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Comparative study between great saphenous vein endovenous laser ablation (EVLA) and modified haemodynamic correction (CHIVA) as a treatment for varicose veins

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Abstract--Varicose veins (VV) could be a handicapping condition which may lead to limb swelling, pain and venous stasis ulcer. Prevalence of VV could present from 1% to 73% and from 2% to 56% at women and men respectively. CHIVA has been developed through the last two decades and is currently the second most common surgical procedure for the operative management of VV. Endovenous laser treatment of GSV was approved by FDA in 2002 and SSV was approved in 2003. EVLT allows delivery of Laser energy directly into the blood vessel lumen. EVLT with a 1470-nm diode Laser system is clinically safe, feasible and well-tolerated technique without scar and allows people to return to their normal daily activities rapidly. In a prospective comparative study between January 2018 and January 2020, 40 patients from those attended the outpatient departments complaining from VV were assessed according to the 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. Cases were reviewed regularly at the outpatient clinic for 6 months for recurrence and complications. The recurrence occurred at 2/20 and 0/20 at CHIVA and EVLA respectively. Regarding the aesthetic satisfaction of the patient, the EVLA was better; 2 unsatisfied patients in EVLA in contrast to 5 unsatisfied patients in CHIVA. The wound infection 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 in CHIVA group if compared to the results with EVLA group which were 9/20, 1/20 and 2/20 respectively. CHIVA is safe, effective and less invasive. Nevertheless, CHIVA to be done properly and lead to complete cure it mandate 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. 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 and aesthetic outcome. EVLA can be done as outpatient procedure as there is no wound and minimal postoperative pain.

Keywords---varicose veins, CEAP classification, CHIVA, EVLA.

Introduction

Varicose veins (VV) could be a handicapping condition which may lead to limb swelling, pain and venous stasis ulcer due to chronic venous insufficiency (CVI). This condition basically originates from incompetence of great saphenous vein, small saphenous vein or both. Prevalence of CVI can occur up to 40% of women and 17% of men, while the varicose veins could present from 1% to 73% and from 2% to 56% at women and men respectively¹ 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% at men and women respectively. The most advanced form of CVD, which is properly named as CVI, accounts for 20% of CVD at elderly patients. This advanced stage could lead to chronic venous ulcer (CVU) which represents 70% of all lower limb ulcers and consequently lead to decreased quality of life (QOL) and significant economic burden²

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 (EVLV/EVLA) is a recent less invasive method for management of refluxing veins, which may be done in an outpatient setting using local anaesthesia. The safety of EVLT and its early postoperative results seem to be considerably competitive with those of traditional surgery³ The Ambulatory conservative hemodynamic correction of venous insufficiency technique (CHIVA) 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 axis⁴

There are three methods of thermal ablation in comprehensive vein centers at present, Radiofrequency (RF) energy from a dedicated generator and endovenous laser (EVL) which uses a laser fiber and generator to produce focused heat, Both RF and EVL are catheter based endovascular intervention 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, 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 (EMA) has been done in Europe. This technique has all the advantages of endovenous laser and radiofrequency ablation, but without some of the drawbacks of both like ecchymosis and skin burns and less postoperative pain. However, it is still an endovenous thermal technique requiring tumescence⁷

One of the most exciting new treatments for varicose veins and venous reflux disease is HIFU: high intensity focused ultrasound. 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 non-invasive 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 non-invasive 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 including 40 patients seek medical advice at vascular surgery outpatient clinic in Beni Suef and Cairo university hospital for management of varicose veins. All patients will be subjected to clinical examination including CEAP clinical classification and venous duplex assessment which will be carried out by expert radiologist. This study evaluates patients from January 2018 to January 2019 with post-operative follow up of 6 months. All patients presented with varicose veins of great saphenous vein will be divided between two groups of treatment, EVLA and CHIVA. Group 1 will include 20 patients who will be treated using CHIVA. Group 2 will include 20 patients who will be treated using EVLA.

Inclusion criteria

- Primary CVD with CEAP clinical class 2-6.
- Presence of SFJ reflux and incompetence of the GSV trunk.
- At least one re-entry perforator located on the GSV trunk.
- At least one incompetent tributary of the GSV.
- E) Patent and competent deep venous system of both lower limbs.

Exclusion criteria

- Patients complain of short saphenous vein varicosities.
- Patients with previous history of DVT.

- 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

CHIVA 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 to 4 cm) using absorbable ligation (braided synthetic polyglactin Vicryl®) 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 suture were used to give better results; polyglactin (Vicryl®) 3/0 for all escape points except for SFJ 2/0 transfixing sutures were used. 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.

Endovenous laser ablation (EVLA)

After duplex venous mapping was done by an expert radiologist and skin marking was painted by indelible ink while patient is standing, patient was taken to operating room. All patients were offered local infiltration and tumescent anesthesia. A 6 F 11 cm sheath (Prelude Sheath Merit Medical®) was inserted in the selected below knee GSV using ultrasound guidance. The Biolitec 1470 nm 600u radial tip laser fiber was inserted through the sheath up to the SFJ. Tumescent anesthesia is infiltrated peri-venous by 21G needle which consist of 500 cc Normal Saline 0.9%, 50 ml lignocaine 1% (Xylocaine®) and 1ml Adrenaline 1 mg ampoule. In longitudinal ultrasound view, pull back the fiber to be 2 cm from the SFJ. Firing of laser power (Biolitec, ELVeS® Radial® ring, Germany) starts with 10 Watt as a power, at first 2 centimeters, 2 cycles are done and 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 hours and replaced by class II compression elastic stocking for 4 weeks.

Post procedure 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 which had been treated by EVLA the bandage was used to minimize bruising and hematomas formation. Then bandages were then replaced with class 2 medical compression stockings after 48 hours and for 4 weeks. All patients were encouraged to start ambulation shortly for intervention either in CHIVA group or in EVLA group. Anticoagulation was given in either group for 3 days. Patients were usually discharged from hospital on the day of surgery at CHIVA and EVLA procedure. Patients were reviewed in the outpatient clinic 2 to 4 weeks following surgery to avoid post-operative 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 post-operative, to assess the outcome of these treatments by clinical examination and duplex assessment.

Results

The present study is a prospective comparative trial and included aged from 22 to 53 years old, 40 subjects, divided into 2 groups (1 and 2). Group 1 (20 case, mean age 32.35 years and sex ratio male: female=1:1.8), underwent CHIVA procedure and group 2 (20 case, mean age 35.2 years and sex ratio male: female= 1:1.5), underwent the Endovenous laser ablation. Age ranged from 22 to 53 at both groups Student t test was performed to test for the difference of age between the CHIVA and EVLA group, there is no significant difference between the 2 groups in the age; P value= 0.834 (Figure 1).

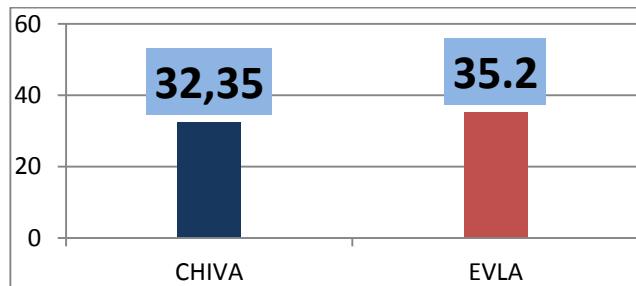


Figure 1. The difference of age between the CHIVA and EVLA group

At group (1) 7 males and 13 females, and group 2 there were 8 males and 12 females. 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) (Figure 2)

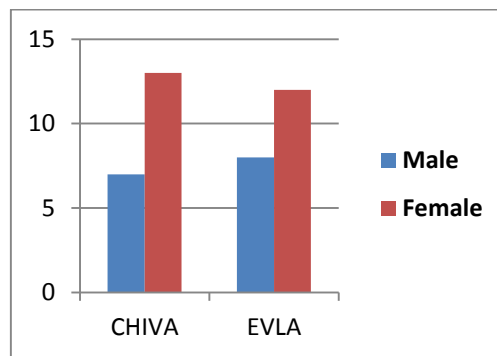


Figure 2. Chi squared test is done to compare between the two groups in the sex distribution

The main symptoms were pain at 17 cases and the varicosities at 14 cases, while the other symptoms were less prominent where ulcerations presented at 5 patients but the cosmetic and pigmentation presented at 3 and 1 patients respectively. 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), (Figure 3).

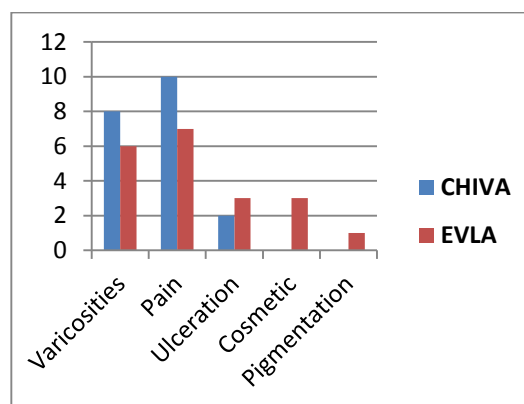


Figure 3. Main preoperative symptom. Chi squared test is done to compare between the two

There is no significant difference between the 2 groups regarding CEAP classification distribution (p value = 0.522) (Table 1& Figure 4)

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

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 2 groups (p value = 0.522)

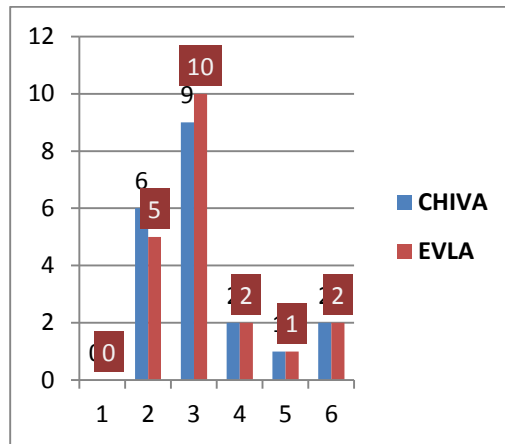


Figure 4. Mann-Whitney Test is done to compare between the two groups in CEAP, but there is no significant difference between the 2 groups (p value = 0.522)

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 EVLA 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 (Figure 5). The nerve damage occurred at all case 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, but it was neither annoying nor impacting the QoL of the patients.

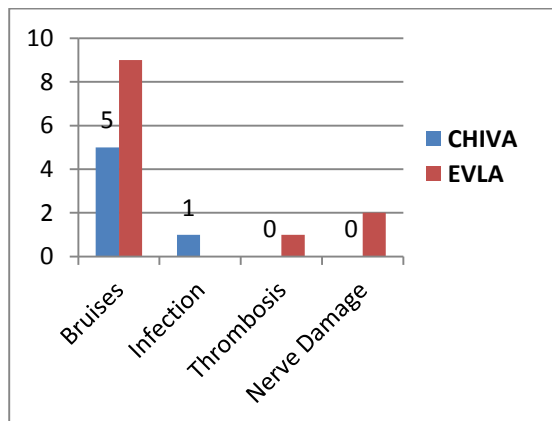


Figure 5. Comparison between the two groups in the occurrence of bruises, there is statistically significant difference between the 2 groups (p value = 0.035)

There is no significant difference between both groups regarding recurrence rate as there were 2 cases of recurrence in CHIVA group but no recurrence in EVLA group.

Table 2
Recurrence rate in both groups.

	CHI VA	EV LA	P Value	Significance
Recurrence	2	0	0,53	Not significant

Chi squared test is done to compare between the two groups in the patient satisfaction, (Figure 6)

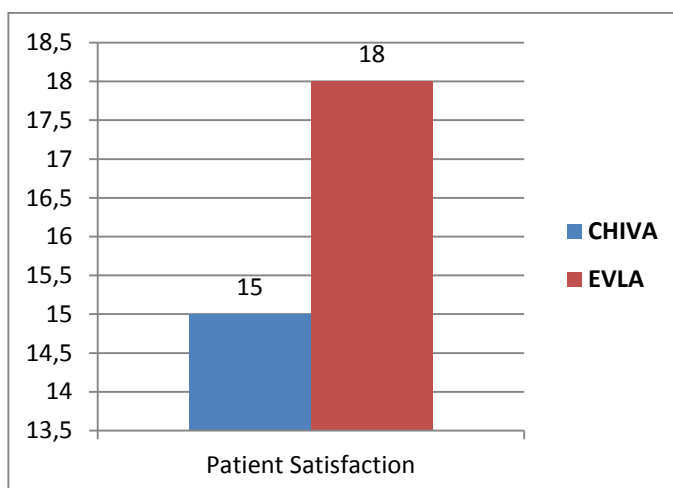


Figure 6. Chi squared test is done to compare between the two groups in the patient satisfaction, but there is no significant difference between the 2 groups

Discussion

Considering the primary outcomes, data recorded of this study revealed that the EVLA is favored over CHIVA as regard the recurrence rates; two patients suffered from recurrence (one due to reflux of previously ligated EP because of angiogenesis, the other one was due to reflux from form the proximal part of GSV into its tributaries. Meanwhile no recurrence was recorded in EVLA group during 6 months follow up. A similar situation has been reported with the patient satisfaction where there were 2 unsatisfied patients in group 2 in contrast to 5 unsatisfied in group 1. However with analysis of the rest of study outcomes, it could be found that the wound infection was not very significant and it is one case in CHIVA group. On the other hand, the CHIVA is non-surprisingly 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 in CHIVA group if compared to the results with EVLA group which were 9/20, 1/20 and 2/20 respectively.

Carandina et al had a close opinion 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 this 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. Moreover, the CHIVA has been found to be more attractive in long term results (10 years). More deepening in the same study results, Carandina finally had recorded the recurrences as 13/70 (18.57%) versus 19/54 (35.18%) at CHIVA and stripping respectively at the 10 years follow up⁸. 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 corroborated the CHIVA as well. At 2010, 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 up⁹

The severity and extent of the recurrence determine the need for retreatment at either groups; Iborra E et al reported that 5/51 (9.81%) at CHIVA and 5/49 (10.20%) at stripping had been in need for surgical retreatment⁹ 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 (4.50%) at stripping¹⁰ 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 results⁹.

Clinical trial experience with diode lasers has produced extremely low rates of deep vein thrombosis (DVT) and paraesthesia, a low risk of skin burns, and no documented cases of pulmonary embolism; both paraesthesia and skin burns have been associated with 1064 nm laser treatment. The most common side 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 superficial¹¹. Some have speculated that the use of a bare laser fiber may lead to inhomogeneous vein wall destruction due 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 significant¹².

Similarly, mild differences in post-procedure pain were identified using the 1470 nm laser catheters with a radial fiber compared with the bare-tip fiber¹³ CHIVA was described by Maldonado-Fernandez N et al in 2016 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 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 surgeries⁴. 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 recurrence 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 satisfactory¹³

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 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 3 per 1000 at CHIVA¹⁴

While CHIVA procedure is highly dependent on the ultrasonographic duplex scan, so this imaging is consequently dependent on the radiologist, who must be a well skilled experienced 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 sharer in this procedure. Thus he should be of a reliable level of experience considering 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 as regards 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 and radiological competence are both mandatory for the primary and secondary outcomes of the CHIVA to be a reliable relevant ones¹⁵.

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 4 patients with ulcerations, 2 at CHIVA and 2 at EVLA groups. 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 the all subjects of the samples of grade 6 CEAP classification with refractory venous ulceration either comparative or non-comparative. The recurrence has been confirmed by subject symptoms, clinical examination and duplex ultrasound scan. The recurrence has occurred at 2 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 due to using absorbable threads and sometimes left segments between ligatures behind, while they should be removed intervals 1-4 cm. The second type of recurrence at 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 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. 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 at EVLA procedure; simply due 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 non-removed competent tributaries making them incompetent and consequently varicosities could recur.

Conclusion and Summary

Hemodynamic surgeries for treatment of varices are intensely argumentative and frequently non-attractive due to being non-familiar and totally different from the classic surgeries. The difficulties in the acceptance and limited spread of these procedures led to lack of the basic data about their principles and steep learning curve in addition to the lack of information supporting their results. However CHIVA is safe, effective and less invasive. Nevertheless, CHIVA to be done properly and lead to complete cure it mandate 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 proper 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 and aesthetic outcome. However, bruises are much more common to occur in EVLA than in CHIVA, it is self-limited and require no intervention. As well, nerve injuries occur twice in this study with no cases in CHIVA, it is non-significant. No recurrence occurred with EVLA. To get the best of EVLA, 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 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.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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