A Comparative Study to Compare Results of Treatment of Incompetent Perforators by Laser *Versus* Foam Sclerotherapy in Chronic Venous Insufficiency Patients

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Received: 12th June, 2024; Revised: 24th August, 2024; Accepted: 04th September, 2024; Available Online: 25th September, 2024

ABSTRACT

Introduction: Patients of chronic venous insufficiency (CVI) of the leg can present with lower limb pain or heaviness, subcutaneous edema, skin changes such as hyperpigmentation with or without dermatitis and in advanced cases with ulcer in the gaiter area. Various modalities are now available for the treatment of CVI, namely endovenous thermal ablation, foam sclerotherapy, open surgical technique (stripping, phlebectomy, subfascial endoscopic perforator surgery and modified Linton procedure for the incompetent perforators.

Methods: In this study, adult patients of primary chronic venous insufficiency (C3-C6) diagnosed by venous duplex USG were enrolled. In both groups, the great saphenous vein (GSV) and short saphenous vein (SSV) were ablated by endovenous laser therapy. However, in group A, incompetent perforators were treated by endovenous laser ablation and in group B, they were treated with ultrasound-guided Foam sclerosant injection (0.5% Polidocanol). Patients were followed up for a period of 6 months.

Results: Technically all the incompetent perforators were feasible to puncture the perforators and to do the procedure. Anatomical closure rate of treated incompetent perforating veins In Group A at 1, 3 and 6 months was 68.33, 63.33 and 60.0%, respectively, while in Group B it was 65.95, 61.72 and 57.0%, respectively (statistically insignificant. Pain in group A at 1-month was mild (50%) and at 3 months only 10% and absent at 6 months, while in group B 50, 20% and absent at 6 months. Hyperpigmentation in group A was 06.66, 01.66 and absent at 1, 3, and 6 months, respectively, while in group B it was 10.63 and 04.25% and absent, respectively.

Conclusion: USG-guided endovenous laser ablation (EVLA) and Foam sclerotherapy are both technically feasible but the closure rate for treated perforators is almost the same for both techniques. In 6 month follow up, we found that EVLA is slightly better than foam sclerotherapy for the treatment of perforators but statistically insignificant.

Keywords- chronic venous insufficiency, Incompetent perforators, Foam sclerotherapy, Laser therapy.

Journal of Surgery Archives (2024);

How to cite this article: Kushwaha J, Singh KK, Khan A, Gupta R, Sonkar AA. A Comparative Study to Compare Results of Treatment of Incompetent Perforators by Laser *Versus* Foam Sclerotherapy in Chronic Venous Insufficiency Patients. Journal of Surgery Archives. 2024;2(2):31-35.

Source of support: Nil.

Conflict of interest: None

INTRODUCTION

A varicose vein is defined as dilated, elongated, tortuous superficial veins of the leg (GSV, SSV and their tributaries with junctional incompetence due to valvular reflux). This can lead to venous hypertension and eventually, various complications occur like venous edema, skin changes and ulcer formation.[1]

Chronic venous insufficiency (CVI) includes patients having venous edema, skin changes, and ulcer formation (C3 and onwards).[2] Patients of CVI most likely have incompetent perforators along with incompetent SFJ/SPJ valves. Isolated incompetent perforators are found only in 5 to 7%.[3]

Patients with CVI are diagnosed clinically and radiologically. Duplex doppler USG is a Gold standard investigation for the diagnosis. This is performed by 7 to 10 M Hz probe on a standing position. Superficial venous valves, SFJ valve, SPJ valve are called incompetent if reflux time is more than 500 msec (on Valsalva or calf muscle compression). Perforating veins are called incompetent if the diameter is more than 3.5 mm and the reflux time is more than 500 msec.[4]

Various modalities for the treatment of CVI are endovenous thermal ablation (laser or radiofrequency), foam sclerotherapy (Polidocanol or sodium tetradecyl sulfate is mixed with four

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times room air, i.e., by Tessari technique), ligation of SFJ and stripping of GSV up to knee joint.[5]

Various modalities for treatment of incompetent perforators are by endovenous thermal (laser or radiofrequency), foam sclerotherapy (0.5–1%), subfascial endoscopic perforator surgery, modified Linton procedure (perforator sites are marked by USG and ligated through a small incision).[6,7]

Endovenous thermal therapy and Foam sclerotherapy are both minimally invasive, scarless and daycare surgery.

In this study, endovenous laser ablation (EVLA) was performed for incompetent superficial veins (GSV/SSV) but for incompetent perforating veins, one of these two modalities was used. i.e., either by laser ablation or by Foam sclerotherapy.

Methods

This study was conducted in the Department of General Surgery, King George's Medical University, Lucknow and patients having Chronic venous insufficiency (CVI) (Figure 1), who came for treatment (after confirmation with Duplex Doppler USG in standing position) enrolled and were categorized as per CEAP 2020 classification. All patients (age >15 years) having unilateral primary CVI (C3-C6) were included in the study. Patients <16 years. Patients having DVT, deep venous reflux, and pregnant ladies with pelvic mass were excluded from the study. Informed consent regarding the procedure and its complications was taken.

Before the procedure Duplex doppler ultrasonography in the venous phase was done. Anatomical mapping of GSV, SSV, posterior venous arch, and sites of perforators was checked. Patients were allocated to either group A or B (non-randomized study). In both groups, incompetent GSV SSV was treated by endovenous laser ablation.

For the treatment of incompetent perforators, patients were allocated to either group A (EVLA of GSV/SSV and EVLA also for incompetent perforators) or group B (EVLA of GSV/SSV but in this group, foam sclerotherapy for the incompetent perforators) were done. For the foam sclerotherapy polidocanol sclerosant was used. It was diluted by normal saline to form 0.5% strength. In one Luer lock syringe, 0.5% of this diluted polidocanol was taken and in the other Luer lock syringe, 4 times room air was taken and both syringes were connected to the Triway stop cock. By to and fro motion content of both syringes was again and again mixed 20 times to generate foam. The foam that was created was used instantly. If the foam was used after 2 minutes of formation, it was reconstituted once again by passing it repeatedly between 2 Luer lock syringes (Figure 2).

The primary endpoints were to compare the anatomical closure rate of treated incompetent perforators in both groups by Duplex scan at 1, 3 and 6 months in follow-up.

Secondary outcomes were to compare pain based on VAS scale, pigmentation, skin necrosis and SSI at the puncture sites.

Patients having GSV or SSV insufficiency (Reflux time > 500 msec) were treated by Endovenous Laser ablation by Biolitec (Diode laser, 1470 nm, double ring, 400 microns, ELVeS radial slim fiber) at 7 watts for 10 sec for 1 cm and then fiber was pulled after every 10 seconds for 1 cm. GSV was treated from 2 cm below SFJ to knee level and SSV was treated 2 cm from SPJ to upper calf level (proximal 6–7 cm ssv). This endovenous laser ablation was done under spinal anesthesia and after injecting normal saline into the perivenous plane below the saphenous fascia to absorb laser heat. Approximation of the venous lumen to the laser catheter was further ensured by applying gentle pressure by the overlying ultrasound probe during ablation therapy.

Incompetent perforators (diameter >3.5 mm and reflux time >500 msec) were treated either by USG-guided laser (same fiber of diameter 400 microns) in group A, at 6w or by USG-guided Foam sclerotherapy in group B (0.5–1.0 mL, 0.5% polidocanol). Perforators sites were identified by Duplex scan and then angiocath (Venflon/Viggo) no 16 was passed into perforators (Figure 3). Angiocath was taken out and 400 microns, 1470 nm laser fiber passed into the perforator through this angiocath. Peri perforator (having laser fiber inside) normal saline (05 mL) was administered and the laser machine was put on for 10 sec. The tip of the laser fiber was put Just below the deep fascia. Leg elevated and Crepe bandage applied from foot to groin for 1-week.

Regarding Perforator ablation by Foam sclerotherapy (Fig 3,4), the site of incompetent perforators was located by Duplex USG on B mode and perforators were punctured by butterfly cannula no 24 G. Polidocanol foam (0.5% foam, 0.5–1.0 mL foam injected into perforator. Leg elevated and Crepe bandage applied from foot to groin for 1-week.

The study of Duration was 1-year and all patients were followed at 1, 3, 6 months.

RESULTS

The demography of patients are given in Table 1.

In both groups, it was technically 100% feasible to puncture the perforators and do that procedure.

Anatomical closure rate of treated incompetent perforating veins In group A at 1, 3 and 6 months was 68.33, 63.33 and 60.0%, respectively, while in group B it was 65.95, 61.72 and 57.0%, respectively (statistically insignificant). Pain In group A, at 1-month was mild (50%) and at 3 month, only 10% and absent at 6 months, while in group B 50, 20% and absent at 6 month.

Hyperpigmentation in group A was 06.66 and, 01.66% and absent at 1,3, 6 months, respectively, while in group B it was 10.63 and, 04.25% and absent, respectively (Table 2).

Skin necrosis in group A was not found in any patients, but in group B one patient had skin necrosis, which disappeared spontaneously before 3 months.

DVT was found in one patient in both group at 1 month in the soleus muscle sinus it was asymptomatic and gradually disappeared before 3 month without any treatments.

In group B, blurring of vision, chest pain, transient ischaemic attack (TIA), anaphylactic reaction, allergic reaction was not found in any patients in the post-operative period.

Table 1: Demographics details of patients

Factors		*Group A (laser) n = 60*	*Group B (Foam) n = 54*	*p-value*
Male		44 (73%)	40 (74.04%)	0.929
Female		16 (26.66%)	14 (25.92%0	
SFJ incompetency		54 (90%)	50 (92.59%)	0.748
SFJ and SPJ incompetency		06 (10%)	04 (07.04%)	0.822
No of Legs having incompetent Perforators		44 (66.66%)	40 (74.07%)	1.00
Total no. incompetent perforators per leg	No. of incompetent Medial (below the knee) perforators	54 (90%)	44 (81%)	0.280
	No of incompetent posterior perforators	06 (10%)	03 (05.5%)	0.496
No of patients in Clinical stage (CEAP classification)				
C3		15 (25%)	12 (22.22%)	0.827
C4		22 (36.66%)	20 (37.03%)	1.00
C5		13 (21.66%)	15 (27.77%)	1.00
C6		10 (16.66%)	07 (12.96%)	1.00

Table 2: Showing results

		1 Month	*3 Month*	*6 Month*
Anatomical occlusion	Group A (n = 60)	41 (68.33.00%)	38 (63.33%)	36 (60.0%)
	Group B (n = 47)	37 (65.95%)	29 (61.70%)	27 (57.4%)
	p-value		0.715	0.950
Pain (vas Score) 0–10	Group A (n = 60)	5 (50%)	1 (10%)	00
	Group B (n = 47)	5 (50%)	2 (20%)	00
	p-value		1.00	
Hyperpigmentation	Group A (n = 60)	4 (06.66%)	1 (1.66%)	00
	Group B (n = 47)	5 (10.63%)	2 (04.25%)	00
	p-value	0.94	0.835	00
Skin necrosis	Group A (n = 60)	00	00	00
	Group B (n = 47)	01 (2.1%)	01	00
	p-value	0.965	0.965	00

Figure 1: Chronic venous insufficiency patients

Figure 2: Foam formation by mixing polidocanol (0.5%) with room air in another syringe

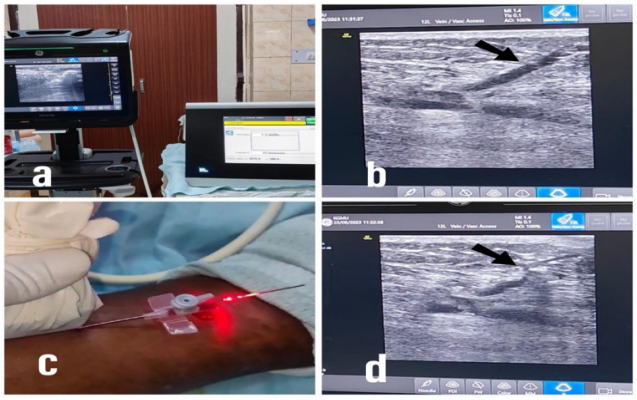

Figure 3: Endovenous laser ablation for perforator. (a) USG and laser machine. (b) Perforating vein (C) USG USG-guided laser fiber passing through angiocath into perforator. (d) Ablation (bubbling) of perforator

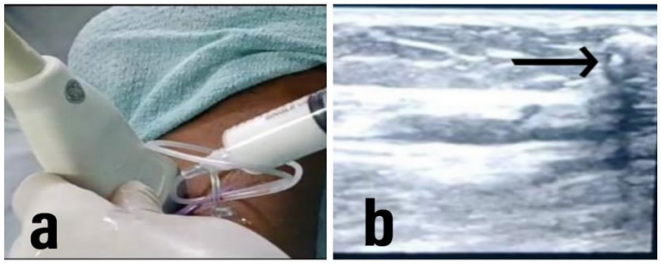

Figure 4: (a) USG-guided passing Foam sclerosant into perforator through butterfly cannula (b)- foam in the perforator

DISCUSSION

Homan first described in 1917, the role of incompetent perforators of the leg and how it causes pathophysiological changes leading to the development of venous ulcer formation.[2] Linton (called as father of perforator surgery) first described the ligation of perforators through a long medial incision from the knee to the Medial malleolus.[7] The disadvantage of this technique was that skin was already compromised due to edema, skin changes and ulcer formation, which causes delayed healing, infection, neuropathy, etc. However, with the advent of newer, less invasive treatment modalities, open surgical ligation has been largely abandoned.

Hauer described the SEPS in which two laparoscopic ports are placed in subfascial space below the knee on the medial aspect. One for the camera and the other for working ports and these perforators are cauterized or clipped.[8]

On follow-up of patients undergoing SEPS, success rates upto 78% were seen for closure of the perforator following the procedure. A meta-analysis of about 20 studies performed by Tenbrook *et al*. revealed the potential side effects of SEPS procedure. Hematoma formation, wound infection and neuralgia were the commonest complications (incidence between 6-9%). Deep vein thrombosis occurred only in 1% of patients. The incidence of these side effects, coupled with the need for formal anesthesia, is what prompted the search for a lesser invasive modality for venous insufficiency, such as image-guided therapeutic procedures, i.e., Endovenous thermal ablation by laser or radiofrequency.[9]

Ultrasound-guided foam sclerotherapy (UGFS) entails the use of micro-foam that is injected into the target perforators under direct ultrasound guidance (Figure 4). It is a relatively easy procedure requiring a short learning curve that is facilitated by the use of ultrasonography during the procedure. Additional advantages include minimal cost and non-requirement of tumescent anesthesia. It is associated with successful closure rates of up to 75% with an associated improvement in clinical severity scores at 20 months.[10,11]

The most common side effects encountered are allergic reactions to the sclerosant that may cause dermatitis or even painful thrombophlebitis. Cases of deep vein thrombosis have also been reported, especially where larger volumes of foam (>1–2 mL) have been used over venous segments. There have been a few isolated case reports suggesting systemic embolization and associated transient ischemic attacks/strokes or even visual disturbance in the form of amaurosis fugax. However, the incidence of these side effects has been found to be very low compared to the number of such procedures being performed worldwide. A few case reports have been published where an inadvertent injection to adjoining arteries with foam has resulted in skin necrosis.

Thermal ablation of perforators has been performed using either radiofrequency (RFA) or laser energy (EVLT). These procedures have been found to be technically more challenging with a greater learning curve. It also incurs higher costs of equipment (laser fiber, laser/RFA machine) There have been numerous studies, however, that have demonstrated higher rates of perforator closure (up to 95%) with the use of thermal ablation compared to guided foam sclerotherapy. Lack of need for formal anesthesia and the ability to conduct the surgery as an outpatient procedure is perhaps the most pertinent advantages of thermal ablation (EVLT or RFA) over conventional open surgery or SEPS.

In a study conducted by Hager *et al*, 296 perforator ablations were performed on 112 patients with C5 and C6 disease after adequately treating superficial venous reflux. 62 of the 296 patients (21%) underwent EVLA, 93 patients underwent radiofrequency induced thermal ablation (31%) RFA, and 141 (48%) underwent foam sclerotherapy. It was noted that at 2 weeks, incompetent perforator closure rates were significantly lower in patients who underwent US-guided foam sclerotherapy (57%) compared to patients who underwent radiofrequency ablation (73%; $p = .05$) but failed to reach significance compared to EVLA (61%; $p = .09$).[12,13]

Following EVLA, the technical success rate for the feasibility of incompetent perforators was 100%. Post-operatively, no statistical difference in complications between the two groups could be ascertained. On follow-up at 1 year, 68 perforators had undergone recanalization and were still incompetent in the EVLA-treated group compared to 437 incompetent perforators in the untreated IPV group (18.7 *vs.* 92.6%; $p < .001$).[14]

A study conducted by Ho, Adkar and Harris that reviewed 81 studies and included 7010 patients determined a complication rate of 11.3%, across all interventions. No incidence of stroke or air embolism was reported. The short-term (1-year) wound healing rates were 99.9% for ultrasound-guided foam sclerotherapy, 72.2% for open incompetent perforator ligation and 96% sub sub-endoscopic perforator surgery.

In our study, we found technical success rate was 100% and the anatomical closure rate of treated perforating veins In group A at 1, 3 and 6 months was 66.66, 63.33 and 58%, respectively, while in group B it was 65.95, 63.82 and 60%, respectively. In group A, pain at 1 month was mild (50%) and at 3 months, only 10% and absent at 6 months, while in group B 50, 20% and absent at 6 months.

CONCLUSION

USG-guided EVLA and foam sclerotherapy are both technically feasible, and the closure rate for perforators are almost the same for both techniques. Follow-up is only for 6 months, in which EVLA for perforator is slightly better than foam sclerotherapy for the treatment of perforators but statistically is insignificant.

Currently, insufficient evidence is available regarding the optimal treatment strategy for incompetent perforator veins in patients with chronic venous insufficiency. This is largely due to poor adherence to global reporting standards and also because of a lack of randomization and blinding in comparative studies. Further studies, ideally good quality, double-blinded, multicentre randomized control trials, are needed to be able to provide concrete statistical information to guide clinical decision-making with regard to surgical treatment options for IPVs.

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