Appendix 1 to Microsclerotherapy Standard

AUSTRALASIAN COLLEGE OF PHLEBOLOGY

CLINICAL PROCEDURES

CP - 'Microsclerotherapy - 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 measured 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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Tibbs DJ. Varicose veins and related disorders. Oxford: Butterworth-Heinemann; 1992. ISBN 0750610328

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4 DEFINITIONS/ACRONYMS

As per ACP Ultrasound Guided Sclerotherapy Standard.

PROCEDURE AND SPECIAL NOTES

Summary of actions	Relevant ACP protocol	Procedural notes for this action
1 CONDUCT INITIAL CONSULTATION **1.1 Information regarding venous incompetence, diagnosis and treatment alternatives**	'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 option 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 • Microsclerotherapy • External laser treatment • Ultrasound Guided Sclerotherapy Advise that UGS is appropriate for all veins, but those of a diameter of > 6 mm may require a longer treatment schedule and increased rates of recanalisation may occur. • Endovenous ablation by Laser or Radiofrequency Advise is appropriate for large diameter veins ≥ 6 mm and may be used for veins with diameter ≥ 4 mm. • Surgery – Advise is an option with increased risks.

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1.2 Patient assessment, and initial consultation records	'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.

Summary of actions	Relevant ACP protocol	Procedural notes for this action
	'Informed consent', '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	'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 than 0.5 sec 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 SVT 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 the risk of venous thromboembolism.

Summary of actions	Relevant ACP protocol	Procedural notes for this action
	'Infection control' and 'Management of waste and Hazardous Substances'	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 TREATMENT PLAN		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. <u>Risks associated with UGS to be explained are:</u> • Telangiectatic matting in < 2% of cases. If this does not naturally resolve over 6 months, further treatment of underlying venous incompetence may be required. • Ulceration. Rare. Apply colloidal dressings.

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3 ESTABLISH AND AGREE TREATMENT PLAN	'Informed Consent'	• Localised inflammation or pain in the treated vein indicated by redness, tenderness or swelling in the specific region of treatment. -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. • Brown staining caused by haemosiderin deposition in the skin. Resolves in 6 – 12 months, although may persist longer in a small number of cases. • Visual disturbances and migraine – rare. • Serious adverse neurological events such as TIA/CVA –very rare. • Cough and chest discomfort - rare. • Rare nerve injury. • Rare possible reactions such as DVT/ Pulmonary embolism/anaphylaxis in < 0.02% of cases – treat DVT/pulmonary embolism by hospitalisation or outpatient treatment for further investigation and treatment with anti-coagulants; - treat anaphylaxis immediately with intramuscular adrenaline, oxygen and other supportive medications. • Risk of arterial injection in <0.1% cases with severe skin and muscle trauma and possible amputation. • 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.

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3 ESTABLISH AND AGREE TREATMENT PLAN	'Informed Consent'	<u>Risks associated with Endovenous ablation by Laser or Radiofrequency to be explained are:</u> • Infection – treat with antibiotics • 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 dimmer blood testing and ultrasound assessment may be helpful in diagnosis. <u>Risks associated with Surgery are:</u> Nerve injury, VTE, wound infection, lymphocoeles, lymphoedema, haematomas, reaction to General anaesthetic, scarring, Telangiectatic matting etc. 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. UGS instructions: • Patient is advised to avoid air or vehicular travel > 4 hours for 1 month prior and 1 month post treatment. If the patient has travelled >4 hours within the last 4 weeks, re-check the deep vein system to exclude DVT • If the patient is to travel >4 hours within 4 weeks post treatment, prescribe Low Molecular weight Heparin as a precaution against DVT.

Summary of actions	Relevant ACP protocol	Procedural notes for this action
…3 ESTABLISH AND AGREE TREATMENT PLAN continued	'Informed Consent'	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.
4. INJECT VEINS WITH SCLEROSANT UNDER ULTRASOUND GUIDANCE	'Infection control', 'Management of waste and Hazardous Substances', '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. Polidocanol or STS can be used as a liquid or foam, but it is recognized that turning a liquid into a foam changes the nature of the agent. Hence foam is an off label use of the liquid. 5. To prepare foam sclerosant for injection, the Tessari technique is recommended, using aseptic techniques, and injecting foam promptly. 6. Change the needle to a new 25 gauge 1½ inch needle to inject.

Summary of actions	Relevant ACP protocol	Procedural notes for this action
	'Infection control', 'Management of waste and Hazardous Substances', 'Clinical emergency response and transfer, surgical emergencies, resuscitation, transfer and referrals'	7. 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 (≡ .12g per patient per day). • Foam dilution range is between 2 parts liquid/3 parts ambient air to 1 part liquid/4 parts ambient air. • The maximum volume of 3% STS used as foam does not exceed 4 ml liquid per day irrespective of dilution used. • The maximum volume of 5% polidocanol injected as a 1:3 ambient air diluted foam is 16 mls (≡.2g) or 20ml for a 1:4 ambient air diluted foam per patient per day. 8. The maximum upper limit of polidocanol is 2mg/kg patient body weight per treatment day. 9. 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 needlestick injury to practitioner and assistant staff. In the event of needle stick injury the procedure must be terminated and the appropriate Needlestick protocol followed. 10. 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 5-10 cm below the SFJ. Subsequent injections will be placed immediately distal to the previous foam interface or spasm.

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	'Infection control', 'Management of waste and Hazardous Substances', 'Clinical emergency response and transfer, surgical emergencies, resuscitation, transfer and referrals'	11.The "ELLE" technique (Extended longline echosclerotherapy) is a variation which involves the use of catheter inserted through an incision up into the vein, 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 2-3 cm below the SFJ, and sclerosant injections are begun as the catheter is withdrawn.
5 PROVIDE POST TREATMENT ADVICE TO PATIENT AND RECORD TREATMENT DETAILS	'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

Summary of actions	Relevant ACP protocol	Procedural notes for this action
	'Clinical records', 'Medicine Management'	• Compression hosiery fitted and class, & time of application • 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
		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