



## **Efficacy of Hydrocortisone Alone and its Combination Therapy with Rainwater for the Treatment of Atopic Dermatitis**

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### **ABSTRACT**

Atopic dermatitis (AD) is a common skin disease in children, a chronic, pruritic inflammatory skin disease that usually starts in early infancy. But also affects many adults. It follows a relapsing course, that adversely affects the quality of life of patients and their families. This study was carried out to evaluate and compare the efficacy of hydrocortisone alone and its combination therapy with rainwater for the treatment of atopic dermatitis. This prospective, comparable study was carried out in the dermatological department of Baqubah teaching hospital, outpatient clinic. A total of 120 patients of (1-12 years) old attending outpatient clinic and diagnosed by dermatological specialist as cases of moderate to severe atopic dermatitis from October 2016 to January 2107 were selected and randomized into two groups of 60 patients of each group, Group -A treated with combination therapy of hydrocortisone with rainwater and Group-B treated with hydrocortisone alone for 8 weeks. Patients were assessed for severity according to the SCORing Atopic Dermatitis (SCORAD) Index. Subsequent examination at weekly interval was used to evaluate the efficacy of the treatment for 8 weeks. A *p*-value lower than 0.05 was considered statistically significant. A total of 117 patients were completed the study period of 8 weeks (group -A,59 and Group-B,58). A statistically significant difference was observed in the family history of atopic dermatitis among both groups. Significant response was observed at the end of 8 weeks of treatment, in Group-A (96.61%), while in Group-B (87.93%), according to the clinical assessment grades of atopic dermatitis, and during the follow up, a statistically significant decrease in SCORing Atopic Dermatitis (SCORAD) in comparison of the two groups. Group -A was found to respond significantly better in term of mean percentage decrease in SCORAD as compared with Group-B during the whole study period (*P* value <0.001) at each follow up. From a medical as well as an economical viewpoint, hydrocortisone combination therapy with rainwater as lotion was safe and highly acceptable to patients and cheap. A good alternative in case a child was unresponsive or intolerable to hydrocortisone and for the treatment of intertiginous areas.

**Keywords:** Atopic dermatitis, Hydrocortisone, Rainwater, SCORAD

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## INTRODUCTION

Atopic dermatitis (AD) is a common, highly pruritic chronic inflammatory skin disorder in children, which is often associated with other atopic diseases such as asthma and allergic rhinitis<sup>1</sup>.

Atopic dermatitis can have a considerable impact on the quality of life of patients and their families, It is a chronic disease, with periods of remission and flare-ups, that adversely affects the quality of life of patients and their families<sup>2</sup>.

Numerous environmental factors have been associated with atopic dermatitis: exposure to allergens, irritants, bacteria, and hard water; socioeconomic status; and large family size<sup>3</sup>.

Atopic dermatitis is the most common childhood skin disorder in developed countries, affecting 15%–20% of young children. It represents a complex interaction between susceptibility genes, immunological and neuroendocrine factors, skin barrier properties, and the environment. Most affected infants outgrow the condition by early childhood, but the course may be prolonged in those with early onset, severe, widespread disease, concomitant asthma or hay fever, and family history of AD. Atopic dermatitis has a significant impact on well-being and quality of life for the whole family not just the patient. Topical treatment forms the mainstay of treatment for most of the patients<sup>4</sup>.

It is important to determine the severity of atopic dermatitis for evaluation of disease improvement after and during therapy. Scoring of the severity of AD is demanded in clinical trials. The European Task Force on Atopic Dermatitis (ETFAD) has developed the SCORAD (Scoring AD) index to create a consensus on assessment methods for AD, so that study results of different trials can be compared<sup>5</sup>.

Patients generally underestimate the appropriate quantity of topical corticosteroids and emollients needed for long-term therapy. Topical corticosteroids are the mainstay of treatment for flare-ups and are the standard to which other treatments are compared<sup>6</sup>.

Preventing flare-ups with good skin-care practices is an important part of the overall treatment of atopic dermatitis. Dry skin is a feature in nearly all patients with the condition. Emollients are the mainstay of maintenance therapy for atopic dermatitis<sup>7</sup>.

A daily bath or shower removes scale, crust, irritants, and allergens and provides an opportunity to moisturize the skin. Water should be lukewarm, and 20 min immersion is adequate. Emollients are the main treatment for all grades of atopic dermatitis. The normally elastic and protective skin barrier is impaired in AD and emollients combat xerosis and transepidermal

water loss. Emollients are available in various formulations. Lotions are thin with a high water content and are useful for hairy areas and weeping eczema but ineffective for severe xerosis. Gels are similar to lotions, with high water content. Creams (emulsions of water and oil) are most popular. Patients should be encouraged to try different emollients, as well as being advised about the best type for their skin condition, climatic conditions, and lifestyle<sup>8</sup>.

The evidence is well established for topical corticosteroids (TCS), which remain first-line anti-inflammatory therapy for active atopic eczema despite their well-known adverse effects. Selecting the right TCS for a particular patient requires skill. Patient factors must be considered, such as age, body site, and severity of atopic eczema. Available guidelines on steroid usage advise different potencies according to severity, body site, and age. With regards to frequency, TCS should be used once or twice daily. There is no evidence for higher efficacy with application more than twice daily<sup>9</sup>.

“Wet wrap therapy” requires two layers: An inner layer which has been soaked in lukewarm water and wrung out, covered by a dry layer. Traditionally, this was used over a steroid and emollient cream applied all over, probably resulting in some systemic absorption of steroid. Wet wraps are now more commonly used over standard treatment with TCS applied to active eczema and emollient all over. Wet wrapping is sometimes helpful for an intractably itchy, insomniac child, but care must be taken to avoid chilling the child, exacerbating infection, and over-treating with steroid, since absorption is enhanced through moist occluded skin<sup>10</sup>.

Water is necessary and fundamental to life. Water is a molecular substance that has unique chemical and physical properties related to functions in the human body<sup>11</sup>.

Some patients with AD have various concepts or questions of using various type of water for bathing or skin cleansing. In underdeveloped or developing countries, some patients are afraid of contamination in tap water or underground water. They sometimes use bottled water, rainwater, normal saline, or even distilled water for their facial cleansing<sup>12</sup>.

### **Aims**

This study was carried out to evaluate and compare the efficacy of hydrocortisone alone and its combination therapy with rainwater for the treatment of atopic dermatitis.

### **MATERIALS AND METHOD**

This prospective, comparable study was carried out in the dermatological department of Baqubah teaching hospital, outpatient clinic. A total of 120 patients of (1-12 years) old attending outpatient clinic and diagnosed by dermatological specialist as cases of moderate to severe atopic

dermatitis from October 2016 to January 2107 were selected and randomized into two groups of 60 patients of each group (Group -A treated with combination therapy of hydrocortisone with rainwater and Group-B treated with hydrocortisone alone for 8 weeks.

**Group-A**, treated with combination therapy of hydrocortisone with rainwater two times daily (as 2.5% hydrocortisone lotion) two times daily.

**Group-B**, treated with hydrocortisone alone two times daily.

A written consent for participation in the study was taken from the parents. The patient records were studied to compile the clinical and diagnostic data including a detailed history, family history, sex, age of onset, type of skin, severity of the disease, dermatological examination of the lesions which include scalp, cheeks and forehead, flexor surfaces of the limbs, the popliteal and antecubital regions, wrists, ankles, hands and feet, according to SCORing Atopic Dermatitis (SCORAD) Index (erythema, edema/papulation, oozing/crusts, excoriations, lichenification, dryness).

Each item should be graded 0-5 (0=absent; 1=Almost clear; 2=mild; 3=moderate; 4=severe; 5=Very severe disease).

#### **Clinical assessment grades of Atopic Dermatitis**

<b><u>Score</u></b>	<b><u>Description</u></b>
0=Clear	No inflammatory signs of AD
1=Almost clear	Just perceptible erythema, and just perceptible papulation/infiltration
2=Mild disease	Mild erythema and mild papulation/infiltration
3=Moderate disease	Moderate erythema and moderate papulation/infiltration
4=Severe disease	Severe erythema and severe papulation/infiltration
5=Very severe disease	<u>Severe erythema and severe papulation/infiltration with oozing/crusting</u>

#### **Periodic assessment**

Subsequent examination at weekly interval was used to evaluate the efficacy of the two treatments for 8 weeks. On each follow up at weekly intervals visit, the response and prognosis of lesions for clinical assessment grades of atopic dermatitis of the two groups were recorded according to the Scoring Atopic Dermatitis (SCORAD) Index. The results of Group-A and B were analysed and compered for the improvement at the end of each week for 8 weeks.

Harvesting of Rainwater and preparing of Hydrocortisone rainwater lotion

Rainwater from rooftop should be carried through down take water pipes or drains to storage/harvesting system. Water from sloping could be caught through gutters and down take pipe. The first shower of rains need to be flushed-off to avoid contaminants of the atmosphere and the catchment roof. The rainwater harvesting after the first rain and put in large pottery

containers. The preparation of 2.5% Hydrocortisone lotion, by dissolving 2.5 g of hydrocortisone in 60 ml of rainwater and put in small pottery containers to be used by the patients .

Statistical analyses

Statistical analyses using computer software and the data analyzed by using SPSS version 20. All findings were analyzed by using student's *t*- test and Chi Square test. A *p*-value lower than 0.05 was considered statistically significant.

## RESULTS AND DISCUSSIONS

Out of 120 patients, three patients were lost to follow up during the study period. The final result analysis, there were 117 patients (group –A,59 and Group-B, 58). No statistically difference was observed in age, sex, and disease characteristics between the two groups. A statistically significant difference was observed in the family history of atopic dermatitis among both groups (Table1).

According to the clinical assessment grades of atopic dermatitis, and during the follow up, a statistically significant decrease in SCORing AD (SCORAD) in comparison of the two groups. Group –A was found to respond significantly better in term of mean percentage decrease in SCORAD as compared with Group-B during the whole study period (*P* value <0.001)at each follow up (Table 2).

Table 3 shows that Significant clinical response was observed at the end of 8 weeks of treatment, in Group-A fifty seven patients (96.61%), while in Group-B fifty one patients (87.93%). In group-A, 22 show excellent response, 25 showed good response, 10 showed fair response, 2 showed poor response. In Group=B, 12 showed excellent response, 20 good response, 19 showed fair response, 7 showed poor response (Table 3).

**Table 1: Demographic profile and groups characteristics**

Patients characteristics		Total (n=117)	Group-A (n=59)	Group-B (n=58)	<i>P</i> value
Gender	male	95	49	45	0.467
	Female	22	10	12	
Age	1-4 yrs	75	39	36	0.686
	5-8 yrs	40	18	20	
	9-12 yrs	2	2	2	
Severity	Moderate	59	30	30	0.990
	Severe	58	29	28	
Type of skin	dry	94	49	45	0.457
	Oily	19	9	10	
	Normal	4	1	3	
Family History	Present	59	35	45	0.013
	Absent	58	24	13	

**Table 2: Mean percentage decrease in SCORAD at deferent times intervals in both Groups**

<b>Weeks of treatments</b>	<b>Group A(n=59) (%)</b>	<b>Group B(n=58) (%)</b>	<b>P value</b>
1	14.30	5.99	<0.001
2	24.73	14.87	<0.001
3	32.64	23.74	<0.001
4	38.52	29.99	<0.001
5	24.80	35.83	<0.001
6	46.75	43.65	<0.001
7	47.96	45.69	<0.001
8	48.48	46.89	<0.001

**Table 3: Clinical response to treatment in Group-A and Group-B at 8 weeks of treatment**

<b>Clinical response to treatment</b>	<b>Group-A(n=59)</b>	<b>Group-B(n=58)</b>
Excellent	22 (37.29%)	12 (20.69%)
Good	25 (42.37%)	20 (34.48%)
Fair	10 (16.95)	19 (32.76%)
Poor	2 (3.39%)	7 (12.07%)

No study was found that directly compares hydrocortisone alone with its combination therapy with rainwater in the treatment of pediatric patients with atopic dermatitis. Hydrocortisone combination therapy with rainwater was safe and highly acceptable to patients.

Rainwater is good for washing the skin because it is a soft, pure water that is neutral in pH, free from disinfection by-products, salts, minerals and other unnatural materials.

## CONCLUSION

From a medical as well as an economical viewpoint, hydrocortisone combination therapy with rainwater as lotion was safe and highly acceptable to patients and cheap. A good alternative in case a child was unresponsive or intolerable to hydrocortisone and for the treatment of intertriginous areas.

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