Mediolateral VS Lateral Episiotomies in Primparus Patient; A randomized Controlled Trial

Thesis

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By

Soad Atef Mohamed Abo El-fetouh

M.B., B.CH, 2011

(Misr University for science and Technology) El Waraak central hospital

Under supervision of

Prof. Dr. Fekria Mohammed Salama

Professor of Obstetrics and Gynecology Faculty of Medicine, Ain Shams University

Dr. Walid EL Basuony Mohammed

Lecturer of Obstetrics and Gynecology Faculty of Medicine, Ain Shams University

Faculty of Medicine
Ain Shams University
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List of Abbreviations

BMI	Body mass index
СВС	Complete blood count
GA	Gestational age
HS	Highly significant
HVAS	Horizontal visual analogue score
IUGR	Intrauterine growth retardation
LE	Lateral episiotomy
MLE	Mediolateral episiotomy
NSAIDs	Nonsteroidal anti-inflammatory drugs
NRS	Numerical rating scale
NS	Non-significant
OASIS	Obstetrical anal sphincter injuries
S	significant
SD	Standard deviation
VAS	Visual analogue score
VRS	Verbal rating score
VVAS	Vertical visual analogue score

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Introduction

Episiotomy is the enlargement of the vaginal orifice by an incision in the perineum during the second stage of labor, it is primarily performed to facilitate delivery in cases of fetal distress, instrumental delivery, or thick inelastic perineum (Jaroslava Karbanova et al., 2013).

An exact definition of the type of episiotomy regarding the location of its beginning, and the direction and length of incision is essential for an exact comparison of results from various studies (*Kalis et al.*, 2012).

Seven different types of episiotomy have been defined (Kalis et al., 2012).

Mediolateral episiotomy (MLE) and lateral episiotomy (LE) are used routinely, and only midline episiotomy and MLE are frequently evaluated (Sooklim et al., 2007; Räisänen et al 2009).

Mediolateral episiotomy was defined as an incision beginning in the midline at the posterior fourchette and directed at an angle of at least 60°

toward the Ischial tuberosity (Kalis et al., 2008; Karbanova et al., 2009; Kalis et al., 2012).

Lateral episiotomy was defined as an incision beginning 1–2 cm laterally from the midline and directed toward the ischial theosity (*Kalis et al.*, 2012).

The studies comparing the 2 types of episiotomies are rarely mentioned in obstetric literature, despite their relatively frequent use.

Aim of study

This study aims to compare between mediolateral and lateral episiotomies in primparaous patients as regards the duration of repair of the wound.

Study hypothesis:

In primparaous women in labor mediolateral episiotomies may be similar to lateral episiotomies in duration of repair.

Study Question:

In primparaous women in labor does mediolateral episiotomies similar to lateral episiotomies in duration of repair?

Patients and Methods

Setting and Duration:

The study will be carried on in Ain Shams Maternity University Hospital from November 2016 until April 2017.

Sample Size:

Three hundred thirty-four women will be included in this study. They will be distributed to two equal groups randomly (*Machin et al.*, 1997).

Sample size justification:

Group sample sizes of 167 and 167 achieve 80% power to detect a difference of -2.0 between th null hypothesis that both group means are 12.0 and the alternative hypothesis that the mean o group 2 is 14.0 with known group standard deviations of 6.0 and 7.0 and with a significance level (alpha) of 0.05000 using a two-sided Mann-Whitney test assuming that the actual distribution is uniform.

According to the study done by *Jaroslava et al.* (2013) where they found that the duration of the

repair of the wound signefically shorter in mediolateral episiotomies. The duration of episiotomy repair was significantly shorter in the mediolateral group (12 vs 14 min).

The sample size calculation based on the following:

- * Power of study=80%*
- *Alpha error=0.05*
- *Beta error=0.199*
- * Estimated required sample size equal 334 patients (167 patients for each group).
- * Program for sample size calculation is PASS 11.0.I (*Machin et al., 1997*).

Type of Patients:

The cases that will be included in our study will be gathered from the delivery room of Ain Shams University Hospital Obstetrics and gynecology department, who fulfill the following criteria.

The inclusion criteria:

- 1-Primparaous patients.
- 2- In the second stage of labor.

- 3-Vertix presentation.
- 4- Maternal Age between 20 and 30 years.
- 5-Gestational age of 37 completed weeks or more.
- 5- Singleton Pregnancy.
- 6-Consenting participation.

The Exclusion criteria:

- 1- History of previous perineal surgery.
- 2- Stillbirth or delivery of a newborn with extensive congenital abnormalities.
- 3- Multiple Pregnancy.
- 4- IUGR fetuses or Macrosomic Fetuses.
- 5- The need of instrumental delivery.
- 6- Severe perineal condylomata or extensive varicose veins

Steps of Procedure:

This is prospective randomized study carried out among primparous women who delivered at 37 weeks or more.

The patients will be counselled to participate in this study during the first stage of labor and an informed written consent will be taken.

- * Personal History will be recorded; also a Family and Past History will be taken.
- * Investigations as (complete blood count, blood group &RH and random blood sugar will be done.
- * All the information will be recorded in the patient's file with accurate time and date.
- * During the Active Phase of Labor Vaginal examination will be done (on admission and every 4hrs to assess the progress of labor by the partogram).
- * Partogram showing cervical dilation versus time include an alert line. It starts at the position where there is 3 or 4cm of cervical dilation. It is then continued diagonally at a rate of 1 cm per hour in primparaous and 1.5 cm in multiparous. An action line is parallel to the alert line, and is located 4 hours to the right of the alert line.
- *Monitor of labor (maternal and fetal)
 - 1- Clinical (partogram).