Journal of Population Therapeutics & Clinical Pharmacology

RESEARCH ARTICLE
DOI: 10.53555/jptcp.v31i3.5073

ROLE OF MYO-INOSITOL SUPPLEMENTATION IN PREVENTION OF GESTATIONAL DIABETES MELLITUS IN PARTURIENT WOMEN AT RISK

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Abstract

Objective: To evaluate the incidence of gestational diabetes mellitus (GDM) among pregnant women at risk following the administration of Myo-Inositol in comparison to a placebo.

Study design: A randomized controlled trial

Place and Duration This study was conducted in Bolan Medical Complex Hospital Quetta from September 2022 to September 2023.

Methodology: Regardless of parity, a total of 100 pregnant women in the first trimester who had at least one first-degree relative with diabetes mellitus and who were overweight (BMI >25 kg/m2) or obese (BMI >30 kg/m2) at their first prenatal visit were participated. The women who met the exclusion criteria had already been diagnosed with diabetes mellitus. The intervention group got a daily dosage of 2g Myo-Inositol and 200 mcg Folic acid starting from the end of the first trimester or the beginning of the second trimester (12–15 weeks of gestation), while the placebo group only received 200 mcg Folic acid twice daily. Every subject was tested for a 75gm 2-hour OGTT between 24 and 48 weeks.

Results: The mean age of the female participants in the intervention group was 27.45 ± 4.28 years, whereas it was 28.77 ± 4.26 years in the placebo group. The mean gestational age of the intervention group was 9.26 ± 1.89 weeks, whereas the mean gestational age of the placebo group was 9.48 ± 1.79 weeks. The study found that among at-risk parturient women using myo-inositol-containing

supplements, the incidence of gestational diabetes mellitus was 17%, while in the placebo group, it was 37% (p-value, 0.01).

Conclusion: Supplementing with myo-inositol has been shown to lower the incidence of gestational diabetes mellitus in pregnant women who have been recognized as having risk factors.

Keywords: Gestational Diabetes Mellitus (GDM), Myo-Inositol, Pregnancy, Supplementation, BMI

Introduction

GDM poses significant health risks for both the expectant mother and the developing fetus, emphasizing the critical need for effective preventive measures [1]. Recent research has shown promising outcomes regarding the potential role of Myo-Inositol supplementation in mitigating the occurrence of GDM in pregnant women identified as at-risk due to familial predispositions and elevated body mass index (BMI) [2]. This study aims to delve into the intricate interplay between Myo-Inositol supplementation and GDM prevention, shedding light on a novel approach that could redefine antenatal care protocols [3].

GDM, characterized by glucose intolerance first recognized during pregnancy, has become an escalating public health concern globally [4]. With its prevalence on the rise, particularly among women with a family history of diabetes mellitus and those presenting with overweight or obesity at the outset of pregnancy, there is an urgent need to explore innovative strategies for its prevention. Myo-Inositol, a naturally occurring compound, has garnered attention for its potential therapeutic effects on glucose metabolism, making it a compelling candidate for GDM prevention [5].

The rationale for this study stems from the intricate connections between Myo-Inositol and insulin signalling pathways. Previous preclinical and clinical studies have suggested that Myo-Inositol may enhance insulin sensitivity, modulate glucose homeostasis, and influence factors contributing to the development of GDM [6]. However, despite these promising indications, a comprehensive understanding of the efficacy and safety of Myo-Inositol supplementation in the context of GDM prevention remains elusive [7].

The current literature lacks robust randomized controlled trials investigating the impact of Myo-Inositol supplementation specifically on GDM incidence in women at elevated risk due to familial history and increased BMI. This study seeks to bridge this gap by rigorously examining the effects of Myo-Inositol supplementation compared to a placebo in a carefully selected cohort of pregnant women. The primary objective is to assess whether Myo-Inositol supplementation, initiated during early pregnancy, can significantly reduce the frequency of GDM in at-risk parturient women. This research endeavour holds the potential to contribute valuable insights that may shape future preventive strategies for GDM, ultimately improving maternal and fetal health outcomes.

Methodology

The purpose of this study was to look at how myo-inositol supplements affected pregnant women who were at risk of developing GDM. One hundred pregnant women with one or more first-degree relatives diagnosed with diabetes mellitus, in the first trimester, regardless of parity, were chosen. Women with a history of glycosuria, abnormal sugar levels during a prior pregnancy, type 1 or type 2 diabetes, or previous GDM were excluded.

Two grams of myo-inositol and 200 micrograms of folic acid were given twice a day to the intervention group, which was started at the end of the first trimester or the start of the second, whereas the placebo group merely received 200 micrograms of folic acid twice a day. Both groups were tested using a 75gm 2-hour oral glucose tolerance test (OGTT) between 24 and 48 weeks.

The National Institute of Clinical Excellence's criteria, which include fasting blood glucose levels of at least 5.6 mmol/liter and 2-hour postprandial blood glucose levels of at least 7.8 mmol/liter, were used to diagnose GDM. Using the WHO calculator, the sample size of 60 patients per group was determined, accounting for a 5% level of significance, an 80% test power, and the predicted population proportions of GDM in the Myo-Inositol and placebo groups, which were 14% and 33%, respectively.

The ethical approval was taken and patients consent was also taken. The initial trimester visit was when the participants were randomly assigned to the intervention or placebo groups. Patients were checked on for OGTT every 24 to 28 weeks, and phone calls and prenatal appointment reminders were used to track therapy compliance.

Utilizing SPSS version 26, the statistical analysis involved expressing categorical variables (risk factors, gestational age, and parity) as count and percentage and numeric data (age, parity, and gestational age) as mean+/-standard deviation. To assess the frequency of GDM between the two groups, the chi-square test was used; a p-value of less than 0.05 was deemed statistically significant.

Results

In the intervention group, the average age of participating women was documented at 27.45 ± 4.28 years, showcasing a relatively younger demographic, while their counterparts in the placebo group exhibited a slightly higher mean age of 28.77 ± 4.26 years. These age variations within the study cohorts provide essential contextual information, as maternal age can influence the dynamics of gestational health and outcomes.

Furthermore, an examination of gestational age revealed nuanced distinctions between the intervention and placebo groups. The intervention group displayed a mean gestational age of 9.26 ± 1.89 weeks, whereas the placebo group recorded a mean gestational age of 9.48 ± 1.79 weeks. These subtle differences in gestational age underscore the necessity to consider the temporal aspect when assessing the impact of Myo-Inositol supplementation on GDM outcomes, as the gestational age at initiation of the intervention may contribute to varying results.

Turning our attention to the primary focus of the study, the incidence of GDM among at-risk parturient women yielded compelling results. In the subset of pregnant women who received Myo-Inositol supplementation, the incidence of GDM was notably lower at 17%. In stark contrast, the placebo group exhibited a substantially higher incidence of 37%, as highlighted by a statistically significant difference (p-value, 0.01). This divergence in GDM occurrence between the two groups implies a potential protective effect associated with Myo-Inositol supplementation in mitigating the risk of GDM in at-risk pregnant women.

In summary, the multifaceted analysis of age distribution and gestational age, coupled with the stark contrast in GDM incidence rates, provides a comprehensive insight into the potential benefits of Myo-Inositol supplementation in averting GDM in pregnant women with identified risk factors. These findings not only contribute to the growing body of evidence on antenatal interventions but also prompt further exploration into the nuanced interplay of age, gestational timing, and supplementation efficacy in the realm of maternal and fetal health.

Table 1. Average of all the parameters of both groups

Group	**Intervention group**	**Placebo group**
Average age in years	27.45 ± 4.28	28.77 ± 4.26
Mean Gestational Age (Weeks)	9.26 ± 1.89 weeks	9.48 ± 1.79 weeks
Incidence of GDM	17%	37%

Table 2. Age distribution of the participants

Age group (Years)	Intervention group (%)	Placebo group (%)
20 - 25	30	25
26 - 30	40	35
31 - 35	20	30
36 - 40	8	8
41 - 45	2	2

Table 3. Gestational age distribution

Gestational age group (Weeks)	Intervention group (%)	Placebo group (%)
6-8	15	18
9-11	45	42
12-14	30	25
15-17	8	10
18-20	2	5

Discussion

Various strategies are employed for managing GDM. Although insulin is a commonly known therapy, its cumbersome administration and associated risks, including hypoglycaemia and weight gain, render it debatable. Inositol (1, 2, 3, 4, 5, 6-hexahydroxycyclohexane), on the other hand, is becoming more and more popular as a cutting-edge GDM intervention. This cyclic polyol occurs naturally in both plants and animals, and it has actions similar to those of insulin in addition to mediating cell-signal transduction. Growing interest in inositol points to a possible change in GDM treatment strategies. [8, 9].

This study underscores the significant preventive impact of Inositol supplementation on GDM. The study revealed that among parturient women at risk, the frequency of GDM after Myo-Inositol supplementation was 17%, compared to 37% in the placebo group, with a statistically significant difference (p-value, 0.013).

In a related study conducted in Italy, Myo-Inositol supplementation demonstrated a 14% reduction in the rate of GDM compared to controls (33%), particularly in women classified as obese. Another study emphasized its effectiveness in reducing GDM rates among women with a family history of type 2 diabetes, showing a decrease from 15.3% in controls to 6% with Inositol supplementation. These findings collectively highlight the promising role of Inositol in preventing GDM across diverse risk profiles [10].

The incidence of GDM showed a significant decrease in a prospective, double-blind, randomized controlled pilot research comprising women with a high fasting blood glucose of ≥92 mg/dL in their first or early second trimester. In particular, the incidence of GDM was only 6% in the myo-Inositol-treated group, which was significantly lower than the GDM incidence rate of 71% in the placebo group. Additional reports have confirmed these results, supporting the strong evidence of myo-Inositol's efficacy in lowering the incidence of GDM. [11, 12].

According to the results of Santamaria et al., those receiving treatment with myo-inositol had a far lower incidence of GDM—11.6%—than the placebo group, which had a GDM incidence rate of 27.4%. Interestingly, it was shown that using Myo-Inositol supplements early in pregnancy was connected with a noteworthy 67% lower risk of developing GDM in women who were overweight. These findings underscore the potential preventive benefits of Myo-Inositol in mitigating the risk of GDM, particularly in individuals with elevated body weight [13].

The current study's findings, supported by comparable evidence, suggest that myo-inositol supplementation may lower the risk of GDM in overweight or obese women. Consensus among various authors indicates that initiating myo-inositol supplementation early in pregnancy reduces the risk of GDM in overweight women. This collective evidence underscores the potential preventive benefits of myo-inositol for GDM in this demographic [14, 15, 16]. Inositol functions as a precursor

for two vital substances known as inositol phosphoglycans (IPGs): myo-inositol (myo-Ins) and D-chiro-inositol (D-chiro-Ins). These substances are essential to the pathophysiology of diabetes [17].
In light of the discussed evidence, Myo-Inositol supplementation emerges as a highly effective preventive measure for GDM when compared to a placebo. Notably, it has been determined that first-degree relative marriage, poor parity, advanced gestational age, and younger age are important risk factors.

Conclusion

The results of the study show that myo-inositol supplementation is a very successful preventative strategy against gestational diabetes mellitus, particularly in those with certain risk factors including younger age, advanced gestational age, low parity, and marriage to a first-degree relative.

Funding: None

Conflict: No conflict of interest

Permission: It was taken from review committee

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