of ligating the SFJ with the aim to reduce the rate of neoreflux.

Method. In a prospective study, 379 patients (500 SFJ ligations) were randomised to one of four surgical procedures at the SFJ (125 groins each). In group A (control group) the SFJ was ligated in standard fashion with Vicryl (absorbable ligature); in group B, after Vicryl ligation continuous Prolene (non-absorbable) was sutured over the stump endothelium to prevent any contact with surrounding tissue; in group C, SFJ ligation was done with Ethibond (non-absorbable); in group D Ethibond ligation was followed by Prolene oversewing. The final study group included 114 patients (152 groins) who were all known to be free from recurrent groin reflux 3 months postoperatively and had colour duplex venous imaging 2 years after operation.

Results. Duplex imaging identified neoreflux at the SFJ in 10 out of 114 groins after 2 years (7%). There were differences in the rates between the four groups: Group A 3/31 (10%), Group B 0/32, Group C 5/44 (11%) and Group D 2/45 (4%). Neoreflux was significantly reduced in the two groups with endothelial closure (B and D): 2/70 (3%) versus 8/75 (11%, p < 0.025).

Conclusion. Recurrent reflux in the groin was reduced by oversewing the ligated SFJ in patients having varicose vein surgery. This adds weight to the theory of neovascularisation as a cause of recurrent veins and offers a means to reduce clinical recurrence rates.

Key Words: Varicose vein surgery; Duplex ultrasound; Neovascularisation; Sapheno-femoral junction.

Introduction

Recurrent varices after surgery are a great problem both for patients and physicians. Operations for recurrence are more difficult and time consuming; complications are more common and can be serious.1–3

Surgical failure at the sapheno-femoral junction (SFJ) remains an important cause of recurrent varicose veins. It is generally agreed that recurrence is minimised by flush ligation of the great saphenous vein (GSV) at its junction with the femoral vein, together with ligation of all tributaries of the SFJ and also any tributaries of the femoral vein in the region.1–3 No prospective data are available to support this specific strategy.3,4 In many patients with recurrent varicose veins, the initial operation was technically incomplete and one or more tributaries and/or a stump of the ligated SFJ remain. However, several authors have described recurrence of veins at the SFJ despite a correctly performed initial operation.1,3–20

This recurrence can be diagnosed as neoreflux by duplex imaging, where a refluxing vein branch can be seen originating from the femoral vein at the site of the ligated SFJ. This refluxing branch may expand and connect with residual thigh veins to cause the clinical picture of symptomatic recurrent varicose veins.

There are two principal possibilities for recurrent veins after correctly ligated SFJ: dilatation of pre-existing venous tributaries from the common femoral vein (CFV),4,5,21–25 or formation of new veins as a result of angiogenic stimulation (termed neovascularisation (NV). Many authors favour the latter hypothesis.1,3–20

Operative techniques have been published which reduce the postoperative incidence of inguinal neoreflux (iNR).1,6,7,11,12,16,26 Nevertheless a number of surgeons do not believe in the existence of NV.21,23,24

The aim of the present investigation was prospectively to study the rate of neoreflux at the SFJ after
varicose vein surgery, and to determine whether the method of ligation or the suture material employed affected the outcome with respect to the development of iNR. Patients were only included when objective evidence showed that the initial saphenofemoral ligation was performed correctly. The outcome was assessed by duplex ultrasonography undertaken 2 years after the original surgery.

Patients and Methods

This randomised trial was considered and approved by the local hospital ethics committee. Patients were recruited between spring and winter 1998, and comprised 500 consecutive SFJ ligations (379 patients) performed by one surgeon. The study was done in a hospital dedicated to venous surgery. Patients were included if they had varicose veins from the CEAP clinical classification: Cs 2–5 (symptomatic; varicose veins to healed ulceration)—Ep (primary etiology)—As (superficial veins), Ap (perforating veins)—Pr (pathophysiological dysfunction: reflux). Patients with active ascending phlebitis or active ulceration (C6) were excluded.

The operation commenced with flush sapheno-femoral ligation. The patients were then divided up into four groups (A–D) consisting of 125 operations each. The operative group was decided by a randomisation procedure in the operating theatre. A nurse took cards out of a box, where the operative technique A–D was noted.

In groups A and B, absorbable 0 Vicryl® (polyclactin 910, Ethicon Robert Koch Str. 1, D 22851 Nordersted) was used for sapheno-femoral ligation. In groups C and D non-absorbable 0 Ethibond® (braided and coated polyester, Ethicon) was employed. In groups B and D, in addition to sapheno-femoral ligation, a continuous Prolene® (polypropylene, Ethicon) was sutured over the stump, so that the endothelial funnel was closed, and endothelium was not in contact with the surrounding subcutaneous tissue. The ligated stump was not buried and the cribiform fascia not closed. This technique avoids the risk of producing a stenosis of the femoral vein (Fig. 1–3). The GSV was either stripped (83% = 415) or—in cases of an isolated incompetence of the SFJ and the anterior accessory saphenous vein (AASV), where the GSV trunk in the thigh remains competent—reseected in the upper third of the thigh (17% = 85). In all groins a suction drain was used, remaining in place until the evening of the operation day or at the following morning. The patients in each of the groups were well matched for clinical parameters including age and sex, apart from the small number of patients with previous thrombophlebitis in Group A (Table 1).

Statistical analysis

Statistical analysis was performed using the Student’s t-test for differences of quotas $\pi$. These differences are as usual approximately $N (0,1)$—distributed under the condition: $N \times \pi \times (1 - \pi) > 9$. That means that usual the $z$-test of the differences is applied. Since this condition is not always given in our study the more adequate distribution of Student was used to carry out the significance tests for the differences of the quotas $\pi$.

Inclusion in the main study

Patients were only included in the main follow-up study if they were found to have a correctly performed sapheno-femoral ligation on postoperative by colour duplex ultrasonography. They were invited for an ultrasound examination three months after surgery and 311 patients (409 groins) attended: 68 patients (91 groins) were lost. These scans were used to determine whether any tributaries had been overlooked or whether early neoreflux had developed. After three months 20/409 (4.9%) groins had residual sapheno-femoral reflux on duplex imaging. Refluxing veins varied in size from 1.8 to 2.5 mm in diameter.

Only patients without any groin reflux at 3 months were invited for a second duplex scan 2 years after surgery. A total of 114 patients (152 groins out of 389 known to be without reflux after three months) agreed to be examined; these patients constituted the study group. The rest of the patients failed to attend late follow-up (Fig. 4).

Duplex imaging

Colour duplex imaging was done with the Hewlett Packard, image Point HX; 3000 Minuteman Road, Andover, Massachusetts 01810), employing a 7.5 MHz probe.

The examinations were undertaken with the patient in the standing position using the Valsalva manoeuvre and manual calf compression. Reflux of more than one second was considered significant. Cross-groin collateral veins without any connection with the CFV, were not classified as NV—according to De Maeseneer. All scans after 2 years were carried out with the investigator blinded to the surgical procedure used and the vast majority were done by one phlebologist.
Results

Of the original 500 procedures, only 152 (30%) fulfilled the inclusion criteria for the study and attended for 2 year imaging. In all these legs colour duplex imaging at 3 months showed that the initial operation had been performed correctly. The number of procedures that remained in each group was as follows: Group A, \( n = 31 \); Group B, \( n = 32 \); Group C, \( n = 44 \) and Group D, \( n = 45 \).

On duplex imaging after 2 years, reflux at the SFJ was identified in 10 legs (7%: seven GSV, three AASV). All were single channelled, which is the most frequent form of neoreflux according to Fischer.\(^4\) Only one of these patients had slightly symptomatic recurrent varicose veins but did not require further surgery. The remaining 142 procedures (93%) had no recurrent sapheno-femoral incompetence (SFI).

There were differences in the rate of neoreflux in the four groups: Group A, \( 3/31 \) (10%); Group B, \( 0/32 \); Group C, \( 5/44 \) (11%) and Group D, \( 2/45 \) (4%). The lowest recurrence rate (zero) followed the use of absorbable suture material and Prolene\(^\circledast\) oversewing (Group B).

The empirical results (Table 2) suggest that the operative technique influences the outcome of the
operation. Applying the t-test of the differences of proportions this presumption was confirmed.

Within the Prolene combinations, we found that the comparison Vicryl®-Prolene® (B) with Ethibond® (C) \(p = 0.025\) and Vicryl®-Prolene® with Vicryl® (A) \(p = 0.05\) were significant in differences of proportions. Especially the groups including Prolene® (B + D: 2/77 = 3%) show significant differences in comparison to those groups without Prolene® (A + C: 8/75 = 11%) \(p = 0.025\).

No significant influence on the success (no reflux) of the operation was found for the other techniques. The results of the t-test are found in details in Table 3.

### Complications

One patient in group C (Ethibond only) developed a significant groin wound infection. No other major complication occurred.

### Discussion

Recurrent varicose veins after ligation of the SFJ can be divided in those caused by technical inadequacy or those without operative error.\(^1,3,4,6,9,15-17\) Both, in our study and in the studies of Creton\(^7\) and De Maeseneer\(^16\) operative mistakes could be excluded by early postoperative duplex imaging. When the first operation had been performed correctly, then two potential pathogenic mechanisms for iNR have been postulated: dilatation of pre-existing veins or true angiogenesis. Dilatation of pre-existing veins may occur in venules in a lymph node venous network, or it may follow dilatation of small adventitial vessels in the vasa vasorum of the femoral vein.\(^4,5,22-25\) Alternatively, it

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**Table 1. Clinical parameters**

<table>
<thead>
<tr>
<th></th>
<th>Group A VI</th>
<th>Group B VI-P</th>
<th>Group C ETH</th>
<th>Group D ETH-P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of limbs (n)</td>
<td>125</td>
<td>125</td>
<td>125</td>
<td>125</td>
</tr>
<tr>
<td>Phlebitis in history (n)</td>
<td>17</td>
<td>34</td>
<td>35</td>
<td>25</td>
</tr>
<tr>
<td>Deep vein insufficiency (n)</td>
<td>65</td>
<td>61</td>
<td>56</td>
<td>61</td>
</tr>
<tr>
<td>Diameter of SFJ (mm) (mean, SD)</td>
<td>11.5 SD 2.4</td>
<td>11.1 SD 2.3</td>
<td>11.5 SD 2.6</td>
<td>11.6 SD 2.8</td>
</tr>
<tr>
<td>Ligated side branches of the com. fem. vein in the region of the SFJ (n)</td>
<td>36</td>
<td>44</td>
<td>41</td>
<td>42</td>
</tr>
<tr>
<td>Number of patients (n)</td>
<td>94</td>
<td>97</td>
<td>99</td>
<td>89</td>
</tr>
<tr>
<td>Male (n)</td>
<td>21</td>
<td>23</td>
<td>22</td>
<td>20</td>
</tr>
<tr>
<td>Female (n)</td>
<td>73</td>
<td>74</td>
<td>77</td>
<td>69</td>
</tr>
<tr>
<td>Height (cm) (mean ± SD)</td>
<td>170 SD 8</td>
<td>168 SD 9</td>
<td>169 SD 9</td>
<td>170 SD 8</td>
</tr>
<tr>
<td>Weight (kg) (mean ± SD)</td>
<td>74.8 SD 14.6</td>
<td>73.9 SD 14.6</td>
<td>74.4 SD 13.1</td>
<td>74.6 SD 15.4</td>
</tr>
<tr>
<td>Age (years) (mean ± SD)</td>
<td>55 SD 10</td>
<td>55 SD 11</td>
<td>56 SD 12</td>
<td>54 SD 10</td>
</tr>
<tr>
<td>Premenopausal female hormones (n)</td>
<td>24/73</td>
<td>23/95</td>
<td>26/77</td>
<td>20/69</td>
</tr>
</tbody>
</table>
may be the result of collaterals. Any of these dilated tributaries may create a new connection between the femoral vein and any residual superficial veins left in the thigh. The second pathogenic mechanism—neovascularisation—might be stimulated by the free endothelium left after simple sapheno-femoral ligation, by vascularisation of residual thrombus or by disturbed venous drainage of the ligated branches of the SFJ. Thorough analysis of the different mechanisms for iNR and NV will be found in articles by Earnshaw, Fischer, and Frings.

All these mechanisms result in a diagnosis of inguinal neoreflux to be made on duplex imaging where a refluxing vein branch with origin in the CFV can be found after correct ligation of SFJ. While its existence has been demonstrated several times, it is difficult to prove that neovascularisation really does exist because the argument that the iNR has been caused by pre-existing vessels cannot be excluded. The present investigation is a strong evidence that it exists, as simple over sewing of the SFJ appeared to reduce the rate of neoreflux. This technique could hardly be expected to affect existing tributaries of the femoral vein.

Other scientific observations that support the theory of neovascularisation include: experimental work on rat femoral vein, reconnection of the GSV after segmental resection and higher recurrence rates after varicose vein surgery that did not involve stripping the GSV, results of varicography, surgical observations on re-exploration, and histological findings from specimens taken at re-operation. Although all these findings are highly suggestive, none is conclusive.

Many surgeons have modified surgical techniques for sapheno-femoral ligation to try and prevent neoreflux. Closing the cribriform fascia or the pectineus fascia over the ligated SFJ should prevent both neovascularisation and dilatation of existing venous tributaries, though it has not proved effective in preventing recurrent varicose veins in a scientific study. The use of a silicone, mersilene or polytetrafluoroethylene patch sutured over the stump of the SFJ should provide a barrier. Similarly, excision of the SFJ from the femoral vein with continuous suture of the femoral vein has proved its effectiveness, but only for a three month interval. Randomised trials confirming their efficacy of these techniques are lacking.

### Table 2. Statistical results table of contingency: results of different operation techniques

<table>
<thead>
<tr>
<th>Group</th>
<th>n</th>
<th>Reflux (%)</th>
<th>No reflux (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vicryl (A)</td>
<td>31</td>
<td>3 (10%)</td>
<td>28 (90%)</td>
</tr>
<tr>
<td>Vicryl-Prolene (B)</td>
<td>32</td>
<td>0 (0%)</td>
<td>100%</td>
</tr>
<tr>
<td>Ethibond (C)</td>
<td>44</td>
<td>5 (11%)</td>
<td>39 (89%)</td>
</tr>
<tr>
<td>Ethibond-Prolene (D)</td>
<td>45</td>
<td>2 (4%)</td>
<td>43 (96%)</td>
</tr>
<tr>
<td>Total</td>
<td>152</td>
<td>10 (7%)</td>
<td>142 (93%)</td>
</tr>
</tbody>
</table>

**Fig. 4.** Summary of patients recruited to the study: the original cohort of operations (SFJ ligations), the quota of excluded (22%) and included (78%) operations and the final study group (152/500 = 30%). Ops, number of operations.
The present prospective randomised single blinded study aimed to eliminate this deficit. Unfortunately, the study has a relatively high loss of patients. As patients attend from locations several 100 km distant from the venous clinic, they were often reluctant to attend for follow-up. This reduced the original group of 379 patients (500 groins) for analysis. In addition, patients were only included in the study group if they had no SFJ reflux detected in the early duplex follow-up studies. The authors acknowledge that this limitation restricts the power of this study to guide future management in patients with varicose veins. The present follow-up study was confined to 114 patients (152 groins). All these patients were shown to have had an effective sapheno-femoral ligation by duplex imaging 3 months after surgery, where no SFJ stump or branch from the CFV remained. This methodology in our study allows us to reject the argument that iNR was caused by a missed venous tributary. It is acknowledged that very small tributaries less than 1–2 mm in diameter could, however, have escaped detection by duplex imaging.

The study confirmed that after 2 years recurrent sapheno-femoral incompetence developed in a proportion of patients (7%) despite technically correct completion of the first operation. This rate was similar to that of De Maeseneer\textsuperscript{16} (38/380 primary operations = 10% after 1 year).

Despite these duplex findings, only one patient complained of slightly symptomatic recurrent varicose veins which were treated by sclerotherapy and hook phlebectomy. Some other patients requested avulsion treatment or sclerotherapy for cosmetic reasons. Whether these patients will develop symptomatic recurrent veins with further follow-up remains to be seen.

The present study failed to find any statistically significant influence of the type of suture material used for SFJ ligation on the development of recurrent SFI. The rate of neoreflux in groups A and C with absorbable sutures was similar to that with Ethibond\textsuperscript{8} in groups B and D. Other authors have previously suggested that the type of suture material might be important.\textsuperscript{4,9,14}

The simple technique of over-sewing the SFJ stump endothelium used in the present study appeared to reduce the development of neoreflux, providing further evidence of the existence of neovascularisation. This could be an important way to reduce the rate of recurrent varicose veins. However, the results after only 2 years represent interim findings that must be confirmed by follow-up to at least 5 years,\textsuperscript{9} and in a larger number of patients.

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### References

10. Glass GM. Neovascularization in recurrence of varices of the...


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