A prospective study to evaluate methylene blue and gentian violet dressing for the management of chronic wounds

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BACKGROUND:

- Chronic wounds are common due to an aging population and increased prevalence of chronic diseases such as diabetes and peripheral vascular diseases.[1]
- Wound healing stalls for a number of reasons, including increased bioburden.[2]
- Early treatment of critical colonization is a priority in the management of chronic wounds to prevent bacteria from spreading into deeper tissue and into the blood.[3]
- Widespread overuse of antibiotics is the key factor contributing to the emergence of multi-drug resistant bacteria; prompt treatment of localized bacterial burden with selected topical antimicrobial agents has been recommended.[3]
- A polyvinyl alcohol foam dressing impregnated with antibacterials methylene blue and gentian violet (MBGV)* has been introduced to the home care setting.
- MBGV dressings are available in a variety of platforms that can be cut to size to fill deep wounds or placed directly on shallow wounds to allow a contact interface between the dressing material and wound tissue.
- MBGV has been shown to be effective against a broad spectrum of bacteria and yeast commonly found in wounds, including methicillin-resistant Staphylococcus aureus and Pseudomonas aeruginosa.

OBJECTIVE:

- The purpose of this study was to evaluate MBGV dressings in managing chronic wounds that exhibit signs of localized infection or critical colonization at baseline.
- Primary endpoints of the study were: 1) changes in wound surface area measurement over time and 2) changes in clinical signs associated with localized wound infection or critical colonization.

METHODS:

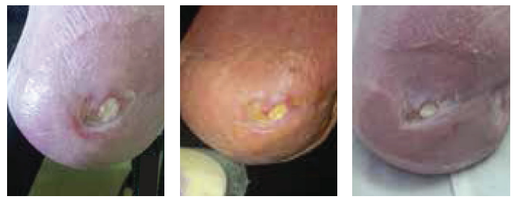
- Prospective enrollment of patients with chronic wounds that exhibited signs of localized infection or critical colonization (Table 1). Ethics approval was obtained.
- All participants received wound care according to local best practice (e.g., compression for venous leg ulcer, pressure redistribution measures for pressure ulcers) and institutional policies. Wounds were cleansed with sterile water or saline.
- MBGV dressings were applied as the primary dressing for all wounds and covered with a secondary dressing according to institutional policies.
- All MBGV dressings were changed at least 3 times per week for total of 4 weeks.
- Three assessment parameters of the PUSH tool[4] were used to describe changes in wound status at baseline and after 4 weeks: size, amount of exudate, and wound surface appearance according to types of tissue present.
- Infection scores were obtained by evaluating the wounds using the ten items on the UPPER and LOWER infection checklist (Table 1).
- The % of devitalized tissue was evaluated by 2 assessors independently to estimate the area of the wound bed that was covered by devitalized tissue. Paired t-test was used to compare the difference in the mean surface areas covered by devitalized tissue at baseline and at week 4.

Table 1. Clinical signs and symptoms of wound infection: UPPER and LOWER[3]

UPPER wound compartment infection	Signs and symptoms related to critical colonization due to infection damage in the upper wound compartment
U–unhealthy tissue	Presence of >50% of debris, red friable tissue, or abnormal discoloration of granulation tissue
P–pain	Sudden emergence of increase in pain
P–poor healing	Changes in wound size of less than 10% in last 7 days
E–exudate	Moderate to heavy amount of exudate
R–reek	Presence of foul odor
LOWER wound compartment infection	**Signs and symptoms of wound infection related to bacterial damage in the lower or deeper wound compartment**
L–larger in size	Increase in wound size or new areas of satellite breakdown
O–osseous tissue	Wound that probes to bone
W–warmth	Increased periwound temperature of more than 2°F compared with temperature on contralateral limb
E–edema	Mild to moderate edema
R–redness	Redness of >2 cm beyond wound margin

Table 2. Results

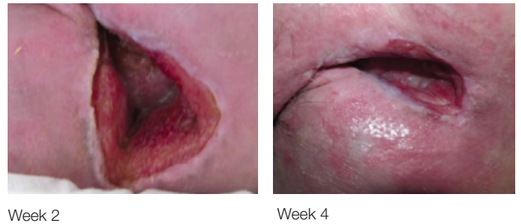
	Mean	Standard Deviation	t value (Degrees of freedom)	p-value
Mean wound surface area at baseline	21.43	27.61		
Mean wound surface area at week 4	12.32	18.74		
Changes in mean surface area between baseline and week 4	9.11	15.97	3.07 (28)	.005
Mean PUSH scores at baseline	13.28	2.15		
Mean PUSH scores at week 4	10.68	2.25		
Changes in mean PUSH scores between baseline and week 4	2.59	1.43	9.76 (28)	<.001
Mean surface areas covered in devitalized tissue (%) at baseline	52.58	32.80		
Mean surface areas covered with devitalized tissue (%) at week 4	11.38	17.67		
Changes in mean surface areas covered with devitalized tissue (%) between baseline and week 4	41.21	27.44	8.09 (28)	<.001
Mean Infection scores at baseline	3.55	1.09		
Mean infection scores at week 4	0.86	0.92		
Changes in mean infection scores between baseline and week 4	2.69	1.47	9.88 (28)	<.001



Case Study 1: Left below knee amputation with non-healing wound. 77% reduction in wound size at week 4.

Case Study 2: Left toe amputation site. An 18% reduction in wound size noted at week 2. Upon dressing removal loose slough and devitalized tissue were noted on the contact surface of the dressing.

Baseline



Week 2 Week 4

Case Study 3: A 20% reduction in wound size at week 2. At 4 weeks, the wound size decreased by 50% with no undermining and edges advancing.

RESULTS (Table 2):

- Twenty-nine participants completed the study; 18 pressure ulcers, 7 surgical/trauma wounds and 4 venous leg ulcers were treated.
- Mean wound surface area was reduced from 21.4 cm^2 to 12.3 cm^2 at week 4 (42.5%; p=.005).
- Mean PUSH score decreased from 13.3 to 10.7 at week 4 (p<.001).
- Mean wound surface area covered with devitalized tissue (%) was reduced from 52.6 % to 11.4% at week 4 (p<.001).
- Mean UPPER and LOWER wound infection score reduced from 3.6 at baseline to 0.9 at week 4 (75%; p<.001).
- Reductions in mean surface area, mean PUSH score, mean wound surface area covered with devitalized tissue and mean infection score were all significant (t-paired tests) during the 4 week study period.
- None of the wounds exhibited signs and symptoms associated with wound infection in the lower compartment (Table 1) that necessitated systemic treatment during the study.

CONCLUSIONS:

- In this prospective study, the MBGV dressings were effective in managing these challenging chronic wounds and helped them to progress towards healing.
- There was a significant change in mean wound surface area, mean PUSH score, mean surface area containing devitalized tissue and mean infection score over the 4-week period with use of MBGV dressings.
- All chronic wound bases were covered with unhealthy tissue at baseline and improved at week 4.
- Evidence from this case series indicated devitalized tissue (e.g. slough) was removed with use of MBGV dressings.

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Hydrofera Blue™ dressing is distributed by Hydrofera LLC.
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