Position Statement

Respective roles for endothermal ablation, Foam UGS, Cyanoacrylate Adhesive Closure and Surgery in the management of incompetent saphenous veins and their major tributaries.

Purpose

The ACP provides information, advocacy and advice on phlebological practice in Australia to health professionals, the community and government. Our focus is to educate, train and maintain highly qualified doctors who work in the field of phlebology and to improve outcomes in vein health of individuals and communities.

The purpose of this position statement is to:

- Advocate for improved standards of vein treatment in Australia and New Zealand.
- Provide recommendations for Phlebologists on the appropriate therapeutic options for incompetence of saphenous veins and their major tributaries.
- Inform the community of the internationally accepted guidelines on saphenous vein treatment protocols.

Position

Beneficial treatment options for incompetent saphenous veins and their major tributaries, including endovenous thermal ablation, ultrasound guided foam sclerotherapy and traditional surgery, have been established by rigorous randomized clinical trials and recommended by several international evidence-based guidelines.^{1,2,3,4}

The ACP consensus document⁵ states; "Cyanoacrylate adhesive closure appears to be an effective endovenous procedure, with short-term closure rates comparable to ETA and therefore greater efficacy than traditional surgery for treating superficial veins of the lower limbs. Ongoing data collection is required to establish the long-term safety".

The recommendation of the ACP for suitably trained medical practitioners is that;

- "For patients with confirmed varicose veins and truncal reflux:
 - Offer endovenous thermal ablation as first-line treatment.
 - If endovenous thermal ablation is unsuitable, offer ultrasound guided foam sclerotherapy or cyanoacrylate adhesive closure.
 - If ultrasound guided foam sclerotherapy and cyanoacrylate adhesive closure are unsuitable, offer surgery.
 - High ligation of the GSV without stripping is not recommended. High ligation with inversion stripping under tumescent local anaesthetic is the recommended surgical technique if surgery is deemed necessary.^{6,7}
 - It is essential that practitioners treat the presenting venous pathology in its entirety and not limit their intervention to the saphenous trunks. This will require treatment of the entire pathway of venous reflux including other vessels such as tributaries and perforating veins if clinically relevant."

Background

For the majority of the 20th century, surgery for varicose veins was the predominant treatment worldwide. This involved various forms of ligation at the sapheno-femoral or sapheno-popliteal junction combined with stripping of the associated saphenous trunk. Phlebectomy was, and remains, a commonly performed treatment for varicose tributaries. These procedures were usually performed under general anaesthesia and involved a stay in hospital.

Sclerotherapy was reportedly invented in the late 17th century and has been gradually developed as a technique to treat varicose tributaries. Sclerotherapy involves the injection of a chemical substance into the vein with the intention to cause irreversible endothelial injury in the targeted vessel, which is subsequently re-absorbed by the body. Until the advent of ultrasound and ultrasound-guidance in the

1980s, its primary role was in its use for smaller superficial veins. Ultrasound guidance allowed more accurate placement of sclerosant and the complete treatment of saphenous trunks and superficial tributaries ⁸. The efficacy of this treatment was enhanced with the development of a simple technique to make foamed sclerosants in the late 1990's⁹. This procedure is now commonly referred to as Ultrasound Guided Foam Sclerotherapy (UGFS).

Endovenous thermal ablation (EVTA) comprises two main treatment modalities, endovenous laser ablation and radiofrequency ablation. These treatments were developed in the early 2000s and were quickly taken on by Australian phlebologists. They have become the most common form of treatment worldwide for saphenous trunks and their major tributaries. Both modalities involve passing a catheter up the involved vein, followed by injection of tumescent local anaesthetic around the vein which is then heated as the catheter is withdrawn to close the vein. This causes irreversible thermal injury. EVTA is combined with another form of treatment, usually ultrasound guided sclerotherapy or ambulatory phlebectomy, to treat tributaries of the saphenous trunks.

Cyanoacrylate Adhesive Closure (CAC) is a more recently developed procedure that uses "medical superglue" to close saphenous trunks and their tributaries. It is delivered intravenously to induce a mechanical occlusion of the target vein, resulting in obstruction to flow⁵. It has the advantage of not requiring as many intraprocedural needle pricks as tumescent local anaesthetic is not required. Early data has been promising with closure rates similar to EVTA. However long-term data for efficacy and complications is currently lacking⁵.

High ligation with/without stripping of the GSV or SSV has been traditional treatment since the 1930s. High ligation without stripping has long been known to have inferior results to high ligation with stripping (HL&S)⁹. High ligation and stripping under general anaesthesia has evolved toward the less invasive procedure of inversion stripping under tumescent local anaesthesia ^{6, 7}.

The ACP has consensus guidelines detailing the appropriate techniques to be used for the procedures of Endovenous Laser Ablation, Ultrasound Guided Sclerotherapy and Cyanoacrylate Closure. These guidelines can be found at <u>https://www.phlebology.com.au/standards</u>.

International Guidelines

This ACP position statement has been developed from international guidelines summarized in the following table.

The National Institute of Health and Care Excellence in the UK (2013) recommends.

For people with confirmed varicose veins and truncal reflux

- Offer endothermal ablation (see Radiofrequency ablation of varicose veins and Endovenous laser treatment of the long saphenous vein
- If endothermal ablation is unsuitable, offer ultrasound-guided foam sclerotherapy
- If ultrasound-guided foam sclerotherapy is unsuitable, offer surgery.
- If incompetent varicose tributaries are to be treated, consider treating them at the same time.¹

The American Venous Forum and the Society for Vascular Surgery (2011) recommends:

For treatment of the incompetent GSV, endovenous thermal ablation (radiofrequency, RF, or endovenous laser therapy, EVLT) is recommended over high ligation and stripping of the saphenous vein to the level of the knee.

Clinical practice guidelines of the European Society for Vascular Surgery (2015) recommend:

For the treatment of great saphenous vein reflux in patients with symptoms and signs of chronic venous disease, endovenous thermal ablation techniques are recommended in preference to surgery³

Key Issues

Training

One of the key determinants of successful outcomes in the management of venous disease is that the medical practitioner has appropriate levels of training. For the procedures of EVTA, RFA, UGFS and CAC, it is recommended under the Australian Medicare descriptor note TN.8.33 that the medical practitioner has completed as substantial course of study and training in the management of venous disease. The ACP considers the successful completion of the 3-year course in Advanced Phlebology necessary to satisfy these recommendations. The course involves extensive theoretical and practical components and has become a model for international education programs in phlebology. In-depth knowledge and hands-on experience in duplex ultrasound are a significant component of the ACP's training program.

Great Saphenous Vein incompetence

Endovenous thermal ablative techniques have been shown to be at least as effective as the traditional surgical stripping procedures in numerous meta-analyses. ^{11,12,13,14,15,16} However, one study has shown an advantage for Surgery over EVTA at 5 years ¹⁷.

Patients treated with EVTA have less pain ^{11,12,18} quicker recovery ¹⁹ and faster return to normal activities ^{12,19}. They also get fewer wound infections ¹² and haematomas ¹⁵. Many of these studies were based on the results using early models of radiofrequency and laser devices. It should be noted that the techniques as well as fibres and catheters used for these procedures have continued to improve over the last decade⁴. Compared to surgery and EVTA, UGFS of saphenous trunks shows only a slightly higher mid-term recanalisation rate ^{12, 21}. The advantages of UGFS over surgery is its simplicity and significantly fewer side effects (less pain, better post procedure QOL and faster return to normal activities ^{4,18,19}). UGFS is easily repeatable and re-treatment of partially sclerosed veins is recommended to improve the mid-term results ²².

Small Saphenous Vein (SSV) Incompetence

EVTA is recommended over UGFS and Surgery of the SSV due to its excellent early and mid-term results⁴. Compared to surgery, EVTA results in fewer post-procedure side-effects⁴. UGFS is an alternative to EVTA in cases where it is not appropriate or possible to treat with EVTA. Surgery of the SSV in general is not recommended because of poor initial results and the significant risks of complications such as sural nerve injury ^{23,24}.

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