

Hemodynamic surgery *versus* conventional surgery in chronic venous disease; a multicenter retrospective study

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Aim. Chronic venous disease (CVD) is a common disease with a high prevalence in western countries. Standard open varicose vein surgery, usually sapheno-femoral junction ligation, great saphenous vein stripping and multiple phlebectomies, has been used to treat varicose veins for a long time. Within the last decade new alternatives to surgical treatment have been developed such as hemodynamic surgery. Aim of this study was to compare hemodynamic strategy versus standard open surgery.

Methods. A retrospective multicenter study, between 1994 and 2012, was conducted; 11026 patients (4051 M; 6975F) with CVD were surgically treated for their conditions (median age 45.5 years; age range 21-67); 6044 were treated with CHIVA procedure (Group A) and 4982 were treated with Stripping procedure (Group B). All patients were followed-up for the following parameters: pain; edema; ectasia; pigmentation; duplex ultrasound controls; recurrence rate.

Results. The median follow-up was 9 years for both groups. Duplex controls showed in Group A (CHIVA) respect to Group B (stripping), from the very beginning of follow-up, an optimal improvement of hemodynamic situation. Disappearance of symptoms and signs was more evident in Group B (stripping) compared to Group A (CHIVA) at the early follow-up. In the middle and in the late follow-up, a higher number of patients of Group A (CHIVA) showed an improvement of all symptoms and signs respect to Group B (stripping).

Conclusion. Hemodynamic surgery, compared to conventional surgery, seems to improve results improving clinical and instrumental conditions of treated patients reducing also recurrence of varicose veins.

KEY WORDS: Varicose veins - Surgical procedures, operative - Hemodynamics.

Chronic venous disease (CVD) is one of the most commonly reported medical conditions. The prevalence of varicose veins among individu-

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als younger than 30 years was <10% from men and for women; prevalence in men and women aged ≥70 years is 57% and 77 respectively.¹⁻⁷ The spectrum of CVD ranges from varicose veins to leg edema, and serious dermal manifestations consisting of hyperpigmentation, eczema, lipodermatosclerosis, and venous skin ulceration. CVD can be classified using CEAP classification.⁸ Skin changes are a result of sustained ambulatory venous hypertension and constitute an advanced form of CVD known as chronic venous insufficiency (CVI). Venous hypertension results from either valve dysfunction with venous reflux, venous thrombosis causing outflow obstruction, or a combination of the two processes. The persistent venous hypertension leads to an inflammatory response by leukocytes, which in turn initiates a cascade of cytokine activity. Various leukocytes mobilize in the dermis from stimulation of specific adhesion molecules on endothelial cells, and cytokines and metalloproteinases are expressed leading to cellular and tissue dysfunction resulting in dermal changes observed clinically in patients with CVI.^{3,9}

Strategies for therapeutic treatment may be surgical¹⁰ and conservative. In the past, several studies

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compared stripping to sclerotherapy in controlled trials of patients with saphenous truncal incompetence and found surgery to be more effective in the long term.^{11, 12} Stripping of incompetent saphenous trunks is considered to be the most appropriate management of varicose veins and CVD.¹³ However, in the last 22 years a number of attempts at conservative surgery for saphenous truncal incompetence have been reported.^{14, 15} These techniques resulted in similar outcomes compared to stripping operations. The Hemodynamic Correction procedure (CHIVA, Cure Conservatrice et Hemodynamique de l'Insuffisance Veineuse en Ambulatoire, [Ambulatory Conservative Hemodynamic Management of Varicose Veins]) was a new system to interpret the venous disease.^{16, 17} The aim of CHIVA was to maintain great saphenous vein (GSV) drainage eliminating reflux points with change of compartments.¹⁸⁻²⁰ CHIVA treatment can transform the varicose altered circulation in a drainage system in order to reestablish a certain functionality of the superficial venous system.²¹

Aim of this retrospective study is to show that the hemodynamic surgical procedure has a better functional results compared to the conventional stripping treatment.

Materials and methods

Institutional Review Board Approval was obtained. All patients provided written informed consent before study participation.

Fourteen thousand two hundred and thirty-three patients (males 4796, females 9437, age range 21-67, mean age 49 years) were treated and followed in 18 years period (1994-2012). The casuistry belonged

to three Clinical Departments of the Interuniversity Center of Phlebology: Catanzaro, Ferrara and Naples. Of the whole population of 14233 patients surgically treated for CVD (males 4796, females 9437), 11026 (77.47%; males 4051 and females 6975) the patients met the inclusion criteria given below in the text. Of the 11026 patients, 6044 were treated with CHIVA procedure (Group A) and 4982 were treated with Stripping procedure (Group B) (Table I).

Inclusion criteria were: ectasia apparent on standing, presence of pain, oedema, pigmentation, primary CVD of CEAP clinical classes 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, a minimum follow-up period of at least 6 months.

Exclusion criteria were: Previous surgical treatments for varicose veins, patients over 70 year old, patients affected by deficit of the calf muscular pump or unable to walk, patients affected by diabetes, autoimmune disease, malignancies, severe renal, hepatic and cardio-respiratory disease, patients with previous history of DVT, abnormalities of deep venous system (Table II).

In both procedures, a precise preoperative anatomical and hemodynamic mapping by Duplex ultrasound examination were performed.

All patients underwent elastic bandaging at the end of surgical procedure.

Follow-up parameters were:

- pain;
- edema;
- ectasia;

TABLE I.—Demographics of eligible patients.

Characteristic	Group A Patients treated with CHIVA	Group B Patients with Stripping
Sex	1996 M (33.02%)–4048 F (66.98%)	2055 M (41.24%) – 2927 F (58.75%)
Age range	21-67	21-67
Median age (years)	45	46.5
Overweight (BMI, 25-29.9 kg/m ²)		1374 (27.57%)
Obesity (BMI, ≥30 kg/m ²)	1755 (29.03%)	
Height ≥177.0 cm	3466 (57.34%)	3302 (66.27%)
Height ≤177.2 cm	2578 (42.65%)	1680 (59.81%)
Smoking	4235 (70.90%)	3802 (76.31%)
Family history for venous disease	3990 (66.01%)	3376 (67.76%)
Diagnosis median age (years)	21-67	21-67
Length of hospitalization (days, mean)	1	2.5
Total	6044	4982

TABLE II.—*Inclusion and exclusion criteria.*

Inclusion criteria	
—	Ectasia apparent on standing
—	Presence of pain, edema, pigmentation
—	Primary CVD of CEAP clinical classes 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
—	A minimum follow up period of at least 6 months
Exclusion criteria	
—	Previous surgical treatments for varicose veins
—	Patients over 70 years old
—	Patients affected by deficit of the calf muscular pump or unable to walk
—	Patients affected by diabetes, auto-immune disease, malignancies, severe renal, hepatic and cardio-respiratory disease
—	Patients with previous history of DVT
—	Abnormalities of deep venous system

- pigmentation;
- Duplex ultrasound controls;
- Recurrence.

No complications were observed in either groups.

In the postoperative management, CHIVA patients wore class 2 medical compression stockings above the knee for three weeks. In stripping patients limbs were bandaged to minimize bruising. Bandages were replaced with class 2 medical compression stocking above the knee 2 days after for the next 14 days. Patients were discharged from hospital on the day of surgery procedure and they were reviewed at 1, 6 and 12 months. Subsequently they were reviewed after 3 and 10 years to assess the outcome. Clinical and Duplex examination were performed at each visit.

Results

*The median follow-up was 9 years.

The length of hospital stay was 1 day for CHIVA patients *vs.* 2-3 days for Stripping patients.

In the beginning of the follow-up results that patients treated with stripping procedure were more satisfying than CHIVA because of rapid improvement of symptoms and signs and a good recovery of functionality of the treated limb. In fact, Table III shows a number of patients who manifest symptoms lower than in patients treated with CHIVA procedure.

In the middle and in the end of follow-up patients who were treated with CHIVA procedure showed a greater objective and subjective benefit.

Pain, edema and detectable venous ectasias were reduced in the first period in Stripping group; improvement of these parameters was minimal in CHIVA Group in the first period of follow-up (Table III).

In the middle and in the end of follow-up, a high number of patients of CHIVA Group showed a disappearance of all symptoms and signs; a lower number of patients only of stripping Group showed a disappearance of all symptoms, while in a high number of patients, pain and oedema did not disappear.

In both groups skin pigmentation was improved.

Duplex ultrasound controls showed in CHIVA patients, from the very beginning of follow-up, an optimal improvement of hemodynamic situation; Duplex ultrasound controls in stripping group showed alternated regions of normal and abnormal venous pressure and irregular disposition in tributary veins.

Recurrence of CVD was observed, at the end of follow-up, in 987 CHIVA patients (16.33%) compared to 1875 of Stripping patients (37.63%).

Contingency tables (Table IV) were used to record and analyze the relation between CHIVA and Stripping procedures and postsurgical outcomes; for each parameter of follow-up was made a contingency table. Odds Ratio (OR) and statistical significance (95% confidence interval [CI], P value) were calculated.

TABLE III.—*Results.*

	Pain	Oedema	Ectasia	Pigmentation	Duplex abnormalities	Recurrences
CHIVA						
Beginning of follow-up	1055 (17.51%)	825 (13.64%)	480 (7.94%)	603 (9.97%)	229 (3.78%)	314 (5.19%)
Middle follow-up	163 (26.96%)	295 (4.88%)	194 (3.21%)	401 (6.63%)	415 (6.87%)	555 (9.18%)
End of follow-up	104 (17.20%)	157 (2.59%)	147 (2.43%)	234 (3.87%)	221 (3.65%)	987 (16.33%)
STRIPPING						
Beginning of follow-up	1034 (20.75%)	302 (6.06%)	265 (5.32%)	354 (7.10%)	475 (9.53%)	539 (10.81%)
Middle follow-up	1015 (20.37%)	1298 (26.05%)	1105 (22.17%)	1533 (30.77%)	1455 (29.20%)	1181 (23.70%)
End of follow-up	1121 (22.50%)	1377 (27.63%)	1323 (26.55%)	1689 (33.90%)	1696 (34.04%)	1875 (37.63%)

TABLE IV.—*Contingency tables.*

	Stripping	CHIVA	Total
Pain +	1121	104	1225
Pain –	3861	5940	9801
Total	4982	6044	11026
P=0.00001, 95% confidence interval=13.51-20.35, Odds Ratio=16.53			
	Stripping	CHIVA	Total
Edema +	1377	157	1534
Edema –	3605	5887	9492
Total	4982	6044	11026
P = 0.00001, 95% confidence interval = 12.08 – 16.98, Odds Ratio = 14.32			
	Stripping	CHIVA	Total
Ectasia +	1323	147	1470
Ectasia –	3659	5897	9556
Total	4982	6044	11026
P=0.00001, 95% confidence interval=12.17-17.28, Odds Ratio=14.50			
	Stripping	CHIVA	Total
Pigmentation +	1689	234	1923
Pigmentation –	3293	5810	9103
Total	4982	6044	11026
P=0.00001, 95% confidence interval=4.74-5.61, Odds Ratio=5.16			
	Stripping	CHIVA	Total
Duplex abnorm. +	1696	221	1917
Duplex abnorm. –	3286	5823	9109
Total	4982	6044	11026
P=0.00001, 95% confidence interval=11.75-15.75, Odds Ratio=13.60			
	Stripping	CHIVA	Total
Recurrences +	1875	987	2962
Recurrences –	3107	5057	8164
Total	4982	6044	11026
P=0.00001, 95% confidence interval=2.83-3.38, Odds Ratio=3.09			

Discussion

Varicose veins of the lower limbs are dilated subcutaneous veins that are >3 mm in diameter measured in the upright position. Varicosity can involve the main axial superficial veins - the GSV or the small saphenous vein (SSV) - or any other superficial vein tributaries of the lower limbs.

Most varicose veins are due to primary venous disease.

The most frequent cause is likely an intrinsic morphologic or biochemical abnormality in the vein wall, although the etiology can also be multifactorial.²⁸

Varicosities can also develop as a result of secondary causes, such as previous deep vein thrombosis

(DVT), deep venous obstruction, superficial thrombophlebitis, or arterio-venous fistula. Varicose veins may also be congenital and present as a venous malformation.

Varicosities are manifestations of CVD. Venous disease has long been recognized as a progressive, debilitating, and recurrent problem. Varicose veins and venous ulcers can be a great financial burden to patients and to society. Varicose veins and associated complications may lead to chronic pain, disability, decreased quality of life (QOL), loss of working days, and early retirement.

The treatment of varicose veins has also undergone dramatic changes with the introduction of percutaneous endovenous ablation techniques, including endovenous laser therapy (EVLA),²⁸ radiofrequency

ablation (RFA),²⁹ and liquid or foam sclerotherapy.³⁰ Open surgical treatment with stripping of the varicose veins performed under general anesthesia, with the associated pain, potential for wound complications, and loss of working days, has been largely replaced by percutaneous office-based procedures that can be performed under local or tumescent anesthesia with similar early and midterm results but with less discomfort to the patient, improved early QOL, and earlier return to work. Saphenous vein stripping is a simple, fast procedure: it involves the interruption of the sapheno-femoral junction, stripping of the GSV, removal of the tributary vein of saphena and ligation of tributary perforating veins. CHIVA maintain the integrity of the superficial venous system: it interrupts hydrostatic pressure responsible for reflux, eliminating shunts.^{16, 31-32} In CHIVA, the surgeon identifies shunts, or abnormal flow between vein compartments (such as between deep and superficial, or saphenous and tributary) with combined reflux and reentry resulting in a blood flow loop. These loops can be diagnosed by ultrasound mapping. Physician thus can interrupt the blood column at the origin of reflux by flush ligation, and preserve reentry points to decrease varicose recurrence.

Conclusions

This study was carried out on a large population. It showed that the hemodynamic surgery is not only less invasive and better accepted by the patient compared to the standard procedure, but it allows also to obtain excellent results both functionally and clinically.

Riassunto

Chirurgia emodinamica versus chirurgia convenzionale nella malattia cronica venosa: uno studio multicentrico retrospettivo

Obiettivo. La malattia venosa cronica è una patologia molto comune con una elevata prevalenza nei paesi occidentali. Le procedure chirurgiche tradizionali come la crossectomia, lo stripping della vena grande safena e le flebectomie multiple vengono utilizzate da molto tempo. Negli ultimi decenni sono comparsi trattamenti chirurgici alternativi quali la chirurgia emodinamica. Scopo di questo lavoro è quello di comparare l'approccio chirurgico tradizionale con il trattamento emodinamico.

Metodi. È stato condotto uno studio retrospettivo multicentrico nel periodo 1994-2012; 11026 pazienti (4051M, 6975F) sono stati sottoposti a trattamento chirurgico per malattia venosa cronica; 6044 pazienti sono stati trattati con procedura CHIVA e 4982 sono stati trattati mediante stripping. Tutti i pazienti sono stati seguiti e valutati in base ai seguenti parametri: dolore, edema, ectasia, pigmentazione cutanea, controlli ultrasonografici, tasso di recidiva.

Risultati. Il follow-up mediano è stato di 9 anni per entrambi i gruppi. I controlli ultrasonografici hanno mostrato migliori risultati, nel senso di miglioramento del quadro emodinamico, fin dall'inizio del follow-up, a favore del gruppo A (CHIVA) rispetto al gruppo B (stripping). La scomparsa dei sintomi e dei segni, invece, era più evidente nel gruppo B (stripping) rispetto al gruppo A (CHIVA) all'inizio del follow-up. Nel follow-up intermedio e tardivo segni e sintomi miglioravano più marcatamente nel gruppo A (CHIVA) rispetto al gruppo B (stripping).

Conclusioni. La chirurgia emodinamica, a confronto con la chirurgia convenzionale, sembra avere risultati migliori sia dal punto di vista clinico che strumentale riducendo, inoltre, la comparsa di recidive.

PAROLE CHIAVE: Vene varicose - Trattamento chirurgico - Emodinamica.

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