Menoufia Medical Journal

PRINT ISSN: 1110-2098 - ONLINE ISSN: 2314-6788

journal hompage: www.menoufia-med-j.com

Volume 36 | Issue 1 Article 4

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Recommended Citation

Amin, Essam A.; Sayyed, Tarek Mohammad; Abdullah, Mohamed Shawk; Elshaer, Aya Ali Mousa; and El Lakwa, Hamed El Sayed () "First trimester fetal heart rate tracing, a novel tool for prediction of gestational diabetes mellitus," *Menoufia Medical Journal*: Vol. 36: Iss. 1, Article 4.
DOI: https://doi.org/10.59204/2314-6788.1003

ORIGINAL STUDY

First-Trimester Fetal Heart Rate Tracing: A Novel Tool for Prediction of Gestational Diabetes Mellitus

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Abstract

Objective: **To evaluate the predictive role of first-trimester fetal heart rate (FHR) in early prediction of gestational diabetes mellitus (GDM).**

Background: **Diabetes represents a clinical challenge, especially in pregnant women, where it is critical to monitor and assess both the maternal and the fetal well-being. Apart from women with pregestational diabetes (type-1 or type-2 diabetes mellitus), there is a growing rate of women who develop GDM.**

Patients and methods: **This cohort study was conducted at Menoufia University Hospitals and Menoufia General Hospital from March 2020 to January 2022. The study participants were pregnant women at first trimester who had attended the outpatient clinic (prenatal care). Each patient had undergone through history taking and physical examination and then had first-trimester ultrasound scan where nuchal translucency, FHR, and crown rump length were recorded.**

Results: **The best cutoff value of first-trimester FHR in predicting GDM was more than or equal to 162 bpm, area under the curve = 0.853, with sensitivity of 76% and specificity of 78.9%, positive predictive value 23.43, negative predictive value 76.57, and accuracy of 78%, while the results of multiple logistic regression analysis indicate that first-trimester FHR was highly significant as a predictor for GDM ($P < 0.001$)**

Conclusion: **First-trimester FHR at cutoff value of more than or equal to 162 had moderate screening parameters for GDM.**

Keywords: Fetal heart rate, First trimester, Gestational diabetes mellitus

1. Introduction

Diabetes represents a clinical challenge, especially in pregnant women, where it is critical to monitor and assess both the maternal and the fetal well-being. Apart from women with pregestational diabetes (type-1 or type-2 diabetes mellitus), there is a growing rate of women who develop gestational diabetes mellitus (GDM) [1]. GDM is defined as carbohydrate intolerance of varying degrees of severity with onset or first recognition during pregnancy and it typically resolves after delivery [2]. The hyperglycemia-associated pregnancy outcome (HAPO) study showed that the association of macrosomia and birth complications with oral glucose tolerance test results is continuous with no clear inflection points [3].

Hyperglycemia is associated with a well-documented range of adverse pregnancy outcomes for the mother and fetus. The linear association between dysglycemia less severe than overt DM and short-term adverse pregnancy outcomes was shown definitively in the landmark HAPO study. Since then, evidence has accumulated to support the HAPO findings and also to suggest that GDM is associated with a range of long-term adverse

Received 8 October 2022; revised 16 November 2022; accepted 4 December 2022.
Available online 15 May 2023

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https://doi.org/10.59204/2314-6788.1003

outcomes for the mother and the offspring. Offspring born to mothers with GDM are at increased risk of multiple immediate complications, including macrosomia, preterm birth, birth injury, shoulder dystocia, neonatal hypoglycemia, neonatal unit admission, and respiratory distress [4].

According to the American Diabetes Association, screening for GDM can be performed at 24−28 gestation weeks with either of two strategies: 'one-step' 75-g OGTT or 'two-step' approach, with a 50-g (nonfasting) screen followed by a 100-g OGTT for those who screen positive. However, it could be important to identify earlier pregnancies at risk for GDM and to correct lifestyle and dietary intake from the beginning of the pregnancy, in order to reduce the percentage of patients that will need insulin therapy and will develop complications related to GDM [5].

A recent FIGO analysis of research priorities in hyperglycemia in pregnancy stated that pressing research issues requiring priority in early pregnancy include the development, testing, and implementation of risk engines to identify women who require earlier testing for hyperglycemia in pregnancy and the development and evaluation of alternative convenient, reliable, quick, low-cost, and nonfasting testing strategies to detect GDM at the point of care or close to home [6].

Therefore, early pregnancy models for prediction of GDM have been proposed, mostly using immunological markers, enzymes, or hormonal markers, but they showed a quite low sensitivity and specificity. A study in Vietnam used the ADA model that used age and BMI in prediction of GDM, another study on Chinese women that used age, BMI, triglyceride (TG), and fasting blood glucose for prediction, which gave a 65% accuracy and needed further improvement [7].

Other studies in Taiwan, Santiago, used SHBG, hemoglobin A1c (HbA1c), LDH, and TG for prediction of GDM with false prediction value of 5%. Another study in California used B-HCG and PAPP-A as prediction tools. In a recent study, it has been demonstrated that in pregnancies complicated by pregestational diabetes, first-trimester fetal heart rate (FHR) is higher than in nondiabetic women [8].

According to ACOG committee recommendation in estimating the due date, they considered first trimester is to be up to and including 13 6/7 weeks of gestation confirmed by crown rump length (CRL) measurement as it has an accuracy of +5−7 days [9].

Therefore, this study was designed to evaluate the predictive role of first-trimester FHR for the development of GDM.

2. Patients and methods

An observational case-series cohort study was conducted at Menoufia University Hospitals and Menoufia General Hospital from March 2020 to January 2022. Explanation of the study protocol to each participant was done before her inclusion in the study. The study participants were pregnant women at first trimester who had attended the outpatient clinic (prenatal care) after the approval of Menoufia University Ethics committee was obtained.

The sample was calculated by assuming that FHR had a prediction rate of 65.2% for gestational diabetes (positive likelihood ratio: 3.26 and negative likelihood ratio: 0.43). To achieve power 80% to detect this rate with a significance level 5% and confidence interval 95%, it is estimated that 175 patients will be recruited in the study. The sample was calculated by using the following equation: $N=(Z1-\alpha/22\ P\ (1-P)/d2$ where $Z1-\alpha/2$ is standard normal variate (at 5% type-I error; $P < 0.05$: it is 1.96. P: is the expected proportion based on previous studies, d: absolute error or precision. Sample size: 175 patients).

Inclusion criteria were singleton pregnancy, nondiabetic pregnant women at 11−14 weeks and BMI less than 30 kg/m^2. While exclusion criteria were patients more than 30 years, previous pregnancy with congenital anomalies, positive consanguinity, family history with congenital anomalies, abnormal nuchal translucency (NT), any exposure to teratogenic risk during pregnancy, patients with tachycardia or fever, patients with elevated first-trimester TG, and past history of GDM.

All study participants were informed about the study and provided a consent before being enrolled. For each patient, the following data were collected: maternal age, BMI, parity, maternal vital signs, NT by ultrasound, FHR by ultrasound, CRL by ultrasound, fasting plasma glucose level, HbA1c, and TG.

2.1. Methodology

Blood samples were collected at 11−14 weeks to patients included in the study. HbA1c and FBS were measured to exclude pregestational diabetic patients, also, patients with elevated TG were excluded as studies that were held on blood-borne biomarkers in prediction of GDM proved that GDM patients had first-trimester-elevated lipid profile, and also some trisomies that affect FHR had elevated TG level. They were excluded to avoid any other factor that may affect FHR or an interfering

with GDM prediction. Patients with tachycardia and fever were excluded in order not to affect FHR.

Ultrasound and FHR scanning: each patient had undergone through history taking and physical examination and then had first-trimester ultrasound scan where NT, FHR, and CRL were recorded in a participant data entry form. A transabdominal pelvic scan with convex probe at 5-Hz frequency Logiq E10 machine (General Electric Company, Boston, Massachusetts, USA) was used for scanning and recording at radiodiagnosis departments at Menoufia University Hospitals and Menoufia General Hospital. During the ultrasound examination, FHR was recorded using a transverse section of fetal thorax at the level of the tricuspid valve. Using Doppler and M-mode imaging, recording of 6–10 cardiac cycles was obtained and the interval between cardiac cycles was measured with electronic calipers and the FHR was calculated using the ultrasound machine software (Fig. 1). At first-trimester scan, ultrasound was done for obtaining CRL, NT, and FHR for all patients included in the study. Either Doppler method or M-mode method was used to measure FHR. In the majority of cases, the Doppler method was only used. In some cases, M-mode and Doppler were used together, the mean of the two values was calculated and used.

At 24–28 weeks of gestation, 75 g OGTT was done to divide patients of the study into two groups: cases (diabetic) and controls (nondiabetic). In all, 75 g OGTT was performed in the morning after overnight fast of 8–14 h, and after at least 3 days of unrestricted diet and unlimited physical activities. The patient should remain seated and should not smoke throughout the test. In all, 75 g OGTT with plasma glucose measurement fasting, 1 and 2 h at 24–28 weeks in women not having preexisting diabetes (all women included in the study), and one or more of the values from a 75 g OGTT must be equal or exceeded for the diagnosis of GDM [10]. Fasting serum glucose of 92 mg/dl (5.1 mmol/l). In all, 1-h serum glucose of 180 mg/dl (10.0 mmol/l). In all, 2-h serum glucose of 153 mg/dl (8.5 mmol/l).

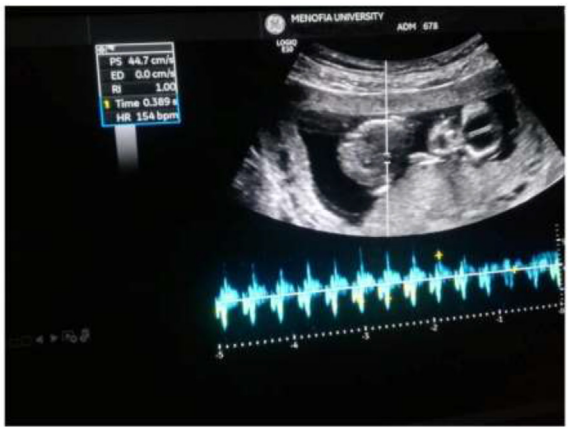

Fig. 1. FHR at the 12th week of gestation measured by Doppler method. FHR, fetal heart rate.

Patients were grouped according to the presence (cases) or absence (controls) of GDM after 75 g OGTT at 24–28 weeks. The participants were followed up till 28 weeks of gestation. Demographic, clinical, laboratory, and ultrasound data were compared between cases and controls. The statistical analysis was used to estimate the predictive role of the first-trimester FHR in prediction of GDM development.

Primary outcome: evaluating the predictive value of first-trimester FHR as a novel tool for early prediction of GDM. Secondary outcome: any recorded antenatal, maternal, or fetal complications during the study duration.

2.2. Statistical analysis

The results were tabulated and statistically analyzed using standard computer program using Microsoft Excel 2019 (MIcrosoft Corp., Redmond, Washington, US) and Statistical Package for Social Sciences (SPSS) version 25 (IBM Corp., Armonk, New York, USA).

Two types of statistics were done: descriptive statistics that includes the following test: the description of data was in the form of mean ± SD for quantitative data, and frequency and proportion for qualitative data. The mean is the sum of all observations by the number of observations. While the SD is a measure of the degree of scatter of individual varieties around their mean. The numerical continuous variables of this research were checked up for their normal distribution.

Analytical statistics that includes the following test:Mann–Whitney test (U): it is a nonparametric test of Student's t test. It is used to indicate the presence of any significant difference between two groups for a not normally distributed quantitative variable. Pearson correlation: it was used to show correlation between two continuous normally distributed variables. Spearman correlation: was used to show correlation between two continuous not normally distributed variables. The receiver-operating characteristic (ROC) curves: This procedure was used to evaluate the performance of classification schemes in which there is one variable of two categories by which patients are classified. They were constructed by calculating the sensitivities and specificities of the variable. Cutoff values: they

represent both standard ranges and optimal health ranges, also, they represent an appropriate value to distinguish healthy person from a specific disease. Sensitivity: the sensitivity of a clinical test refers to the ability of the test to correctly identify those patients with the disease. Specificity: the specificity of a clinical test refers to the ability of the test to correctly identify those patients without the disease. Positive predictive value (PPV): it answers the question how likely is it that this patient has the disease, given that the test result is positive? Negative predictive value (NPV): it answers the question how likely is it this patient does not have the disease, given that the test result is negative. *P* value less than or equal to 0.05 was considered statistically significant. Positive likelihood ratio: (effect of a positive test on the probability of disease) is calculated as sensitivity/1-specificity. Negative likelihood ratio: (effect of a negative test on the probability of disease) is calculated as 1-sensitivity/specificity.

3. Results

According to our study, the studied patients were grouped into control (nondiabetic) and cases (diabetic). Among patients included in the study, 41 patients were diagnosed as gestational diabetic with percentage of 23.43%, while 134 patients were free of diabetes (control) with percentage of 76.57% from the whole studied patients. As regards first-trimester sonographic data among the studied groups, there were no significant differences between the studied groups regarding NT and CRL ($P > 0.05$), while FHR was significantly increased among DM group (164.34 ± 15.16) than non-DM group (141.99 ± 13.90) ($P < 0.05$) (Table 1).

On correlation between FHR with the studied parameters, we found that there was a statistically significant positive correlation between the studied groups regarding OGTT results ($P < 0.001$). On the other hand, there were no significant differences between the studied groups regarding age, parity, BMI, systolic blood pressure (SBP), diastolic blood pressure (DBP), pulse, CRL, NT, FBS, TG, and HbA1c ($P > 0.05$) (Table 2).

Our results reported that the best cutoff value of FHR in predicting GDM was more than or equal to 162 bpm, area under the curve (AUC) = 0.853, with sensitivity of 76% and specificity of 78.9%, PPV 23.43, NPV 76.57, and accuracy of 78% (Table 3).

In our study, the results of multiple logistic regression analysis indicate that FHR was highly significant as a predictor for GDM ($P < 0.001$), also, age and parity were associated factors with detection of GDM ($P < 0.05$). While BMI, SBP, DBP, pulse, CRL, NT, FBS, TG, and HbA1c did not show any association detection of GDM ($P > 0.05$) (Table 4, Fig. 2).

Table 2. Correlation between fetal heart rate with the studied parameters.

Variables	FHR	
	r	*P* value
Age (years)	0.010	0.893
Parity	−0.043[b]	0.571
BMI (kg/m^2)	0.086	0.259
SBP (mmHg)	0.046	0.543
DBP (mmHg)	0.039	0.606
Pulse	0.002	0.976
NT (mm)	0.009	0.902
CRL (mm)	0.009	0.904
FBS (mg/dl)	0.036	0.636
TG (mg/dl)	−0.086	0.258
HbA1c (%)	−0.044	0.559
OGTT results	0.605	<0.001[a]

CRL, crown rump length; DBP, diastolic blood pressure; FBS, fasting blood sugar; FHR, fetal heart rate; HbA1c, hemoglobin A1c; NT, nuchal translucency; OGTT, oral glucose tolerance test; *r*, Pearson correlation; SBP, systolic blood pressure; TG, triglycerides.

[a] Statistically significant.

[b] Spearman correlation.

Table 1. First-trimester sonographic data among the studied groups.

Variables	Non-GDM	GDM	*U*	*P* value	95% CI	
	Control (*N* = 134)	Cases (*N* = 41)			Lower	Upper
NT (mm)						
Mean ± SD	2.10 ± 0.23	2.04 ± 0.35	1.001	0.321	−0.06	0.18
FHR (bpm)						
Mean ± SD	141.99 ± 13.90	164.34 ± 15.16	8.424	<0.001[a]	−27.66	−17.05
CRL (mm)						
Mean ± SD	66.50 ± 11.80	66.27 ± 12.61	0.104	0.917	−4.20	4.66

CI, confidence interval; CRL, crown rump length; FHR, fetal heart rate; GDM, gestational diabetes mellitus; non-GDM, nongestational diabetes mellitus; NT, nuchal translucency; *U*, Mann–Whitney *U* test.

[a] Significant.

Table 3. Receiver-operating characteristic curve for first-trimester fetal heart rate in predicting gestational diabetes mellitus.

AUC	Cut off	SE	Spec.	Sens.	PPV	NPV	*P* value	95% CI		Accuracy %
								Lower bound	Upper bound	
0.853	162	0.042	78.90	76.00	23.43	76.57	<0.001*	0.772	0.935	78

AUC, area under the curve; CI, confidence interval; NPV, negative predictive value; PPV, positive predictive value; Sens, sensitivity; Spec, specificity.
LR+: sensitivity/1−specificity = 3.6.
LR−: 1−sensitivity/specificity = 0.3.

In the present study, the cutoff value of FHR in predicting GDM was more than or equal to 162, AUC = 0.853, with specificity of 78.9% and sensitivity of 76%. Also, age and parity were predicting GDM at cutoff values more than or equal to 22.5 years and more than one previous delivery respectively, with sensitivity of 80.5 and 75.6%, respectively, and specificity of 67.2 and 76.1%, respectively (Table 5).

4. Discussion

There were no significant differences between the studied groups regarding CRL and NT ($P > 0.05$), while FHR was significantly increased among GDM group (164.34 ± 15.16) than non-DM group (141.99 ± 13.90) ($P < 0.05$). However, Sirico et al. [8] had reported that CRL had mean 64 mm in the GDM cases and 64 mm in controls with *P* value of 0.648. NT had mean value 1.9 mm in GDM cases and 1.76 mm in controls with *P* value of 0.057. FHR had mean value 165 bpm in GDM cases and 160 in controls with *P* value of less than 0.001, which meant that there were no significant differences between the studied groups regarding CRL and NT ($P > 0.05$), while FHR was significantly increased among GDM group than non-GDM group ($P < 0.05$).

There were no significant differences or predictive role neither for CRL nor for NT according to our study and according to Sirico et al. [8].

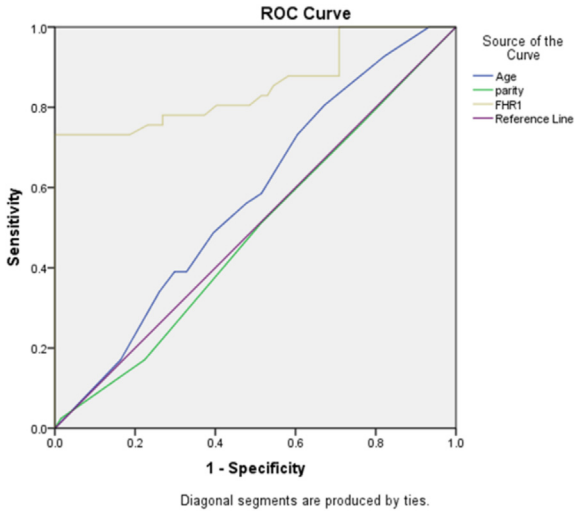

Fig. 2. ROC curve for fetal heart rate, age, parity in predicting GDM.

To the best of our knowledge, there were no other reports concerning first-trimester FHR as a predictive tool for GDM, except for Sirico et al. [8].

The multinomial logistic regression analysis of variables associated with GDM showed that FHR was highly significant as a predictor for GDM ($P < 0.001$), also, age and parity were associated factors with detection of GDM ($P < 0.05$). While BMI, SBP, DBP, pulse, CRL, NT, FBS, TG, and

Table 4. Multinomial logistic regression analysis of variables associated with gestational diabetes mellitus.

	β	SE	Significance	OR	OR (95% confidence interval)	
					Lower bound	Upper bound
FHR	−0.113	0.019	>0.001	0.893	0.860	0.927
Age	−0.282	0.098	0.004*	0.754	0.623	0.914
Parity	0.858	0.339	0.012*	2.358	1.212	4.585
BMI	−0.004	0.016	0.794	0.996	0.966	1.027
SBP	0.054	0.053	0.305	1.056	0.952	1.171
DBP	−0.079	0.079	0.316	0.924	0.792	1.079
Pulse	−0.035	0.040	0.387	0.966	0.893	1.045
CRL	−0.121	0.195	0.536	0.886	0.604	1.299
NT	0.494	0.911	0.587	1.639	0.275	9.772
FBS	−0.033	0.025	0.176	0.967	0.922	1.015
TG	0.020	0.013	0.123	1.020	0.995	1.047
HbA1c	−0.021	0.467	0.964	0.979	0.392	2.448

CRL, crown rump length; DBP, diastolic blood pressure; FBS, fasting blood sugar; FHR, fetal heart rate; HbA1c, hemoglobin A1c; NT, nuchal translucency; OR, odds ratio; SBP, systolic blood pressure; TG, triglycerides; β, beta-coefficient.

Table 5. Receiver-operating characteristic curve for fetal heart rate, age, and parity in predicting gestational diabetes mellitus.

Variables	AUC	Cut off	SE	Sens.	Spec.	PPV	NPV	95% CI		Accuracy %
								Lower bound	Upper bound	
FHR	0.853	162	0.042	76.00	78.90	23.43	76.57	0.772	0.935	78
Age	0.573	22.5	0.048	80.50	67.2	51.43	48.57	0.479	0.667	77
Parity	0.486	1.00	0.051	75.6	76.1	64.00	36.00	0.386	0.585	73

AUC, area under the curve; CI, confidence interval; FHR, fetal heart rate; NPV, negative predictive value; PPV, positive predictive value; Sens, sensitivity; Spec, specificity.

HbA1c did not show any association of detection of GDM ($P > 0.05$).

According to Sweeting et al. [11], maternal age, BMI, ethnicity, history of GDM, and family history of diabetes mellitus have a predictive value for GDM. BMI in our study has no significance in prediction of GDM as patients with BMI more than 30 kg/m^2 were excluded from our study. According to Correa et al. [12], the multinomial logistic regression analysis showed that women with GDM were older and had a higher BMI. They also had higher concentration of TG level than the nondiabetic patients.

In our study, TG has no significance in prediction of GDM as patients with elevated first-trimester TG were excluded. While Sirico et al. [8] considered maternal age and maternal cigarette smoking independently associated with GDM.

ROC curve for first-trimester FHR showed AUC 0.853, SE 0.042 with sensitivity 76% and specificity 78.90%, NPV 76.57, accuracy 78%, and cutoff value is more than or equal to 162 bpm in prediction of GDM. ROC curve for maternal age showed AUC 0.573, SE 0.048 with sensitivity 80.5% and specificity 67.2%, NPV 48.57, accuracy 77%, and cutoff value of 22.5 years in prediction of GDM. ROC curve for parity showed AUC 0.486, SE 0.051 with sensitivity 75.6% and specificity 76.10%, NPV 36.00, accuracy 73%, and cutoff value of one and more previous delivery in prediction of GDM.

In comparison with Sirico et al. [8], they also considered a threshold of 162-bpm FHR and that showed a detection rate of 76.9%, specificity of 67.1%, and NPV of 85.5% for GDM. While Sweeting et al. [11] presented that the mean age of the GDM was 33 years. This difference from our study may be due to a relatively smaller sample size and also as patients more than 30 years were excluded from our study. They also showed that the GDM group had higher parity than the nondiabetic group.

Some fetal and maternal antenatal complications were recorded during the study, two patients in the GDM recorded polyhydramnious with percentage of 4.878%, while in the nondiabetic group, one patient was reported with percentage of 0.746%.

Cases of large-for-gestational age were recorded for four out of 41 patients in the GDM group with percentage of 9.756%, while no patient of the 134 patients in the nondiabetic group recorded it.

Gestational hypertension was recorded as maternal complication, one out of 41 patients in the GDM reported gestational hypertension with percentage of 2.439%, while in the nondiabetic group, one patient out of 134 reported gestational hypertension with percentage of 0.746%.

According to Olmos et al. [13], they mentioned that cases of large-for-gestational age in the nondiabetic group fetuses were less than 10%, while in the GDM group, it was more than 17.5%.

The difference in these percentages between them and our study may be due to the relatively smaller sample size involved in the study and different incidence.

The statistical analysis showed that there was no statistically significant correlation between first-trimester-recorded FHR and polyhydramnios, large-for-gestational age, and gestational hypertension ($P > 0.05$).

The current study had shown a moderate diagnostic of first-trimester FHR, it was implemented at a cutoff value more than or equal to 162 bpm for prediction of GDM. The sensitivity, specificity, NPV, and PPV of concerned cutoff values were 76%, 78.8%, 76.57, and 23.43, respectively.

The positive likelihood ratio was 3.6, which means that the probability to have GDM was increased by 3.6 times when having first-trimester FHR more than or equal to 162. While negative likelihood ratio was 0.3, which means that the risk to develop GDM is reduced to about one-third when having FHR less than 162. Apart from moderate-value screening parameters, the PPV was low. Such finding may be due to the relatively low incidence of GDM in the study.

However, Sirico et al. [8] considered a threshold of 162-bpm FHR and that showed a detection rate of 76.9%, specificity of 67.1%, and NPV of 85.5% for GDM. However, they did not mention the PPV in their study.

The main strengths of our study are the exclusion of possible biases that could affect our analysis through a logistic regression analysis and the prospective study design having accurate information on first-trimester maternal data, sonographic, and laboratory

investigations. The main limitations of our study also were that the relatively smaller sample size included in the study and there were no other included predictive parameters. Recommendations: first-trimester FHR may be used as a novel, cheap, and moderately effective tool for early prediction of GDM. Moreover, first-trimester FHR is a simple modality that may be useful to select women who may benefit from an OGTT screening, avoiding the economic burden of a general screening for national health systems. Larger studies with larger populations comparing FHR as a predictor for GDM with other predictors from previous studies should be done.

4.1. Conclusions

We concluded that first-trimester FHR at cutoff value of more than or equal to 162 had moderate screening parameters for GDM: sensitivity, specificity, NPV, and AUC were 76%, 78.9%, 76.56, and 0.853, respectively. While it had low PPV (23.43). However, the positive likelihood ratio was 3.6, which means that the probability to develop GDM is increased 3.6 times when having first-trimester FHR more than or equal to 162, while negative likelihood ratio was 0.3, which means that the risk to develop GDM is reduced to one-third when first-trimester FHR is less than 162.

Conflict of interest

There are no conflicts of interest.

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