

Hot Topics in Venous and Lymphatic Disease

Dr. Neil Khilnani moderates an expert panel discussion on appropriate use in superficial venous care and the emergence of phlebolymphectomy management in venous practices.

Appropriate Use in Superficial Venous Care

The appropriate use of minimally invasive approaches to treat patients with saphenous reflux and iliac vein obstruction can benefit individual patients, populations, and the economics of our health care systems.

Unfortunately, there is evidence that a reasonable fraction of these interventions are being performed “inappropriately.” Inappropriate, in this context, refers to the practice of recommending treatment that will not result in medical benefit, as well as billing our health care systems for aesthetic care.

Both the American Vein and Lymphatic Society (AVLS) and the American Venous Forum (AVF) have addressed the issue of inappropriate care. I am pleased to have the opportunity to ask several of the societal leaders addressing this effort to help us understand the problem and tell us what they are doing to rectify it.

MODERATOR



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Dr. Khilnani: What is inappropriate care, and do we have evidence to suggest how big of an issue it is in the United States?



Dr. Ozsvath: *Inappropriate.* This is a powerful word, suggesting that something is not suitable, not correct for a given circumstance. The opposite of inappropriate is appropriate. The terminology “appropriate use” as it pertains to medical care and research comes from a method based on the RAND Corporation/University of California, Los Angeles (RAND/UCLA) method of rating appropriateness. This is a tool

that was originally developed to measure over- and under-use of medical and surgical procedures and has been validated in procedures such as carotid endarterectomy, dialysis access interventions, and coronary revascularization.¹⁻⁴

The numbers of venous ablation procedures have skyrocketed over the past 15 years, and not only have the procedure numbers grown exponentially, but the number of specialists performing these procedures from varying backgrounds has increased as well. This trend has raised concerns among payors and vein specialists. Reimbursement for procedures performed in office-based labs is significantly higher for the individual practitioner

than those same procedures performed in the hospital. This could be construed as incentive for a wide range of providers.⁵

In a review of the Medicare Provider Utilization and Payment Database, Crawford et al analyzed endovenous ablation practice trends over 4 years. They found that the number of providers increased by 16% and the number of ablations increased by 28%.⁶ In a press release recently published by MarketWatch, the varicose vein treatment market size was estimated to grow from \$222.4 million in 2017 to \$333.8 million by 2023.⁷ Given the staggering growth, appropriate use as it pertains to the treatment of venous disease is a real question. We hear of “rogue” providers who perform too many procedures on individual patients, perform unindicated procedures, and incentivize vascular lab techs to elicit venous insufficiency when it doesn’t exist—the inappropriateness can go on and on. Is this rampant? Are there truly practitioners more interested in reimbursement than honest patient care? It’s a difficult question and a more difficult problem to resolve.

Venous experts from several societies came together to address this issue. The manuscript, entitled “The 2020 appropriate use criteria for chronic lower extremity venous disease of the American Venous Forum, the Society for Vascular Surgery, the American Vein and Lymphatic Society, and the Society of Interventional Radiology,” was recently published in early March.⁸

We hope that it provides a framework for practitioners to use to determine what the experts consider appropriate use in many clinical scenarios pertaining to treatment of venous disease.

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Dr. Khilnani: What are the main principles of medical ethics in terms of how they relate to inappropriate care?



Dr. Gibson: The main pillars of medical ethics are autonomy, beneficence, non-maleficence, and justice. Autonomy refers to the respect of a patient’s right to self-determination. This is an important part of informed consent, where patients must be given accurate and nonmisleading information on which to base a decision to proceed with an intervention. In venous disease, some examples of violations of this principle are overstating the importance of a finding and exaggerating a risk or benefit, such as claiming that a venous stent for an iliac vein compression seen on duplex ultrasound might prevent future thrombotic events or death from pulmonary embolism. The principle of beneficence means that a physician should always act in the patient’s best interest. Even if the proposed treatment has little risk of harm, it should have benefit to the patient. An example of a violation of this pillar would be recommending saphenous ablation for asymptomatic reflux.

Many medical ethicists consider the principle of nonmaleficence (primum non nocere or “first, do no harm”) to be the most important pillar. The more serious or life-threatening the condition, the more that acceptance of risk or harm is possible. For example, a significant risk of mortality is acceptable for ruptured aneurysm repair but is unacceptable for most venous procedures. The final principle, justice, refers to the fair distribution of scarce resources. The concept of medical triage applies to this principle. Inappropriate procedures consume resources unnecessarily and drive up the costs of medical care for all. Abuse of the medical system leads to restrictions (eg, insurance denials) for patients who may legitimately benefit from care.

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Dr. Khilnani: What is the Appropriate Use Criteria (AUC) project in venous disease, and how do you think this can help reduce unnecessary treatment?



Dr. Masuda: This project was initiated in response to the increasing concern over inappropriate application of minimally invasive techniques in venous therapy. Venous ablation procedures and, in some cases, venous stenting are easily accessible, and requirements for training are nonexistent or at best poorly defined. The AVF developed an Ethics Task Force to address this growing problem and together with the Society for Vascular Surgery, AVLS, and the Society of Interventional Radiology participated in a multisociety appropriate use project. This is the first of its kind for superficial venous care, and the AUC was developed using the RAND/UCLA appropriateness method in which a combination of best available evidence and expert opinion are combined and panelists are presented with scenarios to rate while engaging in a modified Delphi process. The statements were intended to serve as a guide to patient care on a population level (eg, practice patterns) and not to dictate decision-making for individual cases. The document was recently published online ahead of print in *Journal of Vascular Surgery: Venous and Lymphatic Disorders*.¹

The AUC will provide a means of bringing awareness to appropriate and inappropriate treatment indications, as well as insight into the areas of unnecessary procedures and possible abuse. Secondly, the document will support current clinical guidelines and extend beyond traditional statements; it will fill in the gap where scientific evidence and guidelines lack specificity by providing guidance for common clinical scenarios encountered on a day-to-day basis. Finally, the document allowed us to identify many areas in which research is needed to clarify the role of venous procedures and will provide potential groundwork for future studies. By better defining indications for use, unnecessary procedures can be potentially mitigated. The AUC is meant to be a living document and is intended to be updated as more scientific evidence is acquired.

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Dr. Khilnani: What can patients do to protect themselves from overuse of saphenous ablation and iliac stenting?



Dr. Salazar: It has been clinically proven that patient engagement is essential to improving medical treatment outcomes, and as a rule, I think it is important to have patients at the center of the discussion and explain the risks and benefits of the interventions in a way they understand. However, patients are seeking information online for their medical condition from various sources that may not be scientifically sound. Consequently, our job is to educate patients properly. To that end, I believe it is important to mention and promote guidelines and scientific data at our clinical practices and websites. Most medical societies are working on improving patient education, and I think that is key to reducing overutilization of procedures in general. On the other hand, there is a misconception that treatment of varicose veins is purely cosmetic, and there are data showing that men usually seek treatment

in more advanced stages compared with women, leading to further complications and health issues. In my opinion, under- and overutilization go hand in hand, and it is a sign of misinformation and educational gaps that we need to eliminate as a community.

Another form of patient-centered care is to utilize patient-shared decision-making tools. I have worked with the Massachusetts General Hospital Health Decision Sciences Center to develop such tools for women's health, and patients really appreciate it and better understand their options. They also become more confident about their treatment choices, even if they elect to take a more conservative approach.

In my practice, I will discuss symptoms with patients and use venous questionnaires, understand the key reasons why they are seeking treatment, and then present a PowerPoint on why and how we should treat varicose veins. I believe this approach is helpful to reduce patient misinformation and improve compliance with treatment and patient engagement. I also talk to them about disease progression and provide details about

the need to evaluate for central venous obstruction. Not all patients will need cross-sectional studies, but we know that the literature supports further evaluation of venous obstruction in patients with recurrent disease and advanced stages. In my experience, 10% of patients will need further evaluation and, when appropriate, receive a venous stent.

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Dr. Khilnani: What is the Improving Wisely (IW) project in venous disease, and how might these efforts prevent overuse?



Dr. Mann: IW is a quality improvement initiative by the AVLS in collaboration with Johns Hopkins University and the Robert Wood Johnson Foundation to establish benchmarks and minimize extreme variabilities in physicians' practice patterns. At the

heart of IW is ensuring quality and safety while optimizing the value of service physicians deliver to our health care system. Last year, we focused on overuse of venous ablation procedures. Using detailed Medicare claims-based analysis, we established a benchmark for average thermal ablation per patient. Confidential individualized reports were then sent to physicians comparing their practice pattern to that of their peers. By bringing awareness to physicians who are outliers, we hope to inspire physicians to examine their individual practice to see if improvements can be made and reduce unnecessary variations.

Peer comparison feedback has a proven track record—it has curtailed unnecessary antibiotic prescribing, increased handwashing practice, and improved colonoscopy quality, among other improvements. There is something powerful about seeing how we perform relative to established benchmarks and our peers. Since the distribu-

tion of our reports, the reception from our members has been very positive. The IW project has brought greater transparency and awareness of significant variations in vein care. We have had physicians reach out to the AVLS for mentorship and educational support. In the next year, we plan to reexamine the same metric to see if IW produces a reduction in unwarranted utilization.

Although our focus has been on overuse, I would argue that the topic of underuse is equally important when discussing appropriate use. Our preliminary data show that patients with venous ulcers are often undertreated compared with those with lower CEAP (clinical, etiology, anatomy, pathophysiology) scores. We hope to harness the power of IW to exam this topic in the next year.

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Dr. Khilnani: What additional strategies would you recommended to encourage more appropriate use of venous interventions?

Dr. Ozsvath: Strategies to protect patients and guide venous specialists to follow appropriate care are difficult to measure and enforce. The following list may be sensible, but some are nearly impossible to implement or enforce.

- Societal guidelines written by experts and published in peer-reviewed journals
- AUC guidelines, such as the forthcoming publication; experts in venous disease and treatment were polled on many clinical scenarios to determine consensus on appropriate treatment in patients with venous disease

- Prospective, randomized clinical trials to determine the best technology, methods, and treatment for patients suffering from venous disease
- Educational programs for patients to help them understand their disease and the treatments available
- Holding medical device manufacturers accountable for selling equipment to inexperienced practitioners without clinical support, education, or experience
- Educational programs for practitioners to learn from experts run by responsible entities
- Specialty boards to require trainees to be educated and experienced in the field of venous disease treatment prior to graduation

- Scrutinize the education and experience of practitioners and centers by requiring accreditation
- Link reimbursement to accreditation, quality metrics, and practitioner experience

Many ideas come to mind, but again, implementation is difficult.

Dr. Masuda: We should address the problem with a multipronged approach. One method is to work together with professional societies to provide AUC and clinical guidelines. Another is patient education by disseminating information to the public via web-based resources and outreach through the Choosing Wisely campaign. The latter was developed by the American Board of Internal Medicine together with Consumer Reports and creates a platform where patients and physicians address areas of medicine and surgery that are likely unnecessary. Two examples of procedures patients are advised to avoid are ultrasound for asymptomatic spider veins and prophylactic use of inferior vena cava filters.

The Society for Vascular Surgery and AVF have partnered for continued work on the Vascular Quality Initiative national database and are formulating ways that the data may be leveraged to identify potential areas of overuse.

To address overutilization, practitioners may benefit by knowing the average number of ablations per person compared with the national average. As mentioned by Dr. Mann, the IW initiative examined the average number of ablations per person from the Medicare claims database, and this feedback allowed physicians to compare their average to the national average. Several publications on the Medicare claims data between 2013 and 2017, plus a single-center experience, have reported that the mean number of ablations per patient per year was 1.3 to 1.9.¹⁻⁴ Although this should not dictate what is needed for individual cases, the average number serves as a guide for providers to reflect on how their practice patterns compare to their peers.

Another method to address better utilization of venous procedures is by educating future providers. By introducing appropriateness concepts at an early phase in training, such as fellowships, residencies, and medical schools, we can set the stage for future physicians to ensure a stronger foundation in choosing the right indications for the right patient.

Dr. Salazar: Particularly for the use of venous stents, patient selection is key. Although there are sufficient data on their use in patients with advanced venous disease, robust data on the use of stents for pelvic venous

diseases are still lacking, which sometimes can be associated with chronic venous insufficiency. Again, having a discussion with the patient and showing the “gaps in the literature” is an important step, because patients may decide not to have a stent and elect for a more conservative approach. Lastly, there are limitations on cross-sectional imaging and the evaluation of May-Thurner syndrome, with some patients having false-positive results. Therefore, if you decide to perform a venous stenting procedure, it is imperative to perform an intravascular ultrasound evaluation to confirm significant venous compression before stent placement.

Dr. Mann: Our collective vein societies have done a tremendous job of addressing appropriate use in the last few years. We have established benchmarks through the vein registry, provided feedback with IW, encouraged ethical standards, and created AUC. But behavioral change is hard, especially when inappropriate use is tied to financial incentives. I believe we need to increase physician awareness and participation. We need to work with payers to ensure that appropriate procedures are covered and adequately reimbursed.

Dr. Gibson: Various groups and entities can lend a hand in curbing inappropriate use of venous interventions. Included in these groups are physicians, specialty societies, accrediting bodies, and hospital and medical systems—as well as payors. Medical ethics training should begin early in medical school and continue throughout residency and into continuing education programs. Some inappropriate procedures are driven by ignorance of medical evidence and guidelines, and filling these knowledge gaps is an important role for physician educators and medical societies. Registry participation and interpretation of registry data can help us learn more about utilization of venous interventions and pinpoint areas that need further study.

Curbing inappropriate interventions is vitally important to the care of our patients and the future of our specialty. A combination of a good educational foundation, the publication of guidelines and best practices, and an emphasis on always trying to do the right thing (ie, putting the patient’s interests ahead of the physicians’) will lead to excellence in venous care.

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Managing Phlebolymphe¹edema

Physicians who care for patients with venous disorders routinely evaluate patients with lower extremity swelling. Often, the swelling is unrelated to venous disease. In some patients, the swelling may be purely venous in etiology. However, in many, the swelling may be multifactorial, with a venous condition contributing only partially or not at all.

Although not well appreciated by most providers, venous disease is a common cause of a form of secondary

lymphedema known as *phlebolymphe¹edema*. Swelling from this entity can be challenging to manage, particularly if it is addressed late. I am fortunate to be able to assemble an internationally recognized group of experts to ask them questions to help us all better understand the pathophysiology and management of phlebolymphe¹edema.

— Neil Khilnani, MD, FSIR, FAVLS | Moderator

Dr. Khilnani: Why does swelling associated with venous hypertension not always resolve after appropriate treatment of venous disease? Is this phlebolymphe¹edema?



Dr. Lurie: Let's first clarify the terminology. *Venous hypertension* refers to several completely different phenomena. In primary chronic venous disease (CVD), when there is no venous obstruction, this term refers to the lack of pressure drop in the pedal superficial veins during ambulation (ambulatory venous hypertension). There is no increase in venous pressure in such patients, and when swelling is present, it is caused by factors unrelated to venous pressure. In secondary CVD, when there is significant venous obstruction, the venous pressure may be increased immediately upstream to the obstructed vein. A recent study by Kurstjens et al showed that the resting venous pressure in patients with venous obstruction is not significantly different from healthy patients, but it significantly increases during ambulation.¹

Limb edema is a result of imbalance between capillary filtration of water and its reabsorption from the tissue. Because all reabsorption occurs through the lymphatic system, venous procedures can only decrease abnormal filtration. In primary disease, which has no increase in

venous pressure, filtration is not affected by CVD, and a venous treatment (eg, ablation of superficial reflux) cannot resolve edema by itself. Reduced swelling after such procedures should be attributed to other factors, known (increase in physical activity, use of compression) or unknown. However, in cases of venous obstruction when the filtration is abnormally increased, appropriate treatment of obstruction may reduce filtration to the level matching lymphatic reabsorption. In any case of primary or secondary CVD, the presence of edema alone suggests that either central mechanisms (for bilateral edema) or lymphatics are involved. When appropriate treatment of unilateral venous obstruction fails to reduce the swelling, the presence of coexisting lymphedema or phlebolymphe¹edema is a highly probable explanation.

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Dr. Khilnani: What do you tell patients with swelling and either saphenous reflux or iliac vein obstruction to expect after treatment?



Dr. Winokur: I like to inform patients that swelling can be challenging to treat when or if it is the only symptom that is affecting them, due to the potential multifactorial causes of swelling and broad differential diagnosis. However, if swelling is unilateral and associated with ipsilateral saphenous

reflux and/or iliac vein obstruction, it may suggest that the venous abnormality is related to their symptoms. In articles by Raju et al¹ and O'Sullivan et al,² swelling significantly improved after venous stenting to resolve obstruction.

Patients often ask about the timing of improvement in swelling after intervention. I try not to give a specific timeline but do encourage patients that if the venous abnormality is the source of the edema, then the reduction in swelling often occurs soon after the procedure, possibly within a few days. They will continue to see

improvement over time with use of graduated compression stockings and ambulation.

In addition to assessing the venous system, it is important to consider lymphedema and lipedema in the differential diagnosis of unilateral or bilateral leg swelling. Lymphedema can occur as a primary process and will not benefit from either saphenous ablation or iliac vein stenting, but secondary lymphedema can arise from either process. In cases of secondary lymphedema, patients should be informed that they may require manual lymphatic drainage and/or a pneumatic pump to help improve their edema following intervention. In cases of lipedema, the recognition and edu-

cation that it may not improve after treatment is important. Heaviness, aching, cramping, or itching may improve in these patients, but the leg swelling may not change.

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Dr. Khilnani: Is there evidence to support benefit from the use of advanced pneumatic compression in patients with phlebolymphe-



Dr. Maldonado: Although filariasis may represent the most common form of secondary lymphedema worldwide, phlebolymphe-

ma is certainly the most prevalent form of secondary lymphedema in the United States. Defined as swelling of mixed etiology resulting from chronic venous insufficiency combined with lymphatic insufficiency, phlebolymphe-

ma should be recognized and treated as early as possible to avoid later complications resulting from progressive and largely irreversible pathophysiology that accompanies chronic inflammation in an edematous limb.¹ Failure to correct lymphatic dysfunction in this setting paves the way for a spiral of negative complications, including progressive fibrosis and recurrent episodes of cellulitis and ulceration.²⁻⁴ Effectively reducing edema is critical to preempt this negative spiral. Advanced pneumatic compression device (APCD) use is associated with consistent reductions in limb volume (LV). A study by Muluk et al of 196 patients with lower extremity lymphedema (27% with concomitant chronic venous insufficiency) found that 90% of patients experienced significant reductions in LV.⁵ The majority of these patients suffered from secondary rather than primary lymphedema. Use of an APCD was especially advantageous in obese patients. APCDs for treating patients with phlebolymphe-

ma may also result in improved quality of life, likely resulting from a decreased incidence of cellulitis and associated hospital visits. A study at our institution demonstrated significant results by incorporating APCDs in patients with lower extremity phlebolymphe-

ma. A total of 100 patients who were being treated for lower extremity lymphedema (> 70% due to phlebolymphe-

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**Dr. Khilnani: Phlebolymphe-
dema compli-
cating CVD, including in those with venous
leg ulcers and postthrombotic syndrome, is
underappreciated and undertreated in the
United States. Do you believe this is also true
in other countries?**



Dr. Shaydakov: Secondary lymphedema is an integral part of advanced CVD. It initially develops when the lymphatic system fails to compensate for abnormal venous outflow. The mechanisms of secondary injury to the lymphatic system leading to chronic progressive lymphedema are poorly understood. Underestimation of this component of pathogenesis inevitably leads to diagnostic and treatment errors in patients with primary chronic venous insufficiency and postthrombotic disease. Early treatment of venous disease is the best method of preventive management of phlebolymphe-
dema. But, in some patients, correction of venous outflow may not be enough to treat phlebolymphe-
dema.

We recently initiated a large population-based study in Saint Petersburg, Russia. The study includes office workers aged 25 to 35 years with a sedentary lifestyle. Preliminary results, based on more than 1,000 participants, demonstrate the prevalence of CEAP class C1 disease as high as

35% in women. More importantly, various abnormalities in regional lymphatic outflow were detected in 50% of individuals with C1 disease.

Endovenous procedures may effectively eliminate pathologic saphenous reflux and reduce venous hypertension in patients with chronic venous insufficiency. In many cases, they reduce venous edema, accelerate healing of venous ulcers, and prevent their recurrence. However, the importance of eliminating lymphatic hypertension seems to be underestimated. Within the last 10 years, we have been practicing the creation of proximal microsurgical lympho-venous anastomoses in select patients with phlebolymphe-
dema. The midterm outcomes of 215 procedures demonstrated that a lymphovenous anastomosis remains patent for about 1 month (2–5 weeks). During this period, the lymphovenous anastomosis alleviates phlebolymphe-
dema and contributes to venous ulcer healing.

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**Dr. Khilnani: What is the most important thing
about lymphedema that you want physicians
who focus on venous disease to know?**



Dr. Gasparis: The most important thing venous specialists should know is the critical interconnection that exists between veins and lymphatics. Pathology in the venous system, whether it is reflux or obstruction, results in venous hypertension and can lead to increased filtration into the interstitial space. Although the lymphatics can compensate early in the process, their capacity to move interstitial fluid is overwhelmed at some point, resulting in clinical edema. Venous edema tends to be unilateral; however, reflux and or obstruction may coincidentally affect both legs, or it can be related to bilateral iliac vein or inferior vena cava obstruction. In many cases, edema can be multifactorial and related to a combination of medical and venous causes, superimposed on primary or other causes of secondary edema or complicated by phlebolymphe-
dema.

One in four patients with venous disease presents with leg swelling. The differential diagnosis of lower extremity edema is very extensive; therefore, taking a careful history and physical examinations are necessary to appropriately treat patients. The differential includes systemic causes, medications, obesity, primary and secondary lymphedema, and vascular pathology. Failure to perform a careful evaluation

will result in delayed treatment, failure in clinical improvement, or unnecessary treatments including medications (eg, diuretics) or procedures (eg, venous ablation and stenting).

Early treatment of appropriately selected patients with venous hypertension may result in resolution of clinical edema. Prolonged edema of any cause may lead to irreversible lymphatic damage (reflux or scarring/obstruction) and is the reason that treatment of venous pathology may not result in clinical improvement of swelling. Understanding this important relationship between the venous and lymphatic system will allow the venous specialist not only to provide appropriate treatment but also to set patient expectations. Additionally, when venous interventions do not provide clinical improvement, the venous specialist should consider lymphatic therapy. ■

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