Appendix 1 to Ultrasound Guided Sclerotherapy Standard

AUSTRALASIAN COLLEGE OF PHLEBOLOGY

CLINICAL PROCEDURES

CP –Ultrasound Guided Sclerotherapy- Clinical procedure

1 PURPOSE

This procedure summarises the actions required to diagnose venous disease using clinical examination and Duplex/Doppler ultrasound and to treat superficial venous incompetence using injected sclerosant under ultrasound guidance. It is a guideline of procedural notes for the treatment covered by the ACP Ultrasound Guided Sclerotherapy Standard 'Diagnose venous disease and treat superficial venous incompetence with injected sclerosants under Ultrasound Guidance'.

2 SCOPE

This procedure is to be followed by all ACP trainee and certified practitioners delivering this service to patients. Assessment of competence in following this procedure is measure by checking the practitioner as s/he treats the patient against the criteria specified in the ACP Ultrasound Guided Sclerotherapy Standard

3 REFERENCES

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4 DEFINITIONS/ACRONYMS

As per ACP Ultrasound Guided Sclerotherapy Standard.

PROCEDURE AND SPECIAL NOTES

1 CONDUCT INITIAL CONSULTATION

1.1 Information regarding venous incompetence, diagnosis and treatment alternatives.

Relevant to ACP Protocol: 'Informed Consent'

1. Practitioner explains nature of venous incompetence and the following symptoms of venous incompetence are described:
   Aching, throbbing, tired/heavy/restless legs/cramp, burning, itching, heat, varicose ulcers, varicose eczema.

2. Explain that a clinical examination needs to be followed by Duplex/Doppler aided diagnosis to confirm causes before the clinically indicated treatment plan can be confirmed and, at that time, risks of proposed treatment options will be discussed and written consent will be needed.

3. Explain that clinically indicated treatment with associated outcomes may include:

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

- Wearing compression hosiery will reduce symptoms and may limit the rate of deterioration of minor varicose veins.

- Direct Vision Sclerotherapy

- External laser treatment

- Ultrasound Guided Sclerotherapy. Advise that UGS is appropriate for all veins but those of a diameter of > 6mm may require a longer treatment schedule and increased rates of recanalisation may occur.

- Endovenous ablation by Laser or Radiofrequency may be used for saphenous veins. Advice is appropriate for large diameter veins ≥4 mm.

- Surgery – Advise is an option with increased risks.

1.2 Patient assessment and 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. In addition:

    - Previous vein treatment and any complications must be elicited and documented.

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

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

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

4. Determine the CEAP classification based on 1-3.

5. If there are symptoms, or clinical findings, such as abnormal ankle brachial indices suggestive of arterial disease, appropriate referral or investigation is required before treatment of the venous disease.

6. If UGS is being considered and there is history of thrombophilia, or it is suspected, a thrombophilia screen is required.

7. If UGS is a treatment option for the condition, inform the patient that multiple treatments may be needed.

8. It is recommended that photographs be taken before treatment. Pre-treatment photographs are filed with the patient's written or electronic medical records.

Relevant to ACP Protocol: 'Informed Consent' and 'Clinical Records'

9. Give patient a tentative diagnosis of his/her chronic venous disease based on his/her history and your clinical examination and discuss your preferred treatment option, assuming the diagnostic ultrasound confirms your view.

10. Take and record patient measurements to determine support hosiery required.

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

2 MAP DEEP AND SUPERFICIAL VEINS WITH DUPLEX/DOPPLER ULTRASOUND

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

1. With the patient standing, the entire venous system of each leg from groin to ankle is examined. Venous blood flow is augmented by manual muscle compression or the Valsalva manoeuvre.

2. By convention, antegrade blood flow is represented as blue on the Colour Doppler display and retrograde flow is represented as red.

   The competence of all superficial and deep veins and visible perforators is evaluated.

   Incompetence is defined as retrograde flow exceeding 0.5sec in duration and therefore will present as red on the Colour Doppler display.

   NOTE: Retrograde flow of less and 0.5sec can be seen in normal veins.

3. Measure and record the diameter of the GSV at the SFJ, mid thigh and knee: and the SSV at the SPJ and mid calf, to give a guide for technique selection and injection volume required.

4. If superficial thrombophlebitis (STP) is identified, measure and institute appropriate management.

5. If acute DVT is identified, measure its extent and length in the vein and act quickly to initiate a management plan to minimise he risk of venous thromboembolism.

6. Record the nature and location of any pathology relevant to the venous incompetence or in close proximity to the incompetent vein/s. This may include:
   - Bakers cyst
   - Grafts
   - Popliteal artery aneurysm
   - Oedema
   - Lipomas and other masses
   - Fascial herniation
   - Lymphoedema

7. Findings must be accurately recorded in relation to an anatomical landmark and in a pictorial scheme which is in a format able to be interpreted easily at the time of injection.

8. A copy of the findings and the proposed treatment plan for the patient must be sent to the referring practitioner AND the patient's GP.

3 ESTABLISH AND AGREE ON A TREATMENT PLAN

Relevant to ACP Protocol: 'Informed Consent'

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

2. Update initial cost estimate 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.

4. Explain the risks associated with recommended treatment alternatives under this standard and the possible actions needed in the event of adverse outcomes.

Risks associated with UGS 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 or aspiration when due to trapped blood.).

- 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.

- Risk of arterial injection in < 0.1% of cases with severe skin and muscle trauma, large tissue necrosis and possible amputation – isolated cases.

- 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 is the only treatment required.

- Death – extremely rare

*Modified version, Recommendation 1, European Guidelines for Sclerotherapy in Chronic Venous Disorders, Phlebology, 2013.

Risks associated with Endovenous ablation by Laser or Radiofrequency to be explained are:

- Bruising – wait for natural resolution
- Thermal injury to surrounding muscle, skin or nerves – Very rare; treat as a burn; ice packs, elevation.
- VTE – Venous thromboembolism – treat by hospitalisation or outpatient treatment for further investigation and treatment with anti-coagulants. D dimer blood testing and ultrasound assessment may be helpful in diagnosis.
- Infection – treat with antibiotics.
- Laser fibre breakage requiring surgical retrieval (rare)

Risks associated with Surgery include:

- Nerve injury, VTE, wound infection, lymphocoeles, lymphoedema, haematomas, reaction to general anaesthetic, scarring, Telangiectatic matting, etc.

3 ESTABLISH AND AGREE ON A TREATMENT PLAN (CONTINUED)

5. Having agreed on a treatment plan, both practitioner and patient must sign the informed consent document.
6. Instructions are given for the pre-operative requirements and post-operative requirements appropriate to the treatment method agreed.

   i.e. Pre and post-operative UGS instructions:

- Patient is advised that s/he will be required to walk at least 30 minutes/day during and 2 weeks after treatment.
- Patient is advised to avoid strain or strenuous activity for 3 weeks post treatment.
- Patient is instructed to wear Class 2 compression hosiery or compression bandages for a minimum of 2 weeks post treatment.

7. Instructions regarding travel:

Pre operatively.

-Patient is advised to avoid continuous air or vehicular travel > 5 hours for 1 week prior.
-If vehicular travel > 5 hours necessary, advise patient to have regular breaks and mobilise.
-If travel necessary, consider anticoagulation and if long distance travel of >5 hours occurs within one week preoperatively, check for DVT

Post operatively.

-Given risk of DVT associated with flying, we recommend no overseas travel for flights >5 hours for four weeks. If necessary, flights < 5 hours are acceptable, if the patient is mobilising.

-It is common to have phlebiltis 4-6 weeks post op. The patient may want to delay long haul travel until after this time because of difficulties with follow up.
-If patient is going to travel within first week post op, assess DVT risk and if appropriate consider anticoagulation.

4 INJECT VEINS WITH SCLEROSANT UNDER ULTRASOUND GUIDANCE.

Relevant to ACP Protocol: 'Infection control', 'Management of waste and Hazardous Substances' and Clinical emergency response and transfer, surgical emergencies, resuscitation, transfer and referrals'

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

2. The area to be treated must be clean. It may be wiped with an alcohol swab or cleanser and allowed to air 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 to draw sclerosant out of vial into a sterile disposable syringe.

4. The ACP recommends that polidocanol/Laureth-9 or STS can be used as a liquid or foam.

5. Liquid or foam is prepared in the concentration and volume as detailed in the UGS standard, i.e.

    - Maximum volume of 3% STS injected as a liquid is 4 mls (equivalent to 0.12g per patient per day), irrespective of the dilution used.

    - Air or a mixture of carbon dioxide and oxygen is recommended as the gas of choice for generating sclerosant foam for all indications.

    - For any detergent sclerosant, foam dilution range is between 1 part liquid and 1 part appropriate gas (air, CO2, O2), to 1 part liquid/4 parts appropriate gas.

    - The maximum upper limit of polidocanol is 2mg/kg patient body weight per treatment day.

    - The total volume of sclerosant foam injected in one day should not normally exceed 20ml regardless of the ambient air dilution used for STS or polidocanol.

      Truncal veins e.g. GSV: In general, a maximum of 10ml per leg should be adhered to. Care should be taken not to inject large boluses of foam near the junctions. Due to concerns about air embolus, large single volumes should not be used in the proximal trunk veins. We recommend careful administration of sclerosant in small aliquots of 0.5 to 3ml per injection point. We recommend against 'infusion' of foam from a single entry point into saphenous trunks and recommend multiple small boluses.

      Tributaries (once trunks treated): Dose depends on sclerosant concentration, gas used, vein treated. In general, a maximum of 10ml per leg should be adhered to. However once truncal veins have been closed, in very large tributaries volumes can be increased to 15-20ml (provided foam is not noted on ultrasound to extend into the deep system) and no more than 20ml is injected for the session i.e. if larger doses are used the maximum foam injected in that session is 20ml regardless of whether one or two legs are treated.

6. Use aseptic techniques and minimise the time between foam preparation and injection.

7. Use a new 25 gauge 1 ½ inch needle to inject.

8. A new needle and syringe is used for every penetration of the multidose vial containing sclerosant.

   Note 1: Needles are not handled directly and are discarded into "sharp bins" immediately after each injection.

   Note 2: 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 protocol followed.

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

10. To improve the general safety of foam sclerotherapy:
    a. Aim to inject a highly viscous foam into varicose veins
    b. Avoiding patient or leg movement for a few minutes after injection
    c. Avoiding Valsalva manoeuvre

11. Placement of the sclerosant in the vein depends on the technique used, e.g., for Liquid sclerosant, the first injection is placed 3-10 cm below the SFJ; c.f. For Foam sclerosant, more typically, it is placed 5-10cm below the SFJ. Subsequent injections will be placed immediately distal to the previous foam interface or spasm.

12. The "ELLE" technique (Extended longline echosclerotherapy) is a variation which involves the use of catheter inserted into the vein,A through an incision, causing the vein to spasm. The effect of this is a reduction of vein diameter, which minimises the sclerosant volume needed. Ultrasound is used to confirm the placement 2-3cm below the SFJ, and sclerosant injections are begun as the catheter is withdrawn.

13. 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.

14. Before sclerotherapy we recommend to inform the patients about:
    a. Details of the sclerotherapy procedure and post-procedure management plan
    b. Common adverse events, as well as serious risks
    c. The patients should be told about the success rate, rate of recurrence, the possible need for short and medium term follow up, as well as the need for further treatments
    d. Inform patients that foam sclerotherapy is more effective than liquid sclerotherapy. Ultrasound guidance may help prevent adverse events but this does not necessarily reduce the likelihood of common adverse outcomes.
    e. The patients should be made aware of alternative treatment options.

15. Full diagnostic evaluation including history taking, clinical examination and direct ultrasound (DUS) investigation is required before commencing sclerotherapy treatments. Colour wave Doppler, rather than DUS may be sufficient for telangectasias and reticular varicose veins.

5 PROVIDE POST TREATMENT ADVICE TO PATIENT AND RECORD TREATMENT DETAILS.

Relevant to ACP Protocol: 'Clinical Records', 'Medicine Management'

1. Ensure the patient understands all of the following post treatment symptoms and knows to contact the practitioner if any are of concern:

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

2. Treatment records must include:

    - Sclerosant used and its supplied concentration
    - Formulation and technique used (Liquid or foam), and dilution
    - Total volume injected in treated leg
    - Accurate description of veins treated and location, i.e. saphenous trunks, tributaries and/or perforators.
    - Record application and type of Class 2 graduated compression stockings(GCS)
    - Patient instructions given
    - Future treatments or Follow up indicated
    - Any adverse/unexpected events and/or interventions
    - 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

- Treatment parameters used for each area treated

- Any adverse/unexpected events and/or interventions

- Follow up appointments given within 1 week for DVT check, within 6 weeks of treatment series and at 1 year post treatment.

- Post treatment management plan including:

    a) Placement time and class of GCS
    b) Signs of adverse reactions
    c) Recommendations given to patient

3. Assessment records must include degree of success of treatment, including a description of degree of sclerosis of all relevant incompetent vessels, any recanalisation or unexpected outcomes, further treatment indicated/offered and patient satisfaction.

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 'Ultrasound Guided Sclerotherapy'.

7 ATTACHMENTS

1. Ultrasound Guided Sclerotherapy consent form