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Assessing The Compliance Of Lifestyle Modification And Metformin Versus Lifestyle Modification & Insulin In The Management Of Gestational Diabetes, Madinah, KSA

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Abstract

Background: Between October 2023 and October 2024, 147 pregnant women with GDM who received treatment at Madinah's maternity outpatient clinics participated in a retrospective cohort research. Data on demographics, medication adherence, glycemic control, and maternal-neonatal outcomes were gathered using validated questionnaires and medical records. Descriptive statistics, including frequencies and percentages, were used to analyze the data. **Methods:** Between October 2023 and October 2024, 147 pregnant women with GDM who received treatment at Madinah's maternity outpatient clinics participated in a retrospective cohort research. Data on demographics, medication adherence, glycemic control, and maternal-neonatal outcomes were gathered using validated questionnaires and medical records. The data was analyzed using descriptive statistics, such as percentages and frequencies. **Results:** Approximately half (49%) of the participants were on metformin, while 47.6% were on insulin. In total, 46.9% reported complying with the dietary advice given. Over one-third (32.7%) reported complying with the recommendations for diet and exercise. Self-monitoring of blood glucose (SMBG) was reported in 37.4% of cases and absent in 21.1% of cases. Only 32% reported tight glycemic control during the pregnancy. In addition to the high cesareans (59.2%), and 17.7% of cases were reported to have macrosomia. Most morbidities and treatment of gestational diabetes, were reported to begin in the third trimester. **Conclusion:** The results show deficiencies in lifestyle adherence and early diagnosis, which could restrict the best possible glucose control and lead to unfavorable pregnancy outcomes.

Introduction

Gestational diabetes mellitus (GDM) is defined as any degree of glucose intolerance with the onset or first recognition during pregnancy. Previously, the prevalence of GDM was reported to range from 1 to 14%, depending on the population studied and the diagnostic tests employed (Egbe et al., 2018; Chen et al., 2009; Hunt & Schuller, 2007). However, the prevalence of GDM has increased since 2010 by 2 to 3-fold, ranging from 8.9 to 53.4% (Alfadhli et al., 2015). GDM is associated sometimes with adverse maternal or fetal outcomes, including macrosomia, pre-eclampsia, preterm birth, and an increased risk of developing type 2 diabetes later in life (Nakshine & Jogdand, 2023; Malaza et al., 2022). Additionally, compared to healthy pregnant women, those with GDM had a significant decrease in

sensation level, position sense, and balance level (Doğan & Çaltekin, 2023). In addition, there is an increased risk for neonatal death and congenital defects resulting from excessive mother-to-fetus glucose transfer such as cardiac anomalies and hypertrophic cardiomyopathy (Raafat et al., 2020) and impaired fatty acid transport and mitochondrial dysfunction in the placenta (Siemers, Joss-Moore & Baack, 2024).

So the management of GDM is primarily aimed at controlling glycemic level to reduce the incidence of adverse pregnancy outcomes. The previous study has demonstrated that intensive treatment in women with GDM reduced birth weight and incidence of macrosomia in infants born to mothers who had participated in the intervention compared with women who had received routine care (Crowther et al., 2005). Therefore, active treatments - such as dietary therapy, exercise, oral hypoglycemic agents, insulin - are necessary to reduce the complications (Ouyang, 2021). While medical interventions such as insulin therapy and medication management are often used to manage GDM, lifestyle changes have been shown to improve glycemic control and reduce the need for medical intervention (Le et al., 2023). When an appropriate diet, alone or associated with physical exercise, does not suffice to control blood glucose levels in pregnant women, subcutaneous insulin therapy has been considered the standard for management of GDM. However, insulin has several disadvantages, including multiple daily injections, the risk of hypoglycemia, and maternal weight gain. It requires modification based on the patient's body mass index, glucose levels, and lifestyle (Spaulonci et al, 2013).

The first steps in managing GDM include lifestyle modifications by dietary and exercise; around 70% to 85% of cases have been found to be controlled with these modifications alone, while other individuals require insulin or metformin-containing medications to maintain appropriate blood glucose levels (Grant & Kirkman, 2015; Kelley, Carroll & Meyer, 2015). It could be potentially beneficial to reduce the risk of developing GDM if lifestyle interventions implemented during and after pregnancy (Huang et al., 2022). Medication management strategies such as insulin therapy or insulin therapy plus dietary measures are associated with more favorable neonatal outcomes than dietary control alone, even though several types of studies have shown improved neonatal outcomes for dietary management of GDM compared to no treatment. However, some studies also reflected that diet and lifestyle changes alone are not sufficient to achieve glycemic control in some women with GDM (Mnatzaganian et al., 23).

Although many GDM patients prefer metformin instead of insulin treatment in some trials, this could be due to many reasons, such as fear, anxiety, repetitive injections, the need for training on how to inject, dose-adjustment skills, the possibility of hypoglycemia, and more weight gain in pregnant women (Kitwitee et al., 2015). In the gestational Diabetes (MiG) trial, patients seemed to view metformin more positively than insulin as therapy for GDM, given the absence of increased maternal and neonatal risks with metformin (Priya & Kalra, 2018). Two meta-analyses of randomized clinical trials provided benefits and risks of metformin versus insulin. Overall deliver gestational age and weight gain after treatment, neonatal hypoglycemia, and risk of pregnancy-induced hypertension (PIH) were all significantly lower in the metformin group relative to the insulin group (Paschou et al., 2024; Abdullah et al., 2021).

In general, the adherence and effectiveness of treatment can be substantially different depending on the specific treatment option. The purpose of this study was to identify and compare adherence and effectiveness between two commonly used treatments strategies to manage GDM; lifestyle modification with metformin versus lifestyle modification with insulin, used by pregnant women in Madinah, Saudi Arabia.

Methodology

Study Design

A retrospective cohort study design was utilized, with data collected between October 2023 and October 2024. The collected data included demographic variables, medical records, and outcomes related to treatment adherence and lifestyle modifications.

Study Population and Sample

The sampling population selected for this study was comprised of pregnant women who had a diagnosis of GDM and were under evaluation in outpatient clinics in Madinah, Saudi Arabia at maternity and child hospital (MCH) and National Guard Health Affairs (NGHA) outpatient clinics using a validated questionnaire. The sample size consisted of 147 pregnant women with GDM exclusively and were

treated with metformin or insulin with lifestyle modifications, with no sampling or random selection. Complete inclusion was adopted for three reasons; to provide full coverage of the target population, to maximize statistical power for the findings, and to prevent selection bias. Exclusion criteria included women with a history of diabetes, women using medications that were not prescribed according to the protocol.

Data collection

Following IRB approval the questionnaire was generated and then verified by two family medicine consultants and pilot study, then the data were collected after obtaining verbal consent from participants.

Statistical analysis

Statistical analyses were limited to frequencies and percentages to describe the distribution of demographic and health-related variables among participants. Microsoft Excel was used for data organization and graph generation, while SPSS (Statistical Package for the Social Sciences) was employed for calculating frequencies and percentages. No inferential or relational analyses were performed.

Results

1. Demographic Information

According to the demographic distribution, most participants (55.8%) were aged 31-40 years, which is the commonly recognized high-risk group for GDM as noted in the proposal. The majority of participants classified themselves as urban (81.6%) which suggests better accessibility and availabilities to healthcare. Almost all participants were Saudi (96.6%). Smoking rates were low (0.7% were classified as current smokers). Occupationally, the largest group were housewives (36.1%).

Table 1 Demographic Information

	N (%)
Age in years	
<20	4 (2.7%)
20 – 30	46 (31.3%)
31 – 40	82 (55.8%)
>40	15 (10.2%)
Residence	
City	120 (81.6%)
Village	27 (18.4%)
Nationality	
Saudi	142 (96.6%)
Non-Saudi	5 (3.4%)
Smoking	
Yes	1 (0.7%)
No	141 (95.9%)
X-Smoker	5 (3.4%)
Occupation	
Privet work	42 (28.6%)
Self-employed	16 (10.9%)
Student	12 (8.2%)
Housewife	53 (36.1%)
Unemployed	24 (16.3%)

2. General Health and Vital Signs

BMI data illustrates an excess of overweight and obese (34.7% were overweight and 29.9% were obese), consistent with the proposal background and suggesting that BMI is an important risk indicator for GDM. Also, most (84.4%) participants had controlled blood pressure, which indicates that hypertension was likely managed for most individuals. However, 15.6% participants had uncontrolled hypertension, indicating the need for more rigorous health monitoring.

Table 2 General Health and Vital Signs

	N (%)
BMI	
<18.5 underweight	1 (0.7%)
18.5-24.9 Normal	35 (23.8%)
25-29.9 overweight	51 (34.7%)
30-34.9 obese	44 (29.9%)
>35 extremely obese	16 (10.9%)
Blood pressure measurement	
Controlled <135/85	124 (84.4%)
Uncontrolled >135/85	23 (15.6%)

3. Reproductive History

There is a high prevalence of multiparity, with 83.7% of participants having had multiple pregnancies. Among the multiparas the higher number of pregnancies is 3-4 (39%). The abortion rate was 34%, which is high and may be associated with complications, such as GDM or preeclampsia as supported in the literature.

Table 3 Reproductive History

	N (%)
Parity	
Multipara	123 (83.7%)
Nulliparity	24 (16.3%)
If multipara; number of pregnancies	
1-2	38 (30.9%)
3-4	48 (39.0%)
5-6	25 (20.3%)
7 or more	12 (9.8%)
Abortion	
Yes	50 (34.0%)
No	97 (66.0%)

4. Pregnancy-Related Health Conditions

The data indicate the high rate of GDM among participants (78.2%). As expected, insulin was the most common treatment pattern (36.7% of treatments), followed by metformin (30.6%). However, the findings do demonstrate a low incidence of preeclampsia (6.1%) and gestational hypertension (9.5%). Rates of cesarean delivery were high (59.2%).

Table 4 Pregnancy-Related Health Conditions

	N (%)
GDM	
Yes	115 (78.2%)
No	32 (21.8%)
If positive what treatment was used	
Among patients with GDM, treatment modalities were varied. Dietary treatment alone was used in only 5 cases (3.5%), while pharmacological agent were more popular. Insulin was marked as the most frequent form of treatment employed (its various forms were given to 36.7% of patients) whereas metformin, alone or in combination with insulin, was used in 30.6% of patients.	

5. Obstetrical and Neonatal Outcomes

Only 6.1% of the participants had a diagnosis of pre-eclampsia, and gestational hypertension was reported in only 9.5% of the cases. Macrosomia, defined as infant birth weight above 4000 g, was seen in 17.7% of the participants. The majority of participants, 59.2%, reported delivering by Cesarean

delivery. Preterm delivery, defined as birth prior to 37 weeks gestation, was reported in 11.6% of the cases. Congenital anomalies in infants were reported in 19.0%, while 81.0% had infants without any congenital anomalies.

Table 5 Obstetrical and Neonatal Outcomes

	N (%)
Pre-eclampsia	
Yes	9 (6.1%)
No	138 (93.9%)
Gestational Hypertension	
Yes	14 (9.5%)
No	133 (90.5%)
Macrosomia; infant with birth weight >4000g	
Yes	26 (17.7%)
No	121 (82.3%)
Cesarean delivery	
Yes	87 (59.2%)
No	60 (40.8%)
Preterm (delivery at <37wk)	
Yes	17 (11.6%)
No	130 (88.4%)
Infant with congenital anomaly	
Yes	28 (19.0%)
No	119 (81.0%)

6. Details of Gestational Diabetes Mellitus (GDM)

The gestational age at the GDM diagnosis in the study showed that most participants were diagnosed in the third trimester (57.8%, n = 85) as opposed to only 0.7% (n = 1) in the first trimester (weeks 0 to 12). The gestational age at the initiation of treatment shows that the majority (67.3%, n = 99) started treatment in the third trimester.

Table 6 Details of GDM

	N (%)
Gestational age; at the time of diagnosis of GDM	
First trimester: Weeks 0 to 12	1 (0.7%)
Second trimester: Weeks 13 to 24	32 (21.8%)
Third trimester: Weeks 25 to 36	85 (57.8%)
Not sure	29 (19.7%)
Gestational age; at the beginning of treatment	
First trimester: Weeks 0 to 12	1 (0.7%)
Second trimester: Weeks 13 to 24	14 (9.5%)
Third trimester: Weeks 25 to 36	99 (67.3%)
Not sure	33 (22.4%)

7. Family History and Diabetes-Related Symptoms

A significant family history of diabetes (73.5%) and GDM (46%) supports genetic predisposition as an important risk factor. In terms of signs or symptoms of hyperglycemia, 70.7% experienced polyuria, 52.4% reported polydipsia. Infections were reported by 19.7% and 8.8% reported unintentional weight loss.

Table 7 Family History and Diabetes-Related Symptoms

	N (%)
Family history	
Diabetes	108 (73.5%)

Hypertension	59 (40.1%)
GDM	67 (45.6%)
Preeclampsia	7 (4.8%)
Hyperglycemia symptoms	
Polyuria	104 (70.7%)
Polydipsia	77 (52.4%)
Polyphagia	40 (27.2%)
Infection	29 (19.7%)
Losing Wight	13 (8.8%)

8. Treatments and Follow-Up

The degree of compliance varied widely across different treatments and lifestyle changes. Although 32.7% adhered to diet and exercise together, only 44.9% adhered to a diet alone. Metformin was used by 49.0% (n = 72) and insulin by 47.6% (n = 70), while 1.4% reported using other medications. When looking at the frequency of medication use, 46.3% took their medications twice a day. Adherence to dietary advice (46.9%) and SMBG (32%) showed moderate levels of adherence. Adherence to medication was high (46.3% rarely missed doses), but non-compliance in exercise (31.3%) indicates areas where improvement in interventions is necessary. In self-monitoring of blood glucose (SMBG), 37.4% performed monitoring frequently (4–7 times/day) and 21.1% did not monitor at all. Finally, on average, follow-ups (49.0%) had patients returning regularly every 2–4 weeks compared to 10.8% who did not return at all, thus demonstrating compliance.

Table 8 Treatments and Follow-Up

	N (%)
Types of treatment	
Diet only	66 (44.9%)
Diet and exercise	48 (32.7%)
Metformin	72 (49.0%)
Insulin	70 (47.6%)
Other types of medications	2 (1.4%)
Frequency of taking medication	
Once a day	23 (15.6%)
Twice a day	68 (46.3%)
Thrice a day	33 (22.4%)
Four or more	23 (15.6%)
To medication (How often did you forget to take your medications?)	
Never/ rarely; compliance	68 (46.3%)
Sometimes; semi / partial compliance	62 (42.2%)
Usually; non-compliance	16 (10.9%)
To exercise	
Frequently ≥ 4 d/w; compliance	31 (21.1%)
Less frequent < 4 d/w; semi- compliance	68 (46.3%)
Not exercising; non-compliance	46 (31.3%)
To dietary advice	
Not following it at all; non-compliance	11 (7.5%)
Sometimes; semi/ partial compliance	66 (44.9%)
Yes, following it all the time; compliance	69 (46.9%)
SMBG	
Frequently: 4-7 times/day; compliance	55 (37.4%)
Less frequent: less than 4 times/day; semi-compliance	60 (40.8%)
No SMBG; not compliance	31 (21.1%)
Meet target SMBG FBG less than 95; PPr less than 120	
Tight controlled: All readings meet the target	47 (32%)
Semi-controlled: 2-3 readings above the target	86 (58.5%)

	N (%)
Uncontrolled: more than 3 readings above the target	14 (9.5%)
Follow-up	
No F/ U; non compliance	16 (10.8%)
Frequently: every 2-4 week; compliance	72 (49%)
Less frequent more than 4 week; semi-compliance	59 (40.1%)

Discussion

Gestational diabetes mellitus (GDM) continues to be an increasing issue for global health. It is becoming more prevalent in both developed and developing countries, mainly because of rising levels of obesity, changes in sedentary activity levels and maternal age. Globally, the estimated prevalence for GDM is between 1% and 28%, depending on the test used to diagnose and population (Nguyen et al., 2018). In Saudi Arabia, the situation is particularly concerning. A 2024 study conducted in Saudi Arabia found a GDM prevalence rate of 55% from a cross-sectional study done on pregnant women in Taif, which was a shocking revelation pertaining to this issue (Algethami et al., 2024). Appropriate glycemic control is significantly affected by adherence to dietary and lifestyle modifications, the use of antidiabetic drugs, and regular blood glucose monitoring (Pigato et al., 2023). In this study, we tried to evaluate the effects of lifestyle adherence along with the use of insulin or metformin among GDM patients in Madinah, Saudi Arabia. The study provides a local context on optimizing GDM treatment strategies.

The results showed metformin, an oral antihyperglycemic, was utilized by 49% of participants and 47.6% of participants used insulin. The usage of metformin appears to be utilized, largely due to ease of administration and better patient compliance, which is supported by existing literature (Mobin et al., 2025). According to Rowan et al. (2008), adherence rates for oral medications such as metformin are typically much higher than injectable regimens such as insulin. People are overall more adherent to oral agents when we look at adherence rates from larger studies reported that it is so easy to take metformin that the majority of women expressed a larger preference for continuing metformin than insulin due to convenience and tolerability (Rowan et al., 2008). Similarly, a meta-analysis conducted by Musa et al. (2021) revealed that metformin was associated with reduced maternal weight gain and a lower risk of neonatal hypoglycemia and large-for-gestational-age (LGA) births when compared to insulin (Musa et al., 2021). The findings presented in Table 4, explored key pregnancy-related health conditions experienced by participants, in patients with GDM, provided details of this population's maternal health risk and their management. In this cohort, GDM was experienced by 78.2% of the participants which is a high burden of the disorder considering recent national studies in Saudi Arabia reported the prevalence rate to be over 50% (Alsaedi et al., 2020).

Table 5 also outlines the obstetrical and neonatal outcomes of those with GDM allowing for a significant inquiry into maternal and infant health risks associated with this condition. One of the most obvious findings was the high rate of cesarean delivery of 59.2%, which is strikingly more than the global average and consistent with previous literature reporting GDM and an increased risk for cesarean section due to complications such as macrosomia, fetal distress, or poor glycemic (Njogu, Makunyi & Musau, 2022). While, the study did not directly compare delivery outcomes between treatment groups, previous literature has suggested metformin could have lower rates of cesarean deliveries and neonatal morbidity. For example, Morais et al. (2020) reported rates of neonatal hypoglycemia and NICU admission were significantly lower for metformin compared to insulin (Morais et al., 2020). Macrosomia, which is defined as a birth weight greater than 4000 grams, occurred in 17.7% of cases which reinforces the necessity of glucose control in a pregnant woman. This is all the more to be emphasized because most of the participants, 57.8%, had a diagnosis of GDM in the third trimester and 67.3% started treatment in that third trimester. Several studies have shown that insulin treatment is able to reduce the risk of macrosomia to a greater extent than diet alone but it was also shown that for some populations, metformin also resulted in lower birth weight than insulin (Sciacca et al., 2023). Additionally, the study reported that 11.6% of participants experienced preterm delivery (<37 weeks gestation). Although this is lower than some international studies reported, it is still a clinically meaningful burden. In the case of GDM patients, determining preterm birth is often linked to either fetal overgrowth or hypertensive disorders, and the goal of both pharmacological and non-

pharmacological interventions is either to extend the gestation period with the least risk to both mothers and babies (Karcz & Królak-Olejnik, 2024). Another alarming finding reported is the 19% prevalence of congenital anomalies. The prevalence of congenital malformations is indeed higher in pregnancies complicated by type 1 diabetes than those complicated by type 2 diabetes. Increased maternal HbA1c levels during the periconceptional period and early gestation period, are strongly associated with an increased risk of major congenital anomalies; finding this increase illustrates the importance of optimising glucose control in early pregnancy, perhaps more so than with later pregnancy (Fawzy et al., 2023)**.**

The survey also discusses aspects of timing related to GDM diagnosis and management, and the importance of timing relative to maternal and neonatal outcomes (Table 6). The findings demonstrated that most GDM diagnoses were in the third trimester (57.8%) and only 0.7% of GDM was diagnosed first trimester. In a similar way, the initiation of treatment had the same pattern with 67.3% of participants commencing therapy in the third trimester compared to 0.7% starting in the first trimester. The results indicate a considerable delay in both diagnosis and treatment of GDM in the population studied; this raises concerns regarding the late diagnosis of GDM as it limits the time for optimal glycaemic control and increases the risk of negative pregnancy outcomes. Evidence indicates that screening and treatment of GDM is ideally completed by the end of the second trimester. Early interventions reduce rates of complications of macrosomia, preeclampsia and neonatal hypoglycemia (van Hoorn et al., 2022).

The study present significant variation in patient adherence to different elements of treatment. The population of people who received pharmacologic treatments had slightly more people reported using metformin (49.0%) than insulin (47.6%), whereas dietary changes alone were adhered to (44.9%) and dietary changes and exercise (32.7%) were the remaining combinations utilized. Overall, this represents a good balance between pharmacological and lifestyle modifications and is consistent with international guidelines that recommend individualized treatment based on glycemic severity, patient preferences, and acceptability (Dardano et al., 2014). Self-monitoring of blood glucose (SMBG) also had sub-optimal adherence. Only 37.4% of participants performed frequent self-monitoring (here defined as 4-7 times/day), and 21.1% did not perform any self-monitoring of their blood glucose. SMBG is an important part of effective GDM treatment, and it was apparent that neglecting self-monitoring of blood glucose may have a negative impact on glycemic control, as well as increased risk of complications (Rochmah et al., 2024). We also separate glycemic control into various outcomes of glycemic control which indicated that indicate that only 32% of patients achieved tight control (all readings in range), while 58.5% achieved semi-controlled levels, while 9.5% were uncontrolled. These outcomes mirror findings from other studies that emphasize how inconsistent SMBG, dietary non-compliance, and lack of physical activity are major contributors to suboptimal glucose control during pregnancy (Taousani et al., 2025).

Conclusion:

Metformin is favored over insulin because of patient compliance and ease of use. Non-adherence to blood glucose self-monitoring, dietary, and physical activity regimens indicates patients require additional support and education. The prevalence of congenital abnormality, macrosomia, and cesarean deliveries highlights the benefit of early intervention and comprehensive care approaches.

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