Varicose Vein Surgery

Stripping Versus the CHIVA Method: A Randomized Controlled Trial

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Objective: The objective of this randomized study was to compare the efficacy of the CHIVA method for the treatment of varicose veins with respect to the standard treatment of stripping.

Context: Varicose veins are a sign of chronic venous disorder. For over a century, varicose veins have been treated with surgical ablative techniques, with stripping being the standard treatment. Currently, postsurgical varicose veins recurrence (20%–80%) is a common, complex, and costly problem. Ambulatory Conservative Hemodynamic Management of Varicose Veins (CHIVA) is a new option for treating chronic venous disorder.

Methods: In this open-label, randomized controlled trial, 501 adult patients with primary varicose veins were treated in a single center. They were assigned to an experimental group, the CHIVA method (n = 167) and 2 control groups: stripping with clinic marking (n = 167) and stripping with duplex marking (n = 167). The outcome measure was clinical recurrence within 5 years, assessed clinically by previously trained independent observers. Duplex ultrasonography was also used to assess recurrences and causes.

Results: In an intention-to-treat analysis, clinical outcomes in the CHIVA group were better (44.3% cure, 24.6% improvement, 31.1% failure) than in both the stripping with clinic marking (21.0% cure, 26.3% improvement, 52.7% failure) and stripping with duplex marking (29.3% cure, 22.8% improvement, 47.9% failure) groups. The ordinal odds ratio between the stripping with clinic marking and CHIVA groups, of recurrence at 5 years of follow-up, was 2.64, (95% confidence interval [CI]: 1.76–3.97, $P < 0.001$). The ordinal odds ratio of recurrence at 5-years of follow-up, between the stripping with duplex marking and CHIVA group, was 2.01 (95% CI: 1.34–3.00, $P < 0.001$). This trial is registered at ISRCTN and carries the following ID number: ISRCTN52861672, available at: http://isrctn.org.

Conclusions: The present results indicate that, thanks to specific venous hemodynamic evaluation, the CHIVA method is more effective than stripping with clinical marking or stripping with duplex marking to treat varicose veins. When carrying out a stripping intervention, Duplex marking does not improve the clinical results of this ablative technique.

(*Ann Surg* 2010;251: 624–631)

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Supported by the Instituto de Salud Carlos III, Ministerio de Sanidad (Spanish Ministry of Health) y Consumo, by 2 research grant FIS 94/5365 and FIS 97/0694 (Spain), and a research grant from the Non-Invasive Vascular Diagnosis Area of the Spanish Society for Angiology and Vascular and Endovascular Surgery (Sociedad Española de Angiología y Cirugía Vascular), 2003. Josep Jaumira as graphic designer.

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ISSN: 0003-4932/10/25104-0624
DOI: 10.1097/SLA.0b013e3181d0d0a3

Varicose veins (VV) in the lower extremities are a sign of chronic venous disorder due to valvular incompetence of the superficial venous system (SVS). This problem has a high prevalence—a third of the population—and generates an important number of surgical interventions (one of the most frequently performed operation in the world), as shown in the Edinburgh Study.[1,2] Surgical treatment provides symptomatic relief and significant improvements in quality of life in patients with uncomplicated VV.[3] Despite the benefits provided, surgery has a high relapse rate (20%–80%) creating a common, complex, and expensive problem.[4]

For more than 100 years, therapeutic treatment has consisted of ablation of the VV and saphenous veins, with stripping being the standard treatment.[5] Stripping is a good procedure in terms of simplicity, speed, safety, and because the surgical technique is well standardized. For many years, it has been performed without prior hemodynamic evaluations (preoperative duplex ultrasonography and venous mapping). This treatment is based on clinical marking (preoperative map of the veins on the skin) and results in a high percentage of recurrence in the long-term.[6–9] Currently, modern treatments use hemodynamic studies and presurgical duplex ultrasonography for clinical marking.[10] Sclerotherapy, endovenous lasers, and radiofrequency treatments are some recent therapeutic interventions based on the same principle as ablation (destruction), but which are less aggressive surgically.[11–13] Nevertheless, there is no evidence from studies showing that these treatments are more effective than stripping[5,14] and there is currently a debate with no available evidence-based data.

In 1988, Franceschi[15] described a new method called the CHIVA cure ("Conservatrice et Hémodynamique de l'Insuffisance Veineuse en Ambulatoire"—"Ambulatory Conservative Hemodynamic Management of Varicose Veins"). This method represents a change in VV treatment, whose goal is the preservation of the SVS and its functions—cutaneous and subcutaneous tissue drainage. The principles, strategy, and technique of the CHIVA method are described in other publications.[16–21] In practice, the CHIVA method consists of breaking up the hydrostatic pressure column (HPC) by disconnecting venous shunts.[16,17] Thanks to the fragmentation of the HPC and the suction effect of the valvulomuscular pump, the great saphenous vein (GSV), short saphenous vein (SSV), and VV decrease in diameter while continuing to serve their function draining to the deep venous system (DVS), although still via reverse flow (Figs. 1, 2C).[16,17] This is achieved by using sections—specific venous ligatures, previously analyzed in the hemodynamic and duplex ultrasonography data from the DVS and SVS,[10,22] as well as presurgical cutaneous marking and venous mapping.

There are published studies that demonstrate good results from the CHIVA method with respect to stripping[23,24] but almost no randomized studies have been done. Recently, a study was published with results favorable to CHIVA,[25] but it included only patients with 1 of the 6 hemodynamic types of VVs (shunts).

The objective of this randomized study was to compare the efficacy of the CHIVA method for the treatment of VV with respect to the standard treatment of stripping. The secondary objectives

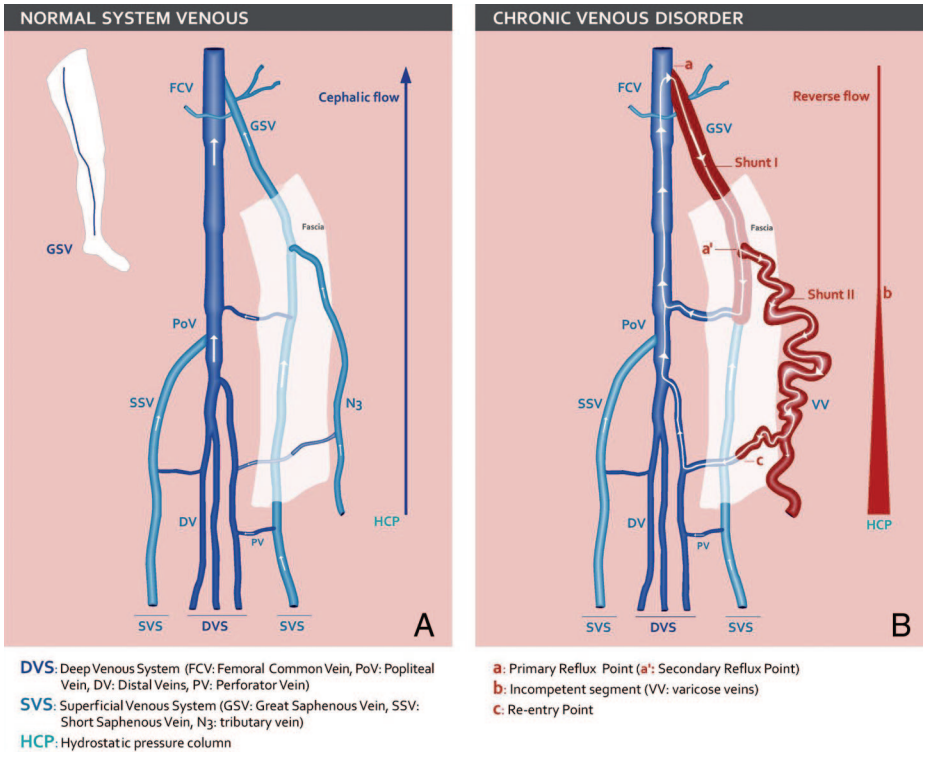

FIGURE 1. An example of normal and pathologic venous systems (Shunt types I+II[12]). A, A healthy SVS is characterized by the presence of cephalic flow, a physiological flow in the direction of the open valves. The valves fragment the pressure of the hydrostatic column, which is pressure related to the weight of the column of blood in the circulatory system. B, A pathologic SVS presents reverse flow, secondary to valvular incontinence which, anatomically, has 3 components: (a) primary reflux points, sites that divert flow from one compartment to another; (b) incontinent segments, trajectories of blood flow between reflux points and reentry points, which encompass the varicose veins; and (c) reentry points, points that drain the flow through a perforator vein. Shunt: a pathologic pathway creating a loop between networks. Example: reflux may occur as a "closed circuit" starting at reflux point into the incontinent segment with flow to the reentry point into the deep venous system and then returning to the reflux point again, etc.[15,16]

were to assess differences with regard to postoperative complications and convalescence between the CHIVA and 2 control groups.

METHODS

Study Design

This was a randomized, open-label controlled trial. It consisted of an experimental group (CHIVA method) and 2 control groups: stripping with clinical marking (S-CM) and stripping with duplex ultrasonography marking (S-DM). The CHIVA method requires duplex ultrasonography. The goal of creating a second control group was to incorporate duplex ultrasonography into preoperative cutaneous marking prior to stripping, to minimize the advantage that ultrasonography brings to the CHIVA group (better knowledge of pathologic SVS).

The efficacy of the intervention was measured by the clinical variable of recurrence at 5 years of follow-up.

Participants

The study was conducted in a regional public teaching hospital with a catchment area of 174,000 inhabitants and a treatment volume of 350 varicose operations per year.

The protocol study was approved by regulatory authorities and ethic review committee of the hospital and written informed consent was provided to the patients.

The study included patients diagnosed with primary VVs in an external consultation by a vascular surgeon, according to the CEAP ($C_{A\text{-}S,\ 2\text{–}6}$; E_P; $A_{S,\ P}$; P_R; LII)[26,27] classification criteria and with permeable, continent DVS upon duplex ultrasonography exploration. In patients with VVs in both extremities, only 1 limb could be randomized.

All patients with congenital venous disease, VVs secondary to prior deep vein thrombosis, postphlebitic side-effects, sclerotherapy, relapse of VVs after surgery, associated systemic pathologies, or who refused to participate in the study, refused surgical treatment, were not ambulatory, could not participate in long-term follow-up or had been pregnant less than 6 months previously were excluded from the study.

Patients were recruited in consecutive order, completed a clinical questionnaire, and were given a physical examination and a DVS ultrasound (duplex; LQ 400 General Electric).

The surgeons who participated in the study were specialists in Angiology and Vascular Surgery, with more than 15 years of experience in their specialty. Of them, 2 had extensive experience with stripping and 1 with CHIVA.

Interventions

Each surgeon independently performed the marking and intervention in an entire treatment or control group (S-CM, S-DM, or CHIVA) to assure the highest quality treatment in each intervention, given that Stripping and CHIVA are conceptually incompatible procedures.

In the interventions, a nonresorbable monofilament was used as a suture, and a clip was used to minimize dead-ends in the ligation and division of the saphenofemoral and/or saphenopopliteal junction. Dexon was used as a closing suture in the fossa ovalis.

All procedures for the study were on an outpatient bases. Anesthesia was epidural in the stripping groups and local in the CHIVA group.

The S-CM Group

The goal of S-CM is to remove the incompetent SVS.

Prior to the intervention, the surgeon decides which is the incompetent section that should be removed. The decision is based on a physical exploration with respect to reflux points, incompetent segments—which include the VV—and reentry points (Fig. 1B). Cutaneous marking with the patient in a standing position is used, which includes the 3 cited points.

The surgical process consists of closure of the reflux points, by ligation and division of the saphenofemoral junction and groin tributary

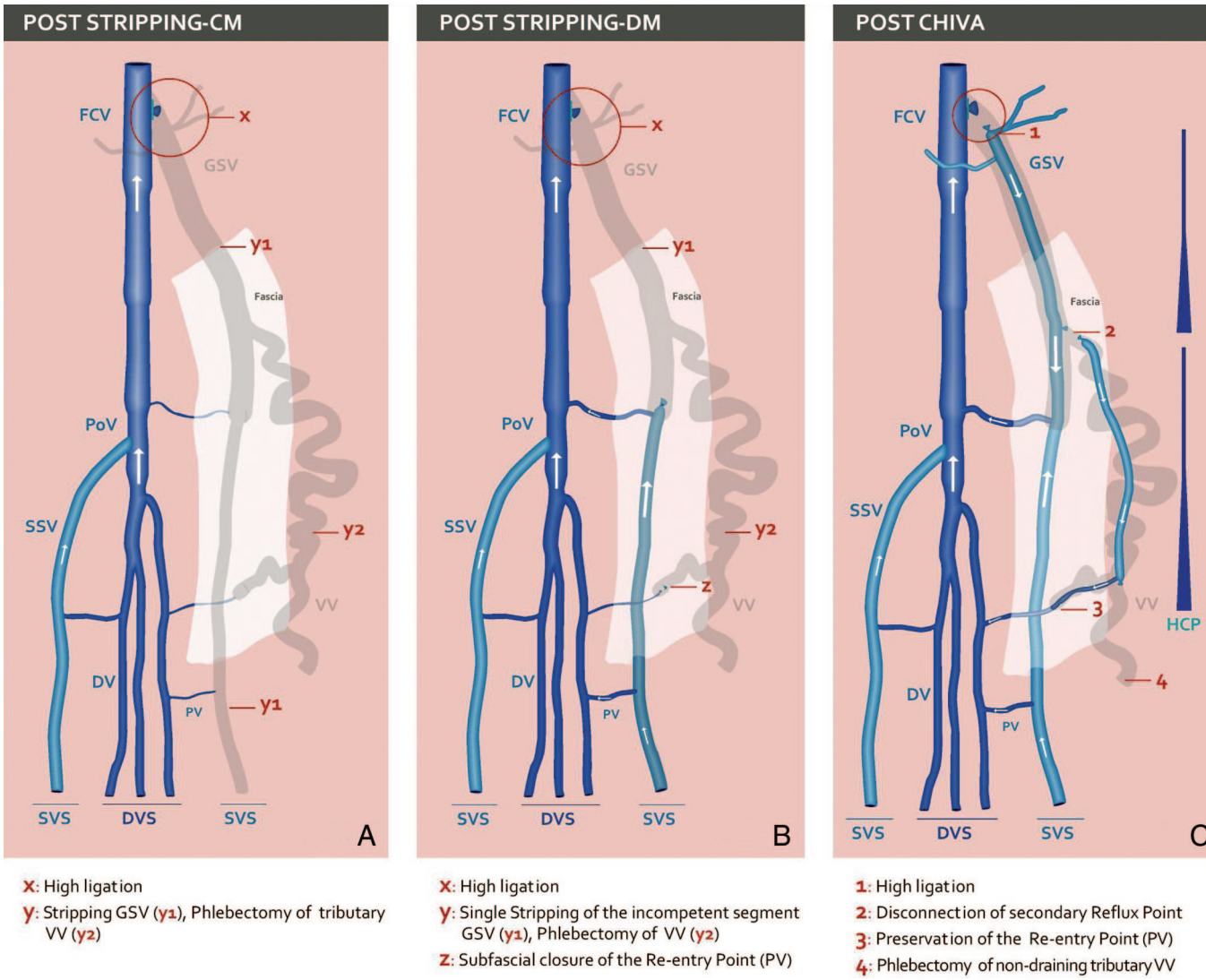

FIGURE 2. Surgical strategy for the different groups in relation to the Figure 1B. High ligation (x) in stripping groups: disconnection of the saphenofemoral or saphenopopliteal junction at the level of the DVS and ligation of the groin tributary veins. Stripping (y_1): removal by invagination of the complete extension of the saphenous vein (A) or simple stripping of the incompetent segment (B). Phlebectomy (y_2): removal of the tributary varicose vein. Closure of the subfascial perforator vein (z): disconnection of the perforator vein and closure of the aponeurosis. High ligation (1) in CHIVA group: disconnection of the saphenofemoral or saphenopopliteal junction at the level of the DVS, preservation of the groin tributary veins draining to the GSV, and the Giacomini vein union with the SSV (C).

veins or ligation and division of the saphenopopliteal junction or subfascial closure of the perforator vein, and the stripping of the entire length of the GSV and/or SSV with VV phlebectomy (Fig. 2A).

The S-DM Group

The goal of S-DM is to remove the incompetent SVS.

In this group, the cutaneous marking with the patient in a standing position, uses physical and duplex ultrasonography exploration to identify the incompetent segments. Once the cutaneous marking is finished, a venous mapping is drawn and ultrasound images are saved in printed form, on which the reflux points, the diameter of the GSV and SSV, and the reentry points are marked. These documents are the basic reference for comparison during follow-up.

The surgical strategy is based on the prior venous mapping. This consists of closure of the reflux points, by ligation and division of the saphenofemoral junction and groin tributary veins or ligation and division of the saphenopopliteal junction or subfascial closure of the perforator vein, stripping only the incompetent segment of the GSV and/or SSV, phlebectomy of the VV and closure of reentry points (Fig. 2B).

CHIVA Group

The goal of the CHIVA method is the disconnection of the reflux points and preservation of SVS drainage to the DVS.

In this group, cutaneous marking with the patient in a standing position uses physical exploration and duplex imaging to identify incompetent segments. Once the cutaneous marking is com-

pleted, a venous mapping is developed and ultrasound images are printed, on which the reflux points, the diameter of the GSV and SSV, and the reentry points are marked. These documents are the basic reference for comparison during follow-up.

The surgical strategy is based on the principles of the CHIVA method described by Franceschi.[15–17] This consists of closing reflux points, by ligation and division of the saphenofemoral junction, preserving drainage of the groin tributary veins to the GSV or ligation and division of saphenopopliteal junction, preserving the drainage of the Giacomini vein or subfascial closure of the perforator vein, preservation of the incompetent segments of the GSV and/or SSV, disconnection of the secondary reflux points originating in the VV, preservation of reentry points (perforator vein), and phlebectomy of improperly draining collateral veins (Fig. 2C).

Postoperative Management

All patients were treated with a pressure bandage from the foot to the inguinal zone for 48 hours, and then elastic stockings for 4 weeks. Analgesic treatment (575 mg Metamizole/8 h) and antithrombotic prophylaxis[28–31] (40 U Enoxaparin/24 h for 10 days) were protocolized.

Efficacy Measures

The clinical efficacy of the intervention (the primary end point) was evaluated based on recurrence, measured using the Hobbs[7] classification: "cure" (absence of VV), "improvement" (presence of VV <0.5 cm), and "failure" (presence of VV >0.5 cm, main trunks, or incompetent perforators).

Recurrence was also measured using ultrasonography as a second-level research variable.[32] This includes "absent or nonvisible recurrence" (patient clinically cured) and "visible recurrence" (patient in situation of clinical failure), with or without a simple reflux point. Duplex ultrasonography imaging was used to study the location of recurrence by examining different anatomic types of shunts.

As measures of safety, most major (deep vein thrombosis, pulmonary thromboembolism, death) and minor (bruises, subcutaneous inguinal hemorrhage, neuralgia of the saphenous nerve, wound infection and phlebitis) postsurgical complications were evaluated at 8 days postintervention. Finally, days of convalescence were recorded. Clinical follow-up and duplex ultrasonography with venous mapping in the 3 groups were at 3, 6, 12, 24, 36, 48, and 60 months after surgery.

The study was designed to detect a 15% decrease in the recurrence rate, with an expected 60% recurrence rate in the control group, with 80% power at a 2-sided 5% significance level, with an intervention-control ratio 1:2 and with an expected loss rate of 15%. The study included 501 patients randomized into 3 groups (by means of 6-element block randomization) with each group representing a different type of intervention: S-CM, S-DM, and CHIVA. Surgeons were assigned to the stripping or the CHIVA groups according to their training and experience with the technique. Two previously trained independent medical observers performed the clinical tests and duplex imaging.

Statistical Analysis

Treatment efficacy was analyzed by intention-to-treat[33] (assigning the worst result to patients excluded before treatment and to patients lost to follow-up after surgery) and by protocol (having included those patients with complete follow-up to 5 years).

Ordinal or simple logistic regressions were used to estimate the effectiveness of treatments at 5 years. Also, the Kaplan-Meier method and the log-rank test were used to assess the evolution of treatments for the 5-years of follow-up.

The differences between treatments in terms of postoperative complications and days of convalescence were analyzed with the χ^2

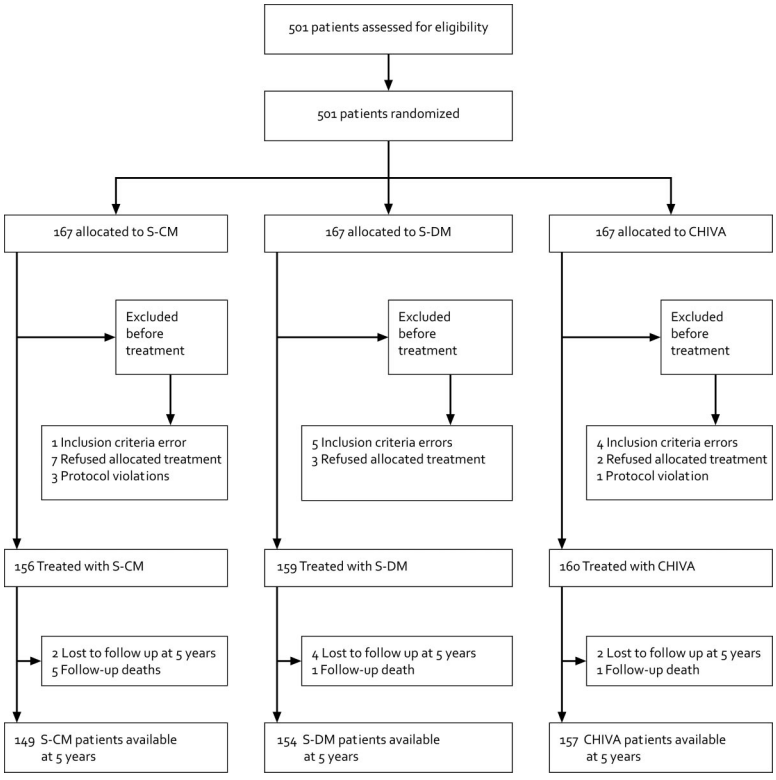

FIGURE 3. Trial design.

TABLE 1. Baseline Characteristics of the Patients

Characteristic	S-CM (N = 167)	S-DM (N = 167)	CHIVA (N = 167)
Sociodemographic			
Sex—number (%)			
Female	110 (65.9)	110 (65.9)	134 (80.2)
Male	57 (34.1)	57 (34.1)	33 (19.9)
Age (yr) mean (SD)*	49.54 ± 12.36	50.00 ± 12.18	48.76 ± 12.19
Body mass index†—mean (SD)*	26.33 ± 3.84	25.99 ± 4.01	26.35 ± 3.76
Pregnancy—mean (SD)*	2.38 ± 1.18	1.96 ± 1.14	2.13 ± 1.31
Standing posture at work (h)—number (%)			
0–4 h	45 (26.9)	55 (32.7)	43 (25.7)
>4 h	122 (73.1)	112 (67.1)	124 (74.7)
Laterality—number (%)			
Right leg	83 (49.7)	76 (45.5)	84 (50.3)
Left leg	84 (50.3)	91(54.5)	83 (50.0)
Symptoms—number (%)			
Heaviness	115 (68.9)	124 (74.3)	122 (73.5)
Itching	82 (49.1)	98 (58.7)	83 (52.6)
Aching			
No	72 (43.1)	89 (53.3)	86 (51.8)
Moderate	90 (53.9)	71 (42.5)	76 (45.8)
Severe	5 (3.0)	7 (4.2)	4 (2.4)
Muscle cramps	76 (45.5)	80 (47.9)	68 (41.0)
Signs—number (%)			
Oedema			
No	84 (50.3)	90 (53.9)	78 (47.0)
Moderate	83 (49.7)	74 (44.3)	88 (52.7)
Severe	0 (0.0)	3 (1.8)	1 (0.6)
Skin pigmentation			
No	158 (94.6)	155 (92.8)	156 (93.4)
Moderate	8 (4.8)	9 (5.4)	8 (4.8)
Extensive	1 (0.6)	3 (1.8)	3 (1.8)
Varicose eczema			
No	164 (98.2)	164 (98.2)	166 (99.4)
Moderate	3 (1.8)	3 (1.8)	1 (0.6)
Lipodermatosclerosis			
No	167 (100.0)	167 (100.0)	166 (99.4)
Moderate	0 (0.0)	0 (0.0)	1 (0.6)
Venous ulcer			
No	167 (100.0)	164 (98.2)	166 (99.4)
Present	0 (0.0)	3 (1.8)	1 (0.6)
Haemodynamic[15]‡			
Primary reflux point—number (%)			
SFJ with reverse flux in GSV§	—	106 (63.4)	89 (53.6)
SFJ with reverse flux in AASV¶	—	10 (5.9)	24 (14.5)
Paraostium	—	19 (11.3)	27 (16.3)
Perineum	—	5 (3.0)	9 (5.4)
Saphenopopliteal junction	—	16 (9.5)	10 (6.0)
Thigh perforator	—	5 (3.0)	4 (2.4)
Lower leg perforator	—	3 (1.7)	0 (0.0)
Type of shunt[15]‖—number (%)			
Shunt I	—	21 (12.6)	27 (16.3)
Shunt II	—	9 (5.3)	13 (7.8)
Shunt III	—	117 (70.0)	97 (58.4)
Shunt IV	—	1 (0.5)	2 (1.2)
Shunt V	—	12 (7.2)	20 (12.0)
Shunt VI	—	4 (2.4)	4 (2.4)
Diameter—mm			
LSV + SSV (SD)*	—	6.48 ± 1.92	6.83 ± 2.02

*Plus-minus values are means ± SD.
†The body-mass index is weight in kilograms divided by the square of the height in meters.
‡The S-CM group does not have hemodynamic measures since S-CM does not use the duplex imaging.
§Saphenofemoral junction with reverse flux in the great saphenous vein.
¶Saphenofemoral junction with reverse flux in the anterior accessory saphenous vein (AASV).
‖A shunt[15] is a pathologic pathway creating a circle between networks.
S-CM indicates stripping with clinical marking; S-DM, stripping with duplex ultrasonography marking; SD, standard deviation; SSV, short saphenous vein; GSV, great saphenous vein; AASV, anterior accessory saphenous vein; SFJ, saphenofemoral junction.

TABLE 2. Analysis During 5-Year of Follow-Up

Intention-to-Treat Analysis	S-CM (N = 167) n (%)	S-DM (N = 167) n (%)	CHIVA (N = 167) n (%)	Total (N = 501) N (%)
Recurrence: clinical assessment				
Cure	35 (21.0%)	49 (29.3%)	74 (44.3%)	158 (31.5%)
Improvement	44 (26.3%)	38 (22.8%)	41 (24.6%)	123 (24.6%)
Failure	88 (52.7%)	80 (47.9%)	52 (31.1%)	220 (43.9%)
Ordinal odds ratio	S-CM vs. CHIVA: 2.64, 95% CI: (1.76–3.97), $P < 0.001$			
	S-DM vs. CHIVA: 2.01, 95% CI: (1.34–3.00), $P < 0.001$			
	S-DM vs. S-CM: 0.76, 95% CI: (0.51–1.14), $P = 0.184$			
Recurrence: duplex assessment				
Absent or nonvisible recurrence	53 (31.7%)	65 (38.9%)	100 (59.9%)	218 (43.5%)
Visible recurrence	114 (68.3%)	102 (61.1%)	67 (40.1%)	283 (56.5%)
Odds ratio	S-CM vs. CHIVA: 3.21, 95% CI: (2.04–5.03), $P < 0.001$			
	S-DM vs. CHIVA: 2.34, 95% CI: (1.51–3.63), $P < 0.001$			
	S-DM vs. S-CM: 0.73, 95% CI: (0.47–1.15), $P = 0.170$			
Analysis by Protocol	**S-CM (N = 149) n (%)**	**S-DM (N = 154) n (%)**	**CHIVA (N = 157) n (%)**	**Total (N = 460) N (%)**
Recurrence: clinical assessment				
Cure	35 (23.5%)	49 (31.8%)	74 (47.1%)	158 (34.3%)
Improvement	44 (29.5%)	38 (24.7%)	41 (26.1%)	123 (26.7%)
Failure	70 (47.0%)	67 (43.5%)	42 (26.8%)	179 (38.9%)
Ordinal odds ratio	S-CM vs. CHIVA: 2.60, 95% CI: (1.70–3.96) $P < 0.001$			
	S-DM vs. CHIVA: 2.03, 95% CI: (1.34–3.08), $P < 0.001$			
	S-DM vs. S-CM: 0.78, 95% CI: (0.51–1.19), $P = 0.254$			
Recurrence: duplex assessment				
Absent or nonvisible recurrence	53 (35.6%)	65 (42.2%)	100 (63.7%)	218 (47.4%)
Visible recurrence	96 (64.4%)	89 (57.8%)	57 (36.3%)	242 (52.6%)
Odds ratio	S-CM vs. CHIVA: 3.17, 95% CI: (1.99–5.07) $P < 0.001$			
	S-DM vs. CHIVA: 2.40, 95% CI: (1.52–3.79) $P < 0.001$			
	S-DM vs. S-CM: 0.75, 95% CI: (0.47–1.20) $P = 0.237$			

S-CM indicates stripping with clinical marking; S-DM, stripping with duplex ultrasonography marking; CI, confidence interval.

and Mann-Whitney tests, respectively. We used the SPSS statistical package, version 15, for data analysis.

RESULTS

Between February 1998 and April 2001, 501 patients were included in the study, randomized into 3 groups (S-CM, n = 167; S-DM, n = 167; CHIVA, n = 167). Twenty-six (5.2%) of randomized patients were excluded from the study before surgical treatment (Fig. 3). The baseline characteristics of the sample were well balanced, with the exception of sex, with a larger percentage of women in the CHIVA group (80.2%) than in the S-CM (65.9%) and S-DM (65.9%) groups (Table 1). The study retention rate was very high (91.8%) at 5 years.

The clinically evaluated recurrence results at 5 years of follow-up, in the intention-to-treat analysis (n = 501), were better in the CHIVA group (44.3% cure, 24.6% improvement, 31.1% failure) than in both the S-CM (21.0% cure, 26.3% improvement, 52.7% failure) and the S-DM (29.3% cure, 22.8% improvement, 47.9% failure) groups. The ordinal odds ratio (OR) of clinically evaluated recurrence between the S-CM and CHIVA groups was 2.64, with a 95% confidence interval (95% CI) of 1.76–3.97 ($P < 0.001$). The ordinal OR of clinically evaluated recurrence between the S-DM and CHIVA groups was 2.01, with a 95% CI of 1.34–3.00 ($P < 0.001$). There were no statistically significant differences between recurrence in the 2 control groups, with an ordinal OR of 0.76, and a 95% CI of 0.51–1.14 ($P = 0.184$) (Table 2).

Recurrence was analyzed by intention-to-treat using ultrasound at 5 years (n = 501), showing that the percentage of "visible recurrence" in the CHIVA group (40.1%) was less than in either the S-CM group (68.3%) or the S-DM group (61.1%). The OR of recurrence, analyzed by intention-to-treat, between the S-CM and CHIVA groups was 3.21 with a 95% CI of 2.05–5.03 ($P < 0.001$) and the OR between the S-DM and CHIVA groups was 2.34, with a 95% CI of 1.51–3.63 ($P < 0.001$). There were no statistically significant differences in recurrence, analyzed by intention-to-treat, between the 2 control groups, with an OR of 0.73, and a 95% CI of 0.47–1.15 ($P = 0.170$) (Table 2).

The results of the recurrence analysis, by protocol, at 5 years (n = 460) were consistent with the intention-to-treat, both in the clinical evaluation and in the ultrasound (Table 2).

The risk of clinical recurrence (not cure) over 5 years is presented in a Kaplan-Meier curve (Fig. 4). Recurrence in the S-CM and S-DM groups followed a similar pattern. On the other hand, the CHIVA group had a significantly lower recurrence rate ($P < 0.001$).

Among treated patients (S-CM, n = 156; S-DM, n = 159; and CHIVA, n = 160) there were no major complications (deep vein thrombosis, pulmonary thromboembolism, death) in any of the 3

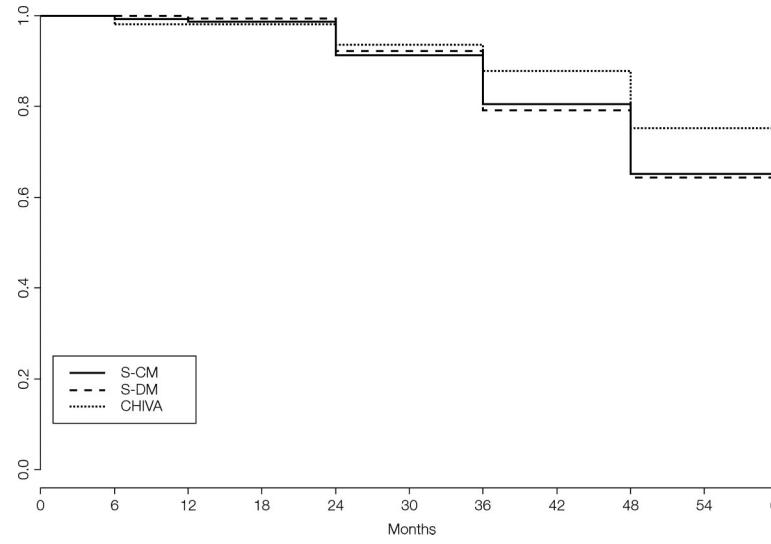

FIGURE 4. Kaplan—Meier Analysis of Clinical Recurrence by Protocol (n = 460). About 47.1% of patients in the CHIVA group, 23.5% in the S-CM group, and 31.8% in the S-DM group were free of varicose veins (VV) at 5 years; $P < 0.001$ (log-rank test).

groups. Some minor complications seen were the following. Bruises: globally 316 (66.5%) and by groups: S-CM 125 (80.1%)/S-DM 115 (72.3%)/CHIVA 76 (47.5%), $P < 0.001$; subcutaneous inguinal hemorrhage: globally 19 (4.00%) and by groups: S-CM 6 (3.8%)/S-DM 7 (4.4%)/CHIVA 6 (3.8%), $P = 0.950$; saphenous nerve neuralgia: globally 15 (3.15%) and by groups: S-CM 9 (5.8%)/S-DM 6 (3.8%)/CHIVA 0 (0.0%), $P = 0.012$; wound infection: globally 10 (2.10%) and by groups: S-CM 1 (0.6%)/S-DM 5 (3.1%)/CHIVA 4 (2.5%), $P = 0.276$; phlebitis: global 6 (1.26%) and by groups: S-CM 1 (0.6%)/S-DM 3 (1.9%)/CHIVA 2 (1.3%), $P = 0.616$. No patients required hospitalization after surgery.

Means (and ranges) of convalescent times were, in the S-CM group 20 (3–60) days, in the S-DM group 15 (1–60) days ($P = 0.036$), in the CHIVA group 3 (0–30) days ($P < 0.001$ with respect to both the S-CM and S-DM groups).

DISCUSSION

The CHIVA method showed a clear improvement in clinical recurrence at 5 years, with respect to stripping. CHIVA also showed better results in the duplex imaging and safety variables (postoperative complications and convalescent time[34,35]).

The 2 control groups, S-CM and S-DM, had similar results for all variables studied, except for days of convalescence, for which S-DM had better results due to a less aggressive surgical technique. In current practice, Duplex imaging is the gold standard for diagnosing VV.[10] Despite this, relevant long-term studies comparing S-CM to S-DM, and other evidence that preoperative duplex imaging may improve the results of stripping, is a field where evidence-based medicine studies are currently lacking.[5,36] In our study, preoperative duplex imaging was used to discard deep-vein pathology, which would affect the results of the trial. Nevertheless, preoperative SVS Duplex marking does not improve the clinical results of stripping, and in practical terms stripping does not require that surgeons have any Duplex experience. The homogeneity of the variables studied in the sample suggests that, despite hemodynamic data not being available for the S-CM group, that they are similar to the other 2 groups, S-DM and CHIVA. This assumption is based on the supposition that duplex imaging was not the decisive factor in the improved results seen in the CHIVA group, which have more to do with the ablation involved in stripping than the technological contribution of imaging.

Despite adding a second control group to the stripping group—the S-DM group—to even out the potential advantage of duplex imaging in the CHIVA process, CHIVA still shows better results. We believe that the CHIVA method preserves the SVS and its functions—as opposed to ablation, which is integral to stripping and probably other destructive techniques as well—and decreases the neogenesis induced by stripping,[4,6,37] creating a stable and hemodynamically adequate situation for skin and subcutaneous cellular tissue drainage. CHIVA's less aggressive surgical procedure, as compared with the 2 control groups, favors decreased complications, reduced convalescence and, no less important, the preservation of venous "capital," which may be needed for future arterial bypasses.[38–42]

The results obtained in our study were consistent with those published by Carandina et al.[25] The differences stem from the patients in their study, which treated VV as the equivalent of a type I+II shunt (Fig. 1), corresponding to 14.5% of all shunts in our study. Our study included all types of shunts, which confirm that CHIVA can be applied globally in patients affected by VV.

In our study, proper surgical execution was guaranteed by the experience of the surgeons—as evidenced by their training as angiologists and vascular surgeons, their years of surgical practice and the volume of patients treated per year. Nevertheless, the CHIVA cure demands significant training, principally in hemodynamic concepts, since the identification of shunts and strategy development with the help of duplex imaging—as well as the technical aspects of a CHIVA intervention—require a great deal of precision to produce a good result. Achieving good results with the CHIVA method is more demanding than stripping, homologous to other surgical methods, which have gone through the same process of scientific and technological adaptation, such as laparoscopic and endovascular surgical techniques. Nevertheless, if training in this method is not possible, a properly executed stripping intervention is better than a poorly executed CHIVA intervention, both with regard to strategic goals as well as surgical execution. Therefore, with the CHIVA method, treatment of VV joins the group of surgical treatments that have seen improvement results thanks to technological and scientific advances. Using these techniques entails ongoing training and adaptation of training programs for new specialists. The CHIVA

method is possible due to Duplex imaging technology and a new strategy of surgical treatment of VV: the opportunity to preserve the SVS with the use of hemodynamic concepts and the surgical treatment of shunts.

It is difficult to apply blinding to the evaluation of non-pharmaceutical randomized controlled trials (surgical, in this case) due to external signs of the intervention. In our study, the independent observer can determine, based on scars, only one type of intervention: the S-CM. In this group, the complete stripping of the GSV and/or SSV leaves a typical identifying scar on the ankle. In our study, no cases from the S-DM group needed complete stripping of the GSV and/or SSV. Therefore, an independent observer could identify the S-CM, but not the S-DM and CHIVA groups.

The fact that each treatment group was operated on by only one expert surgeon experienced with the technique used, as well as the fact that the study was conducted in a single center, increases the internal validity of the study. On the other hand, these benefits are limitations for external validity of the study, since this type of "optimal" treatment is not common in habitual clinical practice.

In conclusion, the results of this study indicate that CHIVA is a safe and effective method for the treatment of VV, in addition to being less surgically aggressive.

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