

Defining the role of extended saphenofemoral junction ligation: A prospective comparative study

James G. Chandler, MD,^a Olivier Pichot, MD,^b Carmine Sessa, MD,^b Sanja Schuller-Petrović, MD, PhD,^c Francisco José Osse, MD,^d and John J. Bergan, MD,^e *Boulder, Colo, Grenoble, France, Graz, Austria, São Paulo, Brazil, and La Jolla, Calif*

Objective: This study explores the added effect of extended saphenofemoral junction (SFJ) ligation when the greater saphenous vein (GSV) has been eliminated from participating in thigh reflux by means of endovenous obliteration. GSV obliteration, unlike surgical stripping, can be done with or without SFJ ligation to isolate and study SFJ ligation's specific contribution to treatment results.

Methods: Sixty limbs treated with SFJ ligation and 120 limbs treated without high ligation were selected from an ongoing, multicenter, endovenous obliteration trial on the basis of their having primary varicose veins, GSV reflux, and early treatment dates.

Results: Five (8%) high-ligation limbs and seven (6%) limbs without high ligation with patent veins at 6 weeks or less were excluded as unsuccessful obliterations. Treatment significantly reduced symptoms and CEAP clinical class in both groups ($P = .0001$). Recurrent reflux developed in one (2%) of 49 high-ligation limbs and eight (8%) of 97 limbs without high ligation by 6 months ($P = .273$). New instances of reflux did not appear thereafter in 57 limbs followed to 12 months. Recurrent varicose veins occurred in three high-ligation limbs and four limbs without high ligation by 6 months and in one additional high-ligation limb and two additional limbs without high ligation by 12 months. Actuarial recurrence curves were not statistically different with or without SFJ ligation ($P > .156$), predicting greater than 90% freedom from recurrent reflux and varicosities at 1 year for both groups.

Conclusion: These early results suggest that extended SFJ ligation may add little to effective GSV obliteration, but our findings are not sufficiently robust to warrant abandonment of SFJ ligation as currently practiced in the management of primary varicose veins associated with GSV vein reflux. (*J Vasc Surg* 2000;32:941-53.)

From the Department of Surgery, University of Colorado Health Sciences Center and VNUS Medical Technologies^a; the Divisions of Vascular Medicine and Vascular Surgery, University of Grenoble^b; the Hautklinik LKH, University of Graz^c; the Vascular Surgery and Angioradiology Services, Irmandade Santa Casa de Misericórdia de São Paulo^d; and the Department of Surgery, the University of California, San Diego.^e

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Reprint requests: James G. Chandler, MD, 3721 Mountain Laurel Place, Boulder, CO 80304.

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The surgical treatment of primary varicose veins associated with greater saphenous vein (GSV) reflux has evolved into high ligation of the GSV, with ligation and resection of all tributaries entering the saphenofemoral junction (SFJ) and stripping of the thigh portion of the GSV, with stab-avulsion phlebectomy of clusters fed by incompetent perforating veins.¹⁻³ Because the GSV itself is rarely varicose, some have objected to inclusion of the thigh saphenectomy, believing it to be unnecessarily traumatic and wasteful of a valuable potential arterial substitute.⁴⁻⁶ These objections are more than offset by the combined results of six prospective randomized studies showing that the GSV stripping reduces recurrence of both reflux and varicosities from 50% or greater after high ligation without saphenectomy to 26% to 28% in limbs followed for 2 to 5 years.⁷⁻¹²

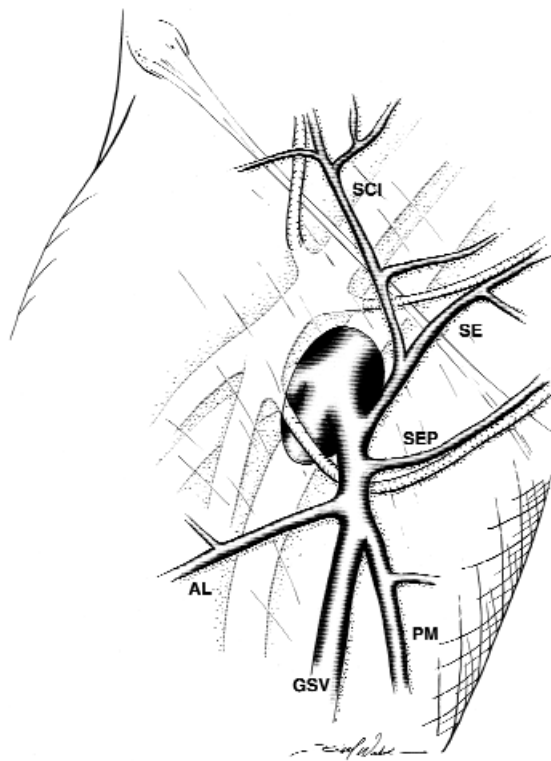


Fig 1. SFJ anatomy. In this variant the superficial circumflex iliac and inferior superficial epigastric veins have a common trunk, which has been reported to occur in 15% of SFJs.²⁷ *AL*, Anterolateral tributary; *PM*, posteromedial tributary; *SCI*, superficial circumflex iliac vein; *SE*, inferior superficial epigastric vein; *SEP*, superficial external pudendal vein.

Studies of recurrent reflux around the SFJ in patients with recurrent varicosities have shown that the principal findings are a network of residual SFJ tributaries connecting to more distal subcutaneous veins or an intact GSV because the GSV was not stripped and newly formed veins (neovascularization) were connecting the deep and superficial systems.¹²⁻¹⁴ These findings have been interpreted as supporting the need for removal of the thigh portion of the GSV and are the basis of the concept of extended resection of SFJ tributaries beyond their own primary tributaries to effect a more thorough disconnection.¹

In the decade since its proposal by Glass,¹⁵ evidence has accumulated to support neovascularity, which is regarded as an extension of groin wound-healing angiogenesis, as a major source of new channels reconnecting superficial veins to the common femoral vein around a divided SFJ.^{12,13,16} Cross-groin newly formed veins have also been observed. These link the superficial drainage of the lower abdomen and pudendum to varicose thigh tributaries.¹⁶

Table I. Choice of high ligation and no high ligation by treating center

Center	High ligation	No high ligation	% High ligation
1	6	22	21
2	0	13	0
3	10	1	91
4	0	11	0
5	10	0	100
6	0	10	0
7	1	8	11
8	8	0	100
9	7	0	100
10	0	7	0
11	0	7	0
12	0	7	0
13	0	6	0
14	2	4	33
15	5	0	100
16	1	4	20
17	0	5	0
18	4	0	100
19	0	4	0
20	1	2	33
21	0	3	0
22	0	3	0
23 and 24*	0	3	0
25-27*	5	0	100
Total	60	120	—

*Centers treating only one or two limbs.

The current study takes advantage of the fact that GSV obliteration can be done without a groin incision and without interrupting the normal drainage of the superficial, inferior, epigastric vein; the circumflex iliac vein; and the external pudendal vein to explore a two-part hypothesis:

1. SFJ tributary ligation and resection may be of little benefit in preventing recurrent reflux and reappearance of varicosities if the thigh portion of the GSV has been effectively eliminated.
2. Tributary ligation and resection, by interfering with the venous drainage of lower abdominal and pudendal tissues, may be an important stimulus to new vessel formation. If this is true, SFJ tributary ligation could be counterproductive when superimposed on successful GSV obliteration.

METHODS

Endovenous obliteration was done with the Closure System (VNUS Medical Technologies, Inc, Sunnyvale, Calif). The system consists of a dedicated, microprocessor-controlled, bipolar generator and catheters with collapsible electrodes that are introduced into the vein lumen and then energized to destroy the intima and contract the vein wall so that it will undergo fibrous obliteration, as previously described.^{17,18}

Table II. Cohort characteristics

<i>Characteristic</i>	<i>High ligation</i>	<i>No high ligation</i>	<i>P value</i>
Mean age ± SD (y)	47 ± 11	47 ± 13	.885
Female predominance	46/60 (77%)	82/106 (77%)	1.00
CEAP clinical class*	2.3 ± 0.5	2.6 ± 0.9	.002
Mean symptom score†	1.9 ± 0.8	1.9 ± 0.9	.704
Treatment dates	Jan 1998-May 1999	Oct 1998-Apr 1999	.538
Veins treated‡			
Above-knee GSV	36 (60%)	95 (79%)	.007
Entire GSV	24	25	
Stab-avulsion phlebectomy	48 (80%)	73 (61%)	.011
Early (≤ 6 wk) patency	5 (8%)	7 (6%)	.538
No. of limbs eligible for 6-mo follow-up	55	113	—
No. of limbs eligible for 12-mo follow-up	51	80	—

*Clinical classification: 0, no visible or palpable signs of venous disease; 1, telangiectases, reticular veins, or malleolar flare; 2, varicose veins; 3, edema without skin changes; 4, skin changes ascribed to venous disease (pigmentation, venous eczema, or lipodermatosclerosis); 5, skin changes with healed ulceration; and 6, skin changes with active ulceration.²³

†One point each for pain, aching-fatigue, and swelling.

‡*Above-knee* indicates treating the thigh portion of the saphenous vein, beginning at the SFJ and terminating just below the popliteal crease. *Entire* indicates treating from the SFJ to just above the ankle.

Table III. Complications

<i>Complications</i>	<i>High ligation</i>	<i>No high ligation</i>	<i>P value</i>
Femoral-vein thrombus propagation	0	1 (0.8%)	—
Paresthesias	15 (25%)	19 (16%)	.159
Perivenous or dermal inflammation	9 (15%)	4 (3%)	.011
Skin burns	2 (3%)	4 (3%)	1.00

The study patients were selected from an ongoing multicenter trial of endovenous obliteration in Europe, the United States, and Australia, which is being conducted by the VNUS Closure-Treatment Study Group (Appendix).¹⁷ To be considered for inclusion, patients had to have primary venous insufficiency manifested by both a greater than 1-second GSV reflux with a Valsalva or calf compression release and readily visible varicosities. Patients with dominant deep-system reflux or post-thrombotic changes were excluded. Treatment dates were then used to select the first 60 limbs treated with high ligation and the first 120 limbs treated without high ligation from the group of qualified limbs to allow the longest possible follow-up. The number of high-ligation limbs was a limiting factor. Twice as many limbs without high ligation were included to reach a sample size that would have reasonable power to detect the expected between-group differences in the principal outcome variables and to add precision to the analysis of the procedure with the greater deviation from conventional ligation and stripping.

The election to use or not include SFJ ligation was not randomized nor was it decided on a case-by-case

basis because of a particular SFJ anatomy. The choice was based on investigator preference and, as shown in Table I, was the same for most patients at an individual treatment center. Eighty-one percent of limbs were treated at centers where all limbs or all but one limb were treated in the same way with respect to inclusion of SFJ ligation. Two centers were exceptions, numbers 1 and 14 in Table I. Center number 1 had two principal investigators, an interventional radiologist and a surgeon, who were committed to percutaneously accessing the GSV immediately below the knee. They were unable to achieve percutaneous access in six of 28 limbs and resorted to a conventional groin incision to access the GSV. Because the groin was now opened, they thought that the patient would be best served by adding SFJ ligation. In their own words, SFJ ligation was simply a “side product” of the venous access problem. Center number 14 also had two principal investigators, both surgeons. The first investigator, who treated two limbs, was adamant that extended SFJ ligation was essential. The other investigator, who treated four limbs, thought that avoiding a groin incision was a substantial advantage and decided, before beginning the study, not to do high ligations.

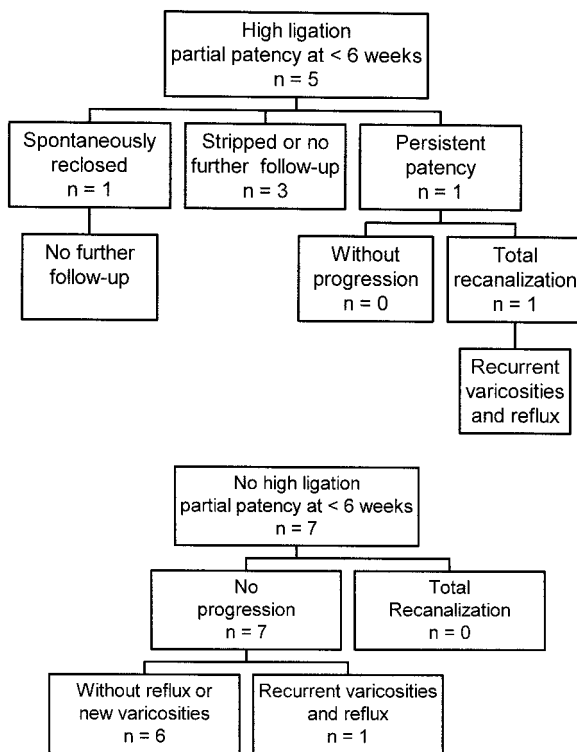


Fig 2. Subsequent course of high-ligation veins and veins without high ligation exhibiting early patency.

SFJ ligation was generally understood to be performed by completely dissecting the SFJ and dividing the cribriform fascia to enable identification of the true junction and its ligation flush with the common femoral vein. The dissection was expected to reveal five or more junctional tributaries (Fig 1). Each was to be drawn into the wound until its own first tributary could be ligated independently along with the main tributary trunk. These principles were agreed on at investigator meetings and in discussions with individual investigators. The protocol, however, focused on the conduct and assessment of the endovenous obliteration and did not impose a study-wide standardized SFJ ligation procedure. As a consequence, the surgical procedure steps that were actually performed were not systematically assayed and were likely to have varied according to individual investigators' interpretations of what constituted a comprehensive SFJ ligation.

Follow-up visits were programmed for 1 and 6 weeks and 3, 6, and 12 months to include a protocol-governed history and clinical assessment in both the recumbent and standing positions and color duplex scanning of the groin and the entire length of treated vein. Reflux testing was done with a Valsalva maneuver with the patient tilted 15 degrees with his

or her head up or with calf compression release while standing.¹⁹

The selected sample size provided 80% power to detect a twofold difference in recurrence of reflux or varicosities at the 0.05 significance level, assuming 20% recurrence rates for the more effective treatment arm.²⁰ The χ^2 test or the Fisher exact test was used to compare proportions. Unpaired continuous and ordinal data were evaluated nonparametrically by the use of the Kruskal-Wallis analysis of variance by ranks, and paired comparisons were assessed with the Wilcoxon signed-rank test.²⁰ Actuarial event-rate calculations were performed according to the method described by Cutler and Ederer²¹ and compared by the use of the log-rank test.²²

RESULTS

Cohort comparability. Patient selection encompassed 128 women and 38 men ranging in age from 19 to 78 years. The characteristics of the two cohorts are shown in Table II. The groups were well matched in age, female predominance, and symptom scores, but the limbs without high ligation had a higher pre-treatment mean CEAP clinical class,²³ which was influenced by three limbs with healed ulcers and one with an active ulcer. Treatment of the limbs without high ligation was less likely to have incorporated stab-avulsion phlebectomies and more likely to have been restricted to the thigh portion of the GSV.

Five high-ligation limbs and seven limbs without high ligation had a greater than 5-cm segment reopening of treated vein within 6 weeks. These were unsuccessful obliterations typically associated with too rapid catheter withdrawal.^{17,18} These obliteration failures were not considered further because they bore no relevance to the study's assessment of the added effect of SFJ ligation when the GSV has been effectively eliminated from the thigh. Their subsequent course is shown in Fig 2, where it can be seen that one limb in each group (20% and 14%, respectively) was known to have developed both recurrent reflux and new or recurrent varicosities.

The complication rates in Table III were similar for thermal injuries to adjacent sensory nerves and skin, but the effects of thermal spread to other perivenous tissues and the deep dermis were more common in the high-ligation group. The one thrombus propagation into the common femoral vein in a limb without high ligation would presumably have been prevented by a properly performed, flush high-ligation. More detailed descriptions of complications encountered with endovenous obliteration have been reported elsewhere.^{17,18}

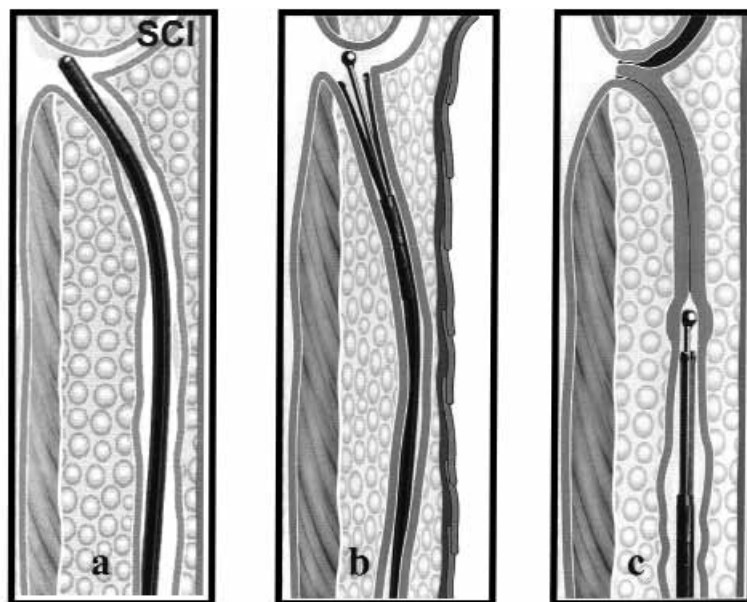


Fig 3. Endovenous obliteration. **a**, Catheter with sheathed electrodes positioned right at the SFJ; **b**, compression wrap applied to limb, electrodes expanded spanning the superficial, circumflex, iliac (SCI) orifice; and **c**, treatment in progress showing limited contraction of the SCI near its orifice and long-segment contraction of GSV (wrapping removed to show undistorted anatomy).

SFJ tributary patency and new vessel formation after endovenous obliteration with and without high ligation. Fig 3 shows the duplex scanning-guided positioning of the catheter at the SFJ and the acute occlusion of a tributary orifice covered by the expanded electrodes. Fig 4 shows persistent patency of an SFJ tributary despite catheter positioning as in Fig 3, B, with no GSV flow, and Fig 5 shows patency of two formerly occluded SFJ tributaries with unimpeded flow into the common femoral vein and persistent GSV occlusion. These color-flow duplex scan images were made at one investigative site where SFJ duplex scan anatomy was studied serially in 15 limbs with terminal- or subterminal-valve incompetence treated by endovenous obliteration without high ligation.²⁴ Duplex scanning was used during treatment to position the electrodes exactly as shown in Fig 3, B. The posttreatment results in this substudy are shown diagrammatically in Fig 6. A third of the limbs showed complete SFJ obliteration at 1 week, including the limb noted in Table III to have femoral vein thrombus propagation. By 6 months, only one SFJ remained completely occluded; the other 14 (93%) had at least one open tributary with prograde SFJ flow. Nearly two thirds of the limbs with patent tributaries had a 1- to 2-cm GSV stump serving as a

conduit for tributary flow. The upper end of the GSV obliteration was sculpted by tributary flow to form a smooth curved path to the SFJ without further intrusion on the obliterated contracted GSV below the open tributary orifices, as shown in the third drawing in Fig 6.

In the overall study color duplex scanning demonstrated one or more patent SFJ tributaries with normal prograde flow through the SFJ in 34 (35%) of 97 limbs without high ligation followed for 6 or more months, which was a significantly ($P = .0001$) greater proportion than the three limbs (6%) with patent SFJ tributaries found among the 49 limbs with high ligation. The external pudendal vein was the most commonly identified open tributary seen by itself or in association with other patent tributaries in 12 limbs (Fig 5). Patent SFJ tributaries were not specifically associated with recurrence of reflux or varicosities. They were seen in four (27%) of 15 limbs with recurrence of one or both and in 33 (25%) of 131 limbs without recurrence ($P = .90$).

SFJ-area connecting veins between the superficial and deep systems, other than those recognized as SFJ tributaries with normal prograde flow, were not observed in either high-ligation groins or groins without high ligation. This negative finding is conditioned by the fact that a concerted duplex scan-

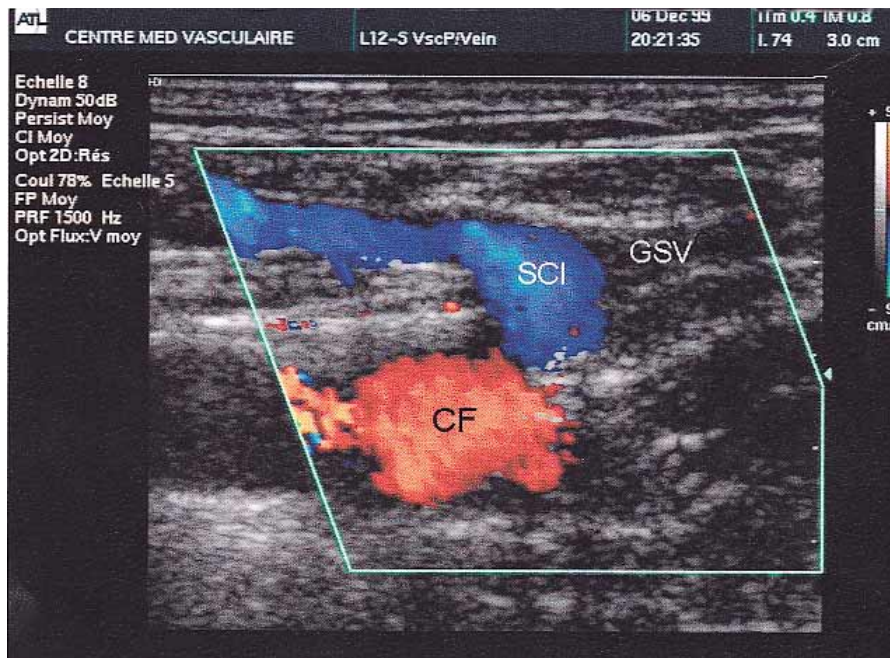


Fig 4. Color flow duplex scan showing patency of the superficial, circumflex, iliac vein (SCI) within 1 week of treatment, with unimpeded flow through the SFJ into the common femoral vein (CF) and an otherwise obliterated GSV.

ning effort was not made to search for such vessels, and posttreatment phlebography was not part of the follow-up.

Principal outcomes. The principal outcome variables are shown at 6- and 12-month follow-up intervals in Table IV. At 6 months, CEAP clinical class and symptom scores were significantly ($P = .0001$) improved in both groups, with 86% of high-ligation limbs and 88% of limbs without high ligation becoming CEAP clinical class 0 or 1. The magnitude ($P = .0001$) of CEAP class improvement was similar in both groups (high ligation, $2.3 \rightarrow 0.7$; no high ligation, $2.6 \rightarrow 0.7$; $P = .151$) and sustained in the 26 high-ligation limbs and 31 limbs without high ligation followed for 12 months. Twelve-month symptom scores also remained significantly ($P = .0001$) improved in both groups.

Recurrent GSV reflux was identified in one high-ligation limb in which a limited segment reopening developed by 6 months. Recurrent reflux was observed in eight limbs without high ligation: four had partially recanalized by 3 months, and the other four showed segmental reopening at 6 months. One of the limbs that was partially open at 3 months went on to totally recanalize by 6 months, and the other three remained stable. Only one newly reopened segment was observed beyond 6 months. It was a 10-cm

nonrefluxing segment immediately distal to the SFJ in a limb without high ligation, which was not noted to have patent SFJ tributaries. Because recurrent reflux and varicosities are continuing time-variable hazards, they are best represented as actuarial data,²⁵ as in Fig 7, where it can be seen that reflux recurrence follows statistically similar courses in both groups ($P = .157$). The data predict greater than 90% freedom from reflux at 1 year, with lower boundary 95% confidence limits of 94% for high-ligation limbs and 87% for limbs without high ligation.

At 6 months, three high-ligation limbs and four limbs without high ligation had recurrent or new visible varicosities. One additional high-ligation limb and two more limbs without high ligation had new varicose veins at 12 months. The recurrent or new varicosities were typically in the leg, with a few in the lower thigh. Varicosity recurrence was associated with limited reopening without reflux in one limb without high ligation and with recurrent reflux in four limbs (one with high ligation and three without) and occurred independent of reflux or recanalization in five limbs (three with high ligation and two without). The actuarial curves of varicose vein recurrence are shown in Fig 8. They are statistically similar for both groups ($P = .696$) and show expectations of greater than 90% freedom from new or

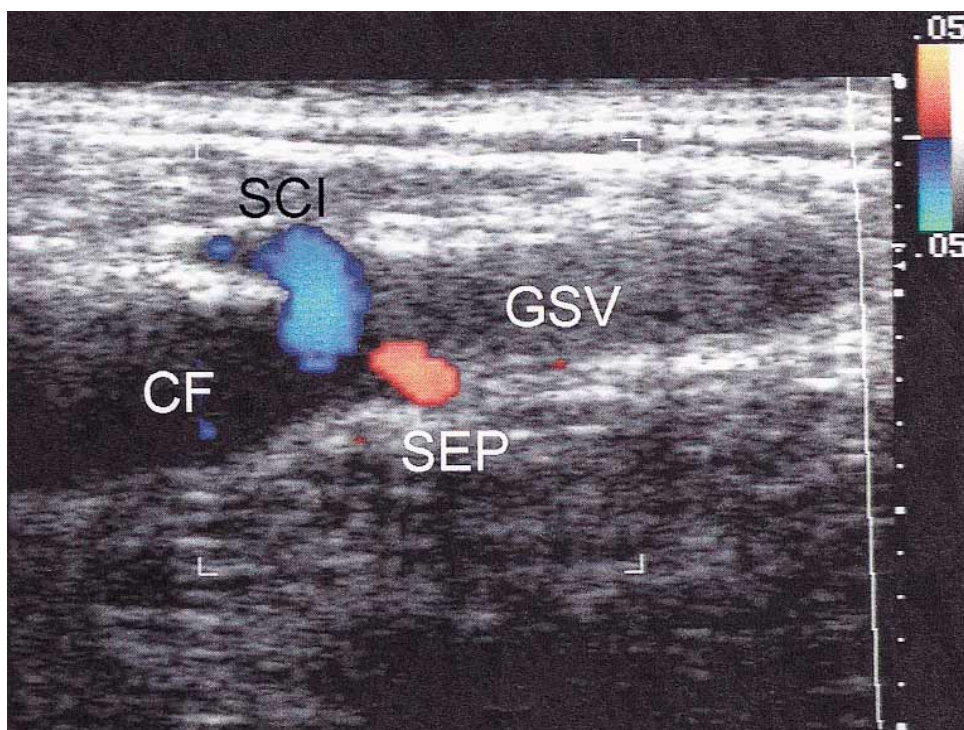


Fig 5. Color flow duplex scan showing patency of the superficial, circumflex, iliac (*SCI*, *blue flow*) and the superficial, external, pudendal (*SEP*, *orange flow*) veins, which were both initially occluded, with noncompressible obliteration of the GSV at 6 months. The common femoral vein (*CF*) flow axis is perpendicular to the color Doppler scan insonation plane.

recurrent varicosities at 1 year, with lower boundary 95% confidence limits of 82% for high-ligation limbs and 88% for limbs without high ligation.

DISCUSSION

Endovenous saphenous vein obliteration with and without extended SFJ tributary ligation offers a unique opportunity to study the incremental value of adding tributary ligation when the thigh portion of the saphenous vein has been effectively eliminated from participating in reflux. The results thus far do not define an important role for SFJ tributary ligation in this setting. Improvements in symptom scores and CEAP clinical class were significant and persisted through 12 months with and without high ligation. The incidences of recurrent reflux and varicosities were similar between groups and also similar to those reported in the literature for high ligation with saphenous stripping in a comparable time frame.^{13,26} The between-group outcome similarities suggest that inclusion of high ligation adds little to effective obliteration with three caveats. The first is that the two cohorts were not randomly allocated. The second is

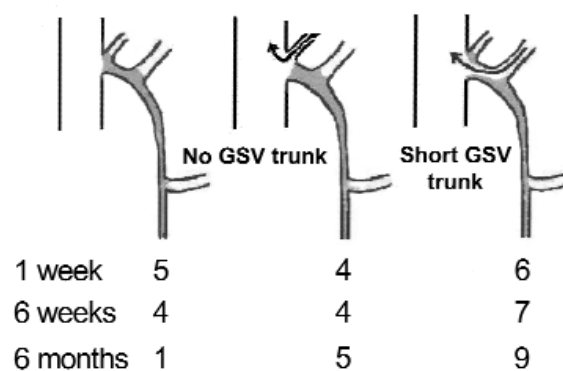


Fig 6. Evolving SFJ duplex-scan anatomy in 15 limbs at various intervals after GSV obliteration.

to note that the between-group comparisons excluded unsuccessful obliterations, where high ligation, as a double treatment, might have mitigated the consequences of obliteration failure. Anecdotally, the single recurrences in each group shown in Fig 2 offer nothing to support this possibility. The third, and

Table IV. Principal outcome variables in limbs followed for 6 months or longer

Outcome	High ligation	No high ligation	P value
Actual no. at 6 mo	49 (89%)	97 (86%)	.633
CEAP clinical class	0.7 ± 1.0	0.7 ± 1.1	.693
Symptom score*	0.2 ± 0.6	0.06 ± 0.3	.024
Recurrent reflux	1 (2%)	8 (8%)	.273
Recurrent or new varicosities	3 (6%)	4 (4%)	.687
Actual no. at 12 mo	26 (51%)	31 (39%)	.207
CEAP clinical class	0.7 ± 0.7	0.8 ± 1.2	.465
Symptom score*	0.3 ± 0.5	0.06 ± 0.25	.073
New recurrent reflux	0	0	1.00
New recurrent varicosities	1 (4%)	2 (7%)	1.00

*One point each for pain, aching-fatigue, and swelling.

Table V. Randomized studies of recurrent truncal vein reflux and varicose veins after high ligation with and without surgical stripping of the GSV

Author	Follow-up (mo)	Limbs or patients undergoing saphenectomy*		Limbs or patients not undergoing saphenectomy*	
		Recurrent reflux	Recurrent varicosities	Recurrent reflux	Recurrent varicosities
Jakobsen ⁷	36	—	16/158*†	—	56/162*
Munn et al ⁸	30-42	—	21/57†	—	34/57
Hammarsten et al ⁴	52 ± 5	—	3/24	—	2/18
Sarin et al ⁹	21	21/43†	15/43†	38/46	38/46
Neglén et al ¹⁰	60	—	30/74	—	53/63
Rutgers and Kitslaar ¹¹	36	10/69†	27/69†	34/73	44/73
Dwerryhouse et al ¹²	60	15/52†	11/52	41/58	8/58
Total	21-60	46/164 (28%)	123/477 (26%)	113/177 (64%)	235/477 (49%)

*Patients at follow-up interval; number of limbs treated not specified.

† $P < .05$ versus same parameter for the high-ligation without saphenectomy group.

perhaps most important, caveat is that the data do not have sufficient power to be negatively conclusive in the face of the 10% or lower recurrence rates that have been encountered thus far.

Table V shows the collective data from seven randomized prospective studies of SFJ ligation with and without GSV stripping, which show that omitting stripping essentially doubles both the risk of development of recurrent reflux and the risk of recurrent varicose veins over 2 to 5 years.^{4,7-12} Earlier studies from two of these centers show that GSV stripping adds significant recurrent reflux protection, as compared with SFJ ligation without stripping, that is evident as soon as 3 or 12 months after treatment.^{13,26} These reported observations are in marked contrast to what was observed in the current study when SFJ ligation was or was not added to successful GSV endovenous obliteration. Together, they suggest that eliminating the GSV as an actual or potential reflux conduit is the main component of traditional ligation and saphenous stripping that affects success.

Reflux recurrence around the SFJ, often associ-

ated with recurrent thigh varicosities, is attributed to what has been termed *inadequate earlier surgery*, meaning persistence of the GSV or missed SFJ tributaries,^{1,2,12-14} or to neovascularity, which is manifested as newly formed superficial-to-deep and cross-groin connecting veins.^{12,13,16} These findings are clearly associated with recurrent reflux and varicosities, but assigning a causal role to them requires a modest leap of faith because the presence of anatomic variants and patent tributaries after high ligation and stripping has not been systematically studied in limbs without recurrent clinical pathology. The current study provides an opportune venue to examine this issue. Currently, the incidence of SFJ tributary patency in limbs followed for 6 months or longer is essentially identical in limbs with recurrent reflux or varicose veins and in those without recurrent clinical or duplex scanning-detectable pathology. Further follow-up and more intensive focus on the status of tributaries should clarify the clinical implications of these and other posttreatment SFJ duplex scanning findings, hopefully, in a manner that

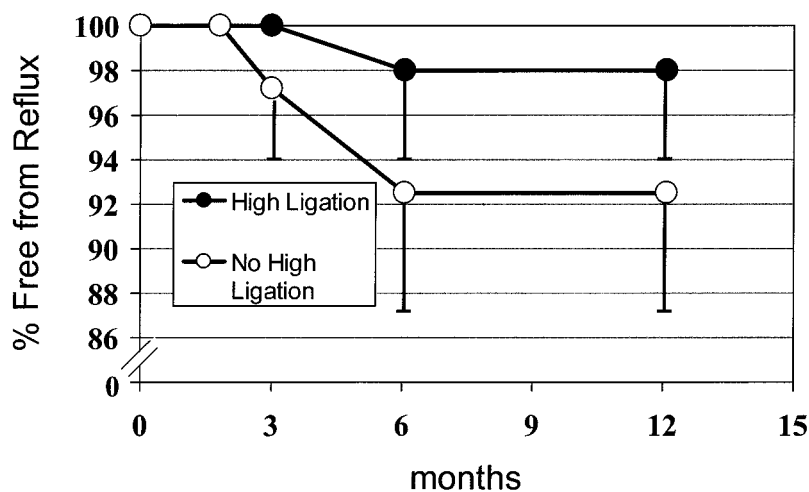


Fig 7. Freedom from recurrent reflux after endovenous obliteration with (filled circles) and without (open circles) high ligation. Range bars indicate lower 95% confidence limits.

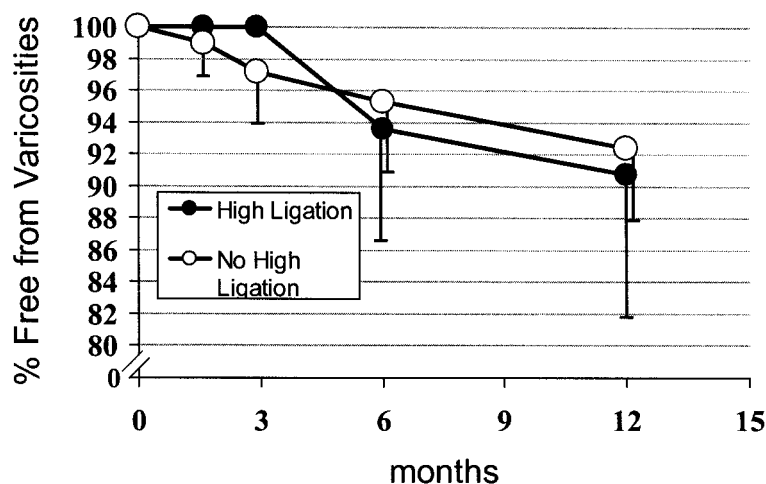


Fig 8. Freedom from new or recurrent varicose veins after endovenous obliteration with (filled circles) and without (open circles) high ligation. Range bars indicate lower 95% confidence limits.

will bear extrapolation to the situation after high ligation and saphenectomy.

Persistence of the GSV can occur because the original operator may have failed to do a true SFJ ligation and did not remove the GSV.²⁶ However, an intact "GSV" has been found after some operations by experienced surgeons who clearly stated in their operative notes that a saphenous stripping was performed. The explanation lies in the extraordinary variability of SFJ and upper saphenous trunk tributaries.²⁷ This is also the principal reason that some SFJ tributaries are overlooked.^{1,2,27} Double saphenous veins, usually meaning a large anterolateral or

posteromedial tributary that rejoins the GSV near the knee, have been reported as being present in 35% of limbs,²⁷ and SFJ tributary patterns show so much variation that the normal SFJ tributary configuration characterizes only a third of limbs.²⁸

Extended SFJ tributary ligation has been proposed as a means of ensuring greater anatomic accuracy and raising the barrier against reconnections between the superficial and deep venous systems. Completely exposing the fossa ovalis, following each tributary out to its own first or second tributary, and sometimes extending the fossa ovalis opening to look for superficial tributaries that might join the common

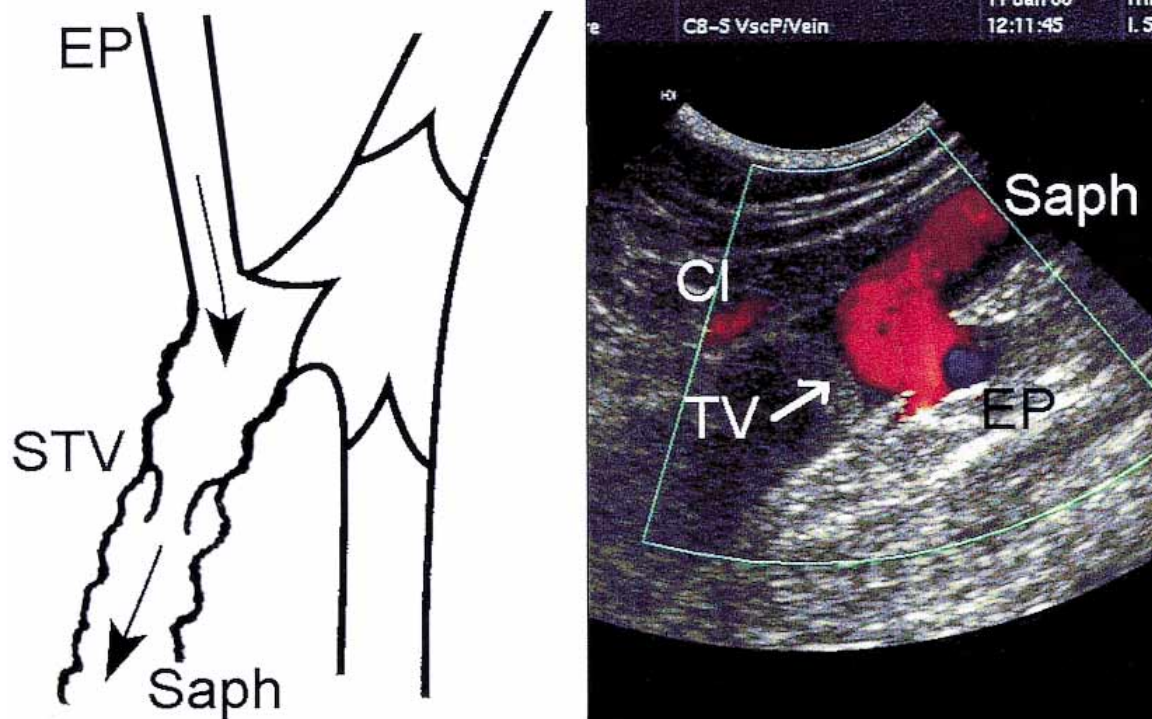


Fig 9. High-flow reflux through an incompetent subterminal valve emanating from the superficial, external, pudendal vein (*EP*) and, to a lesser extent, from the superficial, circumflex, iliac vein (*CI*). *Saph*, GSV; *TV*, competent terminal valve, bowed under pressure, during a Valsalva maneuver.

femoral vein should directly reveal the nature of the anatomy better than a narrower approach to the SFJ. However, the concept that wide tributary excision will make venous reconnections less likely because of spatial separation may be counterposed by an aggravating influence on new vein formation. Alternate routes of venous drainage for the superficial tissues of the lower abdomen and pudendum are not as direct as those through the SFJ. Obliterating the refluxing GSV with an incompetent subterminal valve in Fig 9 that is receiving high flow from the superficial external pudendal vein would restore physiologic external pudendal flow through the competent terminal valve and the SFJ. Ligating the tributary sources would force their drainage to go elsewhere, potentially stimulating neovascularity or enlargement of existing small veins, and still require treatment of the GSV to get at the root cause.

SFJ tributary patency was expected to be more common after endovenous obliteration without SFJ ligation than was actually observed in the study. The obliterative process depends on vein wall collagen contraction and endothelial destruction over substantial segments of vein to preclude recanaliza-

tion.¹⁸ These changes are applied only to the tributary orifices and do not extend very far along the course of the tributary itself, as shown in Fig 3, *C*, making reopening far more likely than in the GSV proper. There was marked disparity between the 6-month findings of SFJ tributary patency in 14 of 15 carefully studied limbs in one series²⁴ and the 35% incidence of tributary patency identification in all groins where high ligation was not part of the procedure. Similarly, although it might be early to expect differences in reflux and varicosity recurrence, if frustrated abdominal and pudendal superficial drainage consequent to SFJ-tributary ligation was to have been a principal stimulant of neovascularity, some evidence of these new vessels could reasonably be anticipated in high-ligation limbs by 6 months. The same would be even more likely if groin wound healing was a major stimulus. This collective paucity of positive SFJ ultrasound scan findings suggests that follow-up duplex scanning was typically more focused on the status of the obliterated saphenous vein than on assessing the SFJ for possible new or persistent superficial-to-deep and cross-groin connecting veins. Further review of

these images seems indicated, but at this point in time the study has not demonstrated any new vessel stimulation that could be attributed to SFJ ligation.

In conclusion, this unprecedented opportunity to examine elimination of a refluxing GSV with and without SFJ ligation has shown no significant advantage or adverse effect of adding extended SFJ ligation to successful endovenous GSV obliteration. GSV obliteration, with or without SFJ ligation, yielded early reflux and varicose vein recurrence rates similar to those seen after high ligation and stripping, with significant and sustained improvement in symptoms and CEAP clinical class scores through 1 year. These are relatively early negative findings in a nonrandomized observational study, lacking sufficient statistical power to exclude possible between-group differences at the low recurrence rates that have been observed thus far. They question the widely held but unproved axiom that SFJ ligation with branch excision is a necessary treatment component in achieving the therapeutic benefits of removing the thigh portion of the GSV but do not provide a definitive answer. The data should be interpreted with caution and certainly are not sufficiently robust to warrant abandonment of SFJ ligation, as currently practiced, in the management of primary varicose veins associated with GSV vein reflux.

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APPENDIX

VNUS Closure-Treatment Study Group participants. Nigel Ackroyd, MD, Harbord, Australia; Anders Albäck, MD, Leena Laasonen, MD, and Tom Scheinin, MD, Helsinki University, Helsinki, Finland; Henrick Åkesson, MD, Malmö University Hospital, Malmö, Sweden; Thomas Bieber, MD, Peter Mulkens, MD, and Eberhard Rabe, MD, Hautklinik-Universität Bonn, Bonn Germany; Yolande Bullens, MD, and H. A. Martino Neumann, MD, PhD, Academische Ziekenhuis Maastricht, Maastricht, The Netherlands; Stephano Camparini, MD, and Gioacchino Coppi, MD, Ospedale S. Agotino, Modena, Italy; Jean-Marie Cardon, MD, Nîmes, France; Denis Creton, MD, Nancy, France; Jean-Pierre Gobin, MD, Lyon, France; Lowell S. Kabnick, MD, Morristown Memorial Hospital, Morristown, NJ; Horst Kniemeyer, MD, and Matthias Widmer, MD, University of Bern, Bern, Switzerland; Christian Lebard, MD, and François Zucarelli, MD, Paris, France; Stefano Manfrini, MD, Vincenzo Gasbarro, MD, and Alberto Cataldi, MD, Università degli Studi di Ferrara, Ferrara, Italy; Kenneth A. Myers, MD, Richmond, Australia;

Andrew Nicolaides, MS, FRCS, Andrew Lennox, MBBS, FRACS, and Zaki A. Zarka, MD, Imperial College School of Medicine, St Mary's Hospital, London, United Kingdom; Philippe Nicolini, MD, Decines, France; Thomas Noppeney, MD, and Jeanette Noppeney, MD, Nürnberg, Germany; Michel Perrin, MD, Chassieu, France; Olivier Pichot, MD, and Carmine Sessa, MD, University of Grenoble, Grenoble, France; Dieter Raithel, MD, Manfred Kaufmann, MD, and Brigitte Gerald, MD, Nürnberg, Germany; Tero Rautio, MD, and Jukka Perälä, MD, Oulu University, Oulu, Finland; Sanja Schuller-Petrović, MD, PhD, Sebastian Reischle, MD, Wolfgang Salmhofer, MD, and Thomas Kern, MD, Hautklinik LKH, University of Graz, Graz, Austria; Ulrich Schultz-Ehrenburg, MD, PhD, and Georg Gallenkemper, MD, Hautklinik-Klinikum Buch, Berlin, Germany; Dimitrios Tsantilas, MD, Augsburg, Germany; Dieter Weber, MD, Berlin, Germany; Robert A. Weiss, MD, Johns Hopkins University, Baltimore, Md; Kalervo Verkkala, MD, Mehiläinen Hospital, Helsinki, Finland; and Cornelius Wittens, MD, Rotterdam, The Netherlands.

DISCUSSION

Dr Harry Schanzer (New York, NY). This paper so nicely just presented by Dr Chandler tries to evaluate the need for what he calls "extended high ligation" of the saphenofemoral junction in the setting of thermally induced GSV obliteration.

The material of the study consists of 60 limbs that underwent high ligation and thermal obliteration and 120 limbs that only had thermal obliteration, without high ligation. The results are that both groups have equally good significant clinical improvement; there's no difference in the incidence of recurrent saphenous reflux and recurrent varicose veins.

Based on their experience, the authors concluded that high ligation does not add advantage to the venous obliteration procedure.

This work is very provocative, because it questions the long- and well-established concept that for a good surgical result, high ligation with division of all tributaries of the GSV is essential. If their hypothesis is true, both surgical stripping and oblitative procedures such as sclerotherapy and thermal obliteration would not need the addition of high ligation.

I have two problems with this paper: One, this paper gives great emphasis to recurrence of reflux through the GSV, due to neovascularization, as a mechanism of varicose vein recurrence. The experience with surgical stripping, nevertheless, has been that the majority of significant recurrences requiring further treatment, as much as 70%,

are due to incomplete high ligation of the SFJ, with persistence of reflux through the uninterrupted tributaries. These types of recurrences may take several years before becoming manifested, and I would not be surprised if in your patients without high ligation, a third of them having patent tributaries, large recurrences developed.

Second, the follow-up is very short. Eighty-four percent of the patients have a follow-up of 6 months, and the remaining 14% go to a year. It is well known that varicose recurrences take a long time to appear, and follow-ups of 5 years are essential in order to evaluate conclusively the quality of any of these therapies.

In conclusion, it is my feeling that until long-term follow-ups are presented supporting the present hypothesis, high ligation of the GSV should be an integral part of the treatment of primary varicose veins of the GSV.

I have three questions for Dr Chandler.

First, are you ready to advise the surgeons that do "old-fashioned surgical treatment" to perform stripping and abandon high ligation?

Second, are you planning to follow up these patients for up to 5 years?

Third, in your experience, is the industry involved in developing new methods for the treatment of varicose veins ready to support scientifically well-designed prospective randomized long-term follow-up periods?

I enjoyed very much reviewing and discussing this provocative and well written paper. I thank the authors for

providing me well ahead of time with the manuscript, and the Forum for the privilege of discussing it.

Dr James Chandler. The worth of extended saphenofemoral junction ligation is based on a wish to do better, not upon evidence that it is an important concomitant of saphenectomy. I am just raising the question; I cannot answer it for you today. I do not have evidence to advocate changing what people do, but I do advocate having

an open mind. Heretical thought is always appropriate in a scientific forum, even on Sunday.

Regarding randomized controlled studies, I believe that is the way the question will finally be answered, but recognize that, today, we have only tradition and dogma, not facts to support the essential nature of extended high ligation when the thigh position of the GSV has been effectively eliminated.

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