"Evaluation of the efficacy of Kailas Jeevan in the management of diaper dermatitis in children -an open clinical study"

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Abstract

Diaper dermatitis *(Ahiputana)* is a widespread skin problem among the neonatal population that is often caused by irritants that promote skin breakdown, such as moisture and fecal enzymes. The disease predominantly affects the convex surfaces in closest contact with wet or soiled diapers. The skin becomes erythematous and scaly with papulovesicular fissures and erosions leading to marked discomfort. It is a known fact that children are easily susceptible to infections and any prescription written towards this population must be well planned to avoid any unwanted side effects. Diaper dermatitis is commonly managed using drugs such as zinc oxide, nystatin etc., that may lead to certain adverse effects such as dermatitises or itching. Therefore, there is a need to treat the condition using safe and promising drugs. *Kailas Jeevan* is a formulation made of several medicinal herbs and minerals and has been a drug of choice among several Ayurvedic physicians over the years. However, there is a need to carry out clinical trials to establish scientific data about its efficacy so as to move towards evidenced based medicine. In the present study, 30 chlidren diagnosed with Diaper dermatitis were enrolled and treated with *Kailas Jeevan* for 10 days. It was observed that therewas statistically significant improvement in features such as colour and area of the dermatitis. Based on the observations made, it can be concluded that Diaper dermatitis can be effectively managed using *Kailas Jeevan*.

Keywords: ***Ahiputana, Kailas Jeevan, Diaper dermatitis, Napkin rash***

Introduction

Diaper dermatitis (DD) is the most common skin disorder seen in young infants. DD is an inflammatory reaction of the perineal skin and perianal areas (diaper area). It is most commonly caused by irritation of the skin ·Another common reason is infection with *Candida albicans,* which can be primary or secondary [1]. It results from a combination of multiple factors such as increased moisture and prolonged contact with urine or feces.

Some of the management approaches include skincare, adequate hygiene, and avoidance of any irritant substance. DD predominantly affects the convex surfaces in closest contact with wet or soiled diapers. The skin becomes erythematous and scaly with papulovesicular fissures and erosions. There is marked discomfort due to intense inflammation [2]. Secondary bacterial or fungal infections may occur. Behavioural changes such as increased crying and agitation and changes in eating and sleeping patterns indicate emotional distress [1].

DD can be seen mentioned in *Ayurveda* as *Ahipootana* and is stated to be caused by frequent stagnated urine, faeces and sweat around the anal region for longer duration, resulting into *Sphota* (papules) with *Kandu* (itching) all over the diaper region [3]. A similar condition can be seen in diarrhoea with anal excoriation and even in diaper dermatitis. If the condition is ignored, it can lead to widespread infection by bacteria or fungi necessitating vigorous and prolonged treatment **[4,5,]**

Ahipootana in *Ayurveda* is said to be *Daruna* (requiring prolonged treatment) and *Ghora* (severe) **[3,4]** Clinical conditions such as diarrhoea can increase the incidence rate of DD in babies**[4]** The worldwide prevalence of DD has been reported to be 4-35% in the 1st two years of life and in India, it is 13% **[3]**

The delicate infantile skin cannot withstand the toxicity of most substances like urine and faeces [6] and the skin is a potential portal of entry for invasive infective organisms in neonates and infants. Skin breakdown is very common during infancy which enhances conditions such as anal excoriation and diaper dermatitis [7,8].

Kailas Jeevan (KJ) is a protective cream used in a variety of skin conditions, especially those that are associated with burning sensation, exfoliation and cracked skin. It has been in the market for the last 60 years, making its efficacy time tested. However, there are no known clinical research studies on the drug as on date, and there is a need for an effective medication in DD. With this outlook, the present work is a clinical trial involving 30 children enrolled for DD. After a treatment period of ten days, a marked improvement has been observed, due to which it can be stated that KJ is effective in the management of DD.

Methods

Trial design - The study carried out was an open clinical study.

Participants - Infants and Toddlers from birth to 3 years suffering from classical sign and symptoms of DD (red or/and tender skin in the diaper region — buttocks or thighs or genitals or all of them) were enrolled into the trial.

Children under the medication for systemic and topical diseases, children with severe infective DD needing emergency medications and children with acute or chronic illnesses that necessitates exclusion were excluded from the study.

Interventions - The trial drug KJ was procured from GMP certified *Kailas Jeevan* manufacturers, Dhayari, Dhayari Phata Rd, Benkar Vasti, Dhayari Phata, Pune, Maharashtra 411041. Children of either sex, suffering from the signs and symptoms of DD were selected from the attending OPD & IPD of KLE Ayurveda Hospital, Shahapur, Belgaum.

Infants and toddlers were screened as per the inclusion criteria and informed written consent was obtained from the parents. The parents were advised to administer (apply as an *Alepa* (topically)) KJ four times a day for a period of 10 days or until recovery

Follow up of all children were carried our on the 3rd, 7th and the 10th day. During each follow up visit, a detailed clinical examination was performed. The parents were advised to discontinue the product any adverse effects were observed or if there was complete recovery. The total period of intervention was 10 days.

Outcomes -In order to assess the effect of KJ on DD, the following assessment criteria were employed:

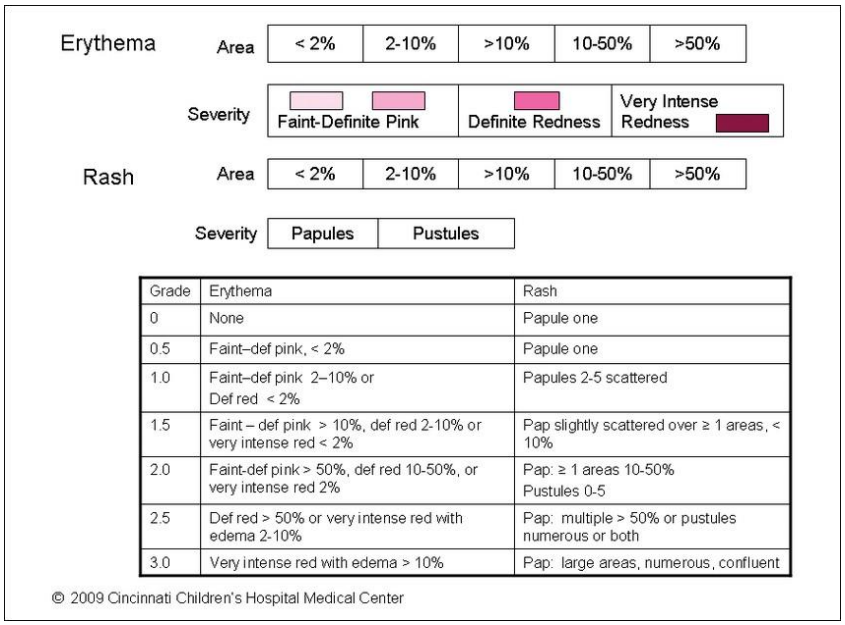
1. **Colour**

No erythema	**- 0**
Erythema without exudation	**- 1**
Erythema with exudation	**- 2**
Erythema with exudation and excoriation	**- 3**

2. **Area affected by the Dermatitises**

0 to2 cm	**-1**
2 to 3 cm	**-2**
3 to 5 cm	**-3**
More than 5 cm	**-4**

3. The following chart was used for assessment [9]



Grade	Erythema	Rash
0	None	Papule one
0.5	Faint–def pink, < 2%	Papule one
1.0	Faint–def pink 2–10% or Def red < 2%	Papules 2-5 scattered
1.5	Faint – def pink > 10%, def red 2-10% or very intense red < 2%	Pap slightly scattered over ≥ 1 areas, < 10%
2.0	Faint-def pink > 50%, def red 10-50%, or very intense red 2%	Pap: ≥ 1 areas 10-50% Pustules 0-5
2.5	Def red > 50% or very intense red with edema 2-10%	Pap: multiple > 50% or pustules numerous or both
3.0	Very intense red with edema > 10%	Pap: large areas, numerous, confluent

Figure 1 – Cincinnati Children's Hospital Medical Center Diaper assessment scale

Sample size - 30 children were enrolled into the trial. There were no dropouts throughout the study period.

Statistical methods - The obtained data was analysed using Wilcoxon matched pairs test.

Results

In presemt study, 53.33% were below or equals to age group 12 months and 46% of sample was equal or more than age of 13 months. In present study,96.67% subjects were belonging to *Anoopa Desha* and 3.33% subjects belongs to *Jangal Desha*. Among the participents of different types of *Prakriti* (body constitutions), 40% were of *Kapha prakriti* 46.67% were of *Pitta prakriti* and 13.33% were of *Vata Prakriti (Table 1).* Colour Parameter showed significant improvement from before treatment to 3rd, 7th and 10th day with P-Value 0.0001, 0.0001, 0.0001 respectively. Overall treatment outcome from baseline to 10th day is highly significant with P- value 0.0001 *(Table 2).* Area Affected by dermatitis Parameter showed significant improvement from before treatment to 3rd, 7th and 10th day with P-Value 0.0001, 0.0001, 0.0001 respectively. Overall treatment outcome from baseline to 10th day is

highly significant with P- value 0.0001 *(Table 3).* CCHMC by the dermatitis Parameter showed significant improvement from before treatment to 3rd, 7th and 10th day with P-Value 0.0001, 0.0001, 0.0001 respectively. Overall treatment outcome from baseline to 10th day is highly significant with P- value 0.0001 *(Table 4).*

Other profile	No of participants	% of participants
Desha		
Anoopa	29	96.67
Jangal	1	3.33
Prakruti		
K	12	40.00
P	14	46.67
V	4	13.33
Total	30	100.00

Table 1: Demographical data of the subjects enrolled

Times	Mean	SD	Median	IQR	% of change	Z-value	P-value	Friedman ANOVA	P-value
Before treatment	1.6	0.6	2.0	0.5					
Day 3	0.7	0.6	1.0	0.5	57.14	4.6226	0.0001*	79.3004	0.0001*
Before treatment	1.6	0.6	2.0	0.5					
Day 7	0.1	0.3	0.0	0.0	91.84	4.7821	0.0001*		
Before treatment	1.6	0.6	2.0	0.5					
Day 10	0.1	0.3	0.0	0.0	95.92	4.7821	0.0001*		
Day 3	0.7	0.6	1.0	0.5					
Day 7	0.1	0.3	0.0	0.0	80.95	3.6214	0.0003*		
Day 3	0.7	0.6	1.0	0.5					

Day 10	0.1	0.3	0.0	0.0	90.48	3.7236	0.0002 *		
Day 7	0.1	0.3	0.0	0.0					
Day 10	0.1	0.3	0.0	0.0	50.00	1.3416	0.1797		

*p<0.05

Times	Mean	SD	Median	IQR	% of change	Z-value	P-value	Friedman ANOVA
Before treatment	1.4	0.6	1.0	0.5				
Day 3	0.7	0.7	1.0	0.5	47.62	3.9199	0.0001 *	71.4508
Before treatment	1.4	0.6	1.0	0.5				
Day 7	0.2	0.4	0.0	0.0	83.33	4.7030	0.0001 *	
Before treatment	1.4	0.6	1.0	0.5				
Day 10	0.0	0.2	0.0	0.0	97.62	4.7821	0.0001 *	
Day 3	0.7	0.7	1.0	0.5				
Day 7	0.2	0.4	0.0	0.0	68.18	3.2958	0.0010 *	
Day 3	0.7	0.7	1.0	0.5				
Day 10	0.0	0.2	0.0	0.0	95.45	3.7236	0.0002 *	
Day 7	0.2	0.4	0.0	0.0				

Table 2:	Day 10	0.0	0.2	0.0	0.0	85.71	2.2014	0.0277*	

Comparison of different treatment time points with status of colour by Wilcoxon matched pairs test

*p<0.05

Table 3: Comparison of different treatment time points with status of Area affected by the dermatitis by Wilcoxon matched pairs test

Times	Mean	SD	Median	IQR	% of change	Z-value	P-value	Friedman ANOVA	P-value
Before treatment	1.0	0.3	1.0	0.0					
Day 3	0.6	0.4	0.5	0.0	43.33	4.4573	0.0001*	81.9498	0.0001*
Before treatment	1.0	0.3	1.0	0.0					
Day 7	0.2	0.4	0.0	0.0	83.33	4.7821	0.0001*		
Before treatment	1.0	0.3	1.0	0.0					
Day 10	0.0	0.2	0.0	0.0	96.67	4.7821	0.0001*		
Day 3	0.6	0.4	0.5	0.0					
Day 7	0.2	0.4	0.0	0.0	70.59	4.2857	0.0001*		
Day 3	0.6	0.4	0.5	0.0					
Day 10	0.0	0.2	0.0	0.0	94.12	4.4573	0.0001*		

Day 7	0.2	0.4	0.0	0.0					
Day 10	0.0	0.2	0.0	0.0	80.00	2.3664	0.0180 *		

Table 4: Comparison of different treatment time points with status of CCHMC (Cincinnati Children's Hospital Medical Center) by the dermatitis by Wilcoxon matched pairs tes

*p<0.05

No Adverse Drug Reactions were reported during the study.

Discussion

The present study was carried out on an OPD level wherein the parents were instructed on the method of administration. However, if the study was carried out on an In-Patient basis, there could have been more certainty on the regularity of drug application and adherence to all do's and don'ts including aseptic precautions. The time taken for cure may be affected by such factors.

All results obtained were statistically analysed using Wilcoxon matched pairs test, wherein the overall treatment outcome from baseline to the tenth day was found to be highly significant with a P-value of 0.0001. Furthermore, population from various regions and *Prakrtis* (body constitutions) were included in the study, due to which it may be expected that the results would be reproduceable.

The efficacy of KJ may be understood by analysing the constituent ingredients.

Sr.No.	Name of the Ingredients	Latin Name	Proportion
1	Coconut Oil	Cocos Nucifera Oil	28.000 %
2	Pandhari Ral	Shorea Robusta Resin	03.700 %
3	Chandan Tel	Santalum Album Oil	00.100 %
4	Bheemseni Kapoor	ISO Borneol	00.145 %
5	Shankhjire	Talc	00.900 %
6	Kadunimba Kadha	Azardirachta Indica Leaf Extract	00.900 %
7	Gokharu Kadha	TribulusTerrestris Fruit Extract	00.900 %

8	Doorva Kadha	Cynodon Dactylon	00.900 %
9	Pahadmool Kadha	Cissampelos Pareira Root Extract	00.900 %
10	Sudhajal	Lime water	Q.S.

Table 5: Composition of Kailas Jeevan

In present study, 53.33% were below or equal to the age of 12 months and 46% of the sample was of age equal to or more than 13 months. Stool of infants and neonates is more acidic [10]. This could explain why the incidence was slightly higher in infants. The incidence of diarrhea in the age group under 6 months can be attributed to dietary changes of the mother. For instance, consumption of tomato and chilli can lead to diarrhea [11]. Certain drugs such as amoxicillin can also induce diarrhea in babies. [11] In the present study, 96.67% subjects hailed from *Anoopa Desha* (marshy land) and 3.33% hailed from *Jangal Desha* (arid land). The higher incidence from *Anoopa Desha* could be due to the excessive *Kleda* (moisture) in the atmosphere that could have contributed to the formation of DD. Further, the hospital was located in *Anoopa Desha* and most patients were from the local regions. Among the participants of different types of *Prakriti* (body constitution), 40% were of *Kaphaprakriti* 46.67% were of *Pittaprakriti* and 13.33% were of *Vataprakriti*. The disease is of *Kapha* and *Pitta* dominance and a reflection of the same can be observed in the study.

Colour Parameter showed significant improvement from before treatment to 3rd, 7th and 10th day with a P-Value of 0.0001, 0.0001 and 0.0001 respectively. Overall treatment outcome with respect to colour from baseline to 10th day is highly significant with a P-value of 0.0001. This is attributed to the *Vranashodhaka* (wound cleansing) property of *Nimba* [12] and *Pittashamak (Pitta pacifying) a* property of *Chandana* [13]. The parameter of "Area Affected" showed significant improvement from before treatment to 3rd, 7th and 10th day with a P-Value of 0.0001, 0.0001 and 0.0001 respectively. The overall treatment outcome with respect to area from baseline to 10th day is highly significant with a P-value of 0.0001. This improvement could be attributed to the *Krimihara* (antimicrobial) property of *Sudhajala* (Lime water) [14], *Vranaropaka* (wound healing) property of *Doorva* [15] and *Nimba* [12] and soothing action of coconut oil [16]. Coconut oil base also forms a thin barrier line which prevents the wound area from coming in contact with the stool and thus may facilitate faster healing. The dermatitis parameter by CCHMC *(Figure 1)* showed significant improvement from before treatment to

3rd, 7th and 10th day with a P-Value of 0.0001, 0.0001 and 0.0001 respectively. Overall treatment outcome from baseline to 10th day is highly significant with a P-value of 0.0001. The overall improvement can be attributed to the overall action of the drug which was found to be soothing, wound healing and antimicrobial. It was also noted that the drug prevented the affected area from being re-infected.

Conclusion

Among the 30 chlidren diagnosed with Diaper dermatitis that were enrolled into the study, all cases showed recovery within the ten-day intervention period. There were no Adverse Drug Reactions and there were no drop outs. Based on the outcomes of the study, it can be concluded that DD can be effectively managed using KJ for topical application.

Other information

Ethical Clearance Number: KLE/BMK/MRC/701/2

CTRI Reg No: CTRI/2021/03/031869

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