

## **Randomized Study Comparing Intrauterine Bupivacaine , Lidocaine Spray and Paracervical Block in Reduction of Patient Discomfort During Outpatient Office Hysteroscopy (El- Minia Maternity Hospital Experience)**

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### **Abstract:**

**Objective:** to assess the efficacy and safety of intrauterine bupivacaine instillation, lidocaine spray and paracervical block in outpatient hysteroscopy.

**Design:** randomized controlled trial

**Setting:** university hospital

**Method:** A total of 160 women planned to do office hysteroscopy (outpatient hysteroscopy (enrolled in this study). The study was performed using 5mL of isobaric bupivacaine hydrochloride 0.5% Group A, n =40 injected transcervically into the uterine cavity or application of 5 sprays lidocaine 10 % spray into the uterine cavity Group B, n =40 or paracervical block using 3 mL of 2% lidocaine Group c, n= 40 or no method of anaesthesia used received placebo (control group, D, n=40

**Main outcome measures:** the evaluation of pain reduction on a visual analogue scales with hysteroscopy and post operative

**Results:** pain scores in intrauterine lidocaine group group B and paracervical block group C were found statistically significantly lower than other groups

**Conclusion:** intrauterine lidocaine spray and paracervical block decrease pain in outpatient office hysteroscopy rather than bupivacaine and placebo.

**Keywords:** bupivacaine, lidocaine spray, paracervical block

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### **1. INTRODUCTION**

Hysteroscopy is increasingly being used in the office setting, as it is well tolerated by many women, even without the use of anaesthesia [1]. It can, however, still be a painful experience for some and there is no consensus on the use of analgesia [2].

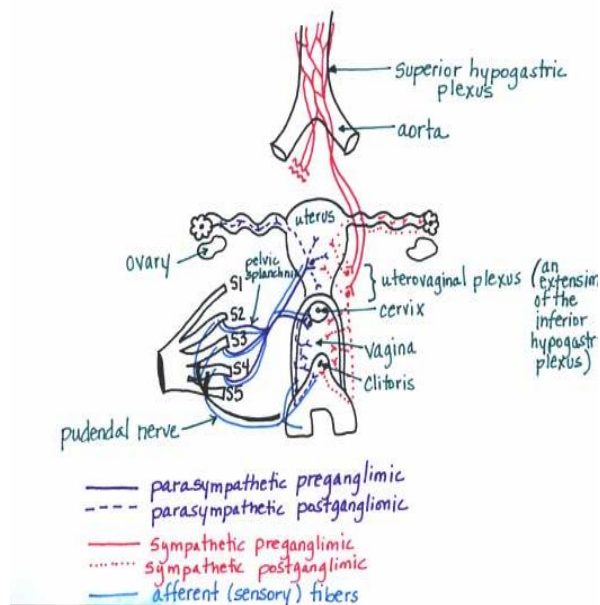
Postoperative analgesia is a key component of patient satisfaction following day case or ambulatory surgery .Postoperative pain may be attributed to occur from the release of prostaglandins from the endometrium causing cramping.It has been suggested that use of intrauterine anesthesia by instilling an anesthetic agent into the uterine cavity may reduce pain [3.]

Sensory supply of cervix and uterus

University of Michigan medical school

Pain from cervix carried out by pelvic splanchnic nerve, while sensation from upper part of cervix and body of uterus carried out with sympathetic fibers via afferent nerves supplying uterus are

T11 and T12. Parasympathetic supply is from second, third and fourth sacral nerves. The cervix and uterus are richly innervated, with Frankenhäuser plexus) parasympathetic (S2–4) supplying the cervix and lower uterus, and by sympathetic nerves via the infundibulo-pelvic ligament from the ovarian plexus supplying the uterine fundus. Various methods of systemic analgesia and local anesthesia have been tested to reduce the discomfort associated with hysteroscopy and post operative [4].



The effectiveness of intrauterine anesthesia for pain relief in gynecological procedures that involve the uterine cavity has been demonstrated in many studies [5].

The intrauterine instillation of a topical anesthetic is easy, relatively painless, and promising for adequate analgesia during endometrial biopsy. This technique could be an ideal method of anesthesia for endometrial biopsies [6].

Local anesthetics drugs act by causing a reversible conduction block along nerve fibers. They don't rely on the systemic circulation for transport to the site of action, but unwanted leak into the circulation is important in terminating the action by decrease concentration of local anesthetic at receptors at the site of injection and on other hand can produce toxic side effects [7].

The rate of systemic absorption of local anesthetics is dependent upon the total dose and concentration of drug administered, vascularity of the administration site and the presence or absence of epinephrine in the anesthetic solution. It is, therefore generally recommended that these compounds should not be used in inflamed or traumatized tissues [8].

Certain studies have not shown any adverse effects or morbidity from intrauterine or direct peritoneal cavity instillation of lidocaine or bupivacaine [9].

These reports provide precedence for safety of intra-uterine anesthesia. As it is easy and painless to perform intrauterine instillation of intrauterine anesthetic under a **mild sedation** and as this may provide postoperative adequate analgesia, this technique may be ideal anesthesia for outpatient office endometrial biopsies. Rather frequently, two short-acting local anesthetics have been investigated for endometrial biopsy and curettage including lidocaine [10] and bupivacaine [11].

One of the methods for pain reduction and local anesthesia is using intrauterine lidocaine. It is proposed to be an effective method for pain relief in the upper part of the uterus by blocking the nerve endings in the uterine corpus and fundus [7].

Bupivacaine is preferred for postoperative analgesia due to its longer duration of action compared to other local analgesics. It takes up to 30 min for full effect with a half-life of 2.7hr. The maximum therapeutic dose is 2 mg/kg with a toxic plasma level of 4mg/l. [8].

The paracervical block is the most common anesthetic technique which has been used for minor surgical procedures since 1925. It relieves pain in the lower part of the uterus and cervix by blocking nerve impulses that are conveyed through the Frankenhäuser plexus. However, it may

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not be effective for pain in the upper part of the uterus, which has a different innervation. Intrauterine anesthesia, by the infusion of a local anesthetic into the uterine cavity, has a theoretical action by blocking nerve endings in the uterine corpus and fundus [3, 4].

Because of the necessity of using a suitable and effective method of analgesia during the intrauterine biopsy, this study was performed to evaluate the different methods of intrauterine lidocaine and cervical spray lidocaine, in order to investigate the best method of anesthesia for pain relief regarding to the results and using it in outpatient clinics as a selected method.

### **2. METHODS**

This randomized study, not blinded study was conducted at the Outpatient Clinic of the Department of obstetrics and gynecology, El-Minia Maternity University hospital during the period from May 2012 up to December 2012.

Randomization was done simply using sealed envelopes. Doctors were not blinded to the group assignments.

One hundred sixty women scheduled for office hysteroscopy were randomly allocated to four groups: A, B, C and D, according to type of anesthesia was received

Group A: received bupivacaine 0.5% injected transcervically into the uterine cavity **n =40**

Group B: received lidocaine spray applied into the uterine cavity **n =40**

Group C: received paracervical block **n =40**

Group D (**control group**) : received no methods of anesthesia but received placebo ( intra utien injection of saline ) **n=40**

The woman was placed in the lithotomy position and a bimanual examination was performed.

A bivalve speculum then inserted to expose the cervix, which was disinfected with antiseptic solution. The anterior lip of the cervix was grasped with single tooth volsellum forceps.

Group A:

An 18 gauge intravenous catheter was inserted into the cervical canal up to the internal os and 5ml of isobaric 0.5% bupivacaine injected transcervical into the uterine cavity.

Group B:

5sprays of lidocaine %10 pump spray was applied to the uterine cavity through long disposable nozzles inserted through the cervical canal.

Group 3:

Paracervical block was performed using a 22-gauge spinal needle and the solution (2 ml of 2% lidocaine) was given at 3, 5, 7, and 9 o'clock of the paracervical region.

Group 4:

No methods of anesthesia was used but 5ml saline was injected intrauterine

All patients was not received any sedation, to evaluate pain sensation intra-operative. If patients record pain during maneuver they received analgesic in the form of fantail 1 µg\ kg \dose, and if not sufficient adding a medazolam as a sedation

Hysteroscopy was started five minutes after the injection. No prior cervical dilatation was performed. A rigid 5 mm diameter hysteroscope with a 30" fore-oblique view) Karl Storz, Germany) was inserted into the uterine cavity under direct vision .Uterine distension was maintained by a steady stream of saline.

A vasovagal reaction was defined as bradycardia (heart rate less than 60 per minute) or hypotension (a reduction in mean blood pressure greater than 20% compared with the baseline or systolic blood pressure reduced below 90mmgh , and associated with one or more of the following symptoms: dizziness, faintness ,sweating, nausea or vomiting.

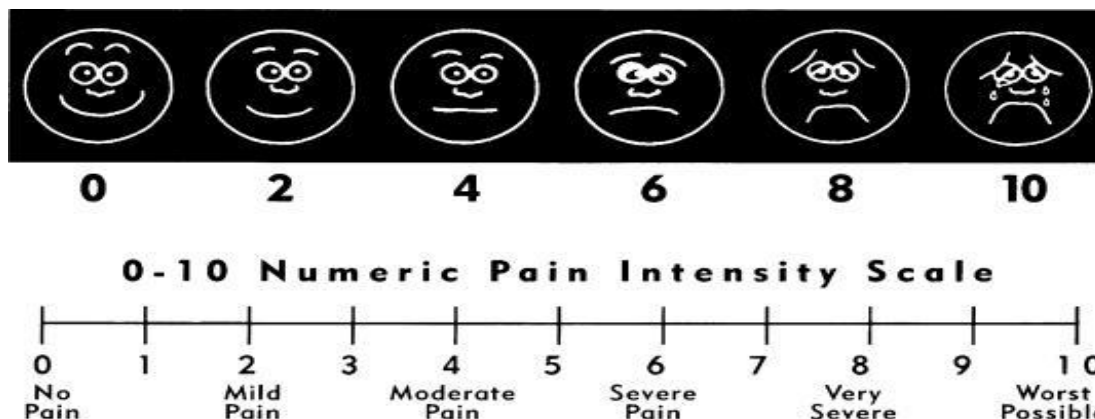
Intra - peratively ,quality of analgesia was recorded as excellent, good, fair and poor, assessed according to the following numerical scale:

4=Excellent (no complaint from patient), 3=Good (minimal complaints without any need for supplemental analgesics) 2= Moderate (complaints which required supplemental analgesics fantail 1 µg\ kg \dose)

1= Unsuccessful (requiring analgesia and sedation fantail 1 µg\ kg \dose, medazolam as a sedation)

Postoperative pain was recorded immediately postoperative and each 5 min, till 15min after the procedure (4 reading).

Pain was assessed using a 10-cm visual analogue pain scale.



The reverse side of the pocket card shown in *Figure* displays the Wong/ Baker faces rating scale, useful with children, the elderly, and patients with language barriers.

And 1<sup>st</sup> analgesic requirement indicate by patients record pain on visual analogue score 3 in the form of non – steroidal anti-inflammatory (decloflonic acid 75mg)

### 3. STATISTICAL ANALYSIS

Statistical analysis was performed using the Statistical Package for Social Science (SPSS Inc, Chicago) version 17 for Microsoft Windows. Data were described in terms of mean ± SEM (standard deviation) for continuous variables and frequencies) number of cases) and percentages for Categorical data. Independent Student’s t-test was used to compare quantitative variables and Chi square test was used to compare categorical data. A P value %0.05> was considered significant

### 4. RESULTS

There were no statistically significant differences in age, gravidity, parity, number of living children or menopausal status of the groups (p<0.05) (table (1)).

**Table1.** Demographic and clinical characteristics of the groups.

	1 <sup>st</sup> .group (n=40) A	2 <sup>nd</sup> . group (n=40) B	3 <sup>rd</sup> . group (n=40) C	4 <sup>th</sup> . group (n=40) D	P value
Age(ys)	42.3±9.3	40.6±7.6	47.7±8.1	46.5±8.2	P=0.061
Gravidity	7.3±3.5	6.8±4.3	7.7±3.3	6.8±2.6	P=0.265
parity	2				
nuliparous	5.8±3.6	4.9±3.9	5.3±2.8	5.4±2.6	0.325
parous	7.6±3.2	7.1±1.5	7.6±3.5	6.8±2.8	0.657
Body mass index	24.80±1.46	23.90±1.56	23.85±1.36	25.36±1.85	0.163
abortion	0.5±1.2	0.8±1.2	0.7±2.3	0.9±1.3	0.482
Live child	4.8±2.1	5.2±2.6	6.3±2.36	5.2±2.9	0.236
History of chronic pelvic pain					
yes	3	5	2	2	0.025
no	37	35	38	38	0.031

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Menopausal status					
Premenopausal (%)	31(0.775)	31(0.775)	31(0.775)	31(0.775)	P=1.000
Postmenopausal (%)	9(0.225)	9(0.225)	9(0.225)	9(0.225)	P=1.000
Previous cervical operations					
yes	1	2	0	1	P=0.652
no	39	38	40	39	P=0.368

Distribution of pain scores among groups was illustrated. When pain scores of groups were compared (Table 3), scores in the intrauterine lidocaine group (2<sup>nd</sup> Group) and paracervical block (3<sup>rd</sup> group) were found statistically significantly lower than in the other two groups (p<0.05).

Distribution of pain scores among groups was illustrated. When pain scores of groups were compared (Table 5), scores in the intrauterine bupivacain group (A Group) and paracervical block (C group) were found statistically significantly lower than in the other two groups (p<0.05).

**Table2.** Quality of intaoperative analgesia among the groups

	EXCELLENT	GOOD	FAIR	POOR	TOTAL
GROUP A	20	8	8	4	40
GROUP B	10	8	12	10	40
GROUP C	16	12	8	4	40
GROUP D	8	8	12	12	40

**Table3.** Comparison of groups for pain scores

Groups compared	P value
Group A-group B	P=0.004
Group A- group D	P=0.001
Group A- group C	P=0.061
Group B- group C	P=0.001
Group B- group D	P=0.05
Group C- group D	P=0.001

**Table4.** Biopsy indications according to the groups

Hysteroscopy indication	1 <sup>st</sup> .group (n=40)	2 <sup>nd</sup> . group (n=40)	3 <sup>rd</sup> . group (n=40)	4 <sup>th</sup> . group (n=40)	P value
diagnostic	25	23	26	24	0.256
operative					
Removal of polyp	3	2	5	4	0.086
Biopsy	2	4	2	6	0.0562
minimal intrauterine adhesions	5	2	3	3	0.258
Vaporization of small myoma	2	7	3	3	0.125
IUD removal	3	2	1	0	0.0520

According, the result show that paracervical block provide adequate intraoperative and postoperative analgesia, while the intraurien bupivacaine provide adequate postoperative analgesia, on other hand, intraurien lidocaine provide adequate intraoperative analgesia

**5. DISCUSSION**

This study evaluated the different methods of intrauterine anesthesia The presumed mechanism of action of the anesthetic in our study was an effect on the nerve endings within the endometrial mucosa.3, 6 Frankenhauer’s plexus, parasympathetic S2-4, provides the sensory innervation of the cervix and lower portion of the uterus (10).However, it has been proposed that the fundal region derives its sensory innervation from the ovarian nerve plexus (8). Intrauterine anesthesia is a method that had been tried in different gynecologic procedures by some investigators and various data on its effectiveness have been reported.

We chose 2% lidocaine for intrauterine anesthetic because it has a quicker onset and shorter duration of action than bupivacaine, which was used in previous studies, and 2% lidocaine might have a theoretic greater efficacy than 1%.(3, 4, and 6).The time interval allowed for the local anesthetic to become effective is also important. The peak anesthetic B effect following topical application of lidocaine occurs within 10 min (14).

This study showed that intrauterine lidocaine and paracervical block reduced pain considerably during intraoperative office hysteroscopy. With preference of Intrauterine lidocaine is a non invasive procedure, no need for prior experience as with paracervical block.

**Edelman** et al. In their (40-patient) study, reported that 5 ml of 4% lidocaine injected into the endometrial cavity after giving a standard paracervical block decreased the pain significantly more than a placebo in dilatation and curettage of first trimester elective abortions (18).

In the study by **Guney** et al. published in 2006, it was reported that intrauterine lidocaine could be an effective anesthetic method for removing lost IUD's (17).

In two different studies by **Cicinelli** et al., the effectiveness of intrauterine anesthesia in postmenopausal patients was investigated during diagnostic hysteroscopy and endometrial biopsy. In the first (19) of those studies, no statistically significant difference was found between intrauterine anesthesia and placebo. However in the second, which was performed with a larger number of subjects, more effective anesthesia was achieved with application of intrauterine anesthesia and this was statistically significant (10). Although both pre- and post-menopausal patients were included in our study, the second study by Cicinelli et al. supports our results.

On the other hand **Davies** et al. suggested that application of lidocaine spray during hysteroscopy, relieved pain significantly only during grasping of the cervix but not during the endometrial biopsy. Since, the cervix did not be grasped with mezzo forceps during pipelle biopsy so it seems that its governing pain did not any role in the study, thus cervical spray of lidocaine in combination with intrauterine lidocaine could not relief pain in more extents. Injection of anesthesia agent into the cervix (paracervical block) not only did not have positive impact on pain relieving but also led to complications such as bradycardia, hypotension and even death.<sup>10</sup>

**Trolice** et al. achieved similar results with applying intrauterine 2% lidocaine, but this samples volume was low.<sup>8</sup>In a double- blind randomized controlled trial, **Chanrachakul** et al. (2001) compared the effects of lidocaine and normal saline in pain reduction of outpatient curettage in 140 women of which 70 received normal saline and the other 70 received intrauterine lidocaine. They reported that the intensity of pain was significantly lower in the lidocaine group than in the normal saline group.<sup>9</sup>

**on other hand , Gerry R et al applied 20ml of 0.5% bupivacaine in patients undergo endometrial ablation, their study record that intrautrien inhection of bupivacaine provide inadequate analgesic effect intraoperative with adequate post operative analgesia (16)**

**Zupi** et al. applied topical anesthesia to relief pain in diagnostic hysteroscopy and endometrial biopsy; they applied 5cc of 2% intrauterine mepivacaine and evaluation of pain reduction on a VAS. Pain intensity was reduced effectively in those who used agent during and after the procedures. (12)

**Lau** et al. reported in two separate studies that neither paracervical block nor intrauterine anesthesia was effective in decreasing pain in hysteroscopy and endometrial biopsy compared to a placebo (5, 8).

**Rattanachaiyanont** et al (21) found statistically significant reductions in pain when a combination of paracervical block since pain is a subjective symptom, it is difficult to evaluate and anxiety may be a potential confounder.

Although these studies are different from ours in terms of material and method, they are significant as they showed that intrauterine anesthesia decreased pain in many gynecologic procedures. A limited number of studies on intrauterine topical anesthesia are available in literature and in most of these studies; the effectiveness of intrauterine anesthesia was investigated either in hysteroscopy or in hysteroscopy combined with endometrial biopsy (5, 8-10, 17).

Analysis of our data showed a statistically significant reduction in pain, during office hysteroscopy with intrauterine lidocaine and paracervical block. Although instillation might lengthen the procedure, we believe the reduction in patient discomfort outweighs the time factor.

It is unclear why intrauterine anesthesia has not been more widely adopted especially for hysteroscopy. Providers may be unaware of new practices; they may lack of awareness of the need for new practices; they may overestimate the potential safety concerns. It is the authors'

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subjective experience that most clinicians are unaware of the technique and unfamiliar with the literature published on the topic. Administering intrauterine anesthesia prior to an office procedure is an effective, low-cost, and low risk intervention. Administration is generally simple, Clinicians should consider adopting intrauterine anesthesia for endometrial biopsy and hysteroscopy in order to improve their patients' comfort during these procedures.

### **6. CONCLUSION**

our study conclude that, paracervical block provide adequate intra-operative and postoperative analgesia , while intrauterine lidocaine provide adequate intra-operative analgesia and require immediately postoperative analgesia on other hand , the intrauterine bupivacaine provide adequate postoperative analgesia , and require analgesia intraoperative , while our study demonstrate that the procedure should not done without anesthesia .

### **ACKNOWLEDGMENT**

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