

Varicose Vein Stripping vs Haemodynamic Correction (CHIVA): a Long Term Randomised Trial

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Objectives. To compare the long-term results of stripping vs. haemodynamic correction (Ambulatory Conservative Haemodynamic Management of Varicose Veins, CHIVA) in the treatment of superficial venous incompetence resulting in chronic venous disease (CVD).

Design. Randomised comparative trial.

Patients. 150 patients affected by CVD, CEAP clinical class 2–6, were randomised to saphenous stripping or to CHIVA.

Methods. The clinical outcome was assessed by an independent observer who recorded the Hobbs clinical score for treated limbs. A subjective report of the outcome was provided by the patients. Recurrence of varices was assessed by both clinical examination and duplex ultrasonography.

Results. The mean follow-up was 10 years, 26 patients were lost to follow-up. The Hobbs score similar in the stripping and CHIVA groups. However recurrence of varicose veins was significantly higher in the stripping group (CHIVA 18%; stripping 35%, $P < 0.04$ Fisher's exact test), without significant differences in the rate of recurrences from the sapheno-femoral junction. The associated risk of recurrence at ten years was doubled in the stripping group (OR 2.2, 95% CI 1–5, $P = 0.04$).

Conclusions. Recurrent varices occurred more frequently following saphenous stripping than after CHIVA treatment. The deliberate preservation of the saphenous trunk as a route of venous drainage in the CHIVA group may have been a factor reducing the recurrence rate.

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Introduction

The estimated prevalence of chronic venous disease (CVD) varies worldwide from 10% to 50%;¹ most patients will have uncomplicated varicose veins but a small proportion (about 10%) will develop venous ulcers.² Surgery is widely used to treated superficial disease resulting in eczema, lipodermatosclerosis and venous ulceration.³ Stripping of incompetent saphenous trunks is widely considered to be the most appropriate management of varicose veins and CVD.^{1,3–6} In the seventies Hobbs, and subsequently Jakobsen compared stripping to sclerotherapy in controlled trials of

patients with saphenous truncal incompetence and found surgery to be more effective in the long-term.^{4–6} However, in the last 20 years a number of attempts at conservative surgery for saphenous truncal incompetence have been reported.^{7–11} A technique which has fallen from favour is flush sapheno-femoral ligation combined with multiple phlebectomies. Some short term reports suggested that this resulted in similar outcomes to stripping operations.^{7–11}

This conservative surgical technique is often confused with the Haemodynamic Correction procedure (CHIVA, Cure Conservatrice et Hémodynamique de l'Insuffisance Veineuse en Ambulatoire, Ambulatory Conservative Haemodynamic Management of Varicose Veins). The aim of CHIVA is not only to preserve the GSV for use as a future vascular graft, but also to maintain its drainage eliminating reflux points with change of compartments.^{12–21} In other words the aim of CHIVA is to treat the varicose vein disease

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by creating a draining saphenous system. A number of clinical series have reported success with this treatment but no controlled trial has been conducted. Here we report the outcome of a randomised trial comparing the outcome of CHIVA with saphenous stripping operations.

Materials and Methods

Patient population

180 consecutive patients who had been referred to the Vascular Laboratory of our Department of Surgery for management of primary CVD of the GSV region were screened for inclusion in the trial (Fig. 1). Patients were screened by clinical examination, including CEAP clinical classification, and duplex ultrasonography undertaken by physicians experienced in the management of venous disease. The inclusion and exclusion criteria are shown in Table 1.

Patients who gave their informed, written consent were included. Patients consented to follow-up over an extended period in order to detect recurrence during a 10 year period following treatment. Some patients refused to undergo stripping procedures after randomisation, preferring a minimally invasive technique. They were excluded from the study (Fig. 1).

In all, 30 patients were excluded from the study on the basis of the above criteria leaving 150 patients who were randomised in accordance to CONSORT

requirements (Fig. 1). Study randomisation was by a computer-generated randomisation list of the 150 patients, structured in balanced blocks of 4 patients and blinded to the treating physicians. The allocated treatment was disclosed shortly before surgical treatment and patients were treated with saphenous stripping or CHIVA, 75 patients by each technique. For each type of procedure there was a different surgical team: one for stripping (CM, AL) and one for CHIVA (PZ, MGM, CC); using this strategy the best team for each technique was used. All the operations were carried out in the same Surgical Department.

Haemodynamic presentation

In this study we deliberately selected patients with SFJ incompetence who were randomized to stripping and CHIVA groups. CHIVA treatment for this type of incompetence necessitates ligation of the SFJ which we have previously described as a type 1 shunt, Fig. 2A. We excluded patients in whom the SFJ was competent and for which CHIVA treatment would not include SFJ ligation. We believe that this made the two groups more comparable.

Pre-operative duplex mapping

A preoperative map of the veins was drawn on the skin with the aid of duplex ultrasonography in order

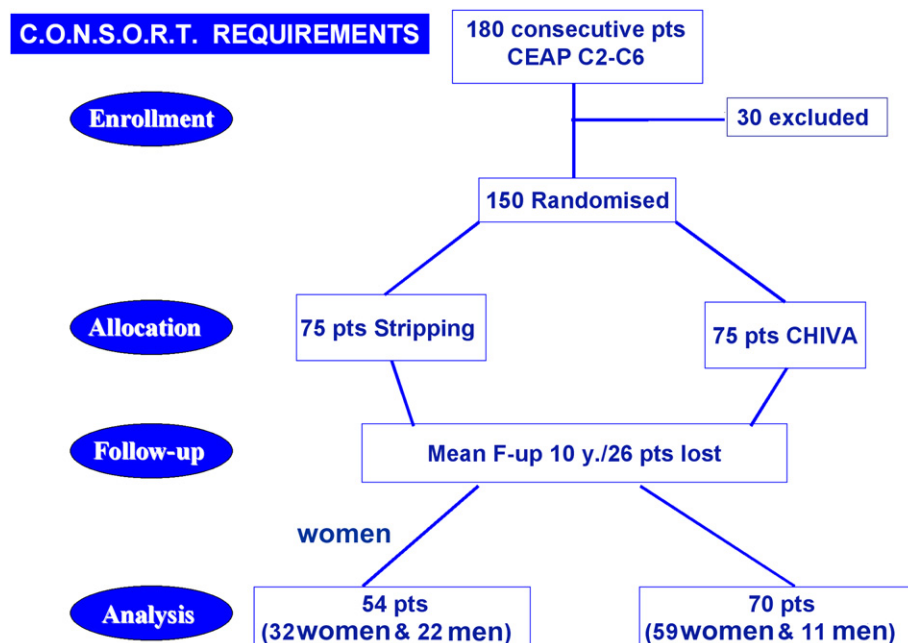


Fig. 1. Flow diagram of the randomised study.

Table 1. Inclusion and exclusion criteria for the trial**Inclusion criteria**

- Primary CVD of CEAP clinical class 2–6 without a history of previous surgery or sclerotherapy.
- Presence of sapheno-femoral reflux and incompetence of the great saphenous trunk
- Presence of a competent and patent deep venous system.
- At least one re-entry perforator located on the saphenous trunk
- One or more incompetent tributaries of the GSV.

Exclusion criteria

- Patients over 70 years old,
- Patients affected by deficit of the calf muscular pump or unable to walk,
- Patients affected by diabetes, auto-immune diseases, malignancies, severe renal, hepatic and cardio-respiratory diseases,
- Patients with previous history of DVT.

to identify the points where the superficial veins had to be interrupted. The ultrasonographic image of the so-called “saphenous eye” is a precise and constant marker clearly demonstrable in a transverse ultrasound image of the GSV in the thigh and calf. The image is due to the duplication of the superficial fascia around the saphenous vein.^{22,23} This appearance was used to identify the saphenous trunk and differentiate it from superficial accessory veins. The Private Circulation (PC) or Shunt was also demonstrated. This is a vicious circle of blood flow between the superficial and the deep veins in primary varicose

veins.^{12–21} The circle starts during muscular relaxation, when the blood from the more proximal reflux point, the SFJ, through the GSV and/or the superficial veins, flows downwards to the re-entry point represented by a Perforating Vein (PV), and then into the deep veins (Fig. 2A). The circle ends during the following muscular contraction, when the blood flows forward through the deep veins, and then again to the proximal reflux point when muscular relaxation occurs.

Stripping procedure

In this group of patients the surgical treatment employed included: flush sapheno-femoral ligation, GSV stripping from groin to knee, multiple phlebectomies of the tributaries and subfascial ligation of thigh perforating veins (Fig. 2C). All the surgical procedures were performed under general or spinal anaesthesia.

Haemodynamic correction (CHIVA)

In keeping with the philosophy of CHIVA treatment, we performed a minimally invasive technique called Haemodynamic Correction type 1 (CHIVA 1).^{12–20}

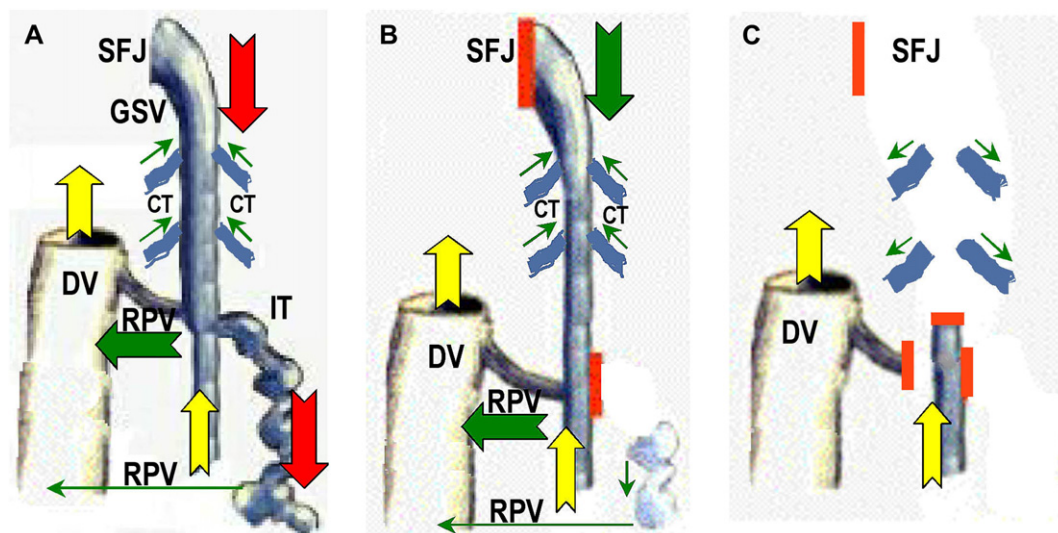


Fig. 2. A) The pattern of haemodynamic presentation in all patients. SFJ: sapheno-femoral junction, GSV: great saphenous vein main trunk, CT: competent tributaries of the GSV, RPV: re-entry perforating veins, IT: incompetent tributaries, DV: deep venous system. Red arrow refers to reflux with change of compartment (from DV to GSV, and from GSV to IT). Green arrow refers to normal flow direction (from CT to GSV, and from GSV and IT to the deep veins through perforators exhibiting an inward flow in muscular diastole). Yellow arrow refers to upward flow in muscular systole in both deep veins and in the competent segment of the GSV. B) CHIVA strategy. Red line refers to interruption of reflux in the points with change of compartment: at the SFJ, and at the origin of the IT. Phlebectomy of the proximal dilated segment can be performed. CT and RPV are both spared for maintaining the drainage of the residual veins. C) Conventional short stripping includes high ligation, multiple stab avulsions, stripping from the groin to below the knee with consequent disconnection of CT, and ligation of RPV.

This is shown in Fig. 2 and consists of flush sapheno-femoral ligation, disconnection from the great saphenous vein of the varicose tributaries and their avulsion through cosmetic incisions. We produced reverse drainage of both the GSV and competent tributaries toward the re-entry PV. Incompetent tributaries were disconnected from the GSV and partially removed; the residual distal segments of these tributaries drain separately through their own re-entry PV (Fig. 2B). All the operations were performed as day surgery cases and under local anaesthesia.

Postoperative management

Following treatment, CHIVA patients wore class 2 medical compression stockings above the knee for three weeks. Limbs which had been treated by saphenous stripping were bandaged to minimise bruising. Bandages were replaced with class 2 medical compression stockings above the knee after 1–3 days and then worn for 14 days. Patients were usually discharged from hospital on the day of surgery. Patients were reviewed in the outpatient clinic 2–4 weeks following surgery to confirm that wounds were well healed and that a satisfactory outcome had been obtained.

Patients were reviewed postoperatively at 1, 6, 12 months, and subsequently, after 3 years and 10 years to assess the outcome of these treatments. Both clinical and ultrasound examinations were performed at each visit.

Clinical assessment of surgical results

All limbs were examined by three independent assessors (SC, MDP, AL1) who had not been involved in previous surgical decision making and operative procedures. They assigned a score to each limb according to the method reported by Hobbs^{4–6} in his RCT comparing the outcome of surgical treatment and sclerotherapy. This comprised the objective evaluation. Scores were assigned as follows:

- Class A (score 1): no visible and palpable varicose veins;
- Class B (score 2): a few visible and palpable varicose veins with diameter < 5 mm;
- Class C (score 3): remaining or newly formed varicose veins with diameter > 5 mm;
- Class D (score 4): incompetent main trunks and perforator.

At the time of scoring the surgical outcome the assessors were unaware of the procedure each patient

had undergone. Subsequently, patients were further analysed by duplex scanning using a standard methodology described previously.^{13,15,16,18,22,23} In addition, functional and cosmetic results were self-assessed by patients at the time of the last examination in Hospital. This used a simple scoring system which was explained to patients by the investigators who again were not aware of the treatment patients had received. Patients were asked to indicate on a form which of the following applied to them:

- Class A (score 1): no inconvenience;
- Class B (score 2): slight functional or cosmetic imperfection, but satisfaction with the result;
- Class C (score 3): appreciable functional or cosmetic failure; improvement but dissatisfaction with the result;
- Class D (score 4): unaltered or increased inconvenience.

The subjective score was obtained from this simple process. Numerical scores were assigned to both of these outcome measures in order to facilitate statistical analysis.

Assessment of recurrences

The assessors considered one or more of the following conditions constituted recurrence of varicose veins:

1. Class C and D of the objective Hobbs score.
2. The presence of reflux on duplex ultrasonography with a demonstrable escape point and change of compartment (for example: sapheno-femoral junction, perforators, pelvic shunts, and, finally tributaries fed by the saphenous trunk).

Data analysis

The number of enrolled patients was estimated by assuming that after three years the rate of surgical recurrence should be 25% less in CHIVA patients, by comparing our institutional survey of stripping to a prospective evaluation of CHIVA.²⁴ The specified significance level was set at 0.05 and statistical power at 0.90. Therefore, we studied a cohort of 150 patients to ensure at least 75 fully evaluable patients per group.

Data descriptors are the mean and standard error (SE) or median and interquartile range where appropriate. Differences between the two randomised groups were tested for significance using Student-T

test; p values less than 0.05 were considered to be significant. We calculated the risk of recurrences at 10 years by comparing the two procedures with Fisher's Exact Test followed by Odds ratio, 95% CI.

Kaplan-Meier actuarial curves for recurrences at 3 and 10 years, respectively, were analysed for significance by using Mantel, Tarone and Breslow test; p values lower than 0.05 were considered to be significant. These life tables were made by using the SYSTAT version 5 (SYSTAT, Inc; Evanston, IL, USA).

Results

The duration of follow-up was 10 years and during this period 26 patients were lost from the study, leaving 54 patients in the stripping group (mean age 50 years) and 70 patients in the CHIVA group (mean age 48 years) (Fig. 1). The length of hospital stay was significantly less for CHIVA patients (median 1 day, IQR. 0.5, in the CHIVA group vs 2 days, IQR. 1, in the stripping one, $P < 0.0001$ Student's t test).

This is probably due to the fact that local anaesthesia was used for the CHIVA patients and spinal or general anaesthesia for the stripping group.

Turning to the outcome data, evaluation of the subjective assessment undertaken by patients, showed no statistical difference between the two groups. The score in the CHIVA group was 1.65 SE 0.11, in the stripping group 1.81 SE 0.12, $P = \text{NS}$, Student's t test). This showed that most patients had scored the outcome of their treatment as class A or B i.e. between excellent and good for both procedures. These data show that patients of both groups were equally satisfied with their treatment.

In contrast, the objective evaluation of outcome by the medical assessor, showed significant differences between groups. There was a slightly higher score in the stripping group than in the CHIVA group, suggesting that the outcome of CHIVA led to slightly less recurrence than stripping (stripping group mean 2.2 SE 0.12, and in CHIVA group mean score 1.9 SE 0.09, $P < 0.038$, Student's t test).

The rate of ultrasound confirmed recurrence was significantly higher in the stripping group, 35% compared to 18% in the CHIVA group, respectively, with a significant P -value ($P < 0.038$, Fisher's exact test) (Fig. 3B). The relative risk of recurrence in the stripping group is doubled at 10 years compared to CHIVA (OR 2.2; 95% CI 1–5, $P = 0.04$, Fisher's exact test).

Duplex analysis of the recurrences identified five different haemodynamic patterns of recurrence (Fig. 3A, 3B), differently distributed in the two

treatment groups. The presence of combined patterns was the rule in the stripping group, while in the CHIVA group a single pattern of recurrence was more common.

- 1) **Type 1 recurrence:** consists of sapheno-femoral recurrence. We found 2 patients out of 70 corresponding to 2.9% in the CHIVA group, and 3 patients out of 54, corresponding to 5.5 % in the stripping group (NS Fisher's exact test).
- 2) **Type 2 recurrence:** consists of reflux coming from the pelvis, through a venous pathway located or in the groin or the perineum, with no associated sapheno-femoral reflux.²¹ This was present in 1/70 pts, 1.4 % in the CHIVA group vs 2/54 pts, 3.7% in the Stripping group, NS, Fisher's exact test).
- 3) **Type 3 recurrence:** consists of duplex ultrasound evidence of incompetent thigh perforators not present at the time of the first procedure. This development was not found after ten years in the CHIVA patients (0/70 pts, 0%); while in the Stripping group we have seen 4 patients out of 54 with this pattern (NS, Fisher's exact test).
- 4) **Type 4 recurrence:** comprises reflux from the proximal saphenous vein (thigh section) to a varicose tributary. This was only found in the CHIVA group and it is typical of the saphenous vein sparing surgery (13/70 pts., 18.5% in the CHIVA group vs 0/54 pts, 0% in the stripping group with P value < 0.01 , Fisher's exact test).
- 5) **Type 5 recurrence:** consists of recurrences from varicose veins greater than 5 mm without any demonstrable escape points or change of compartments. This haemodynamic pattern, in contrast to the previous 4 patterns, is exclusive to the stripping patients and not found in the CHIVA group (0/70 pts, 0% in the CHIVA group vs 12/54 pts, 22% in the stripping group; $P < 0.01$, Fisher's exact test). All the Duplex results with pattern of reflux in each group are given in Fig. 3.

Finally, in Fig. 4 actuarial curves of recurrences at 3 and 10 years are shown. No significant differences were found between the two techniques at 3 years. In the stripping group the recurrences were caused by patterns # 1,2 and 3. In contrast, in the CHIVA group were caused by patterns # 1 and 4. During the period 3–10 years the different recurrence rates in the two groups becomes apparent and significant, Mantel test $P = 0.004$, Tarone test $P = 0.007$, and Breslow test $P = 0.014$. It is noteworthy that, between 3–10 years, in the stripping group the recurrences were caused exclusively by pattern # 5, whereas in the CHIVA patients they were attributable to pattern # 4.

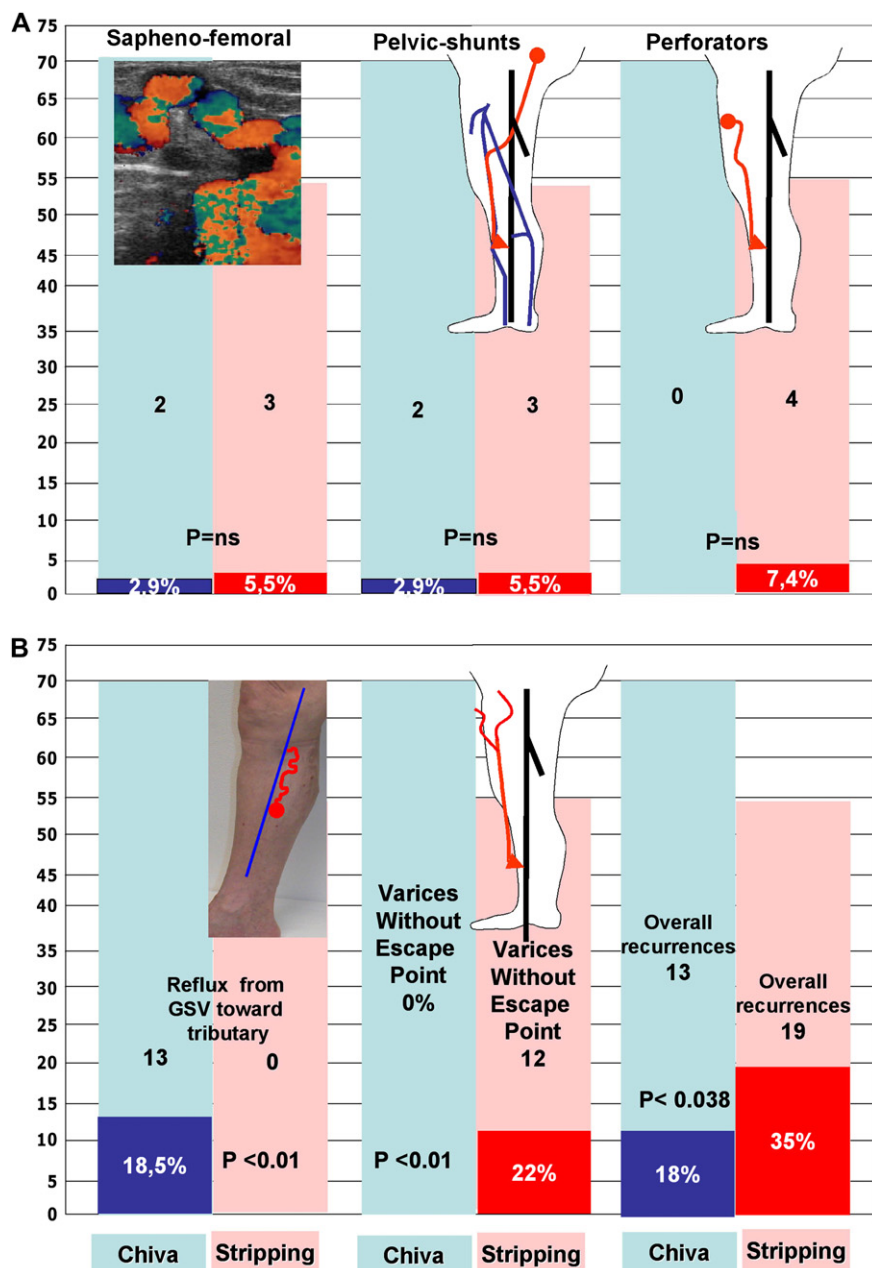


Fig. 3. A: Patterns of recurrence found in the CHIVA and stripping group; number of cases and relative rate are reported. Type 1 compares SF recurrences; type 2 recurrences fed by pelvic reflux; type 3 recurrence from perforators. B: Type 4 recurrence due to reflux from the GSV toward a varicose tributary; type 5 varicose veins greater than 0.5 cm in the absence of any detectable reflux point. The last section of the figure summarises total number of patients with recurrence, and the relative rate in both groups.

Discussion

In the field of varicose vein surgery few long term randomised controlled trials have been published. The last appeared in 1978.⁶ There is the tendency to report short term outcomes without comparison to well-established techniques. These studies do not report end-points used in previous RCTs, which makes

comparison between papers a difficult task. The present study compares the CHIVA strategy with a standard surgical technique. Short-term comparisons previously published were not significantly different,^{15,16,19} and even in our own group of patients we found no differences at 3 years (Fig. 4A).

Since CHIVA is an example of duplex-guided surgery, we performed complete preoperative mapping

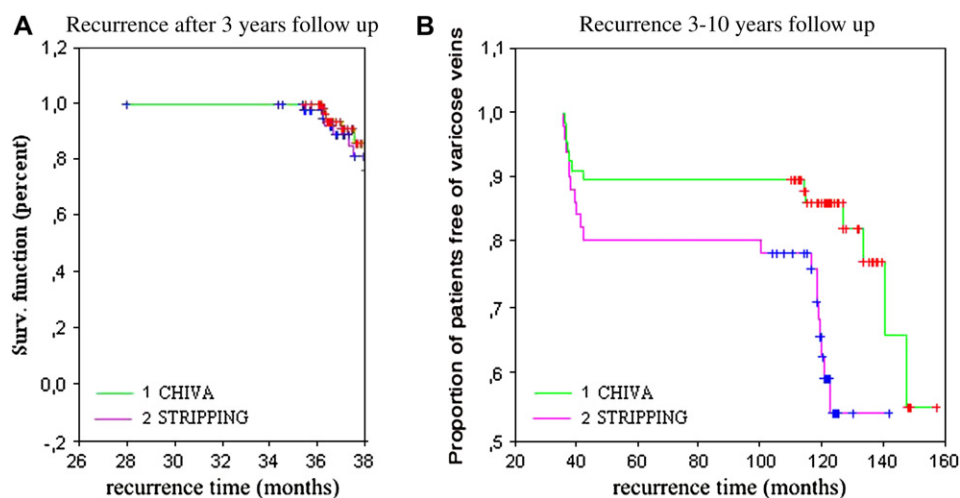


Fig. 4. A) Actuarial rate of recurrence at 3 years. No significant difference was found between the two techniques. In the stripping group recurrence was caused by patterns # 1,2,3. In contrast, development of recurrence in the CHIVA group were caused by patterns # 1 and 4. B) In the period 3–10 years following treatment the recurrence rate in the two groups becomes apparent. In the stripping group recurrence was caused exclusively by pattern # 5, whereas in the CHIVA patients they were referred again to new pattern # 4.

in all patients in order to avoid any criticism about possible advantages of the former technique. In addition, duplex gives us the opportunity to compare patients with the same pre-operative haemodynamic presentation. Under these conditions, our study confirms that preoperative duplex ultrasonography produces good long term outcomes. After ten years, the subjective score from the patients indicates equal satisfaction with both procedures. The objective evaluation of an independent observer confirm that the majority of patients are categorised to Hobbs class B.

The main finding of our study is that the rate of recurrence after ten years was higher in the stripping group as compared to the CHIVA group. Duplex analysis of recurrence allowed us to study the different patterns of varices which developed in the two groups. By summarising the duplex data at ten years we established that:

- i. Rate of recurrence was not due to SF recurrences since this pattern was equally distributed in both groups. This presentation was infrequent, ranging from 2.9 to 5.5%. This is a relatively low rate compared to other series reported in the literature.^{25–29}
- ii. The main pattern of recurrence in the CHIVA group was reflux from the main GSV trunk to a new incompetent tributary (Fig. 3B). This pattern is certainly avoided by stripping of the GSV trunk. Recurrence of this type is easily managed by ligation and phlebectomy under local anaesthesia. The more chaotic nature of the recurrences following stripping make further surgical treatment more

difficult. Foam sclerotherapy may be the most effective measure here.³⁰

- iii. The main difference between the two groups after 10 years, is the 22% of newly formed varicose veins found in the stripping group, without any detectable reflux point. We believe that this type of recurrence is attributable to the lack of a draining saphenous system. The maintenance of drainage seems to be a decisive factor in avoiding neo-angiogenesis after varicose vein surgery.³¹ This observation is confirmed when CHIVA treatment is not correctly performed leading to post-operative GSV thrombosis and occlusion. A non-draining GSV, despite conservative surgery, increases the number of recurrences in comparison to draining GSV systems^{15,16}. This information may also be relevant to modern endovascular techniques aimed at eliminating the GSV. No study of the fate of the GSV in the long term following endovenous laser ablation, radio-frequency ablation, and foam sclerotherapy has been published.

In our study design we tried to minimise possible bias by ensuring that that all patients had SFJ as well as GSV incompetence. In over 50% of cases CHIVA does not require SFJ ligation if the junction is competent, so reducing possible recurrences.^{13–21} However, we recognise that the greater numbers of patients lost to follow-up in the stripping group could significantly affect the final evaluation (Fig. 1).

Correctly performed CHIVA offers a better option for treating varicose veins in the long-term and even

if recurrences do arise they are easily managed. The main difficulty is that the surgeon must also be competent at duplex ultrasonography and capable of analysing patterns of varicose veins by duplex ultrasonography undertaken before the operation. In countries where surgeons usually perform their own duplex ultrasound examinations such as in Italy and Spain, the CHIVA technique is more commonly used. In Spain, a national survey demonstrates this technique is used in about 50 % of cases.¹⁹ In contrast, in France the same kind of evaluation assessed CHIVA performed in less than 5 % of cases.³²

Conclusions

Recurrent varices occurred more frequently following saphenous stripping than after CHIVA treatment. The deliberate preservation of the saphenous trunk as a route of venous drainage in the CHIVA group may have been a factor reducing the recurrence rate.

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