

# A Reprint from Surgical Technology International Volume 35

## IMPROVING THE QUALITY OF CHRONIC WOUND CARE USING AN ADVANCED WOUND MANAGEMENT PROGRAM AND GENTIAN VIOLET/METHYLENE BLUE-IMPREGNATED ANTIBACTERIAL (GV/MB) DRESSINGS: A RETROSPECTIVE STUDY

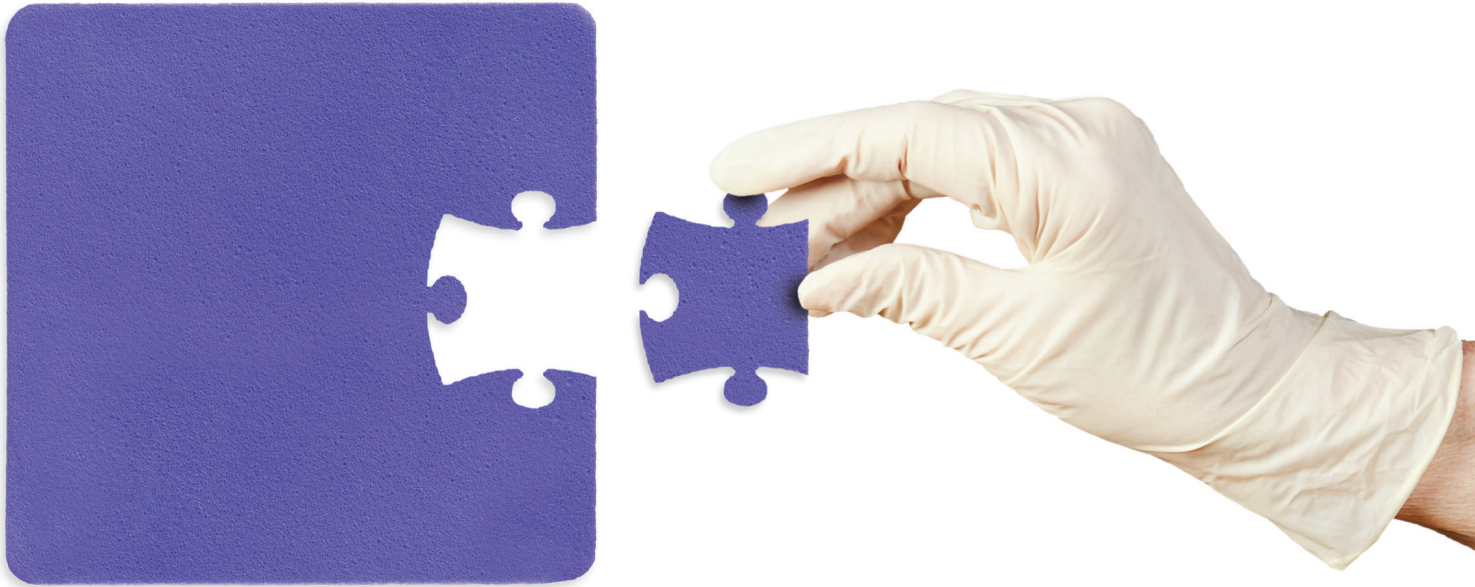


THERESA HURD, PhD, MScN, MSN, ACNP, RN  
PRESIDENT AND CEO  
NURSING PRACTICE SOLUTIONS INC.  
NIAGARA FALLS, CANADA



Restore the body's natural balance with *blue.*

# We've solved the puzzle.



Skilled Clinical Professionals and *blue*.  
Faster healing. Less cost.

The answer is “*teamwork*.”

When partnering with Skilled Clinician care, Hydrofera Blue helps wounds heal faster at less cost.

In a recent retrospective study examining wound treatment data of more than 30,000 patients over a two-year period, Hydrofera Blue Dressings, combined with Comprehensive Skilled Clinical care, showed faster healing times and lower treatment costs.<sup>1</sup>

When compared with other commonly used dressings on patients who were not on a Comprehensive Skilled Nursing program, Hydrofera Blue delivered over a 50% reduction in healing time and a 75% reduction in Nursing Labor cost.<sup>1</sup>

It's a perfect fit: combine Hydrofera Blue with Skilled Clinical care and we can solve the puzzle of accelerating wound healing.

Change to blue. Learn more at [hydrofera.com](http://hydrofera.com).



1. Hurd, T. Improving the Quality of Chronic Wound Care Using an Advanced Wound Management Program and Gentian Violet/Methylene Blue-Impregnated Antibacterial [GV/MV] Dressings: A Retrospective Study. Surg Technol Intl 2019. <http://www.surgcaltechnology.com/35-Wound-Healing.htm>

Hydrofera Blue is a registered trademark of Hydrofera, LLC.  
14-001-042, Rev. 01

# Improving the Quality of Chronic Wound Care Using an Advanced Wound Management Program and Gentian Violet/Methylene Blue-Impregnated Antibacterial (GV/MB) Dressings: A Retrospective Study

THERESA HURD, PhD, MScN, MSN, ACNP, RN  
PRESIDENT AND CEO  
NURSING PRACTICE SOLUTIONS INC.  
NIAGARA FALLS, CANADA

## ABSTRACT

**Introduction:** Comprehensive wound management programs that employ a standardized integrated care bundle (ICB) and advanced wound dressings are generally recognized to decrease healing times and treatment costs. The purpose of this study was to compare wound healing rates and cost efficiencies as measured by nursing-care requirements for patients not on an ICB versus patients on an ICB and using a gentian violet/methylene blue-impregnated (GV/MB) antimicrobial advanced wound dressing.

**Materials and Methods:** The comprehensive wound management programs enabled continuous, standardized measurement of each patient's wound episode from admission with a wound to healing and discharge. Data was recorded over 24 months from 2016 to 2018. The variables recorded for each patient included: wound healing time (number of weeks), wound acuity based on the Bates-Jensen Wound Assessment Tool (BWAT), a comorbidity index (using the Charlson Comorbidity Index), and the number of wound dressing changes. The wound dressing changes required a visit by a registered nurse and, therefore, served as an indicator of care delivery costs where the dressing change visit cost was \$68 (CAD).

**Results:** A total of 6300 patients (25% of the total study population) were identified as using GV/MB dressings within the context of an ICB. The mean healing time for these patients was accelerated more than 50% versus patients not on an ICB. The average total cost of patient care was reduced by more than 75% from diagnosis to wound healing when patients were on an ICB with GV/MB dressings. These results compared well to



patients on ICBs that had other types of advanced dressings.

**Conclusion:** The study demonstrates that a comprehensive wound management program based on integrated care bundles in conjunction with GV/MB dressings can be a highly-effective clinical option. The benefits showed significant reductions in healing times and treatment costs.

## INTRODUCTION

### The need for evidence-based, best-practice wound management

Chronic wounds continue to place ever-increasing burdens on today's healthcare systems, impacting patients, clinicians, care providers, and the healthcare organizations who manage patient care. These wounds are associated with age and comorbidities, such as diabetes, obesity, and vascular diseases that can inhibit wound healing and are more common in older age groups. As populations in most industrialized nations age, the risk and prevalence of chronic conditions are increasing. For example, the prevalence of diabetes ranges between 8.5% and 9.5% in the United States and Canada.<sup>1</sup>

Chronic wounds cause pain, discomfort, and mobility restrictions for patients. They can lead to prolonged hospital stays and adverse clinical outcomes such as amputation, infection, sepsis, disfigurement, and even death.<sup>2-6</sup> There are serious patient safety risks associated with chronic wounds, and frequent hospital admissions and re-admissions that can add significant costs to already strained healthcare systems.<sup>4,7-14</sup> In the United States, where

chronic wounds affect an estimated 8.2 million Medicare patients alone, the total annual cost of wound care has been conservatively estimated at \$28–32 billion (USD) per year.<sup>15</sup> Chronic wound care in the United Kingdom is estimated to cost £2–3 billion annually or about 3% of the total National Health Service budget.<sup>16</sup>

Wound care can be viewed as a routine component of basic nursing practice, yet several recent studies suggest that estimates of wound prevalence and their impact on healthcare systems have been significantly underestimated.<sup>17-20</sup> The true costs of chronic wounds to patients and providers are therefore often underappreciated, despite many wound-care clinicians advocating for improved practices, new strategies, and changes in the role and recognition of wound care in healthcare policy. As long as wound healing is delayed, healthcare costs and hospital stays will continue to rise.<sup>21-24</sup>

### The role of wound management programs or integrated care bundles

In the above context, evidence-based, best-practice wound management programs are becoming increasingly recognized as important for healthcare

organizations. Many of these programs are based upon clinical-care pathways or "integrated care bundles" (ICBs) that specify a series of coordinated, evidence-based, best-practice treatments for common types of wounds throughout the continuum of care. An ICB is a model of care that packages clinical interventions, assessments, referrals, outcomes, products, and client education into comprehensive, full-service "bundles" designed to ensure a seamless care experience across the continuum of treatment. ICBs are based on established, evidence-based best practices and are developed in consultation with clinical staff and field-tested for ease of use. They conform to applicable regulations, accrediting standards, and fiscal reimbursement standards or codes, and they coordinate directly with training and education programs and resources.

One critical objective of ICBs is the prevention of wound infections that can inhibit wound healing, lead to hospital admissions or re-admissions, and, in some cases, lead to the prescription of antibiotic drug treatments which can contribute to antibiotic drug resistance. ICBs are currently being implemented across several large urban regions in Canada to address wound-care challenges. These programs serve patients with a full range of chronic wounds and are being adopted in diverse home- and community-care settings at a large scale.<sup>25</sup> Treatment includes diagnosis to wound healing for common wounds, including diabetic foot ulcers, venous leg ulcers, pressure ulcers, surgical wounds, and burns.

### The impact of infections in the management of chronic wounds

Chronic wounds are defined as wounds that do not heal in an orderly and predictable manner within six weeks.<sup>26,27</sup> Natural healing requires the host to mount a cellular response with proper migration of cells, thereby eliminating invading organisms or foreign



**Figure 1a.** Baseline presentation of an infected toe amputation site.



**Figure 1b.** Site after two weeks of treatment with a GV/MB dressing. Note the removal of slough and devitalized tissue by the dressing.

matter that enters the wound. When the host cannot manage a response, localized or a deep infection can ensue, leading to further chronicity or systemic infection. The persistence of bacteria leads to an intensification of wound chronicity through an increase in proteolytic enzymes and inflammatory mediators that are produced by the influx of phagocytes.<sup>3</sup> Wound infections may delay the natural healing process or the surgical closure of wounds,<sup>23,24,28</sup> causing increased pain or discomfort for patients.<sup>21</sup> Infections also increase the risk of tissue damage, limb loss,<sup>22-23</sup> and even death. Treating a wound's infection is thus an essential part of preventing delayed healing.<sup>23,24,28</sup>

Systemic antibiotics are one option to treat wound infections; however, the excessive and inappropriate use of antibiotics has become a major factor in the development of drug resistance,<sup>7,29</sup> and antibiotic stewardship is now a priority in most healthcare organizations. Research supports that the use of systemic antimicrobials does not effectively reduce bacterial counts in the chronic granulating wound.<sup>30</sup> Furthermore, the increasing prevalence of chronic diseases and the complexity of treating patients with multiple comorbidities are leading risk factors for drug-resistant pathogens which have become a patient safety risk and public threat.<sup>31</sup> Antimicrobial stewardship optimizes antimicrobial use to achieve the best clinical outcomes while minimizing adverse events and limiting selective pressures that drive the emergence of resistance and may also reduce excessive costs attributable to suboptimal antimicrobial use.<sup>32</sup>

### The role of advanced antimicrobial dressings in the management of chronic wounds

Non-systemic strategies to prevent wound infection have included proper cleansing and removal of necrotic tissue, and, in some cases, topical antimicrobials. Advanced antimicrobial dressings provide another option to manage wounds and protect them from bacterial contamination.<sup>22,33</sup> In certain circumstances, antimicrobial dressings can even lead to reduced use of systemic antibiotics.<sup>21-24</sup> There are many advanced antimicrobial dressings available, but three classes of dressings are generally found in Canada: (1) silver-impregnated, (2) iodine-impregnated,

and (3) gentian violet/methylene blue-impregnated. Hydrofera Blue<sup>®</sup> (Hydrofera, LLC, Manchester, Connecticut) represents the third category of antimicrobial dressings and has been demonstrated as effective against microorganisms commonly found in wounds, including methicillin-resistant *Staphylococcus aureus* (MRSA) and vancomycin-resistant *Enterococcus* (VRE).<sup>34-36</sup> The polyvinyl alcohol version of the product has a unique wicking action that draws exudate away from the wound surface. In one example, an infected amputation site demonstrated measurable healing after two weeks of treatment, where slough and devitalized tissue were removed by adherence to the dressing (Figs. 1a and b). At the same time, the dressing was well tolerated by the patient, and reduced pain scores were recorded.<sup>35</sup> In addition, this GV/MB dressing demonstrates autolytic debridement activity and exhibits no inhibition of either enzymatic debriders or growth factor activity.<sup>37,38</sup>

### Integrated care bundles in combination with GV/MB advanced dressings

GV/MB dressings are being incorporated into ICBs as one of a portfolio of advanced tools and practices available to clinicians as they implement comprehensive wound management programs. This retrospective study reviews results from these programs, focusing specifically on chronic wound patients using GV/MB dressings. The purpose of this study is to compare wound healing rates and cost efficiencies as measured by nursing-care requirements (nursing visits) for patients on an ICB and using the Hydrofera GV/MB antimicrobial dressings versus patients not on an ICB.

## MATERIALS AND METHODS

### Wound-care programs and ICBs

The study employed comprehensive wound-care programs implemented across two home- and community-care organizations operating in the Ontario region of Canada, where roughly 33,000 wound-care patients were tracked as part of the first round of data collection and analysis. These programs consist of a coordinated series of evidence-based interventions to support improved quality of care and clinical

outcomes for patients with chronic wounds. Key components of the programs are:

- ◆ A series of ICBs, each defining evidence-based, best-practice standards and protocols for a specific type of chronic wound, serving as the clinical foundation.
- ◆ Clinical-care teams, staffed by the home and community-care organizations, overseeing care delivery and ensuring that practices are consistent with the ICBs.
- ◆ A range of care providers in the community maintain their current delivery roles, while operating within the new framework of standardized practices and clinical oversight.
- ◆ Clinical-care teams provide guidance and support for this effort, backed by user-friendly information technologies that provide measurement of pre-set clinical indicators.
- ◆ The entire program is supported by an evolving portfolio of clinical education and training resources, including professional development opportunities for clinicians as well as learning tools for clinical coordinators and nurses practicing in the community.
- ◆ A central measurement and reporting system incorporates specific indicators and extracts these specific indicators from all client records, thereby facilitating standardized measurement and monitoring across the patient population.

These program components are designed to support improved outcomes by accelerating the adoption of clinical best practices, reducing time spent on documentation and administration, centralizing and standardizing reporting and monitoring, and enabling smooth transitions for patients across care settings and among care providers.

### Study design and methodology

This study follows a non-experimental retrospective design. The methodology includes retrospective chart reviews of secondary data and electronic health records (EHRs). All clinical interventions that were the subject of this study incorporate established, evidence-based, clinical best practices that are designed to provide the highest possible standards of quality and patient safety. Approval was received from the IRB of

**Table I**  
**Baseline patient characteristics**

	ICB and GV/MB Dressing	Not on ICB	
Patient Data	Average (Std. Dev.)	Average (Std. Dev.)	P-value
<b>Total Study Population</b>	<b>N = 6300</b>	<b>N = 2242</b>	
Age (years)	57.7 (11.4)	56.7 (17.9)	< .001
Comorbidity index	2.63 (2.4)	2.40 (0.3)	< .001
BWAT score	30.58 (12.6)	33.20 (9.2)	< .001
<b>Diabetic Foot Ulcer Subgroup</b>	<b>N = 166</b>	<b>N = 179</b>	
Age (years)	57.2 (10.8)	59.4 (16.2)	0.003
Comorbidity index	2.90 (2.4)	3.80 (3.5)	< .001
BWAT score	30.58 (12.6)	32.40 (9.7)	0.02
<b>Venous Leg Ulcer Subgroup</b>	<b>N = 2067</b>	<b>N = 708</b>	
Age (years)	60.6 (11.3)	60.4 (11.5)	< .001
Comorbidity index	2.9 (2.4)	2.5 (2.3)	< .001
BWAT score	32.3 (9.8)	36.9 (8.3)	< .001
<b>Pressure Injury Subgroup</b>	<b>N = 1350</b>	<b>N = 309</b>	
Age (years)	61.4 (11.1)	66.9 (11.4)	0.102
Comorbidity index	3.0 (2.4)	3.0 (2.4)	< .001
BWAT score	29.4 (8.4)	34.0 (8.9)	< .001
<b>Surgical Wound Subgroup</b>	<b>N = 2710</b>	<b>N = 1019</b>	
Age (years)	53.6 (15.8)	52.2 (16.7)	< .001
Comorbidity index	2.2 (1.4)	3.0 (0.3)	< .001
BWAT score	24.9 (7.8)	35.2 (9.1)	< .001
<b>Burns Subgroup</b>	<b>N = 7</b>	<b>N = 27</b>	
Age (years)	65.5 (13.9)	54.9 (12.1)	0.004
Comorbidity index	3.0 (2.4)	2.5 (0.3)	0.460
BWAT score	31.2 (9.9)	40.2 (1.7)	< .001

Abbreviations: Standard deviation (Std. Dev.), Number data points per total study or subgroup (N)

D'Youville College, Buffalo, New York prior to conducting the study.

Patients were not contacted during the study, and retrospective chart reviews did not impact the treatment of patients. The software that web-hooks into the EHR and extracts data did not contain any patient identifiers. The electronic report that was uploaded into the patient record is the standard current report that can extract a number but does not contain any patient identifiers. All data collection and processing procedures were designed to protect patient confidentiality.

The study population included all patients aged 18 years and over, with an admission of a wound, who were receiving care for the wound until it was healed or closed (e.g., pressure ulcer, diabetic foot ulcer, venous leg ulcer, surgical ulcer—open incision). Excluded from the study were patients that are under 18 years of age, have an active infection, are taking immunosuppressant drugs, have positive HIV sta-

tus, have scheduled chemotherapy, or are palliative and/or refuse treatment.

Program implementation began in December 2015. After one quarter, to allow for implementation, data collection started in March 2016 and ended in March 2018. It is important to note that clinicians operating within the comprehensive wound management programs were free to select from among the different advanced antimicrobial wound dressings, including GV/MB, iodine, silver, and other advanced dressings.

#### Data collection and measurement post-program implementation

Data were collected and key indicators were recorded and analyzed monthly by Nursing Practice Solutions Inc. of Ontario, Canada, a consulting company that developed, implemented, and measured the data for the program. The programs enabled continuous, standardized measurement—both clinically and financially—of each patient's

wound episode from admission with a wound to healing and discharge. Each patient's wound had an established acuity, and the progression of treatment and healing was tracked systematically. Nurses submitted electronic reports initially on admission, on an interim basis at three-week intervals, when any variances from expected outcomes were observed, and at discharge.

The following variables were tracked and compared for (1) patients using GV/MB dressings as part of an ICB and (2) patients not on an ICB but using a variety of advanced and absorbent layered dressings:

- ◆ *Demographic variables:* These include age, gender, and comorbidities, such as smoking, diabetes mellitus, cardiac conditions, renal conditions, and pain. The Charlson Comorbidity Index was used to apply a systematic and comparable measure of comorbidities.<sup>17,39</sup>
- ◆ *Wound healing time:* The Bates-Jensen

**Table II**  
**Post-care outcomes**

	ICB and GV/MB Dressing	Not on ICB	
Patient Data	Average (Std. Dev.)	Average (Std. Dev.)	P-value
<b>Total Study Population</b>	<b>N = 6300</b>	<b>N = 2242</b>	
Healing time (weeks)	11.57 (10.2)	25.49 (18.6)	< .001
Days between dressing changes	3.40 (1.8)	1.87 (1.3)	< .001
Labor cost to healing (C\$)	1587 (1402)	6488 (4945)	< .001
<b>Diabetic Foot Ulcer Subgroup</b>	<b>N = 166</b>	<b>N = 179</b>	
Healing time (weeks)	18.90 (15.5)	28.08 (15.8)	< .001
Days between dressing changes	3.40 (1.5)	2.00 (1.0)	< .001
Labor cost to healing (C\$)	2649 (2030)	6552 (5907)	< .001
<b>Venous Leg Ulcer Subgroup</b>	<b>N = 2067</b>	<b>N = 708</b>	
Healing time (weeks)	14.3 (6.6)	34.18 (19.6)	< .001
Days between dressing changes	3.5 (1.5)	2.1 (1.4)	< .001
Labor cost to healing (C\$)	1941 (1094)	7860 (4997)	< .001
<b>Pressure Injury Subgroup</b>	<b>N = 1350</b>	<b>N = 309</b>	
Healing time (weeks)	9.7 (8.3)	31.6 (19.6)	< .001
Days between dressing changes	3.4 (1.3)	2.1 (1.1)	0.019
Labor cost to healing (C\$)	1339 (1029)	7035 (5706)	< .001
<b>Surgical Wound Subgroup</b>	<b>N = 2710</b>	<b>N = 1019</b>	
Healing time (weeks)	10.0 (12.1)	17.5 (14.8)	< .001
Days between dressing changes	3.5 (1.5)	1.6 (1.0)	< .001
Labor cost to healing (C\$)	1380 (1298)	5165 (2885)	< .001
<b>Burns Subgroup</b>	<b>N = 7</b>	<b>N = 27</b>	
Healing time (weeks)	6.1 (4.2)	12.6 (7.9)	0.004
Days between dressing changes	3.5 (3.3)	3.0 (1.0)	0.023
Labor cost to healing (C\$)	1137 (987)	3171 (991)	< .001

Abbreviations: Standard deviation (Std. Dev.), Number data points per total study or subgroup (N), Canadian dollar (C\$)

Wound Assessment Tool (BWAT), wound status continuum score, was selected to measure the wound healing rate. The BWAT is a tool used to assess and monitor the healing of all types of wounds.<sup>40</sup> Thirteen assessment parameters are measured on a scale of 1 to 5. Two additional parameters are measured by a simple check system. The wound location is assessed, recorded, and marked on a body diagram. The shape of the wound is described by its overall pattern, such as round or oval and linear or elongated. Once the numbers are recorded and the scale is complete, a total is calculated using all thirteen parameters and then placed on a linear chart. The total ranges from 1 (Tissue Health) to 13 (Wound Regeneration) to 65 (Wound Degeneration). The higher the total score, the more severe the wound status. Data is collected on admission and subsequently every three weeks to healing (when the wounds closed) unless

there is a variance from the expected healing continuum. Results (post-test) are compared to previous assessments (pre-test). A record of the total number of weeks the wound was present is generated as part of this process.

◆ *Number of dressing changes:* Each dressing change in a home/community setting requires a visit by a licensed and registered nurse. The time and date of each nursing visit/dressing change was recorded for each patient, enabling estimates of the average number of days between dressing changes. The total number of visits per episode of healing was also recorded. These visits are provided by independent private or not-for-profit nursing agencies that are contracted and paid by the community-care organizations on a per-visit basis, nominally \$68 (CAD) per dressing change. The number of nursing visits, therefore, provides a useful indicator of the cost to provide

wound care. ICBs are designed to reduce nursing visits by (a) reducing wound healing time and (b) reducing or eliminating the use of dry gauze dressings (typically changed daily) with advanced dressings (changed at longer intervals, typically up to one week). Financial data on both labor and supplies can be extrapolated from the number of visits.

#### Treatment of data

Data was extracted from the EHR and then analyzed using SPSS version 22 (IBM Corporation, Chicago, Illinois). All variables were described using descriptive statistics. Histograms were used to assess normality for continuous variables. Depending on the variable type, an independent t-test, a Mann-Whitney test, and/or a Chi-square test was used to compare on-bundle patients to off-bundle patients for all variables. Comparisons between patients on a wound bundle with GV/MB dressings versus patients not on a wound bundle



HURD

were also scaled against pre-intervention measures along with direct labor costing for wound healing. A type I error rate of 0.05 was used for all statistical testing.

### Multiple regression for healing time

Multiple linear regression analysis was performed using a backward approach. All variables were entered to predict healing time. A surgical patient was considered the baseline for comparison for wound type.

## RESULTS

A total of 6300 patients from the study population were identified as using GV/MB dressings within the context of an ICB. These patients were compared to 2242 patients who were not on an ICB. In addition, subgroups based on wound type were extracted from the overall study population for additional comparison. Any patients with blank fields that could not be retrieved through the health records were discarded from the study (n=83). Following three iterative models, modelling only bundle yes/no, BWAT, reoccurring wound, and wound type were significant (all  $p < 0.001$ ). The unstandardized beta co-efficients were on a wound bundle (-13.42), BWAT score (.435), burn (-2.199), DFU (4.424), VLU (3.706), and PU (1.434). In all cases, patients not on an ICB had a mixture of dressings types that included iodine-based dressings to a mixture of advanced and absorbent layered dressings. Data on wound healing rates prior to implementation of the comprehensive programs is presented as a baseline reference where available.

### Baseline demographics

Baseline demographic data is shown in Table I for the overall study population and subgroups and include age, Charlson Comorbidity Index, and BWAT score (wound acuity). In the total and subgroup populations, statistical differences were often observed between the two groups. These differences are attributed to the study design.

For the total study population, age (57.7 vs. 56.7) and comorbidity (2.63 vs. 2.40) were slightly higher for patients on a bundle versus not on a

bundle. On the other hand, the more subjective BWAT scores were slightly lower for patients on a bundle (30.58 vs. 33.20). The differences between groups are small from a clinical importance or significance perspective. The magnitude of the post-care outcomes would not reasonably be influenced by differences in baseline patient characteristics.

## POST-CARE OUTCOMES

Table II provides data comparing post-care outcomes for patients on an ICB using GV/MB dressings versus patients not on an ICB.

The mean healing time of 11.57 weeks (standard deviation 10.2) ( $p < 0.001$ ) for patients on an ICB using GV/MB dressings was more than 50% lower than the mean healing time of 25.49 weeks (standard deviation 18.6) ( $p < 0.001$ ) for patients not on an ICB. This result for patients using GV/MB dressings was also more than 70% lower than the preintervention baseline healing time of 43.5 weeks ( $p < 0.001$ ).

Patients on an ICB using GV/MB dressings also required significantly fewer nursing visits. The mean number of days between dressing changes was extended by more than 80% from 1.87 days for patients not on an ICB to 3.40 days for those patients on an ICB using GV/MB dressings.

The combination of faster healing times and less frequent nursing visits for patients using GV/MB dressings resulted in significant reductions in the utilization of healthcare services and the overall cost of care. The average total cost for the entire episode of care for patients using GV/MB dressings was \$1587 (CAD) per patient, representing a reduction of more than 75% when compared to the average cost of \$6488 (CAD) for patients not on an ICB. The average pre-implementation baseline cost per patient was \$12,462 (CAD).

The post-care outcomes for patients on an ICB using GV/MB dressings were comparable to those for patients on an ICB using a range of other advanced dressings. ICB patients using other advanced dressings had a mean healing time of  $12.5 \pm 9.1$  weeks (vs. 11.57 weeks for the GV/MB group), a mean number of days between dressing changes of  $3.4 \pm 1.5$  (vs. 3.40 for the

GV/MB group), and an average cost per patient of \$2088 (CAD) (vs. \$1587 [CAD] for the GV/MB group). Although not the focus of this study, the GV/MB dressings showed better outcomes than the other advanced dressings on an ICB.

## DISCUSSION

The results demonstrate that a comprehensive wound-care program based on ICBs and GV/MB dressings can have a significant impact on wound healing in terms of reduced time to heal, reduced wound acuity during the healing process, and improved predictability and consistency of healing pathways. Improved wound healing leads directly to improved patient care through reduced complications, reduced risk of infection, improved health outcomes, and improved quality of life.

This study also demonstrates the effectiveness of ICBs in wound management across a wide range of clinical priorities in diverse healthcare settings. The results confirm that GV/MB dressings can be readily and successfully integrated into a comprehensive program based on ICBs, leading to measurable and statistically significant improvements in wound healing and nursing resource utilization. The significant reduction in standard deviation for the patient group using GV/MB dressings indicates much greater wound healing consistency and predictability. The significantly reduced number of visits required for patients in an ICB using GV/MB dressings may be expected to translate into substantial cost savings for the community-care organization. For example, when extrapolated across the population served by this study, the average cost per patient using GV/MB dressings within an ICB applied across all 6300 patients would be \$9,998,810 (CAD), a savings of more than \$30 million (CAD) annually when compared to a total cost of \$40,874,400 (CAD), based on the average cost per patient not on an ICB.

Opportunities for further research include comparative performance of GV/MB dressings versus other antimicrobial dressings, better understanding of why clinicians select GV/MB dressings over other antimicrobials, and further examinations of the impact of



GV/MB dressings on systemic wound infections.

## LIMITATIONS

As with many studies in wound care, there are some limitations with confounding variables. However, these limitations are mitigated by the size of the study population as well as the sequence of data and wound status continuum on each patient.

## CONCLUSION

This study was a non-experimental, retrospective evaluation of the effectiveness of a comprehensive wound prevention and care program based on integrated care bundles (ICBs) in combination with an advanced gentian violet/methylene blue-impregnated (GV/MB) antimicrobial dressing. This evaluation has provided a rare opportunity to review healthcare improvement initiatives that are multi-faceted, incorporating a broad range of coordinated interventions and implemented at a large scale across diverse home and community settings in a complex urban region. ICBs serve as a framework for identifying, coordinating, and monitoring evidence-based best-practices along the entire continuum of care. The immediate and direct benefits include more rapid, predictable healing times and cost reductions due to reduced nursing visits and hospital admissions/readmissions.

This study demonstrated that GV/MB dressings can be fully integrated into a comprehensive wound management program and serve as a valuable clinical tool in this context. GV/MB dressings were shown to be clinically effective throughout the course of the study, contributing to very rapid, substantial, and predictable reductions in wound healing times. GV/MB dressings were also shown to be an effective tool in enabling a significant reduction in the number of dressing changes required throughout the course of wound treatment, leading directly to major improvements in the efficiency of clinical resource utilization and major reductions in the cost of care.

Although comparisons of the charac-

teristics and relative performance of various advanced dressings was beyond the scope of this study, it is noteworthy that results for patients on an ICB using GV/MB dressings were comparable and healing times slightly better to those of other patient on ICBs using a range of other advanced dressings.

GV/MB dressings should be considered as an option within a comprehensive, evidence-based wound management program to support high-quality and cost-efficient care delivery. The product can also contribute to the global challenge of improving antibiotic stewardship by aiding in the reduction of microbials in the wound bed and, like other antimicrobial dressings, offering the potential to decrease systemic infections and the use of antibiotics. There are significant opportunities for increased adoption of GV/MB dressings in advanced wound prevention and care programs. **STI**

## AUTHORS' DISCLOSURES

There was no direct funding received for this study; however, the article publication was funded by Hydrofera LLC.

## REFERENCES

- Centers for Disease Control and Prevention. National Diabetes Statistics Report, 2017. Washington, DC: Centers for Disease Control and Prevention, US Dept of Health and Human Services, 2017.
- Krasner DL, Rodeheaver GT, Sibbald R, et al. Chronic Wound Care: A Clinical Source Book for Healthcare Professionals. 5th ed. Malvern, PA: HMP Communications; 2012.
- Baranoski S, Ayello EA. Wound Care Essentials: Practice Principles. Philadelphia, PA: Lippincott Williams & Wilkins; 2012.
- Bachoura A, Guitton TG, Smith RM, et al. Infirmity and injury complexity are risk factors for surgical-site infection after operative fracture care. *Clin Orthop Relat Res* 2011;469(9):2621–30.
- Augustin M, Carville K, Clark M, et al. International consensus. Optimising wellbeing in people living with a wound. An expert working group review. London, UK: Wounds International; 2012.
- Price, P. Psychological impact of skin breakdown. In: Flanagan M, ed. *Wound Healing and Skin Integrity*. Oxford, UK: John Wiley and Sons Ltd; 2013:102–13.
- Center for Disease Control and Prevention. Get Smart: Know when antibiotics work. Treatment Guidelines for Respiratory Tract Infections, 2009. Washington, DC: Centers for Disease Control and Prevention, US Dept of Health and Human Services, 2009.
- Bryant R, Nix D, eds. *Acute & Chronic Wounds, Current Management Concepts*. 4th ed. St. Louis, MO: Elsevier Mosby; 2012.
- Leaper DJ, Harding KG, eds. *Wounds: Biology and Management*, Oxford, UK: Oxford Medical Publications; 1998.
- Jones SG, Edwards R, Thomas DW. Inflammation and wound healing: The role of bacteria in the immuno-regulation of wound healing. *Int J Low Extrem Wounds* 2004; 3(4):201–8.
- Doran DM, Hirdes JP, Blais R, et al. Adverse events among Ontario home care clients associated with emergency room visit or hospitalization: a retrospective cohort study. *BMC Health Serv Res* 2013;13:227.
- Flanagan M, ed. *Wound healing and skin integrity: Principles and practice*, Oxford, UK: Wiley-Blackwell; 2013.
- Goodridge D, Trepman E, Sloan J, et al. Quality of life of adults with unhealed and healed diabetic foot ulcers. *Foot Ankle Int* 2006;27(4):274–80.
- O'Mera S, Cullum N, Majid M, et al. Systematic reviews of wound care management: (3) antimicrobial agents for chronic wounds; (4) diabetic foot ulceration. *Health Technol Assess* 2000;4(21):1–237.
- Nussbaum SR, Carter MJ, Fife CE, et al. An economic evaluation of the impact, cost, and Medicare policy implications of chronic nonhealing wounds. *Value Health* 2018; 21(1):27–32.
- Posnett J, Gottrup F, Lundgren H, et al. The resource impact of wounds on health-care providers in Europe. *J Wound Care* 2009; 18(4):154–61.
- Chan B, Cadarette S, Wodchis W, et al. Cost-of-illness studies in chronic ulcers: a systematic review. *J Wound Care* 2017; 26(sup4):S4–4.
- Guest JF, Ayoub N, McIlwraith T, et al. Health economic burden that wounds impose on the National Health Service in the UK. *BMJ Open* 2015;5(12).
- Harrington C, Zagari MJ, Corea J, et al. A cost analysis of diabetic lower-extremity ulcers. *Diabetes Care* 2000;23(9):1333–8.
- Rice JB, Desai U, Cummings AK, et al. Burden of venous leg ulcers in the United States. *J Med Econ* 2014;17(5):347–56.
- Bamberg R, Sullivan P, Conner-Kerr T. Diagnosis of wound infections: Current culturing practices of US wound care professionals. *Wounds* 2002;14(9):314–27.
- Hopf HW, Ueno C, Aslam R, et al. A. Guidelines for the treatment of arterial insufficiency ulcers. *Wound Repair Regen* 2006;14(6):693–710.
- Steed DL, Attinger C, Colaizzi T, et al. Guidelines for the treatment of diabetic ulcers. *Wound Repair Regen* 2006;14(6): 680–92.
- Whitney J, Philips L, Aslam R, et al. Guidelines for the treatment of pressure ulcers. *Wound Repair Regen* 2006;14(6): 663–79.
- Canadian Institute for Health Information. *Compromised Wounds in Canada*, 2015.

**HURD**

- Ottawa, Canada: Health Canada, 2015.
26. Bowler PG, Davies BJ. The microbiology of acute and chronic wounds. *Wounds* 1999;11:72–99.
27. Sibbald RG, Goodman L, Woo KY, et al. Special considerations in wound bed preparation 2011: an update. *Wound Healing South Africa*, 2011;4(2):55–71.
28. Myers BA. *Wound Management: Principles and Practices*. 3rd ed. London, UK: Pearson; 2011.
29. Bishai W, Morris C, Scanland S. Treatment of community acquired pneumonia. *Clinical Reviews*. New York, NY: Jobson; 2004.
30. Robson MC, Edstrom LE, Krizek TJ, et al. The efficacy of systemic antibiotics in the treatment of granulating wounds. *J Surg Res* 1974;16(4):299–306.
31. Chow A, Benninger MS, Brook I, et al. IDSA clinical practice guideline for acute bacterial rhinosinusitis in children and adults. *Clin Infect Dis* 2012;54(8),1041–5.
32. Morens DM, Fauci AS. Emerging infectious diseases in 2012: 20 years after the institute of medicine report. *MBio* 2012;3(6): e00494–12.
33. Smith APS, Fife CE. Advanced therapeutics: the biochemistry and biophysical basis of wound products. In: Sheffield PJ, Smith APS, Fife CE, eds. *Wound Care Practice*. Flagstaff, AZ: Best Publishing Company; 2004.
34. Hydrofera LLC. Data on file.
35. Woo KY, Heil J. A prospective evaluation of methylene blue and gentian violet dressing for management of chronic wounds with local infection. *Int Wound J* 2017;14(6):1029–35.
36. Edwards K. New Twist on an Old Favorite: Gentian violet and methylene blue antibacterial foams. *Adv Wound Care* 2016; 5(1):11–8.
37. Applewhite AJ, Attar P, Liden B. Gentian violet and methylene blue polyvinyl alcohol foam antibacterial dressing as a viable form of autolytic debridement in the wound bed. *Surg Technol Int* 2015;26:65–7.
38. Shi L, Ermis R, Kiedaisch B, et al. The effect of various wound dressings on the activity of debriding enzymes. *Adv Skin Wound Care* 2010;23(10):456–62.
39. Charlson ME, Pompei P, Ales KL, et al. A new method of classifying prognostic comorbidity in longitudinal studies: development and validation. *J Chronic Dis* 1987; 40(5):373–83.
40. Sussman C, Bates-Jensen BM, eds. *Wound Care: A Collaborative Practice Manual for Health Care Professionals*. 3rd ed. Philadelphia, PA: Wolters Kluwer Health/Lippincott Williams & Wilkins; 2007.
-

When it comes to balancing  
debridement cost,  
*blue* outweighs the competition.



Use *blue* for natural, autolytic debridement.

Gentle but naturally powerful, Hydrofera Blue CLASSIC® antibacterial dressings have a unique capillary action that pulls harmful bacteria-laden exudate, slough, and devitalized tissue away from the wound bed.<sup>1-4</sup> This same action helps draw the body's natural healing agents to the wound, resulting in a balanced healing environment. Non-cytotoxic and compatible with enzymatic debriders, Hydrofera Blue CLASSIC can provide an alternative to costly and painful surgical debridement.

Restore the body's natural balance with *blue*.  
Change to blue at [hydrofera.com](https://hydrofera.com).

*Hydrofera*®



1. Applewhite AJ, Attar P, Liden B, Stevenson Q. Gentian violet and methylene blue polyvinyl alcohol foam antibacterial dressing as a viable form of autolytic debridement in the wound bed. *Surg Technol Int.* 2015;26:65-70.
2. Coutts PM, Ryan J, Sibbald RG. Case series of lower-extremity chronic wounds managed with an antibacterial foam dressing bound with gentian violet and methylene blue. *Adv Skin Wound Care.* 2014; 27(3 Suppl 1):9-13.
3. Edwards K. New twist on an old favorite: gentian violet and methylene blue antibacterial foam dressings. *Adv Wound Care.* 2016;5(1):1-8.
4. Woo K, Heil J. Methylene blue and gentian violet dressing for management of chronic wounds with local infection. *Int Wound J.* 2017;14(6):1029-1035.

Hydrofera Blue and the Hydrofera Blue logo are trademarks of Hydrofera, LLC. ©2023

14-001-042 Rev. 01

MADE IN USA

Hydrofera **BLUE**®



Copyright © 2019 by  
Surgical Technology International™  
Tel. +1 415 704 3160  
Email: [info@surgicaltechnology.com](mailto:info@surgicaltechnology.com)  
Internet: [www.surgicaltechnology.com](http://www.surgicaltechnology.com)