Original Article
Plastic wrap as a dressing material to treat stage III/IV pressure ulcers in the inflammatory phase: a randomized controlled trial

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Abstract: The efficacy of plastic wrap (typically used for food) as dressing material to treat National Pressure Ulcer Advisory Panel stage III/IV pressure ulcers was compared to standard treatment conforming to guidelines. This 12-week open-label randomized controlled trial was conducted in 10 wards of a hospital and 2 care facilities. Primary outcome was absolute surface area reduction. Secondary outcome was Pressure Sore Status Tool score reduction. Of the 142 participants enrolled, 74 were randomly allocated to plastic wrap dressing treatment and 68 to standard treatment. Of these, 71 and 65, respectively, were analyzed. The plastic wrap dressing treatment reduced significantly more surface area than the standard treatment for 12 weeks (P < 0.0001). The mean surface area reduction with plastic wrap dressing treatment and standard treatment at 4, 8, and 12 week was 7.4 ± 7.1 and 4.7 ± 4.8 cm², P = 0.0103, (95% confidence interval of difference 0.7 to 4.8), 10.0 ± 9.3 and 5.8 ± 5.9 cm², P = 0.0020, (1.6 to 6.9), and 11.1 ± 9.9 and 6.7 ± 7.1 cm², P = 0.0032, (1.5 to 7.4), respectively. The median scores of Pressure Sore Status Tool score reduction in plastic wrap dressing treatment and standard treatment at 4, 8, and 12 week was 13 and 9, P = 0.0076, 17 and 11, P = 0.0123, and 19 and 13, P = 0.0065, respectively. These differences were statistically significant. The incidence of adverse events was comparable. These findings suggest that plastic wrap dressing treatment was more effective than standard treatment to manage stage III/IV pressure ulcers.

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

Introduction

Despite advances in various therapeutic methods and materials, the development of a new treatment for severe pressure ulcers is imperative. Occlusive dressing technique (ODT) by modern dressing materials is a recommended standard treatment [1, 2], but has limitations in managing pressure ulcers with much exudate, necrotic tissue, and/or infection, even though the performance of dressing materials has improved. Some ointments with gauze dressing can manage more exudate than ODT, and can treat infected wounds. However, if wounds with massive exudate are treated, excess exudate which cannot be absorbed completely may increase pressure on the wounds, leading to deterioration or infection of the wounds. In addition, if wounds with less exudate are treated, both ointments and gauze dressing tend to let the wounds dry [1, 2]. The effect of negative pressure wound therapy compared with alternatives for the treatment of pressure ulcers have not been well documented [3] although a few studies have suggested its effectiveness [4, 5]. In addition, this therapy is often impractical in many geriatric hospitals and care facilities because of the associated costs and need for special equipment.

Plastic wrap dressing treatment may be one option to meet many kinds of treatment demands although this method is not widely known. Plastic wrap, typically used for foods, has been effectively used as a dressing material to treat National Pressure Ulcer Advisory
Panel (NPUAP) [6] stage II, III, and IV pressure ulcers [7-9]. Because of effectiveness, ease of use, and low cost [8, 10], this treatment has been gradually accepted in many Japanese hospitals and care facilities.

The procedure using this treatment is easy and simple [11, 12]: non-sterile plastic wrap is fixed using non-woven tape. Because the adhesive power of this tape is weak, part of this dressing comes off easily when excess exudate accumulates under the dressing. Therefore, the exudate is drained away from the wound, pressure on the wound reduces, and a moist environment is maintained. Plastic wrap dressing treatment is consistent with the theory of wound bed preparation and moist wound healing [13, 14]. By this mechanism of plastic wrap dressing, stage III/IV pressure ulcers that have more exudate and/or infection can be healed [7, 9, 11].

Although a few studies comparing the effectiveness of plastic wrap dressing to alternative treatments are available [10, 11, 15], no randomized controlled trial has been conducted to compare the effectiveness of plastic wrap dressing versus standard treatments in the management of stage III/IV pressure ulcers in the inflammatory phase. The aim of this randomized controlled study is to determine difference in reduction of surface area and the Pressure Sore Status Tool [PSST] [16] by plastic wrap dressing treatment versus standard treatment for stage III/IV pressure ulcers.

Methods

Trial design and participants

This 12-week prospective randomized controlled trial was conducted in 10 wards of a Japanese psychiatric and geriatric hospital and 2 care facilities between May 2005 and May 2015. This was an open-label design because masking either the participants or the doctors/nurses to the intervention was impossible. This study was performed in accordance with the Declaration of Helsinki and its amendments. The Institutional Review Board approved this study protocol. Written informed consent was obtained from participants or their family members.

Patients aged 20 or older with NPUAP [6] stage III/IV pressure ulcers in inflammatory phase were included. Eligible participants had pressure ulcers measuring 4 cm² to 80 cm² (from 2 to 4 in the item of Size on the PSST), and at least 50% of the surface area was covered by necrotic tissue (from 4 to 5 in the item of Necrotic tissue amount on the PSST). Wounds covered by hard, black eschar were included after surgical removal of the eschar. If a patient had multiple pressure ulcers, the largest one was selected for this study.

Participants were excluded if their skin ulcer was due to other causes, including peripheral arterial occlusive disease, skin cancer; if they had poorly controlled diabetes (HbA1c > 10% measured at registration); or they were treated with corticosteroids, immunosuppressants, cytotoxic agents, or radiotherapy. Pressure ulcers in the red proliferation phase were not included.

Baseline parameters included age, sex, mental disorder, systemic disease (including pneumonia, diabetes, and malignancy), hemoglobin and serum albumin, Braden Scale [17] score, surface area and location of the pressure ulcer, and PSST score. After obtaining these baseline characteristics, consenting participants were randomized to receive plastic wrap dressing treatment or standard treatment 1:1 by simple randomization. This was performed by the registration center, which was independent of the hospital wards and care facilities.

Intervention

Procedure for plastic wrap dressing treatment [11, 12]

After cleansing with plenty of clean tap water or saline, the wound was covered with non-sterile plastic wrap of a suitable size. Non-woven adhesive tape was used to fix four sides of the plastic wrap. The weak adhesive ability of the tape allows part of the dressing to come off easily, thus allowing excess exudate to drain away from the wound, so the wound is not occluded completely. This incomplete occlusion keeps a moist environment adequately for wound healing and mitigates the lack of air permeability of the plastic wrap. Tapes with strong adhesive power are not suitable for this treatment because the wound must not be tightly sealed. If these principles are not followed, the
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wound may deteriorate, leading to serious wound infection and sepsis [18].

Devitalezed tissue was mainly removed by autolytic debridement promoted by the moist environment. Deep undermining or large wound cavities were not packed with dressings, ointments, or gels. 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 antibiotic agents. The frequency of dressing changes depends on the amount of exudate. In this study, dressings were exchanged at least 2 times per day. When an infected wound with much exudate was treated, the dressings were changed 3 or 4 times per day. If much exudate was drained around the wound, a thin paper diaper could be applied to absorb it and to protect the skin.

Procedure for standard treatment [19-22]

Wounds in the standard treatment group were treated with ointments and gauze dressing or ODT after cleansing with clean tap water or saline. If a wound had excess exudate, infection, and/or deep undermining, and ODT could not be applied, various ointments and gauze dressing were used. Ointments used in this study were iodine-sugar, iodine-cadexomer paste, silver sulfadiazine, and enzymes. If ointments and gauze dressing were used, dressings were exchanged 2 or more times per day.

If a wound improved from the yellow inflammatory phase to the red proliferation phase and the amount of exudate was reduced, ODT was applied. The wounds were treated with hydrocolloid dressing, hydrocellular polyurethane dressing, transparent film, and alginate dressing. These dressings were changed 2 or 3 times per week on average. When excess exudate accumulated under the dressing, the dressing was changed once or twice a day.

Common treatment procedures

If cellulitis or systemic infection developed in association with the pressure ulcer, systemic antibiotics were given. Surgical debridement or skin incision was undertaken when wound infection was poorly controlled or necrotic tissue could not be removed by other debridement methods. Depending on the level of risk determined according to the Braden Scale, prevention protocols [22, 23] to improve moisture of skin, activity, and nutrition were implemented by a committee for prevention and management of pressure ulcers that was unrelated to this trial. Specialized mattresses, overlay, and seat cushions which met the needs of patients could be used for pressure redistribution.

Outcome measurement

The primary outcome measure was the absolute surface area reduction (SAR: baseline surface area - actual surface area). Whether the differences between the treatments would affect SAR during the study period was investigated, and the SAR at 4, 8, and 12 week was compared for both treatments. The surface area was measured at baseline, and then every week via digital camera imaging by the same investigator, who was unaware of the treatment allocation. The area was calculated (length × width) using a ruler photographed with the wound.

Secondary outcomes included PSST score reduction at 4, 8, and 12 week compared to baseline (baseline PSST score - actual PSST score), and the incidence of adverse events including wound deterioration, local or systemic infection, hypergranulation, and maceration. Using PSST, qualitative changes were evaluated quantitatively, including depth of ulcer, amount of necrotic tissue and exudate, nature of granulation tissue, and state of skin around the wound. In this study, a doctor and nurse who were trained to treat and assess pressure ulcers marked the PSST score for all wounds separately at baseline and every 4 weeks. The evaluators were aware of the treatment allocation. If the scores were different, they examined the wound together and marked the score again.

The difference in SAR for both groups during the study period was evaluated by a repeated measures analysis of variance (ANOVA) to investigate the effect of time and treatment. The comparisons of SAR at each observation point used the unpaired Student’s t-test and a p-value-based Bonferroni adjustment for multiple comparisons. The difference in PSST score
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Sample size and statistical analysis

We estimated that 140 participants were required to detect 6.0 ± 10.0 cm² of difference in SAR (mean ± standard deviation) between the 2 groups at 12 week, with alpha risk of 0.0167 (to maintain an overall alpha level of 0.05 by Bonferroni adjustment) and a study power of 0.80, allowing for 10% loss to follow-up and unbalanced allocation. This estimate was based on the results of a previous study [11].

All analyses were performed using Stat View, version 5.0 (SAS Institute Inc. USA). The statistical analyses were performed on an intention-to-treat basis. Data from all patients who

To compare categorical variables in descriptive data between two groups, a 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. PWDT = plastic wrap dressing treatment. ST = standard treatment. SD = standard deviation. *P < 0.05 was accepted as significant. †Unpaired Student’s t-test; ‡Chi-square test; §Fisher’s exact test; ™Mann-Whitney U test. ¶In the plastic wrap dressing group, two pressure ulcers were on the head. In the standard treatment group, one was on the head, and one was on the chest.
underwent at least 1 post-baseline observation were included in the analyses, which were performed with the last observation carried forward (LOCF) method. If the values of SAR or reduction of PSST score were negative due to deterioration of the pressure ulcers, these were scored as zero, because wound exacerbation would provide great negative outlier values.

Results

Between May 2005 and May 2015, 152 patients with skin ulcers were screened, and a total of 142 participants were randomized: 74 to plastic wrap dressing treatment and 68 to standard treatment. Baseline patient demographics and wound characteristics are shown in Table 1. The 2 groups were similar in age, sex, type of mental disorder, Braden Scale score, prevalence of systemic diseases, the surface area of the wound and location of pressure ulcer. PSST score in the plastic wrap dressing treatment group were significantly greater than in the standard treatment group (P = 0.0092).

The study flow of participants through the trial is shown in Figure 1. Of these, 3 patients in the plastic wrap dressing group and 3 in the standard treatment group dropped out due to discharge, transfer to another hospital, or death before the first observation. The remaining 136 participants (71 in the plastic wrap dressing treatment group and 65 in the standard treatment group) were included in the analysis. A total of 89 of the 136 participants completed the 12 weeks of the trial. Data from the remaining 47 partici-
pants (25 in the plastic wrap dressing treatment group and 22 in the standard treatment group) were analyzed based on LOCF. During the study period, 20 participants in the plastic wrap dressing treatment group and 16 in the standard treatment group died of causes unrelated to their pressure ulcers. All the data obtained are shown in Supplementary Table.

Primary outcomes

The SAR for both treatment groups is shown in Figure 2. The SAR in the plastic wrap dressing treatment group was greater than in the standard treatment group during the entire study period. This difference was significant (P < 0.0001). The respective SAR values in the plastic wrap dressing treatment group at 4, 8, and 12 weeks were 7.4 ± 7.1, 10.0 ± 9.3, and 11.1 ± 9.9 cm² (mean ± standard deviation). The corresponding values in the standard treatment group were 4.7 ± 4.8, 5.8 ± 5.9, and 6.7 ± 7.1 cm². The plastic wrap dressing treatment reduced the surface area of the pressure ulcers more than the standard treatment at each observation point, and all of these differences were statistically significant. Each p-value and 95% confidence interval of difference is shown in Table 2.

Secondary outcomes

PSST score reductions in both treatment groups are shown in Figure 3. The median scores of the plastic wrap dressing treatment group at 4, 8, and 12 weeks were 13, 17, and 19, and the interquartile ranges were 6-16, 8.5-21, and 10-23, respectively. The corresponding values in the standard treatment group were 9, 11, and 13, and 3-13, 6-16, and 6-19. At every assessment point, the reduction in PSST score from the baseline was significantly greater in the plastic wrap dressing treatment group than in the standard treatment group. During the study period, the wound healed completely in 23/71 (32.4%) in the plastic wrap dressing treatment group and in 18/65 (27.7%) in the standard treatment group.

Table 3 shows the incidence of adverse events. Deterioration of the wound, local wound infection, and bacteremia/sepsis were observed approximately equally in both groups. More maceration developed in the plastic wrap dressing treatment group than in the standard treatment group during the entire study period. This difference was significant (P < 0.0001). The respective SAR values in the plastic wrap dressing treatment group at 4, 8, and 12 weeks were 7.4 ± 7.1, 10.0 ± 9.3, and 11.1 ± 9.9 cm² (mean ± standard deviation). The corresponding values in the standard treatment group were 4.7 ± 4.8, 5.8 ± 5.9, and 6.7 ± 7.1 cm². The plastic wrap dressing treatment reduced the surface area of the pressure ulcers more than the standard treatment at each observation point, and all of these differences were statistically significant. Each p-value and 95% confidence interval of difference is shown in Table 2.

Figure 3. Reduction of PSST scores in plastic wrap dressing and standard treatment groups. Horizontal bar in each box represents the median. Horizontal boundaries of the boxes represent the first and third quartile. Vertical bars indicate the values of the 10th and 90th percentiles. *Statistically significant (P-value based on Mann-Whitney U test. To maintain an overall alpha level of 0.05, Bonferroni adjustment was used).
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The characteristics of plastic wrap dressing treatment and standard treatment were compared. The greatest difference between the treatments is whether the wound is occluded completely. The plastic wrap dressing does not occlude the wound completely because of the weak adhesive power of non-woven adhesive tape used in this treatment, and the exudate is drained outside of the wound. Therefore, even if a wound with massive exudate is treated, plastic wrap dressing can maintain an adequate moist environment to facilitate wound healing, avoid increased pressure on the wound, and prevent wound infection despite maceration around the skin. Conversely, standard treatment occludes completely, and dressing materials or ointments absorb the exudate. Excess exudate that is inadequately absorbed and is sealed under the dressing may make the wound overly wet, which prevents wound healing, causes infection and increased pressure, and aggravates the wound. This difference may contribute to the superiority of plastic wrap dressing treatment in management of stage III/IV ulcers with much exudate, as shown by the present study and a previous non-randomized controlled study [11]. Conversely, differences in efficacy between the treatments were difficult to detect in the management of mild pressure ulcers in prior studies [10, 15]. When mild pressure ulcers with less exudate are treated, both the weak points of standard treatment and the strong points of plastic wrap dressing tend to be minimized, making the effectiveness of both treatments appear equal.

In addition, plastic wrap as dressing material reduces the risk of aggravating the wound. Plastic wrap is smooth and slippery, and does

Table 3. Incidence of adverse events

<table>
<thead>
<tr>
<th></th>
<th>PWDT group (n = 71)</th>
<th>ST group (n = 65)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Local wound infection</td>
<td>4 (5.6%)</td>
<td>5 (7.7%)</td>
<td>0.7366</td>
</tr>
<tr>
<td>Bacteremia/Sepsis</td>
<td>2 (2.8%)</td>
<td>2 (3.1%)</td>
<td>&gt; 0.9999</td>
</tr>
<tr>
<td>Maceration and odor</td>
<td>7 (9.9%)</td>
<td>2 (3.1%)</td>
<td>0.1689</td>
</tr>
<tr>
<td>Hypergranulation</td>
<td>0 (0.0%)</td>
<td>3 (4.6%)</td>
<td>0.1065</td>
</tr>
<tr>
<td>Deterioration of SAR</td>
<td>5 (7.0%)</td>
<td>10 (15.4%)</td>
<td>0.1709</td>
</tr>
<tr>
<td>Deterioration of PSST</td>
<td>3 (4.2%)</td>
<td>7 (10.8%)</td>
<td>0.1934</td>
</tr>
</tbody>
</table>

PWDT = plastic wrap dressing treatment; ST = standard treatment; Fisher's exact test was performed.

dressing treatment group than in the standard treatment group, and hypergranulation developed in the standard treatment group alone, although these differences were not statistically significant. Six of 7 cases of maceration in the plastic wrap dressing treatment group and 2 of 2 in the standard treatment group developed on the heel.

Discussion

This randomized controlled trial demonstrated that stage III/IV pressure ulcers in the inflammatory phase treated with plastic wrap dressing showed significant improvement compared to those receiving standard treatment. Plastic wrap dressing accelerated wound healing more than the standard treatment, in a comparison of SAR. Significant differences in PSST score reduction in both groups indicated that plastic wrap dressing treatment promoted qualitative improvement in pressure ulcers in addition to reducing the surface area. Baseline demographics of patients in both groups were almost similar. Many participants were elderly and in poor general condition, and had severe systemic disease. This study indicated that the plastic wrap dressing was effective, even for severe wounds in patients in poor condition.

No statistical difference between groups was shown in the incidence of adverse events. The incidence of local wound infection and bacteremia/sepsis in the plastic wrap dressing treatment was almost equal to that in the standard treatment group. This finding agrees with prior reports [10, 11, 15]. Plastic wrap dressing can manage bacterial bioburden on a wound with much exudate. Fewer wounds deteriorated with plastic wrap dressing treatment than with standard treatment. Hypergranulation developed only in the standard treatment group, although the reason was unclear. Conversely, more maceration of the peri-ulcer skin was observed in the plastic wrap dressing treatment group. Exudate drainage outside the wound might cause maceration. In addition, almost all maceration involved the heels. The cutaneous tissue at the heel may be more vulnerable to an excessively wet environment. This tendency concurs with prior reports [9, 11]. However, skin problems were treatable adverse events with relatively little clinical importance.

In addition, plastic wrap as dressing material reduces the risk of aggravating the wound. Plastic wrap is smooth and slippery, and does
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not adhere to the surface of the wound and skin, unlike dressings used in standard treatment. Consequently, friction and shear stress as well as the damage caused by rubbing on the surface of the wound by dressing material do not occur with plastic wrap dressing treatment. Moreover, plastic wrap is so thin that local pressure on the wound can be avoided. Plastic wrap and non-woven adhesive tape are not just inexpensive alternative materials, but play important roles in this treatment due to their unique characteristics.

From the view of the burden in standard treatment, doctors and nurses who specialize in managing chronic wounds must select the most appropriate ointment or dressing for each case, depending on the depth of the wound and amount of exudate. Inappropriate selection of dressing or ointment may lead to a wet or dry environment, and can prevent wound healing. In addition, residual ointment or gel after inadequate cleansing leads to wound infection. In particular, when pressure ulcers with deep undermining or large cavities are treated, much effort and time are needed to wash the wound. On the other hand, the procedure for plastic wrap dressing treatment need not change with the stage or condition of the pressure ulcer. Washing the wound is simple and easy, even if the wound has deep undermining or a large cavity. Technique and judgement requiring specialization are not required. Frequent dressing changes and removal of necrotic tissue as needed can heal severe pressure ulcers. Since the procedure of plastic wrap dressing treatment is simple and easy, frequent dressing changes do not increase the workload of caregivers.

The limitations of this study must be considered. 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, this study does not meet all of the conditions set by the CONSORT 2010 checklist [24], although the CONSORT 2001 criteria [25] were fully met. Second, this trial could not be double-blinded because of methodological difficulties. Moreover, the PSST evaluators were aware of the treatment allocation, because it was difficult to obtain information on the wounds using only a digital camera image. Finally, even if plastic wrap dressing treatment is superior, plastic wrap is not a medical material. More discussions are needed about ethics, and further investigations are necessary to confirm the safety of plastic wrap dressing treatment. The incidence of adverse events was not statistically different between groups; however, it is possible that insufficient statistical power due to small sample size led to these findings. In addition, long-term observation is needed.

Conclusion

This study indicated that plastic wrap dressing treatment was more effective than standard treatment for stage III/IV pressure ulcers in the inflammatory phase. The incomplete occlusion of wounds by plastic wrap dressing plays an important role in managing copious exudate and maintaining an adequate environment for wound healing. Plastic wrap dressing can be useful in long-term care of patients with severe pressure ulcers with respect to efficacy and ease of use. More discussions about ethics are needed because plastic wrap is not a medical material.

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Disclosure of conflict of interest

None.

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