The use of transillumination as a rational approach to sclerotherapy and endovascular laser ablation of varices.

Results in the use of an original instrument.

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Marco Apperti*, Ermenegildo Furino**, Antonio Sellitti***, Gennaro Quarto**

**Past-President of S.I.F., Società Italiana di Flebologia (Italian Society of Phlebology)*
***Department of Clincal Medicine and Surgery, "Federico II" University, Naples, Italy*
****General and Oncological Surgery Unit, "A. Tortora" Hospital, Pagani (Salerno), Italy*

The use of transillumination as a rational approach to sclerotherapy amd end endovascular laser ablation of varices. Results in the use of an original instrument

AIM: *To explain the mode of using and the obtained results during EVLA procedures and sclerotherapies with support of Visioven®, a laser transillumination instrument.*
MATERIALS AND METHODS: *205 patients suffering from Chronic Venous Insufficiency – CEAP-C stage 1-2 enrolled (103 females and 102 males) and divided into two groups. A Group: patients candidate for sclerotherapy; B Group: patients to be subjected to endovascular laser ablation (EVLA). In both groups patients were divided into two sub-groups on the basis of the use of Visioven® or not during the procedure. The analyzed outcome variables were the total number of cannulations necessary to treat a whole limb, and the total procedure time.*
RESULTS: *There is a statistically significant difference between the sub-groups in which Visioven® was used and the ones in which the procedure has been performed without using of any tools. Both in the sclerotherapy group than in the EVLA one, there is not a statistically significant difference for the time required to complete the procedures carried out with Visioven® compared with the ones performed without the use of any transillumination.*
DISCUSSION: *Complete closure of the vein was highlighted. Total number of cannulations in sclerotherapy and EVLA procedures was reduced, as a consequence of a "smart" and "targeted" treatment achieved with Visioven®*
CONCLUSION: *The VISIOVEN® system leads to have a more rational approach to sclerotherapy or Laser Ablation of teleangectasias and reticular veins as we can immediately verify the effectiveness of the treatment and adapting it to the desired effects.*

KEY WORDS: Chronic Vein Insufficiency, EVLA, EVLT, Laser, Varicose vein

A correct approach to the treatment of venous diseases, not only limited to traditional surgery, must be based on the ultimate knowledge of pathophysiology and the use of new tools that technology makes available [1,8].
Endovascular laser ablation (EVLA) is an alternative to saphenous stripping or phlebectomy and mixes effectiveness, less hospitalization time and a good aesthetics[2].

Performing EVLA or sclerotherapy, for better results, it becomes mandatory to exactly identify the vessels to be treated. A good solution is represented by the trans-illumination, which allows, through a light source, a direct vision of the vessel to treat.
In fact, reticular varices, in most cases, are not easily viewable at the ultrasound examination because too small and too superficial. Moreover it is very difficult to understand with echo-doppler their hemodynamics, especially as regards the flow directions. For this reason, the use of transillumination makes easier the identification of the trajectory and the direction of reflux that smoother vessels assume in the areas in which are not visible under the skin surface. The same reasons are also valid for scle-

Correspondence to: Prof. Marco Apperti, Piazza de' Sivo 1, 81024 Maddaloni (Caserta), Italy (e-mail: marco.apperti@gmail.com)

rotherapy of telangiectasias, where it is essential to recognize of the supplying vein and the direction of its reflux at the base of the emergence of telangiectasia itself.
The aim of this work is to explain the mode of use and the results obtained with an original laser transillumination instrument we designed and patented, Visioven®.
The idea was born from the need to see better and more compared with the simple use of magnifying glass. For this reason we have used trans-illumination for a decade, before designing Visioven®.
The need to find a system that would have overcome the experimented difficulties, led us, to develop Visioven®. Its characteristics are due to the particular wavelength of laser light - that easily penetrates deeper into the subcutaneous tissues, and reflected towards the surface - and the extreme maneuverability of the handpiece, allowing to have a spectacular vision of varices, reticular veins and telangectases.

Materials and Methods

This study has been performed by Visioven® study group. 205 patients suffering from Chronic Venous Insufficiency – CEAP-C stage 1-2 were enrolled (103 females and 102 males) and divided into two groups. A Group: patients candidate for sclerotherapy; B Group: patients to be subjected to endovascular therapy[4].
A Group includes 127 patients suffering from chronic venous insufficiency of the lower limbs and presenting telangectasias and reticular veins treatable with sclerotherapy. All patients are homogeneous for distribution of reticular varicose veins and telangiectasias. Within this group, two subsets were created: A1 subset includes 63 patients who were subjected to sclerotherapy with the aid of Visioven®; in the A2 subset, 64 patients were subjected to sclerotherapy in direct vision. Within the sclerotherapy group, it was considered as the outcome variable the number of punctures needed to treat the limb with the higher number of teleangiectasias and reticular veins; another considered outcome variable is the time (the sum of the duration of the various sessions that have occurred at intervals of 7-14 days), in minutes, required to treat an entire limb. Lauromacrogol 400 is the drug used for sclerotherapy in the following concentrations: 0.25%, 0.5% and 1%.
B Group includes 88 patients with varicose dilatation of saphenous and extra-saphenous collateral veins treated with EVLA technique. Patients were divided in two subgroups: B1 includes 45 patients subjected to Visioven®-guided EVLA, while B2 subset includes 43 patients treated with EVLA without Visioven®. The effectiveness of the use of transillumination was evaluated by the number of venous cannulations needed to treat varicose collateral veins of a whole limb and the procedure time in minutes. All patients were homogeneous in starting varicosity pattern. The employed laser device utilizes a with an 808 nm wavelength light, which allows the treatment of supra-fascia reticular varices. Cannulation was performed using a 16 G needle to prick the vein and guide laser fiber into the vessel.

Results

In the A1 subgroup, in which the procedure has been supported by use of Visioven®, for the treatment of all telangiectasias and reticular varices of the entire lim,b it have been required from a minimum of 29 to a maximum of 38 stings, with an average of 34.79 and a standard deviation (SD) of 2.50. The average time was 222.19 minutes (SD = 4.27).
In the subgroup A2, treatment has needed an average of 45.70 stings, with a minimum of 37 and a maximum of 52 (SD = 4.23). The average time was 234.20 minutes (SD = 7.51).
In the B1 subgroup, EVLA + Visioven®, an average of 20.23 (SD = 2.78) cannulations were performed with a mean time of 77.21 minutes per procedure (SD = 12.81).
In subgroup B2, in which the EVLA procedure was performed without the use of Visioven®, the complete limb treatment has needed an average of 23.47 (SD = 2.04) cannulations with a mean time of 87.88 minutes (SD = 12.21).
The obtained values averages were compared using two-tailed z test and the null hypothesis was accepted for values $-1.96 < Z < 1.96$. (Tables I, II)
The difference between the number of stings required for sclerotherapy treatment in the A1 and A2 subgroups was statistically significant, while the required average time has not seen significant differences between the A1 and A2 subgroups.
The average number of cannulations necessary in B1 subgroup was statistically lower than the average of cannulations in the B2 subgroup, while there were no statistically significant differences in the time required.

Table I - *Results of average number of needed cannulations*

	Visioven® assisted	Not Visioven® assisted
Scleroterapy	34.79 ±2.50	45.70 ±4.23
EVLA	20.23 ±2.78	23.47 ± 2.04

Table II - *Average procedure time*

	Visioven® assisted	Not Visioven® assisted
Scleroterapy	222.19 ± 4.27 min	234.20 ± 4.27 min
EVLA	77.21 ± 12.81 min	87.88 ± 12.21 min

Discussion

The obtained results show that there is a statistically significant difference between the subgroup in which it was used Visioven® and the one in which the procedure has been performed with the use of any tools, both in the sclerotherapy group than in the EVLA one.
Complete vein closure was immediately highlighted by the presence of a "cord" without flow or, sometimes, by its disappearing. The number of cannulations in the various sclerotherapy sessions was reduced, as a consequence of a "smart" and "targeted" treatment[4].
During EVLA procedure, we were able to easily highlight the veins to be treated. This made it possible to obtain satisfactory results in terms of the effectiveness of therapy. Ensuring the correct position of the laser fiber we have the possibility to apply the most appropriate laser energy without fearing of not closing the vessel or causing skin damage due to the incongruous extra-vascular energy delivering. On the aesthetic side this treatment seems to be highly effective, because, on one hand we have avoided to perform several skin incisions, on the other we have avoided the risk of thermal injuries[5].
However, despite a favorable trend towards the use of Visioven® has been shown, in terms of required time to complete the procedure both in the sclerotherapy group than in the EVLA one, there is not a statistically significant difference for the required time to complete the procedure carried out with Visioven® compared with the one performed without the use of any transillumination.
This can be explained by the required time for positioning the light source in correspondence of the area to be treated, in the case of the use of the static support, or in coordinating the movements to highlight the puncture site and the successive cannulation, especially if the procedure is performed by a single operator.

Conclusions

We used transillumination technique as an effective strategy during sclerotherapy and surgery of varicose veins. Currently, on the market, several devices are present; however, they have shown some disadvantages, like unwieldiness, or the insufficient enhancing of the vessel, or the lack in feasibility during surgery.
The device we developed, Visioven®, effectively solves this "handicap" because it is easy to handle and flexible so that it can be used by the same operator both during surgery and during sclerotherapy. It has a light power and a wavelength which perfectly enhance the vessels to be treated and it also can be used pre-operatively for the venous mapping leading to a "smart" and "targeted" treatment.
Finally, another advantage is that the Visioven® can also be used during surgery, which also led us to develop a new surgical technique: during surgery, instead of practicing phlebectomies (with their incisions and traumas) we can directly cannulate, under the Visioven® guide, the vessel with the laser probe through a needle, with less trauma, more effectiveness, and better aesthetic results[6].
We are convinced that with this system we can immediately begin to have a more rational approach to sclerotherapy of teleangectasias and reticular veins, as we can immediately verify the effectiveness of the treatment and adapting it to the effects achieved[7].
We believe we can say that the Visioven® leads to a rational and effective approach to sclerotherapy of telangectasias and reticular veins and allows to use an effective and minimally-invasive surgical tecnique of the saphenous and extra-saphenous veins.

VISIOVEN® study group:
Marco Apperti, Gennaro Quarto, Ermenegildo Furino, Antonio Molisso, Antonio Sellitti, Lanfranco Scaramuzzino, Luigi Goffredi, Ignazio Verde, Bruno Amato, Giuseppe Veneruso, Francesco Ferrara, Piero Atelli, Mattia Davide della Rocca.

Riassunto

Il lavoro presentato ha come scopo quello di illustrare le potenzialità dell'utilizzo e i risultati ottenuti con Visioven®, uno strumento transilluminazione venosa laser.
Sono stati arruolati 205 pazienti (103 femmine e 102 maschi) affetti da insufficienza venosa cronica - con classe CEAP-C > 3 e divisi in due gruppi. Gruppo A: pazienti candidati alla scleroterapia; Gruppo B: pazienti da sottoporre a ablazione laser endovascolare (EVLA). In entrambi i gruppi i pazienti sono stati divisi in due sottogruppi sulla base dell'uso di Visioven® o meno durante la procedura. Le variabili di risultato analizzate sono state il numero totale di incannulazioni necessarie per trattare un intero arto, e il tempo totale necessario a terminare l'intera procedura.
È stata evidenziata una differenza statisticamente significativa tra il sottogruppo in cui è stato usato Visioven® e quello in cui la procedura è stata eseguita senza l'utilizzo della transilluminazione, sia nel gruppo scleroterapia che nel EVLA. Per quanto riguarda il tempo necessario per completare la procedura, sia nel gruppo scleroterapia che nel gruppo EVLA, non vi è alcuna differenza statisticamente significativa nella procedura eseguita con Visioven® rispetto a quella eseguita in visione diretta.
Il numero di cannulazioni nelle varie sessioni di scleroterapia è stato ridotto, a seguito di un trattamento "intelligente" e "mirato"
Per questo si può concludere che il sistema Visioven® porta ad avere un approccio più razionale alla sclerote-

rapia delle teleangectasie e vene reticolari, dal momento che si può verificare immediatamente l'efficacia del trattamento e modificarlo in corso d'opera, necessario.

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