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Early Experience on The Use of Cyanoacrylate to Treat Patients with Symptomatic Long Saphenous Vein Incompetence

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Disclosure

Speaker name:

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I have the following potential conflicts of interest to report:

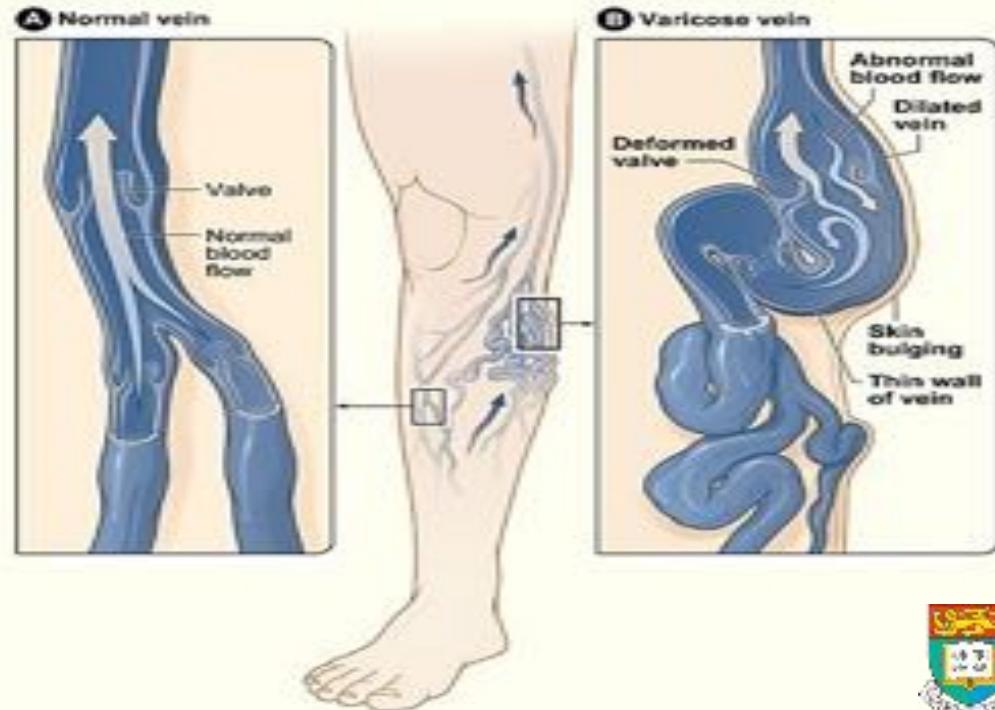
- Consulting
- Employment in industry
- Stockholder of a healthcare company
- Owner of a healthcare company
- Other(s)

- I do not have any potential conflict of interest



Varicose Veins

- Varicose veins are tortuous and dilated veins caused by incompetent valves in the long saphenous vein /short saphenous vein or perforator systems
- 30 million Americans and 40 million Europeans suffer from venous reflux disease
- May cause complications of
 - Ezcema
 - Pigmentation
 - ulceration



VenaSeal™ Cyanoacrylate for Varicose Veins Treatment



- This product had European Conformite Europeen (CE) Mark approval in September 2011, and United States FDA approved February 2015.
- The VenaSeal™ closure system is commercially available in Europe, Australia, Hong Kong, New Zealand, UAE, and Canada.



- ***Proprietary, advanced formulation, high grade medical adhesive***

- Designed specifically for saphenous vein disease treatment
- Seals vein along treatment length without surgery or burning
- Has European CE Mark approval in September 2011
 - VenaSeal has been used to treat over 1,700 veins in patients in Europe
- FDA approved February 2015

- ***Proprietary catheter design***

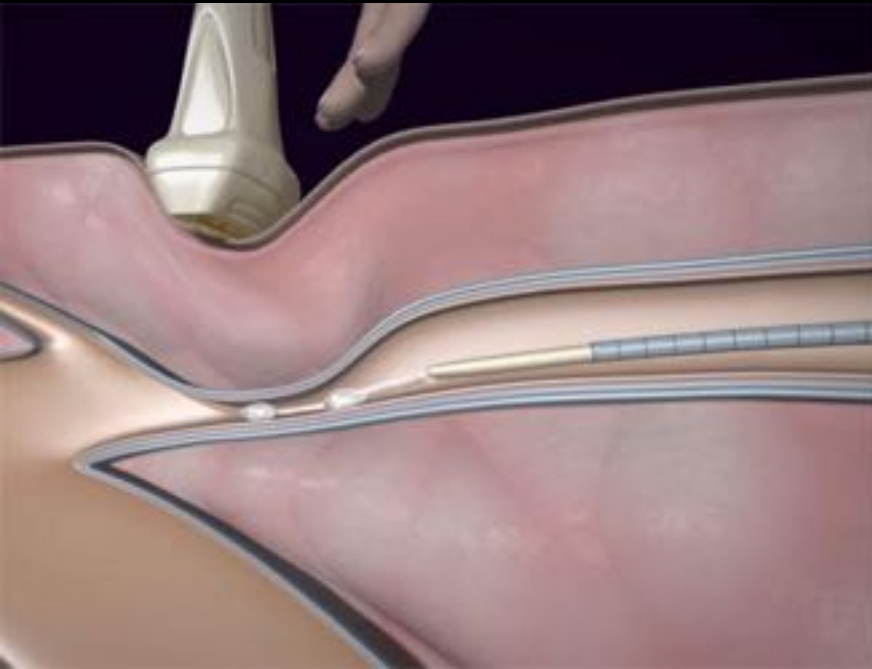
- Engineered to be inert to adhesive
- Provides exceptional high visibility under ultrasound guidance

- ***Proprietary dispenser gun***

- Calibrated to deliver precise amount of Sapheon vein sealant adhesive



Aim of Study



- To evaluate the safety and efficacy of endovenous injection of cyanoacrylate in treating symptomatic varicose veins





The procedure takes place in the operating theatre: local anaesthesia and monitored anaesthetic care with intraoperative ultrasound





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



The tip of the catheter is 4cm from the saphenofemoral junction.



Two injections of approximately 0.09 milliliters were given 1 cm apart at this location, followed by a 3-minutes 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 was treated.



Methods & Materials

- Patients with primary varicose veins due to duplex-proven incompetent long saphenous veins (LSV) were recruited
- All the patients had pre-operative duplex to confirm saphenofemoral junction and long saphenous vein incompetence
- All the procedures took place as day-case in our Minimally Invasive Surgical Centre under local anaesthesia/ monitored anaesthetic care, without tumescence anaesthesia



Outcome Measures

Primary Outcome Measures

- Procedure success rate- saphenous vein obliteration rate
- Cumulative probability of recurrent varicose veins within 24 months after treatment, with *serial clinical and duplex examination* of patient at 1 week, 3 months, 6 months, 1 year, 2 years.

Secondary Outcome Measures:

- **Quality of life** (as measured by SSF36) - Questionnaire style clinical score/ venous clinical severity score (assessment of pain, edema, venous claudication, pigmentation, lipodermatosclerosis, ulcer size), at pre-op, 1 week post op, 3 months post op, 6 months post-op, 1, 2, years post op.
- **Ecchymosis score**
- **Side-effects or major events** from this treatment modality



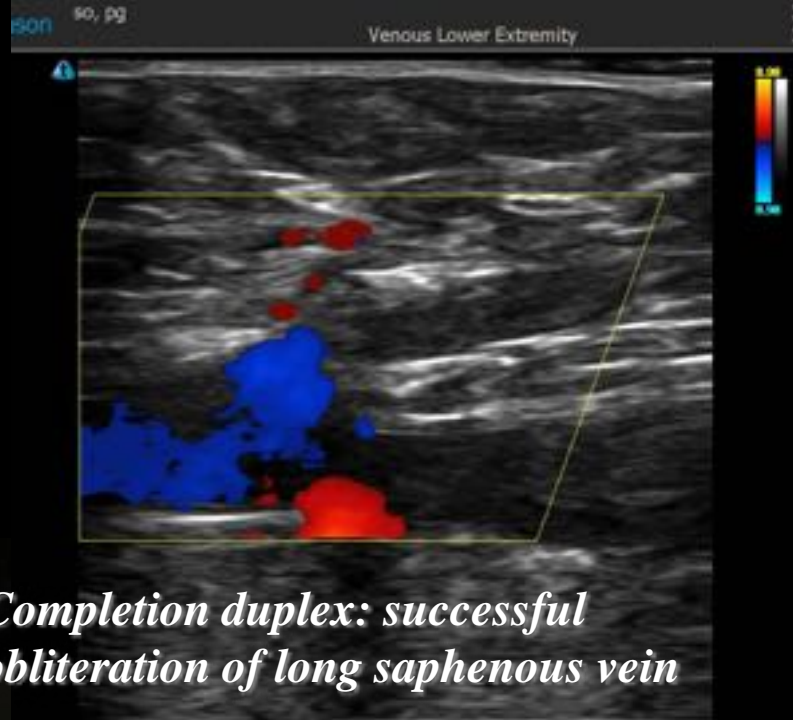
Results

- Thirty-three incompetent LSVs (mean diameter 0.9 (range 0.6-1.1)cm) in 17 patients (4 males, median age 62.6 (range 39-78) from September 2014 to January 2015 were included.
- CEAP: C3-20, C4a-10, C4b-1, C5-1, C6-1.

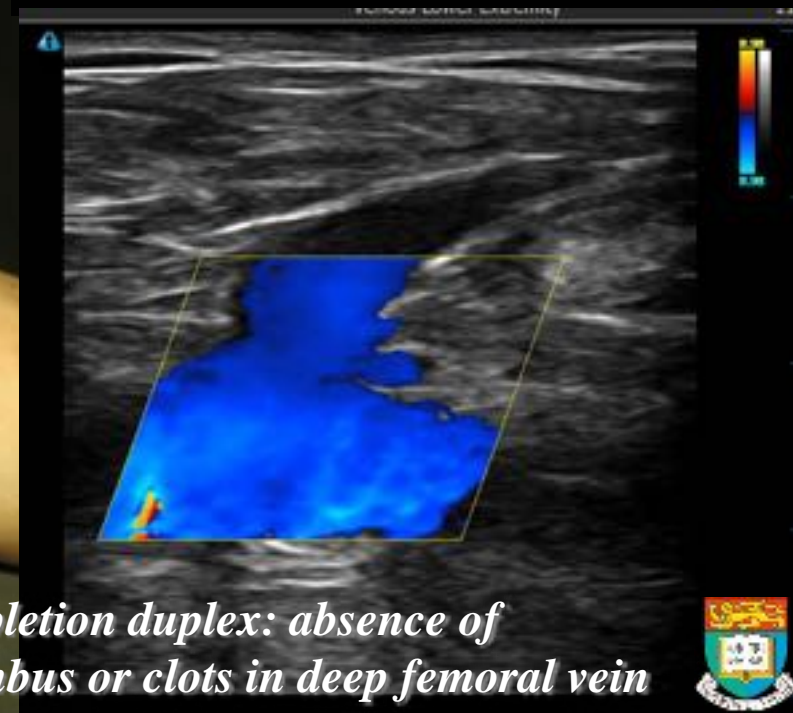


The Result

- *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



Results

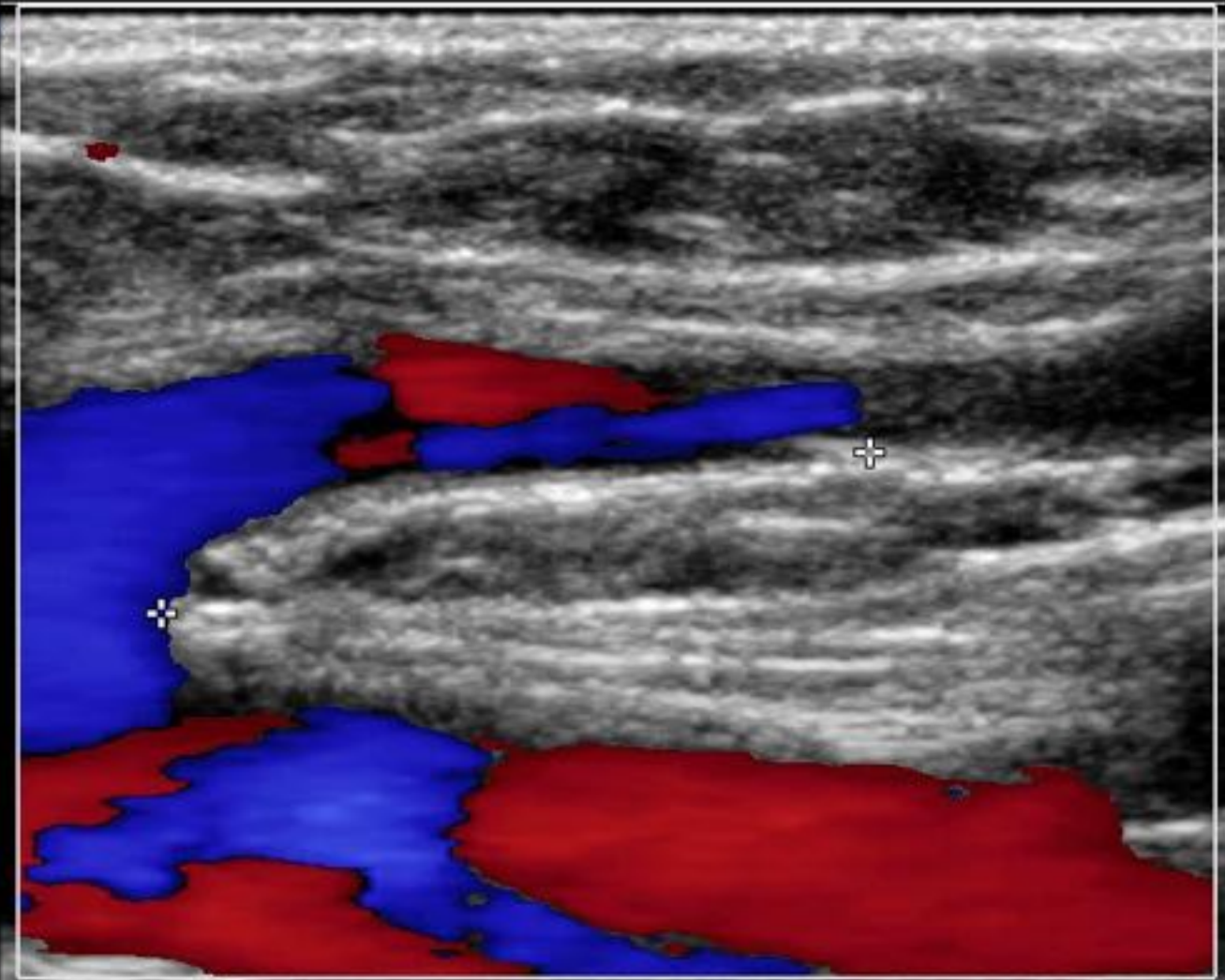
- All the patients were ambulatory immediately post-operatively and discharged on the same day.
- Median follow-up period was 1.28 (range 0.26-3.52) months, and no deep vein thrombosis was detected
- All the treated LSV were successfully obliterated, with the mean LSV stump of 2.68 (range 0.8-6.5cm) cm. Mean post-operative pain score was 0.82 (range 0-3; normal 0-10).



R 23Hz

6%
49
Low
en
4%
500Hz
F 52Hz
ed

P



M2

+1

-1

cm

Follow up duplex showed no DVT, and successful obliteration of LSV

3.5



Questionnaire Results

- Mean scores preoperatively and 1 month postoperative for: *venous severity score*, *Aberdeen varicose vein questionnaire*, SF36 (physical health), SF36 (mental health) were: 7.3 to 2.2 (student's t test: $p < 0.001$), 24.9 to 5.0 ($p < 0.001$). 44.8 to 44.0 ($p = 0.751$), 58.9 to 56.1 ($p = 0.094$) respectively
- There were no side-effects or major events, but one patient developed minor wound infection treated with antibiotics
- No clinical recurrences of varicosities





Summary

- Our short-term experience showed that endovenous cyanoacrylate injection for LSV incompetence was safe and effective
- Longer term results are anticipated



