Comparative Study between Conventional Varicose Vein Stripping and Modified Haemodynamic Correction (CHIVA)

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Abstract: The CHIVA 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 haemodynamic state at both deep and superficial systems via breaking all types of venous shunts at the escape points within the different compartments.

Subjects and Methodology: 60 patients from those attended the outpatient departments of general surgery complaining from CDV or varicose veins were arranged into 2 groups. They were assessed according to theCEAP clinical classification and ultrasonic duplex scanning, randomly arranged into group I (CHIVA or case group) and group II (stripping or control group). CHIVA operation was performed under local anesthesia while the stripping under spinal or general anesthesia. Cases were reviewed regularly at the outpatient clinic for 12 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 stripping 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.

Conclusions: It is suggested forthe CHIVA method to be more efficient 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.

Key Words: Varicose veins surgery, CHIVA, Venous stripping.

Introduction:

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 (high ligation and stripping (HLS)). However recurrence of varicose veins postoperatively still a significant issue of the open surgical management; the recurrence rate at five years postoperative is ranging between 20% and 28% meanwhile endovenous laser therapy/ablation (EVLT/EVLA) is a recent less invasive method for management of refluxing veins, which may be done in an outpatient setting using local anesthesia. The safety of EVLT and its results early postoperative seem to be considerably competitive with those of traditional surgery[4].

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 fashionedindividually for the patients according to the haemodynamic condition implemented in the venous insufficiency, besides preserving the saphenous axis[5].

CHIVA can be achieved via open surgery or via endovascularprocedures includingLASER, radiofrequency or sclerotherapy. Its rationale is to modifythe hemodynamics between the deep and superficial venous systems to eradicatevenous dilations and to preserve the great saphenous vein for future grafting purposes. Results revealed thatCHIVA diminishes the diameter of the saphenous vein(from 2.6 to 1.6 mm) and the femoral vein (from 0.7 to 0.4 mm) has supported this viewpoint[6].

The aim of this study is to evaluate the safety and efficacy of the standard CHIVA procedure in patients that present varicose veins related to the great saphenous vein or the saphenofemoral junction; CHIVA is a surgical approach with

the aim of correctingabnormal haemodynamic pathways in the venoussystem, resulting in targeted intervention. This approachrelies on careful venous duplex assessment to gain adetailed knowledge of the anatomical and haemodynamiccharacteristics of individual patients. InCHIVA, the aim is to maintain the superficial venoussystem, altering the venous hemodynamics to promotemore 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 systems of lower limbs.

Subjects and Methodology

Sixty patients who had sought the medical advice at the general surgery outpatient clinic at Fayoum University Hospital (FUH) for management of their CVD, patients underwent clinical assessment including CEAP clinical classification and duplex ultrasonographic scan has been carried out by expert radiologists either from the staff members of radiology department at faculty of medicine Fayoum University or outside it. This study has been carried out at the period from May 2015 to January 2016, and the cases were followed up between May 2015 and January 2017.

Patients presenting with CVD of the GSV were selected and randomized between treatment with stripping and CHIVA. Group 1, the case group, included 30 patients presenting with primary CVD of GSV system were complaining from heaviness and disfigurement, they have been treated with CHIVA strategy. Group 2, control group, included 30 patients presenting with primary CVD of the GSV system were complaining from heaviness and disfigurement have been treated with Trendelenburg and stripping of the GSV.

Patients of group 1 were consented to be treated with a new less invasive and less radical treatment as a part of a new research plan comparing this method with

the traditional procedures. The main advantages behind this new technique were illustrated to the patients; where they can preserve the GSV trunk for potential future grafting either for coronary or peripheral arteries replacements. Consent as well included the need for regular follow up for one year from the time of the operation, during this period they would be frequently contacted by the surgical team.

On the other hand the patients of group 2 were informed to undergo the traditional combined Trendelenburg and stripping procedures, thus the consent included the conventional items before the moderate surgical operations in addition to the need for regular follow up for the same period as group 1.

Patients were treated and followed up totally for free including the treatment of complications and recurrences, but the CHIVA scan was paid for outside FUH. However no financial motifs were paid for the patients.

The study included all patients with varicose veins with CEAP clinical classes 2-6 associated with the presence of SFJ reflux and incompetence of the GSV trunk.At least one re-entry perforator should be located on the GSV trunk with at least one incompetent tributary of the GSV.Patent and competent deep venous system of both lower limbs must be confirmed preoperative. On the other hand all cases over 75 years old, affected by deficit of the calf muscular pump or unable to walk, affected by auto-immune diseases, severe renal, hepatic and cardio-pulmonary diseases, uncontrolled diabetes or malignancies, with previous history of DVT or patients with a history of previous history of surgery or other non-operative modalities for treatments of varicose veins were excluded from the study.

A preoperative duplex USS mapping of the veins will be drawn on the skin with the 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 *(Figure 46& 47)*.

A vicious circle of blood flow could be formed between the superficial and the deep veins in the primary varicose veins.The circle starts during muscular diastolic phase , when the blood drained from the more proximal EP, the SFJ, via the GSV and/or the superficial veins, moves downwards to the re-entry point passing through by a Perforating Vein (PV), and thus into the deep venous system. The circle is completed during the following muscular contraction, as the blood flows forward via the deep venous system, and again to the proximal reflux point when muscular relaxation occurs and so on.

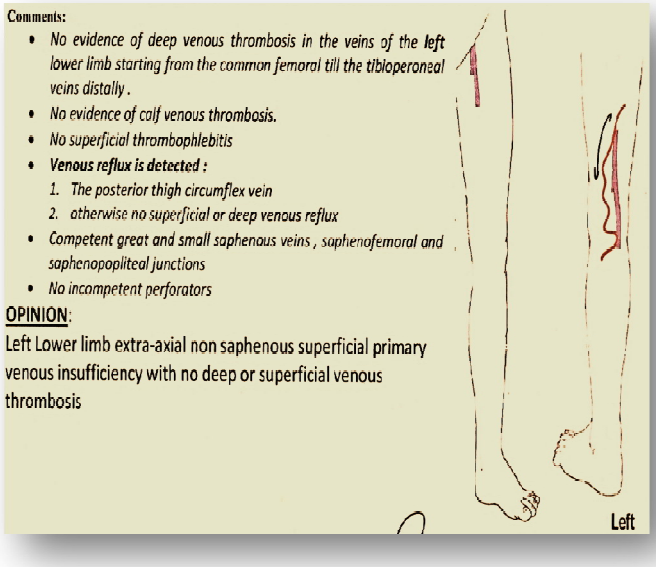

Figure 48: Venous diagrammatic duplex for CHIVA illustrating points of reflux with detailed written report (left side)

The private circulation is illustrated both in the form of diagrams and written reports in addition to colored markings over the patient's skin. The points of reflux

(escape points), refluxing superficial veins and re-entry perforating veins are also delineated.

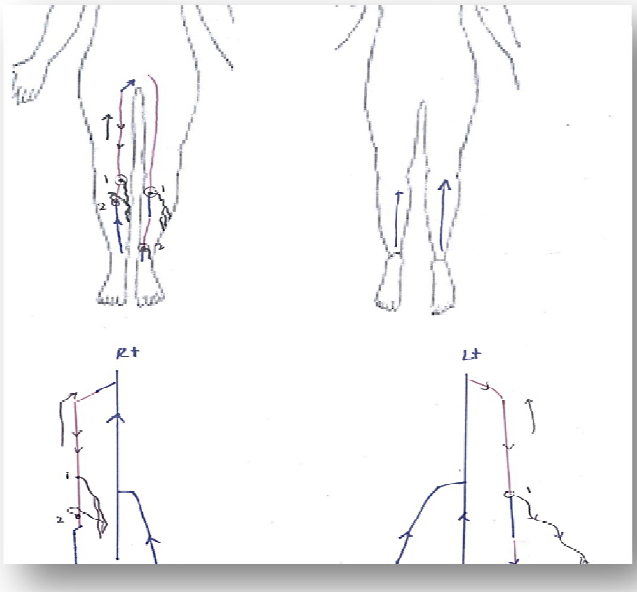

Figure 49: Venous diagrammatic duplex for CHIVA illustrating points of reflux (Bilateral)

Surgical techniques:

According to the CHIVA strategy we performed haemodynamic correction type 1 which was done according to the type of shunt shown upon duplex examination.

However, those regions that theoretically have to be interrupted but 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. Precise marking under duplex ultrasound scan by an operator aware of the surgical necessities is indispensable. Venous short excision (1 to 4 cm) using absorbable ligation with or without non-absorbable closure of the perforated deep fascia seems to be the most precise and long lasting material means to date.

Simple non absorbable ligations are seldom breached or reopened, thus are the most efficient.

Multiple ligations with absorbable relatively thin thread were used to give better results. However, absorbable venous ligation after section could favor an inflammatory angiogenetic effects and thus recanalization due to which recurrence in some cases may occur. This problem could be overcome by resecting considerable segments of the interrupted veins. All CHIVA procedures were carried out under local anesthesia*(Figure 51)*.

Stripping procedure

In this group of patients the surgical 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 the surgical procedures were performed under spinal or general anesthesia *(Figure 52-59)*.

Figure 53: SFJ just before breaching the superficial fascia

Figure 56: GSV just before transfixation at the SFJ.

Figure 58: GSV after its stripping (on the metal stripper).

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

Figure60*:* post-operative skin complication (bruising)

Management of recurrence

All cases with recurrence were managed surgically, using either Trendelenburg and stripping if had been not done at the first procedure or focused stab phlebectomies according to a recent ultrasound duplex scan.

Results: Age distribution: Student t test was performed to test for the difference of age between the CHIVA and Trendelenburg and stripping group, there is no significant difference between the 2 groups in the ageSex distribution: Chi

squared test is done to compare between the two groups in the sex distribution but there is no significant difference between the 2 groups (p value = 0.432)Main preoperative symptom: Chi squared test is done to compare between the two groups in the main preoperative symptom, but there is no significant difference between the 2 groups (p value = 0.052)CEAP classification distribution: Mann-Whitney Test is done to compare between the two groups in CEAP, but there is no significant difference between the 2 groups (p value = 0.522)Post-operative complications: Chi squared test is done to compare between the two groups in the occurrence of bruises, there is statistically significant difference between the 2 groups (p value = 0.035). The occurrence of bruises is higher in the Trendelenburg and stripping group. Fisher's exact test is done to check the difference of occurrence of infection, thrombosis, nerve damage and recurrences in the 2 groups, none of them showed statistically significant difference between the 2 groups.Satisfaction: Chi squared test is done to compare between the two groups in the patient and surgeon satisfaction, but there is no significant difference between the 2 groups.

Discussion: Considering the primary outcomes, data recording of this study revealed that the conventional stripping is favored over CHIVA as regard the recurrence rates; 5/30 versus 0/30, which contradicts the most of the former similar studies. A similar situation has been reported with the aesthetic satisfaction of the patient, the stripping is better; 27/30 in contrast to 21/30.

However with analysis of the rest of the secondary outcomes, the investigator satisfaction is more or less equal, in spite of being slightly bigger with the CHIVA; 22/30 (stripping) to 23/30 (CHIVA). As a general speaking the wound infection is not very significant and it is equal in both groups; 1/30 in each one. 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, 8/30 and 0/30 in CHIVA

group if compared to the more striking and predicted results with stripping group which were 3/30, 16/30 and 1/30 respectively.

At 2015, an extended highly attractive Cochrane meta-analysis series of studies comprised a collection of four top comparative studies between CHIVA and stripping in long duration between 5-10 years of follow up. Recurrence was found to be 471 per 1000 and 297 per 1000 at stripping and CHIVA respectively. Bruises as a side effect was 719 per 1000 at stripping and 453 per 1000 at CHIVA.Considering the limb infection it was 18 per 1000 and 24 per 1000 at stripping and CHIVA respectively. These series also have provided that thrombosis was more than the double at the CHIVA that at the stripping; 23 per 1000 versus 10 per 1000. Nerve damage rates were consistent with the general stream of the most of the studies; where they were68 per 1000 at stripping and 3 per 1000 at CHIVA[84].

It can be concluded that the CHIVA operation in our study is superseded by the stripping technique when thinking about the recurrence rates, but the last is less attractive if one thinks about the post-operative complications, the safety and the preservation of the venous trunks for future vascular replacement surgery. Nevertheless, this hypothesized information could be changed or even reversed if the follow up period extended for 5-10 years either in the same study or at the future similar studies. It is valuable to report, according to similar study series, that increasing the sample size can considerably affect the primary outcomes and significant differences of variables could be reached.

Ethical approval: It was obtained from the Ethical Scientific Committee of Faculty of Medicine Fayoum University.Conflict of interest: Neither the investigator nor the supervisors have any conflict of interest with manufacturers of devices used in this study.Funding: None.