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Original article

Evaluation of Cosmetic Effect of Radio Frequency Ablation of Primary Varicose Veins

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Abstract:

Background: Varicose veins are a common vascular disorder, often causing cosmetic concerns and decreased quality of life. Radiofrequency ablation has emerged as an effective intervention for primary varicose veins, addressing both medical and cosmetic aspects. This study aimed to evaluate the cosmetic effect of radio frequency ablation of primary varicose veins including quality of life (QoL). **Patients and methods:** This prospective interventional study was conducted on 40 patients diagnosed with primary varicose veins. Radiofrequency ablation was performed, and patients were assessed using various parameters, including CEAP classification, visual analogue pain scale, and quality of life measures. **Results:** The study included individuals with a mean age of 33.13 ± 5.5, comprising 35% males and 65% females. Intraoperative and post-procedure Pain scores (VAS) exhibited highly significant differences. The mean hospital stay was 14.00 ± 7.00 hours, the return to normal activity took 4.27 ± 1.31 days, and the return to work required 7.10 ± 1.83 days. Significant differences were observed between Preoperative and Post procedure in terms of the QoL parameter. Strong significant correlations between QoL parameter and age, CEAP, VDS, and VAS were evident in univariate and multivariate correlation regression analyses. **Conclusions:** Radiofrequency technologies are, effective and safe treatments for truncal venous reflux with less side effects. Radio Frequency Ablation treatments have typically short post-procedural recovery times facilitating early return to work and normal activity.

Keywords: Varicose Veins; Radiofrequency Ablation; Cosmetic Effect; Quality Of Life; Pain Assessment.

Introduction

Varicose veins are a common lower limb vascular disorder. The reported incidence of varicose vein ranges from 35-55% for females and 20- 25% in males. It is reported to have negative impact on health-related quality of life. Before the worldwide spread of endogenous therapy, high ligation and stripping of the saphenous vein has been the standard treatment for patients with varicose vein [(1)].

Venous valves play a crucial role in preventing pathologic reflux. The valves also divide the hydrostatic column of blood into segments and prevent the full pressure of the fluid column from exerting force on the distal veins as GSV. When reflux is present, such as from an incompetent GSV, blood re-enters the deep system through perforating veins [(2)].

While these veins may meet diagnostic criteria for venous incompetence, the competence of perforators is regained after successful intervention of incompetent GSV, indicating that their dilation is secondary to reflux only. Similarly, perforating veins transmit high deep venous pressure to superficial veins, causing varicosities, stasis itching and venous ulcers [(1)].

Traditionally, refluxes have been treated with surgical ligation and stripping under general anaesthesia, but, lately, minimally invasive techniques under local anaesthesia have become areas of growing interest. Minimally invasive techniques like ultrasound-guided foam sclerotherapy (USGFS), have revolutionized the management [(3)].

Radiofrequency ablation and ultrasound-guided foam sclerotherapy, which are proven to be as effective as surgery in the treatment of GSV incompetence. These new procedures can be conducted on an outpatient basis with ultrasound guidance under tumescent anaesthesia, and hence return to work is significantly earlier. Ultrasound guidance also helps to evaluate the venous anatomy or its variations in the lower limb; a clear advantage compared with traditional surgery, which is a blind procedure. This can result in non-precise placement of incision, stripping of the wrong vein or leaving behind a refluxing trunk [(4)].

The great saphenous vein (GSV) is the most common site of venous reflux, and the standard treatment is ablation of this vein. Important outcomes after GSV ablation are anatomical occlusion, abolishment of reflux in the treated vein, good function, and good quality of life for treated patients [(5)].

Treatment of varicose veins and spider veins is not just for cosmetic reasons. Varicose vein disease can cause many health problems, such as blood clots, venous eczema, skin breakdown and ulceration, and, rarely, skin cancers [(6)].

This study aimed to evaluate the cosmetic effect of radio frequency ablation of primary varicose veins including quality of life.

Patients and Methods

Patients:

This prospective interventional study was conducted on 40consecutive patients diagnosed with primary varicose veins in the vascular unit of department of surgery of Benha University Hospitals.

Approval of Department of surgery and Ethics Committee in the Faculty of Medicine, Benha University (Approval Code: MS 45-7-2022) was taken before preceding the study during the period from June 2022 to December 2022. An informed written consent was obtained from all patients. all patients were informed about the purpose of the study and each of them was assigned with a secret code number.

Inclusion criteria were age >18 years old, both males and females with primary varicose veins. (CEAP classification C2, C3, C3)

Exclusion criteria were history of deep venous thrombosis, peripheral arterial disease (ABPI < 0.8), pregnancy and

lactation and anticoagulation with warfarin.

Methods:

All patients were subjected to:

Complete history taking including: Personal history, Any complaint, Obstetric history, Menstrual history, Past medical and past surgical history, Family history. Complete physical examination: General examination: Vital signs, Signs of (Pallor, Cyanosis, Jaundice, and Lymph node enlargement). And site, extent of local varicosities, Duplex ultrasonography was used to confirm and map all local varicosities.

Procedures

All the patients were positioned supine with the leg slightly flexed abducted and externally rotated leg to make the GSV more accessible, insertion of 6f sheath, The Closure Fast catheter is passed through the sheath, and the tip is advanced to 2 cm below the saphenofemoral junction under duplex ultrasonographic visualization. With ultrasonographic guidance, a local anesthetic agent is injected into the tissues surrounding the great saphenous vein above and within its fascial sheath.

Post operative the assessment included: Evaluation of GSV reflux, (clinical, aetiological, anatomical and pathophysiological elements) (CEAP) classification and its follow-up during each follow-up visit. Cosmetic effect Radiofrequency ablation and quality of life. As for pain, intra and post procedure pain was be assessed using visual analogue pain scale.

Follow-up visits were scheduled at one week, one, three and six months after procedure.

Sample size:

Epi Info STATCALC was used to calculate the sample size by considering the following assumptions: - 95% two-sided confidence level, with a power of 80%. & an error of 5% odds ratio calculated= 1.115. The final maximum sample size taken from the Epi- Info output was 40. Thus, the sample size was increased to 40 cases to assume any drop out cases during follow up. All cases will be treated with Radiofrequency ablation.

Comparison between before & after treatment with radiofrequency (Figure 2).

Statistical analysis:

Data were collected and analyzed using SPSS 26.0 for Windows (SPSS Inc., Chicago, IL, USA). Qualitative data were expressed as numbers and percentages, while quantitative data included range, mean, standard deviation, and median. Significance was assessed with two-tailed tests, where a p-value ≤ 0.05 indicated significance, $p < 0.001$ indicated high significance, and $p > 0.05$ indicated nonsignificance. Chi-square (X^2) tests compared proportions for qualitative parameters, and independent T-tests compared two independent groups with parametric quantitative data.

Results

The mean age of the studied group was 33.13±5.5, 35% were males while 65% were females according to (CEAP) classification. There were 85% of patients were C2, 12.5% of them were C3 while 2.5% of them were C4-5. There were 10% 0, 85% 1 while 5% were 2. Table 1

There was Statistically significant difference between pre operative and Post operative as regard Pain score (VAS). The mean Hospital stay (hour) was 14.00 ± 7.00, Return normal activity (day) was 4.27 ± 1.31 while return to work (day) was 7.10 ± 1.83. Table 2

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Table 1: Demographic, CEAP, and VDS data among studied cases.

Age, years	
Mean ± SD	33.13±5.5
Median (Minimum - Maximum)	35 (25 - 40)
Sex	
Male	14 (35%)
Female	26 (65%)
CEAP	
C2	34 (85%)
C3	5 (12.5%)
C4-C5	1 (2.5%)
VDS	
0	4 (10%)
1	34 (85%)
2	2 (5%)

Evaluation of GSV reflux, (clinical, etiological, anatomical and pathophysiological elements) (CEAP), Venous Disability Score (VDS).

Table 2: Pain score (VAS) and Postoperative data data among studied cases.

Pain score (VAS)	
Intraoperative	
Mean ± SD	2.06 ± 1.0
Median (Minimum - Maximum)	2.5 (1 - 3.5)
Post procedure	
Mean ± SD	0.8 ± 0.5
Median (Minimum - Maximum)	0.95 (0.1 - 1.5)
P value	<0.001
Postoperative data	
Hospital stays (hour)	
Mean ± SD	14.00 ± 7.00
Median (Minimum - Maximum)	15 (7 - 20)
Return normal activity (day)	
Mean ± SD	4.27 ± 1.31
Median (Minimum - Maximum)	5 (4 - 7)
Return to work (day)	
Mean ± SD	7.10 ± 1.83
Median (Minimum - Maximum)	8 (6 - 9)

T: Two-Sample Independent t Test, p value >0.05: nonsignificant, p value <0.05 significant.

During Post operative follow up, after 1week; There were 2.5% of patients with Erythema, 2.5% with Hematoma, 5% with Bruising & Ecchymosis, 2.5% with Residual varicosities, 5% with Hyperpigmentation, 7.5% with Paraesthesia, 2.5% with Superficial thrombophlebitis, 2.5% had DVT, The success rate was 97.5%.. All of these manifestations didn't need intervention and treated conservatively. After 3-6 months 2.5% of patients developed Paraesthesia, 2.5% had Skin pigmentation, 5% with Residual varicosities, 2.5% with Recurrence. Success rate was 95%. Table 3

In Univariate correlation regression, there were strong significant correlations between QoL parameter and age, CEAP, VDS and Pain score (VAS). In Multivariate correlation regression, there were strong significant correlations between QoL parameter and age, CEAP, VDS and Pain score (VAS). Table 4,5.6; Figure 1

Table 3: Outcomes of 1-week and 3-6 months' postoperative intervention.

1-week	
Erythema	1 (2.5%)
Hematoma	1 (2.5%)
Bruising & Ecchymosis	2 (5%)
Residual varicosities	1 (2.5%)
Hyperpigmentation	2 (5%)
Paraesthesia	3 (7.5%)
Superficial thrombophlebitis	1 (2.5%)
DVT	1 (2.5%)
Success rate	39 (97.5%)
3-6 months	
Paraesthesia	1 (2.5%)
Skin pigmentation	1 (2.5%)
Residual varicosities	2 (5%)
Recurrence	1 (2.5%)
Success rate	38 (95%)

Table 4: QoL parameter preoperative and post-operative.

QoL parameter	Rvcss	AVVQ
Preoperative		
Mean ± SD	7.5 ± 2.5	33.5 ± 12.2
Median (Minimum - Maximum)	8 (5 - 10)	35 (20 - 50)
Postoperative (six months)		
Mean ± SD	2.6 ± 1.1	7.1 ± 5.1
Median (Minimum - Maximum)	3 (1 - 4)	8 (3 - 15)
P1	<0.001	<0.001

AVVQ: Aberdeen Varicose Vein Questionnaire, rVCSS: revised Venous Clinical Severity Score, QoL: Quality of life.

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Table 5: Correlations between QoL parameter anemia and risk factors.

Correlations		
		QoL parameter
Age	r	-.495-**
	P	<0.0001
CEAP	r	.498**
	P	<0.0001
VDS	r	.560**
	P	<0.0001
Pain score (VAS)	r	.720**
	P	<0.0001

P value< 0.05 is significant, P value< 0.01 is highly significant.

Table 6: Univariate Correlations and Multivariate Correlations between QoL parameter anemia and risk factors**.**

Univariate Correlations		
Age	Correlation	0.348
	Significance	<0.0001
CEAP	Correlation	0.471
	Significance	<0.0001
VDS	Correlation	0.412
	Significance	<0.0001
Pain score (VAS)	Correlation	0.357
	Significance	<0.0001
Multivariate Correlations		Value
Age	Correlation	71.305
	Significance	<0.0001
CEAP	Correlation	20.495
	Significance	<0.0001
VDS	Correlation	25.595
	Significance	<0.0001
Pain score (VAS)	Correlation	72.35
	Significance	<0.0001

Correlation regression: ANOVA, P value > 0.05: Statistically non-significant difference | P value < 0.05: Statistically significant difference | P value < 0.001: Statistically high significant difference.

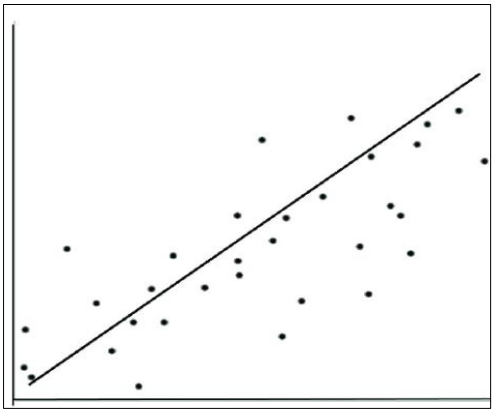

Figure 1: Correlations between QoL parameter and Pain score (VAS)

Figure 2: Comparison between before & after treatment with radiofrequency

Discussion

Primary varicose vein disease is a common condition affecting 25-40% of the adult population worldwide, with prevalence rates varying based on the population studied. Varicose veins, often perceived as a cosmetic concern, can lead to symptoms such as leg discomfort, ulcers, and impaired daily activity. Women are more affected than men, and the condition becomes more common with age. Great saphenous vein (GSV) insufficiency is a leading cause of venous complaints. Radiofrequency ablation and foam sclerotherapy with ultrasound guidance have emerged as effective alternatives to surgery for treating GSV incompetence, offering quicker recovery and improved

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precision in vein treatment. This study aims to assess the cosmetic impact of radiofrequency ablation on primary varicose veins, including its effect on quality of life.

In the current study we found that the mean age was 33.13±5.5 yrs, 35% were males while 65% were females.

In agreement with our results, a researcher reported that in a total of 709 patients (53%; females, 46%; males) were included in the study. The median age of the patients was 48 (19-65) years, and the median follow-up period was 36 (6-53) months. At follow-up after treatment, 673 (94.9%) of the patients had a CEAP clinical score of C0. Postoperative complications were recorded in 7 (1%) patients. Patients' cosmetic expectations can vary with age. Younger individuals may have higher aesthetic expectations and be more focused on achieving a flawless appearance, while older patients might prioritize symptom relief over cosmetic outcomes. Understanding and managing patient expectations is crucial for evaluating the cosmetic effect of RFA in different age groups [(7)].

An author noted that out of a total of 53 patients, 34 (64.15%) were females and 19 (35.85%) were males. Therefore, the sex ratio is 1.79: 1 (women: men). Among the patients studied, 30 came from urban environments (65.2%) and 16 from rural environments (34.8%). For the remaining 7 patients, the environment of origin was not specified in the observation sheets. The average age is 53.88 ± 12.40 SD, and the median age is 54, with the minimum age being 25 years and the maximum 76 years. Most patients are in the age range of 40–70 years (75.5%), with a peak frequency in the age group 50–60 years (32.1%). In some cases, especially among older patients with more severe varicose veins, RFA may be combined with other procedures such as sclerotherapy or phlebectomy to achieve the desired cosmetic effect. These combination treatments can provide comprehensive results but may also introduce additional considerations related to age and recovery [(8)].

In the present study we found that there were 85% C2, 12.5% C3 while 2.5% were C4-5. According to VDS data among studied cases, there were 10% 0, 85% 1 while 5% were 2. There was highly significant difference between Intraoperative and Post procedure as regard Pain score (VAS).

In a study also utilized RFA, the CEAP clinical stage had improved 2.33 ± 0.78 to 1.29 ± 0.96 and Venous clinical severity score (VCSS) score had improved 3.48 ± 0.98 to 0.63 ± 1.16. Two other studies also reported significant improvements in both scores, especially VCSS [(9)].

In another study showed that the CEAP classification showed that 449 limbs (91%) had uncomplicated varicose veins (C2, C3) and 45limbs (9%) had complications (C4-C6) due to lipo-dermatosclerosis (n = 34), healed past venous ulceration (n= 5), or active ulceration (n = 6). Primary disease was present in all limbs, and none had features of the post-thrombotic syndrome [(10)].

In the current study we found that the mean Hospital stay (hour) was 14.00 ± 7.00, Return normal activity (day) was 4.27 ± 1.31 while return to work (day) was 7.10 ± 1.83. Outcomes of 1-week postoperative intervention were 2.5% with Erythema, 2.5% with Hematoma, 5% with Bruising & Ecchymosis, 2.5% with Residual varicosities, 5% with Hyperpigmentation, 7.5% with paraesthesia, 2.5% with Superficial thrombophlebitis, 2.5% had DVT. Success rate was 87.5%. Outcomes of 3-6 months post-operative were 2.5% with paraesthesia, 2.5% with Skin pigmentation, 5% with Residual varicosities, 2.5% with Recurrence. Success rate was 70%.

In agreement with our study, 119 studies evaluated and recognize that success rates (which means total vein occlusion without patent segment) were 94% for EVLA and

84% for RF based on results for 12320 legs which is different from our results and that mostly due to the difference in sample size [11].

The time of operation for Endo-venous laser ablation (EVLA)patients ranged from 20 to 45 minutes, with a mean of 30-5 minutes. All participants had early ambulation and were discharged on the same day. They kept the elastic stocking for 2 weeks post-operatively. At a 6-month follow-up, the patency of the ablated vein was assessed using duplex ultrasound. All 20 EVLA patients had a completely occluded great saphenous vein with no patent intermittent segment, while 16 patients in the other 20 RFA patients had a completely occluded vein with no patent intermittent segment. Only 20% had an intermittent patent segment with no residual refluxing [12].

In consistent with our results, the clinical outcome of varicose vein treatment with RFA was investigated through the pre- and post-treatment evaluation of VCSS and CEAP classification, which showed significant improvements in both parameters. Regarding daily activity, all patients who underwent RFA returned to normal daily activity within 10 days of the procedure. Pain scores were also very low for the large majority of patients, the mean score was 1.34 and only one patient reported a score of 6. RFA treatment was found to provide significant improvements as seen by the improvement in CEAP and VCSS scores of our patients [13].

The average hospital stay of patients was noted was 1.5 days. Return to habitual activity by the postoperative evening was seen in 100% of the patients. None of the patients had any immediate peri-operative adverse events. The postoperative complications seen in these patients, at the end of 24-week follow-up period, are reflected in Table 2. The most common complication was palpation of a cord-like mass in the target GSV territory, present in five patients (17%). he hospital stay for RFA is minimal, the evaluation of the cosmetic effect of the procedure may take some time. Changes in the appearance of varicose veins and associated skin changes may continue to improve over weeks to months as the body naturally absorbs treated veins and as the skin heals [14].

In the present study we found that there was highly significant difference between Preoperative and Post procedure as regard QoL parameter. There were strong significant correlations between QoL parameter and age, CEAP, VDS and Pain score (VAS). In Univariate correlation regression, there were strong significant correlations between QoL parameter and age, CEAP, VDS and Pain score (VAS). In Multivariate correlation regression, there were strong significant correlations between QoL parameter and age, CEAP, VDS and Pain score (VAS).

In a study which is in line with our findings, endo-venous radiofrequency ablation (RFA) for primary varicose veins resulted in a significant improvement in clinical outcomes as measured by the CEAP classification score, with a notable reduction in revised Venous Clinical Severity Score (rVCSS) from a preoperative score of 7.6 to 2.4 at 24 weeks ($P \leq 0.001$). This underscores that RFA not only enhances the cosmetic appearance but also substantially improves patients' quality of life by reducing pain and enhancing mobility [15].

Our results was confirmed by showing that RFA led to improved quality of life scores at one and two years compared to alternative treatments, with comparable clinical and hemodynamic outcomes, reinforcing the effectiveness of RFA in reducing varicose veins' symptoms and recurrence [16].

That RF was showed ablation may also confer economic advantages to individuals, treating hospitals and society. Compared to laser, venefit consistently demonstrates reduced postoperative pain, bruising and tenderness and better quality of life (QoL) scores [17].

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Conclusion

Radiofrequency technologies are, effective and safe treatments for truncal venous reflux with satisfactory cosmetic effect, and less side effects. Radio Frequency Ablation treatments have typically short post-procedural recovery times facilitating early return to work and normal activity.

Conflict of interest

None of the contributors declared any conflict of interest

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