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A DOUBLE BLIND COMPARATIVE EVALUATION OF OINTMENT AND CREAM BASES CONTAINING CORTICOSTEROIDS

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Efficacy of two corticosteroid preparations (halcinonide 0.1% and fluocinolone acetonide 0.025%) in two different bases (ointment and creams) was evaluated on ten healthy volunteers using the wheal suppression technique in a double blind manner. The ointment preparations were more potent than the cream preparations of the same corticosteroid, in the same concentration. These differences were highly significant.

Key words : Corticosteroid, Ointment, Cream, Halcinonide, Fluocinolone, Bioassay.

More and more topical corticosteroid preparations are being introduced with higher claims of effectiveness.[1,2] Among these preparations, cream preparations out-number the ointment preparations, the reasons for which may be purely commercial, although there is sufficient evidence showing superiority of the ointment over the cream bases of the same steroid in the same concentration.[3-6] These reports are however, based on blanching or vasoconstrictor effect of McKenzie and Stoughton[7] which is purely a qualitative method and is not suitable in persons other than those with fair complexions. In 1976, Reddy and Singh[8] developed a very simple and cheap method which was proved to be closer to the clinical situation.[9] It was later on modified by Singh and Singh[10] and thus became more quantitative and a sensitive indicator for the bioassay of topical corticosteroids. This new technique was used to evaluate the relative efficacy of corticosteroids in ointment and cream bases in this study.

Materials and Methods

Singh and Singh's[10] modification of Reddy and Singh technique was used to evaluate the potency of topical corticosteroid preparations under occlusion on the back lateral to the vertebral column,[11] strictly in a double blind manner, in ten healthy volunteers aged 15 to 30 years with no history of corticosteroid or antihistaminic treatment at least 8 weeks prior to the study. Two corticosteroid preparations, one from the most potent group (halcinonide 0.1%) and the other from the mid-potent group[12] (fluocinolone acetonide 0.025%) were chosen for the study. Halcinonide cream and ointment was supplied by one manufacturer and fluocinolone acetonide and bland cream and ointment by another manufacturer. The histamine wheal test was repeated on alternate days till the maximum effect of topical corticosteroid was achieved.[12] After 6 to 8 days tachyphylaxis develops.[13]

Results

The table I shows that halcinonide ointment was superior to halcinonide cream in the same concentration (Fig. 1). Similarly fluocinolone acetonide ointment was much more effective than its cream base (Fig. 2). In both the cases, the differences were statistically highly significant.

Comments

Importance of the base in topical preparations, particularly corticosteroids, is often ignored, in spite of the fact that the base though innocuous, can significantly influence the effectiveness of a particular topical steroid. Ostrenga

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Table I. Mean (± S.D.) volume of the histamine induced wheal in mm^3.

Corticosteroid preparation	Days					p values
	1st	2nd	4th	6th	8th	
Control ointment/cream	52.3±20.5	53.5±20.0	53.0±19.8	52.8±19.5	52.3±19.7	
Halcinonide (0.1%)						
Ointment	50.9±19.4	20.2±11.2	6.1±2.3	0.8±0.1	—	<0.001*
Cream	52.9±20.5	18.5± 7.0	11.0± 4.2	2.7± 2.0	—	
Fluocinolone acetonide (0.025%)						
Ointment	53.5±19.6	18.5± 6.0	9.8± 3.0	5.3± 2.2	1.7± 0.7	<0.001*
Cream	54.1±19.4	17.4± 4.0	9.3± 3.5	4.6± 1.6	3.2± 0.9	

* Statistically significant.

et al[14] stressed that the base in which the corticosteroid is incorporated for topical application, plays an important role in the therapeutic efficacy of the drug. It is also well understood that the activity of corticosteroid is related to the partition coefficient of the drug between the skin and the base, and the viscosity of the base. It has also been reported[8] that pretreatment with a local corticosteroid followed by histamine wheal induction and using the degree of suppression of wheal formation as an indicator of potency, closely correlates with its clinical effectiveness. Our study has shown that halcinonide (0.1%) and fluocinolone acetonide (0.025%) in ointment bases are significantly more effective in suppressing the histamine wheal than the corresponding cream bases.

This is perhaps due to the partial occlusiveness produced by the ointment base. It is certainly less occlusive than occlusion with the polyethylene film. The latter has been shown by Feldman and Maibach[15] to increase the penetration of corticosteroids approximately ten-fold due to enhanced hydration of stratum corneum.

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