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ORIGINAL RESEARCH

Effectiveness of radio-frequency ablation in management of varicose veins

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ABSTRACT

Background: Varicose veins are a prevalent venous disorder affecting up to 40% of the population. Conventional surgical treatments are associated with notable complications and recovery time. Endovenous radio-frequency ablation (RFA) has emerged as a minimally invasive alternative offering faster recovery and reduced morbidity. **Objective:** To evaluate the effectiveness and safety of RFA in managing primary varicose veins in terms of symptom resolution, quality of life (QoL) improvement, and postoperative complications. **Methods:** A prospective study was conducted on 27 patients (42 limbs) with CEAP C2–C6 primary varicose veins involving the great saphenous vein (GSV). Preoperative and postoperative evaluations were done using duplex ultrasound, revised Venous Clinical Severity Score (rVCSS), and Aberdeen Varicose Vein Questionnaire (AVVQ). Follow-up assessments were performed at 24 hours, 1 week, 1 month, and 3 months. Data were analyzed using ANOVA, with significance set at $P < 0.05$. **Results:** The mean rVCSS significantly improved from 9.67 preoperatively to 4.28 at 3 months ($P < 0.0001$), and the mean AVVQ score decreased from 57.78 to 21.46 ($P < 0.0001$). GSV occlusion rate was 96.3% at 3 months, with only one case (3.7%) of recanalization. Minor complications included pain (37%), bruising (14.8%), paresthesia (7.4%), and thrombophlebitis (3.7%), with no cases of DVT, nerve injury, or infection. One case (3.7%) of skin burn was reported. **Conclusion:** Radio-frequency ablation is a safe, effective, and well-tolerated modality for the management of primary varicose veins. It offers significant improvement in QoL and clinical outcomes with minimal complications and early return to daily activities.

Keywords: Varicose veins, radio-frequency ablation, endovenous treatment, CEAP classification, quality of life, rVCSS, AVVQ, GSV occlusion.

INTRODUCTION

Varicose veins are a common problem affecting approximately 5-40 % of the world population. Most of the patients present to secondary care complaining of several commonly experienced symptoms, however, some present with severe complications of venous disease including venous ulceration. (1)

Most patients with varicose veins have incompetence of the saphenofemoral junction (SFJ), resulting in blood reflux from the deep venous system into the superficial great saphenous vein (GSV). In addition, they frequently have tributary vessels arising from the incompetent SFJ or GSV resulting in additional varicosities.(2) Reflux may also involve the small saphenous vein (SSV), usually because of incompetence at the sapheno-popliteal junction (SPJ) and may also occur in perforator veins joining the deep and superficial venous system. (3)

Investigation and confirmation of venous disease are frequently made using color duplex scanning. To standardize the comparison of treatments and description of venous insufficiency, the American Venous Forum published criteria for the classification of venous disease in 1994, summarized as CEAP classification. CEAP classification includes a description of the clinical class (C) of the disease based on objective signs, etiology (E) of insufficiency, anatomical (A) distribution, and underlying pathophysiology (P). (2)

The Aberdeen Varicose Vein Questionnaire and revised Venous Clinical Severity Score (rVCSS) can evaluate the quality of life of patients with varicose veins. The Aberdeen Varicose Vein Questionnaire designed by Garratt et al (3) is a disease-specific questionnaire consisting of 13 domains. It has been shown to correlate well with clinical scoring systems and is responsive to changes following treatment. (3)

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The rVCSS is a scoring system of 10 domains based on the original CEAP classification which provides a score out of 30 based on the presence or absence of symptoms and signs, such as pain, swelling and the presence of skin changes. [4,5)]

For many years, the gold standard treatment was junctional ligation, disconnection, and stripping of the great saphenous vein. These surgeries were associated with various complications like bruising, post-procedure discomfort and serious complications like deep vein thrombosis and nerve injuries (sural and peroneal nerve). [(4)]Recurrence has also been reported in many cases. In the last two decades, the introduction of minimally invasive endovenous treatments for varicose veins has meant that a wide variety of treatment options now exist from which one can choose. Consequently, the treatment of varicose veins is moving away from being performed under general anesthesia in the operating theater to treatment in an outpatient setting under local or tumescent anesthesia.[(6)]

One of the minimally invasive techniques for treating varicose veins is endovascular radio-frequency ablation. The present study evaluates the role of radiofrequency ablation in the management of varicose veins in terms of its effectiveness and complications associated with patients.

MATERIALS AND METHODS

This study was approved by the Institutional Ethics Committee (ECR/1274/Inst/CG/2019) of our institution. Written informed consent was taken from the participants.

A prospective study of 27 patients (42 limbs) with primary varicose veins was undertaken at a tertiary care center. The patients were classified using the Clinical-Etiology-Anatomy-Pathophysiology (CEAP) classification. Those in clinical scales C2–C6, of primary etiology, in GSV anatomical territory, and with reflux as the underlying pathology (Pr), were included in this study.

A preoperative duplex ultrasound (DUS) examination of the venous system for the target lower limb was performed for each patient to identify the condition of deep veins, competency of the saphenofemoral junction (SFJ), and suitability of the truncal vein for radiofrequency ablation (RFA), using established protocols. Linear transducer 12L-RS (4-12 MHz) of GE Voluson S8 ultrasound diagnostic system was used.

Patients with secondary varicose veins due to previous deep vein thrombosis, recurrent varicose veins, with perforators alone and GSV diameter greater than 12mm were excluded. Female patients with pregnancy and patients with congenital anomalies like Klippel-Trenaunay syndrome were also excluded.

The procedure was performed under spinal anesthesia, in a well-hydrated patient, in warm surroundings to prevent vasospasm. Access site to target GSV was identified, and the vein was percutaneously cannulated with an 18G × 7 cm puncture needle under intraoperative ultrasound guidance (Figure 1). Through the needle, a 0.018-inch guidewire was inserted in the GSV (Figure 2); thereafter, the needle was removed, and a 7Fr × 11-cm introducer sheath was advanced over the guidewire (Figure 3). Then, the guidewire was removed, and a flexible bipolar radiofrequency-induced thermotherapy (RFITT) applicator (5.4Fr) was introduced through the sheath (Figure 4). Under ultrasound guidance, the RFITT applicator was advanced till the tip was placed 2 cm below the SFJ (Figure 5) or at the ostium of the superficial epigastric vein, whichever was proximal.

Using a 24G spinal needle, tumescent anesthesia (TA) was manually administered within the fascial envelope of GSV (Figure 6). Intraoperative ultrasound was used to validate the RFITT applicator tip's location before beginning the endovenous ablation. After that, the foot switch was continually pressed while the radiofrequency generator setting was maintained at 18 (Figure 7), and the RFITT applicator was progressively removed with a continuous pullback technique. Using the CELON (Olympus) RFITT system's aural feedback mechanism, the withdrawal velocity of the RFITT applicator was tracked. Concurrently, a rise in vein wall echogenicity and vein shrinkage were confirmed by intraoperative ultrasonography imaging. Each incision was sealed, and the leg receiving treatment had a crepe bandage applied and left in place.

Paracetamol tablets were given as needed as an analgesic after surgery. Following their recovery from spinal anesthesia, all patients were able to move around, and were discharged on the second postoperative day with instructions to wear below-knee Class I graduated compression stockings (Less than 20mmHg) for 2 weeks.

The patients were assessed postoperatively at 1 week, 1 month and 3 months in the outpatient department, clinically and with DUS, for any immediate and late postoperative complications. The occlusion of the GSV trunk, length of residual patent proximal GSV, and improvement in quality of life (QoL) using the revised Venous Clinical Severity Score (rVCSS) and Aberdeen Varicose Vein Questionnaire (AVVQ) were recorded. The QoL indices (rVCSS and AVVQ) were analyzed as a continuous variable by using the Analysis of variance test (ANOVA) and $P < 0.05$ was considered statistically significant.

RESULTS

A total of 27 patients (42 limbs) with varicose veins (C_2 to C_6 Ep $A_S P_R$) were enrolled for our study purpose. The group comprised 20 males and 7 females with the maximum number of patients seen in the 40-49 years age group (25.9%).

Mean venous clinical severity score (rVCSS) pre-operative, at post-operative 24 hours, 1 week, 1 month and 3 months were found to be 9.67, 9.67, 6.66, 5.05 and 4.28 respectively (Table 1). Similarly, Aberdeen

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varicose vein questionnaire (AVVQ) scores pre-operative, at post-operative 24 hours, 1 week, 1 month and 3 months were found to be 57.78, 57.78, 56.27, 28.75 and 21.46 (Table 2).

The occlusion rate of GSV at post-operative 24 Hours, 1 week, 1 month and 3 months showed there was an occlusion rate of 77.78%, 100%, 100% and 96.3% respectively. Only 3.70% of patients developed recanalization of GSV. Intraoperatively, anatomical variants including vein of Giacomini in 2 (7.41%), varices in 1 (3.70%), and tributaries of GSV draining directly into saphenofemoral junction were reported in 1 (3.70%) patient. Duplication of GSV was reported in none of the patients (Figure 9).

The average hospital stay of patients was 2 days. Return to habitual activity by the postoperative evening was seen in 100% of the patients. Compression stockings after the ablation of the great saphenous vein led to an early return to daily activities and prevent recurrence. Major complications (Figure 10) including skin burns were seen in 1 (3.7%) patient only and all other complications including deep vein thrombosis, pulmonary embolism, infection, and nerve damage were not seen in any of the subjects.Minor complications (Figure 11) including pain in 10 (37.04%), paresthesia in 2 (7.41%), bruising in 4 (14.81%) thrombophlebitis in 1 (3.70%) were reported. However, hematomas were reported in none of the patients.

The pre-and post-operative comparison of mean rVCSS and AVVQ scores are shown in Figures 12 and 13. There is significant improvement seen in patients following endovenous RFA at the end of 3 months, as compared to the preoperative period ($P \leq 0.0001$). When the "Analysis of variance test (ANOVA)" was used for statistical analysis, it showed that endovenous RFA of primary varicose veins elicited a statistically significant improvement in QoL score ($P < 0.0001$).

Figure-1: Percutaneous cannulation of GSV through the puncture needle.

Figure-2: Through the needle, a 0.018-inch guidewire is inserted in the GSV.

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Figure-3: 7Fr × 11-cm introducer sheath advanced over the guidewire into the GSV.

Figure-4: RFITT applicator (5.4Fr)

Figure-5: RFITT applicator advanced till the tip was placed 2 cm away from the SFJ.

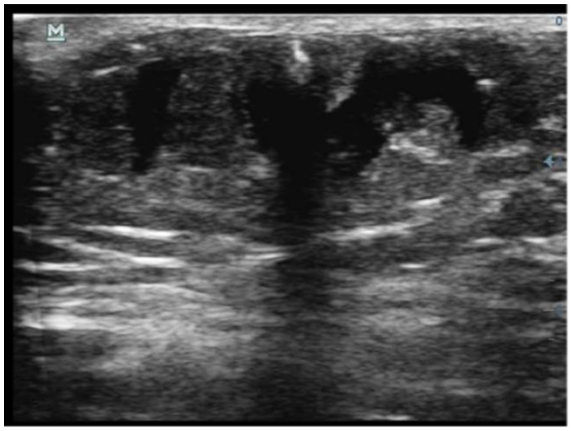

Figure-6: Tumescent anesthesia (TA) manually administered within the fascial envelope of GSV.

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Figure-7: Radiofrequency generator setting maintained at 18.

Figure-8: Second-degree burn in patient along the line of ablation.

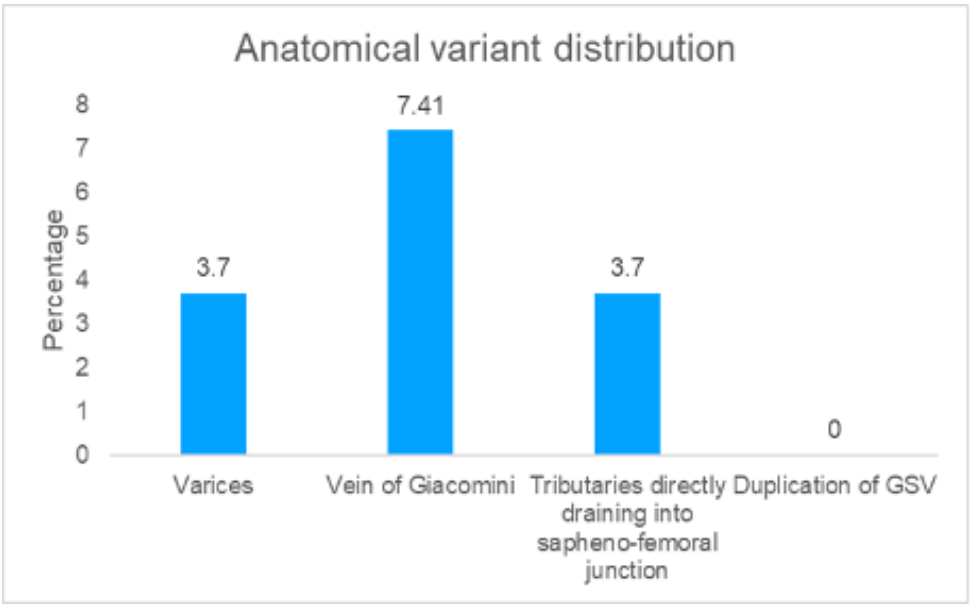

Figure-9: Anatomical variation distribution of GSV among study subjects.

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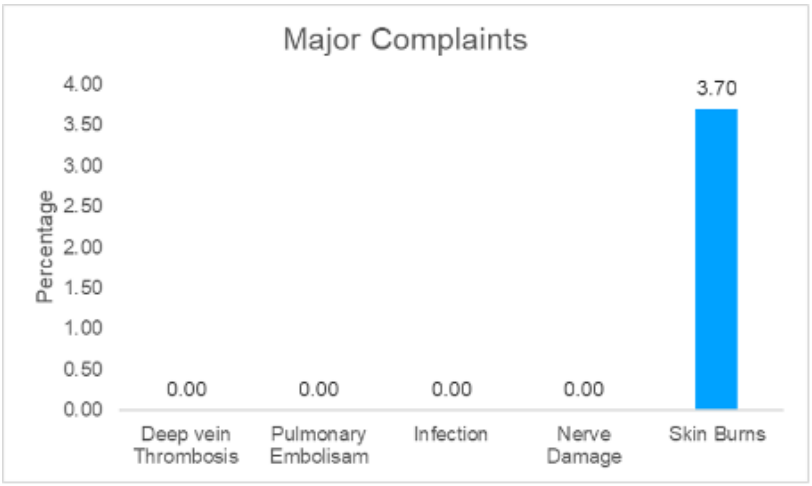

Figure-10: Bar Chart Diagram Showing Frequency Distribution Of Major Complications Among Patients.

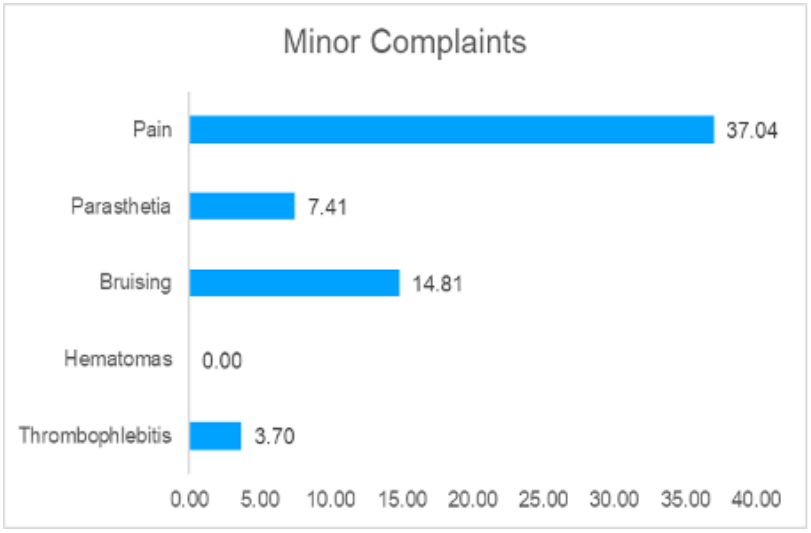

Figure-11: Bar Chart Diagram Showing Frequency Distribution Of Minor Complications Among Patients.

Figure-12: Line Chart Of Mean Venous Clinical Severity Score (rVCSS) Pre-Operative, At Post-Operative 24 Hours, 1 Week, 1 Month And 3 Months.

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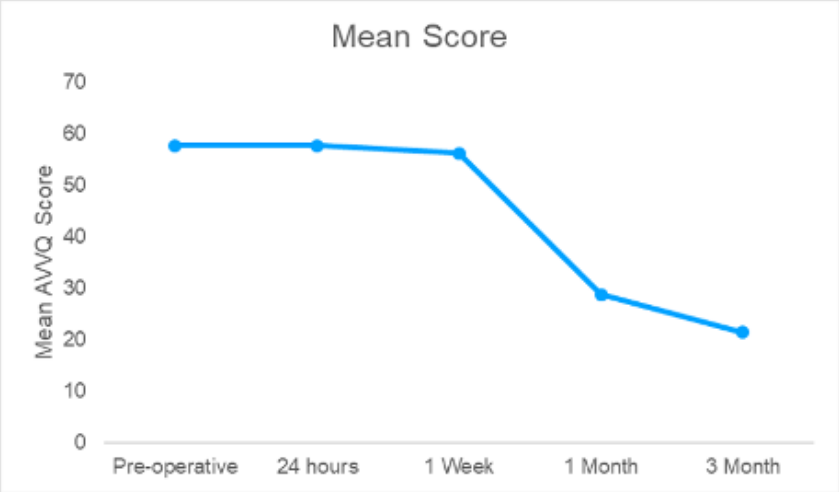

Figure-13: Line Chart Diagram Of Mean Aberdeen Varicose Vein Questionnaire Score(AVVQ) Pre-Operative, At Post-operative 24 Hours, 1 Week, 1 Month And 3 Months.

Table-1: Mean Venous Clinical Severity Score (rVCSS) Pre-Operative, At Post-operative 24 Hours, 1 Week, 1 Month And 3 Months

rVCSS	Mean Score	p-value
Pre-operative	9.67	<0.0001
24 hours	9.67	
1 Week	6.66	
1 Month	5.05	
3 Months	4.28	

Table-2: Mean Aberdeen Varicose Vein Questionnaire Score (AVVQ) Pre-Operative, At Post-Operative 24 Hours, 1 Week, 1 Month And 3 Months

AVVQ	Mean Score	p-Value
Pre-operative	57.78	<0.0001
24 hours	57.78	
1 Week	56.27	
1 Month	28.75	
3 Month	21.46	

DISCUSSION

Varicose veins as an entity have affected mankind for thousands of years and there is documentation of their existence from as early as 3500 BCE [5]. Measuring the state of health to improve quality of life is of major importance throughout all branches of medicine.

Many patients with venous disease report a huge range of symptoms of varying severity, despite the absence of clinical signs. These symptoms frequently impact their daily activities, and ability to work and social lives, and, therefore, have a functional impact on their quality of life to a varying degree. To investigate this impact, quality of life can be evaluated using questionnaires like rVCSS and AVVQ. The introduction of endovenous ablation procedures has resulted in a huge increase in the use of duplex ultrasonography, not only in the assessment of the suitability of patients for the procedure but in the delivery of tumescent anesthesia and the cannulation of the saphenous vein. Based on current evidence all patients presenting with symptomatic venous disease should undergo a full color duplex scan prior to intervention.

The "gold standard" treatment is facing serious competition from endovenous advances made in the last ten years. One such technique is RFA, which was originally licensed for use in the USA in 1999. Numerous studies have since shown this technique's superior results and good safety profile [6,7].

The considerable improvement in rVCSS and AVVQ scores demonstrated the achievement of clinical success. Our findings are consistent with international literatures[8,9]. One of the greatest results of RFA has been the early return of the patient to daily activities, as early as the post-operative evening itself. [10-12]

RFA maintains a postprocedural GSV occlusion rate of nearly 90% at 5 years. [13,14] In our study, the occlusion rate was 96.3%, at 3 months follow-up.

RFA produces heat, which is also conducted to the surrounding nontarget tissues, leading to thermal injuries. [15] The use of TA helps in minimizing these thermal injuries by acting as a heat sink. Despite its use, few patients do develop minor thermal injuries in

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the form of thrombophlebitis (3.70%), bruising (14.81%), paresthesia (7.41%) and pain (37.04%). One patient (3.9%) had a major complication of burns along the line of ablation.

When comparing a novel treatment modality with an established one, the most crucial factors to consider are an improved quality of life, a positive safety profile, and long-lasting outcomes. Regarding these characteristics, the study's findings are statistically and clinically reassuring. Several other writers have also confirmed the safety of the endovenous RFA method and the high rate of GSV occlusion observed in our investigation.There's a chance that this therapeutic approach will speed up recuperation and cut down on lost person days. Currently, the primary barriers to its extensive application appear to be the high expense of care and the scarcity of specialists.

CONCLUSIONS

Thus, our study enables us to draw the conclusion that radio-frequency ablation is as effective as traditional surgery for the management of varicose veins. It is a safe procedure and showed to be a consistently better procedure regarding major and minor complications. It has the benefit of being less painful, minimal post-procedural discomfort, local anesthetic treatment options, superior cosmetic results, and a more rapid return to regular daily activities. Reflux recurrence and recanalization rates are significantly less for radio-frequency ablation.

Conflict of Interest

The authors do not report any financial or personal connections with other persons or organizations, which might negatively affect the contents of this publication and/or claim authorship rights to this publication.

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