

## Efficacy and side effects of Blacksoap® as adjuvant therapy of scabies: a randomized control trial

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### ABSTRACT

**BACKGROUND** Blacksoap® is recognized as adjuvant therapy for scabies, but there has been no significant study on its effectiveness. This study aimed to compare the efficacy and safety between Blacksoap® and placebo on standard treatment for pruritus visual analog scale (VAS) and transepidermal water loss (TEWL) scores before and after receiving therapy.

**METHODS** This single-blind randomized controlled trial was held in a boarding school in West Java in 2018. Subjects were recruited consecutively by random cluster sampling. Both groups received standard permethrin 5% cream therapy. The intervention group (n = 37) obtained Blacksoap®, while the control (n = 41) received baby soap. During the initial assessment, pruritus VAS and TEWL scores were taken. The cure rate, scores of pruritus VAS and TEWL, as well as side effects were assessed and compared during the first and fourth weeks. Data were analyzed using SPSS software version 20 (IBM Corp., USA) by a third party, mostly using non-parametric tests.

**RESULTS** The cure rate of the intervention group was lower than the control in the first week with 75% versus 81% but higher in the fourth week with 97% versus 92%. There was no significant difference in the scores of pruritus VAS and TEWL, as well as side effects between the two groups.

**CONCLUSIONS** The efficacy and safety of scabies treatment were similar between Blacksoap® and placebo adjunctive to standard treatment. Blacksoap®, on top of standard scabies treatment, might benefit patients by providing a higher cure rate in 4 weeks without any considerable adverse effects.

**KEYWORDS** adverse effects, Blacksoap®, itching, mange

Scabies is a skin disease caused by an ectoparasite mite infestation<sup>1,2</sup> through direct skin-to-skin or fomites contact.<sup>3</sup> The risk of transmission is high in communal living groups, such as boarding schools, dormitories, etc.<sup>3</sup> The prevalence of scabies in Indonesia ranges from 32% to 64%.<sup>4</sup>

Scabies causes irritable pruritus, and a study conducted in South Korea found that the intensity, measured by the visual analog scale (VAS) score,

was high and correlated with sleep disturbance.<sup>5</sup> The treatment plays a vital role in eradicating scabies. The critical management includes scabicide for patients and people with close contacts, hygiene maintenance, and correct fomite handling. Scabicide is the mainstay therapy of scabies, but when the infection is not cured, the application (permethrin 5% cream) should be repeated after 1 week.<sup>6</sup> Blacksoap® is a trademark soap containing 8% of sulfur, aloe vera, and bamboo

charcoal, and it is claimed as an adjuvant treatment for scabies.<sup>7</sup> The treatment cost will be more economical when the adjuvant therapy can improve the cure rate. However, its efficacy in reducing scabies incidence rate and side effects has not been known.

In general, using soap as a cleanser may result in skin irritation and barrier function disruption.<sup>8</sup> Sulphur composition in Blacksoap® may potentially raise skin irritation. As part of the safety assessment, it is essential to assess skin barrier function. Various methods are used, such as skin biophysical examination through transepidermal water loss (TEWL) measurement.<sup>9</sup> An increase in TEWL after skin cleansing with water or soap had been reported. A high score indicated damaged stratum corneum barrier function.<sup>10</sup> Hence, this study aimed to compare the scabies cure rate and side effects between the application of permethrin cream and Blacksoap® combination and permethrin cream and baby soap combination. Soap as a cleansing agent gives the risk of skin irritation. This leads the skin barrier function test represented by TEWL value before and after therapy to be conducted. The scores improvement of pruritus VAS and TEWL in both groups were then noted and evaluated.

## METHODS

This study was a single-blind randomized clinical trial conducted from September to October 2018 on the scabies patient population at one of a traditional Islamic boarding school in West Java, Indonesia, with 509 students. The third party who was assigned for the statistical analysis was blinded. This was part of a study and social service by the Department of Dermatology and Venereology, Faculty of Medicine, Universitas Indonesia, Cipto Mangunkusumo Hospital. The subjects were students diagnosed with scabies (fulfilling two out of four cardinal signs of scabies). The cardinal signs are nocturnal pruritus, pruritus among groups of people, the appearance of skin lesions characteristic in predilection sites, and mites through microscopic examination.<sup>1</sup> The estimated sample size to evaluate the proportional difference of subjects with scabies before and after therapy was calculated using the formula of mean comparison between the two groups. The number of samples needed was 38 for each group. All data were analyzed using SPSS software version 20 (IBM Corp., USA) by a single-blinded third party.

Furthermore, the results were considered valid when the  $p$ -value  $\leq 0.05$ .

A random cluster sampling was conducted, and subjects were divided into intervention and control groups. Both groups received standard therapy of permethrin 5% cream (Scabimite®, Indonesia). Permethrin 5% cream was chosen because it was effective for all mites' life stadium.<sup>1,6,11</sup> It should be applied thoroughly throughout the body from the neck to toe and then washed after 8 hours.<sup>16</sup> The intervention group had permethrin 5% cream (30 g) and showered using Blacksoap® (60 g). Meanwhile, the control group had permethrin 5% cream and baby soap (60 g). Soap was used twice daily while showering, and the leader of each cluster supervised the application. All students were briefed on the study and instructed on how to shower properly with soap. Permethrin 5% cream was re-applied during the first follow-up in the first week on both groups. In addition, reapplication of scabicide was conducted to ensure all subjects were cured and to prevent reinfection during the follow-up period.

The subjects' skin scraping was examined with potassium hydroxide (KOH) solution to find the mites in the predilection site. A trained laboratory assistant performed the scraping. The sample was taken from a skin lesion in a predilection site. Pruritus VAS score and TEWL measurement were also noted before giving the suitable therapy to both groups.

In the first and fourth weeks after the initial assessment, a follow-up was conducted to evaluate the scabies cure rate, pruritus VAS score, TEWL score, and adverse events. The subjects were declared fully recovered when no new lesion was detected on the locations during physical examination. TEWL was measured using Tewameter® TM 300 (Courage-Khazaka, Germany), and this tool had a special probe and was connected to the computer. Measurement was taken three times on the subjects' wrists, and the mean value was noted. All measurements were assessed by dermatology residents without the respected group.

This study was approved by the Ethics Committee of the Faculty of Medicine, Universitas Indonesia (No: 0920/UN2.F1/ETIK/2018) and had obtained protocols ID from ClinicalTrials.gov (NCT05025696). Furthermore, written informed consent was obtained from each subject's legal guardians. This study was conducted under the declaration of Helsinki.

## RESULTS

The prevalence of scabies in School X was 36.7% (187/509), and Figure 1 explains the flow of subject enrollment.

Table 1 displays the sociodemographic and clinical characteristics of the subjects. At the initial KOH examination performed by experienced laboratory assistants, no mites were found from the skin scrapings of all subjects. In addition, there was no difference in the median pruritus VAS and TEWL scores between the two groups.

Treatment effectiveness was measured from the proportion of recovered subjects in the first and fourth weeks, as shown in Figure 2a. The examination showed no significant difference in the proportion of recovered subjects between the intervention and control groups.

Figure 2b shows the median pruritus VAS in the first and fourth weeks. The median pruritus VAS decreased, although the change was not statistically significant ( $p = 0.48$ ). In this study, the skin barrier function was evaluated through TEWL measurement. Figure 2, c and d, show the results and changes in the

first and fourth weeks. No significant difference was found between the two groups' mean and median TEWL scores in both weeks. Statistically, there was no significant difference between TEWL median changes in both groups.

Side effects occurrence rate from scabies treatment in the first and fourth weeks was not significantly different between the two groups (Table 2). In the first week, one subject from the intervention group and two from the control reported increased pruritus during the cream application. Moreover, two other subjects from the control complained of pruritus, accompanied by pain after the cream application. In the fourth week, five subjects tendered similar reports. Another side effect complained in both weeks was pain after cream application.

## DISCUSSION

Subjects were declared cured when the skin lesions disappeared, as described in a similar study in Iran.<sup>12</sup> In the first week of follow-up, the cure rates of the intervention and control groups were 75% and 81% and statistically insignificant ( $p = 0.541$ ).

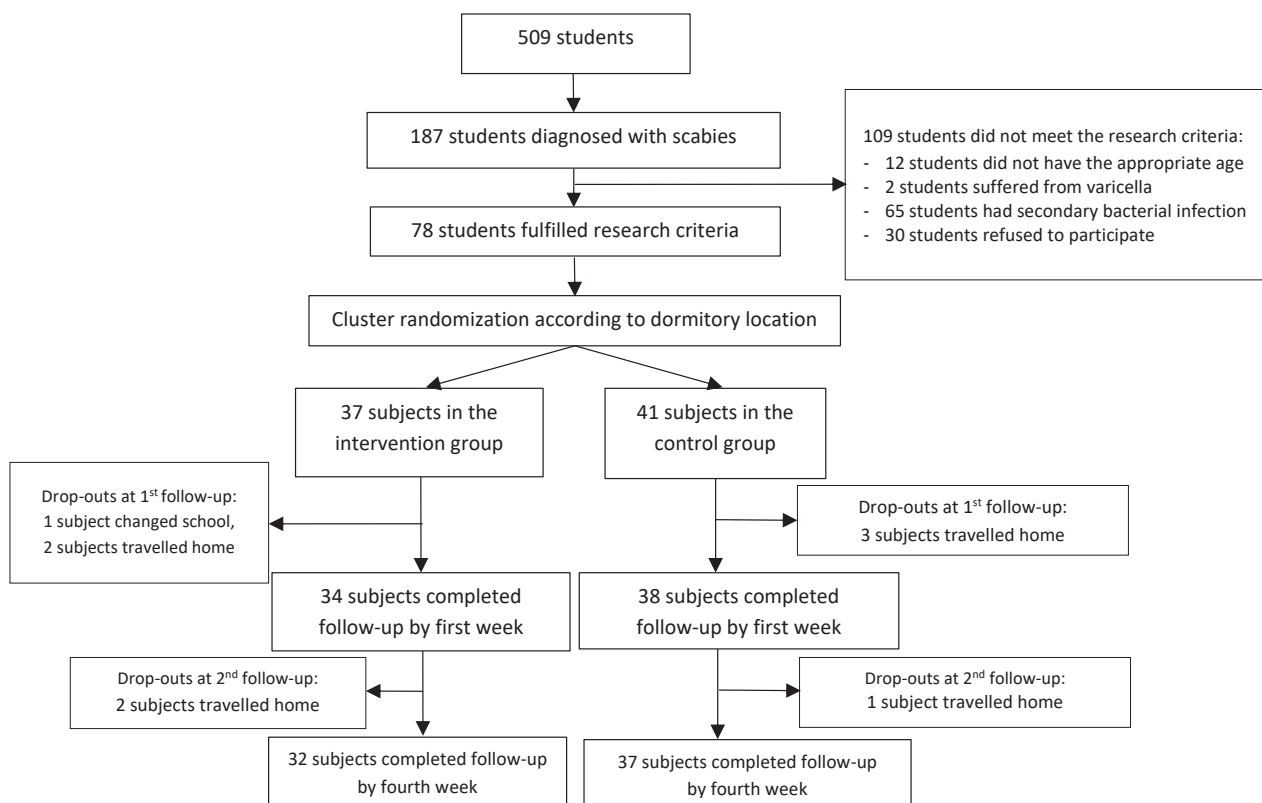


Figure 1. Subjects' enrollment flow-chart

**Table 1.** Sociodemographic and baseline characteristics of subjects

Subject characteristics	Intervention group, n (%) (N = 32)	Control group, n (%) (N = 37)
Age (years), mean (SD)	13.03 (1.33)	12.95 (1.17)
Male sex	6 (19)	28 (76)
Educational level		
Junior high school	31 (97)	35 (95)
Senior high school	1 (3)	2 (5)
Mites finding*	0 (0)	0 (0)
Pruritus VAS, median (min–max)	4 (2–10)	4 (1–8)
TEWL score, median (min–max)	11.8 (7.63–14.57)	11.4 (8.27–19.13)

SD=standard deviation; TEWL=transepidermal water loss; VAS=visual analog scale

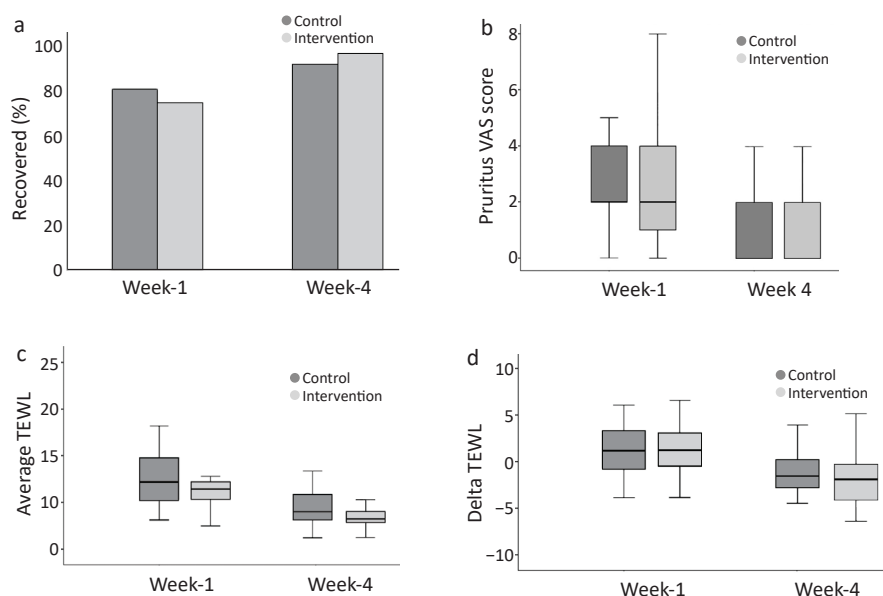
\*With KOH skin scraping

However, the first-week cure rate in the intervention and control groups was higher than permethrin monotherapy in previous studies in Poland and India at 61% and 74.8%.<sup>3,13</sup> This difference can be caused by several factors such as patient compliance, ambient temperature, humidity, and other geographic factors.

In the fourth week of follow-up, the intervention and control groups showed a higher cure rate of 97% and 92%, although it was not statistically significant ( $p = 0.618$ ). This might be due to the sulfur content in Blacksoap®, which has scabidical properties,

thereby improving the cure rate of the intervention group. However, the cure rate in the fourth week was slightly lower compared with scabies patients treated with permethrin 5% cream monotherapy in a previous study, which was 100%.<sup>13</sup> All subjects received permethrin 5% as the backbone therapy. This means that Blacksoap® can be considered an add-on treatment to improve the cure rate of the standard therapy, particularly in the fourth week. However, the difference was not statistically significant since a 5% difference would have clinical and epidemiological benefits in a large population such as boarding schools.

Besides the cure rate, symptom control is also important in treating scabies due to its impact on quality of life. As depicted in Figure 2a, subjects with a pruritus VAS score of 8 were still found in the first week of follow-up. In the fourth week, most of the subjects showed symptom improvement. However, several of them still had pruritus VAS scores reaching 4 even after recovering from scabies. This prolonged pruritus can be caused by post-scabetic pruritus, which may last 2–4 weeks despite adequate treatment.<sup>14</sup> In this trial, the prolonged pruritus in the subjects was possibly caused by post-scabetic pruritus and no reaction to the soap due to constant intensity despite soap application, unlike contact dermatitis, which causes increased pruritus intensity.<sup>15</sup> In this study, there was no significant difference in pruritus VAS score between the two groups. This may be caused by similar efficacy



**Figure 2.** Outcomes of subjects using blacksoap and placebo. (a) Treatment effectiveness (control, N = 37; intervention, N = 32); (b) the median of pruritus VAS; (c) TEWL score; (d) changes of TEWL score. TEWL=transepidermal water loss; VAS=visual analog scale

**Table 2.** Side effects of scabies treatment in the first and fourth weeks

Side effects	First week		Fourth week	
	Intervention group, n (%) (N = 32)	Control group, n (%) (N = 37)	Intervention group, n (%) (N = 32)	Control group, n (%) (N = 37)
Pruritus	1 (3)	2 (5)	0 (0)	2 (5)
Erythema	0 (0)	0 (0)	0 (0)	0 (0)
Stinging sensation	1 (3)	2 (5)	1 (3)	3 (8)

between the intervention and control groups as described previously.

TEWL score is used to assess the skin barrier's intrinsic function. A high score indicates a damaged stratum corneum barrier function.<sup>15</sup> No significant difference in the mean and median TEWL score between both groups was observed in either the first ( $p = 0.986$ ) or fourth ( $p = 0.123$ ) weeks of follow-up. Theoretically, sulfur composition in Blacksoap® potentially causes skin irritation and impairs barrier function. This side effect is somewhat nullified by the presence of aloe vera acting as a humectant, which is deemed beneficial as a skin moisturizer.

There were only slight TEWL score changes in the first and fourth weeks, less than 2 g/h/m<sup>2</sup> in both groups. These changes were clinically not significant for skin barrier function measurement, considering that the median score indicated a healthy-normal skin barrier function (8–20 g/h/m<sup>2</sup>).<sup>16</sup> Therefore, Blacksoap® application for 4 weeks as an adjunct to standard scabies treatment did not cause any TEWL disturbance.

In Indonesia, permethrin 5% cream is still the mainstay of scabies first-line treatment.<sup>6</sup> Besides its effectiveness in all life stages of *Sarcoptes scabiei*, permethrin 5% is selected for its safety profile. It is also safe for pregnant or lactating women and children above 2 months.<sup>17</sup> Permethrin 5% cream application should be repeated when scabies has not been cured, and reapplication shows a better cure rate in those who did not respond to the first course of therapy.<sup>6,11</sup> In this study, reapplication of permethrin 5% cream was conducted to reduce the reinfection risk and improve the cure rate because all subjects lived in groups in a boarding school. In addition, this study performed adverse events monitoring through subjective complaints recording and physical examination findings in the first and fourth weeks. Reported adverse events included pruritus and pain after whole-body topical

therapy administration, which was quite common in permethrin 5% cream application.

This study found no difference in the cure rate, the scores of pruritus VAS and TEWL, as well as scabies treatment side effects with or without Blacksoap® application on the standard permethrin 5% cream. Blacksoap® was considered safe for skin barrier function based on the TEWL score assessment in the first and fourth weeks. Besides, there was no report of adverse events in its application. Other compositions such as aloe vera also act as a humectant to improve skin hydration. Blacksoap® may benefit patients by providing a higher cure rate in 4 weeks without considerable adverse effects. Moreover, Blacksoap® could be considered adjuvant therapy in other dermatoses due to its safety profile and moisturizing effect.

This study had several limitations. The school-age adolescents knew the treatment arms since blinding was not conducted. However, in this trial which employed young adolescents, the absence of blinding might not raise a major effect on the outcome, particularly TEWL that was measured objectively. Recall bias of subjective findings and pruritus VAS score was possible in this study but can be controlled through placebo in future analysis.

In conclusion, the efficacy and safety of scabies treatment were similar between Blacksoap® and placebo adjunctive to standard treatment. Blacksoap® may benefit patients by providing a higher cure rate in 4 weeks without considerable adverse effects. Further studies are promoted to strengthen the role of adjuvant therapy in scabies.

#### Conflict of Interest

Lidwina Anissa, Wresti Indriatmi, Larisa Paramitha Wibawa, and Sandra Widaty received Blacksoap® as the material used in this study provided by PT. Galenium Pharmasia Laboratories.

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