

Original article:

To compare the effectiveness of 2% intrauterine lignocaine in addition to paracervical block with paracervical block alone for pain relief during hysteroscopy and dilatation & curettage

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ABSTRACT

INTRODUCTION: Hysteroscopy and dilatation and curettage (D&C) are two of the common procedures done in ambulatory day care gynecological practice. This is associated with pain (vas score from 4 to 7). This decreases patient's acceptability and compliance. So, goal of our study was to compare the combination of intrauterine lignocaine with paracervical block and paracervical block alone in reducing the pain during Hysteroscopy and dilatation and curettage

MATERIALS AND METHODS: After written informed consent 70 patients were assigned to two groups. Group A (Control) –IV sedation+ Paracervical block with 10ml of 1% lignocaine + intrauterine 5ml saline Group B (Experimental)– IV sedation+ Paracervical block with 10ml of 1% lignocaine + intrauterine 5ml 2% lignocaine The standard protocol for hysteroscopy and D&C were followed in all patients. Pain was measured using visual analogue scale (VAS) score ranging from 0 to 10. All patients received IVS (intravenous sedation) with inj. pentazocine 15mg + inj. Phenergan (promethazine) 12.5mg prior to the procedure.

RESULTS AND OBSERVATION: Pain perceived by the patients was assessed by the VAS score during all four stages of the procedure.

CONCLUSION: The present study concluded that use of intrauterine 2% lignocaine in combination with paracervical block for hysteroscopy and dilatation& curettage leads to lower VAS score without any hemodynamic changes and causes no serious complications.

KEY WORDS; hysteroscopy, VAS score, intrauterine lignocaine

INTRODUCTION:

Hysteroscopy and dilatation and curettage (D&C) are two of the common procedures done in ambulatory day care gynecological practice. It has both diagnostic as well as therapeutic value in patients with abnormal uterine bleeding (AUB)¹. These procedures are routinely being performed in the operation theatres as most patients experience pain and discomfort. Several studies have shown that pain scores are often high during the procedure. Cervical biopsy and cervical curettage are associated with visual analog scale (VAS) pain scores ranging from four to six on a 10-point scale^{2,3}. Endometrial biopsies have been reported to have VAS scores of five to seven^{4,5}. This decreases patient's acceptability and compliance thereby leading to unsuccessful completion of the procedures. Patient's pain and discomfort are the limiting factor for doing these procedures in gynae outpatient department (OPD).

Generally, these procedures are done under paracervical block and IV sedation. Other methods like oral NSAIDS, intrauterine instillation of local anesthesia, total intravenous anesthesia (TIVA) etc. have also been

tried with varied results for pain relief. Sometimes general anesthesia has to be given. Although GA provides complete analgesia, amnesia, and hypnotic effect but it is associated with higher mortality and morbidity risk as compared to properly administered local anesthetics. Effective pain relief during this procedure will cause faster recovery, shorter hospital stays and early return to work. The cervix receives its innervations from S2 to S4 largely through the uterosacral ligaments, whereas the uterine corpus is innervated by T10 to L1 nerve fibers, distributed with the uterine and ovarian vasculature, in the broad ligament. As a result, procedural anesthesia using local anesthetic agents must consider both the pathway. The paracervical block relieves pain in the lower part of the uterus and cervix. Intrauterine instillation of local anesthesia with lignocaine, bupivacaine etc. into the uterine cavity, has a theoretical action by blocking nerve endings in the uterine corpus and fundus⁶⁻⁷.

Till date very few studies have been done with intrauterine anesthesia in combination with paracervical block to evaluate the pain during these procedures. Recent Cochrane reviews have evaluated the existing literature regarding pain control for hysteroscopy, first trimester abortion, IUD insertion, and hysterosalpingography (HSG), and have concluded that optimal methods for pain control are unclear⁸⁻¹⁰.

So, goal of our study was to compare the combination of intrauterine lignocaine with paracervical block and paracervical block alone in reducing the pain during Hysteroscopy and dilatation and curettage

AIMS AND OBJECTIVES

“To compare the effectiveness of intrauterine Lignocaine in addition to paracervical block with paracervical block alone for pain relief during hysteroscopy and Dilatation&Curettage”

Primary objective:

- To compare the VAS score between the two groups.
- To compare change in NIBP & Pulse rate between the two groups

Secondary objectives:

- To see associated complications like severe hemodynamic alteration and nausea & vomiting.

MATERIALS AND METHODS:

After obtaining clearance from Institutional ethical committee, a prospective randomized double blinded study was conducted at Northern Railway Central Hospital, New Delhi. A well-informed written consent was taken from all patients.

STUDY POPULATION:

70 women who underwent hysteroscopy and D&C in the Age group 18- 60 years within ASA Grade 1-3 at NRCH New Delhi, from July 2017 to April 2019 were included in the study. Exclusion criteria were patients who had severe uterine bleeding, known cervical stenosis, refusal to participate, allergic to local Anesthetic drugs, any severe medical disorders, psychiatric illnesses that would interfere with perception and assessment of pain, inability to understand how to score pain, participating in another study. After their written informed consent patients were assigned to either control or experimental groups using computer-generated random numbers.

Group A (Control) –IV sedation+ paracervical block with 10ml of 1% lignocaine + intrauterine 5ml saline

Group B (Experimental)–IV sedation+ paracervical block with 10ml of 1% lignocaine + intrauterine 5ml 2% lignocaine

Sealed envelopes containing the information of the randomization code were kept by the staff not involved in the study. The standard protocol for hysteroscopy and D&C were followed in all patients. Pain was measured

using visual analogue scale (VAS) score ranging from 0 to 10. All patients received IVS (intravenous sedation) with inj. pentazocine 15mg + inj. Phenergan(promethazine) 12.5mg prior to the procedure. Paracervical block was administered with 10 ml of 1 % lignocaine. Instillation of either 5 ml of 2 % lignocaine (experimental group) or 5 ml normal saline (control group) into the uterus was done using infant feeding tube. The feeding tube was left in place for three minutes before it was withdrawn while patients were in the Trendelenburg position to limit backflow and to allow the anesthetic to take effect. This was followed by uterine sounding, cervical dilatation, hysteroscope insertion and uterine curettage in the usual manner. The procedure was performed by an experienced gynecologist. The gynecologist performing procedure and evaluator (Anesthesiologist) both were not aware of drug used. Each patient was evaluated for the severity of pain by asking the participants to rate their pain levels on a 10-cm visual analog scale

1. At the time of cervical dilatation
2. At the time of hysteroscope insertion through cervix
3. At the time of intrauterine curettage/polypectomy
4. 30 minutes after procedure

The pulse rate and blood pressure were recorded simultaneously.

RESULTS

We collected the data from patients and filled the Performa for every patient. Master charts were prepared for both the groups. Statistical analysis was conducted with Statistical Package for the Social Sciences (SPSS) statistical software version 15.0 and Microsoft excel by using Chi-Square test, paired and unpaired student's t-test. The results were expressed as Mean \pm SD. $P < 0.05$ was regarded as statistically significant, $P < 0.001$ was taken as highly significant, and $P > 0.05$ was regarded as non-significant. A sample size of 70 patients (35 in each group) with the power of study to be 80%

Table-1,2 shows Age and BMI and Patients in both the study groups are comparable with regard to BMI and weight with p values being >0.05 .

Table-3(VAS score)- Pain perceived by the patients was assessed by the VAS score during all four stages of the procedure, pain perceived in the experimental group was significantly lower than that in the control group, with P values less than 0.001* during all four stages respectively'.

Table- 4 (pulse rate). In terms of pulse rate changes, there was no significant difference at baseline pulse rate in both groups, with P value 0.112, but there was a statistically significant increase in control group than experimental group during all four stages of the procedure, with P values 0.028*, 0.013*,0.002* and 0.006* respectively. This may be because of more sympathetic stimulation because of more pain felt in control group.

Table - 5,6 -Systolic blood pressure and change in systolic blood pressure

The mean systolic arterial blood pressure at baseline showed statistically significant increase in the experimental group as compare to control group, with P values 0.011*, it was because of more hypertensive patients were present in experimental group than control group. In experimental group there were 24 patients who had systolic blood pressure >150 mm of Hg where as in control group there were only 12 patients who had systolic blood pressure >150 mm of Hg.

Since baseline BP was higher in experimental group, all further readings were higher in the experimental group compared to control group so we compared the change in SBP from baseline SBP in both the groups at all four

events. As compared to the baseline rise in SBP was found to be higher in control group than experimental group, though it was not statistically significant

Table 7-diastolic blood pressure- No significant Changes were seen in diastolic blood pressure in both groups. No significant complications like nausea, vomiting, bradycardia, hypotension or any symptoms suggestive of lignocaine toxicity was seen.

Table:1

Groups	Age (years)				
	Mean	Std. Deviation	Mean Difference	t-test value	p-value
Experimental group (group B)	49.23	7.37	2.06	1.200	0.234
Control group (group A)	47.17	6.96			

Fig.3

Table:2

Groups	BMI				
	Mean	Std. Deviation	Mean Difference	t-test value	p-value
Experimental group (group B)	28.82	3.68	2.48	1.538	0.093
Control group (group A)	26.34	4.44			

Table:3

At the time of	Experimental group (group B)		Control group (group A)		Mean Difference	t-test value	p-value
	Mean	Std. Deviation	Mean	Std. Deviation			
Cervical dilatation	1.49	0.56	2.77	0.91	-1.29	-7.110	< 0.001*
Hysteroscope insertion through cervix	1.89	0.58	4.03	1.36	-2.14	-8.563	< 0.001*
Intrauterine curettage/polypectomy	2.14	0.85	4.86	1.26	-2.71	-10.563	< 0.001*
30 minutes after procedure	1.43	0.61	2.43	1.40	-1.00	-3.878	< 0.001*

Table:4

At the time of	Experimental group (group B)		Control group (group A)		Mean Difference	t-test value	p-value
	Mean	Std. Deviation	Mean	Std. Deviation			
Baseline	76.91	8.32	80.54	10.43	-3.63	-1.609	0.112
Cervical dilatation	81.00	7.63	86.00	10.72	-5.00	-2.248	0.028*
Hysteroscope insertion through cervix	82.03	6.85	87.69	11.15	-5.66	-2.558	0.013*
Intrauterine curettage/polypectomy	82.43	6.45	89.23	10.97	-6.80	-3.161	0.002*
30 minutes after procedure	77.34	6.65	83.40	10.88	-6.06	-2.809	0.006*

Table:5

At the time of	Experimental group (group B)		Control group (group A)		Mean Difference	t-test value	p- value
	Mean	Std. Deviation	Mean	Std. Deviation			
Baseline	153.14	15.13	144.23	13.27	8.91	2.620	0.011*
Cervical dilatation	161.03	13.77	153.20	13.84	7.83	2.373	0.021*
Hysteroscope insertion through cervix	161.54	14.50	154.37	13.98	7.17	2.106	0.039*
Intrauterine curettage/polypectomy	161.43	15.69	154.66	15.64	6.77	1.808	0.075
30 minutes after procedure	154.51	15.47	146.80	13.90	7.71	2.194	0.032*

Table:6

Events	Experimental group (group B)		Control group (group A)		Mean Difference	t-test value	p-value
	Mean	Std. Deviation	Mean	Std. Deviation			
from baseline to Cervical dilatation	7.89	4.52	8.97	4.13	-1.09	-1.049	0.298
from baseline to Hysteroscope insertion through cervix	8.40	5.51	10.14	4.30	-1.74	-1.476	0.144
from baseline to Intrauterine curettage/polypectomy	8.29	7.44	10.43	6.87	-2.14	-1.252	0.215
from baseline to 30 minutes after procedure	1.37	3.17	2.57	4.94	-1.20	-1.210	0.231

Table:7

At the time of	Experimental group (group B)		Control group (group A)		Mean Difference	t-test value	p-value
	Mean	Std. Deviation	Mean	Std. Deviation			
Baseline	80.11	7.71	81.57	6.25	-1.46	-0.868	0.388
Cervical dilatation	85.09	7.58	86.63	6.79	-1.54	-0.897	0.373
Hysteroscope insertion through cervix	85.54	6.86	87.51	6.99	-1.97	-1.191	0.238
Intrauterine curettage/polypectomy	85.20	8.19	87.83	8.05	-2.63	-1.354	0.180
30 minutes after procedure	80.63	6.96	86.17	16.85	-5.54	-1.799	0.076

DISCUSSION-

Abnormal uterine bleeding (AUB) is the second most common gynecological problem in premenopausal and postmenopausal women¹⁵. It accounts for one-third of total outpatient gynecological consultations. Evaluation is a must, for the establishment of treatment plan. In a developing country like India, because of lack of resources and infrastructure it is difficult to performed all such procedures in OT. Hence most of the patients need to undergo the procedures on an OPD basis. The technique of endometrial sampling may vary depending on the patient's age, menopausal status, clinical suspicion of malignancy, availability of instruments etc.²⁰endometrial sampling is routinely done in our institute using uterine curette. This makes the procedure painful.It is very important to control pain adequately during these procedures because pain relief will increase patient's acceptability and compliance for the same.

The limited efficacy of paracervical block alone or intrauterine lignocaine alone is likely because of its inability to block the whole nerves supplying the cervix and the uterus. Hence, it is expected that the combination of the two techniques exerts a more powerful effect than each technique alone.

A strict watch was kept on any adverse event during and after the procedure. The procedures were, in general, well tolerated. In our study we have found significant difference in pain profile between the experimental group (group-B) vs control group (group-A) (pain score 1.49 vs 2.77 during Cervical dilatation, 1.89 vs 4.03 during Hysteroscope insertion through cervix, 2.14 vs 4.86 during Intrauterine curettage/polypectomy and 1.43 vs 2.43 30 minutes after procedure).VAS scores being lower in control group at all stages.

Arora Aashima et al¹⁵. had conducted similar study in which all patients received either intrauterine 2 % lignocaine or normal saline along with oral NSAID and paracervical block prior to the procedure. They found decrease in VAS score in experimental group but their VAS score was much higher than our study most probably because we had used inj.pentazocine and inj. Phenergan as premedication vis a vis NSAIDS in their case. Our results were similar to Alaa El Deen Mahmoud Sayad et al¹⁶ who had observed that intrauterine lidocaine in combination with paracervical block significantly provides adequate intraoperative and postoperative analgesia as compared to only paracervical block. They had to use inj. fentanyl in 18 patients out of 30 patients (Lignocaine +Paracervical) during procedure as they did not give IV sedation prior to procedure like our study. They also found that intrauterine lidocaine alone did not provides adequate intraoperative analgesia Our study in accordance with Rattanachaiyamont et al.¹² who also found statistically significant reductions in pain when a combination of paracervical block and intrauterine anesthesia was used before fractional curettage (pain score 2.3 vs. 4.7) .

In contrast to our study Lau et al¹⁹ reported in their study that intrauterine anesthesia reduced the pain score from 13.4 to 11.5 on a 20 cm scale and was statistically ineffective in decreasing pain in hysteroscopy and endometrial biopsy compared to a placebo (5, 8). This may be because they did not combine both modalities i.e. paracervical block with intrauterine lignocaine also they used CO₂ for distension of uterus with pressure of 100mmhg whereas in our case saline was used to distend the uterus.

Chanrachakul et al.¹¹ also reported that paracervical block with lidocaine as compared to saline decreased pain in fractionated curettage without causing any complications but vas scores in their study were more than 7 as they had used only paracervical block. In our study, in terms of pulse rate changes, there was no significant difference at baseline pulse rate in both groups but there was a statistically significant increase in control group than experimental group during all four stages of the procedure which may suggest a more intense sympathetic response to the greater magnitude of pain perceived in the paracervical block group.

Arora Aashima et al¹⁵ also found the increment in heart rate was significantly more in placebo group. In Alaa El Deen Mahmoud Sayad et al¹⁶ study heart rate showed a significant increase in the paracervical block group in comparison with the combined technique group. Meenambiga and Haribaskar¹⁴ and Rattanachaiyamont et al.¹²also found the change in heart rate profile which was similar to our study. The mean systolic arterial blood pressure at baseline showed statistically significant difference in both the study groups. In experimental group there were 24 patients who had systolic blood pressure >150 mm of Hg where as in control group there were only 12 patients who had systolic blood pressure >150 mm of Hg. In our study change in the mean systolic and diastolic arterial blood pressure showed no significant difference in both the groups. Arora Aashima et al.¹⁵ and Alaa El Deen Mahmoud Sayad et al.¹⁶ who also found that the change in mean systolic and diastolic arterial

blood pressure was statistically not significant in both groups. In contrast with our study Rattanachaiyamont et al.¹² did find increase in the mean systolic and diastolic arterial blood pressure because they had used adrenaline in paracervical block.

Conclusion-

The present study as well as the review of literature on this subject concluded that use of intrauterine 2% lignocaine in combination with paracervical block for hysteroscopy and dilatation& curettage leads to lower VAS score without any hemodynamic changes and causes no serious complications.

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