

Pressure Ulcers - Randomised Controlled Trial Comparing Hydrocolloid and Saline Gauze Dressings

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Summary

An open comparative randomised study comparing the performance of hydrocolloid dressings (DuoDERM CGF) to saline gauze dressings in the treatment of pressure ulcers was done to evaluate the overall dressing performance, wound healing and cost effectiveness. Thirty-four subjects were enrolled at the University Hospital, Kuala Lumpur over a 643 days period. Inclusion criteria were Stage II or III pressure ulcers, at least 18 years of age and written informed consent. Only one pressure ulcer per subject was enrolled in the study. Patients with infected pressure ulcers, diabetes mellitus, an immuno-compromised status and known sensitivity to the study dressings were excluded.

Subjects who met the enrollment criteria were randomised to one of the two dressing regimes. They were expected to participate in the study for a maximum of eight weeks or until the pressure ulcer healed, which ever occurred first.

Overall subject age averaged 58 years and the mean duration of pressure ulcer existence was about 1 month. Twenty-one of the thirty-four ulcers enrolled were stage II and thirteen were stage III. The majority of the ulcers (88%) were located in the sacral area and seventeen subjects (50%) were incontinent.

In the evaluation of dressing performance in terms of adherence to wound bed, exudate handling ability, overall comfort and pain during dressing removal; all favoured the hydrocolloid dressing by a statistically significant margin ($p < 0.001$). Subjects assigned the hydrocolloid dressing experienced a mean 34% reduction from their baseline surface area measurement compared to a mean 9% increase by subjects assigned gauze dressings. This was not statistically significant ($p = 0.2318$). In cost evaluation of the study products, there was no statistical significance in the total cost of wound management per subject. When only labour time and cost was evaluated, there was a statistically significant advantage towards hydrocolloid dressings.

Key Words: Pressure ulcers, Hydrocolloid dressings, Saline gauze

Introduction

Pressure ulcers are of concern to patients and health care providers. The patients most commonly affected

include young patients with neurologic disorders, the elderly who are debilitated, incontinent and bed-ridden and the critically ill who are unconscious and immobile.

Treatment for such patients is expensive in terms of staff time, patient hospitalisation length and dressing materials.¹

This study was conducted to assess the performance of conventional saline gauze dressings as compared to the newer hydrocolloid dressing - DuoDERM CGF, with respect to its overall dressing performance, rate of wound healing and cost effectiveness. The concept of moist wound healing being better is looked at.^{2,3}

Materials and Methods

This study was conducted at the University Hospital, Kuala Lumpur during the period from February 1995 to January 1997. This was an open, comparative, randomised study where the patients were randomised to either one of the two groups; saline gauze dressings or hydrocolloid dressings (DuoDERM CGF). Thirty-four subjects were enrolled, seventeen in each treatment group.

Subjects eligible to participate were required to present with either a stage II or III pressure ulcer, at least 18 years of age and provide written informed consent. In the case of unconscious patients, consent was taken from a close relative. Only one pressure sore per subject was eligible for study entry. Patients who were immunocompromised, with infected pressure ulcers and known sensitivity to the study dressings were excluded.

The mean age of the subjects was 57.6 years (range 20-85yrs). The majority had their ulcers for a mean duration of 33 days (range 4-274 days). The patients were either suffering from neurological problems or advanced malignancies. 21 cases had stage II (CGF:11,Gauze:7) while 13 had stage III (CGF:6,Gauze:7) ulcers. Five of the patients were incontinent of urine, while 16 were incontinent of faeces. Four were incontinent to both. The majority of the pressure ulcers were located in the sacral region (30); while 3 were at the iliac and 1 at the greater trochanteric regions.

The gauze dressings used were plain and did not contain any stimulants or antibiotics and were soaked with sterile normal saline. DuoDERM CGF is an occlusive hydrocolloid dressing. Under the influence of the wound exudate, the hydrocolloids form a gel, which provides a moist wound environment. The outer layer of

the dressing is made of a polyurethane foam which is impermeable to water, gases, vapour and bacteria.

Each subject was assigned wound treatment for a period of up to 8 weeks or less if complete healing was achieved earlier. Subjects who did not continue with dressing changes until healing was complete or a minimum of 3 weeks were considered ineligible for data analysis.

The pressure sores were cleaned with sterile saline and wound tracings of ulcer perimeter were made at each dressing change by moulding a piece of clear plastic food wrap over the ulcer and into the ulcer cavity. The tracings were then transferred onto acetate transparencies. Colour photographs were also taken. For cavity wounds, they were filled with DuoDERM Hydroactive Gel prior to covering with DuoDERM CGF with at least 3 cm extending beyond the wound margin. Patients on the saline gauze dressings arm had their wounds covered with saline soaked gauze and covered with a secondary dressing of gamgee pack.

DuoDERM CGF dressings were left for up to seven days or when leakage occurred. Saline gauze dressings needed changing once a day or when exudate is visible through the secondary dressing. Assessments were done at enrollment then weekly. During the initial assessment, the subject's general health was screened and the subject's eligibility to enter the trial determined. Blood was taken for albumin, haemoglobin and total white count. During mid-study assessment, evaluation was made of dressing performance, photographs and tracings of the pressure sore taken. All dressing changes; materials used and time taken were recorded. A final assessment was made at 8 weeks or earlier if the patient participated in the study for less than 8 weeks.

Any adverse experiences were fully evaluated by the investigator and documented on the Adverse Event Report Form. Follow-up treatment and evaluation continued until the adverse experience cleared.

Statistical Analysis

Overall performance, pain, adherence, comfort, ease of removal was analysed by Wilcoxon Rank Sum Test. Rates of wound healing was analysed by Analysis of Variance and cost effectiveness (based on materials and labour cost and time) was analysed by Mann-Whitney Test.

Results

Both treatment groups were evaluated with respect to the following performance measures

1. Overall Dressing Performance
2. Rate of Wound Healing
3. Cost Effectiveness.

Overall dressing performance

The subjects were evaluated according to six dressing performance measures namely dressing adherence to wound bed, dressing adherence to surrounding skin, exudate handling ability, overall comfort, pain during dressing removal and overall ease of use. All favoured the CGF dressing by a statistically significant margin. (Table I)

Rate of wound healing

The wound surface areas were calculated from the acetate transparencies using an Optomax Image Analyzer. Subjects assigned CGF dressing experienced a mean 34 % reduction from their baseline surface area

measurement compared to a mean 9 % increase by subjects assigned Gauze dressings. This difference was not statistically significant ($p = 0.2318$).

Cost effectiveness

This was evaluated according to the mean dressing time as well as mean nursing cost for each subject throughout the 8 weeks study period. There was a statistical significance in favour of the CGF group as compared to the gauze groups. (Table II)

When the total cost of materials was included in the calculation of the cost of wound management per subject, there was no statistical significant difference ($p=0.12$) in the mean total cost of wound management per subject between DuoGerm CGF dressings (RM 271.45) and saline gauze dressings (RM 173.05).

Adverse Events

There were no adverse events reported against DuoDerm CGF. One subject developed wound infection while on saline gauze dressings.

Table I
Overall Dressing Performance

Parameter	DuoDERM CGF (n=17)	Saline Gauze (n=17)	p-value
a) Adherence to wound bed	Non-adherent 100%	Non-adherent 44%	< 0.01
b) Adherence to surrounding skin	Non-adherent 44%	Non-adherent 94%	< 0.01
c) Exudate handling ability	Good/Excellent 69%	Good Excellent 44%	< 0.019
d) Overall Comfort	Uncomfortable 0%	Uncomfortable 50%	< 0.01
e) Pain during dressing removal	Moderate/Severe 0%	Moderate/Severe 44%	< 0.01
f) Overall ease of use	Very Good/Excellent 62%	Very Good/Excellent 19%	< 0.01

Table II
Nursing Time and Cost

	n	Mean Dressing Time	Mean Cost
DuoDERM CGF	17	245.94 min	RM 45.89
Saline Gauze	17	564.29 min	RM 105.30
p-value		0.025	0.025

Conclusion

The basic principles of medical treatment of established pressure ulcers include improvement in the general health and nutrition, restoration of tissue perfusion by relief of pressure, maintaining a clean wound, preventing and treating infection and stimulation of granulation tissue. A wide range of topical dressings are marketed with claims in its efficacy in promoting wound healing with improved comfort and ease of use.

This clinical trial was carefully conducted to evaluate one such product - hydrocolloid occlusive dressing (DuoDERM CGF). The hydrocolloid dressing outperformed the saline gauze dressings by a statistically significant margin with respect to dressing adherence, comfort, ease of use, pain during removal and exudate handling capability. Although the hydrocolloid dressing rated more favourably with respect to rate of wound healing, this was not statistically significant. It may in part be due to the small sample size. It was obvious that the saline gauze dressings took up a lot of

nursing time and effort due to the necessity for frequent dressing changes; once daily or even more frequently in highly exudative wounds. This was backed by the statistical advantage shown towards hydrocolloid dressings with respect to nursing time and cost. However, this advantage was not reflected when the total cost of wound management per subject was evaluated. It is evident that the hydrocolloid dressings are expensive, thus off-setting the advantage these dressings have in terms of nursing time and cost. However, when one look at it from the patient's point of view, it offers both convenience and comfort with a good prospect of improved rate of wound healing.

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