A Comparison of Wound Healing Efficacy between a Herbal-coated Lipidocolloid Dressing and a Paraffin-based Dressing in Pediatric Burn Patients - A Randomized Controlled Study

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ABSTRACT

Objective: Burn injuries are prevalent among pediatric patients and pose significant challenges in wound management. This study aimed to compare the effectiveness of a herbal-coated lipidocolloid dressing (SI-Herb) versus a paraffin-based dressing (Bactigras) in promoting wound healing in pediatric partial-thickness burns.

Materials and Methods: A randomized controlled trial was conducted at Nakhon Pathom Hospital, Thailand, enrolling patients aged 0 to 15 years with partial-thickness burns covering 20% or less of their total body surface area (TBSA) between November 2021 and July 2023. Patients were randomized into SI-Herb (Group S) or Bactigras (Group B) treatment arms. The primary outcome assessed was days to complete wound epithelialization, with secondary outcomes including pain, bleeding, and dressing removal difficulty scores.

Results: Of the 28 recruited patients, 25 were included in the analysis (13 in Group S, 12 in Group B). There was no significant difference in complete wound epithelialization between the groups overall (9.2 ± 3.1 days in Group S vs. 11.3 ± 5.2 days in Group B, $p = 0.242$). However, subgroup analysis of patients with burns ≥10% TBSA showed a significantly shorter epithelialization time in Group S compared to Group B (11.8 ± 1.5 days vs. 15.8 ± 1.6 days, $p = 0.007$). Additionally, Group S exhibited lower pain, bleeding, and dressing removal difficulty scores compared to Group B ($p = 0.042$, 0.009, 0.003, respectively).

Conclusion: The herbal-coated lipidocolloid dressing demonstrated superior efficacy in promoting faster wound epithelialization in pediatric patients with partial-thickness burns exceeding 10% TBSA compared to the paraffin-based dressing.

Keywords: Bactigras paraffin-based dressing; herbal-coated lipidocolloid dressing; partial- thickness skin burn; pediatrics (Siriraj Med J 2024; 76: 581-588)

INTRODUCTION

Burn injuries constitute a substantial contributor to pediatric trauma, aside from vehicle accidents, suffocation, and drowning.[1] Scald burn injuries are prevalent in toddlers and younger children, while flame burn injuries are more common in older children and adolescents, in contrast to chemical and electrical burns, which are infrequent in the pediatric population.[2,3] Extensive areas of burn injuries lead to mortality, with an incidence ranging metabolic derangements, and give rise to a diverse array of complications affecting multiple from 0.4-2.8%.[3] Severe burns induce significant stress responses, immune system alterations, and organ systems.[3] Wound dressing constitutes a crucial aspect of burn patient

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management. Expedited wound healing and mitigation of associated complications exert substantial influence on patient outcomes, duration of hospitalization, and the overall quality of life.[4] Numerous investigations on materials for burn dressings have been conducted. However, a predominant majority of these studies have been conducted on adult burn patients.

The former standard protocol for the management of burn wounds in the pediatric population at the principal investigator's center entailed the use of silver-zinc sulfadiazine cream. However, the application of silver-zinc sulfadiazine cream is linked to several disadvantages. Primarily, pediatric patients subjected to silver-zinc sulfadiazine cream dressings are required to undergo daily dressing changes, causing discomfort and distress during cream and dressing removal, in addition to recurrent dissatisfaction with the overall wound dressing experience. A study conducted in the past decade on Thai adult patients with partial-thickness burn wounds demonstrated a noteworthy reduction in the frequency of wound dressing changes and a decrease in pain scores in the group treated with an antibiotic-coated dressing (Acticoat™) compared to the group treated with a 1% silver sulfadiazine dressing.[5] Therefore, the innovative commercial dressings offer diverse advantages compared to the application of silver-zinc sulfadiazine cream.

A recently introduced "herbal-coated lipidocolloid dressing" incorporates a herbal extract formulation containing 2.5% *Aloe vera* and 5% *Centella asiatica* impregnated with lipidocolloid. This dressing is intended for use in adult burn patients in Thailand.[6] A comparative study in adults evaluating the effectiveness of the herbal-coated lipidocolloid dressing, incorporating *Aloe vera* and *Centella asiatica*, against a gauze dressing impregnated with paraffin and a 0.5% chlorhexidine acetate dressing has been conducted. The findings indicated a significantly reduced duration of wound healing and diminished pain during dressing changes in the herbal-coated lipidocolloid dressing group.[6] However, it is worth noting that investigations into the usage of herbal-coated lipidocolloid dressings in the pediatric population have not been undertaken.

The principal investigator's center, Nakhon Pathom Hospital, situated in the central region of Thailand, caters to a population of approximately one million. The facility receives a substantial number of pediatric trauma patients, including those with burn injuries, referred from six community hospitals and nearby regions. Consequently, the primary aim of this study is to compare the duration required for complete healing of partial-thickness burns in the pediatric population (aged 0 to 15 years) when treated with either a herbal-coated lipidocolloid dressing or a Bactigras paraffin-based dressing. The secondary objectives encompass assessing and evaluating pain scores and bleeding during dressing changes and determining infection rates.

MATERIALS AND METHODS

The study was a randomized, controlled trial approved by the Ethics Committee, Nakhon Pathom Hospital, Nakhon Pathom province, Thailand (approval number: 019/2021, date of approval: June 18, 2021). The protocol was registered with the Thai Clinical Trials Registry, registration number: TCTR20210822001, date of registration: October 21, 2021. We included patients aged 0 to 15 years old with partial-thickness skin burns from scald or flame burn injuries of less than or equal to 20 percent of the total body surface area (TBSA). The burn area was estimated in terms of percentage per total body surface area (% TBSA), using the original Lund and Browder chart.[7] The exclusion criteria were as follows: patients with chemical or electrical burn injuries; patients with full-thickness burn wounds requiring skin grafting; patients with burn wounds located in the facial, hand, foot, genital, and perineum areas; patients with known underlying diseases that may affect wound healing, e.g., autoimmune diseases, connective tissue diseases, diabetes mellitus, etc.; and patients taking current medication that may affect wound healing, e.g., corticosteroids. We also excluded patients with allergies to the study materials, including chlorhexidine (the Bactigras paraffin-based dressing contains chlorhexidine). Patients who were unable to attend a follow-up were withdrawn from the study.

Data collection took place from November 1, 2021, to July 31, 2023. Written informed consent was obtained from the guardians of all participants. Patients were randomized into one of two groups using computer-generated randomization of a block of four patterns. The allocation concealment was done by using a sealed file with sequentially numbered. The file is confidential and can only be accessed by the principal investigator.

The day that all patients arrived at the Emergency Department, Nakhon Pathom General Hospital, was noted (day 0), and all patients were allocated randomly to one of two groups and received a burn wound dressing: either a herbal-coated lipidocolloid dressing (SI-herb, Specialty Innovation Co., LTD., under the license of Bangkok Botanica Co., LTD., Thailand) (group S) or a Bactigras paraffin-based dressing (Bactigras, Smith & Nephew Medical Limited, Germany) (group B), which was then covered by dry gauze. The participants were blinded to the type of dressing. All patients received a

dose of 15 mg/kg oral acetaminophen as required, at six-hour intervals. Patients with burn wounds covering more than 10% of the TBSA underwent blister removal under general anesthesia in the operating theater on day 1.

Demographic data, including age, gender, cause of burn, weight, height, and underlying disease, were collected. The dressing change protocol was every other day in the first week, then, every 2 days until complete healing of the wound. The complete healing of the wound was defined as 100% epithelialization. The healed area and pain score were recorded on days 3, 5, 8, 11, 14, 17, 20, and 23, or until the wound had completely healed. The determination of complete epithelialization was made through direct visual inspection conducted by medical personnel, including doctors and nurses. The difficulty of dressing removal was graded by the nurse who removed the dressing according to a three-point grading system: 0 = easy removal, 1 = easy removal with soaking in normal saline, and 2 = difficult removal with soaking in normal saline. Additionally, bleeding from the burn wound while removing the dressing was divided into four grades: 0 = none, 1 = minimal bleeding, 2 = moderate bleeding, and 3 = heavy bleeding. Pain score and difficulty in dressing removal, and bleeding on the day of blister removal in the operating theater were not included in the analysis. In patients under 6 years old, the Face, Legs, Activity, Cry and Consolability (FLACC) scale was used to evaluate the pain score.[8] In patients over 6 years old, the Wong-Baker Faces Pain Rating scale was used.[9] The number of patients requiring oral or intravenous antibiotics as well as the rate of wound infection were also recorded throughout the healing duration. The outcome measurements were performed by doctors or nurses in the emergency department who were not involved with this trial.

Statistical analysis

The sample size calculation was derived from the results of Muangman et al.[6], which revealed the results of the usage of a herbal-coated lipidocolloid dressing compared to those of a Bactigras paraffin-based dressing in adult burn patients. The results revealed that the time of wound healing was significantly shorter in the herbal-coated lipidocolloid dressing group (18.53 ± 1.66 days) compared to the Bactigras paraffin-based dressing group (20.06 ± 2.51 days). The author determined that wound healing in the herbal-coated lipidocolloid group would hasten the time to complete wound healing by 2 days (mu1 – mu2), with a standard deviation of 1.66 days, a significance level of 0.05 (alpha), and a power of 80%, using the nQuery Advisor program. The calculated sample size of each group was 12 patients. The principal investigator increased the sample size by approximately 10% to compensate for possible subject loss in this study. Therefore, the total sample size of each group was 14 patients. Overall, there were 28 patients included in this study.

All analyses were performed using PASW Statistics (SPSS) version 18.0 (SPSS Inc., Chicago, IL, USA). The analyses were performed on an intention-to-treat basis. Categorical data are presented as numbers (percentage), while the continuous data are presented as mean ± standard deviation, range (minimum to maximum value), or median [interquartile range]. Chi-square test, independent T-test, and Mann-Whitney U test were used to compare between the two groups. Bleeding score and dressing difficulty score were compared using a linear-by-linear association test. Survival analysis was used and the Kaplan-Meier curve was presented to compare the duration of complete healing between the two groups. P-values lower than 0.05 were considered statistically significant.

RESULTS

In total, 28 patients were initially enrolled in the study. However, due to missing the follow-up, one participant from Group S and two from Group B were excluded. Consequently, a total of 25 patients were included in the final analysis (Fig 1). The average age of the entire group of patients was 2.4 ± 2.6 years, with an average burn area of 8.4 ± 5.0 % TBSA. Details of the demographic and clinical characteristics of both groups are shown in Table 1. All patients included in the study were of Asian ethnicity. No significant differences were observed in demographic characteristics between the two groups. All patients presented with scald burns resulting from boiling water, oil, or soup; none were caused by flame exposure. Burn injuries were distributed across various anatomical sites, including the forearm, arm, chest, abdomen, buttock, thigh, and leg. Table 2 shows the comparison of the time to complete epithelialization, pain score, bleeding grading, and difficulty in dressing removal. None of the patients were allergic to the dressings or developed an infection requiring antibiotics in either group. Nine patients required wound blister removal under general anesthesia in the operation theater on day 1 (group S = four patients, and group B = five patients). Table 3 shows the comparison of complete wound epithelialization between burn areas covering < 10% TBSA and ≥ 10% TBSA. Patients with burn areas more than or equal to 10% of the total body surface area in Group S exhibited

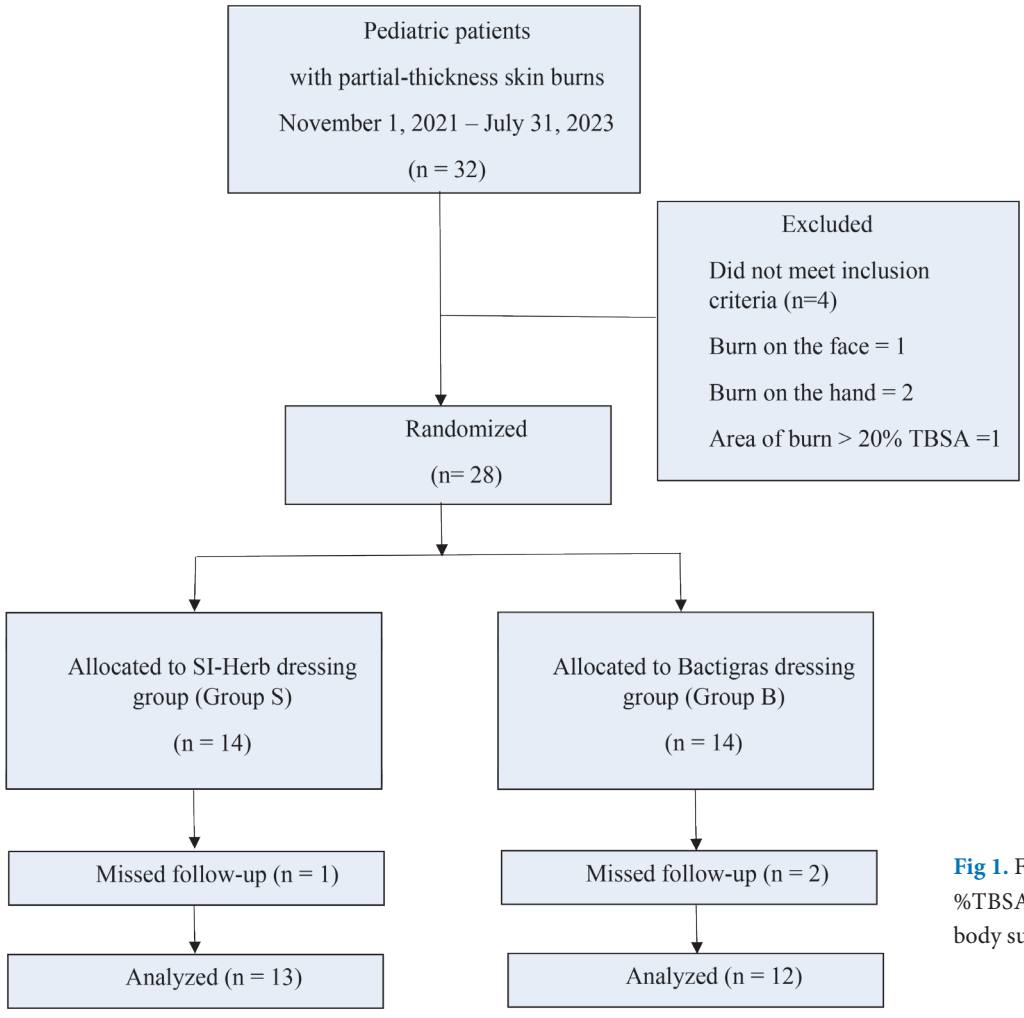

Fig 1. Flow of study
%TBSA: percentage of total body surface area

TABLE 1. Demographic and clinical characteristics (n=25).

Value	All patients N = 25	Si-Herb dressing (Group S) N = 13	Bactigras dressing (Group B) N = 12	P-value
Age (years)	2.4 ± 2.6 (0.4 – 10.4)	3.1 ± 2.9	1.8 ± 2.3	0.220
Male gender	12 (48.0)	4 (30.8)	8(66.7)	0.073
Body weight (kg)	13.1 ± 7.4 (6.0 – 35.0)	15.0 ± 7.8	11.6 ± 5.4	0.250
BMI (kg/m²)	17.2 ± 3.4 (10.4 – 24.7)	16.6 ± 3.6	17.91 ± 3.2	0.354
Burn area (% TBSA)	8.4 ± 5.0 (2.0 – 18.0)	7.7 ± 3.8	9.3 ± 6.2	0.451
Body surface area (m²)	0.52 ± 0.24 (0.30 – 1.08)	0.56 ± 0.24	0.48 ± 0.24	0.407
Cause of burn				
Hot water	18 (72.0)	9 (69.2%)	9 (75.0%)	
Hot oil	1 (4.0)	0 (0)	1 (8.3%)	0.645
Hot soup	6 (24.0)	4 (30.8%)	2 (16.7%)	

Data are presented as mean ± standard deviation (minimum – maximum value) or number (percentage).
Abbreviations: kg: kilogram; TBSA: total body surface area; m^2: square meter

TABLE 2. Comparison of wound epithelialization completion, pain scores, bleeding scores, and dressing difficulty scores between the two groups (n = 25).

	Si-herb dressing (Group S) N = 13	Bactigras dressing (Group B) N = 12	P-value
Wound epithelialization completion (days)	9.2 ± 3.1	11.3 ± 5.2	0.242
Pain score on days 3-8	3 [0, 4]	5.75 [6, 8]	0.042*
Pain score on days 9-17	0 [0, 2]	2.5 [3.5, 6.5]	0.096
Bleeding score on days 3-8			
0	12 (92.3)	5(41.7)	0.009*
1	1(7.7)	5(41.7)	
2	0(0)	2(16.7)	
Bleeding score on days 9-17			
0	5(100)	3(50)	0.093
1	0(0)	1(16.7)	
2	0(0)	2(33.3)	
Dressing difficulty score on days 3-8			
0	13(100)	5(41.7)	0.003*
1	0(0)	3(25.0)	
2	0(0)	4(33.3)	
Dressing difficult score on days 9-17			
0	5(100)	4(66.7)	0.455
1	0(0)	0(0)	
2	0(0)	2(33.3)	

Data are presented as mean ± standard deviation, median [interquartile range] or number (percentage).

TABLE 3. Comparison of completed wound epithelialization between burn areas < 10% TBSA and burn areas ≥ 10% TBSA.

	Si-herb dressing (Group S) N = 13	Bactigras dressing (Group B) N = 12	P-value
Burn area < 10%TBSA (days)	N = 9	N = 7	1.000
N = 16	8.0 ± 3.0	8.0 ± 4.2	
Burn area ≥ 10% TBSA (days)	N = 4	N = 5	0.007*
N = 9	11.8 ± 1.5	15.8 ± 1.6	

Data are presented as mean ± standard deviation.

Abbreviation: TBSA: total body surface area

a significantly shorter time to complete epithelialization of burn wounds. Survival analysis shows the probability of complete wound healing in group S compared to group B (Fig 2).

DISCUSSION

The present study conducted a comparative analysis of wound healing efficacy between a herbal-coated lipidocolloid dressing (group S) and a Bactigras paraffin-based dressing (group B). The findings revealed that the overall rate of complete epithelialization in patients within group S was comparable to that of group B. Nevertheless, in group S, there was expedited wound epithelialization observed in patients with burn areas exceeding 10% of the TBSA compared to such patients in group B. Furthermore, patients in group S exhibited a reduction in pain scores and bleeding scores during wound dressing procedures and reported fewer difficulties in dressing change from days 3 to 8 post-application.

Novel commercial dressings for burn wounds offer distinct advantages over silver sulfadiazine cream, including lower pain scores and reduced frequency of replacement. Dressings such as the Bactigras paraffin-based dressing or Aquacel Ag™ dressing typically require changing every other day or less frequently compared to conventional silver sulfadiazine cream dressings, which necessitate daily replacement.[5] These strategies also offer significant benefits for the pediatric population by minimizing the need for frequent dressing changes, thereby optimizing wound management, reducing the rate of wound healing, decreasing hospital length of stay, and reducing overall cost.[10]

Several studies have elucidated variations in wound healing rates among burn injuries treated with different dressings for partial-thickness wounds in adults. A prior comparative study underscored the efficacy of herbal-coated lipidocolloid dressings, incorporating *Aloe vera* and *Centella asiatica*, in significantly reducing the duration of wound healing and alleviating pain during dressing changes compared to Bactigras dressings.[6] The following study conducted in the adult population, which compared the efficacy of treatment with herbal-coated lipidocolloid dressings in conjunction with silver sulfadiazine cream to treatment solely with silver sulfadiazine cream (control group), demonstrated accelerated wound healing and decreased pain scores.[11] In this study, our focus was on pediatric populations, specifically the herbal-dressing group, where we also observed a decrease in the duration of wound healing in patients with burns to an extent equal to or greater than 10% of the TBSA. This threshold of 10% TBSA is considered indicative of an extensive burn area, aligning with the guidelines for burn management set forth by the American Burn Association and the American College of Surgeons, which recommend transferring patients with such extensive burns to specialized burn centers.[12]

The attributes of *Aloe vera* and *Centella asiatica* serve to hasten the process of re-epithelialization and

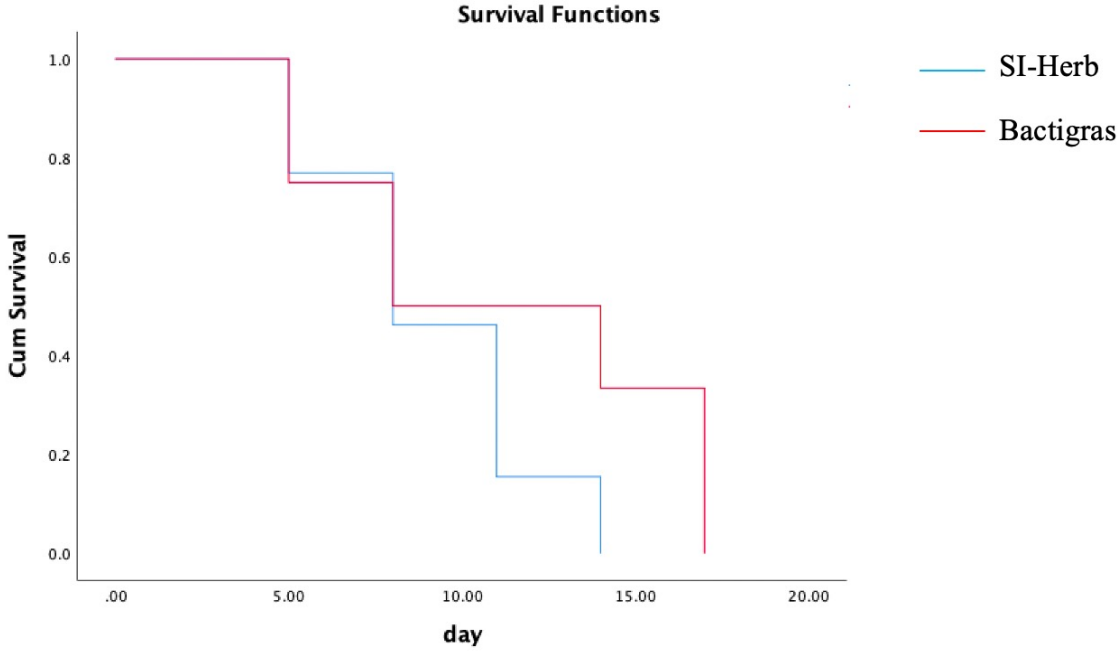

Fig 2. Time to complete wound epithelialization (Log-rank test (Mantel-Cox); p-value = 0.088); Data are presented in day(s).

facilitate the acceleration of wound healing.[13-18] A recent meta-analysis and systematic review showed that these herbs facilitated a faster time of burn wound healing compared to other treatments, such as saline gel, silver sulfadiazine cream, and chlorhexidine gel.[15] Moreover, *Centella asiatica* enhanced wound healing through improved angiogenesis and a stimulating effect on type 1 collagen, fibroblast growth factor, vascular endothelial growth factor production, and its anti-inflammatory effect.[17] *Aloe vera* improves the wound healing process by inhibiting inflammatory reactions and through its regenerative properties, which eventually increase the production of collagen.[18] *Aloe vera* also has anti-viral and anti-bacterial properties, and it helps the skin retain moisture, which affects wound healing.[18] The aforementioned reason explains the shorter duration of burn wound healing observed in the use of herbal-coated lipidocolloid dressings.

Pain during wound dressing changes is a significant concern in pediatric patients due to its potential psychological impact and the risk of future medical procedure avoidance.[19] Pain experienced during wound dressing or dressing removal is notably higher in the first week, which is attributed to increased exudate and incomplete epithelialization. Consequently, we set a cutoff for the pain score and compared observations between the first week and the subsequent week. Nevertheless, our findings are consistent with previous research, showing that the use of herbal dressings was associated with lower pain scores during dressing changes.[11]

None of the patients included in this study experienced wound infection which necessitated additional antibiotic treatment. However, the risk of local or systemic infection remains a significant consideration in the overall management of pediatric burn patients. Early post-burn antibiotic prophylaxis has shown no efficacy in preventing burn wound infections in the general population.[20] Likewise, a meta-analysis investigating antibiotic prophylaxis in pediatric burn patients revealed no notable disparity in the prevalence of local or systemic infections between cohorts receiving antibiotics and those abstaining from them.[21] Additionally, complications exclusively associated with systemic infections did not exhibit variance between patients who were administered antibiotics and those who were untreated.[21]

This study demonstrates the efficacy of herbal-coated lipidocolloid dressings in pediatric patients, leading to significant reductions in pain scores, bleeding, and difficulty during dressing removal when applied between days 3 and 8 post-injury. The findings of this research hold implications for the development of protocols involving the utilization of innovative commercial dressings for managing partial-thickness skin burns in pediatric populations across various community or general hospitals in Thailand. The limitation of this study is that the study was conducted in one institute in one province, therefore limiting the generalizability of the results. Therefore, a multi-center or national-level study should be implemented. A study of the cost-effectiveness of the dressings should also be conducted in the future. Further study on the use of a herbal-coated lipidocolloid dressing in pediatric populations involving less frequent wound dressing should be undertaken.

In conclusion, the application of a herbal-coated lipidocolloid dressing in pediatric patients with partial-thickness burns covering equal to or greater than 10% of the total body surface area resulted in significantly accelerated complete epithelialization compared to application of a paraffin-based dressing. Although no disparities were observed in the duration of complete epithelialization among burn patients with less than 10% of the total body surface area involved, they experienced significant reductions in pain score, bleeding score, and difficulty during wound dressing.

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DECLARATION

Conflict of Interest

This project obtained study material (SI-Herb®) from the Specialty Innovation Co., LTD. (Bangkok Botanica Co., LTD., Thailand) for utilization in this investigation. The principal investigator declares no additional financial conflicts of interest.

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Author Contributions

NH: Investigation, Conceptualization, Methodology, Validation, Resource Management, Formal analysis, Data curation, Writing - Original Draft, Writing - Review & Editing

WM: Data curation, Writing - Original Draft.

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