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PREDICTIVE VALUE OF FIRST TRIMESTER GLYCOSYLATED HEMOGLOBIN (HBA1C) IN GESTATIONAL DIABETES MELLITUS

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ABSTRACT

Background: Gestational diabetes mellitus(GDM), is "any degree of glucose intolerance with onset or first recognition during pregnancy." GDM is steadily rising and increases the risk of adverse maternal and perinatal outcomes. Early diagnosis and treatment can decrease its consequences. The aim of this study was to find the predictive value of HbA1c level in GDM and to compare the mean HbA1c level among GDM and non GDM. **Methods:** A hospital based prospective cohort study was done for a duration of 16 months which included 786 cases visiting in Out Patient Department of obstetrics and gynecology of Kathmandu Medical College. First trimester HbA1c level report were documented. Gestational diabetes mellitus was diagnosed by National Institute For Health And Care Excellence(NICE) guideline at 24 to 28 weeks of gestation. Mean HbA1c level was compared between GDM and non GDM group. ROC curve was used to predict the cut off value of HbA1C. **Results:** Among 786 cases 94 were diagnosed as GDM. The prevalence of GDM was "12%(95% C.I:9.8%-14.4%). The area under the curve(AUC) of HbA1c of GDM was good predictor of GDM with 0.601 with sensitivity of 69.1% and specificity of 41.2%. The cutoff value of HbA1c was 5.04. The mean HbA1c level was significantly higher than non gestational diabetes mellitus(NGDM) group (5.28 ± 0.453 and 5.11 ± 0.412(p-value <0.001). **Conclusion:** This study concludes that cut off value >5.04% of first trimester HbA1c can be used for screening of GDM. The mean HbA1c level in GDM was 5.28 ± 0.453(P-value <.001).

KEYWORDS: Gestational diabetes mellitus, HbA1c, NICE guideline, Predictive value, ROC curve.

INTRODUCTION

Gestational diabetes mellitus, a common medical disorder during pregnancy is described as "any degree of glucose intolerance with onset or first recognition during pregnancy." Gestational diabetes is thought to complicate 1–16% of all pregnancies, depending on the demographic and the diagnostic criteria used.[1] According to World Health Organization (WHO) criteria, only 2.5% of pregnant women in Nepal had GDM, while 6.6% had according to the International Association of the Diabetes and Pregnancy Study Group(IADPSG) criteria.[2] Women who are obese, older than 25 years old, from ethnic groups where diabetes mellitus is more common, have a first-degree relative with diabetes, or have a history of impaired glucose tolerance or poor obstetric outcomes are the most at risk of developing GDM. Clinical features and follow-up data indicate that GDM is a precursor to type 2 diabetes mellitus. GDM recurrence rates in subsequent pregnancies range from 60 to 90%. Seven to ten years after giving birth, 30% of women with GDM develop diabetes mellitus or impaired glucose tolerance (IGT).[3] GDM increases the risk of adverse maternal and perinatal outcomes as well as the mother's and the child's future chance of getting diabetes. Maternal complications of GDM includes polyhydramnios, pre-eclampsia, prolonged labor, obstructed labor, cesarean section, uterine atony, postpartum hemorrhage and infection.[4] Fetal and neonatal complication includes spontaneous abortions, intrauterine death, stillbirth, congenital malformation, shoulder dystocia, birth injuries, neonatal hypoglycemia and infant respiratory distress syndrome (RDS). Early detection and treatment of GDM are necessary to minimizing its adverse effects.[5,6] Usually screening for

GDM is done at 24-28 weeks of gestation.[6] There are different diagnostic criteria for GDM. Hemoglobin in the form of HbA1c is measured to determine the average plasma glucose concentration during a period of 12 weeks. NICE (National Institute for Health and Care Excellence) guidelines 2015 advise monitoring HbA1c levels in all pregnant women with pre-existing diabetes during the initial visit and again in the second and third trimesters.[7] HbA1c, Random blood sugar, fasting blood sugar, hematocrit, uric acid, alanine transaminase, are used as predictor of GDM. Among these predictors HbA1c might be a good predictor for GDM.[8,9]

METHODOLOGY

This was a hospital based prospective cohort study conducted in Out Patient Department of Obstetrics and Gynaecology Kathmandu Medical College, Sinamangal, Kathmandu, Nepal for 16 months duration(November 2021 to February 2023). Ethical approval from the Institutional Review Committee (IRC) (letter No.0108202106), was taken. Seven hundred and eighty six cases were considered for this study by convenient sampling method.

Pregnant women attending antenatal clinic in 1st trimester whose HbA1c report was available and willing to participate were included in this study. Cases of Overt diabetes mellitus, anemia(Hb <10 gm/dl), hemoglobinopathies, chronic renal disease, metabolic disorders were excluded from the study.

After all the respondents were informed about the study and written consent was taken. Data collection was done with the questionnaire on a structured proforma. A detailed history was asked including obstetric history, past medical history, family history, personal history followed by physical examination. BMI was calculated in kg/m².

Their HbA1c report was noted, those with HbA1c level >6.5 were excluded from the study. All 786 participants enrolled in 1st trimester after were again followed in 2nd trimester during 24-28 weeks of gestation. Oral glucose tolerance test(OGTT) was done) and GDM was diagnosed according to NICE guideline 2015 i.e. participants were asked to give venous blood in overnight fasting state and again after 2 hour of ingestion of 75 gm glucose dissolved in 500 ml water within 15 minutes. GDM was diagnosed when fasting blood sugar was >100mg/dl or postprandial blood glucose after 2 hour of ingestion of 75 gm glucose was >140mg/dl. Comparative study of HbA1c, fasting and PP was done. Blood for HbA1c was collected in EDTA vial and then its value was detected using H8 Lifotronic analyzer with High Performance Liquid Chromatography method within 5 minute.

Data Management

All the statistical analysis were done with the statistical package for social science (SPSS version 22) and the results were analysed by using independent sample t test, chi square test. Receiver Operative Characterstics Curve Statistics were used to assess the predictive value of first trimester HbA1c level in the diagnosis of GDM. The comparison between the mean Hba1c level of GDM and non GDM patient was done by using independent sample t test. If the p-value was less than 0.05, it was considered as being statistically significant.

RESULT

Total 786 cases were involved. Out of 786 cases 94 cases were diagnosed as GDM according to NICE guideline. The prevalence of GDM was "12%(95% C.I: 9.8%-14.4%)".

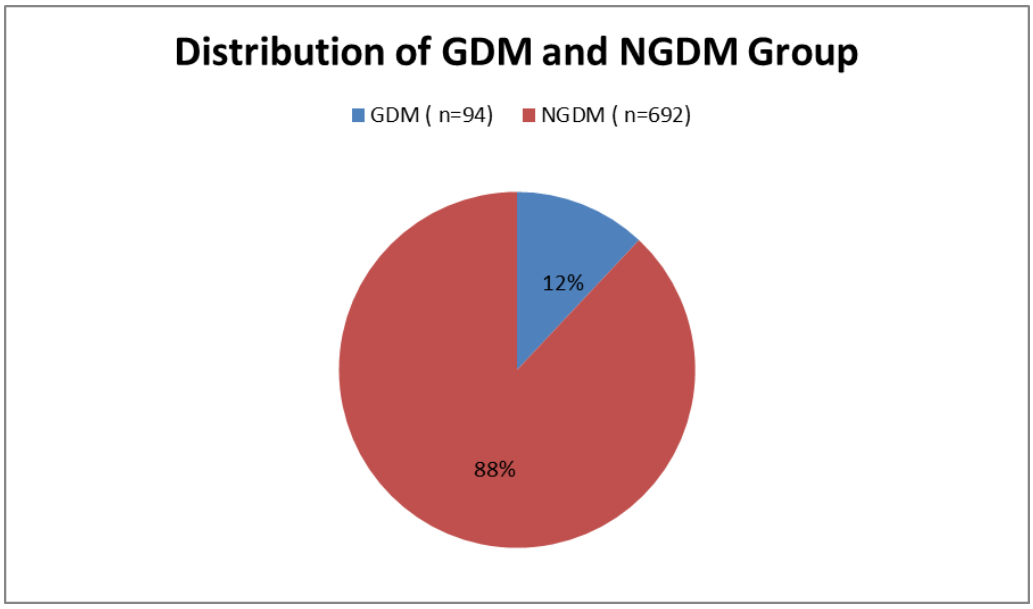

Figure 1: Distribution of GDM and NGDM group.

Table 1: Mean HbA1c levels in GDM and NGDM group.

Variable	GDM, n=94	NGDM, n=692	*p*-value
HbA1c level (%)	5.28 ± 0.453	5.11 ± 0.412	**<0.001**

The mean comparison of HbA1c level between GDM and NGDM group was calculated by using independent sample t test. The result showed that the mean HbA1c of GDM 5.28± 0.453 and NGDM was 5.11 ± 0.412. First trimester mean HbA1c level was significantly higher in the GDM than in non GDM group(p-value <0.001).

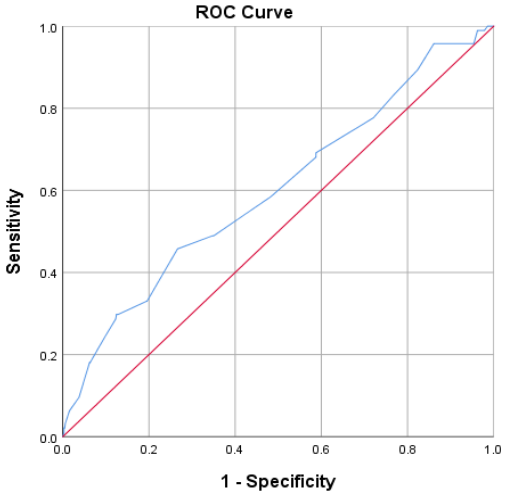

Figure 2: ROC curve for predicting gestational diabetes using Glycosylated Hemoglobin.

Table 2: Predictive accuracy of HbA1C and GDM.

Parameter	Area	p-value	95% C.I		Cut off value	Sensitivity	Specificity
			Lower Bound	Upper Bound			
Hb1Ac	0.601	0.002	0.536	0.664	5.04	0.691	0.412

Interpretation: The ROC curve showed that Glycosylated Hemoglobin was significantly good predictor of Gestational diabetes mellitus with AUC =0.601 with sensitivity of 69.1% and specificity of 41.2% with predicting value of 5.04.

DISCUSSION

The prevalence of GDM was 1.58% in Bajracharya A et al. study done in Kathmandu medical College in 2013.[1] In study conducted by Malhotra et al. in Faridabad in Haryana india found prevalence of GDM as 14.1%(IADPSG) and 6.7%(DIPSI).[10] He Y et al. found prevalence of 18.7% by IADPSG criteria and 14.6% by NICE guideline.[11] However in this study prevalence of GDM was 12%. The prevalence of GDM was different from other studies may be due to different criteria were used for diagnosis and study population were different.

In this study mean HbA1c level in GDM group is 5.28 ± 0.45. There was significant association of mean HbA1c with GDM(P<0.001). This was similar to the the study done by Sun J et al. which shows 5.23% ± 0.29% as a mean value of HbA1c in GDM(P<0.05).[12] Another study done by Hinkle SN et al. also found significantly higher HbA1c (5.3[standard deviation 0.3]%; 34[4]mmol/mol,) in GDM group.[13] Poo ZX et al. demonstrated that a first trimester HbA1c of 5.2% (33 mmol/mol) or more had a sensitivity of 82% and a specificity of 72% as well as NPV of 97% for the detection of GDM among Singaporean women.[14] This was may be due to participants belongs from different ethnicity and the diagnostic criteria used were different.

This study showed that glycosylated hemoglobin was significantly good predictor of gestational diabetes mellitus (AUC= 0.601, Sensitivity = 69.1% Specificity = 41.2%, Predictive cut off value = 5.04). Similar results was found in research done by Sun J et. al which shared that AUC in ROC curve was 0.655 (sensitivity = 73.5%, specificity = 43.5%, predictive cut off value = 5.3).[12] However, a study done by Bhat SK et al. found (AUC= 0.712, Sensitivity = 55.7% Specificity = 83.6 %, Predictive cut off value = 5.55%) varied with our finding.[15] This high specificity results in low rate of false negative which contrary to this study. This may be due to difference in number, ethnicity of study population and different diagnostic criteria used. HbA1c can be used as a predictor of GDM but cannot be used for diagnosis purpose.

CONCLUSION

The study titled as "First trimester HbA1c as a predictor of GDM" was done in KMC. from November 2021 to February 2023. Among 786 cases 94 cases were

diagnosed as GDM. The prevalence of GDM was 12%. This study concludes that the predictive value of first trimester HbA1c was 5.04. The mean HbA1c level in GDM was 5.28 ± 0.453(P-value <.001) and was significantly higher than non GDM group.

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