REPORT ON CLINICAL TRIAL OF DIABET GUARD GRANULES

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REPORT ON THE CLINICAL TRIAL
OF
DIABET GUARD GRANULES IN DIABETES

INTRODUCTION:

Diabetes mellitus is a very common constitutional disease known since the ancient days. It is a heterogeneous primary disorder of carbohydrate metabolism with multiple etiological factors that generally involve absolute or relative insulin deficiency or insulin resistance or both. Due to advancement of the present civilization, urbanization, physical inactivity, over nutrition, chronic under nutrition, obesity, stress, drug abuses etc. the diabetes is becoming commoner day by day. It has world wide distribution. So far about 98.9 million sufferers of diabetes mellitus are in the world of which Asian countries contribute 46.9 millions, almost 50% diabetes of the world. About 20 million are in India.

AIM AND OBJECT:

To evaluate the therapeutic value of DIABET GUARD granules in the patients of DIABETES MELLITUS, the present clinical trial was undertaken. Total 59 cases have been registered for this study. Trial group included 46 cases to whom DIABET GUARD granules, trial product was administered and 13 cases included under control group to whom placebo was given.

MATERIAL AND METHOD:

Total 59 patients of DIABETES MELLITUS were registered during the course of trial. The study consists clinical patterns in Diabetes – Type 2 and the management of the particular condition with the DIABET GUARD granules and the effect of placebo in a control group. In this trial 59 cases were registered, among them 40 cases completed the total tenure of treatment and 19 cases had discontinued. 59 cases were randomly divided in two groups, viz trial group and control group. Trial group consisted of 46 cases, out of which 14 cases had dropped out. Control group consisted of 13 cases, out of which 5 cases had discontinued during the study period.

The clinical patterns were studied in all the 59 cases for incidence of Age, Sex, Religion, Occupation, Economic Status, Education and Social Status etc.

SELECTION OF CASES:

All the patients selected for the study were interrogated and detailed history were recorded in the case record form. All the patients were thoroughly examined and findings were recorded. To establish the final diagnosis the fasting blood sugar and the Post Prandial Blood Sugar (after 75gm of glucose intake), urine for sugar, were 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 diabetes with raised Blood Sugar (Post Prandial) levels above 180 mg/dl were subjected to clinical trial.

METHODS OF DRUG ADMINISTRATION:

The drug DIABET GUARD granules was prepared and supplied by Goodcare Pharma Pvt. Ltd. for the study in this trial. The patients taken for the study were suffering from diabetes type 2 and the drug was administered in the dose of 1 tsf (6gm) twice daily before meal orally for 90 days with water, to all the cases of trial group. To all the patients of control group placebo was given in a similar pattern.

FOLLOW UP:

Follow up study was conducted in all cases at interval of 4 week for 3 months (90 days). Blood Sugar, Fasting & Post Prandial, urine sugar level, body weight was done in each before treatment and after each month of treatment for 3 months. Finally the result was compared with pretreatment and post treatment observation.

CLINICAL PATTERN:

The present study consists of total 59 cases who have symptoms of diabetes – among them 40 cases completed the full course of treatment schedule (i.e. 90 days) and 19 cases had not completed the full course of trial. But the clinical pattern will be discussed in all 59 cases. The result will be analyzed on observation of the findings of 40 cases.

Age Incidence:

Patients of the present study were from 31 to 70 years of age. Patients of different age group are given in table no. 1.

Table No. 1: Showing the incidence of different age group.

Sl. No.	Age Groups (Years)	No. of Patients	Percentage
1.	31 – 40	15	25.42
2.	41 – 50	22	37.29
3.	51 – 60	14	23.73
4.	61 – 70	08	13.56
Total		**59**	**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	38	64.40
2.	Female	21	35.60

Total	**59**	**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	25	42.38
2.	Hindu	19	32.20
3.	Christian	15	25.42
Total		**59**	**100.00**

Occupational Incidence:

In this study patients belonging to various occupations were included. The occupational history as recorded are shown in table no. 4.

Table No. 4: Showing the Incidence of occupation

Sl. No.	Occupation	No. of Patients	Percentage
1.	Service	14	23.73
2.	Housewives	9	15.25
3.	Labour	9	15.25
4.	Cultivator	6	10.17
5.	Student	3	05.09
6.	Businessmen	13	22.03
7.	Retired	5	08.48
Total		**59**	**100.00**

Economical Status Incidence:

In this study patients of different income group 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.	LIG	26	44.07
2.	MIG	21	35.59
3.	HIG	12	20.34
Total		**59**	**100.00**

Educational Status:

When educational status was enquired, patients of both literate and illiterate group were found in this 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	14	23.73
2.	Primary	11	18.64
3.	Madhyamik	11	18.64
4.	Higher Secondary	10	16.95
5.	Graduate	07	11.87
6.	Post Graduate	06	10.17
Total		**59**	**100.00**

Rural 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	23	38.98
2.	Urban	36	61.02
Total		**59**	**100.00**

Incidence of diet habit:

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	49	83.05
2.	Vegetarian	10	16.95
Total		**59**	**100.00**

Incidence of Nature of work:

In this trial nature 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	30	50.85
2.	Moderate	22	37.29
3.	Hardworker	07	11.86

Total	**59**	**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	12	20.34
2.	Married	47	79.66
Total		**59**	**100.00**

RESULT AND OBSERVATION:

Response of treatment in trial group (Group A)

Trial group consisted of 46 patients, among them 32 cases had completed the full tenure of trial and 14 cases had not completed the full trial. All the cases were given the DIABET GUARD granules in the dose of 1 tsf (6gm) twice daily before meal for 90 days, with water.

Patients were observed in terms of subjective improvements before treatment, during treatment and after treatment. The response of treatment of subjective criterias as observed before treatment and after treatment in 32 cases are presented below in table no. 11

Table No. 11 : Showing the response of treatment on subjective features of Diabetes Mellitus (n=32) in trial group.

Sl. No.	Symptoms	No. of patients before treatment	No. of patients relieved after treatment	Percentage of relief
1.	Polyurea	28	19	67.86
2.	Polydipsia	27	18	66.67
3.	Poly Phagia	22	16	72.73
4.	Pruritus	14	10	71.43
5.	Vertigo	28	19	67.86
6.	Inability to work	24	17	70.83
7.	Tingling Sensation/ Numbness	22	13	59.10
8.	Excessive weight losses	26	15	57.10
9.	Excessive perspiration	28	18	64.28
10.	Excessive sleep	20	14	70.00
11.	Excessive tiredness	24	16	66.67
12.	Loss of Memory	20	14	70.00
13.	Loss of libido	26	4	15.39
14.	Joint pain	25	17	68.00
15.	Malaise	28	20	71.43

In all patients who had completed the treatment schedule of 90 days, were also observed in term of improvements on objective features like estimation of fasting blood sugar. Post prandial blood sugar level, urine sugar level body weight. All the objective features was estimated before treatment and after treatment. The observations are presented statistically in table no. 12 to 15.

Table No. 12 : Showing the response of treatment on Fasting Blood Sugar level in patients of diabetes mellitus (n= 32) in trial group.

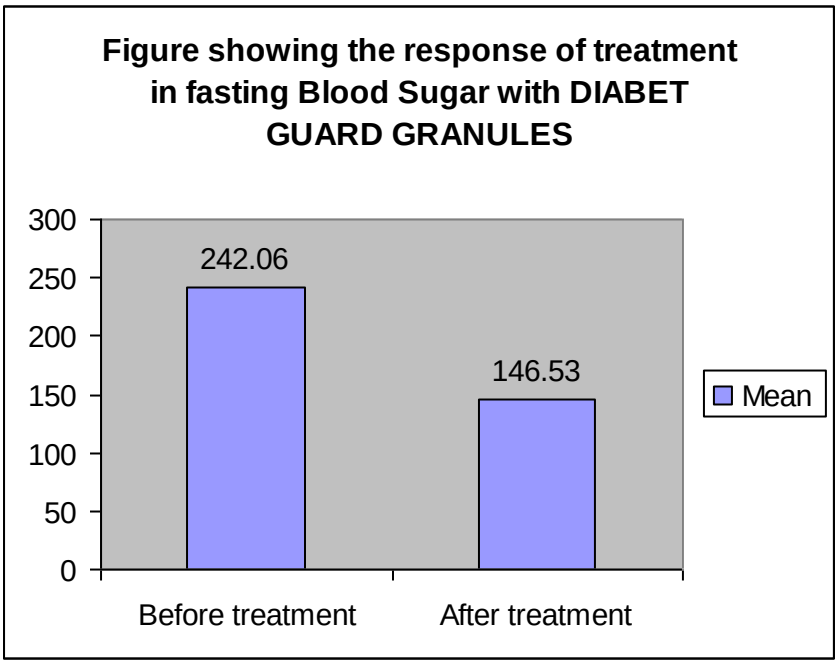
FBS	Before treatment	After treatment	Decreased value
Mean	242.06	146.53	95.53
SD ±	59.002	57.50	13.38
SE ±	10.43	10.16	2.36
t			40.47
p			> 0.001

It is revealed from the above table that the mean fasting blood sugar level was 242.06 mg/dl before treatment and that was reduced to 146.53 mg/dl after treatment and the p value is highly significant (>0.001).

Table No. 13 : Showing the response of treatment on post prandial blood sugar level in patients of diabetes mellitus (n=32) in trial group.

PPBS	Before treatment	After treatment	Decreased value
Mean	300.34	186.40	113.56
SD ±	69.62	67.40	19.61
SE ±	12.30	11.91	3.46
t			32.82
p			>0.001

From the above table it is clear that mean PP Blood Sugar level was 300.34 mg/dl before treatment which reduced to 186.40 mg/dl after treatment and the decreased mean PPBS is 113.56 mg/dl and the p value is highly significant (>0.001).



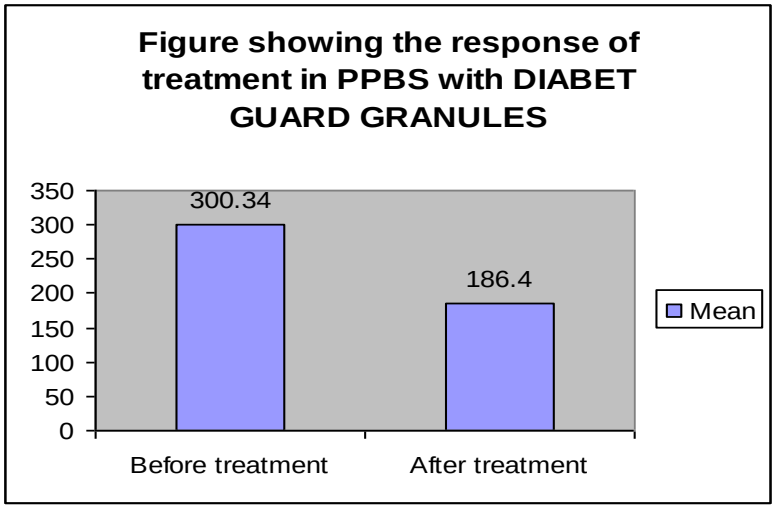


Table No. 14 : Showing the response of treatment on urine sugar in patients of diabetes mellitus (n=32) in trial group.

Urine Sugar	Before treatment	After treatment	Decreased value
Mean	2.96	1.09	1.87

From the above table it is revealed that the mean urine sugar before treatment was 2.96 mg/dl which reduced to 1.09 mg/dl after treatment. So the improvement was 63.17%.

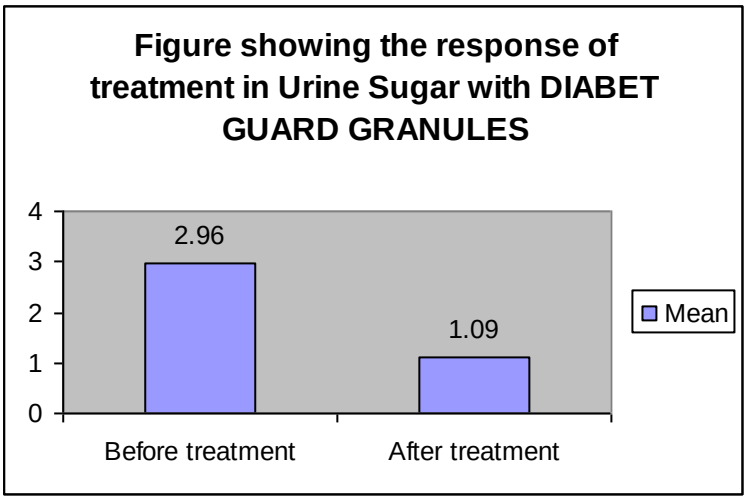
Table No. 15 : Showing the response of treatment on Body weight in patients of diabetes mellitus (n=32) in trial group.

Body Weight	Before treatment	After treatment	Increased value
Mean	48.00	50.34	2.34
SD ±	7.57	7.49	0.78
SE ±	1.33	1.32	0.13
t			18.02
p			>0.001

From the above table it is clear that the mean body weight was 48.00 kg before treatment which increased to 50.34 kg after treatment and the p value is highly significant (>0.001).

Response of treatment in control group (Group B)

Control group (Group B) consisted of 13 patients out of which 5 patients had discontinued the treatment and 8 patients had completed the treatment schedule of 90 days. All the patients were given placebo in the dose of 1 tsf (6 gm) twice daily before meal. Patients were observed in terms of subjective features before treatment during treatment and after treatment. The response of the treatment on subjective criterias as observed before the treatment and after the treatment in 8 cases are presented in table no. 16.



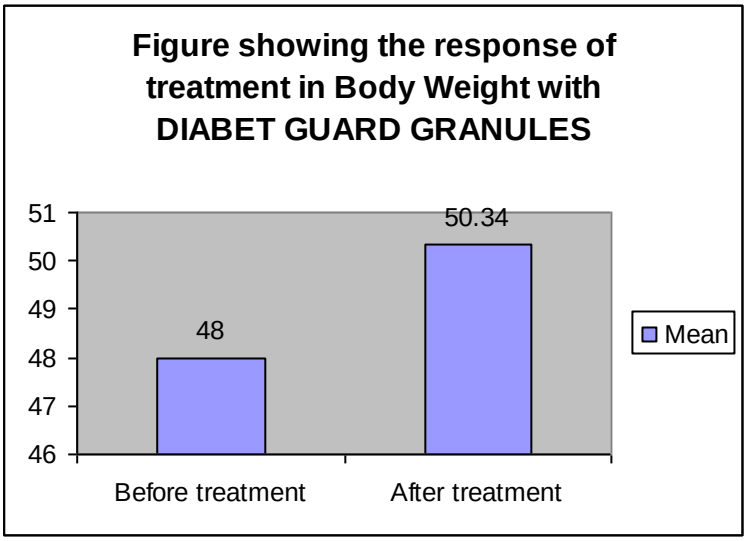


Table No. 16 : Showing the response of treatment on subjective features of Diabetes Mellitus (n=8) in control group.

Sl.No.	Symptoms	No.of patients before treatment	No.of patients relieved after treatment
1.	Polyurea	05	00
2.	Polydipsia	06	00
3.	Poly Phagia	07	-01
4.	Pruritus	06	-01
5.	Vertigo	06	00
6.	Inability to work	04	-01
7.	Tingling Sensation/ Numbness	06	00
8.	Excessive weight losses	07	00
9.	Excessive perspiration	06	-01
10.	Excessive sleep	06	00
11.	Excessive tiredness	06	00
12.	Loss of Memory	05	
13.	Loss of libido	07	00
14.	Joint pain	06	-01
15.	Malaise	07	00

The responses of treatment on subjective features in patients of control group as shown in the above table, it is found that there was no relief in subjective features. Moreover, negative response was noted in some of the subjective features like polyphagia, pruritus, inability to work, excessive perspiration and joint pain etc.

In the patients of control group who had completed the treatment schedule of 90 days. Were also observed in terms of improvements on objective features like estimation of fasting blood sugar, post prandial blood sugar, urine sugar, body weight. All the objective features were estimated before treatment and after treatment. The observations are presented statistically in table no. 17 to 19.

Table No. 17: Showing the response of treatment on Fasting Blood Sugar level in patients of diabetes mellitus (n=08) in control group.

FBS	Before treatment	After treatment	Decreased value
Mean	189.00	230.00	-41.00
SD ±	13.09	27.61	17.49
SE ±	04.62	09.76	06.18
t			-06.63
p			insignificant

It is revealed from the above table that the mean fasting blood sugar level was 189.00 mg/dl before treatment and that was increased to 230.00 mg/dl after treatment and the p value is insignificant.

Table No. 18: Showing the response of treatment of post prandial blood sugar level in patients of diabetes mellitus (n=08) in control group.

PPBS	Before treatment	After treatment	Decreased value
Mean	253.50	284.87	-31.37
SD ±	35.07	38.65	11.57
SE ±	12.40	13.66	04.09
t			-07.67
p			insignificant

From the above table it is clear that mean PP blood sugar level was 253.50 mg/dl before treatment which increased to 284.87 mg/dl after treatment and the increased mean PPBS is 31.37 mg/dl and the p value is insignificant.

Table No. 19: Showing the response of treatment on urine sugar in patients of diabetes mellitus (n=08) in control group.

Urine Sugar	Before treatment	After treatment	Decreased value
Mean	02.25	03.25	-01.00

From the above table it is revealed that the mean urine sugar before treatment was 02.25 mg/dl which increased to 03.25 mg/dl after treatment. So there was no improvement noticed.

DISCUSSION :

In the present study 59 patients suffering from diabetes mellitus (type 2) were included. The total cases were randomly divided in two groups viz. trial group (Group A) and control group (Group B). Trial group consisted of 46 patients to whom DIABET GUARD granules, the trial drug was given for a period of 90 days. In the present series out of 46 cases of trial group 14 cases had discontinued the treatment and 32 cases could be followed up properly during the treatment schedule (i.e. 90 days).

Control group (Group B) included 13 patients, out of which 5 patients had discontinued the treatment and 8 patients could be followed for 90 days.

To all the patients of the trial group DIABET GUARD granules, the trial drug was given in the dose of 1 tsf (6 gm) twice daily before lunch and dinner with water, orally for a period of 90 days. In control group, to all the cases placebo granules were given in the dose of 1 tsf (6 gm) twice daily before lunch and dinner with water, orally for a period of 90 days.

The effect of the treatment on both these group of patients were evaluated during the treatment and assessed at the end of the treatment. The response of the treatment was observed on subjective improvement and objective improvements. At the end of the treatment, the result was assessed in term 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 with reduction of PPBS. The patients were included under good response group when they showed relief of subjective features between 51 to 70% relief with reduction of PPBS. Patients showing relief of subjective features below 51% and reduction of PPBS were labeled under poor response group. In consideration to the effect of the drug in trial group 31.25% cases were included under excellent response group, 43.75% under good response group and 25% under poor response group.

In this study it was interesting to note that almost all the cases had responded to the treatment which was observed by reduction of the blood sugar level. The effect of the treatment on fasting and post prandial blood sugar level, in all the patients of the study have been statistically analysed and found highly significant. The mean fasting blood sugar level which was 242.06 mg/dl before treatment was reduced to 146.53 mg/dl after treatment. Similarly the PPBS before treatment was 300.34 mg/dl and reduced to 186.40 mg/dl after treatment.

Any improvement in patients of control group was not found when the effect of the treatment on subjective criterias and objective criterias were analysed. The response observed was insignificant.

When the response of the treatment in both the groups were analysed and compared it was revealed that there is definite improvement in the patients of diabetes mellitus treated with DIABET GUARD granules.

During the clinical study of the DIABET GUARD granules any clinical toxicity was not recorded.

CONCLUSION :

The drug “DIABET GUARD” granules has been found to be an effective drug on diabetes mellitus type 2 the result has shown encouraging result after 4 week of treatment particularly on the subjective criterias. After 90 days of treatment along with the improvement of subjective criterias significant response was also noticed on objective criterias, particularly on PPBS level. Hence, “DIABET GUARD” granules can be prescribed in diabetes mellitus type 2.

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