

Vein Surgery With or Without Skin Grafting versus Conservative Treatment For Leg Ulcers

A Randomized Prospective Study

FINN E. WARBURG¹, LIS DANIELSEN², SØREN MUNK MADSEN³, HANS OTTO RAASCHOU⁴, STEFFEN MUNKVAD², RENE JENSEN⁴ and HANS ERIK SIERSEN¹

Departments of ¹Orthopaedics, ²Dermatology and ⁴Radiology, Bispebjerg Hospital, ³Coloplast A/S, Humlebaek and Copenhagen Wound Healing Center, Copenhagen, Denmark

In order for us to evaluate the efficiency of perforator vein surgery and skin grafting in leg ulcer patients, 47 patients were randomized into 3 treatment groups (group A: surgery for incompetent perforators, group B: surgery for incompetent perforators and ulcer excision followed by grafting, group C: control group). All the patients were treated with a compression bandage. When cellulitis was observed, a systemic antibiotic was given; eczema was treated with a steroid ointment. Forty patients were evaluated regularly during one year after entry. There were no differences between the 3 treatment groups considering base-line characteristics, median ulcer size at entry and after one year.

According to a review of the initial phlebograms, the occurrence of post-thrombotic changes in the deep veins were recorded in the majority of the legs.

Our results suggest that ligation of incompetent perforators and skin grafting, as used in the present study, may not offer an additional advantage for venous ulcer patients with insufficiency of the deep veins when compared to conservative treatment. However, the removal of insufficient superficial veins was not studied.

(Accepted January 10, 1994.)

Acta Derm Venereol (Stockh) 1994, 74: 307-309.

L. Danielsen, Department of Dermato-venereology, Bispebjerg Hospital, Bispebjerg Bakke 23, DK-2400 København NV, Denmark.

Surgical treatment for varicose ulcers has been an established procedure for more than 80 years. In 1916, Homans (1) described the combined surgery of ulcers and varicose veins using subcutaneous dissection to locate perforators subsequently to be ligated subfascially. Homans stressed that the procedures could be carried out regardless of the ulcer to be excised. Linton (2) produced an elaborate study of perforating veins and suggested dissection for perforators to be carried out subfascially. Operations aimed at correcting insufficient superficial and perforating veins have been reported by several authors (3, 4). More recent studies (5) confirm the advantages of surgery of incompetent perforating veins to accelerate healing of leg ulcers. However, the clinical long-term benefit of such therapy has only rarely been evaluated and not in controlled studies.

Ulceration of the leg is regarded as one of the possible manifestations following deep vein thrombosis. Homans (1) believed the etiology to be "stasis". Venous and capillary hypertension has been the core of later contributions to the understanding of the pathophysiology (6, 7). Due to capillary leakage, the interstitial tissue fills with lipids, proteins and cells in addi-

tion to fluid, inducing a series of events leading to the development of a tight fibrotic tissue with haemosiderin pigmentation extending deep down into the subcutaneous area (lipodermatosclerosis). The pathogenesis of the fibrosis is not known. Browse & Burnand (8) have put forward the hypothesis that leakage of fibrinogen to the interstitial tissue and the development of a fibrin cuff around the capillaries cause a diffusion barrier to oxygen in lipodermatosclerotic skin. However, according to our histological examinations (9) of tissue removed during the present study, the deposition of fibrin appears to be a secondary phenomenon that occurs generally in the area of ulcerated skin and does not play a major role in the development of lipodermatosclerosis and subsequent ulceration. Another prominent hypothesis, put forward by Coleridge Smith et al. (10), explains tissue damage as a consequence of the trapping of white cells in the peripheral circulation of the dependent limb of patients with chronic venous insufficiency, the activated white cells liberating cytotoxic agents.

The chronic leg ulcer will present a mixture of proliferated small vessels and fibrotic tissue as a therapeutical problem, in addition to persistent venous incompetence and hypertension (11).

Leg ulcers are particularly related to old age (12), and as 25% of the residents in the municipal area of Copenhagen are more than 60 years old, many leg ulcer patients are treated in Dermato-venereological department A of Bispebjerg Hospital. In 1984, a Danish investigation revealed 24% of the in-patient capacity of dermatological departments to be occupied by this category of patients (13). Since conservative treatment is resource-consuming and sometimes without convincing results as to healing, it was mandatory to clarify whether an etiologically directed treatment could relieve the problems for venous leg ulcer patients. In consequence, the present prospective study was designed and executed after acceptance from the Scientific-Ethical Committee for the Municipalities of Copenhagen and Frederiksberg.

MATERIAL AND METHODS

The study presents a series of patients with lipodermatosclerosis, leg ulcers and adjacent incompetent perforating veins demonstrated by ascending phlebography using iopamidol as contrast agent (14) and a tilt of 75° initially, supplied with tourniquets below the knee, when necessary. In addition, one of the patients presented clinical evidence of superficial insufficiency. Patients suffering from significant arterial insufficiency of the leg (systolic arterial pressure of first toe <60 mm Hg) (15) were excluded from entry into the study. In addition, the following exclusion criteria were used: diabetes, rheumatoid arthritis,

Table I. Characteristics of the patients in the 3 treatment groups as to sex and age, duration of ulcer before inclusion, and ulcer areas initially and after 1 year

	Group A	Group B	Group C
Sex (numbers) M:F	7:8	8:5	6:6
Age (years)			
median	67	73	59
range	34-83	46-83	44-83
Ulcer duration (months)			
median	24	18	12
range	1-72	3-72	3-96
Initial ulcer area (cm ²)			
median	7.0	41.2	5.2
range	1.1-347	2.1-290	0.3-213
Ulcer area after 1 year (cm ²)			
median	4.1	6.5	0.3
range	0-427	0-63.1	0-205

incompensated heart disease, walking impairment (patients unable to walk by themselves, e.g. because of hemiparesis, arthrosis coxae).

It was decided that the dissection of the suffering subcutaneous tissue should be reduced to a minimum. Subsequent anatomical exposure of veins in subcutaneous tissue was not planned for other than obviously incompetent superficial veins. A compression bandage was used as a compensation for general dilation of superficial veins.

For this reason, Linton's procedure, using a posteromedial incision to the subfascial space, was chosen (2). Further subfascial dissection in search of incompetent perforating veins was easy and non-traumatic in the natural cleavage. Traditional procedures, like Cockett's method, will often lead to some dissection of fibrotic badly perfused fat tissue in search of fascia perforations (3).

Concerning identification of incompetent superficial veins, these can be divided into varicose stems of saphenous veins, which are easily identified, and varicose reticular veins, which are not easy to identify in a hard fibrotic crus. In the study there was no patient with obviously incompetent saphenous stems. In one patient we found a superficial incompetent vein crossing anteromedially from a lateral ulcer. This vein incompetence was treated by local resection and ligation, which was the method planned for such problems.

After informed consent, patients were randomized into 3 treatment groups (A, B and C). Patients in groups A and B received surgery for incompetent perforators, one patient in group A for a superficial incompetent vein. Patients in group B in addition were treated with ulcer excision down to the fascia with a 1-cm rim of surrounding skin followed by skin grafting (meshed split skin).

All the patients were treated with a compression bandage, (Weromedium), patients in groups A and C with a hydrocolloid wound dressing (Comfeel ulcer dressing). In cases where the hydrocolloid dressing was not tolerated because of maceration of the skin and in cases of recurrence in group B the ulcer was dressed with an ointment (carbawax with 0.2% chlorhexidine). When cellulitis of the leg was observed, a systemic antibiotic was given; eczema around the ulcer was treated with a steroid ointment.

All patients in the study were monitored at entry and regularly at ambulatory visits during one year. Ulcer size, being the main parameter, was measured by planimetry of a tracing of the ulcer on a transparent foil sheet. Subjective pain experience was registered in % by the "dot on the line" method as being between "no pain" and "worst thinkable pain".

In order for us to evaluate the frequency of deep venous insufficiency within the 3 treatment groups, the initial phlebograms were reviewed at the end of the study and classified by one of us (H.O.R.), who was unaware of the clinical findings. Absent valves, irregular outlines, narrowing and collaterals bypassing the valves were accepted as evi-

dence of post-thrombotic changes in the deep veins (16). Reflux has been detected by Baker et al. (17) in 19 out of 23 limbs by duplex scan at levels corresponding to the post-thrombotic changes seen on ascending phlebography.

Statistics

Data are reported as the median value with ranges in brackets. The Kruskal-Wallis test was used to evaluate differences of continuous data between the 3 treatment groups. The Fisher exact test was used to evaluate differences of discontinuous variables between the groups. A value of $p < 0.05$ (two-tailed test) was considered statistically significant.

RESULTS

Of the allocated 47 leg ulcer patients, 16 were randomized to group A, 15 to group B and 16 to group C.

After randomization, 3 patients, one in each group, were excluded from the study because they chose to undergo leg ulcer surgery outside Bispebjerg Hospital. During the follow-up period 4 patients dropped out, one from group B (repeatedly absent) and 3 from group C (one of these patients was excluded at his own request, while the other 2 were repeatedly absent). Thus, for the evaluation of the study we present the data of the remaining patients (group A, $n = 15$; group B, $n = 13$; and group C, $n = 12$). The baseline characteristics of these patients are presented in Table I. We observed no statistically significant differences of the variables between the 3 groups (all values of $p > 0.05$).

A review of the phlebograms was possible in 14 patients in group A, 11 patients in group B and 7 patients in Group C. The remaining phlebograms were not possible to evaluate because of their quality; in some cases they were lacking. Post-thrombotic changes in the deep veins were recorded in 11 patients in group A, 11 patients in group B and in 6 patients in group C. One phlebogram in group C showed normal deep veins, 3 phlebograms in group A unfilled segments without collaterals.

At baseline the median ulcer size of group A (7.0 cm² (1.1-347.0 cm²)), group B (41.2 cm² (2.1-290.1 cm²)) and group C (5.2 cm² (0.3-213.3 cm²)) did not deviate significantly ($p > 0.05$). The statistical trend was similar for the median ulcer size at the one-year follow-up: group A (4.1 cm² (0-427.1 cm²)), group B (6.5 cm² (0-63.1 cm²)) and group C (0.3 cm² (0-204.8 cm²)), ($p > 0.05$) (Table I). The proportion of patients with healing of their leg ulcers after one year was similar in group A (6 out of 15 (40%)), group B (5 out of 13 (40%)) and group C (5 out of 12 (42%)), ($p > 0.05$). The time required for healing was in group A: 3 months (1-12 months), in group B: 5.5 months (1.5-12 months) and in group C: 5 months (3-12 months).

Indication for treatment of eczema was found in 11 patients in group A, in 7 in group B and in 8 in group C. Indication for treatment of cellulitis was found in 11 patients in group A, in 11 in group B and in 4 in group C. Of these, haemolytic streptococci were cultured from the ulcers of 4, 2 and 2 patients, respectively, *Staphylococcus aureus* from the ulcers of the remaining patients. Cellulitis was significantly related only to the presence of haemolytic streptococci (to be published).

There was no post-phlebographic thrombosis; nor were there any post-operative septic cases. Pain registration had a course quite parallel to ulcer size.

DISCUSSION

Our results suggest that perforator vein surgery and skin grafting, as used in the present study, do not offer an additional advantage for venous ulcer patients when compared to conservative treatment. The removal of superficial veins was not studied. However, since the occurrence of post-thrombotic changes in the deep veins were recorded in the majority of the legs, our results may only relate to legs with insufficiency of the deep veins. Our results are thus in agreement with those of Burnand et al. (16), Stacey et al. (18) and Åkesson et al. (19). After surgery to communicating veins, Stacey et al. found improvement in relative expelled volume in limbs only with normal deep veins on ascending phlebography. Åkesson et al. observed improvement in venous hypertension and venous reflux following surgery of insufficient superficial veins in legs with deep venous insufficiency, but no improvement following ligation of insufficient perforators. However, 59% of the limbs still had severe hypertension after both operations.

We thus conclude that a registration of insufficiency of the deep veins is necessary, before a ligation of insufficient perforators is decided, since it seems as if surgical treatment is of limited value in cases with deep venous insufficiency.

ACKNOWLEDGEMENTS

We want to express our gratitude to the project nurses Lene Henriksen and Lisbeth Truelsen for their valuable assistance and to Coloplast A/S for providing this assistance and the radiological contrast, as well as to the Danish medical research council for statistical support to the project.

REFERENCES

1. Homans J. The operative treatment of varicose veins and ulcers, based upon a classification of these lesions. *Surg Gynecol Obstet* 1916; 22: 143-158.
2. Linton RR. The communicating veins of the lower leg and the operative technic for their ligation. *Ann Surg* 1938; 107: 582-593.
3. Cockett FB. The pathology and treatment of venous ulcers of the leg. *Br J Surg* 1955; 43: 260-278.

4. Dodd H, Calo AR, Mistry M, Rushford A. Ligation of the ankle communicating veins in the treatment of the venous ulcer syndrome of the leg. *Lancet* 1957; ii: 1249-1252.
5. Schanzer H, Peirce EC. A rational approach to surgery of the chronic venous stasis syndrome. *Ann Surg* 1982; 195: 25-29.
6. Burnand KG, O'Donnell TF, Lea Thomas M, Browse NL. The relative importance of incompetent communicating veins in the production of varicose veins and venous ulcers. *Surgery* 1977; 82: 9-14.
7. Peters K, Sindrup JH, Petersen LJ, Olivarius F, Danielsen L, Kristensen JK. Lower leg subcutaneous blood flow during walking and passive dependency in chronic venous insufficiency. *Br J Dermatol* 1991; 124: 177-180.
8. Browse NL, Burnand KG. The cause of venous ulceration. Hypothesis. *Lancet* 1982; ii: 243-245.
9. Balslev E, Thomsen HK, Danielsen L, Warburg F. The occurrence of pericapillary fibrin in venous hypertension and ischemic leg ulcers: a histopathological study. *Br J Dermatol* 1992; 126: 582-585.
10. Coleridge Smith PD, Thomas P, Scurr JH, Dormandy JA. Causes of venous ulceration: a new hypothesis. *BMJ* 1988; 296: 1726-1727.
11. Dodd H, Cockett FB. The pathology and surgery of the veins of the lower limb. 2nd edn. London: Churchill Livingstone, 1956.
12. Andersson E, Hansson C, Swanbeck G. Leg and foot ulcers: an epidemiological survey. *Acta Derm Venereol (Stockh)* 1984; 64: 227-232.
13. Christoffersen J. *Hudsygdomme i Danmark (Skin diseases in Denmark)*. København: Dansk Institut for Klinisk Epidemiologi, 1984; 140 Disp.
14. Bettman MA, Finkelstein J, Geller S. The use of iopamidol, a new nonionic contrast agent, in lower limb phlebography. *Invest Radiol Suppl* 1984; 19: 225-228.
15. Sindrup JH, Danielsen L, Karlsmark T, Tikjøb G, Jensen BL, Kristensen JK, et al. Prognostic significance of digital blood pressure in leg ulcer patients. *Acta Derm Venereol (Stockh)* 1990; 70: 259-261.
16. Burnand K, Lea Thomas M, O'Donnell T, Browse NL. Relation between postphlebetic changes in the deep veins and results of surgical treatment of venous ulcers. *Lancet* 1976; i: 936-938.
17. Baker SR, Burnand KG, Sommerville KM, Lea Thomas M, Wilson NM, Browse NL. Comparison of venous reflux assessed by duplex scanning and descending phlebography in chronic venous disease. *Lancet* 1993; 341: 400-403.
18. Stacey MC, Burnand KG, Laver GT, Pattison M. Calf pump function in patients with healed venous ulcers is not improved by surgery of the communicating veins or by elastic stockings. *Br J Surg* 1988; 75: 436-439.
19. Åkesson H, Brudin L, Cwikiel W, Ohlin P, Plate G. Does correction of insufficient superficial and perforating veins improve venous function in patients with deep venous insufficiency? In: Åkesson H, ed. *On venous function in chronic venous insufficiency*. Thesis, Graphic Systems AB, Stockholm 1990, 169-194.