

## COMPARISON BETWEEN CONVENTIONAL HIGH LIGATION AND STRIPPING AND RADIOFREQUENCY ABLATION FOR GREAT SAPHENOUS VARICOSE VEINS

## MUSHTAQ A1, SADIQ I22, NASIR M1, SALEEM MU2, SADIQ MA3, SADIQ MH4

<sup>1</sup>Department of General Surgery, Resident Vascular Surgery, Doctor Hospital Lahore, Pakistan <sup>2</sup>Department of Vascular Surgery, Doctor Hospital Lahore, Pakistan <sup>3</sup>Department of Surgery, Jinnah Hospital Lahore, Pakistan <sup>4</sup>Department of Surgery, Services Hospital Lahore, Pakistan \*Correspondence author email address: drilyas123@yahoo.com



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**Abstract:** The prospective study was conducted from December 2022 to May 2023 to assess patient-based, radiological, and clinical outcomes after conventional surgery and radiofrequency ablation for great saphenous varicose veins. Patients were randomly divided to undergo conventional surgery or RFA. American Society of Anesthesiologists fitness grade, Venous Disability Score (VDS), Total Clinical Severity Score (TCSS), Michael's, and CEAP clinical classes were recorded. VEINES-QoL/Sym questionnaire and Aberdeen Varicose Vein Questionnaire were used to estimate baseline QoL. Patients were called for follow-up at the end of 1st and 5th week. The study was conducted on a total of 110 patients. Patients were randomly divided; 57 underwent RFA, and 53 underwent conventional surgery. Results showed that the difference between both groups regarding anesthesia induction, recovery, and discharge from surgery was insignificant. RFA had significantly longer total theater time compared to conventional surgery. Duplex imaging showed that RFA resulted in successful ablation except in two cases where veins had segmental brisk flow. These cases were retreated successfully. Conventional surgery only had the problem of incomplete stripping (6 cases). Post-operative pain, bruising, and the need for analgesia were significantly higher following conservative surgery. Patients in the RFA group returned to work and normal activities more quickly than the conventional surgery group. It is concluded that RFA had a longer intervention time but significantly better outcomes than conventional surgery.

Keywords: Radiofrequency Ablation, Conventional Surgery, Great Saphenous Varicose Veins

#### Introduction

Lower limb varicose vein is a common vascular disorder. It impairs quality of life (QoL) and can be repaired through surgery (Farah et al., 2022). Despite being benign, varicose veins have significant socioeconomic and clinical impact. The most common underlying cause is ineffective, great saphenous venous system. Conventionally, it is managed by stripping the great saphenous vein (GSV) above the knee. Stripping does not yield results in all cases and leads to recurrence in case of failure (Tauraginskii et al., 2022). Stripping and groin dissection may cause wound infection, cutaneous nerve injury, hematoma pain, and bruising, leading to early morbidity and delayed recovery (Müller and Alm, 2020).

Endovenous techniques that require minimal access are becoming increasingly popular. These involve GSV ablation using thermal or chemical energy, avoiding groin dissection and vein stripping. This may reduce postoperative morbidity and speed recovery (Karam et al., 2019). VNUS Closure procedure obliterates the vein lumen through a high-frequency current delivered through an endo luminal catheter (Tawfik et al., 2020). Different studies have reported the efficacy and safety of the process. A study compared conventional surgery with radiofrequency ablation (RFA) and reported that RFA was associated with reduced pain and faster recovery (Sandhya et al., 2020). After 3 years, patients who underwent RFA showed slightly poorer results regarding recurrent varicosities, though the difference was statistically insignificant. Another study was conducted, which also reported early outcomes. The current study aims to assess the local population's patient-based, radiological, and clinical outcomes after conventional surgery and RFA.

#### Methodology

The prospective study was conducted from December 2022 to May 2023. The study included patients aged 18-70 years, both sexes, having GSV reflux, RFA suitability confirmed through duplex scan, and able to undergo general anesthesia and ambulation. Cases with varicose veins without GSV incompetence, associated deep venous or small saphenous incompetence, tortuous GSV, GSV diameter >12 mm or < 3mm, and patients with internal defibrillator or pacemaker were excluded.

Those who fulfilled the inclusion criteria underwent duplex ultrasonography. Informed consent of the participants was taken. The ethical board of the hospital approved the study. Patients were randomly divided to undergo conventional surgery or RFA. American Society of Anesthesiologists fitness grade, Venous Disability Score (VDS), Total Clinical Severity Score (TCSS), Michael's, and CEAP

clinical classes were recorded. VEINES-QoL/Sym questionnaire and Aberdeen Varicose Vein Questionnaire were used to estimate baseline QoL.

All patients were administered prophylactic low-dose molecular heparin, and the procedure was performed under local anesthesia. Experienced surgeons performed RFA. The course of GSV was assessed and marked using a duplex scan (Figures I, II, III). Patients were placed in reverse Trendelenburg position, and the Seldinger technique accessed GSV. VNUS Closure PLUS intravascular catheter was inserted through the sheath and placed in GSV. Overlying tissues were infiltrated with a tumescent solution to achieve vein compression. The patient was positioned in the Trendelenburg position with the leg elevated. The proximal end of the tip of the catheter was connected to a radiofrequency generator. The target temperature was 85 °C, electrodes were unsheathed, and ablation was started distal to the entry point of the superficial epigastric vein. Thrombus formation on the electrode was prevented by infusion of heparinized saline via the catheter. The bandage was removed, and the sheath was withdrawn for treating the lowest segment. Upon completion of the procedure, the duplex scan was performed. The absence of augmented or spontaneous flow, augmented flow through thickened walls, or trickle flow through thick vein walls was considered successful ablation.

The experienced surgeon performed conventional surgery. The patient was placed in the Trendelenburg position, and SFJ was exposed through a skin crease groin incision. GSV tributaries were ligated and separated. The perforate invagination stripper was inserted through the distal end of the vein to the knee, where the skin was incised to retrieve the stripper. The vein was stripped by securing it to the upper end of a stripper, which was pulled down to knee level and removed. The groin wound was closed using absorbable sutures.

All patients were advised to walk frequently and take painkillers (diclofenac (75 mg) and co-codamol (8/500 mg)) when needed. Patients were called for follow-up at the end of 1st and 5th week.

SPSS version 23.0 was used for data analysis. Findings of previous studies were used for data analysis. The primary outcome was the time taken to resume normal activities. After conventional surgery, almost 40% of cases resume normal activities after a week. For RFA to be significantly successful, a 75% improvement in this result was needed. Proportions were compared using Fisher's exact or  $\chi 2$  test and continued data through the test. P value < 0.05 was considered statistically significant.

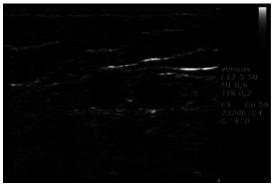


Figure I Great saphenous veins



Figure II Marking course of double GSV

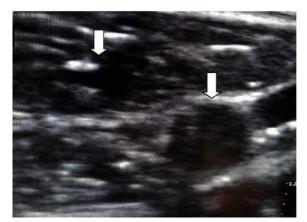


Figure III Thrombosed GSV with the probe in situ.

#### Results

The study was conducted on a total of 110 patients. There were 71 (64.5%) males and 39 (35.4%) females. The mean age of the participants was  $53.35 \pm 15$  years. Patients were randomly divided; 57 underwent RFA, and 53 underwent conventional surgery. There was no requirement for conversion from RFA to surgery due to failed intervention. The difference between both groups regarding anesthesia induction, recovery, and discharge from surgery was insignificant. RFA had significantly longer total theater time than conventional surgery (Table I). The median pullback speed and pullback time for the RFA catheters were 2.21 cm/min and 14.0 min, respectively. The number and timing of stab wounds below and above the knee in both groups were comparable. Duplex imaging showed that RFA resulted in successful ablation except in two cases where veins had segmental brisk flow. These cases were retreated successfully. Regarding RFA, procedural difficulties included thrombus in the catheter tip, GSV perforation due to ablation catheter near SFJ (1 case) and venepuncture site (2 cases), and unsuccessful tumescent infiltration due to venous spasm.

Conventional surgery only had the problem of incomplete stripping (6 cases). In 5 cases, the upper 2/3rd of GSV was successfully stripped, while the lower 1/3rd was stripped separately. In 1 case, reverse stripping was done. At first, a follow-up duplex image revealed that 55 of 57 patients who

underwent RFA had patent GSV stump antegrade flow across SFJ. In 2 cases, there was no flow across SFJ. In all patients who underwent conventional surgery, flow across SFJ was obliterated. Of 6 cases with incomplete stripping, 1 showed brisk flow, 2 showed no flow, and others demonstrated trickle retrograde flow.

Conventional surgery was associated with a significantly higher post-operative cutaneous sensory disorder rate. The medial side of the leg was most frequently affected in both groups. Hematomas in the legs and thighs were more common in the conventional surgery group, but the difference was not statistically significant. Post-operative pain, bruising, and the need for analgesics were significantly higher following conservative surgery. After the first week, pain scores were also better in the RFA group; 8 patients had no pain, and 10 did not need analgesics. All patients in the conservative surgery group experienced pain and required analgesia. A significant number of patients in both groups had improvement in venous disability score and total clinical severity score.

Patients in the RFA group returned to work and normal activities more quickly than the conventional surgery group. After surgery, 27 patients resumed normal activities after a week. For RFA to be successful, 75% improvement in this outcome was required, but more than 100% improvement was observed, with 45 of 57 patients returning to normal life within 5 days following RFA (P <.001).

	Radiofrequency ablation*	Conventional surgery*	P value
Theater time (min)	81(72-90)	54(47-61)	<.001
Procedure time (min)	75(65-85)	47 (38-55)	<.001
VAS during the first week	1.71(0.51-4.31)	4.1 (2.36-6.04)	<.001
Analgesia requirement (days)	3 (0-6)	11(6-15)	0.011
Return to routine activity (days)	4(3-6)	13(5-22)	<.001
Return to driving(days)	5(2-7)	8(6-13)	<.001
Return to work(days)	11 (5-12)	19(12-29)	0.006
Satisfaction score (VAS)	11(9-11)	9(6-10)	0.017

## Discussion

In the current study, outcomes of RFA and conventional surgery were compared. It was found that RFA is a minimally invasive technique with potential benefits. RFA led to early recovery and less pain. Previous studies reported favorable outcomes associated with RFA (Sandhya et al., 2020; Sincos et al., 2019). These studies show that RFA improves QoL after a week of the procedure. In these studies, the majority of patients had uncomplicated varicose veins. In the current study, RFA had significantly longer theater time than conventional surgery. It was because of a thorough duplex scan before and after the procedure and tumescent infiltration. However, the duration of RFA was still significantly quicker than in a previous study (Rai et al., 2019).

Duplex imaging is not performed routinely after conventional surgery. New techniques cause segmental ablation, which reduces treatment time. Radiofrequency ablation is conventionally performed without Esmarch bandage and under tumescent infiltration. This approach will reduce theater time for RFA. RFA results in less trauma, less pain, and a quick return to routine activities. This is associated with increased patient satisfaction and improved quality of life. A previous study also reported this (Epstein et al., 2022). Studies have reported that both interventions significantly improved quality of life; however, scores were higher for RFA even after 2 years of treatment (Barakat et al., 2022; De Maeseneer et al., 2022). Current evidence suggests that RFA has major early benefits in individuals with varicose veins, with five-year outcomes comparable to conventional surgery (Gao et al., 2022). However, unlike RFA, conventional surgery can be performed irrespective of the distribution or configuration of varicosities, reducing the risk of long-term recurrence. It differs from RFA in terms of short-term morbidity and extent of improvement (Rajendran et al., 2022; Whiteley, 2022). Long-term results from studies highlight the impact of leaving the superficial epigastric vein intact at SFJ and the cost-effectiveness of the intervention (Gao et al., 2022; Hamann et al., 2019). The limitation of this study is the small sample size. A larger study is recommended for further analysis.

## Conclusion

RFA had a longer intervention time but significantly better outcomes than conventional surgery.

## Declarations

Data Availability statement All data generated or analyzed during the study are included in the manuscript. Ethics approval and consent to participate Approved by the department Concerned. Consent for publication Approved Funding Not applicable

# **Conflict of interest**

The authors declared an absence of conflict of interest.

## References

- Barakat, Y. M. E. R., Khattab, M. S., Eldin, S. M., AboElneel, H. A., Abd El, M. A. E.-M., and Rizk, S. (2022). A prospective randomized study comparing endovenous radiofrequency ablation and conventional surgery for primary great saphenous reflux. *The Egyptian Journal of Surgery* **41**, 23-29.
- De Maeseneer, M. G., Kakkos, S. K., Aherne, T., Baekgaard, N., Black, S., Blomgren, L., Giannoukas, A., Gohel, M., de Graaf, R., and Hamel-Desnos, C. (2022). Editor's choice– European Society for Vascular Surgery (ESVS) 2022 clinical practice guidelines on the management of chronic venous disease of the lower limbs. European Journal of Vascular and Endovascular Surgery 63, 184-267.
- Epstein, D., Bootun, R., Diop, M., Ortega-Ortega, M., Lane, T. R., and Davies, A. H. (2022). Costeffectiveness analysis of current varicose veins treatments. *Journal of Vascular Surgery: Venous* and Lymphatic Disorders **10**, 504-513. e7.
- Farah, M. H., Nayfeh, T., Urtecho, M., Hasan, B., Amin, M., Sen, I., Wang, Z., Prokop, L. J., Lawrence, P. F., and Gloviczki, P. (2022). A systematic review supporting the Society for Vascular Surgery, the American Venous Forum, and the American Vein and Lymphatic Society guidelines on the management of varicose veins. *Journal of vascular surgery: venous and lymphatic disorders* **10**, 1155-1171.
- Gao, R.-D., Qian, S.-Y., Wang, H.-H., Liu, Y.-S., and Ren, S.-Y. (2022). Strategies and challenges in treatment of varicose veins and venous insufficiency. World Journal of Clinical Cases 10, 5946.
- Hamann, S., Timmer-de Mik, L., Fritschy, W., Kuiters, G., Nijsten, T., and Bos, R. (2019). Randomized clinical trial of endovenous laser ablation versus direct and indirect radiofrequency ablation for the treatment of great saphenous varicose veins. *Journal of British Surgery* **106**, 998-1004.
- Karam, B., Haddad, F., Ataya, K., Jaafar, R., and Nassar, H. (2019). Long-term results of Endovenous Laser Therapy (EVLT) of saphenous vein reflux: up to 9 years follow-up. *European Journal of Vascular* and Endovascular Surgery 58, e766.
- Müller, L., and Alm, J. (2020). Feasibility and technique of endovenous laser ablation (EVLA) of recurrent varicose veins deriving from the sapheno-femoral junction—A case series of 35 consecutive procedures. *Plos one* **15**, e0235656.
- Rai, A., Porsalman, M., Khatony, A., and Sobhiyeh, M. (2019). Comparison of foam sclerotherapy versus radiofrequency ablation in the treatment of primary varicose veins due to incompetent great saphenous vein: randomized clinical trial. *Journal* of Vascular Nursing **37**, 226-231.
- Rajendran, S., Nair, H. R., and Thaikattil, N. J. (2022). Ultrasound-assisted varicose vein surgery and endovenous laser ablation using 1470-nm laser for treatment of great saphenous vein incompetence has similar outcomes at 1 year in a

single-center prospective randomized study. Journal of Vascular Surgery: Venous and Lymphatic Disorders **10**, 370-375.

- Sandhya, P., Mohil, R., and Sricharan, R. (2020). Randomised controlled study to compare radiofrequency ablation with minimally invasive ultrasound-guided non-flush ligation and stripping of great saphenous vein in the treatment of varicose veins. *The Annals of The Royal College of Surgeons of England* **102**, 525-531.
- Sincos, I. R., Baptista, A. P. W., Coelho Neto, F., Labropoulos, N., Alledi, L. B., Marins, E. M. d., Puggina, J., Belczak, S. Q., Cardoso, M. G., and Aun, R. (2019). Prospective randomized trial comparing radiofrequency ablation and complete saphenous vein stripping in patients with mild to moderate chronic venous disease with a 3-year follow-up. *Einstein (Sao Paulo)* 17.
- Tauraginskii, R. A., Lurie, F., Agalarov, R., Simakov, S., and Borsuk, D. (2022). Blood flow from competent tributaries is likely contributor to distally increasing reflux volume in incompetent great saphenous vein. Journal of Vascular Surgery: Venous and Lymphatic Disorders 10, 69-74.
- Tawfik, A. M., Sorour, W. A., and El-Laboudy, M. E. (2020). Laser ablation versus mechanochemical ablation in the treatment of primary varicose veins: a randomized clinical trial. *Journal of Vascular Surgery: Venous and Lymphatic Disorders* 8, 211-215.
- Whiteley, M. S. (2022). Current best practice in the management of varicose veins. *Clinical, Cosmetic and Investigational Dermatology*, 567-583.



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