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Original Research Article

A prospective, parallel group, interventional and open label study to evaluate the effect of probiotics on glycemic control in pre-diabetic patients

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ABSTRACT

Background: Prediabetes represents an intermediate metabolic state characterized by impaired glucose tolerance and a high risk of progression to diabetes. With rising global burden of diabetes, early interventions are essential. Emerging evidence suggests that gut microbiota plays a significant role in metabolism and probiotics may offer a novel and safe therapeutic approach.

Methods: This prospective, parallel-group, interventional and open-label study was conducted on 70 prediabetic patients. Participants were divided into two groups: Group A received a probiotic capsule containing *Lactobacillus acidophilus*, *Lactobacillus rhamnosus*, *Bifidobacterium longum* and *Saccharomyces boulardii* (2.5 billion CFU) once daily along with diet control as per American Diabetes Association recommendations, while Group B was advised only diet control for 90 days. Fasting Plasma Glucose (FPG), 2-Hour Plasma Glucose (2HPG) and HbA1c were assessed as primary objectives along with Total cholesterol, LDL-cholesterol (LDL-C), HDL-cholesterol (HDL-C), Serum Triglycerides, Body weight and BMI as secondary objectives. Safety was evaluated through monitoring of adverse events.

Results: Probiotic supplementation along with diet control resulted in statistically significant reduction in mean FPG ($p=0.018$) within group A. There was a statistically non-significant difference in change in FPG ($p=0.28$), 2HPG ($p=0.48$) and HbA1c ($p=0.17$) between group A and B. Statistically significant difference was seen in reduction in mean Total cholesterol ($p=0.01$), LDL-C ($p=0.009$), body weight ($p=0.03$) and BMI ($p=0.03$), increase in mean HDL - C ($p=0.006$) and a statistically non-significant difference in change in mean Triglyceride ($p=0.17$) levels between group A and B. The intervention was well tolerated, with minimal and non-serious adverse events reported.

Conclusions: Probiotic supplementation did not provide a significant additional benefit over diet control in improving glycemic parameters in prediabetic patients. However, it resulted in significant improvement in lipid profile, body weight and BMI. Both interventions were well tolerated with comparable safety profiles.

Keywords: Prediabetes, Probiotics, Glycemic control, Fasting plasma Glucose, Lipid profile

INTRODUCTION

Prediabetes is a clinically identifiable and critical stage in the evolution of diabetes mellitus, offering an important

opportunity for early intervention before the onset of overt disease. Diabetes mellitus is a chronic metabolic disorder that has become a major global health concern because of its rapidly increasing prevalence and long-term

complications. According to the World Health Organization (WHO), the number of individuals living with diabetes increased from 200 million in 1990 to 830 million in 2022, with the most rapid rise occurring in low- and middle-income countries. China, India and Pakistan had the largest populations of adults aged 20–79 years living with diabetes in 2021. Alongside this rise, the prevalence of prediabetes has also increased substantially. WHO estimates that nearly 77 million adults in India have type 2 diabetes mellitus (T2DM), while approximately 25 million are prediabetic.¹

T2DM is characterized by persistent hyperglycemia resulting from impaired insulin secretion, insulin resistance, or both. Pancreatic β -cell dysfunction reduces insulin secretion, whereas insulin resistance reflects the diminished ability of insulin-sensitive tissues to respond adequately to insulin. Initially, insulin resistance induces compensatory β -cell hyperfunction to maintain normal blood glucose levels. However, progressive β -cell failure eventually leads to insulin deficiency and sustained hyperglycemia. This transition is gradual and largely asymptomatic, often remaining undiagnosed until classical symptoms such as polyuria, polydipsia, blurred vision and weight changes appear, by which time considerable metabolic damage may already have occurred.²

The etiopathogenesis of T2DM is complex and multifactorial, involving an interplay of genetic, environmental and metabolic factors. Non-modifiable risk factors include increasing age, family history of diabetes, genetic predisposition, race or ethnicity and a history of gestational diabetes. Modifiable factors include obesity, physical inactivity, unhealthy dietary habits, hypertension, dyslipidemia, alcohol consumption, stress and poor sleep. Among these, unhealthy diet plays a central role. Diets rich in fats and refined carbohydrates elevate blood glucose and circulating lipoproteins, increase reactive oxygen species production and promote chronic low-grade inflammation. Oxidative stress and inflammatory mediators contribute significantly to insulin resistance and β -cell dysfunction, thereby accelerating the development of T2DM.³

Recent evidence has identified the gut microbiota as an important contributor to glucose metabolism and the pathophysiology of diabetes. The intestinal microbiota regulates immune function, inflammatory responses, gut barrier integrity and metabolic homeostasis while producing metabolites essential for normal physiological functions. Alterations in gut microbial composition (dysbiosis) can disrupt these processes, promote insulin resistance and contribute to the development of T2DM. Although research on the gut microbiome is still evolving, understanding its role may provide new opportunities for preventing or delaying diabetes.⁴

Prediabetes is defined as a state of hyperglycemia in which glycemic parameters are elevated above normal but remain below the diagnostic threshold for diabetes. The American

Diabetes Association diagnostic criteria for prediabetes is defined by following parameters:

2 Hour Plasma Glucose - 140-200 mg/dl (Impaired Glucose Tolerance). Fasting Plasma Glucose - 100-125 mg/dl. Glycosylated hemoglobin (HbA1c) level - 5.7% to 6.4%.⁵

Most individuals with prediabetes are asymptomatic, making early screening particularly important, especially in those with a family history of diabetes. The American Diabetes Association (ADA) estimates that up to 70% of adults with prediabetes will eventually develop T2DM, with approximately 5–10% progressing annually. Therefore, preventing or delaying the progression from prediabetes to diabetes is a major public health concern.⁶

Lifestyle modification remains the first-line intervention for prediabetes and is generally more effective than pharmacological therapy, although metformin is recommended in selected high-risk individuals.⁷ Growing evidence suggests that modulation of the gut microbiota through probiotics may complement lifestyle interventions by improving glycemic control and metabolic health.⁸

According to WHO, probiotics are "live microorganisms that when administered in adequate amounts confer a beneficial health effect on the host."⁹ Common probiotic organisms include species of *Lactobacillus*, *Bifidobacterium*, *Lactococcus*, *Streptococcus*, *Enterococcus*, *Bacillus* and *Propionibacterium*, with *Lactobacillus* and *Bifidobacterium* being the most extensively studied.¹⁰

Probiotics help restore the balance between beneficial and pathogenic gut microorganisms, strengthen intestinal tight junctions and correct dysbiosis. They reduce circulating lipopolysaccharide levels, thereby decreasing metabolic endotoxemia, chronic low-grade inflammation and cytokine-mediated insulin resistance.¹¹ Fermentation of dietary fiber by probiotics produces short-chain fatty acids, which stimulate glucagon-like peptide-1 (GLP-1) and peptide YY (PYY) secretion, enhancing insulin release, promoting satiety and improving insulin sensitivity. Certain probiotic strains also improve lipid metabolism through bile salt deconjugation, contributing to better cholesterol control and indirectly supporting glucose homeostasis. Additionally, probiotics reduce oxidative stress and inflammation, two major contributors to β -cell dysfunction.¹²

Despite these promising mechanisms, evidence regarding the effectiveness of probiotics in individuals with prediabetes remains limited. A better understanding of their clinical efficacy could establish probiotics as a safe and acceptable adjunctive strategy for preventing progression to T2DM. Therefore, the present study was undertaken to evaluate the effect of probiotics compared with diet control on glycemic control in prediabetic patients.

The primary objective was to compare the levels of Fasting Plasma Glucose (FPG), 2 - Hour Plasma Glucose (2h PG) and HbA1c in prediabetic patients on probiotic along with dietary control versus those on dietary control only. Secondary objective was to assess the effect of probiotic on Body Weight, BMI, Total serum cholesterol, LDL cholesterol, HDL cholesterol, and Serum Triglycerides of prediabetic patients with dyslipidemia recruited in the study.

METHODS

Study design and place

This study was conducted in the Department of Pharmacology, Government Medical College, Amritsar in association with Department of Medicine, Guru Nanak Dev Hospital, Amritsar.

Study design and study population

This was prospective, parallel group, interventional and open label study to evaluate the effect of probiotics on glycemic control in prediabetic patients.

Sample size calculation

The sample size was calculated to be a minimum of 64 participants using the formula $n=2[(SD_1+SD_2)^2(Z(1-\alpha)+Z(1-\beta))^2/d^2]$ for one way test where n= sample size, SD1 and SD2 are the standard deviations obtained from similar

previous study and d is the effect size, keeping a 95% confidence level, study power of 80% and an effect size of 6 with standard deviations 6.72 and 6.90 as reported in a similar previous study.¹³

Study population

The study sample comprised of prediabetic patients of age more than 18 years of either sex, visiting the outpatient department of Medicine at Guru Nanak Dev Hospital associated with Government Medical College, Amritsar. 73 prediabetic patients were recruited, out of which 3 dropped out (1 from group A and 2 from group B) as they were not coming regularly for follow ups and 70 completed the study. After considering the total number of dropouts, final number of patients in each group was 35 and sample size was 70.

Randomization

Patients were randomly assigned into two groups – A and B of equal distribution using simple randomization technique with the help of a computer-generated sequence. Written informed consent was obtained after providing the participants with a clear and concise explanation of the study in a language they could easily understand. The study was conducted in accordance with Good Clinical Practice guidelines and received prior approval from the Institutional Ethics Committee of Government Medical College, Amritsar, before its initiation.

Table 1: Experimental groups.

Experimental group	Group A	Group B
Number of patients	35	35
Intervention	- One Probiotic capsule OD with 2.5 billion CFU containing four probiotics strains <i>Lactobacillus acidophilus</i>, <i>Lactobacillus rhamnosus</i>, <i>Bifidobacterium longum</i> and <i>Saccharomyces boulardi</i> - Diet control according to American Diabetes Association recommended Medical Nutrition Therapy	Diet control according to American Diabetes Association recommended Medical Nutrition Therapy
Duration	90 days	90 days

Inclusion criteria

From medicine OPD, both male and female prediabetic (HbA1c level - 5.7% to 6.4%) patients, age more than 18 years, willing to join the study after giving the informed consent were included.

Exclusion criteria

Patient not willing to provide a written consent or on any lipid lowering agents, pregnant and lactating females, seriously and chronically ill patients or having

Inflammatory Bowel Disease and malabsorption were excluded on the basis of history.

CFU dose of probiotic was decided by taking the mean of CFU doses used in previously conducted studies.¹⁴⁻¹⁶

Diet recommended is based on American Diabetes Association, Medical Nutrition Therapy and was as follows:^{17,18}

Patients were advised to achieve and sustain 7-10% weight loss to prevent progression to T2DM. If the patient was

overweight or obese a minimum 5% weight loss was recommended to be achieved and maintained.

The patients were advised to take nutrient dense carbohydrate sources, high in fiber (at least 14 g fiber per 1000 Kcal), non-starchy vegetables like salad greens, broccoli, cauliflower, cucumber, cabbage, fruits like berries, wholegrain, pulses (beans, peas and lentils), dairy products (milk) minimal added sugar and daily intake of 1-1.5 g/Kg body weight per day protein in the form of milk, meat, eggs, fish, nuts and seeds. Patients were advised to take monounsaturated, polyunsaturated fatty acids and long chain-n-3 fatty acids in the form of fatty fish, nuts and seeds. If the patient drinks alcohols he/she was advised to do so in moderation. Patient was advised to take not more than 1 drink per day in case of women and not more than 2 drinks per day in case of men. (1 drink = 30 ml). Sodium intake to be limited to <2,300 mg/day and choose whole food over highly processed foods. Micronutrient supplementation was not needed in patients without an underlying deficiency.

The patients were advised to avoid sugar-sweetened beverages (replace it with water or low calorie or no calorie beverage), sugar-sweetened food products (replace with non-nutritive sweeteners) and starchy foods like white rice, pasta, potatoes, bread and sweets. During the study, if a patient had to take antibiotics, the days of antibiotic intake were subtracted and the patient was given probiotic for increased number of days equal to the days of antibiotic intake.

Following the recording of demographic information of the patients, a complete history was obtained and general physical examination was done. For laboratory

assessments, patients were instructed to report in an overnight fasting state. All clinical findings and investigation results were systematically documented in a completed proforma. Adverse events reported by the patients during the study were noted and appropriately addressed.

Study duration

Total duration of the study was 1.5 years (Sept 2024-Feb 2026) The follow up for glycemic parameters, lipid profile, body weight and BMI was done at the end of 42 days and 90 days. Patients were questioned regarding any adverse events during the period of study. Routine investigations like CBC and urine complete were done on day 0 and day 90.

Statistical analysis

Statistical analysis of data was conducted based on information gathered from patients who finished the whole 90 days research period. Qualitative data was expressed in percentage while, mean $\pm$ SD was used to express all the quantitative data. Comparison of categorical data was done using chi square test and fisher's exact test. Comparison of continuous data from routine investigations, glycaemic parameters and lipid profile in individual groups was done using paired 't' test and for the intergroup comparison, unpaired 't' test was used.

RESULTS

The study groups A and B were statistically comparable at baseline ($p>0.05$) and the group distribution was homogenous (Table 2).

Table 2: Comparison of baseline characteristics between group A and B.

Variables	Group A (n=35) (Mean $\pm$ SD)	Group B (n=35) (Mean $\pm$ SD)	P value
Age (in years)	50.91 $\pm$ 12.86	50.40 $\pm$ 13.63	0.44
Hemoglobin (g/dl)	11.91 $\pm$ 1.06	12.23 $\pm$ 1.12	0.11
TLC (Cell/mm ³)	7597.71 $\pm$ 1443.74	7558.29 $\pm$ 1250.52	0.45
Fasting plasma glucose (mg/dl)	116.46 $\pm$ 12.90	112.12 $\pm$ 10.60	0.06
2 Hour plasma glucose (mg/dl)	155.72 $\pm$ 23.67	150.20 $\pm$ 21.25	0.15
HbA _{1c} (%)	6.11 $\pm$ 0.22	6.04 $\pm$ 0.18	0.10
Total cholesterol (mg/dl)	209.6 $\pm$ 29.66	202.75 $\pm$ 30.15	0.17
LDL-C (mg/dl)	137.49 $\pm$ 27.11	129.89 $\pm$ 24.92	0.11
HDL-C (mg/dl)	40.59 $\pm$ 4.32	41.52 $\pm$ 3.68	0.17
Serum triglycerides (mg/dl)	157.38 $\pm$ 30.20	156.38 $\pm$ 37.30	0.45
Body weight (kg)	75 $\pm$ 11.12	74.49 $\pm$ 7.88	0.41
BMI (kg/m ²)	27.03 $\pm$ 3.73	27.37 $\pm$ 3.40	0.35

TLC – Total Leucocyte Count; HbA_{1c} - Glycosylated hemoglobin; LDL - C - Low density lipoprotein cholesterol; HDL - C High density lipoprotein cholesterol; BMI - Body Mass Index; $p>0.05$: Not significant * $p<0.05$: Significant; ** $p<0.001$: Highly significant (p value: Unpaired t-test)

The intergroup difference between Groups A and B over a period of 90 days of treatment for mean change of Total Cholesterol, LDL – C, HDL – C levels, body weight and BMI were statistically significant ($p<0.05$). Whereas, the

mean change in the levels of glycemic parameters and Triglycerides was statistically non-significant ($p>0.05$) (Table 3). Mean FPG reduction from baseline was statistically significant ($p=0.018$) over 90 days within group A (Figure 1).

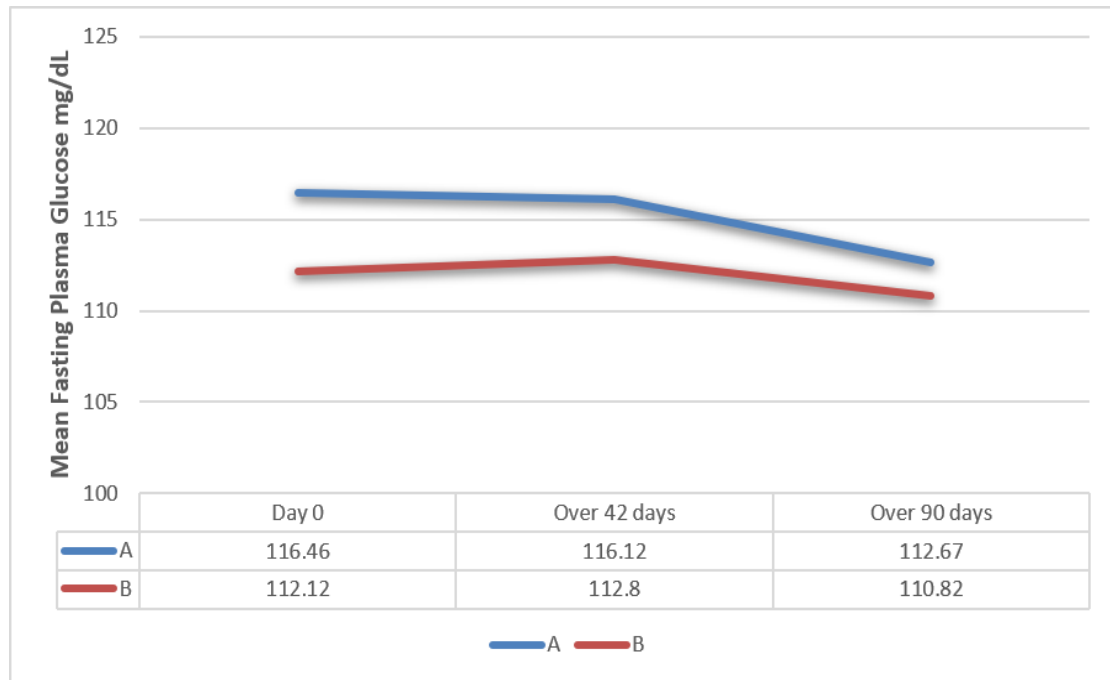


Figure 1: Mean change of fasting plasma glucose levels (mg/dl) in over 90 days of treatment.

It was observed that the total number of adverse events in group A were 10 (9 patients reported bloating and 1 reported an episode of diarrhea). In group B, 3 patients reported bloating. The incidence of bloating was higher in Group A, the difference between the groups was not

statistically significant ($p>0.05$). Diarrhoea was reported in only one participant in Group A and was not observed in Group B. This difference was also not statistically significant ($p>0.05$). These adverse events were disclosed when prompted and were mild in severity that resolved on its own (Table 4).

Table 3: Comparison of mean change in study parameters between group A and B over 90 days of treatment.

Parameter		Group A (n=35) Mean change from Day '0'±SD	Group B (n=35) Mean change from Day '0'±SD	P value
FPG	Over 42 days	-0.34±7.17	0.68±6.17	0.43
	Over 90 days	-3.79±12.83	-1.3±9.31	0.28
2HPG	Over 42 days	0.15±7.33	1.71±8.59	0.24
	Over 90 days	-2.65±13.19	-2.22±11.77	0.48
HbA1c	Over 42 days	-0.0063±0.0277	-0.0054±0.0263	0.46
	Over 90 days	-0.0271±0.1179	-0.0049±0.0868	0.17
Total cholesterol	Over 42 days	-2.05±7.56	0.93±5.34	0.02*
	Over 90 days	-5.31±14.66	0.36±11.03	0.01*
LDL - C	Over 42 days	-2.04±7.67	1.06±4.8	0.013*
	Over 90 days	-5.83±15.62	0.22±10.9	0.009*
HDL - C	Over 42 days	0.16±0.59	-0.23±1.14	0.03*
	Over 90 days	0.57±1.11	-0.36±1.94	0.006*
Serum triglycerides	Over 42 days	-0.60±3.97	0.42±7.23	0.12
	Over 90 days	-3.08±9.77	0.19±20.05	0.17
Body weight	Over 42 days	-0.09±0.30	0.18±0.81	0.03*
	Over 90 days	-0.35±1.10	0.36±2.03	0.03*

Continued.

Parameter		Group A (n=35) Mean change from Day '0'±SD	Group B (n=35) Mean change from Day '0'±SD	P value
BMI	Over 42 days	-0.03±0.08	0.08±0.31	0.02*
	Over 90 days	-0.13±0.39	0.15±0.74	0.03*

FPG – Fasting plasma glucose; 2HPG – 2 Hour plasma glucose; HbA1c - Glycosylated haemoglobin; LDL - C - Low density lipoprotein cholesterol; HDL - C High density lipoprotein cholesterol; BMI – Body mass index; p>0.05: Not significant *p<0.05: Significant; **p<0.001: Highly significant (p value: Unpaired t-test)

Table 4: Adverse events in patients of group A and B at end of 90 days of treatment.

Adverse events	Group A, (n=35) N (%)	Group B, (n=35) N (%)	P value
Bloating	9 (25.71%)	3 (8.57%)	0.06 ^a
Diarrhea	1 (2.86%)	0 (0%)	1.0 ^b

p>0.05: Not significant *p<0.05: Significant; **p<0.001: Highly significant (p value: a-Chi-square test, b-Fisher's exact test)

DISCUSSION

Several studies have demonstrated that probiotic supplementation exerts beneficial effects on glycemic control and lipid profile. However, an extensive review of the literature reveals considerable variability in the magnitude and consistency of these effects, likely due to differences in probiotic strains, dosage, duration of intervention, study populations and concurrent lifestyle modifications.

In the present study, comparison between Groups A and B over a treatment period of 90 days demonstrated a statistically significant intergroup difference in the mean change of total cholesterol, LDL-C, HDL-C, body weight and BMI (p<0.05). In contrast, the mean changes in glycemic parameters, including FPG, 2HPG, HbA1c and serum TG levels, were not statistically significant between the two groups (p>0.05). AkbariRad M et al (2023), in a placebo-controlled trial involving 70 prediabetic patients, evaluated the effects of a probiotic preparation containing *Lactobacillus casei*, *Lactobacillus acidophilus*, *Lactobacillus rhamnosus*, *Lactobacillus bulgaricus*, *Bifidobacterium breve*, *Bifidobacterium longum* and *Streptococcus thermophilus* along with the prebiotic fructooligosaccharide, administered for three months in addition to lifestyle modification. The intervention group demonstrated significant reductions in fasting blood sugar (P<0.001) and HbA1c (P=0.035) from baseline. However, the differences between the probiotic and placebo groups in fasting blood sugar (P=0.764) and HbA1c (P=0.972) were not statistically significant. Interpretation of this study is limited because the probiotic dose in colony-forming units (CFU) was not specified and the preparation also contained fructooligosaccharide, making it difficult to attribute the observed effects solely to probiotics.¹³

Similarly, Jiang et al (2021), in a randomized, double-blind, placebo-controlled trial involving 76 patients with type 2 diabetes mellitus and diabetic nephropathy, administered a daily probiotic supplement containing

3.2×10⁹ CFU for 12 weeks, while the control group received starch capsules. The probiotic formulation consisted of *Bifidobacterium bifidum*, *Lactobacillus acidophilus* and *Streptococcus thermophilus*. At the end of the intervention, significant reductions were observed in fasting blood glucose and HbA1c (P<0.05), whereas the change in 2-hour postprandial blood glucose was not statistically significant (P=0.24).¹⁴

The reduction in fasting plasma glucose observed within the probiotic group in our study is consistent with findings from several previous studies. However, the effects on HbA1c and postprandial glucose remain inconsistent across the literature. In the present study, reductions in 2HPG and HbA1c were not statistically significant. These variations may be explained by differences in probiotic formulations, colony-forming unit dose, number of bacterial strains, duration of supplementation and characteristics of the study population. Overall, evidence suggests that multi-strain probiotic preparations administered at higher CFU doses and for longer durations are more likely to produce significant improvements in glycemic parameters.

The beneficial effects of probiotics on lipid metabolism have been more consistent across studies. In a meta-analysis of 19 randomized controlled trials involving 967 hypercholesterolemic adults receiving probiotic supplementation for 4–12 weeks, Mo et al (2019) reported significant reductions in total cholesterol (P<0.001), LDL-C (P<0.001) and triglycerides (P=0.005), along with a modest but statistically significant increase in HDL-C (P=0.028). Most of the probiotic preparations used contained strains belonging to the *Lactobacillus* and *Bifidobacterium* genera. These findings are largely consistent with the results of the present study, where significant improvements were observed in total cholesterol, LDL-C and HDL-C. However, although serum triglyceride levels declined following probiotic supplementation, the reduction was not statistically significant.¹⁹

The effect of probiotics on anthropometric parameters has also been evaluated in several clinical trials, with generally favorable effects on body weight. Guo et al (2025), in a systematic review and meta-analysis of eight randomized controlled trials involving 412 obese participants, reported significantly greater weight loss in the probiotic group compared with controls ($P < 0.00001$). However, no statistically significant difference was observed in BMI between the two groups.²⁰

In contrast, Sudha M.R. et al (2019), in a placebo-controlled trial involving 90 overweight and obese adults, demonstrated that 12 weeks of supplementation with a multi-strain probiotic preparation containing *Lactobacillus casei*, *Lactobacillus salivarius*, *Lactobacillus plantarum*, *Lactobacillus acidophilus*, *Bifidobacterium breve* and *Bacillus coagulans* (5×10^9 CFU each), along with fructooligosaccharide, resulted in a significant reduction in BMI ($P = 0.0001$).²¹

Overall, available evidence suggests that probiotic supplementation consistently contributes to reductions in body weight, whereas its effect on BMI remains variable across studies. In the present study, both body weight and BMI showed minimal but statistically significant reductions following probiotic supplementation, supporting the potential role of probiotics as an adjunct to dietary intervention in improving anthropometric parameters in individuals with prediabetes.

The variability observed in glycemic outcomes across different studies highlights the influence of probiotic strain selection, CFU dose, treatment duration and patient characteristics. Larger, long-term randomized controlled trials using standardized probiotic formulations are needed to establish the optimal probiotic dose and to better define its role in the prevention of progression from prediabetes to type 2 diabetes mellitus.

Limitations

This was a single-centre, open-label study with a follow-up duration of only 90 days due to time constraints. Dietary adherence was based on counselling and was not measured.

CONCLUSION

This study demonstrated, that probiotic administration to prediabetic patients for a period of three months did not improve the glycemic variables in terms of FPG, 2HPG and HbA1c. Though, it showed a statistically significant improvement in lipid profile, body weight and BMI. Probiotic administration was associated with minor and manageable adverse events. The findings highlight the potential role of probiotic supplementation as an adjunct to dietary therapy in prediabetic individuals, particularly in improving lipid parameters and anthropometric outcomes. Future large-scale studies with longer follow-up durations may help to further evaluate the effects of probiotics on glycemic control.

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