

Great Saphenous Vein Stripping Versus Haemodynamic Correction (A Prospective Randomized Comparative Study)

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ABSTRACT

Introduction: Interventional treatment of superficial venous incompetence can be accomplished by techniques that result in removal, ablation, or ligation of the refluxing venous segment. Current options include high ligation, ligation and stripping, endovascular ablation, sclerotherapy, and phlebectomy. The detailed duplex studies of Labropoulos and others challenged this theory and supported an "ascending" cause of varicose veins, which is initiated in the "distal superficial venous network."^[1] . Two groups of procedures accomplish this approach: CHIVA (Cure Conservatrice et hemodynamique de l'Insuffisance Veineuse en Ambulatoire) and ASVAL (Ambulatory Selective varices Ablation) techniques^[2]. **Patients and Methods:** Fifty six (56) patients who had been referred to the vascular outpatient clinic of our department at Kasralainy teaching hospitals for management of their chronic venous insufficiency (CVI) in the period between July 2014 to December 2015. Patients presenting with CVI of the great saphenous vein (GSV) were randomized and treated with stripping or CHIVA. Patients were consented to follow up over an extended period in order to detect recurrence during 1 year period following treatment. **Results:** Thirty patients were treated with CHIVA technique and 26 were treated by Trendelenberg and stripping. Both Hobb's objective score and subjective score differences between CHIVA and stripping at 1, 3 and 6 were not statistically significant, but were significant at 12 months (p value 0.0242) and (p value 0.0171) respectively. Five patients of the CHIVA group had subjective score 3 all of which recurrences were confirmed by duplex study. Only one patient in the stripping group had 3 which did not correlate clinically with the objective score or by duplex examination. There was no recurrence in the stripping group. There were different patterns of recurrence in the CHIVA group. **Conclusion:** Haemodynamic surgery for the treatment of varicose veins has been highly debated and frequently rejected because of being remote from traditional surgery. CHIVA is safe and effective in the treatment of varicose veins in addition to preserving the GSV for drainage and being less surgically invasive. Nevertheless, the CHIVA cure demands significant training, principally in hemodynamic concepts, since the identification of shunts and technical aspects of a CHIVA intervention require a great deal of precision to produce good results. Nevertheless if that knowledge and training are not acquired, a properly executed stripping intervention is better than a poorly executed CHIVA intervention, both regarding strategic goals and surgical execution. Duplex documented recurrence is much higher in CHIVA group as compared to stripping group on the short term (1 year). Patterns of recurrence in CHIVA are easily managed by phlebectomy or foam injection CHIVA oriented sclerotherapy.

Keywords: stripping , hemodynamic venous surgery , nonablative treatment of varicose veins , CHIVA.

INTRODUCTION

Varicose veins have been recognized since the advent of recorded history, and manifestations of CVI, including edema and ulceration, since biblical times. The use of compression therapy dates back to Roman times, with foot soldiers using tight wraps to reduce discomfort induced by prolonged standing^[3] .

Modern understanding of CVI pathophysiology arose with the work of Brodie and Trendelenberg in the 1850s and 1890s

describing superficial and deep venous reflux. Trendelenberg was the first to introduce surgery for varicose veins marking the beginning of modern vascular surgery for this problem^[3]

Interventional treatment of superficial venous incompetence can be accomplished by techniques that result in removal, ablation, or ligation of the refluxing venous segment. Current options include high ligation, ligation and stripping, endovascular ablation, sclerotherapy, and phlebectomy.

Routine use of duplex ultrasound to map flow dynamics within the great and small saphenous veins, as well as in associated varicosities, has led to the development of hemodynamic-based “saphenous-sparing operations” which challenge the hypothesis, initially presented by Trendelenberg, that an incompetent saphenous vein is the cause of varicosities due to reflux at the saphenofemoral or saphenopopliteal junctions where incompetence in the saphenous vein descends from proximal to distal, then outward to superficial varicosities [2]

The detailed duplex studies of Labropoulos and others challenged this theory and supported an “ascending” cause of varicose veins, which is initiated in the

“distal superficial venous network.” [1]. Two groups of procedures accomplish this approach: CHIVA and ASVAL techniques [2].

Originated in France, CHIVA gained popularity in southern Europe and although its small number of practitioners it continues to draw attention. It critically assesses the current state of knowledge in physiology and pathophysiology of venous circulation in lower extremities, and identifies areas where new or stronger evidence is required [4].

The principles of CHIVA treatment were first introduced by Claude Franceschi in 1988. CHIVA acts by reducing the hydrostatic pressure, and it is done by fractionating the column of blood and disruption of veno-venous shunts within the superficial system thus preserving draining of superficial network [5].

PATIENTS AND METHODS

Patient population

Fifty six (56) patients who had been referred to the vascular outpatient clinic of our department at Kasralainy teaching hospitals for management of their chronic venous insufficiency CVI in the period between July 2014 to December 2015. Patients underwent clinical examination including CEAP classification (clinical, etiological, anatomical and pathophysiological) and duplex ultrasonography undertaken by an expert radiologist.

Patients were consented to follow up over an extended period in order to detect recurrence during 1 year period following treatment.

Patients presenting with CVI of the great saphenous vein (GSV) were randomized and treated with stripping or CHIVA. Thirty (30) patients presenting with primary CVI of GSV complaining of heaviness and disfigurement were treated with CHIVA strategy. Twenty six (26) patients presenting with primary CVI of the GSV complaining of heaviness and disfigurement were treated with Trendelenberg and stripping of the GSV.

Patients over 75 years old, patients affected by deficit of the calf muscular pump or unable to walk, patients affected by auto-immune diseases, severe renal, hepatic and cardio-respiratory diseases were excluded from the study because intact valvulomuscular pump in the lower limb is crucial to the success of hemodynamic surgery.

Preoperative mapping was drawn on the skin with the aid of duplex ultrasonography in order to identify the points where superficial veins had to be interrupted. The ultrasonographic image of the so called “saphenous eye” is used to identify the saphenous trunk and differentiate it from superficial accessory veins. The private circulation is illustrated both on diagrams and written reports with colored markings over the patient’s skin. The point of reflux (escape point), refluxing superficial vein, and re-entry perforator are also demonstrated.

Stripping procedure

In this group of patients the surgical treatment employed included: flush saphenofemoral ligation, GSV stripping below or above the knee, multiple phlebectomies of the tributaries. All the surgical procedures were performed under general or regional anesthesia.

CHIVA strategy

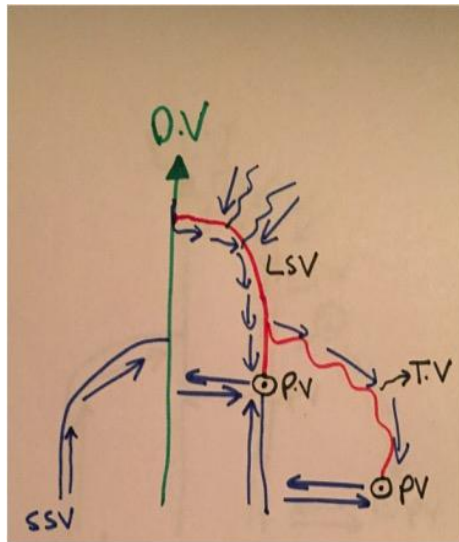
According to the CHIVA strategy we performed haemodynamic correction according to the type of shunt shown upon duplex examination. Finger compression test was used to differentiate between type 1 and type 3 shunts as shown in (Fig 1) in which finger compression on TV (tributary vein) results in reflux elimination and resuming normal antegrade flow in the SFJ and GSV (LSV), in type 3 shunt while in type 1 shunt the reflux continues down the SFJ and GSV to a PV (perforator vein) along the GSV. Duplex images showing the reflux elimination test in type 3 shunts is shown in figures 3 and 4. Type 1 shunts were managed by flush ligation of the varicosed tributaries from the GSV or SSV plus

saphenofemoral junction (SFJ) disconnection above the drainage of the upper tributaries of the GSV (Fig 2). In type 3 shunts only flush ligation of the varicosed tributaries from the GSV or SSV was done (Fig 5).

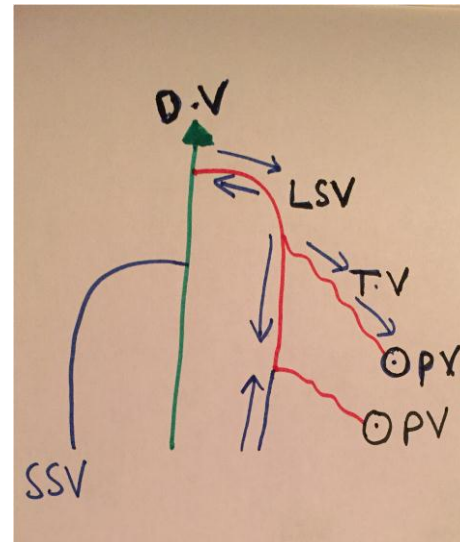
Short phlebectomies (1 to 4 cm) associated with nonabsorbable ligation and nonabsorbable

closure of the perforated fascia seems to be the most precise, efficient, and long lasting method to date.

Absorbable venous ligation after phlebectomy could favor recanalisation due to inflammatory angiogenetic effects which occurred with the very first cases and was the main pattern of recurrence.



A(type 1)



B(type3)

Fig. (1): Type of shunt identification by finger compression test. A: in type 1 shunt finger compression on all refluxing tributaries did not eliminate reflux in the SFJ. B: type 3 shunt , finger compression on all refluxing tributaries eliminates reflux in the SFJ. [6]

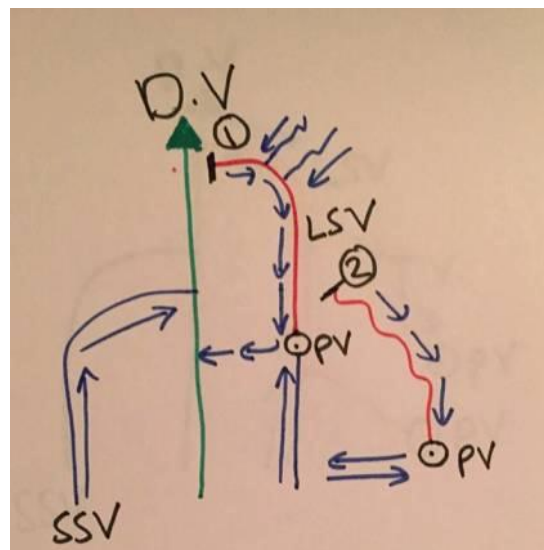


Fig. (2): CHIVA treatment of type 1 shunt. Point 1 is SFJ disconnection without trendelenberg. Point 2 is flush disconnection of the refluxing tributary from the GSV. [6]

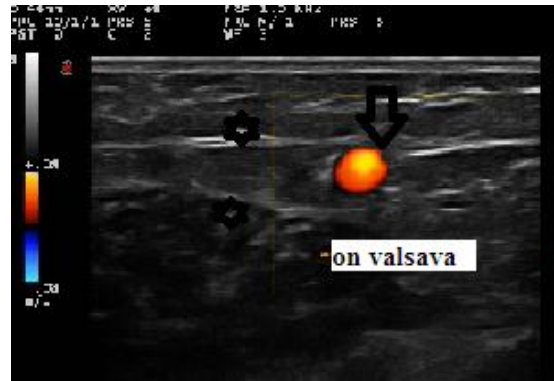


Fig.(3): Color Duplex image showing refluxing great saphenous trunk (within the saphenous compartment between the black asterisks) coded in red color (the black open arrow).

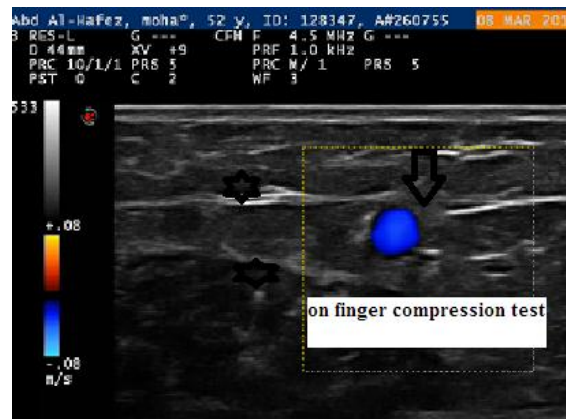


Fig. (4): Color Duplex image for the same venous segment showing restoration of the normal antegrade flow (reflux correction) in the main trunk of the great saphenous trunk (within the saphenous compartment between the black asterisks) coded in blue color (the black open arrow).

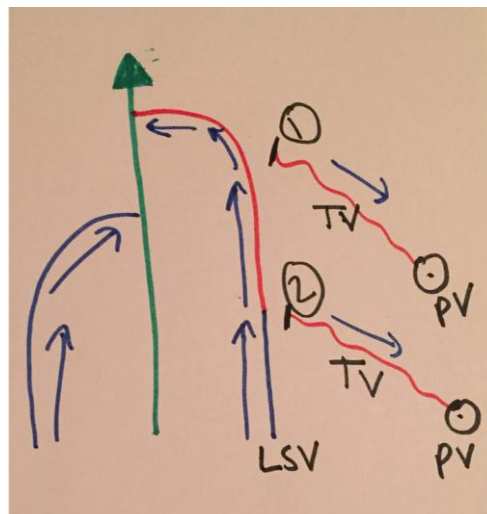


Fig. 5: CHIVA treatment of type 3 shunts . points 1 and 2 represents points of ligation of the refluxing tributaries without SFJ ligation.^[6]

Following treatment, CHIVA patients wore class 2 medical compression stockings above the knee for 1 month. Limbs which had been treated by saphenous stripping were bandaged to minimize bruising. Bandages were replaced with class 2 medical compression stockings above the knee after 1 week and then worn for 1 month. Patients were usually discharged from hospital on the day of surgery or the next day. Patients were reviewed in the outpatient clinic 2 to 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, 3, 6, 12 months, to assess the outcome of these treatments. Clinical examination was performed and patients with objective or subjective score 3 or 4 underwent ultrasound examination to assess for recurrence. Patients with C4-C6 CEAP classification were advised to wear compression stockings indefinitely.

Clinical assessment of surgical results was done by Hobbs score.

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.

In addition, functional and cosmetic results were self assessed by patients at the time of examination in Hospital. This used a simple scoring system which was explained to patients by the examiner. 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 was 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

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

1. Class C and D of the objective Hobbs score.
2. Class C and D subjective score

Recurrence was an indication for duplex ultrasonography with the presence of reflux with a demonstrable escape point and change of compartment (for example: saphenofemoral junction, perforators, pelvic shunts, and, finally tributaries fed by the saphenous trunk).

Patterns of recurrence

1. Pattern 1: saphenofemoral recurrence.
2. Pattern 2: recurrence from incompetent perforators or veins not present at site of initial duplex examination.
3. Pattern 3: reflux from proximal saphenous vein to varicose tributary.
4. Pattern 4: reflux from a previously ligated point by angiogenesis.
5. Pattern 5: reflux from varicose veins with no demonstrable escape points.

Management of recurrence Reflux was managed either surgically or duplex guided CHIVA oriented foam injection sclerotherapy using 0.5-1% polidocanol (Aethoxysclerol).

RESULTS

I. CHIVA versus Stripping

30 patients presenting with primary CVD of GSV were treated with CHIVA strategy. 26 patients presenting with primary CVD of the GSV were treated with Trendelenberg and stripping of the GSV. The demographic data of the patients is shown in table 1. The CEAP scores are shown in table 2.

Table 1: Demographics of the patients

	<i>CHIVA</i>	<i>Stripping</i>
Age	31.27 ± 9	37.04 ± 8
Sex	16 males and 14 females	15 males and 11 females

Table 2: CEAP presentation of patients

	<i>CHIVA</i>	<i>Stripping</i>	<i>Total</i>
C2	22 (73.3%)	23 (88.5%)	45
C3	4 (13.3%)	2 (7.7%)	6
C4a	1 (3.3%)	0 (0%)	1
C4b	2 (6.6%)	0 (0%)	2
C5	1 (3.3%)	0 (0%)	1
C6	0 (0%)	1 (3.8%)	1
Total	30 (100%)	26 (100%)	56

Five cases in the stripping group required adjunctive injection sclerotherapy for better cosmetic outcome while 4 cases in the CHIVA group required reintervention and a second surgical procedure only 1 case in the CHIVA required a third intervention.

The Hobb's objective scores of both CHIVA and stripping are shown in tables 3 and 4, while the subjective scores of both CHIVA and stripping are shown in tables 5 and 6.

Table 3: Hobb's score of CHIVA group of patients

	<i>1</i>	<i>2</i>	<i>3</i>	<i>4</i>	<i>Total</i>
1 month	24(80%)	5(16.7%)	1(3.3%)	0(0%)	30(100%)
3 months	25(83.3%)	5(16.7%)	0(0%)	0(0%)	30(100%)
6 months	21(75%)	7(25%)	0(0%)	0(0%)	28(100%)
1 year	16(66.6%)	6(25%)	1(4.2%)	1(4.2%)	24(100%)

Table 4: Hobb's score of Stripping group of patients

	<i>1</i>	<i>2</i>	<i>3</i>	<i>4</i>	<i>Total</i>
1 month	20(76.9%)	6(23.1%)	0(0%)	0(0%)	26(100%)
3 months	20(76.9%)	6(23.1%)	0(0%)	0(0%)	26(100%)
6 months	22(84.6%)	4(15.4%)	0(0%)	0(0%)	26(100%)
1 year	23(88.5%)	3(11.5%)	0(0%)	0(0%)	26(100%)

Table 5: Subjective score of CHIVA group of patients

	<i>1</i>	<i>2</i>	<i>3</i>	<i>4</i>	<i>Total</i>
1 month	20(66.7%)	10(33.3%)	0(0%)	0(0%)	30(100%)
3 months	24(80%)	6(20%)	0(0%)	0(0%)	30(100%)
6 months	20(71.4%)	6(21.4%)	2(7.1%)	0(0%)	28(100%)
1 year	16(66.7%)	3(12.5%)	5*(20.8%)	0(0%)	24(100%)

Table 6: Subjective score of stripping group of patients

	<i>1</i>	<i>2</i>	<i>3</i>	<i>4</i>	<i>Total</i>
1 month	17(65.4%)	8(30.8%)	0(0%)	1(3.8%)	26(100%)
3 months	19(73.1%)	6(23.1%)	1(3.8%)	0(0%)	26(100%)
6 months	19(73.1%)	6(23.1%)	1(3.8%)	0(0%)	26(100%)
1 year	20(77%)	5(19.2%)	1(3.8%)	0(0%)	26(100%)

Hobb's objective score differences between CHIVA and stripping at 1, 3 and 6 was not statistically significant at 1month (p value 0.556), 3 months (p value 0.547), 6 months(p value

0.381) but was significant at 12 months (p value 0.0242).

Comparison between CHIVA and Stripping regarding subjective assessment to compare recurrence between both groups at 1month (p

value 0.553), 3 months (p value 0.521), 6 months (p value 0.867) was not statistically significant while at 12 months (p value 0.0171) was statistically significant. Five patients of the CHIVA group had subjective score 3 at 1 year follow up all of which recurrences were confirmed by duplex study. Only one patient in the stripping group had score of 3 which did not correlate clinically with the objective score or by duplex examination.

There was no recurrence in the stripping group. There were different patterns of recurrence in the CHIVA groups shown in table 7.

Table 7. Patterns of recurrence in CHIVA group

Types	Number of cases
Type 1	0
Type 2	1
Type 3	3
Type 4	5
Type 5	0

Complications in both groups are shown in table 8.

Table 8. Complications of both procedures

CHIVA	
Wound infection	1
Superficial thrombophlebitis	1
Hematoma	1
Stripping	
Neuralgia	11
Ecchymosis	20
Infection	5
Hematoma	2

All patients in the stripping group were anaesthetized by regional anaesthesia while in the CHIVA group 10 of the 30 patients were done by local anaesthesia and the others by regional anaesthesia.

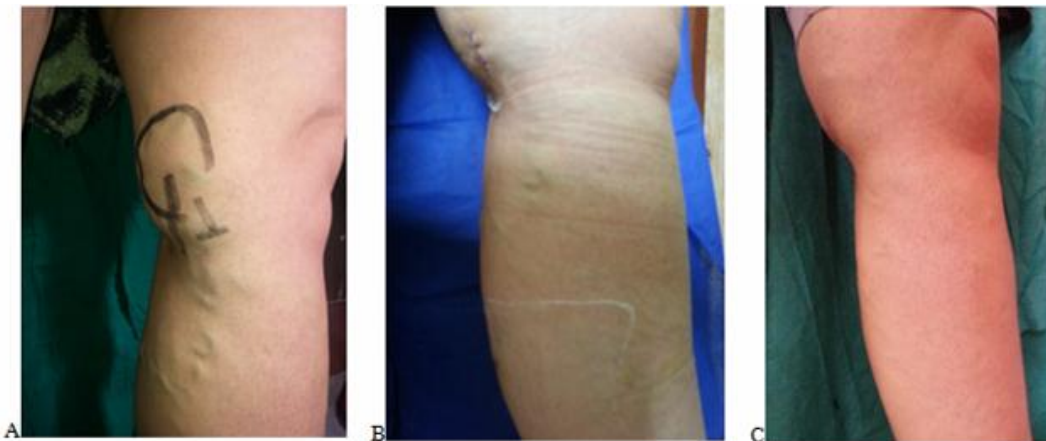


Fig. 6: A case of primary varicose veins treated by CHIVA

DISCUSSION

Originated in France, CHIVA gained popularity in southern Europe and although its small number of practitioners it continued to draw attention. It supports an “ascending” cause of varicose veins, which is initiated in the “distal superficial venous network” challenging the hypothesis, initially presented by Trendelenberg, that an incompetent saphenous vein is the cause of varicosities due to reflux at the saphenofemoral or saphenopopliteal junctions^[3].

The present study compares the CHIVA strategy with a standard surgical technique which is Trendelenberg and stripping.

As regards the outcome data, it has been found that in the immediate postoperative period the patients’ cosmetic satisfaction was significantly better in the stripping group compared to cases with CHIVA without phlebectomy, this is due to the time taken by the varicosed veins to involute and return to their original size but the pain, swelling, ecchymosis and neuralgia were limited to the stripping group only. We have found it mandatory to inform the

patients that the varicose veins will take some time to disappear especially if disfigurement was the main complaint of the patient. Also in the later cases where phlebectomy was added ; it improved very much the initial cosmetic outcome as well as prevented early recurrences.

During 1, 3 and 6 months follow up, there was no statistical significance in the cosmetic outcome both by the hobb's objective score and the subjective score. Hobb's objective score differences between CHIVA and stripping at 1, 3, 6 months was not statistically significant at 1month (p value 0.556), 3 months (p value 0.547), 6 months (p value 0.381)

But at 1 year , clinically detectable recurrence (which was confirmed by duplex) in CHIVA group was significantly higher(20%) compared to no recurrences in stripping group,

Duplex analysis of the recurrences identified three different haemodynamic patterns of recurrence. The most common was type 4 due to recanalization of a previously ligated escape point as shown in 1 of our cases in figure 7. Prevalence of this type of recurrence is most probably due to improper surgical disconnection at the escape points in the early few cases and could be reduced by venous short resection (1 to 4 cm) and ligation by nonabsorbable suture material.

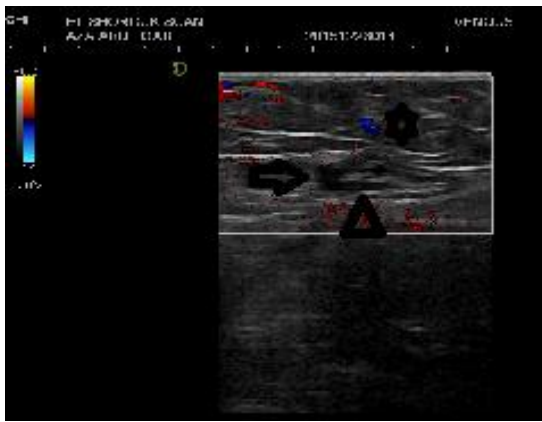


Fig. 7: Color Duplex image for post operative patient showing neoangiogenesis of the previously ligated escape point in terms of minute intra compartmental small venous channels (black arrow head) arising from the main trunk of the great saphenous trunk (the horizontal black open arrow). Note the echogenic vertically oriented subcutaneous scar (black asterisk).

The second most common is type 3 due to reflux in the GSV to a new proximal tributary. This pattern is certainly avoided in the stripping group as the GSV is already removed. Recurrence of this type is easily managed by ligation and/or phlebectomy under local anesthesia or foam injection sclerotherapy.

In the stripping group of *Carandina et al.* the recurrences were caused exclusively by pattern 5, whereas in the CHIVA patients they were attributable to pattern type three ^[7]. Type 5 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. In the later cases where we added phlebectomy to CHIVA techniques this is called (Ambulatory Selective varices Ablation) (ASVAL) , there were no early recurrences in these cases.

We conclude that both stripping and CHIVA are associated with similar recurrence rate on the long term but CHIVA is associated with earlier recurrence and the recurrences are usually less severe than those associated with stripping and more easily treated than stripping associated recurrences, furthermore, it has been shown by many that venous ulcers and more severe CVI can develop in stripping patients in the long term but not in CHIVA due to saphenous preserving nature of the chiva procedure.

In contrast, Results published by *Carandina et al.* in 2007 showed that 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 ^[7]. Also results published by *Parés et al.* in 2010 showed that ultrasound confirmed recurrence in CHIVA at five years of follow up was less than stripping ^[8]. *Parés et al.* in 2010 ^[8] confirmed the data published by *Carandina* ^[7] in his randomized controlled trial containing CHIVA arm and 2 control groups: stripping with clinical marking and stripping with duplex marking. The clinically evaluated recurrence results at 5 years of follow up were better in the CHIVA group (44.3% cure, 24.6% improvement, 31.1% failure) than in stripping with duplex marking group (29.3% cure, 22.8% improvement, 47.9% failure).

The controversy of results between this study and other published results may be due to that CHIVA needs a longer learning curve and thoroughly knowledge of venous hemodynamics,

a competent duplex ultrasonographer, capability of both the surgeon and the duplex ultrasonographer to analyse different patterns of varicose veins shunts before the operation.. We have found that the cosmetic outcome and recurrences were better in the later cases due to refinements in the technique and the continuous feedback with the duplex operator that improved the mapping procedure and minimizing errors in mapping and proper execution of the procedure.

Local tumescent anaesthesia was used only in one third of cases (n=10) of this study , it was found to be associated with less postoperative pain and ecchymosis , earlier ambulation and discharge from hospital as was confirmed by many authors as keel et al in 1999 ^[9] and smith et al in 1998 ^[10]

Correctly performed CHIVA offers a better option for treating varicose veins in the long-term even if in the short term stripping is slightly better. 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 analyzing patterns of varicose veins by duplex ultrasonography undertaken before the operation.

CONCLUSION

Haemodynamic surgery for the treatment of varicose veins has been highly debated and frequently rejected because of being remote from traditional surgery. The continued difficulty in the acceptance and widespread use of this treatment is due to lack of information on its principles, difficulty in learning the strategy and lack of data supporting its results.

CHIVA is safe and effective in the treatment of varicose veins in addition to preserving the GSV for drainage and being less surgically invasive. Nevertheless, the CHIVA cure demands significant training, principally in hemodynamic concepts, since the identification of shunts and technical aspects of a CHIVA intervention require a great deal of precision to produce good results. Achieving good results with CHIVA 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 techniques. Nevertheless if that knowledge and training are not acquired, a properly executed

stripping intervention is better than a poorly executed CHIVA intervention, both regarding strategic goals and surgical execution.

Duplex documented recurrence is much higher in CHIVA group as compared to stripping group on the short term (1 year). Patterns of recurrence in CHIVA are easily managed by phlebectomy or foam injection CHIVA oriented sclerotherapy.

Further follow up for long term periods (10 years or more) is required as most trials show no statistical difference between both CHIVA and stripping on short term results (1-3) years.

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