Original Research Article

Assess clinical outcomes following radiofrequency ablation for varicosevein and to identify subgroups who would benefit most from the treatment modality

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Abstract

Background: Varicose veins is a widespread condition causing widespread symtoms among people. The use of modalities like RFA and edovenous laser surgeries are gaining more attention and have become more popular nowadays compared to the open surgery, Studies comparing the effects and complications of EVRFA with other treatment modalities are still undergoing. **Aim:** To assess the clinical outcomes following Radiofrequency ablation for symptomatic varicose veins using Venous clinical severity scoring and to identify the clinical subgroups who would benefit the most from this treatment modality. **Materials and methods:** 57 cases of varicose veins done by EVRFA were assessed at the time of admission for procedure in Government medical college Kozhikode and their VCSS score and clinical subgroup to which they belong is documented. Data was collected by using questionnaire and these subjects were followed up at 3 months and 6 months post procedure and the same scores calculated again and compared. **Results and Conclusion:** EVRFA showed significant reduction in VCSS score of study subjects with also improvement in their clinical class. All clinical subgroups benefitted from the procedure in terms of VCSS score calculated at 3 months and 6 months post procedure with only C3 females having slightly delayed and lesser benefit compared with others and was found to be statistically significant.

Key Words: EVRFA,VCSS, C3 group.

Introduction

Varicose veins are one of the most common vascular diseases and are present in 10% of general population with a higher prevalence in women. The symptoms include aching or heaviness,ankle swelling,itching[1]. These symptoms aggravate on prolonged standing and is relieved on elevation of leg or compression. It can be due to fundamental causes like inheritance, age, sex or due to precipitating causes like obesity, pregnancy,occupation, trauma. Symptoms depend upon site and degree of valve incompetency, venous dilatation and also complications[3].

CEAP Classification for chronic venous disorders is widely used.Clinically, C0: no signs of venous disease,C1:telengiectasia or reticular veins, C2: varicose veins, C3: oedema, C4a :pigmentation or eczema, C4b: lipodermatosclerosis or atrophic blanche, C5: healed venous ulcer, C6: active venous ulcer.Etiologically, Ec: congenital, Ep: primary, Es: secondary and En: no venous cause. Anatomically to As: superficial veins, Ap: perforator veins, Ad: deep veins, An: no venous location identified. Pathologically as Pr: regurgitation, Po: obstruction, Pro: regurgitation and obstruction, Pn: no venous pathophysiology identified

Different techniques have been developed for the treatment of varicose veins with an important component being the use of elastic compression stockings.Treatment depends upon condition of valves, arterial circulation, age and general condition of the patient. Before prescribing treatment one should determine deep vein patency, SFJ competency, incompetent communicating valves, arterial circulation, comptency of lesser saphenous system, other vascular abnormalities[2]. Complete history and physical evaluation of patient assists us in deciding the appropriate treatment modality. Conventional surgeries like vein stripping has been used for a long time with various degrees of complications.Percutaneous endovenous ablation has revolutionized the treatment for varicose veins. Endovenous Laser Ablation as well as Radiofrequency Ablation have gained popularity in recent years with equal effectiveness and more rapid post-procedure recovery compared to open surgical stripping.

Endovenous RFA is a catheter based endovascular intervention. The direction of radiofrequency energy in to tissue to cause its destruction, it is safer and more controllable than other mechanism. Radiofrequency energy is delivered in continuous or sinusoidal wave mode; there is no stimulation of neuromuscular cells when a high frequency (between 200 and 3000 kHz) is used. The mechanism by which Radiofrequency current heats tissue is resistive (or ohmic) heating of narrow rim of tissue that is in direct contact with the electrode. Therefore, during this resistive heating, the heat is generated in the vein wall and not in the catheter tip. Clinically, the device produces precise tissue destruction with endothelial denudation, denaturing of the media and intramural collagen, with subsequent fibrotic seal of the vein lumen with minimal formation of thrombus and coagulum. The net effect is venous spasm and collagen shrinkage that produces maximum physical contraction[4]. The thermal effect on the vein wall is directly related to the treatment temperature and the treatment time, the latter being a function of catheter pullback speed. With a treatment temperature of 85-90 degree at a pullback speed of 3-4cm/min, the thermal effect induced sufficient collagen contraction to occlude the lumen[5]. Radiofrequency ablation is performed using the closure catheter.

The VNUS Closure FAST catheter is developed to improve the procedure speed and the ease of use compared with the other closure catheters. Good contact between the catheter and the vein wall is established by tumescent infiltration, Trendelenburg position and external compression. The temperature of the heating element is monitored and controlled by a temperature sensor that regulates the amount of energy delivered during the treatment. Closure FAST catheter uses segmental heating approach. Once the catheter is positioned and the vein approximately compressed the heating element is activated with RF energy for the duration of the 20 second

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heating cycle. The 7mm element is heats to 120 degree C. After completion of the 20-second heating cycle the catheter is positioned to the next segment, guided by the shaft markers and the treatment start again. Two heating cycles are applied to the first segment near the SFJ to ensure sufficient treatment of this important segment.(22)
The purpose of this study is to assess the clinical outcomes following Radiofrequency Ablation for symptomatic varicose vein using Venous clinical severity scoring and also to know the clinical subgroup mostly benefitted from this treatment.

Materials and Methods

Study design and settings

After obtaining approval from the institutional ethics committee a prospective study was conducted at the Department of General Surgery, Calicut medical college, Calicut, Kerala, India.

Study population

Patients admitted with symptomatic varicose veins for Radiofrequency Ablation treatment between March 2020 and March 2021 were included in the study excluding those who had previously undergone other surgical treatment for varicose vein and those with underlying skin disorders like SLE, Psoriasis, contact dermatitis.

Data collection and statistical analysis

From previous study (Radiofrequency ablation of varicose veinsimproves venous clinical severity score despite failure of completeclosure of the saphenous vein after 1 year, ASIAN Journal of Surgery 2015), the sample size was calculated as 57.Patients admitted with symptomatic varicose veins for Radiofrequency ablation treatment in the given time period were assessed prior to the procedure and their venous clinical severity score noted along with the clinical class they belonged to (C0-C6) after clinical examination and history taking. These patients were then assessed clinically at 3 months and 6 months post procedure and the venous clinical severity score and clinical class calculated again for measuring the improvement in their symptoms. A master chart was prepared with the above collected data which was coded and entered in Microsoft Excel and statistical analysis was done using the software Statistical Package for Social Sciences(SPSS) using appropriate statistical tests. Results were tabulated for comparison of improvement in VCSS score and the clinical class of patients who would benefit the most in terms of early and better improvement in their symptoms were also identified.

Results

Comparing VCSS score at presentation and at 3 months: In this study all clinical subgroups showed 100% reduction in VCSS score with only exception of C4 andC3 group. Among both only C3 group change was found to be statistically significant by chi-square test -p value of 0.027. In C3 group 13 were females with 8 belonging to 6-10 VCSS score and 5 belonging to 11-15 VCSS score;. and 10 were males with 7 belonging to 6-10 VCSS score and 3 having score between 11-15. In this study in males (C3 group) with VCSS score between 6-10, 85.7% reduced to VCSS score 0-5 and in females with same score only 12.5% reduced to 0-5 VCSS score. In C3 group males with initial VCSS score between 11-15, 66.7% reduced to 6-10 group and 33.3% reduced to 0-5 group. In females with same initial score only 20% reduced to score between 6-10 and 20% reduced to score between 0-5 and 60% did not show reduction in VCSS score. In this study those in C3 group who did not show reduction in VCSS score at 3months were all females.
Comparing VCSS Scores at presentation and after 6 months: In this study all clinical subgroups showed reduction in VCSS score. All groups C2, C4, C5, C6 groups showed 100% reduction in VCSS score with the exception of C3 group. C3 group patients with initial score of 6-10, 93.3% reduced to 0-5 group and 6.7% remained same .And those within 11-15 score, 100% reduced to lower score. This is of statistical significance compared to other groups as indicated by a Chi-square test p value of 0.016.Patients who belonged to all clinical subgroups except C3 had a reduction in VCSS score to lowest value of 0-5.In C3 group all males showed reduction in VCSS score to 0-5. Females in C3 with VCSS between 6-10, 12.5% did not show reduction and is statistically significant by Chi square test, p value-0.015.
Comparing change in clinical subgroup at 3 months and 6 months: Most subjects showed improvement in their clinical class.

Table 1: VCSS score at presentation and at 3 months(including males and females comparison)

VCSS score at presentaton * VCSS score at 3m Cross tabulation								
Clinical subgroup at presentation	GENDER				VCSS score at 3m			Total
					0-5	6-10	11-15	
C2	Male	VCSS score at presentation	6-10	Count	2			2
				%	100.0%			100.0%
		Total		Count	2			2
				%	100.0%			100.0%
C3	Male	VCSS score at presentation	6-10	Count	6	1		7
				%	85.7%	14.3%		100.0%
			11-15	Count	1	2		3
				%	33.3%	66.7%		100.0%
		Total		Count	7	3		10
				%	70.0%	30.0%		100.0%
	Female	VCSS score at presentation	6-10	Count	1	7	0	8
				%	12.5%	87.5%	0.0%	100.0%
			11-15	Count	1	1	3	5
				%	20.0%	20.0%	60.0%	100.0%
		Total		Count	2	8	3	13
				%	15.4%	61.5%	23.1%	100.0%
C4	Male	VCSS score at presentation	6-10	Count	10	2		12
				%	83.3%	16.7%		100.0%
			11-15	Count	0	2		2
				%	0.0%	100.0%		100.0%
		Total		Count	10	4		14
				%	71.4%	28.6%		100.0%
	Female	VCSS score at presentation	6-10	Count	3	2		5

				%	60.0%	40.0%		100.0%
		Total		Count	3	2		5
				%	60.0%	40.0%		100.0%
C5	Male	VCSS score at presentation	6-10	Count	2	0		2
				%	100.0%	0.0%		100.0%
			11-15	Count	2	1		3
				%	66.7%	33.3%		100.0%
		Total		Count	4	1		5
				%	80.0%	20.0%		100.0%
	Female	VCSS score at presentation	6-10	Count	1	0		1
				%	100.0%	0.0%		100.0%
			11-15	Count	0	1		1
				%	0.0%	100.0%		100.0%
		Total		Count	1	1		2
				%	50.0%	50.0%		100.0%
C6	Male	VCSS score at presentation	11-15	Count	1	3		4
				%	25.0%	75.0%		100.0%
		Total		Count	1	3		4
				%	25.0%	75.0%		100.0%
	Female	VCSS score at presentation	11-15	Count		2		2
				%		100.0%		100.0%
		Total		Count		2		2
				%		100.0%		100.0%

Table 2: VCSS score at presentation and at 6 months (including Males and Females comparison)

VCSS SCORE AT PRESENTATON * VCSS SCORE AT 6M Cross tabulation							
Clinical subgroup at presentation	**GENDER**				**VCSS score at 6m**		**Total**
					0-5	6-10	
C2	Male	VCSS score at presentation	6-10	Count	2		2
				%	100.0%		100.0%
		Total		Count	2		2
				%	100.0%		100.0%
C3	Male	VCSS score at presentation	6-10	Count	7		7
				%	100.0%		100.0%
			11-15	Count	3		3
				%	100.0%		100.0%
		Total		Count	10		10
				%	100.0%		100.0%
	Female	VCSS score at presentation	6-10	Count	7	1	8
				%	87.5%	12.5%	100.0%
			11-15	Count	1	4	5
				%	20.0%	80.0%	100.0%
		Total		Count	8	5	13
				%	61.5%	38.5%	100.0%
C4	Male	VCSS score at presentation	6-10	Count	12		12
				%	100.0%		100.0%
			11-15	Count	2		2
				%	100.0%		100.0%
		Total		Count	14		14
				%	100.0%		100.0%
	Female	VCSS score at presentation	6-10	Count	5		5
				%	100.0%		100.0%
		Total		Count	5		5
				%	100.0%		100.0%
C5	Male	VCSS score at presentation	6-10	Count	2		2
				%	100.0%		100.0%
			11-15	Count	3		3
				%	100.0%		100.0%
		Total		Count	5		5
				%	100.0%		100.0%
	Female	VCSS score at presentation	6-10	Count	1		1
				%	100.0%		100.0%
			11-15	Count	1		1
				%	100.0%		100.0%
		Total		Count	2		2
				%	100.0%		100.0%

C6	Male	VCSS score at presentation	11-15	Count	4		4
				%	100.0%		100.0%
		Total		Count	4		4
				%	100.0%		100.0%
	Female	VCSS score at presentation	11-15	Count	2		2
				%	100.0%		100.0%
		Total		Count	2		2
				%	100.0%		100.0%

Table 3: Clinical subgroup change at 3 months

Clinical subgroup at 3m				
Clinical subgroup at presentation			Frequency	Percent
C2	Valid	C0	2	100.0
C3	Valid	C1	7	30.4
		C3	16	69.6
		Total	23	100.0
C4	Valid	C4	19	100.0
C5	Valid	C4	7	100.0
C6	Valid	C5	6	100.0

Table 4: Clinical subgroup change at 6 months

Clinical subgroup at 6m				
Clinical subgroup at 3m			Frequency	Percent
C0	Valid	C0	2	100.0
C1	Valid	C0	3	42.9
		C1	4	57.1
		Total	7	100.0
C3	Valid	C1	10	62.5
		C3	6	37.5
		Total	16	100.0
C4	Valid	C1	7	26.9
		C3	5	19.2
		C4	14	53.8
		Total	26	100.0
C5	Valid	C4	4	66.7
		C5	2	33.3
		Total	6	100.0

Discussion

In this study we assessed the clinical outcomes following RFA in terms of VCSS score. We compared the individual clinical subgroups' improvement in the VCSS score and their relation. And male and female comparison were also done.

Most of the available trials however compare different techniques performed in varicose vein patients. Other studies also compared postoperative side effect profile of RFA with other procedures. For this reason there are only limited studies that can be directly compared to our studies

In a preliminary study of evaluation of radiofrequency ablation for primary varicose veins conducted by the Department of Surgery, KAMSRC, Hyderabad. And the results were similar to our study-reduction in VCSS score and C score post procedure. There was a significant improvement in clinical outcome (C score of CEAP classification) of patients following endovenous RFA at the end of 24 weeks, as compared to preoperative period ($P \leq 0.001$).Mean rVCSS preoperative score of 7.6 (4.1) showed improvement in the follow-up period, with values at 1 week – 6.2 (3.1); 4 weeks – 4.8 (2.2); 12 weeks – 3.4 (1.8); and at 24 weeks – 2.4 (1.3).

In a retrospective comparative study conducted by[6]. Hyeong Yong Jin et al. Asian J Surg.2017 Jan; Duplex scans and VCSS scores were used to document treatment outcome and patient symptoms before and after the procedure. Outcomes assessed at 3 months,6 months and 12 months after procedure and analyzed by paired t test, chi-square test, or Fisher's exact test as well as by logistical regression.

The results showed estimated mean VCSS change over time from 4.0_+ 1.67 at pre procedure to 0.6+_1.05,0.5+_1.02 and 0.6+-1.14 at 3 months, 6 months and 12 months after procedure respectively. The improved VCSS was also mantained 1 year after procedure.

Conclusion

Radiofrequency Ablation procedure for varicose veins is associated with reduction in VCSS score post procedure. There is significant reduction in severity of symptoms like pain swelling varicosites ulcer healing post RFA procedure. All clinical subgroups shows an improvement in their VCSS score. However patients in C3 clinical group showed a slower and lesser symptomatic improvement. And among them males were found to be better benefitted compared to females.RFA treatment also provided improvement in clinical stage(C stage) of disease.

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