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Association between five minute Apgar scores and planned mode of delivery in diabetic pregnancies

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Short version of the title: Mode of delivery in diabetic pregnancies

Conflicts of Interest: No conflicts of interest exist.

Abstract

Objective: Due to the high incidence of neonatal complications in diabetic pregnancies the aim with our study was to investigate if elective cesarean section could prevent adverse neonatal outcome.

Design: Population-based study.

Setting: Data was extracted from the Swedish Medical Birth Registry.

Population: All women (n=13 491) with diabetic pregnancies during the period 1990-2007.

Methods: Neonatal outcome in diabetic pregnancies was compared after elective cesarean section at 38 completed gestational weeks with planned vaginal delivery at 39 completed weeks of gestation or later. Odds ratios with 95 % confidence intervals for Apgar <7 at five minutes after birth were calculated using multiple logistic regression.

Main outcome measures: Apgar score <7 at five minutes after birth.

Results: A significantly decreased risk of Apgar score <7 at five minutes after birth in the group who underwent an elective cesarean section at 38 completed gestational weeks was found compared with those who continued pregnancy to 39 completed weeks of gestation or more, irrespective of final mode of delivery.

Conclusion: Our results indicate a protective effect of planned cesarean section on the risk of low Apgar scores in diabetic pregnancies.

Key words: Apgar-score, cesarean section, delivery, diabetes.

Abbreviations: AGA: appropriate for gestational age, BMI: body mass index, CI: confidence interval, CP: cerebral palsy, CS: cesarean section, DM: diabetes mellitus type 1, EP: epilepsy, GD: gestational diabetes, MBR: Medical Birth Registry, OR: odds ratio, LGA: large for gestational age, SD: standard deviation, SGA: small for gestational age.

Introduction

Maternal diabetes during pregnancy is often related to increased neonatal morbidity and mortality, including congenital anomalies, growth retardation, preterm delivery, respiratory distress and hypoglycaemia (1,2). Furthermore, at birth, neonates to diabetic mothers have higher rates of complications associated with macrosomia, such as shoulder dystocia and asphyxia (3,4,5).

There are no national Swedish guidelines regarding mode of delivery or optimal gestational age at delivery in diabetic pregnancies, but most clinics aim for a vaginal delivery at term. Usually, elective labor induction may be planned around 40 weeks of gestation, or earlier if fetal macrosomia is suspected sonographically. However, the incidence of delivery by cesarean section (CS) is increased in pregnancies complicated by both diabetes mellitus type 1 (DM) (6) and gestational diabetes (GD), ranging from 38-56%, with 55% of all CS's being performed electively (7,8).

The literature regarding the **optimal** route of delivery in diabetic pregnancies is sparse. There is little evidence supporting routine elective delivery (e.g. induction or CS) for the mere reason of suspected macrosomia in non-diabetic patients (9). However, the increased rate of neonatal injury and increased prevalence of macrosomia in diabetic pregnancies might provide a rationale to offer an elective cesarean delivery (10).

Due to the high incidence of neonatal complications in diabetic pregnancies the aim with our study was to investigate if elective CS could prevent adverse neonatal outcome. The association between mode of delivery in 13 491 diabetic pregnancies and neonatal outcome was investigated, comparing five-minute Apgar scores after elective cesarean section at 38 **completed gestational weeks with planned vaginal delivery at 39 completed weeks of gestation or later. Furthermore, long term neurological impairments defined as cerebral palsy (CP) and epilepsy (EP) were compared between the children who were born after elective CS at 38 completed gestational weeks with planned vaginal delivery at 39 completed weeks of gestation or later, irrespective of final mode of delivery.**

Material and Methods

Singletons, born in 1990-2007, to mothers with a diagnosis of preexisting insulin dependent diabetes (DM) (ICD-10 code 0.24.0, ICD-9 code 250) or diabetes mellitus arising in pregnancy (GD) (ICD-10 code 0.24, ICD-9 code 648.8) identified in the Swedish Medical Birth Registry (MBR)(11), were included in the study. No other specification of codes for diabetes is available in the MBR. Information regarding mode of delivery, maternal characteristics and neonatal outcome was collected from the MBR.

The MBR is based on information from standardized record forms used at all antenatal clinics and delivery units, including pediatric examinations of the newborn infant and contains medical information on 99% of deliveries in Sweden. Information regarding maternal smoking and maternal height and weight is collected from interview forms from the first visit at the antenatal care clinic. A copy of this form is sent to the National Board of Health, and is computerized in the form of the MBR. All Swedish women are offered a free routine ultrasound examination at 17-18 postmenstrual weeks in order to confirm fetal life, estimate the expected date of delivery, to identify twin pregnancies, and to detect severe fetal malformations. Thus, information regarding gestational age used in the current study is mostly based on ultrasound estimates. The MBR is annually linked with Statistics Sweden in order to, among other things, obtain information on the date of death.

Apgar score <7 at five minutes after birth were regarded primary endpoints.

Information on 'planned' mode of delivery is not directly recorded in the MBR. Infants born by CS before labor contractions (elective CS) at 38 completed weeks of pregnancy constituted the 'planned CS group' whereas infants born at 39 completed weeks or more (irrespective of mode of delivery) constituted the 'planned vaginal delivery group'. Analysis regarding Apgar scores <7 at five minutes after birth was performed in 4 sets of groups, in the DM+GD group; the DM-group; the GD-group and in the large for gestational age (LGA) group (regardless of type of diabetes).

Intrauterine growth was evaluated in accordance with the national fetal weight-based growth standard (12) and expressed in standard deviation scores (SD-scores). Infants with birthweight

of more than 2 SD below the expected weight for gestational age were classified as small for gestational age (SGA), whereas infants weighing more than 2 SD above expected weight for gestational age were considered LGA.

In order to evaluate long term neurological development a linkage was performed between the MBR and the In-Patient Register to obtain diagnose codes. The In-Patient Register contains the diagnoses (given as ICD-codes) of all patients admitted to a Swedish hospital since 1987. The following ICD-codes were used in the analysis, CP (ICD-9 code 343, ICD-10 code G80) and EP (ICD-9 code 345, ICD-10 code G40)

The study was approved by Lund University Ethics Committee, Sweden.

Statistical analyses

Odds ratios (OR) with 95 % confidence intervals (CI) for Apgar <7 at five minutes after birth were calculated using multiple logistic regression. The following variables were evaluated as possible confounders: fetal year of birth, fetal weight SD-scores, fetal malformations, gestational diabetes, maternal age, parity, smoking, and maternal Body Mass Index (BMI). In order to determine the final multivariate model with the best overall precision combined with a satisfactory goodness of fit the following steps were taken: First, the best univariate model for each investigated possible confounder (linear, quadratic, or divided into designed class variables) was determined by investigating the level of significance and goodness of fit according to the Hosmer-Lemoshov test. Secondly, variables with p-values below 0.20 in the final univariate models were included in the multivariate model. For each model, the number of investigated factors never exceeded 1/10 of the number of cases.

Hazard Ratios (with 95% CI) for CP or EP were computed using Cox analyses considering the different lengths of follow up within the study group. The date of the study exit was set to the date of the first diagnosis of CP or EP, the date of death, or the date of the data retrieval (December 31, 2009), depending on which event happened first. The procedure to determine the final model for the COX analyses was similar to the one described above for the logistic regression analyses.

All statistical analyses were performed using Gauss (GaussTM, Aptech Systems Inc., Maple Valley, WA, USA, <http://www.aptech.com>).

Results

During the period 1990-2007, 13 491 births to women with either DM (n = 3 226) or GD (n = 10 265) from complete 38 weeks of gestation or beyond were included in the analyses.

Maternal and neonatal background characteristics are showed in Table 1. In both diabetic groups, 4 634 women gave birth at 38 completed gestational weeks. An elective CS was performed in 1 305 (28.2 %) of cases. The corresponding numbers at 38 completed gestational weeks for the DM-group and GD-group were 502 (31.1%) and 803 (26.6%), respectively. Sixty-seven infants (2.1%) in the DM group had Apgar score <7 at five minutes after birth and 134 (1.3%) infants had Apgar score <7 at five minutes after birth in the GD-group.

In the crude univariate analysis, no significant difference concerning Apgar score <7 at five minutes after birth between the planned CS group and planned vaginal group was found in the DM+ GD group (p= 0.287). However, in a multivariate logistic regression model that adjusted for age, (second grade model), SD (second grade model), maternal BMI, parity, gestational diabetes, fetal malformations, a significant reduced risk of Apgar scores <7 at five minutes after birth was found in the planned CS group versus the planned vaginal group (p= 0.021). See model specification in Table 2. When numbers needed to treat was calculated, 132 elective cesarean sections have to be performed to avoid 1 newborn with Apgar score <7 at five minutes after birth. No significantly reduced risk of Apgar score <7 at five minutes after birth in the planned CS group versus the planned vaginal group was found in the DM group (p=0.08) or GD group alone (p= 0.12). In Table 2 both crude and adjusted odds ratio and 95% confidence intervals for Apgar scores <7 at five minutes after birth are showed in the DM+GD group. In Table 3, both crude and adjusted odds ratio and 95% confidence intervals for Apgar scores <7 at five minutes after birth are showed in the DM and GD groups separately.

In both diabetic groups, a total of 1 981 (14.7%) infants were LGA of whom 56 (2.6%) had Apgar score <7 at five minutes after birth. Among LGA infants, 8 infants (1.8%) had Apgar score <7 at five minutes after birth in the planned CS group versus 36 (3.54%) in the planned vaginal group. With a multivariate logistic regression model that included age, age (second grade model), SD (second grade model), parity and planned CS, the adjusted odds ratio for

Apgar scores <7 at five minutes after birth was 0.47 (95% CI 0.21-1.03) (p=0.06) in the LGA group, planned CS versus planned vaginal delivery.

There were 57 cases of perinatal and infant deaths, five in the planned CS group and 52 in the planned vaginal group. No significantly reduced risk of death in the planned CS group versus the planned vaginal group was found, the adjusted odds ratio for death was 0.6 (95% CI 0.23-1.62) (p= 0.3). With a low rate of perinatal death in the current cohort, (57/13 491), a power analysis revealed that we had only 14% chance to detect a true 50 % risk reduction for death in the elective CS group.

In the planned CS group one child (0.08%) received the diagnosis CP, and 4 (0.31%) received the diagnosis EP. The corresponding numbers in the planned vaginal group was 16 (0.13%) and 54 (0.44%), respectively. In the planned CS group 15 (1.15%) had Apgar score <7 at five minutes after birth, of which 1 had CP (6.7%) and 1 (6.7%) had EP. In the planned vaginal group, 186 (1.53%) had Apgar score <7 at five minutes after birth, of which 5 (2.69%) had CP and 3 (1.61%) had EP. In a univariate model the hazard ratio for either CP or EP was 1.58 (95% CI 0.58- 4.35)(p= 0.37), between the planned vaginal and planned CS group.

Shoulder dystocia was evident in 38 cases in the DM group and 112 cases in the DM+GD group, all cases of shoulder dystocia were found in the planned vaginal group. Shoulder dystocia contributed to approximately 13 % of low Apgar scores, as 27 of the 201 infants with Apgar score <7 at five minutes after birth were subject to shoulder dystocia.

Discussion and Conclusion

In our study, constituting of 13 491 diabetic pregnancies, after adjusting for potent confounders we found a significantly decreased risk of Apgar score <7 at five minutes after birth after birth in the group who underwent an elective CS at 38 completed gestational weeks compared with those who intended a vaginal delivery, irrespective of the final mode of delivery. When the DM and GD groups were analyzed separately, the odds ratios for Apgar

score <7 at five minutes after birth were of the same magnitude. However, with the diminished power, no significantly decreased risk of Apgar score <7 at five minutes after birth in the group who underwent an elective CS after 38 completed gestational weeks was found within the sub groups.

A Cochrane review concludes that there is very little evidence to support either elective delivery or expectant management at term in pregnant women with insulin-requiring diabetes (13). Only one randomized controlled study has compared elective induction versus expectant management in insulin-requiring diabetic pregnant women at term (n=200). The risk of macrosomia, defined as birthweight above 4 000 g, was reduced in the active induction group, no significant difference was found in CS rates, shoulder dystocia, neonatal hypoglycemia or perinatal deaths (14). Conway et al studied 2 604 diabetic women undergoing ultrasonographic fetal weight estimates during the 37th and 38th week of gestation. If the estimated fetal weight was above or equal to 4 250 grams the patient underwent an elective cesarean section and if the estimated fetal weight was over or equal to the 90th percentile but under 4 250 grams the patient underwent induction of labor. Fewer infants were macrosomic and the incidence of shoulder dystocia was lower in the group undergoing elective cesarean section or labor induction than in the expectant management group (15).

A strength with our study is the large diabetic population studied. To our knowledge, no large randomly controlled studies exist analyzing optimal timing and mode of delivery in diabetic pregnancies. Also, we have not found any studies comparing elective cesarean section with planned vaginal delivery in diabetic pregnancies in regards of fetal outcome and neurological diagnosis. However, very few children in our study received the diagnosis CP or EP and our results are not conclusive.

Our study has certain limitations. We have not investigated other consequences of CS , e.g., the long term maternal effects of elective CS versus planned vaginal delivery. We adjusted for maternal age, parity, BMI, and smoking habits, but other data on socio-demographic factors like maternal educational level or family income were not available and could not be adjusted for. Information regarding fetal blood gas status is not available in the MBR, and could not be analyzed as an indicator of adverse fetal outcome. Although the predictive value of adverse neonatal outcome after a low Apgar score has been questioned, it is still routinely used at all

delivery wards in Sweden, and associated with an increased risk of infant CP, EP, mental retardation and death (16)(17).

Due to the ethical conflicts performing a randomized clinical study comparing elective CS and planned vaginal delivery we chose to analyze data from the MBR. One weakness with the current study is that information on planned mode of delivery was not obtainable, but epidemiological techniques had to be used. In order to exclude women that were planned for an elective CS in 38 completed weeks, but were admitted to the labor unit with labor pains and converted to an emergency CS, the planned vaginal group was restricted to those who continued pregnancy after 39 completed weeks of gestation. With this set-up, the assumption was made that vaginal delivery at term was planned only for the presumed healthiest fetuses, and an over representation of fetal and maternal morbidity should be evident in the planned CS group. **The mothers** in the planned CS group were older, had a higher BMI and a larger percent of the babies were LGA and had malformations. The mentioned systematic bias makes it probable that the true protective effect of an elective CS to prevent low Apgar scores would have been even more pronounced than the estimate obtained.

Despite advances in metabolic control in diabetic pregnancies, a recent Swedish study on DM pregnancies showed a five times higher rate of stillbirth compared to the background population (18). Our diabetic population is a selected healthier diabetic population as premature deliveries before 38 completed weeks of pregnancy were not considered in the analyses. Our study population is too small to have adequate statistical power to analyze death as an endpoint (n=57), and no significant decrease in mortality rate was evident in the planned CS group compared to the planned vaginal group.

The incidence of fetal macrosomia in DM-pregnancies ranges from 30-50% (18,19) compared to 3.6% in the general population (18). Fetal macrosomia has been shown to be the strongest predictor for shoulder dystocia in patients with GD (20). Acker et al., proposed that the risk factors of diabetes and large fetus (4 000 + g) could predict 73% of shoulder dystocia among diabetics (21). **In our study, among LGA infants who underwent an elective CS after 38 completed gestational weeks compared to the planned vaginal group, a close to significant decreased risk of Apgar score <7 at five minutes after birth (p=0.06) was shown. Among**

LGA infants that were delivered with either vacuum extractor (VE) or forceps, as many as 14.1% had Apgar score <7 at five minutes after birth.

The question remains how to deliver the diabetic fetus, in particular if macrosomia is suspected. A trade off exists between the fetal risk of shoulder dystocia or asphyxia during vaginal delivery, in particular when the infant is LGA, and the potential maternal risks associated with an elective CS. Practice guidelines published by ACOG recommend considering a planned CS to prevent shoulder dystocia if the estimated fetal weight exceeds 5 000g in women without diabetes and 4 500 g in women with diabetes (22). A complicating factor, however, is the low-sensitivity and potential inaccuracy of current sonographic methods to detect the LGA fetus (23).

According to our results, 132 elective CS: s are needed to avoid one newborn with Apgar score < 7 at five minutes after birth. One can question the clinical sense to perform 132 CS in order to prevent one child having Apgar score < 7 at five minutes after birth. However, one must keep in mind, in clinical practice the choice is usually not between elective CS and vaginal delivery but instead elective CS and emergency CS /instrumental delivery. Even though a vaginal delivery is planned, a large proportion of diabetic women end up with an operative or instrumental delivery. In the DM group in our study, only 49% had a non-instrumental vaginal delivery and as many as 39% end up with either an elective or emergency CS.

In conclusion, we found a significantly decreased risk of Apgar score <7 at five minutes after birth in diabetic pregnancies that underwent an elective CS after 38 completed gestational weeks compared to those who continued with a vaginal delivery, irrespective of the final mode of delivery. Our results, together with the low prevalence of non-instrumental vaginal deliveries in diabetic pregnancies, should be taken into consideration when managing the diabetic pregnancy.

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Table 1. Maternal and neonatal characteristics by gestational week and mode of delivery in diabetic pregnancies (type 1 and gestational diabetes).

Maternal and fetal characteristics	EICS 38	39 completed weeks of pregnancy or more				
	completed weeks	Total	Vaginal	EICS	EmCS	VE/forceps
	n=1305	n=12 186	n=8 842	n=671	n=1 630	n=10 43
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Maternal age (years)						
<20	2 (0.2)	132 (1.1)	92 (1.0)	3 (0.4)	17 (1.0)	20 (1.9)
20-34	832 (63.7)	8770 (72.0)	6348 (71.8)	450 (67.1)	1178 (72.3)	794 (76.1)
35-39	365 (28.0)	2588 (21.2)	1882 (21.3)	166 (24.7)	356 (21.8)	184 (17.6)
40+	106 (8.1)	696 (5.7)	520 (5.9)	52 (7.7)	79 (4.8)	45 (4.3)
Nullipara	308 (23.6)	4604 (37.8)	2621 (29.6)	208 (31.0)	1018 (62.5)	757 (72.6)
Maternal BMI (kg/m²)						

<20	23 (2.3)	404 (4.4)	331 (5.0)	14 (2.7)	23 (1.8)	36 (4.5)
20-24.9	320 (32.4)	3420 (37.3)	2520 (38.2)	169 (32.5)	411 (33.0)	320 (40.3)
25-29.9	309 (31.3)	2784 (30.4)	1964 (29.7)	159 (30.6)	391 (31.4)	270 (34.0)
30+	335 (33.9)	2552 (27.9)	1787 (27.1)	178 (34.2)	419 (33.7)	168 (21.2)
<i>Missing</i>	<i>318</i>	<i>3026</i>	<i>2240</i>	<i>151</i>	<i>386</i>	<i>249</i>

Weight classification

according to GA

SGA	15 (1.1)	158 (1.3)	88 (1.0)	15 (2.2)	34 (2.1)	21 (2.0)
AGA	833 (63.8)	10521 (86.3)	7837 (88.6)	449 (66.9)	1312 (80.5)	923 (88.5)
LGA	457 (35.0)	1507 (12.4)	917 (10.4)	207 (30.8)	284 (17.4)	99 (9.5)

Malformation	56 (4.3)	323 (2.7)	208 (2.4)	24 (3.6)	64 (3.9)	27 (2.6)
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Apgar scores, 5 minutes

Apg \geq 7	1290 (98.9)	12000 (98.5)	8771 (99.2)	661 (98.5)	1578 (96.8)	990 (94.9)
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Apg<7	15 (1.1)	186 (1.5)	71 (0.8)	10 (1.5)	52 (3.2)	53 (5.1)
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Mortality

Antenatal death	1 (0.1)	30 (0.2)	24 (0.3)	1 (0.1)	2 (0.1)	3 (0.3)
Intrapartal death	0 (0.0)	3 (0.0)	2 (0.0)	0 (0.0)	1 (0.1)	0 (0.0)
Neonatal death	4 (0.3)	19 (0.2)	9 (0.1)	4 (0.6)	4 (0.2)	2 (0.2)

Abbreviations: EICS elective cesarean section; EmCS emergency cesarean section; VE vacuum extraction; Vag vaginal; GA gestational age; BMI Body Mass index; SGA small for gestational age; AGA appropriate for gestational age; LGA large for gestational age.

Table 2. Association between Apgar score <7 at five minutes after birth and planned mode of delivery in both diabetic groups.

Investigated variables	Diabetes mellitus and Gestational diabetes			
	Univariate		Multiple model ^A	
	OR	95%CI	OR	95%CI
Elective CS completed 38 weeks				
weeks	0.75	0.44-1.27	0.51	0.28-0.90
Gestational diabetes (vs DM)	0.62	0.46-0.84	0.67	0.49-0.92
Maternal age, second grade model ^A				
Linear term	0.73	0.59-0.90	0.82	0.66-1.01
Quadratic term	1.01	1.00-1.01	1.00	1.00-1.01
Simoultaneous p-value	p=0.005		p=0.06	
Nulliparity	2.42	1.82-3.20	2.72	2.00-3.71
Maternal smoking (yes vs no)	0.98	0.65-1.49		
Maternal BMI (one step increment)	1.04	1.02-1.07	1.05	1.02-1.08
Significant malformation	2.03	1.10-3.77	1.80	0.96-3.36
SD-scores (one step increment, quadratic term)	1.07	1.05-1.10	1.09	1.06-1.12
Year of delivery (one year increment)	1.01	0.98-1.04		

Odds ratios and 95% CI:s for univariate and multiple models were obtained using logistic regression analyses. ^AThe multivariate model includes all variables shown in the column. All variables with $p < 0.2$ in the univariate analyses were entered in the multiple model.

Abbreviations: CS cesarean section; DM diabetes mellitus type 1; BMI body mass index; SD standard deviation weight scores (12); OR odds ratio; CI confidence interval.

Table 3. Association between Apgar score <7 at 5 minutes after birth and planned mode of delivery by type of diabetes.

Investigated variables	Diabetes mellitus type 1				Gestational diabetes			
	Univariate		Multiple model		Univariate		Multiple model	
	OR	95%CI	OR	95%CI	OR	95%CI	OR	95%CI
Elective CS week 38	0.53	0.23-1.23	0.45	0.19-1.11	0.85	0.43-1.67	0.55	0.26-1.17
Maternal age, second grade model ^A								
Linear term	0.69	0.47-1.01	0.75	0.51-1.10	0.76	0.59-0.99	0.87	0.67-1.13
Quadratic term	1.01	1.00-1.01	1.01	1.00-1.01	1.00	1.00-1.00	1.00	1.0 -1.007
Simoultaneous p-value	p= 0.005		p=0.34				p=0.14	
Nulliparity	2.55	1.52-4.27	2.62	1.50-4.56	2.24	1.59-3.15	2.72	1.88-3.95
Maternal smoking (yes vs no)	0.93	0.44-1.97			1.00	0.61-1.66		
Maternal BMI (one step increment)	1.01	0.95-1.08			1.06	1.03-1.09	1.06	1.03-1.09
Significant malformation	0.36	0.05-2.61			3.32	1.72-6.4	3.06	1.57-5.95
SD-scores (one step increment,	1.05	1.01-1.09	1.08	1.04-1.13	1.08	1.05-1.11	1.09	1.06-1.13

quadratic term)

Year of delivery (one year

increment)

0.99 0.95-1.04

1.02 0.99-1.06

Odds ratios and 95% CI: s for univariate and multiple models were obtained using logistic regression analyses. ^AThe multivariate model includes all variables shown in the column. All variables with $p < 0.2$ in the univariate analyses were entered in the multiple model. Abbreviations: CS cesarean section; DM diabetes mellitus type 1; BMI body mass index; SD standard deviation weight scores (12); OR odds ratio; CI confidence interval.