A RANDOMIZED DOUBLE-BLIND STUDY OF OINTMENTS CONTAINING DIFLUCORTOLONE VALERATE AND HYDROCORTISONE ACETATE

F Handa and K P S Puri

Diflucortolone valerate 0.1 per cent and hydrocortisone acetate 1.0 per cent were compared in a randomized double-blind contralateral, intra-individual trial in fifty two patients. Duration of treatment was three weeks. Both the drugs showed significant response after the first, second and the third weeks of treatment. At all periods, the reduction in pre-treatment signs and symptoms was greater for diflucortolone as compared to hydrocortisone. Response to therapy in eczema was very good in 89.1 per cent cases and good in 10.9 per cent. Patients having psoriasis and chronic DLE showed very good response in 33.3 per cent and good in 66.6 per cent cases. There were no side effects.

Key words : Diflucortolone valerate, Hydrocortisone acetate.

This trial was undertaken to compare ointments containing diflucortolone valerate 0.1 per cent with hydrocortisone acetate 1.0 per cent for therapeutic efficacy, side effects and cosmetic acceptability.

Materials and Methods

A randomized double-blind contralateral, intra-individual comparative study was carried out in fifty two patients. Thirty seven (71.1%) were males and 15 (28.9%) were females. Age of the patients ranged between 10-75 years. No other corticosteroid was given either locally or systemically. Cases of tuberculosis, syphilis, viral diseases (vaccinia, variola and varicella) and pregnant women were excluded from the trial.

The two ointments in identical looking tubes were labelled with code letters or coloured bands for application on the two sides of the body. The ointments were applied without occlusion, three times a day for the first three days, twice a day upto two weeks and then once a day for the third week. Photographic records were kept in all cases. Diagnosis was mainly clinical supported by histopathological evidence where needed.

From the Department of Skin and V. D., Government Medical College, Patiala-147 001, India.
Address correspondence to : Dr. F. Handa.

The patients were observed at weekly intervals. In acute cases, the examination was done more frequently. Special emphasis was laid on the effect of these preparations on the objective symptoms such as erythema, oedema, exudation, dryness, scaling, lichenification and rhagades, and the subjective symptoms such as itching, burning and pain. The therapeutic results were graded as : (1) very good indicating complete healing, (2) good indicating distinct improvement, (3) poor indicating slight improvement, and (4) failure indicating no therapeutic success. The code of the ointments was deciphered after analysing the data.

Results

Fifty two cases completed the trial. In majority of the patients, improvement started within 18-24 hours of commencement of treatment with diflucortolone, while improvement with hydrocortisone started after 72-96 hours. Only in exceptional cases, did the improvement start later i.e. on the seventh day. The drying effect of diflucortolone on exuding lesions was obvious within 18-24 hours. The lesions became dry earlier with diflucortolone than hydrocortisone which took 72-96 hours.

No systemic effect was observed in any of the cases under study. Table I shows the overall results.

Table I. The overall results of ointments containing diflucortolone valerate 0.1 per cent and hydrocortisone acetate 1.0 percent.

S. No.	Diagnosis	Number of cases	Diflucortolone valerate				Hydrocortisone acetate			
			Very good	Good	Poor	Failure	Very good	Good	Poor	Failure
1.	Eczematous dermatitis	27	25	2	—	—	3	20	3	1
2.	Contact dermatitis	7	6	1	—	—	2	4	—	1
3.	Nummular dermatitis	3	3	—	—	—	1	—	2	—
4.	Atopic dermatitis	7	5	2	—	—	—	4	3	—
5.	Psoriasis	4	2	2	—	—	—	2	2	—
6.	Chronic DLE	2	—	2	—	—	—	1	—	1
7.	Neurodermatitis	2	2	—	—	—	—	1	1	—

Comments

A series of clinical investigations[1-7] in the past have also proved that diflucortolone valerate has high efficacy with little systemic toxicity. Moreover, it has an edge over fluocinolone and is well tolerated with excellent cosmetic acceptability.

Acknowledgement

Medical Scientific Department of Schering A. G. Berlin/Bergkamen (Division of German Remedies Limited) supplied both the ointments.

References

1. Caferri De Paolini MI : Diflucortolone valerate : A new corticoid for topical application, Zeitschrift fur Haut-und-Geschlechtskrankheiten, Supplimentum, 1976; (1/76) : 23-26.
2. Carvajal Rosado VM : Topical treatment of dermatoses with diflucortolone valerate in fatty ointment, Zeitschrift fur Haut-und-Geschlechtskrankheiten, Supplimentum, 1976; (1/76) : 27-29.
3. Consigli CA and Gonzales W : Diflucortolone valerate for topical application in dermatology, Zeitschrift fur Haut-und-Geschlechtskrankheiten, Supplimentum, 1976; (1/76) : 30-32.
4. Yanez De Mena E : Clinical trial with a new corticoid for topical application : Nerisona, Zeitschrift fur Haut-und-Geschlechtskrankheiten, Supplimentum, 1976; (1/76) : 37-39.
5. Lopez Sanabria JM : Investigation of a new corticoid in various dermatoses, Zeitschrift fur Haut-und-Geschlechtskrankheiten, Supplimentum, 1976; (1/76) : 43 - 46.
6. Mirande LM, Landolfi M and Pedemonte H : The topical use of the new corticoid diflucortolone valerate in dermatology, Zeitschrift fur Haut-und-Geschlechtskrankheiten, Supplimentum, 1976; (1/76) : 47-50.
7. Muhafra J : Clinical trial with Nerisona cream (SHK 183 MB), Zeitschrift fur Haut-und-Geschlechtskrankheiten, Supplimentum, 1976; (1/76) : 56-59.