

Burn Wound Healing Effect of a Sterilized Traditional Formulation of *Boswellia carteri* vs. Silver Sulfadiazine Cream 1% in Patients Presenting Second-degree Burn Wounds: A Randomized, Double-blind Clinical Trial

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What's Known

- Natural compounds such as oleo-gum-resins have been traditionally applied to treat burn wounds.
- The topical application of a cream containing *Boswellia* on excision wounds affected different phases of wound healing, including collagen synthesis and wound contraction, leading to a faster healing process.

What's New

- In the treatment of burn wounds, the healing effect of a 40% *Boswellia carteri* formulation containing 0.72 mg of β -boswellic acid per 100 g was compared to silver sulfadiazine.
- On each day of the study, both healing time and healing indices were statistically comparable between the groups.

Abstract

Background: Burn wounds rank among the most serious healthcare issues. Many studies reported the effectiveness of natural products in the wound-healing process. The present study compared the effects of a standardized herbal formulation derived from *Boswellia carteri* (*B. carteri*) and silver sulfadiazine (SSD) cream 1% on the healing of burn wounds.

Methods: This randomized double-blind clinical trial was conducted at Shiraz Burn Hospital (Shiraz, Iran) between July 2012 to August 2013. A sterilized formulation comprising *B. carteri* 40% was prepared. 54 second-degree burn patients of both sexes with age ranges of 20 to 60 were invited to participate in this double-blind, randomized clinical trial. They were randomly divided into two groups and given either the *Boswellia* formulation or SSD cream. The healing index was determined based on the wound area assessment using the planimetry technique. The Kaplan-Meier survival analysis was used to assess the primary outcome, which was the amount of time until complete healing.

Results: The trial was completed by 17 patients from the SSD group and 15 patients from the *Boswellia* group. During the study period, both groups showed a progressive healing trend. The mean (95% CI) healing time in the SSD group was 10.94 (9.03-12.85) days and 10.73 (9.23-12.23) days in the *Boswellia* group ($P=0.71$), indicating no significant difference. On the 17th day, the healing index of all patients in the *Boswellia* group reached 1.

Conclusion: *Boswellia* topical formulation had a burn wound healing effect comparable to that of the standard SSD 1% treatment. Based on the findings of this study, the likelihood of contact dermatitis with *Boswellia* should be taken into consideration.

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Introduction

Acute thermal injuries requiring medical care and surgical treatment are prevailing and burdensome. Burns cause the loss of around 18 million disability-adjusted life years and more than

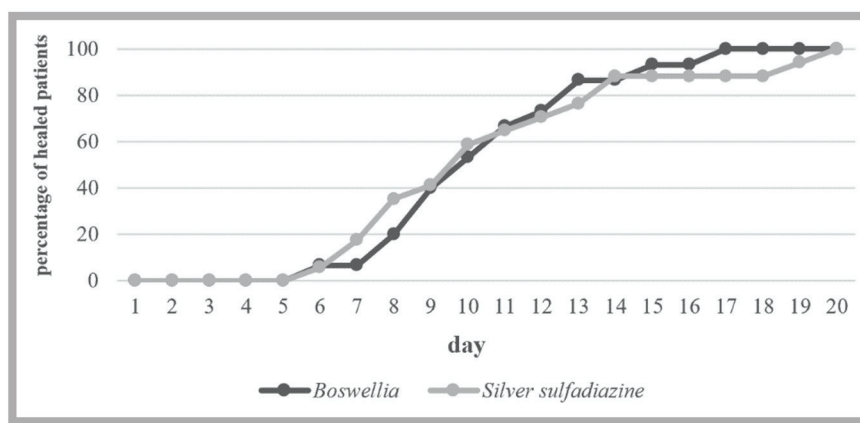


Figure 4: The trends of healed patients (%) in the silver sulfadiazine cream 1% group and *Boswellia carteri* formulation group were compared with each other.

methemoglobinemia, and it is not recommended during pregnancy or infancy.^{26, 27} Therefore, looking for an alternative medication that does not have the limitations of SSD seems helpful. The oleo-gum-resin of *B. carteri* consists of boswellic acids and essential oils, composed mainly of octyl acetate, incensole, and incensole acetate.^{18, 28} The anti-inflammatory effect of boswellic acids were established in many studies.^{29, 30} Furthermore, the essential oils of *Boswellia* species act as antimicrobial agents.^{31,32} Therefore, it is hypothesized that the wound-healing properties of *Boswellia* formulations are mostly due to their anti-inflammatory components such as boswellic acids and essential oils.

To the best of our knowledge, this is the first clinical trial to evaluate the burn wound healing effect of a sterilized product formulated from *B. carteri*. In this study, a topical formulation based on manuscripts from traditional medicine was developed. The main ingredient of the formulation, *B. carteri* oleo-gum-resin, was sterilized using gamma-irradiation to minimize the hazard of pathogenic microorganisms.

In 2004, a case of allergic contact dermatitis was reported in which *Boswellia* oleo-gum-resin was considered a safe herbal medicine.³³ Essential oils are proven to be a potential source of allergic reactions.³⁴ As *B. carteri* contains essential oils, the reaction may be associated with these compounds. Nevertheless, the findings of the present study indicated that utilizing BCF 40% could lead to the possibility of allergic contact dermatitis. Furthermore, exposure to gamma radiation of *B. carteri* might cause degradation of some components to low molecular weight compounds that penetrate the epidermal barrier faster and trigger hypersensitive reactions. The only limitation of the study was the difference between the TBSA of the two groups ($P=0.01$).

Conclusion

The findings of the present study indicated that a 40% BCF had healing activity in treating second-degree burn wounds. According to the results of this randomized clinical trial, BCF and SSD, the standard treatment for burn wounds, provide comparable healing times and healing indices. However, the likelihood of allergic reactions to BCF should be taken into consideration. Consequently, further studies on formulations with a lower concentration of *B. carteri* are suggested as products with lower percentages of oleo-gum-resin might not elicit hypersensitivity reactions.

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Authors' Contribution

P.B: conception, study design, acquisition of data, drafting the manuscript; S.A: conception, revising the manuscript critically; H.R.T: analysis and interpretation of data, revising the manuscript critically; A.A.M: study design, revising the manuscript critically; S.D: conception, study design, revising the manuscript critically; All authors have read and approved the final manuscript and agree to be accountable for all aspects of the work in ensuring that questions