

The following criteria were used to diagnose the psychosomatic cases.

1. *Anxiety neurosis*: Apart from the clinical signs and symptoms, the anxiety score and neuroticism index were measured. EEG, especially the alpha wave pattern, formed the main criterion for the diagnosis of anxiety neurosis. The galvanomic skin response was also measured to diagnose the anxiety state.
2. *Early thyrotoxicosis* was confirmed from the management of I-131 uptake and serum PBI. Similarly, wherever required, T-3 and T-4 were also measured.
3. *Essential hypertension* was confirmed following successive blood pressure recordings, bearing in mind the age and sex of the individual patient. Renal cardiac functions were also determined. We excluded those cases who revealed some physical involvement such as diabetes mellitus or ischaemic heart disease.
4. *Ulcerative colitis* was diagnosed by barium meal X-ray and sigmoidoscopic examinations.

After confirmation of the diagnosis, the cases were subjected to comprehensive clinical, laboratory and psychological investigations to evaluate their psychobiological status before therapy. Of the 115 psychosomatic patients, 31 cases were given a placebo. Similarly, for comparison, 10 of the 40 apparently normal individuals were given a placebo. Comparisons between the study groups and the placebo groups were made using a double-blind method.

Acetylcholine was estimated according to the bioassay method developed by McIntosh⁵ and modified by Pandey *et al.* (1975). Platelet monoamine oxidase was assayed using C¹⁴ tryptamine bisuccinate (specific activity 51.5 mci/mmol) as reported by Parvez and Parvez (1973).⁶ Similarly, plasma cortisol was measured following the method of Mattingly (1962).⁷ In order to observe the effect of 'Geriforte' on skeletal muscles, frequent electromyographic recordings were made. All these investigations were repeated at monthly intervals to assess the changes following 'Geriforte' therapy. The data obtained were then analyzed and compared.

RESULTS

Specific clinical features such as palpitation, nervousness, precordial discomfort and insomnia underwent considerable improvement after therapy. In the Geriforte group, 89.5% of cases showed a significant improvement in their physical and mental health. In the placebo group, no change was observed. No tranquillizers or psychotropic drugs were given apart from specific conventional therapy for each clinical condition. The initial values of acetylcholine revealed a significant improvement after 3 months of 'Geriforte' therapy, except in early thyrotoxicosis cases. In the placebo group, no change was observed in the acetylcholine level (Table 1).

Platelet monoamine oxidase showed considerably lower values in thyrotoxicosis, hypertension and ulcerative colitis cases. In anxiety neurosis cases, the average value was similar to that in the normal series. After 3 months of therapy, there was a significant increase in platelet monoamine oxidase in early thyrotoxicosis and essential hypertension cases. In contrast, the placebo group did not reveal any change (Table 2).

Table 1: Changes in acetylcholine levels following 'Geriforte' therapy							
Sl. No.	Group	Initial value (µg/ml)	After therapy (µg/ml)			Comparison (p) (initial value vs. 3 rd month of therapy)	
			1 st month	2 nd month	3 rd month		
1.	Normal						
	i.	Placebo (n=10)	0.782 ± 0.15	0.800 ± 0.32	0.786 ± 0.28	0.780 ± 0.21	>0.05
	ii.	Treated with Geriforte (n=30)	0.72 ± 0.15	0.725 ± 0.08	0.676 ± 0.09	0.551 ± 0.51	<0.05
2.	Anxiety neurosis						
	i.	Placebo (n=7)	1.856 ±0.85	1.615 ± 0.89	1.480 ± 0.80	1.350 ± 0.78	>0.05
	ii.	Treated with Geriforte (n=26)	1.981 ± 0.57	1.675 ± 0.32	1.250 ± 0.27	0.989 ± 0.28	<0.001
3.	Thyrotoxicosis						
	i.	Placebo (n=8)	1.618 ± 0.96	1.565 ± 0.90	1.560 ± 1.06	1.316 ± 0.92	>0.05
	ii.	Treated with Geriforte (n=16)	1.520 ± 0.98	1.385 ± 0.19	1.210 ± 1.02	0.971 ± 0.76	>0.05
4.	Hypertension						
	i.	Placebo (n=10)	1.386 ± 0.48	1.350 ± 0.51	1.285 ± 0.47	1.265 ± 0.44	>0.05
	ii.	Treated with Geriforte (n=16)	1.356 ± 0.28	1.287 ± 0.26	1.191 ± 0.28	0.980 ± 0.37	<0.001
5.	Ulcerative colitis						
	i.	Placebo (n=6)	1.488 ± 0.28	1.465 ± 0.32	1.378 ± 0.30	1.305 ± 0.23	>0.05
	ii.	Treated with Geriforte (n=16)	1.450 ± 0.33	1.365 ± 0.28	1.182 ± 0.25	0.880 ± 0.38	<0.05

Table 2: Platelet monoamine oxidase activity following oral administration of Geriforte							
Sl. No.	Group	Initial value (n moles /mg/hr)	After therapy (n moles/mg/hr)			Comparison (p) (initial value vs. 3 rd month of therapy)	
			1 st month	2 nd month	3 rd month		
1.	Normal						
	i.	Placebo (n=10)	2.160 ± 0.38	2.195 ± 0.41	2.206 ± 0.39	2.215 ± 0.36	>0.05
	ii.	Treated with Geriforte (n=30)	2.350 ± 0.299	2.428 ± 0.385	2.403 ± 0.258	2.492 ± 0.310	>0.05
2.	Anxiety neurosis						
	i.	Placebo (n=7)	1.986 ±0.41	2.008 ±0.43	2.116 ± 0.52	2.135 ± 0.42	>0.05
	ii.	Treated with Geriforte (n=20)	2.081 ±0.815	2.095 ±0.610	2.185 ±0.522	2.215 ±0.650	>0.05
3.	Thyrotoxicosis						
	i.	Placebo (n=8)	1.386 ±0.29	1.596 ±0.38	1.705 ±0.31	1.785 ± 0.30	>0.05
	ii.	Treated with Geriforte (n=22)	1.355 ± 0.219	1.420 ± 0.401	1.510 ± 0.372	1.812 ± 0.281	<0.01
4.	Hypertension						
	i.	Placebo (n=10)	1.495 ±0.31	1.508 ±0.40	1.615 ± 0.30	1.668 ± 0.33	>0.05
	ii.	Treated with Geriforte (n=26)	1.508 ± 0.210	1.610 ± 0.421	1.750 ±0.281	1.958 ±0.350	<0.001
5.	Ulcerative colitis						
	i.	Placebo (n=6)	1.365 ±0.38	1.385 ± 0.42	1.496 ± 0.40	1.790 ±0.39	>0.05
	ii.	Treated with Geriforte (n=16)	1.426 ± 0.805	1.521 ± 0.850	1.650 ± 0.612	1.782 ± 0.541	>0.05

After 3 months of 'Geriforte' therapy, the plasma cortisol demonstrated a decreasing trend as compared to the initial values in early thyrotoxicosis, hypertension and ulcerative colitis cases. Anxiety neurosis cases in the normal series and the placebo group showed no significant change in plasma cortisol after repeated estimations (Table 3). Electromyographic recordings confirmed considerable muscle relaxation in all the cases of psychosomatic disorders after the oral administration of 'Geriforte' (Figs. 1a and 1b).

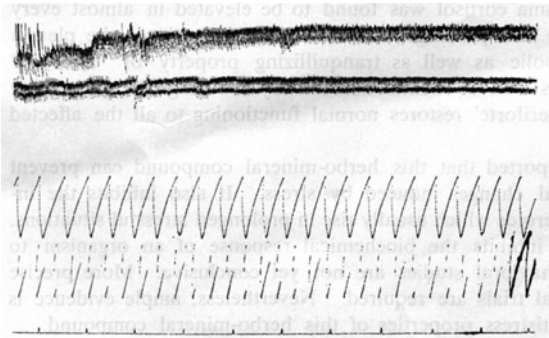


Fig. 1 (a): EMG pattern in anxiety neurosis before Geriforte therapy

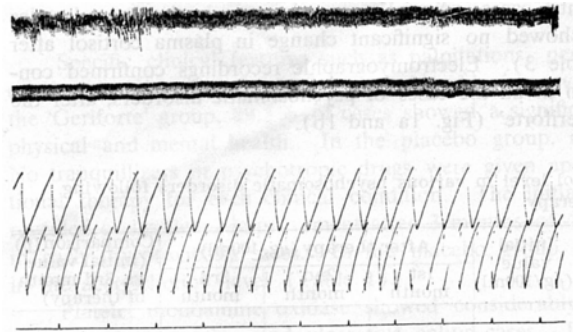


Fig. 1(b): EMG changes in anxiety neurosis following Geriforte therapy

DISCUSSION

It is now generally accepted that constant stress has a profound effect on the body. Adrenocorticotrophic hormone (ACTH), growth hormone and thyroid stimulating hormone (TSH) all demonstrate altered levels in response to stress. Acetylcholine, β -adrenergic catecholamines and plasma cortisol also increase following continuous stress. Anselmi *et al.* (1976)⁸ reported a 40% lower MAO activity in hypertension than that of the control group. Low MAO activity may be associated with a vulnerability to psychosomatic disorders. The role of MAO activity in stress disorders and the effect of stress on epinephrine and norepinephrine levels have been extensively investigated in recent years. Being a metabolizing enzyme, platelet monoamine oxidase is of great clinical value in the assessment of stress factors. In the present study, a significant elevation of platelet monoamine oxidase activity was observed following 'Geriforte' therapy. This provides ample evidence of the antistress property of 'Geriforte'. A negative correlation between platelet monoamine oxidase and acetylcholine was observed in hypertension cases ($r=0.52$). A similar correlation was also found in the normal series of cases ($r=0.38$), ($p<0.05$).

It is well known that plasma cortisol increases in chronic stress disorders. In the present series, plasma cortisol was found to be elevated in almost every stress disorder. Constant and prolonged use of 'Geriforte' reduces the plasma cortisol level. The anabolic as well as tranquillizing property of 'Geriforte' improves both physical as well as mental health. By reducing the excitability of the nervous system, 'Geriforte' restores normal functioning to all the affected organs.

We have already reported that this herbomineral compound can prevent or ameliorate biochemical changes induced by stress. It also inhibits the increase of plasma corticosteroids, which usually rise in prolonged stressful situations.

In brief, 'Geriforte' inhibits the biochemical response of an organism to stress. However, the behavioural studies are not yet conclusive. More precise and comprehensive clinical trials are required. Nevertheless, ample evidence is available to verify the antistress properties of this herbomineral compound.

Table 3: Plasma cortisol levels in various psychosomatic disorders following Geriforte therapy						
Sl. No.	Group	Initial value (µg /100 ml)	After therapy (µg/100 ml)			Comparison (p) (initial value vs. 3 rd month of therapy)
			1 st month	2 nd month	3 rd month	
1.	Normal					
	i. Placebo (n=10)	21.65 ± 8.75	20.95 ± 9.01	20.86 ± 9.21	20.50 ± 8.79	>0.05
	ii. Treated with Geriforte (n=30)	20.89 ±8.68	19.25 ± 5.87	16.50 ± 6.91	15.82 ± 8.12	>0.05
2.	Anxiety neurosis					
	i. Placebo (n=7)	24.86 ±4.85	24.50 ± 5.61	24.00 ± 5.15	22.85 ± 5.32	>0.05
	ii. Treated with Geriforte (n=26)	22.85 ± 4.89	20.70 ± 3.57	17.92 ±3.95	15.72 ±8.90	>0.05
3.	Thyrotoxicosis					
	i. Placebo (n=8)	31.65 ± 5.69	29.00 ±5.72	28.60 ± 5.81	27.50 ± 5.86	>0.05
	ii. Treated with Geriforte (n=16)	30.78 ± 4.05	31.48 ± 3.52	27.55 ± 5.80	24.80 ± 5.42	<0.01
4.	Hypertension					
	i. Placebo (n=10)	36.50 ± 4.98	33.85 ± 5.31	31.00 ± 5.01	28.85 ±5.17	>0.05
	ii. Treated with Geriforte (n=16)	38.96 ± 8.80	34.32 ± 7.92	29.58 ± 6.72	26.50 ± 9.16	<0.001
5.	Ulcerative colitis					
	i. Placebo (n=6)	30.55 ±7.88	28.65 ± 8.02	28.50 ± 7.96	26.50 ± 8.11	>0.05
	ii. Treated with Geriforte (n=16)	30.75 ± 8.21	28.45 ± 6.62	25.96 ± 3.12	20.68 ±8.25	<0.001

SUMMARY

Many indigenous compounds are used in the management of anxiety and stress. Scientific evaluation of such compounds is limited. To assess the antistress properties of the indigenous compound 'Geriforte', 115 cases of various psychosomatic disorders and 40 apparently normal cases were selected. After comprehensive follow-up, a significant improvement in clinical symptomatology was observed in all the stress disorders. Acetylcholine and plasma cortisol were significantly decreased after continuous therapy in early thyrotoxicosis, essential hypertension and ulcerative colitis. Platelet monoamine oxidase showed a significant increasing trend after oral administration of the drug. 'Geriforte' has been shown to provide an effective control of successive muscle spasm. This herbomineral compound prevents or ameliorates neurohumoral and enzymatic changes induced by anxiety and stress. No side-effects have been noted even following over-dose or prolonged use of the drug.

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