

Ultrasound Guided Sclerotherapy

**Diagnose venous disease and
treat superficial venous
incompetence with injected
sclerosants under
ultrasound guidance**

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INTRODUCTION

This standard is for practitioners who need to diagnose and investigate lower limb venous diseases prior to using Ultrasound Guided injections of sclerosant for the treatment of superficial venous incompetence. It has been developed by Australasian College of Phlebology (ACP) doctors working in the Phlebology modality* 'Ultrasound Guided Sclerotherapy' (UGS) to provide an assessment tool for doctors in training towards their ACP Fellowship, and for recertification of ACP certified doctors under the ACP 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:

• <u>Level 1</u> Microsclerotherapy
• <u>Level 2</u> Ultrasound Guided Sclerotherapy Endovenous Ablative techniques Ambulatory Phlebectomy

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 using UGS to diagnose and treat superficial venous incompetence in legs. In addition it is used on an ongoing basis, as a reassessment tool to ensure that doctors continue to meet the standard required in delivering this service to clients
- 1.3 This standard is used periodically during and at the end of the training period. It is also used by trainees and ACP certified doctors working in the modality of Ultrasound Guided Sclerotherapy to self monitor their own performance.
- 1.4 Assessment as competent in this standard is not sufficient for doctors to gain ACP certification. Before being considered for Fellowship of ACP trainees must have completed both the ACP Part 1 training and examination programme, and completed the registrar training programme for advanced phlebology.

2 Purpose

Practitioners credited with this standard are able to establish client needs, communicate and manage risks and deliver safe, timely and appropriate ultrasound guided sclerotherapy to treat superficial venous incompetence, which meets their clients' expectations.

3 Context/Environment/Service Delivery

Premises used by practitioners in delivering this service must comply with the relevant sections of NZS 8164:2005 Day-Stay Surgery and Procedures, and NZS 8165:2005 Rooms/Office-based Surgery and Procedures.

The clauses in the NZS standard relevant to the delivery of this service are those pertaining to 'Office-based surgery and procedures' i.e. the equipment/facilities of an operating theatre are not required.

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.

The facility requirements for UGS include specifically, Section 5.5 Power and Lighting requirements including Notes 1 & 2:

Note 1. All areas where it is intended to use mains operated equipment for patient treatment or diagnosis meet the minimum requirements of Body Protected Areas, as specified in AS/NZS 3003.1:2003: Electrical installations – Patient treatment areas of hospitals and medical, dental practices and dialyzing locations. The provision of a residual current device (RCD) is an appropriate means of compliance.

Note 2. All body Protected Areas shall have an In-service Testing Programme to AS/NZS 3003.1:2003: Electrical installations – Patient areas of hospitals and medical and dental practices – testing requirements.

4 Entry requirements

4.1 Doctors registered with the Australia or NZ Medical Council who meet all the following criteria:

- Membership of ACP
- Hold a pass in Level 5 or higher Advanced Cardiac Life Support (ACLS)
- Successful completion of part 1 ACP Phlebology exam
- Are working under the supervision of a registered Fellow of ACP OR are enrolled in an accredited ACP registrar training programme.

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

5 References

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 ACP requires written informed patient consent before UGS.

6.2 The ACP approved sclerosants covered by this standard are

- Sodium tetradecylsulphate (STS)
- Polidocanol supplied as either Sclerovein™ or as Aethoxysclerol™

6.3 Duplex/Doppler Ultrasound equipment used in delivering this standard must include a high frequency linear array probe with colour flow and Doppler capabilities.

6.4 Under this standard, liquid and foam sclerosant formulations are approved within the maximum allowable limits (Refer **6.5**, **6.6**, and **6.7** below).

6.5 Under the NZ Medicines Act, Foam is an unapproved use of an approved/or unapproved medicine (STS is the only approved sclerosant) but permitted when administered by a Registered Medical Practitioner provided full written informed consent has been given by the patient.

6.6 This standard restricts the use of STS in concentrations of 3% to 4 mls liquid per day (\equiv .12g per patient per day).

6.7 Use of polidocanol must not exceed 2mg/kg body weight per treatment day.

6.8 The minimum resuscitation equipment required is:

Oxygen, intravenous fluids, adrenalin, blood pressure and cardiac monitor, pulse oximetry, defibrillator, and suction.

7 Special Notes

7.1 Notification of Information to Supplier of UnApproved Medicines (NZ Only).

In New Zealand, the following sclerosant is listed as a Prescription Medicine with the Ministry of Health.

- <3%STS (Fibrovein™). This is only listed as a Prescription Medicine if it is supplied in 2 ml ampoules. 3% STS supplied in 5 ml vials are unapproved and can only be used under Section 29 (see below).

All other sclerosants are unapproved at this time. However under Section 29 of the Medicines Act 1981, unapproved medicines can be supplied to a medical practitioner for administration to their own patients.

It is a mandatory requirement for doctors who have been supplied with medicines under Section 29, to furnish the supplier at the end of each month, with the following information:

- Name of patient
- Dose form and strength
- Date medicine was supplied

At the end of each month, the supplier of an unapproved medicine must then notify Medsafe of the following:

- Proprietary name and trade name of product.
- Dose form
- Month and year of supply.
- Name of supplier.

The patient details are recorded and kept by the supplier, and must be available for audit from Medsafe.

The doctor must inform the patient, as part of the consenting procedure that their details will be given to the supplier and will be available for audit from Medsafe.

7.2 Advertising in New Zealand

- Direct to consumer advertising for treatment of varicose 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 Medicines Act (1981)).

7.3 Advertising in Australia

- Under development

7.4 Consent

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

8 **Definitions**

ACP Australasian College of Phlebology

UGS Ultrasound Guided Sclerotherapy

STS Sodium Tetradecyl Sulphate

Varicose vein Any vein >2mm with demonstrated retrograde flow indicating incompetence.

SFJ ≡ Sapheno-Femoral Junction

GSV ≡ Great saphenous vein

SSV ≡ Small saphenous vein

SPJ ≡ Sapheno-Popliteal Junction

SVT ≡ Superficial venous thrombophlebitis

CEAP Classification (basic):

i.e. C = Clinical E = Etiologic A = Anatomic P = Pathophysiologic

1. Clinical classification

C₀ No visible or palpable signs of venous disease

C₁ Telangiectasies or reticular veins

C₂ Varicose veins

C₃ Edema

C_{4a} Pigmentation or eczema

C_{4b} Lipodermatosclerosis or atrophie blanche

C₅ Healed varicose ulcer

C₆ Active venous ulcer

S Symptomatic, including ache, pain, tightness, skin irritation, heaviness, and muscle cramps, and other complaints attributable to venous dysfunction

A Asymptomatic

2. Etiologic classification

- Ec** congenital
- Ep** primary
- Es** secondary (postthrombotic)
- En** no venous cause identified

3. Anatomic classification

- As** superficial veins
- Ap** perforator vein
- Ad** deep veins
- An** no venous location identified

4. Pathophysiologic classification

- Pr** reflux
- Po** obstruction
- Pr,o** reflux and obstruction
- Pn** no venous pathophysiology identifiable

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

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

9 Attachments

Appendix 1 'CPUltrasound Guided Sclerotherapy' - Clinical procedure
(CPUGSJuly2010Vers2.doc)

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 venous incompetence, understands the diagnostic process necessary to confirm the cause, and that the treatment alternatives available will depend on the diagnosis.

Criteria

- 1.1.1 The patient is assessed in person by the treating practitioner at the service delivery location.
- 1.1.2 The patient's expectations are discussed and documented.
- 1.1.3 The patient is informed that treatment of venous incompetence is a two stage process which comprises diagnosis followed by clinically appropriate treatment options.
- 1.1.4 Patient is given adequate opportunity to ask questions.
- 1.1.5 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.

1.2 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

Previous vein treatment

Family History of vein disease and/or thrombophilia

Allergies

Current medications including oral contraceptives and hormone replacement therapy

Smoking history

1.2.2 Pre-operative blood tests appropriate to the patient and the proposed 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:

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.

Deep venous obstruction

Peripheral vascular disease

Skin disease where infection is a possibility

Documented thrombophilia where the individual's relative risk of venous thromboembolism has been established

Inability to mobilize

Acute Superficial Venous Thrombophlebitis

Pregnancy/breastfeeding

Oral contraceptives

Hormone replacement therapy

Uncontrolled asthma as diagnosed by the patient's general practitioner or respiratory physician

Uncontrolled migraine as diagnosed by the patient's general practitioner or neurologist

Poor tolerance of compression hosiery

1.2.6 Clinical examination identifies all visible secondary complications present which result from venous incompetence enabling a CEAP classification.

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 A written estimate of cost for the anticipated course of treatments (to be

confirmed post diagnosis) is given to the patient.

- 1.2.9** Consent for photography is obtained prior to pre-treatment photographs being taken.

2 MAP DEEP AND SUPERFICIAL VEINS WITH DUPLEX/DOPPLER ULTRASOUND

Outcome: Cause and location of venous incompetence is identified and recorded, superficial thrombophlebitis and deep vein thrombosis is excluded, and suitability for subsequent treatment is confirmed.

Criteria

- 2.1** Incompetence in the superficial or in the deep vein system is identified and its location recorded in relation to an anatomical landmark.
- 2.2** All contributing sources of venous incompetence causing visible post surgical recurrences are identified and their location recorded.
- 2.3** Any pathology relevant to the venous incompetence or in close proximity to the incompetent veins is identified and its nature and location recorded.
- 2.4** A documented pictorial scheme/map records extent and location of incompetence in the venous system including its source i.e. saphenous trunks, tributary vessels, perforators, deep vein system.
- 2.5** If present, superficial thrombophlebitis and non-acute deep vein thrombosis are identified and considered as relative contraindications.
- 2.6** If present, Acute DVT is treated as an absolute contraindication, its extent measured in terms of its length in the vein and a management plan is initiated to minimise the risk of venous thromboembolism.
- 2.7** The diameter of each incompetent vessel at intervals throughout its length is accurately measured and recorded, with the GSV measured at the Sapheno-Femoral junction, at mid-thigh and knee; and the SSV measured at the Sapheno-Popliteal junction and mid-calf.

3 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.

Criteria

- 3.1 Findings are discussed with the patient, and treatment options available and recommended are clinically indicated and achievable within patient's expectations.
- 3.2 Risks of proposed treatment and possible actions in the event of adverse outcomes are explained.
- 3.3 If treatment is indicated, the interval between diagnosis by Duplex/Doppler ultrasound and treatment is no more than one year.
- 3.4 Instructions are given for pre-operative requirements and these are appropriate for the treatment method proposed.
- 3.5 The patient understands that in New Zealand if an unapproved sclerosant is selected, his/her name and treatment details are required under Section 29 of the Medical Practitioners Act, 1981 to be recorded and forwarded to the supplier. The patient is informed that this information is as follows:
 - Name of patient
 - Dose form and strength
 - Date medicine was supplied.
- 3.6 The patient is informed that in New Zealand if an unapproved sclerosant is selected, his/her details may be provided to Medsafe for audit purposes.
- 3.7 Written informed consent for the proposed treatment is obtained following the ACP protocol 'Informed Consent', and is signed by both phlebologist and patient.
- 3.8 A copy of the diagnostic findings and proposed treatment plan is sent to the patient's GP and the referring practitioner.

4 INJECT VEINS WITH SCLEROSANT UNDER ULTRASOUND GUIDANCE

Outcome: Sclerosis of target vessels contributing to venous incompetence is achieved in a manner and timeframe which minimises risk and maximises achievable patient expectations.

Criteria

- 4.1 Product concentrate is within the expiry date of the batch and is stored correctly according to manufacturer's specifications.
- 4.2 Containers of stored sclerosant used for injection are legibly labelled with correct concentration for purpose.

- 4.3 Where product requires dilution, sterile preservative-free saline is used.
- 4.4 Sclerosant concentration, formulation and delivery method minimises venous thromboembolism, superficial thrombophlebitis, and anaphylaxis incidents to < 0.02%.
- 4.5 Maximum volume of 3% STS injected as a liquid is 4 mls (\equiv .12g per patient per day).
- 4.6 Foam dilution range is between 2 parts liquid/3 parts ambient air to 1 part liquid/4 parts ambient air.
- 4.7 The maximum volume of 3% STS used as foam does not exceed 4 ml liquid per day irrespective of dilution used.
- 4.8 A new needle and syringe is used for every penetration of the multidose vial containing sclerosant.
- 4.9 The maximum volume of 5% polidocanol injected as a 1:3 ambient air diluted foam is 16 mls (\equiv .2g) per patient per day or as a 1:4 ambient air diluted foam is 20ml.
- 4.10 The maximum dose of polidocanol is 2 mg/kg patient body weight per day regardless of the liquid concentration or liquid/ambient air dilution.
- 4.11 The total volume of foam injected in one day does not exceed 20ml regardless of the liquid:ambient air dilution used for STS or polidocanol.
- 4.12 Further treatment which is clinically appropriate for the patient is offered in the event of current treatment session being terminated as a result of sclerosant volume and dosage limits being reached.
- 4.13 Correct placement and uniform coverage of sclerosant in target vessels is achieved and is confirmed by ultrasound guidance to monitor the process of sclerosis.
- 4.14 Patient is fitted into correctly sized Class 2 compression hosiery immediately post treatment.

5 PROVIDE POST TREATMENT ADVICE TO PATIENT AND RECORD TREATMENT DETAILS

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

Criteria

- 5.1 The patient is reminded of the post operative requirements.

- 5.2** All possible symptoms which may be of concern post treatment are described and the patient is instructed to contact practitioner urgently if any arise.
- 5.3** Practitioner follow-up of patient concerns is appropriate and in a timeframe that minimises risk to patient.
- 5.4** Contact details of the treating practitioner or deputy are provided.
- 5.5** An assessment of the treatment is made by examining the patient on the following occasions:
- within 1 week for a DVT scan
 - within 6 weeks to 3 months
 - 1 year post treatment
- 5.6** At each assessment the findings are recorded and discussed with the patient and include:
- Success of treatment including resolution of symptoms
 - Degree of sclerosis and any recanalisation
 - Any complications
 - Patient satisfaction
- 5.7** Where clinically indicated, further appropriate treatment is offered, or referral made.
- 5.8** Treatment and assessment records are complete and include:
1. Leg and vessels treated
 2. Sclerosant type, dosage or concentration used
 3. Type and size 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 post treatment assessments, any referral made, and whether the treatment plan has been completed.