

Advances in Treating Varicose Veins - ELVA

Toward the end of 2003 we acquired Biolitec's Ceralas D15 980 nm (diode) laser which is FDA approved for endovenous ablation of saphenous veins. In last Spring's *Veno-gram* we announced our initial positive experience with this laser regarding patient acceptance, results, and reliability. We also listed indications for this procedure and reported early promise of its acceptance by Medicare and private insurance companies. That was one year ago, so we figure you deserve an update to see if our favorable early impressions held up over time.

Insurance: A breakthrough in insurance reimbursements occurred on November 15, 2004 when Medicare officially assigned a new unique CPT reimbursement code specifically for endovenous laser ablation (EVLA). Since then most insurance companies have accepted legitimate EVLA claims, some reimbursing as high as 100% of submitted fees.

It is interesting that duplex-guided sclerotherapy still suffers from frequent claims denials after 15 years of experience and proven efficacy, while in comparison, EVLA was embraced almost immediately. Fortunately, most patients are good candidates for EVLA and can expect generous reimbursement levels. By way of review, saphenous veins must have the following characteristics to be suitable for EVLA: uniform diameter > 3 mm, straight course in the thigh, and depth > 2 mm below the skin.

Our Experience: The Biolitec laser has required no repairs and has performed flawlessly. This is important when one considers patients wait an average of two months for an EVLA appointment and often make future plans based on the assumption of successful outcome. Even more importantly, we have not seen a single saphenous vein recanalization after EVLA. While one in four patients requires subsequent direct injections to distal surface varicosities that do not completely recede after EVLA, this is an easy task after successful saphenous vein decompression by EVLA.

Probably most importantly, patients have uniformly raved about their results and the fact they were able to avoid vein surgery. Aside from lower costs and fewer risks, they appreciate the freedom from painful recovery, scars, and lost work time associated with saphenous vein stripping surgery.

Published Long-term Efficacy: As most of you know, RF-Closure (radio frequency) ablation became

available one year before EVLA. Recently published results from an ongoing multi-center trial sponsored by the manufacturer using RF Closure showed 89% vein occlusion at four-years.¹ This was achieved with a low incidence of complications including 1% DVT, 1% skin burns, 0.2% infections, and 10% paresthesia. Lower complication rates were seen in treatment centers with higher patient volumes and in all centers after the introduction of tumescent (perivenous) anesthesia which improved overall efficacy later in the study. This compares with published results from a multi-center trial using a diode laser for EVLA which showed 93% vein occlusion at two years;² the comparable RF Closure rate at **two** years was 86%.

We chose to delay offering EVLA so that we might benefit from the experience of these pioneers. Techniques which have allowed us to avoid complications from the start include the generous use of perivenous local anesthesia and initial placement of the catheter tip 2-3 cm below the saphenofemoral junction. Also relevant is our 14 years' experience using duplex imaging to map and guide saphenous vein treatment, and our good fortune to have an experienced ultrasound tech who participated in the endovenous laser FDA trials.

Accordingly our complication rates have been gratifying with no DVT, no infections, no skin burns, and 2% paresthesia. Although we have been using EVLA for only sixteen months I have no doubt it is here to stay as the most effective currently available treatment for saphenous vein disease in suitable candidates.

1. Merchant RF et al. Four year follow-up on endovascular radiofrequency obliteration of great saphenous reflux. *Dermatol Surg* 2005; 31:129-134

2. Min RJ, Khilnani N, Zimmet SE. Endovenous laser treatment of saphenous veins reflux: long-term results. *J Vasc Interv Radiol* 2003; 14:991-996.

IN OTHER NEWS

Ximelagatran - A New Oral Anticoagulant

Ximelagatran (Exanta) is the first **oral** direct thrombin inhibitor made possible by the addition of a carrier molecule to facilitate crossing the GI mucosal barrier. Unlike Warfarin, Ximelagatran has predictable pharmacokinetics unaffected by obesity, ethnic origin, and food which allow fixed dosing without the need for laboratory monitoring similar to low-molecular-weight heparins.

Prior studies have proven its efficacy for primary prevention of venous thromboembolism (VTE) post-operatively, in atrial fibrillation, and for long-term secondary prevention. Now comes a large multi-center, double-blind, randomized six month trial (Thrombin Inhibitor in Venous Thromboembolism, or THRIVE) which proves its efficacy for both acute treatment and prevention of recurrent VTE.¹

2500 patients with acute DVT were treated with either enoxaparin followed by six months Warfarin or twice daily Ximelagatran for six months. One third of each group had concurrent pulmonary embolism. Both treatments were proven equally effective with similar recurrent VTE rates (2%) and low bleeding risks (1-2% major, 5-6% minor). Patients treated with Ximelagatran had two adverse effects not seen in the Warfarin group:

10% had liver enzyme elevations, and <1% had unexplained acute myocardial ischemic events.

The authors concluded that twice daily oral Ximelagatran was as effective as enoxaparin/Warfarin for the initial and prolonged treatment of DVT/VTE. Although approved in many European countries last year, Ximelagatran remains under FDA study awaiting imminent U.S. approval.

In a related study sponsored by the Agency for Healthcare Research and Quality, testing for hypercoagulable disorders followed by two years of anticoagulation therapy was more cost effective than the usual practice of six months anticoagulation without testing in patients with DVT.² However, lifetime anticoagulation was preferred for **homozygous** Factor V Leiden mutation and antiphospholipid antibody syndrome. Please refer to our winter issue cumulative index for coverage of these and other thrombophilic factors in past *Veno-gram* issues.

1. Fiessinger et al. Ximelagatran vs low-molecular-weight heparin and Warfarin for the treatment of deep venous thrombosis. *JAMA* 2005;293:681-689.

2. Auerbach AD, Sanders GD, Hambleton J. Cost-effectiveness of testing for hypercoagulability and effects on treatment strategies in patients with deep venous thrombosis. *Amer J Med* 2004;116:816-828.

Sclerotherapy Complications with Solution & Foam

A multi-center prospective study funded by the French Society of Phlebology monitored all adverse events that occurred during 12,000 sclerotherapy sessions performed by 22 experts with one month follow-up.¹ All vein calibers were treated with approximately half the treatments involving the use of foam, especially for larger veins such as saphenous trunks and their main tributaries where ultrasound-guidance was commonly employed. Sclerosing techniques and agents, indications, and efficacy were not specified. However, sales of sclerosing agents in France indicate that polidocanol is used most commonly (75 %) followed by sodium tetradecyl sulfate (13%) and chromated glycerin (12%).

An overall 0.4% incidence of side effects was noted with 0 sequela. The most common immediate adverse event (20/49) was visual disturbance with or without headache; this occurred almost exclusively with foam/air injection and more often when treating reticular veins without any correlation to

concentration, volume, or foam/air ratio. The second most common immediate adverse event was vasovagal fainting, with rare cases of cough and paresthesia.

Delayed complications were rare and solely thrombotic with just one case of deep (femoral) vein thrombosis without sequela. There were no reports of intra-arterial injection or tissue necrosis, a finding attributed by the authors to experienced clinicians using ultrasound-guidance to treat sub-surface veins. No cases of anaphylaxis or pulmonary embolism were seen.

The authors concluded that sclerotherapy is an extremely safe procedure in the hands of experts with a very low incidence of complications, an opinion echoed by commentator Dr. John Bergan.

1. Guex JJ et al. Immediate and midterm complications of sclerotherapy: report of a prospective multicenter registry of 12,173 sclerotherapy sessions. *Dermatol Surg* 2005;31:123-128.