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Original Research Article

Efficacy and safety of radiofrequency ablation for lower limb varicose veins

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ABSTRACT

Background: Endovenous Radiofrequency Ablation (RFA) is gradually gaining widespread acceptance as a minimally invasive modality for treatment of varicose veins (VV). The objective of this study was to evaluate the efficacy based on Venous Doppler and Venous Clinical Severity Score (VCSS) and the safety of radiofrequency ablation for varicose veins.
Methods: This is a prospective study of 58 consecutive patients who underwent Radiofrequency ablation of Varicose veins from January 2015 to January 2017 in a single unit of a Multispecialty Tertiary Care Hospital. The mean age was 44.10±13.74 years (19-75 years). A total of 78 limbs were treated in 58 patients. RFA was performed using Closure FastTM catheter according to the manufacturer's recommendation. Treatment outcomes were estimated 15 days, 3 months, 6 months and 1 year after the procedure using Doppler scan and VCSS score.
Results: There was 100% occlusion of the treated veins with no evidence of partial/complete recanalization. However, 2 (2.56%) patients had a GSV stump length > 3cm on Doppler at 6 months, without evidence of significant reflux. Minor complications such as ecchymosis erythema, pain and induration rapidly improved over short term. One patient (1.3%) had evidence of Deep Vein thrombosis (DVT) on follow up Venous Doppler. The mean VCSS improved from mean of 7.98 preoperatively to 2.24 after 1 year (P value <0.001).
Conclusions: Radiofrequency ablation is a safe and effective procedure with minimal major complications. The minor complications were early and resolved rapidly.

Keywords: Radiofrequency ablation, Varicose veins, Venous clinical severity score

INTRODUCTION

Varicose veins of the lower extremities have been estimated to affect about 24% of the adult population in United States with about 6 % having advanced chronic venous disease (e.g. hyperpigmentation, healed and active ulcers).[1] However, the incidence in India is apparently low. This is possibly because of lack of awareness among the population and also as they do not seek medical advice until they develop severe edema and pain or complications like pigmentation and ulceration. Regional differences have also been reported in the prevalence of varicose veins with South India (25.08%) reporting higher prevalence than North India (6.8%).[2] Conventional Surgery involving flush ligation and stripping of GSV with or without multiple phlebectomies or removal of the varicosities has been considered "gold standard" for many decades. However, with the advent of catheter based thermal ablation delivered into the endoluminal space (either radiofrequency ablation or laser), the management has radically changed. Multiple studies followed which assessed findings including less post-operative pain, faster recovery and less adverse effects. The RF ClosureFast^{TM} catheter has resulted in a

dramatic improvement in the procedure by elimination the continuous pull back, short energy cycle and rapid treatment at a constant temperature level of 120°C.

The purpose of our study is to evaluate the clinical effectiveness and safety of Radiofrequency ablation of Varicose Veins based on Venous Doppler and VCSS score.

METHODS

This was a prospective study approved by the ethics committee and written informed consent was obtained from all patients.

All Patients between 18 to 80 years with incompetent SFJ on Duplex Ultrasound and underwent Radiofrequency ablation were included in the study. Exclusion criteria included patients having evidence or history of DVT or thrombus in the vein of interest, malignancy, pregnancy or previous surgery for varicose veins.

In this study, RFA was performed using ClosureFast™ Catheter (Medtronic, San Jose, CA, USA) which consists of a 7 cm heating element at the tip, an integrated handle and a cable connected to VNUS RGF plus generator (VNUS medical Technologies, San Jose, CA , USA). Ultrasound guided puncture was done at the appropriate location below the knee and a 7F sheath was introduced into the vein. The Catheter was introduced and positioned 2 cm below the Saphenofemoral junction under ultrasound guidance. A tumescence injection was done in saphenous compartment under ultrasound guidance using 500 ml normal saline with 20 ml of 2% lodocaine and 2.5 ml sodium bicarbonate. Sequential heating of 7 cm segment each was then performed with the temperature reaching 120°C in a 20 second cycle. The first segment was treated twice in accordance to prevalent guidelines.

The characteristics analyzed at the time of diagnosis included: demographic features, BMI, comorbidities, and presenting complaints. Postoperatively duplex scan were followed up in the Outpatients department at 15 days, 3 months and 6 months intervals. Quality of life assessment according to the venous clinical severity scale was done preoperatively and about 12 to 18 months after the procedure.

Primary end points were technical success of the procedure and complete occlusion of the ablated vein. Secondary end points assessed duration of surgery, hospital stay and complications. Duration of surgery was calculated from the time the sheath was introduced till removal of RFA catheter. Additionally, venous doppler was used to access stump length >3 cm at SFJ on follow up and reflux was considered present if reversal of flow lasted > 0.5 seconds after distal compression in standing position. Continuous data was presented as means±standard deviation. Outcome was analyzed by a paired t test to compare the VCSS score pre and postoperatively. The clinical characteristics were summarized.

RESULTS

A total of 58 patients with 78 affected limbs were enrolled in our study period. The mean age of patients were 44.22 years and mean BMI 24.65. The details of the demographic profile and preoperative CEAP classification are shown in Table 1. The average duration of surgery per limb was 30.70 min. In the initial 29 cases the average duration was 37.17 min while in the later 29 cases it was 24.23 min. 57 (98.27%) patients were discharged in 24 hrs. One patient with bilateral varicose veins had a 48 hours postoperative stay due to pain, which was however managed with oral analgesics.

Table 1: Clinical characteristics of all patients before intervention.

Variable		Values
Sex	Male	30
	Female	28
Age (years)		44.22 +/-12.95
BMI		24.65 +/- 2.64
Limb	Unilateral	38
	Bilateral	20
	Total	78
Smoking		12 (20.68%)
Hypertension / CAD		18 (31.03%)
CEAP Classification	C2	11 (18.9%)
	C3	24 (41.4%)
	C4	10 (17.2%)
	C5	2 (3.4%)
	C6	11 (18.9%)

Table 2: Complications after RFA.

Minor Complication	N (%)
Pain	6 (7.7)
Numbness	2 (2.5)
Induration	9 (11.5)
Erythema	14 (17.9)
Ecchymosis	17 (21.8)
Cord like feeling	21 (26.9)
Major complications	
Deep vein thrombosis	1 (1.3)
Thromboembolism	0 (0)

Minor complications (Table 2) that developed on short term following RFA therapy included ecchymosis in 17, erythema in 14, cord like feeling in 21, induration in 9, pain in 6 and numbness in 2 patients. However, none of the complications were permanent and resolved over 6 months to one year follow up. No incidence of thermal skin injury was observed in any patient. We observed 1 case of non-occlusive asymptomatic deep vein

thrombosis detected on routine follow up Venous Doppler. The patient was managed conservatively with no long-term sequel.

Table 3: Efficacy of radiofrequency ablation.

Venous Doppler	15 Days	3 month	6 months	Overall
Stump length >3 cm	0	0	2	2 (2.56%)
Reflux at SFJ	0	0	0	0 (0%)
Below Knee Varicosities	0	1	4	5 (6.54%)
	Pre-Operative	**Postop (12-18 months)**		**P-value**
VCSS score	7.98 +/- 4.62	2.24 +/- 1.38		0.00

All patients completed a follow up Venous Doppler at 15 days, 3 months and 6 months after surgery (Table 3). GSV stump length >3 cm was noted in 2 (2.56%) patients at 6 months, however there was no evidence of significant reflux. The occlusion rate of GSV on follow up till 6 months was 100%. Recurrent below knee varicosities were noted in 1 (1.28%) and 4 (5.12%) patients at 3 months and 6 months respectively which was managed with foam sclerotherapy. The VCSS after about 12-18 months (mean 16.18 months) improved significantly from mean of 7.98±4.62 preoperatively to 2.24±1.38 (p value <0.001).

DISCUSSION

Varicose vein is a common problem which is usually under reported in the Indian scenario and the patient presents with complications of the disease. It may result in considerable morbidity to the patient. RFA, with the advent of newer generation catheters, is rapidly emerging as a minimally invasive modality for treatment of Varicose veins.

We had a mean treatment time per limb of 30.70 min. Subramonia and Lees reported a much longer mean duration of 76.8 min while Singh et al in their study reported almost similar time as in the present study (28.8 min).[3,4]

However the difference in procedure times in different studies could be owing to difference in technique being used as well as method of calculation of procedure time. In another study by Proebstle TM et al, the average procedure time (defined as catheter insertion to catheter removal) was reported to be as low as 16.4±8.2 minutes.[5] In the present study, duration was calculated from introduction of sheath to removal of RFA catheter.

Present study showed that we could achieve 100% occlusion rate of treated GSV on follow up Doppler. Although 2 patients (2.56%) showed a GSV stump length >3 cm on follow up, showing a technical success rate of 97.43%, there was a overall significant improvement in VCSS score over 1 year follow up. A study by Jin HY et al of 117 patients with 1 year follow up showed an almost similar results with a success rate of 97.7% and a significant improvement of VCSS in the failure group also.[6] Giuseppe G et al, in a single centre study of 98 patients, had a 95.4% occlusion rate at 6 months follow up with a significant improvement in CEAP score over 6 months.[7] The recovery study showed a significant improvement in VCSS score in RFA limbs correlating to reduced postoperative pain and edema.[8]

Minor complication including cord like feeling, ecchymosis and erythema were observed in 26.9%, 21.8% and 17.9% patients respectively. Others included pain (6%), numbness (2.5%) and induration (11.5%). However, all of them resolved within 6 months. Giuseppe G et al showed a slightly higher incidence of ecchymosis which was about 39%, very low incidence each of pain (0.9%) and no paraesthesia (0%).[7] The recovery study comparing RFA and laser also had a 38.9 % incidence of ecchymosis and 2% paraesthesia in the RFA limb.[8]

The only major complication was 1.3 % incidence of DVT detected on follow up. The recovery study on 46 patients had no incidence of DVT.[8] On the other hand, Hingorani AP et al had even reported an incidence of 16% DVT in a series of 73 limbs undergoing RFA with earlier generation RFA catheters.[9] However several multicenter studies and reviews have reported a incidence rate of less than 1% of DVT on long term.[10-11] Both Giuseppe G et al in their series of 98 patients and P Marsh et al, in a large series of 2470 patients undergoing RFA reported the incidence of DVT at 0.7%.[7,12]

CONCLUSION

T Radiofrequency ablation is a reliable, safe and effective procedure with significant improvement in VCSS over 1 year. Most patients required 24 hours hospitalization and with early return to work. Early minor complications were short lived while incidence of major complications was minimal.

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