

Original Article

# Relationship between Screening and Diagnostic Performance of 50gm GCT vs. 75gm DIPSI test of Gestational Diabetes Mellitus: A Cross Sessional Study of Paten Hospital, Lalitpur

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**Abstract:** Gestational diabetes mellitus (GDM) is a common pregnancy-related disorder. Depending on screening policies, diagnostic cut-offs, and study population, its prevalence varies from 1-40%. There is a global upsurge in the prevalence of GDM with the adoption of new diagnostic criteria in screening and diagnosis. This study identified the relationship between screening and diagnostic performance of 50gm GCT vs. 75gm DIPSI test of Gestational Diabetes Mellitus. This is a hospital based cross-sectional analytical study, conducted at the Department of Obstetrics and Gynecology, Patan Academy of Health Sciences, Patan Hospital, Lalitpur, a 450 bedded tertiary center of the country with 130 beds in the department itself. The study period was of 12 months. Informed Consent was obtained from all participants, among all N=248 pregnant women. In both groups, 61 (24.59%) women were diagnosed with GDM, thus result of the study showed that prevalence of GDM was 24.59% in this study. Out of 52 screen positive cases, 25cases were diagnosed to have GDM, four out of 25 GDM patients had GCT more than 200mg/dl, thus did not require further OGTT for diagnosis. Twenty-seven candidates i.e. 43% had a false-positive screening test. Among those subjected to OGTT, 14 had raised fasting blood sugar while 6 of them had deranged one-hour glucose while one of them had altered two-hour value following obtain group b, a total of 36 patients were diagnosed with GDM with a two-hour blood glucose value more than or equal to 140. Out of 248 cases, 14% were diagnosed to have GDM using DIPSI criteria. The study significantly highlighted the relationship between screening and diagnostic performance of 50gm GCT vs. 75gm DIPSI test of Gestational Diabetes Mellitus. It will pave the way forward for future researches and prove a valuable additional in national and international literature.

**Keywords:** gestational diabetes mellitus, diagnosis, Lalitpur

## 1. INTRODUCTION

Gestational diabetes mellitus (GDM) is a common pregnancy-related disorder. Depending on screening policies, diagnostic cut-offs, and study population, its prevalence varies from 1-40% [1]. There is a global upsurge in the prevalence of GDM with the adoption of new diagnostic criteria in screening and diagnosis. Data from the Hyperglycemia and Adverse Pregnancy Outcome (HAPO) study across 15 study centers in

nine countries demonstrated great heterogeneity in the prevalence of GDM based on study center and country wise. Among the centers in the USA, the prevalence of GDM ranged from 15.5 to 25.5 % [2]. Hyperglycemia in pregnancy has its highest prevalence in South-East Asia where one in four pregnancies is affected [3]. Asian women have a higher propensity to develop GDM with common risk factors especially among those with a history of previous GDM, congenital anomalies, microsomal, maternal age and obesity [4]. In a meta-analysis of 84 studies in the Asian population, the pooled prevalence of GDM in Asia was found out to be 11.5% [5]. The prevalence of GDM countrywide is highest in Saudi Arabia (51%) followed by Taiwan (38.6%) and India (0.7-31%). Asians develop GDM at a lower BMI and type 2 DM occurs at a much younger age. With urbanization, GDM prevalence is becoming an epidemic [6]. Though a nationwide prevalence survey is not done yet in our country, a hospital-based study was conducted in three districts representing Mountain, Hill and Teri belts from July 2009 to June 2010 [7]. A total of 564 pregnant women were interviewed and tested for blood glucose as per WHO guidelines. In this study, 2.5% of pregnant women had GDM according to WHO criteria while it was 6.6% according to IADPSG criteria. This study has concluded that the gestational diabetes mellitus is a public health concern in rural communities of Nepal [8]. In a prospective study conducted at Patan Hospital, the incidence of GDM was only 0.4%. The prevalence of GDM was reported to be 9.29% based on a study conducted at National Medical College, Barsing which indicates the rising prevalence of it within the country [9]. Nepal has not been different from other countries and diabetes is growing gradually with changing lifestyle of Nepalese women [10]. Trends of rising antenatal visits and its increased screening along with rising in high-risk pregnancies may have resulted in its increased prevalence at present times. Diabetes mellitus was well recognized as a medical disorder for more than 2000 years. In 1500 BC, the Greek Father of Medicine Hippocrates mentioned "making the water too often" and Aristotle referred to "wasting of the body" for the same. Sullivan first used the term gestational diabetes mellitus in 1961 [11]. The Fourth International Workshop-Conference on Gestational Diabetes in 1980 at Chicago defined GDM as the carbohydrate intolerance of varying severity with onset or first recognition during pregnancy [12]. Since this definition includes women with pre-gestational diabetes who were not identified before pregnancy, the World health organization (WHO) in 2014 has updated recommendations to improve the definition and classification of hyperglycemia during pregnancy which is done either as Diabetes mellitus in pregnancy (DIP) or GDM [13]. Diabetes mellitus has various etiologies and based on it different classification system has been devised, out of which one is given below. In normal pregnancy facilitated insulin action during the first half of pregnancy is followed by diabetogenic stress during the second half of pregnancy [14], increased insulin fasting concentration, increased glucose-stimulated insulin release (peak 18-20 weeks), increased estrogen and progesterone induced beta-cell hyperplasia which finally ends in hyperinsulinemia, insulin being anabolic and anti-catabolic hormone favors, tissue glycogen storage, peripheral glucose utilization from liver & reduction of fasting blood sugar (FBS) by 10% which is normal physiology preventing hyperglycemia in early pregnancy. An increase in human placental lactogenic, prolactin and cortisol leads to diabetogenic stress. Due to this, maternal insulin sensitivity reduces by 50%. Metabolic alterations under influence of insulin and placental hormones facilitate anabolism during feeding and accelerated catabolism during fasting [15]. Fasting blood sugar (FBS) is constantly low due to the constant intake of glucose by the fetus. Moreover, deficient glycogenic amino acids, alanine, and glycine will further decrease FBS [16]. In Pregnancy progressive increase in demands of the growing fetus induces progressive changes in maternal carbohydrate metabolism [17]. As the pregnancy advances insulin resistance increases and increased diabetogenic stress is also caused due to placental hormones which necessitate a compensatory increase in insulin secretion. When this compensation becomes inadequate, Gestational Diabetes mellitus (GDM) is developed [18].

## 2. MATERIALS & METHOD

75gram Oral Glucose test is as good as to 50gm GCT for screening and diagnosing GDM. To compare 50gm glucose and 75gm Oral Glucose test (DIPSI criteria) as a screening and diagnostic procedure for Gestational Diabetes mellitus. To find out the relation of 50gm glucose challenge and 75gm oral Glucose test (DIPSI criteria) as screening and diagnostic procedure for Gestational Diabetes mellitus. This is a Hospital based Cross-sectional Analytical Study. This study was conducted at the Department of Obstetrics and Gynecology, Paten Academy of Health Sciences, Paten Hospital, Lalitpur, a 450 bedded tertiary center of the country with 130 beds in the department itself. The study period was of 12 months and the period of data collection, informed Consent was obtained from all participants. Written consents in English and Nepali language were used. Participants were permitted to withdraw from the study at any time without giving any reason during the study period. A statement indicating that the participant had understood all the information in the consent form and was willing to participate voluntarily in the study was mentioned. Participants were explained about the research details including its significance, benefits, and possible harms caused in the language they could understand. Participants were informed that no extra financial burden would be added to them as the needful cost for the procedure was a component of the routine universal antenatal screening test. Before obtaining the consent, their queries were answered. Confidentiality of patient details was maintained, only the relevant data and information for the study were collected. At Paten hospital, universal screening of all pregnant women at 24-28 weeks of gestation is being practiced. A two-step procedure, CT followed by OGTT in screen-positive women, is offered to all pregnant women at 24-28 weeks of gestation for screening and diagnostic purposes. All women fulfilling the inclusion and exclusion criteria were included in the study after taking informed consent. The study populations were divided into two groups A and B by the simple convenience sampling method, i.e. group a, subjected to 50gm GCT (followed by OGTT in screen-positive cases) & group b, subjected to 2 hour 75gm glucose (DIPSI criteria). Detailed history to assess maternal high-risk factors if any followed by general clinical, systemic and obstetric examination was done in all subjects. Routine antenatal investigations were done and pregnant women were kept on regular follow-up. Group A, fasting was not a prerequisite, pregnant women were asked to drink 50gm of glucose dissolved in 200ml of water, over 5 minutes, irrespective of the time of day or time of last meal & one hour after glucose administration a venous blood sample was collected. Screen positive women were being subjected to 75gm OGTT. Women were instructed to come after overnight fasting (8-14 hours). They were advised to have a carbohydrate unrestricted diet (not less than 150 grams per day) for 3 days before the test is performed. A fasting venous sample was obtained for blood sugar level measurement. They were asked to drink 75gm of glucose dissolved in 200 ml of water over 5 minutes. Venous blood was drawn after 1 hour and 2 hours of glucose ingestion for blood sugar level measurement. Tests were conducted and results were interpreted as per current hospital practice i.e. the value of plasma glucose level  $<140\text{mg/dl}$  was considered as screen negative for which further test was not needed. The value of plasma glucose level  $\geq 200\text{mg/dl}$  in GCT was considered as diagnostic of GDM & the value of plasma glucose level  $\geq 140\text{mg/dl}$  to  $<200\text{mg/dl}$  was considered as screen positive which further needed Oral Glucose Challenge Test (OGTT) as a diagnostic test as per current hospital practice. Oral Glucose Tolerance Test (OGTT), the cut-off plasma glucose values used for the diagnosis of GDM (adopted from IADPSG) are as follows, fasting  $\geq 95\text{mg/dl}$ ; 1-hour post-oral glucose  $\geq 180\text{mg/dl}$  and 2-hour post-oral glucose  $\geq 155\text{mg/dl}$ . Glucose value exceeding anyone three cut-offs was considered diagnostic for Gamin Group B, fasting was not a prerequisite for the test. They were asked to drink 75gm of glucose dissolved in 200ml of water over 5 minutes irrespective of the time of day or time of last meal & Venous blood was drawn after 2 hour of glucose ingestion. The value of plasma glucose level  $\geq 140\text{mg/dl}$  was considered both,

screen positive and diagnosed as Godmother women diagnosed with GDM in both arms were treated as per hospital guidelines. The weighted and packaged anhydrous glucose was dispensed from the pharmacy of PatanHospital. The blood sample was collected and plasma glucose level was estimated in the laboratory of PatanHospital. The sample size in each arm is based on the prevalence rate of 0.7 to 51% in Asia. The odds ratio was calculated to compare the relation of 50gm GCT in group A to DIPSI group B for screening and diagnostic significance.

### 3. RESULTS & DISCUSSION

#### 3.1 Results Interpretations

The purpose of this study was to determine whether or not there is a correlation between the screening and diagnostic power of the 50gm GCT test and the DIPSI test. The selection of all pregnant women between the ages of 24 and 28 weeks of gestation was carried out using the convenience sampling approach, which involved the split of patients into two groups. As a result, pregnant women in both groups saw similar outcomes. According to the findings of our research, the DIPSI test has 1.62 times better probabilities of diagnosing GDM when compared to the criteria of 50 gm. GCT (+OGTT) that are currently being used at our center. There were a total of 248 pregnant women who participated in the study, with 124 women in each arm completing the research. 61 women, or 24.59 percent, were diagnosed with gestational diabetes in both groups. According to the findings of this investigation, the prevalence of GDM was 24.59%.

**Table 01:** Results of tests in both group

Group	Total participants N	Positive screening of GDM N	Diagnosis of GDM N (%)
DIPSI	124	36	36 (29.03%)
GCT (+OGTT)	124	52	25 (20.16%)
<b>Total</b>	<b>248</b>	<b>88</b>	<b>61 (24.59%)</b>

In group a, total of 25 instances were diagnosed with GDM out of the 52 cases that had positive test results. Out of the 25 patients with GDM, four had a GCT that was higher than 200 mg/dl, and as a result, they did not require additional OGTT for diagnosis. In total, twenty-seven candidates, or 43 percent, had a screening test that was a false positive. The results of the OGTT showed that 14 of the individuals had elevated fasting blood sugar, six of them had abnormal glucose levels after one hour, and one of them had a change in glucose levels after two hours. Acquire the Group B, with a blood glucose level between two hours that was greater than or equal to 140, a total of 36 patients were diagnosed with gestational diabetes mellitus. Using the DIPSI criteria, a diagnosis of GDM was made for 14% of the 248 cases. Gestational diabetes mellitus, often known as GDM, is a condition that frequently occurs during pregnancy. Its prevalence can range anywhere from 1-40%, depending on characteristics such as screening procedures, diagnostic cut-offs, and the population under research [1]. As a result of the implementation of revised diagnostic criteria with regard to screening and diagnosis, there has been an increase in the prevalence of GDM all over the world. According to the findings of the Hyperglycemia and Adverse Pregnancy Outcome (HAPO) study, which investigated the prevalence of gestational diabetes mellitus (GDM) across 15 study sites and nine countries, there was a significant amount of variation in the incidence of GDM. The prevalence of type 2 diabetes varies from 15.5% to 25.5% throughout the centers in the United States of America.

**Table 02:** The odds ratio for GDM Screening in two groups

Comparison of tests for screening of GDM			
Screening GDM	DIPSI	GCT	Total
YES	36	52	88
No	88	72	160
Odds Ratio	0.56		

When compared to the GCT that is utilized in our establishment, the likelihood of GDM being detected through the use of DIPSI was reduced by about 44 percent. Because of this, the insulin sensitivity of the mother decreases by fifty percent. During the process of feeding, metabolic changes brought about by insulin and placental hormones foster anabolism, while during fasting, they speed up the process of catabolism. Due to the fact that the fetus consumes glucose on a continuous basis, the fasting blood sugar (FBS) level remains consistently low. A further reduction in FBS will occur if glycogenic amino acids, alanine, and glycine are not present in sufficient quantities. Changes in the mother's glucose metabolism occur gradually throughout pregnancy as a result of the increased demands of the developing fetus. Both insulin resistance and increased diabetogenic stress are generated by placental hormones, which need a compensatory increase in insulin secretion. Insulin resistance grows as the pregnancy progresses, and placental hormones are also responsible for that stress. In the event that this compensation is not sufficient, the development of gestational diabetes mellitus (GDM) takes place.

**Table 03:** The Odds Ratio for GDM Diagnosis in two groups

Comparison of tests for diagnosis of GDM			
Diagnosis of GDM	DIPSI	GCT + OGTT	Total
Yes	36	25	61
No	88	99	187
Odds Ratio	1.62		

The DIPSI have 1.62 times (62%) increase in odds of diagnosing GDM in comparison to the GCT+OGTT that is practiced in our center.

### 3.2 Discussions

The study aimed at finding the relationship between screening and diagnostic performance of 50gm GCT vs DIPSI test. The division of patients into two groups was done for the selection of all pregnant women of gestation age 24-28 weeks based on convenience sampling method [19,20]. Thus pregnant women in both groups were comparable. In our study, the DIPSI test has 1.62 times higher odds of diagnosing GDM in comparison to 50 gm. GCT (+OGTT) criteria currently practiced at our center [21]. Similar studies done in the Indian population found the DIPSI method to have comparable diagnostic efficacy. Have reported the lower diagnostic efficacy of DIPSI compared to other diagnostic criteria (IADPSG and WHO criteria). DIPSI test has a sensitivity of 40%, the false-positive rate of 33%, so that it may miss around 60% of cases and falsely diagnose 33% of cases as having GDM in comparison to WHO and IADPSG criteria [22]. Similarly, one-fourth of cases were missed to diagnose with DIPSI test in the study [23]. Use of single blood sugar value might be cause for missing the cases of GDM by DIPSI criteria in previous studies moreover considering fasting blood sugar might have increase the cases of GDM while using IADPSG and WHO criteria

[24,25]. Thus previous studies donot have a uniform opinion regarding the diagnostic efficacy of the DIPSI method. Nevertheless, it is an adequate diagnostic test in resource-limited areas. In our study, the hospital-based prevalence of GDM was 24% [26]. A similar high prevalence (27%) was found in the study at diabetes and thyroid center in Kathmandu [28,29], Nepal among 200 pregnant women attending obstetrics and gynecology OPD [30,31]. However, the prevalence of GDM was quite low in studies done [32,33]. Though the demographic characters of the studies were similar, altered food habits [34], increased obesity and trends of pregnancy at an advanced age have raised the prevalence of GDM in overtime [35].

#### 4. CONCLUSIONS

Gestational diabetes mellitus, often known as GDM, is a condition that frequently occurs during pregnancy. The percentage of people who have it varies from one to forty percent, depending on the screening practices, diagnostic cut-offs, and research population. As a result of the implementation of revised diagnostic criteria with regard to screening and diagnosis, there has been an increase in the prevalence of GDM all over the world. As a result of the fact that 61 women, or 24.59 percent, were diagnosed with GDM in both groups, the findings of the study indicated that the prevalence of GDM was 24.59 percent. Out of the 52 instances that were positive for the screening test, 25 cases were identified with GDM. Four of the 25 patients with GDM had a GCT that was higher than 200 mg/dl, and as a result, they did not require additional OGTT for diagnosis. In total, twenty-seven candidates, or 43 percent, had a screening test that was a false positive. Among the individuals who were submitted to OGTT, fourteen of them had elevated fasting blood sugar, six of them had abnormal one-hour glucose, and one of them had altered two-hour value. After obtaining group b, a total of thirty-six patients were diagnosed with GDM with a two-hour blood glucose value that was greater than or equal to 140. Using the DIPSI criteria, a diagnosis of GDM was made for 14% of the 248 cases. An important finding of the study was that there is a substantial correlation between the screening and diagnostic performance of the 50gm GCT test and the 75gm DIPSI test for detecting gestational diabetes of the mother. In addition to being an important addition to both national and international literature, it will set the path for future research and prove to be a productive addition.

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