ΣΧΟΛΗ ΕΠΙΣΤΗΜΩΝ ΥΓΕΙΑΣ
ΙΑΤΡΙΚΗ ΣΧΟΛΗ

ΚΟΙΝΟ ΠΡΟΓΡΑΜΜΑ ΜΕΤΑΠΤΥΧΙΑΚΩΝ ΣΠΟΥΔΩΝ

«ΕΝΔΑΓΓΕΙΑΚΕΣ ΤΕΧΝΙΚΕΣ»

ΕΘΝΙΚΟ ΚΑΙ ΚΑΠΟΔΙΣΤΡΙΑΚΟ ΠΑΝΕΠΙΣΤΗΜΙΟ ΑΘΗΝΩΝ

ΙΑΤΡΙΚΗ ΣΧΟΛΗ ΣΕ ΣΥΝΕΡΓΑΣΙΑ ΜΕ ΤΟ ΠΑΝΕΠΙΣΤΗΜΙΟ ΤΟΥ ΜΙΛΑΝΟΥ-BICOCCA

ΔΙΠΛΩΜΑΤΙΚΗ ΕΡΓΑΣΙΑ

ΘΕΜΑ: Ενδαγγειακά υποβοηθούμενη ανάστροφη εκρίζωση της μείζονος σαφηνούς φλέβας

ΜΕΤΑΠΤΥΧΙΑΚΗ ΦΟΙΤΗΤΡΙΑ: Αρετή Βασιλείου

ΑΘΗΝΑ

Ιούλιος, 2024

ΕΛΛΗΝΙΚΗ ΔΗΜΟΚΡΑΤΙΑ
Εθνικόν και Καποδιστριακόν Πανεπιστήμιον Αθηνών
ΙΔΡΥΘΕΝ ΤΟ 1837

ΣΧΟΛΗ ΕΠΙΣΤΗΜΩΝ ΥΓΕΙΑΣ

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ΤΗΣ ΣΥΝΕΔΡΙΑΣΗΣ ΤΗΣ ΤΡΙΜΕΛΟΥΣ ΕΞΕΤΑΣΤΙΚΗΣ ΕΠΙΤΡΟΠΗΣ ΓΙΑ ΤΗΝ ΑΞΙΟΛΟΓΗΣΗ ΤΗΣ ΔΙΠΛΩΜΑΤΙΚΗΣ ΕΡΓΑΣΙΑΣ
της Μεταπτυχιακής Φοιτήτριας Αρετής Βασιλείου.

Εξεταστική Επιτροπή

- Καθηγητής Ιωάννης Κακίσης, Επιβλέπων
- Καθηγητής Αχιλλέας Χατζηϊωάννου
- Ομότιμος Καθηγητής Γεώργιος Γερουλάκος

Η Τριμελής Εξεταστική Επιτροπή για την αξιολόγηση και εξέταση της υποψηφίου κ. Αρετής Βασιλείου, συνεδρίασε σήμερα –/–/2024.

Η Επιτροπή **διαπίστωσε** ότι η Διπλωματική Εργασία της Αρετής Βασιλείου με τίτλο **«Ενδαγγειακά υποβοηθούμενη ανάστροφη εκρίζωση της μείζονος σαφηνούς φλέβας»** είναι πρωτότυπη, επιστημονικά και τεχνικά άρτια και η βιβλιογραφική πληροφορία ολοκληρωμένη και εμπεριστατωμένη.

Η εξεταστική επιτροπή αφού έλαβε υπόψιν το περιεχόμενο της εργασίας και τη συμβολή της στην επιστήμη, με ψήφους ..... προτείνει την απονομή στον παραπάνω Μεταπτυχιακό Φοιτητή του Μεταπτυχιακού Διπλώματος Ειδίκευσης (Master's).

Στην ψηφοφορία για την βαθμολογία ο υποψήφιος έλαβε για τον βαθμό «ΑΡΙΣΤΑ» ψήφους ....., για τον βαθμό «ΛΙΑΝ ΚΑΛΩΣ» ψήφους ..... και για τον βαθμό «ΚΑΛΩΣ» ψήφους ..... Κατά συνέπεια, απονέμεται ο βαθμός «.....».

Τα Μέλη της Εξεταστικής Επιτροπής

- Καθηγητής Ιωάννης Κακίσης, Επιβλέπων (Υπογραφή) _____
- Καθηγητής Αχιλλέας Χατζηϊωάννου (Υπογραφή) _____
- Ομότιμος Καθηγητής Γεώργιος Γερουλάκος (Υπογραφή) _____

Αφιέρωση,

Στην οικογένεια μου.

Ευχαριστίες,

Στον επιμελητή μου,

Βαγγέλη Αλεξίου.

ΠΕΡΙΕΧΟΜΕΝΑ

ΔΗΜΟΣΙΕΥΣΕΙΣ

Μέρος των αποτελεσμάτων της εργασίας έχουν δημοσιευθεί στο περιοδικό **Phlebology** (impact factor 1.8):

1. Alexiou VG, **Vassiliou A,** Mitsis M, Peroulis M. EndoVenous-assisted invaginated stripping of the great saphenous vein: A pilot and feasibility study. Phlebology. 2024 May 30:2683555241257858. doi: 10.1177/02683555241257858. Epub ahead of print. PMID: 38817119.

και παρουσιάστηκαν στα παρακάτω συνέδρια:

1. Alexiou Vangelis, **Areti Vassiliou**, Michael Peroulis. Ambulatory Endovenous-assisted Invaginated Stripping of the Great Saphenous Vein. Oral presentation at the Venous Symposium Europe May 2023, Corfu, Greece
2. ΕΝΔΑΓΓΕΙΑΚΑ ΥΠΟΒΟΗΘΟΥΜΕΝΗ ΑΝΑΣΤΡΟΦΗ ΕΚΡΙΖΩΣΗ ΤΗΣ ΜΕΙΖΟΝΟΣ ΣΑΦΗΝΟΥΣ ΦΛΕΒΑΣ: ΜΙΑ ΠΙΛΟΤΙΚΗ ΜΕΛΕΤΗ ΣΚΟΠΙΜΟΤΗΤΑΣ

   Αλεξίου Ε. **Βασιλείου Α.**, Φαναριώτης Γ., Περούλη Μ. 23ο Πανελλήνιο Συνέδριο Αγγειακής και Ενδαγγειακής Χειρουργικής – Αγγειολογίας, Βόλος Ιούνιος 2024

Part 1

1. Introduction

Venous insufficiency allows venous blood to escape from its normal antegrade flow and to reflux backward. In most cases, it is caused by valvular incompetence in the low-pressure superficial venous system, but it may also be caused by valvular incompetence in the high-pressure deep venous system. Between 25–40% of women and 10–20% of men suffer from chronic venous insufficiency. In addition to family history of venous disease, female sex, older age, chronically elevated intra-abdominal pressure caused by obesity, pregnancy, chronic constipation, or a tumor, prolonged standing can be risk factors. There are several manifestations of CVI that affect patients seeking treatment, including thrombosis, varicose veins, edema in the limbs, venous ulcers, infection, and discoloration of the skin. (1) Even though venous insufficiency is a disabling condition, it is inadequately evaluated and improperly managed. Our understanding of venous disease has improved thanks to advances in noninvasive evaluation, and new treatments are now available that are less invasive and safer.

1.1 High ligation and stripping

High ligation and stripping (HLS) of the great saphenous vein has been the gold standard treatment for varicose veins for years and may still be a valuable option. HLS is generally performed under general anesthetic but can also be performed under local or tumescent anesthesia under ultrasound guidance. Following dissection of the sapheno-femoral junction (SFJ), ligation of all side tributaries, and high ligation of the GSV, a standard olive-tip

stripper is inserted. An ankle or just below the knee incision is used to access the GSV. Stripping of the GSV is followed by closure of the skin at the groin and ankle or below the knee. The long-term (five-year) results of endovenous laser ablation (EVLA) and HLS do not differ in terms of clinical varicose veins recurrence or recurrence of reflux detected by duplex ultrasound (DUS), although the location may be different. The recurrence of reflux at the SFJ was statistically significantly lower after HLS than after EVLA. Complication rates after HLS were higher than those after EVLA, with bleeding and haematomas (4.8% vs. 1.3%), wound infections (1.9% vs. 0.3%), and paraesthesia (12.7% vs. 6.7%).

As technology advances, HLS has been replaced by minimally invasive techniques. With the advent of duplex ultrasound, physicians can now diagnose patients preoperatively, monitor them postoperatively, and perform many procedures. The purpose of these techniques is to disrupt the flow within the incompetent great saphenous vein. The incompetent vessel could be destroyed by using thermal energy (laser or radio frequency ablation) or chemical ablation.

1.2 Endovenous laser ablation (EVLA)

With EVLA, thermal energy is used to close up the saphenous vein, which has largely replaced conventional methods. The thermal energy applied in the vessel as laser causes fibrosis of the vein wall and lumen during the technique. Several months pass before the vein resorbs. Different sizes of fibers allow the physician to treat varicosities with laser. The convalescence period is shorter than after surgery due to this process. (2) The results of laser ablation at wavelengths 810 and 1470 are similar, but the success of these methods depends on tumescent anesthesia, the placement of the sheath, and the delivery of the energy. By

heating the vein wall with a laser fiber, nonthrombotic vein occlusion can be achieved. To cause collagen contraction and endothelium denudation, the vein wall must be sufficiently heated. As a result, the vein wall thickens, and eventually, the vein will contract and fibrose.

1.3 Radio frequency ablation (RFA)

A radio frequency ablation (RFA) procedure is similar to laser ablation in that it uses thermal energy to ablate the saphenous vein. Unlike laser ablation, radiofrequency requires two cycles of energy to be applied to all vein segments according to the manufacturer. At a constant temperature of 120 C, the catheter's active part is kept at a constant temperature of 7 cm during each cycle. The most convenient position for the catheter is 2 cm below the SFJ. The RFA consists of a bipolar heat generator and a catheter with collapsible electrodes that, when introduced intraluminally, effectively closes veins ranging from 2 mm to 12 mm in diameter. Using ultrasound control, access into the vein lumen is performed percutaneously, and the catheter tip is navigated to the SFJ. Tumescent local anesthesia is placed circumferentially along the entire length of the vein. Vein wall impedance and the amount of energy delivered are monitored continuously. Upon completion, absence of flow is assessed with ultrasound. Patent segments are retreated.

1.4 Sclerotherapy

CVI can also be treated with foam sclerotherapy. The aim of sclerotherapy is to obliterate incompetent veins. In order to achieve irreversible endothelium damage, a minimum volume and concentration of sclerosant should be applied to the vein to be sclerosed without collateral damage. Sclerosant allergies are also contraindications for ambulatory phlebectomy. Leg vein sclerotherapy has been performed with many agents, but only a few

are commonly used today. The long-chain fatty acid polidocanol (hydroxypolyethoxydodecane) is a synthetic compound. FDA approval is not available for sclerotherapy using hypertonic saline (23.4% sodium chloride). Nevertheless, it is commonly used to treat telangiectasias and reticular veins. It is readily available, inexpensive, and non-allergenic. The disadvantages of this treatment include burning pain, rapid dilution, and a high risk of extravasation necrosis. When the right sclerosant is selected for the vein being treated, sclerotherapy can be maximized in efficiency and complications minimized. In general, the larger the vein to be treated, the higher the concentration and volume of sclerosant should be. The concentration of sclerosant is generally chosen based on the type and diameter of the vein being treated. Depending on the situation, the patient is positioned supine, prone, or lateral decubitus, so that the veins are relatively empty and the sclerosant and the vein wall are in contact for as long as possible. Sclerosant is administered without undue pressure or speed after veins are cannulated briskly, aspirated gently to confirm intravascular placement, and sclerosant is gently applied. To reduce the risk of concentrated sclerosant spreading into deeper tissues, 1 mL or less is generally injected at a time. The varix is injected approximately every 5 cm to 15 cm. Sclerotherapy can be used to treat incompetent perforators. Under the skin, sclerosant can be injected into incompetent superficial system veins by using duplex ultrasound. Ultrasound-guided sclerotherapy of saphenous veins is an alternative or complementary technique to surgery, endovenous laser, and radiofrequency ablation. Foam therapy is preferred for treating epifascial veins, but it is also effective for treating great saphenous incompetence. (3,4).

1.5 Cyanoacrylic closure

The cyanoacrylic closure procedure is another option for truncal insufficiency. A chemical substance, cyanoacrylate, is used as a "clue" along with a delivery system. The GSV is accessed percutaneously with a micropuncture kit, followed by insertion of a 0.0035 J guidewire. A 5-Fr-sheath is introduced over the wire guided by ultrasound to the point of lowest insufficiency. Then, a 4-Fr-sheath is introduced and a 3 ml syringe with cyanoacrylate is attached to the injection gun.The catheter's configuration is visible under ultrasound guidance. It is also hydrophobic so the substance does not leak to the vein lumen. All segments of the catheter except the last 3 cm are filled with cyanoacrylate. A spinlock mechanism secures the delivery catheter. By using direct visualization with a linear ultrasound probe, a 3 cm segment of the 4F catheter tip is pulled out of the 5F introducer sheath and placed 3 cm away from the SFJ. The injection gun can continuously deliver the substance and can deliver 0.3 cc of polymer with one pull of its trigger. This process continues until the polymer is applied to the entire length of the vein. Pulls must cover a distance of 10 cm in each vein. The process is repeated until the polymer is applied along the entire vein length. (5)

1.6 HLS different approach with endovascular techniques.

Nowadays, incompetence of the GSV is mostly treated with minimally invasive endovenous thermal ablation (EVTA) techniques. EVTA has a low complications rate and can be performed without general anesthesia and thus, is recommended over open surgery of GSV with HLS. (6) Venous reflux elimination with HLS has been the gold standard treatment of varicose veins for many years. It should be noted that similarly to EVTA, HLS can be performed under tumescent anesthesia with ultrasound guidance. (7) Furthermore, EVTA and

HLS do not differ in terms of clinical varicose vein recurrence or recurrent reflux detected by duplex ultrasound over the long term. (8) When you remove general anesthesia from the equation, then complication rates should be the only factor considered when comparing EVTA and HLS. Specifically, HLS has been associated with more bleeding and hematomas (4.8% vs. 1.3%), wound infections (1.9% vs. 0.3%), and paraesthesia (11.3% vs. 6.7%). (9)

In the conventional approach of HLS the olive-shaped head that is mounted on the stripper can cause significant collateral trauma to the vein's adjacent tissues, including nerves and

lymphatics. Consequently, bleeding and hematoma may occur, also increasing the risk of surgical site infections (SSIs). On the other hand, it has been shown that an invaginated strip of the GSV may cause less trauma in the saphenous compartment and is associated with diminished blood loss and less discomfort compared to conventional stripping. (10).

Lastly, there have been studies that question the necessity of high ligation and report that a more distal GSV stripping may produce similar, if not better results (11). In essence, stripping without ligation of the SFJ tributaries mimics the result of EVTA. Stripping may become a minimally invasive procedure if done distal to the SFJ, especially when standard endovascular techniques are used to facilitate the procedure and reduce the need for large incisions.

Based on the above, we present our technique of ambulatory EndoVenous-assisted Invaginated Stripping (EVIS) of the GSV and seek to explore uncertainties around the surgical intervention itself namely technical stability, delivery, safety and effectiveness by

performing a pilot and feasibility study.We also opt for a comparison of our technique with the thermal ablation technique in a population of 17 patients.

2. Operative procedure

EVIS is performed as a day-case surgery as there is no need for general anesthesia or sedation. In addition to the preoperative hair removal, the patient receives a single dose of intravenous antimicrobial prophylaxis. Standard surgical drapes are applied after the skin has been prepared with chlorhexidine gluconate and alcohol solution.

An anti-Trendelenburg position (head elevated by 15 degrees above the feet) is preferred for optimal visualization of the veins with ultrasound. In order to determine whether the GSV has tortuosity, aneurysms, or post-thrombotic changes, a duplex scan along its length is performed. The GSV is punctured under ultrasound guidance at the level of the knee with an 18-gauge needle, and a 5-F sheath is inserted into the vein (Image 1, Figure). A long 0.035” PTFE-coated J-tip guidewire is then navigated across the GSV and through the SFJ to reach the common femoral vein (CFV). The position of the guidewire is secured and confirmed with ultrasound (Image 1). When there is tortuosity of the GSV or post-thrombotic stenoses that prevent easy navigation of the PTFE guidewire, a glide wire with hydrophilic coating may be used and then exchanged with the stiffer J-tip guidewire.

The saphenous compartment along the GSV is then infiltrated with tumescent anesthesia (50 mL of 1% lidocaine, 1 mL of epinephrine 1:1,000, and 12.5 mEq sodium bicarbonate diluted

in 1 L of normal saline) from the knee to the groin under ultrasound guidance. There is no need to infiltrate the subcutaneous plane with tumescent anesthesia as normally done in EVTA where there is a risk of skin thermal injury.

The patient is then placed in the Trendelenburg position (head 15 degrees below the feet). A small 1 cm incision is done near the femoral crease. Ultrasound is used to mark the exact location of the incision. In the subcutaneous plane, the GSV carrying the stiff PTFE guidewire can be easily palpated. The vein is dissected free with a Lahey clamp and secured with a sling (Image 2). The PTFE guidewire is retracted distal to the sling and the GSV is ligated proximally. The ligation is tied about 1-2 cm below the inflow of the superficial inferior epigastric vein at the point where one would normally place the laser fiber tip when performing an EVTA.

The PTFE guidewire tip is recovered from inside the GSV (Image 3). A strong braided thread of at least 70 cm in length, preferably Vicryl 2, is fixed to the guidewire tip (Image 3). The PTFE guidewire carrying the thread is then slowly retracted through the GSV and out of the percutaneous access site at knee level. At the proximal end, the thread is fixed on the GSV stump, in the groin (Figure). A further pull on the thread allows the vein to be invaginated and removed (Figure, Image 4, and Video).

A useful addition to this technique is to allow the extra proximal length of the thread and tie down a 50 cm long gauze pack that has been socked with 2 mL of epinephrine 1:1,000 diluted in 20 ml of normal saline. Traction of the distal end of the thread, at the knee, pulls down the packing within the saphenous vein, causing its invagination. The GSV is turned

outside-in over the packing as it comes out through the percutaneous access point at knee level (Image 4). This minimizes the risk of vein rupture (Image 5), and it also packs the saphenous compartment and aids in hemostasis (Image 6). The gauze is left in the saphenous

compartment until all calf phlebectomies have been completed. The width of this gauze packing depends on the diameter of the saphenous vein.

Incisions are closed according to the surgeon's preference and the leg is dressed and compressed with thigh-level Class II stockings (25-32 mmHg).

Part 2

1. Materials and methods

1.1 Prospective cohort study

This is a prospective observational study that was approved by the Research Ethics Committee of the Hospital and was undertaken from December 2022 to September 2023. This study followed the reporting standards for STrengthening the Reporting of OBservational studies in Epidemiology (STROBE). Informed consent was obtained from all patients for participation in the study, analysis of their data, and publication of images and videos.

A number of 20 patients who were treated using endovascular invagination stripping from December 2022 to September 2023 were evaluated. Venous insufficiency was diagnosed with duplex ultrasound. The inclusion criteria were primary chronic vein insufficiency of the GSV, greater than 18 years of age, and reflux of at least 0.5 seconds at the SFJ. Among the exclusion criteria were reflux at the anterior or posterior accessory saphenous veins, a body mass index of greater than 35, and prior treatment of the GSV in the same limb. The most severely affected leg was treated in patients with bilateral disease.

Based on the Clinical-Etiology-Anatomy-Pathophysiology (CEAP) classification, the C component was used to assess the clinical stage. Preoperative duplex investigations,

demographics, operative time, blood loss, technical success, and length of veins strapped were also recorded.

Blood loss due to vein stripping was considered the blood that accumulated in the subcutaneous upper-leg saphenous compartment. Weighed dry gauzes were used to absorb this blood as it was rolled out towards the groin. The bloody gauzes were weighed again, and the blood loss was calculated by subtracting the weight of the gauzes.

After the operation, patients were discharged home and told to resume normal activities immediately, as well as encouraged to walk regularly. A single dose of thromboprophylaxis with Low Molecular Weight Heparin (LMWH) was administered to all patients.Patients also had to use compression stocking all day for a week.

Patients reported their level of pain using a horizontal axis ranging from none (minimal, VAS = 0) to excruciating (maximum, VAS = 10). This was done immediately after the operation and at 48 hours, 1, 4, and 12 weeks. At one week, duplexes were performed to detect hematomas and Deep Venous Thrombosis (DVT), and at three months, the diameter of the residual stump was measured, and reflux was assessed to determine if it had transferred to the SFJ tributaries that have been left intact eg the anterior or posterior accessory saphenous veins.

To summarize the data, descriptive statistics were used, including mean as a measure of central tendency and range as a measure of variability. In the case of categorical variables, percentages were used.

1.2. Comparative clinical study

It is intended to enroll 30 patients in the trial with primary CVI of the GSV, who will be randomized to one of two techniques, so that we will be able to draw safe conclusions from a relatively large sample size.

a. Goals and outcomes

We sought to analyze and compare the two techniques under investigation in terms of SFJ insufficiency elimination, patient satisfaction with the procedure, and a patient's quality of life after surgery as documented by relevant questionnaires relevant to CVI, intraoperative pain, recovery time after surgery, and disease recurrence as observed and confirmed by duplex scan. Moreover, all complications associated with this technique were evaluated as an additional endpoint.

b. Study population

All participants should be recruited and randomized at one of the techniques and they will be concluded at the trial of the Vascular surgery Unit of the University Hospital of Ioannina.

c. Inclusion Criteria:

Those over 18 years of age with confirmed primary CVI of the great saphenous vein by ultrasound, and a recent duplex study which confirms the diagnosis. As part of the study, participants were required to give written informed consent to participate

d. Exclusion Criteria

- An insufficiency of the anterior or posterior axillary saphenous vein.
- Previous operation for CVI
- Obesity with a BMI>35
- Unwillingness of the patient to follow the study's protocol.
- Lack of a triplex ultrasound that confirms SFJ insufficiency.

In order to demonstrate the efficacy and effectiveness of our technique, we compared Endovenous Laser ablation with Endovenous assisted invagination stripping of the great saphenous vein.

In patients with bilateral disease, the most severely affected leg was treated.

Control group: Patients treated with EVLA (10 patients)

Intervention group: Patients treated with EVIS (7 patients)

Informed consent was obtained from all patients participating in the trial. In addition to comparing the intraoperative and postoperative pain of the two techniques, the main goal was to detect the efficacy and complications of EVIS. Therefore, we kept a record of our patients by completing a form that included information about the patient, such as: age, gender, weight, height, CVI stage, and any comorbid conditions.

The following information was also recorded: the procedure type, the duration, the diameter and length of the saphenous vein removed, the amount of tumescent anesthesia and lidocaine

used, intraoperative drug administration (analgesics, anticoagulant agents, antibiotics), and intraoperative complications and technical failures. (image 9).

Patients were asked to rate the pain they experienced during any intervention on a scale of 0 to 10. (page 35)

The patients were all followed up 48 hours and one month after the interventions. Post-surgery questions included how much pain they experienced, whether they used any analgesics, when they recovered and returned to their daily lives, if there were any complications (hematomas, bruises), how long they used compression stockings, and whether they were generally satisfied with the procedure as a whole. (page 36).

3. Results

3.1 Prospective cohort study

Twenty patients were operated with EVIS and followed up for three months. Fourteen (70%) of the 20 patients were female and the mean age of the sample was 47.9 years. Four patients (20%) had varicose veins without any complications (C2), 10 patients (50%) had varicose veins with oedema (C3) and 6 patients (30%) had skin changes (C4). Three patients did not attend the 4 weeks follow-up consultation and one did not attend the 7-day follow-up consultation, but all remained in the study for 3 months.

The mean operative time was 45 minutes (range 35-70 minutes). An intraoperative pain VAS of 4.8 (range 2-7) was recorded, and a postoperative pain VAS of 2.5, 1.8, 1.2, 0.5 at 48 hours, 1, 4 and 12 weeks, respectively. A mean blood loss of 15ml was observed (range 5-50ml) and the mean length of GSV strapped was 19 cm (range 14-27 cm). There were no complications such as deep vein thrombosis, surgical site infections, or nerve injuries. At 1 week follow-up, the patients did not have any hematomas in the saphenous compartment and the only noticeable skin change was minor bruising of the thigh. The incision at the groin is really small and has a good cosmetic result (Image 7). The GSV stump diameter retracted in all cases compared to the preoperative SFJ diameter at 3 months, and SFJ tributaries vein reflux was not detected.

3.2 Comparative clinical study

Patients treated with EVIS (intervention group) were compared with those treated with EVLA (control group). EVLA was used on 10 patients that were followed-up for at least one month after treatment. Seven of the patients (70%) in the study were female, and the average age was 49.6. The majority of patients had varicose veins without complications (stage C2), 40% had noticeable edema of the extremities (stage C3), and one patient had lipodermatosclerosis (stage C4b).

	Males	Females	Classification of CVI
EVLA group	3/10 (30%)	7/10 (70%)	C2 50% C3 40%
EVIS group	3/7 (42%)	4/7 (57%)	C2 47 % C4 28%

Table 1.Comparison between the sex and CVI class at the two groups.

Seven patients were treated with EVIS. Females constituted 57% of the group. In both groups, the median age was 43 years old. 47% had stage C2, 28% had stage C4 and one had a venous ulcer (C5). There were no severe comorbidities in either group and they did not take any antiplatelet or anticoagulant drugs.

Table 2. Comparison of the duration of the procedures.

	Duration of the procedures
EVIS group	18 min-40 min (mean 24,7 min)
EVLA group	25 min-55 min (mean 31,7 min)

Table 3. Comparison of the diameter of the saphenous and the length of it .

	Max saphenous diameter	Length of eliminated saphenous
EVLA group	6,2 mm-11,9 mm (mean 8,37)	(mean 34,25 cm) 37,5-19 cm
EVIS group	6,3 mm-18 mm (mean 10,80)	(mean 33,28 cm) 29-40 cm

EVIS group intervention lasted 24,7 minutes (18-40 minutes), while EVLA group intervention lasted 31,7 minutes (range 25-55 minutes). Saphenous diameter was 8.37 mm in the EVLA group (range 6,2mm-11,9 mm) and 10,8 mm in the EVIS group (range 6,3-18 mm). EVIS does not use thermal energy, while EVLA uses 5.430 J on average. The length of the vein that was eliminated by EVIS was 33,28 cm and 34,25 cm by EVLA. The EVLA group received 472 cc of local anesthesia, whereas the EVIS group received 281,4 cc of local anesthesia and 9,2 cc of xylocaine.

As part of the intraoperative drug administration, all patients received prophylactic LMW-heparin (0,45), analgesics, and nine patients from each group received one dose of antibiotic.

Table 4. Comparison between pain and anesthesia

	Tumescent anesthesia	Intraoperative pain
EVLA group	472 cc	3,7 (3-5)
EVIS group	281 cc	3,7 (0-8)

In order to measure intra-operative pain, patients used a horizontal axis that ranged from none (minimal, VAS = 0) to excruciating (maximum, VAS = 10). The measurements were taken after surgery, 48 hours later, and a month later. In the EVLA group, the pain level was 3,7 with a maximum of 8 and a minimum of 0. In the EVIS group, a mean of 3,7 was recorded (range from 3-5). All patients had a quick recovery postoperatively.

A two-day follow-up was performed on patients after surgery. Postoperative pain was recorded in both groups. In the EVLA group, the mean score was 0,5, while in the EVIS group, it was 1,5. A total of three patients in the EVIS group took analgesics at home for pain relief, compared to none in the EVLA group. Compression stockings should be worn all day and night, according to our recommendation. There was edema, bruises, and ecchymosis on the limb after surgery in one patient. This patient underwent laser ablation. Patient satisfaction with the overall procedure was 1,6 for the EVLA group (1-absolutely agree, 2-agree), whereas it was 1,5 for the EVIS group. According to all EVLA and EVIS patients, their everyday life has improved by two points (all answers). Patients answered that they would repeat the procedure on their other leg if necessary, and they would also recommend it to their friends.

One month after the procedure, all patients reported no pain. Duplexes were performed in the EVIS group to detect hematomas, Deep Venous Thrombosis (DVT), measure the residual stump diameter, and determine whether reflux had reached the intact SFJ tributaries, such as the anterior or posterior accessory saphenous veins. Duplex scans were also performed on EVLA patients to determine GSV occlusion, DVT, and hematomas. No complications were noted in the EVIS group. One patient was noticed to have a patent proximal part of the GSV and was recorded as treatment failure.

The above results are preliminary and the small number of patients recruited does not allow for meaningful statistical analysis. For the purpose of comparing the EVIS technique with EVLS, we will need to recruit more patients.

4.Discussion

With a creative approach, we have tried to combine the ease and flexibility of endovascular techniques with the benefits of open surgery and get the best of both worlds. There are no revolutionary changes to what has already been described and done over decades of venous insufficiency surgery. However, EVIS may have some considerable advantages over standard HLS and EVTA.

By percutaneously accessing the GSV at knee level, we avoid the incision and tissue handling required to dissect the distal part of the GSV. Studies have shown that there is no need to ablate or strip the GSV below the level of the knee; the clinical results are similar, plus you

avoid sural and saphenous nerve injury. (12, 13) No such complications occurred in our study.

Furthermore, endovascular techniques help tackle anatomic issues such as tortuosity and post-thrombotic stenoses. In the conventional approach of HLS, the surgeon may need to partially strip the GSV or proceed with additional incisions and cut-downs of the vein. Similarly, a laser fiber may not be able to navigate through post-thrombotic stenosis, aneurysm, or acute angulation of the vein and the GSV may need to be partially ablated or ablated in segments. This can be avoided in EVIS by using a vascular catheter and glide wire with a hydrophilic coating. One patient with a post-thrombotic segment was managed with this approach in our cohort.

The anatomic result of saphenous stripping without ligation of the SFJ tributaries is comparable to that of EVTA. Similarly to a previous study (14), our results indicate that the GSV stump diameter is reduced and reflux is not transferred to the SFJ tributary veins. Finally, placing a stiff guidewire across the GSV allows excellent visualization under ultrasound and makes dissection of the GSV possible through a "keyhole" incision at the groin. With less handling, there is less surgical trauma and hematoma, better cosmesis, and even fewer neovascularizations.

It has been well documented that most recurrences in HLS can be attributed to the neovascularization that occurs following surgical dissection of the SFJ. (15) The selective high ligation technique is to ligate the SFJ keeping some of the tributary veins. It has been shown that it decreases the incidence of neovascularizations and recurrent varicose veins in

the operated groin. (16). In EVIS all SFJ tributaries are left intact and there is no dissection of the SFJ. The GSV is ligated and cut at about 1-2 cm below the inflow of the inferior epigastric vein at the point where one would normally place the laser fiber tip when performing an EVTA. Based on the above evidence, we can advocate that neovascularization recurrences might be limited in EVIS. It will be necessary to follow up for a longer period of time to prove this.

Furthermore, when the tributaries are kept open to blood flow, the venous reflux from the groin is reduced and there is no thrombosis of the GSV stump (11). Thus, in theory, thrombus propagating from the GSV stump to the CFV might be less likely in EVIS compared to HLS. In EVTA, endothermal heat-induced thrombosis (EHIT) is a recognized complication. (17) EHIT is a thrombus that develops at the SFJ after EVTA. EHIT thrombus results from thermomechanical damage and coagulation effects (18). DVT may develop in 0.3% and Pulmonary Embolism (PE) in 0.1% of patients treated with EVTA (19). The rates of DVT and PE are similar in HLS but these numbers refer to operations done under general or spinal anesthesia. The risk for DVT is significantly lower in ambulatory procedures. We did not observe DVT or stump thrombus in our small cohort.

"Modern" stripping does not require general anesthesia. This strategy has not been followed in most RCTs comparing open surgery with endovenous techniques. However, there are studies that have shown that stripping can be safely done without any sedation (8,20). EVIS under tumescent has been really well tolerated by the limited number of patients that we have operated on. All patients managed to ambulate immediately following the procedure and

were discharged home on the same day. The pain scores reported by patients included in this study are similar to what has been published for EVTA.

EVIS aims to transform GSV stripping into a minimally invasive procedure by incorporating an endovascular component. It is significantly cheaper compared to EVTA and even HLS. There is no cost for a fiber, stripper, general anesthesia, and hospitalization. The vascular sheaths and guidewires are cheap and readily available in all vascular surgery units. This is a poor man's technique that may provide at least non-inferior results.

The main limitation of EVIS is that a diseased and degenerative GSV may rupture during stripping. However, with invagination, GSV is turned outside-in and the vein wall is significantly reinforced. The vein invagination starts from the proximal part where the GSV is thicker and stronger. Additional strength is achieved by pulling down a gauze pack within the invaginated vein. In our small cohort, there were no cases of vein rupture. Furthermore, there is some bleeding in the saphenous canal from tributaries and perforators to the deep venous system. We try to limit this by packing the space with epinephrine-soaked gauze. However, bruising will certainly develop and patient satisfaction may be less compared to EVTA. Finally, it should be noted that we have applied EVIS to a limited number of selected patients and no safe conclusions can be drawn regarding outcomes and complications.

To conclude, this is the first technical report and cohort study of the Ambulatory Endovenous-assisted Invaginated Stripping of the GSV. EVIS is a smart and cheap combination of standard vascular and endovascular techniques that may prove valuable in managing patients with chronic venous insufficiency. It is an ambulatory minimally invasive

procedure that revisits the way saphenous vein stripping can be done in the modern era. EVIS clinical outcomes and complications need to be further studied and directly compared with EVTA by completing the ongoing clinical trial.

Περίληψη

Ενδαγγειακά υποβοηθούμενη ανάστροφη εκρίζωση της μείζονος σαφηνούς φλέβας

Αντικείμενο:
Η ενδαγγειακά υποβοηθούμενη εκρίζωση (ΕΥΕ) της μείζονος σαφηνούς φλέβας (ΜΣΦ) έχει ως σκοπό την μετατροπή της κλασικής σαφηνεκτομής σε μία ελάχιστα επεμβατική μέθοδο με την αξιοποίηση των ενδαγγειακών τεχνικών.
Μέθοδοι:
Σχήματα, σκίτσα και εικόνες χρησιμοποιήθηκαν για να περιγράψουν την υπό εξέταση τεχνική.Επιπλέον σχεδιάστηκε μια μελέτη κοόρτης καθώς και μία συγκριτική μελέτη με σκοπό την ανάδειξη της αποτελεσματικότητας της τεχνικής.
Αποτελέσματα: Προοπτική μελέτη κοόρτης
Η μελέτη περιλαμβάνει 20 ασθενείς με πρωτογενή χρόνια φλεβική ανεπάρκεια. Η τεχνική επιτυχία ανέρχεται στο 100%, ενώ δεν έχουν καταγραφεί καθόλου επιπλοκες. Η μέση διάρκεια της επέμβασης ήταν 45 λεπτά, η μέση ένταση του πόνου όπως καταγράφεται από τις απαντήσεις των ασθενών ήταν 4,8 κατά την διάρκεια της παρέμβασης ενώ ο μέσος μετεγχειρητικός πόνος υπολογίζεται 2.5, 1.8, 1.2, 0.5 στις επόμενες 48 ώρες, 1, 4 και 12 εβδομάδες αντίστοιχα. Η μέση απώλεια αίματος υπολογίζεται σε 15 ml και το μέσο μήκος της σαφηνούς που εκριζώθηκε σε 19 cm. Ο υπέρηχος που διενεργήθηκε με σκοπό την παρακολούθηση ανέδειξε μείωση της διαμέτρου του κολοβώματος της σαφηνούς.
Τυχαιοποιημένη κλινική μελέτη
Με το ίδιο σκοπό σχεδιάσαμε μια κλινική μελέτη που θα συμπεριλάβει 60 ασθενείς. Οι μισοί ασθενείς θα υποβληθούν σε ΕΘΚ (ομάδα ελέγχου) και οι υπόλοιποι ασθενείς σε ΕΥΕ.Οι πρώτοι 17 ασθενείς που έχουν εισαχθεί στην μελέτη μας οδηγούν σε κάποια προκαταρκτικά αποτελέσματα. Από αυτούς τους ασθενείς 10 υποβλήθηκαν σε ΕΘΚ της σαφηνούς ενώ οι υπόλοιποι 7 σε ΕΥΕ. Μεταξύ των ασθενών το 63% ήταν γυναίκες και όσον αφορά την σταδιοποίηση της φλεβικής ανεπάρκειας το 53% ήταν στο στάδιο C2, το 23% στο C3 και οι υπόλοιποι ασθενείς στα σταδια C4 και C5. Στην ομάδα που υποβλήθηκαν σε ΕΘΚ η μέση διάρκεια της παρέμβασης ήταν 31,7 λεπτά ενώ στην δεύτερη ομάδα η διάρκεια ήταν 23,7 λεπτά. Επιπρόσθετα, όσον αφορά τον περιεγχειρητικό πόνο η μέση τιμή του ανέρχεται σε 3,7 για την ομάδα της θερμικής κατάλυσης και 3 για την ομάδα της ανάστροφης εκρίζωσης.Η μέση διάμετρος σαφηνούς καθώς και το μέσο μήκος στην πρώτη ομάδα ήταν 8,4 mm και 26,9 cm αντίστοιχα ενώ στην δεύτερη ομάδα ήταν 9,1 mm και 33,4 cm αντίστοιχα. Σε αυτό το σημείο πρέπει να σημειωθεί ότι κατά την διενέργεια της ΕΥΕ χορηγείται στον ασθενή λιγότερη ποσότητα tumescent αναισθησίας (μέση ποσότητα 281,4 cc) σε σχέση με την ΕΘΚ (471 cc), ενώ δε χρησιμοποιείται καθόλου θερμική ενέργεια. Η παρακολούθηση των ασθενών αυτών συνεχίζεται για 48 ώρες μετά το χειρουργείο και έπειτα από 1 μήνα.τελέσματα από μία μεγαλύτερη ομάδα ασθενών.
Συμπέρασμα
Η τεχνική ΕΥΕ είναι ένας συνδυασμός κλασικών τεχνικών με τις νέες ενδαγγειακές τεχνικές και μπορεί να είναι πολύ χρήσιμη στην αντιμετώπιση της πρωτογενούς χρόνιας φλεβικής ανεπάρκειας.Η αρχική αυτή σύγκριση των δύο τεχνικών μας οδηγεί στο συμπέρασμα ότι τουλάχιστον η ΕΥΕ δεν είναι κατώτερη της ΕΘΚ.
Λέξεις κλειδιά:Φλεβική ανεπάρκεια, Ανάστροφη εκρίζωση,Μείζον σαφηνής φλέβα, Θερμική κατάλυση.

Abstract

EndoVenous-assisted invaginated stripping of the great saphenous vein

Objective: EndoVenous-assisted Invaginated Stripping (EVIS) aims to transform Great Saphenous Vein (GSV) stripping into a minimally invasive procedure by incorporating an endovascular component.
Methods: Sketches and videos were used to illustrate the technical aspects of EVIS.A cohort and a comparative study was obtained to prove the efficacy of the method.
Results:
Prospective cohort study
The prospective cohort study included 20 patients with primary chronic venous insufficiency. Technical success was 100%, and no complications were recorded. The mean operative time was 45 minutes, intraoperative pain score was 4.8, post-operative pain was 2.5, 1.8, 1.2, 0.5 at 48 hours, 1, 4, and 12 weeks, respectively. The follow-up duplex showed a reduction in the diameter of the residual GSV stump.
Comparative Clinical Study
A clinical trial involving 60 patients was designed. Half of the patients will receive EVLA (standard group) and the other half will receive EVIS.The first 17 patients registered in the trial have been analyzed in the preliminary results. There were 10 patients treated with EVLA and 7 patients treated with EVIS. There were 64% females among them. In terms of chronic venous disease stage, 52% were at stage C2, 23% at stage C3, and the rest at stages C4 and C5. In the EVLA group, the mean operation time was 31.7 minutes, while in the EVIS group it was 23.7 minutes. An additional primary endpoint is intraoperative pain intensity, which was measured as a mean for the EVLA group at 3,7 and for the EVIS group at 3. The mean diameter and length of the ablated GSVs in the EVLA group were 8,4 mm and 26,9 cm, respectively. The mean diameter and length of the stripped GSV in the EVIS group were 9,1 mm and 33,4 cm respectively. Additionally, EVIS is associated with less tumescent anesthesia usage (mean 281,4 cc) than the EVLA technique (mean 472 cc). All the patients were fully mobilized after operation. A 48-hour and one-month follow-up was performed on the patients following the procedure. Pain results are not significantly different between the procedures and patients are generally satisfied with both methods.

Conclusions: EVIS is a combination of standard techniques that may prove valuable in managing patients with chronic venous insufficiency.A preliminary comparison between the two techniques has shown that EVIS is at least non-inferior to EVLA.

Keywords: Chronic venous insufficiency, Invagination, Great saphenous vein, Laser ablation.

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Supplement

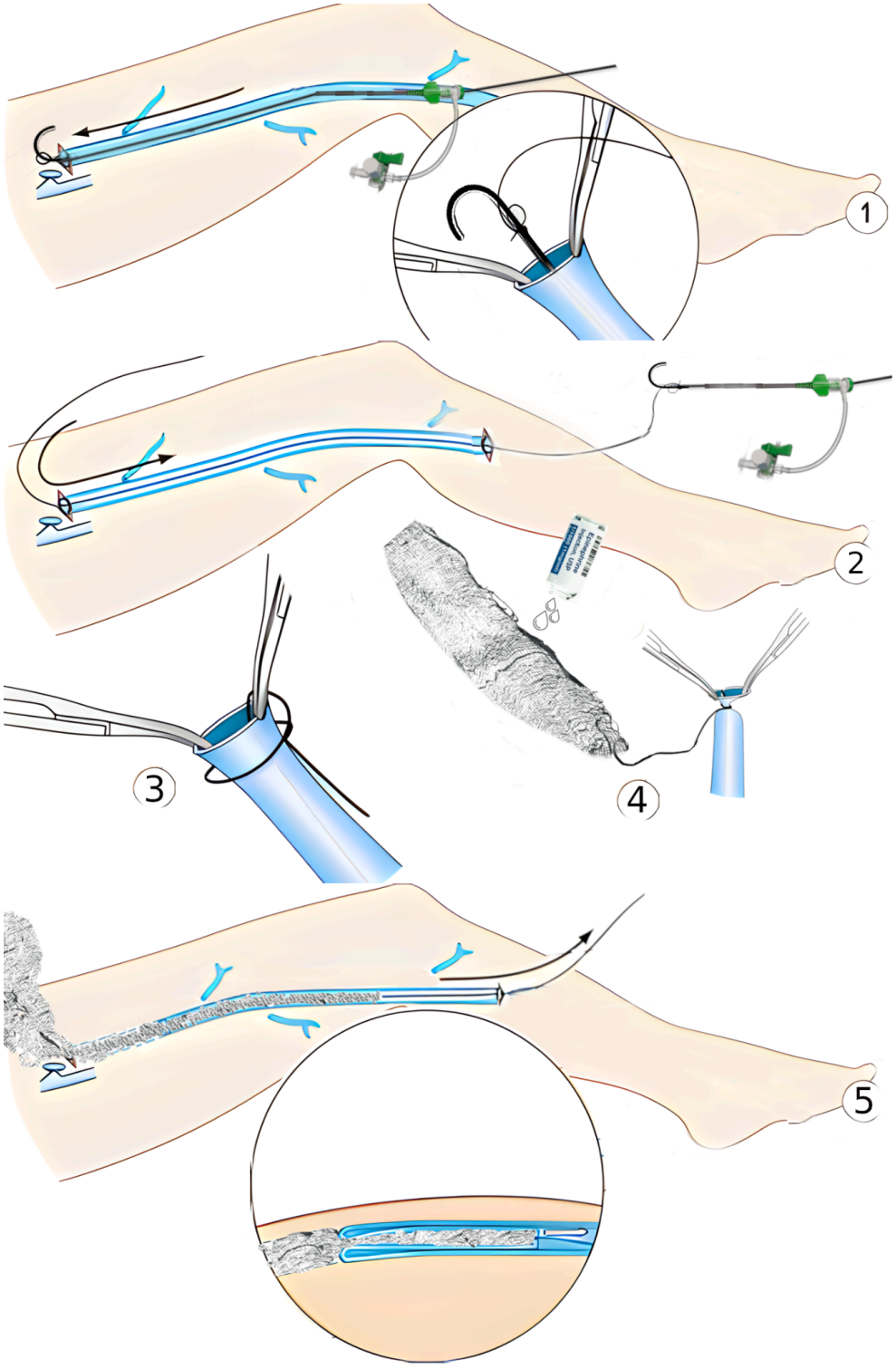

Figure.

Schematic drawing of the Endovenous-assisted Invaginated Stripping (EVIS) of the Great Saphenous Vein (GSV)

1: Percutaneous access at knee level. The guidewire is recovered at the groin and a braided thread is fixed at its tip.

2: The guidewire carrying the thread is retracted out of the access site. The sheath is removed.

3: Tying the thread on the GSV stump

4: An epinephrine-soaked gauze pack is tied at the proximal end of the thread

5: Traction of the distal end of the thread pulls down the packing within the saphenous vein, causing its invagination

Adapted from Perrin M. drawing (16)

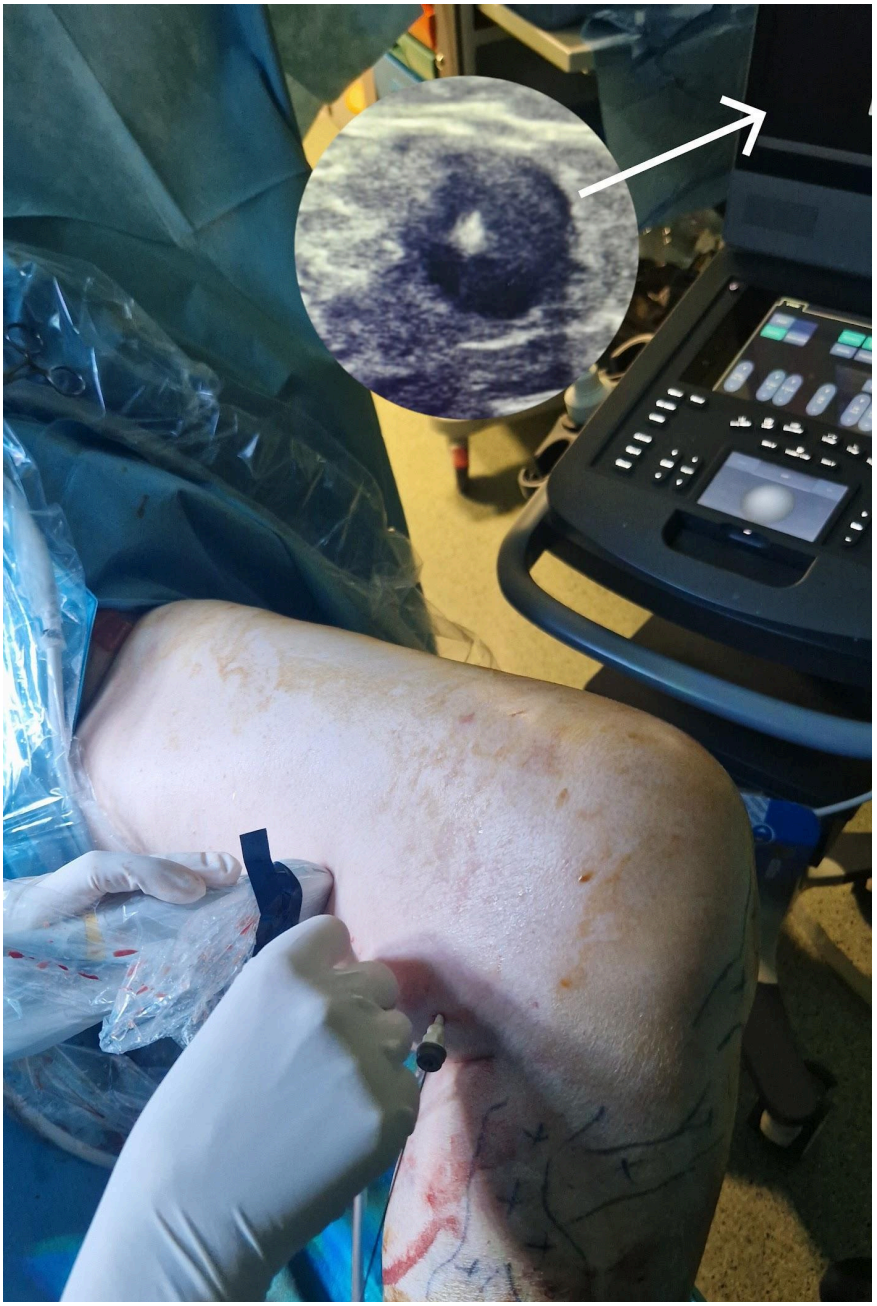

Image 1

Percutaneous access of the great saphenous vein (GSV) with a 5-F sheath at knee level. The position of the guidewire across the GSV is confirmed with ultrasound (arrow)

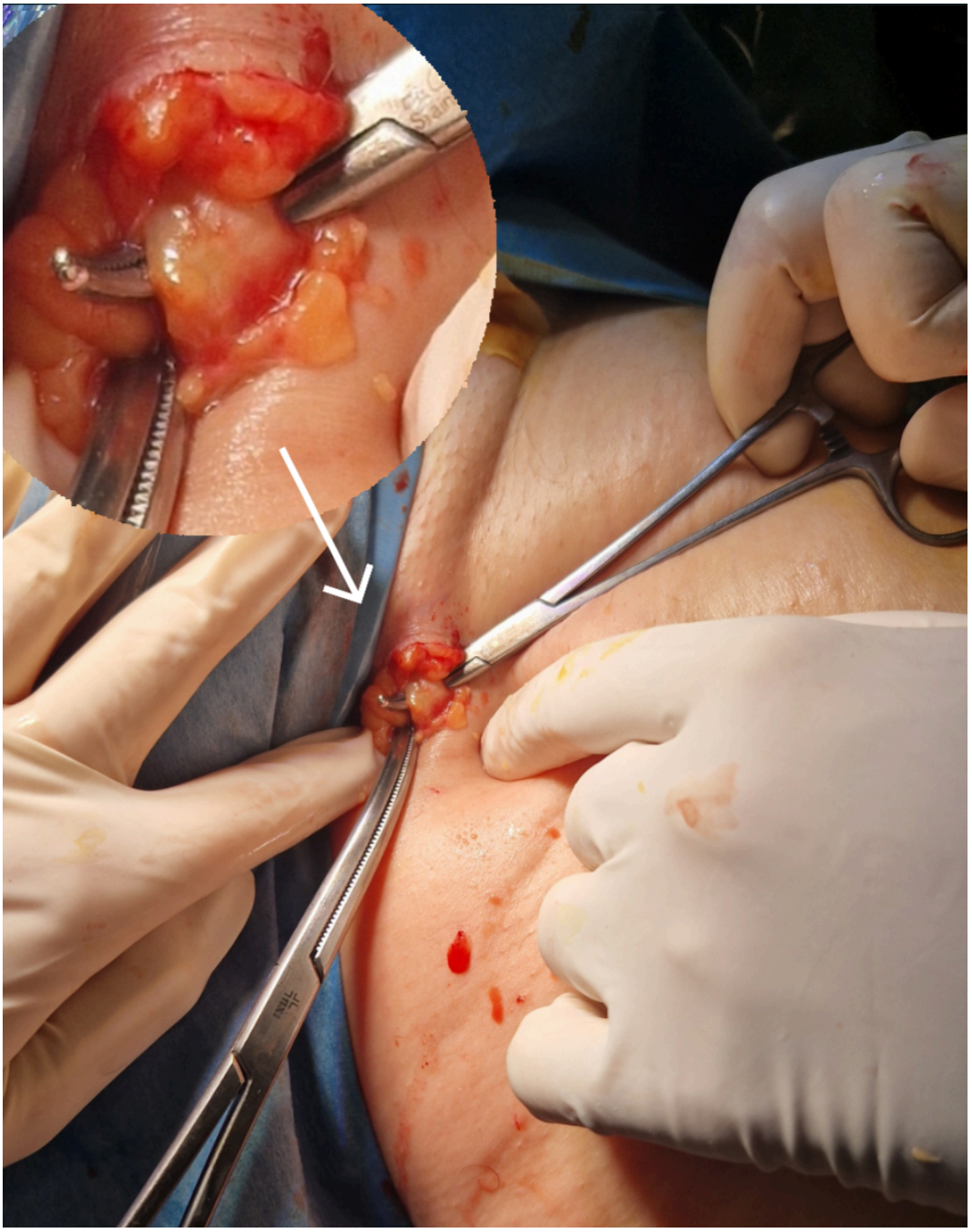

Image 2

A small incision of 1 cm is made over the femoral crease. In the subcutaneous plane, the GSV carrying the stiff PTFE guidewire can be easily palpated. A Lahey clamp is used to dissect the vein (arrow).

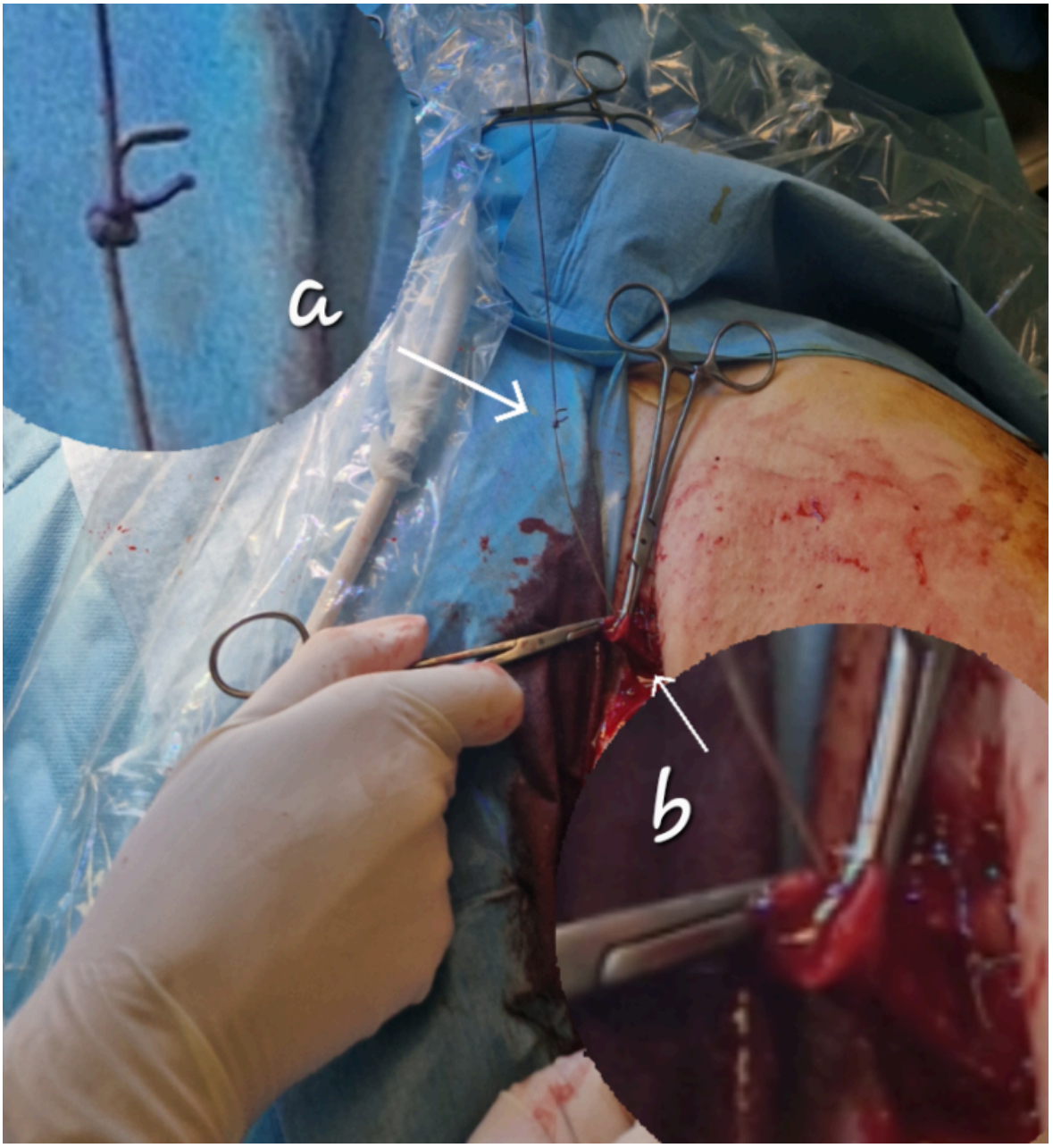

Image 3

The guidewire tip is recovered from inside the GSV near the groin (arrow b). A strong braided thread is fixed to the guidewire tip (arrow a).

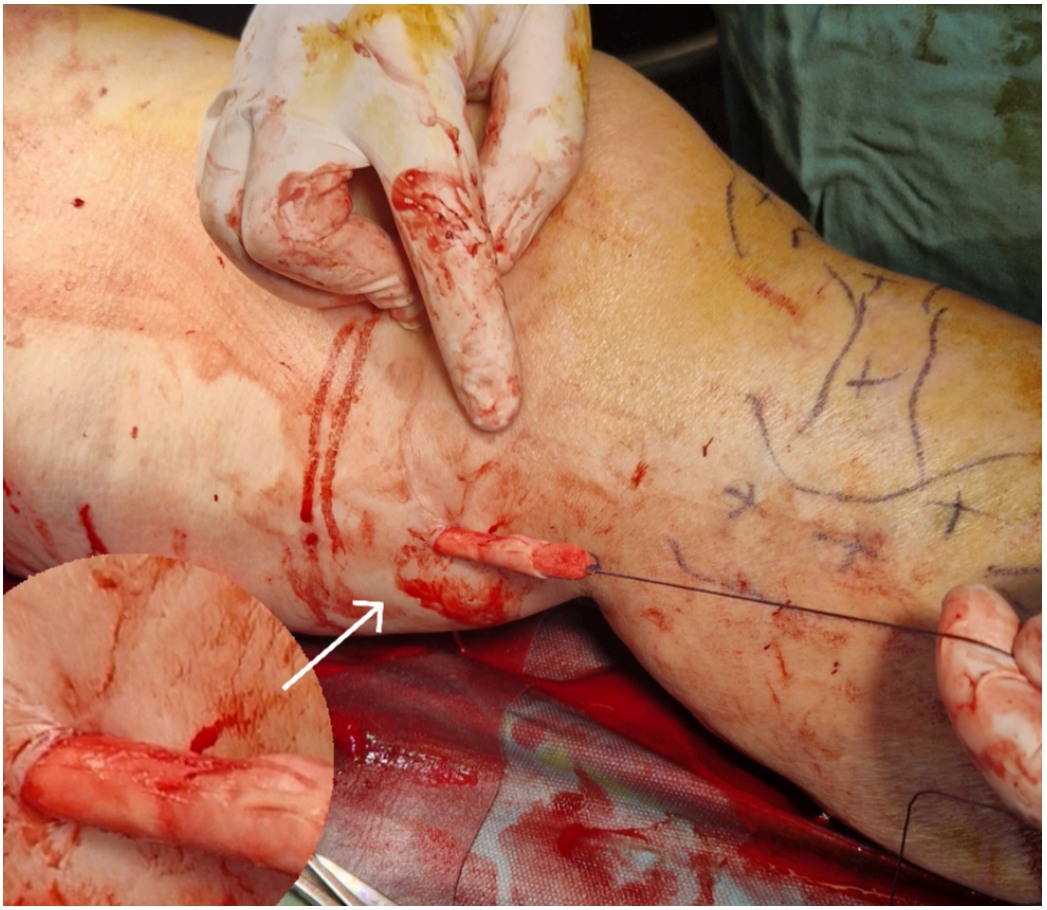

Image 4

Invaginated stripping of the Great Saphenous Vein (GSV) through the site of percutaneous access at knee level (arrow).

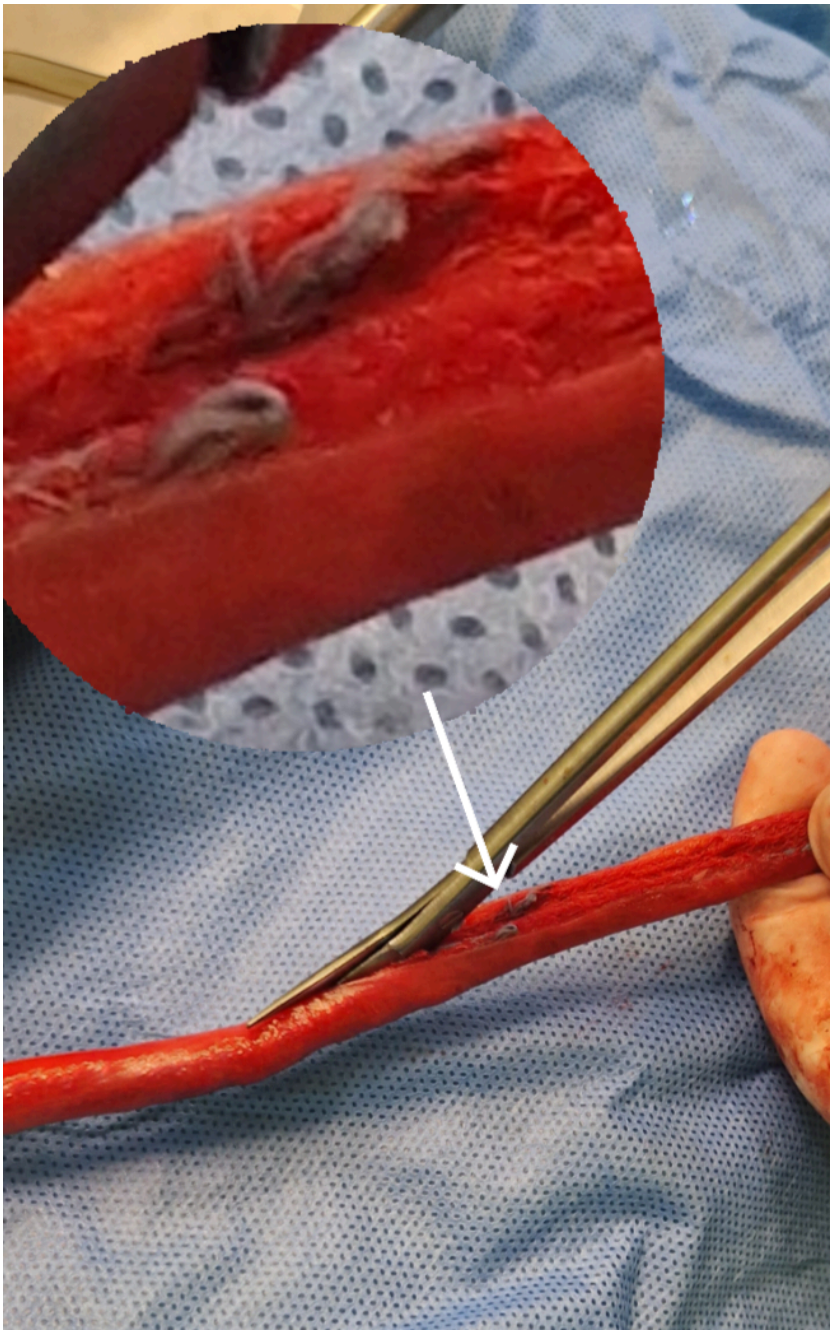

Image 5

Pull down of the gauze packing within the GSV causes its invagination and at the same time minimizes the risk of vein rupture during stripping. The stripped vein is cut longitudinally to display the detail of the gauze pack invaginated in the GSV (arrow).

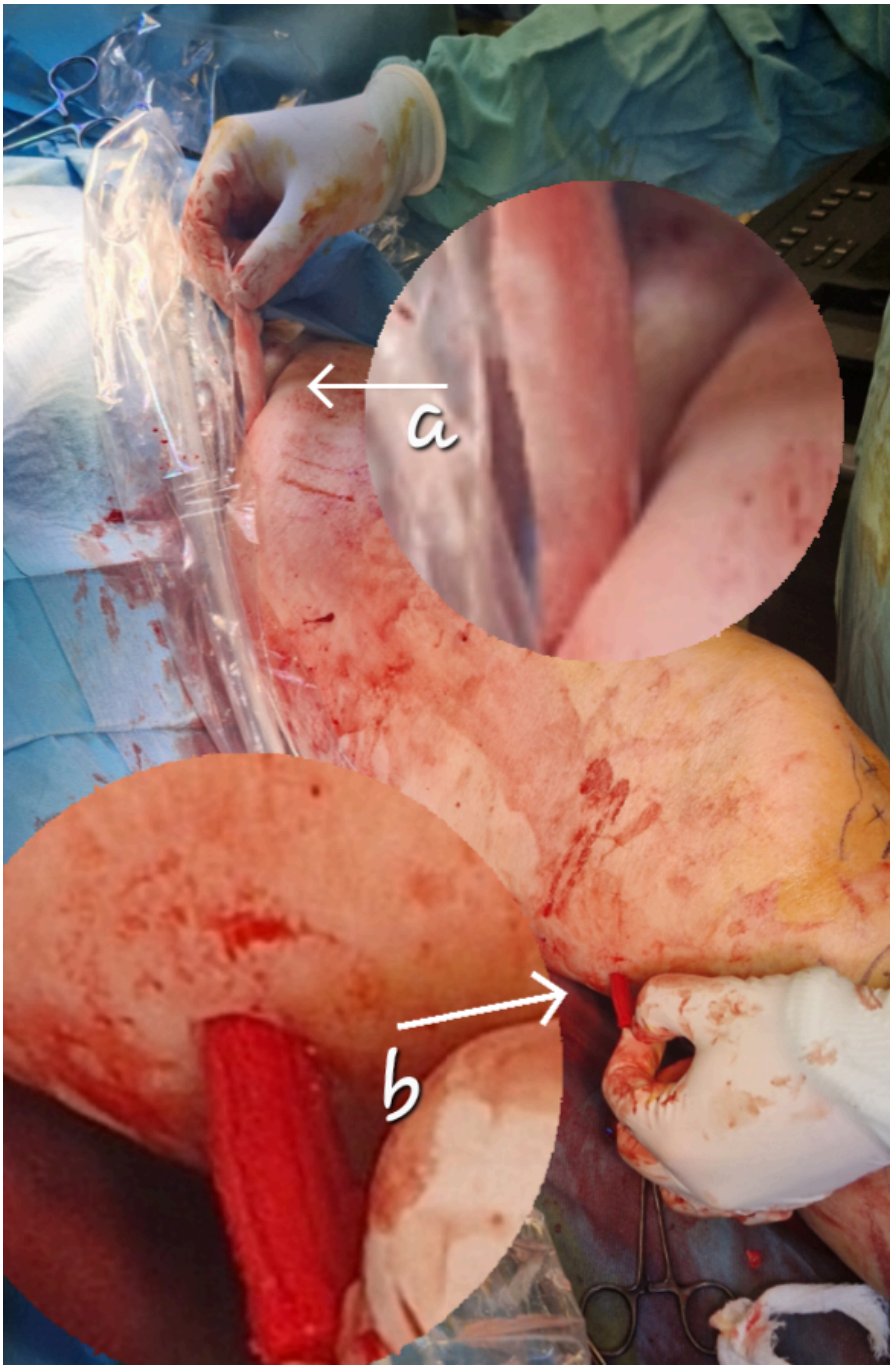

Image 6

The gauze packs the saphenous compartment and aids in hemostasis. The arrows point at the entry point (groin - arrow a) and exit point (percutaneous access point at knee level - arrow b) of the gauze.

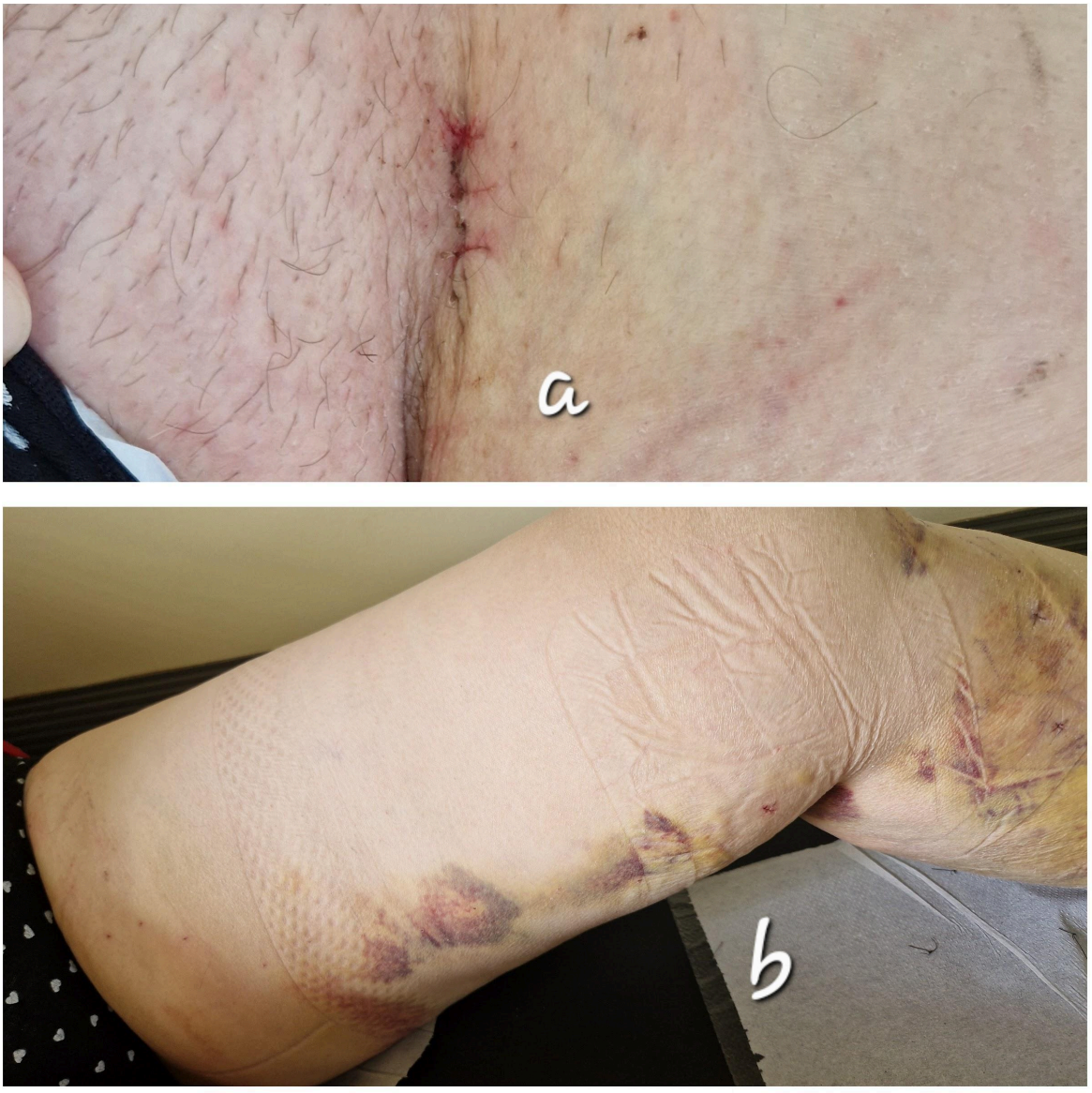

Image 7

a. The incision at the groin is really small and has an excellent cosmetic result b. Minor bruising of the thigh without any significant haematoma at 1 week follow-up

Video (download link)

https://drive.google.com/file/d/1nxW30IcslvnNyLwnnEZrnoT33k9v0Mki/view?usp=sharing

Care report form - CRF

Μελέτη σύγκρισης της θερμικής κατάλυσης της μ. σαφηνούς με την ενδαγγειακή ανεστραμμένη σαφηνεκτομή

ΝΠΣ:

Τηλέφωνο:

Ηλικία:

Φύλο:

Σταδιοποίηση φλεβικής ανεπάρκειας:

Βάρος:

Ύψος:

Σημαντικές συννοσηρότητες:

Λήψη αντιπηκτικών ή αντιαιμοπεταλιακών:

C (Clinical Manifestations), **E** (Etiology), **A** (Anatomic Distribution), **P** (Pathophysiology)

C0	No visible or palpable signs of venous disease
C1	Telangiectasias or reticular veins
C2	Varicose veins
C2r	Recurrent varicose veins
C3	Edema
C4	Changes in skin and subcutaneous tissue secondary to chronic venous disease
C4a	Pigmentation or eczema
C4b	Lipodermatosclerosis or atrophie blanche
C4c	Corona phlebectatica
C5	Healed
C6	Active venous ulcer
C6r	Recurrent active venous ulcer

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Είδος επέμβασης:

Ημερομηνία:

Διάρκεια σε λεπτά:

Διάμετρος μ. σαφηνούς στην σαφηνομηριαία συμβολή:

Μήκος σαφηνούς που καταλύθηκε ή αφαιρέθηκε:

Ποσό ενέργειας που χορηγήθηκε:

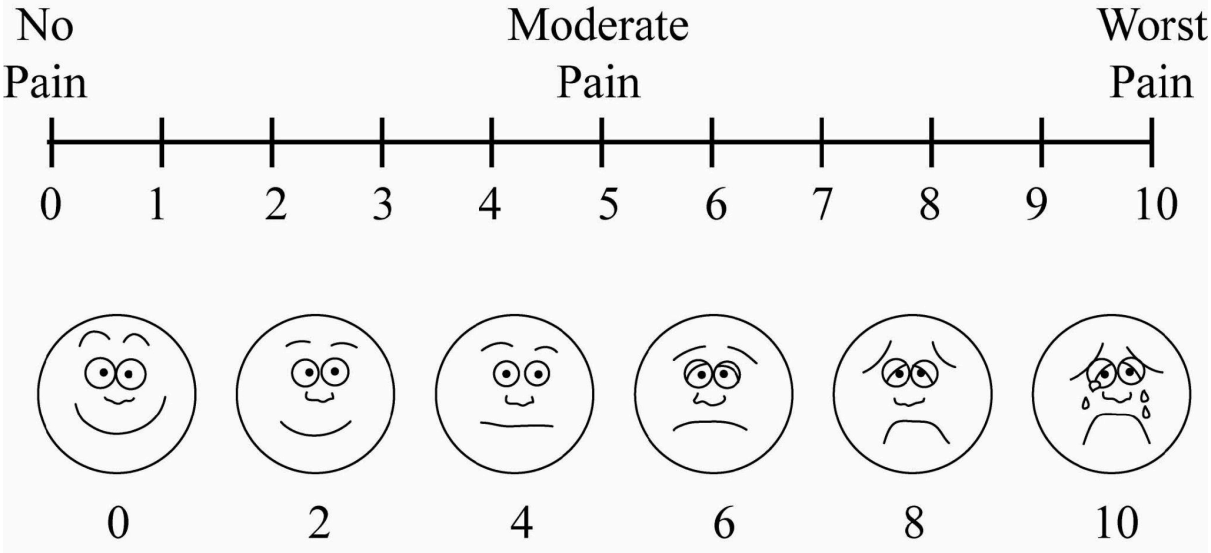
Ποσότητα tumescent:

Ποσότητα ξυλοκαίνης:

Φάρμακα που χορηγήθηκαν διεγχειρητικά:

Διεγχειρητικές επιπλοκές και τεχνικά προβλήματα (αδυναμία καθετηριασμού, προσπέλασης, τμηματική αφαίρεση, ρήξη κλπ):

Διεγχειρητικός πόνος: Μετεγχειρητικός πόνος:



Επιτυχής άμεση κινητοποίηση: ΝΑΙ / ΟΧΙ

Πόνος στις 48 ώρες: Πόνος στις 7 ημέρες: Πόνος στο μήνα:

Αναλγητική αγωγή που απαιτήθηκε στο σπίτι και διάρκεια αυτής:

Χρόνος πλήρους επιστροφής στην καθημερινότητα:

Χρόνος χρήσης κάλτσας διαβαθμισμένης συμπίεσης:

Μετεγχειρητικές επιπλοκές (αιμάτωμα, λοίμωξη, θρόμβωση, άλλο):

Ευρήματα τρίπλεξ στον μήνα:

Ερωτηματολόγιο ικανοποίηση ασθενούς από το χειρουργείο (στις 30 ημέρες):

Σημειώστε με ένα ✓ σε τι βαθμό συμφωνείτε με τα παρακάτω: **1. Συμφωνώ απόλυτα 2. Συμφωνώ 3. Ούτε συμφωνώ ούτε διαφωνώ 4. Διαφωνώ 5. Διαφωνώ απόλυτα**					
	1	**2**	**3**	**4**	**5**
Είμαι ικανοποιημένος/η από την επέμβαση για τους κιρσούς μου					
Δεν έχω πόνο στην περιοχή του χειρουργείου					
Η καθημερινότητά μου βελτιώθηκε σε ό,τι αφόρα στα προβλήματα από τους κιρσούς					
Η επέμβαση ανταποκρίθηκε στις προσδοκίες μου					
Θα έκανα ξανά την ίδια επέμβαση αν χρειαζόταν					
Θα πρότεινα σε κάποιο φίλο ή συγγενή να κάνει την ίδια επέμβαση					

Ευρήματα τρίπλεξ στο έτος: