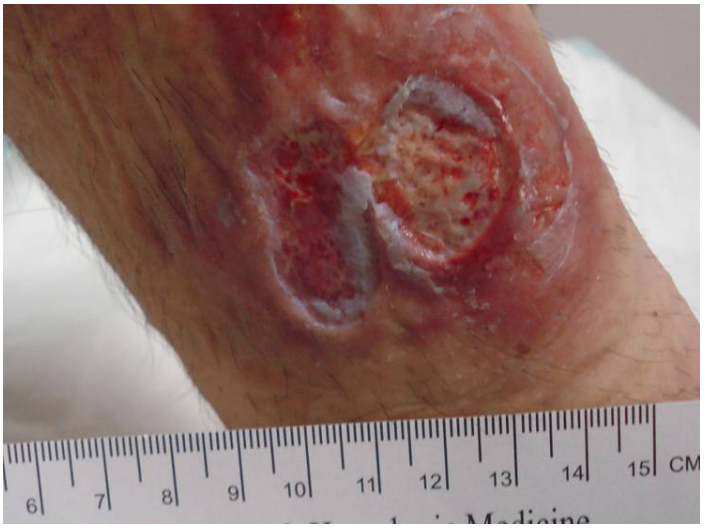
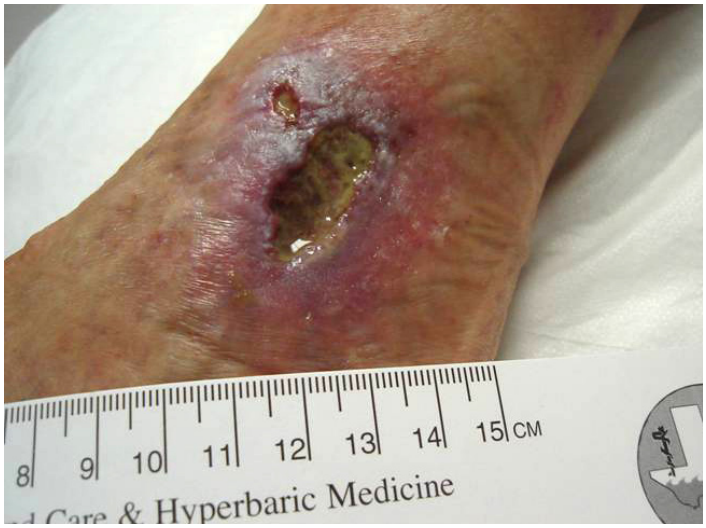


Regenecare Application Reduces Pain Score from 8 to 1 in Male (37 yr.) with Pyoderma gangrenosum



Regenecare® Application Reduces Pain Score from 3 to 0 in Female (53 yr.) with Venous Leg Ulcer

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Ten Patients with Painful Deep Wounds Evaluate Pain with Application of 2% Lidocaine Jelly Versus Regenecare® Wound Gel with 2% Lidocaine During Dressing Change

B. A. Pontani, M.D, FAAFP, CWS, ABPM/UHM, Medical Director,
M. Feste, CHRN, CWS; C. R. Adams, ACHRN, CWS.
Southeast Texas Hyperbaric Medicine Center, Conroe, TX
K. Purdy Lloyd M.S. MPM Medical Inc. Irving, TX
J.B. Spalding, PhD. University of North Texas, Denton, TX.

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Introduction

Pain may possibly be the most feared sensation in life. It disables and distresses more people than any single disease entity and may be the most compelling reason a person seeks healthcare. The significance of pain is neglected in wound care.[1] Clinicians may ignore patient pain because it is not easy to measure, they exhibit biases against pain management, or they lack knowledge of available analgesics.[1] Some analgesics may perform more optimally than others for certain conditions. Pain is definitely a component of quality of life. Patients living with a leg ulcer have described their pain as the most overwhelming characteristic of the condition which was exacerbated by simple activities of daily living such as walking or standing.[1]

Although only limited work has been completed on pain in chronic wounds, much of this has focused on pain at dressing change. In a multinational survey, practitioners consistently rated dressing removal as the time of greatest pain.[2] International study results of 2018 patients, showed that there was a statistically significant difference between the groups with venous, mixed and arterial ulcers being associated with more frequent experiences of pain at dressing change.[3]

Lidocaine HCl 2% Jelly, USP (2% Lidocaine Jelly) is the typical anesthetic available to physicians and nurses for topical application to wounds. Regenecare® Wound Gel with 2% Lidocaine HCl (Regenecare contains 2% Lidocaine) is an FDA registered Hydrogel Medical Device with approval for Management of: Pressure Ulcers, Superficial Wounds and Scrapes, and 1st and 2nd degree burns. Regenecare is available by prescription. Because Regenecare is formulated with skin supporting ingredients in addition to its 2% Lidocaine content, specifically marine collagen, aloe vera gel extract, and glycerin, it was of interest to compare Regenecare Wound Gel with 2% lidocaine versus 2% Lidocaine Jelly as a contact layer during dressing change. Both products contain the same concentration of lidocaine.

Method

Ten subjects with deep painful wounds requiring treatment who were referred to the Southeast Texas Hyperbaric Medicine Center (Conroe, Texas) participated. Informed consent was obtained from patients for voluntary participation in the trial. Participants experienced venous leg ulcers, diabetic foot ulcers, pressure ulcers and calciphylaxis wounds or other open wounds, Grade 3-4, requiring frequent and aggressive treatment. Wound treatments included wet to dry packing, dye impregnated foam, compression wraps, enzymatic debriding agents, negative pressure wound therapy, calcium alginates and hydrogel with silver.

A Numerical Rating Scale of 0 to 10 (none to most severe pain) was explained to patients so that they could assess their pain level during each dressing change. Each subject was evaluated for a baseline score, numerically rating the pain experienced during dressing change receiving no pain medication. Within the next 3-7 days during which the subsequent dressing change took place, 2% Lidocaine Jelly was applied to the wound as a contact layer before dressing change procedure and patients rated the pain. Within the subsequent 3-7 days during which the third dressing change took place, Regenecare Wound Gel with 2% Lidocaine was applied as contact layer before dressing change procedure and patients rated the pain.

The trial established a baseline score of no pain medication, the topical application of the Lidocaine 2% Jelly, and the topical application of Regenecare with 2% Lidocaine in order to compare all conditions. Regenecare was statistically evaluated against 2% Lidocaine Jelly for pain score differences.

The resulting pain scores were evaluated using the Sign Test, the Wilcoxin Signed Rank Test and the Paired T test. All of these tests are robust and indicative of comparing the three sets of scores and were reported.

Pain Management Tool

Numerical Rating Scale

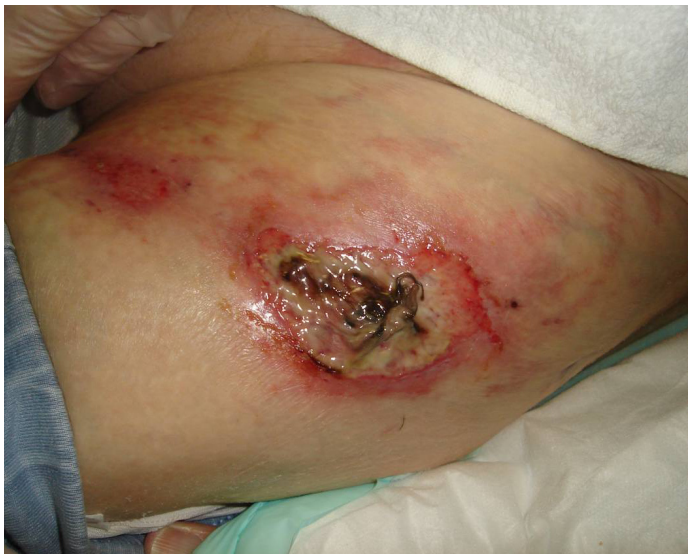
0 1 2 3 4 5 6 7 8 9 10

Ask the patient to choose a number that best reflects his/her present level of pain (0 is no pain and 10 is worst pain)

Results

The results of the Sign Test and the Wilcoxin Signed Rank Test were the same when comparing the 2% Lidocaine Jelly to the Baseline, Regenecare to the Baseline and when comparing 2% Lidocaine Jelly to Regenecare (Sign test $p = 0.05919$ and Chi square = 3.56) and Wilcoxin Signed Rank Test ($p = 0.00195$ and the $T = 45$). Therefore one could state that 2% Lidocaine Jelly is significantly better than no treatment. Regenecare is significantly better than no treatment. Regenecare is significantly better than the 2% Lidocaine Jelly treatment.

When the pain scores of Regenecare with 2% Lidocaine were compared to 2% Lidocaine Jelly, the statistical significance in the paired T test ($p = 0.000137$; SD = 5.7568) showed Regenecare reduced pain scores



Regenecare Application Reduces Pain Score from 10 to 3 in Female (60 yr.) with Calciphylaxis and Renal Failure
(Patient refused dressing change if Regenecare not applied)

during dressing change significantly more than 2% Lidocaine Jelly. All statistics are shown in Table 1.

All of the statistical analyses in this study proved Regenecare more effective at relieving pain than the 2% Lidocaine Jelly.

Table 1: Pain Scores During Application of Regenecare With 2% Lidocaine Versus 2% Lidocaine Jelly

Patient	Baseline	Lidocaine Jelly	Regenecare	Improvement over Baseline		Regenecare vs. Lidocaine Jelly
				Lidocaine Jelly	Regenecare	
	Pain Scores					
A	8	7	0	1	8	7
B	8	6	1	2	7	5
C	6	4	0	2	6	4
D	3	2	0	1	3	2
E	5	4	0	1	5	4
F	8	8	8	0	0	0
G	3.5	3	0	0.5	3.5	3
H	3	2	0	1	3	2
I	9	8	4.5	1	4.5	3.5
J	10	8	3	2	7	5
Mean	6.35	5.2	1.65	1.15	4.7	3.55
Std. Dev.	2.60	2.49	2.73	0.67	2.42	1.95
p value T test				0.0002060	0.0000846	0.000137

Conclusion

Regenecare Wound Gel with 2% Lidocaine HCl is an FDA registered medical device that contains marine collagen, aloe vera gel, and glycerin as primary moisturizers. Aloe vera gel and marine collagen have shown efficacy in animals and humans by supporting healing by increasing collagen formation and crosslinking. Aloe enhances fibroblast migration, microcirculation and acts as an antiflammatory.[4,5,6] Studies have shown that a moist wound bed improves wound healing outcome. The 2% Lidocaine Jelly is an aqueous solution consisting of the following: hypromellose, methylparaben, propylparaben, and sodium hydroxide which are mainly wax excipients.

Because the pain scores of dressing change show Regenecare as more effective in reducing pain than the 2% Lidocaine Jelly it is speculated that the moisturizing ingredients in the formula have efficacy in helping the lidocaine drug absorb into the wound more effectively covering the nerve endings. It was also observed that Regenecare application continued to alleviate pain for up to four hours or more for patients with very painful and sensitive wounds. A thicker more substantive blend of active ingredients in the Regenecare formula may help the dispersal and retention of the lidocaine drug into the wound bed longer. In conclusion the observations of the study showed:

- Regenecare with 2% Lidocaine was statistically more affective in reducing pain of dressing change as compared to Lidocaine 2% Jelly (N=10; paired T test, p=0.000137).
- Regenecare with 2% Lidocaine contains additional active ingredients which appear to improve lidocaine delivery and availability to the wound more effectively than 2% Lidocaine Jelly which contains only aqueous and waxy excipients.
- Regenecare with 2% Lidocaine contains marine collagen, aloe vera gel extract, and glycerin which have shown scientific evidence of moisturizing and supporting wound healing.
- Regenecare with 2% Lidocaine may be a more effective product to use on painful deep wounds during dressing change than 2% Lidocaine Jelly.