

Evaluation of the Effect of Aloe Vera Ointment with Chamomile Ointment on Severity of Children's Diaper Dermatitis: A randomized, double-blind clinical trial

Sima Ghanipour Badelbuu (1)

Yousef Javadzadeh (2)

Mahnaz Jabraeili (3)

Shiva Heidari (4)

Mohammad Arshadi Bostanabad (5)

(1) MSc Student in Pediatric Nursing, Student Research Committee, Faculty of Nursing and Midwifery, Tabriz University of Medical Sciences, Tabriz, Iran

(2) Professor, Department of Pharmaceutics and Biotechnology Research Center, Faculty of Pharmacy, Tabriz University of Medical Sciences, Tabriz, Iran

(3) PhD Candidate, Department of Pediatric Nursing, Faculty of Nursing and Midwifery, Tabriz University of Medical Sciences, Tabriz, Iran

(4) MS in Nursing, Faculty of Nursing and Midwifery school, Urmia Islamic Azad University, Urmia, Iran

(5) PhD, Assistant Professor, Department of Pediatric Nursing, School of Nursing and Midwifery, Tabriz University of Medical Sciences, Tabriz, Iran

Corresponding Author:

Mohammad Arshadi Bostanabad

Department of Pediatric Nursing, School of Nursing and Midwifery,

Tabriz University of Medical Sciences,

Tabriz, Iran

Email: arshadi_m@yahoo.com

Received: December 25, 2017; Accepted: December 30, 2017; Published: March 1, 2018. Citation: Sima Ghanipour Badelbuu et al. Evaluation of the Effect of Aloe Vera Ointment with Chamomile Ointment on Severity of Children's Diaper Dermatitis: A randomized, double-blind clinical trial. *World Family Medicine*. 2018; 16(3):47-51. DOI: 10.5742/MEWFM.2018.93304

Abstract

Introduction: Diaper dermatitis is an inflammation of the skin under the diapers of children, and is relatively common. The disease is seen in children and adolescents with a degree of urinary incontinence. The aim of this study is to replace uncomplicated herbal medicines in the treatment of this disease instead of chemical drugs.

Materials and Methods: This is a randomized, double-blind, clinical trial that was performed on 90 children under 2 years of age who were referred to the Pediatric Department of Tabriz Pediatric Hospital and who used diapers. The children were randomly divided into three groups of 30, and formed a routine group and two other groups, with routine ointment and chamomile and Aloe Vera Ointment. Sampling was performed on the first, third and sixth days of the study using a five point scale. Data were analyzed using SPSS software (version 22) and descriptive and analytical statistics.

Results: According to the statistical results, the severity of dermatitis in all three groups improved during the study on the sixth day compared to the first day, but there was no significant difference in the severity of diaper dermatitis between the three groups during the study period. ($P > 0.05$)

Conclusion: Regarding the treatment process in all three groups and having positive results in the treatment of dermatitis, the three groups of drugs were effective in treatment, but they were not superior to each other.

But due to the lower side effects of herbal medicine, its use is recommended to treat this condition.

Key words: Aloe vera ointment, chamomile ointment, diaper dermatitis

Introduction

Diaper dermatitis is the most common type of contact dermatitis (1). Diaper dermatitis is the most common type of contact dermatitis in children (2). It is present in areas under diapers (3). Although the main cause of this disease is still unclear, several factors such as wear, moisture, urine and stool and PH changes in the area are effective in creating it (3, 4). According to Borujeni Research, the frequency of disease in various studies is from 7 to 35 percent, and in some cases up to 50 percent (2). Irritation of the area and burning, dryness, scratching and skin irritation are key features. Infiltration of agents and germs can cause infectious, bacterial and fungal infections (2-4). Quoted from Emdadi are The most important age groups in children is age 6 to 12 months, and usually the 3 month old age group should be investigated for differential diagnosis of pemphigus, burn and syphilis and seborrheic dermatitis [5]. Many treatments include zinc oxide ointment, corticosteroid and vitamin A + D, talcum powder, some of which, including talcum powder and corticosteroids, have many side effects, including allergic dermatitis, Skin atrophy, respiratory tract disorders and so on (2, 4, 6). The presence of appropriate therapeutic effects and low side effects is one of the effective factors in increasing plant use in the treatment of diseases (7). The use of herbal medicines such as calendula, chamomile, aloe vera, beeswax, and herbs are important factors in the treatment of diaper dermatitis (5).

Chamomile is one of the most effective medicinal plants in the world (8). Chamomile applications include eczema, infections, inflammation, burns, and laparoscopic rheumatism (8). Aloe Vera is also known as Aloebarbazenesis (Aloe verbabens). It is widely used in the treatment of various diseases (9). Among these uses, it can be used to treat stomach ulcer, cancer, diabetes, and wound healing and anti-inflammation (9). With regard to the above, it can be concluded that herbs can have fewer complications and can be more effective treatments for diseases than chemical drugs. In this study, we try to reveal the superiority of one of the two Chamomile and Aloe vera plants to the other in treating the severity of diaper dermatitis.

Materials and Methods

This study was a double-blind, randomized clinical trial that was conducted in Tabriz Children's Hospital between February and June 2006 in children under 2 years of age who use diapers in the hospital. Ninety children were selected through simple sampling.

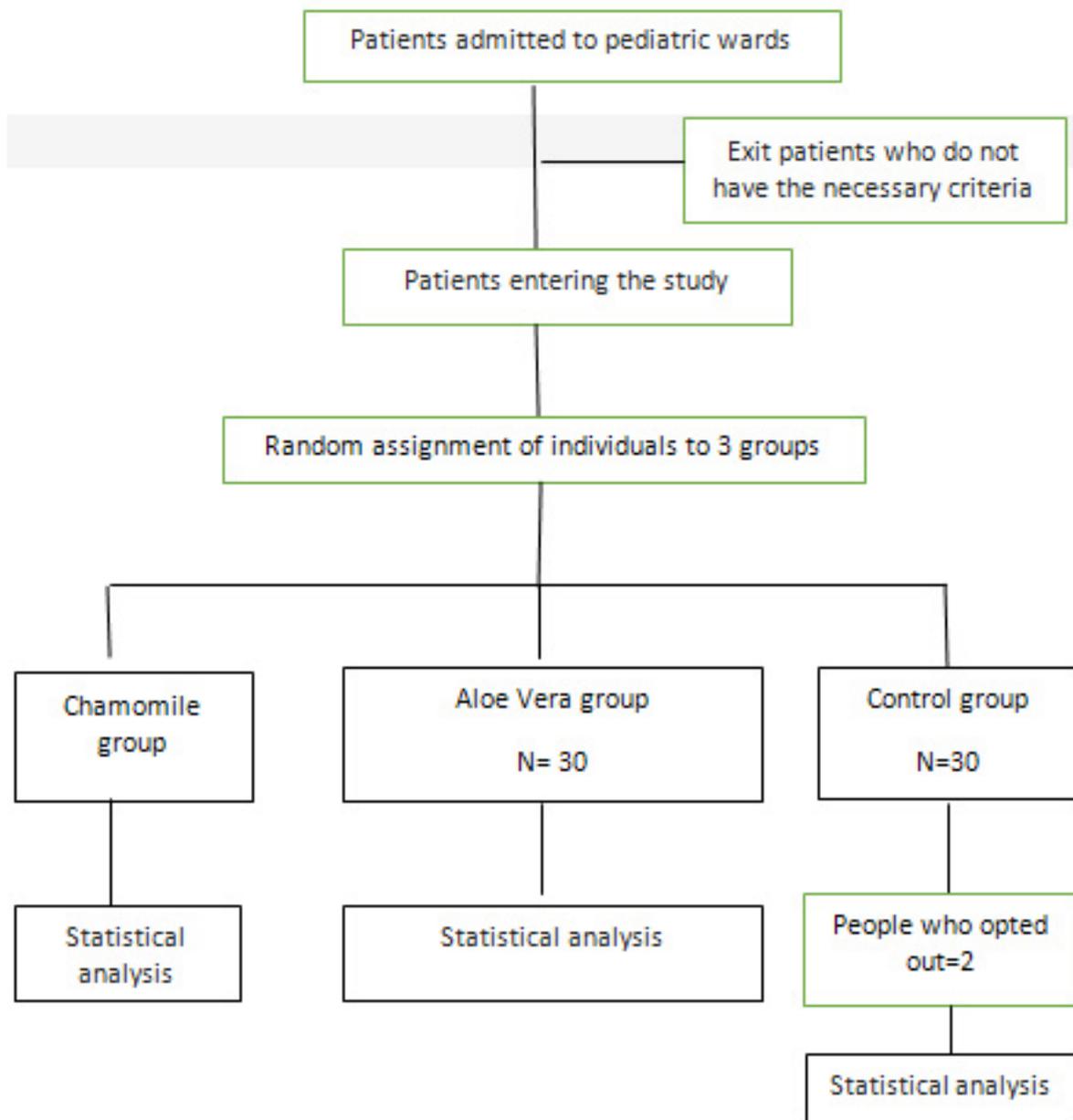
Inclusion criteria included children from the age of 0-24 months, disposable diapers and no known systemic diseases, and the absence of systemic drugs, and criteria for the exclusion of this study was to have a fungal infection, the use of cloth nappies, sensitivity to study drugs and positive culture of faeces.

The sample size in this study was based on the study of Panahi et al. (6) with $\alpha = 0.05$ with a power of 80% and a 10% reduction in the ratio between the two groups of 90. The sample was taken as a simple random sampling. Patients who had inclusion criteria were classified according to Rand List software using six blocks, to three intervention groups, control, chamomile group and Aloe vera group. It should be noted that the groups receiving chamomile and aloe vera with ointments received routine treatment according to the instructions of the practitioner (see Figure 1 - next page).

$$n = \frac{z^2 \cdot p(1-p)}{d^2}$$

In order to examine skin allergy, a little ointment was applied to the child's arm (1 × 1 cm) and controlled after 20 min. In case of no skin sensitivity, 3% chamomile ointment and 95% Aloe Vera ointment with the same shape and weight as A and B specified by the pharmacist were given to the mother by the researcher. It should be noted that the ointment selected for all 89 participants was in closed envelopes, and the researcher and mothers were not aware of the type of the ointment used and selected for each participant.

In the groups, the mothers were trained on how to use the ointments, washing the area, clearing the ointments used as routine treatments, rubbing the ointment on the dermatitis area, and covering the dermatitis area with chamomile or Aloe Vera ointment. They were asked to rub a layer of the ointment on dermatitis area such that it would cover the lesion, three times a day after changing the diaper and washing the area by warm water and drying the area by a soft cloth without damaging. All the participants were evaluated by a trained nursing expert who was not aware of the method of allocating the participants to groups. (At first, informed consent was obtained from the mothers. The tents made at the Pharmacy Faculty of Tabriz were provided to mothers free of charge and were taken on a three-day basis once a day. The assessment was carried out during the first, third and sixth days (in form Summary). Coverage of the lesion, then severity of dermatitis in the first, third and sixth days of the study was estimated by the researcher. It should be noted that routine treatment (hydrocortisone, colutrimazole, zinc oxide) was not eliminated from the ointment group A and B. The instrument used by the researcher in this study was to evaluate the severity of dermatitis using the five-point diaper rash (10) used in AL Waill's study. In this instrument, the severity of diaper dermatitis was defined as 0 = no erythema 1 = mild erythema 2 = moderate erythema 3 = severe erythema with erosion 4 = severe erythema with tenderness and ulcers. Validity and reliability of the tools used in recent research by Afshari and Panahi were confirmed. All samples were evaluated by the researcher who did not know who was assigned to the groups. It should be noted that in this research two parts were used: the first part was a demographic questionnaire and the second part contained a Diaper rash five point scale.

Figure1: The Consort E- FLOWCHART

The significance level was 0.05 and the confidence coefficient was 0.95%.

This study was conducted with the written permission of the Ethics Committee of Tabriz University of Medical Sciences (Code: IR.TBZMED.REC.1395.872) and with all the considerations of clinical trial such as informed consent, randomness of the choice of samples in studying and having the right of Cancellation of subjects from the IRCT (IRCT2016082813691N10) the system was studied at each stage of the study, and the patient information was kept confidential.

In the Aloe Vera group, 17 (56.7%) were girls and 13 children (43.3%) were male; in the chamomile group, 19 (63.3%) were girls and 11 (36.7%) were male, and in control group, 14 (46.7%) were girls and 14 (46.7%) were boys. From the control group, two infants were discharged during the study. The mean age of the children in the control group

was 74.22 ± 55.58 days; in the Aloe vera group it was 140.20 ± 90.96 days and in the chamomile group 146.73 ± 103.00 days. According to the statistical results, the mean age of mothers in the chamomile group was 27.71 ± 5.55 years, in the Aloe vera group was 6.36 ± 28.53 and in the control group was 26.30 ± 6.29 years. According to statistical results, the groups were homogeneous in terms of the demographic characteristics mentioned above.

The results of ANOVA test showed that there was no significant difference between the groups in terms of maternal age and weight ($P > 0.05$). Also, the results showed that there was a significant difference between the data ($p < 0.05$) in the type of children's nutrition, bathing the baby and the type of cleansing, abdominal function and mother's education. Also, the family status ($P = 0.00$), maternal occupation ($P = 0.03$), maternal education level ($P = 0.03$) were significantly different in the three groups ($P < 0.05$).

Table 1: Comparison of the severity of dermatitis based on baby's age, weight, and Mother's age

Group	Aloe vera N=30		Chamomile group N= 30		control group N= 29		Statistics	
	Average	Standard deviation	Average	Standard deviation	Average	Standard deviation	F	P
Age of the baby (days)	90.96	140.20	103.00	146.73	55.58	146.73	1.137	0.32
Age of the Mother (years)	28.53	6.36	27.71	5.55	26.30	6.29	1.02	0.36
Baby weight (grams)	4272.93	2261.78	4061.37	2926.47	3610.17	2003.56	0.56	0.57

Table 2: Comparison of the severity of dermatitis in different treatment days in intervention and control group

Groups under Treatment The severity of dermatitis	Aloe vera		Chamomile group		control group		F	P
	Average	Standard deviation	Average	Standard deviation	Average	Standard deviation		
First day	1.80	.76	1.93	.83	1.70	.70	.70	.49
third day	1.53	.82	1.62	.82	1.33	.72	1.23	.29
Sixth day	.76	.86	1.00	1.10	.60	.67	1.49	.23

Table 2 shows the severity of diaper dermatitis among the groups treated with study drugs. According to the diagram, there is no statistically significant difference in the severity of diaper dermatitis among the three groups according to $P > 0.05$, but the severity of dermatitis in each group was significant with a $P < 0.05$. That is, all three groups were significantly improved during the study in terms of severity of dermatitis found.

Discussion and Conclusion

The aim of this study was to investigate the effect of chamomile ointment and Aloe Vera ointment and routine treatment on the improvement of severity of diaper dermatitis in children under the age of two years. According to the results, improvement in the severity of dermatitis during the six-day study in all three groups, had an upward trend towards the relief of severity of dermatitis ($P < 0.05$). However, in evaluating the severity of dermatitis in the three groups, no group was superior to another for determining the superiority of one group ($p > 0.05$). According to a study chitra In the wound healing of the group that used the Aloe vera gel healed faster than the other group(11). However, the results of the Julan study are not consistent with our study, because in this study, the repair of abdominal surgery wounds in the group using Aloe Vera gel was lower, which could be due to the drop in the samples (12). Also, Saeedi's study was effective in restoring the Aloe Vera breast bone fracture and is consistent with the results of this study (13). Also, in the study of Hys-Gel, Aloe Vera has been effective in treating Lichen Planus, which is in accordance with our study. However, in the Aloe Vera Penile Gel study, in comparison to Calendula, the treatment of diaper dermatitis had a lower rate of improvement that was not consistent with

our study. (14). Also, in the study of Rajar, the Aloe vera gel has been effective in treating lichen planus and is consistent with our study (15). In the study of Afshari in the treatment of dermatitis, chamomile ointment is more successful than calendula, and the results are in agreement with this study (4). Also, in the study of Patzlet, treatment of diaper dermatitis was more effective than chamomile ointment and hydrocortisone and consistent with our study (16). In the study of diabetes, which was the effect of chamomile and steroids on the treatment of ulcers around colostomy, chamomile was more effective than steroids in the study (17). In the study of Aertgeerts, the effect of chamomile ointment on the removal of hand eczema was better than steroids and non steroid, which was the result of this study (8).

In the study of Aertgeerts, the effect of chamomile ointment on the removal of hand eczema was better than steroid and non steroid, which was the result of this study.

According to other studies, this study emphasized the anti-inflammatory effect of Chamomile and Aloe Vera, but Chamomile's superiority on Aloe Vera or vice versa was not proven in the present study.

Acknowledgments

The authors of Tabriz University of Medical Sciences's research assistant to finance and provide the conditions for this study, Tabriz Children's Hospital staff and the parents of hospitalized children participating in research to collaborate with researchers to undertake this research. This article is derived from the Master's Thesis for Pediatric Nursing, No. 667. This study was sponsored by Tabriz University of Medical Sciences. The researcher does not disclose any conflicts of interest in the study.

Research limitations and suggestions for future studies

In the present study, according to the study conditions, the researcher was unable to select samples from children whose background conditions were similar, as well as the type of diapers and auxiliary food in children, which was widely available in other studies. Also, this study was not conducted in children with fungal and bacterial infections, and it is suggested that further studies be carried out on such children. Also, the researcher did not remove the routine treatment in the recipients of Chamomile and Aloe vera, which, if possible, would be appropriate to study the effects of these two drugs by removing routine treatments from the samples. Also, individual differences in response to treatment were one of the limitations of the researcher.

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