

Radiofrequency ablation versus stripping of great saphenous vein in the management of varicose veins



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ABSTRACT

Background: Varicose veins are defined as dilated, tortuous subdermal veins > 3 mm in diameter. It is a common entity affecting an estimated 10% of population. **Aims and Objectives:** The aim was to compare the efficacy of radiofrequency ablation (RFA) with great saphenous vein (GSV) stripping in patients with lower limb varicose veins in terms of disappearance of visible varicosities. **Materials and Methods:** It was a prospective randomized controlled study, conducted in a tertiary care medical college with the study population consisting of patients suffering from varicose veins. Totally 30 patients were enrolled and divided into 2 groups of 15 patients each. Group A underwent RFA while Group B underwent stripping of GSV with flush ligation of saphenofemoral junction. **Results:** The mean duration of the procedure in Group A was 53.67 ± 6.6 min while in Group B it was 101.4 ± 11.85 min which was statistically significant ($P < 0.0001$). The mean duration of return to routine activities and work was 2.2 ± 0.41 days in Group A and 3.07 ± 1.16 days in Group B which was statistically significant ($P = 0.024$). Post-operative analgesic requirement was similar in both groups ($P = 0.224$). Complete remission was observed in all patients at 12 months visit and there was no recurrence identified even after a follow-up period of 4 years. **Conclusion:** RFA was found to be as effective as stripping of GSV in terms of obliteration of veins. The duration of procedure was found to be much less in RFA. Furthermore, cosmetic results, ulcer healing and patient satisfaction rate was better in RFA group. Patient return to normal activity was significantly earlier in RFA group.

Key words: Radiofrequency ablation; Varicose veins; Chronic venous insufficiency

INTRODUCTION

Varicose veins are defined as dilated, tortuous subdermal veins > 3 mm in diameter.¹ Venous insufficiency leading to varicose veins is a common entity affecting an estimated 10% of population.² Risk factors for venous insufficiency include obesity, female gender, inactivity, family history, and long hours of standing. Patients with varicose veins may complain of unsightly appearance, aching, heaviness, pruritus, and early fatigue of the affected leg. These symptoms worsen by prolonged standing. More severe signs include thrombophlebitis, hyperpigmentation, lipodermatosclerosis, ulceration, and bleeding from attenuated venous clusters. Noninvasive measures such

as graduated compression stockings, leg elevation, and ambulatory exercise can help improve symptoms; many patients still require some form of surgical intervention.

Until recently, ankle to groin stripping of the great saphenous vein (GSV) with ligation of the saphenofemoral junction (SFJ) was considered the gold standard in varicose vein surgery, however, with studies showing recurrence rate up to 28%,³ development of minimal access techniques and better understanding of venous physiology, this radical procedure has fallen out of favor.

Radiofrequency ablation (RFA) is a minimally invasive catheter-based procedure which utilizes heat in the form

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of radiofrequency energy to obliterate the incompetent vein thus eliminating reflux.

Aims

Aim was to compare the efficacy of RFA with GSV stripping in patients with lower limb varicose veins in terms of disappearance of visible varicosities.

Objectives

Primary objective and Secondary objectives

- (1) Disappearance of visible varicosities
- (2) Duration of procedure
- (3) Regression of skin changes
- (4) Patient satisfaction.

MATERIALS AND METHODS

It was a prospective randomized controlled study, conducted in the Department of General Surgery, Maulana Azad Medical College and Lok Nayak Hospital, from September 2018 to April 2020 with the study population consisting of patients suffering from varicose veins presenting to outpatient clinics at the hospital.

Patients having varicosities of GSV from C4 to C6 under Clinical-Etiology-Anatomy-Pathophysiology (CEAP) classification were included in the study while exclusion criteria included involvement of short saphenous vein, history of deep venous thrombosis, bleeding disorders, pregnancy, and allergy to anesthetics. All patients were clinically evaluated for saphenofemoral reflux and patency of deep veins by tourniquet test initially after which color Doppler ultrasonography was performed to record incompetence of SFJ, marking incompetent perforators with indelible ink and to confirm patency of deep veins. Pre-anesthetic clearance was obtained and all cases were operated under spinal anesthesia.

A total of 30 patients were enrolled in the study which were divided into 2 groups of 15 patients each by computer-generated random number tables and 30 envelopes were made. An envelope was selected just before the surgery for each patient and respective procedure was performed. Group A underwent RFA using RF generator (Covidien, Ireland) and energy level at 30 while Group B underwent stripping of GSV using Meyer's stripper with flush ligation of SFJ (Figures 1-5). Although RFA can be performed under local anesthesia, was done under spinal anesthesia in this study to have comparable groups, Post-operatively, all patients received non-steroidal analgesics on demand or with visual analogue score of more than 4. Early ambulation was encouraged and patients were discharged on second post-operative day with prescription of non-steroidal anti-inflammatory drugs as required and advice

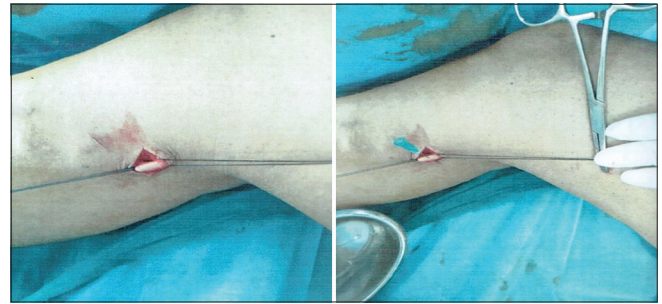


Figure 1: Identification and venesection of great saphenous vein

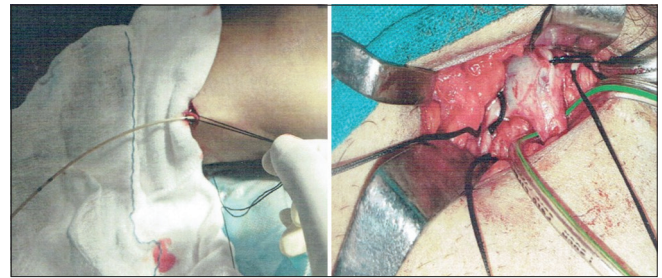


Figure 2: Cannulation of great saphenous vein with radiofrequency ablation probe (left) and ligation of sapheno-femoral junction with tributaries (right)

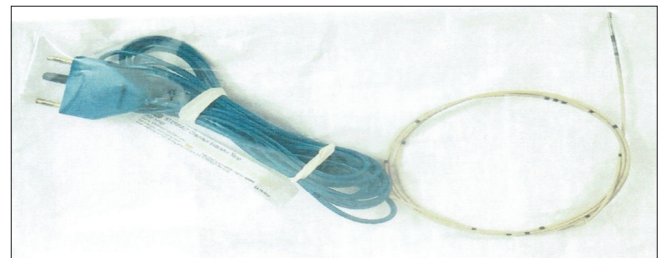


Figure 3: Radiofrequency probe



Figure 4: Radiofrequency ablation of great saphenous vein, preoperative photo on left, postop photo at 3 months follow up on the right

to record the analgesic requirement. Follow-up visits were scheduled on 7 days, 1 month, 6 weeks, 3 months, and 12 months after surgery. Both groups were evaluated



Figure 5: Saphenofemoral junction ligation, preoperative photo on left, postop photo at 3 months follow up on the right

for disappearance of visible varicosities after 3 months, reversal of skin changes if any, healing of ulcers in terms of reduction in size/re-epithelization and any recurrence after 12 months. Data were also collected regarding post-operative analgesic requirement, time to return to routine activity, any numbness or loss of sensation. Ultrasound Doppler was performed 1 month after surgery to assess patency of GSV and saphenofemoral reflux. Patients were followed up till 4 years and assessed for recurrence.

RESULTS

Both groups had comparable demographics with mean age 42 ± 11 years in Group A and 46 ± 12 years in Group B. There were 13 males and 2 females in Group A and 12 males and 3 females in Group B. Most patients (90%) had unilateral lower limb varicose veins. All patients had SFJ incompetence (both radiologically and clinically) in the involved limb and 3 patients in each group had perforator incompetence as well. As per CEAP classification, all patients were symptomatic for varicose veins and further 11 patients were classified as C4 (9 in Group A, 2 in Group B), 14 patients as C5 (4 in Group A, 10 in Group B) and 5 patients as C6 (2 in Group A, 3 in Group B).

The mean GSV diameter in Group A was 4.67 ± 1.1 mm in supine position and 5.99 ± 1.36 mm in erect position while in Group B, it was 6.61 ± 1.16 mm in supine position and 8.04 ± 1.32 mm in erect position and the difference was statistically significant ($P < 0.0001$).

The mean duration of the procedure in Group A was 53.67 ± 6.6 min while in Group B it was 101.4 ± 11.85 min which was statistically significant ($P < 0.0001$). The duration of procedure was found to be much less in RFA group in comparison to open surgery group.

The mean duration of return to routine activities and work was 2.2 ± 0.41 days in Group A and 3.07 ± 1.16 days in Group B which was statistically significant ($P = 0.024$). Hence, return to normal activities and work was much earlier in RFA group. Post-operative analgesic requirement was similar in both groups ($P = 0.224$).

Follow-up visit of patients after 3 months of procedure revealed complete disappearance of varicose veins in great saphenous territory in 14 cases (93.33%) of Group A and 12 cases (80%) of Group B. On ultrasound evaluation, GSV was obliterated completely in 14 patients (93.33%) in Group A and all patients in Group B.

All patients in the study had skin changes in the form of lipodermatosclerosis or healed ulcers or active ulcers and regression of these skin changes was observed in 100% patients in the form of healing of ulcer, decrease in ulcer size, re-epithelization and decrease in hyperpigmentation during follow-up visits.

Patient satisfaction (relief of symptoms) was evaluated at 3 months using a patient satisfaction score of 0–100 where a score of 100 corresponds to highly satisfied with the treatment and zero being extremely dissatisfied. Mean score given by patients in Group A was 95 ± 10.35 while in Group B it was 78.33 ± 18.58 which indicates more satisfaction among patients in the RFA group.

There was no statistically significant difference in immediate or late complications among two groups. One patient in Group A suffered intraoperative burn, one patient in each group developed ecchymoses, and 3 patients in Group B developed hematoma. Surgical site infection was noticed in 2 patients in Group B leading to prolonged hospital stay. One patient in Group B developed paraesthesia in operated limb while no patients of either group had any evidence of deep venous thrombosis at follow-up visits. Complete remission was observed in all patients at 12 months visit and there was no recurrence identified even after a follow-up period of 4 years.

DISCUSSION

Chronic venous insufficiency and its complications are a prevalent disorder in the present era. Management options include rest, limb elevation, and graduated compression stockings for patients with mild symptoms while patients with worsening symptoms despite conservative treatment will need some form of surgical procedure. Jones (1996) proposed that groin hematoma and disrupted superficial pudendal venous drainage during open surgery are stimulants for neovascularization leading to venous

reflux recurrence.⁴ The development of newer minimally invasive techniques to prevent neovascularization and thus recurrence is promising although data is lacking with respect to superiority of any one technique over others. In our study, the mean age of presentation was 42 years which was lower in comparison to studies by Rasmussen with mean age of 51 years⁵ and Biemans with mean age of 52 years⁶ at the time of presentation which may be due to increased prevalence of varicose veins among working class males in Indian population due to long hours of standing or necessity for joining government jobs such as civil services. Varicose veins are more common among females in western world with male: Female ratio in different studies around 1:2⁵⁻⁷ but in our study, there were only 5 females with this ratio being 5:1, probably due to occupational risk factors or females not presenting in OPD as it might not be affecting their household work.

In our study, majority of patients belong to classification of C5 (healed ulcer), followed by C4 (skin changes) and then by C6 (active ulcer) while various other studies such as Shadid *et al.*⁸ Rasmussen,⁵ Joseph *et al.*,⁹ Kalodiki *et al.*,¹⁰ Biemans,⁶ Barrett⁷ had maximum number of patients belonging to C2 group rather than C5 and C6. This may be due to the fact that majority of patients in these studies were European having higher health awareness among the population leading to early presentation.

The mean procedure duration was 53.67 min in Group A and 101.4 min in Group B. In other studies,¹¹⁻¹³ mean duration in RFA group varies from 40 to 76 min while in GSV stripping group varies from 21 to 48 min.

In our study, patients in RFA group had early return to routine activity in comparison to patients in GSV stripping group which is similar to study by Subramonia,¹¹ where mean time to return to routine activities was 2–5 days in RFA group, and 4–21 days in GSV stripping group. Similarly, Stötter *et al.*,¹² observed that mean time to return to normal activity was 7 days in RFA group and 14 days in GSV stripping group which indicates faster recovery in the RFA group. RFA has been found to be associated with less post-operative pain, a lower requirement for analgesia and a reduced pain impact on daily activities than other treatment modalities. Rasmussen *et al.*⁵ reported a mean pain score of 1.21/10 during the first 10 days and the time to return to normal activity was only 1 day. The EVOLVEs study compared RFA with surgery and found that RFA patients returned to normal activities in 1.15 days and had a persistently improved pain score throughout 2 years of follow-up.¹⁴ Thus, patients undergoing RFA procedure may join work earlier, leading to lesser social and economic burden on the family and community.

Our study shows that overall patient satisfaction at 3 months post-procedure was higher in the RFA group as compared to the GSV stripping group. In a meta-analysis of RFA conducted by Luebke in 2008,¹⁵ 8 studies with total of 428 patients were included with 6 studies having quality of life assessment, and definite improvement in quality of life for patients treated with RFA was noticed.

Post-operative complications were similar in both groups, except higher incidence of hematoma (20%) and surgical site infections (13.33%) in the GSV stripping group which reflects the more invasive nature of the procedure. The most common adverse events associated with RFA in different studies¹⁵ are ecchymosis, paraesthesia and phlebitis.

Limitations of the study

Drawbacks of our study include a sample size of 30, and larger studies are needed to confirm the findings.

CONCLUSION

In our study, RFA was found to be as effective as stripping of GSV in terms of obliteration of veins. The duration of procedure was found to be much less in RFA (which was statistically significant) than stripping of GSV. Furthermore, cosmetic results, ulcer healing and patient satisfaction rate was better in RFA group. Even patient return to normal activity was significantly earlier in RFA group. Therefore, we recommend the use of RFA as a treatment of varicose veins of lower limb over stripping of GSV.

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