Comparison of 940 nm and 1470 nm Bare Fibers in Treatment of Great Saphenous Vein Insufficiency

Büyük Safen Ven Yetmezliği Tedavisinde 940 nm ve 1470 nm Çıplak Fiberlerin Karşılaştırılması

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ABSTRACT Objective: Endovenous laser ablation has been easily accepted since present surgical methods are major interventions. The aim of this study was to investigate the effectiveness and early postoperative morbidities of two different wavelengths used in endovenous laser ablation. **Material and Methods:** Randomly selected 200 patients were included in the study. In group 1, 125 lower extremities of 106 patients were treated with 940 nm laser wavelength. In group 2, 110 lower extremities of 94 patients were treated with 1470 nm laser wavelength. **Results:** Percutaneous intervention and endovenous insertion of fiber were successfully completed in both groups. Only induration was statistically significantly more in group 1. There were no statistically significant differences for the other postoperative parameters between two groups. **Conclusion:** Treatment of the great saphenous vein by endovenous laser ablation using a 1470 nm laser wavelength resulted in less postoperative pain. Although it was not statistically significant, the duration of pain was longer in the group with more induration. We suppose that vein should not be perforated in order not to increase postoperative morbidities.

Key Words: Venous insufficiency; ablation techniques; laser therapy

ÖZET Amaç: Endovenöz laser ablasyon, majör cerrahi işlemler nedeniyle kolay kabul görmüştür. Bu çalışmada iki farklı dalga boyunun etkinlik ve erken postoperatif morbiditeleri karşılaştırılmıştır. **Gereç ve Yöntemler:** Rastgele seçilen 200 hasta çalışmaya dahil edilmiştir. Grup 1'de 106 hastanın 125 alt ekstremitesi 940 nm lazer ile, grup 2'de 94 hastanın 110 alt ektremitesi 1470 nm lazer ile tedavi edilmiştir. **Bulgular:** Her iki grupta da perkütan girişim ve endovenöz yerleşim başarı ile yapılmıştır. Grup 1'de sadece endurasyon istatistiksel olarak anlamlı derecede daha fazla bulunmuştur. Her iki grupta da diğer postoperatif parametreler arasında istatistiksel olarak anlamlı bir fark bulunmamıştır. **Sonuç:** Büyük safen venin endovenöz laser ablasyonunda 1470 nm dalga boyu kullanımı ile daha az postoperatif ağrı görülmektedir. Ağrı süresi endurasyon olan grupta daha fazla olmasına rağmen, istatistiksel olarak iki grup arasında bir fark bulunmamıştır. Postoperatif morbidite artışını önlemek için, ablasyonunun venin perfore edilmeden yapılması gerektiğini düşünmekteyiz.

Anahtar Kelimeler: Venöz yetmezlik; ablasyon teknikleri; laser tedavisi

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Chronic venous insufficiency is a serious chronic disorder that affects almost half of society, and it presents with pain, swelling and increase of pigmentation in the lower extremities.[1] To date, surgical ligation and stripping have been accepted as the most successful treatment methods.[2] However, surgical methods have some disadvantages since they are major interventions. Due to these disadvantages, absolute patient satis-

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faction is not possible. Therefore, several alternative techniques were adopted in vascular surgery.[3] Navarro et al. published their first results in 2001.[4] Although different wavelengths have been compared in various studies, the most appropriate wavelength is still the subject of debate.[3,5]

Long-term results about wavelengths do not have scientific evidence. However, some differences have been found in short term results considering some side effects.[6] In all laser types, the most common side effects were pain, discomfort and surface phlebitis in the area where induration was present, and ablation was performed.[7]

The aim of this prospective study was to compare the efficiency and early postoperative morbidities of two different laser wavelengths (1470 nm and 940 nm diode laser).

MATERIAL AND METHODS

A total of 200 patients (235 extremities) were included in the study between May 2013 and February 2014. Written informed consents were obtained from all patients. All patients were examined clinically and with duplex ultrasound (USG) imaging using a SonoSite M-Mode (Bothell, USA) system to assess the deep and superficial veins of both lower limbs to allow the "clinical, etiological, anatomical, and pathological" (CEAP) grade. Duplex examination was performed when patients were in the upright position. Patients were classified according to CEAP. Any reflux longer than 0.5 sec was evaluated with Valsalva maneuver in the proximal area, and with augmentation in the distal area. Saphenous vein radius in saphenofemoral junction (SFJ), and saphenous vein radius at knee level were measured, and the distances from the skin were recorded. Those with an identified deep vein thrombosis (DVT), peripheral arterial disease, immobile patients, recurrent varicosities, pregnant and breastfeeding women, and those with perforating and small saphenous vein insufficiencies were not included in the study.

Two hundred patients were divided into two groups. One hundred and six of them were randomly treated with 940 nm bare laser fiber (Dornier Med Tech, Wessling, Germany) while other 94 were treated with 1470 nm bare laser fiber (Quanta System 1470, Solbiate Olona, Italy). Laser ablation and miniphlebectomy were applied in continuous mode with 940 nm diode laser in 106 patients in group 1. Laser ablation and miniphlebectomy were applied in continuous mode with 1470 nm diode laser in the patients in group 2. Two groups were compared for early postoperative morbidities including ecchymosis, paresthesia, postoperative pain and induration. Intravenous midazolam and endovenous laser ablation (EVLA) procedure were applied to all patients under sedation with oxygen support. The great saphenous veins (GSV) were cannulated with 19-gauge needles (Sigma-Aldrich, Taufkirchen, Germany) at knee level and under USG control when the patients were in Trendelenburg position (in order to increase the vein radius). After that, a guidewire longer than the needle was pushed forward, and a long cover was moved forward on the wire until it reached 2 cm below SFJ. The measuring of the laser fiber was taken outside, before the cover was placed, and it was fixed. The fiber was locked at a position where it was 1-1.5 cm outside the cover. Positions of the tips of the laser fibers were set at 1-2 cm below the SFJ under guidance of USG in both groups, and these positions were checked with direct observation of the red light on the skin. Perivenous tumescent local anesthesia (TLA) [1000 ml 0.9% normal saline (İzotonik NACL; Eczacıbaşı, Istanbul, Turkey), 20 ml 2% (400 mg) prilocaine (Priloc 2%; Vem İlaç, İstanbul, Turkey), 0.5 mg epinephrine (Adrenalin 0.5 mg/1 ml; Biofarma, Istanbul, Turkey), 10 mEq NaHCO3 (Sodyum Bicar; Drogsan, Istanbul, Turkey] was performed under USG control. Laser energy was applied in continuous mode, with a speed corresponding to 90 Joule (J)/cm linear endovenous energy density (LEED), with continuous pulling back. Laser power was set at 30 W in group 1. The fiber retrieval rate for this system was 3 sec, and 90 J/cm energy density was delivered. In group 2, laser power was set at 15 W, the fiber retrieval rate for this system was 6 sec, and 90 J/cm energy density was delivered. Total laser energy used was recorded. Closure of GSV after the fiber was taken out was controlled with USG. Additional

phlebectomies were performed in both groups, and compression bandages were applied for 24 hours to the area treated. Then, the patients used graduated compression stockings (20-30 mmHg, knee-high) in the following 7 days including day and night. They continued to wear stockings only during the day for 2 months. Prophylactic low-molecular weight heparin, tinzaparin sodium (Innohep; Abdi Ibrahim, Istanbul, Turkey) 100 anti-Xa IU/kg was used in both groups at the night of the operation. The patients were advised to walk regularly in the healing period, and flurbiprofen (Majezik tablet; Sanovel İlaç, Istanbul, Turkey) 100 mg was prescribed as an analgesic 3 times a day for 1 week, to be used when needed. After the procedure, the patients came to follow up visits on postoperative day 7, and at postoperative months 1, 3, and 6. USG was performed to evaluate patency of GSV, and clinical examinations were performed. Postoperative pain, side effects, undesired incidents and recurrence rates were recorded on each control visit. Pain, duration of pain, duration of the need for analgesics, the time that passed until getting back to daily activities, ecchymosis, skin burn, indurations and paresthesia in the treated extremity were also recorded. Ecchymosis and paresthesia were seen in the areas near the vein segment that was ablated.

STATISTICAL ANALYSIS

All data obtained were analyzed with Statistical Package for the Social Sciences 16.0 for Windows (SPSS Inc, Chicago, Illinois, USA). Normally distributed data were expressed as mean±standard deviation, and non-normally distributed data were expressed as median (interquartile range). Two-group comparisons for Venous Clinical Severity Score (VCSS), pain duration, need for analgesics and time to get back to daily activities were done with Mann-Whitney U test. Comparisons of side effect rates were performed with the Continuity Correction Chi-Square test. $P<0.05$ was considered as statistically significant.

RESULTS

In all cases, percutaneous intervention and endovenous placing of the laser fiber was successfully performed, and all patients tolerated the operation well. One hundred and twenty five extremities of 106 patients in group 1, and 110 extremities of 94 patients in group 2 were treated.

Demographic characteristics of the patients, preoperative clinical data, and the results of USG examinations are shown in Table 1. The data of the patients were similar in both groups.

Operative data are shown in Table 2. We reached 90 J/cm LEED in both groups. In order to decrease postoperative ecchymosis and paresthesia rates, similar amounts of TLA, 15 ml per centimeters, were used in both groups. No evidence of residual flow or venous reflux was seen in the USG examinations performed on follow-up visits. VCSS

TABLE 1: Preoperative demographic characteristics of the patients.

Parameters	Group 1 (n=106) 940 nm bare fiber	Group 2 (n= 94) 1470 nm bare fiber
Number of extremities treated	125	110
Gender (M/F)	50/75	43/67
Mean age (years)	37±8.1	36±6.2
Radius at SFJ level (mean GSV Radius) (mm)	10.6±3.4	10.9±3.9
Radius at knee level (mean GSV Radius) (mm)	6.7±2.2	7.1±1.9
Average reflux duration at SFJ level (sec)	5.7±1.8	6.2±1.5
GSV's distance from the skin (cm)	3.9±1.9	3.1±2.2
C2 (CEAP classification/extremity)	40	33
C3 (CEAP classification/extremity)	62	52
C4 (CEAP classification/extremity)	23	25

M: Male; F: Female; GSV: Great saphenous vein; SFJ: Saphenofemoral Junction; CEAP: Clinical, etiological, anatomical, and pathological grade.

TABLE 2: Operative data.

Parameters	Group 1 (n=106) 940 nm bare fiber	Group 2 (n= 94) 1470 nm bare fiber
Mean GSV length treated (cm)	40.2±6.5	41.9±6.8
Laser power used (W)	30	15
LEED (J/cm)	90	90
Mean total energy/extremity (j)	3591±576	3712±681
Average TLA amount / extremity (ml)	580±92	565±82
Average operation time/ extremity (minutes)		
(EVLA+Miniphlebectomy)	38±7.6	35±6.5
Number of phlebectomies/extremity	5.1±1.5	4.2±1.1

LEED: Linear endovenous energy density; TLA: Tumescent local anaesthesia; EVLA: Endovenous laser ablation; GSV: Great saphenous vein.

scores improved significantly in both groups at each follow-up visit (Table 3). However, improvements of VCSS on postoperative seventh day and at first month were significantly better in group 2 than in group 1. After first month, there were no differences for the parameters recorded. The side effects in clinical studies and other evaluation results are summarized in Table 4. Most common side effects observed in both groups were ecchymosis, indurations and minor paresthesia. No serious complications including DVT, pulmonary emboli, skin burn, motor nerve damage or arteriovenous fistula developed in either group. The duration of pain, need for analgesics, and ecchymosis rates were found similar between the groups. Mean time to ecchymosis development was about 2 weeks in the

TABLE 3: Changes in the venous clinical severity score.

Time point	Group 1 (n= 106) 940 nm bare fiber	Group 2 (n= 94) 1470 nm bare fiber	p value
Preoperative (IQR)	8.3 (5-12)	8.0 (5-11)	p=0.437
PO seventh day (IQR)	4.9 (3-8)	4.1 (2-6)	p=0.034
PO first month (IQR)	4.2 (2-7)	3.6 (2-5)	p=0.041
PO third month (IQR)	3.1 (1-5)	2.9 (1-5)	p=0.313
PO sixth month (IQR)	2.2 (0-3)	2.0 (0-3)	p=0.445

PO: Postoperative; IQR: Interquantile range.

TABLE 4: Postoperative data.

Parameters	Group 1 (n= 106) 940 nm bare fiber	Group 2 (n= 94) 1470 nm bare fiber	p value
Pain duration (days)	3.6±3.7	3.2±3.4	p=0.461
Need for analgesic (days)	7.1±4.0	6.7±3.1	p=0.383
Induration (number of extremities)	30	11	p=0.006
Ecchymosis (number of extremities)	16	20	p=0.341
Skin burn (number of extremities)	0	0	-
Paresthesia (number of extremities)	14	13	p=1.000
Deep venous thrombosis	0	0	-
Pulmonary embolism	0	0	-
Tine to get back to daily activities (days)	3.5±2.0	3.0±1.6	p=0.317
Closure rate at 6th month (n)	106	94	-

n: The number of patients with totally closed GSV at 6th month.

patients in both groups. Findings such as subcutaneous indurations in the vein segment after EVLA, and contraction in the medial part of femur or palpable cord were found in 30 extremities in group 1, and 11 extremities in group 2 (p=0.006).

DISCUSSION

A number of studies have reported high success rates after EVLA.[3,8] These results are confirmed with duplex USG. When the studies that compared laser and classic surgery were analyzed, it was seen that some studies found laser application more successful, some studies found equal success rates, and some others found the laser method less successful. However, all those studies reported that laser application caused less complications, and it was more comfortable for the patient.[9,10] EVLA has been preferred over surgery for the treatment of varicosities.[11] Tumescent anesthesia is a very important factor that affects the success of EVLA.[12,13] Another important factor for EVLA treatment is the LEED.[12] Almeida et al. reported that ecchymosis appeared less with smaller LEED (20-30/cm) levels due to less perforation of vein walls.[12] Although some studies showed superiority of 1320 nm Nd: Yag system over 940 nm diode laser for less postoperative pain and bruising, in our study we found 1470 nm better only for indurations.[14] Theivacumar et al. reported that the energy amount delivered was the main parameter that affected treatment success, and 60 J/cm or higher levels should be used for a successful treatment.[15] In our study, we found 100% ablation in the veins of both groups on USG controls at postoperative 6th month.[16] Additionally, a study that compared 980 nm and 1500 nm diode lasers reported less induration and less analgesic need with use of high wavelengths.[17] Pannier et al. reported successful endovenous ablation results with 1470 nm laser, but no studies compared it with 940 nm.[5] In this prospective randomized study, no statistically significant differences were found for side effects such as pain, ecchymosis and paresthesia between 1470 nm and 940 nm bare-tip laser fibers. Pannier et al. reported that the side effects were more common in the patients treated with LEED > 100 J/cm.[5] In our study, small rates of side effects in both groups may be related to limiting the LEED at 90 J/cm.

We suppose that vein wall perforation considerably affects postoperative ecchymosis, induration, paresthesia, and pain complications. This is why the fibers such as tulip fiber that reduce direct contact with the vein wall to prevent adhesion and carbonisation have been developed.[18] We may avoid ecchymosis, induration, paresthesia and pain with an ablation operation by avoiding perforation of vein, or by not applying laser to the segment of perforated vein.

Various diode lasers (in different nm) are effective in the treatment of GSV varicosities. However, early postoperative side effects are similar except for indurations. A limitation of this study is that we cannot identify whether these results are attributable solely to the laser frequency.

Conflict of Interest

Authors declared no conflict of interest or financial support.

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