CLINICAL EVALUATION OF 'HISTRYL' ELIXIR IN ALLERGIC DERMATOSES

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Summary

The clinical efficacy of 'Histryl' elixir was studied in 30 patients suffering from various allergic dermatoses. We feel that this drug is a safe and potent antipruritic remedy and is of great value in the management of urticaria and lichen urticatus. The added advantage of this drug is that it can be administered easily to infants and children because it is available in the form of a flavoured liquid. No untoward effects were noted in this study.

Rapid industrialization and development of technology has resulted in the explosive production of a number of chemicals, paints, synthetic fibres, metal products and a wide range of cosmetics. These products are well known for their sensitizing properties and are responsible for the recent increase in the incidence of allergic dermatoses. The role of histamine in allergy is well established. Greaves and Sondergaard[1] recovered histamine from the inflammatory exudate of several cutaneous disorders. It has been reported by Kirkby[2] that the exposure of rat and human skin to 10^{-4} M concentration of histamine in vitro induces inflammatory responses at the cellular and sub-cellular levels. Exposure of human skin in vitro to histamine enhances the permeability of lysosomes and mitochondria and evokes changes exactly similar to inflammation. Thus there is much evidence to say that histamine is one of the inflammatory mediators.

The fact that histamine is concerned in pathological process of allergy has led to the introduction of antihistaminics in the management of several allergic dermatoses. Antihistaminics are competitive antagonists to the histamine and act by selectively blocking the receptor sites of the cell without interfering with the release of histamine. Even in therapeutic doses these drugs may produce untoward effects such as drowsiness and sedation. These products are administered in the form of tablets, spansules, elixirs, and injections but not topically because of the risk of sensitization. Several of these drugs are available in the market and often keep the physician in a dilemma when trying to make the proper choice. Keeping these points in view, we planned a study to evaluate the clinical efficacy and safety of 'Histryl' elixir in the management of various allergic dermatoses.

Pharmacology:—'Histryl' elixir is a clear yellow, flavoured liquid ; each 5 ml.

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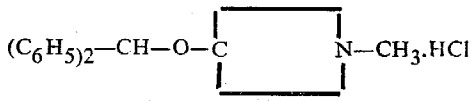
dose containing 1.5 mg. diphenylprayaline hydrochloride. The chemical structure is as follows:



(1-methyl-piperidyl-4-benzhydryl ether)

Recently Swartz[3], Maxwell[4], O'Connell[5], Yawalkar et al[6] and Gill and Govinda Mohan[7] conducted clinical trials with 'Histryl' spansules.

Material and Methods

The present study included 30 patients suffering from various allergic skin disorders attending the Skin Out-patients Clinic of S.S.L. Hospital, Varanasi. Of 30 cases observed, 11 had lichen urticatus, 8 infantile eczema, 6 urticaria, 3 infectious eczematoid dermatitis, 2 atopic dermatitis and one nummular eczema. Duration of their diseases varied from 2 weeks to 6 months. The diagnosis was made on the basis of history and clinical features. The patients were of either sex and in the age group of 6 months to 60 years. (Table 1). None of them had previous therapy with antihistaminics or corticosteroids for the preceding two weeks. Initially the patients were examined and symptoms like itching, burning, oozing, rash and urticaria were recorded as mild (+), moderate (++) and severe (+++). Then they were asked to take 'Histryl' elixir (5 ml. dose contains 1.5 mg. diphenylpyraline hydrochloride) in the following dose schedule for a period of 2 weeks.

0 — 3 years — $\frac{1}{4}$ TSF 6th hourly
3 — 6 years — $\frac{1}{2}$ TSF 6th hourly
6 — 12 years — 1 TSF 6th hourly
12 — and above — 2 TSF 6th hourly

The patients were examined at weekly intervals and the symptoms were noted at each visit as per previous grading. During the trial-period patients were instructed not to take any other medication and advised to inform the physician if they experienced any untoward effects such as drowsiness, sedation or dryness of mouth. The clinical improvement (antipruritic effect) was assessed in each patient at the end of first and second week therapy and the results were recorded as good, fair and poor.

Observations

The following features were noted during the clinical evaluation of 'Histryl' elixir in the management of various allergic dermatoses.

In this study males : females ratio is 2 : 1.

'Histryl' elixir was found to be an effective antipruritic agent in our study, (Table 2). Out of 30 patients observed the response was good in 14 cases, fair in 10 cases and poor in 6 cases at the end of the first week. The results at the end of the second week therapy were good in 16 cases, fair in 11 cases and poor in 3 cases. No untoward effects were noted during this study.

Conclusion

The main purpose of this study was to observe the anti-pruritic action of

TABLE 1

Age and Sex Distribution

Total No. of cases	Males	Females	AGE IN YEARS							
			0—1	2—5	6—10	11—20	21—30	31—40	41—50	51—60
30	20	10	3	14	3	3	3	1	2	1

TABLE 2

Showing Clinical Improvement (Antipruritic effect)

Diagnosis	No. of cases	At the end of 1st week			At the end of 2nd week		
		Good	Fair	Poor	Good	Fair	Poor
Lichen Urticatus	11	5	3	3	6	4	1
Urticaria	5	4	1	—	5	—	—
Infantile eczema	8	3	3	2	3	4	1
Infectious eczematous dermatitis	3	2	—	1	2	—	1
Nummular eczema	1	—	1	—	—	1	—
Atopic dermatitis	2	—	2	—	—	2	—

'Histryl' elixir in various allergic skin disorders. Our results indicated that this drug is an effective and safe antihistaminic. In the majority of the patients (90%) the antipruritic effect was considerable and more so in cases of urticaria and lichen urticatus. No fresh wheals were seen as long as the drug was taken. In a small number of cases (10%) the results were not convincing because of associated secondary infection and eczematization. These cases required concomitant antibiotic and/or steroid therapy.

Yawalkar et al[6] observed gratifying results with 'Histryl' spansules in the management of various skin disorders. The clinical efficacy of 'Histryl' spansules was evaluated in allergic rhinitis with good response by several workers [3, 4, 5, 7]. Our results with 'Histryl' elixir in the management of various allergic skin conditions observed in the present study are in confirmation with those of the above authors. The added advantage with this product is that it can be easily administered to the infants and children because it has been dispensed in a flavoured, palatable syrup.

Acknowledgements

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