Original Research Article

Critical evaluation of radiofrequency ablation as a modality of management in patients of varicose vein

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International Archives of Integrated Medicine, Vol. 7, Issue 9, September, 2020
Available online at http://iaimjournal.com/
ISSN: 2394-0026 (P) **ISSN: 2394-0034 (O)**
Received on: 03-08-2020 **Accepted on:** 14-08-2020
Source of support: Nil **Conflict of interest:** None declared.
How to cite this article: Rajendra Prasad Kathula, Ankita Rai, Harshitha Kathula, Bhargya Rekha. Critical evaluation of radiofrequency ablation as a modality of management in patients of varicose vein. IAIM, 2020; 7(9): 29-34.

Abstract

Background: Varicose vein is a common surgical problem in surgical practice. The study was intended to critically evaluate the patients undergoing the procedure prospectively after a week, 1 month and 6 months the clinical and technical outcome of the procedure.

Material and methods: A prospective study was undertaken in the Department of surgery. About 50 patients attending the OPD were included in to the study. The patients with CEAP clinical class C_2-C_6 and with symptoms or cosmetic concerns will be included. The patients were subjected for Radio frequency ablation and patients were followed up at post-operative day 1, 1 week, 1 month and 6 months after the surgery.

Results: This study had shown that, more than three fourth of the patients had Sapheno – Femoral junction and Sapheno popliteal incompetence. Right greater saphenous vein and short saphenous vein radiofrequency ablation was the main surgery. The CEAP classification had shown that, after 6 months of operation 88% were classified as C0. The mean VAS score had declined to 0.22 (± 0.68) after 6 months of operation. The mean VCSS score had declined to 2.22 (± 1.15) after 6 months after operation. After 6 months of follow up, 78% of the patients with varicose veins had complete occlusion and 90% of the study subjects were satisfied with the procedure.

Conclusion: The study had shown the substantial improvement in occlusion, CEAP classes, VAS scores, VCSS scores and satisfaction with the procedure.

Key words

Varicose veins, Radio frequency ablation, Venous incompetence, Satisfaction, VCSS scores.

Introduction

Varicose veins are common surgical problem in day to day surgical practice. They are more common in adult population causing cosmetic concern as well as bothersome symptoms if left untreated [1]. There is much discrepancy between the estimates of prevalence from different epidemiological studies with estimates for the disease range from 2% to 56% in men and 1% to 73% in women. The prevalence of varicose veins increases with age [2, 3]. The prevalence of varicose veins is more than 20% and 5% may result in venous edema, skin changes or venous ulcerations [4]. In the Indian Subcontinent, an estimated 23% of the adults have the varicose veins, and 6% have more advanced chronic venous disease (CVD), including skin changes and healed or active venous ulcers [5].

Various predisposing factors have been implicated in varicose veins like pregnancy, prolonged standing, obesity, old age, athletics, etc. but heredity also plays an important role. In varicose veins, the problem may lie in superficial veins, deep veins or in the perforating system [6].

The treatment of varicose veins has also undergone dramatic changes with the induction of percutaneous endovenous ablation techniques, including endovenous laser therapy (EVLA), radiofrequency ablation (RFA) and liquid or foam sclerotherapy [7].

Even though radiofrequency ablation is accepted as the first choice in treatment of varicose veins due to great sapheno femoral insufficiency, this treatment modality has not gained popularity in India. Considering the recent development of this procedure, there are very few studies in India which have evaluated the advantages of RFA as the treatment modality in both short and long term. The study was intended to critically evaluate the patients undergoing the procedure prospectively after a week, 1 month and 6 months the clinical and technical outcome of the procedure. This study may help in developing RFA as the alternate treatment of choice for varicose veins in the future.

Materials and methods

A prospective study was conducted in the Department of surgery, for a period of two years beginning from April, 2018 to March, 2020. About 50 patients who attended the department either in Outpatient department or In patient department constituted the study sample. A written, Bilingual and informed consent was obtained before including them as study sample. The patients with CEAP clinical class C_2-$C_{6,}$ with symptoms or cosmetic concerns, aged between 18 to 70 years, Doppler evidence of incompetence and veins with diameter of more than 4 mm, and less than 12 mm in supine position were included. Thrombus in GSV or presence of deep vein thrombosis (DVT), Concomitant peripheral arterial disease, Pregnancy and Pure perforator incompetence were excluded from the study. All basic details including demographic factors, general physical examination and systemic examination were conducted on patients. Laboratory investigations included CBC, BT, CT, LFT, KFT, SE, FBS, PPBS, Urine routine and Microscopy.

ECG, Radiological investigations including chest x-ray, venous and arterial color Doppler of affected limb and Preoperative VCSS (venous clinical severity score) were conducted before the operation and on subsequent follow up.

Access to the varicose vein was obtained with 16 gauge needle under US guidance typically below knee level or distal to the point of reflux. The closure catheter was positioned 1 to 2 cm distally from the junction under longitudinal US visualization. The pods of the catheter were

expanded in the common femoral vein and, with US guidance, withdrawn into the orifice of the junction. A cuff or bandage was used to compress the blood out of the vein. The small electrodes at the end of the "umbrella" catheter were in direct contact with the venous wall and omit high radiofrequency energy (regulated by power, impedance, and time) that is generated by a radiofrequency generator. The RF heats local tissue up to 85°C to 90°C at the site of direct contact, with the heat conducted to deeper tissue planes, causing collagen shrinkage, denudation of endothelium, and obliteration of the venous lumen. A thermocouple monitors the temperature during treatment. Similar to EVLT, perivenous tumescent anesthesia was applied to optimize contact surface and to decrease the pain sensation and risk of dysesthesia. Also, manual compression was recommended during the treatment to enhance contact of the catheter with the vein wall. The catheter was slowly pulled back at about 3 cm/min (total pullback time was about 20 minutes on average for the GSV between SFJ and knee level) but can be faster at higher temperatures. Compressive bandage or long compressive stocking class II was indicated for 1-2 weeks [8].

Patients were followed-up at post-operative day 1, 1 week, 1 month and 6 months after the surgery. Assessment was done in terms of clinical outcomes as CEAP clinical score, VCSS (venous severity clinical score), post-operative pain scoring on VAS (visual anologue scale), fatigue, complications, patient's satisfaction by asking whether they would recommend the procedure to a friend with similar leg problems in the form of 3 answers: "yes" ,"no" , "not sure". The data thus obtained was analyzed by using appropriate statistical methods.

Results

About 30% of the patients belonged to 51 – 60 years of age group in this study. Males outnumbered females in this study. Most of the patients were affected with the varicose veins bilaterally. More than three fourth of the patients had Sapheno – Femoral junction and Sapheno popliteal incompetence. About 52% of the patients in this study, undergone right greater saphenous vein and short saphenous vein radiofrequency ablation, 36% had left great saphenous vein and short saphenous vein radiofrequency ablation, 8% had left great saphenous vein radio frequency ablation and 4% had right great saphenous vein radiofrequency ablation (**Table – 1**).

The CEAP classification of 30% of the patients was C2, 28% of the patients were classified as C4a, 18% were classified as C4b and 12% were classified as C3. On the post-operative day 1, 32% were classified as C1, 28% as C4a and 18% as C4b. One week of the post-operative period, 34% were classified as C0 of CEAP classification, 40% were classified as C3 and 14% as C1. After one month of the post-operative period, about 72% were classified as C0 and 24% as C1. After 6 months of operation 88% were classified as C0 and 12% were classified as C1 (**Table – 2**).

The mean (± SD) VAS score on pre-operative day was 4.26 (± 2.0) and declined to 0.58 (± 0.8) after 1 month and 0.22 (± 0.68) after 6 months of operation (**Graph – 1**).

The mean (± SD) VCSS score on pre operative day was 9.52 (± 2.83) which decreased to 3.22 (± 1.46) after 1 month and 2.22 (± 1.15) after 6 months after operation (**Table – 3**).

After 6 months of follow up, 78% of the patients with varicose veins had complete occlusion and 90% of the study subjects were satisfied with the procedure of radiofrequency ablation. In the patients who were not satisfied, 4% were said there is no satisfaction and 4% were not sure about the satisfaction (**Table – 4**).

Table – 1: Distribution of the study group according to demographic and clinical characteristics.

		Frequency	Percentage
Age group	**21 – 30 years**	7	14.0
	31 – 40 years	4	8.0
	41 – 50 years	13	26.0
	51 – 60 years	15	30.0
	More than 60 years	11	22.0
Sex	**Male**	36	72.0
	Female	14	28.0
Side affected	**Bilateral**	11	22.0
	Left	17	34.0
	Right	22	44.0
Type of incompetence	**SFJ & SPJ incompetence**	43	86.0
	SFJ incompetence	7	14.0
Type of surgery	**Left GSV & SSV RFA**	18	36.0
	LT GSV RFA	4	8.0
	RT GSV & SSV RFA	26	52.0
	RT GSV RFA	2	4.0

Table – 2: Distribution of the study group according to CEAP Classification.

CEAP	Pre-operative N (%)	Post-operative day 1 N (%)	1 week N (%)	1 month N (%)	6 months N (%)
C0	0	0	17 (34.0)	36 (72.0)	44 (88.0)
C1	0	16 (32.0)	7 (14.0)	12 (24.0)	6 (12.0)
C2	15 (30.0)	0	0	0	0
C3	6 (12.0)	5 (10.0)	20 (40.0)	2 (4.0)	0
C4a	14 (28.0)	14 (28.0)	3 (6.0)	0	0
C4b	9 (18.0)	9 (18.0)	0	0	0
C5	2 (4.0)	2 (4.0)	3 (6.0)	0	0
C6	4 (8.0)	4 (8.0)	0	0	0

Graph – 1: Distribution of the study group according to VAS scores.

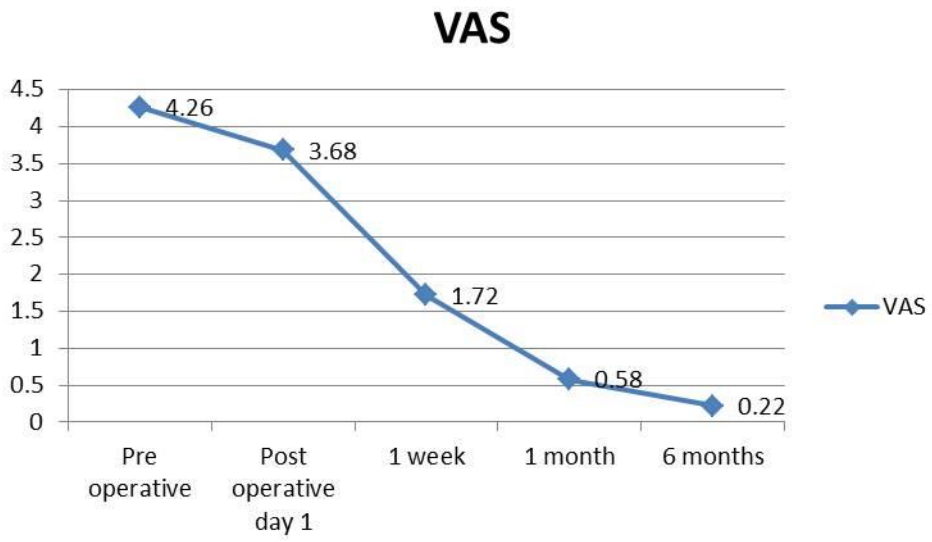

Table – 3: Distribution of the study group according to VCSS scores.

VCSS	Pre-operative	Post-operative day 1	1 week	1 month	6 months
Mean (± SD)	9.52 (2.83)	8.9 (2.6)	5.4 (2.46)	3.22 (1.46)	2.22 (1.15)

Table – 4: Distribution of the study group according to occlusion at 6 months and satisfaction with the procedure.

	Occlusion at 6 months	Frequency	Percentage
Occlusion at 6 months	**Complete occlusion**	39	78.0
	Near complete occlusion	9	18.0
	Incomplete occlusion	2	4.0
Satisfaction with the procedure	**Satisfied**	45	90.0
	Not satisfied	2	4.0
	Not sure	2	4.0

Most of the patients in this study belonged to 41 – 60 years of age group. This age appears to be the most vulnerable for the varicose veins as it falls in earning age group. In a similar study by Sastry, et al., varicose veins were common in the group of 30 – 50 years similar to this study [7]. In a comparative study of radio frequency ablation and stripping, the mean age was 36.4 years and 48.3 years respectively [10]. In this study, males outnumbered females. In a study, Sastry, et al. also observed similar findings of this study. Male sex was more affected than the female sex. Majority of the patients in this study had bilateral varicose veins. While Satry, et al. had observed that, right limb was affected in 30.66% and left limb was involved in 47.33% unlike the findings of this study [7].

In this study, majority of the patients had Sapheno – Femoral junction and Sapheno popliteal incompetence. Sastry, et al. had noted that, 76.5% had shown involvement of long saphenous vein and only 4.9% patients presented with short saphenous involvement. Majority of eth patient had combined saphenous femoral and perforator incompetence in a study of comparison of different methods [7].

About 30% of the patients were classified as C2 before the operation, on the post-operative day 1, 32% were classified as C1, one week of the post-operative period, 34% were classified as C0 of CEAP classification, after one month of the post-operative period, about 72% were classified as C0 and about 88% were classified as C0 after 6 months of follow up. In a study by Sastry, et al., majority of the patients who sought treatment for one or other complication, 44.26% patients had class 4 with symptoms of pigmentation with itching and 9.29% of the patients were treated for ulcer.[7] In a study by Tonev, et al., majority of the patients were in the C2 group of CEAP classification, followed C3 and C4- C5. One year of follow up had shown that, C0 – C1 (84% of patients in Group I and 82% of the patients in Group II), C2 (10% in both groups), C3 (4% in both the groups) and C4-C5 (2% in group I and 4% patients in Group 2) [9].

The mean VAS score were decreased in consistent manner in this study. The mean VCSS score were also decreased upon follow up. In a comparative study of RFA with stripping, post treatment VCSS assessment was performed at 12 months and showed significantly reduced scores with only 8% of the patients in the moderate group form group 1 and 16% from group 2 were in the moderate group [9].

This study had shown complete occlusion was present in more than half of the patients and almost three forth had complete occlusion after 1 month after operation. After 6 months of follow up, 78% had complete occlusion. In a randomized control study by Gale, et al., the results of laser were compared with RFA. All

veins were closed at 1 week after the procedure. The recanalization rate at 1 year was significantly higher RFA group than EVLA [11]. In a study by Toney, et al., 100% patients who had undergone RFA and 98% in stripping group had shown complete vein closure after a follow up of 1 year [9].

This study had shown that about 90% of the study subjects were satisfied with the procedure of radiofrequency ablation.

Conclusion

The study had shown the substantial improvement in occlusion, CEAP classes, VAS scores, VCSS scores and satisfaction with the procedure.

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