

Diagnosis and assessment of secondary lymphedema and associated fibrosis of lower limb skin

By Patrick Danciu

Lymphedema (LE) is a chronic disease and is characterized by an imbalance of lymphatic flow leading to accumulation of protein-rich fluid in the interstitial tissues. LE is classified as primary LE or secondary LE (SLE) according to the underlying causes. Known causes of SLE include radiotherapy, trauma, filariasis, and radical cancer surgery. Secondary lower extremity LE is a common com-

plication of treatment for gynecological cancers, including cervical, ovarian and endometrial cancer.

SLE presents as chronic unilateral or bilateral swelling of the lower limbs and is always accompanied with limb pain, heaviness, skin thickening, hyperpigmentation and altered sensation. Untreated patients are at high risk of

FIBROSIS
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Read our AVLS recap on pages 1 and 4. Photo credit: Jonathan Phillips Photography

Special long-form feature

Seven days with lymphedema

Monika Lecomte Gloviczki MD, PhD,
Amy Rivera and Amanda Sobey

THE BEGINNING

The true heroes in medicine are the patients. Their well-being is the goal of all medical care. Their perception of the disease, however, is often underestimated. It is not until the last two decades that modern medicine has recognized the importance of patient reported outcomes, and quality of life measures have finally become essential components of outcome assessment, together with clinical data on safety, efficacy, and cost effectiveness of a treatment.

Patients with currently incurable chronic diseases are real soldiers who fight to survive, trying everything to get better. They are desperately searching for a cure, looking

for hope and ready to experiment even if the outcome is uncertain. Revolutionary ideas in medicine were frequently implemented in the volunteers who sometimes risked their life to find cure. Remember Louis Joshua Washkansky, the first recipient of human-to-human heart transplant in 1967, who lived for 18 days after the operation performed by Christiaan Barnard. It was the early step on the cardiac transplants' road, needed to achieve the current 80% one-year survival rate.¹ New procedures or new drug treatments can only be introduced with cooperation of patients.

To understand how patients cope with a severe, frequently debilitating, at present still incurable chronic disease and to understand the patients' perception of their conditions, we embarked on a special project and organized a series of Zoom meetings with two patients with chronic lymphedema. They are our heroes and our partners in this

venture – Amy Rivera and Amanda Sobey, two fighters to improve their quality of life and two ambassadors for lymphedema treatment. This article summarizes many hours of our passionate conversations.

DAY ONE: LYMPHEDEMA DIAGNOSIS

Time for a mutual presentation. We discover each other (see Figure 1 on page 10).

Amy was born with lymphedema. One side of her whole body was swollen, further evolving into a lower limb lymphedema. Her mother was told that it was an issue of fetal development in her womb and that nothing can be done. Amy grew up as a beautiful girl, she was Miss Junior America at age 16, in 1999. It took her 32 years to

LYMPHEDEMA
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Recap: AVLS 35th Annual Congress

By Amanda Godwin

A high energy permeated the American Vein & Lymphatic Society's (AVLS) 35th Annual Congress as more than 400 physicians, sonographers, therapists and nurses gathered again. After a year break, everyone was excited to interact once again, learn and network in person.

"It was absolutely great to get back to an in-person meeting for the 2021 AVLS Congress," said Dr. Robert Worthington-Kirsch, AVLS Congress Chair. "We have

AVLS
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¹CJ van Vlijmen, SA Gauw, P Pronk, MC Mooij, MTW Gastra, JA Lawson. Randomized study Endovenous Laser Ablation versus RF VNUS ClosureFAST of Incompetent Great Saphenous Vein Using Tumescence Anesthesia Saphenous Vein: One year results. Veldhoven, Netherlands 31 May 2013



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THE NEWS

1 Diagnosis and assessment of secondary lymphedema and associated fibrosis of lower limb skin

In a study, the use of the SkinFibroMeter to accurately evaluate skin stiffness in patients with SLE of the lower limb was investigated. This portable instrument provides diagnostically valuable information on the severity of skin fibrosis in lymphedematous, edematous lower limbs.

1 Seven days with lymphedema

To understand how patients cope with a severe and frequently debilitating disease, doctors embarked on a special project and organized a series of Zoom meetings with two patients with chronic lymphedema. This article summarizes many hours of passionate conversations with them.

1 2021 AVLS a great success

A retrospective on this year's exciting AVLS conference, with photos and interview excerpts from participants.

4 AVLS quick review

Another quick look at the itinerary of this year's completed AVLS conference. All exhibits and presentations now available online!

6 FDA Clearance for Venclose Maven

Venclose Inc., a privately-held Silicon Valley medical device company focused on innovative treatment procedures for venous reflux disease today announced FDA 510(k) clearance for Venclose Maven™, a novel radiofrequency ablation (RFA) catheter.

THE PRACTICE

19 New leadership at ILWTI

International Lymphedema & Wound Training Institute (ILWTI) has been one of the top providers of educational training in lymphedema since 2012. Recently in 2020, Brandy McKeown OTR/L, CLT-LANA, CLWT, & CEO, a twenty-year veteran specialist in lymphedema acquired IWLTI. She is coming on board with a fresh vision and desire to reach even more people.

PRODUCT NEWS

30 Are you using Modifier 25 correctly?

A look at this often-misused modifier and how to optimize its use in order to increase billing efficiency in your practice.

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AVLS quick review

The AVLS 2021 Annual Congress was held at the Gaylord Rockies Resort & Convention Center in Denver, CO, from October 7 to 10. The 2021 sessions focused on recent research in the field of venous and lymphatic disease, specifically around data from the AVLS PRO 2.0 Venous Registry. Programming especially focused on research around the theme “Show Me the Data!” Recent research and abstracts were featured throughout sessions in addition to the abstract presentations. The opening session keynote address was by Dr. David Lechner, Chief Medical Officer of BlueCross BlueShield of Montana.

AVLS 2021 included 22 hours of live education sessions, 67 hours of on-demand recorded educational sessions, and four FVLD fundraising events with plenty of opportunities for fun and networking. There were also dedicated sessions on Friday and Saturday for residents, fellows, and medical students. The primary target audience of the 35th Annual Congress included physicians, physician assistants, advanced registered nurse practitioners, ultrasound technologists, practice administrators, lymphedema therapists and all other

healthcare professionals currently or planning to care for patients with venous and lymphatic disease.

Learning objectives of the conference included exploring the evaluation of patients with venous and/or lymphatic disease, assessing treatment goals with regard to improving quality of life, and diagnosis and treatment developments, in addition to many other topics! Three physicians-in-training were awarded a full scholarship to attend the 35th Annual Congress with up to \$1,000 towards travel expenses. Additionally, they had the opportunity to serve on AVLS educational committees and develop future educational opportunities with the AVLS. Finally, there were a number of fun outings as well, such as a golf outing and a hiking trip, which let attendees explore the beautiful areas around Denver.

AVLS is a leading entity in the venous/lymphatic world and this year’s conference was another great gathering of thought-leaders from around the medical world. **VTN**



AVLS hosted a number of fun outings, including golf and hiking.



Above: A nice chat around the fire with colleagues.

Right: AVLS 2021 included 22 hours of live education sessions.



Fun Run champions!



AVLS featured a number of keynote addresses by notable voices from the venous and lymphatic world.



A wide array of companies showcased their products at the Innovation Pavilion.



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FDA clearance for Venclose Maven

Venclose Inc., a privately-held Silicon Valley medical device company focused on innovative treatment procedures for venous reflux disease today announced FDA 510(k) clearance for Venclose® Maven™, a novel radiofrequency ablation (RFA) catheter for minimally invasive treatment of incompetent perforator veins (IPVs). The Venclose Maven catheter represents Venclose's commitment to developing next-generation venous treatment solutions that help physicians provide more comprehensive patient care.

"While our existing Venclose RF Ablation System, including the proprietary Venclose Catheter, continues to displace older technology for treating incompetent truncal veins, Venclose Maven will now allow doctors to also address refluxing perforators, a separate category of veins that contributes to more advanced and serious venous disease symptoms including painful venous stasis leg ulcers," said Jerry Gibson, Venclose Chairman and CEO.

Like Venclose's flagship catheter, the Venclose Maven is engineered to facilitate vein wall contact via both segmental and circumferential thermal delivery. These performance features were applied with the knowledge that physicians already familiar with this ablation method could quickly and easily incorporate the Venclose Maven catheter into their practices for IPV treatment.

According to Jeff Carr MD, FACC, board-certified Interventional Cardiologist with CardiaStream of Tyler, TX, "The Venclose Maven Catheter is uniquely designed to expand our options for treating IPVs and associated tributaries. With the 0.5cm length treatment coil and 20-second treatment cycles, I have more confidence in applying a uniform therapeutic effect to the vein. This is a significant improvement over the existing RF device for IPVs." Dr. Carr also spoke to the procedural ease of use by adding, "Delivering treatment is super simple and efficient due to the flexibility, lubricity and low profile of the device."

Board-certified vascular and interventional radiology physician Carlos Hamilton III, MD of Hamilton Vascular, Sugarland, TX, similarly experienced the procedural advantage of the Venclose Maven catheter compared to the decade-old legacy method. "It's a lot smoother procedure with reduced in-vein treatment time." Dr Hamilton added, "The Venclose Maven is a lot easier to work with and seems much better tolerated by my patients. And the higher temperature allows for a much faster procedure."

In addressing Venclose's business outlook, Mr. Gibson stated, "We are very pleased that for the benefit of Venclose stakeholders, the FDA's rapid 510(k) clearance of the

Venclose Maven now allows the company to pursue a 15% growth opportunity in the U.S. Market where it had previously been unable to compete. We intend to also grow the market by helping clinicians who are presently not treating IPVs to expand their patient care services."

Venclose is shipping the Maven catheter to U.S. vein practices as it pursues CE Mark approval for delivery to its expanding EU markets.

THE VENCLOSE SYSTEM

The Venclose System is the next-generation, best-in-class endovenous RF ablation system designed to close the damaged vein and restore healthy blood flow in patients with venous reflux disease, a progressive medical condition which is often associated with varicose veins. **VTN**

READ MORE: https://venclose.com/press_releases/venclose-maven-earns-fda-clearance-to-treat-incompetent-perforator-veins/



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LOOKING BACK

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JANUARY 10-12, 2020



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LYMPHEDEMA
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find out that her swollen leg was the result of a congenital deficiency of the lymphatic system, a genetic condition that she shares in the family with her grandmother and her daughter (the disease spared her mother). At the beginning Amy wasn't bothered by her condition that much, she lived undiagnosed and untreated, until more striking changes occurred, and she developed extreme swelling doubling the volume of the leg and threatening with the possibility of severe disability. She was bullied as a beauty queen. They called her the "elephant girl." After getting a long-due diagnosis and many struggles she decided to fight the malady and took the helm of her destiny. She started compression therapy, adopted a healthy lifestyle with diet and exercise. Some years and three operations later, she has been continuously working to improve her condition. In addition, however, she established the non-profit Ninjas Fighting Lymphedema Foundation and started to help other patients who suffered from lymphedema.²

Amanda was a perfectly healthy little girl and young adult. Then, at age 20, when she was jogging not far away from the Vancouver seaside she had a nasty mosquito bite, and soon after the random assault with the same leg injury. Soon after she noticed persistent ankle swelling, despite compression bandages. She consulted a physician who referred her to a lymphatic specialist. She underwent evaluation and a lymphoscintigraphy test, and she was diagnosed to have lymphedema. She was told her lymphatic system was compromised, with no cure, and a life-long treatment was recommended that included Manual Lymphatic Drainage (MLD) and compression stockings. Amanda went through 16 years of denial and psychological battles with hopelessness, refusal of garments, and a desperate need to forget about her new reality and appearance. Her journey went on with trials, failures, and some positive encounters like with a nice and patient garment fitter and competent MLD therapists who taught her how to perform an efficient self-massage. After an unsuccessful marriage, divorced with two little boys, Amanda moved to her hometown in Winnipeg. She slowly forged her new life as a full-time single mother, bodybuilder, and entrepreneur. She has become a Certified Personal Trainer, Certified Nutritionist and Lymphedema Coach, and creator of the online Sobey program³ for fitness, nutrition, self-care, and lymphedema medical equipment.³

The personal story of the senior author (M.L. Głowiczki, MD, PhD) doesn't include having lymphedema, but includes having plenty of other adventures that shaped her attitude in medicine to increase her attention to patients and become more compassionate. She spent decades in clinical research of venous and lymphatic disorders. Among others, she organized two prospective randomized trials of patients with lymphedema^{4,5} and was closely involved in the construction of the Chronic Venous Insufficiency quality of life Questionnaire – CIVIQ⁶ that was translated from the initial French version and validated in several languages all over the world.

Our first meeting focused on definition, etiology, and prevalence of lymphedema. We discussed that the lymphatic system is composed of a complex network of lymphatic vessels, nodes, and lymphoid organs. In the light of recent research its importance keeps growing, regarding



Figure 1. Zoom conference

circulatory aspect (bringing back to the venous circulation fluid filtrated to the interstitial tissue from the arterioles) and its role in the immune system. Any alteration of the lymphatic system or function can cause chronic swelling – lymphedema. According to the International Lymphedema Framework studies⁷ prevalence in the UK is 3.93/1000, more important in women (5.37 versus 2.48/1000 in men) and increasing dramatically with age (28.75/1000 in over 85 years old). Lymphedema⁷ is divided into primary lymphedema (7-13% of cases of chronic edema) and secondary lymphedema (39-43%) including cancer related and venous disorders related lymphedema. The estimated number of lymphedema patients in the United States, including those with phlebolympedema, is 35 million and around the world it is 140-250 million.^{8,9} Lymphatic filariasis^{10,11} results in more than 17 million lymphedema patients, and in 5.9 million disability years. Secondary lymphedema doesn't exclude genetic predisposition revealed by an external factor.¹² Primary lymphedema is a melting pot containing different syndromes such as Klippel-Trenaunay syndrome, Milroy disease, Meige disease and many others. They can be congenital apparent within two years after birth, pubertal or late onset (after age of 35 years). For many of those specific genetic mutations were found, for example FLT4/VEGFR3 in Milroy disease or FOXC2 in lymphedema-distichiasis, or PIK3CA in common (cystic) lymphatic malformations.

Amy and Amanda each had different experiences. Amy's disease progression was aggravated by a 32-year delay in diagnosis. It appears certain that she would be able to manage her chronic edema better had she known her disease earlier. She likely would have avoided a progression to elephantiasis that required multiple operations to reduce her limb volume. For Amanda the lymphedema diagnosis was almost immediate, and it was followed up with a specialist's consultation. At that time, there was very little information available to educate Amanda about the disease, which made it hard for her to accept the reality and to deal with it. Early recognition and treatment of lymphedema appears crucial, and several key points need to be emphasized:

- **Early lymphedema diagnosis and treatment**, provided by a multidisciplinary team, leads to the optimal lymphedema care with improved outcomes.^{13,14}
- **Complete diagnosis** includes a hx and a physical exam, a consultation with a lymphedema specialist and additional potential diagnostic tests like lymphoscintigraphy,¹⁵ lymphography with indocyanine green (ICG)¹⁶ and diagnosis of possible

genetic mutations.¹⁷ Lymphography with indocyanine green (ICG) maybe important not only for the formal diagnosis, but also because of the implication for future therapy.¹⁵ Indeed, the Manual Lymph Drainage maneuvers, performed by a therapist or by patient, cannot be fully efficient if not based on the precise knowledge of an individual lymphatic system anatomy. Not infrequently compression therapy must be adapted to the individual patient. For example, compression pumps can be harmful in patients with chylous complications or with infections. In addition, any indication for surgery¹⁸⁻²⁰ can only be discussed with the full image of lymphatic system abnormality.

- **Patient-physician communication** is essential. Learning for the first time that someone has lymphedema is like landing on another planet. The abysmal darkness has been opened with a "no cure" expression. Certainly, like for hypertension, diabetes and so many other diseases, we cannot, at this time, eradicate lymphedema. However, even if demanding and far from being perfect, there are effective treatments. Many physicians do not believe this, maybe because of insufficient knowledge of the disease, examples of failures, incomplete diagnosis, lack of compliance of the patients or repeated infections and bleeding complications.

An important aspect is the patient's misconception about the doctor. Most physicians were not trained adequately in lymphatic disorders, and they don't understand the therapeutic tools and spontaneous severe progression of the lymphedema. Anxiety and stress lead to miscommunication. Patient or physician, we are human beings with our imperfections and problems. It takes an effort from the patient to ask the appropriate questions and from the doctor to understand the patient's needs and expectations and to provide adequate guidance.

- **Patient-reported outcome** is an excellent tool to aid the initial assessment and to provide information during follow-up. Several quality-of-life (QOL) questionnaires were recently reviewed and evaluated for lower limb lymphedema^{21,22} (see Table 1). The repeated measurements of QOL could allow better understanding of a patient's progress and the benefit of treatment.

DAY TWO: LYMPHEDEMA AND MENTAL HEALTH/SOCIAL INTERACTIONS

It is probably the most difficult task to learn how to improve your mental health and evolve towards a better life with lymphedema. Depression is around the corner with all range of feelings: sadness, hopelessness, anxiety, and anger. Both, Amy, and Amanda, know this issue too well. They are fighting it daily. The community of other patients can help, but as our new friends point out, it may not help if your support group is constantly complaining. You need energy to get uplifted, to become a warrior. Also, sometimes the unity of the group is broken by divisions between those who have primary and those who have secondary lymphedema.

In her memoir "Lymphedema Journey" Amanda writes that "The best antidote for depression is exercise, proper

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LYMPHEDEMA
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nutrition and self-care.” In the brochure “Ninjas Fighting Lymphedema Foundation,” Amy states that “Together, we can live, laugh and learn how to heal.”

Poor body image is a particularly strong element of psychological troubles related to lymphedema. How can you have romantic relationships if you are considering yourself as disfigured, ugly? Even worse, bullied (remember Amy’s story) or facing a boyfriend’s suspicion of a transmissible disease, because of the look of your lymphedema skin? When I naively asked about Amy’s and Amanda’s social life, they answered in unison: “What social life? There is no social life if you want to take care of your lymphedema.” No alcohol, no junk food, no standing for hours. Amy is telling one of her experiences of going to a party. Precautious, she brought her water and something to eat. Right move as there was nothing but alcoholic or high calorie beverages and unhealthy appetizers. She had some good conversations with some of the guests. From there she and her husband went to the gym, while the rest of the company was heading to a nearby bar.

Healing and self-esteem are earned by constant attention and care. You must adapt your life to make a space for lymphedema requirements and therapy. You need a lot of creativity. Amanda discovered in herself an entrepreneurial fiber and is running a successful online business. After years of studies and trials, she considers herself an expert in nutrition and fitness. Amy devoted herself to her Lymphedema Foundation. She is the best in the mental approach and finds joy in helping others and writing (don’t

miss her book “Drop The Skirt – How My Disability Became My Superpower” on Amazon.com). Following the Sobey training program, she just won the bronze medal at the “Bikini” competition.

The results of a healthy lifestyle and treatments are slow. Like everything else valuable on earth, it demands a “set of 3 P’s”: practice, patience, and persistence (the concept from Dr. John Chuback’s book “The Straight A Handbook”, also on Amazon.com). You must believe in your own power. To quote one of the Amanda’s statements: “Life is too short to leave the key to your happiness in someone else’s pocket.” Amy was told to get familiar with the wheelchair. That simply was not an option for her.

DAY THREE: LYMPHEDEMA AND LIFESTYLE RECOMMENDATIONS – OR – HOW TO CHANGE YOUR LIFE?

Amanda created a booklet called “The Lymphedema Journey”. Mindfulness and recording daily habits and activities are the preparation for change. Knowledge about lymphedema and your body is necessary to evolve. Open positive attitude and motivation of an Olympian are required to win your personal life “gold medal” – control of lymphedema.

Practice of deep breathing is helpful to decrease anxiety among the other effect. Amy tells the story of a lymphedema patient, who was confined to bed but felt so much better just after learning some breathing patterns and tip-toe exercises.

Making peace with their emotions through meditation is a daily routine for Amy and Amanda, just like drinking water first thing in the morning. Working out is another “must,” trying to fit an hour into Amy’s and Amanda’s schedule. The effect of exercise is undeniable. A recent study on patients with elephantiasis,¹⁸ the most severe stage of lymphedema, found that even moderate exercise and foot elevation (15-20 minutes three times a week), significantly improved quality of life and decreased pitting edema. Fitness and reasonable weight training have documented beneficial effects on body strength and severity of the disease.²²⁻²⁴

Every day includes time for body care (MLD massages, hygiene, dry brushing) and compression treatment. Healthy eating style, adequate rest and sleep are non-negotiable.

To further reduce lymphedema, rules to be practiced follow common sense: avoid trauma/injury or skin infection, insects’ bites, limb constriction, extreme temperatures, prolonged standing, prolonged sitting, crossing legs...

The change will not be dramatic: start one thing every day, one baby step after another. Sometimes during the journey comes the transformation empowered by progressively solved problems such as: finding a good fitter for compression, and a good therapist for MLD. However, even in the best-case scenario, it can be a long process. In Amanda’s experience, it is beneficial to move lymph into functioning lymphatics which can be determined by an indocyanine green (ICG) test. These tests will improve the quality of care provided by the therapist and improve the most severe cases.

DAY FOUR: LYMPHEDEMA AND SURGERY

For this session, we have a special guest, Professor Peter Gloviczki. Who else could describe better the surgical

options and answer the questions of lymphedema patients? But of course, we are biased.

Peter Gloviczki talks about the beginning of his interest in lymphedema surgery in 1975, enhanced by the experience of residency in Paris with Professor Marceau Servalles, at St-Michel Hospital, who was at that time a very famous surgeon for lymphatic procedures. Professor Servalles described in detail the excisional interventions, dominating at that time lymphatic surgery. It was major surgery performed in two stages, first at the inner and second at the outer aspect of the limb. The lymphedema mass was removed from skin to the muscles and the excess skin was excised. Altogether, these were difficult and complex operations that reduced the volume of the limb but there were healing issues, lymph leaks, sensory loss, and joints problems, etc.

Dr. Gloviczki’s initial research project in Paris with Professor Hidden was focused on lympho-venous anastomosis. He visited Professor Degni’s team in Brazil who was working on lymphovenous anastomoses with a technique of pulling the lymphatic vessels into the vein. He also visited Professors Nielubowicz and Olszewski in Poland, who first reported on the lymph node-vein anastomoses. Even if not immediately successful, the concept of microsurgical procedures connecting the lymphatic and venous system looked promising. With Dr. LeFloch he wrote his thesis on lymphovenous anastomoses. Coming back to Hungary, Dr. Gloviczki performed several lymphatic procedures and presented the results for international medical conferences. His research on the lymphatic system was one of the reasons why he was offered a position as a research fellow at Mayo Clinic. In the experimental laboratory he mastered the technique. As the lymph fluid does not clot (no clotting factors present), the well-structured anastomoses stay open and function. Patient’s selection for the intervention is the main difficulty when applying these techniques in the clinical research and assessing their safety and efficacy. Currently used lymphoscintigraphy and lymphography with indocyanine green helps to find a suitable anatomy for these procedures. Unfortunately, in most of the patients with congenital lymphedema or with a lot of inflammation, adequate lymphatics for anastomoses cannot always be found. Lymph node transfer, with arterial and venous vessels, can develop lymphatic connections with time, as confirmed on the lymphoscintigraphy.

Special skills are required for tedious microsurgical procedures for working with lymph vessels with less than one millimeter diameter. Several dedicated groups established practices oriented towards lymphatic microsurgery, for example, Campisi²⁵ group in Italy or Baumeister²⁶ in Germany. Dr. Baumeister once visited Mayo Clinic and operated with Dr Gloviczki to perform lymphatic bypass for a patient, with good clinical results. The most common procedures performed at Mayo Clinic Vascular and Endovascular Surgery Division have been lympho-venous anastomoses, and lymphatic bypasses, mostly for lymphedema and fluid collections due to chylous malformations.^{20,27} Usually, the operating team includes consultant surgeon, resident, fellow, scrub nurse and technician. Sometimes another surgeon is helping.



Figure 2. “Drop the Skirt” by Amy Rivera

LYMPHEDEMA
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RESULTS AT 18 WEEKS AFTER LAST TREATMENT

UNCOMPLICATED RETICULAR VEIN TREATMENT* (1 TO 3 MM) PATIENT TREATED WITH 1% ASCLERA



RESULTS AT 18 WEEKS AFTER LAST TREATMENT

TREATMENT SUCCESS:

95% of patients treated with Asclera showed good improvement or complete treatment success as rated by physicians.¹

95%
TREATMENT
SUCCESS

PATIENT SATISFACTION:

88% of patients were satisfied or very satisfied with their Asclera treatments at 12 weeks.¹

88%
PATIENT
SATISFACTION

*INDIVIDUAL RESULTS MAY VARY

INDICATION: Asclera[®] (polidocanol) Injection is a prescription medicine that is used in a procedure called sclerotherapy to remove unwanted veins on your legs. It is administered by a healthcare provider to treat two types of veins:
- Uncomplicated spider veins (very small varicose veins ≤ 1 mm in diameter)
- Uncomplicated small varicose veins (1 to 3 mm in diameter) known as reticular veins

Asclera[®] has not been studied in varicose veins more than 3 mm in diameter.

IMPORTANT SAFETY INFORMATION FOR PATIENTS:

For intravenous use only.

CONTRAINDICATIONS: Asclera[®] (polidocanol) Injection is contraindicated for patients with known allergy (anaphylaxis) to polidocanol and patients with acute vein and blood clotting diseases.

WARNINGS AND PRECAUTIONS:

Anaphylaxis: Severe allergic reactions have been reported following polidocanol use, including anaphylactic reactions, some of them fatal. Severe reactions are most frequent with use of larger volumes (> 3 mL). The dose of polidocanol should be the smallest dose that is effective. Please notify your healthcare provider if you have a known history of severe allergies or allergy to polidocanol.

Venous Thrombosis and Pulmonary Embolism: Asclera can cause venous thrombosis and subsequent pulmonary embolism or other thrombotic events. Your physician should follow administration instructions closely and monitor for signs of venous thrombosis after treatment. Patients with reduced mobility, history of deep vein thrombosis or pulmonary embolism, or recent (within 3 months) major surgery, prolonged hospitalization or pregnancy are at increased risk for developing thrombosis.

Arterial Embolism: Stroke, transient ischemic attack, myocardial infarction, and impaired cardiac function have been reported in close temporal relationship with polidocanol administration. These events may be caused by air embolism when using the product foamed with room air (high nitrogen concentration) or thromboembolism. The safety and efficacy of polidocanol foamed with room air has not been established and its use should be avoided.

Accidental injection into an artery can cause severe necrosis, ischemia or gangrene.

Care should be taken in intravenous needle placement and the smallest effective volume at each injection site should be used. If injection of polidocanol into an artery occurs, consult a vascular surgeon immediately.

After the injection session is completed, apply compression with a stocking or bandage, and walk for 15-20 minutes. Your healthcare provider will provide monitoring during this period to treat any possible anaphylactic or allergic reactions.

Maintain compression for 2 to 3 days after treatment of spider veins and for 5 to 7 days for reticular veins, or as directed by your Healthcare Provider. For extensive varicosities, longer compression treatment with compression bandages or a gradient compression stocking of a higher compression class is recommended. Post-treatment compression is necessary to reduce the risk of deep vein thrombosis.

ADVERSE REACTIONS: In clinical studies, the following adverse reactions were observed after using Asclera[®] and were more common with Asclera[®] than placebo: injection site hematoma, injection site irritation, injection site discoloration, injection site pain, injection site itching, injection site warmth, neovascularization, injection site clotting.

You are encouraged to report any suspected adverse events. To report SUSPECTED ADVERSE REACTIONS, contact your Healthcare Provider, Merz North America at 1-866-862-1211, or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

¹Rabe E, Schliephake D, Otto J, Breu F, Pannier F. Sclerotherapy of telangiectases and reticular veins: a double-blind, randomized, comparative clinical trial of polidocanol, sodium tetradecyl sulphate and isotonic saline (EASI study). *Phlebology*. Jun 2010; 25(3): 124-131.

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Please see the Brief Summary of Asclera Prescribing Information on the next page.

Asclera (polidocanol) Injection, for intravenous use

Initial U.S. Approval: 2010

BRIEF SUMMARY

For Full Prescribing Information please visit Asclera.com.

INDICATIONS AND USAGE

Asclera® (polidocanol) is indicated to sclerose uncomplicated spider veins (varicose veins ≤ 1 mm in diameter) and uncomplicated reticular veins (varicose veins 1 to 3 mm in diameter) in the lower extremity. Asclera has not been studied in varicose veins more than 3 mm in diameter.

DOSAGE FORMS AND STRENGTHS

Asclera is available as a 0.5% and 1% solution in 2 mL glass ampules.

CONTRAINDICATIONS

Asclera is contraindicated for patients with known allergy (anaphylaxis) to polidocanol and patients with acute thromboembolic diseases.

WARNINGS AND PRECAUTIONS

Anaphylaxis

Severe allergic reactions have been reported following polidocanol use, including anaphylactic reactions, some of them fatal. Severe reactions are more frequent with use of larger volumes (> 3 mL). The dose of polidocanol should therefore be minimized. Be prepared to treat anaphylaxis appropriately.

Severe adverse local effects, including tissue necrosis, may occur following extravasation; therefore, care should be taken in intravenous needle placement and the smallest effective volume at each injection site should be used. After the injection session is completed, apply compression with a stocking or bandage, and have the patient walk for 15-20 minutes. Keep the patient under supervision during this period to treat any anaphylactic or allergic reaction.

Venous Thrombosis and Pulmonary Embolism

Asclera can cause venous thrombosis and subsequent pulmonary embolism or other thrombotic events. Follow administration instructions closely and monitor for signs of venous thrombosis after treatment. Patients with reduced mobility, history of deep vein thrombosis or pulmonary embolism, or recent (within 3 months) major surgery, prolonged hospitalization or pregnancy are at increased risk for developing thrombosis.

Arterial Embolism

Stroke, transient ischemic attack, myocardial infarction, and impaired cardiac function have been reported in close temporal relationship with polidocanol administration. These events may be caused by air embolism when using the product foamed with room air (high nitrogen concentration) or thromboembolism. The safety and efficacy of polidocanol foamed with room air has not been established and its use should be avoided.

Tissue Ischemia and Necrosis

Intra-arterial injection or extravasation of polidocanol can cause severe necrosis, ischemia or gangrene. Care should be taken in intravenous needle placement and the smallest effective volume at each injection site should be used. After the injection session is completed, apply compression with a stocking or bandage and have patients walk for 15-20 minutes. If intra-arterial injection of polidocanol occurs, consult a vascular surgeon immediately.

ADVERSE REACTIONS

Clinical Study Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice.

In 5 controlled randomized clinical trials, Asclera has been administered to 401 patients with small or very small varicose veins (reticular and spider veins) and compared with another sclerosing agent and with placebo. Patients were 18 to 70 years old. The patient population was predominately female and consisted of Caucasian and Asian patients.

Table 1 shows adverse events more common with Asclera or sodium tetradecyl sulfate (STS) 1% than with placebo by at least 3% in the placebo- controlled EASI study (see Clinical Studies [14]). All of these were injection site reactions and most were mild.

Table 1: Adverse Reactions in EASI-study

	ASCLERA (180 patients)	STS 1% (105 patients)	Placebo (53 patients)
Injection site haematoma	42%	65%	19%
Injection site irritation	41%	73%	30%
Injection site discoloration	38%	74%	4%
Injection site pain	24%	31%	9%
Injection site pruritus	19%	27%	4%
Injection site warmth	16%	21%	6%
Neovascularisation	8%	20%	4%
Injection site thrombosis	6%	1%	0%

Ultrasound examinations at one week (± 3 days) and 12 weeks (± 2 weeks) after treatment did not reveal deep vein thrombosis in any treatment group.

Post-marketing Safety Experience

The following adverse reactions have been reported during use of polidocanol in world-wide experience; in some of these cases these adverse events have been serious or troublesome. Because these reactions are reported voluntarily from a population of uncertain size and without a control group, it is not possible to estimate their frequency reliably or to establish a causal relationship to drug exposure.

Immune system disorders: Anaphylactic shock, angioedema, urticaria generalized, asthma

Nervous system disorders: Cerebrovascular accident, migraine, paresthesia (local), loss of consciousness, confusional state, dizziness

Cardiac disorders: Cardiac arrest, palpitations

Vascular disorders: Deep vein thrombosis, pulmonary embolism, syncope vasovagal, circulatory collapse, vasculitis

Respiratory, thoracic and mediastinal disorders: Dyspnea

Skin and subcutaneous tissue disorders: Skin hyperpigmentation, dermatitis allergic, hypertrichosis (in the area of sclerotherapy)

General disorders and injection site conditions: Injection site necrosis, pyrexia, hot flush

Injury, poisoning and procedural complications: Nerve injury

DRUG INTERACTIONS

No drug-drug interactions have been studied with Asclera.

USE IN SPECIFIC POPULATIONS

Pregnancy

Pregnancy Category C. Polidocanol has been shown to have an embryocidal effect in rabbits when given in doses approximately equal

(on the basis of body surface area) to the human dose. This effect may have been secondary to maternal toxicity. There are no adequate and well-controlled studies in pregnant women. Asclera should not be used during pregnancy.

Animal Studies

Developmental reproductive toxicity testing was performed in rats and rabbits with intravenous administration. Polidocanol induced maternal and fetal toxicity in rabbits, including reduced mean fetal weight and reduced fetal survival, when administered during gestation days 6-20 at doses of 4 and 10 mg/kg, but it did not cause skeletal or visceral abnormalities. No adverse maternal or fetal effects were observed in rabbits at a dose of 2 mg/kg. No evidence of teratogenicity or fetal toxicity was observed in rats dosed during gestation days 6-17 with doses up to 10 mg/kg. Polidocanol did not affect the ability of rats to deliver and rear pups when administered intermittently by intravenous injection from gestation day 17 to post-partum day 21 at doses up to 10 mg/kg.

Human Studies

There are no adequate and well-controlled studies on the use of Asclera in pregnant women.

Labor and Delivery

The effects of Asclera on labor and delivery in pregnant women are unknown.

Nursing Mothers

It is not known whether polidocanol is excreted in human milk. Because many drugs are excreted in human milk and because of the potential for serious adverse reactions in nursing infants, avoid administering to a nursing woman.

Pediatric Use

The safety and effectiveness of Asclera in pediatric patients have not been established.

Geriatric Use

Clinical studies of Asclera did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects.

OVERDOSAGE

Overdose may result in a higher incidence of localized reactions such as necrosis.

PATIENT COUNSELING INFORMATION

Advise the patient to wear compression stockings or support hose on the treated legs continuously for 2 to 3 days and for 2 to 3 weeks during the daytime. Compression stockings or support hose should be thigh or knee high depending upon the area treated in order to provide adequate coverage. Advise the patient to walk for 15 to 20 minutes immediately after the procedure and daily for the next few days. For two to three days following treatment, advise the patient to avoid heavy exercise, sunbathing, long plane flights, and hot baths or sauna.

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AVLS

continued from page 1

received positive feedback on the range and quality of the scientific program.”

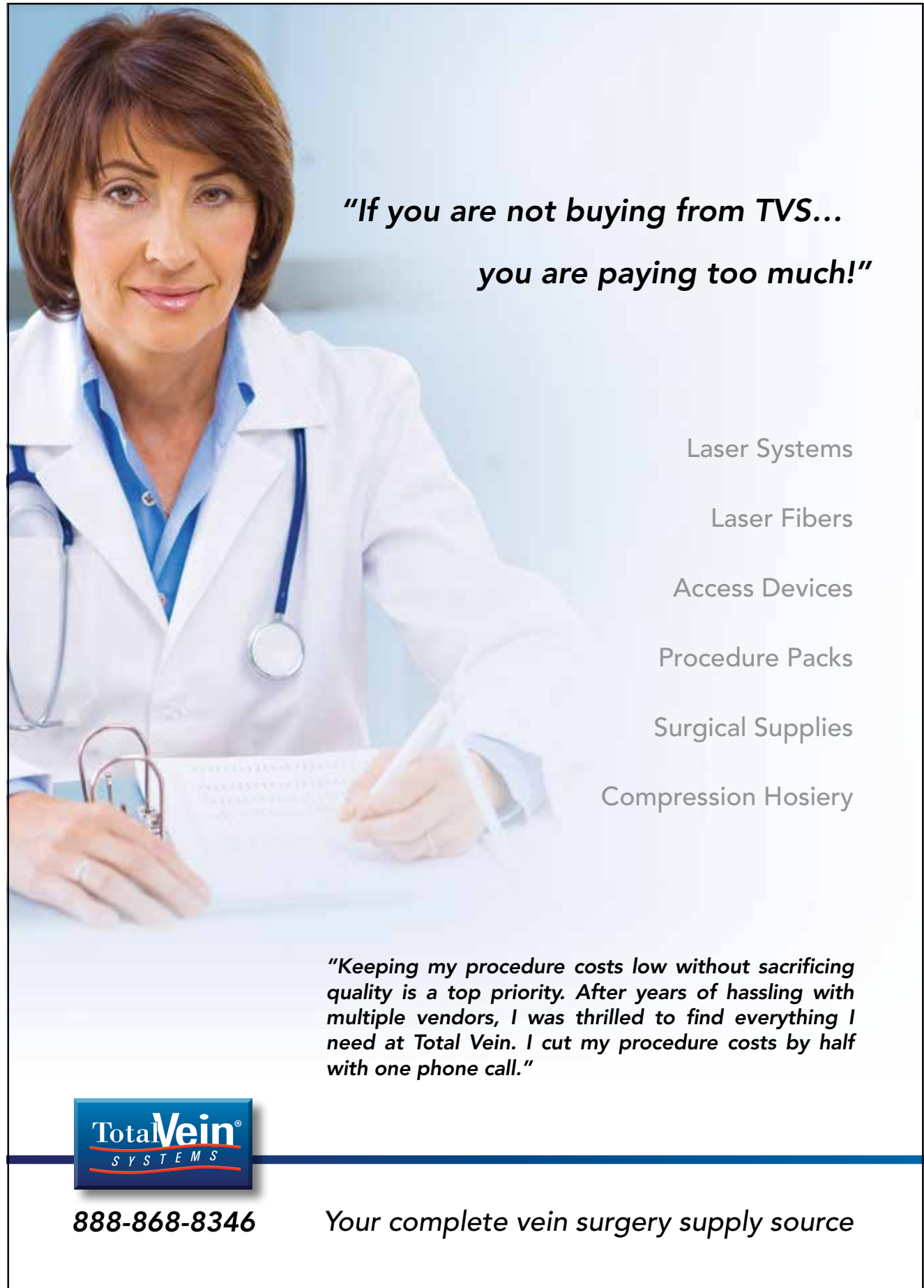
Annual Congress programming opened with a keynote address by Dr. David Lechner with BlueCross BlueShield of Minnesota. Four rooms of educational sessions covering the spectrum of venous and lymphatic medicine filled each day’s programming. Dr. Scott Smith from NASA highlighted Friday’s programming in the Wound Care session with presentations on microgravity and research conducted at the International Space Station. Finally, Saturday closed with a lively discussion of various topics at the Fight Club.

“We have reached a critical juncture in the 20-year evolution of venous and lymphatic medicine, and the important issues were all highlighted in this year’s Annual Congress,” said Dr. Mark Meissner, AVLS President. “Not only did the Annual Congress offer the outstanding educational program that the AVLS is known for, but important issues regarding potential changes in reimbursement and recognition of venous and lymphatic medicine as a subspecialty were emphasized throughout the congress.”

As the first hybrid AVLS Annual Congress, an additional 320 virtual attendees participated online, watching the livestream and browsing the exhibit hall. Thursday through Saturday included a livestream of sessions in Denver, CO, in the primary meeting room. Additionally, recordings of all concurrent sessions are being made available for all attendees.

Returning to in-person meetings in a COVID-19 world will be a slow and steady process. The AVLS was encouraged to see attendees from across the country gathering once again. In-person activities such as the FVLD Expedition, which hiked around Golden, Col., and the Saturday night Taste of Colorado allowed attendees to relax and build relationships, enjoying this time together.


“While the AVLS conducted this Congress under additional health safety protocols, this did not hinder the energy and enthusiasm of those onsite,” said Dean Bender, AVLS Executive Director. “It was great to see our members and attendees interacting between the sessions, in the exhibit hall and during the evening events, which was such a great reminder of the value of in-person learning! Virtual



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AVLS

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LYMPHEDEMA
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Excisional lymphedema surgery has been in the hands of plastic surgeons. Plastic surgeons have been taking over lymphatic microsurgery as well, since they have tremendous experience using the operating microscope.

There is a resurgence of interest in the lymphatic procedures following the improvements of the technique and instruments. More and more articles have been listed. Just recently a systematic review was published with patients' quality-of-life assessment in 30 reconstructive surgery trials picked out of 988 lymphatic surgery studies. The profile of passionate surgeons has evolved, and you can see now more plastic surgeons performing these types of microsurgical interventions.

We have discussed with Amanda and Amy the common misunderstandings of the role of surgery in lymphedema treatment. Patients often do not realize the complexity of the lymphatic system and the need to identify appropriate structures for the successful intervention. Surgery appears to them as a magic solution. They don't anticipate that they can be poor candidates for intervention. They don't think about the possible complications, the difficulty in the healing process, the intensity of post-operative pain, and the failures. Frequently missing from the patients' expectations is also the post-operative continuous need for medical therapy namely compression, MLD, exercises and nutritional supplements.

Characteristics of appropriate candidates for different surgical techniques are difficult to present here but this is an important task for specialized groups.

Preparation for surgery is another aspect. The better condition the patient is in, the more decreased volume the limb has, the better is the self-management of the disease before surgery the more chances of success an intervention has. Healing will be faster, and results of surgery will be better.

How do you find a competent surgeon or physician? Dr. Glociczki's advice is to follow the scientific articles' track. The centers of excellence devoted to lymphedema treatment are often academic centers, like Mayo Clinic or Stanford or Scott & White Clinic, with ongoing research studies, textbooks, and publications.

DAY FIVE: LYMPHEDEMA MEDICAL TREATMENTS I (MLD, HEALTHY NUTRITION, DRUGS/NUTRITIONAL SUPPLEMENTS)

Patients should take the responsibility for the strategy of treatment to be implemented for life. To be successful, every patient must be her/his superhero. Conservative treatment is one part of this strategy with Manual Lymph Drainage (MLD), healthy nutrition, drugs/nutritional supplements and compression discussed in the next chapter.

HEALTHY NUTRITION

Amanda Sobey's method includes a guide on anti-inflammatory foods, following the principle that what we consume influences all body processes. Indeed, we are what we eat. The basic macronutrients needed daily are defined by color codes and the glycemic index, turning the diet plan into a colors' game (*Figure 3*).

Adequate water intake is a necessary element. The U.S. National Academies of Sciences, Engineering and Medicine estimated required daily fluid intake as 3.7 liters for men and 2.7 liters for women. Mayo Clinic website considers eight glasses a day a reasonable goal.

MLD

MLD is still not reimbursed and not recognized as a medical treatment in the province of Manitoba, Canada. Amanda does not have health care benefits and can only afford one session per month at \$125 per hour. But she learned the MLD technique from several therapists and practices it daily. The lymphography with ICG showed Amanda her lymphatic network pattern and enhanced the efficacy of her movements directing the lymph flow to the areas of better lymphatic drainage.

For Amy, 21 MLD sessions (cost \$260 per session with \$40 copay) per year are covered by insurance. However, in her case the most efficient therapy is the "fire and ice" technique, the only one that has a visible effect to reduce her big toe edema.

Certainly, every person has her or his lymphatic anatomy and responds differently to the different degrees of pressure and treatment by different therapists.

DRUGS/NUTRITIONAL SUPPLEMENTS

Amy and Amanda take one capsule of Lymphatic Formula (Micronized Purified Flavonoid Fraction – MPFF 1,000 mg) and one capsule of Vein Formula (MPFF 600 mg) orally daily. With that treatment, they noticed the benefit of the anti-inflammatory effect with the lymphedema tissue getting softer. MPFF was the object of research of the senior author (M. Glociczki) for many years, and she shared with Amy and Amanda the results of some of the experiments like the observation of the microlymphatics in vivo, in the hamster cheek pouch microcirculatory model. The beneficial effect of MPFF was also demonstrated in

clinical studies with microlymphography showing increased lymphangion contractions.²⁸ Another example is a double-blind, placebo-controlled, randomized study in 104 patients with upper limb lymphedema secondary to mastectomy, treated with MPFF 1,000 mg/day. MPFF improved all lymphoscintigraphic parameters such as half-life and clearance of the labelled colloid. As for lymphedema volume, a tendency in favor of MPFF was reported for patients with severe lymphedema.⁵

Similar results were found in another trial⁴ in the subgroup of 24 patients with a severe post-mastectomy lymphedema. Following the MPFF treatment the lymphoscintigraphic lymphatic migration speed was significantly improved (delta Speed cm/minute: 0.84 +/- 0.6 vs placebo 0.14 +/- 0.26, P = 0.005) as well as the half-life of the colloidal compound. These results confirmed the lymphokinetic activity of MPFF.

Amanda's day starts with drinking a glass of Lemon Ginger Turmeric Detox Tea. She believes firmly in multivitamin supplementation and plays with the whole spectrum of natural components including magnesium, selenium, calcium, L-arginine, vitamins B, C, D and others... She carefully recorded her reactions to different supplements and follows the findings of her studies. She is convinced that everyone has a different response to supplements' and needs to find the optimal personalized treatment.

We talked about the time necessary to observe the full effect of the treatment. For example, based on the half-life of the MPFF, the stable concentration is obtained after five to seven days. We also mentioned the potential placebo-effect (positive or negative), regressing with time.

Amy's treatment includes multivitamins, vitamins B/D, magnesium and some homeopathic preparations. She is medically followed with blood tests to check for potential mineral and vitamin deficiency. Pain management is an important issue in Amy's story, having had multiple operations. Her last post-operative experience was particularly traumatic. Prescription pain killers had a toxic side effect causing low blood pressure, dizziness, and constipation. In addition, she was afraid of long-term toxicity and addiction. Alternative pain-control methods appeared to be the best solution.

A supplement with hydroxytyrosol, extracted from olive oil, was proposed based on its antioxidant, anti-bacterial and anti-inflammatory potentials.^{29,30} Studies are ongoing on possible therapeutic options with this supplement in lymphedema.³¹

The clinical stage of lymphedema is important. Before tissue fibrosis develops, in the earlier stages of lymphedema, treatment can be more effective. In addition, comorbidities and complications dictate the hierarchy of different therapies. Among others, in patients with Streptococcus or Staphylococcus infections an aggressive antibiotherapy might be necessary.

DAY SIX: LYMPHEDEMA MEDICAL TREATMENTS II (COMPRESSION THERAPY)

The keystone in lymphedema treatment, compression therapy can be divided into three types: garments, bandages,

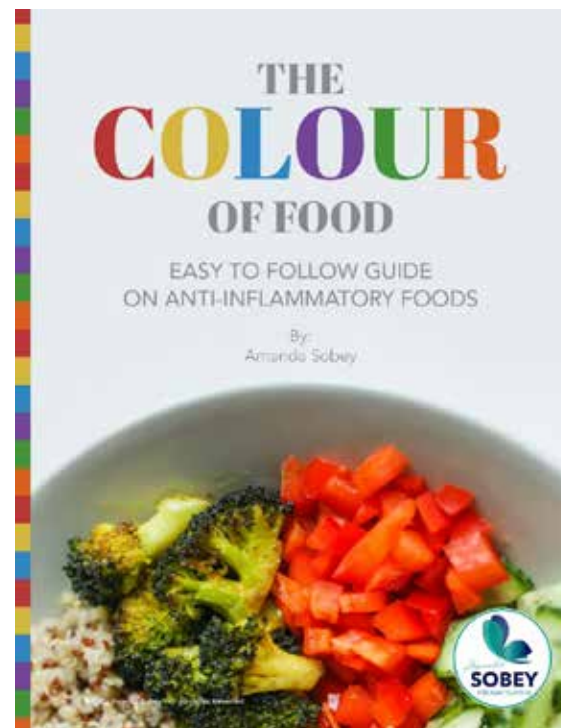


Figure 3. The Colour of Food

LYMPHEDEMA
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If you missed us at AVLS, see Dr. Monika Gloviczki's lecture here by scanning the QR code.



Monika Gloviczki, M.D., PhD,
Chief Scientific and
Clinical Advisor to VitasupportMD

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LYMPHEDEMA

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and pumps. All of them have a role in lymphedema control. Compliance with compression and its strength are rarely assessed in clinical studies. Compression or lack of it for venous leg ulcers is probably the best example: compliance was not or poorly assessed in 28 out of 58 prospective cohorts³² and complications were not reported in two thirds of the studies.

Amy can easily compare the “therapeutic” and “preventive” effects of compression. She has unilateral leg lymphedema, and the other leg is possibly just “at risk” to develop one. She wears custom-made compression for both legs, with less pressure for the “at risk” extremity. She knows that pressure applied on her abdominal area should be low since it can trigger swelling of the legs.

GARMENTS

At the start everybody has difficulty with garments. It is essential to have a good fitter and adviser. You should also follow your inner voice. Contrary to some preconceived opinions, compression should feel good. The fabric should feel nice on your skin. If it is too hard to apply, the patient will not use it. Starting with lesser pressure has the advantage to be acceptable for the patients and avoids buying the expensive garment that will never be worn. For Amanda, compression of 30 mmHg is optimal. She uses this compression only on one leg; therefore, the stockings she buys by the pair serve double time for her. Different companies offer a variety of styles with a possibility of a fancier feminine pantyhose in color options.

The French Phlebology School the senior author (M. Gliviczki) was affiliated with, used to recommend lesser compression strength and two or even three stockings on the same leg. In this way the application is easier, and you can build stronger compression levels with an increased inelasticity index. Multiple layers also have the advantage to be adaptable following different days of the female cycle or for different life situations. Indeed, the volume of the extremity varies, and it is difficult to have an adequate compression with just one garment.

BANDAGES

Bandages are always used, either alone or with Circaid or other garments, or with a pump. Adjustable to the limb shape, it provides the basic layer of compression. They are extremely useful for the large limbs. “Fast and go” products are easy, efficient, washable and durable. Some areas require protective foam.

PUMPS

There are different types of pumps with characteristics optimal for different scenarios of lymphatic network. Both Amanda and Amy tried all of them. Flexitouch, BioCompression, Lympha Press, Air Relax, Huntleigh Hydroven pump etc. ... Three primary types of pumps are: the simplest single-chamber non-programmable pumps, multi-chamber non-programmable pumps, and single- or multi-chamber programmable pumps with possibility to manually adjust the compartments’ pressure, the duration and frequency of the cycles. Some pumps are difficult to use. Some patients are getting worse from using the compression pump. If the lymphatic drainage is abnormal in the abdominal and genital zones, the pumps can be dangerous. The adjustment of the pumps’ sleeves after a decrease of limb volume is also an issue.

Our friends use the compression pump every night, although the garments and bandages are higher in the compression hierarchy list. Amanda uses the pump with sequential chambers on a lowered pressure setting the whole night.

Amy limits the pump application to 60 minutes. She also uses the vibration therapy machine that increases the drainage and decreases the swelling in the abdominal area.

Altogether, the compression therapy is indispensable, but it is only one element of the treatment. Safety is crucial and it should be based on knowing the anatomy of each patient. The choices should fit the patient’s lymphatic system functionality, global situation, and preferences. Patients’ exchanges about therapeutic options are efficient and trustworthy, as they are experts and best judges. Caution is still needed since what works for one can be ineffective or even harmful for another.

DAY SEVEN: FINANCIAL ASPECTS OF LIFE WITH LYMPHEDEMA

Lymphedema care takes time and has a financial burden, mostly carried by the patients. Amanda needs four hours daily to control her lymphedema. The basic compression pump costs her CA\$8,000 (Canadian dollars) per year, plus \$20,000 of other medical expenses (Manual Lymph Drainage sessions, compression garments, Circaid, Fast’n Go bandages, medical visits, and supplements). These treatments keep her in good shape with no complications of lymphedema. They allow her to be a hard-working entrepreneur and a great single mother of two young boys.

Recently, the Lymphedema Advocacy Group undertook an estimate of savings that could result from the reimbursement of the lymphedema compression treatments. They commissioned an independent organization that estimated only the direct costs related to the lymphedema complications: hospitalizations and post-acute care in the nursing facilities. Estimated minimal potential annual savings were: \$126.9 million for Medicare, \$3.5 million for Medicaid and \$19.3 million for private insurance market. Considering frequent underreporting of the disease these numbers should be viewed as underestimated. Based on these calculations, the Lymphedema Treatment Act (S. 1315/H.R. 3630) was proposed to the 117th Congress.

In Amy’s case, after 30 years’ evolution without proper therapy, surgery at one point was indicated in addition to all medical treatments. One intervention with lymph node transfer and two reduction surgeries costed almost \$400,000. Unfortunately, these didn’t prevent her lymphedema-related disability. However, she did avoid the wheelchair. Using all therapeutic tools, Amy is able to function now quite normally, and she helps others through her Ninjas Fighting Lymphedema Foundation.

Early diagnosis and treatment are the best cost-effective strategy in the management of lymphedema (Figure 4). Progress has been slow in this field of medicine and much more has to be done for better education and treatment options for lymphedema patients.

LYMPHEDEMA

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Early lymphedema diagnosis and complete diagnosis	Multidisciplinary lymphedema treatment	Follow up
<ul style="list-style-type: none"> • Lymphoscintigraphy, • Lymphography with indocyanine green (ICG) • Diagnosis of possible genetic mutations • Patient’s quality of life and symptoms’ assessment • Lymphedema volume measurement • Evaluation of affected limb shape and function • Global assessment of patient’s situation: mental health/family/career/self-management skills/financial status 	<ul style="list-style-type: none"> • Mental health/support groups • Lifestyle recommendations with appropriate diet, exercises program, skin care recommendations • Manual lymphatic drainage and massages • Compression therapy <ul style="list-style-type: none"> - Bandages - Garments - Compression pumps • Nutritional supplements/MPFF/drugs treatment for complications (cellulitis etc) • Surgery if indicated and in case of nonresponse to the medical therapy conducted for at least 6 months <ul style="list-style-type: none"> - Reconstructive surgery - Excisional or debulking surgery 	<ul style="list-style-type: none"> • Assessment of lymphedema volume • Evaluation of skin condition and subcutaneous tissue consistency • Evaluation of limb shape and function • Patient’s quality of life and symptoms’ assessment • Complications (type, number, hospitalizations, and treatments) • Improvement in patient’s mental attitude/career involvement/self-management skills • Global evaluation of treatment efficacy

Figure 4. Lymphedema management chart

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LYMPHEDEMA

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CONCLUSIONS

With our seven-days lymphedema project that resulted in writing this article, we hope we brought a message of hope for lymphedema patients and groups specialized in lymphedema treatment. Indeed, despite no cure at present, lymphedema represents a treatable disease. It can be controlled as a condition free of complications and allow a healthy and happy lifestyle. The chart of lymphedema management is complex, but all these therapeutic tools contribute to optimal care and the best results.

ACKNOWLEDGEMENT

We wish to extend our special thanks to Dr. Peter Gloviczki for his support and gracious participation in this project.

ADDENDUM:

Amanda Sobey's method³ is the fruit of 20 years of Amanda's personal research to construct the efficient program for:

- **Lymphedema and lipedema coaching**, includes everything patients need to know about managing and reducing lymphedema and lipedema. This program shows lymphedema and lipedema patients the pathway to follow to improve her/his health and feel better about herself/himself.
- **Fitness & weight loss** demonstrates how to enhance the efficacy of physical exercises whether you are a beginner or an athlete. The aim is to build a personalized fitness plan optimal to be in the best condition and to lose weight.
- **Healthy nutrition & lifestyle** educates about food to help losing weight and food which might be hurtful or pro-inflammatory.

Ninjas Fighting Lymphedema Foundation² is a 501(c)(3) founded by lymphedema patient and spokesperson, Amy Rivera. Amy was born with primary Lymphedema, and was misdiagnosed for over 30 years, leaving her disabled and isolated. Amy thought she was the only one who was suffering in silence. But, after learning the truth about her condition, Amy realized that this community needed a voice. She established the Ninjas Fighting Lymphedema Foundation to ensure that no one suffers alone. Its daily mission is to bring hope and a voice to everyone fighting Lymphedema. The Foundation represents a growing community of survivors and thrivers who refuse to let a lymphedema diagnosis slow them down. Lymphedema is often under-diagnosed and under-treated, even by seasoned medical professionals. The Foundation's goal is to turn that around by providing much-needed education and support for those with Lymphedema, their families and their caregivers. **VTN**



Monika Lecomte Gloviczki, MD, PhD, is a highly respected specialist in venous diseases. She is the Chief Scientific and Clinical Advisor to VitasupportMD, a nutraceutical company. She previously worked as a Research Collaborator, Mayo Clinic College of Medicine, Gonda Vascular Center, Division of Vascular

Table 1. Validated QOL questionnaires in lower limb lymphedema (adapted from: Grunherz L, Hulla H, Uyulmaz S, Giovanoli P, Lindenblatt N. Patient-reported outcomes following lymph reconstructive surgery in lower limb lymphedema: A systematic review of literature. *J Vasc Surg Venous Lymphat Disord* 2021; 9:811-921)

First author (Year)	Measurement Tool	Number of Items	Original Language	Available Translations	Evaluation with COSMIN criteria
Keeley (2010) ³³	LYMQOL	27	English	Dutch, Swedish, Turkish,	1 (+)
Devoogdt (2014) ³⁴	Lymph-ICF-LL	29	English and Dutch	Chinese, German, Portuguese, Turkish	4 (+)
Weiss (2018) ³⁵	LLIS-V2*	18	English	Turkish	3 (+)
Klernas (2018) ³⁶	LyQLI*	45	English, Swedish	NA	3 (+)
Augustin (2018) ³⁷	FLQA-LS*	33	German	NA	3 (+)
Ridner (2018) ³⁸	LSIDS-L	31	English	NA	3 (+)

COSMIN: Consensus-based Standards for the selection of Health Measurement Instruments

NA: Not available

*Validity for upper and lower limb lymphedema

LYMQOL: Lymph Quality of Life Measure for Limb Lymphedema

Lymph-ICF-LL: Lymphoedema Functioning, Disability and Health Questionnaire for Lower Limb Lymphoedema

LLIS-V2: Lymphedema Life Impact Scale - Version 2

LyQLI: Lymphedema Quality of Life Inventory

FLQA-LS: Freiburg Life Quality Assessment for lymphoedema

LSIDS-L: Lymphedema Symptom Intensity and Distress Survey Lower-Limb

Medicine Mayo Clinic, Rochester, MN and a Consultant, for the American Venous Forum. In addition, she is the author of numerous scientific papers and for the past 20 years, she has devoted her research to the treatment of venous disease. She is married to Dr. Peter Gloviczki.

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LYMPHEDEMA
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New leadership at ILWTI

International Lymphedema & Wound Training Institute (ILWTI) has been one of the top providers of educational training in lymphedema since 2012; specializing in certifying medical professionals to successfully treat lymphedema at universities and professional settings around the U.S. Recently in 2020, Brandy Mckeown OTR/L, CLT-LANA, CLWT, & CEO, a twenty-year veteran specialist in lymphedema, managing patients in her two clinics in South Georgia, acquired ILWTI coming on board with a fresh vision and desire to reach even more therapist.

“The COVID-19 pandemic instilled fear in so many of us, restricted businesses, travel, and brought many negatives to our economy and industry...but it also made us broaden our horizons and adapt as a company. We saw opportunity in the ability to expand via Web-based learning and advanced technology.” ILWTI updated curriculum and evolved, expertly creating, and accrediting the option

for a therapist to now become a Certified Lymphedema Therapist via their 100% live teletraining format. “This online option has had a huge impact on course availability and reaches so many students that typically wouldn’t have an option to travel to across country to attend a nine-day in house training course. We can now reach many rural areas and medical professionals that simply can’t miss that time away from work and family; they can now achieve accredited certification in the comfort of their home or office. As a business, we adapted to meet the needs of students because of COVID, not fully realizing just how popular our more affordable and efficient live teletraining courses would be.” ILWTI provides the highest standard of training for their accredited lymphedema and wound courses by utilizing a multitude of elite instructors from around the country to teach each individual element of the 135+-hr Certified Lymphedema and Wound Therapist, CLWT™ course. ILWTI is also the only lymphedema

training institution that includes wound care certification within its full lymphedema therapist certification – and at no additional charge. “Maybe it’s part of our niche, but we truly feel the ability to treat wounds is a vital component to treating the #1 cause of lymphedema in the U.S.: venous insufficiency and venous ulcerations”.

ILWTI is also proud to introduce their Lymphedema Program/Clinic Start-Up course to offer clinicians and clinics the tools necessary to build their program as a private practice, hospital, or home health-based program, or even a venous practice that wants to successfully institute lymphedema therapy services within the practice. “Our mission is to provide excellent education and training in wound care, edema and lymphedema management to enable clinicians to better care for the growing patient population with multiple co-morbidities resulting in wounds and various forms of edema.” **VTN**



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FIBROSIS
continued from page 1

infection, skin fibrosis, and functional limitations of the affected limb. Therefore, the earlier SLE is detected and appropriately treated, the better the outcome. In particular, skin fibrosis is a possible serious and irreversible outcome of SLE and is also one of the most difficult symptoms to treat. During the early stage of skin fibrosis, the affected skin gradually hardens.

Some devices are available for assessing skin fibrosis, including tonometer, E-tonometer, indurometer, magnetic resonance (MR) imaging, and ultrasound; these instruments perhaps have the similar technical principle but they have different characteristics and limitations. The earliest modality for evaluating the tonicity of lymphedematous skin, the tonometer, was developed by Clodius et al. Tonometer measures the resistance of tissue to compression; this resistance depending on the mechanical properties of the skin, and in LE-associated fibrosis on the proportion between subcutaneous matrix and interstitial fluid. However, the plunger of the tonometer needs to be pressed forcibly because of relative insensitivity. Furthermore, the dial must be read while the device is held on the patient, which is challenging for certain measurement sites. In addition, the pits produced by application of the instrument to affected skin can cause pain or discomfort. Therefore, more recently, technologic developments have resulted in modified versions of tonometer, and these have been used in a variety of LE-related studies. The electronic digital tonometer (E-tonometer/ lymphometer) has replaced the outdated tonometer. Although E-tonometer can eliminate the gravity effect and display the value instantly on the screen, the sensitivity of the sensor is still poor (precision



0.1 g/mm²). Furthermore, it is still necessary to press hard on the skin. Another device, the indurometer, is also being designed to replace the tonometer. This electromechanical device uses a 200 g mass and a displacement gauge to objectively measure tissue induration. It has a 0.01 mm resomechanical device uses a 200 g mass and a displacement gauge to objectively measure tissue induration. It has a 0.01 mm resolution and a constant force spring allows it to be used in non-vertical positions. However, Vanderstelt et al. reported that two participants were pinched by the indurometer, indicating a defect in this instrument's design, and this device should be further modified in the assessment of LE. MR imaging and ultrasound can assess changes in fibrotic skin thickness and texture; however, these modalities cannot accurately and quantitatively analyze skin stiffness and their operation is complex and costly. Thus, many limitations of these devices make fibrosis to be often overlooked by both the patient and physician.

The SkinFibroMeter (Delfin, Miami FL), a recently developed, portable, and sensitive instrument, utilizes a small measurement probe (diameter of 23 mm) with an indenter that is briefly pressed on the skin at all anatomical sites, including curved region.

The SkinFibroMeter utilizes an indenter that is briefly pressed on the skin. The skin and especially the subcutaneous tissue resist the change in shape to external force of the indenter. The skin response under a short-term load indicates tissue induration properties.

The SkinFibroMeter consists of a 1 mm length indenter, a reference plate and related built-in force sensors. The device is briefly pressed against the skin and the contact pressure is registered. The indenter imposes a constant deformation when the reference plate is in full contact with the skin. The skin and the underlying upper subcutis resist the deformation and the induration value in Newtons (N) is determined.

The presence and severity of fibrosis are assessed by using a special three-dimensional (3D) computational finite element to analyze the biomechanical response of skin tissue to external force. To the best of our knowledge, there is no similar 3D computational finite element for previous

devices. The skin resists changes in shape when an external force is applied; thus, its ability to resist deformation under a short-term load indicates its stiffness, which is expressed in Newtons (N). The value thus obtained is a measure of skin stiffness, which in turn reflects the presence and severity of skin fibrosis. The SkinFibroMeter has been used in skin care; however, its ability to assess skin fibrosis in patients with SLE of the lower limb has not been explored. The SkinFibroMeter has been used in different studies to diagnose and evaluate fibrotic changes in the skin of patients with stage I–III SLE of the lower limb, upper limb, neck or upper back and analyzed the relationship between the measured values and disease progression. Specifically, most of the studies investigated whether the values measured with the SkinFibroMeter correlate with the severity of skin fibrosis in patients with SLE.

Skin fibrosis is one of the most important pathological changes in limbs with SLE. The diagnosis and assessment of skin fibrosis have been challenging, mainly because of the absence of an appropriate method of diagnosing the stage of SLE. In this study, we investigated the use of the SkinFibroMeter to accurately evaluate skin stiffness in patients with SLE of the lower limb. All the results clearly show that this portable instrument provides diagnostically valuable information on the severity of skin fibrosis in the lymphedematous, edematous lower limb. **VTN**



Patrick Danciu is an expert in vein disease and skin measurement and treatment. He is the CEO of Delfin USA and FCare Systems USA. He participates in many patented product development in Europe and the U.S.

If you have or see venous-related articles or information, please forward to Lucius Walker at lukew@pcinews.com.

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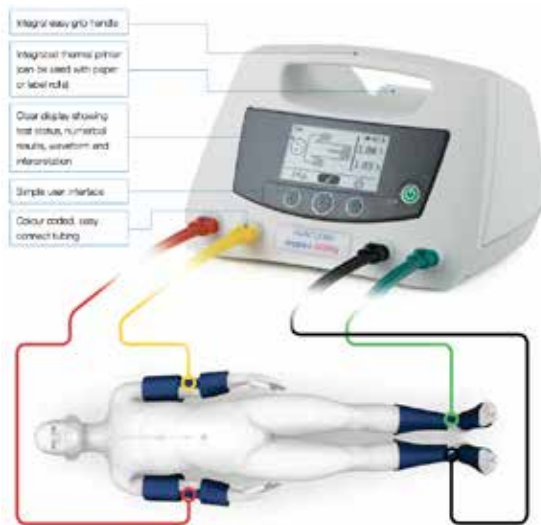
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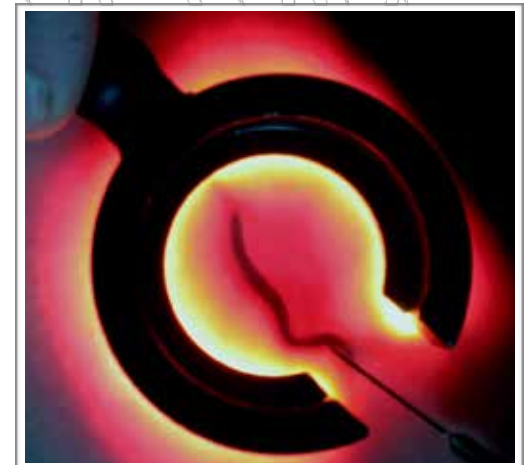
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Are you using Modifier 25 correctly?

By Candice Chandler CPC, CEMC
StreamlineMD

Including Modifier 25 appended to a procedure tells the insurer you should be paid for both an E/M consult and a procedure performed at the same visit. This often-misused modifier indicates that documentation is available in the patient's records which will support the distinct, significant, and separately identifiable nature of the evaluation and management service.

All medical procedures have an "inherent" E/M component that assesses the medical necessity of the procedure and the patient's overall health. Consider the E/M to be part of the service and not separately billable if the office visit briefly touches on the reason for which the procedure is being performed. However, work which is "integral to that procedure" does not support a separately billable E/M service. For Modifier 25 to be assigned, the patient's condition must require the provider to go above and beyond the usual care associated with the procedure.

The Centers for Medicare & Medicaid Services has identified the potential overuse and misuse of Modifier 25 as a cause of concern. This issue has been raised on multiple occasions when the Office of the Inspector General (OIG) published an analysis showing that 35% of Medicare claims with Modifier 25 did not meet Medicare program requirements. Since

then, CMS and private payors have increased their scrutiny of codes reported with this modifier, sometimes resulting in significant repayment to Medicare.

Clinicians should ask themselves the following questions to determine if Modifier 25 is appropriate:

- ✓ Did you perform and document the key components of a problem-oriented E/M service for the complaint or problem?
- ✓ Could the complaint or problem stand alone as a billable service?
- ✓ Is there a different diagnosis for this portion of the visit?
- ✓ Did you perform extra work that went above and beyond the typical pre or post-operative work associated with the procedure code?
- ✓ When appending Modifier 25 to an E/M code, documentation for any additional finding must "stand-alone" and show a separately identifiable (new) problem addressed at the visit. The documentation should include:

A PATIENT HISTORY

A list of co-morbidities and their potential effects on the current condition.

A problem pertinent examination.

An individual plan of care for the new problem.

When completing the record, allow your documentation to "paint a picture" so a payor can follow your thought process. Clearly document the care required that stands alone and goes above and beyond what is normally included in a procedure visit. When documented appropriately, timely reimbursement will soon follow. **VTN**

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<https://oig.hhs.gov/oei/reports/oei-07-03-00470.pdf>

Disclaimer: Accurate coding is the responsibility of the provider. This summary is intended only to serve as a resource to assist in the billing process.



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Learning Objectives

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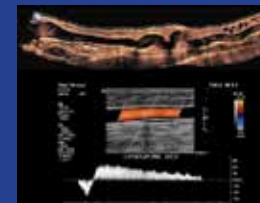
- Identify the treatment options of superficial venous disease.
- Identify the treatment options for non-axial veins, how to discern treatment modality - phlebectomy and sclerotherapy, and when to use a combination of both.
- Master best techniques to perform stab phlebectomy.

Sclerotherapy



- Recognize the benefits of sclerotherapy to optimize clinical outcomes for patients with venous disease.
- Employ proper sclerotherapy techniques for patients presenting with varicose, reticular, and telangiectasias veins.
- Communicate the risks, benefits, and complications of sclerotherapy.

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AVLS
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participation is now a part of our future, but the in-person experience again proved to be all that much better.”

Hybrid meetings will always have a place going forward, allowing those who cannot travel for any reason to still participate and partake in the educational benefits of the Annual Congress. Each year the AVLS will continue to fine-tune its hybrid approach, offering a livestream alternative and on-demand access for all attendees.

Preparations have already begun for the 2022 AVLS 36th Annual Congress in New Orleans on October 13-16, 2022, for an exciting medical education programming chaired by Dr. Christopher Pittman and a celebration for “Veins and all that Jazz.”

ABOUT THE AMERICAN VEIN & LYMPHATIC SOCIETY

The American Vein & Lymphatic Society (AVLS), formerly the American College of Phlebology, is the largest association for physicians and allied health professionals concerned with diagnosing and treating venous and lymphatic disorders as varicose and spider veins, venous ulcers and DVT. Comprised of almost 2,000 members, the AVLS is a forum to exchange medical knowledge, best practices and the latest treatment options and offers continuing live and online education and training to improve the quality of patient care. For over 30 years, the AVLS has advocated advancing venous and lymphatic care through education, resources and research. **VTN**

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ACCESSING DIFFICULT VASCULAR ANATOMY WITH ULTRASOUND

"Drawing blood on a kid is sometimes really very difficult," says William Copeck, Nurse Manager at The Valerie Fund Children's Center for Pediatric Cancer & Blood Disorders (part of St. Joseph's Healthcare System), discussing his center's ultrasound-guided vascular access program. "Before we had the vascular access program, we would often have to have multiple nurses in the room sometimes to hold the child down, to hold them still enough, so that we could get a line in them. It's traumatic for the kids, it's traumatic for the parents, and sometimes it's traumatic for us."

Whether injecting medicine or drawing blood, the Valerie Fund Children's Center team recognized that anything that could make their patients more comfortable would be worth investigating.

ULTRASOUND-GUIDED VASCULAR ACCESS REDUCES TIME, PAIN

St. Joseph's Regional Medical Center, located in Paterson, New Jersey, houses the second-busiest emergency department in the nation, serving over 175,000 patients in

2016. Seeking new ways to offer patients a better overall experience is top-of-mind for executives and practitioners alike.

When St. Joseph's first introduced their ultrasound-guided vascular access program, which trained nurses in using ultrasound visualization to locate and access hard-to-see vasculature, they didn't realize what a huge difference the technology would make.

"Before we had the Sonosite ultrasound technology, we had a lot of patients with multiple sticks, bruises..." says Judy Padula, Vice President of Patient Care Services and Chief Nursing Officer at St. Joseph's Healthcare System. "As minor as that may sound to some people, getting the IV in can be the make or break to their treatment."

Ultrasound allows the specialists at St. Joseph's to clearly visualize the vascular structures that they need to access in real-time. This promotes more accurate needle placement, which can lead to many fewer attempts needed.

"With the ultrasound," says Matthew Ostroff, head of the Vascular Access Program, "we assess the vein before we stick it; we can see our needle going into the vein."

Before St. Joseph's began their specialized vascular access program, point-of-care ultrasound wasn't something most care providers considered essential to their work with sick children.

"It wasn't even on my radar," says Copeck.

And now?

"I would tell people, you're crazy not to have it. I can't even tell you how important it's been to us."

"It takes roughly 40-45 minutes at the bedside to do a PICC line," explains Ostroff. "When we're able to substitute an ultrasound-guided peripheral [IV], it's a 5-10 minute procedure. We've essentially changed the entire landscape of IV-insertion."

A SAVINGS OF \$3.5 MILLION WITH POCUS

The drive to provide a better patient experience propelled the adoption of the Vascular Access program, but the phenomenal savings that the program introduced was a pleasant surprise.

Since the advent of the Vascular Access program in February 2014 and December 2016, St. Joseph's has seen a remarkable and unexpected level of cost-savings; nearly \$3.5 million in total.

Patients cannot be admitted to the hospital (outside of the Emergency Department) until vascular access is obtained. For both children and "difficult stick" adults, the ability to quickly and efficiently insert a peripheral IV can shorten the stay in the ER, and the cost of an overall stay in the hospital, significantly.

When nurse practitioners can use ultrasound to guide needle placement, radiology referrals are reduced, which lessens the cost of care per patient.

Moving from a preference for PICC lines to ultrasound-guided peripheral IVs saved roughly \$250 in catheter costs per insertion. **VTN**

READ MORE: <https://www.sonosite.com/evidence/fewer-sticks-millions-savings-pocus-guidance>

Consider all costs of ownership: Understanding the trade-in value of an ultrasound system

When making a high investment in medical equipment it is important not only to compare the price and quality of each product, in these cases it begins to be necessary to analyze the total cost of ownership (TCO) during the useful life of the equipment, since it could happen that the indirect costs exceed the sale price, plus all the additional problems that can even lead to damage to the reputation of the hospital.

In recent medical meetings, the TCO and the indirect costs that constitute it are being debated. Some of these costs to consider are technical service and repairs, although software updates, possible cybersecurity problems, the duration and coverage of the warranty, the cost of training to use the ultrasound machine, the Average repair cost, breakdown downtime, component replacement, or trade-in value.

In this article we are going to focus on this last variable: the exchange value or the future Trade-in Value of our equipment when we decide to acquire a new equipment. Owners of an ultrasound system must analyze all the variables that make up the resale value of their equipment



and check them over time as the system ages. The overall aim remains to recover part of the investment when the ultrasound system is updated.

The choice of the ultrasound brand can increase the value of the equipment due to a good reputation based on durability, low repair costs, absence of preventive maintenance, etc. In this case, the cost of ownership is lower due to the assumed high exchange value. When buying a computer, reputation and resale value are important aspects.

Another variable to consider is the category of the equipment, a Premium ultrasound will give a greater proportional value, since it will be designed with more resistant materials and will offer more, unlike an economic ultrasound of a lower category and that does not require a large investment to acquire it new. The higher the product category, the more confidence it will bring and therefore its repurchase value will be higher.

Fujifilm Sonosite created a one-off campaign offering a very high trade-in value to upgrade your old ultrasound machine to the Sonosite PX, thus facilitating the acquisition of this new ultrasound machine by of your customers.

A good understanding of the concept of "trade-in value", choosing the right moment and the ultrasound model will allow you to save a significant amount of money and enjoy the latest technology. **VTN**

READ MORE: <https://www.sonosite.com/blog/consider-all-costs-ownership-understanding-trade-value-ultrasound-system>



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