

2nd Mexican Consensus of Endovenous Chemical Ablation (Sclerotherapy) 2018*

Zweiter mexikanischer Konsensus zur endovenösen chemischen Ablation (Sklerotherapie) 2018

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Academia Mexicana de Flebología y Linfología, Mexico City, 2018

Key words

Sclerotherapy, consensus, endovenous chemical ablation (ECA)

Schlüsselwörter

Sklerotherapie, Konsensus, endovenöse chemische Ablation (ECA)

received 03.04.2018

accepted 26.06.2018

Bibliography

DOI <https://doi.org/10.1055/a-0894-9896>

Online-Publikation: 22.05.2019

Phlebologie 2019; 48: 377–387

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ISSN 0939-978X

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ABSTRACT

Background Sclerotherapy has been carried out since 1516 and is accepted and performed worldwide according to many references from books and journals. Mexican doctors participated in other consensus in order to obtain various agreements, references, methods and procedures that are universally accepted to establish this document, including the European consensus of sclerotherapy 2003 and

its last revision in 2006, the Clinical practice guidelines for prevention, diagnosis and treatment of chronic venous insufficiency in 2009 in México, the Argentine and Latin American consensus for sclerotherapy in 2012, European sclerotherapy guidelines in chronic venous diseases of 2013, and various literature sources as well. The first Mexican consensus on sclerotherapy published in January 2014 which was reviewed and updated in this document.

Objective Review and update the general bases of Endovenous Chemical Ablation (ECA) also known as Sclerotherapy, according to evidence-based medicine updating the previously published consensus.

Method General questions about Endovenous Chemical Ablation (ECA) were established concerning: indications, contraindications, types of sclerosing agents and the concentrations used, patient position, methods of application, way to prepare and preserve the sclerosants, necessary equipment, injection volumes, different administration ways, compressive therapy and special comments. To answer these questions the existing literature and the topics in which the reports showed uniformity were consulted. A panel of experts was constituted who provided their personal experience, the answers were formulated in the form of clinical guidelines or general recommendations to provide concrete answers to the specific questions, in some issues we include possible accepted variations.

ZUSAMMENFASSUNG

Hintergrund Die Sklerotherapie wird seit 1516 angewendet und ist laut Veröffentlichungen in Lehrbüchern und Zeitschriften ein weltweit akzeptiertes und durchgeführtes Verfahren zur Therapie von Varizen.

Die verschiedenen Meinungen zu den allgemein akzeptierten und etablierten Methoden und Abläufen konnten mexikanische Ärzte auf Konsensus Konferenzen, wie dem „European consensus of sclerotherapy“ 2003 und 2006, der „Clinical practice guidelines for prevention, diagnosis and treatment of chronic venous insufficiency“ 2009, der „Argentine and Latin American consensus for sclerotherapy“ 2012, der „European sclerotherapy guidelines in chronic venous diseases, 2013“ und durch publizierter Literatur sammeln und in den 2. mexikanischen Konsensus einfließen lassen.

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Der erste mexikanische Sklerotherapie-Konsensus wurde im Januar 2014 publiziert und wurde nun überarbeitet und aktualisiert.

Zielsetzung Überarbeitung und Aktualisierung des 1. mexikanischen Konsensus zur endovenösen chemischen Ablation (ECA), auch bekannt als Sklerotherapie, gemäß der Regeln der Evidenz-basierten Medizin.

Methode Allgemeine Fragen und Themen zur endovenösen chemischen Ablation (ECA) wurden bearbeitet. Im Einzelnen: Indikationen, Kontraindikationen, Sklerosierungsmittel und zu verwendete Konzentrationen, Position des Patienten, Applikationsmethoden, Art und Weise der Zubereitung und

Erhalt des Sklerosierungsmittels, notwendiges Equipment, Injektionsvolumen, unterschiedliche Zugangswege, Kompressionstherapie und speziellen Anmerkungen. Um diese Fragen zu beantworten, wurden die existierende Literatur und Berichte mit einheitlicher Meinung zu einem Thema herangezogen. Eine Gruppe von Experten beantwortete Fragen auf Grundlage ihrer persönlichen Erfahrung. Die Antworten wurden in Form von klinischen Leitlinien oder allgemeinen Empfehlungen formuliert, so dass konkrete Antworten auf spezifische Fragen gegeben werden konnten. In manchen Fällen wurden mehrere mögliche Variationen akzeptiert.

CONSENSUS TOPICS

1. Overview

- 1.1 Prerequisites
- 1.2 Definition of Endovenous Chemical Ablation (Sclerotherapy)
- 1.3 Physical forms of sclerosing application
- 1.4 Indications
- 1.5 Contraindications
 - 1.5.1 Absolute
 - 1.5.2 Relatives
- 1.6 Sclerosing agents
- 1.7 Concentrations and dose of Sclerosing agents
- 1.8 Volumes of Sclerosants (liquid and foam)

2. Material and Equipment

- 2.1 General material
- 2.2 Syringes and Catheters
- 2.3 Needles
- 2.4 Medical Devices
- 2.5 Compression devices

3. About the Patients

- 3.1 Position of the Patient during the ECA
- 3.1 Post-ECA Compression

4. Additional Comments

CONCEPTUAL FRAMEWORK

Many worldwide attempts have been made to have standardized criteria to perform Endovenous Chemical Ablation (ECA), the concept of our consensus will be reflected in two aspects:

- Consensus: Methods and conditions accepted unanimously
- Variations: Methods and conditions that can be changed according to experience of the panel in relation to the general consensus.

This concepts will allow us to establish general guidelines to perform the ECA and at the same time, variations accepted in our country according to medical expertise and the worldwide bibliography.

GLOSSARY

Sclerosing Agent (SA): Chemical that causes damage to the endothelium and the venous wall.

Polidocanol (POL): Aethoxylol (Lauromacrogol 400), chemical substance widely known as sclerosing worldwide. (Formula)

Tetradecyl Sodium Sulfate (TDS): Sclerosing substance for main use in the United States and Europe. (Formula)

Glycerin (GI): Sclerosing substance (glycerol) of oily type. (Formula)

Chromed glycerin (GC): An oily-type sclerosing substance with a Chrome group attached to the glycerol molecule.

Foam (FOAM): Physical form of preparing the sclerosant in different ways (bubbles of different diameter and with different gas).

Tessari Method (TM): Method described by Lorenzo Tessari for the preparation of sclerosant foam using a three-way stopcock.

Room Air (RA): The air commonly used to prepare sclerosant foam.

Oxygen (O₂): Oxidizing gas in its pure form used to prepare sclerosing foam.

Carbon Dioxide (CO₂): Physiological gas used to prepare sclerosant foam.

Pulmonary Embolism (PE): Thrombosis of any branch of the pulmonary artery usually caused by thrombus from a distance.

Deep Venous Thrombosis (DVT): Thrombosis in the deep venous system.

Superficial Venous Thrombosis (SVT): Thrombosis in the superficial venous system.

Great Saphenous Vein (GSV): Vein that originates in the inner side of the ankle and empties into the groin in the Sapheno-femoral junction (Vein Safena interna, or Safena long).

Small Saphenous Vein (SSV): A vein that originates on the external surface of the ankle and usually ends in the saphenous-popliteal junction in the popliteal fossa.

Perforating Vein (PV): Veins that communicate between the superficial and deep system by perforating one or more muscular fasciae.

Doppler Color Ultrasound (DCU): Non-invasive diagnostic method for the anatomical and functional evaluation of the venous system.

Transillumination (TI): Method by which light is applied through the skin to identify veins that are not apparent to the naked eye.

Polarized Light (PL): Method to visualize dermal venous branches.

Consensus

1. Generalities

1.1 Prerequisites

- I. Informed Consent
- II. Medical history (including photos and scheme) where the diagnosis is as specific as possible, including the CEAP system.
- III. Performed by medical personnel who documented Phlebology training.
- IV. Having the necessary equipment
- V. Having the red team gadget (NOM-178-SSA1–1998 Medical Office).
- VI. To be sure the procedure is specifically indicated with each patient.
- VII. Appropriate environmental conditions.

1.2 Definition of Endovenous Chemical Ablation (Sclerotherapy)

ECA is a treatment method for venous pathology consisting of the intravenous administration of a chemical substance which damages the venous endothelium producing the subsequent inflammatory changes, triggering the formation of an expected and controlled thrombus in a selected venous segment with its subsequent defunctionalization.

1.2.1 Forms of Use of Sclerosing Agents

We have two physical forms to apply the sclerosing agents:

- a Liquid
- b Foam

The Foam is prepared by Tessari method using a 3-way tap and two syringes using the following gases:

- Room Air (approximately 70 % of Nitrogen)
- CO₂-O₂ mixture
- O₂ (pure oxygen)

For this preparation, the dilution proposed by Dr. Tessari is used: 1 part sclerosing liquid and 4 parts gas.

Other methods can be considered as „Air Block“. The double syringe system is not yet available in Mexico, however there are other similar devices that can be achieved.

1.3 Indications of the ECA (Endovenous Chemical Ablation)

ECA can be applied in dysfunctional or varicose veins, angiodysplasia or in secondary angiogenesis problems.

Some books and papers talk about the Indications of this procedure, which are the following:

- a Saphenous vessels and their tributaries
- b Secondary varices: Residual or Recurrent
- c Other kind of varicose veins: Post-traumatic, Gestational, Post-thrombotic, post-surgical etc.
- d Telangiectasias
- e Reticular Veins
- f Perforating veins
- g Vulvar varicosity and pelvic congestion syndrome
- h Hemorrhoidal Disease (I-II grades)
- i Some Malformations and Vascular Diseases

Variant: ECA, can be used in selected cases of post-thrombotic syndrome and other body areas.

1.4 Contraindications

1.4.1 Absolute

- a Known allergy to sclerosant
- b Patient with severe acute diseases
- c Chronic arterial insufficiency, with lower ankle-brachial index 0.6, corresponding to arterial occlusion grade III-IV Fontaine scale.
- d Acute or subacute venous thrombosis (less than 6 months)
- e Acute febrile state
- f Unbalanced/uncontrolled systemic diseases
- g Acute eczema
- h Infectious dermatosis
- i Pregnancy, use only in an emergency
- j Immobilized patients

► **Tab. 1** Sclerosing, Dosing and Recommended Puncture Volumes according to the Type of Vein to be treated (Depending on the diameter).

TYPE OF VEIN	POLIDOCANOL (Lauromacrogol 400)			TETRADECYL SODIUM SULPHATE		
	Liquid Concentration	FOAM Concentration	Maximum Volume	Liquid Concentration	FOAM Concentration	Maximum Volume
Great Saphenous Vein & SFJ		3%	10cc		1.5%	6cc
Small Saphenous Vein & SPJ		1–3%	5 cc		1–1.5%	4cc
Tributary Veins	1–3%	1–3%	8 cc	1%	0.75 – 1.5%	3cc
Perforating Veins	1–3%	1–3%	3 cc		0.5–1%	1cc
Reticular Veins	0.5–1%	0.25–0.5%	3 cc	0.3%	0.1–0.15%	0.5cc
Telangiectases	0.25–0.5%	0.1–0.25%	3 cc	0.1–0.15%	0.1%	0.5cc

► **Tab. 2** Sclerosing Agents Used in Small-caliber Veins.

TYPE OF VEIN	CHROMED	GLYCERIN	DEXTROSE		GLYCERIN	
	Liquid Concentration	Maximum Volume	Liquid Concentration	Maximum Volume	Liquid Concentration	Maximum Volume
Reticular Veins	25%	3 cc	50%	5 cc	24%	5 cc
Telangiectases	25%	2 cc	25%	5 cc	24%	4 cc

1.4.2 Relatives

- Bedridden or sedentary, as well as with neurological motor damage
- Thrombophilia
- Multifactorial thrombosis:
 - Hormone therapy
 - Contraceptives
 - Significant Obesity
 - Smoking
 - Severe COPD (Chronic Obstructive Pulmonary disease)
 - Foramen Oval Permeable (in case of using foams)
 - Phlebedema grade IV and Lymphedema grade IV
 - Leucodermatosclerosis not modifiable by compression
 - Anticoagulant therapy
 - Breastfeeding
 - Lactation

1.5 Sclerosing Agents

There are a wide variety of Sclerosing Agents, however, the most used depending on their availability are:

- Polidocanol (Lauromacrogol)
- Tetradecyl Sodium Sulphate
- Glycerin
- Chromic Glycerin
- Hypertonic Solutions (Dextrose and Saline)

In Mexico, the only sclerosing agent authorized by the sanitary authorities is “Aethoxylol®” (Polidocanol, Lauromacrogol 400).

Sclerosants: They are administered in different physical states and concentrations for which; some equipment, additives, gases

► **Tab. 3** Recommended Needle Calibers and Syringes.

TYPE OF VEINS	Needle – Catheter	Syringe
Telangiectases, Spider and Reticular Veins	27–31 G	0.5–3 ml
Veins with diameter > 4 mm	20–25 G	3–5 ml

or diluents widely cited in the world literature are used, the panel endorses the following:

Dosage: The use of liquid form or foam and the suggest doses and volumes are described in ► **Tab. 1** and ► **Tab. 2**.

Gases: Usually room air is used but pure Oxygen, CO₂, and O₂-CO₂ mixtures are also available, as described in different Works.

Diluents: The most used are: Distilled Water, Bidestilated Water, 0.9% Saline Solution, Lactate Ringer’s Solution and 5% Glucose. Depending on the availability of the diluent and personal experience.

1.6 Concentrations and Maximum Dose of Sclerosing Agents

The following doses are recommended in relation to the type of vein to be treated, which will be directly related to their diameters (► **Tab. 1** and ► **Tab. 2**).

Polidocanol (Lauromacrogol 400): It can be supplied in concentrations ranging from 0.25% to 3%. Currently in our country it is available in ampules of to 0.5%, 1%, 2% and 3%. Maximum dose of Polidocanol: 2 mg/Kg of bodyweight.

Tetradecyl Sodium Sulfate: The literature suggests the use of concentrations ranging from 0.1 % to 1.5 %. Maximum Tetradecyl Sodium Sulfate Dose: 4 ml 3 %. (not available in México)

1.7 Volumes of Sclerosants (Liquid and Foam)

There are several works on the volumes of foam that should be administered to each patient, it is important to note that the global variation is very wide, ranging from 1 to 60 ml; which is due to the concentration, gas used for foam, time of administration, number and type of veins to be treated and the personal experience of the physician.

It is recommended to use a maximum volume each session of 10 cc of the sclerosing agent, the average volumen suggested by the panel is 5cc in both liquid or foam form (► **Tab. 1** and ► **Tab. 2**).

Remarks: This consensus DOES NOT limit the use of different concentrations or volumes, since, in different parts of the country, institution or personal experience, they can be varied according to optimizing the results for the patient.

Recommendations after Endovenous Chemical Ablation (Sclerotherapy):

- a Elevation of the treated limb of 10–15° by 5 to 10 min. with flexion-extension exercise of the ankle.
- b Put on a Elastocompression system
- c Immediate mobilization after 5–10 minutes (see above)
- d Consider that adverse effects may occur
- e Keep in touch with the patient.
- f Percutaneous thrombectomy by puncture or aspiration in the next 10 days.

2. Material and Equipment

2.1 Material

- Cotton
- Alcohol
- Disposable gloves
- Adhesive Tapes
- Gauzes
- Antiseptic solutions
- Physiological Solution 100 ml and 250 ml
- Pads with Alcohol (Wipes)
- Work table
- Scissors
- Measuring tape
- Marker (Surgical and Indelible)
- 3 way keys
- Hypodermic needles
- Blood pressure cuff
- Stethoscope
- Lamps
- Elevators for the limb

2.2 Syringes and Catheters

Disposable syringes of: 0.5, 1, 3, 5 and 10cc.

Catheters (short or long) with different needle gauges.

Other devices of similar calibers (punzocats, butterflies, etc.)

10 and 20 cc syringes are recommended only for dilutions (► **Tab. 3**).

2.3 Needles

The following needle size and syringes are recommended to puncture the veins according their diameter. (► **Tab. 3**). When injecting Foam through needles with gauge greater than 27 G, the bubbles are destroyed and liquid is mostly injected, therefore no needles larger than 27 G are recommended for foam injection into large diameter veins.

2.4 Medical Devices

- Venous Transilluminator: The panel agreed that transillumination equipment is mandatory in the ECA procedure.
- Polarized Light and Magnifying Glasses: Polarized light eliminates reflections due to the refraction of light in the dermis, which allows us to observe with greater precision Telangiectasias and small caliber vessels, the magnifying glasses allow to observe not perceptible veins under conventional conditions.
- Vein Visualizer in Real Time: System that emits a near infrared light, which when absorbed by the blood, produce the reflection of it and project a digital image of the veins on the skin.
- Linear Doppler or Hand Doppler: It is essential to have Linear or hand Doppler equipment for diagnosis and verification of the arterial and venous points and verify the ankle-brachial index (ABI).
- Ultrasound Doppler Color: The Color Doppler equipment is accepted worldwide as the ideal device for the diagnosis of venous disease, being also very useful to perform punctures of the vascular system and essential to ultrasound guided ablation and sclerosis treatments.
- Oxygen Tank: Medical Oxygen can be used through nasal tips or to prepare foam.
- CO₂ (Carbon Dioxide) Tank: Medical use gas which is used in a non-routine way to prepare the foam of the sclerosing agent.
- Oximeter: Useful for testing arterial saturation of the O₂ after bandages.
- Photographic camera: For medical records and as clinical evidences.
- Computer

Variant of Equipment and Additional Devices:

- Glucometer
- Needle Extenders
- Podium for Exploration
- Pletismograph

2.5 Material for Compression

The Elastocompression system is considered as indispensable strategy after the treatment of ECA, which can be done with the following materials:

- Elastic bandages of 10 and 15 cm. (High, medium and low compression).
- Compression socks higher than 25 mmHg.

For compression stockings, it can be used below the knee, thigh or pantyhose, depending on the preference and sclerosed area.

3. About the Patients

3.1 Position of the Patient during the ECA

It is preferred to perform the ECA with the patient in lying position, which will avoid the presence of accidents caused by lipothymia or adverse reaction to the sclerosing agent, in addition to offering greater comfort.

In sometimes the evident varicosities in standing position disappear with the lying position, then by this:

- a Proof if the veins can be located with Transillumination device.
- b Mark the insufficient veins with the patient standing before chemical ablation in decubitus.
- c Sit the patient on the examination table with the leg hanging and treat the insufficient veins in this position, immediately afterwards place the patient in lying position.

3.2 Compression After- ECA

The usefulness of compressive therapy is described in many works auxiliary to prevent reflux, promote the venous upflow, decrease venous stasis, edema and pain, in addition to improve the lymphatic function, the microcirculation and promote the healing of venous ulcers.

The placement of a venous compression system after performing ECA (sclerotherapy) is unanimous. The use of bearings, cotton or other direct compression system on the sclerosed veins is convenient but not a generalized practice.

4. Additional Observations

1. Prior to the ECA procedure it is suggested: Avoid the tight clothing, do not apply creams, avoid exposure to sunlight and laser hair removal sessions (2 weeks before).
2. Adverse, Collateral, Secondary Effects and Complications of ECA (Sclerotherapy):

Injection of a sclerosant can produce in some cases: cardiac abnormalities, cough and respiratory disorders, vomiting, visual disturbances, metallic taste, fever, back pain or headache, but it can also produce local reactions such as phlebitis or even ulcers by extravasation.

Like any other substance it can lead to allergic reactions such as rash, urticaria or even anaphylaxis reactions.

The adverse effects of ECA are mainly:

- Ecchymosis
- Local pain when applying the sclerosing agent
- Intense and continuous pain in the treated site
- Superficial Phlebitis and thrombophlebitis
- Dermatitis, itching, non-allergic erythema
- Local necrosis and ulcers due to extravasation
- Cough and dyspnea
- Nausea and vomiting
- Neurological injuries, Neuromas, Neuropraxia or Neuritis
- Deep Venous Thrombosis
- Neovascularization post sclerotherapy (Matting)
- Lipothymia and Disorders in the gait
- Headache, Migraine and Dizziness
- Paresthesias, Aphasia, Ataxia and Hemiparesis
- Transient Loss of Consciousness and Confusion

- Metallic Flavor and Hypoesthesia and/or Oral Dysesthesia (Orofacial)
- Scotoma and Transient disturbance of the vision
- Alteration into the General Condition (Fever, Asthenia, Adynamia)
- Hypertrichosis

Complications of ECA (sclerotherapy) described in the literature worldwide:

- TIA
- Stroke
- Anaphylactic Shock and Angioedema
- Tachycardia, Arrhythmias and Cardio Respiratory Arrest
- Tako-Tsubo Syndrome and other cardiac complications
- Venous Thromboembolic Disease (Pulmonary Embolism)
- Instability of blood pressure (Hypotension-Hypertension)
- Ischemia in the limbs by intra arterial application of the sclerosant
- Vasovagal Syncope
- Angina Pectoris
- Vasculitis

4. Evaluation and therapeutic continuity is recommended from 1 to 4 weeks.

5. Medications and Local Measures after ECA:

Physicians use drugs after Endovenous Chemical Ablation in the following proportions:

- Anti-phlebotic Medications: 10%
- Non-Pharmacological Agents with Anti-phlebotic Effect (naturalist): 90%
- Topical gels: 10%
- Analgesics and Oral Anti-inflammatories: 10%
- Local Cold: 15%

6. It is not advised to apply sclerosants via the perivascular route, although this is described as an option.

7. Post-sclerotherapy thrombectomy is usually required by Percutaneous puncture or Aspiratiion within the first 10 days after the treatment and at any time that is necessary.

8. In México, it is mandatory to collect the following documents, before conducting sessions of Endovenous Chemical Ablation (Sclerotherapy):

- a Complete Medical Record (Printed or Electronic)
- b Medical history according to NOM-004-SSA3-2012 of the Medical Record
- c Phlebological Background Format
- d Informed Consent to treatment
- e Specific Registry of each medical and therapeutic session
- f Authorization to obtain sensitive data and to take photographs

Annexes

- A) Medical history
- Phlebological record Format

B) Informed Consent

Authorization for the procedure, collect sensitive data and take pictures.

Comment

This 2. Mexican consensus on sclerotherapy is valid for Mexican doctors only. In Germany the European guidelines for sclerotherapy in chronic venous disorders are valid (Rabe et al. *Phlebology* 2014; 29(6): 338–354).

Conflicts of interest

The authors declare that they have no conflicts of interest.

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