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Minimally Invasive Surgical Management of Primary Venous Ulcers vs. Compression Treatment: a Randomized Clinical Trial

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Objectives: *to compare minimally invasive surgical haemodynamic correction of reflux with compression in the treatment of venous ulceration.*
Design: *prospective randomised study.*
Materials and Methods: *from a cohort of 80 patients with 87 venous leg ulcers, 47 were randomised to either surgery or compression.*
Results: *at a mean follow-up of 3 years, healing was 100% (31 days) in the surgical and 96% (63 days), in the compression group ($p < 0.02$). The recurrence rate was 9% in the surgical and 38% in the compression group ($p < 0.05$). In the surgical group, all plethysmographic parameters except ejection fraction, had improved significantly at 6 months in the surgical group, and at 3 years residual volume fraction remained in the normal range. Finally, quality of life significantly improved in the operated group.*
Conclusions*: this study supports the effectiveness of surgical therapy for leg ulceration secondary to superficial venous reflux.*

Key Words: Primary venous ulcers; Minimally invasive surgery; Venous haemodynamics; CHIVA; Compression; Quality of life.

Introduction

In developed countries, the lifetime risk of developing venous ulceration is around 1%.[1–10] Superficial venous surgery (comprising sapheno-femoral and/or popliteal ligation, saphenous stripping, sub-fascial endoscopic perforator surgery [SEPS]) and/or compression remain the mainstay of treatment.[11–33] However, randomised data evaluating and comparing the effectiveness of these treatments are lacking. The aim of this study was to compare surgical haemodynamic correction with compression in patients with leg ulcers related to superficial venous insufficiency.

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Materials and Methods

Patients population

Eighty consecutive patients with 87 venous leg ulcers underwent history, clinical and duplex examination (Esa Ote Biomedica, AU5 and/or Technos, 7.5/10 MHz probe, Genoa, Italy). The contour of the ulcer was traced on transparent dressing and area of ulceration calculated (Analitica Lite 3.0, Bareggio, Italy). In patients with bilateral ulcers, each leg was considered separately. If multiple ulcers were present on the same limb their areas were summated. Exclusion criteria comprised age >80 years, patient unable to walk, ulceration $<2\,cm^2$ or $>12\,cm^2$, diabetes, peripheral arterial disease and/or an ankle brachial index <0.9, secondary or congenital venous disease (history of deep vein thrombosis and/or duplex evidence of deep venous reflux/obstruction, and congenital angiodysplasia). The study group therefore comprises

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47 ulcerated limbs in 45 (18 male, 27 female, mean age 63) patients with primary sapheno-femoral and/or popliteal junction (SFJ, SPJ) and long and/or the short saphenous vein (LSV, SSV) disease. Patients were randomised by computer in balanced blocks of four to either compression or minimally invasive surgery and followed for 3 years. Written informed consent and ethical committee approval was obtained (Fig. 1).

The compression group comprised 24 limbs (16 female, 8 male patients) treated with a foam dressing (Aquacell, Convatec, Princeton, U.S.A. or Allevyn, Smith & Nephew, Hull, U.K.), zinc oxide and an inelastic bandage (Lohmann, Rengsdorf, Germany) applied from the foot to below the knee. Antibiotics were used selectively according to sensitivities. Bandages were changed every 3–5 days for the first month and then every 7 days. At the discretion of the treating physician, patients with manageable drainage or without evidence of infection, underwent primary cover with absorptive foam dressings, or no primary cover with the zinc oxide non-elastic bandage. In such cases bandaging was renewed weekly. Once the ulcers were healed elastic stockings exerting 20–30 mmHg of compression at the ankle were prescribed. In the case of recurrence, the bandaging protocol was repeated. The surgical group comprised 21 patients with 23 ulcerated legs. While waiting for surgery compression bandaging was applied as above. Operations were performed as day cases under local anaesthesia following duplex scanning. Two different minimally invasive techniques were performed, in accordance to the location of the re-entry perforator (RPV). Any finger compression above the opening of a perforator leading to the elimination of the reflux wave in the saphenous trunk

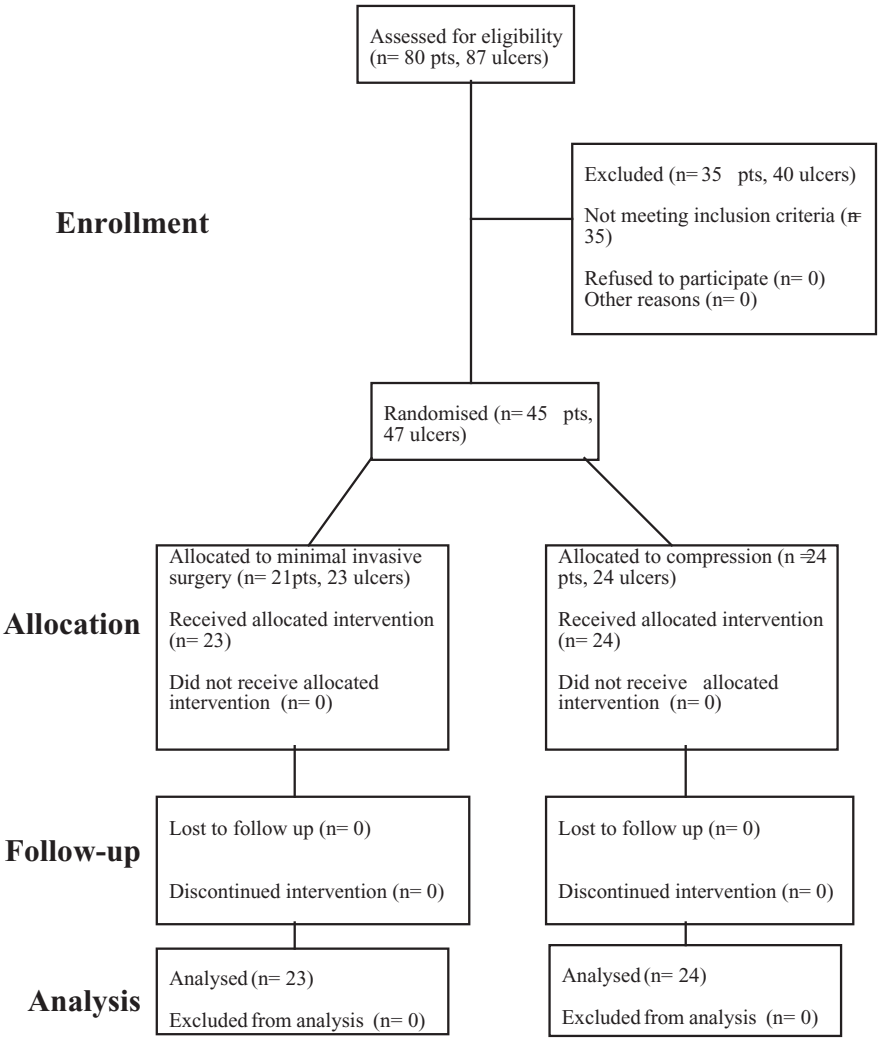

Fig. 1. Flow diagram of the randomised study.

identifies it as a RPV; the opening can be located either on the LSV–SSV main trunk (type I presentation) or on a LSV–SSV tributary (type III presentation). A duplex test, as previously described, can easily differentiate between the two main haemodynamic presentations (Fig. 2).[22] In 16 type I cases the operation comprised a classic high ligation of the SFJ and/or SPJ completed by flush ligation and division from the saphenous trunk and insufficient tributaries (Fig. 3). The result was the creation of a draining downward flow in the saphenous trunk that re-enters the deep circulation through the RPV. In seven type III cases the operation consisted in a flush ligation and disconnection from the saphenous trunk of the insufficient tributaries, which contain the identified RPV (Fig. 4). The procedure may include a second step, consisting in high ligation, if reflux re-appears because of the development of a new re-entry perforator located on the SV.[21,22] Patients began to walk 1 h after the procedure with the ulcer covered by advanced dressing and wearing an elastic stocking exerting 20–30 mmHg of ankle pressure. Patients were discharged within 3 h and were seen twice a week the first week, and subsequently weekly till the ulcer was healed.

Patients in both groups were reviewed clinically, completed the Short Form (SF)-36 quality of life questionnaire, and underwent duplex and air plethysmography six monthly for 3 years.[28,29]

For the purposes of the power calculation, it was assumed that after 3 years the recurrence rate would be 25% less in operated group,[14] so that at least 23 fully assessable ulcers would be required in each group to achieve a significance level <0.05 and statistical power of 90%. Further, it was assumed that as 60–70% of venous ulcers are due to primary superficial reflux, a total cohort of 80–90 ulcerated legs

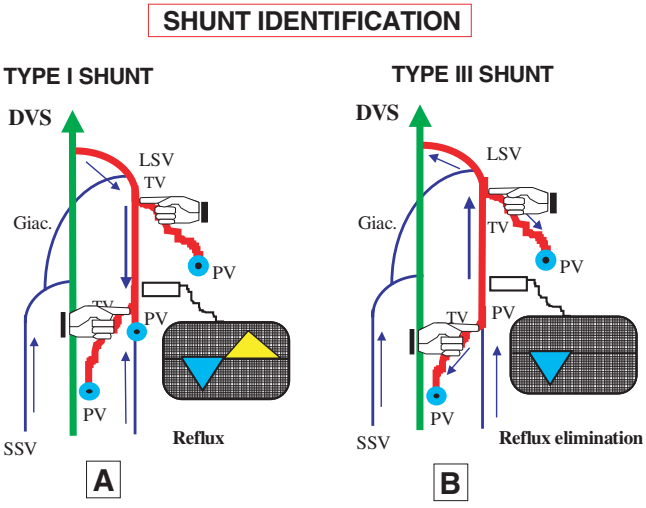

Fig. 2. Finger compression of the insufficient saphenous tributaries (TV) during squeezing manoeuvre permits to differentiate between type I shunt and type III shunt. Left: despite the exclusion of the TV we document the persistence of reflux due to the presence of a gradient between the point of reflux (SFJ) and the re-entry perforator (PV) located on the saphenous trunk (type I shunt). Right: the same manoeuvre determines the reflux elimination in the saphenous trunk due to the exclusion of the gradient created by the PV located on the TV (type III shunt).

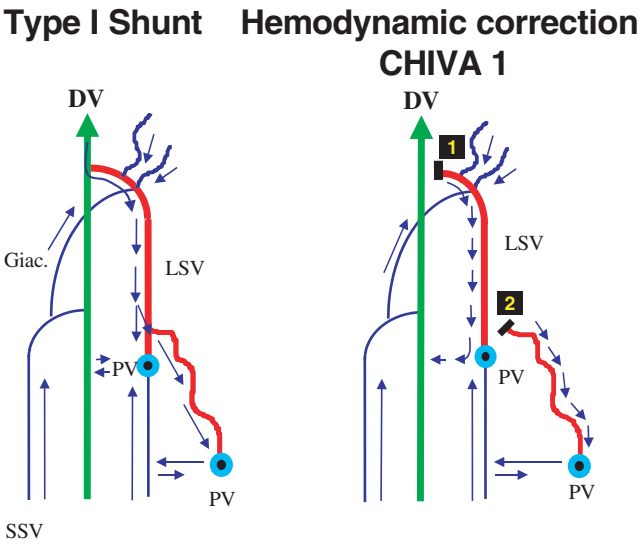

Fig. 3. Left: type I haemodynamic presentation with the re-entry perforators PV, symbolised by a hole, located both on the main saphenous vein trunk (LSV) and on their tributaries (T). Legenda: Giac. = Giacomini Vein, SSV = short saphenous vein. Right: treatment consisted in high ligation complemented by flush ligation and disconnection of T from the saphenous vein. We obtain during muscular diastole a reverse flow toward the deep veins (DV) via the re-entry perforators.

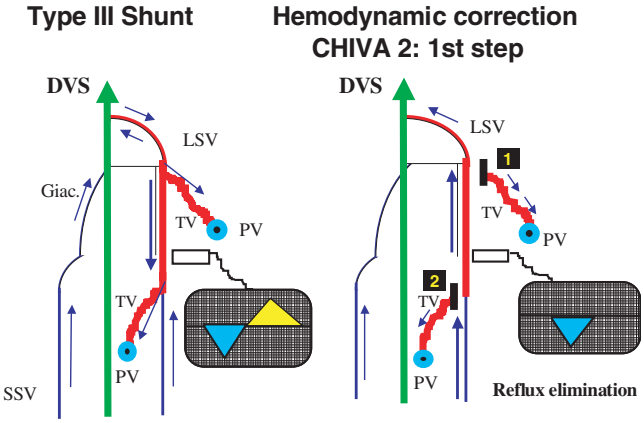

Fig. 4. Left: type III haemodynamic presentation with the re-entry perforators, symbolised by a hole, exclusively on the tributaries (T). Right: treatment consisted in flush ligation and disconnection of T from the saphenous vein. We obtain a forward flow during muscular systole with reflux disappearance.

would have to be evaluated. Of the 87 consecutive ulcerated legs evaluated, 75 (86%) ulcers were pure venous in aetiology. Of these, 47 were due to primary, superficial disease, 14 were due to primary superficial and deep venous disease, 13 were post-thrombotic status, and one was secondary to congenital angiodysplasia. Data are expressed as median and range.

Differences between pre- and post-treatment in the same group were tested for significance using the Wilcoxon test. Differences between the two randomised groups were tested for significance using the Mann–Whitney *U*-test. Ulcer recurrence was assessed using Kaplan–Meyer plots and tested for significance with the log-rank test. p values < 0.05 were considered significant.

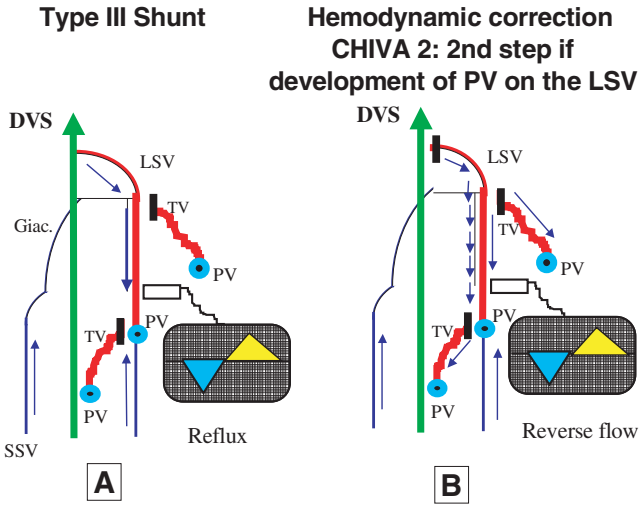

Fig. 5. Survivor function illustrating ulcer recurrence according to treatment. Outcome in patients who underwent minimally invasive surgery was significantly better (log-rank test).

Results

The median [range] ulcerated area in the compression (11 [3–12] cm^2) and surgical (10 [2.6–11.8] cm^2) groups was not significantly different. The healing rate was 96% in a median (range) period of 63 (21–180) days in the compression group compared to 100% in a median (range) 31 (17–53) days in the surgical group ($p < 0.005$ for healing rate). There were nine (38%) recurrences in the compression group compared with only two (9%) in the surgical group ($p < 0.05$) (Fig. 5). The first surgical recurrence was related to sapheno-femoral recurrence on duplex and the second to the development of a sapheno-popliteal reflux. Two patients (29%) showed a saphenous reflux after 6 and 30 months, respectively, following the first step procedures for type III haemodynamic presentation: the occurrence of the development of a new re-entry perforator located on the SV is well established.[21,22]

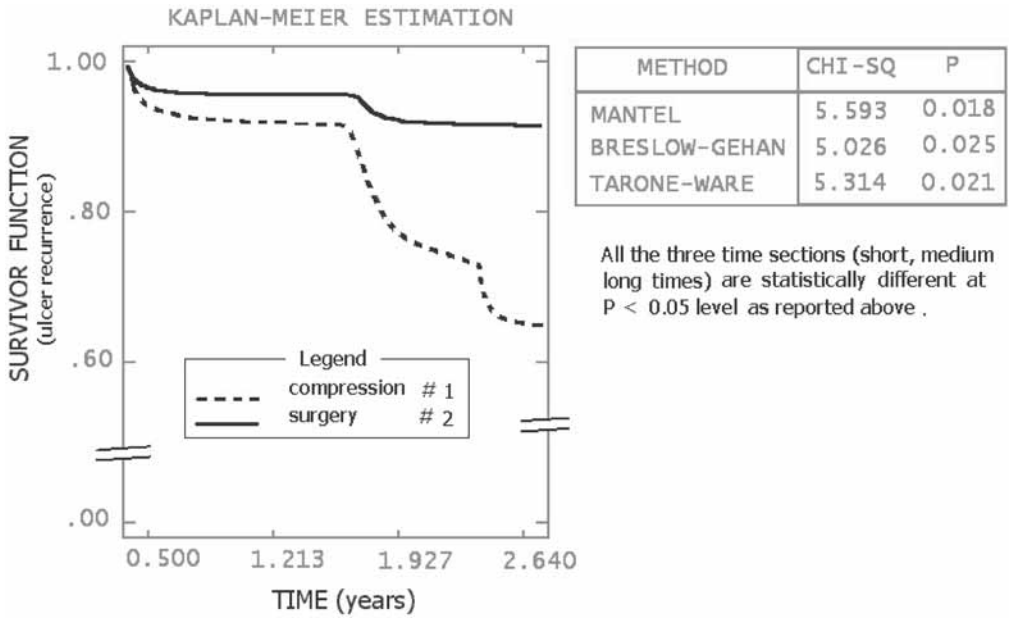

Fig. 6. Median score differences (end of observation-baseline) are shown for the eight domains explored by the SF 36 questionnaire. Legend: * for changes with $p < 0.05$ comparing baseline to end of treatment values, Δ for changes with $p < 0.05$ comparing surgery vs. compression. PF = physical functioning, RP = role-physical limitation, BP = bodily pain, GH = general health, VT = vitality, SF = social functioning, RE = role-emotional limitation, MH = mental health.

Table 1. Pre- and post-operative air phlethysmographic parameters assessed in the surgical group (median value). Bold data in the grey cells describes post-operative parameters significantly different as compared to pre-operative assessment ($p < 0.001$).

	Venous volume (ml)	Venous filling index (ml/s)	Ejection fraction (%)	Residual volume fraction (%)
Pre-operative	187	5.4	56	46
6 m after surgery	124	2.9	54	33
3 years after surgery	152	5	51	31
Parameters in post-operative ulcer recurrence	140	7.5	48	65

In these two cases we performed the second surgical step, represented by high ligation.[21]

At baseline there were no significant differences in venous volume, venous filling index, residual volume fraction (RVF) and ejection fraction. In the surgical group, the first three variables were all significantly improved 6 months after the operation. However, at 3 years, only RFV was found improved (Table 1). In the compression group only the median (range) VV improved significantly from 173 (122–268) to 142 (91–260) ml ($p < 0.05$) at 6 months. However, this improvement was not sustained at 3 years. The results of the SF-36 questionnaire are given in Fig. 6.

Discussion

There is an almost complete absence of randomised controlled data relating to the surgical management of chronic venous insufficiency and, in particular, ulceration. The present randomised study of a well-defined cohort of ulcerated legs affected by primary superficial reflux shows a significant advantage to minimally invasive surgery over compression in terms of healing rates, recurrence and haemodynamic improvement. Although previous uncontrolled studies have suggested a role for venous surgery in such patients,[5–10] there is often a reluctance to operate on such elderly patients who often have significant cardiovascular and respiratory co-morbidity. The present study shows that these concerns can be minimised by operating with duplex guidance under local anaesthesia.[21–25] We believe that the permanent improvement in venous function achieved in the surgical group is the key to understanding the significant differences in terms of healing time and recurrence between the two groups. Compression therapy undoubtedly remains an effective basic therapy[26–33] but it has many disadvantages and contradications not shared by surgery.[34,14]

Haemodynamic correction (the so-called CHIVA treatment), is a minimally invasive technique that is quite different from normal venous surgery. CHIVA eliminates reflux, while maintaining a saphenous drainage and leads to prolonged healing of venous ulcers in patients with primary isolated superficial reflux.

Acknowledgements

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