



Kinesio Taping for Labor Pain Control: A Randomized Controlled Trial

Thesis

*Submitted for Partial Fulfillment of Master Degree
in Obstetric and Gynecology*

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MBBCH (2013)

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2020*

بِسْمِ اللَّهِ الرَّحْمَنِ الرَّحِيمِ

قالوا

سببناك لا علم لنا
إلا ما علمتنا إنك أنت
العليم العظيم

صدق الله العظيم

سورة البقرة الآية: ٣٢

Acknowledgment

*First and foremost, I feel always indebted to **ALLAH**,
the Most Kind and Most Merciful.*

*I'd like to express my respectful thanks and profound gratitude to **Prof. Dr. Ahmed Hamdy Maguib**, Professor of Obstetrics and Gynecology Faculty of Medicine – Ain Shams University for his keen guidance, kind supervision, valuable advice and continuous encouragement, which made possible the completion of this work.*

*I am also delighted to express my deepest gratitude and thanks to **Dr. Ahmed Mohammed Rateb**, Assistant Professor of Obstetrics and Gynecology Faculty of Medicine – Ain Shams University, for his kind care, continuous supervision, valuable instructions, constant help and great assistance throughout this work.*

*I am deeply thankful to **Dr. Marwan Osama Elkady**, Lecturer of Obstetrics and Gynecology Faculty of Medicine – Ain Shams University, for his great help, active participation and guidance.*

Maissa Ahmed

**PROTOCOL OF A THESIS FOR PARTIAL
FULFILMENT OF MASTER DEGREE IN
OBSTETRIC AND GYNECOLOGY**

**Title of the protocol: Kinesio taping for labor
pain control: A Randomized Controlled Trial.**

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**What is already known on this subject? AND
What does this study add?(Maximum 6 lines)“References
are not needed”**

Numerous studies and systematic reviews suggest the use of no pharmacologic approaches to pain management either as a primary method, or as a complement to pharmacologic approaches.

Although Kinesio Taping was found to improve dysfunction and pain, scientific evidences are scarce, and few studies evaluating its use for pain relief during labor exists. Therefore, in this study, Kinesio tape will be investigated as an adjuvant, no pharmacological, non-invasive, and easy-to-apply technique.

1. INTRODUCTION/REVIEW

One aspect of childbirth is the association of this physiologic process with pain and discomfort. Having a fear of pain leads to increase in catecholamine release; adrenaline promotes vasoconstriction and stops oxytocin production decreasing effective uterine contractions and placental blood flow, which can lead to exhaustion, dystocia, fetal suffering, and postpartum post-traumatic stress disorder Leading also to negative birth experiences (**Perla, 2002; Bryanton et al., 2008; Lally et al., 2008; Miquelutti et al., 2013**).

Many studies tested drug interventions during labor such us Inhaled nitrous oxide and oxygen (Entonox®), Non-opioid drugs (e.g. sedatives), epidurals and combined spinal-epidurals. Local anesthetic nerve blocks and Parenteral opioids (pethidine and related drugs),although being effective pharmacological pain relief has many side effects varying from

drowsiness with nitrous oxide to increased forceps or ventouse use, low blood pressure, fever and urine retention with epidurals.

Consequently there is a growing interest in simple, non-invasive, and low-cost techniques for pain control, especially at sites with limited resources (**Chaillet et al. 2014**)

Among alternative techniques for pain control during labor; massage, hot and cold compresses, baths (**Chaillet et al., 2014**), sterile water injections (**Derry et al., 2012**), hypnosis, acupuncture, acupressure, relaxation, and yoga have been shown to be helpful for pain management and patient satisfaction (**Smith et al., 2006; Smith et al., 2011; Smith et al., 2012; Miquelutti et al., 2013**). A meta-analysis conducted by **Chaillet et al. (2014)** found an association between the use of non-pharmacological pain strategies with less epidural analgesia, and better experience of childbirth). Among these techniques Kinesio Tape which was developed by Kenzo Kase, a Japanese chiropractor, in 1970. It is manufactured pre-stretched by 15-25%. It mimics the physical qualities of the skin with same thickness as the epidermis and can be stretched between 30% and 40% of its resting length longitudinally and following application, recoils back towards its unstretched length (**Kase et al., 2003**). Kinesio taping implementation has not been well studied during labor therefore in this study we will assess its effectiveness in reducing labor pain.

2. AIM/OBJECTIVES

Study hypothesis:

In women in active phase of labor, Kinesio tape may relief pain during labor.

Aim:

The purpose of this study is to assess the efficacy of Kinesio tape on relief of pain associated with labor.

Outcome:

Primary Outcome: pain sensation during labor.

Secondary Outcome: mode of delivery, length of active phase, rate of uterotonics, and maternal satisfaction with birth experience and Kinesio bandage usage.

3. METHODOLOGY

- **Type of Study:** A randomized controlled and single-blind trial.
- **Study Setting:** Ain Shams University Maternity Hospital.
- **Study Population:** Women presenting to labor ward should fulfill the following criteria:

Inclusion Criteria:

Inclusion criteria comprises low-risk Primegravida women with a spontaneous onset of labor, single fetus in cephalic presentation and good health, gestational age between 37 and 42 weeks, cervical dilation between 3 and 5 cm, and a minimum of two uterine contractions at 10-min intervals

Exclusion Criteria:

Women with pre-eclampsia, diabetes mellitus, cardiopathy, hypertension, nephropathy, epilepsy, psychiatric dysfunction, drug use, uterine scarring, elective Cesarean

section, dermatitis or skin infection at the site of bandage application, allergies related to Kinesio tape, fetal death or malformation will also be excluded.

Sampling Method:

Convenient sample

Sample Size:

Using G* power 3.0.10, Setting alpha at 5% and power at 80%. Assuming an effect size of 0, 6 (medium effect size) of the Kinesio tape on pain Visual Analogue Scale score, the needed sample will be 50 cases per group (total 100).

Ethical Consideration:

The procedures described in this study protocol would gain approval by the Research Ethics Committee to ensure following the standard ethical principles governing research involving human subjects.

Before being admitted to the clinical study, the subject must be consented to participate after the nature, scope and possible consequences of the clinical study have been explained in a manner understandable to her.

Confidentiality:

Only the patient numbers and patient initials will be recorded in the case report form and if the patient name appears on any other document (e.g., reservation note or pathology report) it must be kept in privacy by the investigators.

Protocol approval:

Before beginning of the trial and in accordance with the local regulation followed, the protocol and all related documents will be declared for ethical and research approval by the Council of Obstetrics and Gynecology Department.

Study procedures:

This study will be conducted on 100 normal full-term Primegravida women presenting in the first stage of labor with regular painful, palpable uterine contraction, and cervical dilatation between 3 and 5 cm. They will be randomly assigned into two equal groups, group A and group B. Group A (the study group) consisted of 50 women, and group B (the control group) consisted of 50 women.

Randomization:

The randomization process was done using Excel (Microsoft, Redmond, WA,USA) to create a random number list. Information regarding group classification will be kept inside an opaque, sealed envelope that was sequentially numbered.

Randomization table:

1	A	26	A		51	A	76	B
2	A	27	A		52	B	77	A
3	B	28	B		53	A	78	B
4	A	29	A		54	A	79	A
5	B	30	B		55	B	80	B
6	B	31	A		56	B	81	B
7	A	32	B		57	A	82	B
8	B	33	A		58	B	83	A
9	A	34	A		59	B	84	B
10	B	35	A		60	B	85	A
11	B	36	B		61	A	86	A
12	B	37	B		62	A	87	B
13	A	38	A		63	A	88	A
14	A	39	B		64	B	89	B
15	B	40	A		65	A	90	B
16	A	41	B		66	B	91	A
17	B	42	B		67	B	92	A
18	B	43	A		68	A	93	B
19	A	44	A		69	B	94	A
20	B	45	B		70	A	95	B
21	A	46	A		71	A	96	A
22	A	47	B		72	B	97	B
23	A	48	A		73	B	98	A
24	B	49	B		74	A	99	B
25	B	50	B		75	A	100	A

A:cases group**B:control group**

Assessment procedures:

Prior to data collection, the purposes and procedures will be fully explained to each participant. Each participant will be evaluated and treated individually following, standard protocol. If the participant meets the inclusion criteria, she will be enrolled in the study.

Initial assessment:

Each participant will pass through the following steps of evaluation (at first and second stages of normal labor).

1-Visual analogue scale:

Pain will be assessed by the visual analogue scale. It is 10 cm horizontal line with one end described as (no pain=0) and other end (worst pain=10). Visual analog scale was considered a valid way of assessing pain, it allows graphic representation and numerical analysis of collected data.

2-Present Pain Intensity(PPI):

Is a portion of the McGill questionnaire (**Menezes Costa et al,2011**),the Present Pain Intensity scale is a measure of the magnitude of pain experienced by an individual, is a numeric-verbal combination that indicates overall pain intensity and includes 6 levels: none (0), mild (1), discomforting (2), distressing (3), horrible (4), and excruciating (5).

3-Cardiotocography(CTG):

For recording the fetal heartbeat and the uterine contractions during normal labor.

Treatment Procedures: Kinesio Taping**Participants in group (A):**

The participants in group (A) will receive the kinesio taping at lumbosacral region. The kinesio taping is comprised of a ureter polymer elastic strand wrapped by 100% cotton fibers. The cotton fibers allow for evaporation of the body moisture and following

application of water allows for quick drying. There is no latex in the tape. The adhesive is 100% acrylic and is heat activated. The skin should be free of oils and lotions and cleaned prior to the application. Anything that limits the acrylic adhesive ability to adhere to the skin will limit both effectiveness and length of application.

Taping procedures will be H technique application, application of bilateral kinesio strip with space correction for bilateral erector spine muscle. The participant will be placed in supine position and the base of kinesio H strip will be applied at T11 and T12 to S1 and S2. The third strip will a space correction technique. 20-25% tension in applied in the vertical tape and 100% tension in the horizontal tape. This zone of tension is placed directly over the region of greatest pain.

Participants in group (B): Control group

A single, vertical “I” strip will be applied on the thoracic region – from T1 to T4. This location was chosen arbitrarily, as it is out of the uterine dermatome region.

Statistical Analysis:

Analyses will be performed using the intention-to-treat approach. Data will be expressed by means and standard deviation, or median, and frequencies. To test the differences between the groups, the Mann–Whitney U-test and Student’s t-test will be used for continuous variables, and the χ^2 -test and Fisher’s exact test will be used for categorical variables. For categorical-dependent variables, risk ratios (RR) will be calculated, together with their respective 95% confidence intervals (95% CI). For numerical-dependent variables, mean differences and their respective 95% CI will be also estimated. Significance will be established at $P < 0.05$. The randomization process regarding the groups and the follow up of the participants in accordance with the flowchart, as suggested by the Consolidated Standards of Reporting Trials CONSORT.

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