

Perinatal and neonatal morbidity among infants of diabetic mothers at a university hospital in Central Saudi Arabia

Abdulrahman M. Al-Nemri, MD, Fahd Alsobime, MD, DES, Asfaq H. Shaik, MBBS, DCH, Ghasan A. El-Hissi, MBBS, Mohammed I. Al-Agha, MBBS, MD, Nada F. Al-Abdulkarim, MBBS, MD, Sarar Mohamed, MD, FRCPC.

ABSTRACT

الأهداف: تحديد معدل المرض خلال الفترة المحيطة بالولادة وأثناءها المرتبطة بالسكري المرتبطة بالحمل.

الطريقة: أجريت هذه دراسة الأستباقية في مستشفى الجامعي في وسط المملكة العربية السعودية. اشتملت الدراسة على جميع حديثي الولادة الذين ولدوا للأمهات المصابات بالسكري المرتبطة بالحمل خلال الفترة من يوليو 2014م ويونيو 2015م لغرض هذه الدراسة. الرضع الذين ولدوا في الأسبوع 23 أو أقل، تم استبعاد الرضع الذين ماتوا في غضون 3 ساعات من الولادة والتوأم، والسيدات الحوامل غير المسجلات.

النتائج: اشتملت الدراسة على 279 من السيدات و 289 رضع. ولوحظ سكري الحمل لدى 84.5% من الأشخاص الذين شملتهم الدراسة نوع السكري الأول في 2.8%، ونوع 2 من داء السكري في 12.5% من الإناث التي تم فحصها. كما لوحظ العديد من المضاعفات الوليدية عند الرضع من الأمهات المصابات بداء السكري بما في ذلك ضخامة الجسم، ونقص السكر في الدم، ونقص كلس الدم، وفرط بيليروبين الدم، ومتلازمة ضيق التنفس، والتشوهات الخلقية. ترتبط ضخامة الجسم، ونقص السكر في الدم، ومتلازمة ضيق التنفس ودخول العناية المركزة للأطفال NICU مع ضعف السيطرة على مرض السكري أثناء الحمل ($HbA1c > 7\%$). علاوة على ذلك، يرتبط وجود التشوهات الخلقية مع ضعف السيطرة على مرض السكري في الربع الأول والثاني ولكن ليس في الثلث الثالث من الحمل.

الخلاصة: ظهر لدى الرضع من الأمهات المصابات بالسكري في هذه المجموعة مجموعة متنوعة من الأحداث حديثي الولادة التي ترتبط إلى حد كبير مع ضعف السيطرة الأيضية أثناء الحمل.

Objectives: To determine the perinatal and neonatal morbidity related to diabetes associated with pregnancy.

Methods: This is a prospective cohort study conducted at a tertiary university hospital in Central Saudi Arabia. All neonates born to mothers with pregnancy associated diabetes between July 2014 and June 2015

were recruited for the purpose of this study. Infants born at 23 weeks or less, infants who died within 3 hours of delivery, twins, and unbooked pregnant ladies were excluded from the study.

Results: A total of 279 ladies and 289 infants were enrolled in the study. Gestational diabetes was observed in 84.5% of study subjects, type 1 diabetes in 2.8%, and type 2 diabetes in 12.5% of the females that were examined. A variety of neonatal complications were observed in infants of diabetic mothers including macrosomia, hypoglycemia, hypocalcemia, hyperbilirubinemia, respiratory distress syndrome, and congenital malformations. Macrosomia, hypoglycemia, respiratory distress syndrome, and NICU admission correlate with poor control of diabetes during pregnancy ($HbA1c > 7\%$). Moreover, the presence of congenital malformations correlates with poor diabetes control in the first and second trimester, but not in the third trimester.

Conclusion: Infants of diabetic mothers in this cohort developed a variety of neonatal events that largely correlates with poor metabolic control during pregnancy.

Saudi Med J 2018; Vol. 39 (6): 592-597
doi: 10.15537/smj.2018.6.22907

From the Department of Pediatric (Al-Nemri, Alsobime, Shaik, El-Hissi, Al-Agha, Al-Abdulkarim, Mohamed), from the Prince Abdullah bin Khaled Coeliac Disease Research Chair (Mohamed), Faculty of Medicine, King Saud University; and from the Department of Pediatric (Mohamed), Prince Sultan Military Medical City, Riyadh Saudi Arabia Riyadh, Kingdom of Saudi Arabia.

Received 11th March 2018. Accepted 16th April 2018.

Address correspondence and reprint request to: Dr. Abdulrahman Al-Nemri, Pediatric Department, College of Medicine, King Saud University, Riyadh, Kingdom of Saudi Arabia.
E-mail: aalnemri@ksu.edu.sa
ORCID ID: orcid.org/0000-0002-4081-3212

In terms of the global diabetes epidemic, Saudi Arabia has been rated among the top 10 countries with a high prevalence of diabetes.¹ Recent studies have shown that the prevalence of type 2 diabetes mellitus (T2DM) is between 21-24% in Saudi Arabia.²⁻⁴ Moreover, the prevalence of diabetes in this country is expected to continue to rise as the result of increasing obesity, fast urbanization with changing dietary habits, and changes in life style. This rise is likely to be reflected in an increase in maternal and possibly gestational diabetes mellitus (GDM). It has been well documented that the prevalence of GDM has increased 5-fold in Saudi Arabia over the last 2 decades.⁴ Diabetes associated with pregnancy applies further strain on pregnant ladies leading to higher maternal, perinatal, and neonatal morbidities.⁵⁻⁸ Diabetes alters the physiological adaptation of both the mother and her fetus. This leads to adverse events during pregnancy including a higher risk of delivery by cesarean section (CS), shoulder dystocia, and other obstetric complications.⁹⁻¹² The long term effects of GDM on mothers include the development of T2DM, obesity, and cardiovascular diseases.¹³⁻¹⁴ Likewise, GDM increases perinatal and neonatal complications including hypoglycemia, hypocalcemia, polythycemia, macrosomia, hyperbilirubinemia, respiratory distress syndrome, and congenital malformation.¹⁵⁻¹⁷ Most of these adverse events were attributed to poor metabolic control during pregnancy and inadequate maternal and neonatal care. Few retrospective studies in Saudi Arabia investigated the perinatal complications, however, these studies did not correlated these complications to the maternal hemoglobin A1C, prospectively.^{2,18,19} The objective of the study is to determine the perinatal and neonatal morbidity related to diabetes associated with pregnancy.

Methods. This is a prospective observation cohort study approved by the Institutional Review Board at the College of Medicine, King Khalid University Hospital, Riyadh, Kingdom of Saudi Arabia. Informed written consent was taken from all mothers participating in the study. We recruited all neonates born to diabetic mothers between July 2014 and June 2015 in King Khalid University Hospital (KKUH) situated within King Saud University Medical City, Riyadh, Saudi Arabia. All infants born to either Saudi or non-Saudi women with confirmed diabetes associated with

pregnancy were included in the study after obtaining their initial consent. Infants born at 23 weeks or less, infants who died within 3 hours of delivery, twins, and unbooked pregnant ladies were excluded from the study. All pregnant ladies attending our institute undergo a standard oral glucose tolerance test (OGTT) and the recording of glucose readings by venous sampling at 24 weeks of gestation. This entails giving a 75-g oral glucose load, and measuring the blood glucose levels at baseline fasting, then at one, 2, and 3 hours after the initial glucose intake. In our study, GDM was diagnosed if ≥ 2 of the 4 blood glucose readings exceeded the cutoff levels which were as follows: fasting (5.8 mmol/l); one hour (10.8 mmol/l); 2 hours (8 mmol/l); and 3 hours (6 mmol/l).

The pregnant ladies who participated in this study attended a regular antenatal clinic throughout their pregnancy. Their blood glucose, HbA1C levels were checked regularly. The infants were admitted to the nursery after delivery and the glucose level of all infants was checked on admission and 3 hourly, thereafter. The glucose level of infants was assessed using a hemogluco-check device. Hypoglycemia was defined as a glucose level < 2.6 mmol/L, which was confirmed by obtaining a sample of venous blood and sending it to the laboratory for analysis. Samples of blood were analyzed for complete blood count (CBC), total bilirubin, magnesium, and calcium for all infants of diabetic mothers upon admission to the nursery. If the glucose level was < 2.6 mmol/L, the infant was admitted to the neonatal intensive care unit (NICU) and dextrose IV was administered with continuous monitoring of glucose levels.

The age, mode of delivery, gravidity, and HbA1C of the diabetic mothers were recorded. Any adverse neonatal outcome/complication including birth trauma, hypoglycemia, congenital anomalies, hypocalcaemia, hyperbilirubinemia, polycythemia, and hypomagnesemia were also reported.

Statistical analysis. Data was analyzed by using the IBM Statistical Package for Social Studies®, version 22 (IBM Corp., New York, NY, USA) for Windows®. Continuous variables were expressed as mean \pm standard deviation and categorical variables were expressed as percentages. An odds ratio with 95% confidence interval was calculated. A Chi square test was used for categorical variables. A *p*-value < 0.05 was considered statistically significant.

Results. Out of the 292 women who were recruited; 12 were excluded from the study. The reasons for exclusion included 10 twin pregnancies, 2 intrauterine fetal deaths (IUFD), and one neonate who died 2

Disclosure. Authors have no conflict of interests, and the work was not supported or funded by any drug company.

hours after delivery (who was born at 34 weeks) due to lung hypoplasia, multi-cystic dysplastic kidney, and oligohydramnios. Subsequently, a total of 279 mothers and 289 infants were enrolled in the study. The GDM was observed in 84.5% of the study subjects, type 1 diabetes in 2.8% of subjects, and type 2 diabetes in 12.5% of all diabetic mothers who participated in the study (Table 1). Poor diabetes control (HbA1c >7%) was observed in a minority of patients in this cohort (Table 2).

The majority of diabetic mothers experienced spontaneous delivery. The exact figure was 177 (61.5%); while 112 (38.5%) mothers underwent an induced delivery. Compared to the subjects with either type 1 or type 2 diabetes, women with GDM had a statistically significant higher rate of elective cesarian sections ($p=0.026$) (Table 3).

A variety of neonatal complications were observed in infants of diabetic mothers during the course of this study (Table 4). A high level of HbA1c (HbA1c >7) in the first trimester was associated with adverse neonatal outcomes such as a long gestational period ($p=0.005$) (odds ratio [OR]=5.35), hypoglycemia ($p=0.008$) (OR=4.71), NICU admission ($p=0.02$) (OR=3.32), and respiratory distress syndrome ($p=0.024$) (OR=3.55) (Table 5). Also, high levels of HbA1c (HbA1c >7) in the second trimester were positively associated with an extended gestational age/period ($p=0.03$) (OR=4.59),

hypoglycemia ($p=0.008$) (OR=6.06), congenital anomalies ($p=0.024$) (OR= 5.00), and NICU admission ($p=0.029$) (OR=5.24) (Table 6). Likewise, high levels of HbA1c (where HbA1c >7) in the 3rd trimester were positively associated with large gestational age ($p=0.02$) (OR=5.27), hypoglycemia ($p=0.03$) (OR=4.69), and hypocalcaemia ($p=0.013$) (OR=19.26) (Table 7).

Discussion. Pregnant ladies with different types of diabetes are at high risk of developing obstetric complications and their offspring, too, are likely to develop perinatal and neonatal adverse events.⁵⁻⁸ In this prospective study, we investigated a cohort of pregnant ladies with diabetes from a country with a high prevalence of diabetes mellitus. Although the reported prevalence of type 2 diabetes in Saudi Arabia is >21%, we observed this type of diabetes in only 12% of our cohort.²⁻⁴ This could be explained by the fact that type 2 diabetes is more common in older age groups compared to child bearing age groups.

Cesarean section delivery is more frequent in pregnant diabetic ladies in comparison with normal healthy pregnant mothers for many reasons. Such reasons include: macrocosmic fetuses, obstetric complications, and previous CS delivery.² In our cohort, we observed that elective CS delivery was more frequent in pregnant ladies with type 2 diabetes compared to gestational and type 1 diabetes ($p=0.026$). This is most

Table 1 - Characteristics of 279 mothers with diabetes mellitus (DM).

DM type (number)	Age (mean years)	Weight (mean Kg)	Gravity	Gravity	Parity (mean)	Miscarriage	BMI
GDM, n=236	32.68	69.1	4	4	2.4	1.03	35.5
Type 1, n=8	32.22	60.0	2.2	2.2	1.0	0.33	29
Type 2, n=35	36.41	80.5	5.08	5.08	3.75	0.82	36.8

BMI - body mass index

Table 2 - Diabetic mothers with hemoglobin A1c levels >7% (N=279).

DM type	1st trimester	2nd trimester	3rd trimester	Overall % of mothers with HbA1c >7%
GDM	1	3	3	(2.5)
T1DM	1	0	1	(0.7)
T2DM	14	8	7	(10.4)
Total	16 (5.73)	11 (3.94)	11 (3.94)	(22.0)

Values are expressed as number and percentage (%). GDM - gestational diabetes, HbA1c - hemoglobin A1c, DM - diabetes mellitus, T1DM - type 1 DM, T2DM - type 2 DM

Table 3 - Mode of delivery of infants in 279 diabetic mothers.

Mode of delivery	GDM	T1DM	T2DM	Total	P-value
NSVD	116 (49.2)	4 (50)	16 (45.7)	136 (48.7)	0.068
Elective CS	37 (15.7)	2 (25)	12 (34.3)	51 (18.3)	0.026
Emergency CS	63 (26.7)	2 (25)	6 (17.1)	71 (25.5)	0.480
Assisted	20 (8.4)	(0)	1 (2.9)	21 (7.5)	0.358

Values are expressed as number and percentage (%). NSVD - normal spontaneous vaginal delivery, CS - cesarean section, GDM - gestational diabetes, T1DM - type 1 diabetes mellitus, T2DM - type 2 diabetes mellitus

Table 4 - Association of neonatal complication with type of diabetes in pregnant mothers.

Neonatal outcome/complication suffered (normal range)	GDM (n=244)	T1DM (n=9)	T2DM (n=36)	Total	P-value
Large gestational age (>4 kg)	25 (10.2)	0	6 (16.0)	31 (10.7)	0.291
Birth trauma	13 (5.3)	0	1 (2.8)	14 (4.8)	0.633
IUGR (Wt & Ht <10th centile for GA)	34 (13.9)	0	3 (8.3)	37 (12.8)	0.325
Hypoglycemia (2.8-4.4 mmole/dl)	26 (10.7)	3 (33.3)	5 (13.9)	34 (11.8)	0.107
Hypocalcaemia (0.7-1.14 mmole/dl)	1 (0.4)	1 (2.9)	3 (1.3)	5 (1.8)	0.085
Hyperbilirubinemia (according to NICU CPG)	28 (11.5)	4 (44.4)	5 (13.9)	37 (12.8)	0.014
Hypomagnesemia (0.7-1.1 mmole/dl)	47 (19.3)	3 (33.3)	4 (11.1)	54 (18.7)	0.261
Polycythemia (36-65%)	12 (5.0)	0	4 (11.4)	16 (5.6)	0.229
Prematurity	35 (14.3)	2 (22.2)	7 (19.4)	44 (15.2)	0.611
Congenital anomalies	22 (9.0)	1 (11.1)	6 (16.7)	29 (10.0)	0.36
NICU admission	51 (20.9)	6 (66.7)	8 (22.2)	65 (22.5)	0.005
Respiratory distress syndrome	33 (13.5)	4 (44.4)	5 (13.9)	42 (14.5)	0.035
Hypoxic ischemic encephalopathy	1 (0.4)	0	1 (2.8)	2 (0.7)	0.269

Values are expressed as number and percentage (%). IUGR - intra-uterine growth restriction, GA - gestational age, NICU - neonatal intensive care unit, T1DM - type 1 diabetes mellitus, T2DM - type 2 diabetes mellitus, CPG - clinical practice guideline, Wt - weight, Ht - height

Table 5 - Adverse neonatal outcome in relation to high HbA1C level in the first trimester.

Neonatal complications	HbA1c <7	HbA1c >7	Total	Odds ratio	95% CI		P-value
	n=270	n=17			Low	High	
Large gestational age	25 (9.3)	6 (35.3)	31	5.35	1.82	15.69	0.005
Birth trauma	14 (5.2)	0	14	-	-	-	0.417
Intrauterine growth restriction	36 (13.3)	1 (5.9)	37	0.41	0.05	3.16	0.328
Hypoglycemia	28 (10.4)	6 (35.3)	34	4.71	1.62	13.73	0.008
Hypocalcemia	5 (1.8)	0	5	-	-	-	0.735
Hypomagnesemia	50 (18.5)	4 (23.5)	54	1.40	0.43	4.52	0.401
Hyperbilirubinemia	33 (12.2)	4 (23.5)	37	2.21	0.68	7.18	0.162
Polycythemia	15 (5.5)	1 (5.9)	16	1.12	0.14	9.06	0.634
Prematurity	39 (14.4)	5 (29.4)	44	2.47	0.82	7.39	0.1
Congenital anomalies	25 (9.3)	4 (23.5)	29	3.02	0.91	9.95	0.079
NICU admission	57 (21.1)	8 (47.1)	65	3.32	1.23	9.00	0.02
Respiratory distress syndrome	36 (13.3)	6 (35.3)	42	3.55	1.23	10.18	0.024
Hypoxic ischemic encephalopathy	1 (0.4)	1 (5.9)	2	-	-	-	0.115

Values are expressed as number and percentage (%).
HbA1c - hemoglobin A1c, NICU - neonatal intensive care unit, 95% CI - 95% confidence intervals

probably because ladies with type 2 diabetes, in this study, were either older or had a higher gravity, parity, and BMI than their counterparts with type 1 diabetes and GDM.²⁻⁶ All these are risk factors for obstetric and perinatal complications and, therefore, doctors are likely to plan elective CS for such individuals. However, various studies have reported a high rate of cesarean delivery in GDM patients despite proper management of glucose levels during pregnancy.^{1-3,5} The outcomes of pregnancies complicated with GDM were significantly worse than those of non-diabetic women with such

patients being 1.7 times more likely to deliver by CS.³ Our data showed that certain perinatal adverse effects such as macrosomia, hypoglycemia, respiratory distress syndrome, and NICU admission all correlate with poor control of diabetes during pregnancy (where HbA1c levels >7%). This was expected; however, as the poor control of diabetes during pregnancy subjects the fetus to high glucose levels and, therefore, stimulates a higher secretion of insulin by the fetal pancreatic B cells.^{6,7} Insulin is an anabolic hormone that promotes intrauterine fetal growth leading to macrosomia, which

Table 6 - Association between adverse neonatal outcomes/complications in relation to high hemoglobin (HbA1c) levels in the second trimester.

Neonatal complications	HbA1c <7 n=275	HbA1c >7 n=12	Total	Odds ratio	95% CI		P-value
					Low	High	
Large gestational age	27 (9.8)	4 (33.3)	31	4.59	1.30	16.26	0.03
Birth trauma	12 (4.3)	2 (16.7)	14	4.38	0.86	22.25	0.11
Intra-uterine growth restriction	36 (13.1)	1 (8.3)	37	0.60	0.08	4.82	0.328
Hypoglycemia	29 (10.5)	5 (41.7)	34	6.06	1.81	20.33	0.008
Hypocalcaemia	5 (1.8)	0 (0)	5	-			0.809
Hypomagnesemia	53 (19.3)	1 (8.3)	54	0.36	0.05	2.87	0.304
Hyperbilirubinemia	36 (13.1)	1 (8.3)	37	0.60	0.08	4.82	0.162
Polycythemia	15 (5.45)	1 (8.3)	16	1.55	0.19	12.83	0.505
Prematurity	43 (15.6)	1 (8.3)	44	0.49	0.06	3.90	0.426
Congenital anomalies	25 (9.1)	4 (33.3)	29	5.00	1.41	17.78	0.024
NICU admission	58 (21.1)	7 (58.3)	65	5.24	1.60	17.11	0.029
Hypoxic ischemic encephalopathy	1 (0.4)	1 (8.3)	2	-			0.082

Values are expressed as number and percentage (%). NICU - neonatal intensive care unit, 95% CI - 95% confidence intervals

Table 7 - Association between adverse neonatal outcomes/complications in relation to high hemoglobin (HbA1c) levels in the third trimester.

Neonatal complications	HbA1c <7 n=276	HbA1c >7 n=11	Total	Odds ratio	95 % CI		P-value
					Low	High	
Large gestational age	27 (9.8)	4 (36.4)	31	5.27	1.45	19.16	0.02
Birth trauma	14 (5.1)	0.00	14	-			0.57
Intra-uterine growth restriction	37 (13.4)	0.00	37	-			0.21
Hypoglycemia	30 (10.9)	4 (36.4)	34	4.69	1.30	16.95	0.03
Hypocalcemia	3 (1.1)	2 (18.2)	5	19.26	2.86	129.88	0.01
Hypomagnesemia	53 (19.2)	1 (9.1)	54	0.40	0.05	3.19	0.35
Hyperbilirubinemia	34 (12.3)	3 (27.3)	37	2.67	0.68	10.55	0.16
Polycythemia	16 (5.8)	0.00	16	-			0.53
Prematurity	41 (14.9)	3 (27.3)	44	2.15	0.55	8.44	0.23
Congenital Anomalies	27 (9.8)	2 (18.2)	29	2.05	0.42	9.98	0.31
NICU admission	61 (22.1)	4 (36.4)	65	2.01	0.57	7.11	0.22
Respiratory distress syndrome	39 (14.1)	3 (27.3)	42	2.28	0.58	8.96	0.21
Hypoxic ischemic encephalopathy	1 (0.4)	1 (9.1)	2	-			0.08

Values are expressed as number and percentage (%). NICU - neonatal intensive care unit, 95% CI - 95% confidence intervals

in turn results in other neonatal adverse effects. This fact is in agreement with previous studies which have reported that poor diabetes control during pregnancy is positively associated with increased maternal and perinatal morbidity and mortality.²⁻⁶ We observed that the tendency towards the presence of congenital malformations correlates with poor diabetes control in the first and second trimester but not in the third trimester. This is because organogenesis occurs in early pregnancy and therefore the risk of congenital malformation is higher when the infant is exposed to

poor metabolic control during this period. Congenital malformation amongst infants of diabetic mothers was the major reason for increased morbidity and mortality rates of these infants.¹²⁻¹⁴

The study assumes significance due to the fact that a substantial number of study subjects developed a variety of neonatal adverse effects including: macrosomia, hyperbilirubinemia, RDS, admission in NICU, hypoglycemia, and congenital anomalies irrespective of the type of diabetes they had. However, because the study was performed at a single center

and included a low population cohort size, the results that were obtained from the data that was accrued has limited generalizability. Moreover, the nutritional status of the study subjects throughout their period of pregnancy and the non-inclusion of controls could have influenced the study results. Therefore, we recommend that larger case control studies be conducted across multiple centers throughout the Kingdom of Saudi Arabia in order to draw firm conclusions regarding the relationship between perinatal complication HbA1c levels in diabetic pregnant mothers.

In conclusion, then, we have shown that infants of diabetic mothers suffer complications which correlate with poor blood sugar level control during pregnancy as indicated by high maternal HbA1c levels.

Acknowledgment. *This research has been financially supported by Prince Abdullah Ben Khalid Celiac Disease Research Chair, under the Vice Deanship of Research Chairs, King Saud University, Riyadh, Kingdom of Saudi Arabia. The authors would like to thank all the participants involved in this study.*

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