Clinical Efficacy Test of Polyester Dressing Containing Herbal Extracts and Silver Sulfadiazine Cream Compared with Silver Sulfadiazine Cream in Healing Burn Wounds: A Prospective Randomized Controlled Trial

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ABSTRACT

Objective: The most common method of burn wound care is the application of silver sulfadiazine cream with sterilized gauze covering. However, conventional gauze fabric with a large pore size may stick to the wound bed and cause wound trauma, leading to the delay of healing and pain. The non-adherent property of a hydrocolloid dressing coated with herbal extract (SI-HERB) can promote wound healing as well as reduce pain. Thus, this study aims to compare clinical efficacy between a "polyester dressing containing herbal extracts and silver sulfadiazine cream" and "silver sulfadiazine cream" alone in second degree burn wound healing.

Materials and Methods: This study compared the two methods of burn wound treatment in the same patients, who were randomly split into a "treatment group", which were applied both silver sulfadiazine cream and hydrocolloid dressing, and "control group", which were applied only silver sulfadiazine cream. The studied outcomes were the number of days for wound closure, the percentage epithelialization, and the pain score. In total, 24 patients at the Burn Unit, Siriraj Hospital were enrolled in this study.

Results: The wound areas were initially ranged from 210–220 cm^2. The treatment group exhibited significant results regarding faster wound healing, referring to the number of days of wound closure (18 days in the control group vs. 15 days in the experimental group) and the percentage epithelialization compared to the control group. The average pain score in the experimental group was also lower on days 9, 12, and 15 after treatment ($p < 0.05$). No adverse effects were observed during the study.

Conclusion: The combination of hydrocolloid dressing and silver sulfadiazine cream could reduce the wound shearing force and wound bed injury, accelerating the rate of wound closure and decreasing the pain during changing the dressing. This technique could improve upon the standard burn wound treatment.

Keywords: Burn; wound; silver sulfadiazine cream; hydrocolloids dressing (Siriraj Med J 2021; 73: 752-757)

INTRODUCTION

Wounds involve a breakdown of the protective function of the skin and the loss of continuity of the epithelium, with or without the loss of underlying connective tissue (i.e., muscle, bone, nerves). Although the body system itself has the ability to heal, there are many factors

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that can affect wound healing, such as age, nutritional status, immunization status, co-morbidity, and the types of wound. Wound care aims to accelerate the healing process and prevent complications that could prolong the wound healing process and length of hospital stay. Wide, open wounds, especially burn wounds, can easily become infected and require a prolonged hospital stay. This can cause an increase in the cost of burn wound care by up to 15,000 USD on average per person.[1] Previous studies have reported a correlation between the area and depth of the burn wound and the cost of treatment.[2,3] Therefore, shortening the healing process may lead to less complications, a decrease length of hospital stay and hospital costs, and also better quality of life of the patients.[4]

Burn wounds are categorized into 3 degrees of burn according to the depth. A first degree burn can heal itself without intervention in a week. A second degree burn can heal with an epithelialization process; however, it can turn to a third degree burn if not properly managed.[5] A third degree burn needs surgical intervention for promoting the healing process. This study focuses on second degree burn wounds.

The most common method of burn wound care in Asia is the application of silver sulfadiazine cream (SSD) with sterilized gauze covering. SSD is composed of silver nitrate, which provides a bactericidal effect, and sodium sulfadiazine for its bacteriostatic property. SSD has a broad spectrum antimicrobial action with wound healing nurture.[6] However in clinical application, there are various factors that are hard to control, such as the thickness of the cream and the amount of cream per area, which are varying in practitioner. Also, the gauze absorbs the SSD, it can dry up and adhere to the wound bed. While peeling the gauze out to change the dressing, this can create a shearing force on the wound bed, causing wound bed trauma and thus slowing the wound healing process.

Lipido-colloid dressing was developed to increase the interval of wound dressing, reduce pain during dressing, due to the decrease adherence between the wound and the gauze dressing.[7] However, the major problem for this treatment is the cost since these products have to be imported.

Our previous study investigated a product comprising a hydrocolloid dressing coated with herbal extract, called SI-HERB.[12] This product has absorption capacities, drainage abilities, and it does not stick to the wound. Furthermore, it is locally made in Thailand and only costs one dollar per piece. It has no clinical side effects and it has already been approved by the Thai FDA. The herbal extracts in this material comprise *Centella asiatica* and Aloe Vera, which show anti-microbial effects, accelerate wound healing, moisten the wound, and show anti-inflammatory effects.[8,9] Some studies have indicated that these two substances can heal a wound faster than SSD.[10,11] Research from Muangman et al. in 2016 compared SI-HERB with old fashioned polyester (Bactigras), and showed that SI-HERB was superior in wound healing and improving tissue regeneration, with a lower cost of treatment and less pain during wound care.[12]

Consequently, this study used a hydrocolloid dressing coated with herbal extract (SI-HERB) combined with SSD on a dermal burn wound, which had some part of the eschar remaining on the wound surface, compared with using SSD alone. We hypothesized that the results would show better wound healing than using SSD alone.

Objective

The objective of this study was to compare the clinical efficacy between a "polyester dressing containing herbal extracts and silver sulfadiazine cream" and "silver sulfadiazine cream" alone in second degree burn wound healing regarding the number of days for wound closure, the percentage epithelialization, and the pain score of patients.

MATERIALS AND METHODS

Population

In total, 24 patients were included in this study. The patients, aged between 18 to 60 years old, had at least two second degree burn wounds. Each patient's burn wound was at least 150 cm^2 in area (approximating to 10% of body surface area by Wallace's rule of nine). The patients were ASA class I or II and ECOG 0 before getting burn wounds. Patients with history of allergy to silver, sulfadiazine or herbal products were excluded. Pregnant, breastfeeding, diabetes, or immunocompromised patients were also excluded from the study.

Study design

This was a single-center, prospective, randomized controlled study comparing wound dressing with a polyester dressing containing herbal extracts and silver sulfadiazine cream with silver sulfadiazine cream alone in second degree burn wound healing. This study was conducted at the Burns Unit, Division of Trauma Surgery Department of Surgery, Faculty of Medicine Siriraj Hospital, Mahidol University, Bangkok. The data were obtained between January 2019 and June 2020.

The second degree burn wounds of at least 150 cm^2 with some areas of eschar in the recruited patients were

randomly allocated to one of two treatment groups. In each patient, after an accurate debridement and cleaning of the burn wound with appropriate steriled normal saline solution, each burn wound size was evaluated by a registered nurse uninvolved with the dressing wound team. Photos of the burn wound were taken and evaluated in terms of size using the Image J program. Burn wound dressing was performed according to the treatment group. In the experimental group, patients were covered with SSD and a polyester dressing containing the herbal extracts. In the control group, they were covered with SSD. All the burn wounds were covered with steriled gauze, gamgee, and tape.

Evaluation was done every 3 days. Photos of each burn wound were taken and the size evaluated using the Image J program. Pain was evaluated by using the visual analog scale (VAS) range 0-10. Complications and other intervention needs were assessed by medical doctors. The evaluation and assessment team were not involved in the dressing procedure.

Wound healing was measured as the %epithelialization calculated by the formula below.

$$\%\text{Epithelialization} = \frac{(\text{Area of initial wound} - \text{Area of wound at exam date})}{\text{Area of initial wound}} \times 100$$

Ethics and material safety

Written informed consent was obtained from each patient or relatives prior to their participation in this study. The study was conducted in accordance with the international code of medical ethics. Patients could withdraw their consent whenever they felt uncomfortable and wished to finish the trial. The trial protocol and subsequent amendments including ethical approval were reviewed and approved by the Human Research Protection Unit, Siriraj Institutional Review Board (SIRB), Thailand.

This product, the polyester dressing containing herbal extracts, is already approved by the Thai FDA. There was no clinical side effects in the previous study utilizing this product.[12]

Statistical analysis

Demographic data are described with descriptive statistics. Quantitative data are described in terms of the mean ± standard deviation, or median (P25, P75). Quantitative data are described in frequency (percentage)

The differences between the treatment groups were evaluated using the paired t-test or Wilcoxon signed ranks test. The difference at each point in time was analyzed by repeated-measure ANOVA. For the qualitative variables, we used Pearson's Chi-square test or Fisher's exact test. All the statistical tests for efficacy were two-sided, with an alpha level = 0.05.

RESULTS

There were 24 second degree burn wound patients eligible for this study. Most were male patients (62.5%). The average age of the patients was 40.13 ± 14.20 years old. The total burn surface area was 35.35% in average. The average hospital stay was 41.96 ± 22.39 days. The most common cause of the burn wounds was scald burns in 35.35 ± 17.49% of cases, as shown in Table 1.

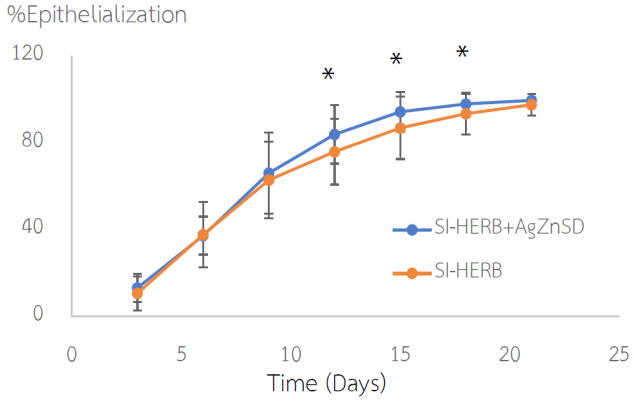
TABLE 1. Demographic data of the burn wound patients included in the study.

Demographic data	
Male patients	15 (62.50%)
Age (year)	40.13 ± 14.20
Burn percentage (%)	35.35 ± 17.49
Hospital stay (day)	41.96 ± 22.39
Causes	
Flame burn	9 (37.50%)
Scald burn	14 (58.33%)
Electrical burn	1 (4.17%)
Underlying diseases	
Hypertension	4 (16.67)
Hypercholesterolemia	1 (4.17)

The burn wounds of each patient were randomly assigned in both treatment groups. The experimental group was applied polyester dressing containing the herbal extracts and silver sulfadiazine cream. The control group was applied silver sulfadiazine cream alone. The initial burn wound area was not statistically significantly different between the two treatment groups: 219.15 ± 52.09 and 211.04 ± 46.18 cm^2 in the experimental and control group, respectively.

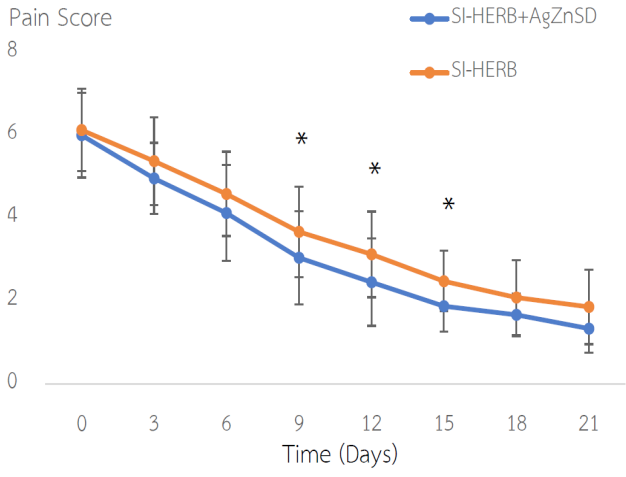
The percentage epithelialization calculated using the formula above is shown in Graph 1. The percentage epithelialization was similar in both groups at day 3 after treatment, at 10%. After that, the percentage epithelialization

rose, especially in the experimental group, as shown in Graph 1. The differences in the percentage epithelialization were statistically different at days 12, 15, and 18 ($p<0.05$). The wounds were more than 90% healed after 12 days and 15 days in the experimental group and control group, respectively. The wounds in the experimental group were completely healed in 15.04 ± 3.76 days on average. This was significantly faster than in the control group, which took 18.04 ± 3.74 days to heal on average ($p < 0.05$).



Graph 1. Percentage epithelialization and days for treatment comparing the experimental group and the control group.

The pain scores were rated by each patient every three days of the experiment and the scores are shown in Graph 2. The initial pain scores were not different in the experimental group and the control group (6.0 ± 1.0 and 6.1 ± 1.0, sequentially). The pain score decreased as time goes on. The experimental group had significantly lower pain scores on days 9, 12, and 15 ($p<0.05$).



Graph 2. Pain scores every three days of treatment comparing the experimental group and the control group.

Some examples of burn wound patients and the wound healing progression are shown in Figs 1-6. These pictures show the progression of the burn wound from initial of treatment until completely heal.

Fig 1. Example photos of the first patient in the control group

Fig 2. Example photos of the first patient in the experimental group

Fig 3. Example photos of the second patient in the control group

Fig 4. Example photos of the second patient in the experimental group

Fig 5. Example photos of the third patient in the control group

Fig 6. Example photos of the third patient in the experimental group

DISCUSSION

This study showed that wound dressing with polyester dressing containing herbal extracts and SSD had a better outcome compared to SSD alone in terms of the days taken for wound closure, the percentage epithelialization, and the pain scores of the patients. This was due to the non-adhesive properties of the dressing to the wound, causing less trauma to the newly generated epithelium.

This study showed similar results for the days taken for wound closure as our previous study in 2016, which reported an average of 15 days for wound closure, which was 2 days faster than the group with the wound not covered with the polyester dressing containing herbal extracts.[12]

The herbal extracts in this product, namely *Centella asiatica* and Aloe vera, had antimicrobial properties. Such an antimicrobial property has previously been reported in an Aloe vera-containing dressing (Barkat et al., 2017 and Khorasani et al., 2009) and *Centella asiatica*-containing dressing, with both showing significant efficacy.

The limitation of this study to note is that the study was not double-blinded. Patients inevitably knew the treatment of each burn wound. Another limitation is the pain scores that were rated by the patients. Sometimes it can be difficult to distinguish pain from each burn wound part in the body.

CONCLUSION

This study can conclude that for second degree burn wounds with some degree of eschar on top of the wounds, the use of a polyester dressing containing herbal extracts combined with silver sulfadiazine cream can promote better wound healing and cause less pain without any clinical side effects.

This treatment strategy might be included in the standard burn wound care protocol in the future to improve burn wound care. Further cost-analysis research might be helpful in future implementation of this treatment in the protocol.

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