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Original Research Article

## Evaluation of glucose challenge test using cut off values 130mg/dl and 140 mg/dl for gestational diabetes mellitus screening

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### ABSTRACT

**Background:** Gestational Diabetes Mellitus (GDM) is associated with several adverse maternal and perinatal outcomes. Thus, screening for early detection of GDM and its treatment is important.

**Methods:** This was hospital based descriptive study done over one year in department of Obstetrics and Gynecology, TUTH, Nepal. Six hundred ninety-seven women fulfilling the inclusion criteria were enrolled at 18-22 weeks of gestation. High risk factors were assessed and GCT was performed in women with risk factors during enrollment. Diagnostic OGTT was performed in women who screened positive (GCT  $\geq$ 130mg/dl). Screen negative high-risk women were re-screened at 24-28 weeks. In women without known risk factors, GCT was performed at 24-28 weeks and OGTT was performed when screen positive. The diagnosis of GDM was made according to Carpenter and Coustan criteria.

**Results:** Out of 697 enrolled women, 12 were excluded for various reasons and 685 women were analyzed. Women having risk of GDM were 28.9%. The prevalence of GDM was 2.92% and 2.48% with GCT cut off 130 mg/dl and 140 mg/dl respectively. Lowering the threshold to 130 mg/dl identified three extra cases ( $p=0.010$ ). The prevalence among high risk group was 8.58% and 7.07% with the cut off value 130 mg/dl and 140 mg/dl respectively with three extra cases detected on taking cut off value 130 mg/dl ( $p=0.014$ ). Among low risk women the prevalence of GDM was same i.e. 0.61% with both the cut off values.

**Conclusions:** Lowering threshold of GCT to 130 mg/dl could identify significant percentage of extra cases of GDM especially in high risk women.

**Keywords:** Glucose challenge test, High risk, Prevalence, Screening

### INTRODUCTION

Gestational Diabetes Mellitus (GDM) is a condition in women who have carbohydrate intolerance with the onset or first recognition during pregnancy regardless of whether the condition has predated pregnancy or persisted after the pregnancy.<sup>1</sup> American Diabetes Association in 2015 defines GDM as diabetes diagnosed in second or third trimester that is not clearly overt diabetes.<sup>2</sup> Diabetes Mellitus affects about 6-7% of pregnancies and 90% of them are GDM.<sup>3</sup> The worldwide

prevalence of GDM is 1-14%.<sup>4</sup> However, studies from different hospitals in Nepal reported the incidence ranging from 0.66% to 5.80%.<sup>5-7</sup>

Gestational Diabetes Mellitus has adverse maternal and perinatal outcomes and is asymptomatic unless it is severe or complications occur. Despite more than 50 years of research there is no consensus regarding optimal approach to screening. The 50-gram oral glucose challenge test (GCT) is the most commonly performed screening test, which if screened positive, is followed by

a 100-gram oral glucose tolerance test (OGTT) for confirmation.<sup>8</sup> However, controversies exist regarding the threshold for a positive GCT. Venous plasma glucose concentration of 140 mg/dl was adopted as the threshold value at the Second, Third and Fourth International Workshop Conferences on Gestational Diabetes,<sup>1,9,10</sup> American Diabetes Association in 2009 and ACOG have stated that a threshold value of 140 mg/dl has sensitivity of 80% which is increased to 90% using a cut-off of 130 mg/dl.<sup>11</sup>

The objectives of this study were to estimate the prevalence of GDM among women both high risk and low risk combined and also separately using the two cut off values (130 mg/dl and 140 mg/dl) and also to observe number of extra women diagnosed with GDM after OGTT with GCT threshold 130 mg/dl.

**METHODS**

This was a hospital based cross sectional descriptive study carried out in the Out Patient Department of the Department of Obstetrics and Gynecology (GOPD), Tribhuvan University Teaching Hospital (TUTH), Kathmandu over a period of one year starting from 15<sup>th</sup> April 2014 to 14<sup>th</sup> April 2015. The sample size of 684 was calculated using the formula  $n = z^2pq / e^2$  where the prevalence of screen positive for gestational diabetes mellitus was taken as 12.3%.<sup>8</sup> Relative error margin of 20% was taken.

Pregnant women between 18 to 22 weeks of pregnancy attending the GOPD for antenatal check-up were enrolled in the study. Women already diagnosed as diabetes mellitus, on long term medications that could affect glucose metabolism such as corticosteroids, beta blockers, beta- agonists or who could not tolerate the glucose load and who refused to take glucose for the test were excluded from the study.

A detailed history was taken including socio-demographic profile, obstetric history, medical history and history pertaining to presence of risk factors associated with GDM and was recorded in structured questionnaire. The risk factors looked for were age 30 years or more, obesity (BMI >30Kg/m<sup>2</sup>), history of GDM or Impaired glucose tolerance in previous pregnancy, diabetes mellitus in first degree relative, bad obstetric history, history of birth weight >4Kg and glycosuria by urine strip.

In the presence of any of the risk factors, 50 gram GCT was performed at enrolling visit i.e. at 18-22 weeks. Women without risk factors were scheduled for GCT at 24-28 weeks. Women with blood glucose value  $\geq 130$  mg/dl were considered screen positive and scheduled for oral glucose tolerance test (OGTT). Blood glucose level >200 mg/dl at screening was considered as direct diagnosis of Gestational Diabetes Mellitus. Screen negative high risk women at 18-22 weeks were scheduled

for re-screening at 24-28 weeks and plan of repeat GCT was mentioned in the OPD ticket. An identification mark was put on the antenatal card with the plan mentioned for all the women who were enrolled so that they could be identified at 24-28 weeks for GCT. The Oral Glucose Tolerance Test was interpreted according to the Carpenter and Coustan criteria. Diagnosis of GDM was made when two or more values were above the threshold.<sup>10</sup> If only one value was above the threshold diagnosis of impaired glucose tolerance (IGT) was made. The diagnosed women were managed according to the hospital protocol.

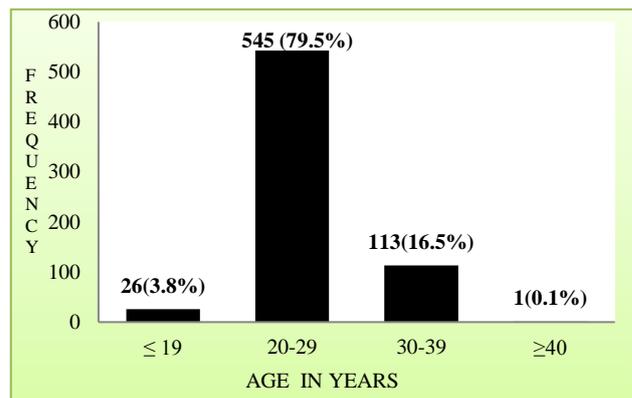
**Statistical analysis**

The data were analyzed using SPSS version 16. Pearson Chi square test was applied where applicable to find out statistical significance. The p-value <0.05 was regarded as statistically significant.

**RESULTS**

During the study period, 697 women attending the OPD for antenatal checkup and fulfilling the inclusion criteria were enrolled. Among them 12 were excluded as 10 did not follow up and two could not tolerate glucose load.

Among 685 women, 198 (28.98%) women with risk factors underwent screening with 50 gram GCT at 18-22 week POG. One hundred seventy women were screen negative and underwent rescreening at 24-28 weeks of gestation. Four hundred eighty seven women without risk factors were screened at 24-28 weeks of gestation. Both groups of women underwent 100 gram OGTT when their GCT values were 130 mg/dl or more.



**Figure 1: Age distribution.**

Almost 80% of women were between the age group 20-29 years. Those below 20 years were 3.8% and above 40 years were 0.1% (Figure 1).

The mean age was  $25.83 \pm 4.34$  years with minimum 17 years and maximum 43 years. Of the study population, 198 (28.90%) women had at least one of the risk factors. Among them 79.29% had single risk factor and 20.71% had multiple risk factors (Figure 2).

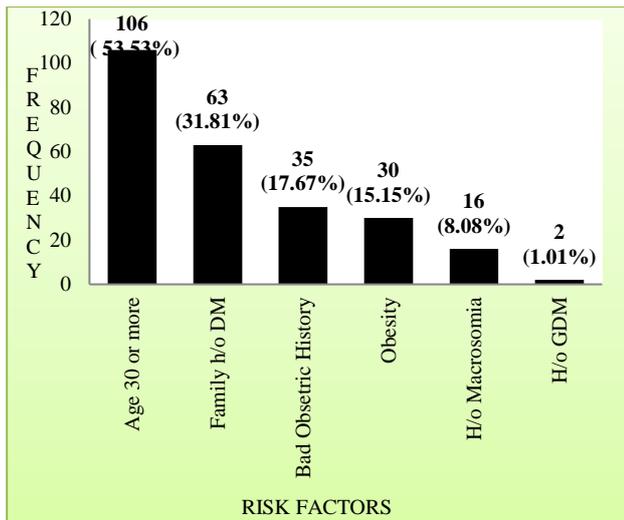


Figure 2: Risk factors.

The incidence of GDM in the study population (n=685) was 2.92% with threshold 130 mg/dl and 2.48% with the threshold 140 mg/dl. Similarly, the prevalence of Impaired Glucose Tolerance with the threshold 130 mg/dl was twice of that with threshold 140 mg/dl (1.90% vs 0.73%). Among high risk group, the incidence of GDM was 8.58% with threshold 130mg/dl and 7.07% with threshold 140mg/dl. Out of 17 cases of GDM, seven cases (41%) were diagnosed during screening at 18-22 weeks gestation. Among low risk group, the prevalence of GDM was same i.e. 0.61% with both the cut off values. The prevalence of IGT was double i.e. 0.82% with cut off value 130 mg/dl than that with cut off value 140 mg/dl i.e. 0.41% (Table 1).

Table 1: Prevalence of gestational diabetes mellitus with two different cut off values.

Whole study population (n=685)						
		OGTT results			Total	P-value
		Normal	IGT	GDM		
GCT cut-off value	≥130mg/dl	82	16	20 (2.91%)	118	0.010
	≥140mg/dl	45	6	17 (2.48%)	68	
High risk group (n=198)						
		OGTT results			Total	P-value
		Normal	IGT	GDM		
GCT cut-off value	≥130mg/dl	36	12	17 (8.58%)	65	0.014
	≥140mg/dl	19	4	14 (7.07%)	37	
Low risk group (n=487)						
		OGTT results			Total	P-value
		Normal	IGT	GDM		
GCT cut-off value	≥130mg/dl	46	4	3 (0.61%)	53	0.300
	≥140mg/dl	26	2	3 (0.61%)	31	

Out of the whole study population, 50 women with GCT 130-139.9 mg/dl underwent OGTT and ten extra cases of IGT and three extra cases of GDM were detected (p-value 0.010). Among high risk group, 28 extra women with

GCT 130-139.9 mg/dl underwent OGTT and eight extra cases of IGT and three extra cases of GDM were detected (p-value 0.040). However, among low risk group, no extra cases of GDM and only two extra cases of IGT were detected on subjecting 22 extra women to OGTT having GCT value 130-139.9 mg/dl (p-value 0.300). (Table 2).

Table 2: Detection of extra cases of GDM with threshold 130-139 mg/dl.

Whole study population (screen positive=118)						
		OGTT results			Total	P-value
		Normal	IGT	GDM		
GCT cut-off value	130-139.9	37	10	3	50	0.010
	≥140	45	6	17	68	
Total		82	16	20	118	
High risk group (screen positive=65)						
		OGTT results			Total	P-value
		Normal	IGT	GDM		
GCT cut-off value	130-139.9	17	8	3	28	0.014
	≥140	19	4	14	37	
Total		36	12	17	65	
Low risk group (screen positive=53)						
		OGTT results			Total	P-value
		Normal	IGT	GDM		
GCT cut-off value	130-139.9	20	2	0	22	0.300
	≥140	26	2	3	31	
Total		46	4	3	53	

DISCUSSION

The prevalence of Type II Diabetes Mellitus is increasing worldwide as well as in Nepal.<sup>12,13</sup> The incidence of GDM is also increasing in proportion with that of Type II DM. Though GDM has been recognized for decades, controversies exist regarding methods and timing of screening, universal or selective screening and various thresholds of screening and diagnostic tests. Fifty gram oral GCT is the main method of screening for GDM with the cut off value 140 mg/dl. Literatures have shown that lowering the threshold of GCT screening will help identify the more number of women with GDM and thus prevent and manage complications associated with it.<sup>11,14</sup> This study was conducted with the aim to find out if significant number of extra cases of GDM could be detected with the lower cut off value (130 mg/dl) of GCT than the one currently being used i.e. 140 mg/dl.

In this study prevalence of GDM among the study population was almost same whether the cut off taken was 130 mg/dl or 140 mg/dl (2.92% and 2.48% respectively). This falls on the reported range of worldwide prevalence of 1-14%.<sup>4</sup> Most of the studies in Nepal were done with the cut off 140 mg/dl and no studies using the cut off value 130 mg/dl were available.

The prevalence is reported to be as low as 0.66% by Rana A and team in 1998 and 0.75% reported by Shrestha A and co-worker in 2010.<sup>7</sup> The low prevalence by Rana A compared to the present study in the same institute may be the result of worldwide increasing trend of Type II DM over the last 13 years since the study was carried out. The prevalence reported by Jali MV and team in a diabetes center at Karnataka using single step 75 gram OGTT was 16%, similar to (16.2%) that reported by Seishah V et al.<sup>15,16</sup>

In a study by Juntarat W and colleagues, the prevalence of GDM was 4.14% with GCT cut off 130mg/dl and 4.08% with the cut off 140 mg/dl. Kosus A and team found the prevalence of 8.1% and 7.1% with the cut off value 130 mg/dl and 140 mg/dl respectively in a retrospective study at University of Ankara, Turkey in 2008.<sup>17</sup> Even higher prevalence of 11.4% with the GCT threshold of 130 mg/dl and 9.5% with the threshold 140 mg/dl were reported by Tan PC and colleague.<sup>18</sup> This may be because almost 50% of the study population was contributed by women with risk factors for GDM.

The prevalence of GDM is significantly high in women with risk factors for GDM. In high risk cases the prevalence of GDM in the current study was 8.58% with screening threshold 130 mg/dl and 7.07% with the threshold 140 mg/dl. However, Juntarat W and colleague reported that the prevalence of GDM among high risk women were 20.41% with the cut off 130 mg/dl and 20.16% with cut off 140 mg/dl.<sup>19</sup>

It has been postulated that low risk women do not need routine screening for GDM.<sup>11,14</sup> But literatures have shown significant prevalence among low risk women.<sup>20,21</sup> There are not many studies done to see the prevalence of GDM among low risk women. In low risk cases the prevalence of GDM was same i.e. 0.61% for both the thresholds showing that the cut off value 140 mg/dl can identify all the cases of GDM in low risk women. Jimenez-Meleon JJ et al in their study in Spain in 1995 also found that the prevalence of GDM among low risk women was 0.6%.<sup>22</sup> Soheilykhah S et al reported the prevalence of GDM among this low risk group was 2.1% with the cut off value 130 mg/dl.<sup>23</sup> However, Najafian A et al studied 1800 low risk women using the cut off 130 mg/dl and 75 gram OGTT as diagnostic test and found that 3.4% women were diagnosed to have GDM.<sup>21</sup> This difference may be due to the different diagnostic criteria used for diagnosis (IADPSG criteria) which require only one value exceeding the threshold for diagnosis.<sup>24</sup>

In the current study, 50 women with GCT 130-139 mg/dl i.e. 7.2% of study population underwent diagnostic OGTT and 3 extra cases of GDM could be detected compared to 17 GDM cases detected from 68 women with GCT  $\geq$ 140 mg/dl i.e. 9.9% of study population (p=0.010). Those 3 cases detected by the threshold 130mg/dl accounted for 15% of total GDM cases and would have been considered as normal if the cut off was taken as 140

mg/dl. This is consistent with Friedman et al who had 10% of GDM cases between threshold 130-139mg/dl.<sup>25</sup> Kosus A and team found that 50 extra women i.e. 6.3% of the study population was subjected for OGTT to detect 8 extra cases i.e. 12% of GDM.<sup>17</sup> Tan PC et al also found that 179 women i. e. 11% of study population had to undergo diagnostic OGTT to detect 28 extra cases (15% of total GDM) as in current study.<sup>22</sup> All the studies showed that more than 10% of GDM cases may be missed with currently used threshold of 140 mg/dl. Significant percentage of GDM cases can be detected by lowering the threshold to 130 mg/dl and subjecting a small extra percentage of women to diagnostic OGTT. This would be more beneficial than leaving these women with undetected GDM and diagnosis at a later stage when effects on mother and fetus have already occurred.

In this study, among high risk population, three extra cases of GDM i.e. 17% of total GDM were detected by subjecting 28 more women i.e. 14% of high risk women to diagnostic OGTT compared to 14 cases from 37 women (p=0.014). These cases detected by the cut off value 130 mg/dl would have been diagnosed normal had the cut off been 140 mg/dl. Unlike current study, Juntarat W et al showed that 109 i.e. 13% of high risk women had to undergo diagnostic OGTT to detect 2 extra cases of GDM (1.1% of GDM) when the threshold was lowered to 130 mg/dl from 140 mg/dl. They concluded that adopting lower threshold subjects more women to diagnostic OGTT unnecessarily.<sup>19</sup> Though lowering the cut off value to 130 mg/dl subjected 4.5% extra women to diagnostic OGTT, no extra cases of GDM was diagnosed among low risk group.

## CONCLUSION

Nearly 30% of the pregnant women attending antenatal clinic are at high risk for developing GDM. Three extra cases i.e. 15% of GDM cases could be detected subjecting 7.2% women to diagnostic OGTT who would have been considered as normal if the cut off was taken as 140 mg/dl. This was more significant in high risk women.

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