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 WOMEN WITH PREVIOUS CESAREAN SECTION : A RANDOMISED TRIAL

BY

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1.0 INTRODUCTION

In developed countries, approximately 20–25% of gravid women undergo induction of labor (IOL) for various indications (1). The purpose of cervical ripening and induction of labour is to achieve vaginal delivery and to avoid operative delivery by caesarean section (CS)(2). Royal College of Obstetricians and Gynaecologists(RCOG) guidance gives a success rate for planned VBAC of 72–75%(3).

The IOL success rate and the delivery to induction interval remains largely similar over the past two decades(4). According to a 2022 individual patient data meta-analysis, balloon catheters and vaginal prostaglandins are widely used to ripen the cervix in labour induction, whilst both methods have comparable caesarean delivery rates and maternal safety profiles, but balloon catheters lead to fewer adverse perinatal events(5).

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(6). Many studies have shown that induction of labour with Foley's catheter seems to be a safe and effective way to achieve successful VBAC with good success rate and few complications to both mother and fetus(6-11).

These studies was conducted with Foley's catheter balloon inflated to 30-60mls with water and passive placement of the balloon for 12-24 hours intracervical. However, 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, typically needed with Foley initiated labour induction.

We surmise that external tugging on the catheter balloon every 3 hours 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 12-24 hours before catheter removal to check for cervical ripening. A lengthy induction process can adversely impact maternal satisfaction.

We hypothesised that tugging of the foley's catheter balloon every three hours during its scheduled 12 hours placement in labour after one previous caesarean induction may shorten the Foley insertion (induction) to delivery interval and improve maternal satisfaction with the birth process.

2.0 OBJECTIVE OF THE STUDY

To evaluate tugging of Foley catheter at 3 hourly intervals during its scheduled 12 hours placement compared to standard care (non-tugging) on
1) induction to delivery interval and
2) maternal satisfaction on the birth process in the labour induction in women who's undergoing induction of labour after previous caesarean section and

3.0 RESEARCH HYPOTHESIS

We hypothesise that the tugging of the Foleys catheter every 3 hours will
1) shorten the induction to delivery interval and
2) increase maternal satisfaction with the birth process.

4.0 MATERIALS AND METHODOLOGY

4.1 STUDY DESIGN
Singe centre, parallel design, randomised trial

4.2 PLACE OF STUDY
Antenatal and labour ward of University Malaya Medical Centre, Kuala Lumpur

4.3 POPULATION STUDY
Women with previous caesarean section delivery planned for elective induction of labour for various indications.

Eligibility form
Inclusion Criteria

• One previous uncomplicated transverse lower segment caesarean section	
• Age ≥ 18 years	
• Gestational age of ≥ 37 weeks	
• Singleton pregnancy	
• Cephalic presentation	
• Intact membrane	
• Reassuring fetal heart rate tracing	
• Absence of significant contraction ≥ 2 in 10 minutes	

• Successful Foley insertion for IOL	

Exclusion Criteria

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

4.4 METHODS

Participant information sheets 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 5 cm, 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 a 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 randomised 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 centre is applied to both arms. They are encouraged to ambulate. Analgesia is given upon request. Cardiotocogram is performed as indicated. Care providers of patients randomised to the 3 hourly tugging will be instructed to "tug" the external end of the foley's catheter to a level of just below patient discomfort and to sustain the tug for at least 30 second to gauge for resistance to descend. If there is comfortable descend, the balloon can be retrieved.

If the foley's catheter is dislodged upon tugging, or if it is spontaneously expelled before 12 hours of scheduled placement, or if there is spontaneous rupture of membrane or if there is clinical need as decided at the discretion of the care provider, patients are transferred to the labour and delivery suite for onward management. A second Bishop score is recorded, amniotomy performed, and oxytocin infusion is initiated according to standard IOL protocol (10 international units of oxytocin in 500mls of Hartmann solution started at 6 ml/ 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).

Failed ripening is diagnosed if amniotomy could not be safely performed and a further ripening measure is needed. Patients 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 before hospital discharge using the Visual Numerical Rating Scale scored from 0-10.

All data 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

Women with 1 previous caesarean delivery undergoing IOL using 16Fr Foley catheter inflated with 60 ml sterile water who were scheduled for 12 hours placement (standard care without intermittent tugging), had a mean induction to delivery interval of 20.1H (standard deviation 7.1){Vallikkannu, 2022 #11}

We postulate that tugging the Foleys every 3 hours to check for balloon dislodgement and ripened cervix may reduce induction to delivery interval by 4 hours. We use a standard deviation of 7.1 hours in both arm for the purpose of sample size calculation.

Using, https://www.openepi.com/SampleSize/SSMean applying Student t test, alpha of 0.05, 80% power, 1 to 1 ratio, standard deviation 7.1 hours to both arms and assumed 4 hours mean difference between trial arms, 50 women are required per arm (total :100). 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 125 , rounded up to total target sample size N = 126 (63 in each arm)

Primary outcome 2: maternal satisfaction with birth experience 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 15mm change in maternal satisfaction (10 Visual Numerical Rating Scale) to be clinically meaningful, 29 women are required per arm (total 58). 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 38 in each arm, total target sample size N = 76.

Hence, we plan to recruit a total N = 126 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 {Dos Santos, 2018 #13}

Maternal outcomes

Change in bishop score after intervention

Use of additional method for cervical ripening

Time to delivery after Foley removal/expulsion

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

Indication for operative delivery

Duration of oxytocin infusion

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

Maternal satisfaction with allocated intervention

Neonatal outcomes

Apgar score at 1 and 5 minutes

NICU admission

Cord artery pH

Neonatal sepsis

Birth weight

Birth trauma

Hypoxic ischaemic encephalopathy/need for therapeutic hypothermia

Before their discharge, participants will be asked to rate using a 11 point (0-10) visual numerical rating scale (VRNS) their satisfaction with allocated intervention for their Foley catheter IOL birth process and to provide a 5-grade Likert scale response on if they will recommend their allocated intervention for their Foley catheter IOL to a friend.

6.1 STATISTICAL ANALYSIS

Data will be entered into SPSS software. Normally distributed continuous data (normality assessment with Kolmogorov-Smirnov test) will be analysed with Student's test. Chi square test (Fisher exact test if cell value <5) 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. Patients will be given an information sheet; they will also have their oral queries addressed and written informed consent will be obtained from all participants. Participants can withdraw at any time without having to provide a reason.

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Ghantt Chart

Duration	December 2022	January 2022	February 2023	March-Oct 2023	November 2023	December 2023
Literature review	+	+				
Proposal preparation & Presentation		+				
Ethics Review			+			
Data Collection				+		
Data Analysis & Writing					+	
Thesis Manuscript Submission						+

1. Please state whether you have submitted this research proposal for funding, now or before
   - ☐ Yes: If Yes, which grant? _____
   - ✓ No

This proposal will be kept strictly private and confidential. It will not be shared with anyone without your prior approval.

Name of Researcher (CAPITAL): YUNESH A/L KRISHNAN @ BALAKRISHNAN

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Signature of Researcher

Date: 19/01/23