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Original Article

Plastic wrap as a dressing material to treat stage II pressure ulcers: a randomized controlled trial to evaluate plastic wrap dressing treatment versus standard treatment

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Abstract: The treatment efficacy of using plastic food wrap as a dressing material was compared to that of standard treatment using hydrocolloid dressing for treating pressure ulcers; scored by the National Pressure Ulcer Advisory Panel stage II. This 12-week open-label randomized controlled trial was conducted in 10 wards of a hospital and two care facilities. The primary measurement outcome was the time to complete epithelialization of the wound. The secondary measurement outcome was the proportion of patients whose pressure ulcers had not healed during the study period, determined using Kaplan-Meier analysis and log-rank test. Of the 230 participants enrolled, 110 were randomly allocated to the plastic wrap dressing treatment group and 120 to the standard treatment group; of these, 108 and 118 patients were analyzed, respectively. The mean (± standard deviation) period required to achieve complete epithelialization in the plastic wrap dressing treatment group was 3.44 ± 3.16 weeks (95% confidence interval [CI]: 2.83-4.04), while that in the standard treatment group was 3.45 ± 3.27 weeks (95% CI: 2.85-4.05). This difference was not significant (P=.974); the 95% CI of the difference was -0.83-0.86. The Kaplan-Meier curves of both treatment groups were similar; no statistical difference was detected (P=.797). The incidence of adverse events was comparable between the groups. Our hypothesis that plastic wrap dressing is more effective than modern dressings was rejected. However, the findings prompted the formulation of a new hypothesis that plastic wrap dressing treatment is equivalent to standard treatment using modern dressings for the management of stage II pressure ulcers.

Keywords: Dressing, food wrap, plastic wrap, pressure ulcer, randomized controlled trial, treatment

Introduction

Plastic food wrap has been successfully used as a dressing material to treat pressure ulcers, scored by the National Pressure Ulcer Advisory Panel [1] (NPUAP) as stage II, III, and IV pressure ulcers in Japan [2-7]. Even though the method is uncommon in many other countries, it has been accepted in many Japanese hospitals and care facilities because it is effective, easy to apply, and inexpensive [3, 5].

The procedure for this treatment is simple [2, 4, 8]: non-sterile plastic wrap is fixed using nonwoven tape. The weak adhesion of the tape ensures that part of the dressing can come away easily, allowing excess exudate to drain away from the wound. Therefore, pressure on the wound is reduced, bacterial bioburden is controlled, and a moist environment, which promotes wound healing, is adequately maintained. In other words, plastic wrap dressing treatment is based on the theory of wound bed preparation [9] and moist wound healing [10, 11].

Two randomized controlled trials have investigated plastic wrap dressing treatment. One compared the efficacy of plastic wrap dressing treatment to that of the Japanese guideline

adhesion treatment for NPUAP stage II/III pressure ulcers. The results found no significant difference between the two treatment groups [8]. The other trial demonstrated that plastic wrap dressing treatment was superior to the standard treatment for the management of stage III/IV pressure ulcers in the inflammatory phase [12]. However, no randomized controlled study has examined the effect of plastic wrap treatment on stage II pressure ulcers only.

The present study compared the effectiveness of plastic wrap dressing with that of standard modern dressing treatment in the management of stage II pressure ulcers. We hypothesized that plastic wrap dressing is more effective than the standard treatment.

Methods

Trial design and participants

This 12-week, prospective, randomized, parallel-group, active controlled trial was conducted between May 2005 and May 2016. The study had an open-label design because it was impossible to mask the participants and medical practitioners to the intervention. The Institutional Review Board approved the protocol, and the study was conducted in accordance with the Declaration of Helsinki and its amendments. Written informed consent was obtained from the study participants or their family members, where relevant.

The study participants were recruited from patients in 10 different wards of a Japanese psychiatric hospital and two other care facilities. Patients aged 20 years or older with stage II pressure ulcers, according to the NPUAP guideline [1], were considered for inclusion. Eligible participants had pressure ulcers in the red proliferation phase measuring between 4 and 36 cm^2. In patients with several pressure ulcers, the largest was selected.

Participants were excluded if they had a skin ulcer due to other causes, such as peripheral arterial occlusive disease, skin cancer, or poorly controlled diabetes (HbA1c > 10%, measured at registration). Those undergoing treatment with corticosteroids, immunosuppressants, cytotoxic agents, or radiotherapy were also excluded.

The baseline parameters included age, sex, mental disorder, systemic disease (including systemic infection, diabetes, and malignancy), hemoglobin, serum albumin, Braden Scale [13, 14] score, and surface area and location of the pressure ulcer. After these baseline characteristics were obtained, consenting participants were randomized at a ratio of 1:1 to the plastic wrap dressing or modern dressing group using simple randomization. This group allocation was performed by the registration center, which was independent of the hospital wards and care facilities.

Intervention

Procedure for plastic wrap dressing treatment [2, 4, 8]: The wound was covered with non-sterile plastic wrap of suitable size. Non-woven adhesive tape was used to fix the four sides of the plastic wrap. When excess exudate accumulated under the dressing, the weak adhesive power of this tape allowed part of this dressing to come away easily, thus ensuring that excess exudate drained away from the wound. As such, the wound was not completely occluded, so an adequately moist environment for wound healing was maintained and the plastic's lack of air permeability was mitigated.

Necrotic tissue was mainly removed by autolytic debridement, which was promoted by the moist environment [15]. In the early stage of treatment, plastic wrap dressing causes a foul odor and copious yellow exudate. However, these are not usually signs of infection or aggravation of the wound. With frequent dressing changes, the yellow exudate becomes translucent, and the amount of exudate and foul odor are reduced within a week without the use of antibiotics. The frequency of dressing changes depended on the amount of exudate. In general, dressings were exchanged once a day throughout the present study.

Procedure for standard treatment [7, 16, 17]: In the standard treatment group, hydrocolloid dressing (HCD) was used in the present study. The dressings were changed twice per week on average. The dressing was exchanged more frequently when excess exudate accumulated under it.

Common treatment procedures [7, 16-19]: The wounds were cleansed using plenty of tap

water or saline, and devitalized tissue was removed when the dressings were exchanged. Depending on the level of risk according to the Braden scale, prevention protocols were implemented by a committee for the prevention and management of pressure ulcers. This committee was independent of the present trial. Specialized mattresses, overlay, and seat cushions were used for pressure redistribution, according to the patients' needs.

Outcome measurements

The primary outcome measure was the time to complete epithelialization of the wounds. The surface area of the ulcer was measured at baseline and every subsequent week using a digital camera. In every case, this measurement was performed by the same investigator who was unaware of the treatment allocation. If the wound had not healed by 12 weeks or if the patients were lost to follow-up before their wound had completely epithelized, the time to complete epithelialization was recorded as 12 weeks.

As secondary outcomes, the Kaplan-Meier analysis curves were compared between treatment groups, with the period until pressure ulcer healing as the end point; in addition, the incidence of adverse events was recorded, including wound deterioration, local or systemic infection, maceration, and hypergranulation.

Sample size and statistical analysis

To detect a 1.0-week difference in the mean healing time between the groups, with a standard deviation of less than 2.5 weeks in both groups, an alpha level of 0.05, and a study power of 0.80, 199 participants were needed. In addition, to allow for a 10% loss to follow-up rate and unbalanced allocation, a sample size of 230 was determined. This estimate was based on our clinical experience and the results of previous studies [5, 8]. All analyses were performed using Stat View version 5.0 (SAS Institute Inc., USA) and EZR [20, 21] (Saitama Medical Center, Jichi Medical University, Saitama, Japan). The statistical analyses were performed on an intention-to-treat basis. The unpaired Student's t-test was used to compare the healing time between the groups. Differences between groups were assessed using a two-sided test with an alpha level of 0.05. The log-rank test was used to compare the Kaplan-Meier plots of both treatments.

Results

Between May 2005 and May 2016, 252 patients with skin ulcers were screened, and a total of 230 participants were randomized, as follows: 110 to the plastic wrap dressing group and 120 to the HCD group. **Table 1** shows the baseline patient demographics and wound characteristics. The two groups were well balanced in terms of age, sex, mental disorders, Braden scale score, prevalence of systemic diseases, and location and size of the pressure ulcer. The hemoglobin level was slightly but significantly higher in the HCD group (P=.0489).

The flow of participants through the trial is shown in **Figure 1**. From among the study participants, two patients in the plastic wrap dressing group and two in the HCD group dropped out because they died before the first observation. The remaining 226 participants (108 in the plastic wrap dressing treatment group and 118 in the HCD group) were included in the analysis.

Primary outcomes

The mean (± standard deviation) period required for complete wound healing in the plastic wrap dressing group was 3.44 ± 3.16 (95% confidence interval [CI]: 2.83-4.04), while that in the HCD treatment group was 3.45 ± 3.27 (95% CI: 2.85-4.05) weeks. The difference was not significant (P=.974). The 95% CI of the difference was -0.83-0.86. All the data obtained are shown in the Supplementary Table 1.

Secondary outcomes

The proportion of patients whose pressure ulcers had not healed was compared using Kaplan-Meier analysis and the log-rank test (**Figure 2**). The survival curves of both treatment groups were similar, and no significant difference was detected (P=.797, log-rank test).

Table 2 shows the incidence of adverse events. Five wounds (three in the plastic wrap dressing group and two in the HCD group) deteriorated and were determined to be stage IV wounds. More maceration developed in the plastic wrap

Table 1. Baseline demographic and wound characteristics of the patients

Characteristics	PWD group (n=110)	HCD group (n=120)	*p*-value
Sex, female	52 (47.3%)	51 (42.5%)	0.5080‡
Age, mean ± SD [year]	76.1 ± 11.8	75.7 ± 13.0	0.7955§
Age, median (interquartile range) [year]	78 (71.75-84)	77.5 (68.25-83)	0.8255ᴷ
Type of mental disorder			0.9443†
Alzheimer's disease	36 (32.7%)	34 (28.3%)	
Vascular dementia	22 (20.0%)	26 (21.7%)	
Mixed dementia	5 (4.5%)	8 (6.7%)	
Other dementia	12 (10.9%)	11 (9.2%)	
Schizophrenia	23 (20.9%)	30 (25.0%)	
Mental retardation	6 (5.5%)	5 (4.2%)	
Others	6 (5.5%)	6 (5.0%)	
Total Braden Scale score, median (interquartile range)	14 (11-17)	15 (12-17)	0.4785ᴷ
Hemoglobin, mean ± SD [g/dL]	10.4 ± 1.7	10.8 ± 1.6	0.0856§
Hemoglobin, median (interquartile range) [g/dL]	10.3 (9.1-11.4)	10.8 (9.8-11.8)	0.0489*,ᴷ
Albumin, mean ± SD [g/dL]	3.1 ± 0.6	3.1 ± 0.6	0.6558§
Albumin, median (interquartile range) [g/dl]	3.0 (2.7-3.5)	3.1 (2.8-3.5)	0.4325ᴷ
Systemic disease			
Pneumonia	19 (17.3%)	18 (15.0%)	0.7203‡
Diabetes mellitus	17 (15.5%)	23 (19.2%)	0.4903‡
Malignancy	8 (7.3%)	16 (13.3%)	0.1944‡
Surface area of pressure ulcer, mean ± SD	7.1 ± 5.3 cm^2	6.8 ± 4.0 cm^2	0.6604§
Location of pressure ulcers			0.7195†
Sacrum	41 (37.3%)	50 (41.7%)	
Greater trochanter	8 (7.3%)	13 (10.8%)	
Iliac spine	5 (4.5%)	3 (2.5%)	
Back	6 (5.5%)	10 (8.3%)	
Heel/feet	36 (32.7%)	33 (27.5%)	
Arm	11 (10.0%)	9 (7.5%)	
Others¶	3 (2.7%)	2 (1.7%)	

To compare categorical variables in descriptive data between the two groups, the Fisher's exact test or chi-square test was performed. The unpaired Student's t-test was applied for parametric variables, and the Mann-Whitney U test for non-parametric variables. PWD, plastic wrap dressing; HCD, hydrocolloid dressing; SD, standard deviation. *P < 0.05 was accepted as significant. §Unpaired Student's t-test. †Chi-square test. ‡Fisher's exact test. ᴷMann-Whitney U test. ¶In the plastic wrap dressing group, two pressure ulcers were on the head and one was on the scrotum. In the standard treatment group, two ulcers were on the head.

dressing group than in the HCD group. All maceration developed on the heel. Hypergranulation only developed in the HCD group. However, these differences were not statistically significant.

Discussion

Comparing the time until complete healing and Kaplan-Meier analysis between the groups in this randomized controlled trial demonstrated no significant difference in the efficacy of the two treatments. The mean, 95% CI, and survival curve of both treatments were similar. Therefore, our hypothesis that the plastic wrap dressing is more effective than modern dressings for the management of stage II pressure ulcers was rejected. The present findings do not indicate that which treatment is superior to the other. The equivalency of both treatments was also not confirmed.

The present study was designed to have statistical power sufficient to detect a 1.0-week difference in the mean period until healing, with a standard deviation less than 2.5 weeks in both

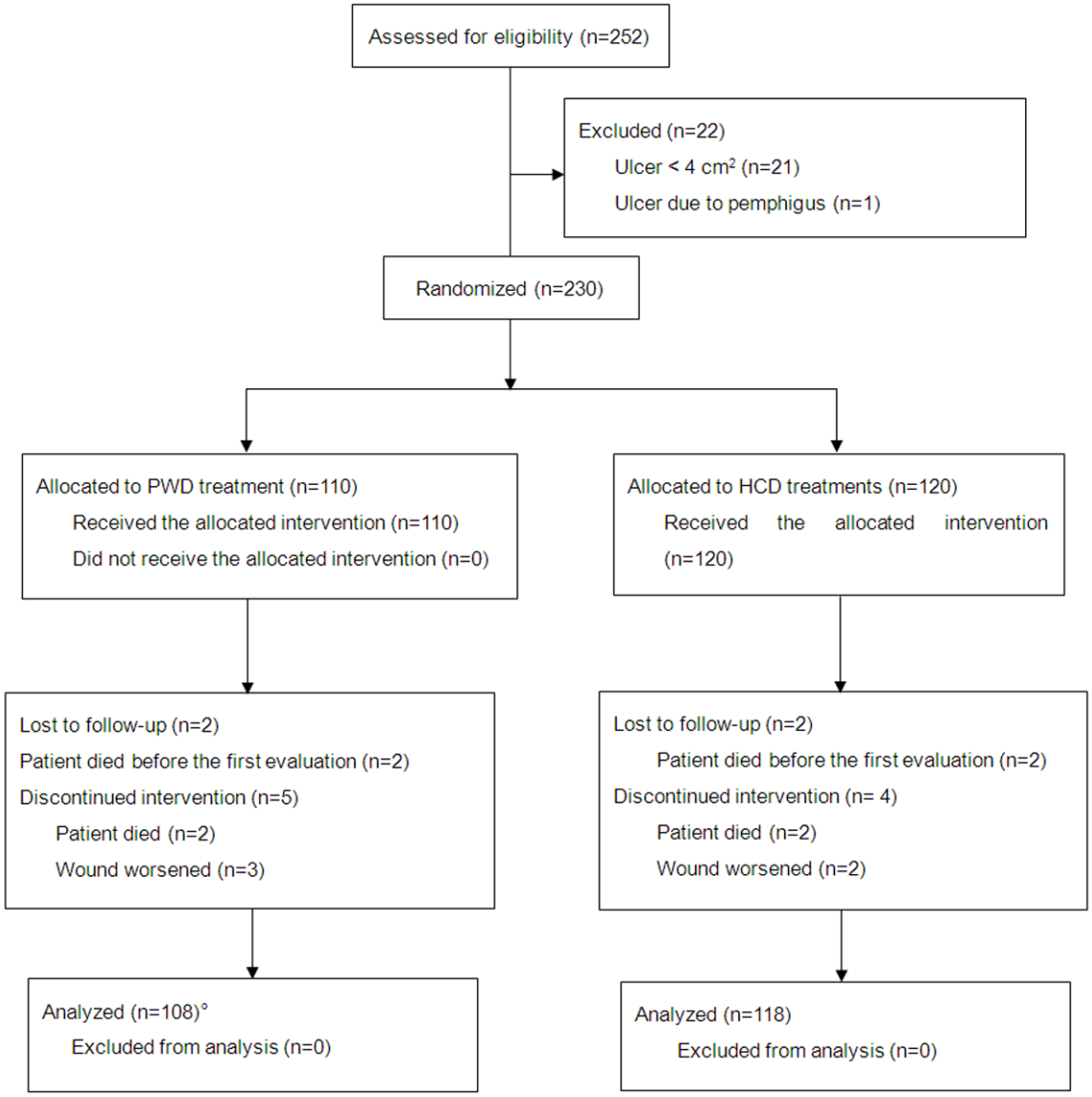

Figure 1. Flow of participants though the trial. HCD: hydrocolloid dressing, PWD: plastic wrap dressing.

groups and a sample size of more than 199 participants. In fact, the standard deviation was 3.160 weeks in the plastic wrap dressing treatment group and 3.268 weeks in the HCD treatment group, and there were 226 participants. Therefore, the present study had statistical power to identify a 1.2-week difference between the two treatment groups in a two-sided test with an alpha level of 0.05. As such, the difference in the mean period until healing between the treatments may have been less than 1.2 weeks. In addition, considering that the 95% CI for the difference was -0.83-0.86 weeks, the true value of the difference between the two treatments may have been less than 1 week. If this difference is clinically acceptable, the effect of both treatments could be considered equivalent.

A significant difference in the incidence of adverse events was not found between the groups. Hypergranulation only developed in the standard treatment group, although the reason for this was unclear. All maceration occurred in the heel. The cutaneous tissue of the heel may be more vulnerable to an excessively moist environment. However, no maceration prevented wound healing in the present

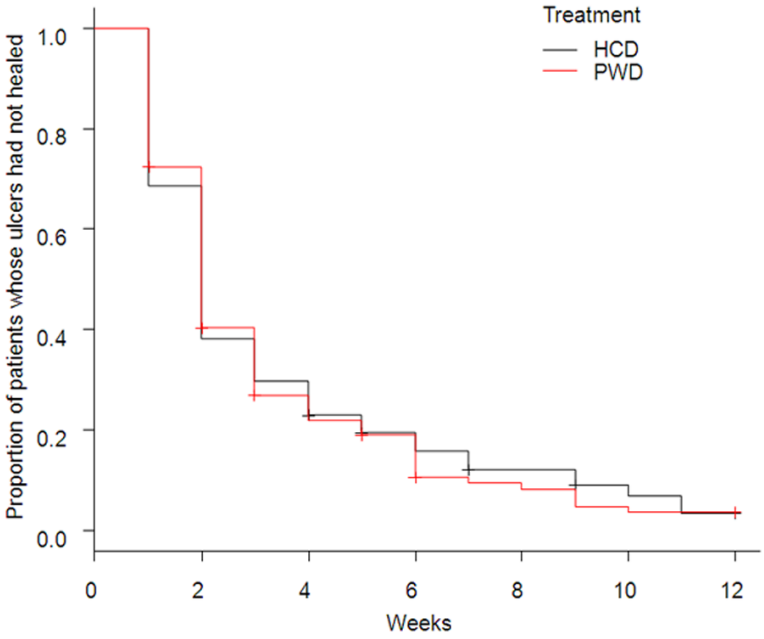

Figure 2. Comparison of the Kaplan-Meier plots between the treatment groups, with the period until healing of the pressure ulcer as the end point. The Y axis shows the proportion of patients whose pressure ulcers had not healed.

Table 2. Incidence of adverse events

	PWD group (n=108)	HCD group (n=118)	*p*-value
Deterioration	3 (2.8%)	2 (1.7%)	0.6718
Maceration	4 (3.7%)	2 (1.7%)	0.4290
Hypergranulation	0 (0.0%)	2 (1.7%)	0.4988
Local and/or systemic infection	0 (0.0%)	0 (0.0%)	> 0.9999

PWD, plastic wrap dressing; HCD, hydrocolloid dressing; Fisher's exact test was performed.

study. Although more frequent dressing changes were needed in the plastic wrap dressing group (once per day) than that in the HCD group (twice per week), the procedure of plastic wrap dressing treatment is simple; therefore, frequent dressing changes did not significantly increase the workload of caregivers. The material cost of the plastic wrap dressing was lower than that of the HCD.

Prior controlled studies on shallow pressure ulcers did not report the superiority of plastic wrap dressing to standard dressings, similar to the present study. A comparative study including many mild pressure ulcers and some severe ulcers (NPUAP classification was not used) [5] and a randomized controlled trial including stage II/III ulcers [8] found no significant difference in efficacy between plastic wrap dressing and standard treatment. A case report comparing two shallow skin ulcers at symmetrical locations in a single patient showed that the healing rates conferred by the plastic wrap dressing and HCD were approximately equal [22]. In contrast, for the management of stage III/IV pressure ulcers, our previous non-randomized controlled study and randomized controlled study showed that plastic wrap dressing was superior to standard treatment [4, 12].

Based on these prior results and the present study, we propose that plastic wrap dressing treatment is equivalent to standard treatment for the management of stage II pressure ulcers and that it is more effective for stage III/IV pressure ulcers. The effect on stage III/IV and stage II ulcers may differ because the exudate amount and management strategies differ between treatments. In the treatment of stage III/IV wounds, which involve massive exudation, plastic wrap dressing treatment may have an advantage over standard treatment using modern dressings because it drains the exudate away from the wound and does not absorb any exudate. However, as stage II pressure ulcers have less exudate, this difference may not significantly affect the effectiveness of the treatments.

Plastic wrap is smooth and slippery, and it does not adhere to the surface of the wound or skin. Consequently, friction, shear stress, and damage caused by rubbing of the dressing material on the surface of the wound do not occur. In addition, plastic wrap is thin; thus, it does not exert local pressure on the wound. Therefore, not only are plastic wrap and non-woven adhesive tape inexpensive alternative materials, owing to their unique properties, they play

important roles in the management of pressure ulcers according to the theory of pressure ulcer treatment.

The present study had several limitations. First, this randomized controlled trial was not registered as an approved, publicly accessible clinical trial. Registration was uncommon when this trial was started in May 2005. Thus, the study does not meet all of the conditions set by the CONSORT 2010 checklist [23], although the CONSORT 2001 criteria [24] were fully met. Secondly, the trial could not be double-blinded because of methodological difficulties. Finally, plastic wrap is not a medical material. More discussions are needed regarding the ethics and safety of plastic wrap treatment. The incidence of adverse events was not statistically different between the two groups; however, this may have been caused by insufficient statistical power due to small sample size. Long-term observation is also needed.

Conclusion

The present results did not show whether plastic wrap dressing or HCD was more effective for the treatment of stage II pressure ulcers. Conversely, statistical equivalence of the two treatments was not confirmed, although the mean (95% CI) time until complete healing and Kaplan-Meier curve of both treatments were similar. These findings and evidence from prior reports prompted the formulation of a new hypothesis that plastic wrap dressing treatment is equivalent to standard treatment using modern dressings for the management of stage II pressure ulcers. Studies designed more adequately to demonstrate the non-inferiority or equivalency of the two treatment methods are required.

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Disclosure of conflict of interest

None.

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