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# **HYBRID THERAPY OF VARICEAL DISEASE:** A RETROSPECTIVE CLINICAL STUDY

TORMA N.1, KOPOLOVETS I.2,3\*, STEFANIC P.2, KOPOLOVETS G.1

<sup>1</sup> Vascular Centrum IMEA, Kosice, Slovak Republic

<sup>2</sup>Clinic of Vascular Surgery, East Slovak Institute of Cardiovascular Diseases, Kosice, Slovak Republic

<sup>3</sup> Department of Surgical Diseases, Medical Faculty, Uzhhorod National University, Uzhhorod, Ukraine

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#### ABSTRACT

The chronic venous disease presents a wide range of morphological and functional abnormalities of the venous system starting with telangiectasia up to venous ulcers. The authors describe possibilities of modern treatment procedures of variceal disease (combination of thermoablation techniques with sclerotherapy and local vein extirpation).

Present study aimed to evaluate the results of treatment of variceal disease using thermoablation techniques combined with sclerotherapy and miniflebectomy of collateral varices.

At our outpatient department and operating room, 457 performances in the venous system of the lower extremities were performed during a year and a half. From thermoablation options available the main venous trunk radio frequency was performed (VNUS closure fast) in 192 cases, and laser ablation (ELVES - 1470 nm) of the main venous trunk in 265 cases.

After a comparison of both thermal ablation techniques for insufficiency treatment of the main venous trunk, the difference was not found. In the group of patients with sclerotherapy, the pain score was higher, mainly in sclerotherapy of great varicocele. In a group of patients with local varices extirpation, a higher number of hematomas was observed.

Thermoablation techniques treatment for superficial venous insufficiency combined with sclerotherapy and miniflebectomy of collateral varices are safe and can be carried out under local anesthesia in an outpatient setting with good patient satisfaction and low complication rates. There are three main indications dominating in the treatment of varicosities of lower extremities. Firstly, the treatment is directed to the prevention of possible complications such as thromboses and prevention of ulcerations in lower limbs in the final stage. The second indication is to relieve the patient from "heavy legs" feeling, swelling and convulsions. The third and no less important is the indication to procedure due to cosmetic reasons

**KEYWORDS:** . varicose veins, ablation techniques, sclerotherapy, miniflebectomy.

### Introduction

Varicose veins of the lower limbs affect between 25% and 35% of adults in the Western world. In more than 80% of cases, the cause is saphenous vein incompetence [Shepherd A et al., 2011]. This disease presents a wide range of morphological and functional abnormalities of the venous system starting with telangiectasia up to venous ulcers [Gujja K et al., 2014]. All these forms of the venous disease are of significant impact on quality of patient's life including significant social and economic impact,

Address for Correspondence:

Ivan Kopolovets, PhD

Kosice 04001, Slovak Republic

Tel.: +421 055/ 789 1510 E-mail: i.kopolovets@gmail.com

Clinic of Vascular Surgery, East Slovak Institute of Cardiovascular Diseases

too [Carradice D et al., 2011] Chronic venous disease can begin discreetly, or at the very beginning, varicose veins appear. Prolonged and untreated disease leads to changes in the area of lower limbs, such as edema, hyperpigmentation, lipodermatosclerosis and finally, results in the formation of ulcers [Bobridge A et al., 2011; Lurie F et al., 2011]. Nowadays the mainstay of treatment of chronic venous insufficiency involves compression therapy, venotonic drugs, classical venous surgery, radio obliteration, sclerotherapy and the choice of treatment depends on the stage of chronic venous insufficiency (CVI) [Burihan MC, 2014; Sell H et al., 2014]. To achieve good treatment results, it is important to take into consideration hemodynamic disturbances for each patient with varicose veins that can be revealed under ultrasonography guidance

[Thomasset S et al., 2010]. Invasive treatment of superficial varicose veins and venous reflux improves quality of life compared with conservative treatment with compression stockings [Sell H et al., 2014]. Compared with conventional surgery, minimally invasive techniques proposed benefits include fewer complications, quicker return to work, improved quality of life scores, reduced need for general anesthesia and equivalent recurrence rates [Lawaetz M et al., 2017]. Endovenous treatment methods of the lower limb varicosity combine a wide range of interventions, the main aim of which is considered to be the obliteration of the venous trunks and the main venous tributaries with minimal invasive puncture access under sonographic guidance [Nesbitt C et al., 2014]. However, to achieve optimal treatment outcomes, the best option is a combination of thermal treatment with miniflebectomy of collateral varices and sclerotherapy [Brittenden J et al., 2015; Venermo M et al., 2016].

The study aimed to evaluate the results of treatment of variceal disease using thermoablation techniques combined with sclerotherapy and miniflebectomy of collateral varices.

#### MATERIAL AND METHODS

At our outpatient department and operating rooms, 457 performances in the venous system of the lower extremities were carried out during two years. Out of these, 263 (57.5%) were females, and 194 (42.5%) were males with an average age of 43.6 years (males: 43.2, females: 39.5). In 442 cases (189 males and 253 females), the thermoablation of the major venous trunks was implemented. In 9 cases, the small saphenous vein was thermoablation (3 males: 6 females), while vena saphena accessory anterior was thermostated in 6

cases (2 males: 4 females).

From the thermoablation options available the main venous trunk radio frequency was performed (VNUS closure fast) in 192 cases (42%) – I group and laser ablation (ELVES - 1470 nm) of the main venous trunk in 265 (58%) cases – II group (Table).

There were no differences in age and gender between groups.

To overcome it is possible, due to the uniting the knowledge and will of all doctors in the world

Table The distribution of patients into groups

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Patients (n=457)	I group	II group
Venous trunks	Radio frequency (n=192)	Laser ablation (n=265)
VSM	188 (41.1 %)	254 (55.6 %)
VSP	2 (0.4 %)	7 (1.5 %)
VSAA	2 (0.4 %)	4 (0.9 %)

Note: VSM - vena saphena magna, VSP - vena saphena parva, VSAA - vena saphena accessoria anterior

Thermoablation was carried out in 11 cases of patients after previously having been operated on the large saphenous system.

After thermoablation on 40 patients (subgroup A), the foam sclerotization of collateral varices was performed as a supplement to thermoablation of the major venous trunk. Sclerotization employed the foam of aethoxysclerol 1% on smaller veins (venectasi) along with up to 2% of the foam on large veins.

In next 57 patients (subgroup B), the treatment in significantly prominent varices in intumescence phlebectomy of the prominent veins was performed.

Statistical processing was performed with the use of "Microsoft Excel 2013". All results are listed in the tables in the form of quantitative characteristics and percentage ratio. Statistical significance of the results in groups was assessed with the use of the Mann-Whitney U test (SPSS 22.0.).

### RESULTS

In the group, I of patients treated with radiofrequency, women (101 patients) predominated with the average age of 39.7 years over men (91 patients) with an average age of 46.9 years. In two cases, the small saphenous vein was thermoablated (1 male: 1 female), while in other two it was vena saphena accessory anterior (2 females).

In group II of patients treated with laser ablation, women (162) predominated over men in 103 cases (the average age was 49.9: 43.2). In this group of patients, vena saphena magna insufficiency in 253 cases (157 females and 96 males) was predominant, and the group includes 5 cases of thermoablation of vena saphena accessory anterior (VSAA) and 7 cases of the small saphenous vein ablation. These were mostly the patients with reflux of the saphenous vein type Hach III. There-

fore, the most common place for puncture entry into the venous system was the area below the knee (proximal half of the tibia), in 197 cases. In other cases, the puncture in the area above the knee was conducted, at the site of the most distal point of the vena saphena magna reflux, in reflux type Hach II. In case of insufficiency of the vena saphena accessory anterior the puncture on the thigh in both cases (approximately 15 cm from the junction) was performed followed by the vein ablation. In ablation of VSM, the puncture opening was in the proximal part of the calf in all cases (Fig. 1).

In 11 cases, thermoablation was carried out in patients after their previous operations on the large saphenous system. In these patients, the insufficient vein suitable for thermoablation was detected by USG examination – secondary great saphenous vein, possibly it was collateral which in its course reminded of VSM. The condition for thermoablation was the direct course of the vein and its sufficient lumen. The average length of thus ablated veins was  $57 \ cm \ (23 - 72 \ cm)$ . Subsequently, collateral veins were extirpated and sclerotized.

After thermoablation performances, the foam sclerotization of collateral varices (subgroup A: patients without an incision, males 13: females 27) was first performed as a supplement to thermoablation of the major venous trunk. Sclerotherapy was performed immediately in the operating room.

In this period, 40 patients have been treated by thermoablation. Such a procedure was implemented in 30 patients (10 without sclerotherapy) and three patients with significant prominent varices. In one case, there was a patient with vena saphena accessory anterior insufficiency and an extensive varicose complex on the thigh. In the other two cases, VSM was treated with thermoablation and subsequently, in one case significant collateral

varices in the knee were sclerotized and in the second case across the tibia, laterally (both Hach II). These significant varices required two months to "disappear" on average and the healing process was, especially at the beginning, very painful.

Out of 30 patients sclerotized in the operating room, sclerotization of varices had to be finished earlier due to their incomplete obstruction in 3 cases after later check-up (Fig. 2).

It was the next day when checking for thermoablation in one patient and one month after thermoablation in the next two patients. In this group of patients, no additional sclerotherapy was needed at the next check-up.

In the next 57 patients (subgroup B: patients with incision, the average age 44.5 years, males:females 34:23) the treatment was started in significantly prominent varices in intumescence phlebectomy of the prominent veins.

The most prominent varicose veins were extirpated in intumescence and from the several small incisions. We tried to realize this performance from as few incisions as possible (approximately four incisions) and removed only prominent varices which after sclerotization could be the cause of severe pain. Subsequently, at check-up after a month, sclerotherapy was conducted in three patients for "hidden varices." In the postoperative period, the postoperative hematomas were present in these patients (the ligature of the veins was not performed) as in the classical surgeries. But their regression is much faster than in patients after stripping the main venous trunks.

From the complications in subgroup A, 3 cases were redness and significant pain present in the sclerotized dilated veins. These occurred approximately three days after sclerotization. The maximum pain and tenderness after sclerotization were



Figure 1. Thermoablation of vena saphena magna.



FIGURE 2. Sclerotherapy of collateral varices.

in the area above the knee medially (collateral varices) and also, in the patient with thermoablation of vena saphenous accessory anterior insufficiency. In this patient, the healing process of sclerotic veins was the most complicated one. Pain and redness lasted for a month and the total healing up to the disappearance of dilated varicose took three months and is not present currently, as well as there is no skin hyperpigmentation. The patient is currently after thermoablation of the second limb, where the prominent varices were extirpated.

In subgroup B of patients with the incision, the great varicose veins have already been excised. In this group of patients, the pain was observed in three cases after the performance, but with a maximum pain not in places of excised varices, but rather in places after thermoablation of the main venous trunks. The intumescence appeared to be excellent in preventing pain.

No statistically significant difference was observed (p NS) between the two methods of thermoablation of the main venous trunks (VNUS closure fast – ELVES 1470 nm) with respect to the duration of performance (laser 4.15 min, radio frequency 4.30 min), pain (observed by one-dimensional pain scale) and a number of hematoma in the course of the venous trunk. The duration of the thermoablation depended on the length and the diameter of the destructed vein.

# **D**iscussion

Endovenous treatments of varices in lower extremities include a wide range of performances whose common feature is the closure of the vein and main venous trunks from the minimally invasive percutaneous approach [Carradice D et al., 2011]. The methods can be divided into thermal, chemical and mechanical. All methods in the treatment of varicose veins of lower limbs were first introduced in the 90s of the last century, and all require knowledge of work with ultrasound examination of the current medical procedure [Lattimer C et al., 2012]. Unlike the thermal ablation techniques that require intumescence, currently used mechanical and chemical methods are implemented without intumescence [Lawaetz M et al., 2017].

Endothermal techniques can not usually treat visible varices, and they are mostly operated by phlebectomy through microincision, or by sclerotherapy. Both of these methods could also be implemented without total or drain anesthesia [Nesbitt C et al., 2014]. Endovenous interventions have some distinct advantages over surgical treat-

ment, mainly they do not require anesthesia and are feasible without the necessity of hospitalization [Venermo M et al., 2016]. Furthermore, after endovenous performances there is less postoperative pain, shorter sick leave, the cost of performance is reduced compared with the cost of performance in hospital facilities, and the patients themselves prefer less invasive procedures [Hamel-Desnos C et al., 2010].

Endovenous techniques disadvantage is the need for technical equipment - a generator and the ultrasound equipment. Also, one catheter is used only in one patient, and a doctor must undergo "training" for such an intervention. In our facility both methods of thermoablation (Radio Frequency Method - VNUS closure fast and the laser radial destruction of wavelength 1470 nm (ELVES)) were employed to destruct the main venous trunks -VSM, VSP, as well as the destruction of the accessory saphenous veins in case when their course made such therapy possible. This method was also used in patients after surgeries on the venous system if retained VSM was found at USG examination, enlarged vein mimicking VSM, or the second VSM at the expected duplicated and retained VSM at the surgery [Burihan M et al., 2014].

Sclerotherapy in which the aethoxysklerol is administered into the surface venous system of the patient has its origin in 1944. Liquid - classical sclerotherapy works on the principle of the direct contact of the sclerotization substance with the vein wall and causes vessel obliteration [Thomasset S et al., 2010; Brittenden J et al., 2015]. Direct contact of the sclerotization substance with the vein endothelium causes damage to the endothelium and the vessel wall itself by irritation. The result is a wall thrombus and finally transformation of the vessel into a fibrous strip [Lattimer C et al., 2012].

The success of the foam sclerotherapy, which is also effective in the treatment of truncal insufficiencies, is in its quantity and volume. The foam pushes the blood out of the vein involving close contact of foam and vein endothelium and subsequent spasms[van der Velden S et al., 2015]. The foam itself is formed by mixing the sclerotization substance with the air, oxygen, or carbon dioxide. The success of foam sclerotherapy depends on the extent of varicose changes and the actual anatomy of the venous system. The main advantage of foam sclerotherapy is that it can be used for any patient with the progressive venous disease, and in patients with morbid obesity and advanced age. The most important performance contraindication is

being allergic to sclerotization substance and obliteration of the deep venous system [Hamel-Desnos C et al., 2010; King J et al., 2015].

We have used the foam sclerotherapy among other procedures as an additional method to thermoablation techniques, and it has been applied in the collateral stream at various concentrations, depending on the vein diameter. Initially, the sclerotherapy has been implemented immediately in the operating room as a supplement to thermoablation, later it has been performed subsequently after some time onto the "missed" veins. Currently, the individual approach has been used, and the sclerotization substance has been applied in both ways [Thomasset S et al., 2010].

Out-patient pholebotomy is one way of removing dilated collateral veins. By now, there is only one randomized study comparing sclerotherapy of collateral varices with their out-patient phlebectomy. In the local anesthesia through small incisions, dilated and insufficient collateral veins are being removed, using a hook. The actual procedure is well tolerated with minimal complications [Lurie F et al., 2011].

In our patients, phlebectomy was started three months after the introduction of thermoablation techniques. They are performed in case of large surface varicosities for which there is hyperpigmentation and more painful feelings reported by patients when applied sclerotherapy.

Currently, each patient is being dealt with individually. For insufficiency of the great and small saphenous vein, thermoablation is the method we are trying to employ. In case of inability of kinking the vein, post-inflammatory obliterative changes and relapses after previous operations, the traditional operations are also performed. If the thermoablation of the truncal vein is possible and successfully implemented, we proceed according to the state of varicosity on the lower limbs. In the case of large and prominent varicosities, we extirpate them in the operating room at local anesthesia (intumescence). The sclerotization of the other not prominent varices is then finished. If tributaries do not become prominent, they are obliterated only by sclerotherapy and phlebectomy are not implemented. The advantage of sclerotherapy is the absence of incisions, and no anesthesia required [Siribumrungwong B et al., 2015]. The disadvantage, especially in dilated varicosities, is redness of the skin above varicosity and pain (especially on the first day after the procedure, but after a pressure also later) of such obliterated varicosity [*Blomgren L et al.*, 2011].

The advantage of phlebectomy is the quick removal of varices, the disadvantage is the need for local anesthesia (intumescence) and postoperative hematoma that disappear in a short time [Galanopoulos G et al., 2012]. The intumescence itself in the area of collateral varices is uncomfortable for some patients, but in the postoperative period, the patients do not feel any pain at the site of the extracted veins and incisions, which is a great advantage over traditional surgery of varices and sclerotherapy.

Currently, the thermoablation of the insufficient, directly ongoing vein has been performed - whether it is the ablation of the saphenous vein, accessory vein or at redo operations in the directly ongoing vein - filling the collateral system with reflux (secondary VSM, accessory VSM). If the collateral vein is linked to the small collateral insufficient system on the saphenofemoral junction, these collaterals are being sclerotized in the operating room. In the case of saphenofemoral insufficiency, if the junction of VSM and VSAA is very close to the vena femoralis communis (VFC) and both are insufficient, the thermoablation of both branches is performed from the separate punctures. After the thermoablation, the extirpation of the prominent varices has been performed in the same session, at intumescence. The prominent varices, previously marked by pen, are being extirpated as in classical surgical interventions. In young patients, where the emphasis is on esthetics, only tiny incisions are made (up to 3 mm), the ligation of collaterals is being performed (less hematoma and hyperpigmentation) and the wounds are left open. The next day, when checking the wound, adhesive strips are applied. Telangiectasia and venectasia are sclerotized later on, according to patient requirement.

#### Conclusion

Thermoablation techniques treatment for superficial venous insufficiency combined with sclerotherapy and miniflebectomy of collateral varices are safe and can be carried out under local anesthesia in an outpatient setting with good patient satisfaction and low complication rates. Three main indications are dominating in the treatment of varicosities of lower extremities. Firstly, the treatment is directed to the prevention of possible complications such as thromboses and prevention of ulcerations in lower limbs in the final stage. The second indication is to relieve the patient from "heavy legs" feeling, swelling and convulsions. The third and no less important is the indication to procedure due to cosmetic reasons.

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