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A Study on the Impact of Pharmaceutical Care on the Management of Diabetes Mellitus During Pregnancy

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The aim of the study was to assess the impact of pharmaceutical care on the management of diabetes mellitus during pregnancy.A prospective observational study was carried out for six months at a hospital in Palakkad. The study assesses pregnant women's medication adherence and health-related quality of life. Patients were randomly allocated to the study population, and data were entered in a self-design data collection form. The collected cases were entered in MS Excel 2019 and calculated percentage of various parameters by descriptive statistics.The study included a total of 60 participants, with an age range ranging from 18 to 45. GDM is more prevalent between the age group of 25-31 years. Among 60 subjects an increase in medication adherence observed with their value from5.72±1.03 to 6.40±0.89 during their initial and follow up visits (p<0.0001) respectively. The EQ-5D-5L mean (SD) index showed significantly lower quality of life during the baseline visit (0.529 ± 0.03) and higher quality of life during the follow-up visits (0.826 ± 0.297) with (p<0.0001), suggesting the importance of clinical pharmacist activities making positive impact on medication adherence and quality life of pregnant women with diabetes.

Keywords: Body mass index(BMI); European quality of life scale (EQ-5D-3L); Gestational mellitus(GDM); Morisky medication adherence scale (MMAS).

Due to rising sedentary behavior and obesity rates, women have recently grown more vulnerable to a variety of pregnancy problems. Gestational diabetes mellitus (GDM), or diabetes discovered during pregnancy, is one such condition.[1] Gestational diabetes (GDM), which is defined as carbohydrate intolerance of varying degrees of severity with the start or first recognition during pregnancy, has developed into the most common medical illness among pregnant people.[2] Over the past 20 years, the prevalence of GDM has increased, reflecting an increase in the incidence of type 2 diabetes in the underlying population. It often happens around the 24th week of pregnancy as a result of a blockage in insulin's action, perhaps caused by hormones generated by the placenta.[3] Fetal macrosomia, which makes a typical birth challenging and dangerous, can

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result from poorly controlled glucose levels during pregnancy. The newborn will be at risk for shoulder injuries and breathing difficulties. A cesarian section is frequently required, endangering the mother's health. Additionally, there is a chance of developing preeclampsia, a condition in which unexpectedly high blood pressure puts the woman and her unborn child's health (and sometimes even their lives) in danger[4].

Women who have experienced gestational diabetes are more prone to have it again during subsequent pregnancies and to acquire type 2 diabetes in later life. Even better lifetime risks of obesity and type 2 diabetes exist for children born to mothers with gestational diabetes. To reduce hazards to the unborn child, women with gestational diabetes or diabetes during pregnancy must keep an eye on and manage their blood sugar levels. In most cases, this can be accomplished by consuming a nutritious diet and engaging in moderate exercise, although occasionally insulin or oral medicine is also required .[3,5]

It is crucial to educate women with GDM (as well as their partners) about the condition and how to manage it. The patient's understanding of the consequences of GDM on herself and the unborn child, as well as the importance of self-monitoring blood sugar levels and appropriate therapy, is necessary for compliance with the treatment plan.[3] Pharmaceutical care is the direct, responsible provision of medication-related care with the goal of attaining specific results that enhance a patient's quality of life. Since different complications in pregnancy cause an imbalance in sleep, quality of life, and medication adherence, proper pharmaceutical care during pregnancy may positively impact the quality of life of pregnant women.[6,7]

MATERIALS AND METHODS

• Hospital based prospective observational study was conducted at Paalana Institute of Medical Sciences, Palakkad. It was done over a period of 6 months.60 pregnant women having either gestational diabetes mellitus or previously diagnosed diabetes mellitus were included in the study. The patients without diabetes and are not willing to give consent are excluded from the study.
• Prior to starting the study, institutional ethical committee approval was acquired **GCP/IEC/112G/2022** dated on 05-07-2022. Before the study began, all of the participants provided their signed informed permission. conducted interviews with them using a validated, semi-structured questionnaire and a form created by ourselves. For the study, we conducted two rounds of interviews with the contributors, lasting roughly 10-15 minutes each. A thorough history will be collected, including the patient's age, gender, occupation, address, and social history. Previous medical and medication histories will also be recorded, as well as test results and medication records.
• A questionnaire will be used to assess each patient's quality of life and medication adherence.
• The Morisky Medication Adherence Scale (MMAS) was used to investigate medication adherence, and the European Quality of Life 5-Dimensional Scale was used to assess health-related quality of life (EQ-5D-3level).
• In order to raise awareness among the study population about the significance of adherence and health-related quality of life on their initial visit, we counseled and also distributed patient information leaflets (PIL).
• Follow-up is conducted within a month to assess the patients' improved clinical status. Data from questionaries are compared before and after patient counseling to assess the impact of such counseling.

Study tool

The Morisky Medication Adherence Scale (MMAS) [5], which consists of 8 questions, was used to measure medication adherence. The responses on the MMAS scale were recorded as either yes or no. An answer of 'yes is scored as zero and 'no is scored as one for the first 7 questions except for the fifth question, where yes is scored as one and no is scored as zero.

A standardized tool for assessing general health status is the EQ-5D 3 LEVEL. The health state description and evaluation are the two parts of the EQ-5D questionnaire. Mobility, self-care, usual activities, pain/discomfort, and anxiety/depression are the five dimensions (5D) through which health status is assessed in the description section.

Using the EQ-5D-3L, the respondents' self-ratings of their levels of severity for each dimension are as follows:
LEVEL 1: Indicating no problem.

LEVEL 2: Indicating some problems.
LEVEL 3: Indicating extreme problems

Statistical analysis

The gathered information was entered into MS-Excel 2019 to calculate the percentage of various factors. When comparing MMAS and EQ-5D-3L between the first and second visits, paired student t-tests were used. The relationships between these variables were expressed as Mean± SD.

RESULTS

The total number of study participants was 60. Among the enrolled subject they were categorized into different age groups among them GDM is more prevalent in the age group between 25-31 years (26 patients 43.33%), followed by 17 patients,28.33% belonging to the age group of 32-38. Below 18-24 years of age shows only fewer occurrences of GDM. Among the 60 patients,29 patients (48.33%) women diagnosed with GDM during the third trimester,26 patients (43.33%) in the second trimester, and it was rarely spotted in the first trimester. Based on body mass index 7 patients (11.6%) were having normal weight,28 patients (63.33%) were overweight and 15 patients (25%) were obese. Among the total study population, 24 patients (40%) were physically active whereas 36 patients (60%) were physically inactive. On assessing the baseline adherence out of 60 patients 38 patients (63.33%) were having low adherence,17 patients (28.33%) had medium adherence and 5 patients (8.33) had high adherence respectively. After properly follow intervention was done the adherence in the

Table 1. Distribution based on age

No.	Age Groups (in years)	Mean Value of Age ±SD	No. of Patients (n=60)	Percentage (%)
1	18- 24	20±2.68	5	8.33
2	25-31	27±2.03	26	43.33
3	32-38	35±2.02	17	28.33
4	39-45	42±2.65	12	20

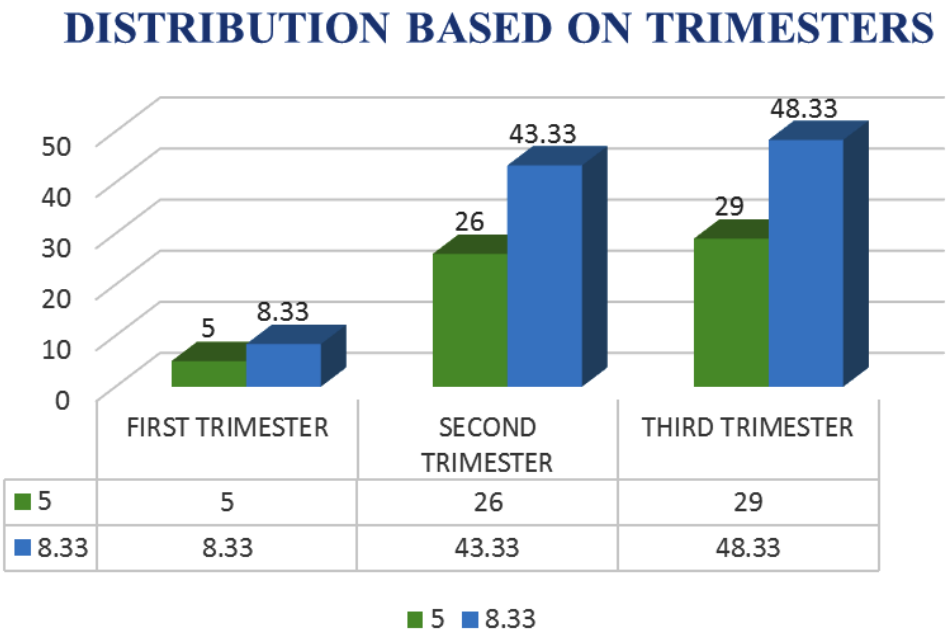
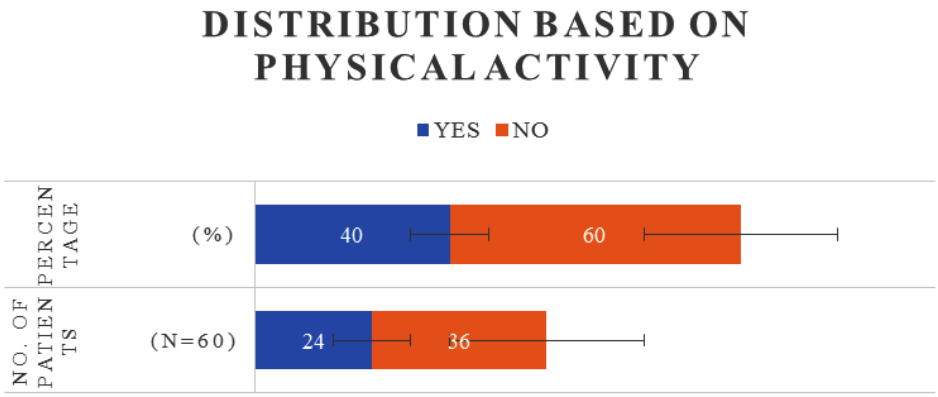


Fig. 1. Distribution based on trimesters

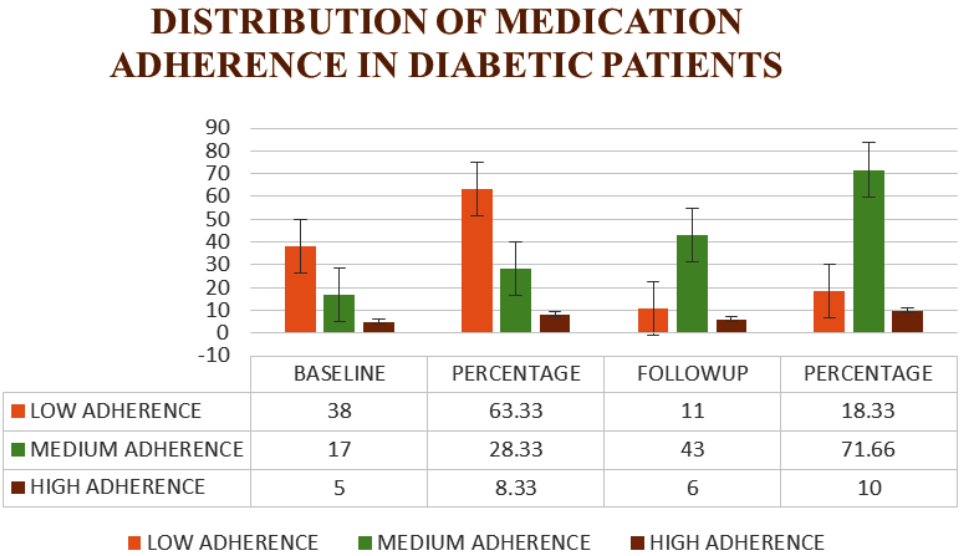
Table 2. Distribution based on BMI

BMI	Mean Value±SD	No. of Patients (n=60)	Percentage (%)
18-24(Normal weight)	20±2.47	7	11.66
25-30(overweight)	26±1.91	38	63.33
>30(obese)	32±1.72	15	25



	NO. OF PATIENTS (n=60)	PERCENTAGE (%)
YES	24	40
NO	36	60

Fig. 2. Distribution based on physical activity



	BASELINE	PERCENTAGE	FOLLOWUP	PERCENTAGE
LOW ADHERENCE	38	63.33	11	18.33
MEDIUM ADHERENCE	17	28.33	43	71.66
HIGH ADHERENCE	5	8.33	6	10

Fig. 3. Distribution of medication adherence in diabetic patients

baseline got changed in the follow-up to 11 patients (18.33) with low adherence,43 patients (71.66) with medium adherence, and 6 patients (10) with high adherence. Among 60 subjects an increase in medication adherence was observed with their value from5.72±1.03 to 6.40±0.89 during their initial follow-up visits ($p<0.0001$) respectively.

The distribution based on the response of the problem based on levels of each EQ-5D-3L dimension is presented in the table during their baseline follow-up visits. The most common response was level 1 in baseline and follow-up visits. The range of reporting no problem was between 66.66% -56.66% during baseline visits and 70%-43.33% during follow-up visits.

From the table, it is evident that the mean of the EQ-5D-3L index had a great increase in follow -up compared to its baseline. The EQ-5D-5L mean (SD) index showed a significantly lower quality of life during the baseline visit (0.529 ± 0.03) and higher quality of life during the follow-up visits (0.826 ± 0.297) with ($p<0.0001$).

DISCUSSION

In the second or third trimester of pregnancy, gestational diabetes mellitus (GDM), which is a common clinical condition, causes variable degrees of glucose intolerance.[8] Due to genetic, societal, and environmental variables, certain populations are more susceptible than others to developing this illness. GDM has substantial long-term effects on the mother and the unborn child, including an increased risk of obesity, metabolic syndrome, Type-2 diabetes, and cardiovascular illnesses in later life.[9] Women and their newborns can do far better if early detection and intervention are used.[10,12] Depending on the risk factors and glycemic management, glucose intolerance during pregnancy can vary in severity.

Table 3. Statistical Analysis of Morisky's Medication Adherence Scale During Baseline And Follow-up (MMAS)

Parameters	MMAS (Baseline)	MMAS (Follow-up)	P Value
Mean	5.72	6.40	0.0001
SD	1.03	0.89	
N	60	60	

Table 4. Distribution Based On EQ-5D-3L Among GDM Patients

Dimensions	Level	Baseline No of Patients (n=60)	Percentage (%)	Follow Up No of Patients (n=60)	Percentage (%)
Mobility	1	20	33.33	42	70
	2	40	66.66	18	30
	3	0	0	0	0
Self Care	1	18	30	36	60
	2	36	60	22	36.66
	3	6	10	2	3.33
Usual Activities	1	21	35	39	65
	2	34	56.66	18	30
	3	5	8.33	3	5
Pain Discomfort	1	6	10	26	43.33
	2	36	60	24	40
	3	18	30	10	16.66
Anxiety/Depression	1	8	13.33	28	46.66
	2	37	61.66	25	41.66
	3	15	25	7	11.66

Table 5. Distribution Based On EQ-5D-3L Index Mean

	Baseline EQ-5D-3L Index Mean	Followup EQ-5D-3L Index Mean
Age		
18- 24	0.09	0.79
25-31	0.594	0.80
32-38	0.59	0.91
39-45	0.53	0.92
FBS&PPBS		
Increased	0.54	0.82
Decreased	0.59	0.83
Vegetable Diet		
>5days	0.52	0.87
≤5days	0.59	0.81
Exercise		
Yes	0.52	0.88
No	0.58	0.87
Exercise Duration		
15min	0.59	0.72
30min	0.60	0.82

The management of patients with GDM, therefore, requires early diagnosis, effective medication, and follow-up. [11]

According to the demographic data gathered from 60 participants in this prospective observational study, GDM is more common among individuals over the age of 25. According to the research by Mohan et al, and Seshiah et al, most women develop GDM when they conceive after the age of 25 years.[3,13] In accordance with the current study, GDM develops more during the third trimester than in the first and second trimesters of pregnancy. A study by Tabasam. N et al. also demonstrate that GDM was diagnosed in the third trimester, or weeks 24 - 28, of pregnancy.[14]

A recent study also discovered obesity to be a serious risk factor. This is due to obesity putting additional demands on the mother's metabolism during pregnancy, which leads to abnormalities in the hormones that control carbohydrate metabolism and insulin sensitivity. From the study population, only 11.66% were having a normal weight that comes under the category of 18-24, and the rest of the subjects 63.33% and 25% percentage were under the category of overweight (25-30) and obese (>30) respectively. The study of Suja et.al, also supports the fact that excess weight is a risk factor for developing GDM.[11] Along with medication doing physical activities like walking, running, house works, and swimming plays a significant role in the prevention and control of GDM. According to the study among 60 subjects, only 24 subjects are physically active rest of them are physically inactive. Pregnant women should do at least 30 minutes of exercise daily as per the physician's advice. Similar findings were made by Jovanovic et al., namely that physical activity is beneficial for the management of GDM.[15]

Table 6. Statistical Analysis of EQ-5D-3L Score

Parameters	EQ-5D-3L (Baseline)	EQ-5D-3L (Follow-up)	P Value
Mean	0.529	0.826	0.0001
SD	0.03	0.297	
N	60	60	

The medication adherence pattern of study subjects was assessed using the Morisky medication adherence scale (MMAS). It is a structured self-report measure of medication-taking behavior, comprises of 8 questionnaires. Based on the score results are categorized into different categories like high adherence, medium adherence, and low adherence. In this study during baseline visits, 38 patients (63.33) were having low adherence, 17 patients (28.33%) had medium adherence and 5 patients (8.33%) had high adherence respectively. After proper follow-up and intervention, the adherence in the baseline got changed to 11 patients (18.33%) with low adherence, 43 patients (71.66%) with medium adherence, and 6 (10%) with high adherence. Out of 60 subjects, an increase in medication adherence is observed with their value from .72±1.03 to 6.40±0.89 during their initial and follow-up visits ($p<0.0001$) respectively. Krishnakumar.S et.al also follow MMAS to assess the medication adherence pattern of pregnant women having GDM. She

discovered in her research that there was a highly significant difference in the medication adherence scores from the baseline to the follow-up after three months (P 0.0001), implying that continuous patient education had a beneficial effect on their medication adherence. [16]

All phase of life, including pregnancy, is important for one's quality of life. Pregnant women's quality of life may be impacted or even jeopardized by the hormonal, emotional, psychological, and physical changes that occur during pregnancy.[17,19] The EQ-5D-3L questionnaire was used in this study to gauge the health-related quality of life of pregnant women with GDM. Baseline and follow-up measurements of the quality of life of pregnant women were compared, and the study reveals that, as a result of effective follow-up and intervention, pregnant women's quality of life increased over the follow-up period compared to baseline. Hatice et al. also employed the EQ-5D-3L technique to evaluate the quality of life of pregnant women with GDM, and they discovered that all these women's health-related quality of life was lower than that of the healthy, non-pregnant controls. [7]

CONCLUSION

From this study, it is concluded that GDM is quite common in pregnant women, especially those over the age of 25. This can be the result of a poor diet strategy that caused one to gain too much weight.t. It can be prevented and treated as soon as it is diagnosed early. The medication adherence and reasons for non-adherence were identified and counseled accordingly which had a positive impact on their glycemic control. On analyzing the quality of life from the domains it can be concluded that pain/discomfort, and mobility contributed more to moderate discomfort which showed an improvement in the follow-up. Thus, the above result suggested the positive impact of clinical pharmacy intervention on GDM patients

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Conflicts of Interest

There are no conflicts of interest between the authors.

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