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A STUDY ON IMPACT OF DIET ON GLYCEMIC CONTROL IN WOMEN WITH GESTATIONAL DIABETES MELLITUS

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ABSTRACT

Background: Good nutrition is an important part of any pregnancy, but it becomes more important if women have GDM. In diabetes the body cannot make or use insulin efficiently. Insulin is produced by pancreas and it allows the cells to use sugar in the blood (glucose) for energy. Large amounts of glucose accumulate in blood but the cells do not have enough fuel for their needs. **Aim and Objectives:** The study aimed to see the effect of diet in achieving glycemic control in women with GDM and also to see the maternal and neonatal outcome in patients of GDM treated with diet modifications. **Material and Methods:** It was a prospective study comprising of patients who had their random blood sugar levels raised above the decided level. The study was carried out in a minimum of 130 established gestational diabetes patients, who were visiting the obstetrics clinic at tertiary care hospital for treatment during the time period of Oct 2020 to March 2021. The purpose and other details of the study was discussed prior with the patients. An oral consent was also taken from all the participating patients, prior inclusion in the study. **Results:** Out of total 1100 deliveries in hospital during study period, the incidence of GDM was found to be 11.8%. Presence of glycosuria (84.61%) and family history of diabetes (57.6%) were most important risk factors statistically. After implementation of diet chart to all women, glycemia improved in 70 patients out of 130. Rest 60 required insulin for achievement of normoglycemia in addition to diet therapy. In this study 23% delivered vaginally and 77% by LSCS. **Conclusion:** Diet alone along with moderate activities can cure the true GDM as reflected in present study and prescription of insulin ever since diagnosis of diabetes during pregnancy is not the correct approach to treat the disease condition that is what is observed here and suggested by this study.

KEYWORDS : Gestational Diabetes Mellitus, Random blood sugar.**BACKGROUND:**

Gestational diabetes (GDM), which represents carbohydrate intolerance first discovered in pregnancy, occurs in 3.8-21% of pregnancies. It is estimated that 1 out of every 200 pregnancies is complicated by the diabetes mellitus and additionally that 5 in every 200 pregnant women will develop GDM.^{1,2} Postpartum, glucose intolerance will return to normal in majority of women with GDM. However, there is a high risk of developing impaired glucose tolerance or overt diabetes mellitus (DM) later in life. Pregnancy is considered to be a diabetogenic state characterized by exaggerated rate and amount of insulin release, associated with decreased sensitivity to insulin at cellular levels. Hormones like estrogen, progesterone, human placental lactogen, cortisone and growth hormone are anti insulinogenic. These increase in mid pregnancy and cause abnormal glucose tolerance in some women rendering them prone for GDM.³ It is important to identify a pregnant woman with GDM because it is associated with significant metabolic alterations, increased perinatal mortality and morbidity, maternal morbidity and exaggerated long term morbidity among the mothers and their offspring.^{2,4} GDM deserves increased recognition; valid diagnostic tests, treatment and long range of follow up of the mother and offspring.^{5,6}

Good nutrition is an important part of any pregnancy, but it becomes more important if women have GDM. In diabetes the body cannot make or use insulin efficiently. Insulin is produced by pancreas and it allows the cells to use sugar in the blood (glucose) for energy. Large amounts of glucose accumulate in blood but the cells do not have enough fuel for their needs.

All pregnant women need to eat well balanced diet. Such diet at proper time can keep blood sugar levels from becoming too high or too low and achieving glycemic control. It can also help women to avoid the need for insulin to control their blood sugar and thus reducing the costs of treatment of GDM. Dietary glycemic control is defined as a part of comprehensive treatment of GDM and diets low in carbohydrates, lipids and proteins have demonstrated to reduce hyperglycemia compared with diets high in carbohydrates alone. Adherence to dietary treatment is difficult in most patients when they intake lower amount of carbohydrates. The findings reported in control of GDM such as changes in weight gain, energy intake and macronutrients are a part of basic treatment to prevent complications for the fetus and mother.

AIM AND OBJECTIVES:**Objective of present research was to:**

1. Study the effect of diet in achieving glycemic control in women with GDM.

2. Study neonatal outcome in women with GDM treated with diet.
3. Study maternal outcome in women with GDM treated with dietary modification.

MATERIALS AND METHODS:

- (i) Study Design:** It was a prospective study comprising of patients who had their random blood sugar levels raised above the decided level. Duration of study was 6 months starting from Oct 2020.
- (ii) Sample size:** The estimated sample size was calculated by the formula

$$Z1-a/2^2 p(1-p)/d^2$$

So, $Z1-a/2^2$ = standard normal variant (at 5% type I error ($p < 0.05$) it is 19.6) P = expected proportion in population based on previous studies (9%) d = absolute error or precision (at absolute error of 5% and at type I error of 5%).

Sample size = $1.96^2 \times 0.09(1-0.09)/5^2$. So the sample size is calculated as 130.

- (iii) Methodology:** The study was carried out in a minimum of 130 established gestational diabetes patients, who were visiting the obstetrics clinic of a tertiary care hospital for treatment during the time period of Oct 2020 to March 2021. The purpose and other details of the study was discussed prior with the patients. An oral consent was also taken from all the participating patients, prior inclusion in the study.

(iv) INCLUSION CRITERIA:

- All pregnant women once reported with random sugar level > 140 mg/dl
- History of GDM in previous pregnancy/pregnancies

(v) EXCLUSION CRITERIA:

- History of Overt Diabetes Mellitus
- Presence of morbid obesity (BMI > 30 kg/m²) or hypertension.

- (vi) Procedure:** Once the consultation by the physician was over, the prescriptions were reviewed and the patients interviewed using structured questionnaire (open question method). The information includes patient's demographic details like age, sex, body weight, height, major disorders, co-morbid conditions, family history. Patients were studied in a row after screening inclusion and exclusion criteria and management of GDM was started with diet therapy in them. Obese women were excluded in study because prevalence of obesity is less in rural area and the study had mixed patient population. Also, obesity

may make diagnosis of pure GDM difficult as many of obese women may be overt diabetic already before pregnancy.

All women were assessed according to their body weight and preliminary blood sugar values. Thereafter they were followed-up regularly and the outcome of diet therapy in management of GDM was assessed.

(vii) STATISTICAL ANALYSIS:

The differences in proportions were compared by unpaired t-test where appropriate. Statistical significance was set for $p < 0.05$. All statistical analysis was performed using SPSS version 17.0.

RESULTS:

In present study, the prevalence rate of GDM is high. Out of total 1100 deliveries in hospital during study period, the incidence of GDM was found to be 11.8%. Prevalence of GDM was found to be highest among the 26-30 year age group in this study.

Table 1: Existing risk factors (Factors favoring GDM)

| Risk factors | Frequency | % |
|--------------------------------|-----------|-------|
| None | 15 | 11.5 |
| Maternal age >25 | 65 | 50.0 |
| Poor pregnancy outcome in past | 30 | 23.0 |
| Glycosuria | 110 | 84.61 |
| Family history of diabetes | 75 | 57.6 |
| Gestational hypertension | 20 | 15.3 |

Presence of glycosuria (84.61%) and family history of diabetes (57.6%) were most important risk factors statistically. However, 11.5% cases didn't have any significant risk factor out of which 2 were primigravida and 4 were multigravida (i.e. gravida ≥ 2). None of them had higher age or history of GDM in previous pregnancy, but they could not comment upon history of DM in family. In these women, the development of GDM might be genetically related.

Out of 130 women studied here 50 had history of GDM in previous pregnancy and 80 didn't have any such history. It shows the effect of previous history of GDM on occurrence of GDM in present pregnancy.

Table 2: Treatment taken for Diabetes and improvement of glycemia

| H/O treatment taken | Glycemia improved | | | | Test of significance | |
|---------------------|-------------------|------|-----------|------|--------------------------------|--|
| | Yes | | No | | Chi square=9.87, p value=0.002 | |
| | Frequency | % | Frequency | % | | |
| Yes | 25 | 19.2 | 20 | 15.5 | | |
| No | 05 | 3.8 | 80 | 61.5 | | |
| Total | 30 | 23.0 | 100 | 77.0 | | |

There was a statistical significance between Glycemic improvement and history of treatment with chi-square value of 9.87, d.f. 2 and p-value of 0.002. Out of 45 patients who knew that they have GDM, 45 had taken treatment in form of dietary therapy and ultimately landed up with insulin added for glycemic control. Still only 25 had improved glycemia with insulin and 20 didn't improve. Non-compliance to insulin therapy may be the reason for it. There are multiple problems existing in rural population for decreased compliance to any kind of therapy whether it is in form of dietary modification or taking insulin such as difficulty in taking insulin regularly, fear of hypoglycemia due to excess dose, lack of cost-effectiveness of insulin in poor people etc. These all lead to development of complications gradually due to uncontrolled glycemia.

Table 3: Glycemic improvement with type of management

| Glycemia improved | Inpatient (50) | | Outpatient (80) | | Total (130) | | Test of significance |
|----------------------|----------------|------|-----------------|------|-------------|------|-------------------------------|
| | Frequency | % | Frequency | % | Frequency | % | |
| Diet alone(70) | 30 | 23.1 | 40 | 30.7 | 70 | 53.8 | Chi square=4.41, p value=0.05 |
| Insulin required(60) | 20 | 15.4 | 40 | 30.7 | 60 | 46.2 | |
| Total (130) | 50 | 38.5 | 80 | 61.5 | 130 | 100 | |

Here polyhydramnios was the commonest complication developed in women with GDM (18.52%) followed by gestational hypertension (14.81%). IUGR and oligohydramnios were developed in the same patient. She had breech presentation. She was diagnosed with GDM at 32 weeks of amenorrhea and achieved desired glycemia with dietary treatment alone.

Total of 130 women in the study, however there were 70 such women who did not develop any complication after diagnosis of GDM. From these 70, 40 had achieved desired glycemia with diet alone and 30 needed insulin along with diet. This suggests that those who achieve desired glycemia probably develop less complication, whether it is diet alone or insulin along with diet. This was the observation in present study.

After implementation of diet chart to all women, glycemia improved in 70 patients out of 130. Rest 60 required insulin for achievement of normoglycemia in addition to diet therapy. After implementation of insulin all the 60 patients achieved normoglycemia. This up holds the fact that less than 50% GDM cases require insulin therapy if diet therapy is properly followed with good compliance. According to recent issue of MIMS Journal of Thailand 80-90% of GDM cases can be cured only with dietary modification and lifestyle intervention if good compliance is achieved. This probably suggests the greater importance in controlling hyperglycemia without any kind of pharmacological treatment of the disease. Dietary modification and lifestyle intervention can be the first step towards achievement of normoglycemia in women with GDM that is what observed here. But for the strong effect of this non-pharmacological treatment of hyperglycemia it is necessary to adhere strictly to the recommended dietary regime and lifestyle modification in form of physical activity. Otherwise ultimately insulin is needed to achieve desired glycemia. This may be stated by the results of present study.

30 out of 50 patients (23.1%) who were managed as inpatient improved their glycemic levels with dietary therapy. Rest both had 38 weeks of GA at time of admission and was given a short trial of dietary therapy for 3 days followed by adding insulin to achieve prompt glycemia before delivery. Out of total 80 outpatient managed women glycemia improved with diet in just 40 and rest failed to achieve normoglycemia with given dietary regime at their home so insulin was added in their treatment plan.

But there was no statistical significance of treatment needed for glycemic improvement with the basis of patient management (p-value > 0.05). Whether the woman was managed on inpatient basis or outpatient basis, the glycemia could be improved in woman with GDM once she was started with any treatment whether diet alone or insulin therapy added to diet.

Table 4: Neonatal morbidity and mortality in GDM.

| Neonatal morbidity | Frequency | % |
|----------------------------------|-----------|------|
| Hyperbilirubinemia | 15 | 11.5 |
| Hypoglycemia | 30 | 23.0 |
| Birth Asphyxia | 10 | 7.7 |
| Respiratory distress syndrome | 06 | 4.6 |
| Transient tachypnoea of new born | 05 | 3.8 |
| Neonatal mortality | 04 | 3.0 |
| Intra uterine death | 00 | 0.0 |
| None | 60 | 46.1 |

In this study 23% delivered vaginally and 77% by LSCS. There were no cases of instrumental delivery. All 6 cases of vaginal delivery were full term and 1 out of 21 caesarean cases was preterm. Incidence of LSCS is relatively high here. History of previous LSCS was in 18.52% cases. Cephalopelvic disproportion was in 18.52% cases. Failed induction and fetal distress were indications in 14.81% and 33.33% respectively. 14.81% had malpresentation including breech.

14.81% cases had perineal tears from those who delivered vaginally (i.e. 22.22% cases had FTND). Incidence of shoulder dystocia was 0 in this study probably because of high rate of elective caesarean section in cases of clinically suspected macrosomia. Thus, it contributed in increasing the rate of LSCS in this study. It may also be because of genetically lower baby weights in Indian population due to ethnicity factor.

Presence of macrosomia may increase the incidence of shoulder dystocia but clinical estimation of higher baby weight by SFH

measurement in woman lead to the increment in elective caesarean section rates for borderline cephalopelvic disproportion may be caused by suspected macrosomia. Incidence of Postpartum hemorrhage due to atonicity was 11.11%. Here all patients who were managed as inpatient had achieved desired glycemic levels with either of the therapy. Here incidence of neonatal mortality was 3.0% (i.e.4 cases).

Table 5: Analysis according to treatment and following blood sugar levels

| Blood sugar level | Value (mean) | Per treatment (mg/dl) | After treatment (mg/dl) |
|-------------------|--------------|-----------------------|-------------------------|
| Diet alone | FBS | 120.35 | 98.50 |
| | 2H PPBS | 155.25 | 128.50 |
| Insulin needed | FBS | 120.55 | 110.20 |
| | 2 H PPBS | 160.55 | 140.10 |

Mean FBS of those women who achieved desired glycemia only with diet was 98.50 mg/dL after treatment with dietary therapy and mean PP2BS was 128.5 mg/dL. Those women who ultimately landed up with insulin had mean FBS of 110.20 mg/dL and mean PP2BS of 140.10 mg/dL after dietary therapy implementation. Total 35 out of 70 had at last succeeded in maintaining FBS values \leq mg/dL at 3 months postpartum with dietary therapy alone.

All the patients who had achieved desired glycemia with diet alone were received at follow-up at 6 weeks postpartum followed by at 3 months postpartum also.

Table 6: Effect of dietary therapy on blood sugar values at postpartum follow up

| Only with diet therapy blood sugar levels at follow up | 6 Weeks Post-Partum (70) | | 3 months Post-Partum (70) | |
|--|--------------------------|------|---------------------------|------|
| | Frequency | % | Frequency | % |
| FBS \leq 95 mg/dl | 40 | 57.1 | 35 | 50.0 |
| 2H PPBS \leq 120 mg/dl | 20 | 28.5 | 10 | 14.2 |
| RBS \leq 120 mg/dl | 10 | 14.2 | 00 | 0.0 |

60 out of 130 had required insulin in addition to diet to achieve desired glycemia. From 60 patients who had received diet plus insulin and followed up at 6 weeks postpartum, 30 had maintained FBS levels \leq 95 mg/dL and 30 out of these 6 had maintained same glycemia at 3 months postpartum too.

Table 7: Effect of diet plus insulin on blood sugar levels at postpartum follow up

| Insulin with diet therapy blood sugar levels at follow up | 6 Weeks Post-Partum (60) | | 3 months Post-Partum (60) | |
|---|--------------------------|------|---------------------------|------|
| | Frequency | % | Frequency | % |
| FBS \leq 95 mg/dl | 30 | 50.0 | 30 | 50.0 |
| 2H PPBS \leq 120 mg/dl | 20 | 30.0 | 10 | 20.0 |
| RBS \leq 120 mg/dl | 10 | 20.0 | 00 | 0.0 |

Fasting blood sugar levels achieved at 6 weeks postpartum followed by 3 months postpartum in both groups of patients achieving glycemia-one that only with diet and the other who needed insulin for glycemic control, were not much different statistically. 20 patients maintained their PP2BS levels and 10 maintained their RBS level \leq 120 mg/dL at 6 weeks postpartum. Only 10 had maintained her PP2BS level \leq 120 mg/dL but not a single woman had been able to maintain desired glycemia at random measurement at 3 months postpartum from those who were taking insulin beforehand for it.

No oral hypoglycemic drugs were used in this study. Also, Glyburide is not available easily in rural area. Metformin can be alternatively used and easily available but due to the ongoing Meig trial for Metformin efficacy which is yet not proved.

DISCUSSION:

Worldwide prevalence of GDM varies between 0.6 - 13.7% (WHO) criteria.⁷ The prevalence of GDM in India varies from 3.8 to 21% in different parts of the country, depending on the geographical locations and diagnostic methods used. GDM found to be more prevalent in urban than rural areas according to DIPSI (Indian Guidelines for GDM).⁸ According to British Nutrition Journal GDM affects 1 to 14% of all pregnancies which is comparable to this study.⁹ Uncertainties over its diagnosis and lack of agreement over which screening protocols and diagnostic thresholds should be used make GDM prevalence estimates difficult.

Prevalence of GDM was found to be highest among the 26-30 year age group in this study. Indian Journal of Community Medicine-2008 showed the mean age of study group 25.2 \pm 7.6 years.¹⁰ Various authors from India have observed GDM in higher age groups, majority of which were carried out in urban areas. In this study majority of women were in 26-30 years group (62.96%). The reason for it is likely to be because most of the women in rural area get married at young age and their families are completed by the age of 30 years. Therefore, they are likely to undergo sterilization around this period. Hence there is decline in number of pregnant women after the age of 30 years. Moreover, GDM clinically follows the pattern of type 2 diabetes and not the juvenile type which appears at young age.

Multiparity is a risk factor for GDM due to moderate obesity and failure to lose weight after delivery. Patient's history alone bears higher sensitivity for diagnosis of GDM. Previous history of GDM, positive family history of diabetes, history of excessive weight gain and previous foetal loss are significant factors for development of GDM. Main risk factors are presence of glycosuria and positive family history of diabetes followed by higher maternal age. The patients with GDM are likely to gain more weight than normal. This also worsens glycemia. A fact revealed that such significant proportion of cases (22.22%) without any risk factors developed GDM calls for necessity of screening in such cases. This suggests that those who don't have any risk factors would be missed if history alone was chosen as a screening test.¹¹ According to American Diabetes Association's Position Statement on Gestational Diabetes Mellitus recommendations, low risk women don't require glucose testing.¹² (Low risk criteria include age $<$ 25 years, normal pre-pregnancy weight, low ethnic prevalence of GDM, no history of poor obstetric outcome and no history of abnormal glucose tolerance or first-degree relatives with diabetes.). According to RACGP (Royal Australian College of General Practitioners) August 2013, the best means of testing lower risk women has not been defined, but a fasting or non-fasting plasma glucose (PG), or an HbA1c (although not currently, Medicare reimbursed for this purpose) can be considered.¹²⁻¹⁵

Maternal and perinatal morbidity are likely to increase as duration of GDM increases. However, control of glycemia is more important in this reference. In present study majority of patients were unaware about development of diabetes in their current pregnancy. This probably contributed to high rate of maternal and foetal complications. Postpartum fever was the commonest morbidity observed. Neonatal morbidity was highest in form if hypoglycaemia followed by hyperbilirubinemia and birth asphyxia. Improvement of glycemia with diet alone may not reduce incidence of some complications like macrosomia. Here glycemic control failed to prevent occurrence of macrosomia in women with GDM. Therefore, assuming that other factors might be leading to cause increase in fetal weight like maternal and fetal growth factors, placental growth factors, pregnancy associated plasma protein-A (PAPP-A) etc.

The mode of delivery in GDM differed a lot from that of general population. Achievement of desired glycemia failed to decrease rate of caesarean section in present study. In general, GDM population had too high rate of LSCS as compared to non-GDM population. Most of the caesarean sections were for fetal indications here. History of LSCS in previous pregnancy, previous fetal loss/losses and borderline cephalon-pelvic disproportion urged for elective caesarean section in patients with GDM. Fetal distress, meconium stained liquor and failed induction compelled to opt for emergency caesarean section. Worldwide declining practice of instrumental delivery due to higher chances of maternal and fetal trauma eventually proved to be a reason for increment in the practice of LSCS. According to "Pregnancy at Risk Concepts" by FOGSI, fetal deaths usually occur after 36th week of pregnancy in patients with poor glycemic control, hydramnios, fetal macrosomia, preeclampsia or in women with vascular disease.¹⁶ Patients should be kept under observation and tight metabolic control should be achieved with intensive insulin administration in those who do not achieve desired glycemia with diet alone. However desired glycemia which was achieved in all patients succeeded in prevention of intrauterine death in them. Diabetes during pregnancy is a major cause of sudden intrauterine death but there was no case of IUD or still birth reported in this study.

Implementation of dietary therapy and its success rate in achieving desired glycemic levels solely depends upon patient compliance. Many limiting factors exist in rural area which may disable patients to adhere to strict guidelines and instructions given to them in order to achieve desired outcome.

Level of glycemia achieved with diet alone was much effective at 6 months postpartum than those who required insulin in addition to diet. This difference could probably be due to non-compliance to take insulin.

Women with fasting blood sugar >120 mg/dL on admission failed to achieve glycemic control with diet within 1 week of therapy. Consideration might be given to immediate insulin prescription in this subset, particularly if GDM is diagnosed late in gestation as happened in present study; or to a longer trial of dietary therapy if women show near-optimal control early in treatment with diet alone.

Limitations of study:

As it was a single center study the results cannot be generalized to entire population. Furthermore comprehensive and multi centric studies including meta-analysis of various earlier studies should be done, to have a more meaningful and high impact results.

CONCLUSION:

Diet alone along with moderate activities can cure the true GDM as reflected in present study and prescription of insulin ever since diagnosis of diabetes during pregnancy is not the correct approach to treat the disease condition that is what is observed here and suggested by this study.

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