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Original Research Article

Comparison of maternal and fetal outcomes in gestational diabetes mellitus diagnosed either by oral glucose tolerance test or diabetes in pregnancy study group India

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ABSTRACT

Background: The optimal strategy for screening and diagnosis of Gestational Diabetes Mellitus (GDM) is still controversial and elusive. There is possibility of difference in maternal and fetal outcome depending on the diagnostic method used. This study throws light on the efficacy of two screening tests "Oral Glucose Tolerance Test'' and "Diabetes in Pregnancy Study Group India" and to know maternal and fetal outcome in pregnancy complicated by GDM in Indian setting.

Methods: Depending on the diagnostic method used 100 GDM patients were divided in 2 groups: 1. OGTT, 2. DIPSI. Maternal outcomes were measured in terms of pregnancy induced hypertension, polyhydramnios, preterm labour, genital tract injury and methods of termination of pregnancy, gestational age at delivery. Congenital malformation, macrosomia, hypoglycemia, hyperbilirubinimia, respiratory distress, duration of NICU stay was studied in newborns.

Results: 22% of DIPSI group and 26% of OGTT group had PIH as comorbidity. Preterm delivery was noted in 22% of DIPSI group and 30% of OGTT group. 50% patients of both the groups underwent LSCS. No intrapartum complications were seen in 82% of patients. Malformations were noted in 18% of DIPSI group and 14% of OGTT group. In DIPSI group 14% of baby had macrosomia compared to 10% and in that of OGTT group.

In neonates, hypoglycaemia, respiratory distress syndrome and hyperbilirubinemia seen in 46.8%, 31% and 42.6% respectively in DIPSI group compared to 50%, 45.5% and 47.7% respectively in OGTT group.

Conclusions: No statistically significant difference was noted with respect to maternal and fetal outcomes between the two groups.

Keywords: DIPSI, Gestational diabetes mellitus, Oral glucose tolerance test

INTRODUCTION

There is a progressive increase in the incidence on diabetes mellitus all over the world and it is expected to increase by 165% by the year 2050.[1] The increasing incidence of type 2 diabetes mellitus in the younger people in general has contributed to the increase in the incidence of Gestational Diabetes Mellitus (GDM). GDM is defined as carbohydrate intolerance of variable severity with onset or first recognition during pregnancy.[1] It occurs when women's β-cell function is not able to overcome the antagonism created by anti-insulin hormone of pregnancy and increased fuel consumption required to provide for growing fetomaternal unit.

Asian women are ethnically more prone to develop glucose intolerance compared to other ethnic groups.[2] The relative risk of Indian women developing GDM is 11.3 times compared to White women.[3]

Major concern remains regarding the implications of GDM diagnosis on the pregnant woman and her baby and family, the effect of diagnosis on obstetric interventions. The perinatal, neonatal, maternal outcomes as well as overall health care costs can improve by early identification and treatment of GDM.[4]

The risk is higher in pregestational diabetes, but unrecognized and/or poorly managed gestational diabetes (GDM) may have similar consequences.[5] As such GDM has implications beyond the index pregnancy, identifying two generations (mother and her offspring) at risk of future diabetes. Far-reaching implications can be seen by better identification and treatment of mothers and fetuses at risk.[6]

So, detection and management of GDM is very important. The optimal strategy for screening and diagnosis of GDM is still controversial. Universal versus. Selective screening is under debate.

American Diabetes Association (ADA) recommends two step procedures of 75 grams Oral Glucose Tolerance Test (OGTT) for screening and diagnosis. In India "Diabetes in Pregnancy Study Group India" (DIPSI) single step universal screening of all pregnant women between 24-28 weeks of gestation is being recommended due to high prevalence of GDM in India.

Diabetes in Pregnancy Study Group India (DIPSI), 75 gms oral glucose load in fasting state is given and after 2 hr venous blood sample is collected for estimating blood glucose level.[7]

	Normal	IGT (impaired glucose tolerance)	GDM (Gestational Diabetes Mellitus)
Fasting	< 100 mg/dl	110-125mg/dl	≥126 mg/dl
After 2 hours	< 140 mg/dl	> 140-199mg/dl	≥200 mg /dl

GDM is diagnosed if 2-hour plasma glucose is ≥ 140 mg/dl. Advantages of DIPSI procedure are

- Pregnant woman need not be fasting
- Causes least disturbance in a pregnant woman's routine activities
- Serves as both screening and diagnostic procedure
- This single step procedure has been approved by the Ministry of Health, Government of India and also recommended by the WHO.[8]

The present study was undertaken in a tertiary care hospital to throw light on the efficacy of two screening tests and its relevance in Indian setting for knowing adverse maternal and fetal outcome in pregnancy complicated by GDM.

METHODS

The present study was carried out in a tertiary care hospital in Mumbai, India. After the approval of the Institutional Ethics Committee.

The data collection was performed over a period of 18 months. It was a comparative study which included both OPD patients and admitted pregnant patients.

Inclusion criteria

All patient with fasting blood sugar 95mg/dl and above or post prandial blood sugar more than 140mg/dl were enrolled in the study.

Exclusion criteria

Known cases of Diabetes Mellitus prior to pregnancy, irrespective whether on treatment or not.

Study procedure

- Proper consent of patient and relative for participation in study was taken.
- Patients were allotted in DIPSI and OGTT group alternately.
- Patients in the DIPSI Group were given 75gms of glucose at visit irrespective of fasting status and blood sample was collected after 2 hrs. The sample was sent to Clinical Chemistry Lab (CCL).
- GDM was diagnosed if blood sugar level of sample was >140 but <200mg/dl.
- In the OGTT group Total of 4 Samples of blood were collected from patients: 1st sample after fasting of >8 hrs but < 14hrs.Following this 100gms of anhydrous glucose diluted in 1 glass of water was given to patient orally. Three samples were drawn after 1hr, 2hr and 3hr. GDM was diagnosed as per ADA criteria.
- All the above blood investigations were done in the biochemistry laboratory by the GOD-POD method. The reports of each case were recorded and analysed. The cut-offs for each glucose level were as follows: FBS >92mg/dl, 1 Hour >180mg/dl and 2 Hour >153mg/dl. If any one of the above 3 values was abnormal the patient was diagnosed as GDM.

End point

Once confirmed as GDM, 50 patients in each group were followed up throughout pregnancy till delivery in KEM Hospital, Mumbai, India and 7 days after that.

Outcome measures

Maternal outcome

- Pregnancy Induced Hypertension
- Polyhydramnios(AFI>=15)
- Preterm delivery (<37 completed weeks)
- Methods of termination of pregnancy
- Genital tract injury

Neonatal outcome

- Macrosomia (baby wt>3500gms)
- Congenital malformation
- Hypoglycaemia (Capillary blood glucose <=2.6 mmol)
- Hyperbilirubinimia
- Respiratory distress
- Duration of NICU stay

Statistical analysis

Data collected were both qualitative data eg. maternal outcome and quantitative data eg. gestational age. The results were compared by Chi square test. P value of <0.05 was considered significant for the study.

RESULTS

Table 1: Comparison of incidence of pregnancy induced hypertension in DIPSI group and OGTT group.

	Test		
Preeclampsia		**DIPSI**	**OGTT**
N	Count	39	37
	% within Test	78.00%	74.00%
Y	Count	11	13
	% within Test	22.00%	26.00%
Total	Count	50	50
	% within Test	100.00%	100.00%
	Value	df	p-value
Pearson Chi-Square	0.219	1	0.64

22% patients in DIPSI group and 26% patients in OGTT group has pregnancy complicated by PIH. But majority patients had no PIH in present pregnancy (DIPSI 78% versus OGTT 74%) No statistically significant difference was seen between both groups (p=0.64).

Approximately equal number of cases of polyhydramnios were detected by both tests DIPSI 12% versus OGTT 10%. Statistically significant difference was not seen (p=0.743).

Preterm delivery was seen in 22% patient of DIPSI group and 30% of OGTT group. 76% of patient of DIPSI group compared to 66% that of OGTT group had term delivery. No post-dated delivery in both groups was seen. Difference is not statistically significant (p=0.522).

Table 2: Comparison of incidence of polyhydramnios in DIPSI group and OGTT group.

	Test		
AFI		**DIPSI**	**OGTT**
<15	Count	44	45
	% within Test	88.00%	90.00%
>15	Count	6	5
	% within Test	12.00%	10.00%
Total		50	50
	% within Test	100.00%	100.00%
	Value	df	p-value
Pearson Chi-Square	0.1021	1	0.7493

Table 3: Comparison of gestational age at confinement in DIPSI group and OGTT group.

Gestational age at	Test		
Confinement (wks)		**DIPSI**	**OGTT**
0 to 27	Count	1	2
	% within Test	2.00%	4.00%
28 to 36	Count	11	15
	% within Test	22.00%	30.00%
37 to 40	Count	38	33
	% within Test	76.00%	66.00%
Total	Count	50	50
	% within Test	100.00%	100.00%
	Value	df	p-value
Pearson Chi-Square	1.301	2	0.522

Table 4: Comparison of outcome of pregnancy in DIPSI group and OGTT group.

	Test		
Outcome		**DIPSI**	**OGTT**
Induction of labour	Count	3	8
	% within Test	6.00%	16.00%
LSCS	Count	25	25
	% within Test	50.00%	50.00%
MTP	Count	1	0
	% within Test	2.00%	0.00%
Outlet forcep	Count	1	3
	% within Test	2.00%	6.00%
Spontaneous	Count	20	14
	% within Test	40.00%	28.00%
Total	Count	50	50
	% within Test	100.00%	100.00%
	Value	df	p-value
Pearson Chi-Square	5.332	4	0.255

50% patients of both the groups underwent LSCS. 40% patients of DIPSI group compared to 28% of that of OGTT group delivered due to spontaneous onset of labour. MTP was performed only one patient of DIPSI group and none in OGTT group. Difference was not statistically significant (p=0.255). 2% patient of DIPSI group compared to 6% in OGTT group had outlet forcep delivery.

Table 5: Comparison of intrapartum complications in DIPSI group and OGTT group.

Test				
Complications		**DIPSI**	**OGTT**	**Total**
Adhesion	Count	2	3	5
	% within Test	4.00%	6.00%	5.00%
Genital injury	Count	4	4	8
	% within Test	8.00%	8.00%	8.00%
Shoulder dystocia	Count	3	2	5
	% within Test	6.00%	4.00%	5.00%
No	Count	41	41	82
	% within Test	82.00%	82.00%	82.00%
Total	Count	50	50	100
	% within Test	100.00%	100.00%	100.00%
		Value	df	p-value
Pearson Chi-Square		0.4	3	0.94

No intrapartum complication was seen in equal number (n=41) 82% of patients in both groups. Genital injury was same in both groups 8% (n=4) of both group. 6% (n=3) patients of DIPSI group compared to 4% (n=2) that of OGTT had shoulder dystocia. Difference was not statistically significant (p=0.94)

Table 6: Comparison of weight of baby in DIPSI group and OGTT group.

Test			
Baby wt (gms)		**DIPSI**	**OGTT**
< 2000	Count	6	9
	% within Test	12.00%	18.00%
2000 to 3500	Count	37	36
	% within Test	74.00%	72.00%
>3500	Count	7	5
	% within Test	14.00%	10.00%
Total	Count	50	50
	% within Test	100.00%	100.00%
	Value	df	p-value
Pearson Chi-Square	1.459	4	0.834

Macrosomia was seen in 14% (n=7) of baby of DIPSI group and 10% (n=5) of OGTT group. Baby weight less than 2kg was seen in 12% (n=6) of DIPSI group and 18% (n=9) of OGTT group. 2 babies from each group were term IUGR. One patient from DIPSI group had MTP. This baby was admitted in NICU and had greater incidence of hypoglycemia. Difference was not statistically significant (p=0.834)

Table 7: Comparison of malformations in baby in DIPSI and OGTT group.

Test				
Malformation		**DIPSI**	**OGTT**	**Total**
N	N	41	43	84
	%	82.00%	86.00%	84.00%
Y	N	9	7	16
	%	18.00%	14.00%	16.00%
Total	N	50	50	100
	%	100.00%	100.00%	100.00%
	Value	df	p-value	
Pearson Chi-Square	0.298	1	0.585	

Table 8: Comparison of incidence of hypoglycemia in DIPSI group and OGTT group.

Test			
Hypoglycemia		**DIPSI**	**OGTT**
N	Count	25	22
	% within Test	53.20%	50.00%
Y	Count	22	22
	% within Test	46.80%	50.00%
Total	Count	47	44
	% within Test	100.00%	100.00%
	Value	df	p-value
Pearson Chi-Square	0.093	1	0.761

Incidence of malformations were comparable 18% (n=9) in DIPSI group and 14% (n=7) of OGTT group.

NTD was seen in 4 babies of DIPSI group compared to 2 babies of OGTT group. 2 babies of DIPSI group and 3 of OGTT group had VSD. 1 baby from each group had renal anomaly. Difference was not statistically significant (p=0.585).

46.8% of babies of DIPSI group and 50% that of OGTT group developed hypoglycemia. Difference is not statistically significant (p=0.761)

Table 9: Comparison of incidence of respiratory distress In DIPSI group and OGTT group.

Test			
Respiratory distress		**DIPSI**	**OGTT**
N	Count	32	24
	% within Test	68.10%	54.50%
Y	Count	15	20
	% within Test	31.90%	45.50%
Total	Count	47	44
	% within Test	100.00%	100.00%
	Value	df	p-value
Pearson Chi-Square	1.76	1	0.185

31% (n=15) cases of DIPSI group compared to 45.50% (n=20) that of OGTT group developed Respiratory Distress Syndrome. Difference is not statistically significant (p=0.185).

Table 10: Comparison of incidence of hyperbilirubinimia in DIPSI group and OGTT group.

Test			
Hyperbilirubinimia		**DIPSI**	**OGTT**
N	Count	27	23
	% within Test	57.40%	52.30%
Y	Count	20	21
	% within Test	42.60%	47.70%
Total	Count	47	44
	% within Test	100.00%	100.00%
Pearson Chi-Square	Value	df	p-value
	0.246	1	0.62

Hyperbilirubinimia developed in 42.60% (n=20) cases of DIPSI group compared to 47.70% (n=21) that of OGTT group. Difference is not statistically significant. (p=0.62)

Table 11: Comparison of duration of NICU stay in DIPSI group and OGTT group.

Test			
NICU stay (days)		**DIPSI**	**OGTT**
0	Count	10	12
	% within Test	20.00%	24.00%
1 to 4	Count	29	22
	% within Test	58.00%	44.00%
> 4	Count	8	13
	% within Test	16.00%	26.00%
NA	Count	3	3
	% within Test	6.00%	6.00%
Total	Count	50	50
	% within Test	100.00%	100.00%
	Value	df	p-value
Pearson Chi-Square	1.245	3	0.742

Infants of GDM mothers managed on diet i.e. 20% (n=10) cases of DIPSI group and 24% (n=12) cases of OGTT group did not require NICU admission. Prolong admission for more than 4 days was required by 16% (n=8) cases of DIPSI group and 26% (n=13) of OGTT group. Majority of cases of both groups (DIPSI 58% vs OGTT 44%) were admitted for 1 to 4 days. (p=0.742)

DISCUSSION

The present study was undertaken in a tertiary care hospital in Mumbai, India after the approval of Institutional Ethics Committee. The main aim was to compare maternal and fetal outcomes in cases diagnosed as Gestational diabetes mellitus either by "Oral Glucose Tolerance Test''(OGTT) or "Diabetes in Pregnancy Study Group India" (DIPSI) and a short follow-up of these cases post-partum. 1602 antenatal patients during the study period of 18 months were screened for FBS and PLBS at any gestational age.

Patients having fasting blood sugar (FBS) 95mg/dl and above or post prandial blood sugar (PLBS) 140mg/dl and above were taken after proper consent. Out of these patients 28 patients were known type 2 diabetics and were not included in the present study. A total of 175 patients were subjected to OGTT and DIPSI test alternatively. 102 patients were diagnosed as gestational diabetes mellitus according to ADA diagnostic criteria (any one reading of fasting > 92mg/dl, 1 hour > 180mg/dl,2 hour > 153mg/dl). 84 patients were followed till 7 days after birth. 16 patients referred from other hospital who were diagnosed as GDM by same criteria were also included.

Pregnancy induced hypertension

In the study, be Saxena et al, the incidence of PIH was 40%.[9] According to Wahi et al in Jammu, India it was 6.45%.[10] Xiong et al reported mothers with GDM were at increased risk of presenting with pre-eclampsia as they have similar risk profile. [11]

In the present study, 22% patients in DIPSI group and 26% patients in OGTT group has pregnancy complicated by both GDM and PIH. But majority patients had no PIH in present pregnancy (DIPSI 78% versus OGTT 74%) No statistically significant difference was seen between both groups(p=0.64). Thus, there is an association between PIH and GDM and early diagnosis and initiation of treatment should be done to improve the outcome.

Polyhydramnios

Bhat et al found a 14.7% incidence of polyhydramnios versus 2.7% in controls.[12] In the present study, approximately equal number of cases of GDM was detected by both tests DIPSI 12 % (n= 6) vs OGTT 10% (n=5). Polyhydramnios in diabetes is probably related to fetal polyuria due to fetal hyperglycemia.

Polyhydramnios complicating GDM pregnancies is associated with higher perinatal mortality and morbidity rates than pregnancies with normal amniotic fluid.[9]

Preterm delivery

In a study by Mahalakshmi et al MM in South India, 19% were preterm live birth.[13] Saxena et al reported a 12% incidence of preterm babies.

In the present study, Preterm delivery was seen in 22% patient of DIPSI group and 30% of OGTT group. Preterm births in present study were attributed to premature preterm rupture of membranes, preterm labour and early induction in cases of severe preeclampsia. No pregnancy was continued till postdatism as chances of IUFD are increased.

Mode of termination

According to Kale et al, the incidence of LSCS in patients with GDM was found to be 60%.[14] According to Saxena et al, caesarean was done in 42% cases.[9] Wahi et al reported 22.58% incidence of caesarean.[10] Cassey et alreported caesarean section rates of 30% in women with GDM.[15] A study in Denmark by Jenson et al, and in Sweden by Aberg et al also found an increased rate of caesarean section in patients with GDM.[16,17]

Kraiem et al found that rate of caesarean section significantly increased among the patients who delivered after labour induction as compared to those who went into spontaneous labour.[18] In the present study, 50% patients of both the groups underwent LSCS. 40% patients of DIPSI group compared to 28% of that of OGTT group delivered due to spontaneous onset of labour. Difference was not statistically significant (p=0.255).

Labour was induced in most patients at about 38 weeks in this study. A part of patients induced vaginally underwent LSCS in view of non-progress of labour or fetal distress or meconium stained amniotic fluid in first stage of labour while elective caesarean sections were performed for indications like previous 2 LSCS, previous LSCS not willing for VBAC, cephalopelvic disproportion, bad obstetric history, breech presentation, placenta previa, precious pregnancy.

MTP was performed in only one patient of DIPSI group and none in OGTT group as anencephaly was detected before 20 weeks of gestation. 2% patient of DIPSI group compared to 6% in OGTT group had outlet forceps delivery. In both group, statistically significant difference was not (p=0.225).

Genital injury

Genital injury was seen 8% (n=4) of both group. 6% (n=3) patients of DIPSI group compared to 4% (n=2) that of OGTT had shoulder dystocia. Statistically significant difference was not seen in both groups (p=0.94) in terms of intrapartum complications. Vaginal laceration and periurethral tear was seen.

Macrosomia

In the Polish study by Cypryk et al, history of big baby (macrosomia) was present in 11% of patients.[19] Najafian et al found incidence of macrosomia in 9% cases.[20] Balaji et al found incidence of macrosomia in India as 9.9%.[21]

In present study, macrosomia was seen in 14% of baby of DIPSI group and 10% of OGTT group. Difference was not statistically significant. Gestational diabetes, maternal obesity (BMI), maternal age and positive history of previous macrosomia were the major risk factors for macrosomia which were compared with the normal weight infant groups.

Fetal macrosomia is a common adverse infant outcome of GDM if unrecognized and untreated in time. For the infant, macrosomia increases the risk of shoulder dystocia, postpartum hemorrhage and genital injury.

Malformed baby

According to Shefali et al, 1.4% babies had congenital anomalies.[22] Saxena et al reported congenital anomalies in 10% of babies.[9]

In present study, malformed baby was seen in 18% (n=9) in DIPSI group and 14% (n=7) of OGTT group.

Statistically significant difference between two groups was not seen (p=0.585).

Variation is seen due to blood sugar levels during period of organogenesis. Neural tube defect, ventricular septal defect and renal malformation were seen. IUFD occurred in 2 patients of DIPSI group while number in OGTT group was 3. These were seen in patients who had poor compliance and poorly controlled blood sugars

Hypoglycemia

Mahalakshmi et al reported hypoglycemia in 10.4% patients.[13] In the present study, 46.8% of babies of DIPSI group and 50% that of OGTT group developed hypoglycemia. Difference was not statistically significant (p=0.761).

Respiratory distress

Mitanchez in literature review found there was limited data from which to report on the prevalence of respiratory distress in infants born to mothers with GDM.[23]

31% (n=15) cases of DIPSI group compared to 45.50% (n=20) that of OGTT group developed respiratory distress syndrome. Difference was not statistically significant (p=0.185). 8 newborns of DIPSI group and 12 from OGTT group who underwent LSCS developed transient tachypnoea of newborn. 3 newborns of DIPSI group and 2 of OGTT group received surfactant.

Hyperbilirubinimia

In the present study, hyperbilirubinimia developed in 42.60% (n=20) cases of DIPSI group compared to 47.70% (n=21) that of OGTT group. Difference was not statistically significant (p=0.62). 20% (n=10) cases of DIPSI group and 24% (n=12) cases of OGTT group did not require NICU admission. Majority were baby of GDM mothers who had blood sugar well controlled on diet.

Duration of NICU stay

Malak et al noted the incidence of neonatal intensive care admission was 4.9%. The mean length of stay in the NICU was 16 days. The commonest cause of neonatal NICU admission was hyperbilirubinimia (41.2%).[24]

Majority of cases of both groups (DIPSI 58% vs OGTT 44%) were admitted for 1 to 4 days. These were babies of GDM mothers who were managed on insulin, OHA were admitted in NICU prophylactically for monitoring. Asymptomatic newborns were discharged after 1 day.

Prolong NICU admission of more than 4 days were seen in babies who developed respiratory distress, hypoglycemia or hyperbilirubinimia.

These comprised 16% (n=8) cases of DIPSI group and 26%(n=13) of OGTT group. No statistically significant difference (p=0.742) was seen in duration of NICU stay of both groups.

CONCLUSION

The prevalence of GDM seen was 5.09% which is comparable to other parts of India. Both test diagnosed GDM in different period without much difference. No statistically significant difference was observed between all the parameters of maternal and fetal outcomes between the two tests in the present study. It is concluded that fetal and maternal outcome is independent of method of screening and depends on maternal glycemic control during pregnancy.

GDM is a window of opportunity for prevention of diabetes in future life but this opportunity provided by GDM can be utilized only if optimal medical and obstetric care is provided to the antenatal patient with GDM. Optimal management of GDM remains a challenge for the obstetricians and endocrinologists. Most cases of GDM can be managed by lifestyle and dietary modification, but when required, pharmacological treatment becomes necessary. Team effort on part of obstetricians, endocrinologists and neonatologist is required to manage GDM effectively, not only for the present generation but also for the generations to come. We should try our Medicare system to convert “the diabetes capital of the world” into “the diabetes care capital of the world”.

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