Guidelines and recommendation on surgery for venous incompetence and leg ulcer

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Access this article online

Website: www.idoj.in

DOI: 10.4103/2229-5178.137825

Quick Response Code:

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INTRODUCTION

Various modes of surgeries are done for management of venous incompetence and leg ulcer. Technical details of these procedures in detail are beyond the scope of this article. Thus, methods of surgical procedures have been described in short to provide the readers some ideas on the same. Original studies, reviews, case reports, guidelines and recommendation have been reviewed.

Based on the available evidence of comparative advantages and disadvantages, recommendations on surgical management of venous incompetence and leg ulcer have been made.

DIFFERENT SURGERIES

Open venous surgery

Open surgery encompasses high ligation, division and stripping (HL/S) of the great saphenous vein (GSV) or short saphenous vein (SSV), combined with excision of segments of varicose veins if required. Open surgical procedure has been the gold standard surgical procedure for leg ulcer and venous incompetence. Although associated with hospitalization and many other surgical complications, this has given significantly good results in competent hands. For some situations, open surgery is particularly useful like in the case of large dilated and tortuous saphenous vein located immediately under the skin or aneurysmal enlargement at the saphenofemoral junction or in case of thrombosed vein from past thrombophlebitis attack where the probe or channel for endovenous ablation cannot be inserted.

High ligation and division

High ligation and division of GSV is performed at the level of its confluence with common femoral vein. Ligation of GSV should be flushed with the femoral vein to avoid a cul-de-sac but extreme care has to be taken to avoid narrowing of the femoral vein. All the tributaries of GSV should also be ligated and divided.

Ligation and division of SSV is done at the level of popleteal crease after the SSV is identified with an intra-operative duplex scanning. Unlike GSV, SSV can also be ligated just below skin 3-4 cm distal to the saphenopopleteal junction to make the operation simpler.

Stripping

Complete stripping is usually avoided to avoid possible trauma to the nerves. For GSV, stripping is done up to knee and for SSV, up to mid-calf. Perivenous tumescent anesthetic infiltration reduces hemorrhages. Postoperative compression bandage also helps to reduce bleeding.

Stripping can be done either with:

- Intraluminal stripping method with silk thread or
- Cryostripping method, which is a new technique, needs more study and is done with liquid nitrogen.

High ligation with stripping versus only high ligation

One prospective trial showed that GSV below knee stripping prevented deep vein reflux significantly at 24 months follow-up.[1]

In another randomized controlled trial (RCT) on 133 legs of 100 patients, only ligation was associated with much higher need of reoperation at 5 years (6% HL/S vs. 20%) in only HL group ($P > 0.02$).[2]

Phlebectomy

This is an additional treatment and not done regularly. Two common methods are:

- Ambulatory phlebectomy: The operation

is done with tumescent anesthesia. Varicose veins are avulsed with hooks or forceps (stab or hook phlebectomy or miniphlebectomy)
- Powered phlebectomy: Hydrodissection of varicose vein is done with fibreoptic transillumination powered phlebectomy instrument. This is much faster and can remove the larger number of varicose veins.

Conservative surgical approach

These are more sophisticated procedure and needs special skill. Two techniques - Conservative ambulatory HemodynamIc management of VAricose vein (CHIVA) technique and Ablation Sélective des Varices sous Anesthésie Locale (ASVAL) technique are done. Ablation of incompetent portion of saphenous vein is done preserving all competent tributaries and saphenous trunk in CHIVA tributaries, and saphenous vein (even incompetent portion) is spared in ASVAL.

EVIDENCE AND RECOMMENDATION

- For the treatment of venous incompetence without ulcer (for simple varicosity; clinical-etiology- anatomy- pathophysiology [CEAP] Class 2): Surgery is recommended over compression therapy as it offers higher compliance, better symptom control and quality of life (QoL) improvement, higher cost effectiveness to simple compression therapy[3,4] (evidence Level A)
- For the treatment of venous incompetence with ulcer: (CEAP Class C3-C6 including leg ulcers: Surgery (HL/S and phlebectomy) offers no additional advantage over compression alone[5-7] (evidence Level A). Thus, compression (without surgery) is recommended for treatment of venous leg ulcer
- For the prevention of venous ulcer recurrence: Surgical management (HL/S and phlebectomy) along with compression offers definite advantage to reduce venous ulcer recurrence[6-8] (evidence Level A). Thus, HL/S and phlebectomy) along with compression is recommended for prevention of ulcer recurrence
- There is some advantage of powered phlebectomy over the conventional one like fewer incisions, less traumatic thus less potential complication and better learning curve. So powered phlebectomy is suggested. Newer generation instrument, if available should be used
- CHIVA and compression had no significant difference in ulcer healing rate. But CHIVA had significantly less recurrence rate than compression.[9] Evidence Level B. As this need expertise, conservative surgeries can be undertaken only in selected candidates for reducing recurrence of ulcer if facilities are available
- There is limited advantage of stripping along with HL (over HL alone). Evidence Level C. More numbers of RCT are required to assess the efficacy of ligation alone without stripping.

Endovenous ablation

Endovenous intervention to induce ablation of the incompetent vein has been introduced to reduce the complications associated with open surgical procedure. Endovenous ablation can be done with thermal or chemical (sclerotherapy) techniques.

Endovenous thermal ablation

Incompetent veins can be ablated without surgically opening the area. These are called endovenous thermal ablation and are performed with the laser, radiofrequency or superheated steam. These are new techniques, minimally invasive and have been increasingly used since the last decade. Ultrasonographically guided percutaneous catheter is placed inside the vein at required places. Thermal ablation damages the endothelium and denatures the collagen leading to fibrosis of the vein. Of late, radial emitting laser tip has been introduced. This requires lesser energy and thus has a lesser chance of side-effects.

Endovenous laser ablation

Hemoglobin specific laser wavelengths (810, 940, and 980 nm) and water specific laser wavelengths (1319, 1320, and 1470 nm) are used to destroy the incompetent veins. 1320-nm neodymium-doped yttrium aluminum garnet laser and 1470-nm diode laser gave good results with minimum side effects.[10,11]

Endovenous laser ablation (EVLA) has the advantage of nil or minimum hospital stay, less pain and discomfort, early return to work, minimum surgical hazards thus lesser chance of adverse effects like bleeding or abrasion.

Short-term efficacy of EVLA in saphenous incompetence was assessed in many RCTs. Occlusion of the SSV after 3 months was achieved in 98-95.9% at 1 year.[12-14]

There is one Indian trial (uncontrolled, un-blinded) on 1470 mm laser which has a short follow-up period.[15] It showed venous occlusion rate and ulcer healing rate as 98.61% and 85%, respectively. Overall, studies on higher wavelength laser are scanty and RCT on this seems necessary to prove its efficacy.

Complication

Bruising is very common and is seen in most patients. Also seen are paresthesia, thrombophlebitis, skin burns in 0.46%, and thrombotic events with occasional pulmonary embolism and sural nerve paresthesia.

Endovenous radiofrequency ablation

Radiofrequency ablation (RFA) was approved by the US Food and Drug Administration (FDA) in 1999 for saphenous ablation.[16] This is a rapid and minimally invasive procedure. For RFA, ideal vein should have a diameter within 2-15 mm range.

There are chances of extension of thrombus into the femoral vein. The risk increases with larger vein diameter (>8 mm) and history of deep venous thrombosis (DVT).[17]

Complication

Use of local anesthetics in liver disorder should be carefully monitored. Coagulopathy, immobility, pregnancy and breastfeeding are considered as relative contraindications for thermal ablation procedures. Obstructed saphenous vein from a previous surgery or procedure or thrombophlebitis may restrict insertion of the probe in thermal ablation indicating necessity for open surgery.

Sclerotherapy

Injury to the endothelial cells and collagen tissue underneath leading to fibrosis and obliteration of vein lumen is a well-accepted modality of treatment of venous incompetence. Now foam sclerosants are used more frequently and give much better result than previously used liquid sclerosants. FDA approved sclerosing agents are glycerine (along with epinephrine), detergents as sodium tetradecyl sulfate (STS), polidocanol and sodium morrhuate.

Liquid sclerotherapy

This is primarily used for spider veins or telengiectasia (size ≤3 mm). The agent is injected with tuberculin syringes and 30- or 32-gauge needle. Larger varicose veins and proximal parts affected are treated first followed by the smaller ones and the distal parts. Extravasation causes severe pain and so care should be taken to prevent its occurrence. Magnification loupes and transillumination may help in better visualization during the procedure. Maximum 1.0 ml of the agent per site and maximum 10-20 injections per session is recommended.[18]

Foam sclerotherapy

This is one of the most effective and the least invasive among all endovenous ablation techniques with lower complication rates.[19,20] Solution of STS or polidocanol mixed with carbon dioxide (preferred) or air (max 20 ml), is injected, while the limb is elevated at 30° and kept in that position for 10-20 min. Intra-operative ultrasonography can monitor the movement of the foam. One RCT suggested follow-up with compression bandage for more than 24 h with thromboembolus-deterrent stockings for another 2 weeks.[21]

Complications

Common complications are dose dependent and include pigmentation, pain, allergy, and urticaria. Serious complications are rare and include thrombophlebitis, pulmonary emboli, stroke, skin necrosis, nerve damage (saphenous, sural), DVT, anaphylactic reaction, visual disturbances, migraine-like headache or confusion and even death.

Results

Average early improvement rate is 70% as reported in some prospective studies.[22] Long term success and a chance of relapse depend on the presence of axial reflux.

Liquid sclerotherapy performs poorly in the treatment of GSV incompetence where foam sclerotherapy appears much more efficacious and equally safe as found in a randomized controlled multicenter clinical trial.[23]

Recurrence rate was also significantly higher in the liquid sclerotherapy treated cases when compared to the foam therapy.

Comparative analysis

Endovenous laser ablation versus standard surgery (HL/S) (in saphenous incompetence, reflux and primary varicosity). There are many RCTs on the short-term efficacy of EVLA and comparison with HL/S and ablation. There was a significant improvement in venous clinical severity score in both EVLA and standard surgery as found in one RCT. There was significantly less pain score and early recovery in EVLA.[24]

Less pain and earlier return to normal activity with EVLA (average 2 days vs. 7 days [P = 0.001]) was reported in other study.[25] However, some studies have reported more pain and restricted mobility after EVLA.[26] Postoperative hematomas[27] were found to be lesser with laser.

Other studies have reported no difference in short-term safety and efficacy or early QoL between EVLA using a wavelength of 980 nm and HL/S. However, EVLA was more expensive than open surgery.[28]

Radiofrequency ablation versus surgery (high ligation, division, and stripping)

One international, multicenter, prospective RCT on 85 patients compared RFA and HL/S and followed it up for 2 years. The RFA reported significant short-term (4 months) advantage in terms of earlier recovery, less postoperative pain, fewer adverse events, and superior QoL scores.[29] At 2 years, there was almost equal chance of reflux.[30]

Radiofrequency ablation was found to take less time to perform; 25 versus 40 min as reported by Hinchliffe *et al*.[31]

There was significantly lesser pain, faster recovery and earlier return to work after RFA than after surgery.[32]

On evaluating all the RCTs on this aspect, the venous Guideline Committee of The Society for Vascular Surgery and the American Venous Forum accepted the immediate advantage of RFA over HL/S but concluded that the RCTs were of low quality as these lacked bias protection measures. Thus, high

quality RCTs is still required to assess the comparative efficacy of RFA over HL/S in superficial venous insufficiency and reflux. There is no evidence on long term effect of RFA.

Endovenous laser ablation versus radiofrequency ablation

Not many RCTs exist in this comparison. Single-center randomized trial on 50 patients with right left comparison-insignificant higher occlusion rate of saphenous vein in favor of RFA. Complication rate was similar.[33] Another trial reported lesser perioperative pain after RFA.[34] Clinical and QoL improvements were similar in both groups at 6 weeks. Recanalization rate at 1 year indicated laser ablation was significantly better than RFA.[35]

Sclerotherapy versus surgery

Less recurrence was found in sclerotherapy in comparison to surgery in 1 year[36] and 2 years[37] in two large uncontrolled trials. Polidocanol foam sclerotherapy was found to be less efficacious in a RCT[38] and a systematic review.[39]

Sclerotherapy versus radiofrequency ablation versus surgery

In one meta-analysis on 64 studies, foam therapy and RFA were equally effective as surgery after 3 years. However, they reported EVLA had the highest success rate in short-term and long term.[40]

Radiofrequency ablation versus endovenous laser ablation versus sclerotherapy

In a systematic review and meta-analysis of RFA, EVLA, and foam sclerotherapy for primary varicose veins. Luebke and Brunkwall found EVLA as superior in saphenous occlusion rate, phlebitis, DVT, and paresthesias.[41] There was higher recurrence rate in the presence of saphenofemoral incompetence with foam sclerotherapy. No conclusive remarks were possible on a long term results.

EVIDENCE AND RECOMMENDATION

- Laser is safe, effective, less invasive, requires shorter hospital stay, causes less bleeding, bruising, and is possibly less painful in most of the cases
- Thus, they are recommended in saphenous incompetence, reflux and primary varicosity (evidence Level B)
- Lasers are preferred over HL/S for short-term benefit. For comparison of long-term benefit between EVLA and HL/S, more studies are required
- Comparative efficacy between EVLA and RFA is unknown due to lack of evidence. More RCTs are necessary
- Sclerotherapy is recommended for telangiectasia, reticular veins, and varicose veins (evidence Level B)
- Foam sclerotherapy is recommended over liquid sclerotherapy for incompetence
- As per the available evidence (evidence Level C), sclerotherapy cannot be recommended over standard surgery for saphenous vein incompetency, about success and prevention of relapse. More studies are required
- Due to gross heterogeneity in the study methods as well as in the results, a meaningful comparison of endovenous methods with open surgery was difficult especially about the long term efficacy and recurrence. EVLA may offer some advantage in short-term over RFA and surgery, but no recommendation can be made.

PERFORATOR INCOMPETENCE

Techniques for treating perforator incompetence are subfascial endoscopic perforator vein surgery, percutaneous ablation of perforators (PAPs), RFA and EVLA.

Subfascial endoscopic perforator vein surgery is done under general or epidural anesthesia. Deep posterior compartment is opened through division of the fascia and the perforators transected with ultrasonic harmonic scalpel. In PAPs, perforators are punctured under ultrasound guidance with local anesthesia.

Results

In an uncontrolled prospective cohort study with 810-nm diode laser, 78% occlusion of the perforating veins was achieved after 3 months of procedure.[42]

EVIDENCE AND RECOMMENDATION

Ablation of incompetent perforator vein either alone or in addition to classical GSV ligation and stripping was not found to have any significant positive effect on ulcer healing or preventing recurrence as found in the review by O'Donnell.[43] They suggested GSV ablation to reduce ulcer recurrence.[43] More RCTs are required to evaluate the exact role of perforator ablation in ulcer healing.

Perforator ablation is currently not recommended for management of ulcer.

Skin grafting for venous ulcers

Whilst compression therapy treats the underlying pathology, ulcers remain open in some cases for months or years, or heal very slowly. Additional treatments such as skin grafts or tissue-engineered skin may be used to hasten the healing process.

Skin grafts used for venous leg ulcers are pinch grafts and split-thickness skin, or meshed grafts may also be performed on larger wounds. Grafting should be considered for large or refractory ulcers, when the venous hypertension is well-controlled and when the ulcer bed is clean with healthy granulation tissue.[44] Despite the common use of skin grafts in venous leg ulcers, no valuable study is available to assess and quantify the effect of grafting on the healing of venous ulcers

and to compare this strategy of treatment with other strategies, such as standard wound care.[45]

Skin grafting generally is not effective if there is persistent edema, which is common with venous insufficiency, and if the underlying venous disease is not addressed.

Other newer modalities of treatment

The efficacy of other emerging treatments such as topical recombinant growth factors or other products of tissue engineering is not sufficiently evident. Randomized controlled studies are lacking for many biological products.[46]

Apligraf™ is a living bi-layered bioengineered skin substitute, composed of a Type I collagen matrix. It was approved by the FDA in 1998 for the treatment of leg ulcers of >1-month duration that have not adequately responded to conventional therapy.

EVIDENCE

Used with compression, Apligraf™ heals venous leg ulcers more effectively than simple dressings and compression, from 49% of complete closure to 63% at 6 months.[45,47] (evidence Level D).

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Cite this article as: Sarma N. Guidelines and recommendation on surgery for venous incompetence and leg ulcer. Indian Dermatol Online J 2014;5:390-5.
Source of Support: Nil, **Conflict of Interest:** None declared.