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ORIGINAL ARTICLE

The postprandial glucose-lowering effect of dietary fiber (Psyllium Husk) in patients with type 2 diabetes mellitus.

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ABSTRACT… Objectives: To compare the mean reduction in postprandial plasma glucose in patients with diabetes mellitus type 2 by dietary fibre (psyllium husk) to those not using dietary fibre (psyllium husk) and on standard treatment. **Study Design:** Randomized Controlled Trial. **Setting:** Department of Medicine, Allied Hospital, Faisalabad. **Period:** 30th November 2022 to 29th May 2023. **Methods:** A total of 60 type 2 diabetes mellitus patients of both genders, age >18 to 60 years, diagnosed with DM for more than two years, were selected. Patients undergoing insulin therapy, history of DSF allergy, gastrointestinal surgery, and pregnant or lactating women were excluded. Group A received soluble ffibre10.5 g daily for 12 weeks of intervention and standard medications oforDM. Postprandial glucose was checked after 2 hours of meal. In comparison, Group B did not receive any food supplements throughout the intervention period and continued regular diets. The outcome of Blood samples was obtained in terms of mean reduction in postprandial glucose. **Results:** Mean reduction in Postprandial glucose in Patients with type 2 diabetes mellitus by dietary fibre (psyllium husk) was 14.33 ± 2.04 mmol/l, and in those who are not using dietary fibre (psyllium husk) and on standard treatment, it was 10.83 ± 1.95 mmol/l (p-value = 0.0001). **Conclusion:** This study concluded that the mean reduction in Postprandial glucose in Patients with type 2 diabetes mellitus by dietary fibre (psyllium husk) is relatively high.

Key words: Type 2 Diabetes, Dietary Fibre (Psyllium Husk), Postprandial Glucose.

INTRODUCTION

The prevalence of diabetes continues on the rise at a staggering pace worldwide. By 2045, approximately 629 million adults between 20 and 79 will live with diabetes. Diabetes raises the likelihood of significant consequences, which is now well known.[1] To be more exact, the pathophysiology of late diabetes complications, particularly the onset of cardiovascular disease (CVD), appears to be heavily influenced by postprandial hyperglycemia.[2] For patients with diabetes mellitus type 2, achieving adequate glycemic control is crucial because postprandial hyperglycemia can be effectively treated to produce more significant advantages for CVD and mortality reduction.[3]

The three glycemic variables—HbA1c, FPG, and postprandial glucose—appears to be independently meaningful, according to mounting data. Postprandial glucose (PPG) has been acknowledged by the American Diabetic Association (ADA) as a separate contribution to both HbA1c and diabetic complications since 2001.[4] In the past, treating type 2 diabetes has been done in a progressive manner, starting with lifestyle changes and metformin as first-line medication and moving on to second-line medicine if necessary to achieve optimal glucose control. However, first, combination pharmacotherapy is a substitute, more intense strategy. The recommendations of American Diabetes Association (ADA) and European Association for the Study of Diabetes (EASD) are, initial combination therapy when a patient's glycated haemoglobin (HbA1c) is >1.5% above the patient's target, while the recommendation of American Association of Clinical Endocrinologists

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(AACE) and the American College of Endocrinology (ACE) is when a patient's HbA1c is >7.5%.[2,3]

Because of its impact on the intestinal absorption of macronutrients, numerous research conducted over the past ten years have demonstrated that viscous soluble fibre is essential for regulating postprandial hyp`erglycemia and insulin responses. To improve glycemic control and stave off the onset of diabetes mellitus type 2 and cardiovascular disease, the American Diabetes Association advises diabetic patients to ingest 14 g/1000 kcal of fibre daily. However, there is still debate and misunderstanding regarding the physiological effects of soluble dietary fibres on postprandial blood glucose and satiety induction in type 2 diabetic patients. Although soluble fibre has been shown to improve blood glucose management in diabetics, its precise mechanism of action is yet unknown.[5] In people with type 2 diabetes, psyllium which is a water-soluble fibre and is extracted from the husks of mature Plantago ovate seeds, may help with glycemic management, body weight, and bowel movements.[6]

In a study, Kang et al. examined how type 2 diabetics' postprandial glycemic response, insulin response, and stomach emptying were affected by soluble dietary fibre (SDF). To measure plasma glucose and insulin, fasting and postprandial samples from venous blood were taken at intervals of 30–60 minutes for 180 minutes. After two hours, SDF had a substantial impact on DM patients' postprandial plasma glucose levels (mean reduction 14.25.2 vs. 10.63.1 mmol/L).[7]

This study investigated the benefits of addition of soluble fibre to the regular diet among diabetes type 2 patients. If significant results are obtained, proper dietary guidelines, including the benefits of soluble fibre such as psyllium, will be promoted to inform people of its benefits for preventing and treating type 2 Diabetes.

The study was conducted with an objective:
"To compare the mean reduction in Postprandial glucose in Patients with diabetes mellitus type 2 by dietary fibre (psyllium husk) to those who are not using dietary fibre (psyllium husk) and on standard treatment."

Diabetes mellitus type 2:
Previously diagnosed case of diabetes Mellitus type 2 (defined as 2 hours post prandial ≥200 mg/dl, Fasting blood sugar ≥126 mg/dl, HbA1c (Glycosylated Haemoglobin) ≥6.5% for more than one occasion) and using antidiabetic medicines for at least 3 months.

Postprandial Hyperglycemia:
Postprandial hyperglycemia was defined according to IDF as" a plasma glucose level > 7.8 mmo1/1 (140 mg/dl) 2 hours after food intake."

Reduction in Postprandial Glucose: was calculated by Postprandial Glucose at 12 weeks follow-up from baseline Postprandial Glucose.

Reduction in Postprandial Glucose = baseline HbA1c- HbA1c at follow-up

HYPOTHESIS

There is a difference in the mean reduction in the 2 hours Post meal glucose in patients with diabetes mellitus type 2 by dietary fibre (psyllium husk) to those who are not using dietary fibre (psyllium husk).

METHODS

This Randomised controlled trial was conducted at Department of Medicine, Faisalabad Medical University, Faisalabad from 30th November 2022 to 29th May 2023.

The Non-probability, consecutive sampling technique was adopted.
The sample size is calculated by using the WHO Sample size calculator for two proportions.
Level of significance 5%
Power of study 80%
The mean reduction in the SDF group (P1) =14.2±5.2(7)
The mean decrease in SDF free group (P2) = 10.6±3.1(7)
The sample size is 60 (30 in each group)

Sample Selection

Inclusion Criteria
The patients with diabetes mellitus type 2 of both genders, Aged>18 to 60 years, were diagnosed with DM for over 2 years.

Exclusion Criteria
Participants with type 1 diabetes mellitus or diabetic ketoacidosis
Undergoing insulin therapy
Known history of allergy to DSF
History of gastrointestinal surgery
Women who were pregnant or lactating.

Data Collection Procedure
The study was commenced after getting approval from the Institutional Ethical Review Committee via letter No. F.28-ERC/FMU/2022-23/. Before including in the study an Informed, written, consent was taken from each participant to participate in this study; they were briefed about the objectives of the studies and were ensured the information's confidentiality. Patients were selected according to inclusion criteria and assigned into two groups A and B by using randomisation with the help of computer-generated number table. Group A received soluble fibre 10.5 g per day for a study period of 12 weeks as intervention along with standard medications for DM. Postprandial glucose was checked after 2 hours of meal. At the same time, Group B was kept on regular diet without any supplemental fibre during intervention period of the study. Blood samples were obtained. Contacting subjects by phone at weekly intervals ensured compliance with the intervention program. Anthropometric measurements and postprandial glucose were taken at the baseline and after three months. The outcome was noted in terms of mean reduction in postprandial glucose. All the data was recorded on a pre-approved proforma.

Data Analysis Procedure
Data was entered and analysed using SPSS 25. Frequency and percentages were calculated for qualitative variables like gender (Male/Female). Mean with SD was calculated for quantitative variables like Age, Age, height, weight, BMI, duration of diabetes, Postprandial Glucose at baseline, post-treatment Postprandial Glucose and reduction. An Independent sample t-test was applied to compare the decline between the two groups.

Effect modifiers such as gender, Age and BMI were controlled through stratification. Post-stratification independent sample t-test was applied, and P $\leq$0.05 was taken as significant.

RESULTS
The age range in this study was from 18-60 years, with a mean age of 45.31 $\pm$ 6.16 years. The mean Age of patients in group A was 45.27 $\pm$ 6.19 years, and in group B was 45.80 $\pm$ 6.29 years. The majority of the patients, 45 (75.0%), were between 41 to 60 years of Age, as shown in Table-I.

Out of 60 patients, 28 (46.67%) were males, and 32 (53.33%) were females, with male to female ratio of 1:1.1 as shown in Table-II. Mean time since diagnosis was 11.78 $\pm$ 4.89 years. The mean BMI was 28.94 $\pm$ 3.23 kg/m2 (Table-III). The mean height was 165.86 $\pm$ 14.76 cm. The mean weight was 75.63 $\pm$ 8.35 cm.

The mean reduction in Postprandial glucose in Patients with type 2 diabetes mellitus by dietary fibre (psyllium husk) was 14.33 $\pm$ 2.04 mmol/l, and in those who are not using dietary fibre (psyllium husk), and on standard treatment was 10.83 $\pm$ 1.95 mmol/l (p-value = 0.0001) as shown in Table-IV.

Stratification of reduction in Postprandial glucose concerning Age, gender and BMI is shown in Table-V.

DISCUSSION
When the husk from the psyllium seed (Plantago ovata) is mechanically removed, a viscous, primarily water-soluble fibre known as psyllium husk fibre is created.

Age (Years)	Group A (n=30)		Group B (n=30)		Total (n=60)	
	No. of the Patients	%age	No. of the Patients	%age	No. of the Patients	%age
18-40	08	26.67	07	23.33	15	25.0
41-60	22	73.33	23	76.67	45	75.0
Mean ± SD	45.27 ± 6.19		45.80 ± 6.29		45.31 ± 6.16	

Table-I. Age stratification for both groups (n=60).

Gender	Group A (n=30)		Group B (n=30)		Total (n=60)	
	No. of the Patients	%age	No. of the Patients	%age	No. of the Patients	%age
Male	15	50.0	13	43.33	28	46.67
Female	15	50.0	17	56.67	32	53.33

Table-II. Gender stratification for both groups (n=60).

BMI	Group A (n=30)		Group B (n=30)		Total (n=60)	
	No. of the Patients	%age	No. of the Patients	%age	No. of the Patients	%age
≤30 kg/m2	16	53.33	20	66.67	36	60.0
>30 kg/m2	14	46.67	10	33.33	24	40.0
Mean ± SD	29.57 ± 3.37		28.53 ± 3.18		28.54 ± 3.23	

Table-III. Stratification of the patients according to BMI (n=60).

Post Prandial Glucose (mmol/l)	Group D (n=30)	Group P (n=30)	P-Value
	Mean ± SD	Mean ± SD	
Pre-treatment (Baseline)	29.10 ± 4.20	28.99 ± 3.49	0.913
Post-treatment	14.77 ± 2.16	18.16 ± 1.54	0.0001
Reduction	14.33 ± 2.04	10.83 ± 1.95	0.0001

Table-IV. Comparison of the mean reduction in postprandial glucose in patients with diabetes mellitus type 2 by dietary fibre (psyllium husk) to those not using dietary fibre (psyllium husk) and on standard treatment.

		Group D (n=30)		Group P (n=30)		P-Value
		Reduction in Postprandial Glucose		Reduction in Postprandial Glucose		
		Mean	SD	Mean	SD	
Age (years)	18-40	14.88	1.73	10.29	1.25	0.0001
	41-60	14.14	2.14	11.0	2.11	0.0001
Gender	Male	14.40	1.92	11.23	2.05	0.0001
	Female	14.27	2.22	10.53	1.87	0.0001
BMI (kg/m2)	≤30	14.13	1.93	10.90	1.97	0.0001
	>30	14.57	2.21	10.70	2.00	0.0001

Table-V. Stratification of reduction in postprandial glucose concerning Age, gender and BMI.

Early studies have showed that psyllium helped people with diabetes mellitus type 2 in better control of their blood glucose and cholesterol measurements.[8-12] Although a more recent study with strict controls found that diabetes mellitus type 2 patients with psyllium supplementation had lower postprandial glucose and insulin concentrations[13], other studies found no effect on plasma glucose control[14] except when psyllium was sprinkled on or included in a cereal meal.[15] It has been demonstrated that psyllium dramatically lowers postprandial blood glucose and insulin concentrations in people who do not have diabetes.[15]

We conducted this study to compare the mean reduction in Postprandial glucose in patients with diabetes mellitus type 2 by dietary fibre (psyllium husk) to those not using dietary fibre (psyllium husk) and on standard treatment. In my study, the mean reduction in post meal glucose in patients with diabetes mellitus type 2 by dietary fibre

(psyllium husk) was 14.33 ± 2.04 mmol/l and in those who are not using dietary fibre (psyllium husk) and on standard treatment was 10.83 ± 1.95 mmol/l (p-value = 0.0001). In a study, Kang et al. looked at the effects of soluble dietary fibre (SDF) on postprandial glycemic response, insulin response, and stomach emptying in people with type 2 diabetes. To measure plasma glucose and insulin, fasting and postprandial blood were collected at 30-minute intervals for 180 minutes. SDF significantly decreased the postprandial plasma glucose in DM patients after 2 hours (mean reduction 14.2±5.2 vs 10.6±3.1 mmol/L).[7]

In earlier research, it was found that psyllium decreased either the postprandial blood glucose concentrations[16] or the fasting plasma glucose level[8] in people with type 2 diabetes. In a different study, psyllium only had an effect on diabetic subjects' glycemic reaction to a test meal of flaked bran cereal when it was mixed into or sprinkled on top of the cereal.[15] Postprandial serum glucose values were 14% lower postprandial breakfast, 31% lower postprandial lunch, and 20% lower postprandial dinner with psyllium in a meticulously controlled crossover study about the effects of psyllium supplementation in people with diabetes mellitus type 2 compared to the effects of supplementation with placebo, cellulose.[13] It has been demonstrated in non-diabetic people that soluble fibres can decrease the 2 hours post-meal glucose response to food consumed couple of hours after fibre administration (for example, the presumed second meal effect).[17,18]

In their clinical research, Feinglos et al. found that psyllium doses of 3.4 gm and 6.8 gm effectively decreased glycosylated haemoglobin A1c and Fasting Blood Sugar.[19] Another study found that psyllium use of 5.1 gm/day effectively reduced glycosylated haemoglobin A1c and Fasting Blood Sugar.[20] Similar to this, when these changes were compared to glycosylated haemoglobin A1c, Fasting Blood Sugar, insulin, and C-peptide in the current investigation, all glycemic control markers notably improved (p 0.001, p 0.001, p 0.001, and p = 0.001, respectively). It's intriguing that these positive results were caused by the soluble fibre's ability to reduce absorption of the glucose by about 12.2% and act as a therapeutic measure for other metabolic controls.[21] While consistent dietary use of soluble fibres, in particular, may play a preventive effect in patients with diabetes mellitus type 2, who exhibit metabolic syndrome. However, psyllium, a specific form of viscose and functionally water-soluble fibre, may prolong intestinal transit time and make patient feel full[22], delaying the absorption of glucose into the blood and reducing the post meal rise in plasma sugar level.[23] This may decrease the need for insulin.[24]

The release and absorption of macronutrients may occur more gradually and over a longer length of time as a result of the increased intraluminal viscosity brought on by soluble fibre.[25] Soluble fibre produces a gel-like substance in the colon that passes considerably more slowly through the digestive system and holds nutrients inside its gel. The gel protects nutrients from the action of digestive enzymes, reducing the likelihood of their absorption from the intestine.[26] This decreases the pronounced increase in plasma sugar post meals and helps in raising the cells' responsiveness to the insulin. Additionally, water-soluble fibre makes the unstirred water layer that covers the surface of the intestines thicker, making nutrients to pass through and diffuse into the body relatively harder.[27] Furthermore, it has been discovered that soluble fibre decreased post meal glucose and insulin responses and impacted contemporaneous Glucagon like peptide responses, particularly release of ghrelin and Peptide YY.[25]

Psyllium dramatically raises FBS, insulin, the HOMA Index, and HbA1C, according to a different clinical investigation.[28] Those with diabetes mellitus type 2 who consume a lot of dietary fibre, particularly soluble fibre, have better glycemic control, less hyperinsulinemia, and lower plasma lipid concentrations, according to another randomised crossover research.[29] In addition, pathophysiology in people whose glucose tolerance is impaired can be identified utilising HOMA to evaluate -cell function and insulin sensitivity. HOMA is therefore an advantageous analysis technique for the therapy.[30] Recent research among hyperglycemic people without

a history of diabetes mellitus has shown that it enhances sensitivity of the insulin and other crucial metabolic parameters.[31-35] This is probably caused by the viscosity of the soluble fibres in the digestive tract.[36]

CONCLUSION

This study concluded that the mean reduction in Postprandial glucose in Patients of Diabetes mellitus type 2 by dietary fibre (psyllium husk) is relatively high. So, we recommend using dietary fibre (psyllium husk) routinely in type II diabetes mellitus to achieve better glycemic control.

CONFLICT OF INTEREST

The authors declare no conflict of interest.

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