



Lidocaine-prilocaine (EMLA®) Cream in Hysteroscopy Practice: a Prospective, Randomized, Non-blinded, Controlled Study

Thesis

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بِسْمِ اللَّهِ الرَّحْمَنِ الرَّحِيمِ

قالوا

سبحانك لا علم لنا
إلا ما علمتنا إنك أنت
العليم العظيم

صدق الله العظيم

سورة البقرة الآية: ٣٢



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Researcher/



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List of Abbreviations

<i>Abbr.</i>	<i>Full-term</i>
AAGL	: American Association of Gynecologic Laparoscopists
ACD	: Allergic contact dermatitis
ACLS	: Activate advanced cardiac life support
ACOG	: American college of obstetricians and gynecology
BMI	: Body mass index
CC	: Cardiovascular collapse
CO₂	: Carbon dioxide
EMS	: Emergency Medical Services
GX	: Glycinexylidide
HE	: Hyponatremic encephalopathy
IUDs	: Intrauterine devices
IUP	: Intrauterine Pressure
JCAAI	: Joint Council of Allergy, Asthma, and Immunology
MEGX	: Monoethylglycinexylidide
NRS	: Numeric rating scale
PABA	: Pseudocholinesterases on the amino ester paraaminobenzoic acid
PI	: Pain intensity
RF	: Radiofrequency
SPSS	: Statistical package for social science
VAS	: Visual analog scale
VRS	: Verbal rating scale

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Introduction

Local anesthetic techniques are being used at an increasing rate in modern gynecology. The increased expense of hospital admission has caused many gynecologists to perform uterine operation, hysteroscopy, colposcopy, Laparoscopy, and diagnostic curettage employing local anesthesia in offices and clinics (*Downes and Al-Azzawi, 2009*).

Direct cervical stromal infiltration or uterosacral ligament block have been most often used for operations on the uterine cervix and corpus; but these methods are seldom totally effective, they required expertise for consistent good results, and potentially toxic doses of anesthetic agents are required in these vascular areas where direct venous injection and systemic toxicity are constant hazards (*O'Flynn et al., 2011*).

General anesthesia is discouraged, especially for more minor procedures because of the associated risks and attendant costs (*Stigliano et al., 2010*).

Hysteroscopy with endometrial biopsy has become a standard investigation for abnormal uterine bleeding which has been shown to be effective in detecting intrauterine pathology. It is usually performed as an outpatient procedure under either local or no anesthesia. Although it is generally well tolerated (*Downes and Al-Azzawi, 2009*). It is

associated with some degree of pain and carries a risk of a vaso-vagal reaction. Pain is the commonest reason for failure to complete the procedure (*O'Flynn et al., 2011*). Although paracervical anesthesia is useful for local ablation of the cervix and suction evacuation of the uterus, it has not been shown to reduce pain during hysteroscopy and endometrial biopsy in randomized trials suggesting that the use of topical anesthesia by instilling an anesthetic agent may reduce the pain (*Lau et al., 2008*).

EMLA (a eutectic mixture of the local anesthetics, lidocaine 2.5% and prilocaine 2.5%) is the best-studied topical anesthetic. It produces effective analgesia for superficial surgical procedures after application for 5-10 minutes and has been extensively studied in various procedures including removal of genital warts, vulval biopsy, laser treatment of CIN lesions, and hysteroscopy (*Arnau et al., 2014*). EMLA is well tolerated and provides good pain relief for procedures involving the surface tissues such as removal of genital warts and hysteroscopy (*Ahmad et al., 2011*).

Abstract

This study was double blind placebo-controlled to evaluate the efficacy of a topical anesthetic cream EMLA. In reducing pain and discomfort associating outpatient hysteroscopy when applied on the uterine cervix. Sixty Patients were included, randomly were allocated into two groups equal in size, premeditation counseling was performed in the waiting room before the procedure so that the patients would be cooperative with the researcher. Full medical history and clinical examination were carried out before the procedure, so that no item of the exclusion criteria could be missed.

There was no significant difference in pain score associated with endometrial samplings. An explanation to this observation probably related to the different innervation of the uterine body and the cervix; that the sensory nerve supply of the uterus is derived from Frankenhauser's plexus which supplies the cervix and the lower portion of the uterus; however, the fundal region derives its sensory innervation from the ovarian nerve plexus.

There was no significant difference in the whole procedure time between both groups, although the mean time in EMLA group is slightly shorter this could be attributed to the cervical entrance time was shorter, and the uterine evaluation time was longer than in the placebo group. The differences in

acceptance score after 1 & 5 minute, and that in the preference score were highly significant between both groups.

No procedure complication was detected in both groups.

Key Word :

- Lidocaine Cream / hysteroscopy.

Aim of the Work

This is a non-blinded, drug-placebo controlled study to assess the anesthetic efficacy of lidocaine / prilocaine cream (EMLA) versus placebo on cervical mucosa in reducing pain & discomfort during outpatient hysteroscopy.

Panoramic hysteroscopy

Panoramic hysteroscopy is an endoscopic method utilizing a fiberoptic telescope and a mechanism to distend the uterine cavity so that it may be examined in selected patients (*Bradley et al., 2009*).

Techniques for hysteroscopy have been employed sporadically for many years with limited acceptance, but recent reports claiming more successful and diverse applications have renewed an interest in the procedure. Earlier attempts to inspect the uterine cavity were delayed because of inability to sustained adequate expansion, concern about introducing infection into the peritoneal cavity through the tubes with liquid or gaseous media, and the provocation of endometrial bleeding during manipulation. As technologic refinement provided safety and simplicity and clinical experience grew, hysteroscopy has become more practical, and new applications have been developed. Dilatation and curettage may miss focal intrauterine lesions because they are either small or located at an area that is difficult to curette (*Bradley et al., 2009*).

Hysteroscopy can guide the curette and permit directed biopsies of these lesions and their removal (*Bennett et al., 2008*).

The most common indications for hysteroscopy include: -

- Evaluation of unexplained abnormal uterine bleeding in Premenopausal or postmenopausal patients.
- The location and retrieval of "missed" IUDs.
- The evaluation of the infertile patient who has an abnormal Hystrogram.
- The diagnosis and therapy of intrauterine adhesions.
- The exploration of the internal os and uterine cavity in patients who have repeated abortions.
- The diagnosis and removal of pedunculated endometrial polyps, submucous myomas, and the transection of small septa.

Experience with hysteroscopy will increase the operator's skill and confidence of interpretation, but observations of suspicious areas must be accompanied by biopsy. Therapeutic hysteroscopy requires additional experience and dexterity; so that these maneuvers should be tailored to the endoscopist's experience, particularly in the removal of submucous myomas, the division of thick connective tissue adhesions, uterine septa, and tubal cannulation (*Bradley et al., 2009*).

The uterine cavity is accessed with a hysteroscopy through the cervical os via the vaginal canal. The degree of cervical dilatation and vaginal retraction performed during

hysteroscopy is the surgeon's choice and the design of the hysteroscope. A hysteroscope is a type of endoscope that has a double-channeled sheath allowing continuous flow of distention fluid or gas into the uterus through the larger channel, while allowing for less out-flow through the smaller channel. This pressure gradient results in distention of the uterine cavity. With optical improvements, hysteroscopes can be flexible or rigid and have a smaller diameter while still providing for larger and brighter images (*Copper et al., 2010*).

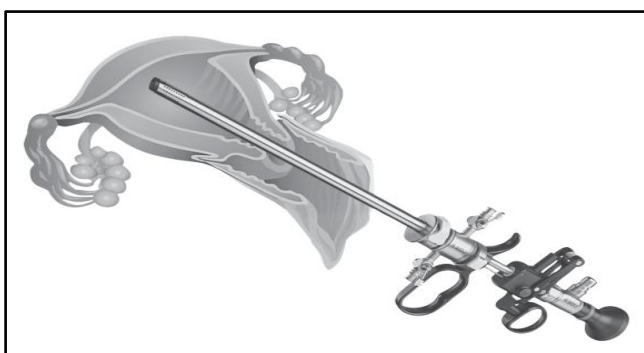


Figure (1): Double-channeled hysteroscope

Complications of Hysteroscopy Surgery and management

General Considerations

Hysteroscopic procedures are associated with a low number of adverse events with an incidence of 0.24% of 21,676 cases in Germany (*Aydeniz et al., 2002*). In general, it is apparent that more complicated procedures are associated with a much higher operative risk. Operative hysteroscopy is associated