

Evaluating the Role of Probiotic Supplementation in Gestational Diabetes Prevention: A Single-Arm Interventional Study

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SUMMARY

Background/Aim: Gestational Diabetes Mellitus (GDM) is a common pregnancy complication associated with significant adverse maternal and neonatal outcomes. Probiotic supplementation has emerged as a potential preventive strategy through modulation of gut microbiota and improvement of metabolic parameters.

Objective: To evaluate the role of daily probiotic supplementation with *Lactobacillus acidophilus* and *Bifidobacterium animalis* subsp. *lactis* in preventing GDM among high-risk pregnant women.

Methods: This single-arm interventional study enrolled 60 high-risk pregnant women (14-16 weeks' gestation) attending October 6th University Hospital, Egypt. Inclusion criteria included at least one GDM risk factor: previous GDM, previous macrosomia (birth weight ≥ 4000 g), pre-pregnancy BMI ≥ 30 kg/m², PCOS, or first-degree family history of diabetes. Participants received daily probiotics (Linex Adult Probio-tec AB Blend 64, minimum 1×10^{10} CFU) from 14-16 weeks until the 24-28-week Oral Glucose Tolerance Test (OGTT). The primary outcome was GDM incidence by IADPSG criteria (fasting ≥ 92 mg/dL, 1-hour ≥ 180 mg/dL, or 2-hour ≥ 153 mg/dL). Secondary outcomes included OGTT values, change in fasting glucose from baseline, maternal weight gain, adherence, and maternal-neonatal outcomes. Statistical analysis was performed using IBM SPSS version 28.

Results: Mean age was 28.7 years, mean BMI 30.0 kg/m² (55% obese). Mean baseline fasting glucose was 97.1 mg/dL. GDM incidence was 65.0% (39/60). Among GDM cases, 30.8% had isolated 1-hour hyperglycemia, 20.5% isolated fasting hyperglycemia, and 35.9% met multiple criteria. Adherence was excellent (84.8%), with no participant below 70%. Fasting glucose remained stable (baseline 97.1 vs. OGTT 98.2 mg/dL, $p=0.498$). Women with GDM had significantly higher OGTT values at all-time points ($p<0.001$). Mean weight gain was 11.7 kg over 10-14 weeks, exceeding IOM recommendations. Mean gestational age at delivery was 38.4 weeks, with preterm birth rate 5.0% and post term birth rate 13.3%. Cesarean section rate was 81.6% (33.3% elective, 48.3% emergency). Neonatal outcomes showed mean birth weight 3483g, macrosomia 16.7%, neonatal hypoglycemia 50.0%, and NICU admission 23.3%. Apgar scores were favorable (7.4 at 1-min, 9.0 at 5-min). Maternal complications included hypertensive disorders (38.3%) and postpartum hemorrhage (11.3%). Subgroup analysis showed highest GDM risk in obese women (72.7%) and those with multiple risk factors. Women with excellent adherence ($\geq 90\%$) had lower GDM incidence (59.1%) than those with moderate adherence (73.7%). Weak non-significant negative correlations were found between adherence and OGTT values ($r = -0.15$ to -0.22).

Conclusion: GDM incidence in this high-risk cohort receiving probiotics was 65%. Excellent adherence confirms intervention feasibility. Suggests

a possible trend, although no statistically significant association was observed. High rates of adverse outcomes underscore the urgent need for effective preventive strategies in this vulnerable population

Keywords: Gestational Diabetes Mellitus, Probiotics, *Lactobacillus Acidophilus*, *Bifidobacterium Lactis*, High-Risk Pregnancy

INTRODUCTION

Gestational Diabetes Mellitus (GDM) is a common metabolic condition of pregnancy that has serious acute and long-term effects for both the mother and child. affects approximately 14-16% of all pregnancies worldwide and is now one of the most common medical problems in pregnancy. Rising maternal obesity and maternal age have increased GDM prevalence globally, but there is still no universally effective primary prevention method. Growing data relates GDM to changes in gut microbiota and inflammation, implying that microbiota-targeted therapies like probiotics could provide a novel preventive strategy [1]. Chronic insulin resistance combined with pregnancy-related hormonal changes and poor pancreatic β cell compensation causes hyperglycemia in the second and third trimesters [2].

Traditional management focuses on dietary changes, physical exercise, and medication (insulin or oral medicines), which enhance glycemia but do not constitute primary prevention and are usually started after GDM is identified at 24-28 weeks. Data demonstrating fetal overgrowth before normal diagnostic timing underline the importance of early, preventative interventions [3]. Pregnancy causes dramatic changes in the gut microbiota, with decreased richness and increased Proteobacteria and Actinobacteria toward late gestation, changes that can promote obesity and insulin resistance. Gut dysbiosis in women with GDM is characterized by increased bacterial richness, changes in major phyla (increased Firmicutes, decreased Bacteroidetes and Actinobacteria), and strong relationships between specific species and fasting glucose, insulin resistance, and inflammatory markers [4].

Probiotics, which are live microorganisms that provide health benefits to the host, can change gut composition, reduce inflammation, and enhance metabolic parameters. Short-term probiotic supplementation with *Lactobacillus* and *Bifidobacterium* strains improves fasting glucose, fasting insulin, and HOMA IR in women with established diet-controlled GDM compared to placebo, without affecting weight gain, implying improved insulin sensitivity as an adjunct to medical nutrition therapy. Probiotics are

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one of the interventions having the strongest evidence for improving glycemic control in GDM and promoting maternal and fetal health, according to reviews of microbiota focused therapy [5].

Probiotics may help prevent GDM by repairing eubiosis, increasing beneficial metabolites such short chain fatty acids, and reducing low-grade inflammation and insulin resistance. Given that gut dysbiosis and inflammatory markers are visible in early pregnancy, intervention before or during the early second trimester may be especially important. At the population level, a safe, low-cost probiotic strategy could supplement lifestyle counseling in high-risk women and general obstetric treatment [6].

PATIENTS AND METHODS

Study Design and Setting

This study was designed as a prospective, single-arm interventional clinical study to evaluate the efficacy and safety of probiotic supplementation in a high-risk obstetric population. It was conducted at the antenatal care clinic of the Obstetrics and Gynaecology Department, October 6th University Hospital, Giza, Egypt, a tertiary care center with standardized protocols for Gestational Diabetes Mellitus (GDM) screening and management. The study duration was seven months, including a preparatory phase, an active recruitment and follow-up phase, and a final phase for data analysis.

Study Population

Pregnant women with a confirmed viable singleton pregnancy between 14 and 16 weeks of gestation were screened for eligibility. Inclusion required the presence of at least one risk factor for GDM, including previous GDM, history of macrosomia, obesity (BMI ≥ 30 kg/m²), polycystic ovary syndrome, or a first-degree family history of diabetes mellitus. Exclusion criteria included pre-existing diabetes mellitus, multiple pregnancy, use of medications affecting glucose metabolism, significant gastrointestinal disorders or prior bariatric surgery, known hypersensitivity to probiotics, and recent probiotic supplementation.

Sample Size and Sampling Technique

A consecutive sampling technique was employed during the recruitment phase. A minimum sample size of 60 participants was targeted to provide a stable estimate of the primary outcome and adequate power to detect clinically significant changes in glycemic parameters.

Intervention Protocol

All enrolled participants received the probiotic intervention (Linex Adult Probio-tec AB Blend 64, Sandoz), containing *Lactobacillus acidophilus* and *Bifidobacterium animalis* with a total viable count of at least 1×10^9 CFU per capsule. Participants were instructed to take one capsule orally once daily with meals from enrollment until the time of the oral glucose tolerance test (OGTT) at 24–28 weeks' gestation.

Adherence Monitoring

Adherence to the intervention was assessed through monthly pill counts of returned medication packs and participant-maintained daily intake diaries.

Data Collection and Follow-up

Data were collected at predefined time points, including a baseline visit at enrollment, monthly follow-up visits. Baseline evaluation included demographic and clinical data, physical examination, and fasting plasma glucose measurement. Follow-up visits included monitoring of adherence, adverse events, and clinical parameters such as weight and blood pressure. At 24–28 weeks of gestation, all participants underwent a standardized 75-g OGTT with plasma glucose measurements at fasting, 1 hour, and 2 hours' post-load.

Outcome Measures The primary outcome was the incidence of Gestational Diabetes Mellitus (GDM), diagnosed according to the International Association of Diabetes and Pregnancy Study Groups (IADPSG) criteria. Secondary outcomes included changes in glycemic parameters, maternal weight gain, and the safety profile of the intervention based on reported gastrointestinal adverse events.

Ethical consideration

The study received approval from the Ethical Committee of the Faculty of Medicine, 6th of October University. The study objectives were explained to all of the participating women, and written informed consent was obtained prior to inclusion. Data confidentiality was strictly maintained throughout the study, and no additional risks were imposed on the participants. (Ethical code: SCCREIRB-MEDICINGOCT-PU-001-121224-018) Dual Trigger, Oocyte Retrieval and Embryo Transfer

STATISTICAL ANALYSIS

Statistical analysis was performed using IBM SPSS software package version 20.0 (Armonk, NY: IBM Corp). Qualitative variables were summarized as frequencies and percentages, while quantitative variables were presented as mean $\pm$ standard deviation, median, and range (minimum–maximum) according to data distribution. Normality of quantitative variables was assessed using the Kolmogorov–Smirnov test. Comparisons between categorical variables were performed using the Chi-square test. For quantitative variables, the independent two-sample t-test was used for normally distributed data, while the Mann–Whitney U test was applied for non-normally distributed variables. Correlation analysis was conducted using Spearman's correlation coefficient when appropriate. Regression analyses were performed to evaluate predictors of clinical outcomes. Univariate and multivariate logistic regression models were used for binary outcomes, and results were expressed as odds ratios (OR) with 95% Confidence Intervals (CI). Linear regression models were used for continuous outcomes, and results were expressed as unstandardized beta coefficients (β). Statistical significance was set at $p \leq 0.05$.

RESULTS

A total of 60 participants were enrolled in the study and followed from 14–16 weeks of gestation until delivery. All

participants received the probiotic intervention daily until the 24–28-week Oral Glucose Tolerance Test (OGTT). This single-arm interventional study demonstrated that among high-risk pregnant women receiving daily probiotic supplementation with *Lactobacillus acidophilus* and *Bifidobacterium animalis* subsp. *lactis*, the incidence of GDM was 65.0%. While this rate remains high, reflecting the high-risk nature of the cohort, several observations merit consideration. The high rates of adverse neonatal outcomes (macrosomia 16.7%, neonatal hypoglycemia 50.0%, NICU admission 23.3%) underscore the clinical importance of effective GDM prevention strategies in this vulnerable population.

The overall mean adherence rate was excellent at 84.8%, with more than two-thirds of participants (68.4%) achieving good to excellent adherence ($\geq 80\%$). No participants had adherence below 70%, indicating high compliance with the intervention protocol. The study population comprised women with a mean age of 28.7 years, predominantly overweight or obese (85%). The most common risk factor was family history of diabetes (58.3%), followed equally by previous GDM and PCOS (46.7% each). Mean baseline fasting glucose was within normal range at 97.1 mg/dL (Table 1). OGTT time points compared to those who remained normoglycemic ($p < 0.001$ for all comparisons). Although women who developed GDM gained slightly more weight on average (12.0 kg vs. 11.2 kg), this difference was not statistically significant ($p = 0.198$) (Table 2).

Delivery outcomes were generally favorable in terms of gestational age, with a mean of 38.4 weeks and 81.6% of participants delivering at term and 13.3% post term deliveries, while the preterm birth rate (5%) remained within expected population ranges. However, cesarean section rates were markedly elevated at 81.6%, far exceeding recommended levels, likely reflecting the high-risk profile of the cohort, including advanced maternal

age, obesity, and a high prevalence of Gestational Diabetes Mellitus (GDM) (Table 3). Emergency cesarean sections accounted for more than half of the deliveries, possibly due to complications such as fetal distress or suspected macrosomia. Neonatal outcomes showed a mean birth weight of 3483 g, though macrosomia occurred in 16.7% of cases, consistent with maternal hyperglycemia. Apgar scores were generally reassuring. However, neonatal hypoglycemia was notably high (50%), and NICU admissions reached 23.3%, highlighting the importance of effective GDM prevention and management strategies (Table 4).

Although the GDM group showed numerically higher rates of adverse neonatal outcomes (higher birth weight, more macrosomia, more hypoglycemia), none of these differences reached statistical significance, possibly due to the sample size. Maternal obstetric complications were highly prevalent in this high-risk cohort. Hypertensive disorders of pregnancy affected 38.3% of participants, markedly exceeding the 5–10% typically reported in the general population (Table 5) prevention and management strategies.. GDM incidence was highest among obese women (72.7%), compared to 55.6% in both normal weight and overweight groups. There was a clear trend toward increasing GDM incidence with a greater number of baseline risk factors, from 50.0% in women with a single risk factor to 70.4% in those with three risk factors Although GDM incidence was lowest among women with excellent adherence (59.1%) and highest among those with moderate adherence (73.7%), the difference was not statistically significant (Chi-square = 1.03, $p = 0.597$). There was a weak, non-significant negative correlation between adherence and all OGTT glucose values, suggesting a possible trend toward lower glucose with higher adherence that did not reach statistical significance in this sample (Table 6).

Tab. 1. Baseline Demographic and Clinical Characteristics and Adherence to Probiotic Supplementation (N=60).

Characteristic	Mean $\pm$ SD / n (%)	Range
Age (years)	28.7 $\pm$ 5.6	22 – 40
Gravidity	2.4 $\pm$ 1.1	1 – 4
Parity	1.4 $\pm$ 1.1	0 – 3
Height (cm)	160.7 $\pm$ 5.8	150 – 170
Weight (kg)	77.5 $\pm$ 10.2	60 – 90
Pre-pregnancy BMI (kg/m ²)	30.0 $\pm$ 4.4	20.8 – 38.0
- Normal weight (BMI < 25)	9 (15.0%)	
- Overweight (BMI 25–29.9)	18 (30.0%)	
- Obese (BMI $\geq$ 30)	33 (55.0%)	
Baseline Fasting Plasma Glucose (mg/dL)	97.1 $\pm$ 8.3	85 – 110
Risk Factors Present		
- Family History of Diabetes	35 (58.3%)	
- Previous GDM	28 (46.7%)	
- Polycystic Ovary Syndrome (PCOS)	28 (46.7%)	
- Previous Macrosomia	0 (0%)*	
Adherence to Probiotic Supplementation		
Mean Adherence Rate (%)	84.8 $\pm$ 9.5%	
Range (%)	70 – 100%	
Adherence Categories:		
- Excellent ($\geq 90\%$)	22 (36.7%)	
- Good (80–89%)	19 (31.7%)	
- Moderate (70–79%)	19 (31.7%)	
- Poor (<70%)	0 (0%)	
N: number of patients ; Mean $\pm$ SD: standard deviation ; BMI: body mass index.		

Tab. 2. Comparison of OGTT* Glucose Values by GDM* Status.

	GDM Group (n=39)	Non-GDM Group (n=21)	Mean Difference	p-value*
OGTT Glucose Values by GDM Status				
Fasting Glucose (mg/dL)	103.4 ± 6.2	88.6 ± 3.1	14.8	<0.001
1-Hour Glucose (mg/dL)	181.2 ± 12.1	150.5 ± 9.8	30.7	<0.001
2-Hour Glucose (mg/dL)	151.8 ± 11.5	122.5 ± 7.3	29.3	<0.001
OGTT: Oral Glucose Tolerance Test GDM: Gestational diabetes mellitus				
* p-value ≤0.05 was considered statistically significant (95% confidence interval).				

Tab. 3. Neonatal Outcomes and Delivery Characteristics Among the Study Population (N=60).

Parameter	n (%) / Mean ± SD	Range
Delivery Characteristics		
Gestational Age at Delivery (weeks)	38.4 ± 0.9	
- Preterm (<37 weeks)	3 (5.0%)	
- Term (37–40 weeks)	49 (81.6%)	
-post-term (>40 weeks)	8 (13.3)	
Mode of Delivery:		
- Normal Vaginal Delivery (NVD)	23 (38.3%)	
- Elective Cesarean Section	20 (33.3%)	
- Emergency Cesarean Section	29 (48.3%)	
Neonatal Outcomes		
Birth Weight (grams)	3483 ± 473	2616 – 4288
Macrosomia (≥4000g)	10 (16.7%)	
Apgar Score (1-minute)	7.4 ± 1.1	6 – 9
Apgar Score (5-minute)	9.0 ± 0.9	8 – 10
Neonatal Hypoglycemia	30 (50.0%)	
NICU Admission	14 (23.3%)	
N: number of patients ; Mean ± SD: standard deviation ; NICU: neonatal intensive care unit.		

Tab. 4. Neonatal Outcomes by GDM Status.

Outcome	GDM Group (n=39)	Non-GDM Group (n=21)	p-value
Birth Weight (g)	3541 ± 489	3375 ± 429	0.192*
Macrosomia (≥4000g)	8 (20.5%)	2 (9.5%)	0.272**
Neonatal Hypoglycemia	22 (56.4%)	8 (38.1%)	0.171**
NICU Admission	10 (25.6%)	4 (19.1%)	0.679**
N: number of patients; GDM: Gestational diabetes mellitus; NICU: neonatal intensive care unit.			

Tab. 5. Stratified Analysis of Gestational Diabetes Mellitus (GDM) Incidence According to Pre-Pregnancy Body Mass Index, Number of Risk Factors, and Adherence Category.

	Total (n)	GDM (n)	GDM Incidence(%)
BMI Category			
Normal (<25)	9	5	55.60%
Overweight (25–29.9)	18	10	55.60%
Obese (≥30)	33	24	72.70%
Number of Risk Factors			
1 Risk Factor	10	5	50.00%
2 Risk Factors	23	15	65.20%
3 Risk Factors	27	19	70.40%
Adherence Level			
Excellent (≥90%)	22	13	59.10%
Good (80–89%)	19	12	63.20%
Moderate (70–79%)	19	14	73.70%
N: number of patients; GDM: Gestational diabetes mellitus; BMI: body mass index.			

Tab. 6. Correlation Between Adherence and OGTT Values.

Parameter	Correlation Coefficient (r)	p-value
Adherence vs. Fasting Glucose	-0.18	0.168
Adherence vs. 1-Hour Glucose	-0.22	0.092
Adherence vs. 2-Hour Glucose	-0.15	0.251

DISCUSSION

The present study was designed to evaluate the role of probiotic supplementation with *Lactobacillus acidophilus* and *Bifidobacterium animalis* subsp. *lactis* (Linex Adult Probio-tec AB Blend 64) in preventing GDM among high-risk pregnant women attending a tertiary care hospital in Egypt. The study cohort comprised 60 pregnant women with a mean age of 28.7 years, which aligns closely with

the demographic profile of high-risk obstetric populations in Middle Eastern settings. found that advanced maternal age (>30 years) was significantly associated with increased GDM risk in a large Saudi cohort (OR 2.1, 95% CI 1.7-2.6) [7].

The mean pre-pregnancy BMI of 30.0 kg/m² in the current cohort study confirms the high-risk nature of the population, with 55% of participants classified as obese. This finding is consistent with who demonstrated in a systematic review and meta-analysis that the risk of GDM

increases linearly with increasing BMI, with overweight women having an odds ratio of 2.1 (95% CI 1.8-2.5) and obese women having an odds ratio of 3.6 (95% CI 3.1-4.2) compared to normal-weight women [8].

Family history of diabetes was present in 58.3% of participants, a finding consistent with Moosazadeh M, et al. who conducted a systematic review and meta-analysis of 79 studies and reported that first-degree family history of diabetes increases GDM risk by approximately 2.5-fold (OR 2.49, 95% CI 2.15-2.89) [9]. The prevalence of previous GDM (46.7%) in this cohort study is comparable to that reported by Tousles KA, et al. confirmed these findings, reporting an odds ratio (OR) of 3.43 (95% CI 2.49-4.74) for GDM in women with PCOS [10]. The baseline fasting plasma glucose of 97.1 mg/dL in this current cohort study approaches the IADPSG fasting threshold of 92 mg/dL, consistent with Riskin-Mashiah et al (2010), who demonstrated that first-trimester fasting glucose levels >87 mg/dL are associated with increased GDM risk later in pregnancy [11]. Conversely, Zhu WW, et al. in a large Chinese cohort, found that first-trimester fasting glucose ≥ 100 mg/dL was highly predictive of GDM (sensitivity 76.5%, specificity 80.2%), suggesting ethnic variations in optimal predictive thresholds [12].

The incidence of GDM in this high-risk cohort receiving probiotic supplementation was 65.0% (39 of 60 participants). This rate must be interpreted within the context of the deliberately selected high-risk population. Comparative literature on GDM incidence in high-risk cohorts varies considerably depending on diagnostic criteria, population characteristics, and geographic region. Luoto et al (2010) reported a GDM incidence of 36% in the placebo arm of a Finnish probiotic trial involving women with BMI ≥ 25 kg/m², substantially lower than our finding. However, this discrepancy may be explained by differences in diagnostic criteria (the Finnish study used a 2-hour OGTT threshold of ≥ 7.8 mmol/L for GDM diagnosis, which is less sensitive than IADPSG criteria) and ethnic differences in baseline metabolic risk. The higher incidence in this cohort study may reflect population characteristics, but cannot be used to infer intervention effectiveness [13].

Conversely, Wickens KL, et al. reported that *Lactobacillus rhamnosus* HN001 supplementation from 14-16 weeks' gestation until delivery significantly reduced GDM incidence (2.1% vs. 6.5%, OR 0.31, 95% CI 0.13-0.74) in a New Zealand cohort. The discrepancy between the current study findings and those of Wickens KL, et al. may be explained by differences in probiotic strains (HN001 vs. *Lactobacillus acidophilus* and *Bifidobacterium animalis*), population characteristics (mixed ethnicity vs. Egyptian), and baseline GDM risk profiles [14] documented GDM prevalence of 37.7% in a large Saudi cohort using IADPSG criteria, with rates exceeding 50% among women with multiple risk factors, supporting our finding that truly high-risk populations may have baseline GDM rates approaching or exceeding 60% [5].

The mean OGTT values observed in this cohort (fasting 98.2 mg/dL, 1-hour 170.5 mg/dL, 2-hour 141.6 mg/dL) reflect the overall glycemic profile of this high-risk population. These values are higher than those reported by Lain, Catalano, and Catalano (2007) in a low-risk reference population (fasting 78 mg/dL, 1-hour 122 mg/dL, 2-hour 109 mg/dL). The wide ranges observed for all

three time points, particularly the 1-hour value extending from 140 to 204 mg/dL, illustrate the substantial inter-individual variability in glucose tolerance and underscore the importance of universal screening rather than selective testing based on risk factors alone [15].

The subgroup analyses revealed important patterns of risk modification within the cohort. The finding that GDM incidence was highest among obese women (72.7%) and lowest among normal-weight women (55.6%) is consistent with the extensive literature documenting a dose-response relationship between BMI and GDM risk.

demonstrated that the odds of GDM increase by approximately 0.92% for each 1 kg/m² increase in BMI above 25 kg/m². The lack of statistical significance in this analysis ($p=0.225$) reflects the limited sample size within BMI subgroups, with only 9 normal-weight women included. Despite the non-significant p -value, the 17.1% absolute difference in GDM incidence between obese and normal-weight women is clinically meaningful and supports targeted preventive interventions for obese pregnant women [8].

The trend toward increasing GDM incidence with a greater number of baseline risk factors (from 50.0% with one risk factor to 70.4% with three risk factors) aligns with the cumulative risk model proposed by Naylor CD, et al. This finding supports the concept that GDM risk is multifactorial, with each risk factor contributing incrementally to overall probability. The clinical implication is that risk stratification should consider the full constellation of risk factors rather than focusing on any single characteristic. Women with multiple risk factors, particularly the combination of obesity, previous GDM, and family history, represent an ultra-high-risk group meriting intensive preventive interventions and early screening [16].

Perhaps the most intriguing subgroup finding is the trend toward lower GDM incidence among women with excellent adherence (59.1%) compared to those with moderate adherence (73.7%). This 14.6% absolute reduction, while not statistically significant ($p=0.597$), the observed difference may suggest a trend but should be interpreted cautiously. The weak negative correlations between adherence and all OGTT glucose values provide additional support for this hypothesis. The strongest correlation was with 1-hour glucose ($r = -0.22$, $p=0.092$), suggesting that postprandial glycemic excursions may be particularly responsive to probiotic intervention.

This pattern aligns with the findings. who reported that probiotic supplementation was associated with improved glucose metabolism in pregnant women. who demonstrated that higher probiotic adherence was associated with better metabolic outcomes in a randomized trial [17,18]

The biological plausibility of a dose-response relationship is supported by evidence that probiotics exert their metabolic effects through multiple mechanisms including modulation of gut microbiota composition, enhancement of intestinal barrier function, reduction of systemic inflammation, and alteration of bile acid metabolism. These effects may be dose-dependent, with higher bacterial loads required to achieve meaningful shifts in microbial ecology and host metabolism. The observation that only women with excellent adherence ($\geq 90\%$) showed lower GDM incidence suggests that consistent daily supplementation may be necessary to achieve clinically relevant benefits,

while intermittent use may be insufficient. This finding has important implications for the design of future trials and for clinical implementation if probiotic supplementation is ultimately proven effective [19-23].

CONCLUSION

GDM incidence in this high-risk cohort receiving probiotics was 65%. Excellent adherence confirms intervention

feasibility. Suggests a possible trend, although no statistically significant association was observed. High rates of adverse outcomes underscore the urgent need for effective preventive strategies in this vulnerable population. These findings highlight a substantial maternal morbidity burden and emphasize the need for vigilant obstetric care, including preventive strategies, active labor management, and readiness for emergency interventions in high-risk pregnancies.

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