

Efficacy of Traditional Medicine Product Henna and Hydrocortisone on Diaper Dermatitis in Infants

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Abstract

Background: Diaper dermatitis (DD) is a common inflammatory disorder in infants, including newborns.

Objectives: This study aimed to compare the effects of a traditional medicine product (containing natural henna oil 25%) and hydrocortisone 1% cream on DD in infants.

Patients and Methods: In a triple-blind, randomized trial, 82 children aged two years or less were randomly divided into two groups of 41 children each to receive either hydrocortisone ointment or henna medicinal product. Infants were treated 3 times a day for 5 days. The severity of dermatitis was assessed on the first, third, and fifth days using a six-point scale. The study was conducted in 2013 in a children teaching hospital in Qazvin, Iran.

Results: Both groups showed an improvement in the severity of DD (mean DD severity on the first, third and fifth days, respectively, was 3.20, 1.39, and 1.20 in the henna group versus 3.20, 2.05, and 1.90 in the hydrocortisone group; $P < 0.001$). The henna group showed a better response when compared with the hydrocortisone group: the rate of improvement on the fifth day of treatment was 90.2% (37 of 41 children without erythema) in the former versus 61% (25 of 41 patients) in the latter ($P = 0.042$). No significant side effects were observed in both the groups.

Conclusions: Henna, a traditional medicine product, can be considered an effective and appropriate treatment for DD in infants and children.

Keywords: Diaper Rash, Henna Plant, *Lawsonia inermis*, Hydrocortisone

1. Background

Contact dermatitis caused by the use of diapers is common between the age of 1 to 24 months (1-3), and about 7% to 35% of all infants are affected (3). The highest incidence has been reported in the 9- to 12-month age group (4).

Regarding clinical presentation, the skin of the affected area is moist and painful, appears red and spotty, and is sometimes itchy; in some cases, it may be cracked or even ulcerated (2, 3). This type of dermatitis must be differentiated from other skin conditions such as inflammatory or infectious reactions, nutrient deficiencies, and malignancies (1, 3). Secondary infections with bacteria and fungi are common and may cause severe discomfort owing to widespread inflammation (5). The use of inhibitor drugs may prevent diaper use-related contact dermatitis. Active ingredients of such formulations include zinc oxide, vitamins A and D, petroleum jelly, vitamin E, lanolin, etc. (6, 7). Topical steroids are also effective in the treatment of con-

tact and allergic dermatitis (8). Hydrocortisone, a glucocorticoid, is used as anti-inflammatory drug in the treatment of contact dermatitis, atopic dermatitis, and psoriasis (9).

Henna is used as a topical treatment for fungal diseases of the skin, particularly those caused by Tinea (10). It is also used to relieve rheumatic pain. A review of experimental animal studies indicates that henna extract enhances wound contraction, reduces epithelialization time, skin cancer chemo preventive activity (11, 12); it significantly increases the weight of granulation tissue and, thus, its use has been suggested for improving wound healing (13).

Henna formulation is composed of dried leaves of *Lawsonia inermis* L. of the *Lythraceae* family, and contains at least 0.3% of Lawsone. The molecular formula and weight of Lawsone is C₁₀H₆O₃ and 174.15, respectively. Lawsone is responsible for the anti-fungal and anti-bacterial effects, as well as the coloring property, of henna (14, 15). The tannin

content of henna extract is astringent and decreases sweating (16, 17). Henna is traditionally used to reduce sweating of hands and feet (18).

2. Objectives

There is limited research evidence on the effects of henna topical products on skin lesions, although its use is cost effective and easy. Therefore, we conducted this study with the aim of comparing the healing effect of products of the traditional medicine henna with that of hydrocortisone 1% on diaper dermatitis (DD) in children age 2 years or less.

3. Patients and Methods

This clinical trial was conducted during the summer, autumn, and winter of 2013 in a children teaching hospital in Qazvin, Iran, which is a government referral center for children. The study population comprised infants with DD who were referred to the pediatrics hospital in Qazvin. The trial registration code is IRCT2014080318665N1. Eligible children were selected as per the research protocol and inclusion criteria. Necessary explanations were provided to the parents. Under their initial agreement to participate in the study, a full informed consent was taken. Inclusion criteria were age under 24 months and presence of DD. The exclusion criteria included 1, presence of known diseases requiring special treatment (skin or kidney diseases, congenital anomalies, oral or genital thrush); 2, use of other medications for the treatment of DD; 3, use of topical antibiotics in the diaper area, and 4, fungal DD (diagnosed by a pediatrician) (19). The eligible infants were randomly assigned to either of the two groups of 41 children each: henna traditional medicine product (blue group) and hydrocortisone 1% (red group) groups. Randomization was done by using the permuted block randomization method. Allocation was concealed by using the opaque and impenetrable envelopes. Considering the blinding of all infants and mothers, examining physicians, and data analyst toward the allocation, a triple blind study was performed. Allocation information was only available to the principle investigator who had no role in the evaluation of the children. Identical training on medication use was provided to mothers in both groups.

The traditional medicine product (henna oil cream 25%) was prepared in the Herbal medicine department of the research institute for Islamic and complementary medicine, Iran University of Medical Sciences, and was approved by experts. Hydrocortisone cream required for the study was prepared in the hospital pharmacy. Both products were packed in identical tubes in terms of shape and

size and provided to the participating parents. Follow-up and treatment of all children were performed by the same pediatrician.

Validity of the measurement tool was confirmed by a panel of expert pediatricians. To evaluate the healing process, a six-point scale was used (20, 21), where 0 meant no erythema and 5 indicated severe erythema with infiltration or vesiculation or epidermal side effects. Measurements were done on Days 1 (the first visit), 3, and 5 in both groups. Given the type I and type II errors of 0.05 and 0.2, respectively, and assumed recovery rate of 63.3% for henna and 90% for hydrocortisone 1%, the calculated sample size was 40 per group (total = 80). Considering a dropout rate of 10 percent, the final sample size was calculated as 88.

Sample size formula is provided below:

$$n = 2 \frac{(z_{1-\frac{\alpha}{2}} + z_{1-\beta})^2 \bar{p}\bar{q}}{(p_1 - p_2)^2} \quad (1)$$

Finally, 82 children were enrolled and six were excluded from the study (Figure 1).

3.1. Statistical Analysis

Data description and analyses were done using SPSS software version 21. Descriptive data are provided as mean, standard deviation, and standard error. To compare data, we used Friedman, Mann-Whitney U, and Fisher's exact tests as well as the chi-square test. $P < 0.05$ was considered statistically significant.

4. Results

Eighty-two infants two years or younger were divided randomly into two groups (41 children received hydrocortisone 1% ointment and 41 received the henna medicinal product).

There was no significant difference between the groups before the intervention ($P > 0.05$; Table 1).

Friedman's test showed a significant improvement in DD severity and intensity in both groups ($P < 0.001$; Table 2).

There was no significant difference between the two groups on the first and third days ($P > 0.05$), but on the fifth day, the henna product showed a statistically significant better effect than the hydrocortisone product ($P = 0.042$); Table 3.

5. Discussion

Diaper rash holds significance to parents, pediatricians, and other health care providers. A common problem that causes frequent visits to the pediatricians, DD is

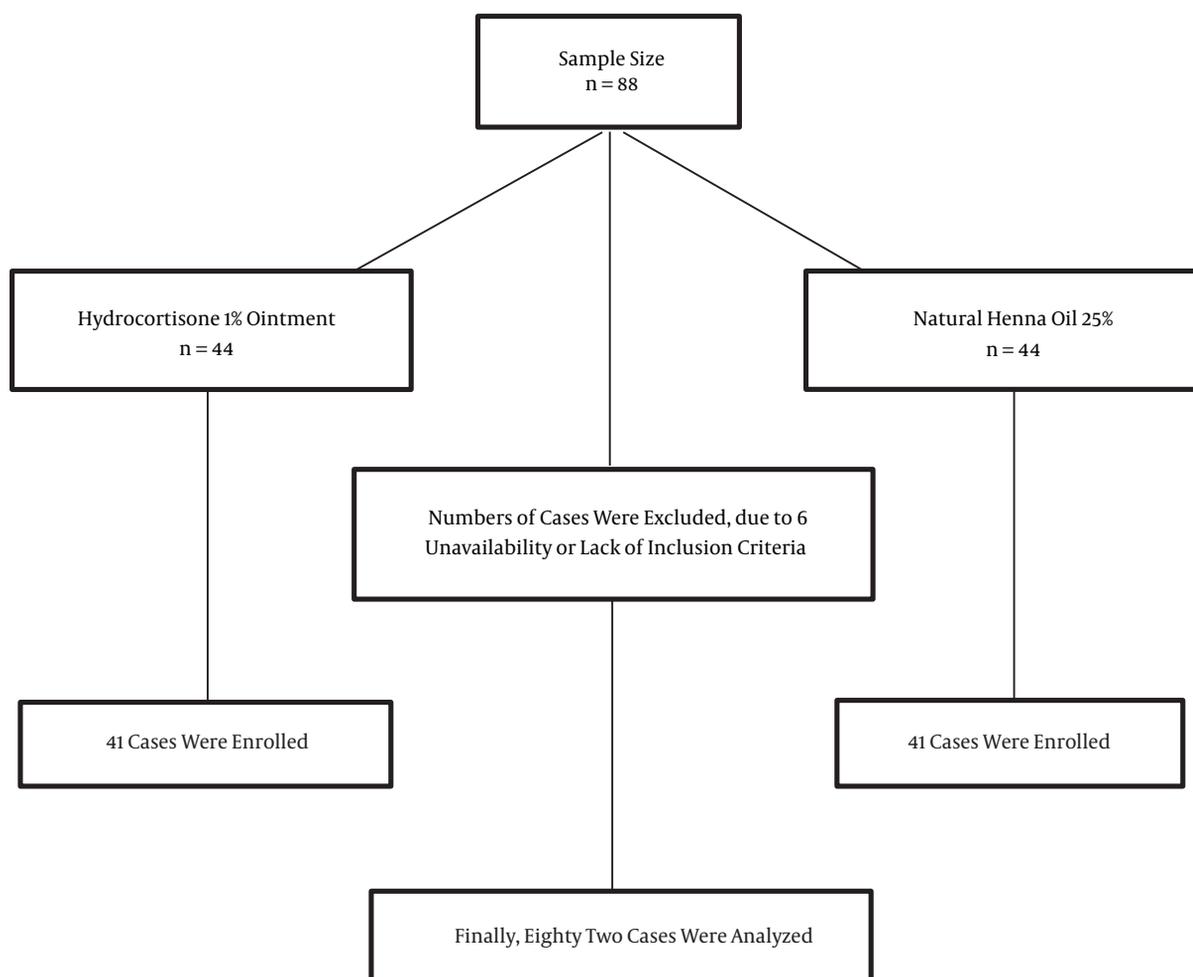


Figure 1. Participant Flow During the Study

a matter of concern for families. A good approach to the diagnosis and treatment is therefore essential (22, 23).

Doctors should be familiar with the advantages and disadvantages of existing hygiene-care products used for the treatment of DD. Many products such as petroleum jelly, zinc oxide, corticosteroids, talcum powder, lanolin, and vitamins A and D are available for the uncomplicated management of this type of dermatitis (19, 24, 25).

Use of natural substances for the treatment of diseases, particularly in Iranian traditional medicine, goes long back in history. Medicinal herbs have been used for treatment for many years, and are still the first choice in the treatment of diseases in some parts of the world. Herbal henna (*Lawsonia inermis*) has been used in herbal

medicine for years; however, the medical benefits of this herb have been proposed in only a few published papers (26).

The present study revealed that traditional medicinal products made from natural henna of Iran are even more effective than conventional steroids in the healing of the lesions of DD in infants (although healing was observed in both groups after treatment). The beneficial effects can be attributed to the known anti-inflammatory and antimicrobial properties of henna. The anti-fungal and antibacterial effects, as well as its color, are attributed to the Lawsone content of henna. The tannin content of henna extract is astringent and decreases sweating (16, 17).

A study on patients varying in type of skin infections,

Table 1. Demographic Characteristics of the Study Groups Before the Intervention^a

Parameters	Henna (n = 41)	Hydrocortisone (n = 41)	P Value
Pregnancy age, months	8.91	8.85	0.365
Infant age, days	70.53	46.43	0.636
Gender			0.269
Male	23 (56.1)	24 (58.5)	
Female	18 (43.9)	17 (41.5)	
Medical history			0.201
Yes	1 (2.4)	5 (12.2)	
No	40 (97.6)	36 (87.8)	
Drug history for diaper rash			0.244
Yes	11 (26.8)	17 (41.5)	
No	30 (73.2)	24 (58.5)	
Type of diaper			> 0.9999
Disposable nappies	32 (78)	31 (75.6)	
Reusable	9 (22)	10 (24.4)	
Washing baby after each diaper change			> 0.9999
Yes	40 (97.6)	40 (97.6)	
No	1 (2.4)	1 (2.4)	
Using hygienic cleaning components			> 0.9999
Yes	15 (36.6)	14 (34.1)	
No	26 (63.4)	27 (65.9)	
History of prescribed drugs' side effects			0.675
Yes	2 (4.9)	4 (9.8)	
No	39 (95.1)	37 (90.2)	
History of urgent extra visit			0.675
Yes	2 (4.9)	4 (9.8)	
No	39 (95.1)	37 (90.2)	
History of alternative therapeutic extra activity			> 0.9999
Yes	2 (4.9)	5 (12.2)	
No	39 (95.1)	36 (87.8)	
Complementary nutrition			0.756
Yes	7 (17.1)	5 (12.2)	
No	34 (82.9)	36 (87.8)	

^aValues are expressed as No. (%) unless otherwise indicated.

Table 2. Rate of DD Improvement in the Study Groups

	Number of cases	Mean intensity of DD on Day 1	Mean intensity of DD on Day 3	Mean intensity of DD on Day 5	P Value
Henna	41	3.20	1.39	1.20	< 0.001
Hydrocortisone	41	3.20	2.05	1.90	< 0.001

Table 3. Rate of Improvement Between Groups on the First, Third, and Fifth Day of Treatment^{a,b}

Rate of healing	First day		Third day		Fifth day	
	Henna (n = 41)	Hydrocortison (n = 41)	Hydrocortiso (n = 41)	Henna (n = 41)	Henna (n = 41)	Hydrocortisone (n = 41)
Without erythema	0	0	21 (51.2)	31 (75.6)	37 (90.2)	25 (61)
Slight erythema	3 (7.3)	2 (4.9)	4 (9.8)	5 (12.2)	1 (2.4)	2 (4.9)
Marked erythema	28 (68.3)	30 (73.2)	10 (24.4)	4 (9.8)	2 (4.9)	8 (19.5)
Severe erythema Without infiltration	9 (22)	8 (19.5)	5 (12.2)	1 (2.4)	1 (2.4)	5 (12.2)
Severe erythema with infiltration	1 (2.4)	1 (2.4)	1 (2.4)	0	0	1 (2.4)
Severe erythema with infiltration and vesicles or epidermal complications	0	0	0	0	0	0
P Value	0.955		0.082		0.042	

^aValues are expressed as No. (%).

^bNo significant side effects were observed in both the groups.

who were referred to the dermatology clinic of a public hospital in Basra, was conducted to examine the anti-bacterial effects of water, ethanol, and oil extracts of *Lawsonia inermis* leaves against bacterial strains isolated from different diseases of the skin, and antibiotics such as tetracycline, ampicillin, gentamicin, and ciprofloxacin were compared. The study results suggested a favorable effect of henna on studied bacterial strains (27).

In another double-blind randomized clinical study aimed at comparing the effectiveness of alpha topical ointment (containing a natural henna extract) with hydrocortisone 1% cream on the recovery of radiation-induced dermatitis in breast cancer patients, it was found that the alpha topical ointment was more effective than topical hydrocortisone 1% cream in alleviating radiation-induced dermatitis (28).

Henna is an inexpensive natural plant agent with anti-inflammatory, antipyretic, and analgesic effects. It also plays an antioxidant and immune-modulatory role and lacks the potential acute and late adverse effects of corticosteroids. There is some evidence supporting the safety and efficacy of natural henna in wound healing (28). Another noteworthy point is the safety of this herbal product in common and recommended uses, as evident in this study where we did not observe any side effect. The lack of co-operation and consent of patients for study participation is a limitation of the study. Further research on the comparison of this natural product with other available products is recommended.

In summary, DD is a common skin condition that affects infants, including newborns. Diaper occlusion cre-

ates an environment conducive to skin irritation, beginning with damage to the skin barrier caused by components of urine and feces. Supporting the skin barrier with appropriate creams coupled with frequent diaper changes is an effective preventive strategy.

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Footnote

Authors' Contribution: Abdollah Keshavarz, Ali Akbar Zeinaloo, Manoochehr Mahram, Navid Mohammadi, Omid Sadeghpour, Mohammad Reza Maleki contributed to study design; Navid Mohammadi contributed to data analysis and interpretation. All the authors contributed to data acquisition and writing of the preliminary draft of the manuscript.

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