ORIGINAL ARTICLE

Efficacy of 2% Coal Tar in Petroleum Jelly Over Plain Petroleum Jelly (Emollient) in The Treatment of Atopic Dermatitis in Pediatric Population

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ABSTRACT

Objective: The study was performed to evaluate the efficacy of topical 2% coal tar in petroleum jelly as compared to plain petroleum jelly (Emollient) in the management of mild to moderate atopic dermatitis in children 1 to 16 years of age.

Study Design: Quasi-experimental study design.

Place and Duration of Study: The study was carried out at the Department of Dermatology, Capital Hospital Islamabad, Pakistan over a period of six months, from January 2023 to July 2023.

Methods: A total of 68 patients, 34 in each group who fulfilled the inclusion criteria were enrolled in this study. Group- A received topical 2% coal tar in petroleum jelly while Group B was only administered plain petroleum jelly, twice daily for 12 weeks. The response was recorded using the eczema area severity index (EASI) and then analyzed using Statistical Package for the Social Sciences version 20.

Results: The mean age and the duration of disease in Group-A was 6.8±4.8 years & 27.9±28.0 months respectively, while it was 4.9±3.7 years & 20.9±18.2 months in Group-B. Males were predominant in Group-B n= 21 (61.8%), while males and females were equal in Group-A n=17 (50%). Final analysis at 12 weeks comparing the EASI revealed that treatment of Group-A (52.9%) was more effective than Group-B (17.7%). The difference being statistically significant (*P*=0.002).

Conclusion: Topical 2% coal tar in petroleum jelly was more effective than petroleum jelly alone in treating mild to moderate AD in the pediatric population.

Keywords: *Atopic Dermatitis, Coal Tar, Petroleum Jelly*.

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Introduction

Atopic dermatitis (AD) is a chronic pruritic relapsing inflammatory skin condition that often starts in early childhood. Globally it is the leading cause of skin disease burden with the prevalence of more than 200 million cases worldwide. A lifelong prevalence of 5-25% has been reported in different countries. The prevalence of AD is increasing worldwide; in Taiwan, this has increased from 2.4% to 4.0%. A similar trend has been seen in China, Japan, and South Korea. This is most often attributed to rapid urbanization and improved socioeconomic status.[1]

AD results from skin barrier dysfunction and defective immune response mediated by the lymphocytes. The disruption of the skin barrier results from altered differentiation of the epidermal keratinocytes, filaggrin (filament-aggregating protein) insufficiency, and impaired skin lipid production. Altered microbial colonization of atopic skin also plays a role. Both genetic and environmental factors are responsible for disease.

Patients of AD present with itching associated with a chronic rash. In the infantile phase the rash starts on

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the face and then involves the extensor aspects of elbows and knees when child begins to crawl. In the childhood phase, the rash typically involves the elbow and knee flexures presenting as redness, crusting, excoriation, hypo or hyperpigmentation and lichenification. Cold temperatures and low humidity exacerbate the disease. Fifty to 70% of AD children grow out of their disease by adolescence.[2]

AD has a profound effect on the quality of a patient's life. Severe itching is associated with exhaustion, sleep deprivation, anxiety, and depression. Thirty to 50% of patients with AD can develop asthma and allergic rhinitis later on. Secondary bacterial and viral infection of AD lesions causes exacerbation of the disease and worsening of symptoms. The diagnosis of atopic eczema is mainly based on history and clinical examination. The severity of atopic eczema is assessed using different scoring systems like Eczema Area and Severity Index (EASI) and Scoring Atopic Dermatitis (SCORAD).[3]

As AD is a chronic disease, a good management strategy is based on; consistent cooperation between the health career provider and the patient, accurate initial severity assessment, and recognizing the trigger factors. Treatment options include patient education, avoidance of trigger factors, regular use of emollients, oral anti-histamines, topical therapy including corticosteroids, calcineurin inhibitors, and phototherapy. Systemic therapy includes oral corticosteroids, immunomodulators, and biologics. Emollient plays a vital role in the treatment of AD in acute exacerbation as well as during periods of remission. In addition to reducing the need for steroids, they can also help certain populations in preventing the development of atopic dermatitis.[4]

As topical corticosteroids and calcineurin inhibitors are associated with long-term side effects including systemic absorption, therefore a nonsteroidal drug for pediatric disease modification is needed which is free of systemic side effects. Topical coal tar has been used for the treatment of atopic dermatitis and psoriasis for ages. Coal tar restores the skin barrier by inducing keratinocyte differentiation and reducing immune response. It also alters the microbial composition of the lesional AD microbiome shifting towards that of healthy skin.[5]

Van der Valk et al. conducted a study in the Netherlands in 1996 in which topical application of crude coal tar was studied in patients with AD, significant improvement was observed with this application.[6] In 2019, Peppers et al. conducted a study with taping of (having a similar mechanism of action as that to coal tar - through AHR receptor) vs vehicle alone in patients with AD. This study showed that the treatment efficacy for taping of was 53% as compared to 24% for the vehicle alone.[7] Munkvad et al. also conducted a study to compare purified coal tar cream (Cliniiar) with 1% hydrocortisone cream. The result was that the treatment options were equally effective in reducing symptoms.[8]

All the above mentioned studies show promising results of coal tar for the treatment of AD. It is a cost effective, safe and easily available treatment modality for a wide spread disease with no significant systemic side effects. However, no such studies have been done so far in Pakistan regarding its efficacy on our population. Therefore, this study aims to compare the efficacy of coal tar vs. emollient in the management of atopic dermatitis in children in our local population.

Methods

This study was carried out at the Department of Dermatology, Capital Hospital Islamabad, Pakistan over a period of six months, from January 2023 to July 2023 after obtaining approval from the Research and Ethical Committee of the hospital on dated: 2nd January 2023 vide IRB approval no: 0404.

The sample size (n) was 68 patients (34 patients in each group). Level of significance 10%, power of the test 80%, anticipated population 53%, and 24%.[7] Non-probability sampling with purposive sampling was used as the sampling technique.

Inclusion Criteria: Children with AD in the age range 1-16 years (according to criteria of Hanfin & Rajka), having mild to moderate AD determined by EASI score and involved Body surface area less than 50% were included in the study.[9]

Exclusion Criteria: Patients were excluded from the study if they had any secondary bacterial or viral infection at the time of presentation. Children with severe disease (as determined by EASI score), those having hypersensitivity to the ingredients of the preparation, those having any known

photosensitivity disorder, or patients on photosensitizing drugs were not included in the present study. Also, those who had used topical steroids, systemic steroids, or topical tacrolimus in the last 4 weeks or had any co-morbidities like genetic syndromes, congenital anomalies, or severe protein energy malnutrition were excluded from the study.

Data Collection Procedure

All patients of AD between the ages of 1 to 16 years presenting in dermatology OPD, Capital Hospital Islamabad diagnosed based on history and clinical examination, fulfilling the inclusion criteria were enrolled in the study.

Informed written consent was taken from the parents. Demographic data like age, gender, address, and education was noted. The baseline EASI score was calculated and photographs were taken.

Patients were allocated randomly in 2 groups A and B by lottery method. Group A received topical 2% coal tar in petroleum jelly twice daily and Group B received emollient (plain petroleum jelly) twice daily for 12 weeks. Patients in both groups were advised to keep the application for at least 4 hours and avoid sun exposure for 6 hours between 1000-1600 hours.

Both groups were given syrup cetrizine (single daily dose of 0.25mg/kg of oral cetrizine solution with a maximum dose of 2.5 mg twice daily for children less than 2 years) and glycerine soap as supportive treatment.

Patients were followed up in OPD at 2 weekly intervals for evaluation. At each follow-up visit EASI score was calculated, and pictures were taken. All the detailed information was recorded in a specially designed proforma (Appendix–A). The final improvement was calculated by the comparison of EASI Score at the presentation and EASI Score at the end of 12 weeks of treatment.

Data Analysis

The efficacy of both treatments was noted at the end of 12 weeks of treatment. The results were grouped into 'poor response' as being <30% response from the start of treatment, 'partial response' as 30–60% healing from baseline, 'good response' as 60–90% improvement from the baseline while 'excellent' response was for >90% reduction of the disease. Excellent response was considered as the treatment being efficacious. The statistical analysis was performed using IBM-SPSS V20. Frequencies and percentages were calculated for categorical variables like gender, family history of atopy, and efficacy. Mean and standard deviation were calculated for continuous variables like the age of the patients, and duration of the disease. The *chi-square* test was used to compare the efficacy of treatment modalities in both groups (P value of < 0.05 was considered as significant). Stratification of data with respect to age, gender and duration of disease was done to see their effect on treatment efficacy. Post-stratification chi-square test for both groups was also applied (P value of ≤ 0.05 was considered as significant).

Results

A total of 68 patients (34 in each group) were enrolled in the current study. Patients ranged between 1-16 years of age. In group-A, a mean age of the patients was 6.8+4.8 years, and in Group-B 4.9+3.7 years. Males were predominant in Group-B (61.8%). The comparison of other clinical parameters like family history of atopy and duration of disease are listed in table-1. There was a positive family history of atopy in 22 patients (64.7%) in Group-A, while it was positive in only 15 patients (44.1%) in Group-B. Patients in Group-A had the disease for a longer duration (>12 months), 21 patients (61.8%) in Group-A as compared to 15 patients (44.2%) in Group-B. (Table-1).

Comparing from the baseline EASI score, excellent response (>90% improvement in EASI) was noted in 18 patients (52.9%) in Group-A as compared to only 6 (17.7%) in Group-B. Good response (60-90% improvement in EASI) was noted in 7 patients (20.6%) in Group-A as compared to 5 patients (14.7%) in Group-B. A partial response (30-60% improvement in EASI) was present in 5 patients (14.7%) in Group-A as compared to 14 patients (41.1%) in Group-B. A poor response (<30% improvement in EASI) was present in only 4 patients (11.8%) in Group-A as compared to 9 patients (26.5%) in Group-B.

Comparison of efficacy at the end of treatment by taking excellent treatment response as an indicator, Group-A was more efficacious as compared to Group-B with 18 patients having excellent response

Table-1: Comparison of demographics, clinical parameters and efficacy of treatment

Characteristics		Group-A (Topical 2% Coal Tar) n (%)	Group-B (Petroleum Jelly) n (%)
Age	1-5 years	17 (50%)	22 (64.7%)
	6-10 years	08 (23.5%)	07 (20.6%)
	11-16 years	09 (26.5%)	05 (14.7%)
	Mean+ SD	6.8+ 4.8	4.9 + 3.7
Gender	Male	17 (50%)	21 (61.8%)
	Female	17 (50%)	13 (38.2%)
Family History of Atopy	Yes	22 (64.7%)	15 (44.1%)
	No	12 (35.3%)	19 (55.9%)
Duration of Disease*	<12	13 (38.2%)	19 (55.8%)
	>12	21 (61.8%)	15 (44.2%)
	Mean + SD	27.9 + 28	20.9 + 18.2
Distribution of Efficacy	Excellent	18 (52.9%)	06 (17.7%)
	Good	07 (20.6%)	05 (14.7%)
	Partial	05 (14.7%)	14 (41.1%)
	Poor	04 (11.8%)	09 (26.5%)
Efficacy	>90%EASI ** improvement	18 (52.9%)	6 (17.7%)
	<90%EASI improvement	16 (47.1%)	28 (82.3%)
Chi-square	9.273		
P value	0.002		

**Months, **EASI= eczema area severity index*

to treatment in Group-A as compared to only 6 patients (52.9% vs 17.7%) in Group-B. The difference between the two groups was statistically significant. (*P*=0.002) (Table-1). Further stratification based on age, gender and duration of disease was also carried out. (Table-2). This subsequent analysis was done by using a two by two table and applying chi-square test with a 95% confidence interval taking the *P* value (2-tail) < 0.05 as significant. The analysis revealed that although Group-A showed higher efficacy as compared to Group-B across all age groups, genders and for any duration of disease, this was only statistically significant for age group 6-10 years (*P*=0.019), female subgroup (*P*=0.024) and disease duration < 12 months (*P*=0.007).

Discussion

Atopic dermatitis (AD) is the most common inflammatory skin condition in childhood and is now becoming one of the major health concerns in developing countries.[10] This chronic inflammatory disease leads to morbidity and a lot of psychological stress among the children and their parents. The prevalence of the disease is affected by many factors including socioeconomic status, diet, environmental allergens, genetics, and access to healthcare.[11] Silverberg JI et al in a global survey involving eighteen countries during 2021 found out that a substantial proportion of the pediatric population (as high as 41.9%) had atopic dermatitis.[12]

A study in India involving 174 patients to estimate the frequency of minor diagnostic criteria among AD children showed that the mean age of enrolled patients was 4.6+ 3.9 years, while another study showed the mean age to be 4.94.[13,14] Majeed A. et al. in his study on the dermatological conditions among children in Pakistan found out that mean age of presentation among children of atopic dermatitis was 5.7±4.1 years very much comparable to our study (6.8+4.8 years vs Group-B- 4.9+3.7 years).[15]

Our study had a male predominance of 55.9%

Table-2: Stratification of demographic and baseline characteristics

Characteristics	Group	Efficacy		n	*Chi-square*	*P*-value (2 tail)
		Yes	No			
Age						
	A	9	8	17		
1-5 years	B	5	17	22	3.804	0.051
	n	14	25	39		
	A	6	2	8		
6-10 years	B	1	6	7	5.529	0.019
	n	7	8	15		
	A	3	6	9		
11-16 years	B	0	5	5	2.121	0.145
	n	3	11	14		
Gender						
	A	7	10	17		
Male	B	3	18	21	3.503	0.061
	n	10	28	38		
	A	11	6	17		
Female	B	3	10	13	5.129	0.024
	n	14	16	30		
Duration of Disease						
	A	8	5	13		
< 12 years	B	3	16	19	7.161	0.007
	n	11	21	32		
	A	10	11	21		
>12 years	B	3	12	15	2.893	0.089
	n	13	23	36		

(38/68). Indeed, a review of the literature concurs with this finding. Simpson EL et al in a randomized clinical trial on moderate to severe atopic dermatitis noted similar findings among the patients of AD (59% male patients).[16] Same was observed in another study done by Dutta A et al. where the male population was 51%.[11] Although data from large-scale prevalence studies is lacking for Pakistan, it has been noted in a recent survey by Saleem et al. that an overall male predominance (56.5%) exists in children with atopic dermatitis.[17]

Treatment of AD is important not only just for symptom relief but also to prevent further health issues thus improving the long-term quality of life. Various treatment options including steroids and steroid spearing agents, immunomodulators, and immunosuppressants are available but not without side effects. Emollients by improving the epidermal barrier do help in reducing the symptoms of AD and prevent the environmental stressors that cause TH2 sensitization.[18] Indeed, Simpson EL et al. in their study on early moisturization for effective treatment of atopic dermatitis found a decrease in the cumulative incidence of AD, with a relative risk reduction of 50%.[19] However, the BEEP randomized control trial, one of the largest trials for evaluating the role of emollients in atopic dermatitis showed no effect of emollients alone in the treatment of atopic dermatitis.[20]

Coal tar is an inexpensive, readily available, and viable treatment option for the treatment of AD in children. In our study, 2% Coal tar in petroleum jelly was found to be more efficacious as compared to plain petroleum jelly. The findings of current study are consistent with a study carried out by Peppers et al. they demonstrated 53% efficacy for tapinarof as compared with, 24% for the emollient alone.[7] Van der Valk et al. also reported comparable results while working with crude coal tar where he noted an average decrease in Costa score of 35.0 ± 10.9 after 3.7 ± 1.0 weeks of treatment.[6] Munkvad et al. reported, while doing a slit body comparison using

purified coal tar cream and 1% hydrocortisone cream, that both treatments were equally effective.[8] Van den Bogaard EH et al. in their study on the effect of coal tar in atopic dermatitis found out that coal tar among other mechanisms, induces AHR-dependent skin barrier repair in atopic dermatitis.[21] Similarly Smith SH et al. in the study with tapiranof found out that, it improved atopic dermatitis in a similar way as to coal tar, by acting on the AHR receptor.[22]

Roelofzen JH et al. while comparing the efficacy and safety of coal tar with corticosteroids found it not only to be beneficial but also without significant side effects.[23] Dennis M et al. showed outstanding efficacy with 44/55 (80%) of patients achieving at least 90% clearance of clinical signs and symptoms of the disease while being treated with coal tar.[24]

Potential strengths of the study are represented by the clinical criteria-based AD diagnosis performed by dermatologists with experience in pediatric dermatology and the improvement assessed by physicians using a valid scoring system and not self-reported by the patients. Possible limitations of this study are represented by the small sample size and study design (single center). Variables like environmental factors, exposure to allergens, and diet were not evaluated and may lead to poor disease control.

Further larger, multi-centric studies are needed to establish concrete evidence of coal tar as a better treatment choice in selected patients.

Conclusion

To the best of our knowledge, this is the first study to assess the efficacy of 2% coal tar in petroleum jelly over plain petroleum jelly (emollient) for the treatment of atopic dermatitis in the pediatric population in Pakistan. In our study population, we identified that topical 2% coal tar in petroleum jelly for the treatment of pediatric atopic dermatitis is very effective.

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Conflict of Interest: The author declares no conflict of interest.

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Authors Contribution

ME: Idea conception, study designing, data analysis, results and interpretation, manuscript writing and proofreading
UA: Idea conception, study designing, data collection, manuscript writing and proofreading
WJ: Idea conception, study designing, data collection
TMS: Idea conception, data analysis, results and interpretation, manuscript writing and proofreading
HN: Data analysis, results and interpretation, manuscript writing and proofreading