

The efficacy of lidocaine spray on Pain perception during IUD insertion. A Randomized Controlled Trial.

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By

Karim Hussein Zaki Eltawil

M.B.B.Ch – Cairo University – 2008
Resident of Obstetrics and Gynecology
Elsahel teaching hospital

Under Supervision of

Prof. Ayman Abd Elrazek Abo Elnoor

Professor of Obstetrics and Gynecology
Faculty of medicine
Ain Shams University

Dr. Mohamed Elmandoooh Mohamed

Assistant professor of Obstetrics and Gynecology
Faculty of medicine
Ain Shams University

Dr. Ahmed Mohamed Bahaa Eldin Ahmed

Lecturer of Obstetrics and Gynecology
Faculty of medicine
Ain Shams University

Faculty of Medicine
Ain Shams University

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LIST OF ABBREVIATIONS

ARHP	Association of Reproductive Health Professionals
ARV	Antiretroviral
CI	Confidence Interval
COX	Cyclo-Oxygenase
CS	Cesarian Section
DRG	Dorsal Root Ganglia
HIV	Human Immune Deficiency Virus
HSG	Hystrosalpingography
IHP	Inferior Hypogastric Plexus
IUCD	Intrauterine contraceptive device
LMP	Last Menstrual Period
LNG-IUS	LevoNorGestrel-releasing IntraUterine System
MEC	Medical Eligibility Criteria
NS	Not Significant
NSAID	Non-Steroidal Anti-Inflammatory Drugs
NVD	Normal Vaginal Delivery
OR	Odds Ratio
P value	probability value
PID	Pelvic Inflammatory Disease
RCT	Randomized Controlled Trial
REA	Research Executive Agency
SHP	Superior Hypogastric Plexus
SPSS	Statistical Package for the Social Sciences
STI	Sexually Transmitted Diseases
USFDA	US Food and Drug Administration
VAS	Visual Analogue Scale
WHO	World Health Organization



Protocol

Introduction

The intrauterine contraceptive device (IUCD) provides long-term reversible contraception equal in efficacy to tubal sterilization (**Grimes, 2008**). The IUCD is one of the safest, least expensive and most effective contraceptive devices available. The IUCD is often an excellent choice for women who do not anticipate future pregnancies but wish not to be sterilized. It is a convenient method of contraception; once inserted, it is nearly maintenance-free (except for monthly self-checks to locate the IUCD string) for up to a decade. (**Cetinkaya k,et al. , 2011**)

Depending on the country, the use of IUCDs worldwide ranges from 2% to 75%. On average, 15% of reproductive-aged women in developing countries and 8% in developed countries use it (**d'Arcangues, 2007**).

Increasing the number of women using IUCDs is an important public health goal. Fear of pain during IUCD insertion is one reason women may not want to use this highly effective birth control method. Determining an optimal method for reducing pain during IUCD insertion will benefit women and may increase the uptake of IUCDs as a contraceptive method (**Allen et al., 2009**).

Components of the insertion procedure that may cause pain include the application of the tenaculum to the cervix to stabilize the uterus and provide traction for straightening the cervical canal, passing the uterine sound, inserting the IUCD in the inserter tube through the cervix, and irritation of the endometrial cavity with the device. (**Whiteman et al. ,2013**)

While some IUCDs are inserted postpartum or postabortal, most are inserted remote (more than four weeks) from pregnancy as a clinic-based procedure. The levels of pain that women experience during IUCD insertion vary in published reports. Most women experience mild to moderate discomfort during IUCD insertion. Rarely, the pain is severe and associated

with nausea and weakness and sometimes, pain may persist for a few days after insertion. Predictors of pain during IUCD insertion include age greater than 30 years, lengthier time since last pregnancy or last menses, and not currently breastfeeding (**Hubacher, 2006**). Psychosocial factors including expected pain also influence the pain perceived by women undergoing the procedure (**Goldstuck, 1985; Murty, 2003**).

Pain perception from the cervix and the corpus of the uterus appears to pass through two distinct neural pathways. Innervation to the cervix arises from parasympathetic fibers from the pelvic splanchnic nerves (S2–4), which also supply the lower portion of the uterus and travel up to hypogastric nerves to the lower thoracic spinal cord (**Moore et al., 1999**).

Different ways of reducing pain during IUCD insertion have been explored. These include drugs that reduce cramping of the uterus (NSAIDs), drugs that soften and open the cervix, and drugs that numb the cervix. Prophylactic NSAIDs, as studied, do not appear to reduce pain during IUCD insertion (**Massey, 1974; Jensen, 1998; Hubacher, 2006**). The use of misoprostol to prime the cervix in addition to diclofenac before IUCD insertion did not appear to reduce pain and may increase side effects (**Ibrahim et al., 2013**).

Currently, we have no good evidence to recommend a specific method to reduce pain during IUCD insertion (**Allen et al., 2009**).

The oral mucosal use of lidocaine 10% spray has been seen as a safe and effective way of pain control in dentistry (**Karasahin et al., 2009**), which inspired us for this study.

Topical agents may be applied either to the exocervix or in the cervical canal while vehicles include spray solutions and topical gels and creams. The use of topical anesthetic sprays on the exocervix has generally

been demonstrated ineffective for biopsy, (*Prefontaine et al., 1991*) but one well designed, placebo-controlled RCT demonstrated that there was less pain with tenaculum attachment. (*Soriano D et al. 2000*).

Local anesthetics that are administered topically may decrease cervical pain by blocking pain nerve fibers. (*Gemzell-Danielsson K et al., 2013*).

Evaluation of pain as a symptom is difficult because it is subjective feeling and composed of sensory, emotional and cognitive components. Pain tolerance is deeply influenced by culture. A Visual Analogue 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. This validated pain scale uses a 10 cm line to represent the continuum of 'no pain' to 'worst imaginable pain' (*Sriwatanakul et al., 1983*).