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Original Research Article

Maternal and fetal outcomes in diabetes mellitus in hospitalized women at a tertiary care institute in South India

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ABSTRACT

Background: Objectives of current study were to find out the proportion of types of diabetes and to know the factors for adverse maternal and fetal outcome in pre-gestational diabetes and gestational diabetes at a tertiary care Institute and to compare the outcomes between pre-gestational diabetes and GDM.

Methods: Prospective descriptive study conducted in the department of obstetrics and gynaecology, at a tertiary care center over a period of 1 year. The inclusion criteria were: pre-gestational diabetes (pregnant women with type 1 & type 2 diabetes mellitus) and gestational diabetes mellitus. Exclusion criteria were steroid induced diabetes, tuberculosis, heart disease, autoimmune disorder, chronic renal failure. Statistical analysis: Maternal & fetal outcomes, presence of complications were expressed as proportions and comparison between the 2 groups is done using Chi-square test.

Results: Majority of the women (81.5%) were GDM and 18.5% were pre-gestational diabetics (type I DM-5% and Type II-13.5% of total). Past history of GDM was present in 29% of GDM and 31% of type II DM. Sixty percent of GDM and 40% of PGDM were primigravidae. Significantly a greater number of women were obese in PGDM than GDM. Blood sugars were uncontrolled in 20% more so in women with PGDM. Pregnancy loss was more in PGDM when compared to GDM (17.5% vs. 9.1%). Statistically significantly more number with PGDM suffered from hypertension and preterm labour.

Conclusions: Obesity, uncontrolled blood sugars, development of hypertension and pre-term labour are the significant factors resulting in adverse maternal and fetal outcomes and these are more common in women with PGDM.

Keywords: Gestational diabetes, Pre-gestational diabetes, Caesarean Section, Macrosomia, Stillbirth, Glycaemic control

INTRODUCTION

Diabetes is commonly encountered medical problem during pregnancy. In India, 10-20% of pregnant women are suffering from gestational diabetes mellitus.¹ All forms of diabetes can be encountered during pregnancy. The two major classification of diabetes mellitus are type 1 diabetes mellitus and type 2 diabetes mellitus. Type 1 DM is usually characterized by an abrupt onset at young age and absolute insulinopenia with lifelong requirements for insulin replacement. Type 2 DM is due to insulin

resistance or inadequate insulin response. Gestational diabetes mellitus is an early manifestation of type 2 diabetes mellitus and is the most common condition of glucose intolerance.

Diabetes in pregnancy causes risk to both the mother and the developing fetus. Diabetes mellitus increases the risk of certain pregnancy complications like spontaneous miscarriage, recurrent miscarriage, preterm labour, polyhydramnios, pregnancy induced hypertension, genitourinary infections, postpartum hemorrhage,

operative delivery. Few studies have reported that there was increased incidence of pre-eclampsia and adverse neonatal outcome.² Fetal complications are congenital malformations, macrosomia, respiratory distress, neonatal hypoglycaemia, birth trauma, hyperbilirubinemia, hypocalcaemia, and convulsions. Maternal and fetal outcomes differ in pregestational diabetes and gestational diabetes and also from place to place.

Objectives

This study was conducted with the following objectives: to find out the proportion of types of diabetes and to know the factors for adverse maternal and fetal outcome in pre-gestational diabetes (PGDM) and gestational diabetes (GDM) at a tertiary care Institute and to compare the outcomes between pre-gestational diabetes and GDM.

METHODS

This was a prospective descriptive study conducted in the department of obstetrics and gynaecology, JIPMER over a period of 1 year (2015-2016). All women diagnosed with Diabetes and who were willing to deliver in JIPMER were included in the study.

Inclusion and exclusion criteria

The inclusion criteria were: pregnant women with type 1 and type 2 diabetes mellitus, gestational diabetes mellitus. Exclusion criteria were steroid induced diabetes, tuberculosis, heart disease, autoimmune disorder, chronic renal failure.

Sampling population, sample size and sampling technique

Pregnant women with diabetes mellitus were included in the study. The study was conducted over a period of 1 year. The sample size was estimated to be around 360 diabetic women in 1 year, considering the incidence of Diabetes in pregnant women as 3% and the total number of deliveries around 12,000 to 14,000 per year. Consecutive sampling was used as sampling technique.

The following parameters were studied: maternal outcomes: spontaneous abortion, uncontrolled diabetes, diabetic-ketoacidosis, hypertensive disorders, polyhydramnios, PPRM, preterm labour, infections, UTI, cervicovaginal infections, operative delivery, postpartum haemorrhage.

Fetal or neonatal outcomes: live birth or still birth, congenital malformations, birth weight, birth trauma, need for NICU admission, need for phototherapy for hyperbilirubinemia, hypocalcaemia, macrosomia (birth weight >3.5 kg is considered as LGA), neonatal hypoglycaemia (blood sugar of <40 mg/dl considered neonatal hypoglycaemia), prematurity, neonatal sepsis, and neonatal convulsions.

Study procedure

All adult women diagnosed with pre-gestational diabetes mellitus and GDM who were attending OPD or hospitalized for any reason have been explained about the study protocol and if they were willing to come for follow up and delivery in JIPMER they were included in the study after taking informed consent. A detailed history regarding present pregnancy and past obstetric history, time of diagnosis of diabetes, treatment taken were recorded. Family history and history of other comorbidities like hypothyroidism, chronic hypertension and the duration of the co-morbidities and the therapy for the same have been recorded. A general physical examination and obstetric examination were done. Screening for infections like, Urinary Tract infection and cervicovaginal infections were undertaken. Details of therapy during pregnancy and labour were noted. Mode of delivery, complications and neonatal outcomes have been noted as mentioned above. Uncontrolled glycaemia is diagnosed when fasting Blood sugar >100 mg/dl and post prandial blood sugar >140 mg/dl.³

Outcome variables

Maternal: spontaneous abortion, hypertensive disorders, polyhydramnios, PPRM, infections (UTI, cervicovaginal infections), operative delivery, postpartum haemorrhage. Fetal: congenital malformations, birth trauma, need for NICU admission, need for phototherapy hypocalcaemia, macrosomia, neonatal hypoglycaemia, neonatal sepsis, and neonatal convulsions.

Variable wise statistical test

Continuous variable: age, weight, gestational age, HbA1c were expressed as mean and SD. Comparison of these parameters between the 2 groups is done using 't' test. Categorical variable: maternal and fetal outcomes, presence of complications were expressed as proportions and comparison between the 2 groups is done using Chi-square test.

RESULTS

The clinicodemographic profile is shown in Table 1. Majority of the women (81.5%) were GDM and 18.5% were pre-gestational diabetics. Only 0.5% belong to teenage and 34% were more than 30 years of age the most common age group 19-24 years and there was no significant difference between PGDM and GDM. Overall, 1.3% were underweight, 44% overweight and 23.45% were obese. Significantly, greater number of women were obese in PGDM than GDM. Fifty six percent of diabetics were primigravidae and in GDM 60% and in PGDM 40% were primigravidae. Past history of GDM was present in 29% of GDM and 31% of type II

DM. Past history of recurrent pregnancy loss was present in 12.6% of PGDM and 4.3% of GDM and this is

significant. Significantly more number women in PGDM had past history of pre-eclampsia and preterm labour.

Table 1: Clinico-demographic profile of the women.

Demographic characteristics	Pregestational diabetes mellitus (PGDM)			GDM (N=700 81.5%) Frequency (%)	Total (n=859) Frequency (%)	P value
	Type 1 DM (N=43, 5%) Frequency (%)	Type 2 DM (N=116, 73%) Frequency (%)	Total (N=159, 18.5%) Frequency (%)			
Age (years)						
≤19	1 (2.3)	1 (2.3)	2(1.26)	2 (0.3)	4 (0.5)	0.1041
20-24	23 (53.3)	27(23.2)	50 (31.45)	245(35)	295(34.3)	0.3943
25-29	9 (20.9)	35 (30.2)	44 (27.67)	225(32.1)	269(31.3)	0.2726
≥30	10 (23.3)	53 (45.7)	63 (39.62)	228 (32.6)	291 (33.9)	0.0899
BMI						
Underweight	2 (4.7)	3 (2.5)	5 (3.144)	7 (1)	12 (1.3)	0.0375
Normal	10 (23.2)	32 (27.6)	42 (26.42)	230(32.9)	272 (31.7)	0.1149
Overweight	16 (37.2)	46 (39.7)	62 (38.89)	312 (44.6)	374 (43.5)	0.1403
Obese	15 (34.9)	35 (30.2)	50 (31.45)	151 (21.6)	201 (23.4)	0.0079
Obstetric status						
Primigravida	23 (53.5)	40 (34.5)	63 (39.62)	418 (59.7)	481 (56)	<0.0001
Multigravida	20 (46.5)	76 (65.5)	96 (60.38)	282(40.3)	378 (44)	<0.0001
Past history						
RPL	7 (16.2)	13 (11.1)	20 (12.59)	30 (4.3)	50 (5.8)	<0.0001
GDM	-	36 (31)	36(22.64)	204(29.1)	240(27.9)	0.0991
Preeclampsia	2 (4.6)	15 (12.9)	17(10.69)	32 (4.6)	49(5.7)	0.0027
Preterm Labour	3 (6.9)	22 (19)	25(15.72)	51 (7.3)	76 (8.8)	0.0007
Macrosomic baby	1(2.3)	12(10.3)	13(8.17)	65(9.3)	78 (9.1)	0.6602
Prev. caesarean Section	22 (51.1)	36 (31)	58(36.48)	100 (14.3)	158 (18.4)	< 0.0001
Congenital anomaly	7 (16.2)	13(11.2)	20(12.58)	31(4.4)	51(5.9)	<0.0001
Family history						
DM	22 (51.1)	24 (20.7)	46(28.93)	224 (32)	270 (31.4)	0.4517
Congenital anomaly	11 (25.6)	12 (10.3)	33(20.75)	6 (0.8)	29 (3.4)	< 0.0001

Twelve percent of women with PGDM and 4.4% of GDM had congenital anomaly and this is significant. Family history of diabetes was present in 30% of women PGDM and 32% of women with GDM. The mode of therapy is represented in (Table 2). All women with type I diabetes received insulin and 80% of type II diabetes received insulin and only 12% received metformin. Eight percent of women with type II DM required metformin as well as insulin. Insulin and metformin along with diet control was required for 7.7% of type II diabetics. One third of women with GDM were controlled on diet and 30% received metformin and 33% received insulin and 2.1% required metformin and Insulin along with medical nutritional therapy.

The maternal outcome in 20% of diabetic pregnant women the blood sugars were uncontrolled and significantly in a greater number of women with PGDM this was the situation (Table 2). Diabetic ketoacidosis was diagnosed in 1.75% of women and significantly

more number of women with PGDM went in to ketoacidosis. Pregnancy loss also was more in women with PGDM when compared to GDM (17.5% vs 9.1%). Similarly hypertension and preterm labour were more common in women with PGDM. Polyhydramnios and PROM were diagnosed in 20% and 36% of women respectively and there was no statistical significance between PGDM and GDM. But PPRM was significantly more common in women with PGDM. Labour induction was undertaken in 61% and more commonly in women with GDM. Prolonged labour was significantly more in women with PGDM. Caesarean section rate was high in women with PGDM and instrumental delivery rate was high in women with GDM. Postpartum hemorrhage occurred in 18% and there was no statistical difference between PGDM and GDM.

The fetal and neonatal outcome live birth rate was more than 70% in GDM and PGDM but still birth rate was higher in PGDM when compared GDM (29% vs. 17.8%).

Table 2: Distribution of different modes of treatment.

Mode of treatment	Pregestational diabetes mellitus (PGDM)		GDM (N=700) Frequency (%)	Total (n=859)
	Type1 DM (N=43) Frequency (%)	Type 2 DM (N=116) Frequency (%)		
MNT	-	-	300 (42.85)	300 (34.92)
MNT+Metformin	-	14 (12.1)	245 (35)	259 (30.15)
MNT+Insulin	43 (100)	93 (80.2)	146 (21)	282 (32.8)
MNT+Insulin+Metformin	-	9 (7.7)	9 (1.2)	18 (2.1)

(MNT= medical nutrition therapy)

Table 3: Maternal outcome.

Outcome	Pregestational diabetes mellitus (N=159)	GDM (N=700)	Total (N=859)	P value
Uncontrolled blood sugar	83 (52.2)	87 (12.42)	171 (19.9)	<0.0001
Diabetic ketoacidosis	13 (8.2)	2 (0.29)	15 (1.75)	<0.0001
Spontaneous abortion	28 (17.6)	64 (9.1)	92 (10.7)	0.0018
Polyhydramnios	28 (17.6)	134 (19.1)	162 (18.9)	0.6556
Hypertension	35 (22)	77 (11)	112 (13.03)	0.0002
PPROM	56 (35.2)	120 (17.1)	176 (21.5)	<0.0001
Cervicovaginal infections	24 (15.1)	73 (10.4)	97 (11.29)	0.0933
PROM	60 (37.7)	248 (28.9)	308 (35.8)	0.5839
Preterm labour	19 (20.4)	42 (8.3)	61 (7.10)	0.0084
Induced labour	85 (53.4)	438 (62.6)	523 (60.9)	0.0335
Prolonged labour	43 (27)	116 (16.6)	159 (18.5)	0.0021
Post-partum hemorrhage	35 (22)	118 (16.9)	153 (17.8)	0.1251
Mode of delivery				
SVD	71 (44.6)	309 (44.4)	380 (44.2)	0.9067
Instrumental delivery	15 (9.4)	173 (24.7)	188 (21.8)	0.0001
Total vaginal deliveries	86 (54.08)	482 (68.85)	568 (66.12)	0.0004
Emergency CS	61 (38.4)	198 (28.3)	259 (31.2)	0.0124
Elective CS	12 (7.5)	20 (2.9)	32 (3.7)	0.0048
Total CS	73 (45.91)	398 (56.85)	291 (33.87)	0.0048
Puerperal sepsis	4 (2.5)	17 (2.4)	21 (2.45)	0.9488

Table 4: Fetal and neonatal outcome.

Outcome	PGDM (N=131)	GDM (N=636)	Total (N=767)	P value
Live birth	93 (71)	523 (82.23)	616 (80.3)	0.0032
Total still birth	38 (29)	113 (17.8)	151 (19.68)	0.0032
MSB	19 (14.5)	39 (6.1)	58 (7.56)	0.0010
FSB	19 (14.5)	74 (11.6)	93 (12.12)	0.5082
Congenital malformations	28 (21.4)	90 (14.1)	118 (15.38)	0.0369
CNS	12 (9.1)	32 (5)	44 (5.73)	0.0642
CVS	5 (3.8)	7 (1.1)	12 (1.56)	0.0225
Gastrointestinal	6 (4.5)	18 (2.8)	24 (3.12)	0.2948
Renal	2 (1.5)	20 (2.9)	22 (2.86)	0.3124
Multiple anomalies	3 (2.3)	13 (2)	16 (2.09)	0.3124
Birth weight				
SGA	27 (20.6)	72 (11.7)	99(12.90)	0.0039
AGA	90 (68.7)	414 (67.2)	504(65.71)	0.4282
LGA	19 (14.5)	125 (20.3)	144(18.77)	0.1693

More number of macerated still births occurred in PGDM. (14.5% vs. 6.1% PGDM vs. GDM). Congenital Malformations were (21.4%) in PGDM as against 14.1%

in GDM and the most common anomaly involved CNS. More number of neonates were small for gestational age (SGA) in women with PGDM.

The neonatal morbidity is shown in (Table 5). Approximately 30% of neonates in both the groups required NICU admission. Hypoglycemia was significantly more in neonates born to PGDM. Hyperbilirubinemia was more common in neonates of

GDM. There are no significant differences in terms of early neonatal deaths convulsions, neonatal sepsis, birth trauma and shoulder dystocia. Significantly more number of neonates were premature in PGDM.

Table 5: Neonatal morbidity.

Neonatal morbidity parameters	PGDM (N=93)	GDM (N=503)	Total (N=623)	P value
NICU admission	32 (34.4)	158 (31.4)	190 (30.49)	0.5688
Neonatal hypoglycaemia	48 (51.6)	127 (25.2)	175 (28.08)	<0.0001
Hyperbilirubinemia	18 (19.3)	150 (29.8)	168 (26.96)	0.0393
Resp distress syndrome	9 (9.7)	61 (12.1)	70 (11.23)	0.5002
Complications				
Early neonatal deaths	2 (2.1)	35 (6.9)	37 (5.93)	0.0775
Convulsions	7 (7.5)	18 (3.6)	25 (4.01)	0.0810
Neonatal sepsis	3 (3.2)	14 (2.8)	17 (2.71)	0.8138
Birth trauma	0	14 (2.7)	14 (2.24)	0.1035
Shoulder dystocia	0	11 (2.2)	11 (1.76)	0.1500
Prematurity	19 (20.4)	42 (8.3)	61 (9.79)	0.0004

DISCUSSION

Diabetes is the most common medical problem, encountered during pregnancy, 6-7% of pregnancies are complicated by diabetes mellitus, of which 90% represent women with GDM.⁴ In the present study 82% were GDM. The mean age of the women in present study was 28.1±2.7 (years) in PGDM and 29.4±2.9 (years) in GDM. This is similar to the study of Patil and colleagues in which the mean age in PGDM was 28.5±2.2 years and contrast to that of DEPOSIT study in which the mean age was higher (31.5±4.9 & 33.1±4.5 in pre-gestational DM & GDM).⁵ Age of the pregnant women plays an important role in terms of development of complications which in turn affect the maternal and fetal outcome.

In the present study, women were classified based on WHO modification for the Asian population for BMI as underweight, normal, overweight and obese.⁷ The incidence of DM in normal weight, overweight and obese pregnant women was 31.7%, 43.5% and 23.4% respectively. In pre-gestational DM overweight women constituted 16.6% and in gestational DM overweight was 83.4%. In DEPOSIT study, the incidence of DM was more in normal weight pregnant women (41.9%) pre-gestational DM being 45.7%; and gestational DM was 38.2%.⁶ The incidences of DM in overweight and obese women were 27.8% and 22.8% respectively. In the present study, maximum women were primigravidae (56%).

Of these PGDM were 13.1% and GDM were 86.9%. Multipara accounted for 44% (Pre-gestational DM-25% and GDM 75%). Similar results were found in the DEPOSIT study, which had 56% primigravidae and 44% multigravida.⁶

The overall incidence of hypertensive morbidity associated with Diabetes mellitus was 13% in the present study. Hypertensive disorders were more commonly associated with type 2 DM (25.8%). Majority of diabetic pregnant women had associated Gestational hypertension. These findings are in contrast to the studies of Patil and colleagues and DEPOSIT study in which the hypertensive morbidity was reported to be 7.8% and 6% respectively in pre-gestational DM and GDM. Patil et al reported hypertensive morbidity to be high (21%) in GDM group and it is double when compared to the present study (11%).⁵ Development of hypertension in PGDM and GDM increases the maternal and fetal morbidity. Poor glycaemic control itself is independent risk factor for development of hypertension and insulin resistance also contributes for the same.⁸ (Sullivan). Elevated blood glucose levels in pregnancy predispose to the development of placental vascular compromise and triggers intracellular changes resulting in dysfunction of cytotrophoblasts and abnormal placentation and development of pre-eclampsia.⁹ In the present study, the overall incidence of spontaneous abortion was 10.7%, with the incidence being more in Pre-gestational DM (17.6%), when compared to GDM (9.1%). In the study of Patil and colleagues⁵, the incidence of abortion was 22%, and is similar in the pre-gestational (21%) and gestational DM (23%) groups were comparable. In the study of Shefali et al the rate of abortion was higher in pre-gestational DM group (10.1%) when compared to gestational DM (2.7%), and it is lower than the present study.^{10,11} The association of pregnancy loss in diabetic pregnancies was well documented in literature. An increase of 1-SD of in first trimester glycosylated hemoglobin from normal was associated with a 3.1% increase in the rate of pregnancy loss, and a 4-SD increase was associated with >40% pregnancy loss.¹²

Polyhydramnios was diagnosed in 18.9% of the present study population and most of them were women with GDM. In study by Nili et al and Patil et al, similar results were found, with the incidence of polyhydramnios being high in gestational diabetes mellitus.^{5,9} Induction of labour was necessary in 61% of the current study and this is high when compared to the study of Patil et al, where only 35.5% underwent induction.⁵ The rate of Caesarean section was 33.8% in the present study, 45% of Pre-gestational DM and 31% of GDM underwent Caesarean section.. Similar results were found in DEPOSIT study and Wahabi et al and colleagues, where the incidence of caesarean section was higher in pre-gestational and GDM.^{6,13} On the contrary, the incidence of caesarean section was high in GDM group than Pre-gestational DM group in Patil study.⁵

In the present study the overall incidence of diabetic ketoacidosis was 1.7%, around 8% in pre-gestational DM and 0.3% in GDM, with the fetal mortality of 13% (2 out of 15). A retrospective study by Chauhan and colleagues over 5 years, DKA occurred in 3% and fetal mortality was 10%.¹⁴ Cullen et al reported the incidence of DKA as 2% with the fetal mortality of 9%.¹⁵ Diabetic ketoacidosis is a life threatening condition which results in renal failure, adult respiratory distress syndrome, cerebral oedema and death. The fetal mortality ranged from 9 to 36%.¹⁶

Ten percent women with DM delivered premature babies, the incidence being more in Pre-gestational diabetes than gestational DM in the present study. This is lower than the studies of Patil and colleagues and Wahabi et al.^{5,10} A threefold increase in prematurity was reported in the DEPOSIT study. In the present study, the overall incidence of congenital malformations was 15.3%, with rate being higher in Pre-gestational DM (21.3%) than Gestational DM (14.1%). In the DEPOSIT study, the congenital malformations were almost comparable in both (Pre-gestational DM & GDM), with the overall incidence of 2.7%, which is lower than the present study.⁶ In the study of Shefali et al, the presence of congenital malformations was more in pre-gestational DM (3.8%) than gestational DM (1.4%). The higher rate of congenital anomalies in the present study is due to inclusion of women with congenital anomalies during the second trimester also, whereas the congenital anomaly rate reported in other studies was at birth only.

The incidence of macrosomia in the present study was 19.3%, with incidence being higher in gestational diabetes mellitus (20.3%) than pre-gestational DM (14.5%). This is similar to the study of Patil et al who reported 7.9% macrosomia in PGDM and 22.9% in GDM. Whereas the incidence of macrosomia was higher in pre-gestational DM when compared in GDM in other studies (DEPOSIT study 37.5% PGDM, and 15.9% GDM; Nili et al 30.3% PGDM, 24.3% GDM). Wahabi et al reported low incidence of macrosomia (PGDM vs. GDM 11.2% vs. 5.3%). The differences may be due to

the difference time of diagnosis and therapy used to manage diabetic women.

In the present study, the incidence of neonatal hypoglycaemia was higher in pre-gestational DM (51.6%) when compared to GDM (25.2%) and similar results were obtained in the study by Nili et al (PGDM 42%, GDM 22.9%) Patil S et al reported the incidence of neonatal hypoglycaemia as 16.5% in PGDM and 21.8% in GDM.⁵ The stillbirth rate was significantly high in PGDM (29%) than GDM (17.8%) and this is high when compared to the studies of Nili et al who reported 12.2% in PGDM and 81% in GDM. Wahabi et al reported a very low still birth rate (PGDM 3.4%; GDM 0.9%). In contrast Patel et al reported 7.2% still birth rate in PGDM and 15.8% in GDM. The differences may be due to the presence of complications and the glycaemic control in various studies. Admission to NICU was high in the studies of Patil et al (PGDM vs., GDM: 78% vs. 42.6%) and DEPOSIT Study (83.7% vs. 45.8% PGDM vs. GDM). In the present study only 34.4% of babies of PGDM and 31.4% of GDM were admitted to NICU. This difference is due to low incidence of prematurity in this study when compared to other studies. The early neonatal death rate is lower in the present study (6.2%) when compared to Nili et al (9.3%) and Patil et al (11.5%).^{5,9} Wahabi and colleagues reported very low early neonatal death rate (2.1%).

CONCLUSION

Obesity, uncontrolled blood sugars, development of hypertension and pre-term labour are the significant factors resulting in adverse maternal and fetal outcome and these are more common in women with PGDM. Pregnancy loss in the form of spontaneous abortions, congenital malformations, and stillbirths is significantly more common in PGDM when compared to GDM. Hence pre-conceptional care and quality obstetric care to achieve control of blood sugars is essential to improve maternal and fetal outcomes.

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