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Retrospective Cohort Study to Investigate Pregnancy Outcomes in a Population of Advanced Maternal Age Congolese Women of Kinshasa: A Study Protocol

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Abstract

Introduction: Pregnancies at advanced maternal age (AMA) are those occurring after the age of 35 years old. They carry a high risk of maternal-fetal morbidity and mortality, thus constituting a public health problem. Several African countries have reported an upward trend in both the age of childbirth and the frequency of women with AMA over the past 20 years. In the Democratic Republic of Congo (DRC), where maternal and neonatal morbidity and mortality remain very high, data on AMA pregnancies go back more than 20 years. **Objective**: We propose evaluating obstetrical outcomes among women in AMA in our setting and the associated factors. **Methods**: This retrospective cohort study will be conducted in two healthcare facilities (ESS) in Kinshasa. The study population will consist of all women who delivered a single fetus after 28 weeks of gestation between January 2012 and December 2022 (10 years) in the selected ESS. The data collected will be analyzed using R software version 4.2.0. Quantitative variables will be summarized as means with standard deviation or medians with interquartile range. Qualitative variables will be presented as proportions (%). Multivariate logistic regression will be used to determine the main maternal-fetal complications associated with AMA and predictors of obstetric outcomes. $P < 0.05$ will be considered statistically significant. Results will be presented in tabular and graphical form. **Discussion**: The high maternal and infant mortality rates in DRC are among the highest in the world. The context of maternal age has become a topic of growing interest due to its potential implications for the health of women and newborns, it is crucial to identify the risk factors associated with obstetric

outcomes by identifying obstetrical outcomes associated with advanced maternal age in the DRC. Many Congolese women tend to start their maternity journey at a relatively young age. However, there is also an emerging trend towards delayed childbearing, particularly in urban areas and among women with access to education and family planning services. **Conclusion**: The results of this study will enable us to update the frequency of AMA pregnancies in our environment. The socio-demographic and clinical profile of these pregnancies will be determined. The main maternal-fetal complications associated with AMA in our setting and the associated factors will be identified.

Keywords

Advanced Maternal Age, Adverse Maternal and Perinatal Outcome, Congolese Women, Kinshasa

1. Introduction

1.1. Background and Rationale

Any pregnancy contracted after the age of 35 years old is considered to be an advanced maternal age (AMA) pregnancy. Fertility specialists refer to late-onset pregnancies from the age of forty onwards [1].

AMA pregnancies are high-risk pregnancies in terms of maternal-fetal morbidity and mortality and are a matter of public health concern. This risk is increased by the physiological and physical changes associated with age, as well as the morbid histories of pregnant women, such as uterine myomectomy or cesarean section scars [2].

Several studies have described risks such as high blood pressure, pre-eclampsia, gestational diabetes, miscarriage, cesarean section, and even death for the mother [3]. According to CNGOF (Collège national des gynécologues et obstétriciens français), chronic hypertension and diabetes are the two most frequent pathologies associated with AMA [4] [5] In the case of diabetes mellitus, the risk is multiplied by 4 for women aged between 40 and 50, compared with women aged between 20 and 34 [3]. Pre-eclampsia (PE) is one of the leading causes of maternal mortality [3] [6]. In France, 8% of deaths are linked to PE, and this risk is multiplied by 2 for women over 40, regardless of parity [3]-[6]. According to a study by Cleany-Goldman *et al.*, AMA is significantly associated with a higher risk of retroplacental hematoma (RPH) in women over 40 than in those under 35 [4]. Fetal presentation abnormalities may partly explain the increased rate of cesarean sections and spontaneous miscarriages.

Complications in newborns have also been reported, including chromosomal abnormalities, prematurity, low birth weight, and macrosomia [3] [4]. According to Warburton, the rate rises to 33.8% after age 40, compared with 11.7% between 30 and 34, 17.7% between 35 and 39 and 53.2% after 45 [5]. At least 60%

of early abortions are linked to age-related chromosomal aberrations [5]. The risk of chromosomal aberration is 1.6% at 38, 2.21% at 40, and 4% at 42 [5]. In terms of birth weight, women over 40 are more likely to have a low birth weight (18.6%) than women under 35 (11.3%) [5]-[7]. In a study in Ethiopia, adverse fetal outcomes, including stillbirth and premature birth, were significantly associated with pregnancy at advanced maternal age [6] [8]. In a study in the Democratic Republic of Congo (DRC) in the province of Haut Katanga, more precisely in Lubumbashi, advanced maternal age was associated with perinatal mortality [9].

Over the past four decades, the transition from high to low fertility has been observed in most parts of the world, including Africa [8] [9]. This reduction in fertility is associated with an increase in the age at childbirth and the frequency of women with AMA [10]. According to a WHO survey of three continents (Latin America, Middle East, and Africa) from 2010 to 2011, the overall prevalence of women with AMA was 12.3% [4]. In Canada, the proportion of women with AMA rose from 15% in 1998 to 18% in 2007, and 1 primiparous woman in 3 was aged over 35 [7]. In France, the proportion of women undergoing AMA rose from 19% in 2010 to 21% in 2016 [7]. Several African countries have also reported an increase in the frequency of pregnancy postponements (a concept referring to the decision to schedule one's pregnancy at a later date. This may be due to a variety of factors, such as personal, professional, or medical circumstances and AMA [8]-[10]. Longer periods of study for women, family planning, and the advent of medically assisted reproduction (MAP) are the main reasons for the rise in these frequencies [9] [11]-[13].

Maternal mortality has reached unacceptable levels worldwide [8]. Almost all maternal deaths (99%) occur in developing countries, with 62% in sub-Saharan Africa (179,000) [9]. The DRC is one of the countries in Sub-Saharan Africa with one of the highest maternal mortality ratios, estimated at 547 maternal deaths per 100,000 live births [9] [14]. The underlying causes of these maternal and neonatal deaths are complex and multifactorial [10], including advanced maternal age [11]. Indeed, as a consequence of the fertility transition, an increase in the proportion of women with AMA in our environment could contribute to the persistence of the high risk of maternal and perinatal morbidity and mortality [10] [15]-[19].

In the DRC, where maternal and neonatal morbidity and mortality remain very high, there is very little data on AMA and its impact on pregnancy outcomes. Also, data concerning AMA pregnancies date back more than 20 years [20] [21]. Hence, there is an interest in carrying out this study.

1.2. Objectives

1.2.1. General Objective

To assess obstetric outcomes in advanced maternal age in our setting and the factors associated with them.

1.2.2. Specific Objectives

- Determine the frequency of advanced maternal-age pregnancies in our setting;
- Describe the socio-demographic and clinical profile of these pregnancies;
- Identify the main maternal-fetal complications associated with advanced maternal age;
- Determine the factors associated with obstetrical outcome of pregnancy at advanced maternal age.

2. Materials and Methods

2.1. Type of Study and Survey Period

The study will be a retrospective cohort study. The survey will run from January 2012 to December 2022, i.e. for 10 years.

2.2. Study Population

2.2.1. Inclusion Criteria

- Women who have given birth in the selected Health care facilities to a newborn of gestational age ≥ 28 weeks, spontaneous single pregnancy in cephalic presentation.
- Only women followed up in the selected healthcare facilities since the beginning of their pregnancy.

2.2.2. Non-Inclusion Criteria

- Women who had given birth in the selected Health care facilities to a newborn of gestational age < 28 weeks, multiple pregnancy and pregnancy under medically assisted procreation.
- Women transferred for maternal or fetal pathology during pregnancy. Women with a severe illness before pregnancy.
- Patients with incomplete medical records (contain less than 50% of the needed information).

2.3. Sampling

2.3.1. Sample Size

All women who gave birth during our data collection period and who met our inclusion criteria.

The minimum sample size will be calculated according to the following formula:

$$n = \frac{Z^2 p(1-p)}{d^2}$$

where

n: is the minimum sample size required;

Z = 1.96 (95% confidence at the significance level of 0.05);

p = 50% (assumed prevalence of obstetrical outcomes in AMA);

d = 0.05 (desired margin of error).

Consequently,

$$n = \frac{1.96^2 \times 0.5(1-0.5)}{0.05^2} \geq 384$$

2.3.2. Sampling Technique

We will use three levels of cluster sampling:

- At the first level, we will select two districts in Kinshasa.
- We will choose one second- or third-level hospital per selected district at the second level.
- At the third level, we will consider all women who gave birth during our data collection period and met our inclusion criteria.

2.3.3. Data Collection Techniques

Data will be collected from medical records and registers in the delivery room and operating theatre.

Variables of interest:

- Maternal socio-demographic variables: age, occupation, marital status, level of education, province of origin;
- Clinical variables: parity, gestational age, abortion, BMI before 20th week, smoking;
- Obstetrical history: history of illness before pregnancy (diabetes, hypertension, autoimmune pathology), postpartum hemorrhage, scar uterus, Pre-eclampsia, prematurity;
- Maternal and neonatal variables: pregnancy age, fetal heart sounds, mode of delivery, APGAR, birth weight, neonatal stays.
- Outcomes considered in this work:

➢ Obstetrical outcomes:

- Pre-eclampsia, Gestational diabetes, Premature delivery, Placenta previa;
- Premature detachment of placenta, Caesarean section, Instrumental delivery, postpartum hemorrhage.

➢ Immediate neonatal outcomes:

- Stillbirth, Prematurity, Low birth weight (<2500 g);
- Macrosomia (≥4000 g), IUGR;
- Neonatology admission rate (hospitalization in neonatal intensive care unit);
- Neonatal airway complications.

2.4. Data Organization and Processing

Data will be organized in Excel spreadsheets before analysis using R software version 4.2.0.

2.5. Analyses des Données

Based on previous studies [23], we will compare maternal and perinatal outcomes in different groups using women aged 20 to 29 as a reference group. In addition, this age group corresponds to the optimal age for childbearing in Africa

[24] [25].

Age group:

- ✓ Group 1: ≤19 years old;
- ✓ Group 2: 20 - 29 years old (reference group);
- ✓ Group 3: 30 - 34 years old;
- ✓ Group 4: 35 - 39 years old;
- ✓ Group 5: ≥40 years old.

- In the descriptive statistics section, we will calculate frequency, central tendency, and dispersion measures. Thus, quantitative variables will be summarized as means with their standard deviation or medians with their interquartile range, as appropriate, while qualitative variables will be presented as proportions (%).
- A multivariate logistic regression analysis will be performed to determine the main maternal-fetal complications associated with advanced maternal age.
- A logistic regression analysis to determine the predictors of obstetric pregnancy outcomes at advanced maternal age.
- For all statistical analyses, the significance threshold will be set at $P < 0.05$. The results will be presented in the form of tables and graphs.

2.6. Expected Results

- The frequency of AMA pregnancies in our environment will be known;
- The socio-demographic and clinical profile of these pregnancies will be described;
- The main maternal-fetal complications associated with advanced maternal age will be identified;
- Factors associated with obstetrical outcome of pregnancy at advanced maternal age will also be identified.

Ethics and dissémination

This project was approved by the Department of Gynecology-Obstetrics and has been submitted to the Ethics Committee of the School of Public Health of the University of Kinshasa for approval. Information will be collected, processed, and published anonymously and confidentially.

3. Discussion

The Democratic Republic of Congo (DRC) faces major maternal health challenges, with high maternal and infant mortality rates. According to the World Health Organization (WHO), the maternal mortality rate in the DRC is among the highest in the world, with around 473 deaths per 100,000 live births [5] [9] [20] [21]. In this context, it is crucial to identify the risk factors associated with obstetric outcomes to develop effective interventions to reduce maternal morbidity and mortality [26] [27].

Advanced maternal age has become a topic of growing interest due to its potential implications for the health of women and newborns. The main objective of this study is to identify obstetrical outcomes associated with advanced maternal

age in the DRC, as well as the underlying risk factors [3] [4] [20] [21]. Although precise data on maternal age in the DRC are limited, it is widely recognized that many Congolese women tend to start their maternity journey at a relatively young age. However, there is also an emerging trend towards delayed childbearing, particularly in urban areas and among women with access to education and family planning services [15] [22]-[26].

4. Conclusions

With the increased frequency of postponement of the first birth, this study will update data on obstetrical outcomes in AMA in the Kinshasa population. By identifying adverse maternal and neonatal outcomes, we will be able to understand better the challenges faced by women of advanced age in the DRC.

In addition, this study will examine the risk factors associated with these obstetric outcomes, including medical history, socio-economic status, and other relevant variables. This analysis will allow us to identify high-risk populations and direct prevention and intervention efforts towards the most vulnerable women.

We will test the hypothesis that advanced maternal age increases the risk of obstetric complications of pregnancy.

Strengths of the Study

Our study will be the first after 20 years to evaluate the advanced maternal age and obstetric outcomes in the population of Kinshasa.

The consistency of the result of this study will offer the updating in the hypothesis that advanced maternal age increases the risk of obstetric complications of pregnancy, and that according to socio-economic changes of population and new concepts of gender in DRC.

Study Limitations

Our sample will not be representative of the city of Kinshasa and future studies will have to take this into account.

The prospective nature of the study can face the loss of some data.

Conflicts of Interest

The authors do not declare any conflict of interest regarding the publication of this article.

Disclosure

The authors report no conflicts of interest for this work.

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