VERSION NO: 4
VERSION DATE: 21/07/2021

UNIVERSITY OF MALAYA MEDICAL CENTRE **PROTOCOL**

RESEARCH

Study Time frame: 1 April 2021- 11 October 2022

1. Particulars of Researcher

Full Name: AISHAH BINTI MOHD

Title: DR
(Please indicate title: Prof/Assoc. Prof/Dr)

Present Position: MEDICAL OFFICER

Department: OBSTETRICS AND GYNAECOLOGY

Office contact number: Tel:

Mobile Number: 0167028475

Email: aishah.mohd@ummc.edu.my

Research expertise (List up to 5 fields of expertise):

2. List of Co-researchers (Include all who have participated in the drafting of this proposal)

1. Name: PROF DR TAN PENG CHIONG
   Department: OBSTETRICS & GYNAECOLOGY
   Email: pctan@um.edu.my

2. Name: DR MAHERAH BINTI KAMARUDIN
   Department: OBSTETRICS & GYNAECOLOGY
   Email: maherah @ummc.edu.my

3. **Research Proposal.** Please draft a concept paper using the template provided below. Maximum of 3 pages only.

TITLE OF RESEARCH PROPOSAL

Randomized controlled trial of four hour versus eight hour vaginal examination intervals after amniotomy and cervical ripening with Foleys catheter in multiparous women.

KEY WORDS

Four hours versus eight hours vaginal examination

BACKGROUND/ JUSTIFICATION

Vaginal examination is an essential examination in pregnant women presented with labour symptoms. It is an indispensable tool to diagnose labour and monitoring progress of labour in first stage and second stage of labour[1] It might be routine for physician to perform vaginal examination, however for labouring women, it is largely associated with pain of varying degree in both physical and psychological aspect [2]

In a study done in Egypt by Amira et al in 2018 [3], it shows large proportion of women reporting had vaginal examination done more than 4 times and up to 12 times during their labour process (70% report >4 vaginal examination done). This is higher frequency than recommended by WHO, vaginal examination in 4 hours interval and if possible, conducted by same provider [4]. In the same study almost 95% report of having pain either physical or psychological related or both.

A study by Abu Khalil [5], comparing 2 hourly vs 4 hourly vaginal examinations and its influence on duration of labour. It shows no statistically significant different in the duration of first and second stage of labour. It also shows that there is no association between assisted vaginal delivery, caesarean section rate or augmentation with oxytocin.

Experience during vaginal examination may negatively impact maternal satisfaction by feeling of pain, anxiety, fear, shame, exposed and powerlessness[6][7][8][9]. In a study by Sahar et al in Palestine [10], 38% women report as had >4 vaginal examination done during their labour process by different provider and 83% report severe pain during vaginal examination[11]

In study by Tan et al [12], comparing immediate versus delayed oxytocin following amniotomy in labour induction in multiparous, it shows vaginal delivery after 12 hours are 94.8% and 96.8% respectively. The immediate oxytocin arm had a shorter amniotomy to delivery interval of 5.3±3.1 compared with 6.9±2.9 hours. This is to highlight, labouring women may not require the 4 hours assessment or the 8 hours assessment.

In a large retrospective study[13], where the progress of labouring women in first stage of labour was observed and plotted on a partogram according to centiles, it shows, labouring women will follow the expected curve removing doubts on precipitated labour. They will typically follows first stage of labour which divided into latent phase and active phase, before they entered second stage of labour which end with delivery of fetus.

Based on these two studies, showing high rate of successful induction of labour in grand multiparous women and progression of labour in these women is following expected timeframe. As this current study want to look into women's satisfaction on labour, increasing the interval of vaginal examination and performing vaginal examination as when needed may improves women's satisfaction. This is without jeopardizing the safety of mother and fetus, as other monitoring will be continued as per standard. Many women desire a delivery process that is as

near as natural as possible, even when they are consenting to induction of labour due to various beneficial indications. Furthermore, as mention above, most women reported high frequency of vaginal examination done during their labour, with reducing examination interval may help women to alleviate a proportion of their physical and emotional pain during labour. Repeated vaginal examination also has shown to increase risk of postpartum and neonatal infection.

OBJECTIVES/OUTCOMES

Objectives:

The objective of this study is to compare maternal satisfaction and amniotomy to delivery interval in multiparous patients who had routine digital vaginal examination at four hours interval(control) versus eight hours interval(interval).

Outcomes:

Primary outcome

1. Maternal satisfaction of labour care measured using a visual numerical rating score from 0-10, assessed after delivery.
2. Duration of active labour, defined as amniotomy to delivery interval.

Secondary outcome

Maternal outcome

1. Mode of delivery
2. Rate of caesarean section
3. Intrapartum and day 1 postpartum fever which defined as single temperature reading of ≥ 38ºC
4. Analgesia used in labour
5. Estimated blood loss

Neonatal outcomes

1. Apgar score at 1 and 5 minutes
2. Arterial cord pH
3. Birth weight
4. Neonatal care admission

METHODOLOGY

Study design

Randomised controlled trial

Inclusion criteria

i) Multiparous women
ii) 18 years of age
iii) Planned labour induction
iv) Gestational age of > 37 weeks at enrolment of scheduled induction of labour

v) Cephalic presentation
vi) Singleton pregnancy
vii) Women who had cervical ripening with Foleys catheter and favourable cervix with cervical dilatation of 3cm or greater (suitable for amniotomy) with contraction <2:10
viii) Reassuring fetal cardiotocography (CTG), interpretation as per Appendix 1

Exclusion criteria

1. Previous uterine incision/ injury (caesarean delivery, myomectomy, perforation)
2. Gross fetal anomaly
3. Contraindication for vaginal birth
4. Estimated foetal weight ≥ 4.0kg before induction

Method

1. Patient recruitment

All potential candidates who fulfilled the inclusion criteria are identified by investigators at delivery suite and antenatal ward. Potential candidates will be assessed for recruitment eligibility by using Eligibility Form. Potential candidates who fulfilled the eligible criteria will be provided with patient information sheet and explained for participation on this study, emphasizing on the voluntary participation and patient have the right to refuse participation and that her subsequent care will not be compromised. If the candidates agree to participate, written and informed consent will be taken from participants.

Following removal of Foleys catheter, manually or spontaneously, vaginal examination will be performed and participants with cervical dilatation ≥3cm will be send to labour ward for amniotomy followed by cardiotocograph tracing. Subsequently, induction process will be continued with oxytocin commencement. After candidates had amniotomy done, cardiotocograph tracing normal and started on oxytocin, randomization will be done.

Randomisation will be carried out by opening the lowest numbered sealed opaque envelope. Patients are randomised into 1:1 ratio with blocks of 4 and 8, into intervention group (8 hourly vaginal examination) or control group (4 hourly vaginal examination).

Participants in both groups will be subjected to additional vaginal examination as per standard care in the events of:

1. Prior to administration of analgesia or epidural
2. Fully dilated cervical os
3. Application of foetal scalp electrode
4. Non-reassuring foetal heart tracing

Labour progress and uterine activity will be plotted on partogram. Foetal heart rate activity will be monitored continuously during labour.

Following delivery, maternal satisfaction score (regarding her whole labour process) will be rated by the participants on both group via Visual Numerical Rating Scale (VNRS) with scoring from 0-10, with 0 being completely dissatisfied and 10 being completely satisfied. Patient demographic data will be collected and recorded in case report form. Each patient will be given new identification number, their personal data will be kept confidential and will not appear in case report form. Detail of participants delivery outcome will be retrieved from medical notes and will be included in case report form.

2. Definition of operational terms

Vaginal examination is performed digitally with a sterile gloved hand. The digital vaginal examination primarily assesses how far the uterine cervix has thinned and dilated. The full components of the vaginal examination, as described in detail by Simkin[14]
The cervix:

- Position of the cervical os (posterior to anterior)
- Consistency of the cervix (from hard to soft, or 'ripe')
- Effacement of the cervix (from thick to thin)
- Dilation of the cervical os (from 0 to 10 centimetres, nominally)

The foetal presenting part:

- Degree of rotation (to the anterior)
- Degree of flexion (from deflexed to flexed)
- Amount of moulding (if cephalic)
- Degree of descent into the maternal pelvis

State of the amnion:

- Intact or not
- Degree of application to the presenting part of the foetus
- Degree of bulging when under pressure from a contraction

State of mother:

- Any obvious contraction of the maternal pelvis

According to Smyth et al, 2013 **amniotomy** is artificial rupture of membranes, which can be performed during vaginal examination, as a method of induction of labour once cervix is favourable because it has been associated with the release of chemicals and hormones that stimulate contractions. It is a painless procedure and does not require anaesthesia.

Standard induction of labour procedure using Foleys Catheter.

During the process of induction, CTG pre-induction will be done and Foleys catheter size 16F is introduced through outer cervical canal using either digital or speculum method. Once the tip of catheter passed through the internal os, the catheter will be inflated with 60 ml of water and retracted so that the balloon will be rested on cervical os and the external end of the Foleys catheter will be taped without tension to their medial aspect of the women's thigh.

Standard labour room practice in UMMC during admission to labour ward.

The partogram must be started on diagnosis of established labour and relevant findings recorded in a timely fashion. An entry should be made in patient's notes at least every hour by the care staff in additional to partogram and other relevant charting. Continuous monitoring of electronic foetal heart rate status will be monitored at least hourly, maternal temperature will be monitored at least four hourly, bladder catheterisation and urine analysis will be done every four hours.

Standard oxytocin regime.

Oxytocin infusion will be prepared by diluting 10 units of oxytocin in 500ml Hartmann's solution (oxytocin concentration of 20miliunits/ml). It will be titrated every half an hour based on uterine activity starting at 6ml/hours, doubling up, to the maximal rate of 96mls/hour.
The optimal contraction needed are about 3 to 4 moderate to strong contractions in 10 minutes, and when the optimal contraction is obtained, the oxytocin is maintained at the current rate.

Sample size

With two primary outcomes, P value of significant for this study is ≤ 0.025. For maternal satisfaction, assuming we are trying to detect a 1-point difference in the visual numerical rating scale and that the SD score is 2, power 80%, one to one randomization ratio, Delta 1 and using Student T-test the number of each arm is 77, and by applying the Mann Whitney U test in a non-normally distributed data, another 15% is added to achieve level of significance: total number of each arm is 91. Also assuming there will be a 10% dropout, the sample size needed for each arm will be 101 patients, making total sample size of 202.

We also made literature review on membrane rupture to delivery interval. Tan et al (2013) through retrospective randomised controlled trial of immediate compared with delayed oxytocin after amniotomy labour induction in parous women reported that the immediate oxytocin arm had a shorter amniotomy-to-delivery interval of 5.3±3.1 compared with 6.9±2.9 hours (P<.001).
There are few others study that report amniotomy to delivery interval in multiparous women[15][16][17]

Using the above data, we expect CI 98%, power 80% with ratio 1 to 1, mean 5.3 with SD 3.1 and mean 6.9 with SD 2.9, by using open Epi-Software and PS Software, the number come out as single digit, thus sample size for maternal satisfaction is use for this study.

Data Analysis

Data will be entered into SPSS statistical software. Normally distributed continuous data will be analysed with paired Student's 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. During this trial, an interim analysis will be conducted.

RESEARCH DATA

Where will the data be kept? (Please provide details)
Patient data will be collected as per case report form and will be kept in a secured, locked cupboard, where only the investigators will have the key to.

Who will have access to the research data?
Access to data will be granted to investigators and representative from Sponsor(s) for monitoring and/or audit purposes only.

How long will the data be kept?
The data will be kept at least 7years

BUDGET / FINANCIAL SUPPORT (NON APPLICABLE):

No	Budget Detail	Amount (RM)
1.		
2.		
3.		
	Grand Total	

GANTT CHART

	2021				2022		
	Jan - Feb	Feb - March	April - Sept	Oct - April	April - May	June - July	August
Research proposal and preparation	■						
Presentation to department		■					
Presentation to ethics committee and approval			■				
Patient recruitment and data collection				■			
Data entry					■		
Data analysis						■	
Thesis writing							■
Thesis submission							

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POTENTIAL IMPACT

This study is important as to our best knowledge there is lack of data within a clinical trial in context of vaginal examination interval on maternal satisfaction and duration of labour post amniotomy in nulliparous women. Furthermore it will change our standard practice.

4. 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): AISHAH BINTI MOHD

Signature of Researcher: ……

Date: ……..

(PLEASE ATTACH THE INTERVIEW GUIDE, QUESTIONNAIRE, DATA COLLECTING SHEET, ANY RELEVANT DOCUMENT AS APPENDICES, IF NECESSARY.)

APPENDIX 1 : CTG interpretation (NICE GUIDELINE)

Description	Feature		
	Baseline (beats/ minute)	**Baseline variability (beats/ minute)**	**Decelerations**
Reassuring	110 to 160	5 to 25	None or early Variable decelerations with no concerning characteristics* for less than 90 minutes
Non-reassuring	100 to 109† OR 161 to 180	Less than 5 for 30 to 50 minutes OR More than 25 for 15 to 25 minutes	Variable decelerations with no concerning characteristics* for 90 minutes or more OR Variable decelerations with any concerning characteristics* in up to 50% of contractions for 30 minutes or more OR Variable decelerations with any concerning characteristics* in over 50% of contractions for less than 30 minutes OR Late decelerations in over 50% of contractions for less than 30 minutes, with no maternal or fetal clinical risk factors such as vaginal bleeding or significant meconium
Abnormal	Below 100 OR Above 180	Less than 5 for more than 50 minutes OR More than 25 for more than 25 minutes OR Sinusoidal	Variable decelerations with any concerning characteristics* in over 50% of contractions for 30 minutes (or less if any maternal or fetal clinical risk factors [see above]) OR Late decelerations for 30 minutes (or less if any maternal or fetal clinical risk factors) OR Acute bradycardia, or a single prolonged deceleration lasting 3 minutes or more

Abbreviation: CTG, cardiotocography.

* Regard the following as concerning characteristics of variable decelerations: lasting more than 60 seconds; reduced baseline variability within the deceleration; failure to return to baseline; biphasic (W) shape; no shouldering.

† Although a baseline fetal heart rate between 100 and 109 beats/minute is a non-reassuring feature, continue usual care if there is normal baseline variability and no variable or late decelerations.

Table 2 Management based on interpretation of cardiotocograph traces

Category	Definition	Management
Normal	All features are reassuring	• Continue CTG (unless it was started because of concerns arising from intermittent auscultation and there are no ongoing risk factors; see recommendation 1.10.8) and usual care • Talk to the woman and her birth companion(s) about what is happening
Suspicious	1 non-reassuring feature AND 2 reassuring features	• Correct any underlying causes, such as hypotension or uterine hyperstimulation • Perform a full set of maternal observations • Start 1 or more conservative measures* • Inform an obstetrician **or** a senior midwife • Document a plan for reviewing the whole clinical picture and the CTG findings • Talk to the woman and her birth companion(s) about what is happening and take her preferences into account
Pathological	1 abnormal feature OR 2 non-reassuring features	• Obtain a review by an obstetrician **and** a senior midwife • Exclude acute events (for example, cord prolapse, suspected placental abruption or suspected uterine rupture) • Correct any underlying causes, such as hypotension or uterine hyperstimulation • Start 1 or more conservative measures* • Talk to the woman and her birth companion(s) about what is happening and take her preferences into account • If the cardiotocograph trace is still pathological after implementing conservative measures: – obtain a further review by an obstetrician **and** a senior midwife – offer digital fetal scalp stimulation (see recommendation 1.10.38) and document the outcome • If the cardiotocograph trace is still pathological after fetal scalp stimulation: – consider fetal blood sampling – consider expediting the birth – take the woman's preferences into account

APPENDIX 2

ELIGIBILITY SCREENING AND RECRUITMENT FORM
STUDY TITLE: 4 HOURLY VERSUS 8 HOURLY VAGINAL EXAMINATON IN MULTIPAROUS WOMEN

Patient's Sticker

Date: _____/_____/_____
EDD _____/_____/_____ (_____ POA/POG)

Inclusion criteria

- ☐ a) Multiparous women
- ☐ b) Aged ≥18 years
- ☐ c) Gestational age of > 37 weeks at enrolment of scheduled induction of labour
- ☐ d) Viable pregnancy
- ☐ e) Cephalic presentation
- ☐ f) Singleton pregnancy
- ☐ g) Favourable cervix, (cervical os ≥ 3cm), with no regular contraction
- ☐ h) Post Foleys induction
- ☐ i) Reassuring foetal heart status (CTG)

Exclusion criteria

- ☐ j) Previous uterine incision/ injury (Caesarean delivery, myomectomy, perforation)
- ☐ k) Gross foetal anomaly
- ☐ l) Contraindication for vaginal birth
- m) Estimated foetal weight> 4 kg before induction

Participant preference

☐ 4 hourly ☐ 8 hourly ☐ None

Not Eligible ☐ **Eligible but declined** ☐ **Eligible and consented** ☐

VERSION NO:
VERSION DATE:

CASE REPORT FORM

Study Number

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

Patient's Sticker

Patient characteristics

Age : _____
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 : _____

Foley's inserted :
Date : _____ Time : _____
Foley's removed/dropped
Date : _____ Time : _____

Primary Outcome

1. Time of amniotomy

Date : __ / __ / __ (dd/ mm/ yy)
Time of amniotomy: ___: ___ (hr: min)

2. Time of oxytocin

Date : __ / __ / __ (dd/ mm/ yy)
Time of oxytocin: ___: ___ (hr: min)

3. Time of delivery

Date : __ / __ / __ (dd/ mm/ yy)
Time of delivery: ___: ___ (hr: min)

4. Maternal satisfaction

Please rate your satisfaction on your allotted care during your labour.

0	1	2	3	4	5	6	7	8	9	10

Completely dissatisfied

Completely satisfied

Secondary Outcome

5. Mode of Delivery:
   - ☐ SVD
   - ☐ Caesarean section. Indication: _____
   - ☐ Instrumental delivery: Forceps / Vacuum. Indication: _____

8. Maximum Temperature: Intrapartum _____ ^{0}C Day 1 Postpartum _____ ^{0}C

9. Analgesic use in labour?
   ☐ Yes, please specify: _____ ☐ No

10. Estimated blood loss at delivery: _____ ml

11. Degree of perineal tear

    ☐ 1st degree ☐ 2nd degree ☐ 3rd degree

    Requiring EUA? ☐ Yes, please specify _____ ☐ No

Neonatal Outcome

1. Pathological CTG
   - ☐ Yes _____
   - ☐ No _____

2. Apgar Score: _____ 1 min /_____ 5 mins / _____ 10 mins

3. Arterial Cord pH: _____ Base Excess: _____

4. Birth weight: _____ kg

5. Required neonatal admission:
   - ☐ Yes
   - ☐ No

   Place of admission : SCN / NICU / Others

   Reason for admission: _____