# Role of Pre-emptive Local Lidocaine 2% Infiltration in Postoperative Pain Management in Cesarean Delivery Performed under Spinal Anesthesia (Randomized Clinical Trial)

**Thesis**

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*Samaa AbdElBary AboSrea' Ahmed*

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# List of Abbreviations

**(ACOG):** American College of Obstetrics and Gynecology

**(ALTENS):** Acupuncture-like transcutaneous electrical stimulation

**(AMPA):** 2-amino-3-hydroxy-5-methyl-4-isoxazole-propionic acid

**(ASUMH):** Ain Shams University Maternity Hospital

**(BMI):** The Body Mass Index

**(CDMR):** Caesarean delivery on maternal request

**(CNS):** Central nervous system

**(COX-2):** Cyclooxygenase

**(CS):** Caesarean Section

**(CTG):** Cardiotocography

**(EFM):** Electronic fetal monitoring

**(IASP):** International Association for the Study of Pain

**(ICU):** Intensive Care Unit

**(N):** Number of cases

**(NICE):** National Institute for Health and Clinical Excellence

**(NMDA):** N-methyl-D-aspartate

**(NS):** Nociceptive-specific

**(NSAIDs):** Non-steroidal anti-inflammatory drugs

**(PCA):** Patient Controlled Analgesia

**(PENS):** Percutaneous electrical nerve stimulation

**(RCOG):** Royal College of Obstetrics and Gynecology

**(SD):** Standard Deviation

**(SPSS):** Statistical Package for the Social Science

**(TAP):** Transversus abdominis plane

**(TENS):** Transcutaneous electrical nerve stimulation

**(TNS):** Transcutaneous nerve stimulation

**(VAS):** Visual Analogue Scale

**(VBAC):** Vaginal birth after caesarean

**(WDR):** Wide-dynamic-range

**(WHO):** World Health Organization

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## Introduction

Cesarean section is the most common major surgery which is performed for women in the United States currently, and it is estimated that more than 1.3 million cesareans performed annually. Postoperative pain relief is an important consideration issue as in clinic. Although different methods have been described for proper pain relief, it is not sufficient and satisfactory in some patients ***(Cunningham FG et al., 2010; Ronald D et al.).***

Childbirth is an emotional experience for a woman and her family. The mother needs to bond with the new baby as early as possible and initiate early breastfeeding, which helps to contract the uterus and accelerates the process of uterine involution in the postpartum period. Any form of intervention that leads to improvement in pain relief can positively impaction early breastfeeding. Prompt and adequate postoperative pain relief is therefore an important component of caesarean delivery that can make the period immediately after the operation less uncomfortable and more emotionally gratifying ***(Novy MJ. et al., 1991)***.

Due to several aspects such as maternal and neonatal wellbeing, postoperative pain relief in cesarean delivery is crucial. Providing a proper and efficient pain management is necessary during hospitalization which prevents cesarean section related complications which could affect

breastfeeding and mother and neonate health status ***(Ritter J et al., 2008).***

Any intervention that leads to improvement in pain relief is worthy of investigation. Local anesthetics have been employed as an adjunct to other methods of postoperative pain relief, but reports on the effectiveness of this strategy are conflicting ***(Anthony Akinloye Bamigboye et al., 2010).***

Several studies have been conducted to evaluate the efficacy of different post-partum pain management protocols for cesarean section ***(Gibbs R. et al., 2003).***

On the other hand, pain control method depends on individual variability, such as age, genetic and psychological factors and also sensitivity to pain. These methods might vary in different region and center regard to their facilities ***(Ronald D et al.; Ritter J et al., 2008).***

Local analgesics usage during surgery has fewer side effects in compare with opioids or neuro-axial method ***(Cunningham FG et al. 2010).***

# Aim of the Work

This study aims to assess the efficacy of pre-emptive infiltration of Lidocaine 2%in improving pain feeling during post operative period.

## Research question:

In women undergoing elective cesarean section, does pre-emptive Lidocaine 2% infiltration improve pain feeling during post operative period?

## Research hypothesis:

In women undergoing elective cesarean section, pre-emptive anesthesia with lidocaine 2% infiltration may improve pain feeling during post operative period.

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# Study design

Prospective randomized clinical trial.

## Recruitment and Eligibility:

After ethics committee approval, one hundred twenty eight consecutive patients will be randomly assigned to one of the two equal groups of the study.

Surgeons and nurses who will evaluate pain will be blinded about the injected solution.

- **Site**: participants are chosen from Ain Shams University Maternity Hospital (ASUMH), Cairo, Egypt, who are planned for planned cesarean section.
- **Selection**

a) **Inclusion criteria :**

Of the subject population under study:

The sample of population under study will be selected according to:

1. Women with previous one cesarean section or more.
2. The Body Mass Index (BMI): between (18.5 – 29.9).
3. Minimum education level: Completed high school education to be able to understand and sign the consent and to cooperate in pain assessment.

**b) Exclusion criteria:**

1. Patients with co morbidity.

2. Contraindication for spinal anesthesia.
3. Contraindication for local anesthetic use as allergy to the anesthetic.
4. Patients with heart block.
5. Contraindications for lower segment cesarean section.
6. Patients in Intensive Care Unit (ICU).
7. Ventilated patients.

## Randomization:

After identifying the patient fulfilling the criteria of the study participants will be randomized into two equal groups using computer generated random numbers.

## Allocation and Concealment:

Women undergoing elective cesarean section will randomly be allocated to one of the two equal groups of the study.

Allocation will be done using a computer generated numbers that will be kept secure in concealed envelopes.

Each woman will drag an envelope that contains her unique number that will assign her to one the two groups of the trial.

## Cesarean Section:

Procedures will be done as Cesarean section technique that will be:

- Performed by senior registrars of the same level.
- The surgery technique and postoperative protocol were same.
- Cesarean section will be performed with transverse lower segment incision.
- Anesthesia method will be spinal in all cases.
- Pain will be assessed using Visual Analogue Scale for Pain.
- Visual Analog Scale for Pain was described for all patients before operation and they were asked to estimate their post operative pain between zero and 10. VAS was recorded for 12 hours after surgery as below: every one hour in the first 4 hour after surgery, and every 4 hour for the rest of the time. If the patient complained from pain, a 75 mg diclofenac injection will be administered and time was recorded ***(Mandana Mansour Ghenaee et al., 2015).***

## Intervention:

Patients of both groups who are planned for cesarean section done by obstetrics and gynecology surgeons who will perform the pre-emptive infiltration of Lidocaine 2% to the patient in the anterior abdominal wall.

**Group A**: will include 64 women planned for elective cesarean section who will undergo pre-emptive local infiltration by 4mg/kg of lidocaine 2% to the subcutaneous layer of the anterior abdominal wall.

**Group B:** will include 64 patients will receive local infiltration of 4mg/kg of normal saline, and then this will be pre-emptively injected in the subcutaneous layer of the anterior abdominal wall.

## Data collection:

a) Outcome of pre-emptive lidocaine 2% infiltration in anterior abdominal wall layers in cesarean section incision will be done mainly to evaluate the ability of lidocaine 2% local injection to relieve postoperative pain in cesarean delivery and reduce use of analgesics.

b) Data or results will be collected after arrangement in a suitable manner by a process known as processing of data which may be manual or computerized.

c) These data should be confidentially protected.

## Blinding

- Care givers and participants are blind to trial arms.
- Outcome assessors are blinded to trial arms.

## Ethical issues:

a) The hospital ethics committee will approve the study.

b) Consent process:

The population sample under study will be instructed about research protocol and informed consents are granted from each participant before randomization.

## Outcome measures:

- (Follow up & outcome measures):

After presentation of data two end points will appear showing either primary or secondary outcome variables.

**A) Primary outcome measures:**

The primary outcome measures are the:

1. Postoperative pain assessment after cesarean section estimated by Visual Analogue Scale (VAS) at (1, 2, 3, 4, 8 and 12) hours after cesarean section.

2. First analgesic request.

3. Dosage of analgesic consumption in twelve hours duration.

**B) Secondary outcome measures:**

1. The duration needed for removing urinary catheters and walking after surgery.
2. The development of adverse event or side effect in patients.
3. Initiation of breast feeding.