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RESEARCH PROPOSAL FOR MASTER OF MEDICINE

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DEPARTMENT OF OBSTETRICS & GYNAECOLOGY

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COMBINED MASSAGE AND WARM COMPRESS TO THE PERINEUM DURING ACTIVE SECOND STAGE OF LABOUR IN NULLIPARAS : A RANDOMISED TRIAL.

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1. INTRODUCTION

Perineal trauma — either spontaneous or episiotomy-induced can be associated with significant short-term and long-term morbidity such as bleeding, infection, suturing, dyspareunia, urinary and anal incontinence, perineal pain, etc. [1-3] Perineal trauma can be caused by episiotomy, one of the most common obstetric interventions, [4] particularly in nulliparas. It is commonly performed in Asian countries, as it is thought that the perineum is smaller and tighter in Asians thus more succeptible to extended tear. [5] Women who had childbirth with intact perineum reported less pain promptly after delivery, and they could have better intercourse too. [6]

A 2011 Cochrane review showed that the application of warm compresses to the perineum as well as intra-partum perineal massage both decrease obstetric anal sphincter injuries. [7] Canadian Obstetrics & Gynaecology Society recommended perineal massage and warm compress to decrease the rate of obstetric anal sphincter injuries. [8] However, a BMJ trial report concluded that there is “no benefit from massage on rates of intact perineums and trauma, pain, or urinary, faecal, and sexual outcomes at any assessment point.” [9]

A PubMed search up to 1 October 2017, using the search terms, perineal massage, perineal warm compress or perineal warm pack, randomized or randomised trials, retrieved 42 publications. We identified 30 clinical trials and we able to access 24 publications in full text. Out of the 24 publications, 5 trials are on intrapartum warm compress, 13 on intrapartum perineal massage and 6 on antepartum perineal massage. There is no trial that had combined both perineal massage and warm compress during active second stage of labour.

An acceptability survey was done among 20 women from antenatal clinic in University of Malaya Medical Centre who were more than 36 weeks of gestation and planned for vaginal delivery, all were willingly to participate in this study.

2.0 OBJECTIVE OF THE STUDY

# To evaluate the effects of combined perineal massage and warm compresses during active second stage of labour on perineal injury, including episiotomy, or spontaneous perineal tears that require suturing.

3.0 RESEARCH HYPOTHESIS

 3.1 Combined perineal massage and warm compress during active second

 stage of labour will decrease the rate of perineal injury that require suturing.

4.0 PRIMARY OUTCOME

 4.1 Perineal injury (episiotomy or spontaneous perineal tears) at birth that require

 suturing.

1. SECONDARY OUTCOMES

 5.1 Maternal outcomes

5.1.1 Interval from intervention to delivery

 5.1.2 Mode of delivery

 5.1.3 Third- and fourth-degree perineal tears

 5.1.4 Maternal satisfaction with intervention

 5.1.5 Estimated blood loss at delivery

 5.2 Fetal outcomes

 5.2.1 Apgar score at 1 min and 5 min

 5.2.2 Birth weight

 5.2.3 Arterial cord pH

 5.2.4 Neonatal admission and indication

6.0 MATERIALS AND METHODOLOGY

6.1 STUDY DESIGN

Single centre, randomised controlled trial.

6.2 PLACE OF STUDY

Labour Ward, University Malaya Medical Centre, Kuala Lumpur.

6.3 POPULATION OF STUDY

Women presenting in labour (those not in pain, leaking liquor, and with show) to the labour ward of University of Malaya Medical Centre will be assessed for eligibility. Participant information sheet will be given to all potential recruits, the recruiter will answer any queries. Written consent will be obtained from all participants who are eligible to participate.

6.3.1 Inclusion criteria

 6.3.1.1 Presumed labour (including ruptured membrane)

 6.3.1.2 Nulliparous

 6.3.1.3 Age of > 18

 6.3.1.4 Gestational age of > 37 weeks at enrolment

 6.3.1.5 Singleton pregnancy

 6.3.1.6 Planned vaginal birth

 6.3.1.7 Cephalic presentation

 6.3.1.8 Reassuring fetal status

 6.3.1.9 Not distress by pain that may impact decision making

 6.3.2 Exclusion criteria

 6.3.2.1 Has performed antenatal perineal massage

 6.3.2.2 Gross fetal anomaly

 6.3.2.3 Gross perineal scarring (e.g. female genital mutilation)

 6.3.2.4 Caesarean section (post-randomisation

 exclusion)

6.4 METHODS

Posters publicizing the study will be posted in antenatal clinic and labour ward and pamphlets made available to aid the informed consent process. Participants will be assigned by the sequential opening of numbered, sealed, opaque envelopes with randomization numbers outside. These numbered envelopes were prepared by an author not involved in recruitment in random blocks of eight using a computer-generated randomization sequence (performed at <http://www.random.org>). Patients can be recruited once they fulfil the inclusion criteria but the envelope will be kept inside the medical officer’s room. It will be assigned only in second stage of labour and opened once in active second stage of labour. The study group will receive usual care during labour until the patient starts to push, then actual intervention will be started.

Perineal massage will be performed during contractions to minimize contractions. A generous quantity of the KY-jelly will be poured onto fingers and using a gentle, slow massage, with 2 fingers of the gloved hand moving from side to side just inside the patient’s vagina. Mild, downward pressure (towards the rectum) is applied with steady, lateral strokes, which last 1 second in each direction. Pressure will be maintained at an intensity at which the woman did not feel any pain. [10]

Warm compress will be applied between contractions. A sterile towel will be soaked in a metal container ﬁlled with warm water (~50◦C) and queezed before being placed gently on the perineum during each uterine contraction. The temperature should ranged from 38◦C to 44◦C during its application. During contractions, the towel should be re-soaked in the water to maintain warmth then reapplied again. The water in the metal container will be replaced every 15 minutes until delivery or if the temperature dropped below 45◦C. The water temperature will be checked with a thermometer placed into the container. [11]

The control group will receive the routine care during the second stage of labour which presently does not include the application of perineal massage and warm compress.

**STUDY PROTOCOL FLOW CHART**

Identification of term women (> 37 weeks) who presenting to Labour Ward in presumed labour (those not in pain, leaking liquor and show )

Ineligible

Eligible

Approach, Participant information sheet and counselling

Decline to participate

Agree to participate

Exclude :

- not in labour

- do not reach second

 stage with pushing

- caesarean section

Obtain written consent

Reach second stage and ready to push

Standard care

Combined perineal massage and warm compress

Second stage caesarean section Caesarean delivery

Available for analysis outcome measures

Vaginal delivery (including instrumental delivery) Available for analysis outcome measures

**CASE REPORT FORM**

Study Number

Date of recruitment : \_\_ / \_\_ / \_\_ (dd/ mm/ yy)

EDD : \_\_ / \_\_ / \_\_ (dd/ mm/ yy)

Patient’s Sticker

**Patient’s characteristics**

Age : \_\_\_\_\_

Gravida : \_\_\_\_\_ Para : \_\_\_\_\_ Abortion : \_\_\_\_\_\_

Gestational age : \_\_\_\_\_\_\_\_\_\_

Latest recorded weight : \_\_\_\_\_\_\_\_ kg

Height : \_\_\_\_\_\_\_\_\_ cm

BMI : \_\_\_\_\_\_\_\_

Education level :

* Up to primary
* Secondary
* Diploma
* Degree
* Masters
* PhD

Occupation :

* Employed
* Self employed
* Student
* Housewife
* Other : \_\_\_\_\_\_\_\_\_\_\_

Ethnicity :

* Malay
* Chinese
* Indian
* Other : \_\_\_\_\_\_\_\_\_\_\_

When I start pushing, I prefer :

* Perineal massage and warm compress to my perineum
* Standard care wihout perineal massage and warm compress to my perineum

**Primary Outcome**

1. Time of Recruitment :

 Date : \_\_ / \_\_ / \_\_ (dd/ mm/ yy)

 Time : \_\_\_:\_\_\_(hr:min)

1. Time of intervention started :

Date : \_\_ / \_\_ / \_\_ (dd/ mm/ yy)

Time started : \_\_\_:\_\_\_(hr:min)

3. Time of delivery :

 Date : \_\_ / \_\_ / \_\_ (dd/ mm/ yy)

Time : \_\_\_:\_\_\_(hr:min)

4. Mode of delivery :

* SVD
* Instrumental : Vacuum/ Forceps
* Caesarean Section

5. Perineal Outcome :

 (a) Perineal Condition

* Intact
* Episiotomy
* Tear

 (b) Vaginal tear

* Yes
* No

 (c) Labial tear

* Yes
* No

 (d) Perineal tear

* Yes
* No

 (e) Degree of Perineal tear

* First
* Second
* Third
* Fourth

(f) Suturing needed

* Yes
* No

**Maternal Outcome**

1. Patient’s satisfaction score

What is your satisfaction with the care you have received since you started pushing? Circle

the score below :

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |

Completely satisfy

Completely dissatisfy

2. Usage of regional anaesthesia during labour :

* Yes Please specify: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
* No

3. Estimated blood loss at delivery: \_\_\_\_\_\_\_\_\_\_ ml

4. Delivery to discharge interval :

 Date of discharge : \_\_ / \_\_ / \_\_ (dd/ mm/ yy)

**Neonatal Outcome**

1. Apgar Score : \_\_\_\_\_\_ 1 mins / \_\_\_\_\_\_ 5 mins
2. Arterial Cord pH : \_\_\_\_\_\_\_
3. Birth weight : \_\_\_\_\_\_\_\_\_\_ kg
4. Required neonatal admission :
* Yes
* No

Place of admission : SCN / NICU / Others

Reason for admission :

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**STUDY FLOW CHART**

Identification of term women (> 37 weeks) who presenting to Labour Ward in presumed labour (those not in pain, leaking liquor and with show)

Ineligible

Eligible

Approach, Participant information sheet and counselling

Decline to participate

Agree to participate

Obtain informed consent

Exclude :

- not in labour

- do not reach second

 stage with pushing

- caesarean section

Reach second stage and ready to push

Standard care

Combined perineal massage and warm compress

Second stage caesarean section Caesarean delivery

Available for analysis outcome measures

Vaginal delivery (including instrumental delivery) Available for analysis outcome measures

Data collection

Statistical analysis

Thesis submission

6.5 SAMPLE SIZE CALCULATION

We expect 90% (P0 0.9) perineal injuries with standard care vs 70% (P1 0.7) with perineal massage and warm compress, 20% reduction of injuries if these perineal techniques are combined. The sample size is calculated with 1:1 ratio, alpha of 0.05 and power of 80%, N = 124 (each arm, n = 62). Using Chi-square test (10% increase to sample size), we planned to recruit 78 in each arm (N = 156).

A Cochrane review – Belizan 1999 concluded that “The restrictive use of episiotomy shows a lower risk of clinically relevant morbidities including posterior perineal trauma need for suturing perineal trauma (RR 0.74, 95% CI 0.71 to 0.77). [12] In BMJ trial report on primigravid patients refraining from performing episiotomy unless considered to be essential the incidence of episiotomy was reduced to 8% from 89%, retained an intact perineum and 25% sustained only a first degree tear. [13]

A Cochrane review on perineal techniques during second stage of labour for reducing perineal trauma has shown that the use of warm compresses led to RR 0.46 in third- to fourth-degree tears. Women who received perineal massage experience has RR 0.49 third- to fourth-degree perineal tears. [14]

We expect 90% perineal injuries with standard care vs 70% with warm compresses and perineal massage, a 20% reduction of injuries if these perineal techniques are combined.

The sample size is calculated with alpha of 0.05 and power of 80%, N = 124 (each arm, n = 62). Using Student t test (assuming non normal data distribution; 10% increase to sample size, 15% drop outs and rounding up, we planned to recruit 78 in each arm (N = 156).

6.6 STATISTICAL ANALYSIS

Data will be entered into SPSS statistical software. 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.

 6.7 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 informed consent obtained to participate in the study. Patients can withdraw at anytime without having to provide a reason.

**GANNT CHART**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Duration** | **June – July 2017** | **July – Sept 2017** | **Sept – Oct 2017** | **Nov 2016 – April 2017** | **May 2017** | **June 2017** |
| **Literature review** | ✓ |   |   |   |   |   |
| **Proposal preparation****& presentation** | ✓ | ✓ |   |   |   |   |
| **Ethics review** |   |  | ✓ |  ✓ |   |   |
| **Data collection** |   |   |   | ✓ |  ✓ |   |
| **Data analysis and writing** |   |   |   |   | ✓ |  ✓ |
| **Thesis submission** |   |   |   |   |   | ✓ |

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