Mechanochemical abla-on versus ultrasound-guided foam sclerotherapy of the great saphenous vein. Randomized clinical trial.

NCT Number: Not yet assigned

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List of Abbrevia-ons

cm – cen-meter(s)
CVD – chronic venous disease
CDU – color Doppler ultrasound
Fr – French
G – Gauge
CVI – chronic venous insufficiency
SFJ – saphenofemoral junc-on
MHz – megahertz
min – minute(s)
mm – millimeter(s)
mmHg – millimeters of mercury
TM – trademark
sec – second(s)
ICF – informed consent form
DVT – deep vein thrombosis
USP – University of São Paulo
GSV – great saphenous vein
VCSS – Venous Clinical Severity Score

Abstract

Background/Introduc-on

Ultrasound-guided foam sclerotherapy is a method frequently used in the treatment of lower limb varicose veins. Its main advantages are applicability in pa-ents with high surgical risk and an immediate or early return to work. However, it requires a higher number of reinterven-ons compared to other methods due to a higher rate of venous recanaliza-on, especially in veins with larger diameters.

On the other hand, mechanochemical abla-on offers the same advantages and, addi-onally, has a low recanaliza-on rate.

Objec-ve

To compare ultrasound-guided foam sclerotherapy of the great saphenous vein (GSV) with mechanochemical abla-on using the Flebogrif® catheter in the treatment of chronic venous insufficiency (CVI) associated with GSV disease.

The primary outcomes will be:

- Quality of life analysis
- GSV occlusion rate assessed by color Doppler ultrasound (CDU) over -me

The secondary outcome will be:

- Incidence of complica-ons inherent to treatment
- Pain level during the procedure

Material and Methods

A total of 50 pa-ents with primary varicose veins presen-ng:

- Lower limb pain
- Edema
- Skin changes (hyperpigmenta-on, eczema, lipodermatosclerosis)
- CEAP classifica-on C2, C3, or C4 EpAsPr

All must have:

- GSV insufficiency
- Diameter between 6–12 mm measured at mid-thigh by CDU

Pa-ents will be:

- Evaluated in the venous disease outpa-ent clinic
- Treated in the minor surgery opera-ng room at the Hospital

Study Design

- Prospec-ve study
- Randomized alloca-on into two groups

Group 1

- Percutaneous puncture
- Ultrasound-guided injec-on of sclerosing foam using 18-gauge catheter

Group 2

- Use of Flebogrif® catheter
- Posi-oned 2 cm from SFJ
- Mechanical trac-on combined with foam injec-on

In both groups:

- 20 mL of 0.9% saline will be infused before polidocanol
- Local anesthesia with 2% lidocaine (without vasoconstrictor)

Puncture Site

Depends on the extent of the disease:

- Knee region → segmental insufficiency
- Medial malleolus → total insufficiency

Addi-onal Procedure

- Varicose tributaries treated with 1% polidocanol
-

Expected Results

Mechanochemical abla-on will:

- Achieve higher occlusion rates
- Present lower recanaliza-on
- Does not increase pain

- Maintain similar complica-on rates

1. Introduc-on

Chronic venous insufficiency (CVI) affects millions worldwide, leading to reduced quality of life and high healthcare costs.

In 1944, Egmont James Orbach described a technique involving the injec-on of air bubbles with a sclerosing agent, increasing endothelial contact.

In the 1990s, Tessari developed a simple low-cost foam produc-on technique using two syringes and a three-way stopcock.

Foam sclerotherapy with polidocanol is widely used globally. Its advantages include:

- Use in high-risk pa-ents
- Rapid recovery

However, it has:

- Higher recanaliza-on rates, especially in larger veins.

In 2010, the Flebogrif® catheter was introduced:

- Produces mechanical endothelial injury
- Combined with chemical injury (polidocanol foam)

Advantages:

- Lower recanaliza-on
- Outpa-ent procedure
- Reduced opera-ve -me
- Cost-effec-ve
- Non-thermal (no burn or nerve injury risk)
- No need for tumescent anesthesia

2. Study Type

A randomized clinical trial comparing:

- Foam sclerotherapy
- Mechanochemical abla-on

3. Loca-on

- Venous outpa-ent clinic
- Minor surgery opera-ng room at University of São Paulo Hospital

4. Sample

4.1 Sampling

50 pa-ents mee-ng clinical and ultrasound criteria.

4.2 Inclusion Criteria

- Age ≥ 18 years
- CEAP C2–C4
- Great saphenous vein (GSV) insufficiency (6–12 mm) in mid-thigh by color Doppler ultrasound (CDU)

4.3 Non-inclusion Criteria

- Allergy to sclerosant
- Acute deep vein thrombosis (DVT) or pulmonary embolism
- Local or systemic infec-on
- Prolonged immobiliza-on
- Symptoma-c patent foramen ovale
- Pregnancy
- Peripheral arterial disease
- Small saphenous vein insufficiency
- Refusal to sign informed consent form

4.4 Exclusion Criteria

- Loss to follow-up
- Missing ultrasound data or ques-onnaires

5. Methods

5.1 Data Collec-on

- Medical history
- Physical examina-on
- CDU

Reflux criteria:

- Superficial veins: >0.5 second (sec)
- Perforators: >0.35 sec
- Deep veins: >1 sec

Quality of Life Assessment and Severity Score

- Aberdeen Varicose Veins Ques-onnaire
- Venous Clinical Severity Score (VCSS)

Follow-up Schedule

- 7 days
- 28 days
- 168 days
- 365 days

Ultrasound Goals

- Detect DVT
- Assess occlusion
- Evaluate recanaliza-on

5.2 Procedural Details

- Trendelenburg posi-oning
- Ultrasound-guided puncture
- Guidewire and introducer technique
- Foam prepara-on (Tessari method)
- polidocanol at a concentra-on of 3%
- Compression therapy (20–30 millimeters of mercury compression stockings for 48 hours)

5.3 Clinical Outcomes

Primary:

- Quality of life assessment and severity scores
- GSV occlusion

Secondary:

- Complica-ons
- Pain during procedure

5.4 Sta-s-cal Method

- Kaplan–Meier survival curves
- Cox regression

Parameters:

- Power: 80%
- Significance: 5%
- Sample size: 50 pa-ents

6. Timeline

Pa-ents will be monitored for 365 days

7. References

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