Radiofrequency ablation versus high ligation and stripping of great saphenous veins (short term results): Prospective comparative randomized study

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ABSTRACT

Aim of the study: *The aim of the study is to compare the radiofrequency ablation (RFA) and high ligation and stripping (HLS) of the great saphenous vein (GSV) in patients suffer lower limb varicose veins.* ***Patients and methods****: Forty two (42) patients including 29males 13females were referred to the vascular outpatient clinic of our department at Kasr Al Ainy hospital for management of their chronic venous disease(CVD) in the period from June 2016 to January 2017.The patients were randomized ,treated with either radiofrequency ablation (RFA),or high ligation and stripping (HLS) . Nineteen (19) patients were treated with RFA. Twenty three (23) patients were treated with HLS of the GSV.* ***Results:*** *The study includes 29 males and 13 females.Thepatients' complaints were heaviness 90% and 100%, disfigurement 52% and 48% in the FRA and HLS, respectively. All patients included in the study were CEAP class 2 apart from one patient in the RFA group who was CEAP class 3.RFA was applied to the left GSV in 6 (30%) and to right GSV in 13 (70%) patients. The left GSV in 14 (60,8%) and the right GSV in 9 (34.7%) patient were highly ligated and stripped.*

INTRODUCTION

Lower-limb varicose veins (VVs) are relatively common, with reported prevalenceat the end of the twentieth century ranging between 10% and 30% worldwide. Approximately one-third of men and women aged 18 to 64 years have varicose veins[(1)]. The high prevalence leads to significant health care expenditure on treatments of varicose veins. Treatment modalities include surgical treatment and other non-surgical less invasive treatment. Surgical treatment of varicose veins includes high ligation and saphenous vein stripping(HLS), with or without phlebectomy. However, several other less invasive treatment modalities, that are claimed to be as effective as surgery, are currently available, including radiofrequency ablation(RFA) or laser ablation of the great (GSV) or small saphenous veins (SSV), or both, combined with or without phlebectomy, elasticstockings, pharmacological treatment, liquid sclerotherapy, and foam sclerotherapy.[(2)(3)].

PATIENTS AND METHODS

Demographic data

Forty two (42) patients including 29males,13 females referred to the vascular outpatient clinic of our department at Kasr Al Ainy hospital for management of their CVD in the period from June 2016 to January 2017. All patients underwent clinical examination, duplex ultrasonography,and were consented to follow up over an extended period of 6 months period following treatment.

The patients were randomizedby simplerandomization by Microsoft excel for varicose veins treatment by either radiofrequency ablation (RFA) ,or high ligation and stripping (HLS) of the GSV . Nineteen (19) patients were treated with RFA. Twenty three (23) patients were treated with HLS of the GSV.

Inclusion criteria

1. Symptomatic patients who haveincompetent saphenofemoral junction, and incompetent longsaphenous vein (symptomatic C2 or C3 according to CEAP classification).
2. Patients who failed conservative medical treatment for their varicose veins.

Exclusion criteria

1. Past history of deep venous thrombosis of the affected limb.
2. Recurrent varicose veins.
3. Connective tissue disorders.

4. incompetentSapheno-popliteal junction.
5. C (4a, 4b, 5,6) according to CEAP classification

Aim of the study

The primary end point is to compare the technical success ofradiofrequency ablation (RFA) of GSV (confirmed by measuring GSV diameter pre, and post the procedure at 1 ,3 and 6 month), with the 6 month occlusion rate of the standard surgical procedure; GSV high ligation and stripping (HLS).

The secondary endpoint is to compare the short term results between (RFA), and (HLS) concerning the early post-operative pain and patient satisfaction, and the rate of complications.

Preoperative duplex mapping

Duplex scanning is performed to document the patency of the deep veins and to evaluate the extent and severity of the reflux ($\geq$ 0.5 sec of retrograde flow in the superficial venous system (GSV, small saphenous vein and perforators) of patients in the standing position. We used GE LOGIQ P3 ® Ultrasound system, USA, using the superficial linear probe (7.5MHz to 10.8MHz.) raised ridge(nose) facing medial side of the limb.
A preoperative map of veins was drawn on the skin with the aid of duplex ultrasonography in cases of extra-axial varicosities below knee for punchectomy.

High ligation and Stripping(HLS) procedure

The surgical treatment employed included: flush saphenofemoral ligation, GSV stripping above the knee, multiple phlebectomies of the tributaries. All the surgical procedures were performed under general or regional anesthesia.[4]

Radiofrequency ablation (RFA)

A catheter electrode was used to deliver a high frequency alternating radiofrequency at wavelength 3nm.At twentysecond treatment cycles, generator timer counts down from 20 to 0 .Energy delivery automatically stops at end of each cycle. Device temperaturereaches 120°C and maximum power of 40 Wattscurrent that leads to venous spasm, Collagen shrinkage and physical contraction then issued. The device used was ClosureFast ™ of Medtronic, USA. The procedure was done either in an angiography-suite using local infiltration anesthesia or in an operating theatre under regional spinal anesthesia.

Steps of the procedure

The local tumescent anesthetic was previously prepared by 20 ml lidocaine 1%, 20 ml 8.4% sodium bicarbonate and 1ml adrenaline 1/1000, in 500 ml saline and was kept at low temperature.

The patient's leg is prepped with antiseptic solution and draped in a sterile fashion. With ultrasound guidance, the vein is cannulated percutaneously (or through venous cut down). The catheter electrode is 7 cm long, "7F Closure FAST".

The catheter is then introduced through a 7 FG sheath up to point 1-2 cm below the saphenofemoral junction under ultrasound guidance. Then local tumescent anesthetic is then injected within the saphenous fascia around the target venous segment using a spinal anesthesia needle.

The radiofrequency current is then delivered, resulting in circular homogeneous denaturation of the venous collagen matrix and endothelial destruction at a temperature of 110°–120° C. Venous segments 7 cm in length were treated in 20-second cycles with gradual withdrawal of the catheter.[5]

Concerning the surgical group, the procedure is done under General anaesthesia or regional anaesthesia in the operating theater, the target limb is marked before surgery. A 2-3 cm oblique incision in the medial aspect of the inguinal crease ,another 1-1.5 cm were done just below the knee. Ligation and disconnection of the saphenofemoral junction, striping of the GSV from above downwards, then haemostasis, and closure in layers were performed.[4]

Postoperative management

Following RFA treatment, class II graduated compression stockings above the knee was put on the treated limb throughout the day, except during sleep, for the next 3 months. Patients were prescribed suitable anticoagulant at prophylactic dose during the first postoperative week. Limbs that had been treated by HLS were bandaged first to minimize bruising. Bandages were replaced with class 2 medical compression stockings above the knee after 1 week and used for 3 months thereafter. Patients were usually discharged from hospital on the day of surgery or the next day.

Patients were reviewed postoperatively at one week, 1, 3 and 6 month, to assess the outcome of these treatments, and examined by duplex to pick up the occlusion rate and recurrence.

Clinical assessment of the results

This is done by functional , cosmetic subjective score, and subjective numerical pain rating scale(NPRS).Functional and cosmetic results were self-assessed by patients at the time ofexamination in hospital. A subjective simple scoring system was used,being explained to patients by the examiner. Patients were asked to indicate on a form which of the following applied to them:

- **Class A** (score 1): no inconvenience.
- **Class B** (score 2): slight functional or cosmetic imperfection, but
- Satisfied with the result.
- **Class C** (score 3): appreciable functional or cosmetic imperfection.
- **Class D** (score 4): unaltered or increased inconvenience.[6]

The subjective score was obtained by this simple process. Numerical scores were assigned to both(the subjective score , and the NPRS) of these outcome measures in order to facilitate

Statistical analysis

Another subjective method for pain rating which is the (NPRS) is a subjective measurewhich is composed of 0 (no **pain** at all) to 10 (worst imaginable **pain**).

Patients were asked to indicate the intensity of current, best, and worst pain levels on "The NPRS"; a scale of 0 (no pain) 1-3(mild), 4-6 (moderate), 7-9 (severe) and 10 (worstimaginable pain).[7]

RESULTS

The study includes 29 males and 13 females, themean age for RF patients was 28 years, while that for stripping group 33years.

The patients complaint were heaviness; 90% and 100%, disfigurement; 52% and 48% in the FRA and HLS, respectively. All patients were CEAP class 2 apart from one patient only in the RFA group who was CEAP class 3. There was no difference in patient's complain among both groups; the chi-square was0.5624,the *p*-value =0.45.

RFA was applied to the left GSV in 6 (30%) and to right GSV in 13 (70%) patients. The left GSV in 14 (60,8%) and the right GSV in 9 (34.7%) patient were ligated and strippedThe chi-square statistic is 3.5788. The *p*-value is .058. The result is *not* significant at $p < .05$.Regarding the HLS group, There were added punchectomy in right , left, and bilaterally by 21.7% (5),17.4% (4),and 4.3% (1) respectively.

All patients inthe HLS group had spinal anesthesia while in RFA group,12 patients (63%) had spinal anesthesia while the remaining 7 (37%) patients hadlocaltumescent anesthesia.

Table 1: Shows that there was significant reduction of GSV diameter before, and after RFA at upper, middle, and lower thigh at 1 month, 3 months and 6 months with p value (<0.001)

	RFA															**P value**
	Mean			**SD**			**median**			**Min**			**Max**			
GSV	Upper Ø	Middle Ø	Lower Ø	Upper Ø	Middle Ø	Lower Ø	Upper Ø	Middle Ø	Lower Ø	Upper Ø	Middle Ø	Lower Ø	Upper Ø	Middle Ø	Lower Ø	
Pre	.51	.44	.46	.08	.06	0.08	.52	.46	.45	.36	.32	.33	.65	.52	.63	<0.001
1 m	,38	.34	.33	.07	.06	.05	.40	.34	.34	.23	.24	.23	.46	.41	.40	
3 m	.35	,31	.31	.07	.06	.05	.37	.31	.31	.20	.19	.22	.43	.38	.37	
6 m	.32	.30	.31	.07	.07	.02	.33	.29	.30	.14	.15	.22	.41	.38	.35	

Ø=diameter

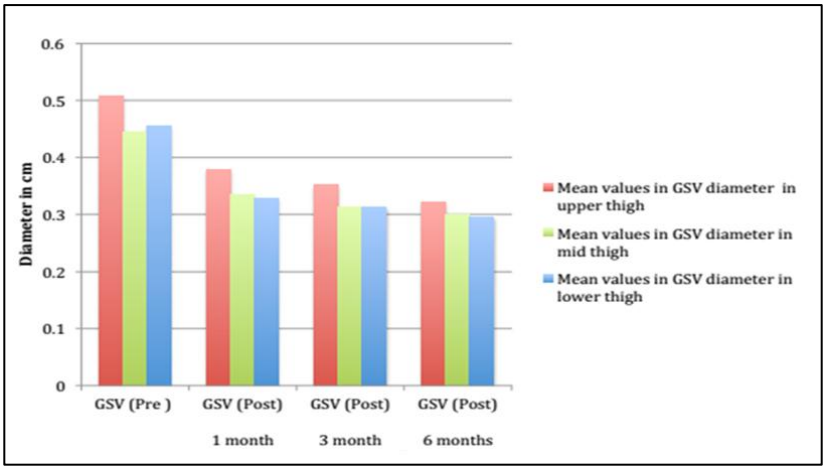

Figure 1: Difference in GSV diameter before and after RFA at upper, middle and lower thigh at 1 month, 3 months and 6 months, respectively.

Table 2: Comparison regarding subjective scoring (1-4) between HLS and RFA

	HLS	RFA	P value
	Mean	Mean	
Subjective Clinical Ex. Score (out of 4) at 1 month	1.33	1.40	0.821
Subjective Clinical Ex. Score (out of 4) at 3 months	1.33	1.40	1
Subjective Clinical Ex. Score (out of 4) at 6 months	1.25	1.30	0.702

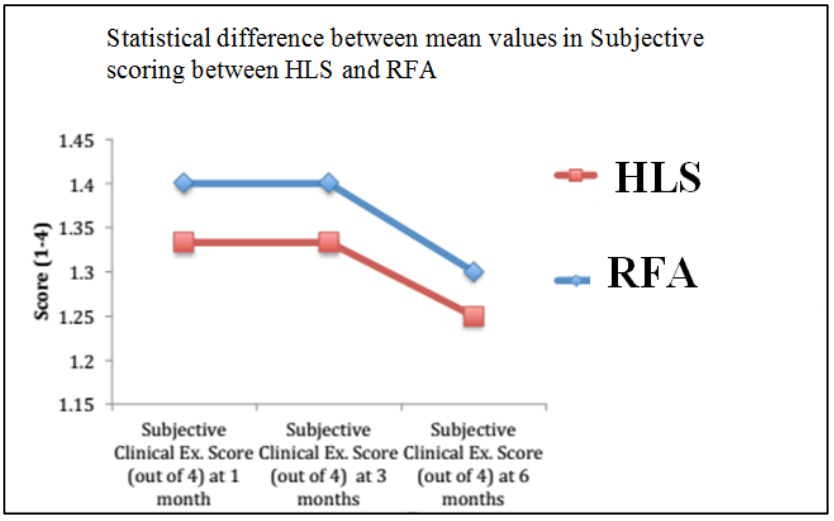

Fig. (2): Comparison of Subjective scoring (1-4) between HLS and RFA groups

Comparison regarding Subjective scoring (1-4) between HLS ,and RFA. Subjective scoring was better in the HLSrather than the RFAgroup ,although there was no statistical significance.

Table 3: There was the statistical analysis in numerical pain score through the follow up period in 1 month, 3 month, 6 month, in HLS, and RFA groups.

	HLS					RFA					P value
	Mean	**SD**	**Median**	**Mini.**	**Maxi.**	**Mean**	**SD**	**Median**	**Mini.**	**Maxi.**	
Pain Score (out of 10) before Procedure	8.33	.78	8.50	7.00	9.00	7.30	1.16	7.50	5.00	9.00	0.036
Pain score (out of 10) at 1 month	.25	.62	.00	00	2.00	3.20	1.48	4.00	00	5.00	<0.001
Pain score (out of 10) at 3 months	.00	.00	.00	.00	.00	2.80	1.23	3.00	.00	3.00	<0.001
Pain score (out of 10) at 6 months	.00	.00	.00	.00	.00	2.60	1.26	3.00	.00	3.00	<0.001

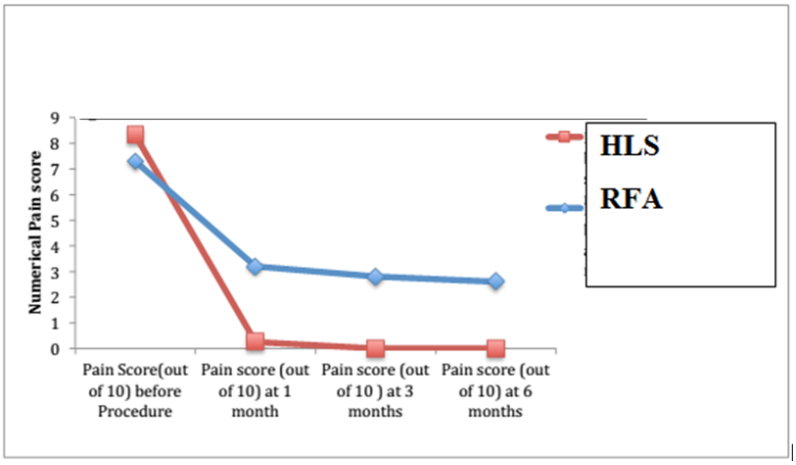

Fig. (3): Differences between mean values in pain score between HLS group and RFA before and after the procedure at 1 month, 3 months and 6 months

Comparing both groups pain score on the numerical pain scale (1-10) between HLS and RFA revealed improvement in the numerical pain scorethroughout the follow up period, and it is better in the HLS group than the RFA group.

Recurrence

Recurrence was observed in one case in 3 month follow up ,presented by neovascularization and partial recanalization with tributary inflow into GSV in the RFA group while no recurrence was detected in the HLS group.

Complication

The complications was one case(4.3%) ofpostoperative wound infection in the HLS group, which improved on medical treatment and repeated dressing.The RFA Group showed one case (5.2 %) of superficial thrombophlebitis, and one case(5.2%) of paresthesia on the medial aspect of the treated thigh (resolved after two weeks) . There were no cases of skin burns or skin discoloration.

DISCUSSION

Overtime, theEndovenous ablation is challengingthe surgicaltechniques (ligation and stripping) of GSV One of the new techniques of endovenous ablation is radiofrequency. The radiofrequency ablation of GSV is often requested by the patient as it is less invasive and with better cosmetic results.[7]

The present study compares the Radiofrequency ablation in GSV reflux with a standard high ligation, andstripping (HLS) .The

GSV ligation and stripping is still recommended by guidelines in **SVS 2017**[8]

In this study, 42 patients were randomized into 19 patients for RFA, and 23 patients for HLS. The mean age of patient in the radiofrequency group was 27 years (± 6) whereas the mean age of patients in group for the stripping & ligation group was 33 (± 6). Outof 42 patients, 29 were males.

The majority of patients in the study were classified as C2,C3 according to CEAP classification which is the same as other studies conducted by**, *Subromania et al 2010*** [9] The data outcome of the our study showed occlusion rate of 90%, 100% of RFA group, HLS group respectively. **Sincos et al in 2019** recorded occlusion rate in RFA 93.4% at 3 years.,their results were similar to the present study[10].

Proebstle et al 2015 reported occlusion rate of RF 95% at 5 years.[11]

The lower primary occlusion rate in this study may be attribute to early learning curve of the operators although, it is the same device used in the other study reported by **Sincos et al (2019)**[10]

Metta et al in 2019 uses other device in RFA which is CELON (Olympus) with occlusion rate at 6 months was 93.1%, it is similar to the primary occlusion rate of the current study.[12] **Swenil et al in 2017,** used CELON (Olympus) as RFA in comparison to endovenous laser ,the RFA occlusion rate was 94%,90%,88% at 1 , 6,12 months respectively which is similar to this study RFA occlusion rate, although different RFA device.[13]

A study conducted by ***ElKaffas et al*** **2011**, which includes 180 patients who were randomly divide into 2 groups. Group A with RFA including 90 patients, group B with surgical stripping of GSV and stripping. After 24 months follow up, the occlusion rate was 94.5%, 100% in group AandB, respectively. Group A showed failure to occlude in 6.6% which require stripping and ligation of GSV. The 24 months follow up in the same study, showed improvement of clinical scoring of both groups according to CEAP grading.[14]

The study of **Subromania et al 2009** who randomized patients to treatment by RFA and surgery, found ,RFA was successful in all 47 patients while surgery showed failure in 7 out of 41 patients,the 7 patients were one with brisk reflux, two with no flow,4 showed tickling retrograde .($P<0.001$)[14]

In ***F. Lurie et al*** in ***2005, reported on*** 85 patients divided into 45 patients (46 limbs) allocated to RFA, and 40 patients to (HLS), and 79 patients (80 limbs) received treatment after exclusion of 4 patients who don't fulfil the inclusion criteria and 2 patients who refused to do surgery. A 2-year clinical follow up of patients from this trial showed that the results of RFA were at least equal to those after high ligation and stripping of the great saphenous vein. This was similar to our study in early short time 6 months.[15]

Hingorani et al 2004 [16] and ***Puggioni et al 2005***[17]**,** showed 96% primary occlusion rate and 100% occlusion rate after radiofrequency ablation, respectively.

Regarding the pain evaluation assessment, our study showed statistical difference between the two groups after 6 months follow up with P value=< ***0.001.*** It showed that the RFA group had a marked reduction in their pain with an average of 2.6 after 6 months on the pain numerical scale while in the HLS group; the pain nearly totally disappeared after 6 months.

Unlike this study ***Rasmussen et al 2011***[7] in randomized controlled trial between RFA and HLS, recording lesser pain in RFA rather than HLS.

They also mentioned phlebectomies that didn'tsignificantly influence the pain scores[7]. In the present study pain was more in RFA which may be attributed to injection of 500 cc saline/lidocaine,whileothers (with better pain score) injected 1000 cc saline/lidocaine. The theory of inflammatory mediators may be masked by huge amount of tumescent anaesthesia.

The evaluation of the subjective assessment undertaken by

patients, showed no statistical difference between the two groups after 6 months follow up with P value=***0.702***. This showed that most patients had scored the outcome of their treatment as class A or B i.e. between no inconvenience (excellent), andsatisfaction with the result(good) for both procedures. Despite that, 1 patient (10%) had scored class C in the RF group, which indicates dissatisfaction (needs further intervention) with results in comparison to two patients in the stripping group however it was not statistically significant.

ElKaffas et al in ***2010, reported on*** recurrence rate at 2 years follow-up of 13.3% in the RFA group, with a comparable rate of 10% in the HLS group.[14] Other studies of ***Van den Bos et al*** in ***2009***[18] and ***Perrin*** in ***2004***[18] have reported recurrence rates ranging from 10% to 25% following RFA .

In our study, the rate of complications was low with 1 (4.3%) case of postoperative wound infection in the stripping group, which improved on medical treatment , and repeated dressing whereas the RFA Group showed 1 case (5.2 %) of superficial thrombophlebitis and 1 case (10%) of paresthesia. There were no cases recorded with skin burns or skin discoloration.

In ***Subramonia et al*** in ***2010,*** a significantly higher rate of cutaneous sensory abnormalities was observed after HLS group. These were most frequently observed along the medial aspect of the leg in both groups. The commonest paresthesia experienced was a tingling sensation. Groin wound problems noted after conventional surgery included mild inflammation 7.7%), serous wound discharge 5.1%, hematoma. 2.5% and wound breakdown 2.5%, all of which resolved spontaneously. Clinically evident hematomas in the thigh and leg were slightly more common after HLS but did not differ significantly between the groups. Five patients developed a non-tender palpable GSV with overlying pigmentation after RFA that showed progressive resolution by the second follow-up.[9]

Patients' preference had stood behind the higher use of regional anesthesia in our RFA group. Ten percent of patients in the RFA group required foam sclerotherapy injection whereas, none of the stripping group required injection. During the follow up period elastic stocking compression was planned up to a 3 months follow up period. Twenty five percent ofpatients in the stripping group and 30% of the RFA group required continuing on the compression therapy regimen for further 3 months with marked improvement in their symptoms.

CONCLUSION

RFA is a minimally invasive procedure. Its potential early benefits, by Avoiding groin dissection and GSV stripping, have been confirmed by the findings from this trial. Both techniques led to high levels of patient satisfaction, Subjective scoring was better in the HLS rather than the RFA group, although there was no statistical difference. Numerical pain scale (1-10) between HLS and RFA revealed improvement in the numerical pain score throughout the follow up period, and it is better in the HLS group than the RFA group.

Further follow up for long term periods (1-3 years or more) is required as most trials show no statistical difference between both RFA,andHLS on short term results.

REFERENCES

1. Evans CJ, Fowkes FGR, Ruckley C V., Lee AJ. Prevalence of varicose veins and chronic venous insufficiency in men and women in the general population: Edinburgh Vein Study. J Epidemiol Community Health. 1999;53(3):149–53.
2. Murad MH, Coto-Yglesias F, Zumaeta-Garcia M, Elamin MB, Duggirala MK, Erwin PJ, et al. A systematic review and meta-analysis of the treatments of varicose veins. Vol. 53, Journal of Vascular Surgery. Mosby Inc.; 2011. p. 49S-65S.
3. PERRIN, Michel Chassieu, France GGIC of S, Technology and Medicine, London U. Pharmacological treatment of chronic venous disorders - Servier - Phlebolymphology Servier – Phlebolymphology [Internet]. Phlebolymphology. [cited 2019 Dec 5]. p. 23. Available from: https://www.phlebolymphology.org/pharmacological-treatment-of-chronic-venous-disorders/
4. Sarma N. Guidelines and recommendation on surgery for venous incompetence and leg ulcer. Indian Dermatol Online J. 2014; 5(3):390.
5. Weiss RA, Weiss MA. Controlled radiofrequency endovenous occlusion using a unique radiofrequency catheter under duplex guidance to eliminate saphenous varicose vein reflux: A 2-year follow-up. Dermatologic Surg. 2002;28(1):38–42.
6. Carandina S, Mari C, De Palma M, Marcellino MG, Cisno C, Legnaro A, et al. Varicose Vein Stripping vs Haemodynamic Correction (CHIVA): a Long Term Randomised Trial. Eur J Vasc Endovasc Surg. 2008 Feb;35(2):230–7.

7. Rasmussen LH, Lawaetz M, Bjoern L, Vennits B, Blemings A, Eklof B. Randomized clinical trial comparing endovenous laser ablation, radiofrequency ablation, foam sclerotherapy and surgical stripping for great saphenous varicose veins. Br J Surg. 2011 Aug;98(8):1079–87.
8. Gloviczki P, Dalsing MC, Henke P, Lal BK, O'Donnell TF, Shortell CK, et al. Report of the Society for Vascular Surgery and the American Venous Forum on the July 20, 2016 meeting of the Medicare Evidence Development and Coverage Advisory Committee panel on lower extremity chronic venous disease. In: Journal of Vascular Surgery: Venous and Lymphatic Disorders. Elsevier Inc.; 2017. p. 378–98.
9. Subramonia S, Lees T. Randomized clinical trial of radiofrequency ablation or conventional high ligation and stripping for great saphenous varicose veins. Br J Surg. 2010 Mar;97(3):328–36.
10. Sincos IR, Baptista APW, Coelho Neto F, Labropoulos N, Alledi LB, Marins EM de, et al. Prospective randomized trial comparing radiofrequency ablation and complete saphenous vein stripping in patients with mild to moderate chronic venous disease with a 3-year follow-up. Einstein (Sao Paulo). 2019 May 2;17(2):eAO4526.
11. Proebstle TM, Alm BJ, Göckeritz O, Wenzel C, Noppeney T, Lebard C, et al. Five-year results from the prospective European multicentre cohort study on radiofrequency segmental thermal ablation for incompetent great saphenous veins. Br J Surg. 2015 Feb 1;102(3).
12. Metta, Mehra R, Jaiswal SS, Bhagwat AR, Singh G. Evaluation of radiofrequency ablation for primary varicose veins: A preliminary study. Indian J Vasc Endovasc Surg. 2019;6(1):37.
13. Swenil DS. RFA vs EVLT: A Comparison of Treatment Options for Varicose Veins. J Med Sci Clin Res [Internet]. 2017 Oct 15 [cited 2019 Nov 16];5(10). Available from: http://jmscr.igmpublication.org/v5-i10/81 jmscr.pdf
14. Helmy Elkaffas K, Elkashef O, Elbaz W. Great saphenous vein radiofrequency ablation versus standard stripping in the management of primary varicose veins-A randomized clinical trial. Angiology. 2011 Jan;62(1):49–54.
15. Lurie F, Creton D, Eklof B, Kabnick LS, Kistner RL, Pichot O, et al. Prospective randomised study of endovenous radiofrequency obliteration (closure) versus ligation and vein stripping (EVOLVeS): Two-year follow-up. Eur J Vasc Endovasc Surg. 2005 Jan;29(1):67–73.
16. Hingorani AP, Ascher E, Markevich N, Schutzer RW, Kallakuri S, Hou A, et al. Deep venous thrombosis after radiofrequency ablation of greater saphenous vein: A word of caution. J Vasc Surg. 2004 Sep;40(3):500–4.
17. Puggioni A, Kalra M, Carmo M, Mozes G, Gloviczki P. Endovenous laser therapy and radiofrequency ablation of the great saphenous vein: Analysis of early efficacy and complications. J Vasc Surg. 2005 Sep;42(3):488–93.
18. van den Bos R, Arends L, Kockaert M, Neumann M, Nijsten T. Endovenous therapies of lower extremity varicosities: A meta-analysis. Vol. 49, Journal of Vascular Surgery. 2009. p. 230–9.