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Gestational Diabetes Mellitus in Kisangani (Democratic Republic of the Congo): Study Protocol on Epidemiology, Determinants, Clinical Characteristics, and Maternal, Fetal, and Neonatal Outcomes

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Abstract **Review Article**

Introduction: Gestational diabetes mellitus (GDM) is one of the most common metabolic complications of pregnancy and is a global public health concern. Its prevalence varies and is increasing worldwide in both low- and middle-income countries. Sub-Saharan Africa is undergoing an epidemiologic transition characterized by a rising burden of noncommunicable diseases, with substantial variation depending on the diagnostic criteria and study setting. In the Democratic Republic of the Congo (DRC), available data remain limited and heterogeneous across regions. To date, no documented study has been identified in Kisangani. ***Objective:*** The objective of this study is to determine the hospital-based incidence of gestational diabetes mellitus in Kisangani, identify associated determinants, describe the clinical characteristics of pregnant women with confirmed GDM, and assess maternal, fetal, and neonatal outcomes. ***Methods:*** This will be a longitudinal, descriptive, and analytical study with prospective data collection. It will be conducted over six months, from June through December 2026, at seven health facilities in Kisangani (referral health centers and general referral hospitals). Pregnant women at 24 to 32 weeks of gestation will be consecutively enrolled after providing informed consent and followed through delivery to assess maternal, fetal, and neonatal complications. GDM will be diagnosed using a 75-g oral glucose tolerance test (OGTT) according to the criteria of the International Association of Diabetes and Pregnancy Study Groups (IADPSG). Sociodemographic, clinical, laboratory, and obstetric data will be collected and analyzed using R software, version 4.4.2. Associations will be assessed using multivariable logistic regression, with statistical significance set at $p < 0.05$. ***Expected Results:*** The study will determine the incidence of GDM in Kisangani, identify its determinants, and evaluate its effect on maternal, fetal, and neonatal complications. ***Discussion:*** The findings will be compared with those reported in the national and international scientific literature, while accounting for the specific features of Kisangani's health care context. ***Conclusion:*** GDM is a major global public health concern, yet its magnitude remains insufficiently documented in the specific context of Kisangani. The findings will provide essential local data for developing appropriate strategies for screening and managing GDM in Kisangani, Tshopo Province, DRC.

Keywords: gestational diabetes mellitus, pregnancy, determinants, maternal outcomes, neonatal outcomes, OGTT, Kisangani, DRC.

INTRODUCTION

According to the World Health Organization (WHO) and the American Diabetes Association (ADA), GDM is defined as glucose intolerance first diagnosed during pregnancy, regardless of the treatment initiated or its course in the postpartum period [1,2].

Although it most often resolves after delivery as blood glucose returns to normal, GDM is not a transient condition without consequences; it poses a major challenge to the short- and long-term health of both mother and child [1,3]. It is considered an early form of type 2 diabetes that emerges in the particular context of pregnancy [4].

Screening traditionally relies on an oral glucose tolerance test (OGTT) performed between 24 and 28 weeks of gestation [5]. Reactive hypoglycemia may occur after this test [6].

Its incidence is increasing worldwide due to rising maternal age, obesity, lifestyle changes [7-9], and urbanization [10]. However, screening remains inadequate in several countries because of organizational and financial constraints [10,11]. According to the International Diabetes Federation, approximately one in six pregnancies is complicated by maternal hyperglycemia [12].

In sub-Saharan Africa, the prevalence of GDM is estimated at approximately 14%, with substantial variation across geographic settings and diagnostic criteria [13-15]. In the DRC, reported prevalence ranges from 2.15% to more than 21%, reflecting heterogeneity in screening methods and study populations.

No documented data on GDM are currently available for Kisangani. This lack of information limits the implementation of appropriate prevention and management strategies. This study therefore aims to document the magnitude of the condition in this setting.

Research Question

Main Research Question

"What is the magnitude of GDM in Kisangani; what are its determinants and clinical characteristics; and how does it affect maternal, fetal, and neonatal outcomes?"

Specific Research Questions

- What is the overall hospital-based incidence of GDM in Kisangani?
- What are the determinants of GDM in Kisangani?
- What are the sociodemographic, clinical, obstetric, and laboratory characteristics of pregnant women with confirmed GDM in Kisangani?
- What is the effect of GDM on maternal, fetal, and neonatal outcomes?

Hypotheses

Main Hypothesis

"The magnitude of GDM diagnosed using a one-step OGTT is increasing among pregnant women in Kisangani and is associated with risk factors, specific clinical manifestations, and adverse maternal and neonatal outcomes."

Specific Hypotheses

- The incidence of GDM is high among pregnant women screened using the one-step 75-g OGTT in Kisangani.
- The occurrence of GDM among pregnant women screened in Kisangani is associated with certain risk factors, including advanced maternal age, a family history of diabetes, and a history of macrosomia.
- GDM is associated with specific clinical and obstetric characteristics among pregnant women diagnosed in Kisangani.
- GDM increases the risk of maternal, fetal, and neonatal complications.

Objectives

Primary Objective

"To describe the epidemiologic and clinical profile of GDM in Kisangani, identify the associated determinants, and assess its effect on maternal, fetal, and neonatal outcomes."

Specific Objectives

- To determine the hospital-based incidence of GDM among pregnant women systematically screened using an OGTT between 24 and 32 weeks of gestation at selected health facilities in Kisangani.
- To identify the determinants of GDM in Kisangani.
- To describe the clinical characteristics of GDM in Kisangani.
- To assess the effect of GDM on maternal complications during pregnancy and delivery in Kisangani.
- To determine the effect of GDM on fetal and neonatal outcomes in Kisangani.

METHODS

Study Setting

The study will be conducted in Kisangani, the capital of Tshopo Province in the Democratic Republic of the Congo. This multisite study will be conducted at six health facilities in the city.

Study Design and Period

This will be a prospective longitudinal study with descriptive and analytical aims, conducted over six months from June through December 2026.

Study Population

The study will include pregnant women receiving prenatal care at the selected facilities.

Inclusion Criteria

Pregnant women at 24 to 32 weeks of gestation who consent to participate and agree to be followed through delivery will be included.

Sampling

The minimum sample size was calculated using Schwartz's formula and an estimated prevalence of 8.9%. After adjustment for an anticipated 10% loss to follow-up, the minimum sample size was set at 137 participants.

Diagnosis of GDM

Screening will be based on a 75-g OGTT performed in the morning after a fast of at least eight hours. GDM will be diagnosed according to IADPSG criteria when at least one of the following thresholds is met:

- Fasting plasma glucose ≥ 92 mg/dL;
- 1-hour plasma glucose ≥ 180 mg/dL;
- 2-hour plasma glucose ≥ 153 mg/dL.

Study Variables

Dependent Variable

"Gestational diabetes mellitus"

Independent Variables

- Sociodemographic characteristics;
- Medical and obstetric history;
- Anthropometric measurements;
- Laboratory parameters;
- Maternal complications;
- Fetal and neonatal parameters.

Statistical Analysis

Categorical variables will be reported as frequencies and percentages. Continuous variables will be presented as means with standard deviations or as medians, depending on their distribution. Associations will be assessed using the chi-square test or Fisher's exact test for categorical variables and Student's t-test or the Mann-Whitney U test for continuous variables. Multivariable logistic regression will be used to identify factors independently associated with GDM.

Ethical Considerations

The study will be conducted after approval by the University of Kisangani Ethics Committee (approval number: UNIKIS/CE/KGB/008/06/2026) and after the required administrative authorizations have been obtained. Written informed consent will be obtained from each participant before enrollment, and data confidentiality will be ensured through anonymous coding.

Expected Discussion

This study will compare the incidence of GDM observed in Kisangani with rates reported in other regions of the DRC and sub-Saharan Africa. It will help identify risk factors specific to this population and assess the maternal, fetal, and neonatal consequences of GDM.

Future Directions

- Conduct nationwide multicenter studies to estimate the true burden of GDM in the Democratic Republic of the Congo.
- Establish a provincial GDM registry.

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ACTIVITY SCHEDULE OR TIMELINE

ACTIVITIES	RESPONSIBLE PARTY	M	A	M	J	J	A	S	O	N	D
Presentation of the research protocol to the Department of Gynecology and Obstetrics	Principal Investigator										
Presentation of the research protocol to the Ethics Committee	Principal Investigator										
Acquisition of research authorization	UNIKIS School of Medicine										
Ordering and purchasing materials and reagents	Principal Investigator										
Site preparation and research team training	Principal Investigator										
Data collection	Research Team and Data Collectors										
Presentation of preliminary results to the department	Principal Investigator										
Presentation of preliminary results at doctoral research sessions	Principal Investigator										
Presentation of final results	Principal Investigator										
Drafting and publication of scientific articles	Principal Investigator										
Writing the specialization thesis	Principal Investigator and Statistician										
Submission of the thesis to the faculty	Principal Investigator										