

Risk factors for constant glycemic variability in pregnant women: a case-control study

Fatores de risco para variabilidade glicêmica constante em gestantes: estudo caso - controle

Factores de riesgo para la variabilidad glicémica constante en mujeres embarazadas: un estudio de caso-control

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ABSTRACT

Objective: to identify the factors associated with pregnancy that influence constant glycemic variability. **Method:** a case-control study with random sampling. The medical records of 417 pregnant women were divided into case group (200 pregnant women with constant glycemic variability) and control group (217 pregnant women without constant glycemic variability). Data were collected from 2009 to 2015. **Results:** pregnant women aged 25 years and over, with family history of diabetes mellitus, with systemic arterial hypertension, overweightness or obesity, sedentarism and polycystic ovarian syndrome are more likely to present changes in blood glucose. **Conclusion:** The study demonstrated that risk factors associated with pregnancy increase the risk of constant glycemic variability. The findings will allow reassessment of the interventions during pregnancy, providing an increase in nursing care quality.

Descriptors: Nursing Diagnosis; Gestational Diabetes; Pregnant Women; Blood Glucose; Risk Factors.

RESUMO

Objetivo: identificar os fatores associados à gravidez que influenciam na variabilidade glicêmica constante. **Método:** estudo de caso-controle com amostragem aleatória. Prontuários de 417 gestantes foram divididos em: grupo de caso (200 gestantes com variabilidade glicêmica constante) e grupo de controle (217 gestantes sem variabilidade glicêmica constante). Os dados foram coletados no período de 2009 a 2015. **Resultados:** gestantes com 25 anos ou mais, história familiar de diabetes mellitus, hipertensão arterial sistêmica, sobrepeso ou obesidade, sedentarismo e síndrome do ovário policístico apresentam maior probabilidade de apresentar alterações na glicemia. **Conclusão:** o estudo demonstrou que os fatores de risco associados à gestação aumentam o risco de variabilidade glicêmica constante. Os achados permitirão reavaliar as intervenções durante a gestação, proporcionando um aumento na qualidade da assistência de enfermagem.

Descritores: Diagnóstico de Enfermagem; Diabetes Gestacional; Gestantes; Glicemia; Fatores de Risco.

RESUMEN

Objetivo: identificar los factores de riesgo asociados con el embarazo que influyen en la variabilidad glucémica constante. **Método:** estudio de casos y controles con muestreo aleatorio. Los registros médicos de 417 mujeres embarazadas se dividieron en: grupo de casos (200 mujeres embarazadas con variabilidad glucémica constante) y grupo de control (217 gestantes sin variabilidad glucémica constante). Los datos se recopilaron de 2009 a 2015. **Resultados:** mujeres embarazadas de 25 años o más, antecedentes familiares de Diabetes Mellitus, hipertensión arterial sistémica, sobrepeso u obesidad, sedentarismo y síndrome de ovario poliquístico son más propensos a presentar cambios en la glucemia. **Conclusión:** el estudio demostró que los factores de riesgo asociados con el embarazo aumentan el riesgo de variabilidad glucémica constante. Los hallazgos permitirán reevaluar las intervenciones durante el embarazo, proporcionando un aumento en la calidad de la atención de enfermería.

Descriptor: Diagnóstico de Enfermería; Diabetes Gestacional; Mujeres Embarazadas; Glucemia; Factores de Riesgo.

INTRODUCTION

During pregnancy, women's metabolism presents alterations that facilitate fetal development, considering their specific necessities and the absorption⁽¹⁻²⁾. However, there are metabolic disorders resulting from the pregnant woman's health lifestyle, as well as the placental production of diabetogenic hormones that counteract the action of insulin, resulting in its resistance and causing variations to blood sugar levels in relation to normal parameters⁽¹⁻⁶⁾. This fluctuation may contribute to compromise the health of the pregnant woman and her baby. Thus, nurses who care for pregnant women should be alert to these risks when diagnosing and intervening, to achieve results that increase safety and control of this variation.

In the search for a nursing diagnosis that describes the susceptibility to variation in glycemic levels during pregnancy, nurses can use the NANDA-International classification (NANDA-I), which presents the diagnosis Risk for Unstable Blood Glucose Level (00179) in domain 2 - nutrition and class 4 - metabolism, introduced in this classification in 2006 and modified in 2013⁽⁷⁾. This nursing diagnosis is defined as "susceptible variation in serum of glucose from the normal range, which may compromise health."7:177. It attributes pregnancy as a risk factor for vulnerability to variation of blood glucose levels in relation to normal variation. However, this study questions the existence of other factors that, associated with pregnancy, could cause this glycemic variation.

No previous studies have been found that investigated factors associated with pregnancy, and which may increase risk for development of variation in blood glucose levels when compared to the related diagnosis. The exception is one cross-sectional study that verified the relationship between demographic and clinical characteristics with this nursing diagnosis in 237 patients in a Diabetes Mellitus Education Program (167) and in a Women's Health Program (70), which identified the nursing diagnosis "Risk for Unstable Blood Glucose Level" in only 4.3% of pregnant women⁽⁸⁾.

The extent of the need to control glycemic variability becomes evident when a descriptive-comparative study is analyzed; it was conducted in 2013 among pregnant women at health centers in Iran. The study investigated the lifestyle of 100 pregnant women diagnosed with gestational diabetes and 100 healthy pregnant women. It was concluded that dietary style, with ingestion of fruit and vegetables, physical activity, and self-care during prenatal care were associated with healthy pregnant women, while pregnant women with high glycemic index and lack of knowledge about the need to maintain physical activity during pregnancy generated an increased risk for the development of gestational diabetes⁽⁹⁾.

This way, it is fundamental for nurses to know all the risk factors. It is necessary to consider the possibility of creating clinical protocols to prevent dysfunctions and provide guidance in a more effective way for the self-care of pregnant women⁽¹⁰⁾.

OBJECTIVE

To identify the factors associated with pregnancy that influence constant glycemic variability.

METHODS

Ethical aspects

The study respected formal requirements for human subjects and protection, with institutional review board approval.

Study design

This is a retrospective case-control study. In this type of study, the researcher analyses a selection of people divided into two groups: the case group, in which people manifested common characteristics to a specific pathology; and the control group, in which people did not manifest such characteristics⁽¹¹⁾.

The case group consisted of pregnant women who presented constant glycemic variability; and the control group consisted of pregnant women who did not present constant glycemic variability.

The hospital unit selected for the survey was the Maternity School of a Federal University in Rio de Janeiro, Brazil. The study included medical records of all pregnant women who completed prenatal care at the hospital during the timeframe from 2009 to 2015, independently of gestational age (GA) they were in. Those with a diagnosis of Diabetes Mellitus (DM) prior to pregnancy were excluded.

Data collection

In order to calculate the population that was part of this study, a survey of pregnant women's medical records was carried out, through an institutional book called "Reception Book - Nursing - Registration of prenatal records", in which pregnant women's prenatal records were kept. With the number of 5,937 medical records, randomization was carried out through the program *Random Permutation*⁽¹²⁾, which made it possible to establish 297 numerical sequences of twenty numbers related to medical records. Following each sequence, the medical files were requested in the archives of the institution. After analyzing 1040 medical records, 623 were excluded because they did not meet the criteria established in the study, thus 417 eligible medical records remained.

Inclusion Criteria: the medical records of all pregnant women included in the previously mentioned outpatient clinic were included, regardless of GA at which the pregnant women were, and who completed all prenatal care at the observed hospital unit.

Exclusion Criteria: pregnant women enrolled in the prenatal outpatient clinic in the period from 2009 to 2015 who presented a history of DM diagnosis prior to the studied pregnancy were excluded. To determine the group samples, the following established criteria were applied:

- Case group: women who present constant glycemic variability during pregnancy. The results of laboratory tests were considered as constant glycemic variability when presenting: fasting blood glucose - values above 92 mg/dl and in the postprandial or oral tolerance test a glucose, blood glucose test; blood glucose after 1 hour of glucose overload - values above 180 mg/dl; blood glucose after 2 hours of glucose overload - values above 153 mg/dl^(2,4,13);
- Control group: women who did not present such constant glycemic variability.

The sample size was estimated in at least 200 cases and 200 controls, based on a pilot study with 17 cases (pregnant women with unstable blood glucose level) and 31 controls (pregnant women who did not present unstable blood glucose level) and considering a bilateral level of confidence 95% ($Z_{(\alpha/2)} = 1,96$), a power level 80% ($Z_{1-\beta} = 0,84$), and control ratio for cases $r = 1$, obtaining $n_1 = n_2 = 200$, because when the aim of the study is to establish whether an association exists and there is no restriction in evaluating cases and controls, the optimal ratio of controls to cases is 1: 1. In studies in which cases are rare, up to 4 controls for each case are allowed. The aim of the study was to investigate significant associations and there were no operational restrictions to assess cases and controls. In addition, unstable blood glucose is not a rare condition, with an estimated incidence of 7.6% in Brazil. Therefore, it was chosen to use the optimal ratio of 1:1⁽¹⁴⁾.

A composite data collection instrument was used in three stages: the first stage established criteria for selecting the medical charts according to inclusion and exclusion criteria; the second one established the identification data of pregnant women; and the third one comprised obstetric history and childbirth.

Analysis of results and statistics

Data were analyzed through the Statistical Package for Social Science (SPSS) version 22.0 and synthesized by calculating descriptive statistics (mean, median, minimum, maximum, standard deviation, coefficient of variation, proportions of interest), distributions of simple frequencies and in cross-tabulations, comparing the results of the case and control groups. To investigate the significant association between a given factor and unstable blood glucose level, chi-square and Fisher's exact test were used. The measure used to express the risk was the *Odds Ratio* (OR).

When at least in one of the groups the hypothesis for distribution of normality was rejected by at least one of the tests, the comparison of the two groups was done by non-parametric Mann-Whitney test.

The independent variables investigated in the medical records were: overweightness or obesity, family members with DM, age, height, systemic hypertension (SH), excessive maternal weight gain, sedentary lifestyle, use of hyperglycemic drugs, polycystic ovarian syndrome (PCOS), which are variables that can identify the risk factors for constant glycemic variability. In addition, laboratory results that present unstable blood glucose level were also investigated for the unstable glycemic dependent variable.

RESULTS

The sample of this study consisted of 417 pregnant women, with 217 pregnant women (52.0%) without constant glycemic variability (control group) and 200 pregnant women (48.0%) with constant glycemic variability (case group). However, understanding this is a retrospective study, some items analyzed in the medical records presented incomplete information, preventing the inclusion of such records in the statistical calculations, justifying the diversity of the quantitative data (N) in the tables below. It should be noted that the statistical data were calculated based on the records in the medical charts. The age of the pregnant women

in the groups presented an average of 30 years old, while in the control group, the average was 27 years old (Table 1). The age statistics of the two groups were compared by the non-parametric Mann-Whitney test, which resulted in a p value <0.001, demonstrating that there was a significant difference between the age of the pregnant women in the case and control groups.

The most frequent education levels among subjects were complete Elementary Education, complete and incomplete High School. There was no significant difference in the educational background profile of pregnant women in the case and control groups (p value = 0.901).

The pregnant women were married or lived in a civil union in both groups. The chi-square test, used to determine if there was a significant difference in the marital status distribution of the case and control groups, was incomplete because it contained 50% of the cells with an expected frequency of less than 5, but it left no evidence that there was no significant difference between two distributions (p value = 0.129).

Table 1 - Distribution of pregnant women, according to the sociodemographic variables (N=417)

Variables	Case n(%) n=(200)	Control n(%) n=(217)	P value
Age	30 (25-36 [†])	27(21-33 [†])	< 0.001
Educational Background [‡]			0.901
Complete Elementary School	52(26.5)	51(23.7)	
Incomplete Elementary School	12(6.1)	10(4.7)	
Complete High School	55(28.1)	66(30.7)	
Incomplete High School	44(22.4)	55(25.6)	
Complete Higher Education	16(8.2)	17(7.9)	
Incomplete Higher Education	17(8.7)	16(7.4)	
Total	196 (100)	215 (100)	
Marital Status [§]			0.129
Married/Civil union	142(71.0)	132(60.8)	
Single	55(27.5)	82(37.8)	
Widower	2(1.0)	1(0.5)	
Separated/Divorced	1(0.5)	2(0.9)	
Total	200 (100)	217 (100)	

Note: [†] Interquartile range 25-75; [‡] The quantitative data of the total sample was not obtained in the investigation of this item. [§] N of the investigated item.

Table 2 presents the synthesis of the risk for constant glycemic variability in pregnant women, showing the risk synthesis for unstable blood glucose level in pregnant women, the p values of the chi-square test evaluating the significance of the association, while OR and Confidence Interval (CI) of the OR were also observed. A risk is increased for constant glycemic variability in pregnant women if the p value of the chi-square test is less than 5%, the OR is greater than 1 and the CI of the OR does not contain a value of 1. In this table, it is possible to quantitative record of pregnant women who presented constant glycemic variability within the universe of independent variables studied. Pregnant women aged 25 or over (p<0.001), first-degree relatives of DM (p<0.001), second-or-over-degree relatives of DM (p=0.035), with SH (p <0.001), with PCOS (p=0.034), leading a sedentary lifestyle (p = 0.005) and presenting pre-gestational obesity (p = 0.001) were more likely to have unstable blood glucose level (UG). There were no risk factors for UG height below 150 cm (p = 0.875) and use of hyperglycemic drugs (p = 0.101).

Table 2 - Synthesis of the risk for constant glycemic variability in pregnant women (N=417)

Variables	Cases/ Group length	Incidence of gestational diabetes %/ Total Analyzed	χ^2 p value	OR	CI of OR
Age [§]					
< 25 years old	44/129	34.1% / 129	<0.001	2.3	1.5~ 3.5
≥ 25 years old	156/287	54.4% / 287			
Family History					
First-grade [§]			< 0.001	2.5	1.60~3.81
No	125/302	41.4% / 302			
Yes	71/111	64.0% / 111			
Family History					
Second-degree onwards [§]			0.035	1.5	1.03~1.32
No	116/266	43.6% / 266			
Yes	80/147	54.4% / 147			
SH [†]			< 0.001	3.2	1.68~5.95
No	162/364	44.5% / 364			
Yes	38/53	71.7% / 53			
PCOS [§]			0.034	3.0	1.04~8.45
No	186/398	46.7% / 398			
Yes	13/18	72.2% / 18			
Sedentarism [§]			0.005	4.7	1.5~ 14.4
No	8/17	43.1% / 17			
Yes	54/67	80.6% / 67			
Pre-Gestational Obesity [§]			0.001	2.3	1.4~3.7
No	125/267	46.8% / 267			
Yes	62/93	66.7% / 93			
Height [§]			0.875	0.92	0.34~ 2.5
< 150 cm	8/16	50.0% / 16			
≥ 150 cm	191/398	48.0% / 398			
Hyperglycemic drug use [§]			0.101	1.81	0.35~1.43
No	178/378	47.1% / 378			
Yes	21/34	61.8% / 34			

Note: OR - Odds Ratio; CI - Confidence Interval; SH, Systemic Hypertension; PCOS, Polycystic Ovarian Syndrome; [§] Data of the total sample was not obtained in the investigation of this item; [†] N of the investigated item.

Table 3 - Frequency of body mass index classification of the pregnant women (N=417)

Classification	Case n(%) (n=200)	CI of %	Control n(%) (n=217)	CI of %	P value
Pre-Gestational BMI [§]					<0.001
Regular Weight	54(28.9%)	28.46~29.34	102(59%)	58.55~59.44	
Overweight	71(38.0%)	37.52~ 38.47	40 (23.1%)	22.72~23.48	
Obesity	62(33.1%)	32.74~ 33.66	31 (17.9%)	17.65~18.25	
Total	187 (100%)		173 (100%)		
Gestational BMI [§]					<0.001
Regular Weight	36(18.1%)	17.72~ 18.48	104 (48.4%)	47.94~48.86	
Overweight	79(39.7%)	39.22~ 40.18	66 (30.7%)	30.28~31.12	
Obesity	84(42.2%)	41.71~ 42.69	45 (20.9%)	20.53~21.27	
Total	199 (100%)		215 (100%)		
Gestational weight gain (g) [†]	7.650		10.200		<0.001

Note: † Average; CI - Confidence Interval; BMI - Body Mass Index; [§] Quantitative data of the total sample was not obtained in the investigation of this item; [†] N of the investigated item.

A higher proportion of pregnant women with normal weight in the control group (59.0%) and, consequently, a higher proportion of overweight (38.0%) and obese (33.2%) women in the case group were observed (Table 3). The association between pre-gestational BMI and UG scores was statistically significant, and the p value for the presented distribution was <0.001. In fact, the CI of the proportions between the case and control groups did not intersect.

Analysis based on the classification of gestational BMI was also performed as presented in the table, with the frequency distribution of the classification of gestational BMI in the case and control groups. Corroborating the conclusion of the previous analysis, there was a higher proportion of pregnant women with normal weight in the control group (48.4%) and, consequently, a higher proportion of overweight (39.7%) and obese (42.2%) women in the case group. The association between gestational BMI and the constant glycemic variability scores was statistically significant: the p value of the chi-square test for the distribution presented was <0.001 (Table 3). In fact, the CI of the proportions of the case and control groups do not intersect. In the control group, women gained between -2,800 g and 24,500 g, with an average of 10,200 g, showing high variability in gestational weight gain. In the case group, women gained between -6,500 g and 24,600 g, which resulted in the average of 7,650 g, showing high variability in the weight gain distribution of women in this group as well.

There is a significant difference between the gestational weight gain of women in the control and case groups (p value <0.001). The women in the case group gained, statistically, significantly lower weight than the women in the control group. However, the late prenatal insertion of some pregnant women with UG who were referred from the Basic Health Units (BHU) with advanced GA was presented as a limitation, and the weight gained during gestation until the arrival at maternity was unknown.

DISCUSSION

The study demonstrated risk factors that, when associated with pregnancy, make women susceptible to constant blood glucose variability. Pregnant women older than or at 25 years old, with a family history of DM, SH, overweightness or obesity evidenced by pre-pregnancy BMI, with gestational BMI, leading a sedentary lifestyle, and with PCOS, are more likely to present changes in blood glucose, which should be associated with pregnancy in the nursing diagnosis risk for unstable blood glucose level.

A cross-sectional study conducted in Yemen, between 2013 and 2014, divided 311 pregnant women, 15 to 49 years old, and UG between 24 and 40 weeks into two groups, one group of pregnant women with risk factors and one group without risk factors. The following risk factors for GDM were identified: age ≥35 years, BMI ≥30 kg/m², family history of diabetes, and history of PCOS. The study found that the probability of GDM increased by 8.97 times for age ≥35 years, up to 3.76 times in pregnant women with BMI ≥30 kg/ 2, 3.01 times in

pregnant women with a family history of diabetes, in 12.9 times in pregnant women with PCOS⁽¹⁵⁾.

The data above corroborate the results of the present study, except for the age that differs between the two studies. In the present case, the age that shows significant difference is ≥ 25 years (<0.001) and the chance of presenting constant glycemic variability is 2.3 times.

A study conducted between 2007 and 2008 at *Universidade Federal de Minas Gerais* (UFMG) in Brazil, with 66 GDM patients, found that 89% of the pregnant women presented some risk factor for GDM, among them: 56%, aged over 35 years old; 65%, family history of diabetes; 70%, overweightness and obesity; 27%, excessive gain of weight; 42%, maternal complications including preeclampsia and urinary tract infection⁽¹⁶⁾.

That research confirms the results of the present study, since it found a significant difference in pregnant women with a family history of diabetes; with overweightness and obesity. However, it differs in relation to age, since, as mentioned about the previous study, it was therein evidenced a risk for age above 35 years, while in the present study the age ≥ 25 years was observed as a risk factor for constant glycemic variability.

In northern Iran, a case-control study conducted in the time-frame from 2012 to 2015 selected 100 pregnant women with gestational diabetes, who composed the case group, and 100 healthy pregnant women, members of the control group. The study found that women with lower physical activity during pregnancy were at four times greater risk of developing Gestational Diabetes compared to women who reported a high level of physical activity. In addition, after adjusting for age, BMI and family history of diabetes, women with less physical activity during the first 20 weeks of pregnancy were at a significantly higher risk of developing Gestational Diabetes⁽¹⁷⁾.

The cited studies confirm the findings of this study, which identified p value of 0.005 for sedentary pregnant women and their chance of presenting constant glycemic variability being 4.7 times higher than that of a non-sedentary woman.

In Rio Grande do Sul, Brazil, a cross-sectional study evaluated the impact of BMI at the beginning and at the end of gestation, in addition to weight gain. Newborns were included in the period from January 1 to December 31, 2007, and 1,117 puerperal subjects were selected for BMI. There was no significant association between weight gain/BMI and risk of diabetes. However, it was evidenced that in overweight and obese women at the beginning of gestation, and in those with greater weight gain in the gestational period, there was a higher risk of macrosomia, born with the mother's weight gain⁽¹⁸⁾.

That study, when evaluating the association between weight gain/BMI and risk of diabetes, did not find statistically significant results, refuting the results found in the present study, which presented pre-gestational BMI (<0.001), gestational BMI (<0.001), as well as gestational weight gain (<0.001) as risk factors for the constant glycemic variability.

Previous studies performed in several scenarios corroborated the results of this study, which presents the following significant evidence in the following variables: pregnant women aged 25 years old or older ($p <0.001$), first-degree relatives of DM ($p <0.001$), and second-or-over degree relatives ($p = 0.035$), SH (p

<0.001), pre-gestational obesity ($p = 0.001$), sedentarism ($p = 0.034$), excessive maternal weight gain in relation to constant glycemic variability.

On the other hand, the results of this study refute some of the previous findings, which evidences the need for further studies in this area. Regarding the maternal weight gain during gestation, it is worth reflecting whether this finding would not be, instead of a risk factor, a consequence of blood glucose level variability. Therefore, a cohort study is suggested to more safely identify what is actually occurring: whether gestational weight gain is a risk factor or a consequence of the constant glycemic variability.

The variables short height (less than 1,5 m) and use of hyperglycemic drugs did not present significant results. Therefore, they did not constitute risk factors. Although NANDA-I presents another 15 risk factors for the nursing diagnosis of risk for unstable blood glucose level, most of them do not present direct correlations to the pregnancy period⁽⁸⁾. Pregnancy is the unique risk factor proposed by NANDA-I to the nursing diagnosis risk for unstable blood glucose level.

Within this diagnosis, one has the risk factors of lacking daily physical activity, excessive weight gain, and compromised physical health status⁽⁸⁾. Although these risk factors present characteristics related to weight control, they do not present objective evidence that may be associated with the gestational period. Thus, overweightness and/or obesity risk factors evidenced by pre-pregnancy or gestational BMI and sedentary lifestyle during pregnancy are suggested.

In addition, risk factors for poor control of diabetes, ineffective drug control, and lack of adherence to the diabetes control plan are factors that, although representing general groups of adults and elderly people with diabetes, do not apply to pregnant women who present, in their majority, an initial and specific change related to the gestational period itself.

Pregnant women older than or at 25 years old, with SH, or with PCOS, when associated with pregnancy, also face increased risks of constant glycemic variability. In addition, it is also important to consider patient history. In the case of pregnant women evidences were not included in the current risk for UG. Among these risks, a family history of DM and SH was identified. Therefore, it is suggested to include the aforementioned risk factors to improve the qualification of nursing diagnosis during the gestational period.

Study limitations

This study has a limitation related to the retrospective data collection, since the information was recorded in medical charts and by several professionals. The study respected the reliability of the information recorded in medical charts. However, certain data were not subject to analysis because the information in the medical charts was incomplete. It is, therefore, suggested that studies in other scenarios and different populations be developed.

Contributions to nursing, health or public policies

Identifying and classifying risk factors associated with pregnancy that contribute to the increased risk for unstable blood glucose level will allow nurses to, the possibility of promoting health education. Therefore, it may help to promote glycemic stability and

collaborate to the control of occurrences of perinatal morbidity and mortality, and consequent reduction of medical care costs.

CONCLUSION

This study identified that factors such as being older than 25 years, having relatives with DM, having SH or PCOS, leading a sedentary lifestyle, and presenting pre-gestational obesity, while associated to pregnancy, contribute to constant glycemic

variability. These findings will enable the nursing diagnosis of unstable blood glucose level risks to be restructured in nurses' performance, providing improvement in care quality.

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