

Project Title:

Comparing Efficacy of Topical Steroids in Cream vs Ointment Formulations Using Wet Dressings for the Treatment of Atopic Dermatitis

Principal Investigator

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Grant Information:

IRB Approval: This project is not currently IRB approved

Proposed Starting Date of Research: February/March 2016

Anticipated Date of Completion: August/September 2016

Timeline of activities: Estimate 2-3 months for IRB approval. Once approved the study will likely take 2-3 months, possibly sooner given the volume of patients with atopic flares (especially during winter months) seen at the pediatric dermatology clinic. After data collection, 1-2 months will be required for statistical analysis. Overall, we project to have research completed and data analyzed by August/September of 2016

Overall goals and background

Atopic Dermatitis (AD) is a common skin condition affecting 10-20% of children in the United States. Atopic dermatitis is associated with chronic pruritus and inflammation leading to significant discomfort, stress and social stigma. Wet wraps (corticosteroid contained in a vehicle wrapped in wet dressings) have been used for many years and are an effective means of improving moderate to severe atopic dermatitis. A wet wrap's efficacy is a product of a corticosteroid's activity at the site of action, as well as patient compliance. Wet wraps can be messy and difficult to use for patients and families and has been associated with variable adherence. Interestingly, little research has been done regarding wet wrap comparable efficacy and patient tolerability. Recent studies have shown that wet wraps with topical steroids are superior to emollients alone. However, there are no studies comparing different vehicles for topical steroids when used for this treatment.

The purpose of this study is to

1. Compare efficacy of 0.1% triamcinolone containing wet wrap as an ointment or as a cream formulation in patients with moderate to severe atopic dermatitis

2. The relative patient/subject acceptance and adherence will also be compared between the two wet wrap types

Hypothesis

Significant controversy exists on the optimal vehicle for wet wraps. Some advocate for cream (oil in water) formulations because they are hydrophilic and therefore may be absorbed better in the aqueous environment of a wet dressing. Others prefer ointments (water in oil) because they are more potent than creams. We hypothesize that the overall difference will be negligible and that patient preference should be the largest factor in deciding which to use. Many patients prefer creams because they are lighter and more elegant while others prefer the thickness of ointments.

Methodology and Rationale

Inclusion Criteria

1. Patients between the ages of 3-17 experiencing a symmetric, bilateral flare of atopic dermatitis
2. The flares must reach a certain threshold for inclusion based on the investigator's global assessment scale

Exclusion Criteria

1. Systemic infection or bacterial skin infections
2. Eczema herpeticum
3. Evidence of suppression of the Hypothalamic-Pituitary-Adrenal axis
4. Non-English or Non-Spanish speaking

Methods

Patients and/or parents will be asked to sign an informed consent authorizing their participation in the study. All information will be de-identified to protect the patient's privacy.

In this study, we will examine the effectiveness of wet wraps with topical steroids in different formulations for patients with a history of atopic dermatitis who are experiencing an acute flare. A validated clinical tool such Investigator's Global Assessment (IGA) will be used in order to assess severity of the condition as well as demonstrate the appropriateness of using wet wrap therapy as a treatment modality. IGA will measure intensity of the atopic dermatitis regarding erythema, lichenification, swelling and excoriation as well as subjective symptoms of the patient on a numeric scale. The treating clinician will be asked to rate their assessment before and after therapy.

Patients will be asked to apply a topical steroid in a cream formulation to one extremity and then apply the same topical steroid in an ointment formulation to the other using the wet wrap technique. One of the investigators or nursing staff will provide detailed instructions to the patient and parents on how to perform the wet dressing (this is already routinely done for patients initiating wet wrap therapy in the pediatric dermatology clinic). Patients will also be given a sealed and coded envelope containing

instructions to apply one steroid formulation to the right extremity and the other to the left. In this manner the providers will be blinded to treatment modality during the follow-up visit. Only the research coordinator will have access to the envelope code key. An additional handout will also be provided to reinforce appropriate treatment technique. After several days (3-5) the patient will return to the dermatology clinic for a nurse visit and evaluation of any improvement of the affected areas as well as comparison of improvement of the right and left extremities. The physician investigator will examine the patient and measure improvement using the IGA. Detailed photos of the affected areas will also be taken. After a certain number of patients have enrolled in the study and completed it, the de-identified data will be examined by a statistician for comparison. Other studies evaluating the effectiveness of wet wraps have commonly had 40-50 patients enrolled which will likely be the target of this study. The statistician will compare the IGA before and after treatment on each side to allow for interpretation of the data. Stratification of data may include ages and/or severity (moderate vs severe).

Patient Oriented Eczema Measure (POEM) and/or a Quality of Life (QoL) index will also be provided before and after treatment in order to determine the patient's point of view regarding their management using validated tools. They will also be asked their opinion regarding if one side was better controlled than the other, if at all, as well as their personal preference for treatment of choice.

Compliance will be determined by weighing the medication before and after each visit and a medication calendar.

The participating clinicians, including myself, will be performing the IGA before and after treatment. I will also be responsible for data collection as well as help with statistical analysis under the mentorship of Collin Hovinga and possibly a statistician if needed.

Relevance to Professional Career

The dermatology service recently had an inpatient with erythroderma who was not responding to topical steroids used with wet dressings. In our discussion during grand rounds, someone suggested that switching from a cream to ointment may help. We did a quick literature search and could not find any relevant insight. Given that atopic dermatitis makes up a significant portion of the diseases in pediatric patients seen by dermatologists, I would like to elucidate whether one formulation is superior to another for this often used treatment. Although I have no research experience with topical steroids or eczema, I have conducted dermatologic research through surveys in the past. I hope the information acquired from this study will fill the knowledge gap that currently exists and will provide an opportunity to improve patient care. If there is truly no clinical difference between topical steroid creams and ointments used in wet wraps, then patient preference will play the largest role in deciding which to use. One of my professional goals is to continue to be involved in research and this experience will help me to build a foundation for future investigations.

Bibliography

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Budget

There are 2 major barriers to carrying out this project. First, the funds needed to pay for the prescription topical steroids. Although many, if not all, of our patients will be insured, it is unlikely their insurance will pay for 2 formulations of the same topical steroid for 1 patient. Given that a significant portion of patients who present to the pediatric dermatology clinic qualify for Medicaid, the cost of the extra topical medicine may be too much to cover for them. We would like to cover one or both of the medications for the patient. We estimate this could cost \$30-50 per patient (\$50 x 50 patients= \$2500). Second, considering how difficult it can be for patients, especially with small children, to make return visits to the clinic, we would like to provide a small compensation for their participation. A gift card in the amount of \$50 (\$25 x 50 patients= \$1250) is the goal. Hopefully, this will encourage our patients to keep their follow up visit. Because we are working with English and Spanish speaking patients, we will need all forms, questionnaires and consents officially translated into Spanish by the translating service. The expected cost would be about \$400. We will also need funds to pay for statistical analysis as well as publication of data (posters etc). Our estimated costs would be around \$4800. Should we exceed receive the grant and our budget exceeds \$4800, there may be some departmental funding available to meet those extra costs.