

## Factors That Influence Venous Leg Ulcer Healing And Recurrence Rate After Endovenous Ablation Of Truncal Veins

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## Disclosure

- No disclosure

## Background

- Compression therapy mainstay of venous leg ulcer treatment
- The ESCHAR trial : Surgical treatment of superficial venous reflux addition to compression therapy reduces recurrence rate of VLU
- Most patients with leg ulcers (CEAP C5 and C6) and saphenous vein reflux are currently treated with thermal ablation, but little information is available on the long-term results after RFA



The ESCHAR Trial – Lancet 2004

## Objective

- **Primary objective**
  - Rate of VLU healing at 1 year after radiofrequency ablation (RFA) of incompetent GSV or AASV
- **Secondary objective**
  - Rate of VLU recurrence at 3 years after RFA of incompetent GSV or AASV
  - Influencing factors for VLU healing and VLU recurrence

## Materials and Methods

**Retrospective study** : 1 January 2011 to 31 December 2017

### Inclusion criteria

- Age > 18 years
- CEAP: C5 & C6 limb
- GSV or AASV reflux treated with endovenous RFA

### Exclusion criteria

- Follow up < 24 weeks
- Significant ilio caval venous obstruction

## Methods

- **Venous duplex ultrasound (DUS)**
  - Reflux examination : Standing position
  - Superficial venous reflux : retrograde flow >0.5 second
  - Deep vein reflux : retrograde flow >1.0 second
  - Pathologic perforating vein : size > 3.5 mm, reflux > 0.5 sec and located beneath ulcer



J Vasc Surg 2011;53(5 Suppl):2S-48S

### Methods


**Radiofrequency ablation (RFA ) procedure**

- 7Fr- ClosureFast RFA catheter
- Tumescant anesthesia

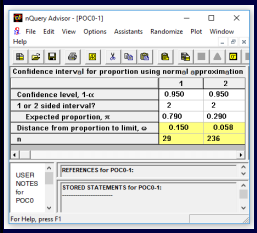
**Ultrasound guide foam sclerosing injection (UGFS)**

- 1% or 3% polidocanol mix with air (1:4) by Tessari method

- Above knee GSV or AASV reflux : RFA
- Below knee GSV reflux : UGFS
- Pathologic perforator vein: UGFS
- Tributary varicosity : Phlebectomy



### Sample size calculation



- Study population
- C5,C6 under went RFA GSV or AASV.
- VLU healing rate at 1 year  
-> n= 29 legs

(Healing rate of C6=79% at 1 year)

J Vasc Surg 5, no. 4 (2017): 525-32.

### Statistical analysis

- To assess time to ulcer healing and time to recurrence
  - Kaplan-Meier method
- To compare time to ulcer healing and time to recurrence between two groups
  - Log rank test
- To identify factor associated with ulcer healing and recurrence
  - Cox regression
  - To evaluate the magnitude of association :hazard ratio with 95% confidence intervals
- Statistical significance : P < .05

### Result : Patient and limb characteristic

- 55 patients
  - Age 65.4±9.8 years
  - BMI 26.5 ± 5.6 kg/m<sup>2</sup>
  - Female 80%
- 62 legs
  - Left legs 57%
  - CEAP C5 = 30 legs (48%)
  - CEAP C6 = 32 legs (52%)

### Duplex ultrasound characteristics of C5 and C6 limbs

Duplex ultrasound	C5 (n=30)	C6 (n=32)	Total(n=62)
GSV reflux	27(90%)	29(91%)	56(90%)
AASV reflux	2(7%)	3(9%)	5(8%)
GSV+AASV reflux	1 (3%)	0(0%)	1(2%)
Deep vein reflux	4(13%)	6(19%)	10(16%)
Perforator vein reflux	10(33%)	7(22%)	17(27%)

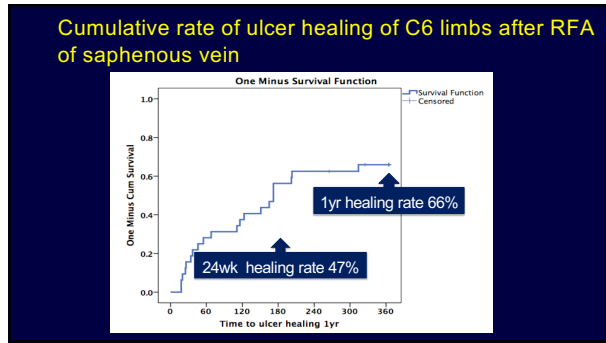
### Operative procedure of C5 and C6 limbs

RFA Saphenous vein ablated	C5 (n=30)	C6 (n=32)	Total
GSV only	27(90%)	29(91%)	56(90%)
AASV only	2(7%)	3(9%)	5(8%)
GSV and AASV	1(3%)	0(0%)	1(2%)
Concomitant phlebectomy of tributary varicosity	8(27%)	11(34%)	19(31%)
Concomitant perforator ablation	6(20%)	6(19%)	12(19%)

### Postoperative results

Post operative duplex result	62 limbs
Successful complete vein closure*	62 limbs (100 %)
Reopening of the treated vein was identified in DUS during follow-up	0 case(0%)
EHIT class 1,2,3	6 limbs (10%)
EHIT class 4	1limb (2%)

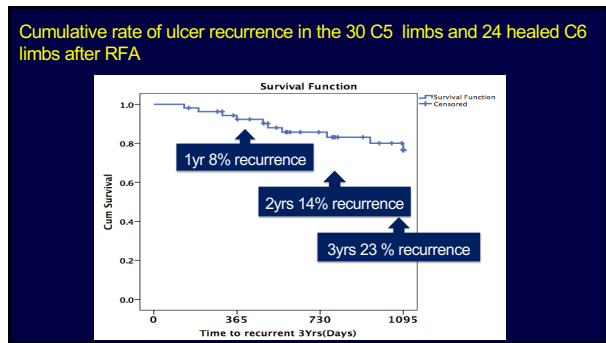
EHIT = endovenous heat induce thrombosis DUS = duplex ultrasound  
\* Successful closure was defined as closure of the entire planned segment of GSV or AASV with no flow to within 5 cm of the SFJ  
J Vasc Surg 2013;1(3):257-62.



### Healing rate of VLU among 4 studies

	Healing rate of VLU	
	24 wk	1yr
ESCHAR 2004 (Surgery group)	65%	
Marston et al, 2017(EVTA )	74%	79%
EVRA 2018 (Early saphenous ablation group)	86%	
<b>Our study</b>	<b>47%</b>	<b>66%</b>

The ESCHAR Trial , Lancet 2004  
The EVRA trial , NEJM 2018  
J Vasc Surg 5, no. 4 (2017): 525-32



### Recurrent rate of VLU among 4 studies

Study	Recurrent rate of VLU		
	1yr	2yrs	3yrs
ESCHAR 2004 (Surgery group)	12%		
Marston et al, 2017(EVTA )	9%	20%	29%
EVRA 2018 (Early saphenous ablation group)	11%		
<b>Our study (RFA group)</b>	<b>8%</b>	<b>14%</b>	<b>23%</b>

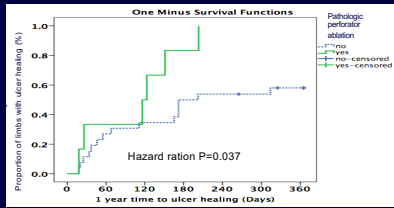
The ESCHAR Trial , Lancet 2004  
The EVRA trial , NEJM 2018  
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### Clinical and operative factors associated with 1-year ulcer healing

Factors	P	HR (95%CI)
Deep vein reflux	0.863	0.91 (0.31-2.71)
Diabetes mellitus	0.056	4.42 (0.96-20.29)
<b>Pathologic perforator ablation</b>	<b>0.037</b>	<b>2.84 (1.07-7.55)</b>
Concomitant phlebectomy	0.310	1.58 (0.65-3.83)

HR = hazard ratio  
UGFS = ultrasound guide foam sclerosing perforator vein

Cumulative rate of ulcer healing of C6 after RFA in patients with or without pathologic perforator vein ablation



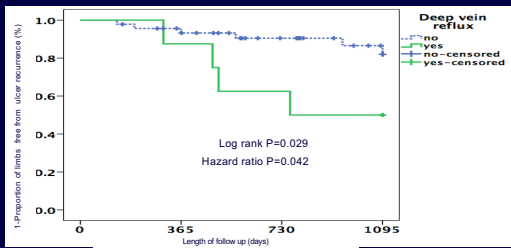
No perforator ablation	26	19	17	13	12	11	9
Pathologic perforator ablation	6	4	3	1	0	0	0

Clinical and operative factors associated with 3-year ulcer recurrence

Factors	P	HR (95%CI)
Deep vein reflux	0.042	3.72(1.05-13.21)
Diabetes mellitus	0.450	0.04(0-167.39)
Concomitant pathologic perforator vein ablation	0.340	0.04(0-33.43)
Concomitant phlebectomy	0.238	0.29(0.04-2.28)

HR = hazard ratio

Cumulative rate free from ulcer recurrence of C5 and healed C6 after RFA with or without deep vein reflux



No Deep vein reflux	46	39	28	18
Deep vein reflux	8	7	5	3

Limitations

- Retrospective study
- Low sample size in recurrent ulcer group

Conclusions

- Concomitant ablation of pathologic perforating vein with UGFS was the associated factor for ulcer healing after RFA of saphenous vein
- Deep vein reflux is the risk factor for ulcer recurrence after RFA of saphenous vein

**Factor that influence venous leg ulcer healing and recurrence rate after endovenous radiofrequency ablation of incompetent saphenous vein**

**Abstract**

**Background:** Venous leg ulcers (VLUs) are a common complication of chronic venous insufficiency (CVI). The aim of this study was to evaluate the impact of concomitant ablation of pathologic perforating veins (PPVs) on the healing and recurrence rate of VLUs after radiofrequency ablation (RFA) of the saphenous vein (SV).

**Methods:** This retrospective study included 100 patients who underwent RFA of the SV and concomitant ablation of PPVs. The primary endpoint was the time to ulcer healing, and the secondary endpoint was the 3-year ulcer recurrence rate. The impact of various clinical and operative factors on these outcomes was analyzed.

**Results:** The mean time to ulcer healing was significantly shorter in the group with concomitant PPV ablation compared to the group without (P < 0.05). Additionally, the 3-year ulcer recurrence rate was significantly lower in the group with concomitant PPV ablation (P < 0.05).

**Conclusions:** Concomitant ablation of pathologic perforating veins with UGFS was associated with faster ulcer healing and lower recurrence rates after RFA of the saphenous vein.

Thank you



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