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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:

...........................................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
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:
  - Eczema
  - 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 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 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).
Follow up duplex showed no DVT, and successful obliteration of LSV.
Questionnaire Results

- Mean scores preoperatively and 1 month postoperatively 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.