

## EVALUATION OF EFFICACY OF DIFFERENT TOPICAL CORTICOSTEROIDS

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Four different proprietary preparations of topical corticosteroids in cream base were evaluated for their relative efficacy on forty adult human volunteers using a modification of the method described by Reddy and Singh.<sup>1</sup> Fluocinolone acetonide 0.025% (Flucort) was rated to be the most efficacious, followed by halcinonide 0.1% (Halcinonide), beclomethasone dipropionate 0.025% (Beclate) and betamethasone valerate 0.12% (Betnovate). However, the differences between these four topical corticosteroids did not reach the level of statistical significance.

**Key words :** Topical, Corticosteroids, Fluocinolone, Halcinonide, Beclomethasone, Betamethasone.

There being a distinct lack of clinical data on the comparative efficacy of proprietary preparations of topical corticosteroids, the present study aims at evaluating the relative efficacy of four commonly used topical corticosteroids from the market.

### Materials and Methods

Forty adult human volunteers (19 males and 21 females) aged 15 to 40 years were selected for the study. It was ensured that, (1) they did not have any systemic disease or skin infection or any contraindication to the use of corticosteroids, (2) there was no history of atopy, (3) they did not have any systemic or local corticosteroid or antihistamine for at least 8 weeks prior to the study, and (4) females on contraceptive pills or during pregnancy or menstruation period were not included.

Four different topical corticosteroids in cream base selected for the study, included, (1) beclomethasone dipropionate 0.025% (Beclate), (2) betamethasone valerate 0.12% (Betnovate), (3) fluocinolone acetonide 0.025% (Flucort), and (4) halcinonide 0.1% (Halcinonide).

The method of evaluation was a modification of that described by Reddy and Singh.<sup>1</sup> Five sites were selected on the front of both forearms, which were cleaned with soap and water and then dried. On four sites, 100 mg $\pm$ 10 mg of four different topical corticosteroids were applied in a random fashion to exclude site to site variation. These areas were covered with 3.5 cm $\times$ 3.5 cm size polythene patches, over which 5.5 cm $\times$ 5.5 cm size cotton backed adhesive tapes were pasted keeping the polythene patches in the centre. One site was kept as control and covered with only a polythene patch and a cotton backed adhesive tape. After 18 hours the patches were removed, the areas were washed with soap and water, and after about half an hour when the erythema of the sticking tapes had subsided, two drops of 0.1% histamine acid phosphate solution were placed over each of the test sites, and pricked with the sterilised blood-gun through the histamine acid phosphate solution to a depth of 2 mm. The solution was then allowed to stay at the site for one minute and then it was wiped off. Five minutes later, the average diameter of the wheal was measured by measuring the maximum and the minimum diameters of the wheal through a thin transparent scale in mm. The wheals were almost circular in most of the cases. The surface area was then calculated.

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**Table I.** Comparison of histamine wheals induced at the sites of application of different corticosteroids and control.

No.	Topical application	Number of sites tested	Mean $\pm$ SD surface area of wheals in mm <sup>2</sup>	Reduction in surface area of wheals in mm <sup>2</sup> /(%) compared with the control
1.	Control	40	23.6 $\pm$ 6.62	--
2.	Fluocinolone acetonide 0.025%	40	13.5 $\pm$ 5.31	10.1 (42.8%)
3.	Halcinonide 0.1%	40	13.9 $\pm$ 4.3	9.7 (41.1%)
4.	Beclomethasone dipropionate 0.025%	40	14.7 $\pm$ 6.14	8.9 (37.7%)
5.	Betamethasone valerate 0.12%	40	16.1 $\pm$ 6.52	7.5 (31.78%)

The surface areas of the wheals over the sites treated with corticosteroids were compared to that of the control and with each other.

### Results

There was a highly significant reduction ( $p < 0.01$ ) in the surface areas of the wheals at corticosteroid applied sites in comparison to the control. The reduction in the surface area of the wheal and thereby percent reduction was maximum (42.8%) in the case of fluocinolone acetonide 0.025% cream, followed by halcinonide 0.1% cream (41.1%), beclomethasone dipropionate 0.025% cream (37.7%), and betamethasone valerate 0.12% cream (31.78%). However, the differences between the surface areas of the wheals of four topical corticosteroid creams did not reach the level of statistical significance (Table I).

### Comments

Topically used corticosteroids produce vasoconstriction in normal human skin as observed by Mc Kenzie and Stoughton.<sup>2</sup> The realisation that the degree of topically used corticosteroids could provide a means for comparing the efficacy of topically used corticosteroids, led to the development of the vasoconstrictor test which had been extensively used since then, for evaluating the efficacy of topical corticosteroids. There is a rough correlation between the vasoconstrictor potency of a topical corticosteroid and its clinical usefulness.<sup>3,4</sup>

The present method which is also based on vasoconstriction has an edge over the vasoconstrictor test, because, (1) it can be done on white and dark individuals with an equal ease, (2) it is a simple, reliable and reproducible procedure, (3) more than two or three subjects may be tested at a time on a single subject, and (4) it resembles clinical conditions very closely having some similarity to the processes in the development of inflammatory dermatoses, even though it is a non-clinical assay.<sup>1</sup>

Fluocinolone acetonide 0.025% was rated superior in potency to betamethasone valerate 0.1% by the vasoconstrictor test also.<sup>5,6</sup> Barry and Woodford<sup>6</sup> had evaluated thirty proprietary creams and gels and found betamethasone valerate 0.1% cream more potent than beclomethasone dipropionate 0.025% cream, but in their study also, the difference was not statistically significant. Superiority of halcinonide 0.1% cream over betamethasone valerate 0.12% cream in the present study is similar to the results in clinical trials.<sup>7,8</sup>

Wilkinson<sup>9</sup> classified the topical corticosteroids into four grades and kept halcinonide 0.1% in group I (extremely potent), and the remaining three corticosteroids studied by us in group II (potent). In the present study, halcinonide 0.1% cream was second to fluocinolone acetonide 0.025 cream in efficacy. However, Maddin,<sup>10</sup> while grouping topical corticosteroids for a rough guide from mild to very potent, listed all the topical corti-

costeroids of the present study in the potent group.

#### Acknowledgements

Cipla India, Glaxo Laboratories India Ltd, Synbiotics Ltd and Lyka Labs India provided their proprietary preparations for this work.

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