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6 vs 12 Hours of Foley Catheter Placement for Labour Induction in One Previous Caesarean with Unripe Cervices: A Randomised Trial

BY
USHA YOGAMOORTHY
MGG 190008

SUPERVISOR
PROF. DR. TAN PENG CHIONG
PROFESSOR
DEPARTMENT OF OBSTETRICS & GYNAECOLOGY
UNIVERSITY MALAYA MEDICAL CENTRE

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INTRODUCTION

Induction of labour (IOL) after one previous Caesarean is a high-risk procedure: however, induction of labour is performed in as high as 27-32.7 % of women attempting vaginal birth after one previous Caesarean scar (VBAC)(1, 2). Labour induction after one previous Caesarean is an accepted practice and considered safe when conducted in a well-resourced setting after appropriate counselling.(3) Following VBAC, maternal and fetal outcomes are usually excellent and future pregnancies are more straightforward.(4) The American College of Obstetricians and Gynaecologists (ACOG) considered trial of labour after Caesarean (TOLAC) as appropriate for many women as VBAC is associated with decreased maternal morbidity and a decreased risk of complications in future pregnancies as well as a decrease in the overall caesarean delivery rate at the population level(5).

A 2017 Cochrane meta analysis (eight studies with 707 women) on methods (Foley catheter and dinoprostone included) of term labour induction for women with a previous Caesarean section concludes randomized control trial evidence is inadequate.(6) A subsequent 2019 systematic review and meta analysis finds low to very low certainty evidence for cervical ripening and/or labour induction techniques for VBAC.(7) A 2021 trial reports balloon catheter tended to be associated with a higher probability of vaginal delivery as compared with low-dose intravenous oxytocin when used for induction of labour in women with a previous Caesarean section and low Bishop score at induction.(8)

The two major techniques for cervical ripening are mechanical or use of pharmacologic agents.(9, 10) Mechanical cervical ripening of the cervix can be done with the use of a Foley catheter or double balloon device (i.e. Cook catheter) placed through the endocervical canal.(11) Osmotic dilators, Laminaria and synthetic dilators placed in the cervical os are also used for mechanical cervical ripening. Pharmacological forms of induction include prostaglandins and oxytocin. The World Health Organization (WHO) strongly recommends the use of balloon catheter for induction of labour(12).

Time to delivery is an important consideration during IOL because of its association with increased risk of caesarean delivery, postpartum haemorrhage, and maternal and neonatal infections. (9, 11, 13). Moreover, a lengthy IOL process can overburden busy delivery wards, can contribute to rising healthcare costs and is associated with lower patient satisfaction scores. (14) Previous studies have compared balloon catheter placement for 12 vs 24 hours and demonstrated that 12 hours of balloon catheter placement is associated with shorter time to delivery and higher rates of vaginal deliveries.(15, 16) Recently, the first randomized controlled trial (RCT) comparing placement for 6 vs 12 hours for the double balloon catheter was published, demonstrating faster time to delivery with adequate cervical ripening with 6 hour placement.(17)

A second RCT also shows time to delivery is shorter for women who undergo IOL with one balloon of the double balloon catheter inflated plus concurrent oxytocin and planned removal of the catheter at 6 hours or 12 hours.(18) Both above-mentioned studies used the costly double-balloon catheter.

A 2017 meta-analysis, (5 RCT 996 women) comparing single to double-balloon catheters for IOL, the time from catheter insertion to delivery did not differ between the two catheter types. (19) Currently, the Foley catheter balloon is the most used mechanical device for labour induction acting, not only as a mechanical dilator of the cervix but also as a stimulator of endogenous prostaglandins release from the fetal membrane. (20, 21) Foley balloon catheter cervical ripening, is associated with low cost and reduces risk of uterine tachysystole compared with prostaglandins. (22)

A 2018 systematic review on complications from insertion to expulsion of a balloon catheter during labour induction reports adverse event rates of 0.0-0.26% with 'pain/discomfort' having the highest prevalence.(23) Foley induction ripens the cervix and infrequently causes progression to labour without amniotomy and oxytocin augmentation.(24) As for Foley catheter balloon inflation for IOL, comparing 60 to 80 mL vs 30 ml, a 2018 meta-analysis (7 RCT and 1432 women) finds that the larger volume reduces total time to delivery.(25)

The aim of the present original study is to evaluate 6 vs 12 hours placement of the low-cost Foley catheter in women with one previous Caesarean with unripe cervixes who are planned for IOL with the hypothesis that removal at 6 hours will shorten the induction to delivery interval.

OBJECTIVE OF THE STUDY

The purpose of this study is to evaluate whether time to delivery is shorter for women who undergo Induction of labour in women with one previous caesarean delivery with foley's Catheter with planned removal at 6 hours versus 12 hours.

RESEARCH HYPOTHESIS

We hypothesize that Induction of labour with Foley catheter removed at 6 hours in women with one previous caesarean delivery will result in a shorter interval to delivery.

MATERIALS AND METHODOLOGY

STUDY DESIGN

Single centre , randomised controlled trial.

PLACE OF STUDY

Antenatal and labour ward, University Malaya Medical Centre, Kuala Lumpur.

POPULATION OF STUDY

Women with one previous caesarean delivery planned for elective induction of labour for various indications admitted to antenatal or labour ward of University of Malaya Medical Centre will be assessed for enrolment using the eligibility form.

Eligibility Form

Inclusion Criteria

• One previous Caesarean delivery • Bishop score ≤ 5
• 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 catheter insertion

Exclusion Criteria

● History of hysterotomy/uterine perforation/myomectomy
● Preference for repeat caesarean section
● Latex Allergy
● Estimated Fetal weight less than 2kg or > 4kg
● Placenta previa including minor previa
● Major fetal malformations
● Contraindication for vaginal delivery
● Patient who is suspected COVID 19 infection or COVID 19 positive
● Inability to given consent

METHODS

This is a randomised control trial involving women with one previous caesarean delivery age at term (≥ 37 weeks) who are planned for IOL for various indications. All eligible women will be approached, provided with the Patient Information, verbally counselled and queries answered by the care provider to provide for informed consenting. Women agreeing to participate will be asked for their written consent.

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 using either by digital or speculum method (at the discretion of the introducer). Once the tip of the catheter has passed the internal os by 4 to 5cm, the balloon will be inflated with 80ml of water and retracted so the balloon rests on the internal cervical os. The other end of the Foley catheter will be taped without tension to the medial aspect of the women's thigh. (26)

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, assigned in strict order. Randomisation sequence will be generated using a random number generator at Random.org in random blocks of 4 or 8 sequence, generated by an investigator who is not involved in recruitment. Blinding is not possible due to the nature of the intervention.

Participants will be randomised into two trial arms: Foley removal following its insertion

1. at 6 hours

or

2. 12 hours

Labour 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 allowed to ambulate. Analgesia is given upon request. Subsequent cardiotocogram is performed as indicated. Patients are transferred to the labour and delivery suite if the catheter is spontaneously expelled before the designated 6 or 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 [2 mU/min] and doubled every 30 minutes until 3–5/10 min regular painful contractions is achieved at which rate infusion rate is maintained to delivery if no untoward reaction, maximum dose at 48ml/hr [16 mU/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 Bishop score is ≤ 5 after removal of catheter. 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 induction process will be assessed as soon as possible after delivery using the Visual Numerical Rating Scale scored from 0-10.

All data captured will be transcribed onto the Case Report Form.

SAMPLE SIZE CALCULATION

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

Induction to delivery interval

Hong et al reports mean induction to delivery interval in Foley (24-hour placement) IOL for TOLAC of 25.2 ± 9.8 (adjunctive membrane sweeping) vs 27.0 ± 9.4 (control no membrane sweeping) hours.

Sulaiman et al reports mean induction to delivery interval in their Foley (24-hour placement) IOL for TOLAC arm of 31.4 ± 8.1 hours.

Using https://www.openepi.com/SampleSize/SSMean.htm and applying alpha of 0.05, 80% power, 1 to 1 ratio, assuming a mean difference of 6 hours in the intervention to delivery interval between the 6 h vs 12 hour trial arms and a conservative standard distribution of 12 hours in both arms, 63 participants are needed in each arm (N = 126).

PRIMARY OUTCOME

Foley's catheter insertion to delivery interval.

SECONDARY OUTCOMES

- Based on core outcome set for trials on induction of labour : CROWN (19)

<u>Maternal outcomes</u>

6.1.1 Change in bishop score after intervention

6.1.2 Use of additional method for cervical ripening

6.1.3 Time to delivery after Foley's Catheter removal

6.1.4 Mode of delivery

a) spontaneous vaginal
b) vacuum
c) forceps
d) caesarean section

6.1.5 Indication for caesarean section

6.1.5 Duration of oxytocin infusion

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

6.1.7 Blood loss during delivery

6.1.8 Third or fourth degree tear

6.1.9 Maternal infection

6.1.10 Use of regional analgesia in labour?

6.1.11 Length of hospital stay

6.1.12 ICU admission

6.1.13 Cardiorespiratory arrest

6.1.14 Needing hysterectomy

6.1.15 Uterine scar or dehiscence

Neonatal outcomes

6.2.1 Apgar score at 1 and 5 minutes

6.2.2 NICU admission

6.2.3 Cord pH

6.2.4 Neonatal sepsis

6.2.5 Birth weight

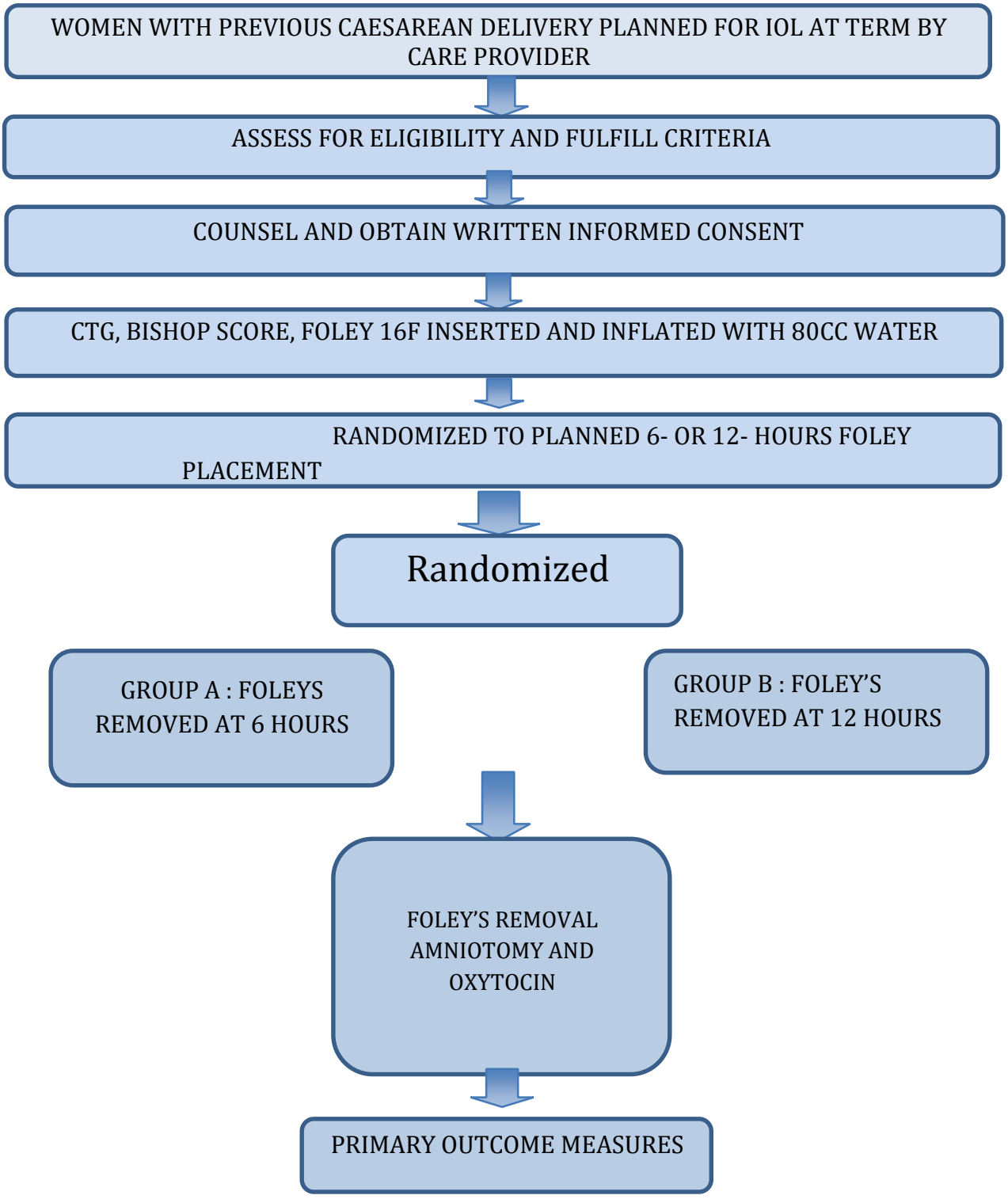
6.2.6 Birth trauma

6.2.7 Hypoxic ischaemic encephalopathy/need for therapeutic hypothermia

Trial Protocol

Patient admitted for induction of labour to antenatal ward/ labour ward

PROTOCOL FLOW CHART



STATISTICAL ANALYSIS

Data will be entered into SPSS statistical software. Normally distributed continuous data will be analysed with t test. Chi square test will be used for categorical or nominal data and Mann-Whitney U test will be used on non-normally distributed or ordinal data.

ETHICAL CONSIDERATIONS

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 an information sheet, have their oral queries addressed and written consent obtained to participate in the study. Patients can withdraw at any time of the study without having to provide a reason.
My supervisors will closely monitor the study. SAE will be reported to UMMC-MREC. If any one of them has any severe SAE, events will be updated and brought to the attention to be discussed with the committee.

GANNT Chart

Duration	June to July 2021	August to September2021	October-November 2021	Jan 2022-Jan 2023	Feb 2023	March 2023
Literature Review	✓					
Proposal preparation and Presentation		✓				
Ethics Review			✓			
Data Collection				✓		
Data analysis and writing					✓	
Thesis Submission						✓

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CASE REPORT FORM

STUDY NUMBER

PATIENT STICKER

Date of recruitment: __ / __ / __ (dd/ mm/ yy)
LMP: __ / __ / __ (dd/ mm/ yy)
EDD: __ / __ / __ (dd/ mm/ yy)

Patient characteristics

D.O.B: _____ (dd/ mm/ yy)
Gravida: _____ Para: _____ Abortion: _____
Gestational age: _____
Latest recorded Weight: _____ kg
Height: _____ cm

Education level:

Up to primary
Secondary
Diploma
Degree
Masters
PhD

Occupation:

Employed
Self employed
Student
Housewife
Other: _____

Ethnicity:

Malay
Chinese
Indian
Other: _____

Indication/s for IOL: _____

Pre induction Bishop Score: _____

Score	0	1	2	3
Dilatation	Closed	1-2 cm	3-4	5 cm
Length	> 4 cm	3-4 cm	1-2 cm	0
Consistency	Firm	medium	soft	-

Position	Posterior	mid	anterior	-
Station	≤ -3	-2	-1 to 0	+1, +2

Primary Outcome:

1. **IOL to delivery interval [Date/Time delivery - Date/Time catheter inserted**

Dates and times

1. Date / Time catheter inserted: __ /__ / __ (dd/ mm/ yy): ___: ___ (hr:min)
2. Date / Time catheter removed/ dislodged: __ / __ / __ (dd/ mm/ yy): ___: ___ (hr:min)
3. Date / Time ARM/SROM: __ / __ / __ (dd/ mm/ yy): ___: ___ (hr:min)
4. Date / Time oxytocin infusion start (if any): __ /__ / __ (dd/ mm/ yy): ___: ___ (hr:min)
5. Date / Time oxytocin infusion stop (if before delivery):

   __ /__ / __ (dd/ mm/ yy): ___: ___ (hr:min) ☐ @ delivery
6. Date / Time of 2nd stage: __ / __ / __ (dd/ mm/ yy): ___: ___ (hr:min)
7. Date / Time of pushing: __ / __ / __ (dd/ mm/ yy): ___: ___ (hr:min)
8. Date / Time of delivery: __ / __ / __ (dd/ mm/ yy): ___: ___ (hr:min)
9. Date / Time of Hospital Discharge (as per EMR): __ / __ / __ (dd/ mm/ yy): ___: ___(hr:min)

Secondary Outcome

Maternal Outcome

1. Bishop score at catheter removal/ dislodgement

Score	0	1	2	3
Dilatation	Closed	1-2 cm	3-4 cm	5 cm
Length	> 4 cm	3-4 cm	1-2 cm	0
Consistency	Firm	medium	soft	
Position	Posterior	midline	anterior	
Station	-3	-2	-1 to 0	+1, +2

2. Additional cervical ripening used?
   a) Foley
   b) Prostaglandin Please specify: _____
   c) Others Please specify: _____
   d) None

3. Mode of Delivery:
   a) SVD
   b) Caesarean section. Indication: _____
   c) Instrumental delivery. Indication: _____
      i. Forceps
      ii. Vacuum

4. Use of analgesia in labour?
   Circle as many as used
   a) None

b) Entonox
c) Opiate i.m
d) Neuraxial analgesia
e) Others. Please specify _____

5. Estimated blood loss at delivery: _____ ml

6. Type of perineal tear sustained:
Intact perineum/ First°/ Second°/ Third°/ Fourth°/ Episiotomy

7. Required ICU admission
Yes
No
Reason for admission: _____

8. Cardiopulmonary resuscitation (CPR) before hospital discharge
Yes
No

9. Hysterectomy before hospital discharge
Yes
No

10. Maternal fever (highest recorded temperature from IOL to discharge): _____^{0}C

11. Antibiotics given (from IOL to discharge)
Yes Indication_____
No

12. Uterine Scar Rupture or dehiscence
Yes
No

Neonatal outcome

1. Apgar Score: _____ 1 mins / _____ 5 mins

2. Cord Arterial pH: _____ Base excess : _____

3. Birth weight: _____ kg

4. Required neonatal admission:
   Yes
   No
   Place of admission: PNW / SCN / NICU / Others
   Indication for admission: _____

5. Diagnosed with Hypoxic ischaemic encephalopathy (HIE)
   Yes
   No

6. Cooling therapy for HIE
   Yes
   No

7. Neonatal sepsis diagnosed
   Yes Please specify_____
   No

8. Birth trauma
   Yes Please specify_____
   No

To be completed by participant

1) Rate your satisfaction with the experience of your allocated intervention of placement (of 6 or 12 hours) of the Foley catheter for labour induction.
   Circle your score below (higher score, greater satisfaction)

0	1	2	3	4	5	6	7	8	9	10

Totally dissatisfied Totally satisfied

(To be assessed within 24 hours of delivery)

2) I would recommend my allocated intervention of placement (of 6 or 12 hours) of the Foley catheter for labour induction to a friend

a) Strongly agree

b) Agree

c) Neither agree nor disagree

d) Disagree

e) Strongly disagree