

## Outcome Of Early CAC And Compression Therapy In Healing Of VLU

**Nuttawut Sermathanasawadi, MD, PhD**, Wasin Panchawirat, MD

Division of Vascular Surgery, Department of Surgery  
Faculty of Medicine Siriraj Hospital, Mahidol University,  
Bangkok, Thailand





## Disclosure

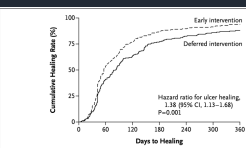
No Disclosure

## Background

ORIGINAL ARTICLE

### A Randomized Trial of Early Endovenous Ablation in Venous Ulceration

**Efficacy of early endovenous therapy Combined with compression therapy Reduces time to ulcer healing**



**Figure 2. Kaplan-Meier Curves for Time to Ulcer Healing in the Two Treatment Groups.**

No. at Risk	0	60	120	180	240	300	360
Early intervention	223	104	51	25	19	14	14
Deferred intervention	225	131	81	50	34	28	23

N Engl J Med. 2018;378:2105-2114.

## Background

ORIGINAL ARTICLE

### A Randomized Trial of Early Endovenous Ablation in Venous Ulceration

No data for cyanoacrylate closure

Type of endovenous intervention	No. (%) used
Endothermal ablation only	125 (27.8)
Foam sclerotherapy only	211 (46.9)
Mechanochemical ablation only	6 (1.3)
Endothermal ablation and foam sclerotherapy	43 (9.7)
Mechanochemical ablation and foam sclerotherapy	3 (0.7)

N Engl J Med. 2018;378:2105-2114.

## Objectives

**Primary objective**

- To evaluate **ulcer healing rates at 24 weeks** in VLU patients with SVR treated with early cyanoacrylate closure (eCAC) combined with compression therapy, and compared with compression therapy alone

**Secondary objectives**

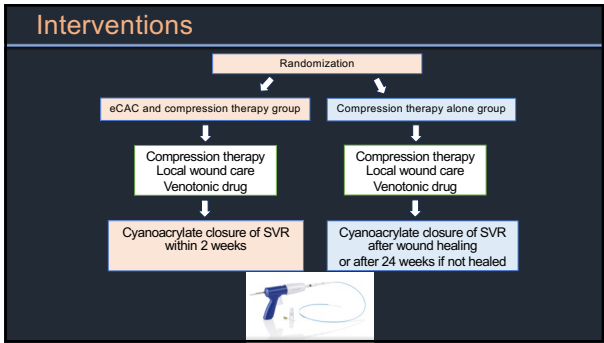
- To evaluate **time to healing** in VLU patients with SVR treated with eCAC combined with compression therapy, and compared with compression therapy alone

## Materials and Methods

- Prospective randomized-controlled trial
  - Block randomization with random permuted block of 4
  - Generated in advance and sealed, 1:1 allocation ratio
- September 2017 – December 2023
- SiRB COA no. Si 544/2017
- ClinicalTrials.gov registration number : NCT03666754



### Materials and Methods

Inclusion criteria	Exclusion criteria
Age > 18 years old	DUS or CTV demonstrated deep venous obstruction
Venous leg ulcer	Contraindication to compression therapy
Ulcer size < 25 cm <sup>2</sup>	Pregnancy
DUS examination demonstrated SVR of GSV or AASV	On anticoagulant or antiplatelet drugs
Good compliance to follow up visit	Allergy/Contraindication / Anatomy not suitable for CAC
	ABI < 0.8



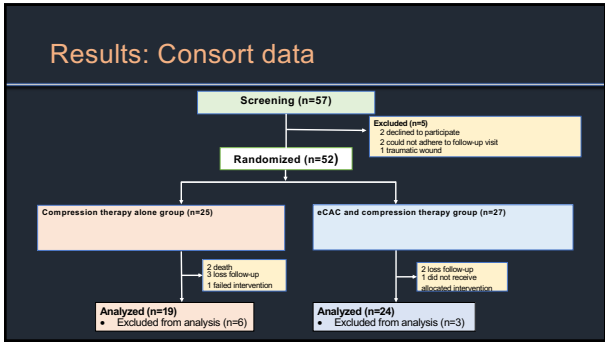
### Materials and Methods

- Wound size was evaluated every 4 weeks, until 24 weeks
- Assessment of wound size was performed by research assistance, who did not know the group of the patients
- Using *eKare inSight™ 3D digital wound machine*

### Materials and Methods

- Statistical analysis** : intention-to-treat analysis
- Chi-square test
- Log-rank test (two-tailed, 5% significance level) combines with Kaplan-Meier survival curves
- Fisher exact test and t-test as appropriate



### Results: baseline characteristics

Parameter	eCAC and compression (n = 24)	Compression alone (n = 19)	P-value
Age (yr) – mean±SD	61 ± 16	60 ± 15	0.854
Female – no. (%)	14 (58.3)	9 (47.4)	0.547
BMI (kg/cm <sup>2</sup> ) – mean±SD	30.5 ± 6.3	29.9 ± 8.2	0.811
Initial ulcer size (cm <sup>2</sup> ) – mean±SD	3.8 ± 4.6	2.7 ± 2.8	0.154
Ulcer duration (weeks) – mean±SD	28.6 ± 8.9	22.1 ± 6.3	0.607
Ulcer side (Right) – no. (%)	16 (68.4)	11 (58.3)	0.462

### Results: baseline characteristics

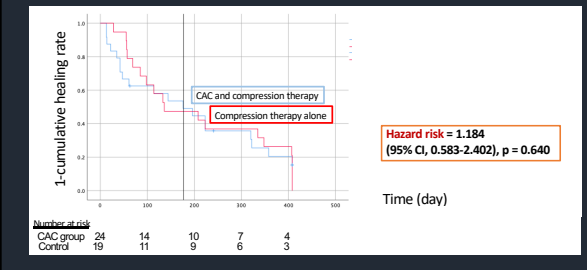
	eCAC and compression (n = 24)	Compression alone (n = 19)	P-value
Presence of deep venous reflux - no.(%)	2 (8.4)	0 (0)	0.436
Presence of perforator reflux - no.(%)	9 (37.6)	8 (42.1)	0.680
Presence of ICVO - no.(%)	1 (4.2)	1 (5.3)	0.826
GSV reflux - no.(%)	21 (87.5)	19 (100)	0.243
AASV reflux - no.(%)	2 (8.3)	0 (0)	0.495
SSV reflux - no.(%)	6 (25.0)	2 (10.5)	0.270
Presence of two superficial vein reflux - no.(%)	5 (20.8)	2 (10.5)	0.437
Customized pressured guided bandage	9 (37.5%)	6 (31.6%)	0.561

### Results: Healing rate at 24 weeks

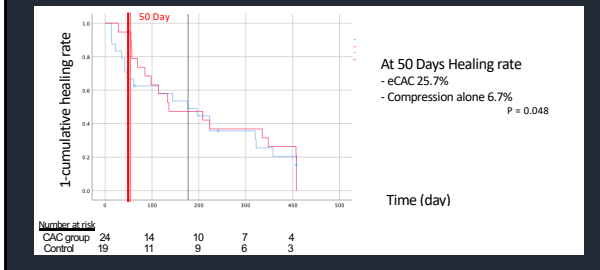
	eCAC and compression (n = 24)	Compression alone (n = 19)	P-value
Healing rate at 24 weeks - no. (%)	12 (50.0%)	10 (52.6)	0.864

The rate of ulcer healing at 24 weeks were comparable

### Result: Time to ulcer healing



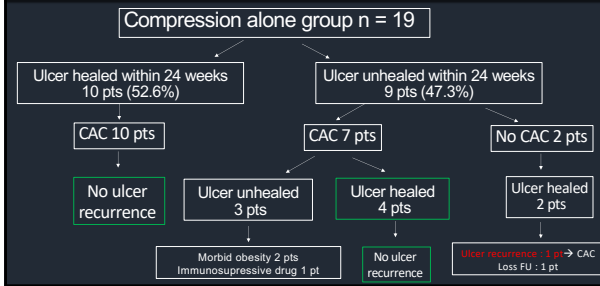
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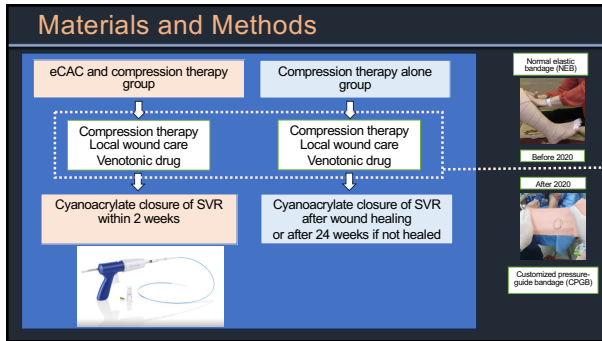


### Result: eCAC group n = 24

- After CAC
- Ulcer Healing
    - Ulcer healed within 24 wks : 12 pts (50%)
    - Ulcer healed within 1 yr : 18 pts (75%)
    - Ulcer healed within study period : 20 pts (83%)
    - Unhealed ulcer: 4 pts (16.7%)
      - Poor compliance of compression : 3 pts
      - CIV stenosis: 1 pt
  - Ulcer recurrence 3 pts (12.5%)
    - Perforator reflux+ BTK GSV reflux → Tx with UGFS

### Result: Compression alone group n = 19





### Customized pressure-guide elastic bandage (CPGB)

Adequate sub-bandage pressure was achieved with

- Normal bandage without marker 33%
- Customized bandage with marker (CPGB) 60%

Sermathanasawadi et al. Int Wound J 2017; 14:636-640  
Sermathanasawadi et al. Phlebology 2016, Vol. 33(9) 627-635

### Customized pressure-guide elastic bandage (CPGB)

- From 2020, VLU patients at Siriraj Hospital have been treated with CPGB

### From 43 patients

- Non healing ulcer until end of trial n= 7
  - Standard group n=3
    - Morbid obesity 2
    - Immunosuppressive agent (MTX) 1
  - eCAC group n=4
    - Poor compliance for bandaging 3
    - CIV stenosis 1
- Delayed Wound healing (> 1 year) n =5
  - Standard group n= 3
    - Large wound 20cm<sup>2</sup> 1
    - Infection 1
  - eCAC group n=2
    - Large wound 20 cm<sup>2</sup> 1
    - Infection 1

Subgroup analysis in 31 patients with complete wound healing at 1 year

### Subgroup analysis in 31 patients with complete wound healing at 1 year : Time to ulcer healing

Time to ulcer healing Patients with complete wound healing at 1 years (n=31)																											
Time to ulcer healing - mean ± SD	NEB (n = 16)	CPGB (n = 15)	P-value																								
	175.6 ± 101.6	95.8 ± 109.6	0.044																								
<table border="1"> <thead> <tr> <th colspan="4">Early cyanoacrylate closure and compression therapy group (n=18)</th> </tr> <tr> <th>Time to ulcer healing - mean ± SD</th> <th>NEB (n = 9)</th> <th>CPGB (n = 9)</th> <th>P-value</th> </tr> </thead> <tbody> <tr> <td></td> <td>175.6 ± 111.7</td> <td>73.2 ± 84.8</td> <td>0.038</td> </tr> </tbody> </table> <table border="1"> <thead> <tr> <th colspan="4">Compression therapy alone group (n=13)</th> </tr> <tr> <th>Time to ulcer healing - mean ± SD</th> <th>NEB (n = 7)</th> <th>CPGB (n = 6)</th> <th>P-value</th> </tr> </thead> <tbody> <tr> <td></td> <td>167.0 ± 94.9</td> <td>129.6 ± 140.3</td> <td>0.253</td> </tr> </tbody> </table>				Early cyanoacrylate closure and compression therapy group (n=18)				Time to ulcer healing - mean ± SD	NEB (n = 9)	CPGB (n = 9)	P-value		175.6 ± 111.7	73.2 ± 84.8	0.038	Compression therapy alone group (n=13)				Time to ulcer healing - mean ± SD	NEB (n = 7)	CPGB (n = 6)	P-value		167.0 ± 94.9	129.6 ± 140.3	0.253
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### Conclusions

- The rate of ulcer healing at 24 weeks was comparable between the compression therapy alone and the eCAC with compression therapy group.
- eCAC had rate of ulcer healing at 50 days higher than compression alone group
- Combined effective compression therapy with customized pressure guided bandage and early cyanoacrylate closure of SVR might be the factors improving healing of VLU.

