Original Article

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Prospective Study on Local Wound Management of Pressure Ulcers in a Critical Colonization State

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Abstract

Aims

Critical colonization has attracted attention as a cause of delayed healing of pressure ulcers. However, there is no clear strategy for local wound management in such cases. Here, we prospectively investigated exudate, infection, and pressure ulcer status in a critical colonization state to determine the optimal strategy for local wound management of such pressure ulcers.

Methods

This prospective cohort study was conducted in three facilities: a university hospital, a general hospital, and a long-term care hospital. Subjects were patients with pressure ulcers at a depth deeper than the dermis with a diagnosis of critical colonization by a dermatologist or wound ostomy continence nurse. Patients were divided into three groups according to local wound management: Group A, hydrating ointment with infection control or low exudate-absorption dressing material; Group B, high exudate-absorption dressing material; and Group C, hydrating ointment with exudate-absorption and infection control. Exudate, the moisture of the surrounding wound skin, stratum corneum hydration, area of biofilm, bacterial count, and wound severity assessed by DESIGN-R, were measured at baseline and at 1 week. The relative changes in these variables at 1 week were calculated for the analysis.

Results

Overall, 16 patients were classified into Group A ($n = 7$), Group B ($n = 5$), and Group C ($n = 4$). The patients in all three groups ranged in age from 78 to 86 years old and ≥ 50% were male. At baseline, the median proportion of wound area covered by the biofilm was similar between the three groups (0.50, 0.59, and 0.30, respectively). The median total DESIGN-R score in Group A was lower than those in the other groups (12, 24, and 21.5, respectively). With regard to the changes after 1 week, the proportion of wound area covered by the biofilm in Group C was larger than those in the other groups (-0.18, -0.27, and -0.87, respectively). However, the change in total DESIGN-R score in Group C was smaller than those in the other groups (-0.12, -0.11, and -0.01, respectively).

Conclusion

Changes in infection and pressure ulcer status in cases of critical colonization were described according to local wound management. However, due to the small number of patients, it was not possible to determine the most appropriate local wound management for pressure ulcers in a critical colonization state.

KEY WORDS

critical colonization, biofilm, pressure ulcer, exudate, infection control

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Introduction

The process of pressure ulcer healing involves four stages: blood coagulation, inflammation, proliferation, and maturation. Healthcare personnel involved in pressure ulcer management are expected to accelerate these four stages. Local wound management is based on the TIME theory wherein interventions for the following four conditions are involved: non-viable or deficient tissue (T), infection or inflammation (I), moisture imbalance (M), and edge of wound non-advancing or undermined epidermal margin (E)[1].

Infection is one of the factors that deteriorate pressure ulcers, and persistent inflammation caused by infection impedes the healing of pressure ulcers. The clinical guidelines of the Japanese Society of Pressure Ulcers recommend the use of a mixture of povidone–iodine solution, sugar, and cadexomer iodine (topical ointments for infection control) in cases in which the four cardinal signs of inflammation (erythema, raised local temperature, swelling, and pain) are present[2].

Critical colonization, a condition characterized by the absence of evident symptoms of infection, has recently evoked attention as a cause of delayed healing of pressure ulcers in clinical settings. Critical colonization represents an intermediate state between colonization and overt infection marked by higher bacterial counts than those observed in a colonization state[3]. In the presence of critical colonization, pressure ulcers are assumed to form a biofilm and to be transitioning toward overt infection. A biofilm is a membrane formed by bacteria and extracellular polysaccharides secreted by the bacteria that covers the bacterial surface. This membrane exhibits strong resistance to phagocytosis by neutrophils and macrophages and antimicrobial therapy[3]. Therefore, the removal of exudates, a source of nutrients for bacterial growth, and elimination of biofilms are believed to accelerate the healing of pressure ulcers in a critical colonization state.

There are some contentious issues pertaining to the local wound management of pressure ulcers in a critical colonization state. The use of ointments with anti-infective properties to intervene with the critical colonization in accordance with the TIME theory leads to the failure of the epithelium to reach the wound edge and wound healing delay. A case report documented acceleration of healing with the use of polyurethane/silicone foam dressings with no antimicrobial effect on the exudates in pressure ulcers that exhibited no obvious signs of infection[4]. On the other hand, another study reported faster healing in patients in whom antibacterial wound dressings were used for pressure ulcers with no obvious signs of infection following necrotic tissue resection than in patients in whom antibacterial wound dressings were not used[5]. In these previous studies, the relationship between local wound management and biofilm elimination/exudate removal was not clarified. Thus, the type of local wound management methods to be selected for pressure ulcers in a critical colonization state remains unclear.

It is evident that there is no clear policy for the local management of pressure ulcers in a critical colonization state. In this study, we prospectively investigated exudates, infections, and pressure ulcer conditions associated with the use of different local wound management methods.

Setting

1. Participating Health Facilities

This study was conducted across three health facilities in Japan: a university hospital in Tokyo, a general hospital in Kanagawa Prefecture, and a long-term care hospital in Ishikawa Prefecture. All three facilities had a pressure ulcer team that performed regular visits for pressure ulcer management. The pressure ulcer teams included wound ostomy continence nurses (WOCNs) specifically trained in pressure ulcer prevention and management. During visits, the WOCNs performed pressure ulcer risk assessments and recommended preventive measures based on patients' conditions. In these facilities, decisions on local wound management of pressure ulcers were made by doctors and the WOCNs belonging to the pressure ulcer teams based on the DESIGN-R[6] scoring system.

2. Subjects

The study subjects included patients with pressure ulcers at a depth deeper than the dermis who were diagnosed as being in a critical colonization state by a dermatologist or WOCN. Only patients who provided consent for participation in the study and who had been hospitalized for more than 2 weeks were included. Patients with poor general conditions for whom it would have been too difficult to participate in this study

were excluded.

3. Study Design

In this prospective cohort study, exudates, infections, and pressure ulcer conditions were assessed at two time points: at baseline and after 1 week.

4. Measurement

1) Characteristics of Subjects

Characteristics included age, sex, and medical facility type based on the Ministry of Health, Labor and Welfare classification[7] and Braden Scale scores[8]. These data were collected from medical records obtained during the first survey. The Braden Scale scores were assessed by one researcher.

2) Characteristics of Pressure Ulcers

Pressure ulcers were evaluated based on the location, DESIGN-R score, and wound area. DESIGN-R is a tool developed by the Japanese Society of Pressure Ulcers for assessing the severity of pressure ulcers and evaluating the healing process. The severity is assessed by the total scores for exudate (E), size (S), inflammation/infection (I), granulation (G), necrotic tissue (N), and pockets (P), with higher total scores on the six items indicating greater severity. Scoring is performed based on a clinical evaluation and photographs captured using a digital camera. In this study, scoring was performed by a single researcher, a WOCN. The digital photographs were imported into a personal computer, and the wound area was measured using the image analysis software Image J1.51 (Image J).

3) Exudate Volume and Stratum Corneum Hydration

Exudate volume was measured by the ESTimation method[9]. Scores were calculated by a single researcher. This method involves the estimation of daily exudate volume (mL) using a regression equation employing several sub-scores of DESIGN-R. The E (exudate), S (size), and T (total score) items of DESIGN-R were used as the parameters for the regression model.

The stratum corneum hydration of the skin surrounding pressure ulcers was measured at four points: 12, 3, 6, and 9 o'clock positions (Figure 1). The measurement site was set at a distance of 1.5 cm from the wound edge, and a healthy site unaffected by exudates was set as the control site to compare the stratum corneum hydration of the skin surrounding the wound. A healthy site was defined as an area not affected by wound dressings or exudates; therefore, the measurement site was set at a position 10 cm from the proximal wound edge. A portable moisture meter (Mobile MoistureHP10-N®, Integral Co.) was used as the measuring device. The device was shown to exhibit good intra-observer reliability (intra-class correlation coefficient (ICC): 0.97–0.99][10]. Measurements were performed in triplicate by a single researcher, and the median value was recorded for analysis.

The difference between the stratum corneum hydration of the healthy skin and that of the skin surrounding the pressure ulcer was calculated. The sum of the positive difference values of the four measurement sites and that of the negative difference values of the measurement sites were calculated for separate sites. In other words, a larger sum of the positive values indicated greater stratum corneum hydration of the wound area than the healthy site, while a larger sum of the negative values indicated lower hydration of the wound area than the healthy site.

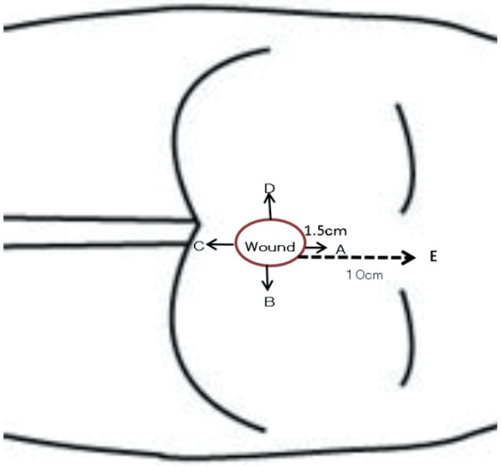

Fig.1 Measurement site for moisture level of the stratum corneum
A：12 o'clock, B：3 o'clock, C：6 o'clock, D：9 o'clock, E：Healthy site
The moisture level of the stratum corneum of the skin surrounding the wound was measured at four points(A-E). The measurement site was considered 1.5 cm from the wound periphery. A healthy site was defined as a site unaffected by the dressing and exudate. The measurement site was considered 10 cm cranial from the wound periphery.

4) Infection-state pressure ulcers

Infection-state pressure ulcers included the biofilm area and bacterial count on the wound surface. To identify the biofilm distribution, wound exudate was collected by wound blotting[11] (Figure 2). The biofilm

area was measured by the following procedure. The wound area was determined using a protein staining kit. Next, after decolorizing the protein stain, the wound area was stained with ruthenium red, which reacts with extracellular soluble polysaccharide (ESP), a component of biofilms. The area that exhibited brown to dark red staining was defined as the biofilm area. The stained membrane was captured using a scanner. The proportion of biofilm occupying the wound was measured, and its area was measured using Image J.

The bacterial count in 1-mL samples of the specimens obtained from the wound surface was measured using a bacteria counter (Panasonic Healthcare Holdings Co). A single researcher performed the entire process, from sample collection to bacterial count measurement. A supplied pressure specimen sampling device was used to apply a constant pressure during the swab method, and the wound surface was scraped three times to collect specimens for measurement[12].

5. Procedure

Data collection was conducted during bedside visits by the pressure ulcer team using the following steps: 1) patients were positioned such that the procedures performed did not cause them distress; 2) their clothes were removed; 3) their wound dressings were removed; 4) the skin surrounding the wound was wiped using gauze; 5) stratum corneum hydration was measured; 6) the wound was cleansed with sterile physiological saline; 7) wound blotting was performed; 8) bacterial count was measured on the wound; 9) the wound and surrounding skin were cleansed by hot water and soap; 10) photographs of the pressure ulcers were taken; 11) scoring was performed by DESIGN-R; and 12) local wound management was performed.

6. Analytical Method

The subjects were divided into three groups and analyzed. Group A consisted of patients in whom topical medication for hydration and infection control or dressing material with low exudate absorption was

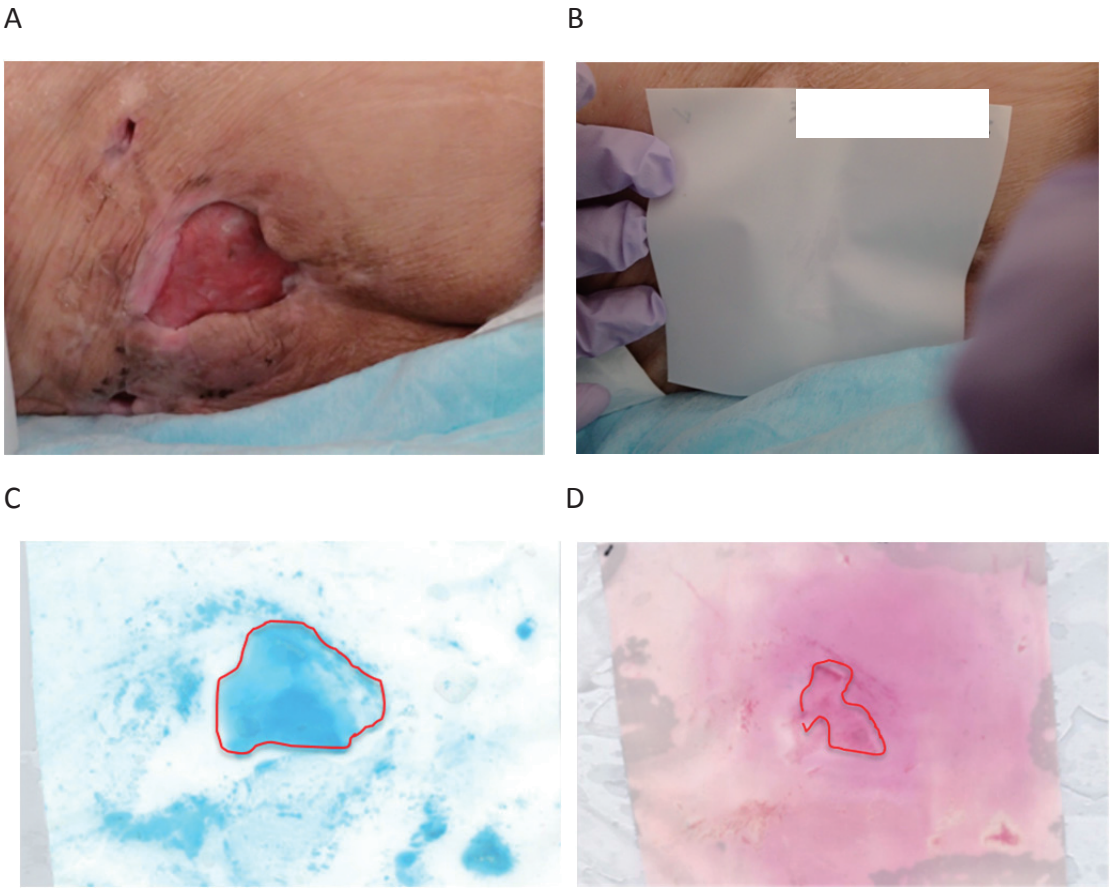

Fig.2 The wound blotting method for detecting biofilm in the wound bed
A: Wound bed B: Attached membrane to the wound bed C: Blue staining indicates protein positive area. D: Brownish-red to dark-red staining indicates biofilm positive area.

used. Group B consisted of those in whom dressing material with high exudate absorption was used. Finally, Group C consisted of those in whom topical medication for exudate absorption and infection control was used.

Changes related to exudates, infections, and pressure ulcer conditions after 1 week were calculated using the following formula: Relative value of change after one week = (second measurement value − baseline value) / baseline value.

Descriptive statistics were shown as median (range) values or n(%) using SPSS ver.21 and Excel Statcel 3.

7. Ethical Consideration

Written informed consent was obtained from all subjects or family members prior to their enrolment. The study was approved by the Kanazawa University School of Medicine Ethics Review Committee (Approval number 533-1).

Results

1) Characteristics of Subjects and Pressure Ulcers

Overall, 16 patients were classified into Group A (n = 7), Group B (n = 5), and Group C (n = 4). The median age of the three groups ranged from 78 to 86 years old, and 50% or more of patients were male. About 70% of the Group A patients were inpatients of the general hospital. In contrast, 60% of the Group B patients and 75% of the Group C patients were inpatients of the long-term care hospital. The median total Braden score of Group A was higher than those of the other groups (16 vs. 10 vs. 10.5) (Table 1). Regarding the

Table1. Characteristics of the subjects

Characteristic	Group A(n=7)	Group B (n=5)	Group C (n=4)
Age (years) medians (range)	78 (55–89)	86 (78–93)	84 (77–91)
Sex, n (%)			
Male	4 (57)	3 (60)	2 (50)
Female	3 (43)	2 (40)	2 (50)
Type of medical facility[a], n , (%)			
Long-term care hospital	0 (0)	3 (60)	3 (75)
General hospital	5 (71)	1 (20)	1 (25)
Special functioning hospital	2 (29)	1 (20)	0 (0)
Braden scale medians (range)			
Sensory perception	4 (2–4)	2 (1–4)	2 (1–3)
Moisture	3 (3–4)	3 (3–4)	3 (3–3)
Mobility	2 (1–3)	1 (1–2)	1.5 (1–3)
Activity	2 (1–4)	1 (1–3)	1 (1–2)
Nutrition	3 (2–4)	2 (2–2)	1.5 (1–2)
Friction & Shear	2 (1–2)	1 (1–2)	1 (1–2)
Total	16 (10–18)	10 (9–17)	10.5 (8–14)

Group A: hydrating ointment with infection control or low exudate-absorption dressing material, Group B: high exudate-absorption dressing material, Group C: hydrating ointment with exudate-absorption and infection-control action.
a: The type of medical facility was classified according to hospital functions, as provided by the Ministry of Health, Labor and Welfare.
Long-term care hospital (having medical treatment sickbeds): A hospital that has sickbeds to hospitalize patients who mainly require long-term medical treatment.
General hospital: Any hospital except a hospital having only a mental sickbeds and a hospital having only a tuberculosis sickbeds.
Special functioning hospital (university hospital): A hospital that the Ministry of Health, Labor, and Welfare approves as a hospital with extensive medical offerings, med-tech development, and staff placement that possesses the ability to perform training in severe medical care and has appropriate structural facilities.

Table2. Pressure ulcer site and local wound management

	Group A(n=7)	Group B (n=5)	Group C (n=4)
Pressure ulcer site*, n, (%)			
Trunk	5 (71)	4 (80)	2 (50)
Lower limb	2 (29)	1 (20)	2 (50)
Local wound management	Polyurethane foam 4	Polyurethane foam/soft silicone 5	Sucrose Povidone-Iodine 2
	Hydrocolloid 1		Dry gauze 2
	Sulfadiazine silver 2		

*Trunk: sacrum, ilium, tuber ischiadicum. Lower limb: heel, malleolus, greater trochanter, fibula.
Group A: hydrating ointment with infection control or low exudate-absorption dressing material, Group B: high exudate-absorption dressing material, Group C: hydrating ointment with exudate-absorption and infection-control action.

Table3. Exudate, infection, pressure ulcer state, and wound size at baseline

Outcome measurement	Group A(n=7)	Group B (n=5)	Group C (n=4)
Exudate			
ESTimation method (ml)	0.2 (0.24-4)	4 (0.2-9)	2.1 (0.2-9)
Difference between measured values on skin surrounding wound and the healthy site			
Sum of the positive values	25.5 (12-89)	34 (0-128)	37 (20-54)
Sum of the negative values	32 (7-65)	31(1-48)	87.2 (8-169)
Infection			
Biofilm area, (mm^2)	27.97 (5.54-154.49)	323.34 (259.48-349.89)	287.14 (255.26-472.88)
Proportion of the wound area covered by the biofilm	0.50 (0.1-0.83)	0.59 (0.25-1)	0.30 (0.15-0.76)
Wound surface bacterial count (cfu/mL)	$3.53*10^5$ ($1.0*10^5$-$5.66*10^6$)	$1.5*10^5$ ($1.0*10^5$-$5.81*10^6$)	$1.0*10^5$ ($1.0*10^5$-$1.82*10^6$)
Pressure ulcer state : DESIGN-R			
Depth	2 (2-3)	3 (2-3)	3 (2-4)
Exudate	1 (0-3)	3 (1-3)	3 (1-3)
Size	3 (1-8)	12 (6-12)	7 (6-12)
Inflammation/Infection	0 (0-0)	0 (0-1)	0 (0-1)
Granulation tissue	4 (0-5)	3 (1-5)	4.5 (3-6)
Necrotic tissue	3 (0-3)	0 (0-3)	4.5 (0-6)
Pocket	0 (0-0)	0 (0-12)	0 (0-9)
Total	12 (4-17)	24 (9-30)	21.5 (15-27)
Wound size(mm^2)	99.71 (9.4-258.46)	701.3 (546.7-1028.6)	913.14 (622.21-1977.1)

・Data were presented as median (range)
Group A: hydrating ointment with infection control or low exudate-absorption dressing material, Group B: high exudate-absorption dressing material, Group C: hydrating ointment with exudate-absorption and infection-control action.

pressure ulcer site, the most predominant site was the trunk in Groups A and B (71% and 80%, respectively). In contrast, the percentage of trunk pressure ulcers in Group C was 50% (Table 2).

2) Baseline Exudates, Infections, and Pressure Ulcer Conditions

At baseline, the median exudate ranged from 0.2 to 4 (mL). The difference in the stratum corneum hydration between the healthy skin and the skin surrounding the pressure ulcer ranged from 25.5 to 37 in the sum of the positive value. However, the negative value of Group C was higher than those of Groups A and B (32 vs. 31 vs. 87.2). With regard to the infection state, the proportions of the wound area covered by the biofilm were similar (0.50 vs. 0.59 vs. 0.30). Moreover, the bacterial count values of each group were similar. The median total DESIGN-R score of Group A was lower than those of the other groups (12 vs. 24 vs. 21.5) (Table 3).

3) Relative value of change after 1 week

The median exudate change rate was 0 in each group. With regard to the change rate of the difference in the stratum corneum hydration, the sum of the negative value of Group A was 0.52, while those of Groups B and C were different (-0.97 and -0.87, respectively). The proportion of the wound area covered by the biofilm of Group C was larger than those of the other groups (-0.18 vs. -0.27 vs. -0.87). However, the relative value of change of the total DESIGN-R score of Group C was smaller than those of the other groups (-0.12 vs. -0.11 vs. -0.01) (Table 4).

Discussion

In this study, we prospectively investigated exudates, infections, and pressure ulcer conditions in a critical

Table4. Change rate of each measurement after a week

Outcome measurement	Group A(n=7)	Group B (n=5)	Group C (n=4)
Exudate			
ESTimation method	0 (−0.95−0)	0 (−0.98−3)	0 (0−0.5)
Difference between the measured values on the skin surrounding the wound and the healthy site			
Sum of the positive values	−1 (−4−2)	−0.69 (−0.93− −0.26)	−0.23 (−1−0.54)
Sum of the negative values	0.52 (0.08−1.18)	−0.97 (−1−0.27)	−0.87 (−1− −0.47)
Infection			
Biofilm area	−0.57 (−1−0.66)	−0.97 (−1−1.72)	−0.23 (−0.54−0.64)
Proportion of the wound area covered by the biofilm	−0.18 (−1−1.3)	−0.27 (−1−2.34)	−0.87 (−0.22−1.07)
Wound surface bacterial count	0 (−0.25−0)	0 (−57.1−0)	−0.25 (0.05−1)
Pressure ulcer state : DESIGN−R			
Depth	0 (−0.33−O)	0 (0−0)	−0.13 (−0.25−0)
Exudate	0 (−0.5−2)	0	0 (−0.67−0)
Size	0 (−0.25−2)	0 (−0.5−0)	0 (−0.25−0)
Inflammation/Infection	0 (0−0)	0 (−1−0)	0 (−1−0)
Granulation tissue	0 (−0.5−0)	0 (−0.67−0)	−0.17 (−0.67−0)
Necrotic tissue	0 (−1−0)	0 (0−0)	0 (0−0)
Pocket	0 (0−0)	0 (0−0)	0 (0−0.33)
Total	−0.12 (−0.38−0.13)	−0.11 (− 0.44− 0)	−0.01 (−0.21−0.16)
Wound size	−0.26 (−1− −0.04)	−0.34 (−0.8− −0.09)	−0.30 (−0.61−0.64)

・Data were presented as median (range)
Group A: hydrating ointment with infection control or low exudate-absorption dressing material, Group B: high exudate-absorption dressing material, Group C: hydrating ointment with exudate-absorption and infection-control action.

colonization state to determine the optimal strategy for the wound management of such pressure ulcers. In clinical settings, the selection of the appropriate local wound management method for the infection control of pressure ulcers in a critical colonization state is a challenge for medical personnel. To the best of our knowledge, no previous studies have used biofilm related to critical colonization as a parameter for evaluation. In this study, we measured biofilms directly using wound blotting and observed whether they were eliminated following local wound management.

Unlike Groups B and C, Group A showed a positive tendency with respect to the sum of negative values after 1 week. A positive trend suggests the leakage of exudates into the surrounding area and their adherence to the surrounding skin. On the other hand, a negative trend suggests that exudates are persisting within the wound or are being absorbed by dressing materials. These results might depend on the effects of exudate absorption in each local wound management case. In a previous report, the condition of a pressure ulcer was shown to improve with a decrease in transepidermal water loss using gauze or wound dressing[13]. This report also suggested that local wound management affected the condition of the skin surrounding the pressure ulcers. The positive trend observed in Group A is likely attributable to the use of an ointment with a hydrating base, hydrocolloid dressing, and hydropolymer, contributing to the maintenance of a moist environment. Further, the negative trend observed in Group B is probably attributable to the use of wound dressing materials that absorbed and retained the exudate. Similarly, in Group C, the use of an ointment that absorbed moisture and dressing materials that absorbed the exudate likely led to the negative trend.

Regarding the local management of critical colonization, to date, the four elements of the TIME theory have been considered important for the local wound management of pressure ulcers. In the absence of any obvious signs of infection (i.e., a critical colonization state), a moist environment is often selected to promote healing. However, in this study, the treatment method used in Group A involved local wound management to hydrate and maintain a moist environment, which may not promote the healing of pressure ulcers in a critical colonization state. In our view, regarding the use of an antimicrobial ointment, it has been suggested that ointment with moisture-absorbing action, but not hydrating action, may accelerate healing in a critical colonization state.

The limitations of this study include the limited number of patients, low number of assessment time points, and study design. Future studies with larger sample sizes and more frequent measurements are required.

Conclusion

In this study, changes in infection and pressure ulcer status in a critical colonization state were described for each local wound management case. However, because of the small number of patients, we could not reveal the appropriate local wound management method for pressure ulcers in a critical colonization state.

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クリティカルコロナイゼーション状態の褥瘡の局所管理に関する前向き調査

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要　旨

【目的】クリティカルコロナイゼーションは、褥瘡の治癒遅延の原因として、最近注目を受けている。しかし、クリティカルコロナイゼーション状態への局所管理に関する対策は明らかでない。この研究において、私たちは、クリティカルコロナイゼーション状態の褥瘡の局所管理の最適な方法を検討するために、滲出液、感染と褥瘡状態を前向きに調査した。

【方法】本研究は、前向きコホート研究であり、大学病院、総合病院、長期ケア病院の 3 施設で実施した。対象者は、皮膚科医師または皮膚・排泄ケア認定看護師によって真皮より深い褥瘡で、かつクリティカルコロナイゼーション状態であると判断された褥瘡を有する入院患者である。患者は、局所管理方法によって 3 つの群に分けられた：A 群（補水と感染制御作用がある外用薬または滲出液吸収作用の低いドレッシング材）;B 群（滲出液吸収作用が高いドレッシング材）;C 群（滲出液吸収作用と感染制御作用がある外用薬）。滲出液、褥瘡周囲皮膚と健常皮膚の角質水分量、バイオフィルム面積、褥瘡表面の細菌数と DESIGN-R による褥瘡状態得点を、ベースラインと 1 週間後に測定した。これらの変数の 1 週間後の変化量の相対値により分析した。

【結果】全 16 例の患者は、A 群（n = 7）、B 群（n = 5）、C 群（n = 4）に分類された。3 群の年齢の中央値は 78 〜 86 歳であった。また患者の 50% 以上は男性だった。ベースライン時に、バイオフィフムの面積が創面の面積に占める割合の中央値は同程度であった (0.50 vs. 0.59 vs. 0.30)。さらに、A 群の DESIGN-R 総点の中央値は、他の群より低かった (12 vs. 24 vs. 21.5)。一方、1 週間後の変化量の相対値は、バイオフィフムの面積が創面の面積に占める割合は C 群が他の群より大きかった（-0.18 vs. -0.27 vs. -0.87)。DESIGN-R の合計点は C 群が他の群より低かった（-0.12 vs. -0.11 vs. -0.01)。

【結論】本研究では、褥瘡の局所管理方法別に、バイオフィルムの面積、バイオフィルムの面積が創面の面積に占める割合、褥瘡表面の細菌数、DESIGN-R による創傷治癒過程を記述した。しかし、症例数が少なく、クリティカルコロナイゼーションの褥瘡の管理方法を明らかにすることはできなかった。