



RESEARCH ARTICLE

Effect of Gluten Free diet (GFD) on blood sugar: a clinical trial

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ABSTRACT

The present study was aimed to assess the effect of gluten free diet on the patients of type-II diabetes mellitus. Present findings shows that how, short term intervention of GFD effects fasting and post prandial blood sugar of diabetes patients. Through randomization process 100 patients of already diagnosed type-II diabetes mellitus are registered for the study, within two groups (n=50). First group received a intervention of gluten free diet (GFD) and other which was control group followed regular diet. The intervention was done for 12 weeks (3months), in which biochemical parameters of FBS and PPBS was recorded initially and follow up was taken at an interval of each month. In comparison between the two groups are seen through statistical analysis. Significant changes was seen in intervention group in fasting blood sugar (FBS) in comparison to control group ($p=0.000$). However, less significant changes was observed in post prandial blood sugar (PPBS) ($p=0.029$). Gluten free diet intervention for short interval helps in reduction of fasting blood sugar in type-II diabetes mellitus patients. GFD diet can act as a preventive measure in type-II diabetes mellitus.

Keywords: Gluten free diet, type-II diabetes mellitus, fasting and post prandial blood sugar, diet intervention.

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INTRODUCTION

Among metabolic disorders which are very common in today's globalizing world, Diabetes is a chronic metabolic disorder in which body is unable to utilize the glucose properly. Diet and physical inactivity plays a vital role in incidence of type-II diabetes, studies have shown that other metabolic disorders like cardiovascular diseases, obesity are related to progression and occurrence of diabetes (Hemmingsen et al., 2017). With the help of proper management of through coordinated medical nourishment therapy (MNT) given by registered professionals help in diabetes mellitus. Weight reduction, calorie limitation and low fat and starches with proper nutritional intake helps in management of type-II diabetes (Viswanathan et al., 2019). Some studies also relationship between osteoarthritis (OA) and type-II diabetes as both of the diseases are related to abundance of weight. Therefore weight management is not only necessary in type-II DM but also for the other bone diseases also (Veronese et al., 2019)

Gluten is a group of proteins which is present in the endosperm part of cereals especially in wheat, rye and barley. Many studies have shown that adherence to gluten-free diet is not still very familiar to the people (Silvester et al., 2016). Some studies also shown about the concept of gluten free diet as a fad or necessity (Amy, 2017). A hypothetical relation is also shown in an study that how the GFD intake helps in lowering of type-I diabetes mellitus (Jorgensen et al., 2018). Wheat Belly book have shown that the intake of wheat products leads to increase in the level of blood glucose in the body. The book also shows the addictive property of wheat which increases the appetite level in the body (William Davis, 2011). Non-gluten containing cereals are considered not only safe for celiac diseases patients but also for improving immunity in the patients (Biagetti et al., 2013).

MATERIALS AND METHODS

Design of the study and inclusion, exclusion criteria

The design of the study used for the present study is randomized controlled clinical trial. The sample size for the present was 100 patients, after allocation in two groups, 50 in each group. The inclusion criteria of the patients for the study are:

For blood sugar, the patients were selected according to **American Diabetes Association, Diabetes Care 2021,**

- i) Fasting plasma glucose (FPG) \geq 126mg/dl
- ii) 2 hour plasma glucose (PPBG) \geq 200mg/dl

The age of the patients were not less than 35 years and not more than 65 years. Blood glucose of the patients is between 126-200mg/dl for FBS and between 200-300mg/dl for PPBS. Patients suffering from Type 2 diabetes mellitus without suffering any other complications and attending the OPD of Ayurveda, Department of Kayachikitsa SSH, IMS, BHU, Varanasi. The exclusion criteria for the present study are patients more than age of 65 years. More than 400mg/dl of blood glucose and presence of any complications in the patients. Pregnant and lactating women and patients suffering from Type 1 diabetes mellitus are excluded from study. The criteria for withdrawal from the study if the chances of moving out of location because of their specific reason. Occurrence of any serious ailments during trial also. If the patient is on other therapy or having gluten sensitivity or allergy to gluten.

Ethical consideration

After designing and planning of research plan proposal was), the protocol was approved by the **Institutional Ethics Committee, Institute of Medical Sciences, Banaras Hindu University, Varanasi** was registered in the Clinical Trials Registry- India (CTRI) website. The registration number of this trial is **CTRI/2021/02/031224**.

Allocation of groups

In intervention group, patient were informed about the intervention as they were told not to change their dietary habits and not to take other any other specific diet during the study period. Therefore, blinding in the study could not be maintained.

In intervention, patients were asked to follow gluten-free diet which were given and explained in the form of diet chart. The diet chart of GFD was given to the patients, and the assumption was made that the patients were receiving not more than 2gm gluten every day. Along with the diet, patients were also given instructions to avoid gluten containing cereals specifically wheat, rye, and barley with their other products like chapattis, breads, cakes, biscuits etc. In fact they were informed to eat a Chappatis/Rotis made of gluten-free flour (Chappatis/Daliya of corn or Chappatis of sorghum flour). In control group patient were asked to follow regular diet however they were also given instructions for diabetes management. Both the groups were on going with ayurvedic treatment. No additional diet besides this dietary intervention in groups.

Biochemical assessment and dietary assessment:

Fasting blood glucose (FBS) and Post-prandial blood glucose (PPBS) levels of patients are noted. Food frequency questionnaire and 24 hour recall method were used for dietary assessment.

Interview technique

Consent form is taken by the patients of Type II Diabetes Mellitus and those were investigated through Proforma.

Follow-ups

The follow up was taken for 3 months. The patients were called after every 1 month along with their report at each follow up. At every follow up patients were weighed and reports of fasting and post-prandial blood sugar are noted. Initially at the time of starting of intervention and at the time of ending of intervention after the treatment for 3 months, biochemical and dietary intake of them are noted.

At every follow up, patients were weighed and reports of fasting and post-prandial blood sugar are noted. Initially at the time of starting of intervention and at the time of ending of intervention after the treatment for 3 months, anthropometric, biochemical and dietary intake of them are noted.

Statistical analysis

Analysis of data was done through **IBM SPSS Statistics Version 21**. Paired t-test is used for intra-group comparison within the group. Independent t-test is used for comparison between the different groups. The mean differences of outcome variables are seen before and after trial. In the statistical tests, P value is considered for significance and non-significance.

RESULTS

Out of 100 patients, 95 patients completed the study. In group-I that was intervention group, out of 50 patients, 46 patients completed the study while in control group out of 50 patients, 49 patients were assessed.

Fasting blood sugar analysis

In analysis of blood sugar it was observed that a decrease in the mean FBS was observed at 1st FU, while increase at 2nd FU was observed in both the groups. However in Group-I the mean decrease in 3rd FU as compared to BT was 12.54 and which

was statistically highly significant ($p=0.000$). Whereas, in Group-II the mean FBS was increased to 3.11 at 3rd FU and which was also statistically significant ($p=0.002$). The inter-group comparison was statistically significant only at 3rd FU ($p=0.000$).

Post prandial blood sugar analysis

While in post prandial blood sugar (PPBS) Decrease in mean PPBS was observed at 1st FU then there is increased in 2nd FU and 3rd FU in both the groups. The mean increase in Group-I after the treatment at 3rd FU as compared to BT which was not statistically significant ($p=0.705$). However, the mean increase in Group-II was observed at 3rd FU was 3.16 which was statistically significant ($p=0.038$). The inter group comparison was not observed statistically significant at BT ($p=0.202$) and at 1st FU ($p=0.114$), at 2nd FU ($p=0.268$). And statistically significant at 3rd FU ($p=0.029$). On the basis of observed mean there is over all increase in the PPBS in both the groups.

Table 1: Effect of Trial treatment on Fasting Blood Sugar (FBS) (n=95)

Groups	Fasting Blood sugar Mean \pm SD				Within the group comparison (Paired t-test) (BT-FU3)
	BT	FU1	FU2	FU3	
Group-I: (n=46)	164.25 \pm 14.25	158.46 \pm 12.11	160.51 \pm 12.41	151.71 \pm 13.86	12.54 \pm 12.86 t = 6.611 p = 0.000
Group-II: (n=49)	161.98 \pm 13.42	158.45 \pm 12.025	159.59 \pm 11.88	165.10 \pm 11.62	-3.11 \pm 6.56 t = 3.320 p = 0.002
Between the group comparison (Unpaired t-test)	t = 0.798 p = 0.427	t = 0.005 p = 0.996	t = 0.370 p = 0.712	t = -5.11 p = 0.000	

Note: Gr.-I (intervention group), Gr.-II (control group), Values are means \pm SD, p-values indicates level of significance between the group through unpaired t-test (Chi square), within the group through paired t-test ($p<0.00$).

Table 2: Effect of Trial treatment on Fasting Blood Sugar (PPBS) (n=95)

Groups	Postprandial Blood Sugar Mean \pm SD				Within the group comparison (Paired t-test) (BT-FU3)
	BT	FU1	FU2	FU3	
Group-I: (n=46)	253.82 \pm 27.54	244.47 \pm 31.19	253.84 \pm 24.42	254.69 \pm 21.91	- 0.87 \pm 15.65 t = 0.381 p = 0.705
Group-II: (n=49)	260.33 \pm 21.70	253.34 \pm 22.63	258.86 \pm 19.31	263.50 \pm 16.42	- 3.16 \pm 10.363 t = 2.139 p = 0.038
Between the group comparison (Unpaired t-test)	t = 1.285 p = 0.202	t = 1.593 p = 0.114	t = 1.114 p = 0.268	t = 2.225 p = 0.029	

Note: Values are means \pm SD, FU1-first follow up, FU2- second follow up, FU3-third follow up, p-values indicates level of significance between the group through unpaired t-test (Chi square), within the group through paired t-test ($p<0.00$)

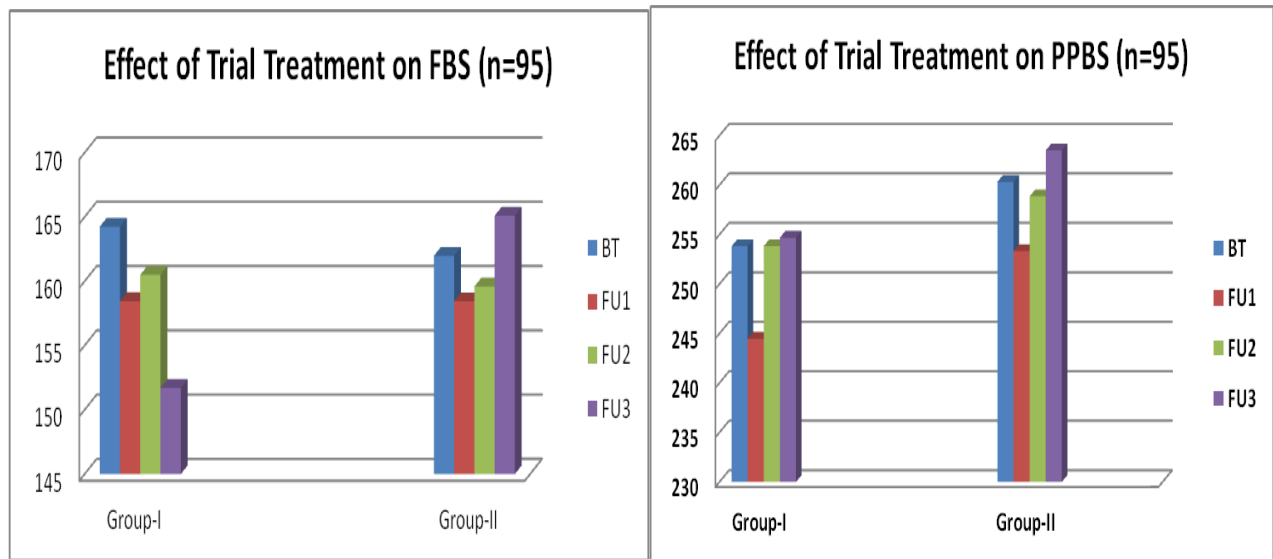


Fig.3: Fasting blood sugar and post prandial blood sugar after the intervention of gluten free diet in group I and group II respectively. Different colors of bars are showing the follow ups.

DISCUSSION

Studies have shown that the patients which are having celiac diseases with intake of gluten free diet are closely prone to have type-I diabetes (Serena et al., 2015; Ehteshami et al., 2018) However, the number of studies on association of type-II diabetes and GFD are less in number. Our findings of the study have shown that there is significance decrease in FBS of patients. In Intervention group, the mean decrease in FBS after treatment was highly significant ($p=0.000$), which were also shown in other studies. Few studies also have shown that GFD acts as a causative factor in occurrence of type-I and II diabetes (Kim et al., 2017). The relationship of type-I DM and celiac diseases by reduction in hypoglycemic risk by intake of gluten free diet (Hansen et al., 2006). Process techniques of foods have its impact on post prandial thermogenesis of food. The studies also show that thermogenic properties induce by gluten free foods are low in comparison to whole food meal (Dioneda et al., 2020). Some findings also suggested about the gluten free pasta intake shows low glycemic load in the patients who takes the pasta which is made of only rice flour (Bacchetti et al., 2014). Few studies also had shown the intervention of GFD for 8 weeks also shown the changes in micro biome in patents body (Khoury et al., 2018). Studies have also shown that GFD affects the feeling of satiety also (Balakireva and Zamyatnin, 2016). Although GFD diet should be taken with proper assessment and observation, food sources present in it contains sometimes food of higher glycemic index which can be the risk of many cardio vascular disorders (Scaramuzza et al., 2013). Our findings of the study shows a significance decrease fasting blood sugar but the changes in post prandial were not significant. Limitations of the present study the intervention is assessed through patients own information. No other food allergy test could be detected in the patients. It is a short term intervention, long term studies are needed for better results.

CONCLUSION

Our findings from the study suggested that gluten free diet acts as preventive measure in lowering of fasting blood sugar more than in comparison to post prandial blood sugar. Although GFD diet is mainly used in the treatment of celiac diseases but it can also be helpful in preventing and lowering of blood glucose in the body. Intake of gluten-free diet is helpful in controlling weight and body mass index, which are main risk factors of type-II diabetes. This study was short term intervention, therefore long term studies are recommended in enhancing and proving the relationship between gluten free diet and type-II diabetes. The limitation of the present study is that on the basis of information of the patient, the intervention group following GFD diet can be assessed. Other food allergy tests could not be detected in patients. This study imparts a short term dietary effect. For other metabolic disorders also the effect of gluten free diet can be assessed. A large sample sized and long duration studies are recommended for further analysis of this dietary intervention.


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