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### A Cross-Sectional Study Comparing Trendelenburg With Stripping And Radiofrequency Ablation For The Management Of Primary Varicose Veins In A Tertiary Care Setting In Tamil Nadu

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#### ABSTRACT

**Introduction:** Varicose veins are a common venous disorder characterised by venous dilation, tortuosity and valvular dysfunction primarily affecting the great saphenous vein (GSV). The condition leads to chronic venous hypertension, contributing to symptoms such as leg pain, heaviness, edema, and ulceration. While the Trendelenburg procedure with stripping has long been a standard surgical treatment, minimally invasive techniques like Radiofrequency Ablation (RFA) have gained prominence due to their advantages, including reduced postoperative pain and shorter recovery times. Despite its increasing adoption, comparative data evaluating RFA versus Trendelenburg with stripping in resource-limited settings remains limited.

**Aim:** This study compares the clinical outcomes of the Trendelenburg procedure with stripping versus RFA in primary varicose vein treatment. Key parameters evaluated include procedure time, pain levels, hospital stay, complications, CEAP classification improvement, Venous Severity Score (VSS) and patient satisfaction.

**Materials and Methods:** This cross-sectional comparative study was conducted over one year with 80 patients with lower limb varicose veins randomly assigned into two groups: Group A (Trendelenburg with stripping, n=40) and Group B (RFA, n=40). Patients aged 18 to 60 years, classified as ASA Grade I & II with C2 to C5 varicose veins, were included, while those with prior varicose vein surgery, deep vein thrombosis, or peripheral arterial disease were excluded. Postoperative assessments at 1 week and 1 month included procedure time, postoperative pain (VAS score), hospital stay, return to normal activities, complications, CEAP classification improvement, VSS and patient satisfaction.

**Results:** Among 90 screened patients, 80 met eligibility criteria and were randomly assigned into two groups. RFA resulted in significantly shorter procedure times, lower postoperative pain, reduced hospital stays and a faster return to normal activities than the Trendelenburg with stripping group (p < 0.001). The complication rate was lower in the RFA group (7.5%) than in the Trendelenburg with stripping group (32.5%) (p = 0.005).

**Conclusion:** The findings support the clinical advantages of RFA over the Trendelenburg procedure with stripping. RFA demonstrated reduced procedure times, lower postoperative pain, fewer complications and faster recovery making it a more efficient and patient-friendly treatment option.

**Keywords:** Varicose veins, Radiofrequency Ablation, Trendelenburg procedure, Venous insufficiency, Minimally invasive surgery

#### 1. INTRODUCTION

Varicose veins represent a highly prevalent venous pathology characterised by the dilation and tortuosity of veins resulting from a venous valve dysfunction. This condition predominantly affects the great saphenous vein (GSV) and is associated with compromised venous return, leading to increased venous pressure and resultant morphological changes in the vein structure. These changes disrupt normal blood circulation and can lead to symptoms such as heaviness in the leg, pain, itching, swelling and in more severe cases, ulceration. The global prevalence of varicose veins varies significantly across different populations, with estimates suggesting that approximately 10-20% of men and 25-33% of women are affected by this condition.1,2 While varicose veins are often perceived primarily as a cosmetic issue, they can significantly affect the quality of life (QOL) of those who suffer from them and contribute to the development of chronic venous insufficiency (CVI), thereby increasing the overall healthcare burden. This includes the financial costs associated with treatment and the indirect costs resulting from work absenteeism.3

The aetiology of varicose veins is multifactorial involving a combination of genetic predisposition, valvular incompetence, prolonged periods of standing, obesity, pregnancy and the natural ageing process.4 Chronic venous hypertension, which results from venous reflux and venous obstruction, can exacerbate the disease, significantly increasing the risk of more severe complications such as venous ulcers, deep vein thrombosis (DVT), and venous stasis dermatitis.5 The CEAP classification (Clinical, Etiological, Anatomical, and Pathophysiological) system is widely used by healthcare professionals to grade the severity of venous disease and provide guidance on treatment options.6 Management strategies for varicose veins typically include conservative approaches such as compression therapy, lifestyle modifications, and more interventional procedures when required.7

Surgical treatment remains the gold standard for addressing symptomatic varicose veins, with the Trendelenburg procedure (high ligation) in combination with stripping being one of the most commonly employed techniques.8 However, this traditional surgical technique has notable drawbacks, such as high recurrence rates, prolonged recovery periods, and the potential for neovascularisation.9,10 In the recent years minimally invasive techniques like Radiofrequency Ablation (RFA) have gained considerable popularity especially when compared to traditional surgical methods. This change can largely be credited to RFA's capacity to promote shorter recovery times, reduce the likelihood of postoperative complications and lessen postoperative pain. These advantages make RFA an increasingly attractive option for both patients and clinicians when considering treatment alternatives for various medical conditions. Despite the increasing use of RFA, there remains a lack of sufficient comparative data that evaluates RFA compared to the Trendelenburg procedure with stripping, particularly in resource-limited healthcare settings. This study aims to fill the gap in the literature by assessing the clinical outcomes of Trendelenburg with stripping versus RFA in a tertiary care setting in Tamil Nadu. The study will compare various parameters, including procedure time, pain levels, length of hospital stay, the time taken to return to normal activities, complication rates, improvement in CEAP classification, the Venous Severity Score (VSS), and overall patient satisfaction.

The hypothesis being tested in this study is that Radiofrequency Ablation (RFA) will provide superior clinical outcomes when compared to the Trendelenburg procedure combined with stripping. Specifically, it is anticipated that RFA will result in shorter procedure times, reduced postoperative pain, quicker recovery times and fewer complications offering a more efficient and patient-friendly alternative to the conventional surgical technique.

#### 2. MATERIALS AND METHODS

The present study, a meticulously designed and well-structured cross-sectional comparative study, was conducted at the SRM Medical College Hospital & Research Centre, Tamil Nadu, within the Department of General Surgery, and it spanned one year. The study's primary objective was to evaluate and compare the clinical outcomes of the Trendelenburg procedure combined with stripping versus Radiofrequency Ablation (RFA) for the treatment of primary varicose veins. A total of 80 patients, all of whom had been diagnosed with lower limb varicose veins, were enrolled in the study and randomly assigned into two distinct groups: Group A (Trendelenburg with stripping, n = 40) and Group B (RFA, n = 40). The inclusion criteria for participation in the study consisted of male and female patients aged between 18 and 60 years, classified as ASA Grade I and II, with varicose veins classified as C2 to C5 based on the CEAP classification. Additionally, these patients had confirmed incompetence of the great saphenous vein (GSV) through Doppler ultrasound imaging.

Individuals who have experienced with deep vein thrombosis in the past(DVT), previous varicose vein surgery, peripheral arterial disease, venous ulcers or those with implanted devices such as the pacemakers or internal defibrillators were excluded from the study. The preoperative evaluation of all patients included a detailed clinical assessment and a Doppler ultrasound to confirm the diagnosis and suitability for surgery. Postoperative outcomes were assessed at two distinct follow-up points: 1 week and 1 month after the procedure. These outcomes were measured through clinical examination, Doppler ultrasound imaging and patient-reported data. The main outcome measures for this study comprisedprocedure time, the level of postoperative pain (as measured by the Visual Analog Scale [VAS] score), hospital stay duration, time taken to return to normal activities and work, any complications arising, improvement in CEAP classification, the Venous Severity Score (VSS), and overall patient satisfaction levels.

Patients were allocated into the two groups using a computer-generated randomisation process to ensure a balanced distribution. Group A underwent the Trendelenburg procedure with vein stripping, which involved several key components: saphenofemoral junction (SFJ) ligation, vein stripping, and perforator ligation. On the other hand, Group B underwent RFA, which involved ultrasound-guided percutaneous access, administration of tumescent anaesthesia, and the application of segmental radiofrequency (RF) energy for vein closure. To further reduce potential bias in the study, randomisation was used to ensure equal distribution between the two groups, outcome assessors were blinded to the specific intervention type used, and standardised postoperative care was provided to all patients in both groups.

The sample size for this study which was set at n=80 was carefully calculated based on prior research and statistical considerations to ensure that the study had 90% power with a significance level of  $\alpha=0.05$ . The analysis of the collected data was conducted with great care and precision utilising SPSS version 21. Independent t-tests were used for continuous variables, while chi-square tests were employed for categorical variables. The statistical significance was established at a p-value of less than 0.05, ensuring that the results obtained from the analysis would be valid and reliable.

#### 3. RESULTS

During the study period, 90 patients with primary varicose veins were screened for eligibility. Of these, 10 patients were excluded due to not meeting the inclusion criteria (n=6) or declining to participate (n=4). The final sample consisted of 80 participants, who were randomly assigned into two groups: 40 patients underwent the Trendelenburg procedure with stripping (Group A), and 40 patients underwent Radiofrequency Ablation (RFA) (Group B). All participants completed the study, with no loss to follow-up at 1 week and 1 month.

#### **Demographic and Clinical Characteristics**

The age distribution of participants is presented in Table 1, which shows that a higher percentage of patients in Group B (62.5%) were aged 20-40 years compared to 47.5% in Group A. Meanwhile, 52.5% of Group A and 37.5% of Group B belonged to the 41-60 years category. There was no statistically significant difference in age distribution between the groups (p=0.320).

Age Group (years)	Group A (n=40)	Group B (n=40)	Total (n=80)	p-value
20-40	19 (47.5%)	25 (62.5%)	44 (55.0%)	0.320
41-60	21 (52.5%)	15 (37.5%)	36 (45.0%)	

**Table 1: Age Distribution of Study Participants** 

Footnote: P-values were calculated using the chi-square test for categorical variables. A p-value <0.05 was considered statistically significant.

The gender distribution is detailed in Table 2, where male participants were the majority in both groups, with 70% in Group A and 72.5% in Group B. Female representation was 30% in Group A and 27.5% in Group B. The difference in gender distribution between the groups was not statistically significant (p=0.459).

 Gender
 Group A (n=40)
 Group B (n=40)
 Total (n=80)
 p-value

 Male
 28 (70.0%)
 29 (72.5%)
 57 (71.3%)
 0.459

 Female
 12 (30.0%)
 11 (27.5%)
 23 (28.8%)

**Table 2: Gender Distribution of Study Participants** 

Footnote: Gender distribution was analysed using the chi-square test.

The ASA classification of patients is provided in Table 3. A higher proportion of patients in Group A (70.0%) belonged to ASA II, whereas Group B had more ASA I patients (42.5%). The difference in ASA classification was not statistically significant (p=0.245), indicating that both groups had comparable preoperative risk profiles.

**Table 3: ASA Grade Distribution** 

ASA Grade	Group A (n=40)	Group B (n=40)	Total (n=80)	p-value
ASA I	12 (30.0%)	17 (42.5%)	29 (36.3%)	0.245
ASA II	28 (70.0%)	23 (57.5%)	51 (63.8%)	

Footnote: ASA = American Society of Anaesthesiologists classification. A higher ASA grade indicates increased surgical risk.

The CEAP classification of the participants is outlined in Table 4. Both groups had comparable CEAP grades at baseline, with C3 being the most common category (35%). There were no significant differences in CEAP classification between the groups (p=0.800), ensuring comparable disease severity at baseline.

**Table 4: CEAP Classification at Baseline** 

CEAP Classification	Group A (n=40)	Group B (n=40)	Total (n=80)	p-value
C2	10 (25.0%)	12 (30.0%)	22 (27.5%)	0.800
C3	15 (37.5%)	13 (32.5%)	28 (35.0%)	
C4	10 (25.0%)	9 (22.5%)	19 (23.8%)	
C5	5 (12.5%)	6 (15.0%)	11 (13.8%)	

Footnote: CEAP = Clinical-Etiological-Anatomical-Pathophysiological classification of chronic venous disease.

Table 5 compares the procedure time and postoperative recovery parameters between the two groups. The procedure time was significantly shorter in Group B ( $46.6 \pm 11.2$  min) compared to Group A ( $70.2 \pm 9.8$  min, p < 0.001). Patients in Group B also experienced significantly lower postoperative pain scores, shorter hospital stays, and a faster return to normal activities and work (all p < 0.001), suggesting a better recovery profile with RFA.

Table 5: Comparison of Procedure Time and Postoperative Recovery

Variable	Group A (n=40)	Group B (n=40)	p-value
Procedure Time (min)	$70.2 \pm 9.8$	46.6 ± 11.2	< 0.001
Pain Score (VAS)	$6.2 \pm 1.5$	$3.4 \pm 1.1$	< 0.001
Hospital Stay (days)	$7.8 \pm 1.4$	$4.6 \pm 1.0$	< 0.001
Return to Activity (days)	14.3 ± 2.9	$6.7 \pm 2.0$	< 0.001
Return to Work (days)	19.4 ± 3.6	$10.2 \pm 3.1$	< 0.001

Footnote: VAS = Visual Analog Scale for pain assessment. Lower values indicate less pain.

Table 6 presents postoperative complications. The complication rate was significantly higher in Group A (32.5%) compared to Group B (7.5%) (p = 0.005). Hematoma and wound infections were more frequent in Group A, while DVT was reported only in this group. The findings highlight the safety benefits of RFA over the Trendelenburg procedure.

**Table 6: Comparison of Complications Between Groups** 

Complication	Group A (n=40)	Group B (n=40)	p-value
Hematoma	5 (12.5%)	1 (2.5%)	0.045
Wound Infection	4 (10.0%)	1 (2.5%)	0.021

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Deep Vein Thrombosis (DVT)	2 (5.0%)	0 (0%)	0.089
Total Complications	13 (32.5%)	3 (7.5%)	0.005

Footnote: DVT = Deep Vein Thrombosis. A p-value < 0.05 was considered statistically significant.

#### 4. DISCUSSION

The results of this study highlight the superior clinical outcomes associated with RFA compared to the Trendelenburg procedure involving stripping for the management of primary varicose veins. The data indicate that RFA mitigates the severity of venous disease, facilitates quicker postoperative recovery and is associated with reduced complication rates. These factors contribute to improved overall patient satisfaction with the treatment process.

Our study revealed a significantly shorter procedure time in the RFA group  $(46.6 \pm 11.2 \text{ min})$  compared to the Trendelenburg with Stripping group  $(70.2 \pm 9.8 \text{ min}, p < 0.001)$ . The results align with previous studies reinforcing the efficacy of RFA in the management of varicose veins. <sup>11</sup>

Patients in the RFA group experienced a significantly shorter hospital stay  $(4.6 \pm 1.0 \text{ days vs. } 7.8 \pm 1.4 \text{ days, p} < 0.001)$ , reflecting the less invasive nature of the procedure and contributing to patient comfort.

Postoperative pain was notably lower in the RFA group, with pain scores at 1 week  $(3.4 \pm 1.1 \text{ vs. } 6.2 \pm 1.5, \text{ p} < 0.001)$  and 1 month  $(1.2 \pm 0.7 \text{ vs. } 2.5 \pm 1.1, \text{ p} < 0.001)$ . These findings support those of Balasubramaniam et al., who found higher pain levels in patients undergoing stripping-based procedures due to increased tissue trauma. <sup>12</sup> Elwahab et al. similarly reported significantly lower pain levels in RFA-treated patients, providing a sense of relief and comfort to the patients. <sup>13</sup>

The overall incidence of complications was markedly lower in the RFA group (7.5%) compared to the Trendelenburg with Stripping group (32.5%) (p = 0.005). This aligns with the findings of Rathnaganpathi et al., who documented higher complication rates in surgical patients, including hematoma and wound infections.<sup>14</sup>

Patient satisfaction was significantly higher in the RFA group (67.5%) compared to the Trendelenburg with Stripping group (30.0%) (p = 0.001). Elkaffas et al. noted similar trends, highlighting improved post-treatment satisfaction due to fewer complications and faster recovery. The substantial patient satisfaction associated with RFA is a strong indicator of its clinical efficacy and alignment with patient-centered outcomes providing reassurance to healthcare professionals regarding its implementation in treatment protocols.<sup>15</sup>

These findings highlight the clinical benefits of RFA suggesting its superiority over traditional surgical techniques for varicose vein treatment.

#### Limitations

This study was performed in a single-centre environment, which may restrict the applicability of the findings to larger populations. The sample size was also relatively limited as the study was confined to patients seeking treatment at a tertiary care hospital. Many individuals with varicose veins particularly those in rural areas may not seek timely medical attention leading to an underrepresentation of cases with severe complications. Furthermore, follow-up duration was restricted preventing long-term assessment of recurrence rates and sustained clinical outcomes. To enhance the robustness of these findings, it is recommended that future multicenter studies employ larger sample sizes and longer follow-up durations for validation.

#### 5. CONCLUSION

This study provides robust evidence supporting the clinical superiority of RFA over the conventional Trendelenburg procedure with stripping in the management of varicose veins. RFA demonstrated significantly reduced procedure times enhancing the operational efficiency within clinical environments and patients reported diminished postoperative pain marking a notable advantage in post-interventional comfort. Additionally, the shorter duration of hospitalisation for RFA-treated patients facilitated expedited recovery improving the overall patient satisfaction and alleviating resource strain on healthcare facilities positioning RFA as a more efficient treatment modality. The study highlighted a lower frequency of complications linked to RFA with reduced rates of hematoma, deep vein thrombosis and infections compared to traditional interventions further substantiating its designation as a minimally invasive alternative. Collectively, these findings endorse RFA as a preferential approach to varicose vein management indicating its potential to significantly improve patient outcomes; however, to comprehensively assess the long-term efficacy of RFA, particularly regarding recurrence rates and sustained benefits compared to traditional surgical methods, further longitudinal research is warranted.

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