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ARAŞTIRMA YAZISI / ORIGINAL ARTICLE

Endovenous Laser Ablation of Varicose Veins of the Lower Extremities: Report of the relationship Between Vascular Access And Procedural Pain

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ABSTRACT

Objective: The aim of this study is to evaluate the effects of vascular access (proximal or distal) on postoperative pain in patients diagnosed with isolated varicose small saphenous vein who underwent endovenous laser ablation.

Materials and Methods: Medical records of 49 patients (35 female, 14 male) with isolated saphenous venous insufficiency were reviewed. Endovenous laser ablation was performed in all patients at an emission wavelength of 1470 nm, using 7 Watt laser energy at the proximal and distal ports. The pain was evaluated using a visual analog scale at 7 days, 1, 3 and 6 months.

Results: In 30 of the 49 patients, vascular access was performed from the distal to the below the knee section of the small saphenous vein and in 19 cases from proximal to the small saphenous vein. The results of these two groups showed that access into the larger proximal part of the varicose vein provides an easy route with reduced local pain scores in the endovenous laser ablation of varicose veins ($p<0.001$).

Conclusion: In patients diagnosed with isolated varicose small saphenous vein and undergoing endovenous laser ablation, the vascular access route (proximal or distal) did not have a significant effect on postoperative pain, but the proximal route was more easily accessed and the procedure lasted shorter.

Keywords: Laser therapy, saphenous vein, visual analog scale

ALT EKSTREMİTE VARİKÖZ VENLERİNİN ENDOVENÖZ LAZER ABLASYONU: VASKÜLER GİRİŞ YERİNİN İŞLEME BAĞLI AĞRI İLE İLİŞKİSİNİN RAPORLANMASI

ÖZET

Amaç: Bu çalışmanın amacı izole variköz küçük safen ven tanısı alan ve endovenöz lazer ablasyon uygulanan hastalarda vasküler giriş yolunun (proksimal veya distal) postoperatif ağrı üzerine olan etkilerini değerlendirmektir.

Gereç ve Yöntemler: Çalışma izole küçük safen venöz yetmezlik tanısı alan 49 hastanın (35 kadın, 14 erkek) tıbbi dosyaları taranarak yapıldı. Endovenöz lazer ablasyonu tüm hastalarda 1470 nm emisyon dalga boyunda, proksimal ve distal girişlerde 7 Watt lazer enerjisi kullanılarak gerçekleştirildi. Ağrının değerlendirilmesi görsel analog skala kullanılarak 7. gün, 1., 3. ve 6. aylarda yapıldı.

Bulgular: Kırk dokuz hastadan 30'unda küçük safen veninin dizaltı distal kesiminden ve 19'unda da küçük safen venin proksimalinden giriş yapıldı. Bu iki grubun sonuçları variköz venin proksimal geniş olan kısmından erişilebilmesinin, variköz venlerin endovenöz lazer ablasyon tedavisinde azalmış lokal ağrı skorları ile kolay bir yol sağladığını göstermiştir ($p<0,001$).

Sonuç: İzole variköz küçük safen ven tanısı alan ve endovenöz lazer ablasyon uygulanan hastalarda vasküler giriş yolunun (proksimal veya distal) postoperatif ağrı üzerine anlamlı bir etkisi olmasa da, proksimal giriş yolunun daha kolay erişildiği ve bu yolla işlemin daha kısa sürdüğü görülmüştür.

Anahtar sözcükler: Lazer tedavisi, safen ven, görsel analog skala

Symptomatic varicose veins and chronic venous insufficiency are common problems that worsen the quality of life (1, 2). The main principle for management is that priority must be given to handling venous reflux. Otherwise, the failure of elimination of the cause will inevitably lead to the occurrence of varicose veins. Even though open surgery constitutes the conventional mode of treatment, minimally invasive and endovascular approaches have been popularized such as radiofrequency ablation, ultrasound-guided foam sclerotherapy, and endovenous laser ablation (EVLA) (3–5).

After the first successful results reported by Navarro, EVLA has become a reliable alternative method in the treatment of saphenous vein reflux (6). This novel method has provided lower rates of recurrence compared to traditional options such as ligation of sapheno-femoral junction and stripping of the saphenous vein (7–9). Pain is a common complaint encountered after EVLA, and it tends to subside within a few weeks (8, 9). It has been reported that there is no correlation between the pain experienced after EVLA and the deposition of laser energy (10).

Laser treatment displays its effect via the thermal destruction of vascular endothelium resulting in occlusion of the vein. In addition to the success rate comparable to that of conventional surgery, EVLA may bring about complications such as pain, ecchymosis and hematoma (11).

The aim of the current study was to assess and report the postoperative pain in patients treated with EVLA with 1470 nm wavelength and two different routes of access (proximal and distal part of small saphenous vein).

Patients and Methods

Study design

This study was carried out in 2012 in the Radiology Department of Kelkit Government Hospital. Data derived from 49 patients complaining of symptomatic varicose small saphenous veins were analyzed.

Standard history, routine physical examination and color Doppler ultrasound scanning were performed in all patients prior to EVLA.

In routine clinical practice, access to the varicose vein is achieved through an ultrasound guided puncture at the most distal point where insufficiency is detected (Distal Route Group). However, as the diameter of the small saphenous vein is larger proximally, the intervention was performed through the proximal site in a subgroup of patients (Proximal Route Group).

As a result, the patients were divided into proximal access (3 cm distal from the saphenopopliteal junction) and distal access (the most distal part where the small saphenous vein insufficiency and dilatation began) groups according to the vascular access sites.

Exclusion criteria for EVLA treatment consisted of a history of superficial thrombophlebitis, aneurysmal veins with a diameter >2.0 cm, impalpable foot pulses, deep venous thrombosis, incompetent perforator veins, additional great saphenous vein insufficiency, pregnancy, breastfeeding or poor general condition. Subsequent to initial consultation and evaluation, patients who accepted EVLA as an alternative modality to surgery were treated.

Color Doppler ultrasound scanning

All procedures were performed under the supervision of the senior author (Kosti Can Çalışkan, KCC). Patency of the deep veins and the competence of the superficial veins were evaluated by the same experienced vascular radiologist (Emin Çakmakcı, EC). The reflux was assessed with the patient in the erect position, weight bearing on the other leg, after manual calf compression. Venous reflux was defined as a reverse flow of more than 0.5 sec. Symptomatic cases with varicose small saphenous veins were addressed as candidates for EVLA. Route of access (distal or proximal) was chosen according to the preference of the consultant physician of the patient.

Laser technique

Laser fibers were placed with ultrasound guidance in both study groups. After the laser fiber was placed, the anesthetic solution was given to the perivenous area with a 50 cc syringe with ultrasound guidance along the procedure. Tumescent local anesthesia composed of prilocaine (30 cc) with 0.2 cc adrenaline and 5 cc of sodium bicarbonate diluted in 50 mL of cool saline was administered to the perivenous space under sonographic guidance. After the insertion of the laser fiber, a total energy of 7 W was delivered at 1470 nm wave-length. The VenaCure EVLT™ (*Angiodynamics, Queensbury, NY, USA*) generator was used to apply laser energy. Compression stocking was made as soon as the procedure is over and patients were observed for several hours in the ward. Patients were instructed to wear the compression stockings for 24 hours for the first week, and during daytime only for the following 3 weeks. Topical chondroitin polysulfate (*Hirudoid Forte Creme®*,

Santa Farma, Istanbul, Turkey) was locally administered after the first week, when socks were removed and worn 30 min before. The patients carried on their routine daily activities; however, strenuous exercise was omitted for 1 week. Compression therapy was continued for up to two months in patients suffering from pain and tenderness.

Outcome parameters

Descriptive data, as well as the procedural details (the amount of energy applied, the duration of the intervention, number of attempts for access, and the duration of access) and visual analogue scales indicating pain severity of our series were noted from the charts of the patients. These parameters were reported in patients with proximal and distal routes of access for saphenous veins. Patients had been controlled routinely 1 week after the intervention. Evaluation of pain was made at 1st week, 1st month, 3rd and 6th month after EVLA by means of a visual analog scale (VAS) rating of 0 (no pain) to 10 (excruciating pain) for each leg separately in successive times after the procedure (12).

Statistical analysis

Data were analyzed using the Statistical Package for Social Sciences 21.0 for Windows (SPSS Inc., Chicago, IL). Parametric tests were applied to data of normal distribution and non-parametric tests were applied to data of questionably normal distribution. Independent-samples t-test was used to compare independent groups; while, the paired-samples T-test was used to compare dependent groups. To calculate the correlation coefficient, Spearman/ Pearson correlation test was used. Data are expressed as mean ± SD or median (interquartile range), as appropriate. All differences associated with a chance probability of. 05 or less were considered statistically significant.

This study was performed using the medical files of patients in two institutions subsequent to the approval of the Institutional Review Board.

Results

This study was performed using data extracted from files of 49 patients with symptomatic varicose veins treated with EVLA. Descriptive data and procedural information are demonstrated in Table 1. The distal route of access was the treatment of choice in 30 patients. Of these 30 patients, 15 were treated in both legs, 14 were in the left legs, and one patient was treated in the right leg. Totally 45 legs were included in the distal route group. The proximal route of access was the treatment of choice in 19 patients. Of these 19 patients, six were treated in both legs, five were in the left legs, and eight patients were treated in the right legs. Totally 25 legs were included in the proximal route group. Distal Route Group included 30 patients (4 males, 26 females) with a mean age of 48.67±7.85 years. Proximal Route Group included 19 patients (10 males, 9 females) with a mean age of 52.79±11.20 years. Both groups did not differ from each other by means of age (p=0.723), and differ significantly for gender (p=0.003). As for the intervention, the amount of energy applied, the duration of the intervention, the number of attempts for access, and the duration of access were all significantly different for both groups and in both legs (Table 1).

The alteration of VAS for grading pain over time in patients with a proximal or distal route of endovascular access is demonstrated in Table 2 and Figure 1. No difference was observed between the two groups in the follow-up period.

Table 1. Characteristics and procedural details compared in patients with distal and proximal routes of access for EVLA

Variable	*Route of access*		*p value*
	Distal (n=30)	*Proximal (n=19)*	
Gender			
Female	26 (86.7%)	9 (47.4%)	0.003*
Male	4 (13.3%)	10 (52.6%)	
Height (cm)	166.10±7.39	168.47±5.12	0.227
Weight (kg)	75.10±12.68	78.89±13.21	0.32
Age (years)	48.67±7.85	52.79±11.20	0.136
Left leg			
Energy (J)	1478.00±689.16	688.09±240.86	0.001*
Duration (msn)	173.97±42.84	69.18±23.97	<0.001*
No. of attempts for access	3.38±1.08	1.27±0.47	<0.001*
Duration of access (min)	4.14±1.73	1.50±0.45	<0.001*
Right leg			
Energy (J)	1924.38±1053.06	827.79±391.90	<0.001*
Duration (msn)	207.56±53.65	82.79±39.17	<0.001*
No. of attempts for access	3.69±0.79	1.21±0.43	<0.001*
Duration of access (min)	4.72±1.78	1.18±0.37	<0.001*

cm, centimeters; J, joules; msn, milliseconds; min, minutes

Table 2. A visual analog scale indicating pain scores at various time intervals in the legs with proximal and distal routes of access to the saphenous vein

Variable		*Route of access*		*p value*
		Distal (n=45)	*Proximal (n=25)*	
VAS	Basal	2.97±1.03	4.84±0.96	< 0.001
	Postoperative 7th day	2.73±0.94	2.84±0.83	NS
	Postoperative 1st month	1.47±0.63	1.47±0.61	NS
	Postoperative 3rd month	0.63±0.49	0.68±0.48	NS
	Postoperative 6th month	0.07±0.25	0.05±0.03	NS

VAS, visual analogue scale; **NS**, not ssignificant.

Even though minor side effects like hematomas and paresthesia were noted, we did not come across any major complications such as deep venous thrombosis, pulmonary embolism or skin ulceration. The duration of access to the small saphenous venous via proximal or distal routes is shown in Figure 2.

Correlation analysis of variables revealed that age (rs=-0.425, p=0.048) was negatively correlated with basal VAS scores; while the number of attempts for access (rs=-0.559, p=0.001), and duration of access (rs=-0.564, p=0.001) were positively correlated with basal VAS scores (Table 3).

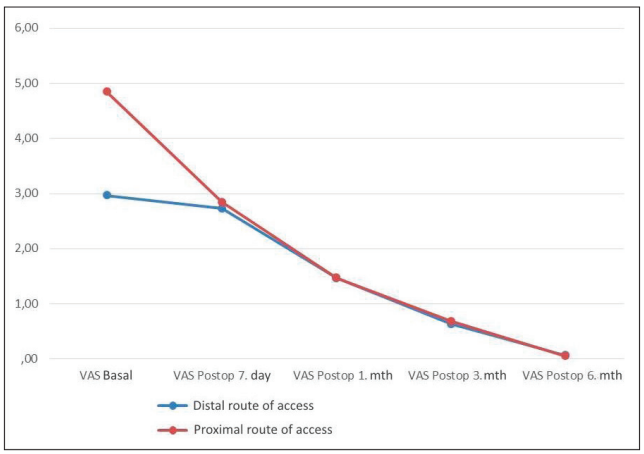

Figure 1. The course of visual analogue scales for pain over time.

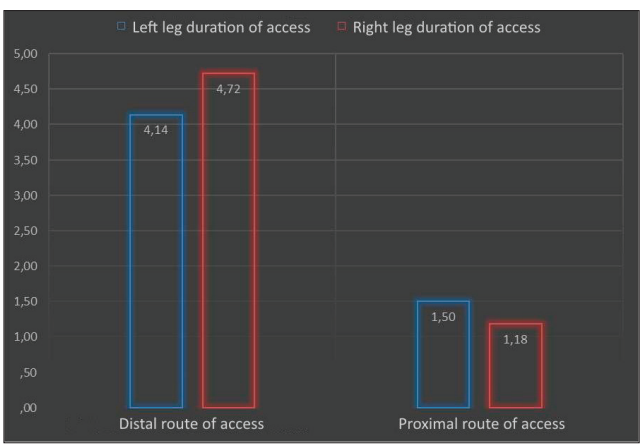

Figure 2. Duration of access to the vein by proximal and distal routes.

Table 3. Correlation analysis of variables correlated with basal VAS scores

Correlations			*r*	*p value*
Age (years)	*	Basal VAS score	-0.425*	0.048
No. of attempts for access	*	Basal VAS score	0.559**	0.001
Duration of access (min)	*	Basal VAS score	0.564**	0.001

Pearson Correlation - Kendall's tau b

Discussion

The aim of the current study was to assess and report the postoperative pain in two different routes of access (proximal or distal part of the small saphenous vein) in patients treated with EVLA. According to our results, access through the proximal part of small saphenous vein seems to provide a practical option with short duration of intervention because of the reduced possibility of repeated attempts at entry due to wide entry of the vessel, and decreased local pain scores in endovenous laser ablation treatment for varicose veins.

Minimally invasive treatment modalities have simplified and facilitated the treatment of varicose veins. In order to determine the appropriate mode of management, proper evaluation of the venous system is crucial. In this purpose, ultrasonography with color Doppler and spectral analysis has gained importance and is currently being used commonly (13, 14).

Endovenous laser ablation constitutes a good alternative for conventional therapy in the treatment of venous insufficiency and varicose veins (6). It exerts its action via getting in direct contact with the venous wall and resulting injury. In this purpose, different wavelengths such as 810, 940, 980, 1064, 1319, 1320, and 1470 nm can be used. Wavelengths of 810, 940, 980, and 1064 nm possess the highest specificity for hemoglobin, and they are termed as "hemoglobin-specific lasers". On the other hand, lasers with wavelengths of 1320 and 1470 nm are "water-specific" since they exhibit greater affinity for water absorption (15). These laser systems having higher wavelengths may presumably result in less pain and bruising after the intervention. EVLA is one of the most promising of the new techniques such as radiofrequency ablation and chemical ablation, and is becoming an established treatment option for great and small saphenous veins incompetence (16). In the recent years, minimally invasive surgery has proved to be better than conservative treatment in symptomatic primary varicosis of great saphenous vein. By the confirmation of the histological examination, the occlusion of the lumen was caused by a series of pathological alterations. In sequence, there were ectasis? and hiatus of vein endothelial cells, breakage of middle elastic fiber, a disorder of tissue structure, and secondary thrombosis in the lumen, adhesion of lumen. Proebstle et al. considered that laser treatment had a destructive effect of thermal damage on vascular endothelial cells and intima, and then it caused the occlusion of the vein (10).

The main complications seen after EVLA include pain, bruising, tenderness, and indurations along the treated vein (17, 18). These complaints are mostly transient, and they can even be reduced by measures like compression stockings and anti-inflammatory medications (13). Pain is one of the most important issues related with EVLA and our study was aimed to correlate with pain after this procedure. The severity and pattern of pain exhibit a wide spectrum from almost no pain to significant pain leading to absence from work (19). Moreover, a sensation of "pulling cord" along the course of the vein may be reported by some patients. This sensation is thought to be sourcing from developing venous fibrosis, which may interfere with flexion of the knee and walking. Therefore, scaling and assessing pain is a challenge attributed to personal variations in perception. Pain is a common complaint encountered after EVLA, and it tends to subside within a few weeks (20). It has been reported that there is no correlation between the pain experienced after EVLA and the deposition of laser energy deposition (10).

Previous studies have reported a good safety index for EVLA with an overall complication rate ranging from 0 to 15%. These complications are usually minor, transient and self-limited problems such as paraesthesia, skin pigmentation, induration, ecchymosis, and thrombophlebitis (6, 21). Skin pigmentation, which is a side effect of sclerotherapy, can be seen rarely after the EVLA procedure, especially along the course of superficial veins. Superficial thrombophlebitis along the treated venous segment or around the nearby tributaries may be managed via simple symptomatic treatment with compression and anti-inflammatory medications (11, 14, 22). Serious adverse events, including arterial events, pulmonary embolism, deep venous thrombosis, cutaneous necrosis and ulceration, are rare and none occurred in our series.

Access via the proximal route is associated with a short duration of intervention and less number of attempts. We found that pain experienced by the patient was correlated with these two variables, duration of the procedure and number of the attempts for the access. Therefore, it can be stated that the proximal route is linked with more acceptable pain scores. Based on our results, we suggest the endovascular access to the small saphenous vein to be made from the proximal route. In contrast to the conventional distal route, this approach offers a simple, practical and safe option with a short duration of intervention and good comfort of the patient. The thick diameter of the blood vessels in the cephalic part of the body is a factor responsible for the ease of intervention.

Some limitations of our study must be mentioned. The small number of our series and retrospective study design constitute the major restrictions. Secondly, the absence of long-term results and the variability of patients in terms of pain tolerance constitute other important remarks that must be kept in mind during the interpretation of our results. Thirdly, the absence of randomization in the design of the present study may cause a selection bias which must always be kept in mind. Lastly, pain is related with many factors including clinical symptoms, the severity of the disease, anatomic variation, duration of symptoms, etc. which were discussed vastly in the literature. So, although we evaluate "pain scores regarding entry sites" we should have matched the groups without any significant differences other than the proposed factors.

In patients diagnosed with isolated varicose small saphenous vein and undergoing endovenous laser ablation, the vascular access route (proximal or distal) did not have a significant effect on postoperative pain, but the proximal route was more easily accessed and the procedure lasted shorter. Further prospective, randomized, controlled clinical trials on larger series are warranted to document the efficacy of this procedure.

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