

A Non-Randomised Prospective Study Comparing the Efficacy of Endovenous Laser Therapy and Trendelenburg's Procedure for Sapheno-Femoral Junction Incompetence

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Abstract: ***Background:** Endovenous laser therapy (EVLT) for ablation of the great saphenous vein (GSV) is a popular method, thought to minimize postoperative morbidity compared with Trendelenburg's Surgery. There are however no RCTs comparing the two. This prospective non-randomized trial compared EVLT (980nm) and Trendelenburg's Surgery results at 6 days, 6 weeks and 6 months. **Method:** A total of 400 consecutive patients agreed to take part in the study, 200 in the EVLT group and 200 in the Trendelenburg's surgery group. Phlebectomy and ligation of incompetent perforators were performed whenever indicated in both groups. Patients were re-examined clinically at 6 days, 6 weeks and 6 months. Clinical success rate, operative time, complication rate, time to return to normal activity and the Varicose Venous Clinical Severity Score (VVCSS) were recorded. **Results:** The clinical success at the end of 6 months was not statistically different in patients in EVLT and Trendelenburg groups. The mean days required to return to normal activity in the Trendelenburg group (4.73 ± 0.58 days) was lesser than that in the EVLT group (4.87 ± 1.07 days). VVCSS score in the Trendelenburg's group was lesser compared to those in the EVLT group both pre-operatively and post-operatively. There was a single incident of DVT which was in the Trendelenburg group. **Conclusions:** Both Trendelenburg and EVLT are safe day case procedures. Patients in the Trendelenburg group had significantly lesser complications in the post-operative period in comparison and lesser post-operative pain compared to those in the EVLT group. Trendelenburg's procedure was a faster procedure and had a shorter hospital stay in comparison with EVLT procedure.*

Keywords: EVLT, Varicose vein, Trendelenburg, laser, vein

1. Introduction

Varicose veins are a common problem [1] and, apart from cosmetic concerns, it causes significant impairment in health-related quality of life. [2- 4] Venous insufficiency is extraordinarily common with estimates of up to 25% of women and 10% of men suffering from some form of superficial venous insufficiency. [5] Most patients with superficial venous insufficiency have leg symptoms which include aches, fatigue, throbbing, heaviness and night cramps. Severe cases can lead to skin damage. Heredity is the primary risk factor for developing superficial venous insufficiency. Prolonged standing can increase the risk of developing varicose veins in those genetically susceptible or can worsen existing cases. [6] Varicose veins causing symptoms in spite of conservative management warrant surgical treatment. Other indications include treatment or prevention of complications. Treatment begins with elimination of all the underlying sources of truncal reflux. [7] The goal of treatment is to maximize clinical improvement and minimize the risk of progression of this chronic disease. [7] Trendelenburg described Sapheno-femoral junction ligation alone, without stripping of the incompetent saphenous vein, in the 1890s. [8, 9]

Complementary GSV stripping came many years later with W.L. Keller in 1905 (internal stripping), C. Mayo in 1906 (external stripping) and W.W. Babcock in 1907 (flexible stripper). [10] The advantages of ligation alone over ligation and stripping, which are still debated today, include preservation of the saphenous trunk for possible future use as a bypass graft and avoidance of nerve injury. [11]

High ligation by itself is less invasive, quicker and simpler to perform, and associated with an easier recovery when compared to vein stripping. [11] Many studies have compared high ligation alone with high ligation and stripping and concluded that the former was associated with higher recurrence rates and higher re-operation rates. The main reasons for recurrences were inadequate groin surgery, thigh perforator incompetence and neovascularization. They have concluded that stripping of the vein is essential to reduce recurrence. [12]

High ligation and stripping of the saphenous vein has been the treatment of choice for many years; however, this procedure is not without its complications and ~5 to 10% of the patients developed recurrences during the first 5 years. [12, 13, 14 & 15] Studies have shown that recurrence of varicose vein stripping occurs early [16] with 73% of limbs destined for recurrent varicosities at 5 years already having them at 1 year [17, 18] Doppler USG was the cornerstone in changing the current knowledge and attitude in the management of varicose veins. Conventional high ligation and vein stripping was based on varicose vein descending progression hemodynamic concept that was established in the beginning of 20th century. It was believed that reflux always started at the SFJ or SPJ due to incompetence of the terminal valve and extended progressively in a distal direction within the GSV. Hence high ligation with stripping \pm phlebectomy of varices was the 'cure all' method. However systematic USG use has shown that this concept was wrong. [19]

In recent years new tools have been added, the so-called minimally invasive therapies such as EVLT & RFA which

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through an endovenous path of the respective catheters produces thermal energy, causing closure and fibrosis of the treated vein segment. [18, 20] In 1999, Dr. Bone first reported on delivery of endoluminal laser energy [21]. Since then, a method for treating the entire incompetent GSV segment has been described by Min and Navarro. [20, 22, 23] Relative contraindications for EVLT include absent pedal pulses, liver abnormalities limiting LA administration, pregnancy, breast feeding, inability to ambulate or uncorrectable coagulopathies. [7] Although rare, endovenous laser is not entirely free of complications. Mozes et al reported 3 cases (7.7%) of thrombus extension into the femoral vein following EVLT, underlining the importance of technique when performing EVLT. [24]

Another potential complication reported by Timperman is development of an AV fistula occurring after EVLT of SSV [25]. The remarkably low rate of true adverse reactions following EVLT compares favorably to other catheter-based procedures such as radiofrequency and US guided foam sclerotherapy. Endovenous laser treatment which received FDA approval in Jan 2002 creates non thrombotic vein occlusion by delivery of laser energy directly into the lumen via a 600-micron laser fibre. Maximal contact between the laser fibre and vein wall is necessary to cause sufficient damage to the vein resulting in wall thickening with eventual contraction and fibrosis of the vein. Over the past 10 years reports of impressive clinical success and low complication rates have made endovenous laser treatment an accepted option to eliminate reflux from incompetent truncal veins.

This study is intended to compare the outcome of EVLT and the standard Trendelenburg's procedure in order to find out if EVLT is indeed better in efficacy and gives more patient satisfaction. I have also tried to find out if at all EVLT has any new complications or pit falls in comparison with Trendelenburg's procedure.

AIM: To determine whether EVLA is more or less effective than Trendelenburg's surgery in the management of SFJ Incompetence and, additionally, whether there are any benefits beyond those of surgery.

2. Patients & Methods

Study Design: A Non-Randomized Prospective study.

Setting: General Surgery unit of Kerala Institute of Medical Sciences Hospital, which is a multi-specialty tertiary care center in South Kerala, India catering to about 200-300 patients per day in out-patients department.

Study population: Patients more than 18 years old presenting to Out Patients Department of Kerala institute of medical sciences with primary symptomatic varicose veins from June 2012 to May 2014 were assessed for suitability for trial participation

Inclusion Criteria: Varicose veins caused by incompetence of the SFJ with GSV reflux as demonstrated by Doppler and duplex US imaging. Incompetence was defined as reflux of at least 1 sec on spectral Doppler analysis, Age at least 18

years, completed written informed consent form, Ability to return for scheduled follow-up examinations, CEAP grade 2-4.

Exclusion Criteria: Nonpalpable pedal pulses, Inability to ambulate, Deep vein thrombosis, Mid-thigh perforator incompetence on Doppler, Recurrent varicose veins after previous surgery, Previous surgical interventions in the groin area with the exception of inguinal herniotomy, Acute deep venous thrombosis or post-thrombotic syndrome, Known thrombophilia associated with a high risk of thromboembolism, Active malignant disease (diagnosed during the past 5 years), Women who are pregnant or nursing, Arterio-venous malformation.

Duration of study - June 2012 to May 2014.

Consent and Ethics: Informed written consent was taken from patient and his close relative and documented in patient's record. This non randomized controlled trial was approved by the Hospital ethics committee and the Institutional Research Department

Sample Size: As per the previous studies reviewed during this study, with power of 80% and alpha error of 5% it was estimated that a sample size of about 191/ group would be sufficient.

Trendelenburgs procedure:

The whole leg up to the groin cleaned with antiseptic and draped. A short transverse incision, 1–2 inches below the Inguinal ligament is made along the Langers lines. At that level, the anatomical position of the great saphenous vein is relatively constant, compared with the mid-thigh level (original Trendelenburg's procedure) where variations are frequent. Palpating the femoral artery in the groin wound was always helpful in finding the great saphenous vein, without carrying out extensive dissection. Ligation and division of the great saphenous vein just below the saphenofemoral junction at the saphenous opening was done after dealing all the small tributaries of the GSV. A 2-5 cm segment of GSV was removed from the distal limb

EVLT: The whole leg up to the groin was cleaned with antiseptic and draped. Tourniquet was applied at the mid-thigh level before puncturing the distal part of the greater saphenous main trunk with puncture needle No.18G under B-mode US guide at just above the knee level. The puncture site was infiltrated with 1% lignocaine before puncturing. Hydrophilic angled guide wire (0.32- or 0.35-inches diameter) was accessed via the puncture needle to the proximal part of GSV and common femoral vein while the tourniquet was removed. Five or six French long-sheath (40 cm or 55 cm long) was inserted over the guide wire into the common femoral vein under visual guidance by B-mode ultrasound, followed by the withdrawal of its stylet. 600 micro-meter laser fiber was inserted through the long-sheath into the common femoral vein and adjusted under intraoperative B-mode US. The laser beam in the present study was a diode laser of 980-nm wavelength (LASERING S.R.L., Laser model – VELURE S9) with 12-watt power and continuous pulse (3-second on time and 1-second off time). The tip of the laser fiber must be at about 2 cm distal

to the Saphenofemoral junction and out of the long-sheath before delivering the laser beam. At this stage, tumescent anesthesia was administered. The anesthetic solution included 500 ml saline, 5 ml 10% lidocaine, 10 ml 8.4% sodium bicarbonate and 1 ml adrenaline. Protective laser goggles were mandatory for staff and patients. Laser beam was delivered along the course of the GSV from the final position toward the initial puncture site. External compression was applied simultaneously at the area around the tip of laser probe to promote coaptation of the venous intima during laser beam deployment.

When necessary, the two treatment groups received an equal distribution of stab evulsions of clearly visible varicose branches and ligations of visibly ineffective perforators. Without regard to group, all Trendelenburgs and EVLT procedures were carried out under spinal anesthesia. The leg was covered with a double-layered elastic bandage that was changed 4 to 6 hours after the procedure and then wrapped in sterile absorbent bandages. After 48 hours, the patient took off the bandage and used a class II (30 mm Hg) below-knee elastic stocking for 3 weeks solely during the day. Enoxaparin (20 or 40 mg) was administered subcutaneously to the patient once day for 10 days as thrombosis prophylaxis, depending on weight.

Patient characteristics: There was a clear female majority in both the trial groups (54% in the EVLT group & 59% in the Trendelenburg group) which confirms the fact that the disease is more common in the female gender (Fig 1). 34% of the patients in the EVLT group belonged to the 3rd & 4th decade in comparison to 17% of the Trendelenburg group. Whereas 83 % of the patients in the Trendelenburg group belonged to the 5th, 6th and 7th decade in comparison to 66% in the EVLT group. Even though the difference was not statistically significant, the modern procedure EVLT was more popular with people in the younger age group whereas the traditional procedures were well acceptable for those in the older age group.

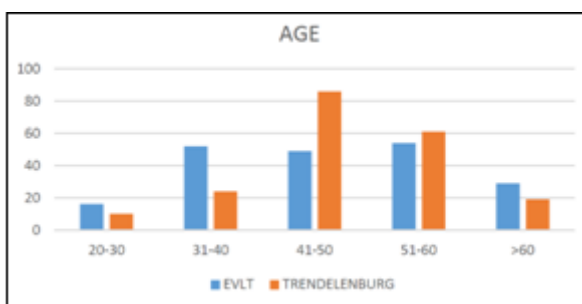


Figure 1: Female majority in both the trial groups

Patients were followed up at 6 days, 6 weeks & 6 months postoperatively. Clinical assessment (including symptom improvement, complications and recurrence) and complications of the procedure were the outcome indicators. Post-operative pain was analyzed by Visual pain score (0 to 10). Post procedure pain scores were recorded in a patient diary daily for the first 10 days using an unmarked 10-cm visual analogue scale. Presence of DVT if any was noted clinically and then confirmed with the help of US. Other complications like burns, ecchymosis, paresthesia was noted. Total number of days of hospital stay, time for

resumption of normal activities & work was noted during the 6th day and 6th week follow up visit. Satisfaction score was noted from the patients at the 6 months visit, which was scored from 1 to 5 [27]. (1 – Not satisfied, 2 – Minimal satisfaction, 3 – Just satisfied, 4 – Satisfied, 5 – Fully satisfied)

Outcome Measures:

Primary Outcome: Clinical response, Complications of the procedure,

Secondary Outcome: Hospital stay and time required for resumption to work Patient satisfaction

Statistical analysis: Data was analyzed using Statistical Package for Social Sciences (SPSS) 20.0. Means and standard deviation were calculated for continuous variables. Descriptive statistics mean and percentages were used to summarize the findings. Value of $P < 0.05$ was taken as the level of statistical significance

3. Results

625 patients were initially assessed for eligibility for taking part in the study. (Figure 2) Out of which 225 patients were excluded as they did not meet the inclusion criteria. A total of 400 consecutive patients agreed to take part in the study and gave written informed consent for inclusion in the study. All patients were offered both the treatments and explained the pros and cons of both treatments. After that they made an informed decision of which treatment they want to undergo. the patients in the Trendelenburg group had a statistically significant lower CEAP score compared to those in the EVLT group GSV diameter of patients undergoing the Trendelenburg procedure was significantly larger than those undergoing EVLT procedure at 6 months, 15 patients in the EVLT group were lost to follow up, whereas 25 patients in the Trendelenburg group was lost to follow up. 6 patients in EVLT group and 12 patients in the Trendelenburg group had some residual veins at 6 months in the GSV territory. But, none of them needed surgery and they were asymptomatic. patients in the Trendelenburg group had significantly lower pain compared to those in the EVLT group (Figure 3).

Table 1: A comparison of Mean Operation time of both the intervention group

	Intervention	N	Mean	Std. Deviation	Std. Error Mean
Surgery Time	EVLT	200	33.7300	5.63434	.39841
	Trendelenburg	200	24.7700	5.72020	.40448

Table 2

	EVLT	Trendelenburg	% Total
Day 1	169	188	89.25%
Day 2	29	12	10.25%
Day 3	2	0	0.50%
Mean	1.165	1.06	
Std Deviation	0.39	0.24	

Trendelenburg's procedure was significantly faster compared to EVLT procedure (Table 1). Patients in the

Trendelenburg group had significantly lesser complications in the post-operative period (Figure 4). Patients in the Trendelenburg group had a significantly shorter hospital stay in comparison to those in the EVLT group. (Table 2). 49/200 patients in the EVLT group had pigmentation in the postoperative period along the GSV territory which was treated, in comparison to only 24/200 patients in the

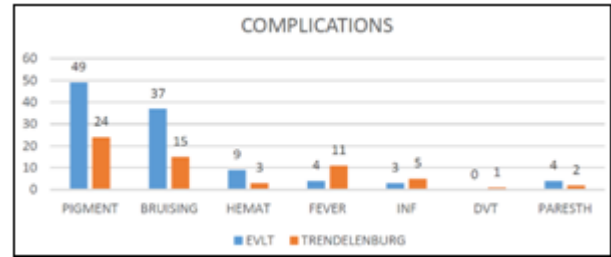


Figure 5

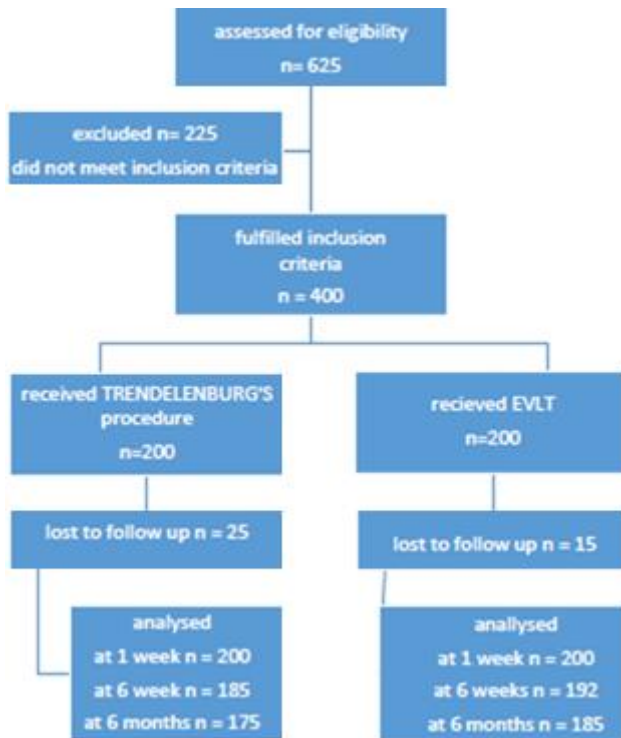


Figure 3: CONSORT chart showing the flow of patients through the trial of Trendelenburg's surgery versus EVLT

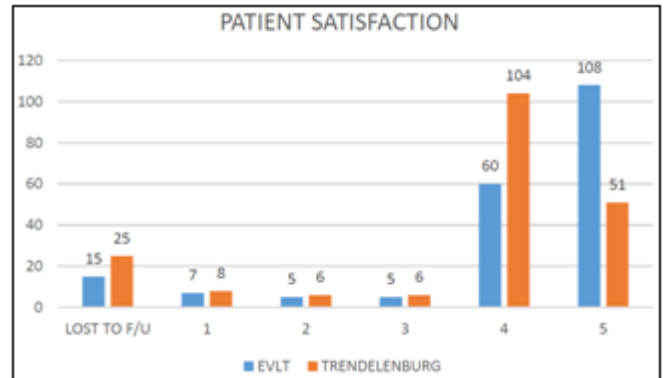


Figure 6

Trendelenburg group. 37/200 patients in the EVLT group had bruising in the postoperative period along the GSV territory which was treated; in comparison only 15/200 patients in the Trendelenburg group had the same complaint. Nine patients in the EVLT group and three patients in the Trendelenburg group developed hematoma in the operated site. Three of the patients in the EVLT group who had hematoma went on to have an infection and had consequent fever in the postoperative period. In comparison, five patients in the Trendelenburg group who had hematoma developed infection and then fever. In addition, six more patients in the Trendelenburg group developed unexplained fever in the postoperative period. But all of them resolved spontaneously. Few of them needed a course of antibiotics which was given parenterally for few days and then patient was discharged with oral antibiotics. There was a single incident of DVT which was in the Trendelenburg group. It was sub clinical and noticed incidentally on follow up. This patient was asymptomatic, and the diagnosis of DVT was based solely on the routine post-operative examination. This patient was managed conservatively with Low molecular heparin (Enoxaparin sodium, 1.5 mg/kg/day) which was administered subcutaneously for five days. Subsequent Doppler study showed resolving DVT and the patient made an unremarkable recovery. Four patients in the EVLT group had slight paresthesia in the medial aspect of thigh in comparison to twopatients in the Trendelenburg group who had some paresthesia in the groin region. All patients were told to start normal activity when they feel comfortable in doing so though they were asked to wear compression stockings or crepe bandage for at least six weeks. The mean days required to return to normal activity in the Trendelenburg group (4.73 ± 0.58 days) was lesser than that in the EVLT group (4.87 ± 1.07 days). Approximately, patients in both the groups returned to work a week after surgery. The mean days required to return to work in the Trendelenburg group (6.88 ± 0.94 days) was lesser than that in the EVLT group (7.1 ± 1.85 days). VCSS score in the

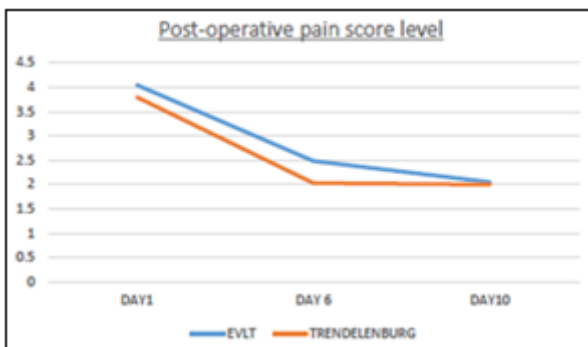


Figure 3

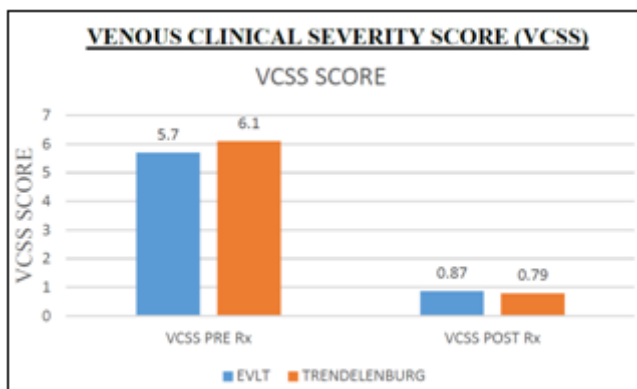


Figure 4

Trendelenburg group, pre and post intervention were 6.1 ± 0.67 and 0.79 ± 1.04 respectively, where as in the EVLT group it was 5.7 ± 0.9 and 0.87 ± 0.56 respectively (Figure 5). The patient in the EVLT groups were more satisfied with the treatment than those in the Trendelenburg group (Figure 6). Clinical success in both groups were comparable (Figure 7).

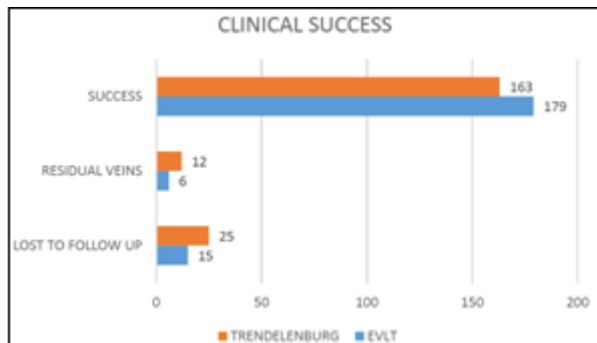


Figure 7

4. Discussion

In 1890, Friedrich Trendelenburg (Fig 6.5), a German surgeon, published his original paper on great saphenous vein ligation, which paved the way for modern-day venous surgery. This intervention was based on the hypothesis that great saphenous vein reflux and related venous hypertension could be eliminated by ligating the incompetent great saphenous vein. Trendelenburg tied off the great saphenous vein at the junction of the middle and lower thirds of the thigh using a longitudinal incision. [26] In 1896, 6 years after Trendelenburg's publication, Jerry Moore suggested modifications to the original procedure based on his own experience. As Trendelenburg ligated the great saphenous vein at mid-thigh level, several proximal tributaries of the vein remained under pressure by the persistence of reflux in the proximal great saphenous vein. In contrast, Moore recommended ligation and division of the great saphenous vein just below the sapheno-femoral junction at the saphenous opening. He presented a case series of 22 patients. 17 out of those 22 patients had ulcers and their ulcers healed or nearly healed within 10 days. He also noticed that the previously enlarged veins were markedly diminished after the surgery. [27] These are two landmark papers with respect to Trendelenburg's procedure for varicose veins. Then came the era of "High ligation and stripping", which finally became the gold standard for the past few decades. For more than a century, the classic treatment for saphenous vein insufficiency has been high ligation and stripping. [28] Many studies compared Trendelenburg's procedure with high ligation and stripping and finally the verdict was out with Neglen's study in 1991, that vein stripping was essential and it reduced recurrences after varicose vein surgery. [29] Then came the time of minimally invasive surgery like EVLT and RFA trying to replace the conventional high ligation and stripping. Unfortunately, both these interventions resulted in destruction of the GSV which has multiple uses in cardiovascular surgery and in vascular reconstructions. Trendelenburg's procedure is an old procedure and not frequently done these days as studies had showed increased recurrences. But there hasn't been any

RCT comparing Trendelenburg's procedure with other minimally invasive modalities. Trendelenburg's procedure preserves the GSV in comparison to EVLT and High ligation and stripping. GSV is an important vein which is used in cardiac surgeries and other vessel reconstruction. In an age where the average life span of people is increasing, the need to preserve the GSV cannot be over emphasized. There is another school of thought that the varicose vein even if preserved cannot be used for vascular reconstruction though the evidence is not there to support this. A landmark study by J Hammersten in 1990, involved 42 patients who were randomly allocated to treatment with high ligation alone or stripping of the GSV. They found that recurrence rate was 12% and 11% in the stripping and high ligation group respectively. He did USG on follow up, which showed that 78% of the preserved GSV were suitable for being used as vein conduits. This study showed that removal of the GSV had no therapeutic value if insufficient perforators have been ligated. [30] Conventional high ligation and vein stripping was based on varicose vein descending progression hemodynamic concept that was established in the beginning of 20th century. It was believed that reflux always started at the SFJ or SPJ due to incompetence of the terminal valve and extended progressively in a distal direction within the GSV. Hence high ligation with stripping \pm phlebectomy of varices was the 'cure all' method. [10] USG use has shown that this concept was wrong. Reflux and dilatation were frequently segmental and onset of varicose vein can occur in any segment without SFJ incompetence. [10] EVL ablation was introduced as an alternative to Ligation and stripping by Navarro et al. in 2002 [22] and has rapidly become the treatment of choice for treating saphenous vein insufficiency. [20] EVL ablation is proven to be very successful and durable in the treatment of saphenous vein insufficiency. One distinct major difference compared with classic varicose vein surgery is that endoluminal laser energy solely occludes the GSV without affecting tributaries at the level of the SFJ. This is remarkable, because it is generally accepted that recurrent varicose veins after surgery often have their origin in residual tributaries of the SFJ or in a residual saphenous stump. Surprisingly, the combined experiences with transcatheter endovenous ablation procedures have shown lower recurrence rates than with surgical ligation and stripping. Perhaps minimizing dissection in the groin and preserving venous drainage in normal, competent tributaries while removing only the abnormal refluxing segments does not incite neovascularization. [31, 32, 33, 34]

Traditional surgical methods to treat varicose veins are associated with significant complications, high recurrence rates and some patient dissatisfaction. McBride KD et al. did a randomized trial of SFJ ligation methods for primary saphenous incompetence which showed the **two-year** clinical recurrence rate of 33% and Doppler ultrasound (DUS) proven recurrence was up to 22%. However, the clinical benefits and cost-effectiveness of surgery are well established. [35] Navarro et al. conducted a study in 2001 and found out that early results of EVLT indicate a very effective and safe way to eliminate SFJ incompetence and close the GSV. With proper patient selection, the ease of methodology and the reduced risk and cost associated with

endovenous laser treatment may make it a successful minimally invasive alternative for a wide group of patients that previously would have required ligation and stripping. [37] Jose I. Almeida et al conducted a study From March 2002 until June 2005 during which endovenous thermal ablation was performed on 947 refluxing veins in 899 limbs of 694 patients by a single vascular surgeon at Miami Vein Centre. Cessation of retrograde flow in the target vein was observed in all patients at the completion of the procedure Recanalization was observed in 21 veins. Ninety percent (19 of 21) of the recanalizations occurred within the first 12 months after treatment. Percentage of recanalization was 1.7% with EVL. [36] Delivering more energy to the treated segment and closing multiple refluxing veins at the same setting has been reported as an advantage by other authors. [25, 37]

Agus et al. did a study to examine EVL in a multicenter study 1076 limbs in 1050 patients, mean age of 54.5 years, 241 males and 809 females affected by chronic venous insufficiency (CVI) were considered eligible for surgery and stratified by CEAP classification in a four-year period (January 1999 December 2003). They found out that in the immediate postoperative period the results have been impressive; with a very effective closure of incompetent great saphenous vein and the other treated varicose veins (the early occlusion rate has been 99%). After 36 months, the total occlusion rate of saphenous trunks was 97%. [38]

Min et al. conducted an uncontrolled study design in USA which included 423 patients (499 limbs). After 1 month, 9 limbs had repeat procedure. 8/9 were successfully closed with the second treatment. 40 patients have been followed up for 3 years – no new recurrences have been reported. All recurrences were noted before 9 months 24% limbs developed bruising outside the puncture site (resolved before 1-month follow up) 90% of patients felt tightness (lasting 3–10 days) 5% of patients developed superficial phlebitis of varicose tributaries. [20]

Proebstle et al. (2003) did an uncontrolled Study design in Germany which included 85 patients (109 legs); 62 women & 23 men; Procedure performed in one limb in 61 patients and in both in 24 patients. Follow up period was 12 months. He found out that 70 patients (67% limbs) had pain along the vein for a median duration of 1 week; 47 patients (45% limbs) a palpable in duration was noted along the treated GSV (3 weeks); 10 patients (10% limbs) had overt thrombophlebitis of the treated GSV or adjunct varicose tributary vessels, with redness and swelling. [33]

In a review done by Van den Bos et al., besides anatomic success rates, patient- reported outcomes such as health related quality of life, treatment satisfaction, symptom relief, and side effects were analysed. Compared with surgery, EVLA-treated patients appreciated EVLA more than surgery because they reported fewer side effects and their health-related quality of life improved better and faster. [39]

From the above literature it's clear that EVLT is as safe a procedure in comparison to open surgery if not safer. According to the American Venous Forum Guidelines

(4.10.0) recommendation endovenous laser therapy of GSV is safe and effective and has a grade 1A recommendation level. Many studies have already concluded that patient satisfaction is better with EVLT and complications are rare. In comparison, Trendelenburg's procedure is an age-old procedure almost lost in the books of history. It's out of favor due to increased recurrences associated with it.

On a PubMed search I found lots of studies comparing EVLT with high ligation and stripping, but there haven't been any comparing EVLT with Trendelenburg's procedure. In my study, Trendelenburg's and EVLT procedure had fairly equal outcomes except few increased complications in the EVLT group. Both were equally efficient but Trendelenburg's procedure resulted in a faster recovery. The conclusion of my study is that Trendelenburg gives comparable results to modern treatments like EVLT for varicose veins with a better adverse effects profile. Though longer follow up is required to comment on recurrences associated with each intervention.

Strengths of the Study: This is probably the first study comparing EVLT with Trendelenburg's procedure. US Doppler guided venous mapping was done routinely pre-operatively which probably was the reason of good responses seen in the Trendelenburg group

5. Limitations

The Study sample was not randomized. The follow up was only 6 months. Longer follow up is required in order to comment on recurrences. Patients with thigh perforator incompetence were excluded, because they can't be dealt with by Trendelenburg's procedure. Clinical success was used as an indicator of efficacy rather than radiological assessment. The quality-of-life perspective of the patient was not studied in this study.

In retrospect: If we were to perform the study again, we would perform the study as a Randomized Controlled Trial and follow up the patients for a longer duration. We would also like to follow up the patients with USG (SFJ reflux) rather than clinically. We would also like to study the impact of either procedure on the quality of life of the patient and the cost effectiveness both procedure.

6. Conclusion

The clinical success at the end of 6 months was not statistically different inpatients in EVLT and Trendelenburg groups. Patients in the Trendelenburg group had significantly lesser complications in the post-operative period in comparison and lesser post-operative pain compared to those in the EVLT group, and it was statistically significant. Trendelenburg's procedure was a faster procedure and had a shorter hospital stay in comparison with EVLT procedure. Both Trendelenburg and EVLT are safe day case procedures. The number of days to return to normal activities and to return to work was not statistically different in either group. VCSS score in the Trendelenburg's group was lesser compared to those in the EVLT group both pre-operatively and post-operatively. At the end of 6 weeks, the patients in the EVLT groups were

more satisfied with the treatment outcome than those in the Trendelenburg group and the difference was statistically significant.

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