ORIGINAL RESEARCH PAPER

Volume-7 | Issue-9 | September-2018 | PRINT ISSN No 2277 - 8179

INTERNATIONAL JOURNAL OF SCIENTIFIC RESEARCH

A COMPARATIVE STUDY OF OUTCOMES BETWEEN FOAM SCLEROTHERAPY AND ENDOVENOUS LASER ABLATION FOR THE TREATMENT OF GREAT SAPHENOUS VEIN INSUFFICIENCY: A STUDY FROM A DEVELOPING COUNTRY

Surgery

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ABSTRACT

Introduction Prevalence rate of Varicose vein (VV) is approximately 25-55% of population. Various modalities regarding treatment of VVs are Endovenous Laser or Radiofrequency ablation, Foam sclerotherapy, conventional surgery. Endovenous thermal ablation is costly for the most of Indian patients and both works at higher temperature.Foam sclerotherapy is very cheap as copmpared to Laser or Radiofrequency ablation. This study is to compare outcomes between ultrasound guided Foam sclerotherapy(USGFS) and Endovenous laser Ablation (EVLA) in the Indian patients.

Methods In group A 15 patients were treated by USGFS and Group B 18 patients VV were treated by EVLA. Patients were followed at 1 and 3 months to compare various outcomes.

Results Hyperpigmentation at one month was 33.33% in USGFS and 16.67% patients in Laser group while at 3 months it was 13.33 %and 5.56%. Hyperpigmentation was more in USGFS but was statistically insignificant.

Wound infection was in 26.67 % patients in USGFS and 11.11% patients in Laser group at one month. Although it was more in USGFS group but was statistically insignificant.

Paresthesia(numbness , tingling in thigh) was in 20.0% patients and in 27.78% patients in USGFS and Laser therapy respectively at 1month while it was in 6.67% and 11.11% patients at 6month respectively. It was also statistically insignificant

Conclusion As Endovenous thermal ablation is costly for people of Indian populations. Foam slerotherapy may be another option for those patient having economic burden. USGFS is safe and feasible . Wound infection and hyperpigmentation is slightly more in USGFS but is acceptable and insignificant. Being nonthermal USGFS is nonthermal it causes less paresthesia.

KEYWORDS

Varicose Vein, Laser Therapy, Foam Sclerotherapy

MANUSCRIPT

Varicose veins caused by venous insufficiency of the legs affect approximately 25%-55% of the population and have a substantial impact on patient's health-related quality of life (HRQoL)(1).

For the patient with varicose veins there is often persistent discomfort and disability extending over long periods of time. Various treatment options available for varicose veins are endovenous laser (EVLA) or radiofrequency(RFA) ablation, USG guided Foam sclerotherapy (USGFS), conventional surgery(CS). Both laser and radiofrequency have 95% occlusion rate at 10 days postoperatively(2).EVLA and RFA are thermal procedure works at higher temperature so a subsets of patients have pareshthesia, hyperpigmentation around GSV, bruise and pain.

Currently available clinical trial evidence suggests that USGFS, EVLA and RFA are at least as effective as surgery in the treatment of Great saphenous varicose veins(3). EVLA and RFA are costly for developing country people .

USGFS proved to be the simplest, quickest and cheapest method of varicose vein treatment and requires no tumescent or regional anaesthesia. It yielded satisfactory functional and cosmetic results. Side effects do occur, but are acceptable, in particular at long term(4).The trial-based cost-effectiveness analysis showed that, at 6 months, foam had the highest probability of being considered cost-effective at a ceiling willingness-to-pay ratio. There is fewer procedural complications in the EVLA group (1%) than after foam (7%) and surgery (8%)($p < 0.001$ (5).USGFS as treatment for CVI is safe and can achieve high occlusion rates at a low cost(6). Both EVLA and RFA causes economical burden for developing country patients.

This study is done to compare outcomes between Endovenous laser therapy (by1470nm fibre) and USG guided Foam sclerotherapy (polidocanol) in patients of Chronic Great saphenous venous insufficiency at single centre i.e. Department of General surgery,King George's Medical University , Lucknow ,India.

To of my best knowledge this type of study is first study in a developing country

METHODS

This study was designed as Interventional non randomized study, parallel group, comparative study having two arms (Group A and Group B) at Department of General surgery, King George's Medical University, Lucknow, India.

Patients between February 16 to Dec to February 18 were enrolled for the study

Adult patients(>15 year) getting symptomatic primary incompetent GSV having reflux time of ≥0.5 seconds on color duplex ultrasound (HDI) in standing position after valsalva and calf muscle pumping having diameter of GSV >3 mm at midthigh were included for this study.

Exclusion criteria were previous treatment of the ipsilateral GSV, deep vein incompetency or obstruction, agenesis of the deep venous system, vascular malformations, Patient on anticoagulation, pregnancy, heart failure, contraindication for one of the treatments (eg, allergy for polidocanol or xylocaine), immobility, arterial insufficiency (defined as an ankle brachial index ≤0.8 .

On the basis of inclusion criteria and exclusion criteria patients were enrolled and demography of patients were documented. Patients were classified on the basis of CEAP classification developed by American venous forum.

Objective of this study was to compare postoperative outcomes in both groups

Patients enrolled were decided regarding the treatment on the basis of his choice. Regarding each procedure it was well explained to patients and informed consent was taken.

EVLA was performed under ultrasound guidance with a 1470 nm diode laser as described. In brief, venous access was obtained by puncturing the vein at knee level, with a 16 Fr seldinger needle under ultrasound guidance (7). After entrance to varicose vein , J guide wire was passed and needle was taken out and then fascial dilator with introducer sheath passed into the GSV and then fascial dilator taken out, 1470 nm passed into GSV through introducer sheath upto 2 cm below to SFJ. Tumescent anesthesia infiltrated in perivenous space below to saphenous fascia (5 ml/cm). Tumescent anesthesia was prepared by mixing 20 ml Xylocaine 2% with adrenaline and 10 ml sodabicarbonate in 500 ml normal saline. Laser fibre connected to laser machine at 8W and energy 60 j/cm on pulse mode. Machine switched on and fibre pulled 1 cm after every 10 seconds after beep sound.

USGFS was performed as described (8,9).In brief just above knee joint, USG guided GSV was marked. Small incision was given and Infant feeding tube was passed into the GSV upto 5 cm below to SFJ. Foam prepared by to and fro motion of 2ml Polidocanol (Askelerol 3%) diluted to 2% in one luer lock syringe (Low silicone) and 4 times air in other luer lock syringe connected through triway stopcock as described by Tessari. USG guided marked SFJ was pressed by thumb and 1ml of Foam passed for every 2cm length of GSV , gradually feeding tube pulled out. Immediately elastic crepe bandage applied then thumb released.

For incompetent perforators in both groups USG guided 0.1 ml 0.5 % foam was passed into the perforators toward superficial venous side.

Elastic Crepe bandage was applied for one week in both groups.

Duplex Doppler USG was performed at baseline and at one and three month follow up in both supine and standing position after valsalva procedure. In follow up anatomical closure (complete obliteration of GSV in thigh) and recurrence (neovascularisation at SFJ) was checked.

TABLE 1.Distributions of characteristics of patents in each group

	USGFS(15)	EVLA(n=18)
Age (range)	18-32yr	17-60yr
Sex Male patients Female patients	10 05	14 04
Side (no of patients) Right side Left side	9 6	8 10
GSV diameter(SD) at SFJ(Mean) GSV diameter(SD) at mid thigh (Mean)	11.2mm(2.1) 8.6mm(2.0)	11.4mm(1.8) 7.6mm(1.6)
No of Incompetent perforators	4	3
CEAP Classification (no of Patients) C1 C2 C3 C4 C5 C6	0 2 4 3 4 2	0 2 3 5 5 3

Table 2- Comparing outcomes in both groups

		USGFS (n-15)	EVLA (n-18)	P Value	USGFS (n-15)	EVLA (n-18)	P value
		At 1 month			At 3 months		
1	Hyperpigmentation	5 (33.33%)	3 (16.67%)	0.280	2 (13.33%)	1 (5.56%)	0.455
3	Wound infection	4 (26.67%)	2 (11.11%)	0.262	0 (0.0%)	0 (0.0%)	-
4	Paresthesia	3 (20.0%)	5 (27.78%)	0.217	1 (6.67%)	2 (11.11%)	0.670
5	DVT	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	0 (0.0%)	-
6	Pulmonary embolism	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	0 (0.0%)	-
7	Death due to therapy	0 (0.0%)	0 (0.0%)	-	0 (0.0%)	0 (0.0%)	-
8	Recurrence	0(0.0%)	0(0.0%0	-	0(0.0%)	0 (0.0%0	-

RESULTS:

Foam Sclerotherapy and Laser procedures were performed in total of 15 and 18 patients of Great saphenous veins insufficiency respectively. The mean diameter of the saphenous vein at the level of just below to SFJ was 11.2 mm(2.2) and the mean diameter at mid thigh level was 8.6 mm(1.8) in the Foam group, whereas in the Laser group the values were 11.4(2.2) and 7.6 mm(1.7) respectively.

Hyperpigmentation at one month was 33.33% in USGFS and 16.67% patients in Laser group while at 3 months was 13.33% and 5.56%. Hyperpigmentation was more in USGFS but was statistically in significant. (Table 1).

Wound infection was at one month in 26.67 % patients in USGFS and 11.11% patients in Laser group. Although it was more in USGFS group but was statistically insignificant.

Paresthesia(numbness , tingling) was in 20.0% and in 27.78% in USGFS and Laser therapy at 1month while 6.67% and 11.11% at 6month respectively.It was statistically insignificant (Table 2).

DVT,pulmonary embolism , death were absent in each group .Recurrence was absent in both group at 3 month.

DISCUSSION

In a study minor complications in EVLA and RFA were hyperemia at 20.7% and 31.0%, ecchymosis at 31.0% and 51.7% and edema at 27.6% and 65.5%, respectively. The rate of recanalization was 6.8% in the RFA group. No recanalization was observed in the EVLA group. The level of patients satisfied with EVLA was 51.7%, compared to 31.0% for RFA, while 17.2% of patients were satisfied with both the procedures. Times to return to daily activity were 0.9 days in the EVLA group and 1.3 days in the RFA group(10-12).

In a study between radiofrequency and Laser by 1470 nm Authors found that no recanalization was observed in the EVLA group. Success rates in the EVLA and RFA groups were 100% and 95%, respectively. Mean time to return to daily activity was 0.7 days in the EVLA group and 1.4 days in the RFA group ($P < 0.006$), whereas mean time to return to work was 1.8 days in the EVLA group and 2.2 days in the RFA group ($P < 0.07$). There was no statistically significant difference between the groups in terms of pain during the procedure or postoperatively. Less pain was reported in the EVLA during both ($P < 0.02$)(13)

In a study between Endovenous laser therapy and Foam sclerotherapy of one year follow up, occlusion of the great saphenous vein was confirmed in 93.4% (42/) of limbs studied in the laser group and 77.4% (41/53) of limbs in the foam group ($P < .0465$). Venous clinical severity score significantly improved in both groups ($P < .0001$). Procedure associated pain was higher in the laser group ($P < .0082$). Induration, phlebitis, and ecchymosis were the most common complications. Logistical regression and subgroups analysis shown that a larger great saphenous vein diameter measured before treatment was associated with treatment failure in the foam (odds ratio 1.68, 95% CI 1.24-2.27, $P < .0008$) and in the laser group (odds ratio 1.91, 95% CI 1.02-3.59, $P < .0428$). A 90% treatment success is predicted for veins <6.5 mm in the foam group versus veins <12 mm in the laser group (15)

The health gain in SF-36 mental component score for foam was worse than that for EVLA (effect size 1.54, 95% CI 0.01 to 3.06; $p = 0.048$) but similar to that for surgery. At 5 years EVLA had the highest probability (≈ 79%) of being cost-effective at conventional thresholds, followed by foam (≈ 17%) and surgery (≈ 5%).here were fewer procedural complications in the EVLA group (1%) than after foam (7%) and surgery (8%) ($p < 0.001$). Participants returned to a wide range of behaviours more quickly following foam or EVLA than following surgery ($p < 0.05$). There were no differences in VCSS between the three treatments(laser, foam and surgery) (5).

In a study More than 80% of the study population was classified as C2 or C3 venous disease. After 1 year, the anatomic success rate was highest after EVLA (88.5%), followed by CS (88.2%) and UGFS (72.2%) ($P < .001$).

CONCLUSION

As Endovenous thermal ablation is costly for people of Indian populations. Foam slerotherapy may be another option for those patient having economic burden. USGFS is safe and feasible . Wound

infection and hyperpigmentation is slightly more in USGFS but is acceptable and insignificant. As USGFS is nonthermal it causes less paresthesia.

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