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Original Article

Effect of Bilva Herbal Ointment and Silver Sulfadiazine on Healing, Pain and Itching of Burn Wounds

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Abstract

Introduction: The most common method for burn wound dressing is silver sulfadiazine (SSD); however, its side effects on wound healing and the need for repeated use are often painful. This study sought to compare two different dressings, namely Bilva and SSD ointments, on wound healing, pain, itching, and scarring of burn wounds.

Methods: This clinical trial was performed on 35 patients with superficial second-degree burns hospitalized in the Burn Ward of Sina Hospital in Tabriz, Iran, from 2019 to 2020. After irrigation of the wound, Bilva ointment was applied randomly on one side and SSD ointment on the other side to treat the burns. Patients were followed on days 1, 7, 14, 21, and the first, second, and third months after burns; data related to the wound healing process, pain, itching, and scar status of the patients were collected with a checklist.

Results: There was no statistically significant difference between the two groups of variables related to the wound healing process on any of the time-points. The amount of burn wound scar did not differ between the two groups on day 21 and the first, second, and third months. Pain and itching were significantly better in the Bilva group on the 7th ($P<0.01$), 14th ($P<0.01$), 21st days ($P<0.01$), and the first month ($P<0.01$) after burns.

Conclusion: Bilva ointment had a similar effect on healing of the burn wounds of patients compared to SSD, and it was more effective in controlling pain and itching of burn wounds. Further studies are needed to evaluate the cost-effectiveness of this dressing method on superficial burn wounds.

Keywords: Burn, Silver Sulfadiazine Ointment, Bilva Ointment.

Introduction

Unfortunately, burn wound management remains a matter of debate, and an ideal dressing for burn wounds has not yet been found [1,2]. Pain, itching, scar hypertrophy, prolonged hospital stays, and recovery are the main concerns of burn patients. Moreover, the burn wound can harm the lives of these patients. Pain and itching caused by burns, especially 1-2 weeks after the start of wound healing, cause anxiety, decreased contact with others, sleep disturbance, movement defects, reduced appetite, declined quality of life, and increased costs of health care [3-5].

Infection is another common problem of burn wounds that, in addition to complications such as fever and weakness, also delays wound healing [6]. Hypertrophic

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scarring is a significant, long-term functional and aesthetic problem resulting from burn wounds [7, 8].

There are several topical treatments for burn wounds. Among these treatments, SSD ointment is extensively used in patients. Side effects of this ointment include pain, leukopenia, nephrotoxicity, methemoglobinemia, silver poisoning (argyria), and discoloration of the skin following its use; therefore, it should be used with caution in people who are allergic to sulfonamides [9]. Consequently, it is recommended to find alternative natural medicines that are superior in terms of effects on these burns and even have fewer side effects. Research has shown that the combination protocols is highly effective in treating burn patients [10].

Aloe vera, turmeric, beeswax, and castor oil have unique properties that can be effective in healing burn wounds. Castor oil has anti-inflammatory and moisturizing properties, and it is rich in fatty acids. Aloe vera promotes wound healing and reduces inflammation. Turmeric has anti-inflammatory and immune system stimulating effects. Besides, curcumin in turmeric helps form new blood vessels and increases collagen content, thus healing wounds. Beeswax has powerful antiseptic properties; on the other hand, honey can accelerate wound healing by absorbing water in swollen tissues. Sweet almond oil is appropriate for itchy skin, skin inflammation, and burns, and it is a rich source of vitamin E, protein, and minerals. The combination of these drugs brings together their individual effective properties. Therefore, applying these items in the form of an herbal ointment can be adequate[11-13].

As 24-hour caregivers of burn patients, the nurses have a crucial and undeniable role in the wound outcomes of these patients. Pain relief is among the most important nursing interventions. The ability to prevent and relieve pain as well as training to adapt to it is one of the beautiful arts of nursing [14]. Therefore, nurses prefer to use ointments for burn dressings that accelerate healing, impose less pain on the patient, and prevent side effects such as infection and scarring. Therefore, it seems that the natural compounds have fewer side effects, and more acceptance can provide a more effective dressing method for both nurses and patients. This study aimed to compare the impact of two dressings, namely Bilva and SSD ointment, on the healing, pain, itching, and scarring of burn wounds in Sina Hospital.

Methods

After obtaining the ethics code (IR.TBZMED.REC.1396.227) and IRCT registration number (IRCT20160424027561N11), this randomized clinical trial was performed in the Burn Ward of Sina Hospital, Tabriz, Iran, from 2019 to 2020. Moreover, after obtaining permission from the hospital management and related departments, eligible hospitalized patients were invited to participate in the study and were recruited after giving informed consent. For this study, patients with superficial second-degree burns were selected, and each part of the symmetrical organs with burns was randomly divided into two groups of intervention and control. The control member received a routine dressing with SSD, and the intervention member was treated with Bilva ointment. The healing process, pain, itching, and hypertrophic scar were evaluated and compared between the two groups.

Sample size was estimated to be 33 people by G power software (Power of a test 85%, significance level α = 0.01, and Cohen impact size 0.80). Samples were taken by convenience sampling.

Inclusion criteria were women patients with burns up to 20% of the body surface and depth of second-degree burns, the presence of burns in symmetrical organs with the same depth, the cause of burns being something other than chemical and electrical, application of anything other than drinking water and normal saline to irrigation the burn site, lack of inhalation damage, and >2 hours past the burning. Exclusion criteria were underlying diseases such as diabetes mellitus, allergic skin diseases, malignancy, AIDS, hypertension, use of cytotoxic drugs, symptomatic infection in different parts of the body, referral to other medical centers, withdrawal from the study, increased depth of burn in the healing process, presence of infection signs and a positive culture response from the burn wound.

Contents of Bilva Ointment

In this study, Bilva herbal ointment was used to dress the burn wounds of patients. The plant names were checked with (http://www.theplantlist.org). Ingredients of this ointment include Castor oil plant (Local name:

Roghan karchak, scientific name: Ricinus communis L.) (52.8%), Beeswax (38%), Turmeric (Local name: Zardchobeh, scientific name: Curcuma longa L) (3%), Aloe vera (Local name: Sabre zard) (2%), and, Sweet Almond oil (Local name: Badam shirin, scientific name: Prunus dulcis (Mill.) D.A.Webb) (1.2%). The raw materials were mixed thoroughly in a steel tank, and the temperature increased to 70 degrees. After melting the materials, the temperature reached to 40 degrees; Aloe vera was added, transferred to a storage tank, and then packed in sterile containers.

Data Collection Tools

Data were collected through a six-part checklist. The first part was related to the individual-social characteristics of the participants

Part two, namely Wound Healing Evaluation with a Healing Checklist, was performed based on the review of prepared texts, content validity, and simultaneous reliability of observers.

Patients' pain was assessed, in the third part, using the Visual Analogue Scale (VAS). This tool is developed by Mac Gill and looks like a ruler, which has a score range of 0-10. A zero score means no pain, and a score 10 indicates the highest pain intensity. The validity and reliability of the scale have already been reviewed and confirmed in similar studies[15].

The fourth part was related to the evaluation of itching of the wound site among patients with the Visual Analogue Scale (VAS). This tool was created by Mac Gill; the zero score means no itching, and the ten score indicates the highest intensity of itching. The validity and reliability of the scale have already been reviewed and confirmed in similar studies[16].

The fifth part was concerned with scar hypertrophy, which was measured using the Vancouver scar scale (VSS) developed by Sullivan. This tool examines the four variables of vascularity, thickness, flexibility, and skin color of the burned area. The total score of this tool is 0 to 16, with a score of zero indicating healthy skin and a score of 16 showing the highest degree of skin problems. The validity and reliability of the tool have already been reviewed and confirmed in similar studies[17].

Burn Wound Evaluation and Randomization

The researcher visited the women's Burn Ward every day and selected eligible patients by available methods; subsequently, the objectives of the study were explained to them, and by providing informed consent form to literate people and oral explanation in the presence of a third party for illiterate people, written consent was obtained from patients to participate in the research. Also, the selected patients were given the necessary explanations about the random assignment of each burn organ to the intervention and control groups. To randomly allocate the ointment application site in patients, a simple coin-based random method for each patient was performed by the nurse. This allocation continued until the complete healing of the wound. On one side of the coin, the label L indicated the left side, and on the other side, the label R represented the right side of the body. These designations were randomly assigned to the dressing group with Bilva, and the opposite side was treated with the usual dressing with SSD ointment (Fig. 1).

A burned limb was treated with SSD ointment following the hospital routine, and its symmetrical site was treated with Bilva ointment. Other nursing cares, such as daily bathing, initial irrigation of wounds with normal saline before dressing, management of wound blisters, and same method for both organs.

Wound healing in both groups was assessed daily by the researcher, who was unaware of the intervention and control groups before dressing, and the severity of pain and itching was controlled and evaluated half an hour after the dressing. Wound healing status was assessed on days 1, 7, 14, and 28, as well as in the first, second, and third months after the first dressing. Pain and itching at the wound site were evaluated separately for each group on days 1, 7, 14, and 28. Then, the status of wound hypertrophy was assessed at 1, 2, and 3 months after the intervention.

Data analysis

Data were obtained using descriptive statistics (frequency, frequency percentage, mean and standard deviation). After examining the homogeneity of data through the Kolmogorov-Smirnov test, analytical statistics were done with the Wilcoxon Signed-Rank

Test and Paired-Samples T-Test with level of alpha set at 0.05. Data were analyzed using SPSS software version 22 by a blind statistician.

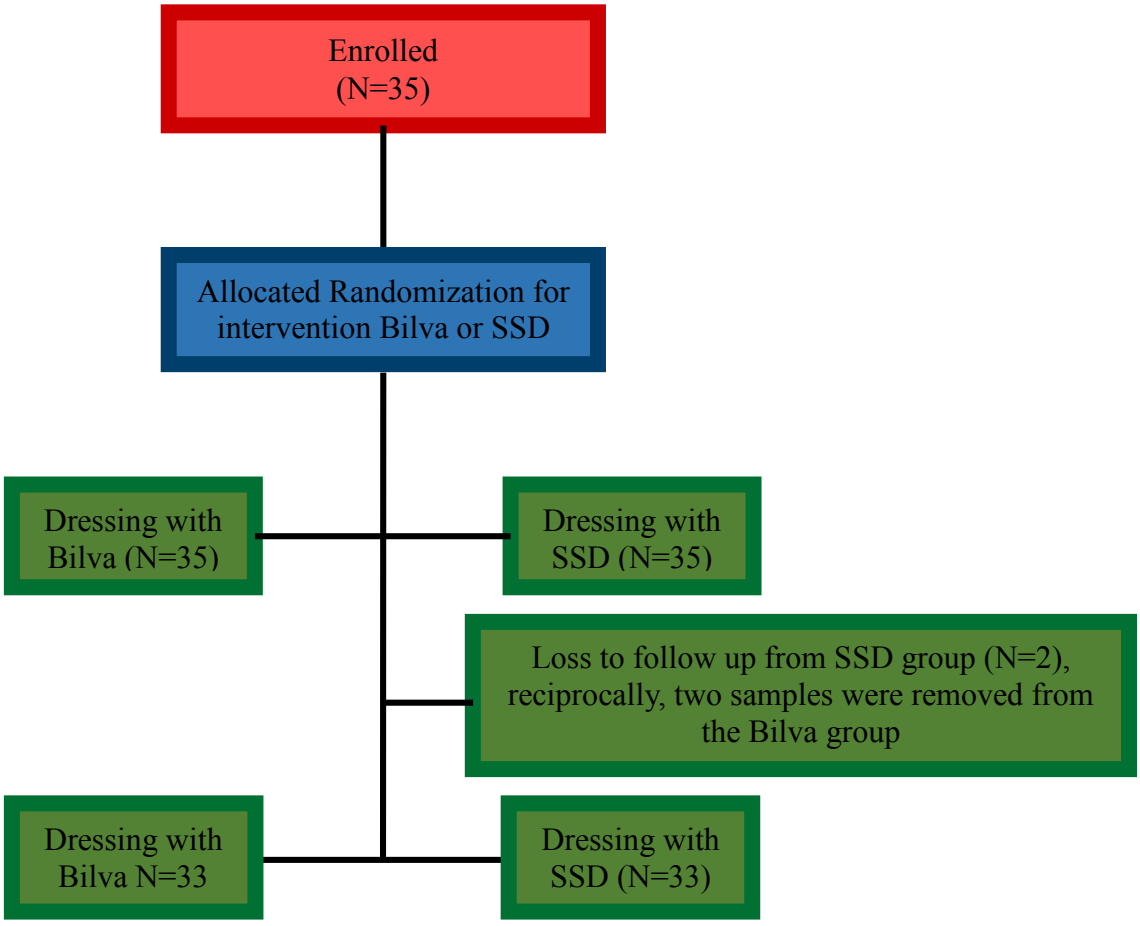

Fig. 1. CONSORT diagram, including the number of patients who started and continued trial treatment, and stopped.

Results

In this study, 35 patients with superficial second-degree burns were recruited after presenting informed consent. In wounds on both sides, 35 patients were randomly and consecutively divided into two dressing groups: SSD and Bilva ointment. In the SSD group, two patients were excluded due to increased depth of the burn and early signs of infection (higher discharge and discoloration at the wound site), and the number of samples was 33(Fig. 1).

The mean age of patients was 40.6±16.1 years, and all of them were female. Fifteen subjects (42.8%) had burns due to hot water, and fifteen people (42.8%) had burns due to fire. The percentage of TBSA in all patients was <20%. Other demographic information of the participants is given in Table 1.

Table 1- Socio-demographic characteristics of the participants(N=35)

Variables		X±SD/n (%)
Age, years		40.6±16.1
Residence location	Urban	11(31.4%)
	Rural	20(57.1%)
	The country side	4(11.4%)
Marital Status	Married	31(88.5%)
	Divorced	4(11.4%)
Education status	Illiterate	15(42.8%)
	Primary	4(11.4%)
	Guidance	8(22.8%)
	Diploma	8(22.8%)
Financial situation	Bad	15(42.8%)
	Average	15(42.8%)
	Good	5(14.2%)
History of Drug	Yes	11(31.4%)
	No	24(68.5%)
History of disease	Yes	8(22.8%)
	No	27(77.2%)
Burn percentage	0-10	11(31.4%)
	10-20	11(31.4%)
	20-30	5(14.2%)
	30-40	4(11.4%)
	50-60	4(11.4%)
Lengths Hospitalization, days	0-10	23(65.7%)
	10-20	7(20%)
	20-30	5(14.2%)
Burning cause	Boiling water	15(42.8%)
	Hot liquid	5(14.2%)
	Fire	15(42.8%)

Wound healing in three distinct stages of inflammation, granulation, and epithelialization in the two groups treated with SSD ointment and Bilva ointment is shown in Fig. 2. The results revealed no statistically significant difference between the two groups of variables related to the wound healing process over the study period. The amount of burn wound scar did not differ between the two groups on day 21 as well as on the first, second, and third months (Table 2). Patients' pain and itching were significantly better in the Bilva group on the 7th ($p<0.01$), 14th ($p<0.01$), 21st day ($p<0.01$), the first month ($p<0.01$), and the second month ($p<0.05$) after burns than the SSD group (Fig. 3).

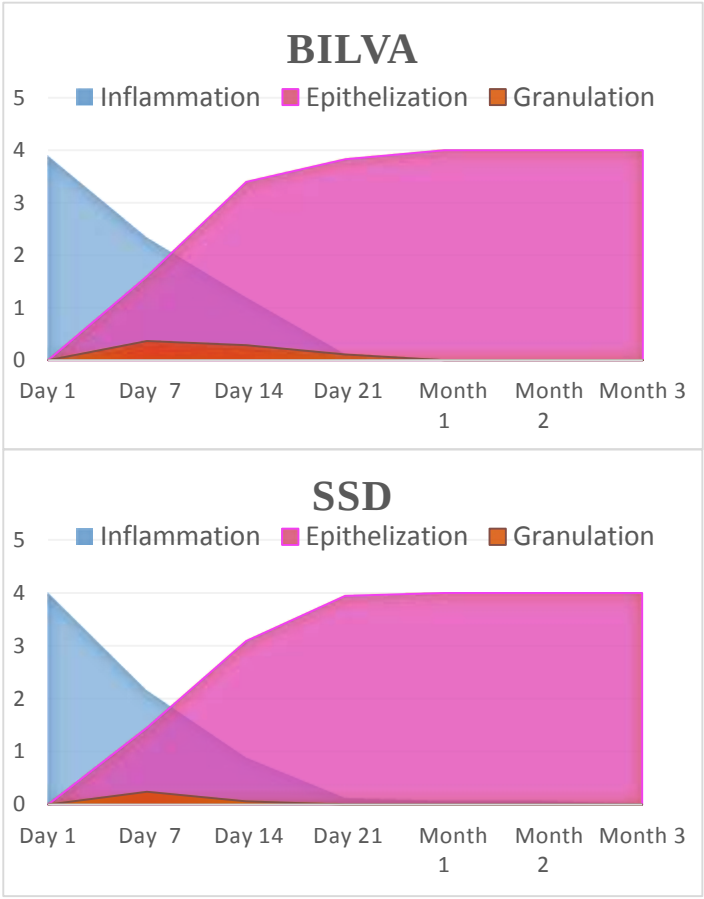

Fig. 2. Timeline of cutaneous wound healing. Wound healing in three overlapping stages: inflammation, epithelization, and

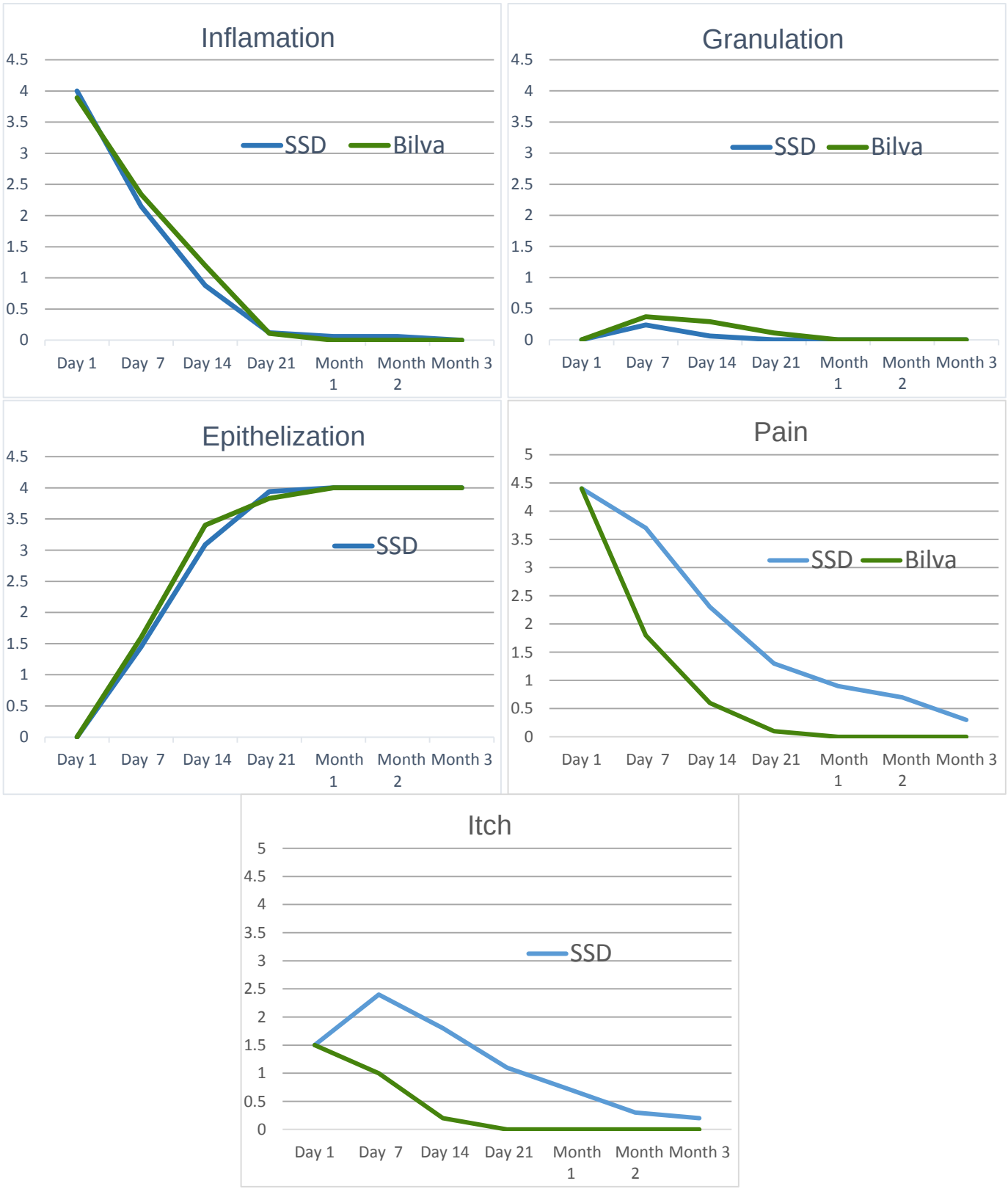

Fig. 3. Compare two different dressings, Bilva and SSD ointments, on wound healing, pain, and itching of burn wounds.

Table 2- Comparison of the mean score of wound scars in the two groups bandaged with SSD and Bilva

Date	SSD	Bilva	P-Value
Day 21	2.3±0.8*	2.3±1.4	1.00
Mouth 1	2.4±0.9	2.6±1.5	0.64
Mouth 2	2.3±1.5	2.6±1.8	0.53
Mouth 3	1.9±1.6	1.9±1.9	0.75

* Burn Scar Status Score Based on the Vancouver Scar Scale (0-13)

Discussion

The findings of the present study showed that the process of wound healing and final scarring in the use of Bilva ointment in dressing second-degree burns is not significantly different from the standard treatment of burn wounds, namely 1% silver sulfadiazine ointment. On the other hand, the severity of pain and itching in patients in the dressing group with Bilva was much lower than SSD.

Bilva ointment was more effective than SSD in controlling pain and itching among patients. One of the ingredients in this ointment is sweet almond oil, which is helpful for relieving itchy skin, alleviating skin inflammation and treating burns. Almond oil is also a rich source of vitamin E, protein, and minerals. In a study by Malakouti et al. (2016) in Iran and a research by Dhiman et al. (2011) in India, the anti-Itching effect and reduction of stretch marks in pregnant women were indicated using sweet almond oil [13, 18].

In a study of Mahboub et al. the aloe vera gel significantly reduced the itching and pain of burn patients compared to SSD [19]. Shahzad et al. revealed that in patients with grade two burns treated with aloe vera gel, there was earlier pain relief compared to those treated with SSD. Aloe vera causes premature wound epithelialization and early pain relief, and it is more cost-effective than SSD ointment [20]. Aloe vera gel has been used in the composition of Bilva ointment. For this reason, in the present study, the burn site dressed with Bilva ointment reported less pain than the place where SSD ointment was used.

The beeswax of this herbal ointment has moisturizing properties like vitamin A, and it has an anti-inflammatory action similar to an analgesic on wounds, which causes a feeling of relaxation on the skin. A review study conducted by Yilmaz et al. (2020) reported the effects of honey on wound dressing, and its pain-reducing outcomes have also been reported [21].

In the present study, there was no significant difference between Bilva ointment and SSD in terms of the wound healing process, such as inflammation, epithelization, and granulation during the study period; however, the positive effects of herbal ointments have been shown in various studies compared to the current conventional dressing, namely SSD ointment [2, 22, 23]

In the study of Nasiri et al. in 2016, the use of Abu Khalsa herbal ointment had a better effect in the treatment of second-degree burn wounds compared to SSD, which significantly accelerated the wound healing process [24].

Saeedinia et al. in 2017, found that the use of Centiderm ointment, which is made from C. Asiatica, had an apparent effect on physical and mental symptoms in less than three days; this ointment also causes epithelialization and complete healing without any infection among burn patients. Therefore, due to the cost-effectiveness and superiority of this ointment, they recommended it instead of SSD ointment[2]. Also, a study by Heydari et al. in 2011 showed that the healing time of burn wounds in the group treated with Fundermol ointment (alpha), whose main ingredient is Lawsonia Inermis, was shorter than the SSD group and that Fundermol ointment can be used as a proper alternative for the treatment of burn wounds [25]. Due to the numerous identified side effects of SSD ointment in treating burns, more studies are still underway to find more effective drugs.

Various studies have applied at least one of the compounds in Bilva ointment for the treatment of burn wounds and showed the positive effects of honey [26, 27], aloe vera gel[28-30], and turmeric in the healing of burn wounds[31, 32].

Silver sulfadiazine ointment has been shown to reduce bacterial contamination, accelerate epithelialization, and delay wound contraction[33, 34]; however, SSD delays wound healing and causes atrophic and hypertrophic scars [22, 35]. On the other hand, we expected that despite the active ingredients in the composition of Bilva ointments, such as aloe vera and honey, the amount of scar left is relatively negligible[11]. However, in this study, the piece of the scar left in the two dressings with Bilva ointment and SSD in second-degree burn wounds was not significantly different. Because of the superficiality of the burns in this study and the relatively limited scar left, a detailed study of the effect of interventions on the scar rate could not be established.

Therefore, in future studies, to investigate the effect of Bilva ointment on burn wound scars, it is recommended to perform interventions on deeper burn wounds.

Limitation

The limitations of this study were the small number of patients under research and the superficiality of burn wounds that prevented a detailed assessment of the effects of interventions on the hypertrophic scar.

Conclusion

In this study, Bilva ointment with herbal compounds and fewer side effects acted similar to 1% silver sulfadiazine ointment in terms of speed and healing process of second-degree burn wounds. The pain and itching of burn wounds at the application site of Bilva ointment were less than SSD ointment. Given these benefits and their cost-effectiveness, Bilva ointment seems to be an excellent alternative to SSD ointment. However, due to limited studies, further studies are recommended.

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Conflict of Interest Disclosures

The author declared no potential conflict of interest.

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The authors received no financial funding or support for the research.

Authors' Contributions

ML did overall supervision and design. ST preparation of the ointment. ST, BD, and AN acquisition of data of clinical data. AMAA did statistical analysis and interpretation of data, MHR wrote the first draft and managed the research, and ML did the final edit. The authors read and approved the final manuscript.

Ethical Statement

After obtaining the ethics code (IR.TBZMED.REC.1396.227) and IRCT registration number (IRCT20160424027561N11), this randomized clinical trial was performed in the Burn Ward of Sina Hospital, Tabriz, Iran, from 2019 to 20.

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