

# Endovenous laser ablation with tulip fibre on treatment of chronic venous disease

## Kronik venöz yetersizlik tedavisinde lale uçlu fiber ile endovenöz lazer ablasyon

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### SUMMARY

#### Aim :

Tulip Fibre as a new aproach to Chronic Venous Insufficiency (CVI), avoids venous and perivenous ulceration and perforation by preventing the lasers direct contact to the vein walls . The aim of our study is to show the efficiacy of the Endovenous Laser Ablation (EVLA) with Tulip Fibre in CVI.

#### Methods:

Between March 2012 and June 2012, 70 patients with the grade 4 vena saphena magna reflux were included to the study and Endovenous Laser Ablation with Tulip Fibre was applied. Patients were checked twice after the operation once for ecchymosis, pain, ulcer, thrombophlebitis and deep vein thrombosis (DVT) at the end of the first week and second at the end of the sixth month for CVI with doppler ultrasonography. Preoperative and postoperative colored doppler ultrasonography was performed by the same radiologist.

#### Result:

None of the patients had ecchymosis, ulceration and infection, in one of the patients pain without need of an analgesic was reported. DVT was not reported. In one of the patients at the end of the six months Vena Saphena Magna was reported as not obliterated enough.

#### Conclusion:

Endovenous Laser Ablation (EVLA) with Tulip Fiber in CVI is a safe and effective treatment method.

**Keywords :** Endovenous laser ablation, tulip fibre, chronic venous insufficiency

### ÖZET:

#### Amaç

Kronik venöz yetmezlikte (KVY) yeni bir yaklaşım olan lale uçlu fiber ven duvarı ile direkt teması önleyerek venöz ve perivenöz ülser ve perforasyonu engeller. Çalışmamızın amacı KVY’de lale uçlu fiberle endovenöz lazer ablasyonun etkilerini göstermektir.

#### Metod:

Mart 2014 ve Haziran 2014 tarihleri arasındaki grade 4 vena safena manga reflusu olan 70 hasta çalışmaya dahil edildi ve lale fiberle endovenous lazer ablasyon uygulandı. Hastalar birinci haftanın sonunda ağrı ekimoz ülser tromboflebit ve derin ven trombozu için ve altıncı ayın sonunda KVY için Doppler ultrasonografi ile kontrol edildi. Preoperatif ve postoperatif renkli Doppler ultrasonografi aynı radyolog tarafından uygulandı.

#### Bulgular:

Hastaların hiçbirinde ekimoz ülser ve enfeksiyon yoktu, bir hastada analjezik ihtiyacı olmayan ağrı bildirildi. DVT bildirilmedi. Altıncı ayın sonunda bir hastada vena safena manganın yeterince oblitere olmadığı saptandı.

**Sonuç:** Lale uçlu fiber ile endovenöz lazer ablasyon kronik venöz yetmezlik tedavisinde güvenli ve etkin bir yöntemdir.

**Anahtar kelimeler:** endovenöz lazer ablasyon, lale fiber, kronik venöz yetmezlik

## Introduction

Lower extremity venous insufficiency is a common illness. Clinical presentation has a great variation from asymptomatic variceal veins to ulcerative skin lesions. Demographically %25 of women and %15 of men are reported to have CVI(1). The most common form is the great saphenous veins ( GSV) insufficiency, other saphenous veins insufficiencies can be a part of the illness too. In the lower extremities, blood stream acts against the gravity. Venous valves are required to provide the efficient blood return from distal to the proximal in the lower extremities. Venous valves incompetence may occur by many reasons and ends with damaged circulation of blood which is called venous reflux. Female gender, family history, pregnancy, obesity, prolonged standing and sitting, DVT at the background are the most important factors leading to the development of CVI. CVI in the lower extremities may cause pain, oedema, varicose veins, venous ulcerations. Colored Doppler Ultrasonography is the gold standard for the diagnosis. It is important to check the lower extremities for venous reflux of the deep, superficial and perforator veins. Treatment methods can be divided in to three conservative methods, minimally invasive methods, classical surgical procedures. Conservative methods include manual compression, lymphatic massage therapy, compression stockings, medications and exercise programs . Surgical treatments include high ligation of saphenofemoral junction(SFJ), complete stripping and excisions of the varicose veins. Minimally invasive methods includes endovenous ablation (Radiofrequency and laser energy) and foam sclerotherapy. The aim of any treatment procedure applied should be ending up the complaints, stabilization of the well being, lowering the complication risks, early mobilization after the operation and after all cosmetically satisfying the patients. EVLA as an alternative for the saphene stripping is becoming more common for the last years(2). EVLA can be performed with different kinds of fibers. Tulip fibre is a new type of catheter designed for minimizing the periveneous tissue harm. Lazer is placed in the center of the fiber and it is surrounded like a core. By this way the vein walls direct contact with laser is avoided and kept intact. This reduces the venous ulceration and perforation risks. Vein walls ulceration and perforation causes destruction in periveneous tissue which ends with inflammation. Inflammation causes pain, ecchymosis, thrombophlebitis and also may cause DVT. Our aim of this study is to evaluate the outcomes of EVLA with the Tulip Fibre.

## Materials and Methods

**Participants:** This single centered, prospective study included a group of 70 patients which were applied unilateral EVLA for the grade 4 vena saphena magna reflux from March 2014 to June 2014 in

our center. The venous reflux diagnosis and grading was performed with colored doppler ultrasonography preoperative and postoperatively by the same radiologist. Patients with bilateral GSV insufficiency were excluded. For the evaluation of the outcomes classical C.E.A.P. (clinical, etiologic,anathomic,-pathophysiologic) classification was used.

**Tulip Fibre Endovenous Laser Ablation:** Laser ending of the fiber is surrounded by four extendable blades in this catheter.(Tobrix Tulip Fibre, Figure 1) Without harming the vein walls, laser effects homogeneously the whole endothel and performs proper obliteration. Vulsteke et al. showed the destruction induced during EVLA of the saphenous vein and the periveneous tissue in an animal model (goats) (2).

**Technique:** All of the patients were implemented spinal anesthesia in the sitting position with a 22 Gauge spinal needle (Exelint International, USA) according to the asepsis and antisepsis procedures. The standard spinal anesthesia techniques are used, from the interspaces between L3-L4 or L4-L5 reached the subarachnoid space and injected 20 mg of % 0.5 hyperbaric bupivacain (Marcaine Spinal Heavy Ampoules, % 0.5, Astra Zeneca). In the supine position saphenous vein was punctured below the knee using the Seldinger Technique with the ultrasonography guidance and the sheath was placed. A tumescent anesthesia was applied with lidocaine and physiological saline solution (500 ml, + 4 degrees). Tulip fibre laser catheter was placed 1cm distal to the saphenofemoral junction. Patients received 1470 nm diode laser with 80 joule/cm energy density. After the operation, elastical bandaging for compression applied. First day after the operation, bandages were changed and compression continued for another three days. Patients were taken in follow-up at the postoperative 7th day and doppler ultrasonography at the 6th month.

**Statistical Analysis:** Statistical analyses were performed using a computer software Statistical Package for Social Sciences , version 16 (SPSS Inc.,Chicago, illinois ,USA ). Parametrical hypothesis were analysed with One Sample T and Independent SampleT tests. When the confidence interval was  $p > 0,05$  ,H(o)hypothesis was accepted to be correct.



**Figure 1.** Tobrix tulip fibre.

## Results

39 patients were woman (%55,8), 31 was man (%44,2). Mean age was 44.5 years (standard devi-

ation is 11,8 years). Only one patient was CEAP 6. Other patients median value was CEAP 2,21 (standard deviation is 0,71 CEAP) . Laser ablation applied saphene vein segments mean length was 40,01 cm (standard deviation 3,45 cm). The mean diameter of the largest width of the saphene segment is calculated as 0.71cm (standard deviation 0,14 cm) .One patient had ecchymosis in the postoperative term. One patient had slight pain, without need of an analgesics. There were no postoperative infection case or DVT reported. One patient at the 6th month control with colored doppler ultrasonography had found to have a recanalized saphene vein. All the other patients were found to be properly occluded . None of the patients had clinical complaints. Occlusion grade and the saphene veins length ( $p=0,561$ ,  $p>0,05$ ) and mean diameter ( $p=0,941$ ,  $p>0,05$ ) does not have a correlation. Pain complaints ( $p=0,083$ ,  $p>0,05$ ) and ecchymosis ( $p=0,15$ ,  $p>0,05$ ) are statistically significantly decreased in EVLA . Relapse ratio ( $p=0,98$ ,  $p>0,05$ ) and clinical stage was not found to be correlated .

### Discussion

Minimally invasive methods in many fields of surgery are being preferred more and more each day because the recovery period is less, hospitalization period is less and cosmetical outcomes are much better. This is also true for CVI, classical surgery methods like stripping and flebectomies places are being taken by the minimally invasive methods. Endovenous procedures comes first in minimally invasive methods. EVLA and radiofrequency ablation (RFA) is being used for the treatment of the lower extremities venous reflux, variceal veins and perforator venous insufficiency (3). In both procedures the common principle is to damage the vein endothelium to stimulate the inflammation, forming thrombosis and afterwards fibrosis process starts and obliterates the vein(4). High ligation in different serials has %18 and %40 relapsing ratios in 5 years time period(5). Recurrence rates comparing classical surgery methods with RFA and EVLA does not have a statistically significant difference(6,7,8). EVLA and RFA, compared with surgery postoperative recovery period is shorter, mobilization is earlier and patients return to their normal activities much earlier(9).

EVLA can be applied with different laser wave lengths(WL), energy densities and catheter sorts. In the literature, there are studies with 940 nm, 980 nm, 1470 nm and 1500 nm WL (10,11,12). There is no significant difference between these different WL in EVLA implementations. Vuysteke et al compared 980 nm and 1500 nm WL and found out that saphene veins occlusion ratios are the same but side effects are less with 1500 nm WL(13). Prince et al. practiced with different energy densities as 60 joule/cm, 60-80 joule/cm, 81-100 joule/cm, 100 joule/cm and higher and found out that there were no significant differences in the outcomes. In our study we found out that there is no correlation between the occlusion ratios with saphene veins diameter and length. After the CVI treatment patients generally

complain about ecchymosis and cosmetical problems. For those reasons EVLA is a comfortable way of treatment for the patients. In the literature, side effects are minimal but can be seen. The complications mostly occur because of the arterio-venous fistula applications The puncture needles traumatization is generally the reason(15). Because of the endothelial effects of the EVLA, thrombus progression can be aggravated thus, iliofemoral and popliteal thrombosis may occur and this can increase the pulmonary embolism risk(16). None of our patients had such complications. In EVLA applications radial fibers are being used generally. Postoperative side effects like ecchymosis and perivenous tissue damage can be explained with the bare fibers, direct contact to the vein walls .(2) Patients that we treated with Tulip Fibre did not have complications such as postoperative ecchymosis , pain, tromboflebitis and pulmonary embolism and this supports the same idea. The follow up at the end of the 6th months saphene veins obliteration was nearly all (%99), pointing out that the catheter can be used safely.

Today as shown in experimental studies and confirmed in clinical studies EVLA for CVI is safe and effective. Tulip Fibre Laser Catheter for EVLA must be further studied with larger patient groups.

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