Office-Based Venous Care: Deep and Superficial

A brief review of available therapies for venous conditions and commentary on current reimbursement for services.

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Hospitals have become large, integrated systems, as required for the complex infrastructure and teams of people necessary to care for patients with acute, life-threatening vascular disorders. However, for the treatment of patients with chronic vascular conditions, hospital care is bloated and expensive. The physician's office, or office-based lab (OBL), offers a lower-cost alternative for the delivery of streamlined outpatient vascular care. Catheter-based platforms for vascular interventions have created an opportunity for physicians to open comprehensive outpatient vascular centers. Patients with venous conditions present with a broad range of disease severity, as captured in the Clinical Etiology Anatomy Pathophysiology (CEAP) classification: spider telangiectasia (C1), varicose veins (C2), edema (C3), skin changes (C4a, b), or venous ulcers (C5–6). It is then reasonable that the procedures to treat these conditions are also broad, ranging from small injections to complex vascular reconstructions.

Most venous disorders can be safely treated in OBLs. It is critical to recognize that OBLs function as small businesses that require generous financial investment for initiation and maintenance. Capital is required for diagnostic transcutaneous ultrasound; lasers and radiofrequency (RF) devices; medications such as local anesthetics, intravenous sedatives, and sclerosants; and other imaging equipment such as portable C-arm fluoroscopy and intravascular ultrasound (IVUS). A front and back office must manage operations such as preauthorization, billing, collections, payroll, IT, and a dynamic regulatory environment. Success is inherently dependent on delivering high-quality care and having the business savvy to manage increasing operating expenses in this era of payment reform.

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C1 VENOUS DISEASE

Sclerotherapy

Injection of a chemical into a vein to achieve endoluminal fibrosis has been used for almost a century. Sclerotherapy is considered the most versatile treatment option for venous ablation and can be used to treat a large range of vein sizes from telangiectasias to large varicose veins. For smaller veins such as telangiectasias, venulectasias, and small reticular veins, liquid sclerotherapy is used; for larger reticular veins and varicose veins, liquid sclerotherapy at higher concentrations or foam sclerotherapy is more effective. Foam sclerotherapy involves the addition of air to a detergent sclerosing agent by means of agitation to produce a foam-like consistency. The injected foam has tensioactive

Figure 1. Liquid sclerotherapy of spider telangiectasia.

properties, which allows for enhanced interaction with the vein wall (Figure 1).

Light Source Technology

In addition to sclerotherapy, light source technology is an emerging treatment for small spider telangiectasias. Cutaneous lasers and intense pulse light devices penetrate the skin to treat the vessel. To avoid damaging the overlying skin, the target vein is precisely selected using the appropriate wavelength, pulse duration, spot size, and fluence. C1 disease is a cosmetic problem, and treatment is not covered by payers; thus, the cash revenue can augment a medical practice.

C2 VENOUS DISEASE

Truncal Veins (Saphenous System)

Thermal ablation. The two most popular methods of thermal ablation currently in use are RF ablation, which uses a catheter to direct RF energy from a dedicated generator, and endovenous laser (EVL) ablation, which employs a laser fiber and generator. Both RF and EVL are catheter-based endovascular interventions that use electromagnetic energy to occlude (ablate) the target vein by heat transfer. Both require local tumescent anesthesia and are performed under sonographic guidance (Figure 2).

RF ablation was approved by the US Food and Drug Administration in 1999. The current rendition of the RF catheter was introduced in 2007 and is more effective and faster than the first-generation device. EVL was approved in 2002. Currently available laser systems include hemoglobin-specific laser wavelengths (810, 940, and 980 nm) and water-specific laser wavelengths (1,319, 1,320, and 1,470 nm). Data do not show superiority of one EVL wavelength over another; the device choice is a matter of physician preference.

Dedicated CPT codes are available for reimbursement, and procedures are covered by most payers; however, medical necessity criteria differ between payers. Most vendors will offer reduced pricing on generators in exchange for guaranteed minimum purchase volumes on disposable catheters, fibers, and access kits. However, this can create a situation where OBLs are tied to a high target volume of cases and may cause a misalignment of incentives.

Nonthermal ablation. Nonthermal alternatives for truncal vein closure have generated some interest to mitigate nerve injuries and reduce the number of injections required for placement of perivenous tumescent anesthesia during thermal ablation. Polidocanol endovenous microfoam, a proprietary pharmaceutical-grade foam and oxygen-carbon dioxide mixture dispensed from a proprietary canister device, was approved by the FDA for use in 2014. Mechanochemical ablation involves a catheter with a fast-rotating, thin wire tip and an infusion of liquid sclerosing agent. It can be applied along the saphenous trunk without tumescent anesthesia and has satisfactory closure rates. Endovenous glue is delivered via catheter (a proprietary formulation of n-butyl cyanoacrylate) to treat refluxing truncal veins. It can also be applied along the saphenous trunk without tumescent anesthesia and has satisfactory closure rates. All of the aforementioned nonthermal technologies have demonstrated satisfactory early clinical data but do not have dedicated CPT codes for reimbursement.

Nontruncal Veins (Varicosed Tributaries)

Stab phlebectomy. Elimination of an incompetent great saphenous vein reduces venous hypertension and relieves patient symptoms, but is not sufficient to eliminate all existing varicose veins. Stab phlebectomy is simple to perform, well tolerated with tumescent anesthesia, and can be used in conjunction with other treatment modalities.

Sclerotherapy. Similar to the treatment of truncal vein reflux, foam sclerosant is more effective for varicosities when compared to the liquid counterpart and is more readily visualized with ultrasound imaging (ultrasound-guided foam sclerotherapy).

Pelvic congestion syndrome. The development of varicose veins in the pelvis may cause disabling symptoms, mainly in women of childbearing age; the disease is known as *pelvic congestion syndrome.* Transabdominal/vaginal duplex ultrasound or CT/magnetic resonance venography can be performed to confirm ovarian vein reflux into a plexus in the broad ligament to form pelvic varicose veins. Endovascular

Figure 2. Placement of tumescent anesthesia for treatment of concomitant saphenous vein and mid-thigh perforator vein incompetence with EVL (under ultrasound control).

therapy relies on coil embolization alone or in conjunction with foam sclerotherapy. Despite a growing body of evidence demonstrating that these interventions benefit properly selected patients, the medical necessity criteria among payers is inconsistent—some go as far as to call the interventions "experimental."

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C3 THROUGH C6 VENOUS DISEASE

Chronic Deep Venous Obstruction

The etiology of venous obstruction can be primary (nonthrombotic) or secondary (postthrombotic), with roughly equal prevalence estimates in patients with chronic venous disease. Signs and symptoms of chronic venous obstruction and reflux overlap with some differences. Limb swelling beyond ankle edema is rare with pure superficial reflux alone. Primary obstruction, often referred to as *nonthrombotic iliac vein lesions,* usually arises from compression of the left common iliac vein by crossing of the overlying right common iliac artery. Other compression sites commonly occur at proximal or distal locations such as the hypogastric artery bifurcations. Postthrombotic obstruction is more extensive, often involving the femoral and iliac venous systems.

The endovenous treatment of iliocaval obstruction includes traversing the obstruction with a guidewire (occlusions need to be recanalized), followed by balloon angioplasty and placement of a stent to maintain patency of the obstructed vein segment. Self-expandable stents with a high radial force and sufficient flexibility should be used. Multiple centers report the use of braided stents made of elgiloy (cobalt, chromium, and nickel). Recently, dedicated nitinol venous stents have been designed, but clinical results are lacking.

One caveat with the endovenous treatment of iliocaval obstruction is the use of IVUS, which is invaluable both in diagnosis and as an intraoperative tool in stent placement because contrast venography, even with the transfemoral approach, has poor sensitivity in assessing the iliac venous segment (Figure 3). Currently, there is no reimbursement for the disposable IVUS catheters for OBLs. This may cause a misalignment of incentives when the costs of the diagnostic imaging procedure are higher than the reimbursement. To achieve a net profit, an intravascular stent must be placed to treat a clinically significant lesion, and if a lesion is not identified by

Figure 3. Intravascular stenting of iliac vein occlusive disease using fluoroscopic and IVUS guidance.

IVUS, the OBL will lose money on that case. Beginning January 2016, IVUS will be a covered expense by the Centers for Medicare & Medicaid Services.

CONCLUSION

OBLs are efficient, streamlined, and have been well received by patients. Now in our 15th year of operating a dedicated OBL focused on venous disease in downtown Miami, Florida, it is clear that this is the best environment for treating venous disease. However, we are facing payers who have steadily implemented convoluted and capricious coverage policies to curb utilization, and reimbursement is cut annually. The preauthorization process has become quite labor intensive, requiring the need for extra staff. We are doing more, even with less reimbursement.

Recently, a widely publicized *New York Times* article reported on unnecessary vascular procedures in OBLs.[1] In response, the Society for Vascular Surgery's President, Dr. Peter Lawrence, noted that the current system may foster inappropriate vascular procedures because the environment and incentives are wrong.[2] Of note, OBLs may be owned and operated by interventionists from vascular surgery, interventional radiology, or cardiology specialties, which may operate under different policies and procedures. For these reasons, additional oversight is needed by our vascular societies to monitor inappropriate use. The Vascular Quality Initiative (VQI) was launched in 2011 under the auspices of the Society for Vascular Surgery and may help in this regard. The VQI is housed within a patient safety organization, which allows operator anonymity and protection against discovery in the legal system, and claims are audited, ensuring that all procedures are submitted, thus avoiding selection bias. The VQI is further addressed in this issue of *Endovascular Today* (see "The Vascular Quality Initiative Varicose Vein Registry," page 66).

Payment reform has embraced moving away from a fee-for-service model due to perceived perverse incentives that encourage increased procedural volume. The shift to accountable payment models is happening quickly. Reducing demand for high-cost services is a key determinant of success under these risk arrangements, which is the opposite incentive from traditional fee-for-service medicine. Going forward, providers must transform both their payment models and care models, ideally in a synchronized manner. ■

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