

Topical Corticosteroids (Hydrocortisone 0.5%)

1. Primary Literature

Reference

Ramsay, C., J. Savoie, M. Gilbert, M. Gidon, and P. Kidson. "The Treatment of Atopic Dermatitis with Topical Fusidic Acid and Hydrocortisone Acetate." *Journal of the European Academy of Dermatology and Venereology* 7 (1996): S15-22.

Study Objective

The objective of this study was to compare the clinical efficacy of a cream combination containing 2% fusidic acid and 1% hydrocortisone acetate in the treatment of patients with mild to moderate atopic dermatitis.

Methods

The study was a randomized double blinded prospective parallel group trial. The trial consisted of two studies. The first study involved 186 patients and compared the combination of fusidic acid 2% and hydrocortisone acetate 1% with only hydrocortisone 1% cream. The second study involved 68 patients and compared the combination of fusidic acid 2% and hydrocortisone acetate 1% with only fusidic acid 2%. Patients had to be diagnosed with mild to moderately severe atopic dermatitis to be included in the study. The primary efficacy criterion consisted of clinical and bacteriological efficacy measures. Clinicians evaluated patients with a sign/symptom score on a weekly basis. Clinicians also measured the amount of pathogen (*S. Aureus*) was present at baseline and at the end of the treatment (in 2 weeks). Treatments were received for a total of 2 weeks at which point the results were tabulated.

Main Results

Results with study 1 in patients with pathogens at baseline showed significant favour of the combination in terms of the primary efficacy criterion. However, when all the patients were analyzed there was no significant clinical difference between the two groups despite the combinations superior efficacy at reducing the amount of pathogen. The results in study 2 demonstrated that the combination of hydrocortisone 1% and fusidic acid 2% was far more superior at reducing pathogens and clinical symptoms than the fusidic acid 2% cream on its own. Both preparations were similarly effective at eradicating pathogens.

Conclusion

The authors concluded that fusidic acid 2% and hydrocortisone acetate 1% cream is an effective therapy in patients with mild to moderate degrees of atopic dermatitis. Since this combination was clearly superior to fusidic acid on its own, logically, we can argue that it is the

hydrocortisone acetate 1% that contributed to the efficacy of the mixture. Even though the study could not conclude that hydrocortisone was responsible for the eradication of pathogens associated with dermatitis, it significantly improved clinical symptoms of dermatitis.

Comments/Critical Appraisal

The trial was double blinded and randomized thus eliminating the bias or placebo effect that could have taken place in favor of one therapy over the other. Patients in all groups had similar prognosis as they were all diagnosed with mild to moderate atopic dermatitis.

The external validity may be compromised by the fact that the compound used in treatment was hydrocortisone 1% which is not available for self-care. The corticosteroid available in Ontario without a prescription is hydrocortisone 0.5%. Assuming that both strengths are just as effective threatens the study's validity for self-care purposes. Hydrocortisone was also used in combination. The synergistic effect with fusidic acid may have contributed to the compound's efficacy despite the fact that fusidic acid on its own did not prove efficacious. Therefore the second assumption we have to make is that hydrocortisone is as effective on its own as it is in combination with fusidic acid.

2. Primary Literature

Reference

Robinson, Harry M., and C. V. Raymond. "Treatment of Dermatoses with Local Application of Hydrocortisone Acetate." *The Journal of the American Medical Association* 155.14 (1954): 1213-216.

Study Objective

The study's aim is to critically evaluate the efficacy of hydrocortisone in treating various dermatoses and to evaluate the effect various vehicles have on the efficacy of hydrocortisone.

Methods

The authors did not give any information related to the blinding of the study. They did however mention that the various strengths of cortisone treatments were compared to a placebo lotion that was applied on an opposing side of the body. Participants chosen were divided based on their respective diagnosis: generalized atopic dermatitis, localized atopic dermatitis, seborrheic dermatitis, contact dermatitis, stasis dermatitis, alopecia areata, psoriasis, pityriasis rosea, acne vulgaris, chronic discoid lupus erythematosus, pruritus or lichen planus. They were selected from the author's private practices and from the dermatology clinic of the University Hospital. During treatment, patients were instructed to discontinue previous treatments they were on whether systemic or topical. Follow up was performed on a weekly basis. Patients who did not follow up were automatically excluded from the study. 84 patients were treated with

hydrocortisone lotion 0.5% 1% and 2.5 %. 133 patients were treated with 1% hydrocortisone cream, 176 patients were treated with 2.5% hydrocortisone ointment or cream.

Main Results

From the 37 patients with dermatitis that were treated with hydrocortisone 0.5% (regardless of the vehicle), 13 patients experienced complete involution of lesions (35%) while the rest experienced no improvement (65%). From the 89 patients with dermatitis that were treated with hydrocortisone 1.0% (regardless of the vehicle), 77 patients experienced complete involution of lesions (87%) while the rest experienced no improvement (13%). From the 154 patients with dermatitis treated with hydrocortisone 2.5% (regardless of the vehicle), 116 experienced complete involution of lesions (75%), 21 patients experienced partial involution of lesions (15%) and 17 experienced no improvement (10%).

The incidence of adverse reactions was also evaluated. This was defined by an increase in erythema and subjectively an increase in itching. The adverse reactions were not serious in any case. The results indicated that 12 out of 41 patients (29%) experienced adverse reactions when using hydrocortisone 0.5%, 12 patients out of 174 patients (7%) experienced adverse reactions when using hydrocortisone 1.0% and 14 out of 203 patients (7%) experienced adverse reactions when using hydrocortisone 2.5%.

Conclusion

Based on these results, the authors concluded that a concentration of less than 1.0% hydrocortisone acetate is found to be relatively ineffective (only 35% showed signs of improvement vs 87% for hydrocortisone 1.0% and 90% for hydrocortisone 2.5%) in treating dermatitis. In all instances, relapse occurred upon discontinuation of therapy. Hydrocortisone 0.5% also exposed patients to a higher incidence of erythema and an increase in itchiness.

Comments/Critical Appraisal

The study could not be blinded as patients received both the actual treatment on one side of their bodies and a placebo cream on the other side. This method does not fully eliminate the bias and placebo effect associated with the treatments. Patients were not randomized but were selected by the authors conducting the study. This can lead to a huge selection bias that can affect the validity of the results. Patients were also instructed on how to apply the lotions and creams. This was performed in a private manner where clinicians cannot confirm a proper application of the treatments. We are not informed on patient characteristics. Thi The study dated back to 1954. The vehicles utilized to deliver the hydrocortisone may not have been the same ones that are used today. The 3 different vehicles employed in the study yielded different results

regardless on the strength of hydrocortisone they contained. Therefore the type of vehicle may have contributed to the efficacy and adverse reactions associated with the treatments.

3. Textbook

Reference

Sibbald D. Atopic, Contact and Stasis Dermatitis. In: Repchinsky C, Hutsul J, Jovaisas B, Lewis G, Perrier H, Riachi M, Ross A, editors. Patient Self-Care. Ottawa, ON: Canadian Pharmacists Association; 2010: 510-533.

Source Description

The source is Patient Self-Care, a text book that is referenced and peer-reviewed by healthcare professionals. The information given is based on two reviews. The first article, “The pharmacological properties of corticosteroids in relation to clinical efficacy” was published in The British journal of dermatology in 1976. The second article, “Clinical use of topical corticosteroids” was published in the journal Drugs also in 1976.

Summary

The author recommends the use of hydrocortisone for acute, mild or chronic atopic or contact dermatitis. It is recommended that a treatment course of hydrocortisone may not exceed 2 weeks. The author also warns that the use of hydrocortisone 0.5% may aggravate or be ineffective in treating dermatitis in some patients. If this occurs, the use of a more potent corticosteroid is warranted. It is also mentioned that hydrocortisone is the corticosteroid of choice for dermatitis located on the face or skin folds.

Comments/Critical Appraisal

Patient Self-Care is a textbook that presents information on a particular condition and its treatment in a very general manner. The sources it relies on are referenced. However, the internal validity and external validity of these sources (that are mostly reviews in this case) are not clearly defined. Various forms of dermatitis were discussed including contact, atopic and stasis. Many pharmacological options were also presented. The evidence to support these treatments and to associated them with specific types of dermatitis was not demonstrated.

4. Web Resource

Reference

Skin Disorders: Atopic Dermatitis. [Updated November 2011; Cited July 5, 2012]. Available from www.e-therapeutics.ca.

Source Description

e-Therapeutics is a web resource that is created and peer-reviewed by health professionals. The information presented describes the pathophysiology, goals of therapy and treatment alternatives available for atopic dermatitis. The majority of the information presented is referenced and based on primary literature, reviews and meta-analyses. The information is updated periodically. The last date of revision was November 2011.

Summary

Corticosteroids work quickly and are available in a wide variety of potencies and vehicles. They affect several inflammatory pathways in the skin and carry a risk of skin atrophy, telangiectasia, striae and purpura. The actual clinical potency of topical corticosteroids depends on the molecular structure and vehicle (ointment vehicles are said to be the most effective) as well as the thickness and integrity of the skin. Hydrocortisone 0.5% is not mentioned. The lowest potency corticosteroid that is comparable is hydrocortisone 1.0% that is recommended as a first line treatment in dermatitis that affects the face or intertriginous areas.

Comments/Critical Appraisal

e-Therapeutics is a reliable source of information as it is primarily based on primary literature. The information is peer-reviewed and revised periodically. Consequently, the information provided is up to date and consistent with current literature. For these reasons, the information is valid. The external validity, however, is compromised as we cannot apply it to a self-care scenario. There is no information given on hydrocortisone 1.0% which is only available by prescription. Therefore, we cannot make the assumption that the 0.5% strength available without a prescription is as effective as the stronger preparations.

5. Web Resource

Reference

Treatment Guide to Common Skin Conditions. [Updated January 2004; Cited July 8 2012]. Available from www.rxfiles.ca

Source Description

Rx Files is an independent, academic detailing provider of objective, comparative drug information and education in Canada. The information presented is based on evidence and primary literature. Its purpose is to aid physicians, pharmacists and allied health professionals make clinical decisions based on evidence. The information provided is peer-reviewed.

Summary

Rx Files claims that hydrocortisone 0.5% should be used only for flare-ups and acute contact dermatitis. They do not recommend its use as prophylaxis. They recommend to use the lowest effective dose for as short duration as possible. Other recommendations include using the ointment form of hydrocortisone 0.5% as it has proven to be more effective than the cream formulation. They indicate that the ointment should be applied sparingly twice a day for the treatment of dermatitis.

Comments/Critical Appraisal

Rx Files' recommendations were brief. The level of effectiveness and safety were not discussed. However, the information provided was based on primary literature and provides a good starting point for the management of dermatitis. The information provided was also the result of a consensus between health professionals on the over-the counter use of topical corticosteroids. Thus, the information may not be fully evidence-based but also a reliance on professional expertise and experience. The information is not very current as it was last updated in 2004.