Great saphenous vein surgery without high ligation of the saphenofemoral junction

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Objective: **The aim of this study was to evaluate whether great saphenous vein (GSV) surgery without high ligation of the saphenofemoral junction (SFJ) is beneficial in terms of varicose vein recurrence.**
Methods: **This was a prospective randomized trial set in a private practice. From December 2000 to May 2004, 120 patients were enrolled. Patients were randomly allocated preoperatively to two groups undergoing GSV surgery with (group A, n = 60) or without (group B, n = 60) high ligation of the SFJ. In four patients (two in each group), both limbs were operated on. Inclusion criteria were primary varicose veins with SFJ incompetence resulting in GSV reflux. Exclusion criteria were age <18 years, inability to give informed consent, associated small saphenous vein incompetence, and prior GSV surgery. Mean follow-up was 8 years and was complete in all but one patient (99.2%). The primary end point was varicose vein recurrence, defined as treated lower limbs with new thigh varices at clinical evaluation (CEAP ≥2) or venous reflux at the thigh or groin level, as assessed by duplex ultrasound imaging.**
Results: **The follow-up included 123 limbs. The combined clinical and ultrasound-determined recurrence rate was 24.4% (30 of 123): 32.2% (20 of 62) in group A vs 16.4% (10 of 61) in group B ($P = .045$). Postoperatively, recurrence of even minimal varices was observed in 24 limbs (19.5%): 18 of 62 (29.0%) in group A vs six of 61 (9.8%) in group B ($P = .014$). The ultrasound-detected recurrence rate was 22% (27 of 123): 32.2% (20 of 62) in group A vs 11.4% (7 of 61) in group B ($P = .010$). The average time to recurrence was 3.5 ± 1.2 years in group A and 4.1 ± 1.6 years in group B ($P = .258$).**
Conclusions: **GSV surgery without high ligation of the SFJ is associated with low rates of clinical and ultrasound-determined recurrence of varicose veins. (J Vasc Surg 2013;58:173-8.)**

Previous theories[1,2] assuming that primary venous reflux was due to the absence or incompetence of valves above the saphenofemoral junction (SFJ) have now been soundly discredited.[3] Several studies reported saphenous retrograde flow also in patients with a competent SFJ or saphenopopliteal junction,[4,5] and saphenous vein varicosities, hypothetically resulting from valvular incompetence, were observed even in the presence of competent valves.[6] These findings suggest that primary venous reflux seems to be a local or multifocal process in addition to or separate from a retrograde process.[3]

As a consequence, during the last decade, the question whether high ligation of the SFJ is necessary has become one of the most debated issues. Although a number of retrospective series reported good results with high ligation of the SFJ,[7,8] more recently, the trend is toward avoiding SFJ ligation on the basis of new anatomic, clinical, and hemodynamic evidence.[9-11]

The aim of this prospective randomized study was to evaluate whether great saphenous vein (GSV) surgery without high ligation of the SFJ is beneficial in terms of varicose vein recurrence.

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METHODS

Study population. The study enrolled 120 patients from December 2000 to May 2004. Patients were randomly allocated preoperatively to two groups undergoing GSV surgery with (group A) or without (group B) high ligation of the SFJ. In four patients (two from each group), both limbs were operated on by a staged procedure. Thus, the final study cohort included 60 patients and 62 limbs in each group.

A previous retrospective database was used to determine the necessary sample size in each group to achieve 80% power at an $\alpha = .05$. The primary end point was varicose vein recurrence defined as minimal thigh varices at clinical evaluation or venous reflux, even of mild degree at the thigh or groin level, as assessed by duplex ultrasound (DUS) imaging, or both. A sample size of 57 patients per group was estimated to detect a 15% difference in the primary outcome. Randomization was performed by a computer-generated random-numbers algorithm. Informed consent was obtained from all patients during the preoperative interview. Inclusion criteria were primary varicose veins with SFJ incompetence resulting in GSV reflux. Exclusion criteria were age <18 years, inability to give informed consent, associated small saphenous vein incompetence, aneurysm of the SFJ, and prior GSV surgery. Preoperative characteristics of the study population are reported in Table I.

Preoperative evaluation. All patients underwent clinical evaluation including assessment of symptoms (pain,

Table I. Preoperative characteristics of the study patients

Variable[a]	*Group A (n = 60)*	*Group B (n = 60)*	P
Age, years	45 ± 14	47 ± 15	.452
Sex			
Male	12 (20)	15 (25)	
Female	48 (80)	45 (75)	.662
Body mass index, kg/m^2	24.5 ± 0.70	24.7 ± 0.50	.142
Bilateral surgery	2 (3.3)	2 (3.3)	.609
Limbs	62	62	
Asymptomatic limbs	21 (34)	20 (32)	.966
Venous disability score	1.41 ± 0.09	1.39 ± 0.06	.148
CEAP classification			.837
C_2-C_3	47 (76)	45 (73)	
C_4-C_6	15 (24)	17 (27)	

[a]Continuous data are presented as mean ± standard deviation and categoric data as count (percentage).

heaviness, swelling sensation, pruritus, night cramps, restlessness, tingling, heat), regardless of their location on the limb. Venous clinical severity was graded according to the venous disability score (0, symptomatic; 1, symptomatic but able to perform usual activities without compressive therapy; 2, able to perform usual activities only with compression or limb elevation, or both; 3, unable to perform usual activities even with compression or limb elevation, or both).

Anatomic and hemodynamic data were obtained by means of DUS imaging (Esaote AV4, Esaote Group, Genoa, Italy) performed by the same operator (P.C.) with the patient standing. Venous reflux of the great and small saphenous veins was assessed using the manual venous flushing maneuver in the calf region and recorded at the time of the sudden release of manual compression. A reflux duration >0.5 second for the superficial veins and 1 second for the deep veins was considered pathologic. Photographs were taken of all patients before and after surgery and at each follow-up visit, to detect the development of new varicose veins, even of very small caliber. Terminal valve competence at the groin level was assessed by performing a Valsalva maneuver.

Surgical procedure. Surgery was performed under tumescent local anesthesia and continuous femoral block and Kleine tumescence, comprising 2% lidocaine (20 mL), 1:1000 adrenaline (1 mL), and 8.4% sodium bicarbonate (5 mL) mixed with 500 mL lactated Ringer's solution. All operations were performed by a single expert surgeon (P.C.).

Group A patients underwent standard GSV surgery, including high ligation of the SFJ, foramen ovale plasty and infolding suture to hide the free endothelium of the saphenous stump.

Group B patients underwent GSV surgery without high ligation of the SFJ. After the GSV was hooked through a small incision at lower leg level, a stripper device was inserted. Invagination stripping was performed without echographic guidance. The GSV was hooked at the thigh level, 2 to 3 cm below the groin (SFJ), and GSV ligature was performed in distal to epigastric and perineal veins to preserve physiologic drainage.

Associated phlebectomy was performed in all patients. In the four patients who underwent operations on both legs, a staged procedure was preferred.

Follow-up and end points. Clinical evaluation and DUS scanning were performed at 6 months and yearly thereafter. The follow-up of the last operated-on patient ended in May 2012, so that all the patients had a minimal follow-up of 8 years. Follow-up was complete in all but one patient (99.2%). At each follow-up visit, patients underwent DUS examination of both lower limbs. The primary end point was varicose vein recurrence, defined as an operated-on limb with new minimal thigh varices at clinical evaluation (CEAP ≥2) or venous reflux at the thigh or groin level, as assessed by DUS, or both. New varicose or missed veins as well as stump evolution were evaluated using DUS scanning. Stump evolution was classified into four types: S1, thrombosis and fibrosis; S2, low turbulence during Valsalva maneuver and deflection at rest; S3, flow turbulence with venous reflux at rest; and S4, preserved drainage function and competent terminal valve. S1, S2, and S4 types were considered as a favorable evolution, whereas S3 was considered to define varices recurrence.

Statistical analysis. Categoric data are reported as counts and percentages. Normality of continuous data was assessed by Kolmogorov-Smirnov test. Continuous data are expressed as mean ± standard deviation. For comparisons of continuous and categoric variables, the Mann-Whitney U test, χ^2, or the Fisher exact test was used, as appropriate. Kaplan-Meier curves were used to compare long-term results of the two surgical approaches. Comparisons were made using log-rank test. The significance level was set at $P < .05$. Statistical analysis was performed using SPSS software (SPSS Inc, Chicago, Ill).

RESULTS

A total of 123 limbs were followed up 8 years after surgery. The combined clinical and DUS-determined recurrence rate was 24.4% (30 of 123), consisting of 32.2% (20 of 62) in group A vs 16.4% (10 of 61) in group B ($P = .045$; Fig 1). Postoperative recurrence of even minimal varices was observed in 24 limbs (19.5%), consisting of 18 of 62 (29.0%) in group A vs six of 61 (9.8%) in group B ($P = .014$; Fig 1). The DUS-detected recurrence rate was 22% (27 of 123), consisting of 32.2% (20/62) in group A vs 11.4% (7/61) in group B ($P = .010$; Fig 1). The average time to recurrence was 3.5 ± 1.2 years in group A and 4.1 ± 1.6 years in group B ($P = .258$). In Table II, our results are compared with results reported in the literature.

Long-term actuarial freedom from varicose vein recurrence was significantly higher in group B (85% ± 5%) than in group A (67 ± 5%, $P = .045$; Fig 2).

Ultrasound-guided foam sclerotherapy (UGFS) was used to treat the 30 limbs with recurrence, with the

exception of five patients in group A and two in group B, where a needle-hook-assisted phlebectomy was preferred.

DISCUSSION

Traditional surgical treatment of varicose disease requires highly invasive procedures, resulting in high recurrence rates, especially in the long term.[12] To overcome these drawbacks, new endovascular techniques have been developed, such as endovenous laser ablation (EVLA),[9,10,23-25] radiofrequency ablation (RFA),[15-17] and UGFS.[13,26]

Although these techniques are less invasive and associated with lower recurrence rates (Table II),[11-22] high ligation of the SFJ is still largely performed. A prospective analysis in the United Kingdom showed that in 2007 to 2008, conventional surgery was performed by 96% of public centers and by 89% of private centers. In addition, when asked to consider future practice, 70% of surgeons felt that conventional surgery would remain the most common treatment modality.[27] This is mainly due to extra costs of endovenous methods (£1250 for EVLA and £1600 for RFA) compared with conventional surgery (£933).[26]

To reduce costs and recurrence rates, a new minimally invasive approach has been proposed.[11,28] Pittaluga et al[11] demonstrated that preservation of the SFJ during GSV stripping using a limited inguinal approach is associated with good results in hemodynamic efficacy and SFJ neovascularization at 2-year follow-up (1.8%), with a clinical recurrence rate of 6.3%. However, given the retrospective nature of this study, no comparison with a control group undergoing conventional surgery could be performed. In addition, only 57.4% of the lower limbs were followed up after the first postoperative year. In our study, the ultrasound-determined recurrence rate at the 2-year follow-up was quite similar, but the clinical recurrence rate was nearly one-half lower (3.3%).

Surgery with vs without high ligation of the SFJ. Our minimally invasive surgical approach was associated with a lower rate of treatment failure at short-term and long-term follow-up compared with conventional surgery. The freedom from recurrence curves in our series starts to diverge at 3 years, reaching significance at 5 years. Several authors reported short-term recurrence rates of 4.8% to 24%,[13-15] significantly higher than the 3.3% observed in our series. At 5 years postoperatively, surgery without high ligation of the SFJ resulted in a recurrence rate of 9.8%, which is significantly lower than the 25% to 47.1% reported for conventional surgery.[12,29] A recent randomized trial comparing different surgical treatment strategies[13] observed rates of varicose vein recurrence at 1-year follow-up of 11.6% for EVLA, 7.3% for RFA, 13.8% for UGFS, and 14.8% for conventional surgery, which were not significantly different ($P = .155$), lending support to the hypothesis that SFJ ligation does not prevent the development of new varices. Hence, our findings raise the pathophysiologic question of the possible mechanisms underlying the superiority of minimally invasive surgery.

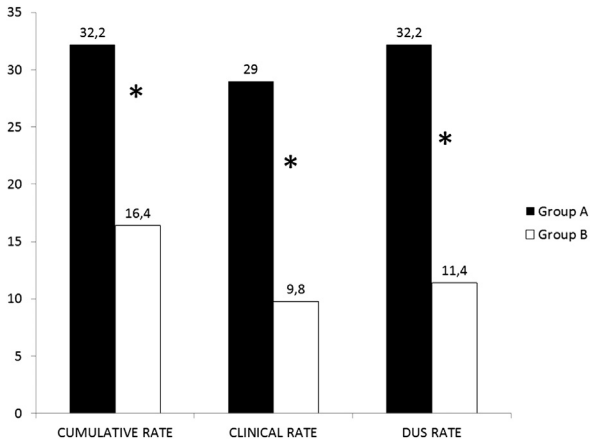

Fig 1. Cumulative, clinical, and duplex ultrasound (*DUS*) recurrence rates are shown in group A and group B patients. $*P < .05$.

Traditionally, varicose disease has been considered to arise from incompetence of the junction (perforator vein, SFJ, or saphenopopliteal junction) of the superficial (saphenous vein) and deep venous systems (femoral and popliteal veins). This causes blood from deep veins to flow in a reverse flow pattern into the superficial main veins of the leg, leading to the development of varices.[1,2] However, Pittaluga et al[11] suggested that varicose disease may progressively extend in an antegrade fashion rather than showing a traditional retrograde hemodynamic evolution, endorsing the theory that venous incompetence spreads from the superficial distal venous network toward the deep venous system. This hypothesis provided new insights into the mechanisms responsible for the development of recurrent varices after radical high ligation of the SFJ. In addition, these authors also supported the idea that preservation of the SFJ during GSV reflux treatment enables preservation of some normal, competent tributaries (epigastric and perineal vein draining the residual stump).[11]

Further, avoidance of high ligation of the SFJ may be preferable to conventional surgery because it is less invasive and is associated with a reduced risk of inflammatory reactions at the site of groin dissection, resulting in a lower grade of neovascularization. Glass[30] was among the first to advocate that neovascularization plays a crucial role in recurrence of varices. A later study by De Maeseneer et al[31] documented neovascularization at the site of saphenous ligation in 68% of limbs with clinically detectable recurrent varicose veins. Lefebvre-Vilardebo[32] also showed that lymph nodes in the neighborhood of the ligated saphenous stump might actually contribute to the recurrence of disease. The presence of tiny veins (1-4 mm) passing through the surrounding lymph nodes was detected at a postoperative DUS examination of the groin, suggesting a role of lymph nodes in the neovascularization process. These observations indicate that when high ligation is performed, a more invasive treatment via groin access may act as an inflammatory trigger for neovascularization and subsequent high recurrence rates. In our

Table II. Recurrence rate assessed by Doppler ultrasound imaging: our results and review of the literature

		Follow-up, %					
Surgical technique	*No. of limbs*	*1 year*	*2 years*	*3 years*	*4 years*	*5 years*	*>5 years*
Conventional surgery							
Our series	62	1.6	4.8	17.7	25.8	30.6	32.2 (8 years)
Kostas[12]	113					25	
Rasmussen[13]	108	4.8					
Pronk[14]	68	9.0					
Theivacumar[15]	60		24.0				
S/WL							
Our series	61	3.3	3.3	4.9	6.6	9.8	11.9 (8 years)
Pittaluga[11]	195		2.7				
EVLA							
Rasmussen[13]	121	5.8					
Pronk[14]	62	9.0					
Theivacumar[15]	69		7				
Min[16]	499		7				
Ravi[17]	126						14 (6.7 years)
Agus[18]	1076			3			
Disselhoff[19]							
With ligation	30					35	
Without ligation	30					21	
RFA							
Pichot[20]	63		11.1				
Rasmussen[13]	124	4.8					
Merchant[21]	1078				21.4		
UGFS							
Rasmussen[13]	123	16.3					
Belcaro[22]	211					44	51 (10 years)

EVLA, Endovenous laser ablation; *RFA,* radiofrequency ablation; *S/WL,* great saphenous vein stripping without high ligation of the saphenofemoral junction; *UGFS,* ultrasound-guided foam sclerotherapy.

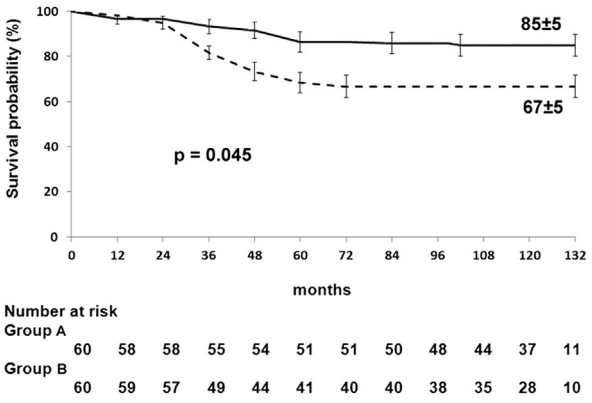

Fig 2. Actuarial freedom from recurrence is shown in group A (*dashed line*) and group B (*solid line*) patients. Standard errors (*range bars*) are plotted.

experience, a very small incision was performed 2 to 3 cm below the groin, preventing the proinflammatory stimulus of surgical groin access.

Surgery without high ligation vs endovenous techniques. Most studies that evaluated the safety and efficacy of endovenous techniques reported good short-term and medium-term results, as assessed by DUS imaging. In our study population, the 1-year recurrence rate of 3.3% was lower than that achieved with EVLA (5.8%-9%),[13,14] RFA (4.8%),[13] or UGFS (16.3%).[13] This difference was even more notable at the 4-year and 5-year follow-up (6.6% and 9.8% in our series vs ~20% in other reports).[19,21] After 5 years, the DUS recurrence rate in our series was 11.9% vs 14% with EVLA[27] and 51% with UGFS.[27] The clinical recurrence rate was even higher with RFA (from 22.8% to 27.4%)[26,33] or with EVLA (from 12.5% to 15%).[16,34]

Other advantages of GSV surgery without high ligation include lower costs of the procedure and earlier return to work as in our experience (median 2.5 days with a total approximate cost of €1500). In a comparative randomized trial, time to resume work ranged from 2.9 days (for UGFS and RFA) to 3.6 days (for EVLA) with total costs, including indirect costs of time lost from work, being similar among the different approaches (€2199 for conventional surgery, €2200 for EVLA, €1996 for RFA, and €1554 for UGFS).[13]

In addition, endovenous procedures have several other disadvantages compared with our minimally invasive surgical approach: (1) in the immediate postoperative period, EVLA may induce significant pain, whereas none of our patients experienced postoperative pain; (2) RFA and UGFS were associated with high rates of postoperative phlebitis (9.6% and 13.7%, respectively)[13]; and (3) individuals with tortuous or thrombosed varicose veins are usually unsuitable for endovenous treatment, especially with increasing age.[35]

Study limitations. Some limitations should be acknowledged. The ultrasonographer and provider who performed the follow-up examinations were not blinded to treatment assignment. In addition, this study aimed at comparing surgery with vs without high ligation of the SFJ but did not provide a direct comparison between minimally invasive GSV surgery without high ligation of the SFJ and other minimally invasive surgical approaches such as EVLA and RFA.

CONCLUSIONS

Minimally invasive surgery consisting of GSV stripping without SFJ ligation is associated with low clinical and DUS-determined recurrence rates because it allows preservation of normal, competent tributaries draining the abdominal wall. The challenge for the future is the development of less invasive surgical approaches leading to the implementation of saphenous vein-sparing techniques for incompetent GSVs.

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AUTHOR CONTRIBUTIONS

Conception and design: PCa
Analysis and interpretation: PCa
Data collection: FV, PCo
Writing the article: PCa
Critical revision of the article: MV
Final approval of the article: PCa
Statistical analysis: PCo
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