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Abnormal glucose challenge test in pregnancy: A study at tertiary care hospital

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Abstract
The study was carried out to find out prevalence of abnormal glucose challenge test (GCT), using DIPSI guidelines by using venous as well as capillary glucometer test in pregnant women and also to study the risk factors along with feto-maternal outcome in diagnosed cases of abnormal GCT.

Material & Methods: The present longitudinal study was conducted between June 2015 to May 2017 in GMCH, Aurangabad. A total of 700 pregnant women seeking antenatal care between 16-32 weeks gestation were enrolled for study. Selected women were subjected for 75gm oral glucose challenge test. Venous plasma glucose as well as capillary blood glucose values were estimated and compared. Abnormal glucose tolerance was diagnosed on the basis of 2 hour plasma glucose values more than 120 mg/dl. Prevalence of abnormal GCT & risk factors were studied. Women diagnosed and treated as per DIPSI guidelines and followed up for maternal and fetal outcome. Data collected was entered in Microsoft excel and analysed further using SPSS Software version 23 package.

Results: Out of 700 antenatal women, 70 women were diagnosed as having abnormal GCT by venous plasma glucose. method. Abnormal GCT was seen in 10% of the screened participants. Statistically Significant association was found between abnormal GCT and age, BMI, gravidity, positive family history, history of previous fetal or early neonatal deaths. Sensitivity of capillary glucometer method was 100% and specificity was 99.68% when compared to venous laboratory method. Out of 70 cases diagnosed as abnormal GCT, 6 lost to follow up. In follow up of 64 women with abnormal GCT, 50 women were treated with medical nutritional therapy and 20 required MNT & insulin. 56 women delivered at term & 8 women had preterm delivery.

Conclusion: In low resource settings where Venous plasma glucose is impossible, universal and timely screening of all pregnant women with 75 gm GCT with glucometer should be done to reduce adverse pregnancy outcome and for preventing type 2 DM. Creating awareness regarding risk factors and targeting this population for lifestyle modification is very essential in order to prevent fetal origin of adult onset diseases.

Keywords: Abnormal glucose challenge test, decreased gestational glucose tolerance, gestational diabetes, medical nutritional therapy, venous plasma glucose

Introduction
Gestational Diabetes Mellitus (GDM) has been identified as a potential risk factor for poor health status in pregnant mothers which has a causal relationship with various complications during pregnancy and child birth, contributing directly to increase in maternal and neonatal morbidity and mortality. Diagnosis and management of GDM is a step forward in preventing morbidity and mortality among mothers and young infants. DIPSI has endorsed "A one step procedure with a single glycemic value" to diagnose GDM in the community which causes least disturbance in a pregnant woman's life and serves screening as well as diagnostic procedure. This single step procedure has been approved by Ministry of Health, Government of India (GOI). DIPSI also clearly categorizes Abnormal Glucose Tolerance in Pregnancy as decreased gestational glucose tolerance (DGGT), gestational diabetes mellitus (GDM) and diabetes mellitus (DM) [1].

Prevalence rate of GDM vary widely by ethnicity. South Asian countries and Indian women have the highest frequency of GDM. It is difficult to give a single accurate figure for the prevalence of GDM for India, since data is lacking from many parts of the country, and different authors used different tests and varying criteria for diagnosing GDM. The available data suggest that, the prevalence of GDM in India varies from 3.8% to 21% in different parts of the country depending on geographical locations and diagnostic methods used [2]. The HAPO study showed a continuous strong association between maternal glucose levels below those diagnostic of

diabetes and adverse pregnancy outcomes [3]. If we would consider only GDM cases, we would miss DGGT which is equally important. After implementation of GOI guidelines in 2014, we considered that it is important to generate region-based evidence on the abnormal glucose tolerance in pregnancy as it may be an important predictor of adverse pregnancy outcome.Moreover women with GDM and their offspring are at increased risk of developing type 2 diabetes later in life. Diagnosis and management of abnormal GCT is a step forward in preventing the risk factors and causes of morbidity and mortality among mothers and young infants.

In periphery, even though we decide to screen all pregnant women for GDM, availability of semi auto-analyser or auto-analyser or any other testing methodology may lead to delay in getting results immediately. It will be difficult for pregnant woman to come another day to just collect the results. This will solely destroy the purpose of "A one step procedure with a single glycemic value", to diagnose GDM in the community. To overcome this difficulty, GOI has endorsed use of glucometer at each facility [4]. Keeping this in mind, this study was being carried out to find out prevalence of abnormal glucose challenge test(GCT), using DIPSI guidelines by using venous as well as capillary glucometer test in pregnant women attending antenatal clinic and also to study the risk factors along with feto-maternal outcome in diagnosed cases of abnormal GCT.

Materials & Methods

The present study was conducted at the antenatal clinic in the Department of Obstetrics and Gynaecology at Government Medical College & Hospital, Aurangabad, Maharashtra, India between June 2015 to May 2017. Sample size was calculated by using this formula: sample size $n=4pq/L^2$ (p=positive character in % of the reference study [5], q=100-p, L=allowable error 20% n which was calculated was 628.7 and the sample size of our study is n=700). A total of 700 pregnant women seeking antenatal care between 16-32 weeks gestation attending OPD or admitted as in patients for the first time during this pregnancy were enrolled for study. This longitudinal observational study was approved by institutional ethics committee and informed consent was taken from the women. Inclusion criteria included singleton pregnant women at 16-32 weeks of gestation irrespective of parity. All pregnant women with pre-gestational diabetes, major chronic diseases like carcinoma, tuberculosis, congestive cardiac failure, renal failure and liver failure or who vomited after taking 75 gm glucose within 30 minutes of intake were excluded from the study.

Detailed history was taken and clinical examination of the enrolled women was carried out. A proforma containing general information like age, parity, socioeconomic status (according to Kuppuswamy classification), family history of diabetes in first degree relatives, past history of GDM and detailed past obstetric history was filled up for each women. BMI was calculated by asking pre-pregnancy weight and measuring the height and BP was recorded. Selected women were subjected for DIPSI test. Women were given 75gm oral glucose(Emcure Uth G75) dissolved in 300ml of water irrespective of their last meal timing. They were asked to drink it within 5 to 10 minutes, time was noted and women were asked to take rest for 2 hours during which they were asked to avoid physical activity. Venous blood sample was drawn at 2 hours and plasma glucose was estimated in the central laboratory by the glucose oxidise – peroxidise (GOD-POD) method. At the same time under all aseptic precautions, pre-calibrated Accu-chek active glucometer (Model GU) reading of capillary blood obtained by pricking the tip of index finger pad which uses conversion of glucose to gulunolactone using glucose oxidase enzyme was taken. Abnormal glucose tolerance was diagnosed on the basis of 2 hour plasma glucose values. Decreased Gestational Glucose Tolerance(DGGT) was diagnosed when the value was between 120-139mg/dl, Gestational Diabetes(GDM) when the value was between 140-199mg/dl and Diabetes Mellitus(DM) when the value ≥200mg/dl. Prevalence of risk factors for GDM like advanced age >25, BMI>25, family h/o diabetes, Previous fetal loss or early neonatal death, were studied in women with abnormal glucose tolerance and normal glucose tolerance group and results were statistically analysed. Results were expressed as numbers and percentages. Women diagnosed as DGGT, GDM & DM were treated as per DIPSI guidelines [1] and followed up for maternal (gestational age at the time of delivery, mode of delivery and complications like preeclampsia, hydramnios, postpartum hemorrhage and preterm labour) and fetal outcome(Apgar's score, birth weight, congenital anomalies, hypoglycemia and admission to NICU).

Data collected was entered in Microsoft excel and analysed further using SPSS Software version 23 package. Descriptive statistics were calculated, chi – square test applied, "p" valve <0.05 was considered statistically significant.

Results: Out of 700 antenatal women tested by 75gGCT, 86.7% belonged to the age group of 20-29 years, 89.8% were belonging to lower (upper lower & lower) class of socioeconomic class and 38.7% of participants were primigravida.

All the cases of abnormal GCT which were diagnosed by laboratory venous method were also diagnosed by capillary glucometer method. Abnormal GCT was seen in 10% of the screened participants among which 8% were diagnosed to have GDM. There was overestimation in 2 cases of diagnosing DGGT by capillary glucose method. (Table 1)

Statistically Significant association was found between abnormal GCT and age, BMI, gravidity, positive family history, history of previous fetal or early neonatal deaths *(*Table 2)

Sensitivity of capillary glucometer method was 100% when compared to venous laboratory method which means no case diagnosed by venous method was missed by capillary method. Negative predictive value being 100%, possibility of having abnormal GCT inspite of normal capillary glucometer values was minimal. Specificity of capillary glucometer method was 99.68% when compared to venous laboratory method while positive predictive value being 97.2% (Table 3)

Out of 64 women with abnormal GCT followed up, 31(48.43%) landed up in LSCS for obstetric indications. Pre-eclampsia was seen in 9 women. Polyhydramnios was seen in 6 and preterm labour was seen in 8 women. (Table 4)

Out of 64 women with abnormal GCT who were followed up, 5 (7.81%) women had macrosomic babies, 6 neonates had Apgar score <7 at 5 minutes and 3 neonates were born with congenital anomalies and all these 3 neonates were belonging to mothers with Diabetes Mellitus (Table 5)

Results

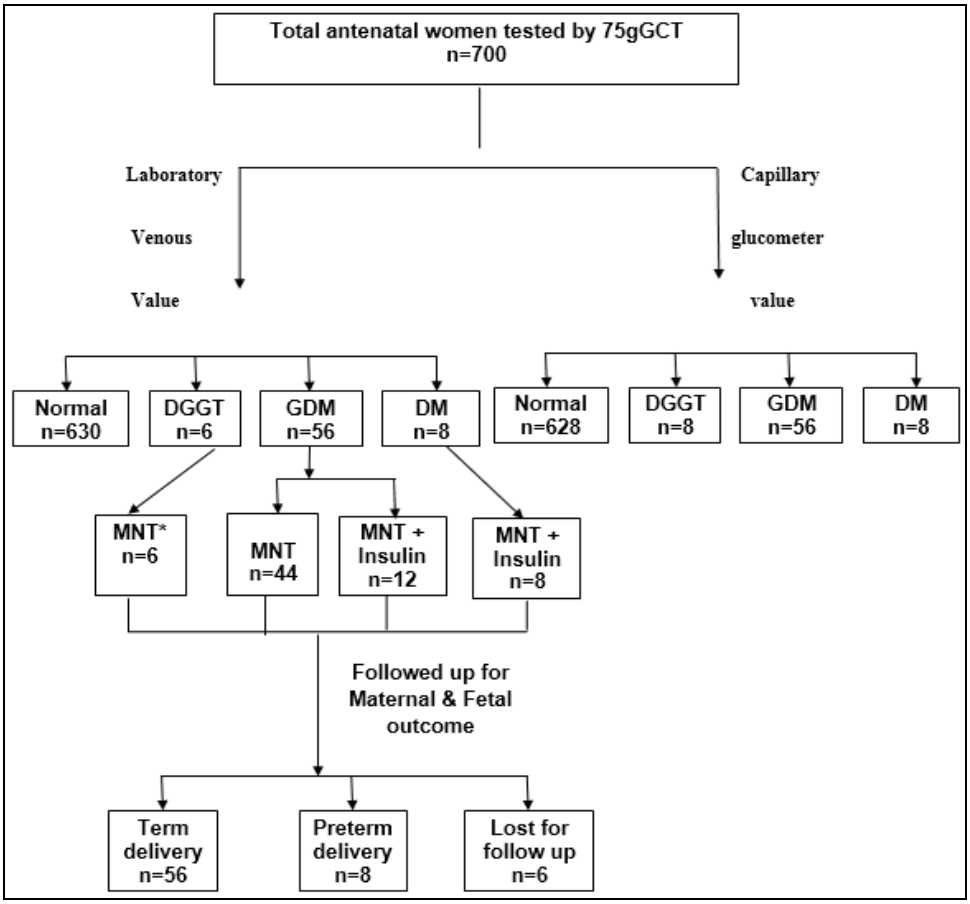

Fig 1: *MNT is medical nutritional therapy

Table 1: Comparison of 75g GCT venous versus capillary glucometer values in study participants:

Category		Results of Venous plasma values n=700(%)	Results of Capillary glucometer values n=700(%)
Normal GCT<120mg/dl		630(90)	628(89.71)
Abnormal GCT >120mg/dl	DGGT(120-140mg/dl)	006(0.8)	008(1.14)
	GDM (140-200mg/dl)	056(8)	056(8)
	DM (>200mg/dl)	008(1.2)	008(1.14)

Table 2: Comparison according to Risk Factors in women abnormal & normal Glucose Challenge test:

Risk Factor		Abnormal GCT n=70	Normal GCT n=630	Statistical test
Age in years	≤19	4	26	Chi square value = 21.48; p value = 0.00025*
	20-24	28	399	
	25-29	25	155	
	30-34	8	41	
	≥35	5	9	
Body Mass Index (kg/m^2)	Underweight(<18.5)	1	82	Chi square value = 136.05; p value = 0.00001 *
	Normal (18.5-25)	32	506	
	Overweight & Obese(>25)	37	42	
Socioeconomic Status	Lower Middle	4	67	Chi square value with Yate's correction= 3.705; p = 0.1568
	Upper Lower	39	390	
	Lower	27	173	
Gravida	One	20	251	Chi square value= 13.06; p=0.011*
	Two	22	194	
	Three	13	126	
	Four	9	44	
	Five	6	15	
Family history	Present	14	28	Chi square value= 27.03; p < 0.00001*
	Absent	56	602	
Previous fetal loss or early neonatal death	Present	21	90	Chi square value= 11.66; p=0.0006387 *
	Absent	49	540	

*Statistically significant association.

Table 3: Evaluation of Validity of capillary glucometer method with Laboratory venous method.

Capillary glucometer values	Venous laboratory values		Total
	Positive	Negative	
Positive	70	02	72
Negative	00	628	628
Total	70	630	700

Sensitivity=100% Specificity=99.68%

Table 4: Maternal Outcome in women abnormal GCT

Maternal Outcome		Abnormal GCT			n =64* (%)
		DGGT n=4	GDM n=52	DM n=8	
Modes of treatment	MNT alone	4	40	0	44(68.75)
	MNT+Insulin	0	12	8	20(31.25)
Gestational age at the time of delivery(weeks)	<37	1	6	1	8(12.50)
	37-40	3	46	7	56(87.50)
Mode of delivery	Vaginal	2	29	1	32(50.00)
	LSCS	2	22	7	31(48.43)
	Instrumental**	0	1	0	1(1.56)
Complications	Pre-eclampsia	2	4	3	9(14.06)
	Preterm Labour	1	6	1	8(12.50)
	Polyhydramnios	0	6	0	6(9.37)
	PPH	0	2	0	2(3.13)

*****Out of 70 women with abnormal GCT,6 were lost to follow up
** Vaccum assisted delivery

Table 5: Fetal outcome of women with abnormal GCT

Fetal Outcome		Abnormal GCT			n =64 (%)
		DGGT n=4	GDM n=52	DM n=8	
Birth weight(kg)	<2.5	1	4	1	6(9.38)
	2.5-2.9	3	7	2	12(18.75)
	3-3.4	0	29	2	31(48.43)
	3.5-4	0	8	2	10(15.63)
	>4	0	4	1	5(7.81)
Apgar score	≥7	4	48	6	58(90.63)
	4-6	0	4	2	6(9.37)
	<4	0	0	0	0
Congenital anomaly	Congenital Heart Disease	0	0	1	1(1.56)
	Cleft Palate	0	0	1	1(1.56)
	CTEV	0	0	1	1(1.56)
NICU Admission	Hypoglycemia	0	4	1	5(7.81)
	RDS	0	0	2	2(3.13)
	Congenital anomaly	0	1	0	1(1.56)

*Out of 70 women with abnormal GCT, 6 were lost to follow up.

Discussion

A universal screening which is simple, feasible, acceptable and a single step procedure is applicable in Indian scenario as Indian women have an eleven fold increased risk of developing glucose intolerance during pregnancy. Screening and diagnosis of GDM and treating it effectively not only prevent adverse maternal and perinatal outcome but also prevents future diabetes in both mother and child. In our study, abnormal GCT was noted in 10% of antenatal women belonging to 16-32 weeks of gestational age. The limitation of the present study was women with normal glucose tolerance at first visit were not asked to repeat test at 24-28 weeks & 32-34 weeks of gestational age as advised by recent national guidelines. So, some cases might have gone un-noticed. There were many studies published from India to see the prevalence of GDM but not a single study was published to see the prevalence of abnormal GCT which is known to have adverse pregnancy outcome.

Global age-adjusted prevalence for GDM has been shown to increase over time with decrease in physical activities, increase in BMI and other associated risk factors. However, variation in this prevalence is seen in different ethnic groups. Though universal screening is recommended in national guidelines, identifying the risk factors will help to create awareness regarding modifying these factors so as to reduce the incidence of GDM and later type 2 diabetes in next generation also.

In our study, advanced maternal age, high BMI and positive family history of DM had statistically significant association with abnormal GCT which is similar to other studies (6,7,8) where advanced maternal age, high BMI and positive family history of DM had statistically significant association with GDM($p < 0.05$).

In the study conducted by Sharma K, Wahi P *et al.* there was a statistically significant association between higher order pregnancies with GDM which is similar to our study wherein abnormal GCT was more common in patients with increasing gravidity [13].

Abnormal GCT women had a statistically significant association with the history of early neonatal or fetal losses in our study. Similarly statistically significant association was seen between GDM patients and history of early neonatal or fetal losses in the study conducted by Kalra P, Kachhwaha C P *et al.* [10].

The most common risk factors observed in women with abnormal GCT were advanced maternal age, high BMI, positive family history of diabetes, previous fetal loss & increasing birth

order. There was no statistically significant association between socioeconomic class and abnormal GCT. Out of the risk factors observed, obesity was a modifiable risk factor.

In many parts of rural India, getting venous blood samples is next to impossible. Hence, several authors have tried to evaluate whether capillary blood glucose (CBG) testing can be used for screening for GDM. Balaji V *et al.* compared capillary and venous samples using WHO 1999 criteria and showed that a CBG value at 2-h plasma glucose level of ≥140 mg/dl had a sensitivity of 80.2% and specificity of 98.5% [11]. Though CBG cannot replace VPG for diagnosis of GDM, it can be used as a screening test, maximizing the sensitivity by using lower 2 h cut-points, in low resource settings where VPG is impossible. In present study, we reported that the sensitivity of CBG using DIPSI criteria was 100% & specificity was 99.68%.This discrepancy might be due to the inclusion of women with abnormal GCT (DGGT and GDM) instead of just GDM.

Good maternal and fetal outcome is the main aim of every Obstetrician. Hence both maternal and fetal outcome was studied in women with abnormal GCT in our study. Among 64 abnormal GCT women in our study, 68.75% required MNT alone and 31.25% required Insulin injection along with MNT which is similar to the study conducted by Kalra P, Kachhwaha C P et al in which 57.27% of GDM women had controlled their sugars by MNT and 42.73% required Inj Insulin along with MNT[10]. Premix insulin (30/70) was given starting with an initial dose of 4U subcutaneously and was increased according to monitored values. Six women with abnormal GCT were lost for follow up were on MNT.

Women with abnormal GCT who were followed up, 12.5% had preterm delivery in our study which is consistent with the study conducted by Wasim T, Wasim A *et al.* in which 13.2% of women with GDM had preterm delivery [12]. In a study conducted by Jain R, Pathak R *et al.* 52% of women with GDM landed up in Cesarean section which is consistent with the present study in which 48.43% women with abnormal GCT landed up in cesarean section [13]. In our study, among women with abnormal GCT, 14% developed pre-eclampsia which is similar to the studies conducted by Qadar S Y, Yasmin T *et al.* [13] and Dahiya K, Saahu J *et al.* [14]. In present study, 9.37% and 3.13% of women with abnormal GCT developed polyhydramnios and PPH respectively.

In our study, 7.81% ofwomen with abnormal GCT developed macrosomia which is consistent with the study conducted by Dahiya K, Saahu J *et al.* [14]. In present study, 4.68% women had congenital anomalies in their babies which is similar to the study conducted by Jain R, Davey S *et al.* [15] NICU admission was required to 12.5% babies in women with abnormal GCT in our study which is consistent with the study conducted by Dahiya K, Saahu J *et al.* [14]. In present study, 7.81% of the babies delivered to abnormal GCT women developed hypoglycaemia which is similar to the study conducted by Qadar S, Tayyaba Y *et al.* [13]

Conclusion

In low resource settings where Venous plasma glucose is impossible, universal and timely screening of all pregnant women with 75 gm GCT with glucometer should be done to reduce adverse pregnancy outcome and for preventing type 2 DM. Creating awareness regarding risk factors and targeting this population for lifestyle modification is very essential in order to prevent fetal origin of adult onset diseases.

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