

Efficacy of Topical *Coriandrum sativum* Extract on Treatment of Infants with Diaper Dermatitis: A Single Blinded Non-Randomised Controlled Trial

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Abstract

Diaper dermatitis is a common disorder. *Coriandrum sativum* is a herbal remedy with anti-inflammatory, analgesic, anti-microbial and anti-oxidant activities effects. In this non-randomised clinical trial which was performed on 58 infants with diaper dermatitis referred to Faghihi Hospital, Shiraz University of Medical Sciences, the efficacy and safety of topical *Coriandrum* extract cream is compared with hydrocortisone ointment. *Coriandrum sativum* extract cream was administered for 37 (intervention group) and hydrocortisone 1% ointment for 21 (control group) patients. Patients were examined on days 3 and 10. Chi-square test was applied for statistical analysis. The results demonstrated a statistically significant difference in the cure rate (20 (54.1%) for the intervention group versus 19 (90.5%) for the control group) (P -value = 0.005) and side effects (10 (27%) for the intervention group versus 0 (0%) for control group) (P -value = 0.009) both in favor of hydrocortisone. This trial failed to confirm the efficacy of *Coriandrum sativum* in the treatment of diaper dermatitis; however, it seems that if soothing compounds are used in combination with *Coriandrum sativum* to reduce the mild irritation, *Coriandrum* extract can be an alternative treatment for diaper dermatitis.

Keywords: *Coriandrum*, hydrocortisone, dermatitis

Introduction

Diaper dermatitis is a common cutaneous disease in the diaper area in infants (1, 2). The basic cause of this condition is over-hydration and increased temperature in the napkin area; consequently, it creates an environment which

renders the skin vulnerable to damage and degradation (1, 3). Commonly used materials to cure the rash are oils, soaps and powders, which are not free of complications like irritation and aggravation of the eruptions (1, 4). Topical steroids, as the routine treatment, is potent to cause side effects (5). Essential oils are a mixture

of substances extracted from plants by different methods (6). *Coriandrum sativum*, a plant of the family *Apiaceae*, is traditionally used in various cultures. Among the diverse range of its pharmacological potential, anti-microbial, anti-inflammatory and anti-oxidant activities can be mentioned (7). Given the numerous pharmaceutical benefits of *Coriandrum* extract, playing a role in the treatment of cutaneous infections and inflammations seems to be promising.

In this study, we aimed to investigate the effect of *Coriandrum sativum* seed essential oil on the diaper dermatitis in infants and compare it with hydrocortisone 1% ointment.

Methods

This non-randomised clinical trial was conducted on 58 infants with diaper dermatitis referred to Faghihi Hospital, Shiraz University of Medical Sciences. The inclusion criteria for both case and control groups were infants less than 2 years of age with diaper dermatitis identified by diaper dermatitis severity index score of ≥ 3 (3–8), and without any known systemic or cutaneous diseases. Infants with severe dermatitis or systemic diseases, who were above 2 years old and patients who lost the follow up or irregular use of therapy were excluded from the study, but there was no limitation on gender. The participants were enrolled either in the intervention group or control group based on their parents' desire after providing written informed consent. Parents were explained about the study, each treatment method and facts and potential side effects. After all, 37 infants were included in the intervention group, and the control group consisted of 21 infants. Parents were asked to fill out a questionnaire with the help of a physician, which contained information about age, gender, duration of diaper dermatitis and KOH test result, in order to rule out *Candida* super infection, before starting the therapy. The intervention group underwent treatment with *Coriandrum* ointment made by a pharmacist and the control group was treated with hydrocortisone 1% ointment.

Coriandrum extract cream consists of the total extract of the seed in a base of vanishing cream (complete formulation of the cream: *Coriandrum* seed oil, stearic acid, cetyl alcohol, polyethylene glycol, propylene glycol, triethanolamine and distilled water). For processing the *Coriandrum* extract cream, firstly

the seed oil and other fatty compounds were mixed at the melting point of the ingredients. Afterwards, 45 degrees centigrade hot distilled water was added to the oily portion of the formula. The mixture was fully homogenised and then cooled to 25 degrees centigrade. Cream shelf life is as long as 2 years at normal temperature. The extract was obtained through cold compress method, without the use of solvents; therefore, the seed oils are not affected by the possible impact of solvent polarity.

Both ointments were applied twice daily. After 3 days, both groups were assessed by a single blinded dermatologist. For those who presented with complications such as redness, inflammation, itching, restlessness, or wound maceration, the therapy was stopped. Patients whose conditions had relatively improved continued their current therapy for extra 7 days and received a second checkup on day 10. If the patients were cured, the therapy was terminated; otherwise, their treatment was shifted to the routine. The complete and partial cures were assessed by diaper dermatitis severity index score; the score of 0 indicated the complete cure and any extent of decline in severity score was assigned to the partial cure. Finally, R programming language (version 3.3.1 for Windows) and rattle graphical user interface (GUI) package and Chi-square test were applied for statistical analysis. P -value ≤ 0.05 was considered as statistically significant. The study protocol was approved by the Ethics Committee of Shiraz University of Medical Sciences. CONSORT 2010 Flow Diagram was implemented in the study (Figure 1).

Result

The control group consisted of 14 male (67%) and 7 female (33%) patients. The intervention group consisted of 18 male (49%) and 19 female (51%) patients. Duration of diaper dermatitis in both groups was classified into 3 subgroups. The number (%) of patients in each subgroup (1–3 days, 3–7 days and more than 7 days) was 8 (22%), 12 (32%) and 17 (46%) for the cases and 5 (24%), 5 (24%) and 11 (52%) for the controls.

The number (%) of patients completely cured, failed to cure, and had side effects was 20 (54.1%), 17 (45.9%), and 10 (27%) for the intervention group and 19 (90.5%), 2 (9.5%), and 0 (0%) for the control group, respectively. The results of the analysis were significantly in favor

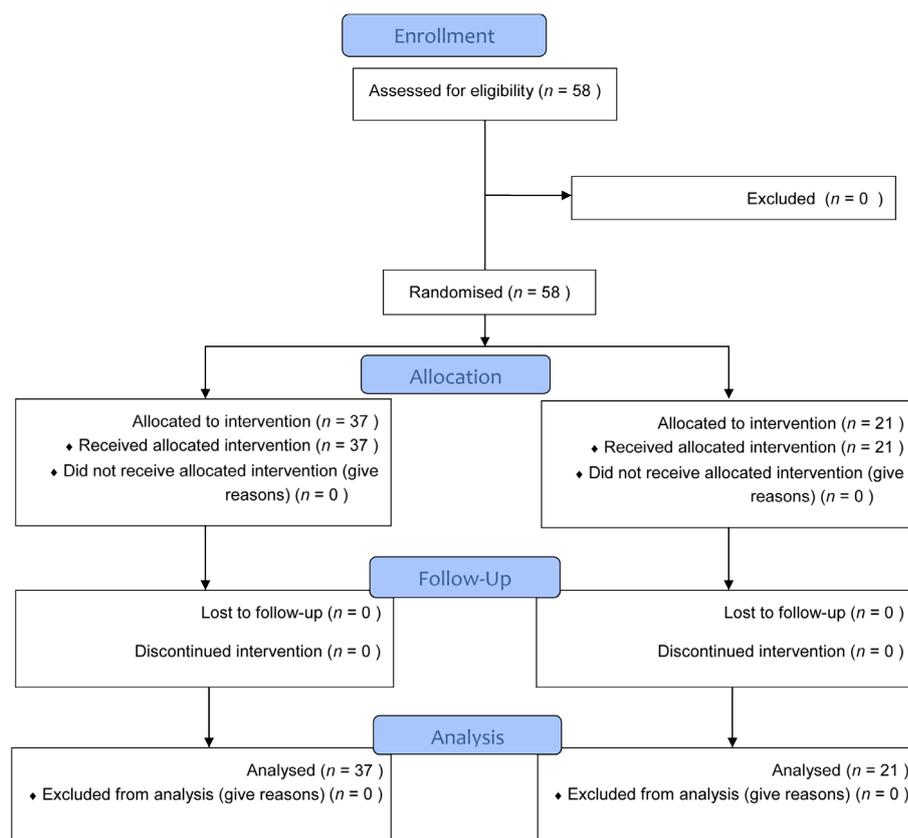


Figure 1. CONSORT 2010 flow diagram

of hydrocortisone regarding the percentage of patients who were cured (P -value = 0.005). Also, a highly significant difference was noticed in developing side effects (P -value = 0.009), as no patient in the control group presented with any adverse effects (Table 1).

Discussion

There are studies which strongly support dermal protection and healing features of *Coriandrum sativum*, such as having antioxidant effect on human keratinocytes against H_2O_2 oxidative stress (8), antiseptic properties

against gram-positive bacterial infections like *Streptococcus pyogenes*, *Staphylococcus aureus* and methicillin resistant *Staphylococcus aureus* (MRSA) (9–11); and even bactericidal effect on bacteria which are pathogenic in plants and mushrooms and, therefore, used for organic agriculture (12). The last but not least of *Coriandrum sativum* therapeutic properties is the healing ability in treatment of wounds (13).

Although comparison of the results between the cured patients in the case and control groups showed a significant difference in favor of hydrocortisone, the number of treated patients with *Coriandrum sativum*

Table 1. Clinical characteristics of infants with diaper dermatitis

		Control n (%)	Intervention n (%)	χ^2 - statistic ^a (df)	P-value ^a
Cure rate	Cured	19 (90.5)	20 (54.1)	8.07 (1)	.005
	Not cured	2 (9.5)	17 (45.9)		
Side effects	Positive	0 (0)	10 (27)	6.86 (1)	.009
	Negative	21 (100)	27 (73)		

^aChi-square test for independence.

extract was considerable. On the other hand, a study performed by Casetti et al. (9) reported no skin irritation presentation in any of the study volunteers, but the present study showed irritating side effects like redness and itching in some patients; therefore, this may be related to *Coriandrum* extract cream formula or processing and indicates that modification of the cream formula by adding soothing substances like soapstone (soaprock, steatite) which are used in combination with *Coriandrum sativum* traditionally, zinc oxide, allantoin and dexpanthenol might be advantageous in improving the cure percentage and decreasing the adverse effects. In addition to the short number of subjects, another limitation of the study was the lack of randomisation which results in the so called choice bias. In addition, considering the short duration of the follow up, it is estimated that an adequate follow up time of 2–3 weeks could probably reveal the beneficial effects of *Coriandrum* essential and side effects of hydrocortisone ointment much more conclusively. Therefore, we suggest a randomised study with more cases, use of soothing materials in *Coriandrum* extract cream, and longer duration of therapy to achieve more definitive results.

Conclusion

Our study results were in favor of hydrocortisone 1% ointment and did not confirm the efficacy of *Coriandrum sativum* which may reflect how the study was designed. It seems that in a new study, if soothing compounds like soapstone, zinc oxide, allantoin and dexpanthenol are reused in combination with *Coriandrum sativum* to reduce the irritating side effects, *Coriandrum* extract can be used as an alternative treatment for diaper dermatitis. Adequate sample size, randomisation in order to prevent the choice bias, and longer follow up period should be taken into account.

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Conflict of Interest

Authors have no conflicts of interest.

Authors' Contributions

Conception and design: LD, NP
Analysis and interpretation of the data: NS, AH
Drafting of the article: NS, AH
Critical revision of the article for important intellectual content: LD, NP, NS, SK, BK, FT, SA, AH
Final approval of the article: LD, NP, NS, SK, BK, FT, SA, AH
Provision of study materials or patients: SK, BK, FT, SA
Statistical expertise: NS, AH
Obtaining of funding: NS

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