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Can the management of blood sugar levels in gestational diabetes mellitus cases be an indicator of maternal and fetal outcomes? The results of a prospective cohort study from India

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ABSTRACT

Background: Gestational diabetes mellitus (GDM) is emerging as an important public health problem in India owing to its increasing prevalence since the last decade. The issue addressed in the study was whether the management of blood sugar levels in GDM cases can predict maternal and fetal outcomes. **Materials and Methods:** A prospective cohort study was done for 1 year from October 1, 2013, to September 31, 2014, at 652 diabetic screening units as a part of the Gestational Diabetes Prevention and Control Project approved by the Indian Government in the district of Kanpur, state of Uttar Pradesh. A total of 57,108 pregnant women were screened during their 24–28th weeks of pregnancy by impaired oral glucose test. All types of maternal and perinatal outcomes were followed up in both GDM and non-GDM categories in the 2nd year (2013–2014) after blood sugar levels were controlled. **Results:** It was seen that for all kinds of maternal and fetal outcomes, the differences between GDM cases and non-GDM cases were highly significant ($P < 0.0001$, relative risk > 1 in every case). Moreover, perinatal mortality also increased significantly from 5.7% to 8.9% when blood sugar levels increased from 199 mg/dl and above. Perinatal and maternal outcomes in GDM cases were also significantly related to the control of blood sugar levels ($P < 0.0001$). **Conclusion:** Blood sugar levels can be an indicator of maternal and perinatal morbidity and mortality in GDM cases, provided unified diagnostic criteria are used by Indian laboratories. However, to get an accurate picture on this issue, all factors need further study.

Key words: Blood sugar, diabetes mellitus, gestation, India, indicator, maternal, perinatal

INTRODUCTION

Gestational diabetes mellitus (GDM) appears as glucose intolerance, which begins or is first detected during pregnancy.^[1-4] GDM is emerging as an important public health problem across the world as it affects 7% of all pregnancies. Nearly, 200,000 cases are seen per year.^[2] A significantly higher prevalence of GDM in pregnant Indian

women, i.e., 6–13.4% has been reported in many studies.^[1-5] Moreover, the Indian scenario is more difficult to manage since the majority of pregnant women, whether urban or rural, have no knowledge about GDM.^[5]

It has now been established that GDM has many potential complications for both mother and child and that screening,

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diagnosis, and management of hyperglycemia in GDM are essential.^[4-6] Treatment through medical nutrition therapy and close monitoring of glucose levels can help to reduce the complications.^[4-6] It has been further seen that increasing levels of plasma glucose are associated with birth weight above the 90th percentile, and the cornerstone of the management of GDM cases is glycemic control.^[6] An antepartum control of sugars is found to provide good peripartum control for the reduction of neonatal complications.^[7] In the peripartum management of diabetes, the avoidance of maternal hyperglycemia is very important to reduce the chances of neonatal hypoglycemia.^[7] Therefore, many studies postulate an emphasis on the proper control of blood sugar levels in managing GDM cases.^[4-8] Most studies, therefore, indicate that an appropriate management of GDM can improve both maternal and perinatal outcomes.^[4-8] A few studies^[5,9] have also indicated that poor perinatal outcomes (6% and 43%) can be associated with a bad glycemic control in mothers. Despite these studies^[1-8] which give evidence of an increasing number of GDM cases in India, there are hardly any studies in the literature on the actual follow-up of management of various blood sugar levels and the consequent impact on maternal and fetal outcomes. Though, there are few studies^[4-9] on perinatal outcomes on patients in India with GDM, in the literature there are no studies on perinatal outcomes of the GDM patients in India with their controlled as well as uncontrolled blood sugar levels. Therefore, this study is unique in that no such cohort study has been done after the mass screening of GDM cases in North India. The objective of the study was to determine the impact of the management of various blood sugar levels in reducing maternal and perinatal complications in GDM cases.

MATERIALS AND METHODS

The study was approved by the Ministry of Health and Family Welfare, Government of India, New Delhi (India) as a part of a Gestational Diabetes Prevention and Control Project (Project No: WDF12-678) and Government of Uttar Pradesh, India.

The consent forms were completed by all pregnant women to participate in this project. Moreover, approval was sought from a chief medical officer, Kanpur district of the state Uttar Pradesh where this study was proposed. All private health facilities in Kanpur district of the state Uttar Pradesh, which gave their consent to participate in this study, were also included.

A prospective cohort study was done for 1 year from October 1, 2013, to September 31, 2014, at 652 diabetic screening units (covering both Government and Private health facilities including camps) as a part of the Gestational Diabetes Prevention and Control Project. A total of 57,108

pregnant women were screened in their 24–28th weeks of pregnancy (to get the maximum effect of GDM) by impaired oral glucose test. To measure GDM, Accu-check glucometer from Roche was used and 75 g glucose packets together with glucometers and strips, lancets, glass, spoon, etc., were distributed to all 652 screening units.

The Diabetes in Pregnancy Study Group India (DIPSI) criteria was used to diagnose GDM. These DIPSI criteria were used as per the WHO guidelines, which suggest that DIPSI can serve both as a screening and diagnostic test and can also be a useful test for managing GDM cases in the Indian environment.^[10,11] DIPSI is a single test procedure to diagnose GDM in the community in which the measurement of only 2 h postglucose (75 g) >140 mg/dl by the GOD-POD method is done to screen positive for GDM. In this test, women were diagnosed as diabetic if 2 h postprandial blood plasma glucose after breakfast was ≥ 200 mg/dl and they were advised, exercise, diet, and insulin therapy. The women were labeled as “prediabetes” if blood sugar was 140–199 mg/dl. These women were given treatment and advised on exercise and diet control. Blood sugar values were considered as controlled when they were below 140 mg/dl but were labeled as “decreased gestational glucose tolerance,” and the women were also advised to exercise.

First of all, GDM cases were discovered in the previous year's study (2012–2013), which had only looked for GDM cases. In the 2nd year (2013–2014), all GDM and non-GDM cases were taken as two groups and were followed up after control of their blood sugar levels, but no randomization or blinding was done. All types maternal and perinatal outcomes were followed up in both the GDM and non-GDM categories for 2nd year (2013–2014). The fetal outcomes were seen separately in both the GDM and non-GDM categories, when a history of previous fetal complications was present. Perinatal mortality was further seen as a function of blood sugar (mg/dl) value from 100 mg/dl to ≥ 200 mg/dl and its comparison with H/O previous perinatal loss was done by applying a test of significance. From them, the effect of blood sugar levels was seen in relation to maternal and perinatal outcomes in GDM cases.

All types of data were analyzed by means of special GDM software supplied under Gestational Diabetes Prevention and Control Project, which did all statistical calculations. Chi-square test was used to test the differences in obtained qualitative data. Odds ratios and relative risk (RR) were calculated for different risk factors using bivariate and multiple logistic regression analysis.

RESULTS

Of the 7641 pregnant women who were diagnosed with GDM, 6657 were followed-up for blood sugar monitoring

(87%) once, and 4327 of these GDM women were followed.

Labeled as “Prediabetes” were 1996 who had the value of 120–139 mg/dl. and 1137 who had blood sugar 140 - <199 mg/dl. Diabetics were 648 and had blood sugar value ≥200 mg/dl. The 334 in the GDM category had the value ≥140 mg/dl.

It was seen that for all kinds of maternal outcomes such as cesarean section, pregnancy-induced hypertension (PIH), premature baby unit (PBU) care, family H/O DM and antepartum hemorrhage/postpartum hemorrhage (APH/PPH), the differences between GDM and non-GDM cases were highly statistically significant ($P < 0.0001$, $RR > 1$ in every case). This was also seen in the outcomes of neonates in terms of perinatal death, stillbirth, neonatal death, congenital malformations, low gestation for age (LGA), low birth weight (LBW), jaundice. Here also the differences between GDM and non-GDM cases were statistically significant ($P < 0.0001$, $RR > 1$ in every case) [Table 1].

In terms of H/O previous birth complications, again in the category of stillbirths and perinatal deaths both in GDM and non-GDM cases, the differences were statistically significant ($P < 0.0001$). However, in neonatal deaths, it was not significant in both GDM and non-GDM category ($P > 0.05$) [Table 2].

As the blood sugar level rose above 120 mg/dl, perinatal mortality rose significantly as compared to previous perinatal loss ($P < 0.0001$). This increased significantly from (5.7% to 8.9%) when blood sugar level was ≥199 mg/dl [Table 3 and Figure 1].

When 5043 GDM cases were segregated into blood sugar controlled (<140 mg%) and uncontrolled (≥140 mg%) and followed for the development of complications, it was found that outcomes in both neonatal and maternal were related to the control of blood sugar levels significantly ($P < 0.0001$) except in the case of congenital malformations [Table 4 and Figure 2].

DISCUSSION

DM is increasing worldwide and this rise is more prevalent in developing countries such as India, which is going to become the future “Diabetic-Capital,” for which GDM is thought to be a real contributor.^[12] This emphasizes the importance of prevalence studies in India in pregnant women in order to reveal the exact prevalence of GDM.^[12] Hence, GDM is emerging as a rising public health problem in pregnant women in India as many studies have indicated.^[5,12-15] Various prevalence rates from places such as

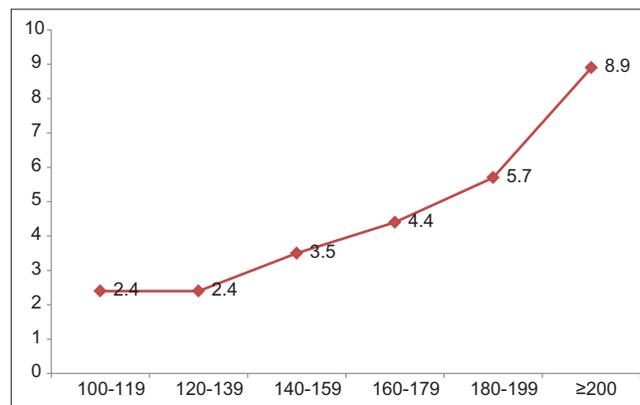


Figure 1: Perinatal mortality (%) in gestational diabetes mellitus cases in relation to the maternal blood sugar levels (in g/dl)

Table 1: Maternal and fetal outcomes of gestational diabetes mellitus and nongestational diabetes mellitus pregnant women

Outcomes	GDM cases (n=7641) N (%)	Non-GDM cases (n=8000) N (%)	RR	95% CI	p-value
Stillbirth	247 (3.2)	102 (1.3)	2.53	2.0-3.1	<0.0001
Neonatal death	128 (1.7)	56 (0.7)	2.39	1.75-3.27	<0.0001
Perinatal death	375 (4.9)	158 (1.97)	2.48	2.0-2.9	<0.0001
Congenital malformations	382 (5)	82 (1.03)	4.87	3.8-6.1	<0.0001
Cesarean section	2242 (29.3)	1814 (22.67)	1.21	1.2-1.3	<0.0001
PBU care	234 (3.06)	85 (1.06)	2.88	2.25-3.68	<0.0001
LGA	684 (9)	67 (.83)	10.6	8.3-13.7	<0.0001
LBW	863 (11.3)	758 (9.4)	1.19	1.1-1.3	<0.0002
PIH	686 (9)	483 (6)	1.83	1.6-2.0	<0.0001
Jaundice	382 (5)	84 (1)	4.76	3.7-6.0	<0.0001
Family history of DM	1372 (17.9)	546 (6.8)	2.62	2.3-2.8	<0.0001
APH/PPH	64 (0.84)	26 (0.32)	2.57	1.6-4.0	<0.0001

APH: Antepartum hemorrhage; PPH: Postpartum hemorrhage; PIH: Pregnancy-induced hypertension; LBW: Low birth weight; LGA: Low gestation for age; PBU: Premature baby unit; OR: Odds ratio; RR: Relative risk; DM: Diabetes mellitus; GDM: Gestational diabetes mellitus

Table 2: Fetal outcomes in gestational diabetes mellitus versus nongestational diabetes mellitus and its relationship with history of previous birth complications

Outcomes in neonate	GDM present (n=7641) N (%)	Previous fetal loss present N (%)	p-value	GDM absent (n=8000) N (%)	Previous fetal loss present N (%)	p-value
Stillbirth	247 (3.3)	916 (12)	<0.0001	102 (1.2)	212 (2.6)	<0.0001
Neonatal death	128 (1.6)	156 (2)	<0.09	56 (0.7)	62 (0.8)	<0.5
Perinatal death	375 (4.9)	1072 (14)	<0.0001	158 (1.9)	274 (3.4)	<0.0001

GDM: Gestational diabetes mellitus

Table 3: Perinatal mortality as a function of blood sugar (mg/dl) value and its comparison with a history of previous perinatal loss

Blood sugar levels (mg/dl)	Samples tested (n=57,018)	Perinatal mortality present N (%)	History of previous perinatal mortality N (%)	p-value
<100	n1=12,560	-	-	
100-119	n2=31,075	776 (2.4)	768 (2.5)	<0.44
120-139	n3=5742	137 (2.4)	214 (3.7)	<0.0001
140-159	n4=3915	137 (3.5)	417 (10)	<0.0001
160-179	n5=1451	65 (4.4)	176 (12.1)	<0.0001
180-199	n6=940	54 (5.7)	168 (17.8)	<0.0001
≥200	n7=1335	119 (8.9)	311 (23.2)	<0.0001

Kanpur - 13.4%, Haryana - 7.1%, Kashmir - 3.8%, South India - 21%, and 16.5% in random surveys across many cities of India have shown this. This is in agreement with varying GDM of 2.5% to 21% found across developing world.^[14] This variation also indicates that different criteria may have been used for the diagnosis of GDM.^[12]

In present study, for all the studied maternal outcomes, there were higher rates in findings such as cesarean section, PIH, PBU care, family H/O DM, and APH/PPH among GDM cases. The neonatal outcomes had also a higher percentage of perinatal deaths, stillbirths, neonatal death, congenital malformations, LGA, LBW, and jaundice. Both kinds of outcomes in the maternal and neonatal categories had a significant association with the presence of GDM. It was further seen that for all kinds of maternal and neonatal outcomes, the differences between GDM and non-GDM cases were highly statistically significant (for both - $P < 0.0001$, $RR \geq 1$ in every case, respectively). This finding was unique in contrast to many related studies on GDM^[5,16] in terms of types of outcomes in the past in India, which indicates that gestational diabetes can result in significant feto-maternal outcomes. Many studies have also reported that the Type 2 DM risk is higher for patients with GDM.^[16-18] Our study shows that the differences were highly statistically significant ($P < 0.0001$). In terms of fetal outcomes with H/O previous birth complications again in the category of stillbirths and perinatal deaths both in GDM and non-GDM cases. This indicates that diabetic

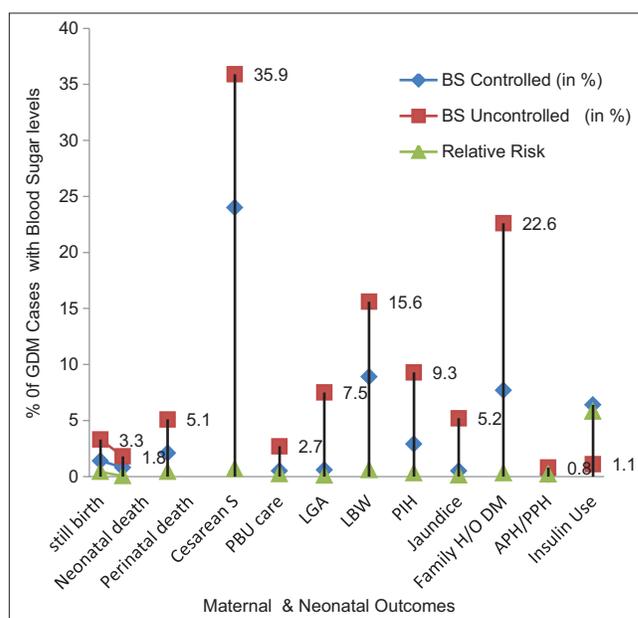


Figure 2: Maternal and perinatal outcomes (in %) in gestational diabetes mellitus cases in relation to the maternal blood sugar levels controlled by treatment (in g/dl)

complications affect the fetus of gestational diabetic women as also found in another study.^[16] Scientific evidence now also reveals that the control of blood glucose levels with management strategies can reduce the frequency of congenital anomalies and improve maternal and neonatal outcomes in GDM cases.^[19]

The most important finding in our study was that as blood sugar levels rose above 120 mg/dl, there was significant perinatal mortality compared to previous perinatal loss ($P < 0.0001$). This perinatal loss increased significantly from (5.7% to 8.9%) when blood sugar level was ≥ 199 mg/dl. This finding was also unique in contrast to many related studies.^[19-26] It has been seen that the values of oral glucose tolerance test in the middle phase of pregnancy and antenatal random glycemia can to some extent also predict PIH, preterm births, or stillbirths.^[20]

In the present study, when perinatal mortality as a function of blood sugar (mg/dl) value was compared with H/O previous perinatal loss, it was also highly statistically significant ($P < 0.0001$). This further means that a rise

Table 4: Post follow-up complications of gestational diabetes diagnosed in controlled and uncontrolled blood sugar after treatment

Maternal and neonatal outcomes	BS-controlled (<140 mg%) (n=4589) N (%)	BS-uncontrolled (>140 mg%) (n=454) N (%)	RR	95% CI	p-value
Stillbirth	64 (1.4)	15 (3.3)	0.42	2.0-3.1	<0.0023
Neonatal death	37 (0.8)	8 (1.8)	0.04	30.28-0.98	<0.043
Perinatal death	101 (2.19)	23 (5.1)	0.43	0.28-0.68	<0.0002
Congenital malformations	206 (4.5)	22 (4.8)	0.93	0.60-1.4	<0.73
Cesarean section	1101 (24.0)	163 (35.9)	0.67	0.58-0.76	<0.0001
PBU care	27 (0.59)	12 (2.75)	0.22	0.11-0.44	<0.0001
LGA	30 (.65)	34 (7.5)	0.087	0.054-0.14	<0.0001
LBW	413 (8.9)	71 (15.6)	0.57	0.46-0.73	<0.0001
PIH	137 (2.98)	42 (9.3)	0.32	0.23-0.45	<0.0001
Jaundice	26 (0.56)	24 (5.2)	0.11	0.062-0.18	<0.0001
Family history of DM	357 (7.7)	103 (22.6)	0.34	0.28-0.41	<0.0001
APH/PPH	11 (0.23)	4 (0.88)	0.27	0.087-0.85	<0.025
Insulin use	298 (6.4)	5 (1.1)	5.89	2.4-14.1	<0.0001

APH: Antepartum hemorrhage; PPH: Postpartum hemorrhage; PIH: Pregnancy-induced hypertension; LBW: Low birth weight; LGA: Low gestation for age; PBU: Premature baby unit; BS: Blood sugar; OR: Odds ratio; RR: Relative risk; DM: Diabetes mellitus

in perinatal mortality was seen in terms of the rise of blood sugar (mg/dl) from 120 mg/dl to 200 mg/dl. This association was also unique in contrast to related studies on GDM^[21-27] in the literature. There is scientific evidence that monitoring of diet, glycemic control can bring about a successful outcome of pregnancy in women with diabetes.^[21] All pregnant diabetic women should have strict metabolic control because of the possible negative impact on the mother's and fetus' health.^[22] It has also been seen that gestational diabetes generally leads to fetal growth alterations, leading to perinatal mortalities.^[23] Scientific evidence also indicates that increased glucose levels are associated with a continuous increase in the risk of macrosomia and cesarean section as a few studies have shown.^[24,25] The loss of pregnancy is also found to be significantly higher among women with diabetes compared to the nondiabetic population.^[26] The study by Schaefer *et al.* also found a two-fold increase in the risk of congenital anomalies when fasting glucose levels were <120 mg/dl when detected during pregnancy.^[27] All these studies indicate that perinatal mortality appears as a function of blood sugar in pregnant women, which is also a major finding of our study.

When GDM cases were segregated into blood sugar controlled (<140 mg%) and uncontrolled (\geq 140 mg%) and further followed up for the development of complications, it was found that both perinatal and maternal outcomes were related to control of blood sugar levels significantly ($P < 0.0001$). This finding in our study corroborates findings in a few studies,^[27-31] which clearly reveal that blood sugar levels and consequent diabetic state are associated with maternal and perinatal morbidity and mortality. Many studies on GDM^[29-31] also suggest that early screening

and dietary control of gestational diabetes can promote the curtailment of maternal and perinatal morbidities. Therefore, early proper diagnosis coupled with postpartum testing and follow-up in women with GDM can improve perinatal outcomes.^[32] Similar to the findings of our present study, scientific evidence also endorses the thesis that pregnancies complicated by GDM are associated with a higher frequency of adverse maternal and fetal outcomes.^[33] Hence, finally what we can say that there is a need for proper unified programs to manage GDM cases to reduce the growing burden of diabetes in India as advocated by some studies in North India^[34,35] which addressed issues similar to those in our present study.

Limitations of study

Ours was a prospective cohort study in which maternal and perinatal outcomes of GDM cases after controlling blood sugar levels were seen, without any randomization and blinding approach typically used in an intervention study. Moreover, DIPSI criteria were used according to its suitability to the Indian environment. Any generalization of the study findings should be done with caution.

CONCLUSION

Maternal and fetal outcomes in GDM cases are poor. Perinatal and maternal outcomes in GDM cases are also significantly related to control of blood sugar levels. Therefore, blood sugar levels appear to be an important possible indicator of maternal and perinatal morbidity and mortality in Indian GDM cases. However, there is a need to unify diagnostic criteria in practices throughout the Indian subcontinent for a better validation of results from this study as well as other GDM studies conducted in

India. Moreover, all other multiple factors in combination also need further detailed study for a true picture on this issue to emerge.

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Conflicts of interest

There are no conflicts of interest.

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