Extraluminal valvuloplasty of the great saphenous vein: surgical technique and long-term results

Die extraluminale Valvuloplastie der V. saphena magna: Technik und Langzeitergebnisse

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ABSTRACT

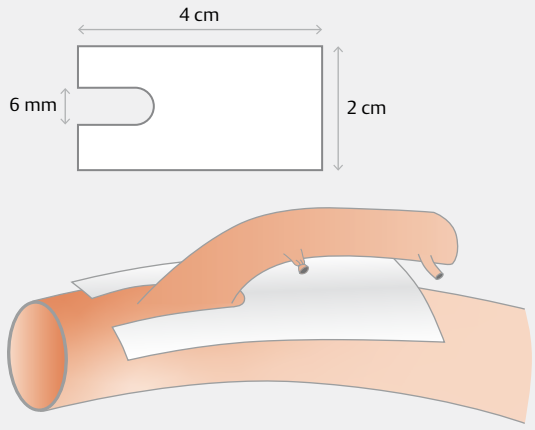
The extraluminal valvuloplasty of the sapheno-femoral junction is a vein-sparing operative technique which can be used in selected patients with incompetence of the greater saphenous vein. The operation can be performed safely and cosmetically favourable through a small groin incision. The follow-up of a group of 43 legs after a mean interval of 8.5 years demonstrated good results in terms of patient satisfaction, relief of symptoms and regression of previously dilated veins. Treatment for recurrent varicose veins was necessary in 10 cases (18,5 %). Judging from our experience, extraluminal valvuloplasty seems to be a vein-sparing alternative to stripping in selected patients.

ZUSAMMENFASSUNG

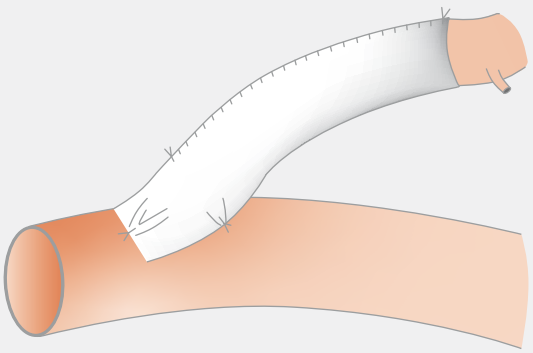
Die extraluminale Valvuloplastie der V.-saphena-magna-Mündungsklappe ist eine venenerhaltende operative Therapie, die bei ausgewählten Patienten mit einer Stamminsuffizienz der V. saphena magna angewendet werden kann. Die Operation kann schonend und komplikationsarm über einen kleinen Leistenschnitt durchgeführt werden.
Aus einem Kollektiv von 73 Patienten, die auf diese Weise operiert worden waren, konnten 43 nach im Schnitt 8,5 Jahren nachuntersucht werden. Im Langzeitverlauf konnten gute Ergebnisse bezüglich Patientenzufriedenheit, Symptomerleichterung und Rückbildung dilatierter Venen dokumentiert werden. Eine behandlungsbedürftige Rezidivvarikosis trat in 10 (18,5 %) Fällen auf. Unserer Erfahrung nach stellt die extraluminale Valvuloplastie bei ausgewählten Patienten eine venenerhaltende Alternative zur klassischen Strippingoperation dar.

Introduction

The conventional surgical treatment for an incompetent great saphenous vein (GSV) is to strip the vein from the saphenofemoral junction down to below the knee or as far as the ankle. If performed correctly, this is a safe and effective procedure that achieves good results, also in the long term [24], and remains the operation of choice in a large number of patients with trunk varicose veins. One possible disadvantage of such surgery is that the vein is no longer available as a graft for subsequent coronary or peripheral artery bypass grafting. It may also be advantageous to maintain a competent GSV as a drainage vessel in patients with post-thrombotic changes in the deep venous system. Furthermore, the distal incisions, especially when made at the ankle, carry a risk of injury or irritation of the saphenous nerve, which may lead to persistent paraesthesia



▶ **Fig. 1** Cut and placement of the Dacron cuff.



▶ **Fig. 2** Dacron cuff fixed in position. Note the distal tributary that serves as the indicator vein.

in some cases. These considerations have led to the development of surgical techniques that should ensure treatment of the reflux without simultaneously stripping the vein. One such procedure is extraluminal valvuloplasty of the terminal valve of the GSV. The procedure works on the principle of approximating the leaflets of the valve by placing a cuff around the outside of the GSV at the saphenofemoral junction (SFJ) and thereby restoring valve function. We reported the outcome of this surgical technique after five years [7] and are now presenting the results in the same patient population after a mean follow-up period of 8.5 years.

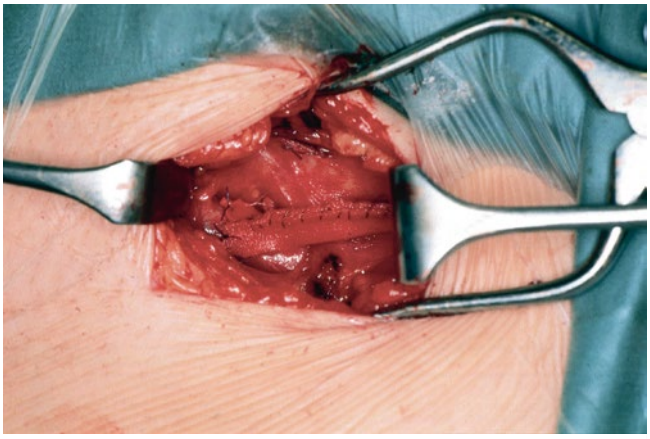
Patients and methods

Eighty-one extraluminal valvuloplasties were carried out on 76 patients in our clinic between January 1995 and December 1997. A total of 704 patients underwent surgery of the superficial venous system during this period.

Patients undergoing extraluminal valvuloplasty were recruited prospectively and reviewed retrospectively. The retrospective analysis of the follow-up data forms the basis of the present study. The Ethics Committee of the Ruhr University Bochum approved the study.

All 76 patients had symptomatic great saphenous vein incompetence: according to the CEAP classification [23], 50 (61 %) cases were in class C2, 24 (30 %) in C3, 5 (6 %) in C4 and 2 (3 %) in C5. The indication for valvuloplasty depended on three additional factors: the diameter of the great saphenous vein was not more than 12 mm at the saphenofemoral junction, the terminal saphenofemoral valve leaflets were intact on duplex ultrasonography and an absence of haemodynamically significant perforating veins in the thigh.

The operation was carried out through a small (3–4 cm) incision in the groin. The region around the saphenofemoral junction (SFJ) was exposed. All tributary veins around the SFJ were divided between ligatures; one distal tributary was left to serve as an indicator vein (▶ **Fig. 1**). A U-shaped opening measuring about 6 mm across was made on one side of an approximately 4 × 2 cm rectangular piece of Dacron (▶ **Fig. 1**). The Dacron strip was placed under the GSV, so that the U-shaped opening lay in the angle formed between the GSV and the deep vein at their junction (▶ **Fig. 1**). The



▶ **Fig. 3** The surgical field at the end of valvuloplasty.

Dacron patch was then wrapped around the SFJ like a cuff. If the operation was carried out under a spinal anaesthetic, the patient was asked to perform a Valsalva manoeuvre, while the anaesthetist applied positive pressure ventilation, if it was carried out under general anaesthetic. The distal indicator vein was then used to demonstrate whether any reflux was still present during this positive pressure phase. If any reflux was still seen, the Dacron cuff was tightened until it stopped, while at the same time taking care not to occlude the GSV. The Dacron cuff was then fixed in this position by also anchoring the proximal end of the cuff to the adventitia of the deep vein to prevent it slipping distally (▶ **Fig. 2**). ▶ **Fig. 3** shows the surgical field at the end of the valvuloplasty. Tributary varicose veins were removed by miniphlebectomy during the same session. The wound in the groin was closed in layers and the leg wrapped in an elastic bandage. On the first postoperative day, the compression bandage was replaced by a Class II compression stocking that should be worn for six weeks. If any tributary varicose veins or incompetent perforators still remained after the operation, they were treated with sclerotherapy.

All patients assessed the severity of their symptoms before the operation and at the follow-up check. The symptoms were divided into seven categories (feeling of heaviness, feeling of tension/

tightness, swelling of the leg, pain in the leg when sitting, pain in the leg on standing, itching, burning sensation on the sole of the foot). The severity of each symptom was evaluated on a linear scale of 1 to 6, where 1 was "no symptoms" and 6 was "very severe symptoms". The patient's satisfaction with the cosmetic appearance of the leg was measured on a scale of 1 "very satisfied" to 6 "not at all satisfied". At the follow-up check, the patients were also asked whether they were generally satisfied with the results of the procedure and whether they would undergo the same operation again.

The site and extent of the reflux were determined using duplex ultrasonography preoperatively and at the follow-up check. The GSV trunk was divided into four segments according to Hach's classification [9] and the number of segments affected by reflux recorded. Furthermore, duplex ultrasound was used to measure the diameter of the great saphenous vein where it joined the femoral vein, at rest and during a Valsalva manoeuvre, and also the diameter of the vein 3 cm distal to the SFJ.

The venous refilling time was determined by photoplethysmography prior to surgery and at the time of the follow-up check.

Appropriate software was used for the statistical analysis. For values that did not show a normal distribution on visual inspection of the histogram, we used the Mann-Whitney U-Test and the chi-squared test for the analysis of data with only two variables. Data showing a normal distribution were compared with the aid of a *t* test. A result of $p < 0.05$ was taken to be significant.

Results

None of the 81 cases had any intraoperative complications. Two patients had a haematoma of the wound in the groin, which delayed their discharge from hospital, but did not require any renewed intervention. Up to the time of the follow-up check, no-one had developed any groin infection that had necessitated removal of the Dacron cuff.

Out of the 76 patients, 43 patients with 47 operated legs were followed up for a mean of 8.5 years (minimum 7.1 years, maximum 10.6 years). ▶ **Table 1** shows the demographic data of the patients.

Sixteen legs (29.6 %) did not require any sclerotherapy between the operation and follow-up check, 17 legs (31.5 %) required one session of sclerotherapy, 14 legs (25.9 %) needed two sessions and 7 legs (13 %) had more than two sclerotherapy sessions. All cases concerned sclerotherapy of tributary veins and/or incompetent perforating veins and no leg required sclerotherapy of the GSV trunk.

At the follow-up check, there were two patients with intermittent pain in the inguinal scar, while the rest of the patients did not have any pain. In response to the question of whether they were satisfied with the results of the procedure and would have the same operation again, 46 cases (85 %) answered "yes" and 8 cases (15 %) said "no".

Assessment of symptom severity on the linear scales showed a significant reduction of the symptoms in all categories at the follow-up check (▶ **Table 2**). In addition, there was a significantly greater satisfaction with the cosmetic appearance of the leg (▶ **Table 2**).

The venous refilling time on photoplethysmography was 5 seconds longer at the follow-up check (▶ **Table 3**); measurements with the proximal tourniquet showed no significant difference between pre- and postoperative values (▶ **Table 3**).

Duplex ultrasonography showed reflux in the GSV trunk in 24 legs (44.4 %). In six of these legs (11.1 %), reflux was also demonstrated at the SFJ. In two cases (3.7 %), the reflux was caused by small tributary veins that originated from the deep vein and opened into the main GSV distal to the functioning valvuloplasty; reflux in the other four legs (7.4 %) was related to persistent valve incompetence despite valvuloplasty. Reflux into the GSV in the re-

▶ **Table 1** Data on operated patients and patients who attended for follow-up.

	Operation	Follow-up examination
Number of patients	76	43
Number of legs	81	47
Mean age (years)	45.9 (26–78)	47.0 (32–77)
Women : Men	54:22	28:15

▶ **Table 2** Mean severity of symptoms and satisfaction with the cosmetic appearance of the leg on a scale of 1 to 6 prior to surgery and at follow-up. * = $p < 0.01$; ** = $p < 0.001$; ns = not significant.

	Prior to surgery	Follow-up examination
Feeling of heaviness	2.52	1.78**
Feeling of tension	2.61	2.00**
Swelling of the leg	2.41	1.76*
Pain when sitting	2.33	1.83*
Pain on standing	2.61	1.91*
Itching	1.81	1.63ns
Burning sensation on the sole of the foot	1.78	1.48ns
Cosmetic appearance	3.72	3.15**

no symptoms 1 2 3 4 5 6 very severe symptoms
very satisfied with cosmetic appearance — not at all satisfied with cosmetic appearance

▶ **Table 3** Venous refilling time with and without a proximal tourniquet. Values given are the mean and standard deviation. * = $p < 0.01$; ns = not significant.

	Venous refilling time [s]	Venous refilling time with proximal tourniquet [s]
Before surgery	20.63 ± 9.42	31.18 ± 11.98
At follow-up	25.81 ± 11.47*	28.62 ± 11.54ns

▶ **Table 4** Extent of reflux in the trunk of the great saphenous vein (GSV) before surgery and at follow-up. GSV = great saphenous vein.

	Reflux in the 1st segment of the GSV	Reflux in the 2nd segment of the GSV	Reflux in the 3rd segment of the GSV	Reflux in the 4th segment of the GSV
Number of legs, before surgery	0	3	7	14
Number of legs, at follow-up	6	11	6	1

▶ **Table 5** Diameter of the great saphenous vein (GSV) at the saphenofemoral junction (SFJ) at rest and during a Valsalva manoeuvre and the diameter of the GSV 3 cm distal to the SFJ, before surgery and at follow-up. Mean ± standard deviation. * = $p < 0.001$.

	GSV at SFJ, at rest	GSV at SFJ, during Valsalva	GSV, 3 cm distal at rest
Diameter before surgery [mm]	7.1 ± 1.4	7.6 ± 1.7	6.5 ± 1.7
Diameter at follow-up [mm]	4.4 ± 1.2*	4.8 ± 1.6*	4.7 ± 1.5*

maining 18 legs (33.3 %) was due to incompetent perforating veins and tributary varicose veins. Taking into consideration all 24 legs that showed evidence of reflux at the follow-up check, significantly fewer segments of the GSV were affected than at the preoperative examination (▶ **Table 4**).

At the follow-up check, four patients (7.4 %) were recommended to have revision surgery (stripping of the great saphenous vein with phlebectomy of tributaries in two cases and phlebectomy of tributaries alone in the other two cases); a further six patients (11.1 %) were recommended to have sclerotherapy for tributary veins or incompetent perforating veins. A total of 10 cases (18.5 %) therefore had recurrent varicose veins requiring treatment at the time of the follow-up check.

The circumference of the GSV at the SFJ at the follow-up check, as measured by duplex ultrasonography, was reduced by an average of about 3 mm both at rest and during the Valsalva manoeuvre (▶ **Table 5**). The diameter of the vein 3 cm distal to the opening was likewise reduced, by an average of 2 mm (▶ **Table 5**).

Discussion

The desire to maintain the great saphenous vein as a potential graft for bypass surgery as well as to minimise surgical trauma has led to the development of vein-preserving surgical techniques in patients with incompetence of the trunk of the GSV. Jessup [15] was the first to describe the extraluminal valvuloplasty of venous valves using a commercially manufactured Dacron cuff (Venocuff). In recent years, this technique or modifications of the procedure have also been used to treat reflux in the saphenofemoral junction and, with it, the venous insufficiency without resorting to stripping of the great saphenous vein [3, 12, 13, 27, 28]. The reasoning behind this surgical technique is that treating the reflux at the saphenofemoral junction is enough to protect the GSV trunk from further varicose degeneration and relieve the symptoms of venous insufficiency. This approach has been supported by several studies, which show that although reflux may arise at various sites in the venous system [8, 16], reflux through the terminal valve of the GSV seems to be the leading cause of the haemodynamic disorder in patients with primary varicose veins [17, 25, 26]. Correction of the reflux restores normal haemodynamic conditions with regression of previously dilated perforating veins as well as providing relief from severe symptoms [17, 25, 26].

A number of studies have reported good functional outcomes of extraluminal valvuloplasty for SFJ incompetence. The review article by Mumme et al. [22] summarises the results. Corcos et al. [3] performed valvuloplasties on 40 patients and reported good results after two years with restoration of valve function and reduction of the vein diameter in 35 cases (87.5 %). Schanzer and Skladany [27] followed up 15 legs at a mean interval of 9.4 months after extraluminal valvuloplasty and found a patent GSV without any reflux in 12 cases (80 %). The GSV still showed reflux in one case and was thrombosed in two cases. Ik Kim et al. [12] reported the postoperative ultrasound results from a collective of 79 limbs treated with valvuloplasty. They found a patent and competent GSV in 63 cases (79.7 %), persistent reflux through the reconstructed valve in 14 legs (17.7 %) and evidence of thrombus in the GSV trunk in 2 legs (2.5 %). Incandela and co-workers [13] described their experience with extraluminal valvuloplasty in 14 patients: they found a patent and competent GSV without reflux in all cases after one year.

Zamboni et al. [28] found a patent great saphenous vein with a competent valvuloplasty in 94 % of cases after a longer follow-up period of 52 months. The varicose vein recurrence rate was 12 %.

Lane and his co-workers in Australia are the group with the greatest experience of the extraluminal valvuloplasty technique and they have followed more than 1500 cases that have undergone this procedure over a period of 15 years [18]. They reported their results involving a population of 107 patients after a mean follow-up of 4.8 years and found a competent valvuloplasty in 90 % of cases. The mean diameter of the GSV below the cuff had decreased from 7.6 mm to 4.9 mm, while the diameter at the level of the knee went from 6.9 mm to 3.7 mm. The rate of clinically rel-

evant recurrent varicose veins was 9 %. In a more recent publication, the same group reported their findings on 193 patients and 386 legs that had been treated with high ligation and perforate invagination (PIN) stripping of the GSV on one side and extraluminal valvuloplasty on the contralateral side [19]. Follow-up examinations were carried out after a mean period of 68 months up to a maximum of 147 months. Residual reflux in GSV trunk was found in 9 % of the treated legs despite the valvuloplasty. Recurrent varicose veins requiring treatment were present in 4.9 % of the legs treated with valvuloplasty, while the recurrence rate in the contralateral legs treated with high ligation and stripping was significantly higher.

Our own working group has already reported the results of extraluminal valvuloplasty in 54 legs after a mean follow-up period of 54 months [7]. We found a competent terminal valve in 48 cases (88.9 %), while the rate of recurrent varicous veins requiring treatment was 18.5 %. On average, the GSV diameter was 3 mm smaller.

The present study considers 43 patients with 47 operated legs from the same patient population, who were re-examined after a mean of 8.5 years. Even after this length of time, a patent great saphenous vein was present in 94.4 % of cases, while a competent valvuloplasty was found in 92.6 % of cases. Even though persistent or recurrent reflux was present in part of the GSV in 44.4 % of the legs, it was clinically relevant and in need of treatment in only 18.5 % of cases. The diameter of the GSV was reduced by 3 mm at the SFJ and by 2 mm in the main trunk. There were no cases of infection or foreign body reaction to the Dacron patch in the patient population that we followed up. Our findings agree with those of Belcaro et al. [1], who reported a similarly good tolerance to PTFE implants used for valvuloplasty in 101 patients over a period of 15 years.

In our experience, extraluminal valvuloplasty also protects the GSV from varicose degeneration over a long period and maintains it as a potential graft for bypass surgery. In a recent publication in this journal, the Bochum group demonstrated that such grafts are not only theoretically possible, but can actually be used in routine clinical practice [21].

One point of criticism of the technique, however, is that the number of patients, who have so far actually needed a bypass graft using the preserved GSV is so small that it does not seem to justify the time and expense of valvuloplasty. Even though no studies have addressed this specific question, given the basically aging general population, we can assume that the number of patients, who have cardiovascular disease in addition to venous insufficiency, will progressively increase. It therefore seems justified to try and preserve the GSV as potential graft material in this patient group, as it remains the vessel of choice for both coronary and peripheral artery bypass grafting.

A second patient group that would potentially benefit from the preservation of the GSV are patients with post-thrombotic syndrome in addition to a superficial saphenofemoral incompetence. Treating the reflux in these patients with valvuloplasty preserves the GSV as a collateral vessel for drainage rather than for bypass purposes.

A third – and in our experience, the largest – group consists of patients, with a terminal valve insufficiency, in whom the reflux is transmitted into the lateral accessory vein, while there is no reflux into the GSV trunk and varicose dilatation has not yet developed. Valvuloplasty in these patients can eliminate SFJ reflux, thus maintaining a healthy GSV and protecting it from varicose degeneration.

With its retrospective analysis of prospectively collected data, the present study certainly has some limitations: the number of patients examined is relatively small and the drop-out rate during follow-up may favour a selection bias. Even so, we consider that a follow-up rate of 58 % after a mean of 8.5 years is acceptable and in the same order of magnitude as that found in other studies over a similarly long period of time. Even though the level of evidence is low, our results still suggest that extraluminal valvuloplasty is an effective method of treatment, also in the long term.

In summary, it can be stated that, in our experience, extraluminal valvuloplasty of the saphenofemoral junction is a safe procedure that is effective, also in the long-term, with respect to patient satisfaction, improvement of symptoms and preservation of a healthy great saphenous vein.

It has to be emphasised, however, that extraluminal valvuloplasty can be used in only a relatively small selected group of patients with symptomatic varicose veins – just 15 % in our patient population. For this reason alone, it is not a substitute for conventional stripping operations or therapeutic endovenous procedures. It should, however, be viewed as a safe and effective method for use in patients in whom the GSV can be preserved.

Conflict of interest

The authors declare that they have no conflict of interest.

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