RESEARCH PROPOSAL FOR MASTER OF MEDICINE

(OBSTETRICS AND GYNAECOLOGY)
DEPARTMENT OF OBSTETRICS & GYNAECOLOGY
UNIVERSITY OF MALAYA

Tugging the Foley Catheter Every Three Hours in the Labour Induction of Multiparas: A Randomised Trial

BY

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CONTENTS

1.0 INTRODUCTION

In developed countries, approximately 20–25% of gravid women undergo induction of labor (IOL) for various indications. (1) The goal of IOL is to achieve vaginal delivery by stimulating uterine contractions before the onset of labor. In considering IOL the benefits of labor induction must be weighted against the potential maternal and fetal risk associated with this procedure. (2)

An unripe cervix is a risk factor for failed IOL and caesarean delivery whereas prior vaginal delivery has the opposite impact. (3)

The two major methods for cervical ripening are mechanical intervention and the use of pharmacologic agents.(4) Mechanical dilatation of the cervix via transcervical placement is effective in ripening the cervix. Mechanical dilatation methods include single balloon catheter (i.e., Foley catheter). the double balloon catheter (i.e. Cook catheter) or with the use of other osmotic natural compound dilators such as Laminaria, or other synthetic compounds such as Lamicel and Dilapan.(5) Pharmacological forms of induction include prostaglandins and oxytocin.(6, 7)

Mechanical induction particularly with the single-balloon Foley catheter is widely used as the primary IOL method when cervical ripening is needed due to its low cost and reduced likelihood of uterine hyperstimulation compared to prostaglandins. (8) Placing a weight at the end of Foley catheter for induction of labor does not affect the time of delivery. (9)

A 2022 meta-analysis (three randomized trials: 790 singleton gestation) reports that Foley catheter with continuous traction applied for cervical ripening shows no decrease in time to delivery.(10)

The process of cervical ripening with Foleys balloon is typically not painful. After the cervix has ripened (usually to at least 3cm dilatation), amniotomy can then be easily and safely performed and titrated intravenous oxytocin infusion started to initiate contractions that leads to the establishment of labor and eventually birth.

The usual practice is to leave the Foley balloon in place for 12 hours after insertion before removing it to check if the cervix has dilated to allow amniotomy. In multiparas especially, the balloon can pass through the dilated cervix after only a few hours but is retained in the vagina for a prolonged period without causing discomfort. This scenario can delay amniotomy and oxytocin commencement in the labor induction process.

We hypothesise that externally tugging on the catheter once every 3 hours to gauge for a lack of resistance to the balloon descend will allow earlier discovery of adequate cervical dilatation. This will permit timely amniotomy and oxytocin infusion and thence for birth to be expedited compared to the standard practice of waiting up to 12 hours before catheter removal to check for cervical ripening.

A lengthy induction process can increase the burden on health care resources and adversely impact maternal satisfaction. Three hourly tugging of the Foley catheter balloon during its schedule 12 hours placement in multiparous labour induction may shorten the induction to delivery interval and improve maternal satisfaction

2.0 OBJECTIVE OF THE STUDY

To evaluate the impact of 3 hourly tugging of Foleys catheter compared to standard care (non tugging) on induction to 1) delivery interval and 2)maternal satisfaction on the birth process after labour induction

3.0 RESERCH HYPOTHESIS

We hypothesise that tugging of the Foleys catheter balloon will shorten the induction to delivery and increase maternal satisfaction with the birth process.

4.0 MATERIALS AND METHODOLOGY

4.1 STUDY DESIGN

Singe center, randomized controlled trial

4.2 PLACE OF STUDY

Antenatal and labour ward, University Malaya Medical Center, Kuala Lumpur

4.3 POPULATION STUDY

Multiparas planned for elective induction of Labour for various indications admitted will be assessed for enrolment using Eligibility form

Eligibility form

Inclusion Criteria

• Pregnant women (at least 1 vaginal delivery ≥ 24 weeks)	
• Age ≥ 18 years	
• Gestational age of ≥ 37 weeks	
• Singleton pregnancy	
• Cephalic presentation	
• Intact membrane	
• Reassuring fetal heart tracing	
• Absence of significant contraction ≥ 2 in 10 minutes	
• Successful Foley insertion for IOL	

Exclusion Criteria

• History of caesarean delivery or hysterotomy/ uterine perforation/ previous myomectomy	
• Latex Allergy	
• Estimated Fetal weight less than 2kg or > 4kg	
• Known major fetal malformations	
• Contraindication for vaginal delivery	
• Patient who is suspected COVID 19 infection or COVID 19 positive	

4.4 METHODS

Participant information sheet will be given to all potential recruits and any inquiries by the participants will be answered by the recruiting care provider. Written consent will be obtained from all participants.

All participants will undergo standard assessment by the care provider before their IOL; including their personal characteristics, obstetric assessment and fetal wellbeing (using a nonstress cardiotocogram) assessment.

Insertion of Foley Catheter

Participants will be positioned in the dorsal position. Bishop score will be ascertained during the vaginal examination prior to Foley insertion. A Foley catheter size 16F is then introduced through the external os digitally or via speculum (at discretion of care

provider). Once the tip of the catheter has passed the internal os by 4 to 5cm, the balloon will be inflated with 30 ml of water and retracted so the balloon rests on the internal cervical os. The external end of the Foley will be closed with a spigot and taped without tension to the medial aspect of the women's thigh.

Randomisation

Randomisation will be performed and intention to treat revealed only after successful Foley insertion. Randomisation is done by opening the lowest number, sealed and opaque envelope that is available. Randomization sequence will be generated using random number generator in random blocks of 4 or 8 by an investigator who is not involved in recruitment. Blinding is not possible due to the nature of intervention.

Participants will be randomized into two trial arms: Tugging (every 3 hours) compared to standard care (no tugging) of the Foleys catheter.

Induction Care

After catheter insertion, the patient will be monitored in the ward or labour suite with the cardiotocogram which is discontinued when reassuring. Standard care for Foley IOL in our center is applied to both arms. They are allowed to ambulate. Analgesia is given upon request. Cardiotocogram is performed as indicated. Patients are transferred to labour and delivery suite if the catheter is spontaneously expelled (or tugged free) before 12 hours. The catheter is removed if spontaneous rupture of membrane occurs or there is clinical need as decided at the discretion of the care provider.

Upon Foley removal (or if spontaneously expelled before removal), a second Bishop score is recorded, artificial rupture of membranes performed, and oxytocin infusion is initiated according to standard IOL protocol (10 international units of oxytocin in 500mls of Hartmann solution started at 6ml/ hr (2mU/min) and doubled every 30 minutes until 3-4/10 minutes regular moderate to strong contractions is achieved at which the infusion rate is maintained to delivery if no untoward reaction, maximum dose at 96 mL/ hr (32mU/min). if artificial rupture of membranes is not possible or safe (i.e., fetal head at high station, oxytocin can be initiated prior to artificial rupture of membrane.

Failed ripening is diagnosed if amniotomy could not be safely performed and a further ripening measure is needed. Patient will then be assessed and counselled by the care provider as standard care in these circumstances for medical induction with prostaglandin, oxytocin, another Foley or caesarean section. Standard care will be provided to all participants during their labour induction, intrapartum and postpartum. Care providers always have full discretion in deciding care to the participants' best interest.

Maternal satisfaction with the birth process will be assessed after delivery using the Visual Numerical Rating Scale scored from 0-10.
All date captured will be transcribed onto the Case Report Form.

4.5 SAMPLE SIZE CALCULATION

To calculate our sample size for the primary outcomes, we obtained data from literature review on:

5.0 PRIMARY OUTCOME

Primary outcome 1: Induction to delivery interval

Kuper S.G et al reports in patient multiparous IOL using 16F Foley catheter inflated with 30 mL sterile water are schedule for 12 hours placement (standard care without intermittent tugging), a mean induction to delivery interval of 13.5 hours (standard deviation 7.0). (11)

Connolly K.A et al, reports in in patient multiparous IOL using 16F Foley inflated with 60mL sterile water and scheduled 12 hours placement (standard care without intermittent tugging), a mean induction to delivery interval of 11.4 hours (standard deviation 5.4). (12)

Levine L.D et al, reports in inpatient multiparous IOL using 18F Foley catheter inflated with 60mL sterile water and scheduled 12 hours placement (standard care without intermittent tugging), a mean induction to delivery interval of 14.6 hours (standard deviation 6.1). (13)

From this studies with induction to delivery interval ranging from 11.4-14.6 with standard care (no tugging) Foleys balloon IOL, we postulate that tugging the Foleys every 3 hours to check for balloon dislodgement and ripened cervix will reduce induction to delivery interval by 3 hours. We use of standard deviation of 7.0 hours for the purpose of sample size calculation which is conservative compared as other trials have reported standard deviations of 6.1 (13) and 5,4 (12) in the induction to delivery interval.

Using, https://www.openepi.com/SampleSize/SSMean applying Student t test, alpha of 0.05, 80% power, 1 to 1 ratio, standard deviation 7.0 hours (11) to both arms and assumed 3 hours mean difference between trial arms, 86 women are required per arm (total :172). Factoring in the possibility of non-normal data distribution requiring Mann Whitney U test application, we increase sample size by 15% and assuming 10% dropout rate, we plan to recruit 86 x 1.15/0.9=109 in each arm, rounded up to total target sample size N = 220

Primary outcome 2: maternal satisfaction with birth process after labour induction

Using https://www.openepi.com/SampleSize/SSMean applying Student t test, alpha of 0.05, 80% power, 1 to 1 ratio, standard deviation of 2 to both arms and assumed 1 unit change in maternal satisfaction (0-10 visual numerical rating scale) to be clinically significant, 63 women are required per arm (total 126). Factoring in using Mann Whitney U test application as the data is ordinal, we increase sample size by 15% and assuming 10% dropout rate, we plan to recruit 63 x 1.15/0.9 = 80.5 in each arm, total target sample size N = 161.

Hence, we plan to recruit a total N = 220 women to cover the sample size calculated for both primary outcomes.

6.0 SECONDARY OUTCOMES

Based on core outcome set for trials on induction of labour: CROWN cite

Maternal outcomes

Change in bishop score after intervention

Use of additional method for cervical ripening

Time to delivery after Foley removal

Mode of delivery
- a) spontaneous vaginal
- b) vacuum
- c) forceps
- d) caesarean section

Indication for caesarean section

Duration of oxytocin infusion

Maternal satisfaction-based allocation to intervention until birth (11-point VNRS)

Blood loss during delivery

Third -or fourth-degree tear

Maternal infection

Use of regional analgesia in labour (epidural)

Length of hospital stay

ICU admission

Cardiorespiratory arrest

Needing hysterectomy

Postnatal depression

Neonatal outcomes

Apgar score at 1 and 5 minutes

NICU admission

Cord pH

Neonatal sepsis

Birth weight

Birth trauma

Hypoxic ischaemic encephalopathy/need for therapeutic hypothermia

Before their discharge, participants will be asked

1) to rate using a 11 point (0-10) visual numerical rating scale their satisfaction with allocated intervention of tugging or standard care (no tugging) for their Foley catheter IOL
2) to provide a Likert scale response on if they will recommend their allocated intervention of tugging or standard care (no tugging) for their Foley catheter IOL to a friend

6.1 STATISTICAL ANALYSIS

Data will be entered into SPSS software. Normally distributed continuous data (assessment with Kolmogorov-Smirnov test) will be analysed with Student's test. Chi square test will be used for categorical or nominal data and Mann-Whitney test will be used on non-normally distributed or ordinal data. 2 sided $p < 0.05$will be taken as the level of significance.

6.2 ETHICAL CONSIDERATION

This study is submitted to the University of Malaya Medical Centre Medical Research and Ethics committee, the local institutional review board for approval. Patient will be given and information sheet, have their oral queries addresses and written informed consent obtained to participate in the study. Patient can withdraw at any time of study without having to providing a reason.

7.0 REFERENCES

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Ghantt Chart

Duration	July 2022	August 2022	October 2022	July 2023	August 2023	September2023
Literature review	+					
Proposal preparation & Presentation		+				
Ethics Review			+			
Data Collection				+		
Data Analysis & Writing					+	
Thesis Manuscript Submission						+