Appendix 1 to Direct Vision Sclerotherapy

AUSTRALASIAN COLLEGE OF PHLEBOLOGY

CLINICAL PROCEDURES

CP – Direct Vision Sclerotherapy 'Clinical procedure'

1 PURPOSE

This procedure summarises the actions required to:

a. establish patient needs, assess abnormal superficial venous networks and communicate and manage risks,

b. deliver safe, timely and appropriate direct sclerotherapy to the abnormal superficial venous network in a way that meets patients' expectations.

It is a guideline of procedural notes for the treatment covered by the ACP Direct Vision Sclerotherapy Standard 'Assess and treat abnormal superficial venous network with injected sclerosants'

2 SCOPE

This procedure is to be followed by ACP trainees and certified practitioners delivering this service to patients. Assessment of competence in following this procedure is measured by checking the practitioner as s/he treats the patient against the criteria specified in the ACP Direct Vision Sclerotherapy Standard.

3 REFERENCES

As per ACP Direct Vision Sclerotherapy Standard

4 DEFINITIONS/ACRONYMS

As per ACP Direct Vision Sclerotherapy Standard

5 PROCEDURE AND SPECIAL NOTES

1 CONDUCT INITIAL CONSULTATION

1.1 Information regarding venous incompetence, diagnosis and direct vision sclerotherapy (DVS)
'Informed Consent'

1. Explain that a clinical examination needs to be followed by Duplex/Doppler aided diagnosis to rule out underlying venous incompetence as a cause of the patient's presenting complaint and to confirm the suitability of DVS to treat the patient's needs.

2. Identify the problem areas and concerns of the patient and explain the procedure.

Risks associated with DVS to be explained are:

Local

- Localised inflammation or pain in the treated vein indicated by redness, tenderness or swelling in the specific region of treatment – very uncommon. Treated by non-steroidal anti-inflammatories, e.g. ibuprofen, diclofenac.

- Blood trapping giving rise to tender raised lumps in treated veins, which can be expected to resolve over 3-6 months. Treated by aspiration or skin puncture and manual expression if necessary.

- Ulceration - Rare. Apply colloidal dressings.

- Telangiectatic matting in 1-10% of cases. If this does not naturally resolve over 6 months, further treatment of underlying venous incompetence may be required.

- Brown staining caused by haemosiderin deposition in the skin – common. Resolves in 6 – 12 months, although may persist longer in a small number of cases.

- Nerve injury: sensory nerve injury - uncommon, motor nerve injury – isolated cases

- Embolica cutis – very rare

Systemic:

- Anaphylaxis in < 0.02% of cases –treat immediately with intramuscular adrenaline, oxygen and other supportive interventions.

- Visual disturbances, headaches and migraine -very uncommon.

- Serious adverse neurological events, such as TIA/CVA – very rare.

- Cough and chest discomfort - rare.

- DVT/Pulmonary embolism < 0.02% of cases treat by hospitalisation or outpatient treatment for further investigation and treatment with anti-coagulants.

- A haemolytic reaction may occur with larger doses of STS, with malaise – a flu-like illness feeling for some hours and microscopic haematuria. Adequate fluids are the only treatment required.

- Death – extremely rare

3. Explain the following clinically indicated treatment options and their implications:

    - No treatment, e.g. the patient may have no symptoms, trivial telangiectasias but just needs reassurance and advice should include a warning that the situation could deteriorate.

    - Wearing support hosiery may reduce any associated symptoms.

    - Treatment of underlying superficial venous incompetence with UGS, EVLA or surgery.

    - Direct Vision Sclerotherapy

    - External Laster treatment.

1.2 Patient assessment, initial consultation records

Relevant to ACP Protocol: 'Informed Consent'

1. The patient may be asked to complete a health questionnaire prior to seeing the physician and the doctor should then go through the completed questionnaire to confirm the details given.

2. Previous vein treatment and any complications must be elicited and documented. Patients who have had previous vein treatment must be referred for Duplex/Doppler ultrasound mapping prior to DVS.

3. Any history of miscarriage and other relevant gynaecological history, with particular emphasis on pelvic congestion syndrome is taken and documented.

4. Appropriate psychological history is elicited, noting any anxiety disorders such as needle phobia and claustrophobia.

5. All visual secondary complications such as varicose eczema, venous ulceration, chronic venous hypertension and lipodermatosclerosis are identified during careful clinical examination.

6. With the patient standing the venous system of both legs from groin to ankle is examined. A continuous wave Doppler is used to assess the superficial venous network. During the examination venous blood flow is augmented by manual muscle compression or the Valsalva manoeuvre.

7. Arterial supply is assessed digitally and, if necessary, by ankle/brachial index.

8. If there are symptoms, or clinical findings suggestive of arterial disease appropriate referral or investigation is required before treatment of the venous disease.

9. Identify any obvious vascular changes around the medial aspect of the ankle with corona phlebectaticaindicative of chronic venous hypertension. Patients presenting these signs should undergo duplex ultrasound assessment prior to DVS.

10. Signs of an extensive broad distribution of an abnormal superficial venous network suggest underlying venous incompetence and patients must be referred for a Duplex ultrasound assessment.

11. Discuss your clinical findings with the patient and if diagnostic results eliminate underlying venous incompetence and there are no other diagnostic results pending, accept the patient for DVS treatment.

12. If UGS is indicated as a likely treatment for the patient's superficial venous incompetence, refer to an approved ACP phlebologist.

13. Blood tests are considered.

14. Photographs must be taken before treatment.

15. Give patient a written estimate of cost for the anticipated course of treatments but advise it will be confirmed post ultrasound diagnosis.

16. Send a letter to the patient's general practitioner outlining your findings and treatment plan.

2 ESTABLISH AND AGREE TREATMENT PLAN

Relevant to ACP Protocol: 'Informed Consent'

1. Discuss findings from ultrasound diagnosis where appropriate and recommend a clinically appropriate treatment plan.

2. Update initial estimate of quote if diagnostic findings indicate a different treatment plan.

3. Give the patient other treatment options and/or referral if you are unable to deliver the most appropriate treatment for his/her condition.

Other treatment options:

- No treatment, e.g. the patient may have no symptoms, trivial telangectasias but just needs reassurance and advice should include a warning that the situation could deteriorate.

- Wearing support hosiery may reduce any associated symptoms.

- External Laser treatment

- Graduated compression stockings

- Laser treatment

4. Having agreed that DVS is the preferred treatment, both practitioner and patient must sign the informed consent document.

5. Instructions are given for the pre-operative requirements and post-operative requirements appropriate to the treatment method agreed.

3 INJECT VEINS WITH SCLEROSTANT

Relevant to ACP Protocol: 'Infection control' and 'Management of waste and Hazardous Substances'

1. The patient is usually supine as the practitioner prefers.

2. The proposed area to be treated may be wiped with an alcohol swab or cleanser and allowed to dry.

3. In preparing the liquid for injection clean the rubber stopper of multidose vials using an alcohol swab and ensure aseptic technique is followed.

4. To avoid cross contamination a sterile needle and syringe are used for each penetration of multidose vials of sclerosant (after wiping with an alcohol swab) to aspirate the contents. Multidose vials should be checked for an expiry date.

5. Change the needle to a new 30 gauge ½ inch needle to inject spider veins. A 27g or 30g needle can be used for reticular veins.

6. Needles are discarded into "sharps bins" immediately after use. Needles should not be recapped in this process.

7. Maximum care must be taken to avoid needle stick injury to practitioner and assistant staff. In the event of needle stick injury, the procedure must be terminated and the appropriate needle stick injury protocol followed.

8. Concentration of the sclerosant injected must be appropriate to the size of the vessel and the degree of flow in the vessel and must be in the following ranges:

    a. Sodium tetradecyl sulphate (STS) 0.1 – 1%. The maximum upper limit per person per treatment day is 4 mls of 3% STS.

    b. Polidocanol/Laureth-9 (Aethoxysklerol/ or (Sclerovein) 0.25 – 1.5%. The maximum upper limit of polidocanol is 2mg/kg patient body weight per treatment day because of potential for local anaesthetic toxicity.

9. Graduated compression stockings appropriate to the patient and the sclerosant treatment is applied immediately after treatment and before mobilisation.

10. Avoid high volume injections to reduce the risk of skin necrosis Inject the sclerosant with minimal pressures.

11. For patients with a history of neurological symptoms, including migraine, after previous sclerotherapy:
    a. Avoid injection of large volumes of foam or consider liquid sclerotherapy instead.
    b. Avoid Valsalva manoeuvres in the early period after injection
    c. The practitioner to place stocking on patient before they first stand up.
    d. Decide on case by case basis, whether to proceed based on clinical indication.

12. Removal of superficial clots is recommended to reduce the risk of pigmentation.

4 PROVIDE POST TREATMENT ADVICE TO PATIENT AND RECORD TREATMENT DETAILS

1. Patient is advised that s/he will be required to walk immediately after treatment and for a minimum of 30 minutes per day during treatment and for 2 weeks after the treatment course.

2. Patient is advised to avoid strain or strenuous activity for 7 days post treatment.

3. Ensure the patient understands all of the following symptoms of concern and knows when to contact the practitioner:

- Painful swollen limbs
- Chest pain
- Shortness of breath
- Migraines
- Cough
- Visual disturbance
- Weakness in arms or legs
- Difficulty speaking
- Sensory deficit
- Redness, heat or localised swelling over the treated vessel

4. Treatment records must include:

- Sclerosant used and its supplied concentration
- Sclerosant type, dosage or injected concentration
- Total volume injected in treated limb
- Accurate description of veins treated and location, i.e. saphenous trunks, tributaries and/or perforators.
- Compression hosiery fitted, size and class and recommended time of application.
- Patient instructions given
- Future treatments or Follow up indicated.
- Any adverse/unexpected events and/or interventions.
- Follow up appointment given within 6 weeks
- Post treatment assessment of degree of vein removal.
- Whether further treatment is indicated/offered after the post treatment assessment including the type of treatment, or whether the treatment plan has been completed.
- Any medication given?

5. Assessment records must include success of treatment and a description of degree of sclerosis of all relevant incompetent vessels.

6. Follow up is suggested for 3 month review and further treatment as indicated.

6 REVIEW AND AUDIT OF THIS PROCEDURE

This procedure will be reviewed annually by the ACP Education Committee. Compliance with this procedure will be assessed against the ACP standard Direct Vision Sclerotherapy ‘