COMPARATIVE STUDY OF DIPSI AND WHO 2018 CRITERIA FOR DIAGNOSIS OF GDM

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ABSTRACT

Gestational Diabetes Mellitus (GDM) is an important public health problem. Prevalence has shown an increasing trend and varies based on diagnostic criteria used and the ethnic group studied. It is more common in Asia. Presently, there is no international consensus on the screening and diagnostic criteria for GDM. The Diabetes in Pregnancy Study Group of India (DIPSI) guidelines recommend the non-fasting 75g oral glucose tolerance test (OGTT) as a single-step screening and diagnostic test for GDM, is simple, easy and more feasible. The objective of this study was to compare whether the DIPSI criteria is equally sensitive to WHO 2018 criteria. This was a hospital based cross-sectional study done at Nepal Medical College Teaching Hospital, Kathmandu. Among 425 cases, 25 (5.88%) were diagnosed GDM, 6 (1.41%) were diagnosed only by DIPSI, 5 (1.18) only by WHO 2018 and 14 (3.29%) by both methods. The study showed that the sensitivity of DIPSI was 73.68% and specificity was 98.52%. The agreement between the DIPSI and WHO 2018 criteria ranged from 60% to 80% (Kappa value = 0.68). This study proves that DIPSI criteria is comparable to WHO 2018 criteria and can be adopted in our institution for the diagnosis of GDM as it is more feasible, easy and less expensive.

KEYWORDS

GDM, OGTT, DIPSI, WHO 2018 criteria, comparison

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INTRODUCTION

Gestational Diabetes Mellitus (GDM) is an important public health problem. GDM is defined as any degree of glucose intolerance with onset or first recognition during pregnancy.[1] Prevalence of GDM is increasing because pregnancy has become more common in sedentary lifestyle, obesity, and older age. Women diagnosed to have GDM are at increased risk of future diabetes predominantly type-2 diabetes mellitus (DM) as are their children.[2] It is also associated with adverse maternal and perinatal outcome.[3,4]

Of the total live births, twenty-one million thirty thousand live births (16.2%) had some form of hyperglycemia in pregnancy. Approximately 18.4 million of these cases were due to GDM.[5] Prevalence of GDM varied widely based on the diagnostic criteria used[6-8] and the ethnic group studied.[9-11] In a study carried out by Shrestha *et al*,[12] the prevalence was 4.5% using WHO criteria among pregnant women attending a tertiary hospital in Kathmandu, Nepal.

Screening is essential in all pregnant women in Asia as they are with increased risk of developing glucose intolerance during pregnancy as compared to Caucasian women.[10,11] Unfortunately, there is no international consensus on the screening and diagnostic criteria for GDM. There are different types of screening methods: universal or risk based, one step or two step and different thresholds for diagnosis.

The International Association of the Diabetes and Pregnancy Study Groups (IADPSG) criteria has more sensitivity, universally accepted and even an isolated fasting glucose levels have higher incidence of poor maternal and fetal out-come. In 2010, the hyperglycemia and adverse pregnancy out-come (HAPO) study suggested that fasting blood sugar values could be used to diagnose GDM. Seventy-five gm of oral glucose load given and after 1-hour and 2-hour venous blood glucose is to be taken. If fasting plasma glucose ≥92mgs/dl (5.1mmol/l), 1-hour plasma glucose ≥180mgs/dl (10mmol/l), 2-hour plasma glucose ≥153mgs/dl (8.5mmol/l), GDM is diagnosed.[13]

Recent WHO recommendation 2018 has been integrated from WHO 2013 publication "Diagnostic criteria and classification of hyperglycaemia first detected in pregnancy". It stated that GDM should be diagnosed if one or more of the following criteria are met: fasting plasma glucose 92-125 mg/dl, 1-hour plasma glucose 180 mg/dl and 2-hour plasma glucose 153-199 mg/dl following a 75 g oral glucose load.[14]

The Diabetes in Pregnancy Study Group of India (DIPSI) guidelines recommended the non-fasting 75 g oral glucose tolerance test (OGTT) as a single-step screening and diagnostic test for GDM,[15] as it is simple, easy, feasible in non-fasting state. Advantages of DIPSI procedures are: (1) Pregnant women need not be fasting state. (2) Causes least disturbance in a pregnant woman's routine activities and (3) Serves as both screening and diagnostic procedure.

The aim of this study was to compare the non-fasting DIPSI criteria with fasting state of the WHO 2018 for the diagnosis of GDM in our hospital setting.

MATERIALS AND METHODS

This study was a hospital-based cross-sectional descriptive study. The study was carried out on consecutive pregnant women attending in the OPD of Obstetrics and Gynecology Department of Nepal Medical College Teaching Hospital (NMCTH). The study was conducted between May to August 2019.

After approval of proposal by NMC Institutional Review Committee, all women who had singleton pregnancy irrespective of age, parity and socioeconomic status were included in the study. The patients who were diagnosed with diabetes before pregnancy and multiple pregnancy were excluded from the study. A standardized questionnaire was used to collect details including demography, family history and the obstetric history. The body mass index (BMI) was calculated using the formula weight in kg divided by height in meters square. All procedures followed were in accordance with the ethical standards. All participants have given informed consent prior to participating in the study.

The enrolled pregnant ladies at 24 to 28 weeks of gestation were sent to laboratory and given 75 g of glucose measured by laboratory workers with 300 ml of water per orally within 5 minutes, irrespective of the timing of the last meal. A venous blood sample was drawn 2-hours after the glucose intake. All these women were then invited to return 2 or 3 days later for the OGTT recommended for the WHO 2018 criteria. This time after an overnight fast of at least 8-hour, venous blood sample was drawn in laboratory at fasting and 1 and 2-hours after the 75 gm glucose load with 300 ml of water. If the patient vomited, then the test was repeated next day for either criteria.

Collected venous blood sample was measured by glucose oxidase peroxidase method. If plasma glucose level was ≥140mg/dl, after 2-hours of 75 g glucose intake at non fasting state, it was diagnosed as GDM according to DIPSI criteria.

After an overnight fast of at least 8-hours, if fasting plasma glucose was ≥92mg/dl and if after 1-hour and 2-hours of 75 g glucose load, plasma glucose level ≥180 mg/dl and ≥153 mg/dl respectively, the patient was diagnosed GDM according to WHO 2018 criteria.

The result of prevalence obtained by WHO 2018 and DIPSI methods were compared by their sensitivity and specificity. Data was tabulated and calculated by SPSS version 17, chi-square was used for data analysis.

Table 1: Comparison between DIPSI and WHO 2018 criteria among pregnant women

	GDM Positive	GDM Negative	Total	p-value
DIPSI	20 (4.71%)	405 (95.29%)	425	0.434
WHO 2018	19 (4.47%)	406 (95.53%)	425	

RESULTS

A total of 425 pregnant women were enrolled in the study. Among them, 20 (4.71%) were diagnosed GDM by DIPSI criteria and 19 (4.47%) by WHO 2018. Table 1

In the study, mean age of GDM positive women was 26.56 (±5.02) years and GDM negative was 25.9 (±4.66) years. There was no difference in mean age among GDM positive and negative women (P value 0.50) (Table 2).

Similarly no differences were found in mean BMI of GDM positive and negative women. Mean BMI in GDM positive was 24.8 (±4.43) and GDM negative was 23.5 (±4.04) (P value 0.12) (Table 2).

In the study, when DIPSI was compared to WHO 2018, number of both GDM positive of DIPSI and WHO 2018 was 14, both negative 400, DIPSI positive with WHO 2018 negative 6 and DIPSI negative with WHO positive 5 (Table 3).

The sensitivity of DIPSI in comparison to WHO 2018 was 73.68%, specificity 98.52%, positive predictive value 70% and negative predictive value 98.76% (Table 4).

This study showed DIPSI criteria is comparable to WHO 2018 criteria. The Kappa value 0.68 (95% CI 0.61-0.80) indicates a substantial agreement between the two criteria ranging from 60% to 80% (Table 5).

Table 2: Comparison of mean age and BMI between GDM positive and negative women

	GDM	No	Mean	S D	P value
Age	Positive	25	26.56	5.026	0.505
	Negative	400	25.92	4.662	
BMI	Positive	25	24.79	4.432	0.123
	Negative	400	23.49	4.048	

Table 3: Comparison of GDM positive, DIPSI with WHO 2018 criteria

	WHO 2018		
DIPSI	**Positive**	**Negative**	**Total**
Positive	14 (3.29%)	6 (1.41%)	20 (4.70%)
Negative	5 (1.17%)	400 (94.11%)	405 (95.29%)
Total	**19 (4.47%)**	**406 (95.52%)**	**425**

Table 4: Statistical parameters of DIPSI with WHO 2018 criteria

Statistical parameters	Value
Sensitivity	73.7%
Specificity	98.5%
Positive predictive value	70.0%
Negative predictive value	98.8%

DISCUSSION

International Diabetes Federation (IDF) in 2017 estimated that the majority of cases of hyper-glycemia in pregnancy occurred in low

Table 5: Measure of agreement, DIPSI with WHO 2018 criteria

	WHO 2018					Measure of agreement	
DIPSI	**Positive**	**Negative**	**Total**	**Chi-square**	**p-value**	**Kappa value**	**p-value**
Positive	14	6	20 (95.29%)	2.110	0.000	0.68	0.000
Negative	5	400	405 (4.71%)				
Total	**19 (4.47%)**	**406 (95.53%)**	**425**				

(0.61-0.80 substantial strength of agreement)

and middle-income countries where access to maternal care is often limited.[5]

By ethnicity and geographical location, Nepal seems to be prone to GDM. As the prevalence in Nepal is not low, universal screening is necessary among pregnant women in our country.[12] As Nepal is resource constrained, a feasible screening test for GDM is required. A one-step method is more feasible than a two-step method.

Based on HAPO study findings, IADPSG consensus panel recommended that GDM should be diagnosed based on IADPSG criteria, which has more sensitivity and specificity, more precise and accurate for diagnosing GDM and to have uniform diagnosing method all over the world. IADPSG criteria, was adopted by WHO expert group in 2013. Recent WHO 2018 recommendation has integrated recommendation from WHO 2013 publication.

In the present study, age and BMI did not have any significant difference in women with and without GDM which was also seen in other studies.[16-18] The overall prevalence of GDM was 5.8% including both method (DIPSI and WHO 2018) which is higher than previous study done in same institution in which only WHO 1999 criteria was used.[12] This difference may be due to time period of study as GDM is at increasing trend or may be due to use of multiple diagnostic criteria.

Using DIPSI criteria, the prevalence was marginally higher than WHO 2018 criteria in present study. There was a substantial strength of agreement between the two criteria. The test has a good sensitivity and specificity in our setting. In addition, the DIPSI criteria is easy, economic, single test and does not require the pregnant woman to be in a fasting state.

The disadvantage with WHO 2018 criteria is that it requires the pregnant woman to be in a fasting state and blood has to be drawn thrice. Patient may not follow the given instruction, if they need to come repeatedly.

Such high sensitivity was seen in other studies done in India. Srinivasan *et al*, in their study, they found sensitivity and specificity of DIPSI was 45% and 87% and IADPSG was 40% and 89% respectively. They concluded that screening is very essential in all pregnant women due to high prevalence of GDM in India and sensitivity of DIPSI was better than IADPSG criteria.[19] Similarly, in the study Geetha *et al*, 14% were diagnosed by DIPSI criteria, 9% were diagnosed by IADPSG criteria and 4% were diagnosed by both. Diagnosis of GDM by IADPSG criteria leaves 5% undiagnosed, which may be easily detected through DIPSI.[16] Both the studies were prospective but sample size were small 144 and 100 respectively. Saxena *et al*, concluded that for low and middle income countries with high prevalence of diabetes, universal, early screening with a single step, DIPSI criteria seems to be convenient highly cost effective.[20]

There are other studies in which DIPSI showed less sensitivity. In the study done by Mohan *et al*, when GDM prevalence was compared DIPSI with WHO 1999 and IADPSG, sensitivity was very low 27.7% and 22.6% respectively.[17] Polur *et al*, identified by WHO method 63 cases of GDM and by DIPSI 58 cases i.e. 92% of GDM cases identified by WHO were found to be identified by DIPSI. Correlation of DIPSI with WHO 2nd hours is extremely significant and concluded DIPSI has all those qualities of screening test. The authors emphasized DIPSI as cost effective and evidence based procedure in the low resource countries and with high risk ethnic population who require universal screening as a single step definitive glucose test.[21] Viz *et al*, showed diagnosis of GDM by DIPSI criteria leaves 22.36% undiagnosed which may easily be detected through IADPSG. Since the DIPSI criteria would miss a substantial number of patients, they suggest that the IADPSG criteria are better for screening of GDM in India.[18] Sujoy *et al*, among the 1470 women screened, IADPSG criteria identified 176(11.97%) cases of GDM vs. 58(3.94%) by DIPSI criteria. They concluded DIPSI criteria has low diagnostic rate as compared to IADPSG criteria because it ignored the fasting blood glucose (FBG) levels. Patients diagnosed as GDM by fasting value have similar severity of GDM as those diagnosed by non-fasting values.[22]

Bhavadharini *et al*, highlighted the GDM diagnosis strategy based on women in India with GDM Strategy (WINGS) project carried out in Chennai. They suggested that despite the constraints of

low resource, fasting state, three blood samples in IADPSG criteria, it appears to be the best which will help to bring out a uniform criteria for screening and diagnosis of GDM.[23] Though all the studies done above were comparison of DIPSI with IADPSG, in present study DIPSI was compared to WHO 2018 which was adopted from IADPSG criteria in 2013.

Since, present study showed that DIPSI criteria was comparable to WHO 2018 for diagnosis of GDM, it can be adopted in our institution. However, more evidence is needed to adopt this at the national level.

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