The Effect of 3rd trimester Ramdan fasting on Obestetric outcome

Thesis protocol

Submitted for partial fulfillment of master degree in

Obstetrics & Gynecology

BY

Ahmed Khalil Abd Elshafi

M.B, B.Ch, Benha University 2011

Resident of Obstetrics & Gynecology Ghamra Military Hospital

Under supervision

Prof .Mohammed Abd Allah ElMaraghi

Professor of Obstetric & Gynecology

Faculty of medicine – Ain shams university

Dr. Ayman Abd Elkader Mohammed

Lecturer of Obstetrics & Gynecology

Faculty of medicine - Ain shams university

(2015)

Introduction

Ramadan is the holiest month in the Islamic calendar and Muslims fast during this month. Ramadan fasting is one of the five pillars of Islam, and is observed by millions of Muslims all over the world. Believers are commanded to abstain from food, drink and conjugal relationships from sunrise to sunset as a sign of restraint and introspection. Food and fluid intake are mainly nocturnal and usually, food frequency and quantity, sleep duration at night and daily physical activity are reduced. The food habits are not similar outside and during Ramadan in that the proportion of fat, protein and carbohydrate intake can differ during Ramadan. There is a tendency to consume foods and drinks that are richer in carbohydrates than those consumed during other months of the year. The quality of ingested nutrients can also differ during Ramadan compared with the rest of the year. The period in which the person fasts may vary depending on the geographical location of the country and the season of the year, and can be as long as 18 hours/day in the summer of temperate regions *(Ziaee, 2006).*

During the month of Ramadan, adult Muslims abstain from eating, drinking, smoking, and sexual activity from

sunrise to sunset. Fasting during Ramadan forms one of the five pillars of Islam, along with announcement of faith, praying five times a day, Zakat (giving to the poor), and Hajj (pilgrimage to Mecca). In 2010, there were approximately 1.6 billion Muslims worldwide and this number is growing *(Kridli, 2015).*

Concurrence of fasting with pregnancy as a physiological condition introduces some controversies regarding the condition of the mother and the fetus. Pregnant women are exempt from fasting if it poses a risk to the fetus; however, many still fast while others are more cautious about its practice. Many pregnant show great interest in fasting and are able to perform this religious practice; however, they are concerned about their fetus and inquire about the possible associated complications during pregnancy According to the statics, in West Africa, 90% of pregnant women fasted during the month of Ramadan. The prolonged hunger presents itself as hypoglycemia or hyperketonuria, which may affect the neonatal weight, neonatal mortality and disability. During fasting, pregnant and breastfeeding women experience changes in metabolism, sleep patterns and daily physical activity *(Cunigham et al., 2010).*

Most Muslims observe Ramadan every year. Exemption from fasting is permitted for women who are pregnant or breastfeeding, but the missed fasts must be completed before the next Ramadan **(Rashed, 2010)**.

Muslim women choose to fast during pregnancy because of a sense of religious duty, familial support, positive views on fasting, and difficulty in completing the missed fasts at another time. A previous study found that Muslim women believed the only reason not to fast would be perceived harm to mother or fetus, but that fasting during pregnancy is safe for healthy women. Women feel strong spiritual, emotional, physical, and social benefits from fasting; it is seen as a way of maintaining cultural identity and unity among their communities **(Robinson et al., 2005).**

Many women asking their obstetrician if fasting is safe for their baby or not? There have been many studies on metabolic changes and different aspects of human health during and after Ramadan, but there have been few studies on the effect of fasting on pregnancy outcome and there are also some controversies in the findings of different studies **(Ziaee et al., 2006).**

Ramadan fasting during pregnancy is a controversial issue. A group of pregnant women do not fast due to the probable harmful effect on fetal health. Although Ramadan fasting may be postponed to the postnatal period, some pregnant women obey it as a religious activity *(Joosoph, 2004).*

There are several reports regarding the effects of Ramadan fasting on the human metabolism. Fasting leads to a decrease in serum glucose, insulin, lactate, and carnitine, as well as an increase in free fatty acids, hydroxy butirate, cholesterol, and triglyceride levels. As we know, maternal glucose infusion causes stimulation of short-term fetal activity and uteroplacental blood flow is essential for fetal development and wellbeing *(Osol, 2009).*

During the month of Ramadan, healthy adults abstain from food and drink from dawn to sunset. Pregnant are allowed, if they choose, to postpone the fast until after delivery. However, most of the women would like to fast with their families rather than doing this alone later. Therefore, most Muslim pregnant women fast during the holy month of Ramadan. Consequently, diet restriction and fasting could adversely affect pregnancy outcome, especially if Ramadan

falls during the hot summer months with long days of fasting

(Mirghani, 2006).

Aim of the Work

This study aimed to find out the association between fasting during Ramadan and obstetric outcome in third trimester regarding to hypoglycemic symptoms, fetal growth, AFI, mode of delivery, birth weight and neonatal outcome.

Study question:

In pregnant women in the third trimester, does fasting during the holy month of Ramadan has a poor obstetric outcome regarding to hypoglycemic symptoms, fetal growth, AFI, mode of delivery, birth weight and neonatal outcome?

Patient and Methods

Type of the study :

Prospective Comparative Cohort Study.

Study setting :

EL- Demerdash outpatient clinic.

Duration of the setting :

The Holy month of Ramadan (from 18th June To 16th July 2015.Averge hours of fasting 16 hours.

Population (study will include):

The patients will be recruited from outpatient clinic during Ramadan then followed during the holy month then grouped into three groups A ,B, C regarding fasting state and each group contain 53 patient after exclusion drop out patient

A- *Non fasting group*

B- *Partially fasting group (average days of fasting 10-20 day).*

C- *Totally fasting group*

Inclusion criteria:

- *Within the range of 20 – 35 years.*

- *3ʳᵈ trimester pregnancy (starting from 28 weeks) which is going to be calculated according to the date of the last menstrual period & confirmed by ultrasonography.*

- *Normal healthy women with average body mass index (BMI). Normal range (18.5 to 25).*

- *Women included have no medical disorder.*

Exclusion criteria :

- *History of systemic disorder.*

- *Smoking narcotics or alcohol use.*

- *Have previous history of fetal loss.*

- *Multiple pregnancies.*

Methodology

Women who fulfilled the eligibility criteria are going to be subjected to:

1) *Complete history taking:*

   a. *Personal history.*

   b. *Medical history.*

   c. *Obstetric history.*

   d. *History of present pregnancy: with special emphasis on signs & symptoms of hypoglycemia in the form of fatigue, dizziness, fainting, blurred vision, vomiting.*

   e. *Fetal kicks.*

2) *General examination: assessment of vital data.*

3) *Ultrasound fetal biometry every 2 weeks till delivery looking for*

- o ***Fetal biometry.***
- o ***AFI (ammonic fluid index)***
- o ***Doppler.***

4) Fetal weight after delivery.

Sample Size Justification:

The required sample size has been calculated using the G*Power Software (Universität Düsseldorf, Germany).

The primary outcome measure is the difference between the three study groups as regards the fetal birth weight. The secondary outcome measures are the incidence of unwanted fetal outcomes (e.g., IUGR, PTL, or NICU admission).

Since there is currently no adequate information regarding the outcome measures in patients who are fasted for the whole or part of the month, the current exploratory study would target an effect size that could be clinically relevant.

So, it is estimated that a sample of 53 patients in each study group (total 159 patients) would achieve a power of 80% (type II error, 0.2) to detect a statistically significant difference among the three groups as regards the fetal birth weight for a medium effect size (eta squared, η2) of 0.25. The effect size (eta squared, η2) is calculated as follows: η2 = between-group sum of squares/total sum of squares. This calculation used a two-sided F test with a numerator degree of freedom (k-1) of 2, a denominator degree of freedom (n-k) of 156, and a confidence level of 95% (type I error, 0.05), where k is the number of groups and n is the total sample size.This sample size of 159 patients would achieve a power of 93% (type II error, 0.07) to detect a statistically significant difference among the three groups as regards the secondary outcome measures (IUGR, PTL, and NICU admission) for a medium effect size (w) of 0.3. The effect size (w) is calculated as follows: w =√(χ^2/N), where χ2 is the chi-squared statistic and N

is the total sample size. This calculation used a two-sided chi-squared test with a confidence level of 95% (type I error, 0.05).

A medium effect size of $\eta2 = 0.25$ or $w = 0.3$ for the primary or secondary outcome measures, respectively, has been chosen as it could be regarded as a clinically relevant difference to seek in this exploratory study.

Assuming an expected drop-out rate of approximately 10%, a total sample size of 180 patients (60 patients per group) will be recruited.

Statistical Methods:

Data will be collected, tabulated, then analyzed using IBM© SPSS© Statistics version 22 (IBM© Corp., Armonk, NY).

Normally distributed numerical data will be presented as mean and SD, and skewed data as median and interquartile range. Qualitative data will be presented as number and percentage. Comparison of normally distributed numerical data will be done using one-way analysis of variance (ANOVA). Skewed data will be compared using the Kruskal Wallis test. Categorical data will be compared using the chi-squared test, or Fisher's exact test when appropriate. A two-sided p-value <0.05 will be considered statistically significant.