

CLINICAL STUDY

Venous leg ulcers – a surgical treatment

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Abstract: *Objective:* To assess the complex anti-reflux treatment of pure venous ulcers on all levels of venous system.

Patients: In the last 20 years the authors treated 793 patients with venous ulceration and compared the therapeutic results of 4 groups of patients treated either surgically (Linton+v.v. surgery) or with sclerotherapy (Fegan,s technique) combined with the anti-reflux operation on deep veins in torpid ulcerations non responding to superficial and perforators therapy.

Results and conclusion: The authors consider a compression sclerotherapy (the Fegan,s technique) the easiest and the most effective way of treating patients with venous ulcer. The direct valve repair techniques are appropriate only in non-thrombotic deep vein reflux, which is very rare (4 patients – 0.6 %). In patients with torpid ulcers, where the compression sclerotherapy failed (4.6 % – 28 pts), the in situ construction of a new valve could help (Tab. 2, Ref. 19). Full Text (Free, PDF) www.bmj.sk.

Key words: venous ulcer, chronic venous insufficiency, sclerotherapy, valvuloplasty.

The chronic venous insufficiency CEAP 5–6 with healed or florid ulcer is a significant cause of disability in the work. The various forms of venous insufficiency are due to obstruction or incontinence of the veins (1). The incidence in the European society is estimated to be approximately 2 %, the prevalence of venous ulceration is approximately 1 %. Deep vein reflux is the main and the primary cause of calf pump failure and has been identified in up to 90 % of patients with venous ulceration (2). The venous outflow obstruction is an important pathological factor in only 5–12 % of cases (3). The majority of patients with the stasis skin changes demonstrate a multi-valvular, multi system reflux (3). Venous insufficiency is only a symptom indicating that something somewhere is impeding the normal blood flow to the heart (4). The relative importance of reflux at different sites in the deep and superficial venous system remains unclear. The deep and superficial venous reflux is common in legs clinically not affected by the skin changes characteristic for chronic venous insufficiency.

In every patient, there must be an additional factor, possibly at microvascular level, which determines, whether a particular pattern and severity of reflux leads to skin changes and ulceration. It is common to see patients with gross superficial varicosities but without any skin changes. In patients with the post-thrombotic syndrome, there is a poor correlation between the pattern and severity of the reflux and symptoms (5).

The aim of this retrospective study is to evaluate the complex anti-reflux treatment of pure venous ulcers on all levels of venous system. This treatment should be the most effective and most economical treatment of this serious problem.

Patients and methods

In the last 20 years, we treated 793 patients with a venous ulceration with the mean age of 59 years (29–81). 81 % of patients were women (643 pts) with the mean age of 53 (32–79) and the rest 19 % were men (150 pts) with the mean age of 49 years (29–81). The median maximum ulcer diameter was 32 (9–170) mm and the majority of ulcers were located in the gaiter region (706 pts – 89 %). The rest was located on the foot (39 pts – 5 %) and on the lateral calf (48 pts – 6 %).

The median duration of the current episode of ulceration was 5 (3–142) months, the median number of episodes of ulceration was 2 (1–9). The phlebography (ascendent and descendent under the skiascopic control) was done in 246 patients, in 198 patients the colour duplex scan and in 342 patients only clinical investigation and tests were done. Using the ascending phlebography, a tourniquet was applied just above the ankle and under the skiascopic control the whole venous system was checked in the standing position. The localised reflux points (perforators) were marked.

The duplex ultrasonography using ACUSON 125 colour flow duplex scanner (USA) was performed at the predefined sites: common femoral, superficial femoral, popliteal, peroneal, anterior and posterior tibial. Patients were examined as standing using a manual calf compression and the Valsalva manoeuvre. A venous reflux was defined as a presence of reverse flow lasting

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longer than 0.5 s. Clinical investigation is based on palpation the raised leg with the muscles relaxed. The orifices in the deep fascia are identified and marked and they are often the sites that control filling of the superficial venous complex. A further test is carried out to see if these are the points from which filling of the superficial venous complex takes place. As many points as possible are compressed by the doctor's fingers and by patient with the compression maintained, and the doctor watches the filling of the superficial complex. This test is repeated until sites which prevent filling are discovered. Removal of the compressing fingers one by one, working proximally will further show how the superficial complexes are filled. In 1973–79 we preferred a surgical treatment in general anaesthesia. In 39 patients (5 %) the classical Linton operation (longitudinal fasciotomy) with stripping and extirpation of varicose complex was done. In 1979–81 we used the same technique but a subfascial division of perforators was done using a hockey instrument which was introduced through small transversal incision of fascia in the middle calf and 56 patients were treated this way (7 %). In this period we used a phlebography as the only diagnostic and control investigation. From 1981 up till now we have not operated and switched to the compression sclerotherapy using the Fegan,s and Sigg,s technique. The Sigg,s technique is based on total sclerotisation of the entire varicose vein without any apparent pathophysiological orientation. Both techniques treat from distal to proximal, but Fegan prefers a permanent obliteration of the superficial veins in the point of abnormal venous flow from the deep to the superficial venous system. It means that the sclerotherapy of the incompetent perforating veins should be performed first to restore normal function of the venous pumps. An immediate application of a graduate compression at treated sites is the basic condition of a good result. We used Polidocanol (Aethoxysklerol Kressler Germany) and S.T.D (sodium tetradecyl sulfate, Fibro vein, England) as a sclerosant. Between 1992–1997 we continued to use the Fegan,s technique but we combined both sclerosants to increase the effect and decrease the number of visits. In each injection shot there was 0.05 cc of the air, which was injected before given the sclerosant. By using Polidocanol 3 % we injected a maximum of 2 cc (usually 0.5–1 cc) in one suspected or diagnosed leaking point by raised leg in empty vein and immediately applied compression. In one visit we injected 3–4 points. Using Fegan,s technique we injected a maximum of 0.5 cc of S.T.D. 3 % into 5–8 vein segments isolated by firm finger compression. Using a combination of two sclerosants (Polidocanol and S.T.D.) it was possible to decrease the amount of sclerosant solution and increase the number of treated leaking points (8–12).

In the group of patients with torpid ulcer with present pathological reflux in the popliteal region which was resistant to this treatment we performed a valvuloplasty with transplantation of the axillar valve-bearing segments in 28 patients (4 %), as suggested by Wilson et al 1991 in experiments in dogs (6). This technique requires first to prolong the chosen vein to three times its diameter. To lengthen the popliteal vein, an interposition graft from the axillar vein with its last valve was used. Intussusception

was always placed below the transplanted segment, avoiding ligated side branches. We managed to pull the distal part of the vein proximal using the new constructed valve of 1.5 diameter of the vein lumen using 5/0 Prolene – two sutures diametrically opposed. After the valve was constructed, its competence was checked using the Harvey,s test. There was a group of 4 patients (0.6 %) with torpid ulceration resistant to sclerotherapy and compression treatment with a sufficient popliteal valve but with a gross reflux in femoral vein region. In this group of patients a direct valvuloplasty (Kistner technique) through longitudinal vein incision was done. In diagnosed reflux in saphenous vein by proximal (saphenofemoral or saphenopopliteal) insufficiency, an echosclerotherapy was done.

In the last 5 years, we used a duplex scan as the main diagnostic and control tool. The phlebography was used in all operated patients for the assessment of valvular deep venous system, for the localisation of atypical reflux points (perforators), for an atypical clinical picture or if duplex scan was not available or couldnot identify the clinical clear perforator.

Clinical diagnosis was used in outpatient praxis where the scan or phlebography were not available.

The topical treatment was the same in all patients. On the ulcers only pads soaked with the Ringer solution were applied and a 3-layer compression bandage (gauze, Cotton, crepe) was kept until the ulcers healed. Skin grafting was done if the ulcer diameter was more than 5 cm. Compression stockings of the second grade 25–35 mmHg were advised for the rest of life. Antibiotics or local desinfiens were never used. We treated 698 patients (88 %) this way.

All patients were checked by the same group of surgeons in outpatients setting weekly until the ulcer healed and then in 2 month intervals during the first year and later every 6 months. If the recurrence occurred, the surgeon was informed immediately and a routine duplex scan was done before any treatment started.

Results

In the group of patients with venous ulcerations (444 pts) where the deep venous system was checked by phlebography or duplex scan, 84 % of patients had a pathological reflux on the deep venous system (diagnosed by duplex scan) and all (100 %) had insufficiency of perforators (diagnosed by phlebography). In our study, none of the patients with inconsequential incompetent calf perforating veins had skin changes or ulcerations, 68 % of those had moderate ones. All patients with severe perforator incompetence had skin changes with ulcerations (C5–6). In the group of patients where phlebography was done (246 pts), 177 pts (72 %) had signs of posttrombotic syndrom. Only 28 % (69 pts) did not show signs of previous thrombosis. Out of 78 patients with truncal varices (31 % – 24 pts) had sufficiency of the saphenofemoral junction. Using the Fegan,s technique of the compression sclerotherapy (sodium tetradecyl sulfate – Fibro vein 1–3 %, air-block technique, compression 45 mmHg for 6 weeks or unless the ulcer heals, walking 3–5 miles daily) we managed to close 95 % of all ulcers of venous origin with the average time

Tab. 1. Method of treatment and results.

Method of treatment	Patients	Hospitalisation	Time of healing	5 years recurrence	Complications
Classical Linton+stripping+ v.v. surgery 1973–1979 Ph	39 (5%)	21 days	84±8 days	31 % (12 pts) N.S.	29 % (11 pts)
Linton SPS (hook instrument)+ stripping+ v.v. surgery 1979–1981 Ph	56 (7 %)	13 days	56±6 days	29 % (16 pts) N.S.	24 % (13 pts)
Compression sclerotherapy (Sigg+Fegan) Ph+Us+Cl	698 (88 %)	0 days	39±12 days	18 % (126 pts) N.S.	7 % (49 pts)
Antireflux operation on the deep venous system Us+Ph	32 (5 %)	7 days	12–120 days	?	6 % (2 pts)

Ph – phlebography, Us – Colour duplex scan, Cl – clinical investigation
 ☐ – not significant ■ – significant (p<0.005)

Tab. 2. Results.

Pts	Healing time	Femoral vein reflux	Popliteal vein reflux	Crural vein reflux
116	Up to 8 weeks	48 % (56 pts)	55% (64 pts)	58 % (67 pts)
48	8–12 weeks	56 % (27 pts)	79 % (39 pts)	67 % (32 pts)
34	More than 12 weeks	62 % (21 pts)	94 % (32 pts)	71 % (24 pts)
Σ 198				

☐ – not significant ■ – significant (p<0.005)

of complete epithelisation of ulcer of 39±12 days. Epithelisation was supported by the skin transplant. The recurrence rate within 5 years of follow-up was 18 % (126 pts). The recurrence rate of surgical treatment (Linton+extirpation of varicose veins) was between 29–31 %. The differences were statistically not significant. The average time of inability to work in the case of operation was between 56–84 days, in sclerotisation only 7 days and without hospitalisation. The difference is statistically highly significant (p<0.001).

Healing process depends on the present reflux in the popliteal vein, is statistically significant more rapid if the reflux is not present. There is a statistically not significant difference in ulcer healing regarding the sclerotherapeutic technique or sclerosant, except for less sclerotherapeutic sessions in favour of the Fegan,s technique with combination of two sclerosants. There is not a difference in therapeutic results if duplex scan was used or diagnosis was done clinically only. The duplex scan with an identified reflux could be used as a prognostic factor of ulcer healing. Where the new valve or a direct valvuloplasty was done, all ulcers (except of 3) responded on the compression treatment and healed within 3 months. Descendent phlebography confirmed the sufficiency of 27 new constructed or repaired valves, 2 were insufficient (technical error) and 3 showed leakage (Tabs 1 and 2).

Discussion

Any untargeted treatment: clipping, ligation, stripping, resection of superficial veins and collaterals is useless and will fail (7, 8). The treatment will have no long lasting result unless the

cause of reflux and all leaking points causing superficial venous hypertension are located and corrected (4, 9).

The targeted ascendent phlebography is still superior to other non-invasive methods of investigation, giving a complete and detailed overview of the venous circulation and anatomy. It is still the gold standard in the diagnosis of peripheral DVT. Injury caused by DVT at the valvular level (postphlebotic syndrome) is visualized and a primary deep vein insufficiency caused by valvular disorders (valvular aplasia) could be identified and corrected. Superficial and perforating veins that must be treated by surgery or sclerotherapy are mapped. Duplex scan examination is very sensitive in identifying reflux and incompetent perforators. Unfortunately this technique has a very high false-positive rate in identifying individual incompetent perforators, and is not more accurate than physical examination in predicting the presence of individual location of incompetent perforators. Although phlebography has a significantly lower occurrence of false-positive findings than Doppler ultrasound evaluation, it has been shown that neither phlebography nor Doppler evaluation is superior to clinical examination in the diagnosis of the presence or localization of the site of insufficient perforators – the most thoroughly documented factor in the aetiology of CHVI and ulcers of venous origin (10). Variations in the anatomical arrangement are so common that constant features are only few. VanLimborgh (1961) (11) lists 214 perforators which show that they may be found almost anywhere on the limb. It was found that the origins of these vessels and the places at which they penetrate the deep fascia are not constant (12). Staubesand and Hacklander (1995) (12) found that the typical Cockett perforators occupy the typi-

cal position only in 7 %. In 90 out of 100 patients a classic clinical investigation should yield a perfect diagnosis, it means that clinical examination with the patient explaining his/her symptoms is still the most reliable noninvasive technique (7). Despite the lack of accuracy of clinical diagnosis of incompetent perforating veins, migration of the sclerosing solution in isolated segments (digital compression or applying a soft rubber ring) of injected superficial vein by raised leg can reliably close the perforator or complex of perforators. The development of deep vein valve incompetence after the deep vein thrombosis is a progressive process over more than 5 years (8). Venous ulcerations in the leg have been predominantly associated with deep venous insufficiency, although a few reports have implicated the superficial veins. Raju and Frederick (1988) (3) found, that 75–88 % of patients with venous ulceration have pure deep vein reflux and suggest that superficial and perforator pathological reflux is secondary phenomenon. There is a strong association between a severe postthrombotic syndrom and a venous reflux. It may be considered that venous reflux is necessary for the development of severe postthrombotic syndrom. However, many patients with severe reflux have only mild symptoms and there must be additional factors contributing to the development of severe postthrombotic syndrom. There was a poor correlation between the presence and extent of such reflux and the severity of symptoms. The popliteal vein is the critical area and we almost always (55 % up to 94 %) found pathological reflux in this area. Popliteal vein incompetence is an indicator of a poor response to compression therapy for venous ulceration (13). In patients with unilateral leg ulceration of purely venous etiology, the only difference in venous reflux between affected and non-affected legs was with respect to the popliteal and crural veins (14). Surgery should be directed at correcting reflux present in the ulcerated limb but not in the unaffected limb.

The correction of deep venous reflux is not only important for improving the function of calf pump but also the most difficult task. It is important for healing venous ulceration to correct the reflux in all relevant venous systems. Correction of superficial and perforator refluxes could be done by technique of compression sclerotherapy (Fegan,s procedure). 95 % of all ulcers could be healed this way. The rest of patients with gross reflux in deep venous system need reduction of reflux in this damaged part. Postthrombotic destroyed valve could not be reconstructed, the cusps are so damaged that only transplantation of the venous segment with valve and valvuloplasty can reduce the reflux as was suggested by Wilson (6, 16). Valvuloplasty is proposed and is effective only after an appropriate superficial and perforators therapy has failed (15). An absolute indication for this operation are patients with ulcers refractory to conservative treatment who have previously undergone correction of superficial and perforator vein reflux.

In situ made valvuloplasty has several advantages:

- 1) The valve is constructed from autogenous vein wall
- 2) All luminal valve surfaces are native venous endothelium
- 3) There is no foreign material intraluminally (16).

The likelihood of thrombosis is reduced to a minimum. The valve is size-matched to the host vein.

An antireflux operation (valvuloplasty, valve transplantation) is more likely to be successful in limbs in which the ejected volume and ejection fraction are normal or near to be normal and the main problem is reflux (4). First we have to improve the efficacy of the calf muscle pump and then to reduce the reflux. When both obstruction and reflux are present, the reflux component is more important in the genesis of venous ulcer (17).

The patients with persistent ulcer despite of superficial and communicating vein surgery or sclerotherapy and using graduated compression hosiery are most likely to benefit from deep vein valve surgery (4). Patient will benefit from any decrease of pathological deep venous reflux. The microcirculation plays the most important role in the development of venous ulcers. Cutaneous blood flow regulation is disturbed in severe CHVI. The feedback system between the transmural pressure in the postcapillary venules and the precapillary resistance regulating arterioles has gone away. The unregulated control system causes a luxury hyperperfusion. Even after venous ulcers have healed the postural feedback system remains disturbed (18). A complete evaluation of all venous systems from groin to ankle with duplex scan ultrasonography in patients with venous ulceration is practical on a routine basis and will be particularly valuable before surgery in order to target intervention at specific incompetent sites (19). Correction of superficial and perforator insufficiency is very successful in healing and preventing recurrent ulcer in the absence of deep reflux by postthrombotic destroyed valves.

Direct valve repair techniques are appropriate only in non-thrombotic deep vein reflux, which is very rare. In postthrombotic syndrom the valves are permanently damaged during the recanalisation process and the transplantation of a valve with the creation of a new valve is indicated.

Conclusion

In the last 20 years, the authors treated 793 patients with venous ulceration. In the group of patients with venous ulcerations (444 patients) where the deep venous system was checked by phlebography or duplex scan, 84% of patients had pathological reflux in the deep venous system (diagnosed by duplex scan) and all (100 %) had insufficiency of perforators (diagnosed by phlebography). Only 28 % of the patients presenting with venous ulcer have a normal deep venous system with reflux confined to the superficial system. The rest 72 % of patients have venous hypertension and reflux due to destroyed valves in deep and perforating veins. The only effective way how to reduce reflux is an interruption of leaking points, mainly perforating veins. The authors consider the compression sclerotherapy (the Fegan,s technique) the easiest and the most effective way of treating patients with venous ulcer (95 % of healed ulcers by 5-years of follow-up with 18 % recurrence rate). Valve repair techniques are appropriate only in non-thrombotic deep vein reflux which is very rare (4 patients, 0.5 %). In patients with torpid ulcers,

where compression sclerotherapy failed (28 patients, 4 %), the in situ construction of a new valve using intussusception with transplantation of a segment axillar vein bearing a healthy valve on popliteal vein was performed, in 4 patients a direct valvuloplasty on the femoral vein valves was done. A descending phlebogram was performed to confirm competence of the valve. All valves (except of 3) were competent and sufficient and all torpid ulcers (except of 2) healed rapidly.

There are 3 basic principles for an effective treatment of venous ulcers: compression, cutting of reflux points using the Fegan's sclerotherapy and reconstruction of deep vein valves if the reflux is present and ulcers don't respond to compression sclerotherapy treatment.

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