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# Prediction Of Different Treatment Modalities In Women With Gestational Diabetes Mellitus In Minia University Maternity Hospital. A Prospective Cohort Study

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## ABSTRACT

**Backgroud:** Gestational diabetes mellitus (GDM) is glucose intolerance first recognized in pregnancy, often managed with diet or medication to reduce maternal and neonatal complications.

**Aim:** To develop a predictive model for the necessity of different treatment modalities in women with GDM in Minia University Maternity Hospital [MUMH].

**Patients and methods:** This prospective cohort study included 109 GDM patients at MUMH (May 2022–December 2023). Diagnosis was based on IADPSG criteria, excluding pre-existing diabetes. Management was stepwise: diet first, then metformin if uncontrolled, and insulin if needed. Patients were classified into three groups: diet only (n=32), metformin (n=42), and insulin (n=35).

**Results:** The three groups were comparable in age, BMI, gravidity, parity, gestational age at delivery, mode of delivery, and neonatal birth weight ($p > 0.05$). Fasting and postprandial glucose levels were significantly higher in Groups II and III compared to Group I ($p < 0.001$). Neonatal outcomes showed no deaths in Groups I and II, while Group III had one neonatal death (2.9%) and two IUFD cases (5.7%). Congenital anomalies were more frequent in Group III (17.1%), and significant differences were observed in neonatal hypoglycemia ($p = 0.048$) and macrosomia ($p = 0.003$), whereas other complications were not statistically different.

**Concluion:** Higher fasting and postprandial glucose levels in women with GDM were associated with the need for more intensive treatment, underscoring the importance of close glucose monitoring to guide management.

**KEYWORDS**: Gestational diabetes mellitus, glucose monitoring, treatment modalities, pregnancy outcomes.

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## INTRODUCTION

Glucose intolerance at the onset of or at first recognition during pregnancy is historically defined as Gestational Diabetes Mellitus (GDM) [1]. GDM develops in women whose pancreatic function is insufficient to overcome the insulin resistance associated with the pregnant state, GDM is associated with various complications, with the more prominent being an increased risk of spontaneous abortion, fetal anomalies, preeclampsia, fetal macrosomia, cesarean delivery, and neonatal hypoglycemia, along with their associated morbidities [2].

Insulin has been used as the standard treatment for GDM for a long time. However, researchers have demonstrated the safety of oral hypoglycemic agents, such as metformin, in the initial treatment when diet alone is not enough to achieve the desired glucose levels [3].

Appropriate monitoring and treatment of gestational diabetes can improve pregnancy outcome [4]. Many women can achieve euglycemia and improved pregnancy outcomes with nutritional therapy alone, with only 15% to 30% of women with GDM requiring insulin therapy [5].

However, the American College of Obstetricians and Gynecologists has suggested intensified antenatal maternal and fetal assessments in all women treated with insulin [6]. In addition, employing the new criteria for the diagnosis of GDM introduced by the International Association of Diabetes and Pregnancy Study Groups (IADPSG), increased the global prevalence of GDM to about 18%, which, in turn, increases the need for more efficient and effective monitoring and treatment strategies [7].

The aim of this study was to develop a predictive model for the necessity of different treatment modalities in women with GDM in Minia University Maternity Hospital [MUMH].

## PATIENTS AND METHODS

This prospective cohort study was conducted at MUMH from May 2022 to December 2023 after approval by the local ethical committee. A total of **109 pregnant women** diagnosed with GDM according to the IADPSG criteria (75-g OGTT at 24–28 weeks: fasting ≥92 mg/dl, 1-hour ≥180 mg/dl, or 2-hour ≥153 mg/dl; one abnormal value sufficient for diagnosis) were recruited. In high-risk cases, the test was performed at the first prenatal visit. If OGTT was not tolerated or declined, fasting blood sugar was used. Women with pre-existing diabetes mellitus were excluded. After diagnosis, all women were advised to follow a strict diabetic diet for two weeks as first-line therapy. Blood sugar was monitored by fasting and 2-hour postprandial testing. Metformin (500–1500 mg daily) was initiated if optimal glycemic targets (fasting <95 mg/dl, 2-hour postprandial <140 mg/dl) were not reached within two weeks (>30% of readings out of range). Insulin was started if targets were not achieved after two weeks of metformin therapy, or at any time when diet and metformin failed to provide sustained control. CTG was performed when indicated. Accordingly, patients were categorized into three groups: Group I (diet only, n=32), Group II (metformin, n=42), and Group III (insulin, n=35).

## METHODS

All participants received thorough counseling and provided written informed consent, including consent for anonymized data use in research.

Baseline and follow-up assessments included: Full history and clinical examination. Antenatal routine laboratory investigations (blood group, Rh typing, complete blood count, hepatitis B and C markers). Anomaly scan at 18–22 weeks if GDM was diagnosed early. Fetal growth scan at 28–32 weeks. Ultrasound at ≥36 weeks for fetal weight, presentation, amniotic fluid index, placental grading, and delivery-related parameters.

**Follow up of all patients up to delivery:** All patients were followed up until delivery. The timing of delivery was determined according to the line of treatment and the level of glycemic control. Patients who achieved sustained blood sugar control with diet or metformin were offered delivery at 40 weeks, provided there were no other obstetric indications for early intervention. Patients who required insulin treatment were offered delivery at 38 weeks. The mode of delivery was individualized based on maternal condition, fetal condition, and cervical status at the time of delivery. CTG and ultrasound findings were taken into account in decision-making.

The following outcome measures were recorded: **Primary outcome measure:** Optimal glycemic control. **Secondary outcome measures:** Maternal outcomes: mode of delivery, hypoglycemic attacks, diabetic ketoacidosis, diabetic neuropathy, diabetic retinopathy, and diabetic nephropathy. Neonatal outcomes: gestational age at birth, birth weight, Apgar scores, neonatal hypoglycemia, NICU admission, and perinatal morbidity or mortality.

**Statistical analysis**

Data were entered and analyzed using IBM SPSS software package version 20.0 (Armonk, NY: IBM Corp). Qualitative data were presented as numbers and percentages, and the Kolmogorov–Smirnov test was used to assess normality. Quantitative data were described using range (minimum–maximum), mean, and standard deviation. The significance of results was judged at the 5% level. Statistical tests included the Chi-square test for categorical variables, ANOVA for normally distributed quantitative variables, and Kruskal–Wallis H test for abnormally distributed quantitative variables. References: Kotz S, Balakrishnan N, Read CB, Vidakovic B. *Encyclopedia of Statistical Sciences.* 2nd ed. Hoboken, NJ: Wiley-Interscience; 2006. Kirkpatrick LA, Feeney BC. *A Simple Guide to IBM SPSS Statistics for Version 20.0.* Student ed. Belmont, CA: Wadsworth, Cengage Learning; 2013.

## RESULTS

Age ranged 23–44 years (33.53 ± 4.83) in Group (1), 21–43 years (34.43 ± 4.68) in Group (2), and 27–42 years (33.23 ± 4.22) in Group (3). BMI ranged 21.9–34.1 kg/m² (27.24 ± 3.70), 22.1–34.2 kg/m² (27.39 ± 3.55), and 22.0–33.9 kg/m² (27.32 ± 3.53) in Groups (1–3), respectively. Gravidity showed primigravida/multigravida rates of 34.4%/65.6%, 19.0%/81.0%, and 22.9%/77.1%, while parity showed nulliparous/primiparous/multiparous rates of 37.5%/28.1%/34.4%, 19.0%/23.8%/57.1%, and 25.7%/25.7%/48.6% in Groups (1–3), respectively. No statistically significant differences were detected among groups (**Table 1**).

**Table (1): Comparison between groups as regard to patient's demographic data**

| | Group (1) (n=32) | | Group (2) (n=42) | | Group (3) (n=35) | | P Value | Test of sig. between groups |
|---|---|---|---|---|---|---|---|---|
| | No. | % | No. | % | No. | % | | |
| **Age** | | | | | | | | |
| Range | 23-44 | | 21-43 | | 27-42 | | 0.488 | 1 vs 2 =0.406<br>1 vs 3 =0.787<br>2 vs 3 =0.255 |
| Mean± S. D | 33.53±4.826 | | 34.43±4.676 | | 33.23±4.215 | | | |

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| **BMI** | | | | | | | | |
| Min.-Max. | 21.9-34.1 | | 22.1-34.2 | | 22.0-33.9 | | 0.962 | 1 vs 2 =0.806<br>1 vs 3 =0.836<br>2 vs 3 =0.902 |
| Mean± S. D | 27.24±3.697 | | 27.39±3.546 | | 27.32±3.528 | | | |
| **Gravidity** | | | | | | | | |
| Primigravida | 11 | 34.4 | 8 | 19.0 | 8 | 22.9 | 0.303 | 1 vs 2 =0.181<br>1 vs 3 =0.416<br>2 vs 3 =0.781 |
| Multigravida | 21 | 65.6 | 34 | 81.0 | 27 | 77.1 | | |
| **Parity** | | | | | | | | |
| Nulliparous | 12 | 37.5 | 8 | 19.0 | 9 | 25.7 | 0.348 | 1 vs 2 =0.110<br>1 vs 3 =0.453<br>2 vs 3 =0.713 |
| Primiparous | 9 | 28.1 | 10 | 23.8 | 9 | 25.7 | | |
| Multiparous | 11 | 34.4 | 24 | 57.1 | 17 | 48.6 | | |

P: p value for comparing between the studied groups
*: Statistically significant at P <0.05

Fasting blood glucose on admission, in Group (1) was ranged between 82-98 with mean±S.D. 88.97±4.575 and it was increased significantly to be at 2nd hours with a mean value of 146.31±17.525 while in Group (2) was ranged between 87-115 with mean±S.D. 101.19±8.730 and it was increased significantly to be at 2nd hours with a mean value of 148.95±12.806 and in Group (3) was ranged between 93-130 with mean±S.D. 112.94±12.180 and it was increased significantly to be at 2nd hours with a mean value of 162.57±16.105. There were highly statistically significant differences between groups **Table 2.**

**Table (2): Comparison between groups as regard to patient's fasting blood glucose at the initial diagnosis or first prenatal visit (on admission).**

| | Group (1) (n=32) | Group (2) (n=42) | Group (3) (n=35) | P Value | Test of sig. between groups |
|---|---|---|---|---|---|
| **Baseline** | | | | | |
| Range | 82-98 | 87-115 | 93-130 | <0.001* | 1 vs 2 <0.001*<br>1 vs 3 <0.001*<br>2 vs 3 <0.001* |
| Mean± S.D | 88.97±4.575 | 101.19±8.730 | 112.94±12.180 | | |
| **At 1st hour** | | | | | |
| Range | 139-185 | 149-198 | 160-195 | <0.001* | 1 vs 2 <0.001*<br>1 vs 3 =0.001*<br>2 vs 3 =0.775* |
| Mean± S.D | 165.97±13.294 | 178.52±15.396 | 177.63±11.652 | | |
| **At 2nd hours** | | | | | |
| Range | 116-174 | 127-172 | 138-188 | <0.001* | 1 vs 2 =0.466<br>1 vs 3 <0.001*<br>2 vs 3 <0.001* |
| Mean± S.D | 146.31±17.525 | 148.95±12.806 | 162.57±16.105 | | |

P: p value for comparing between the studied groups
*: Statistically significant at P <0.05

Gestational age at delivery time in Group (1) was ranged between 38-40 weeks with mean± S.D. 39.1 ±1.3 weeks while in Group (2) was ranged between 38-40 weeks with mean± S.D38.8 ±0.9 weeks and in Group (3) was ranged between 37-39 weeks with mean± S.D. 38.3 ± 1.8 weeks. There were no statistically significant differences between group **Table 3.**

**Table (3): Comparison between groups as regard to patient's Gestational age at delivery time**

| | Group (1) (n=32) | Group (2) (n=42) | Group (3) (n=35) | P Value | Test of sig. between groups |
|---|---|---|---|---|---|
| Range | 38-40 | 38 - 40 | 37- 39 | 0.067 | 1 vs 2 =0.639<br>1 vs 3 =0.058<br>2 vs 3 =0.274 |
| Mean± S. D | 39.1 ±1.3 | 38.8 ±0.9 | 38.3 ± 1.8 | | |

P: p value for comparing between the studied groups
*: Statistically significant at P <0.05

Mode of delivery in Group (1) show that 11(34.4%) were NVD and 21(65.6%) were CS while in Group (2) 17(40.5%) were NVD and 25(59.5%) were CS and in Group (3) 17(48.6%) were NVD and 18(51.4%) were CS. There were no statistically significant differences between groups. **Table4** .

**Table (4): Comparison between groups as regard to patient's mode of delivery**

| | Group (1) (n=32) | | Group (2) (n=42) | | Group (3) (n=35) | | P Value | Test of sig. between groups |
|---|---|---|---|---|---|---|---|---|
| | No. | % | No. | % | No. | % | | |
| NVD | 11 | 34.4 | 17 | 40.5 | 17 | 48.6 | 0.495 | 1 vs 2 =0.635<br>1 vs 3 =0.322<br>2 vs 3 =0.499 |
| CS | 21 | 65.6 | 25 | 59.5 | 18 | 51.4 | | |
| Total | 32 | 100 | 42 | 100 | 35 | 100 | | |

P: p value for comparing between the studied groups
*: Statistically significant at P <0.05

Neonatal birth weight in Group (1) was ranged between 2680-3700 gm with mean± S.D. 3430.8± 430.4 gm while in Group (2) was ranged between 3000 - 4500gm with mean± S.D 3610±500 gm and in Group (3) was ranged between 3100 - 4700 gm with mean± S.D. 3700.6±491.8 gm. There were no statistically significant differences between groups **Table 5.**

**Table (5): Comparison between groups as regard to patient's Neonatal birth weight**

| | Group (1) (n=32) | Group (2) (n=42) | Group (3) (n=35) | P Value | Test of sig. between groups |
|---|---|---|---|---|---|
| Range | 2680-3700 | 3000-4500 | 3100-4700 | 0.069 | 1 vs 2 =0.251<br>1 vs 3 =0.059<br>2 vs 3 =0.686 |
| Mean± S. D | 3430.8± 430.4 | 3610±500 | 3700.6±491.8 | | |

P: p value for comparing between the studied groups
*: Statistically significant at P <0.05

Neonatal outcomes showed no deaths in Groups I and II, while Group III had 1 neonatal death (2.9%) and 2 IUFD cases (5.7%). Congenital anomalies were reported in 3.1%, 4.8%, and 17.1% of Groups I, II, and III respectively. NICU admission was required in 12.5%, 23.8%, and 20% of the groups, while RDS occurred infrequently across all groups. A statistically significant difference was observed in neonatal hypoglycemia, higher in Group III (14.3%, p = 0.048), and in macrosomia, which was more frequent in Groups II (19.04%) and III (31.4%) compared to Group I (p = 0.003). Other complications showed no significant differences

**Table 6.**

**Table (6): Comparison between groups as regard to patient's neonatal complications and outcomes**

| | Group (1) (n=32) | | Group (2) (n=42) | | Group (3) (n=35) | | P Value | Test of sig. between groups |
|---|---|---|---|---|---|---|---|---|
| | No. | % | No. | % | No. | % | | |
| Congenital anomalies | 1 | 3.1 | 2 | 4.8 | 6 | 17.1 | 0.213 | 1 vs 2 = 0.723<br>1 vs 3 = 0.061<br>2 vs 3 = 0.076 |
| Intrauterine growth restriction | 0 | 0 | 0 | 0 | 0 | 0 | ----- | 1 vs 2 =------<br>1 vs 3 =------<br>2 vs 3 =------ |
| Respiratory Distress Syndrome | 2 | 6.3 | 1 | 2.4 | 1 | 2.9 | 0.649 | 1 vs 2 =0.575<br>1 vs 3 =0.603<br>2 vs 3 =1.000 |
| NICU admission | 4 | 12.5 | 10 | 23.8 | 7 | 20 | 0.469 | 1 vs 2 =0.218<br>1 vs 3 =0.822<br>2 vs 3 =0.457 |
| Neonatal hypoglycemia | 1 | 3.1 | 3 | 7.1 | 7 | 20 | **0.048*** | 1 vs 2 = 0.449<br>1 vs 3 **= 0.033***<br>2 vs 3 = 0.094 |
| IUD | 0 | 0 | 0 | 0 | 2 | 5.7 | 0.130 | 1 vs 2 =1.000<br>1 vs 3 =0.169<br>2 vs 3 =0.169 |
| Early neonatal death < week | 0 | 0 | 0 | 0 | 1 | 2.9 | 0.130 | 1 vs 2 =1.000<br>1 vs 3 =0.335<br>2 vs 3 =0.270 |

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| Macrosomia | 0 | 0 | 8 | 19.04 | 11 | 31.4 | **0.003*** | 1 vs 2 =**0.008*** 1 vs 3 **< 0.001*** 2 vs 3 =0.209 |

P: p value for comparing between the studied groups
*: Statistically significant at P <0.05, IUD: Intra uterine death.

## DISCUSSION

This prospective cohort study was carried out in MUMH and was conducted on 109 women were divided into three groups (group 1 those controlled with diet only), group 2 (those failed with died control and controlled with metformin) and group 3 (those failed to be controlled with diet, metformine but controlled with insulin).

In the current study, we found that there were no statistically significant differences between the studied groups regarding age, BMI, gravidity and parity.

Our findings are consistent with those of Sapienza et al., [8], who aimed to identify factors predicting insulin requirements in pregnancies complicated by gestational diabetes mellitus (GDM). Their study divided patients into two groups—diet-controlled and insulin-dependent—and similarly reported no statistically significant differences between the groups in terms of maternal age (P=0.645) and nulliparity (P=0.057). Maternal age was 32.99 ± 5.97 years in the diet group and 32.32 ± 5.93 years in the insulin group, while nulliparity was observed in 39% of the diet group and 28.2% of the insulin group.

Similarly, results of this study were agreed with, Samir Kh Galal et al., [9], who aimed to assess the efficacy of metformin in controlling gestational diabetes compared to insulin. The comparison between Group A (Metformin) and Group B (Insulin) revealed no statistically significant differences across patient characteristics. Maternal age, BMI and parity were all comparable between the two groups, as indicated by p-values greater than 0.05 in each category. Specifically, maternal age (p = 0.174) and BMI (p = 0.676), showed no significant variation, suggesting that both groups were well-matched in terms of baseline characteristics. Additionally, the distribution of primigravida and multigravida participants (p = 0.104) and smoking status (p = 0.737) did not differ significantly, further supporting the homogeneity of the groups at the outset of the study. This ensures that any observed outcomes during the study can be attributed to the interventions rather than differences in patient characteristics.

Our study showed that there were highly statistically significant differences between groups with respect to fasting blood glucose. These findings were consistent with those reported by Barnes et al., [10] who similarly demonstrated a highly significant difference between the MNT-only group and the MNT+I group regarding fasting blood glucose levels in oral glucose tolerance test (OGTT) (mmol/L) and 2-hour postprandial BGL in OGTT (mmol/L), with a p-value of <0.001 in both comparisons. Specifically, their study found fasting BGL to be 5.0 ± 0.7 mmol/L in the MNT-only group and 5.5 ± 1.0 mmol/L in the MNT+I group, while 2-hour BGL was 8.7 ± 1.3 mmol/L and 8.9 ± 1.7 mmol/L, respectively.

Additionally, our results were supported by similar findings from Sapienza el al., [8] , who observed a statistically significant difference between the diet-controlled and insulin-requiring groups regarding the number of abnormal 100-g OGTT values and HbA1c levels, with p-values <0.001 for both measures. In their study, 60.5% of patients in the diet-controlled group had two abnormal OGTT values, compared to 32.5% in the insulin group, while three and four abnormal values were reported in 27.1% and 12.4% of the diet group, compared to 35.9% and 31.6% in the insulin group, respectively. Additionally, HbA1c levels were significantly higher in the insulin group (5.88 ± 0.66) compared to the diet group (5.44 ± 0.56).

This study results revealed that there were no statistically significant differences between groups according to gestational age (GA) at delivery time and mode of delivery.

This finding is in agreement with those of Sapienza el al., [8] who reported no statistically significant difference in gestational age at diagnosis between the studied groups, with a P-value of 0.062. Specifically, the gestational age at diagnosis was 29.4 ± 2.2 weeks in the diet group compared to 29.26 ± 2.32 weeks in the insulin group. These results suggest that, regardless of treatment modality, the timing of diagnosis did not significantly differ between the two groups.

In this findings, no statistically significant differences between groups were observed concerning neonatal birth weight and in term of Apgar score.

These results aligned with the study by Samir Kh Galal et al., [9], who also reported no significant differences between the groups concerning 5-minute Apgar scores. However, in contrast to our findings, they found that neonatal birth weight was significantly lower in the metformin group compared to the insulin group.

In this study, regarding the neonatal complications and outcomes, we found that there were no statistically significant differences between groups. However, there was a statistically significant difference in the incidence of neonatal hypoglycemia and the incidence of macrosomia.

This study was concordance with, Barnes et al., [10] who found that there were no significant differences in neonatal outcomes regarding shoulder dystocia. However, there was no statistically significant differences regarding neonatal hypoglycaemia.

Also, this results supported by Samir Kh Galal et al., [9], they also found no significant differences between the groups regarding 1eonatal respiratory distress. Consistent with our study, they reported a significant difference in neonatal hypoglycemia. However, NICU admissions were statistically significantly lower in the metformin group compared with the insulin group.

However, in contrast with our findings, Ouyang et al., [11] who conducted a meta-analysis study to compare and rank the effects of different glucose-lowering measures on maternal and infant outcomes in pregnant women with gestational diabetes mellitus (GDM). They concluded that Metformin is a potentially superior choice for GDM treatment because it is associated with minimal incidences of multiple adverse pregnancy outcome indicators and does not lead to high values of certain adverse outcome indices. Other hypoglycemic agent or diet groups exhibit high incidences of certain adverse outcomes. Therefore, when selecting a GDM treatment strategy, the efficacies and risks of different treatment programs should be evaluated according to the scenario in hand.

## CONCLUSION

This study developed a predictive model to determine treatment needs in women with gestational diabetes mellitus (GDM) at Minia University Maternity Hospital. Although no significant differences were found regarding neonatal outcomes, higher fasting and postprandial glucose levels were linked to the need for more intensive treatment. These results highlight the importance of strict glucose monitoring to guide management, while further research is required to refine predictive models and improve individualized care.

## RECOMMENDATIONS

Conduct larger studies with longer follow-up to validate and refine predictive models. Use well-designed randomized controlled trials or large observational studies. Ensure representative samples and adequate size to reduce confounding factors. Include multicenter studies to confirm generalizability of findings.

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