Early Single-centre Comparative Results on Non-thermal Ablation of Symptomatic Incompetent Great Saphenous Veins (GSV): Cyanoacrylate Glue (VenaSeal) versus Mechanicochemical ablation (ClariVein)

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Disclosure

Speaker name:

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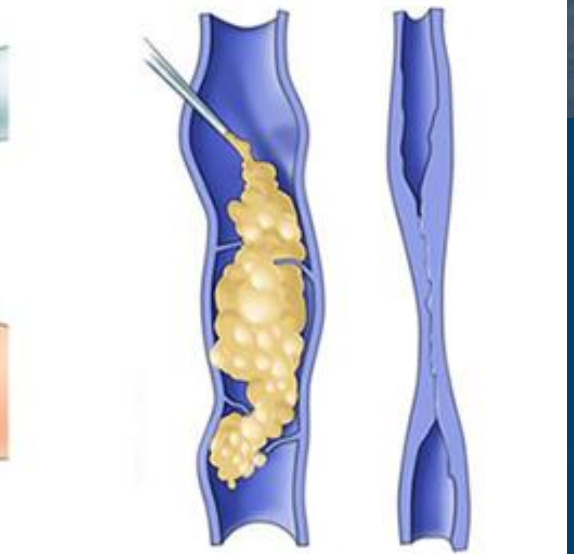
I have the following potential conflicts of interest to report:

- Trip sponsorship by IntegMed Ltd

I do not have any potential conflict of interest

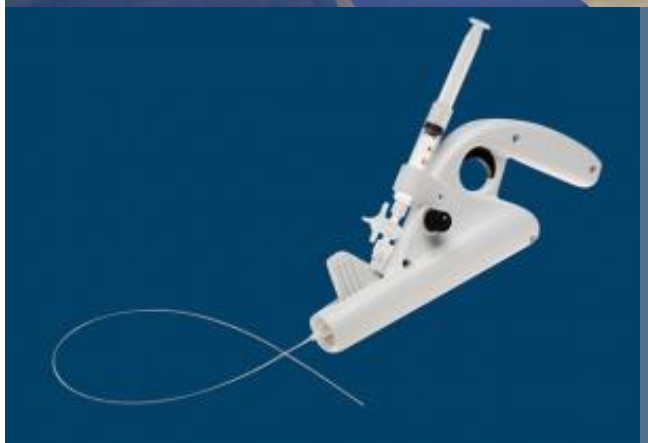
- Consulting
- Employment in industry
- Stockholder of a healthcare company
- Owner of a healthcare company
- Other(s)

静脉腔内静脉曲张治疗

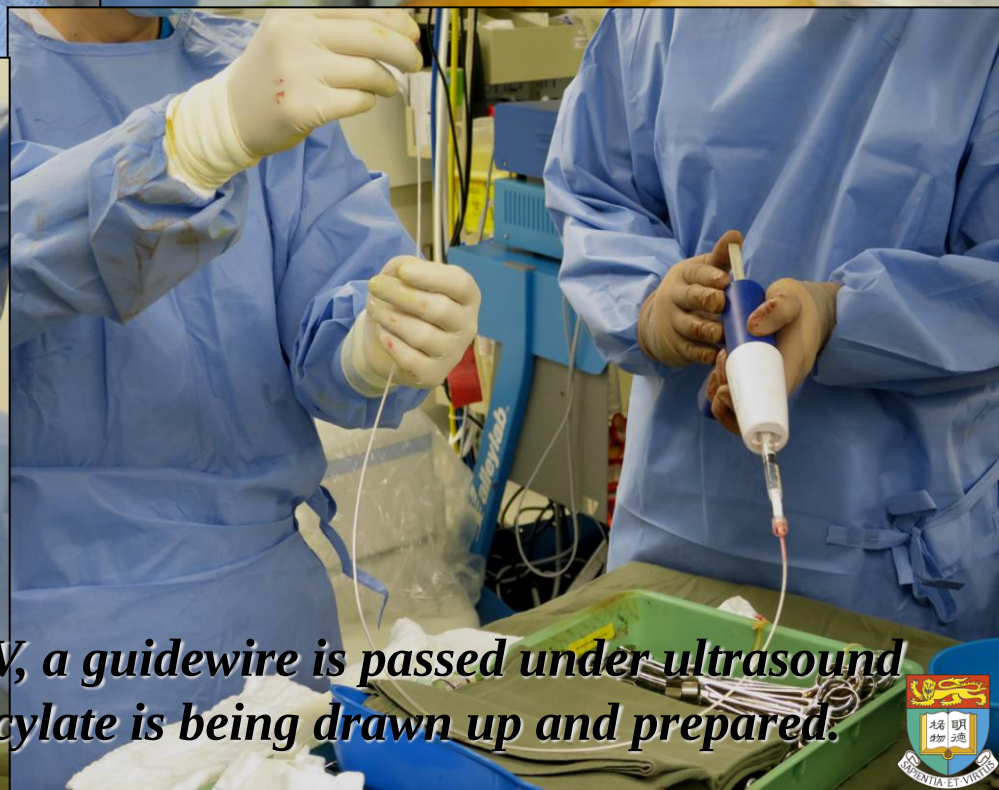


Endovenous Varicose vein treatment are minimally invasive and office based

- ***Thermal energy*** *(+ tumescence anaethesia)*
  - *Radiofrequency ablation*
  - *Laser*
  - *steam*
- ***Sclerotherapy***
- ***Non thermal ablation***
  - *Mechanical and sclerosant (ClariVein)*
  - *Cyanoacylate (Venaseal)*

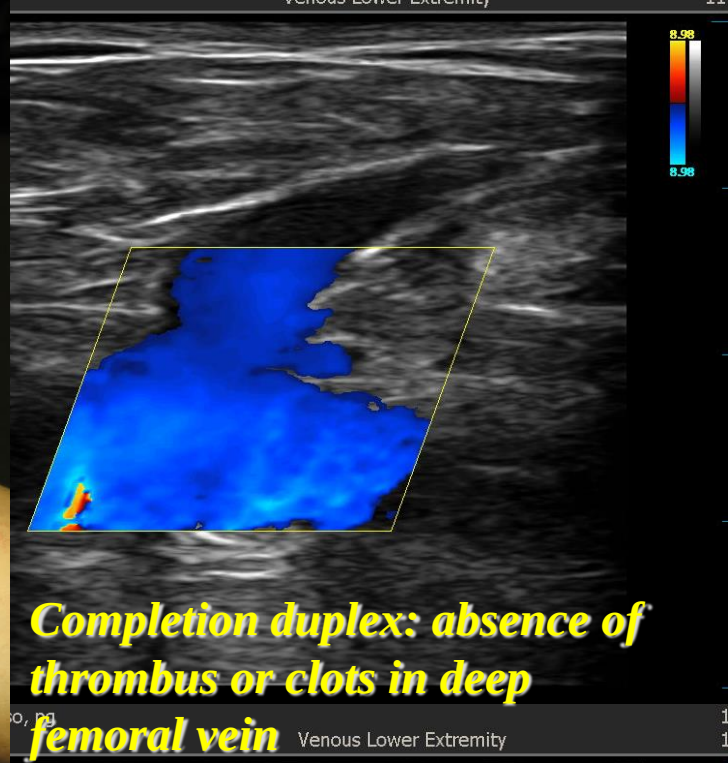


Cyanoacrylate Glue (VenaSeal)



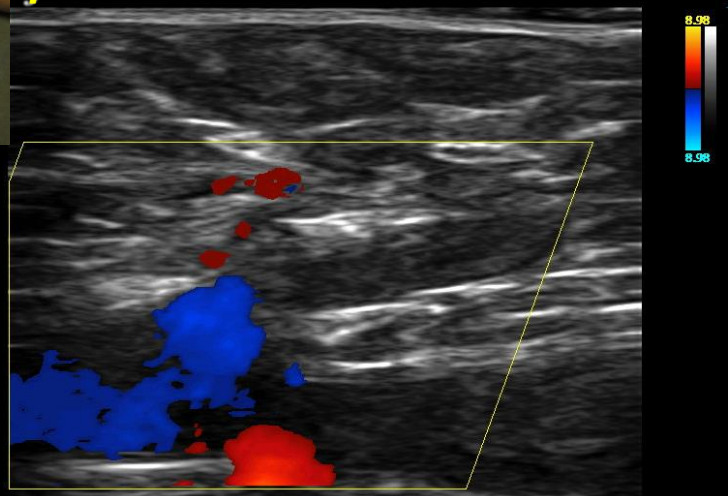
After successful cannulation of the GSV, a guidewire is passed under ultrasound guidance. In the meantime, the cyanoacylate is being drawn up and prepared.

Mechanicochemical ablation (ClariVein)



Completion duplex: absence of thrombus or clots in deep femoral vein

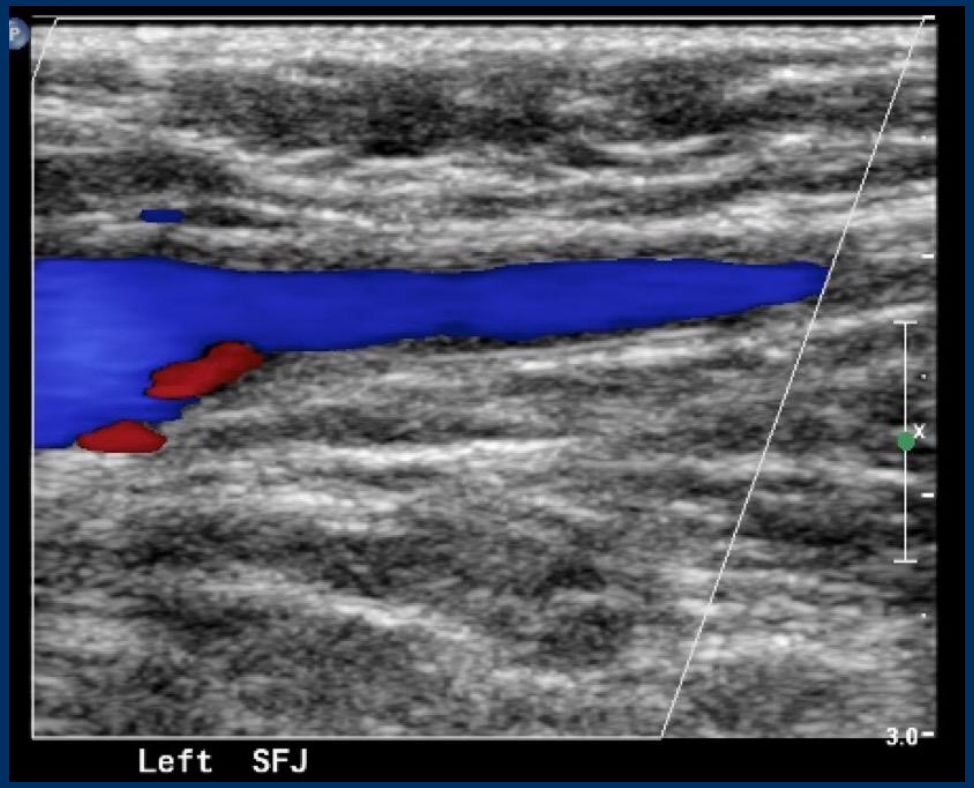
Venous Lower Extremity



Completion duplex: successful obliteration of great saphenous vein

Methods

- Single center prospective, non randomized comparative study for evaluation of safety and efficacy of VenaSeal v.s. Clarivein
- Primary outcomes:
  - Complications
  - Clinical recurrence of varicosity and re-intervention
  - Radiological duplex ultrasound GSV obliteration rate: 4 days, 1 week, 1 month, 3 months, 6 months



Patients' characteristics

VenaSeal group: 43 legs in 22 patients
ClariVein group: 30 legs in 18 patients

	VenaSeal (n=22)	ClariVein (n=24)	P value
Median age	62 (range 39-80)	60.5 (range 44-76)	NS*
Male: Female	6:16	8:16	NS^
Co-morbidities			
- DM	2/22	0/24	NS^
- HT	9/22	4/24	NS^
- Cardiac	6/22	2/24	NS^
- Renal	1/22	0/24	NS^
- COPD	0/22	0/24	NS^
Sides			
- Unilateral	1/22	18/24	<0.001^
- Bilateral	21/22	6/24	

*Student t test, ^chi square test

Leg varicose vein characteristics

	VenaSeal (n=43)	ClariVein (n=30)	P value
CEAP clinical classification - C3 - C4a - C4b - C5 - C6	28 12 1 1 1	15 9 3 0 3	NS^
Mean diameter of GSV (mm)	7.2 (range 3.9-11.4)	6.5 (range 5.0-10.0)	NS*
Mean treatment length of GSV (cm)	28.4 (range 20-33)	32.8 (range 25-38)	0.001*

*Student t test, ^chi square test

Operative outcomes

	VenaSeal (n=43)	ClariVein (n=30)	P value
Mean operative time (minutes)	64.6 (range 28-99)	72.0 (range 25-125)	NS*
Primary success	43/43 (100%)	29/30 (96.7%)	NS^
Access - Percutaneous - Open	 43/43 (100%) 0/43	 27/30 (90%) 3/30	NS^

*Student t test, ^chi square test

One procedure failure for ClariVein group due to very tortuous GSV; and hence excluded from subsequent analysis

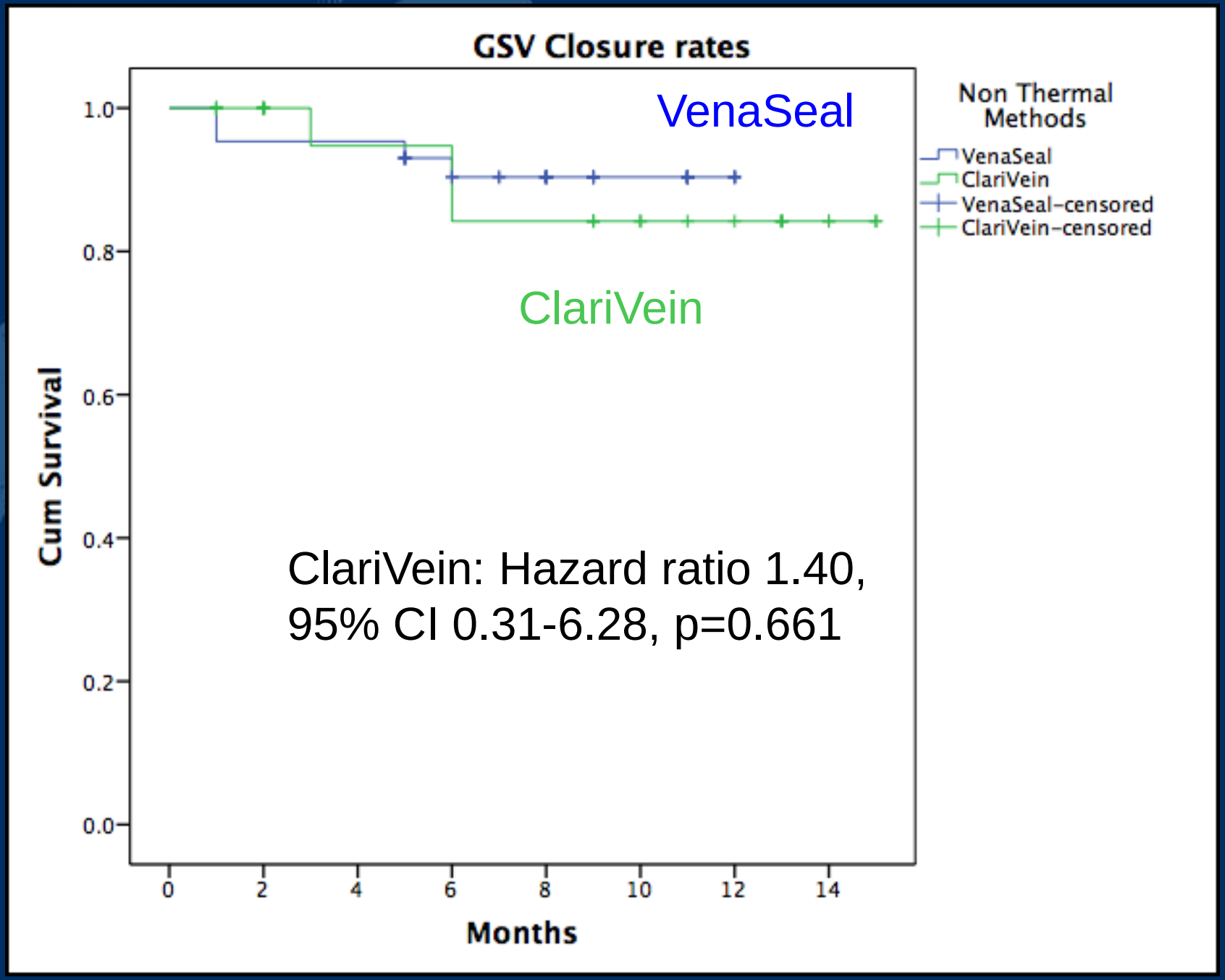
Post-operative complications

	VenaSeal (n=43)	ClariVein (n=29)	
Deep Vein thrombosis	0	0	NS^
Thrombus extension to deep vein	0	3	NS^
Parenthesis	1	0	NS^
Weakness	0	0	NS^
Wound infection	1	0	NS^
Cellulitis	0	1	NS^
Symptomatic thrombophlebitis	0	2	NS^

^chi square test

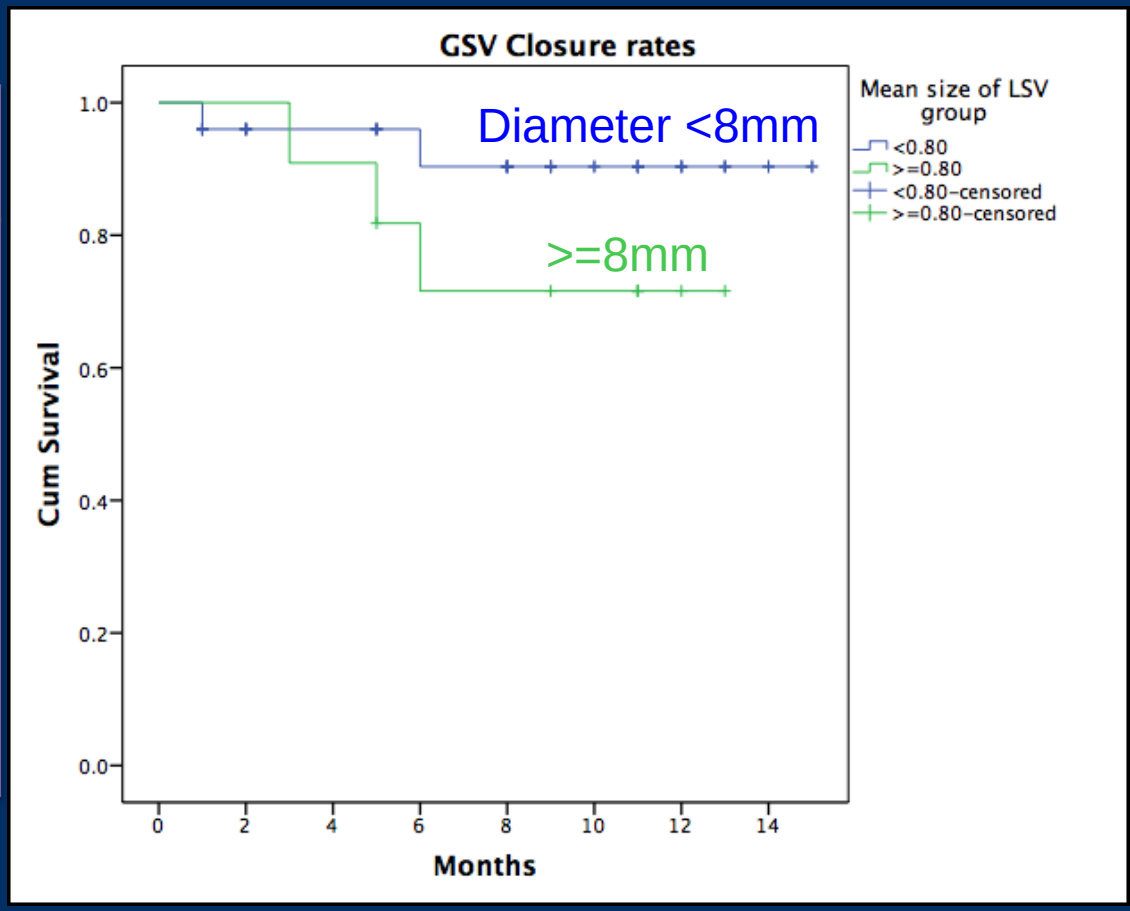
Clinical outcomes

- VenaSeal group: median follow up period 9 months (range 5-12)
- ClariVein group: median follow up period 9.5 months (range 1-15)
- No clinical recurrence or secondary intervention


GSV Closure rates
VenaSeal
ClariVein
Non Thermal Methods
VenaSeal
ClariVein
VenaSeal-censored
ClariVein-censored
Cum Survival
1.0
0.8
0.6
0.4
0.2
0.0
0
2
4
6
8
10
12
14
Months
ClariVein: Hazard ratio 1.40,
95% CI 0.31-6.28, p=0.661

Predictors of recanalization

	Hazard ratio	95% CI	P value
ClariVein	1.40	0.31-6.28	0.661
Mean diameter >= 8mm	3.10	0.69-13.89	0.139
Mean treatment length <20cm	3.05	0.53-17.62	0.212



Conclusion

- Both treatment modalities were safe with comparable clinical and radiological outcomes
- Trend towards more recanalization in GSV with larger diameter

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