Conventional surgery versus endovenous radiofrequency ablation in management of patients with primary varicose veins

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Abstract

Conventional surgery has been used for a long time for treatment of varicose veins with variable degrees of minor to major complications. Endovenous RA of VV has been established as a practical and effective alternative to conventional surgery. Segmental radiofrequency ablation 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. 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 intimad 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, followed by a short stripping to the knee, ligation of the saphenopopliteal junction (SPJ) only [3].

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].

Chronic venous insufficiency has a great impact on patients’ health-related quality of life (HRQOL), which is comparable to other common diseases, and is associated with considerable health care costs. The treatment of varicose veins reduces the symptoms and complications of chronic venous insufficiency and improves HRQOL of patients [1].

Surgery has been the standard of care in the treatment of truncal varicose veins for decades. The current principles of surgical treatment of varicose veins were established at the beginning of the 20th century by Perthes, Keller, Mayo, Bacbock and others. The great saphenous vein (GSV) is historically treated by high ligation at the saphenofemoral junction (SFJ) followed by a short stripping to the knee, ligation and division of the saphenous trunk and all proximal tributaries are followed either by stripping of the vein or by avulsion phlebectomy. Proximal ligation requires a substantial incision at the groin crease. Stripping of the vein requires additional incisions at the knee or below and is associated with a high incidence of minor surgical complications. Avulsion phlebectomy requires multiple 2- to 3-mm incisions along the course of the vein and can cause damage to adjacent nerves and lymphatic vessels. Most commonly, the small saphenous vein (SSV) is ligated at the saphenopopliteal junction (SPJ) only [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].

A study with a mean follow-up of 34 years showed recurrence in 60% of 125 limbs after SFJ ligation and GSV stripping. Failure after surgery may be due to neovascularization, double saphenous vein system, technical and tactical failure (up to 30%), and/or incomplete procedure [1].

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Other disadvantages of surgical therapy are the use of general or epidural anesthesia, presence of at least two long scars, postoperative down-time, and risk of adverse events such as femoral artery and/or vein damage, wound infection, neurologic injury (about 7% in short to 40% in long stripping of GSV) and lymphatic complications [1].

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 [1,3].

The development of these minimally invasive procedures for the treatment of varicose veins has been led by a desire to improve efficacy, patients’ health-related quality of life HRQOL, and treatment satisfaction and to reduce serious side effects, costs, and postoperative pain and trauma and bruising associated with standard surgical techniques [1,5].

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. The resultant functional obliteration of the saphenous vein is less invasive than open surgery and can be performed under local anesthetic as a day case, requiring no hospital stay. This therefore avoids the complications of open surgery with comparable [1,4].

This study is designed to evaluate the effectiveness of endovenous Radiofrequency ablation of primary varicose veins in comparison with conventional surgery regarding: pain and bruising, complications, recurrence, quality of life, and returning to normal activity.

Patients and 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 in cases of GSV disease or ligation of saphenopopliteal junction with stripping of the short saphenous vein. Adjunctive procedures associated at the time of treatment included phlebeectomy 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 [Figure 1].

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 summarized in [Table 1].

Preoperative preparation

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) [6].

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) [7].

Before surgery, accurate mapping (cartography) should be done using the duplex-scanning method from the groin to the ankle to...
highlight tortuous veins stretches, ectasia areas, and incompetent, perforator, and varicose veins.

**Intraoperative procedures**

In the both groups the time of the procedure as well as the steps and any adjunct technique was recorded. A record was made of length of vein treated in both groups and any intra operative complications.

**The first group**

All patients in this group preferred spinal anesthesia.

**Surgery on the Great Saphenous Vein and the saphenofemoral junction**

DUS was used to preoperatively mark the saphenofemoral to allows precise placement of the skin incision and permitting very small incisions with limited subcutaneous dissection [8].

The GSV is approached through an oblique incision 1 cm above and parallel to the groin crease starting over the palpable femoral artery and extending medially to ensure appropriate visualization of the saphenofemoral junction and its tributaries. As the subcutaneous tissue is split, the main trunk of the GSV is identified. The plane over the saphenous vein is extended toward the saphenofemoral junction. Each of the six main tributaries is divided and ligated [9].

High ligation of the GSV is performed close to the femoral vein. Double ligation is generally performed on a proximal stump with the second ligation being a suture ligature. Care should be taken to avoid narrowing the femoral vein in the process and avoid leaving a long stump with a risk for thrombus formation and potential embolism [10].

GSV stripping is the central component of the classic operation for varicose veins. Unless the caudal below-knee saphenous vein is obviously incompetent and varicose, there is no need to remove it. This targeted approach to stripping leaves normal distal veins for potential future grafting, avoids injury to the saphenous nerve, and results in less postoperative pain and bruising without compromising the goals of surgery. If present, incompetent accessary saphenous veins should be ligated and stripped during the initial surgery [8].

After flush ligation is performed, a transverse venotomy is created and a stripper is passed distally. In most cases the presence of reflux allows easy passage of the stripper to the level of the knee. A second small incision is made over the palpable stripper near the knee. The caudal incision is made transversely, and the subcutaneous tissues dissected to allow recovery of the saphenous vein. This top-down passage of the stripper not only facilitates identification of the saphenous vein at the knee and allows a small lower incision to be made but also avoids the potential for the stripper passed from below to enter the femoral vein through a thigh perforator and cause the femoral vein to be mistaken for the saphenous vein. The GSV should be stripped in a downward direction, which results in improved avulsion of tributaries and diminished injuries to the saphenous nerve [11].

To avulse the vein with the endoluminal stripper; it is fixed by attaching the classic stripper head to the top of it after placing a silk ligature around the vein and the stripper just below the head to the most cephalic portion of the vein. Stripping should be performed as the last step of the procedure if concurrent tributary varices or perforator disease is to be addressed at the same setting. In this way the leg can be immediately wrapped in a compressive dressing and elevated after the vein stripping is performed. If the vein is to be removed from the knee incision, the groin incision can be closed with the stripper head in place and only the distal incision at the knee left to close after stripping [12].

Elevation of the leg reduces the venous bleeding and ecchymosis associated with stripping. The leg should be elevated before the actual stripping procedure is performed. Postoperatively, the patient should ambulate as soon as possible [8].

**Surgery on the Small Saphenous Vein and Veins of the Popliteal Fossa**

Patients are positioned prone with care taken to pad bony areas. To provide laxity of the neurovascular structures in the popliteal fossa, the affected limb is slightly flexed at the knee with a rolled towel placed under the ankle. Preoperative marking guided by DUS allows a small skin incision to be made just distal to the previously marked saphenopopliteal junction. The fascia is opened along the line of the skin incision and the SSV identified. The SSV is traced distally to its position between the fascia and calf muscles. The SSV is then divided between two right-angle clamps. Care is taken to dissect in the perivenous plane, and any nerve structure-usually sural-is carefully dissected from the SSV. Gentle retraction is used to avoid injury to the tibial nerve and to visualize the saphenopopliteal junction [8].

If DUS identifies reflux in the gastrocnemius or popliteal area veins, the exposure is extended, and the target veins ligated. The stump of the SSV is ligated with a 3-0 monofilament transection suture. If present, the common trunk of the SSV with either the gastrocnemius or intersaphenous veins is ligated proximally just above the popliteal vein, and the two veins in turn are also ligated. The SSV is ligated distally with 3-0 monofilament suture. The popliteal wound is then irrigated and closed in layers with attention paid to approximating the fascia to avoid unsightly hernias. The short skin incision is approximated with running 5-0 subcuticular suture [8].

**Ligation of incompetent perforators and excision of local Varicosities (Ambulatory Phlebectomy)**

If the remaining superficial varicosities are left uninterrupted, they will drain via alternative pathways and may remain both symptomatic and cosmetically displeasing to patients [13].

Because it is time-consuming procedure; preoperative marking is very important in ambulatory phlebectomy. These target veins are often difficult to see when the patient is reclining. Robert Mueller is credited with popularizing and refining the technique of stab avulsion [13].

The skin incision is most commonly made with a No. 11 blade. The incisions are typically oriented longitudinally except in the groin, knee, and ankle, where a transverse orientation aligns with the lines of Langer.

Using fine-pointed clamps the small dermal varicosities are hooked and avulsed. Larger veins are grasped and brought up through the incision.

The vein loop is cleared of fat, doubly clamped, and divided. By applying in-line traction, varicosities can be teased out and several centimeters removed from each end. Rolling the vein onto the snap prevents the vein from avulsing prematurely. The varicose segments should be removed in their entirety, and if the vein breaks during the process, it may be reobtained through a new incision [8].

On the other hand, incompetent perforating veins associated with clusters of varices should be ligated. The skin incisions are
small enough that Steri-Strip closure is usually sufficient. Should an individual incision be larger than usual, a single interrupted absorbable subcuticular or nylon skin closure will suffice [8].

Post procedural crepe bandage then compression stockings for several weeks were systematically proposed. Patients were advised to be ambulatory as soon as they can. Aspirin was given to all patients, nonsteroidal anti-inflammatory drugs and analgesics were provided to the patients as needed.

The second group: Radiofrequency procedure

We performed the procedure under ultrasound guidance. We accessed the GSV and/or SSV via percutaneous technique using the Seldinger technique using a 7F, 11-cm-long sheath to introduce the catheter. The preferred site access site for the GSV is just below knee [14] [Figure 2, Figure 3].

Once the GSV has been catheterized, the catheter tip was positioned just below the ostium of the superficial epigastric vein, about 1 cm below the saphenofemoral junction (SFJ). Patients are positioned in reverse Trendelenburg position to allow better GSV exsanguination [Figure 4, Figure 5].

For most patients, this procedure was done with local tumescent anesthesia consisting of Lactated Ringer’s or saline combined with lidocaine, epinephrine, and bicarbonate. Using ultrasound guidance, this solution is instilled percutaneously below the saphenous fascia and above the deep muscular fascia to surround the vein. Commitment to a dose of 35 mg/kg is safe and extremely effective [15] [Figure 6].

17 patients refused local tumescent anesthesia and preferred spinal anesthesia, in this group of patients we injected a solution consists of lactated ringer’s or saline combined with, epinephrine using ultrasound guidance [15].

Duplex ultrasound (DUS) imaging is performed again before starting the RF ablation to check the tumescence quality, to ensure that the catheter position was at least 1 cm below the skin surface and confirm the catheters tip position [16].

We began procedure with two 20 sec therapeutic cycles delivered at the GSV termination to increase the energy dose delivered on the first treated part; then, each segment of the vein was treated for only one cycle except veins segments with ectasia a second 20-second cycle was used in some cases [16]. Those veins segments with ectasia can benefit from a second 20-second cycle [14].

Before starting a new therapeutic cycle, the catheter was repositioned to the adjacent segment guided by shaft markers in 6.5 cm steps to allow a 5 mm overlap of the treated vein segments [16].

During the whole energy delivery, the treated part was compressed manually. Once the procedure was performed, according to the selected puncture point, the introducer shaft could be removed, to allow treatment of the distal part of the saphenous trunk [16].

Complementary percutaneous ultrasound guided foam injection sclerotherapy (Aethoxysklerol 3 %) was performed for incompetent perforators and superficial varicosities.

The most widely used method is that of Tessari; he has described a method of preparing foam using two disposable syringes and a three-way tap [17].
The Tessari method was used to produce the sclerosing foam 2 mL of purified 3% Aethoxysklerol and 6 mL of air (ratio 1:3) were mixed with 2 syringes connected by a 3-way stopcock. Sclerosing detergent STD and air were drawn back and forth by at least 20 pump movements to produce 8 mL of sclerosing foam [17]. The Maximum safest amount used is 6 to 8 mL of foam per session. Patients’ legs should be elevated for fear of complications of foam embolization such as dyspnea or retinal artery thrombosis [18] [Figure 7-11].

At the end of the procedure, we conducted an ultrasonography check control to assess that the treated segment is efficacious, to confirm shrinkage of the vein, to identify an increase in echogenicity of the vein wall and that common femoral veins permeability is correct, to rule out any thrombotic-type complication, specifically heat-induced thrombosis (EHIT) and DVT.

Post procedurally 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 [16].

Postoperatively

All patients received a standard postoperative regimen; dressings were placed over the wounds and crepe bandages wrapped around the treated limbs. Patients were instructed to remove all dressings on the 3rd postoperative day, to shower and then to apply class II full length compression hosiery for 2 weeks.

Evaluation was done after 72hrs, one week, one month, and 6 months. Items to be evaluated will be: pain and bruising and other complications, returning to normal activity, health related quality of life, and recurrence. Follow up will continue for at least 6 months up to 2 years.

Patients were asked to complete post-operative assessment data sheets for 14 days assessing for pain, bruising, return to activity and any analgesia taken.

A 10 cm visual analogue scale (VAS) was used for self-assessment of pain with patients filling out a VAS for each leg treated. Scores were measured in centimeters. The respondents are asked to assess their pain intensity between the end-points of no pain to worst possible pain on the scale. They were asked to return to normal activity as soon as they wished [5].

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 [19].

During each patient’s visit a standard set of information was collected. Physicians assessed patient’s signs and symptoms utilizing VCSS classification and the patient were asked to complete another 20-question CIVIQ2 quality of life questionnaire.

We assessed patient’s limbs for the presence of recurrent varicose veins. In cases where varicose veins were present, the question of whether varicosities were new, or pre-existing was considered. New varicose veins below the knee were classified as recurrent varicosities. Ultrasound examination included measuring the external (adventitia-adventitia) and internal (intima-to-intima) diameters of the great saphenous vein (GSV) and characteristics of outflow and reflux.
Special attention was paid to visualization of the GSV after RFO to detect recanalization of this vein and whether there was any residual flow in the GSV. In many cases the GSV was completely obliterated by the treatment and could not be identified on ultrasound.

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 5 cm segment of flow within the SFJ or an otherwise occluded vein trunk. Inefficiently occluded (IO) veins were defined as greater than 5 cm of flow in any treated vein segment.

Reflux was defined as any evidence of reverse flow for more than 0.5 s in any treated vein segment or at the level of SFJ or SPJ.

The presence of neovascularisation in the groin was assessed by duplex ultrasound examination. This was defined as multiple small vessels in the groin reconnecting more proximal vein or its tributaries and the distal patent vein below the site of interruption (S and L) or occlusion (RFO).

Data collection is ongoing. Further follow-up is planned after 3 and 5 years to assess the long-term outcome.

Results

There was non-significant difference in age and sex between both groups [Table 2].

There was non-significant difference in type of affected veins between both groups. There was non-significant difference whether veins were unilateral or bilateral diseased affected veins in between both groups. There was non-significant difference in side of affected veins between both groups. There was non-significant difference in distribution of CEAP classification between both groups [Table 3].

It was found that there is high significant difference in the type of anesthesia between both groups. There is high significant difference in the Length of hospital stay (hour) between both groups. There is high significant difference in the visual analogue scale between both groups. There is high significant difference in the time to return to normal activities between both groups [Figure 12-14].

There was non-significant difference in the VCSS between both groups preoperatively, but 6 months postoperatively it was found that there is high significant difference in the VCSS between both groups.

There was non-significant difference in the CIVIQ2 questionnaire between both groups preoperatively, but 6 months postoperatively it was found that there is high significant difference in the CIVIQ2 questionnaire between both groups.

There was high significant difference in the postoperative score of VCSS and the CIVIQ2 questionnaire in comparison with preoperative scores in group 1. There was high significant difference in the postoperative score of VCSS and the CIVIQ2 questionnaire in comparison with preoperative scores in group 2 [Table 4].

Discussion

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

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), 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 (RR, 0.94; 95% CI, 0.25-3.46; I2 = 50%) [23].

Most of these studies used the Closure PLUS (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 Closure FAST (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 [14].

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 [16].

The routine uses of tumescent anesthesia in a clinic room setting has now become established as a safe and expedient way to treat varicose veins [24].

<table>
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<tr>
<th>Table 2. Demographic data of patients</th>
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<tr>
<td>Group 1 (N=57)</td>
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<tr>
<td>Age</td>
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<tr>
<td>Sex</td>
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<tr>
<td>Male</td>
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<td>Female</td>
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<th>Table 3. Descriptive data of patients</th>
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<td>Group 1 (N=50)</td>
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<tr>
<td>VEN</td>
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<tr>
<td>GSV</td>
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<tr>
<td>GSV and SSV</td>
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| CEAP class | Group 1 | Group 2 | T | P |
| C2 | 7(12.2%) | 14(22.5%) | 5.02 | NS |
| C3 | 34(59.6%) | 37(59.6%) | | |
| C4 | 13(22.8%) | 11(17.9%) | | |
| C5 | 3(5.4%) | 0(0%) | | |
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 postoperative day.

Proesbstle et al. [25] 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.

Creton et al. [16] 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.

In the 1st group (surgery) the mean was 17.2±7.2 while the 2nd group (RFA) the mean time was 6.4±2.5 showing significant decrease of hospital stay.

In our study we found that the decreased hospital stays 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 et al. [16] 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.

Proesbstle et al. [25] reported return to normal daily activities took place on the same day in more than half of patients, with an average ± SD of 1.0 ± 1.9 days.

The strength of the VCSS lies in its ability to identify subtle intra-subject changes after intervention over time [6].

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 [26].

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. [6] 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.

Proesbstle et al. [25] reported the average VCSS score was 1.5 ± 1.8 at 6 months compared with 3.9 ± 2.0 preoperatively.

Kapoor et al. [27] reported post treatment VCSS showed significant reduced scores at 3 months.

Proesbstle et al. [28] 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.

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 [29].

In both groups the CIVIQ2 questionnaire showed improvement 6 months postoperative but in comparing the 2 groups at the 6 months postoperative 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.

Creton et al. [16] and Proebstle et al. [25] reported that 99% of the patients said they would recommend this procedure to friends or relatives.

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 criterion 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 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 [30].

A multicentre trial using the Closure FAST catheter has achieved an occlusion rate of 99.6% at six months [25].

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 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 et al. [16] reported hematomas in 1.4% of cases along the course of the saphenous trunk. Proebstle et al. [25] reported hematomas in 1.6% of the cases.

Kapoor et al. [31] reported 7% as well.

As regard to phlebitis; in our study it was encountered in 4 limbs (8%); which is like other studies. Nesbitt et al. [31] reported a meta-analysis with an early phlebitis rate of 8% with RFA (by combining the results of three large trials).

Other recent studies have reported rates of 7–9.6% [32, 33]. Creton et al. [16] reported the incidence of superficial venous thrombosis was only 1%.

In the 2nd (RFA) group there was no incidence of Endothermal Heat Induced Thrombosis EKIT. There was one case (2%) of Deep vein thrombosis (DVT) in the post tibial vein which improved with

Table 4. Operative data of patients

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<tr>
<th>Group 1 (N=50)</th>
<th>Group 2 (N=50)</th>
<th>χ²</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anesthesia Spinal</td>
<td>50 (100%)</td>
<td>17 (34%)</td>
<td>49.2</td>
</tr>
<tr>
<td>Tumacent</td>
<td>0 (0%)</td>
<td>33 (66%)</td>
<td>9.8</td>
</tr>
<tr>
<td>Length of hospital stay (hour)</td>
<td>17.2±7.2</td>
<td>6.4±2.5</td>
<td>4.6</td>
</tr>
<tr>
<td>VAS</td>
<td>5.9±2.2</td>
<td>4.2±1.7</td>
<td>NS</td>
</tr>
<tr>
<td>Return to activities (d)</td>
<td>8.8±3.4</td>
<td>4.8±1.8</td>
<td>7.2</td>
</tr>
<tr>
<td>VCSS</td>
<td>6.6±3.5</td>
<td>6.6±3.4</td>
<td>0.04</td>
</tr>
<tr>
<td>After 6 months VCSS</td>
<td>3.5±2.1</td>
<td>2.5±1.9</td>
<td>2.5</td>
</tr>
<tr>
<td>CIVIQ2 questionnaire</td>
<td>50±21.9</td>
<td>4.5±20.2</td>
<td>1.3</td>
</tr>
<tr>
<td>After 6-month CIVIQ2 questionnaire</td>
<td>37±16</td>
<td>19.4±9.8</td>
<td>7.2</td>
</tr>
<tr>
<td>Group 1 Pre</td>
<td>6.6±3.5</td>
<td>3.5±2.1</td>
<td>11.4</td>
</tr>
<tr>
<td>CIVIQ2 questionnaire</td>
<td>50±21.9</td>
<td>37±16</td>
<td>14.9</td>
</tr>
<tr>
<td>Group 2 Pre</td>
<td>6.6±3.4</td>
<td>2.5±1.9</td>
<td>11.7</td>
</tr>
<tr>
<td>CIVIQ2 questionnaire</td>
<td>45±20.2</td>
<td>19.4±9.8</td>
<td>18.4</td>
</tr>
</tbody>
</table>

Table 5. Postoperative complications

<table>
<thead>
<tr>
<th>Complication</th>
<th>Group 1 (N=50)</th>
<th>%</th>
<th>Group 2 (N=50)</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Recurrence</td>
<td>5</td>
<td>10</td>
<td>4</td>
<td>8</td>
</tr>
<tr>
<td>Missed AASV</td>
<td>2</td>
<td>4</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>Recanalization &gt; 5cm</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>Thigh Perforator</td>
<td>1</td>
<td>2</td>
<td>2</td>
<td>4</td>
</tr>
<tr>
<td>Neovascularization</td>
<td>2</td>
<td>4</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>
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 et al. [16] reported no thromboembolic complications. Similar results were reported by Kapoor et al. [27] and Markovic and Shortell [34].

We agree with Kapoor et al. [27] that the cause being significantly reduced procedure time, less duration of catheter insertion and improved collagen shrinkage of vessel wall.

We also agree with Haqani et al. [35] 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.

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 [36].

We did not use Pharmacological prophylaxis for all patients undergoing treatment as it is probably unnecessary in many patients.

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 [36].

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 antiplatelet activity and analgesic effect [37].

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 burn occurred in the 2nd group was in the form of mild erythema in 7 limbs (14%) of the cases and in 1 limb (2%) 2nd degree burn which might be due to insufficient tumescent anesthesia and very superficial veins. All cases improved with conservative management.

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% [38].

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 et al. [16] study.

Proebstle et al. [25] reported skin pigmentation in the course of phlebitis or ecchymosis developed in 2% which decreased to 0.4% at 36 months [28].

Paraesthesia or numbness may arise following RFA but in most cases, improves over the course of a few weeks [38].

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% [39] with other studies reporting it as 4.8–12% [14, 36]. Creton et al. [16] reported incidence as low as 3.4% of the cases.

Proebstle et al. [25] reported paraesthesia in (3.2) of the cases which decreased to 0.4% at 36 months [28].

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 [40].

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 [41].

We agree with Bush et al. [42] that the three most important factors associated with varicose vein recurrence included new or recurrent perforating veins; recalanized GSV and new anterior accessory great saphenous vein (AAGSV) reflux, in decreasing frequency. Technical problems such as difficult access, problems in advancing the catheter or a tortuous GSV may also lead to recurrence.

Kianifard et al. [20] did not observe neovascularization in those patients who had undergone RFA versus 11% in those who underwent stripping.

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 [20].

Lohr and Kulwicki [15] 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. Kapoor et al. [27] reported 1% neovascularization at one year follow up.

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 [43].

Kapoor et al. [27] 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.

Proebstle et al. [28] reported in a 3-year follow-up 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.

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. [44] 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.
Overall, it appears that recurrence after either L/S or ETA is a complex phenomenon. Neither technique completely addresses all potential causes. Xenos and colleague’s 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 [45].

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 [45].

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 adaption 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 [46], 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.

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 [47].

This technique was extremely easy to apply, very reliable both in terms of patient’s satisfaction and the clinical results. The only maneuver that requires a certain degree of training is ultrasound observation and tumescence infiltration in the GSV space within the fascia [2].

The Closure FAST TM catheter 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 [2].

Conclusion

Conventional surgery has been used for a long time for treatment of varicose veins with variable degrees of minor to major complications.

Segmental radiofrequency ablation provides high ablation rates in conjunction with a very moderate side effect profile.

Of most importance is an adequate Duplex scan to identify accessory channels and double superficial systems.

Tumescent anesthesia should be instilled below the saphenous fascia and above the deep muscular fascia surrounding the vein using ultrasound guidance.

The GSV should be compressed to separate it from the inflow tributaries, to maintain an adequate internal temperature in contact with the vein wall.

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