Original Article

Comparison of maternal and fetal outcomes among Asian Indian pregnant women with or without gestational diabetes mellitus: A situational analysis study (WINGS-3)

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ABSTRACT

Aim: To compare the existing maternal and fetal outcomes in Asian Indian women with or without gestational diabetes mellitus (GDM) before the development of the Women in India with GDM Strategy (WINGS) GDM model of care (MOC). **Materials and Methods:** Records of pregnant women were extracted retrospectively from three maternity centers in Chennai. GDM was diagnosed using the International Association for Pregnancy Study Groups criteria or the Carpenter and Coustan criteria. Demographic details, obstetric history, antenatal follow-up, treatment for GDM, and outcomes of delivery were collected from the electronic medical records. **Results:** Of the 3642 records analyzed, 799 (21.9%) had GDM, of whom 456 (57.1%) were treated with insulin and medical nutrition therapy (MNT), 339 (42.4%) with MNT alone, and 4 (0.5%) with metformin. Women with GDM were older than those without (28.5 ± 4.5 vs. 27.1 ± 4.5 years; $P < 0.001$) and had higher mean body mass index at first booking (26.4 ± 5.2 kg/m² vs. 25.2 ± 5.1 kg/m²; $P < 0.001$). Rates of cesarean section (26.2% vs. 18.7%; $P < 0.001$), preeclampsia (1.8% vs. 0.8%; $P = 0.04$), and macrosomia (13.9% vs. 10.8%; $P = 0.02$) were significantly higher among women with GDM. In women with GDM treated with insulin and MNT, emergency cesarean section (16.2% vs. 36.6%; $P < 0.0001$), preeclampsia (0.7% vs. 3.2%; $P = 0.015$), and macrosomia (9.9% vs. 18.6%; $P = 0.0006$) were significantly lesser compared to those treated with MNT alone. **Conclusion:** Pregnancy outcomes were in general worse in GDM women. Treatment with insulin was associated with a significantly lower risk of complications. However, in countries with limited access to insulin and other medicines may lead to poor follow-up and management of GDM. Data from this retrospective study will form the basis for the development of the WINGS GDM MOC, which will address these gaps in GDM care in low-resource settings.

Key words: Asian Indians, fetal outcomes, gestational diabetes mellitus, maternal outcomes, South Asians

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Introduction

Gestational diabetes mellitus (GDM) occurs in 2–5% of all pregnancies and is known to be associated with

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poor maternal and fetal outcomes.[1-5] Apart from being implicated as a risk factor for future type 2 diabetes in the mother,[6] GDM also leads to several adverse fetal outcomes such as macrosomia, shoulder dystocia and other birth injuries, and neonatal hypoglycemia, in addition to congenital anomalies and stillbirths, all of which contribute to the increase in neonatal mortality and morbidity.[7,8]

The Hyperglycemia and Adverse Pregnancy Outcomes (HAPO) study showed a continuous relationship between maternal glucose and increasing birth weight and cord blood C-peptide levels even at glucose levels below those considered diagnostic of GDM.[9] The Australian Carbohydrate Intolerance Study (ACHOIS), a randomized trial of the treatment of women with GDM concluded that treatment of GDM reduces perinatal complications and also improves the health quality of life.[10] A systematic review by Falavigna *et al*.[11] reported that treatment of GDM was effective in reducing the rates of macrosomia, preeclampsia, and shoulder dystocia.

Unfortunately, there is still no uniformity in the diagnosis and treatment of GDM internationally and in India. To address these barriers related to GDM diagnosis and management, the Women in India with GDM Strategy (WINGS) project was launched.[12] The project aimed to develop a model of care (MOC) for GDM seeking to improve the health outcomes of women with GDM and their newborn, especially in resource-limited settings of the world. To establish a strong comparative baseline to help in the development of the MOC, a comprehensive situational analysis was conducted. The several components studied under WINGS situational analysis has been discussed in the previous publication.[13] This study deals with the results from one of the components, i.e., retrospective review of medical records of pregnant women attending antenatal care in three urban maternity centers in Chennai city. This retrospective records review was carried out to understand the current state of art, gaps, and barriers to GDM care that needs to be addressed by the WINGS GDM MOC and to compare the existing maternal and fetal outcomes in Asian Indian women with or without GDM before the development of the WINGS MOC.

Materials and Methods

Study sites

Three urban maternity centers in Chennai participated in this study. Clinical records of pregnant women who were followed up and delivered at these centers during January 2011–December 2012 were retrospectively reviewed.

Data collection

Demographic details, obstetric/medical history, antenatal care follow-up, treatment of GDM, outcome of delivery, and maternal and neonatal complications were retrieved from the collaborating center's electronic medical records.

Anthropometric measurements

Although patient management and practice patterns vary between hospitals, the overall management with respect to booking visits and screening and diagnosis of GDM were similar. At first antenatal visit (first booking), usually in the first trimester, women underwent routine checkup. Anthropometric measurements and other demographic details were collected during this first visit.

Diagnosis of gestational diabetes mellitus

At 24–28 weeks, women underwent an oral glucose tolerance test and GDM was diagnosed using the Carpenter and Coustan (Old American Diabetes Association) criteria until 2011[14] and subsequently, by the International Association of the Diabetes and Pregnancy Study Groups (IADPSG) criteria,[15] after its introduction. Although the IADPSG criteria were published in 2010, several health care professionals still continue to follow old ADA 2005 criteria, even till date as shown in our earlier recent publication.[16] The three centers adopted IADPSG criteria only after 2011.

Management of gestational diabetes mellitus and follow-up

In all three maternity centers, women diagnosed as GDM were initiated on lifestyle modification which included medical nutrition therapy (MNT) and face to face counseling with the dietitian. Glycemic targets were (<90 mg/dl in fasting and <120 mg/dl for 2 h postprandial)[17] set by the diabetologists/physicians in the respective maternity centers. If MNT fails, pharmacotherapy was initiated. Insulin doses were customized based on women's weight and gestational week depending on the self-monitoring of blood glucose or fasting and postprandial testing. Noncompliance to insulin was addressed by the diabetologists and in such cases, women were given metformin. The frequency of antenatal follow-up of women with GDM varied fortnightly/monthly between the three maternity centers. Women without GDM underwent routine antenatal checkup. The outcome of pregnancy and maternal and fetal complications were retrieved from medical records. Macrosomia was defined as birth weight above 3.5 kg.[18]

Ethical clearance

The study was approved by the Independent Ethics Committee of the Madras Diabetes Research Foundation.

Results

Of 4081 records retrieved, a total of 3642 records (89.2%) could be used for analysis after data cleaning. This included

799 women with GDM and 2843 without GDM. Table 1 shows the clinical characteristics of women with or without GDM. Women with GDM were older than those without (28.5 ± 4.5 vs. 27.1 ± 4.5 years; $P < 0.001$) and their mean body mass index at the first booking was higher (26.4 ± 5.2 kg/m² vs. 25.2 ± 5.1 kg/m²; $P < 0.001$). Women with GDM gained lesser weight during pregnancy probably due to the strict diet control. The family history of type 2 diabetes was significantly higher in women with GDM (11% vs. 7%, $P = 0.0009$).

As seen in Figure 1 and 339 (42.4%) women were on MNT alone while 456 (57.1%) were on insulin and MNT and 4 (0.5%) were on metformin alone. Average daily dose of insulin used by women with GDM was 16 units/day while that of metformin was 1000 mg/day. Data on glycemic control of these women through pregnancy was not available due to retrospective nature of the study.

Table 2 shows that the percentage of spontaneous vaginal deliveries was significantly lower in women with GDM compared to those without (42.8% vs. 49.6%; $P < 0.001$). Emergency cesarean section rates were higher among women with GDM when compared to those without (26.2% vs. 18.7%; $P < 0.001$) while elective cesarean section rates were not. Prevalence of macrosomia (13.9% vs. 10.8%; $P = 0.02$) and preeclampsia (1.8% vs. 0.8%; $P = 0.04$) were significantly higher in women with GDM.

With respect to maternal complications [Table 3], preeclampsia was found to be higher among women with GDM (1.8% vs. 0.8%; $P = 0.04$). There were no significant differences between women with or without GDM with respect to other maternal complications. Except for macrosomia (13.9% vs. 10.8%; $P = 0.02$), there were no significant differences in adverse neonatal outcomes (preterm delivery, fetal distress, jaundice, hypoglycemia, shoulder dystocia) between two groups.

Table 4 shows that rates of emergency cesarean section (16.2% vs. 36.6%; $P < 0.0001$), preeclampsia (0.7% vs. 3.2%; $P = 0.015$), and macrosomia (9.9% vs. 18.6%; $P = 0.0006$) were significantly lesser in women treated with insulin and MNT than those treated with MNT alone while fetal distress (6.1% vs. 0.6%; $P < 0.0001$) was found to be significantly higher.

Table 1: Clinical characteristics of pregnant women with or without gestational diabetes mellitus

Clinical parameters	With GDM (*n*=799)	Without GDM (*n*=2843)	*P*
Age (in years)	28.5±4.5	27.1±4.5	<0.001
Height at first booking (in cm)	156.9±8.9	157.9±9.3	0.007
Weight at first booking (in kg)	65±11.1	62.8±11.6	<0.001
BMI at first booking (in kg/m²)	26.4±5.2	25.2±5.1	<0.001
Weight gain during pregnancy (kg)	5.8±6.3	6.7±6.4	0.0007
Primi mothers (%)	361 (48.2)	1414 (49.7)	0.4537
Family history of type 2 diabetes (%)	88 (11)	199 (7)	0.0009

BMI: Body mass index, GDM: Gestational diabetes mellitus

Table 2: Pregnancy outcomes of pregnant women with or without gestational diabetes mellitus

Variables	With GDM (*n*=799) (%)	Without GDM (*n*=2843) (%)	*P*
Mode of delivery			
Spontaneous vaginal delivery	323 (42.8)	1316 (49.6)	0.0006
Instrumental	89 (11.8)	344 (13)	0.3577
Elective cesarean section	131 (17.4)	320 (18.7)	0.395
Emergency cesarean section	198 (26.2)	497 (18.7)	<0.001
Abortion	14 (1.9)	178 (6.7)	<0.001
Intra uterine death	4 (0.5)	15 (0.5)	1
Birth weight (in kg)			
Mean birth weight	2.9±0.6	2.9±0.6	1
<2.5 (low birth weight)	113 (14.5)	322 (12.1)	0.0839
2.5-3.0	301 (38.5)	1144 (43.1)	0.01
3.01-3.5	259 (33.1)	908 (34.1)	0.5964
>3.5 (macrosomia)	109 (13.9)	286 (10.8)	0.02

GDM: Gestational diabetes mellitus

Discussion

This study forms a part of a comprehensive situational analysis conducted as part of the WINGS project, the purpose of which was to understand the burden of GDM and subsequently, develop the WINGS MOC for GDM.

The prevalence of GDM prevalence noted from this study is 22%. However, this may not indicate the true prevalence since data was obtained from three urban maternity centers. Moreover, the prevalence of GDM varies across India from 3.8% to 21% depending on geographical locations, and the criteria used for diagnosis.[19] Even higher prevalence has been reported in other parts of India, 34.9% in Punjab[20] and 41.9% in Uttar Pradesh.[21]

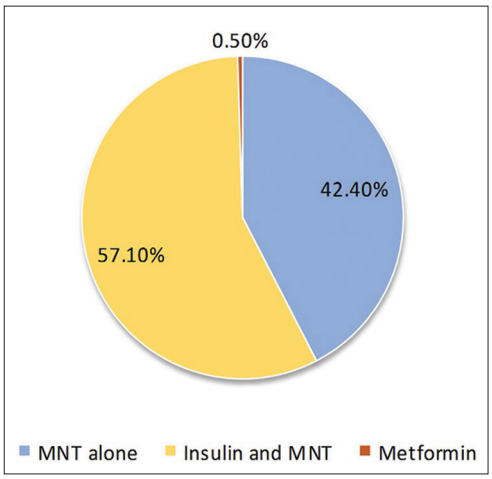

Figure 1: Management of gestational diabetes mellitus

Table 3: Maternal and neonatal outcomes in pregnant women with or without gestational diabetes mellitus

Pregnancy outcome	With GDM (*n*=799)	Without GDM (*n*=2843)	*P*
Maternal complications			
Preeclampsia	14 (1.8)	23 (0.8)	0.04
Placenta previa	8 (1)	16 (0.6)	0.03
Oligohydramnios/ polyhydramnios	19 (2.4)	83 (2.9)	0.4249
Anemia	82 (10.3)	311 (11.1)	0.5143
Hypothyroidism	30 (3.8)	92 (3.2)	0.4256
Neonatal complications			
Preterm birth	69 (8.6)	195 (6.9)	0.069
Macrosomia	109 (13.9)	286 (10.8)	0.02
Jaundice	13 (1.6)	33 (1.2)	0.4133
Respiratory distress syndrome	9 (1.1)	31 (1.1)	1
Shoulder dystocia	0	16 (0.6)	-
Fetal distress	30 (6.4)	95 (5.3)	0.2533

GDM: Gestational diabetes mellitus

Table 4: Comparison of pregnancy outcome in women with gestational diabetes mellitus treated with medical nutrition therapy alone with those on insulin and medical nutrition therapy

Pregnancy outcome	GDM on MNT alone (*n*=339) (%)	GDM on insulin and MNT (*n*=456) (%)	*P*
Mode of delivery			
Spontaneous vaginal delivery	115 (33.9)	207 (45.4)	0.0009
Instrumental	30 (8.8)	58 (12.7)	0.0754
Elective cesarean section	48 (14.2)	82 (18.0)	0.1465
Emergency cesarean section	124 (36.6)	74 (16.2)	<0.0001
Abortion	3 (0.9)	11 (2.4)	0.0892
Maternal and fetal complications			
Preeclampsia	11 (3.2)	3 (0.7)	0.0156
Oligo/polyhydramnios	9 (2.7)	10 (2.2)	0.6547
Placenta previa	2 (0.6)	6 (1.3)	0.3012
Intra uterine death	1 (0.3)	3 (0.7)	0.4154
Jaundice	5 (1.5)	8 (1.8)	0.7413
Respiratory distress syndrome	4 (1.2)	5 (1.1)	0.8964
Fetal distress	2 (0.6)	28 (6.1)	<0.0001
Macrosomia	63 (18.6)	45 (9.9)	0.0006
Low birth weight	40 (11.8)	72 (15.8)	0.1026
Preterm delivery	24 (7.1)	45 (9.9)	0.1569

GDM: Gestational diabetes mellitus, MNT: Medical nutrition therapy

Results from this retrospective study indicate a higher prevalence of macrosomia, preeclampsia, and increased rates of emergency cesarean sections in women with GDM compared to counterparts without GDM in urban maternity centers in Chennai, Tamil Nadu. In agreement with two large cohorts of American and Canadian women, our results confirm that GDM is associated with macrosomia and preeclampsia.[22,23] Schneider *et al*.[24] reported macrosomia, shoulder dystocia, and still birth were the most serious neonatal complications of GDM. Despite the fact that our rates of macrosomia were higher in women with GDM, other perinatal morbidities such as hyperbilirubinemia, respiratory distress syndrome and shoulder dystocia were not different between women with GDM and non GDM, probably reflecting better obstetric care in these urban centers.

Goldman *et al*.[25] reported an overall cesarean section rate of 35.3% in women with GDM compared to 22% in those without. In a population-based study as early as 1989, Jacobson and Cousins[26] reported a higher cesarean section rate in patients with GDM compared with nondiabetic women (29.9% vs. 18.9%). Our results also show higher cesarean section rates in women with GDM compared to those without (26.2% vs. 18.7%; $P < 0.001$).

The Tri-Toronto Hospital Gestational Diabetes Project[27] reported that rates of macrosomia were low in women treated for GDM. Earlier studies have clearly indicated that untreated GDM is associated with higher rates of maternal and perinatal morbidity and mortality.[28,29] There is also strong evidence to suggest that significant reduction in these complications can be achieved through aggressive treatment of GDM.[30] In a population-based study, Hod *et al*.[31] showed that strict control of blood sugars during pregnancy reduced the rates of macrosomia and brought down cesarean section rates. This underscores the fact that early detection and good metabolic control of GDM can significantly lower the rate of complications. Ours being a retrospective study, information on the level of glycemic control achieved in the women with GDM was not available, and this is a major limitation of our study.

A study by Buchanan *et al*.[32] reported that GDM women treated with insulin had reduced rates of macrosomia compared to those treated with diet alone. We also found that rates of the emergency cesarean section, macrosomia, and preeclampsia were lower in GDM women treated with insulin and MNT than those treated on MNT alone. Results from our study are in line with the study by Coustan and Imarah[33] who showed that women who are treated with diet alone had a higher incidence of operative delivery, birth trauma, and macrosomia when compared to those treated with insulin and MNT. Similar results were reported by Metzger *et al*.,[34] who showed that use of insulin in GDM women with fasting plasma glucose >105 mg/dl brought down the rates of macrosomia. A systematic review of six randomized controlled trials that compared the treatment of GDM showed that use of insulin plus MNT decreases the incidence of macrosomia indicating the potential benefit of using insulin.[35]

Nevertheless, use of insulin has certain implications, especially in resource-constrained settings. Qualitative

studies which report on barriers to GDM treatment indicate financial barriers related to health care and unaffordability as some of the reasons for nonadherence to treatment among women with GDM even in developed countries like the United States.[36,37] In low- and middle-income countries, this situation is likely to be more severe, especially in countries like India, where not all the rural primary health centers are equipped to offer insulin treatment. The cost of insulin is almost 5–10 fold higher than other pharmacological drugs in India.[38] Adherence or compliance to insulin therapy, problem of storage,[39] inconvenience of multiple injections, and needle phobia[40] are other limitations that hinder timely follow-up. Burdened with several such constraints and lack of validated guidelines for GDM care in low- and middle-income countries present a formidable barrier to ensuring cost-effective patient management leading to less than optimal care and poor patient outcomes.

Conclusion

Data from this retrospective study calls for a standardized approach to GDM care in resource-constrained settings like India. The WINGS GDM MOC[13] addresses these gaps in GDM care through a multidisciplinary approach that will be both effective and feasible for implementation in resource-constrained settings. The WINGS GDM MOC was piloted in Chennai in 2013–2015, the results of which will be described in subsequent publications. The WINGS GDM MOC will help integrate the model into existing health services and is being planned to be scaled up to other low-resource settings.

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Conflicts of interest

There are no conflicts of interest.

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