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Original Article

# Impact of patient education on KAP, medication adherence and therapeutic outcomes of metformin versus insulin therapy in patients with gestational diabetes: A Hospital based pilot study in South India

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ABSTRACT

*Background and aim:* The study assessed the impact of continuous patient education on Knowledge, Attitude, Practice (KAP), medication adherence and extent of glycemic control in pregnant women with gestational diabetes on insulin or metformin therapy.
*Methods:* 81 women with gestational diabetes (37 on insulin and 44 on metformin) were assessed for KAP using a validated questionnaire and medication adherence using the 8-items Morisky medication adherence scale, fasting, and postprandial blood glucose levels at the baseline and after two education sessions on drug therapy at one and three months intervals. The difference in mean KAP, medication adherence scores, fasting, and postprandial blood glucose levels and the extent of glycemic control with insulin or metformin therapy were assessed statistically.
*Results:* There was a highly significant difference in the mean KAP, medication adherence scores, fasting and postprandial blood glucose levels from baseline to follow-up after three months, ($P < 0.0001$) indicating that continuous patient education had a positive impact on their KAP, medication adherence, blood glucose levels.
*Conclusion:* The study identified that continuous patient education improved their knowledge and practice of medication adherence which reflected on lowered fasting and postprandial blood glucose levels. Glycemic control was found to be the same with metformin and insulin in gestational diabetes.


## 1. Introduction

Gestational Diabetes Mellitus (GDM) is one of the most common medical disorders complicating pregnancy and its incidence in women of a reproductive age group is increasing globally. Gestational diabetes constitutes 88% and type 2 diabetes accounts for eight percent of all cases of diabetes in pregnancy. The overall incidence of gestational diabetes is 3–6% with a variation of 2–15% observed, depending on the diagnostic criteria used and the incidence is fifteen percent in India [1–3].

It has been reported that intensive glycemic control in women with GDM had shown a reduction in the incidence of macrosomia in infants born to mothers who had participated in the intervention compared with women who had received routine care [4]. Women with GDM are treated with insulin-Neutral Protamine Hagedorn (NPH), and regular insulin. Over the past few years, clinical experience with insulin analogs in pregnancy has increased dramatically [5].

As compared with insulin, metformin (alone or with supplemental insulin) is not associated with increased perinatal complications in women with GDM. Metformin decreases intestinal glucose absorption and hepatic glucose output by inhibition of gluconeogenesis, enhances peripheral glucose uptake in the muscles and adipose tissues, resulting in improved insulin sensitivity and reduced fasting and postprandial plasma glucose [6].

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Metformin is a category B medication in pregnancy with a potential risk pregnancy for neonatal hypoglycemia and a maternal-to-foetal transfer rate of 10–16%. Metformin use in gestational diabetes was not considered as an optimal choice, as it crosses the placenta freely and could increase the risk of lactic acidosis, both of which could harm maternal and foetal health [6]. However, studies have reported that there was no increase in the rate of neonatal hypoglycemia after delivery in metformin-treated women when compared with women who received insulin [7].

Medication adherence is an important goal in the management of diseases and conditions that necessitates complex therapeutic regimens. Pregnant women with GDM are among the most challenging patients in terms of medication adherence, that the health care teams must deal with on a day to day basis [8]. It is crucial to adhere to the prescribed medication regimen in pregnancies complicated by GDM toprevent further complications in mothers and babies. These patients will require multiple daily insulin injections or a scheduled administration of metformin to normalize their blood glucose levels. Even for the most motivated patients, adherence to treatment may be difficult. Pregnant women who have GDM need special attention by the multidisciplinary team, because of the risks that may affect the balance of both: mother and child. This includes constant explanations about GDM, treatment and, above all, continuing health education, aiming the self-care. Providing quality information during pregnancy is recommended to ensure health care for pregnant women, educate and make women more participants; may help to reduce maternal morbidity and mortality [9].

However, clinical practice has shown that little is known about the knowledge that women with gestational diabetes have about this pathology, its respective treatment and the importance of adherence, as well as self-care measures to be practiced in daily life [10]. Hence this study was done to assess the impact of patient education on the KAP, medication adherence and clinical outcomes in women with gestational diabetes on metformin or insulin therapy.

## 2. Materials and methods

A prospective observational study was conducted in 81 pregnant women, aged 18 years and above, diagnosed with gestational diabetes at the time of the study, attending the prenatal clinic and prescribed with insulin or metformin based on the clinician's decision. The study was conducted with the approval of the Institutional ethics committee and the informed consent of the study population.

Data on patient demographics (age in years), number of pregnancies, parity, gestational age at the time of the diagnosis of GDM, gestational age at the beginning of the medical therapy were obtained from the patients' case records and through direct history interview at the time of initiation of the study. The study cohort receiving Insulin therapy was clustered as Group I and the cohort on Metformin therapy were included in Group II. Both the groups were reviewed after two months and were subjected to estimation of blood glucose levels at baseline and at second follow up after 2 months. The clinical outcome of two groups of patients on insulin and metformin therapy in GDM was assessed by evaluating the fasting and the postprandial blood glucose levels at the baseline and on follow up after 2 consecutive months.

### 2.1. Questionnaires used

#### 2.1.1. KAP questionnaire

The knowledge, attitude, and practice of the pregnant women on gestational diabetes prescribed with metformin or insulin were assessed by using the KAP questionnaire by Subish Palaian et al. with the author's permission [11]. It has 25 questions (Knowledge – 18, Attitude and Practice – 7 questions) and each correct answer is given a score of 1 and each wrong answer is given a score 0.

#### 2.1.2. Morisky 8-item medication adherence questionnaire

Medication adherence was assessed using Morisky Medication Adherence Scale – 8 by Donald Morisky et al. [12] The Morisky medication adherence scale (MMAS – 8) is a generic self-reported, medication-taking behavior scale, initially validated for hypertension but used for a wide variety of medical conditions. The items are summed to give a range of scores from low to high adherence. The total score is a summation of all 8 items and ranges between 0 and 8, with scores of >8 reflecting high adherence, 7 or 6 reflecting medium adherence, and <6 reflecting low adherence.

The patients were made to answer both the questionnaires at the baseline, then they were educated both verbally and by providing a patient education leaflet in both English and local language (Tamil) at baseline, at first follow up after one month and during the second follow up at the end of the third month. The patients were again made to answer the above two questionnaires after the patient education session during the second follow up. Each education session was for around 30 min per patient. The patients were also monitored for the extent of glycemic control with insulin or metformin therapy by assessing the fasting and post prandial blood glucose values at baseline and on the second follow up.

#### 2.1.3. Statistical analysis

The collected data were analyzed with SPSS 16.0 version. Categorical variables were expressed as frequency and percentage and continuous variables were expressed as mean and standard deviation. The differences in mean KAP, medication adherence scores, fasting and post prandial blood glucose values of both groups from baseline to second follow up were assessed using paired t - test. The extent of glycemic control with insulin and with metformin therapy were assessed by comparing the differences in mean fasting and post prandial blood glucose values at baseline and on follow up after two months using Mann-Whitney *U* test. A P value of <0.05 was considered to be statistically significant.

## 3. Results

The study was conducted in 81 pregnant women with gestational diabetes, in the age range of 18–35 years, with a mean age of 26.05 ± 2.45 years. The age distribution was as follows: 18 (2.22%) patients in the age range of 18–25 years; 63 (77.8%) patients in the age range of 26–35years. There were 30 (38.27%) patients with a gestational age of less than 30 weeks and 50 (61.73%) patients with a gestational age of 31–35 weeks.

Of 81 patients, 43 (53.08%) patients had gestational diabetes during their first pregnancy, 24 (29.62%) patients had gestational diabetes during second pregnancy and 14 (17.28%) patients had gestational diabetes during both first and second pregnancy. There were 34 (41.98%) patients with a family history of diabetes mellitus and 47 (58.02%) had no family history of diabetes mellitus. There were 37 (45.68%) patients in group I prescribed with insulin (Isophane insulin) and 44 (54.32%) patients in group II prescribed with Metformin.

The medication adherence pattern of the study population was assessed using MMAS-8. Of 81 patients, 58 (72%) patients had a medium medication adherence score of 6–8 and 23 (28%) patients had a low medication adherence score of <6. None of the patients had a high medication adherence score (<8).

The mean knowledge score of the study population (N = 81) was

found to be 12.65 ± 2.46 at the baseline and 14.77 ± 2.72 at outcome evaluation after second follow up; attitude and practice score were 4.40 ± 1.19 at baseline evaluation and 5.64 ± 0.93 at outcome evaluation and Morisky medication adherence score for the study population was found to be 5.0 ± 1.15 at the baseline and 6.38 ± 0.70 during outcome evaluation following patient education at the second follow up. There was a highly significant increase in the knowledge, attitude and practice scores and a decrease in the medication adherence scores from baseline to the outcome evaluation on second follow up ($P < 0.0001$) indicating that patient education had a significant impact on their KAP and medication adherence (Table 1).

In patients receiving metformin ($n = 44$), the mean knowledge score was 12.50 ± 2.35 at the baseline and 14.59 ± 2.78 at outcome evaluation after second follow up; attitude and practice score was 4.34 ± 1.16 at baseline and 5.57 ± 0.93 at outcome evaluation and Morisky medication adherence score was found to be 4.84 ± 1.14 at the baseline and 6.43 ± 0.36 at outcome evaluation. There was a highly significant increase in the knowledge, attitude and practice scores and a decrease in the medication adherence scores from baseline to the outcome evaluation on second follow up ($P < 0.0001$) indicating that patient education had a significant impact on their KAP and medication adherence in patients receiving metformin (Table 2).

In patients receiving insulin ($n = 37$), the mean knowledge score was 12.84 ± 2.60 at baseline and it was found to be 14.97 ± 2.67 at outcome evaluation after second follow up; attitude and practice score were 4.46 ± 1.24 at baseline and 5.73 ± 0.93 at outcome evaluation and Morisky medication adherence score was found to be 4.77 ± 1.17 at the baseline and 6.62 ± 0.53 at outcome evaluation. There was a highly significant increase in the knowledge, attitude and practice scores and a decrease in the medication adherence scores from baseline to the outcome evaluation on second follow up ($P < 0.0001$) indicating that patient education had a significant impact on their KAP and medication adherence in patients receiving insulin (Table 3).

Table 4 depicts the mean differences in the KAP and the medication adherence scores from baseline to second follow up in patients on insulin and metformin therapy. The mean difference in the knowledge, attitude and practice, and medication adherence scores of the patients on metformin therapy was found to be 2.09 ± 0.43, 1.23 ± 0.23 and 2.21 ± 0.48 respectively; the mean difference in the KAP and medication adherence scores of the patients on insulin was found to be 2.13 ± 0.07, 1.27 ± 0.31 and 2.25 ± 0.64 respectively. There were no statistically significant differences in the KAP scores from baseline to the second follow up in patients on metformin and insulin therapy ($P = 0.12$, 0.64 and 0.18 respectively).

The mean value of fasting blood glucose in patients receiving insulin ($n = 37$) was 103.81 ± 7.98 mg/dL at baseline and it was 94.59 ± 5.77 mg/dL at second follow up after 2 months. Though there was a mean difference of 9.22 ± 8.63 mg/dL in these patients. In patients receiving metformin, ($N = 44$) the mean fasting blood glucose was 105.16 ± 15.16 mg/dL at baseline and it was 94.84 ± 6.18 mg/dL after the second follow up. There was a highly significant reduction in fasting blood glucose level from baseline to follow up in both the groups on insulin and metformin ($P < 0.0001$) (Table 5). The mean difference in fasting blood glucose in these patients was 10.32 ± 15.17 mg/dL. There was no statistically significant difference in the reduction in the fasting blood glucose level for insulin or metformin ($P = 0.921$).

The mean value of postprandial blood glucose level in group I patients receiving insulin was 128.30 ± 7.26 mg/dL at baseline and was 116.05 ± 6.01 mg/dL at follow up after 2 months. The mean difference of Post prandial blood glucose levels in these patients was 12.24 ± 7.90 mg/dL. The mean postprandial blood glucose level in group II patients was 130.23. ± 16.83 mg/dL at baseline and it was 117.86 ± 6.54 mg/dL at follow up. There was a statistically significant reduction in Post prandial blood glucose level from baseline to follow in group I and group II patients on insulin and metformin respectively ($P = 0.0001$) (Table 6). The mean difference in Post prandial blood glucose in these patients was 12.36 ± 16.47 mg/dL. There was no statistically significant difference in the reduction in the Post prandial blood glucose level for insulin or metformin therapy ($P = 0.324$).

**Table 1**
**- Comparison of KAP and MMAS-8 in the study population.**

| Parameters | Baseline | Outcome | |
|---|---|---|---|
| (n = 81) | Evaluation | evaluation | Significance |
| | (mean ± SD) | (mean ± SD) | P |
| Knowledge | 12.65 ± 2.46 | 14.77 ± 2.72 | <0.0001** |
| Attitude/Practice | 4.40 ± 1.19 | 5.64 ± 0.93 | <0.0001** |
| Medication adherence | 5.60 ± 1.15 | 6.38 ± 0.70 | <0.0001** |

P < 0.0001** was considered highly significant.

## 4. Discussion

The rise in diabetes has taken on international significance. GDM is a condition that can have adverse outcomes on women's health and the health of their offspring. GDM occurs in approximately 17.8% of all pregnant women. Women at risk for developing GDM may have a personal history of GDM with the previous pregnancy, family history of diabetes, advanced maternal age (≥35 years), obesity, and a BMI > 30 kg/m$^2$ [13]. In this study, majority (40%) of the women developed GDM during the first pregnancy and 10% during their second pregnancy. The knowledge, attitude, and practice of pregnant women towards the disease was found to be 65% (16 out of 25 questions were answered correctly).

The results of the present study are in concordance with the results of the studies done by Carolan M [14], and Bhavadharini et al. [15] These studies identified that a greater proportion of the women were aware of the conditions of DM and GDM. The majority of the women in the study had high knowledge and attitude about the significance of the time of diagnosis of GDM, diet, and exercise as a treatment option for GDM, and the probability of untreated GDM posing a risk to the unborn child. However, knowledge about the risk factors for GDM and the course of GDM, and that the women diagnosed with GDM are at an increased risk for future type 2 diabetes was low. A good knowledge about the risk factors and the consequences of untreated GDM may aid the pregnant women to take proper precautions and self-care.

In the present study, there was a significant improvement in the mean KAP scores of pregnant women towards GDM and its management from baseline to the second follow up after patient education. There was no association between the type of therapy and the knowledge, attitude, and practice of the patients. There was no difference between the baseline and the final follow up KAP scores and medication adherence scores in patients on insulin and metformin therapy. This indicates that patient education plays a significant role in KAP of the patients irrespective of the type of drug therapy. Hence patient education needs to be focused on the risk factors of the disease, the future complications, disease management, lifestyle modifications and on the drug prescribed, its dose, dosing interval, time of administration, the route, the side effects profile of the drug given and the importance of adhering to the drug regimen.

An uncontrolled glycemic level in GDM may result in

**Table 2**
**- KAP and MMAS-8 scores of Group I (Insulin).**

| Parameters (n = 37) | Baseline evaluation (mean ± SD) | Outcome evaluation (mean ± SD) | Significance P |
|---|---|---|---|
| Knowledge | 12.84 ± 2.60 | 14.97 ± 2.67 | <0.001** |
| Attitude/Practice | 4.46 ± 1.24 | 5.73 ± 0.93 | <0.0001** |
| Medication adherence | 4.77 ± 1.17 | 6.62 ± 0.53 | <0.0001** |

P < 0.0001** was considered highly significant.

**Table 3**
**- KAP and MMAS-8 scores of Group II (Metformin).**

| Parameters (n = 44) | Baseline evaluation (mean ± sd) | Outcome evaluation (mean ± sd) | Significance P |
|---|---|---|---|
| Knowledge | 12.50 ± 2.35 | 14.59 ± 2.78 | <0.0001** |
| Attitude/Practice | 4.34 ± 1.16 | 5.57 ± 0.93 | <0.0001** |
| Medication adherence | 4.84 ± 1.14 | 6.43 ± 0.36 | <0.0001** |

P < 0.0001** was considered highly significant.

**Table 4**
**–Mean differences in KAP and MMAS-8 scores between groups.**

| Parameters (N = 81) | Mean difference in scores from baseline to second follow up: Group I (n = 37) (Insulin) | Group II (n = 44) Metformin | Significance P |
|---|---|---|---|
| Knowledge | 2.13 ± 0.07 | 2.09 ± 0.43 | 0.12 (NS) |
| Attitude/Practice | 1.27 ± 0.31 | 1.23 ± 0.23 | 0.64 (NS) |
| Medication adherence | 2.25 ± 0.64 | 2.21 ± 0.48 | 0.18 (NS) |

NS- Non-significant.

**Table 5**
**– Fasting blood glucose at baseline and follow up.**

| Parameter (N = 81) | Fasting blood glucose (mg/dL) (Mean ± SD) Baseline | Follow up After 2 months | Significance P |
|---|---|---|---|
| Group I (n = 37) | 103.81 ± 7.98 | 94.59 ± 5.77 | <0.0001** |
| Group II (n = 44) | 105.16 ± 15.16 | 94.84 ± 6.18 | <0.0001** |

P < 0.0001** was considered highly significant.

complications ranging from death or injury to the baby and subject the mother to an increased risk of caesarean delivery. This risk to both the mother and the baby may be reduced by adherence to the medication regimen. In the present study, the medication adherence patterns were found to be medium in 77% patients and low in 23% of patients. There was a significant increase in the mean medication adherence score of the study population from baseline to second follow up after patient education. The improvement in medication adherence patterns was significantly high in patients irrespective of the drug therapy they were receiving. The outcome of improvement in medication adherence was also clinically evident from the decrease in the fasting and Post prandial blood glucose levels from baseline to the second follow up after two consecutive months. The A1C test is an effective measure of adherence in people with GDM or other types of diabetes as it represents the average blood glucose control during the 2–3 months before the test is performed. A1C tests done on a routine basis may serve as a proxy for medication adherence [16].

**Table 6**
**– Post prandial blood glucose at baseline and on follow up.**

| Parameter (N = 81) | Post prandial Blood Glucose (mg/dL) (Mean ± SD) Baseline | 2nd follow up | Significance P |
|---|---|---|---|
| Group I (n = 37) | 128.30 ± 7.26 | 116.05 ± 6.01 | <0.0001** |
| Group II (n = 44) | 130.23. ± 16.83 | 117.86 ± 6.54 | <0.0001** |

P < 0.0001** was considered highly significant.

Another effective measure to enhance medication adherence is a tailor-made treatment based on individuals' needs. In the present study, insulin and metformin were the hypoglycaemic agents given for the study population. The glycemic control achieved by both insulin and metformin was equal which was observed by a significant reduction in the mean fasting and post prandial blood glucose levels from baseline to the second follow up. But the difference in these values from baseline to second follow did not vary significantly in patients on insulin or metformin. No significant side effects and adverse effects were reported by the study population on insulin or metformin therapy.

A study conducted by Singh et al. [17] reported a better glycemic control in 93.8% women with GDM on metformin therapy, without any incidence of hypoglycemia or perinatal mortality. The study also reported a 54% caesarean section rate and an increased weight for gestational age in 15.6% of neonates. The study also indicated the use of metformin as a safe and effective oral hypoglycaemic agent in GDM, especially in low-resource settings with issues like cost, storage, and patient compliance. Another study conducted by Gupta et al. [18] in North India had reported a significant glycemic control in 96.2% of patients with gestational diabetes, on therapy with varied doses of Metformin. The study also stated a better acceptability of the patients towards metformin therapy and there were no serious side effects reported.

The present study implies that metformin is also an effective and safer treatment option for women with GDM like insulin, equally efficacious in achieving glycemic control with an added advantage of its oral administration. A similar report was given by Mohammed Galal et al., which suggested that metformin alone or with supplemental insulin was not associated with perinatal complications as compared with insulin in women with GDM and also the women preferred metformin to insulin treatment [19].

There are very few studies conducted in the Indian population

on the therapeutic outcomes of insulin and metformin [6,17,20] in Gestational diabetes. These studies have not compared the impact of insulin and metformin on GDM. Also, no studies have focused on the knowledge, attitude, and practice of the patients with GDM and their adherence patterns. The present study focused on these factors as they pose a significant impact on the therapeutic outcomes of the therapy. This study also attempted to compare the extent of glycemic control with insulin and metformin (therapeutic outcome) which would significantly add on to the existing literature in the Indian population.

This study suggests that education on GDM is required for women, both before conception and during pregnancy to improve medication adherence and to promote better therapeutic outcomes in them. This is mandatory for all high-risk pregnant women with pre-existing diabetes and those who develop gestational diabetes.

## 5. Conclusion

The study identified that continuous patient education had a positive impact on the knowledge, attitude, and practice of pregnant women with GDM and also on their medication adherence patterns. The study also observed that there was no significant difference between insulin and metformin in achieving effective glycemic control. The findings of this study suggest that both insulin and metformin are equally efficacious in GDM. The study suggests that an educational program, which will include early education for high-risk pregnant women and continuous education for those with GDM may be beneficial in obtaining better outcomes.

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## CRediT authorship contribution statement

**Sneha Krishnakumar:** Data curation, Project administration. **Yeswanth Govindarajulu:** Methodology, Formal analysis. **Usha Vishwanath:** Conceptualization, Supervision. **Vanitha Rani Nagasubramanian:** Conceptualization, Writing - original draft. **Thennarasu Palani:** Writing - original draft.

## Declaration of competing interest

Nil.

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