

The effects of Bentonite and *Calendula* on the improvement of infantile diaper dermatitis

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Background: Diaper dermatitis is one of the most common skin disorders of infancy and childhood. The present study aimed to compare the effects of Bentonite and *Calendula* on the improvement of diaper dermatitis in infants. **Materials and Methods:** A double-blind randomized controlled trial, which was conducted on 60 out-patient infants referred to health care centers or pediatric clinics in Khomein city and diagnosed with diaper dermatitis. Data were collected by checklist and observation, and analyzed using *t*-test, Chi-square, and Fisher's exact test. **Results:** Mean (standard error) age of the total sample was 6.55 ± 0.69 months. Totally, 93.3% of lesions in the Bentonite group started its recovery in the first 6 h, while this rate was 40% in *Calendula* group ($P < 0.001$). Furthermore, 90% of infants in the Bentonite group and 36.7% in the *Calendula* group were improved completely in the first 3 days ($P < 0.001$). **Conclusion:** Bentonite was effective on the improvement of diaper dermatitis, and also had faster effects compared with *Calendula*.

Key words: Bentonite, *Calendula*, diaper dermatitis

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INTRODUCTION

Diaper dermatitis is one of the most common skin disorders of infancy and childhood.^[1] It is characterized by an acute inflammatory reaction of the skin around diaper.^[2] This disorder may cause by frequent and prolonged contact of the skin with the urine, stool and moisture, and exacerbated by candidiasis infection and abrasion.^[2,3] Signs and symptoms of this disorder may include erythema, flaking, papules and lesions in the areas such as buttocks, thighs, scrotum, and mons pubis.^[4] This disorder commonly occurs in the age of 9-12 months old,^[5] and its prevalence have reported to be around 7-35 and even 50%.^[6] The prevalence of diaper dermatitis among the infants is reported to be 75% in the United States (US), 87% in Japan, 15% in Italy,^[7] and 34.9% in Iran.^[8] The onset of this disorder commonly occurs within the first 3rd to 12th weeks of life, but its peak is in the first 7th to 12th weeks.^[9]

The routine treatment options for diaper dermatitis includes changing the diaper and washing the genital area frequently, applying Vaseline or zinc oxide, and corticosteroids. Furthermore, a topical antifungal agent (such as miconazole, clotrimazole, and nystatin) may be used if fungal infections occurred.^[10,11] *Calendula* may also be effective in noncomplicated cases.^[12] *Calendula* is a plant

with the yellow color, which is used to cure skin disorders and pain. It also has antiseptic and anti-inflammatory properties.^[13,14] Bentonite is basically a kind of mineral, which is in the form of aluminum phyllosilicates with $Al_2O_3 \cdot 4SiO_2 \cdot H_2O$ formula. This material can absorb several folds of water as its own volume, and makes a jellified, plastic, and viscose form. It also is called as mineral or formal soap in pharmacy industries. Medical powder of Bentonite is so fine, odorless, with the color of white to grey, or yellow or pink. This gelable and viscose material is used as moisturizer, protector and water absorbent.^[15] Studies have shown that Bentonite was effective on the treatment of chronic dermatitis of the hands.^[16] Likely, it may be effective on the treatment of skin disorders and diaper dermatitis, but no published studies are found in this regard. On the other hand, in local observations, the researchers observed that parents traditionally apply this mineral to decrease redness, severity, and extent of affected area by diaper dermatitis. As regard to the observed positive effects, no side-effects and cost-effectiveness of Bentonite, and the high prevalence of diaper dermatitis among infants and children which leads to frequent refers to pediatricians and increased stress and anxiety among families, the present study was conducted to compare the effects of Bentonite and *Calendula* on the improvement of infantile diaper dermatitis.

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MATERIALS AND METHODS

The present study was a double-blinded randomized controlled trial which was conducted during February and March 2013 on 60 outpatient infants referred to health care centers or pediatric clinics in Khomein city. All patients were visited by a general practitioner or a pediatrician and diagnosed with diaper dermatitis. Inclusion criteria were: Age range of 1-24 months, and having mild (redness, abrasion, and skin atrophy) to medium (redness with papules, abrasion, and skin atrophy) diaper dermatitis. Furthermore, not having infantile eczema, diarrhea, and urinary tract infection, not having fungus dermatitis, and not using corticosteroids for present lesions were selected as additional inclusion criteria. Exclusion criteria were using corticosteroids during study (even once), not following the program during the period, exacerbation of the lesions, and developing diarrhea during the study.

To keep the study blind from the physician and the mothers, *Calendula* and Bentonite were prepared in cans with similar color, shape and weight and then all cans were coded by the pharmacist as "a" or "b." The treating physician and also the mothers were not aware of cods.

Before the sampling started, a randomization plan was developed using the SPSS (SPSS Inc., Chicago, IL, USA) software. For this purpose, we entered numbers 1-60 in the data sheet of the software that represented a sample of 60 subjects. Then, using the "random numbers" option in the "compute" and "function group box" in the transform menu we randomly assigned 60 supposed samples into the two conditions, each condition was representative of one group with 30 samples. The numbers in each group were then sorted and passed to the doctor and he prescribed the medication with code "a" for one group and medication with code "b" to the second group.

To begin the study, the researcher talked to the parents, explained the study process, took their agreement (by taking the written informed consent), and then took an initial skin test on the infant's arm to ensure not having allergic reaction. To do so, the researcher applied one fingertip of Bentonite and *Calendula* on the internal surface of the infant's arm (1 cm × 1 cm). If redness or any other allergic reactions were not observed after 20 min,^[17] the researcher gave Bentonite or *Calendula* to them. Using a random number table, the samples were assigned randomly in Bentonite group or in the *Calendula* group (if redness or any other allergic reactions were not observed).

A consort flow diagram of this study was as described in Figure 1.

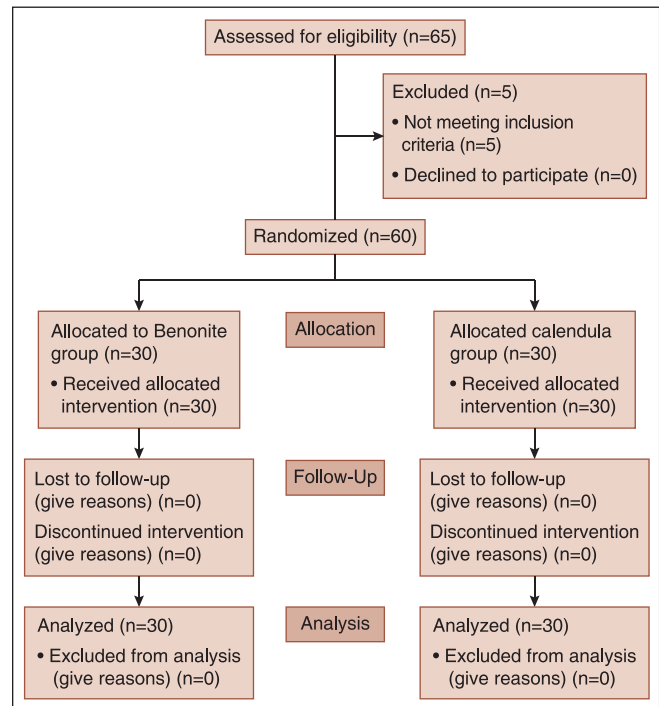


Figure 1: Consort flow diagram

To produce Bentonite 50%, the mineral was squashed and turned into powder, sterilized an oven, mixed with water (50 g Bentonite was mixed with 50 ml of distilled water) and poured in sterile cans and prepared in the form of Bentonite 50% cream in 30 g cans by a pharmacist. To produce *Calendula*, two 15 g creams of *Calendula* 1.5% (produced by Dineh Company) were poured in the similar 30 g sterile cans. *Calendula* and Bentonite were prepared in cans with similar shape and weight and then all cans were coded by the pharmacist.

To gather the data, a checklist was prepared through literature review and then its content validity was assessed by 10 faculty members in Kashan and Arak Universities of Medical Sciences. The reliability of the checklist was assessed through inter-observers reliability. To do this, the checklist was completed by the second researcher and a coresearcher (who was trained formerly), for 10 patients (2 times with a short break between them) and a rate of agreement of 0.93 was calculated between them. The checklist was included the characteristics of the infants (age, gender, and weight), and mother (education level, age, and job), type of feeding (breast feeding, formula milk, cow's milk, or combined) history of diaper dermatitis, and its severity, drugs used in the previous episodes of the disease and the frequency of changing diaper in a day. There also was a table for recording the effects of treatment including: Onset of recovery in the first 6 h (yes, no), improvement in the 1st, 2nd, and 3rd day (yes/no), time of the complete recovery (1, 2, 3, and more days after the start of treatment).

Checklists were completed by the second researcher for each infant and then the physician (who was unaware of the cans cods) visited the baby and prescribed one of the two creams according to the random plan previously prepared. A can contained one of the drugs was given to the mother of each infant, and they were told that additional drugs will be prescribed in the next visit if necessary. All mothers were taught to apply the cream on the affected area 4 times a day after changing the diaper. The second researcher educated both groups' of parents about the following items and wanted them to do the 1st time at her presence for ensuring both the researcher and the mothers of the correct care:

1. To wash the affected area only with lukewarm water and dry it with a clean cotton towel.
2. To spread the prescribed cream on the affected area as it covers 1 cm over the lesions borders, then diaper the baby, and repeat this work every 4-6 h. If needed, they could repeat this work more times.
3. Not to apply any other material on the affected area such as wet wipes, essence contained soaps, or other medications.

The second researcher followed the process of administrating the cream, following the treatment program and the effect of treatment 3 times a day by phone. Also, every other day (up to 3 times), the infants were visited and assessed both by the researcher and the physician and additional cream of the same code was given to the parents if needed. The effect of treatment (improvement or nonimprovement) was documented based on the physician's decision.

The study was approved by the Institutional Review Board and the Human Research Ethics Committee in the Kashan University of Medical Sciences (project number: 91121). In addition, parents of all babies were informed about the design of the study and assured about data confidentiality, safeness of the study, and their right not to participate. They also signed a written informed consent. The parents were also assured that the baby will be under the close and frequent observation of the research team for any possible side-effect or the delay in recovery. We also observed all ethical issues in accordance with the last version of the Declaration of Helsinki.

Data were analyzed using SPSS software, version 16.0. Independent sample *t*-test was used to compare quantitative variables (i.e., age, weight), and Chi-square and Fisher's exact test were used to compare qualitative variables between two groups such as improvement.

RESULT

The mean (standard error) age of infants was 5.68 ± 0.84 months in *Calendula* group and 6.88 ± 1.02 months in Bentonite

group ($P = 0.42$). In *Calendula* group, 10 samples were males (33.3%) and 20 were female (66.7%), and in Bentonite group nine samples were males (30%) and 21 were female (70%); however, no significant difference was observed between the two groups ($P = 0.78$) [Table 1].

In total, 93.3% of lesions in the infants in Bentonite group started its recovery in the first 6 h while this rate was 40% in *Calendula* group, and the higher rate of improvement in the Bentonite group was significant ($P < 0.001$) [Table 2].

Furthermore, 90% of infants in the Bentonite group and 36.7% in the *Calendula* group were improved completely in the first 3 days. This higher rate of improvement in Bentonite group was significant ($P < 0.001$) [Table 2].

DISCUSSION

Findings of the present study showed that the onset of improvement in the first 6 h was significantly higher in Bentonite group than in *Calendula* group. Also, the complete improvement in the first 3 days was significantly higher in Bentonite group. Emami-Razavi *et al.*, in a study on animal samples made 2 cm lesions on the mature rats' skins and reported that Bentonite was effective on the improvement of these lesions.^[18] In another study, Fowler assessed the

Table 1: Basic characteristics of the infants and their mothers

Variable	Bentonite (%)	<i>Calendula</i> (%)	Test results
Age (month) Mean \pm sd	6.88 \pm 5.62	5.68 \pm 4.63	$P=0.42$
Weight (kg) Mean \pm sd	6.94 \pm 2.59	6.60 \pm 2.66	$P=0.93$
Gender			
Female	21 (70)	20 (66.7)	$P=0.78$
Male	9 (30)	10 (33.3)	
History of diaper dermatitis			
Yes	17 (56.7)	13 (43.3)	$P=0.3$
No	13 (43.3)	17 (56.7)	
Nutrition type			
Breast feeding	26 (86.7)	24 (80)	$P=0.78$
Formula milk	2 (6.7)	3 (10)	
Breast feeding+formula milk	2(6.7)	3 (10)	
Severity of diaper dermatitis			
Mild	16 (53.3)	10 (34.5)	$P=0.11$
Moderate	14 (46.7)	19 (65.5)	
Education level of mother			
Primary	1 (3.3)	1 (3.3)	$P=0.84$
Intermediate	8 (26.7)	7 (23.3)	
High school and over	21 (70)	22 (73.3)	
Job of mother			
Housekeeper	26 (86.7)	28 (93.3)	$P=0.38$
Employee	4 (13.3)	2 (6.7)	
The frequency of changing diaper a day (Mean \pm sd)	5.66 \pm 3.03	5.35 \pm 1.87	$P=0.15$
Age of mother (year)	27.6 \pm 5.27	27 \pm 5.06	$P=0.52$

Table 2: The start of improvement in the first 6 h and complete improvement in the first 3 days

Time of assessment	Improvement	Group		Test results
		Calendula group	Bentonite group	
		N (%)	N (%)	
Start of improvement in the first 6 h	Yes	12 (40.0)	28 (93.3)	$P < 0.001$
	No	18 (60.0)	2 (6.7)	$\chi^2 = 19.200$
Improvement in the first 3 days	Yes	11 (36.7)	27 (90.0)	$P < 0.001$
	No	19 (63.3)	3 (10.0)	$\chi^2 = 18.373$

effectiveness of Bentonite on the improvement of chronic dermatitis of the hands on human samples and reported that using the moisturizer cream containing Bentonite in an 8 weeks period, significantly accelerated the improvement of chronic dermatitis.^[16]

Despite searching the scientific databases, no studies about the effectiveness of Bentonite on the improvement of diaper dermatitis were found. Some studies have assessed the effects of some herbal products on the improvement of diaper dermatitis. One study has assessed the effects of a cream containing honey, olive oil and beeswax, and another study has assessed the effects of olive oil in diaper dermatitis and reported relatively positive effects.^[19,20] Fotouhi *et al.*, in a study aimed to compare the effects of *Calendula* and Betamethasone in the prevention of acute radiation dermatitis reported that *Calendula* and Betamethasone had the same effects in the palliation of the disease severity.^[21]

In the present study, the rate of improvement in Bentonite group was greater than the mentioned studies. In a study, Panahi *et al.*, compared the effects of *Aloe vera* and *Calendula* on children younger than 3 years old with diaper dermatitis and reported that *Calendula* was more effective than *A. vera* in a 10 day period.^[12] Finding of the study by Panahi *et al.*, showed the effectiveness of *Calendula* on the improvement of diaper dermatitis; however, the present study showed that Bentonite was not only more effective than *Calendula* on the improvement of diaper dermatitis, but it accelerated the speed of improvement, too.

CONCLUSIONS

In the present study, the effects of *Calendula* and Bentonite were compared on the improvement of diaper dermatitis. Findings showed that Bentonite was effective on the improvement of diaper dermatitis, and also Bentonite had faster effects compare to *Calendula*. These advantages may be related to anti-inflammatory, antibacterial, water absorbing and skin protecting properties of this traditional product. It is also important to note that no side-effects were observed in the two groups. However, the study sample in the present study was small, and it is recommended to conduct similar studies with a larger sample. Furthermore, the present study was conducted

on the samples with mild to moderate diaper dermatitis, so it is recommended to conduct multicenter studies on severe diaper dermatitis.

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