Vein Surgery With or Without Skin Grafting versus Conservative Treatment For Leg Ulcers
A Randomized Prospective Study

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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 baseline 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.

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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.

Ulcration 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 addition 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. Browe & Burman (8) have put forward the hypothesis that leakage of fibrinogen to the interstitial tissue and the development of a fibrin cuff around the capillaries causes 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. 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 insufficient, the activated white cells liberating cytotoxic agents.

The chronic leg ulcer will present a mixture of proliferated small vessels and fibrotic tissue as a therapeutic 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,
incompensated heart disease, walking impairment (patients unable to walk by themselves, e.g. because of hemiparesis, antritis 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 postmedial incision to the subfascial space, was chosen. Further subfascial dissection in search of incompetent perforating veins was easy and non-traumatic in the natural cleavage. Traditional procedures, like Cocklett’s method, will often lead to some dissection of fibrotic and badly perfused fat tissue in search of fascial perforations.

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 ligature, 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 surgical treatment 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, (Pomax, Medipsan, 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 (carbocrem 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 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 evidence 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).
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.

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