Direct Vision Sclerotherapy

Assess and treat abnormal superficial venous network with injected sclerosants

Contents

INTRODUCTION

This standard is for practitioners needing to identify that presenting superficial and reticular veins are indicative of superficial venous disease, and to treat these using injected sclerosants. It has been developed by Australasian College of Phlebology (ACP) doctors working in the Phlebology modality***** 'Direct Vision Sclerotherapy' as an assessment tool for doctors in training for their Part I qualification (ACP Certificate in Phlebology), and for recertification of doctors in their maintenance of professional standards (MOPS) programme.

The criteria and outcomes of this standard consider competency in terms of interpersonal, diagnostic and management interactions. It is strongly procedure based, while at the same time focusing on the systems and processes required to ensure a safe and responsive service is provided.

*****ACP defined modalities of Phlebology:

Part 1 Direct Vision Sclerotherapy
Part 2 Ultrasound Guided Sclerotherapy Ambulatory Phlebectomy Endovenous Ablative techniques

1. Scope of Application

1.1 This Standard is copyright to ACP.

1.2 It is used by certified ACP phlebologists in their role as supervisors to assess trainee competence in treating superficial reticular veins and telangiectases. In addition it is used on an ongoing basis, as a reassessment tool to ensure that phlebologists/doctors continue to meet the standard required in delivering this service to patients.

1.3 This standard is used periodically during and at the end of the training period. It is also used by ACP trainees, and ACP certified phlebologists working in the modality of direct vision sclerotherapy to self-monitor their own performance.

1.4 Assessment as competent in this standard* IS sufficient for doctors to gain ACP Level 1 certification.

1.5 * Refer ACP Training Protocols for Training (including examination) and supervision requirements mandatory under this standard.

1.6 The training programme required for this standard is not open to nurses. If however an ACP phlebologist employs a nurse to perform direct vision sclerotherapy the nurse must meet this standard.

2. Purpose

Practitioners credited with this standard are able to establish patient needs, communicate and manage risks and deliver safe, timely and appropriate direct vision sclerotherapy treatment to an abnormal superficial venous network which meets their patients' expectations.

3. Context/Environment/Service Delivery

3.1. Australia
The licensing requirements for private hospitals, of which day procedures and are a part, differ in each State and Territory. It is the obligation of each practicing member of ACP to comply with the licensing standards outlined in the Acts and Regulations of their state or territory.

In summary:

New South Wales
In NSW private hospitals and day procedure centers are licensed under the *Private Health Facilities Act 2007* Private health facilities must meet all the general licensing standards set out in Schedule 1 of the *Private Health Facilities Regulation 2010* and any associated licensing standards that apply to each class of the facility as detailed in Schedule 2 of the Regulation.Licensing is overseen by the Private Hospital Unit within NSW Ministry of Health.

Victoria
The Department of Health is responsible for the regulation of private hospitals and day procedure centers under the Health Services Act 1988 and the Health Services (Private Hospitals and Day Procedure Centers) Regulations 2002.

Queensland
Private hospitals within Queensland are licensed under the *Private Health Facilities Act 1999*. Queensland has a Clinical Services Capability Framework for Licensed Private Health Facilities that specifies support services, staff profiles and minimum safety standards that should be met by private health facilities to ensure safe and appropriate supported clinical services.

Additional reporting requirements are imposed on licensed private hospitals through the *Health Quality and Complaints Commission Act 2006*.

In addition to these quality and safety reporting requirements, private hospitals in Queensland are required to provide data to the Queensland Health Admitted Patient Data Collection (QHAPDC) and to the Queensland Health Monthly Activity Collection (QHMAC).

South Australia
Within South Australia, the *Health Care Regulations 2008* and the *Health Care Act 2008* specify the regulations that govern the licensing of private hospitals.

Western Australia
Private hospitals and day hospitals are licensed within Western under the legislative framework provided by the *Hospitals and Health Services Act 1927*, the *Hospitals (Licensing and Conduct of Private Hospitals) Regulations 1987*, the *Hospitals and Health Services (Day Hospital Facility) Determination 2005*, and the *Hospitals and Health Services (Day Hospital Facility) Determination (No. 2) 2005*.

Tasmania
In Tasmania, private hospitals and private day hospitals are licensed under the *Health Services Establishments Act 2006.*

Northern Territory
In NT, private hospitals are licensed under the *Private Hospitals Act*. This Act specifies the requirements for licensing and arrangements for the management and inspection of private hospitals.

Australian Capital Territory
In the ACT, private hospitals are licensed under the *Public Health Act 1997*.

3.2 New Zealand
Premises used by practitioners in delivering this service must comply with the relevant sections of ANZS Draft 'Standards for Day Stay and Office based surgery and other procedures'.
The clauses in the NZS Draft Standard relevant to the delivery of this service are those pertaining to 'Office-based surgery, or other procedures' i.e. this standard does not require the equipment/facilities of an operating theatre.

These clauses require persons delivering this service to meet both facility requirements and those pertaining to consumer/patient rights, consent, Treaty of Waitangi (NZ), cultural safety issues, and complaints. In addition management specifications relating to clinical management and personnel, quality and risk management including Infection control, consumer/patient selection, clinical emergency response and transfer, clinical records, and medicine management must be met in the delivery of this service.

4. Entry Requirements

4.1 Doctors registered with the Australian or NZ Medical Council who are enrolled as members of ACP and are in training towards the ACP Part 1 Certificate. (Refer ACP Training Protocol for criteria for enrolment).

4.2 Phlebologists registered with the Australian or NZ Medical Council who are Fellows of ACP undergoing recertification.

5. References

Australia:
Private Hospital Data Collection Final Review, Department of Health. Australian Government, http://www.health.gov.au/internet/publications/publishing.nsf/Content/
NSW Ministry of Health, Licensing of Private Health Facilities, http://www.health.nsw.gov.au/Hospitals/privatehealth/Pages/licensing-of-private-health-facilities.aspx
Private Health Facilities Regulation 2010, NSW Government www.legislation.nsw.gov.au
Private Health Facilities Act 2007 No 9, NSW Government, Current version for 2 November 2015 to date, www.legislation.nsw.gov.au
NSW Ministry of Health, Policy Directive: Clinical Procedure Safety, 2014
Health Services (Private Hospitals and Day Procedure Centres) Regulations 2013, www.legislation.vic.gov.au
Health Services Act 1988. Victorian Government.
Queensland Government *Private Health Facilities Act 1999*, https://legislation.qld.gov.au
Monthly Activity Collection Manual, Private Facilities. Queensland Health, July 2010.
Health Care Regulations 2008 and the Health Care Act 2008, South Australia Health, South Australia Government, http://www.legislation.sa.gov.au
Hospitals and Health Services Act 1927, updated 2010, Western Australia Health, Western Australia Government, http://www.slp.wa.gov.au
Private Hospitals Act, Department of Health and Families, Northern Territory, Northern Territory Government, http://www.austlii.edu.au/au/legis/nt/consol_act/pha215/
Health Services Establishments Act 2006, Department of Health and Human Services, Tasmania, Tasmanian Government, http://www5.austlii.edu.au/au/legis/tas/consol_act/hsea2006295/
Public Health Act 1997, ACT Health, ACT Government, http://www.legislation.act.gov.au

New Zealand:
NZS 8164:2005 Day-Stay Surgery and Procedures.
NZS 8165:2005 Rooms/Office-based Surgery and Procedures. ACP/NZCAM Maintenance of Professional Standards (MOPS) Programmes.

'Training Programme towards NZCAM Membership and Fellowship Certification' including: ACP Protocols: 'Training', 'Informed Consent', 'Infection Control', 'Management of waste and hazardous substances', 'Clinical Records', 'Medicine management', 'Local and regional anaesthesia', 'Clinical emergency response and transfer, surgical emergencies, resuscitation, and referrals', 'New procedures/products Approvals', 'Advertising', 'Ethics'.

AND Modality specific Training Curriculum.
TAPS (Therapeutic Advertising Pre-vetting system) Guideline No. 16 'Advertising by Healthcare Professionals Appearance Medicine and Eye Clinics' (NZ)
Medical Practitioners Act (1995) (NZ) Medicines Act 1981(NZ)
Medicines Regulations 1984(NZ) Medsafe guidelines (January 2001) (NZ) Health Practitioners Competency Act (Sept 2004)

6. Risk Management

6.1 All agents other than Fibrovein TM (STD, Pharm, UK) have not been approved for sclerotherapy in New Zealand. The Medicines Act (1981) requires written patient consent to be obtained prior to the treatment for other sclerosants.

6.2 FibroveinTM is approved for its use in treating leg veins with up to 4 mls of 3 % per session

6.3 The ACP approved sclerosants covered by this standard are: STS (FibroveinTM) supplied as a 0.2%, 0.5%, 1%, 3% solution

6.4 AethoxysklerolTM (Kreussler Pharma, Germany) i.e Polidocanol/ Lauromacrogol 400 supplied as a 0.5%,1% and 3% solution or Sclerovein(Resinag AG or Omega Laboratories, Canada) as a 5% solution.

6.5 The maximum dosage of STS injected per patient per day (regardless of concentration used), under this standard, is 4mls of 3% liquid.

6.6 Maximum dosage of polidocanol per patient per day under this standard is 2mg/Kg body weight.

6.7 ACP recommends use of sclerosants in liquid or foam form.

6.8 Exclude a past history of anaphylaxis to sclerosants, thrombophilia and note any absolute or relative contraindications to direct vision sclerotherapy.

6.9 If there is a prothrombotic tendency, consider the need for prophylactic anticoagulation for 5-7 days post treatment.

6.10 All potential sources of venous reflux should be excluded by a full assessment with Duplex ultrasound before embarking on direct vision sclerotherapy.

7. Special Notes

7.1 Advertising

7.1.1 in Australia:

Section 133 of the National Law prohibits advertising that:

- is false, misleading or deceptive or is likely to be so
- offers a gift, discount or other inducement to attract a user of the health service without stating the terms and conditions of the offer
- uses testimonials or purported testimonials
- creates an unreasonable expectation of beneficial treatment, and/or encourages the indiscriminate or unnecessary use of health services.
- These guidelines cover all types of advertising, including social media, blogs and websites.
- See AHPRA Guidelines for Advertising Regulated Health Services under Codes, Guidelines and Policies, http://www.medicalboard.gov.au

7.1.2 in New Zealand:

Direct to consumer advertising for treatment of veins must not mislead the public. Practitioners must not front, speak or appear in advertisements for medical clinics as this would be regarded as 'healthcare professional endorsement by implication' (Section 58 of the NZ Medicines Act (1981).

7.2 Consent

Written informed consent is obtained following the ACP Informed Consent Protocol.

8. Definitions

ACP = Australasian College of Phlebology

STS = Sodium Tetradecyl Sulphate

UGS = Ultrasound Guided Sclerotherapy

POL = Polidocanol

Varicose Vein = Any superficial vein >2.5mm which is an abnormal, tortuous, subcutaneous, palpable vessel demonstrating reflux.

Reticular Vein = Vessels belonging to the subdermal venous plexus appearing in a reticulate pattern which may be competent or incompetent and are not palpable.

Venulectases = >1mm size telangiectatic vessels which appear blue because of their larger size.

Telangiectases = <1mm size veins which lie superficially in the dermis and appear red.

Definition of Phlebologist = Fellow of ACP whose training includes vascular ultrasound, who is providing treatment to patients under this standard.

Definition of Practitioner = Fellow or Member of ACP who is providing this service under this standard.

Definition of Consumer = For the purposes of this Standard, patient refers to the consumer.

9. Attachments

Appendix 1	'Direct vision sclerotherapy - Clinical procedure' (CP- direct vision sclerotherapy.doc)
Appendix 2	'ACP Training Requirements' in ACP Handbook – Specifications for the modality.
Appendix 3	ACP Curriculum content for modality.

STANDARD ELEMENTS AND CRITERIA

1 CONDUCT INITIAL CONSULTATION AND CLINICAL ASSESSMENT

1.1 Information regarding venous incompetence, diagnosis and treatment alternatives

Outcome: The patient is fully informed of the nature of direct vision sclerotherapy treatment. S/he understands that a diagnostic process is necessary before treatment to confirm that the presenting superficial venous network is not indicative of underlying venous incompetence.

Criteria

1.1.1 The patient is assessed personally by the practitioner.

1.1.2 The patient's expectations are discussed and documented.

1.1.3 The patient is informed that treatment of abnormal superficial venous networks is a two stage process which comprises diagnosis followed by clinically appropriate treatment.

1.1.4 Risks of the proposed treatment and possible actions in the event of adverse outcomes are explained.

1.1.5 The patient is given adequate opportunity to ask questions.

1.1.6 The patient understands that after diagnosis, s/he will be asked for written consent to authorise the treatment, and is offered more time to consider the treatment before proceeding if s/he is unsure in any way.

1.1.7 The patient is advised that the wearing of graduated compression hosiery appropriate to the size of the vessel treated is required. The duration of application varies from but needs to be related to the size of the vessel, concentration of sclerosant and other clinical parameters such as thrombophilia risk factors.

1.2 Patient assessment and initial consultation records

Outcome

A full medical history and clinical assessment of the patient is documented and discussed with the patient; contra-indications are excluded, and suitability for diagnostic and subsequent treatment confirmed.

Criteria

1.2.1 The following patient information is documented:

- Age
- Onset of vein problem
- Onset of symptoms if appropriate
- Past medical /surgical history and associated complications including thrombophilia, patent foramen ovale (PFO) and migraine with aura.
- Previous vein treatment
- Family History of vein disease, thrombophilia, coronary artery disease, peripheral vascular disease Allergies
- Current medications including oral contraceptives and hormone replacement therapy Smoking history
- Obstetric history

1.2.2 Pre-operative blood tests appropriate to the treatment are ordered.

1.2.3 The CEAP clinical classification of the chronic venous insufficiency is accurate and documented.

1.2.4 The following absolute contra-indications are:

- Allergy to proposed sclerosant
- Acute Deep Vein Thromboembolism
- Permanent neurological adverse effect from a previous sclerotherapy interventionKnown symptomatic cardiac septal defect e.g. PFO or atrial septal defect

1.2.5 The following relative contra-indications are identified, risk/benefits evaluated, and any modifications clinically indicated are reflected in the dosage or method used, and agreed with the patient:

- Severe peripheral vascular disease High risk of venous thromboembolism
- Acute Superficial Venous Thrombophlebitis Pregnancy
- Breastfeeding within 48 hours Oral contraceptives
- Hormone replacement therapy
- Neurological events or disturbances, including migraine, following previous sclerotherapy Potential for lack of compliance
- Recent travel of greater than 4 hours

1.2.6 Clinical examination identifies all visual secondary complications present which result from venous hypertension.

1.2.7 The patient is informed of the practitioner's initial assessment of the cause of the problem, and an anticipated course of treatments is explained, based on the assumption that the diagnostic process will confirm the practitioner's assessment.

1.2.8 Patients presenting with the following should undergo a detailed relevant Duplex/Doppler ultrasound mapping prior to direct vision sclerotherapy treatment:

- Patients who have had previous vein treatment
- Patients presenting with vascular changes around the medial aspect of the ankle with associated corona phlebectatica
- Patients whose abnormal superficial venous network is extensively distributed and/or suggestive of underlying venous incompetence.

1.2.9 Patient measurements appropriate for selected support hosiery are made and recorded.

1.2.10 A photograph of the area proposed for treatment isrecorded.

2 ESTABLISH AND AGREE ON A TREATMENTPLAN

Outcome

The patient is fully informed of the diagnostic results, the suggested treatment plan, any potential risks, and results expected to be achieved at the end of the treatment period. The recommended treatment plan is clinically appropriate and is the best option to addresses patient's needs. Written consent is obtained.

2.1.1 Findings are discussed with the patient, and treatment options recommended are clinically indicated and achievable within patient's expectations.

2.1.2 All incompetent truncal veins are to be treated by endovenous thermal ablation, ultrasound guided sclerotherapy or cyanoacrylate adhesive ablation prior to superficial veins being treated.

2.1.3 Larger subcutaneous tributary veins should be treated with ultrasound guided sclerotherapy or ambulatory phlebectomy.

2.1.4 It can be beneficial to leave a gap of 4-12 weeks after treating trunks and tributaries before treating the reticular veins and spider veins.

2.1.5 Risks of proposed treatment, and possible management in the event of adverse events are explained.

2.1.6 If treatment is indicated, the interval between diagnosis by Duplex/Doppler ultrasound and treatment is no more than one year or more frequently depending on clinical circumstances.

2.1.7 Instructions are given for post treatment management, and these are appropriate for the treatment method proposed.

2.1.8 Written informed consent for the proposed treatment is obtained following the ACP protocol 'Informed Consent', and is signed by both the practitioner and patient.

2.1.9 A copy of the diagnostic findings and proposed treatment plan is sent to the patient's GP and the referring practitioner.

2.2 A written estimate of cost for the anticipated course of treatments is given to the patient.

3 INJECT VEINS WITH SCLEROSANT

Outcome
Affected veins are injected in an orderly manner which maximises the effectiveness of the treatment and achievable patient expectations in a manner and timeframe which minimises risk.

3.1.1 Product concentrate is within the expiry date of the batch and is stored correctly according to manufacturer's specifications.

3.1.2 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:

Sodium tetradecyl sulphate (Fibrovein™) 0.1 – 1% Polidocanol(Lauromacrogol 400) supplied as Aethoxysklerol™ or Sclerovein 0.25 – 2%

Recommended concentration ranges for each sclerosant as liquid or foam according to the type of vessel to be treated

Vein Type	STS Concentration Range	POL Concentration Range
*Sub-dermal tributary veins	0.5- 1%	1-2%
*Sub-dermal reticular veins	0.2-0.5%	0.5-1%
Dermal veins: Venulectasia/Telangiectasia	0.1-0.3%	0.25-0.5%

* Sub-dermal veins are vessels anatomically located below the dermis and visible to the naked eye.

3.1.3 The maximum upper limit of polidocanol (Lauromacrogol 400) is 2mg/kg patient body weight per treatment day because of potential for local anaesthetic toxicity.

3.1.4 Product is diluted with sterile preservative-free normal saline and stored in correctly labelled sterile containers.

3.1.5 Diluted product is an off label use and must be made for the patient and used on the day of preparation.

3.1.6 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.

3.2 Tributaries are treated first then reticular veins and finally spider veins

3.2.1 Compression hosiery may be applied immediately after treatment and before mobilisation. An appropriate level of graduated compression hosiery should be considered for 3-7 days.

3.2.2 For patients with a history of neurological symptoms, including migraine after previous sclerotherapy sessions, we recommend:
- avoid injecting large volumes of foam or instead consider performing liquid sclerotherapy
-The avoidance of Valsalva manoeuvre in the early period after the injection
-the placement of compression stockings by the practitioner/staff before the patient stands up

3.3 To reduce the risk of pigmentation we recommend the removal of superficial trapped blood.

4 PROVIDE POST TREATMENT ADVICE TO PATIENT AND RECORD TREATMENT DETAILS

Outcome
Treatment outcomes are optimised in the recovery period and patient safety and welfare is followed post treatment.

Criteria

4.1.1 The patient is reminded of the post treatment requirements.

4.1.2 The patient is instructed that if post-treatment symptoms of leg swelling, ulceration and/or increasing pain arise, to make urgent contact with the practitioner.

4.1.3 All possible symptoms which may be of concern post treatment are described and patient is instructed to contact practitioner if they arise.

4.1.4 Contact details of the treating practitioner or deputy are provided.

4.1.5 Practitioner follow-up of patient concerns is appropriate and, in a timeframe, that minimises risk to patient.

4.1.6 Where appropriate an assessment of the treatment is made by examining the patient within eight weeks post treatment.

4.1.7 The assessment findings are discussed with the patient, and where clinically indicated, further appropriate treatment offered.

4.1.8 Treatment records are complete and include:
- Leg and vessels treated.
- Sclerosant type, dosage or concentration used.
- Type of compression hosiery applied and recommended time of application.
- Post treatment assessment of resolution of symptoms
- Any adverse effects or interventions.
- What further treatment is indicated/offered (if any) after the post treatment assessment, any referral made, and whether the treatment plan has been completed.