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Assessment of glycemic status of gestational diabetic women on antihyperglycemic medication and neonatal outcome of their offspring

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Abstract
Aim: The study was initiated with the aim of assessing and comparing the glycemic status of gestational diabetic women on antihyperglycemic medication therapy and neonatal outcome of their offspring.
Methodology: The study was conducted in a tertiary care teaching hospital set up located in northern Kerala. The two-step approach of American Diabetes Association (ADA) guidelines was followed to confirm the diagnosis of GDM. The participants with confirmed GDM were sent to a physician for consultation and antihyperglycemic medication was prescribed to the GDM women, who failed to achieve euglycemic status on physical exercise and dietary modifications.
Result: During the study period 286 pregnant women were diagnosed with GDM, among them 146 participants were treated with metformin, and 140 were treated with insulin. The result of the study showed that both the drug treatments were found to be effective in maintaining blood sugar levels in the normal range throughout the pregnancy period. Also, metformin treatment was observed to cause better neonatal outcomes in offsprings of the study participants.
Conclusion: The study concluded both metformin and insulin exhibited excellent glycemic control in GDM women and metformin treatment was observed to cause minimal neonatal complications when compared with Insulin therapy.

Keywords: Gestation diabetes mellitus, antihyperglycemic therapy, glycemic control, neonatal outcome

Introduction
Gestational Diabetes Mellitus (GDM) is a condition in which pregnant women without previously diagnosed diabetes exhibit elevated blood glucose levels [1]. The American Diabetes Association (ADA) defines GDM as the glucose intolerance of any degree with onset or recognition during pregnancy [2]. Nowadays, GDM has emerged as a global public healthcare problem and it causes serious complications in pregnancy. Uncontrolled blood sugar complicates about 1-4% of all pregnancies, which may range from a mild degree of hyperglycemia to insulin-dependent diabetes [3]. The incidence of GDM is increasing drastically and it is entirely different from the other two common types of diabetes [4]. GDM is an asymptomatic condition usually diagnosed during the second and third trimesters of pregnancy. The development of GDM is found to be associated with several pregnancy complications as well as neonatal complications [5]. The neonatal complications of GDM include perinatal mortality, macrosomia, neonatal hypoglycemia, congenital malformation, hyperbilirubinemia, polycythemia, hypocalcaemia, and respiratory distress syndrome [6]. The offspring of GDM women probably may have the future risk of type 2 diabetes mellitus, obesity, and metabolic syndrome, whereas the GDM mothers might have a higher risk of future development of metabolic syndrome and type 2 diabetes [7].
The increasing trend of GDM in India has become a potential public health problem and timely action should be taken to screen all pregnant women for glucose intolerance. A healthy diet, regular physical activity, and follow-up at the antenatal clinic would definitely reduce the further rise of GDM, poor outcome of the pregnancy, and neonatal complications [8]. Maintenance of maternal blood sugar levels within the normal range might reduce various risks and complications [9]. Three strategies are being applied in GDM management including Medical Nutritional Therapy, Physical exercise, and pharmacological interventions with drug therapy.

Non-pharmacological intervention with dietary modification along with mild physical exercise should be the initial strategy for most GDM women [10]. GDM is major pathology in pregnancy and pharmacological management is essential mainly due to the little effect of dietary modification on glycemic status during the pregnancy period. Glycemic control is important in GDM women as blood sugar control improves maternal and neonatal complications [11]. Pharmacotherapy is indicated in GDM women when physical exercise and medical nutrition therapy do not reflect in glycemic status. Insulin remains the gold standard in the treatment of GDM women that do not reach glycemic targets with lifestyle intervention. Insulin is considered the first-line drug of choice in the management of gestational diabetes mellitus [12]. Metformin is an oral hypoglycemic agent used in the mainstay of treating type 2 Diabetes Mellitus. Metformin might be a cost-effective as well as a more logical alternative to insulin for women with GDM, who are unable to cooperate with the unwanted effects of insulin preparations. A prospective observational study was conducted with the objective of assessment of glycemic status among GDM women on antihyperglycemic medication and the neonatal offspring of their offsprings.

Materials and Methods

The study was conducted in a tertiary care teaching hospital located in northern Kerala for a period of four years. The Institutional Ethics Committee of MES Medical College Hospital reviewed the research proposal and the study was initiated after obtaining the IEC approval (No: IEC/MES/51/2014). At the time of enrolment, the diagnosis of the GDM was confirmed by a two-step approach as per the guidelines the of American Diabetes Association (ADA). The pregnant women who visited the OBG department during the study period for antenatal care were considered to be enrolled as participants for the study. Women with GDM were given counseling and advised for dietary modifications along with moderate physical exercise. Then they were advised to repeat the Fasting Blood Sugar (FBS) and Post Prandial Blood Sugar (PPBS) after two weeks. Those with abnormal FBS and PPBS were referred to a physician consultation to confirm the diagnosis and to initiate antihyperglycemic medication therapy. Young pregnant women with gestational age between 20-34 weeks, who could not able to maintain fasting blood glucose levels less than 95 mg/dl or 2 hours postprandial blood glucose less than 120 mg/dl were enrolled in the study. Subjects with contraindication to metformin, fetal anomaly, essential hypertension, gestational hypertension, pre-eclampsia, foetal growth restrictions and ruptured membranes, Intrauterine growth retardation, abnormal glucose tolerance before pregnancy, twin pregnancy, treatment initiated before 12 weeks or after 34 weeks of gestation were excluded from the study.

The study protocol was explained to each participant and written informed consent in vernacular language was obtained before their enrolment. The study data were collected by patient direct interview and investigational reports were collected from the medical records department. Baseline values of GCT, OGTT were recorded. FBS, PPBS, and Hb1Ac were recorded at the start and end of the study. In this study 140 study subjects were treated with Insulin and 146 were given Metformin. The goal of the treatment was to achieve a mean glucose concentration of 90 to 105 mg/dl. The study subjects were they were followed up until delivery and details regarding fetal outcome like birth weight, blood sugar level, bilirubin level, calcium level, 5 min Apgar score, and pH of umbilical cord blood were recorded assessed.

Collected data were entered in an Excel sheet and statistical analysis was carried out by using SPSS software. During the study period, among pregnant women who attended and were diagnosed with Gestational Diabetes Mellitus 146 subjects were treated with Metformin, and 140 were treated with Insulin. All the values are expressed in Mean ± Standard Deviation (SD). The student's t-test was performed to analyze the statistical significance between the parameters of the Metformin group and Insulin treatment groups. A p-value <0.05 was considered to be significant and P<0.01 was considered to be statistically highly significant.

Result and Discussion

Among 286 patients diagnosed with GDM during the study period, 140 were treated with Insulin, and 146 were treated with Metformin. Out of 140 patients in the Insulin Group, 5 were in the age group 18-20 years, 30 in the age group 21-24 years, 47 were in the age group 25-28 years, 27 were in the age group 29-32 years and 31 were in the age group above 32 years. Whereas in the Metformin group 15 were in the age group 18-20 years, 37 in the age group 21-24 years, 51 were in the age group 25-28 years, 34 were in the age group 29-32 years and 9 were in the age group above 32 years. The graphical representation of the age-wise distribution of participants of both treatment groups is given in Figure 1. Both the drug treatment made excellent control on blood sugar level of GDM women, with a slight upper hand of Insulin over metformin. Insulin made a mean change in HbA1c level by 0.909%, whereas metformin caused a mean change of 0.297%. The comparison of glycemic control in terms of assessment of insulin and metformin is given in Figure 2. The effect of the antihyperglycemic agent on the neonatal outcome of offspring of GDM women are given in Figure 3 to figure 9. In the assessment of neonatal outcomes, metformin was found to cause less neonatal complications when compared to that of the insulin treatment group.

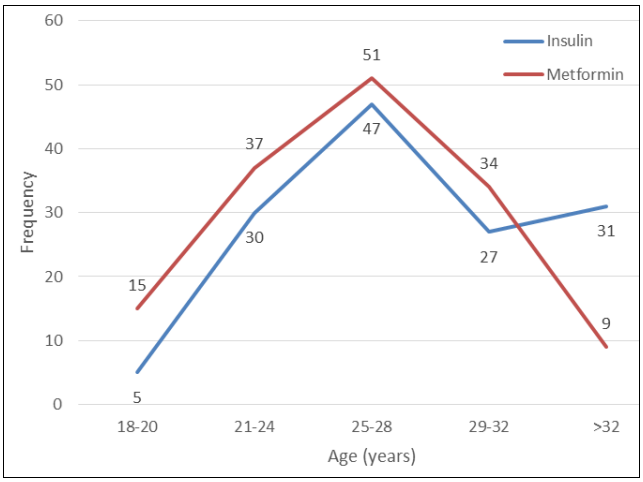

Fig 1: Age distribution of participants in two treatment groups

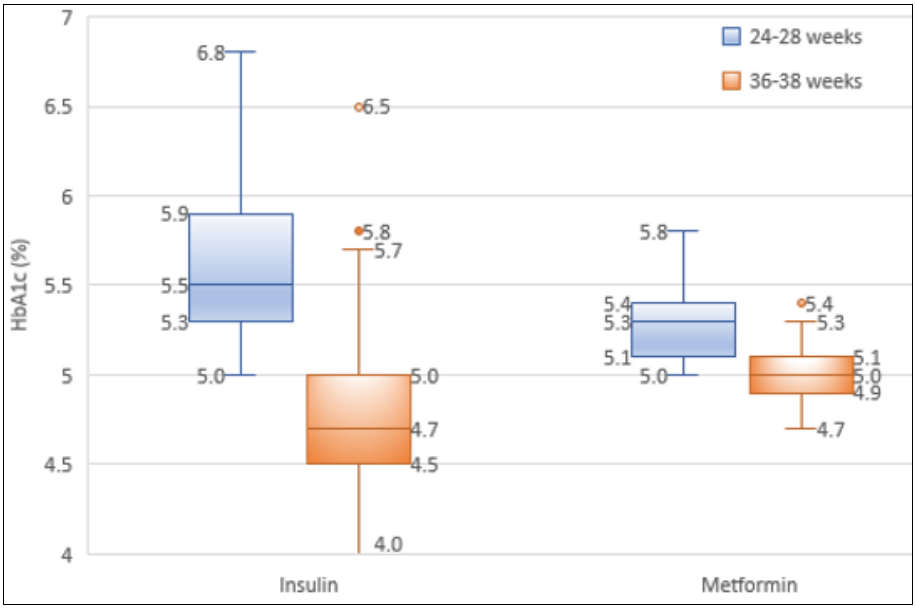

Fig 2: Comparison of HbA1c at 24-28 and 36-38 weeks of gestation in two treatment groups

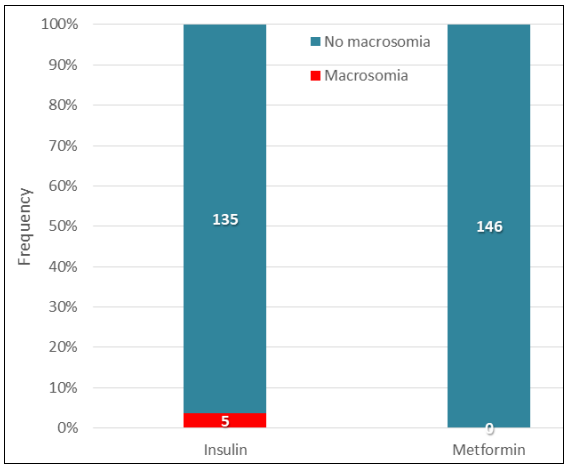

Fig 3: Distribution of macrosomia among neonates of participants of two treatment groups

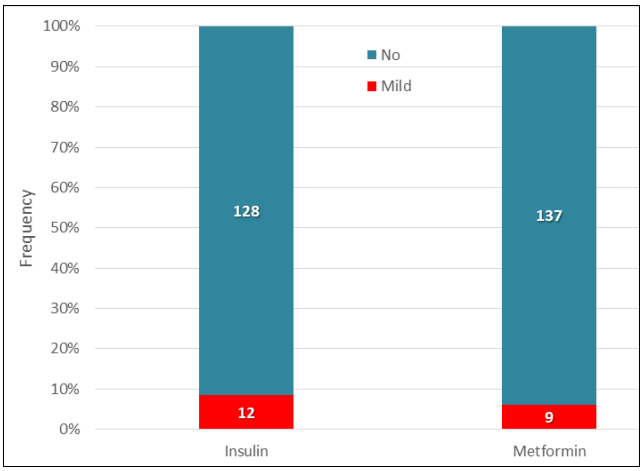

Fig 5: Distribution of neonates of participants in two groups according to birth injuries

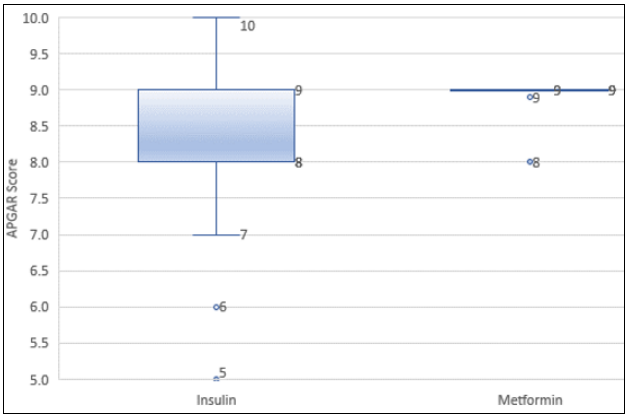

Fig 4: Distribution of neonates of participants in two treatment groups according to Apgar score at 5 minutes

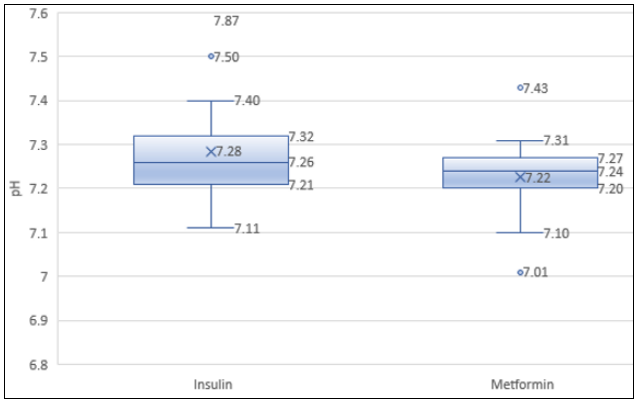

Fig 6: Distribution of umbilical artery pH in neonates among participants in two groups

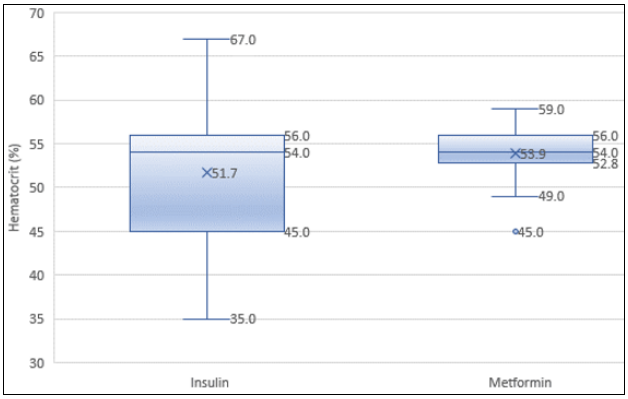

Fig 7: Comparison of haematocrit in neonates of participants in two groups

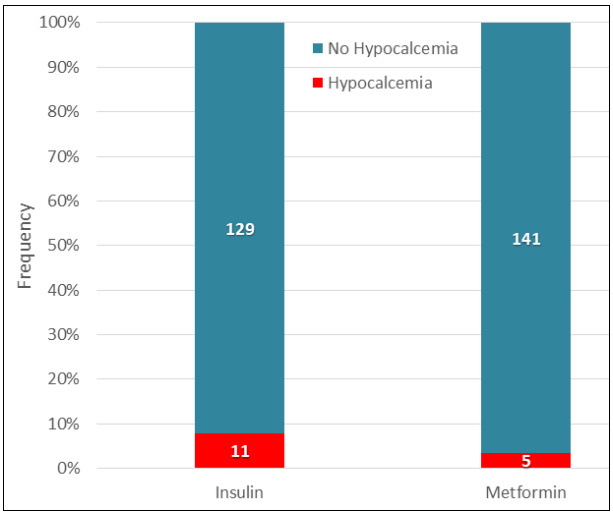

Fig 8: Distribution of Hypocalcaemia in neonates of participants in two group

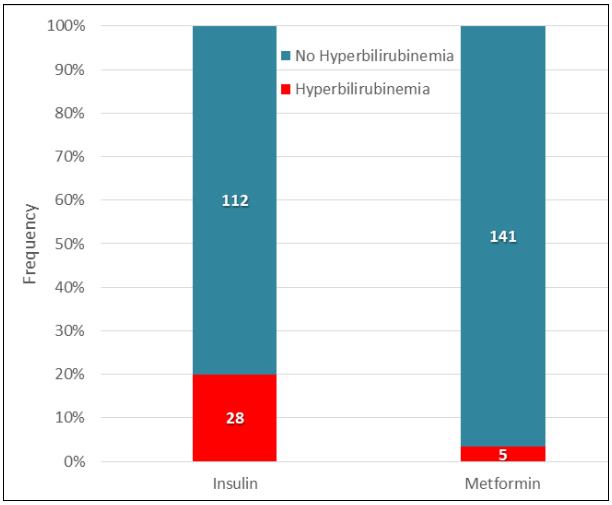

Fig 9: Distribution of hyperbilirubinemia among neonates of participants of two treatment groups

Conclusion

The overall result from the study says that Metformin was found as effective as Insulin in the management of GDM. Moreover, metformin was found to be contributing improved neonatal outcomes when compared to that of Insulin treated group. Also, the affordable cost and convenience of oral administration might make metformin more patient-friendly.

Acknowledgments

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