Evaluation of different methods for pain management in office hysteroscopy

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Abstract

Objective: : to detect the most effective pain control modality for the performance of office Hysteroscopy.

Methods: This was a double-blind randomized comparative study. Both sample size and randomization were done by a computer program. Patients were classified into four groups: Group one received 50 mg diclofenac potassium orally 30 minutes before hysteroscopy, group two received lidocaine 2% gel applied to cervix 5 minutes before hysteroscopy, group three received 10 ml 2% lidocaine solution injection in the cervix, group four received placebo drugs before hysteroscopy. Adjustments were made so that the 4 groups receive the 3 forms of analgesic drugs either in active form or placebo to ensure the integrity of double-blind study. The woman was asked by an independent observer to evaluate the pain felt at different stages of the procedure using VAS.

Results: There was a statistically significant difference in two groups (oral NSAIDs and paracervical block) in the VAS.

Conclusion: oral NSAIDs is an effective method in reducing pain during hysteroscopy. paracervical block reduce pain significantly only during introduction of hysteroscopy through the cervix, hindered by the time it takes, bleeding, lack of effectiveness through other stages of the procedure, while application of anesthetic gel though is proved to be an ineffective way to control pain during the procedures.

Keyword: office hysteroscopy, pain management, oral NSAIDs, paracervical block.

INTRODUCTION

Hysteroscopy is the best method used for evaluation of endometrium in cases of vaginal bleeding, recurrent miscarriage, and anomalies of the uterus, cervix, and vagina (1).

When it comes to hysteroscopy, a novel technique known as "office hysteroscopy" has evolved since early nineties. The "see and treat" procedure, which blurs the separating line between diagnosis of uterine pathology and operative

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maneuvers, reveals the concept of one procedure which integrate the management with the diagnosis (2).

In comparison to operating room-based hysteroscopy, office hysteroscopy has various benefits, including the omission of hospital stay, preoperative tests, and general anesthesia (3). Notably, it has decreased the duration needed for improvement after operation, the overall expenses of the therapy, and the how common are problems such as lacerations of the cervix, perforation of the uterus, and those brought on by the media that will be used for distending the uterus (4).

Despite being largely accepted to a great level, unpleasant painful stimuli, vaso-vagal attacks, falling of blood pressure, and loss of ease are frequently narrated by patients have hysteroscopy performed to them (4). Pain is still by far considered the most important factor in office hysteroscopy failure, despite the truth that a "no-touch" modality may be done easily in the majority of instances without anesthetics (3).

The origin of the painful stimuli sensed during hysteroscopy are currently not well understood. Also, there is no consensus on the use of medications for treating pain and anesthetic modalities for hysteroscopy in the ordinary clinic room because there is a deficiency of enough high-quality evidence in this area (4).

84% of failed hysteroscopies, according to Nagele et al, were caused by severe discomfort and pain during the procedure (5).

It is stated that around 35% of individuals who have a hysteroscopy for getting pathology diagnosed without anesthetic claim a very severe painful experience (6).

Around 68% of patients revealed feeling intermediate to agonizing level of discomfort (detected by (VAS) scoring system of five or above) right away by the time their assessment has ended (3).

When we try to understand the pathophysiology of discomfort during hysteroscopic maneuvers, one must have a sufficient knowledge of the female genital tract anatomy (7, 8). The tissues of the female pelvis are supplied by two nervous systems (8, 9). The upper part of the uterus is supplied by the sympathetic system from the tenth thoracic to the second lumbar segment by the inferior hypogastric plexus of nerves (7). That get access to the uterine body by two ligaments of the uterus, and they are sacro-cervical ligament and the suspensory ligament of the ovary, forming together the ovarian plexuses (8).

The upper part of the vagina, cervical tissue, and inferior part of the uterus are supplied by parasympathetic nerves from second to fourth sacral, which combine together to give rise to the uterovaginal plexus of nerves, which get access to the uterus through the mackenrodt's ligament (8,9).

While performing hysteroscopic techniques, discomfort is for the most part arise from the use of instruments to grasp cervix, dilatation of the cervical canal, passage of the hysteroscope through the canal of the uterine cervix, and separation of the two uterine walls from each other by media (10,11). Operative techniques which destroy the endometrial tissue, such as getting tissue biopsy of the endometrium, removal of a polyp or excision of myoma can also cause a great deal of discomfort (10,11).

This intricate nerve supply means that good anesthesia and pain control demands targeting of many sites at the same time, such as paracervical and intracervical anesthetic modalities as well as topical medicines for the lining of the cervix and uterine cavity (9).

Pain during office hysteroscopy remains a determining factor for patient acceptability of the procedure.in our study we investigate the most common pain control modalities to control pain during office hysteroscopy and they are oral NSAIDs, paracervical block, topical anesthetics applied to the cervix.

MATERIALS AND METHODS

Our study is prospective randomized double-blind study. This study was conducted in the outpatient clinics of Mansoura University Hospitals in the period from September 2021 to September 2022. Ninety-two women were enlisted for hysteroscopy in Mansoura gynecological center outpatient clinic and that comes after good counselling and signing their consent. The 92 patients were randomized into four groups using a computer program designed for research purposes. Group one got 50 mg diclofenac potassium orally 1 hour before hysteroscopy and 10 ml normal saline injection in the paracervical region and 5 mg placebo gel applied to the cervix 10 minutes before hysteroscopy, group two received placebo drug orally 1 hour before hysteroscopy and 10 ml normal saline injection in paracervical region and 5 mg lidocaine 2% gel applied to cervix 10 minutes before hysteroscopy, group three received placebo drug orally 30 minutes before hysteroscopy and 10 ml 2% lidocaine solution injection in the paracervical region and 5 mg placebo gel applied to cervix 10 minutes before hysteroscopy, group four received placebo drug orally 1 hour before hysteroscopy and 10 ml normal saline injection in the paracervical region and 5 mg placebo gel applied to cervix 10 minutes before hysteroscopy.

The random division of the groups and preparation of the drugs were made by a health care worker who did not attend the hysteroscopy setting. The physician who performed the procedure, physician assistant and the patient did not recognize the medication used. The patient was asked to lie in the lithotomy position and gynecologic examination using the two hand simultaneously through the vagina and over the abdomen was performed. A speculum was then introduced through the vagina to show the cervix, then disinfection the cervix takes place. The upper cervical lip was held firmly with volsellum forceps by the physician. Paracervical anesthesia was then achieved by the use of spinal needle and the drug was injected at third, fifth, seventh and ninth o'clock of the junction between cervix and vagina, in four equally divided doses. The gel was then put on the Ectocervix. Hysteroscopic procedure began 5 minutes after the application of the gel. Dilatation of the cervix was not performed before the start of the hysteroscopy. The type of the hysteroscopy in this study is the rigid type. And its diameter is 5 mm with 30-degree angle. The hysteroscopy was advanced through cervical canal till the uterine cavity vision is attained. Saline solution was used to distend the uterus and to maintain the separation of the uterine walls. The patient was demanded to give a pain score to another independent attendant to evaluate the discomfort during every single stage of the hysteroscopy using VAS. Discomfort was evaluated when the cervix was held firm by volsellum; during advancement of hysteroscope through the cervical canal; just after the procedure was finished; and half hour after the procedure was performed. Blood pressure and pulse were recorded during the same stages of the procedures during which pain was recorded.

RESULTS

Table 1: The baseline characteristics of the study participants.

characteristics	Local lidocaine gel group N=23	Diclofenac group N=23	Paracervical block group N=23	Placebo group N=23	P value
Age/years mean±SD	30.83±9.78	36.52±13.6	34.61±9.43	35.35±7.81	0.281
BMI(kg/m^2) mean±SD	28.58±2.18	28.79±2.34	29.79±3.05	28.65±1.61	0.316
Residence Urban Rural	 9(39.1) 14(60.9)	 8(34.8) 15(65.2)	 7(30.4) 16(69.6)	 9(39.1) 14(60.9)	0.915

Used test : One Way ANOVA test , Chi-Square test

First table leads to the conclusion that there is no difference between studied groups that signify importance in relation to statistics as regard age , body mass index and residence. Mean age is 30.83 , 36.52 , 34.61 & 35.35 years for the local lidocaine group , Diclofenac group, Paracervical block and placebo groups. Mean body mass index is 28.58 , 28.79 , 29.79 and 28.65 kg/m^2 . Rural residence is detected among the following; 60.9% , 65.2% , 69.6% & 60.9% , respectively for local lidocaine group , Diclofenac group, Paracervical block and placebo groups.

Table (2): comparison of obstetric history between studied groups.

characteristics	Local lidocaine gel group N=23	Diclofenac group N=23	Paracervical block group N=23	Placebo group N=23	P value
Parity	0(0-3)	1(0-6)	2(0-5)	0(0-4)	0.226
Gravidity	1(0-7)	2(0-7)	2(0-5)	2(0-7)	0.364
Previous vaginal delivery	2(1-3)	4(1-6)	2(1-5)	2(1-3)	0.784
Previous cs	2(1-3)	1(1-3)	2(1-3)	1(1-3)	0.412
Previous miscarriage	2(1-7)	1(1-5)	1(1-2)	1(1-7)	0.461

Used test : Kruskal Wallis test

Second table help us conclude that the groups don't differ to the level that signify value in the fields of statistics as regard median parity , gravidity , previous vaginal , CS and miscarriage.

Table (3): comparison of medical and surgical history between studied groups.

characteristics	Local lidocaine gel group N=23	Diclofenac group N=23	Paracervical block group N=23	Placebo group N=23	P value
Medical history -ve +ve	18(78.3) 5(21.7)	18(78.3) 5(21.7)	13(56.5) 10(43.5)	18(78.3) 5(21.7)	0.249
Surgical history -ve +ve	13(56.5) 10(43.5)	16(69.6) 7(30.4)	8(34.8) 15(65.2)	10(43.5) 13(56.5)	0.09

Used test: Chi-Square test

Third table demonstrates the relation that there is no significant differentiation between studied groups when it comes to statistics as regard medical and surgical history. Positive medical history is detected among 21.7% , 21.7% , 43.5% &21.7% , for local lidocaine group , Diclofenac group, Paracervical block and placebo groups , respectively.

Table (4): Vas score among studied groups.

outcomes	Local lidocaine gel group N=23	Diclofenac group N=23	Paracervical block group N=23	Placebo group N=23	P value
VAS when the cervix was grasped	5.09±0.85[a]	3.17±1.11	5.87±1.01	5.22±1.31a	F=26.29 p<0.001*
VAS at the time of insertion of hysteroscopy	7.13±0.81	4.30±0.76	3.74±0.86	6.13±0.86	F=83.22 p<0.001*
VAS immediately after hysteroscopy	5.83±0.98[a]	4.30±0.82	6.04±0.92[a]	5.09±0.85	F=17.74 p<0.001*
VAS 30 minutes after hysteroscopy	4.0±0.85	1.78±1.24[a]	2.78±0.79	2.22±1.24[a]	F=19.13 p<0.001*

Used test: ANOVA test.

Fourth table demonstrates the relation that there is a significant differentiation between studied groups when it comes to statistics as regard VAS score when the cervix was grasped, at the time of insertion of hysteroscopy, immediately after hysteroscopy and 30 minutes after hysteroscopy. Post Hoc Tukey test was used to assess within group significance and demonstrates that for VAS when cervix was grasped; no significant difference between local lidocaine gel group & Placebo group, for VAS immediately after hysteroscopy no significant difference detected between Local lidocaine gel group & Paracervical block group, for VAS 30 minutes after hysteroscopy; no significant difference is detected between Diclofenac & placebo groups

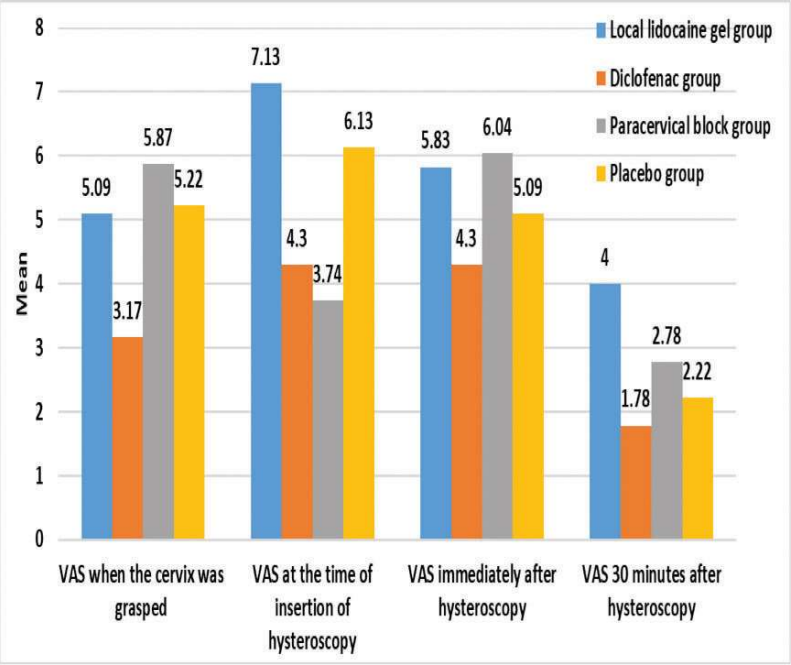

Figure (1) distribution of the studied groups according to VAS score during follow up.

Table (5): systolic blood pressure among studied groups.

Systolic blood pressure	Local lidocaine gel group N=23	Diclofenac group N=23	Paracervical block group N=23	Placebo group N=23	P value
Basal	112.17±12.78	114.78±122.17	122.17±13.47	118.69±16.04	F=1.89 P=0.137
When the cervix was grasped	123.04±11.85[a]	120.87±15.86[a]	134.56±11.77	136.96±9.7	F=9.61 p<0.001*
At the time of insertion of hysteroscopy	134.35±8.95	128.91±14.77	125.22±10.38	131.74±11.14	F=2.66 P=0.053
Immediately after hysteroscopy	127.61±11.66	133.47±13.93	136.08±10.66	129.13±13.11	F=2.28 P=0.085
30 minutes after hysteroscopy	117.61±12.78	118.69±16.94	123.91±13.05	125.22±12.01	F=1.71 P=0.171

Used test: One Way ANOVA test, *statistically significant, similar superscripted letters denote non-significant difference between groups.

Fifth table demonstrates that there is statistically significant difference between studied groups as regard systolic blood pressure when cervix was grasped except between Local lidocaine gel group & Diclofenac group.

Table (6): diastolic blood pressure among studied groups.

diastolic blood pressure	Local lidocaine gel group N=23	Diclofenac group N=23	Paracervical block group N=23	Placebo group N=23	P value
Basal	76.09±7.22	74.35±6.62	76.52±6.47	76.96±5.58	F=0.711 P=0.548
When the cervix was grasped	78.91±6.56[a]	78.04±8.22[a]	86.74±7.48[b]	85.22±5.11[b]	F=9.19 p<0.001*
At the time of insertion of hysteroscopy	86.74±6.68[ab]	82.95±8.54 [acd]	80.43±6.38[ce]	83.48±6.47[bde]	F=3.10 P=0.03*
Immediately after hysteroscopy	81.30±7.57[a]	86.74±7.01[bc]	87.83±6.71[bd]	84.35±5.07[acd]	F=4.34 P=0.007*
30 minutes after hysteroscopy	75.87±6.34[a]	75.65±8.02	81.09±6.73[b]	80.0±6.03[ab]	F=3.87 P=0.012*

Used test: One Way ANOVA test, *statistically significant, similar superscripted letters denote non-significant difference between groups.

Sixth table shows that there is statistically significant difference between studied groups as regard diastolic blood pressure at the following studied periods; when the cervix was grasped, at the time of insertion of hysteroscopy, immediately after hysteroscopy and 30 minutes after hysteroscopy.

Table (7): pulse distribution among studied groups.

pulse	Local lidocaine gel group N=23	Diclofenac group N=23	Paracervical block group N=23	Placebo group N=23	P value
Basal	78.35±5.87	78.61±5.34	76.26±5.54	79.56±6.87	F=1.27 P=0.291
When the cervix was grasped	90.09±7.45	85.56±5.66	94.61±7.92[a]	95.22±7.30[a]	F=9.14 p<0.001*
At the time of insertion of hysteroscopy	105.65±7.88	91.22±6.02[a]	86.0±4.94	90.87±5.15[a]	F=44.41 p<0.001*
Immediately after hysteroscopy	94.35±8.43[a]	96.25±6.45[ab]	99.57±8.79[b]	89.13±5.15	F=8.11 p<0.001*
30 minutes after hysteroscopy	86.22±5.20	83.83±5.22	84.96±5.22	85.48±4.68	F=0.899 P=0.445

Used test: One Way ANOVA test, *statistically significant, similar superscripted letters denote non-significant difference between groups.

Seventh table demonstrates statistically significant change in pulse among the following follow up periods; when the cervix was grasped, at the time of insertion of hysteroscopy, immediately after hysteroscopy and 30 minutes after hysteroscopy.

DISCUSSION

Because it can be performed in an office environment lacking anesthesia, office hysteroscopy is now less complex, faster, and cheaper and poses less complications for the patient. Even while technological advancements, including as the use of thinner, flexible equipment and no-touch procedures, have tremendously decreased patient pain and discomfort during office hysteroscopy, pain is still an important factor in configuring whether this procedure is accepted for most women (12).

In our study, we evaluate how three distinct pain management techniques affect pain and discomfort both during and following office hysteroscopy procedures.

Additionally, a 10 cm VAS was utilized to assess how uncomfortable the treatment was both during and immediately following various process stages.

In contrast to the paracervical block group, which only experienced pain reduction during hysteroscopy advancement through the cervical canal, the group that received diclofenac K preoperatively demonstrated reduced pain scores using VAS during various stages of the procedure and postoperatively.

However, the pain scores in the group that had lidocaine gel applied locally to the cervix are not decreased during or after the procedure.

Our outcome was consistent with these studies regard the effectiveness of diclofenac as a pain control modality for office hysteroscopy:

Abbas and his colleagues come to the conclusion that, VAS scores during hysteroscopy were much less in diclofenac group than placebo group (13).

El-Gamal and his colleagues come to the result that using with 100 mg diclofenac orally one hour before office hysteroscopy decreased median pain scores during and after the procedure (14)

Mohammadi and his colleagues found that the mean pain score was much lower during advancement of the hysteroscope through the cervical canal and removal of the hysteroscope from cervix in the diclofenac group (15)

Our study matched the result of these studies regard the ineffectiveness of paracervical block and topical cervical anesthesia:

Vercellini and colleagues, examined the effect of paracervical anesthetic modality in pain decreasing during hysteroscopy in the outpatient and concluded that it is not effective modality of anesthesia in finishing the procedure without discomfort (16).

Lau and his colleagues found that Paracervical block modality fails to decrease discomfort and agony during outpatient hysteroscopy in addition to posing a tremendous risk of decreasing heart rate and hemodynamic instability that may be originated from accidental injection of anesthetics into the vessels in the cervix (17)

Wong and his colleagues found that there were no differences that signify significance in VAS score of each step and the collective discomfort score between the group that used the local anesthetic gel lignocaine and the control group in their study and concluded that the use of lignocaine gel locally applied to the cervix is not a reliable method in decreasing pain and discomfort at the time of performing hysteroscopy in outpatient setting. (18)

Van den Bosch and colleagues tested the application of lidocaine gel locally to the cervix before performing office hysteroscopy and come to the conclusion that it does not decrease the pain and agony resulting from the procedure (19)

But this result runs counter to these studies regards the effectiveness of diclofenac as a pain control modality for office hysteroscopy:

Yuen and colleagues come to the consensus that there were no positive effects regarding decreased pain neither during performing hysteroscopy nor after the procedure if hysteroscopy is performed one to two hours after diclofenac taken orally by the patients (20).

Hassa and colleagues come to the conclusion that there was no benefit regards decreasing pain by the rectal use of one hundred milligrams of diclofenac one hour before the performance of hysteroscopy in ordinary clinic settings in a trial in which test subject were aligned in two groups in a random controlled fashion. (21)

Our study results were different from these studies regard the effectiveness of paracervical block and topical cervical anesthesia:

Cooper and his colleagues come to the result that Paracervical anesthesia injected into the cervix is the most effective modality to decrease pain and discomfort for female patients getting hysteroscopy performed to them in the office setting in a huge meta-analysis research study; around twenty studies were performed (around 29 hundred patients were enrolled). Included data in fifteen studies were analyzed. Intracervical modality of anesthesia and the local use of anesthetic material for paracervical injections significantly decrease the discomfort and pain in a great deal in female patients underwent hysteroscopy in the office, whereas application of anesthetics locally to the cervical canal and ectocervix resulted in no decrease regard pain scores. Further analysis shows that paracervical injection was by far the most effective pain control modality (22).

Bendary and colleagues examined how effective the use of topical anesthetic agents in a randomly aligned research. They examined the use of EMLA cream, an emulsion mixture, containing two and half percent each of lidocaine/prilocaine to control discomfort and agony during the performance of hysteroscopy in the outpatient

setting, and come to the conclusion that the local application of EMLA cream as an anesthetic modality for hysteroscopy in the outpatient facility is effective, reliable, and easy to use by gynecologists (23).

Chudnoff and colleagues examined the use of paracervical anesthetic injection modality by the use of one percent lidocaine before office hysteroscopic sterilization in a randomly aligned controlled trial and come to the conclusion that the use of lidocaine injected paracervically decreased pain scores tremendously for grasping the cervix and advancement of the hysteroscopy through the cervical canal. At the end they come to the result that Paracervical anesthetic modality by injecting one percent lidocaine give us an effective method to decrease discomfort, agony and pain during different phases of performing hysteroscopy in the outpatient facility, on the other hand it had no effect on reducing discomfort related to distension media use and distending the upper part of the uterus. (24)

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