

Outcome of endovenous laser ablation (EVLA) in patients with active and healed venous ulcers

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Abstract

Background: Venous ulcer is defined as a full-thickness defect of skin, most frequently in ankle region, that fails to heal spontaneously and is sustained by CVD (duplex studies). Recommended treatment in patients with healed or active venous ulcers are percutaneous thermal ablation, sclerotherapy, or endoscopic ligation apart from the open surgical approach. In present study we evaluated outcome of endovenous laser ablation in patients with active and healed venous ulcers. **Material and Methods:** Present study was a prospective, observational study conducted in patients with symptomatic, active/healed venous ulcers due to varicose veins or chronic venous insufficiency (CEAP clinical class 5,6). EVLA was done with Laser Machine Biolitec 1470nm. Statistical analysis was done using descriptive statistics. **Results:** During study period 70 patients (79 legs) underwent EVLA for active and healed venous ulcers. 59 % patients had healed venous ulcer (CEAP clinical class 5) while 41 % patients had active venous ulcer (CEAP clinical class 6). Female patients (56%) were more than male (44%). Cardiovascular disease (33%), history of DVT (33%), smoking 14 (20%) and diabetes mellitus (16%) were common co-morbid conditions. Postoperative complications such as pain, bruising and tightness (23%), paresthesia (20%), induration (11%), superficial vein thrombophlebitis (5%), hematoma (4%), puncture site infection (4%) and DVT (1%) were noted in present study. At the end of 1 year 68% healed ulcers were noted while ulcer area was reduced in 23% patients. 9% were unchanged and 6 % recurrence rate was noted. **Conclusion:** Endovenous laser ablation is useful treatment modality in patients with healed or active venous ulcers associated with better ulcer healing, low recurrence rates and low rate of complications.

Key Words: Endovenous laser ablation, venous ulcer, outcomes, ulcer recurrence

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INTRODUCTION

Venous ulcer is defined as a full-thickness defect of skin, most frequently in ankle region, that fails to heal spontaneously and is sustained by CVD (duplex studies).¹ Up to 50% of patients with significant superficial venous

insufficiency will eventually progress to chronic venous insufficiency (CVI) characterized by lower extremity swelling, and up to 30% will develop skin changes that may lead to ulceration.² Venous ulcers are the result from the consequences of dysfunctional macro-circulation and micro-circulation caused by unrelieved or ambulatory hypertension in the veins of the calf often resulting from deep venous thrombosis (DVT) that destroys venous valves rendering these incompetent and therefore unable to prevent venous backflow into the legs. The mainstay of management has been compression therapy with or without interventions to correct superficial venous reflux.³ However, all strategies are known to be associated with a recurrence rate of 25-56% in the longer term.⁴ Practice guidelines of the Society for Vascular Surgery and American Venous Forum suggest treating pathologic perforator veins (PPVs) in patients with nearly healed or

active venous ulcers (CEAP clinical class C5 or C6) or those with skin damage (CEAP clinical class C4b) with methods that may include percutaneous thermal ablation, sclerotherapy, or endoscopic ligation apart from open surgical approach.⁵ Endovenous thermal ablative techniques are minimally invasive procedures involve the application of duplex guided, catheter-directed thermal energy inside the incompetent superficial veins themselves, to result in a permanent vein occlusion. The principle mechanism of EVLA therapy is ablation and photocoagulation of the vein interior by laser-induced thermal effects. EVLA therapy can also be applied for superficial veins and perforators of suitable length and diameter.⁶ By removal of superficial reflux and reflux in the perforating veins, the improvement of micro-circulation can be achieved, which subsequently restored the recovery potential of the tissue.⁷ In present study we evaluated outcome of endovenous laser ablation in patients with active and healed venous ulcers.

MATERIAL AND METHODS

Present study was a prospective, observational study conducted in department of interventional radiology, bharti vidyapeeth medical college and hospital, Study duration was of 2 years (from feb 2017- feb 2019). Institutional ethical committee approval was taken.

Inclusion Criteria

Patients more than 18 years, with symptomatic, active/healed venous ulcers due to varicose veins or chronic venous insufficiency (CEAP clinical class 5,6), willing to participate and follow up

Exclusion Criteria

Pregnancy; Acute DVT, D-dimer positive; Peripheral Vascular Disease (PVD); Uncorrected coagulation

disorders, contrast allergy; Known case of deep vein reflux, individuals with congenital absence of valves in deep system; Lost to follow up.

Patients referred for EVLA underwent record review, preliminary investigations. Patients fit for procedure were selected for ablation therapy. Study was explained to patients and a written informed consent was taken. Under all aseptic precautions Great saphenous vein (GSV) was accessed under ultrasound guidance after infiltration of local anesthetic agent using 18G single wall puncture needle and utilizing Seldinger technique. EVLA was done with Laser Machine biolitec 1470nm. Guide wire followed by sheath placement was done and guide wire was then exchanged with Laser fiber (4 French Radial fibre) after check contrast venogram, under flouroscopy, to rule out deep vein reflux, Position from Sapheno-Femoral Junction (SFJ) was confirmed (at least 2 to 3 cm away from SFJ) followed by perivenular infiltration of anesthetic agent and laser ablation was done in sequential segments from proximal to distal (in some cases with technical issues antegrade ablations were done with due precautions). Hemostasis was achieved. Any other vein which was found to be affected was dealt similarly. GSV Ablation was done in all C5/C6 cases. GSV, SSV or a large perforator were ablated if ulcer was found in that distribution in same setting; similarly large ulcer with adjacent/underlying perforator (pathological perforator) was ablated. For perforator ablation, similarly coaxial direct Ultrasound guided 18G needle accesses was taken at or just below the fascia-plane level. Standard postoperative care was provided to all patients. Follow up was kept till 1 year. Patients lost to follow up were excluded. Data was collected and analysed. Statistical analysis was done using descriptive statistics.

RESULTS

During study period 70 patients (79 legs) underwent EVLA for active and healed venous ulcers. 59 % patients had healed venous ulcer (CEAP clinical class 5) while 41 % patients had active venous ulcer (CEAP clinical class 6). Female patients (56%) were more than male (44%). Cardiovascular disease (33%), history of DVT (33%), smoking 14 (20%) and diabetes mellitus (16%) were common co-morbid conditions.

Table 1: Demographics and characteristics of patients with healed and active ulcer at the time of EVLA treatment.

CHARACTERISTIC	CEAP clinical class 5 (Healed venous ulcer)	CEAP clinical class 6 (Active venous ulcer)	Total
Patients	41 (59%)	29 (41%)	70
No. of legs	46 (58%)	33 (42%)	79
Age (mean ± SD, years)	61.2 ± 12.5	62.8 ± 9.1	61.6 ± 10.4
Gender			
Male	18 (26%)	13 (19%)	31 (44%)
Female	23 (33%)	16 (23%)	39 (56%)
Co-morbid factors			
Cardiovascular disease	16 (23%)	7 (10%)	23 (33%)
History of DVT	9 (13%)	14 (20%)	23 (33%)
Smoking	5 (7%)	9 (13%)	14 (20%)

Diabetes mellitus	6 (9%)	5 (7%)	11 (16%)
Endovenous laser ablation (EVLA)			
Great saphenous vein	38 (58%)	28 (42%)	66
Small saphenous vein	11 (61%)	7 (39%)	18
Anterior accessory saphenous vein	5 (71%)	2 (29%)	7
Perforator vein	2 (100%)	0	2

Postoperative complications such as pain, bruising and tightness (23%), paresthesia (20%), induration (11%), superficial vein thrombophlebitis (5%), hematoma (4%), puncture site infection (4%) and DVT (1%) were noted in present study.

Table 2: Percentage of postoperative complications

Complications	No. of limbs treated (n=79)	Percentage
Pain, bruising and tightness	18	23%
Paraesthesia	16	20%
Induration	9	11%
Superficial vein thrombophlebitis	4	5%
Hematoma	3	4%
Puncture site infection	3	4%
DVT	1	1%

In present study at the end of 1 year 68% healed ulcers were noted while ulcer area was reduced in 23% patients. 9% were unchanged and 6 % recurrence rate was noted.

Table 3: Ulcer outcome.

Follow up	6 weeks	1 year
Healed	58 (73%)	54 (68%)
Reduced	15 (19%)	18 (23%)
Unchanged	6 (8%)	7 (9%)
Recurrence	0	5 (6%)



Case-1: 27 yrs shop keeper with large varicosities in GSV territory with dilated GSV.

The GSV was treated with LASER therapy and varicosities were treated with foam sclerotherapy by using sodium tetradecyl acetate (setrol). Post treatment the varicose veins were completely ablated and disappeared in 1 month. A- Pre Laser, B-one month post LASER.



Case-2: This is a 45 yrs clerk with non healing venous ulcer since a year. All conservative treatments were tried but failed. There was reflux in GSV with a incompetent perforator under the ulcer. The GSV and the incompetent perforator were treated by LASER and the ulcer started healing in a weeks time. A: Venous ulcer before LASER treatment; B: Healed venous ulcer after a week of LASER therapy.



Case 3: 45 yrs female with nonhealing venous ulcer just above the medial malleolus. Doppler s/o SFJ reflux with dilated GSV till lower leg. Treated with LASER and ulcer healed in 4 weeks time. A-Pre laser, B-4 weeks post LASER.

DISCUSSION

Active ulceration is known to have a profoundly detrimental effect upon quality of life, including significant pain and restriction in mobility, which result in limitations of physical and social roles.⁸ The socioeconomic impact of these non-healing ulcers and wounds is immense and may result in significant morbidity in affected individuals. Venous ulcer disease describes the most severe end of a spectrum of chronic venous insufficiency, as categorized by the CEAP (Clinical severity, Etiology, Anatomy and Pathophysiology) classification system. Clinical severity is scored from C0 (no disease) to C6 (active ulceration); C5 describes a healed ulcer.⁹ Elevated venous pressure, turbulent flow and insufficient venous return due to venous occlusion or venous reflux are the proposed aetiologies for venous ulcers, which activate inflammatory processes, triggering leukocyte activation, endothelial damage, platelet aggregation and intracellular edema. Older age, obesity, previous leg injuries, deep venous thrombosis and phlebitis are the various risk factors aggravating this complication.¹⁰ Clinically venous ulcers occur as “pure” venous causes, when there is directed axial great saphenous vein reflux or incompetent perforator reflux directly into the ulcer bed, or as “mixed” venous plus other causes, as in cases in which

arterial ischemia, scarred tissue of the gaiter area, hypersensitive skin, lymphedema, autoimmune disease, local trauma, infection, and other processes coexist with the venous hypertension. Conservative therapy of venous ulcers and the prevention of new ulcers includes control of edema and venous hypertension by adequate compression therapy, wound cleaning or surgical debridement and systemic antibiotic therapy.¹¹ A large Indian study revealed that CVD is more prevalent at an average age of 43 years and it affects women more than men.¹² In present study women were more than men. Abhinav Mohan studied 72 patients with peripheral chronic venous insufficiency, males were found to be affected predominantly with an M: F ratio of 1:0.53.¹³ It is a well-known fact that minimally invasive interventional radiology procedures for management of chronic venous insufficiency are associated with decrease morbidity and excellent outcomes even in patients having co-morbid conditions.¹⁴ In clinical practice EVLA and RFA are increasingly used to treat patients with venous ulcers and there are several reports of low recurrence rates but with small groups and short follow-up.^{15,16} The ‘walk-in, walk-out’ local anaesthetic technique that can be used with endovenous thermal ablation may be more acceptable to patients with venous ulcers, avoiding the difficulties

associated with general anaesthesia and minimising the morbidity, recovery time and even early recurrence following intervention.¹⁷ In a comparative study, Viarengo *et al.*,¹⁸ noted 82% of EVLA treated patients and 24% of the compression group had healed ulcers after 1 year follow up. EVLA of incompetent saphenous trunks promotes venous ulcer healing.¹⁸ In present study at the end of 1 year, 68% patients had healed ulcers. In study by Sharif *et al.*,¹⁹ endovenous laser ablation in CEAP: C4-C6 patients, cumulative healing rates after 3 months was 87%; after 1 year was 100% and after 22 months was 95%. They noted that EVLA is effective in the treatment and prevention of venous ulcers.¹⁹ In the Effect of Surgery and Compression on Healing and Recurrence (ESCHAR) study showed that when VU patients were treated by compression and superficial venous surgery, the recurrence rate of VU was reduced with an absolute risk reduction of 25% compared with compression only.²⁰ When endovenous laser ablation (EVLA) and radiofrequency ablation (RFA) were compared with high ligation and stripping in treating varicose veins (VVs), treatments were found to be as effective and safe 5 years after treatment.²¹ Rueda *et al.*,²² noted that, during a mean patient follow-up of 37 months, 41 patients treated with SEPS and 23 with radiofrequency ablation had ulcer healing in 88% and 100%, respectively. The authors concluded that they support an “aggressive approach to patients with C5/C6 disease,” which would include treatment of incompetent perforating veins when appropriate.²² Gohel *et al.* in their study noted that 84% of the treated legs (still) had a healed ulcer without recurrence after 3.5 years in a group of 170 patients where 16% were lost to follow-up. Complications were mostly minor and 15% had undergone repeat treatment of VVs.²³ Recently, another clinical trial (EVRA Trial) evaluated the role of early endovenous treatment of superficial venous reflux as an adjunct to compression therapy in patients with venous leg ulcers and they concluded that compression therapy combined with early endovenous ablation treatment could promote ulcer healing, reduce ulcer recurrence and prolong the patients’ ulcer-free time within 1 year after the intervention.²⁴ Results of large randomized studies have suggested that the rate of technical success (i.e., complete venous occlusion) may be lower with foam sclerotherapy than with endovenous thermal ablation.^{21,25} Deep venous reflux, large ulcer area and reduced ankle mobility are considered risk factors for ulcer recurrence.²⁶ Factors associated with ulcer nonhealing and recurrence are overweight body mass index, history of deep venous thrombosis, large ulcer area, noncompliance with compression therapy, and triple-system venous disease involving superficial, perforating, and deep veins.²⁷ In present study 6% recurrence was noted. Present study had

small sample size; institution based with 1 year follow up. Large scale, multicentric, randomised controlled studies about the efficacy of endovenous methods in treating patients with healed or active venous ulcers are needed for definitive results.

CONCLUSION

Endovenous laser ablation is useful treatment modality in patients with healed or active venous ulcers associated with better ulcer healing, low recurrence rates and a low rate of complications.

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