

ADHESIVE HYDROCELLULAR DRESSING VS HYDROCOLLOID DRESSING IN THE MANAGEMENT OF 2nd and 3rd DEGREE PUS

A Prospective, controlled randomized comparative multi-center clinical evaluation

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ABSTRACT

Studies have shown the effectiveness of hydrocolloids[^] (HDC) in the treatment of various wound types. The evaluated adhesive hydrocellular* (AA) dressing has been shown to be more absorbent and therefore able to remain in place longer than HDC. The purpose of this study was to evaluate and to compare the performance of these dressings in the management of patients with stage II and III Pressure Ulcers (PU). Eighty patients in a hospital and nursing home setting were recruited to the study. The % of sloughy tissue present at the start and at the end of the study went from 17.3% to 9.3% in the AA group vs 11.8% to 16% in the HDC group.($p < 0.04$). All AA dressings were removed in less than 3 minutes vs a range of 3 to 5 minutes in the HDC group.($p < 0.006$) At day 21 in the AA group 90% of the dressings stayed in place for 4 days vs 35% in the HDC group. ($p < 0.0007$). 95% In the AA group had normal skin condition after dressing removal, 1% had slight redness and no damage, vs 54% normal, 7% redness and 17% damage upon dressing removal in the HDC group ($p < 0.008$).

INTRODUCTION

One of the problems frequently associated with the management of bed-ridden patients, is the occurrence of PU. These ulcers often appear in specific areas, difficult to manage with conventional dressings. The AA dressing has been reported to enable optimal management of several wound types. The dressing is easy to use, alleviates pain and does not cause injury to the wound bed when it is removed (1)(2)(3)(6).

Studies have shown the effectiveness of HDC in the treatment of various wound types. The evaluated AA dressing has been shown to be more absorbent and therefore able to remain in place longer than the HDC dressing.(5) This suggests that AA dressings may be of particular use in the management of PU. The purpose of this study was to evaluate the performance of a hydrocellular dressing (Allevyn Adhesive) and to compare it with that of a hydrocolloid dressing (Duoderm CGF) in the management of stage II and III PU.

MATERIAL AND METHODS

The AA dressing used in this study consists of 3 layers. The external layer, a vapour-permeable polyurethane film, creates a bacterial barrier (4) and inhibits fluid from leaking. Ameen et al.(4) showed that AA inhibits bacterial transmission over an 11-day challenge period. The investigators suggested that AA may facilitate infection control by acting as a physical barrier to the transmission of pathogenic and antibiotic-resistant wound bacteria (4). The hydrophilic core accounts for the high absorbency of the dressing (10 times its weight) and for its structural integrity; the dressing can be left in the wound for more than four days.(5)(6) The third layer, a polyurethane hypoallergenic adhesive film which adheres to the surrounding skin, offers protection due to friction. This layer in contact with the wound prevents the dressing from sticking to the wound bed. It makes changing the dressing easier and less painful (3)(5)(6).

The hydrocolloid dressing under evaluation consists of a thin layer of a semi-open-cell polyurethane foam bonded onto a polyurethane film which acts as a carrier for the hydrocolloid base.

This was a prospective multi-center comparative randomized study. Eighty patients from a hospital – and home care setting were recruited, who fulfilled the following inclusion criteria: Patients of either sex, aged at least 18 years, with 2nd and 3rd degree PU,(7) were compliant with medical treatment and able to give consent.

Exclusion criteria were: Pregnant women; patients with plasma proteins <6mg/100ml, Hb<10mg/100ml, or those with clinically infected wounds. A clinical infection was defined as follows: Inflammation or cellulitis around the ulcers, purulent exudate, fever, these patients could only be recruited once the infection had cleared up. At the initial evaluation the following was assessed: The time since occurrence of the PU, the stage of the ulcer, ulcer site, ulcer size, description of the wound bed and peri-wound skin condition. For assessment of the condition of the wound bed a red/yellow/black color classification model was used. The three colors were documented for each wound and the percentages present were indicated on ulcer tracings/photographs upon each dressing change and at the end of the study. Tracings were taken using a measuring grid (Opsite Flexigrid); the number of whole and half squares were counted. Photographs were taken using a standardized technique and equipment. Test and control ulcers were photographed on the same standard blue background (disposable surgical drape) and aperture, exposure time and distance were kept constant. The color and odor of the exudate in the dressing were used as parameters to assess possible clinical infection. The peri-wound skin condition was assessed for information on any increase in pain reported by the patient. To analyze pain, a 10cm scale was used to record. At each dressing removal, subjects were asked to put a single stroke on the line to indicate their level of pain (0=no pain, 10=unbearable pain).

The trial and control dressings were changed at the discretion of the clinician, depending on the amount of exudate produced, at a maximum every four days. The treatment lasted until 10 dressing changes were performed or until one of the following endpoints had been reached: re-

epithelialisation; an adverse incident; patient withdrawn for other reasons. At each dressing removal the reason for changing the dressing was described, as well as the size and depth of the wound, and rate of exudate production. At the same time an evaluation of the ease of application and removal of the dressing took place. The final evaluation included the clinicians' subjective assessment of the features of the trial dressing compared to the control dressing.

METHOD OF ANALYSIS

Data from the completed and validated questionnaires were entered into a program written in Microsoft Access. A randomization code was used to define and allocate the patients to the trial - and control treatment. Summary baseline statistics were compiled to help evaluate the validity of statistical assumptions. Discrete variables (e.g. gender) were analyzed using the Chi-square statistic or Fisher's exact test where appropriate. Continuous variables (e.g. age) were analyzed using Student's t-test. To evaluate the effect on wound healing (i.e. percent change in area) a repeated measure analysis of variance was used, in which the effect of ulcers in the trial group vs. ulcers in the control group, time (days 0 through the end of study) and their interaction were assessed. Statistical analysis included the chi-square test and variance analysis (one-way Anova).

RESULTS

The study population consisted of 80 patients with stage II and III PU(7).

The Clinical Investigator sought the permission of the relevant consultant for their patients to be included in the study. Before being admitted to the clinical evaluation, the patient consented to participate, after the nature, scope and possible consequences of the study had been explained in an understandable form. Patients were questioned on their previous medical and social history.

Assessments were made to determine the main cause of ulceration and risk assessment was performed using an adapted Braden Risk Score.

Patients were recruited in several centers in Italy between December 1996 and December 1999 (Table 1 and 2). Of the 80 patients that were recruited, 63 were evaluated. 9 Patients were lost to follow up, 3 patients died and 5 were withdrawn for reasons not related to the PU treatment. There was no difference in age, stage of the ulcers and mobility between the two cohorts. As shown in table 3, upon recruitment to the study the ulcers in the AA group were significantly deeper.

Evolution in ulcer size and appearance of the wound bed

As shown in table 4, at day 14 there was a difference in ulcer size reduction in favor of the AA group. Comparing the evolution in wound bed appearance, the % of sloughy tissue present at the start and end of the study went from 22% to 6% in the AA group vs. 13% to 14% in the HDC group. This difference was statistically significant $p < 0.05$. Complete epithelialisation at 10 dressing changes, end of the study period is 85% (estimate); treatment difference: 25%; significance: 5%; power: 80%.

Dressing application, removal, time in situ

The % of dressings that stayed in place for 4 days was significantly higher in the AA group at day 7, ($p < 0.001$) day 14 ($p < 0.0007$) and day 21 ($p < 0.0007$).

At days 7 and 14 the level of pain reported upon dressing removal, was lower for AA, compared to HDC ($p < 0.07$). Further into the trial, days 21 and 28 there was no difference reported between the two groups.

Time taken for dressing removal: All AA dressings were removed in less than 3 minutes vs. a range of 3 to 5 minutes in the HDC group. At day 21 assessment, there was a significant difference shown in time required for dressing removal in the AA group vs. the HDC group ($p < 0.006$).

Ease of dressing removal is shown in table 5. Regarding adherence of the dressing to the wound bed, there was a highly significant difference at day 28, when most of the wounds assessed are granulating wounds. At day 7, there was a significant difference in peri-wound skin condition in favor of the AA group, 89% had normal skin condition after dressing removal, 11% slight redness

and no damage, vs. 48% normal skin condition, 34% redness and 18% skin damage in the HDC group ($p < 0.007$).

At day 14 in the AA group 95% had normal skin condition after dressing removal, 1% redness and no damage, vs. 54% normal, 7% redness and 17% damage upon dressing removal in the HDC group ($p < 0.008$).

DISCUSSION

In conducting Randomized Controlled Trials comparing Moist Wound Healing dressings using chronic wounds as a model, one encounters difficulties in defining standards and categories on chronic wounds. Methodological problems regarding patient numbers and difficulties regarding relevance on time, i.e. path, may influence the quality of such studies. Factors influencing quality of life, equally important for the clinician to make an appropriate choice are often left out of the equation. There may be methodological approaches that support avoiding bias, which are complex, time consuming and therefore costly and not necessarily producing better results.

The defined study period was limited for reasons of practicality and ethics. This comported that we developed the above study design focussing on practical aspects of PU management rather than healing time.

Occlusive dressings possess the characteristic of promoting a local moist environment in chronic wounds (8). With the growing number of dressing types available a better understanding of properties is essential for the caregiver to provide appropriate management for each wound type (6). Apart from the biophysical properties, practical aspects of the dressing chosen may influence the outcome. PU often appear in specific areas, such as the sacral area, complex to manage, especially in incontinent patients (3). Depending on exudate production and the absorbent capacity of the dressing, maceration of the wound edges may occur. Typical disadvantages observed with adhesive dressings are damage to the peri-wound skin, which may be enhanced when maceration occurs. The results shown in the present study regarding skin condition, suggest that an enhanced absorbent capacity of the dressing may aid to inhibit skin damage.

CONCLUSIONS

The overall performance of the AA dressing was shown to have clinical advantages over the HDC dressing in all the parameters under evaluation.

The use of AA proved to be safe and did not cause mechanical injuries upon dressing changes in comparison to the HDC group, where skin damage was reported in up to 18% of the cases. The patients reported little or no pain upon dressing removal in the AA group vs. significantly more pain in the HDC group. The AA dressing was shown to be easier to apply and to remove, as well as having a greater absorbent capacity than the HDC.

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Pressure Ulcer Stages according to Shea# Classification (7).

Stage 2 = Partial thickness skin loss involving epidermis and/or dermis. The wound is superficial and presents clinically as an erosion, blister or superficial ulcer.

Stage 3 = Full thickness skin loss involving damage or necrosis of subcutaneous tissue which may extend down to but not through underlying fascia. The wound presents clinically as a deep ulcer with or without undermining of adjacent tissue.

Stage 4 = full thickness skin loss with extensive destruction, tissue necrosis, or damage to muscle, bone or supporting structures (eg. tendon, joint capsule etc.)