Endovenous Thermal vs Non-Thermal Treatment in Chronic Venous Disease

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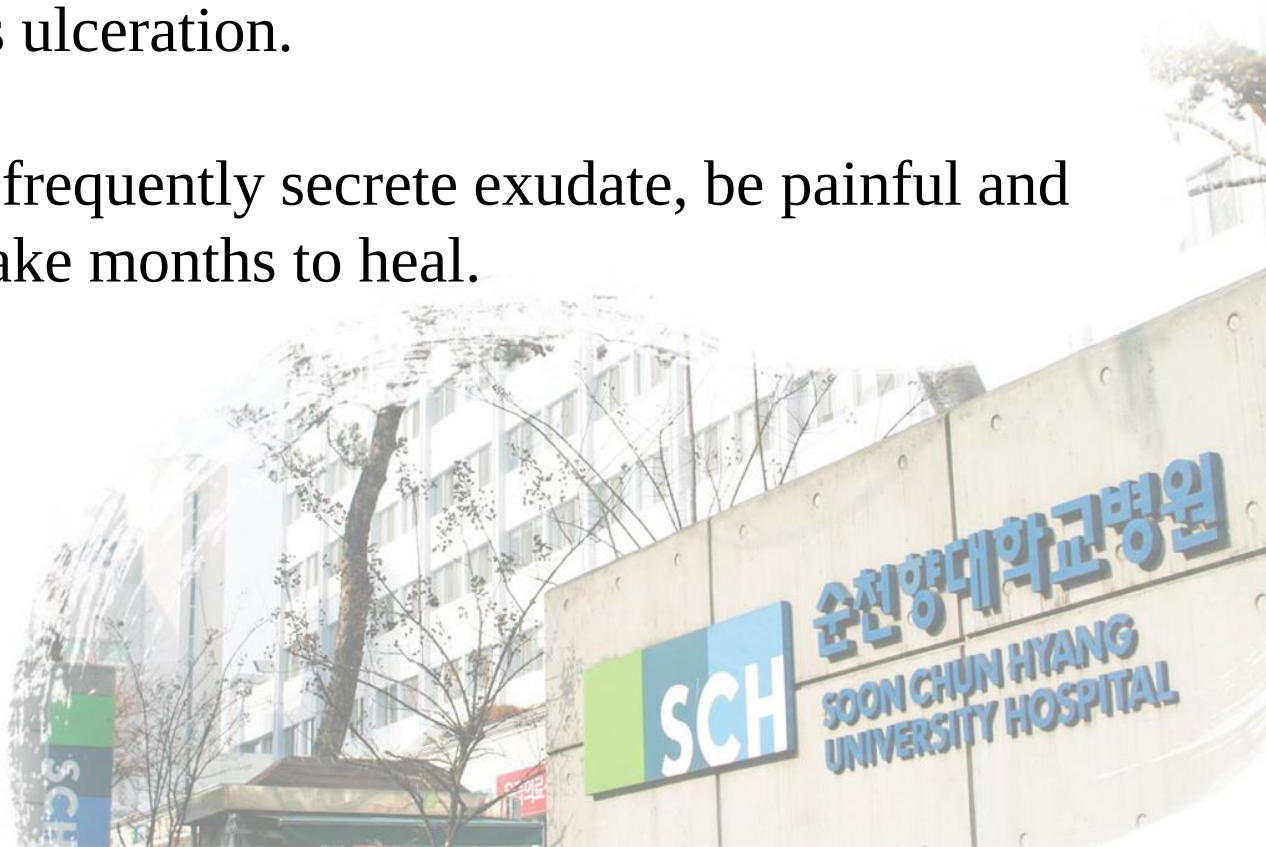
Chronic venous disease

The leading cause of leg ulcers

CVI and skin changes appear to be at a greater risk of developing venous ulceration.

Venous ulcers can frequently secrete exudate, be painful and malodorous, and take months to heal.



Chronic venous disease

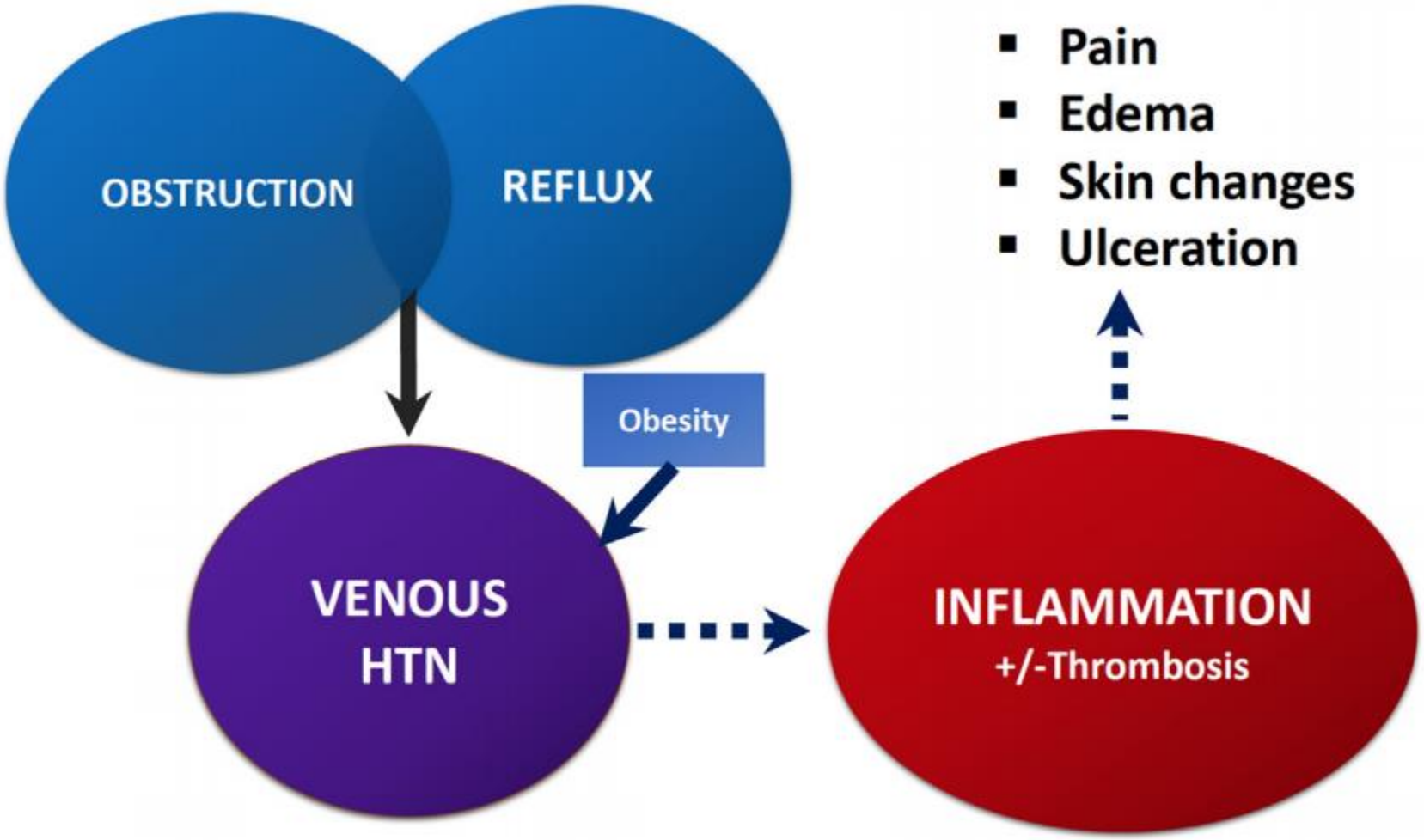
They are typically found in the gaiter zone of the legs (particularly at the medial and lateral aspects of malleoli and pretibial regions).

They are associated with depression and poor quality of life.

Chronic venous disease

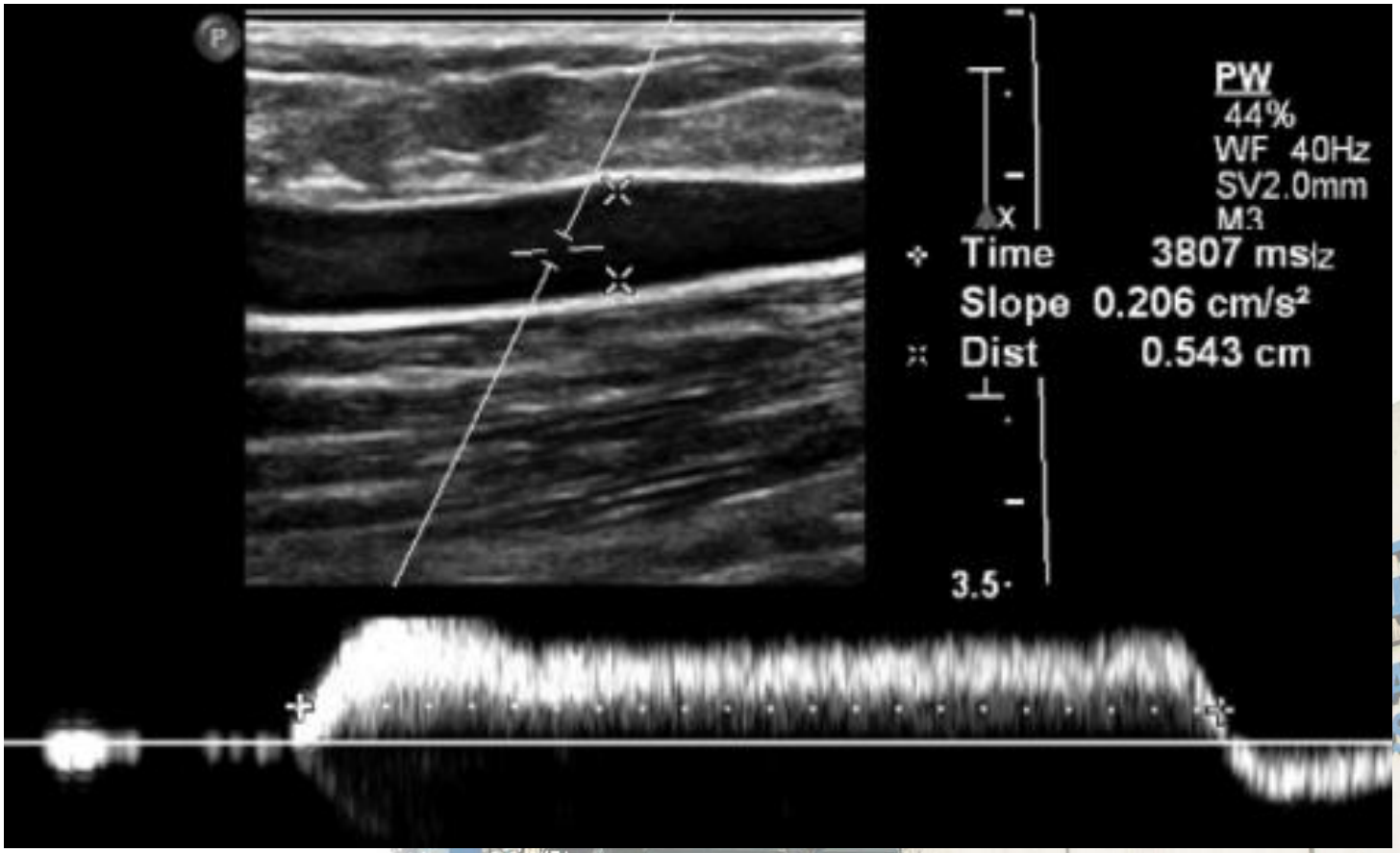
Chronic venous disease

Pathophysiology



Superficial vein reflux

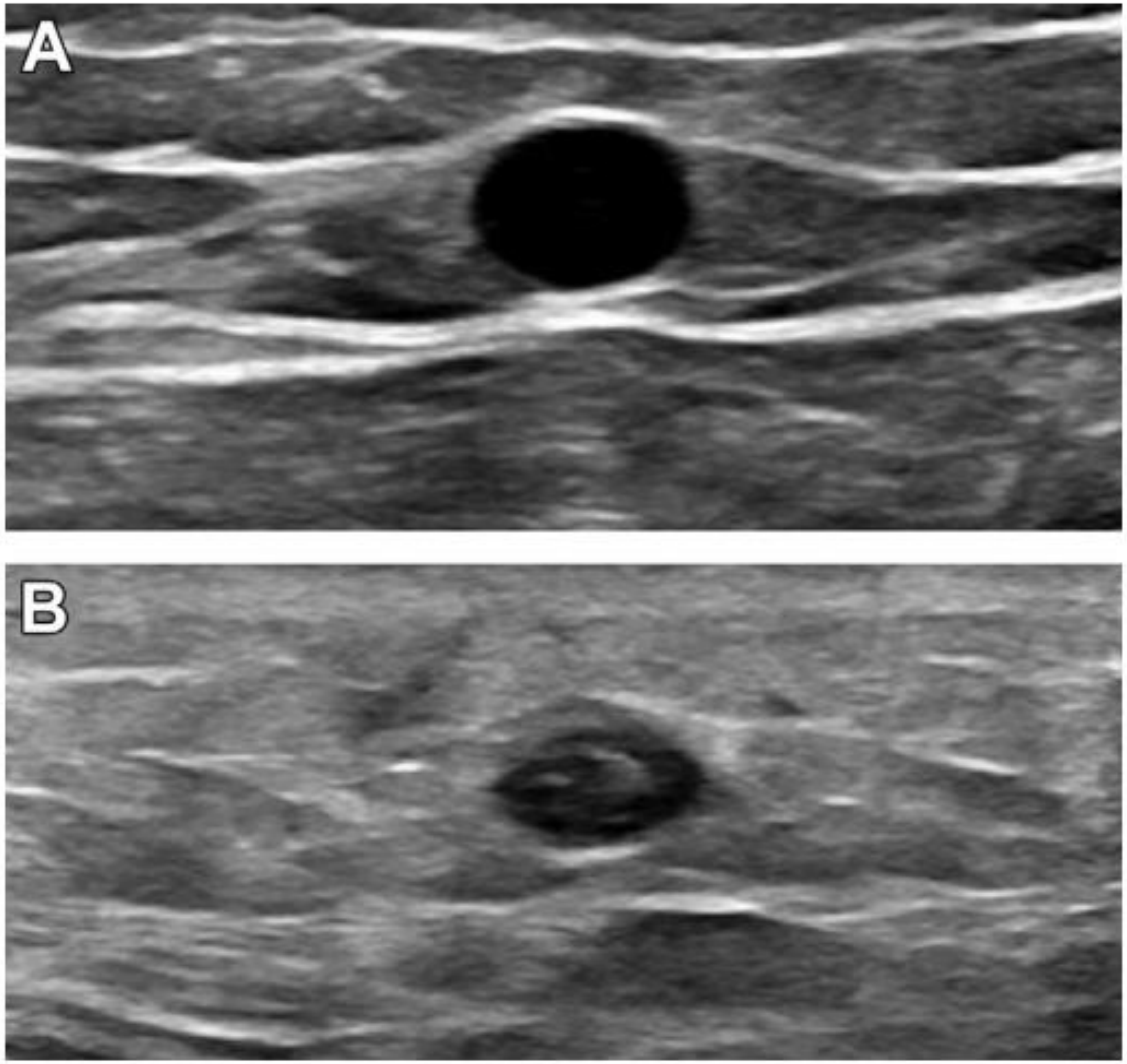
Superficial valvular incompetence has been frequently found in individuals with CVI and venous ulcers



Superficial vein reflux

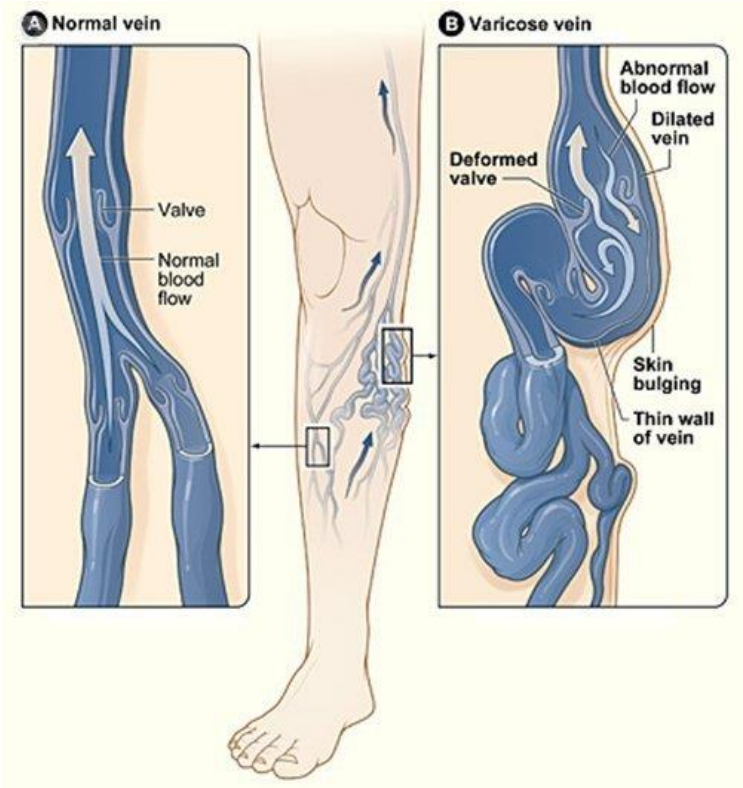
Endovenous laser ablation (EVLA) and radiofrequency ablation (RFA) are percutaneous modes of thermal ablation. Intravenously, both devices employ a low-profile fiber, directly delivering heat energy to the venous endothelium, leading to injury, thrombosis, and eventual fibrosis and occlusion of the vein.

Thermal Ablation



Current indication of varicose vein treatments

Endovenous treatment should constitute the first treatment of choice for people with confirmed varicose veins and truncal reflux : IA compared to surgery, IA compared to foam



The different endovenous treatments

Radiofrequency thermoablation.
Laser thermoablation (EVLA).
Steam thermoablation.
Ablation by cyanoacrylat glue (VenaSeal) : no tumescence
Mecanochemical ablation (MOCA).
Foams clerotherapy.

Indications

Stage C2 to C6 (CEAP) of venous chronic disease,
mostly C2-C4.
Effective on rectilinear recurrences
with significant perforating veins.
Anticoagulation : no contraindication

Indication according to the depth of the trunk

Intrafascial, deep and rectilinear : thermal ablation.

Suprafascial : phlebectomy
Both : mixed treatment

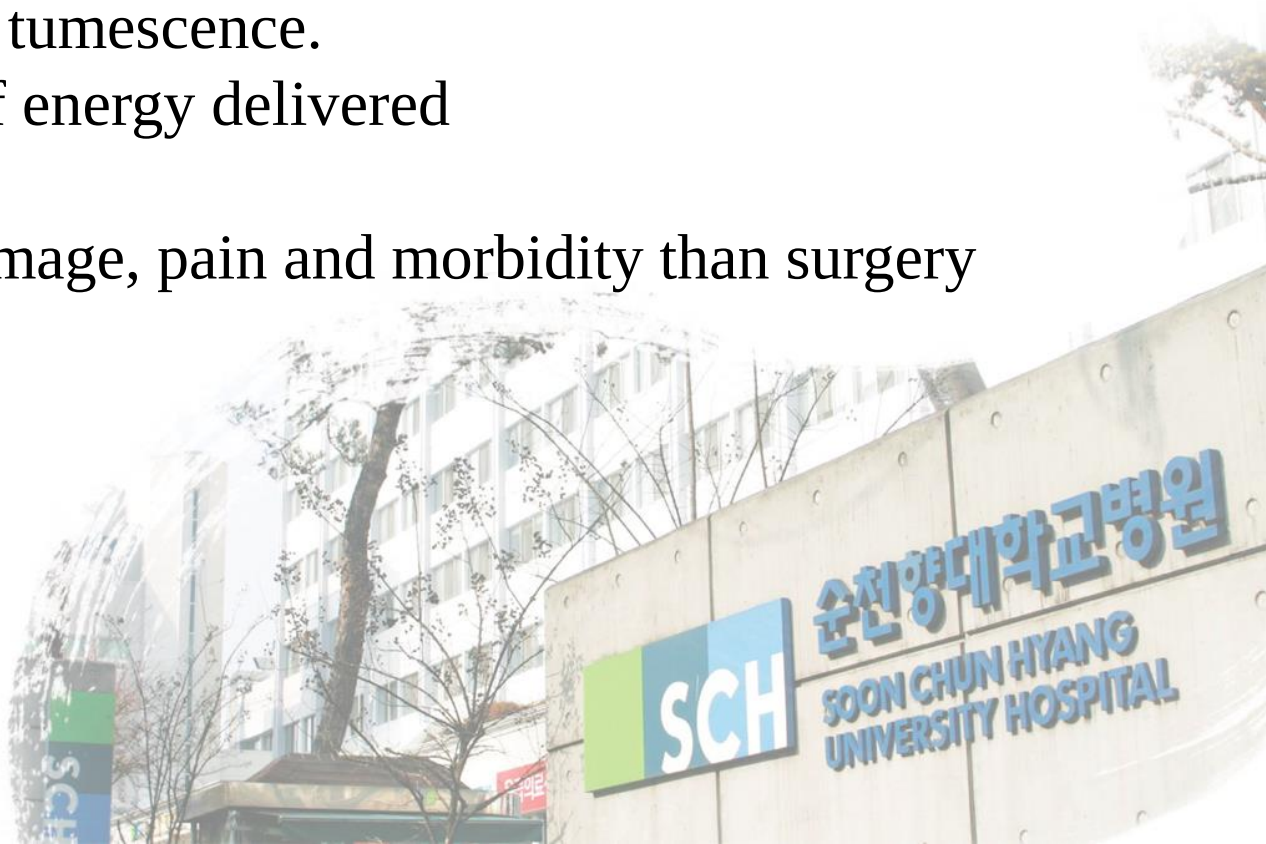
Essentiel points related to thermoablation

Protocol well followed.

Quality of the result :

- On the correct indication.
- On the quality of tumescence.
- On the amount of energy delivered

Less collateral damage, pain and morbidity than surgery



Tumescent Preparation

Tumescent preparations typically contain lidocaine, epinephrine, bicarbonate, and saline.

They act as anesthetics and heat sinks for thermal ablation and protect surrounding structures from thermal injury.

Epinephrine can constrict the vein, allowing for better contact with the ablation device.

Endovenous Laser Ablation (EVLA)

The laser wavelength can target water or hemoglobin.

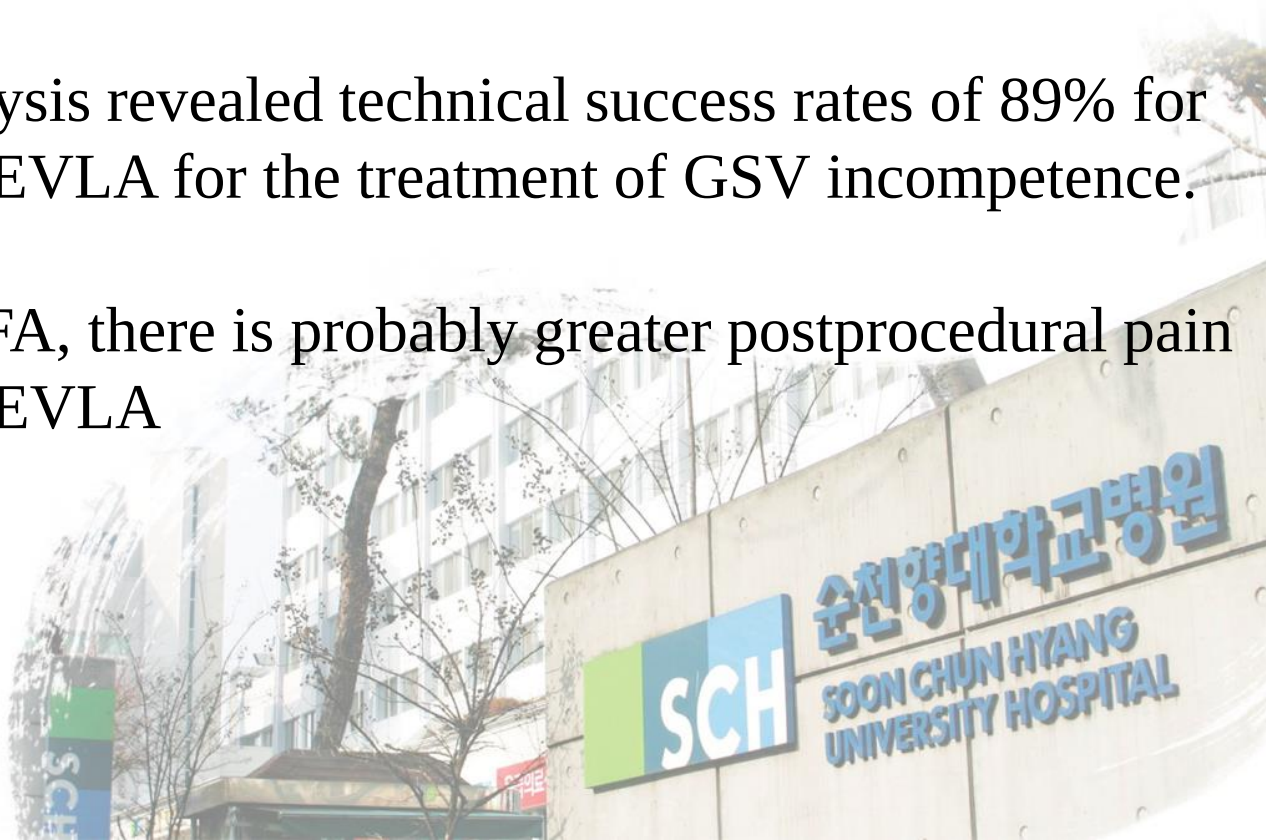
The 1-year vein occlusion rates can surpass 90% with EVLA.

Radiofrequency Ablation (RFA)

Five-year follow-up after RFA in patients with venous insufficiency revealed an occlusion rate of 92% and sustained symptom improvement

A 2016 meta-analysis revealed technical success rates of 89% for RFA and 85% for EVLA for the treatment of GSV incompetence.

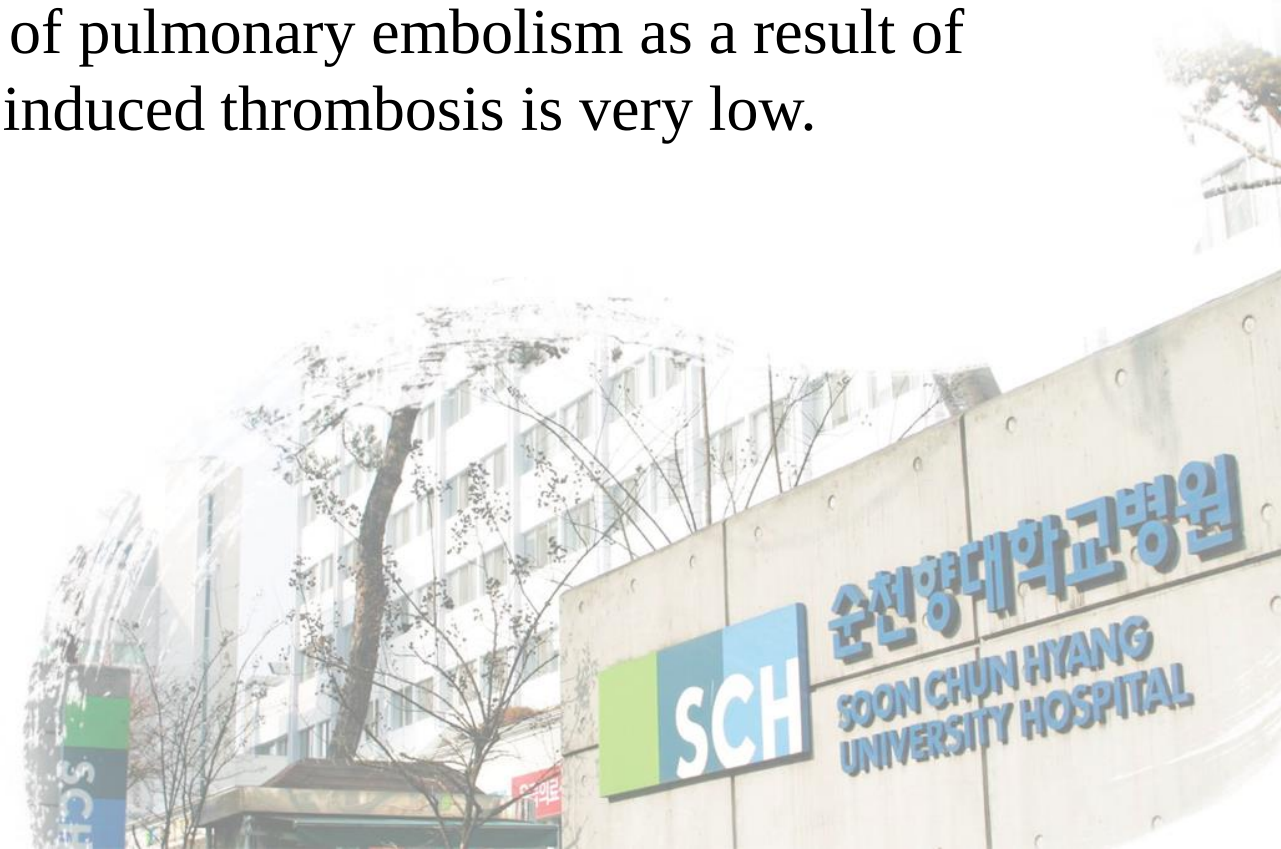
Compared with RFA, there is probably greater postprocedural pain and bruising after EVLA



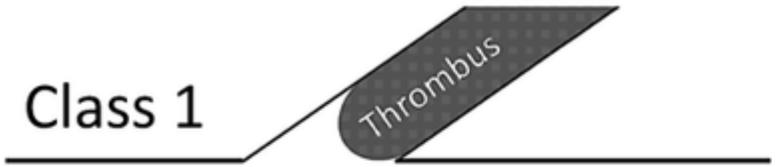
Complication of Thermal Ablation

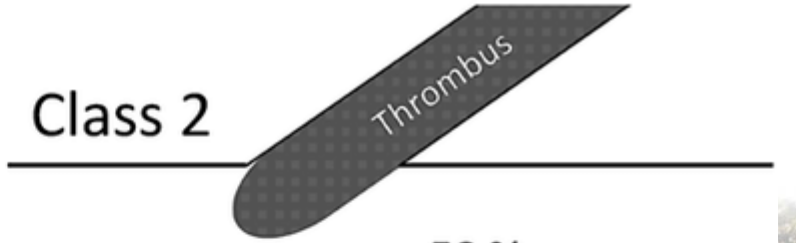
Endothermal heat-induced thrombosis in <1% cases, wherein a thrombus may propagate into the deep system.

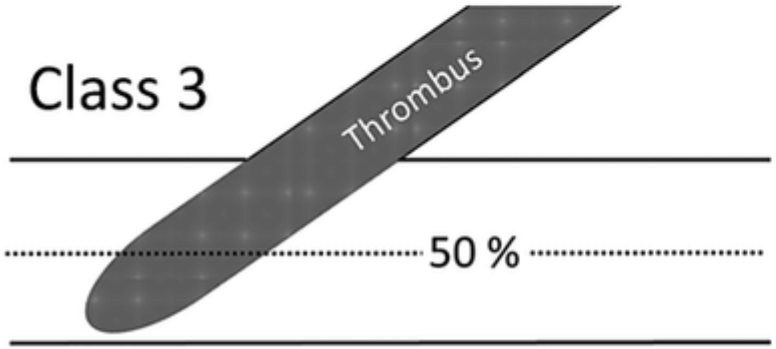
However, the risk of pulmonary embolism as a result of endothermal heat-induced thrombosis is very low.

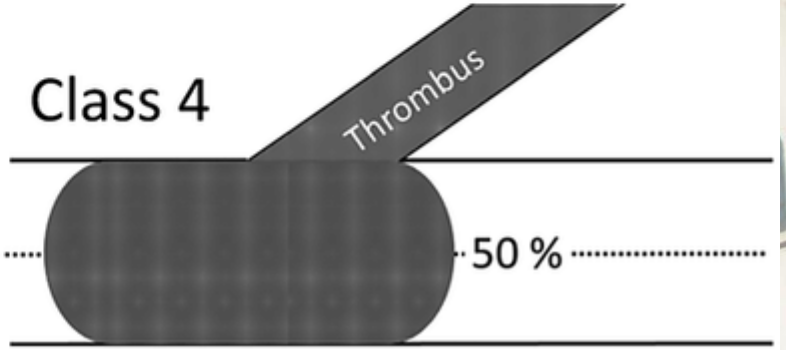


Endothermal heat-induced thrombosis









Endothermal heat-induced thrombosis

Non-Thermal Non-Tumescent Ablation

Cyanoacrylate adhesive closure (CAC)

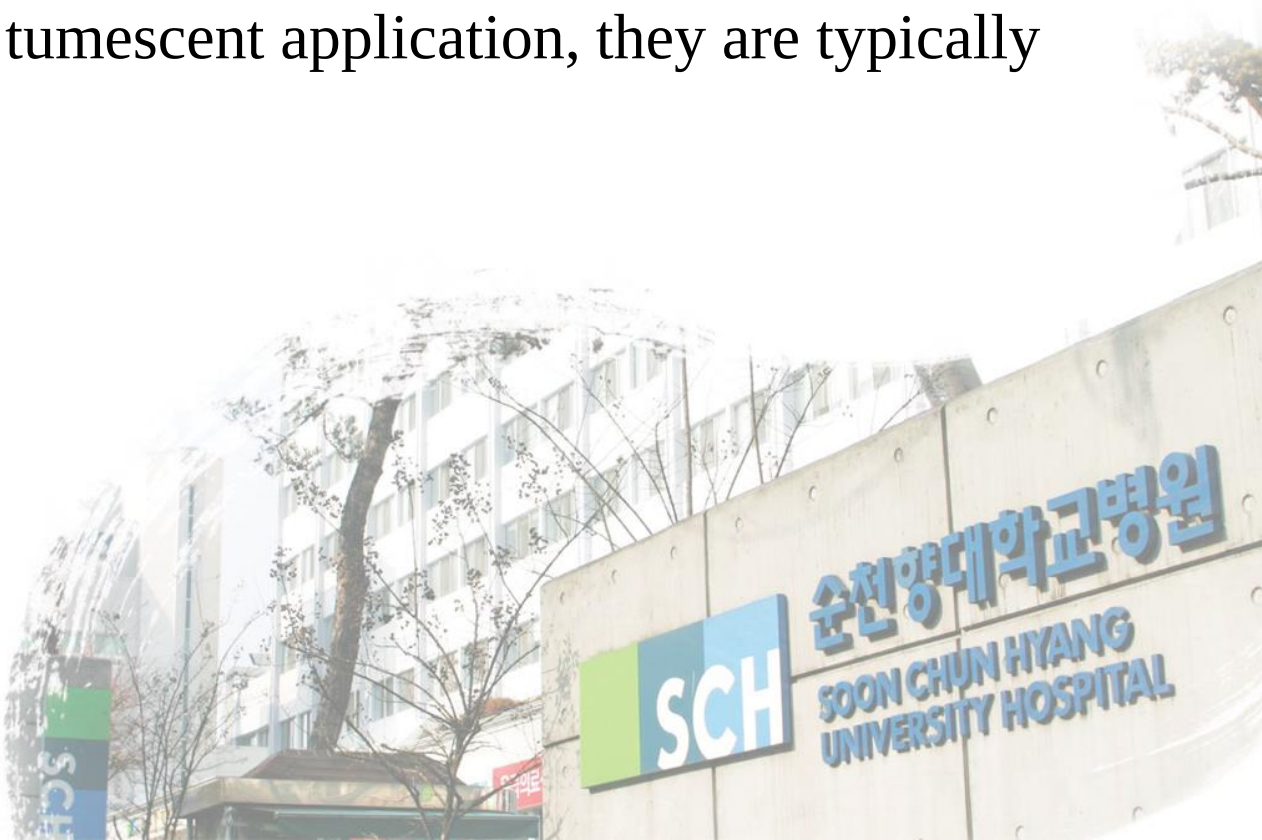
Mechanochemical ablation (MOCA)

Foam sclerotherapy.

Advantages of Non-Thermal Ablation

They do not cause thermal injury such as burns or nerve damage.

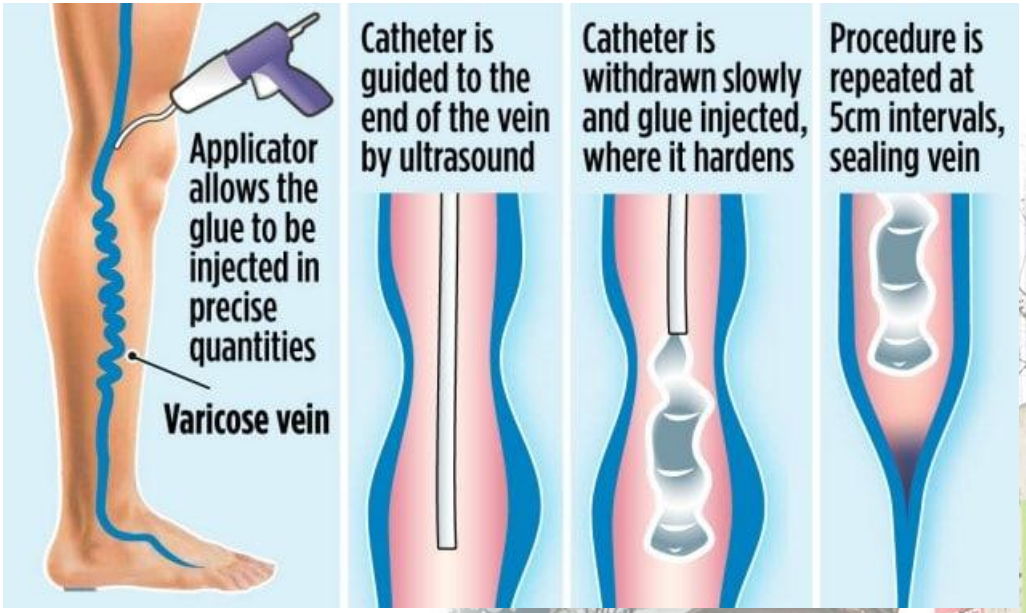
Without the need for tumescent application, they are typically less painful

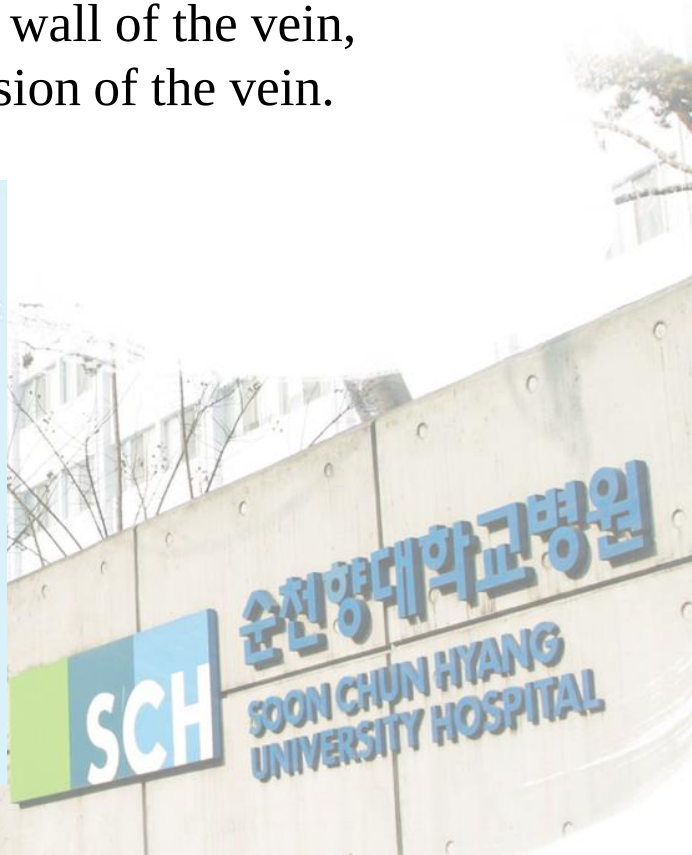


Non-Thermal Non-Tumescent Ablation

Cyanoacrylate (CA) has high viscosity to assure exact positioning of an appropriate dose of glue and to prevent unwanted wash-out into the deep venous system.

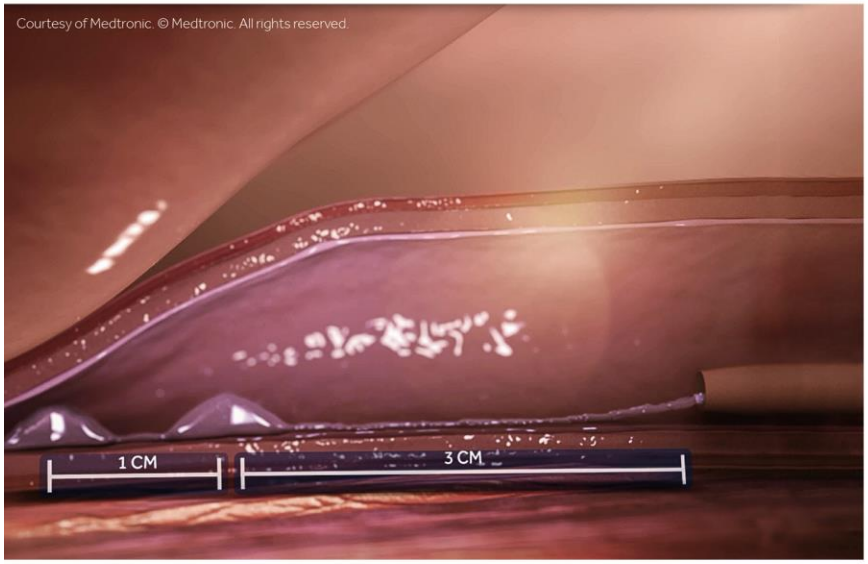
It induces an inflammatory reaction within the wall of the vein, eventually leading to long term fibrotic occlusion of the vein.

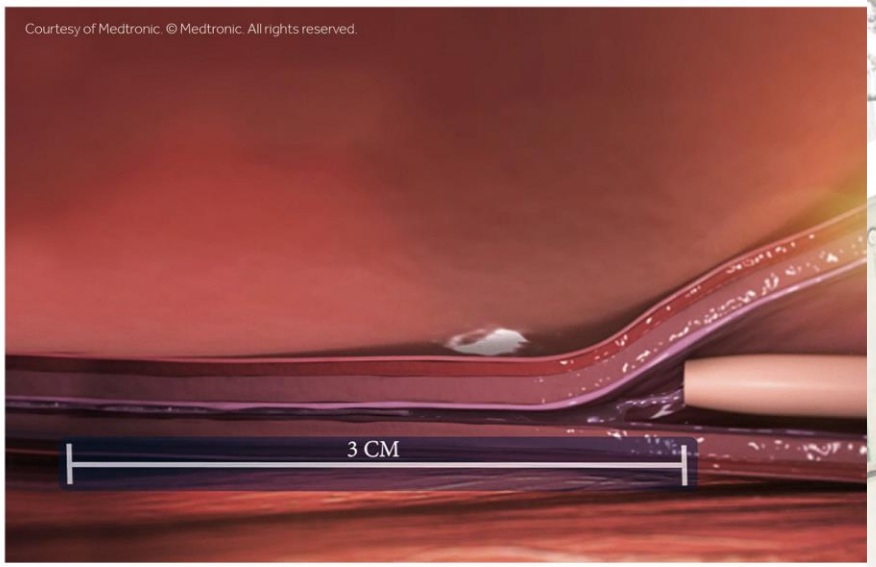




VenaSeal ™

It received CE mark certification in 2011 and FDA approval in 2015 for “the permanent closure of lower extremity superficial truncal veins, such as the great saphenous vein (GSV), through endovascular embolization with coaptation”.

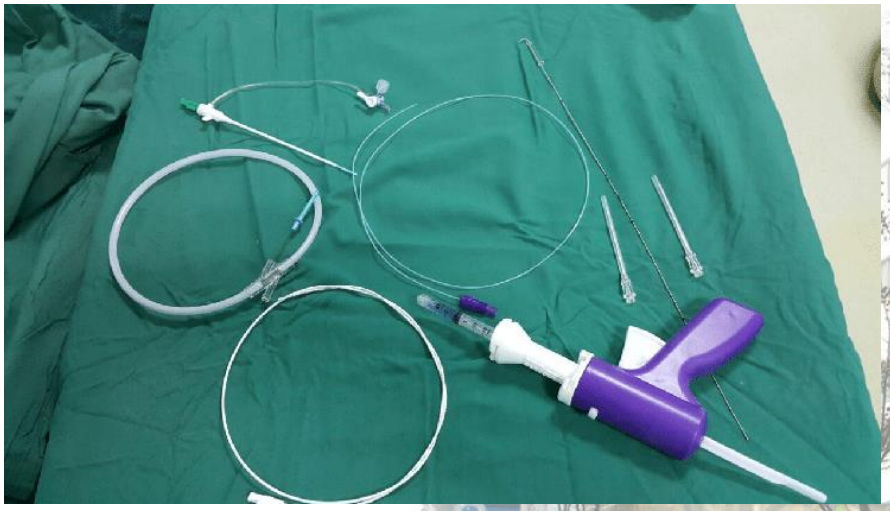




VariClose ™

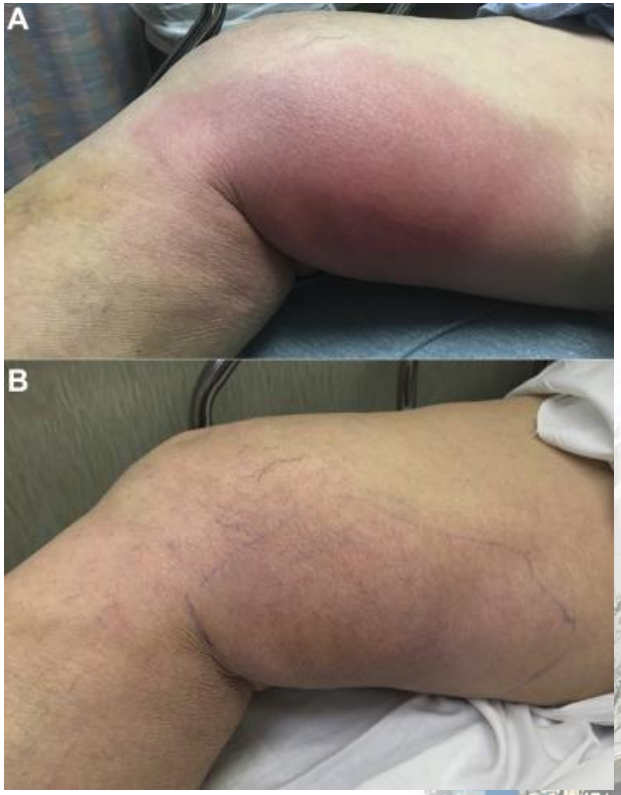
Technique of administration differs from that of VenaSeal and it also uses low viscosity CA glue with purported advantages of faster polymerization and sealing of the veins thus culminating into shorter duration of the procedure.

Presently, only a handful number of studies have evaluated this device but results from the available studies appear to be promising



Contraindication for CAC

Absolute contraindications include hypersensitivity to CA, previous history of deep vein thrombosis and superficial thrombophebitis of GSV.



Contraindication for CAC

Pregnancy, patients with hypercoagulable disorders, patients on anticoagulants and recurrent varicose veins have been excluded from most of the studies.

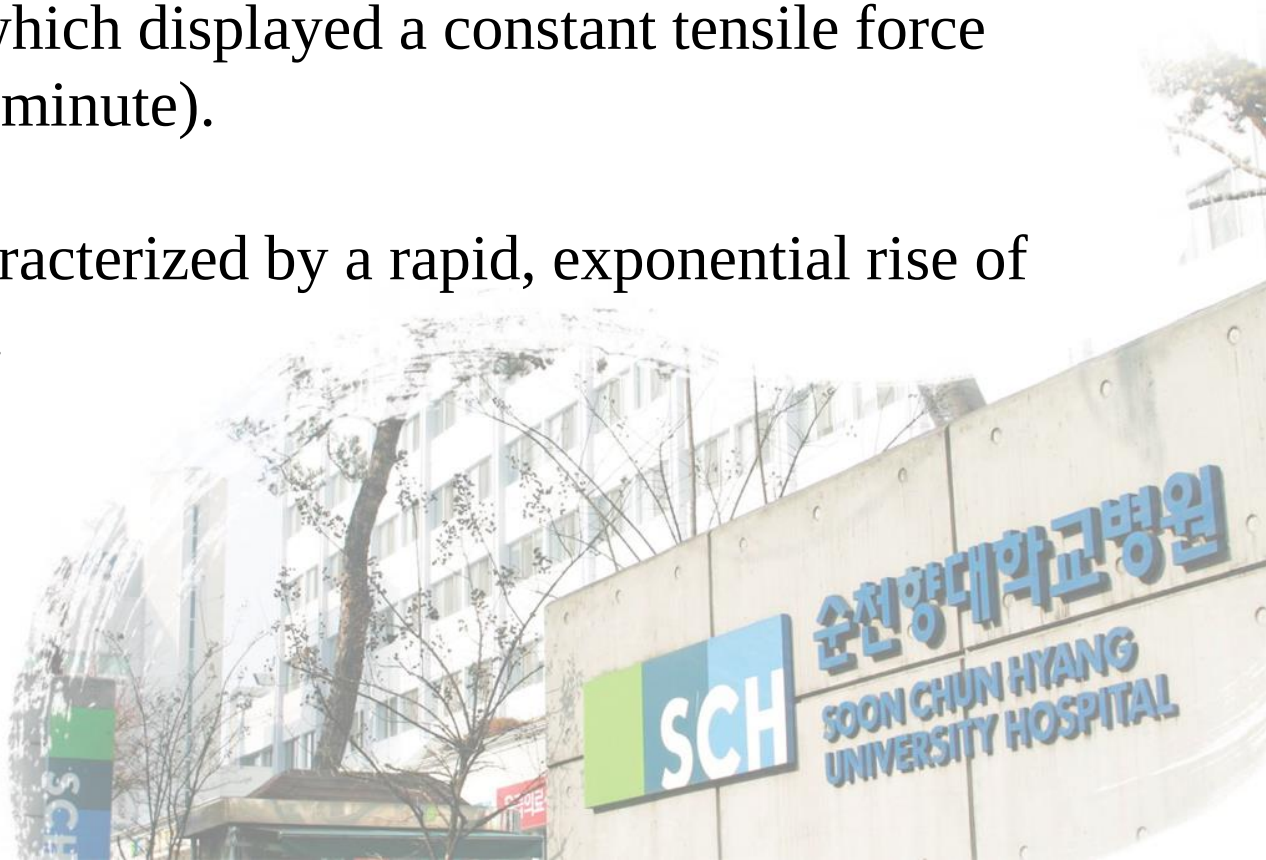
Tortuous GSV that can limit catheter placement or require more than one primary access site is considered relative contraindication.

Mechanism of Action

First phase that lasts for around 10 seconds consists of initial rapid polymerization with increasing tensile

Second phase which displayed a constant tensile force (lasting up to 1 minute).

Final phase characterized by a rapid, exponential rise of tensile strength.

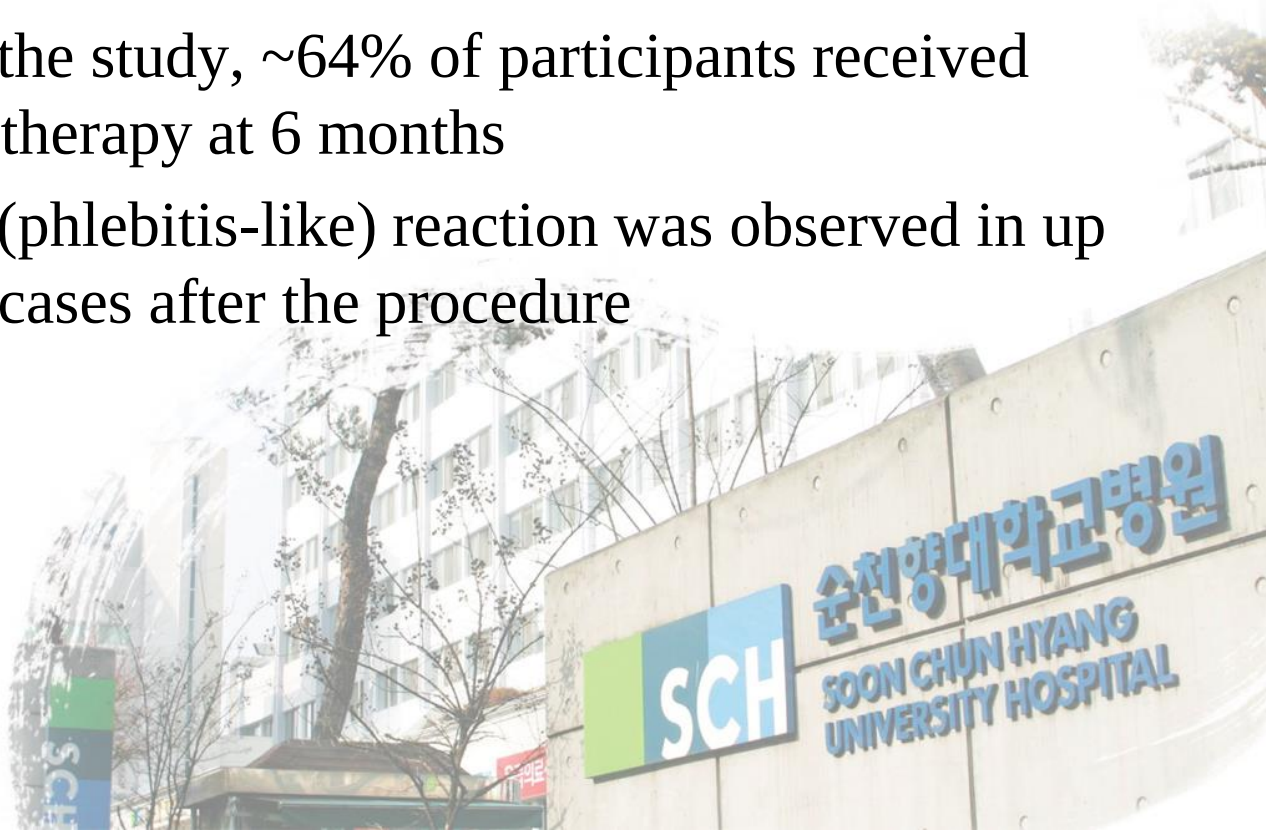


Clinical Outcome of CAC

In a head-to-head RCT, at 5 years, CAC demonstrated equivalent GSV occlusion rates and relief of symptoms compared with RFA.

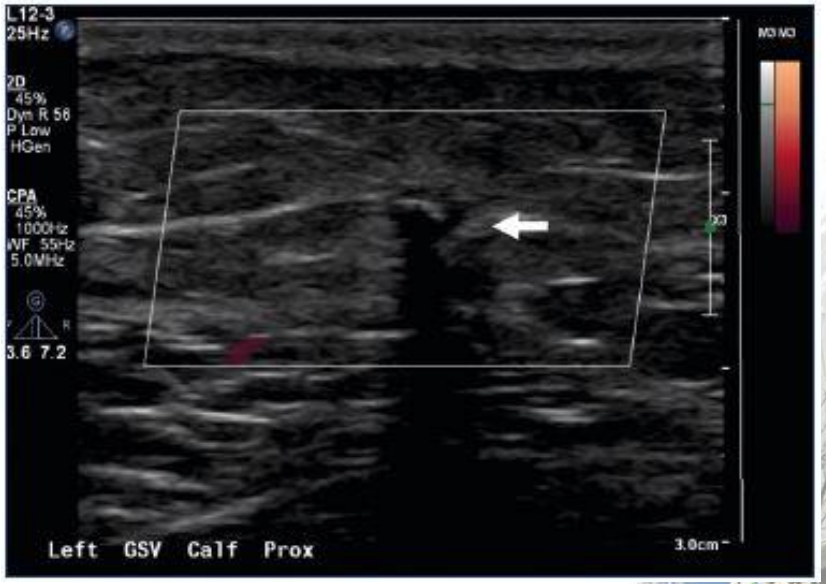
In both the arms of the study, ~64% of participants received adjunctive sclerotherapy at 6 months

A hypersensitivity (phlebitis-like) reaction was observed in up to 23% of CAC cases after the procedure



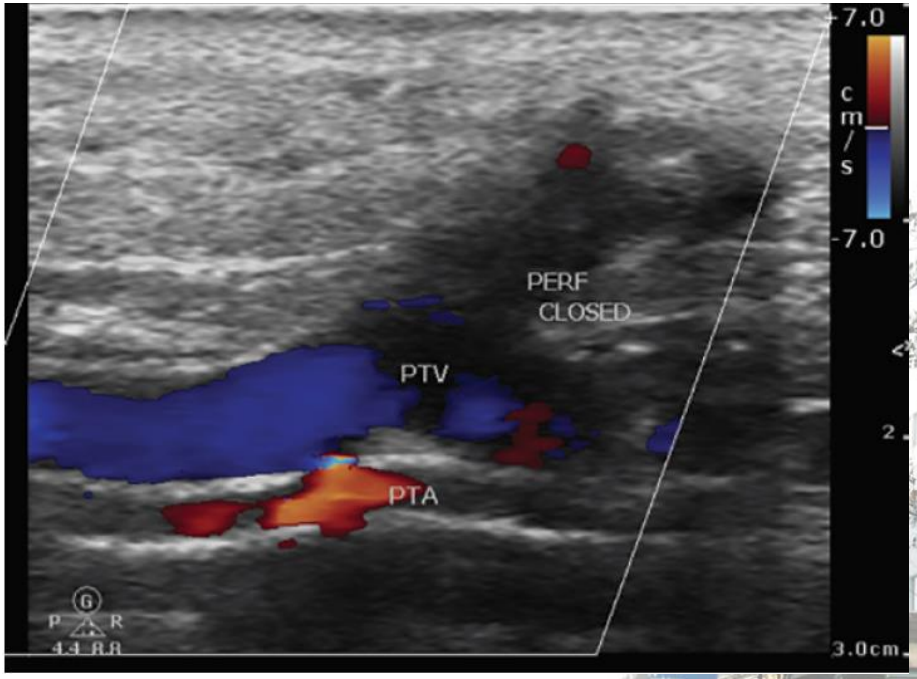
Anatomical success rates

Parameter	Almeida [12,21]	Morrison [23,27]	Proebstle [28,29]	Gibson [30]	Yasim [18,32]	Bozkurt [16]	Chan [19]
Year of Publication	2013/2015	2015/2017	2015	2016	2016/2017	2016	2017
Study design	P	RCT	P	P	P	P	P
Anatomical success							
<1 month	97% (38)	100% (105)	97% (NA)	100% (70)	100% (180)	96.7 (153)	92% (102)
3 months	95% (38)	97% (104)	94% (NA)	NA	100% (180)	96.6 (145)	NA
6 months	92% (36)	NA	93% (NA)	NA	98% (159)	NA	89% (63)
12 months	92% (36)	97% (95)	93% (68)	NA	96.6% (159)	95.8 (142)	75% (37)
24 months	92% (24)	NA	NA	NA	NA	NA	NA
30 months	NA		NA	NA	94% (159)	NA	NA



Type of veins and duration of procedure

Type of vein	Almeida [12,21]	Morrison [23,27]	Proebstle [28,29]	Gibson [30]	Yasim [18,32]	Bozkurt [16]	Chan [19]
GSV	38	108	70	48	169	154	108
SSV	0	0	0	8	11	0	0
ASV	0	0	0	14	0	0	0
Total	38	108	70	70	180	154	108
Duration of the procedure (min)	21 (14-32)	24 (11-44)	18.6 (8-74)	23 (11-43)	15.2 (10-25)	15 ± 2.5	64 (28-116)

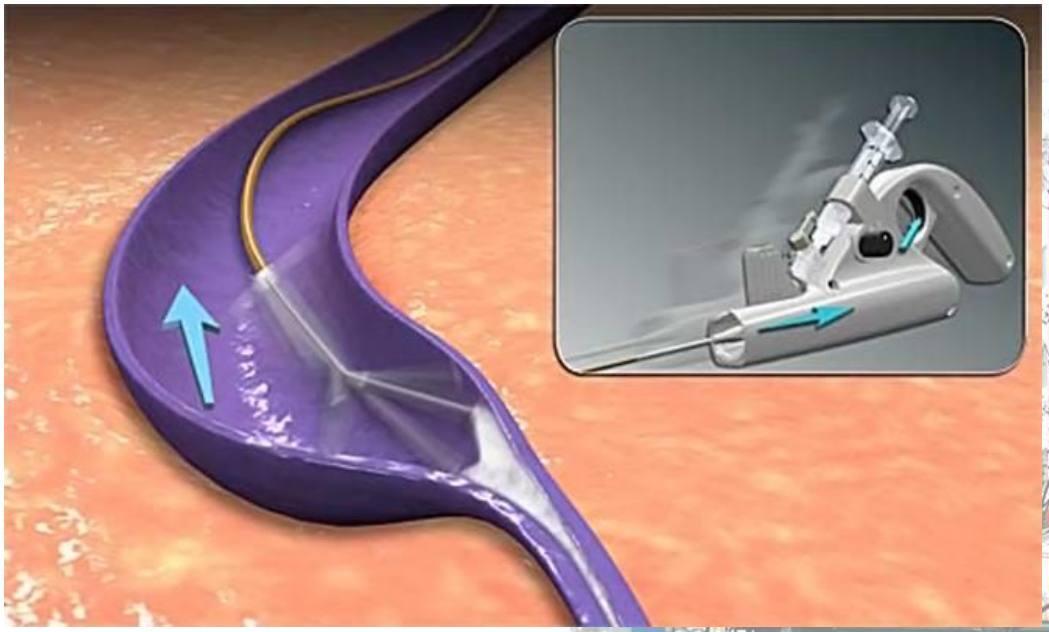


Complication

Complication	Almeida [12,21]	Morrison [23,27]	Proebstle [28,29]	Gibson [30]	Yasim [18,32]	Tekin [33]	Bozkurt [16]	Chan [19]
Phlebitis	16%	20%	11%	20%	0	3.2%	7%	4%
SVT	3%	4%	NR	NR	NR	NR	NR	4%
SSI	3%	1%	1%	2%	NR	NR	NR	1%
DVT/PE	NR	0/0	0/NR	0/0	0/0	0/0	NR	0/NR
Allergic reaction	NR	NR	NR	2%	NR	NR	NR	NR

Mechanochemical Ablation (MOCA)

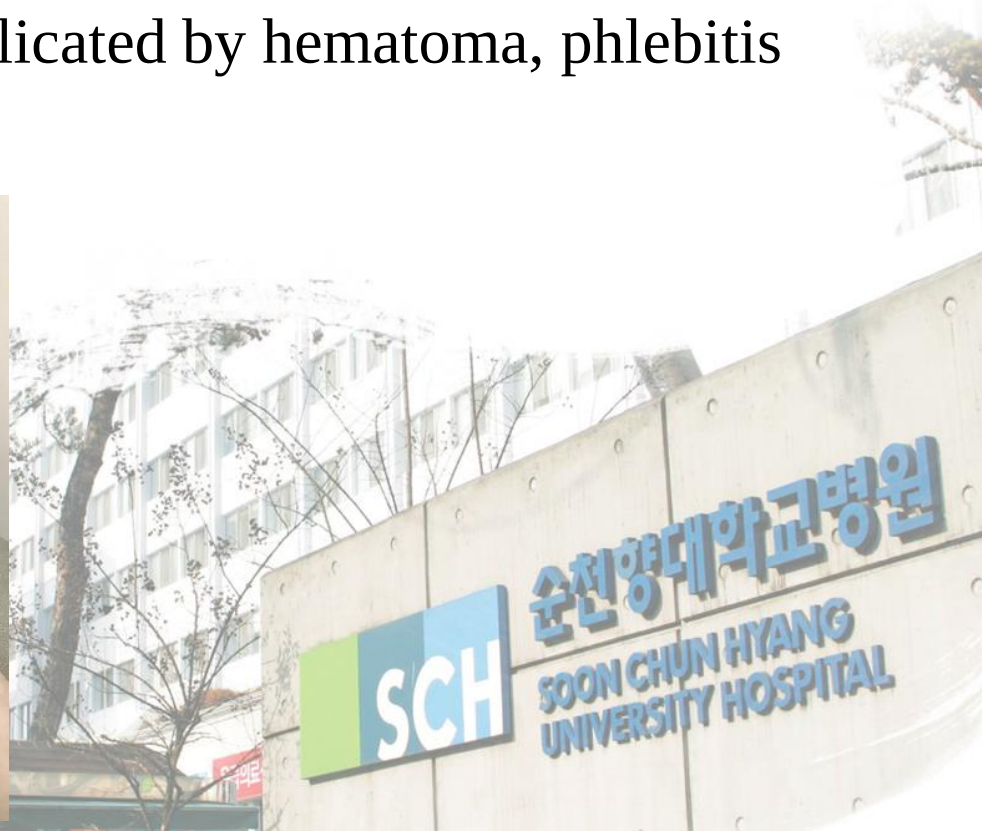
In MOCA(ClariVein; Merit Medical), a rotating metallic tip is used to scrape the venous endothelium at 3500 rpm while the operator simultaneously injects a sclerosant and slowly withdraws the rotating tip, leading to eventual endothelial fibrosis and vein occlusion.



Mechanochemical Ablation (MOCA)

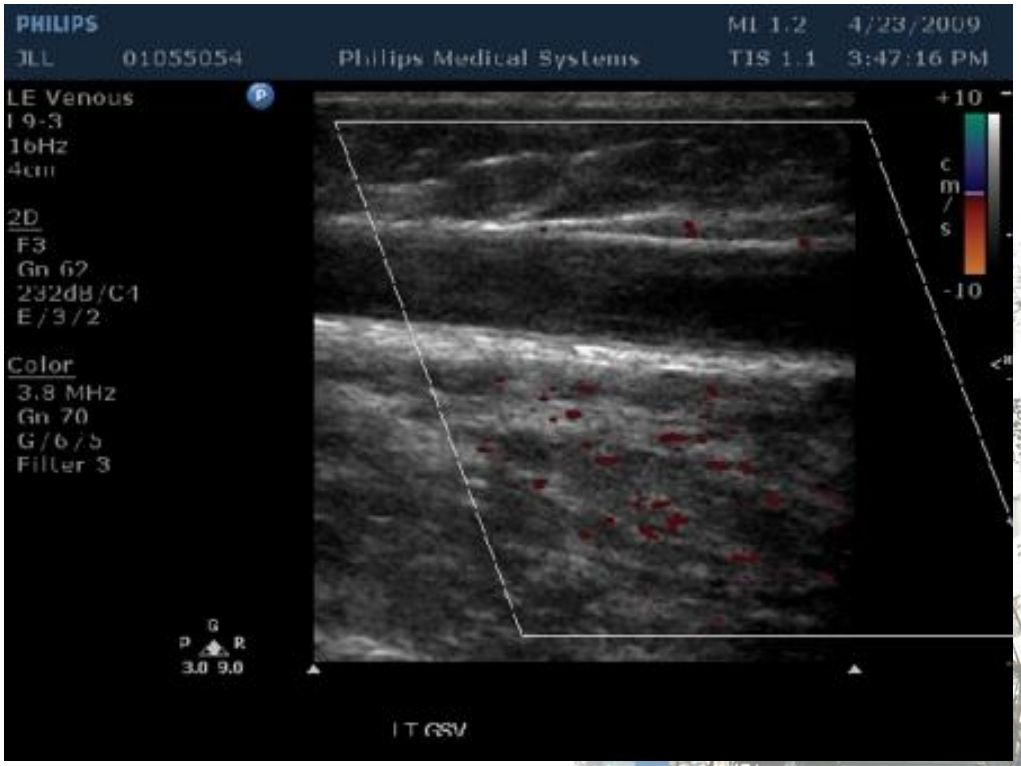
At 1 year of follow-up, MOCA demonstrated an 88% GSV occlusion and significant improvement of venous symptoms.

However, MOCA can be complicated by hematoma, phlebitis and, rarely, DVT.



Mechanochemical Ablation (MOCA)

An RCT comparing MOCA with thermal ablation found lower GSV saphenous occlusion rates with MOCA but equivalent symptom score improvements at 1 year.

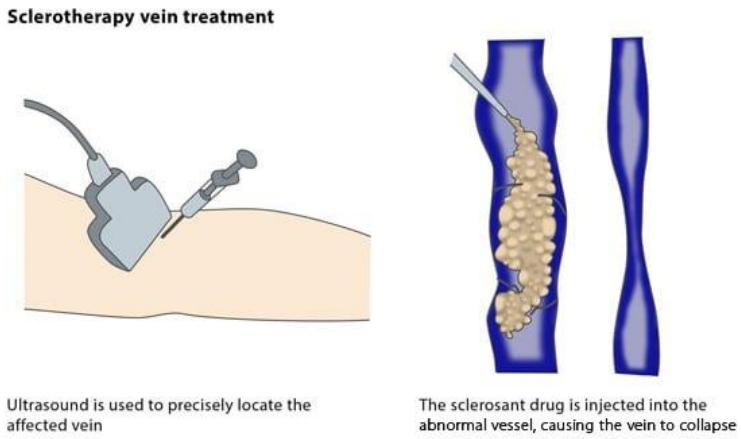


Foam Sclerotherapy

Sclerotherapy utilizes agents that once injected into a target vein, cause denaturation of surface proteins, luminal fibrosis, and obstruction.

Sclerosants have been used for telangiectasis as well as reticular and varicose veins.

Sclerotherapy improves the cosmetic appearance of varicose veins and, possibly, quality of life



Foam Sclerotherapy

The potential complications with their use include hyperpigmentation and telangiectatic matting.

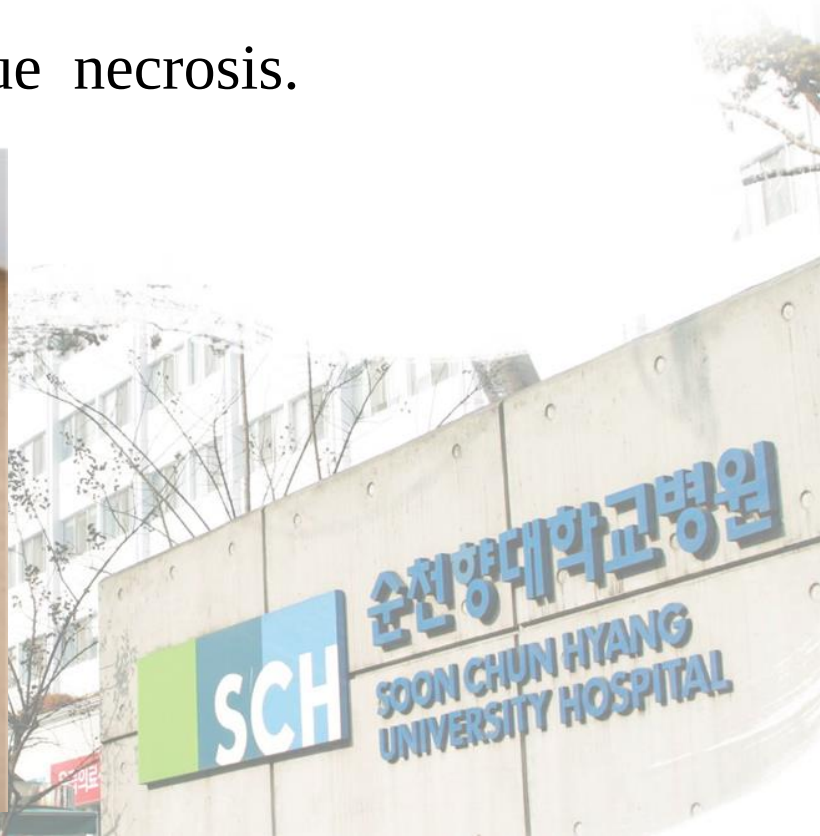
There is little evidence to suggest clinically significant right-to-left shunting of sclerosants

Foam Sclerotherapy

There are reports of transient visual disturbance after sclerotherapy, although it is rare.

DVT or ulceration is also rare.

Intra-arterial injection can lead to tissue necrosis.

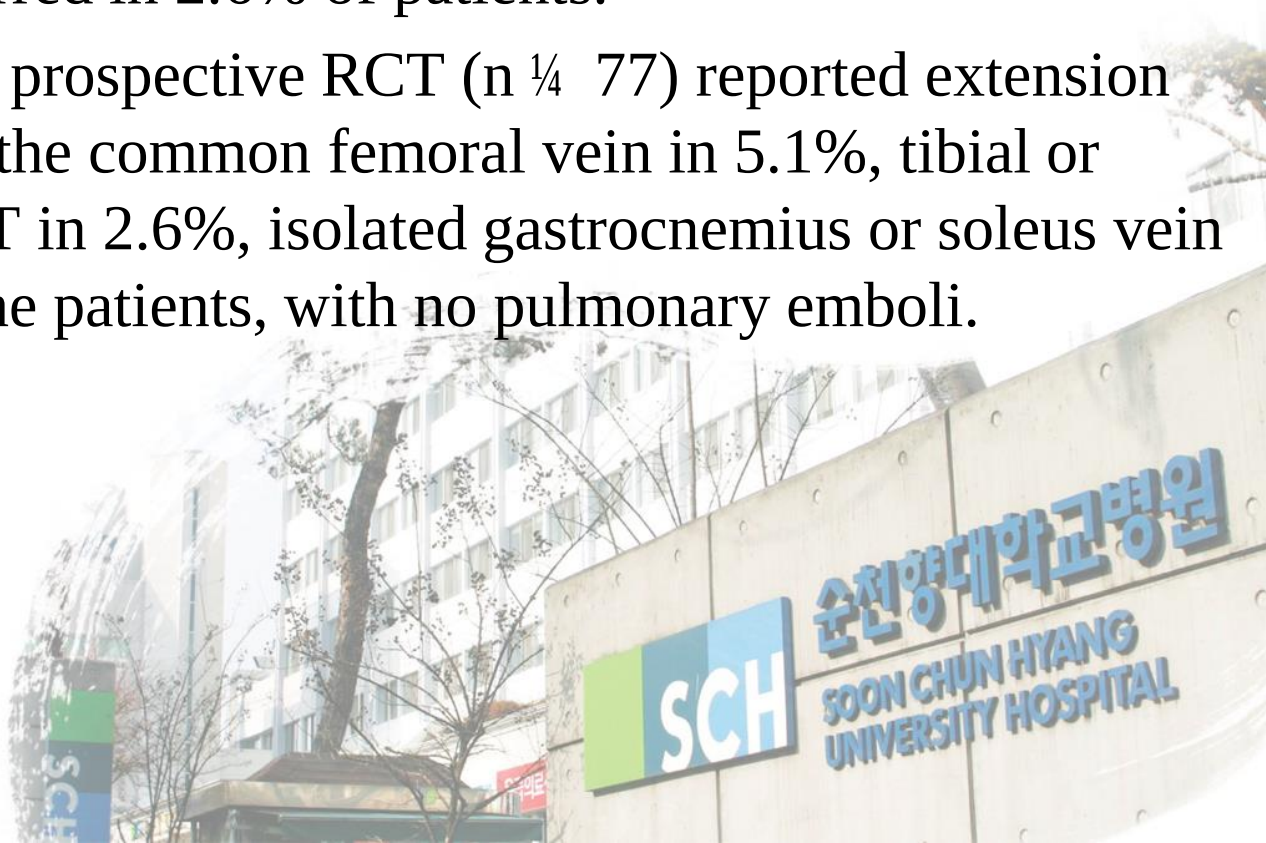


Foam Sclerotherapy

The efficacy of Sclerosant in reducing the symptoms of venous reflux was demonstrated in VANISH-2.

Proximal DVT occurred in 2.6% of patients.

A small multicenter, prospective RCT (n ¼ 77) reported extension of Sclerosant into the common femoral vein in 5.1%, tibial or peroneal vein DVT in 2.6%, isolated gastrocnemius or soleus vein DVT in 7.7% of the patients, with no pulmonary emboli.



Thermal Versus Non-Thermal Ablation

No statistically significant difference in occlusion rate at all time points.

Non-thermal ablation was tolerated better and had less risk of nerve injury.

Shahzad N, Elsherif M, Obaidat I, Brar R.
A Systematic Review and Meta-Analysis of Randomised Controlled Trials Comparing Thermal Versus Non-Thermal Endovenous Ablation in Superficial Venous Incompetence.
Eur J Vasc Endovasc Surg. 2023

Thermal Versus Non-Thermal Ablation

There was no statistically significant difference in risk of endothermal heat induced thrombosis (EHIT).

There was improvement in quality of life scores post-procedure but there was no statistically significant difference in thermal vs. non-thermal ablation.

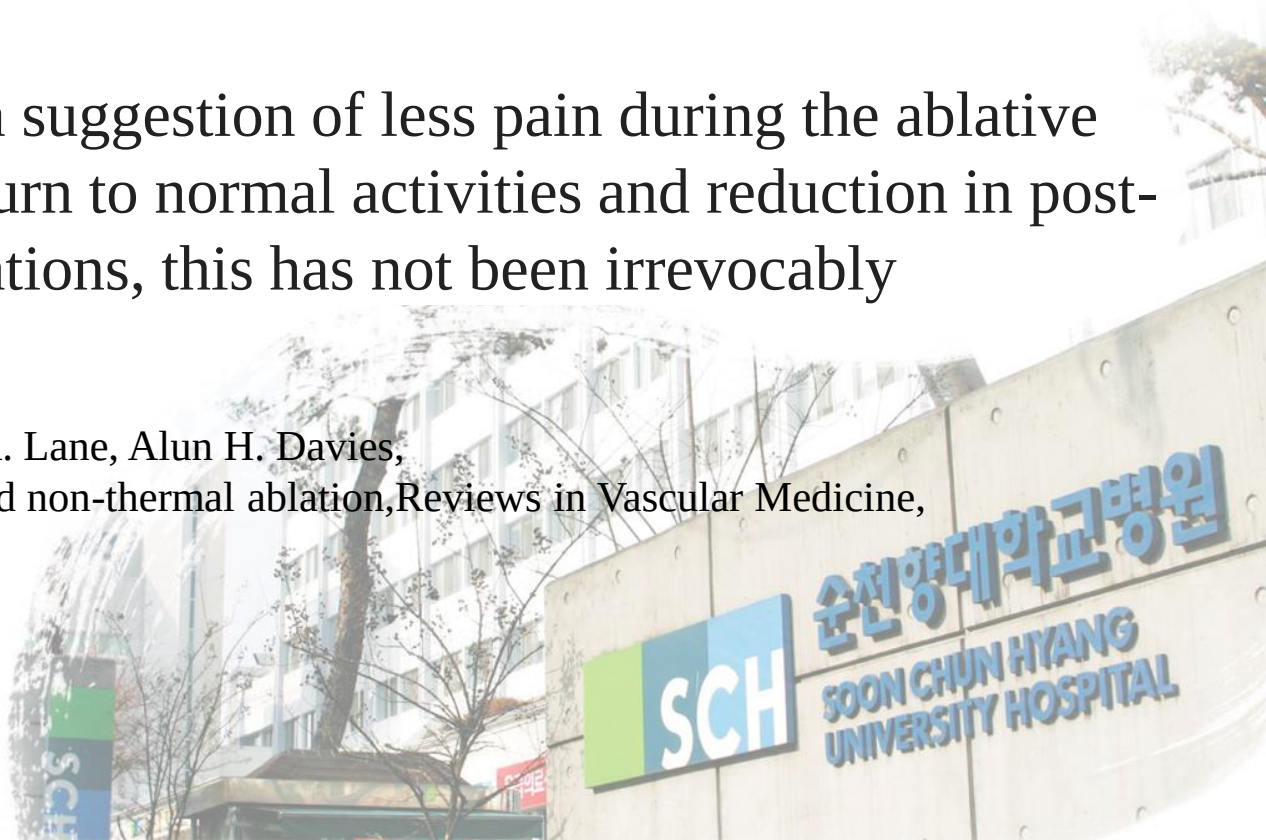
Shahzad N, Elsherif M, Obaidat I, Brar R.
A Systematic Review and Meta-Analysis of Randomised Controlled Trials Comparing Thermal Versus Non-Thermal Endovenous Ablation in Superficial Venous Incompetence.
Eur J Vasc Endovasc Surg. 2023

Thermal Versus Non-Thermal Ablation

Studies conducted up to now appear to show similar occlusion rates as well as clinical and quality of life improvement of NTNTs compared to the endothermal techniques.

Although there is a suggestion of less pain during the ablative process, earlier return to normal activities and reduction in post-operative complications, this has not been irrevocably demonstrated.

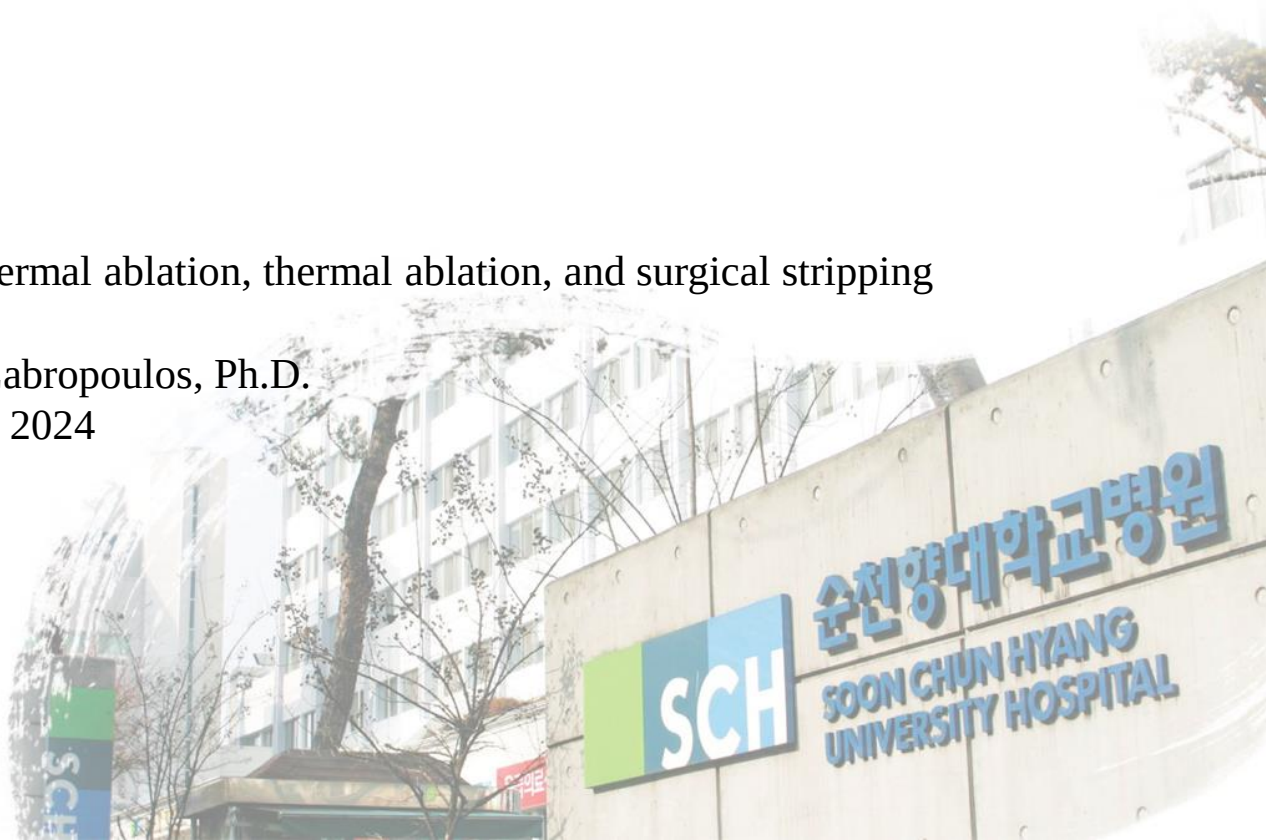
Roshan Bootun, Tristan R.A. Lane, Alun H. Davies,
A comparison of thermal and non-thermal ablation,Reviews in Vascular Medicine,
Volumes 4–5, 2016,



Thermal Versus Non-Thermal Ablation

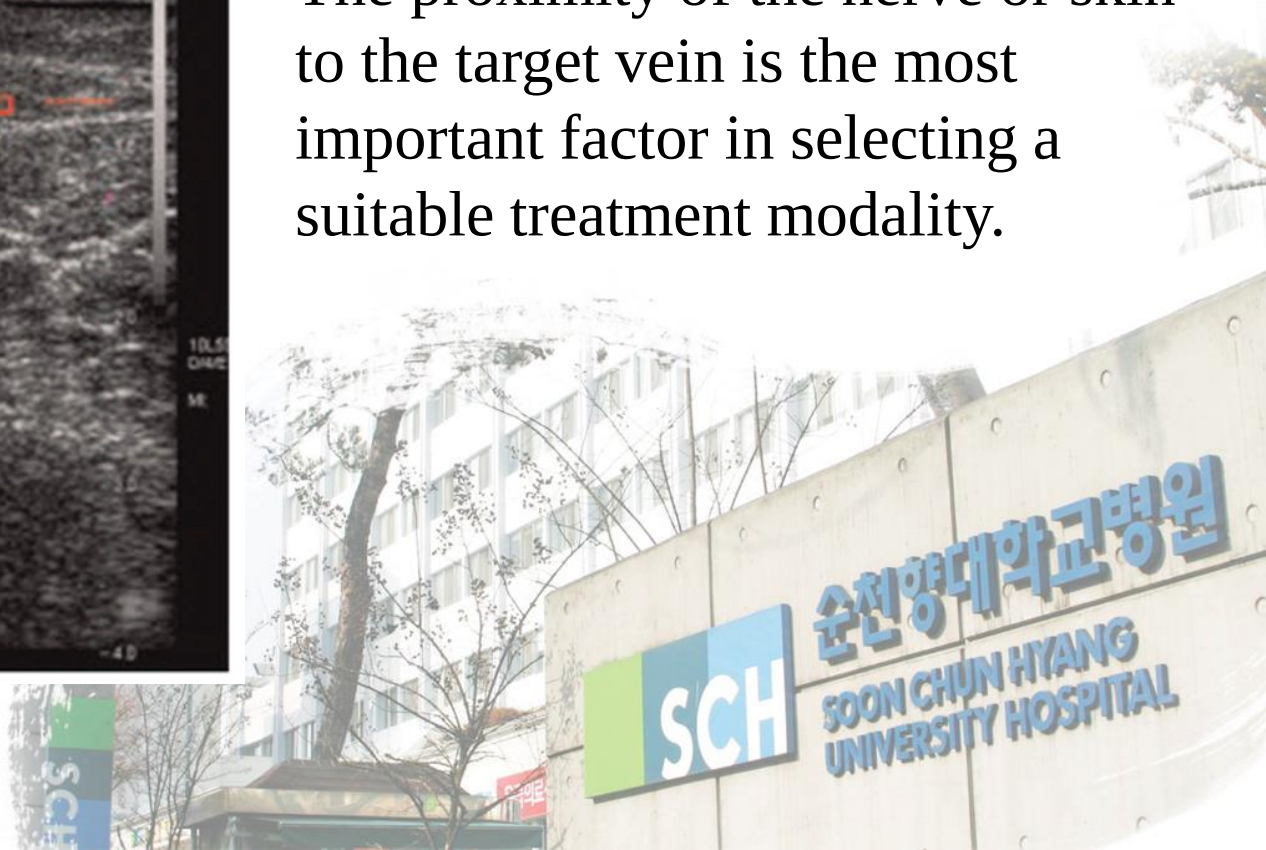
Clinical outcomes with improvement in quality of life were comparable among the different treatment modalities.

Clinical outcomes of non-thermal ablation, thermal ablation, and surgical stripping for varicose veins
Hyangkyoung Kim, Nicos Labropoulos, Ph.D.
Journal of Vascular Surgery, 2024



Thermal Versus Non-Thermal Ablation

The proximity of the nerve or skin to the target vein is the most important factor in selecting a suitable treatment modality.



Patients with symptomatic truncal vein reflux and varicosity

- ❖ Junctional aneurysm
- ❖ Superficially located truncal vein < 5mm depth

→ **SS**

- ❖ Risk for nerve injury
- ❖ Local anesthesia prefer
- ❖ Outpatient-based treatment
- ❖ Mild varicosity

→ **Non-thermal**

- ❖ Pathologic perforator below the venous ulcer
- ❖ Isolated small saphenous vein reflux

→ **CAC**

- ❖ High risk of allergic reaction for cyanoacrylate glue

→ **MOCA**

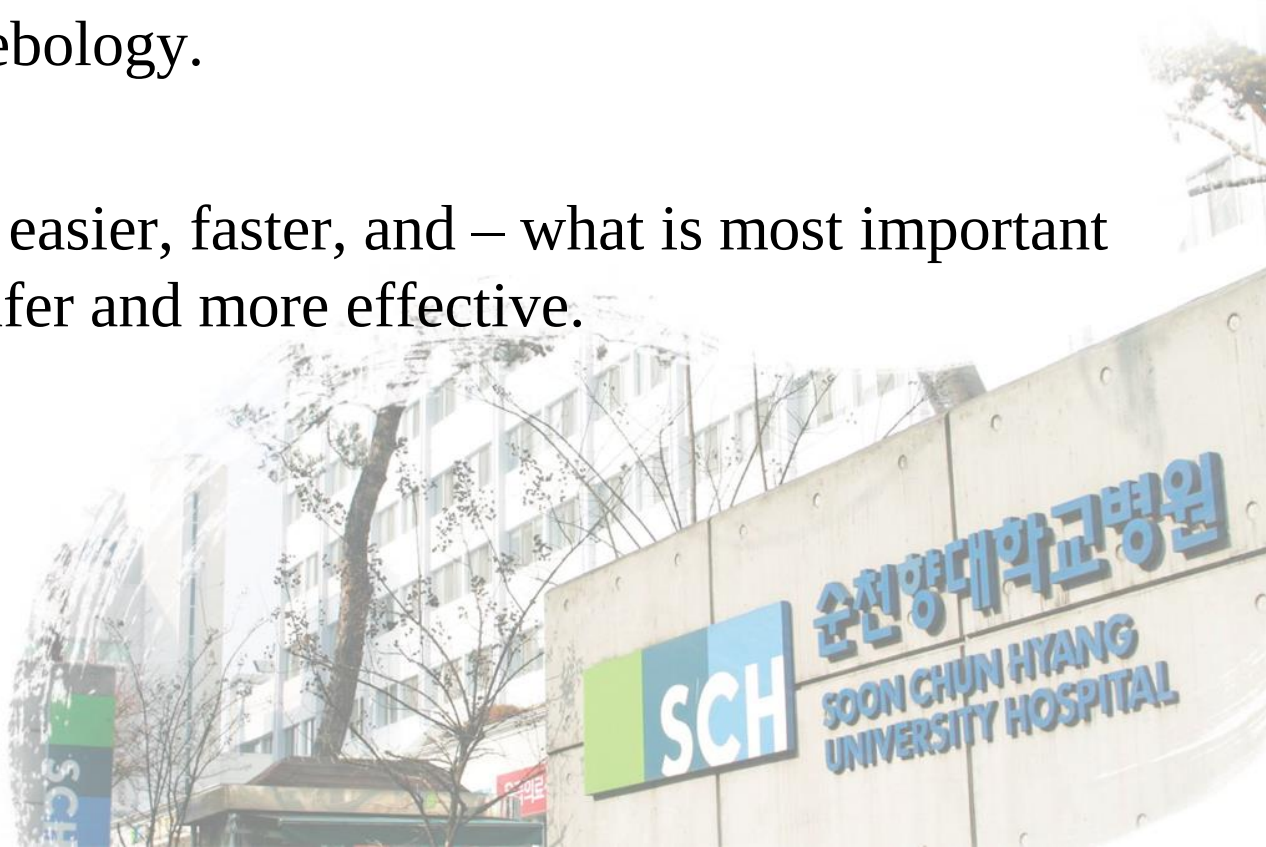
- ❖ General anesthesia prefer
- ❖ Inpatient-based treatment
- ❖ Moderate to severe varicosity

→ **RFA**

Conclusion

It is clearly visible that the development of endovenous techniques used in chronic venous disease has created a new perspective in phlebology.

The treatment can be easier, faster, and – what is most important for the patient – safer and more effective.



Conclusion

As an evident reduction of complications and improvement of quality of life of the patients after the procedures can be reached by all endovenous methods, it is crucial to adjust the proper mode of therapy to the specific patient and type of disease.

Each minimally invasive way is valuable unless used by a skilled and qualified specialist.

Conclusion

The differences of effectiveness among the modalities are very small and require further investigations and well-designed trials without any commercial bias.

It is crucial to wait for long follow-up assessment of the newest techniques to be able to compare them to the older ones.

Currently it is not clear that non-tumescent non-thermal modalities should be chosen as a first option in the treatment to eliminate saphenous reflux.