Neonatal hypoglycemia in infants born to mothers with gestational diabetes mellitus. Comparison of its incidence based on maternal treatment

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ABSTRACT

Introduction. Neonatal hypoglycemia is a complication of gestational diabetes mellitus. Few studies have been conducted to support a systematic screening in the first hours of life of this population group.

Objectives. To assess the association between the treatment administered to the mother (diet vs. insulin) and the development of hypoglycemia, and to identify associated risk factors.

Population and methods. Observational, analytical, and retrospective study carried out at the Buenos Aires and San Justo maternal centers of a general, tertiary care hospital between 01-01-2017 and 12-31-2018. The incidence of neonatal hypoglycemia (≤ 47 mg/dL) based on the management of maternal diabetes was estimated and a multivariate analysis was done to assess related factors.

Results. A total of 195 patients were included. No statistical difference was found in the incidence of hypoglycemia based on the treatment administered to the mother (45.3% vs. 39.7%; $p = 0.45$) and no associated risk factors were identified. Once the cutoff point was changed to ≤ 40 mg/dL, no differences were found in the incidence either (23.4% versus 19%, $p = 0.48$); however, patients with hypoglycemia had a significantly higher hematocrit level and a lower prevalence of exclusive breastfeeding upon discharge. Multivariate analysis showed an independent association between a high birth weight and hypoglycemia, requiring correction.

Conclusions. The incidence of neonatal hypoglycemia in the studied population did not vary based on the treatment received by the mother. This study supports the control of glycemia in these infants in daily practice.

Key words: *hypoglycemia, gestational diabetes, newborn infant, glycemic control.*

http://dx.doi.org/10.5546/aap.2022.eng.232

To cite: Cioccale A, Brener Dik P, Galletti MF, Mariani G, Lupo E. Neonatal hypoglycemia in infants born to mothers with gestational diabetes mellitus. Comparison of its incidence based on maternal treatment. *Arch Argent Pediatr* 2022;120(4):232-239.

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Funding:
None.

Conflict of interest:
None.

Received: 7-13-2021
Accepted: 11-30-2021

INTRODUCTION

Gestational diabetes mellitus (GDM) is carbohydrate intolerance of varying severity with first recognition during pregnancy, and comprises two distinct entities: 1) GDM diagnosed in the last half of pregnancy which goes away at least temporarily after delivery, and 2) pre-existing or pre-gestational diabetes, diagnosed during pregnancy or triggered by pregnancy which persists after delivery.[1-4] Treatment begins with a program of dietary and lifestyle counseling; insulin should be added if glycemic targets are not achieved.[5]

Newborn infants (NBIs) born to mothers with GDM have higher morbidity compared to children born to non-diabetic mothers. Among the complications that may occur, the following are described: hypoglycemia, fetal macrosomia, birth trauma, hypocalcemia, hypomagnesemia, polycythemia and hyperbilirubinemia.[3] Healthy NBIs without risk factors may have low blood glucose values as an expression of a physiological, transient and self-limited process.[6,7] In an infant of a diabetic mother (IDM), hypoglycemia occurs due to transient hyperinsulinism as a consequence of the maternal hyperglycemic status. When maternal glycemia is well controlled, neonatal hypoglycemia is usually transient, asymptomatic and does not persist beyond 48 hours of life. When this is not achieved, it can cause symptomatic and/or difficult to manage neonatal hypoglycemia.[8]

Few studies have been conducted comparing the incidence of hypoglycemia among NBIs born to diet-treated or insulin-treated pregnant women. Sarkar et al. have reported that infants of diet-treated diabetic mothers do not have higher morbidity, including hypoglycemia, compared to infants of non-diabetic mothers, and suggest not to perform controls beyond 3 hours of life.[3] However, a Danish study shows that the number of hypoglycemic events among infants of diabetic mothers was similar, regardless the maternal treatment used.[9]

Thus, the literature seems controversial. For this reason, in daily practice, a question arises about the need to perform a routine screening in all infants of mothers with gestational diabetes during the first hours of life.

The primary objective of this study was to assess the association between the treatment given to the mother and the development of hypoglycemia. The secondary objective was to identify risk factors associated with hypoglycemia in this population group. The working hypothesis was that infants of diet-treated diabetic mothers have a lower incidence of hypoglycemia in the first 6 hours of life compared to infants of insulin-treated diabetic mothers.

METHODS

Design: retrospective observational cohort study.

Population: IDMs born at ≥ 35 weeks of gestational age (GA) at the Buenos Aires and San Justo maternal centers of a general hospital between January 2017 and December 2018 were included. They stayed in the sector of rooming-in and underwent at least one of the standard screening in our unit: blood sugar test at 2, 4 and 6 hours of life and/or chemical glucose test, in addition to hematocrit in this latter control.

Exclusion criteria: major congenital malformations, metabolopathies and genetic syndromes associated with hypoglycemia.

Study outcome measure or exposure: treatment administered during pregnancy (diet or insulin). Primary outcome measure: presence of hypoglycemia in the NBI (≤ 47 mg/dL).[6,10-12]

Other outcome measures studied: maternal age, gravidity (number of pregnancies), body mass index (BMI), overweight, GA, birth weight (BW), classification of birth weight according to GA, sex, hematocrit, feeding at the time of discharge.

Analysis of results

The analysis was performed for the overall population and stratified by maternal center. Continuous outcome measures were presented as measures of central tendency (mean-median) and dispersion (standard deviation and interquartile range) according to the distribution assessed by Shapiro-Wilk test. Categorical outcome measures were reported as absolute and relative frequencies. Univariate analysis was performed according to maternal treatment, assessing the null hypothesis of equal proportion of NBIs with hypoglycemia, and another analysis to identify associated risk factors. Continuous outcome measures were compared with the Student's t-test or Mann–Whitney test according to the distribution while categorical outcome measures were compared with the χ^2 test or Fisher's test. A *post hoc* analysis was performed by modifying the cut-off point for hypoglycemia (≤ 40 mg/dL) upon observing that 100% of the patients who had received the correction had a lower or equal value. A logistic regression model was developed to identify independent outcome measures associated to this result. A value of $p < 0,05$ was considered statistically significant. The STATA 13 software was used for statistical analysis.

As for the sample size, all NBIs within the period studied who met the inclusion criteria were included through a non-probabilistic consecutive sampling.

The protocol was approved by the Ethics and Research Committee of Hospital Italiano de Buenos Aires on February 28, 2019.

RESULTS

During the study period, 6075 infants were born between both maternal centers, 350 were infants born to mothers with GDM. *Figure 1* shows the flow chart of patients. Of the total of patients, 67.2% were diet-treated; the mean maternal age was 34.7 ± 5.4 years and 39.4% were primiparous.

Intrapartum glycemic control was registered in 14 pregnant women: 92 mg/dL (range: 61-118 mg/dL). The characteristics of the population are presented in *Table 1*. When stratified by maternal center, it was observed that the maternal population of San Justo was significantly younger (36.6 ± 4.6 vs. 32.7 ± 5.6; $p = 0.001$) and more overweight at the beginning of pregnancy: 25 (22-28.5) vs. 27.7 (24.4-32) $p = 0.006$ (*Figure 2*). There was no significant difference between the two maternal centers in terms of the treatment administered to diabetic patients.

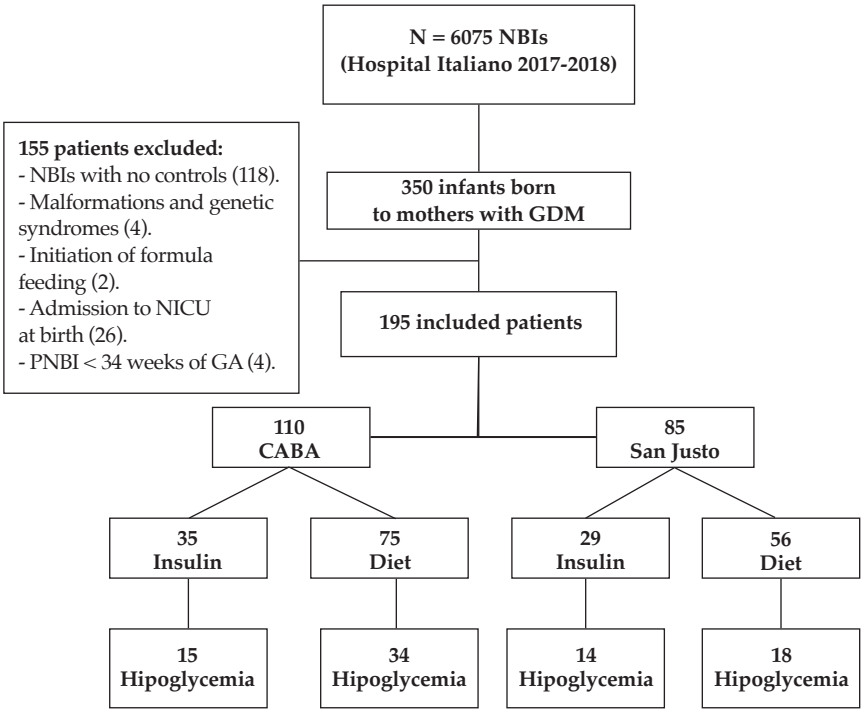
Neonatal demographic outcome measures were similar when comparing both maternal centers. The median gestational age was 37-39 weeks, with a tendency to newborn infants having a higher birth weight in San Justo, although the difference was not significant (10% vs. 17.6%; $p = 0.11$).

TABLE 1. *Baseline characteristics of the population*

Outcome measures	Overall population (n = 195)
Maternal	
Maternal age (years), mean ± SD	34.7 ± 5.4
Primiparous, n (%)	77 (39.4)
Weight gain (kg), median (IQR)	9.1 (5.8-12)
Baseline BMI, median (IQR)	26.6 (22.5-30.8)
Baseline BMI > 25 (n = 172), n (%)	104 (60.4)
Maternal treatment, n (%)	
-Diet	131 (67.2%)
-Insulin	64 (32.8%)
Neonatal	
GA (weeks), median (IQR)	38 (38-39)
BW (g), mean ± SD	3290 ± 505
Weight classification, n (%)	
-HBWGA	26 (13.3)
-ABWGA	160 (82)
-LBWGA	9 (4.6)
Sex distribution, n (%)	
-Female	80 (41)

BMI: body mass index; GA: gestational age; BW: birth weight; HBWGA: high birth weight for gestational age; ABWGA: adequate weight for gestational age; LBWGA: low birth weight for gestational age; SD: standard deviation; IQR: interquartile range.

FIGURE 1. *Flow chart of patients*



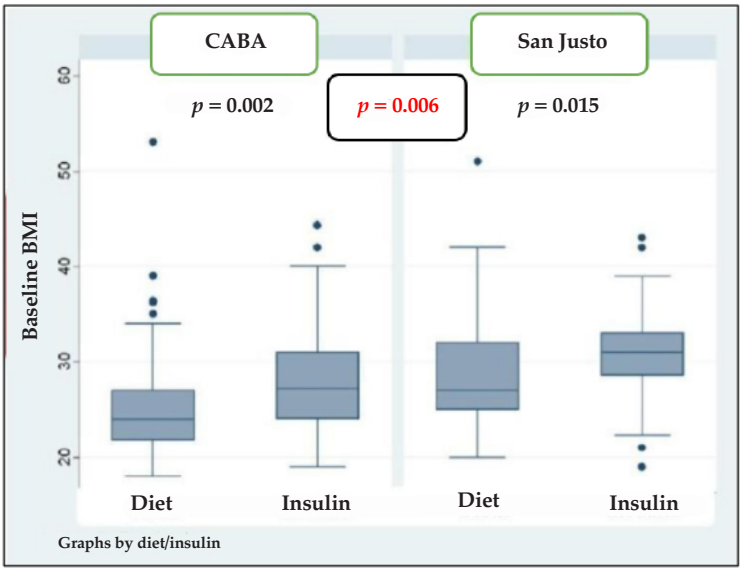
NBI: newborn infant; NICU: neonatal intensive care unit; PNBI: preterm newborn infant; GDM: gestational diabetes mellitus; GA: gestational age; CABA: Autonomous City of Buenos Aires.

TABLE 2. *Univariate analysis based on maternal treatment, stratified by maternal center*

Outcome measures	Insulin (n = 64)	Diet (n = 131)	*p* value
Maternal			
Maternal age (years), mean ± SD	35.2 (4.8)	34.5 (5.6)	0.45 (*)
-CABA	36.5 (4.2)	36.2 (4.9)	0.8
-San Justo	33.6 (5.1)	32.3 (5.9)	0.3
Primiparous women, n (%)	23 (35.9)	54 (41.2)	0.47 (Ŧ)
-CABA	13 (37.1)	31 (41.3)	0.67
-San Justo	10 (34.5)	23 (41)	0.55
Weight gain (kg), median (IQR)	9.2 (5-12.2)	9 (6-11.9)	0.74 (¥)
-CABA	8 (5-13.5)	11 (7.5-12.1)	0.46
-San Justo	9.4 (4.3-11.9)	8 (3.95-10.75)	0.7
Baseline BMI > 25, n (%)	38 (79.1)	66 (53.2)	0.002 (Ŧ)
-CABA	20 (74)	31 (46.6)	0.007
-San Justo	18 (85.7)	35 (66)	0.09
Neonatal			
GA (weeks), median (IQR)	38 (37-39)	39 (38-39)	0.032 (¥)
-CABA	38 (37-39)	39 (38-39)	0.04
-San Justo	38 (38-39)	39 (38-39)	0.39
BW (g), mean ± SD	3280 (468.3)	3295 (524.6)	0.85 (*)
-CABA	3230 (502)	3231.53 (502.1)	0.97
-San Justo	3335.8 (463.9)	3381.9 (546.1)	0.69
Weight classification, n (%)			
-HBWGA	11 (17.1)	15 (11.4)	
-ABWGA	51 (79.6)	109 (83.2)	
-LBWGA	2 (3)	7 (5.3)	
Female sex, n (%)	30 (46.9)	50 (38.2)	0.24 (Ŧ)
-CABA	12 (34.3)	27 (36)	0.86
-San Justo	18 (62.1)	23 (41.1)	0.06
Hypoglycemia, n (%)	29 (45.3%)	52 (39.7%)	0.45 (Ŧ)
BGT 2 h, median (IQR)	50.5 (42-57)	52 (44-61)	0.15 (¥
BGT 4 h, median (IQR)	56 (49-69)	56 (48-65)	0.6 (¥)
BGT 6 h, mean (SD)	60 (10.8)	58.2 (13.1)	0.42 (*)
BGT after 6 h of life n analyzed 22, mean (SD)	55 (9.9)	51.1 (11)	0.49 (*)
Exclusive breastfeeding at discharge, n (%)	56 (87.5)	109 (83.2)	0.43 (Ŧ)

CABA: Autonomous City of Buenos Aires, BMI: body mass index; GA: gestational age; BW: birth weight; HWGA: high weight for gestational age; ABWGA: adequate weight for gestational age; LWGA: low weight for gestational age; BGT: blood glucose test; SD: standard deviation; IQR: interquartile range.
* Student's t test. Ŧ χ^2 test. ¥ Mann-Whitney test.

FIGURE 2. *Body mass index at baseline by maternal center and maternal treatment*



BMI: body mass index; CABA: Autonomous City of Buenos Aires.

The incidence of hypoglycemia in the population studied was 41.5% (95% confidence interval [CI]: 34-48). The analysis performed according to maternal treatment is presented in *Table 2*. When comparing both groups, no significant difference was found regarding the incidence of hypoglycemia (45.3% vs. 39.7%; $p = 0.45$). When comparing hypoglycemic NBIs (≤ 47 mg/dL) and normoglycemic NBIs, no significant differences were found in any of the outcome measures studied: maternal age (35.5 ± 5.2 vs. 34.3 ± 5.5; $p = 0.12$), insulin treatment (35.8% vs. 30.7%; $p = 0.45$), NBI with high birth weight for gestational age (HBWGA) (16.1% vs. 11.4%; $p = 0.34$). Of the group of NBIs that had hypoglycemia, 19% received some type of correction: bottle feeding, 12 (75%); enteroclysis, 2 (12.5%) and intravenous line, 2 (12.5%). In all cases it was performed with a blood glucose level ≤ 40 mg/dL. When modifying the cut-off value, the incidence of hypoglycemia was 20.5% (95% CI: 15-26), without a statistical difference when comparing both groups: 23.4% vs. 19%; $p = 0.48$. Based on this cut-off point, 40% of the patients received some type of correction. The univariate analysis according to a hypoglycemia value ≤ 40 mg/dL in which the hematocrit value was significantly higher in the hypoglycemic group is shown in *Table 3*. The multivariate analysis is presented in *Table 4*. Having a HBWGA was associated with hypoglycemia ≤ 40 mg/dL, regardless of the other outcome measures included in the model.

DISCUSSION

Transient hypoglycemia in the early neonatal period is a physiological adaptive phenomenon and it has been described that about 10% of NBIs may develop it.[6,7,10] Universal screening is not recommended, as it is inadequate, unnecessary and potentially harmful.[6,10] However, it is widely disseminated that neonatal hypoglycemia leads to long-term neurological morbidity and that there are risk factors.[6,8,11]

The American Pediatric Association recommends screening of NBIs at risk for

TABLE 3. *Univariate analysis by hypoglycemia ≤ 40 mg/dL*

Outcome measures	Hypoglycemia (n = 40)	Normal glycemia (n = 155)	*p* value	OR
Maternal age (years), mean ± SD	35.7 (5.5)	34.5 (5.4)	0.21 (*)	NA
Primiparous women, n (%)	17 (42.5)	60 (38.7)	0.66 (Ŧ)	1.17 (0.5-2.5)
Weight gain (kg), median (IQR)	9.2 (7.2-11)	9.1 (5.2-12)	0.95 (¥)	NA
Baseline BMI (n = 172), median (IQR)	28.4 (23.7-31.3)	26 (22.5-30)	0.29 (¥)	
Baseline BMI > 25 (n = 172), n (%)	25 (65.7)	79 (58.9)	0.4 (Ŧ)	1.3 (0.5-3.1)
Maternal treatment with insulin, n (%)	15 (37.5)	49 (31.6)	0.48 (Ŧ)	1.29 (0.5-2.8)
GA (weeks), median (IQR)	38 (37-39)	39 (38-39)	0.24 (¥)	NA
BW (g), mean ± SD	3294 (668)	3289 (456)	0.95 (*)	NA
Weight classification, n (%)				
HBWGA	8 (20)	18 (11.6)	0.16 (Ŧ)	1.9 (0.6-5)
Hct at 6 h, mean (SD)	57 (7.6)	53.9 (6.8)	0.04 (*)	NA
Exclusive breastfeeding at discharge, n (%)	29 (72.5%)	136 (87.7%)	0.17 (Ŧ)	2.7 (1.04-6.7)

BMI: body mass index; GA: gestational age; BW: birth weight; HBWGA: high birth weight for gestational age; Hct: hematocrit; SD: standard deviation; IQR: interquartile range; OR: odds ratio.
* Student's t test. Ŧ χ^2 test. ¥ Mann-Whitney test. NA: not applicable.

TABLE 4. *Analysis of outcome measures associated with hypoglycemia ≤ 40 mg/dL (n = 104)*

Outcome measures	OR (95% CI)	*p* value	aOR (95% CI)	*p* value
Baseline BMI	1.04 (0.98-1.09)	0.15	0.98 (0.90-1.06)	0.65
Maternal treatment with insulin	1.29 (0.62-2.67)	0.48	1.46 (0.54-3.94)	0.45
HBWGA	1.9 (0.76-4.76)	0.16	3.93 (1.04-14.9)	0.04
Hct at 6 h of life	1.06 (1.0-1.13)	0.04	1.06 (0.99-1.14)	0.06

BMI: body mass index; HBWGA: high birth weight for gestational age; Hct hematocrit;
OR: odds ratio. aOR: adjusted OR.
Hosmer-Lemeshow test (goodness-of-fit): dF = 10 χ^2 (8) = 4.7 p = 0,79.
Area under the ROC curve of the multivariate model: 0.69.

hypoglycemia, including IDMs, to maintain blood glucose values ≥ 45 mg/dL and control during the first 12 hours of life.[6] Instead, the American Society of Pediatric Endocrinology recommends values higher than 50 mg/dL during the 48 hours after birth.[7] It should be pointed out that no consensus has been achieved regarding the value to be used to define hypoglycemia[13] or when or how treatment should be administered. GDM is a relevant risk factor for neonatal hypoglycemia and its incidence in the present study is within the range (25% to 48%) described in the literature.[14,15]

While Maayan-Metzger et al.,[14] report a significant difference in the incidence of hypoglycemia when comparing NBIs born to diabetic mothers treated with diet or insulin, Jensen et al.[9] report that hypoglycemia was similar regardless of the treatment administered to the mother. On the other hand, Flores et al.,[15] show that the use of insulin during pregnancy is significantly associated with the development of hypoglycemia. Another prospective study that evaluated newborn infants born to diet-treated diabetic mothers compared to a control group of newborn infants without risk factors shows that the incidence of hypoglycemia was similar and that low blood glucose levels during the first hours of life can be managed with early and frequent oral feedings.[3] It could be inferred that children of gestational diabetic mothers treated with diet behave in the same way as NBIs without risk factors.

Based on these results and in our clinical practice, the following hypothesis was worked out, that infants of gestational diabetic mothers with insulin requirement have a significantly higher incidence of hypoglycemia compared to the infants of diabetic mothers managed with diet. If this had been the case, we would have assumed that NBIs born to diet-treated diabetic mothers were comparable to NBIs without risk factors, so that the recommendations of not performing routine controls could be followed. However, results obtained do not support this hypothesis. On the contrary, the present work shows that the incidence of hypoglycemia in gestational IDM does not differ significantly according to the maternal treatment received. Moreover, the incidence of hypoglycemia in the infants of patients managed with diet was 4 times higher than the expected physiological incidence for NBIs without risk factors. According to these results, the focus on this subgroup of newborn infants should not be neglected and their screening should be standardized.

A study published by Harris et al.,[12] showed that 50% of the NBIs with risk factors may present hypoglycemia considering 47 mg/dL as the cut-off value and that the sum of these factors made them more prone to developing severe hypoglycemia. In another study recently published by Sarkar et al.,[3] the same associated risk factors were identified but using a lower cut-off value: 40 mg/dL. In a recent multicenter randomized trial, a group of newborns ≥ 35 weeks at risk of hypoglycemia was studied comparing correction with a cut-off value of 36 mg/dL versus 47 mg/dL. By finding no differences in the psychomotor development at 18 months of age, they concluded that correction at a lower threshold than the traditionally recommended one is safe.[16]

This study shows that in daily practice corrections were made with a blood glucose level ≤ 40 mg/dL. This observation, together with the results of that clinical trial,[16] motivated us to carry out an analysis by lowering the cut-off point. In our study, no associated risk factors were identified for hypoglycemia (≤ 47 mg/dL), but when the cut-off value was modified (≤ 40 mg/dL), hematocrit is significantly associated, although it is lost when adjusting for other outcome measures. Additionally, HBWGA was almost twice as prevalent in the hypoglycemic group compared to the normoglycemic group, which is consistent with the literature regarding the sum of risk factors. However, in the adjusted analysis, the fact of being born with a HWGA was significantly associated with hypoglycemia, regardless of other risk factors such as baseline BMI and the maternal treatment administered.

Frequent breastfeeding helps to better regulate blood glucose levels and reduces the possibility of developing hypoglycemia. It is recommended to initiate breastfeeding within the first hour of life in all newborn infants.[11,10] Approximately 40% of the patients in the study who developed hypoglycemia received correction in a different way than breastfeeding; the breastfeeding process was discontinued in the first hours of life. A unique opportunity for its implementation could thus be lost by causing the separation of their parents. When analyzing outcome measures associated with hypoglycemia with greater need for correction, it was observed that the group that remained normoglycemic was associated with a higher rate of breastfeeding at discharge.

Administration of dextrose gel may be

effective in reversing hypoglycemia, may be a method to support breastfeeding, and may help avoid admission to the neonatal intensive care unit.[17] During the study period, the unit did not have this alternative. Nevertheless, the overall breastfeeding rate at discharge, similar in both maternal centers, is high and comparable to that reported in the literature.[18,19]

This study has certain limitations. Because it is observational in nature, it has an inherent information bias. This is reflected in almost 45% of IDMs excluded from the analysis out of the total number of IDMs born during the study period. Whereas 25% of the excluded patients had some appropriate criteria, the other 75% were excluded due to lack of controls. It would be interesting to know whether this loss of patients was balanced between the two groups, which could influence the outcome of the study. Unfortunately, this data, which could also add information on the association between the outcome measures studied and the primary outcome, was not obtained. Another limitation could be to have considered hemoglucotest controls, in addition to central glycemia. In any case, the former is considered the recommended method for screening; chemical glycemia is used only for confirmation of an event.[6,10]

A factor that could affect the primary outcome is that the study was performed in two maternal centers located in different geographical locations with baseline differences. In any case, the stratified analysis by maternal center was consistent with the results of the overall population. Finally, the number of patients included in the multivariate model was smaller than the total sample analyzed (BMI and Hct were not available in all patients). However, the result of the model is biologically plausible, is consistent with the literature and, moreover, the results of the model adjustment and the ROC curve are within an acceptable range. To our knowledge, the main strength of this study is that it is the first one conducted in our setting comparing results based on the maternal management.

Therefore, it can be concluded that the incidence of neonatal hypoglycemia in infants born to mothers with GDM in the studied population did not differ based on the maternal treatment administered. This study provides information that suggests continuing to monitor all newborns born to diabetic mothers, regardless of the management of the mother. Newborn infants born with a HWGA or a higher hematocrit value could have an additional risk. It would be important to have prospective studies to support these findings. ■

Acknowledgments

We would like to thank Pablo Pochettino, M.D., from the Department of Obstetrics of Hospital Italiano de San Justo.

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