

Comparison of Screening for Hyperglycemia in Pregnancy by OGCT v/s HBA1C

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Abstract: ***Aims and Objectives:** To compare HBA1C as a screening test to diagnose GDM with OGCT. **Background:** India, being a high risk group for GDM needs a screening program for early diagnosis and to initiate treatment at the earliest. Owing to the many adverse effects of GDM on the mother and the fetus, it makes it of utmost importance to formulate a method. Thus, this study is undertaken to analyse the available modalities to screen antenatal patients and to use the most accurate one, to routinely screen for GDM. HBA1C being a more convenient method, must be evaluated for its usefulness in screening of GDM. **Methodology:** This study was undertaken over a period of 2 years, between October 2015 to September 2017, In department of Obstetrics and Gynaecology at Father Muller Medical College, Mangalore, Karnataka. 100 women attending the Antenatal clinic in FMMC were enrolled in the study. Consents were taken, and blood drawn for OGCT and HBA1C. The same patients were then subjected to OGTT. Test results were then obtained from biochemistry laboratory records and patients were diagnosed to either be cases of gestational Diabetes mellitus or not depending on the OGTT results. The relation between the OGCT and HBA1C results of these patients and the carbohydrate tolerance status was then established following subjecting the results to statistical analysis. **Results:** On statistical analysis it was identified that OGCT was a better screening test for GDM in comparison to HBA1C with the following values*

	Sensitivity	Specificity	PPV	NPV	P value
OGCT	78.60%	70.50%	77.20%	72.10%	<0.001
HBA1C	55.40%	61.40%	64.60%	58.00%	0.110

Conclusion: *To conclude, it was identified that OGCT was a more sensitive, specific screening test and had higher positive and negative predictive value to screen for GDM in high risk groups like antenatal patients in India.*

Keywords: GDM, HBA1C, OGCT

1. Introduction

GDM is defined as “carbohydrate intolerance with recognition or onset during pregnancy” irrespective of the treatment with diet or insulin.¹

It is seen as a result of lack of beta cell function that makes the patient unable to overcome the action of anti-insulin hormones released in pregnancy.²

Gestational diabetes mellitus is highly prevalent in the Indian subcontinent making ours a high risk population.³

The recent prevalence of GDM in our country was found to be 16.55% by WHO.³

According to WHO a 75gms OGTT is used for diagnosis of GDM, and a value of more than 120 mg/dl is suggestive of decreased gestational glucose tolerance, and 140mg/dl diagnostic for GDM. A value of more than 200mg/dl is diagnostic of diabetes mellitus.⁴

The implications of GDM are debilitating to the mother and fetus and hence early diagnosis and management is of utmost importance.^{5,6}

Use of HBA1c as a screening modality has been suggested due to its convenience. It does not subject the patients to adverse effects like nausea and when done in the first

trimester, it is suggestive of the blood sugar status of the patient for the last 3 months, thus differentiating GDM patients from those with overt Diabetes.⁸

Hence this study was undertaken, to identify the apt screening modality for early diagnosis of Gestational diabetes and initiation early treatment either by medical nutrition therapy, oral hypoglycemic agents or insulin depending on the severity.

2. Aim

To compare HBA1C as a screening test to diagnose GDM with OGCT

3. Methodology

This study was undertaken over a period of 2 years, between October 2015 to September 2017, In department of Obstetrics and Gynaecology at Father Muller Medical College, Mangalore, Karnataka

100 women attending the Antenatal clinic in FMMC were enrolled in the study. Consents were taken, and blood drawn for OGCT and HBA1C. The same patients were then subjected to OGTT.

Test results were then obtained from biochemistry laboratory records and patients were diagnosed to either be

cases of gestational Diabetes mellitus or not depending on the OGTT results.

The relation between the OGCT and HBA1C results of these patients and the carbohydrate tolerance status was then established following subjecting the results to statistical analysis.

A total of 100 patients who underwent oral glucose tolerance test were identified from biochemistry laboratory records, and 56 were identified as gestational diabetes mellitus and 44 were not found to be cases of gestational diabetes mellitus.

N=100

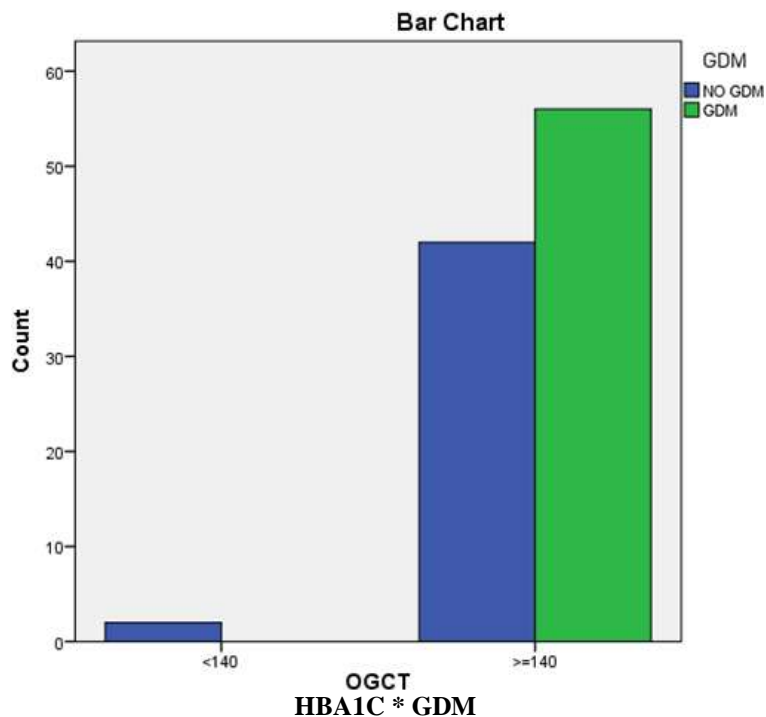
4. Results

OGCT		HBA1C	
Normal	Abnormal	Normal	Abnormal
2	98	87	13

OGCT * GDM

Crosstab					
			GDM		Total
			NO GDM	GDM	
OGCT	<140	Count	2	0	2
		% within OGCT	100.0%	0.0%	100.0%
		% within GDM	4.5%	0.0%	2.0%
	>=140	Count	42	56	98
		% within OGCT	42.9%	57.1%	100.0%
		% within GDM	95.5%	100.0%	98.0%
Total		Count	44	56	100
		% within OGCT	44.0%	56.0%	100.0%
		% within GDM	100.0%	100.0%	100.0%

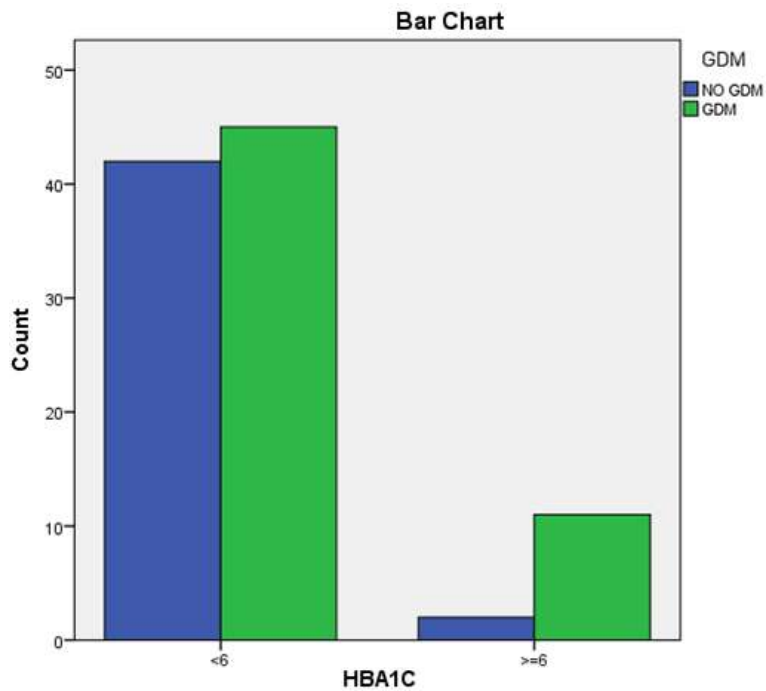
Symmetric Measures						
		Value	Asymp. Std. Error ^a	Approx. T ^b	Approx. Sig.	Exact Sig.
Measure of Agreement	Kappa	.051	.035	1.612	.107	.191
N of Valid Cases		100				
a. Not assuming the null hypothesis.						
b. Using the asymptotic standard error assuming the null hypothesis.						



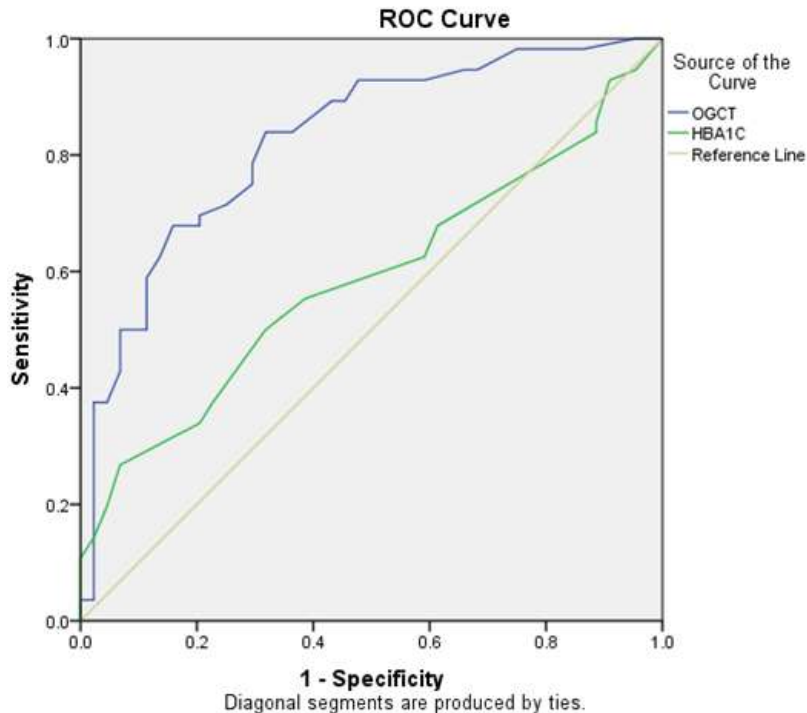
Crosstab					
			GDM		Total
			NO GDM	GDM	
HBA1C	<6	Count	42	45	87
		% within HBA1C	48.3%	51.7%	100.0%
		% within GDM	95.5%	80.4%	87.0%
	>=6	Count	2	11	13

		% within HBA1C	15.4%	84.6%	100.0%
		% within GDM	4.5%	19.6%	13.0%
Total		Count	44	56	100
		% within HBA1C	44.0%	56.0%	100.0%
		% within GDM	100.0%	100.0%	100.0%

Symmetric Measures						
		Value	Asymp. Std. Error ^a	Approx. T ^b	Approx. Sig.	Exact Sig.
Measure of Agreement	Kappa	.137	.058	2.228	.026	.035
N of Valid Cases		100				
a. Not assuming the null hypothesis.						
b. Using the asymptotic standard error assuming the null hypothesis.						



Roc curve analysis for assessment of cutoff



Area Under the Curve					
Test Result Variable(s)	Area	Std. Error ^a	P value	Asymptotic 95% Confidence Interval	
				Lower Bound	Upper Bound
OGCT	.827	.042	<0.001	.745	.908
HBA1C	.587	.057	.138	.476	.698
The test result variable(s): OGCT, HBA1C has at least one tie between the positive actual state group and the negative actual state group. Statistics may be biased.					
a. Under the nonparametric assumption					
b. Null hypothesis: true area = 0.5					

The area under the curve is higher for OGCT so that is a better indicator of GDM

Cutoffs coordinate

Test Result Variable(s)	Positive if Greater Than or Equal To a	Sensitivity	Specificity
OGCT	131	100.00%	0.00%
	135	100.00%	2.30%
	139	100.00%	4.50%
	140.5	98.20%	13.60%
	141.5	98.20%	20.50%
	142.5	98.20%	22.70%
	143.5	98.20%	25.00%
	144.5	94.60%	31.80%
	145.5	94.60%	34.10%
	146.5	92.90%	40.90%
	147.5	92.90%	43.20%
	148.5	92.90%	47.70%
	149.5	92.90%	52.30%
	150.5	89.30%	54.50%
	151.5	89.30%	56.80%
	152.5	87.50%	59.10%
	153.5	83.90%	63.60%
	154.5	83.90%	68.20%
	155.5	78.60%	70.50%
	156.5	76.80%	70.50%
	157.5	75.00%	70.50%
	159	71.40%	75.00%
	160.5	69.60%	79.50%
	161.5	67.90%	79.50%
	162.5	67.90%	81.80%
	163.5	67.90%	84.10%
	164.5	62.50%	86.40%
	165.5	58.90%	88.60%
	166.5	51.80%	88.60%
	167.5	50.00%	88.60%
	168.5	50.00%	90.90%
	169.5	50.00%	93.20%
	171	48.20%	93.20%
	173	46.40%	93.20%
	174.5	42.90%	93.20%
	175.5	37.50%	95.50%
	176.5	37.50%	97.70%
	177.5	32.10%	97.70%
	179.5	26.80%	97.70%
	184.5	25.00%	97.70%
	188.5	23.20%	97.70%
	189.5	21.40%	97.70%
	190.5	19.60%	97.70%
	194	17.90%	97.70%
	198	16.10%	97.70%
	200	10.70%	97.70%
	203	7.10%	97.70%
	207.5	5.40%	97.70%
	215.5	3.60%	97.70%

	229.5	3.60%	100.00%
	239	1.80%	100.00%
	241	0.00%	100.00%
HBA1C	3.8	100.00%	0.00%
	4.85	94.60%	4.50%
	4.95	92.90%	9.10%
	5.05	85.70%	11.40%
	5.15	83.90%	11.40%
	5.25	67.90%	38.60%
	5.35	62.50%	40.90%
	5.45	55.40%	61.40%
	5.55	50.00%	68.20%
	5.65	37.50%	77.30%
	5.75	33.90%	79.50%
	5.85	26.80%	93.20%
	5.95	19.60%	95.50%
	6.1	14.30%	97.70%
	6.3	10.70%	100.00%
	6.5	8.90%	100.00%
	6.65	7.10%	100.00%
	6.8	5.40%	100.00%
	7.25	3.60%	100.00%
	8.6	0.00%	100.00%

Sensitivity Specificity Based on New Cutoffs

Parameter	Both Negative	Both Positive	Test Negative Gold Standard Positive	Test Positive Gold Standard Negative	Sensitivity	Specificity	Positive Predictive Value	Negative Predictive Value	Diagnostic Accuracy	Gold Standard	Kappa Statistics	P Value
OGCT (Cutoff Of 155.5)	31	44	12	13	78.60%	70.50%	77.20%	72.10%	75.00%	GDM	0.4910	<0.001
HBA1C (Cutoff Of 5.45)	27	31	25	17	55.40%	61.40%	64.60%	51.90%	58.00%	GDM	0.1640	0.1100

On comparison of the test group OGCT (CUTOFF OF 155.5) with the Gold standard of GDM the test group has a sensitivity of 78.6 % and specificity of 70.5%. The test has a positive predictive value of 77.2% and Negative predictive value of 72.1%. The test and the gold standard agree on 75 out of 100 having a diagnostic accuracy of 75%. The Kappa value of 0.491 indicates Good agreement with a p value of <0.001.

On comparison of the test group HBA1C (CUTOFF OF 5.45) with the Gold standard of GDM the test group has a sensitivity of 55.4 % and specificity of 61.4%. The test has a positive predictive value of 64.6% and Negative predictive value of 51.9%. The test and the gold standard agree on 58 out of 100 having a diagnostic accuracy of 58%. The Kappa value of 0.164 indicates Poor agreement with a p value of 0.11.

5. Discussion

A two step approach normally implemented for screening and diagnosis of GDM has been found to be cumbersome for the patient. Hence various studies have been undertaken to identify and establish an alternate method that is easier and thus increasing patient compliance.

This study was undertaken to analyse if HBA1C can be used for screening of GDM like in non pregnant Diabetes Mellitus were its role has already been proven.

According to a study conducted by Odsaeter et al (2016) HBA1C may be used to exclude GDM in a significant number of antenatal women with a sensitivity of 88% if the cut off is considered as 4.8% and 97% if the cut off considered is 5% at 32-36weeks. The study also concluded that at 18-22weeks the sensitivity of HBA1C was 96% for a cut off value of 4.7% to rule out the risk of developing GDM thus eliminating the need for an OGTT. ⁸

Rajput et al (2012) evaluated 607 women to analyse the usefulness of HBA1C in diagnosis of cases of GDM that were diagnosed based on the American Diabetes Association criteria that is 75gms OGTT studied. The cut off considered was 5.4%. 607 women between 24 and 28 weeks' gestation, similar to our study, and they established a sensitivity of 85.7% and specificity of 61.1% for HBA1C. ⁹

Aldasouqi et al (2008) was also of the opinion that when HBA1C was used in 145 high risk women diagnosed with GDM based on OGTT, it diagnosed 87% cases of GDM, when the cut off of HBA1C considered was 6%. ¹⁰

In our study, Of the 100 patients that underwent OGTT, 56 patients were identified to be gestational diabetes mellitus, while 44 patients were found to be normal. The Oral glucose challenge test results of the same patients were identified and compared between patients diagnosed as GDM and not. The similar procedure was carried with HBA1C levels. By this study, it can thus be concluded that the more suitable modality to screen for GDM in high risk groups is OGCT

(cut off – 155.5) , with Sensitivity-78.60%, Specificity-70.50%, Positive predictive value-77.20%

Negative predictive value-72.10% and P value, <0.001, In comparison to HBA1C (cut off 5.45) with Sensitivity-55.40%, Specificity-61.40%, Positive predictive value-64.60%

Negative predictive value-51.90% and P value, 0.110

Hence, with the contrasting results obtained in this study, It may be understood that with a larger sample size an attempt at establishing HBA1C as a single non fasting screening modality for GDM with an appropriate cut off.

6. Conclusion

Thus from the above results and discussion it can be concluded that in a high risk group like Indian population, screening of GDM is of utmost importance. According to the above study OGCT has a better sensitivity, specificity and predictive value in comparison to HBA1C., that could be a feasible as well as accurate to screen for Gestational Diabetes Mellitus, allowing early diagnosis and management, thereby reducing complications associated with GDM. Hence a study on larger study sample must be considered with an optimal cut off must be tried.

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