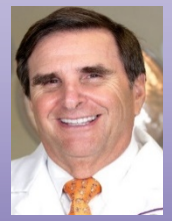
CONTROVERSES ET ACTUALITÉS EN CHIRURGIE VASCULAIRE

CONTROVERSIES & UPDATES IN VASCULAR SURGERY

FEBRUARY 7-9, 2019

MARRIOTT RIVE GAUCHE & CONFERENCE CENTER, PARIS, FRANCE

Thrombus Propagation after EHIT and EnIT: How to Avoid and Manage Them



Lowell S. Kabnick, MD

Disclosure

Speaker name: Lowell S. Kabnick, MD, FACS, FACPh, RPhS

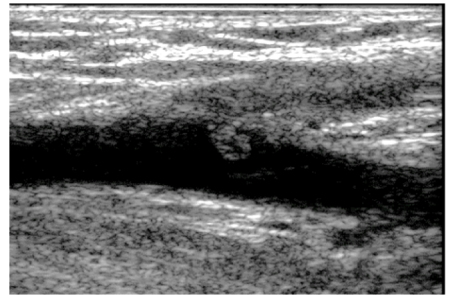
.....

I HAVE NO CONFLICTS WITH THIS TALK

WHAT IS PASTE?

- Percutaneous Ablation Superficial Thrombus Extension.

- PASTE=EHIT + n-EHIT



What is EHIT?

Not clinically Significant

- **Endothermal Heat-Induced Thrombosis:**

EHIT Class	Definition	Recommend d Treatment
1	T... ...tension up to level of SFJ or SPJ	...vation
2	**Thrombus extension into the deep venous system, with cross-sectional area <50%**	Left to discretion of interventionalist
3	**Thrombus extension into the deep venous system, with cross-sectional area >50%**	Therapeutic Anticoagulation with LMWH until ultrasonographic resolution
4	**Complete occlusion of deep vein**	Long term anticoagulation

Perioperative Duplex Ultrasound Following Endothermal Ablation of the Saphenous Vein:

2014

Is It Worthless?

The Journal of Invasive Cardiology

Why Look for EHIT?

What we thought then…

- **EHIT 2 post-op duplex:**

Doctor: you have a clot

Patient: oh my blood thinners

What we know now…

- **Incidence of EHIT:**
  - **All-comers:**
    - **EHIT 1 - 4: 3-4%**
    - **EHIT 2 : 1-2%**
- **Incidence of PE by EHIT:**
  - **At *most* 0.03%**

Sufian S, Arnez A, et al. Incidence, progression, and risk factors for endovenous heat induced thrombosis after radiofrequency ablation. JVS 2013 April; 1(2); 159-64

Dexter D, Kabnick L,, et al. Complications of endovenous lasers. Phlebology 2012; 27 Suppl 1:40-45

Are EHITs even Dangerous?

- **Our own short series:**
  - 9 patients with EHIT 2
  - All monitored with serial duplex
  - 8/9 placed on therapeutic LMWH
  - 9/9 had resolution of EHIT within 14 days

- After resolution of EHIT:
  - Chest CT showed PE in 2/9
  - All patients were asymptomatic
  - None suffered significant sequelae

- What does it mean?

Let's Look at Thrombus Burden

- How much thrombus does it take to cause a clinically significant PE?
- Nobody knows…
- Is an EHIT 2 enough?
  - Probably not…

VENASEAL

VenaSeal Thrombus Extension What is it?

1. Pure thrombus
2. Thrombus/glue combinations
3. Pure glue extensions –user error

n-EHIT

Feasibility Study

- 38 Patients, enrollment completed Aug. 2011
- 1 day, 1, 3, 6, 12, 24 and 36 month follow-ups
- Primary endpoint: Safety: rate of serious adverse events, Efficacy: vein closure during follow-up

8

eSCOPE *(European multicenter study)*

- 70 patients, enrollment completed Sept. 2012
- 2 day, 1, 3, 6, 12, 24 and 36 month follow-ups
- Primary endpoint: closure w/o use of sedation, tumescent anesthesia or compression stockings

1

VeClose *(U.S. pivotal trial)*

- 242 patients, enrollment completed Sept. 2013
- 3 day, 1, 3, 6, 12 , 24 and 36 month follow-ups
- Primary endpoint: non-inferior to RFA in GSV closure
- Secondary endpoint: superiority in reduction of post procedural pain and bruising

0

From the American Venous Forum

Journal of Vascular Surgery
Venous and Lymphatic Disorders™

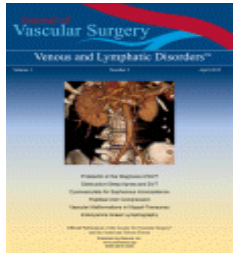
First human use of cyanoacrylate adhesive for treatment of saphenous vein incompetence

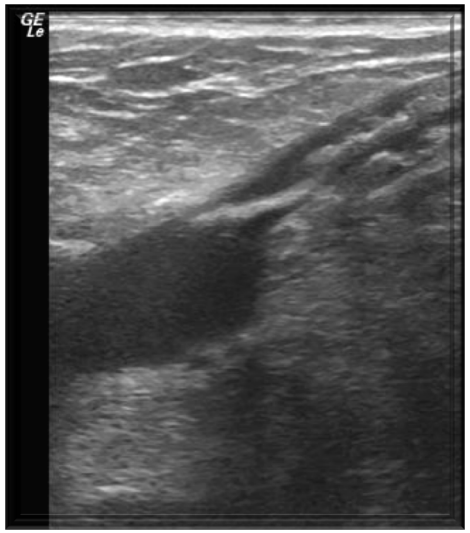
8/38 (21%) had thrombus/glue extension. None were treated
All disappeared at 6 months

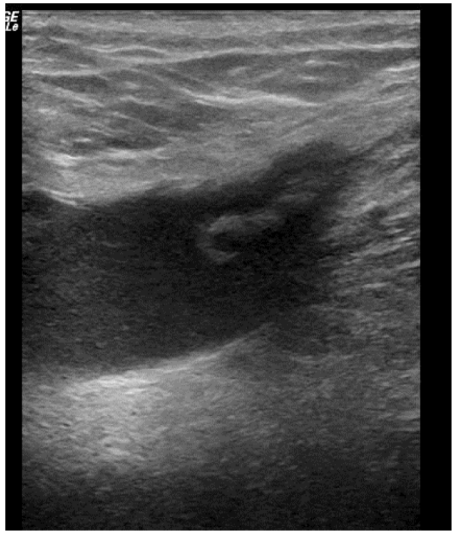
By protocol design, perivenous tumescent anesthesia and compression stockings were omitted. Duplex ultrasound imaging and clinical follow-up were performed immediately after the procedure, at 48 hours, and 1, 3, 6, and 12 months. *Results:* The mean total volume of endovenous CA delivered was 1.3 ± 0.4 mL (range, 0.6-2.3 mL). Immediately after the procedure and at the 48-hour follow-up, the 38 patients (100%) demonstrated complete closure of the GSV. One complete and two partial recanalizations were observed during

visible varicosities and an additional eight legs (25%) showed limited varicosities.
Conclusions: The first human use of endovenous CA for closure of insufficient GSVs proved to be feasible, safe, and effective. Endovenous delivery of CA may prove to be an alternative for the correction of saphenous incompetence and may be used without tumescent anesthesia and medical compression stockings. (J Vasc Surg: Venous and Lym Dis 2013;1:174-80.)

2013







Sapheon
Glue extension
FIH trial

eSCOPE Study- Results
Follow-up through 12-Months

2014

1/70 nEHIT 3

2 weeks of LMWH = RESOLVED

Proebstle, T et al., The European Multicenter Cohort Study on Cyanoacrylate Embolization of Refluxing Great Saphenous Veins. JVS: Venous and Lymphatic Disorders 2014; **Accepted for publication.**

TREATMENT EnHIT

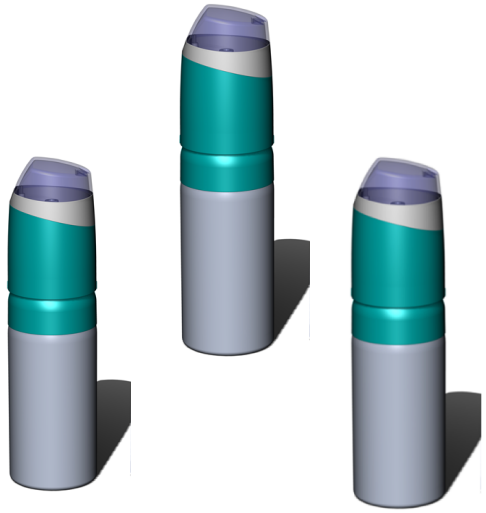
- Feasibility trial 21% 0 treated f/u six months resolved
- eScope 1 ENHIT 3 treated with LMWH for 2 weeks resolved
- **Do we know enough?**

Consider the Following Treatment

Suggested EnHIT Treatment

1. ? EnHIT 2 = EHIT 2 nothing
2. ? EnHIT3 = EHIT 3 nothing/LMWH?DOACS until gone
3. ? EnHIT4 = Not reported, consider anticoagulation until gone

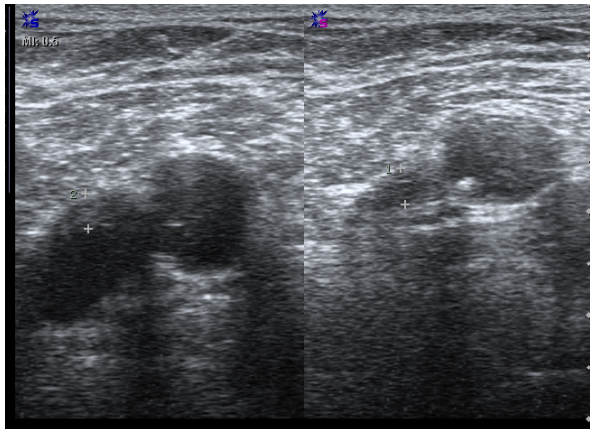
VARITHENA (PEM)

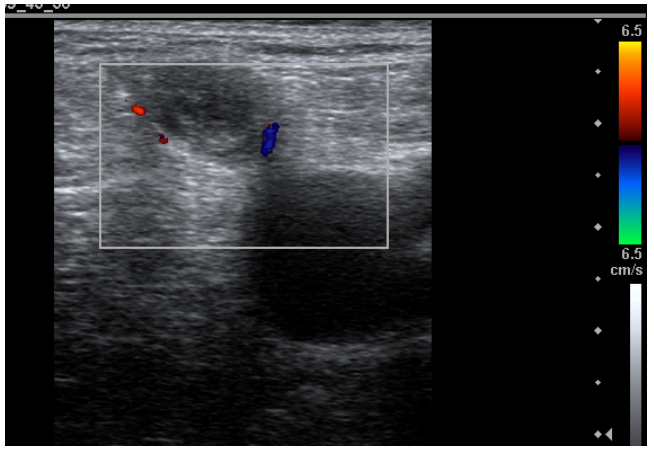


Natural History

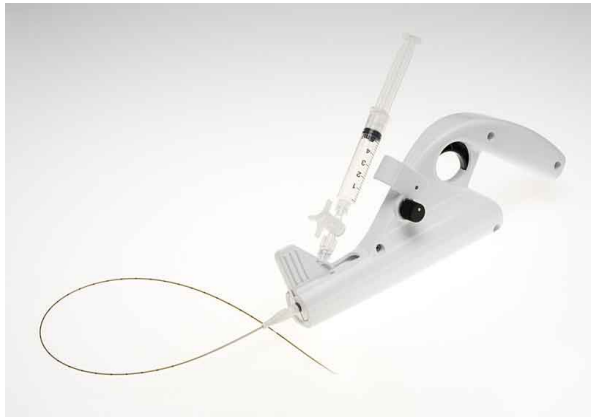
- Company no specific recommendations
- Trials 41% no anticoagulation. MDs prefer anticoagulation more central than the CFV
- Resolution within 3-4 weeks; no difference between anticoagulation or not
- Most patients receiving anticoagulation received 2weeks

nEHIT Varithena





Clarivein

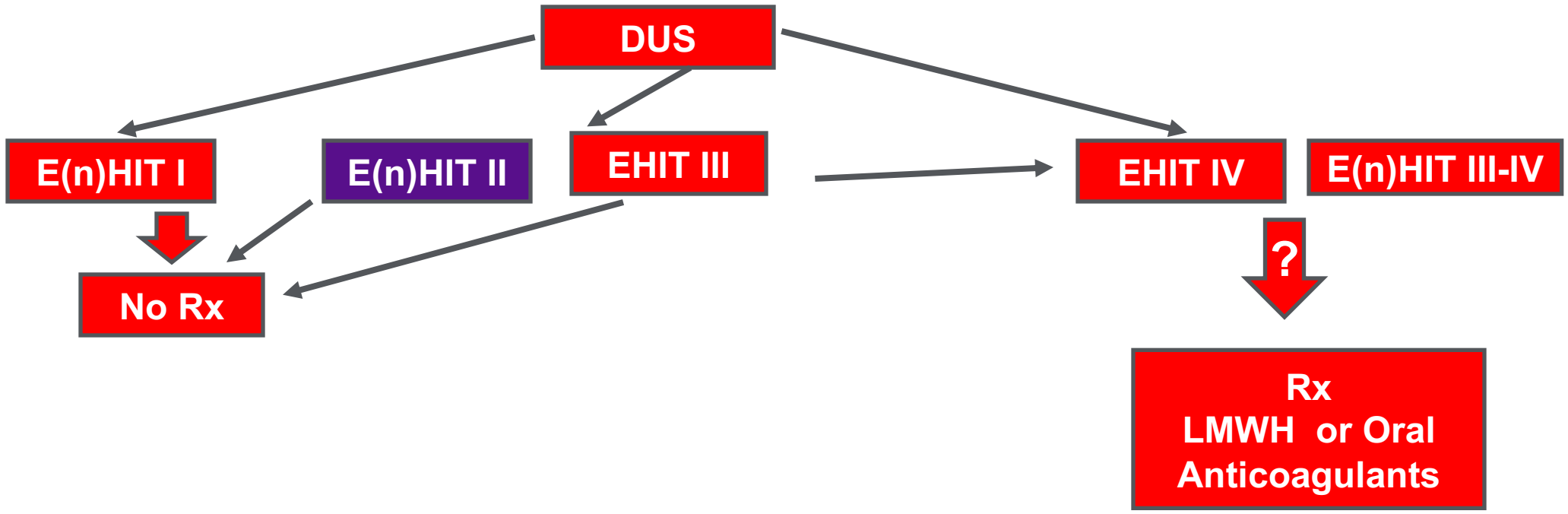


Recent, Global Peer-Reviewed Studies

STUDY	SAMPLE SIZE	DURATION	OCCLUSION	PATIENT PAIN SCORES (VAS 100MM OR 10 POINT)	RETURN TO NORMAL ACTIVITIES / WORK	MAJOR ADVERSE EVENTS
ELIAS ET AL, 2013[11]	29 patients 30 veins	2 years	Immediate- 100% 6 months- 96.7% 2 years – 96%	No complaints of pain	N/A	None
OZEN ET AL, 2014[15]	63 patients 73 veins	2 years	Immediate- 98% 6 months- 94% 1 and 2 years- 95%	N/A	N/A	None
KIM ET AL, 2016[16]	126 patients	2 years	1 week – 100% 3 months 98% 1 and 2 years – 95%	N/A	N/A	None
WITTE ET AL, 2016[18]	85 patients 104 limbs	3 years	1 year- 91.8% 2 years- 89.5% 3 years- 86.5%	NA	1 day/ 1 day	None
STANISIC ET AL[21]	50 patients 60 limbs GSV & SSV	1 year	Immediate- 100% 1 year- 93.3%	NA	NA	None
BOERSMA ET AL, 2012[12]	50 patients	1 year	Immediate- 100% 6 Week- 100% 1 year- 94%	2	N/A	None
BOOTUN ET AL, 2014[6] **RCT V RFA**	117 patients 119 veins (59 ClariVein® veins)	1 month	92%	19.3 mm (v. 34.5mm)	3.5 days (v. 4.8 days) *Study performed in UK	None
LANE ET AL, 2016[19] **RCT V RFA**	170 patients (87 ClariVein®)	6 months	1 month- 93% 6 months- 87%	15mm (v.34 mm)	1 days/1 days *Study performed in UK	1 DVT
VAN EEKEREN ET AL, 2014[9]	92 patients 106 veins	6 months	Immediate- 100% 6 months- 93.2% 1 year- 88.2%	20 mm 14 days- 7.5mm	1 day / 1 day	None
TANG ET AL, 2016[20]	300 patients 393 veins GSV & SSV	8 weeks	Immediate- 100% 8 weeks- GSV- 97% SSV- 100%	.8 90% had no pain	NA	None
BISHAWI ET AL, 2013[10]	126 patients	6 months	Immediate- 100% 6 months- 94%	2 1 week- >1	N/A	None
VUN ET AL, 2014[7]	127 patients 147 veins (57 ClariVein® veins)	Immediate	91%	1	N/A	None
DEIJEN ET AL, 2015[17]	449 patients 506 veins	3 Months	90%	N/A	N/A	1 DVT
	>1700 Patients	**ST and LT Studies**	**Gold Standard Occlusion**	**Virtually Painless**	**Rapid Recovery**	**Safe**

Note: see appendix for complete listing of studies

Paradigm for Treatment For EHIT and EnHIT



LSK@lowellkabnickmd.com