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Original Research Article

Assessment of pain relief following intrauterine lignocaine in addition to paracervical block for fractional curettage

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ABSTRACT

Background: To assess the pain relief using visual analog score following intrauterine lignocaine in addition to paracervical block for fractional curettage.

Methods: This study was a prospective, double blinded randomized controlled trial conducted in 168 patients in the department of obstetrics and Gynecology, Thanjavur Medical College with abnormal uterine bleeding. All patients received either intrauterine 2% lignocaine or Normal saline along with oral misoprostol 200µg and paracervical block prior to the procedure. The primary outcome was the assessment of pain perceived at the time of curette, soon after procedure (5 mins); 30 minutes later using VAS.

Results: Both the groups were matched for age, parity, BMI, menopausal status, socioeconomic status and indication for the procedure. Patients in lignocaine group perceived less pain when compared to that in placebo group. There was no difference in both groups with respect to other outcomes.

Conclusions: Addition of intrauterine 2% lignocaine in addition to paracervical block and oral misoprostol reduces pain making fractional curettage as a patient friendly procedure.

Keywords: Fractional curettage, Intrauterine lignocaine, Pain relief

INTRODUCTION

Dilatation and curettage (D and C) and fractional curettage (F/C) are two commonly performed gynecological procedures which were traditionally done in the operation theatre (OT) but are now routinely performed in the outpatient department (OPD) because of increasing work load and relative lack of time. A major obstacle to the successful completion of outpatient gynecologic procedures is pain. Most patients can tolerate pain to complete necessary procedures but studies show that pain scores are often high. Cervical biopsy and cervical curettage are associated with visual analog scale (VAS) pain scores ranging from four to six on a 10-point scale.^{1,2} Endometrial biopsies have been reported to have VAS scores of five to seven.^{3,4}

Fractional curettage is a common procedure for investigating the causes of abnormal uterine bleeding in perimenopausal women. Fractional curettage is usually performed under a local anesthesia, paracervical block, which has been used for minor gynecologic procedures since 1925.¹ The paracervical block is shown to be effective for pain reduction during fractional curettage, but the pain intensity under paracervical block is still considered moderate pain.^{5,6} The reason that paracervical block cannot totally alleviate the pain during fractional curettage can be partly explained by the neuroanatomy of the uterus and cervix. The paracervical block relieves pain in the lower part of the uterus and cervix by blocking nerve impulses that are conveyed through the uterovaginal plexus, but it may not be effective for pain in the upper part of the uterus, which has a different

innervations. Intrauterine anesthesia, by infusion of local anesthesia in the uterine cavity, has theoretical action by blocking nerve endings in the uterine corpus and fundus. The effectiveness of intrauterine anesthesia for pain relief in gynecologic procedures that involve the uterine cavity has been demonstrated in many studies.^{7,8} It is logical to add intrauterine anesthesia to the paracervical block to enhance the anesthetic effect.⁹⁻¹¹

METHODS

This study was a prospective double blinded randomised controlled trial conducted in the department of obstetrics and gynaecology, Thanjavur Medical College.

Selection criteria

Women with AUB after careful assessment by the gynecologist in the premenstrual phase. Consent for the procedure obtained.

Exclusion criteria

Virgins; previous surgeries on cervix, >2 LSCS, Acute PID, H/o pelvic radiotherapy, previous H/o allergy to lignocaine or to misoprostol.

Patients were allocated to either control or experimental groups using computer generated random numbers. A person not involved in the study produced the experiment code. Those codes were provided in sealed packet containing the drug for the control as well as experimental groups. The placebo drug was identical in physical appearance (i.e. colorless clear solution) and was filled in 5ml disposable syringe without labelling. The packets were opened by the staff nurse just prior to procedure. Thus the gynecologist, the staff nurse and the patients were blinded to the experiment. All the procedures and pain assessment were carried out by a single operator to avoid bias.

The standard protocol of the department for FC was followed in all patients. All patients received oral misoprostol 200 µg 1 h prior to the procedure. Paracervical block was administered to all as per the standard protocol. A total of 10ml of 1% lignocaine was injected through a 23 G disposable syringe at 3 and 9 o'clock positions of cervi-covaginal junction at approximately 1 cm depth after prior aspiration to avoid intravenous injection. It was attempted to keep cervical manipulation to minimal to avoid imparting pain to patient. Instillation of either 5 ml of 2% lignocaine (experimental group) or 5 ml normal saline (control group) into the uterus was done using 20 G spinal needle. The needle was left in place for 2 min before withdrawing to limit the backflow and allow contact time for the anesthetic to act. This was followed by uterine sounding, cervical dilatation (if found necessary), and uterine curettage in the usual manner.

Each patient made three assessment of the severity of pain using a visual analog scale. Immediately after the procedure was over, the pain score during the point of curettage and soon after procedure was evaluated by asking the participants to rate their pain levels on a 10-cm VAS where 0 signified no pain and 10 described worst-ever, agonizing unbearable pain. The pain was reassessed in a similar way half an hour after the procedure. The pulse rate was recorded immediately after the procedure.

The primary outcome measures of this study were the severity of the pain perceived by the patient, whereas the secondary outcomes were the complications associated with the procedure, the adverse effects of the drugs being used, and the effect on the yield of the specimen.

Data were analyzed by SPSS 15. Before comparing the groups, each variable was tested for normality distribution. The data were processed using the student t test and the Chi-square test which ever was appropriate.

RESULTS

The patients in both groups were matched for age, parity, BMI, menopausal status and indications for AUB as shown in Table 1.

Table 1: Demographic profile of the study group.

Features	Lignocaine (n=84)	Placebo (n=84)
Age (yrs)	43.3±4.01	44.81±6.46
Mean BMI	24.6±3.8	25±3.3
Parity		
0 - 1	16	4
2 - 3	54	58
4 or more	14	22
Previous Births		
Vaginal	60	58
Previous 1 LSCS	22	25
Previous 2 LSCS	2	1
Menopausal Status		
Premeno pausal	76	66
Postmeno pausal	8	18
Low socioeconomic status	60	58
Indications		
Menorrhagia	24	22
Poly Menorrhoea	30	26
Irregular Bleed	10	08
Post Meno pausal bleed	8	18
USG reveals hyperplasia (or) Thickened endometrium	10	8
Others (endometritis, polyp)	2	2
Co- morbidities		
HT	15	20
Type 2 DM	20	22
Thyroid disorders	10	12
Previous 2 LSCS	2	1

Three nulliparous women underwent fractional curettage in view of secondary infertility, endometritis not responding to antibiotics and hemostatics.

Patients with co-morbidities underwent the procedure only if the blood pressure, blood sugars and TSH values are under Control.

As most of the patients were multiparous cervical dilation was not needed. As oral misoprostol was given prior to procedure even in nulliparous women cervical dilation was not needed.

Perception of pain was assessed using VAS scale (0-10) at the time of curette, 5 minutes after procedure and 30 minutes later. At all the three stages, along with VAS scale pulse rate, blood pressure, SPO₂ were monitored. At all the three stages, pain experienced in lignocaine group was significantly less as compared to that in placebo group.

There is no difference in pain based on the parity, menopausal status and BMI. VAS > 6 was considered as severe pain. Severe pain (VAS >6) was noticed in 86% of placebo group in contrast to 40% of lignocaine group. This was statistically significant. (P=0.001)

Rise in pulse rate was observed in 30 patients in placebo group when compared to lignocaine group (10 patients). Four patients in placebo group developed vasovagal reaction which was timely identified and treated with supine posture, I.V. fluid. No vasovagal shock happened in lignocaine group.

Endometrial samples were adequate in both groups. There was no effect of lignocaine or normal saline on the samples analysed by the pathologists.

Table 2: Vas score.

	Placebo group	Lignocaine group	P value
The time of curette	6.8±1.4	5.3±1.1	0.00
5 minutes after procedure	5.2±1.3	3.7±1.3	0.00
30 minutes after procedure	3.3±1.4	2.1±1.2	0.002

Table 3: Complications.

	Placebo group	Lignocaine group
Severe pain (VAS >6)	86%	40%
Vasovagal shock	7%	0
Increment in pulse rate (>15 beats /min)	21%	6.4%

DISCUSSION

Next to leucorrhoea, abnormal uterine bleeding is the second most common gynaec complaint in premenopausal and post menopausal women. AUB constitutes about 30% of gynecological consultations. To decide the treatment plan endometrial evaluation is must in cases of AUB. In low resource settings, endometrial evaluation has to be planned as an outpatient procedure since most women are not willing to undergo procedures as inpatients.

The technique of endometrial sampling may vary depending on patient's age, menopausal status, clinical suspicion of malignancy, availability of instruments, etc. In the present times, FC has largely been replaced by non-invasive instruments like Pipelle or Vibra vacuum aspirator. The efficacy of these instruments for diagnosis of endometrial hyperplasia and carcinoma has been proven in multiple studies over last 2 decades. However, it has been seen in these studies that these devices are superior for diagnosing malignancy as compared to benign diseases. Also, these devices are ideal for postmenopausal women where suspicion of malignancy or its precursors is high. For premenopausal women, where the cause of AUB is expected to be benign, Pipelle may prove to be less efficacious. Studies have shown that the sensitivity of Pipelle in diagnosing polyps and endometritis is 57-60%. Also, in countries like India where tubercular endometritis is still prevalent, instruments like Pipelle which sample only 4% of the endometrial surface may not be ideal. Pipelle is not freely available in this part of the country, and its disposable nature also increases the cost of the procedure. Considering all these factors, endometrial sampling is routinely done in our institute using Novak's uterine curette. This makes the procedure painful. Studies have found that 60-80% of patients who did not receive anesthesia experienced moderate to severe pain. Patient acceptability and compliance might be difficult; therefore, adequate measures for pain relief are necessary before performing these procedures.

The present study indicates that two percent intrauterine lignocaine significantly decreases the pain perception during intrauterine gynecological procedures such as FC. This is a simple, effective, inexpensive, and low risk intervention which can potentially increase the patient acceptability and compliance with such procedures. In this study, a combination of intrauterine lignocaine and paracervical block was compared with intrauterine placebo and paracervical block. The combination may have synergistic effects because of different neural pathways of uterus and cervix. Major autonomic nerves arise from S2 to S4 roots and innervate uterus in the lower portion of broad ligament as the Frankenhauser plexus. The basis of paracervical block is the interruption of this dense plexus. However, the uterus and cervix receive nerve supply from other sources as well. Sympathetic innervations from T10 to L1 roots enter the

uterus following the anastomosis of the uterine artery. Also well-defined nerve plexuses lie in the endometrium and along the mucosal surface of the cervix which are fed by both the ascending and descending roots. The limited efficacy of paracervical block is likely due to its inability to block these nerves. Hence it is expected that intrauterine anesthesia, which may reach these nerves more effectively, will provide more global anesthesia, especially in conjunction with paracervical block.

Rattanachaiyamont et al carried out a double blinded, randomized, placebo-controlled trial in 66 patients with abnormal uterine bleeding undergoing FC with Sims curette.¹² All patients received paracervical block in conjunction with either intrauterine lignocaine or saline. They observed statistically significant difference in the pain profile between the two groups (pain score 2.3 vs. 4.7). However, there was no difference in the profiles of pulse rate and mean arterial blood pressures. We found that in our patients, the increment in heart rate was significantly more in placebo group which may suggest a more intense sympathetic response to the greater magnitude of pain perceived in this group.

Another randomized, double-blind controlled trial in 200 patients by Hui et al found that the use of intrauterine lignocaine reduced pain during suction curettage in endometrial sampling (pain score 2.1 vs. 4.2).¹³

Dogan et al in a randomized, double-blind, placebo controlled study in 1230 patients undergoing endometrial biopsy using Pipelle device.¹⁴ The mean pain scores in NSAID only and lignocaine only groups were not significantly different compared with placebo group. However, the pain score in lignocaine plus NSAID group showed significant reduction (4.6 vs. 7.1).

One of the major concerns in the use of anesthetic agents is the safety of the drug used. Lignocaine can be associated with adverse effects ranging from mild toxicity such as perioral numbness and dizziness to convulsion and respiratory arrest. The safety of this modality of pain relief has been proven in various studies.

Even with the use of 4% lidocaine, the highest serum lidocaine level recorded was 4.0 µg/ml which is well below the known toxicity level of 8µg/ml. This was also proven by Edelman et al in a randomized double-blind, placebo controlled trial of 80 women undergoing first trimester abortion.¹⁵ Due to this wide gap between pharmacological and toxicity levels, we did not measure the serum lignocaine in our patients. However, a strict watch was kept on any adverse event during and after the procedure. The procedures were, in general, well tolerated; however, four patients in placebo group had vasovagal reaction. All the patients recovered rapidly on being put to rest in supine position with their respective pulse rates and blood pressures picking up within 10 min.

The present study as well as the review of literature on this subject shows that there is good evidence to support use of intrauterine lignocaine for endometrial biopsy and curettage.

CONCLUSION

The combination of paracervical block and intrauterine anaesthesia is more effective than paracervical block alone in the pain relief during fractional curettage. The addition of intrauterine anaesthesia does not increase the adverse effects of paracervical block. In low resource settings this procedure can be done performed safely as an outpatient procedure thereby it proves to be cost effective.

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Ethical approval: The study was approved by the Institutional Ethics Committee

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