Implementation of a Comprehensive Therapy Concept in the Treatment of Venous Leg Ulcers in Daily Practice

A summary of a satellite symposium held at the 18th annual conference of the Canadian Association of Wound Care – November 8, 2012

Introduction

Approximately 90% of lower leg ulcers are of vascular origin. Venous leg ulcers (VLUs) are extremely painful, and have a negative impact on quality of life. Moreover, they present a significant burden on health-care resources. The Canadian Medical Advisory Secretariat reports the prevalence of leg ulcers to be 0.12% to 0.32% of the general population. Other reports indicate a prevalence of 1% to 2% of adults.[1]

A recent systematic review demonstrated that compression therapy is the most effective therapeutic intervention for VLUs.[2]

- Compression therapy improves ulcer-healing rates.
- Multi-layer systems are more effective than single-layer systems.
- High-compression bandaging is more effective than low-compression bandaging.

The authors concluded: "Compression therapy consists of specialized bandaging applied by appropriately trained health professionals followed by long-term use of compression stockings. This increases ulcer healing better than non-compression therapies."[2]

Unfortunately, VLUs are often improperly treated. Gottrup and colleagues noted that in patients with chronic wound problems, only 51% had a significant diagnostic examination; furthermore, 40% of patients with VLUs are not treated with compression, the accepted standard therapy.[3]

In an effort to gain an understanding of the implementation of a complex therapy regimen for the treatment of VLUs in clinical practice, patients in Germany (n=29), Italy (n=28) and Austria (n=6) were treated with moist wound dressings and compression therapy in the setting of routine medical care.[4]

The methodological approach to the study consisted of the following:[4]

- **Graduated compression** (liner and overstocking; Jobst® Ulcer Care Compression System, 40 mmHg), to counteract venous hypertension and to reduce and control edema.
- **Moist wound care** (Cutimed® Siltec® B), to absorb excess wound fluid, promote moist wound healing, and to provide protection at the wound and periwound sites.
- **Antimicrobial therapy** (Cutimed® Sorbact®), in the presence of unclean, colonized or infected wounds.

At the completion of the 12-week study, 84% of patients' wounds were reduced significantly in size, and 57% of wounds had healed completely. Of particular note is that some of the larger wounds (~5 cm in size) were treated successfully.[4]

"The majority of patients had not experienced any wound healing progress for extended periods of time prior to the study, due in large part to complex health situations (underlying diseases, obesity, infection) or use of inadequate therapies," noted Dr. Brambilla. "Thus, the rapid healing results noted in our study were rated very positively by both patients and physicians." Moreover, patients' well-being was substantially improved, which resulted in a high level of compliance during the study period.

The use of Cutimed® Sorbact® rendered possible the treatment of infected wounds without antibiotics; this is an important consideration, noted Dr. Brambilla, as 43% of the wounds included in the study showed signs of infection.

Study investigators also noted that the therapeutic intervention was straightforward to apply, and was well-tolerated by patients. Benefits included:[4]

- Stability of wound dressings under compression.
- Speedy wound healing led to improvement of patients' well-being, which in turn resulted in a high rate of compliance; indeed, the majority of patients indicated that they would use similar products should a venous ulcer develop again.

Figure 1
Male with VLU at enrollment (A) and study end (B)

Figure 1 depicts one of the study enrollees. This 59-year-old male presented with a VLU, which was complicated by the additional risk factors of adiposity and diabetes (Figure 1a). He had shown disturbed wound healing over the last 3 months, and signs of infection were present. Upon completion of the study, the patient's ulcer was almost completely healed (Figure 1b).

The 3 major study conclusions, noted Dr. Brambilla, were: 1) complete ulcer healing in more than half of study participants; 2) significant improvement in wound status for the majority of patients; and 3) increased quality of life for all enrollees. He added, "It is clear that treatment pathways of this nature can be implemented successfully in daily practice."

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Understanding Antimicrobial Dressings and Their Role in Wound Care

A summary of a satellite symposium held at the 18th annual conference of the Canadian Association of Wound Care – November 8, 2012

Introduction

Dr. Keast began the session by noting the importance of distinguishing between inflammation and infection. Key determinants are noted in Table 1.[1] He added that the most common cause of chronic inflammation in a wound is bacteria. Three key considerations regarding wound infection are: the number of bacteria present, the virulence of the bacteria and host resistance (which requires assessment of comorbid conditions that may affect the ability of the patient to manage bacterial loads).

He further noted that the diagnosis of infection is a clinical judgment; hence, assessment of bioburden through documentation of clinical signs and symptoms is crucial in helping to determine the proper wound care intervention. Surface swabs, appropriately obtained, may assist in guiding treatment; the Levine method is the best approach to obtain a swab. Furthermore, the management of infection requires a global approach, which includes maximizing host resistance, debridement and the selection of appropriate dressings.

Table 1

Inflammation vs. infection[1]

Inflammation	Factor	Infection
Coexisting systemic disease	*Comorbidity*	Decreased host resistance
Constant, onset with lesions	*Pain*	Increasing
Multiple sites, symmetric	*Location*	Single location, asymmetric
Palpable purpura, livedo pattern, rolled border, focal necrosis, satellite lesions	*Morphology*	Classic or subtle signs of infection, soft tissue crepitus
Local	*Erythema*	Advancing
Normal or warm	*Skin temperature*	Warm or hot

Silver dressings

Silver dressings play 2 main roles in the treatment of wounds: 1) they reduce bioburden and 2) they act as an antimicrobial barrier.

Silver dressings are appropriate for use on wounds that present with localized, spreading or systemic infection, e.g. acute traumatic wounds, including burns and surgical wounds, and for chronic wounds.

Biatain Alginate Ag (formerly SeaSorb Ag)

Biatain Alginate Ag (SeaSorb Ag) is a highly absorbent, sterile, non-woven, antimicrobial pad composed of calcium alginate, carboxymethylcellulose and an ionic silver complex (Alphasan). The silver complex releases silver ions when exposed to positive ions such as sodium from the wound exudate. The dressing has a 7-day wear time, and possesses hemostatic capabilities due to the sodium–calcium ion exchange.

Biatain Alginate Ag (SeaSorb Ag) works in the following manner: As exudate is absorbed, the carboxymethylcellulose swells and the alginate saturates – this in turn forms a high tensile strength gel that can be removed in 1 piece. The Na+ that discharges from the wound exudate allows the release of Alphasan silver complex. Hemostasis occurs due to the sodium–calcium ion exchange process; calcium replaces the sodium, which stops the bleeding.

Biatain Ag foam

Münter and colleagues studied the effect of a sustained silver-releasing dressing on ulcers with delayed healing.[2] This was the first large-scale (>600 patients), international, randomized controlled trial using an outcomes approach to investigate the clinical performance of a wound dressing. Compared with traditional clinical trials, this approach mimics real-life situations, as it allows the inclusion of data from patients seen in everyday clinical practice situations rather than data from carefully selected patients only.

During the 4-week study, investigators compared an antibacterial sustained silver-releasing hydro-activated foam dressing (Biatain Ag) with local best practice in the treatment of diabetic foot ulcers, venous/arterial/mixed ulcers, pressure ulcers and several other types of wounds with delayed healing.

The results of the study demonstrated that:

- The wound area decreased significantly faster in patients treated with Biatain Ag than with local best practice (50.0% vs. 34.3%, respectively; P=0.002).
- Progress toward complete healing was achieved to a larger extent (P=0.0001) compared with local best practice.
- Faster reduction of odor occurred with Biatain Ag (P <0.001).
- The exudate level decreased faster with Biatain Ag (P=0.006).
- There were fewer leakages and significantly fewer occurrences of maceration with Biatain Ag than local best practice (P=0.04).
- Biatain Ag had significantly longer wear time than local best practice (3.1 days vs. 2.1 days, respectively; P <0.0001).
- Biatain Ag was easier to use than local best practice (P <0.0001).

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Wound Infection

An Old Problem with New Solutions: PHMB in Practice

A summary of a power breakfast held at the 18th annual conference of the Canadian Association of Wound Care – November 10, 2012

Surgical site infections are the cause of 20% of all healthcare-associated infections, and at least 5% of patients undergoing a surgical procedure develop a surgical site infection. However, patients with chronic wounds are also at high risk for wound infection; since the wound is open for so long, the opportunity for infection is greater.[1]

The "TIME" matrix (assessment of tissue, infection or inflammation, moisture imbalance, epidermal margin) is critical with respect to clinical observations, wound bed preparation clinical actions and overall clinical outcomes.[1]

Singh and colleagues noted that in many chronic infections, bacteria live in biofilms.[2] The transition from a free-living, independent existence to a biofilm lifestyle can be devastating, as biofilms are notoriously resistant to the host defence mechanisms and antibiotics.[2] Electron micrographs reveal biofilms on 60% of chronic wounds and <10% of acute wounds.[3]

Lazarus and colleagues reported that some presently utilized antibacterial regimens may actually promote the presence of ecological profiles that inhibit wound healing, since they target inappropriate bacteria populations or fail to deliver adequate concentrations of drug to the wound bacteria. They further noted that other interventions have been developed to target key processes in this complex biological system and include regimens that deal with populations of organisms and the destruction of biofilms.[4]

Wound characteristics that may increase the risk of infection are noted in Table 1.

As clinicians' understanding of the intricate balance between wound healing and the bio-community of organisms living within the wound expands, new challenges arise regarding the provision of effective strategies to manage wound bioburden without inducing pathogen resistance and negatively influencing the healing process. The increase in antibiotic-resistant organisms has led to renewed interest in the use of antiseptics such as biguanides for managing wound pain and infection; polyhexamethylene biguanide (PHMB) is one particular example.[5]

In 2001, Reitsma and colleagues evaluated the effectiveness of gauze treated with PHMB to prevent external contamination from reaching the skin of normal volunteers. The results clearly demonstrated that 0.2% PHMB prevented the migration of 106 organisms through the gauze and kept underlying skin free from bacteria.[6]

PHMB binds to the bacterial phospholipid outer membrane; it then disrupts the membrane, causing cytoplasm to leak out. This in turn causes the cell's protective layer to disintegrate; the cell then collapses and dies.

In a tertiary wound healing centre, 12 patients with chronic wounds (10 with venous leg ulcers, 2 with vasculitic ulcers) with a history of recurrent systemic and local infection were given PHMB-embedded antimicrobial foam dressings. The patients were followed weekly until the wound healed or the patient no longer required an antimicrobial foam dressing. At each visit, the patients' wounds were assessed, a pain assessment was conducted, and pain experienced during dressing change was measured. As well, reduction in wound area was determined using a tracing grid, and the condition of the wound bed and peri-ulcer skin were also recorded.

The results showed that: in 7 patients, wounds decreased in size; wounds healed for 3 patients, while wounds remained static for 2 patients. Wound pain increased in 1 patient and maceration was experienced by 3 patients. "That is a much higher success rate than many other antimicrobial agents," noted Dr. Harding. "Although this was not a randomized controlled trial, the healing rates give clinicians hope."

A randomized controlled trial was conducted to compare the effectiveness of Kendall AMD antimicrobial foam dressing with Allevyn Ag hydrocellular antimicrobial dressing in the reduction in size, change in bioburden and wound biochemistry of hard-to-heal chronic venous leg ulcers.

All 32 of the patients studied had venous ulcers for >6 months, which had failed to respond to standard therapy. The mean age of study subjects was 67.7 years; the AMD group mean wound area was 7.8 cm^2; the comparator group mean wound area was 10 cm^2.

Although the results of this study have not yet been published, Dr. Harding noted the following results:

- The dressing was well-tolerated in >87.5% of patients.
- 15 patients scored >70% satisfaction with the AMD dressing.
- The dressing was easy to apply and remove.

Table 1

Wound characteristics that may increase the risk of infection

Acute wounds	Chronic wounds
Contaminated surgery	Necrotic tissue or foreign body
Long operative procedure	Prolonged duration
Trauma with delayed treatment	Large in size and/or deep
Necrotic tissue or foreign body	Anatomically situated near a site of potential contamination

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Efficacy and Cost of Wound Debridement

A summary of a Lunch-and-Learn session held at the 18th annual conference of the Canadian Association of Wound Care – November 11, 2012

Wound debridement – overview

Dr. Despatis began by noting that the stages of molecular and cellular events in skin wound healing are: clotting; vascular response; inflammation; scar formation; epithelial healing; contraction; and scar remodeling.[1] Wounds that remain in the inflammatory phase are often not able to clear necrotic tissue and debris, and require debridement.

Debridement methods include: autolytic; enzymatic; biological; mechanical; and surgical. Regardless of which method is chosen, healing potential and outcome goals must be determined before commencing debridement.[2]

Autolytic debridement uses the patient's own enzymes to break down necrotic tissue in the wound. As illustrated in Table 1,[3] many patients do not have the ability to facilitate debridement, because the leucocytes needed may not be able to migrate to the wound bed, they may be few in number, they may not be functional and/or they may not be able to produce the enzymes needed to break down necrotic tissue.

Enzymatic debridement uses enzymes to facilitate the removal of dead tissue from a wound. The topical application of enzymes to break down devitalized tissue uses proteolytic enzymes (e.g. collagenase). As the collagenase enzyme liquefies the collagen fibers within necrotic tissue, the cellular and fibrotic debris loosen their connections from each other and the wound bed, so they more easily wash away during routine cleansing at each dressing change.

Biological debridement involves of the use of fly larvae from the species *Lucilia sericata*, which feed on dead tissue. This method is little used in Canada – in large part due to patient reluctance – however, it remains a viable therapy.

Mechanical debridement involves hydrosurgery, whereby pressurized water is delivered using a hand piece to control the pressure. This is a very rapid method of debridement; however, clinicians must be aware that blood loss is involved.

Surgical debridement involves the removal of necrotic or septic tissue by a skilled practitioner. This method is quite painful for patients, an issue that must be addressed before the procedure commences.

Treating the diabetic foot: How can we shape our outcomes?

Dr. Mayer noted that debridement is essential in the treatment of hard-to-heal wounds, especially diabetic foot ulcers.

Diabetes presents a significant risk for lower-limb complications. These include neuropathy, ulceration, peripheral arterial disease, infection and amputation. Moulik and colleagues noted that diabetic foot disease is associated with a 5-year mortality rate of 50 to 80%.[4] This mortality rate is higher than almost all cancers, except lung and pancreatic cancer. Diabetic foot ulcers are the most common complication of diabetes, and Dr. Mayer noted the following statistics:[5]

- The infected diabetic foot is the most common reason for admission to hospital for a person with diabetes.
- 1 in 5 ulcers leads to lower extremity amputation.
- After a major amputation, 50% of people will have the contralateral limb amputated within 2 years.
- 20 to 40% of total diabetes healthcare costs are related to the diabetic foot.

When diabetic foot ulcers develop, the mainstays of treatment are offloading and debridement. Many patients with diabetes are unable to clear necrotic tissue that builds up during the inflammatory phase due to poor circulation and a dampened immune response. Without the availability and proper function of cells that produce the enzymes, these patients require clinical intervention. Where appropriate, surgical debridement is the fastest way to remove large amounts of necrotic tissue. This procedure can be followed with an enzymatic agent such as collagenase to provide continuous debridement. In patients who are unable to undergo surgical debridement (lack of a skilled clinician, bleeding issues, pain), an enzymatic agent provides the necessary enzymes to rapidly clear the wound bed of necrotic tissue.

Frequent debridement is crucial. Clinicians should act immediately to optimize wound milieu, determine viable vs. non-viable tissue and choose the appropriate method of debridement that best supports wound healing.[6] With respect to the cost of various debridement methods, Canadian data are shown in Table 2. Dr. Mayer noted that innovative debridement techniques such as the use of collagenase produce excellent results at significant cost savings, compared with autolysis.[7]

Table 1

Health conditions that affect the activity of leukocytes responsible for debridement[3]

Condition	Number	Migration	Metabolism
Advanced age	√	√	√
Diabetes		√	√
Arterial insufficiency		√	
Venous insufficiency		√	
Kidney insufficiency			√
Hepatic insufficiency			√
Corticosteroids	√	√	√
Chemotherapy	√		√
Cancer	√		
Obesity		√	
HIV	√		
Malnutrition			√
Smoking		√	√
Paralysis		√	
Transfusion			√

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Table 2

Cost of debridement

Method	Time to clean wound bed (weeks)	Cost ($, CAD)
Surgical sharp	3	1,039.09
Biological	3	2,150.89
Enzymatic	4	1,264.69
Conservative sharp	6	1,119.60
Mechanical	6	1,840.74
Autolytic	10	1,504.73

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The Essential Role of Nutrition in Pressure Ulcer Management

A summary of a satellite symposium held at the 18th annual conference of the Canadian Association of Wound Care – November 8, 2012

Introduction

Pressure ulcers (PUs) have a significant impact on quality of life. Pain and depression are common, and are associated with increased mortality in the elderly in long-term care.[1,2] The financial burden of PUs is substantial. Canadian data show that complex care for 3 months, per ulcer, costs $24,050; for community care, the cost is $27,500 per ulcer.[3] The prevalence of PUs in Canada is shown in Figure 1.[4]

Barriers to healing

Once a PU develops, modifiable risk factors become barriers to healing. Thus, it is imperative that clinicians ask the following questions:

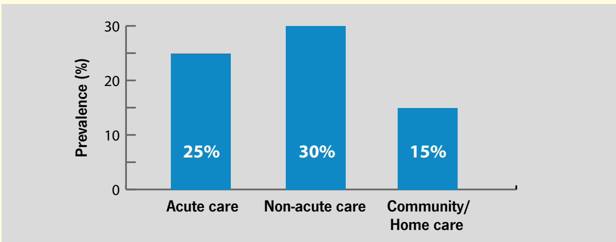
- Are the patient's nutritional and hydration status being addressed?
- Will the specialized dressings and other treatments be effective if the patient is not optimally nourished and hydrated?

Assessments

Current guidelines regarding PUs and nutritional considerations note that, "All individuals must have a comprehensive nutritional assessment upon admission to a healthcare facility, with each condition change, and/or when progress toward PU closure is not observed."[5] This requires an interprofessional approach, and the following steps should be taken:

- Initiate a referral to a registered dietitian.
- Obtain a current body weight.
- Initiate an order for pertinent blood work.
- Initiate intake records.
- Initiate queries regarding appetite, food allergies and intolerances, dentition, swallowing, preferences, cultural dietary requirements and the need for physical assistance to eat or drink.
- Establish an appropriate bowel care program.

Figure 1
Prevalence of pressure ulcers in Canada



Healthcare practitioners must consider not only adequacy of nutritional intake but also common routes of nutritional loss, including gastrointestinal and urinary tract loss and wound exudate and fistulae loss. A comprehensive assessment to help identify all underlying, resolvable barriers to wound healing includes investigation of blood work indices. Tests should investigate for anemia, hyperglycemia, dehydration, hypothyroidism and indicators of risk for malnutrition related to the severity of illness or injury.

Nutrients in wound healing

Key nutrients in wound healing include: energy from non-protein sources; protein; water; and vitamins and minerals. Nutrients are involved in all four phases of wound healing, and play a role in the cellular, structural and immune functions. Some guidelines recommend that patients with nutritional risk and PU risk factors should be offered a minimum of 30–35 kcal/kg body weight/day with 1.25–1.5 g/kg/day protein.[5] Whey protein supplements may prove helpful in this regard, and should be incorporated into a PU management plan. Precautions and contraindications to protein supplementation include impaired renal and hepatic function. Optimal hydration is crucial in patients with PUs, as dehydration can lead to skin breakdown, loss of appetite, physical and cognitive impairments, infection, bowel impairment, renal failure and death. The general recommendation regarding hydration is a minimum of 1 mL/kcal consumed; this should be increased based on fluid losses, and signs and symptoms of dehydration. Precautions and contraindications regarding hydration include: impaired renal function; congestive heart failure; and syndrome of inappropriate antidiuretic hormone secretion. Precautions and contraindications regarding hydration must be considered.

Supplementation should be based upon assessed adequacy of intake from all sources, consideration of losses, knowledge of the metabolism of nutrients with physiological stress, and when deficiencies are confirmed or suspected. Zinc, vitamin C and vitamin A play crucial roles at all levels of PU healing. Clinical judgment – based on comprehensive assessment – is needed in the absence of tests that definitively identify deficiencies. To meet the nutritional needs of an individual with a PU, a nutrition care plan may include one or more of the following: meals plus snacks; liquid and/or powder supplements; med pass program; vitamin and mineral supplementation; enteral nutrition support; and total parenteral nutrition (if gastrointestinal dysfunction or disease precludes adequate oral intake or tube feeding).

Conclusions

PUs have a significant healthcare and financial impact and can be prevented. Clinicians should be aware of their patients' extrinsic and intrinsic risk factors for PUs, and work to modify them. Once a PU ulcer develops risk factors such as malnutrition become barriers to healing; these barriers must be addressed. Adequate energy, protein, fluid and micronutrient intake are essential.

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