ACTA DERMATO-VENEROLOGICA
SUPPLEMENTUM 149

Care of Pressure Sores: A Controlled Study of the Use of a Hydrocolloid Dressing compared with wet Saline Gauze Compresses

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Graphic design: Jerk-Olof Werkmäster
Printed in Sweden by Almqvist & Wiksell Tryckeri, Uppsala 1989

ALM A, HORNMARK AM, FALL PA, LINDER L, BERGSTRAND B, EHRNEBO M, MADSEN SM, and SETTERBERG G.

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An occlusive hydrocolloid dressing (Comfeel Ulcus) was compared with a conventional wet saline gauze dressing regarding the effect on ulcer cleansing and healing processes, experience of pain and the consumption of nursing time, in a controlled, randomized and partially single-blind study with parallel groups of long-stay patients with pressure sores. After a few weeks' treatment the relative decrease in ulcer areas with time was larger in the group treated with the hydrocolloid dressing. The difference was almost statistically significant at week 5 ($p=0.054$) and definite at week 6 ($p=0.006$). At week 6 the median remaining ulcer area in per cent of the initial area was 0% in the hydrocolloid dressing group and 31% in the group treated with saline gauze ($p=0.016$). Analysis of the healing distribution function showed the hydrocolloid dressing to be more effective, although the overall difference was non-significant ($p=0.15$). Care of the pressure sore took significantly less time with hydrocolloid dressings. *Key words: pressure sores, healing time, long-stay patients, nursing time, hydrocolloid dressings, occlusive dressings.*

Acta Derm Venereol (Stockh) 1989; Suppl 149

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The number of patients with pressure sores is rising concurrently with increasing expectations of life (1), since higher age results in more advanced diseases in need of hospital care. Scandinavian studies of the prevalence of pressure sores have shown rates of 3.0% among hospitalized patients (2) and 4% among patients in acute or long-term wards (3). The care of a patient with a pressure sore is time-consuming and often physically strenuous for the nursing staff and relatives (4, 5).

Pressure sores often occur as a complication of other illnesses. Many factors contribute to their development. The main one is external pressure on the skin, but shearing forces, friction, and continued moistening of the skin also play a large role (1, 6, 7, 8). The general condition of the patient is of course a factor of major importance.

If prevention fails and a pressure sore develops, the treatment aiming at healing of the ulcer has to be individually designed (1). Part of the regime is the topical treatment of the ulcer. Cleansing or debridement must be initially performed if soft or hard necrotic tissue is present, in order to control bacterial colonization and remove hindrances to tissue regrowth. When a clean ulcer base has been obtained, an optimum environment for tissue regeneration must be established.

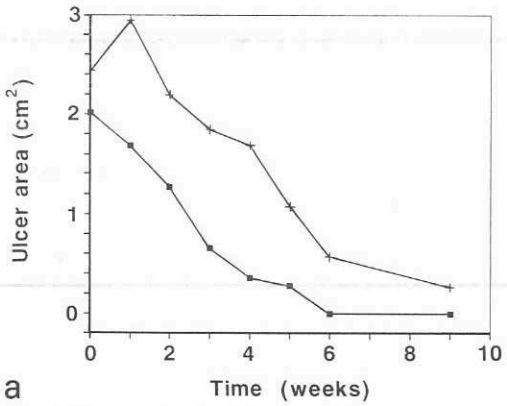
It has been pointed out that desiccation of the ulcer must be avoided (1) and that occlusive dressings are very suitable for this purpose and in general for establishment of a milieu which is favourable for tissue regeneration in acute and chronic wounds (9). A traditional dressing for care of pressure sores is wet to dry saline gauze (8, 10). In the present study an occlusive hydrocolloid dressing was compared with a wet saline gauze dressing regarding their effects in promoting debridement and healing of pressure sores and the consumption of nursing time for the ulcer care.

MATERIALS AND METHODS

Design of the study

The study was conducted as a controlled multicentre, partially single-blind trial with parallel groups. Long-term ward patients were randomly allocated to groups in which their pressure sores were to be dressed with either wet saline gauze dressings (changed routinely twice daily) or hydrocolloid dressings (changed when necessary). In the allocation procedure the condition of the patient (evaluated by the Norton rating scale (11)) was taken into consideration. The cutting point in this stratified randomization was a Norton score of less than or equal to 9. Patients with a Norton score of less than 7 were excluded from the study.

After randomization, all patients had their pressure sore dressed with wet saline gauze dressings for one week (regarded as a wash-out period). The ulcer was



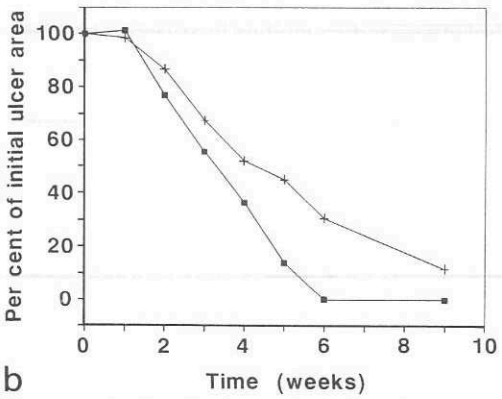


Fig. 1. Decrease in absolute and relative pressure sore area during care with hydrocolloid dressings (■) or wet saline gauze dressings (+). (*a*) Median ulcer area versus time. (*b*) Relative changes in ulcer areas with time (median values). The regression line for the median values during week 1 to week 6 for the hydrocolloid dressings group was $Y=118.7-20.4X$ ($r=0.998$), and for the saline gauze dressing group $Y=111.4-13.7X$ ($r=0.994$).

Statistics

The main part of the statistical analysis was performed by means of the software package SYSTAT (Systat Inc., Illinois, USA). Data referring to the individual pressure sore and the patient concerned were treated as one sample. Mean values, standard deviations (SD) and *t*-test were used when the values were apparently normally distributed. When values were not normally distributed, median values and lower and upper hinges were calculated (the hinge is the value where approximately 25% of the values are between the upper or lower range and the median value). The Mann-Whitney U-test was then used for probability evaluations. To test whether data should be treated as normally or non-normally distributed, the Kolmogorov-Smirnov one-sample test was applied. The healing outcome was analysed by means of the lifetest program in the SAS software package (SAS Institute Inc., Cary, USA). The probability outcome was analyzed by the log rank test. A two-tailed p value of ≤ 0.05 was accepted as statistical significance.

RESULTS

Ulcer area

The time courses of the median ulcer areas are shown in Fig. 1 *a*. It is seen that the median for the hydrocolloid dressing group was always lower than that for the saline gauze group. The difference between the groups was close to statistical signficance at week 5 ($p=0.054$) and was definite at week 6 ($p=0.006$).

The time courses of the relative ulcer areas (in per cent of the area of the individual ulcer on inclusion) are presented in Fig. 1 *b*. After one week of treatment hardly any difference was noted either within or between the groups. Thus, the median values of relative ulcer areas did not reflect the increase in absolute area of some of the ulcers dressed with saline gauze. During the period between 1 and 6 weeks of treatment, the median of the relative ulcer area seemed to decrease linearly with time. The healing rate was higher in the hydrocolloid dressing group and there was a statistically significant difference in the relative ulcer area at the 6th week, when the median value was 0% for the hydrocolloid dressing group and 31% for the group treated with saline gauze dressing ($p=0.016$).

Ulcer depth

The median depth of the pressure sores as estimated by the patient's doctor was lower in the hydrocolloid dressing group during the wash-out period and the first 5 weeks of treatment, but the difference was statistically significant only at week 4 ($p=0.047$). It was not possible to calculate and analyse the ulcer depths as a percentage of the individual initial depth, as the initial values were close to zero for several patients, introducing considerable interindividual variation.

Appearance of ulcers

The distribution of scores obtained in the blind evaluation of ulcer depth, extent of granulation and cleanness is illustrated in Fig. 2 *a–c*.

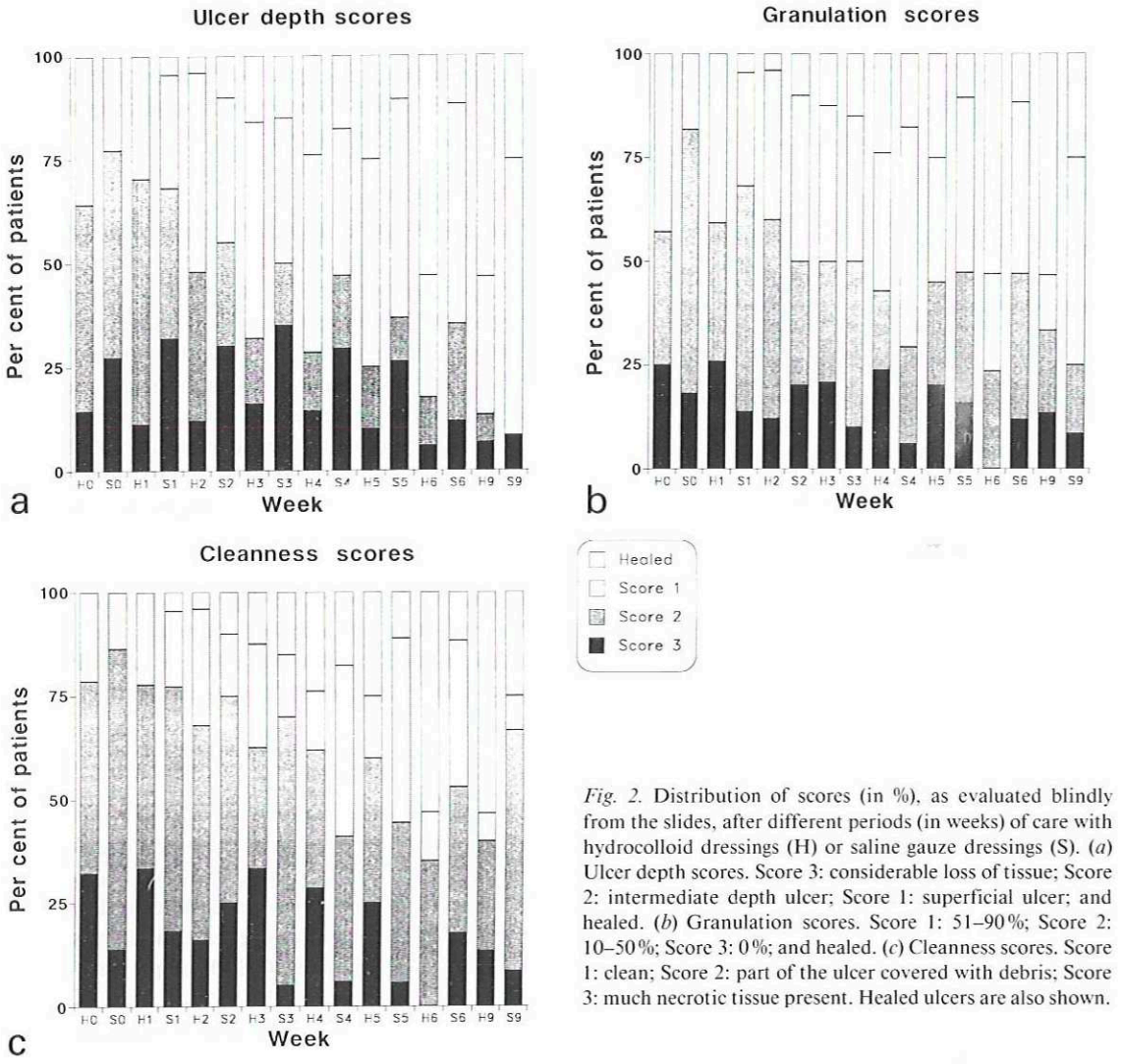


Fig. 2. Distribution of scores (in %), as evaluated blindly from the slides, after different periods (in weeks) of care with hydrocolloid dressings (H) or saline gauze dressings (S). (*a*) Ulcer depth scores. Score 3: considerable loss of tissue; Score 2: intermediate depth ulcer; Score 1: superficial ulcer; and healed. (*b*) Granulation scores. Score 1: 51–90%; Score 2: 10–50%; Score 3: 0%; and healed. (*c*) Cleanness scores. Score 1: clean; Score 2: part of the ulcer covered with debris; Score 3: much necrotic tissue present. Healed ulcers are also shown.

The time courses of ulcer depth and extent of granulation indicate that pressure sores dressed with the hydrocolloid dressing filled with granulation tissue more quickly than those dressed with saline gauze, but a difference was present already from week 0. Judging from the cleanness scores about one-third of the pressure sores were healed or clean after 2 to 3 weeks of treatment in both groups. Subsequently healing was faster in ulcers dressed with the hydrocolloid dressing.

The percentage number of patients showing no maceration was rather constant in the two groups. As the care period proceeded, there was a tendency towards more maceration in the saline gauze group.

The median value for the part of the ulcer that was covered with granulation tissue was larger in the hydrocolloid dressing group than in the saline gauze group at the start of treatment (Table III), but from week 1 and onwards the median areas were invariably lower in the hydrocolloid dressing group. However, the granulation tissue area per se is not a good indicator of the ulcer condition, since at the same time the majority of the ulcers in the hydrocolloid dressing group apparently healed faster (Fig. 2 *b*).

Quality of ulcer assessments

Twenty-nine of the slides were blindly assessed on two separate occasions. The mean ratio between the results of the two determinations of the total ulcer area was 1.03, with an SD of 0.09. The scores for the

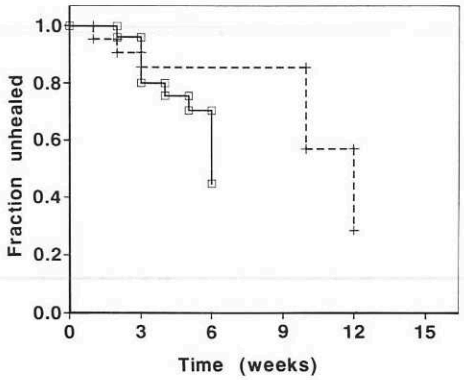


Fig. 3. Ulcer healing distribution function for the hydrocolloid dressing group (□—□) and the saline gauze group (+---+) as estimated with a survival analysis technique. The fraction of the patients in each group with unhealed ulcers is plotted against time in the ward, taking into account right censored values also. The overall significance level for the difference between groups was $p=0.15$.

depth of the ulcer were equal at the two assessments in 20 cases; the scores for percentage of ulcer area covered with granulation tissue were equal in 19 cases; the values for cleanness in 23 cases and the values for maceration in 17 cases.

Healing distribution function

The doctor's estimation of when the ulcer could be regarded as healed was analysed with a "survival" distribution technique. This method takes into account points in time when patients left the ward with unhealed ulcers ("right censored estimates"). Thus, the few data from late observations (i.e. week 12) could also be considered. Patients in the hydrocolloid dressing group had the most favorable healing distribution function (Fig. 3), although the overall difference compared with the saline gauze group appeared to be non-significant ($p=0.15$).

Consumption of nursing time

The recorded consumption of nursing time for changing of dressings was summed up each week. The median weekly time consumption decreased with time for both dressings during the initial cleansing and healing phase (Fig. 4), mainly because less time was required for cleansing of the undressed ulcer. The reason for the considerable difference in the weekly time consumption between the two dressing types is the difference in time intervals between changing of dressings. Wet saline gauze dressings were always changed twice daily, while the time intervals between the changes of the hydrocolloid dressing could be lengthened as the healing process proceeded. The difference in time consumption was statistically significant ($p<0.001$) every week.

Adverse reactions

Evaluation of pain at changing of dressings. Neither the patients nor the staff were of the opinion that the dressing change was painful at any stage. There were no apparent differences between the two groups.

General. The hydrocolloid dressing adhered quite tightly to the skin, thus retaining moisture and preventing seepage of secretion. During removal, the sheet occasionally pulled the skin slightly. If the patient had thin and frail skin more care had to be taken when removing the sheet. This problem could be lessened by use of a moistening skin cream before application of the sheet. In a few cases sticky fragments were formed when the dressing was removed. Treatment with the hydrocolloid dressing had to be stopped in one patient because the adhesiveness caused great pain when the dressing was to be changed.

DISCUSSION

The majority of pressure sores are superficial and can be managed with conservative therapy. The proportion of pressure sores that are able to heal without surgery depends on the patient material. In this study the ulcers had healed in 10–20% of patients in the saline gauze group and in 50–60% of patients in the hydrocolloid dressing group after 6 weeks of treatment.

Covering the pressure sore with an absorbent, occlusive dressing is a convenient way of achieving wound debridement and promoting subsequent healing. An environment favorable to tissue proliferation is thereby created and, in addition, the pressure sore and the surrounding skin are protected from friction and continued moistening. Continued moistening, most often caused by urinary incontinence and with resulting heavy maceration of the skin, disrupts the barrier function of the epidermis (4). In addition, the bacteria decomposing urine are assumed to break down the skin (12).

An important factor in practical, conservative pressure sore care is the length of the time intervals between changes of dressings. In the present study the time interval between changes of the hydrocolloid

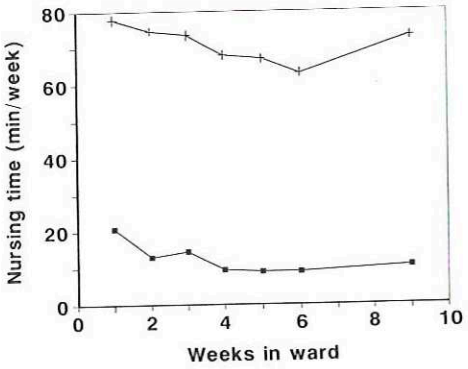


Fig. 4. Nursing time spent on pressure sore care (median values of recorded time (minutes) per ulcer per week) versus duration of treatment with hydrocolloid dressings (■) or saline gauze dressings (+). The numbers of ulcers treated with hydrocolloid and saline gauze dressings were as follows. Week 1: 28 and 22 respectively; week 2: 26 and 20; week 3: 24 and 18; week 4: 19 and 17; week 5: 19 and 17; week 6: 13 and 14; week 9: 8 and 5.

dressing was most often 3 to 4 days, and in the late stage of healing up to 7 days. Apart from the economic benefit obtained by reducing nursing time consumption (cf. Fig. 4), a regime involving a change of dressing once or twice a week can mean additional savings by making home care feasible, whereas two visits daily by a nurse may be impossible in communities in sparsely populated districts.

Most of the patients in this study were usual geriatric patients, in a stable nutritional condition and a proper hydration state. Serum albumin was not markedly low in any of the patients (Table I), but the mean haemoglobin concentration was around 120 g/l in both patient groups. This haemoglobin concentration is equal to the value below which Schell and Wolcott (12) have demonstrated that many ulcers are unable to heal.

The one-week "wash-out period" used in this study served the purpose of eliminating possible variable effects of earlier wound care. Usually no surgical debridement was performed before application of the hydrocolloid dressing or wet saline gauze, or during the observation period. The use of wet saline gauze during the pre-inclusion week resulted in some cleansing of the ulcers, but a considerable amount of debris was still present on initiation of the "real observation period".

The primary means for prevention of possible spread of infection from pressure sores is careful wound cleansing and debridement (13). The gentle debridement and rapid angiogenesis observed with both dressing types, in particular the hydrocolloid dressing (Fig. 2*c*), in the present study is likely to improve infection control in pressure sores.

None of the ulcers in the present study had symptoms of invasive bacterial growth during the observation period.

In a classical study (14) dealing with traumatic wounds in young persons and in a more recent study on leg ulcers (15), the rate of healing was found to be proportional to the current wound area, i. e. an exponential decline was seen when the wound area was plotted against time. In the light of this finding the apparently linear relation between ulcer area and time found in the present study, after an initial phase of unchanged or increasing area, is surprising. However, a slight curvature, corresponding to a declining healing rate, can be seen, and the apparent linearity of part of the curves is probably arbitrary. The initial phase of an unchanged or increased ulcer area can be ascribed to debridement of the ulcers, as the dressing removes necrotic tissue at the edges.

It has been suggested (16) that important efficacy end-points should be analysed by survival distribution methods, as is often done for occurrence of death, graft survival and side reactions. The main advantage of this method is that it considers overall healing during the entire observation period and also takes into account the events when patients leave the ward with unhealed ulcers. Although the overall group difference in this study was not significant, the same trend as in the ulcer area measurements was seen. We consider that survival distribution analysis would be most valuable in future ulcer care studies.

In conclusion, the hydrocolloid dressing used in this study (Comfeel Ulcus) showed many advantages over conventional treatment with wet saline gauze dressings. A larger number of the pressure sores treated with Comfeel Ulcus than with saline gauze treatment resolved or improved. Usually Comfeel Ulcus only required changing every three to five days, which meant a considerable saving in nursing time.

ACKNOWLEDGEMENT

We wish to express our thanks to the staff at the participating centres: Stureby Hospital, Enskede; Valla Hospital, Linköping; Kungsgärdet Hospital, Uppsala; Tierp Hospital, Tierp; Kronparkens Hospital, Uppsala; Tunåsen Hospital, Uppsala; and Enköping Hospital, Enköping.

We are especially grateful to Gerd Egnestam at Stureby Hospital for her assistance in this study.

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