Perinatal and Maternal Outcomes Following Induction of Labour at 39 Versus 41 Weeks in Pregnant Women age 35 Years or over: Controlled Clinical Trial

Thesis

Submitted for Partial Fulfillment of the Master Degree in Obstetrics and Gynecology

By

Rania Awad Ahmed Mahgoub

M.B. B.Ch., International University of Africa

Under Supervisors

Prof. Dr. Sabry Sayed Mohamed

Professor of Obstetrics and Gynecology
Faculty of Medicine – Ain Shams University

Assist Prof. Dr. Tarek Aly Raafat

Assistant Professor of Obstetrics and Gynecology
Faculty of Medicine – Ain Shams University

Dr. Amr Ahmed Mahamoud Riad

Lecturer of Obstetrics and Gynecology
Faculty of Medicine – Ain Shams University

Faculty of Medicine
Ain Shams University
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List of Abbreviations

ACOG : American College of Obstetricians and Gynecologists

fFN : Fetal fibronectin

LBW : Low birth weight

PTD : Preterm delivery

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PROTOCOL OF A THESIS FOR PARTIAL FULFILMENT
OF
MASTER DEGREE IN OBSTETRICS AND
GYNECOLOGY

Title of the Protocol:

Perinatal and Maternal Outcomes Following Induction of Labour at 39 Versus 41 Weeks in Pregnant Women age 35 Years or over: Controlled Clinical Trial

Postgraduate Student: Rania Awad Ahmed Mahgoub
Degree: M.B. B.Ch., International University of Africa

DIRECTOR: Sabry Sayed Mohamed
Academic Position: Professor
Department: Obstetrics and Gynecology

Co-DIRECTOR: Tarek Aly Raafat
Academic Position: Assistant Professor
Department: Obstetrics and Gynecology

Co-DIRECTOR: Amr Ahmed Mahamoud Riad
Academic Position: Lecturer
Department: Obstetrics and Gynecology

2018

What is already known on this subject? AND
What does this study add?

The aim of the current work is to compare maternal and prenatal outcome among pregnant women aged 35 years or above undergoing induction of labour at 39 weeks and 41 weeks.

1. INTRODUCTION/ REVIEW

The increased occurrence of births at older maternal ages is due to the increased population of women aged 35 to 45, as well as later marriage, second marriage, the availability of better contraceptive options, and wider opportunities for further education and career advancement **(Wu et al., 2008; Uptodate, 2018).**

Fertility clearly declines with advancing age, especially after the mid-30s, and women who conceive are at greater risk of pregnancy complications **(Luke & Brown, 2007).**

Older women are at increased risk of pregnancy complications, including gestational diabetes, placenta praevia, and postpartum haemorrhage **(Josef et al., 2005; Knight et al., 2017),** and experience higher rates of intervention during labour and delivery **(Smith et al., 2008; Knight et al., 2017),** women ≥35 years of age are more likely than younger women to be delivered by cesarean **(Richard et al., 2016).**

The risk of antepartum stillbirth at term is higher among women aged ≥35 years than among younger women **(Huang et al., 2008)** and is higher still for nulliparous women aged ≥35 years **(Smith et al., 2001; Knight et al., 2017).**

Some obstetrical complications in older women appear to be related to the aging process alone, while others are largely related to coexisting factors such as multiple gestation, higher parity, and chronic medical conditions, which are less likely to be observed in younger women **(Yogev et al., 2010; Uptodate, 2018).**

Observational data indicate that induction of labour at or before term may be beneficial because the risk of perinatal death is at its lowest for births between 38 and 39 weeks of gestation **(Smith et al., 2001; Knight et al., 2017).** However,

current United Kingdom guidelines recommend that induction for prolonged gestation is offered to women between 41 to 42 weeks of gestation, when the risk of stillbirth is 2 to 3 per 1,000 deliveries **(NICE, 2008; Knight et al., 2017).**

2. AIM/ OBJECTIVES

The aim of the current work is to compare perinatal and maternal outcome among pregnant women aged 35 years or above undergoing induction of labour at 39 weeks and 41 weeks.

Research hypothesis: routine induction of labour at 39 weeks of gestation may reduce the risk of perinatal and maternal outcome in pregnant women older than 35 years, compared to routine induction of labour at 41 weeks.

Research question: Does routine induction of labour at 39 weeks of gestation reduce the risk of perinatal and maternal outcome in pregnant women older than 35 years, compared to routine induction of labour at 41 weeks?

3. METHODOLOGY:
Patients and Methods

Type of the study: Controlled clinical trial.

Study Setting: Ain Shams University Maternity Hospital.

Population of the study: The study will include 100 pregnant women and will be divided into 2 groups:

Group I: pregnant women older than 35 years who are admitted to Ain Shams University Maternity Hospital for induction of labour at 39 weeks.

Group II: pregnant women older than 35 years who are admitted to Ain Shams University Maternity Hospital for routine induction of labour at 41 weeks

Inclusion criteria:

1- Age $\geq$ 35 years.

2- Singleton pregnancy.

3- Cephalic presentation of the foetus.

4- Multiparty.

Exclusion criteria:

1- Medical comorbities such as HTN, DM.

2- Births complicated by fetal malpresentation, and placenta praevia.

3- Age < 35 years.

4- Nullipara.

5- Early in labor (CTG contraction 2/10).

6- Previous CS.

Sample Size Justification:

The only published paper on this topic was a retrospective study and it can't be related on it as it was not adjusted for basic maternal and feta condition.

So our controlled trial study will primarily focus on neonatal admission to ICU & secondarily on maternal and perinatal outcome following induction of labor at 39 weeks in pregnant women aged 35 years or above.

So, the study will include two groups consisting of 100 women.

Ethical and legal issue:

Good clinical practice:

The procedures set out in this study protocol, pertaining to the conduct, evaluation and documentation of this study, are designed to ensure that the investigators abide by the principles of good clinical practice and the ethical principles laid down in the current revision of the ethical committee of Faculty of Medicine Ain Shams University.

Delegation of investigator Responsibilities:

The investigator will ensure that all persons assisting with the trial are adequately informed about the protocol, any amendments to the protocol, the study treatments, and their trial related duties and functions.

Patient information and medical consent:

Before being admitted to the clinical study, all patients must consent to participate after the nature, scope, and possible consequences of the clinical study have been explained in a form that understandable to them, in Arabic language.

Confidentiality:

The investigator will maintain a personal patient identification list (patient numbers with the corresponding patient name) to enable record to be identified.

Protocol Approval:

Before the beginning of the study and in accordance with the local regulation followed, the protocol and all corresponding documents will be declared for Ethical Research approval by the Council of OB/GYN Department, Ain Shams University.

The selected cases will be subjected to the following:

Detailed history taking.

Clinical Examination:

General examination: pulse, temperature, blood pressure, body weight and height, body mass index.

Abdominal examination: by inspection, and palpation for assessment of fundal level, amount of liquor, fetal lie and presentation, estimated fetal weight, fetal heart sounds, and scar of previous surgeries.

Vaginal examination: cervical dilatation, effacement, station, position, consistency to assess the Bishop score for prediction of success of induction (higher score associated with increase likelihood of successful labor induction).

Study procedure:

After admission of the patients and assessment of both mother and foetus induction of labour will be done either by amniotomy and oxytocin low dose regimen 2mlu /min with increment 2mlU / min every 25 to 40 minutes, or cervical ripening with either mechanical or pharmacological methods for those pregnant women with unfavourable cervix. This will be done by 3mg dinoglandin controlled vaginal insert every 6 hours for maximum 3 doses.

Uterine contractions and fetal heart sounds will be monitored continuously by CTG.

After delivery of the baby, the following outcomes will be assessed

Primary outcome: neonatal admission to ICU

Secondary outcome: Apgar score at 10 mins, birth injury, shoulder dystocia, meconium aspiration syndrome and neonatal seizures. Maternal outcomes: emergency caesarean section, instrumental delivery, third or fourth degree perineal tear and emergency readmission to hospital within 28 days of delivery.

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 the unpaired Student t test. Skewed data will be compared using the Mann-Whitney U 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.

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Introduction

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