

## Cryostripping Versus Conventional Safenectomy in Chronic Venous Disease Treatment: A Single Center Retrospective Cohort Study

Sergiu-Ciprian Matei<sup>1,2</sup>, Daniela Radu-Teodorescu<sup>1,2,3\*</sup>, Marius Sorin Murariu<sup>1,2,3</sup>, Cristina Ștefania Dumitru<sup>4</sup>, Sorin Olariu<sup>1,2,3</sup>

<sup>1</sup>Abdominal Surgery and Phlebology Research Center, Victor Babeș University of Medicine and Pharmacy Timișoara, Romania

<sup>2</sup>1<sup>st</sup> Surgical Department, Pius Brînzeu Emergency County Hospital Timișoara, Romania

<sup>3</sup>Victor Babeș University of Medicine and Pharmacy, X Surgical Department, Timișoara, Romania

<sup>4</sup>Department of Microscopic Morphology/Histology, Victor Babeș University of Medicine and Pharmacy, Timișoara, Romania

### \*Corresponding author:

Abdominal Surgery and Phlebology  
Research Center, Victor Babeș  
University of Medicine and Pharmacy  
Timișoara, Romania  
E-mail: radu.daniela@umft.ro

### Rezumat

*Cryostripping versus safenectomia convențională în tratamentul bolilor venoase cronice: un studiu de cohortă retrospectiv într-un singur centru*

**Scop:** Analiza comparativă a cryostripping-ului în raport cu safenectomia convențională.

**Materiale și Metode:** Studiul a inclus 2191 pacienți dispensarizați în Compartimentul de Flebologie din cadrul Clinicii I Chirurgie SCJUT, în perioada septembrie 2013 – aprilie 2023, 1-a care s-a practicat safenectomia prin cryostripping (1327 pacienți) sau pe cale convențională (864 pacienți). Am analizat comparativ durata și costurile intervenției, perioada de spitalizare, rezultatele post-operatorii, fezabilitatea metodei, precum și avantajele tehnice ale cryostripping-ului raportat la safenectomia convențională.

**Rezultate:** Tehnic cyostrippingul prezintă următoarele avantaje: o incizie proximală mai mică, comparativ cu operația clasică, și lipsa necesității contrainciziei distale. Timpul mediu necesar intervenției a fost  $41 \pm 12,8$  minute, având un cost mediu de  $52 \pm 10$  €/intervenție. Spitalizarea medie a fost  $1,05 \pm 0,41$  zile. Rezultatele post-operatorii au fost favorabile, rata complicațiilor precoce fiind redusă (echimoze  $\Phi < 2$  cm - 33,23%; hematom - 2,11%; tromboză venoasă profundă - 0,15%; parestezii tranzitorii 3,01%). Comparativ cu safenectomia clasică, costurile consumabilelor/ intervenție sunt similare, iar durata intervenției, perioada de spitalizare și rata complicațiilor sunt statistic semnificativ mai reduse. Cryosondele sunt sterilizabile și reutilizabile, economic metoda pretându-se atât în spitalele publice, cât și în mediul privat.

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**Concluzii:** Cryostripping-ul este o procedură chirurgicală radicală, fiind o modalitate eficientă pentru tratamentul insuficienței valvulare venoase și aducând un număr mare de avantaje comparativ cu safenectomia clasică.

**Cuvinte cheie:** cryostripping, safenectomie, insuficiență venoasă cronică, reflux venos, spital de stat

## Abstract

**Aim:** This study presents a comparative analysis of cryostripping to conventional saphenectomy.

**Materials and Methods:** The study included 2191 patients admitted in the Phlebology Department, 1<sup>st</sup> Surgical Department, Emergency County Hospital Timișoara, between September 2013 and April 2023, who underwent saphenectomy by cryostripping (1327 patients) or conventionally (864 patients). We compared the duration and costs of the procedure, hospitalization period, post-operative results, method feasibility, as well as the technical advantages of cryostripping compared to conventional surgery.

**Results:** A smaller proximal incision, compared to the classic operation, as well the fact that distal counter incision is not necessary, represents technical advantages of this procedure. Average duration of the intervention was  $41 \pm 12.8$  minutes, consumables costs were about  $52 \pm 10$  €/intervention, with an average hospitalization period was  $1.05 \pm 0.41$  days. The post-operative results were favourable, early complications rate being reduced (ecchymoses  $\Phi < 2$  cm - 33.23%; hematoma - 2.11%; deep vein thrombosis - 0.15%; transient paresthesias 3.01%). Compared to classic saphenectomy, the costs of consumables/intervention are similar, intervention time, hospitalization period and complication rate being statistically significantly lower. An advantage of the method is the fact that the cryo-probes can be sterilized, being reusable; from the economic point of view, the technique perfectly fits in both public hospitals and private clinics.

**Conclusions:** Cryostripping is a radical surgical procedure which bring a significant number of advantages compared to the classic saphenectomy, being an effective alternative in CVD treatment.

**Key words:** cryostripping, conventional saphenectomy, chronic venous insufficiency, venous reflux, public hospital

## Introduction

Chronic venous disease (CVD) is the consequence of venous reflux. It is a prevalent condition worldwide spread, with a highest prevalence in the Western countries (1). Venous reflux may occur in all parts of the great saphenous vein (GSV), or small saphenous vein (SSV). Whether it is about truncal or tributary reflux, it is recommended to treat symptomatic venous reflux (2), in order to relieve symptoms and prevent complications. The insufficient veins should be removed or occluded.

Traditionally, the gold standard for varicose

veins removal surgery has been the conventional saphenectomy, a time-tested approach with a well-established track record. However, the landscape of chronic venous disease treatment has evolved, ushering in alternative methods that prioritize minimally invasive techniques (3). In addition to the conventional saphenectomy performed by stripping, minimally invasive techniques including endo-venous laser or radiofrequency ablation, microwawe or mechano-chemical ablation, VenaSeal (cyanoacrylate adhesive closure), cryostripping, and others, were developed (4). Although the most recent data in the litera-

ture recommend endovenous thermal ablation (radiofrequency or laser) rather than high ligation and stripping of the GSV to the level of the knee (5), due to the high costs of these procedures, as well as the fact that it has been proven that in the long term they prone to a series of complications (6), open surgery remains a feasible treatment option, especially in low and middle income countries.

Among these modern alternatives, cryostripping has emerged as a notable contender. Representing a paradigm shift from traditional approaches, cryostripping is an open procedure that combines minimally invasive principles with effectiveness and safety. Its role in chronic venous disease treatment has garnered attention, offering patients a viable and efficient option for addressing the challenges posed by symptomatic venous reflux.

Cryostripping is a minimally invasive open procedure used in varicose veins cure, being an effective and safe treatment option in terms of postoperative complications, recurrence and cosmetic results (7). Cryostripping surgeries were practiced for the first time in 1987, and since 1990 this procedure is successfully used in some phlebological centers from Germany. Even though the cryoprobe vein removal procedure is simple, it is not widely known (8). Although some studies claimed that patients may prefer endovenous laser ablation because of less pain and low postoperative morbidity, in addition to a quicker return to normal activity (9), outpatient cryostripping provide lower costs and it seems to be more effective long term (10). The clinical outcomes of cryostripping are not inferior to those of endovenous laser ablation. Further, considering its cost-effectiveness, cryostripping is a safe and feasible method for CVD treatment (11). As national premiere, this procedure was introduced in Romania in our Phlebology Department (1<sup>st</sup> Surgical Department, Pius Brînzeu Emergency County Hospital Timișoara) in September 2013, by Professor Sorin Olariu.

This study aims to assess the efficacy and safety of this surgical technique - cryostripping, in terms of patient management,

complications, clinical and economical implications. Outcomes, recurrence rate, advantages and disadvantages of this procedure were analysed and compared to conventional saphenectomy.

## Material and Methods

This cohort retrospective study included 2191 patients diagnosed with CVD which were treated in the Phlebology Department, Emergency County Hospital Timișoara, between September 2013 and April 2023, for whom we had an at least six months follow-up. All the patients were evaluated before surgery by the same physicians team, and venous reflux was found. The 'pulse-wave' Doppler examination was used to highlight the reflux at the ostium level in the case of great or small saphenous vein by the Valsalva maneuver performed in orthostatic position. Regarding the reflux on the collateral and perforator veins, it was objectified to the Doppler examination in an orthostatic position through a fast-filling time after decompression. The evaluated patients have undergone subsequently surgical treatment. Open procedures (cryostripping or conventional stripping) were performed. According to the surgical procedure that was practiced, all the cases were subsequently divided into a cryostripping group (CG) - 1327 patients, and group a conventional saphenectomy group (CSG) - 864 patients. The type of surgical intervention performed was chosen depending on the surgeon's experience, logistical support and patient compliance with the surgeon's recommendation.

The technical advantages of the procedure, the duration and costs of the intervention, the hospitalization period, the post-operative results, and the feasibility of the method were analyzed. The obtained data were compared with those resulting from patients operated by conventional saphenectomy.

## Statistical Analyses

Statistical analyses were completed using MedCalc® Statistical Software version 20.118

(MedCalc Software Ltd., Ostend, Belgium; 2022). The results were analyzed using the Mann-Whitney test and Chi-square test for nonparametric data. The normality of distribution was analysed using the Kolmogorov-Smirnov test. Comparisons of continuous parametric data was performed using Student's t-test. All p-values were two-sided, and a p-value < 0.05 was considered statistically significant.

## Surgical Technique

### Anaesthesia

Regional (spinal) or general (laryngeal mask) anaesthesia is recommended. Although the possibility of performing the surgery under local anaesthesia +/- tumescent anaesthesia has also been described in literature, we did not practice this method, considering that it is not so comfortable for the patient.

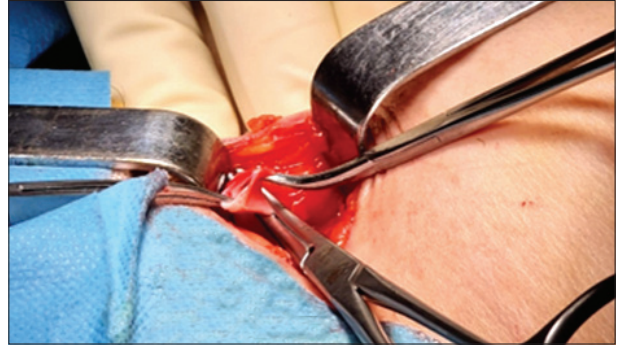
### Position

The patient is supine with the thigh and knee in slight external rotation and flexion.

### Procedure

The principle of this method consists in venous catheterization with a special probe which is cooled to  $-85^{\circ}\text{C}$  and makes a good adherence to the vein and thus it can be removed. In technical terms, the procedure starts with the crossotomy. A 1.5-2 centimetres long incision is placed in the groin fold. The saphenous vein is clamped and cut from the beginning, and thus by traction on the proximal stump, from confluence of femoral vein, the collaterals were stretched, being more easily highlighted and ligated (*Fig. 1*).

The ligation and section of the saphenous vein cross is practiced at the entrance to the femoral vein. Retrograde vein catheterization is performed then, from thigh to the lower leg in case of GSV and from popliteal fossa to malleolus, in case of SSV. The probe is smooth and sustained by light calf flexion and extension movements on the thigh, it can be easily inserted



**Figure 1.** Great saphenous vein cryostripping, intraoperative aspect. First, the vein is high ligated and cut, the stump being prepared for retrograde catheterisation with the probe



**Figure 2.** By withdrawing the probe, the insufficient great saphenous vein is easily removed



**Figure 3.** Small saphenous vein ablation, intraoperative aspect. While the cooling device is stopped, the vein can be easily removed from the probe. The insufficient vein is fully removed, following the preoperative mapping

even if saphenous vein path is tortuous. By connecting the probe to the device ERBE ERBOKRYO which use liquid nitrogen, the cooling occurs at  $-85^{\circ}\text{C}$ . When the vein becomes adherent to the probe, it is extracted by repeated traction at every 4-5 seconds (*Fig. 2*), time needed for cooling the probe. The complete insufficient vein removal takes about 45-60 seconds (*Fig. 3*).

When it is necessary (venous reflux revealed by preoperative ultrasound), perforants veins are ligated. Phlebectomies can be performed additionally through skin punctures for collaterals veins removal. Steri-strips are used for skin closure.

### Results

A comprehensive comparison of patient demographics and disease characteristics between the cryostripping group and conventional saphenectomy group cohorts revealed generally comparable baseline attributes. Parameters such as gender, age, native environment, and disease stage were examined; with differences not reaching statistical significance ( $p > 0.05$ ). The mean Body Mass Index (BMI) for the CG was  $28.6 \pm 4.43 \text{ kg/m}^2$ , while the CSG had a mean BMI of  $27.4 \pm 4.21 \text{ kg/m}^2$ . However, the p-value for this parameter was calculated as 3.161, indicating that the observed difference in BMI between the two groups was not statistically significant. Considering these results, the groups are considered equivalent.

Both treatment modalities, cryostripping and conventional saphenectomy, were com-

pared in terms of patient management, complications, clinical outcomes, and economic implications (Table 1).

Cryostripping exhibited distinct technical advantages, characterized by a smaller proximal incision in comparison to conventional saphenectomy, due to the significantly smaller diameter of the cryoprobe compared to the classical stripper's metal olive which allows an easier catheterization of the insufficient vein. The study demonstrated superior outcomes for cryostripping when compared to conventional saphenectomy, particularly in key outcome measures. The procedure streamlined with the absence of a distal counter incision, resulting in a remarkably brief average intervention duration of  $41 \pm 12.8$  minutes. Consumable costs for cryostripping were estimated at approximately  $52 \pm 10 \text{ €}$  per intervention.

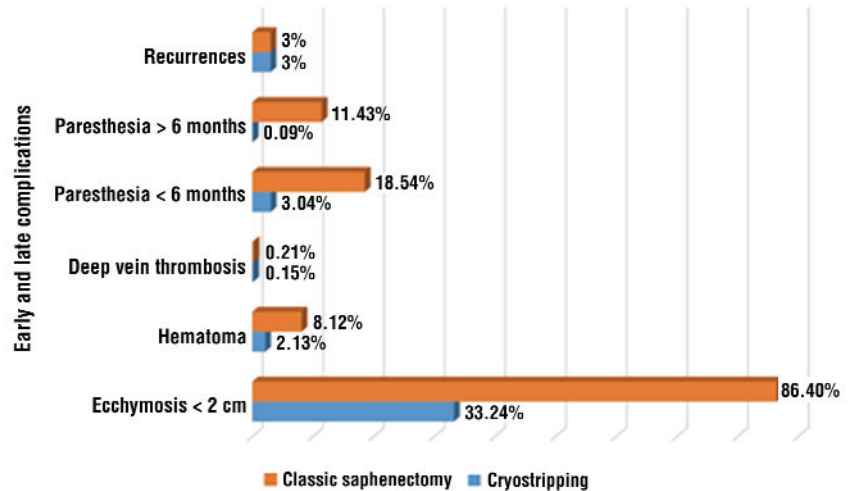
Importantly, the cryoprobes are reusable, providing an economic edge suitable for both state hospitals and private clinics.

Cryostripping led to faster postoperative mobilization and a shorter hospitalization duration, as evidenced by a significantly lower mean duration compared to conventional saphenectomy.

**Table 1.** Comparison of the two methods: cryostripping and conventional saphenectomy

Parameter	Cryostripping group		Conventional saphenectomy group		p-value
	N(%)	mean ± SD	N(%)	mean ± SD	
Women	67.22	8.532 ± 7.189	59.50	7.887 ± 6.988	0.054
Men	32.78	4.731 ± 6.544	40.50	3.277 ± 2.865	0.143
Age (19-87 years)	1327 patients	48.53 ± 12.17	864 patients	45.85 ± 13.267	0.341
	mean ± SD		mean ± SD		p-value
BMI (kg/m <sup>2</sup> )	28.6 ± 4.43	27.4 ± 4.21	3.161		
	Native environment				
Urban	24.19	3.532 ± 2.651	28.47	4.222 ± 4.071	0.205
Rural	75.81	8.733 ± 6.954	71.53	5.246 ± 4.589	0.075
	Disease stage according to the CEAP classification				
C2-C3	79.48	7.134 ± 6.274	75.21	6.421 ± 6.475	0.241
C4	15.08	2.744 ± 1.813	19.15	4.211 ± 3.323	0.312
C5-C6	5.44	0.788 ± 0.423	5.64	0.622 ± 0.360	0.078
<b>Surgery</b>	mean ± SD		mean ± SD		p-value
Duration of intervention (minutes)	41 ± 6.928		54 ± 13.279		0.017
Postoperative mobilization (hours)	2.6 ± 0.207		3.4 ± 0.565		0.042
Hospitalization period (days)	1.05 ± 0.242		3.14 ± 0.560		0.001
Consumable costs (euro)	52 ± 5.77		58 ± 8.66		0.072

**Graph 1.** Postoperative complications rate in the study and control group



*Graph 1* visually presents the postoperative complication rates in the study and control groups. Early complications for cryostripping were notably reduced, with rates for ecchymoses (< 2 cm) at 33%, hematoma at 2.11%, deep vein thrombosis at 0.15%, and transient paresthesia at 3.01%. The overall complication rate was lower for cryostripping than for conventional saphenectomy ( $p=0.024$ ). This suggests a favorable safety profile for cryostripping compared to conventional saphenectomy.

## Discussion

From the technical point of view, the action principle of cryostripping consists in the Joule-Thompson effect. Under the action of the reduced temperature, the vein adheres to the tip of the probe and by traction invaginates on it. Low temperatures are obtained with nitrous oxide. The probes must be sealed and have no gas leaks. The adhesion of the endovain is very strong, and this is how stripping is practiced at the time of withdrawing the probe. Cryostripping of the great saphenous vein with a percutaneously guided probe was also described in the literature, but we did not use this method (8).

There are literature data which confirmed significant improvement in patients quality of life after both conventional and cryostripping

with no difference between the two stripping techniques (12). However, cryostripping brings a number of advantages. First of all, it is a less invasive method compared to conventional surgery because it is performed through a single proximal incision. The procedure eliminates the insufficient veins and implicitly the reflux, thus respecting the principles of venous disease surgery. Compared to other stripping techniques that can be practiced on a single incision such as the InvisiGrip Vein Stripper which removes the GSV through a single groin incision, endovascular cutting and stripping by inversion (13,14), it has the advantage that by freezing the main venous trunk, the collaterals are practically amputated, not pulled out, due to the very low temperatures, their emergence being spastic and then coagulated. Thus, the rate of postoperative hematomas is considerably reduced. Cryostripping results in less bruising than conventional stripping, too. Considering the results of our study, we recommend the use of cryostripping instead of conventional saphenectomy in all cases where the hospital equipment and the the surgical team experience allow it.

At the same time, there are data which confirmed that cryostripping does not result in a lower risk for thromboembolic complications due to superficial vein thrombosis, but can be

an alternative method to treat the ascending thrombophlebitis of the great saphenous vein because it has some advantages over conservative treatment (15). Due to the reduced diameter of the probe compared to the classic instruments, as well as the avoidance of additional incisions, the risk of interception of the nerve threads, and implicitly of complications such as paresthesias, also decreases.

Unlike endovenous laser ablation (EVLA) or radiofrequency ablation (RFA), cryostripping does not predispose to thermal damage to the skin (16), and by removing the insufficient vein, there is no risk of reflux recurrence. Varicose recurrences that occur after cryostripping are newly formed varicose veins, which can be the result of collateral reflux or some tactical mistakes (failure to perform preoperative doppler mapping of the superficial venous network and refluxes, failure to treat the insufficient small saphenous vein, omission of an insufficient accessory saphenous vein, etc.). The procedure is recommended in all cases of ostial venous insufficiency that requires ablation of the saphenous vein (s.magna or s.parva); in the case of reflux at the level of the collaterals of the cross, or the saphenous trunks, regardless of the stage of the disease; in patients which presents aneurismal degeneration of the saphenous vein; in patients with distal oedema of the lower limbs - method of choice.

The procedure lends itself as day surgery, due to the short execution time and quick recovery, the socio-professional reintegration of the patients being fast. From an economic point of view, the method is cheap because cryoprobes can be sterilized and are reusable, unlike laser or radio frequency fibers which are disposable, requiring additional costs (10, 17). However, we must take into account the fact that there are some modern versions of cryoprobes, which are flexible, and like laser or radio frequency fibers, are disposable. Of course, using them would generate costs per intervention similar to other endovenous procedures, but since the Phlebology Department, Emergency County Hospital Timișoara, is not equipped with such devices,

due to the fact that their costs are not covered by the public health insurance system, we have no experience with them. This study refers to re-usable classic metal cryoprobes.

Although there are numerous sources in the literature claiming that great saphenous vein incompetence leading to CVD is optimally managed by endovenous ablation using mini-invasive techniques, rather than surgical stripping (18), given the limitations of EVLA and RFA devices that preclude their usage in the treatment of more tortuous vein segments, secondary procedures should be used to address veins that are not treated using these thermal ablation methods (19). Technical failures were more common in the EVLA, whereas postoperative complications were more common in the surgery patients. However, comparing EVLA to conventional surgery, in terms of short-term and long-term outcomes of these two modalities on headings like procedural time, technical success, recovery time, recurrences, cost-effectiveness, and complications, both have comparable clinical effectiveness, and neither modality has clear superiority over the other (20,21). Parameters like cost-effectiveness must be assessed at the hospital level before choosing the right procedure for the patients (22). Considering those data, as well the highest recurrence rate and potential complications after endovenous procedures (23,24), open procedures like cryostripping still remains a feasible treatment method in great saphenous vein incompetence patients. Furthermore, it is simple, safe, associated with good cosmetic results and no preoperative selection of patients is necessary.

## Conclusions

Cryostripping is a radical surgical procedure which bring a significant number of advantages compared to the conventional saphenectomy, being a safe, effective, and cost-effective procedure in CVD treatment. It combines the principles of conventional surgery with cosmetic results similar to endothermic procedures, being suitable as day surgery.

This procedure is perfectly adapted to the economic conditions of government hospitals in low- and middle-income countries, but it can also be practiced successfully in private clinics.

### Study Limitations

The retrospective design could be considered a study limitation. Considering this type of study design, no specific data referring to the criterion according to which the type of surgical intervention was chosen for the patients included in this study can be provided.

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### Author's Contributions

Sergiu-Ciprian Matei, Daniela Radu-Teodorescu and Marius Sorin Murariu contributed to the data acquisition, analysis, and interpretation, and to the manuscript first draft; Cristina Ștefania Dumitru has given substantial contributions to the manuscript first draft and performed the statistical analysis; Sorin Olariu revised critically the manuscript and has given substantial contributions to writing and editing the final version. All authors read and approved the final version of the manuscript.

### Conflicts of Interests

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### Ethical Approval

The ethics committee of Victor Babeș University of Medicine and Pharmacy Timișoara, approved this study (REC number: 34/23.11.2023).

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