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# RESEARCH PROPOSAL FOR MASTER OF MEDICINE (OBSTETRICS AND GYNAECOLOGY) DEPARTMENT OF OBSTETRICS & GYNAECOLOGY UNIVERSITY OF MALAYA

## EFFECTIVENESS OF ABDOMINAL BINDING USING KINESIOTAPE ON CAESAREAN SURGICAL SITE INFECTION

BY

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## 1. INTRODUCTION

Latest available data (2010–2018) from 154 countries covering 94.5% of world live births shows that 21.1% of women gave birth by caesarean worldwide, averages ranging from 5% in sub-Saharan Africa to 42.8% in Latin America and the Caribbean[1]. Caesarean delivery related superficial surgical site infection (SSI) rate ranges from 3% to 15% worldwide.[2] SSI after cesarean section is associated with increased maternal morbidity, prolonged hospital stay, and increased medical costs.[3]

Risk factors for wound infections include obesity, hypertensive disorder, premature rupture of membranes, diabetes mellitus, emergency Caesarean delivery and twin delivery: combined obesity and diabetes (gestational and pregestational) increased the risk for wound infection 9.3-fold.[4] Adipose tissue is poorly vascularized and susceptible to tissue hypoxia and ischemia that affects wound healing. Inherent increased tension on fascia in an obese patient and increased incidence of seroma and hematoma formation as a result of dead space between fascia and skin increase the risk of wound failure and dehiscence. The SSI rate is 11% in the obese (BMI ≥30) after abdominal or gynecological operations, compared with a 5% infection the non-obese (BMI 20–29).[5] WHO in 2004 recommended categories of body mass index (BMI) for Asians as: less than 18.5 kg/m2 (underweight); 18.5–23 kg/m2 (normal); 23–27.5 kg/m2 (overweight) and 27.5 kg/m2 or higher (obesity). They identified further potential public health action points (23·0, 27·5, 32·5, and 37·5 kg/$m^2$). It has been re-iterated that Asians have a higher percentage of body fat than Caucasian people of the same age, sex and BMI.[6]

Effective measures against Caesarean-related SSI are prophylactic antibiotics[7], pre-op skin preparation[8] and vaginal cleansing[9]. A 2021 systematic review and meta-analysis of randomized controlled trials (6 trials with 702 women) evaluated abdominal binder in relieving pain after cesarean delivery concludes that VAS pain scores 24 and 48 h after delivery and lower distress scores 24 and 48 h postoperatively were lower compared to the control group.[10] In the obese person, the area around skin fold tends to have excessive sweating, thus increases skin moisture and consequently increases risk for bacterial/fungal invasion, especially within deep skin folds. Immobility, friction, and shear due to the substantial weight stress the skin's barrier function.[11] This can be alleviated by keeping the skin dry and reducing weight stress about the skin folds. We propose kinesiotape abdominal binding to lift up the skin fold and plausibly reducing SSI after Caesarean.

The kinesiotape is made of elastic polymer strand wrapped in cotton fibers (100%). free of latex, with acrylic adhesive capacity, and activated by body heat. Its features exceed the tapes commonly used in bandages, for it allows quick drying, longer time of usage and thinner and more elastic material (stretching / longitudinal stretching of 55-60% in resting position or overall elasticity of 120-140%). Many different indications for the use of kinesiotape have been proposed, such as influencing the muscular tone, supporting joint functions, affecting pain perception, and reducing swelling. Possible mechanism that reduce swelling - the pre-tension of the tape subtly lifts the skin, thereby possibly improving the lymphatic flow and directing it to pathways that suffer less congestion.[12]

The kinesiotape are costed RM 7.00 for 5 meters and the control/sham micropore tape are costed RM 6.00 for 10 meters.

## 2.0 RESEARCH HYPOTHESIS

Abdominal binding will benefit obese women by lifting up the abdominal skin fold at the incision site and disrupting a favourable environment for SSI. The hypothesis is to use kinesiotape as a method for binding the abdomen after Cesarean delivery.

## 3. OBJECTIVES

3.1 The specific objective is to evaluate abdominal binding using kinesiotape against "sham" micropore tape in reducing post Caesarean section SSI.

## 4. PRIMARY OUTCOME

4.1 Specified primary outcome is cumulative SSI rates to day 30 after Caesarean delivery, by clinical assessment up to hospital discharge and further by phone-based questionnaire on day 15 and day 30.

## 5. SECONDARY OUTCOMES

5.1 Patient's satisfaction with abdominal binding at day 15 and day 30

5.2 Pain score on mobilisation at day 1, 15 and 30

## 6.0 MATERIALS AND METHOD

### 6.1 STUDY DESIGN
Single centre randomised controlled trial

### 6.2 PLACE OF STUDY
University Malaya Medical Centre

### 6.3 SAMPLING

Women scheduled for all Caesarean section (planned and unplanned) in UMMC are identified by health care providers in our antenatal or labour ward. Potential participants are assessed using Eligibility Form. Those who fulfilled the eligibility criteria will be provided with the participants' information sheet and have queries encouraged and answered by the recruiter. Written informed consent will be taken from all who agree to participate.

6.3.1 Inclusion criteria

6.3.1.1 Age 18 years and above

6.3.1.2 Scheduled for caesarean section (planned or unplanned)

6.3.1.3 BMI ≥ 27.5 kg/m2

6.3.1.4 Access to telephone

6.3.2 Exclusion criteria

6.3.2.1 Preexisting abdominal skin infection

6.3.2.2 Hypersensitivity to abdominal kinesiotape or micropore

6.3.2.3 Midline skin incision

6.3.2.4 Category 1 (emergent) Caesarean section

## 6.4 METHODOLOGY

The study protocol is distributed to the whole department with poster advertising in the antenatal clinic, antenatal and labour ward to create awareness of the study to women attending UMMC for antenatal care. Patients scheduled for Caesarean section who fulfilled the inclusion and exclusion criteria will be approached for recruitment. Written informed consent will be taken from all participants.

Participants will be randomised in the operating theatre during surgery after closure of the skin by opening the lowest number remaining, sealed and opaque envelope. The envelopes will be kept in a known location within obstetric operation theatres in a box with numbered envelopes arranged in sequence. Opened/unsealed envelopes will be discarded. The random allocation sequence will be generated by an investigator with no clinical involvement in the study. Blinding is not possible due to the nature of the intervention.

After skin closure, the incision site is cleansed, dried and covered with standard dressing or left undressed according to care provider preference. After vaginal cleansing, the abdominal binding will be applied according to randomization.

On day 1 post operative, wound will be exposed (if dressed) and assessed using the Center for Disease Control (USA) [CDC] SSI criteria and in addition, participants will be asked the following :

- Rate satisfaction with their abdominal binding using the 11-point (0-10) visual numerical rating scale (VNRS)
- Pain score on mobilisation using an 11-point VNRS
- Recommend their abdominal binding to a friend undergoing Caesarean delivery using a Likert scale response.

Participants are encouraged to wash their abdomen and shower and afterward to dry their abdomen. If the abdominal binding causes discomfort or is soiled, it can be changed. Additional kinesiotape and micropore are provided for binding changes.

Before discharge, the wound will be assessed using the CDC criteria for diagnosing superficial SSI and participants will again be asked to rate their satisfaction with abdominal binding Participants are to remove abdominal binding tape and stop using abdominal binding on day 3 after Caesarean delivery.

A validated telephone-based questionnaire[13] would be used to assess SSI on days 15 and 30 post-surgery to minimise face to face interactions in Covid 19 pandemic times and to accommodate confinement at hometowns which is expected to make onsite assessment impractical. A study done by E.W Taylor et al published in the Journal of Hospital Infection 2003 on telephone call contact for post-discharge surveillance of surgical site infection had a compliance rate of 93% and patients appeared to welcome the concept of telephone contact.[13]

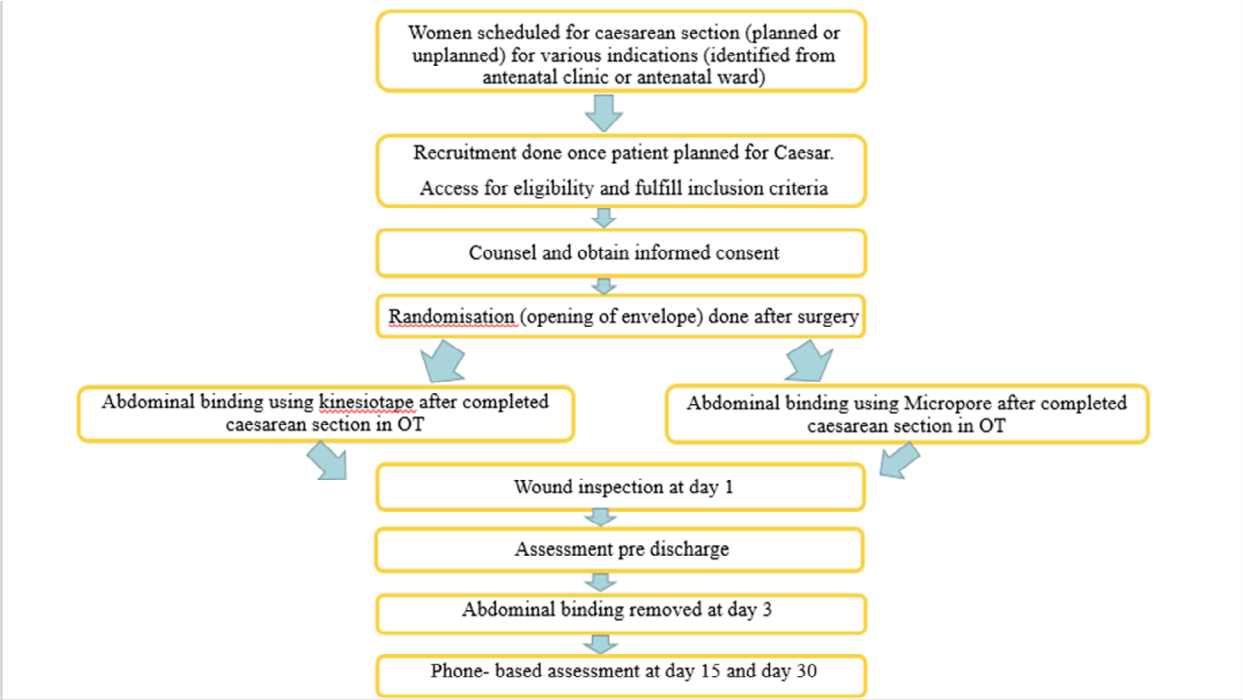
On day 15 and day 30 after delivery, participants will be contacted through phone, and participants will be asked :

- •Questionnaire to evaluate SSI[13]
- •Rate satisfaction with their **abdominal binding (day 15)** and **their wound (day 30)** using 11-point VNRS
- •Pain score on mobilisation using an 11-point VNRS (day 15 and 30)
- • Recommend their abdominal binding to a friend undergoing Caesarean delivery using a Likert scale response (day 15)
- • Use abdominal binder to Day 3 (day 15 only)
- • Continue using the allocated abdominal binder after Day 3 removal (day 15)
- • Continue using the allocated abdominal binder after Day 15 (day 30)

## 6.5 SAMPLE SIZE CALCULATION

From the literature, it was found that the control base rate incidence of Caesarean SSI is 10%. Using openepi.com/SampleSize/SSCohort, taking $\alpha = 0.05$, $\beta = 0.2$ (power 80%), R = 0.1. relative risk of 0.5, 1 to 1 ratio and applying Chi Square test, we will need 435 experimental and 435 control subjects. Hence, we planned to recruit 870 participants.

TRIAL PROTOCOL FLOW CHART




## 6.6 STATISTICAL ANALYSIS

Data will be entered into SPSS statistical software. Normally distributed continuous data will be analyzed with the 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.

## 6.7 ETHICAL CONSIDERATIONS

This study will be submitted to the UMMC Medical Research and Ethic committee, the local institutional review board for approval. Good Clinical Practice will be applied for this trial. All the participants in this study will be reassured about data confidentiality. Informed consent is compulsory, and potential participants will be given information sheets. This trial is designed as a randomised controlled trial. There is no conflict of interest of investigators in this study to report. The study will not be funded by entities with commercial interests related to trial products

**GANNT Chart**

| Duration | June-July 2021 | August-September 2021 | November 2021 | Jan 2022-Jan 2023 | Jan-Feb 2023 | Feb-March 2023 |
|---|---|---|---|---|---|---|
| Literature Review | ✓ | | | | | |
| Proposal preparation and presentation | | ✓ | | | | |
| Ethics Review | | | ✓ | | | |
| Data Collection | | | | ✓ | | |
| Data analysis and writing | | | | | ✓ | |
| Thesis Submission | | | | | | ✓ |

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