

Sono-Guided Endostripping: An Appropriate Alternative for Endovascular Varice Procedures

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Abstract

Objective: This article is aimed at introducing Sono-Guided Endostripping Technique of the Great Saphenous vein and comparing it with radiofrequency ablation in 104 patients. **Methods:** 52 patients underwent Sono-Guided Endostripping and 52 patients had radiofrequency ablation with Celon Olympus device. They were followed for 3 months with physical examination and Doppler Sonography for possible complications and recanalization. **Results:** Recanalization rate was 11.5% in RFAs while it was 0.0% in the Endostripping group. There were no significant differences for other complications (hematoma, DVT, paresthesia) but pain, which had 1.21 and 3.15 VAS scores for RFA and Endostripping groups, respectively. Recanalization rate was more in RFA comparing with the Endostripping group (11.5% vs. 0.0%, $P < 0.013$). RFA was more expensive. **Conclusion:** Sono-Guided Endostripping is a safe and cost-effective method (due to no need for using RFA probe); however, the patient must be admitted to the hospital and take appropriate anesthesia. Cosmetic result of the technique is fairly comparable with RFA scars in the thigh and leg.

Keywords

Catheter Ablation, Saphenous Vein, Surgical Procedures, Varicose Veins-Surgery

1. Introduction

Lower extremity venous insufficiency is a major health problem in the Western World and often impairs the

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quality of life [1] [2]. The prevalence of this condition is estimated to be in range of 30% to 35% in women and 10% to 15% in men in Western society [2]. The possible risk factors include family history, increased age, female gender, pregnancy [3]. The disease most commonly arises from a reflux in the great saphenous veins secondary to an incompetent saphenofemoral junction [1] [2]. Some patients with varicose veins will go on to develop serious complications including pain, haemorrhage, thrombophlebitis and venous ulcer [3].

The treatment of this disease may be for either cosmetic or symptomatic reasons [2] [3]. Commonly, patients undergo a trial of therapy with prescription-strength compression stockings while other conservative treatment options include doing regular exercise, weight loss, and elevation of the legs whenever possible [3]. However, none of these therapies, including compression therapy, will really cure the underlying disease process and the majority of patients seek more definite interventional treatments [3]. Historically, the traditional treatment for the condition was surgical stripping and ligation with ancillary phlebectomy of tributary varicose veins [2] [3].

Surgical treatment, based on clinical presentation and underlying pathophysiology, has been shown to improve the quality of life [1] [4]. Over 30,000 operations are performed annually for varicose veins in England and Wales [1]. However, treatment of varicose veins of the lower limb has significantly evolved over the last 20 years [1]-[3] [5]. In patients with great saphenous vein reflux and associated large varicosities, the typical treatment includes thermal ablation of the incompetent vein segment [3] [4]. While endovascular therapies are safe and effective, there are some general exclusion criteria. These include: deep venous thrombosis, pregnancy or planned pregnancy during course of follow-up, severe peripheral arterial disease, and inability to ambulate [3]. Thus, as mentioned above, there have been different methods and procedures to treat varicose veins but this article is intended to present a new technique treating patients with varicose veins named as sono-guided Endostripping.

2. The Technique of Sono-Guided Endostripping

In this procedure, first a vascular sheath is inserted through the saphenous vein at the site localized by sonography without making any incision (**Figure 1**).

This sheath is usually entered around the knee, above the knee or the middle of the thigh so that later, the probe and stripper could be guided toward Saphenofemoral Junction (SFJ) easily and without any sticking or tortuosity (**Figure 2**).

Next, a narrow metal stripper is passed through the sheath toward the SFJ (**Figure 3**). The actual site of the SFJ is also found by sonography.

With making a small incision, about 2 centimeters around the inguinal skin fold, the SFJ branches are ligated and the saphenous vein is brought out easily by Endostripping and inverted Endostripping with minimal hemorrhage and trauma (**Figure 4**).

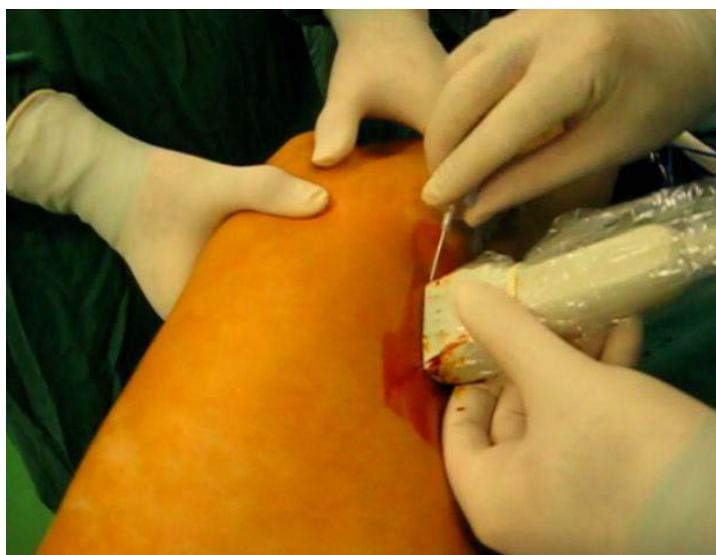


Figure 1. Localizing the insertion site by sonography.



Figure 2. Inserting the vascular sheath through the saphenous vein.



Figure 3. Inserting the narrow metal stripper through the sheath.

3. Materials & Methods

Among patients referring to Vascular Surgery Department of Razi Hospital in Rasht who were candidates for varicose vein surgery (according to the pilot study), 104 ones were selected and enrolled in the study and regarding their selection, they were divided into two groups. 52 patients were treated by means of the new Sono-Guided Endostripping.

On the other hand, the other 52 patients were treated with radiofrequency procedure (by Celon device) by sonography guided pullback method above the knee and sclerotherapy of varicose veins and perforants of the leg.

All patients were interviewed and underwent physical examination in first two weeks and three months after surgery in the clinic for probable complications (pain, thigh and leg paresthesia, haematoma and DVT) also sonography was performed in the third post operation month by a radiologist (who was fully justified about the research) in the clinic for recanalization of the saphenous trunk and DVT.

To evaluate the data, descriptive statistics and diagrams were used and to analyze the data and respond to research theories, Chi square and T-test were applied. The significance rate was $P < 0.05$ in all the tests.

Whereas the Endostripping procedure is sonography guided, it is safer than the traditional procedure, thus as a



Figure 4. Endostripping & inverted endostripping of saphenous vein.

new unique method no special complication or risk would threaten the patients. Despite the facts above, the written consent form was taken from all the patients.

4. Results

The total of 104 patients were included in present study, 52 patients underwent Endostripping surgery (33 men, 19 women, mean age = 45/59 years, range = 19 to 78 years old) and the other 52 patients (23 men, 29 women, mean age = 39/63 years, range = 28 to 52 years old) had RFA as their treatment method. The common complication of the two methods included: hematoma, post-surgical pain, thigh and leg paresthesia & DVT. As shown in **Diagram 1**, 6 patients (11.5%) were found to have recanalization in the third post-RFA Doppler sonography assessment, whereas there were no cases with recanalization in the Endostripping group, thus the difference was significant ($P < 0.013$).

As discussed below there were no cases with early (2nd week) or delayed (3rd month) hematoma in none of the groups. Neither were DVT nor thigh paresthesia cases. 2 patients (3.8%) had leg paresthesia in 3rd month follow-up in the Endostripping group which was statistically insignificant ($P < 0.248$).

In order to evaluate the post-surgical pain, the VAS score was used. As shown in **Diagram 2**, the mean scores were 1.21 (SD = 0.49) and 3.15 (SD = 0.69) in RFA and Endostripping groups, respectively. The difference of post-surgical pain was significant between two groups ($P < 0.001$) (**Diagram 2**).

Comparing the costs of the two procedures, the probe expenses in RFA was significantly higher than the utilities used in the Endostripping technique but the expenses relating to the admission and anesthesia counterbalanced the thrift.

The duration of performing the two procedures were 58 and 47 min for RFA and Endostripping, respectively. The difference was statistically significant ($P < 0.001$).

5. Discussion

After a century of study on treatment of varicose veins, yet questions about the best treatment procedure for the disease remain unsolved. Application of neovascularisation after groin exploration is still controversial and it is not quite clear how much effective the ligation of lateral proximal branches of saphenous vein could be in prevention or decrease in recurrence of the disease [5].

Regarding this fact, it's still not possible to state that the recurrence and recanalization rates in procedures with ligating SFJ branches (e.g. the former traditional surgery or the new sono-guided Endostripping technique) are less than the procedures without ligating SFJ branches (e.g. RFA).

Most surgeons believe that ligation of SFJ and stripping (extracting) the insufficient saphenous vein is the most effective way to treat varicose veins and also better results are achieved when the stripping is limited to a

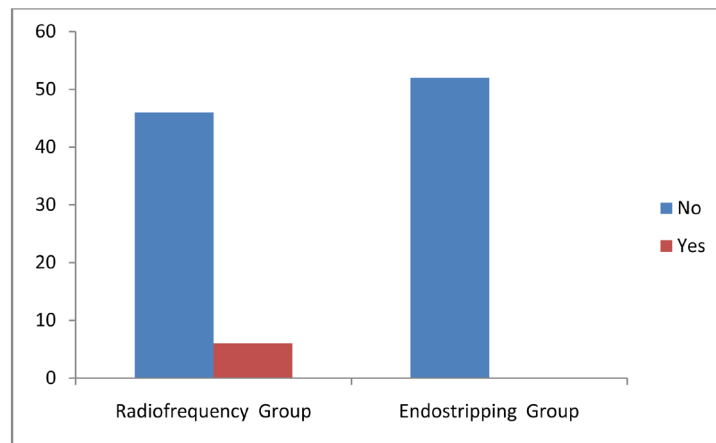


Diagram 1. Recanalization in two groups.

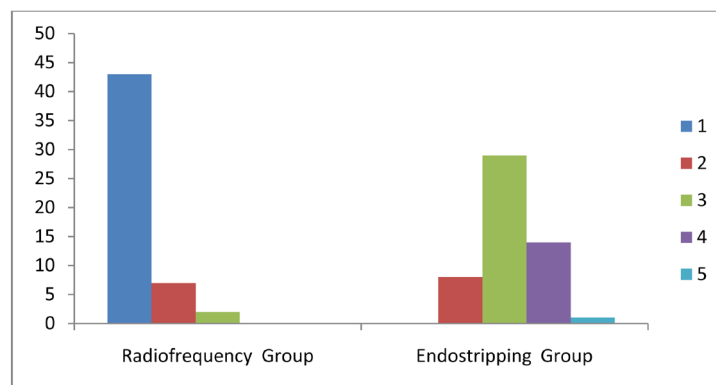


Diagram 2. Pain in two groups based on vas score.

short segment of vein (which is located between the groin and the knee), therefore, the possibility of saphenous nerve injury is less [6] [7].

Yet, the best stripping technique, amount of expenses, possible complications and recurrence rate of minimally invasive procedures such as RFA and comparing them with surgical procedures remain controversial [7].

In most studies comparing the recurrence and recanalization rates, there were no significant differences between surgery and RFA method [8]-[10]. In present study, the recanalization rates were 11.5% (6 cases) for RFA and 0% (no cases) for Endostripping group which was statistically significant ($P < 0.013$).

This difference and the significant recanalization rate found in RFA procedure could be due to the use of Celon device in the study compared with other studies replacing Celon with Closure Fast (VNUS) devices.

On the other hand, it's possible that by using Doppler sonography and cannulation of saphenous veins in the most inferior extreme segment on the thigh and also defining collateral branches and the two saphenous veins, recanalization is far less in Endostripping procedure than the other methods.

Although if the recanalization is found in follow-ups, the defect can be resolved by foam sclerotherapy which was done for these patients and acceptable results were achieved. However, there still exists no long-term information about the results of foam sclerotherapy.

Among previous studies which compared RFA with surgery, there was a remarkable difference in pain rates between the two groups [11]-[13]. The average pain rates were 1.7 and 4 in RFA and surgery procedures, respectively (based on Vas score) (in range of 1 to 10) [13].

In present study as well as previous ones, the pain rate in RFA method was significantly less than the Endostripping procedure ($P < 0.001$). These rates were 1.21 and 3.15 in RFA and Endostripping procedures, respectively (based on Vas score).

Most studies revealed the same complication rates for both RFA and surgery groups and only in one study, minor complications (e.g. ankle paresthesia) were more [11] [12] in surgery and haematoma was significantly

less in RFA than in surgery [14]. In present study, the complication rates weren't significantly different as well as most of the previous studies.

Among studies comparing the expenses of the procedures, the amount of expenses for RFA procedure was a little more than surgery in one study (1275.9 £ vs. 559.12 £) [1] [12] while in another one, this difference between expenses was not significant (3396 € vs. 3084 €). In our effort, the RFA expenses are significantly higher than the Endostripping procedure performed in private services (15,000,000 Rials vs. 11,000,000 Rials).

In a prior study, the mean times of performing the procedures were reported about 76 and 48 mins for RFA and surgery, respectively [13]. In ongoing study, these were 58 and 47 min for RFA and Endostripping procedures, respectively (the latter less than the former) which was statistically significant and even less than the previous studies ($P < 0.001$).

Since in our procedure which is being introduced for the first time, sonography is exploited for guiding the cannulation of the distal segment of saphenous vein, exploration and dissection compared with former traditional surgical method is less required (even compared with the most similar procedures which dissection is performed without sonography for saphenous stripping and exploration of SFJ). In this novel method, pain and haemorrhage rates are less in addition to no incisions around the knee [15].

Sonography is also used to better guide the stripper for cases in which passing the stripper toward the SFJ is not easily achieved. However, in non sono-guided procedures, the passage of stripper results in soft tissue injury and is time-consuming. Moreover, in cases with crotch saphenous veins, sonography is also used to either find and extract the crotch or significantly prevent the recurrence rate.

Since technologies such as radiofrequency are counted as importing technologies in Iran beside the fact that the new surgery technique (sono-guided Endostripping) is not so dependent on technology, it seems that if we find solutions for better pain management and using appropriate anesthetic methods, this new procedure can be used as a safe and cost benefit method to treat varicose veins with less expenses, and the same complications and cosmetic results compared with RFA. Furthermore, the recanalization rate in this method is less than RFA. Yet, the long-term recurrence rate necessitates more years of follow-up.

In conclusion, based upon our study we propose that in future studies the follow-up visits increase up to two years in order to evaluate the long-term recurrence rates for the RFA and Endostripping procedures. We also suggest the sample size increase and weighing the blood gases (before and after surgery) with a digital balance to accurately measure the intraoperative haemorrhage rate. To reduce the possible decrease of recanalization in RFA method, applying newer effective devices instead of Celon is highly recommended for further studies.

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