**Original article:**

**Insulin usage among Gestational diabetic mothers and its prevalence**

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**ABSTRACT**

**Aim & Objective:** To estimate the prevalence of insulin usage among gestational diabetic women and to analyse the significance of the mother’s age, level of occupation, gestational age, gravidity on the disease.

**Method:** A cross-sectional study was conducted from January 2020 to July 2020 among non-diabetic pregnant women. Venous blood glucose was analysed 2 hours after 75 g of the glucose load. Diagnosis of Gestational Diabetes Mellitus was made using DIPSI criteria.

**Results:** There were a total of 60 gestational diabetic women and their mean age was 26.4years. The average gestational age at diagnosis was 23+/- 1 week. There were 33 multi (55 %) and 27 primi (45 %). The No. of patients on meal plan was 22 (37%), metformin 18 (30%) and insulin 20 (33%). 25 patients (42%) were below 25years, 26 patients (43%) between 25-30 and 9 patients (15%) above 30 years of age. Of these 9 patients, 22% (2/9) controlled with diet alone, 11% (1/9) with Metformin and 67% (6/9) with insulin. The need for insulin was more in the elderly and the difference was statistically significant at *p* < .05. Our study was the first to reveal the comparison between age groups and mode of treatment. Analysis of parity and insulin requirement showed a low level of association between multiparity and insulin usage. Prior BOH did not have any influence on the mode of treatment.

**Conclusion****:** The prevalence of insulin usage among our patients was 33%. The need for insulin usage was significantly higher among elderly than among younger women. There was a low level of association between multiparity and insulin requirement.

**Keywords:** Diet, Gestational diabetes, Insulin, Metformin.

**INTRODUCTION:**

India has become the diabetic capital of the world and Tamil Nadu the Diabetic Capital of India. This is because of the ethnicity, lack of exercise, sedentary life style, fast food, urbanization, increased life expectancy and increasing incidence of obesity. Ethnic origin is a major determinant. In a study done in West London, the adjusted odds ratio for women from Indian subcontinent, in comparison with those of European origin, was 11.3 (95 % confidence interval 6–8–18.8). Thus, Indian women have a 11-fold increased risk of developing glucose intolerance compared to Caucasian women. [1,2]. Incidence of diabetes is increasing among women of reproductive age in similar proportion in India [3]. The World Health Organisation and the Diabetes in Pregnancy Study Group of India (DIPSI) defined GDM as ‘carbohydrate intolerance resulting in hyperglycaemia of variable severity with onset or first recognition during pregnancy [4]. More women of childbearing age are having pre-existing (type 1 or type 2) diabetes or they develop gestational diabetes mellitus (GDM) during pregnancy. Prevalence of GDM in our country is 16.55% according to WHO, using the 2-hour value of 140 mg % [5]. For detection and diagnosis of gestational diabetes mellitus, recommendations are as follows: Screen for undiagnosed diabetes at the first prenatal visit. Again, screen for GDM once at 24–28 weeks of gestation and again at 32-34 weeks in pregnant women who were not previously known to have diabetes using the Single Step 75 g OGTT. [6,7]

Diabetes during pregnancy has adverse outcome for the mother, foetus/neonate. A team approach is ideal for managing women with GDM. The team would usually comprise of an obstetrician, diabetologist, dietician, midwife and paediatrician. Intensive monitoring, diet, metformin and insulin are the treatment modalities in GDM management. In this present study, we planned to assess the prevalence of insulin usage among gestational diabetic mothers in selected urban population.

**MATERIALS AND METHODS:**

A cross-sectional study was conducted from January 2020 to July 2020 at Saveetha medical college and Hospital, Chennai, among antenatal women. All antenatal women without any medical complications, diagnosed as GDM by DIPSI method were included for the study and those with known Type I or Type II diabetes were excluded from the study.

 Diagnosis of GDM was done according to Diabetes in Pregnancy study group of India – DIPSI. Irrespective of the meal, 75-gram glucose was given in 300 ml of water. Venous blood sample was collected after 2 hours and blood glucose level measured using Glucose Oxidase- Peroxidase method. Blood glucose level more than 140mg/dl was taken as gestational diabetes. A total of 60 pregnant women diagnosed with GDM were managed by a multidisciplinary team. Data about the mother’s age, occupation, socioeconomic profile, gravidity, gestational age at the onset of GDM and mode of treatment -whether diet only/ metformin / insulin - were collected and the results analysed.

**DATA ANALYSIS:**

The collected data were tabulated. Chi-square test and ODDs Ratio were used for comparing selected characteristic variables between age group, parity, previous obstetric history and mode of treatment.

**RESULTS:**

There was a total of 60 gestational diabetic women in this cross-sectional study. Of these 60 patients, 33 were multigravid (55 %) and 27 primigravid (45 %). Our aim was to analyse the data in such a way that we could draw certain inferences regarding pregnant mothers having diabetes.

**AGE AND OCCUPATION:**

 Patients were categorised as less than 25 years, 26 to 30 years and more than 30 years. Around 51 women (85%) were below 30 years and 9 women (15%) above 30 years. [Table: 1]. The mean age of women was 26.35years.

Around 70% (42) of the women were unemployed and 30% (18) women were employed. [Table 1]

**TABLE: 1: AGE AND OCCUPATION WISE DISTRIBUTION (N=60).**

|  |  |  |
| --- | --- | --- |
| AGE GROUP | NUMBER | PERCENTAGE |
| 25 YEARS | 25 | 42% |
| 26- 30 YEARS | 26 | 43% |
| 30 YEARS | 9 | 15% |
| OCCUPATION  |   |  |
| EMPLOYED | 18 | 30% |
| UNEMPLOYED | 42 | 70% |

**Table 2** shows the distribution of diabetic women according to their Obstetric history. There were 27 primigravid women and 33 multigravida women accounting to 45%and 55% respectively. The average gestational age at the time of diagnosis was 23 +/- 1 week

The number of women having prior BOH- Recurrent miscarriages and Perinatal death was found to be 3 in the diet group, 3 in the metformin group and 5 in the insulin treated group.

**TABLE: 2 OBSTETRIC HISTORY OF DIABETIC WOMEN**

|  |  |  |
| --- | --- | --- |
| **PARITY** | **NUMBER** | **PERCENTAGE** |
| **PRIMI** | **27** | **45%** |
| **MULTI** | **33** | **55%** |
| MODE OF TREATMENT | GESTATIONAL AGE- AVERAGE |
| Diet | 23.2 |
| Metformin | 23.6 |
| Insulin | 22.5 |
| MODE OF TREATMENT | RECURRENT MISCARRIAGE | PERINATAL DEATH |
| Diet | 2 | 1 |
| Metformin | 1 | 2 |
| Insulin | 3 | 2 |

**MODE OF TREATMENT**- **AGE BASED ANALYSIS**

Among these 60 GDM patients **the number of patients on insulin was 20 (33%),** on metformin 18 (30%) and on meal plan 22 (37%) [Figure 1]

**FIGURE 1: DISTRIBUTION BASED ON MODE OF TREATMENT.**

 Of the 60 GDM patients, 51 patients were less than 30 years of age and 9 patients above 30years. Among those less than 30 years of age, 20 patients (39.2%), 17 patients (33.3%) and 14 patients (27.4%) were on diet, metformin and insulin respectively.

Whereas of those above 30 years of age, 2 patients i.e. 22% controlled with diet alone, 1patient, i.e. 11% needed Metformin and 6 patients i.e. 67% could be managed only with insulin. Thus, in the elderly age group the need for insulin was more and the difference was statistically significant, \* p value is .05. The same is shown below in Table 3.

**TABLE 3: DIFFERENCE IN MODE OF TREATMENT NEEDED BASED ON AGE**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | **Meal plan** | **Metformin** | **Insulin** | ***Row Total*** |
| **<30yrs** | **20** | **17** | **14** | **51** |
| **>30yrs** | **2** | **1** | **6** | **9** |
| **Column Total** | **22** | **18** | **20** | **60** |

The chi-square statistic is 5.8912. The \**p*-value is 0.047503. The result is significant at \**p* < .05.

**MODE OF TREATMENT- PARITY BASED ANALYSIS**

The women were analysed whether there was any significant difference on the mode of treatment based on the parity and on the past obstetric history.Among the diet group there were 10 Primi and 12 Multi, (45%and 55%), in the metformin group it was 11

Primi and 7 multi, (61% and 39%) and among the Insulin group it was 6 and 14 (30% and 70 %) Primi and Multi respectively. [Figure 2.]

**FIGURE 2: DISTRIBUTION BASED ON PARITY**

 The results on Insulin versus Non-insulin treatment among Primi and Multi were assessed. The\* p-value was .09648. Not significant at p < .05. When subjected to Odds Ratio analysis the OR was 0.3878, showing that there may be a low association between multi parity and insulin usage. [Table 4 and Table 5]

**TABLE 4: DIFFERENCE IN MODE OF TREATMENT NEEDED BASED ON PARITY**

|  |  |  |  |
| --- | --- | --- | --- |
|  | **Insulin** | **Non Insulin** | ***Row Totals*** |
| **Primi** | **6** | **21** | **27** |
| **Multi** | **14** | **19** | **33** |
|  ***Column Totals*** | **20** | **40** | **60 (Grand Total)** |

The chi-square statistic is 2.7273. The \**p*-value is .098648. ***Not* significant**

**TABLE 5: DIFFERENCE IN MODE OF TREATMENT NEEDED**

|  |  |  |  |
| --- | --- | --- | --- |
|  | **Insulin** | **Non Insulin** | ***Marginal Row Totals*** |
| **Primi** | **6** | **21** | **27** |
| **Multi** | **14** | **19** | **33** |
| ***Marginal Column Totals*** | **20** | **40** | **60 (Grand Total)** |
|  |  |  |  |

|  |  |
| --- | --- |
| Odds ratio  | 0.3878 |
| z statistic | 1.629 |
| Significance level | P = 0.1034 |

1.OR > 1 means greater **odds** of association with the exposure and outcome.

2.OR = 1 means there is no association between exposure and outcome.

3.OR < 1 means there is a lower odd of association between the exposure and outcome.

**MODE OF TREATMENT**- **OBSTETRIC HISTORY BASED ANALYSIS**

The number of women having prior BOH- Recurrent miscarriages and Perinatal death was analysed to see if they had resulted in any difference in the mode of treatment. There were 3 patients in the diet group, 3 in the metformin group and 5 in the insulin treated group. [ Table 6]

**TABLE 6: DIFFERENCE IN MODE OF TREATMENT NEEDED BASED ON PAST OBSTETRIC HISTORY**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|   | Diet | Metformin | Insulin | ***Row Totals*** |
| Recurrent Abortions | 2  | 1  | 3 | 6 |
| Perinatal death | 1  | 2  | 2  | 5 |
| ***Column Totals*** | 3 | 3 | 5 | **11** **(Grand Total)** |

The chi-square statistic is 0.7822. The\* *p*-value is .676305. The result is ***not* significant at *p* < .05**

**DISCUSSION**

 This study was conducted to determine the prevalence of insulin usage among GDM and associated factors among women undergoing ANC at Saveetha Medical College and Hospital. A total of 60 pregnant women with GDM diagnosed using DIPSI criteria were included in the study. All GDM women were initially started on Diet and if needed Metformin. Follow up of Fasting and Postprandial sugars were done. Insulin therapy was started when diet and Metformin were unable to maintain glucose homeostasis. The women were grouped into those whose sugars were controlled with diet alone or those who needed Metformin or Insulin. The results were analysed based on their age, parity and mode of treatment. Age of patients was categorised as less than 25 years, 26 to 30 years and more than 30 years. Around 51 women with Gestational Diabetes were below 30 years which accounts to about 85% of all cases. The mean maternal age of these 60 women was 26.35 years. This is similar to the study by V Balaji, Madhuri Balaji et al [8] who had a mean maternal age of 23.60+/-3.32 years. According to M Hematyar et al, [9] the mean age of women was 30.4+/- 5 years. More than 90% of their women were above 24 years similar to our study.

Around 70% (42) of the women were unemployed and depended on their spouse, and 30% (18) women were employed. The mean gestational age at diagnosis reported by V. Balaji et al was 27.9+/-5.56 weeks and in our study it is 23+/- 1 week. [8] There were 27 primigravid women and 33 multigravid women accounting to 45%and 55% respectively. The number of women having prior BOH- Recurrent miscarriages and perinatal death was found to be 3 patients in the diet group, 3 in the metformin group and 5 in the insulin-treated group. Of these 60 GDM patients, the number of patients on insulin was 20 which accounted for 33% and the number of patients on metformin 18 (30%) and on meal plan 22 (37%). Thus the prevalence of insulin usage in our study accounted to 33%.

Now with these parameters available we tried to analyse if age, parity and prior BOH had any influence on the mode of treatment, diet alone, metformin or insulin.

 Of the 60 GDM patients, 51 patients were less than 30 years of age and 9 patients above 30years. Among those less than 30 years of age, 20 patients (39.2%), 17 patients (33.3%) and 14 patients (27.4%) were on diet, metformin and insulin respectively.

Whereas of those above 30years of age, 2 patients i.e. 22% were controlled with diet alone, 1 patient, i.e. 11% needed Metformin and 6 patients i.e. 67% could be managed only with insulin. Thus, in the elderly age group the need for insulin was more. We analysed using the Chi square test to see if the difference had any statistical significance, and it was statistically significant. The chi-square statistic is 5.8912. \*The *p*-value is .05, thus the result is significant at *p* < .05.

According to the prevalence study Akwilina, [10] 2015 of GDM, in the urban community in Tanzania, it is difficult to compare prevalence with age groups due to variations in screening methods, diagnostic criteria and mode of treatment. Proper planned screening, care and prevention strategies for GDM would improve maternal and child care and may help prevent the future increase in type 2 diabetes in the country. Our present study was the first to reveal the comparison and significance between age groups and mode of treatment. The\* p-value is 0.047503 which is statistically significant.

 Taking the parity into consideration, we found that among those who were treated with diet alone there were 10 Primi and 12 Multi, (45%and 55%), in the metformin group it was 11 Primi and 7 multi, (61% and 39%) whereas among the Insulin group it was 6 and 14 (30% and 70 %) Primi and Multi respectively.It appeared that 70 % in the insulin group were multigravida compared to only 30 % Primi who needed insulin. In a study by Gitte Skajaa, Jens Fuglsang et al [11] have proven that parity increased the insulin requirements among pregnant women with Type I diabetes, in Type II diabetes and in GDM increasing parity may increase the need for insulin.

 We tried to analyse if multi gravida had an increased requirement for insulin. The results on Insulin versus Non-insulin treatment among Primi and Multi were assessed but the results were not statistically significant. The chi-square statistic is 2.7273. The\* *p*-value is .098648. It was n*ot* significant. When subjected to Odds Ratio analysis the OR was 0.3878, which shows that there may be a low association between multiparity and insulin usage.

 The number of women having prior BOH- Recurrent miscarriages and perinatal death was analysed to see if they had resulted in any difference in the mode of treatment. There were 3 patients in the diet group, 3 in the metformin group and 5 in the insulin treated group. The chi-square statistic is 0.7822. The *p*-value is .676305. The result is *not* significant at *p* < .05.

 This study is a pilot study to assess the prevalence of Insulin usage among GDM patients and to concurrently assess the significance of women more than 30 years requiring insulin for their glycaemic control.

Pregnant women with diabetes should be regularly followed up; diet control, exercise should be explained. Metformin usage has become safe during pregnancy and it is used along with diet control. Insulin should be started if above measures are unable to control blood sugar. Diabetic women should be managed by multidisciplinary team and regular antenatal foetal surveillance should be done. GDM women should be explained about the risk of developing diabetes when they are in their middle age. Mother should be counselled that baby has a potential to develop metabolic syndrome in his or her life. The best course of action for the management of diabetes is screening, early detection, and intervention if necessary.

**CONCLUSION:**

DIPSI criteria is a single step, excellent screening tool in low resource countries for diagnosing GDM. Routine screening of pregnant women and healthy lifestyle are strongly recommended. We have assessed the prevalence of insulin usage among our patients to be 33%. Those controlled with diet were 37% and requiring metformin were 30%. We need to use insulin judiciously and advocate its usage in the situations where it is absolutely needed. We additionally tried to analyse if age, parity and prior BOH had any influence on the mode of treatment- diet alone, metformin or insulin. We found that among women more than 30 years of age, the need for insulin usage was significantly higher than among younger women who were managed with diet and metformin alone. We also found that there was a low level of association between multiparity and insulin requirement and further studies are needed to prove its definitive association.

 This study highlights the importance of carrying out prevalence studies in different geographical regions of India on larger scale to delineate the exact prevalence of GDM in the country. The differences in treatment modalities based on age, parity, BOH etc have to be analysed to have a better obstetric outcome to reduce the morbidity and mortality in both the mother and the neonate.

**Conflict of interest:** None.

**Author Funding:** Saveetha Medical College and Hospital, Thandalam.

**Ethical standard:**

This study was approved by the Institutional Ethics Committee of the Saveetha institute of Medical and Technical science, Thandalam, Kancheepuram District, TamilNadu- 602105, India.

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