

Preliminary results of severe venous insufficiency treatment with thermal ablation of the great saphenous vein by endovascular technique with laser diode 980nm developed in Brazil, associated with sclerotherapy with polidocanol

Resultados preliminares do tratamento de insuficiência venosa grave com termoablação da veia safena magna por técnica endovascular com laser de diodo 980nm desenvolvido no Brasil, associado à escleroterapia com polidocanol

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ABSTRACT

The endovenous laser ablation (EVLA) of the insufficient saphenous vein has similar results to open conventional surgery, but less morbidity. The echo-guided polidocanol foam sclerotherapy technique has been used for the same purpose. The combined techniques may play a role for more severe diseases, such as those with varicose ulcers. An EVLA device (called VELAS) has been developed in the Optics and Photonics Research Center of USP-São Carlos in agreement with FMB-UNESP. In this study, we present the preliminary results of the VELAS device (MMO 980nm diode) in patients with chronic venous ulcer, associated with echo-guided polidocanol foam sclerotherapy for the treatment of varicosities. Primary outcomes were healing time of the venous ulcer, occlusion of the treated veins and treatment-related adverse events. We included 12 patients with insufficient saphenous vein and chronic venous ulcer. Initially, we treated all of them with thermoablation of the insufficient saphenous vein (VELAS), on an outpatient basis, with local anesthesia. After one week of the procedure, we sclerosed the varicosities with polidocanol foam (Tessari technique). The national VELAS device was easily handled. Total venous occlusion occurred in 83.3% of the patients (in seven days) and the association of the techniques was responsible for a wound healing rate of 83.3%, with no adverse events.

Keywords: Laser Therapy. Laser Coagulation. Varicose veins. Varicose Ulcer. Venous Insufficiency.

INTRODUCTION

The conventional treatment of lower limbs varicose veins consists of surgical removal of insufficient veins. Among the procedures for this condition, when there is insufficiency of the great saphenous vein (GSV), phlebectomy is the recommended treatment and has been performed for decades with relative safety and efficacy^{1,2}. In addition to the conventional method, the sclerosing treatment with polidocanol foam by the Tessari technique³, generally used when there is some contraindication to the surgical procedure, is a useful alternative. More recently, endovascular treatments for varicose veins have been available. These techniques have achieved great popularity, especially in first-world countries, because they are less invasive and

involve fewer anesthesia-related risks. These include photothermolysis and photocoagulation, which can be performed with a laser or a radiofrequency device, respectively⁴⁻⁷. However, non-invasive surgery equipment for varicose veins is imported and costly, making it difficult to popularize its use in patients treated by the Brazilian Unified Health System (SUS). In view of the need to reduce costs for the incorporation of this technique by SUS, a new MMO 980nm diode laser equipment (endovascular laser ablation – EVLA) was developed and made available for evaluation of efficacy and safety, as result of a national research involving USP and UNESP, and received the trade name VELAS. The complementation of the thermoablation with sclerosis with polidocanol is scarce in the literature. In this work, we present the preliminary

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results obtained in 13 surgeries performed in patients with great saphenous vein (GSV) or lesser saphenous vein (LSV) severe insufficiency with active chronic venous ulcer in the lower limb (CEAP 6). We performed a treatment session with 1% polidocanol and air microsurgery sclerotherapy using the Tessari technique in an echo-guided fashion to treat the residual varices one week after the laser treatment, when necessary.

Ethics

The equipment was approved for use in patients, as part of a clinical research protocol, after numerous electronic and physical tests, as well as extensive performance regulation initially in corpses' parts (veins) and also pre-clinical tests in experimental animals (rabbits), the equivalence with imported devices being demonstrated.

This project was submitted to, and approved by, the Ethics in Research Committee (CEP) of the Botucatu Medical School (FMB-UNESP), with protocol number 3240/2009.

We thoroughly oriented all the patients and provided them with all information regarding the procedures to be performed before they signed the Informed Consent Form (TCLE).

Inclusion and exclusion criteria

We included consecutive patients of the FMB-UNESP Clinics Hospital, in an outpatient follow-up, of both genders, older than 18 years, with chronic venous insufficiency and active chronic venous ulcers (CEAP classification 6). Exclusion criteria were patients less than 18 years of age, history of deep vein thrombosis (DVT) or post thrombotic syndrome, use of anticoagulants, varicose veins classified as CEAP 5 or less, previous total great and lesser saphenectomy in the affected limb, ulcers with signs of active infection, concomitant peripheral arterial disease, pregnancy or puerperium, active cellulites or erysipelas, signs of active mycoses, personal history of alcohol or drug abuse, clinically decompensated comorbidities, disagreement with the research terms, ulcer healing occurring before the procedure, and refusal to sign the Informed Consent Form.

The equipment

The endovascular venous laser ablation (EVLA) device, VELAS, was developed through an agreement between the Optics and Photonics Research Center of the Physics Institute of São Carlos – USP – and the FMB-UNESP (Process 1084/2007). A 980nm diode laser equipment was built, with regulation of power, time of pulsed or continuous energy exposure and accompanied by a 600 micron optical fiber, protection goggles, hand-piece and carrying case.

Operative technique

The procedures were performed in a standardized way, under local anesthesia with 20ml of 2% Xylocaine without vasoconstrictor plus 20ml of 0.5% isobaric bupivacaine, diluted in 200ml of cold saline solution (0.9%), injected with a 27G spinal anesthesia needle, guided by a portable Ultrasound (US) instrument, aiming to anesthetize the GSV (or LSV) pathway. We anesthetized the inguinal region (or the popliteal fossa in the one case of LSV treatment) with the same solution, to dissect and ligate the saphenous arc. This was sectioned and doubly ligated with unabsorbable suture. We then proceeded to the retrograde introduction of a 0.035" x 260mm stiff hydrophilic guidewire through the sectioned saphenous vein to the distal third of the leg in an echo-guided fashion. We inserted a Levine number six probe (with cut tip) over the guide wire. We echographically performed an additional intumescence inside the saphenous compartment with ice-cold 0.9% saline. After removing the guide wire, we introduced the laser fiber optic into the Levine, making a retrograde movement with the probe for exposing the optical fiber. We calibrated the laser at 15W, with continuous shooting, with thermoablation application speed of 3mm/s, with optical fiber of 600 microns. The laser was fired in a distal to proximal direction in the saphenous vein, and we repeated the firing until we noticed the ultrasonographic obliteration of the more calibrous veins. The procedures took approximately an hour and a half, a time spent, for the most part, for anesthesia and intumescence. We did not surgically treat

Table 1. Epidemiological data and results.

Patient	Age (years)	Gender	Saphenous vein diameter (cm)	Saphenous vein	Foam in varicose veins (7 days)	DVT	PO Infection	Saphenous vein occlusion (7 days)	Ulcer healed after one year	Healing time (months)	Saphenous vein occlusion (1 year)
MLSG	50	F	1.65	Greater	Yes	No	No	Yes	Yes	7	Yes
CCZ	58	F	1.37	Greater	No	No	No	Yes	Yes	2	Yes
JS	53	F	1.42	Greater	Yes	No	No	Yes	Yes	0.5	Yes
TFFG	57	F	1.7	Greater	Yes	No	Yes	Yes	Yes	6	Partial
JVS	64	M	0.49	Greater	Yes	No	No	Yes	No	-	Yes
MLBG	64	F	1.35	Greater	Yes	No	No	Yes	Yes	12	Partial
VS	71	M	1.27	Greater	No	No	No	Yes	Yes	4	Yes
MBL	50	F	1.05	Greater	No	No	No	Yes	Yes	1.5	Partial
CSLG	43	F	0.38	Lesser	Yes	No	No	Yes	No	-	Yes
ESP	47	F	1.34	Greater	No	No	No	Yes	Yes	3	Yes
JBP	50	M	1.6	Greater	Yes	No	No	Partial	Yes	0.5	Partial
AGM	41	F	1.39	Greater	Yes	No	No	Partial	Yes	0.75	Partial
Total Average (~)	~ 54	3 M 9 F	~ 1.27	11 GSV 1 LSV	8/12	12/12	1/12	10/12	10/12	~ 3.7 (~111 days)	7/12

M: male; F: female; ~: average.

additional varicosities at the same operative time. After ablation of the GSV or LSV, we sutured the inguinal or popliteal fossa incision by planes. We applied a semi-compressive and inelastic dressing throughout the operated limb. We observed the patients for four hours before discharge, and advised them to maintain relative rest until the following day.

Follow-up

We instructed the patients to return to the clinic one week after surgery. In this return, we made an US examination to evaluate the occlusion or not of the treated vein and the patency of the deep venous system. We then treated varicose veins of the saphenous system with 10ml solution containing 2ml of 1% Polidocanol and 8ml of ambient air in the form of foam by the Tessari technique, a volume fractionated by the caliber and length of the varicosities, when necessary.

The patients had biweekly returns in an outpatient clinic for dressings to follow the wound healing, or in other periods as determined by the attending physician. After wound healing, we discharged

the patients from the outpatient clinic and followed them up every six months in a returning clinic.

We performed a further US examination after one year of treatment to assess the maintenance of obliteration of the treated vein, as well as clinical data.

RESULTS

In the period from February 2014 to June 2015, we treated 30 consecutive patients with active chronic venous ulcer of difficult treatment in the vascular dressing outpatient clinic of our service, of whom 12 could be included and treated by the EVLA method with the new laser device VELAS (Table 1). We excluded 18 patients (preoperative ulcer closure, withdrawal, absence of significant saphenous vein changes in the US, signs of involvement of the deep venous system by prior DVT or concomitant arterial disease). Among the 12 patients selected, ten had a saphenous vein with a greater caliber than 1.0cm (Table 1). There was no inclusion restriction due to the saphenous vein caliber.



Figure 1. Venous ulcers: A, C, E – pretreatment; B, D, F – posttreatment.

Regarding laser treatment, there were no hospital complications (burns, bleeding, cardiovascular events or DVT). Eleven patients had GSV treatment, and only one, LSV. All patients reported improved clinical symptoms one week after surgery.

At the end of the seven-day follow-up period, one patient had an infection characterized as erysipela, which was treated with an oral antibiotic (Amoxicillin 875mg + Clavulanate 125mg b.i.d.) for seven days, with success. In eight patients (67%), we carried out the complementary treatment of varicosities with sclerotherapy with 1% polidocanol by the Tessari technique. Also at the one week return, ten patients presented total obliteration of the treated saphenous vein (83.3%) and two presented partial occlusion, predominantly present in small segments of the vein where they were more dilated (Table 1).

The mean time of total ulcer healing was 3.7 months (0.5 to 12), which occurred in ten patients (83.3%) (Figure 1). Two patients (16.7%) did not have complete healing of the venous ulcers in the follow-up period, both presenting a decrease in the perimeter and depth of the ulcers. One had reflux of the proximal deep venous system (femoral vein) not associated with known prior DVT and received LSV treatment. The other did not show complete healing with one year of follow-up despite the treatments performed. At the one-year follow-up, 58.3% of the treated patients sustained obliteration of the treated vein, and the remaining patients remained with partial occlusion with recanalized segments, but all of them maintained the clinical improvements obtained with the treatment (Table 1).

DISCUSSION

The equipment tested included safety requirements (goggles, safety switches, etc.), as well a LED light on the tip of the fiber optics, which facilitated the monitoring of its progression inside the vessel by transillumination through the skin. The VELAS laser displayed good performance and ease of handling, mainly because it has a practical Touch-Screen panel, friendly programming and easy adjustment and access by the auxiliary team. The laser emission occurred safely, as previously calibrated and tested by the engineers. This laser device has a frequency of 980nm and is quite effective in venous ablation; equipment with a higher frequency (1470nm) report to have a higher affinity for water⁸.

The use of this VELAS laser device with retrograde ablation technique was sufficiently capable of promoting the closure of most treated veins in the evaluation in seven days, similar to what is found in the literature^{9,10}. At points of caliber of less than 1cm, it promoted permanent vein fibrosis. However, since the selected patients had greater venous insufficiency, the treated veins exceeded the maximum recommended diameter of 1cm in some segments (mean larger diameter of 1.27cm). Thus, as expected, there was not fibrosis of the entire course of the treated vein, and some patients presented segment phlebitis and partial recanalization in the one-year follow-up. In these cases, the ligation of the saphenous arc in all cases contributed to prevent embolization. In any case, three patients presented partial recanalization of segments

initially considered obliterated in the follow-up of one year. According to the literature, these recanalizations usually occur in segments of veins with a caliber greater than 1cm, a fact corroborated by this study^{11,12}.

Sclerotherapy performed with 1% polidocanol by the Tessari technique for varicosities of the GSV or LSV was effective in promoting their obliteration in the one-year follow-up (80%). In this sense, thermoablation supplemented by sclerosis with polidocanol may be a less invasive and efficient alternative, often serving as rescue for more complicated cases. This association of techniques is an unusual procedure and the preliminary results were promising, leading to future research with a greater number of cases.

The mean wound healing time was 3.7 months, which was considered precocious compared with the time they remained open. No patient presented any type of major complication associated with both methods. This study suggests that the techniques employed complemented each other in promoting patients' clinical improvement, besides increasing the chances of ulcer healing^{13,14}.

We conclude that the VELAS laser apparatus was easy to handle, showed good performance and similar safety to imported equipment. Ambulatory thermoablation in association with complementary sclerotherapy with echogenic polidocanol foam was an unusual and promising technique for the treatment of patients with severe venous insufficiency, with good clinical success rates. Studies with more cases will be necessary to confirm these findings.

R E S U M O

A termoablação endovascular das veias safenas insuficientes com laser é descrita como uma técnica menos invasiva, com resultados semelhantes à cirurgia convencional, porém, com efeitos adversos menos frequentes. A técnica de escleroterapia com espuma de polidocanol ecoguiada vem sendo empregada com a mesma finalidade. A combinação de técnicas pode representar uma alternativa para pacientes mais graves, como os portadores de úlcera varicosa. Um equipamento de laser (denominado VELAS) foi desenvolvido no Centro de Pesquisas em Ótica e Fotônica da USP-São Carlos em convênio com a FMB-UNESP para termoablação endoluminal da veia safena insuficiente. Neste estudo apresentamos os resultados preliminares do uso do aparelho de laser VELAS (diodo MMO 980nm) na termoablação endovascular de veias safenas insuficientes, em portadores de úlcera venosa crônica, associado à complementação com espuma de polidocanol para o tratamento de varicosidades, após uma semana. Os desfechos analisados foram o tempo de cicatrização da úlcera venosa, oclusão das veias tratadas e eventos adversos relacionados aos tratamentos. Foram incluídos 12 pacientes portadores de insuficiência de veia safena e úlcera venosa crônica que aceitaram participar do projeto. Todos foram tratados em regime ambulatorial, com anestesia local e termoablação da veia safena insuficiente (VELAS). Após uma semana da cirurgia, as varicosidades foram esclerosadas com polidocanol espuma (técnica de Tessari). O equipamento laser VELAS nacional apresentou fácil manuseio, oclusão venosa total em 83,3% dos pacientes (em sete dias) e a associação das técnicas foi responsável por uma taxa de cicatrização de feridas de 83,3%, sem ocorrência de eventos adversos.

Descritores: Terapia a Laser. Fotocoagulação a Laser. Varizes. Úlcera Varicosa. Insuficiência Venosa.

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