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ROLE OF PROBIOTICS-BASED SUPPLEMENTS IN THE PREVENTION AND TREATMENT OF GESTATIONAL DIABETES MELLITUS

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ABSTRACT

Background: Gestational diabetes mellitus (GDM) is a common pregnancy-related metabolic disorder, and the effectiveness of probiotic supplementation in preventing GDM and improving glycaemic control in the Pakistani population remains unclear.

Objective: To determine the prevalence of gestational diabetes mellitus (GDM) in at-risk pregnant women taking probiotic-based supplements versus controls, as well as to assess the impact of probiotics on glycaemic control, in relation to the mean change in fasting blood sugar (FBS) in women with GDM.

Methods: A non-randomised controlled trial was conducted at the Department of Gynaecology and Obstetrics at IIMCT Railway Hospital, Rawalpindi from January 2026 to May 2026. One hundred pregnant women with at least one GDM risk factor, aged 18–40 years and with a gestational age of not more than 20 weeks, were recruited. Group A (n=50) underwent standardised probiotic supplementation and routine antenatal care; Group B (n=50) underwent routine antenatal care alone. FBS was measured at baseline, at 24–28 weeks, and four weeks after GDM diagnosis in GDM-positive women. Data analysis was conducted using SPSS version 23.

Results: Participants averaged 26.36±4.21 years in Group A and 28.36±4.06 years in Group B. GDM was confirmed in 7 (14%) women in Group A versus 17 (34%) in Group B (χ^2=5.48, p=0.019). Among GDM-positive patients, mean FBS declined from 107.4 to 97.5 mg/dL in Group A (p=0.003), compared with a lesser reduction from 107.5 to 103.2 mg/dL in Group B (p=0.026).

Conclusion: Daily probiotic supplementation was associated with a markedly lower GDM frequency and a greater reduction in fasting blood glucose among women who nonetheless developed GDM.

KEYWORDS: Gestational Diabetes Mellitus, Probiotics, Glycaemic Control, Fasting Blood Sugar (FBS), Socioeconomic Status (SES), Pregnancy

INTRODUCTION

Gestational diabetes mellitus (GDM) is characterised by carbohydrate intolerance that emerges for the first time during gestation in women who have no established pre-pregnancy diagnosis of diabetes. The condition poses substantial health risks to both the mother and her offspring, affecting a considerable share of pregnancies worldwide [1]. Epidemiological data suggest that roughly one in seven pregnancies is affected by GDM, imposing a considerable strain on antenatal healthcare systems worldwide [2].

Maternal and perinatal complications attributable to GDM encompass hypertensive disorders, operative delivery, fetal overgrowth, neonatal hypoglycaemia, and a substantially elevated long-term likelihood of progression to overt type 2 diabetes mellitus in both mother and child [3, 4]. The GDM prevalence is usually higher among South Asian communities, such as those in Pakistan, a pattern explained by unique genetic susceptibility profiles, dietary habits, and physical inactivity. Among the local determinants, the high body mass index (BMI), polycystic ovary syndrome (PCOS), a positive family history of type 2 diabetes mellitus, and the increasing maternal age are the main risk factors [5, 6].

Probiotics are viable strains of microbes that, at appropriate doses, provide beneficial physiological effects to the host by altering the composition of the intestinal microbiota. Their relevance to metabolic conditions has grown substantially, given that disruption of the gut microbial ecosystem during gestation is now recognised as a contributor to insulin resistance and pro-inflammatory states [7, 8]. Strains belonging to the Lactobacillus and Bifidobacterium genera have been shown to reinforce intestinal mucosal integrity, attenuate cytokine-mediated inflammation, and improve insulin responsiveness by producing short-chain fatty acids [9, 10]. These mechanisms contribute to reduced

fasting plasma glucose and to the mitigation of GDM-associated metabolic dysfunction. Evidence from randomised controlled trials demonstrates that initiating probiotic supplementation in early pregnancy is associated with a lower incidence of GDM and favourable changes in fasting glucose and markers of insulin resistance [11, 12].

The rationale of the current study is to compare the frequency of GDM in high-risk pregnant women who take probiotic supplements with that in those who do not, and to determine the glycaemic response, defined as the mean reduction in fasting blood sugar, in women who still develop GDM despite supplementation. Despite growing international evidence, published data examining the utility of probiotic supplementation in Pakistani at-risk pregnant women, particularly with respect to GDM incidence and glycaemic response, remain sparse. In addition, the majority of the available literature appraises single-strain preparations without commenting on the clinical significance of the glucose-enhancing effect observed in women who develop GDM despite taking probiotics.

METHODS

This was a non-randomised controlled trial conducted in the Department of Gynaecology and Obstetrics at IIMCT Railway Hospital, Rawalpindi. The institutional review committee gave ethical clearance (Appl. # Riphah/IRC/23/3125, dated December 12th, 2023). Written informed consent was obtained from each participant after explaining the study procedures and assuring their safety. Data were collected from January 2026 to May 2026. The sample size was estimated using GDM rates of 13% and 34% in the probiotic and control arms, respectively [13], with 80% statistical power and significance level of 5%, yielding a sample size of 50 subjects per arm (n=100) using formulae $n = \{ Z(1-\alpha) \times \sqrt{[2\bar{P}(1-\bar{P})]} + Z(1-\beta) \times \sqrt{[P1(1-P1) + P2(1-P2)]} \}^2 / (P1 - P2)^2$. Non-probability consecutive sampling was used for enrolment.

The women had to be aged 18–40 years, have a singleton pregnancy with a gestational age of not more than 20 weeks, and be categorised as at risk. At-risk classification was based on the presence of any one of the following recognised risk factors: BMI of 25kg/m^2 or higher, history of GDM in pregnancy or delivery of a macrosomic infant, family history of type 2 diabetes mellitus in first-degree relatives, PCOS, or maternal age of 35 years or older. Exclusion criteria included pre-existing type 1 or type 2 diabetes, a prior history of GDM, clinically significant gastrointestinal pathology such as inflammatory bowel disease or coeliac disease, active infection or immunosuppressive therapy.

At the initial visit, a 5 mL venous blood sample was collected for baseline fasting blood glucose estimation and OGTT. Body mass index was derived from each participant's pre-pregnancy weight, or the earliest first-trimester weight when a pre-pregnancy value was not available, together with measured height, and was classified using the standard World Health Organisation categories, in keeping with accepted obstetric practice [14]. Assignment to a study arm was at the attending consultant's discretion. Group A (Intervention, n=50) was prescribed a standardised daily probiotic formulation encompassing Lactobacillus and Bifidobacterium strains, commencing at enrolment and continuing to delivery, alongside standard antenatal care. Group B (Control, n=50) continued with standard antenatal care without probiotic supplementation. The probiotic used was a commercially available, locally registered oral multi-strain capsule containing Lactobacillus acidophilus, Lactobacillus rhamnosus, Bifidobacterium longum and Bifidobacterium bifidum, providing approximately 5 billion colony-forming units (5×10^9 CFU) per capsule. One capsule was taken orally once daily after a meal from enrolment until delivery. A senior gynaecologist supervised all participants throughout the study. Repeat fasting blood glucose and OGTT evaluations were undertaken at 24–28 weeks of gestation to screen for GDM. The diagnosis of GDM was made according to the IADPSG diagnostic framework, requiring at least one abnormal value on a 75 g OGTT: fasting plasma glucose ≥92 mg/dL, one-hour plasma glucose ≥180 mg/dL, or two-hour plasma glucose ≥153 mg/dL [15, 16]. Participants found to have GDM underwent follow-up; Fasting Blood Sugar (FBS) was measured at baseline, at the time of GDM diagnosis (24–28 weeks), and again four weeks thereafter, with Group A continuing probiotic supplementation and Group B managed per standard protocol. The primary measure of glycaemic response was the mean difference in FBS between the point of GDM diagnosis and the four-week reassessment. Any participant who developed GDM or persistent hyperglycaemia, or who failed to respond to supplementation, was referred for standard clinical management (medical nutrition therapy, with insulin initiated where indicated per local protocol); supplementation was continued only as an adjunct.

All statistical computations were performed using SPSS version 23. Normality of continuous data was evaluated using the Shapiro–Wilk test. Between-group comparison of GDM frequency was conducted with the chi-square test, while within-group changes in FBS were examined using the paired t-test. Results with a p-value not exceeding 0.05 were deemed statistically significant.

RESULTS

One hundred at-risk pregnant women, with 50 participants per group, were included. Pre-intervention characteristics for both groups are detailed in Table 1. The mean age recorded for Group A was 26.36±4.21 years, while Group B participants averaged 28.36±4.06 years. Groups A and B had gestational ages at enrolment of 14.06±2.72 weeks and 14.10±2.45 weeks, respectively, and baseline body mass indices of 23.74±2.50 kg/m^2 and 23.79±2.49 kg/m^2, respectively. The most common predisposing factor between the two groups was a positive family history of diabetes mellitus. The baseline profiles of the two groups were well matched.

Table 1: Baseline characteristics of the study participants.

Variable	Probiotics (n=50)	Control (n=50)
Age (years) – Mean±SD	26.36 ± 4.21	28.36 ± 4.06
Gestational Age (weeks) – Mean±SD	14.06 ± 2.72	14.10 ± 2.45
BMI (kg/m²) – Mean±SD	23.74 ± 2.50	23.79 ± 2.49
FBS Baseline (mg/dL) – Mean±SD	81.75 ± 5.45	83.49 ± 6.15
Residence – Urban n (%)	28 (56%)	26 (52%)
Residence – Rural n (%)	22 (44%)	24 (48%)
Socioeconomic status (SES) – Good n (%)	17 (34%)	22 (44%)
Socioeconomic status (SES) – Poor n (%)	33 (66%)	28 (56%)
Previous History of GDM n (%)	6 (12%)	10 (20%)
Family History of DM n (%)	34 (68%)	36 (72%)
PCOS n (%)	15 (30%)	10 (20%)

Table 2 presents data on BMI categories. The most common in both groups was normal body weight (BMI 18.5–24.9 kg/m^2). Among the women in Group A, 36 (72%) were within the normal range, 13 (26%) were overweight, and one (2%) was obese. In group B, 33 (66%) were of normal BMI; 16 (32%) were overweight, and 1 (2%) was underweight. None of the registered women was morbidly obese.

Table 2: BMI category distribution by study group.

BMI Category	Probiotics– n (%)	Control – n (%)	Total – n (%)
Underweight (<18.5)	0 (0%)	1 (2%)	1 (1%)
Normal (18.5–24.9)	36 (72%)	33 (66%)	69 (69%)
Overweight (25.0–29.9)	13 (26%)	16 (32%)	29 (29%)
Obese (≥30.0)	1 (2%)	0 (0%)	1 (1%)
Total	**50 (100%)**	**50 (100%)**	**100 (100%)**

The results of the GDM diagnosis at the 24–28 week evaluation are summarised in Table 3. A significantly lower GDM rate was observed in women who received probiotic supplementation: 7 of 50 women (14%) in Group A, compared with 17 of 50 women (34%) in Group B. The difference was statistically significant ($\chi^2 = 5.48$, $p = 0.019$).

Table 3: Frequency of GDM at 24–28 weeks by study group.

GDM Status	Probiotics n (%)	Control n (%)	p-value
Positive	7 (14%)	17 (34%)	**0.019***

Negative	43 (86%)	33 (66%)	
Total	50 (100%)	50 (100%)	χ^2=5.48

In the subgroup of women who developed GDM, glucose changes over four weeks of follow-up are displayed in Table 4. Group A demonstrated a mean FBS decline from 107.4±6.2 mg/dL at the time of diagnosis to 97.5±5.1 mg/dL at the four-week re-evaluation, representing a mean reduction of 9.9 mg/dL (t=−4.65, p=0.003). Group B also showed improvement, with FBS falling from 107.5±8.1 mg/dL to 103.2±6.3 mg/dL (mean reduction: 4.3 mg/dL; t=−1.90, p=0.026). However, the magnitude of FBS reduction was substantially larger in the probiotic group.

Table 4: Mean FBS at GDM diagnosis and after four weeks of management (GDM-positive patients only).

Parameter	**Probiotics (n=7)**	**Control (n=17)**
FBS at Diagnosis (mg/dL) – Mean±SD	107.4 ± 6.2	107.5 ± 8.1
FBS after 4 Weeks (mg/dL) – Mean±SD	97.5 ± 5.1	103.2 ± 6.3
Mean Change (mg/dL)	−9.9	−4.3
Paired t-test result	t=−4.65	t=−1.90
p-value	0.003*	0.026*

DISCUSSION

The results of this study were that GDM was diagnosed in only 14% of women who received probiotic supplements, compared with 34% of the controls, a statistically significant difference ($\chi 2$ = 5.48, p = 0.019). This finding is consistent with the existing literature on the preventive effect of probiotics in GDM. Pakmehr et al. conducted a systematic review and meta-analysis of randomised, placebo-controlled trials and demonstrated that probiotic supplementation significantly reduced the incidence of GDM [12]. In line with this, the relative risk of GDM among probiotic users was 0.71 in an umbrella meta-analysis by Gao et al., which combined 27 studies and more than 83,000 participants [17]. The current results add to this evidence the generalisability of the protective effect to a Pakistani hospital-based cohort.

The mechanisms by which probiotic supplementation reduces the risk of GDM are multifactorial. During pregnancy, the intestinal microbiome undergoes dramatic compositional changes, and probiotic colonisation can help restore microbial balance. Species of the genera Lactobacillus and Bifidobacterium have been reported to enhance gut barrier function by reducing endotoxin translocation across the intestinal epithelium, thereby attenuating systemic inflammation and maintaining insulin receptor signalling [7]. The short-chain fatty acids produced by the fermentation of dietary substances by the probiotic bacteria activate G-protein-linked receptors on enteroendocrine cells, which subsequently stimulate the release of glucagon-like peptide-1 (GLP-1), which causes the release of insulin by the pancreas and the disposal of glucose by the peripheral tissues. Uzair et al.'s scoping review of 29 randomised controlled trials found that these actions were supported by a consistent decrease in fasting glucose, insulin resistance indices, and inflammatory biomarkers in women with GDM receiving Lactobacillus and Bifidobacterium supplementation [9]. In the present study, a multi-strain capsule combining Lactobacillus acidophilus, Lactobacillus rhamnosus, Bifidobacterium longum, and Bifidobacterium bifidum was used, which may have strengthened these effects relative to the single-strain preparations that comprise much of the existing evidence.

The glycaemic-response analysis was limited to women who were diagnosed with GDM. Still, the results showed that women in the probiotic arm had a 4-week decline in FBS from 107.4 mg/dL to 97.5 mg/dL, a difference of 9.9 mg/dL. In contrast, controls showed only a relatively small drop in FBS of 4.3 mg/dL. Although the two changes were statistically significant, the therapeutic benefit of probiotic supplementation was much greater. This finding shows that probiotics not only preserve quantifiable glucose-reducing effects after the onset of GDM but also act as a preventive measure. In line with this interpretation, Lin et al. studied the effects of probiotic and prebiotic supplementation during pregnancy. They found that the gut microbiota could counteract elevated fasting glucose levels by modulating the expression of metabolic genes via fermentation-derived short-chain fatty acids and epigenetic mechanisms [18]. Wan and Ma reported complementary results, showing a decrease in glycaemic indices in women with previously diagnosed GDM after gut-microbiome-targeted supplementation [10].

Analysis of baseline data showed that the most common risk factor was a familial history of diabetes mellitus, which was found in 68% of Group A and 72% of Group B participants. The second most common predisposing condition was polycystic ovary syndrome. Collectively, these trends indicate that the high GDM risk in this group is more likely to be hereditary or endocrine-mediated than adiposity-related. In line with this, the vast majority of participants had a normal BMI, with overweight in 29% and obesity in only 1%. The beneficial effect of probiotic supplementation in

this predominantly non-obese cohort is clinically noteworthy, indicating that this intervention is valuable for a broader spectrum of vulnerable pregnant women beyond those with adiposity-driven risk.

The susceptibility of South Asian women to GDM at relatively modest BMI levels is well documented; Choudhury and Devi Rajeswari attributed this to ethnic differences in adipose tissue distribution and intrinsic insulin sensitivity, which predispose to glucose intolerance even in the absence of frank obesity [19]. Within the Pakistani context specifically, reports on the usefulness of probiotic therapy in high-risk pregnant women are sparse. A pilot microbiome investigation by Kousar et al., utilising 16S rRNA metagenomic sequencing, identified characteristic dysbiotic signatures in Pakistani women with GDM, lending biological support to the rationale for probiotic intervention in this population [20]. Given resource constraints that often impede access to specialised nutritional counselling and pharmaceutical management in local healthcare settings, the practical relevance of the current findings is considerable. Probiotic preparations are available, cost-effective and have a well-established safety history in pregnancy [21]. Mechanistic corroboration is provided by Su et al., whose integrative multi-omics approach showed that 8 weeks of probiotic intake in women with GDM increased intestinal Lactobacillus abundance (7.6-fold), improved insulin sensitivity, and reduced inflammatory activity, thereby supporting the clinical outcomes reported here at the molecular level [22]. The strength of the study was the structured glucose-monitoring schedule, with fasting glucose and OGTT assessed at baseline, at 24–28 weeks, and at 4 weeks after diagnosis, which enabled timely detection and management of GDM.

Several limitations should be noted. The lack of randomisation and allocation blinding predisposes the study to inherent selection bias. The sample size (50 participants per group) was sufficient to conduct the main comparison; however, the results should not be generalised to non-homogeneous populations. The probiotic product was standardised at all times, but the formulation used may have differed from that prepared in standard clinical practice. Formal quantitative monitoring of adherence to supplementation and dietary intake was not conducted during the study. Outcomes of neonatal care, including birth weight and mode of delivery, as well as long-term glycaemic profiles, were beyond the scope of the study. These initial observations in the Pakistani context will need to be validated and elaborated by future randomised controlled studies with larger sample sizes, stratified study designs and longer follow-ups.

CONCLUSION

Daily probiotic supplementation in high-risk pregnant women was associated with a much lower rate of GDM compared with controls. In women who developed GDM despite supplementation, there was a greater decrease in fasting blood glucose during the four-week follow-up with probiotic use, indicating a quantifiable change in glycaemic state. These findings support the incorporation of probiotic supplementation into both primary prevention and adjunctive treatment for managing GDM in the Pakistani obstetric context.

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