CLINICAL EVALUATION OF TAVEGYL (HS-592) IN SKIN DISORDERS

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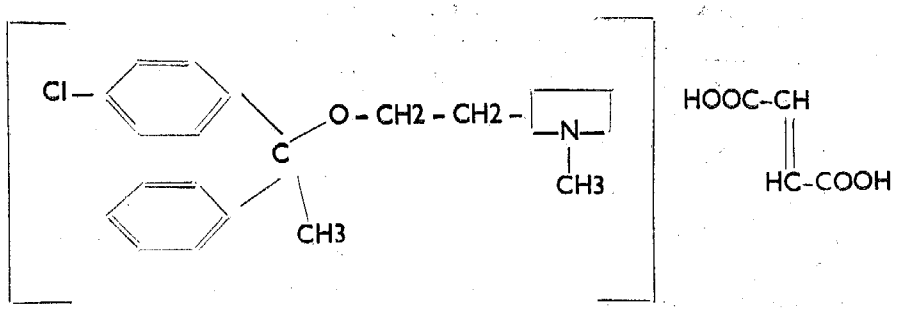
Tavegyl is the hydrogen fumarate of 1-methy 1-2-[2-(∝-methyl-p-chlordiphenylmethyloxy ethyl] pyrrolidine. It has the following structure :—



The ethyl-2-pyrrolidinyl structure is new to antihistamines. Tavegyl has been found to be very well tolerated and is devoid of embryotoxic and teratogenic properties. Special features of Tavegyl are :—

1. Powerful selective inhibition of histamine
2. Pronounced reduction in capillay permeability
3. Prompt antipruritic effect
4. Long duration of action and
5. Negligible side-effects.

So far, Tavegyl has been successfully tried abroad on about 3,000 patients. Kerp and Wodiansky have shown that Tavegyl has a striking inhibitory effect on histamine and compound 48/80 skin reactions. They found the drug equally effective by the parenteral as well as oral route. Tavegyl has so far been tried clinically in 1,555 dermatological cases and very good or good results were obtained in 79 2 per eent of these cases. In Nasemann's series of 196 cases, itching could be improved in 81% of the cases. In patients with acute or chronic urticaria, not only itching but also new crops of wheals were considerably reduced. So far, the longest time of administration of the drug was recorded on a 26-year old female with severe urticaria. She took Tavegyl for 18 months with short interruptions and tolerated it very well (Nasemann).

Material and Methods. Patients attending the Dermatology Clinic of the Government G. T. Hospital, Bombay, were included in a controlled study on Tavegyl

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in which its clinical efficacy was compared with a placebo. Similarly looking tablets coded as HSX and HSY were supplied to us. The study started as a double-blind one but HSX tablets had to be stopped after 12 patients since the results were obviously poor. HSY tablets were tried in 38 patients. HSX and HSY both were tried in two patients. The series comprised of a total 50 cases. Every patient received 1 tablet (1 mg.) b. d. for 15 days. Other forms of therapy, e. g. other antihistaminics, corticosteroids, calcium preparations, tranquillisers and local therapy were not given to the patients meant for this study. All the patients were followed up for 15 days. 24 patients were men while 26 patients were women.

HSX series of cases comprised of following :—

Chronic eczematous dermatitis	5	cases
Neurodermatitis	1	case
Lichen planus	3	cases
Dermatitis venenata	1	case
Scabies with secondary eczematization	1	case
and Tinea circinata with secondary eczematization	1	case

HSY series of cases comprised of below-mentioned 38 cases :—

Chronic eczematous dermatitis	16	cases
Tinea circinata with secondary eczematization	7	cases
Scabies with secondary eczematization	5	cases
Urticaria	4	cases
Angioneurotic cedema with urticaria	1	cases
Neurodermatitis	2	cases
Essential pruritus	2	cases
Dermatitis Herpetiformis	1	cases

As the main aim of this study was to evaluate the antipruritic effect, only the cases complaining of severe itching were included in this study. Except HSX or HSX tablets, no other internal or external therapy was allowed in these cases. Subjective symptoms like itching, smarting were recorded as: severe + + +, moderate + + and negligible +. All patients were called every 5 days for clinical evaluation and for noting the side-effects or toxic reactions of the drug. Clinical response was labelled as 'good, fair and poor'. In 17 cases, following investigations were done to detect any side-effect of the drug on liver and haematopoietic system :—
RBC, Hb, WBC, E. S. R., routine urine examination, serum bilirubin, serum alkaline phosphatase, zinc turbidity and Vanden Bergh.

Observations : In this series, HSX tablets rendered poor results in 10 case and showed fair antipruritic effect only in 2 cases (table 1). HSX were placebo tablets.

TABLE 1

HSX TABLETS

Disease	Total No. of cases	Clinical Response Good	Fair	Poor
Scabies with secondary sensitization	1		1	1
Fungus with secondary ecsematization	1			1
Eczematous dermatoses	5			5
Neurodermatitis	1			1
Dermatitis venenata	1			1
Lichen planus	3		1	2
	12	0	2	10

HSY tablets were tried in 38 cases. HSY tablets gave good antipruritic effect in 17 cases and fair results in 16 cases. There were poor results in only 5 out of the 38 cases.

HSY tablets were especially effective in controlling subjective symptoms in cases of urticaria, essential pruritus and eczematous dermatoses. As no topical applications were allowed, only negligible objective improvement was noticed in the lessions.

TABLE 2

HSY TABLETS

Disease	Total No. of cases	Good	Fair	Poor
Eczematous dermatitis	16	8	6	2
Fungus infection with eczsematization	7	1	5	1
Scabies with eczaematization	5	2	2	1
Urticaria	4	3	1	
Neurodermatitis	2	1	1	
Essential pruritus	2	1	1	
Dermatitis Herpetiformis	1			1
Angioneurotic oedema	1	1		
	38	17	16	5

Side-effects and Toxic Reactions. In this series of 38 cases, Tavegyl (HSY) tablets were extremely well tolerated. Most of the patients tolerated the drug well. Only 3 out of 38 patients complained of mild and minor side-effects, e. g. one with mild diarrhoea, one of dryness of mouth for 8 days, and slight drowsiness in one patient. Liver function tests and other investigations did not reveal any toxic action of Tavegyl on liver, kidneys and haematopoietic system. The drug was well accepted by all the patients and in no case had the drug to be discontinued due to sedation or adverse effects.

Summary and Conclusion : In a controlled comparative study, the antihistaminic Tavegyl was found to have good antipruritic effect. In this series of 38 patients, the clinical response was good in 17 cases and fair in 16 cases. Only in 5 cases were the results poor. Tavegyl was very well tolerated and no adverse effects or toxic reactions were observed in this series. Tavegyl is no doubt a valuable addition to the available antihistmlnics with potent antihistaminic effect. It is especially effective in cases of eczematous dermatoses, superficial fungus infections with secondary eczematization, neurodermatitis, urticaria, angioneurotic oedema and essential pruritus.

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