بسم الله الرحمن الرحيم

MONA MAGHRABY

شبكة المعلومات الجامعية

التوثيق الالكتروني والميكروفيلم

MONA MAGHRABY

شبكة المعلومات الجامعية

التوثيق الإلكتروني والميكروفيلم

جامعة عين شمس

التوثيق الإلكتروني والميكروفيلم

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MONA MAGHRABY

Faculty of Medicine

Ain Shams University

Transvaginal sonographic assessment of the cervix for prediction of successful induction of labor in nulliparous women

Thesis

For Fulfillment Of Master Degree In Obstetrics & Gynaecology

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2020

بسم الله الرحمن الرحيم

Uf سُبْحَانَكَ لَا عِلْمَ لَنَا إِلَّا مَا
عَلَّمْتَنَا e إِنَّكَ أَنْتَ الْعَلِيمُ الْحَكِيمُ

صدق الله العظيم

«*;آية (rr)

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Mohamed Abu LlFetoh Mohamed Hamed

List Of Contents

List of Abbreviations

AOP	Angle of progression
BMI	Body mass index
CBC	Complete blood count
CI	Confidence interval
CL	Cervical length
CS	Cesaren section
CTG	Cardiotocography
D5W	5 percent dextrose in water
FHR	Fetal heart rate
GBS	Group B streptococcus
HELLP	Hemolysis, elevated liver enzymes, low platelets
IOL	Induction of labor
IV	Intravenous
IQR	Interquantile range
LEEP	Loop electrosurgical excision procedure
LSCS	Lower segment cesarean section
OR	Odds ratio
OS	Ostium
RR	Relative risk
SD	Standard deviation
TVU	Transvaginal sonographic examination
UCA	Uteurocervical angle

List Of Ta6Ces

List Of Figures

PROTOCOL OF A THESIS FOR PARTIAL FULFILMENT OF MASTER DEGREE IN OBSTETRICS & GYNAECOLOGY

Title of the Protocol:Transvaginal sonographic assessment of the cervix for prediction of successful induction of labor in nulliparous women

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

Transvaginal sonography may be of important value in prediction of successful induction of labor in nulliparous women. This study will assess whether transvaginal sonographic assessment of the cervical length, utero-cervical angle are useful for prediction of successful induction of labor in nulliparous women or not.

1.INTRODUCTION/ REVIEW

Approximately 20% of parturients undergo induction of labor (IOL) for various reasons. ***(Martin et al., 2011).***

Observational studies have shown that nulliparous women with an unfavorable cervix undergoing induction of labor have about a two-fold increased risk of cesarean delivery. ***(Bailit et al., 2010)***

Urgent cesarean section during labor has additional risks for maternal and/or fetal complications as compared with elective cesarean delivery. ***(Creedy et al., 2000)***

The risks of a cesarean delivery are not limited to the index pregnancy but also implicate future pregnancies. ***(Huang et al., 2011)***

Thus, identification of women at high risk for cesarean delivery before the induction of labor process has a significant clinical value. The Bishop score remains the standard method for predicting the duration and safety of induced labor. ***(Bishop, 1964)***

However, this method of assessment is subjective and was shown to be a poor predictor for the outcome of labor in women scheduled for induction. ***(Kolkman et al., 2013)***

Sonographic measurement of cervical length, before induction of labor was suggested as a predictor of a successful induction. Nevertheless, a recent meta-analysis has shown that cervical length has only moderate capacity in the prediction of induction outcome. ***(Verhoeven et al., 2013)***

Currently, there is no objective and reliable way to predict a successful induction of labor.

In recent years, a new ultra-sonographic parameter called the utero-cervical angle (UCA) has been identified as a predictive tool for predicting successful induction of labor. ***(Sepulveda et al., 2017)***

The utero-cervical angle is defined as the angle formed between the anterior uterine wall and the endo-cervical canal. Basic physics play an important role in determining the utero-cervical angle and prediction of labor.

The force that a uterus exerts on the cervix varies depending on the utero-cervical angle. For example, the force of the uterus on an acute utero-cervical angle fortifies the closure of the endo-cervical canal, whereas the same uterine force applied on an obtuse angle can facilitate the opening of the cervix resulting in a quicker emptying of the uterine contents into the vagina.

Studies in literature report that the successful induction of labor increases as the uterocervical angle increases. ***(Sepulveda et al., 2017)***

The objective of this study is to assess whether transvaginal sonographic assessment of the cervical length, utero-cervical angle useful for prediction of successful induction of labor in nulliparous women or not.

2. AIM / OBJECTIVES

The aim of this study is to assess to the accuracy of transvaginal sonographic assessment of the cervical length, utero-cervical angle in prediction of successful induction of labor in nulliparous women.

Research hypothesis:

In prediction of successful induction of labor in nulliparous women transvaginal sonographic assessment of the cervical length, utero-cervical angle may be useful.
Research question:

In prediction of successful induction of labor in nulliparous women is transvaginal sonographic assessment of the cervical length, utero-cervical angle useful?

3. METHODOLOGY:

Patients and Methods/ Subjects and Methods/ Material and Methods

Type of Study: Prospective cohort study

Study Setting: The study will be conducted at Ain Shams university maternity hospital.

Study Population**: nulliparous women undergoing induction of labor.**

Inclusion criteria:

1. **Women with gestational age 38 weeks or more.**
2. **Nulliparity.**
3. **Singleton pregnancy.**
4. **With a vertex presentation.**
5. **Unfavorable cervix (defined as Bishop score less than 6) and not in labor (defined as the presence of regular uterine contractions).**

Exclusion criteria:

1. **Previous uterine surgery.**
2. **Previous cervical surgery (LEEP, conization).**
3. **Macrosomic baby (>4000 g).**
4. **Major fetal congenital abnormality or fetal death.**
5. **Any contraindications to vaginal birth (e.g. active genital herpes, placenta praevia).**

Sampling Size and Method:

This study will be conducted on nulliparous women attending Ain Shams university maternity hospital for trial of induction of labor, the least number (88) women but we will include (150) women for possible attrition.

Sample Justification:

Sample size was calculated using STATA program, setting the type-1 error (a) at 0.05 and the power (1-P) at 0.8. Result from previous study (pandis et al., 2001), showed that using ROC curve, the best cut-off point for the prediction of successful induction was 28 mm for cervical

length with a sensitivity of 87% and a specificity of 71%, with a successful induction in about 50% of primigravida cases. Calculation according to these values produced a minimal sample size of 88 cases (including 44 with successful induction)

Ethical Consideration:

This study will be done after approval of the ethical committee of the department of obstetrics and gynecology, faculty of medicine, Ain Shams University. Informed consent will be taken from all participants before recruitment in the study, and after explaining the purpose and procedures of the study. The investigator will obtain the written, signed informed consent of each subject prior to performing any study specific procedures on the subject. The investigator will retain the original signed informed consent form. All laboratory specimens, evaluation forms, reports, video recordings and other records that leave the site will not include unique personal to maintain subject confidentiality. The study will be based on the investigator self-funding.

Study Procedures:

Women will be subjected to full history taking including personal history, menstrual history, obstetric history, present history, past history& medical history, general examination, complete abdominal examination, complete pelvic examination and investigations include (transvaginal ultrasound, CTG, CBC, RH, random blood glucose level, liver function tests, renal function tests, urine analysis, coagulation profile)

Study Interventions:

All women that met the inclusion criteria and accepted to participate in our study will undergo cervical assessment by both Bishop score and transvaginal ultrasound examinations. Prior to the induction of labor, all examinations will be performed.

The cervical length (CL) will be measured tracing a single straight line from the internal to external os.

Utero-cervical angle (UCA) measurements will be obtained by placing the first ray from the internal os to the external os through the endo-cervical canal and by placing the second ray to delineate the lower uterine segment.

Bishop score is a group of measurements made at internal examination, used to determine whether the cervix is favourable or not. The score is based on the station, dilation, effacement (or length), position and consistency of the cervix. A score of 7 or more generally indicates that the cervix is ripe.

Cervical feature	0	1_2	3_4	5_6
Dilatation(cm)	0	1	2	3
Effacement(%)	0-30	40-50	60-70	80
Station(relative to ischial spine)	-3	-2	-1/0	+1/+2
Consistency	Firm	Medium	Soft	_
Position	Posterior	Mid	Anterior	

UCA, CL will be measured before the IOL. The demographic [age, body mass index (BMI)] and obstetric (gestational age) data of the participants, indications for labor induction, CL, UCA and neonatal birth weights will be recorded.

After the ultrasound evaluation of the participants, IOL will begin by administrating a vaginal misoprostol 50 pg every 6 hours. This process is continued until the desired cervical ripening has been achieved (defined as Bishop score >7) or until 24 h have elapsed. Fetal heart monitoring will be performed 1 h after the misoprostol placement and every 6 h thereafter.

The participants which responded successfully to the IOL will be transferred to the delivery room, and if necessary, augmentation of labor with oxytocin will be performed.

The decision of administering oxytocin will be made according to the uterine contraction patterns. Oxytocin will be administered intravenously as a diluted solution using a constant-infusion pump. The initial dose will be set at 5.3 mlU/ min, and will be increased by one-half of the previous infusion rate every 30 min up to a maximum dose of 40 mlU/min until the time of delivery.

Our study population will be grouped according to successful/ failed IOL based on entering the active phase of labor within 24 h of administering misoprostol. The successful group will be continued with the augmentation of contractions via intravenous oxytocin while the failed group will be ended up having a CS.

- The primary outcome will be successful induction of labor ended by vaginal delivery.
- The secondary outcome will be the assessment of correlations between the CL, UCA and the different phases of labor (duration of induction, duration of active phase and time to delivery).