

COMPARATIVE STUDY BETWEEN CONVENTIONAL SURGERY & ENDOVENOUS RADIOFREQUENCY ABLATION IN MANAGEMENT OF PATIENTS WITH PRIMARY VARICOSE VEINS

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ABSTRACT

Background: Conventional surgery has been used for a long time for treatment of varicose veins with variable degrees of minor to major complications. Endovenous RFA of VV has emerged as a practical and effective alternative to conventional surgery.

Methods: This is a single center, non-randomized, non-blinded prospective study in which we evaluated short term results of both endovenous radiofrequency ablation & conventional surgery in management of truncal varicosities in patients with lower extremity primary venous insufficiency. The patients were divided into two groups; 50 patients in each group. The 1st group underwent conventional surgery in the form of high ligation of the saphenofemoral junction with short stripping to just below the knee. The 2nd group underwent endovenous radiofrequency ablation using the VNUS[®] radiofrequency generator and the closure fast[®] catheter (VNUS Medical Technologies, San Jose, CA) under duplex scan guidance.

Results: RFA resulted in shorter duration of hospital stay, faster return to normal activities, less post-operative pain, better improvement of VCSS and CIVIQ2 scores 6 months post-operative and less incidence of complications. Recurrence rates in both groups were not significantly different in this short term (6 months) follow up.

Conclusion: Segmental radiofrequency ablation actually provides high ablation rates in conjunction with a very moderate side effect profile. Further follow up and studies is needed to improve the efficiency and decrease the incidence of complications and recurrence of this well established technique. A spectrum that needs more studies is the use of this technique in difficult, risky or recurrent cases making use of its minimal invasive nature and wide patients' acceptance and satisfaction.

Keywords: Ablation, Endovenous, Radiofrequency, Surgery, Varicose, Veins.

Abbreviations: BMI: Body Mass Index, CIVIQ2: Chronic Venous Insufficiency Questionnaire 2, DVT: Deep Venous Thrombosis, EHIT: Endothermal Heat Induced Thrombosis, GSV: Great Saphenous Vein, RFA: Radiofrequency Ablation, UGFS: Ultrasound-Guided Foam Sclerotherapy, VAS: Visual Analogue Scale, VCSS: Venous Clinical Severity Score.

INTRODUCTION

Venous insufficiency is a widespread condition. Half of the adult population has stigmata of minor venous disease and about 25% of the population has lower extremity varicose veins. More than 25% of people with varicose veins have insufficiency of the truncal veins of the legs.^[1] In addition to causing symptoms such as swelling and leg pain, superficial venous insufficiency could lead to severe limitations in normal daily activities and a poor quality of life, because it can progress to cause complications of venous hypertension including skin ulceration, even in the absence of deep venous insufficiency. Most patients who seek surgery for cosmetic purposes or pain not controlled by compression hose are relatively young and desire rapid return to work or exercise.^[2]

Surgery has been the standard of care in the treatment of truncal varicose veins for decades.^[3] Recurrence rates after surgery are about 25% and 50% at 5 years for the GSV and SSV, respectively^[1] and 20% of all varicose vein operations are for recurrence^[4]

These principles have been increasingly challenged since the advent of new minimally invasive techniques, such as ultrasound-guided

foam sclerotherapy (UGFS), endovenous laser therapy (EVLT), and radiofrequency ablation (RFA), have been introduced in the last decade.^[3] and ^[1] Radiofrequency ablation uses high-frequency electric current, to produce irreversible occlusion with subsequent fibrosis. In UGFS, liquid sclerosing solution, which is used in classic sclerotherapy, is mixed with air to create a foam. This foam of fine bubbles is injected intravenously with ultrasound (US) guidance.^{[4] and [1]}

Methods:

This is a single center, non-randomized, non-blinded prospective study in which we evaluated short term results of both endovenous radiofrequency ablation & conventional surgery in management of truncal varicosities in patients with lower extremity primary venous insufficiency. This study was conducted in both the Zagazig university hospital as well as in private practices between June 2010 and June 2012.

The patients were divided into two groups; 50 patients in each group. The 1st group underwent conventional surgery in the form of high ligation of the saphenofemoral junction with short stripping to just below the knee in cases of GSV disease or ligation of saphenopopliteal junction in cases of SSV disease. Adjunctive procedures associated at

the time of treatment included phlebectomy of the varicose veins and triple ligations of incompetent perforators by mini incisions.

The 2nd group underwent endovenous radiofrequency ablation using the VNUS[®] radiofrequency generator and the closure fast[®] catheter (VNUS Medical Technologies, San Jose, CA) under duplex scan guidance. An adjunctive procedure associated at the time of treatment is foam sclerotherapy of incompetent perforators and superficial varicosities.

Post procedural crepe bandage then compression stockings for several weeks were systematically proposed. All procedures are ambulatory, and patients do not have any physical activity restrictions. Aspirin was given to all patients, non-steroidal anti-inflammatory drugs and analgesics were provided to the patients as needed.^[5]

Pre-operative and post-operative duplex scans were assessed by two vascular technologists using with duplex ultrasonography (GE Logic 3 and GE logic 5 Ultrasound System, GE Medical System, Milwaukee, Wisconsin, USA) Patients were matched in each group using the same inclusion & exclusion criteria. Inclusion criteria include; duplex scan confirmed primary GSV incompetence, physical condition allowing ambulation after the procedure, patient able to give informed consent, requirement for intervention agreed between patient and the surgeon, availability of patients for all follow up visits. Exclusion criteria are varicose veins without GSV or SSV incompetence on duplex scan, recurrent varicose veins, associated deep venous incompetence on duplex scan, presence of an aneurysmal vein segment or tortuous GSV above the knee felt to be unsuitable for catheterization, GSV diameter <3 mm or >13mm in the supine position, thrombus in the GSV, patients with a pacemaker or internal defibrillator, patients on anticoagulants, concomitant peripheral arterial disease (ankle-brachial pressure index of <0.9) , patient has a serious systemic disease, pregnancy, BMI more than 30.

PRE OPERATIVE

Before the procedure each patient was evaluated by taking full history, clinical examination of the limb, the CEAP classification and the VCSS were assigned by a surgeon skilled in the management of venous disease.

The VCSS is composed of 10 parameters (pain, varicose veins, edema, pigmentation, inflammation, induration, number of ulcers, duration of ulcers, size of ulcers, compressive therapy) that escalate in severity with increased area of the limb involved and are graded 0 to 3 (absent, mild, moderate, severe). In order to

generate a dynamic score, VCSS categories are scored individually, which adds emphasis to the most severe sequelae of venous disease that are likely to show the greatest response to therapy.^[6] The VCSS has been evaluated in clinical practice and validated as an important instrument for longitudinal research to assess outcomes after treatment with low variability. [7] The VCSS has been demonstrated to increase with higher CEAP clinical class in a strong linear relationship.^[8]

Duplex ultrasonography was undertaken in all patients preoperatively to assess the extent of venous disease. Reflux was assessed by response to a Valsalva maneuver in a reverse Trendelenburg position or with manual limb compression and release; with the patient in a standing position. The mean vein diameter was recorded in both groups

In addition, each patient completed the 20-question Chronic Venous Insufficiency Questionnaire (CIVIQ2) quality of life questionnaire that has been validated for use in patients with chronic venous disease after being translated to Arabic.

The CIVIQ comprises 20 questions in four quality-of-life domains: physical (items 5, 6, 7 and 9), psychological (items 12–20), social (items 8, 10 and 11), and pain (items 1–4).^[9] All questions have a 5-point response category, with higher scores reflecting more severe impairment. Three separate scores can be calculated: a score per item (1–5), a score of each of the four dimensions (0–100) and a global score (value 0–100). Higher scores represent lower HRQOL due to CVI or varicose veins.^[10]

In the analysis, each of the dimension scores, and the global scores, were transformed into a scale of 0–100. Zero represents the least possible impact on daily activities and well-being, i.e. highest quality of life, while 100 represent a maximum negative impact. CIVIQ-20 was highly sensitive to changes in the quality-of-life of patients clinically improved after drug treatment.^[11] Both versions of the CIVIQ have been used in studies^[11, 12] and proven to be valid quality-of-life measurements.

The CIVIQ is a valid and reliable questionnaire; its clinical validity was excellent. The reproducibility was found to be excellent in all dimensions and the responsiveness to change over time was also found to be excellent, specifically toward pain relief.^[11]

We made a modification in the translation of item 10 in the CIVIQ2 to Arabic to be more accurate and applicable to the social and cultural characters of our community.

Before surgery, accurate mapping (cartography) should be done using the duplex-scanning method from the groin to the ankle to highlight

C5 5.4%. In the 2nd group the distribution was C2 22.5%, C3 17.9%, C4 17.9% and C5 0%. The mean vein diameter was 8.5±2.6 mm in the 1st group and 7.9±1.6 mm in the 2nd group.

Operative Data of Patients:

Spinal anesthesia was used in 100% of all cases in the 1st group, while in the 2nd group only 34% of the cases took spinal anesthesia and 66 % took tumescent anesthesia. The average treated length in the 1st group 41.7±10.5 cm and the average treated length in the 2nd group 41.5±10.3 cm

Post-operative findings are concluded in the following tables:

	Group 1	Group 2	t	P
Length of hospital stay (hour)	17.2±7.2	6.4±2.5	9.8	<0.001
Return to activities (d)	8.8±3.4	4.8±1.8	7.2	<0.001
VAS	5.9±2.2	4.2±1.7	4.6	<0.001
VCSS	6.63±3.5	6.6±3.4	0.04	NS
6 mVCSS	3.5±2.1	2.5±1.9	2.5	<0.05
CIVIQ2	50.2±21.9	45±20.2	1.3	NS
6 m CIVIQ2	37.3±16	19.4±9.8	7.2	<0.001

Post-operative Complications:

The overall number of complications encountered in the 1st group was 41(72%) occurred in 57 limbs: (55GSV and 2SSV), while the overall number of complications encountered in the 2nd group was 24 (39 %) occurred in 62 Limbs: (61GSV and 1 SSV), in some patients more than one complication occurred.

Complications	G1%	G2%
Perforation of SFJ	0	1.6
Groin hematoma	3.5	0
Bruises	14	4.9
Wound infection	5.3	1.6
Wound dehiscence	7	0
Erythema	0	9.7
2nd D Skin burn	0	1.6
DVT	0	1.6
Phlebitis	0	6.5
Nerve injury	8.8	1.6

Hypertrophied scars	12.3	0.00
Hyperpigmentation	10.5	4.9
Recurrence	8.8	4.9

Short-term technical success is defined as the successful occlusion of the vein lumen. Immediate vein occlusion with lack of spontaneous and augmented flow demonstrated by duplex ultrasound and vein wall thickening was achieved in 100% of the treated veins in our series. No cases of failure of closure were identified at the time of the procedure by the completion of a duplex ultrasound scan.

In the 1st(surgery)group there were 3.5% cases of groin hematomas which resolved spontaneously, there were 14% cases presented with bruises,5.3 % cases with infection at the site of perforator ligation , 7% cases of wound break, 10.5 % cases of skin hyper-pigmentation (5.3% cases persisted), 12.3% cases of hypertrophied scarring and 8.8% cases of paraesthesia; 4 along the supply of the saphenous nerve and 1 along the course of the sural nerve, 3 cases improved and 2 cases persisted beyond 6 months

In the 2nd group there was one case (1.6%) of a perforationof the GSV 1 cm from the SFJ Immediate exploration of the SFJ was done and ligation of the junction & the GSV and after closure of the wound RFA was completed as usual.

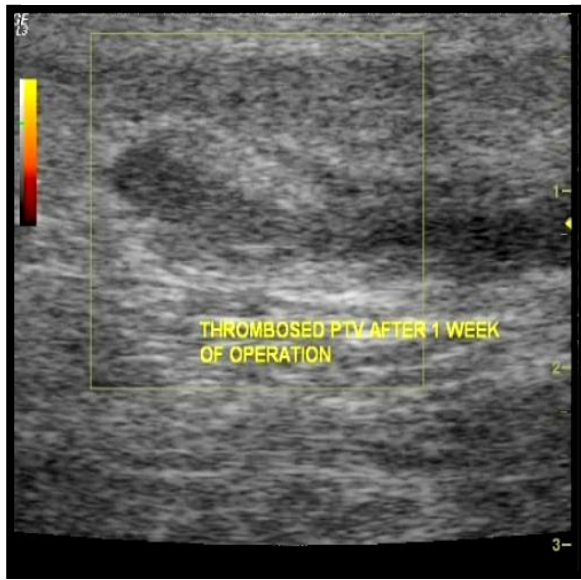
In the 2nd (RFA) groupthere were 4.9% cases of bruises (without distinction between those due to treatment itself or due to tumescent injection or foam sclerotherapy),1.6%infection at the site of cannulation of the vein. Skin burn occurred in the form of mild erythema in 9.7% of the cases and in 1.6% 2nd degree burn which might be due to insufficient tumescent anesthesia and very superficial veins. All cases improved with conservative management. As regard Phlebitis which occurred at the site of the treated GSV and related varicosities, it was encountered in 6.5% of cases which showed mild phlebitis along the course of the GSV and related varicosities discovered 48 hours after the procedure and resolved spontaneously.

In the 2nd group there was no incidence of Endothermal Heat Induced Thrombosis EHIT which is a thrombus protruding into the Common femoral vein, and we usually approximate the tip of the catheter just proximal to the level of the superficial epigastric v. with no incidence of EHIT. There was one case (1.6%) of **Deep vein thrombosis** (DVT) in the post tibial vein which improved with full anticoagulation but we were

uncertain that it was due to RFA or associated use of Foam inj. sclerotherapy for perforating veins.

In the 2nd group; no cases of lignocaine toxicity occurred. Close observation of the patients was done, talking to the patient throughout the procedure to notice any suspicious symptoms of toxicity arising. There was no incidence of pulmonary embolism nor femoral vein injuries in our study.

Figure: DUS showing thrombosed Posterior tibial vein (PTV)



In the 2nd group there was skin hyperpigmentation in 4.9% (3.2% improved over 3-4 months and 1 limb 1.6% persisted). Nerve damage (paraesthesia) occurred in 4.9% along the supply of the saphenous nerve due to ablation of the lower part of GSV, RFA of the distal GSV should be abandoned, all except 1 case of them improved and after 6 months there were no residual paraesthesia.

RECURRENCE

Efficacy of vein obliteration was categorized as follows: Totally occluded (TO) veins were defined as those with no evidence of flow. Partially occluded (PO) veins were defined as less than or equal to 3 cm segment of flow within the SFJ or an otherwise occluded vein trunk. Inefficiently occluded (IO) veins were defined as greater than 3 cm of flow in any treated vein segment.

1st Group: At 6 months postoperative DUS follow-up the totally occluded (TO) till the SFJ was 52 limbs (91%). DUS follow-up of the other 5 cases showed that 2 cases (3.5%) showed veins related to missed anterior accessory saphenous in one case and in one case (1.8%) an incompetent thigh perforator connected to a superficial vein connected to the SFJ. The other 2 cases (3.5%) Neovascularization was found.

2nd Group: At 6 months postoperative DUS follow-up the totally occluded (TO) till the SFJ was 59

cases (95%). DUS follow-up of the other 3 cases showed that 3 cases (4-9%) showed partially occluded (PO) veins related to missed anterior accessory saphenous in one case, an incompetent thigh perforator was defined in one case and the last case had inefficiently occluded (IO) vein related to recanalization of the vein.

DISCUSSION

Four RCTs and three observational studies compared radiofrequency endoluminal ablation with surgery in patients with symptomatic varicose veins. [17], [18, 19], [20], [21], [22], [23], [24] and [25].

These studies had short-term follow-up, with the longest study extending to 3 years. Endovascular obliteration of the GSV compared with conventional vein stripping was associated with faster return to work (1.15 vs 3.89 days; $P = .02$), shorter time to return to normal activity (7 vs 14 days; $P < .05$), 51 lower pain scores, better short-term quality of life scores, and higher patient satisfaction. A meta-analysis of these studies shows no significant difference between the two procedures on varicosity recurrence. [26]

Most of these studies used the ClosurePLUS (VNUS Medical Technologies Inc.) catheter which had main disadvantages of slowness, variability and at times, the need to remove the catheter during treatment to clean the clot, which formed at the electrode level. In 2006, the ClosureFAST (VNUS Medical Technologies Inc.) catheter was introduced. This new catheter allowed for segmental ablation as opposed to continuous pull-back. This catheter treats a 7-cm vein segment in one 20-second energy cycle. The vein wall is heated conductively by a 7-cm coil at the distal end of the catheter. The treatment temperature is 120°C. [27]

Anesthesia: Patients accepted the concept of tumescent anesthesia due to the minimally invasive nature of radiofrequency ablation procedure. In the 2nd (RFA) group 66% of patients underwent the procedure using the tumescent technique aided by conscious sedation when needed. This aided with early ambulation of the patient post-operative and decreased the duration of post-operative hospitalization.

In one study, while the tumescent liquid was injected, a temperature decrease was commonly observed at the thermocouple level, about 6 cm from the catheter tip, which ensured the correct working of the thermocouple and an accurate position of the catheter in the GSV. [5]

The routine use of tumescent anaesthesia in a clinic room setting has now become established as a safe and expedient way to treat varicose veins. [28]

VAS: A visual analogue scale (VAS) is often used to assess the intensity of postoperative pain and it

is the most sensitive scale for measuring treatment characteristics. The respondents are asked to assess their pain intensity between the end-points of no pain to worst possible pain on the scale.^{[14]And [15]}

In our study the score of the VAS was significantly less in the 2nd Group (RFA) than the 1st group (surgery) as well as the need to take analgesics was less in the 2nd Group (RFA) than the 1st group (surgery) with the most distinct difference between the 3rd to the 14th post-operative day.

Proesbtle and colleagues reported that the average pain score was 0.7 ± 1.6 during the first 3 days. For patients who experienced limb pain at any time during the follow-up period, the maximum pain score was 2.8 ± 1.6 .^[29]

Creton and colleagues reported on the third day, using a visual analog scale of 0-10, the patients evaluated the mean pain intensity at 0.7 ± 1.6 . The maximum postprocedural pain was 2.8 ± 1.6 . During the follow-up, 70.1% of the treated limbs were no longer painful after the procedure.^[5]

Rautio and colleagues reported significantly less postoperative pain, quantitated with a visual analog scale, in the RFA group than in the stripping group at rest, on standing, and on walking, with the most distinct differences between the 5th to the 14th post-operative days. The analgesics needed in the RFA patients were statistically less for the stripping group.^[25]

Length of hospital stay (hr) and Return to normal activities (d): The 2nd group (RFA) the mean time was 6.4 ± 2.5 hr showing significant decrease of hospital stay.

In our study we found that the decreased hospital stay in the 2nd group was mainly due to the use of tumescent anesthesia, the early ambulation of the patients, less post-operative pain, the minimal need for analgesics.

In the 1st group (surgery) the mean was 8.8 ± 3.4 while the 2nd group (RFA) the mean time was 4.8 ± 1.8 showing significant decrease in the time to return to normal activities.

In our study we found that the decrease in the time to return to normal activities in of the 2nd group was due to the early ambulation of the patients, less post-operative pain, the minimal need for analgesics, the satisfaction of patients due to absence of surgical wounds.

Creton and colleagues reported that return to normal daily activities took an average of 1.22 days (range 0-3.2). Symptoms and clinical signs of improvement could be observed from the third day onward.^[5]

Proesbtle and colleagues reported return to normal daily activities took place on the same day

in more than half of patients, with an average \pm SD of 1.0 ± 1.9 days.^[29]

Rautio et al., confirmed that sick leaves were also significantly shorter in the RFA group, and physical function was restored faster in the RFA patients.^[25]

VCSS: The strength of the VCSS lies in its ability to identify subtle intra-subject changes after intervention over time. [30] The components of the VCSS provide outcome analysis on many levels, including technical, patient reported, and clinical. In this sense, the VCSS is unique among clinical outcome assessments and quality-of-life instruments.^[31]

In the 1st group (surgery) the VCSS was pre-operative 6.63 ± 3.5 and 3.5 ± 2.1 6 months post-operative while the 2nd group (RFA) the VCSS was pre-operative 6.6 ± 3.4 and 2.5 ± 1.9 6 months post-operative showing significant improvement in both groups but in comparing between both groups 6 months post-operative; there is better improvement in the 2nd (RFA). **Vasquez** et al examined the results of RFA on venous clinical severity score and CEAP classification in 682 limbs treated with RFA. Overall mean baseline venous clinical severity scores were 8.8 at baseline and 3.6 at last follow-up visit.^[30]

Proesbtle and colleagues reported the average VCSS score was 1.5 ± 1.8 at 6 months compared with 3.9 ± 2.0 preoperatively.^[29] Kapoor and colleagues reported post treatment VCSS showed significant reduced scores at 3 months.^[32]

Proesbtle and colleagues reported after 36 months follow up the average reduction in VCSS scores from screening and at 1 week to 3, 6, 12, 24, and 36 months were statistically significant at the .05 level.^[16]

Patient satisfaction and health related quality of life: Outcome measurement in treatment of venous disorders cannot only rely on DUS evaluation of ablated saphenous veins, even though it is a necessary condition for the improvement of the patient's clinical condition.

The CIVIQ is a valid and reliable questionnaire; its clinical validity was excellent. The reproducibility was found to be excellent in all dimensions and the responsiveness to change over time was also found to be excellent, specifically toward pain relief.^[11]

In both groups the CIVIQ2 questionnaire showed improvement 6 months postoperative but in comparing the 2 groups at the 6 months post-operative interval the improvement was more significant in the 2nd group. In our opinion this is due to the minimally invasive nature of the RFA and foam sclerotherapy, decreased incidence of nerve injury and better cosmesis in the 2nd group

due to absence of scars and wound dehiscence and decreased incidence of hematomas and pigmentation. This reflected positively on the morale and activity of the patients in this group improving health related quality of life.

A study showed that up to one third of the patients may remain dissatisfied in the long term after surgery.^[33]

Creton and colleagues and **Proebstle** and colleagues reported that 99% of the patients said they would recommend this procedure to friends or relatives.^[5, 29]

COMPLICATIONS

Perforation of the vein: Perforation of the vein by the catheter tip is a very rare complication most probably due to marked tortuosity of the GSV. Forcible manipulation of the catheter should be avoided and can be prevented by gentle manipulation of the catheter duplex guided. No studies showed any criteria for evaluation of the degree of tortuosity of varicose veins and if this is a patient criteria increasing possibility of perforation. If there is sever tortuosity multiple level cannulations of the GSV or in sometimes conversion to conventional surgery may be wise.

Failure of closure: Failure of closure should be identified at the time of the procedure by the completion of a duplex ultrasound scan and another cycle may be repeated in this segment. Immediate technical success rates of more than 95% with RFA have been reported.^[13, 21, 34] A multicentre trial using the ClosureFAST catheter has achieved an occlusion rate of 99.6% at six months.^[29]

Immediate vein occlusion with lack of spontaneous and augmented flow demonstrated by duplex ultrasound and vein wall thickening was achieved in 100% of the treated veins in our series. No cases of failure of closure were identified at the time of the procedure by the completion of a duplex ultrasound scan.

Hematomas and Bruises: In our study no significant hematomas; defined as a three-dimensional ultrasound-detectable interstitial clot, occurred in the 2nd (RFA) group in the contrary to the 1st (surgery) group. **Creton** and colleagues reported hematomas in 1.4% of cases along the course of the saphenous trunk.^[5] **Proebstle** and colleagues reported hematomas in 1.6% of the cases.^[29]

4.9% cases of bruises occurred in the 2nd group without distinction between those due to treatment itself or due to tumescent injection or foam sclerotherapy.

Similarly, bruises (ecchymoses) were observed in 5.8% of the limbs by **Creton** and colleagues^[5] **Proebstle** and colleagues reported hematomas in 6.4% of the

cases.^[29] **kapoor** and colleagues reported 7% as well^[32]

Phlebitis: As regard to phlebitis; in our study it was encountered in 6.5%; which are similar to other studies. **Nesbitt** and colleagues reported a meta-analysis with an early phlebitis rate of 8% with RFA (by combining the results of three large trials)^[35] other recent studies have reported rates of 7–9.6%.^[36, 37] **Creton** and colleagues reported the incidence of superficial venous thrombosis was only 1%.^[5]

Deep vein thrombosis (DVT) and Endothermal Heat Induced Thrombosis (EHIT): In the 2nd (RFA) group there was no incidence of Endothermal Heat Induced Thrombosis EHIT. There was one case (1.6%) of **Deep vein thrombosis (DVT)** in the post tibial vein which improved with full anticoagulation but we were uncertain that it was due to RFA or associated use of Foam inj. sclerotherapy for perforating veins.

In the 2nd (RFA) group we advanced the tip of the catheter to the level of the superficial epigastric vein to a distance of 1.1±0.2 cm from the saphenofemoral valve with no cases of EHIT and one case of DVT in the post tibial vein.

Creton and colleagues reported no thromboembolic complications.^[5] Similar results were reported by **Kapoor** and colleagues and **Markovic** and **Shortell**.^[32, 38]

We agree with **kapoor** and colleagues that the cause being significantly reduced procedure time, less duration of catheter insertion and improved collagen shrinkage of vessel wall. (**Kapoor** et al., 2010)

We also agree with **Haqqani** and colleagues that the catheter must be advanced under direct DUS visualization to the saphenofemoral region. Blind positioning of the catheter must be avoided, as well as the advancement of the catheter into the femoral vein before it was positioned in the proximal GSV, as all these factors play an important role in preventing EHIT and DVT.^[39]

Factors which may increase the risk of EHIT/DVT include; patient age, undiagnosed hypercoagulable states and severity of chronic venous disease. Concomitant SSV or transluminal occlusions of perforator with RFA have been considered risk factors for high calf DVT.^[40]

We did not use Pharmacological prophylaxis for all patients undergoing treatment as it is probably unnecessary in many patients. In **March** and colleagues series all patients whom complicated with DVT or EHIT received a single prophylactic dose of LMW heparin. Failure of this strategy for prophylaxis has been reported previously, especially in patients with a history of VTE.^[41]

This suggests that a greater duration of prophylaxis may be appropriate only in selected cases like patients with a history of thromboembolism; on the opposite side pre-operative anticoagulation might interfere with thrombotic vessel occlusion.^[40]

We routinely used crepe bandage and aspirin 150mg daily for two weeks although we did not evaluate the effect of aspirin in our study; A low DVT rate in a large series (0.1%) was attributed to post-operative treatment with non-steroidal anti-inflammatory drugs for their anti-platelet activity and analgesic effect.^[42]

Although there was no evidence to support this; we also encouraged women on estrogen containing oral contraceptives or on hormone replacement therapy to stop it and shift to another method but this may lead to unwanted pregnancy.

Skin burns & pigmentation:The key to avoid and decrease incidence of skin burns & pigmentation is the very generous use of tumescent fluid under DUS guidance and making sure that at least 1 cm of fluid is surrounding the treated vein all around. Also it is wise to manage *very* superficial veins by other modalities rather than RFA.

The incidence of skin burns has reduced since the advent of tumescent anesthesia from 1.8% to 0.5%.^[43]

In the 2nd group there was skin hyper pigmentation in 4 cases (8%); 3(6 %) improved over 3-4 months and 1 limb (2%) persisted. Pigmentations were observed in 3.1% of the cases in **Creton** and colleagues study.^[5]

Proesbtle and colleagues reported skin pigmentation in the course of phlebitis or ecchymosis developed in 2%^[29] which decreased to 0.4% at 36 months.^[16]

Paraesthesia:Paraesthesia or numbness may arise following RFA but in most cases improves over the course of a few weeks.^[43] In the 2nd group nerve damage (paraesthesia) occurred in 4 limbs (8%) along the supply of the saphenous nerve due to ablation of the lower part of GSV, RFA of the distal GSV should be abandoned, all of them improved and after 6 months there were no residual paraesthesia.

The median rate of paraesthesia has been reported as high as 13%^[44] with other studies reporting it as 4.8–12%.^[27, 40] **Creton** and colleagues reported incidence as low as 3.4% of the cases.^[5] **Proesbtle** and colleagues reported paraesthesia in (3.2) of the cases^[29] which decreased to 0.4% at 36 months.^[16]

In a review of case series of patients who underwent RFA, Also here the very generous use of tumescent fluid under DUS guidance leads to

significant reduction in the incidence of paraesthesia; from 14.5% to 9.1%.^[45]

For treatment of the short saphenous vein, mid-calf cannulation may avoid thermal damage to the sural nerve. The ideal site for GSV cannulation is just below the knee to avoid thermal damage to the saphenous nerve.^[46]

Recurrence:Recurrence remains a significant problem after either endovenous or open surgical ablation. After L/S, neovascularization in the subcutaneous tissue around the saphenofemoral junction can lead to recurrence.^[47] The process of neovascularization may be associated with a groin incision. The presence of incompetent tributaries after L/S is another possible cause of recurrence. Clinical problems are caused by a connection between a remaining segment of GSV and new vessels or incompetent tributaries.^[48]

We agree with **Bush** and colleagues that the three most important factors associated with varicose vein recurrence included new or recurrent perforating veins; recanalized GSV and new anterior accessory great saphenous vein (AAGSV) reflux, in decreasing frequency.^[49] Technical problems such as difficult access, problems in advancing the catheter or a tortuous GSV may also lead to recurrence.

Kianifard and colleagues did not observe neovascularization in those patients who had undergone RFA versus 11% in those who underwent stripping.^[19] Other authors also report that inguinal neovascularization is almost absent after endovenous procedure.^[50] RFA maintains permeable epigastric vein, which at first could constitute a cause of recurrence in accordance to conventional surgery. However, it seems that it could protect against neovascularization by preserving physiological drainage of the abdominal wall.^[19]

Lohr and Kulwicki stated that neovascularization, though less frequent with RFA than surgery, is also considered a cause and has been seen in 2.8–7% of cases.^[51] **kapoor** and colleagues reported 1% neovascularization at one year follow up.^[32]

Another cause of recurrence prevention in RFA is the absence of revascularization of the saphenectomy tract that happens between 6% and 17% of stripping after one year.^[52]

kapoor and colleagues reported that in 3 % there was some flow seen across SFJ for a distance of 1-2 cm with no reflux and in 1 % a denovo reflux was seen in the anterolateral vein which opened separately into the common femoral vein.^[32]

Another potential factor affecting recurrence is the pre-operative venous function and extent of venous reflux (superficial versus

superficial/deep/perforator reflux). **Van Rij** et al demonstrated that a preoperative venous filling index of greater than 2 s was present in 58% of patients with late recurrences. Reflux of perforators and deep venous reflux were present in 83% of limbs with recurrent disease. Furthermore, **Bhatti** et al reported that patients with deep venous incompetence have an increased incidence of recurrence.^[53, 54]

Overall, it appears that recurrence after either ligation or stripping (L/S) or endovenous thermal ablation ETA is a complex phenomenon. Neither technique completely addresses all potential causes. Xenos and colleagues analysis indicates that catheter-based treatments and traditional venous stripping with high ligation have similar long-term results. Further studies with long-term follow-up and thorough preoperative evaluation of venous function, as well as clinical classification of the severity of the disease, are needed to determine whether either approach is superior or whether the choice of saphenous.^[55]

Establishing preoperative criteria for each method may improve outcomes but, presently, neither technique appears to confer an advantage in terms of mid- to long-term freedom from recurrent symptoms.^[55]

This study has some limitations. It only includes early clinical experiences from a limited number of patients and only has short-term data available. Some interesting conclusions, however, should be possible from long-term follow-up, which is currently in progress. With a wider adoption of this procedure, a variety of procedural techniques and settings could potentially affect the consistent results seen in this study.

In a review presented by **McBride** in 2010 confirmed that endovenous therapies are at least as safe and effective as standard surgery, but in most of the comparative data presented both EVLA and RFA are consistently better regarding minor and major complications, post-procedure pain and bruising and time to return to work and normal activities.^[56]

In 2012 a recent Systematic Review and Meta-analysis of Randomized Controlled Trials (RCTs) comparing Endovenous Ablation and Surgical Intervention in Patients with varicose veins up to august 2011 was presented, it included 28 RCTs.

Primary failure and recurrence rates with EVLA and RFA were not different compared with surgery, but had a lower rate of complications such as wound infection and hematomas, less pain and shorter return to work. Within the endovenous techniques, RFA seems to be slightly better tolerated than EVLA except that it shows a

significantly higher rate of superficial thrombophlebitis.^[57]

More RCTs with long follow up are needed to establish the long term results of RFA using the ClosureFast™ catheter; the longest trial up till now is 3 years follow up reported by **Proebstle** and colleagues. They reported that the high ablation rates obtained initially could not only be maintained but could also transfer into durable clinical benefits in VCSS and clinical CEAP stage. In only 4.3% of treated GSVs was new reflux detected by DUS imaging, and only 2.0% of treated legs revealed new axial reflux with 86.4% of treated legs examined at the 3-year follow-up.^[16]

CONCLUSION

Conventional surgery has been used for a long time for treatment of varicose veins with variable degrees of minor to major complications. Endovenous RFA of VV has been established as a practical and effective alternative to conventional surgery.

Segmental radiofrequency ablation actually provides high ablation rates in conjunction with a very moderate side effect profile. The advantages of RFA are far greater than its associated risks. There are certain points, which need to be carefully addressed during the RFA technique which was taken into consideration during gaining more experience with more number of cases which allowed to clarify our message from the study to achieve better results and avoid complications.

This technique was extremely easy to apply, very reliable both in terms of patient's satisfaction and the clinical results. The only maneuvers that require a certain degree of training is ultrasound observation, accurate intravenous UGFS and tumescence infiltration in the GSV space within the fascia.

The ClosureFAST™ catheter completely eliminates the pullback, unlike other and older devices. The catheter has a segmental distribution of heat 7 cm in length, and the average energy delivery time for a 40-cm long GSV is around 2 min. This also has a significant influence on the number of patients that can be treated in an allocated time schedule.

Of most importance is an adequate Duplex scan to identify accessory channels and double superficial systems. Reconfirming the catheter tip position after leg elevation is a must. Blind positioning of the catheter must be avoided, as is the advancement of the catheter into the femoral vein to prevent unnecessary intimal damage.

Tumescent anesthesia should be instilled below the saphenous fascia and above the deep muscular fascia surrounding the vein using ultrasound guidance. The purpose of tumescence is threefold;

analgesia, protecting skin by displacing the vein away from it and neighboring structures against heat (heat sink effect) to displace heat radiating up to 1.5 mm beyond the vein wall, favoring the contact made between the electrode and a dry "saphenous vein" with inflow tributaries eliminated by compression is also created. The GSV should be compressed to separate it from the inflow tributaries, to maintain an adequate probe temperature in contact with the vein wall. The avoidance of propagation of steam bubbles (or thrombus) by compression is of extreme importance.

It is now established that endovenous therapies are at least as safe and effective as standard surgery, but in most of the comparative data presented RFA is consistently better regarding minor and major complications, post-procedure pain and bruising and time to return to work and normal activities. Further follow up studies are needed to improve the efficiency and decrease the incidence of complications of this well established technique. A spectrum that needs more studies is the use of this technique in difficult, risky or recurrent cases making use of its minimal invasive nature and wide patients' acceptance and satisfaction.

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