

INTRACERVICAL LIDOCAINE GEL 2% REDUCES PAIN DURING IUCD INSERTION A RANDOMIZED CONTROLLED STUDY

Thesis

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List of Abbreviations

BMI	Basal metabolic index
CNS	Central nervous system
CS	Cesrean section
CT	Chlamydia trachomatis
EPF	Early pregnancy factor
FDA	Food and drug administration
HCG	Human chorionic gonadotropin hormone
HIV	Human immuno-deficiency virus
HLD	High level dis-infected
IUCD	Intra uterine contraceptive device
ILNT	Intra laminar nucleus of the thalamus
LNG-IUS	Levonoregestrel-intrauterine system
LEEP	Looop electro-surgical excersion procedure
LMP	Last menstrual period
NSAID	Non-steroidal anti-inflammatory drugs
PID	Pelvic inflammatory disease
STI	Sexually transmitted infection
SPSS	Statistical package for the social science
VPLNT	Ventral postero lateral nucleus of the thalamus
VAS	Visual analogue scale
VD	Vaginal delivery

Introduction

Unintended pregnancy is an important public health concern. Increased use of the intrauterine contraceptive device (IUCD), a highly effective, long-acting, reversible method of contraception, could decrease unintended pregnancies and their consequences (*Maguire et al., 2012*).

The IUCD is equal in efficacy to tubal sterilization (*Grimes, 2008*).

Depending on the country, the use of IUCDs worldwide ranges from 2% to 75% (*D'Arcangues, 2007*).

On average, 15% of reproductive-aged women in developing countries and 8% in developed countries use IUCDs (*D'Arcangues, 2007*).

Nulliparous women, nonlactating women and women with a distant pregnancy, report more insertional pain. Concerns about pain could be a barrier to IUCD initiation for women and their health care providers (*Maguire et al., 2012*).

Increasing the number of women using IUCDs is an important public health goal. One barrier to IUCD use is the fear of pain during insertion. 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 (*Hubacher et al., 2006*).

Cervical pain is mediated by S2 to S4 parasympathetic nerves and the T10 to L1 sympathetic fibers innervate the uterine fundus. While some IUCDs are inserted postpartum or postabortal, most are inserted remote (> four weeks) from pregnancy as a clinic-based procedure (*Hubacher et al., 2006*).

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. Pain may persist for a few days after insertion (*Hubacher et al., 2006*).

Predictors of pain during IUCD insertion include nulliparity, age greater than 30 years, long time since last pregnancy or last menses, and not currently breastfeeding (*Hubacher et al., 2006*).

Psychosocial factors including expected pain also influence the pain perceived by women undergoing the procedure (*Goldstuck and Mathews 1985*).

Pharmacological methods of pain control used for IUCD insertion commonly include non-steroidal anti-inflammatory drugs (NSAIDs), anxiolytics, and local anesthetics in the form of intracervical gel, cervical and paracervical block. One survey of United Kingdom (UK) physicians found a wide variation in the use of analgesia or anesthesia for IUCD insertions from no routine use to always using prophylactic NSAIDs or 2% lidocaine gel intracervically during the procedure (*Tolcher, 2003*).

Local anesthetics that are administered topically or through injection may decrease cervical pain by blocking nerve fibers.

Anxiolytics reduce pre-insertion anxiety and may lead to decreased pain perception by the woman (*Murty, 2003*).

Topical analgesia such as lidocaine gel may alleviate pain with IUCD insertion. Lidocaine gel has been studied during other gynecologic procedures, with inconsistent results (*Harmanli et al., 2009*).

A Cochrane Review that evaluated interventions for pain during IUCD insertion identified one randomized trial that reported decreased pain with a

2% intracervicallidocaine gel. That study had limitations such as lack of blinding (*Allen et al., 2009*).

Evaluation of pain as a symptom is difficult because it is subjective feeling and composed of sensory, emotional, and cognitive components (*Allen et al., 2009*).

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 can not easily be directly measured. This validated pain scale uses a 10 cm line to represent the continuum of 'no pain' to 'worst imaginable pain' (*Allen et al., 2009*).

Aim of the Work

To detect the effect of intracervical application of lidocaine gel 2% in decreasing pain during IUCD insertion.

Research question

Is lidocaine gel 2% application effective in decreasing pain threshold during IUCD insertion?

Research hypothesis

It is known that 1ml of lidocaine gel 2% usage is minimally effective in reducing pain threshold during IUCD insertion.

It is not known that is 3ml of lidocaine gel 2% usage highly effective in reducing pain threshold during IUCD insertion?

Medical application

When compared with placebo, lidocaine gel 2% intracervical application during IUCD insertion appears to be effective in decreasing the pain, cost effective, does not require equipments and does not require skilled personnel.

Chapter I

Anatomy

Anatomy of the bony pelvis:

The bony pelvis is made up of four bones, the two innominates, the sacrum and the coccyx, which are united by four joints. The articulated bony pelvis is divided into false and true pelvis by the pelvic brim or inlet. The false pelvis lies above the pelvic brim and forms the lower boundary of the abdominal cavity, while the true pelvis lies below the pelvic brim and bounds the pelvic cavity and the perineal space (*Kumazawa, 1986*).

The pelvic inlet is bounded by the pubic crest, pubic spine, pectin pubis and iliopectineal line of the innominate bone and the anterior border of the ala and the promontory on the sacrum (*Troll et al., 1991*).

The pelvic cavity is a curved canal with a shallow anterior wall and a deep concave posterior wall. It is bounded by the pubis, the ischium, part of the body of the ilium and by the sacrum and coccyx (*Kumazawa, 1986*).

The pelvic outlet is bounded by the arcuate pubic ligament, and the pubic arch anteriorly, the ischial tuberosities and sacrotuberous ligaments laterally, and the tip of the coccyx posteriorly (*Troll et al., 1991*).

Ligaments and joints of the pelvis :

The pelvic joints are the symphysis pubis, the sacroiliac joints and the sacrococcygeal joints. The sacroiliac joint is the largest and most important of the pelvic joints since the weight of the body is transmitted through this joint to the lower limbs (*ACOG, 1996*).

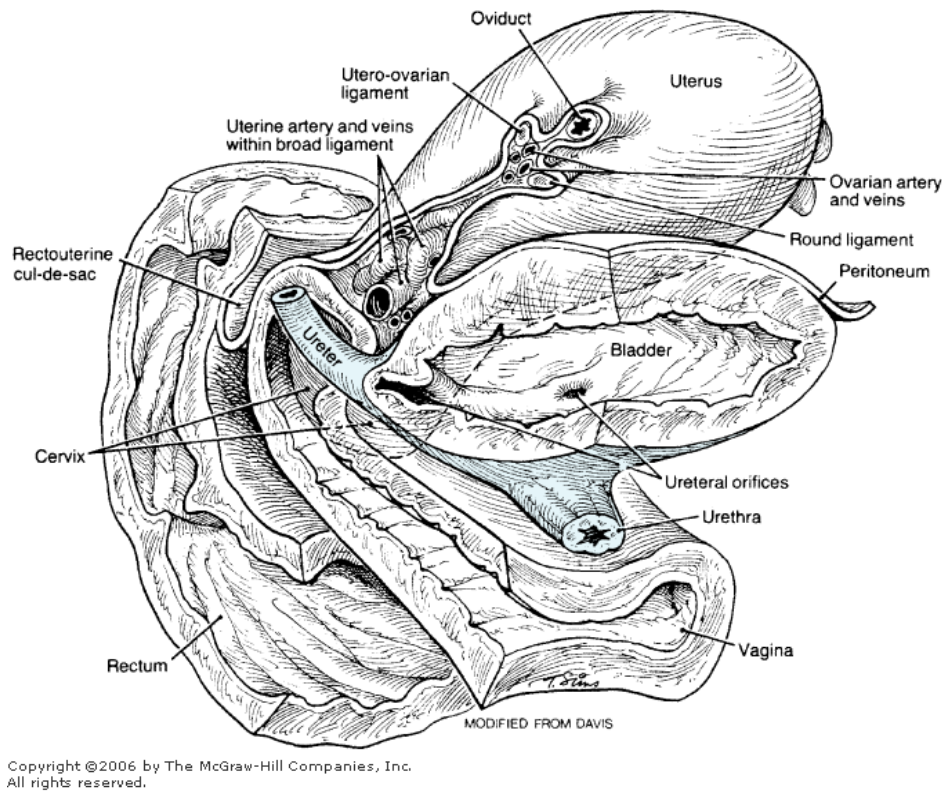


Figure (1): Ligaments of the pelvis, (ACOG, 1996).

There are four clearly identifiable ligamentous structures in the pelvis the broad ligaments, the round ligaments, the ovarian ligaments and the utero-sacral ligaments (*Troll et al., 1991*).

- **Broad ligaments:**

Each broad ligament consists of a double sheet of peritoneum that extends from the pelvic wall to the lateral surface of the uterus. The broad ligament encircles the fallopian tube at its upper border and continues laterally as the infundibulo-pelvic ligament. The ovarian vessels and the sympathetic nerves and lymphatic that accompany them traverse this component of the broad ligament toward the tube and ovary (*Chamberlain, 1993*).

• Round ligaments:

They are muscular bands arise from the fundus on its lateral aspect. Crossing laterally and anteriorly in the upper broad ligament in a curved fashion, the ligaments exit the pelvic cavity through the internal inguinal ring. Passing through the inguinal canal, then descend into the vulva and spread out in a manlike fashion to fuse with the connective tissue of the labia majora. They are structurally continuous with the ovarian ligaments, serving to connect the lower pole of the ovary to the inguinal canal (**Troll et al., 1991**).

• Ovarian ligaments:

They are cord like fibromuscular ligaments link the inner and lower pole of the ovary to the cornu of the uterus. Lying within the posterior leaf of the broad ligaments, they are morphologically continuous with the round ligament (**Chamberlain, 1993**).

• Uterosacral ligaments:

If the uterus is pulled forward, two folds of peritoneum can be seen to pass backward from the cervicouterine junction to reach the parietal peritoneum lateral to the rectum. The uterosacral ligaments serve as a route for the sympathetic and parasympathetic nervous supply to the pelvic viscera. Their insertion on the sacral wall is at about the junction of the second and third sacral vertebrae (**Troll et al., 1991**).

Anatomy of the uterus :

The uterus is a pear shaped organ. It is covered partially by peritoneum and its cavity lined by endometrium. It is composed of uterine body (isthmus, cornua and fundus) and cervix. The cervix is bounded at the upper end by the internal os and at the lower end by the external os.

The uterus is about 7.5 cm long, 5 cm wide at the fundus, and its walls are about 1.25 cm thick. According to Davis, the virginal uterus weights from 40 to 50 grams and the parous uterus 50 to 70 grams during reproductive life (*Dan et al., 1991*).

Anatomy of the vagina:

It is a tubular musculo membranous structure that extends from the vulva to the uterus. It lies between the urinary bladder and rectum. In virginal women the vaginal opening is hidden by overlapping labia minora and when exposed appears completely closed by membranous hymen which varies in shape and consistency (*Campbell, 2003*).

The vaginal vault is subdivided into the anterior, posterior and two lateral fornices by the uterine cervix. There are prominent ridges that project into the vaginal lumen which are called rugae forming corrugated surface which is gradually obliterated after repeated child birth (*Lavender and Bricker, 2002*).

Anatomy of the perineum:

The pelvic and the urogenital diaphragm support it. The pelvic diaphragm consists of the levator ani muscle and coccygeus. The levator ani muscle originates from the superior rami of pubis, ischial spine and

obturator fascia. It is inserted around the vagina and rectum, forming efficient functional sphincters (*ACOG, 1996*).

The innervation of the birth canal is derived from autonomic nervous system, which consists of sympathetic and parasympathetic nerve fibres, and these fibres are called postganglionic. The preganglionic fibres relay in ganglion cells and originate from the spinal cord and brain stem (*Kumazawa, 1986*).

Nerve supply of the female genital tract:

On the posterior abdominal wall, there is a network of sympathetic fibres, situated in front of the aorta and known as the preaortic plexus of intermesenteric nerves. This plexus is derived from the coeliac and renal ganglia. There are two main strands of nervous tissue running down on either side of the preaortic plexus - derived from the lumbar sympathetic ganglia (*Scott, 1991*).

These strands fuse with the preaortic plexus in front of the fifth lumbar vertebra, on the bifurcation of the aorta, behind the peritoneum forming the presacral nerve or superior hypogastric plexus. It consists of a median and two lateral roots. Between the presacral nerve and the anterior surface of the body of the fifth lumbar vertebra is the median sacral artery, and rupture of this vessel is a common complication of attempts to elevate the plexus (*Dundee and Ghaly, 1991*).

The presacral nerve or superior hypogastric plexus may retain its identity in the pelvis and passing over the promontory, and in front of the upper part of the sacrum becomes the middle hypogastric plexus. But at varying levels in the pelvic cavity it divides into two parts around the