A Controlled, Randomized, Comparative Study of a Radiant Heat Bandage on the Healing of Stage 3–4 Pressure Ulcers: A Pilot Study

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Objectives: Pressure ulcers, like other chronic wounds, fail to proceed through an orderly and timely process to produce anatomical or functional integrity. Treatment of pressure ulcers is directed to improving host factors and providing an optimum wound environment. In addition to providing a moist wound environment, it has been theorized that preventing hypothermia in a wound and maintaining a normothermic state might improve wound healing.

Design/Setting: Forty-one subjects with a stage 3 or stage 4 truncal pressure ulcer >1.0 cm² were recruited from outpatient clinics, long-term care nursing homes, and a rehabilitation center. The experimental group was randomized to a radiant-heat dressing device and the control group was randomized to a hydrocolloid dressing, with or without a calcium alginate filler. Subjects were followed until healed or for 12 weeks.

Results: Eight subjects (57%) in the experimental group had complete healing of their pressure ulcer compared with 7 subjects (44%) with complete healing in the control group (P = .46).

Conclusion: Although a 13% difference in healing rate between the two arms of the study was found, this difference was not statistically significant. At almost all points along the healing curve, the proportion not healed was higher in the control arm. (J Am Med Dir Assoc 2005; 6: 46–49)

Keywords: Pressure ulcer; wounds; wound healing; decubitus ulcer

Pressure ulcers represent a critical problem for clinicians. Pressure ulcers, like other chronic wounds, fail to proceed through an orderly and timely process to produce anatomical or functional integrity.1 About 75% of stage 2 pressure ulcers heal in 8 weeks, but only 17% of stage 3/4 pressure ulcers healed in that time.2 Twenty-three percent of stage 2 pressure ulcers remain unhealed at 1 year, and 48% of stage 4 pressure ulcers are unhealed at 1 year. At 2 years, 8% of stage 2 pressure ulcers, 29% of stage 3, and 38% of stage 4 remained unhealed.3 The considerable length of time to healing increases the morbidity and cost of treating pressure ulcers, and is often frustrating to the patient and caregivers.

Therapy for pressure ulcers is generally empiric, based on anecdotal experience, or borrowed from the treatment of patients with acute wounds. The treatment of pressure ulcers is problematic because of multiple comorbidities of patients, the chronic duration of pressure ulcers, and often by the physician’s relative unfamiliarity with treatment options. Considerable dogma and rhetoric, rather than evidence-based results, have accompanied recommendations for prevention and treatment of pressure ulcers.4,5

Treatment of pressure ulcers is directed to improving host factors and providing an optimum wound environment.6 The critical factor in optimizing the local wound environment is moisture. In addition to providing a moist wound environment, it has been theorized that preventing hypothermia in a wound and maintaining a normothermic state might improve wound healing.

To investigate this hypothesis, we compared the efficacy of a radiant-heat dressing device or a sterile control hydrocolloid dressing with or without a calcium alginate filler in expediting the closure of stage 3 and 4 pressure ulcers.

METHODS

A 12-week, randomized, controlled study in subjects with a stage 3 or a stage 4 pressure ulcer was performed. Subjects were recruited from outpatient clinics, long-term care nursing homes, and a rehabilitation center. Inclusion criteria included male or female subjects, who were at least 18 years old with a diagnosis of a non-infected stage 3 or stage 4 pressure ulcer with an area greater than or equal to 1.0 cm². Only subjects with a truncal pressure ulcer were enrolled due to difficulty in
applying dressings to heel ulcers. Only one pressure ulcer was evaluated per subject. Exclusion criteria included a history of sensitivity to adhesive products, a wound with a sinus tract and/or extensive undermining (greater than 1 cm), a nonpressure ulcer (venous stasis or arterial insufficiency or vasculitis or diabetic ulcer) based on the investigator’s diagnosis, an infected ulcer (one or more of the following: clinically significant increase in periwound erythema, edema, purulence, and body temperature, elevation of the white blood cell count, pain, change in exudate color, an uncharacteristic or foul odor, or suspected or confirmed active osteomyelitis under the study ulcer), concomitant use of other topical medication to study ulcer; human immune deficiency virus positive; pregnant, breast-feeding or not on acceptable means of contraception in premenopausal women; current diagnosis of cancer (subjects whose cancer is in remission and who are not receiving concomitant chemotherapy may be included in the study), severe generalized medical condition with estimated survival of less than 6 months; concomitant systemic steroid therapy at a dose equivalent to greater than 10 mg prednisone daily, or current alcohol or drug abuse. Informed consent was obtained from the subject and/or appropriate legal representative under the supervision of the Institutional Review Board of the Saint Louis University Health Sciences Center.

A standard computer-generated, block stratification process, using opaque envelopes, was used to randomize subjects to either the experimental or control group. The experimental group was randomized to a radiant-heat dressing device (Warm-Up,™ Augustine Medical, Inc., Eden Prairie, MN) and the control group was randomized to a sterile control hydrocolloid dressing (Duoderm,™ Convatec, Inc., Princeton, NJ) with or without a calcium alginate filler (Sorbasan,™ Smith-Nephew, Inc., Largo, FL). The radiant-heat dressing consists of two layers of plastic film (semi-occlusive and water vapor permeable) supported by and attached to an open-cell pad that adheres to the skin surrounding the wound area. The window portion of the bandage, centered over the wound, is a twolayered pocket into which the warming card (heating element) is inserted. The warming card delivers heat at 38°C, warming the wound and periwound area, without coming into direct contact with the wound tissue. The warming card was used for a 1-hour treatment every 8 hours for the duration of the study. The dressing was changed every 7 days or when the occlusive seal was broken.

The control treatment was a sterile hydrocolloid dressing. A calcium alginate filler was used if necessary to control exudate. Calcium alginate was a seaweed-derived product that absorbs wound exudate. Calcium alginate was applied when the wound was highly exudative, since under these conditions the seal for the hydrocolloid dressing is quickly overwhelmed, negating the hypothesized benefit of the dressing. No calcium alginate was used with the experimental dressing. The dressing was changed every 7 days or when the occlusive seal was broken. Both treatment modalities are FDA-approved medical devices currently in use for the treatment of pressure ulcers.

A medical history and pressure ulcer history, physical examination, Mini Nutritional Assessment (MNA), and a risk assessment using the Braden Scale were assessed. Each ulcer was measured at baseline and followed with weekly wound measurement until complete wound closure or for 12 weeks, whichever occurred first. The ulcer was assessed at each visit by removing the dressing and noting the odor, color, consistency and amount of exudate, and wound and periwound appearance. The ulcer was then cleansed by gently wiping the wound with a gauze moistened with normal saline. The wound bed was also assessed for color and type of tissue (granulation, slough, necrosis, epithelialization) and the status of the wound margins. The area (length, width, and depth) of the wound was measured and a plastic acetate tracing of the wound perimeter was made using a felt tip pen. The wound was assessed using the Pressure Ulcer Status for Healing (PUSH) tool, a scoring system for area, exudate amount, and surface appearance. Vital signs (blood pressure, pulse, respiration, and temperature) and pain during the dressing change were obtained at baseline and weekly. Adverse events and serious adverse events were assessed at each weekly visit. Both groups received standard offloading and pressure-reducing devices.

A total of 41 subjects with a stage 3 or 4 pressure ulcer gave informed consent and were enrolled in the study. The mean age of the subjects was 75.5 ± 12.6 years, and 68% were male. Stage 3 pressure ulcers were present in 54% of subjects, and stage 4 pressure ulcers were present in 46% of subjects. Most ulcers were in the sacral region (42%), the ischial region (21%), or coccyx region (15%). There were no differences between the experimental group and control group at baseline (see Table 1). Two subjects died in the experimental group and 1 died in the control group. Two subjects were hospitalized in the experimental group and 3 subjects were hospitalized in the control group. Two subjects dropped out of the experimental group for non-study-related reasons while none dropped out in the control group. There was no difference between groups in mortality, dropout rate, and hospitalization (P = .64). Twenty-one subjects were randomized to the

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experimental group and 20 were randomized to the control group. Subjects were analyzed by intent-to-treat.

Statistical analysis was performed using the STATISTICA software package. Simple demographic statistics were used to describe the population. A contingency table was constructed using χ² techniques to compare healing rates. Kaplan–Meier survival analysis was performed to compare the probability of healing between groups.

RESULTS

Eight subjects (57%) in the experimental group had complete healing of their pressure ulcer compared with 7 subjects (44%) with complete healing in the control group. Six subjects in the experimental group did not heal their ulcer during the 12-week observational period compared with 9 subjects in the control group. Six subjects in the experimental group did not heal their ulcer during the observation period, and two stage 3 pressure ulcers failed to heal in either group. The proportion not healed and remaining in the study was not different between groups (Figure 1).

DISCUSSION

The theoretical basis for tissue warming in wound healing derives from several physiological observations. Local warming using heated compresses has been used for centuries to treat wounds. There is a known association between lower body temperature and surgical wound infections. Mild hypothermia (core temperature 36°C) often occurs after general anesthesia because of thermal redistribution of body heat, anesthesia-induced depression of the core temperature threshold for vasoconstriction, exposure to a cold operating room, infusions of room temperature IV fluids, and a variety of other factors. This perioperative hypothermia can lead to an increased incidence of surgical wound infections, along with other effects including peripheral vasoconstriction, impaired coagulation and immune response, myocardial ischemia, cardiac arrhythmias, and increased norepinephrine concentrations. Hypothermic patients experience prolonged discharge from the postanesthesia care unit, and prolonged hospitalization. A variety of methods, such as warm blankets, radiant heat, and convective warming, have been used to rewarm hypothermic patients.

At core body temperatures below 36°C, physiological effects include a reduction in localized blood flow, reduced subcutaneous oxygen tension, general and progressive inhibition of biochemical reactions, enzyme reactions, and cellular functions. Activation of an inhibitory substance found in chronic wound fluid and found to adversely affect fibroblast activity occurs at lower temperatures.

These observations have led to studies of the effect of localized warming on acute wounds. Studies examining localized wound warming in surgical patients have demonstrated an increase in blood flow, hypothesized to be the result of localized vasodilation. Ikeda found that active localized warming increased subcutaneous oxygen tension by approximately 50% in healthy volunteer subjects cooled to a skin temperature of 36°C. This elevated subcutaneous oxygen tension persisted for 3 hours after heating was stopped. In a dose-ranging in vitro study, maximum stimulation of endothelial cell proliferation occurred under the 38°C card, with cells numbering 135% to 158% of the controls (P < .05).

Typical skin ulcer temperatures are cooler than core body temperature and average 33°C. At this skin temperature, there is a reduction in the movement and growth of fibroblasts and epithelial cell proliferation. The proliferation of fibroblasts increases and cell metabolism tends to increase after in vitro cultures are returned to normal body temperatures. In vitro, wound fluid from venous leg ulcers shows that heat increases cellular growth and proliferation.

These physiological and in vitro biochemical benefits have been tested in pressure ulcers. A radiant heat dressing was evaluated in a trial of 20 subjects with 21 stage 3 and stage 4 pressure ulcers. Wounds treated with standard care plus the heated dressing had a reduction in mean surface area of 60.73%. In another trial of a radiant heat dressing in stage 3 and stage 4 pressure ulcers, time to reduction of 75% of original area occurred in 6.4 days and time to reduction of 50% in original area occurred in 9.6 days, compared with standard treatment (P = .057 and P = .039, respectively). In another trial, 15 were randomized to receive a radiant heat dressing and 14 subjects were randomized to receive standard care. The linear rate of healing was significantly faster in the group treated with the radiant heat dressing (P = .01).

In our trial, which used the outcome of complete healing, the radiant-heat dressing device and a hydrocolloid dressing are equally effective in the treatment of stage 3 and stage 4 pressure ulcers. Observational data suggests that the radiant heat dressing produces a cleaner, debrided wound earlier in the treatment course.

The most commonly used dressing for pressure ulcers at hospital discharge in the United States is dry gauze. The use of dry gauze persists despite clear data suggesting that it results in delayed healing. Compared with wet-to-dry gauze dressings, moist dressings are clearly superior. Moist wound healing allows experimentally induced wounds to resurface up to 40% faster than air-exposed wounds. A meta-analysis of five reports (χ² = 5.76, df = 4, P = .218) comparing a hydrocolloid dressing with a traditional treatment suggested that treat-
ment with hydrocolloid resulted in a statistically-significant improvement in the rate of pressure sore healing (OR, 2.57; 95% CI, 1.58, 4.18). Hydrocolloid dressings arguably represent the gold standard of pressure ulcer care. This study suggests a 13% difference in healing rate between the two arms of the study. This difference was not statistically significant; however, the study was powered to detect a difference of at least 40%. At almost all points along the healing curve, the proportion not healed was higher in the control arm. Further research using a larger sample size is clearly warranted.

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