

Original research

Evaluation of the results of varicose vein surgery with radio frequency ablation and sclerotherapy in the same or separate sessions

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Abstract

Varicose veins are the most common vascular disease in humans. They are long, dilated, tortuous veins often seen on the lower legs. We aimed to compare the treatment of varicose veins by radiofrequency ablation (RFA) and sclerotherapy in one session with two sessions with a two weeks interval. One hundred patients with varicose vein were randomly allocated to receive RFA and sclerotherapy in one session (Group A) or two sessions with a two weeks interval (Group B). Immediate and late postoperative complications such as ecchymosis, hematoma, infection, paresthesia, arterial injury, pain, deep vein thrombosis (DVT) and hyperpigmentation, as well as satisfaction and cost effectiveness were compared between two methods. Group A were significantly more satisfied than group B (90% vs. 64%, $p=0.01$). Due to less hospitalization time, hospital costs of RFA and sclerotherapy in one session (group A) were significantly lower than RFA and sclerotherapy in two sessions (group B) ($p < 0.05$). Therefore, RFA and sclerotherapy in one session was more cost effective. Two methods have high procedure success rate, but due to the lower complication rate and faster recovery period in patients receiving RFA and sclerotherapy in one session, it seems more acceptable treatment for varicose veins.

Keywords: Radio frequency ablation, Sclerotherapy, Varicose vein

Introduction

The lower limb varicose veins are the most common vascular dysfunction in humans who need long standing, which cause serious symptoms in patients and sometimes lead to surgical treatment [1-3]. A different prevalence of varicose veins has been reported in different populations, genders and ages (more prevalent in European countries, women and older) [4-6].

The traditional method of varicose vein surgery involves disconnecting the greater saphenous vein in the femoral popliteal junction or small saphenous vein insaphenopopliteal junctions, and then removing certain varicose branches [7, 8].

In 2001, endovascular laser ablation (EVLA) and radiofrequency ablation (RFA) were approved for use in the UK. Since then, the rate of use of these methods

is steadily increasing for the treatment of varicose veins [9-11] and in comparison to the old methods, they have less complications, the least amount of pain is faster after the procedure and recovery time [12-17].

Sclerotherapy is an injectable and non-surgical procedure that can be used to treat small, medium and large superficial and communicative veins and vascular lesions [18, 19].

Considering the above method has the high cost of treatment for patients because of two times admission and also in order to save time and manpower and reduce the probability of infection of the patient's wounds due to a decrease in the number of hospitalization, the use of the treatment as a synchronous sclerotherapy and RFA, so that after disconnecting the saphenous vein with the femoral vein by the RFA, it is injected into the varicose veins

of the sclerosing agent and the patient is treated at one session.

So far, no study of varicose vein treatment by RFA and sclerotherapy has been investigated in a single session or in two different sessions. Therefore, we decided to evaluate this topic in this study.

Materials and Methods

The study was approved by the Tabriz University of Medical Science's ethical committee (IR.TBZMED.REC.1395.1241) and Iranian Registry of Clinical Trials (IRCT2017030916473N8), and all patients who participated in this study signed an informed consent form.

A total of 100 patients who referred to the vascular clinic due to problems with varicose veins of the lower extremity was selected considering the inclusion criteria (age 18-75, visible varicose veins in the lower extremity, confirmation of saphenofemoral junction reflux by Duplex ultrasound) and exclusion criteria (intolerance to supine position, intolerance to surgery with local anesthesia, the presence of concurrent ischemic evidence in the lower extremities, the use of any anticoagulant, the presence of any uncontrolled disease, such as advanced cancer or connective tissue disease, and lymphedema, pregnancy, thrombophilic history, veins with a diameter greater than 20 mm, tortuous varicose great saphenous vein (GSV)) and randomly divided into two equal groups.

RFA and sclerotherapy was performed in one session in group A and in two separate sessions in group B. So that sclerotherapy was performed two weeks after the RFA. Before the procedure, the severity and extent of GSV reflux were evaluated with Duplex ultrasonography in all patients. In all patients Duplex ultrasonography was performed with a color duplex system (RS80, Samsung, South Korea) in vascular clinic. Reflux in the superficial (GSV and small saphenous vein) and deep (femoral vein and popliteal vein) vein was assessed with patients in the standing position by inflation/deflation of a calf plethysmographic cuff. Reflux was defined as reversed flow which is lasting more than 0.5 seconds.

To perform RFA, the patients were placed in the supine position and under duplex ultrasonography guidance, the GSV was punctured with an 18-gauge needle at the knee level and then radiofrequency catheter was advanced over a wire and its position

confirmed to be distal to the saphenofemoral Junction (SFJ), 1 cm below the confluence of the inferior epigastric vein.

This procedure was performed in the operating room under local tumescent anesthesia along the GSV (50 mL of 1% lidocaine and 1 mL of epinephrine [1:1,000] diluted in 1L of normal saline) under duplex ultrasonography guidance around the catheter. Patients were placed in Trendelenburg position and varicose veins were treated with RFA.

To perform sclerotherapy, sodium tetradecyl sulfate was used as sclerosant agent with different concentration that is depended on the size of the target vessel that is being treated. Telangiectasias (bluish veins <1 mm in diameter) and reticular veins (1-3 mm in diameter) can be treated with sodium tetradecyl sulfate in concentrations of 0.1% or 0.3% (for larger vessels). Reticular veins and branches varicosities can be treated with 0.3% or 1% sodium tetradecyl sulfate.

Once the appropriate sclerosant is drawn into a 1mL insulin syringe with 28G needle and (at the operator's preference) it may be bent at a little depth angle. The patient is positioned in a way that is comfortable for surgeon to access the target veins, and the skin is prepared with alcohol. The needle was inserted into the target vein almost parallel with the skin and the sclerosant agent was injected.

Small amount of blood was aspirated into hub of needle before injection to ensure that the needle is inserted into the vein. This is harder with small vessels. Sclerosant is injected into the vein until the area around the puncture site blanches or resistance is felt, and the injection is immediately discontinued if there is evidence of extravasation (most often apparent as the development of a wheal).

Elastic compression bandage was used to wrap thigh and knee for 48 hours. After that, compression stocking were used for 2 weeks. In patients group A, RFA and sclerotherapy performed in one session and in patients group B, RFA and sclerotherapy performed in two sessions with a two weeks interval (in first session RFA and in second session sclerotherapy).

All procedures were performed by a vascular surgeon (Dr. Alvandfar) for better control of the results. Then, patients were evaluated after procedure for early recurrence, postoperative complications include early pain, long-term pain, hematoma after

the first operation, wound infection, burn, paresthesia, arterial injury, skin pigmentation, evidence of thrombosis in deep vein, pulmonary embolism, duration of admission, and time to return to daily activity and work.

The severity of pain after the procedure was evaluated using VAS criteria.

Results

In this study, 100 patients were studied. Patients were randomly divided into two equal groups: Group A with 50 patients who were undergoing sclerotherapy and RFA in one session and Group B with 50 patients who had sclerotherapy and RFA separately in two sessions with a 2 week interval.

Demographic data of patients are shown in Table 1. In all patients, the procedure was performed using local anesthetic.

Immediate postoperative complications (up to 24 hours) in both groups were demonstrated in Table 2. There was no significant difference between the two groups regarding the incidence of hematoma, ecchymosis and thrombophlebitis. However, the incidence of hematoma and ecchymosis was lower in group A.

Late postoperative complications (after 24 hours) in both groups were shown in Table 3. None of the patients in the two groups were observed deep vein thrombosis, and hemorrhage and hematoma damage.

Frequency of ecchymosis, infection, paresthesia, pain and VAS score were decreased on 1, 3, 7, 14, and 28 days after surgery. Hyperpigmentation were increased in this period. Although the incidence of complications in group A was lower than group B, however, there was no significant difference between the two groups.

Satisfaction was by 90% (45 patients) in group A and by 64% (32 patients) in group B, which was significantly higher in group A ($p = 0.01$).

Hospital costs of RFA and sclerotherapy in one session (group A) were significantly lower than RFA and sclerotherapy in two sessions (group B), due to less hospitalization time ($p < 0.05$). Therefore, RFA and sclerotherapy was more cost effective in one session.

Discussion

A similar study has not been done in this regard. Varicose is the most common vascular disease in humans, which is affecting about 10% of the population [20]. Varicose veins are long, dilated and tortuous vein and often they are seen on the lower levels of the lower limbs. The major risk factors are females, obesity, family history, long standing, immobility and others [15]. The highest prevalence of varicose is estimated in women between the ages of 49-40 [21].

Modern sclerotherapy started for the first time in Europe in the 20th century and developed by Tournay in France, Sigg in Switzerland and Fegan in Ireland. Recently, ultrasound-guided sclerotherapy seems to be one of the main methods for treating the saphenous trunk and the perforator veins. The exact diagnosis of varicose vein and the determination of the most proximal location of the reflux determine the choice of optimal treatment and reduce the risk of recurrence and complications such as pigmentation or matting. The risk of complications depends on the type of sclerosing agent, the concentration and quality of the injection. Sclerotherapy is a selective treatment for spider veins and it is also indicated for the treatment of varicose veins of reticular and short saphenous veins [18].

A new method for managing saphenous vein reflux is endovascular obliteration of varicose vein by a radiofrequency probe that is embedded in percutaneous or small incision in the calf [16]. Most of the studies have compared the methods of endovenous laser ablation (EVLA) and RFA [15, 17, 22] or conventional stripping operation and Radiofrequency surgery [16, 23]. The results of these studies showed that the RFA with or without sclerotherapy, have had less complications compare to EVLA and stripping operation and getting back to work and daily and costly effective, while the efficacy and rate of recurrences are similar to the above methods.

The results of this study demonstrated that immediate postoperative complications were not significantly different in both groups, although the incidence of these complications were lower in group A (sclerotherapy and RFA in one session) than group B (sclerotherapy and RFA in two sessions with a 2-week interval). Hyun Joh and et al. recommended that sclerotherapy after RFA was deferred by 2 weeks.

Table 1. Demographic data of studied patients

Variable	Group A	Group B	P-Value
Age (yrs)	57.41±18.2	59.49±16.84	0.56
Sex			
Male	22 (44%)	18 (36%)	0.66
female	28 (56%)	32 (64%)	
BMI	26.6±4.6	26.1±3.7	0.07
GSV diameter (mm)	6.6±4.6	7.9±2.1	0.09
PMH			
DM	8	7	0.07
COPD	2	4	
Immunodeficiency	0	0	
Heart disease	6	4	
HTN	16	15	
Smoking	22	25	0.85
Opioid	6	4	0.65

Table 2. Immediately postoperative complications

Variable	Group A	Group B	P-Value
Ecchymosis at knee			0.249
Yes	15	18	
No	35	32	
Thrombophlebitis			0.681
Yes	35	31	
No	15	19	
Start daily activities	Day of the procedure	Day of the procedure	0.07

BMI: Body Mass Index; GSV: Great Saphenous Vein; PMH: Past Medical History; DM: Diabetes Mellitus; COPD: Chronic obstructive pulmonary disease; HTN: Hypertention.

Table 3. Late postoperative complications- 1, 3, 7, 14, and 28 days after procedure

Variable	One day after procedure	3 days after procedure	7 days after procedure	14 days after procedure	28 days after procedure	P-Value
Ecchymosis						0.187
Group A	39	25	13	5	0	
Group B	44	29	20	12	0	
Hematoma						1
Group A	0	0	0	0	0	
Group B	0	0	0	0	0	
Infection						0.504
Group A	4	3	2	0	0	
Group B	5	4	2	0	0	
Paresthesia						0.165
Group A	22	18	13	9	0	
Group B	25	20	17	12	0	
Arterial Injury						1
Group A	0	0	0	0	0	
Group B	0	0	0	0	0	
Pain						0.732
Group A	15	12	7	3	0	
Group B	27	25	15	11	0	
VAS						0.615
Group A	4	3	2	1	0	
Group B	5	5	4	3	2	
DVT						1
Group A	0	0	0	0	0	
Group B	0	0	0	0	0	
Hyperpigmentation						0.23
Group A	0	0	4	6	20	
Group B	0	0	6	8	23	

VAS: Visual Analog Scale; DVT: Deep Vein Thrombosis.

Based on the results of this study, RFA with sclerotherapy is an ideal method for treating varicose veins and has low side effects. It is also recommended that patients were ambulated for prevent post-operative embolism [19].

In our study, all patients were ambulated immediately after the procedure in both groups. According to the results of Abd El-Mabood et al., RFA with foam sclerotherapy was more effective, minimally invasive, higher efficacy, higher patient satisfaction and quality of life, better cosmetic results, and less day's away work than stripping. The incidence of complications was also lower in RFA and sclerotherapy [24].

Based on our study, long-term complications were not significantly different in both groups; although the incidence of these complications such as paresthesia, ecchymosis, pain and infection was lower in group A (sclerotherapy and RFA in one session) than group B (sclerotherapy and RFA in two sessions with a 2-week interval). Also, patients' satisfaction was significantly higher in group A and it is more cost effective.

Rautio et al., in their study showed that RFA with or without sclerotherapy has fewer complications and less pain than stripping and it is more affordable [23]. Three clinical trials compared RFA with HL/S and showed that RFA has significant benefits, including faster healing, low postoperative pain, lower side effects and higher quality of life [6, 16, 25].

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This study shows that immediate and late postoperative complications, efficacy in eliminating GSV (Great saphenous vein) reflux and recurrence rates, reducing varicose symptoms and improving the quality of life of both groups are similar and there is no significant difference between the two methods, however, due to the lower incidence of complications and the faster recovery and more effective in group A (RFA and sclerotherapy in one session), it seems to be preferable to the two-sessions method and the choice for treatment for varicose veins. However, further studies are recommended in this area with a larger sample size and other parameters to obtain more accurate results and select the preferred method.

Author contribution

All authors contributed equally and approved the final version of the manuscript.

Conflict of Interest

The authors have no conflicts of interest to declare.

Ethical declaration

Not applicable

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