Microsclerotherapy

Assess and treat abnormal superficial venous network with injected sclerosants

Australasian College of Phlebology

www.phlebology.com.au

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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***** 'Microsclerotherapy' 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.

For doctors working in the field of Appearance Medicine, this standard is accepted as an equivalent to that required under the AMSA modality***** 'Microsclerotherapy', towards the AMSA Level 1 Diploma. Similarly, it is used for recertification of AMSA certified doctors under the AMSA 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 Microsclerotherapy
• 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 microsclerotherapy to self monitor their own performance.

1.4 Assessment as competent in this standard* IS sufficient for doctors to gain ACP Level 1 certification.
*** Refer ACP Training Protocols for Training (including examination) and supervision requirements mandatory under this standard.**

1.5 The training programme required for this standard is not open to nurses. If however an ACP phlebologist employs a nurse to perform microsclerotherapy 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 microsclerotherapy treatment to an abnormal superficial venous network which meets their patients' expectations.

3. Context/Environment/Service Delivery

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

ACP Maintenance of Professional Standards Programmes
ACP Protocols: 'Training', 'Informed Consent', Infection Control, 'Clinical emergency response and transfer', 'Management of waste and Hazardous substances', 'Clinical Records', 'Medicine management', 'New procedures/products Approvals'.

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).

6. Risk Management

6.1 All agents other than Fibrovein (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 Fibrovein is approved for its use in treating leg veins with up to 4 mls at 3 % per leg. ?

6.3 The ACP/AMSA approved sclerosants covered by this standard are:

- STS (Fibrovein) supplied as a 0.2%, 0.5%, 1%, 3% solution
- Aethoxysclerol (Kreussler Pharma, Germany) i.e Polidocanol supplied as a 0.5%,1% and 3% solution, or Sclerovein (Resinag AG or Omega Laboratories, Canada) as a 5% solution.

6.4 Maximum dosage of 3%STS solution per patient per day under this standard is 4mls or 10ml of 0.5% or 1%.

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

6.6 ACP approves sclerosants in liquid (NOT FOAM) form only under this standard. The use of foam sclerosants is an off label use of the product.

6.7 Exclude a past history of anaphylaxis to sclerosants, thrombophilia and note any absolute or relative contraindications to microsclerotherapy.

6.8 If there is a prothrombotic tendency plan for anticoagulant evaluation.

6.9 All potential sources of venous reflux should be excluded by a full assessment with Duplex ultrasound before embarking on microsclerotherapy.

7. Special Notes

7.1 Advertising

- 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 'Microsclerotherapy' - Clinical procedure' (CP-Microscl.doc)
Appendix 2 'ACP Training Requirements' in ACP Handbook' – Specifications for the modality 'Microsclerotherapy'.
Appendix 3 ACP Curriculum content for modality 'Microsclerotherapy'.

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 microsclerotherapy 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 The patient is assessed personally by the practitioner.

1..2 The patient's expectations are discussed and documented.

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

1..5 The patient is given adequate opportunity to ask questions.

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..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 thrombophilic 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 and skin type

Onset of vein problem

Onset of symptoms if appropriate

Past medical /surgical and venous history and associated complications including thrombophilia

Previous vein treatment

Family History of vein disease and thromboembolism

Allergies

Current medications including oral contraceptives and HRT

Smoking history

Weight

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

1.2.3 The following contra-indications are excluded:

1.2.4 The following absolute contra-indications are excluded:

Previous anaphylaxis to proposed sclerosants

Acute Deep Vein Thrombosis

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.

Pregnancy/breastfeeding

Oral contraceptives

Inability to mobilize

Deep venous obstruction/Severe arterial obstruction

Allergy to sclerosant

Skin disease in the area to be treated

Acute Superficial Venous Thrombosis (SVT)

Peripheral vascular disease

Severe deep vein incompetence

Thrombophilia

Warfarin medication/Hypercoagulable states

Diabetes with poor control

Asthma

Migraine

Poor tolerance of compression hosiery

Presence of untreated varicose veins

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

1.2.6 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.

1.2.7 Patients presenting with the following are referred for Duplex/Doppler ultrasound mapping prior to microsclerotherapy treatment:

. Patients who have had previous vein treatment

. Patients presenting with vascular changes around the medial aspect of the ankle with associated corona phlebectica

. Patients whose abnormal superficial venous network is extensively distributed and/or suggestive of underlying venous incompetence.

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

1.2.9 A photograph of the area proposed for treatment is recorded.

2 ESTABLISH AND AGREE TREATMENT PLAN

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 patients needs. Written consent is obtained.

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

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

2.3 If treatment is indicated, the interval between diagnosis by Duplex/Doppler ultrasound and treatment is no more than one year.

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

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

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

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

3.2 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 (STS) 0.1 – 0.75%
Polidocanol (Aethoxysclerol or Sclerovein) 0.25 – 1.5%

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

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

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

3.6 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.

3.7 Reticular veins are treated first and then the smaller vessels, either at the same or a later session.

3.8 Compression hosiery, appropriate to the patient and the sclerosant treatment, are applied immediately after treatment and before mobilisation.

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 The patient is reminded of the post treatment requirements.

4.2 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.

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

4.4 Contact details of the treating practitioner or deputy are provided.
Practitioner follow-up of patient concerns is appropriate and in a timeframe that minimises risk to patient.

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

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

4.7 Treatment records are complete and include:

1. Leg and vessels treated.
2. Sclerosant type, dosage or concentration used.
3. Type of compression hosiery applied and recommended time of application.
4. Post treatment assessment of resolution of symptoms
5. Any adverse effects or interventions.
6. What further treatment is indicated/offered (if any) after the post treatment assessment, any referral made, and whether the treatment plan has been completed.