The Use of Venaseal in South East Asia

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Disclosure

Speaker name:

............................................ Yiu-Che CHAN............................................

I have the following potential conflicts of interest to report:

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

- I do not have any potential conflict of interest
Saphenofemoral junction ligation, strip of long saphenous vein may result in significant bruises or discomfort.
Endovenous treatment of Varicose veins are minimally invasive and office based

- **Thermal energy** (+ tumescence anaesthesia)
  - Radiofrequency ablation
  - Laser
  - Steam
- **Sclerotherapy**
- **Non thermal ablation**
  - Mechanical and sclerosant (ClariVein)
  - Cyanoacrylate (Venaseal)
Endovenous Cyanoacrylate Glue
Venaseal™ Sapheon Closure System, Sapheon Inc (Santa Rosa, USA) now Medtronic, Gorway, Ireland

- A new modality for treating varicose veins with the use of a medical adhesive without thermal energy
  - European Conformite Europeen (CE) Mark approval in September 2011
  - United States FDA approved February 2015
  - Hong Kong is the first place in Asia
  - HKU is first centre in Asia to use this
  - Medtronic’s VenaSeal closure system has been granted pre-market approval (PMA) from the US FDA November 2015
Cyanoacrylate Superglue to Treat Varicose Veins: Truly Office Based and Minimally Invasive?

One of the disadvantages of endovenous therapy for ablation of trunkal incompetence for patients with varicose veins is the requirement for tumescence anaesthesia, which may result in pain, swelling and bruising.

The use of intravenous injection of cyanoacrylate glue for trunkal ablation is a recently developed concept. Cyanoacrylate glue is a liquid adhesive that has been used in humans to treat varicosities for more than 20 years and was first used in endoscopic intravenous injections of peptic varicosities. It has also been used in the treatment of arteriovenous malformations. The mechanism of haemostatic or embolisation agents, it is generally not, but rare cases of bleeding and pulmonary embolism after the use of cyanoacrylate have been reported. In a recent case, endoscopic-guided injection of a peptic varicosity was performed.

Wang et al. demonstrated that when cyanoacrylate glue was mixed with lipiodol and injected into the shunt, the vessels were obliterated immediately. This resulted in a sub-acute vasculitis and a chronic granulomatous body reaction, to be replaced by fibrous tissue. Min et al. reported that at 30 days' post-injection, the treated varicosities were confirmed, with this non-thermal ablative modality, endovenous therapy using cyanoacrylate glue is effective, without the need for peri-venous injection of anaesthesia or compression stockings. The results of 1-year clinical follow-up on 38 patients who underwent treatment of their symptomatic varicose veins with cyanoacrylate glue injection into the long saphenous vein were published recently. All the treated veins were closed at 24–72 h, and at 30 days, 97% of the veins were completely closed. There were no significant side effects or complications. The patients did not have any deep vein thrombosis or pulmonary embolism, but Proebstle showed that the first

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The procedure takes place in the operating theatre: local anaesthesia and monitored anaesthetic care with intraoperative ultrasound.
After successful cannulation of the GSV, a guidewire is passed under ultrasound guidance. In the meantime, the cyanoacrylate is being drawn up and prepared.
The tip of the catheter is 4 cm from the saphenofemoral junction.

Two injections of approximately 0.09 milliliters were given 1 cm apart at this location, followed by a 3-minute period of local compression, and then repeated injections and 30-second ultrasound probe and hand compression sequences until the entire length of the target vein segment is treated.
Cyanoacrylate glue delivered with withdrawal of the catheter
LINC

- Minimally invasive with very small wounds and minimal bruising
- Technical success in all cases
- Avulsions of varicosities under local anesthesia took place in same setting

Completion duplex: successful obliteration of long saphenous vein

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

Primary Outcome Measures

• **Procedure success rate** - saphenous vein obliteration rate
• Cumulative probability of recurrent varicose veins within 12-24 months after treatment, with *serial clinical and duplex examination* of patient at 1 week, 3 months, 6 months, (1 year, 2 years).
• **Definition of complete closure**
  – Doppler ultrasound examination showing closure along entire treated target vein segment with **any** discrete segments of patency

Secondary Outcome Measures at pre-op, 1 week post op, 6 months post-op, 12 months post-op.

• **Pain Score** (at discharge) 0-10
• **Quality of life Questionnaires** (SF36) assessment of pain, edema, venous claudication, pigmentation, lipodermatosclerosis, ulcer size)
• **Venous clinical severity score (VCSS)**
• **Aberdeen varicose vein questionnaire (AVVQ)**
• **Ecchymosis score** (at 1 week: mild, moderate, severe)
• **Side-effects or major events** from this treatment modality

Follow up duplex showed no DVT, and successful obliteration of LSV
Example of a 6 month follow-up duplex showing recanalisation of the previously obliterated proximal long saphenous vein.
Post-operative.
Cyanoacrylate glue used to treat great saphenous reflux: Measures of outcome

Yiu Che Chan, Yuk Law, Grace C Cheung, Albert C Ting and Stephen W Cheng

Abstract

Introduction: This is a single-center clinical study for the evaluation of safety, efficacy, and performance of endovenous cyanoacrylate (Sapheon Venaseal Closure System, now Medtronic Medical) for the treatment of great saphenous vein (GSV) reflux.

Methods: Primary outcome measures included the GSV obliteration, with clinical recurrence on follow up as detected by serial clinical and duplex examinations of patients at 1 week, 1 month, 6 months, and 1 year. Venous clinical severity score (VCSS), Aberdeen varicose vein questionnaire (AVVQ), Short Form Health Survey 36 Item (SF-36) questionnaires were used at clinical follow up. Diameter of the GSV, treatment length of the GSV, and pretreatment clinical severity of the varicose vein were analyzed to predict recanalization using Cox regression analysis.

Results: Fifty-seven legs in 29 patients with primary varicose veins were included. One week follow-up duplex showed successful obliteration of the GSV in all except one of the legs. Two legs had minimal extension of thrombus to deep vein. None of the patients had deep venous thrombosis. All the patients were discharged the same day of operation. Median time to return to work was 1 day (range 1–16 days). Our VCSS, AVVQ, and the SF-36 physical and mental scores changed from a mean of 6.91, 23.66, 44.24, 54.26 at baseline to 2.43, 6.10, 43.85, 52.50 at 1 month post operation, respectively. Kaplan–Meier analysis showed that the GSV closure rates were 98.2%, 94.3%, 89.7%, and 78.5% at post-op 1 week, 1 month, 6 months, and 1 year, respectively. With median follow-up period of 9 months (range 1–13 months), no clinical recurrence of varicosity was observed. Mean GSV diameter ≥ 8 mm was a significant predictor for recanalization (hazard ratio 6.92, 95%CI 1.34–35.67, p = 0.021).

Conclusion: This study showed that the use of endovenous cyanoacrylate in the treatment of the GSV reflux was safe. All patients had symptomatic improvement as shown by the VCSS and AVVQ.
57 incompetent GSVs in 29 patients

<table>
<thead>
<tr>
<th>Patients’ characteristics (n = 29)</th>
<th>Number</th>
<th>Percentage</th>
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</thead>
<tbody>
<tr>
<td>Age</td>
<td>Median 63 (range 39–80)</td>
<td></td>
</tr>
<tr>
<td>Male: Female</td>
<td>9:20</td>
<td></td>
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<tr>
<td>Co-morbidities</td>
<td></td>
<td></td>
</tr>
<tr>
<td>DM</td>
<td>3/29</td>
<td>10.3</td>
</tr>
<tr>
<td>HT</td>
<td>11/29</td>
<td>37.9</td>
</tr>
<tr>
<td>Cardiac</td>
<td>7/29</td>
<td>24.1</td>
</tr>
<tr>
<td>Renal</td>
<td>1/29</td>
<td>3.4</td>
</tr>
<tr>
<td>COPD</td>
<td>0/29</td>
<td>0</td>
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</tbody>
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<tr>
<th>Leg varicose vein characteristics (n = 57)</th>
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<tbody>
<tr>
<td>CEAP clinical classification</td>
<td></td>
</tr>
<tr>
<td>C3</td>
<td>33/57</td>
</tr>
<tr>
<td>C4a</td>
<td>20/57</td>
</tr>
<tr>
<td>C4b</td>
<td>2/57</td>
</tr>
<tr>
<td>C5</td>
<td>1/57</td>
</tr>
<tr>
<td>C6</td>
<td>1/57</td>
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| Mean diameter of GSV | Median 7.1 mm (range 3.9–11.4 mm) |
| Treatment length of GSV | Median 27.0 cm (range 17–33 cm) |
• Closure rates (n=57)
  1 week 100%
  1 month 95.3%
  6 months 90.3%
  12 months 78.5%

Predictors of Recanalisation
(Cox Regression analysis)

<table>
<thead>
<tr>
<th>predictor</th>
<th>Hazard ratio</th>
<th>95% Confidence interval</th>
<th>p-Value</th>
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<tbody>
<tr>
<td>Mean GSV diameter ≥8 mm</td>
<td>6.92</td>
<td>1.34–35.67</td>
<td>0.021</td>
</tr>
<tr>
<td>Treatment length &lt;30 cm</td>
<td>2.59</td>
<td>0.34–19.81</td>
<td>0.359</td>
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<tr>
<td>Pretreatment CEAP score C4-6</td>
<td>2.29</td>
<td>0.51–10.23</td>
<td>0.280</td>
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</table>
VSS and AVVQ statistically significant irrespective of recanalisation.

Figure 3. Graphical representation of the venous severity scores (a), Aberdeen varicose vein questionnaires (b), and SF 36 questionnaires (c).
Closure of GSV (n=80)

Mean vein size 67 (36-114) mm

Closure rates (n=80)
1 week 100%
1 month 95.6%
6 months 90.9%
12 months 79.3%
Closure of GSV (n=80)

Closure of GSV (n=80)

<table>
<thead>
<tr>
<th>Closure</th>
<th>&lt; 8 mm*</th>
<th>≥ 8 mm*</th>
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<tbody>
<tr>
<td>1 week</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>1 month</td>
<td>0.957</td>
<td>0.808</td>
</tr>
<tr>
<td>6 months</td>
<td>0.957</td>
<td>0.707</td>
</tr>
<tr>
<td>12 months</td>
<td>0.87</td>
<td>0.505</td>
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Logrank: $p = 0.018$
Summary

• Our experience at the University of Hong Kong showed that endovenous cyanoacrylate treatment of incompetence long saphenous veins is safe and effective

• Longer term results are anticipated
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