

Comparative study between great saphenous vein endovenous laser ablation and modified hemodynamic correction (conservative hemodynamic correction of venous insufficiency) as a treatment for varicose veins

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Background

Varicose veins could be a complicated condition, which may lead to limb swelling, pain, and venous ulcer. Conservative hemodynamic correction of venous insufficiency (CHIVA) has been developed through the past two decades and is currently the second most common surgical procedure for the operative treatment of varicose veins. Endovenous laser treatment of great saphenous vein was approved by FDA in 2002 and short saphenous vein (SSV) was approved in 2003. Endovenous laser ablation (EVLA) is a clinically safe, feasible, and well-tolerated technique without scar and allows people to return to their normal daily activities rapidly.

Patients and methods

In a prospective comparative study between January 2018 and January 2020, 40 patients complaining of varicose veins were assessed according to the Clinical-Etiological-Anatomical-Pathophysiological (CEAP) classification and ultrasonic duplex and arranged into group I (CHIVA) and group II (EVLA). Both CHIVA operation and EVLA were performed under local anesthesia. Follow-up for 6 months was done.

Results

Recurrence occurred in 2/20 and 0/20 patients in CHIVA and EVLA groups, respectively. Regarding the aesthetic satisfaction of the patient, EVLA was better, with two unsatisfied patients in EVLA in contrast to five unsatisfied patients in CHIVA. The wound infection rate was 1/20 and 0/20 in CHIVA and EVLA, respectively. CHIVA is favored over EVLA considering the rest of the complications. Bruises, thrombosis, and nerve damage are found to be 5/20, 0/20, and 0/20, respectively, in CHIVA group when compared with the results of EVLA group, which were 9/20, 1/20, and 2/20, respectively.

Conclusion

CHIVA is safe, effective, and less invasive. EVLA is now considered as one of the top technologies to be used in the management of varicose veins with good functional outcome. EVLA can be done as an outpatient procedure. Each type of these interventions should be tailored according to each patient's variables such as degree of reflux in great saphenous vein, presence of incompetent perforators, and aesthetic requirements of the patient.

Keywords:

CEAP classification, conservative hemodynamic correction of venous insufficiency, endovenous laser ablation, varicose veins

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Introduction

Varicose veins could be a complicated condition, which may lead to limb swelling, pain, and venous ulcer owing to chronic venous insufficiency (CVI). This condition basically originates from incompetence and reflux of great saphenous vein (GSV), small saphenous vein, or both. Prevalence of CVI can occur in up to 40% of women and 17% of men, whereas the varicose veins could present from 1 to 73% and from 2 to 56% in women and men, respectively [1].

Chronic venous disease (CVD) extensively presents among adult age groups, where it is less than 10% at age younger than 30 years and rises at age above 70 years to be 57 and 77% in men and women, respectively. The most advanced form of CVD, which is properly named as CVI, accounts for 20%

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of CVD in elderly patients. This advanced stage could lead to chronic venous ulcer, which represents 70% of all lower limb ulcers and consequently leads to decreased quality of life and significant economic problems [2].

Conventionally, the surgical treatment of varicose veins has been performed via high saphenofemoral ligation and stripping of the GSV to just below the knee (high ligation and stripping). However, recurrence of varicose veins postoperatively is still a significant issue of the open surgical management; the recurrence rate at 5 years postoperatively ranges between 20 and 28%, meanwhile endovenous laser (EVL) therapy/endovenous laser ablation (EVLA) is a recent less-invasive method for management of refluxing veins, which may be done on an outpatient basis using local anesthesia. The safety of EVL therapy and its early postoperative results seem to be considerably competitive with those of traditional surgery [3].

The ambulatory conservative hemodynamic correction of venous insufficiency (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 tailored individually for the patients according to the hemodynamic condition implemented in the venous insufficiency, besides preserving the saphenous axis [4].

There are three methods of thermal ablation in comprehensive vein centers at present: radiofrequency (RF) energy from a dedicated generator, and EVL, which uses a laser fiber and generator to produce focused heat; both RF and EVL are catheter-based endovascular interventions that use electromagnetic energy to destroy the refluxing saphenous system. Steam vein sclerosis is another technique developed by CermaVein (France). To emit steam at 150°C, we pressurize water, and then force it through a very small diameter tube (0.1 mm) heated by an electrical current. The main advantages is that it can be used in tortuous vein and in very superficial veins [5,6].

Undoubtedly, new endovenous devices will appear. Indeed, the first endovenous microwave ablation has been done in Europe. This technique has all the advantages of EVL and RF ablation but without some of the drawbacks of both, like pigmentation, ecchymosis, and skin burns and less postoperative pain. However, it is still an endovenous thermal technique requiring tumescence [7].

One of the most exciting new treatments for varicose veins and venous reflux disease is high-intensity focused ultrasound (HIFU). This new technique has only recently been presented at meetings, so only the principles and very earliest results are known. However, HIFU has been used in other clinical scenarios for noninvasive tissue ablation, and so, the probability that it will be successful in veins is high. By externally focusing ultrasound to cause ablation at one specific point targeted internally, HIFU is a truly noninvasive technique, a quantum leap forward from minimally invasive techniques, by being able to externally target specific venous areas [7].

Patients and methods

This is a comparative study that included 40 patients seeking medical advice at the vascular surgery outpatient clinic in Beni Suef University Hospital for management of varicose veins. Oral consent was obtained from all patients before study.

All patients were subjected to clinical examination including Clinical-Etiological-Anatomical-Pathophysiological (CEAP) clinical classification and venous duplex assessment which were carried out by an expert radiologist. This study evaluates patients from January 2018 to January 2020 with postoperative follow-up of 6 months.

All patients presented with varicose veins of GSV were divided between two groups of treatment: EVLA and CHIVA. Group I included 20 patients who were treated using CHIVA, and group II included 20 patients who were treated using EVLA.

Inclusion criteria were (a) primary CVD with CEAP clinical class 2–6, (b) presence of saphenofemoral junction (SFJ) reflux and incompetence of the GSV trunk, (c) at least one re-entry perforator located on the GSV trunk, (d) at least one incompetent tributary of the GSV, and (e) patent and competent deep venous system of both lower limbs.

Exclusion criteria were (a) patients complain of short saphenous vein varicosities, (b) patients with previous history of deep vein thrombosis, and (c) patients with a history of previous surgery for treatments of varicose veins.

Preprocedural preparation included the following: (a) history taking, where full personal and medical history was taken; (b) clinical examination; (c) duplex mapping, to document the patency of the deep veins

and to evaluate the extent and severity of the reflux in the superficial venous system (GSV), and also the depth of GSV is assessed to determine the suitability for EVLA; and (d) obtaining a written consent, after which the patients were randomized using a simple card numbering randomization method.

Procedural technique

Conservative hemodynamic correction of venous insufficiency technique

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

Precise marking under duplex ultrasound scan by an operator aware of the surgical necessities is indispensable. Venous short excision (1–4 cm) using absorbable ligation (braided synthetic polyglactin Vicryl) with or without nonabsorbable closure of the perforated deep fascia seems to be the most precise and long-lasting material means to date. Simple nonabsorbable ligations are seldom breached or reopened, thus are the most efficient.

Multiple ligations with absorbable suture were used to give better results; polyglactin (Vicryl) 3/0 sutures were used for all escape points, except for SFJ, where 2/0 transfixing sutures were used. However, absorbable venous ligation after section could favor an inflammatory angiogenetic effect, 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.

Endovenous laser ablation

After duplex venous mapping was done by an expert radiologist and skin marking was painted by indelible ink while patient is standing, the patient was taken to the operating room. All patients were offered local infiltration and tumescent anesthesia.

A 6-F 11-cm sheath (Prelude Sheath Merit Medical, Merit Company, USA) was inserted in the selected below-knee GSV using ultrasound guidance. The Biolitec 1470-nm 600- μ m radial tip laser fiber was inserted through the sheath up to the SFJ. Tumescent anesthesia is infiltrated perivenous by 21-G needle, which consists of 500-ml normal saline 0.9%, 50-ml lignocaine 1% (Xylocaine), and 1-ml adrenaline 1-mg ampoule. In longitudinal ultrasound view, pull back of the fiber was done to be 2 cm from the SFJ.

Firing of laser power (Biolitec; ELVeS Radial Ring, Germany) starts with 10 W as a power, at first 2 cm, where two cycles are done, and a single cycle for each centimeter after then. We usually compress over the vein during firing laser so as to collapse the vein and enhance coaptation with laser fiber as well. At last 11 cm of the laser fiber, we remove the sheath from the skin and complete the firing after then to stop firing 2 cm from skin entry point so as not to burn the skin.

After completion of vein ablation, the limb was wrapped using compression garments to be removed 48 h and replaced by class 2 compression elastic stocking for 4 weeks.

Postprocedure management

Following treatment, CHIVA patients were recommended to use medical compression stockings above the level of the most proximal varicosities for 1 month, but at the limbs that had been treated by EVLA, a bandage was used to minimize bruising and hematoma formation. Then bandages were then replaced with class 2 medical compression stockings after 48 h and for 4 weeks.

All patients were encouraged to start ambulation shortly for intervention either in CHIVA group or in EVLA group.

Patients were usually discharged from hospital on the day of surgery in CHIVA and EVLA procedures.

Patients were reviewed in the outpatient clinic 2–4 weeks following surgery to avoid postoperative complications and confirm wound healing in cases of CHIVA and if satisfactory outcomes had been reached.

Patients further were followed up at 3 and 6 months postoperatively, to assess the outcome of these treatments by clinical examination and duplex assessment.

Results

The present study is a prospective comparative trial and included patients aged from 22 to 53 years old. A total of 40 participants were included who were divided into two groups (I and II). Group I (20 case, mean age 32.35 years, and sex ratio male : female=1 : 1.8) underwent CHIVA procedure, and group II (20 case, mean age 35.2 years and sex ratio male : female=1 : 1.5) underwent EVLA.

Age ranged from 22 to 53 years in both groups. Student *t* test was performed to test for the difference of age between the CHIVA and EVLA groups, and there is

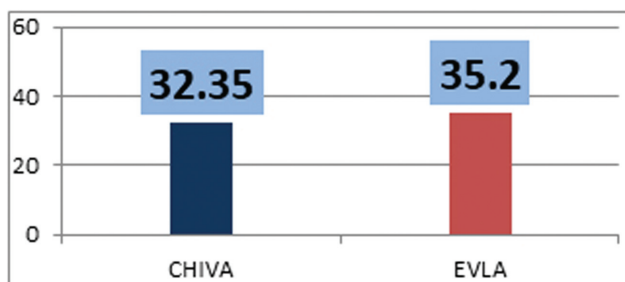
no significant difference between the two groups regarding age ($P=0.834$) (Fig. 1).

Group I included seven males and 13 females, and group II had eight males and 12 females. χ^2 test was done to compare between the two groups in the sex distribution, but there is no significant difference between the two groups regarding sex ($P=0.432$) (Fig. 2).

The main symptoms were pain in 17 cases and varicosities in 14 cases, whereas the other symptoms were less prominent, where ulcerations were presented in five patients, and cosmetic and pigmentation were presented at three and one patients, respectively. χ^2 test was done to compare between the two groups regarding the main preoperative symptoms, but there was no significant difference between the two groups ($P=0.052$) (Fig. 3).

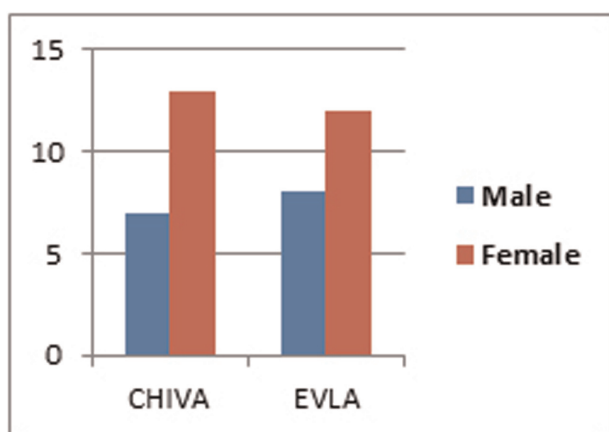
There is no significant difference between the two groups regarding CEAP classification distribution ($P=0.522$) (Table 1 and Fig. 4).

Figure 1



The difference of age between the CHIVA and EVLA group. CHIVA, conservative hemodynamic correction of venous insufficiency; EVLA, endovenous laser ablation.

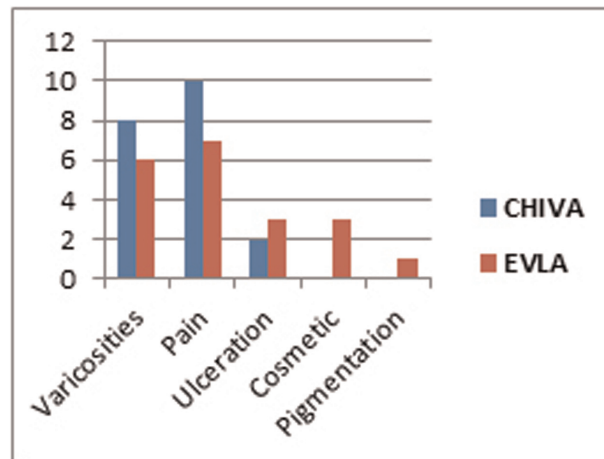
Figure 2



χ^2 test is done to compare between the two groups in the sex distribution.

χ^2 test was done to compare between the two groups in the occurrence of bruises, and there was a statistically significant difference between the two groups ($P=0.035$). The occurrence of bruises is higher in

Figure 3



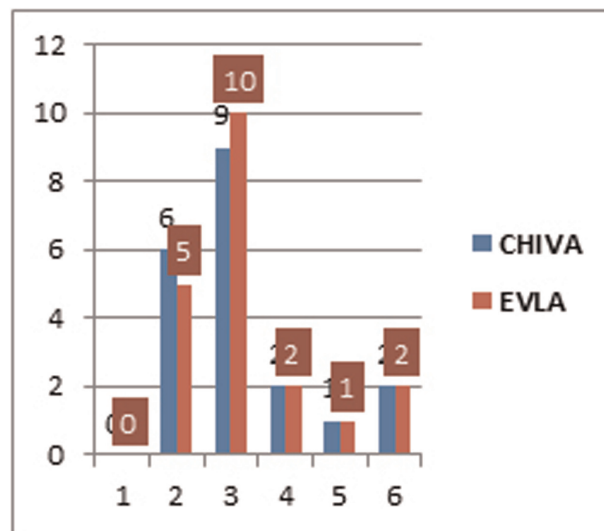
Main preoperative symptom. χ^2 test is done to compare between the two groups.

Table 1 CEAP classification distribution: Mann-Whitney test is done to compare between the two groups in CEAP, but there is no significant difference between the two groups ($P=0.522$)

	CHIVA	EVLA	P value	Significance
CEAP 2-6	2-6	2-6	0.522	Not significant

CEAP, Clinical-Etiological-Anatomical-Pathophysiological; CHIVA, conservative hemodynamic correction of venous insufficiency; EVLA, endovenous laser ablation.

Figure 4



Mann-Whitney test is done to compare between the two groups in CEAP, but there is no significant difference between the two groups ($P=0.522$).

the EVLA group. Fisher's exact test was done to check the difference of occurrence of infection, thrombosis, nerve damage, and recurrences in the two groups, and none of them showed a statistically significant difference between the two groups (Fig. 5).

Recurrence occurred in two cases in CHIVA group (Table 2).

Nerve damage occurred in all cases and 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 in all cases with supportive treatment, but it was neither annoying nor affecting the quality of life of the patients.

There is no significant difference between both groups regarding recurrence rate, as there were two cases of recurrence in CHIVA group but no recurrence in EVLA group.

χ^2 test was done to compare between the two groups regarding patient satisfaction (Fig. 6).

Discussion

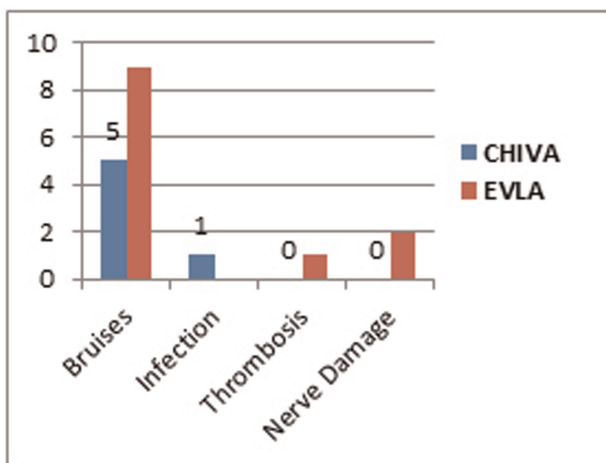
Considering the primary outcomes, data recorded of this study revealed that the EVLA is favored over CHIVA regarding the recurrence rates: two patients

experienced recurrence (one due to reflux of previously ligated escape point because of angiogenesis, and the other one was due to reflux from the proximal part of GSV into its tributaries). However, no recurrence was recorded in EVLA group during the 6-month follow-up. A similar situation has been reported with the patient satisfaction, where there were two unsatisfied patients in group II in contrast to five unsatisfied in group I.

However, with analysis of the rest of the study outcomes, it was found that the wound infection was not very significant, and it was seen in one case in CHIVA group. On the contrary, the CHIVA is nonsurprisingly favored over EVLA considering the rest of the complications. Bruises, thrombosis, and nerve damage are found to be 5/20, 0/20, and 0/20, respectively, in CHIVA group when compared with the results with EVLA group, which were 9/20, 1/20, and 2/20, respectively.

Carandina *et al.* [8] had a close opinion, where they had found the patient satisfaction was 80% with CHIVA, but it was 95% with stripping in a comparative study that included 124 patients in both groups. The same series supported this study's results, as it found that the recurrence rates were less with stripping than with CHIVA on the short-term results (12 months); unfortunately, this was statistically insignificant. Moreover, the CHIVA was found to be more attractive in long-term results (10 years). More illustration of the same study results, Carandina *et al.* [8] finally had recorded the recurrences as 13/70 (18.57%) versus 19/54 (35.18%) at CHIVA and stripping, respectively, at the 10-year follow-up.

Figure 5



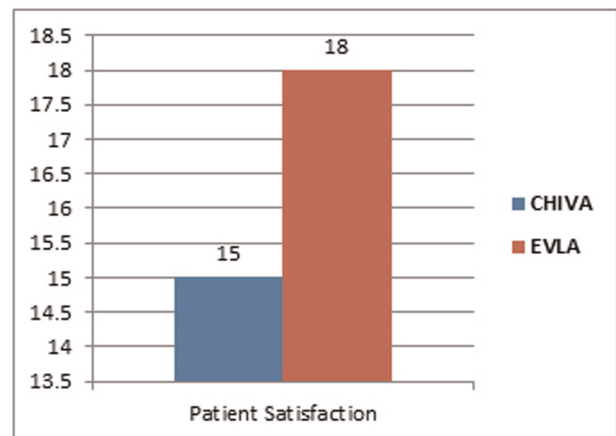
Comparison between the two groups in the occurrence of bruises, and there is statistically significant difference between the two groups ($P=0.035$).

Table 2 Recurrence rate in both groups

	CHIVA	EVLA	P value	Significance
Recurrence	2	0	0.522	Not significant

CHIVA, conservative hemodynamic correction of venous insufficiency; EVLA, endovenous laser ablation.

Figure 6



χ^2 test is done to compare between the two groups in the patient satisfaction, but there is no significant difference between the two groups.

Iborra-Ortega *et al.* [9] had found the recurrences as 16/49 (32.65%) in CHIVA group and 18/47 (38.29%) in stripping group at a 5-year follow-up; the study that corroborated the CHIVA as well. The study in 2010 by Pares and colleagues supported the results of Iborra-Ortega *et al.* [9] in a series of studies that 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-year follow-up.

The severity and extent of the recurrence determine the need for retreatment in either groups. Iborra-Ortega *et al.* [9] reported that 5/51 (9.81%) in CHIVA and 5/49 (10.20%) in stripping had been in need for surgical retreatment.

Pares *et al.* [10] had reached that 4/167 (2.40%) with CHIVA and 6/334 (1.80%) with stripping have had a wound infection. They also found that superficial vein thrombosis was nearly equal in 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 (4.50%) at stripping [10].

Additionally, Iborra-Ortega *et al.* [9] found the same results regarding nerve damage, showing 0/51 with CHIVA, but with worse result in stripping group, with 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 [9].

A clinical trial experience with diode lasers has produced extremely low rates of deep vein thrombosis and paresthesia, a low risk of skin burns, and no documented cases of pulmonary embolism; both paresthesia and skin burns have been associated with 1064-nm laser treatment. The most common adverse effects seen with all laser types are bruising (due to needle tumescent injection and vein perforation occurring during laser firing), localized pain, induration and discomfort along the treated vein, and superficial [11].

Some have speculated that the use of a bare laser fiber may lead to inhomogeneous vein wall destruction owing to a tendency of the tip to become located eccentrically within the vein. A flared tip (Tulip Tip, Tobrix), designed to center the laser and promote more homogeneous heating, is commercially available in Europe, but not in the United States. One trial using this device noted reduced postoperative ecchymosis

and pain; however, the differences demonstrated were small and likely not clinically significant [12].

Similarly, mild differences in postprocedure pain were identified using the 1470-nm laser catheters with a radial fiber compared with the bare-tip fiber [13].

CHIVA was described by Maldonado-Fernandez *et al.* [4] to be a new hemodynamic treatment method for varicose veins, which can present successful hemodynamic 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 anterior accessory saphenous vein-related varices without having to operate on the SFJ or the GSV, which continues to function correctly and is potentially useable for revascularization surgeries.

Eva *et al.* [14] hypothesized that CHIVA technique permits a considerable decrease of variceal recurrence. Follow-ups at 1 and 3 years evidenced only two recurrence cases. CHIVA appears as a vital therapy, applicable even under ambulatory conditions. The postsurgery results recorded are excellent, whereas patients' comfort was appreciated and highly satisfactory [13].

In 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 and 10 years of follow-up. Recurrence was found to be 471 per 1000 and 297 per 1000 at stripping and CHIVA, respectively. Bruises as an adverse 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 than 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 were 68 per 1000 at stripping and three per 1000 at CHIVA [14].

As CHIVA procedure is highly dependent on the ultrasonographic duplex scan, and therefore, this imaging is consequently dependent on the radiologist, who must be a well-skilled experienced physician with a considerable log book of these imaging studies, it is clearly inarguable that the result of the CHIVA is a direct consequence of the duplex scan results. However, the surgeon must not be excluded from being implicated in the resulting recurrence rates and the accompanying complications, as the surgeon is the only other

participant in this procedure. Thus, he/she should be of a reliable level of experience regarding tissue handling, anatomical awareness of the deep and superficial venous systems including compartments, territories and types of networks and shunts, in addition to the absorption of the rules and hypotheses regarding the venous system physiology and the pathological events related to the pathogenesis of varicose vein development. Moreover, the operator should have a considerable history of dealing with vascular tissues and rules of surgical handling of venous tissues. The combined surgical competence and radiological competence are both mandatory for the primary and secondary outcomes of the CHIVA to be a reliable relevant ones [15].

From the present study, it was concluded that both CHIVA and EVLA were equally effective in the treatment of venous ulcers (CEAP 6); the study included four patients with ulcerations: two in CHIVA group and two in EVLA group. All have healed sufficiently in an interval of time 2–6 months from the procedure.

However, it was just a secondary outcome not included in this work to be analyzed due to the small sample size which would be insignificant. Hence, it is recommended for this outcome to be a core of further researches with all participants of the samples of grade 6 CEAP classification with refractory venous ulceration either comparative or noncomparative.

The recurrence has been confirmed by patient symptoms, clinical examination, and duplex ultrasound scan. The recurrence has occurred in two cases; one of them is due to refluxing in the previously ligated escape points. This pattern of recurrence is the most common one in other similar studies as well. The present study suggestion behind this type of recurrence is owing to the use absorbable threads and sometimes the segments between ligatures left behind, as they should be removed at intervals of 1–4 cm. The second type of recurrence in our study and other ones is due to the reflux of the proximal part of GSV ensues. This pattern may occur as a result of ligation of any escape point, 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. Additionally, the absorbable sutures could induce neovascularization and hence reopening and refluxing of the previously ligated points.

It is clearly understood that recurrence does not take place in the EVLA procedure, simply owing to the

total ablation of the proximal part of the GSV. It is however concluded from some studies that these operations – in addition to loss of the GSV as a reserve for future revascularization surgeries – could result in the relative venous hypertension at the nonremoved competent tributaries making them incompetent, and consequently varicosities could recur.

Conclusion

CHIVA is safe, effective, and less invasive. In our study, CHIVA proved to be better in patients with incompetent perforators. Recurrence was documented in two cases, and no pigmentation or bruises were detected. Nevertheless, CHIVA to be done properly and lead to complete cure, it mandates considerable training supporting the surgeon to truly identify types of shunts and absorb the technical aspects of intervention which require a great volume of precision and meticulousness to produce the best results. Due to being more conservative and less radical, CHIVA operation should be performed professionally; otherwise, recurrences and complications could be worse than that with the conventional surgery. Therefore, it is totally clear to state that properly carried out stripping is much more beneficial to patients than poorly performed CHIVA procedure.

EVLA is considered now one of the top technologies to be used in management of varicose veins. It presents the best patient satisfaction regarding functional outcome. However, bruises are much more common to occur in EVLA than in CHIVA; however, bruises are self-limited and require no intervention. Although nerve injuries occur twice in this study with no cases in CHIVA, the results are nonsignificant. No recurrence occurred with EVLA.

To get the best of EVLA, the surgeon should be aware of using the duplex ultrasound and doing percutaneous intervention efficiently. EVLA can be done as outpatient procedure, as there is no wound and minimal postoperative pain. The risk of infection is minimal compared with varicose vein traditional surgeries.

It can be concluded that the CHIVA operation in this study is defeated by the EVLA when thinking about the recurrence rates, but EVLA cases had reported certain complications such as nerve injury and bruises. CHIVA gives advantage 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 in 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.

At last, we conclude that each type of varicose veins treatment (CHIVA-EVLA) has its advantage and disadvantages. Each type of these interventions should be tailored according to each patient variable, such as degree of reflux in GSV, presence of incompetent perforators, and aesthetic requirements of the patient.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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