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Effects of Aloe Vera Gel versus Chamomile Ointment on extent of Diaper Dermatitis in Children: A Double-Blind Randomized Controlled Trial

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Abstract

Background

Diaper dermatitis is one of the most prevalent skin disorders in neonates and children. The purpose of this study was to compare the effects of Aloe Vera and chamomile ointment on the degree of diaper dermatitis in children.

Materials and Methods

In this double-blinded randomized clinical trial, 90 children below two years of age, who had diaper dermatitis and were hospitalized in the Tabriz Pediatric Hospital, Tabriz city- Iran, were included in the study using random sampling. The children were divided into three equal groups, with one group receiving routine treatments and the other two receiving chamomile and Aloe Vera ointment three times a day. The samples were examined on the first, third, and sixth day of the study using a diaper rash five-point scale. The data were analyzed by descriptive and analytical tests in SPSS software version 22.0.

Results

Baseline criteria such as age, gender, and education of mothers were similar in all the groups ($P>0.05$). Moreover, the dermatitis extent recovery was achieved over time ($P<0.001$) in all the three groups; however, comparison among the three groups showed no significant difference in all the types of treatment ($P>0.05$).

Conclusion

There was no difference between the Aloe Vera, chamomile, and routine treatments in dermatitis extent recovery.

Key Words: Aloe Vera, Chamomile, Children, Diaper dermatitis.

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1- INTRODUCTION

Diaper dermatitis is the most common skin disorder during infancy (1). Moreover, diaper dermatitis is the most common contact dermatitis in children (1, 2). This disorder often occurs around 3-12 weeks after birth, with the peak of occurrence during 6-12 months (3). In recent studies, the prevalence of diaper dermatitis has been reported to be 7-35%, sometimes even reaching 50%. Accordingly, the diaper dermatitis prevalence reaches 75% in the United States, 87% in Japan, 15% in Italy, and 34.9% in Iran (4, 5). This disorder sets the stage for bacterial and fungal infection due to the scars with flaking, itching, burning, scratching and abrasion as well as penetration of stimulating factors and germs (5). The obstruction of the child's groin and genitals with diapers increases the concentration of moisture in the area under the diaper, resulting in the breakdown of the skin under the diaper.

Although diaper rash is often mild, self-limiting, and transient, the skin is sometimes hurt under favorable conditions with the influx of bacteria and fungi, which requires therapeutic and medical measures (6). The main cause of this disorder is not clear yet, but factors such as friction, moisture, abrasion, urine and stool contact, and pH changes in the area under diaper are considered as the causing factors (3, 7). Diaper dermatitis in infants leads to crying, poor breastfeeding, as well as poor sleeping; all such problems affect peace of mind for parents, and play a major role in the emergence of stress (5). Additionally, in the case of no treatment in acute cases, surface wounds can form in areas under the diaper, leading to painful urination, vesicoureteral reflux, and blood spots on the infant's diaper by causing sores on the genitals. This mild bleeding through urine can cause anemia and many other problems (8). Nowadays, many medications are used for the treatment of diaper dermatitis, including Vaseline, talcum powder, zinc oxide, vitamin A+D, and corticosteroids; however, each of these medications has side effects including allergy. For instance, talcum powder can cause respiratory damage due to the possibility of inhalation (1, 9), and corticosteroids are not recommended since they cause systemic absorption, skin atrophy, allergic dermatitis, and telangiectasia (10). It has also been proven that the systemic absorption of this medication in infants with low birth weight interferes with testicular descent (11). Other treatments for diabetic dermatitis include fish oil, triamcinolone, fluocinolone, clobetasol, antifungal drugs such as clotrimazole and nystatin, and antibiotics such as gentamicin and bleomycin, each with its own side effects (12). Adalat showed that the incidence and recurrence of diaper dermatitis were higher among children who used protective creams (12). Favorable therapeutic effects and low side effects are among the factors contributing to the increased use of medicinal plants in recent decades (13).

Moreover, for more than two decades, the search for antibacterial agents in plants has been expanded with the aim of discovering chemical structures that can overcome these complications because of an increase in side effects of medications and antibiotic resistance (10, 14). The use of herbal drugs and ointments including mixed calendula and chamomile ointments or bees wax combined with olive oil and clay shampoo (15) is a common practice for the relief and treatment of dermatitis in Iranian traditional medicine (1). Herbal products have fewer complications than chemical ones, have more effective pharmacological effects on the skin, and are used in the preparation of pharmaceutical and cosmetic products (16). Among medicinal herbs, chamomile flowers have been considered for having numerous health benefits and successful

treatment of some diseases and have been introduced as one of the standard medicinal herbs (13). This plant is widely used worldwide, is listed as one of the 21 well-known medicinal herbs in the world, and can be used internally and externally in the treatment of eczema, allergies, infections, inflammations, burns, and rheumatic pains (17). The most common use of chamomile for skin diseases is for its impact on the treatment of itching and skin inflammation (17). Moreover, chamomile can be used as a moisturizer, softener, and protector, as well as an anti-inflammation, anti-acne, anti-fat, anti-itching, and anti-dandruff properties (18). Because of its therapeutic, antibacterial, antifungal, and anti-inflammatory properties, chamomile is known to be effective in the treatment of skin diseases, reducing pain, and enhancing damaged tissue repair (19). Chamomile extract has compounds that are effective for staphylococci and Candidia species. One of these compounds is alpha-Bisabolol with the strongest antibacterial activity against Gram-negative bacteria and– Gram-positive bacteria (13).

Chamazulene, alpha bisabolol, flavonoids, and umbelliferone found in chamomile have antifungal effects on trichophyton, mentagrophytes, Trichophyton rubrum, and candida albicans. It is possible that the anti-inflammatory properties of chamomile are associated with preventing the formation of leukotrienes as well as the antioxidant activity of this plant (13). Aloe Vera is among other medicinal herbs that are used for the treatment of diaper dermatitis. Aloe Vera (aloe barbadensis) (Miller) from the Liliaceae family is a medicinal plant that has been used for a long time and has many applications (20). The Aloe Vera gel forms new skin with strong cooling, refreshing, and moisturizing properties (16). The leaves contain high concentrations of anthraquinone compounds and are used in many countries as a laxative. This plant has wound-healing, anti-inflammatory, anti-cancer, anti-diabetic, anti-oxidant, and anti-ulcer properties (20). In other studies, the anti-inflammatory and wound-healing effects of Aloe Vera have been proven (15). The use of Aloe Vera products in doses 100-300 mg/kg body weight leads to wound healing effects similar to those of hydrocortisone (21). Aloe Vera also has antiseptic, anti-inflammatory, anti-bactericidal, anti-viral, and anti-fungal effects, and is nutritious for tissues. It also increases immunity and reduces skin irritations. Moreover, it has an approved effect on the collagen and aldehyde content and, as a result, accelerates wound healing. The effect of Aloe Vera on wound healing in diseases such as ulcerative colitis, psoriasis, oral ulcers, diabetic ulcers, herpes, and bedsores has been approved in various works (9). Aviggan showed that the mean duration of treatment with Aloe Vera is shorter than that of previous treatments (9).

With regard to what has been said, it can be concluded that herbal medicines can be a good alternative for chemical drugs in the treatment of diaper dermatitis. The researcher could not show the superiority of using either Aloe Vera or chamomile in the treatment of diaper dermatitis using the evidence-based studies. The results of this study can lead to more effective drug selection and, in addition to clinical and therapeutic benefits, can reduce medical expenses. Therefore, the present study attempted to compare the effect of chamomile ointment with Aloe Vera ointment in the treatment of diaper dermatitis to clarify the superiority of one of these two herbs.

2- MATERIALS AND METHODS

2-1. Study Design and Population

This double-blind (except the pharmacists, the researchers and mothers did not have any information about the

type of drugs) clinical trial was conducted on children with diaper dermatitis from February 2016 to June 2017. The population included 90 children below two years of age referring to the Pediatric Department of the Tabriz Pediatric Hospital. The sample size was estimated as 60 based on the results of Panahi et al. (22) and according to the following formula (22):

Considering α=0.05, 80% power, and 10% difference reduction ratio. Nevertheless, to increase the validity of the study and consider the risk of attrition, we selected 90 participants. Of the patients selected in this study, 88 patients (Chamomile [n=30], Aloe Vera [n=30], and control group [n=28]) completed the study (**Figure.1**).

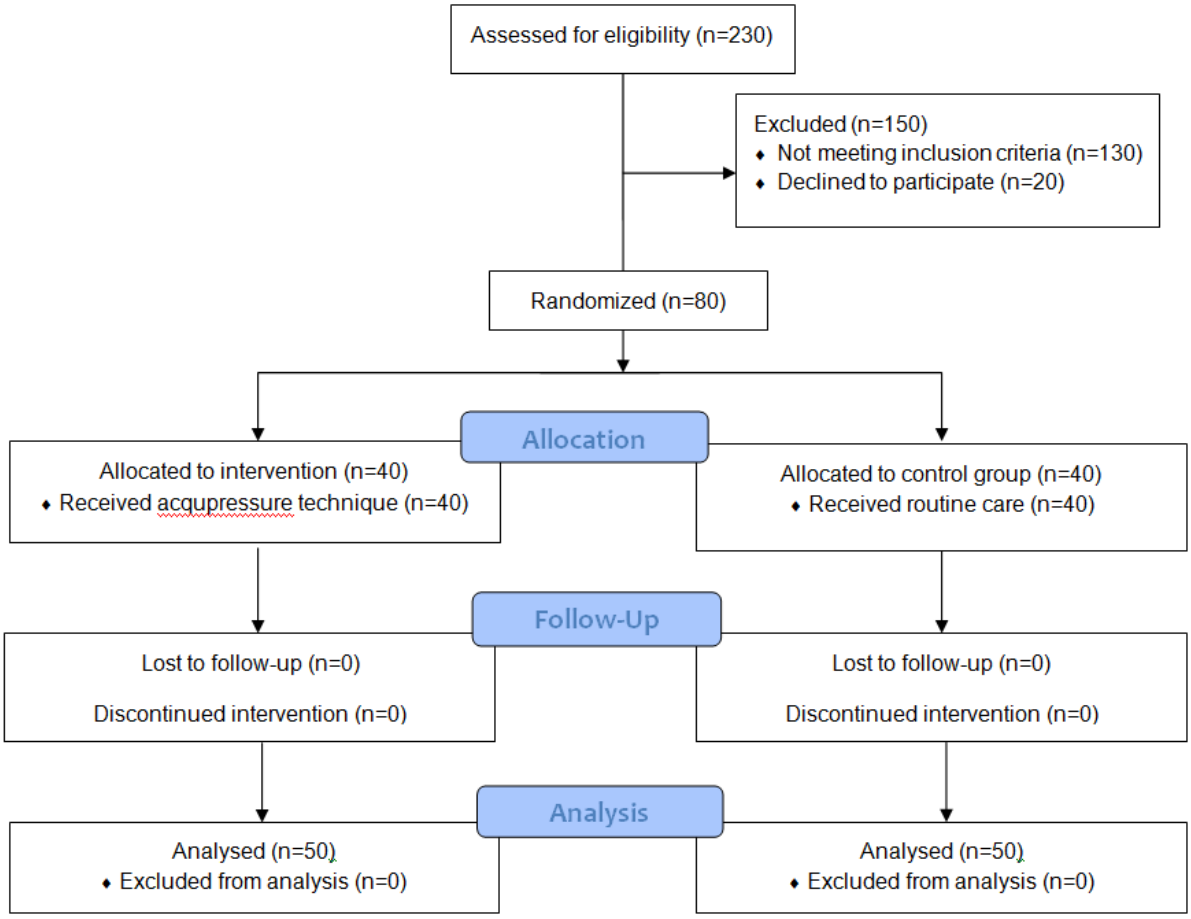

Fig1: Consort diagram

2-2. Methods

Ninety children admitted in the Tabriz Pediatric Hospital were selected and allocated in three groups with six size blocks. A convenience sampling was performed (assignment of the samples was done randomly using a roll-list software), in which the participants were selected from among all the patients admitted to the Pediatric Department. Then, the patients who met the inclusion criteria were randomly allocated into 3 intervention groups by Rand List using 6 random blocks: treatment with chamomile ointment, treatment with Aloe Vera, and routine treatment (a mixture of zinc oxide, hydrocortisone, and Clotrimazole). All the

participants received the routine treatment. Moreover, chamomile and Aloe Vera were added to the treatment in the two intervention groups (the Aloe Vera group: routine treatment + Aloe Vera ointment; the chamomile group: routine treatment + chamomile ointment; and the control group: routine treatment).

2-3. Randomization and Intervention

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 the 88 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. At first, informed consent was obtained from the mothers. The ointments made at the pharmacy faculty of the Tabriz University were provided to the mothers free of charge and were taken on for a three-day period. The assessment was carried out on the first, third and sixth day of the study.

In the groups, the mothers were trained on how to use the ointments, wash the area, clear the ointments used as the routine treatments, rub the ointments on the dermatitis area, and cover the dermatitis area with the chamomile or Aloe Vera ointment. The mothers were asked to rub a layer of the ointment on the dermatitis area such that it would cover the lesion three times a day after changing the diaper, washing the area with warm water, and drying the area with 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 the groups.

2-4. Measuring tests

The data collection tools in this research included the Size Scale by Dabirian et al. (1999) to determine the degree of dermatitis. In this scale, degree of dermatitis is determined as 1. No symptoms, 2. Low (genital), 3. Moderate (genital with buttocks), 4. High (genital, buttocks, and groin), and 5. Severe (genital, buttocks, groin, and abdomen) (23). The validity and reliability of this tool have been approved in previous studies, e.g., Afshari et al. (1). The reliability of this questionnaire has been reported 0.8 by Afshari et al. (1). In the present study, the reliability of the test was equal to 0.73.

2-5. Inclusion Criteria

The inclusion criteria in this study were: having age of below two years, using disposable diapers, having no known immune system weaknesses (determined by a specialist physician), receiving no immunosuppressive drugs, having no extensive infections, having no history of candida infection, having no particular food or drug allergy, having no skin allergy or congenital diseases, having no diaper dermatitis and having willingness to participate in the study.

2-6. Exclusion Criteria

The exclusion criteria were: using other drugs to treat diaper dermatitis, using items other than typical disposable diapers (such as aromatic diapers or rags) during the study, having allergy to Aloe Vera or chamomile, and having positive stool culture.

2-7. Ethical Considerations

This study was performed with written permission from the Ethics Committee of the Tabriz University of Medical Sciences (Code: IR.TBZMED.REC.1395.872), and with respect to all ethical considerations of clinical trials, such as obtaining informed consent from participating units, being aware of random allocation to intervention

groups, and having the right to withdraw in any phase of the research. All the data were encoded and the patient data were kept confidential. This research is registered with the trial code IRCT2016082813691N10.

2-8. Data Analyses

Data analysis was performed in SPSS software version 22.0. Descriptive statistics (mean and standard deviation) were used for analyzing the demographic variables. One-way analysis of variance (ANOVA) was performed for comparison of the three groups and repeated measure ANOVA was used to compare the three times in terms of the degree of dermatitis as a primary outcome. P-value < 0.05 was considered as significance level.

3- RESULTS

There were 17 females (56.7%) and 13 males (43.3%) in the Aloe Vera group, 19 females (63.3%) and 11 males (36.7%) in the chamomile group, and 14 females (53.3%) and 14 males (46.7%) in the control group. Result of the one-way ANOVA test showed no significant difference among the groups in terms of maternal age, weight and child age ($P \geq 0.05$) (**Table.1**). Moreover, in terms of family economic status (P=0.00), maternal occupation (P=0.03), and maternal education level (P=0.03), a significant difference was found among the three groups (P<0.05). The results of the ANOVA test demonstrated a significant difference in the recovery of dermatitis in all the three groups: the Aloe Vera group (P<0.05), the chamomile group (P<0.05), and the control group (P<0.05). **Table.2** shows degree of dermatitis in the intervention and control groups. Comparing degree of diaper dermatitis among the three treatment groups showed no superiority among the groups (P<0.05).

Table-1: Characteristics of the participants in the study groups

Variables	Groups			P-value*
	Aloe Vera, n=30	Chamomile, n=30	Control, n=29	
	Mean (SD)	Mean (SD)	Mean (SD)	
Infant age, day	90.96 (140.20)	103.00 (146.73)	55.58 (146.73)	0.32
Mother age, year	28.53 (6.36)	27.71(5.55)	26.30 (6.29)	0.36
Baby weight (gr)	4272.93 (2261.78)	4061.37 (2926.47)	3610.17 (2003.56)	0.57

* One-way ANOVA.

Table-2: Comparison of degree of dermatitis during the treatment days in the intervention and control groups

Degree of dermatitis	Groups			P-value*
	Aloe Vera, n=30	Chamomile, n=30	Control, n=29	
	Mean (SD)	Mean (SD)	Mean (SD)	
First day	1.80 (0.76)	1.93 (0.82)	1.70 (0.70)	0.49
Third day	1.53 (0.83)	1.62 (0.82)	1.33 (0.47)	0.29
Sixth day	0.76 (0.85)	1.00 (1.10)	0.60 (0.67)	0.23
P-value **	0.001	0.001	0.001	

***** One-way ANOVA, ****** Repeated measure test.

4- DISCUSSION

This study was performed to compare the effect of topical application of the chamomile and Aloe Vera ointments with the routine treatment (a mixture of zinc oxide, hydrocortisone and clotrimazole) for the treatment of diaper dermatitis in children below two years of age on the first, third, and sixth day of the study. According to the results, degree of dermatitis in all the three groups during the study was improved on the sixth day compared to the first day. However, the comparison among the three groups showed no significant difference in the treatment of diaper dermatitis. In other words, no superiority was seen in the Aloe Vera, chamomile, and routine treatments.

Comparing the effect of chamomile and calendula on infants, Afshari et al. showed that chamomile had a better effect than calendula on the treatment of diaper dermatitis (1). Moreover, Panahi et al. conducted a study on 90 children with diaper dermatitis and compared the effects of Aloe Vera and calendula ointments after 10 days of their application. Panahi et al. showed that the effect of the calendula ointment was significantly better than the Aloe Vera ointment (22). In another research by Patzlet et al. on 72 children with atopic dermatitis treated using chamomile ointment and 0.05% hydrocortisone, it became clear that treatment in the chamomile group was faster and better than that in the hydrocortisone group, and chamomile did not have the side effects of corticosteroids (1, 24). The superiority of chamomile over steroids was also approved in the study by Dabirian et al. on dermatitis around the stoma treated using chamomile cream and topical steroid (23). In another work evaluating the effect of chamomile-containing cream and fluocinolone acetonide on the treatment of hand eczema conducted by Marandi et al., the effect of the chamomile-containing cream was higher than fluocinolone (25). In the study by Tafazoli et al. (2009) on the breast fissure of 100 breastfeeding mothers treated with Aloe Vera and lanolin ointments, the chamomile ointment was observed to have a higher effect than lanolin after 7 days of treatment (26). Further, in the research by Amanat et al. (27) on 50 patients with oral lichen planus, the use of Aloe Vera ointment was compared to triamcinolone. After 8 weeks, according to the statistical data, the use of Aloe Vera gel was suggested in the treatment of erosive and atrophic lesions of oral lichen planus. However, for ulcerative lesions, based on the results of this study, the use of steroids was recommended as the appropriate treatment (22, 26, 28).

In the present study, the researcher could not select the participants from among children with the same underlying disease. Moreover, the type of diapers and complementary food in children had a great variety, which can be partly eliminated in subsequent studies. This study was not performed on children with fungal and bacterial infections. Thus, further works are suggested to be focused on such participants. The researcher failed to eliminate the routine treatment in the recipients of chamomile and Aloe Vera. Due to the limited time available in the hands of the researcher for this study, also, in some cases, financial constraints in providing a specific type of nappy and auxiliary food for both the researcher and the patient, and in some cases, the differences in the tastes and attitudes of the subjects. The use of certain types of diapers and auxiliary foods caused these restrictions and these factors were entirely beyond the control of the researcher in this study.

5- CONCLUSION

In each of the three study groups, during the six days of using the study

ointments, the recovery was achieved in an significant difference in the treatment between the three groups), and none of the three groups was superior to the other groups. Moreover, due to observation of the research ethics, the researcher could not abandon the use of the routine treatment in the groups treated with the herbal ointments. It is suggested to carry out a fair comparison in future studies to specify the superiority of using either chamomile ointment or Aloe Vera ointment for the treatment of diaper dermatitis by eliminating the routine therapy in groups receiving the ointments.

6- CONFLICT OF INTEREST: None.

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