

A Cross Over Clinical Study of Forty Seven Patients with Painful Deep Wounds Showed Use of a Hydrogel Containing 2% Lidocaine-HCl and Collagen as Contact Layer was Significant in Alleviating Dressing Related Pain.

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Introduction: Pain management during wound dressing changes improves quality of life, patient compliance and can ease anxiety. A pain relieving gel with aloe extract to reduce inflammation, marine collagen as a humectant and 2% lidocaine-HCl provides pain relief and an environment conducive to stimulating healing. The pain relieving gel was used as an adjuvant to standard wound treatment protocols which consisted of wound dressings (foams, debriders, collagen, alginates, silver dressings, packing, etc.) selected for individual wounds.

Methods: Forty seven subjects (ages 20 to 91) with painful venous ulcers, infected, pressure, diabetic foot, surgical or trauma wounds were evaluated weekly in a clinic or hospital setting. Selection criteria eliminated patients with contraindication to lidocaine or hydrogel ingredients. Subjects received an advanced wound dressing selected by the physician for wound treatment. Wounds were treated with the wound dressing. Patients responded to a numeric pain score 0-10 (least to worst) during dressing changes and these were recorded. Patients were crossed over to receive the pain relieving hydrogel under the wound dressing during subsequent dressing changes. Patient pain scores were assessed and

recorded. Wound bed healing, inflammation, and diameter were assessed during dressing changes.

Results: Pain scores varied from no improvement to 8 levels of pain relief with the use of the pain relieving hydrogel during dressing changes. Ninety percent of patients assessed the hydrogel as relieving pain experienced during dressing change. The mean pain relief scores using Regenecare hydrogel showed 4.5 levels of pain reduction as compared to no hydrogel use. Statistical evaluation of pain score differences with use of Regenecare vs. control analyzed by the Sign Test (Chi Square = 21.511) and by the Wilcoxin Matched Pairs Signed Ranks Test both showed $p < .00001$ in significance.

Conclusion: Regenecare hydrogel reduces pain by a highly significant amount when applied as a contact layer during dressing changes with no untoward side effects noticeable.



Introduction

In recent years there has been growing evidence that the experience of living with a chronic wound has a huge impact on a patient's quality of life. The significance of pain in wound healing is much neglected because of biases against pain management in general, a lack of knowledge of available analgesics and difficulties associated with pain measurement.¹ In a study describing patients' experiences living with a leg ulcer, pain was found to be the most overwhelming characteristic of the condition and was exacerbated by simple activities of daily living such as walking or standing. Most patients are concerned and worried about healing of the wound as well.²

The United States House of Representatives enacted the "National Pain Care Policy Act of 2007" in order to address current issues in health care and pain management. Issues addressed were "pain is often improperly assessed, misdiagnosed, mistreated or undertreated, and many health care professionals are inadequately trained in the proper assessment, diagnosis, treatment and management of pain." The Act also stated that "improving pain care research, education, access, and care are national health care priorities of the United States."³

Pain assessment tools such as the Numerical Rating Scale (NRS) are commonly used to measure pain and pain relief



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)

the issue of wound pain as evidenced by the involvement of the European Wound Management Association Position Document, the dedication of a supplement in Ostomy Wound Management to this topic, and the Consensus Document on Minimizing Pain at Wound Dressing Procedures launched at the World Union of Wound Healing Societies meeting. However, evidence still exists across many health states that there is a major gap between an increasingly sophisticated understanding of the pathophysiology of pain and widespread inadequate pain management.¹

A cross-sectional international survey (Phase II trial) was conducted by Price et al., on 2018 patients with deep wounds from 15 different countries (Australia, Belgium, Canada, Denmark, Finland, France, Germany, Italy, Mexico, Norway, Spain, Sweden, Switzerland, UK and the U.S.). The mean age of patients evaluated was 68.6 years. The wounds were categorized into ten different types with a mean duration of 19.6 months. Venous, mixed and arterial ulcers were associated with more frequent pain at dressing change. All patients surveyed reported "the wound itself" was the most painful location. When surveyed, 40% of patients indicated that the pain of dressing change was the worst part of living with a wound. Forty percent of these patients reported that it took < 1 hour for the pain to subside after a dressing change, 22% reported it took 1-2 hours for the pain to subside and 10% reported it took 3-5 hours, and for 8% of patients it took more than 5 hours for pain to subside.¹

The survey also recognized the order of the problematic symptoms as pain, impaired mobility, and difficulties in

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)

in the clinical or research setting. Evidence suggests that Numeric Rating Scales are easier to apply and are associated with better compliance than Visual Analog Scales. Based on available evidence the use of a standard 0-10 Numeric Rating Scale has been found to be optimal in assessing pain intensity and a good measure for patients to compare pain now as compared to previous pain.⁴

In a multinational survey, practitioners consistently rated dressing removal as the time of greatest pain. Health professionals are now recognizing the importance of addressing

bathing, leakage, odor and slippage of the dressing or bandage. Patients with leg ulcers are usually elderly with particularly fragile skin and the removal of dressings that stick to the wound may well be the most painful part of the dressing procedure.¹

Method

Informed consent was obtained from patients for voluntary participation in the trial. Forty seven subjects experiencing a deep painful wound, of ages between 20 and 91 years were evaluated. Participants experienced a broad range of wound types which included venous leg ulcers, diabetic foot ulcers, cellulitis and abscesses, pressure ulcers, pyoderma gangrenosum, calciphylaxis wounds, necrotizing fasciitis, post surgical wounds, failed flaps, and traumatic wounds. The dressing types selected for wound treatment included dye impregnated foam, compression wraps, calcium alginates with silver and with collagen, cadexomer iodine, wet to dry packing, enzymatic debriding agents, negative pressure wound therapy, and hydrogel with silver.

Patients' wound dressings were changed as indicated by the wound type and followed weekly in the clinic or hospital. The Pain Assessment Tool used was a Numeric Rating Scale



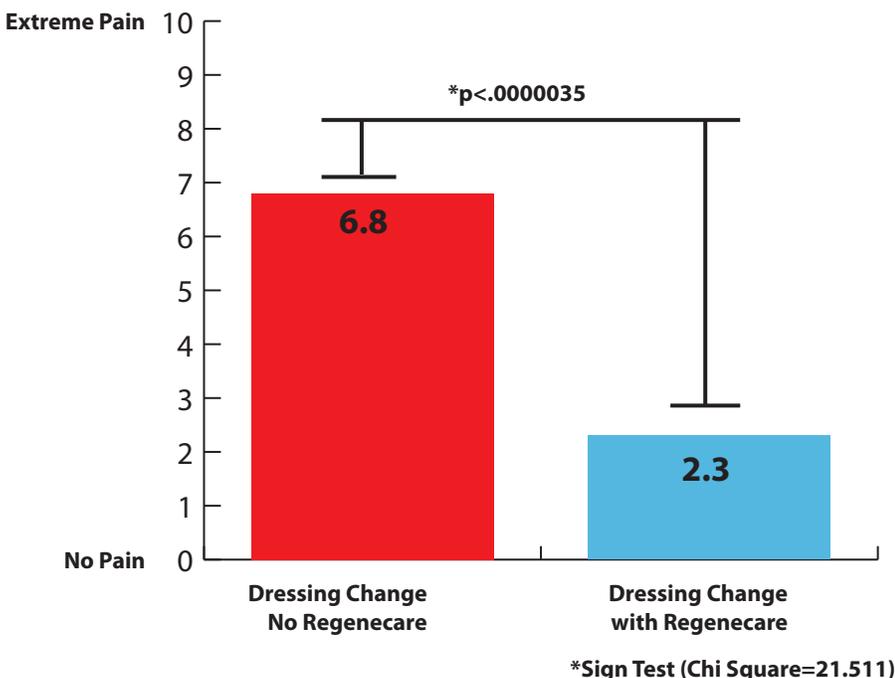
Regenecare Application Reduces Pain Score from 3 to 0 in Female (53 yr.) with Venous Leg Ulcer

of 0 to 10 (none to most severe pain) which included a Visual Analog Scale of faces expressing degree of pain for further clarification. Healthcare professionals informed patients of the pain scale explaining that a rating of 0 meant no pain with intermediate scoring (1-9 least to worst degrees of pain) up to 10 which represented extreme pain. This standard Pain Assessment Tool was given to each patient to communicate the degree of comparative pain. This visual assessment tool has been shown to help clinicians comply with The Joint Commission on Accreditation of Healthcare Organizations Pain Management Standards.

Each patient rated the pain associated with the first dressing change which served as the control. Controls lacked application of any type of pain medication or Regenecare application. The patient was then crossed over during subsequent visits to receive an application of Regenecare hydrogel to the wound during the dressing change. Patients were asked to rate the pain associated with the dressing change using the Regenecare gel. Each patient acted as their own control and pain scores without Regenecare or any pain medication were compared to pain scores with the application of Regenecare as contact layer during dressing change.

Regenecare Hydrogel (MPM Medical Inc. Irving, Texas) contains 2% lidocaine-HCl

Average Pain Scores During Dressing Change Control vs. Regenecare in 47 Patients with Deep Wounds



in a base of concentrated aloe vera extract (high molecular weight components) and collagen as a natural humectant and moisturizer. Aloe vera has been shown to increase fibroblast migration, enhance wound repair time and act as an anti-inflammatory.^{5,6,7} Lidocaine HCl (2%) is a safe and effective anesthetic.^{8,9} Collagen has been shown to enhance wound repair mechanisms in the epidermis.^{10,11} Regenecare Hydrogel is an FDA registered Medical Device approved for the management of pressure ulcers, superficial wounds and scrapes, and 1st and 2nd degree burns.

Results

The pain scores were reported and evaluated. The scores were from two related samples (as a before and after evaluation on the same subject). The data were analyzed using the Wilcoxin Matched Pairs with Signed Ranks test (MPSR) and also the Sign Test. These nonparametric tests were considered robust and straight forward in their interpretation.

The Sign Test (Chi Square = 21.511) resulted in $p < .0000035$. The Wilcoxin MPSR test resulted in $p < .0000000000000071$. Since these results are very highly significant, it is concluded that Regenecare Hydrogel reduces pain by a very highly significant amount when applied as a contact layer during dressing changes.

Conclusion

Pain scores varied from no improvement to 8 levels of pain relief with the use of Regenecare during dressing changes. Ninety percent of patients assessed the gel as relieving pain experienced during dressing change. The mean pain relief scores using Regenecare Hydrogel showed 4.5 levels of reduced pain as compared to when no Regenecare Hydrogel was used.



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

Pain management during dressing changes can be substantially reduced with a topical pain relieving gel that contains lidocaine, collagen and other important ingredients supporting a moist wound environment for optimizing healing outcome.

Gowland et al., reported in a clinical study that Regenecare reduced pain and itching for up to four hours in Grade 1 and 2 cutaneous toxicity caused by Epidermal Growth Factor Receptor Inhibitors drugs. The cutaneous toxicity results in pruritis, pain, desquamation and inflamed rash.¹²

Regenecare Hydrogel substantially enhanced bioavailability of lidocaine to the wound bed over time substantially diminishing pain after dressing change. Regenecare was not observed to burn or sting when applied to the wound bed, as compared to some pharmaceutical lidocaine preparations which sting upon application. No adverse side effects in this clinical evaluation were observed.

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