



**SAVE A LEG
SAVE A LIFE
FOUNDATION**

"To reduce the number of lower extremity amputations and to improve the quality of life for our fellow citizens who are afflicted with wounds, complications of diabetes and peripheral artery disease."

WNY Chapter: Save A Leg, Save A Life Newsletter
January 2012

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Informational Links

SALSAL Foundation Website
<http://savealegsavealife.org/>

ECMCC Wound and Hyperbaric Medicine
<http://www.ecmc.edu/medicalservices/wound/>

Catholic Health Advanced Wound Healing Centers
<http://www.chsbuffalo.org/Services/Wound>

VIA (Vascular Interventional Associates)
<http://www.viabuf.com/>

Diversified Clinical Services
www.diversifiedcs.com

Precision Healthcare
<http://www.precisionhealthcare.com/>

What is Save a Leg, Save a Life?

Save A Leg, Save A Life is our way of creating awareness and implementing the steps recommended by the CDC in our region. Wound Summit Outreach, Inc. is accomplishing these goals through the Southeastern Interactive Wound Summit, and the Save A Leg, Save A Life Foundation. Originally started as a spin-off organization from the Southeastern Interactive Wound Summit in 2006, designed to increase the community knowledge about current CDC recommendations regarding wound healing and the prevention of limb amputation.

Here are the national statistics with respect to limb amputation: The cost of a lower extremity amputation aftercare is approximately \$49,000 annually. Less than 50% of below knee amputees, and less than 25% of above knee amputees will become ambulatory with the use of a prosthesis. The result is many amputees become institutionalized, which can lead to annual nursing home costs of greater than \$100,000 per patient. The cost of follow up care in patients where amputation is prevented is estimated at \$800 per year, per patient.

Additionally, patients who undergo a lower extremity amputation have a greater than 50% chance of having an amputation of the remaining lower extremity. The life expectancy of the patients who survive the initial 30 day post-operative period is typically less than 5 years.

A \$4 Billion per year savings could occur in the United States with a 25% reduction in lower extremity amputations!

When compared with others, many patients with chronic wounds of the lower extremity have co-existing medical conditions that put them at a greater risk for a catastrophic event, such as a heart attack or stroke.

Peripheral Arterial Disease, or PAD, is a condition commonly found in the lower extremities in persons with and without diabetes. Risk factors include persons over the age of 50 who have diabetes or smoke, and anyone over the age of 70. PAD affects 12-20 % of



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Dr. Desmond Bell, Founder and President of the National Save a Leg, Save a Life Foundation, visited the WNY Chapter in May 2011

Americans age 65 and older and approximately 12 million Americans alone have PAD.

The Center for Disease Control (CDC) has recommended 5 steps to improve PAD treatment and outcomes per the Prevention of Atherothrombotic Disease Network (PAD Network).

The steps are outlined as follows:

1. Increase awareness of PAD and its consequences.
2. Identify people with symptomatic PAD.
3. Screen for patients at high risk.
4. Improve treatment for symptomatic PAD cases.
5. Increase early detection of symptomatic cases.

Locally, a chapter has started as collaboration between Vascular Interventional Associates, ECMC's Center for Wound Care and Hyperbaric Medicine, Catholic Health Advanced Healing Centers, The Visiting Nurses Association and Kaleida Health Hospitals. This is an exciting time as we move forward in the direction of local research, community outreach and the formation of a multidisciplinary team with one goal in common: to reduce the number of limb amputations locally.

Meetings are held every two months and open to anyone who has an interest in affecting change, improving patient outcomes and forwarding the best clinical practice guidelines. For more information on the next meeting, please contact Michele Fisher at 859-2738 or Blanka Heary at 859-2681.

Save A Leg, Save A Life Foundation Mission Statement

"To Reduce the Number of Lower Extremity Amputations and to Improve the Quality of Life of Our Fellow Citizens Who are Afflicted with Wounds"

We Will Accomplish These Goals by Using Advanced Evidence Based Methods, by Educating Fellow Practitioners and Patients, and through Community Outreach.



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Contact Us:

Contact Michele Fisher for more information on upcoming chapter events, meetings, and to obtain more information

716-859-2738 or
mfisher@viabuf.com

Please join us at our next Chapter Meeting Monday February 6, 2012 at 6pm. Dr. Paula Pons, Area Medical Director for Diversified Clinical Services will be the distinguished speaker

Comprehensive Wound Care *by Elizabeth Engler, Program Director, Center for Wound Care and Hyperbaric Medicine at the Erie County Medical Center Corporation*

Comprehensive wound management requires a physician driven, multidisciplinary based program that directs critical resources required for evaluation and treatments to patients suffering from wound healing failure. Traditional approaches to the management of these patients have typically been ineffective. Successful management of these challenging problems can easily exceed the capabilities of the primary care physician's office due the complexity and time consuming nature of the care required. Comprehensive wound care centers provide this type of highly specialized care that many patients require.

Diabetic wound healing problems have a major impact on patient quality of life and represents a significant portion of all health care dollars spent. Venous leg ulcers represent the largest category of outpatient chronic wound in most industrialized countries with a frequency of almost 500,000 new ulcers developing annually. Diabetic foot ulcers affect over 15 percent of the 21 million diabetics in the U.S and account for more than half of all lower extremity amputations in the subset representing only 4-8 percent of the total population. In these patients who progress to lower extremity amputation, the 3 year mortality approaches 50 percent. Pressure Ulcers account for the largest wound category in institutionalized patients who are frequently debilitated by multiple medical problems, malnutrition, and mobility impairment. Evidence has shown that when these patients are evaluated and managed within a comprehensive wound care program, morbidity is decreased and outcomes improved.

Comprehensive wound centers provide structured patient assessment process including a complete assessment of local and systemic factors affecting wound healing, co-morbidities that impact response to treatment, peripheral vascular assessment including transcutaneous PO₂ measurement and other diagnostic interventions as required. This initial assessment is designed to address the specific pathophysiology of wound healing failure and specific plan of management and care from evidenced based medicine and the best practice based Clinical Practice Guidelines©.



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3. Brown, K., Chronic venous insufficiency. Available: <http://emedicine.medscape.com/article/461449-overview>. Accessed: 8/5/2011
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A treatment plan is developed by a specially trained wound care physician and may involve local wound debridement, specialized topical wound care, local edema control, local and systemic antimicrobial therapy, revascularization or angioplasty, recombinant growth factor therapy, bioengineered tissue grafts and dermal substitutes, negative pressure wound therapy, and off-loading and protection. Hyperbaric Oxygen may be part of the treatment plan. Hyperbaric Oxygen therapy greatly increases the amount of oxygen delivered to the body tissues by the blood. Patient nutritional and rehabilitation needs are also addressed. Wound care specialist physicians can also assist in arranging recommended medical and surgical specialist physician consultations.

Referrals to a Comprehensive Wound Care Center should be made whenever one or more of the following criteria have been met:

- Full or partial thickness wounds that fail to show significant progress towards healing after four weeks of conventional treatment
- Full thickness wound with exposed tendon, bone and/or joint capsule
- Wounds occurring in immune compromised patients or patients with diabetes mellitus or peripheral vascular disease
- Rapidly progressive, necrotizing soft tissue infections
- Refractory osteomyelitis
- Radiation Tissue injury
- Crush Injury, compartment syndromes and other acute traumatic ischemias or compromised/failing skin grafts or flash when hyperbaric oxygen treatment may be considered for limb or tissue survival



Diagnostic consideration and therapeutic role of percutaneous iliac stenting. *Vascular*. 2007; 15(5):273-280.

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Chronic Venous Insufficiency *by Michelle Fisher, PA VIA*

Chronic venous insufficiency of the lower extremities is a common progressive condition. Symptoms are statistically more common in women (4) however venous reflux is seen sonographically more in men (9.4%) in comparison to 6.6% of women in the general population and its prevalence increases steeply with age(1). It may be caused by valve incompetence and secondary venous reflux, by ilio caval stenosis or obstruction or by combination of these two entities. The presence of common iliac vein stenosis continues to be a frequently overlooked cause of chronic venous changes. Iliac vein compression syndrome occurs when fibrosis within the common iliac vein forms as a result of chronic compression by the contralateral common iliac artery (2). This occurs most frequently in the left common iliac vein when it crosses beneath the right common iliac artery just distal to the iliac bifurcation. The condition is termed May-Thurner syndrome when the common iliac vein compression is accompanied by acute or chronic venous thrombosis.

There is significant reduction in quality of life in patients who suffer from chronic venous changes in the lower extremities. Patients present with complaints of presence of varicose and spider veins, edema, sensation of heaviness, aching, tiredness, pruritus and restlessness of the lower extremities (3). The symptoms typically intensify with leg dependency with most significant discomfort in the evening and at night. Clinical manifestations may include leg edema, tenderness, varicosities, pigmentation, lipodermatosclerosis, and ulceration.

The extent of diagnostic evaluation should be based on individual patient presentation. The initial testing should include venous Doppler to rule out acute or chronic deep vein thrombus as well as standing and supine venous insufficiency study to assess for reflux of superficial and deep veins. The latter study should include measurements of great and small saphenous vein diameters and should assess for presence of collateral veins, vein of Giacomini as well as incompetent perforator veins. In patients with unilateral predominance of symptoms, pain that exceeds physical presentation, presence of deep and superficial vein reflux on ultrasound or recurrent symptoms despite previous venous treatment, MRV of pelvis should be considered for evaluation of iliac vein or inferior vena cava stenosis and obstruction.



early clinical outcome.

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Comprehensive treatment of venous insufficiency includes conservative, endovascular and surgical modality. Thigh or waist high compression stockings with 20-30 mmHg pressure gradient should be used in all patients in combination with leg elevation as the initial course of treatment. Compression therapy is contraindicated in patients with severe peripheral arterial disease. Radiofrequency or laser venous ablation can be used for treatment of reflux in great and small saphenous veins in patients who do not benefit from conservative treatment. Ultrasound guided foam sclerotherapy can be performed for the treatment of incompetent perforators and large painful varicose veins. Pelvic venogram with intravenous ultrasound (IVUS) is performed in patients with ilio caval stenoses identified on MRV.

Endoluminal stenosis of 50% or greater as measured with IVUS is considered significant and endovascular management of these lesions is recommended (5). Percutaneous iliac vein venoplasty and stenting is now considered the "method-of-choice" in lieu of surgical bypass with open surgery performed only on patients with failed and reoccluded stent procedures (5). The procedure can be performed with "low morbidity, no mortality, a long-term high patency rate, and a low rate of in-stent restenosis" (5). It is performed in the angiography suite under local anesthesia and intravenous sedation. Clinical outcomes of significant improvement in symptoms, ulcer healing rate and quality of life have been demonstrated after endovascular venous interventions (6).

In conclusion, chronic venous insufficiency can be successfully treated with endovascular techniques for patients who fail conservative therapy. Early recognition, diagnosis and treatment of chronic venous insufficiency may prevent advanced skin changes and chronic leg ulcerations.



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The Role of Hyperbaric Oxygen Therapy in Lower Limb Preservation

by *Lee C. Ruotsi, MD, FACCWS, UHM Medical Director; Catholic Health Advanced Wound Healing Centers*

Hyperbaric oxygen therapy (HBOT) has been studied and used for hundreds of years, but only in the past twenty to thirty years has gained true acceptance in the clinical practice of medicine. Thanks to the groundbreaking hard work of physicians and scientists such as Paul Cianci, T.K. Hunt, Robert Marx, Enrico Faglia, Caroline Fife and Robert Warriner, we now have a scientific basis for the treatment of at least thirteen separate clinical disease processes with HBOT.

Hyperbaric oxygen therapy is defined as "a treatment in which a patient breathes 100% oxygen, intermittently, while in a treatment chamber at a pressure higher than atmospheric pressure". This treatment can be administered in a multiplace chamber, which can treat as many as 10 patients at one time or, more commonly, in a monoplace chamber which treats one patient at a time. The majority of non diving related HBOT in the United States at the present time is delivered in monoplace units.



In terms of lower extremity limb preservation, HBOT has its broadest acceptance and greatest utility in the treatment of ischemic diabetic foot ulcers and in several wound types caused by acute and/or traumatic arterial insufficiency. In these settings, the intermittent, usually once daily, administration of 100% oxygen at 2.0 - 2.5 atmospheres absolute (1,520 mm Hg, 29.4 psi) catalyzes a sequence of enzyme and growth factor mediated steps that ultimately lead to angiogenesis. With this process we are able to realize more rapid wound healing velocities, a lower risk of infection and amputation, improved quality of life for the patient, and savings in health care dollars.

In conclusion, hyperbaric oxygen therapy is a valuable tool in the fight against lower extremity wounding and amputation. Like any other treatment modality, its application to individual patients must be based on good clinical judgement and accepted best practices. When these principles are followed, HBOT can add a powerful dimension to the wound healing and limb preservation arsenal.



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Diabetic Foot Ulcers *by: David Davidson, DPM Panel Physician, Center for Wound Care and Hyperbaric Medicine at The Erie County Medical Center Corporation*

Foot disorders such as ulceration, infection, and gangrene are the leading causes of hospitalization in patients with diabetes mellitus. Approximately 15 to 20 percent of the estimated 16 million persons in the United States with diabetes mellitus will be hospitalized with a foot complication at some time during the course of their disease. Unfortunately, many of these patients will require amputation within the foot or above the ankle because of severe infection or peripheral ischemia. Neuropathy is often a predisposing factor to ulceration and amputation.

The diabetic foot and its sequelae account for billions of dollars in direct medical expenditures, as well as lengthy hospital stays and periods of disability. The most characteristic lesion of the diabetic foot is ulceration, which consequently is one of the major risk factors for amputation. Approximately 85 percent of all diabetes-related lower-extremity amputations are preceded by foot ulcers. The etiology of diabetic foot ulcers usually has many components. A recent multicenter study attributed 63 percent of diabetic foot ulcers to the critical triad of peripheral sensory neuropathy, trauma, and deformity. Other factors in ulceration are ischemia, callus formation, and edema. Although infection is rarely implicated in the etiology of diabetic foot ulcers, the ulcers are susceptible to infection once the wound is present. Many of the risk factors for foot ulcer are also predisposing factors for amputation, because ulcers are primary causes leading to amputation.

A thorough evaluation of any ulcer is critical and should direct management. The evaluation should determine the etiology of the ulcer and ascertain whether the lesion is neuropathic, ischemic, or neuro-ischemic. Failure to perceive the pressure of a 10-g monofilament is a proven indicator of peripheral sensory neuropathy and loss of protective sensation. Other common modalities that can detect insensitivity are a standard tuning fork (128 cycles per second) and a neurologic reflex hammer.

After describing the dimensions and appearance of the ulcer, the physician should examine the ulcer with a blunt sterile probe. Gentle probing can detect sinus tract formation, undermining of ulcer margins, and dissection of the ulcer into tendon sheaths,





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bone, or joints. A positive probe-to-bone finding has a high predictive value for osteomyelitis. Failure to diagnose underlying osteomyelitis often results in failure of wound healing. The existence of odor and exudate, and the presence and extent of cellulitis must be noted.

Generally, limb-threatening infections can be defined by cellulitis extending beyond 2 cm from the ulcer perimeter, as well as deep abscess, osteomyelitis, or critical ischemia. Aerobic and anaerobic cultures should be taken when signs of infection, such as purulence or inflammation, are present. Cultures are best taken from purulent drainage or curetted material from the ulcer base.

Because all ulcers are contaminated, culture of non-infected wounds is generally not recommended. Polymicrobial infections predominate in severe diabetic foot infections and include a variety of aerobic gram-positive cocci, gram-negative rods, and anaerobes.

Radiographs should be obtained in most patients with deep or longstanding ulcers to rule out osteomyelitis; however, radiographs are not a very sensitive indicator of acute bone infection. When clinical suspicion indicates osteomyelitis but radiographs are negative, additional bone or leukocyte scanning is helpful in ascertaining bone involvement. However, in the neuropathic patient, bone scans are often falsely positive because of hyperemia or Charcot's arthropathy. Leukocyte scanning or magnetic resonance imaging offers better specificity in this situation. Ultimately, bone biopsy is necessary to firmly establish the diagnosis of osteomyelitis.

Vascular status must always be assessed because ischemia portends a poor prognosis for healing without vascular intervention. The simple palpation of both pedal pulses and popliteal pulses is the most reliable indication of arterial perfusion to the foot. The absence of pedal pulses in the presence of a palpable popliteal pulse is a classic finding in diabetic arterial disease because of the selective involvement of the tibial arteries below the knee. Noninvasive Doppler studies should be used to augment the clinical examination as needed, although even with these tests, the severity of arterial insufficiency can be underestimated. Vascular surgical consultation is warranted when there is significant suspicion of ischemia.



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The primary goal in the treatment of diabetic foot ulcers is to obtain wound closure. Management of the foot ulcer is largely determined by its severity (grade) and vascularity, and the presence of infection. A systematic approach to treatment should be taken for all diabetic foot lesions. A multidisciplinary approach should be employed because of the multifaceted nature of foot ulcers and the numerous comorbidities that can occur in these patients. This approach has demonstrated significant improvements in outcomes, including reduction in the incidence of major amputation.

Rest, elevation of the affected foot, and relief of pressure are essential components of treatment and should be initiated at first presentation. Ill-fitting footwear should be replaced with a postoperative shoe or another type of pressure-relieving footwear. Crutches or a wheelchair might also be recommended to totally off-load pressure from the foot. Although total contact casting (TCC) is considered the optimal method of management for neuropathic ulcers, it must be reapplied weekly and requires considerable experience to avoid iatrogenic lesions. Acceptable alternatives to TCC are removable walking braces and special, off-loading shoes.

A mainstay of ulcer therapy is debridement of all necrotic, callus, and fibrous tissue. Unhealthy tissue must be sharply debrided back to bleeding tissue to allow full visualization of the extent of the ulcer and detect underlying abscesses or sinuses. Topical enzymes have not been proved effective for this purpose and should only be considered as adjuncts to sharp debridement. Soaking ulcers should be avoided because the neuropathic patient can easily be scalded by hot water.

Topical antiseptics, such as povidone-iodine, are usually considered to be toxic to healing wounds. Generally, a warm, moist environment that is protected from external contamination is most conducive to wound healing. This can be provided by a number of commercially available special dressings, including semipermeable films, foams, hydrocolloids, and calcium alginate swabs.

The genetically engineered platelet-derived growth factor becaplermin (Regranex gel) is approved for use on neuropathic diabetic foot ulcers and can expedite healing. Growth factors stimulate chemotaxis and mitogenesis of neutrophils, fibroblasts, and monocytes, as well as other components that form the



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cellular basis of wound healing.

Bioengineered skin (Apligraf) and human dermis (Dermagraft) are types of biologically active implants for ulcers that are derived from fibroblasts of neonatal foreskins. These bioengineered products enhance healing by acting as delivery systems for growth factors and extracellular matrix components through the activity of live human fibroblasts contained in their dermal elements.

Prevention of an initial or subsequent foot lesion is crucial to avoiding amputation. The best approach is to make use of a team of multidisciplinary professionals who are committed to limb salvage. Centers that have instituted teams specifically for this purpose have subsequently reported dramatic reductions in lower-extremity amputation and improved rates of primary-ulcer healing. Patient education has a central role in treatment and should include instruction on foot hygiene, daily inspection, proper footwear, and the necessity of prompt treatment of new lesions.

Regular foot-care examinations, including debridement of calluses and ingrown toe-nails, provide an opportunity to reinforce appropriate self-care behaviors and allow for early detection of new or impending foot problems. Therapeutic shoes with pressure-relieving insoles are an essential element of ulcer prevention and have been associated with significant reductions in their development.

Elective surgery to correct structural deformities that cannot be accommodated by therapeutic footwear can be performed as needed in certain patients. Common procedures include hammertoe repair, metatarsal osteotomies, plantar exostectomies, and Achilles tendon lengthening.

Working in unison with a vascular surgeon or interventional radiologist/cardiologist, these foot-sparing reconstructive procedures can even be performed after revascularization in an ischemic patient who might otherwise have needed amputation. Diabetic foot ulcers can be managed without amputation by following the principles discussed in this article and having a thorough understanding of the pathogenesis of these ulcers.



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