Intracervical 2% Lidocaine Gel to Reduce IUCD Insertional Pain: A Randomized Controlled Trial

Thesis

Submitted for Partial Fulfillment of Master Degree in Obstetrics and Gynecology

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Abstract

Regarding pain felt uterine sound insertion (measured by VAS), the median in group A was 3 and the interquartile range was from 1 to 5. In group B the median was 3 and the interquartile range was from 2 to 5. on comparing the 2 groups, the p value was 0.720 which was statistically insignificant.

Regarding pain felt after IUCD insertion (measured by VAS), the median in group A was 2 and the interquartile range was from 1 to 4. In group B the median was 3 and the interquartile range was from 1 to 5. on comparing the 2 groups, the p value was 0.546 which was statistically insignificant.

Results proved that lidocaine 2% gel application to the cervix during IUCD insertion doesn't seem to reduce pain felt during this process.

Keywords: Case Record Form- Hystrosalpingography - Intrauterine contraceptive device - Probability value

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Protocol of a Thesis

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Introduction

Copper IUD is a long term and reversible contraception which equals tubal ligation in terms of sterilization ***(Berek et al., 2007).*** One of the barriers to using this contraception method is the fear and the pain associated with its insertion ***(Murty, 2003).***

The mucosal lining of female genitalia is extremely sensitive to pain and most small procedures in that area are performed without analgesia ***(Rodney et al., 1992; De LacoMarabini et al., 2000).***

Studies show that about half of the people suffer average to severe IUD insertion pain ***(Mohammad-Alizadeh-Charandabi et al., 2010).*** This feeling varies from a little pain and discomfort to severe cramps with nausea and malaise ***(Murty, 2003).*** Since nerve endings are more abundant in cervix particularly internal os than in the body of uterus ***(Kozman et al., 2001).***

IUD insertion causes pain in many different ways including: using tenaculum to hold cervix, using tenaculum to straighten uterus axis, inserting the catheter and IUD insertion tube, and finally inserting IUD. The factors that can aggravate the pain of IUD insertion include nulliparity, age over 30, long interval with pregnancy or last menstrual, and absence of breast feeding ***(Hubacher et al., 2006).***

If the pain is not relieved, it can increase the risk of vasovagal shock and cardiac arrhythmias ***(Tolcher, 2003; Berek et al., 2007).***

Studies show that common medication such as uterine cramp reducing medication (Non-steroidal anti-inflammatory drugs), cervix ripening medications (Misoprostol) and local anesthetics (lidocaine gel) are not effective in reducing IUD insertion pain ***(Hubacher et al., 2006, Saav et al., 2007, Allen et al., 2009, Mohammad- Alizadeh- Charandabi et al., 2010).***

Alizadeh et al. studied the effect of lidocaine gel on IUD insertion pain in Tabriz in 2011 and found no significant difference between the lidocaine gel group and placebo group in terms of IUD insertion pain. The reasons behind this finding can be use of little amount of anesthetic (1 ml), little time of application of the gel on the cervix before procedure (1 min) and lack of variety of anesthetics ***(De Laco et al., 2000).***

Lidocaine gel is routinely used in the distal urethra prior to Foley catheter placement, as well as in the nasal canal prior to nasogastric or nasotracheal tube placement. In each of these cases lidocaine gel has been shown to decrease pain scores associated with insertion ***(Siderias et al., 2004; Gross et al., 1984; Singer et al., 1999).***

The endocervical canal is lined with columnar epithelium as is the nasal canal. The ecto-cervix and distal urethra share

stratified squamous epithelium lending biologic plausibility to this intervention for both tenaculum placement to the ectocervix as well as IUD insertion ***(Singer et al., 1999).***

Aim of the Work

This study aims to assess the efficacy of intracervical 2% lidocaine gel prior to IUD insertion in reducing pain compared to placebo.

Study Question

In women going to have IUD inserted, does intracervical 2% lidocaine gel reduce pain compared to placebo?

Resarch Hypothesis

In women going to have IUD inserted, intracervical 2% lidocaine gel application may reduce the pain associated with insertion.

Patients and Methods

Study Design:

Randomized controlled clinical trial.

Setting:

The study will be conducted at Ain Shams University Maternity Hospital.

The duration of the study is 1 year from January 2016 to January 2017.

Protocol Approval:

Protocol will be approved and reviewed by research ethics comittee (Institutional review board) at Ain Shams University.

Before the beginning of the study and in accordance with the local regulation followed, the protocol and all the procedures set out in this study protocol, pertaining to the conduct, evaluation and documentation of this study, are designed to ensure that the investigators abide by the principles of good clinical practice and the ethical principles laid down in the current revision of the Declaration of Helsinki.

Sample Size Justification:

The required sample size has been calculated using the IBM© SamplePower© Software (IBM© Corp., Armonk, NY, USA).

The primary outcome measure is the pain score during insertion of the uterine sound, which is the most painful stage of IUD insertion.

A previous study reported that the mean ± SD pain score on the VAS scale during insertion of the uterine sound was 3.11 ± 2.53 versus 5.2 ± 2.31 in patients receiving lidocaine gel or a placebo, respectively ***(Tavakolian et al., 2015).***

So, it is estimated that a total sample size of 84 patients equally randomized into either study group (n=42 patients per group) would achieve a power of 90% (type II error, 0.1) to detect a statistically significant difference between the two groups as regards the pain score using a two-side unpaired Student *t* test with a confidence level of 99% (type I error, 0.01). The pain score in both groups is assumed to be identical and to equal 5.2 ± 2.31 under the null hypothesis. Under the alternative hypothesis, the pain score is assumed to equal 3.11 ± 2.53 or 5.2 ± 2.31 in patients receiving lidocaine gel or placebo, respectively. The expected drop out rate is about 10% So 100 patient will be included.

Inclusion criteria:

1- Age:20-45 years.

2- Parity:parous women (previous cesarean section).

3- Timing:last day of menstruation – postabortion(by one week) – postpartum(after puerperium).

4- Not taking analgesics (acetaminophen, ibuprofen, mefenamic acid) 6 hours before admission.

5- Abscence of sedative use 24 hours before admissions.

6- No history of severe mental stress in the past two months.

Exclusion criteria:

1- Uterine fibroid with distortion of the cavity.

2- Anatomical abnormality with distortion of the cavity.

3- Current pelvic inflammatory disease.

4- Current purulent cervicitis (chlamydia or gonorrhea)

5- Immediately after septic abortion.

6- Known allergy to lidocaine gel (pruritis, burning sensation, edema in cervix).

7- Uterus size less than 6 cm and more than 9 cm.

Randomization:

Will be done using computer generated randomization sheet using MedCalc© software version 12.5.

Allocation Concealment:

One hundred opaque envelopes will be numbered serially and in each envelope the corresponding letter which denotes the allocated group will be put according to randomization table then all envelopes will be closed and put in one box.when the first patient arrives the first envelope will be opened and the patient will be allocated according to the letter inside.

Blinding:

The investigator will know lidocaine, placebo gel and groups but both IUD inserter and patient will be blind (double blind).

Intervention:

All patients will undergo complete clinical examination and detailed medical history will be obtained. Each patient will have a Case Record Form (CRF) in which the following data will be recorded.

- Patient initials.
- Previous deliveries and abortions.

- Age, height and weight.
- Medications taken within the last 4 weeks and discontinued.
- Concomitant illnesses.
- Clinical examination: including general, abdominal and vaginal.

Patients will be distrubuted equally into 2 groups

- **Group A:** Study group 50 cases (will be applied 2% lidocaine gel which contains lidocaine hydrochloride as local anaesthetic to the cervix).
- **Group B:** Control group 50 cases (will be applied K-Y gel which contains glycerin and hydroxyethyl cellulose as lubricant to the cervix).

The gel (3ml) will be applied to the cervix prior to IUD insertion by 3 minutes, pain in three steps, after using tenaculum, after insertion of uterine sound and after insertion IUD will be assessed with visual analog scale and will be compared in lidocaine gel group and placebo group.

The placebo will be identical to lidocaine gel in terms of appearance, viscosity, color and smell. In order for blinding, the gels will be packaged in similar sterile containers.

IUD Insertion Steps:

1- The provider conducts a pelvic examination to assess eligibility. The provider first does the bimanual examination and then inserts a speculum into the vagina to inspect the cervix.

2- The provider cleans the cervix and vagina with appeopriate antiseptic.

3- The provider applies the gel to the site of tenaculum attachment of the cervix and cervical canal by.

4- The provider slowly inserts the tenaculum after 3 minutes through the speculum and closes the tenaculum just enough to gently hold the cervix and uterus steady and pain will be assessed with VAS and will be compared in lidocaine group and placebo group.

5- The provider slowly and gently passes the uterine sound through the cervix to measure the depth and position of the uterus and pain will be assessed with VAS and will be compared in lidocaine group and placebo group.

6- The provider slowly and gently inserts the IUD and removes the inserter and pain will be assessed with VAS and will be compared in lidocaine group and placebo group.

7- The provider cuts the strings on the IUD,leaving 3 centimeters hanging out of the cervix.

8- After the insertion, the woman rests. She remains on the examination table until she feels ready to get dressed.

Ethical and legal aspects:

Patient Information and Informed Consent:

Before being admitted to the clinical study, the patient must consent to participate after the nature, scope, and possible consequences of the clinical study have been explained in a form understandable to her. An informed consent document, in Arabic language, contains all locally corresponding documents will be declared for Ethical and Research approval.

Written informed consent will be obtained from all patients prior to screening and enrollment.

Statistical Methods:

Data will be collected, tabulated, then analyzed using IBM© SPSS© Statistics version 22 (IBM© Corp., Armonk, NY).

Normally distributed numerical data will be presented as mean and SD, and skewed data as median and interquartile range. Qualitative data will be presented as number and percentage.

Comparison of normally distributed numerical data will be done using the unpaired Student *t* test. Skewed data will be compared using the Mann-Whitney U test. Categorical data will be compared using the chi-squared test or Fisher's exact test, when appropriate.

A two-sided p-value <0.05 will be considered statistically significant.

Outcome Measures:

Primary outcome:

The gel will be applied to the cervix prior to IUD insertion by 3 minutes, pain in three steps, after using tenaculum, after insertion hystrometr and after insertion IUD will be assessed with visual analog scale and will be compared in lidocaine gel group and placebo group.

A Visual Analog Scale (VAS) is a measurement instrument that tries to measure a characteristic or attitude that is believed to range across a continuum of values and cannot easily be directly measured. For example, the amount of pain that a patient feels ranges across a continuum from none to an extreme amount of pain. From the patient's perspective this spectrum appears continuous ± their pain does not take discrete jumps, as a categorization of none, mild, moderate and severe would suggest. It was to capture this idea of an underlying continuum that the VAS was devised.

Operationally a VAS is usually a horizontal line, 100 mm in length, anchored by word descriptors at each end. The patient marks on the line the point that they feel represents their perception of their current state.