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Original study

TREATMENT OF VARICOSE VEINS OF LOWER LIMB; PROSPECTIVE RANDOMIZED COMPARISON OF RADIO-FREQUENCY ABLATION AND CONVENTIONAL SURGERY.

Alt ekstremite variköz venlerinin tedavisinde klasik cerrahi yaklaşım ve radyofrekans ablasyon yöntemlerinin prospektif bir değerlendirmesi.

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ABSTRACT

To compare effectiveness of conventional surgery and radiofrequency ablation in the treatment of varicose veins with respect to; 1) duration of procedure, 2) postoperative pain, 3) complications, 4) duration of stay in hospital and 5) return to normal routine work.

Prospective comparative study in which 60 patients were divided randomly into two treatment groups-conventional surgery and radiofrequency ablation (RFA), for treatment of varicose veins, each treatment group comprising of 30 patients. The level of significance was set at a p value less than 0.05.p-value was found to be significant for duration of surgery (0.00), duration of stay in hospital (0.00), average pain score (0.00), average intake of oral analgesics (0.00), ambulation period (0.00), and resumption of normal activities (0.00) in RFA group. Complications did not vary significantly in both groups.

Compared to stripping and ligation, RFA has a number of benefits including less pain and cost.

Key words: Varicose veins, treatment, stripping, ligation, and radiofrequency ablation.

ÖZET

Klasik cerrahi tedavi ve radyofrekans ablasyon tedavisinin etkinliği; işlem süresi, postoperatif ağrı, komplikasyonlar, hastanede kalma süresi ve işe dönüş kriterleri bakımından prospektif olarak değerlendirildi.

Prospektif çalışmada 60 hasta randomize olarak klasik tedavi ve radyofrekans ablasyon (RFA) grubu olmak üzere iki gruba ayrıldı. Sonuçlar p- value testi ile p>0.05 olarak değerlendirildi. Cerrahi ve RFA yapılan gruplar arasındaki sonuçların p-value değeri ameliyat süresinde, hastanede kalma süresinde, ağrı skorunda, ağrı kesici kullanma bakımından, ayağa kalkma dönemi ve normal işe dönüş bakımından 0.00 olarak değerlendirildi. Komplikasyonlar arasında anlamlı bir farklılık yoktu.

RFA işleminin striping ve ligasyon işlemine göre daha az ağrılı ve daha düşük maliyetli olması bakımından daha avantajlı olduğu saptanmıştır.

Anahtar kelimeler: Variköz venler, tedavi, striping, ligasyon ve radyofrekans ablasyon.

INTRODUCTION

The description of varicose veins as a clinical entity can be traced back as early as the fifth century BC. Forefathers of medicine including Hippocrates and Galen described the disease and treatment modalities, which are still used today. Varicose veins are veins that have become enlarged and tortuous. The term commonly refers to the veins on the leg, although varicose veins can occur elsewhere (1).

Varicose veins are most common in the superficial veins of the legs, which are subject to high pressure when standing. Besides cosmetic problems,

varicose veins often itch and are painful, especially when standing or walking. Though varicose veins rarely present with an acute emergency or life threatening complication, symptoms like dragging sensation, heaviness, pain, bleeding, ulceration or lipodermatosclerosis require an active intervention to get relief from the disease.

Non-surgical treatments include, compression elastic stockings, elevating the legs, and exercise. The traditional surgical treatment has been vein stripping to remove the affected veins. Because most of the blood in the legs is returned by the deep veins, the superficial veins, which return only about 10 per cent of the total blood of the legs, can usually be removed or ablated without serious harm (2,3). Conventional surgery (stripping of the veins) has been the time tested modality of treatment for varicose veins. But newer modalities have arisen which are less invasive. Newer, less invasive treatments, such as ultrasound-guided foam sclerotherapy, radiofrequency ablation and endovenous laser treatment, are slowly replacing traditional surgical treatments. Further experience with these procedures will help to determine which one will become method of choice for treating this complex disease process.

Increasingly well informed patients who pressure the treating surgeon for cosmetically acceptable results in conjunction with expansion of minimally invasive techniques have made the treatment of superficial venous reflux and varicose veins a rapidly evolving field. It is very likely that some of these procedures like RFA will replace the procedures that we currently use today (4). In our study we will focus on the various aspects of conventional surgery and radiofrequency ablation and make a comparison between the two modalities.

MATERIAL AND METHOD

This was a prospective study comparing radiofrequency ablation and conventional surgery in the management of varicose veins of lower limbs. It was performed between November 2010 and April 2012. 60 patients were randomized to one of the two treatment groups in 1:1 ratio for management of varicose veins. Patients were selected using random number table. The protocol was approved by the ethical review board of the institute. According to the principles of the declaration of Helsinki1975, written, informed consent was obtained from all participants.

All patients presented in outpatient department were assessed. 68 patients were enrolled , 8 excluded. Participants were aged between 15 and 62 years. Inclusion criteria were- all the patients with features of chronic venous insufficiency underwent screening with venous colour Doppler and the subjects with great saphenous vein (GSV) varicosity with incompetent SFJ (Sapheno Femoral Junction) were considered for the study, varicose veins along with its complications like: venous ulcers, lipodermatosclerosis. Exclusion criteria were- subjects with short saphenous vein varicosity, with only perforator incompetency, with past or present deep vein thrombosis, recurrent cases of varicose veins, patients with severe co-morbidities not able to sustain anaesthesia.

A thorough history was taken and physical examination was done with emphasis on lower limb examination for varicose veins and SFJ incompetence. All patients presenting with saphenous varicosity were subjected to bilateral venous doppler and information on SFJ incompetence, perforator status, deep vein status, short saphenous varicosity and sapheno popliteal junction incompetence was collected.

All the patients selected for surgery were counselled about the procedure. The Sapheno femoral site was marked with Doppler on the day of surgery. The procedure was done under either general,regional or local anaesthesia. Intra operatively patients were assessed for “time taken for the procedure” and postoperative assessment was done for;

1.Pain; Monitored by visual analogue scale (VAS) over 0-10, at day 1, 3 and 7 of surgery. Pain killers after day 1 were used on SOS basis. Medicine used was Diclofenac sodium (50 mg).

2. Local side effects; Bruising, oedema, skin damage, haematoma, pain, tingling sensation etc.

3. Duration of stay in hospital.

4. Return to routine work meaning thereby patient resumed his/her work as before surgery.

5. All patients who underwent RFA were given deep vein thrombosis prophylaxis (DVT) for 1week & venous Doppler to look for DVT and completion of ablation was seen at 7th day.

Conventional Surgery Group;

All patients were operated under local/regional anaesthesia. SFJ was marked before surgery. Perforators and cluster veins were also marked. Trendelenberg operation was done in classical way and then vein was stripped up to below knee from below upwards. Perforators below this level were ligated and cluster veins avulsed by multiple small stab incisions. Compression bandage were applied from below upwards and was first removed on Day 3. Patients were ambulated 12 hours after surgery as per patient’s convenience. 8 hourly analgesics were given orally on post-operative day 1 and then switched to SOS Diclofenac from day 2 onwards. On day 3 patient’s dressing was opened to see for any complications. No DVT prophylaxis was given in this group. Venous Doppler findings were recorded on day 7.

Radio Frequency Ablation Group;

Patients were operated under local anaesthesia. Machine used was Celon Precesıon(200-240 V) SFJ and entire course of GSV was marked under USG guidance. Tumescent anaesthesia infiltrated along the whole course of GSV. Great saphenous vein was assessed 2cm above the medial maleolus by making a small venous cut down. RFA probe inserted at this point and passed upwards below 2cm to SFJ. A tem-

perature of 85-120 C was generated and the probe pulled slowly downward while ablating the vein. A continuous beep sound heard, indicating proper ablation. Any interruption of the sound indicated faulty ablation and the procedure stopped for a moment. The procedure started again from that point onwards and completed while obtaining continuous sound. Local cooling along the GSV was maintained throughout the procedure. Post operative management was based on same guidelines as conventional surgery but here DVT prophylaxis was given in form of inj. clexane 0.4 ml O.D. for one week.

Statistical Analysis;

All the data collected from both the groups were tabulated and analysed, mean and standard deviation were calculated for continuous variables. Comparison of categorical variables was performed by chi square analysis or Fisher's exact test. The continuous variables were assessed by student t-test. The level of significance was set at $p< 0.05$.

RESULTS

General characteristics:

The age of the patients in this study ranged from 15 to 62 years with mean of 38.67 yrs. 19 out of 60 patients (31.67%) were in the age group of 31-40 years. Out of 60 patients, 31(51.67%) were males and 29 (48.33%) were females.

Average Duration of Surgery:

Average duration was far less for RFA than Stripping and Ligation. In RFA, the average time was 28.8 minutes, with maximum patients 21/30 (70%) got operated in 20-30 minutes, while in stripping and ligation group, average time required was 51.3 minutes with maximum number ofpatients i.e. 16/30 (51.33%) got operated in 50-60 minutes (Table1). The result was grossly significant with p value 0.000.

Average duration of stay in the hospital:

The mean duration of hospital stay in RFA group was 4.6 days, whereas in Stripping Ligation group, it was 8 days, with a p value of 0.000, showing gross significance. The duration of hospital stay clearly favoured RFA group. Maximum no. of patients in RFA group 14/30 (46.67%) stayed in hospital for 4 days whereas in stripping ligation group 12/30(40%) patients stayed for 8 days (Table 1).

VAS Pain Score POD 1

The patients who underwent RFA experienced less pain than those who underwent Stripping and Ligation. The severity of pain on p*ost operative day* (POD) 1 as measured on Visual Analogue Scale 0-10, showed an average pain score of 3.5 in RFA group whereas it was 7 for Stripping Ligation group. In RFA group maximum number of patients i.e. 14/30(42.67%) reported mild pain (VAS score 3)whereas 12/30(40%) patients in Stripping Ligation had pain score of 8 on VAS (Table 2).

VAS Pain Score POD 3

On POD 3, the pain score reduced significantly in RFA group patients, as maximum patients experienced mild pain or none on VAS. 23/30 patients (72%) in RFA group had pain of 1-2 on VAS but pain score was on higher side 4-5 for maximum 17/30(57.67%) in Stripping and Ligation group. Average pain score for RFA group patients was 1.4 but in Stripping and Ligation group it was 4.3 (Table 2).

VAS Pain Score POD 7

On POD 7, the patients in RFA group did not complain of any pain, VAS score 0 for maximum 26/30(86.67%). Whereas in stripping Ligation Group, the patients still complained of mild pain in groin area with VAS 2-3. Average pain score in RFA group patients was 0.1, but for Stripping Ligation patients it was 1.8 (Table 2).

Oral Analgesics POD 2

Average Oral analgesic requirement for Stripping Ligation group on POD 2 was 3 tablets per person. All patients took 3 tabs on POD 2. For RFA group patients the average intake was 2.16 tablets, with maximum number of patients 27/30 (90%) taking 2 tablets on day 2 (Table 3).

Oral Analgesics POD 5

Analgesic requirement was almost nil on POD 5, for RFA group of patients. Maximum no. of patients 23/30(71.67%) did not ask for any analgesic on POD 5. But in Stripping and Ligation group , patients still asked for analgesics, either 2 or 3 tabs were required by every patient in Stripping Ligation group. In RFA the average analgesic required on pod 5 was 0.36 tabs but it was 2.53 tabs for Stripping Ligation group. With a p value of 0.00 again the result favours the RFA group in terms of analgesic requirement (Table 3).

Oral Analgesics POD 7

On POD 7 the patients of RFA group did not ask for analgesics at all except a few ones. But in Stripping Ligation group patients still needed 1-2 tabs to carry out their normal activities smoothly. Average required analgesic in RFA group being 0.10 tabs, as compared to 1.10 tabs in Stripping Ligation group, denotes the better postoperative experience in RFA group patients (Table 3).

Complications

Complications in each group was measured on the above 4 parameters. Though complications did not vary significantly in both the groups, the stripping and ligation outnumbered RFA in complications like haematoma, oedema and bleeding. However bruise occurred more in RFA.

Total number of patients having complications was definitely more in Stripping Ligation group (total-12 patients) as compared to RFA group where a total of 6 patients experienced some sort of complications. The complications were analysed on fisher test ($p = 0.612$, 1.00, 0.2512, and 1.00 for haematoma, bruise, oedema, and bleeding respectively) and chi square test, but the results were not statistically significant.

Table 1: Showing different variables.

Variables		RFA	SL	P value
Average duration of surgery	Average duration (min)	28.8	51.3	0.000
	S.D	5.42	6.19	
Average duration of stay in hospital	Average duration (days)	4.6	8.0	0.00
	S.D	2.31	1.11	
Ambulation period	Average duration (days)	1.46	2.67	0.00
	S.D	0.68	0.60	
Resumption of activities	Average number of days	4.63	7.76	0.000
	S.D	2.73	0.93	
Abnormal Doppler findings on day 7	Patients with abnormal findings	3	1	0.60
	S.D	0.30	0.18	

Number of patients in each group: 30, S.D: Standard deviation, SL: Stripping ligation
RFA: Radiofrequency ablation, SL: Stripping and ligation

Table 2: VAS pain score in post-operative period

VAS pain score		RFA	SL	P value
Post-operative Day 1	Average pain score	3.5	7	0.00
	S.D	0.68	0.85	
Day 3	Average pain score	1.4	4.3	0.00
	S.D	0.85	1.05	
Day 7	Average pain score	0.1	1.86	0.00
	S.D	0.40	0.82	

Number of patients in each group: 30, S.D: Standard deviation, VAS: Visual analogue scale.
RFA: Radiofrequency ablation, SL: Stripping and ligation

Table 3: Average number of analgesics used in post-operative period.

Oral analgesics (post-operative day)		RFA	SL	P value
Day 2	Average number of analgesics	0.37	2.16	0.00
	S.D	3	0	
Day 5	Average number of analgesics	0.36	2.53	0.00
	S.D	0.76	0.50	
Day 7	Average number of analgesics	0.10	1.10	0.000
	S.D	0.40	0.75	

Number of patients in each group: 30, S.D: Standard deviation,
RFA: Radiofrequency ablation, SL: Stripping and ligation

Ambulation Period

Patients were ambulated early in RFA group, with an average of 1.46 days. Maximum number of patients 18/30 (60%) were ambulated on day 1 and others on day 2. The average ambulation period in Stripping Ligation group was 2.67 days with most of the patients 16/30 (53.33%) being ambulated on day 3. Early ambulation favoured RFA group to be a better modality of treatment with regard to quality of life in post-operative period (Table 1).

Resumption of Activities

Resumption of routine activities was earlier for RFA group patients than stripping ligation. As compared to 7-8 days for most patients 20/30(66.67%) of Stripping and Ligation group, the maximum no of patients 20/30(66.67%) of RFA group resumed their activities in 3-4 days only. The average number of days for resumption of activities in RFA group was 4.63 days whereas it was 7.76 days in stripping ligation group. Again, this parameter, with a p value of 0.00, favored RFA over stripping ligation (Table 1).

Abnormal Doppler Finding On Day 7

All of the patients 60/60 were followed up for Doppler on POD 7. Most of the patients Doppler showed thrombosed veins with absence of any flow in GSV. However, in RFA group 3 patients (10%) reported with a mild flow in GSV. In Stripping Ligation group the Doppler showed flow in only 1 patient (average 3.3%). However the result when analysed on chi square test, found to be statistically insignificant. Here, Stripping Ligation group had the advantage over the RFA group by obliterating the vein under direct vision and ultimately being superior to RFA for having less number of incomplete treatment or chances of recurrence (Table 1).

DISCUSSION

Varicose veins affect a significant percentage (40%) of the middle-aged population. It may not cause any mortality in the patients but causes a significant morbidity if left untreated. Itis important to properly localize the problem before surgical management, to avoid recurrence of the disease.

The majority of patients were in the age group of 30-40 years (32 %), i.e. young adults. Age distribution in most studies varied from 30-40 years. In the present study, 52% were males and only 48 % females. But according to the literature, women are affected twice more often than men. This predominance of males in our study might be due to a male dominant society, with more males turning up for the treatment. The common clinical complaints were tiredness and aching sensations in the leg, ankle swelling and cosmetic appearance.

Successful treatment of varicose veins requires a balance between their complete removal with treatment of underlying etiology and an optimal cosmetic outcome. Complete treatment of clinically symptomatic varicose veins must therefore involve treatment of the saphenous vein reflux as well as the varicosities. Current strategies designed to eliminate reflux within the saphenous vein include surgical stripping, radiofrequency ablation (RFA), and endovenous laser ablation.

In our study, a comparison was made between the stripping ligation and RFA on various parameters. These parameters were duration of surgery, hospital stay, postoperative pain and analgesic requirement, complications and resumption of activities.

Technically, stripping ligation was more difficult to perform, requiring a good expertise and also higher chances of femoral artery and vein injury during the surgery. It even became more difficult in obese patients where proper dissection required much more effort. These difficulties were not associated with RFA. The procedure was easier to perform, especially in obese patients. Because no incision was made in the groin, essentially all complications and pain related to this part of the procedure were eliminated.

However RFA required an initial capital investment for equipment and correct identification of the SFJ and GSV with ultra sound is essential for tumescent anaesthesia and proper obliteration of SFJ. That required imaging skills and detailed knowledge of venous anatomy by the surgeon. The average duration of surgery was definitely higher for surgical stripping and ligation in our study. In RFA the average time was 28.8 minutes, with maximum patients 21/30 (70%) getting operated in 20-30 minutes, whereas in Stripping Ligation average time required was 51.3 minutes with maximum number of patients i.e. 16/30 (51.33%) getting operated in 50-60 minutes. Lurie F. et al (5) also in his comparative study between RFA and Stripping Ligation found that RFA required less time as compared to stripping ligation. In RFA the time was less because the procedure consisted of venous cut down and canulation of probe, that did not require much time, whereas Stripping Ligation required meticulous dissection in groin area, searching for all tributaries and also avoiding any sort of major vascular injury in the vicinity. All these factors combine to increase the duration of surgery.

Duration of hospital stay was also more in stripping ligation group patients than RFA patients. The similar results were seen in other study conducted by Elkaffas et al (6). In our study, the mean duration of hospital stay in RFA group was 4.6 days, whereas in Stripping ligation group it was 8 days, with a p value of 0.000, showing gross significance. The duration of hospital stay clearly favored RFA group. The duration of hospital stay was more because of the pain resulting from the dissection in groin area.

Postoperative pain for both procedures was analysed on Visual Analogue Score (0-10). All patients were assessed for pain on POD 1, POD 3 and POD 7. When the patients were asked about the pain in postoperative period, it was found that the patients who underwent RFA had mild to moderate pain in

initial 2-3 days. That pain even reduced to minimal or nil in next few days. But in Stripping ligation group, the severity of pain experienced by the patients was definitely on higher side. An average pain score on POD 1 was 3.5 in RFA group whereas it was 7 for Stripping ligation group. In RFA group maximum number of patients i.e. 14/30(42.67%) reported mild pain (VAS score 3) whereas 12/30(40%) patients in Stripping Ligation had pain score of 8 on VAS. The similar results were observed in other various studies (5-9).

The resulting difference of pain experience may be explained on the basis that tissue handling and amount of dissection was minimal in RFA i.e. amounting only to a venous cut down whereas in Stripping ligation, gross dissection had to be done in groin area. The more the amount of trauma to tissue, more the amount of pain resulted. The pain score on POD 3 and POD 7 also showed the same results. Average pain score on POD 3 for RFA group patients was 1.4 but in Stripping ligation group it was 4.3. On POD 7, the patients in RFA group did not complain of any pain, VAS score 0 for maximum 26/30 (86.67%).

Where as in SL Group, the patients still complained of mild pain in groin area with VAS 2-3. Average pain score in RFA group patients was only 0.1, but for SL patients it was 1.8. This single parameter of markedly less post-operative pain in RFA makes it a modality of choice for treatment of varicose veins. Others authors also recommend RFA over SL on this factor. Since every patient wants to avoid pain, be it intra operative or postoperative, and RFA stands better on this ground so RFA is going to replace other treatment modalities and would be considered the procedure of choice in future RFA being less painful required less number of analgesics. The patients of this group took 2-3 tabs on POD 2 to stay pain free. Average Oral analgesic requirement for SL group on POD 2 was 3 tabs per person. All patients had to take 3 tabs on POD 2 to be free from pain. For RFA group patients the average intake was 2.16 tabs, with maximum number of patients 27/30 (90%) taking 2 tabs on day 2. The patient compliance was definitely better in RFA group.

Analgesic requirement was almost nil on POD 5 for RFA group of patients. Most of the patients 23/30 (71.67%) did not ask for any analgesic on POD 5. But in stripping ligation group, patients still asked for analgesics, and 2 or 3 tablets were required by every patient in stripping ligation group. Also it was observed that in RFA group, patients became relatively pain free on 3rd or 4th postoperative day only but there was only partial relief for SL group even on 5th postoperative day.

The ambulation period also followed the same trend for both the groups. Patients were ambulated early in RFA group, with an average of 1.46 days. Maximum number of patients 18/30 (60%) were ambulated on day 1 and others on day 2. The average ambulation period in Stripping Ligation group was 2.67 days with most of the patients 16/30 (53.33%) being ambulated on day 3. The early ambulation was possible because of the pain free status of the patient in RFA group. Early ambulation again favoured RFA group to be a better modality of treatment with regard to quality of life in postoperative period. Subramonia et al (10) and Lurie F et al (5) also in their study favoured RFA on early ambulation and better quality of life in postoperative period.

The resumption of activities occurred earlier in RFA group. As compared to 7-8 days for the patients (20/30 (66.67%)) of stripping ligation group, the maximum no of patients (20/30 (66.67%)) of RFA group resumed their activities in 3-4 days only. The average number of days for resumption of activities in RFA group was 4.63 days whereas it was 7.76 days in SL group. Again, this parameter, with a p value of 0.00, favored RFA over SL. The earlier resumption of activities makes RFA a preferred choice of treatment as it saves time, reduces financial burden and provides a psychological support of well being in very early post-operative period.

In this study, some complications occurred more in RFA group and others in SL group. Though complications did not vary significantly in both groups, the SL outnumbered RFA in complications like haematoma (1 in RFA, 3 in SL), oedema (2 in RFA, 6 in SL) and bleeding (1 in RFA, 2 in SL). This may be attributed to the gross amount of dissection required in stripping and ligation where as in RFA dissection was minimal in form of venous cut down only. However, bruise (2 in RFA, 1 in SL) occurred more in RFA. Bruise may have occurred at the time of withdrawal of hot catheter tip mistakenly touching the skin. However, total number of patients having complications was definitely more in SL group (total-12 patients) as compared to RFA group where a total of 6 patients experienced some sort of complications. In EVOLVES study (11) and another study conducted by Elkaffas et al (6) similar results were obtained, and they also supported RFA having fewer number of complications.

Some patients also reported with complain of paraesthesia around the ankle in postoperative period. That may be due to the injury to saphenous nerve that lies in close proximity of GSV. Paresthesia slowly reduced with time and disappeared in those cases even without any active management.

In a period of one week follow up, the completeness of the procedure was assessed. All of the patients 60/60 were followed up for Doppler on POD 7. Most of the patients Doppler showed thrombosed veins with absence of any flow in GSV. However, in RFA group 3 patients (10%) reported with a mild flow in GSV. Merchant et al (12), Chandler et al (13), Weiss and Weiss et al (14) and EVOLVES study (11) also reported the similar achievement of complete obliteration of GSV in approximately 90-95% cases of RFA group. The failure in RFA group was due to inability to pass catheter through the GSV to the SFJ

in one patient and indeterminate vein contracture in another case in which catheter was used in large vein. In SL group the Doppler showed flow in only 1 patient (average 3.3%). However the result when analysed on chi square test, found to be statistically insignificant. Here, SL group had the advantage over the RFA group by obliterating the vein under direct vision and ultimately being superior to RFA for having less number of incomplete treatment or chances of recurrence.

In conclusion, compared to SL, RFA has a number of benefits; 1) it is relatively fast and safe, (2) there is no use of general anesthesia, (3) done with a very small incision, (4) less extensive procedure, (5) minimal pain after the procedure, (6) less bleeding and haematoma and thus less pain, (7) little downtime, most individuals are able to return to work in 4-5days and (8) overall patient satisfaction is more. There is growing clinical evidence that RFA of the saphenous vein is beneficial. Results from ablation of the saphenous vein are as good or better as those from the conventional surgical treatment. Imaging studies show that the treated vein disappears as a defined ultrasonographic object after the procedure. Clinical observations suggest that patients are much more comfortable in the early postoperative period and experience quicker recovery after saphenous vein ablation compared with surgical stripping. Also there is a cost saving for employed patients after RFA because physical function is restored earlier. So, our study recommends RFA as a preferred modality over stripping ligation for the treatment of varicose veins.

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