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Office Hysteroscopy and Pain Management by Adding Lignocaine with Distension Media Versus Paracervical Block: A Randomized Controlled Clinical Trial

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ABSTRACT

Background: Office hysteroscopy is an excellent tool for assessing the uterine cavity, with a very low rate of complication. Oral medicines, local anesthetics, or inhalation-conscious sedation could be used for pain management. Local anesthetics, lignocaine, and use during the office procedure are evident to improve patient satisfaction and increase pain tolerance levels.

Objectives: The current study aims to compare the effectiveness of adding lignocaine 2% to the distension media versus paracervical block during office hysteroscopy in pain reduction, and also to compare the need for rescue analgesia, complications rate, and satisfaction of both patients and gynecologists.

Patients and methods: A randomized controlled clinical trial was conducted at the Laparoscopy and Cytogenetic Unit of Zagazig University Hospital, between January 2020 and September 2022. A total of 240 women who were eligible for diagnostic hysteroscopy were randomly assigned either to *Group 1* (lignocaine 2% mixed with saline distention media) or Group 2 (lignocaine 2% through the paracervical block). We compared pain scores before and after the procedure, patient satisfaction, and surgeons' satisfaction in each group.

Results: Paracervical pain during cervical canal passage was greater in *Group 2* than in *Group 1*. However, there was no significant difference in pain levels between the 2 studied groups during the examination of the cavity and for the following 10 minutes. *Group 1* had higher satisfied patients and surgeons compared to *Group 2*.

Conclusion: When compared to a paracervical block, the use of lignocaine 2% with saline distension medium was more effective in managing pain without making the patients feel uncomfortable.

Keywords: Office hysteroscopy, Pain, Distention media, Lignocaine, Clinical trial, Zagazig University**.**

INTRODUCTION

Office hysteroscopy is a well-acknowledged minimal-invasive tool in gynecology practice for the assessment of the endometrial cavity [(1)].

By avoiding unnecessary operational procedures, office hysteroscopy procedures have the potential to enhance both patient care and satisfaction. Additionally, it facilitates faster diagnostic and treatment planning while lowering the financial and logistical constraints [(2).] However, severe pain and discomfort remain concerning to the patient and limiting steps to the gynecologists. In this regard, pain management during the office hysteroscopy involves nonpharmacological methods like engaging the patient all through the procedure, and music. Pharmacological methods usually include oral non-steroidal anti-inflammatory medication, local anesthetic agents, or oral or inhaled conscious sedation. [(3).]

Meanwhile, local anesthetics and lignocaine use during the office procedure are evident to improve patient satisfaction and increase pain tolerance. Several factors related to the technique can cause pain initiation during the process. The Ergonomic of the hysteroscopy instruments includes the tenaculum, speculum, hysteroscope diameter, the procedure duration, and experience of the operator [(4)].

Patient-related factors include cervical stenosis and patient anxiety. All these factors may make it difficult to accurately assess the pain that results from the hysteroscope entering the uterus [(5).] The best evidence practices limiting the patient discomfort in office hysteroscopy relays on; the non-touch technique through vaginoscopy, the right selection of patient, the right time for the procedure, and the preparation of the cervical region for those who are most likely to experience cervical stenosis or pain with dilation, individualized pain-management techniques, the distension media usage, and video monitoring to engage the patients involved in the procedure [(6).]

The current study compares the efficiency of including 2% lignocaine to the saline distension media during office hysteroscopy versus paracervical block injection to reduce patient pain and improve satisfaction.

PATIENTS AND METHODS.

This prospective randomized controlled clinical trial was approved by the ethical committee of Zagazig University.

We included all patients indicated for office hysteroscopy either for cavity assessment, investigation of abnormal uterine bleeding, or removal of an intrauterine device at Zagazig University Laparoscopy and Cytogenetic Unit, during the period from January 2020 to September 2022.

Exclusion criteria were a pelvic inflammatory disease, endometriosis, need for prolonged operative hysteroscopy, previously failed diagnostic hysteroscopy, lignocaine allergy, and patients with psychiatric disorders or neurological disorders affecting their pain perception.

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Women who were eligible for diagnostic hysteroscopy were randomly assigned either to *Group 1* (lignocaine 2 % was mixed with 1000 mL of saline solution that was used as the distension medium for hysteroscopy) or Group 2 (lignocaine 2 % was given via paracervical block which consisted of 20 mL buffered 2% lidocaine with 2 mL injected at the tenaculum site and the remaining 18 mL injected slowly and deeply in equal amounts paracervical. The four-site block was injected at 2, 4, 8, and 10 o'clock avoiding the 3 and 9 o'clock sites of lateral cervical artery branches).

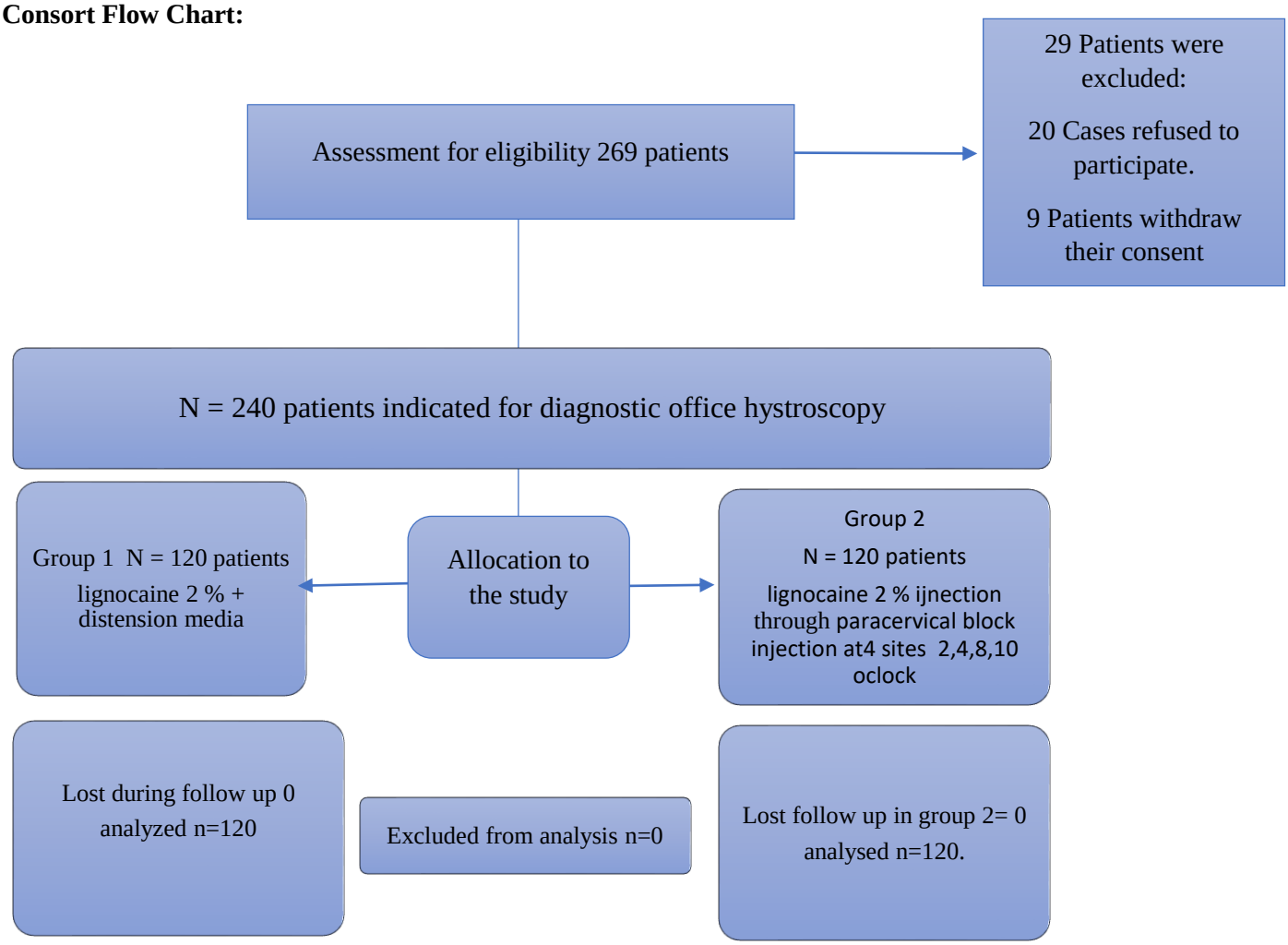
When the cervical canal was passed and the hysteroscope was within the cavity, the pain was measured with a Visual Analog Scale (VAS) right before starting the process. All of the patients had their level of discomfort assessed once again ten minutes after the surgery. VAS was utilized to assess the level of pain. Patients were asked to rate their level of discomfort from five distinct photos of faces on a scale of 0 to 10, and the relevant points were then assigned [(7).]

A size 3 hysteroscope, (Karl Storz, Tuttlingen, Germany), based on a 2.9-mm rod-lens system with a 30-degree forward oblique view and an outside diameter equivalent to 3 mm was used for all diagnostic operations. Vaginoscopy non-touch technique was to negotiate the cervical canal and the fluid pressure was between 80-100 mg.

Outcomes:

1. The VAS scoring for pain assessment was taken immediately before introducing the hysteroscopy, during cervical entry, and immediately after the removal of the hysteroscopy. The score was from 1 to 10 on the ruler with each 1 cm corresponding to a score of 1 [(8)].
2. Surgeon's satisfaction was measured by asking the surgeon about the difficulty of the procedure with 1 being the easiest straightforward procedure while 10 was the most difficult procedure.
3. Patient's satisfaction score was rated by asking the patient how much they are stratified by the procedures: 1/5 very unsatisfied; 2/5 unsatisfied;3/5 neutral /4/5 satisfied/ 5/5 very satisfied.

Consort Flow Chart:



Ethical approval:

This study was ethically approved by the Institutional Review Board of the Faculty of Medicine, Zagazig University. Written informed consent was obtained from all participants. This study was executed according to the code of ethics of the World Medical Association (Declaration of Helsinki) for studies on humans.

Statistical analysis

The collected data were introduced and statistically analyzed by utilizing the Statistical Package for Social Sciences (SPSS) version 21 for windows. Qualitative data were defined as numbers and percentages. The chi-Square test and Fisher's exact test were used for comparison between categorical variables as appropriate. Quantitative data were tested for normality by the Kolmogorov-Smirnov test. The normal distribution of variables was described as means and SD, and an independent sample t-test was used for comparison between groups. To calculate the odds ratio and 95% confidence interval, Epi Info 7 was used. P value ≤0.05 was considered to be statistically significant.

RESULTS

There was a difference of no statistical significance among both groups regarding patient characteristics; patient age, BMI, menopausal status, and the number of deliveries (**Table 1**).

Table 1: Sociodemographic characteristics of patients in the 2 studied groups.

Variable	*Group 1:* Lignocaine 2 % + distension media	*Group 2:* Paracervical block with lignocaine 2 %	P-value
Age	35.65 ± 5.6	36.43 ± 3.8	>0.05
BMI	27.1 ± 2.8	25.3 ± 1.3	>0.05
No of Deliveries	3.12 ± 2.9	3.26 ± 3	>0.05
Post-Menopausal	12 (10.7%)	10 (8.77%)	>0.05
Premenopausal	108 (89.3%)	110 (91.23%)	>0.05

Table 2 shows that the most frequent indications for office hysteroscopy are abnormal uterine bleeding followed by missed IUD then thickened endometrial and the least frequent indication was amenorrhea. No statistical difference between both groups regarding the indication.

Table 2: The various indications of hysteroscopy in the 2 studied groups.

Variable	Group 1: lignocaine 2 % + distension media (N= 120)	Group 2: Paracervical block with lignocaine 2 % (N= 120)	P-value
Abnormal uterine bleeding	44 (36.6%)	48 (40%)	>0.05
Endometrial polyp	10 (8.33%)	12 (10%)	>0.05
Thickened endometrium	15 (12.5%)	11 (9.16%)	>0.05
Infertility	18 (15%)	20 (16.6%)	>0.05
Recurrent miscarriage	6 (5%)	2 (1.66%)	>0.05
Amenorrhea	1 (0.83%)	3 (2.5%)	>0.05
Missed IUCD	14 (11.6%)	16 (13.3%)	>0.05
Post-menopausal bleeding	12 (10%)	8 (6.66%)	>0.05

Both groups have no statistical difference, and the most common findings of office hysteroscopy were endometrial polyps, impeded IUD, and endometritis (**Table 3).**

Table 3: Intraoperative hysteroscopic findings of the 2 studied groups.

Variable	Group 1 Lignocaine 2 % + distension media (N= 120)	Group 2 Paracervical block with lignocaine 2 % (N= 120)	P-value
Normal	40 (33.3%)	32 (26.6%)	>0.05
Endometrial polyp	38 (31.6)	30 (25%)	>0.05
Thickened endometrium	12 (10)	14 (11.6%)	>0.05
Retained product of conception	4 (3.33%)	6 (5%)	>0.05
Submucous myoma	6 (5%)	10 (8.3%)	>0.05
Endometritis	13 (10.8%)	11 (9.16%)	>0.05
Uterine septum	2 (1.66)	5 (4.16%)	>0.05
Impeded IUD	14 (11.6%)	12 (10%)	>0.05

In terms of intra-operative outcomes, the mean average time was near significant in *Group 1* 265.3 (SD 0.1) seconds compared to 292.1 (SD 3.6) seconds in *Group 2*. When compared to *Group 1*, *Group 2*'s VAS score was statistically higher, mainly during the cervical entry. However, *Group 1* required more rescue analgesia than *Group 2*, despite this not being statistically significant. Additionally, the vasovagal attack was encountered more in *Group 2* higher than in *Group 1*. Finally, both patient and surgeon satisfaction were higher in *Group 1* where lignocaine was added to the distension media more than those who received it through paracervical injection (**Table 4**).

Table 4: Comparison of outcomes between both groups.

Variants	Group 1: Lignocaine 2 %+ distension media (N= 120)	Group 2: Paracervical block with lignocaine 2 % (N=120)	P-value
Duration of procedure in seconds	265.3 ± 6.1	292.1 ± 3.6	>0.05
Haemodynamic			
Heart rate	87.90 ± 9.2	80.52 ± 11.1	>0.05
Mean arterial blood pressure	106 ± 7.05	103 ± 9.27	>0.05
VAS			
Before the procedure	0 ± 1.1	0.7 ± 0.9	>0.05
During the procedure	1.9 ± 0.6	2.1 ± 0.1	0.09*
After the procedure	1.6 ± 0.22	2.0 ± 1.5	0.11
VAS			
During cervical entry	1.3 ± 0.22	1.5 ± 0.8	0.07*
After cervical entry	1.5 ± 0.22	1.4 ± 1.1	0.57
Rescue analgesia	4	3	>0.4
Vasovagal attack	1	6	>0.02*
Patient Satisfaction	4.3 ± 0.6	1.2 ± 0.38	0.001*
Surgeon Satisfaction	7.6 ± 1.2	3.1 ± 0.92	0.001*

DISCUSSION

Office hysteroscopy procedure setting has gained acceptability over the past few decades. Initially, only diagnostic treatments could be performed in the office setting. However, as hysteroscopic technology advanced involving tiny instruments and improved surgical skills [(9)]. Currently, several surgical operations are carried out in offices rather than operating rooms while under anaesthesia. Patients with abnormal uterine bleeding (AUB), infertility, and retained foreign bodies are the major focus of diagnostic investigations. Many pharmacological and non-pharmacological techniques are effective, even though it is occasionally seen as a painful process, including transcutaneous electrical nerve stimulation (TENS), the use of a warm distension medium, hypnosis, and music [(10)], additionally, using a small instrument size while treating pain is necessary to lessen discomfort and the chance of vasovagal responses [(11)]. A review of the literature revealed that several studies had been conducted to evaluate the effectiveness of various pain control techniques used during office-based hysteroscopy. De Fortis et al assessed 558 patients who underwent diagnostic office hysteroscopy without anesthesia through vaginoscopy non-touch technique he concluded that the risk and predictors for having pain during office hysteroscopy were commonly in cases with dysmenorrhea, nulliparity, and chronic pelvic pain [(12)]. Some technical steps might contribute to exaggerated pain perception: the use of a wider 5 mm hysteroscopy, speculum, tenaculum, removal of polyps, gas distension media, and the length of the procedure [(13)]. ***Charlo et al.*** concluded that hysteroscopic procedures exceeding 3 minutes or with a low-level experienced operator are associated with higher pain scores. Patients with high-risk factors to suffer from unacceptable pain should be candidates for the procedure under general anesthesia. A Cochran review and meta-analysis did not demonstrate any significant value in pain reduction from non-steroidal anti-inflammatory medication. According to the aforementioned coach review, the use of local anesthesia during office hysteroscopy reduces intraoperative pain and immediate postoperative pain for 30 min [(14)]. However, to lessen intra- and post-procedure pain, the Royal College of Obstetrics and Gynaecology advised women to take the necessary doses of non-steroidal anti-inflammatory medicines one hour before the office hysteroscopy as suggested in guideline number 59.

In the current randomized experiment, we demonstrated that adding lignocaine 2% to the distention medium before office hysteroscopy lowers discomfort associated with the operation. Similar to this, prior research found that using local anesthetic gel instead of saline for contrast sonohysterography led to decreased pain levels during subsequent hysteroscopy and endometrial biopsies as well as during contrast sonography of the uterine cavity [(15,16)]. However, Studies on the use of topical anesthesia in the uterine cavity have shown conflicting outcomes. Before hysteroscopy or endometrial sampling, lignocaine injections into the cervix were used in two rather modest randomized double-blind investigations. These studies discovered a positive outcome. [(17)].

Hui et al. reported lower pain scores in the group that received lidocaine 2% before endometrial biopsy;

however, upon lidocaine instillation, ***Lau et al.*** and ***Wong et al.*** (both trials were randomized and double-blind) observed no superiority in the pain experienced during hysteroscopy or endometrial sampling [18-21]. Based on the studies, it is essential to preclude all the confounders to obtain an accurate assessment of pain related to the procedure. To gain insight into procedure-related accompanied pain, which was attained in our study, an experienced clinician employing a small-diameter hysteroscope and accessing the cavity swiftly, gently, and with little damage, is required.

According to this study, *Group 2* experienced more paracervical-related pain when going through the cervical canal than group 1 did. But lignocaine 2% injected into the cavity directly reaching the nerve fibers might account for the lack of a significant difference in pain levels between groups during cavity inspection and 10 minutes following. The increment of pain was comparable in both groups. The use of lignocaine with distension media alone was effective as a paracervical injection in controlling the pain during the procedure. However patient satisfaction and surgeon satisfaction was higher among Lignocaine 2% along with distention media group 1. No side effects were reported from lignocaine use either with distension media or paracervical injection.

Strength and Limitation of the study:

Our study's strength from being a randomized prospective clinical trial. However, its limitation small sample size, the results reflect the patient characteristics of a single center, the total volume of distension media, and the total doses of analgesia were not calculated.

CONCLUSION

With the proper experience and training, Office hysteroscopy provides a simple and affordable method for enhancing the gynecologic treatment for our patients. We recommend that local anaesthetic use with distention media would improve patient satisfaction and reduce the pain-related procedure.

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Conflict of interest: none.

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