Comparative outcomes of radiofrequency endoluminal ablation, invagination stripping, and cryostripping in the treatment of great saphenous vein insufficiency

L Stötter*, I Schaff† and A Bockelbrink‡
*Chirurgische Praxisklinik, Landshut; †Institut für med. Statistik der TU München, München, Germany

Abstract

Objective: Prospective, randomized comparison of short-term and one-year postoperative outcomes after radiofrequency endoluminal ablation (REA) of the great saphenous vein (GSV), saphenofemoral junction (SFJ) ligation with extended tributary ligation and invagination GSV stripping, and SFJ ligation with extended tributary ligation and GSV cryostripping.

Methods: In all, 60 consenting patients were randomly allocated to three groups and treated contemporaneously over a nine-month period. Clinical, duplex Doppler, analogue scale pain scoring and activity impairment assessments were performed one day postoperatively, and after one, two, and six weeks, and then repeated after one year, adding patient satisfaction scoring and the CIVIQ 2 quality-of-life questionnaire, specifically designed for lower limb venous insufficiency.

Results: Immediate success was achieved in 19/20 REA limbs with one open segment that subsequently spontaneously closed, in 20/20 invagination stripping limbs, and in 18/20 cryostripped limbs, two having residual open segments. Cumulative up to six-week impairment scores, cumulative up to six-week pain scores, and time to return to full activity were all statistically superior for REA patients. At one year, segmental recanalization on less than 10 cm was detected in two REA patients, and for all REA patients the GSV trunk was sonographically no longer visible, beginning from 10 cm below the SFJ. REA patients continued to be significantly more satisfied with both their operative procedures and the cosmetic appearance of their treated lower extremity compared with patients in the two other treatment cohorts.

Conclusion: REA offers significant short-term, patient-oriented advantages over extended ligation and invagination or cryostripping through one year.


Keywords: Great saphenous vein; invagination stripping; radiofrequency endoluminal ablation; cryostripping

Introduction

High ligation of the saphenofemoral junction (SFJ), resection of all junctional tributaries, and stripping of the thigh portion of the great saphenous vein (GSV) with stab avulsion phlebectomy of clusters fed by incompetent perforating veins has been widely accepted as the surgical standard for treating primary varicose veins associated with GSV reflux.1,2 This pre-eminence was first seriously challenged in a presentation by Manfrini3 in 1999, wherein he described microprocessor-controlled, radiofrequency endoluminal ablation (REA) of the GSV as an effective, less-
invasive means of eliminating the GSV from the thigh.

Subsequent publications have documented that REA can be done without making a groin incision and ligating the junctional tributaries, with minimal complications if tumescent anaesthesia is used, either as a supplement to or as the sole anaesthetic, with significant advantages in terms of patient comfort, satisfaction and earlier return to normal activities. Moreover, REA has demonstrated the long-term durability of the procedure, with up to four-year efficacy rates comparable with the historical data on the standard surgical procedure.

We chose to begin our experience with less-invasive GSV elimination by comparing immediate and one-year outcomes of REA, invagination stripping and cryostripping. We were early proponents of invagination stripping as it causes less haematoma and pain, and thought it to be a more appropriate ‘gold standard’ than various other stripping methods. Cryostripping, a less-invasive technique although not widely used, closely simulates invagination stripping in the manner in which the stripping progresses.

Methods

Between October 2001 and June 2002, 60 consenting patients (60 limbs) presenting with >0.5 s incompetence of the SFJ and GSV, and with primary varicose veins that met the REA size criteria, and not needing avulsion phlebectomies in the thigh were randomly allocated to REA, invagination stripping or cryostripping, with 20 patients entered into each group. Need for an avulsion phlebectomy in the thigh was an excluding criterion because of its potential as a confounding factor in assessing pain and haematoma surface area. The statistical department of the Klinikum Rechts der Isar, Munich, Germany performed the randomization as well as the statistical analysis. The Kruskal–Wallis test was used for continuous variables and Fisher’s exact test was used to compare proportions. An alpha value of <0.05 was deemed to be significant.

Aside from the usual clinical and duplex Doppler surveillance after one day and after one, two, and six weeks, pain scoring was evaluated with patient standing, walking on the flat or climbing stairs, using a 10-point analogue visual scale, and activity impairment was measured by the CIVIQ 2 quality-of-life questionnaire. The time required to return to full normal activity was recorded on each patient. Irrespective of their treatment arm, all patients were encouraged to wear compression stockings for six weeks. Presence of haematoma was documented, and at one week the haematoma area was measured using a cm² grid. After one year, the focus was on duplex Doppler findings, clinical evaluation, overall and cosmetic-specific outcome satisfaction (on a 1–10 visual analogue scale), and a CIVIQ quality-of-life questionnaire.

REA was performed using the Closure® system (VNUS Medical Technologies, Inc., San Jose, CA, USA). The procedures were performed under general anaesthesia in order to maintain coherence between the study arms. When the vein intended for treatment was within a cm of the skin, saline infiltration was used to separate the vein and skin. Catheters of 5 or 8 Fr were used according to the vein size. Vein access was above the ankle and the catheter was passed prograde to lie just distal to the SFJ, guided by duplex imaging. Treatment proceeded at 85°C and 3 cm/min pullback speed, up to a level immediately below the knee, in accord with the published technique.

As has been our custom for more than 15 years, crossectomy and invagination stripping were performed using the ‘Faden stripper’, introduced through the groin incision after SFJ ligation with extended tributary ligation, typically stripping to just below the knee.

Cryostripping was also performed after ligation of SFJ and of the tributaries. The cryoprobe was introduced through the groin incision and passed immediately to the below-knee level of the GSV. Controlled freezing was used to limit adherence to the GSV and not to the perivascular tissue. The GSV was extracted by pulling on the cryostripper.

Results

One day to six weeks

The three groups were homogenous for gender (6m/14f for REA; 5m/15f for invagination stripping; 6m/14f for cryostripping), age (41 years for men and 44 years for women in the REA group; 54 years for men and 51 years for women in the invagination stripping group; 42 years for men and 41 years for women in the cryostripping group) and duration of pathology (9.6 years for the REA group; 7.1 years for the invagination stripping group; 7.5 years for the cryostripping group). The mean GSV diameters immediately distal to the saphenofemoral ostium were 6.8 (4.5–12) mm for the REA group, 7.1 (5–14) mm for the invagination stripping limbs, and 7.4 (4.5–10) mm for the cryostripping cohort, values that were not significantly different. The 24-h to six-weeks’ results are
presented in Table 1. One REA limb had a partially patent segment at 24 h that spontaneously closed within two weeks. Although the treatment time appeared to be longer, REA results were significantly superior. At one week, haematoma area was 55 cm² for REA surface compared with 109 cm² for invagination stripping and 150 cm² for cryostripping. Up to six weeks, cumulative impairment score (Figure 1) was significantly lower for REA: 2.8* compared with invagination stripping 7.9 and cryostripping 17.1 (P = 0.012). In terms of the cumulative up to six-week pain score (Figure 2), REA presented significantly lower scores than the other study arms – 4.6* compared with 7.5 for invagination stripping and 10.6 for cryostripping (P = 0.014). These results were mirrored by the subjective global impressions of the evaluating physician, significantly in favour of REA: 0.62 compared with 0.86 for invagination stripping and 1.38 for cryostripping (P = 0.007).

In terms of return to normal activity (Figure 3), the duration was significantly lower for REA: seven days compared with 14 for invagination stripping and 12 for cryostripping (P = 0.021).

No patient experienced detectable deep vein thrombosis, pulmonary embolism or saphenous nerve injury.

### One year

Table 2 and Figures 4 and 5 summarize the results of the one-year assessments. One patient from each group was unavailable for this follow-up. One cryostripping limb had developed vessels in the groin due to neovascularization, despite having had extended tributary ligation. Less than 10 cm segmental recanalization occurred in two REA limbs. Short stumps were detectable in seven patients (four patients with 1-cm stump and three patients with 3-cm stump), in accordance with the distance from the SFJ where the occlusion was...
performed. Below 10 cm from the SFJ, the treated portion of the GSV was ultrasonically invisible in all REA limbs at one year. By one year, there was no difference in the physician-assessed clinical status between the three groups, but the REA patients continued to be significantly more satisfied with both their operative procedures \( (P = 0.001) \) (Figure 4) and the cosmetic appearance \( (P = 0.006) \) (Figure 5) of their treated lower extremities than patients in the other two study arms.

Discussion

Conventional flush SFJ ligation, tributary ligation, and stripping of the thigh portion of the GSV are followed by recurrent SFJ reflux in 20–25% of limbs, of which approximately 1/3 will result in consideration of a secondary procedure.\(^2,9\) Some of these are due to misidentification of the true junction.\(^9,18\) Other recurrences are linked to groin neovascularization that has a remarkable affinity for reconnecting at the site of the former SFJ.\(^19-22\) Surgeon dissatisfaction with a 20–25% failure to achieve the anatomic goal of SFJ ligation and GSV stripping has given rise to two lines of remediation. The first was to extend tributary ligation beyond the first available vein joining the target tributary.\(^1\) This extended dissection has attracted relatively few adherents, and is no guarantee against neovascular reconnection. In fact, destroying the superficial drainage of the lower abdomen and pudendum might actually stimulate neovascularization beyond that which is an integral part of the wound healing process.\(^9,22\) REA, laser endoluminal ablation, and sclerofoam offer an alternative remediation: eliminating an incompetent and varicose GSV from the thigh without groin incision and tributary interruption neovascular stimuli. Given the published two- to four-years REA outcomes that are essentially similar to those of SFJ ligation and GSV stripping, it is reasonable and proper to focus on their short-term patient-oriented advantages.\(^5-8\) The Lurie et al.\(^5\) randomized study comparing 44 REA and 36 ligation and stripping limbs showed most of the short-term advantages observed in the current study: significantly less pain, fewer adverse events, less time to return to routine activities and work, and superior patient

![Figure 3](image-url) Time to return to normal activities (days) \( (P = 0.021 \) groups significantly different)

### Table 2 One-year assessment

<table>
<thead>
<tr>
<th>Variable</th>
<th>Radiofrequency endoluminal ablation</th>
<th>Invagination stripping</th>
<th>Cryoablation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Groin neovascularization</td>
<td>0/19</td>
<td>0/19</td>
<td>1/19</td>
</tr>
<tr>
<td>Segmental recanalization</td>
<td>2/19</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Persistent impairment</td>
<td>0/19</td>
<td>0/19</td>
<td>0/19</td>
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![Figure 4](image-url) One-year patient satisfaction ratings with their respective treatment \( (P = 0.001 \) groups significantly different)

![Figure 5](image-url) One-year patient satisfaction ratings with the appearance of their treated lower extremity \( (P = 0.006 \) groups significantly different)
quality of life, with most of the differences tending towards equality by four months.

We chose invagination stripping as our ‘conventional’ comparison because we have extensive experience with this form of stripping and regard it as minimizing haematoma accumulation as well as post-stripping discomfort. The literature, however, does not support this contention, except for a minor cosmetic advantage of the smaller exit site. Our expectations for cryoablation were considerably better than our observations. Cryoablation did mimic the progressive inversion of invagination stripping, but left residual segments in two limbs and offered no comfort or early rehabilitation advantage because, as we used it, it did not obviate making a groin incision, or lessen haematoma formation. As we have gained experience with REA, we are more inclined to use local or tumescent anaesthesia, adding yet another REA advantage.

There was a disconnection between the findings of residual segmental flow and compression-release inducible reflux and no corresponding increase in symptoms, recurrence of varicose veins, or diminution in overall patient satisfaction. This has been noted before, and is probably attributable to substantial amelioration of the original pathophysiology, particularly when only short-flow segments are involved, as well as evaluation by the treating surgeon. This was true in our study even for the cases with recanalization up to 10 cm, but further surveillance of the clinical evolution is needed.

REA offers significant short-term, patient-oriented advantages over extended ligation and invagination or cryoablation through one year. The persistence of the findings is to be assessed in the future for longer-term follow-up, as well as to be compared with other novel endovenous methods.

References