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A Comparative Study between Radio Frequency Ablation and Laser Therapy in the Treatment and Management of Varicose Veins

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ABSTRACT

Background: Various studies have recorded the comparison of use of both surgical techniques endovenous laser ablation (EVLA) and radiofrequency ablation (RFA) in the treatment of varicose veins. However, it is still not clear that which technique out of these two methods is more effective and useful for the treatment of varicose veins is more effective. Therefore the present study was designed to compare the effectiveness of EVLA and RFA in the treatment of varicose veins. **Methods:** Hundred patients, with symptomatic great saphenous vein deficiency in both lower extremities were enrolled in this study. Patients' ages ranged between 29 and 64. Two groups were made group 1 ELVA consisting of fifty patients and group II RFA consisting of fifty patients. A 12 W diode laser source with a wavelength of 1470 nm and radial fiber were used for EVLA. Radiofrequency Ablation Procedure was applied to the saphenous vein in the form of 25 W every 0.5 cm from the distal aspect of the saphenofemoral junction. **Results:** Pain score (inter-operative) was 1.7 ± 0.8 for ELVA group while 1.8 ± 0.9 for RFA group which was insignificant ($p>0.05$). Further, there was a significant lesser post-operative pain score in ELVA group (1.2 ± 0.6/ d) compare to RFA group (1.4 ± 0.8/ d) with $p <0.05$. There was an insignificant difference between the post-operative analgesic requirement of both groups (800 ± 150 mg/d vs 900 ± 200 mg/d, $p>0.05$). In addition a significantly less time duration to start post-operative activity was recorded in ELVA group (22 ± 4.5 hrs) in comparison of RFA group (28 ± 5.2 hrs) with p value <0.05. **Conclusion:** Finding of the present study showed that success rate of both techniques in the treatment of varicose veins was almost similar. However, there was significantly better patients' satisfaction along with lesser post-operative complications in EVLA group compare to RFA group. Therefore, we conclude that ELVA method EVLA at a wavelength of 1470 nm and using radial fibre is superior to RFA technique.

Keywords: Varicose veins, Surgery, ELVA, RFA

INTRODUCTION

In spite of vast research, aetiology of commonly occurring varicose is still inadequately understood. Increase incidence of varicose veins has been found associated with aging and various other risk factors like long standing, parity, obesity and family history.[1,2] Valvular insufficiency and venous dilation are among the prominent aetiological factors of varicose veins.[1-4]

Ligation and stripping method was one of the most commonly used surgical procedures for the treatment of varicose veins in past decades. Nevertheless, research is in progress for the advancement in technologies of surgical procedure using endovenous methods. A considerable progress has been recorded in the field of endovenous methods for treating the disease.[5]

Thermal endovenous ablation was initially used with 810 nm diode laser by Navarro et al in 2001. Various studies have been performed to improve the efficacy of laser technique with different types and wavelengths in last decade.[5-8]

Thermal ablation is another technique which has been profoundly used for the treatment of varicose veins in recent years. Endovenous ablation is done by using radiofrequency energy in this surgical method.[9] Weiss et al performed this technique using radiofrequency energy first time in their study. Since then different studies have been done to explore the usefulness of this technique in the treatment of varicose veins.[9-13]

Various studies have recorded the comparison of use of both surgical techniques endovenous laser ablation (EVLA) and radiofrequency ablation (RFA) in the treatment of varicose veins. Most of the studies showed that both the methods were equally effective in the treatment of varicose veins. While few studies suggested that RFA had an edge over

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ELVA due to lesser side effects and greater patient satisfaction.[13,14] Most of among these studies compared the effects of low wavelengths laser with radio frequency. Whereas, few studies compared high wavelength laser energy and radial frequency in the treatment of varicose veins with higher satisfaction and fewer side effects.[15] However, it is still not clear that which technique out of these two methods is more effective and useful for the treatment of varicose veins is more effective.[10-13] Therefore the present study was designed to compare the effectiveness of EVLA and RFA in the treatment of varicose veins.

MATERIALS AND METHODS

This study was conducted in a tertiary care centre from February 2015 to November 2018. Hundred patients, with symptomatic great saphenous vein deficiency in both lower extremities were enrolled in this study. Patients' ages ranged between 29 and 64. Two groups were made group 1 ELVA consisting of fifty patients and group II RFA consisting of fifty patients. Fifty EVLA and Fifty RFA methods were applied to the saphenous veins in the lower extremities of the hundred patients Ethical committee approval was obtained before the study began.

Exclusion criteria- Patients with unilateral vena saphena magna insufficiency, patients receiving the same technique to both legs, patients not permitting intervention on both legs in different sessions and patients who permitted interventions in both legs in separate sessions but in whom technical failure occurred in one or both sessions were excluded from this study.

Patients were classified on the basis of clinical severity, etiology, anatomy and pathophysiology before the process began. Venous clinical severity score values based on scoring of pre-procedural clinical symptoms and findings were documented. EVLA and RFA procedures were decided on in the light of insufficiency in both existing VSM at colored Doppler ultrasonography performed for diagnostic purposes. No advanced insufficiency or obstruction was determined in the deep veins of any extremity. A 12 W diode laser source with a wavelength of 1470 nm and radial fiber were used for EVLA . An endovenous radio frequency CR45i device and catheter were used for RFA. A 21gauze needle was used to perform a percutaneous entery accompanied by caudal section ultrasonography appropriate for treatment of saphenous vein with reflux determined in all patients under regional anesthesia. Tumescent local anesthesia consisting of 20 mL 2% prilocaine, 500 mL 0.9% isotonic solution, 20 mL 8.4% sodium bicarbonate and 0.5 mg adrenalin was administered to the area surrounding the saphenous vein with 21gauze needles guided by ultrasonography.

Endovenous Laser Ablation Procedure was applied by adjusting the laser parameters in pulse mode that is the interval of 0.2 second depending on the diameter of vein and depth from the skin of the saphenous vein, such as to be greater in those areas close to the saphenofemoral junction.

Radiofrequency Ablation Procedure was applied to the saphenous vein in the form of 25 W every 0.5 cm from the distal aspect of the saphenofemoral junction. After both procedures analgesics was prescribed for all patients. By using a visual analog scale pain during and after the procedure was reviewed. Patients indicated the pain felt on a scale of 1 to 5. For two days to the leg receiving the procedure an elastic bandage was applied Afterward compression socks were suggested for three months. Patients were encouraged to return to their routine activities as early as possible. Times to return to routine activities were recorded. Follow-ups were performed clinically on the second day post-procedure and both clinically and using CDUSG on the 1st week and at the first, third and sixth months. Major and minor complications were investigated and saphenous vein occlusion, recanalization, perforating veins and residual varicosities were recorded by CDUSG

Statistical Analysis

Data were expressed as mean ± standard deviation (SD) or as median and range. Demographic and clinical measures were tested using paired samples t tests for parametric variables and Wilcoxon signed ranks tests for non-normally distributed data. McNemar test was used to analyze quantitative data. All calculations were performed using SPSS version 17.0 (SPSS Inc., Chicago, IL, USA). $P < 0.05$ was considered statistically significant.

RESULTS

Table 1: Demographic and clinical characteristics

Variables	ELVA	RFA	p value
Age (Years)	45.6 ± 10.8	46.4 ± 12.3	>0.05
Gender M/F	24/26	23/25	>0.05
VCSS	9.6 ± 2.7	9.8 ± 2.7	>0.05
ECAP	3.3 ± 0.8	3.5 ± 0.6	>0.05
VSM diameter (SFJ) mm	9.4 ± 1.9	9.8 ± 2.1	>0.05
VSM diameter (Femur) mm	7.8 ± 1.8	8.2 ± 2.7	>0.05
Mean SFJ reflux time (Sec)	3.6 ± 2.2	3.8 ± 2.1	>0.05
Distance from skin (mm)	15.8 ± 6.6	15.2 ± 4.9	>0.05
Length of saphenous vein (Cm)	28.6 ± 4.8	29.2 ± 4.2	>0.05
Duration of surgery (Min)	32.8 ± 6.9	33.9 ± 7.2	>0.05

Results of the current study showed that there was no significant difference between age, VCSS and CEAP of both group I (ELVA) and group II (RFA). Similarly, there was an insignificant difference

between VSM diameter (SFJ), VSM diameter (Femur), distance from skin, length of saphenous vein and duration of surgery of both groups. [Table 1]

[Table 2] shows that pain score (inter-operative) was 1.7 ± 0.8 for ELVA group while 1.8 ± 0.9 for RFA group which was insignificant (p>0.05). Further, there was a significant lesser post-operative pain score in ELVA group (1.2 ± 0.6/ d) compare to RFA group (1.4 ± 0.8/ d) with p <0.05.

There was an insignificant difference between the post-operative analgesic requirement of both groups (800 ± 150 mg/d vs 900 ± 200 mg/d, p>0.05). In addition a significantly less time duration to start post-operative activity was recorded in ELVA group (22 ± 4.5 hrs) in comparison of RFA group (28 ± 5.2 hrs) with p value <0.05. However, there was an insignificant difference between the times to return to work of both groups.

Table 2: Post-operative data

Variables	ELVA	RFA	p value
Pain scores intra-operative /d	1.7 ± 0.8	1.8 ± 0.9	>0.05
Pain scores post-operative /d	1.2 ± 0.6	1.4 ± 0.8	<0.05
Analgesic used mg/d	800 ± 150	900 ± 200	>0.05
Time to return to activity/ Hrs	22 ± 4.5	28 ± 5.2	<0.05
Time to return to work/ Hrs	46 ± 6.8	54.6 ± 7.4	>0.05

It is evident from [Figure 1] that there was an insignificant difference between the post operative induration and ecchymosis of both groups. However, post-operative oedema development was significantly high in RFA group compare to ELVA group with p value >0.05. Further, all the post-operative complications were esolved entirely at the end of 2 weeks. No major complication like deep venous thrombosis, pulmonary embolism and skin burn were recorded in the present study. After the completion of surgical procedure 53 % patients of ELVA group were satisfied with procedure; while, 35% patients of RFA group were satisfied with the surgical procedure.

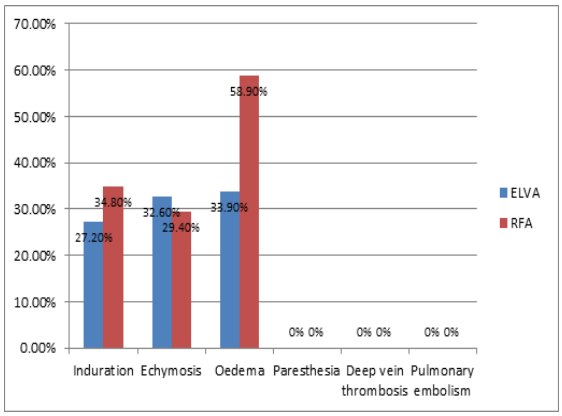

Figure 1: Comparison of post-operative complications

DISCUSSION

Development of varicose veins is associated with various risk factors; among these chronic venous insufficiencies in lower limb is most important aetiological factor. Varicose vein is a disease which significantly affects the quality of life.[16] Different approaches have been applied to threat this condition in recent few decades. Among all, endovenous ablation techniques have been emerged as successful procedure to an extant compare to other techniques. ELVA and RFA are the most commonly used endovenous ablation techniques in modern time.

Various studies have done to assess the effectiveness of both procedures without concluding the supremacy of any of these technique compare to each other. Most of the studies concluded with equal efficiency of both ablation techniques. However, studies recorded significantly lesser post-operative pain and complications in RFA procedure compare to ELVA technique.[13,17-21]

Majority of these studies used laser of low wavelength. In contrast to this few recent studies advocated for the use of higher wavelength laser for better results. In addition, one of the recent studies recorded significantly better satisfaction with use of radial laser fibre at a wavelength of 1470 nm compare to bare fibre at a wavelength of 980 nm.[19,23]

Results of the present study recorded 100% ablation rate in ELVA group compare to 93.2% in RFA group. However, this difference was statistically insignificant. These findings are consistent withthe findings of the earlier study of Van den Bos et al,[22] as they observed ablation rate was higher up to 94% in EVLA patients compare to 84% in RFA patients. Similarly, Almeida et al,[13] recorded significantly higher ablation rate in ELVA group in comparison of RFA group. Alike, Puggioni et al,[18] showed 100% success rate for ELVA patients and 96% for RFA patients at 1 month follow up.

This might be due to during the procedure of RFA catheter touches the vein wall; on the other hand, there is no need to touch the vein wall during ELVA. Moreover, maximum earlier studies have reported better patients' satisfaction with RFA than ELVA; however, most of these studies use lower wavelength laser compare to our study.[13,18-20]

Further, results revealed that patient satisfaction level was higher in ELVA group compare to RFA group. In addition, there was comparatively lesser intra-operative pain, post-operative pain, requirement of analgesics, time duration of activity and return to work in ELVA group in comparison of RFA group. However, among all these differences in postoperative pain and time to return to activity were statistically significant for ELVA group.

This higher patients satisfaction in ELVA group compare to RFA group as well previous studies might be due use of high wavelength laser rays along

with water as a chromophore.[21] Whereas, previous studies have used low wavelengths laser rays with bare tip laser catheters which were less effective in penetrating venous wall compare to high wavelength laser rays used in present study.

In addition, there was no significant difference between the post operative indurations and ecchymosis of both groups. Nonetheless, significantly high incidence of post-operative oedema was recorded in RFA group compare to ELVA group. Present study has not recorded any procedure-linked major complications like skin burn, pulmonary embolism etc in either groups. These findings are consistent with the findings of earlier studies of Shepherd AC et al,[22] and Van den Bos R et al,[23] as they did not recoded any major complication in ELVA or RFA group. This might be due to radial dissemination of rays allows a uniform contact with the venous wall which in turn leads to decrease incidence of perforation.

CONCLUSION

Finding of the present study showed that success rate of both techniques in the treatment of varicose veins was almost similar. However, there was significantly better patients' satisfaction along with lesser post-operative complications in EVLA group compare to RFA group. Therefore, we conclude that ELVA method EVLA at a wavelength of 1470 nm and using radial fibre is superior to RFA technique. However, more studies on larger populations are required to establish the supremacy of either method.

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