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Comparing the effects of Bentonite & Calendula on the improvement of infantile diaper dermatitis: A randomized controlled trial

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***Background & objectives*: Infantile diaper dermatitis is a common, acute inflammatory reaction of the skin around diaper among infants. This study was undertaken to compare the effect of topical application of Bentonite and Calendula creams on the improvement of infantile diaper dermatitis.**

***Methods*: This double blind randomized controlled trial was undertaken on 100 patients of infantile diaper dermatitis. The 100 participants were randomly assigned into two groups of 50 each, and were prescribed the coded medicine. The mothers were trained to apply the cream and level of improvement was judged by observing the affected area on the first visit and then after three days of receiving treatment.**

***Results:* The mean age of infants was 6.45±5.53 months in Calendula group and 7.35±6.28 months in Bentonite group. Overall, 88 per cent of lesions in the Bentonite group started improving in the first six hours while this rate was 54 per cent in Calendula group (P<0.001). The risk ratio for the improvement in the first six hours was 2.99 folds in the Bentonite group. Also, lesions in 86 per cent infants in the Bentonite group and 52 per cent in the Calendula group were completely improved in the first three days after treatment (P<0.001).**

***Interpretation & conclusions*: Our results showed that in comparison with Calendula, Bentonite had faster healing effect and was more effective on the improvement of infantile diaper dermatitis (IRCT ID: IRCT 2012112811593N1).**

Key words Bentonite - Calendula - diaper dermatitis - infants - treatment

Infantile diaper dermatitis (DD) or diaper rash is a common skin problem among infants who wear diapers[1]. It is an acute inflammatory reaction of the skin around diaper[2] that may be caused by frequent and prolonged contact of the skin with the urine, stool and moisture, and exacerbated by *Candida* infection and abrasion[2,3]. This may be characterized with erythema, flaking, papules and lesions in the areas such as buttocks, thighs, scrotum and mons pubis[4].

The routine treatments for DD include changing the diaper and washing the genital area frequently, applying petrolatum or zinc oxide, and corticosteroids. A topical

antifungal agent may also be used if fungal infections occurred[5,6]. Calendula may also be effective in non-complicated cases[7]. Bentonite is a kind of mineral which is in the form of aluminum phyllosilicate and is also called as mineral or formal soap in pharmacy industries. It can absorb several folds of water as its own volume, and makes a jellified, plastic and viscous form. This material is used as moisturizer, skin protector and water absorbent[8]. In a previous study Bentonite was found to be effective in the treatment of chronic hand dermatitis[9]. Bentonite has no side effects and of low cost and has not been systematically evaluated for the treatment of DD. The present study was thus performed to compare the effects of Bentonite and Calendula for the treatment of infantile DD.

Material & Methods

This double blind randomized controlled trial was undertaken during February and May 2013 on 100 infants referred to the outpatient paediatric clinics of Imam Khomeini hospital and a healthcare centre in Khomein city, Iran. Sample size was calculated based on a previous study in which the per cent of severe DD was 33.3 and it decreased to 6.3 after using Calendula in intervention group[7]. The sample size calculated was 50 each in the experimental and control groups with a power of 0.8 and the type I error probability of 0.05.

Infants in the age range of 1 to 24 months, and having mild to moderate DD were included in the study. Also, those not having infantile eczema, diarrhoea, and urinary tract infection, fungus dermatitis (based on the physician's diagnosis), and not using corticosteroids for present lesions were also selected. Exclusion criteria were not following the researchers recommendations and exacerbation of the lesions and developing diarrhoea during the study.

Before the study, a grading system was developed for grading the lesions. Panahi *et al*[7] categorized the DD into four categories of mild, moderate, severe and extreme. We clubbed the categories of moderate and severe and modified this grading system into three categories of mild (erythema with or without satellite papules, with maceration and chafing), moderate (erythema with papulopustules and maceration) and severe (erythema with erosions or ulceration). Only mild and moderate cases were included in the study.

Data collection: The study process was explained to the parents and their written informed consent was obtained for participation in the study. A skin test was performed on the infant's arm to ensure not having allergic reaction. To do this, one fingertip of Bentonite and Calendula was applied on the internal surface of the infant's arm (1×1 cm) and observed for redness or any other allergic reactions after 20 min. Random numbers 1-100 were generated and entered in the data sheet. We randomly assigned 100 participants into the two conditions (a or b). Each condition was representative of one group with 50 participants. The numbers in each group were 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. A consort flow diagram of this study presented in the Figure.

To produce Bentonite 50 per cent, the mineral was squashed and turned into powder, sterilized in 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 per cent cream in 30 g cans by a pharmacist. To produce Calendula, two 15 g creams of Calendula 1.5 per cent (produced by Dineh Company, Iran) were poured in the similar 30 g sterile cans. Calendula and Bentonit were prepared in cans with similar shape and weight and then all cans were coded as "a" or "b" by the pharmacist.

To gather the data, a checklist was prepared and 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 with a rate of agreement of 0.93. The checklist included the characteristics of the infants (age, gender, weight), and mother (education level, age, job), type of feeding (breastfeeding, formula milk, cow's milk or combined) history of DD and drugs used in the previous episodes of the disease. Also there was a question for recording the frequency of changing diaper in a day and a question for grading the severity of DD. A Table was made for recording the effects of treatment including onset of recovery in the first six hour (yes, no), and improvement in the first, second and third day (yes/no), and time of the complete recovery (hours after the start of treatment). For judgment on the level of improvement, digital photographs were recorded of the affected areas of each infant at the first visit and the third day after receiving the treatment.

Checklists were completed for each infant and then the physician (who was unaware of the cans cods) prescribed one of the two creams. All mothers were

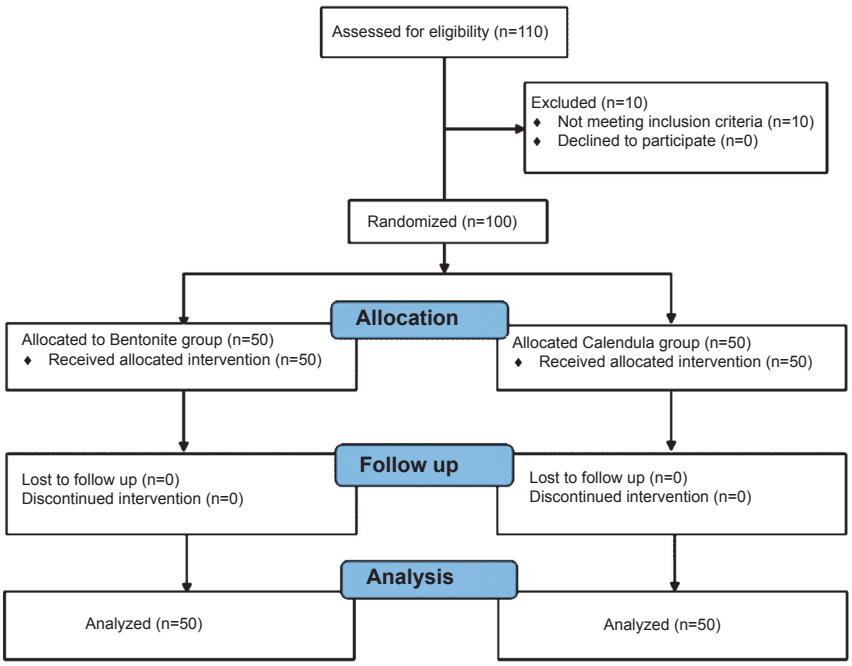

Figure. Flow diagram showing the study design.

trained to apply the cream on the affected area four times a day after changing the diaper.

The process of applying the cream was done under supervision for the first time and the effect of treatment was followed up three times a day by phone. Also, every other day (up to 3 times), the infants were visited and assessed by the physician and additional cream was given to the parents if needed. The effect of treatment (improvement or non-improvement) was documented based on the physician's decision.

The study protocol was approved by the Research Council and the Human Research Ethics Committee of Kashan University of Medical Sciences, Iran.

Statistical analysis: The data were analyzed through SPSS software, version 16.0 (SPSS Inc., Chicago, IL, USA). Independent sample T test was used to compare quantitative variables (*i.e.* age, weight), and chi square, risk ratio, and Fisher's exact test were used to compare qualitative variables between the two groups such as improvement.

Results

The mean age of infants was 7.35±6.28 months in Bentonite group and 6.45±5.53 months in Calendula group. In Bentonite group 19 were males (38%) and 31 were females (62%) and in Calendula group, there were 22 males (44%) and 28 females (56%), (Table I).

In total, 88 per cent of the lesions in the infants in Bentonite group started recovering in the first six hours while this rate was 54 per cent in Calendula group, and the rate of improvement in the Bentonite group was significantly higher than the Calendula group (P<0.001) (Table II). Also, the risk ratio for the start of improvement in the first six hours was 2.99 folds in the Bentonite group than in Calendula group (95% CI=1.43 - 6.25). Significantly higher numbers (P<0.001) of infants (86%) in the Bentonite group were improved completely in the first three days compared to 52 per cent in the Calendula group (Table II). Also, the risk ratio for the complete improvement in the first three days was 3.31 folds in Bentonite group than in Calendula group (95% CI=1.66, 6.56). The mean times of recovery in Bentonite and in Calendula groups were 44.14±23.95 and 86.34±24.13 hour, respectively (P<0.001; 95% CI: 32.65-51.74).

Discussion

The present study results showed that the onset of improvement in the first six hours was about three folds in Bentonite group than in Calendula group. Also the complete improvement in the first three days was more than three folds in Bentonite group. In an experimental study on rats, two centimeters lesions were made on the mature rats' skin and Bentonite was reported to be effective in healing of these lesions[10]. Fowler[11] has also assessed the effectiveness of Bentonite on the

Table I. Demographic and clinical characteristics of the infants and their mothers

Variable		Bentonite	Calendula
Age of the child (months)		7.35 ± 6.28	6.45 ± 5.53
Weight (kg)		6.84 ± 2.49	6.92 ± 2.85
Gender N (%)	Female	31 (62)	28 (44)
	Male	19 (38)	22 (56)
History of diaper dermatitis N (%)	Yes	24 (48)	24 (48)
	No	26 (52)	26 (52)
Nutrition type N (%)	Breastfeeding	43 (86)	40 (80)
	Formula milk	2 (4)	4 (8)
	Breast feeding+ formula milk	5 (10)	6 (12)
Severity of diaper dermatitis N (%)	Mild	20 (40)	26 (52)
	Moderate	30 (60)	24 (48)
Education level of mother N (%)	Primary	1 (2)	1 (2)
	Intermediate	10 (20)	8 (16)
	High school and over	39 (78)	41 (82)
Job of mother N (%)	Housekeeper	42 (86)	45 (90%)
	Employee	7 (14)	5 (10%)
The frequency of changing diaper a day		5.38 ± 2.49	5.24 ± 1.81
Age of mother (yr)		27.36 ± 5.31	27.36 ± 5.30

improvement of chronic hand dermatitis in human subjects and reported that using the moisturizer cream containing Bentonite for an eight weeks period significantly accelerated the improvement of chronic hand dermatitis.

In some studies the effects of some herbal products have been assessed on the improvement of DD[12,13]. Fotouhi *et al*[14] compared the effects of Calendula and Betamethasone in the prevention of acute radiation dermatitis and reported that both had the same effects in the palliation of the disease severity.

In the current study, the rate of improvement in Bentonite group was greater than the mentioned studies. Panahi *et al*[7], compared the effects of *Aloe vera* and Calendula on children younger than three years with DD and reported that Calendula was more effective than *Aloe vera* in a 10 day period. Our study showed that Bentonite was not only more effective than Calendula on the improvement of DD, but it also accelerated the speed of improvement. 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. Also, the present study was conducted on the samples with mild to moderate DD, so it is recommended to conduct multicenter studies on severe DD.

Table II. The onset of improvement in the first six hours and complete improvement in the first three days after treatment

		Group	
		Calendula, N (%)	Bentonite, N (%)
Start of improvement in the first six hours	Yes	27 (54.0)	44 (88.0)**
	No	23 (46.0)	6 (12.0)
Complete improvement in the first three days	Yes	22 (44)	43 (86)**
	No	28 (56)	7 (14)

**$P<0.001$ compared to Calendula group

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***Conflicts of Interest*:** None.

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