Research Article

Endovascular laser therapy of Great saphenous vein reflux, is it effective?

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Abstract
Background: Chronic venous insufficiency and varicose veins have a detrimental effect on the patient quality of life. Great saphenous vein (GSV) reflux is the most common underlying cause of symptomatic varicose veins. Traditional treatment of GSV reflux has been surgical removal of the GSV. In recent years, endovenous laser ablation (EVLA) therapies have been recommended to be the treatment of choice. **Aim of the work**: evaluation of the immediate and short-term outcome of endovascular laser therapy of great saphenous vein reflux. **Material and methods**: The study included 85 great saphenous veins, in 73 patients (61 unilateral and 12 bilateral) having symptomatic great saphenous vein reflux, were treated over a period of 24 months with endovenous laser therapy. The selected Patients were through nonrandomized prospective study. Patients assessment was done clinically and by color Doppler ultrasound one week, 4 weeks, 3 months, 6 months, and 12 months after the procedure to estimate the effect of endovenous laser treatment. **Results**: Technical success was achieved in all cases. Out of the 85 incompetent saphenofemoral junctions, 5(5.9%) continued to have evidence of reflux detected within the first 3 months by color Doppler ultrasound. Patients had minimal bruising at the laser fiber access site and reported slight discomfort along the treated vein at one week. No patient had nerve affection, skin burns or thrombosis of deep venous system. **Conclusion**: Endovascular laser therapy is a minimally invasive, and efficient procedure for the treatment of great saphenous vein reflux and provides impressive short-term and up to 12 months results
Abbreviations: EVLA: endovascular Laser ablation. GSV: great saphenous vein.
Keywords: great saphenous veins, endovascular laser therapy.

Introduction
About 15% of men and 25 % of women have lower extremity superficial venous insufficiency[(1)]. Varicose veins are affecting significantly the patient's life quality, causing significant pain, burning sensation, cramping, and leg fatigue. In advanced stages, patients may show color changes of the skin, leg swelling due to underlying edema and ulceration[(2-3)]. Refluxing great saphenous vein is considered the commonest reason of symptommatic varicose veins. Surgical excision of the great saphenous vein was the only way of treatment of the vein reflux. Tributary varicosities require multiple phlebectomy or follow up treatment with sclerotherapy.

Recently, because of significant postoperative morbidity and complications of surgical ligation and stripping of the saphenous venous system, the Joint Committee of the Society for Vascular Surgery/American Venous Forum recommended that endovenous laser therapy is the best method for treatment of varicose veins reflux[(4-6)]. The recent management of chronic venous insufficiency is the treatment of the reflux before varicose veins to avoid their recurrence[(7)]. Recently, endovascular venous laser therapy is very effective and safe method in the management of a refluxing saphenous vein and provide another alternative choice with surgery for the refluxing veins[(8-9)]. Additionally, it is becoming increasingly popular all over the world to be the best treatment of any refluxing vein[(10-11)].

Material and methods

patients

Between January 2016 and December 2017; seventy-three patients(85 limbs), were treated with endovenous laser therapy. All patients were presented to Saudi German hospital, Riyadh, KSA, with the incompetent saphenofemoral junction, great saphenous vein reflux, and varicose veins (Fig.1,2,3). The hospital institutional review board approved this study. All patients signed a written informed consent included awareness of other available treatment like surgical and radio frequency options, and the possible side effects of the procedure. The selected Patients were through nonrandomized, prospective study. No controls were used. All treated patients were symptomatic with visible varicose veins presented at least in one limb (figure1-A). Also, cramps, minimal bleeding, pain, and changes in the skin color were presented (table1). No previous surgical or interventional management for varicose veins has been done for all the patients enrolled in this study. Before the procedure, an ultrasound color Doppler was done for tracking the targeted vein on the patient skin in the upright position and evaluation of the flow and reflux by manual compression and Valsalva maneuver (Fig. 1, 2,3).

Inclusion criteria: Patients with great saphenous vein insufficiency diagnosed by color Doppler ultrasound with an incompetent saphenofemoral junction.

Exclusion criteria: Absent distal arterial pulsations, difficult walking, thrombosis of the deep venous system, and pregnant women

Technique:

Color Doppler ultrasound was done for all patients to find out the incompetent vein and accurately detect the abnormal waves. The diameter of the great saphenous vein was measured at 2 cm below the saphenofemoral junction while the patient was standing. After leg disinfection with alcohol and betadine, local anesthesia was performed. Under ultrasound guidance, a small gouge needle was inserted through the vein blow the level of the knee, while the patient was in the supine position. We used a linear ultrasound probe 7.5 to 10 MHz of LOGIQ 9 and S8 GE SYSTEMS. After needle insertion into the vein, a 0.018-inch guide wire was inserted into the vein which was exchanged with a 0.035-inch standard J guide wire through the sheath of the micropuncture set. After that, the guide wire was placed along the saphenofemoral junction and 5 F sheath was introduced over it. Then removal of the wire was done and the upper end of the sheath was positioned about one inch caudal to the saphenofemoral junction. At this stage, tumescent anesthetic solution (50 ml lidocaine 1% in 500ml saline) was instilled, by a pump, outside the whole length of the venous wall and surrounding subcutaneous tissue.

Laser ablation

After confirming the position of the fiber tip to be 2 cm below the saphenofemoral junction by color Doppler ultrasound (Fig. 4), the ablation procedure started using a laser fiber with bare tip of 600um in diameter, then by firing the laser 100 J/ cm with a continuous pulling back with a power value 10 watts (LASER SYSTEM, VENACURE 1470nm). After complete ablation of the vein, coverage of the puncture area with adhesive bandage was done after removal of the fiber and sheath. Graduated compression stocking was worn for one week after treatment (class two 30-40mmHg). After the procedure, the patients were recommended to walk immediately and for at least 1 hour every day and return to their normal daily activities except for the extraordinary work. After the procedure, analgesics were given to the patients for 1 to 2 weeks according to the degree of pain. Follow up of the patients by color Doppler ultrasound was done after 1 week of the procedure for detection of any thrombus at the saphenofemoral junctions and subsequent follow up after 3months, 6 months and 12 months to evaluate the venous occlusion and subsequently the effectiveness of the procedures by assessing the compressibility, echogenicity, diameter and flow pattern of the great saphenous vein treated part(Fig 5,6,7). Our technique was considered successful when optimal catheterizations and obliteration of the incompetent great saphenous veins were done either immediately or during follow up by color Doppler ultrasound (Fig. 8&9) with subsequent non compressible or non visualized great saphenous vein with non flow pattern and also recanalization or recurrence were documented. The reflux was defined as the compressibility of greats saphenous vein or a reflux on Doppler ultrasound examination.

Results

Seventy-three patients (46 ± 14y) were treated, the ratio between males and females was (M: F 19:54). The mean diameter of great saphenous vein was 6mm, the range was 3-15mm and the mean length was 23.3cm (table1). Technical success was achieved in all cases. Out of the 85 incompetent saphenofemoral junctions, 5 (5.9%) only continued to have evidence of reflux detected within the first 3 months by color Doppler ultrasound, 2 of them at 6 weeks and had more than 1 second ,significant reflux, and persistent varicosities indicating primary failure and the other 3 at 3 months, had recanalization without significant reflux (less than 1 second) and remained patent with only flash reflux at 12 months (table2). On the other side, patients had minimal bruising at the laser fiber access site and along the points of the instillation of tumescent anesthesia and reported negligible discomfort along the treated vein at one week. No one had significant swelling or tenderness. No nerve injury, skin burns or deep veins thrombosis.

Table I: Demographic and clinical data of 73 patients in whom 85 endovenous laser ablations were performed

Age	**Years**
Mean ± SD	46 ± 14
Median	49
Range	20–68
Sex	n
Male	19(26%)
Female	54(74%)
Treated limb	n
Right	39 (46%)
Left	46(54%)
CEAP classification	n
Clinical	
C0 : no visible venous disease	0
C1: Telangiectatic or reticular veins	0
C2: varicose veins	60(70%)
C3: edema	0
C4: skin changes without ulceration	25 (30%)
C5: skin changes with healed ulceration	0
C6: skin changes with active ulceration	0
Etiology	
Congenital	0
Primary	85 (100%)
Secondary	0
Diameter of GVS mm Mean (range)	6(3-15)

CEAP: (Clinical-Etiologic-Anatomic-Pathologic classification system for chronic venous disorders), GSV, great saphenous vein).

Table II. Evaluation of Obliteration of GSV by Color Doppler Ultrasound

	Follow-up time/month			
outcome	*one*	*3*	*6*	*12*
total occlusion	*83*	*80*	*85*	*85*
Failure of occlusion	*2*	*5*	*5*	*5*

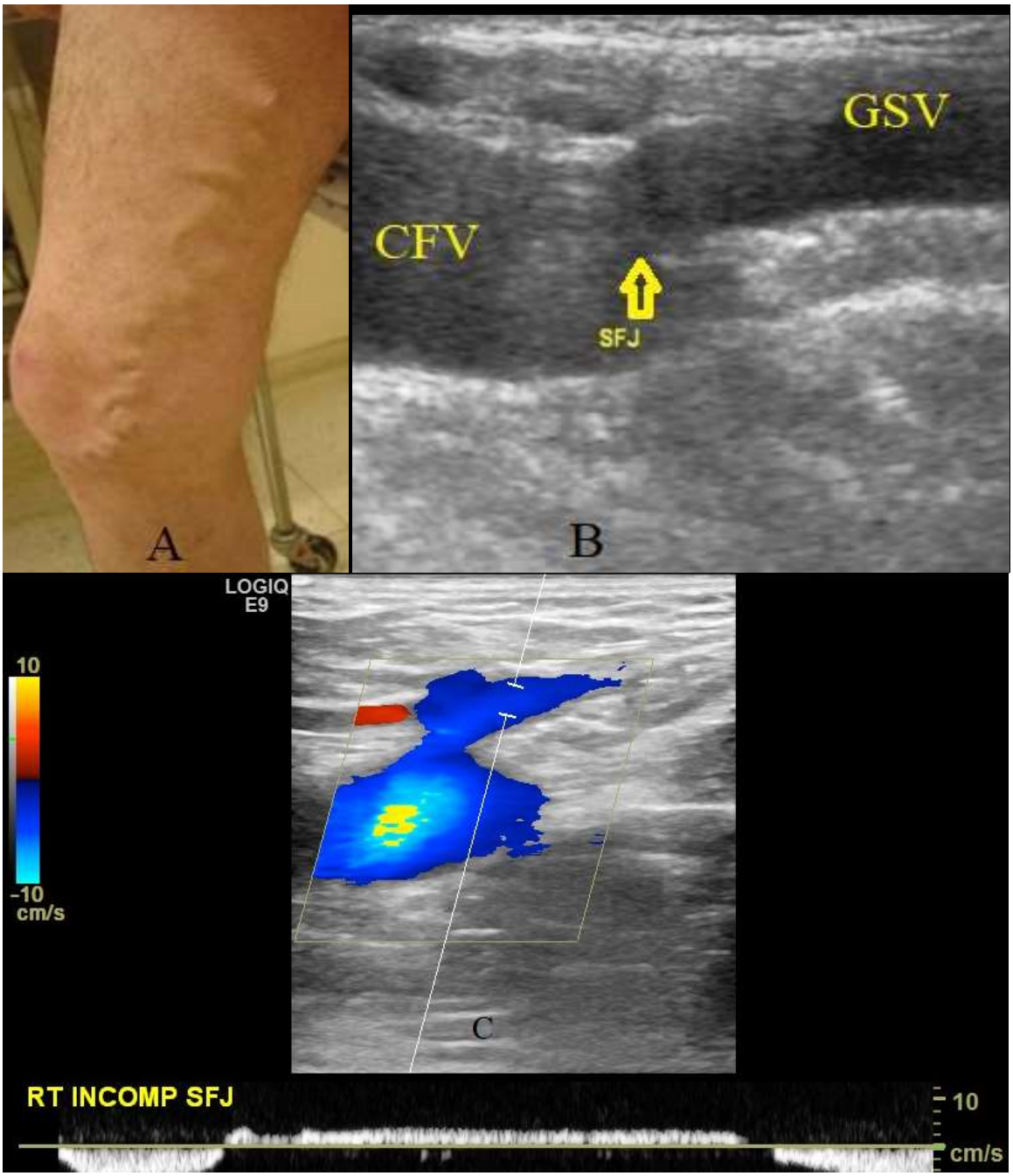

Figure 1. Color Doppler ultrasound .a-c A male patient of 45 years old presented with venous insufficiency symptoms a) the Right knee shows significant varicose veins along the medial aspect suggestive of great saphenous vein (GSV) reflux b) ultrasound showing the saphenofemoral junction(c) shows reflux with the Valsalva maneuver on Color Doppler examination .

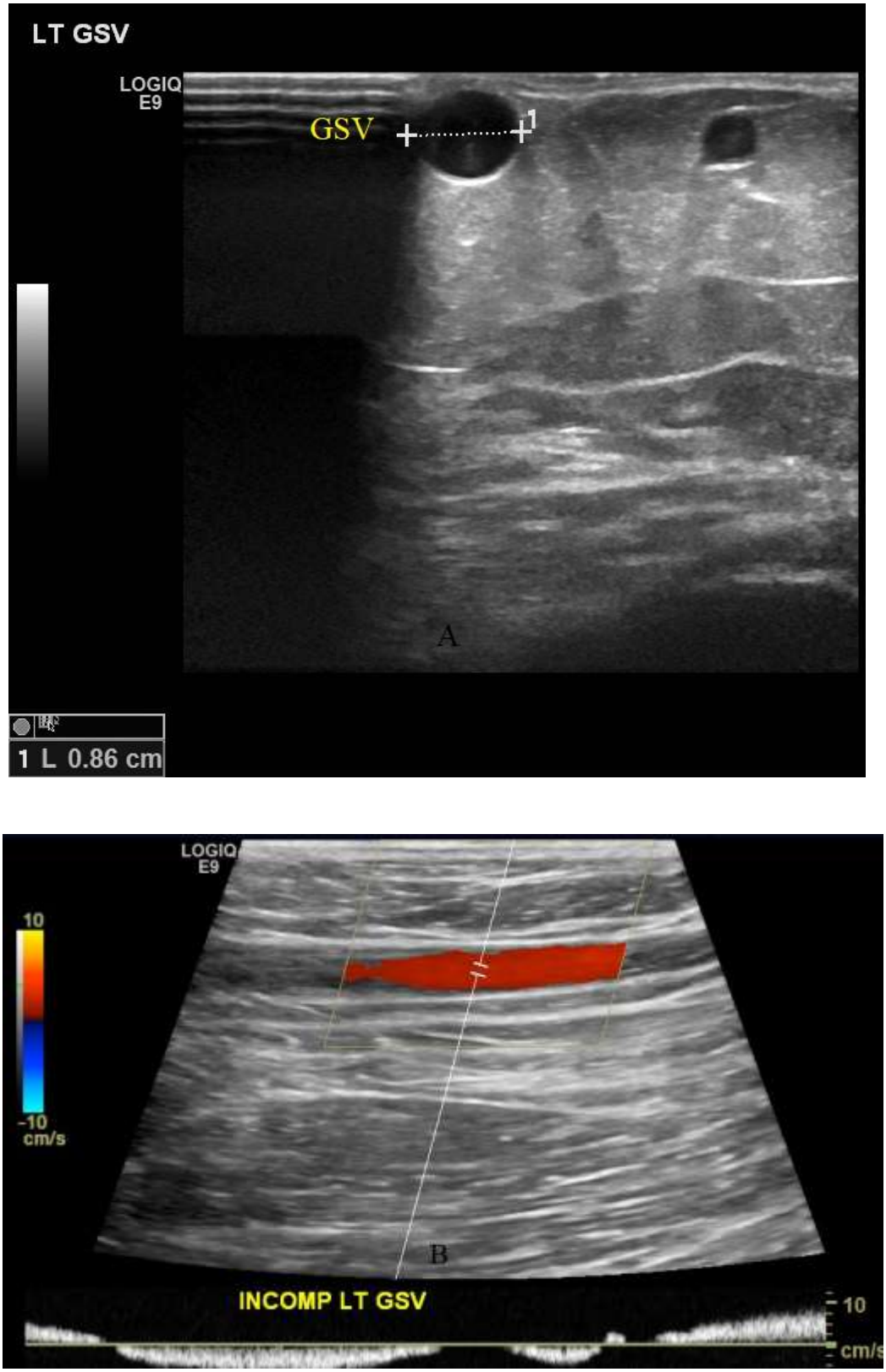

Figure 2. A-B Color Doppler ultrasound: Incompetent left saphenofemoral junction and dilated GS. ultrasound (A) and color Doppler (B) images.

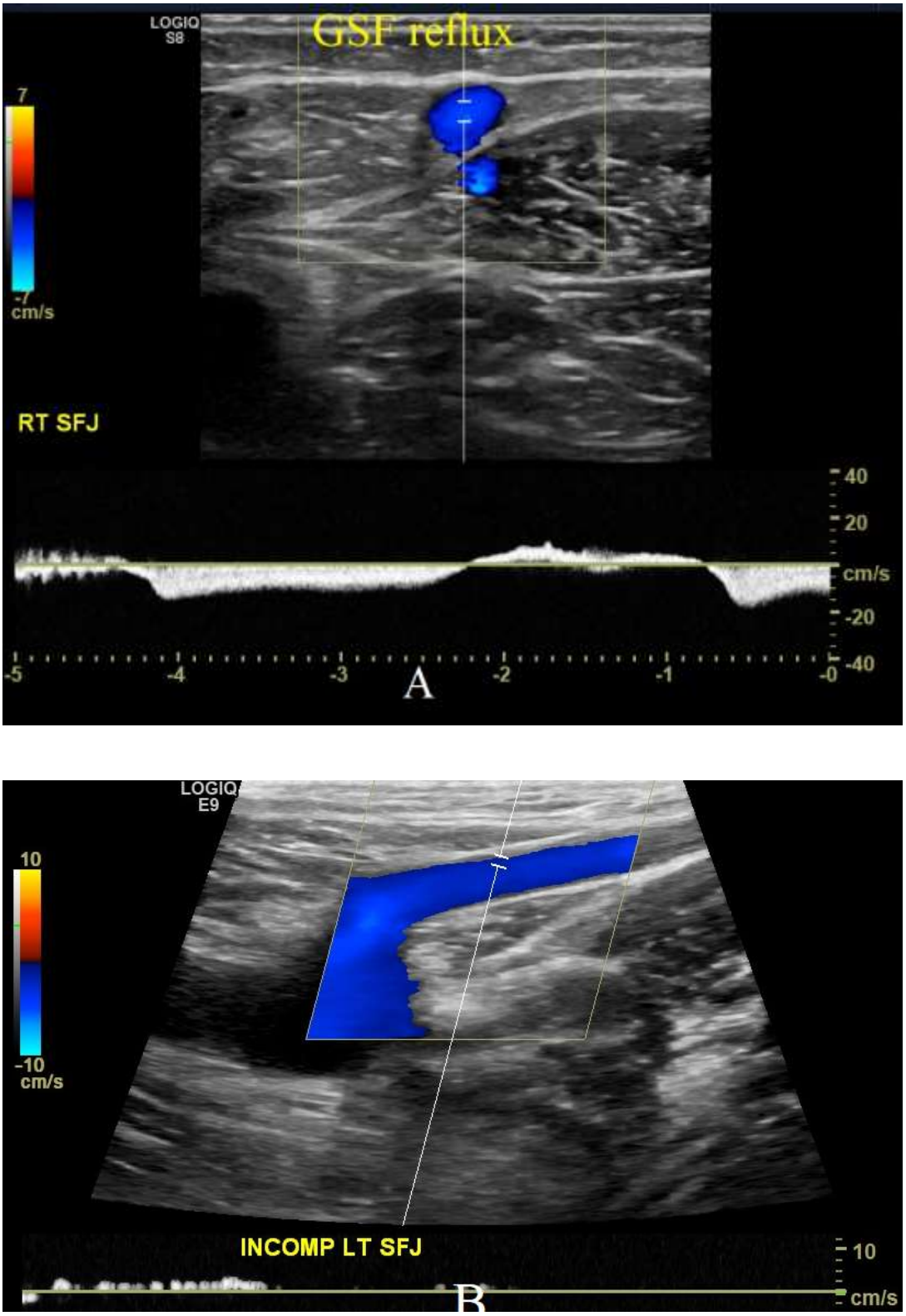

Figure 3. A-B Color Doppler ultrasound: Incompetent left saphenofemoral junction. Axial (A) and longitudinal (B) images.

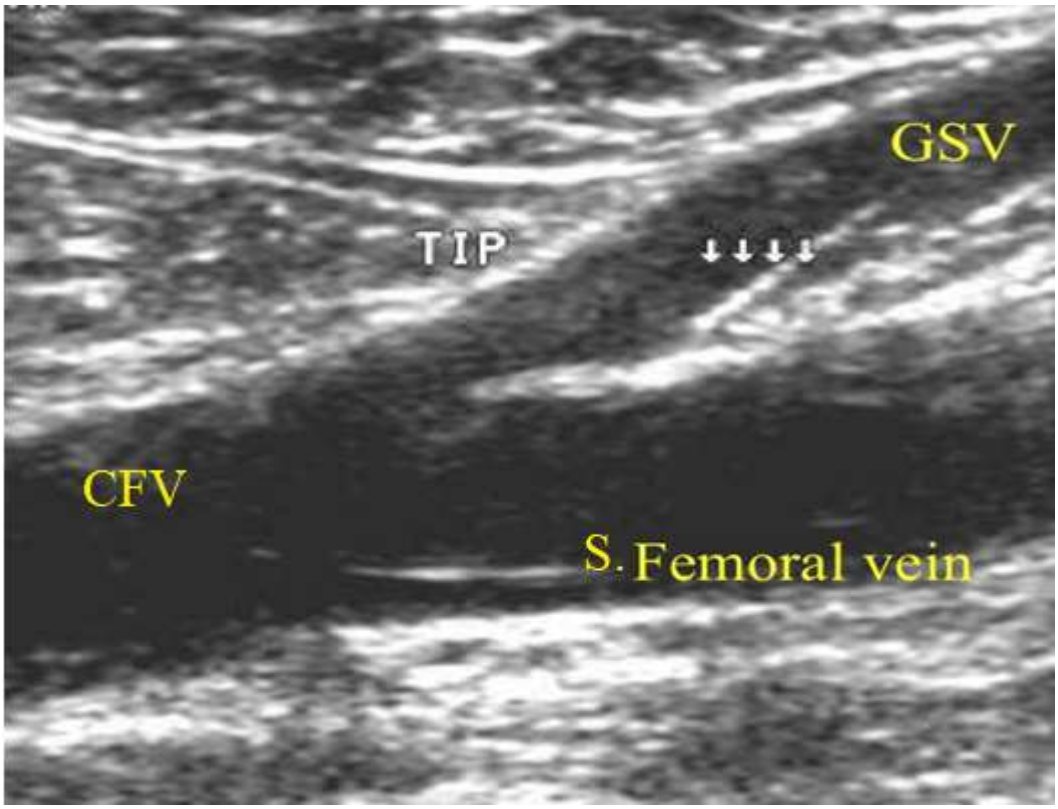

Figure 4. Ultrasound shows the tip of the sheath is seen about 2 centimeters distal to the saphenofemoral junction.

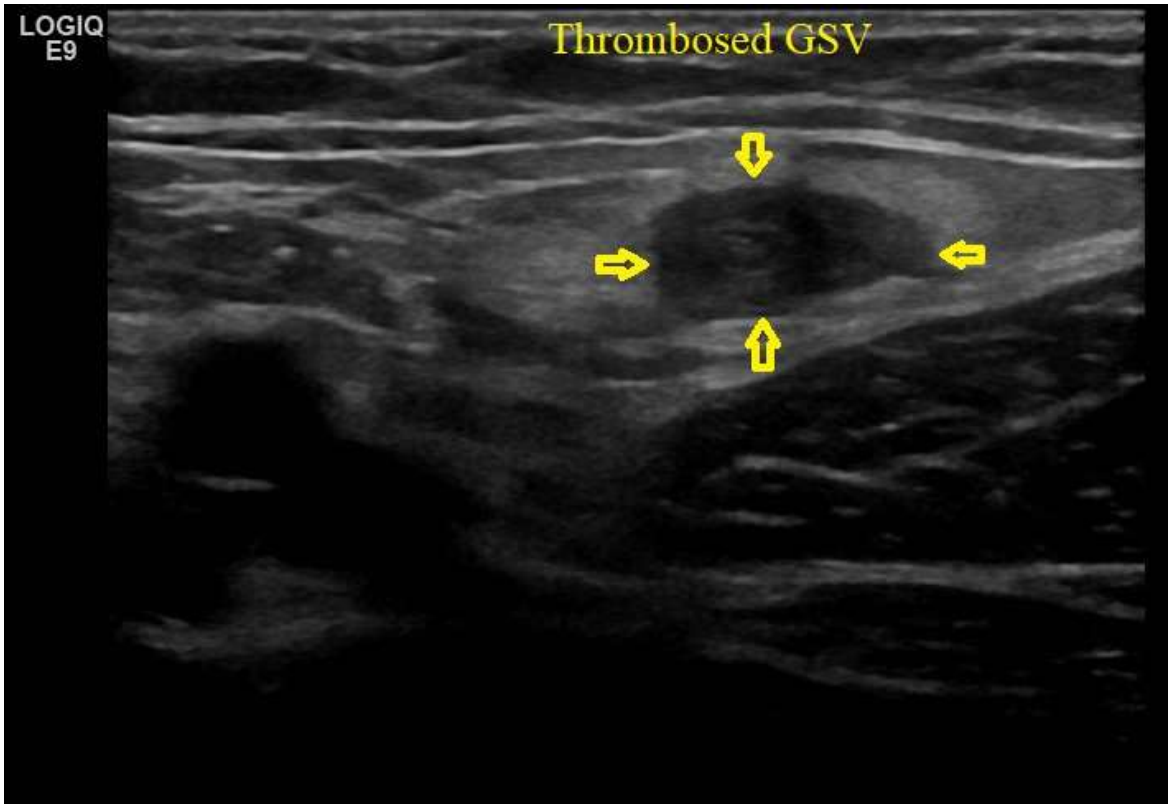

Figure 5. Ultrasound done after one month follow up revealed thrombosis of the GSV.

Figure 6. Ultrasound done after 3 months follow up revealed significant reduction in the size of the thrombosed GSV.

Figure 7. Ultrasound done after 3 months follow up revealed significant reduction in the size of the thrombosed GSV.

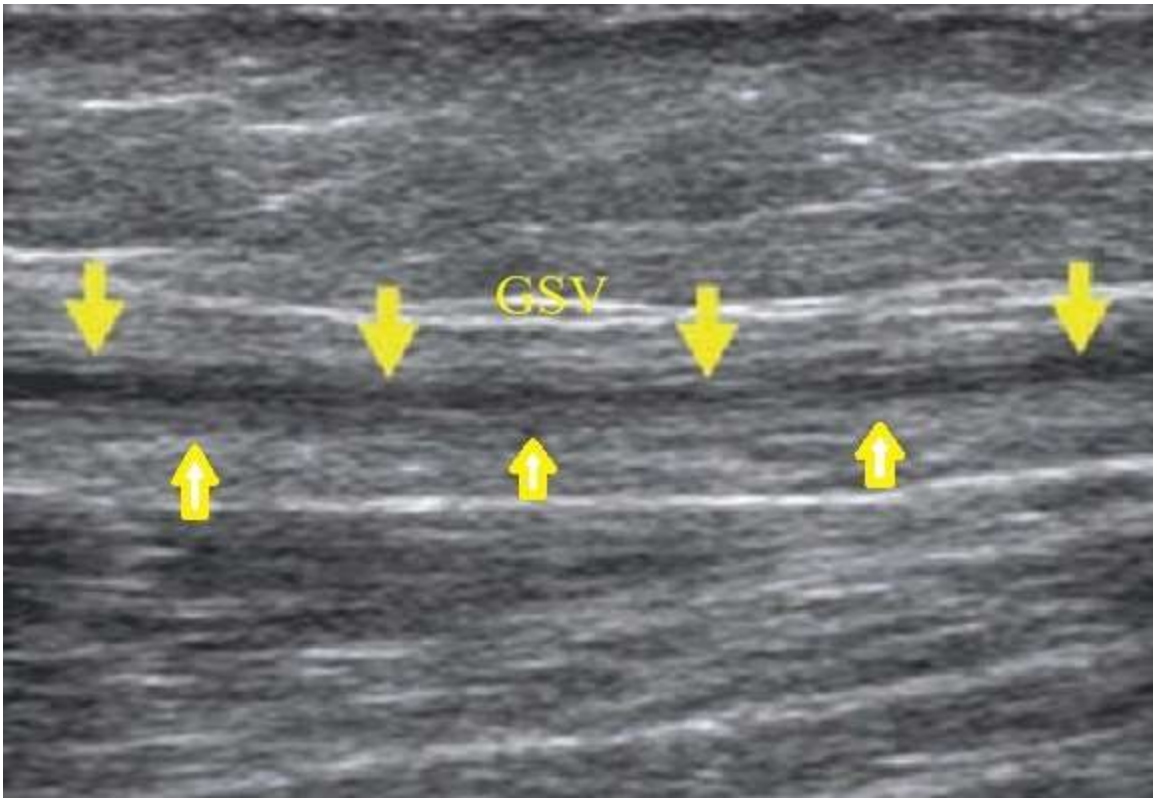

Figure 8. Ultrasound done after 6 months follow up revealed significant reduction in the size of the GSV.

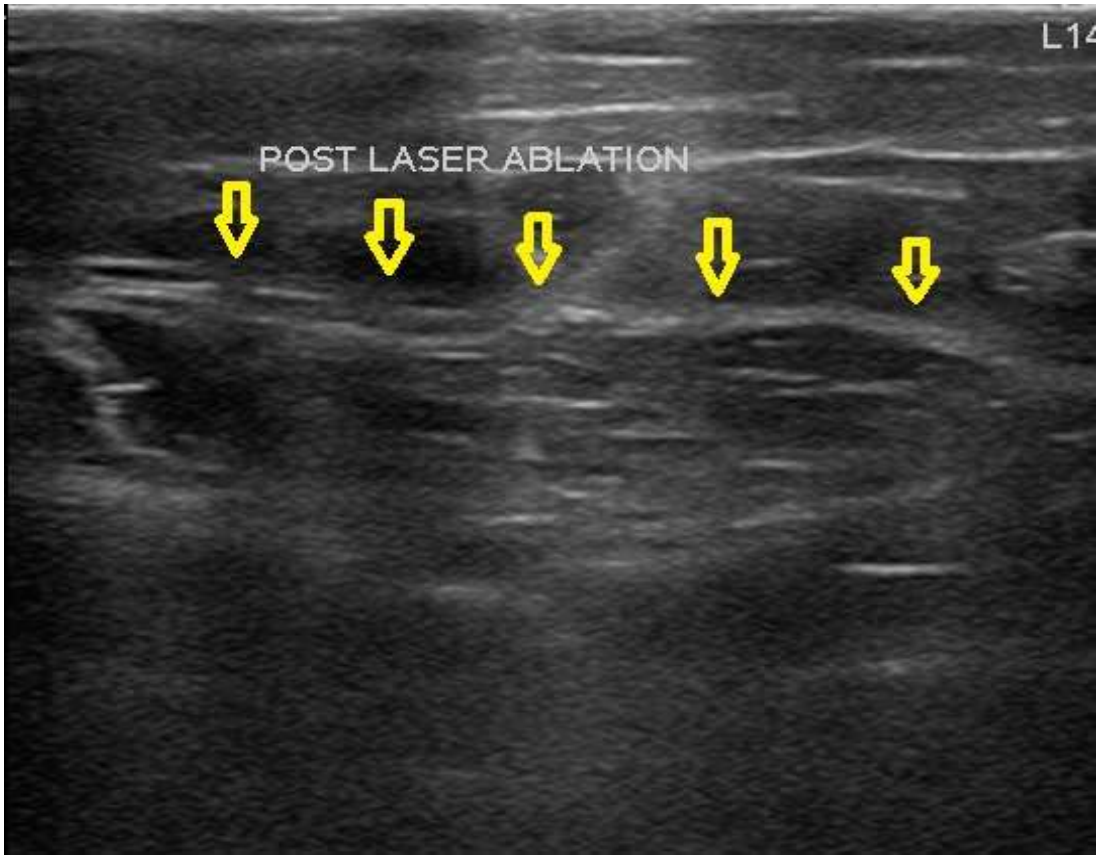

Figure 9. Ultrasound done after 6 months follow up revealed nearly obliterated lumen of the GSV.

Discussion

Surgical treatment of varicose veins imposes a potential risk and relatively high rate of recurrence. Sarin and co-workers stated that 18% recurrence rate of great saphenous vein insufficiency after ligation and stripping and 45% rate of recurrence after high ligation only, appeared early after 3 months of surgery[12]

Also, Dwerryhouse et al detected a recurrence rate of 25% after ligation and stripping of the great saphenous vein and 75% after high ligation only[13]. Further, Navarro et al used endovascular laser therapy as an alternative treatment to ligation and stripping with rapidly progress to be the first line of treatment for the saphenous vein reflux; they used the thermal ablation of laser passed through a fiber inserted inside the lumen of the treated vein[14].

Treatment of saphenous vein insufficiency by endovenous laser therapy is proved to be very efficient and long-lasting. A study was done including a large number of patients, the rate of success of the procedure was approximately 100%, also the success rate up to 5 years ranged from 90% to 100%[15]. Our study reported that the success rate of the endovascular laser therapy reached about 94% and the other five cases (5.9%) of the 85 incompetent sapheno-femoral junctions, continued to have evidence of reflux detected within the first 3 months by color Doppler ultrasound, 2 of them at 6 weeks and the other 3 at 3 months. In another study, although the success rate after one week of the procedure reached 100%, yet it reduced gradually by time and persisted more than 90% in a big group of patients[16-18].

Furthermore, It has been reported that the degree of vein obliteration is depending upon the degree of energy used in the procedure[19]; if it is less than 70 J/cm, may lead to increased incidence of recurrence, and failure of venous occlusion[19-21]. In our study, the parameters of the laser used were the wavelength of 1470 nm with continuous mode energy delivered through a regular pullback speed with the energy of 100 J/cm and power of 10W. We established the short to intermediate term efficacy of endovenous laser therapy.

Recanalization of the great saphenous veins did not happened after 3 months post endovenous laser therapy. Successful occlusion has been seen in 80 patients who have completed their six and twelve months evaluations(figure 4,5,6 and 7). The short-term results of this study were in accordance with the results of Navarro and co-workers, who had done 40 great saphenous veins by the same procedure and all of them were keeping obliterated up to 1 year. In their study, they reported neither skin burns, parae-sthesia nor other significant side effects[14].

Moreover, endovascular laser therapy complications are very limited, the most serious one is thrombosis of the deep venous system with a very low incidence ranging from (0-5.7%). The incidence of Skin burns in the majority of the studies is less than 1%. The most consequential risk factor of endovascular laser therapy is discoloration of the skin as a result of vein micro-perforation, due to the release of energy through the bare fiber forward, also the incidence of paraesthesia as a result of nerve injury can reach up to 22%. Another side effect that can occur after the procedure, is the appearance of bruising at the sites of tumescent anesthesia infiltration, but commonly will disappear after one week of the procedure. Also, the incidence of Superficial thrombophlebitis may reach up to 25%[22].

Our study revealed that all cases had minimal bruising at the laser fiber access site and along the points of the administration of tumescent solution reported negligible discomfort along the treated vein at one week, additionally, patients had neither swelling, tenderness, nerve injury, skin burns, nor DVT.

Conclusion

Endovascular laser ablation technique is an ideal, efficient procedure with immediate technical success for great saphenous vein insufficiency treatment and impressive results along the short-term and up to 12 months results. This technique has the advantages of short recovery time and excellent cosmetic outcome with minor temporary self-limited complications. In addition, the endovascular therapy is done as an outpatient procedure providing a significant low-cost solution in comparison with the surgical intervention, moreover, the low-cost treatment is currently highly encouraged and recommended all over the world.

Conflict of interest: Authors declare that there is no competing or conflict of interests and all uthors shared equally in the preparation of the manuscript.

Funding sources: This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

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