

Great Saphenous Vein Stripping versus Hemodynamic Correction (CHIVA) in Treatment of Varicose Veins of Great Saphenous Venous System

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ABSTRACT

Background: The CHIVA (Cure Conservatrice et He'modynamique de L'Insuffisance Veineuse en Ambulatoire, Ambulatory Conservative Haemodynamic Management of Varicose Veins) technique has appeared at the decade of eighties of the last century. It has been identified to be an attractive method for the treatment of lower limb varicosities, in spite of the little number of surgeons skilled at this procedure at its beginning. The CHIVA has been continuing to be more effective although the huge revolution of the more recent modalities for the treatment of varicosities. This relatively new procedure depends in its management of varicose veins on the reversion of the venous blood flow to its normal hemodynamic state at both deep and superficial systems via breaking all types of venous shunts at the escape points within the different compartments. **Subject and Methodology:** 60 patients from those attended the outpatient departments of general surgery complaining from chronic venous disease (CVD) or varicose veins were randomly arranged into 2 groups 30 cases in each group; group I were subjected to (CHIVA) and group II to high ligation and stripping (HLS). They were assessed according to the CEAP clinical classification and ultrasonic duplex scanning. CHIVA operation was performed under local anesthesia while the stripping under spinal or general anesthesia. This study has been carried out at the general surgery department in Fayoum University Hospital (FUH) in the period from May 2015 to September 2017. Cases were reviewed regularly at the outpatient clinic for 24 months to assess recurrence rates and complications at both groups; data were recorded and statistically analyzed. **Results:** The recurrence occurred at 5/30 and 0/30 at CHIVA and HLS respectively. Regarding the aesthetic satisfaction of the patient, the stripping was better; 27/30 in contrast to 21/30, while the investigator satisfaction was more or less equal; 22/30 for stripping and 23/30 for CHIVA. The wound infection was 1/30 in each group. Nerve damage, bruises and superficial venous thrombosis were found to be 0/30, 8/30 and 0/30 in CHIVA group, while at the stripping group were 3/30, 16/30 and 1/30 respectively. **Conclusion:** CHIVA is safe, less invasive, effective and if done properly it lead to complete cure. Also properly carried out stripping is much more beneficial to patients than poorly performed CHIVA procedure.

Keywords: Varicose veins surgery, CHIVA, Venous stripping.

INTRODUCTION

Varicose vein VV disease is a chronic, gravity dependent condition, which affects approximately one third of adults⁽¹⁾. It is characterized by the slow, progressive onset of symptoms such as visible varicosities, edema, pain or discomfort, itching, and a sensation of heaviness in the affected limbs⁽²⁾. Primary VV is often caused by valvular incompetence resulting in reflux of blood into the superficial system of veins and impaired antegrade venous return to the central circulation. The pooling, veno-venous shunting and venous hypertension lead to chronic venous disease (CVD) and the development of distended and tortuous leg veins⁽¹⁾.

The most advanced form of CVD, properly named as Chronic Venous Insufficiency (CVI). It accounts for 20% of CVD at elderly patients and can progress to chronic venous ulcer which represents 70% of all lower limb ulcers and lead to decreased quality of life (QOL) and significant economic burden⁽²⁾. Healing times are often protracted, sometimes taking many years, with some ulcers failing to heal⁽³⁾.

While there is a wide range of modalities for the treatment of VV the most common method(s) utilize a technique that completely ablates the greater saphenous vein⁽⁴⁾. Conventionally, the open surgical treatment of varicose veins has been performed via high saphenofemoral ligation and stripping of the great saphenous vein (GSV) to just below the knee (HLS). However recurrence

of varicose veins postoperatively is still a significant issue of the open surgical management. The recurrence rate at five years postoperative is ranging between 20% and 28%⁽⁵⁾.

Liquid sclerotherapy causes an inflammatory reaction and consequent venous occlusion. Foam sclerotherapy is a modification of liquid sclerotherapy in which the liquid is transformed into foam by mixing it with air or other gas, such as oxygen or carbon dioxide. Foam sclerotherapy is a potential treatment for all categories of venous disease. Comparing Stripping to sclerotherapy in controlled trials of patients with saphenous truncal incompetence found surgery to be more effective in the long term^(6,7).

Endovenous Laser Therapy/Ablation (EVLT/EVLA) is a recent less invasive method for management of refluxing veins done in an outpatient setting using local anesthesia. The safety of EVLT and its early results postoperative seem to be considerably competitive with those of traditional surgery⁽⁸⁾.

The CHIVA technique has been developed through the last two decades and is currently the second most common surgical procedure superseded by saphenectomy for the operative management of CVI. This method is a therapy fashioned individually for the patients according to the haemodynamic condition implemented in the venous insufficiency, besides preserving the saphenous axis⁽⁹⁾.

CHIVA can be achieved via open surgery or via endovascular procedures including laser, radiofrequency or sclerotherapy. Its rationale is to modify the hemodynamic between the deep and superficial venous systems to eradicate venous dilations and to preserve the great saphenous vein for future grafting purposes. Results revealed that CHIVA diminishes the diameter of the saphenous vein (from 2.6 to 1.6 cm) and the femoral vein (from 0.7 to 0.4cm)⁽¹⁰⁾.

This approach relies on careful venous duplex assessment to gain a detailed knowledge of the anatomical and haemodynamic characteristics of individual patients. In CHIVA, the aim is to maintain the superficial venous system, altering the venous hemodynamics to promote more efficient drainage into the deep venous system. Consequentially not only less invasive procedure will be performed instead of traditional HLS, but as well preserving the GSV for possible future grafting and maintaining the normal anatomy of

the superficial and deep venous system of lower limbs^(1,11).

The aim of this study is to evaluate the safety and efficacy of the standard CHIVA procedure in patients with varicose veins related to the great saphenous vein or the saphenofemoral junction and comparing this safety and efficacy with that of HLS procedures.

PATIENTS AND METHODS

Between May 2015 and September 2017, 71 patients sought medical advice at the general surgery outpatient clinic at Fayoum University Hospital for management of their CVD. Informed consent was obtained from all patients.

All patients were subjected to clinical assessment including CEAP clinical classification and duplex ultrasonographic scan. All patients presented with varicose veins of GSV system and complaining from heaviness, pain, edema, pigmentation, disfigurement and / or ulceration were selected and randomized between two groups of treatment; **Group 1**, included 30 patients, treated with CHIVA strategy, **Group 2**, included 30 patients treated with HLS of GSV.

Inclusion criteria were patients with primary varicose veins with CEAP clinical class (2-6), those with patent and competent deep venous system of both lower limbs, duplex findings showing presence of SFJ reflux and incompetence of GSV trunk, and at least one re-entry perforator on the GSV trunk or at least one incompetent tributary of the GSV.

Exclusion criteria were patients over 75 years, or those unable to walk or with deficit calf muscular pump, and patients with previous history of DVT or patients with a previous history of surgery or other non-operative treatment modalities of varicose veins.

A preoperative duplex scanning will be done in order to identify the points where the superficial veins will have to be ligated or interrupted. The ultrasonographic characteristic sign of the so-called "saphenous eye" is a precise constant and mandatory clue clearly demonstrable in a transverse ultrasound scan image of the GSV in the thigh and calf. This appearance will be used to locate the saphenous trunk and differentiating it from superficial accessory saphenous veins. Fig (1)

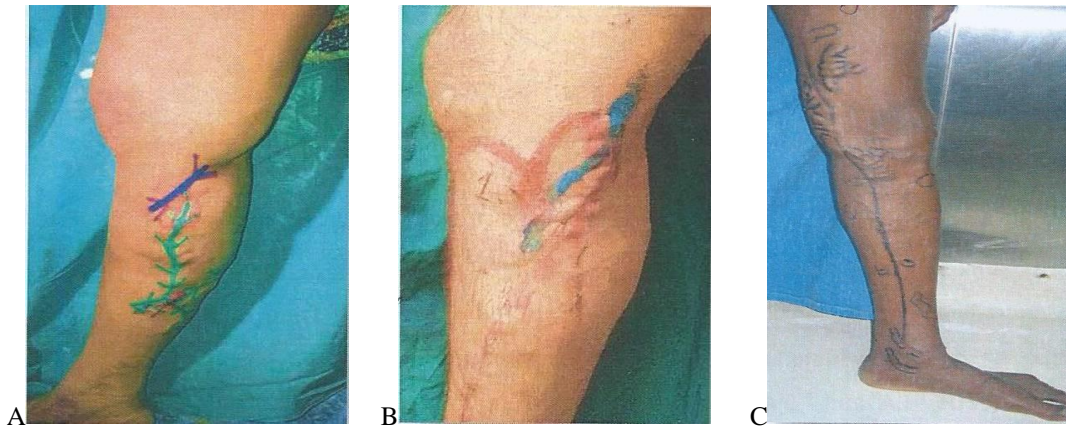


Fig. (1): A,B) Examples of skin marking after duplex examination just the day prior to the procedure. C) Duplex ultrasound venous mapping

The points of reflux (escape points), refluxing superficial veins an re-entry perforating veins are also delineated and colored markings over the patient's skin.

Appraisal criteria included; operative difficulties, type of anesthesia, hospital stay, cost effectiveness of both procedures in addition to primary and secondary outcomes of both

procedures including recurrence rate and postoperative complications.

Surgical techniques:

According to the CHIVA strategy we performed haemodynamic correction type 1 and type 2 which was done according to the type of shunt shown upon duplex examination. Fig(2,3)

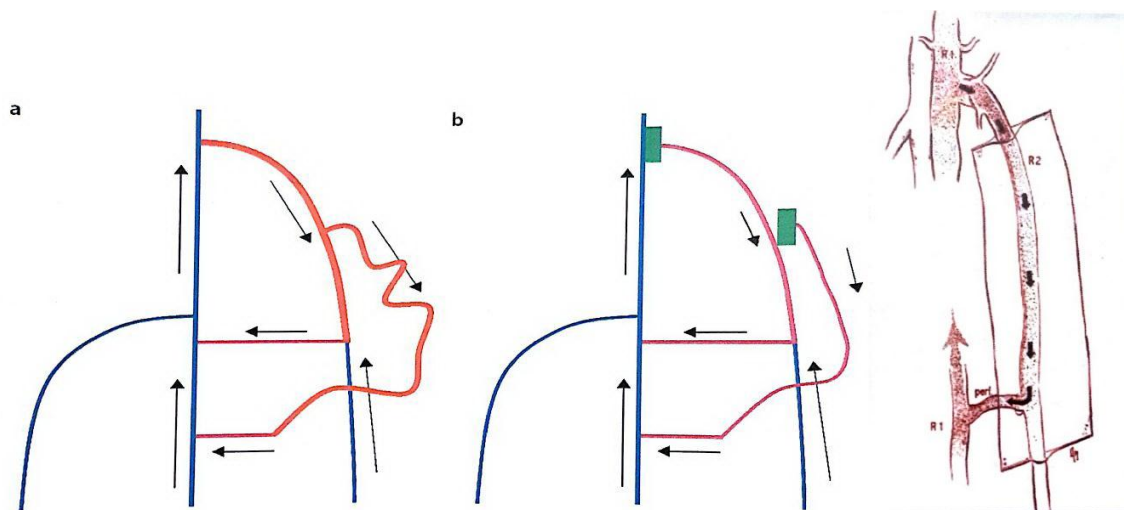


Fig. (2): Type 1 when sahenofemoral junction is incompetent and a segment of saphenous vein refluxes distally until flow re-enters the deep system through a perforating vein.

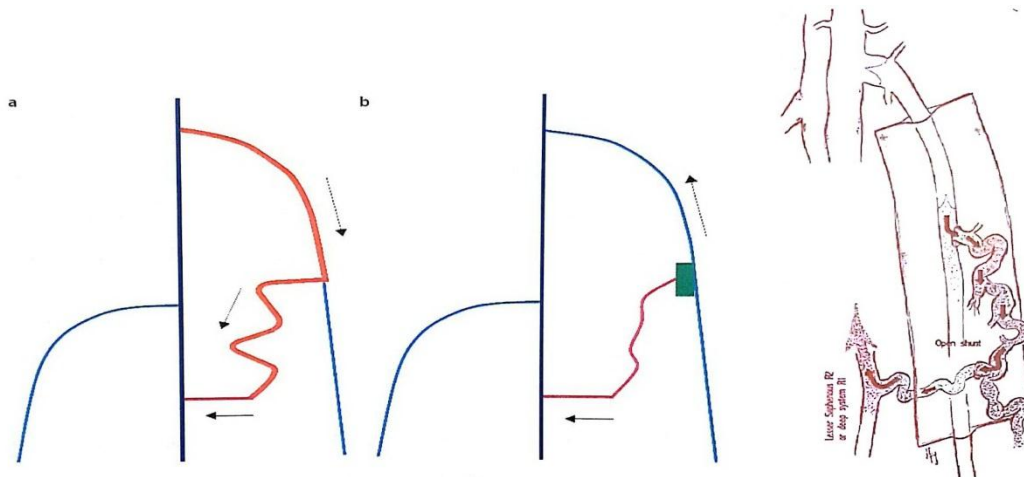


Fig (3): Type 2 when saphenofemoral junction is competent and a direct tributary of the saphenous vein refluxes , re-entering the saphenous trunk at a more distal level.

However, if those regions that have to be interrupted yet involve inflamed unhealthy tissues were not touched at the first operation. A procedure is performed only at sites having healthy tissues then another procedure is performed at the remaining sites when their trophicity could be improved by the first procedure. Actually, correct and long-term durable interruptions cannot be obtained in inflamed tissues⁽²⁰⁾. Venous short excision(1 to 4cm) using absorbable ligature with or without non-absorbable closure of the fascial defect seems to be the most precise and long lasting means to date. Fig (4), (5),(6),(7),(8)

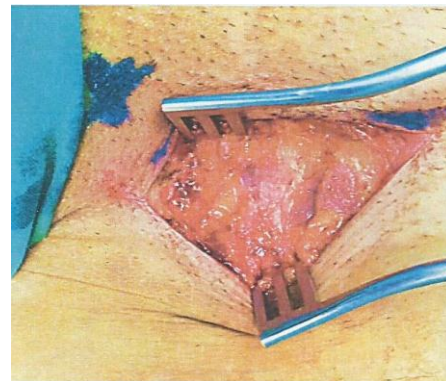


Fig. (5): SFJ just before breaching the superficial fascia (at CHIVA 2)



Fig. (4): Identification of escape point at GSV of the patient

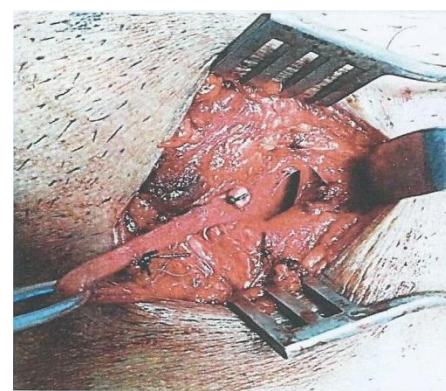


Fig. (6): Identification and control of an inguinal point



Fig. (7): Saphena varix

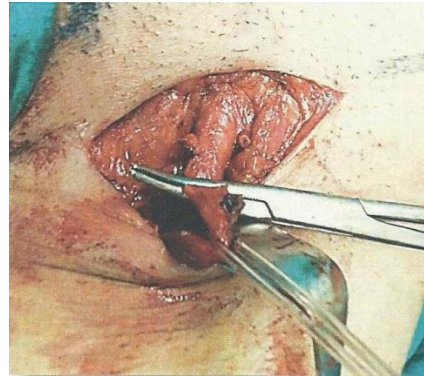


Fig. (9): GSV just before transfixation at the SFJ (at HLS operation)



Fig. (8): EP ligation with removal of intervening segment about 2 cm between ligatures.



Fig. (10): GSV after its stripping (on the metal stripper)

Multiple ligations with absorbable relatively thin thread were used to give better results, vicryl 3/0 for all escape points except for SFJ Vicryl 2/0 transfixing sutures were used. However, absorbable venous ligation after section could favor an inflammatory angiogenetic effect. Thus recanalization and recurrence may occur in some cases. This problem could be overcome by resecting considerable segments of the interrupted veins. All CHIVA procedures were carried out under local anesthesia.

The surgical Stripping procedure performed included, ligation and division of all proximal tributaries of the GSV, flush SFJ ligation, GSV stripping below or above the knee and multiple phlebectomies of the more distal tributaries. All were performed under spinal or general anesthesia. Fig.(9),(10)

Postoperative management:

Following surgical treatment CHIVA patients were recommended to use medical compression stockings above the level of the most proximal varicosities for 1 month, and the limbs treated by GSV stripping the conational bandage was used to minimize bruising and hematomas formation. Then bandages were replaced with compression stockings after 1 week and for one month.

Patients were usually discharged on the day of surgery at CHIVA due to minimal manipulation and dissection or the next day at stripping. Postoperative pain was covered by NSAID analgesia.

A score was applied for clinical assessment to each limb following surgical method (Hobbs' score system). This comprised objective evaluation

(Score 1): neither visible nor palpable varicose veins

(Score 2): A few visible and palpable varicose veins with diameter < 5mm

(Score 3): remaining or newly formed varicose veins with diameter \geq 5mm

(Score 4): in competent main trunks and perforator.

In addition, functional and cosmetic results were self assessed by patients (subjective evaluation)(Fligelstone score) (Score 3) considerable functional or cosmetic failure, in spite of improvement , but with dissatisfaction

(Score 4) : inconvenience

Patients were followed up at 3, 6, 9, 12 and 24 months post-operative, to assess the outcome of these treatments. Outpatient clinical assessment was performed and patients with objective or subjective score 3 or 4 underwent Doppler ultrasound examination to exclude recurrence. Patients with C4-C6 CEAP classification were strongly recommended to wear compression stockings indefinitely.

Score 3 and 4 of the objective Hobbs score and of the subjective score are the conditions consistent with recurrence of varicose veins which constituted a mandate for duplex ultrasound scan with presence of reflux with a demonstrable escape point . All cases with recurrence were managed surgically, using either Trendlenburg and stripping if had been not done at the first procedure or focused stab phlebectomies according to a recent ultrasound duplex scan.

Statistical analysis:

Data of patients' demographics, clinical & investigation records were all collected .Categorical variables were quoted as number, fraction or percentage; tests used were Pearson's Chi squared test and Fisher's exact test. For ordinal variables Mann-Whitney test has been used. P value was utilized and significant at univariate analysis and threshold set to be < 0.05. While quantitative variables were quoted as range and mean, and student t test was used for this data type. The central tendency measure used was the standard deviation. Statistical calculations were accomplished by Statistical Package for Social Science; version 15 (SPSS Inc., Chicago, IL, USA).

RESULTS

This prospective comparative randomized controlled study included 71 patients aged from 21 to 53 years, divided into two groups. However 11 patients (2 from group I and 9 from group II) were totally missed in the follow up period and

cannot be contacted back, thus were excluded totally from the study.

Group I included 30 patients with a mean age 33.4 years and sex ratio male to female = 1:1.7 and treated by CHIVA procedure

Group II included 30 patients with a mean age 33.9 years and sex ratio male to female = 1:1.1 and treated by the conventional combined HLS.

As regard demographic data, there was no significant difference between both groups as regard age and sex (P value, 0.834 and 0.432 respectively).

Also there was no significant difference between the two groups as regard the main preoperative symptoms (pain 25 patients, varicosities 22, ulcerations 6, cosmetic disfigurement and pigmentation 4 and 3 respectively) and CEAP classification distribution (P Value; 0.052 and 0.522 respectively).

Comparing postoperative complications in both groups, results showed statistically significant difference between both groups in occurrence of bruises (P value 0.035).

Results showed no statistically significant difference between both groups as regard other postoperative complications of infection (1/30 , 1/30) thrombosis (0/30, 1/30) nerve damage (0/30, 3/30) and recurrences (5/30, 0/30).The nerve damage occurred was related to the distribution of the saphenous nerve with trivial numbness at the medial aspect of the lower part of the leg. It was self limiting within 6 months at all cases with supportive treatment of Vitamin B complex. Superficial thrombosis occurred once and was mild and resolved within 2 weeks using Aspirin 75mg twice daily and leg elevation. Wound infection was managed using broad spectrum antibiotics with daily dressing. Study showed no statistically significant results as regard postoperative pain and hospital stay.

Results comparing patient (Subjective) and surgeon (objective) satisfaction between both groups showed no significant difference. According to Hobb's scoring system, patient satisfaction was 16 at grade A and 5 at grade B of group I (21/30) while at group II, grade A 21 and 6 grade B (27/30). Objective satisfaction was 19 at grade A and 4 at grade B at group I (23/30) while in group II it was 18 at grade A and 4 at grade B (22/30).

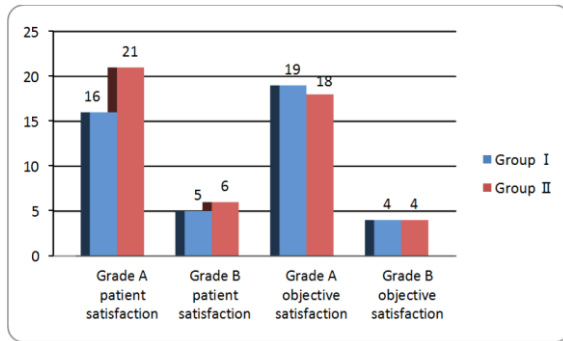


Fig (11): Hobb's scoring system

DISCUSSION

The beginning of CHIVA was created by Claude Franceschi in France at the eighties of the last century spreading from there to the whole Europe. It has been an attractive method for the treatment of varicose veins in the absence of other competitive modalities, apart from the conventional surgery described by Trendelenburg. However with the huge revolution of more recent techniques such as injection sclerotherapy, laser and radio frequency the CHIVA continue to draw attention.^{(13), (14)}

The creativity behind CHIVA is the ability to contradict the hypothesis of Trendelenburg; who had stated that the incompetent SFJ or SPJ is the main cause implicated in the pathogenesis of varicosities. CHIVA appeared to state that the main cause is the distal superficial network refluxing leading to several types of shunts that ascendingly can result in SFJ Or SPJ incompetence. Consequently via identifying and ligating these escape points of reflux, this procedure can regain the normal haemodynamic states leading to competent SFJ or SPJ and thus varicosities fade away.⁽¹⁵⁾

This study is a prospective comparative randomized controlled trial contrasting the CHIVA against HLS as regard the recurrence rates, in addition to associated complications, such as bruises, superficial vein thrombosis, wound infection and nerve damage. The study as well signified the subjective (patients) and objective (investigators) satisfaction.

Considering the primary outcomes, data recorded of this study revealed that the conventional stripping is favored over CHIVA as regard the recurrence rates; five patients suffered

recurrence; $5/30=16.67\%$. Meanwhile no recurrences were recorded at group 2 ($0/30 = 0\%$). This contradicts the most of the former similar studies regardless of the follow up periods. A similar situation has been reported with the aesthetic satisfaction of the patient; where there were three unsatisfied cases only at group 2 in contrast to 9 cases at group 1.

However with analysis of the rest of the secondary outcomes, the investigator satisfaction is more or less equal, in spite of being slightly larger with the CHIVA; $22/30$ cases (73.33%) were satisfied with HLS in contrast to $23/30$ (76.67%) at CHIVA. The wound infection was not very significant and it is equal in both groups; one case at each group (3.33% for each group). On the other hand, the CHIVA is non-surprisingly favored over the stripping considering the rest of the complications. Nerve damage, bruises and superficial venous thrombosis are found to be $0/30$ (0%), $16/30$ (53.33%) and $1/30$ (3.33%) respectively.

Carandina et al had close results where they had found the patient satisfaction 80% with CHIVA but it was 95% with stripping in a comparative study included 124 patients in both groups. The same series have supported our study results as *Carandina* and his colleagues found that the recurrence rates were less with stripping than with CHIVA on the short term results (12 months), unfortunately this was statistically insignificant (P Value = 0.242). Moreover, the CHIVA has been found to be more attractive in long term –results; as with further deepening in the same study, *Carandina* finally had concluded the recurrences as $13/70$ (18.57%) versus $19/54$ (35.18%) at CHIVA and stripping respectively at the 10 years follow up.⁽¹⁶⁾

Iborra-Ortega et al had found the recurrences as $16/49$ (32.65%) at CHIVA and $18/47$ (38.29%) at stripping at a 5 years follow up; the study that has favored the CHIVA as well.⁽¹⁷⁾

Pares JO et al came to support the *Iborra-Ortega's* results by series of studies included 501 cases and revealed the recurrences as $52/167$ (31.15%) in CHIVA group and $168/334$ (50.30%) in stripping one at 5 years follow up.⁽¹⁸⁾

The Severity and extent of the recurrence determine the need for retreatment at either groups (meant by which the Hobb's classification grades 3 and 4, from which patients ask for

retreatment; all grade 3 and some of grade 4); *Iborra-Ortega et al* reported that 5/51 (9.81%) at CHIVA and 5/49 (10.20%) at stripping had been in need for surgical retreatment.⁽¹³⁾

Pares JO et al, had reached that 4/167 (2.40%) with CHIVA and 6/334 (1.80%) with stripping has had a wound infection. They also found that superficial vein thrombosis was nearly equal at both groups (1.20% each). Regarding nerve damage, they agreed with our study that CHIVA is not associated with nerve damage or even nerve related symptoms (0/167) versus 15/334 (4.5%) at stripping.⁽¹⁹⁾

Additionally, *Iborra-Ortega* found the same result as regard nerve damage; 0/51 with CHIVA, but with worse result at stripping; 11/49 (11.45%). In contrast the superficial venous thrombosis was attractive (0/49) at stripping, but poor and somewhat strange with CHIVA 4/51 (7.84%); however this study did not present a clear explanation behind the superficial thrombophlebitis results. They also presented a comparison as regard subjective satisfaction which was slightly better in CHIVA 46/49 (93.88%) versus 43/47 (91.49%) with the other group, while the objective satisfaction in CHIVA was more satisfying 35/49 (71.43%) versus 30/47 (63.83%).⁽²⁰⁾

CHIVA was described by *Maldonado – Ferna'ndez N et al* to be a new haemodynamic treatment method for varicose veins which can present successful haemodynamic and clinical results 12 months later, with considerable patient satisfaction. It is safe, and complications are local and self-limiting. It enables one, for example, to correct AASV-related (anterior accessory saphenous vein) varices without having to operate on the saphenofemoral junction or the GSV, which continues to function correctly and is potentially useable for revascularization surgeries.⁽²¹⁾

Eva I. et al hypothesized that CHIVA technique permits a considerable decrease of variceal recurrence. A follow up of 1 and 3 year evidenced only two recurrences cases. CHIVA appears as a vital therapy, applicable even under ambulatory conditions. The post-surgery results recorded are excellent, while patients' comfort was appreciated and highly satisfactory.⁽²²⁾

Contradicting most of the previous studies, recurrence in this study is associated more with CHIVA than stripping.

This could be attributed to small number of cases in both groups in relation to other studies. More important the short duration of follow up especially when compared to other studies which have follow up periods ranging from 5-10 years. Also CHIVA procedure is highly dependent on the ultrasonographic duplex scan depending on skilled radiologist. Therefore combined surgical and radiological competence are both mandatory for the outcomes of CHIVA to be reliable and relevant.

On the other hand, the secondary outcomes are found to be less significantly different to the other studies. Regarding nerve damage and wound infection, the result are totally or partially similar, apart from Pares Jo et al studies, which in reverse of others, reported that wound infection is more prominent with CHIVA.

It was concluded in the present study that both CHIVA and stripping were equally effective in the treatment of venous ulcers (CEAP 6). Six Patients with ulcerations, 2 CHIVA and 4 at stripping groups) have healed sufficiently in an interval of 1-3 months from the procedure. However due to small number of patients with venous ulcers, the results were insignificant.

On the other hand, pain and varicosities faded away at 3 weeks and 3 months respectively in both groups. The recurrence has been confirmed by patient symptoms, clinical examination and duplex ultrasound scan. The recurrence occurred in 5 cases ; 3 of them pattern 4 ,due to refluxing in previously ligated escape points. This pattern of recurrence is the most common in this study and other similar studies as well. The reason behind this type of recurrence is probably due to using absorbable threads and sometimes left segments between ligatures behind ,while they should be removed at intervals 1-4cm⁽²⁰⁾.

The second most common type of recurrence at this study and others is type 3, where the reflux of the proximal part of GSV ensues. This pattern may occur as a result of ligation of any EP, but mostly due to ligation of SFJ and thus reopening and refluxing of the GSV itself and its tributaries because of the relative venous hypertension at the previously competent segments of GSV, in addition of the absorbable sutures, that can induce neovascularization and hence reopening and refluxing of previously ligated points.

Type 3 recurrences does not take place at traditional combined stripping and trendlenburg

surgery, due to total removal of the proximal part of the GSV and total crosssection of the SFJ. In addition to loss of the GSV as a reserve for future revascularization surgeries, stripping and trendelenburg procedure could result in relative venous hypertension at the non-removed competent tributaries making them incompetent and consequently varicosities could recur.

CONCLUSION

CHIVA is safe, less invasive, effective and if done properly it lead to complete cure.

Also properly carried out stripping is much more beneficial to patients than poorly performed CHIVA procedure.

It is suggested for the CHIVA method to be more effective if it was followed up on longer time scale; at least 60-120 months. Proper surgical techniques in the form of using non-absorbable ligatures with removal of venous segments 1-4 cm as well could lead to more satisfying results. Additionally, the bigger samples size could add to the reliability of conclusions of such comparative studies.

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