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Effectiveness of calamine lotion as an adjunctive therapy to mometasone furoate ointment in the treatment of infant eczema

A retrospective study

Yuan-Cui Meng, MM[a], Jin-Chao Fan, MB[b], Wei-Ni Bian, MB[a,*]

Abstract

This retrospective study investigated the effectiveness of calamine lotion (CL) as an adjunctive therapy to mometasone furoate ointment (MFO) in the treatment of infant eczema (IE).

This retrospective study analyzed the electronic medical records of 50 IE infants. They were allocated to a treatment group or a control group, with 25 subjects in each group. All infants in both groups received MFO. In addition, infants in the treatment group underwent CL. The outcomes were effectiveness based on the eczema area and severity index, lesion area, and pruritus severity. We analyzed the outcomes before and after treatment.

The results of this study showed that infants in the treatment group had more effective in effectiveness based on eczema area and severity index ($P < .01$), lesion area ($P < .01$), and pruritus severity ($P = .01$) than those in the control group. However, no medical records reported any adverse events in either group.

The results of this study showed that CL added to MFO was more effective than MFO alone in the treatment of infants with IE.

Abbreviations: CL = calamine lotion, EASI = eczema are and severity index, IE = infant eczema, MFO = mometasone furoate ointment.

Keywords: calamine lotion, eczema, effectiveness, mometasone furoate ointment

1. Introduction

Eczema is one of the most common and chronic skin disorders and manifests as inflamed, itchy, dry, and oozing skin.[1–4] It often occurs in early infancy and is present on the cheeks, forehead, face, arms, legs, or even the entire body.[5–7] Several risk factors are responsible for these disorder.[8–10] Although it is greatly influenced by genetic factors and environmental exposure, its pathogenesis is still not fully understood.[8–11] Study reported that its prevalence has increased around the world.[12–14] If such condition can not be treated fairly well, they may result in food allergies, wheezing, asthma, allergic rhinitis, and psychological and behavioral disorders.[10,15–19]

Mometasone furoate ointment (MFO) is a hormone that is absorbed little or can be quickly catabolized into an inactive degradation product after being absorbed in the skin. However, it retains a high degree of activity in the local areas. Thus, it can greatly improve the clinical efficacy and reduce adverse reactions by inhibiting its effects on the hypothalamic-pituitary-adrenal axis. Therefore, it is often used to treat eczema in infants, children, and the elderly. Calamine lotion (CL) mainly consists of calamine, zinc oxide and glycerin. It has astringent, antipruritic, antiseptic, hemostatic, antibacterial, moisturizing, and protective effects. Thus, it is used for to manage skin exudation, rashes, and itching.

Various studies have reported that MFO can effectively manage infant eczema (IE).[20–24] However, some infants still experience unsatisfactory outcomes. Fortunately, CL is reported to manage eczema very well.[25–29] However, there is limited evidence regarding the comparison between CL plus MFO and MFO alone for IE treatment. Therefore, this retrospective study investigated the effectiveness of CL in combination with MFO for the treatment of IE.

2. Methods

2.1. Ethical statement

Ethical approval for this retrospective study was waived because the study was conducted based on electronic medical records.

2.2. Study design

Fifty electronic medical records of IE infants were included in this study. Of these, 25 records were allocated to the treatment

The authors have no conflicts of interest to disclose.

The datasets generated during and/or analyzed during the current study are available from the corresponding author on reasonable request.

[a] Department of Neonatology, The Second Affiliated Hospital of Xi'an Medical University, Xi'an, China, [b] Department of Medical Imaging, The Second Affiliated Hospital of Xi'an Medical University, Xi'an, China.

**Correspondence: Wei-Ni Bian, Department of Neonatology, The Second Affiliated Hospital of Xi'an Medical University, No. 167, East Street of Fangzhicheng, Dongjiao District, Xi'an, Shaanxi 710038, China (e-mail: tislas8@21cn.com).*

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group (administered MFO and CL), and the other 25 were assigned to the control group (administered CL). They were allocated to different groups according to the different managements administered. All the infants were admitted to the Second Affiliated Hospital of Xi'an Medical University between January 2019 and December 2021. Written informed consent was obtained from all case records.

2.3. Study population

This study retrospectively collected medical records of infants (≤24 months old) with eczema. Eczema was diagnosed in accordance with the Diagnostic Standard of Western Medicine for Infantile Eczema.[30] The exclusion criteria were as follows: age > 24 months; infants with severe eczema or who had been treated with topical glucocorticoid therapy; infants with local bacterial, viral or fungal infections; combined with other skin diseases, such as seborrheic dermatitis and stasis dermatitis; severe diseases or mental disorders; allergy to the study medications; and incomplete medical case records.

2.4. Treatment approach

All the infants in both groups received 0.1% MOF (Shanghai Lingbaoya Pharmaceutical Co., Ltd., National Medicine Permission No. H19991418) was applied evenly to the affected area once daily for 2 weeks, as appropriate.[31] In addition, infants in the treatment group were administered CL (Changshu Xinghai Pharmaceutical Co., Ltd., National Medicine Permission No. 20060203). We shook it well before use and applied it to the affected area, 2 to 3 times daily for 2 weeks, as appropriate.

2.5. Outcome measurements

Effectiveness was assessed in accordance with the eczema area and severity index (EASI), lesion area, and pruritus severity. EASI was evaluated according to previously published studies.[32,33] The severity of systemic pruritus was evaluated according to the Guiding Principles for Clinical Research of New Chinese Materia Medica.[34] The pruritus severity was graded as follows[34]: score 0, normal, no itching; score 1, mild, mild itching, occasional scratching, did not affect sleep; score 2, moderate, paroxysmal itching, mild and severe at times, affected sleep; and score 3, severe, severe itching, severe scratching, affected sleep.

The standard curative effect was established according to the literature.[34] Effectiveness based on the criteria of EASI: cure, EASI reduction rate ≥ 90%; marked effect, 60% ≤ EASI reduction rate < 90%; effective, 30% ≤ EASI reduction rate < 60%; ineffective, EASI reduction rate < 30%, no obvious regression of skin lesions, and no alleviation or deterioration. Pruritus severity was graded as follows[32,33]: 0, no skin lesions after careful observation or can not be determined; 1, mild skin lesions, need careful observation to check; 2, moderate skin lesions, can be checked easily; and 3, severe skin lesions, very obvious to identify.

Adverse events were evaluated to assess safety. Possible adverse reactions and their severity, such as exacerbation of eczema and drug allergy were recorded.

2.6. Statistical analysis

All analyses were performed using the SPSS software (SPSS 17.0; IBM Corp., Armonk, NY). Student *t* test or Mann–Whitney *U* test was used to analyze continuous data according to the normal or non-normal distribution. The χ^2 test or Fisher exact test was used to analyze categorical data. All statistical tests were 2-sided. Statistically significance was set at $P < .05$.

3. Results

This retrospective study screened 120 medical records of infants with IE. We excluded 70 records due to incomplete medical records, age of infants over 2 years, and inappropriate comparisons. Finally, 50 infants who met the inclusion criteria were enrolled in the study. These records were allocated to the treatment group (n = 25) and control group (n = 25; Fig. 1).

The general characteristics of the 50 infants with eczema are presented in Table 1. We summarized and compared the age, sex, race, and duration of eczema between the 2 groups. No significant differences in general characteristics were found between the 2 groups (Table 1).

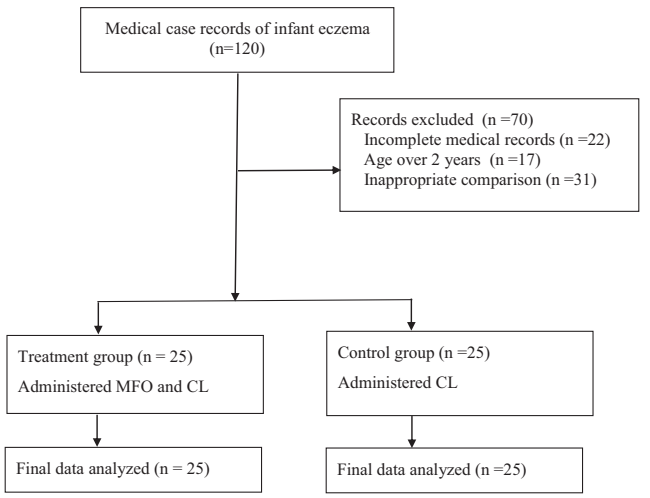

Figure 1. Flow chart of eligible infants enrolled in this study. CL = calamine lotion, MFO = mometasone furoate ointment.

Table 1

General characteristics of included infants.

Characteristics	Treatment group (n = 25)	Controlgroup (n = 25)	*P*
Age (mo)	12.2 (4.1)	11.9 (4.4)	.80
Gender			
Male	13 (52.0)	11 (44.0)	.57
Female	12 (48.0)	14 (56.0)	–
Race (ethnicity)			
Han	23 (92.0)	22 (88.0)	.64
Hui	2 (8.0)	3 (12.0)	–
Duration of eczema (d)	7.4 (3.3)	7.1 (3.5)	.76

Data are present as mean ± standard deviation or number (%).

Table 2

Effectiveness was assessed based on EASI.

Groups	Cure	Marked effect	Effective	Ineffective	*P*
Treatment group (n = 25)	6 (24.0)	7 (28.0)	8 (32.0)	4 (16.0)	<.01
Control group (n = 25)	14 (56.0)	11 (44.0)	0 (0)	0 (0)	

Data are present as number (%).
EASI = eczema area and severity index.

Table 3

Comparison of lesion area between the 2 groups.

Lesion area (cm)	Treatment (n = 25)	Control group (n = 25)	*P*
Before treatment	3.8 (2.3)	3.6 (2.6)	.77
Aftertreatment	0.4 (0.5)	1.2 (1.4)	<.01
Change from treatment before	−3.4 (−4.3 to −2.0)	−2.4 (−3.3 to −1.5)	
Difference between 2 groups		−1.0 (−1.3 to −0.7)	<.01

Data are present as mean ± standard deviation (range).

Table 4

Comparison of pruritus severity between the 2 groups.

Lesion area (cm)	Treatment (n = 25)	Control group (n = 25)	*P*
Before treatment	2.0 (0.6)	2.2 (0.7)	.28
Aftertreatment	0.3 (0.5)	0.9 (1.1)	.01
Change from treatment before	−1.7 (−2.4 to −1.1)	−1.3 (−3.3 to −1.1)	
Difference between 2 groups		−0.4 (−0.6 to −0.2)	.01

Data are present as mean ± standard deviation (range).

The effectiveness based on the EASI is summarized and presented in Table 2. Significant differences were identified between the 2 groups ($P < .01$; Table 2). In the treatment group, 14 infants were cured, and 11 achieved a marked effect. In the control group, 6 infants were cured, 11 infants had a marked effect, 8 infants were effective, and 4 subjects were ineffective.

The lesion area results are shown in Table 3. There were no significant differences in the lesion area before treatment between the 2 groups ($P = .77$; Table 3). However, we identified significant differences in the lesion area between the 2 groups after treatment ($P < .01$; Table 3).

The severity of pruritusis is shown in Table 4. Before treatment, there were no significant differences in pruritus severity between the 2 groups ($P = .28$; Table 4). After treatment, there were significant differences in pruritus severity between the 2 groups ($P = .01$; Table 3).

In terms of safety, no electronic medical records reported treatment-related adverse events in either group.

4. Discussion

Eczema is one of the most common skin diseases among infants. They often affect the cheek, forehead, or limbs. Although studies have found that several risk factors are closely associated with IE, its pathogenesis has not been fully explained. Previous studies have reported that CL and MFO can be used to treat IE. However, there is limited evidence regarding the use of CL in combination with MFO for the treatment of IE. This study explored this issue.

CL is mainly composed of calamine, zinc oxide and glycerin. Study has reported that calamine exerts astringent, antipruritic, antiseptic, hemostatic, myogenic effect.[35] Zinc oxide has astringent, antibacterial, moisturizing, and protective effects.[36] Thus, CL shows promising effects for managing skin exudation, rashes, and itching. MFO is an adrenocortical hormone with anti-infective, anti-allergic, and immunosuppressive properties. The effects of MFO on the treamtents of infants with IE were enhanced by the addition of CL. Thus, the addition of CL to MFO can quickly and effectively relieve skin irritation and other symptoms in infants with IE.

This retrospective study analyzed 50 IE medical records. They were allocated to treatment and control groups according to the different treatments they received. This study investigated the effectiveness of EASI, lesion area, and pruritus severity. The results of this study showed significant differences in effectiveness based on EASI, lesion area, and pruritus severity between the 2 groups. This indicates that CL added to MFO is more effective than MFO alone for the treatment of infants with eczema. In addition, no medical records reported treatment-related adverse events in either of the groups. This indicates that both treatments are safe for infants with IE.

This retrospective study has the following limitations. First, the small sample size was small, which may have affected the results of this study. Second, data homogeneity could not be guaranteed because of the retrospective nature of the study. Third, the severity of IE in the selected population varied, which may not reflect the clinical characteristics of all infants with eczema. Fourth, this was a single-center study, and the findings may not be generalizable to all infants with eczema or severe eczema. Finally, this study did not apply randomization, allocation, and blinding procedures to the patients, researchers, and outcome assessors because it only collected data from completed medical records. This may have affected the selection, performance, and detection bias in this study.

5. Conclusion

This study showed that the addition of CL to MFO benefit infants with eczema more than MFO alone. Further studies with larger sample sizes are needed to validate the present findings.

Author contributions

Conceptualization: Yuan-Cui Meng, Wei-Ni Bian.
Data curation: Yuan-Cui Meng, Jin-Chao Fan, Wei-Ni Bian.
Formal analysis: Jin-Chao Fan, Wei-Ni Bian.
Investigation: Wei-Ni Bian.
Methodology: Yuan-Cui Meng, Wei-Ni Bian.
Project administration: Wei-Ni Bian.
Resources: Yuan-Cui Meng, Jin-Chao Fan, Wei-Ni Bian.
Software: Yuan-Cui Meng, Jin-Chao Fan.
Supervision: Wei-Ni Bian.
Validation: Yuan-Cui Meng, Jin-Chao Fan, Wei-Ni Bian.
Visualization: Yuan-Cui Meng, Jin-Chao Fan, Wei-Ni Bian.
Writing – original draft: Yuan-Cui Meng, Jin-Chao Fan, Wei-Ni Bian.

Writing – review & editing: Yuan-Cui Meng, Jin-Chao Fan, Wei-Ni Bian.

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