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TREATMENT PATTERNS AND PREGNANCY OUTCOMES IN GESTATIONAL DIABETES: A SOUTH INDIAN PROSPECTIVE COHORT STUDY

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ABSTRACT
Background: Gestational Diabetes Mellitus (GDM) poses significant risks to both maternal and neonatal health. This study evaluated and compared glycemic and perinatal outcomes across treatment modalities, including pharmacological therapies (insulin and metformin), lifestyle interventions (diet and physical activity), and combinations thereof.
Methods: A prospective cohort study was conducted at a tertiary care hospital in South India involving 200 pregnant women with GDM. Participants were divided into five groups: G1 (lifestyle only), G2 (metformin), G3 (insulin only), G4 (metformin + lifestyle), and G5 (insulin + lifestyle). Fasting blood sugar (FBS) and postprandial blood sugar (PPBS) were recorded at baseline, during the second and third trimesters, and postpartum. Postpartum glucose tolerance was assessed via OGTT. Obstetric outcomes, neonatal complications, delivery mode, and NICU admissions were documented. Statistical analysis included ANOVA and post hoc tests.
Results: All groups showed significant reductions in FBS and PPBS ($p < 0.05$), with the greatest improvements in G4 and G5. Postpartum normoglycemia was highest in G5 (88.37%) and G4 (85.11%). Maternal and neonatal complications were lowest in these combination groups, while G1 showed minimal benefit.
Conclusion: Combination treatment was associated with greater improvements in glycemic measures and more favourable maternal and neonatal outcomes in this cohort; however, these findings should be interpreted in view of baseline differences between treatment groups and the nonrandomized treatment allocation.

KEYWORDS: Gestational Diabetes Mellitus, Insulin, Metformin, Lifestyle Intervention, Glycemic Control, Pregnancy Outcomes.

INTRODUCTION

Gestational Diabetes Mellitus (GDM), defined as glucose intolerance with onset or first recognition during pregnancy, is among the most prevalent metabolic complications affecting pregnant women globally. The global prevalence of GDM ranges from 5% to 20%, depending on diagnostic criteria and the population studied [1]. In India, GDM affects approximately 10–25% of pregnancies, reflecting a growing public health challenge driven by increasing maternal age, obesity, sedentary lifestyles, and genetic predisposition [2.]

GDM is primarily characterized by a combination of peripheral insulin resistance and an inadequate compensatory insulin secretory response, largely due to the hormonal milieu of pregnancy [3.] Uncontrolled GDM increases the risk of serious maternal and neonatal complications, including hypertensive disorders, preterm labor, foetal macrosomia, neonatal hypoglycemia, and shoulder dystocia [4]. Moreover, GDM is a major risk factor for the future development of Type 2 Diabetes Mellitus (T2DM) in both the mother and offspring, with up to 50% of affected women developing T2DM within 10 years of delivery [5,6].

Standard management of GDM begins with medical nutrition therapy and lifestyle modifications, including dietary regulation and physical activity [7.] These interventions have demonstrated significant benefits in controlling glucose levels and reducing perinatal risks when implemented early [8]. However, pharmacologic treatment becomes necessary when target glycemic levels are not achieved with lifestyle changes alone. Insulin remains the treatment of choice for such cases, offering precise control without placental transfer [9.] Metformin, an oral hypoglycemic agent, is increasingly being used as an alternative or adjunct due to its efficacy, affordability, and favorable safety profile, although long-term data on offspring outcomes remain under study [10,11].

While randomized trials have demonstrated the effectiveness of pharmacologic and non-pharmacologic therapies, few real-world prospective studies from South Asia have systematically compared their individual and combined effects on glycemic control and pregnancy outcomes. Moreover, limited literature exists on how different treatment modalities influence postpartum glucose tolerance and the risk of persistent dysglycemia.

This study aimed to evaluate and compare the glycemic trends, maternal and neonatal outcomes, and postpartum glucose profiles among GDM patients managed with insulin, metformin, lifestyle interventions, and their combinations. By focusing on a South Indian cohort in a tertiary care setting, this research seeks to provide region-

specific, real-world insights to inform evidence-based clinical decision-making and promote integrated care approaches for GDM.

MATERIALS AND METHODS

This prospective observational cohort study was conducted at the SS Institute of Medical Sciences and Research Centre (SSIMS&RC), a 1000-bed tertiary care teaching hospital in Davangere, Karnataka, India (Fig 1). The study period extended from June 2024 to March 2025 and included both antenatal and postpartum follow-up phases. The institution serves a heterogeneous population from both urban and rural areas, providing an ideal setting for evaluating gestational diabetes mellitus (GDM) management in a real-world context. Ethical clearance for the study was obtained from the Institutional Ethics Committee (IEC) of Bapuji Pharmacy College, Davangere (Ref No.: BPC/IEC/120/2024), and written informed consent was secured from all participants.

The study was conducted in accordance with the ethical principles outlined in the relevant Indian Council of Medical Research (ICMR) ethical guidelines for human research [12]

Pregnant women aged 18 years and above were screened for GDM between 24 and 28 weeks of gestation using the 75-gram oral glucose tolerance test (OGTT). Diagnosis was based on IADPSG/WHO/ICMR criteria, including fasting blood sugar (FBS) ≥ 92 mg/dL, 1-hour ≥ 180 mg/dL, or 2-hour ≥ 153 mg/dL [13]. Women with pre-existing Type 1 or Type 2 diabetes mellitus, multiple pregnancies, severe chronic systemic illnesses, or psychiatric disorders that could hinder adherence were excluded. A total of 200 eligible women were enrolled and assigned to five treatment groups based on clinical assessment and physician discretion, in accordance with current ADA and national guidelines for GDM management [14,15.] Group G1 included patients managed with structured lifestyle modifications comprising a balanced diet and exercise; Group G2 comprised patients treated with metformin monotherapy; Group G3 received insulin therapy alone using regular or rapid-acting analogues; Group G4 received oral hypoglycaemic therapy with lifestyle interventions; and Group G5 received insulin therapy along with lifestyle modifications. Metformin was initiated at 500 mg twice daily and titrated up to a maximum of 2000 mg/day according to glycaemic response and gastrointestinal tolerance. Insulin was initiated when glycaemic targets were not achieved with diet or metformin alone and was adjusted according to patient glucose logs and clinical response.

Adherence to lifestyle interventions, including dietary recommendations and prescribed physical activity, was not objectively quantified, which may have influenced the observed glycaemic outcomes. Metformin was initiated at 500 mg twice daily and titrated up to a maximum of 2000 mg/day depending on glycemic response and gastrointestinal tolerance. Insulin was initiated when glycemic targets were not met by diet or metformin alone and was adjusted based on patient glucose logs and clinical response. Glycemic control was monitored at four time points: baseline (at diagnosis), second trimester (around 28–30 weeks), third trimester (around 36 weeks), and postpartum (6–12 weeks after delivery).

The primary outcomes assessed included changes in FBS and postprandial blood sugar (PPBS) across the study timeline. Secondary outcomes involved postpartum glycemic status as determined by repeat OGTT, mode of delivery, maternal complications (such as preeclampsia, preterm labor, urinary tract infection, and polyhydramnios), neonatal complications (including macrosomia, neonatal hypoglycemia, hyperbilirubinemia, and respiratory distress), and NICU admissions. Data were collected using a pre-validated structured case record form and were verified through patient interviews, prescription audits, and electronic health records.

Descriptive statistics were used to summarize demographic data, treatment characteristics, and outcome variables. Continuous variables such as FBS and PPBS were expressed as mean ± standard deviation (SD), and categorical variables were expressed as frequencies and percentages. Intergroup comparisons were performed using one-way analysis of variance (ANOVA), and Dunnett's post hoc tests were applied to evaluate statistical differences from baseline. Chi-square tests were used to analyze categorical outcomes such as complication rates and NICU admissions. A p-value of less than 0.05 was considered statistically significant.

RESULTS

Treatment Group Stratification

A total of 200 pregnant women diagnosed with gestational diabetes mellitus (GDM) were included in the final analysis. Patients were enrolled following predefined eligibility criteria and were stratified into five therapeutic groups based on their treatment regimen: Group G1 (lifestyle intervention only, n=26), Group G2 (oral hypoglycemic agents [OHA] – metformin, n=44), Group G3 (insulin only, n=40), Group G4 (OHA + lifestyle interventions, n=47), and Group G5 (insulin + lifestyle interventions, n=43). All participants were followed from diagnosis through the postpartum period.

Socio-Demographic Analysis

The socio-demographic analysis revealed that the majority of patients were between 26 and 35 years of age, with 31.5% in the 26–30 age group and 31.0% in the 31–35 age group. Urban and rural patients were nearly equally represented (51.5% and 48.5%, respectively). The predominant occupational category was housewives (78.5%), while 21.5% were employed (Fig. 2). Regarding body mass index (BMI), only 10% of patients had normal BMI, whereas 90% were categorized as overweight, pre-obese, or obese. A significant proportion (53%) had a positive family history of diabetes, and 24% reported a previous history of GDM. Notably, most patients were primigravida (76.5%) and nulliparous (79.5%).

Longitudinal Glycemic Trends Across Treatment Groups

Group G1 (Lifestyle Interventions Only):

Patients in this group (n = 26) demonstrated modest glycemic improvements through structured non-pharmacologic management, including balanced dietary planning, prenatal yoga, and daily brisk walking. **FBS increased from a baseline of 108.85 ± 13.04 mg/dL to 112.00 ± 2.51 mg/dL in the second trimester, followed by a decrease to 109.83 ± 2.83 mg/dL in the third trimester and 102.63 ± 15.38 mg/dL postpartum**. PPBS showed a less pronounced trend, increasing from 145.91 ± 17.54 mg/dL at baseline to 154.08 ± 5.68 mg/dL in the second trimester, before decreasing to 149.82 ± 6.20 mg/dL and 142.39 ± 32.69 mg/dL in the third trimester and postpartum, respectively. The reduction in FBS was statistically significant ($p = 0.0099$), while the change in PPBS did not reach significance ($p = 0.1480$). Postpartum OGTT revealed that 61.54% of patients returned to normoglycemia, whereas 26.92% remained in the IFG/IGT range, and 11.54% were classified as diabetic.

Group G2 (Metformin Only):

Among patients treated with metformin monotherapy (n = 44), FBS and PPBS showed an initial increase during pregnancy, followed by a reduction by the postpartum assessment. FBS increased from 105.73 ± 11.35 mg/dL at baseline to 164.03 ± 5.69 mg/dL in the second trimester ($p < 0.001$), then decreased to 153.93 ± 6.70 mg/dL in the third trimester ($p < 0.01$) and 100.52 ± 16.81 mg/dL postpartum ($p < 0.05$) PPBS rose initially from 139.58 ± 17.19 mg/dL at baseline to 233.73 ± 8.08 mg/dL in the second trimester ($p < 0.001$), then decreased to 213.47 ± 8.70 mg/dL ($p < 0.01$), and finally to 139.15 ± 33.13 mg/dL postpartum ($p < 0.05$). Postpartum OGTT indicated that 68.18% of patients had normal glycemia, 20.45% remained in the IFG/IGT category, and 11.36% were diabetic.

Group G3 (Insulin Only):

In this group (n = 40), insulin monotherapy (Regular/Lispro) was associated with substantial glycemic improvement. FBS reduced from 109.28 ± 11.30 mg/dL at baseline to 172.91 ± 5.48 mg/dL in the second trimester ($p < 0.001$), 161.13 ± 6.22 mg/dL in the third trimester ($p < 0.01$), and 100.11 ± 17.04 mg/dL postpartum ($p < 0.05$). PPBS showed a similar pattern, increasing from 152.21 ± 17.18 mg/dL at baseline to 241.02 ± 9.13 mg/dL in the second trimester ($p < 0.001$), followed by a decrease to 220.30 ± 10.06 mg/dL in the third trimester ($p < 0.01$) and 139.57 ± 31.14 mg/dL postpartum ($p < 0.05$). ANOVA confirmed the reductions were statistically significant (FBS: $F = 437.774$; PPBS: $F = 275.199$; $p < 0.001$ for both). Postpartum OGTT outcomes showed normoglycemia in 70% of patients, IFG/IGT in 20%, and persistent diabetes in 10%.

Group G4 (OHA + Lifestyle Interventions):

This group (n = 47) demonstrated the most robust glycemic response. FBS dropped significantly from 180.53 ± 2.95 mg/dL at baseline to 163.00 ± 2.97 mg/dL ($p < 0.001$), 145.62 ± 3.33 mg/dL ($p < 0.01$), and 94.19 ± 10.33 mg/dL postpartum ($p < 0.05$). Similarly, PPBS reduced from 268.13 ± 3.88 mg/dL to 238.70 ± 4.77 mg/dL ($p < 0.001$), 208.69 ± 5.23 mg/dL ($p < 0.01$), and 129.73 ± 20.29 mg/dL postpartum ($p < 0.05$). One-way ANOVA revealed highly significant reductions for both FBS ($F = 1927.872$) and PPBS ($F = 1398.943$), both $p < 0.0001$. Postpartum OGTT classification indicated 85.11% of patients achieved normoglycemia, 12.77% had IFG/IGT, and 2.13% remained diabetic.

Group G5 (Insulin + Lifestyle Interventions):

Among patients receiving combined insulin and lifestyle therapy (n = 43), glycemic control was similarly profound. FBS declined from 179.93 ± 2.94 mg/dL to 162.41 ± 3.44 mg/dL ($p < 0.001$), 144.70 ± 3.60 mg/dL ($p < 0.01$), and 93.99 ± 11.87 mg/dL postpartum ($p < 0.05$). PPBS values also showed a consistent decrease from 269.54 ± 2.97 mg/dL to 239.99 ± 3.83 mg/dL ($p < 0.001$), 210.00 ± 4.67 mg/dL ($p < 0.01$), and 129.24 ± 24.83 mg/dL postpartum ($p < 0.05$). Statistical analysis confirmed significant reductions in both parameters (FBS: $F = 1927.872$; PPBS: $F = 1398.943$; $p < 0.0001$). Postpartum OGTT revealed normoglycemia in 88.37% of patients, IFG/IGT in 6.98%, and persistent diabetes in only 4.65%.

Overall, the treatment groups demonstrated different patterns of change in FBS and PPBS across the follow-up period. G4 and G5 showed progressive declines in both parameters across the reported time points, whereas G1, G2, and G3 showed increases during pregnancy followed by lower postpartum values. While lifestyle modification alone (G1) offered moderate benefit, its postpartum normalization rate (61.54%) was lower compared to pharmacological and combined approaches. These findings reinforce the superior efficacy of integrated management strategies in GDM, both for antenatal glycemic control and postpartum metabolic recovery.

Comparative Evaluation of Glycemic Trends and Postpartum Outcomes

A comparative analysis of fasting blood sugar (FBS) and postprandial blood sugar (PPBS) levels was conducted across five therapeutic groups in patients with gestational diabetes mellitus (GDM) (Table 1). Across all groups, statistically significant reductions in FBS and PPBS were observed from baseline to postpartum. Analysis using one-way ANOVA followed by Dunnett's post hoc test confirmed that the reductions were significant within each group ($p < 0.05$), with marked intergroup variation in magnitude and clinical outcome. Groups G4 and G5, which received combination therapy with either OHA or insulin plus structured lifestyle modification, exhibited the most pronounced reductions. In Group G4, FBS decreased from 180.53 ± 2.95 mg/dL at baseline to 94.19 ± 10.33 mg/dL postpartum ($\Delta = 86.34$ mg/dL), while PPBS declined from 268.13 ± 3.88 mg/dL to 129.73 ± 20.29 mg/dL ($\Delta = 138.40$ mg/dL). Similarly, Group G5 showed a reduction in FBS from 179.93 ± 2.94 mg/dL to 93.99 ± 11.87 mg/dL ($\Delta = 85.94$ mg/dL) and PPBS from 269.54 ± 2.97 mg/dL to 129.24 ± 24.83 mg/dL ($\Delta = 140.30$ mg/dL).

Group G1, treated exclusively with lifestyle modification, demonstrated the least change, with FBS reducing by only 6.22 mg/dL (from 108.85 ± 13.04 to 102.63 ± 15.38 mg/dL) and PPBS by 3.52 mg/dL (from 145.91 ± 17.54 to 142.39 ± 32.69 mg/dL). Although statistically significant, these changes were relatively modest compared to pharmacologically managed groups. Group G2 (metformin only) and Group G3 (insulin only) showed intermediate outcomes, with postpartum FBS values of 100.52 ± 16.81 mg/dL and 100.11 ± 17.04 mg/dL, respectively, and PPBS values of 139.15 ± 33.13 mg/dL and 139.57 ± 31.14 mg/dL.

Postpartum glycemic classification further illustrated differences in treatment efficacy. Group G5 recorded the highest proportion of patients achieving normoglycemia (88.37%), followed closely by Group G4 (85.11%). In contrast, Group G1 had the lowest normalization rate at 61.54%, with higher rates of residual dysglycemia (26.92% IFG/IGT and 11.54% diabetic). Groups G2 and G3 had comparable outcomes, with 68.18% and 70.00% achieving normoglycemia, respectively, and approximately 30% exhibiting persistent glucose abnormalities (Table 2).

The comparative ANOVA analysis of postpartum glycemic indices across all five groups revealed highly significant intergroup differences in both FBS ($F = 152.880$, $p < 0.0001$) and PPBS ($F = 77.034$, $p < 0.0001$). Because treatment allocation was determined by clinical assessment and physician discretion rather than randomization, baseline differences in glycemic severity may have influenced treatment selection and subsequent outcomes. Therefore, observed differences between treatment groups should be interpreted as associations rather than causal treatment effects.

Comparative Analysis of Postpartum Obstetric Outcomes

A comprehensive analysis of postpartum obstetric and neonatal outcomes among GDM patients across five intervention groups (G1 to G5), as summarized in Table 3. The parameters assessed include mode of delivery, maternal and neonatal complications, and NICU admissions.

Group G5 (Insulin + Lifestyle Interventions) demonstrated the most favorable outcomes, achieving the highest rate of normal vaginal deliveries (62.79%) and the lowest incidences of maternal complications (20.93%), neonatal complications (16.28%), and NICU admissions (13.95%). These results underscore the synergistic benefit of integrating insulin therapy with structured lifestyle modifications in optimizing delivery outcomes and minimizing perinatal risks. Group G4 (OHA + Lifestyle Interventions) also yielded positive outcomes, with 57.45% normal deliveries and relatively low maternal (23.40%) and NICU admission rates (17.02%). This supports the value of non-pharmacological adjuncts in enhancing the efficacy of oral hypoglycemic agents. Conversely, Group G3 (Insulin Only) recorded the highest maternal complication rate (37.50%) and elevated neonatal complication (27.50%) and NICU admission (25%) rates, suggesting that pharmacological control alone, in the absence of lifestyle support, may be insufficient to mitigate obstetric risks. Similarly, Group G2 (OHA Only – Metformin) exhibited high maternal (34.09%) and neonatal (29.55%) complication rates, and a 25% NICU admission rate, highlighting the potential limitations of Metformin monotherapy in addressing broader perinatal health concerns. Group G1 (Lifestyle Only) showed moderate outcomes, with 57.69% normal deliveries, 26.92% maternal complications, and 19.23% NICU admissions. These results suggest that while lifestyle interventions may be adequate for glycemic control in milder cases, they may not fully prevent adverse outcomes in higher-risk pregnancies.

Overall, the comparative trends strongly indicate that combined pharmacological and lifestyle-based interventions (G4 and G5) offer superior maternal and neonatal outcomes. These findings advocate for integrated, patient-specific management strategies in GDM to enhance safety and efficacy, reduce intervention burden, and improve long-term health trajectories for both mother and child.

Incidence and Distribution of Maternal and Neonatal Complications with Corresponding NICU Admissions

The distribution of maternal complications (Table 4), neonatal complications (Table 5), and NICU admissions (Table 6) across the five treatment groups in patients with gestational diabetes mellitus is presented below.

Maternal Complications

As shown in Table 4, the most common maternal complications across groups were Pregnancy-Induced Hypertension (PIH) and Preterm Labor, with the highest incidence observed in Group G3 (Insulin Only) 5 cases of PIH and 3 cases of preterm labor. Group G2 (OHA Only) also showed elevated rates, including 4 cases of PIH and 4 of preterm labor. In contrast, Groups G4 (OHA + Lifestyle) and G5 (Insulin + Lifestyle) demonstrated relatively lower complication frequencies, suggesting a beneficial role of lifestyle modifications in minimizing maternal risk. Group G1 (Lifestyle Only) showed the fewest complications overall, though it also had the smallest sample size.

Neonatal Complications

Neonatal complication patterns, summarized in Table 5, indicate that hypoglycemia and hyperbilirubinemia were the most frequently reported conditions. Groups G2 and G3 again reported the highest number of affected neonates, whereas Groups G4 and G5 had fewer instances of each complication. Notably, 37 to 38 neonates in these groups experienced no complications, indicating a protective influence of combining pharmacotherapy with lifestyle interventions. Group G1 showed the lowest overall complication rate, consistent with milder cases of GDM managed through lifestyle changes alone.

NICU Admissions

As detailed in Table 6, NICU admissions were most frequent in Group G2 (n = 11) and Group G3 (n = 10), aligning with their higher rates of maternal and neonatal complications. Conversely, Group G5 (Insulin + Lifestyle) had

the lowest NICU admission rate (n = 6), further supporting the clinical value of integrated care approaches in GDM management. Groups G4 and G1 also had relatively fewer admissions, reflecting favorable perinatal outcomes.

Comparative Insights

The data presented reveal distinct trends, indicating that treatment groups incorporating lifestyle interventions (G4 and G5) consistently experienced lower rates of maternal and neonatal complications, as well as reduced NICU admissions, compared to groups receiving pharmacotherapy alone. These findings highlight the importance of a multimodal approach to gestational diabetes management, demonstrating that the integration of lifestyle support with pharmacological treatment can significantly enhance both maternal and neonatal outcomes.

DISCUSSION

Principal findings

This prospective cohort study compared glycaemic patterns, maternal and neonatal outcomes and postpartum glycaemic status in women with GDM managed with lifestyle modification, pharmacological treatment (metformin or insulin), or combinations of pharmacological and lifestyle interventions. The results indicate that glycaemic variation was different in the various treatment groups. Pharmacological treatment combined with lifestyle modification resulted in greater decreases in FBS and PPBS at postpartum assessment than did the other treatments, which resulted in varied changes during pregnancy and postpartum. A higher proportion of women in the combination groups achieved postpartum normoglycaemia. It is however important to take these results into account in conjunction with the difference in baseline glycaemic levels and the clinical indications for treatment choice.

Comparison with previous studies

The overall approach outlined in this study is similar to the contemporary management of GDM, where lifestyle modification is a key part of the management plan and pharmacological treatment is added when good glycaemic control is not obtained. NICE guidelines suggest a dietary and physical-activity intervention as a standard part of GDM care and pharmacologic treatment if glycaemic targets are not achieved using lifestyle changes alone [9]. There is also evidence that diet can help women with GDM to have better glycaemic control, but no single diet appears to be better than others [8]. They are an example of the combined management typical of daily clinical practice and, therefore, represent the type of management that was used in the present study.

Interpretation of glycaemic trends

This study is important with regard to the glycaemic trends observed. FBS and PPBS values for G4 and G5 decreased consistently from the baseline to the postpartum evaluation, and those for G1, G2, and G3 increased during pregnancy and decreased during the postpartum evaluation. In interpreting these changes, it is important to take into consideration the higher baseline glucose levels in G4 and G5. The more glycaemic-disturbed women were more likely to receive increased treatment and part of the subsequent decrease may have been due to the increased starting value, not to the level of various glycaemic profiles of the treatment groups than superior treatment.

The findings are consistent with earlier evidence that both metformin and insulin are therapeutic interventions for GDM. Metformin combined with insulin, if necessary, was shown to be an alternative treatment option to insulin in GDM in the MiG trial, which yielded generally similar short-term pregnancy outcomes [10]. In a similar way, a systematic review showed there were generally similar maternal and neonatal outcomes with the use of metformin or insulin, and further evidence was needed on longer-term outcomes [11]. In the present study, a real-world perspective is provided by the evaluation of these therapies in the same population in conjunction with lifestyle interventions.

Maternal outcomes

The maternal outcomes were also different between groups. G4 and G5 had fewer reported maternal complications compared with G2 and G3. The proportion of maternal complications (20.93%) was lowest in G5, while higher proportions were observed in G3. The differences found in the present study have to be interpreted with caution, however. Before starting treatment, women treated with insulin or combination therapy might have been more severely affected by the disease or had other clinical characteristics than those treated with other therapies. It follows that the comparatively low complication rate associated with the combination treatments cannot be attributed to the actual treatment.

Neonatal outcomes

G4 and G5 also had fewer reported neonatal complications and fewer NICU admissions compared with G2 and G3. The proportions of neonatal complications (16.28%) and NICU admissions (13.95%) were lowest in G5, while higher proportions were observed in G3. These findings are clinically relevant because hyperglycaemia during pregnancy has been associated with adverse maternal and foetal outcomes [4]. The differences found in the present study have to be interpreted with caution, however, as differences in baseline glycaemic status and other clinical characteristics may also have contributed to the observed neonatal outcomes.

Postpartum glucose tolerance

The postpartum findings are a further perspective. 88.37% of the women in G5 and 85.11% of the women in G4 had normoglycaemia, whereas the proportion of women with normoglycaemia in G2 and G3 was in between, at 68.18% and 70.00%, respectively. This is significant since GDM may not be the end of the story: Women with GDM are at increased risk for developing type 2 diabetes later in life [5,6]. The postpartum evaluation in this

study therefore highlights the importance of metabolic monitoring after pregnancy. However, the relatively short follow-up time does not provide evidence for long-term prevention of diabetes.

Clinical implications

Clinically, the results indicate a combined strategy to GDM care where lifestyle awareness is important as well as pharmacological treatment. The combination groups exhibited positive trends in this population; however, it is not shown that it is always better to combine treatment modalities. The clinical factors of the mother and foetus, as well as the glycaemic status prior to pregnancy, lifestyle changes, and requirements for different treatments should continue to be taken into account when making treatment decisions. This is also in line with the overall data available for individualised management of GDM [9–11].

Strengths

Several strengths of this study should be considered when interpreting the findings. The prospective design allowed participants to be followed longitudinally from the diagnosis of GDM through pregnancy and into the postpartum period. The study was conducted in a real-world clinical setting and included multiple treatment patterns, allowing comparison of different approaches used in routine GDM management. The assessment was not limited to glycaemic outcomes; postpartum OGTT, maternal outcomes, neonatal outcomes and NICU admissions were also evaluated. In addition, the study provides real-world evidence from a South Indian tertiary-care population, which adds to the limited evidence on GDM treatment patterns in this setting.

Limitations

There are a number of limitations that must be taken into consideration when interpreting this study. First, it took place in one tertiary care centre, and the number of women with GDM who participated was relatively small (n = 200). Thus, the results cannot be directly applied to other hospitals or to populations with other demographic, clinical and/or healthcare characteristics.

Second, there was no randomisation of treatment, but rather treatment allocation was based on clinical assessment and physician discretion. Thus, the clinical parameters of the treatment groups could have been different prior to treatment. This is especially relevant as the baseline glycaemic values were not equivalent across all groups, with the groups taking insulin-based combination therapy having significantly higher values. Therefore, comparisons between treatment groups cannot be used to draw conclusions about superiority of one treatment strategy over the other. There is also a risk of confounding by indication because the choice of treatment may have been influenced by the level of glycaemic disturbance or other clinical factors which were not adequately described in the analysis. Some of the observed decreases in glycaemic variables could also be due to regression to the mean, especially for those with higher initial glucose levels. The follow-up information contained in the prospective study is longitudinal, but it is not completely possible to eliminate residual confounding due to clinical and patient-related issues.

Another limitation relates to adherence to the interventions. Lifestyle management comprised diet and exercise such as brisk walking, prenatal yoga, and light resistance exercise, but there was no objective measurement of adherence. Likewise, there was no detailed information available about medication adherence. Hence, the contribution of adherence to the observed outcomes of glycaemia cannot be assessed as a result of any differences. The follow-up postpartum period was also short. Postpartum glycaemic status was assessed, but it is not possible to conclude, for the follow-up period, on the progression to type 2 diabetes or long-term metabolic health. Moreover, the long-term outcomes of the neonates were not followed up, and it was not possible to conclude whether the observed pattern of glycaemic changes during gestation was related to later long-term outcomes in the baby or child.

Lastly, although the prospective design and systematic evaluation of glycaemic measures are strengths of this study, associations observed may have been influenced by unmeasured or incompletely measured factors. The conclusions should thus be interpreted as describing patterns and associations between treatment strategies and glycaemic outcomes, rather than treatment effects. Larger, multicentre studies with objective assessment of adherence, longer postpartum follow-up, and appropriate adjustment for baseline differences would help confirm these findings.

SUMMARY & CONCLUSION

This prospective cohort study provides compelling real-world evidence on the **outcomes associated with** various pharmacological and lifestyle-based interventions in the management of gestational diabetes mellitus (GDM). All treatment modalities demonstrated statistically significant improvements in glycemic indices from baseline to postpartum; however, the magnitude and consistency of these improvements varied notably between groups. Patients receiving combination therapies particularly insulin or metformin in conjunction with structured lifestyle modifications achieved the most favorable glycemic control during pregnancy and demonstrated the highest rates of postpartum glycemic normalization.

In addition to superior metabolic outcomes, the combination therapy groups (G4 and G5) exhibited the lowest rates of maternal and neonatal complications and NICU admissions. Conversely, monotherapy with either metformin or insulin was associated with relatively higher incidences of obstetric and neonatal adverse outcomes. While lifestyle interventions alone offered moderate glycemic benefit in less severe cases, they were insufficient in preventing postpartum dysglycemia in a significant proportion of patients.

These findings underscore the importance of integrated, multidisciplinary care approaches that combine individualized pharmacologic regimens with evidence-based lifestyle interventions. Implementing such strategies not only optimizes glycemic control during pregnancy but also minimizes maternal-fetal complications and improves long-term metabolic outcomes. Tailored intervention protocols that address both pharmacological and behavioral components should be prioritized in GDM management, particularly in resource-limited settings where the burden of diabetes is rapidly increasing.

Future research should aim to explore the long-term metabolic trajectories of mothers and offspring exposed to different GDM treatments and assess the cost-effectiveness and scalability of combination therapy models in broader healthcare systems.

AI Assistance Declaration

The authors declare that generative AI tools (such as ChatGPT) were used only for language enhancement and grammar correction during the preparation of this manuscript. The authors have carefully revised the content and taken full responsibility for the final version of the manuscript.

Conflict of Interest: The authors declare that they have no competing interests.

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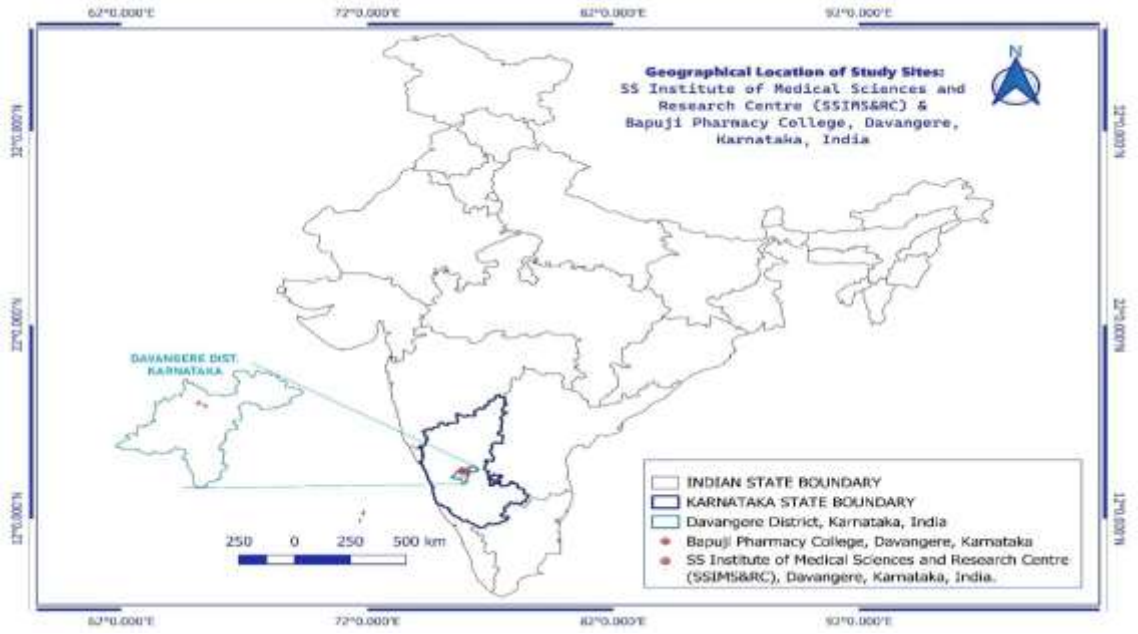


Fig 1: Geographical Location of Study Sites

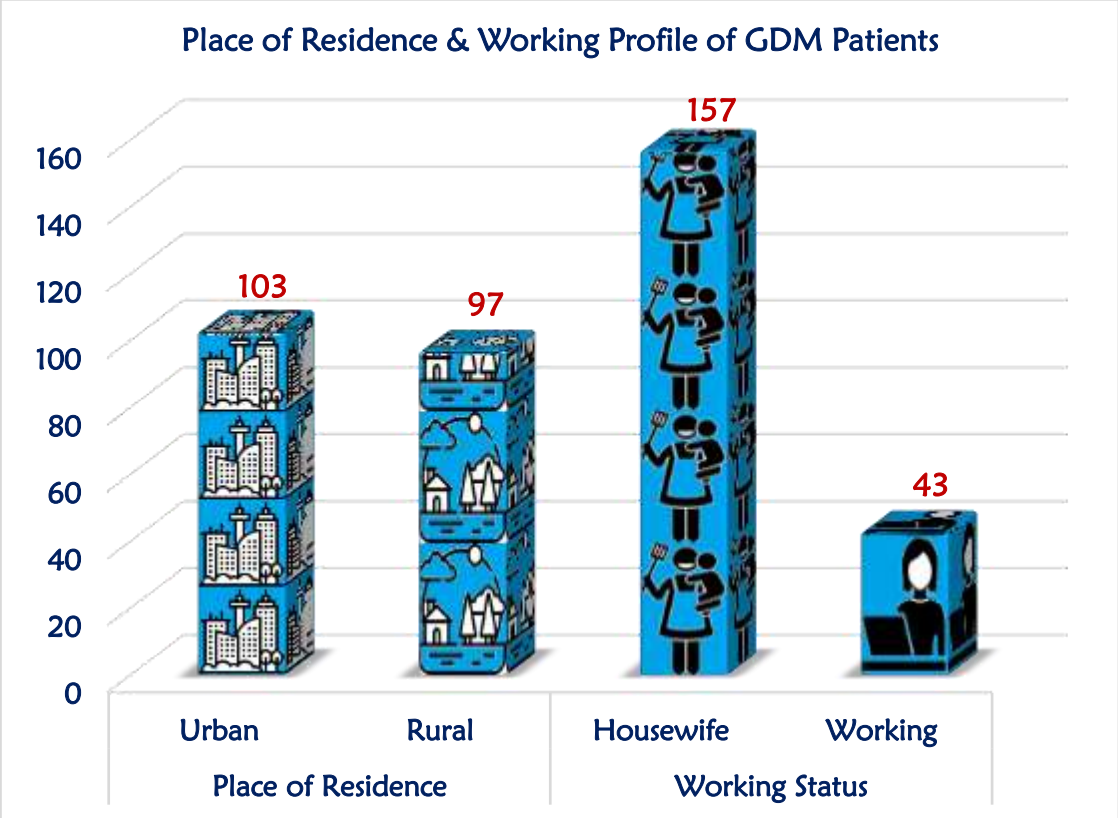


Fig 2: Urban–Rural Classification & Occupational Status of GDM Patients

Table 1: Comparative Evaluation of Fasting and Postprandial Blood Glucose Trends Across Treatment Modalities in Gestational Diabetes Mellitus (GDM) Patients Over Pregnancy and Postpartum Phases

Treatment Groups	Blood Glucose level (mg/dl)							
	FBS				PPBS			
Time points (in weeks)	Baseline	2nd Trimester	3rd Trimester	Postpartum	Baseline	2nd Trimester	3rd Trimester	Postpartum
G1 (Lifestyle Interventions)	108.85 ± 13.04	112.00 ± 2.51***	109.83 ± 2.83**	102.63 ± 15.38*	145.91 ± 17.54	154.08 ± 5.68***	149.82 ± 6.20**	142.39 ± 32.69*

Treatment Groups	Blood Glucose level (mg/dl)							
	FBS				PPBS			
G2 (OHA Only_Metformin)	105.73 ± 11.35	164.03 ± 5.69***	153.93 ± 6.70**	100.52 ± 16.81*	139.58 ± 17.19	233.73 ± 8.08***	213.47 ± 8.70**	139.15 ± 33.13*
G3 (Insulin Only_Regular/Lispro)	109.28 ± 11.30	172.91 ± 5.48***	161.13 ± 6.22**	100.11 ± 17.04*	152.21 ± 17.18	241.02 ± 9.13***	220.30 ± 10.06**	139.57 ± 31.14*
G4 (OHA + Lifestyle Interventions)	180.53 ± 2.95	163.00 ± 2.97***	145.62 ± 3.33**	94.19 ± 10.33*	268.13 ± 3.88	238.70 ± 4.77***	208.69 ± 5.23**	129.73 ± 20.29*
G5 (Insulin + Lifestyle Interventions)	179.93 ± 2.94	162.41 ± 3.44***	144.70 ± 3.60**	93.99 ± 11.87*	269.54 ± 2.97	239.99 ± 3.83***	210.00 ± 4.67**	129.24 ± 24.83*

Data are represented as Mean ± SD. Significance was evaluated using One-way ANOVA, and Dunnett's post hoc tests compared with baseline (0 weeks). Where *** $P < 0.001$ – Extremely significant; ** $P < 0.01$ – Highly significant; * $P < 0.05$ – Significant.

Table 2. Distribution of Glycemic Status Among GDM Patients Across Treatment Groups: Proportion of Normal, IFG/IGT, and Diabetic Cases

Group	Normal	IFG/IGT	Diabetic	Total	% Normal	% IFG/IGT	% Diabetic
G1 (Lifestyle Interventions)	16	7	3	26	61.54	26.92	11.54
G2 (OHA Only_Metformin)	30	9	5	44	68.18	20.45	11.36
G3 (Insulin Only_Regular/Lispro)	28	8	4	40	70.00	20.00	10.00
G4 (OHA + Lifestyle Interventions)	40	6	1	47	85.11	12.77	2.13
G5 (Insulin + Lifestyle Interventions)	38	3	2	43	88.37	6.98	4.65
TOTAL	152	33	15	200			

Table 3 Obstetric Outcome Summary Among GDM Patients by Treatment Modality: Postpartum Delivery Mode and Complication Analysis

Group	Total Patients	% Normal Delivery	% LSCS	% Maternal Comp.	% Neonatal Comp.	% NICU Admission
G1 (Lifestyle Interventions)	26	57.69	38.46	26.92	23.08	19.23
G2 (OHA Only_Metformin)	44	54.55	43.18	34.09	29.55	25.00
G3 (Insulin Only_Regular/Lispro)	40	50.00	50.00	37.50	27.50	25.00
G4 (OHA + Lifestyle Interventions)	47	57.45	40.43	23.40	19.15	17.02
G5 (Insulin + Lifestyle Interventions)	43	62.79	34.88	20.93	16.28	13.95

Table 4. Maternal Complications

Maternal Complication	G1 (Lifestyle)	G2 (OHA Only)	G3 (Insulin Only)	G4 (OHA + Lifestyle)	G5 (Insulin + Lifestyle)
PIH	2	4	5	3	2
UTI	1	2	2	1	1
Polyhydramnios	2	3	3	2	2
Preterm Labor	1	4	3	3	2
Preeclampsia	1	2	2	2	2
No Complications	19	29	25	36	34

Table 5 Neonatal Complications

Neonatal Complication	G1 (Lifestyle)	G2 (OHA Only)	G3 (Insulin Only)	G4 (OHA + Lifestyle)	G5 (Insulin + Lifestyle)
Hypoglycemia	2	4	4	3	2
Hyperbilirubinemia	1	3	2	2	1

Neonatal Complication	G1 (Lifestyle)	G2 (OHA Only)	G3 (Insulin Only)	G4 (OHA + Lifestyle)	G5 (Insulin + Lifestyle)
Macrosomia	1	2	2	1	1
Preterm Baby	1	2	2	2	1
RDS (Respiratory Distress Syndrome)	1	2	1	1	1
No Complications	20	31	29	38	37

Table 6 NICU Admissions

Group	NICU Admissions
G1 (Lifestyle Interventions)	5
G2 (OHA Only – Metformin)	11
G3 (Insulin Only – Regular/Lispro)	10
G4 (OHA + Lifestyle Interventions)	8
G5 (Insulin + Lifestyle Interventions)	6