ARE 4% TOPICAL ALPHA HYDROXY ACID PREPARATIONS AS EFFECTIVE AS 0.25% TOPICAL HYDROCORTISONE PREPARATIONS IN REDUCING THE SIZE OF ATOPIC DERMATITIS SKIN LESIONS IN INFANTS UP TO AGE TWO?

By

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A clinical research proposal submitted in partial fulfillment of the requirements for the degree of

MASTER OF NURSING

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Intercollegiate Center for Nursing Education

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To the faculty of Whitworth College:

The members of the Committee appointed to examine the clinical research project of FRANCES DAILY COLLINS find it satisfactory and recommend that it be accepted.

Joan Thiele  
Chair

Barbara Johnston  

daynoground
Acknowledgments

I would like to express my appreciation to the faculty and members of my committee for nurturing the seeds of my curiosity, cultivating knowledge, pulling out the weeds, and helping ideas flower.
Are topical Alpha hydroxy acid preparations as effective as topical Hydrocortisone preparations in reducing the size of Atopic Dermatitis lesions in infants up to age two?

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Intercollegiate Center for Nursing Education
Chapter One

Introduction to the Problem

Atopic dermatitis (AD) is one of the most common skin conditions according to AAD Derminfo Net (World Wide Web, 1996) afflicting ten percent of infants and three percent of the U.S. population. It is a significant source of morbidity in children as well as adolescents (Hornung & Prose, 1992). In a sample of 1,104 English children ages three to eleven, mixed socially and ethnically, lifetime incidence of AD was twenty percent of males and nineteen percent of females” (Romeo 1994, p.157). There has been an increase in the number of cases of AD in the last thirty years (Ahavista, 1996; Hornung & Prose, 1992; John, 1996).

Standard treatment in the acute phase of AD includes the use of topical steroidal creams or ointments in varying strengths which correspond to the severity of the skin condition (Cohen, 1992). The aim of preventative treatment is to decrease the degree of skin dryness and thereby prevent exacerbations. Other treatments used are topical alpha hydroxy acids (in varying strengths), emollients, reducing or eliminating the causative allergen, the use of antibiotics for secondary infection, wet dressings, PUVA, UVA, tar applications, antihistamines and rarely, systemic steroids (Hay et al., 1995; Hornung & Prose, 1992; John, 1996; Romeo, 1994; Tierney et al., 1995). There are no comparative studies reported in the literature on the use of topical hydrocortisone creams and alpha hydroxy acids which may clarify effective treatment and relieve suffering.
Statement of the Problem

Although topical steroid use, alone or combined with other above mentioned modalities is the prevalent treatment regimen for AD, there are contradictory research studies verifying the safety of topical steroid use in infants and children. Farrington (1992) discussed the need for tapering products containing hydrocortisone as well as limiting use to one week, "to minimize the risk of systemic toxicity from absorption" (p.81). She also warned that "hydrocortisone at 0.5% strength is not indicated for use on infants less than two years of age" (p. 81). The strength of steroidal creams or lotions varies from mild potency (Group VII) to super high potency (Group 1) and each group contains from four to six generic kinds of steroidal preparations in varying strengths. The choice of steroidal preparation used for treatment is dependent upon clinician judgment about severity of the skin lesion, personal preference of drug, availability of drug, and whether there are other conditions complicating the treatment choice. For these reasons, it is difficult to state the usual strength of steroidal preparation used for infants to age two years. Farrington points out that topical steroid preparations do not alter the cause of AD, but only treat the inflammatory symptoms of the condition. Some important adverse side effects from use of steroid preparations include: 1) thinning of the skin, 2) hyper or hypo pigmentation of the steroid treated skin, 3) cutaneous absorption of topical steroids leading to systemic effects, such as adrenalcortical suppression, 4) striae, 5) atrophy of the treated skin 6) increased risk
of developing contact dermatitis (Clinical News, 1993), and 7) development of telangiectases (Hay et al., 1995; Tierney et al., 1995; John, 1996). Practitioners use steroids to treat the symptom of inflammation; these drugs do not always treat skin dryness, which is the cause of intense itching/inflammation cycle (Hay et al., 1995; John, 1996). The use of alpha hydroxy acids is only advocated by John,(1996) who practices in New Jersey. To my knowledge, no practitioners in the Spokane area are using alpha hydroxy acids in the treatment of AD. In order to most effectively and safely treat AD in infants and children, constant evaluation of treatment protocols must be studied and reported.

Statement of the Purpose

The purpose of this investigation is to compare the use of 4% topical alpha hydroxy acid preparations with 0.25% topical hydrocortisone preparations in reducing AD skin lesion size in infants up to the age of two years.

Theoretical Framework

Marit Kirkevold (1994) proposed a theory of caring for people with chronic skin disease, specifically those people with atopic dermatitis and those with psoriasis (PS). The following diagram shows the theory by demonstrating the relationships between disease manifestation of chronic skin disease and nursing care.
Biophysiological and psychosocial implications of skin disease are profound because skin is not only the largest, but a highly visible organ. Similarities between AD and PS include: 1) chronicity  2) consideration by health care professionals and the public as a cosmetic problem rather than a serious condition and 3) scarcity of literature dealing with how nurses may empower clients with AD to care for themselves. Kirkevold outlines the progression of AD as a recurring skin condition with exacerbations that require prevention. There is a strong relationship between the cutaneous flares and emotional stress. AD activity is unpredictable and at present uncontrollable. The cardinal symptom in AD is severe itching associated with dry skin. Because infants are unable to verbalize the sensation of itching, they express their discomfort by being fussy and irritable. Basic values of nursing reflected in Kirkevold’s
theory are “alleviating the client’s stress or burdens associated with the disease, and enabling the client to manage the disease and its impact” (p. 45). By determining the best therapy for alleviating the itch-inflammation cycle of AD, the client will obtain relief from the burdens and stress of the disease.

Review of the Literature

Romeo’s 1994 article on AD explains the historical derivation of the term atopic dermatitis from the term eczema which means “to boil over”, (p. 157). Eczema refers to the more acute, weeping dermatitis phase, while atopic dermatitis indicates a triad of conditions, (allergic rhinitis, asthma and AD) which have a genetic nature (Romeo, 1995). AD encompasses the entire process of acute exacerbations followed by dryness, lichenification, and remission. The terms are used interchangeably. Hornung & Prose, 1992, state that both terms indicate superficial inflammation of the dermis and epidermis accompanied by “cracking, excoriation, weeping and crusting” (p. 353).

Pathogenesis of AD is believed to be multifactoral although the etiology remains unknown. Common laboratory findings include elevated IgE antibody levels, abnormal monocytic and polymorphonuclear cell chemotactic ability, depressed T-suppressor cell counts and elevation of histamine in skin and serum (Hornung & Prose, 1992). Werner, Lindberg, & Forslind, 1992 as cited in (Romeo, 1995) explain that structural defects in the stratum corneum of children with AD cause a reduced water binding ability with subsequent transepidermal water loss, and reduced water content. This explains why so many treatments rely on hydration of the skin in an effort to decrease dryness. Hay et al. (1995) states that there are many subtypes of dermatitis, but all may present with
"acute edema, erythema, oozing with crusting, mild erythema alone, or lichenification" (p.408) irrespective of cause. There are three clinical phases for many AD clients. The first phase is known as infantile eczema where lesions first express on the cheeks, scalp, trunk, and later on extensor surfaces (Hay et al., 1995). Hortung & Prose (1992) add the chin and specify extensor surfaces of lower legs. Romeo (1994) stated sixty percent of those affected by AD will have onset in the first year of life and seventy-five percent before age six months. Eighty-five percent will have onset of symptoms before age six (Rajka, 1989). The areas of involvement change in childhood to include flexural surfaces, specifically the antecubital and popliteal fossa, as well as the folds of wrists and ankles. Hands and feet may be involved, or some may have dermatitis of the soles of the feet only. The childhood flexural eczema lasts from two years of age to adolescence. The third phase includes adolescence to age thirty, although it is unusual after age thirty. This final phase is characterized by xerosis and lichenification without weeping lesions. Location is on the hands only (Hay et al., 1995). In black children, the lesions are more papular and have follicular specificity (Hornung & Prose, 1992).

The literature encourages basically uniform treatment, although there are contradictions about whether bathing or showering will restore water to the epidermis/dermis. There are also contradictions about whether to use occlusive ointments, such as petrolatum or not since their use increases production of sweat which exacerbates AD. Romeo (1994) declared that "confusion about management of AD exists among parents and providers alike" (p.157). It is difficult to determine the
best and safest treatment because many factors are involved in the disease process. Treatment is individualized according to severity of skin lesions, other extant medical problems, and whether other allergies are expressed.

The use and dose strengths of hydrocortisone cream are dependent upon the judgment of the practitioner. There is contradiction in the literature about treatment protocols for infants and children. Hay et al., (1995) and Tierney et al., (1995) recommend different approaches. Tierney et al. state that acute, weepy lesions require wet compresses for 10-30 minute periods, two to four times daily with application of steroid lotions or creams rather than ointments (mild potency for children) avoiding the face and body folds. In the subacute phase, compresses are not needed, but mild potency steroids will still be applied to the red, pruritic areas until itching is decreased and the scaling, elevated skin lesions are cleared. In children, instead of decreasing steroid application over two to four weeks, both sets of editors recommend a change from mild potency to low potency steroids. The taper schedule is not given for children in the Tierney et al., (1995) treatment regimen, but is identified for adults. Hay et al.,(1995) also recommend wet dressings and topical steroid application for acute, weeping atopic eczema, but state that steroids should be applied four times daily, then covered with wet dressings. This is opposite the therapy recommendations of Tierney et al., (1995). In order to determine a standard treatment regimen, which will benefit practitioners, parents and clients, research studies are needed.

Research Question
This study will examine the question: "Are 4% topical Alpha hydroxy acid preparations as effective as 0.25% topical Hydrocortisone preparations in reducing the size of Atopic Dermatitis skin lesions in infants up to age two?"

**Definition of Terms**

**atopic dermatitis:** “a chronic inflammatory, pruritic, eczematous skin disorder in individuals with a hereditary predisposition to cutaneous pruritis; often accompanied by allergic rhinitis, hayfever ever, and asthma” (Dorland's, 1995).

**alpha hydroxy lotion:** a preparation containing various percentages of acids; also, water, glycolic acid, ammonium hydroxide, propylene glycol, PEG-40 stearate, glycerol stearate, PEG-100 stearate, petrolatum, isopropyl palmitate, sorbitan stearate, cetyl alcohol, dimethicone, isostearic acid, stearic acid, magnesium aluminum silicate, hydroxyethylcellulose, sorbic acid, BHT, imidazolidinyl urea (from a product ingredient label). This product is used as an over the counter skin exfoliate.

**atopy:** “a genetic predisposition toward the development of immediate hypersensitivity reactions against common environmental antigens (atopic allergy), most commonly manifest as allergic rhinitis but also as bronchial asthma, atopic dermatitis, or food allergy” (Dorland’s, 1995).

**Atopic dermatitis:** “a chronic inflammatory, pruritic, eczematous skin disorder in individuals with a hereditary predisposition to cutaneous pruritis; often accompanied by allergic rhinitis, hayfever, and asthma” (Dorland's, 1995).
**dermatitis:** “inflammation of the skin” (Dorland’s, 1995).

**emollient:** “1) softening or smoothing, 2) an agent that softens or smoothes the skin, or soothes an irritated internal surface” (Dorland’s, 1995).

**hydrocortisone:** “the name given to natural or synthetic cortisol when it is used as a pharmaceutical; it has life maintaining properties and limited mineralocorticoid activity. The base and its salts are used in treatment of inflammations, allergies, pruritus, collagen diseases, adrenocortical deficiency, severe status asthmaticus, shock, and certain neoplasms (Dorland’s, 1995).

**lichenification:** “thickening and hardening of the skin, with exaggeration of its normal markings” (Dorland’s, 1995).

**Significance to Nursing**

The relevance of maintaining the integrity of the skin as an important physiological organ is primary to nursing. Kirkevold’s (1994) study explored the assimilation of nurse’s knowledge over time in caring for clients who have chronic skin disease. Their experiences identified a practice which “values alleviating the client of stress or burdens associated with the disease, and enabling the patient to manage the disease and its impact”, (p. 45). Given the lifelong course of AD with the implications for severe physiological as well as psychological consequences, determining the most effective and safe treatments will reduce possible adverse effects while optimizing benefits of safe therapy.
Chapter Two

Methods

Research Question

Are 4% topical Alpha hydroxy acid preparations as effective as 0.25% topical Hydrocortisone preparations in reducing the size of AD skin lesions in infants up to age two years?

Design

This study will use a comparative descriptive design to examine differences in the size of skin lesion(s) in two study groups. The dependent variable in this study is size of the skin lesion(s). The independent variables are treatment with topical hydrocortisone cream 0.25% or topical alpha hydroxy cream 4%. The hydrocortisone and alpha hydroxy preparations will be available at no cost to the clients. A disposable plastic ruler will be used to measure the linear size of skin lesion(s).

Setting

The study will be conducted in the Inland Northwest community of Spokane, Washington. Participants will be clients in primary care health practices being seen for routine well baby checks or for AD. All participants will meet study criteria.

Sample

A convenience sample of 30 participants will be used for this study. Participants in the study will be seen initially for well baby checks, or will be previously identified at well baby checks or from birth as having AD. Atopic Dermatitis will be diagnostically determined by using the criteria table listed in Rajka, (1986). Infants up to the age of two years who meet the criteria for AD, have no systemic or skin infections, or other
pathological medical conditions, and whose parents have been educated about study benefits as well as risks and agree for their children to participate will be considered for admission to the study.

Instrumentation

Ruler Method: The researcher will measure the length and width in millimeters of the skin lesion(s). An indelible mark will be made on the ruler at the point which correlates with the appropriate border of the lesion. The measurement will be recorded in millimeters. Measurements will be made at the initial visit and each week after treatment begins for a period of 4 weeks. Lesion(s) will be demarcated by drawing their location on a representative body pictograph then numbering the lesions on the pictograph. These linear measurements will be ratio level. A plastic disposable ruler will be used once then discarded to prevent contamination from client to client. The same brand of ruler will be used for all measurements.

Reliability

The researcher will perform and record all linear measurements of skin lesions. The same brand of ruler will be used for all measurements. The researcher will gather the client medical history, the family medical history as well as demographic data.

Data Collection

Pediatric populations will be selected from Pediatric Clinics, and Family Clinics. An information sheet will be posted asking for parents who have infants with AD to participate in the study. If a parent of an AD infant would like to find out more about the study, then the researcher’s phone number will be available by requesting it from the receptionist. As the parents of AD infants initiate questions about the study, the
The investigator will introduce herself and will explain the study. After receiving information about the study, informed consent and human subject risks to benefits, the prospective parents of study participants will be given written information to reinforce knowledge about the purpose of the study, when and where the study will be performed and how the results will be determined. The parents of the study participants will be advised of the confidential nature of the study as well as their right to decline further involvement in the study at any time without penalty. After permission is obtained, the data collection will begin. Demographic data including client sex, ethnicity, location, and size of skin lesions will be recorded. Client medical history and family medical history will be recorded. Treatment groups will be color coded and assigned randomly to the participating clinics in a blind study. A list of all participants will be randomly assigned either a blue or red color code. The researcher will not know which color is assigned to either of the two treatments until the data has been analyzed.

Data Analysis Plan

Demographic data regarding sex, ethnicity, age, environmental factors such as smoking in the home or living near an industrial complex, family medical history including those with allergies or asthma, and linear measurement of the skin lesion(s) will be analyzed to describe the sample. Ratio level data will be organized using descriptive statistical information, then analyzed using the student’s t-test. Determination of the efficacy of one treatment over the other will be made by size difference measurements of the skin lesions.

Protection Of Human Subjects
Confidentiality and anonymity have been insured by the deletion of client names from the data collection form. The subjects will be protected by delineation of risk to benefit criteria including: 1) parent(s) of the child will be able to stop treatment if they determine the AD skin lesions are not decreasing in size or are becoming more severe have increased weeping, excoriation, or are infected 2) the parent(s) decide to withdraw from the research study for any reason 3) the parent(s) determine the child is having an allergic reaction to the treatment by educational handout which will define signs and symptoms of allergic reaction. They will have printed instructions to stop treatment and to call their primary care provider or to stop the treatment then call 911. The parent will be informed that withdrawing or stopping treatment will not change their status at their health care clinic. Informed consent will be obtained and submitted with the proposal. Individual subjects and clinics will not be identified in the research results. Results will be shared with the practitioners and families of the clients. IRB approval will be obtained before the study is implemented.