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Evaluation of four different methods of analgesia for pain relief in patients of dilatation & curettage: A randomized comparative study

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Abstract
Introduction: Dilatation and curettage is a diagnostic procedure in management of abnormal uterine bleeding. In a developing country like India with dense population and limited resources it becomes a necessity to provide simple, effective, inexpensive and low-risk method of pain relief which can be used in an outpatient setup. So, this study was planned to determine an effective modality of pain relief for this procedure.
Methods: This was a prospective, randomized, comparative study conducted among 140 patients. The patients were divided into 4 groups:
Group A: Paracervical block
Group B: Paracervical block with intrauterine lignocaine
Group C: Intravenous diclofenac
Group D: Intravenous diclofenac with intrauterine lignocaine
Pain was analyzed using pain rating scale immediately and 30 min after the procedure. Patient was assessed 2 hourly after the procedure using PADSS score (post anaesthetic discharge scoring system scale) and patient was discharged if PADSS score is more than 9.
Results: The patients were well matched in age, parity, weight, number of vaginal births, menopausal status and indications for intervention among the groups and no statistically significant differences were observed in the baseline characteristics. Patients in Group B (Paracervical block with intrauterine lignocaine) had significantly low pain score immediately (1.69±0.47)as well as 30 min after the procedure(2.37±0.49), followed by group D (intravenous diclofenac with intrauterine lignocaine 3.71±0.75, 4.51±0.65).
Group A and Group C required rescue analgesic in 25 and 22 patients respectively. However, rescue analgesic was required in only 3 patients of group D
Early discharge of the patient was observed in group using combination of paracervical block with intrauterine lignocaine which had maximum PADDS score (11.71±0.45 at 2 hours after the procedure). No serious adverse effects were observed during the study. Most common adverse effect observed was nausea and vomiting apart from other minor adverse effect like dizziness, light-headiness, nausea/vomiting, metallic taste and perioral numbness.
Conclusion: Adequate intraoperative and postoperative analgesia is ensured when combination of analgesic/ anaesthetic agent is used. Maximum pain relief, as reflected by pain scores was in group using combination of paracervical block and intrauterine lignocaine which also had highest PADDS score that allowed early discharge of the patient.

Keywords: Dilatation and curettage, pain, analgesia, intrauterine lignocaine, paracervical block

Introduction

Abnormal uterine bleeding (AUB) is defined as bleeding from the uterine corpus that is abnormal in regularity, volume, frequency, or duration and occurs in the absence of pregnancy [1, 2]. Abnormal uterine bleeding is very common among women of reproductive age group affecting 9 to 30% of women between menarche and menopause. It may be acute or chronic. Acute AUB refers to an episode of heavy bleeding that is of sufficient quantity to require immediate intervention to prevent further blood loss [2] Acute AUB may occur spontaneously or superimposed on chronic AUB (abnormal uterine bleeding present for most of the previous 6 months).

In India, abnormal uterine bleeding has a high prevalence (17.9%) and has a significant impact on the physical, social and emotional aspects of the life of the women [3].

Dilatation and curettage is a diagnostic procedure in management of abnormal uterine bleeding, in which cervix is dilated and uterine contents are curetted. Histopathological examination of these contents helps in management of abnormal uterine bleeding. Earlier, it was commonly performed in the operation theatre (OT) but due to paucity of time, clinicians prefer to do it as outpatient department (OPD) procedure. The chief obstacle in satisfactory completion of procedure is pain. The neuroanatomy of cervix & uterus explains the origin of pain [4]. In a developing country like India with dense population and limited resources it becomes a necessity to provide simple, effective, inexpensive and low-risk method of pain relief which can be used in an outpatient setup. Different methods have been used for pain relief in Dilatation & Curettage *viz*. IV sedation, IV NSAIDS, general anesthesia & local administration of anesthetic agent. Among local methods, the most commonly used methods are local lignocaine jelly, intrauterine lignocaine and paracervical block with lignocaine. Paracervical block relieves pain in the lower part of the uterus and cervix by blocking nerve impulses that are conveyed through the Franken Hauser plexus (parasympathetic S2-S4), but are not effective for pain in the upper part of the uterus (sympathetic nerves T_{10} to L1 via the infundibulopelvic ligament from the ovarian plexus) [4,5]. Paracervical block has routinely been used for pain reduction during minor procedures but the pain intensity during paracervical block is still considered as moderate. Paracervical block alone is not very effective in pain relief in minor procedures. Intrauterine anesthesia, by the infusion of a local anesthetic into the uterine cavity provides pain relief by blocking nerve endings in the uterine corpus and fundus [6]. The peak anesthetic effect occurs within 5-10 min after topical application of lignocaine [7].

Randomized controlled trials have shown that topical anesthesia effectively reduces pain in endometrial sampling and hysteroscopy. Varied results in pain relief have been observed with the use of local anaesthetics ranging from mild to moderate relief of pain. Although use of general anesthesia provides complete analgesia, amnesia, and a hypnotic effect, but it is also associated with higher morbidity compared to local anesthetics.

Intravenous sedation agents relieve pain of minor procedures moderately but cause prolonged hospital stay. Non-steroidal anti-inflammatory drugs (NSAIDs) such as diclofenac and dexketoprofen, trometamol have established role in the management of dysmenorrhea and related inflammatory disorders. Diclofenac is a cyclooxygenase inhibitor. Cyclooxygenase is the key enzyme involved in the metabolism of arachidonic acid into various prostaglandin mediators of inflammation and pain. Pain during fractional curettage occurs from the direct stimulation of the uterine wall and disruption of endometrium. This results in prostaglandin release leading to uterine contraction and pain sensation in the upper part of the uterus [8, 9].

Combination of intravenous diclofenac & local anaesthetic is supposed to have good pain relief due to dual mechanism of action. However, limited literature is available using combination of these two modalities in Indian population. Though local anaesthetic methods may have the benefit of early ambulation & decreased duration of hospital stay but it needs to be evaluated whether pain relief offered by them is comparable to intravenous diclofenac. In this context the present study was planned to evaluate effects of different methods of pain relief (Paracervical block, paracervical block with intrauterine lignocaine, intravenous diclofenac, and intravenous diclofenac with intrauterine lignocaine) for pain relief in dilatation and curettage.

Material& Methods

This was a prospective, randomized, comparative study conducted among 140 patients at Department of Obstetrics and Gynecology in Deen Dayal Upadhyay Hospital, New Delhi from Jan 2020 to May 2021 after obtaining institutional scientific and ethical committee clearance. All adult married females with abnormal uterine bleeding undergoing dilatation & curettage were included in study. Women with medical disorders including severe cardiovascular disorder, epilepsy, respiratory illness, psychiatric illness, allergy to local anaesthetic agent, allergy to non-steroid anti-inflammatory drugs, inability to comprehend pain score, history of bleeding disorder, thrombocytopenia and gastric ulcer were excluded from the study.

Sample size Calculation: The study of Aashima Arora, *et al*. (2015) [4] observed that pain score during procedure and immediate post procedure in lignocaine was 5.36±1.2 and 3.7±1.2 respectively. Taking these values as reference and assuming difference of 1 in pain score between lignocaine and paracervical block, the minimum required sample size with 90% power of study and 5% level of significance is 31 patients in each study group. Taking lost to follow up as 10%, total sample size taken is 140 (35 patients per group).

Formula used is:

For comparing mean of two groups

N>=2 (standard deviation) 2* (Zα + Zβ) 2 (Mean difference) 2

Where

Zα is value of Z at two sided alpha error of 5%

Zβ is value of Z at power of 90%

Mean difference is difference in mean values of two groups.

Calculations:

Pain score during procedure

N>=2(1.2)2 *(1.96+1.28)2 (1)2
>=30.23=31(approx.)

Pain score immediate post procedure

N>=2(1.2)2 *(1.96+1.28)2 (1)2
>=30.23=31(approx.)

Taking lost to follow up as 20%, n>=31/.9=34.44=35 (approx.)

140 patients were selected and divided into 4 groups using concealed envelope method. The patients were divided into 4 groups: paracervical block or intravenous diclofenac with or without 1% intrauterine lignocaine.

Before the procedure a written and informed consent was obtained from the patient. Vitals (pulse rate, blood pressure, respiratory rate) were checked before the procedure.

Group A: Paracervical block was administered using a 22 G needle; 5 ml of 1% lidocaine was injected after sensitivity test at 2 and 8 o'clock position.

Group B: Paracervical block was administered using a 22 G needle, and 5 ml of 1% lignocaine was injected after sensitivity test at 2 and 8 o'clock position. The intrauterine instillation was given immediately after paracervical block. A suction catheter (size 6 Fr) was inserted after sensitivity test into the endometrial

cavity up to 2–3 cm distal to the internal os. Thereafter, 5 ml of 1% lignocaine solution was instilled slowly through the catheter into the uterine cavity and then clamped for 5 min until withdrawal of the catheter to decrease backflow and allow the anesthetic to take effect.

Group C: In patients with intravenous diclofenac 1mg/kg with max of 75 mg was given 10 min before procedure.

Group D: Intravenous diclofenac 1mg/kg with max of 75 mg was given 10 min before procedure followed by intrauterine block. Suction catheter (size 6 Fr) was inserted into the endometrial cavity up to 2–3 cm distal to the internal os. Thereafter, 5 ml of 1% lignocaine solution was instilled after sensitivity test slowly through the catheter into the uterine cavity and then clamped for 5 min until withdrawal of the catheter to decrease backflow and allow the anaesthetic to take effect. All the groups were analyzed for pain scores and duration of hospital stay. Pain was analyzed immediately after the procedure & 30 min after the procedure using pain rating scale. Subsequently, pain was assessed as part of the PADSS score every 2 hours. If the pain score was more than 3 at any assessment, intravenous paracetamol was given as rescue analgesic as per institutional protocol. Fitness of patient for discharge was assessed 2 hourly after the procedure using PADSS score (post anaesthetic discharge scoring system scale: Table 1) [10] and patient was discharged if PADSS score was more than 9.

Results

The 140 study patients were randomized in 4 groups-paracervical block and intravenous diclofenac with and without intrauterine lignocaine using envelope method. They were well matched in age, parity, weight, number of vaginal births, menopausal status and indications for intervention among the groups and no statistically significant differences were observed in the baseline characteristics. The mean age of the groups was 41.46±3.92, 41.06±4.03, 41.69±5.44 and 40.43±4.92 and was comparable.

Patients in Group B (Paracervical block with intrauterine lignocaine) had significantly low pain score immediately as well as 30 min after the procedure, followed by group D (intravenous diclofenac with intrauterine lignocaine) as shown in Table 2.

The requisite PADSS score a was achieved earlier in group B (Paracervical block with intrauterine lignocaine) and group D (intravenous diclofenac with intrauterine lignocaine) as shown in Table 3. As the desired PADDS score of 9 or more was achieved just after 2 hours of the procedure, it allowed early discharge of patients in group B (Paracervical block with intrauterine lignocaine) followed by group D (intravenous diclofenac with intrauterine lignocaine). This was followed by group A (paracervical block alone) and group C (intravenous diclofenac alone). Consequently, duration of hospital stay was significantly low in Group B as shown in Table 4.

Group A and Group C required rescue analgesic in 25 and 22 patients respectively. However, rescue analgesic was required in only 3 patients of group D. None of the patients of Group B required administration of rescue analgesic. In the patients of group A and C, the pain score 30 minutes after the procedure however was still higher than other groups (6.06 and 6.43 v/s 2.37 and 4.51) as depicted in Table 2.

Only few complications were observed in this study (Table 5). One patient reported vasovagal reaction with was resolved within few minutes with supportive management. Tachycardia though not significant was observed in few patients may be because of pain or anxiety of the procedure. These patients also had high PRS scores and received rescue analgesic as per protocol. Inadequate specimen was observed mostly in group C & A probably because of inadequate analgesic/anaesthetic effect.

No serious adverse effects were observed during the study. Most common adverse effect observed was nausea and vomiting apart from other minor adverse effect like dizziness, light-headiness, nausea/vomiting, metallic taste and perioral numbness (Table 6).

Discussion

Abnormal uterine bleeding is common among perimenopausal and postmenopausal age group. Evaluation of endometrium is required in women with abnormal uterine bleeding in this age group and also for women more than 35 years with a history suggestive of unopposed estrogen exposure [4]. Earlier, it was performed in the operation theatre (OT) but due to crunch of time & increasing number of cases, clinicians prefer to do it as an outpatient department (OPD) procedure. The main hurdle for proper completion of procedure is pain. Procedural pain control should be done properly, as this determines patient acceptability to the procedure.

The present study showed maximum pain relief with paracervical block and intrauterine lignocaine followed by intravenous diclofenac with intrauterine lignocaine.

This finding is also reiterated in another study conducted by Sayed *et al* [5] who observed that the group using combination of paracervical block with intrauterine lignocaine had more significant decrease in pain score. It provided adequate intraoperative and postoperative analgesia, more than paracervical alone or intrauterine lignocaine alone.

On, review of literature, no study was found using combination of intravenous diclofenac with intrauterine lignocaine. Combination of intravenous diclofenac with intrauterine lignocaine significantly decreased pain scores in comparison to intravenous diclofenac alone. The above data reiterates the importance of a local anesthetic agent for painless intrauterine procedure. However, one local anesthetic agent alone was not sufficient for pain relief in these minor procedures as reflected from the data of Group A (Paracervical block alone alone). The role of NSAIDs cannot be underestimated as their systemic effect of inhibiting prostaglandin synthesis acts in synergy with local anesthesia to provide the best possible analgesia to the patient. This was also proven by Dogan *et al* [11] in a randomized, double-blind, placebo-controlled study conducted among 120 patients. He compared the efficacy of combination of intrauterine lignocaine with oral naproxen sodium v/s oral naproxen alone v/s intrauterine lignocaine alone on pain perception among the patients undergoing endometrial biopsy using pipelle instrument. He concluded that intrauterine lignocaine instillation significantly decreases pain associated with pipelle endometrial biopsy when it is used with oral naproxen.

Majority of patients of Group A (paracervical block alone) and Group C (iv diclofenac alone) received rescue analgesic. The effect of rescue analgesic might not have been attained by 30 minutes as reflected in the high pain scores in these patients 30 minutes after the procedure.

However, relief of pain was gradually achieved in these patients as depicted in the improving PADSS scores 2, 4, 6 and 8 hours after the procedure.

During the procedure, when the patient experiences no or minimal pain, adequate histopathological sample can be

obtained. Although not statistically significant, higher frequency of inadequate histopathological sample was observed in Group A and C. This may probably be explained by high pain score in these patients which may cause difficulty in completion of the procedure.

In the present study, tachycardia was observed in higher frequency in Group A (Paracervical alone) & Group C (intravenous diclofenac alone) as compared to other two groups. These patients also had high pain scores mandating use of rescue analgesic indicating that the most probable cause of tachycardia was pain. Interestingly tachycardia was observed in only a small fraction of the patients with high pain scores. This dissociation between pain and tachycardia in real world clinical settings has been observed in other studies also [12]. As pain in this study is a self-reported subjective sensation, variation in pain tolerance may explain this dissociation. Arora Aashima *et al*. [4] also found that the increment in heart rate was significantly more in placebo group. In the study by Sayed *et al*. [5], heart rate showed a significant increase in the paracervical block group in comparison with the combined technique group.

Anesthetic agents are to be used with caution as they are associated with variety of adverse effects. Lignocaine is associated with mild adverse effect like perioral numbness, dizziness, light headiness to severe adverse effect like convulsion and respiratory arrest. Various studies have proven the safety of lignocaine in pain relief.

To obtain objective evidence of safety of lignocaine, Rousseau *et al*. [13]. measured plasma lidocaine concentrations following insertion of 2% lidocaine gel into the uterine cavity after uterine balloon thermal ablation. They injected 11 ml of 2% lidocaine gel into the uterine cavity at the end of the procedure. Blood samples were taken at 5, 15, 30, and 60 min after insertion, and lidocaine concentrations were measured using high-performance liquid chromatography. They concluded that there was minimal absorption of lidocaine systemically from the uterus following uterine balloon thermal ablation. Measured concentrations were well below the toxic plasma concentration for lidocaine. Even with the use of 4% lignocaine, the highest serum lidocaine level recorded was 4.0 µg/ml which is well below the known toxicity level of 8 µg/ml. In the present study we used 5 ml of 1% lignocaine which was found safe and no severe adverse event was observed.

However, a strict watch was kept on any adverse event during and after the procedure. The procedures were, in general, well tolerated.

On evaluation of PADSS score it was found that patient with Group B (paracervical block with intrauterine lignocaine) had high PADSS score i.e., >9 even after 2 hrs. of procedure. This allowed discharge of the patient few hours after the procedure. Group D patients (intravenous diclofenac with intrauterine lignocaine) achieved requisite PADSS score 4 hours after procedure. However, same was achieved 6-8 hour after the procedure in other two group (intravenous diclofenac alone and paracervical block alone).

On, review of literature we could not find any study which had evaluated PADSS score with use of different anesthetic or analgesic agent. However, the data of present study reflect that decreased pain score with use of combination of paracervical block with intrauterine lignocaine and intravenous diclofenac with intrauterine lignocaine permitted us to discharge the patient quite early after the procedure. Also the novel combination of intravenous diclofenac with intrauterine lignocaine showed promising results and needs evaluation with a larger sample size. The limitations of the study included a small sample size and use of only NSAID in one of the groups.

Reduced duration of hospital stay is a measure of quality care. Early discharge from the hospital ensures reduced chances of getting hospital acquired infection. This definitely transforms into less morbidity among patients and decreased loss of man hours for the patient and her family. Also, it significantly decreases work load on health care workers and decreases bed occupancy in the hospital.

Needless to say, choosing an anesthetic agent / analgesic agent wisely in this minor procedure can go a long way in decreasing burden on the patient and the hospital.

Table 1: Post Anaesthetic Discharge Scoring System (P.A.D.S.S)

Components	0	1	2
Vital Signs (blood pressure, pulse, heart rate)	>40% of preoperative value	20 - 40% of preoperative value	Within 20% of preoperative value
Ambulation	difficult / impossible	toddle	Steady
Post-operative nausea /vomiting (PONV)*	Severe	Moderate	Minimal
Pain**	Severe	Moderate	Minimal
Surgical bleeding***	Severe	Moderate	minimal / absent
Voiding	retention	difficult	Normal

*Postop nausea vomiting- mild- only nausea, moderate -nausea with retching, severe- vomiting

**Pain- mild -<3, moderate -3-6, severe->6

***Bleeding- moderate -upto2 pads, severe- >2 pads

Table 2: Comparison of PRS score between all groups at different interval

PRS	Group A (n=35)	Group B (n=35)	Group C (n=35)	Group D (n=35)	p value
Immediately after procedure	5.49±0.70	1.69±0.47	6.06±0.68	3.71±0.75	<0.001
30 min after procedure	6.06±0.63	2.37±0.49	6.43±0.50	4.51±0.65	<0.001

Table 3: Comparison of PADSS score between all groups at different interval

PADSS	Group A (n=35)	Group B (n=35)	Group C (n=35)	Group D (n=35)	p value
2 hrs. after procedure	7.71±0.45	11.71±0.45	7.06±0.76	7.97±0.89	<0.001
4 hrs. after procedure	8.03±0.45	-	7.46±0.61	9.52±1.27	<0.001
6 hrs. after procedure	9.61±0.95	-	8.68±0.80	10.55±0.68	<0.001
8 hrs. after procedure	9.75±0.50	-	9.25±0.45	-	<0.001

Table 4: Duration of Hospital Stay

	Group A (n=35)	Group B (n=35)	Group C (n=35)	Group D (n=35)	p value
Duration of hospital stay (hrs.)	6.0±0.97	2.0±0.0	6.69±0.96	4.51±1.12	<0.001

Table 5: Complications

Complications	Group A (n=35)	Group B (n=35)	Group C (n=35)	Group D (n=35)	p value
Excessive pain	2 (5.7%)	0	6 (17.1%)	0	<0.01
Vasovagal reaction	0	0	1	0	0.38
Increment in pulse	2 (5.7%)	0	4 (11.4%)	2 (5.7%)	0.23
Inadequate specimen	3 (8.6%)	1 (2.9%)	5 (14.3%)	2 (5.7%)	0.32

Table 6: Adverse effect in study subjects

Adverse effect	Group A (n=35)	Group B (n=35)	Group C (n=35)	Group D (n=35)	p value
Dizziness	3 (8.6%)	2 (5.7%)	1 (2.9%)	1 (2.9%)	0.64
Light-headiness	1 (2.9%)	0	0	1 (2.9%)	0.56
Metallic taste	2 (5.7%)	1 (2.9%)	0	0	0.29
Nausea/vomiting	2 (5.7%)	4 (11.4%)	4 (11.4%)	4 (11.4%)	0.81
Perioral numbness	2 (5.7%)	1 (2.9%)	0	0	0.29

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Author's Contribution
Dr. U Miglani: Concept of study, drafting of protocol, Finalizing the results and discussion
Dr. G Mishra: Draft of protocol and collection of data
Dr. P Laul: Concept of study, drafting of protocol, Finalizing the results and discussion
Dr. D. Taneja: Concept of study, drafting of protocol, Finalizing the results and discussion

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Not available

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