

## Need to Redefine the Glucose Challenge Test Threshold in Screening for Gestational Diabetes Mellitus

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### Abstract

**Aim of the study:** To determine the need to change the present glucose challenge threshold value in screening for gestational diabetes mellitus (GDM) among women in Dakshina Kannada and neighboring areas. **Study Design:** Retrospective and Cross Sectional study. **Materials & Methods:** 997 patients were analysed in the retrospective study having a GCT done between 24 – 28 weeks from October 2009 to October 2010 and complications of GDM observed in them. A mean GCT was identified above which complications (maternal and fetal/neonatal) were noted. Following this, in the cross sectional study done between November 2010 to September 2011, 209 patients were identified as having a GCT above that determined by the retrospective study. They were subjected to a 100g glucose threshold test to diagnose GDM (using Carpenter Couston values). Sensitivity, specificity, positive and negative predictive value was calculated for each GCT threshold value. **Results:** The mean GCT at which complications of GDM were observed in the retrospective study was 123.56 (maternal complications) and 124.15 (fetal/neonatal complications). In the Cross Sectional Study, therefore, 124 mg/dl was taken as the cut off above which women were subjected to a 100g oral GTT. The ROC curve identified a value of 143mg/dl showing a sensitivity of 83.3% and specificity of 72.3%. A value of 135mg/dl, however showed a high sensitivity (91%) which is required in a high prevalence area. This value had a moderate specificity (52%). **Conclusion:** A high prevalence area like ours requires a GCT threshold with

a high sensitivity which in our study was observed at a threshold value of 135mg/dl.

Diabetes mellitus is a group of metabolic disorders characterised by hyperglycemia resulting from defects in insulin secretion, insulin action or both. Recent estimates indicate there were 171 million people in the world with diabetes in the year 2000 and this is projected to increase to 366 million by 2030. [1] It is estimated that 3% to 5% of pregnancies are complicated by diabetes. Approximately 0.2% to 0.5% of all pregnancies occur in women with a pre-existing diagnosis of type 1 diabetes mellitus [2] and a similar number have preexisting type 2 diabetes mellitus. An additional 1% to 6% of women will develop sufficient hyperglycemia during pregnancy to meet the criteria for a diagnosis of gestational diabetes mellitus or GDM [3].

The increasing prevalence of type 2 diabetes in general and in younger people in particular, has led to an increasing number of pregnancies with this complication [4]. Indeed, the incidence of diabetes complicating pregnancy has increased approximately 40% between 1989 and 2004 [5].

In India, the prevalence varied from 3.8% to 21% indifferent parts of the country depending on the geographical locations and diagnostic methods used [6]. GDM has been found to be more prevalent in urban areas than in rural areas. A random survey was performed for the first time in 2002 to determine the prevalence of GDM in our country. Of the total number of pregnant women (n = 3674) screened in that study, 16.55% were found to have GDM. In a similar study conducted in Tamil Nadu, the prevalence of GDM was found to be similar with the prevalence of GDM in the urban, semi-urban and rural areas were 17.8%, 13.8% and 9.9% respectively [7].

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In such high prevalence areas like ours, it is therefore necessary to diagnose accurately as many women with GDM as practically possible to reduce the maternal and perinatal morbidity associated with it. The aim of the study was therefore to determine the need to change the present glucose challenge test (GCT) threshold value in screening for gestational diabetes among women in Dakshina Kannada and neighboring areas.

This was achieved by dividing the study into two parts, a retrospective and a cross-sectional study. The objectives of the retrospective study were to find out the various maternal and perinatal complications of GDM in women at different GCT thresholds and also to determine the mean GCT threshold value at which complications of GDM were observed. The objectives of the cross-sectional study were to determine the proportion of women with GDM diagnosed at different GCT thresholds and to determine the sensitivity, specificity, positive and negative predictive values of different GCT thresholds for predicting GDM.

### Methodology

The study was done in two parts – A retrospective study and a cross-sectional study in Government Lady Goschen Hospital, Mangalore. The retrospective study was done by reviewing records of delivered women from October 2009 to October 2010 having a GCT done between 24 to 28 weeks of gestation and the maternal and perinatal outcome (with respect to

complications associated with GDM) was recorded. Patients included were singleton pregnancies without any history of pre-gestational diabetes having a GCT done between 24 to 28 weeks.

The second part of the study was continued from November 2010 till September 2011 and included all antenatal (singleton pregnancies) between 24 to 28 weeks (excluding multiple pregnancies and pre-gestational diabetes). In these women, a 50g GCT was done and in those women with a value more than that determined by the retrospective study (the mean value at which maternal/ perinatal complications were noted) were subjected to a 100g oral glucose tolerance test. Carpenter Couston criteria were taken for diagnosis for GDM. Sensitivity, specificity, positive and negative predictive values were calculated for different GCT thresholds. The GCT was performed by administering 50g glucose (mixed in 100ml water) orally irrespective of the prandial state. A venous sample was collected at 1 hour following administration and subjected to glucose assessment in milligrams/ deciliter. In the women in whom a 100g oral GTT was done, the test was performed if the GCT value was above the mean calculated in the retrospective study (fig. 1). The woman was either admitted and the test performed or she was given the choice of it being done in the OPD where she was asked to present in a fasting state. A fasting venous blood sample was then collected. Following this, 100 grams of glucose (mixed in 100ml water) was given and venous blood samples were collected at 1 hour, 2 hour and 3 hour intervals and subjected to glucose analysis. The following were taken as cut off values for diagnosis of Gestational

**Table 1: Maternal & Perinatal Complications**

	Maternal Complications			Fetal/ Neonatal Complications		
	Present	Absent	Total	Present	Absent	Total
<b>Number (%)</b>	48 (4.81)	949 (95.18)	997 (100)	110 (11.03)	887 (88.97)	997 (100)

**Table 2: Mean GCT at which maternal and fetal/ neonatal complications seen**

	Mean GCT	SD	Mean SE
Maternal Complication Present (N = 48)	123.56	23.8	3.435
Fetal/ Neonatal Complication Present (N =110)	124.15	24.5	2.329

Diabetes Mellitus (GDM) as per the Carpenter Couston Criteria.

Data was collected using a pre-tested semi structured proforma, the proforma is designed taking inputs from previous studies. The collected data was analysed using SPSS Version 11.5

### Results

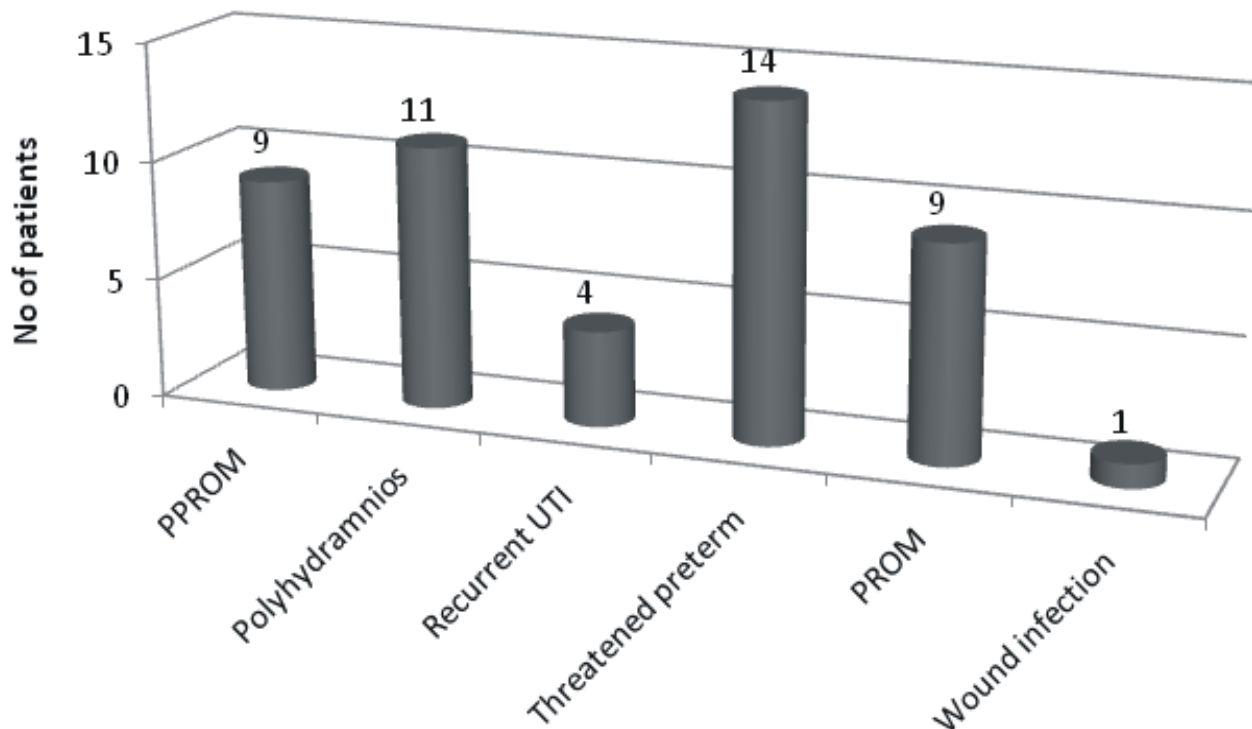
The Retrospective study included 997 women with a GCT value between 24 to 28 weeks. Irrespective of this value, complications of GDM were noted. Maternal complications of GDM were noted in 4.81% (table 1) and the mean value of GCT at which complications were noted was  $123.56 \pm 23.8$  (table 2). Fetal and neonatal complications of GDM were seen in 11% (table 1) and the mean GCT at which these complications were seen at a value of  $124.15 \pm 24.5$  (table 2).

Graph 1 shows the distribution of maternal complications (of gestational diabetes mellitus) in women who had a GCT done between 24 to 28 weeks, i.e. among 48 women, The most common complication

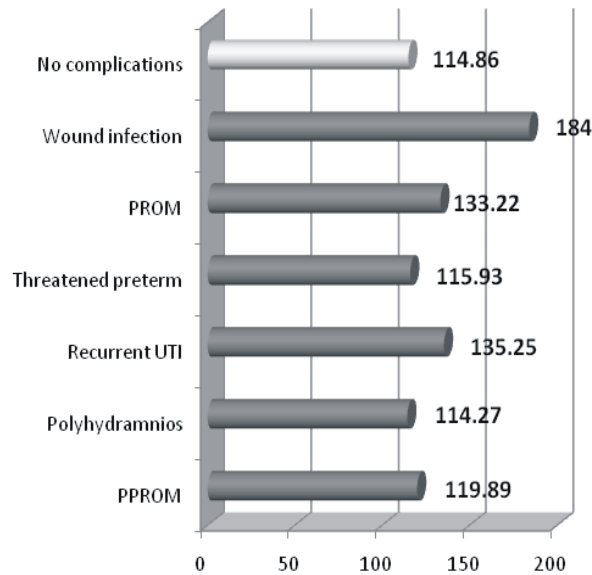
seen was threatened preterm (14). The other complications were preterm prelabor rupture of membranes, polyhydramnios, and recurrent urinary tract infection. Wound infection was seen only in 1 patient. Graph 2 depicts the mean GCT at which different maternal complications were seen. For most complications (except wound infection), the mean GCT was observed at  $< 140$  mg/dl.

Similarly, graph 3 shows the distribution of fetal and neonatal complications of gestational diabetes in women who had a GCT done between 24 to 28 weeks, i.e. among 110 women. The most common complication amongst them observed was preterm labor seen in 35 patients. Respiratory distress syndrome (21 patients) and low Apgar was also seen commonly (20 patients). Other complications observed were Intrauterine death (8 patients), Macrosomia (13 patients), electrolyte imbalance (2 patients), hypoglycaemia (5 patients) and hyperbilirubinemia (7 patients). Graph 4 depicts the mean GCT at which different fetal and neonatal complications were seen. For most complications (except macrosomia), the mean GCT was observed at  $< 140$  mg/dl.

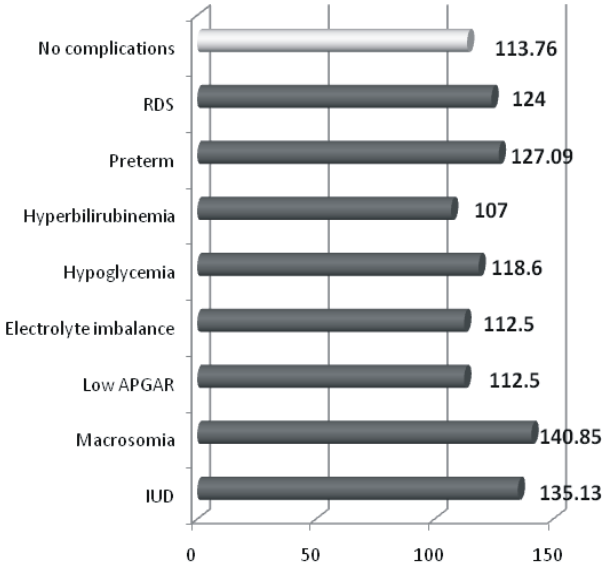
**Graph 1: Maternal Complications**



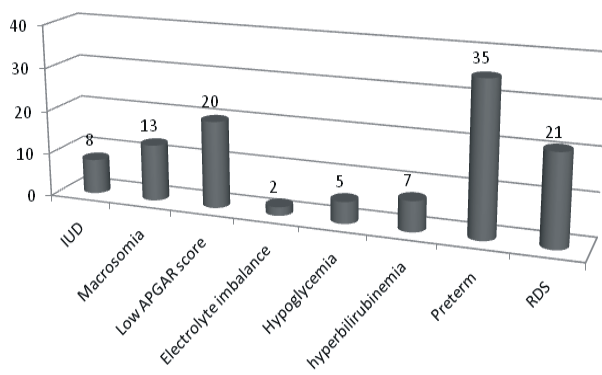
**Graph 2: Mean GCT at which Maternal Complications Observed**



**Graph 4: Mean GCT at which Fetal/ Neonatal Complications Observed**



**Graph 3: Fetal/ Neonatal Complications**



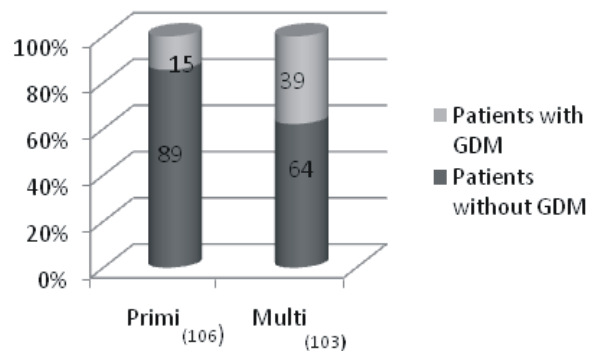
**Table 3: Demographic Characteristics of the population studied: Age**

Age (years)	No. Of Cases (N)	Abnormal GTT (%)
< 19	1	0 (0)
20 – 24	52	10 (19.2)
25 – 29	113	29 (25.66)
30 – 34	35	11 (31.4)
35 – 39	8	4 (50)
Total	209	54

The mean GCT at which maternal, fetal and neonatal complications were seen in the retrospective study was 124mg/dl. Hence, in the cross-sectional study, 124mg/dl was taken as the lower threshold above which a 100g OGTT was done. Thus, all patients between 24 to 28 weeks whose GCT was 124mg/dl were subjected to a 100g OGTT. The number of women thus recruited in the study was 209. The demographic characteristics (age and parity) are as shown below. .

Table 4 shows the number of patients with abnormal GTT (i.e. diagnosed to have GDM) in different GCT groups (at increments of 10mg/dl). Out of a total of 209 patients, 54 were diagnosed to have GDM (25.8%). In the first group, i.e. women with a GCT between 124 to 129 mg/dl, there were 60 patients

**Graph 5: Distribution by Parity**



**Table 4: No. of patients with GDM in different GCT groups**

GCT Group	GTT		
	Normal (%)	Abnormal (%); i.e. GDM +	Total (%)
124 – 129	58 (96.7)	2 (3.3)	60
130 – 139	43 (89.6)	5 (10.4)	48
140 – 149	27 (71.1)	11 (28.9)	38
150 – 159	18 (51.4)	17 (48.6)	35
160 – 169	6 (50)	6 (50)	12
170 – 179	0 (0)	4 (100)	4
180 – 189	3 (42.9)	4 (57.1)	7
190 – 199	0	5 (100)	5
Total	155 (74.2)	54 (25.8)	209 (100)

**Table 5: No. of patients with GDM at different GCT threshold values**

GCT Threshold Value (mg/dl)	No of patients (n)	Diagnosed to be GDM (%)
= 125	203	54 (26.6)
= 130	152	51 (33.55)
= 135	124	49 (39.51)
= 140	101	47 (46.53)
= 145	87	42 (47.72)
= 150	61	34 (55.73)
= 155	53	23 (53.48)
= 160	27	18 (66.66)
= 165	24	17 (70.83)
= 170	16	13 (81.25)
= 175	15	12 (80)
= 180	12	9 (75)
= 185	8	7 (87.5)
= 190	5	5 (100)

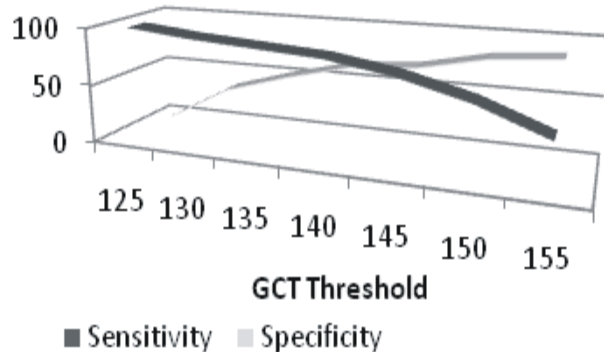
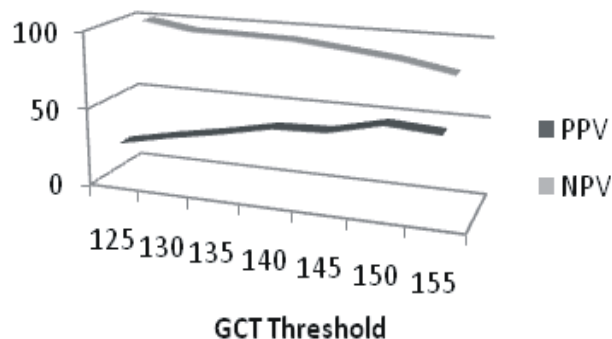
out of which only 2 had GDM. As the GCT increased, the number of patients with GDM also increased as seen in the last group (GCT 190 – 199mg/dl), all 5 patients had GDM. Similarly, we also distributed the patients according to different threshold values for GCT starting from 125mg/dl till 190mg/dl (table 5) At a cut off threshold of 125mg/dl, there were 26.6% patients diagnosed with GDM. As the threshold value increased, the number of patients decreased and the proportion of those diagnosed with GDM increased.

Table 6 shows the sensitivity, specificity, positive and negative predictive values are shown. Most

guidelines suggest a cut-off value of 140 mg/dl. At this cut off, we observed a sensitivity of 87.03%, a specificity of 65.8%, a positive predictive value of 46.53% and a negative predictive value of 93.57%. As the threshold values increased, the sensitivity decreased (100% at 125mg/dl to 41.07% at 155mg/dl) and the specificity increased (3.87% at a threshold value of 125mg/dl and 87.09% at a threshold value of 155mg/dl). Similarly the negative predictive value decreased with increasing thresholds and the positive predictive value increased with increasing GCT thresholds (graph 6 & 7).

**Table 6: Sensitivity, Specificity, PPV & NPV at different threshold values**

GCT Threshold Value	Sensitivity (%)	Specificity (%)	Positive Predictive value (%)	Negative Predictive Value (%)
125	100	3.87	26.6	100
130	94.44	34.83	33.55	94.73
135	90.74	51.62	39.51	94.11
140	87.03	65.80	46.53	93.57
145	77.77	70.32	47.72	90.16
150	62.96	82.58	55.73	86.48
155	41.07	87.09	53.48	80.35

**Graph 6: Sensitivity/Specificity at GCT Thresholds****Graph 7: Positive & Negative Predictive Values**

The Receiver-Operator Characteristic (ROC) curve was used to identify the cut-off value of GCT for detecting GDM. In a ROC curve the true positive rate (Sensitivity) is plotted in function of the false positive rate (100-Specificity) for different cut-off points. A test with perfect discrimination has a ROC curve that

passes through the upper left corner (100% sensitivity, 100% specificity). When we plotted the different GCT threshold values on the curve, it was observed that at a value of 143mg/dl, the area under the curve is the maximum and hence for the study done, at this level the sensitivity and specificity are maximum. Thus, statistically, the ideal GCT threshold value for diagnosing GDM is at a value of 143 mg/dl.

### Discussion

The present study involved two parts – a retrospective study and a cross sectional study. The retrospective study was initially done to determine the mean GCT at which maternal, fetal and neonatal complications of Gestational Diabetes Mellitus (GDM) were seen. This value was also used in the cross sectional study. In this, women having a GCT value over and above this pre-determined level were subjected to a 100g GTT to diagnose GDM. This pre-determined level was 124mg/dl as complications were seen to occur even at this level in the retrospective study. South Asian population is known to be a high prevalence area for GDM. However there aren't many studies done in India or more specifically in the Dakshina Kannada population to determine the exact prevalence. One study done in Tamil Nadu in which a total of 4151, 3960 and 3945 pregnant women in Chennai city (Urban), Saidapet (Semi urban) and Thiruvallur (Rural) in the state of Tamil Nadu were screened during 2005 – 2007. Out of this, 1679 pregnant women were detected to have GDM. The prevalence of GDM in the urban, semi urban and rural area was 739 (17.8%), 548 (13.8%) and 392 (9.9%), respectively. The prevalence of GDM across the age group of women in urban area ranged from 10.6% to 35.8%. [6]

The original cut-offs proposed by O'Sullivan in the GCT were obtained from confidence intervals of around 2 SDs when applied to a population of Caucasian and black women in Boston, so the proportion affected was 3% by definition. Similar criteria are now applied to other population. However the prevalence varies according to other factors. One of the major determinants of the risk for the development of subsequent type 2 diabetes is ethnic origin. Thus, GDM may affect as many as 15% of south Asian women in different populations (As demonstrated in the example in Tamil Nadu above), while for Caucasian women whose overall risk of type 2 diabetes is lower, the risk may be as low as 3%. [8]

Because this is a screening test, the cut-off value to define a "positive" result should take into account the prevalence of GDM in a given population. The threshold for "positive" must provide an appropriate balance between identifying as many people who have the disease as possible, without exposing too many normal patients to tests that are more dangerous, costly, or time consuming. The most commonly used cut-off value for the GCT is 140 mg/dl which results in approximately 15% positive tests. By reducing the cut-off to 130 mg/dl, the sensitivity of the test (i.e., the proportion of women who have GDM who have a "positive" screen) can improve, at the expense of specificity. [9]

**Table 7: Comparison of different threshold values for GCT**

	Threshold (mg/dl)	Sensitivity (%)	Specificity (%)
O'Sullivan (1973) <sup>10</sup>	140	79	87
Marshall (1982) <sup>11</sup>	135	99	95
Jirapinyo (2003) <sup>12</sup>	140	86	65
Miyakoshi (2003) <sup>13</sup>	140	96	76
Yogev (2004) <sup>14</sup>	130 (recommended)	97	63
Juntarat (2007) <sup>15</sup>	150 (by ROC)	80.1	62.7
Gandevani et al (2011) <sup>16</sup>	140 (recommended)	95.3	48.6
	135 (by ROC)	95	80
	130	94.4	34.61
Present Study (2011)	135	90.7	51.9
	140	87	65.4
	143 (ROC)	83.3	72.3

Various population based studies have thus been carried out assessing the cut off of the glucose challenge test based on the prevalence of GDM in that particular population as shown in table 7 along with O'Sullivan's original study where he first determined the cut-off value of GCT.

In the comparison of different GCT threshold values in different studies as shown above the recommended value ranges between as low as 130 mg/dl to as high as 150 mg/dl. O'Sullivan recommended a cut off value of 140 mg/dl which gave a sensitivity of 79% and a specificity which was quite high (87%) [10]. Marshall et al (1982) [11] recommended the threshold value to be 135mg/dl whereas Jirapinyo [12] and Miyakoshi et al [13] recommended the threshold to be at 140 mg/dl and not lower. These 2 studies were done in Asian populations (Thailand and Japan respectively) [12, 13]. Yogev et al [14] which based their study on a Mexican American population (a high risk population) revealed that a threshold of 130 mg/dl may be recommended as a screening threshold for GDM in these women. They found that

the sensitivity and negative predictive value for GDM was highest at 130mg/dl. The other high risk population recently studied (2011) was in an Iranian population [16] in which a total of 1804 consecutive native Iranian women who underwent a glucose challenge test were prospectively investigated. The test was performed between 24 to 28 weeks of gestation; each subject received a 50-g oral glucose load regardless of her fasting or fed state; the 1-h venous plasma glucose level was then determined. Women exceeding 130 mg/dl received the diagnostic 100-g, 3-h oral glucose tolerance test to determine whether or not they had gestational diabetes mellitus. The receiver-operator characteristic curve in this study identified a glucose challenge test finding above 135 mg/dl as the cut-off value for detecting gestational diabetes mellitus, which showed a sensitivity and specificity of 95% and 80%, respectively. They suggested that the cut-off value of a 50-g glucose challenge test is 135 mg/dl to identify pregnancies with gestational diabetes mellitus in an Iranian population [16].

**Table 8: Comparison of sensitivity, specificity, PPV & NPV of threshold value of GCT = 130mg/dl in different studies**

Reference	GCT threshold (mg/dl)	Sensitivity (%)	Specificity (%)	PPV (%)	NPV (%)
Yogev et al (2004) <sup>14</sup>	130*	97	63	16	99
Juntarat et al (2007) <sup>15</sup>	130	100	38.2	-	-
Present Study (2011)	130	94.4	34.6	33.3	94.7

**Table 9: Comparison of sensitivity, specificity, PPV & NPV of threshold value of GCT = 135mg/dl in different studies**

Reference	GCT threshold (mg/dl)	Sensitivity (%)	Specificity (%)	PPV (%)	NPV (%)
Yogev et al (2004) <sup>14</sup>	135	91	73	20	99
Juntarat et al(2007) <sup>15</sup>	135	98.8	418.	-	-
Present Study (2011)	135	90.7	51.9	39.5	94.1

**Table 10: Comparison of sensitivity, specificity, PPV & NPV of threshold value of GCT = 140mg/dl in different studies**

Reference	GCT threshold (mg/dl)	Sensitivity (%)	Specificity (%)	PPV (%)	NPV (%)
Yogev et al (2004) <sup>14</sup>	140	85	78	23	98.6
Juntarat et al(2007) <sup>15</sup>	140*	95.3	48.6	-	-
Present Study (2011)	140	87	65.3	40.5	93.5

\* Recommended

Two most recent studies i.e. Yogev et al and Juntarat et al, both of which have been done in populations with a high prevalence of gestational diabetes are similar to our study. In the study by Yogev et al [14] in Mexican American women done in 2004, a value of 130mg/dl was recommended for diagnosing GDM. The sensitivity and specificity found in their study at values of 130mg/dl and 140mg/dl were practically the same [14]; therefore, as a screening procedure, there is no difference between these threshold values. However, the high prevalence of GDM in Mexican Americans directed them to select a lower threshold for screening, i.e. 130mg/dl. In the study by Juntarat et al [15] done in Thailand; by using the ROC curve, at the level of 150mg/dl, the sensitivity and specificity were 80.1% and 62.7% respectively which was statistically the best value for screening. However, in high-risk group, the screening must have high sensitivity that was more efficient in identifying almost all cases of GDM. If the authors used 140 mg/dl as the cut-off value, the sensitivity was increased to 95.3% with the specificity of 48.6%. Therefore, in the study, the authors recommended a cut-off value for the GCT of 140mg/dl when screening

GDM in high-risk pregnancy. Only two cases (0.24%) were missed diagnosis with these values. Using 130 or 135 mg/dl as the cut off, only slightly increased the sensitivity but greatly reduced the specificity of the test. This led to unnecessarily performing unnecessarily OGTT in 109 cases.

Similarly in our study, we got a very high sensitivity at a cut off at 130mg/dl, i.e. 94.4% but a low specificity (only 34.6%). But when this cut off was raised to 135mg/dl and further more to 140mg/dl, although the sensitivity slightly reduced, the specificity increased. The specificity at a threshold value of 135mg/dl was 51.9%. The receiver operator characteristic (ROC) curve suggested a cut-off of 143mg/dl for a good sensitivity and specificity but in a high prevalence population like ours, especially in the presence of high risk factors, we recommend lowering the threshold to 135mg/dl. One important reason behind this was that in spite of the statistically calculated value of 143mg/dl, when a cut off of 135mg/dl was taken, 5 cases of GDM were not diagnosed. At a value of 143mg/dl, 9 cases were not diagnosed. Hence, by decreasing the threshold from 143mg/dl to 135 mg/dl, an additional 4 cases were



diagnosed at the cost of performing an extra of only 30 diagnostic tests (100g GTT). In other words, by decreasing the threshold to 135mg/dl, for every extra case diagnosed, only 5 extra GTT's had to be done. In a high prevalence population and where the complications of GDM can cause significant mortality/ morbidity, a GCT threshold value of 135mg/dl thus seems to be ideal.

Critical analysis of our study revealed the following drawbacks which we would like to bring forward and discuss. Firstly, in the retrospective study, various complications of GDM were noted in women who had a GCT done between 24 to 28 weeks, for example preterm labor, wound infections, hyperbilirubinemia etc. These complications though can occur as a result of GDM, they are also the result of other conditions. Secondly, the outcome of women diagnosed as GDM by our analysis in the cross sectional study was not analysed thereby not allowing us to actually observe if lowering the threshold and diagnosing more cases of GDM was beneficial in terms of improving maternal, fetal and neonatal outcome. Though our study helped us to determine whether or not we should lower our current threshold value of GCT in our population, these results are limited to women of Dakshina Kannada and further studies from other parts of India are needed to determine if the same can be replicated and guidelines made based on the common findings.

## Conclusion

Statistically, a threshold of 143mg/dl has the best diagnostic accuracy for a 1h 50g GCT for gestational diabetes. As there is an increased prevalence of GDM in the Indian population [7]; a lower threshold of 135mg/dl may be recommended as a screening threshold for a 1h 50g GCT. This value has a high sensitivity (91%) and moderate specificity (52%).

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