REPORT ON CLINICAL TRIAL OF STRESS GUARD CAPSULE

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REPORT ON THE CLINICAL TRIAL
OF
"STRESS GUARD" CAPSULE IN STRESS DISORDERS

INTRODUCTION:

Most people find it difficult to define stress, yet they can experience it often. In general term, stress can be defined as an excessive demand on physical and mental energy, often leading to anxiety anger, distress, fear, irritability and frustration. This causes in increase in the secretions of pituitary, adrenal and thyroid hormones and angiotension secretion from kidneys. All these lead to rise in the cholesterol levels as well as rise in blood pressure.

A stressful life styles resulting from day to day problems of finance, education, family and inter personal relationships; as also the demand of work, travel, insecurity job and business, and an urge to exceed and accomplish more that what we already possess- all lead to a degree of stress that results in slow but progressive damage to our different system.

Stress is a time bomb that must be diffused. One should develop the art of laughing. In fact laughter is the best medicine for stress and stress related diseases smiling and laughing can bring about positive changes in our body hormone.

So reducing the stress level cannot only protect from the disease but also enhance our quality of life enormously.

According to latest health report, stress is said to be one of the largest killer of man today. It is now becoming more accepted as being crucially related to our total health – physical, mental and emotional.

Two powerful body systems cope with stress. The nervous system control the rapid body changed, while endocrine system regulates by releasing hormones into the blood. The adrenal activates the sympathetic nervous system, reducing the normalizing effects of body function. This increases the metabolic rate, heart rate, circulation and blood pressure. In addition, effectiveness of the digestive system is diminished and disturbances in sleep pattern become common.

AIMS AND OBJECTS :

To evaluate the therapeutic value of "STRESS GUARD" capsule in the patients of stress disorders, the present clinical trial was undertaken. Total 45 cases have been included in this study who were studies in different groups, viz. trial group and control group. Trial group included 30 patients to whom STRESS GUARD, trial product was administered. Control group included 15 patients to whom placebo was administered in the similar way.

MATERIAL AND METHOD :

45 patients of stress disorder were registered during the course of trial. The study consisted clinical patterns in stress disorder and the management of the particular conditions with "STRESS GUARD" capsule.

Out of 30 patients of the trial group, 26 cases had completed the full treatment schedule (i.e. 60 days) till now and remaining 4 cases had discontinued the course of treatment.

The control group included 15 patients, out of which 10 patients, followed the full term treatment (i.e. 60 days) and rest 5 patient had discontinued the course of treatment.

The clinical pattern were studied in all 45 cases for incidence of age, sex (male & female), religion, occupation, economic status, educational status, social status and symptoms of stress disorders following the incidence of blood cortisol, which will be presented in the final reports.

Selection of Cases:

All patients selected for study were interrogated and the details history was recorded in the prescribed case history sheet. All patients were thoroughly examined and findings were also recorded. To establish the final diagnosis, the Blood Cortisol was done and routine examination of blood; stool and urine etc. were also done, in addition to the observation of subjective features.

Criteria of Final Diagnosis:

All the patients included in clinical study were carefully examined and records were maintained with detail clinical history. The individual who have symptoms of stress disorders with or without raised Blood Cartisol levels were subjected to clinical trial.

Method of Drug Administration:

The product "STRESS GUARD" was administered orally to the patients of the trial group in the form of capsules prepared and supplied by Goodcare Pharma Pvt. Ltd., 1 Gupta Lane, Kolkata – 700006. The patients of stress disorders taken for the study were administered 2 capsules (each 500mg) twice daily morning and evening with water for a period of 60 days.

'Placebo' capsule was administered orally to the patients of control group in the similar way which was also prepared and supplied by the Goodcare Pharma Pvt. Ltd., 1 Gupta Lane, Kolkata – 700006.

Diet:

Any specific diet schedule was not prescribed to the patients.

Follow Up:

Follow up study was conducted in all cases at interval of 15 days for 2 months (60 days). Blood Cortisol was done in each case before treatment and after 2 months (60 days) of treatment. Cortisol was done in each case before treatment and after 60 days of treatment.

CLINICAL PATTERN:

The present study consists of total 45 cases who have symptoms of stress disorders and completed the full course of treatment schedule (i.e 60 days). Though we had registered 45 cases for the present study, out of which 10 cases (5 patient trial group and 5 patient control group) had not completed the full course of treatment. So the clinical pattern will be discussed on 45 cases. But the result will be analyzed on observation of the findings of 36 cases (i.e 26 patient in trial group and 10 patients in control group).

Age Incidence:

Patients of the present study were from 20 to 60 years of age. Patients of different age group are given in Table No. 1

Table 1: Showing the incidence of different Age Group

Sl. No.	Age Group (years)	No. of patients	Percentage
1.	20 – 35	15	33.33
2.	36 – 50	20	44.45
3.	51 and above	10	22.22
	Total	**45**	**100.00**

Sex Incidence:

Patients of both sexes were registered for the present study. The sex groups are given in Table No. 2.

Table No. 2: Showing the incidence of Sex

Sl. No.	Sex	No. of patients	Percentage
1.	Male	37	82.22
2.	Female	08	17.78
	Total	**45**	**100.00**

Religion Incidence:

Patients of various religions were included in this study. Patients belonging to different religion are shown in Table No. 3.

Table No. 3: Showing the incidence of Religion

Sl. No.	Religion	No. of patients	Percentage
1.	Muslim	04	08.89
2.	Hindu	38	84.44
3.	Christian	03	06.67
	Total	**45**	**100.00**

Occupation Incidence:

In this study patients belonging to various occupations were included and shown in Table No. 4

Table No. 4: Showing the incidence of Occupation

Sl. No.	Occupation	No. of patients	Percentage
1.	Service	09	20.00
2.	House wives	06	13.33
3.	Cultivator	03	06.67
4.	Student	06	13.33
5.	Labour	09	20.00
6.	Businessmen	08	17.78
7.	Retired	04	8.89
	Total	**45**	**100.00**

Economic Status:

In this study patients of different income groups were recorded and shown in Table No. 5.

Table No. 5: Showing the incidence of Income Status

Sl. No.	Income Status	No. of patients	Percentage
1.	H.I.G	10	22.22
2.	M.I.G	15	33.33
3.	L.I.G	20	44.44
Total		**45**	**100.00**

Educational Status:

When educational status was enquired, patients of both literate and illiterate were found in the series. The educational status as found are given in Table No. 6.

Table No. 6: Showing the incidence of Educational Status

Sl. No.	Educational Status	No. of patients	Percentage
1.	Illiterate	3	06.67
2.	Primary	16	35.56
3.	Madhyamik	7	15.56
4.	Higher Secondary	6	13.32
5.	Graduate	11	24.44
6.	Post graduate	2	04.45
Total		**45**	**100.00**

Rural and Urban Incidence:

This study included patients from urban and rural areas and shown in Table No. 7.

Table No. 7: Showing the incidence of Rural and Urban

Sl. No.	Rural/ Urban	No. of patients	Percentage
1.	Rural	17	37.78
2.	Urban	28	62.22
Total		**45**	**100.00**

Incidence of Diet Habits:

Patients included in the present study were found to have both types of diet habits (vegetarian and non-vegetarian), which are presented in Table No. 8.

Table No. 8: Showing the incidence of Diet Habits

Sl. No.	Diet Habits	No. of patients	Percentage
1.	Non Vegetarian	34	75.56
2.	Vegetarian	11	24.44
Total		**45**	**100.00**

Incidence of Nature of Work:

In this trial study of work were studied which are presented in Table No. 9

Table No. 9: Showing the incidence of Nature of Work

Sl. No.	Nature of Work	No. of patients	Percentage
1.	Sedentary	25	55.55
2.	Moderate	12	26.67
3.	Hardworker	08	17.78
Total		**45**	**100.00**

Incidence of Marital Status:

In this study married and unmarried both patients are included which are presented in Table No. 10.

Table No. 10: Showing the incidence of Marital Status

Sl. No.	Marital Status	No. of patients	Percentage
1.	Unmarried	10	22.22
2.	Married	35	77.78
Total		**45**	**100.00**

RESULT AND OBSERVATION :

Response of Treatment in Group A (Trial Group):

Group A or Trial Group consisted of 30 patients, out of which four patients had discontinued and 26 cases had completed the treatment schedule of 60 days. Patients were observed in terms of subjective criterias before treatment, during treatment and after treatment. The response of treatment on subjective criterias as observed before treatment and after treatment are presented below in Table No. 11

Table No. 11: Showing the response of treatment on subjective features of stress disorders in trial group (Group A).

Sl. No.	Symptoms	No.of patients B.T	No.of patients Relieved A.T	Percentage of Relief
1.	Anorexia	25	16	64.00
2.	Apprehension	24	17	70.83
3.	Breathlessness	24	16	66.67
4.	Constipation	20	16	80.00
5.	Diarrhoea	26	17	65.39
6.	Disinterest of life	24	18	75.00
7.	Dizziness	20	14	70.00
8.	Fatigue	24	19	79.16
9.	Frequency of micturation	20	12	60.00
10.	Headache	22	12	54.55
11.	Hopelessness/Helplessness	20	14	70.00
12.	Inability to work	25	16	64.00
13.	Insomnia	20	12	60.00
14.	Lack of concentration	20	13	65.00
15.	Lack of self confidence	21	13	61.10
16.	Loss of libido	20	8	40.00
17	Loss of weight	20	9	45.00
18.	Pain-chest/ Abdomen	18	10	55.56
19.	Recurrent thought for death/ suicide	18	12	66.67
20.	Slowing of thinking	20	9	45.00
21.	Slowing of speed	21	11	52.39
22.	Skin rashes/ ulcer	11	5	45.46
23.	Sweating	22	14	63.64
24.	Tremor	15	9	60.00

It is revealed from the above table that more than 70% of relief was observed in symptoms like apprehension, disinterest of life, fatigue, hopelessness, dizziness and constipation. More than 50% of relief was observed in symptoms like recurrent thought for death, diarrhea, inability to work, anorexia, sweating, lack of concentration, lack of self confidence, frequency of micturation, insomnia, tremor, pain in chest or abdomen, headache etc. In other symptoms, the relief found was less than 50%. In all patients who had completed the treatment schedule of 60 days, were also observed in terms of improvements on objective freatures (estimation of Blood Cortisol Level AM). The level of cortisol was estimated before treatment and after treatment. The observations are presented statistically in Table No. 12.

Table No. 12: Showing the response of treatment on cortisol level (AM ng/dl) of blood in patients of stress disorders in trial group (Group A, n=26)

Sl.No.	Schedule of Examination	Mean	SD ±	SE ±	t	p
1.	Before Treatment	289.81	92.20	18.08	16.03	< 0.001
2.	After Treatment	254.92	71.81	14.08	18.11	

It is clear from the above table that in trial group (Group A) the mean level of cortisol before treatment was 289.81 ng/dl and reduced to 254.92 ng/dl (mean level) after treatment. The P-value is highly significant.

Response of treatment in Group 'B' (Control Group)

Group B or Control Group consisted of 15 patients out of which 5 patients had discontinued the treatment and 10 patients had completed the treatment schedule of 60 days. Patients were observed in terms of subjective features (as in Trial Group A) before treatment, during treatment and after treatment. The response of the treatment on subjective criterias as observed before the treatment and after the treatment are presented below in Table No. 13.

Table No. 13: Showing the response of treatment on subjective features of stress disorder in control group 'Group B'

Sl. No.	Symptoms	No.of patients B.T	No.of patients Relieved A.T	Percentage of Relief
1.	Anorexia	8	8	00.00
2.	Apprehension	6	7	-16.67
3.	Breathlessness	6	6	00.00
4.	Constipation	8	8	00.00
5.	Diarrhea	8	9	-12.50
6.	Disinterest of life	5	7	-40.00
7.	Dizziness	4	6	-50.00
8.	Fatigue	4	5	-25.00
9.	Frequency of micturation	7	7	00.00
10.	Headache	9	11	-22.22
11.	Hopelessness/Helplessness	4	6	-50.00
12.	Inability to work	5	6	-20.00
13.	Insomnia	8	10	-25.00
14.	Lack of concentration	7	8	-14.29
15.	Lack of self confidence	9	9	00.00
16.	Loss of libido	3	3	00.00
17	Loss of weight	6	7	-16.67
18.	Pain-chest/ Abdomen	4	4	00.00
19.	Recurrent thought for death/ suicide	7	7	00.00
20.	Slowing of thinking	5	5	00.00
21.	Slowing of speed	21	21	00.00
22.	Skin rashes/ ulcer	2	2	00.00
23.	Sweating	6	7	-16.67
24.	Tremor	3	3	00.00

The responses of treatment on subjective features in patients of Group B (control group) as revealed from the above table. It is found that there was no relief in subjective features.

Moreover, negative relief was observed in some of the subjective features like dizziness, helplessness, insomnia, fatigue, disinterest of life, headache.

In the patients of Group B (control group) who had completed the treatment schedule of 60 days, were also observed in terms of improvements on objective features (estimation of Blood Cortisol level-AM). The level of cortisol was estimated before treatment and after treatment. The observations are presented statistically in Table No. 14.

Table No. 14: Showing response of treatment on cortisol level (AM ng/dl) of blood in patients of stress disorders in Control Group B (N=10).

Sl. No.	Schedule of Examination	Mean	SD ±	SE ±	t
1.	Before Treatment	266.30	88.54	27.10	10.93
2.	After Treatment	311.40	86.55	8.66	35.96

The response of treatment on cortisol level in Group B (control group) shows that the mean cortisol level which was 266.30 ng/dl before treatment had increased upto 311.40 ng/dl after treatment. This indicates that there was no improvement in control group.

DISCUSSION:

In the present clinical study, 45 patients suffering from stress-disorders were included. The total cases were a randomly divided into two groups viz (1) Group A (Trial Group) consisted of 30 patients to whom "STRESS GUARD", the trial product was given for a period of 60 days; (2) Group B (Control Group) consisted of 15 cases to whom placebo was given for 60 days. Out of these cases 4 cases could not be followed in Group A (Trial Group) and 5 cases in Group B (Control Group). 26 cases in Group A (Trial Group) and 10 cases in Group B (Control Group) could be followed up properly.

In trial group to all the patients "STRESS GUARD" capsules (each 500mg) was given in the dose of 2 capsules twice daily morning and evening with water for a period of 60 days. Similarly in control group to all the cases 'PLACEBO' capsule (each 500mg) was given in the dose of 2 caps twice daily morning and evening with water.

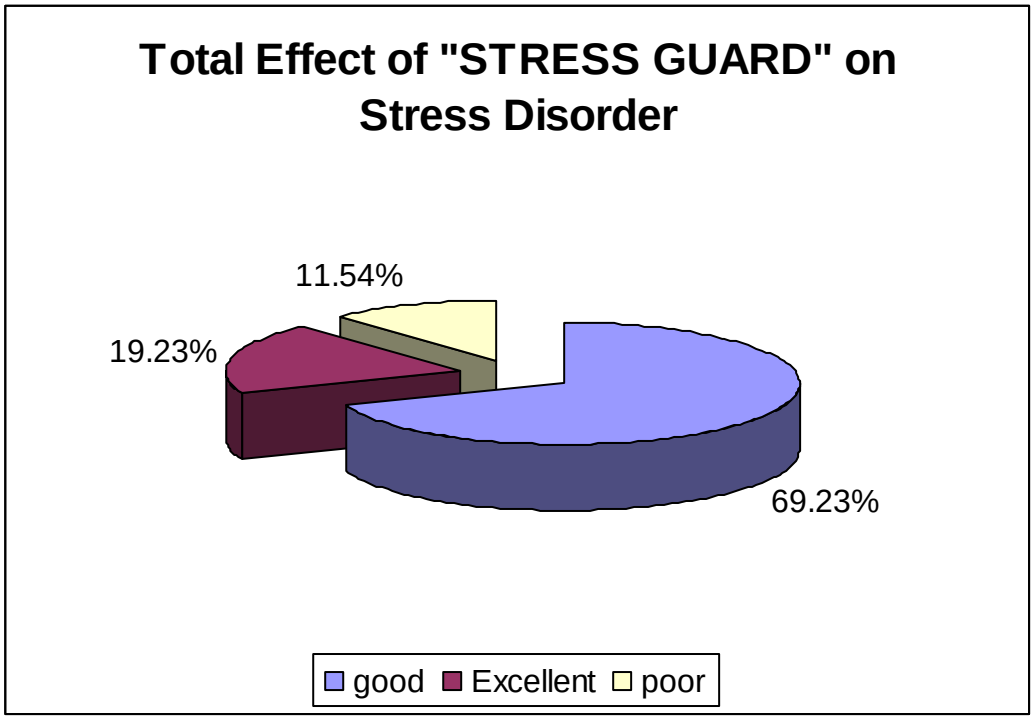
The effect of treatment on both the group of patients were assessed at the end of the treatment. The response of the treatment was observed mainly on subjective improvements. At the end of the treatment, the result was assessed in terms of excellent improvement, good improvement and poor improvement. The patients were included under excellent response group when they showed more than 70% relief of subjective features. The patients were included under good response group when they showed between 51 to 70% relief of subjective feature and patients showing relief of subjective features below 51% were leveled under poor response group. In consideration to the effects of the product in Trial Group 19.23% cases were included under excellent response group, 69.23% under good response groups and 11.54% in poor response group.

In the trial group in most of the cases of the cortisol level was found to be reduced. The effects of the treatment on cortisol levels in patient of group A (Trial Group) have been statistically analysed and found highly significant (P <0.001).

Any improvement in patients of Control Group (Group B) was not found when the effect of the treatment on subjective criterias were analysed. When the effect on cortisol level was observed, it was seen that the mean cortisol value which was 266.30 ng/dl before treatment had increased upto 311.40 ng/dl after treatment.

When the response of treatment in both the groups were analysed and compared, it is revealed that, there is definite improvement in the patients of Group A or Trial Group, treated with "STRESS GUARD".

During the clinical study of the "STRESS GUARD" capsules, none of the patients had shown any side effects.



CONCLUSION:

The product "STRESS GUARD" capsule has been found to be an effective product on stress disorders. The result in the trial group has shown encouraging results after 4 weeks of treatment, particularly on the subjective criterias. After 60 days of treatment along with the improvements of the subjective criterias significant response was also noticed on objective criteria, particularly on serum cortisol level in trial group. Hence "STRESS GUARD" can safely be prescribed in cases of stress.

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