







# OUTCOMES OF CLARIVEIN TREATMENT FOR CHRONIC VEIN INSUFFICIENCY IN CHO RAY HOSPITAL

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- Chronic venous insufficiency is lower extremity venous dysfunction due to failure of the venous valves in the superficial or deep veins.
- The ratio of the disease is 80% (international) and 62% (in Vietnam)
- Increase the costs for health care system.
- Treatment of venous insufficiency by ultrasound-guided endovascular treatment is a minimally invasive method:
  - help the patient recovers quickly
  - decrease length of stay in hospital
  - and reduce complications









#### **Before**

Stripping

<u>Drawbacks:</u>wound pain, haematomas, infection

#### **Nowadays**

- Sclerotherapy
- RFA
- Laser

<u>Drawbacks:</u> lidocaine usage, tissue damage, nerve damage, skin burns









New method to prevent those drawbacks?

**ClariVein**(endovenous mechanochemical ablation: MOCA) new method consisting of

- a mechanical system combines with sclerosing drugs
- damaging the endothelium and injecting a sclerosant









#### **ClariVein**

- NO lidocaine
- NO heat during the intervention
- NO damage to surrounding tissue
- NO nerve damage
- NO skin burns and LESS pain after the intervention
- => Available at Cho Ray hospital since 2018









#### Study design

Retrospective descriptive case series

### Research period

From July to August 2018

#### **Research location**

Department of Vascular Surgery, Cho Ray Hospital









### Sample selection criteria

 Cases suffered from superficial venous failure in the lower extremities were treated with endovascular ClariVein at the Department of Vascular Surgery, Cho Ray Hospital

#### Exclusion criteria

- Vascular failure in the lower extremities is treated with sclerotherapy, high frequency waves (RFA), intravascular laser.
- Vascular failure of the lower extremities treated by surgery









• CEAP classification













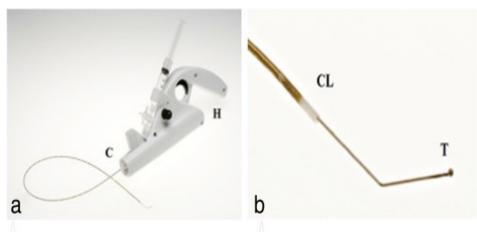








ClariVein is a set of superficial venous interventions in the lower extremities that work by 2 movements at the same time: continuous rotation of the catheter tip at a rate of 3,000 rpm in combination with Sclerosant 2% mixed with gas at a ratio of 1: 3 injected directly into the vein through the catheter.



































**Outcomes** 

Based on clinical and doppler ultrasound examinations after 1 and 4 weeks









From July 1st 2018 to July 30th 2018

28 patients with superficial venous insufficiency of the lower extremities were diagnosed and treated with ClariVein technique at the Department of Vascular Surgery

There are 28 cases of large saphenous vein with regurgitation on doppler ultrasound, there are 3 cases of ipsilateral small saphenous vein failure









Variables	Median
Age	52 ± 14,5 (35 - 73)
Male(%)	08 (28,6)
Female(%)	20 (71,4)
Total(%)	28 (100)









C	Clinical classification	<b>C1</b>	C2	C3	C4	<b>C</b> 5	C6	total
	N(%)	0(0)	5(17,9)	11(39,3)	9(32,1)	5(10,7)	0(0)	28(100)

Great saphenous veins (N = 28)		Small saphenous veins (N = 3)		
Median diameter (mm)	Median length	Median diameter	Median length	
	(cm)	(mm)	(cm)	
5,9 (4,5 – 9,8)	38(35 - 42)	4,1(4 – 4,4)	18,5(16 -21)	









Mean intervention (minute)		Sclerosant volume (ml)	Complication(%)	
25 ± 7,5		8,5 ± 3,5	0(0)	
1 week results (%)	Satisfaction (%)	4 weeks results (%)	Satisfaction (%)	
Completely occlusion (100)		1 case with regugitation in the distal end (3,6)		
3 cases with pain along the great saphenous vein (10,7)	(100)	2 cases with mild pain along the large saphenous vein (7,1)	27(96,4)	

- The result after the intervention was technically successful 100%, 28 cases of great saphenous vein failure and 3 cases of ipsilateral small saphenous varicose veins were intervened at the same time and all cases are completely occluded, no regurgitation and non-collapsed varicose veins on doppler ultrasound examination.
- There were no notable complications
- Clinical symptoms significantly improved









- <u>Tang TY et al in 2017 (UK):</u> 300 cases, female 69%, median age 58 ± 13: 100% with complete occlusion of the vein, no serious complications were recorded, average time was 27 minutes
- After 8-week follow up, doppler ultrasound recorded complete occlusion of the large saphenous vein in 97% of the cases, the small saphenous vein was occluded 100% of the cases.









- <u>Lam YL et</u> all carried out a research to determine the dose of polidocanol in order to block the great saphenous vein using the ClariVein technique instead of sclerosant (2016): 87 cases, female 60.9%, median age 55, the length of the large saphenous vein blocked was 30cm, the intervention time was 16 minutes, the diameter of the saphenous vein was 7.7mm.
- After 6 weeks recorded: occlusion in group 1 accounted for 88%, group 2 accounted for 85.7%, group 3 accounted for 30.4%.
- The occlusion of the large saphenous veins by the ClariVein technique combined with 1% polidocanol was significantly less effective.









- There was a comparison of pain parameters and quality of life after saphenous vein occlusion using ClariVein technique (MOCA) compared with RFA which was done by Ramon R J P van Eekeren et al. in 2013:
- 68 cases
- Conclusion: patients treated with MOCA had significant pain relief, recovered quickly, and returned to work sooner than with RFA; both MOCA and RFA significantly improved quality of life after the interventions.









- Another comparative study of a randomized clinical trial of Laser, RFA, sclerotherapy and stripping for the treatment of large saphenous veins was carried out by Rasmussen et al. in 2011
- 500 patients with 580 lower limbs were randomly selected for laser, RFA, sclerotherapy, and stripping surgery
- Conclusion: Among all effective treatment methods, the highest technical failure rate medthod is sclerotherapy; the patient who treated with RFA and sclerotherapy healed faster and suffered less pain than with laser and stripping









# 5. CONCLUSION

MOCA treatment of superficial venous insufficiency in the lower extremities is a new method with high efficiency, short recovery time and few complications









### PREFERENCES

1. Marsden G, Perry M, Kelley K, et al. Diagnosis and management of varicose veins in the legs: summary of NICE guidance. BMJ 2013; 347: f4279–f4279. [PubMed] [Google Scholar]

2. Siribumrungwong B, Noorit P, Wilasrusmee C, et al. A systematic review and meta-analysis of randomised controlled trials comparing endovenous ablation and surgical intervention in patients with varicose vein. Eur J Vasc Endovasc Surg 2012; 44: 214–223. [PubMed] [Google Scholar]

3. Sichlau MJ, Ryu RK. Cutaneous thermal injury after endovenous laser ablation of the great saphenous vein. J Vasc

Interv Radiol 2004; 15: 865–867. [PubMed] [Google Scholar]

4. Van Den Bos RR, Neumann M, De Roos KP, et al. Endovenous laser ablation-induced complications: review of the

literature and new cases. Dermatol Surg 2009; 35: 1206–1214. [PubMed] [Google Scholar]

5. Van Eekeren RR, Boersma D, Elias S, et al. Endovenous mechanochemical ablation of great saphenous vein incompetence using the ClariVein device: a safety study. J Endovasc Ther 2011; 18: 328–334. [PubMed] [Google Scholar] 6. Van Eekeren RR, Boersma D, Konijn V, et al. Postoperative pain and early quality of life after radiofrequency ablation and mechanochemical endovenous ablation of incompetent great saphenous veins. J Vasc Surg 2013; 57: 445–450. [PubMed] [Google Scholar]

7. Rasmussen LH, Lawaetz M, Bjoern L, et al. Randomized clinical trial comparing endovenous laser ablation, radiofrequency ablation, foam sclerotherapy and surgical stripping for great saphenous varicose veins. Br J Surg 2011; 98:

1079–1087. [PubMed] [Google Scholar]

8. Lam YL, Toonder IM, Wittens CH. Clarivein® mechano-chemical ablation an interim analysis of a randomized controlled

trial dose-finding study. Phlebology 2015. 2016; 31: 170–176. [PubMed] [Google Scholar]

9. van Eekeren RR, Boérsma D, Holewijn S, et al. Mechanochemical endovenous Ablation versus RADiOfrequeNcy Ablation in the treatment of primary great saphenous vein incompetence (MARADONA): study protocol for a randomized controlled trial. Trials 2014; 15: 121–121. [PMC free article] [PubMed] [Google Scholar]
10. TY Tang,1 JW Kam,2 and ME Gaunt3 ClariVein® – Early results from a large single-centre series of mechanochemical

endovenous ablation for varicose veins. Phlebology. 2017 Feb; 32(1): 6–12. [PMC free article] [PubMed] [Google Scholar]









