External banding valvuloplasty for incompetence of the great saphenous vein: 10-year results

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OBJECTIVES: External banding valvuloplasty (EBV) of the great saphenous vein (GSV) in patients with varicose veins is still controversial. The present study evaluated the effectiveness of EBV in selected patients with an insufficiency of the GSV after a mean follow-up of 92.6 months.

METHODS: A total of 101 limbs underwent EBV for the treatment of a GSV insufficiency. Thirty-one limbs from 27 patients (three men, 24 women; mean age 44.2 years; range 19 to 58 years) were re-examined and followed for a mean of 92.6 months. The venous volume, venous filling index, ejection fraction and residual venous fraction were analyzed preoperatively and at the follow-up using air plethysmography. The diameter and reflux of the GSV were evaluated using duplex ultrasound.

RESULTS: Overall, the mean (± SD) follow-up time was 92.6±22.3 months (range 46 to 138 months). At the follow-up, the preoperative venous hemodynamic states had improved significantly, to the following values: venous volume 96.0±32.3 mL to 83.4±32.6 mL; venous filling index 3.6±2.9 mL/min to 2.4±2.2 mL/min; and residual venous fraction 39.7%±18.6% to 26.1%±16.8% ($P<0.05$). The diameter of the GSV was 6.4±1.4 mm preoperatively and 4.8±1.7 mm postoperatively ($P<0.01$). Reflux in the proximal GSV was demonstrated preoperatively in 19 (61.3%) of 31 limbs. During the follow-up period, four limbs (12.9%) had high ligation and stripping of the GSV performed due to the recurrence of varicosity.

CONCLUSION: EBV of the GSV provides good results in terms of the venous hemodynamics and decreasing the diameter of the GSV. EBV may be an alternative procedure to stripping or endovenous ablation therapy in selected patients.

Key Words: *Hemodynamics; Valvuloplasty; Varicose vein*

Surgical methods such as high ligation and stripping, radiofrequency ablation, and endovenous laser therapy for the treatment of great saphenous vein (GSV) insufficiency are widely performed. If performed correctly, these are safe and effective procedures that can achieve good short- and long-term outcomes for most patients. However, the loss of the GSV as a potential bypass graft is one disadvantage of this method (1).

The repair of incompetent deep venous valves in patients with primary valve incompetence was first reported by Kistner in 1968 (2). The operation, which was performed under direct vision, involved a venotomy of the femoral vein and placement of sutures to shorten the vein cusps. Valvuloplasty of the superficial venous system has also been used to treat venous incompetence (3,4). The operation was performed with plication of the saphenofemoral junction (SFJ), which reduced the calibre of the vein by 60% to 70% for a length of 1.5 cm to allow the valve cusps to close.

Saphenous vein-sparing surgery for superficial venous incompetence is still controversial. Some authors report increased recurrence of varicose veins if the saphenous vein is not excised at the time of initial surgery (5,6). On the other hand, some studies reported no significant differences in the rate of recurrence between stripped and nonstripped limbs (7,8).

The principle purpose of the procedure is to restore the function of the venous valves in the SFJ through extraluminal wrapping of the dilated GSV, thereby reducing its diameter and bringing the valve cusps together. Our experience with external banding valvuloplasty (EBV) dates back to 1996, and in 1999 we reported favourable initial results for GSV insufficiency correction by EBV in 79 limbs at a mean follow-up of 92.6 months (9).

METHODS

A total of 101 limbs underwent EBV for GSV insufficiency. The mean (± SD) duration of varicosity was 12.5±7.7 years. Thirty-one limbs of 27 patients (three men, 24 women; mean age 44.2 years, range 19 to 58 years) were re-examined and followed for a mean of 92.6 months (range 46 to 138 months). Limbs with a history of deep venous thrombosis, congenital vascular malformation, deep venous valvular insufficiency and grossly tortuous or focal aneurysmal dilation of the GSV on duplex ultrasound were excluded. Terminal and/or subterminal valvular incompetence of the GSV due to a valvular annulus dilation with a normal valvular cusp on duplex ultrasound was considered a suitable indication for EBV.

All patients were evaluated according to their history and physical examinations before surgery, and also at one, six, 12 and 24 months after surgery, and at final follow-up. Duplex ultrasound was performed preoperatively and at follow-up. The reflux, patency and diameter of the whole length of the GSV were evaluated by specialized vascular diagnostic technicians who were registered vascular technologists. Following the classification proposed by Hach (10), the GSV trunk was divided into four segments (GSV 1, groin to mid-thigh;

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TABLE 1
Extent of reflux in the 31 limbs with persistent great saphenous vein (GSV) reflux at postoperative day (POD) 30 and at follow-up

	GSV 1	GSV 2	GSV 3	GSV 4
Preoperative	27	26	22	21
POD 30	4	9	9	7
Follow-up	19	21	21	21

Data presented as number of limbs. GSV 1 = groin to mid-thigh; GSV 2 = mid-thigh to knee; GSV 3 = knee to mid-calf; GSV 4 = mid-calf to ankle

TABLE 2
Diameter of the great saphenous vein (GSV) preoperatively and at follow-up

	Preoperative, mm	Follow-up, mm	P
GSV 1	6.4±1.4	4.8±1.7	0.001
GSV 2	4.6±1.2	4.2±1.1	0.085
GSV 3	4.7±1.5	4.1±1.2	0.013
GSV 4	3.7±1.0	3.6±1.3	0.786

Data presented as mean ± SD. GSV 1 = groin to mid-thigh; GSV 2 = mid-thigh to knee; GSV 3 = knee to mid-calf; GSV 4 = mid-calf to ankle

GSV 2, mid-thigh to knee; GSV 3, knee to mid-calf; GSV 4, mid-calf to ankle). Air plethysmography measurements were performed in each limb using an APG Model 3000 (ACI Medical Inc, USA) according to the standard protocol reported by Christopoulos et al (11). The venous volume (VV) on standing, the ejection volume after one tiptoe rise and the residual limb volume after 10 tiptoe rises were also measured. From these measurements, three ratios were determined in the standard manner: venous filling index (VFI), ejection fraction and residual volume fraction (RVF).

The detailed surgical procedure is described elsewhere (9). The operation was performed through a small (4 cm to 5 cm) longitudinal skin incision in the groin under general or spinal anesthesia. The SFJ was exposed and all tributaries of the GSV in the vicinity of the SFJ were ligated and divided. Any loose areolar tissue surrounding the vein was dissected approximately 5 cm along the course of the GSV. The intraoperative test of valvular incompetence was evaluated with the milking technique. Polyester-tailored mesh (LARS Mesh, Meadox Medical Inc, USA) was placed under the GSV and was wrapped around the vein like a cuff. The banding material was tightened over the dilated GSV to maintain the GSV at its minimum diameter during spasm. The mesh was then fixed in that position using a 5-0 prolene suture. The successful correction of the reflux after surgery was confirmed using the intraoperative milking technique and the luminal patency was checked. The nonsaphenous varicosities of the lower leg were treated with stab avulsion.

Immediately after surgery, the patients' legs were wrapped with elastic bandages, which were replaced with compression stockings at discharge. The patients were advised to wear the stockings for one month. All patients were re-examined after one month.

All statistical analyses were performed using SPSS version 11.0 (SPSS Inc, USA) statistics software. The Wilcoxon signed-rank test was used to compare the set of data collected before surgery with the respective set of data collected at the follow-up visit. A value of $P<0.05$ indicated a significant difference between the data sets, a value of $P<0.01$ indicated a strongly significant difference and a value of $P>0.05$ indicated no significant difference between the data sets.

The present study did not require ethical approval because no private information that could expose the patients to abuse was revealed.

TABLE 3
Venous hemodynamic changes preoperatively and at follow-up

	Preoperative	Follow-up	P
VV, mL	96.0±32.3	83.4±32.6	0.006
VFI, mL/s	3.6±2.9	2.4±2.2	0.012
EF, %	56.8±24.7	58.4±19.8	0.781
RVF, %	39.7±18.6	26.1±16.8	0.003

Data presented as mean ± SD. EF Ejection fraction; RVF Residual venous fraction; VFI Venous filling index; VV Venous volume

RESULTS

No intraoperative complications occurred in any of the 101 limbs. At the final follow-up, a total of 27 patients and 31 limbs (15 right and 16 left) were evaluated. There were four patients with bilateral limbs evaluated.

Between the operation and re-examination, six limbs (19.4%) showed recurrent varicosity. In four of these six limbs additional operations on the GSV were necessary. Two patients had become pregnant by the time of the follow-up and one of them showed varicosity later on.

At final follow-up, the duplex ultrasound demonstrated reflux in the proximal GSV trunk in 19 of 31 limbs (61.3%) (Table 1). The mean diameter of the GSV 1 had decreased significantly from 6.4±1.4 mm to 4.8±1.7 mm (P=0.001), and the mean diameter of the GSV 3 had decreased significantly from 4.7±1.5 mm to 4.1±1.2 mm (P=0.013). The remaining segments of GSV 2 and GSV 4 did not show any significant decrease in diameter (Table 2). The air plethysmographic evaluation demonstrated a significant reduction of the VV and RVF, from 96.0±32.3 mL to 83.4±32.6 mL (P=0.006) and from 39.7%±18.6% to 26.1%±16.8%, respectively (P=0.003). The preoperative VFI decreased significantly from 3.6±2.9 mL/s to 2.4±2.2 mL/s (P=0.012) at follow-up (Table 3).

DISCUSSION

GSV-sparing surgical procedures have three main end points: to improve the venous functions, effectively treat GSV varicosis and preserve the GSV for future use as a conduit of bypass surgery. Jessup and Lane (12) first described external valvuloplasty of the venous valves using a preformed Dacron cuff (Venocuff; AllVascular, Australia). This technique, or modifications of it, has been used in recent years to restore the competence of the valves at the SFJ, thereby attempting to treat the GSV reflux without stripping the vein (13-15). The rationale of this technique is that the correction of the SFJ reflux alone is sufficient to prevent the GSV from further varicose degeneration and treat the symptoms caused by the venous insufficiency. This theory is supported by several studies demonstrating that SFJ reflux appears to be the main hemodynamic disturbance in patients with primary varicose veins (16,17). Some authors, however, have established a different hypothesis

in which the primary factor for the pathogenesis of varicose veins is change in the elastic properties of the venous wall, which leads to a dilation of the affected veins causing secondary insufficiency of their valves (18,19).

There are a number of reports showing good results after vein-sparing surgery for GSV reflux using external valvuloplasty of the SFJ. Corcos et al (13) reported their two-year experience with good results following valvuloplasty in 40 patients with restoration of the valvular function and a decrease in the GSV diameter in 35 cases (87.5%). In our initial experience of external valvuloplasty in 79 limbs (9), we found patent GSVs with competent valves in 63 limbs (79.7%), while 14 limbs (17.7%) showed reflux and two limbs (2.5%) had a thrombus within the GSV. Geier et al (20) reported the results of external valvuloplasty of the GSV with a Dacron cuff in 54 legs after a mean follow-up of 54 months. The authors evaluated the severity of the patients' symptoms, their satisfaction with the procedure, the venous refilling time with photoplethysmography, the severity of the reflux and the diameter of the GSV using duplex ultrasound. Forty-six of their patients (85%) were satisfied with the procedure and the mean severity of their symptoms was significantly lower than before surgery. The venous refilling time was significantly reduced to the time of 5 s, and the diameter of the GSV was significantly reduced to a mean of 3 mm (20). Incandela et al (15) reported the results of 14 cases of external valvuloplasty using a surgical device (Gore External Valve Support – EVS; WL Gore and Associates, USA) after a follow-up of one year and described patent GSVs without reflux in all 14 cases. Belcaro et al (21) reported their 15 years clinical experience of external valvuloplasty with the same surgical device in 101 patients. The authors completed a four-year follow-up of a total of 82 patients without infections, thrombosis, foreign body reactions or other prosthesis-related complications.

The extent of the diameter reduction of the dilated GSV affects the results of EBV. Too loose or too tight banding during valvuloplasty can cause valvular incompetence or an obstruction of the GSV after surgery. Schanzer and Skladany (14) used a 1.5 cm-wide strip of Dacron-reinforced silicone (Venocuff). Geier et al (20) used a square piece of Dacron measuring approximately 4 cm by 2 cm with a transverse diameter of 6 mm. Incandela et al (15) used a preformed surgical device, the Gore External Valve Support, and determined the optimum size of the SFJ using the 'San Valentino formula'. The San Valentino Vascular Screening Project (22), and epidemological screening study, indicated that the optimum size of the SFJ was associated with the competence of the vein according to the findings of an epidemiological vascular study. The San Valentino formula calculated the optimum size of the SFJ using the patient's height in the following formula: height in cm/20. A decreased or absent valvular reflux in the spasmodic condition of the GSV was experienced during the dissection. The diameter of the dilated vein should be corrected to its minimum diameter during spasm (9). Intraoperative angioscopy and high-resolution ultrasonography were used by some authors to determine the status of valvular competence during surgery (23).

The results from the EBV procedure in our cases were obtained after a mean follow-up of 92.6 months. There was persistent or recurrent reflux in some GSV trunk segments in 19 (61.3%) limbs, but this was only clinically significant (requiring treatment) in six (19.4%) limbs. This finding suggests that local reflux in the GSV causes fewer clinical problems than reflux originating from the SFJ.

CONCLUSION

EBV of the GSV at the SFJ offers good results in terms of the venous hemodynamics (VV, VFI and RVF) and decreasing the diameter of the GSV. Our results support literature data that EBV may be considered as an alternative procedure to classic surgery or endovenous ablation therapy for treating GSV incompetence at the SFJ for selected patients.

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