Appendix 1 to Endovenous Laser Ablation Standard

AUSTRALASIAN COLLEGE OF PHLEBOLOGY

CLINICAL PROCEDURES

CP - 'Endovenous Laser Ablation - 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 Endovenous Laser Ablation (EVLA). It is a guideline of procedural notes for the treatment covered by the ACP Endovenous Laser Ablation Standard 'Diagnose venous disease and treat superficial venous incompetence with Endovenous Laser Ablation'.

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 Endovenous Laser Ablation Standard.

3 REFERENCES

As per ACP Endovenous Laser Ablation Standard, including

Bergan, J. The Vein Book. Academic Press. **ISBN:** 0123695155.

Goldman MP, Bergan JJ, editors. Ambulatory treatment of venous disease: an illustrative guide. St Louis: Mosby; 1996. ISBN 0815137583

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

Tretbar LL. Venous disorders of the legs: principles and practice. London: Springer; 1999. ISBN 1852330074

Weiss Robert A,Feied Craigt, Weiss Margaret A. Vein Diagnosis and Treatment – A Comprehensive Approach. McGraw-Hill 2001

4 DEFINITIONS/ACRONYMS

As per ACP Endovenous Laser Ablation Standard.
SFJ ≡ Sapheno-Femoral Junction
SVT ≡ Superficial venous thrombophlebitis
Varicose vein ≡ Any vein >2mm with demonstrated retrograde flow indicating incompetence.
EVLA Endovenous Laser Ablation
TA Tumescent Anaesthesia

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5 PROCEDURE AND SPECIAL NOTES

Summary of actions	Must follow 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, trivial 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 trivial varicose veins • Microsclerotherapy • External laser treatment for spider veins • 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 as 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', 'Clinical records'	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. 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. 2. All visual secondary complications such as varicose eczema, venous ulceration, chronic venous hypertension, and lipodermatosclerosis are identified during careful clinical examination. 3. If there are symptoms, or clinical findings such as abnormal ankle brachial indices suggestive of arterial disease, it will be appropriate referral or investigation is required before treatment of the venous disease. 4. If EVLA is being considered and there is history of thrombophilia or it is suspected, a thrombophilic screen is required. 5. If EVLA is a treatment option for the condition, inform the patient that multiple treatments of UGS may be needed following EVLA in order to complete the treatment. 6. It is recommended that photographs be taken before treatment. Pre-treatment photographs are filed with the patient/s written or electronic medical records. 7. 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. 8. Take and record patient measurements to determine support hosiery required. 9. 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	'Infection control' and 'Management of waste and	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

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DUPLEX/DOPPLER ULTRASOUND	Hazardous Substances'	manouevre. 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. 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.

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3 ESTABLISH AND AGREE TREATMENT PLAN	'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.

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…3 ESTABLISH AND AGREE TREATMENT PLAN **continued** Continued over…	'Informed Consent'	Risks associated with Endovenous ablation by Laser to be explained are: • 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 as required. Risks associated with UGS to be explained are: • Telangiectatic matting in 10-30% of cases. If this does not naturally resolve over 6 months, further treatment of underlying venous incompetence may be required. • 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 if necessary by the phlebologist. • 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 in < 2 % of cases. • Cough and chest disorders - 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.

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…3 ESTABLISH AND AGREE TREATMENT PLAN continued	'Informed Consent'	Risks associated with Surgery are: 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. Instructions are given for the pre-operative requirements and post-operative requirements appropriate to the treatment method agreed. e.g. For EVLA + UGS: • 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, repeat the mapping? I.e. re-check the deep vein system to exclude DVT; . If the patient is on Warfarin, ensure that the INR is within the therapeutic range • If the patient is to travel >4 hours within 4 weeks post treatment, prescribe Low Molecular weight Heparin as a precaution against DVT. • 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 1 week post treatment.

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4 Endovenous Laser Ablation of Incompetent Saphenous Veins	'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 and prepped for a sterile theatre procedure. 3. The SFJ or SPJ is marked by a sonographer or phlebologist and the contour of the vein is also marked. 4. The entry point for percutaneous entry of the vascular needle is anaesthetized with local anaesthetic. The stab incisions are made with a no 11 surgical blade through the dermis. 5. A percutaneous entry needle such as the Cook BSDN-18-7.0 is inserted into the appropriate entry point of the saphenous vein (typically the most distal straight component of the incompetent saphenous vein) 6. An appropriate guide wire is inserted through the vascular needle to within 2-3cm of the SFJ or SPJ to allow insertion of the introducer set. The vascular needle is then removed. 7. As preparation the introducer is inserted inside the sheath. With some laser systems such as Biolitec 980 nm, no introducer is used and the sheath acts as an introducer. 8. The sheath (and introducer) is then placed over the guide wire to within 2-3cm of the SFJ or SPJ under ultrasound guidance. 9. The guide wire is removed leaving the sheath (and introducer) positioned to within 2-3cm of the SPJ or SFJ. The laser fibre may be introduced at this stage or after administration of the tumescent anaesthesia. To avoid clotting the sheath is kept flushed with saline when it is not occupied by the introducer or the laser fibre. 10. Tumescent anaesthesia is administered to the entire length of the saphenous vein to be treated with EVLA. The TA can be administered by serial injections creating a halo of TA around the saphenous vein under ultrasound guidance ensuring that placement is such that there are no gaps. An infiltration pump (such as a Klein pump) can be used to pump the TA. Ensure coverage is even over the length of the targeted vein and take particular care to ensure adequate coverage of the proximal section of the vein near the junction as this is the hardest area to achieve good compression.

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…4 INJECT VEINS WITH SCLEROSANT UNDER ULTRASOUND GUIDANCE Continued	'Infection control', 'Management of waste and Hazardous Substances', 'Clinical emergency response and transfer, surgical emergencies, resuscitation, transfer and referrals'	11. It must be clearly identified on ultrasound that the needle is not intravascular before administering the TA to avoid lignocaine toxicity. An early warning that this may have occurred is tachycardia due to the adrenaline in the TA. Systemic symptoms such as tachycardia may indicate inadvertent intravascular injection of TA. Immediately cease injection of TA and monitor patient with pulse oximetry, blood pressure and monitor cardiac rhythm. 12. Once adequate coverage of TA is documented by ultrasound, the laser fibre is inserted into to the sheath to within 1-3cm of the SFJ or SPJ. The sheath is then removed. NB. With the Cooltouch 1320nm system a fibre test should be performed on the laser fibre. A failed test will require re-cleaving the laser fibre. Laser fibres have FDA approval for repeat use upto 9 times. Each fibre should be examined thoroughly before use for flexibility and potential breaks before the fibre test. 13. With Cooltouch the laser fibre is then placed in the mechanical drawback device 14. The appropriate settings are selected on the laser eg for Cooltouch 1320nm typical settings are 50Hz and between 5 to 10W depending on the size of the vein and the results of the fibre test. Appropriate settings for Biolitec 980nm are patient/vein dependent but typical settings are 12-14 watts on continuous mode. To achieve the recommended 60-80 Joules/second delivery the withdrawal speed is 3-4 mm per second. For Diomed 810nm the settings are 14W with a withdrawal speed of 3mm/second. In general the energy delivered by any of the lasers should generate between 60-100J/cm. 15. The aiming beam is turned on as double confirmation that the laser fibre is below the SFJ 16. The laser is then activated. Probe pressure over the SFJ or SPJ ensures protection of the femoral vein from the laser energy. Drawback of the laser fibre as the laser is activated may be manual or via a mechanical pullback device. For Cooltouch the rate of withdrawal can be varied between 0.5mm/sec to 1mm/sec but is generally at 1mm/second. Pulsing is not started with mechanical pullback devices until there is ultrasound evidence that withdrawal has commenced. 17. The laser is placed on standby just before withdrawal of the fibre from the skin. 18. Recordings are taken of the number of pulses fired, the energy used and the length of the treated vein.

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5 PROVIDE POST TREATMENT ADVICE TO PATIENT AND RECORD TREATMENT DETAILS		1. Ensure the patient understands all of the following symptoms of concern, and knows when to contact the practitioner: • Painful or swollen limbs – may indicate DVT and requires immediate assessment by ultrasound. • Chest pain, cough or shortness of breath may indicate a pulmonary embolus in which case patients are directed to ring an emergency ambulance. • Redness, heat or localised swelling over the treated vessel indicates a thrombophlebitis or panniculitis which can be treated with NSAID's. 2. Where there are risk factors for thrombophilia such as age >60, obesity, immobility, OC/HRT use, cancer or a PH or FH history of STP or DVT consider covering the procedure with prophylactic low molecular weight heparin such as Clexane 20-40mg daily for 5-7 days starting at the time of the EVLA.
…5 PROVIDE POST TREATMENT ADVICE TO PATIENT AND RECORD TREATMENT DETAILS continued	'Clinical records', 'Medicine Management'	3. Treatment records must include: Laser settings and number of times laser fibre has been used. Length of vein treated • Accurate description of veins treated and location • i.e. saphenous trunks, tributaries and/or perforators • If UGS is performed record:Sclerosant used and its supplied concentration • Formulation and technique used (Liquid or foam), and dilution • Total volume injected in treated leg • 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, within 6 weeks, within 6 months and at 1 year post treatment. 4. 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 'Endovenous Laser Ablation'.